SoundBite®品音®牙骨传导听力系统

临床与科学信息汇编

Collection for Clinical & Scientific Information

2021 年 06 月

声佗医疗科技（上海）有限公司

Sonitus Medical （Shanghai）Co., Ltd.

各位老师如需此资料汇编的电子版本，或有意和声佗医疗开展相关的科学研究项目，

请与声佗医疗科技（上海）有限公司销售部/市场部联系！

声伦医疗科技（上海）有限公司（Sonitus Medical）专注为听损人士提供持续创新的听力解决方案来自于中国和美国硅谷的研发团队致力于将最前沿的黑科技运用于听力设备的创新。公司在全球拥有超过128项专利*，特别是全球独创的牙骨传导听力技术的临床价值已经在中国和美国的多项临床研究中得到充分验证，获得美国FDA、中国NMPA和欧盟CE批准，用于单侧听力损失和传导性听力损失。公司的愿景是成为全球听力业界有影响的创新者和领导者，造福全球的听损人士。

Summary
综述

品音®牙骨传导听力系统自面世以来，受到了业界广泛的关注。我们收集了国内外多篇已经发表的文章，这些文章从品音®牙骨传导听力系统的安全性、有效性和患者使用的便利性等方面进行了深入的研究，结论都表明该产品是安全的、有效的，且便于患者使用的。患者使用后能改善与人沟通交流，提高生活质量。所有研究测量助听器收益简表（APHAB）和/或噪声下言语测试（HINT）得分均显示了改善，且在某些情况下优于骨锚定听力设备。在所有已发表的文献中，仅有一例轻微的不良事件：一例轻度口疮，在适当的牙科护理后得到解决。患者对品音®的满意度一致地很高，同时在所有研究中，大于96%的患者报告他们将推荐给具有相似听力损失的朋友或家人。

Since its introduction, the SoundBite hearing system has received a great deal of attention from the industry. We have collected a number of published articles, both nationally and internationally, which have conducted in-depth studies on the safety, effectiveness and patient-friendliness of the SoundBite hearing system, all of which conclude that the product is safe, effective and patient-friendl. Patients can improve communication and improve the quality of life. All studies that measure APHAB and/or HINT scores show improvement, and in some cases superiority to bone anchored hearing devices. In all published literature, there has been only 1 minor adverse event: a superficial mouth sore that was resolved after appropriate dental care. Patient satisfaction with SoundBite is consistently high, and in all studies where asked, >95% of patients reported they would recommend SoundBite to a friend or family member with similar hearing loss.

品音®牙骨传导听力系统

全球唯一非手术的**直接骨传导**，无损传导声音，言语清晰度高

- 口内机（ITM）佩戴于用户的上颌磨牙，将无线信号经过能量转换为精密的振动信号。专属定制，轻松佩戴，隐形，不影响饮食。

■ 扫码观看 ■
佩戴视频

- 耳背机（BTE）佩戴在耳后或衣领处，主要收集听损侧的声音信号，通过转换为数字信号并经过特有的算法优化处理后，使用无线方式将信号传送到口内机。多种佩戴方式，满足用户需求：

· 耳后：隐形，美观。置于耳道口的麦克风可提高4-6dB高频增益。　· 衣领处：适用于小耳畸形等耳后不便佩戴的场景，更满足用户对于隐形美观的极致追求。

A款

B款

✓ 适用于**单侧耳聋**

（单侧听力损失）

其他常见方案的不足:

软带或眼镜式骨导：言语清晰度差，属于经皮传导，皮肤和软组织吸收衰减15-20分贝，尤其是对方向判别和噪音下语音识别重要的高频信号；对皮肤的压迫甚至损伤；

信号对传式助听器：需双耳佩戴，由于堵耳效应，健耳自身听力受影响

人工耳蜗植入：需手术植入；健耳自然听力和机器声质差别大；听神经损伤患者无效

植入式骨导设备：需外科手术；术后感染风险；费用高

✓ 适用于**传导性耳聋**

（单侧或双侧传导性听力损失）

其他常见方案的不足:

软带或眼镜式骨导：言语清晰度差，属于经皮传导，皮肤和软组织吸收衰减15-20分贝，尤其是对方向判别和噪音下语音识别重要的高频信号；对皮肤的压迫甚至损伤；

气导助听器：佩戴困难、言语清晰度差

植入式骨导设备：需外科手术；术后感染风险；费用高

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0. 中英双语摘要

(1). "The SoundBite Hearing System: Patient-Assessed Safety and Benefit Study"

The Laryngoscope, November 2013

This 6-month study to determine the safety and efficacy of SoundBite for patients with Single-Sided Deafness concludes that SoundBite offers advantages over traditional osseointegrated devices that require surgical placement. For the 34 patients that completed the study, mean APHAB scores show significant improvement in ease of communication, background noise, reverberation, and global benefit. There are no adverse events, although 17.5% of patients report acoustic feedback. 100% of patients report they would recommend SoundBite to a friend or family member with similar hearing loss.

OBJECTIVES/HYPOTHESIS

To determine the safety and efficacy of the SoundBite for patients over a 6 month period of use.

STUDY DESIGN

Prospective, multisite, nonrandomized patient enrollment with outcomes based on audiometric profile and self-reported assessment.

METHODS

Patients with single-sided deafness were eligible for the study. Patients were fit with the standard SoundBite sound transducer and were asked to wear the device regularly for 6 months. At the end of the trial period, patients completed both a self-assessment and the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaires.

RESULTS

Thirty-four subjects completed the study. Mean APHAB scores improved significantly for ease of communication ($P < 0.001$), background noise ($P < 0.001$), reverberation ($P < 0.001$), and global benefit ($P < 0.001$). Patients reported high rates of auditory benefit in a variety of listening situations and high rates of overall satisfaction with the device. One adverse event with a superficial mouth sore was reported and resolved after appropriate dental care. Twelve patients (35%) reported acoustic feedback. In six of these patients, the feedback resolved after device adjustment.

CONCLUSION

The SoundBite is a new hearing prosthesis that delivers bone conduction energy. It offers advantages over traditional osseointegrated devices that require surgical placement. Patient satisfaction with the device after 6 months of regular use is high. The SoundBite provided improvement in ease of communication, hearing in background noise, sound reverberation, and an overall global hearing benefit. Acoustic feedback is the most commonly reported problem with the SoundBite, and this is minimized with proper fitting.

参考译文：

(1). 品音®牙骨传导听力系统：基于患者评估的安全性和有效性研究

《喉镜》2013 年 11 月

这项长达6个月的研究用以确定品音®(SoundBite®)对单侧耳聋患者的安全性和有效性，结论显示品音®(SoundBite®)比需要手术放置的传统骨导植入设备更具优势。对于完成研究的34个患者，APHAB问卷平均得分在交流方便、背景噪音、混响和综合效益方面表现出显著提升，其中，17.5%的患者反馈有声音啸叫，未有不良事件发生。100%患者反馈他们会把品音®(SoundBite®)推荐给具有相似听力损失的朋友或家庭成员。

目标/假设：确定患者使用品音®(SoundBite)6 个月的安全性和有效性。

研究设计：这是一项患者非随机入组的，基于听力测试和自我评价报告作为评估结果的前瞻性、多中心的研究。

方法：单侧耳聋的患者符合研究条件。患者配戴品音®(SoundBite)牙骨传导听力系统，要求按时佩戴设备6个月。在试验阶段的最后，患者同时完成了自我评估和助听效果评估简表(APHAB)问卷。

结果：34 例受试者完成了研究。平均APHAB得分在交流方便(P < 0.001)、背景噪音(P < 0.001)、混响(P < 0.001)和综合效益(P < 0.001)方面表现出了显著提升。患者报告了在不同聆听环境下获得的听觉增益很高，并且对设备的总体满意度很高。据报道，有一例浅表性口腔溃疡的不良事件，并且在适当的牙科护理后得到了解决。12例患者(35%)报告有声音啸叫。这些患者中的6人，在设备调整后啸叫得到了解决。

结论：品音®(SoundBite)是一种通过骨导传递能量的新型听力设备。它比需要手术放置的传统植入设备更有优势。患者在6个月后的常规使用后的满意度很高。品音®(SoundBite)在交流方便、背景噪音中的听力、声音混响和总体综合效果方面提供了改善。声音啸叫是品音®(SoundBite)经常报告的问题，但可以通过合适的验配调试使之降至最低。

(2). "Preliminary comparison of bone-anchored hearing instruments and a dental device as treatments for unilateral hearing loss"

International Journal of Audiology, October 2013

This 30-day study to compare the efficacy of bone anchored hearing instruments (BAHI) and SoundBite concludes that SoundBite lead to lower aided thresholds and better APHAB scores than the BAHI devices. Patients wore BAHI or SoundBite for 30 days, then the devices were swapped, and the second device was worn for 30 days. Aided sound-field thresholds are consistently lower for SoundBite than for BAHI by 10dB on average.

OBJECTIVE

To compare the effectiveness of two types of treatment for unilateral hearing loss (UHL), bone-anchored hearing instruments (BAHI) and a dental device (SoundBite).

DESIGN

Either BAHI or SoundBite were worn for 30 days, and then the devices were swapped and the second device was worn for 30 days. Measures included unaided and aided sound-field thresholds, sound localization, and perception of speech in babble. The APHAB questionnaire was administered for each trial period.

STUDY SAMPLE

Nine adult BAHI wearers with UHL.

RESULTS

Mid-frequency aided thresholds were lower for SoundBite than for BAHI. Both devices gave benefits for localization after 30 days, but there was no difference between devices. Speech perception was better for both devices than for unaided listening when the target speech came from the poorer hearing side or in front, and the interfering babble came from the better- hearing side. There was no consistent difference between devices. APHAB scores were better for SoundBite than for BAHI.

CONCLUSIONS

Speech perception and sound localization were similar for the two types of device, but the SoundBite led to lower aided thresholds and better APHAB scores than the BAHI.

参考译文：

(2). 骨锚式听力设备和牙骨传导听力系统治疗单侧听力损失的初步比较

*《国际听力学杂志》*2013 *年* 10 *月*

这项30天的研究比较了骨锚式助听器 (BAHI)和品音®(SoundBite)的效果，结论是比起BAHI，品音®(SoundBite)具有较低的助听听阈和更好的APHAB得分。患者佩戴BAHI或品音®(SoundBite)30天，然后 更换另一种设备也佩戴30天。品音®(SoundBite)的助听声场阈值始终比BAHI低平均10dB。

目的： 为了比较骨锚式助听器 (BAHI)和品音®(SoundBite)两种类型的设备对于单侧传导性听力损失（UHL）的治疗效果。

实验设计：患者均佩戴 BAHI或品音®(SoundBite)设备30天，然后更换另一种设备也佩戴30天，听力测试包括裸耳和助听声场阈值测试，声源定位、噪音背景下的言语感知，每个实验阶段均采用APHAB问卷。

研究对象：9 例佩戴 BAHI 的成人单侧听力损失患者。

结果：品音®(SoundBite)的中频助听阈值低于 BAHI。佩戴 30 天后，两种设备均有助于声源定位，但是两种设备的效果无差异。当声音来自听力较差的耳朵或前方，干扰音来自听力较好的耳朵时，使用两种设备的言语感知能力均优于裸耳听力，且设备之间无差异。品音®(SoundBite)的APHAB得分优于 BAHI。

结论：两种设备的言语感知和声源定位结果类似，但是品音®(SoundBite)和BAHI相比具有更低的助听听阈和更好的APHAB得分。

(3). "Long term safety and benefit of a new intraoral device for Single-Sided Deafness"

Otology & Neurotology, October 2011

This multi-center 6-month study to determine long-term safety and benefit of SoundBite concludes that SoundBite is safe, and continues to provide substantial benefit for SSD patients. 22 SSD patients with no current use of a hearing device wore SoundBite over a 6-month period. APHAB scores show improvement in background noise, reverberation, ease of communication, and global benefit. The vast majority (<90%) of patients report satisfaction and improvement in a variety of areas after wearing the device long-term.

OBJECTIVE

To determine the long-term safety and benefit of a new intraoral bone conduction device (SoundBite Hearing System by Sonitus Medical) for single-sided deafness (SSD).

STUDY DESIGN

A multi-center, controlled, nonrandomized, prospective unblinded study of SSD patients wearing the device over a 6-month period.

SETTINGS

Ambulatory care centers typical of those where SSD patients are diagnosed and treated.

PATIENTS

Adults (N = 22) with acquired, permanent SSD and no current use of any other SSD device.

INTERVENTION

Continual daily wear of the new device for 6 months.

MAIN OUTCOME MEASURES

Comprehensive medical, audiologic, and dental measures; aided thresholds; Abbreviated Profile of Hearing Aid Benefit scores, and an SSD questionnaire.

RESULTS

There were no related adverse events or changes in the medical or audiologic findings at the end of the trial compared with the beginning. There were no significant changes in the mean aided thresholds ($p > 0.01$) or the mean dental measures ($p > 0.05$) at 3 or 6 months compared with pretrial measures. The mean Abbreviated Profile of Hearing Aid Benefit benefit scores showed improvement ($p < 0.01$) for the Background Noise, Reverberation, and Ease of Communication subscales and the Global scale at 3 and 6 months. The results of the SSD questionnaire indicated that the vast majority (>90%) of the subjects reported satisfaction and improvement in a variety of areas after wearing the device long term.

CONCLUSION

The SoundBite system is safe and continues to provide substantial benefit for SSD patients with continual daily use over a 6-month period.

参考译文：

(3). 确定用于单侧耳聋的新型牙骨传导听力系统的长期有效性和安全性

《耳科学和神经耳科学》2011 年 10 月

本次多中心的6个月研究用来确定品音®(SoundBite)的长期安全性和有效性，结论是品音®(SoundBite)安全且持续地为单侧耳聋患者提供实质性效益。目前未佩戴听力设备的 22 例单侧耳聋患者佩戴品音®(SoundBite)超过6个月时间。APHAB得分表明在背景噪声、混响、交流方便和整体效益上的提升。大部分(<90%)患者反馈佩戴设备后长期在不同领域的满意度和提升。

目的：确定一种用于单侧耳聋(SSD)的牙骨传导听力系统的长期安全性和有效性(Sonitus医疗的品音®(SoundBite)牙骨传导听力系统)。

研究设计：单侧耳聋(SSD)患者佩戴设备 6 个月的多中心，对照，非随机，前瞻性的非盲研究。

设施：单侧耳聋(SSD)患者诊断和治疗的典型门诊护理日间医疗中心。

受试者：获得性、永久性单侧耳聋(SSD)成人(N = 22)，并且目前没有使用任何单侧耳聋(SSD)设备。

干预：6 个月持续地日常佩戴新设备。

主要结果测量：综合的医疗，听力学和牙科测量方法；助听听阈；助听效果评估简表(APHAB)得分，和单侧耳聋(SSD)问卷。

结果：与开始时相比，试验结束后在医疗和听力学研究中没有发现相关不良事件或变化。试验前测量结果与3或6个月的平均助听听阈($p>0.01$)或平均牙科测量结果($p>0.05$)相比没有重大变化。平均助听效果评估简表(APHAB)得分表明在3个月和6 个月的背景噪声、混响、交流方便分量表以及整体量表有提升($p < 0.01$)。单侧耳聋(SSD)问卷的结果表明大部分(>90%)受试者报告了佩戴设备后长期在不同领域的满意度和提升。

结论：在 6 个月期间，品音®(SoundBite)牙骨传导听力系统安全且持续地为日常使用的单侧耳聋患者提供实质性效益。

(4). " Safety of an intra-oral hearing device utilizing split-mouth research design "

Miller, R., et al. The Journal of Clinical Dentistry, 2011

This 6-month study of 22 patients concludes that the intra-oral component of the SoundBite Hearing System does not adversely affect dental structures. Compared to the non-device teeth, the hearing device teeth do not exhibit any increased recession, pocket depth, root resorption, or alveolar bone loss.

OBJECTIVE

The auditory deficits of Single Sided Deafness (SSD) can be treated effectively with a novel device, SoundBite, that delivers sound by applying imperceptible vibratory signals to the teeth (hereafter to as an intra-oral hearing device). The intra-oral hearing device is placed around two maxillary teeth similar to a small partial denture or retainer. The goal of this study was to report how this removable hearing device affects the oral structures.

METHODS

Twenty-two SSD patients wearing an intra-oral hearing device were enrolled in a prospective study for six months. Differences (delta) between the device-anchoring teeth and the equivalent contralateral non-device teeth were evaluated with four dental parameters using a paired t-test. Hearing thresholds were evaluated as a function of alveolar bone support using linear regression.

RESULTS

Compared to the non-device teeth, the hearing device teeth did not exhibit any increased recession (delta = 0.1 mm, p-value = 0.48), increased pocket depth (delta = 0.0 mm, p-value =0.48), increased root resorption (delta = 4%, p-value = 0.43), or increased alveolar bone loss(delta = 0.0 %, p-value = 0.43). There was no association between the amount of alveolar support and hearing thresholds (delta = 0.2, p-value = 0.34).

CONCLUSION

The intra-oral component of the hearing device did not adversely affect the dental structures of the subjects in this trial.

参考译文：

(4). 牙骨传导听力系统安全性的自身对照研究

Miller, R., et al.《临床牙医学杂志》2011

本次22例患者的6个月研究结论是品音®(SoundBite)牙骨传导听力系统的口腔内组件对牙齿结构没有不良影响。对照没有佩戴装置的牙齿，佩戴听力装置的牙齿没有呈现任何牙龈退缩，牙周袋深度，根吸收或牙槽骨吸收的加重。

目的：单侧耳聋(SSD)的听觉障碍可以使用品音®(SoundBite)牙骨传导听力系统有效地治疗，其通过应用细微的振动信号传递声音到牙齿(以下简称品音®(SoundBite)。品音®(SoundBite)口内机放置在两颗上颌牙齿上，类似局部义齿或保持器。本次研究的目的是报告该可移除的听力设备如何影响口腔结构。

方法：22例单侧耳聋患者佩戴口内听力设备参与了为期6个月的前瞻性研究。用配对t检验的方法， 使用四个牙科参数评估了固定装置的牙齿与等效的对侧非装置牙齿之间的差异(δ)。使用线性回归评估听力阈值与牙槽骨支撑的关系。

结果：和无装置牙齿相比，佩戴听力设备的牙齿未呈现任何牙龈退缩(δ= 0.1 mm, p 值=0.48)，牙周袋深度(δ = 0.0 mm, p 值= 0.48)，根吸收(δ = 4%, p 值= 0.43)或牙槽骨吸收的加重(δ = 0.0 %, p值= 0.43)。牙槽骨量和听力阈值(δ= 0.2, p 值= 0.34)之间没有关联。

结论：本次试验中，该听力设备的口腔内组件对受试者的口腔结构没有不良影响。

(5). "Efficacy and safety of an in-the-mouth bone conduction device for Single-Sided Deafness"

Murray, M., et al. Otology & Neurotology, February 2011

This 30-day study concludes that SoundBite is safe and effective, and provides substantial benefit for SSD patients. 28 patients with SSD and no current use of an SSD device wore SoundBite for a 30-day period. HINT scores show an average improvement of -2.5 dB. APHAB scores show improvement for all subjects in global benefit and background noise. For all but 1 subject, reverberation and ease of communication scores also improved.

OBJECTIVE

To determine the efficacy, benefit, and safety of a new in-the-mouth bone conduction device (SoundBite Hearing System) for single-sided deafness (SSD).

STUDY DESIGN

A multicenter, controlled, nonrandomized prospective unblinded study of SSD patients wearing the device.

SETTINGS

Ambulatory care centers typical of those where SSD patients are diagnosed and treated.

PATIENTS

Adults (ages >18 and <80 yr) with acquired, permanent SSD (N=28) and no current use of any SSD device.

INTERVENTION

Continual daily wear of the new device over a 30-day trial period.

MAIN OUTCOME MEASURES

The Hearing in Noise Test (HINT), the Abbreviated Profile of Hearing Aid Benefit (APHAB), comprehensive pretrial and posttrial medical, audiologic, and dental examinations and an SSD questionnaire.

RESULTS

The Hearing in Noise Test scores improved an average of -2.5 dB after 30 days, compared with wearing no device ($p<0.001$). The Abbreviated Profile of Hearing Aid Benefit scores improved ($p<0.05$) for all subjects for the Global and Background Noise subscales and for all but 1 subject for the Reverberation and Ease of Communication subscales. There were no medical, audiologic, or dental complications.

CONCLUSION

The SoundBite system is safe and effective and provides substantial benefit for SSD patients with continual daily use over a 30-day period.

参考译文：

(5). 用于单侧耳聋的牙骨传导听力系统的有效性和安全性

Murray, M., et al.《耳科学与神经耳科学》2011 年 2 月

本次30天研究的结论是，品音®(SoundBite)用于单侧耳聋(SSD)患者是安全有效的，同时提供了实质性效果。28例单侧耳聋(SSD)患者，同时目前未使用单侧耳聋(SSD)设备，佩戴品音®(SoundBite)30天的周期。HINT得分显示出平均-2.5dB的改善。APHAB 得分显示出所有受试者在综合效益和背景噪音的改善。所有受试者除1例，混响和交流方便得分也得到了提高。

目的：确定用于单侧耳聋(SSD)的品音®(SoundBite)牙骨传导听力系统的有效性和安全性。

研究设计：一项对佩戴设备的单侧耳聋(SSD)患者进行的多中心，对照，非随机，前瞻性的非盲研究。

设施：单侧耳聋(SSD)患者诊断和治疗的典型门诊护理中心。

受试者：获得性、永久性单侧耳聋(SSD)(N=28)成人(年龄 >18 并 <80 岁)，并且目前没有使用任何单侧耳聋(SSD)设备。

干预：30 天试验周期持续地日常佩戴新设备。

主要结果测量：噪声下听力测试(HINT)；助听效果评估简表(APHAB)得分，综合的试验前后医疗，听力学和牙科测量方法以及单侧耳聋(SSD)问卷。

结果：30天后，较于不佩戴设备(p<0.001)，噪声下听力测试(HINT)得分平均提高了-2.5dB。对于助听效果评估简表（APHAB），所有受试者的综合和背景噪声子量表以及除1例受试者以外的混响及交流方便子量表得分均有所提高（p＜0.05）。未出现医疗、听力学或牙科并发症。

结论：在30天期间，品音®(SoundBite)牙骨传导听力系统安全且持续地为日常使用的单侧耳聋患者提供实质性效益。

(6). "Preliminary evaluation of a novel bone-conduction device for Single-Sided Deafness"

Popelka, G., et al. Otology & Neurotology, October 2010

This laboratory study using normal-hearing subjects concludes that SoundBite provides useful gain and output for SSD patients, is comfortable, does not seem to have detrimental effects on oral function or health, and has several advantages over existing devices. Specifically, microphone placement is optimized for reducing the auditory deficit caused by SSD, frequency bandwidth is much greater, and the system does not require surgical placement.

HYPOTHESIS

A new intraoral bone-conduction device has advantages over existing bone-conduction devices for reducing the auditory deficits associated with single-sided deafness (SSD).

BACKGROUND

Existing bone-conduction devices effectively mitigate auditory deficits from single-sided deafness but have suboptimal microphone locations, limited frequency range, and/or require invasive surgery. A new device has been designed to improve microphone placement (in the ear canal of the deaf ear), provide a wider frequency range, and eliminate surgery by delivering bone- conduction signals to the teeth via a removable oral appliance.

METHODS

Forces applied by the oral appliance were compared with forces typically experienced by the teeth from normal functions such as mastication or from other appliances. Tooth surface changes were measured on extracted teeth, and transducer temperature was measured under typical use conditions. Dynamic operating range, including gain, bandwidth, and maximum output limits, were determined from uncomfortable loudness levels and vibrotactile thresholds, and speech recognition scores were measured using normal-hearing subjects. Auditory performance in noise (Hearing in Noise Test) was measured in a limited sample of SSD subjects. Overall comfort, ease of insertion, and removal and visibility of the oral appliance in comparison with traditional hearing aids were measured using a rating scale.

RESULTS

The oral appliance produces forces that are far below those experienced by the teeth from normal functions or conventional dental appliances. The bone-conduction signal level can be adjusted to prevent tactile perception yet provide sufficient gain and output at frequencies from 250 to 12000 Hz. The device does not damage tooth surfaces nor produce heat, can be inserted and removed easily, and is as comfortable to wear as traditional hearing aids.

The new microphone location has advantages for reducing the auditory deficits caused by SSD, including the potential to provide spatial cues introduced by reflections from the pinna, compared with microphone locations for existing devices.

CONCLUSION

A new approach for SSD has been proposed that optimizes microphone location and delivers sound by bone conduction through a removable oral appliance. Measures in the laboratory using normal-hearing subjects indicate that the device provides useful gain and output for SSD patients, is comfortable, does not seem to have detrimental effects on oral function or oral health, and has several advantages over existing devices. Specifically, microphone placement is optimized for reducing the auditory deficit caused by SSD, frequency bandwidth is much greater, and the system does not require surgical placement. Auditory performance in a small sample of SSD subjects indicated a substantial advantage compared with not wearing the device. Future studies will involve performance measures on SSD patients wearing the device for longer periods.

参考译文：

(6). 对用于单侧耳聋的牙骨传导听力系统的初步评价

Popelka, G., et al.《耳科学与神经耳科学》2010 年 10 月

本次实验室研究使用正常听力的受试者，结论是品音®(SoundBite)向单侧耳聋(SSD)患者提供有用的增益和输出，佩戴舒适，暂未发现在口腔功能或健康存在不利影响，且比现有设备具有一些优势。具体来说，麦克风的放置最优地降低了单侧耳聋引发的听力缺陷，频率带宽更宽，并且该系统无需手术放置。

假设：牙骨传导听力系统比现有骨传导设备在降低单侧耳聋(SSD)相关的听力缺陷方面具有优势。

背景：现有骨传导设备有效的缓解了单侧耳聋的听力缺陷，然而具有麦克风位置欠佳，有限

的频率范围，和/或需要介入手术。牙骨传导听力系统的设计改善了麦克风放置(在聋侧耳道内)，提供更宽的带宽范围，同时通过一个可取出的口腔装置传递骨传导信号到牙齿上以避免手术。

方法：将口腔矫治器所施加的力与正常功能（例如咀嚼）或其他矫治器中牙齿通常承受的力进行了比较。在选取的牙齿上测量牙齿表面的变化，在代表性的使用条件下测量传感器温度。用正常听力受试者测量响度不适级和振动感知阈值以及言语识别得分以确定动态的操作范围，包含增益、带宽和最大输出限制。在有限的SSD受试者样本中测量了噪声中的听觉行为(噪声下听力测试(HINT))。对照传统助听器，使用等级量表测量总体舒适度，嵌入的方便性以及口腔装置的取出和可见性。

结果：口腔装置产生的力远低于牙齿经受的普通功能或常规牙科矫正器的力。骨传导信号水平能够调整到防止触觉感知的同时仍在 250Hz 至 12,000 Hz 频率提供足够的增益和输出。该设备不会损坏牙齿表面，也不产生热度，能够轻松的嵌入和取出，和传统助听器具有同样的佩戴舒适度。新的麦克风定位在降低SSD引发的听力缺陷方面有优势，包括和现有设备的麦克风定位相比，提供耳廓反射所引入的空间特性的潜在可能。

结论：提出了一种用于单侧耳聋(SSD)的新方法，其优化了麦克风位置，并且通过一个可取出的口腔装置经骨传导传递声音。使用正常听力的受试者在实验室的测量结果表面，该设备为单侧耳聋患者提供有用的增益和输出，暂未发现对口腔功能或健康存在不利影响，且比现有设备具有一些优势。具体来说，麦克风的放置最优地降低了单侧耳聋引发的听力缺陷，频率带宽更宽，并且该系统无需手术放置。小样本SSD受试者的听觉行为显示出比没有佩戴设备的实质性优势。未来的研究将引入 SSD 患者长期佩戴设备的性能测量。

(7). "SoundBite Hearing System by Sonitus Medical: A new approach to Single-Sided Deafness"

Popelka, G. Seminars in Hearing, 2010

This study of 18 patients concludes that the SoundBite device delivers a much broader frequency bandwidth than existing SSD devices, and that SSD patients indicate a substantial 2dB advantage on HINT scores compared to an unaided condition.

A new approach (SoundBite Hearing System) for single-sided deafness (SSD) has been developed (Sonitus Medical, San Mateo, CA). It consists of one component that resembles a conventional behind-the-ear (BTE) hearing aid that wirelessly connects to a second component worn in-the- mouth (ITM) that resembles a conventional dental appliance. The BTE component positions a microphone in the ear canal on the poorer-hearing side to capture the spatial hearing acoustic qualities of a normal ear canal and pinna. The ITM component delivers bone conduction signals via the surfaces of the teeth with an embedded transducer that delivers signals to 12,000 Hz, a much broader frequency bandwidth than existing SSD devices. The signal is transferred to the better-hearing ear via direct bone conduction, but without the need for surgery. An ITM hearing device is safe, comfortable, generally invisible, and easy to insert and remove. The two components use full digital processing with all the advanced functions of contemporary digital hearing aids. Measures of the Hearing in Noise Test on SSD patients (n = 18) indicated a substantial and immediate 2 dB advantage compared to the unaided condition. These results warrant a full multisite clinical trial that is underway and will be completed in 2010.

参考译文：

(7).声佗医疗的品音®牙骨传导听力系统：一种用于单侧耳聋的新方法

Popelka,G. 2010 *听力学研讨会*

本次本次18例患者的研究结论是，较于现有的单侧耳聋(SSD)设备，品音®(SoundBite)传递更宽的频率带宽，同时单侧耳聋(SSD)患者表明，较于未助听的情形，品音®(SoundBite)的HINT得分具有实质性的2dB优势。

一种用于单侧耳聋(SSD)的新方法(品音®(SoundBite)牙传导听力系统)已完成开发(Sonitus医疗，圣马特奥，加利福尼亚州)。它由一种类似于耳背机(BTE)助听器，以及无线连接于另一种类似于传统牙科装置的佩戴在口内的组件(ITM)组成。BTE 组件放置一个麦克风在较差听力侧的耳道以获取正常耳道和耳廓的空间听力原声品质。 ITM组件使用嵌入式换能器通过牙齿表面传递骨传导信号，该传感器将信号传递到12,000 Hz，这比现有的SSD设备具有更宽的频率带宽。

信号通过直接骨传导传递至听力更好的耳朵，且无需手术。ITM 听力装置安全、舒适、通常不可见，且便于嵌入和取出。两个组件使用全数字处理技术，并使用了目前数字助听器的所有先进功能。较于未助听情况下，单侧耳聋(SSD)患者(n = 18)在噪声下听力测试(HINT)测量显示出实质性和即时的2 dB优势。这些结果保证一个全面的多中心临床试验在起步，即将于2010年完成。

(8) . "It's time we listened to our teeth : The SoundB ite Hearing System"

Miller, R. American Journal of Orthodontics and Dentofacial Orthopedics, November 2010

This article describes the SoundBite Hearing System as a nonsurgical, noninvasive treatment for SSD that requires the expertise of 3 health care specialists: a physician, an audiologist, and a dentist.

The SoundBite hearing system (Sonitus Medical, San Mateo, Calif) allows people with single-sided deafness to wear an intraoral device and a small microphone in the deaf ear to regain lost hearing. A piezoelectric activator in a small removable uni-lateral oral appliance conducts sound through the bone via the teeth to the good ear. The goal of this article is to introduce the SoundBite, a new bone-conduction hear-ing device, to dentists and orthodontists.

参考译文：

(8). 是时候用牙齿听声音了：品音®(SoundBite)牙骨传导听力系统

Miller, R.《美国正牙学与牙面矫形学杂志》 2010年 11月

本文叙述了品音®(SoundBite)牙骨传导听力系统作为一种用于单侧耳聋的非手术，非介入治疗方法需要三位医疗专员的专业领域：一位临床医师，一位听力学家和一位牙科医师。

品音®(SoundBite)牙骨传导听力系统(Sonitus 医疗，圣马特奥，加利福尼亚州)给予单侧耳聋的人群佩戴一个口内装置和一个患耳上的小型麦克风以重获损失听力。压电陶瓷驱动器在小型可移除单边口腔装置中通过骨传导声音、经牙齿到正常的耳朵。本文的目的为向牙科医师和正牙医师介绍品音®(SoundBite) 一种新型骨传导听力设备。

(9). " Bone Conduction Hearing: Device Auditory Capability to Aid in Device Selection "

Mark J. Syms. Otolaryngology–Head and Neck Surgery 2014

In this study, the maximum output and gain of 7 surgical instruments and 1 non-surgical dental device were tested, and the results showed that the non-surgical dental instruments had the highest output (up to 30dB) and gain (up to 26dB) within the PTA range and above.

Objective

To obtain identical laboratory measures of 8 (surgical and nonsurgical) bone conduction devices and relate them to clinical function.

Study Design

Each device was measured with a single laboratory system and characterized with descriptive statistics.

Setting

Laboratory.

Subjects and Methods

Seven surgical devices (Intenso, BP110, BP100, and Cordelle [Cochlear, Denver, Colorado]; Ponto Pro and Ponto Pro Power [Oticon Medical, Somerset, New Jersey]; and Alpha 2 [Sophono, Inc, Boulder, Colorado]) and 1 nonsurgi-cal dental device (SoundBite; Sonitus Medical, Inc, San Mateo, California) constituted the independent variables. Measured maximum output and gain parameters were the dependent variables.

Results

Maximum output varied across devices in the pure tone average (PTA; 500-500-3000 Hz) frequency range (mean, 109.7 dB re 1 μN; range, 98.8-119.2 and in the above-PTA (4000-8000 Hz) frequency range (mean, 102.6 dB re 1μN; range, 88.99-119.6 dB). Maximum gain varied in the PTA frequency range (mean, 40 dB; range, 29.1-49.1 dB) and was higher in the frequency rangeabove the PTA (mean, 32.0 dB; range, 20.8-46.0 dB).

Conclusion

All devices have sufficient maximum output and gain for the PTA frequency range for single-sided deafness(SSD). The devices differed in maximum output and gain for the frequency range above the PTA, a consideration for accommodating presbycusis and optimizing auditory function for SSD. The surgical devices have less maximum output and gain in the above-PTA range than in the PTA range. The nonsurgical dental device had the highest output (up to 30 dB higher) and gain (up to 26 dB higher) in the above-PTA range.

参考译文：

(9). 骨传导听力设备：基于可听度选择助听装置

Mark J. Syms 《耳鼻咽喉头颈外科》 2014

本研究通过对 7 个外科器械与 1 个非外科的牙科装置进行最大输出与增益的测试，获得结果为在PTA 以上范围内，非手术的牙科器械具有最高的输出(最高达 30dB)和增益(最高达 26dB)。

目标：获得 8 个(外科和非外科)骨传导装置相同的实验室测量值，并将它们与临床功能相关联。

研究设计：每个装置都用单一的实验室系统进行测量，并用描述性统计进行表征。

设施：实验室。

对象和方法：7个外科器械(Intenso, BP110, BP100, and Cordelle [Cochlear,Denver, Colorado]; Ponto Pro and Ponto Pro Power [Oticon Medical, Somerset, New Jersey]; and Alpha 2 [Sophono, Inc, Boulder, Colorado]) 和1个非外科的牙科装置(SoundBite; Sonitus Medical, Inc, San Mateo, California)构成了独立变量。测得的最大输出和增益参数为因变量。

结果：在纯音平均频率范围(PTA；500-3000Hz)的最大输出(平均，109.7 dB re 1 μN；范围，98.8-119.2 dB)，在纯音平均频率以上(4000-8000Hz)最大输出(平均，102.6 dB re 1μN；范围，88.99-119.6 dB)。最大增益在PTA频率范围内变化(平均为40 dB;范围:29.1-49.1 dB)，在PTA以上频率范围较高(平均32.0 dB;范围20.8-46.0 dB) 。

结论：所有的装置都有足够的最大输出和增益用于单侧耳聋(SSD)的 PTA 频率范围。在 PTA以上的频率范围内，设备的最大输出和增益不同，这是处于对适应老年性聋和优化 SSD 患者的听觉功能的考虑。PTA 以上范围的手术器械最大输出和增益小于 PTA 范围。在 PTA 以上范围内，非手术的牙科器械具有最高的输出(最高达 30dB)和增益(最高达 26dB)。

(10). "Patients Satisfied with Intraoral Device for Single-Sided Deafness "

Woodby, Lily, Galow, Linda. Hearing Journal. 2014

This study included 117 patients with the device. Because SoundBite is different from the surgical bone conduction device in terms of how to obtain and wear it, and how to solve the problem of unilateral deafness, the tailored measurement is used instead of standardized result measurement. Patients completed an online survey after wearing the device under typical daily conditions for at least 30 days. The online questionnaire items were centered on important patient satisfaction and real-world benefit factors. They employed typical rating scales on several dimensions (satisfaction, improvement, etc.), ranging from completely positive to completely negative. The questionnaire also allowed open-ended responses. Real-word information about patient satisfaction and benefits can be obtained through device-specific, non-standardized questionnaires. The results showed that the patients were highly satisfied with their daily wear and could adapt quickly. Although designed to allow patients to eat with their clothes on, patients said in open-ended responses that they were uncomfortable with the idea that the food might stay around the device, or worried that chewing would damage the device. Sonitus Medical has addressed many of the concerns of patients in open answers, and the release of the next generation device will address others.

参考译文：

(10). 单侧聋患者对牙骨传导听力系统的满意度

Woodby, Lily, Galow, Linda《听力期刊》2014

本文研究包括佩戴该装置的117名患者。因品音®(SoundBite)系统在获取和佩戴方式上，以及在如何解决单侧耳聋这一问题上，与外科骨传导装置都存在差异，于是使用为该设备量身定制的测量，而不是标准化的结果测量。患者在典型的日常情况下佩戴该设备至少 30 天后完成了在线调查。在线问卷项目以患者重要满意度和现实生活的益处为主，在几个维度(满意度、改善等)上使用了典型的评定量表，范围从完全积极到完全消极。问卷也允许开放式回答。通过针对特定设备定制的非标准化问卷，可以获得真实生活中患者满意度和受益的信息。结果显示出了患者的高满意度，患者对日常佩戴基本满意，并能快速适应。虽然设计的目的是让患者可以戴着吃东西，但患者在开放式回答中表示，他们对食物可能会留在设备周围感到不舒服，或担心咀嚼时会损坏设备。在开放式回答中患者所担心的问题，声佗医疗已经解决了很多，下一代设备的发布也将解决其他问题。

(11). " A Novel Intraoral Bone Conduction Hearing Prosthesis: One-Year Safety and Efficacy Study "

Richard K Gurgel , et al. Otology & Neurotology. 2014

The safety and efficacy of IOBC were evaluated by APHAB questionnaire and SSD questionnaire in this 12-month multicentre study.The results of 81 patients who completed the study were that IOBDC had significant benefits in terms of communication convenience, reverberation, background noise, and overall scoring. Participants showed high satisfaction and no adverse events.

Objective

To assess the safety and efficacy of an intraoral bone conduction (IOBC) hearing prosthesis after 12 months of use.

Study design

Prospective cohort study.

Setting

Multisite study including private practice, hospital based practice, tertiary care, and academic medical centers.

Patients

Patients aged 18 years or older with single-sided deafness (SSD).

Main outcome measure(s)

At the end of 6 months and 12 months, patients were asked to complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire and SSD questionnaire in addition to audiometric testing.

Results

Eighty-one patients completed the study. Hearing thresholds remained the same throughout the study. APHAB results showed a significant benefit ($p < 0.001$) in categories of ease of communication, reverberation, background noise, and global score. The SSD questionnaire showed a high satisfaction among participants, with 93.8% of patients likely to recommend the IOBC. Dissatisfaction was highest with regard to patient's ability to eat with device, with only 55.6% satisfied. No serious adverse events were reported during the study.

Conclusion

The IOBC is a safe and effective alternative to percutaneous osseointegrated hearing implants for patients with SSD. Patient satisfaction and improved hearing benefit are observed after 1 year of using

the device. The IOBC significantly benefitted patients in APHAB categories of ease of communication, reverberation, background noise, and the overall global hearing score. The in-the-mouth transducer is the least-liked feature for some patients, particularly with regard to eating; however, the majority of patients are willing to deal with the size of the device for the hearing benefit gained.

参考译文：

(11). 牙骨传导听力系统：使用一年的安全性和有效性研究

Richard K Gurgel , et al.《耳科学与神经耳科学》2014

本次 12 个月的多中心研究通过 APHAB 问卷与 SSD 问卷评价了 IOBC 的安全性和有效性。81 例完成研究的患者获得结果为 IOBDC 在沟通便利性、混响、背景噪音和整体评分方面有显著的好处，参与者显示了高满意度，未出现不良事件。

目的：评价使用 12 个月后牙骨传导(IOBC)人工耳蜗的安全性和有效性。

研究设计：前瞻性队列研究。

环境：多机构研究，包括私人诊所、医院实习、三级护理和学术医疗中心。

患者：18 岁及以上单侧耳聋(SSD)患者。

主要结果测量：在 6 个月和 12 个月结束时，除了听力测试外，患者还被要求完成助听器效果评估简表(APHAB) 问卷和 SSD 问卷。

结果：81 例患者完成研究。在整个研究过程中，听力阈值保持不变。APHAB 的结果显示，在沟通便利性、混响、背景噪音和整体评分方面有显著的好处($p < 0.001$)。SSD 问卷显示了参与者的高满意度，93.8%的患者可能推荐 IOBC 。病人满意度最低的是对佩戴设备进食，只有 55.6%的人满意。研究期间未报告严重不良事件。

结论：对于SSD患者，IOBC是一种安全有效的替代经皮骨导和植入式骨导设备的方法。观察使用1年后患者满意度和听力改善情况。IOBC在APHAB类别中沟通便利性、混响性、背景噪音和整体听力评分等获益显著。口内机存在一些患者不喜欢的地方，尤其是在饮食方面；然而，大多数患者更看中它为改善听力带来的好处。

(12). "Effects of SoundBite Bone Conduction Hearing Aids on Speech Recognition and Quality of Life in Patients with Single-Sided Deafness"

Qiong Luo, et al. Neural Plasticity Volume 2020

SoundBite bone conduction hearing aids are a good choice for patients with SSD, as it could improve the speech recognition ability of patients both in a quiet and noisy environment and improves the quality of life after wearing hearing aids.

Objectives

To analyse the clinical application of SoundBite bone conduction hearing aids by assessing the improvement of speech recognition and the scores of the benefit scale questionnaire for patients with single-sided deafness (SSD).

Study design

The measurements were evaluated before and after one month of wearing hearing aids using the pure tone audiometry threshold, speech recognition in quiet and in noise, and the Glasgow Benefit Inventory (GBI) benefit scale score.

Patients

Nine patients aged 24 to 61 years with SSD for more than 3 months were enrolled in this study.

Results

The average hearing threshold of bad ears after fitting the hearing aid was 23.5±9.0 dB HL,

representing a significantly improved hearing of 66.4±14.9 dB compared to that before wearing the hearing aid(P<0.001). after wearing the hearing aid, the SRS for the bad ears, obtained at 50 and 65 dB SPL, was increased by 40±12 and 71±15 percentage points, respectively. After wearing the hearing aid, the SRS scores were 45±16% and 18±9%, which significantly increased by 17±6 and 94 percentage points compared to that before wearing the aid(P<0.001).

The GBI results of the questions showed that patients' quality of life improved significantly after wearing soundbite bone conduction hearing aids.

Conclusions

SoundBite bone conduction hearing aids are a good choice for patients with SSD, as it could improve the speech recognition ability of patients both in quiet and noisy environment and improves the quality the speech recognition ability of patients both in a quiet and noisy environment and improves the quality of life after wearing hearing aids.

参考译文：

(12). 品音®(SoundBite)牙骨传导听力系统对单侧聋患者语音识别和生活质量的影响

罗琼等。《神经可塑性》2020

品音®(SoundBite)牙骨传导听力系统是单侧耳聋患者一种很好的听力解决方案，可以提高患者在安静和嘈杂环境中的言语识别能力，提高佩戴后的生活质量。

研究目的：通过对单侧聋(SSD)患者的言语识别能力评估和GBI量表的得分，分析品音®(SoundBite)牙骨传导听力系统的的临床应用价值。

研究设计：在未佩戴助听器和佩戴助听器一个月之后，使用纯音测听阈值、安静和噪声中的言语识别率和GBI量表对测量结果进行全面评估。

患者：9 例年龄在 24~61 岁的 SSD 患者，病程均超过 3 个月。

结果：佩戴品音®(SoundBite)牙骨传导听力系统后，差耳的平均听阈为 23.5±9.0dB HL，与佩戴前相比，听力显著提高66.4±14.9dB(P<0.001)。在50和60dBHL下，差耳提高了40±12%和71±15%。SRS评分分别为45±16%和18±9%，较佩戴助听器前分别提高了17±6%和9±4%(p<0.001)。GBI问卷结果显示，佩戴后患者的生活质量显著改善。

结论：品音®(SoundBite)牙骨传导听力系统对单侧聋患者有益。佩戴一个月后，能提高患者在安静、嘈杂环境下的言语识别能力和生活质量。然而，本实验的样本量很小，该装置在不同听力环境下对言语识别和生活质量的长期影响有待进一步的研究。

(13). A preliminary study on the effect of intraoral bone conduction device on abutment tooth

Objective:

To explore the effect of wearing intraoral bone conduction device on the oral health of patients with single-sided deafness in a short period of time, so as to provide guidance for the promotion and application of intraoral bone conduction device.

Methods:

From October 2018 to May 2019, a total of 18 patients with unilateral deafness were recruited the Chinese PLA General Hospital. The patients were taught to wear the components of intraoral devices for 8 weeks. All patients took panoramic tomography, and were examined the abutment teeth before and after the study, recorded the probing depth, bleeding on probing, tooth mobility, and observed whether there were obvious adverse reactions.

Results:

all the 18 patients were well cooperate, and 36 teeth were included in the study, all of which were the first and second maxillary molars. There was no statistics difference in the probing depth of abutment teeth before and after wearing, which was 3.04±0.59mm and 3.06±0.57mm, respectively; the bleeding on probing rate was 13.89%±8.66% and 15.72%±8.60% before and after wearing, which also had no statistical difference; there was no change in the mobility of all teeth.

Conclusion:

It is safe to wear intraoral bone conduction device in a short period of time. However, the large sample and long-term research in needed to further verify.

参考译文：

（13）.牙骨传导听力系统对基牙影响的初步研究

时权等。中华老年口腔医学杂志,2021 年第19 卷第1 期.

目的：初步探索单侧耳聋患者短期内佩戴牙骨传导听力系统对佩戴区域口腔健康情况的影响，为牙骨传导助听器的推广与应用提供指导依据。

方法：2018年10月至2019年5月间于中国人民解放军总医院招募符合条件的单侧耳聋患者共18人，为患者制作口内助听器部件并教会其佩戴，佩戴时间为8周。所有患者在研究前后对基牙进行检查，记录探诊深度、探诊出血、松动度等情况，并观察是否有明显不良反应情况。

结果：18名受试患者均配合良好，共36颗牙齿纳入研究，均为上颌第一、二磨牙。佩戴前后基牙的探诊深度分别为3.04±0.59mm、3.06±0.57mm，无统计学差异；探诊出血率在试验前后为13.89%±8.66%、15.72%±8.60%，无统计学差异；所有牙齿松动度均无变化。

结论：短期内佩戴牙骨传导听力系统并不会引起基牙的探诊深度加深、探诊出血，松动度无加大，具有一定的安全性，但需要大样本、长期的研究来进一步验证。

（14）.牙骨传导听力系统对成人单侧感音神经性听力损失患者干预早期的听力学成效分析

郗昕 赵辉 庞安然 张贤华 王龙豪 王倩 苏钰 袁永一 赵立东 时权
中华耳鼻咽喉头颈外科杂志2021年5月第56卷第5期

目的：分析Soundbite™品音牙骨传导听力系统(通过牙齿上配戴微型骨振器将声信号直接传至健侧耳蜗)对单侧感音神经性听力损失患者干预早期的听力改善情况,探讨该装置的应用前景。

方法：招募单侧感音神经性听力损失成人患者18例,其中男10例,女8例,年龄19~66岁;纯音测听500、1000、20004000Hz四频率纯音平均听阈患耳≥70dBHL,健耳平均听阈均≤30dBHL。其中先天或自幼单耳失聪8例,突发性聋7例,梅尼埃病1例,听神经瘤术后1例,慢性中耳炎术后失聪1例。患者上颌后牙槽部位须至少一侧有连续两颗牙齿,以保证微型骨振器(称为口内机)的制作与日常佩戴。成效观测期限为配戴 Soundbite™/品音®装置后的(30±7)d,未同时使用其他单侧聋干预装置。成效评估包括:应用TDH50P气导耳机测试患侧助听前后的纯音听阈;以“心爱飞扬”言语测听软件测试患耳在5065 dB SPL声级下的单音节识别率;在声场中采用普通话版矩阵式语句(CMNmatrix)测试信噪不同方位下的信噪比识别阈(50% threshold of signal-to- noise ratio,SNR3),以反映患者头影效应、静噪效应及双耳加合效应;采用助听器效果缩略简表(Abυreviated Profile of hearing aid benefit,APHAB)、言语空间-听音质量(Speech, Spatial and Qualities of Hearing Scale,S9Q)问卷来评价患者使用牙骨装置后的助听效果、空间言语感知等方面的改善程度。

结果：配戴 SoundBite™品音®装置30d后,患侧助听听阈和单音节识别率均显著提高(P值均<0.001);声场中患侧扬声器播放语句而健侧播放稳态言语谱噪声时的SNRo下降幅度(反映头影效应)为(2.6±2.11B;而患者前方播放语句而患侧播放噪声时的SNR3(反映静噪效应)降幅则为(0.3±2.8)dB,差异无统计学意义(P值均>0.5);患者前方同时播放语句和噪声时的SNR下降幅度(反映加合效应)为(1.0±2.2)dB。 APHAB的四个亚项中EC(交流便利)、RV(混响环境)、BN嘈杂背景)三个亚项及整体得分均有显著提升(P值均<0.01);更能反映单侧聋交流困境的SSQ问卷中,事关空间听觉、言语识别及听音质量的得分均有显著性的改善(P值均<0.05)。结论 Soundbite™/品音®牙骨传导听力系统干预早期成效表明,其能显著提升单侧聋患侧的听力及言语识别能力,帮助患者克服在声场噪声环境下识别语句时的头影效应,改善空间听觉的主观感受和言语交流能力,是一种很有前景的非植入式骨导助听装置。

The Laryngoscope

The SoundBite Hearing System: Patient-Assessed Safety and Benefit Study

Richard K. Gurgel, MD; Clough Shelton, MD

Objectives/Hypothesis: To determine the safety and efficacy of the SoundBite for patients over a 6 month period of use.

Study Design: Prospective, multisite, nonrandomized patient enrollment with outcomes based on audiometric profile and self-reported assessment.

Methods: Patients with single-sided deafness were eligible for the study. Patients were fit with the standard SoundBite sound transducer and were asked to wear the device regularly for 6 months. At the end of the trial period, patients completed both a self-assessment and the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaires.

Results: Thirty-four subjects completed the study. Mean APHAB scores improved significantly for ease of communication ($P < 0.001$), background noise ($P < 0.001$), reverberation ($P < 0.001$), and global benefit ($P < 0.001$). Patients reported high rates of auditory benefit in a variety of listening situations and high rates of overall satisfaction with the device. One adverse event with a superficial mouth sore was reported and resolved after appropriate dental care. Twelve patients (35%) reported acoustic feedback. In six of these patients, the feedback resolved after device adjustment.

Conclusion: The SoundBite is a new hearing prosthesis that delivers bone conduction energy. It offers advantages over traditional osseointegrated devices that require surgical placement. Patient satisfaction with the device after 6 months of regular use is high. The SoundBite provided improvement in ease of communication, hearing in background noise, sound reverberation, and an overall global hearing benefit. Acoustic feedback is the most commonly reported problem with the SoundBite, and this is minimized with proper fitting.

Key Words: SoundBite, bone anchored hearing aid, Baha, single-sided deafness.

Level of Evidence: 2c.

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INTRODUCTION

Bone conduction is an effective way to deliver sound to the inner ear. When compared to transcutaneous stimulation, direct coupling of acoustic energy to bone provides improved aided thresholds, speech-in-noise, and overall hearing performance.[1–3] In 1981, Tjellstrom et al. provided one of the early clinical reports of using an osseointegrated titanium implant in the temporal bone, later known as the bone anchored hearing aid.[4] More recently, a new device called the SoundBite (SonitusMedical, Inc., San Mateo, CA) has been developed as an alternative to percutaneous titanium implants.[5]

The SoundBite utilizes a behind-the-ear (BTE) transmitter that is connected to a microphone placed in the ear canal of the hearing-impaired ear (Fig. 1). The BTE module sends a signal to a custom made in-the-mouth (ITM) transducer that couples the buccal surface of the maxillary molars to a piezoelectric bone stimulator capable of conducting sound (Fig. 1). Reports have shown the efficacy of the SoundBite in amplifying sounds over a wide range of frequencies (250-12,000 Hz) and improving hearing in noise.[5,6] The purpose of this study was to assess the safety and efficacy of the SoundBite for patients over a 6 month period of use.

MATERIALS AND METHODS

Seven study sites located in Arizona, California, Florida, Michigan, Texas, and Utah enrolled patients in the study. To reflect a broad population of users, the sites were chosen to represent small- and medium-sized private practices; hospital-based practices; and a tertiary care, academic medical center. Institutional review board approval was obtained for each site. Patients who had already elected to use the SoundBite were then subsequently informed and enrolled in the study. There was no randomization of the subjects as all wore the same SoundBite device. Patients were financially reimbursed a nominal amount ($100 paid by Sonitus medical) for completing the outcome questionnaires, but were personally responsible for all other medical, dental, travel, and device costs.

All medical, dental, and audiologic services were provided by licensed professionals. Adult patients with unilateral, acquired sensorineural hearing loss of any etiology were eligible for enrollment. In the better hearing ear, a four-tone (500, 1000, 2000, and 3000 Hz) pure tone average (PTA) of $\leq$25dB with no

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Fig. 1. The SoundBite in-the-mouth (left panel) and behind-the-ear components (right panel).

air bone gap was required. In the poorer hearing ear, no measurable hearing or a PTA of $\geq$75dB was required. Inclusion criteria also included a minimum of three posterior maxillary teeth on the aided side, no active dental carries, periodontal disease, or current orthodontic hardware. The ITM device was fit by a dentist who first obtained a dental impression of the patient's mouth and then adjusted the ITM as needed.

All diagnostic audiometry was performed by measuring conventional thresholds with standardized earphones calibrated in dB HL according to American National Standards Institute (ANSI) standards.[7] When evaluating hearing devices in cases of single-sided deafness (SSD), it is impossible to obtain accurate aided thresholds in the sound field because the better hearing ear will detect sound by air conduction. Plugging the good ear alters the thresholds for SSD devices (SoundBite, Baha, etc.) because this artificially increases bone conduction sensitivity (for the same reason that the Weber lateralizes to the ear of a unilateral conductive loss cases). Therefore, conventional aided sound field thresholds typically cannot be used when testing patients with SSD. However, when considering a hearing device where the microphone is located in the external canal such as with the SoundBite, a conventional earphone can be placed over the aided ear to obtain accurate and calibrated aided thresholds. The aided thresholds reported in the study were obtained this way.

After the ITM component was built, patients wore the standard, commercially available SoundBite system. This was programmed to produce equal loudness for tones in the 1000 Hz to 6000 Hz range. Patients were asked to use the device for 6 months and then complete a questionnaire. The questionnaire evaluated the patients' experience for hearing improvement, satisfaction, preference of the device, and likelihood of recommending the device as well as any procedure- or device-related adverse events (see online Appendix 1). This questionnaire was developed to evaluate patients' experience specifically with the SoundBite and is a non-standardized and non-validated metric.

Patients also completed the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire. The APHAB is assessment tool used to quantify benefit from hearing prosthetics.[8] The APHAB is a 24-item, self-reported inventory that assesses outcomes for ease of communication (EC), background noise (BN) and reverberation (RV), and aversiveness (AV). The AV score was not included and is not typically used for single-sided deafness patients because this metric is generally significant only for regular hearing aid patients who have some degree of sensorineural hearing loss in the ear receiving the signal. We included a global function (GBL) score, which is an average of EC, BN, and RV scores, and is meant to represent overall function. While the GBL score is not part of original APHAB scoring, the GBL score has been used in similar fashion in other articles evaluating bone conduction devices.[6,9,10] APHAB scores before and after the trial were obtained with larger scores representing more difficulty hearing in everyday situations. A significant benefit was defined as a difference of $\geq$22 on any one of three sub scales (EC or RV or BN) or $\geq$5 on all three sub scales (EC or RV or BN). The statistical differences in mean APHAB scores were determined by Student's t tests.

RESULTS

Forty patients were enrolled in the study. Three subjects were excluded because they did not meet audiometric inclusion criteria. Three subjects were excluded because of inadvertent data collection errors. Data from 34 subjects were analyzed. The average patient age was 51.4 years old, with a gender distribution of 14 men and 20 women. The demographic data for each subject and audiologic results are shown in Table I.

Aided thresholds were within the normal hearing range and did not change during the study (average pre-trial PTA was 11.8 dB HL with a standard deviation [SD] of 6.1; average post-trial PTA was 11.1 [SD 4.9]). For the device conditions, the average pre-trial aided threshold was 17.5 dB HL (SD 10) and average post-trial aided threshold was 21.3 dB HL (SD 8.5). There was no statistical difference between mean pre- and post-trial aided thresholds ($P > 0.001$). Mean APHAB benefit scores are shown in Figure 2. Mean APHAB scores improved significantly for ease of communication ($P < 0.001$), background noise ($P < 0.001$), reverberation ($P < 0.001$), and global benefit ($P < 0.001$). Individual APHAB benefit scores, which represent the difference between the initial unaided scores and the 6-month aided scores, reached significance in 76% of the subjects.

The patient satisfaction questionnaire results showed that 100% of patients would be likely to recommend the device to other SSD patients, 91% preferred wearing the device to not wearing the device, and 88% were satisfied with the process of obtaining the device. On average, patients reported becoming acclimated to the device within 1 week of use. Sixty-eight percent of patients thought the SoundBite system was a good value for the money. Questionnaire results regarding auditory function and satisfaction in wearing the device are shown in Figures 3 and 4, respectively. All unedited questionnaire responses are available on Appendix 2.

There were no adverse events related to the dental, fitting, or subsequent audiology procedures. One adverse event was reported related to wearing the device. The patient had minor soreness in the mouth adjacent to the ITM component. The patient's dentist diagnosed a superficial fungal infection and treated the patient with topic antifungals; the condition resolved.

Twelve patients (35%) reported acoustic feedback. In six of these patients, the feedback resolved after the ITM, microphone, or gain were adjusted. For six patients, the feedback did not resolve, despite adjustments, but occurred only occasionally for four of those six patients (two were unknown due to inadequate

TABLE I.
Patient Demographics.

	Site				PTA		Aided Thresholds	
N	Locationn	Type	Gender	Age	Pre	Post	Pre	Post
1	TN	P (M)	M	73	18.8	16.3	44.2	42.5
2	TN	P (M)	M	42	21.3	22.5	44.0	31.7
3	TN	P (M)	F	47	20.0	16.3	26.9	31.7
4	TN	P (M)	M	68	13.8	12.5	22.7	25.0
5	CA (s)	P (S)	F	71	12.5	8.8	19.4	25.8
6	CA (s)	P (S)	F	24	6.3	5.0	5.2	15.0
7	AZ	P (S)	F	53	8.8	10.0	19.8	24.2
8	AZ	P (S)	F	58	13.8	13.8	24.6	25.8
9	AZ	P (S)	F	78	22.5	18.8	26.9	29.2
10	AZ	P (S)	F	60	10.0	8.8	12.3	17.5
11	AZ	P (S)	F	71	13.8	13.8	15.5	27.5
12	AZ	P (S)	M	67	11.3	6.3	22.9	24.2
13	AZ	P (S)	F	44	1.9	6.3	8.4	10.0
14	AZ	P (S)	F	44	5.0	10.0	8.0	10.8
15	AZ	P (S)	M	55	20.6	17.5	25.1	26.7
16	CA (n)	P (M)	F	40	5.0	7.5	8.8	14.2
17	CA (n)	P (M)	M	62	6.3	7.5	16.5	18.3
18	CA (n)	P (M)	M	38	8.8	11.3	7.5	10.0
19	CA (n)	P (M)	M	38	8.8	7.5	11.0	15.0
20	CA (n)	P (M)	M	42	20.0	17.5	23.8	19.2
21	CA (n)	P (M)	M	41	16.3	11.3	13.8	14.2
22	CA (n)	P (M)	F	53	11.3	12.5	11.5	23.3
23	FL	P (S)	F	71	6.3	10.0	13.5	28.3
24	FL	P (S)	M	46	17.5	17.5	33.0	30.0
25	MI	H	F	53	12.5	8.8	12.7	25.0
26	MI	H	M	39	10.0	11.3	13.5	17.5
27	UT	A	M	43	3.8	3.8	4.6	7.5
28	UT	A	F	54	0.0	3.8	6.5	13.3
29	UT	A	F	46	22.5	13.8	21.0	17.5
30	UT	A	F	49	10.0	16.3	20.2	39.2
31	UT	A	F	50	16.3	15.0	18.5	19.2
32	UT	A	M	33	8.8	8.8	10.4	20.8
33	UT	A	F	37	5.0	2.5	1.3	9.2
34	UT	A	F	59	11.3	5.0	21.9	15.8
mean				51.4	11.8	11.1	17.5	21.3
SD				13.1	6.1	4.9	10.1	8.5

Aided Threshold = average of thresholds at 1000, 2000, 3000, 4000, and 6000 Hz; Location (AZ = Arizona, CA = California, FL = Florida, MI = Michigan, TX = Texas, UT = Utah; n = northern, s = southern); PTA = average of thresholds at 500, 1000, 2000 and 3000 Hz, in dB HL; SD = standard deviation; Type (A = academic center, H = hospital, P = private practice, M = medium, S = small).

follow-up). Sixty-eight percent of patients were satisfied with their ability to eat with the SoundBite in place, whereas 21% were dissatisfied and 12% were very dissatisfied with their ability to eat with the ITM. Seven patients (21%) identified issues with ITM—i.e., size or comfort—as their least-liked aspect. Five patients (15%) identified issues with the BTE—i.e., fitting appropriately, causing itching of the ear canal, or having a device on the ear—as their least-liked aspect. Three patients (8%) reported issues with the battery—i.e., battery life and remembering to charge it—as their least-liked aspect of the SoundBite.

DISCUSSION

This study has shown that the SoundBite is safe and effective in subjects with single-sided deafness who used the device daily over a 6 month period. Other than one patient with soreness near the ITM due to a superficial fungal infection that resolved with topical treatment, no adverse dental or other events were reported. As shown in similar outcomes studies, the SoundBite did not alter the subjects' intrinsic hearing ability, as determined by the unchanged pre- and post-trail hearing thresholds.[5,6,9,11] The pre- and post-trial unaided audiometric thresholds did not change during the trial,

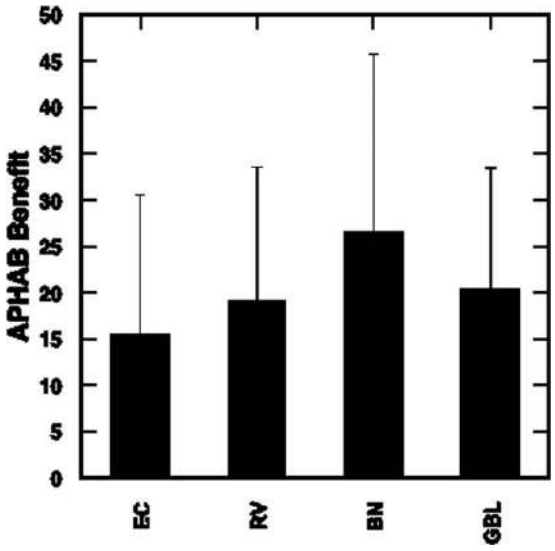

Fig. 2. Mean APHAB benefit scores (+ 1 SD) at 6 months for ease of communication (EC), reverberation (RV), background noise (BN), and global (GBL). Benefit scores represent the difference of the 6 month aided and initial unaided scores.

suggesting that the device is safe to native hearing. This finding also means that aided thresholds can be used to accurately assess device performance; any changes in aided thresholds would not be confounded by changes in hearing sensitivity. The pre- and posttrial aided thresholds also did not change, suggesting that the device performance is stable and that the anatomic structures conducting sound (tooth, tooth ligament, maxilla, and temporal bone) were not altered in a way that affected sound conduction during the trial period.

Study subjects reported a significant hearing benefit from the SoundBite in everyday listening environments. Effectiveness was demonstrated by the statistically significant improvement in APHAB scores. Each APHAB subscore—ease of communication, background noise, reverberation, and global benefit—reached statistical significance for improvement when comparing pre- and postaided score. Subjects' self-reported assessments were very positive, with all patients being likely to recommend the SoundBite to other SSD patients and 91% preferring to wear the device rather than not wear the device. These results help confirm that patients subjectively benefit from regular use of the SoundBite.

This study only investigated patients with single-sided deafness. A PTA for the better hearing contralateral ear of $\leq$25 dB HL was an inclusion criteria. The SoundBite has not yet been FDA approved for sensorineural hearing loss $>$ 25 dB HL in the better hearing ear. Though the SoundBite has gain and output equivalent to other osseointegrated devices, clinical studies have not yet been completed to determine the maximum sensorineural hearing level in the better ear.

Results from this study show that the SoundBite is a reasonable, nonsurgical alternative to ossteointegrated, percutaneous implants. While the ossteointegrated implants provide high-quality bone conduction, there are some limitations. They require a procedure for placement and regular postoperative hygiene. Moreover, complications such as local inflammatory response, skin overgrowth, and infection are also possible. In multiple large series evaluating bone anchored hearing aid complications, the need for revision surgery has been reported in 5.8% to 25% of patients.[12–14] In the pediatric population, this rate can be even higher, with one series reporting 37% of children requiring revision surgery or removal of the implant.[15]

The most commonly raised problem in this study group was with acoustic feedback of the SoundBite. Feedback results from acoustic energy of the bone conduction transducer entering the microphone. The source

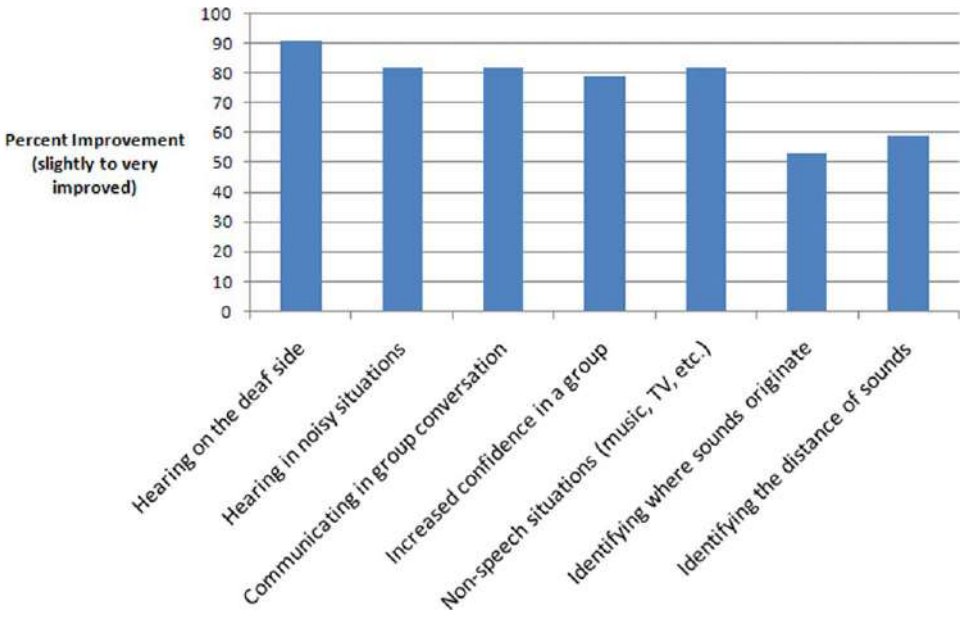

Fig. 3. Results from the patient questionnaire regarding auditory benefits of SoundBite. Patients scored each question based on the following options: very much improved, improved, slightly improved, no change, or worse. This graph shows the aggregate percentage for all of the "improved" categories. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

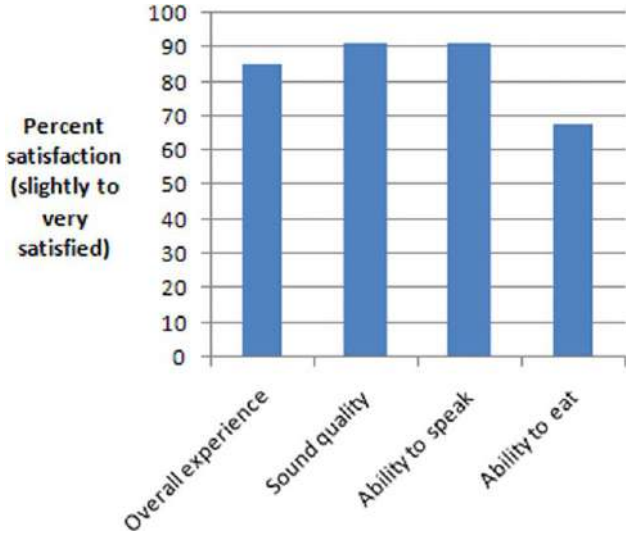

Fig. 4. Results from the patient questionnaire regarding satisfaction from using the SoundBite. Patients scored each question based on the following options: very satisfied, satisfied, slightly satisfied, slightly dissatisfied, dissatisfied, very dissatisfied. This graph shows the aggregate percentage for all of the "satisfied" categories. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

of the acoustic radiation can differ for each patient. Radiant acoustic energy entering the microphone can originate directly from the ITM or indirectly from the soft tissues touching the ITM (cheek, or lateral portion of the ear canal), or from the adjacent hard tissues (the teeth or bony portion of the ear canal).

Controlling the fit of the ITM reduces the possibility of radiant acoustic energy, as does reducing the gain from the microphone for the BTE. Some of the feedback was reduced in cases where the ITM was remade for comfort. When a better fit was obtained, less gain from the microphone was needed, so a change in the BTE also simultaneously reduced the feedback. Feedback during the fitting process is a different situation than feedback after the fitting process. The information from the questionnaires tried to separate these two.

As shown in Figure 4, 68% of patients were satisfied with their ability to eat with the SoundBite in place. While this percentage is favorable overall, it did represent the lowest patient satisfaction score. The ITM does have some bulk that may require an adjustment period. This is similar to issues patients have wearing traditional retainers for orthodontic procedures and is generally found tolerable.[16–18] The SoundBite ITM component does not cover the occlusal surfaces of the teeth, and there is no trough to collect food or liquids. In addition, there is no increase in amplification of the sounds from mastication because the microphone is not in the mouth. Therefore all eating and liquid ingestion can occur while wearing the device. There will be some patients, however, who will likely feel that the ITM is too bulky for comfort, especially while eating. These patients will have to decide if the benefits of wearing the device outweigh the difficulty with eating and speaking, or if they will selectively remove the device while eating, which would limit the hearing benefit of the device. No patients in this study stopped using the device because of these inconveniences.

Global limitations of this study include its subjective assessment, which is prone to user bias. A selection bias is also possible in those patients who were willing to participate in the study as these patients may feel more strongly for or against the device than other users. This study, however, was intended to assess patient feedback and the quality of their experience. The questionnaire was, therefore, an appropriate metric to collect these data.

This device and other osseointegrated devices are prosthetic devices that are not directly comparable to a hearing aid with regard to cost and reimbursement. Therefore, the out-of-pocket cost will depend on the prosthetic coverage of the patient's insurance plan for the device (≈$6,800), plus dentist fees (≈$150), plus provider fees (≈$750). Note that the costs cited are approximations of expense at the time that this article was written. Some insurance companies already cover the cost; others are likely to do so in the future. Out-of-pocket expenses for the patient are one possible barrier to access to the SoundBite. Reimbursement issues for the SoundBite to cover the dental, audiological, and physician costs continue to be negotiated with the both private insurers and public payers.

CONCLUSION

The SoundBite is a new hearing prosthesis that delivers bone conduction energy. It offers advantages over traditional osseointegrated devices in that it does not require surgical placement. Patient satisfaction with the device after 6 months of regular use is high. The SoundBite provided improvement in ease of communication, hearing in background noise, sound reverberation, and an overall global hearing benefit. Acoustic feedback is the most commonly reported problem with the SoundBite, and this is minimized with proper fitting.

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APPENDIX: 1

PATIENT QUESTIONNAIRE

This patient questionnaire was filled out by patients at the end of 6 months of SoundBite use.

APPENDIX: 2

PATIENT QUESTIONNAIRE RESPONSE

These are the unedited patient responses to the patient questionnaire found in Appendix 1. Where free text answers were an option, the patient's full responses are included.

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Original Article

Preliminary comparison of bone-anchored hearing instruments and a dental device as treatments for unilateral hearing loss

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Abstract

Objective: To compare the effectiveness of two types of treatment for unilateral hearing loss (UHL), bone-anchored hearing instruments (BAHI) and a dental device (SoundBite). *Design:* Either BAHI or SoundBite were worn for 30 days, and then the devices were swapped and the second device was worn for 30 days. Measures included unaided and aided sound-f eld thresholds, sound localization, and perception of speech in babble. The APHAB questionnaire was administered for each trial period. *Study sample:* Nine adult BAHI wearers with UHL. *Results*: Mid-frequency aided thresholds were lower for SoundBite than for BAHI. Both devices gave benef ts for localization after 30 days, but there was no difference between devices. Speech perception was better for both devices than for unaided listening when the target speech came from the poorer hearing side or in front, and the interfering babble came from the better-hearing side. There was no consistent difference between devices. APHAB scores were better for SoundBite than for BAHI. *Conclusions*: Speech perception and sound localization were similar for the two types of device, but the SoundBite led to lower aided thresholds and better APHAB scores than the BAHI.

Key Words: Unilateral hearing loss; single-sided deafness; bone conduction; bone-anchored hearing device; speech perception; sound localization

Hearing device options for unilateral hearing loss (UHL) have increased greatly in the last few years; for reviews, see Valente and Oeding (2011) and Dillon (2012). All of these devices have similar primary elements, with a microphone positioned close to the poorer-hearing ear, a method of transferring the microphone signal across the head, and a method of delivery of the microphone signal to the better-hearing ear. All of the devices have the same basic design goals, including improved ability to hear sounds coming from the poorer-hearing side and improved speech communication in quiet and in noisy situations, especially situations where the target speech comes from the poorer-hearing side.

Although devices for treating UHL have similar elements and intended purposes, the details of the implementation differ substantially in ways that may affect both the effectiveness of the device and the patient's decision about which device is most appropriate for them. Table 1 lists the primary differences between current devices for treating UHL.

Some of the differences affect the patient's selection decision regardless of functional performance. These include: (1) Is surgery required? Willingness to undergo surgery can be affected by physical health and any recent history of surgery, reversibility, and the possibility of ongoing complications, such as infection or skin irritation around an implanted pedestal; (2) Financial considerations, since insurance coverage is not uniform; (3) Physical comfort, for example pressure from transdermal coupling force; (4) The possibility of a trial period, since some devices can be returned after a trial while others cannot. In addition, differences across devices complicate the process of demonstration of function prior to selection. For some devices, performance can only be demonstrated via the use of simulators that may not represent actual device performance.

Some of the differences across devices can affect the patient's selection decision because they may be associated with differences in functional performance. For a device using a microphone mounted behind the poorer hearing ear, sounds coming from in front may be partly shielded by the pinna (Stenfelt, 2005), which could adversely affect the intelligibility of speech coming from the front, especially when there is noise coming from behind or the poorer hearing side. This disadvantage may be partly overcome by use of a directional microphone (Olsen et al, 2011). When the microphone is located in the pinna, the microphone will respond better to sounds coming from the front than to sounds coming from behind, because of the natural directivity of the pinna (Shaw, 1974). This may be advantageous in noisy situations. In addition, the direction-dependent f ltering produced by the pinna provides cues for sound location (Batteau, 1967; Blauert, 1997; Moore, 2012b), and a microphone in the pinna provides access to these cues, potentially allowing improved sound localization, especially a reduction of front-back and up-down errors (Best et al, 2010).

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Abbreviations

APHAB	Abbreviated prof le of hearing aid benef t
AC	Air conduction
BAHI	Bone-anchored hearing instrument
BC	Bone conduction
BTE	Behind-the-ear
ITM	In-the-mouth
OFL	Output force level
PTA	Pure-tone average
SNR	Signal-to-noise ratio
UHL	Unilateral hearing loss

Another factor that may affect the relative benef t of different devices is the effective bandwidth, and especially the upper frequency limit. A wider bandwidth can lead to improved sound quality (Moore et al, 2004; Ricketts et al, 2008; Moore & Sek, 2013; Moore, 2012a), an improved ability to understand speech in noise (Moore et al, 2010), and improved localization of speech and other sounds (Best et al, 2005). Unfortunately, there are few published data that can be used to make meaningful comparisons of effective frequency range across devices used for the treatment of UHL. This is unfortunate, as it limits the ability of the patient to make an informed decision. Clinical measures of unaided and aided thresholds for frequency-specif c narrowband signals may be used to estimate the maximum effective functional gain, but sound f eld measures are complex and have substantial complications for UHL cases. First, the measured sound-f eld aided thresholds greatly depend on the device settings, including frequency-specif c and overall gain and whether or not the device is operating in a linear range (Hodgetts et al, 2010). Second, the direct, non-device route to the better cochlea is diff cult to eliminate. If reduction of sound transmission to the better ear is implemented by plugging the external ear canal on the better side, this can affect the sensitivity of the better-hearing ear for bone-conducted (BC) stimuli (Stenfelt & Reinfeldt, 2007). Third, internal noise in the device may limit the audibility of weak sounds (Hodgetts et al, 2010).

Clinical measures of spatial hearing ability are also complex and have complications for UHL cases. First, the usual measures of sound localization of signals in the horizontal plane are based on binaural hearing and UHL cases have monaural hearing with or without a device. Second, the sound f eld acoustic environment in traditional clinical sound booths will be highly variable based on differences in booth size, ref ectivity of interior spaces, number of loudspeakers and loudspeaker placement. Third, most clinics will only have one or two loudspeakers available, whereas testing of localization ability requires several loudspeakers.

Clinical measures of the ability to understand speech in noise also have complications for UHL cases, especially when the testing involves presentation of speech and background sounds coming from different directions. First, such tests are not standardized or optimized for the clinic. Second, they may require additional equipment, such as multiple loudspeakers, which are not available in many audiology clinics. Third, they often require considerable testing time. Finally, because they are language based, suff cient equivalent forms and versions in multiple languages may not be available. In this study, we used the QuickSIN test (Killion et al, 2004), which is rapid to administer and which has been recommended for use for evaluation of bone-anchored hearing instruments (BAHI) f tted to patients with UHL (Snapp & Telishi, 2008; Snapp et al, 2010).

This paper reports a comparison of auditory performance measures for two classes of UHL device. One class was BAHI of various models from different manufacturers; all participants had previously been f tted with such devices. For these devices, surgery had been performed previously to implant a pedestal in the skull behind the ear on the poorer-hearing side. It was decided to test existing BAHI wearers to avoid the need for surgery as part of the study. The BAHI devices all used a microphone behind the ear on the poorer-hearing side. The effective frequency range over which the BAHI produced useful gain is hard to determine, but the gain and maximum output of most BAHI tend to fall off with increasing frequency above 1000 Hz and both gain and maximum output level are usually low above 6000 Hz (Bosman et al, 2009; Hodgetts et al, 2010). For most of the devices, the claimed upper frequency limit was 7000 Hz.

The other class of device was a newly-f tted dental device (SoundBite by Sonitus Medical; see Popelka et al, 2010; Miller et al, 2011; Murray et al, 2011a, b). This device has a microphone positioned at the entrance to the ear canal on the poorer-hearing side. The microphone signal is amplif ed, given frequency-dependent gain, and transmitted to a receiver mounted on a rear molar, usually on the better-hearing side. The tooth-mounted part includes a transducer and actuator that produces a BC signal, which is perceived in the

Table 1. Features of current devices for treating UHL ([1]Contralateral routing of signal devices from various hearing-aid manufacturers; [2]Various models from Cochlear Corp; [3]Various models from Oticon Medical; [4]Sophono Inc; [5]MED-EL; [6]Sonitus Medical; [7]Ear Technology Corp.).

Device	*Microphone location*	*Transfer method*	*Output transducer location*	*Patient control of component*	*Signal delivery pathway*
CROS[1]	On top of pinna	Wire or wireless link	In external ear canal on better side	Removable	AC to better cochlea
BAHA[2] Ponto[3]	Behind pinna	BC	On post surgically implanted in skull on the poorer side	Not removable	BC to better cochlea
Alpha1[4]	Behind pinna	BC	In module surgically implanted in skull on the poorer side	Not removable	BC to better cochlea
Bonebridge[5]	Behind pinna	BC	In module surgically implanted in skull on the poorer side	Not removable	BC to better cochlea
SoundBite[6]	In external ear canal	BC	In module on teeth usually on the better side	Removable	BC to better cochlea
Transear[7]	On top of pinna	BC	In external ear canal on the poorer side	Removable	BC to better cochlea

better-hearing ear. The SoundBite system uses rechargeable batteries. The battery for the behind-the-ear (BTE) part typically lasts for a whole day, but the battery for in-the-mouth (ITM) part typically lasts for 6–8 hours, so two ITM parts are provided to each user. The ITM part is designed so the user can eat and drink with it. However in practice, based on a survey conducted by Sonitus Medical, about 35% of SoundBite users eat with the ITM part in place all the time, another 30% only eat with it when they are in a social setting, and the remainder take the ITM part out for eating. The SoundBite system includes an adaptive feedback canceller. The SoundBite system is capable of providing useful gain for frequencies up to at least 10 000 Hz, as determined by loudness balancing of high-frequency sounds presented via the device and via air conduction to the better ear (Popelka et al, 2010); see below for details. A loudness match can be achieved for frequencies up to 10 000 Hz for most participants with normal or near-normal hearing in the better ear. However, for the version of the SoundBite system tested in this study, the upper frequency limit was 9000 Hz, because of the limited bandwidth of the wireless transmission system.

The main purpose of the present study was to compare the effectiveness of the two classes of device, BAHI and SoundBite. A second purpose was to evaluate the practical usage of measures of BC device efficacy that are feasible in typical clinical settings.

Study Design

Study sample

A heterogenous sample (N = 9) of participants was recruited via advertisements in offices of multiple physicians who perform BAHI surgeries. Inclusion criteria were age (> 18 years old), a diagnosis of UHL with pure-tone average (PTA) air-conduction (AC) thresholds at 500, 1000, 2000, and 3000 Hz better than 25 dB HL in the better ear and worse than 75 dB HL in the poorer ear, currently wearing a BAHI system, English as their native language, and no full dentures. Each participant received payment only for travel expenses. Table 2 shows each participant's age, gender, PTA, affected ear, current BAHI device, and total duration of BAHI experience regardless of which BAHI devices were used prior to the current BAHI device.

Research design

Regardless of the length of time that the current BAHI had been worn, for the purpose of this trial, each type of device was worn for a 30-day experimental period in a randomized crossover design. A single licensed and certified research audiologist from Sonitus Medical, who was familiar with fitting the SoundBite device, was used to fit the SoundBite device and obtain all measures according to a strict written research protocol. The experimental period began with random selection of one device (logistical factors such as device ordering periods were considered, but there were no other considerations such as particular current BAHI model or total BAHI experience). At 30 days, the devices were swapped for a second 30-day period (total of 60 days). All measures were obtained at Day 1 and Day 30 for each device (i.e. for each 30-day period). At the end of the experimental period, the SoundBite device was returned and the participants continued to wear their current BAHI device. The settings of the BAHI devices remained as the participants were wearing them and were not changed during the study. The fitting procedure for the SoundBite device is described below. All results were statistically analysed using paired sample t-tests.

Fitting and characteristics of the BAHI devices

All BAHI devices had a microphone integrated into the device and located behind the ear on the poorer-hearing side. All BAHI had been fitted according to the recommended protocol of the manufacturer of each device in centres with extensive experience of such devices. All participants reported that the BAHI devices were working in the same way as when originally fitted. All of the audiologists who fitted the BAHI devices were experienced at fitting such devices. The BAHI devices were not re-fitted for this study. The main characteristics of each BAHI device are summarized below. It should be noted that when the better ear of a client with UHL has near-normal hearing, the BAHI devices are usually programmed to provide linear amplification, but with output compression limiting. When the better ear has high-frequency hearing loss, compression at high frequencies is sometimes applied.

The Cochlear BP100 device, used by six participants, incorporates wide dynamic range compression using 12 channels. It features an adaptive multichannel directional microphone, adaptive noise cancellation, and adaptive feedback cancellation. The frequency range is specified as 250 to 7000 Hz. It has a volume up-down button.

The Cochlear Divino device, used by one participant, incorporates compression with attack time of 8 ms and release time of 500 ms (number of channels not specified). It features a non-adaptive

Table 2. Participant age, gender, PTA in the better ear, PTA in the poorer ear, current BAHI, and total BAHI wearing experience.

No	*Age (years)*	*Gender*	*Better ear PTA (dB HL)*	*Poorer ear PTA (dB HL)*	*Current BAHI*	*Total BAHI experience (years)*
1	48	M	15.0	> 115.0 (L)	Oticon Medical Ponto Pro Power	7
2	44	F	7.5	> 115.0 (L)	Cochlear BP100	7
3	66	F	16.3	98.8 (L)	Cochlear BP100	2
4	56	F	8.8	108.8 (R)	Cochlear Divino	3
5	68	F	12.5	> 115.0 (L)	Cochlear BP100	2
6	60	F	3.8	> 115.0 (R)	Cochlear BP100	2
7	62	M	12.5	110.0 (R)	Cochlear BAHA Compact	7
8	47	M	21.3	75.0 (L)	Cochlear Intenso	2
9	38	M	5.0	> 115.0 (L)	Oticon Medical Ponto Pro	1

directional microphone. The frequency range is specif ed as 250 to 7000 Hz. It has a volume control.

The Cochlear Intenso device, worn by one participant, incorporates compression with attack time of 10 ms and release time of 500 ms (number of channels not specif ed). It features multi-band adaptive feedback cancellation. The frequency range is specif ed as 250 to 7000 Hz. The specif cation does not mention directionality, so it is assumed to be non-directional. It has a volume control.

The Cochlear BAHA Compact device, worn by one participant, is similar to the Cochlear Divino, but is smaller.

The Oticon Medical Ponto Pro and Ponto Pro Power devices, each of which was used by one participant, incorporate multi-channel compression with unspecif ed time constants, but the compression is presumed to be predominantly slow-acting, since it incorporates 'speech guard', which is intended to preserve the modulation patterns of speech while providing a rapid decrease in gain when the sound level increases abruptly. The devices incorporate automatic adaptive directionality, and adaptive noise reduction and feedback cancellation. The frequency range is not specif ed, but the highest frequency for which the gain can be adjusted in the f tting software is 8000 Hz and the gain functions plotted in the specif cation sheet do not extend above 8000 Hz. The Ponto Pro devices have a learning volume control.

Fitting and characteristics of the SoundBite device

The SoundBite device has a non-directional microphone positioned at the entrance to the ear canal on the poorer-hearing side. For the version of the device used in this study, the output force level (OFL, in dB re 1 μN) was measured using a Bruel and Kjaer 8001 impedance head, with integrated force gauge, mounted on a f xed platform. The mechanical impedance load of the impedance head was much higher than the SoundBite source impedance and provided a measure of the maximum OFL delivered by the system, analogous to driving the skull directly through a f xed/implanted tooth. The microphone of the BTE part was positioned in an anechoic test chamber at a calibrated position. The ITM part was coupled to the impedance head with a static clamping force, and OFL in response to an input of f xed sound level was measured. The OFL increased gradually as the input frequency was increased from 1500 to about 7000 Hz, and rolled off above this. The maximum output force was above 118 dB re 1 μN for frequencies from 2500 to 7400 Hz and above 105 dB for frequencies from 1700 to 8500 Hz. The SoundBite device does not have a volume control and usually operates as a linear amplif er with frequency-response shaping and output compression limiting. It includes an adaptive feedback cancellation system.

The SoundBite was f tted using a behavioral real-ear method, in which the loudness of a BC and AC signal of the same frequency was matched. The ANSI Standard (ANSI, 2004) provides reference equivalent threshold values for specif c diagnostic air-conduction transducers, including the Sennheiser HDA200 used here, as well as a loudness-balancing procedure to transfer these known values to an unspecif ed transducer (SoundBite, in this case). When the audiometer signal from the calibrated transducer (Sennheiser earphone on the good ear) is balanced in loudness to the same signal from the Soundbite, this means that the bone conduction level from the SoundBite is equivalent to the calibrated signal from the earphone. This method accounts for individual differences in the total pathway from device microphone to the cochlea of the better-hearing ear.

Details of the loudness balancing procedure for SoundBite, including typical standard deviations of the loudness matches, are given in Popelka et al (2010), so only a brief description is given here. A f xed acoustical signal was delivered via a Sennheiser HDA200 headphone to the device microphone (mounted at the entrance to the ear canal on the poorer hearing side). This was transformed to a BC signal by the SoundBite device, producing a signal of f xed loudness in the better ear. This signal was alternated with a signal of the same frequency delivered acoustically via a Sennheiser HDA200 headphone mounted on the better ear. The level of the latter was adjusted until the participant reported that the loudness was matched for the two signals. This was easy to judge, as the two signals were perceived via the same cochlea and had the same pitch. These loudness judgments were repeated for the standard audiometric frequencies from 1000 to 6000 Hz, and the results were used to program the behind-the-ear component so that sounds coming from the poorer-hearing side were heard as having the same loudness as sounds of the same level coming from the better side, for all frequencies. Such a setting is appropriate when hearing on the better side is normal or near-normal. The gain values were then subject to minor adjustments, separately for each frequency channel, for a variety of other purposes, such as to accommodate hearing loss in the better ear, to reduce acoustic feedback, and to accommodate patient preferences. For example, if the participant reported that sounds from the poorer hearing side were too 'tinny', the high-frequency gain was reduced slightly. Usually, gain adjustments were below 5 dB.

Measures obtained

For all measurements, if the BAHI devices had a volume control, participants were asked to adjust it to the value that they would use in everyday life.

Sound-f eld thresholds

Absolute detection thresholds were measured in the sound f eld for narrowband frequency-modulated signals presented in a clinical sound booth at 0 degrees azimuth in accordance with ANSI (2004) and ISO 389-7 (2005). Calibration was performed using a sound-level meter at the position of the centre of the listener's head, without the listener present. The measures were obtained with the better ear covered with a Sennhesier HDA 200 headphone to attenuate the sound f eld signals traveling directly to the cochlea of the better ear and to reduce the change in BC sensitivity that can occur with other methods of blocking this route, such as with an ear plug (Stenfelt & Reinfeldt, 2007). The passive attenuation provided by the HDA 200 is about 14 dB at 125 Hz, and increases progressively to 46 dB at 4000 Hz. The measurements were made with no device (unaided) and with the device f tted and switched on (aided).

The center frequencies of the signals were 1000, 1500, 2000, 3000, 4000, and 6000 Hz. Frequencies of 1000 Hz and above were chosen since devices for treating UHL do not need to provide gain for frequencies below about 1000–1500 Hz. The main function of UHL devices is to transfer sound picked up from the poorer-hearing side to the better ear. Sounds composed of frequency components below 1000 Hz that come from the poorer-hearing side bend around the head and reach the better ear with very little attenuation (Feddersen et al, 1957). Hence no gain is needed. Indeed, there may be some benef ts of attenuating rather than amplifying low-frequency components (Pf ffner et al, 2011).

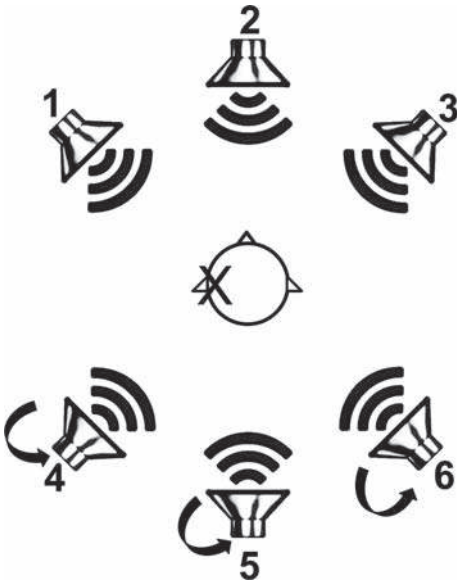

Figure 1. Illustration of the spatial arrangement of the loudspeakers for the sound localization and speech perception in noise testing. The X indicates the poorer hearing ear. For sound localization testing, all loudspeakers (1, 2, 3, 4, 5, 6) faced towards the participant. For speech perception in noise testing, the three rear loudspeakers (4, 5, and 6) were rotated by 180° to face away from the participant. This created a more diffuse sound f eld and simulated a situation where different background talkers face different directions.

Sound localization

The ability to localize sounds in the horizontal plane was measured in a conventional room (not sound treated) typical of an off ce. This was done to make the listening conditions more realistic and representative of everyday life and because in clinical practice a sound booth suff cient in size to accommodate all of the loudspeakers would not routinely be available. The participant was seated in the center of an array of six loudspeakers arranged as illustrated in Figure 1. Each loudspeaker was 1 metre from the centre of the participant's head and faced towards the participant. Levels were calibrated using a sound level meter at the position of the centre of the listener's head, without the listener present. On each trial, a sound (speech-shaped noise, 5 s in duration, with a level of 72 dBA) was presented from one of the loudspeakers, selected randomly. The loudspeakers were numbered, and the participant was asked to indicate which loudspeaker the sound appeared to come from, by specifying the appropriate number. Thirty six responses were obtained for each participant (Six presentations randomized from each of the six loudspeakers).

Perception of speech in noise

The ability to understand speech in a background of babble was measured using the QuickSIN test (Killion et al, 2004; 2006). This test gives an estimate of the signal-to-noise ratio (SNR) required for 50% correct identif cation. The results are expressed as the signal-to-noise ratio loss (SNR Loss) relative to participants with normal hearing. The target speech was a series of simple sentences presented at 72 dBA and the background was the four-talker babble supplied with the QuickSIN test. The babble in the recorded QuickSIN stimuli varied in level relative to that of the target speech, and the score was recorded for each babble level. The spatial arrangement of the loudspeakers was identical to that illustrated in Figure 1, except that the three loudspeakers to the rear of the participant were rotated by 180° so as to face outwards. This was intended to simulate the situation of having some interfering talkers facing away from the listener. For medium to high frequencies, the loudspeakers used, like human talkers, produce a greater output in the frontal than in the rear-ward direction. Hence, when the loudspeakers faced outwards, the higher-frequency components mainly reached the listener via ref ections from the walls, f oor, and ceiling, making the sound more diffuse.

For a participant with the poorer-hearing ear on the left, the target speech came from loudspeaker 1 (−45° azimuth) or loudspeaker 2 (0° azimuth, i.e. straight ahead). The interfering babble came from one or more loudspeakers, as specif ed in Table 3. When two or more interfering loudspeakers were active, the babble from each loudspeaker was uncorrelated; each loudspeaker emitted a different section of the four-talker babble. The loudspeaker positions were 'mirrored' when the poorer-hearing ear was on the right. Performance was assessed for unaided listening (better ear unoccluded and no device active) and aided (better ear unoccluded and the device worn normally).

It was anticipated that the benef t of each device would be especially large when the target speech came from the poorer-hearing side or in front and the interfering speech came from the better side (for example, tests 2 and 3 in Table 3).

APHAB questionnaire

Subjective benef t was measured using the Abbreviated Prof le of Hearing Aid Benef t (APHAB) questionnaire (Cox & Alexander, 1995). The measures relating to unaided listening were obtained at initial enrollment (by def nition, after various periods of BAHI experience but with no SoundBite experience). Participants were asked to answer the questions in relation to perceived performance and problems when their BAHI was turned off. Responses about experience with each BC device were obtained at the end of the 30-day trial period for that device. The APHAB benef t scores were calculated by subtracting the aided responses from the unaided responses in such a way that positive numbers indicate a benef t.

Results

Sound-f eld thresholds

Mean sound-f eld thresholds for the unaided and the aided conditions for each device are shown in Figure 2. The f gure also shows mean audiometric thresholds for the better ear, obtained using conventional AC audiometry with earphones.

The sound-f eld thresholds were reliable and stable over the 30 days. The unaided sound-f eld thresholds do not ref ect audiometric AC thresholds for the poorer ear (which were all greater than 90 dB HL except for the participant with a PTA of 75 dB HL) but instead ref ect the sound-f eld signal reaching the cochlea of the better ear, either by leakage of sound past the earmuff or by being converted into a BC signal. The aided sound-f eld thresholds were consistently lower for SoundBite than for BAHI, by about 10 dB on average. Thus, for low-level input signals, SoundBite provided more functional gain than BAHI, potentially allowing better audibility of sounds coming from the poorer-hearing side. We do not know if this difference between Soundbite and BAHI ref ects a difference in the devices, a difference in f tting methods, or both. The BAHI devices sometimes incorporated amplitude compression at high frequencies, which means that their gain would have reduced with increasing input

Table 3. Test conditions for the measures of speech perception in babble, indicating the direction of the speech and the babble with respect to the side with the poorer ear: front = 0° azimuth; + angles to better side; − angles to poorer side (see Figure 1 for loudspeaker numbers). Direct means that the loudspeaker faced the participant. Diffuse means that the loudspeaker faced away from the participant.

Test	*Speech direction*	*Speech loudspeaker*	*Babble direction(s)*	*Babble loudspeaker(s)*
#1	Poorer side	1 (−45°)	Direct better side	3 (+45°)
#2	Poorer side	1 (−45°)	Direct better side & Diffuse back better side	3, 6 (+45°, +135°)
#3	Front	2 (0°)	Direct better side	3 (+45°)
#4	Front	2 (0°)	Direct better side & Diffuse back better side	3, 6 (+45°, +135°)
#5	Front	2 (0°)	Diffuse back	5 (180°)
#6	Front	2 (0°)	Diffuse back & Diffuse back better side	5, 6 (180°, +135°)
#7	Front	2 (0°)	Diffuse back poorer side Diffuse back & Diffuse back better side	4, 5, 6 (−135°, 180°, +135°)
#8	Front	2 (0°)	Front better side Diffuse back poorer side Diffuse back & Diffuse back better side	3, 4, 5, 6 (+45°, −135°, 180°, +135°)

level, while the SoundBite provided level-invariant gain. Hence, the differences in effective gain between SoundBite and BAHI represent the minimum that would occur for medium sound levels.

Sound localization

The results for sound localization were analysed in two ways. First, an overall percent-correct score was obtained, based on the proportion of trials on which the loudspeaker emitting the sound was correctly identified. Second, the responses were scored in terms of whether there was a front-back error. For example, if the sound came from loudspeaker 1, 2, or 3 and the response was either 1, 2, or 3, this counted as 'correct' in terms of front-back errors. If the sound came from loudspeaker 1, 2, or 3 and the response was either 4, 5, or 6, this was counted as 'incorrect'. It was anticipated that the BC devices might not improve discrimination in azimuth, but that the SoundBite might improve front-back discrimination because of the location of the microphone in the pinna.

The results are shown in Figure 3. For comparison, results for a group of participants (N = 3) with bilaterally normal hearing are also shown. The left group of six bars shows overall percent

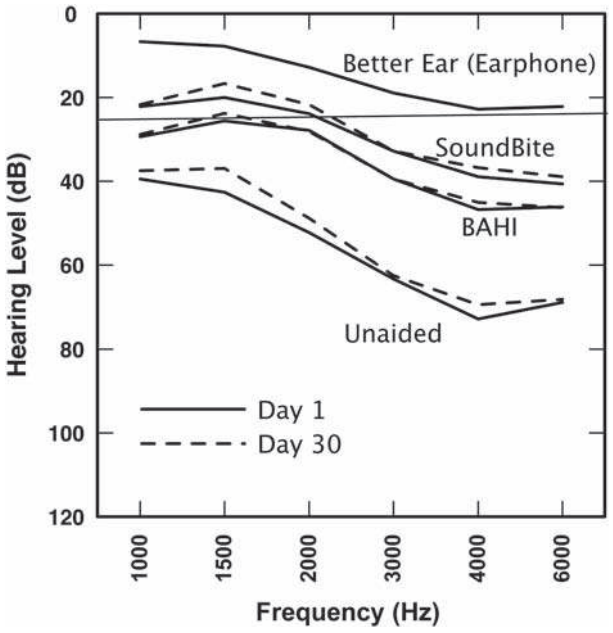

Figure 2. Mean sound field thresholds (dB HL) for Day 1 (solid lines) and Day 30 (dashed lines) for unaided listening and aided listening with the SoundBite and BAHI. For these measures, the better ear was covered by a circumaural muff. Audiometric thresholds for the better ear obtained using conventional audiometry with an earphone are also shown.

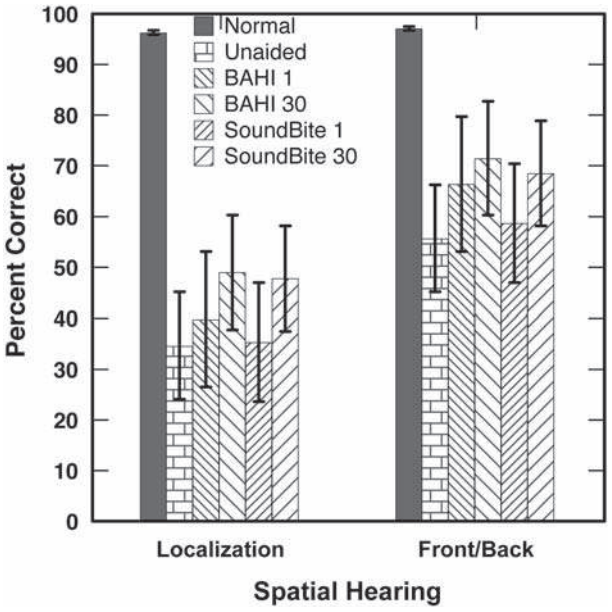

Figure 3. Mean results for the spatial hearing testing. Within each group of six bars, results are shown for: a control group of participants with bilaterally normal hearing; the UHL participants listening unaided; the UHL participants listening aided via BAHI at Day 1 and Day 30; and the UHL participants listening aided via SoundBite at Day 1 and Day 30. The left group of bars shows overall scores for the accuracy of location in azimuth and the right group of bars shows overall scores for the accuracy of front-back discrimination. Error bars indicate ± one standard deviation.

correct scores for identification of azimuth. Performance of the UHL participants was much poorer than for the normal-hearing participants, as expected. Based on matched-sample t-tests, there was no significant difference in azimuth identification scores between the two devices at Day 1 ($p > 0.05$) or at Day 30 ($p > 0.05$). However, relative to unaided listening, both devices led to some improvement in performance after 30 days of experience. Scores after 30 days were about 50% with both devices, which is well above the chance score of about 17%.

The right-most group of bars in Figure 3 show results for front-back discrimination. Again, the performance of the UHL participants was much poorer than for the normal-hearing participants. There was no significant difference in front-back identification between the two devices at Day 1 ($p > 0.05$) or at Day 30 ($p > 0.05$). Relative to unaided listening, both devices led to some improvement in performance after 30 days of experience. The scores at 30 days were about 70% correct for both device types, which is well above the chance score of 50% correct. The possible benefit of having the microphone in the pinna for the SoundBite device was not found; front-back errors were not lower for SoundBite than for BAHI. This might reflect a number of factors. First, the frequency response of the SoundBite device as used here rolled off above 7000 Hz. Pinna cues are most useful for frequencies in the range 6000 to 16 000 Hz (Blauert, 1997) and the SoundBite device provided useful gain only over a part of that range. Second, the participants mostly had some high-frequency hearing loss in their better ear, and that may have limited their ability to make use of the high-frequency spectral cues provided by the pinna. Even if the high-frequency spectral cues were partly audible, reduced frequency selectivity may have limited their usefulness (Jin et al, 2002; Boyd et al, 2012). Third, participants may need more time to learn to make effective use of pinna cues transferred from the contralateral side; to some extent these cues conflict with the cues provided by the pinna on the better-hearing side whenever the sound source is not in the median plane (Shaw, 1974).

Perception of speech in babble

The mean results for the perception of speech in babble are shown in Figure 4. The scores are plotted as 'loss in signal-to-noise ratio (SNR Loss)' in dB (Killion et al, 2004) relative to normal hearing, so lower numbers indicate better performance. Roughly, each 1-dB change in the SNR loss corresponds to a 10% change in intelligibility. Both BC devices led to improvements well over 2 dB relative to unaided listening for tests 1, 2, and 3. These are all situations where the target speech came from the poorer side or in front and the background babble came from the better side. Previous work has also shown benefits of BC devices under such conditions (Hol et al, 2005; Dumper et al, 2009; Snapp et al, 2010). For test 2, the improvement was almost 4 dB. The improvements were not significant for tests 1 and 3. The improvement for test 2 was significant for SoundBite (paired t-test, $p = 0.016$) and marginally significant for BAHI ($p = 0.058$). For the remaining tests, there was no clear difference between results for the aided and unaided conditions. There was no difference in the improvements between the two devices for any of the tests ($p > 0.05$).

The results show that the QuickSIN test is able to reveal the benefits of BC devices under appropriate listening conditions. Therefore, the QuickSIN may be appropriate for verifying device benefit for groups of subjects, as suggested by Snapp and co-workers (Snapp & Telishi, 2008; Snapp et al, 2010). Other speech-in-noise tests, such as the HINT (Nilsson et al, 1994), may also be appropriate, although the QuickSIN is faster to administer than most other tests.

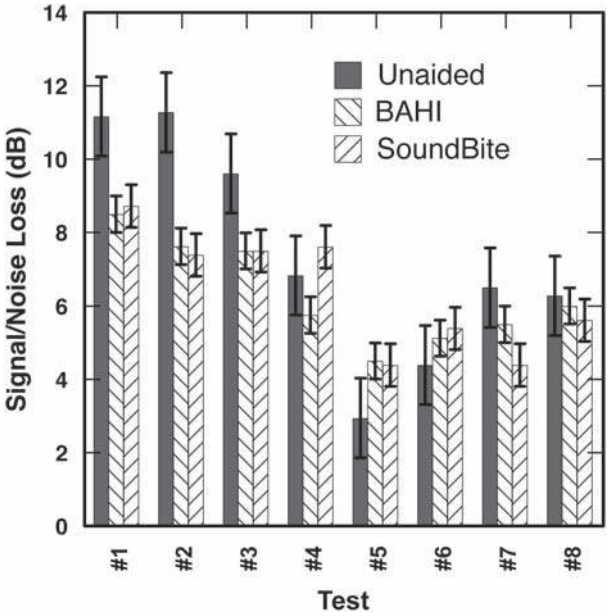

Figure 4. Mean results for the speech perception testing in noise (Day 30) for each condition listed in Table 3. Each group of three bars shows the SNR loss (dB) for: unaided listening; aided listening via BAHI, and aided listening via SoundBite. Lower numbers indicate better performance.

APHAB questionnaire

The mean results for the APHAB questionnaire are plotted in Figure 5. Results are shown as benefit scores (the reduction in the reported percentage of problems relative to unaided listening). Hence, larger numbers mean better performance. The scores are presented for four subscales: (1) Ease of communication (EC), relating mainly to listening problems in quiet situations; (2) Reverberation (RV),

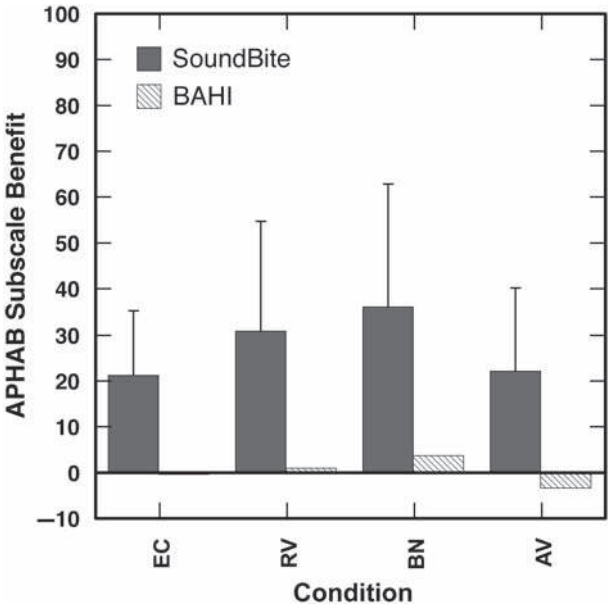

Figure 5. Mean APHAB benefit scores for the SoundBite and the BAHI. Larger numbers indicate better performance. Error bars show ± one standard deviation. The four subscales are described in the text.

relating to listening problems in reverberant conditions; (3) Background noise (BN), relating to difficulties in listening in background noise; (4) Aversiveness (AV), relating to the extent to which everyday sounds are perceived as unpleasant. For all subscales, SoundBite was judged as providing markedly more benefit than BAHI ($p < 0.05$). Indeed, it is remarkable how low the benefit scores were for BAHI. The benefit scores for BAHI are lower than reported in previous studies for such devices (Bosman et al, 2003; Hol et al, 2010) and are inconsistent with the measures of speech perception in noise. The reason for this is not clear. It is possible that the participants who responded to the recruitment advertisement were those who were least satisfied with their BAHI. It is also possible that, for those participants who were tested first using the Soundbite, their experience with the SoundBite made them less satisfied with their BAHI during the subsequent 30 days. However, the low BAHI scores were not associated with the order of use of the two trial devices; of the two highest overall APHAB benefit scores (the average of the scores for EC, RV, and BN, referred to as Global) for the BAHI devices, one was for a participant in the group that started with BAHI and one was for a participant in the group that started with SoundBite.

Discussion and Conclusions

A limitation of our study was that the participants were all BAHI users prior to the start of the study. This was done to avoid the need for surgery as part of the study. The recruitment of existing BAHI users may have introduced some bias, especially in relation to the APHAB results, since there is a tendency for 'new' devices to be judged as superior to 'older' devices, even when there are no real differences between devices (Bentler et al, 2003; Dawes et al, 2011). Also, the participants may have been less satisfied with their BAHI than typical BAHI users, as discussed above. In future studies of this type, it would be desirable to select users who had no experience with either type of device, and to assign participants randomly to a group fitted with BAHI and a group fitted with SoundBite.

One purpose of this study was to assess the feasibility and efficacy of performance measures for evaluating the benefits of BC treatments for UHL. The aided sound field thresholds revealed consistent differences between the two types of BC device, thresholds being generally lower for SoundBite than for BAHI. Thus, aided sound-field thresholds can be useful for demonstrating differences in low-level gain between devices, although in the present study it is unclear whether the difference arose from the devices themselves or from differences in fitting method.

The measures of sound localization were somewhat inconclusive. Both the overall measure of accuracy in azimuth judgments (Figure 3, left group) and the measure of front-back confusions showed that each of the BC devices slightly improved accuracy relative to unaided listening after a 30-day period of experience with the device. The results did not show any clear difference between the two devices, and the possible benefit of reduced front/back confusions for the SoundBite device resulting from placement of the microphone in the pinna was not found. The lack of benefit may have been the result of the limited bandwidth of the SoundBite, the high-frequency hearing losses in the better ear of the participants, or insufficient time for acclimatization. It would be interesting to see if a benefit of microphone placement in the pinna would become apparent after an acclimatization period that was longer than 30 days.

The speech perception measures, conducted using the QuickSIN test, did not reveal any consistent differences between the two BC devices. However, the SNR loss values showed benefits of the BC devices over unaided listening for situations where the target speech came from the poorer side or in front and the background babble came from the better side. This is consistent with the conclusion of Stenfelt (2005, page 189) that a speech perception benefit of BAHI for people with UHL is 'only expected when the speech and noise source is spatially separated, and the speech source is located at the impaired side, while the noise source is located at the good side or is diffuse'. For demonstrating the benefits of BC treatments for UHL, future evaluations could reasonably be restricted to those conditions. On the other hand, presenting sound picked up by a microphone on the poorer hearing side is likely to be detrimental under conditions where the target speech comes from the better side and interfering sounds come mainly from the poorer side. Further, this effect might be greater for devices whose functional gain is greater. Thus, tests of speech perception under a variety of spatial conditions, with target speech coming from both the poorer and better side, might be prudent to evaluate both the beneficial and detrimental effects of BC devices.

The APHAB scores showed consistently greater benefit for SoundBite than for BAHI. The reasons for this are not clear. The greater benefit might partly result from the greater functional gain provided by SoundBite, as indicated by the lower (better) sound-field aided thresholds for medium frequencies (Figure 2). The greater subjective benefit of SoundBite might also be related to the greater bandwidth of the SoundBite, although we were unable to confirm this difference in bandwidth using the measures of aided sound-field thresholds. Finally, the greater benefit might have been partly a result of biases, as discussed earlier. After the trial was completed, four participants independently decided to discontinue use of the BAHI, have the pedestal removed, and obtain the SoundBite system.

Consistent differences between the two devices were not revealed by the localization or speech perception testing. This may indicate that there are differences between the two BC devices that become apparent to the user in everyday life, as reflected in the APHAB scores and by the decision of four participants to switch from BAHI to SoundBite, but that are not revealed by the localization and speech perception tests conducted here. However, it is difficult to rule out the possibility that the APHAB scores were influenced by biases and by the participants' overall feelings about the devices, such as comfort, usability, and visibility, even though the APHAB questions are concerned solely with listening experience.

In summary, the results revealed lower aided sound-field thresholds for SoundBite than for the BAHI devices, and better APHAB scores for SoundBite than for BAHI. The results for sound localization and perception of speech did not show any difference between the two device types, but both device types led to better performance than for unaided listening.

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Long-Term Safety and Benefit of a New Intraoral Device for Single-Sided Deafness

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Objective: To determine the long-term safety and benefit of a new intraoral bone conduction device (SoundBite Hearing System by Sonitus Medical) for single-sided deafness (SSD).
Study Design: A multi-center, controlled, nonrandomized, prospective unblinded study of SSD patients wearing the device over a 6-month period.
Settings: Ambulatory care centers typical of those where SSD patients are diagnosed and treated.
Patients: Adults (N = 22) with acquired, permanent SSD and no current use of any other SSD device.
Intervention: Continual daily wear of the new device for 6 months.
Main Outcome Measures: Comprehensive medical, audiologic, and dental measures; aided thresholds; Abbreviated Profile of Hearing Aid Benefit scores, and an SSD questionnaire.
Results: There were no related adverse events or changes in the medical or audiologic findings at the end of the trial compared with the beginning. There were no significant changes in the mean aided thresholds ($p > 0.01$) or the mean dental measures ($p > 0.05$) at 3 or 6 months compared with pretrial measures. The mean Abbreviated Profile of Hearing Aid Benefit benefit scores showed improvement ($p < 0.01$) for the Background Noise, Reverberation, and Ease of Communication subscales and the Global scale at 3 and 6 months. The results of the SSD questionnaire indicated that the vast majority (>90%) of the subjects reported satisfaction and improvement in a variety of areas after wearing the device long term.
Conclusion: The SoundBite system is safe and continues to provide substantial benefit for SSD patients with continual daily use over a 6-month period. **Key Words:** Abbreviated Profile of Hearing Aid Benefit—Bone-Anchored Hearing Aid—Bone conduction—Dental—Osseointegrated post—Single-sided deafness.
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A new device (1,2) for single-sided deafness (SSD) is illustrated in Figure 1 (SoundBite Hearing System; Sonitus Medical Inc., San Mateo, CA, USA). It uses the same functional principles as the commonly used and effective surgically implanted osseointegrated post system (BAHA; Cochlear Corp., Lane Cove, NSW, Australia) but with substantial improvements. First, the primary microphone is located in the ear canal of the poorer ear to capitalize on the spatial hearing acoustic properties of a normal pinna. Second, the signal is transferred to the better hearing ear by the proven method of direct bone conduction to the cranium but with a removable in-the-mouth (ITM) component via the teeth rather than via a surgically implanted post. Third, a new bone conduction transducer adds much more high-frequency capability, as shown in Figure 2, known to be beneficial for spatial hearing (2).

The device does not change tooth enamel surfaces based on laboratory studies on extracted natural teeth with equivalent use of 10 years (3). The device was shown to be safe and effective in SSD patients over a 1-month trial period (4). A long-term safety and benefit study is warranted under typical wearing conditions.

PURPOSE OF STUDY

The purpose of this study was to assess the long-term safety and benefit of the SoundBite Hearing System in SSD subjects over a 6-month period.

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Sonitus Medical, Inc., provided the devices, patient medical and related expenses and professional fees (M. M. and R. M.) and data analysis fees (G. R. P.).

The following authors are not employees of Sonitus Medical, Inc., but have these relationships: Dr. Murray owns stock options and provides consulting to Sonitus Medical, Inc. Dr. Miller owns stock and stock options and provides consulting to Sonitus Medical, Inc. Dr. Hujoel provides consulting to Sonitus Medical, Inc. Dr. Popelka provides consulting to Sonitus Medical, Inc.

METHODS

Subjects

The subjects (N = 22) were adults with SSD (IRB protocol CLN005.00). Comprehensive medical and neurotologic evaluations, including magnetic resonance images, were conducted by an experienced neurotologist (M. M.). All were diagnosed with permanent acquired SSD, beyond any acute stage with no indication of any further medical or otologic intervention. The causes included sudden sensorineural hearing loss (11/22 or 50%), acoustic neuroma (5/22 or 23%), Ménière's syndrome (3/22 or 14%), unknown cause (2/22 or 9%), and jugular schwannoma (1/22 or 5%). The subjects were typical of those in published SSD studies (5–9).

Comprehensive audiologic measures were obtained by experienced audiologists using a defined protocol. The SSD was defined as pure tone average (PTA) of hearing thresholds at 500, 1,000, 2,000, and 3,000 Hz in one ear adequate to preclude benefit from a conventional hearing aid (PTA, ≤25 dB HL) and permanent severe or worse sensorineural hearing loss in the opposite ear (PTA, ≥70 dB HL). None of the subjects was a current user of any SSD device.

Comprehensive dental measures were obtained by an experienced dentist (R. M.) using a defined protocol. Dental criteria included number of teeth (a minimum of 6 posterior maxillary teeth, 3 teeth per side), no current orthodontics, no active caries, and no active periodontal disease.

All subjects were given custom devices fitted for physical comfort and programmed to produce equal loudness (2,4) over the optimal frequency range (1,000–6,000 Hz) for SSD patients (10). The subjects were instructed to wear the device daily.

Safety Outcomes

The safety outcomes were defined as no change in medical, auditory, or dental status and no device- or procedure-related adverse events.

The actuator rested against the first and second molars in 21 of 22 subjects and against the first molar and second bicuspid in the remaining subject. The ITM component was fitted on the same side as the poorer hearing ear, leaving the opposite side in its natural state and allowing dental safety to be evaluated using a split-mouth design. Comprehensive periodontal and dental measures on the device side were compared with the equivalent measures on the contralateral nondevice, or control side, during the trial.

The periodontal and dental measures were made under a defined protocol by direct observation or by analysis of x-ray images including a full mouth x-ray image at the beginning of the trial and partial mouth x-ray images (4 bitewing views and 4 periapical views) of the 2 device-side teeth and the 2 control-side teeth at 3 and 6 months.

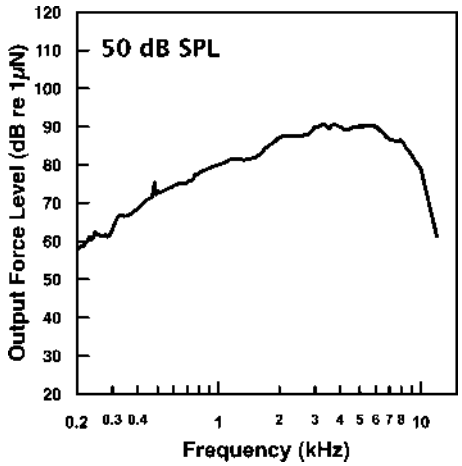

FIG. 2. The default output force level in dB re 1 μN as a function of frequency with a 50-dB SPL acoustic input level measured on a calibrated laboratory system in a format identical to published measures for the osseointegrated post systems.

Calculus Score

Calculus indices used in clinical trials for periodontal disease were not used because subjects with periodontal disease were excluded. Instead, the usual and customary dental measures for calculus (11,12) were performed. Calculus was visually identified as present (score, 1) or absent (score, 0) using a periodontal probe at 4 locations (Fig. 3A) and averaged as a single score.

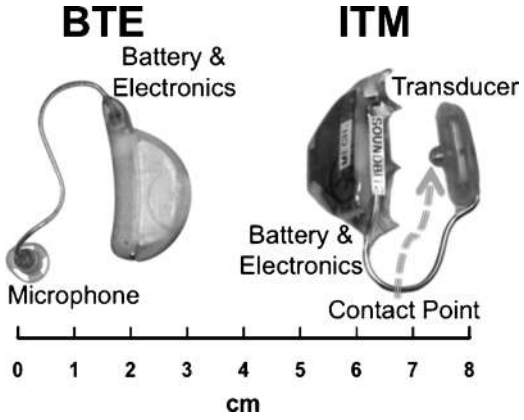

FIG. 1. The SoundBite system by Sonitus Medical consists of a behind-the-ear (BTE) component (left) and an ITM component (right) that connect wirelessly. The BTE is similar to a BTE hearing aid but positions a microphone in the ear canal of the poorer ear. The ITM is similar to a small partial dental retainer but applies a bone conduction signal via a small contact point positioned between 2 posterior maxillary teeth.

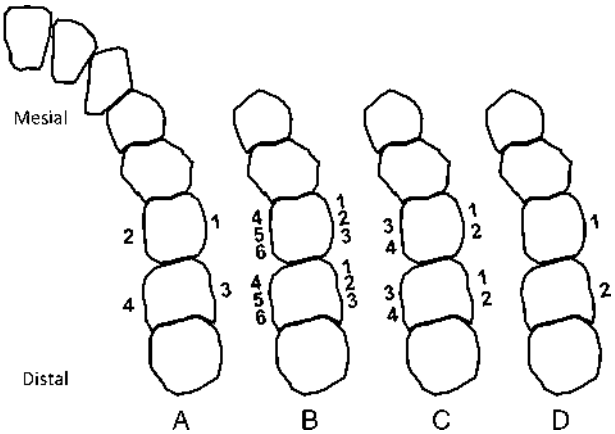

FIG. 3. Schematic drawings of the upper dental arch on one side showing the locations (numbers) of the periodontal and dental measures for the Calculus Score (*A*), Periodontal Health Score (*B*), Plaque Score (*C*), Gingival Bleeding Score, (*A*), Gingival Recession Score (*B*), Bone Support Score (*D*), and Root Resorption (*D*).

Periodontal Health Score

Periodontal health was quantified as the pocket depth around a tooth as measured with a periodontal probe (Marquis Type with mm marks) placed with light pressure into the gingival sulcus (13). Pocket depth in healthy tissue is 3 mm or less, with greater depths associated with periodontitis. Pocket depth was measured at 6 sites (Fig. 3B) and averaged as a single score.

Plaque Score

A modified version of the O'Leary Index (14,15) was used to determine if plaque was present (score, 1) or absent (score, 0) at 8 sites (Fig. 3C) and averaged as a single score.

Gingival Bleeding Score

Gingival bleeding on probing is a standard method for evaluating gingival inflammation (16). A periodontal probe was passed along the sulcus to determine if bleeding was present (score, 1) or absent (score, 0) at 4 sites (Fig. 3A) and averaged as a single score.

Gingival Recession Score

Gingival recession (17,18) was determined by measuring the position of the gingiva with respect to the occlusal table of the teeth (Fig. 4A) on a plaster cast from a dental impression (also necessary for creating the custom fit ITM). The dental impressions were made with alginate and poured with white plaster to form a dental model. Digital calipers were used to measure gingival recession at 6 sites (Fig. 3B) and averaged as a single score.

Bone Support Scores

Alveolar bone and the periodontal ligament anchor the teeth in the maxilla (19). Bone support for each tooth was defined as the ratio of 2 lengths from the root apex to the height of the alveolar bone and to the cemento-enamel junction (Fig. 4B) and averaged on the mesial and distal sides of the tooth. Bone support measures were determined from the x-ray images (20) (ImageJ (21) image analysis software) and then averaged for the 2 maxillary teeth (Fig. 3D) as a single score.

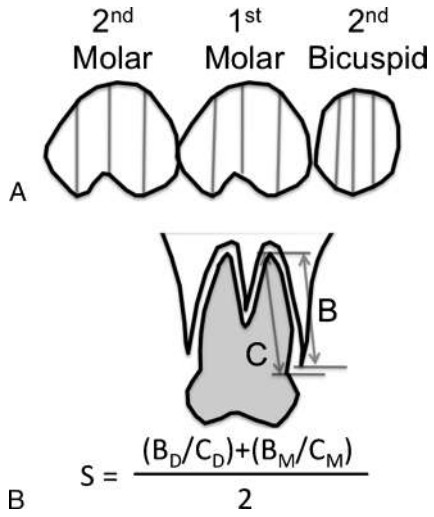

FIG. 4. Schematic drawings of maxillary teeth in the upper dental arch on one side showing (*A*) the locations (*gray lines*) where the gingival recession measures and (*B*) the bone support measures were made. Bone support (S) was defined as the ratio of 2 lengths (*lines B and C*) averaged for the distal (*subscript D*) and medial (*subscript M*) sides of the tooth.

Root Resorption

Tooth root resorption generally found on the anterior teeth and single-rooted teeth, rather than on the multi-rooted teeth involved in this study, has been associated with orthodontic braces and can affect the long-term prognosis of the teeth (22–24). Root resorption was measured from digital periapical x-ray images in 19 of the subjects and from analog full mouth series x-rays digitally scanned for the remaining 3 subjects. Resorption was defined as the distance from the root apex to the cemento-enamel-junction (Fig. 4B). Measures were made on one root on each of the two maxillary teeth (Fig. 3D) and averaged as a single score.

Structural Changes

In addition to these quantitative measures, qualitative changes or damage to the teeth, soft tissue, or any other related areas also were noted.

Benefit Outcomes

Device benefit was measured with the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire (25) resulting in an overall Global score (GBL) and the 3 subscale scores of Ease of Communication (EC), Background Noise (BN), and Reverberation (RV). The benefit of a device is determined by subtracting the APHAB scores measured after wearing the device from the equivalent pretrial scores.

Device benefit also was assessed with a 15-item questionnaire (Appendix A) centered on SSD and device issues. The items used Likert-like responses for satisfaction (very satisfied to very dissatisfied), improvement (very much improved to worse), preference (very much prefer device, to very much prefer no device), and likelihood (very likely to very unlikely) of recommending the device to other SSD patients.

Experimental Design

The experimental design was a controlled, prospective, multisite study with unblinded clinicians, data analysts, and subjects and no randomization because all subjects received a device. Enrollment and termination were performed at Site 1 (Camino Ear Nose and Throat Clinic, San Jose, CA). Auditory measures, device fittings and questionnaires were performed at Site 1 or Site 2 (Sonitus Medical, San Mateo, CA).

Data Analysis

To determine if the SSD condition remained the same during the trial, the pretrial and posttrial medical health measures were compared. The SSD condition was considered not to have changed significantly if no new medical findings or adverse events occurred associated with the SSD cause.

To determine if hearing remained the same during the trial, pretrial and posttrial hearing thresholds (250, 500, 1,000, 2,000, 3,000, 4,000, and 8,000 Hz) were compared. Hearing was considered not to have changed significantly if the difference between pretrial and posttrial thresholds was 5 dB or less at 6 of the 7 frequencies and 10 dB or less at the remaining frequency.

To determine if the device provided the same sound to the cochlea during the trial, pretrial aided thresholds (for 1,000, 2,000, 3,000, 4,000, and 6,000 Hz and for speech signals) were compared with the aided thresholds at 3 and 6 months (paired *t* tests). Before aided threshold measures, the device gain setting

at each frequency was verified to be the same as the pretrial setting.

To determine if the device affected the dentition or related structures, pretrial periodontal and dental measures on both the device side and the nondevice side of the mouth were compared with the measures at 3 and 6 months. Differences in mean measured values were analyzed using a general linear model (GLM model) for subject averages to compare the effect of wearing the ITM device. The robustness of this method was evaluated using a site-specific statistical analysis (GENMOD). Both methods take into account the correlation of split-mouth measures (GLM) or sites (GENMOD) within subjects. The results of both analyses led to the same conclusions, so only the results of the GLM models are reported.

To determine if the device provided any benefit, mean pretrial APHAB scores were compared with the scores at 3 and at 6 months (paired *t* tests). Individual APHAB scores also were analyzed using the criteria (26) that a significant benefit resulted for an individual subject if a benefit score (difference between the pretrial and posttrial scores) of 22 or greater occurred on any one of 3 subscales (EC or RV or BN) or 5 or greater occurred on all the 3 subscales.

To determine if the SSD questionnaire responses changed over time, the scores at 3 and 6 months were compared (paired *t* tests). The responses were then summarized individually by category.

RESULTS

Subject demographics are shown in Table 1. Sex was split equally in the sample. All subjects enrolled in the trial wore the device daily and completed the trial. There was no difference ($p > 0.05$) between the mean daily wearing time at 3 months (mean, 6.9 h; standard deviation [SD], 3.1) compared with 6 months (mean, 7.0 h; SD, 3.4). The daily wearing times were typical for SSD patients wearing an SSD device (27).

Medical and Audiologic Results

There were no changes in the medical findings between enrollment and posttrial termination in any subject. There were no changes in the conventional auditory diagnostic measures (air- and bone-conduction hearing thresholds, speech audiometry, and tympanometry results) in either ear in any subject. The device did not cause any medical conditions or symptoms, and there were no medical adverse events related either to the procedures used to create the device or to wearing the device for a 6-month period.

Device Performance

Because hearing thresholds and device settings remained constant during the trial, aided thresholds were used as a measure of device performance. In this case, a change in aided thresholds would indicate either a change in the coupling of the device to the teeth or a change in the bone conduction pathway from the teeth to the cochlea. There was no significant difference at any frequency between the mean pretrial aided thresholds and the mean aided thresholds at either 3 months ($p > 0.01$with 95% confidence intervals of <±5 dB) or at 6 months ($p > 0.01$ with 95% confidence intervals of <±6 dB). Because these differences were not significant and close to the step size of the threshold measures (5 dB), the frequency-specific aided thresholds were characterized as a single number for each subject by averaging the aided thresholds for the 5 frequencies. There also was no significant difference between the mean pretrial aided speech reception threshold and the mean aided speech reception threshold at either 3 or 6 months ($p > 0.01$ with a 95% confidence interval of <±3 dB).

The change in aided thresholds at 3 and 6 months for the 5-frequency average threshold and for the speech reception threshold for each subject are shown in Table 2. During the 6-month trial, the mean threshold changed less than 2 dB for the 5-frequency average threshold and less than 4 dB for the speech reception threshold, both less than the threshold measurement step size. The standard deviations of the aided threshold changes also were very low (<7 dB) and typical of test/retest variability associated with most auditory threshold measures.

TABLE 1. *Subject demographics*

Subject demographics			
Age (yr)	Sex	Single-sided deafness duration (yr)	Impaired ear
Mean: 44.4 Range: 25–65	Male 50% Female: 50%	Mean: 6.7 Range: 1–30	Right: 41% Left: 59%

TABLE 2. *Change in aided thresholds (compared with pretrial) at 3 and 6 months for the 5-frequency average threshold and for the speech reception threshold*

	Change in aided thresholds (dB)			
	5-Frequency average		Speech reception	
Subject	3 mo	6 mo	3 mo	6 mo
1	2.0	4.0	5	5
2	1.0	4.0	5	5
3	−8.0	3.0	−15	0
4	1.0	−2.0	0	0
5	2.0	4.0	0	5
6	−1.0	3.0	−5	−5
7	0.0	1.0	15	15
8	−2.0	4.0	5	0
9	−5.0	−1.0	0	−5
10	3.0	11.0	5	10
11	1.0	2.0	−5	5
12	−4.0	1.0	−5	−5
13	−1.0	0.0	5	5
14	−1.0	−3.0	0	0
15	2.0	−4.0	0	10
16	0.0	−1.0	10	10
17	−4.0	−1.0	−10	−5
18	1.0	4.0	5	5
19	−5.3	−5.0	−5	0
20	3.0	4.0	10	5
21	−2.0	−2.0	0	0
22	−2.0	8.0	5	15
Mean	−0.9	1.5	1.1	3.4
SD	2.9	3.9	6.9	6.1

There were no significant differences between the mean pretrial aided thresholds and the mean aided thresholds at 3 months ($p > 0.01$) or at 6 months ($p > 0.01$) for either measure.

SD indicates standard deviation.

With no change in hearing, device gain, or aided thresholds, it can be assumed that the device provided very consistent sound to the cochlea throughout the trial. There seemed to be no changes in the coupling of the device to the teeth and no changes in the bone conduction pathway from the teeth to the cochlea that affected sound delivery to the cochlea during the 6-month trial.

Dental Results

The mean (and SD) periodontal and dental measures on the device side and on the nondevice side at pretrial and 3 and 6 months are shown in Table 3. There was no significant difference ($p > 0.05$) between the mean measures on the device side compared with the nondevice side at pretrial and 3 or 6 months for all scores. There also was no significant difference ($p > 0.05$) between the mean pretrial measures compared with 3 months or compared with 6 months on the device side for all scores. The Plaque and Bleeding scores were obtained only at 3 and 6 months, so the values at 3 months were considered pretrial for these 2 scores. The device had no measurable impact on any of the periodontal or dental measures during the trial.

There were 3 unrelated dental events. One subject enrolled in the trial with large palatal tori, slow growing benign bony growths observed in more than 25% of all dental patients. Although palatal tori are sometimes surgically removed before an oral device is made, in this subject, the ITM was modified to fit around the tori. A second subject fell off a bicycle and experienced incisor trauma that required crowns and root canals. A third subject lost a 25-year-old occluso-lingual filling along with part of the distal cusp on Tooth 14 while eating but was not wearing the ITM device at the time. The tooth was restored with the usual and customary restorative care by a private dentist. These 3 dental events likely were unrelated to wearing the ITM.

The restoration status of the 44 maxillary teeth on the device side represented the usual variety of typical dental conditions. There were 13 natural teeth with no restorations, 23 with amalgam restorations, 2 with resin composite restorations, and 6 with crowns. Only 1 tooth required a new restoration during the trial as previously mentioned. As reported in a previous study (4), device performance across these types of typical restorations does not differ compared with device performance on teeth with no restorations. The aided threshold results also confirmed this finding in the present study.

No significant qualitative changes were observed in the teeth, soft tissues, or related oral structures. Minor temporary soft tissue changes identical to those typically observed in denture patients (28) were observed in 36% (8/22) of the subjects, but these have no clinical consequence.

Device Benefit Results

The individual APHAB benefit scores at 3 and at 6 months are shown in Table 4, and the mean (and SD) APHAB benefit scores are plotted in Figure 5. The mean APHAB scores improved significantly for the BN, RV, and EV subscales and the overall GBL scale both at 3 ($p < 0.001$) and at 6 months ($p < 0.001$). On an individual basis, 73% (16/22) of the subjects showed a significant APHAB benefit at 3 months, increasing to 82% (18/22) of the subjects at 6 months.

There was no significant difference between the SSD questionnaire scores at 3 months compared with 6 months ($p > 0.05$). The responses were largely on the positive side of the scales, with very few responses on the negative side.

The percentage of subjects reporting improvement or satisfaction at 6 months for 13 items is shown in Figure 6. The percentages of subjects reporting improvement (slightly improved to very improved) exceeded 90% for 7 of the 8 improvement items, reaching 100% for 3 of

TABLE 3. *Mean and standard deviation periodontal and dental measures on the device side and on the nondevice side at pretrial and 3 and 6 months*

		Device side			Nondevice side		
		Pretrial	3 mo	6 mo	Pretrial	3 mo	6 mo
Calculus	Mean	0.000	0.023	0.023	0.000	0.000	0.000
	SD	0.000	0.104	0.104	0.000	0.000	0.000
Pocket depth (mm)	Mean	2.920	2.753	2.450	2.902	2.670	2.386
	SD	0.250	0.348	0.376	0.293	0.350	0.390
Plaque	Mean	NA	0.034	0.023	NA	0.045	0.000
	SD	0.117	0.107	0.125	0.000		
Bleeding	Mean	NA	0.080	0.000	NA	0.068	0.011
	SD	0.142	0.000	0.138	0.053		
Gingival recession	Mean	6.080	6.050	5.865	6.132	6.145	5.827
	SD	0.683	0.664	0.705	0.611	0.951	0.412
Bone support	Mean	0.892	0.878	0.896	0.892	0.876	0.887
	SD	0.038	0.042	0.051	0.055	0.044	0.038
Root resorption (%)	Mean	100.000	97.909	97.790	100.000	100.134	101.505
	SD	0.000	10.904	11.346	0.000	15.283	13.325

There was no significant difference ($p > 0.05$) between the mean measures on the device side compared with the nondevice side at pretrial and 3 or 6 months for all scores. There also was no significant difference ($p > 0.05$) between the mean pretrial measures compared with 3 months or compared with 6 months on the device side for all scores. The Plaque and Bleeding scores were obtained only at 3 and 6 months, so the values at 3 months were considered pretrial for these 2 scores.

SD indicates standard deviation.

TABLE 4. *Individual, mean and standard deviation Abbreviated Profile of Hearing Aid Benefit scores at 3 and 6 months*

	APHAB							
	Benefit score at 3 mo				Benefit score at 6 mo			
Subject	BN	RV	EC	GBL	BN	RV	EC	GBL
1	58.0	29.3	51.0	46.1	26.8	1.8	47.0	25.2
2	53.3	53.2	42.7	49.7	42.3	42.2	31.7	38.7
3	68.8	52.5	56.5	59.3	68.8	52.5	56.5	59.3
4	31.2	10.3	8.2	16.6	39.7	18.8	16.3	24.9
5	43.8	10.8	8.0	20.9	31.2	6.3	4.3	13.9
6	58.0	60.2	40.8	53.0	55.8	50.2	39.0	48.3
7	14.7	−6.5	8.2	5.4	−4.2	−7.8	0.0	−4.0
8	12.5	6.3	6.3	8.4	24.8	6.3	8.5	13.2
9	12.5	18.8	8.0	13.1	14.5	1.8	6.2	7.5
10	24.8	8.5	10.2	21.6	33.2	2.2	8.5	14.6
11	22.5	9.1	5.7	12.4	24.7	39.5	24.3	29.5
12	20.8	10.7	5.5	12.3	18.8	19.0	5.8	14.6
13	2.2	19.2	0.0	7.1	25.3	10.8	1.8	12.7
14	33.2	−12.8	8.0	9.4	28.8	2.2	8.0	13.0
15	18.7	3.7	1.8	8.1	8.2	1.8	1.8	3.9
16	10.2	2.2	1.8	4.7	10.2	2.2	3.7	5.3
17	26.8	18.7	32.5	26.0	62.7	50.2	29.2	47.3
18	45.3	16.5	23.2	28.3	61.8	16.7	31.5	36.7
19	27.2	37.7	10.7	25.2	27.2	35.5	10.7	24.4
20	12.5	44.8	29.5	6.5	21.1	28.8	22.8	24.2
21	47.5	27.2	21.2	31.9	37.2	22.8	19.0	26.3
22	6.0	−6.2	24.3	8.1	39.0	10.8	17.0	22.3
Mean	29.6	16.9	17.6	21.3	32.3	19.4	18.0	23.1
SD	19.0	19.6	16.8	16.9	18.4	19.1	15.8	16.0

The APHAB benefit scores indicated significant improvement at 3 months ($p < 0.001$) and at 6 months ($p < 0.001$) for all scales.

APHAB indicates Abbreviated Profile of Hearing Aid Benefit; BN, Background Noise; EC, Ease of Communication; GBL, Global; RV, Reverberation.

the items. The remaining improvement item, a binaural function not expected to show an improvement in SSD, was reported as an improvement for 82% of the subjects.

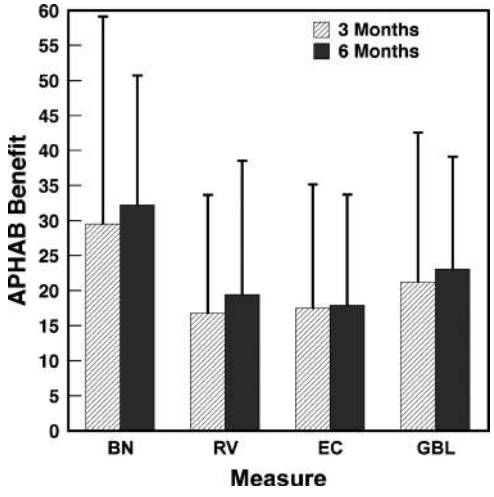

FIG. 5. Mean (+1 SD) APHAB Benefit scores for the BN, RV, and EC subscales and the overall GBL scale at 3 and 6 months. There was a significant improvement in the mean APHAB scores at 3 months ($p < 0.001$) and at 6 months ($p < 0.001$) for all scales.

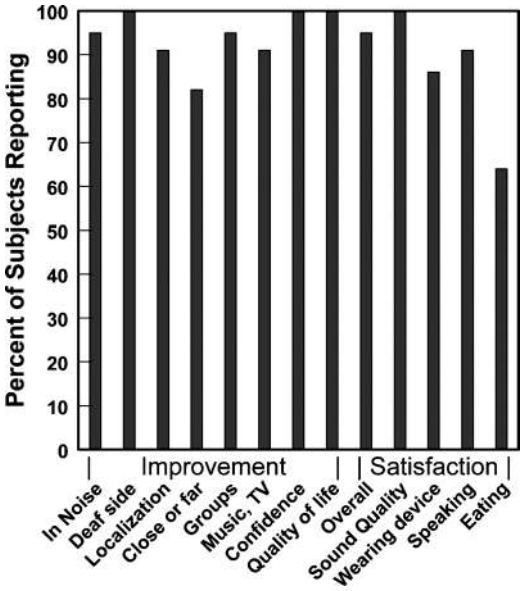

FIG. 6. Percentage of subjects reporting improvement or satisfaction for 13 items on the SSD questionnaire at 6 months. There was no significant difference in the mean SSD scores at 3 months compared with that at 6 months ($p > 0.01$) for all questions, indicating that the benefit was realized early in the trial.

The percentage of subjects reporting satisfaction (slightly satisfied to very satisfied) exceeded 90% for 3 of the 5 satisfaction items, reaching 100% for one of the items, dropping slightly to 86% of the subjects for the fourth item.

The lowest score on the SSD questionnaire concerned satisfaction with ability to eat while wearing the device. Although almost two-thirds (64%) of the subjects reported being satisfied with ability to eat while wearing the device, just over a third (36%) reported being dissatisfied.

A very high percentage (95%) of the subjects preferred wearing the device to not wearing the device. All of the subjects (100%) were likely to recommend the device to other SSD patients.

DISCUSSION

No medical, audiologic, or dental safety issues were discovered during the long-term trial. None of the comprehensive array of quantifiable audiologic, periodontal, or dental safety measures differed at the end of the trial from those at the beginning. No qualitative changes or damage to the teeth, supporting structures, or soft tissues were observed either. The ITM component interacts with oral tissues in the same manner as all removable dental appliances. The same cautions for dental retainers or partial dentures should be used with SoundBite. The patient's teeth should be healthy and maintained when using the device (or at all times).

The SoundBite Hearing System provided very stable performance over the 6-month period. There were no measurable changes in the device, in the coupling of the device to the teeth, or in the transmission pathway to the cochlea.

Although difficult to compare directly because of study differences (sample size, wearing times, device configurations, etc) the mean APHAB Global benefit score for the SoundBite device(23.2) was considerably higher than typical published scores for the BAHA (~7–17) (29–34). Only a single published study (35) reported a mean BAHA APHAB global benefit score as high as the value reported here.

The APHAB benefit results were substantial at both 3 and 6 months compared with no device. The positive findings seen in a very high percentage (>90%) of subjects for almost every SSD questionnaire item at 6 months were already seen at 3 months. In general, the benefits of this device are seen early on and do not require a long period of adaptation.

The adult subjects in this study were experiencing the substantial auditory deficits resulting from SSD. None were using any SSD device including the surgically implanted osseointegrated post system, the most common SSD intervention, yet one that often is rejected. The SoundBite is a novel alternative that uses the proven bone conduction principle of the surgical device but has no waiting period before activation, has better acoustic properties, is noninvasive and safe, and provides substantial benefit for the vast majority of SSD subjects in the specific conditions in which they have difficulty, specifically when listening in background noise or reverberant environments and when communicating.

With no identified safety issues, the nonsurgical SoundBite has a far better risk benefit profile than surgically based systems. Because the SoundBite hearing system is safe for long-term use, does not require surgery, and provides effectiveness and benefit either equivalent or superior to surgery-based systems, it is a reasonable alternative to the surgically based osseointegrated post systems.

This study extends the previously published short-term safety and benefit findings for long-term use. The U.S. Food and Drug Administration recently cleared this device for SSD based in part on the results of this study and previous studies (1–3,36).

CONCLUSION

There were no measurable medical, audiologic, periodontal, or dental safety effects of wearing the SoundBite device for a 6-month period. The device continued to provide substantial benefit for the SSD subjects at the end of the 6-month period.

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APPENDIX A

SSD QUESTIONNAIRE

Improvement
(Very Much Improved, Improved, Slightly Improved, No change, Worse)

3. Please use the scale below to rate the performance of your device in terms of how well it improved your experience in each of the following situations. (Write a letter on each line.)
   ____ 3.1 Hearing in noisy environments
   ____ 3.2 Hearing a person speaking to you on your deaf side
   ____ 3.3 Your ability to tell where sounds are coming from
   ____ 3.4 Your ability to tell how close or far away a sound is
   ____ 3.5 Your ability to participate in group conversations
   ____ 3.6 Your experience of listening to music, TV, or radio
   ____ 3.7 Your overall confidence in group situations
   ____ 3.8 Your overall quality of life

Satisfaction
(Very Satisfied, Satisfied, Slightly Satisfied, Slightly Dissatisfied, Dissatisfied, Very Dissatisfied)

1. Overall, how satisfied were you with the performance of your device in terms of addressing your hearing problem? (circle one)
2. How satisfied were you with the quality of sound delivered by the device? (circle one)

Long Term Results of New Intraoral SSD Device

5. How satisfied were you with the experience of wearing the device? (circle one)
6. How satisfied were you with your ability to speak while wearing the device once you had acclimated to it? (circle one)
7. How satisfied were you with your ability to eat while wearing the device? (circle one)

Preference
(Very Much Prefer Device, Prefer Device, Slightly Prefer Device, Slightly Prefer No Device, Prefer No Device, Very Much Prefer No Device)

4. Compared to your previous situation in which you had no device and your hearing problem was left untreated, do you prefer having this hearing device?

Likelihood
Very Likely, Likely, Slightly Likely, Slightly Unlikely, Unlikely, Very Unlikely

8. How likely would you be to recommend this device to a friend who had the same hearing problem as yours?

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Safety of an Intra-Oral Hearing Device Utilizing a Split-Mouth Research Design

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Abstract

- **Objective:** The auditory deficits of Single Sided Deafness (SSD) can be treated effectively with a novel device, SoundBite™, that delivers sound by applying imperceptible vibratory signals to the teeth (hereafter referred to as an intra-oral hearing device). The intra-oral hearing device is placed around two maxillary teeth and is similar to a small partial denture or retainer. The goal of this study was to report how this removable hearing device affects the oral structures.
- **Methods:** Twenty-two SSD patients wearing an intra-oral hearing device were enrolled in a prospective study for six months. Differences (Δ) between the device-anchoring teeth and the equivalent contralateral non-device teeth were evaluated with four dental parameters using a paired t-test. Hearing thresholds were evaluated as a function of alveolar bone support using linear regression.
- **Results:** Compared to the non-device teeth, the hearing device teeth did not exhibit any increased recession (Δ = 0.1 mm, p-value = 0.48), increased pocket depth (Δ = 0.0 mm, p-value = 0.48), increased root resorption (Δ = 4%, p-value = 0.43), or increased alveolar bone loss (Δ = 0.0 %, p-value = 0.43). There was no association between the amount of alveolar support and hearing thresholds (Δ = 0.2, p-value = 0.34).
- **Conclusion:** The intra-oral component of the hearing device did not adversely affect the dental structures of the subjects in this trial.

(J Clin Dent 2011;22:159–162)

Introduction

It is estimated that nine million people in the United States suffer from Single Sided Deafness (SSD).[1] SSD can affect quality of life in several ways and can be debilitating. SSD removes the sense of omnidirectional hearing, can affect the ability to hear speech in noisy situations, and makes it difficult to detect the direction from which sound originates. Simple activities such as walking near cars, cycling, or running become more dangerous. A primary obstacle for SSD sufferers occurs when socializing in large groups or in rooms with an elevated background sound. In such circumstances, SSD sufferers may feel excluded because they cannot hear conversations, or worry they may appear rude or ignorant if they do not hear a question or parts of the conversation.

Currently, the only treatments for the auditory effects of SSD utilize bone conduction signals applied to the skull to transfer the signal to the opposite, better hearing ear. Transear® (Ear Technology Corporation, Johnson City, TN, USA) produces a bone conduction device that is worn around the ear, with a vibratory transducer positioned deep in the ear canal, against the bony portion of the ear canal wall. The Baha® from Cochlear (Macquarie University, NSW Australia), the most common treatment,[2] consists of a titanium post, much like a titanium dental implant, which is surgically implanted into the mastoid process of the temporal bone on which a small external electronic module is attached to deliver the bone-conducted signal. The Baha is invasive, expensive, not readily reversible, requires general anesthesia to be implanted, and is associated with failure to integrate with the bone and significant numbers of skin infections.[3]

The oral component tested in this trial was fabricated from a standard full or quadrant dental model made from an alginate impression.[4] This study was designed to determine how normal use of the intra-oral hearing device interacts with a number of parameters associated with the teeth and periodontal structures.

Materials and Methods

Sonitus Medical, Inc. (San Mateo, CA, USA) has developed a tooth-borne sound conduction hearing device which utilizes two separate components that communicate wirelessly (SoundBite™, Figures 1 and 2); one component fits in the ear and the other in an oral device that fits around two posterior teeth. The device has previously been shown to substantially improve the auditory deficits of SSD[5,6] in an initial one-month trial of 28 patients.

In order to evaluate dental safety, a six-month prospective trial was designed. The trial subjects (n = 22) were all adults with SSD. Comprehensive medical and neurotologic evaluations were conducted by a neurotologist. The causes included sudden sensorineural hearing loss (11/22), acoustic neuroma (5/22), Meniere's syndrome (3/22), unknown cause (2/22), and jugular

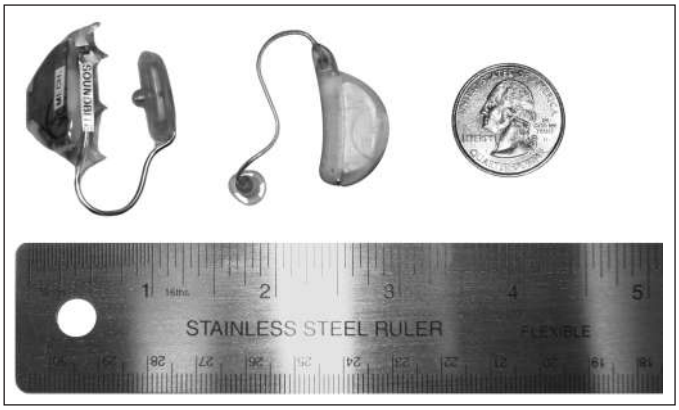
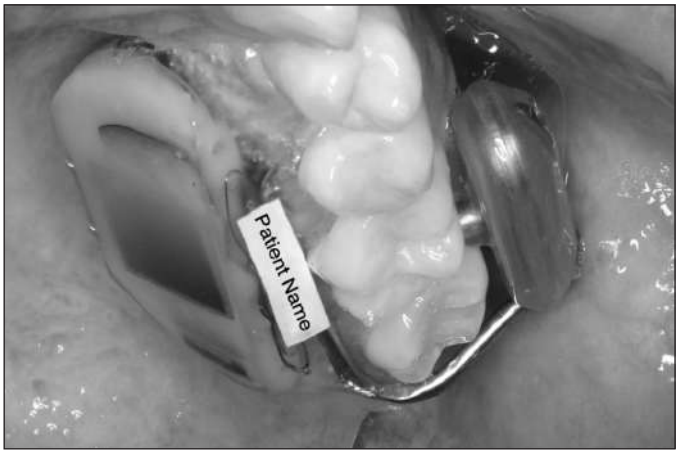


Figure 1. *The SoundBite tooth-borne sound conduction hearing device which utilizes two separate components that communicate wirelessly.*



schwannoma (1/22). Comprehensive audiological measures were obtained by experienced audiologists. The SSD was defined as pure tone average (PTA) of hearing thresholds at 500, 1000, and 2000 Hz in one ear, adequate to preclude benefit from a conventional hearing aid (PTA ≤ 25 dB HL), and permanent severe or worse sensorineural hearing loss in the opposite ear (PTA ≥ 70 dB HL). None of the subjects were current users of any SSD device.

The dental measures were partially blinded in that all measures were recorded on the patient x-rays or models, without the clinician knowing on which side the oral device was placed. All measures were obtained by a dentist with specialty training in orthodontics, and a consulting periodontal specialist who is also an epidemiologist.

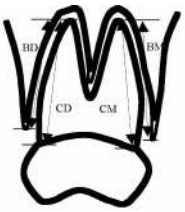
All patients signed an informed consent, and the trial was conducted with IRB review. Periodontal, mucosal, and device measures were evaluated at baseline and six months in a group of 22 SSD patients wearing the intraoral hearing device daily. The dental examinations were conducted in an ear-nose-throat chair using lighting similar to that of a dental chair. The periodontal outcome measures included 1) periodontal probing, 2) gingival recession, 3) bone support, and 4) root resorption.

Periodontal probing was performed using a graded 3 mm periodontal probe (Marquis Type) at six sites per tooth (three buccal and three palatal).[7]

Gingival recession was measured on dental models. All impressions were taken with alginate and poured up in white plaster; bubbles and debris were removed from study models using a scalpel. Digital calipers were used to measure from gingiva to the height of the crown. Six measures were performed for each tooth, three on the lingual and three on the buccal.[8,9] The three measures on the buccal surface of the crown were mesial crown to gingival margin, mid-crown to gingival margin, and distal crown to gingival margin; three analogous measures were made on the lingual surface of the crown.

Bone support and root resorption were determined radiographically. Digital, non-standard periapicals (PA) and bitewings[10] were taken at the initial and six-month time points. The same technician took all the x-rays, but there was no mechanical device used to standardize the angulations of x-rays. Digital calipers were used on study models to get a known distance to standardize the radiographs (all measurements in mm).[11,12]

Bone support was measured using the PA films on the two teeth contacted by the device actuator and the two teeth on the opposite side of the mouth (controls). Four measurements were made per tooth. Measurements were made from the mesial root apex to the mesial cemento-enamel junction (CEJ), and mesial root apex to mesial alveolar bone crest, then from the distal root apex to the distal CEJ, and the distal root apex to the distal alveolar bone crest. The same measurements were done on the teeth contacted by the actuator and control teeth for each time point (Figure 3).



Measurements:

BD: Distance from root apex to the alveolar bone crest on the distal of the tooth.

CD: Distance from root apex to the CEJ on distal of the tooth.

BM: Distance from root apex to the alveolar bone crest on the mesial of the tooth.

CM: Distance from root apex to the CEJ on mesial of the tooth.

Bone support per tooth = [(BD/CD) + (BM/CM)] × 1/2 (i.e., The average of distal and mesial bone support).

ImageJ software for Macintosh (public domain Java image processing program), based on NIH imaging, was employed to quantify radiographic measures.[13] Bone support for each individual tooth was calculated as a ratio of the distance from the root apex to the height of the alveolar bone, to the distance from the root apex to the CEJ, averaged on the mesial and distal aspects of the tooth. The hearing aid was always on the side of the hearing loss (and thus not randomly assigned).

All data were imported into an SAS database and analyzed with SAS® Proprietary Software 9.2 (TS2M2; SAS Institute, Cary, NC, USA). Both general linear model procedures (for patient averages and obtaining the paired t-statistic) and generalized linear models (for site-specific measures) were used to compare the effect of the appliance on periodontal parameters. Both methods take into account the correlation between split-mouths (GLM) and sites (GENMOD) within patients. The association between alveolar bone support and hearing threshold was evaluated using simple linear regression and the correlation coefficient. The results of both analyses, GLM and GENMOD, were robust as they led to the same conclusions; only the GLM (leading to the paired t-test) are reported.

Results

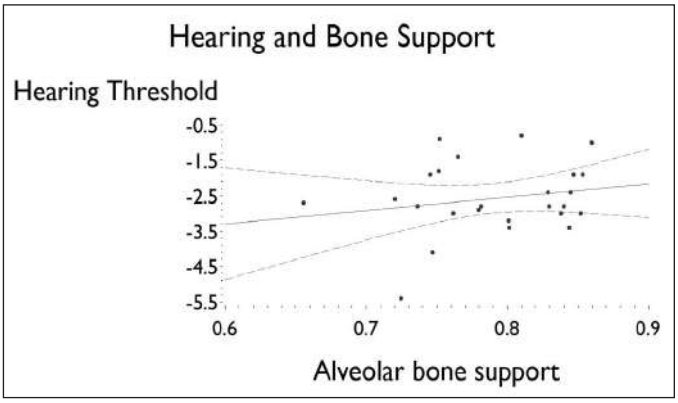
The patients were recruited between September 5, 2009 and May 6, 2010 and seen in the office of an ear, nose, and throat specialist located in San Jose, California. In twenty-one patients, the actuator held against the 1st and 2nd molar, in one patient it touched the 2nd bicuspid and 1st molar. Twelve of the patients were male and ten were female. The average age was 44 years old, with the oldest patient being 65 and the youngest being 25. Eleven patients had SSD on the left and eleven had it on the right. Five of the 22 patients had not been to the dentist for two or more years prior to entering the trial; seventeen of the patients routinely had dental appointments. One patient never went to the dentist, though he was reminded at each visit to establish a pattern of regular dental care. Referrals were made for the patients that had not seen a dentist for two or more years.

No change during the six-month trial was found in periodontal pocket depth between the teeth that anchored the hearing device and the non-device teeth (Δ = 0.0 mm, p-value = 0.48). Similarly, there was no difference in gingival recession between the device side and the non-device side (Δ = 0.1 mm, p-value = 0.48); the device side actually showed a little less recession than the non-device side. Alveolar support remained unchanged during the study (Δ = 0.0%, p-value = 0.43). There were no significant differences in root resorption between the device teeth and the non-device teeth (Δ = 4%, p-value = 0.43; Table I).

There was no significant correlation between the hearing threshold and the alveolar bone support measures (Figure 4). For every 1% decrease in bone support, the hearing ability improved by 0.04 units (standard deviation of slope coefficient = 0.04).

There were no long-term clinical soft tissue changes in 17 of the subjects. In the remaining five patients, soft tissue changes commonly seen with denture wearers, namely minor indentations caused by partial dentures or full dentures worn many hours a day, were observed.[14]

Three dental issues occurred during the trial, but none were related directly to wearing the device. One patient had a palatal torus requiring the slight modification to the device. Another patient damaged her front teeth in a bicycle accident. A third patient had an old occlusal lingual filling on tooth #14 break out with part of the distal cusp. The patient was eating at the time but not wearing the intra-oral hearing device. Although this tooth was an abutment tooth, it was the opinion of the trial dentist and the patient's private dentist that this event was unrelated to the intra-oral hearing device. This private dentist prepared a crown with usual and customary restorative care. Thus, out of the 44 abutment teeth in this trial, one required a new restoration during the trial due to an unrelated event, while 23 started the trial with an amalgam restoration, 13 were natural with no restorations, six were crowns, and two had resin composites; there were a number of root canals.



No broken teeth, soft tissue changes, or any other changes were noted that would be considered unusual for removable dental devices.

Discussion

This study demonstrated that no adverse effects were associated with the wearing of an intra-oral hearing device that is anchored to two maxillary teeth in the subjects studied. This association was bi-directional. Hearing characteristics were not affected by the amount of alveolar support; that is, there were no adverse effects when wearing the intra-oral hearing device and no effect on hearing from variations in bone levels in the sample. However, these conclusions have to be tempered with the small sample size and subjects' periodontal health, which was a pre-requisite for entering into a study.

It was expected that increased bone loss across the sample would lead to decreased benefit of the intra-oral hearing device. The observed trend was actually opposite, with less bone support being associated with better hearing thresholds. However, future

Table I
Dental Measures

	Device Side			Non-Device Side		
	Baseline	Change to Six Months	Six Months	Baseline	Change to Six Months	Six Months
Probing depth (mm)	2.9 (0.05)[y]	2.4 (0.08)	– 0.5[1] (0.09)	2.9 (0.06)	2.4 (0.08)	– 0.5 (0.09)
Gingival Recession (mm)	6.1 (0.1)	5.9 (0.2)	– 0.2[2] (0.1)	6.1 (0.1)	5.8 (0.1)	– 0.3 (0.1)
Alveolar bone support (%)	0.9 (0.01)	0.9 (0.01)	– 0.0[3] (0.1)	0.9 (0.01)	0.9 (0.01)	0.0 (0.01)
Root resorption	100 (0)[x]	98 (2.4)	– 2[4] (2.5)	100 (0)	102 (2.9)	2 (2.9)

[1]p-value < 0.48.
[2]p-value < 0.48.
[3]p-value < 0.43.
[4]p-value < 0.43.
[x]All roots were assumed to have 100% root length at baseline.
[y]Mean (standard error).

research will need to determine what effect periodontal disease or endodontic disease would have on intra-oral hearing devices. In this trial, there was no detectable effect of dental materials, including crowns, amalgams, resins, endodontics, or implants, on the conduction of sound. This is an area of future research as well.

Although five patients had minor soft tissue changes on the palate, these types of changes are clinically insignificant and familiar to those who fashion retainers or complete dentures on a regular basis in their clinical practices.

The intra-oral hearing device appears to interact with oral tissues in the same manner as other removable dental appliances. The same cautions observed in using retainers or partial dentures should be observed when using the intra-oral hearing device; namely, the patient's teeth should be healthy and maintained during the time of the device's use. Patients do have to continue to see their dentist regularly and perhaps increase their vigilance regarding their home care. There was no increase in probing depth, alveolar bone loss, root resorption, or gingival recession. We found no damage to the teeth, soft tissues, or supporting tooth structures.

The findings of this study are promising for those patients who want a discreet, non-invasive way of treating their SSD. Neither dental restorations nor moderate periodontal bone loss seemed to affect the perceived benefit. Although no patients were enrolled in this study who had dramatically reduced periodontal support, extrapolation of available data suggests hearing characteristics should be minimally affected when periodontal support is reduced significantly. Further research on patients with periodontal disease would be valuable in identifying the true limits of sound conduction through the teeth.

Conclusion

The intra-oral component of the hearing device did not adversely affect the dental structures studied among the subjects in this trial. From a dental safety standpoint, it appears that the SoundBite device had no observable detrimental effects on dental structures during this six-month trial. The intraoral hearing device had oral effects similar to commonly used removable dentures or retainers.

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Efficacy and Safety of an In-the-Mouth Bone Conduction Device for Single-Sided Deafness

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Objective: To determine the efficacy, benefit, and safety of a new in-the-mouth bone conduction device (SoundBite Hearing System) for single-sided deafness (SSD).
Study Design: A multicenter, controlled, nonrandomized prospective unblinded study of SSD patients wearing the device.
Settings: Ambulatory care centers typical of those where SSD patients are diagnosed and treated.
Patients: Adults (ages >18 and <80 yr) with acquired, permanent SSD (N = 28) and no current use of any SSD device.
Intervention: Continual daily wear of the new device over a 30-day trial period.
Main Outcome Measures: The Hearing in Noise Test (HINT), the Abbreviated Profile of Hearing Aid Benefit (APHAB), comprehensive pretrial and posttrial medical, audiologic, and dental examinations and an SSD questionnaire.
Results: The Hearing in Noise Test scores improved an average of –2.5 dB after 30 days, compared with wearing no device ($p < 0.001$). The Abbreviated Profile of Hearing Aid Benefit scores improved ($p < 0.05$) for all subjects for the Global and Background Noise subscales and for all but 1 subject for the Reverberation and Ease of Communication subscales. There were no medical, audiologic, or dental complications.
Conclusion: The SoundBite system is safe and effective and provides substantial benefit for SSD patients with continual daily use over a 30-day period. **Key Words:** Abbreviated Profile of Hearing Aid Benefit—Bone-anchored hearing aid—Bone conduction—Osseointegrated post—Hearing in Noise Test—Single-sided deafness.

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Spatial hearing ability (1) is compromised in patients with single-sided deafness (SSD) resulting in a significant auditory handicap (2,3). Deficits include a lost sense of omnidirectional hearing and difficulties in hearing sounds originating on the poorer hearing side, localizing sound sources, and understanding speech in noisy situations (4). The most widely used intervention is a surgery-based system (Bone-Anchored Hearing Aid; Cochlear Corp., Lane Cove, New South Wales, Australia) composed of an osseointegrated titanium post implanted surgically directly into the cranium behind the poorer ear with an electronic module mounted to the post that picks up sound on the poorer ear side and transfers it to the better ear by bone conduction. This approach is effective at reducing spatial hearing deficits (5,6), relatively safe (7,8) and generally well tolerated (8–10).

However, this approach still has substantial limitations. First, it requires invasive surgery and is therefore routinely rejected by large percentages of SSD patients (5,11). Second, 5.8% (8) to 12.1% (12) of the cases have complications that require revision surgery. Third, the spatial hearing improvement may not be optimal (13) because the microphone is positioned in the acoustic shadow of the pinna (14), and the device has very limited frequency bandwidth with no significant output above 4,000 Hz (15).

A new SSD device (SoundBite Hearing System; Sonitus Medical, San Mateo, CA, USA) uses the same functional principles as the osseointegrated post system, but with substantial improvements. First, the microphone is located in the ear canal of the poorer ear to capitalize on the spatial hearing acoustic properties of a normal pinna (1). Second, a removable in-the-mouth (ITM) device provides direct coupling to the cranium via the teeth and the proven method of signal transfer by direct bone conduction but eliminates the need for surgery. Third, a new bone conduction transducer adds much higher frequency capability known to be beneficial for spatial hearing (16–19).

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Potential Conflicts of Interest: The authors are not employees of Sonitus Medical, Inc., but have these relationships: Dr. Murray owns stock options and provides consulting to Sonitus Medical, Inc.; Dr. Popelka provides consulting to Sonitus Medical, Inc.; and Dr. Miller owns stock and stock options and provides consulting to Sonitus Medical, Inc.

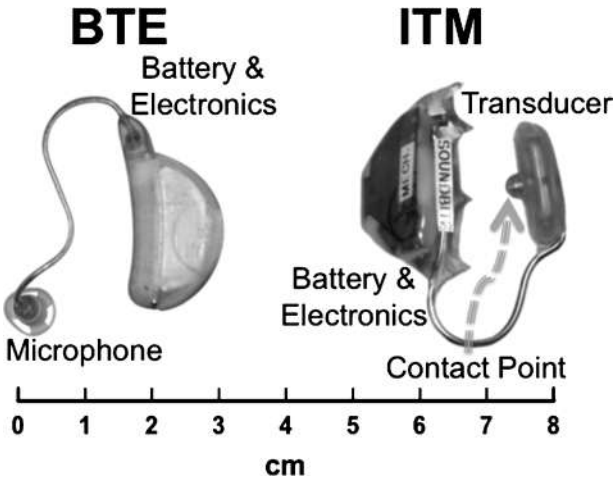

FIG. 1. The SoundBite system by Sonitus Medical consists of a BTE component (left) and an ITM component (right) that connect wirelessly. The BTE is similar to a BTE hearing aid but positions the microphone in the ear canal of the poorer ear. The ITM is similar to a small partial dental retainer but applies a bone conduction signal via a small contact point positioned between 2 teeth.

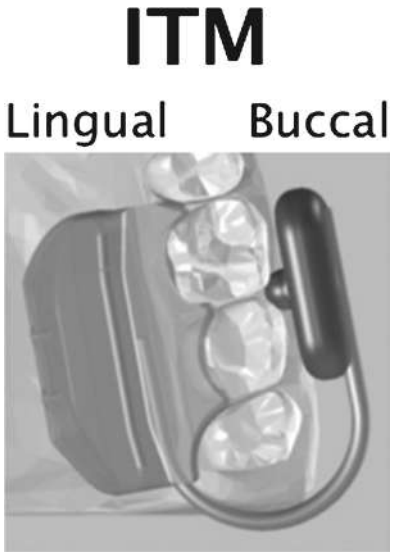

FIG. 2. The ITM positioned on the upper teeth showing the location of the individual components. The lingual component arches upward along the palate, and the buccal component fits between the teeth and the cheek. All components are positioned on the lateral surfaces of the teeth, leaving the bite zone open.

Figure 1 illustrates the system. One component is a removable behind-the-ear (BTE) microphone unit with full digital processing that captures the acoustics of the normal pinna and external auditory canal by positioning the microphone in the ear canal of the poorer ear. The second component is a removable In-the-Mouth (ITM) device similar to a small partial dental retainer that does not require surgery yet delivers a direct bone conduction signal to the cranium by way of the teeth with substantial high frequency output. The custom ITM device is composed of 2 modules, one containing electronics and a new bone-conduction transducer with a small contact point on the buccal side of the molars and one containing a rechargeable battery on the lingual side of the molars.

Figure 2 illustrates the ITM positioned on the teeth. The ITM is individually manufactured from a dental impression taken from the patient to ensure optimal wearing comfort and account for intraoral variations. A spring wire wraps around the last molar to electronically connect the 2 ITM modules and simultaneously maintain a constant coupling force against the lateral surfaces of the teeth to maintain consistent sound transfer. This form factor eliminates surgery, requires no modification of the teeth, and allows the ITM device to be fitted to either side of the mouth and to be inserted and removed easily. The custom fit to the individual patient's own teeth assures retention similar to partial dentures that have been used safely for many years. The retentive spring force keeps it firmly anchored to the teeth with no part in the bite zone preventing biting forces from dislodging it. The ITM dimensions significantly exceed the transverse internal diameter of the adult human esophagus or bronchi, preventing it from being accidentally swallowed or aspirated. Preliminary studies with prototype devices in limited numbers of subjects suggested that this approach is safe (4,20) and effective (4,20).

Figure 3 shows the default output force level in dB re 1 μN plotted as a function of frequency with a 50 dB SPL acoustic input level for a typical device measured on a calibrated laboratory system in a format identical to published measures for the osseointegrated post systems (15). Gain of the device while set in linear mode (no compression, no automatic gain control, etc.) is equivalent to published values for osseointegrated post systems (15) and meets the requirements of SSD patients (15,20). A comparison of the data in Figure 3 with published data (15)

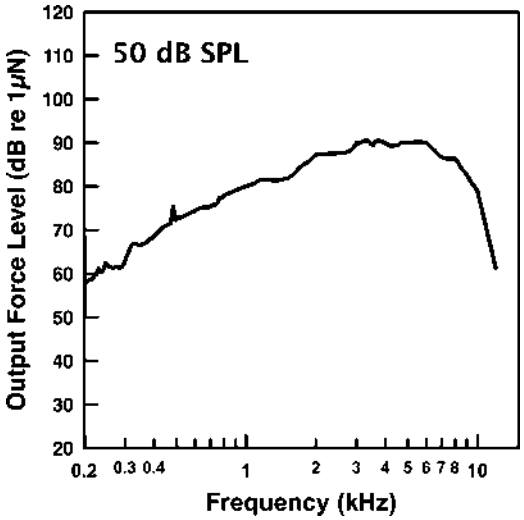

FIG. 3. The default output force level in dB re 1 μN plotted as a function of frequency with a 50-dB SPL acoustic input level for a typical device measured on a calibrated laboratory system in format identical to published measures for the osseointegrated post systems.

for the osseointegrated device under identical measurement conditions (Fig. 1 in the citation) indicates that this new device has a much wider frequency bandwidth, with up to an additional 30 dB of output for frequencies greater than 1,600 Hz up to 12,000 Hz.

The purpose of this study was to determine the efficacy, benefit, and safety of this new ITM bone conduction device for SSD. The hypotheses concerned whether this new device provides an improvement in the ability of SSD patients to understand speech in noise, provides benefit, and is safe with continual daily use over a 30-day period.

METHODS

Subjects

Subjects were individuals diagnosed with acquired, permanent SSD with no known active medical cause, no active middle ear pathology, and onset of 3 months or greater. A neurotologist (M. M.) made the medical diagnosis based on comprehensive medical examinations including an otologic history, a physical examination, and magnetic resonance imaging to rule out active disease processes that may cause SSD. The SSD was considered permanent with no further medical or otologic intervention. Subject criteria also included age (>18 and <80 yr old), fluency in English, and no current use of any SSD device. An audiologist performed the initial and final comprehensive audiologic examinations (air and bone conduction thresholds, speech audiometry, and tympanometry) and the auditory outcome measures.

A dentist (R. M.) performed the dental examinations that included a full-mouth x-ray, an assessment of oral health and a dental impression of the upper dentition for dental evaluation and for fabrication of the ITM device. Dental criteria included a minimum of 6 posterior teeth in the upper arch, no ongoing dental treatment of any kind, good oral hygiene, no active caries, and no active moderate or worse periodontal disease.

Main Outcome Measure(s)

Efficacy

The primary efficacy outcome was a measure of the ability to understand speech in noise while wearing the device compared with not wearing the device using the most widely used measure for SSD devices. The Hearing in Noise Test (HINT) (23) presents speech to the front of the subject while noise is presented to the front, to one side, to the opposite side, or without noise and determines the signal-to-noise ratio that results in 50% correct understanding of words in sentences. This recorded test uses adaptive procedures and has published normative signal-to-noise ratio values (~–6 dB) and variability (standard deviation [SD], ~1.0 dB) (23). A more negative (–dB) value indicates an improvement in understanding speech in noise. An improvement in a HINT score of –1 dB is equivalent to a 10% improvement in the ability to understand speech in noise (23) and is likely of clinical benefit (24).

The secondary efficacy outcome was a measure of the benefit of the device using the Abbreviated Profile of Hearing Aid Benefit (APHAB) (25), a 24-item self-assessment inventory in which the amount of difficulty in everyday situations is reported with larger numbers indicating more difficulty. Device benefit is calculated by subtracting the score obtained after using a device from the score obtained before using the device. The APHAB provides an overall global benefit (GB) score and subscale scores that assess ease of communication (EC), difficulties with listening in reverberation (RV) or listening with background noise (BN), and aversiveness to amplified sounds (AV) (26). The APHAB is well characterized and broadly used as a quantifiable measurement of device benefit (25).

The third efficacy outcome measure was an analysis of the results of an SSD questionnaire. This questionnaire uses rating scales for satisfaction, improvement, and preference specifically for SSD patients, although it has not been validated.

Safety

Subjects were monitored for discomfort associated with the dental impression and fitting process; oral health risks (exposure to oral contamination if cleaning instructions were not followed; intraoral gingival, palatal, or dental soreness); and any health problems from the medical, dental, and audiologic examinations. At the end of the 30-day period, each subject also received a complete medical and audiologic reexamination to determine any change in medical status, a complete dental reexamination including a partial x-ray of the teeth that were in contact with the oral device and comprehensive measures of wear on the enamel surface of the teeth based on direct examination, and a microscopic analysis of a final full arch upper dental impression. Measurements of the initial upper cast and final upper cast using digital calipers were taken to check for tooth movement.

Procedures

The study was a multisite, controlled, nonrandomized prospective design with unblinded clinicians, data analysts, and subjects. The sites were ambulatory care centers typical of those where SSD patients are diagnosed and treated. All medical, audiologic, and dental examinations were performed at 1 site (A). All auditory performance measures and questionnaires were performed at 2 sites (A and B) by 2 different audiologists. Measures of efficacy and safety were obtained over a 30-day trial period. The study was conducted according to U.S. and international ethical standards under an institutional review board approved study protocol (IRB 08132-02B).

Devices

After candidacy was determined, the fitting process involved selection of the side of the mouth, manufacture of the device from the dental impression, setting and verifying default vibratory output, fitting the ITM for comfort and optimal sound transmission, programming the BTE for a variety of settings including equal output across frequencies and overall gain appropriate for SSD (15), and all of the related counseling and instructions. The subjects were instructed to wear the device for all daily activities including eating, drinking, and exercising and to remove the device while sleeping so that the batteries could be recharged. Each subject was furnished with 1 BTE microphone unit, 2 ITM devices, and a battery charger. This arrangement allowed continuous daily use. A third ITM device was fitted as a backup.

The device output was measured on each subject individually with a loudness-matching procedure (21,22) using a conventional audiometer. The resulting values were used to program the system. The method accounted for individual differences in the tooth-to-cochlea bone-conduction pathway and is directly analogous to ''real ear'' measures used with conventional hearing aids. After programming, each subject perceived only a comfortable auditory sensation and no tactile sensation on the teeth (4,20).

RESULTS

Demographics

The patients enrolled in the study (N = 28) were typical of SSD patients with etiologies that included sudden sensorineural hearing loss of unknown cause (17/28 or 61%), acoustic neuroma (6/28 or 21%), and Ménière's syndrome (5/28 or 18%). Hearing thresholds for conventional audiometric test frequencies (250–8,000 Hz) were less than 30 dB HL (ANSI-2004) in the better ear and greater than 55 dB HL in the poorer ear with no conductive component in either ear. These subject's medical conditions and hearing status were representative of the typical SSD population and very similar to subjects in studies that investigate performance of SSD devices (8,24).

Individual demographic data are shown in Table 1. The average age was 46 years (SD, 13.0; range, 25–73 yr), an equivalent sex mix (male subjects, 54%; female subjects, 46%), and SSD equally divided among left and right ears. The average SSD duration was 9.0 years (SD, 9.1; range, 1–30 yr) with subjects divided almost equally between the 2 clinical sites (A = 16, B = 12). The average trial period was 35.0 days (SD, 6.1), and the average daily wearing time was 8.2 hours (SD, 2.21).

HINT Results

Table 2 shows the mean (SD) HINT dB advantage scores (aided compared with unaided) for the 4 HINT conditions at each of 2 clinical sites (A and B) at the beginning of the study (Day 1), and at the end of the study (Day 30). There were no statistical differences in the scores between the 2 clinical sites, so the scores were combined (total). An ''a'' indicates a statistically significant change.

TABLE 1. *Subject demographic data and descriptive statistics*

Subject no.	Age (yr)	Sex	Single-sided deafness ear	Years of single-sided deafness	Site	Trial period (d)	Daily usage (h)
1	73	Male	Right	20.0	A	35	10
2	58	Male	Left	2.0	B	32	7
3	57	Male	Right	10.0	B	35	8
4	50	Male	Right	2.8	B	36	6
5	46	Male	Left	4.0	B	42	8
6	44	Male	Left	3.0	A	35	6
7	44	Male	Left	30.0	B	35	7
8	41	Male	Left	25.0	B	36	6
9	40	Male	Left	1.0	A	30	12
10	36	Male	Right	2.0	A	31	12
11	31	Male	Left	13.0	A	35	10
12	31	Male	Left	6.5	A	30	9
13	31	Male	Left	2.0	A	31	10
14	27	Male	Right	4.5	A	35	11
15	25	Male	Left	25.0	B	38	6
16	65	Female	Right	5.0	A	35	8
17	63	Female	Left	4.0	B	30	7
18	62	Female	Right	20.0	B	36	12
19	58	Female	Left	2.0	B	38	6
20	57	Female	Right	17.0	B	39	5
21	56	Female	Right	2.0	B	36	6
22	53	Female	Right	5.5	B	30	10
23	51	Female	Right	4.3	A	62	6
24	46	Female	Right	2.4	B	31	11
25	45	Female	Right	2.3	B	32	7
26	41	Female	Left	2.3	A	32	6
27	37	Female	Right	26.0	A	35	10
28	25	Female	Left	8.4	B	30	7

TABLE 2. *Mean (standard deviation) Hearing in Noise Test decibel advantage scores (aided compared with unaided) for the 4 Hearing in Noise Test conditions at each of 2 clinical sites (A and B)*

Site	Day	HINT (dB) mean (SD) no noise	HINT (dB) mean (SD) noise front	HINT (dB) mean (SD) noise poorer	HINT (dB) mean (SD) noise better
A	1	0.6 (3.00)	0.6 (1.17)	1.7 (1.33)	−1.5 (1.31)
B	1	−0.6 (4.58)	0.1 (1.43)	2.5 (1.52)	−1.8 (0.67)
Total	1	−0.2 (4.00)	0.2 (1.53)	2.1 (1.57)[a]	−1.7 (0.97)[a]
A	30	0.2 (2.51)	0.4 (1.02)	2.0 (1.39)	−2.2 (0.92)
B	30	−2.1 (5.56)	−0.3 (1.75)	2.6 (1.12)	−2.8 (0.98)
Total	30	−1.1 (4.59)	0.0 (1.50)	2.3 (1.26)[a]	−2.5 (1.00)[a]

There were no statistical differences in the scores between the 2 clinical sites (*t* test), so the scores were combined (total).

[a]Statistically significant change with the device compared with the no device condition (paired *t* test, $p < 0.001$).

The HINT advantage scores for the most adverse noise condition for SSD patients (noise to better ear) are the most relevant. It is well documented that the ability to understand speech in noise for this condition improves in SSD patients with device experience as reflected by improved HINT scores over time (7). Consistent with this finding, the HINT advantage scores at Day 30 were consistently better than the HINT advantages scores at Day 1. The HINT advantage score for this condition at the beginning of the trial showed an advantage of –1.7 dB (SD, 0.97 dB) which was statistically significant ($p < 0.001$). At the end of the trial period, the HINT advantage score for this condition improved further to –2.5 dB (SD, 1.00 dB), also a statistically significant improvement ($p < 0.001$). On average, for the most adverse noise situation for SSD patients, the SoundBite device immediately allowed a 17% improvement in the ability to understand speech in noise with no experience wearing the device and, on average, allowed a 25% improvement at the end of 30 days of regular daily use. On an individual basis, all 28 subjects had an improved HINT score at the end of 30 days of regular daily use with improved HINT scores of between –1 and –2 dB in 8 subjects, between –2 and –3 dB in 9 subjects, and greater than –3 dB in 9 subjects.

The HINT advantage scores for the conditions of no noise or noise to front were not expected to change because SSD patients have normal hearing on one side, and the head shadow effect for these 2 conditions is much less of a factor. Neither this device nor any other SSD device is expected to improve speech understanding for these 2 conditions, and as expected, there were no statistically significant differences in the HINT scores.

The HINT advantage scores for the condition of noise to the poorer ear showed a disadvantage that was statistically significant ($p < 0.001$). In this condition, a disadvantage is expected for every SSD device because of an increase in noise routed to the normal hearing side.

APHAB Questionnaire Results

The average (SD) APHAB benefit scores are shown in Figure 4. The average GB score and the average subscale benefit scores that deal specifically with noisy environments (BN and RV) and EC were statistically significant ($p < 0.05$). The average benefit for the AV score did not reach statistical significance. This AV subscale score often does not reach significance for any hearing device and is not relevant for evaluating SSD devices because the amplification is directed to a normal ear, rather than to an ear with sensorineural hearing loss.

Individually, the APHAB scores improved for all subjects for the GB and BN scores and for all but 1 subject (27/28) for the RV and EC scores. Using the criteria of a change of 22 points or higher on any one of the EC or RV or BN scores (25), an overall significant improvement in the APHAB occurred in 64% of the subjects (18/28). Using the criteria of a change of 5 points or greater on all 3 of the EC and RV and BN scores (25), an overall significant improvement in the APHAB occurred in no subjects.

SSD Questionnaire Results

A total of 79% of subjects reported that they were either ''satisfied'' or ''very satisfied'' with the overall performance of the device, with the remaining subjects reporting that they were at least ''slightly satisfied.'' A total of 64% of subjects reported that they were either ''satisfied'' or ''very satisfied,'' and an additional 14% at least were ''slightly satisfied'' with the experience of wearing the device. The remaining 21% were only ''slightly dissatisfied,'' with none ''dissatisfied'' or ''very dissatisfied.'' This finding in combination with the long daily wearing times suggests that the device was comfortable. A total of 67% of subjects were ''satisfied'' or ''very satisfied'' with the sound quality of the device, with all but 7% reporting that they were at least ''slightly satisfied.'' Consistent with the primary and secondary outcomes, 100% of the subjects reported an improvement in hearing a person speaking on the poorer side, and 93% reported at least ''slightly improved'' ability of hearing in noisy environments. A total of 71% reported an improvement in the ability to localize sounds, 96% reported an improvement in the ability to participate in group conversations, and 89% reported an improvement in their overall quality of life. Compared with their situations before wearing the SoundBite device, 75% of the subjects reported that they either ''prefer'' or ''very much prefer'' having the device. Finally, 96% of the subjects reported that they were ''likely'' or ''very likely'' to recommend the SoundBite device to a friend with the same hearing problem, and the remaining 4% reported ''slightly likely'' to do so.

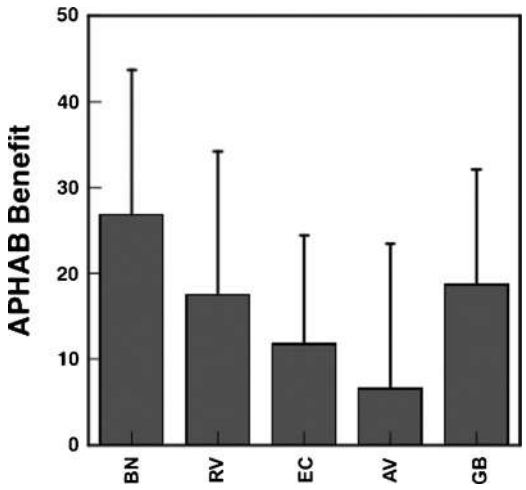

FIG. 4. Mean APHAB benefit scores (+1 SD) when listening in background noise (BN) or reverberation (RV), an assessment of ease of communication (EC) or aversiveness to sound (AV), and an overall global score (GB). A benefit score is the reduction in difficulty while wearing the SoundBite system at the end of a 30-day trial period compared with wearing no device. All benefit scores were statistically significant ($p < 0.05$) except for AV.

Medical Safety Results

Use of the device did not change the existing SSD medical condition and did not cause any other medical conditions or symptoms or audiologic changes. There were no medical or audiologic complications related to wearing the device during the trial period.

Dental Safety Results

No obvious changes were found on periodontal probing, and there were no reports of broken teeth or broken fillings. No dental changes occurred based on before and after dental examinations and by examining before and after full-arch models of the subjects' teeth. No tooth movement could be detected within the 0.01-mm measurement error.

Four subjects were found to have some level of soft tissue changes that were very similar to those typically found with conventional dental appliances such as dentures or retainers. One subject had a minor irritation on a palatal torus that resulted in replacement of the ITM device. All soft tissue changes reverted back to normal upon instruction to discontinue wear of the device for 24 hours and apply warm salt-water rinses.

The contact point for sound transmission was placed between the first and second molars on 26 of 28 subjects, between the second bicuspid and first molar on 1 subject and between the second and third molars on the remaining subject. The device was worn on a variety of tooth conditions including natural teeth, teeth with restorations, crowns, previous root canals, and dental implants. Of the 84 total devices fitted for the 28 subjects on Day 1, 60 were fitted with no adjustments, and 24 (29% of the devices) required minor adjustments across 19 subjects (68% of the subjects). To improve comfort while occluding the teeth, 20 devices needed a minor adjustment that involved adjusting the tension of the clip or minor filing with an acrylic bur in a slow speed dental hand piece. Only 6 subjects required similar minor adjustments between the initial fitting and completion of the trial.

TABLE 3. *Comparison of improved ability to understand speech in noise for the most adverse listening condition and percentage of subjects receiving benefit from a single-sided deafness device for comparable conditions*

Study	Device	HINT improvement mean (SD)	N	APHAB improvement % of subjects	APHAB improvement 95% confidence
Linstrom et al., 2009	Osseointegrated post	−1.3 dB (2.30)	7	Not reported	Not reported
Lin et al., 2006	Osseointegrated post	−2.4 dB (2.95)	14	43%	16.9%–68.8%
Current study	In the mouth	−2.5 dB (0.99)	28	64%	46.5%–82.0%

Comparison of improved ability to understand speech in noise (Hearing in Noise Test score improvement) for the most adverse listening condition (speech to front, noise to the better ear) and percentage of subjects receiving benefit (Abbreviated Profile of Hearing Aid Benefit and 95% confidence interval) from an single-sided deafness device for comparable conditions (acquired single-sided deafness, adults, English language, and 30-day trial period).

The ITM component of the SoundBite system adapted well around third molars (5/28 or 19%) and operated well on natural teeth and teeth with the typical dental interventions. Post hoc analysis showed that there were no statistically significant differences in the average HINT improvement scores (analysis of variance, $p = 0.82$) whether the device was worn on natural teeth (6/28 or 21%), simple restorations (14/28 or 50%), dental crowns (3/28 or 11%), root canals with dental crown (4/28 or 14%), or a dental implant (1/28 or 4%).

DISCUSSION

The SoundBite device is safe with daily use for a 30-day trial period and an average daily use of 8.2 hours, which is typical for such devices. The device did not change the existing SSD medical condition nor cause any other medical, audiologic, or any significant dental changes including any wear on the tooth surface or any dental disease. The only dental findings were the typical transient and insignificant tissue changes seen in some patients with retainers or partial dentures.

Only 2 recent studies (6,27) have reported the same efficacy measures for an osseointegrated post system under conditions equivalent to those used in this study (equivalent subject age, proficiency in the same language, and an equal trial period). Table 3 shows the mean HINT score improvements for the most adverse listening condition for SSD subjects (speech to front, noise to the better ear) from these 2 studies and the current study. The SoundBite system is at least as effective as the osseointegrated post system in improving the ability to understand speech in noise. The SoundBite system improves the ability to understand speech in noise (an average of 25%). For one-third of the subjects, the improvement was well more than 30%.

One of the comparison efficacy studies in Table 3 also reported APHAB benefit scores. The SoundBite system provided benefit to a substantially higher percentage of subjects than the osseointegrated post system as measured with the APHAB.

The adult subjects in this study experienced substantial auditory deficits resulting from SSD. None were currently using any SSD device, and none had ever used the most common SSD treatment, the osseointegrated post systems. The surgery-based systems are rejected by a large percentage of SSD patients, require at least a 3-month period before the device can be fitted, have medical complications, use microphones located in the acoustic shadow of the pinna, and have limited frequency bandwidth. The new SoundBite system addresses these problems and provides equivalent or better performance for ameliorating the spatial hearing deficits of SSD in a safe and effective manner. This new approach is a viable alternative to an osseointegrated post system for SSD patients.

The trial period for this study was 30 days of continual wear with daily wearing times similar to other SSD devices, sufficient to conclude that the new device can be worn comfortably, safely, and effectively on a regular basis. Although no medical, auditory, or dental concerns were raised, longer term safety, efficacy, and benefit studies are warranted.

This study showed that a nonsurgical device provided equivalent or better auditory performance than that published for osseointegrated surgical devices. However, this study did not involve a direct comparison with osseointegrated devices or any other SSD devices on the same subject. Although such studies would be complex because of a wide variety of factors (large aesthetic differences, surgery versus nonsurgery, etc.), direct comparison studies are warranted.

CONCLUSION

The SoundBite system is safe and effective and provides substantial benefit for SSD patients with continual daily use over a 30-day period.

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Preliminary Evaluation of a Novel Bone-Conduction Device for Single-Sided Deafness

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Hypothesis: A new intraoral bone-conduction device has advantages over existing bone-conduction devices for reducing the auditory deficits associated with single-sided deafness (SSD).
Background: Existing bone-conduction devices effectively mitigate auditory deficits from single-sided deafness but have suboptimal microphone locations, limited frequency range, and/or require invasive surgery. A new device has been designed to improve microphone placement (in the ear canal of the deaf ear), provide a wider frequency range, and eliminate surgery by delivering bone-conduction signals to the teeth via a removable oral appliance.
Methods: Forces applied by the oral appliance were compared with forces typically experienced by the teeth from normal functions such as mastication or from other appliances. Tooth surface changes were measured on extracted teeth, and transducer temperature was measured under typical use conditions. Dynamic operating range, including gain, bandwidth, and maximum output limits, were determined from uncomfortable loudness levels and vibrotactile thresholds, and speech recognition scores were measured using normal-hearing subjects. Auditory performance in noise (Hearing in Noise Test) was measured in a limited sample of SSD subjects. Overall comfort, ease of insertion, and removal and visibility of the oral appliance in comparison with traditional hearing aids were measured using a rating scale.
Results: The oral appliance produces forces that are far below those experienced by the teeth from normal functions or conventional dental appliances. The bone-conduction signal level can be adjusted to prevent tactile perception yet provide sufficient gain and output at frequencies from 250 to 12,000 Hz. The device does not damage tooth surfaces nor produce heat, can be inserted and removed easily, and is as comfortable to wear as traditional hearing aids. The new microphone location has advantages for reducing the auditory deficits caused by SSD, including the potential to provide spatial cues introduced by reflections from the pinna, compared with microphone locations for existing devices.
Conclusion: A new approach for SSD has been proposed that optimizes microphone location and delivers sound by bone conduction through a removable oral appliance. Measures in the laboratory using normal-hearing subjects indicate that the device provides useful gain and output for SSD patients, is comfortable, does not seem to have detrimental effects on oral function or oral health, and has several advantages over existing devices. Specifically, microphone placement is optimized for reducing the auditory deficit caused by SSD, frequency bandwidth is much greater, and the system does not require surgical placement. Auditory performance in a small sample of SSD subjects indicated a substantial advantage compared with not wearing the device. Future studies will involve performance measures on SSD patients wearing the device for longer periods. **Key Words:** BAHA—Bone conduction—Dental—Single-sided deafness.
Otol Neurotol **31:**492–497, 2010.

HYPOTHESIS

A new intraoral bone-conduction device has advantages over existing bone-conduction devices for reducing the auditory deficits associated with single-sided deafness (SSD).

BACKGROUND

Patients with SSD, of whom there are approximately 60,000 new cases per year in the United States, have significant functional deficits. One of the most important

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Sonitus Medical, Inc., provided the devices and fees.

is a limited ability to hear sounds originating from the deaf side caused by the head-shadow effect. These deficits are mitigated with devices that transmit sound on the deaf side to the opposite hearing ear. Sound transmission by bone conduction has proven much more effective than transmission by air conduction (1,2) for SSD patients most likely because the hearing ear is not blocked with any device.

One existing bone-conduction device for SSD, the bone-anchored hearing aid (BAHA, Cochlear Nordic AB), vibrates the skull directly via a percutaneous osseointegrated titanium post (3) that provides excellent coupling but requires surgery. Other bone-conduction devices for SSD (Transear, Ear Technology Corporation; Baha Softband, Cochlear Corp.) vibrate the skull transcutaneously (4) with coupling that can cause signal variability (5) and physical discomfort associated with the necessary high coupling force. All existing devices for SSD have electrodynamic transducers that are limited in frequency range, and all but 1 (Transear) use a suboptimal microphone location.

Figure 1 shows a new bone-conduction device (Sonitus Medical, Inc.) for SSD. It uses a miniature microphone in the ear canal of the deaf ear, a location that capitalizes on the acoustic properties of a normal pinna and external ear canal on the deaf side to more directly address the hearing deficit caused by SSD. Although the primary cues for spatial hearing are related to differences in the signals reaching the 2 ears, and therefore require binaural hearing, sound localization and other spatial hearing effects with 1 ear are possible on the basis of cues provided by the reflection of sound from the pinna. The preservation and transmission of such cues require a microphone placed inside or at the entrance to the ear canal, as in the Sonitus device. Microphone placement within the ear canal has the advantages of reducing wind noise and preserving the usual ear canal effect that enhances the level of sounds at frequencies ~3 kHz. The microphone is connected to a behind-the-ear (BTE) module that wirelessly transmits the signal to a custom, removable oral appliance. The oral appliance contains a transducer held against the buccal surfaces of the maxillary molars, allowing the sound to reach the opposite normal-hearing cochlea by bone conduction. The oral appliance requires no modification of the teeth and allows virtually direct coupling of the transducer to the skull, similar to that of an implanted post, but does not require surgical placement and avoids the physical discomfort associated with the substantial coupling forces of transcutaneous devices. The electronics module in the oral appliance is flat and very thin, has small physical dimensions appropriate to the restricted space in the oral cavity, and uses a piezoelectric, rather than an electrodynamic bone-conduction transducer that has potential for a much wider frequency range.

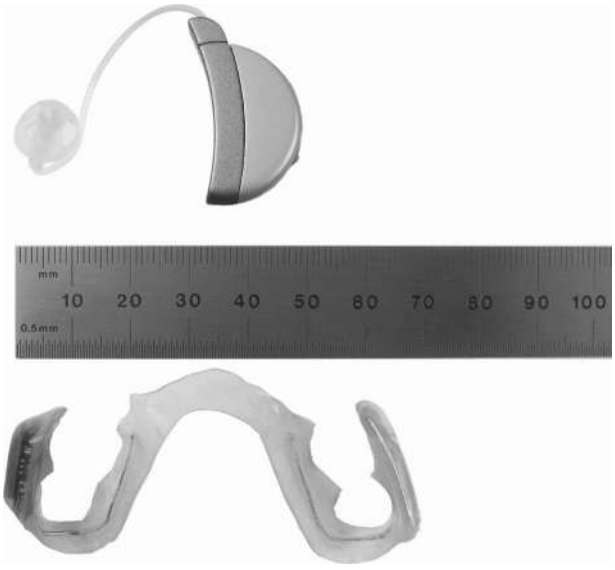

FIG. 1. The prototype device consisting of an external behind-the-ear module (top) with a microphone for the ear canal and an oral appliance (*bottom*) with a sealed thin, flat, piezoelectric vibratory transducer (*left side*) and a small battery (*right side*). The 2 components communicate wirelessly.

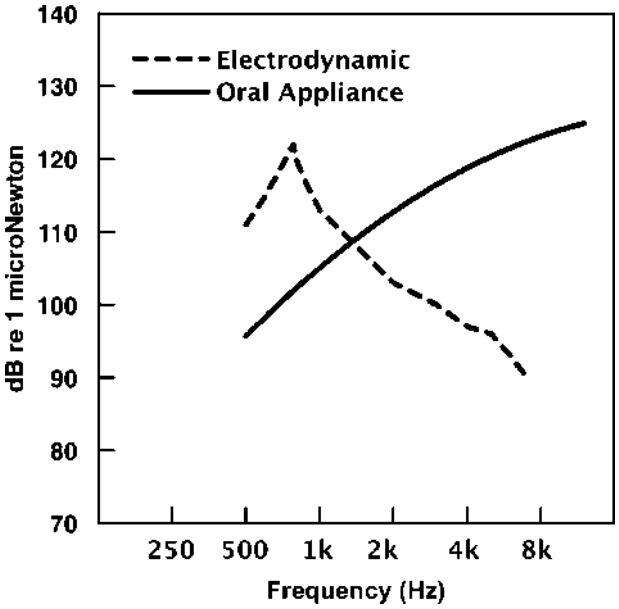

FIG. 2. Output of a typical electrodynamic transducer (*dashed line*) and the oral transducer (*solid line*) in decibels with reference to 1 μN as a function of frequency for a constant level input.

A multidisciplinary scientific advisory panel with expertise in dentistry, otolaryngology, audiology, psychoacoustics, bioengineering, and other disciplines was assembled to evaluate the feasibility of this new approach. The purpose of this article is to report this panel's evaluation based on laboratory measures and auditory performance using normal-hearing subjects and a limited number of subjects with SSD.

To effectively reduce the auditory deficits of the SSD patient, the new system must minimize the head-shadow effect over a frequency range at least sufficient to process speech. It also must produce sufficient output by bone conduction appropriate for the contralateral normal-hearing

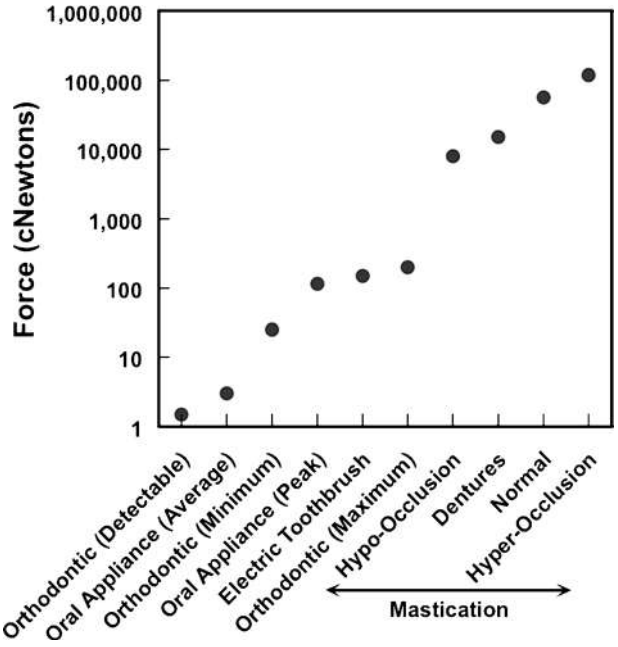

FIG. 3. Comparison of forces, in centinewtons on a logarithmic scale, delivered to the teeth by the new oral appliance, electric toothbrushes, orthodontics, and mastication.

ear. These characteristics can be measured with conventional methods.

Because the device involves a totally new oral appliance, additional factors must be considered. The oral appliance must be physically comfortable yet not affect normal oral function or oral health and elicit no vibrotactile sensation. Because the oral appliance is based on conventional dental appliance technology, much is already known from the long history of dental applications. A conventional dental appliance can affect some oral functions such as saliva production, speech production, and eating, but these effects are well known, very minor, transient, well accepted, dependent on the particular configuration of the dental appliance, and should be similar for the new oral appliance. The new oral appliance does not cover the occlusal surfaces of the teeth and can be removed by the patient so eating concerns may be even less of a consideration.

Oral health effects also have not been seen in the long history of dental appliances, so a properly fitted oral appliance itself is not expected to cause any oral health issues. However, the new oral appliance applies forces that may differ from those typically experienced by the teeth. The forces applied to the teeth are well known for normal functions such as mastication (6–8), devices such as electric toothbrushes (9), and other oral appliances such as those used for orthodontia (10–13), and these should be compared with forces produced by the new oral appliance.

Certain characteristics of the oral appliance can affect oral comfort such as the physical dimensions, whereas other characteristics can affect dental health, such as damage to tooth surfaces. In addition, a piezoelectric transducer may generate heat, particularly at high frequencies (14), which may be perceptible or detrimental to oral health. These particular characteristics are unrelated to the presence or absence of SSD and can be studied in any subject. In addition, because the device is intended for the normal-hearing ear of the SSD patient, some device characteristics, including amplification, frequency response, maximum output, vibrotactile responses, and word recognition, can be measured using normal-hearing subjects. Still, other characteristics are uniquely related to SSD patients and can be measured accurately only after long-term use in SSD patients. The goal of this study is to investigate measureable characteristics in isolation before long-term use.

METHODS

Experiment 1

Oral Health

Changes to the tooth surface were measured directly by applying forces produced by the new oral appliance to extracted human molars mounted in a dental model. The oral appliance was coupled to 4 samples of a tooth, and signals were applied at levels equivalent to normal use with a wearing schedule that represented 1.5 years. Tooth surface changes were assessed by an experienced dentist directly under 10× magnification, and if any wear was observed, under 40× magnification.

To determine the amount of heat the device generates under normal use, the temperature at 4 different locations on the oral appliance near the transducer was measured with a thermocouple before, during, and immediately after continuous operation on a dental model during a 24-hour period.

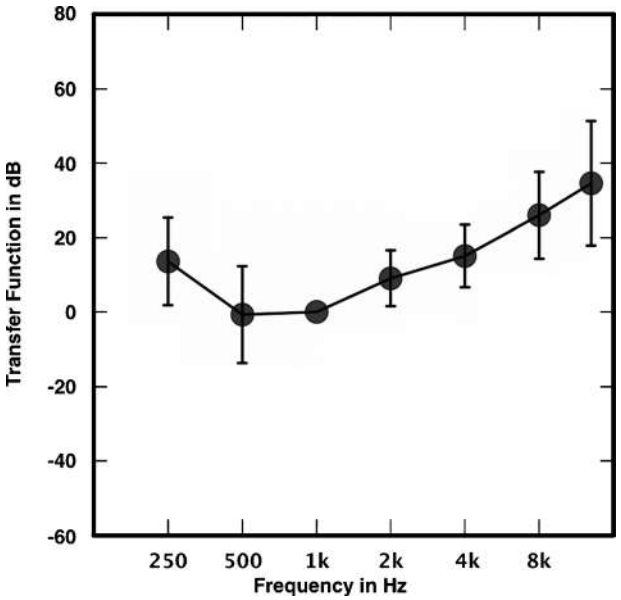

FIG. 4. Average difference (decibels ± 1 standard deviation; n = 12) between calibrated air-conduction signals (dB SPL) and calibrated oral-appliance signals (dB SPL_{equiv}) normalized at 1,000 Hz (68 dB SPL).

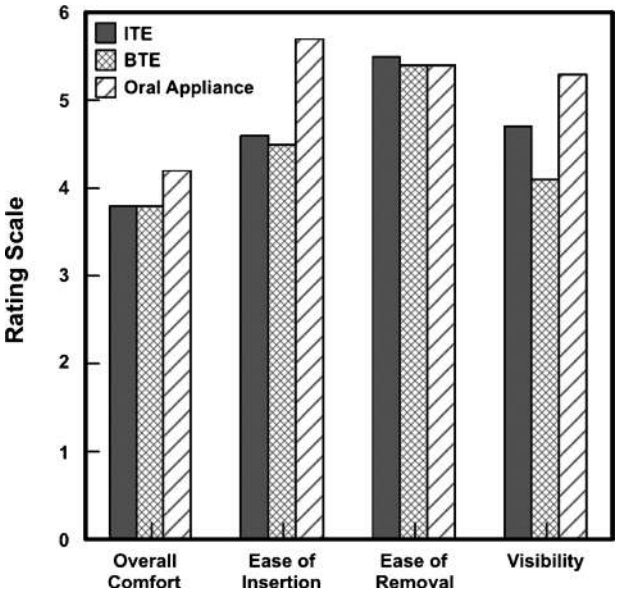

FIG. 5. Mean rating results for 4 dimensions on a 6-point scale from "extremely dissatisfied" (1) to "extremely satisfied" (6) for the oral appliance and 2 conventional hearing devices (n = 12).

Experiment 2

Auditory Performance

The oral appliance should produce amplified signals with effective levels in the range of normal conversational speech (equivalent to ~70 dB SPL), should not produce signals that exceed uncomfortable loudness levels in normal-hearing ears (equivalent to ~100 dB SPL), and should not reach vibrotactile threshold over a wide frequency range. To be able to assess the full dynamic range of the device, all initial measures were made on normal-hearing subjects (n = 12, 3 men, 9 women, with a mean age of 33 yr and a range of 23–44 yr; institutional review board approval no. 07014-02, IRC, Corte Madera, CA, USA). Each had normal hearing (thresholds ≤25 dB HL) (15) at standard frequencies from 250 to 12,000 Hz. An automatic threshold measurement system (AMTAS, Minneapolis, MN, USA) that controlled a calibrated standard diagnostic audiometer (GSI 61, Madison, WI, USA) was used to measure hearing thresholds. This automated system correctly accounted for subjects' response variability without influence of subject state or tester bias. The same system was used for other psychoacoustic measures such as loudness balancing, uncomfortable loudness levels, vibrotactile thresholds, and speech audiometry.

After the initial measures were completed on normal-hearing subjects, additional measures were conducted on SSD patients (n = 5) using the standard Hearing in Noise Test (HINT). This test measures the ability to hear speech in noise under conditions that represent a particular difficulty for SSD patients, listening to speech originating from the front with noise originating from the normal-hearing side. Although the SSD subjects were not specifically selected for factors such as duration of deafness, experience with other devices, age, etc., they met the typical criteria for SSD. Hearing sensitivity (4 frequency pure-tone average) in the better ear was better than 25 dB HL for 4 of the subjects and better than 40 dB HL for the fifth subject. Hearing sensitivity in the poorer ear was greater than 60 dB HL for 1 subject, greater than 80 dB HL for a second subject, and not measurable for the remaining subjects. None had any conductive component.

Signal levels from transcutaneous bone-conduction devices intended for placement on the mastoid process are typically measured with a standard accelerometer in force units (dB re 1 microNewton) (15). Signal levels from the oral appliance cannot be measured with this apparatus because the oral appliance cannot be coupled to the measurement apparatus and the tooth-to-bone-conduction pathway differs substantially from the transcutaneous bone-conduction pathway. It already is known that a vibratory force at a fixed level leads to substantially greater hearing sensitivity when applied to the teeth than when applied transcutaneously to the skull (16).

Despite these known differences, an attempt was made to measure the output of the device in force units using a custom coupler that had characteristics at least similar to those of normal teeth. The oral transducer was coupled to 2 real teeth cemented into a full dental model. Attached to this model was a measurement transducer calibrated in force units and output processed to smooth the small fluctuations that could not be differentiated between resonances in the transducer and resonances in the dental model. Figure 2 shows the output of the transducer in microNewtons as a function of frequency for a constant level input. The result for a typical electrodynamic transducer is shown for comparison. The frequency response of the oral transducer in the high frequencies showed substantially more output than an electrodynamic transducer, with useable output for frequencies as high as 12,000 Hz.

As an alternative to coupler measures, an uncalibrated bone-conduction signal can be matched in loudness to a calibrated air-conduction signal, resulting in elimination of the transmission pathway differences between the two and allowing the unknown level of the bone-conduction signal to be specified in terms of equivalent acoustic levels (17). The oral device was calibrated for each subject by alternating a signal (200 ms on, 200 ms off) between the device and a calibrated air-conduction signal (in decibels sound pressure level), and asking the subject to adjust the level of the air-conducted signal until the loudness of the bone-conduction signal matched the loudness of the air-conduction signal. The air-conducted signal was delivered via an earphone (Sennheiser HDA200), and its level was varied in 5-dB steps. Unlike for the SSD case, the air-conduction signals were presented binaurally for these normal-hearing subjects to more closely match the binaural stimulation provided by bone conduction. A correction for the occlusion effect caused by the earphone was considered, but because this effect is small for circumaural earphones and occurs primarily at low frequencies, it was not implemented. This procedure was very easy for the subjects, took only a few minutes, and allowed the bone-conduction signal levels from the oral appliance to be calibrated in equivalent acoustic units (dB SPL_{equiv}), rather than force units.

Once calibration was performed for each subject, the oral appliance was equalized to produce a flat frequency response, and word recognition scores were obtained with recordings (CID-W-22, 50 items) sent directly to the oral appliance. These were then compared with word recognition scores obtained with conventional air-conduction testing via the audiometer.

Experiment 3

Physical Comfort and Related Factors

Reactions to overall comfort and related factors such as ease of insertion, ease of removal, and visibility of the oral appliance

were compared with those for other hearing devices. A custom-fit prototype oral appliance was created individually (n = 12, 6 men, 6 women, with a mean age of 28 yr and a range of 18–59 yr) along with a conventional BTE hearing aid with an open ear mold and a custom in-the-ear hearing aid. Each device was worn continuously in random order over a 2-day period. None of the subjects was hearing impaired or had any experience with hearing devices, and none of the prototype devices provided any auditory function, so that the reaction to these particular factors could be isolated from the influence of unrelated factors. Each subject rated each device on 4 dimensions (overall comfort, ease of insertion, ease of removal, visibility) using a 6-point scale from ''extremely dissatisfied'' to ''extremely satisfied.''

RESULTS

Oral Health

Figure 3 shows the existing forces experienced by the teeth under a variety of conditions along with typical vibratory forces delivered by the oral appliance. The typical applied force of the oral appliance is similar to the minimum perceptible tactile force threshold and at least 4 orders of magnitude below the force of normal mastication. The force during peak sound delivery slightly exceeds the minimal orthodontic forces, although orthodontic forces are always constant in 1 direction and intended to move the teeth, whereas sound signal forces are cyclic, reach peak values only occasionally, and simultaneously ''squeeze'' the tooth from opposite sides. Because the oral appliance typically will produce only very small cyclic forces and the device acts as a retainer for the teeth, tooth movement is not likely to occur.

The forces applied by the oral appliance are several orders of magnitude lower than those from an electric toothbrush. In addition, electric toothbrushes are used with abrasive toothpaste particles and apply vibratory forces in both normal and shear directions. The oral appliance material is significantly softer than tooth enamel, is used without any abrasive particles, and applies forces only normal to the tooth surface.

Direct inspection of the extracted human teeth in vitro showed no evidence of wear to the tooth surface that was in contact with the transducer. Tooth surface changes were not observed under either 10× or 40× magnification after 1.5 years of simulated use.

The temperature at each of the 4 locations on the transducer was near the ambient room temperature before activation. The temperatures for all 4 locations never exceeded these initial levels either during or at the end of a 24-hour period of continuous operation.

Auditory Performance

Figure 4 shows the average decibel difference (and standard deviations) between the calibrated level of the air-conduction signal and the calibrated level of the signal sent to the oral appliance, for frequencies from 250 to 12,000 Hz, normalized at 1,000 Hz at 68 dB SPL. The output of the oral appliance was very smooth, with no obvious resonances in the frequency response and low variability across subjects. More importantly, the output of the device increased substantially with frequency, rather than decreasing with frequency as is the case with electrodynamic transducers, resulting in a very wide frequency bandwidth. This average calibration curve can be used to set the electronics of the device for all users. However, because the loudness matching is an easy task that produces reliable measures, calibration data can be obtained easily and rapidly on an individual basis to account for individual differences in the bone-conduction transmission pathway and to produce a measure analogous to the real-ear measures commonly used for acoustic hearing aids. Individual calibration also obviates the need for development of a new calibration coupler.

Signal levels were increased to a maximum defined as the maximum output of the device or the level at which an uncomfortable loudness level was reached, whichever was lower. As signals were increased to this maximum, the subjects were asked to report if they perceived an uncomfortable vibrotactile sensation on their teeth. For frequencies up to 500 Hz, only 2 subjects reported an uncomfortable vibrotactile sensation (at 62 and 82 dB SPL_{equiv} for 250 Hz and at 64 and 79 dB SPL_{equiv} for 500 Hz). For 1,000 Hz, only 1 subject reported an uncomfortable tactile sensation (at 98 dB SPL_{equiv}). For frequencies from 2,000 to 12,000 Hz, no subjects reported an uncomfortable vibrotactile sensation up to uncomfortable loudness levels or the maximum signal levels. These data suggest that the device should produce useable auditory signals for SSD patients over a very wide frequency range and a wide level range. It should be noted that, in practice, the device would not be required to have a substantial output for frequencies 500 Hz and less because the head-shadow effect is very small for such frequencies, so low-frequency sounds presented on the deaf side would reach the ''good'' ear via the normal air-conduction path.

Speech Intelligibility

As shown in Figures 2 and 4, the frequency bandwidth of the device certainly should be adequate for reproducing speech, and this was confirmed by conventional word recognition testing. The word recognition scores were normal (better than 92%) and not statistically different (*t* test; $p = 0.05$) from those obtained with a standard audiometer by air conduction.

As another measure of auditory performance, the standard HINT was performed on 5 SSD patients. Relative to performance without the device, the average change in signal-to-noise ratio for 50% sentence recognition for the most difficult condition for SSD patients (speech from the front, noise from the side with normal hearing) was 3.72 dB (range, 1.9–6.0 dB). This decibel advantage represents a clinically significant improvement in auditory performance for devices designed to reduce the auditory deficits of SSD. Using the common relation between percent correct and signal-to-noise ratio (~10%/dB), this result is equivalent to an improvement of speech

intelligibility in noise of approximately 37% compared to without the device. Of course, these preliminary results must be further validated with carefully controlled clinical trials that will be the topic of future research.

Physical Comfort and Related Factors

Figure 5 shows the average rating results for overall comfort, ease of insertion, ease of removal, and visibility for the oral appliance and for other hearing devices. The prototype oral appliance was rated equal to or better than the BTE or in-the-ear hearing aid devices on all 4 dimensions, including overall comfort. It also was rated easiest to insert and the most acceptable regarding visibility.

Implications for SSD Patients

Placement of the microphone in the ear canal of the deaf ear of an SSD patient is expected to capitalize on the natural acoustic characteristics of the typically normal external ear canal and pinna. This microphone location should result in a passive gain of approximately 12 dB at 2,500 Hz (18) and preserving the natural spatial cues provided by reflections of sound from the pinna (19). These natural acoustic cues are more likely to contribute to certain spatial hearing abilities, including the restoration of omnidirectional hearing and the understanding of speech in noise, compared with devices that do not use them. Because it is very difficult to accurately simulate SSD by blocking 1 ear in normal-hearing subjects, and because significant wearing time is necessary to develop changes in hearing abilities, measurement of any performance changes provided by the device can be made accurately only in SSD patients who have worn the device for a period of time. Detailed auditory measures on SSD patients will be the topic of future research. Future studies also will involve more advanced measures concerning dental surface wear and other possible oral health issues such as root resorption, use with dentures or dental implants, dental conditions other than normal healthy teeth, and the effects on signal output, if any, of normal oral functions such as mastication and speech production.

CONCLUSION

A new bone-conduction device for SSD has been proposed that optimizes microphone location and delivers sound by bone conduction through a removable oral appliance. Measures in the laboratory using normal-hearing subjects indicate that the device is as comfortable as traditional hearing devices, should not have detrimental effects on oral function or oral health, and has several advantages over existing devices. Specifically, microphone placement is optimized for the specific auditory deficits caused by SSD, frequency range is much wider, and the bone-conduction transducer does not require surgery.

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SoundBite Hearing System by Sonitus Medical: A New Approach to Single-Sided Deafness

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ABSTRACT

A new approach (SoundBite Hearing System) for single-sided deafness (SSD) has been developed (Sonitus Medical, San Mateo, CA). It consists of one component that resembles a conventional behind-the-ear (BTE) hearing aid that wirelessly connects to a second component worn in-the-mouth (ITM) that resembles a conventional dental appliance. The BTE component positions a microphone in the ear canal on the poorer-hearing side to capture the spatial hearing acoustic qualities of a normal ear canal and pinna. The ITM component delivers bone conduction signals via the surfaces of the teeth with an embedded transducer that delivers signals to 12,000 Hz, a much broader frequency bandwidth than existing SSD devices. The signal is transferred to the better-hearing ear via direct bone conduction, but without the need for surgery. An ITM hearing device is safe, comfortable, generally invisible, and easy to insert and remove. The two components use full digital processing with all the advanced functions of contemporary digital hearing aids. Measures of the Hearing in Noise Test on SSD patients ($n = 18$) indicated a substantial and immediate 2 dB advantage compared to the unaided condition. These results warrant a full multisite clinical trial that is underway and will be completed in 2010.

KEYWORDS: Single-sided deafness, bone conduction, teeth, high frequency

Learning Outcomes: As a result of this activity, the participant will be able to (1) list five conceptual differences among single-sided deafness (SSD) devices, and (2) describe three differences that distinguish the Sonitus SoundBite Hearing System from other direct bone conduction SSD devices.

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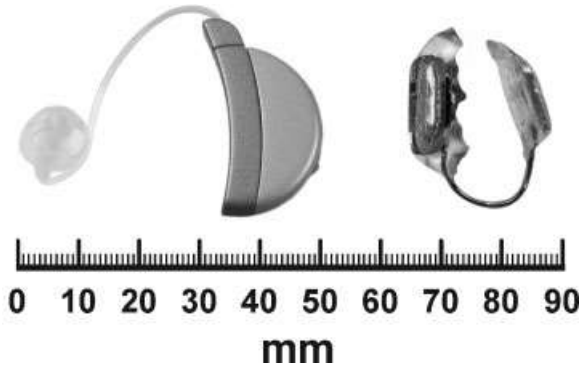

Figure 1 The SoundBite Hearing System by Sonitus Medical for single-sided deafness. The system consists of a behind-the-ear (BTE) microphone component similar to a BTE hearing aid (left) and a removable in-the-mouth component similar to a dental appliance (right).

Sonitus Medical (San Mateo, CA) (http://www.sonitusmedical.com) has developed a new approach to single-sided deafness (SSD) that addresses the limitations of existing SSD devices. The system, called SoundBite Hearing System, consists of the two components illustrated in Fig. 1. The first component is a behind-the-ear (BTE) microphone unit optimized specifically to improve spatial hearing ability. The second component is a removable in-the-mouth (ITM) hearing device that does not require surgery yet delivers a bone conduction signal directly to the skull with substantial high-frequency output by way of the teeth. This article explains the background and development of this system, provides measures of its performance on patients with SSD, and discusses its characteristics from an audiological perspective.

BACKGROUND

A normal-hearing person possesses extraordinary abilities to detect, process, and interpret sounds that occur in our natural, three-dimensional, spatial acoustic environment. These abilities are generally referred to as *spatial hearing ability* and provide a sense of omnidirectional hearing, allowing normal-hearing persons to identify and locate the sources and directions of sounds accurately, to discriminate sounds in noisy environments, and to interpret our acoustic environment accurately, which in turn helps with sound source identification.

Spatial hearing ability depends on a variety of factors including the detection and interpretation of monaural and binaural sound cues resulting from the interaction of sounds entering our two ears, which is affected by the size of the head and the morphology of the pinnae. Identification of sound sources originating in the horizontal plane is based primarily on differences in the sounds reaching the two ears with time differences prominent at low frequencies and intensity-level differences prominent at higher frequencies. In certain frequency regions, the correct interpretation of these two cues is compromised but often can be resolved by perceiving alterations of the sound due to the shape and configuration of the pinnae that in turn can facilitate the ability to distinguish between sounds originating from the front or behind, the ability to locate the source of sounds originating in the vertical plane, and, under certain conditions, the ability to localize sound sources using one ear alone.[1]

SSD causes substantial spatial hearing deficits. The most prominent spatial hearing deficits include loss of omnidirectional hearing, a reduction in the ability to hear sounds originating on the poorer side, a reduction in the ability to localize sound sources, and a reduction in the ability to hear in noisy situations, especially when the noise source is on the normal-hearing side. As a result, SSD patients have a significant auditory handicap.[2,3] There are ~200 new cases of SSD per million indi-

viduals (http://www.singlesideddeafness.com/) or ~60,000 new cases per year in the United States and far more in the rest of the world.

By definition, the term *single-sided deafness* refers to unilateral hearing loss with normal hearing on one side and deafness on the other side; the definition applies to a significant portion of the population with unilateral hearing loss. However, there is a larger group of patients who may not have completely normal hearing in the better-hearing ear and may not be deaf in the poorer-hearing ear. Therefore, a more comprehensive definition would include patients with asymmetrical hearing loss with (1) hearing on the better-hearing side that is either normal or with a mild degree of hearing loss that does not benefit from a hearing aid in that ear and (2) hearing loss on the poorer-hearing side that is either profound or severe enough that this poorer ear does not contribute significantly to overall hearing ability. Patients with true SSD, or the more comprehensively defined *asymmetrical hearing loss*, all have the same auditory deficits. In this article, the term *single-sided deafness* will apply to both types of hearing loss.

Once it has been determined that SSD is a permanent condition that does not require further medical intervention, the fundamental approach is to reduce auditory deficits by providing devices that transmit sound from the poorer-hearing side to the contralateral better-hearing ear. Several approaches have been developed to accomplish this overarching goal.

The original approach used two devices: one with a microphone to pick up the acoustic signal on the poorer-hearing side and one on the contralateral side to deliver the signal acoustically to the better-hearing ear. The transfer process was either by a wire or wirelessly. These and all subsequent devices that deliver the signal acoustically to the better-hearing ear are categorized as *contralateral routing of signals* (CROS) devices and are discussed in great detail in the article by Taylor in this issue. The distinguishing factor for a CROS system is that the sound is delivered acoustically to the better-hearing ear. Though there has been some acceptance of this approach, CROS devices are routinely rejected by SSD patients.[4] Currently, very few manufacturers (Phonak AG, Stäfa, Switzerland; Unitron, Kitchener, Canada; and Interton AS, Ballerup, Denmark) produce wireless CROS devices, and CROS devices represent only a small portion of the total devices adopted by SSD patients. The reasons SSD patients reject CROS devices are varied and largely speculative, but a common conclusion is that SSD patients prefer to have no device of any kind that blocks the normal acoustic pathway to the only hearing ear.[5,6]

Later approaches used a device that also had a microphone located on the poorer-hearing side, but transferred the signal by bone conduction to the contralateral better-hearing ear. Because there is little or no interaural attenuation by bone conduction, the bone conduction transducer can be located anywhere on the skull providing a signal to the better-hearing ear. The primary auditory advantage of transferring the signal by bone conduction is that the better-hearing ear does not have any device at all, keeping the normal acoustic pathway open.

A bone conduction transducer can be coupled to the skull in several ways. It can be placed on the soft tissue overlying the mastoid process and held in place either with a metal headband or a soft, cloth-based headband or placed against the soft tissue overlying the bony portion of the ear canal (TransEar, Ear Technology Corp, Johnson City, TN), where it is held in place by a tight-fitting custom ear mold. All of these transcutaneous methods require substantial coupling force to minimize the energy loss from the underlying soft tissue and, therefore, can be physically uncomfortable, especially for long-term use. Alternatively, a titanium screw and abutment can be surgically implanted through the soft tissue directly into the skull where, over a period of a few months, a tight bond is established with the bone through a process called *osseointegration*. A device that contains a microphone or microphones, a battery, analog or digital electronics, and a vibratory transducer can be coupled directly to the abutment forming a bone-anchored SSD system (Cochlear BP-100, Cochlear Corp, Lane Cove, Australia; Oticon Medical Ponto/Ponto Pro, Oticon Medical AB, Askim, Sweden). This approach

is discussed in great detail by Flynn et al in this issue and eliminates the energy losses from the soft tissue,[7] eliminates the discomfort resulting from the substantial coupling force on soft tissue necessary for transcutaneous devices, and minimizes the number of separate external components. Though the directly coupled osseointegrated abutment is comfortable for long-term use, it does require surgery as well as ongoing maintenance of the skin-to-abutment interface to prevent infections.

The surgically implanted osseointegrated abutment system is very effective at mitigating the spatial hearing deficits caused by SSD.[8] It is safe[9,10] and well tolerated.[9,11] Currently, the surgically implanted osseointegrated abutment approach is the largest category of devices adopted by SSD patients. However, the surgically implanted osseointegrated abutment system has some nonauditory limitations. It is a rather permanent solution that requires invasive surgery and it is routinely rejected by large percentages of SSD patients[12] for a variety of reasons that include resistance to surgery or cosmetic and aesthetic concerns.

The surgically implanted osseointegrated abutment system also has some auditory limitations. The major purpose of any device for all SSD patients is to reduce spatial hearing deficits. Even though these spatial hearing deficits are demonstrably improved with a surgically implanted osseointegrated abutment system,[5] the resulting spatial hearing improvements may not be optimal.[13] First, the microphone location is less than optimal for improving spatial hearing because it is positioned in a device located on the abutment itself and thus limited by where the screw and abutment are implanted. The abutment is usually placed behind the pinna for aesthetic and surgical reasons, a location optimal for abutment placement but suboptimal for spatial hearing improvement because the pinna may interfere with sound arriving from the front reaching the microphone.

Second, the ease with which sound can be controlled with certain existing surgically implanted osseointegrated abutment systems may not be optimal. This includes the ease of turning the sound off and on by removing and applying the device, the ease of operating the controls to implement other program or volume settings, and the lack of automated adaptive features. Because adverse acoustic environments either may not be present all the time or may interfere with auditory function, easy user control of the sound from an SSD device is an important consideration. For example, an SSD patient may wish to use no device in a quiet environment or may wish to adjust the device if the noise source is on the poorer-hearing side and is unnecessarily sending high levels of noise to the better-hearing side. In these listening situations, the patient should be able to easily turn off, adjust the device, or implement features that are designed to accommodate these adverse listening conditions. The majority of surgically implanted osseointegrated abutment systems may not be easy to turn on and off. The manual control buttons on the device itself may not be easy to manipulate for some patients. Few of the existing devices have automatic and adaptive features such as automatic switching of multiple memories or multiple microphones, adaptive acoustic feedback reduction circuits, remote controls, and other very useful features found in contemporary digital hearing aids to accommodate changing acoustic environments. Only very recently has digital processing been included in devices to allow these features (Cochlear Corporation BP-100, Oticon Ponto/Ponto Pro). Regardless of whether these advanced features are available, when the device is removed, the surgically implanted screw and abutment remain.

Third, the existing surgically implanted osseointegrated abutment systems have a limited bandwidth. On a practical basis, no significant output above 2000 Hz is available with these systems.[14] From contemporary research findings, it is known that frequency regions higher than 2000 Hz can contribute greatly to enhancing spatial hearing ability. First, it is known that speech contains more high-frequency information above 4000 Hz than previously thought.[15] Second, speech localization ability is influenced positively by high-frequency perception.[16] Third, speech recognition ability in noise is influenced positively by high-frequency perception.[17] Complementing these findings are improvements in the ability to

quantify auditory function for frequencies up to 16,000 Hz with new bone conduction measures.[18] New SSD devices that provide higher-frequency signals than current devices may markedly enhance spatial hearing abilities, which is the primary purpose of a device for an SSD patient.

In summary, the functional requirements for mitigating auditory deficits in SSD patients include a system with a microphone on the poorer-hearing side, signal transfer to the contralateral better-hearing side by bone conduction, wide bandwidth, and easy control of the sound to accommodate challenging listening environments. This approach affords the better-hearing ear normal access to the acoustic environment and provides as much spatial hearing ability as possible, including the restoration of the sense of omnidirectional hearing, improvement of speech recognition in noise, and potential improvement in sound localization ability. Current surgically implanted osseointegrated abutment systems address these functional considerations. However, even with the recent addition of digital processing, these devices still have significant limitations due to the requirement of surgery and less than optimal spatial hearing function because of less than optimal microphone location and limited signal bandwidth.

The SoundBite Hearing System by Sonitus Medical addresses some of the limitations of existing SSD devices. First, the microphone is positioned in the ear canal of the poorer-hearing ear to capture the spatial hearing acoustical properties of a normal pinna and ear canal. Second, the signal is transferred to the better-hearing ear by the proven method of direct bone conduction, but with an entirely new transducer directly coupled to the skull by way of the teeth, a method that eliminates soft tissue in the path without surgery, yet does not require surgery. Third, the new transducer adds greater higher-frequency capability than existing systems (up to 12,000 Hz). Finally, the SoundBite Hearing System provides all the modern features associated with contemporary digital hearing aids to maximize control of the device both by the patient and by automated capabilities in the device itself.

The Sonitus SoundBite Hearing System consists of two components: a BTE microphone component and an ITM component that delivers bone conduction signals.

BTE Microphone Component

Normal spatial hearing ability relies on a variety of functions including binaural hearing and the acoustic characteristics of the normal pinna. Though true binaural hearing cannot be restored in SSD patients, the spatial hearing acoustic characteristics of a normal pinna and ear canal can be captured by locating the microphone in the ear canal of the poorer-hearing ear. Fig. 2 illustrates the BTE microphone component. It is similar in size and configuration to a contemporary open-fit, BTE hearing aid. It is placed on the poorer-hearing ear and has the cosmetic, aesthetic, and conven-

Figure 2 The SoundBite Hearing System behind-the-ear (BTE) microphone unit. This component is similar to a conventional BTE hearing aid, but positions the microphone in the external ear canal rather than in the body of the unit. The microphone is held in place with a ''dome'' similar to that which holds the receiver in place in an open-fit ''receiver in the canal'' hearing aid.

ience characteristics of a contemporary open-fit hearing aid. Unlike a conventional BTE hearing aid, or the existing surgically implanted osseointegrated abutment systems, the microphone is placed in the ear canal of the poorer-hearing ear, a location that optimizes the natural, spatial hearing acoustical characteristics of a normal pinna and ear canal. It is held in place with an open grommet similar to the "domes" used in conventional open-fit hearing aids. The BTE component also can contain a second microphone in the unit itself to further enhance spatial hearing functions and improve the signal-to-noise ratio (SNR). The BTE component also includes a rechargeable battery that currently provides 12 to 15 hours of use per charge and wireless communication ability that transmits control signals and audio signals to the ITM component and to other components such as cell phones and remote controls. Separation of the microphone component from the remaining components allows optimal placement of the microphone without requiring that the other components be fixed in the same location as is the case in osseointegrated abutment systems.

ITM Component

The ITM component contains a new transducer that applies a bone conduction signal to the surface of the teeth—a novel approach for an SSD device. Application of a bone conduction transducer against the tooth surface is a well-known concept that provides an excellent bone-conducted signal. This approach maintains the bone conduction transfer process by coupling the transducer directly to the skull with no soft tissue in the path, similar to the surgically implanted osseointegrated abutment systems. However, no surgery is required because the transducer is positioned completely inside a removable ITM component.

The ITM component is based on conventional dental appliance technology. Because of this, many oral issues concerning the ITM component, including effects of materials, fitting, and adjustment methods, and other nonauditory factors are very well known with a long history of safe use. The ITM component contains embedded subcomponents that include a new type of bone conduction transducer, a rechargeable battery, digital electronics, and wireless capability for communicating with the BTE microphone component. All of these subcomponents are completely sealed within conventional dental appliance material (acrylic) known to be safe and appropriate for long-term use in the mouth. No surgery is required because the transducer is positioned completely inside the removable ITM component. The component is held against the surface of one or two maxillary molars and no modifications to the teeth are necessary. The performance effects of common dental conditions other than normal teeth (crowns, dental implants, etc.) have yet to be investigated so final dental candidacy requirements have yet to be determined. Static coupling force, a known factor that affects bone conduction sensitivity,[19,20] easily can be controlled during fitting of the ITM component by adjusting the spring mechanism that holds the device against the tooth surface. The nonauditory characteristics of conventional dental appliances are also known, with a long history of successful use, and are applicable to the ITM component. The ITM component easily can be inserted and removed by the patient.[21]

The use of a bone conduction transducer embedded in an ITM hearing device solves several problems inherent with surgically implanted osseointegrated abutment devices. First, the need for surgery is eliminated. Second, it is a completely reversible process because when the device is removed, it is completely removed and no components remain. Third, because the system can be removed and inserted easily by the patient and because it contains full digital signal processing, more control is given to the patient concerning when to use it (the signal can be shut off by removal of either component or with a remote control) and when to implement advanced automated adaptive processing. However, this innovative approach is completely new and intended for long-term use; therefore, several other factors concerning an ITM hearing device must be considered including any effects on normal oral function, oral health, and physical comfort.

A conventional dental appliance can affect some oral functions, such as saliva production, speech production, and eating. These effects are minor, transient, and well accepted, depending

on the particular configuration of the dental appliance, and should be similar for the new ITM hearing device. The ITM component does not cover the occlusal surfaces of the teeth and can be easily removed by the patient, so eating concerns may be less of a consideration than for a conventional dental appliance.

Negative oral health effects have not been reported in the long history of dental appliances, so a properly fitted ITM component itself is not expected to cause any oral health issues. Because the new ITM component applies forces that differ from those typically experienced by the teeth, several laboratory experiments were conducted. The forces applied by the ITM component for signals strong enough to elicit an auditory sensation were found to be much lower than forces typically experienced by the teeth from normal oral functions such as mastication or from other devices such as electric tooth brushes.[21] Under typical use conditions on extracted teeth, no tooth surface changes were detected for an equivalent wearing period of 6 months.[21] The SoundBite ITM hearing device, therefore, should be safe for the tooth surface.

Exposure to the electronic components embedded in the ITM component may also be a safety consideration. Because these electrical components are completely sealed within the device, the only safety concern is if the hermetic seal of the ITM component is breached. The material used for the ITM component is very strong, has a long history of not cracking in dental applications, and is expected to maintain a hermetic seal in this auditory application for the life of the ITM component. Because the ITM component does not cover the occlusal surfaces of the teeth, the massive forces exerted by chewing or mastication are not transferred to the ITM component. Also, safety systems have been engineered into the internal components to detect any breach of the ITM component case and send an alarm to alert the patient to remove the device. Complete biocompatibility testing has been performed including cytotoxicity, sensitization tests, and local dermal irritant effects of leachable materials from the components. The results were within acceptable guidelines of stringent biocompatibility standards and ensure a safe ITM component for this application.

The development of an ITM hearing device for this application required several practical and auditory considerations, resulting in several designs. The physical size of the ITM hearing device was an engineering challenge and an important consideration. Though a conventional dental appliance is small enough to be physically comfortable, the ITM hearing device has to accommodate all the internal components without becoming too large to cause physical discomfort, especially with long-term use.

Fig. 3 illustrates the design of the first prototype ITM component. This prototype had four possible locations to embed the internal components, the lingual and buccal side of the ITM component, on each side of the mouth. For the first prototype, the electronics

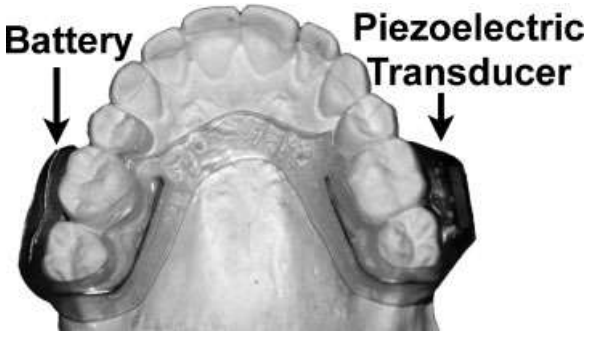

Figure 3 The Sonitus prototype in-the-mouth hearing device positioned on a model of the upper-teeth cast from a dental impression. The component on the left (patient's right side) contains the battery and the component the right (patient's left side) contains the piezoelectric bone conduction transducer and the electronics.

and the transducer were embedded on the buccal side of the ITM component on one side of the mouth and a battery was embedded on the buccal side of the ITM component on the opposite side of the mouth. Spring clips that wrapped around the last molar to the lingual side were used to hold the device against the teeth and control static coupling force of the transducer. The components on either side of the mouth were connected to each other electronically with wires embedded in the arch.

All existing bone conduction SSD systems use an electrodynamic transducer similar to the bone conduction transducer commonly used on diagnostic audiometers. Besides having limited bandwidth, electrodynamic transducers are inherently bulky in all three dimensions and much too large to embed into an ITM component. A custom-designed flat piezoelectric transducer was developed to solve both the physical size and bandwidth limitations. The new piezoelectric transducer is inherently flat and much better suited to the remaining limited space in the oral cavity. Because a piezoelectric transducer has a higher-frequency output than an electrodynamic bone conduction transducer, the new transducer also solved the bandwidth limitation found in all bone conduction SSD systems. Though a piezoelectric transducer has the potential to generate heat, particularly at high frequencies, preliminary results indicated that for this application, no change in temperature of the transducer could be measured under typical use conditions.[21] The prototype ITM component was used for initial comfort studies and for auditory measurements to provide important proof of concept information and to guide development of subsequent, improved versions.

VERIFICATION

Measurement of the output of this new device requires additional considerations. The output of a conventional air conduction hearing aid (acoustic units in decibel sound pressure level [SPL]) is measured with a coupler called an "artificial ear," or 2 cc cavity, that represents the acoustic characteristics of an average ear. The output of a conventional bone conduction device (force units in decibels re 1 μN) such as the one used for diagnostic audiometry (Radio Ear B-71, Radioear Corp, New Eagle, PA), is measured with an "artificial mastoid" coupler that represents the mechanical vibratory characteristics of the average mastoid process. The vibratory output levels from the SoundBite Hearing System cannot be measured validly with an "artificial ear" coupler because the output is not acoustic. The output cannot be measured with an "artificial mastoid" coupler because the ITM component is not applied to the mastoid process. It is known that the direct tooth-to-cochlea bone conduction pathway differs substantially from the transcutaneous mastoid-to-cochlea pathway. A vibratory force at a fixed level results in substantially better-hearing sensitivity when applied to the teeth than when applied transcutaneously to the skull,[22] an inherent advantage of the SoundBite Hearing System over transcutaneous systems. By analogy, it would be necessary to develop an "artificial tooth" coupler to measure the output of the SoundBite Hearing System.

As an alternative to coupler measures, the output of the SoundBite Hearing System can be determined by a loudness-matching procedure.[23,24] After applying a new SoundBite Hearing System, the patient is instructed to match the loudness of a signal that originates from a conventional audiometer but alternates between a calibrated air conduction audiometer earphone in the better-hearing ear and the uncalibrated SoundBite Hearing System. The audiologist then sets the level of the signal to the earphone to a constant value such as 60 dB hearing level (HL). The level of the signal to the SoundBite Hearing System is varied either with the audiometer sound field system (using frequency modulated tones in this case) or with the programming software of the SoundBite Hearing System until the patient reports that the signals from the two devices match in loudness. The bone conduction output of the SoundBite Hearing System for that signal can then be specified as equivalent to the acoustic level of the tone from the calibrated earphone. The loudness balancing then can be repeated for as many test signals as desired. This method solves three problems. First, it eliminates the need to develop an "artificial tooth" coupler.

Second, the level of the SoundBite Hearing System is specified in equivalent acoustic measurement units (either dB HL_{equiv} or dB SPL_{equiv}) that are directly comparable to the measurement units used for measuring the output of conventional hearing aids (dB HL or dB SPL). Third, the method accounts for individual differences in the bone conduction pathway for each patient on a frequency-by-frequency basis. The loudness matching procedure is easy for patients to understand and accomplish with little training. After this measurement procedure, audiologists need not change their hearing aid fitting and adjustment protocols in any other way. All conventional hearing aid procedures, such as the use of fitting formula, and all aided measures such as thresholds, speech audiometry, speech in noise testing, and so on, can be implemented without modification.

The audiologist can send an audiogram for the better-hearing ear to the manufacturer who sets the initial output characteristics of the SoundBite Hearing System based on this audiogram and average real-ear bone conduction characteristics. A new device with this setting will provide reasonable and expected average output on the first fitting of the device, similar to when a conventional acoustic hearing aid is first fitted with factory settings. The loudness matching procedure can then be accomplished to allow the output of the SoundBite Hearing System to be specified in real-ear, dB SPL_{equiv} units that are familiar to audiologists and comparable to conventional hearing aid measurement units.

Conventional hearing aid fitting procedures that include adjustments of the maximum output also can be implemented with the SoundBite Hearing System, but with one additional consideration. Uncomfortable loudness, an auditory percept, can have a complementary uncomfortable tactile percept with a device on the teeth, felt as a vibratory sensation on the teeth that does not originate from the auditory system. Similar to adjusting a conventional air conduction hearing aid, or even a cochlear implant, the audiologist must make sure that the device does not produce uncomfortable perceptions of any kind, whether loudness or tactile. For frequencies from 1000 Hz and higher, the output of the SoundBite Hearing System can be increased until typically uncomfortable loudness levels are reached without causing any tactile sensation on the teeth.[21] For frequencies above 1000 Hz, the determination of uncomfortable levels is identical to that used for conventional air conduction hearing aids. For frequencies below 1000 Hz, and for only a small percentage of patients, a tactile sensation on the teeth can be perceived at levels lower than those that elicit an uncomfortable loudness percept. For frequencies below 1000 Hz, the instructions to the patient can be modified to include not only "uncomfortable loudness" but also "uncomfortable vibratory sensation on the teeth" and measured the same way. The measured uncomfortable levels can be used to set the maximum output. Alternatively, this step can be completely avoided for SSD patients because the head shadow effect only occurs for frequencies above 1000 Hz. By keeping the output low for frequencies below 1000 Hz, no tactile sensation will occur on the teeth, and the auditory performance of the device will not be affected. Similar to a properly adjusted conventional air conduction hearing aid, a properly adjusted SoundBite Hearing System will result only in a comfortable auditory sensation with no tactile perception of any signals applied to the teeth.

INITIAL RESULTS

Several measures were obtained with the initial prototype device in normal-hearing subjects.[21] The overall oral comfort, ease of insertion and removal, and visibility of the ITM component were equivalent to those for conventional air conduction hearing aids as measured with a rating scale.[21] Gain was sufficient to accommodate normal hearing in the better ear and maximum output could be adjusted as high as 90 dB SPL_{equiv} with no acoustic feedback, indicating that the dynamic operating range of the prototype system met the gain and output requirements of SSD patients.[14] The auditory signals were clear, and conventional word recognition ability was normal (92% or greater).[21] Bandwidth, however, far exceeded that from available bone conduction devices and from conventional air conduction hearing

aids as well. Although gain and maximum output for frequencies greater than 4000 Hz are severely limited for surgically implanted osseointegrated abutment systems that use an electrodynamic transducer, the piezoelectric transducer of the SoundBite Hearing System provided greater output for high frequencies, up to an additional 30 dB of output for frequencies up to 12,000 Hz.[21] This greatly enhanced high-frequency output directly addresses the primary purpose of an SSD device—to enhance spatial hearing ability.

Scientific assessment of changes in spatial hearing ability that an SSD device provides is very challenging. It is difficult to separate and control for nonauditory factors such as cost, reactions to coupling methods that either differ greatly (implanted titanium screw and abutment versus ITM component) or cannot be randomized (surgery versus nonsurgery, etc.), and reactions to different cosmetic and aesthetic features. It is difficult to control for some auditory factors such as duration of SSD, actual acoustic environments (the amount of time spent in noisy versus quiet situations), and so on. Also, experience with any SSD device, on the order of a month or more, allows neural plasticity and other adaptive factors to come into play that result in some measures that may improve over time. Finally, the available measures of spatial hearing are designed to assess only one of the many factors that underlie overall spatial hearing ability such as the ability to localize specific sounds (narrow band noise, frequency-modulated tones, speech, etc.) or the ability to hear speech in noise. Measurement of the ability to hear speech in noise is complicated further because this ability is greatly affected by the various possible different spatial locations of the sources of the speech and of the noise. A simple test to measure spatial ability with and without the device becomes complex because of these considerations. Yet, it is imperative to determine if this new approach enhances spatial hearing ability in actual SSD patients.

The initial approach used a single measure of spatial hearing ability and eliminated the variable effects of adaptation by measuring spatial hearing ability with and without the device before the subject wore it for any length of time. This allowed a determination of whether the new device provided any benefit in the worst-case scenario.

A common spatial hearing deficit in SSD patients is a reduction of the ability to hear speech in noise. There are several conventional audiological tools that measure this ability, and there are differences among them.[25] However, the most widely used test for SSD devices at this time is the Hearing in Noise Test (HINT) test. The HINT test provides an aggregate measure across several acoustic conditions that involve presentation of speech to the front of the patient while noise is presented from various directions including from the front (0-degree azimuth) or to either side ($\pm$90-degree azimuth) of the patient. For the SSD patient, the relevant condition is with speech presented from the front and noise presented from the side with better hearing. Therefore, initial attempts at measuring spatial hearing changes provided by the SoundBite Hearing System were obtained with the HINT under this condition.

The HINT uses an adaptive procedure to determine the SNR that results in 50% correct speech recognition of words in sentences. A change in the measured SNR of 1 dB is equivalent to a 10% improvement in the ability to hear speech in noise, and it is commonly accepted that a 10% increase in the ability to hear speech in noise is clinically relevant.

Auditory performance with the prototype device using the HINT test was measured initially in five SSD subjects.[21] The five subjects were intentionally selected to cover a wide range of factors including duration of SSD, gender, age, experience with other SSD devices, among others. The HINT scores for the most adverse listening condition (speech from the front and noise to the normal-hearing side) resulted in an average advantage of 3.7 dB with the SoundBite Hearing System compared with unaided. This is a substantial HINT advantage, equivalent to an improvement of 37% in speech recognition in this adverse listening condition. Anecdotally, all of these subjects reported that their sense of omnidirectional hearing was restored and that they experienced only an auditory percept and no vibrotactile perception associated with the teeth. There was every indication from the initial prototype measures

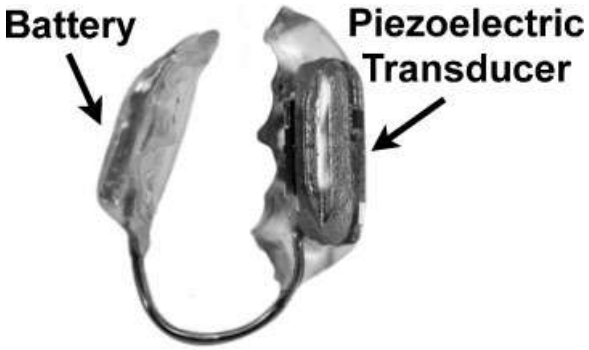

Figure 4 The SoundBite Hearing System Generation 1 version of the in-the-mouth (ITM) hearing device. It is considerably smaller than the prototype ITM hearing device with both components located on one side of the mouth connected by a wire clip.

that this approach would result in a viable system for SSD patients.

Given these positive results, it was surmised that this new approach to SSD would provide improvements in spatial hearing ability without the need for surgery and warranted the development of a new ITM component. Because the new ITM component design went beyond experimental prototypes and was the first version to be a viable clinical device, it is referred to as Generation 1. Fig. 4 illustrates the Generation 1 ITM component with primary design changes including a reduction in overall size and location of the entire ITM component on the same side of the mouth. The transducer and the electronics are located on the buccal side and the battery on the lingual side. The Generation 1 version was easier to insert and remove and had higher auditory output and longer battery life. Because the Generation 1 version can be worn on either side of the mouth, new concepts can be explored. Placement of the ITM component on the better-hearing side potentially allows more energy transfer to the cochlea of interest, especially for high frequencies where interaural attenuation by bone conduction is more than the 0 dB interaural attenuation for lower frequencies. Should local dental conditions prevent use of the device on a particular side, the ITM component can be placed on the opposite side of the mouth.[26] The sealed rechargeable battery provides 6 to 8 hours of use per charge and with recharge times much less than this, the provision of two identical devices ensures that a charged ITM component can be available continuously.

The new Generation 1 version was designed to maximize a variety of other factors. Comfort studies were evaluated sequentially in 11 subjects using four different models of the device under the direction of a dentist familiar with the creation, fitting, and adjustment of the ITM component. Each subject was fitted with a nonfunctioning ITM component that mimicked the shape and fit of each iteration of a Generation 1 device. These normal-hearing subjects were asked to wear the device during waking hours for 5 to 7 days. At the end of the period, ratings on a 6-point scale were obtained for a wide variety of factors including ability to take the device on and off, ability to speak clearly while wearing it, changes in facial appearance, ability to eat while wearing the device, and ability to clean the device. Improvement was demonstrated in successive versions of the device on these key factors. The overall average satisfaction score rose from 3.8 (on the 6-point scale) to 4.6 over the four iterations of the Generation 1 device. On perhaps the most important measure of "I would be willing to wear this device to solve a hearing problem," scores increased from 3.7 for the first design of the initial ITM component to 5.2 for the most recent design. Fig. 5 Illustrates how the current version of the Generation 1 ITM component is inserted and provides a sense of the actual size of the device, how easy it is to insert, how it fits in the mouth, and how invisible it can be.

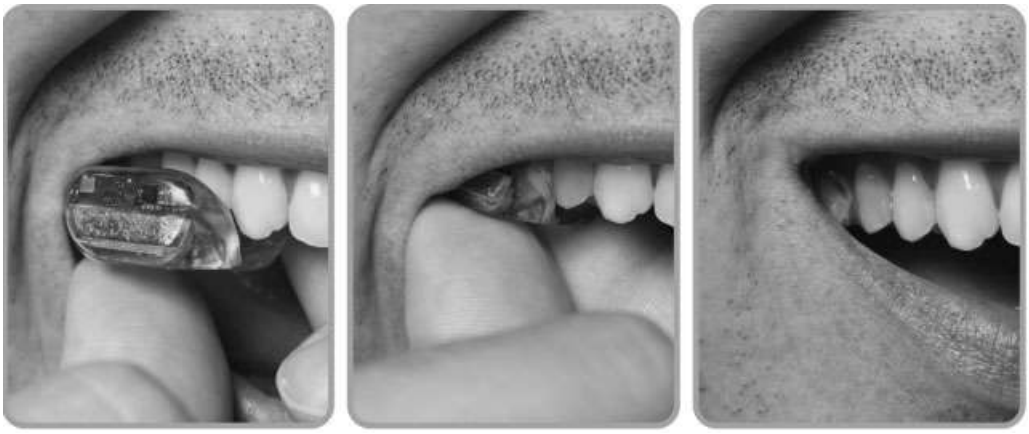

Figure 5 A series of images that demonstrates how the SoundBite Hearing System Generation 1 version of the in-the-mouth hearing device is inserted. This series provides a sense of the actual size of the device, how easy it is to insert, and how visible it is while in place.

Generation 1 development also included further development of the internal components. In particular, the transducer was modified and digital processing features were enhanced to include more gain and more effective acoustic feedback reduction to allow increased output capabilities. Fig. 6 illustrates representative real-ear output for the new design in a format directly comparable to a conventional hearing aid, that is, gain for an input signal at 60 dB SPL and maximum power output in dB SPL_{equiv}. Note first that substantial gain is available to accommodate SSD subjects, even with some degree of hearing loss in the better-hearing ear. Also, note that substantial gain and output are available for frequencies to 12,000 Hz. Table 1 reports a summary of factors that differentiate the nonsurgical SoundBite Hearing System from current surgical osseointegrated systems including factors that are important for enhancing spatial hearing.

AUDITORY PERFORMANCE MEASURES

A systematic and larger study of SSD patients with control conditions was recently conducted. An additional 18 SSD subjects were recruited under an Institutional Review Board protocol and measured with the final Generation 1 ITM component. These SSD subjects were defined by a more restrictive definition (all thresholds from 250 Hz through 4000 Hz <25 dB HL) and were intentionally selected to cover a narrower range of factors than the first study. Table 2 reports the basic characteristics of these subjects.

The average improvement for the HINT was 2 dB (standard deviation = 0.97 dB) compared with unaided for the most difficult listening situation for SSD patients (speech from the front and noise to the better-hearing ear). These results are equivalent to those typically reported with the surgically implanted osseointegrated abutment systems. Commonly, such improvements are not seen until the device is worn for some time, usually a month or longer,[11] so these HINT results are expected to be even better with additional wearing time.

The SoundBite Hearing System appears to be a viable approach for SSD. These positive clinical findings warranted a full multicenter Food and Drug Administration (FDA) study that is now underway and includes a 30-day wearing period. This study is due to be completed in 2010 with the findings published soon after.

AUDIOLOGY PERSPECTIVE

The process for fitting the SoundBite Hearing System has similarities and differences compared to the process for fitting a surgically implanted osseointegrated abutment system. The auditory candidacy requirements for both are identical. Both require that a medical

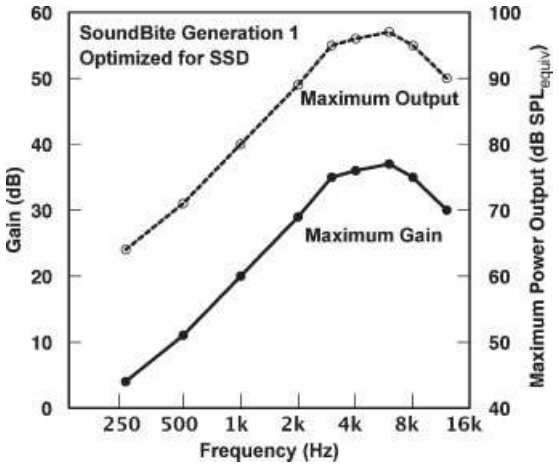

Figure 6 Maximum real-ear gain and maximum real-ear power output of the SoundBite Generation 1 version as optimized for single-sided deafness (SSD) in a format directly comparable to frequency response curves for a conventional hearing aid. Gain is in decibels (solid line, left axis) for a constant input signal of 60 dB sound pressure level (SPL). Maximum power output is in dB SPL equivalent acoustic measurement units (SPL_{equiv}; dashed line, right axis) that represents the maximum real-ear power output that the device is able to produce. These response curves can be adjusted to accommodate all SSD patients, even those with some degree of hearing loss in the better-hearing ear. The low-frequency performance is intentionally reduced because SSD patients do not require amplification in this frequency range.

diagnosis for SSD be identified, that all medical intervention be completed, and that the SSD is permanent. Once this process has been completed, the patient can be offered an increasingly larger number of devices to consider including CROS devices, transcutaneous bone conduction devices (transcranial CROS, TransEar, Oticon Medical headband, cochlear soft band), or direct bone conduction devices that provide stimulation by way of an osseointegrated surgically implanted abutment (cochlear Baha or Oticon Ponto) or by way of a custom ITM hearing device (Sonitus SoundBite). Because the ITM component does not require surgery, the SoundBite Hearing System can be fit directly by the audiologist and much earlier because the patient does not have to wait for the 3- to 6-month osseointegration process.[27] A patient may consider the SoundBite Hearing System first, and then a surgically implanted osseointegrated abutment system. Though the reverse order is possible, it is not very practical.

Once the SoundBite approach is chosen, the fitting process differs from other direct bone conduction devices. First a dental exam by a certified Sonitus dentist is necessary to ensure that the teeth are in good health and to determine if any local dental conditions will result in one side being favored over the other side (dental crowns, other dental work, etc.). At this time, a conventional dental impression is taken and shipped to the manufacturer along with audiometric information. This dental impression is used to create the custom ITM component. Similar to an ear impression for an ear mold or a custom in-the-ear conventional hearing aid, the dental impression can be kept by the manufacturer if any additional devices are needed.

The audiologist or otolaryngologist then receives the newly manufactured ITM component and delivers it to the patient. The audiologist then fits the BTE component for physical comfort and instructs the patient on how to insert, remove, and care for the BTE component using conventional BTE hearing aid procedures. Finally, the audiologist programs the system and adjusts it for auditory comfort, feature preferences, wearing schedules, sound preferences, and so on. At this point, the audiologist can implement any regular audiological procedures that do not differ from conventional hearing aid fitting processes, including device programming, verification

Table 1 Summary of Factors That Differentiate Direct Bone Conduction Devices for SSD

Factor	Cochlear Original Baha	Cochlear BP-100 Baha	Oticon Medical Ponto	Oticon Medical Ponto Pro	Sonitus Medical SoundBite
Surgery	Yes	Yes	Yes	Yes	No
Coupling method	Osseointegrated abutment	Osseointegrated abutment	Osseointegrated abutment	Osseointegrated abutment	Oral appliance
Removable by patient	No	No	No	No	Yes
Time between initiation and use	3 mo	3 mo	3 mo	3 mo	2 wk
Microphone location	Behind the pinna	Behind the pinna	Behind the pinna	Behind the pinna	In the ear canal
High-frequency capability	No (6000 Hz)	No (7000 Hz)	No (8000 Hz)	No (8000 Hz)	Yes (12,000 Hz)
Advanced processing features	No (or minimal)	Yes	Yes	Yes	Yes

Baha, bone-anchored hearing aid.

processes, and counseling. Currently, the programming process is implemented with a separate computer laptop and software provided by the manufacturer that allows selection of channels and implementation of the usual features provided by conventional digital hearing aids (multiple memories, feedback suppression, adaptive control of volume, etc.). In the future, this programming process could be integrated into the standard NOAH system (HIMSA, Copenhagen, Denmark).

A common question is often raised concerning noise from oral functions that may interfere with the system. Though oral functions such as chewing and swallowing produce noise levels that are quite high, these are not an issue for the SoundBite Hearing System because the microphone is not in the oral cavity, it is in the ear canal. Though oral functions like chewing may generate noise in the ear canal, it remains to be determined if the noise from these oral functions propagate to the ear canal at sufficient levels to cause perceptible acoustic noise. Oral function noise was not reported by any of the subjects in the initial experiments.

Eating and chewing may be a nonauditory factor of concern to SSD patients. It is common for SSD patients to want increased spatial hearing ability in noisy environments that involve eating, such as in a restaurant. It remains to be seen if the device provides benefit while eating, though there are several factors that mitigate this concern. First, the occlusal surfaces of the teeth are not covered by the ITM component. Second, it is likely that certain types of eating may be less of a concern than others. For example, it is very likely that drinking liquids or eating soft foods such as tofu or pudding may be less of a concern than eating more firm foods such as peanuts or celery. An alternative for those who may prefer eating without the ITM component in place is to remove it while eating certain foods. Survey results from these initial measures indicated that eating is generally not a concern.

The advanced technology in the SoundBite Hearing System affords the possibility of implementing other beneficial features. Because both the control signals and audio signals are transmitted wirelessly, advantageous features such as the more modern "streaming"

Table 2 Subject Characteristics in a Study of Speech Recognition in Noise with and without the SoundBite Hearing System

Subject	Age (Years)	Gender	SSD Duration (Years)	Better Ear PTA (dB HL)	Poorer Ear PTA (dB HL)	Poorer Ear
S1	36	M	0.7	10.0	81.3	R
S2	31	M	13.0	10.0	>110.0	L
S3	56	F	2.0	11.7	>110.0	R
S4	41	M	25.0	15.0	83.8	L
S5	47	M	7.0	11.7	>110.0	R
S6	37	F	26.0	8.3	>110.0	R
S7	62	F	20.0	5.0	65.0	R
S8	51	F	4.3	3.3	90.0	R
S9	31	M	6.5	8.3	80.0	L
S10	53	F	5.5	13.3	67.5	R
S11	40	M	1.0	16.7	78.8	L
S12	31	M	2.0	13.3	80.0	L
S13	41	F	2.3	8.3	85.0	L
S14	63	F	4.0	6.7	72.5	L
S15	36	M	2.0	6.7	>110.0	R
S16	38	F	2.0	10.0	>110.0	L
S17	52	F	22.0	11.5	86.3	R
S18	52	F	7.5	10.3	80.0	L

capability of contemporary hearing aids are certainly worth pursuing to allow connection to other devices such as remote microphones, television, and cell phones.

The new design also allows systematic investigation of bilateral applications not only for SSD. There is already some suggestion that bilateral osseointegrated abutment devices may provide an advantage.[26,28,29] Though spatial hearing abilities provided by two functioning ears always will be compromised in SSD because there is only a single hearing ear, a bilateral bone conduction approach may provide some additional spatial hearing ability. Because interaural attenuation is greater than 0 dB for high frequencies, a separate bone conduction transducer on each side of the mouth can provide clear left and right perception for high-frequency signals in bilaterally symmetrical hearing cases. Potential spatial hearing advantages from bilateral devices[26,28,30] should be investigated with this new device in the future. There also is potential for use in children. Additional details need to be considered because of the significant differences in the dental development of children.

SUMMARY

The SoundBite Hearing System by Sonitus Medical is a novel approach to treating SSD. It is based on the proven, effective principle of a microphone on the poorer-hearing ear and bone conduction transfer to the opposite better-hearing ear, but with several advantages over current bone conduction SSD devices. The system captures the known spatial hearing acoustic characteristics of a normal pinna and ear canal by locating the microphone in the ear canal of the poorer-hearing ear rather than behind the pinna as with osseointegrated abutment systems. The bone conduction signal is applied by way of the teeth with a safe, comfortable, generally invisible, and easily removable ITM device that does not require any modification of the teeth nor the surgery and healing processes of osseointegrated abutment systems. This direct bone conduction path is similar to the direct bone conduction path used by osseointegrated abutment systems and thus also avoids the discomfort and transmission loss of transcutaneous systems. The system provides a much broader bandwidth than all other SSD devices, to 12,000

Hz, which is important for optimizing spatial hearing ability. Auditory performance in a group of SSD patients suggested that a full multisite FDA study is warranted.

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It's time we listened to our teeth: The SoundBite hearing system

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The SoundBite hearing system (Sonitus Medical, San Mateo, Calif) allows people with single-sided deafness to wear an intraoral device and a small microphone in the deaf ear to regain lost hearing. A piezoelectric activator in a small removable unilateral oral appliance conducts sound through the bone via the teeth to the good ear. The goal of this article is to introduce the SoundBite, a new bone-conduction hearing device, to dentists and orthodontists. (Am J Orthod Dentofacial Orthop 2010;138:666-9)

Perhaps you remember old stories about people hearing sounds in their teeth when they got new fillings or braces. In 1942, Lucille Ball discussed hearing radio broadcasts through her teeth with her friends Ethel Merman and Buster Keaton at MGM Studios. That story ended up in a Cole Porter musical and various sitcoms over the years. It is no longer just a Hollywood legend.

Sound can travel along 2 pathways—air conduction and bone conduction. Dentists know that moving the jaw and clenching the teeth can play a part in the way we perceive sound. Place a forefinger into each ear; then open and close your mouth. As you open, you can clearly feel the condyle of the mandible moving and changing the size of the external ear canal. You can hear your own teeth tap together. We hear that tapping through bone conduction to the ear. The oral structures are close to the auditory structures.

A brief review of the ear is in order. The ear consists of an outer ear, a middle ear, and an inner ear. Hearing occurs when sound vibrations strike the eardrum, the thin membrane between the outer and middle parts of the ear. The auditory ossicles vibrate, and the footplate of the stapes moves at the oval window. Movement of the oval window causes the fluid inside the scala vestibuli and the scala typani to move. Fluid movement against the cochlear duct sets off nerve impulses, which are carried to the brain via the cochlear nerve.

Although dentists are not involved in the health of the ears, as health care professionals, we use our ears every day to help diagnose our patients and manage our staff and our businesses. Many of us have treated patients with hearing loss, and more than likely we will eventually have some level of hearing loss. Dentists in general are prone to hearing loss in the sound frequencies associated with the air turbine hand pieces that we use daily.[1]

It is estimated that single-sided deafness (SSD) afflicts almost 9 million people in the United States alone.[2] SSD is the complete or significant loss of hearing in 1 ear. SSD can be associated with tinnitus and affects the way sound is perceived. SSD affects sufferers in different ways and can be debilitating. The inability to determine the direction or point of origin of a sound can make even the simplest day-to-day tasks such as crossing the road, cycling, and jogging both difficult and dangerous. But by far the biggest obstacle for SSD sufferers is socializing in large groups or noisy environments. In these circumstances, many sufferers feel excluded because they miss out on conversations, whereas others worry that they will appear ignorant or rude if they do not hear a question. There is a constant need to turn the good ear toward the sound; this requires unusual movements of the head, and some SSD sufferers find it embarrassing.

SOUNDBITE TECHNOLOGY

Sonitus Medical has developed an intraoral device called the SoundBite hearing system. SoundBite is different from conventional hearing aids, which use air conduction to simply turn up the volume of sound traveling into the ear. Conventional hearing aids require a functional ear. As a bone-conduction device, the SoundBite hearing system does not require a functional middle or outer ear to deliver sound. The SoundBite hearing system is designed to allow sound to travel via the teeth, through the bones, to both cochleae, bypassing the middle and outer ears entirely. By using

The author is a consultant to Sonitus Medical. He is compensated for this work on clinical trials, and he has an option to purchase stock in the company.
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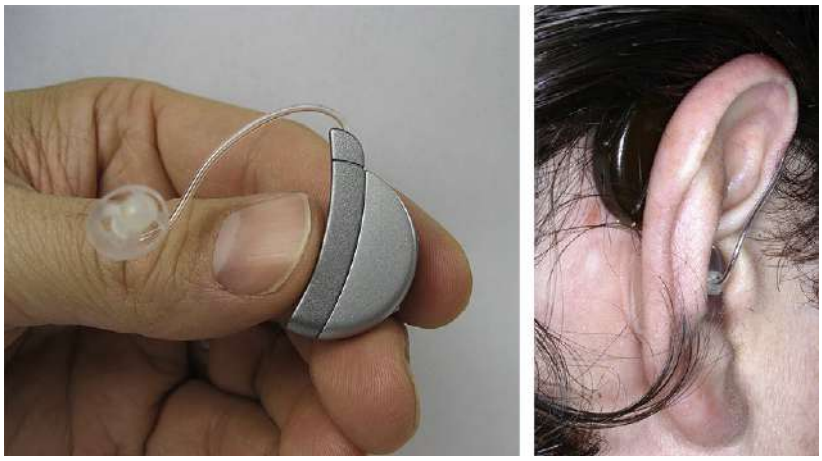

Fig 1. BTE microphone unit houses the receiver, wireless transmitter, and attached microphone.

bone conduction via the teeth, the SoundBite is intended to restore normal hearing to patients with SSD, conductive, or mixed hearing loss, all without surgery. The most prevalent devices that use bone conduction require surgery and are more expensive, such as bone-anchored hearing aids.

According to a traditional audiologic test called HINT (hearing in noise test), a 1-decibel increase is associated with a 10% increase in perceived sound for the patient. Preliminary data from ongoing trials with the SoundBite hearing system show that patients on average have an improvement of 2.6 decibels—a 26% increase in perceived hearing.[3]

HOW SOUNDBITE WORKS

Merging the well-known principles of bone conduction with advanced wireless and sound processing technology, the SoundBite is a nonsurgical, removable bone-conduction hearing system designed to transmit sound via the teeth. The SoundBite hearing system consists of a behind-the-ear (BTE) microphone unit (Fig 1), housing the receiver, wireless transmitter, and attached microphone, and a discreet, removable in-the-mouth (ITM) device (Fig 2). The tiny microphone sits in an open-fit dome in the ear canal of the impaired ear, where it detects sounds. Placing the microphone in the ear canal is intended to allow the SoundBite hearing system to capitalize on the natural acoustic benefit provided by the patient's own pinna, or outer ear, to capture and direct sound. Once sound is captured by the microphone, it is processed by the BTE digital audio device and transmitted wirelessly to the removable ITM hearing device. The ITM device uses advanced technology to produce imperceptible sound vibrations that are conducted via the teeth, through bone, to both cochleae. In this way, the SoundBite hearing system is intended to provide clear, high-fidelity sound and thus restore hearing to patients who are essentially deaf in 1 ear; no surgery or modifications to the teeth are required.

The SoundBite hearing system is intended for patients who have SSD, conductive hearing loss, or mixed hearing loss and who seek a nonsurgical, noninvasive hearing device that delivers high-fidelity sound.

Sonitus Medical is conducting trials of the SoundBite system; orthodontists and dentists could start seeing the devices in their patients' mouths in the not too distant future.

SoundBite is currently dispensed by a physician, such as an ear, nose, and throat specialist, who works closely with an audiologist. The physician will usually diagnose and treat any disease process of the ear. The audiologist performs a number of tests to determine the exact level of hearing loss and at what frequencies. If a decision is made that the SoundBite is the right form of treatment, then a dentist will take an impression of the maxillary arch and help with any appliance adjustments of the oral part of the device. Because this device spans several health care professions, it is an opportunity to reevaluate current referral patterns or create new ones.

The patients who might benefit from SoundBite vary in age. In our trial, a number of patients lost hearing due to acoustic neuromas—slow-growing benign tumors that can damage the acoustic nerve and are generally removed surgically. Other causes include other types of tumors, infections, and trauma. One patient had a motorcycle accident, and another caught a really bad cold that left 1 ear deaf. In the end, something damages some part of 1 ear, creating SSD.

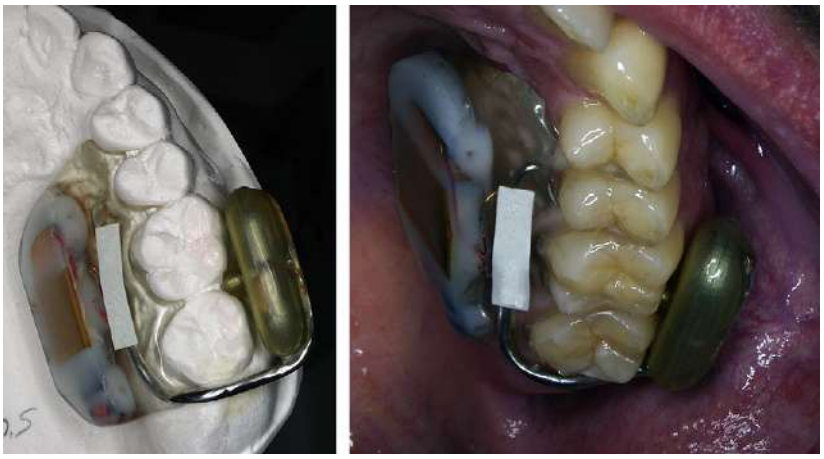

Fig 2. Removable ITM hearing device receives information wirelessly from the transmitter and produces imperceptible vibrations that are conducted through tooth and bone to the cochleae.

CLINICAL CONSIDERATIONS

How is the dentist involved in the use of SoundBite? The SoundBite intraoral device is similar to a retainer or partial denture worn in the maxillary arch. Parts of the SoundBite touch the gingiva, teeth, and inner cheek. An actuator on the buccal side of the device has a round post that fits typically between the 2 most distal teeth; this is the part that creates the sound. The battery and electronic components are on the lingual surface and connect to the actuator via a wire from the buccal to the lingual aspects along the distal surface of the most distal tooth.

Before fitting a SoundBite appliance, the dentist should do a complete examination, including x-rays and probing to make sure that the teeth are healthy. Be suspicious of old crowns; these teeth might need endodontic treatment, and, if there is any question, the patient should be referred to an endodontist for further evaluation. There can be no active caries or periodontal or endodontic conditions affecting the abutment teeth. The SoundBite is a removable device, and the abutment teeth are usually the last three 3 in an arch. The device can be worn on either side.

SoundBite has been successfully used on teeth with fillings, crowns, or implants, or that have had endodontic treatment. Anatomy and orthodontic placement must be considered. If a tooth is worn or a crown poorly contoured, the SoundBite might not have enough retention. If the position of the teeth is poor, then the patient might not derive the full benefit from the device. Orthodontic treatment might be needed to align the teeth before using the device.

SoundBite is worn in the mouth and has side effects similar to all removable dental appliances. The teeth and gingival tissues might be sore during the first few days. Sometimes the gingiva will be a little red. Rinses of warm salt water are recommended for any irritation. Cleaning of the device is done with a toothbrush and toothpaste. Liquid hand soap is a good alternative to the more abrasive toothpaste. The device is small enough that it does not affect speech. Most patients find it surprisingly comfortable, especially those who have had orthodontic treatment and are accustomed to wearing a retainer.

In clinical trials, SoundBite devices were made on plaster models from alginate impressions. Both maxillary full-arch trays and quadrants have been used to make the device. Yellow or white model stone can be used for the pour up. An accurate impression is a must. Just like all dental devices made from plaster casts, the impressions can distort, and the casts can break. Care must be taken, and, unlike most diagnostic impressions, it is critical to capture information around the most distal tooth, which will often be a third molar. The trays must fit, and sometimes the trays must be bent to accommodate the last teeth on the left and right. One must capture the tissue to the lingual, distal, and buccal aspects in order for the device to fit.

SSD affects 9 million people in the United States, and many of them have not had orthodontic treatment as a child or an adult. Some might not have been to a dentist for many years. It is important to bring these patients to a level of general dental health, before the SoundBite is used—much like orthodontic treatment itself.

PATIENT CARE

On delivery, show the patient how the device fits on the model. Have the patient place it on the model and

remove it before trying it in his or her mouth. Have a mirror handy. The SoundBite should have a little snap. The SoundBite can be adjusted with 3-prong pliers, but the doctor should be careful not to damage the wire connector; small electric wires are contained in it, and they can be damaged with incautious use of pliers. To increase the retention, squeeze the device between the thumb and forefinger. Check the occlusion by using the articulating paper of your choice. Spot-grind any areas that are in contact with the opposing teeth, but avoid accidentally penetrating the sealed electronic components. Occlusal contacts should be seen only near the teeth, away from the electronics of the device. Slight occlusal contact during biting, although not desirable, is sometimes impossible to correct. Every patient's occlusion is different, and slight contact might occur; this is normal. Some patients have little oral space available. That compromise must be weighed with the patient's other options of having surgery or doing nothing. Most patients find the SoundBite comfortable.

Patients are given detailed, printed instructions for the use of their SoundBite. Every patient is different; some will adapt quickly, and some will need a little handholding. Most patients can eat with the device in the mouth, but alcoholic beverages should be avoided; if a patient's judgment or physical responses are impaired, the device could be damaged, lost, or even swallowed or aspirated. Although this is highly unlikely, it is a removable device that is about half the size of a retainer. Again, this risk must be weighed against the risks of other treatments.

CONCLUSIONS

The SoundBite is a nonsurgical, noninvasive treatment for SSD. It requires the expertise of at least 3 health care specialists: a physician, an audiologist, and a dentist. The patient must have healthy teeth with acceptable alignment and good undercuts for the appliance to have the right amount of retention.

We live in an exciting time in the world of medicine and dentistry in which we can truly be part of the health of the total patient.

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Bone Conduction Hearing: Device Auditory Capability to Aid in Device Selection

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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Abstract

Objective. To obtain identical laboratory measures of 8 (surgical and nonsurgical) bone conduction devices and relate them to clinical function.

Study Design. Each device was measured with a single laboratory system and characterized with descriptive statistics.

Setting. Laboratory.

Subjects and Methods. Seven surgical devices (Intenso, BP110, BP100, and Cordelle [Cochlear, Denver, Colorado]; Ponto Pro and Ponto Pro Power [Oticon Medical, Somerset, New Jersey]; and Alpha 2 [Sophono, Inc, Boulder, Colorado]) and 1 nonsurgical dental device (SoundBite; Sonitus Medical, Inc, San Mateo, California) constituted the independent variables. Measured maximum output and gain parameters were the dependent variables.

Results. Maximum output varied across devices in the pure-tone average (PTA; 500-3000 Hz) frequency range (mean, 109.7 dB re 1 μN; range, 98.8-119.2 dB) and in the above-PTA (4000-8000 Hz) frequency range (mean, 102.6 dB re 1 μN; range, 88.99-119.6 dB). Maximum gain varied in the PTA frequency range (mean, 40 dB; range, 29.1-49.1 dB) and was higher in the frequency range above the PTA (mean, 32.0 dB; range, 20.8-46.0 dB).

Conclusion. All devices have sufficient maximum output and gain for the PTA frequency range for single-sided deafness (SSD). The devices differed in maximum output and gain for the frequency range above the PTA, a consideration for accommodating presbycusis and optimizing auditory function for SSD. The surgical devices have less maximum output and gain in the above-PTA range than in the PTA range. The nonsurgical dental device had the highest output (up to 30 dB higher) and gain (up to 26 dB higher) in the above-PTA range.

Keywords

bone conduction, Baha, dental, presbycusis, single-sided deafness

Clinical interest and treatment options for patients with single-sided deafness (SSD) have increased markedly over the recent past with many more device options available. The clinical manifestations of SSD are multiple and well documented.[1] Patients with SSD are unable to hear on the SSD side and often have to turn their head to engage in conversation. In addition, patients are unable to locate sounds and have problems with background noise. Many patients are disturbed by the hearing struggles associated with SSD and can be effectively rehabilitated with devices intended to overcome the hearing difficulties.[2-4]

When counseling patients regarding the various available bone conduction technologies, the mechanisms and surgical differences can be clearly articulated. However, patients often inquire about the hearing performance of the various bone conduction options. The hearing performance is dependent on both the specific capabilities of the device as well as the status of the cochlea that is going to be stimulated.

Multiple systems have a simulator that can be used to demonstrate the technology. For an osseointegrated post system, the simulations often have limited efficacy since there is intervening soft tissue during the simulation that is not present in the implanted system. For a magnetically coupled system, the simulation also has limited efficacy since the implant placed in the bone is absent. For a dental system, the simulator (Acoustiq; Sonitus Medical, Inc, San Mateo, California) does directly contact the patient's teeth and is not limited by soft tissue or lack of the presence of implant but

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Table 1. Manufacturer, Device Name, Transducer Type, and Coupling Method of 8 Bone Conduction Devices.

Manufacturer	Device	Transducer	Coupling Method
1. Cochlear	BP100	Electrodynamic	Implanted percutaneous post
2. Cochlear	BP110	Electrodynamic	Implanted percutaneous post
3. Cochlear	Cordelle	Electrodynamic	Implanted percutaneous post
4. Cochlear	Intenso	Electrodynamic	Implanted percutaneous post
5. Oticon Medical	Ponto Pro	Electrodynamic	Implanted percutaneous post
6. Oticon Medical	Ponto Pro Power	Electrodynamic	Implanted percutaneous post
7. Sonitus Medical	SoundBite	Piezoelectric	Removable dental module
8. Sophono	Alpha 2	Electrodynamic	Implanted subdermal plate

also may be limited because the front teeth can be used rather than the molars.

An additional limitation for simulation of all systems is the status of the cochlea to be stimulated by the device. If the patient has a high-frequency hearing loss, the simulation device needs to be programmed to match the patient's hearing loss. Given that programming the device is time-consuming and consideration of the soft-tissue limitations, the simulation is often performed without programming and in the audiology booth. Overall, the simulation of the various devices does demonstrate the phenomenon of bone conduction hearing. However, demonstrating the hearing experience for a patient is limited.

When counseling patients regarding the various bone conduction technologies, clinicians should consider both the current status of the cochlea and the natural history of hearing loss in the functional cochlea. A patient who may be able to be rehabilitated with a device based on the current status of his or her cochlea should be informed of the possible progression of the hearing loss in the only hearing ear. Clinicians and patients should consider the efficacy of the device over the patients' lifetime. The ability of a device to provide lifelong rehabilitation should be emphasized for patients undergoing surgery if additional surgery may be needed.

Patients considering a bone conduction option for hearing loss often request a comparison of performance among the various devices. Clinical studies with head-to-head comparisons are either compromised because they often involve earlier generation technologies or unavailable because it is virtually impossible to randomize devices that require surgery specific to the device. In the hearing device dispensing environment, the objective gains of the devices during simulation are used for comparison. The purpose of this article is to obtain identical laboratory measures for direct comparison of 8 bone conduction devices and relate the laboratory measures to clinical function.

Methods

Eight bone conduction devices were investigated representing those currently cleared by the US Food and Drug Administration (FDA) in the United States from 4 manufacturers. There were 7 surgical devices and 1 nonsurgical device, constituting the independent variable. The surgical devices used electrodynamic transducers but differed by coupling method, with 6 devices coupled to a percutaneous post implanted into the temporal bone, traditionally called a Baha (Intenso, BP110, BP100, and Cordelle [Cochlear, Denver, Colorado] and Ponto Pro and Ponto Pro Power [Oticon Medical Somerset, New Jersey]), and 1 held against a magnetic subcutaneous plate screwed into a surgically prepared well in the temporal bone (Alpha 2; Sophono, Inc, Boulder, Colorado). The nonsurgical device consisted of a piezoelectric transducer mounted in a patient-removable dental module held against the lateral surfaces of 2 maxillary teeth (SoundBite; Sonitus Medical, Inc). **Table 1** lists the manufacturers, devices, transducer types, and coupling methods.

The study design consisted of a comparison of laboratory measures from an example of each of these devices obtained with a single laboratory measurement system. Standard descriptive statistics (mean, range, and SD) were used to characterize the measures for each device and to quantify measurement variability.

Devices were characterized using a custom laboratory system (Sonitus Medical, Inc) that enabled testing of both implantable and nonsurgical dental devices. The system consisted of a bench-top anechoic chamber (Anechoic Test Box Type 4232; Bruel & Kjaer, Naerum, Denmark) with a loudspeaker driven by a computer with a sound card that delivered calibrated acoustic signals (swept frequency from 100-10,000 Hz) to the microphone of the device and a calibrated precision force gauge (B&K 8001) that measured output of the device (force in dB re 1 μN). The force gauge was assembled with a vibration mount and bracket, having a total mass that presented a sufficiently high mechanical impedance load to the transducer under test for accurate measures of output force (>20 dB higher than transducer output impedance).

Each processor was configured to have the widest frequency response, highest gain, and minimum effect from automatic gain control and other adaptive features such as noise or acoustic feedback suppression to ensure valid comparisons across devices. Maximum force output and acousto-mechanical gain were evaluated according to methods defined in the international standard IEC60118-9:1985 using 90-dB sound pressure level (SPL) and 60-dB SPL input

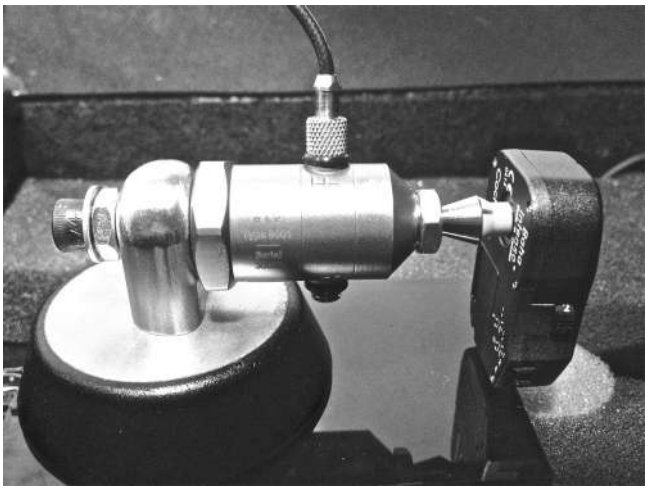

Figure 1. Photo of the custom laboratory measurement system measuring a Baha device.

signals, respectively. Implantable bone-anchored devices were tested with a Baha abutment modified with an M2/10-32 brass fitting to interface to the force gauge. **Figure 1** shows an image of the force gauge assembly with the Cochlear Intenso attached. The nonsurgical dental device was tested using a steel fitting attached to the force gauge that allowed coupling via a spring wire to replicate its attachment to the teeth. Data for the dental device were compensated for the effect of the tooth interface to the skull to provide a measure of the skull stimulation force for direct comparison to the surgically implanted devices.

Results

Figure 2 shows the maximum output (force in dB re 1 μN) for the measurements (solid line) and for the published manufacturers' results (filled circles) for each device. The measures for the subdermal surgical device were comparable to the manufacturers' published results, although only the manufacturers' values are shown for this device because a soft-tissue component was not developed for the measurement system. The nonsurgical dental device (SoundBite) response is compensated for the effect of the tooth interface to the skull and represents the actual skull stimulation force. The measures for all devices were reliable (test-retest SD of <0.5 dB) and valid (generally within ±2 dB of the manufacturers' published result). This indicates that the measures are comparable across devices.

Figure 3 shows the maximum output for all devices displayed in a format that uses a standard (ANSI S3.6:2004) clinical audiometric frequency range (250-8000 Hz) with values at octave frequencies (250-8000 Hz) and select inter-octave frequencies (750-6000 Hz). The maximum output differed across devices and by frequency region. These results can be described using the clinically relevant pure-tone average (PTA) of the values at 500, 1000, 2000, and 3000 Hz and the average of the values above the PTA (4000, 6000, and 8000 Hz). Maximum output varied across devices in the PTA frequency range (mean, 109.7 dB re 1 μN; range, 98.8-119.2 dB) and in the above-PTA frequency range (mean, 102.6 dB re 1 μN; range, 88.99-119.6 dB).

Maximum acousto-mechanical gain was also found to be comparable to the manufacturers' published data (generally within ±2 dB). As with maximum output force, gain differs across devices and frequency region. Maximum gain varied in the PTA frequency range (mean, 40.0 dB; range, 29.1-49.1 dB) and in the above-PTA frequency range (mean, 32.0 dB; range, 20.8-46.0 dB). **Figure 4** shows the maximum gain for each device (in dB) for the standard clinical frequency range (PTA) and the high-frequency range (above PTA).

Figure 5 illustrates the presbycusis consideration for all devices. This figure shows the maximum output of each device displayed in an audiogram format (dB hearing level [HL]) with a frequency range indicated for the conventional clinical description (PTA range) and the frequency range indicated for changes in thresholds for 2 typical presbycusis cases represented by the average hearing thresholds for women and men aged 70 years.[5] In addition, the range of the hearing loss by frequency for these 2 groups (10th-90th percentiles) is displayed.[6]

Discussion

The measures reported enable direct comparison of output and gain among devices in a clinically relevant format and are very useful since they can help in device selection. The maximum output information is particularly useful for device selection since these maximum output values suggest a fitting range for each device. The maximum gain information is also useful, but less so for purposes of device selection because the actual use gain is always much less than maximum and adjusted for each patient individually.

All of these devices are FDA approved for patients with a normal-functioning cochlea with either conductive hearing loss or SSD. In these cases, the reported maximum output is sufficient, but the maximum gain for all devices will far exceed the patient's gain requirements. The maximum gain can be adjusted for all these devices down to the required 0-dB to 10-dB target value for activating a normal cochlea.[7] For the devices that are FDA approved for patients in whom the cochlea is not normal (mixed hearing loss), the maximum gain measure will be useful in device selection depending on the individual bone conduction sensitivity.

Two very common clinical entities also should be considered during the process of device selection. First, all of these devices are intended to be a long-term solution for patients, and this is especially true of the patients using a device requiring a surgical intervention. Changes in hearing not associated with the primary pathology, presbycusis in particular, should be considered for all cases. Second, patient selection is often described in terms of air conduction hearing loss over a very restricted frequency range, the PTA, when in fact bone conduction sensitivity is the only factor to consider for all bone conduction devices, by definition. Each of these 2 considerations will be described in a clinical context.

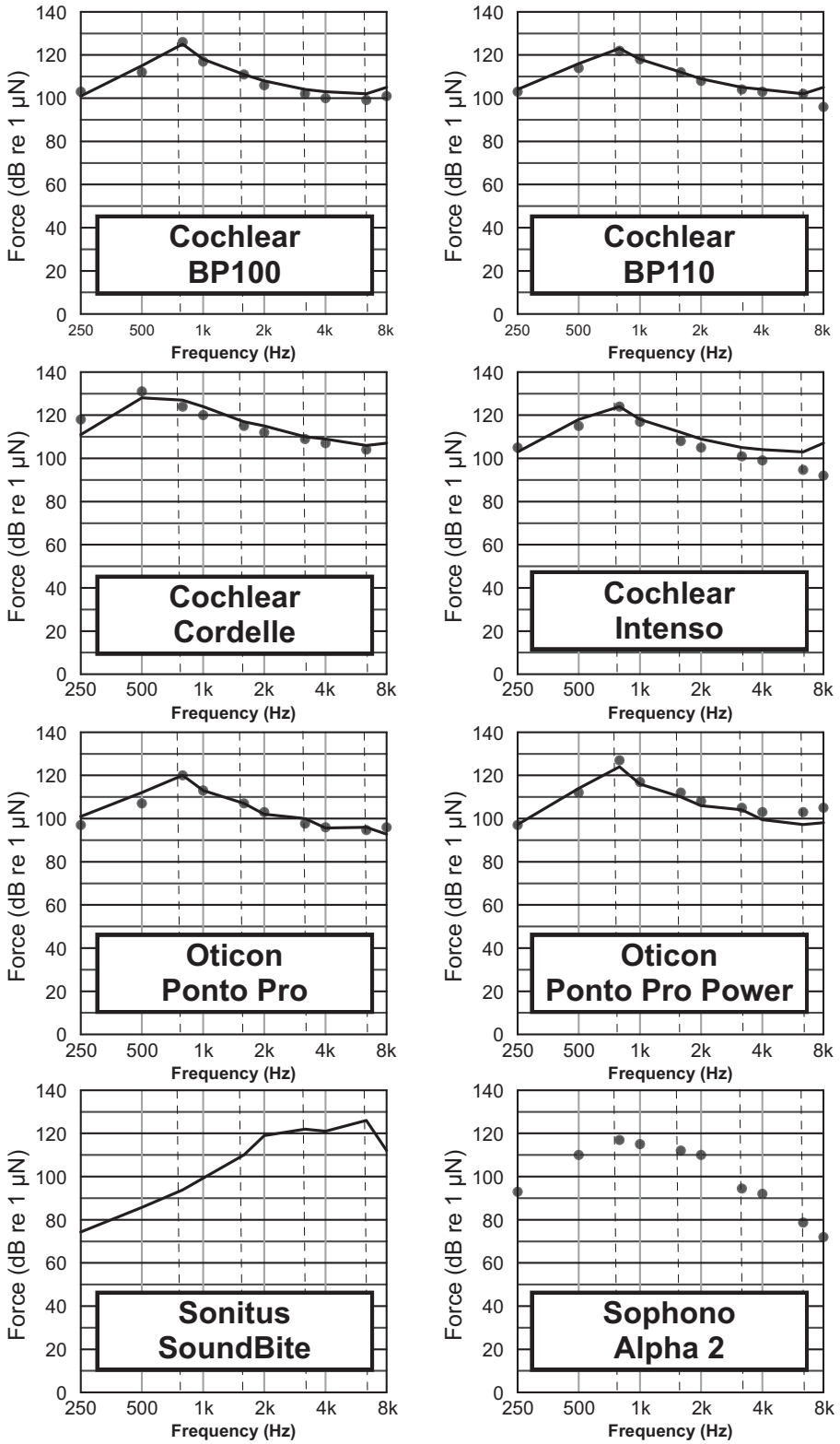

Figure 2. Maximum output force (dB re 1 μN) for 90-dB sound pressure level input for measurements (solid line) and from published manufacturer results (filled circles) for each device.

Presbycusis, age-related progressive bilateral sensorineural hearing loss, affects men more than women. It is measurable epidemiologically for frequencies >2000 Hz beginning at 50 years of age and progresses systematically with age.[8] None of the devices considered in this study is FDA approved for presbycusis. However, many cases will have a presbycusis consideration. Often times, patients with a longstanding SSD present for evaluation and rehabilitation with the onset of presbycusis in the only hearing ear.[9]

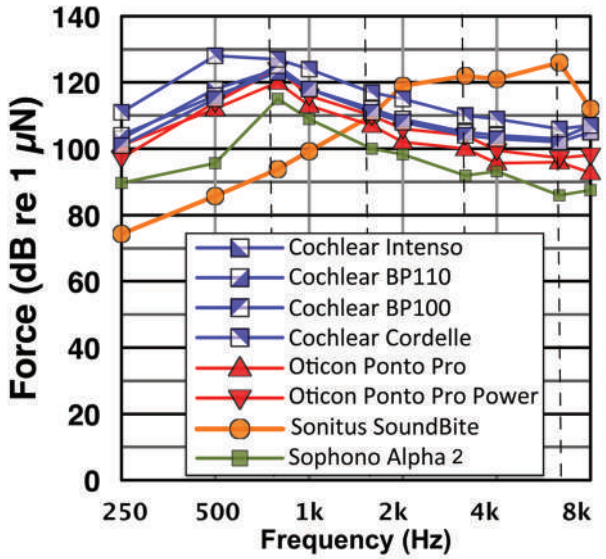

Figure 3. Maximum output force for each device (dB re 1 μN) for 90-dB sound pressure level input. Each manufacturer is represented by a color (Cochlear: blue, Oticon Medical: red, Sonitus Medical: orange, and Sophono: green) and each device by a separate symbol.

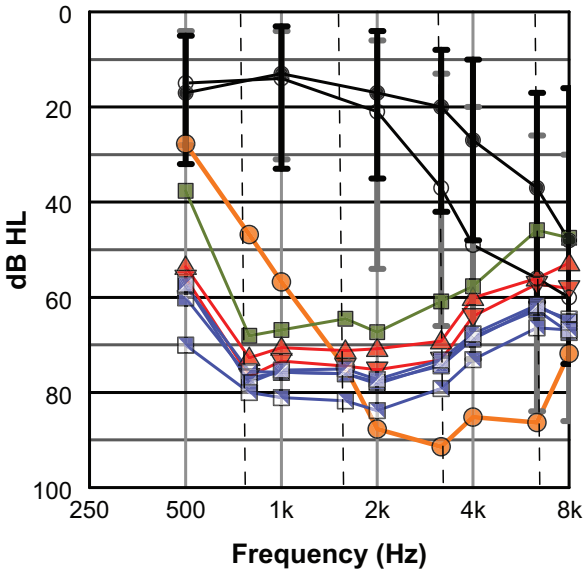

Figure 5. Maximum output of each device (see **Figure 3** for device identification) displayed in an audiogram format. The gray circles represent the typical presbycusis audiogram of a 70-year-old woman, and black circles represent the same for a 70-year-old man. The correlating bars represent the mean change in threshold in the 10th to 90th percentiles for women and men age 70 years.[8]

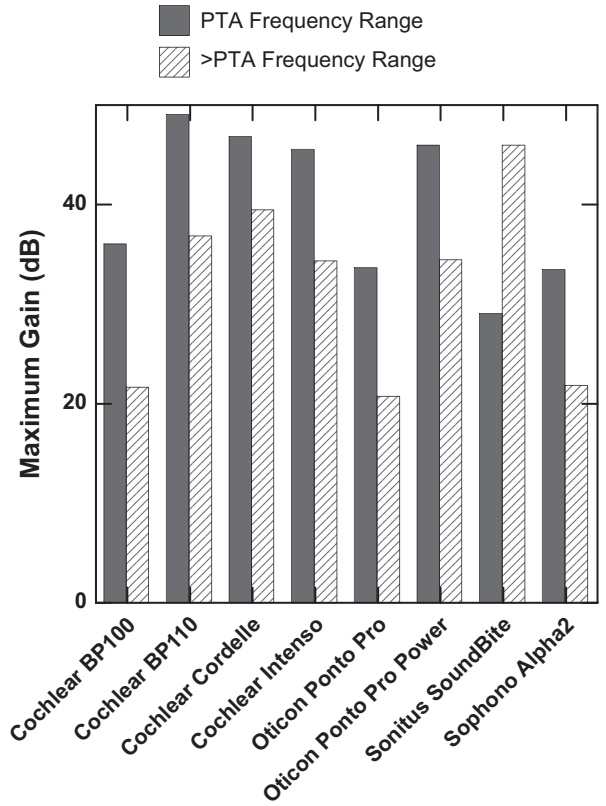

Figure 4. Maximum acousto-mechanical gain for each device in dB (difference between force in dB re 1 μN and 60dB sound pressure level [SPL] input sound pressure) averaged over the standard clinical pure-tone average (PTA) frequency range (solid bars, 500-3000 Hz) and the higher frequency range above the PTA (hashed bars, 4000-8000 Hz).

Figure 5 illustrates that both of the typical presbycusis cases will require gain and maximum output increases in the frequency range well above the PTA. The Sophono device will perhaps not have enough output to maximally rehabilitate the typical 70-year-old male or female presbycusis patient. The Sophono, Oticon Ponto Pro, or Oticon Ponto Pro Power will not have enough output to maximally rehabilitate a typical 70-year-old man. As demonstrated in **Figure 4**, none of the implantable surgical devices evaluated in this study is able to provide enough high-frequency gain to maximally rehabilitate the more severe cases of presbycusis. The SoundBite device is able to provide enough high-frequency gain and output except at 8000 Hz in the range of hearing loss that occurs in the 90th percentile range and worse in 70-year-old men.

The maximum output levels are similar across the each manufacturer's family of devices. The difference in maximum output among the Cochlear BP100, Cochlear BP110, and Cochlear Cordelle devices is not great. Similarly, the difference in maximum output between the Oticon Ponto Pro and Oticon Ponto Pro Power is not great either. This finding suggests that factors other than the maximum output such as the potential increased size of the processor, and thus less favorable aesthetic satisfaction, should be discussed with a patient since the potential clinical advantage may not be significant.

Single-sided deafness is a common application for these devices,[5] a condition where the device activates a normal cochlea. It is often reported using the air conduction hearing sensitivity of the better hearing ear in the PTA frequency range. Devices that produce signals in the PTA frequency range provide a minimum signal for understanding speech

even though sound quality may not be optimal. Primary complaints of patients with SSD are reductions in spatial hearing ability and reductions in speech understanding in noise.[1] The frequency range above the PTA optimizes auditory function for spatial hearing and understanding speech in noise as well as improves sound quality.[10] In fact, the frequency range for optimizing function for all SSD cases should be 1500 Hz and higher because frequencies lower than 1500 Hz are perceived normally with no device in SSD cases.[11]

Acoustic feedback has been an issue with many of these devices. Many variables determine if a patient will experience acoustic feedback.[2] When counseling patients, the potential for acoustic feedback should be discussed. The current investigation does not evaluate the level of gain for each device in the context of the variables that can lead to acoustic feedback. Although a device may have a demonstrable level of gain in an anechoic chamber, this maximum level may not be able to be obtained in a patient due to acoustic feedback limitations.

Conclusion

All but one of the devices can be measured accurately with a single custom laboratory system. All devices have sufficient maximum output and gain for the PTA frequency range (500-3000 Hz). The devices differ in maximum output and gain for the frequency range above the PTA (4000-8000 Hz), a consideration for accommodating presbycusis and for optimizing the auditory function for SSD.

The surgical devices have less output and gain in the frequency range above the PTA than in the PTA frequency range. The nonsurgical dental device has the highest output (up to 30 dB higher) and highest gain (up to 26 dB higher) in the frequency range above the PTA.

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Author Contributions

Mark J. Syms, analysis and writing; **Kelly E. Hernandez**, analysis and writing.

Disclosures

Competing interests: Mark J. Syms is a consultant and shareholder for Cochlear, a consultant and a member of the Surgeon's Advisory Board for Sonitus, and an investigator for a protocol sponsored by Sonitus. Kelly E. Hernandez is a consultant and a member of the Surgeon's Advisory Board for Sonitus and an investigator for a protocol sponsored by Sonitus. The protocol, which started in November 2013, is called "Evaluation for Benefit for Treatment of Single Sided Deafness Between Two Bone Conduction Prosthetic Devices: Osseointegrated Implant versus Maxilla Anchored Removable Oral Appliance."

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Original Research

Patients Satisfied with Intraoral Device for Single-Sided Deafness

By Lily Woodby, AuD, & Linda Galow, MS
Sonitus Medical

Patient satisfaction is increasingly becoming an important outcome measure for healthcare overall and for audiological services specifically, with a growing trend linking the measure with provider performance and reimbursement. Similarly, the real-world benefit of devices fit by audiologists is developing into a focal outcome that complements standardized measures.

Given the importance of these two outcomes, the new study described in this paper evaluated patient satisfaction and real-world benefit in a nonsurgical bone conduction device, finding positive patient-reported results for each.

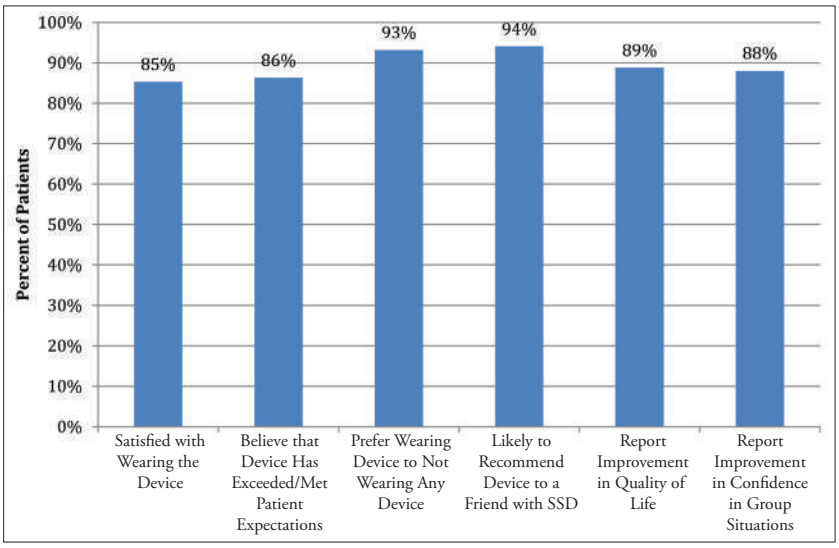

Figure 1. *Overall Experience and Quality of Life*

Patient satisfaction and real-world benefit can be difficult to measure because, together, they encompass a very broad and disparate set of factors, including logistics (e.g., appointment wait times) and the process of obtaining and adjusting a hearing device (e.g., number of office visits required).

Furthermore, the measures incorporate the patient's perception of how well the device improved the condition, regardless of objective benefits or standardized verification and validation results.

The device improved quality of life and offered real-world benefits.

Still, consideration and ascertainment of these factors is warranted. They can provide critical information for understanding and improving the overall patient experience, and they bring attention to the impact of devices on quality of life, going beyond the technology alone.

SIMILARITIES AND DIFFERENCES

Acquired single-sided deafness (SSD) causes a loss of omnidirectional hearing, difficulty hearing sounds on the deaf side, diminished accuracy in localizing sound sources, and reduction in the ability to understand speech in noisy environments. Many of these auditory losses can be reduced with an SSD device that picks up sound on the deaf side and delivers it to the contralateral, better hearing ear.

Bone conduction devices transfer the signal across the head and bring it to the better hearing ear simultaneously, while keeping the external ear canal of the hearing ear open.

Surgical bone conduction prosthetic SSD devices deliver a vibratory signal to the skull without soft tissue compression through an implanted titanium post. After three or more months, the post establishes a rigid coupling to the skull through a process called osseointegration. A module that contains a microphone and a vibration transducer is coupled directly to the post after healing occurs.

SoundBite Hearing System is a nonsurgical prosthetic bone conduction SSD device that delivers the vibratory signal to the teeth—the natural posts already rigidly coupled to the skull.

The product was cleared by the Food and Drug Administration in January 2011 for single-sided deafness. Peer-reviewed articles have demonstrated oral and dental safety using short- and

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long-term standardized measures, such as dental surface wear and bone resorption.

Overall effectiveness has also been shown using a variety of validated outcome measures, including sensitivity (aided thresholds), ability to hear in noise (Hearing in Noise Test [HINT]), and overall hearing benefit (Abbreviated Profile of Hearing Aid Benefit [APHAB]).

Though SoundBite is functionally identical to an osseointegrated device, there are differences in how it's obtained and worn and, possibly, in how the device addresses the real-world issues of single-sided deafness.

No surgical intervention or healing time is required, and a routine dental health screening and quadrant impression is performed by a dental professional. Given these differences, it is important to measure and understand patient satisfaction and real-world benefit as a complement to the more rigorous scientific measures.

TAILORED MEASUREMENTS USED

This study included 117 patients fitted with the SoundBite device between October 2011 and January 2013. Measures tailored to the device were used instead of standardized outcome measures according to research protocols.

Patients completed an online survey after wearing the device under typical daily conditions for at least 30 days. They were paid $25 for their participation.

The online questionnaire items were centered on important patient satisfaction and real-world benefit factors. They employed typical rating scales on several dimensions (satisfaction, improvement, etc.), ranging from completely positive to completely negative. The questionnaire also allowed open-ended responses.

The survey tool had 30 items in four categories:

- **Overall experience and quality-of-life** items focused on broader factors that determine patient satisfaction and real-world device benefit.
- **Hearing ability** items centered specifically on the real-world auditory factors and experiences most important to patients with SSD.
- **Daily use** items covered factors associated with daily wearing of the device.
- **Process** items addressed issues unique to selecting, obtaining, fitting, and programming the device.

Information on real-world patient satisfaction and benefits can be obtained with non-standardized questionnaires tailored to the specific device.

HIGH PATIENT SATISFACTION

Figure 1 summarizes the six items on general experience and quality of life. The percentage of patients reporting satisfaction with the overall experience of wearing the device was 85 percent. In addition, 89 percent and 88 percent, respectively, reported better quality of life overall and more confidence in group situations.

Figure 2 shows the results for seven specific hearing categories important to the patient with single-sided deafness.

The percentage of patients satisfied with the performance of the device in addressing their overall hearing problem was 91 percent, and high percentages of patients indicated improvements in the ability to hear a person speaking on the deaf side (96%), participate in group conversations (91%), and hear in noisy environments (84%).

Two categories associated with sound localization and true binaural hearing had lower percentages of patients reporting satisfaction—65 percent and 63 percent, respectively.

Figure 3 shows the results for four items concerned with daily use of the device. The percentages of patients reporting satisfaction with the overall experience of wearing the intraoral device and with their ability to speak while wearing it were 85 percent and 89 percent, respectively, while the proportion of patients satisfied with their ability

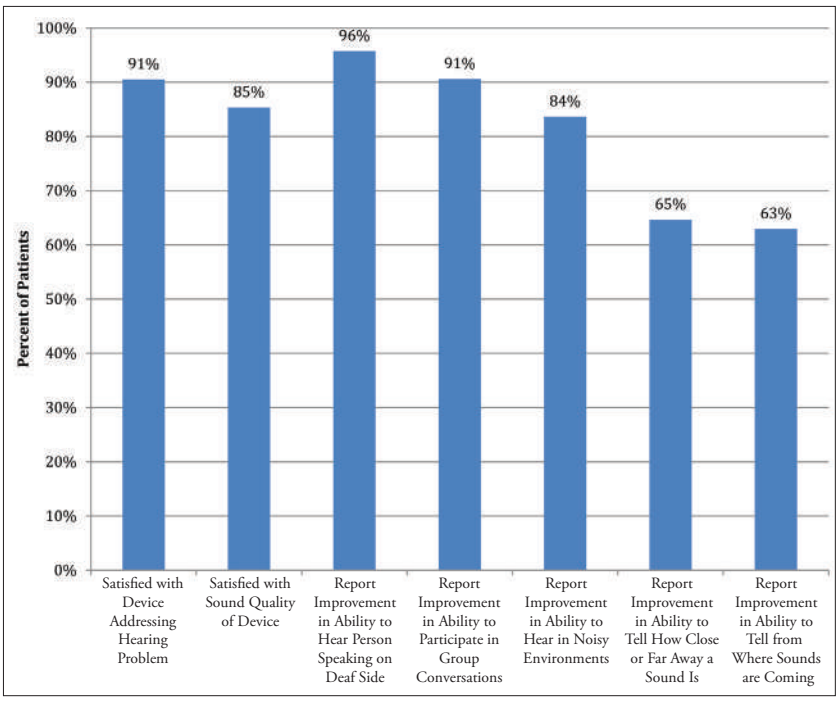

Figure 2. *Hearing Ability*

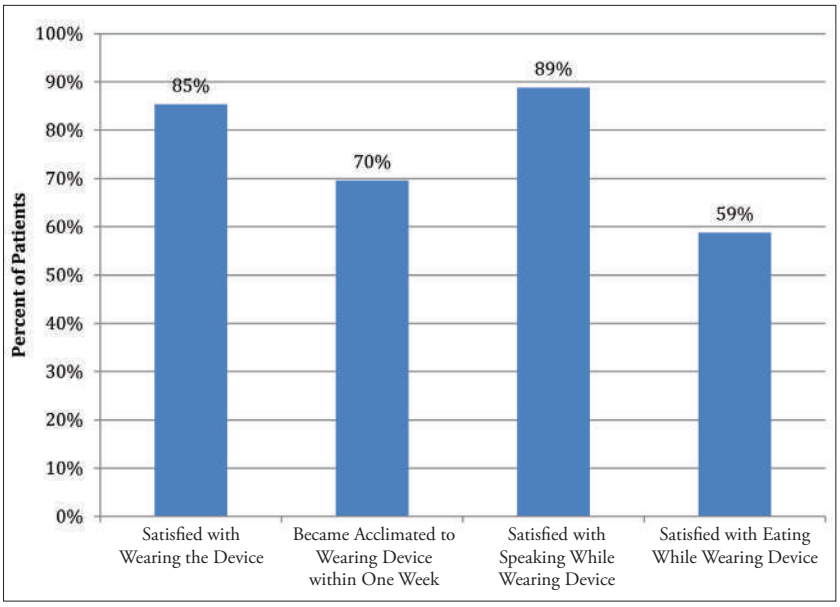

Figure 3. *Daily Use of the Device*

These photos show the different components of the SoundBite Hearing System. On the far left, a removable, custom-manufactured in-the-mouth (ITM) component containing the bone conduction transducer is pictured. On the far right, a behind-the-ear (BTE) microphone unit that processes and wirelessly transmits sound to the ITM is shown.

to eat while wearing the device was lower—59 percent. On average, patients said they wore their device for 8.7 hours a day.

The study specifically asked patients about their experience obtaining the device, as an additional provider—a dentist—is required. In the study sample, 85 percent of patients were satisfied with the process.

HELP FOR COUNSELING PATIENTS

Information on real-world patient satisfaction and benefits can be obtained with non-standardized questionnaires tailored to the specific device. The average results reported here can be used for counseling patients with single-sided deafness.

In defining and measuring patient satisfaction for a non-surgical prosthetic bone conduction device, this study found that the device improved quality of life and provided real-world benefit specific to hearing challenges faced by SSD patients, such as the ability to hear someone speaking on the deaf side, as well as the ability to hear in noise and in groups. Patients were satisfied overall with wearing the device daily and acclimated to it quickly.

In contrast, fewer participants were satisfied with eating while wearing the device. Although SoundBite is designed so patients can eat while wearing it, patients reported in the open-ended responses that they were uncomfortable with the possibility of food being lodged around the device or feared damaging the device while chewing.

Also in the open-ended portion of the questionnaire, patients who expressed concerns with SoundBite identified the following areas for improvement: acoustic feedback reduction, fragility of the behind-the-ear device and charger cradle, performance consistency for the ITM device, the need for a volume control, and the desire for a smaller ITM device.

Sonitus Medical, the maker of SoundBite, has addressed many of these concerns, and others will be addressed with the release of the next-generation device.

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A Novel Intraoral Bone Conduction Hearing Prosthesis: One-Year Safety and Efficacy Study

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Objective: To assess the safety and efficacy of an intraoral bone conduction (IOBC) hearing prosthesis after 12 months of use.
Study design: Prospective cohort study.
Setting: Multisite study including private practice, hospital-based practice, tertiary care, and academic medical centers.
Patients: Patients aged 18 years or older with single-sided deafness (SSD).
Main outcome measure(s): At the end of 6 months and 12 months, patients were asked to complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire and SSD questionnaire in addition to audiometric testing.
Results: Eighty-one patients completed the study. Hearing thresholds remained the same throughout the study. APHAB results showed a significant benefit ($p < 0.001$) in categories of ease of communication, reverberation, background noise, and global score. The SSD questionnaire showed a high satisfaction among participants, with 93.8% of patients likely to recommend the IOBC. Dissatisfaction was highest with regard to patient's ability to eat with device, with only 55.6% satisfied. No serious adverse events were reported during the study.
Conclusion: The IOBC is a safe and effective alternative to percutaneous osseointegrated hearing implants for patients with SSD. Patient satisfaction and improved hearing benefit are observed after 1 year of using the device. The IOBC significantly benefitted patients in APHAB categories of ease of communication, reverberation, background noise, and the overall global hearing score. The in-the-mouth transducer is the least-liked feature for some patients, particularly with regard to eating; however, the majority of patients are willing to deal with the size of the device for the hearing benefit gained. **Key Words:** SoundBite—Bone-anchored hearing aid—Single-sided deafness.

Otol Neurotol **36:**106–110, 2015.

Since the introduction of an intraoral bone conduction (IOBC) hearing prosthesis in 2010 (Fig. 1), it has become a nonsurgical alternative to percutaneous osseointegrated implants for patients with single-sided deafness (SSD) and conductive hearing loss (1–3). The IOBC uses a microphone within the ear canal and a behind-the-ear (BTE) transmitter in conjunction with an in-the-mouth (ITM) transducer to transmit sound via bone conduction and does not require implantation of any part of the system.

Early investigation of the IOBC has shown it to be relatively safe, without causing damage to the teeth or surrounding dental structures (4). Forces generated by the device are less than that of normal daily forces on dentition (5). Studies have shown that patients benefit from the device and that it is safe for use during a 6-month period (1,3,4). The long-term safety and efficacy of the IOBC, however, have not been studied. The purpose of this study was to assess the safety and efficacy of the IOBC, with patient follow-up at 6 and 12 months.

MATERIALS AND METHODS

This study expands on an initial cohort of patients using the SoundBite (Sonitus Medical, Inc., San Mateo, CA, USA) IOBC, and a detailed description of the methods has been previously published (3). The initial study sites of Arizona, California, Florida, Michigan, Texas, and Utah were included, in addition to sites in the District of Columbia, New York, and North Carolina. The sites represent small- and medium-sized private practices, hospital-based practices, and tertiary care and academic medical centers. Institutional review board approval was obtained for each site. Patients who had already elected to use the IOBC were then subsequently informed and enrolled in the study. There was no randomization of the subjects because all wore the same commercially available IOBC device. Patients were financially reimbursed a nominal amount ($100 paid by Sonitus Medical) for completing the outcome questionnaires (see Supplemental Digital Content 1, http://links.lww.com/MAO/A259) but were personally responsible for all other medical, dental, travel, and device costs.

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The authors disclose no conflicts of interest.
Supplemental digital content is available in the text.

FIG. 1. This figure is a picture of the intraoral bone conductor with ITM component *(left)* and the BTE component *(right)*. As shown, the ITM is custom made to fit around the patient's back molars. The BTE microphone is situated in the ear canal of the patient with a silicone ear piece.

Patients aged 18 years or older with acquired unilateral sensorineural hearing loss of any etiology were considered eligible for enrollment in this study. Unilateral hearing loss was characterized by a four-tone (500, 1,000, 2,000, 3,000) pure-tone average (PTA) of 75 dB or higher or unmeasurable hearing in the poorer hearing ear and 25 dB or less with no air-bone gap in the better-hearing ear. Two patients who were missing 3-kHz data had their value interpolated by averaging 2 and 4 kHz (6). Inclusion criteria also required patients to have at least three posterior maxillary teeth on the aided side and no periodontal disease or existing hardware.

Obtaining accurate aided thresholds in a sound field is problematic for hearing devices in cases of SSD because the better-hearing ear will detect sound by air conduction. Plugging the good ear alters the thresholds for SSD devices (SoundBite, BAHA, etc.) because this artificially increases bone conduction sensitivity (for the same reason the Weber lateralizes to the ear of a unilateral conductive loss case). With the IOBC, however, the microphone sits in the ear canal, and a conventional earphone can be placed over the BTE component on the aided ear to obtain accurate and calibrated aided thresholds. The aided thresholds reported in the study were obtained this way, and standardized earphones calibrated in decibel hearing loss in accordance to American National Standards Institute standards were used for diagnostic audiometry. Thresholds were always measured in the better-hearing ear.

Each patient's ITM component was properly fitted and adjusted by a dentist. The device was programmed to produce equal loudness in both ears for tones in the 1,000- to 6,000-Hz range. Patients were instructed to use the device and then complete questionnaires after 6 and 12 months of use. Questionnaires consisted of the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, which is a validated assessment tool used to quantify benefit from hearing prosthetics (7), and an SSD questionnaire. The SSD questionnaire was adapted to specifically evaluate the IOBC device and included what patients liked least and most about the device. The APHAB questionnaire assessed patient outcomes in the subscales ease of communication (EC), reverberation (RE), aversiveness (AV), and background noise (BN). A global (GL) score was also included and consisted of an average of all three subscales. Mean APHAB scores were calculated at 6 and 12 months for both aided and unaided hearing. APHAB benefit was calculated from the difference between the two scores. The Student's *t* test was used to evaluate the difference between aided and unaided APHAB scores at 6 and 12 months and also to evaluate the change in APHAB benefit score from 6 to 12 months.

RESULTS

Patient enrollment in the study initially included 127 subjects. Thirty-seven were terminated from the study because of incomplete in-person follow-up. Of these, 21 were contacted and stated that their drop out was unrelated to the device and 16 patients were lost to follow-up despite repeated attempts to contact and therefore device relatedness is unknown. Nine subjects withdrew from the study for various other reasons, leaving 81 subjects for analysis. A more detailed description of subjects can be found in Table 1.

Hearing thresholds remained the same during the trial, with the standard deviation (SD) being equivalent to the audiometer step size. The pretrial average PTA was 11.14 dB HL (SD, 5.89 dB), and the posttrial average PTA was 11.43 dB HL (SD, 5.98 dB). Aided thresholds with the IOBC showed a posttrial average of 19.1 dB HL (SD, 7.1 dB), which reflects actual use settings. The aided thresholds were well in the normal hearing range (<25 dB HL).

There were 65 patients who filled out the 6-month APHAB questionnaire, which was an optional follow-up time point for the patients, and 80 patients who filled out the 12-month questionnaire. Results for the APHAB questionnaire (Table 2) showed a significant difference between the mean aided and unaided scores at 6 months ($p < 0.001$) and 12 months ($p < 0.001$), with the device providing benefit in all categories. The highest APHAB benefit was observed in the subscale of background noise. There was no difference in APHAB benefit from 6 to 12 months (Table 3). The SSD questionnaire

TABLE 1. *This table shows how many patients were enrolled in the study and how many were included in the final analysis*

Subjects		
127	Enrolled	(134 approached, 7 did not complete the enrollment process)
37	Terminated	Unrelated to device (unable to complete measures at specified time)
	20	Unrelated to device (unwilling to travel, vacation, etc.)
	1	Unrelated to device (death from existing unrelated cancer)
	16	Unknown if related to device (lost to follow-up even after repeated attempts)
9	Withdrew	(Subject chose to not wear device)
	3	Subject perception (no benefit)
	2	Subject acquired condition (fungal infection, lichen planus)
	1	Subject anatomic condition (palatal tori)
	2	Subject response to device problems (feedback, ITM breakage, dome)
	1	Subject response to ITM comfort (refused adjustment)
81	Used for analysis	

ITM indicates in-the-mouth processor.

TABLE 2. *This table shows the results of the APHAB questionnaire scores with comparisons between the unaided score to scores with using the IOBC at 6 and 12 months*

APHAB	UNEC	UNRE	UNBN	UNAV	UNGL	AidEC	AidRE	AidBN	AidAV	AidGL
6 M mean	30.2	43.8	65.2	41.4	46.4	15.1	22.5	38.6	32.7	25.4
6 M SD	16.9	16.2	17.1	27.7	13.3	10.3	12.1	18.4	23.0	10.5
p value						<0.001	<0.001	<0.001	<0.001	<0.001
12 M mean	31.4	44.2	65.1	42.0	46.9	15.1	23.1	38.6	31.0	25.6
12 M SD	17.3	16.4	16.9	25.5	13.6	8.7	12.6	19.4	22.9	11.3
p value						<0.001	<0.001	<0.001	<0.001	<0.001

UN indicates unaided; Aid, aided; EC, ease of communication; RE, reverberation; BN, background noise; AV, aversiveness, GL, global score; M, months; SD, standard deviation.

revealed that 85% or more of patients were very satisfied with the IOBC system in five of the six domains (Table 4). Ninety percent of patients preferred the device to no device, and 94% were likely to recommend this device. Patients were least satisfied in their ability to eat with the ITM component, with satisfaction only reaching 55.6%. Acclimatization to the device occurred within 4 days for 54% of the patients.

In response to what patients like most about the IOBC, hearing by far was the most common answer, with ease of use and no surgery following at second and third most liked features. The three most prevalent features least liked by patients were regarding ITM, feedback, and battery life (Fig. 2).

There were nine nonserious (nonreportable) adverse events throughout the duration of this study and no serious events (Table 5). Of these nine events, five were device related, including a common superficial fungal infection at the site of the ITM, which resolved with topical treatment. Another patient experienced problems with food becoming impacted between the teeth and the ITM. This resolved with remaking the ITM. Fewer problems were reported with regard to the BTE. One patient had to have the dome removed from the ear canal by an audiologist after it became disconnected from the BTE.

DISCUSSION

Bone conduction is an effective way to deliver sound to the inner ear. Although bone conduction was achieved historically via an osseointegrated conductor, emerging technologies have allowed for bone coupling through dentition (2). One of these devices, the IOBC, was evaluated in this study. Our results show that daily use of the IOBC system is safe and effective in subjects with SSD during a 6-month period, and that these results continue when reassessed at 12 months. Safety of the IOBC was illustrated by the lack of serious adverse events during the study and only a handful of minor nonreportable adverse events related to the device, all of which resolved when addressed. As observed in previous studies, the device does not seem to have any deleterious effects on the baseline hearing, and pretrial and posttrial hearing thresholds at 1 year remained unchanged (1,4,5,8).

In addition to patient safety, overall patient satisfaction is very high and a statistically significant improvement

TABLE 3. *This table shows the difference in APHAB scores between 6- and 12-month outcomes*

APHAB benefit	6 M (SD)	12 M (SD)	*p* value
EC	15.1 (±13.5)	16.3 (±15.8)	>0.05
RE	21.3 (±15.6)	21.1 (±16.5)	>0.05
BN	26.6 (±18.4)	26.5 (±19.6)	>0.05
AV	8.8 (±19.2)	11.0 (±18.8)	>0.05
GL	21.0 (±13.5)	21.3 (±14.7)	>0.05

EC indicates ease of communication; RE, reverberation; BN, background noise; GL, global score; M, months; SD, standard deviation; APHAB, Abbreviated Profile of Hearing Aid Benefit.

TABLE 4. *This table shows the results of the Single-Sided Deafness Questionnaire*

Satisfaction	
88.9%	1. Addressing your hearing problem
92.6%	2. Quality of sound
85.2%	5. Experience of wearing the device
87.7%	7. Ability to speak
55.6%	8. Ability to eat
93.8%	9. Process of getting your device
Improvement	
78.8%	3.1 Hearing in noisy environments
96.3%	3.2 Hearing a person speaking to you on your deaf side
66.3%	3.3 Your ability to tell where sounds are coming from
70.9%	3.4 Your ability to tell how close or far away a sound is
88.8%	3.5 Your ability to participate in group conversations
81.0%	3.6 Your experience of listening to music, TV, or radio
83.8%	3.7 Your overall confidence in group situations
87.5%	3.8 Your overall quality of life
Preference	
90.1%	4. Compared with no device
Acclimatization	
54.4%	6. Acclimated within 4 days
Likely to recommend	
93.8%	10. Likely to recommend this device
Met expectations	
91.3%	11. Met my expectations
Good value for the money?	
59%; 10%; 31%	15. Yes; No; Not sure

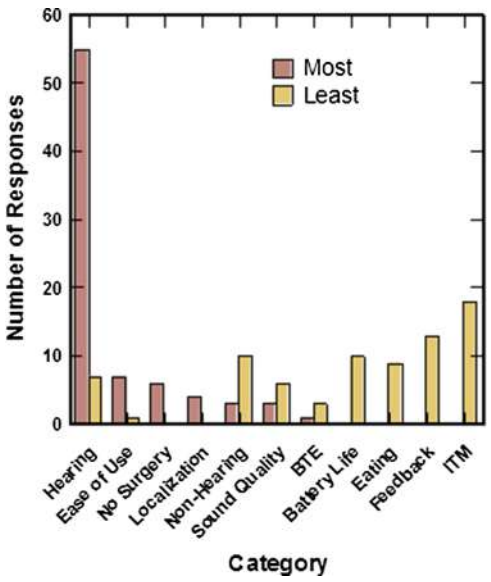

FIG. 2. This figure is a bar graph representing the number of participant responses for most and least liked features of the IOBC.

was seen in each of the four APHAB categories (EC, RE, AV, and BN) as well as in the global score (GL). This APHAB benefit was observed at 6 months and 1 year of use. More than 90% of patients responded that they preferred the device compared with no device and would likely recommend the device. This percentage may be artificially high because nine subjects withdrew from the study secondary to device-related problems and did not complete the evaluation. Subjective improvement in hearing was observed in a number of different situations from noisy environments to group conversations.

Self-reported sound localization of individuals improved somewhat with the use of the IOBC, although this still remains a challenge for patients with SSD. Sixty-six percent of patients subjectively responded that their ''ability to tell where sounds are coming from'' had improved with device use. Although improvement is modest, it may be an improvement over osseointegrated devices for patients with unilateral sensorineural hearing loss; however, formal evaluation using objective measures is warranted. A study by Grantham et al. (9) evaluated horizontal plane localization in patients with SSD and an osseointegrated device using a 33-loudspeaker array. Although improvement was seen in patients with conductive hearing loss, patients with sensorineural hearing loss actually performed worse when using the device. Failure to improve sound localization was observed in other studies as well and certainly continues to be an area of focus for future hearing prostheses (10,11).

When patients were asked to comment on changing one thing about the device, 14 (17%) of 81 indicated a desire for a smaller ITM. This corresponds to patients selecting the ITM as the least liked feature of the IOBC and why many patients struggled to acclimate to the device, especially while eating. Only 55.6% of patients were satisfied with their ability to eat with the ITM in place. This percentage dropped from 68% in the previous study. The buildup of food around the device made eating uncomfortable for several people in the study. This caused them to remove the ITM during meals, thus sacrificing the hearing benefit of the device while eating.

Feedback remained an issue for some patients beyond the 6 months, and it was the second most disliked item with regard to the IOBC. Feedback results from acoustic energy of the bone conduction transducer entering the microphone. The source of the acoustic radiation can differ for each patient. Radiant acoustic energy entering the microphone can originate directly from the ITM, indirectly from the soft tissues touching the ITM (cheek or lateral portion of the ear canal), or from the adjacent hard tissues (the teeth or bony portion of the ear canal) (3). Feedback could often be addressed with adjustment of the gain or refitting of the device, but not all occurrences could be resolved. Displeasure with the battery life followed closely behind feedback for least liked aspects of IOBC. In addition, the battery does not always last an entire work day and some patients found it inconvenient to transport the charger to work so patients typically keep a second ITM with them.

Even with some of the limitations of the IOBC expressed by study participants, these results show that it remains a reasonable alternative to surgically placed percutaneous osseointegrated implants. Osseointegrated implants such as the BAHA (Cochlear Corporation), in addition to requiring an operative procedure, also have potential risks of infection, skin overgrowth, and need for revision surgery (12–16). A study of potential candidates for use of an osseointegrated device revealed that the most common reason for refusing surgery and implantation was concern for social acceptance and cosmetic outcome (17). Direct comparison of an osseointegrated device and the IOBC system was performed in a crossover study done by Moore

TABLE 5. *This table lists all of the adverse events related to using the IOBC*

9	Adverse events (all)		
0	Serious adverse events (reportable)		
	0	Device related	
	0	Procedure related	
9	Nonserious adverse events (nonreportable)		
	5	Device related	
		1 BTE	Dome disconnected, audiologist removed, resolved
		1 BTE	Pain from existing naturally ejected tympanostomy tube, resolved
		1 BTE	Old crown remade, unrelated to ITM use, resolved
		1 ITM	Likely fungal infection, treated, resolved
		1 ITM	Food between teeth, remade ITM, resolved
	4		Non–device related
		1	Lichen planus, unrelated to device
		1	Middle ear infection non-BTE ear, tympanostomy tube, resolved
		1	Death, preexisting cancer, unrelated to device
		1	Shingles, unrelated to device, resolved

BTE indicates behind-the-ear; ITM, in-the-mouth.

and Popelka (2) with nine participants already using a bone-anchored hearing instrument. Patients were monitored for 30 days using their previously implanted bone-anchored hearing instrument device and then switched to the IOBC for 30 days. Results showed that both devices were beneficial for localization and speech perception, but no differences were found between the two. The IOBC did show significant differences in lowering the mid frequency aided thresholds and improving the APHAB scores.

Another nonsurgical alternative for routing sound from the deaf ear to a better-hearing ear is the contralateral routing of signal (CROS) or bilateral contralateral routing of signal hearing aid systems. CROS systems have improved patient satisfaction over older generations of devices that used this technology (18,19). These newer versions of the CROS hearing aids have been shown to improve APHAB scores and sentence recognition in noise for users (20–22). Although there have been studies comparing the CROS to traditional osseointegrated prostheses (22), to date, there has not been a comparative effectiveness trial with CROS, traditional osseointegrated prostheses, and the novel IOCB described in this report.

This study does have a number of limitations. Despite the APHAB being a well-validated way to assess the benefit of hearing prosthesis, the questionnaire responses are subjective and subject to bias. Because this study was designed to gather participant response, the questionnaire was an appropriate way to collect the data. When we compared our 6- and 12-month APHAB results, 65 and 80 patients filled out the two questionnaires, respectively. The 6-month visit was not a required follow-up time, which explains the difference in participation. The results shown in Table 3 have some potential to be skewed because of the differential participation at the two time points, but the 6- and 12-month APHAB results were very similar, with no statistically significant differences. A selection bias is also possible in those patients who were willing to participate in the study as well as providers who have incorporated the IOBC into their practice. These patients and providers may feel more strongly for or against the device than more objective users.

CONCLUSION

The IOBC is a safe and effective hearing prosthesis for patients with SSD. As such, it provides an alternative to osseointegrated hearing implants. The IOBC significantly benefitted patients in APHAB categories of EC, RE, BN, and the overall global hearing score. The ITM transducer is the least liked feature for some patients, particularly with regard to eating; however, a majority of patients are willing to deal with the size of the ITM for hearing benefit gained. Patient satisfaction and improved hearing benefit were observed even after 1 year of using the device.

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Research Article

Effects of SoundBite Bone Conduction Hearing Aids on Speech Recognition and Quality of Life in Patients with Single-Sided Deafness

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Objectives. To analyze the clinical application of SoundBite bone conduction hearing aids by assessing the improvement of speech recognition and the scores of the benefit scale questionnaire for patients with single-sided deafness (SSD). *Design*. Nine patients aged 24 to 61 years with SSD for more than 3 months were enrolled in this study. The patients could understand and repeat Mandarin and have good compliance with the study. The measurements were evaluated before and after one month of wearing hearing aids using the pure tone audiometry threshold, speech recognition in quiet and in noise, and the Glasgow Benefit Inventory (GBI) benefit scale score. *Results*. Pure tone audiometry results showed that the average hearing threshold of good ears and bad ears was 11.4 ± 2.6 dB HL and 89.9 ± 6.4 dB HL, respectively. The average hearing threshold of bad ears after wearing hearing aids was 23.5 ± 9.0 dB HL. Statistical analysis showed that the hearing improvement for the bad ears after wearing hearing aids was significant. The speech audiometry results showed that the disyllable word recognition score of the bad ears in quiet increased significantly at 50 dB SPL by 40 ± 12 percentage points and at 65 dB SPL by 71 ± 15 percentage points. As for the speech recognition in noise, when the signal sound came from the bad ear side and the noise from the good ear side ($S_{SSD}N_{AH}$), the speech recognition score (SRS) significantly increased by 17 ± 6 and 9 ± 4 at a signal-to-noise ratio (SNR) of -2 dB and -5 dB, respectively, after wearing the hearing aids. When the signal sound came from the front of the patient and the noise from the bad ear side (S_0N_{SSD}), the SRS scores were reduced by 5 ± 5 and 7 ± 5 percentage points at SNR equal to -2 dB and -5 dB, which was significantly different from that before wearing the hearing aids. When the signal and noise both came from the front of the patients (S_0N_0), the SRS was not significantly increased by 5 ± 4 percentage points at SNR equal to -2 dB compared to before wearing hearing aids. However, the SRS was significantly increased by 5 ± 2 percentage points at SNR equal to -5 dB compared to before wearing hearing aids. The average total GBI score was 31 ± 12 for the nine patients, with an average score of 32 ± 10, 31 ± 8, and 30 ± 7 for general conditions, social support, and physical health, respectively. The results of the questionnaires showed that patients' quality of life was improved after wearing SoundBite bone conduction hearing aids. *Conclusions*. SoundBite bone conduction hearing aids are a good choice for patients with SSD, as it could improve the speech recognition ability of patients both in a quiet and noisy environment and improves the quality of life after wearing hearing aids.

1. Introduction

Single-sided deafness (SSD) refers to severe to profound sensorineural hearing loss on one side (>70 dB HL) and an average hearing threshold of 0.5 to 4 kHz ≤25 dB HL on the good ear [1]. People with SSD generally do not wear hearing aids because they can depend on the good ear in daily life. Slattery tested the ability of human listeners to localize broadband noise bursts in the absence of binaural localization cues. The patients demonstrate that monaural cues can provide useful localization information in the horizontal as well as in the vertical dimension [2]. However, they often face

barriers for speech communication in a noisy environment, especially when the sound source is on the bad ear side [3]. Patients with SSD often need to turn their head when communicating with others in order to use their good ears, with some patients feeling embarrassed or inconvenienced [4]. Moreover, the SSD patients are not able to distinguish the source of the sound.

Current intervention options for SSD include cochlear implants and hearing aids. Previous studies have shown that cochlear implants in SSD patients can improve speech recognition and sound source localization [5, 6]. However, studies have shown that SSD patients have different benefits after cochlear implantation, and cochlear implants are expensive, which makes patients unwilling to choose cochlear implants. As for hearing aids for SSD intervention, air conduction hearing aids and bone conduction hearing aids can be used. Air conduction hearing aids can be implemented on the bad side or on the healthy side by means of signal transmission. Contralateral routing of the signal system is a choice. Both ears need to be equipped with hearing aids. The auxiliary hearing device is worn on the bad ear to receive signals and transmit them to the contralateral ear. The main hearing device is worn on the good ear to receive and amplify the contralateral signals. Bone conduction hearing aid is another treatment method for SSD, which includes surgically implanted hearing aids and nonsurgically implanted hearing aids. However, implantable bone conduction hearing aids fix the sound processor onto the skull, which generates a large amount of pressure on the skull and can stimulate skin hyperplasia and cause pain in the patient. In addition, the transmission of sound is weakened due to the barrier of soft tissue. Nowadays, BAHA (Cochlear in Australia) is the most commonly used bone conduction hearing aid, which requires surgical implantation. Many patients have concerns about the impact of surgery and the infection on the wound. Studies have shown that 29% of surgical patients will experience infections near the implanted device, soft tissue proliferation, skin irritation, and displacement of implant [7]. In addition, bone conduction hearing aids offer no obvious hearing improvement at frequencies above 4 kHz [8]. Some studies [9–11] have shown that the average air conduction hearing threshold of 0.25 to 4 kHz after the subject wears BAHA was improved by 30.2 to 39.1 dB. Xia et al. tested [12] 12 cases wearing soft-band bone conduction hearing aids; the SRT was improved to 5.91 dB, which was better than naked ears with 13.64 dB. BAHA also has defects in the localization of the sound source in patients with extremely severe SSD. Currently, some controversies about hearing aid gain, sound source localization ability, and speech recognition under noise in implanted patients exist [13, 14]. Therefore, some patients with SSD are reluctant to use implantable bone conduction hearing aids [15, 16].

The advantage of nonimplantable bone conduction hearing aids is that they do not require complicated surgical procedures. A nonimplantable bone conduction device on the skull [17] requires placing a behind-the-ear (BTE) microphone in a hearing-impaired ear to simulate the acoustic characteristics of normal auricles. SoundBite bone conduction hearing aid is such a hearing device. The microphone receives the sound, and then, the sound is processed by BTE digital audio equipment. A removable in-the-mouth (ITM) device is fixed onto the teeth and directly coupled to the skull. The ITM device generates vibration that passes through the skull to the cochlea. The ITM device is directly fixed onto the dental bones, and the sound transmission will not be hindered by soft tissues. The sound transmission efficiency is higher than that achieved by adhesion or clamping.

A previous study compared eight bone conduction hearing aids' maximum output and gain; the researchers found that within the frequency range of 4 to 8 kHz, the maximum output and gain for each bone conduction device were different, with SoundBite demonstrating better performance [17]. In another study, the researchers measured the speech recognition threshold (SRT) with the noise from different directions while wearing SoundBite for SSD patients. The results showed that the SRT was an average of 2.5 dB lower than that without wearing SoundBite with the signal coming from the front and the noise from the good ear side. The SRT did not change when the noise came from the front. The SRT was reduced by 2.3 dB when the noise came from the bad ear side [18]. Also, studies have shown that SoundBite is comparable to, or even better than, BAHA in English speakers.

To date, however, there is no research investigating SoundBite bone conduction hearing aids in Chinese SSD patients. In this study, Chinese speech recognition in quiet and in noisy environments was evaluated before and after wearing the hearing aids. The GBI scale is designed for use only once postintervention, as a measure of change related to a specific surgical or medical intervention. The questionnaire consists of 18 questions answered using a five-point Likert scale, addressing change in health status post any intervention. The responses are then scaled and averaged to give a score with a range -100 (poorest outcome) through 0 (no change) to +100 (best outcome). A positive value indicates that the patient has benefited to a certain degree in quality of life after medical intervention, a zero score indicates no change, and a negative value indicates that the health level has deteriorated after the intervention. It is widely used in otolaryngology to report change in the quality of life postintervention [19]. The GBI scale was used to assess the impact of patients' general conditions, social support, and physical health benefit of hearing aids and to explore the clinical application of SoundBite bone conduction hearing aids in Chinese patients with SSD.

2. Materials and Methods

2.1. Ethics Statement. The study and the informed consent procedures were approved by the local ethics committee (Ethics Committee of the Shanghai Sixth People's Hospital, approval number: 2018-092), and written informed consent was obtained before participation.

2.2. Enrollment Indications. SSD patients who were 18 years or older were enrolled in this study. All the enrolled patients should have SSD history longer than 3 months. Before fitting

Table 1: Characteristics of the single-side deafness patients in this study.

Subject no.	Gender	Age	Deafness ear	Duration of deafness	Causes of deafness
01	Male	61	Right	20 years	Sudden deafness
02	Male	35	Right	20 years	Postoperative acoustic neuroma
03	Female	41	Left	2 years	Postoperative acoustic neuroma
04	Male	40	Right	2 years	Sudden deafness
05	Female	24	Right	3 years	Sudden deafness
06	Female	30	Right	2 years	Sudden deafness
07	Male	46	Left	6 months	Sudden deafness
08	Female	35	Left	More than 30 years	Congenital deafness
09	Female	44	Right	7 years	Postoperative acoustic neuroma

a SoundBite appliance (Sonitus Medical Technology Company, Shanghai), the teeth of the patients were examined completely by a dentist to make sure that the teeth are healthy; there can be no active caries or periodontal or endodontic conditions affecting the abutment teeth [4].

Subjects were excluded if they met any of the following criteria: (1) currently using other hearing aids, such as BAHA, contralateral routing of signals, and TransEar; (2) speech recognition score (SRS) is disproportionately lower than what would be predicted with the pure tone audiometry (PTA); and (3) patients have psychological or mental conditions that may interfere with understanding, informed consent, compliance, and cooperation.

2.3. Basic Characteristics of Patients. Altogether, 9 patients with SSD for more than 3 months were enrolled in this study. The patients aged between 24 and 61 years with an average age of 39.3 ± 10.8 years, including 4 males and 5 females (see Table 1). The patients could understand and repeat Mandarin and demonstrated good compliance to wearing the hearing aid and to the evaluation of the hearing aid. The subjects had an average hearing threshold on the good ear ≤ 25 dB HL across 0.5, 1, 2, and 4 kHz. The etiology for SSD includes 5 cases of sudden deafness, 3 cases of postoperative acoustic neuroma, and 1 case of congenital unilateral sensorineural hearing loss.

2.4. Hearing Aid Fitting. During the whole study, the devices were fitted using the open SoundBite fitting software. The gain was adjusted to the most comfortable level for the patient. PTA was tested after adjustment. The fitted PTA must meet the criteria that the difference between the average air conduction hearing threshold (averaged across 0.5, 1, 2, and 4 kHz) after fitting and that in the healthy ear is within 15 dB. Feedback noise cancellation was turned on if there was howling.

2.5. Testing Procedure. The patients completed the PTA and tympanogram test before wearing a hearing aid. The Middle Ear Analyzer (Flute Basic, Italy) was used for the tympanogram. PTA tests were performed in a sound-proofed room with noise less than 30 dB (A) and a calibrated GSI-61™ audiometer (The United States) coupled with TDH 39 headphones.

The speech audiometry test was performed in a standard sound-proofed room with noise less than 30 dB (A) calibrated sound field. Before the test, the subjects were familiarized with the test process. The subjects were required to repeat what they heard; then, the audiologist judged whether the restatement was correct. After the test, the system will automatically calculate the SRS and display the results.

The materials named XinAiFeiYang issued by the People's Liberation Army General Hospital of Chinese were used for disyllable word recognition in quiet. The material includes 5 test lists, each list contains 40 words, which are enough to make the consonants and tones present in each list representative of those in the language used in daily life [20]. It has been clinically verified by many centers that it can meet the clinical requirements for test reliability, validity, and practicality [21]. Disyllable word recognition test was performed with a calibrated audiometer (Astera Conera, Denmark). TDH39 headphones were used to test the disyllable word SRS at 50 and 65 dB sound pressure level (SPL) which represents low and medium sound levels for communication.

The Mandarin HINT materials were used for SRS under noise. The Mandarin HINT test materials were donated by the House Ear Research Institute. It includes an exercise list, 12 test lists, and 20 sentences each list. Two calibrated loudspeakers (System 600, Tannoy) were used to present the sound. Both loudspeakers were placed at 1 m distance from the subject's head. The SRS under noise was evaluated under the following sound field conditions: (1) the signal sound came from the bad ear side and the noise from the good ear side ($S_{SSD}N_{AH}$), (2) the signal sound came from the front of the patient and the noise from the bad ear side (S_0N_{SSD}), and (3) the signal and noise both came from the front of the patients (S_0N_0). The noise for SRS is steady-state noise, which is spectrally matched to the average spectrum of the sentences. The sentence recognition score was measured at a noise intensity of 65 dB SPL and SNR of -2 and -5 dB.

The subjects underwent PTA, the abovementioned speech audiometry test before and after one month of wearing hearing aids, and the GBI questionnaire test one month after wearing a hearing aid. The impacts of SoundBite bone conduction hearing aids on hearing and speech audiometry results were analyzed before and after wearing the hearing aids, and the GBI questionnaire score result was analyzed after wearing the hearing aids.

All tests and the GBI questionnaire evaluation were performed by an experienced and professionally trained audiologist.

2.6. Statistical Analysis. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS) version 19.0 (Chicago, IL, USA). The hearing thresholds, SRS under quiet and noisy environment between before and after wearing hearing aids, were compared with paired-sample t-tests.

3. Results

3.1. Pure Tone Audiometry. The average hearing threshold of good and bad ears before wearing the hearing aids was 11.4 ± 2.6 dB HL and 89.9 ± 6.4 dB HL, respectively. The average hearing threshold of bad ears after fitting the hearing aid was 23.5 ± 9.0 dB HL (see Figure 1), representing a significantly improved hearing of 66.4 ± 14.9 dB compared to that before wearing the hearing aid ($p < 0.001$).

3.2. Speech Audiometry in Quiet. The disyllable word SRS under quiet condition at 50 and 65 dB SPL for the good ears was 70 ± 20% and 89 ± 16%. The SRS in quiet at the two intensities was both 0% for the bad ears before wearing the hearing aids. After wearing the hearing aid, the SRS for the bad ears, obtained at 50 and 65 dB SPL, was increased by 40 ± 12 and 71 ± 15 percentage points (see Figure 2), respectively. The differences of SRS between before and after wearing the hearing aid were significant for both speech intensities ($p < 0.001$).

3.3. Speech Audiometry in Noisy. The speech recognition in noise was evaluated with sentence materials. When the signal came from the bad ear side and the noise came from the good ear side ($S_{SSD}N_{AH}$), the SRS scores were 28 ± 17% and 9 ± 10% without a hearing aid with the SNR at -2 dB and -5 dB, respectively. After wearing the hearing aid, the SRS scores were 45 ± 16% and 18 ± 9%, which significantly increased by 17 ± 6 and 9 ± 4 percentage points compared to that before wearing the hearing aid ($p < 0.001$).

When the signal came from the front of the patient and the noise came from the bad ear side (S_0N_{SSD}), the SRS scores were 95 ± 3% and 84 ± 7% without a hearing aid with the SNR at -2 dB and -5 dB, respectively. After wearing the hearing aid, the SRS scores were 90 ± 5% and 77 ± 8%. The SRS scores were reduced by 5 ± 5 and 7 ± 5 percentage points with the two SNRs, respectively. The differences between the two SRSs before and after fitting the hearing aid were statistically significant ($p < 0.05$).

When the signal and noise both came from the front of the patients (S_0N_0), the SRS scores were 75 ± 9% and 43 ± 11% without a hearing aid with the SNR at -2 and -5 dB, respectively. After wearing the hearing aid, the SRS scores were 80 ± 10% and 48 ± 11% with the two SNRs, respectively. The SRS was not significantly increased by5 ± 4 percentage points with the SNR at -2 dB compared with that before wearing hearing aids ($p > 0.05$); however, the SRS was significantly increased by 5 ± 2 percentage points with the SNR at -5 dB compared with that before wearing hearing aids ($p < 0.05$) (see Figure 3).

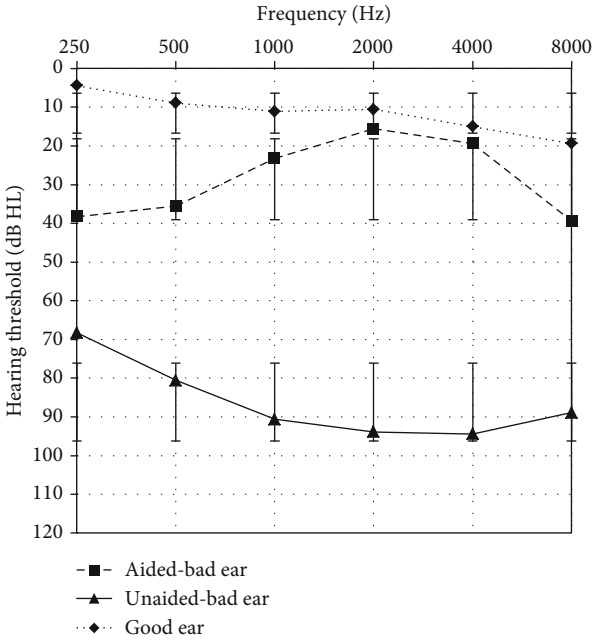

Figure 1: Average pure tone thresholds of SSD patients at frequencies of 250 to 8000 Hz before and after wearing a SoundBite bone conduction hearing aid. The lines represent the threshold of the good ear, the bad ear without the hearing aid, and the bad ear with the hearing aid. The bars represent one standard deviation.

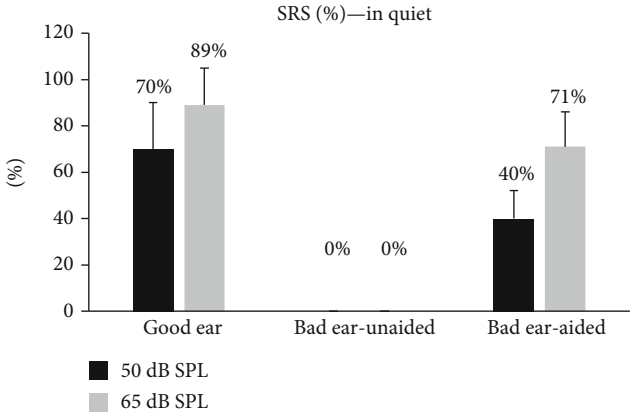

Figure 2: Disyllable word SRS under quiet environment of the good ear and the bad ear before and after wearing SoundBite bone conduction hearing aids for SSD patients at sound intensity 50 and 65 dB SPL. The bars represent one standard deviation.

3.4. GBI Score. The average GBI total score from the nine patients was 31 ± 12, with the average scores for the three subscales of general, social support, and physical health of 32 ± 10, 31 ± 8, and 30 ± 7, respectively. The results of the questionnaires showed that patients' quality of life improved significantly after wearing SoundBite bone conduction hearing aids (see Figure 4).

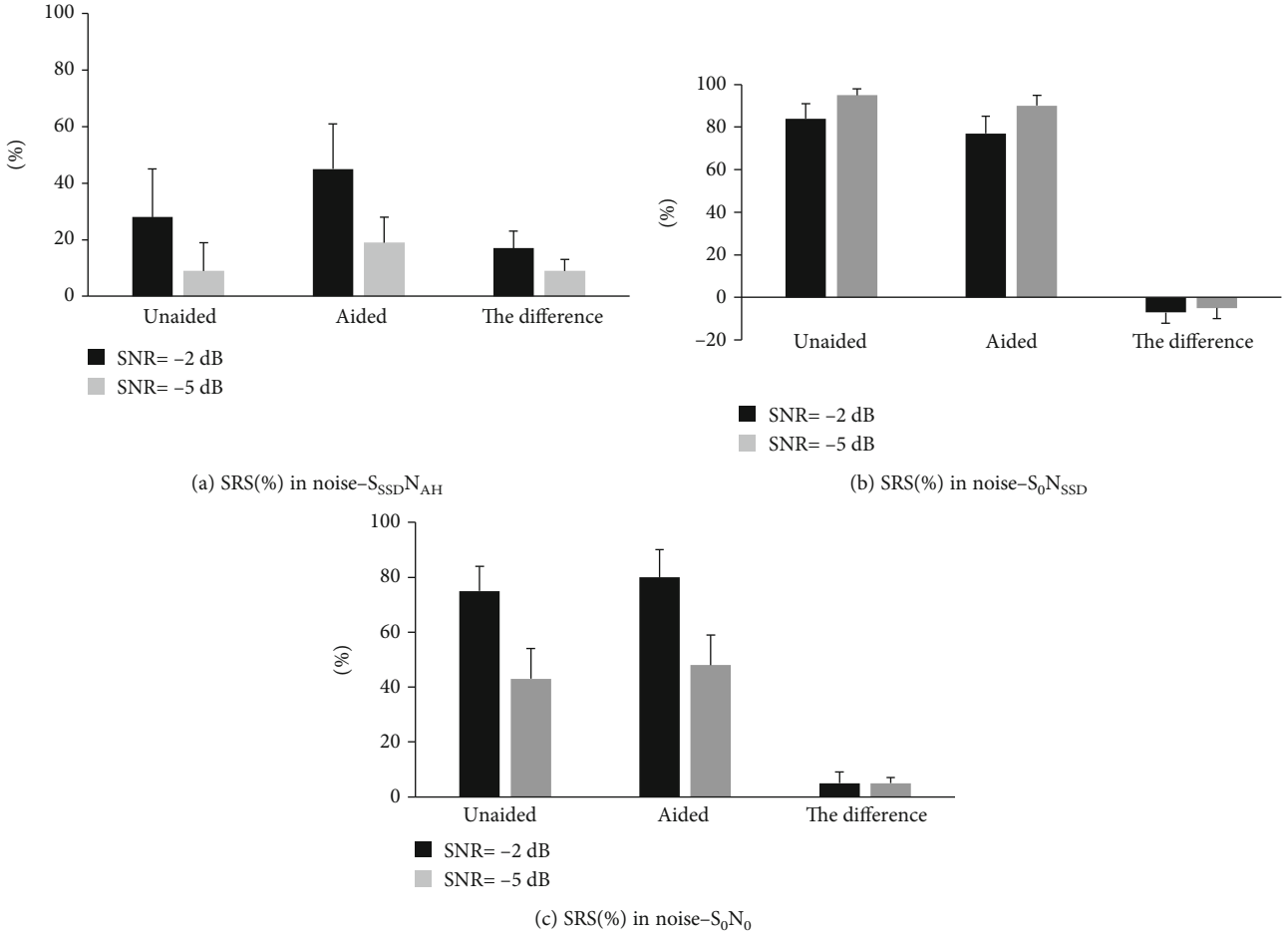

Figure 3: SRS under noisy environment before and after wearing SoundBite bone conduction hearing aids for SSD patients. The noise was at 65 dB SPL, and the SNR was equal to −2 and −5 dB. (a) $S_{SSD}N_{AH}$: the signal sound came from the bad ear side and the noise came from the good ear side. (b) S_0N_{SSD}: the signal sound came from the front of the patient and the noise came from the bad ear side. (c) S_0N_0: the signal and noise both came from the front of the patients. The bars represent one standard deviation.

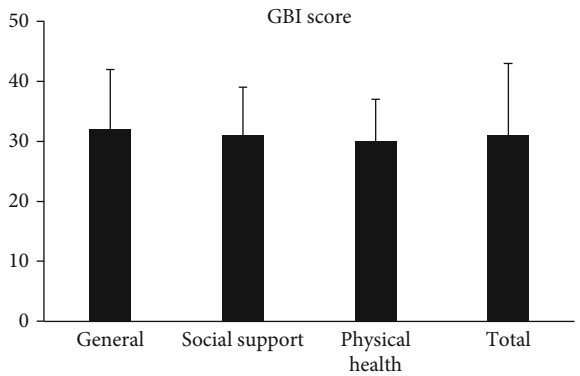

Figure 4: Glasgow Benefit Inventory (GBI) scores after wearing SoundBite bone conduction hearing aids for SSD patients. The total score and three subscale scores of general, social support, and physical health are shown separately. The bars represent one standard deviation.

4. Discussion

In this study, 9 patients with SSD wore SoundBite bone conduction hearing aids for one month. Their hearing, speech recognition, and life benefits were evaluated before and after one month of wearing. This study was first performed in Mandarin Chinese speakers with speech tests using Chinese materials. The results showed that after wearing the hearing aid, the air conduction hearing threshold (across 0.5-4 kHz) decreased by 66.4 ± 14.9 dB for the bad ear. Under a quiet environment, the disyllable word SRS in the bad ear was improved by 40 ± 12 and 71 ± 15 percentage points after wearing the hearing aid with the speech signal at 50 and 65 dB SPL, respectively. Under a noisy environment, the SRS was increased by 17 ± 6 and 9 ± 4 percentage points with $S_{SSD}N_{AH}$ at SNR -2 and -5 dB, respectively. The SRS scores were reduced by 5 ± 5 and 7 ± 5 percentage points with S_0N_{SSD} at SNR -2 and -5 dB, respectively. The SRS scores were improved by 5 ± 4 and 5 ± 2 percentage points with S_0N_0 at SNR -2 and -5 dB, respectively. The GBI benefit scale showed that the general conditions, social support, and physical health were improved after wearing the hearing aid.

Our study showed that the average aided hearing threshold for frequencies across 0.5, 1, 2, and 4 kHz was 23.5 dB HL. These results are consistent with previous studies, which showed the aided threshold of 21.3 dB for frequencies across 1, 2, 3, 4, and 6 kHz after wearing SoundBite for one month

[22]. A previous study showed that BAHA is less effective at a frequency compensation of 4 kHz and above. This may be related to the attenuation of high-frequency sound vibration through subcutaneous tissues; thus, the acoustic signal could be weakened by 10-15 dB [23]. Our study showed that the average hearing threshold for frequencies across 4 and 8 kHz after wearing SoundBite was 29.4 dB HL. Therefore, SoundBite hearing aids are better than BAHA in the improvement of hearing at medium and high frequencies, which is critical for speech clearance and helps to improve speech intelligibility and speech recognition [14].

Disyllable word has an important value in auditory speech evaluation [24]. The results of this study showed that in patients with SSD, the SRS for disyllable word under quiet is increased with the signal at the bad ear side, especially at a moderate sound level. The SRS at the soft sound level of 50 dB SPL increased by 40 percentage points, and the SRS at a moderate sound level of 65 dB SPL increased by 71 percentage points after wearing the hearing aid, representing significant differences compared to that before wearing the hearing aid ($p < 0.001$). After wearing SoundBite, the improvement at moderate sound intensity was better than that at soft sound intensity, suggesting that the speech recognition of patients in a quiet environment was greatly improved at the everyday life sound level.

Spatial hearing and binaural hearing play an important role in the localization of sound sources, especially in a noisy environment. The main reason for speech recognition disturbance in a noisy environment for patients with SSD is the head shadow effect [25]. This is a physical phenomenon caused by the blocking of the sound by the head. When the sound reaches the opposite ear, it is attenuated and results in the SNR of the side closer to the signal higher than that in the other ear. Therefore, people are able to benefit from the head shadow effect regardless of the direction of the noise [26]. The results of this study showed that speech recognition improved significantly in both SNRs of -2 and -5 dB. In a previous study of 28 patients who wore SoundBite for 6 months, the speech recognition threshold decreased by 2.5 dB [18], which is equivalent to 25 percentage points increase in SRS, as 1 dB decrease in speech recognition threshold is equivalent to 10 percentage points increase in SRS [27]. The difference between these two studies could be explained by the difference in the configuration of speech and noise. Although the noise in both studies was on the good ear side, the voice in this study came from the bad ear side while the speech in Murray's study came from the front. The head shadow effect in this study increased the difficulty of speech recognition. Therefore, the SRS in noise seems to be a little lower than that in Murray's study. Moreover, the small sample size of this study and the short wearing time may also explain the difference between these two studies. A previous study comparing the SRT after wearing SoundBite one day and one month showed that the increase by 0.8 dB between one day and one month was statistically significant [18]. Therefore, the speech improvement could be more significant with the extension time of wearing the hearing aids. The speech audiometry was evaluated after one month of wearing in this study, while it was evaluated after 6 months of wearing in Murray's study. It may be expected that the effect on SRS will gradually increase with the longtime use of the hearing aid by the patients. The improved head shadow effect in SSD patients wearing SoundBite could be explained by the output of the device. Mark found that the maximum output frequency of SoundBite is above 2 kHz, which help the patients overcome the head shadow effect, so the SRS under noise was improved significantly by SoundBite bone conduction hearing aids [17].

When the signal and noise both came from the front of the patients (S_0N_0), both ears receive the signal and noise, which is different from listening with one ear, the subject hears louder. The subjects rely on the redundant information provided at the two ears, enhanced detection of smaller differences in signals, and improved speech recognition [28]. The auditory system is able to adjust the signals arriving at both ears by using the distinct time, level, and spectral cues occurring between the two ears. This permits a better separation of target and masker and improves intelligibility of the desired signal [29]. Gantz studied 10 patients with bilateral cochlear implants at condition S_0N_0 and found the SRS increased by 10.6 percentage points [30]. Our result obtained from the condition S_0N_0 showed that the SRS under noise environment increased significantly after wearing the hearing aid, which is consistent with the results obtained from bilateral cochlear implants.

While for the condition S_0N_{SSD}, the signal came from the front of the patient and the noise from the bad ear side, the noise and the signals are spatially separated. Our results show that the SRS deteriorates after wearing aid. The main reason is that when the noise is located at the bad ear side, the noise is amplified by the SoundBite and also be transmitted to the good ear side. As a result, the SNR of the good ear decreases and the noise interference results in a decrease in speech recognition.

SSD patients cannot accurately determine the sound source and need to turn their heads to find the sound. Moreover, speech recognition is not ideal in a noisy environment, which greatly affects the quality of life of patients [31, 32]. The abbreviated profile of hearing aid benefit (APHAB) hearing aid gain scale is usually used to evaluate the benefit of SoundBite. Studies have shown that the average APHAB score with SoundBite was 23.2, which was higher than the BAHA score -7 to 17 [33–36]. In this study, the GBI benefit scale was used to evaluate the general conditions, social support, and physical health of patients with SSD after wearing SoundBite. The average score after wearing SoundBite was 31 ± 12. A previous study using GBI to evaluate the life quality showed that GBI questionnaire total score with the Sophono Alpha 2 transcutaneous bone-anchored sound processor was 14 ± 11.0, with subscale general situation score 18 ± 18.3, social support score 18 ± 22.7, and physical health score -4 ± 11.1 [37]. The scores in all aspects were worse than those of the SoundBite in this study, especially for the impact of hearing aids on physical health. The main reason for significant improvement is that the SoundBite does not require surgery, which reduces the patient's fear and the chance of postoperative infection. Also, the device without surgery can gain more support from family members and

friends. The easy procedure to remove the device also makes the subjects feel convenient. All these factors result in higher GBI score compared with that of implanted bone conduction hearing aids.

5. Conclusions

SoundBite bone conduction hearing aids are beneficial for SSD patients. It could improve the speech recognition ability of patients in a quiet and noisy environment and quality of life after wearing it for one month. However, the sample size in this experiment is small, and the long-term effects of this device on the speech recognition and quality of life under various listening environment should be explored in further clinical research.

Data Availability

The form data used to support the findings of this study are available on request to the corresponding author: Dr. Yanmei Feng, email: feng.yanmei@126.com.

Additional Points

Research direction is audiology and vestibular function evaluation.

Conflicts of Interest

The authors have no conflicts of interest to disclose.

Authors' Contributions

Qiong Luo and Ying Shen contribute equally to the paper.

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·论著·

牙骨传导助听器对基牙影响的初步研究

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【摘要】 **目的**：初步探索单侧耳聋患者短期内佩戴牙骨传导助听器的对佩戴区域口腔健康情况的影响，为牙骨传导助听器的推广与应用提供指导依据。**方法**：2018 年 10 月至 2019 年 5 月间于中国人民解放军总医院招募符合条件的单侧耳聋患者共 18 人，为患者制作口内助听器部件并教会其佩戴，佩戴时间为 8 周。所有患者在研究前后对基牙进行检查，记录探诊深度、探诊出血、松动度情况，并观察是否有明显不良反应情况。**结果**：18名受试患者均配合良好，共 36 颗牙齿纳入研究，均为上颌第一、二磨牙。佩戴前后基牙的探诊深度分别为 3.04±0.59mm、3.06±0.57mm，无统计学差异；探诊出血率在试验前后为 13.89%±8.66%、15.72%±8.60%，无统计学差异；所有牙齿松动度均无变化。**结论**：短期内佩戴牙骨传导助听器并不会引起基牙的探诊深度加深、探诊出血，松动度无加大，具有一定的安全性，但需要大样本、长期的研究来进一步验证。

关键词：牙骨传导助听器；单侧耳聋；探诊出血；探诊深度

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A preliminary study on the effect of intraoral bone conduction device on abutment teeth

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[Abstract] Objective: To explore the effect of wearing intraoral bone conduction device on the oral health of patients with single-sided deafness in a short period of time, so as to provide guidance for the promotion and application of intraoral bone conduction device. **Methods:** Ffrom October 2018 to May 2019, a total of 18 patients with unilateral deafness were recruited the Chinese PLA General Hospital. The patients were taught to wear the components of intraoral devices for 8 weeks. All patients took panoramic tomography, and were examined the abutment teeth before and after the study, recorded the probing depth, bleeding on probing, tooth mobility, and observed whether there were obvious adverse reactions. **Results:** all the 18 patients were well cooperate, and 36 teeth were included in the study, all of which were the first and second maxillary molars. There was no statistical difference in the probing depth of abutment teeth before and after wearing, which was 3.04±0.59mm and 3.06±0.57mm, respectively; the bleeding on probing rate was 13.89%±8.66% and 15.72%±8.60% before and after wearing, which also had no statistical difference; there was no change in the mobility of all teeth. **Conclusion:** it is safe to wear intraoral bone conduction device in a short period of time. However, the large sample and long-term research is needed to further verify.

Key words: intraoral bone conduction device; single-sided deafness; probing depth; bleeding on probing

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牙骨传导的助听器(SoundBite™)是利用牙齿实现声音骨传导的一类助听器。相比于目前的听力受损干预手段，其优势在于不需要复杂的外科手术植入，只需要在患者牙齿上配戴类似于活动义齿的助听装置，其内置有微型震荡器将信号直接传到内耳实现声音的感知，且研究表明其传声效率高于黏附或夹持于头颅的其他非植入式骨传导设备。单侧聋(single-sided deafness，SSD)或不对称性听力损失(asymmetric hearing loss，AHL)患者由于双耳总

和效应及静噪效应缺失、出现头影效应并影响声源定位能力，给患者的生活、工作等带了不便与困扰。[1]目前已有的研究显示牙骨传导助听器在单侧耳聋的患者中有较好的治疗效果，但因其是佩戴于口腔中，依靠牙齿固位，其对口腔的影响尚不完全明确。本研究旨在初步探索佩戴牙骨传导助听器的单侧耳聋患者在短期内对佩戴区域口腔情况的影响，为将来牙骨传导助听器的推广与应用提供指导依据。

1. 对象和方法

1.1 研究对象　本研究获得中国人民解放军总医院伦理委员会的批准。2018 年 10 月至 2019 年 5 月期间于中国人民解放军总医院招募的单侧耳聋患者，共 18 人，纳入与排除标准为：

1.1.1 纳入标准　(1)年龄在 18 岁至 80 之间的中国人群，男女不限；(2)诊断为单侧感音神经性听力损失，确诊不小于 3 个月；(3)经研究者判定能听懂并会讲普通话；(4)签署知情同意书并能按照所规定的时间 2 个月内来医院进行 3～4 次随访；(5)上后牙有连续两颗牙齿(可为种植牙，但不能为活动假牙)。无重度牙周病、颌面部肿瘤，无正在进行的口腔治疗(如正畸治疗等)。

1.1.2 排除标准　(1)听力测试不符合要求者；(2)受试者后牙区无两颗连续的牙齿，或牙齿有明显龋坏、根尖周炎、牙髓炎；(3)受试区牙齿松动 II°及以上或探诊深度大于 5mm；(4)患者由于咽反射明显等原因导致的无法取牙列模型、或无法忍受口内佩戴助听器部件。

1.2 研究方法　本研究所有患者的听力筛选具由我院耳鼻喉科医师进行，所有患者佩戴的牙骨传导助听器系统为 SoundBite™ 品音® 牙骨传导听力系统(声陀医疗科技有限公司，上海，如图 1 所示)。

图 1　SoundBite™ 品音®牙骨传导听力系统口内机佩戴示意图

在研究开始前，每位受试者拍摄全口曲面断层片，确定受试对象复合纳入条件，并根据患者口内具体情况，由两位口腔医师选定做助听器的部位，对患者目标牙齿进行探诊，记录探诊深度、探诊出血情况。采用硅橡胶为受试者制取口腔牙列印模，记录咬合关系，并灌制石膏模型，在模型上为患者制作口内助听器部件。随后为患者进行佩戴，将助听器口内机部分调整至松紧适宜，并充分教会患者自行摘戴，同时进行口腔卫生宣教，告知其口腔卫生维护方法。8 周后结束佩戴，并再次对患者的受试部位的牙齿进行探诊，并观察局部是否有红肿或探诊出血情况，记录是否有某些不良反应或者症状。

1.3 数据收集

1.3.1 牙齿检查　由两名口腔医师在试验开始前及结束后对选定区域的两颗牙齿进行标准牙周探诊，每个牙齿分为六个位点，即颊侧近中、中部、远中；舌侧近中，中部、远中，记录探诊深度。是否有探诊出血的情况，并记录所有探诊位点中出血位点数。

对受试区域牙齿进行松动度测试，根据情况将其分为：不松、Ⅰ°、Ⅱ°、Ⅲ°。

1.3.2 口腔不良情况　在受试者每次随访时由相同的口腔医师检查患者的口腔，观察是否有某些改变，例如红肿、溃疡等。同时对患者佩戴期间的情况进行询问，如果受试者由相关问题则进行记录，查找原因并进行解决。

1.4 统计方法　使用 SPSS 19.0 软件进行统计分析，采用描述性统计评价受试者的基本人口学数据，对于受试者牙齿探诊深度的变化、探诊出血变化采用配对 t 检验，$P<0.05$ 认为有统计学差异。

2. 结果

2.1 患者的基本资料　本研究最终纳入患者 18 名，其中男性 10 名，女性 8 名，8 人基牙位于右上颌，10 人位于左上颌(表 1)。所有受试患者均良好配合完成试验，无中途退出者。

2.2 基牙情况变化

2.2.1 探诊深度　共有 36 颗牙齿纳入研究，均为上颌第一、第二磨牙。所有受试者佩戴前的基牙探诊深度为 3.04±0.59mm；试验结束后基牙探诊深度为 3.06±0.57mm(表 2)。配对 t 检验显示 $t=-1.12$，$P=0.28$，无统计学差异。

表 1　受试者基础信息表

受试者序号	性别	年龄	佩戴部位
1	男	18	16-17
2	女	51	26-27
3	女	24	26-27
4	男	52	26-27
5	男	61	26-27
6	男	39	26-27
7	男	55	16-17
8	男	29	26-27
9	女	59	16-17
10	男	37	16-17
11	女	27	26-27
12	男	36	16-17
13	男	49	16-17
14	男	35	26-27
15	女	29	16-17
16	女	66	26-27
17	女	55	16-17
18	女	51	26-27

表 2　受试者探诊深度及探诊出血情况

受试者序号	探诊深度均值(mm)		探诊出血位点数		牙齿松动度			
					佩戴前		佩戴后	
	佩戴前	佩戴后	佩戴前	佩戴后	6	7	6	7
1	2.00	2.17	0	1	不松	不松	不松	不松
2	2.75	2.75	1	1	不松	不松	不松	不松
3	2.00	2.08	1	0	不松	不松	不松	不松
4	3.67	3.58	3	4	Ⅰ°	不松	Ⅰ°	不松
5	3.50	3.58	2	3	不松	不松	不松	不松
6	2.67	2.58	1	2	不松	不松	不松	不松
7	4.17	4.17	4	3	Ⅰ°	Ⅰ°	Ⅰ°	Ⅰ°
8	3.08	3.25	2	2	不松	不松	不松	不松
9	3.25	3.25	1	2	不松	不松	不松	不松
10	3.25	3.33	2	2	不松	不松	不松	不松
11	3.42	3.42	2	2	不松	不松	不松	不松
12	3.42	3.33	2	3	不松	不松	不松	不松
13	3.00	2.92	1	3	不松	不松	不松	不松
14	2.83	2.92	1	1	不松	不松	不松	不松
15	2.08	2.17	0	1	不松	不松	不松	不松
16	2.83	2.75	2	1	不松	不松	不松	不松
17	3.50	3.58	3	2	Ⅰ°	不松	Ⅰ°	不松
18	3.25	3.25	2	1	不松	不松	不松	不松

2.2.2 探诊出血　在试验开始前，216 个探诊位点中有 30 个位点探诊出血阳性，总平均探诊出血率为 13.89%±8.66%；有 34 个位点出血阳性，总平均探诊出血率为 15.72%±8.60%(表 2)，统计结果显示无统计学差异，P=0.339。

2.2.3 松动度　36 颗基牙中有 4 颗牙齿(3 人次)在实验开始前为 I°松动，其余牙齿均不松动。在试验结束后，所有牙齿松动度均无变化，详见表 2。

2.3 患者不良症状　18 名受试者在整个研究过程中，口腔医师未检测到受试区牙齿不良的症状。1 名受试者佩戴区域检测到有压痕，可能是由于口内机制作过紧导致；有 1 名受试者自述在佩戴期间有口腔溃疡出现，后经证实在佩戴区对应的颊黏膜有红色充血区，未做处理且很快缓解；1 名受试者由于倒凹明显反应每次摘戴困难；1 名受试者由于基牙临床冠高度不足，咀嚼时偶有咬合干扰情况发生，但对日常进食无明显影响。

本次研究中通过与耳鼻喉科的医生配合我们也对患者的听力改善情况进行了研究，但不是此文章关注重点，将在其他文章中另行介绍。

3．讨论

单侧听损发病率在全球范围内较高，美国有将近 900 万人，成人的发病率为 7.20%，每年有 6 万名新增单侧听损患者，而英国每年约 7500 名新增单侧听损患者[2–5]。当患者的听力出现问题后，也可以利用口腔中的余留牙齿制作助听器来实现对患者听力的改善，实现利用牙齿来感知声音。简单来说此类助听器通常分为两部分，一个组件是可移动式入耳式(BTE)麦克风单元，可通过将麦克风放置在较差的耳朵的耳道中来捕获正常耳廓和外耳道的声音。第二个组件是可移动的口腔内(ITM)设备，类似于小型局部可摘义齿，它不需要外科手术，通过一个紧贴上颌磨牙颊面的换能器，使声音通过颅骨传导到达正常听觉耳蜗[6]。

目前已有的研究显示使用 SoundBite™ 品音® 牙骨传导听力系统可以有效的缓解由于 SSD 导致的听力受损，使患者获益。但由于其有一部分关键的部件(口内机部分)位于口腔内，因此必须确保口腔内的部件不会引起相关的口腔问题，且不能影响正常的口腔功能或口腔健康。从可摘义齿应用悠久历史中就可以知道，传统的可摘局部义齿会影响某些口腔功能，例如唾液分泌，发音和进食，但这些影响非常轻微，短暂，易于接受。作为一种新的单侧听力受损治疗装置，只有在保证其安全性的情况下，才能最终被患者接受并广泛应用。Michael Murray 等通过一系列研究显示，受试者佩戴 30 天、3 个月、6 个月的结果显示，该装置可以有效的提高受试者的听力，而且没有给受试者带来牙体、牙周、黏膜等方面的不良反应[7,8]。Richard K. Gurgel

等通过非随机对照临床研究显示，受试者的听力得分显著提高，无论是在沟通便利性、杂音感扰等情况下。[9]但同时作者也报告了一例真菌性的感染，经过简单的治疗很快好转[9]。在体外研究中，没有发现与口内机接触的人离体牙齿表面磨损的迹象，在模拟使用 1.5 年后，在 10 倍或 40 倍放大下均未观察到牙齿表面变化[10]。从相关研究者的结论可以看出，SoundBite™ 可以为患者带来巨大的改善，且具有安全性，但是目前国内尚无相关的研究数据。

我们目前的研究显示，18 名受试者短期内佩戴 SoundBite™ 的口内机并未对基牙本身带来明显不良的影响，虽然从探诊深度、探诊出血率的数值上看略有所增加，但是统计结果显示，试验前后的数据无统计学差异。整个过程中仅有一例受试者在对应的口腔黏膜区域出现红肿充血情况，可能是患者初次佩戴助听器对黏膜摩擦所致，这和临床上牙列缺失患者初次佩戴局部义齿的不良反应有些类似。Miller R 等通过半口对照研究显示，对对侧牙齿相比，基牙佩戴助听器并未导致明显的牙龈退缩，并未引起探诊深度增加，因此认为助听器的口内机不会对受试者的牙齿结构造成不良的影响。[11]这些结果与我们的研究结果相类似。

SSD 或 AHL 可在不同的年龄阶段出现，本次研究中，共有 2 名 60 岁以上的此类患者纳入，虽然例数不多，但是在临床助听器制作、患者自我佩戴的过程中，均未发现与年轻患者的不同，这提示我们此种助听器的口内机使用范围比较广，年龄大的患者也可以适应。但应注意 SoundBite™ 的口内机需要后牙区有两颗连续的牙齿存在方可行使功能，相比较于年轻的患者，老年患者可能存在各种原因导致的后牙缺失而不符合佩戴条件的情况，这也可能是导致本研究老年患者较少的原因之一。

此外，通过本次研究，我们也发现一些临床问题。如果患者佩戴前最好进行口腔的全面检查及处理，例如口腔洁治、楔状缺损充填，彻底清除口腔佩戴区域内牙齿上的牙结石、减小倒凹，利于维护基牙健康以及口内机的制作与佩戴。对于男性患者，一般上颌牙弓比较宽大，如果患者的拟佩戴区域有智齿，则有可能导致常规的托盘不能很好的将该区域的模型复制完整，此时可以建议患者拔除智齿或者采用光学口腔扫描系统复制患者的牙列与口腔情况，以期获得精准的模型，提高助听器口内机的匹配性。某些患者由于张口受限，导致印模制取困难而筛败未入组，对于此类患者也可借助口腔光学扫描方法。因此虽然此种助听器具有无创性，效果良好，但尚需进一步改进，以适应不同的单侧听力受损患者。在向患者交付设备前，应该充分的教会患者摘戴与日常保养，告知其可能出现的情况，并告诉他们应对措施，增强他们使用信心，帮助其快速适应。

4．总结

我们的研究显示短期内佩戴牙骨传导助听器并不会引起基牙的探诊深度加深、探诊出血，松动度无加大，具有一定的安全性。但因本研究纳入样本较少，观察周期较短，将来需要大样本、长期的研究来进一步验证。

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·新技术新材料·

牙骨传导听力系统对成人单侧感音神经性听力损失患者干预早期的听力学成效分析

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【摘要】 目的 分析 SoundBite™/品音®牙骨传导听力系统（通过牙齿上配戴微型骨振器将声信号直接传至健侧耳蜗）对单侧感音神经性听力损失患者干预早期的听力改善情况，探讨该装置的应用前景。**方法** 招募单侧感音神经性听力损失成人患者 18 例，其中男 10 例，女 8 例，年龄 19~66 岁；纯音测听 500、1 000、2 000、4 000 Hz 四频率纯音平均听阈患耳≥70 dB HL，健耳平均听阈均≤30 dB HL。其中先天或自幼单耳失聪 8 例，突发性聋 7 例，梅尼埃病 1 例，听神经瘤术后 1 例，慢性中耳炎术后失聪 1 例。患者上颌后牙槽部位须至少一侧有连续两颗牙齿，以保证微型骨振器（称为口内机）的制作与日常佩戴。成效观测期限为配戴 SoundBite™/品音®装置后的（30±7）d，未同时使用其他单侧聋干预装置。成效评估包括：应用 TDH50P 气导耳机测试患侧助听前后的纯音听阈；以“心爱飞扬”言语测听软件测试患耳在 50、65 dB SPL 声级下的单音节识别率；在声场中采用普通话版矩阵式语句（CMNmatrix）测试信噪不同方位下的信噪比识别阈（50% threshold of signal-to-noise ratio，SNR_{50}），以反映患者头影效应、静噪效应及双耳加合效应；采用助听器效果缩略简表（Abbreviated Profile of Hearing Aid Benefit，APHAB）、言语-空间-听音质量（Speech，Spatial and Qualities of Hearing Scale，SSQ）问卷来评价患者使用牙骨装置后的助听效果、空间言语感知等方面的改善程度。**结果** 配戴 SoundBite™/品音®装置 30 d 后，患侧助听听阈和单音节识别率均显著提高（P 值均<0.001）；声场中患侧扬声器播放语句而健侧播放稳态言语谱噪声时的 SNR_{50} 下降幅度（反映头影效应）为（2.6±2.1）dB；而患者前方播放语句而患侧播放噪声时的 SNR_{50}（反映静噪效应）降幅则为（0.3±2.8）dB，差异无统计学意义（P 值均>0.05）；患者前方同时播放语句和噪声时的 SNR_{50} 下降幅度（反映加合效应）为（1.0±2.2）dB。APHAB 的四个亚项中 EC（交流便利）、RV（混响环境）、BN（嘈杂背景）三个亚项及整体得分均有显著提升（P 值均<0.01）；更能反映单侧聋交流困境的 SSQ 问卷中，事关空间听觉、言语识别及听音质量的得分均有显著性的改善（P 值均<0.05）。**结论** SoundBite™/品音®牙骨传导听力系统干预早期成效表明，其能显著提升单侧聋患侧的听力及言语识别能力，帮助患者克服在声场噪声环境下识别语句时的头影效应，改善空间听觉的主观感受和言语交流能力，是一种很有前景的非植入式骨导助听装置。

【关键词】 听觉丧失，感音神经性；听觉丧失，单侧性；骨传导装置；噪声下言语识别；问卷

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Preliminary audiological evaluation of the SoundBite bone conduction devices in adults with single-sided deafness

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【**Abstract**】 **Objective** The auditory deficits of single-sided deafness (SSD) can be treated with a novel intra-oral device, SoundBite, which delivers sound by applying vibratory signal to the teeth. The purpose of this study was to evaluate the efficacy and benefit of the bone conduction device for Chinese adults with SSD. **Methods** Eighteen patients aged 19-66 yrs with acquired, permanent sensorineural SSD and no current treatment by any other devices for SSD, were recruited in a prospective controlled, nonrandomized, unblinded study. They were requested the continually daily wear of the new device over a 30-day free trial period. The intra-oral hearing device was placed around two maxillary teeth and was similar to a small partial denture or retainer. The audiological tests included pure tone air conduction thresholds, monosyllable word recognition score (WRS) in quiet and sentence reception thresholds in noise (via CMNmatrix test). The benefit was determined with the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire. **Results** The monosyllable WRS and the 50% threshold of signal-to-noise ratio (SNR_{50}) were significantly better in all aided conditions. The head shadow effect, assessed by the SNR_{50} via CMNmatrix test improved an average of 2.6 dB after 30 days' wearing compared with unaided condition (P<0.001). The APHAB scores improved (P<0.05) for all subjects for the Global and Ease of Communication, Reverberation, Background Noise subscales. The SSQ scores improved (P<0.05) for all subjects for Speech, Spatial and Qualities of Hearing subscales. **Conclusion** The SoundBite is a good alternative to the well-established implantable bone conduction devices in patients with SSD. An improvement in listening ability in noise and quiet as well as a decrease of the head shadow effect is validated as the expected.

【**Key words**】 Hearing Loss, sensorineural; Hearing Loss, unilateral; Bone conduction devices; Speech perception in noise; Questionnaire

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单侧感音神经性听力损失，简称单侧聋（single-sided deafness，SSD），是指一侧耳为重度到极重度感音神经性听力下降，而对侧耳听力基本正常。SSD 总发病率为 3%~9.3%，在新生儿中的发病率为 0.4‰~34‰，其潜在危害往往被忽视[1]。

成人可因突发性聋、听神经瘤手术等原因出现 SSD[2-3]，由于双耳加合效应及静噪效应缺失，出现头影效应并影响声源定位能力，噪声环境下的言语识别能力变差，患者往往出现社交窘迫、精神紧张、自我评价下降等状况[4]。因缺少有效的干预措施，一些患者被迫接受现实而不再寻求干预及康复，限制了他们的职业发展和社会生活[5-6]。近年来，信号对传式（contralateral routing of signal，CROS）助听器、骨传导装置（bone-conductive devices，BCD）以及人工耳蜗（cochlear implant，CI）领域的技术进步，使得 SSD 患者看到了一线曙光[7-14]。其中由 Sonitus Medical 公司开发的可摘戴式牙骨传导听力系统[15-16]，为 SSD 患者提供了新的干预选项。

鉴于社会角色以及对生活品质期望值的不同，成人 SSD 患者最终可能会在以上选项中有不同抉择，甚至包括放弃干预，目前并无明确统一的临床路径[17]。很多研究机构都有各自的研究方案和技术路线[5, 18]，Van de Heyning 等[19]2016 年推出了统一的 SSD 研究框架专家共识。我们依据该多国专家共识推荐的测试框架[20]，围绕牙骨传导技术的有效性，开展了一项前瞻性的非随机、自身对照、非盲法的听力学干预成效研究。

资料与方法

一、牙骨传导助听装置

SoundBite™/品音®牙骨传导听力系统是一种完全无创的可摘戴式助听装置[21-22]，由耳背机（behind-the-ear）、口内机（in-the-mouth）和充电系统

组成(图1)。耳背机装置结合了接收声音的麦克风和发射器部件:麦克风位于患耳的外耳道中,可无损地利用耳廓和外耳道的集音功能;发射器位于患侧耳后,将声音转换为数字信号并经过特有的算法优化处理后,通过近场无线方式传输到口内机。口内机类似于一个活动义齿,摆持在健侧或患侧上颌的臼齿上,它将无线信号还原为电信号,压电振子在电信号激励下产生机械振动,通过上颌牙齿传送到颅骨,通过健侧耳蜗,患者可以听到来自患侧的声音。无论耳背机还是口内机,充电一次可使用14 h,能够满足患者日间使用的需要。

图1 SoundBite™/品音®牙骨传导听力系统外观及佩戴情况 A:耳背机外观;B:耳背机佩戴图示;C:口内机在牙模上调试;D:口内机佩戴时摆持于上颌最外侧臼齿

二、研究对象

根据多国专家共识所定义的SSD听力学诊断标准[500、1 000、2 000、4 000 Hz四频率健耳纯音平均听阈(4 Frequencies Average, 4FA)≤30 dB HL,患耳4FA≥70 dB HL][19],自2018年11月至2019年4月在解放军总医院耳科门诊及微信挂号平台招募成人SSD患者,由耳科、听力学及口腔科专家依照以下纳入和排除标准遴选入组患者。

纳入标准:(1)18~80岁中国成人SSD患者;(2)能理解并复述普通话的音节和语句;(3)诊断SSD不少于3个月;(4)上颌后牙槽部位至少一侧有连续两颗牙齿(可接受种植体,但不接受义齿);(5)依从性良好,同意签署知情同意书。排除标准:(1)正在使用其他助听装置,如骨锚式助听器(BAHA)、CROS和TransEar等;(2)对环氧树脂聚合物过敏者;(3)不适合佩戴口内机的牙齿异常状况;(4)已知患有危及生命的疾病,或与所选择牙科或医疗手段相悖的禁忌证;(5)存在可能干扰依从性、理解、知情和配合能力的心理或精神问题;(6)受教育程度低于6年,存在言语理解障碍者。

经耳科初诊符合纳入标准的患者53例,其中35例因牙齿或口腔状态、改善交流的意愿不强烈、地域遥远、依从性差等原因未入组。最终18例SSD患者入组,其中男10例,女8例;年龄19~66岁,中位年龄45岁;左侧12例,右侧6例;先天或自幼单耳失聪8例,突发性聋7例,梅尼埃病1例,听神经瘤术后1例,慢性中耳炎术后失聪1例。签署知情同意书后,免费接受测试检查,并给予差旅费补贴。研究期限为配戴SoundBite™装置后的(30±7)d,未同时使用其他SSD干预装置。本研究通过解放军总医院伦理委员会审批(2018伦审第018号)。

三、研究方案

本课题为非盲法、非随机入组的、患者使用SoundBite™/品音®牙骨传导系统30 d自身前后对照的前瞻性研究。入选患者一般历经三次访视。访视一,测试双耳纯音听阈及单音节识别率;向患者讲解助听器效果问卷所涉及的场景,要求其细心体验在日常生活中的感受;取全口牙印模,送厂家制备口内机等全套产品。访视二,声场中测试不同方位噪声下的言语识别阈;患者填报未助听时的问卷体验;教会患者自主摘戴口内机,听力师运行调试软件,通过HiPro助听器编程器及编程导线与耳背机相连,根据患者的反馈,对不同频段的增益做出个性化的调试;患者在使用过程中也可随时来访做口腔舒适度或增益微调。访视三,患者使用(30±7)d后,测试助听后的两耳纯音听阈及单音节识别率、噪声下言语识别阈,完成助听后的问卷调查。

1.纯音听阈测试:依照国标GB/T 16296.1-2018纯音听阈测听方法,在我院隔声室中应用GSI 61型听力计测试患者双耳各自的气导听阈,并恰当地实施掩蔽。由于耳背机的机身体积小巧且麦克风深入患侧耳道,距离口内机较远而不必担心反馈啸叫的发生,所以佩戴TDH50P压耳式耳机来测试助听后的纯音听阈及言语识别率并无妨碍。

2. 单音节识别率测试:依照GB/T 16296.3-2017言语测听国家标准,运行"心爱飞扬"中文言语测听软件,经GSI 61型听力计及其TDH50P耳机,播放普通话单音节测试表,测得50、65 dB SPL的轻声、中等言语强度下的单音节识别率。

3. 噪声下言语测试：在本底噪声低于 25 dB（A）、面积为 3 m×3 m 的声场中，测试患者在噪声下的言语识别阈。参照 SSD 研究框架多国专家共识[19]，扬声器空间布局及信\噪组合如图 2 所示。每一扬声器均与患者坐姿耳部等高，距离双耳连线的中点 1 m。以自适应方式测试不同信噪方位下普通话版矩阵式语句（CMNmatrix）的信噪比识别阈 SNR_{50}[23]，以反映患者头影效应、静噪效应及双耳加合效应，见表 1。

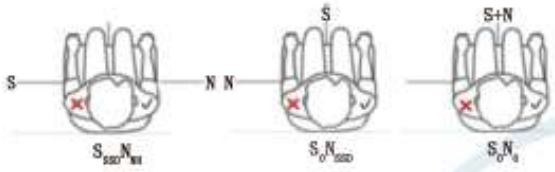

图 2 声场中噪声下语句识别阈测试的三种信\噪组合模式 $S_{SSD}N_{NH}$ 组合：语句播放于患侧而噪声播放于健侧，评估头影效应对言语识别的影响；S_0N_{SSD} 组合：语句播放于正前方而噪声播放于患侧，评估静噪效应对言语识别的影响；S_0N_0 组合：语句和噪声均播放于正前方，评估加合效应对于言语识别的影响；S：语句信号；N：噪声

4. 助听器效果问卷：患者在听力师引导下完成助听器效果缩略简表（APHAB）问卷[25]，对比使用牙骨传导听力系统前后，患者在 EC（交流便利）、RV（混响环境）、BN（嘈杂背景）、AV（烦扰声厌恶）四个方面及其总体上的困扰程度，以百分数表述。分值越高，困扰程度越大。助听后分值降低的程度，代表了助听器收益。前三个分项（EC，RV 和 BN）是从正面角度反映助听器的潜在收益，又可汇总为一个总体收益。若患者的总体收益≥50 个百分点，则代表效果非常好。另外，助听前后某一单项（EC 或 RV 或 BN）分差≥22% 或总体分差≥5%，即说明患者可从助听器中受益。

设计一款运用视觉模拟评分法（visual analog scale，VAS）的小程序，完成言语-空间-听音质量（The Speech，Spatial and Qualities of Hearing scale，SSQ）问卷调查[26]，评价患者在言语识别、空间听觉和听音质量方面的改善程度。

四、统计学处理

采用 SPSS v18 统计软件对助听前后的纯音听阈（重复测量的方差分析）、单音节识别率（一般线性模式下的多因素方差分析）、噪声下言语识别阈（配对 t 检验）及 APHAB 和 SSQ 问卷结果（配对 t 检验）进行统计分析，$P<0.05$ 为差异有统计学意义。

结　果

一、纯音听阈

18 例 SSD 患者配戴牙骨传导系统 30 d 前后的健耳及患耳的纯音听阈，如图 3 散点图所示。经重复测量的方差分析，健侧各频率的纯音听阈差异无统计学意义（P 值均>0.05）；而患侧各频率纯音听阈的改善十分明显（P 值均<0.001），尤以 1 000~4 000 Hz 显著。患侧补偿后的 250、500 Hz 听阈仍比健侧听阈高 25~30 dB。

二、单音节识别率

未助听前，SSD 患者健耳对于轻声（50 dB SPL）和中等强度（65 dB SPL）单音节的识别率分别为（79.8±12.0）%和（96.0±3.6）%，患耳几近为零（中位数均为 0）。使用牙骨传导系统后，健耳对于轻声和中等强度单音节的识别率分别为（79.0±12.5）%和（96.0±3.1）%，患耳则变为（49.3±13.2）%和（81.6±8.2）%，详见图 4。经多因素（侧别、强度、助听）方差分析，健耳的单音节识别率在助听前后无明显改变，差异无统计学意义（P=0.923 5），助听后患侧对轻声和中等强度的单音节识别率均较未助听时有大幅提升（P 值均<0.000 1），但仍逊色于健耳的识别率（P=0.01 及 P=0.008）。

三、噪声下言语测试

对比未助听与助听后的 $S_{SSD}N_{NH}$、S_0N_{SSD}、S_0N_0 三种组合模式下的语句识别阈 SNR_{50}，分别进行配对 t 检验。反映头影效应的 $S_{SSD}N_{NH}$ 组合，助听前后的差异为（2.6±2.1）dB，差异有统计学意义（P=0.001）；反映静噪效应的 S_0N_{SSD} 组合，助听前后的差异为（−0.3±2.8）dB，差异无统计学意义（P=0.49）；反映

表 1 噪声下言语测试的空间布局及聆听状态[24]

双耳效应	空间布局	聆听状态	双耳效应的计算
头影效应	$S_{SSD}N_{NH}$	助听，未助听	头影效应（dB）=未助听时 SRT-助听时 SRT
静噪效应	S_0N_{SSD}	助听，未助听	静噪效应（dB）=未助听时 SRT-助听时 SRT
加合效应	S_0N_0	助听，未助听	加合效应（dB）=未助听时 SRT-助听时 SRT

注：以上均为声场中对双耳聆听效应的定量测试，计算所得的 dB 数值若为正数，则表示获得了双耳收益。SSD：单侧聋侧；NH：健侧；SRT：以 SNR_{50} 为指标的噪声下语句识别阈

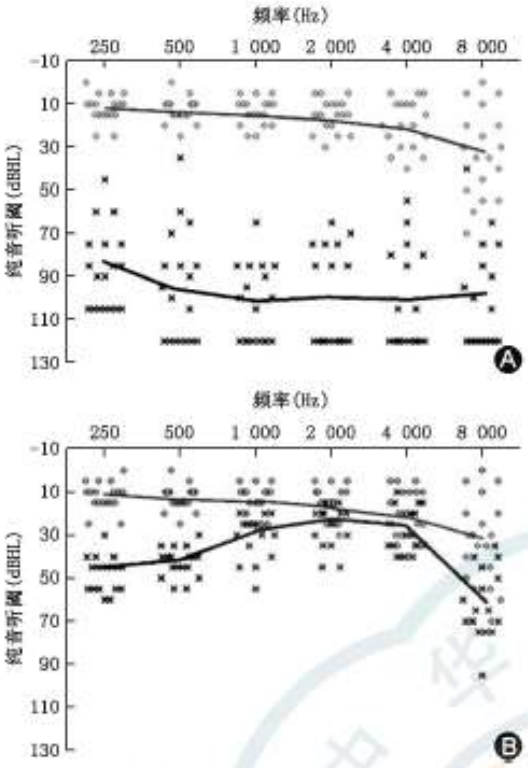

图3 18例单侧聋患者配戴SoundBite™/品音®牙骨传导系统助听前、后纯音听阈散点图 健耳以°标识，患耳以x标识。A：未助听；B：助听

图4 18例单侧聋患者配戴SoundBite™/品音®牙骨传导系统助听前、后健耳与患耳的单音节识别率 NH：健耳；SSD：单侧聋患耳

加合效应的S_0N_0组合，助听前后的差异为(1.0±2.2) dB，差异有统计学意义(P=0.001)，详见图5。

四、助听器效果问卷

根据SSD患者APHAB问卷中的回答，计算出其在交流便利(EC)、混响环境(RV)、嘈杂背景(BN)和烦扰声厌恶(AV)四个方面的困扰程度。18例SSD患者中有15例助听前后的单项(EC或RV或BN)分差≥22%或总体分差≥5%，即可从助听器中受益，详见图6。将助听前后的前三分项及总体分值分别进行配对t检验，发现三个亚项及总体分值均有显著改善(P值均<0.01)。

分别统计SSQ问卷中有关言语识别(Speech)、空间听觉(Spatial)和听音质量(Quality)三个亚类

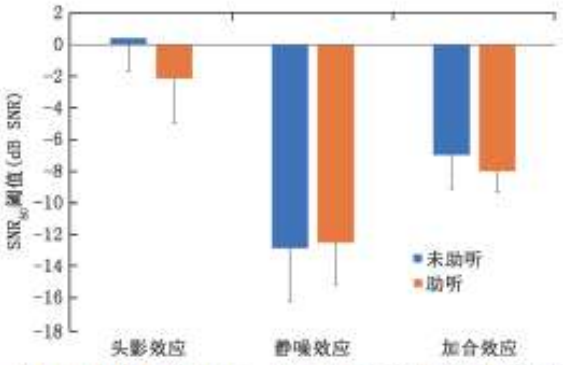

图5 单侧聋患者配戴SoundBite™/品音®牙骨传导系统带来的头影、静噪和加合效应 深色条带为未助听时$S_{SSD}N_{NH}$、S_0N_{SSD}、S_0N_0三种组合模式下的语句识别阈SNR_{50}，浅色条带则为对应的助听后三种组合模式的语句识别阈SNR_{50}，二者之差分别反映了单侧聋患者在头影、静噪和加合效应上的收益(n=18)

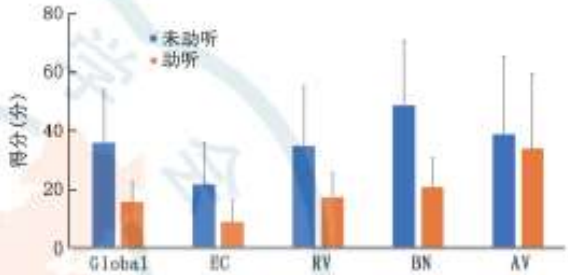

图6 18例单侧聋患者配戴SoundBite™/品音®牙骨传导系统助听前后助听器效果缩略简表问卷总体及各项得分对比 Global：总体得分；EC：交流便利；RV：混响环境；BN：嘈杂背景；AV：烦扰声厌恶

的得分，SSD患者使用牙骨传导系统助听后，无论Speech、Spatial还是Quality的得分均有显著改善(P值均<0.05)，详见图7。

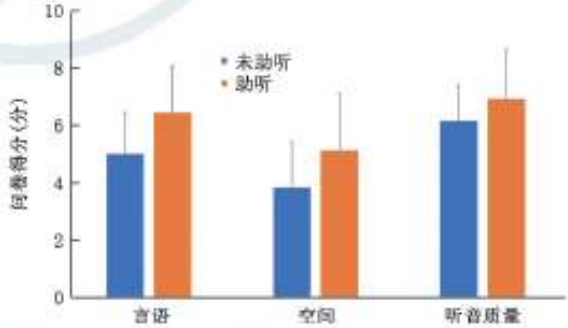

图7 18例单侧聋患者配戴SoundBite™/品音®牙骨传导系统助听前后言语-空间-听音质量问卷(SSQ)各项得分对比 Speech：言语识别；Spatial：空间听觉；Quality：听音质量

讨 论

一、SSD的干预现状

SSD的诊断和康复一直是全球听力学家面临

的难题[27]。SSD的干预，既可以用气导助听器在患侧或利用信号对传(CROS)方式在健侧实施，也可以用骨导传声机制将患侧接收到的声波经颅骨振动直接刺激对侧耳蜗。骨导刺激装置可以是有创的植入式产品[1]，也可以是黏附(如 Med-EL 公司 Adhear 粘贴式)、夹持(如发卡式、眼镜式)、绷固(如软带式 BAHA)在头颅表面的非植入式骨导装置。近年来欧洲开始尝试在 SSD 患者中实施 CI 植入，理由是 CI 相较于 CROS 助听器和 BCD，是唯一能使听觉信号从患侧听觉通路输入并由此为重塑双耳听觉系统提供可能性的装置。

欧盟 CE 认可的 CI 植入适应证中对 SSD 的定义为，健耳 500、1 000、2 000、4 000 Hz 平均纯音听阈不高于 30 dB HL，差耳平均听阈不小于 70 dB HL[28]。本研究 SSD 入选标准遵循了后一种定义。

二、高效的骨传导新途径

非植入式骨导助听器出现在 20 世纪初期。为了提升振动传递效率，头带或发卡等必须提供至少 2N 的静压力，较大的静压力不仅使佩戴不舒适，还可能造成皮肤压痛和缺血。此外，振动隔着皮肤传递到颅骨时，由于皮肤及皮下组织与骨组织的特征阻抗率不同，会造成 2 000 Hz 以上的高频能量衰减，影响传音质量。而牙齿是裸露于体表的唯一骨组织，若能利用与颅骨紧密连接的牙齿作为天然基座，通过戴在牙齿上的微小振动装置，将声音振动信号极低损耗地通过颅骨传至耳蜗，就可以避免上述因皮肤及皮下组织介导而导致的高频能量衰减，补偿效果也应优于其他非植入式骨导助听装置。

SoundBite™/品音®牙骨传导听力系统是全球首创的一种完全无创的牙骨穿戴式听力设备，主要由耳背机、口内机和充电系统组成。耳背机与近年来主流的 RIC(Receiver-in-Canal)式助听器外型十分相像，外观小巧隐蔽，主要收集听损侧的声信号，转换为数字信号并经过特有的算法优化处理后，通过近场无线方式将数字电信号传送到口内机。口内机使用压电振子原理将电信号转换为精密的振动信号，通过上颌牙齿传送到颅骨及健侧耳蜗，从而使患者听到听损侧的声音。

目前，骨传导听觉装置主要有电磁式和压电式两种设计。电磁式骨导听觉装置已有较成熟的产品(如 BAHA 等)，工作性能较好，但其功率越大，越难以微型化。压电式骨导装置则利用了压电振子在电信号激励下可产生机械振动的特性，佩戴过程中不受电磁辐射影响，具有体积小、功耗低、响应速度快等优点，故近年来受到广泛关注。为了保证振动所产生的力远低于正常咀嚼对牙齿施加的咬力(这样不会损伤上颌白齿表面)[29]，并提高口内机佩戴的舒适度，SoundBite™/品音®牙骨传导听力系统采用了压电式原理。

现有多种骨传导设备有效地缓解了 SSD 患者的听力问题，但或多或少都有一些设计上的局限，如麦克风位置欠佳(多位于耳后乳突)、频率范围有限、和(或)需要植入手术。新型的 SoundBite™/品音®牙骨传导听力系统，在设计上改善了麦克风位置(置于患侧耳道内)，提供更多的中高频增益；同时通过一个可摘取的类似活动义齿的口内机装置，传递骨传导信号到牙齿上，从而避免了手术。早期研究证实，牙骨传导听力系统与同类骨传导助听装置相比，具有更低的助听听阈和更好的 APHAB 得分[30]。

三、患侧借助健侧耳蜗感知

由于牙骨传导听力系统直接通过牙齿传递声音，因而高频补偿效果好。骨导助听装置的本质是将到达患侧的声音借助健侧耳蜗来感知。但由于骨导的耳间衰减值在 0~15 dB 之间[31]，故 1 000 Hz 以上的高频听阈与健侧仍有 10 dB 左右的差距，但骨导装置可提供至少 10 dB 的增益以弥补耳间衰减。患侧补偿后的低频听阈也提升至实用水平，但 250、500 Hz 听阈仍比健侧听阈高 25~30 dB。这在设计时基于以下考虑：(1)为了避免低频的有感振动，人为降低压电振子的低频增益；(2)1 000 Hz 声波的波长 34 cm，大致相当于成人头颅直径的 2 倍，患侧低于 1 000 Hz 的声波完全可以经衍射而被健耳捕捉[32]。因此低频听阈也无须补偿到接近健侧的水平。

正是基于这样的考虑，补偿后患侧在轻声和中等言语强度下的单音节识别率虽有极为显著的提升，但也未完全达到健侧的识别率水平，却足以应对日常来自患侧的言语交流。绝大多数患者都表示他们在安静条件下，再也无需将健耳一侧转向说话人。

针对少部分患者担心的“患侧语音借助健侧耳蜗接收是否会加重健侧的负担而使其听力减退”的问题，我们对比使用 30 d 前后健侧的纯音听阈及单音节识别率，差异均无统计学意义，从一定程度上佐证了 SoundBite™/品音®牙骨传导听力系统的安全性。参与本研究的口腔科医师已另撰文报告[33]，大多数患者在佩戴初期会对口内装置有异物感，但经

过短暂适应期后均能舒适佩戴，不会引起基牙探诊深度加深、探诊出血，松动度无加大，具有一定的安全性，也期待大样本、长期随访的验证。佩戴口内机不会影响言语发音，甚至可以在宴会时佩戴，解决了与左右宾客交谈的困扰。

四、缓解了噪声下的聆听困扰

有关头影效应对SSD患者造成困扰最极端的例子，就是当讲话人在其患侧而健侧恰有噪声的场合。虽然在不少有关双耳听觉头影效应的研究中，也曾有过S_0N_{NH}（言语信号来自前方，而噪声施加于健侧）的方案[34]，牙骨传导听力系统在早期研发阶段的有效性和安全性评价中也采用了此方案[16]，并得出可使HINT语句识别阈改善2.5 dB SNR的结果，但2016年多国专家共识建议研究者遵循统一的SSD研究评估框架以利于各自研究能汇集成可比较的数据池，避免之前研究的异质性[19]。故本研究采用$S_{SSD}N_{NH}$（言语信号来自患侧，而噪声施加于健侧）的方案，普通话版Matrix语句识别阈有2.6 dB SNR的改善。Salcher等[35]采用德语版Matrix语句材料和$S_{SSD}N_{NH}$方案，发现经皮主动式骨导植入装置（骨桥）对于SSD患者在头影效应上的收益约为2.5 dB。说明牙骨装置的效果不逊于植入式的骨传导产品。

对于听力正常人，双耳加合效应归因于与双侧刺激关联的响度增加，以及双侧神经通路对两耳各自接收到的刺激中的冗余信息的加工。在中等感觉级刺激时，双耳这一优势比单耳达到相同响度级所需的刺激强度可降低约5 dB；在高感觉级刺激时的改善则高达10 dB[36]。实施双侧干预的听力受损者，无论在阈值和阈上水平，仍可获得与正常听力者程度相近的双耳加合[36]。但对于单侧聋患者而言，将患侧信息“借道”健侧耳蜗传递的骨导装置，仍靠健侧的听觉传导通路，并不能重塑双耳听觉，能否获得加合效应的助益以及潜在的中枢处理机制仍不明确。本研究数据显示，配戴牙骨传导听力系统的SSD患者仍可部分地获益于加合效应，采用S_0N_0方案（言语和稳态噪声信号均来自前方），CMNmatrix语句识别阈有1.0 dB SNR的改善。

在稳态噪声背景下，双耳接收的噪声在相位及强度上都是一致的，故言语信号到达双耳时的相位和强度差能使健听人较单侧听损患者更有效、更准确地聆听言语，产生约3 dB的收益[37]。但对于借用健侧骨导传声的SSD患者，采用S_0N_{SSD}空间布局（言语信号来自患者前方，患侧播放噪声）方案，却不能收获静噪效应。患侧使用BCD会接受到更多的噪声信号并将其引入健侧，有可能降低了健侧的有效信噪比，从而导致言语识别能力的下降[38]。但本研究中，助听30 d前后的S_0N_{SSD}布局时噪声下CMNmatrix语句识别阈差异无统计学意义，原因可能是SoundBite™/品音®牙骨传导听力系统的增益偏保守，即使是在中高频，补偿后的听阈仍低于健侧。前人对于头颅衍射造成的声级衰减已有明确结论：低频（200~1 000 Hz）衰减3~7 dB，而高频（2 000~8 000 Hz）衰减9~21 dB[39]。从本研究纯音听阈的改善结果来估算（图3），患侧播放的噪声经该牙骨传导系统传递至健侧耳蜗的声级会与经头颅衍射到健侧的声级相当（高频）或更小（低频）。

五、助听成效问卷调查

对助听装置效果的评价，除了实验室中的听阈等数据，患者主观心理感受的评估也是其重要指标。本文采用了两种经典的助听器成效评估问卷对SSD患者佩戴前后的主观感受进行测定。

助听前后的SSQ问卷结果显示，在言语识别、空间感知、听音质量三个方面均有显著性提升。18例SSD患者使用牙骨传导系统后的APHAB问卷得分及在交流顺畅、混响环境、嘈杂背景三个方面的困扰度均有明显的下降，15例患者有效获益。两份问卷的结果都表明，患者主观上认可牙骨传导听力系统对日常生活的辅助作用，但由于这两问卷并非专为SSD患者开发的测评问卷，SSD患者的心态、社会角色、发病年龄等因素都直接影响他们对助听器效果的评价。例如APHAB问卷显示无效的3例患者中有2例是自幼单侧失聪、不满30岁的研究生，他们凭借个人努力在学业成长中并未经历什么困扰（助听前的困扰度分值就很低），只是在一些特定场景中如手术台、圆桌会议体会到了SSD的困扰；而说起牙骨传导听力系统在解决这些场景中的困扰时，他们又十分满意，但困扰度分值的降低幅度达不到5个百分点。这说明针对SSD患者，可能还需要采用一些涉及使用便利性、美观、每日使用时长、是否愿意推荐给病友等话题的问卷[40-41]，我们也将在后续的长效评价研究中予以改进。

总之，SSD患者佩戴SoundBite™/品音®牙骨传导听力系统，能显著改善患侧听力状况，提高其在安静及噪声下的言语识别能力，患者主观满意度较高[42]，可作为成人SSD患者的听力解决方案之一。

利益冲突 本研究内容是在上海市药监局备案的《评价Soundbite牙骨传导听力系统用于改善单侧耳聋（SSD）者听觉能力的有效性

和安全性的前瞻性、多中心、单组目标值的临床研究）》的一部分

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