

Solving Challenges In Deep Canal Fittings, Part I

New approaches to hearing instrument fitting, such as the utilization of deep canal technology, bring new fitting challenges which must be solved through on-going research. Peritympanic technology, a new concept brought to the hearing instrument field almost six years ago with the introduction of the XP Peritympanic deep canal instrument by Philips Hearing Instruments, was deemed radical at its inception. Today, however, instruments incorporating deep canal technology are capturing an ever-increasing share of market. Introduction of the various types of instruments utilizing deep canal technology has stimulated research designed to solve for dispensers the challenges encountered in fitting these instruments.

Part I

The development of the BST® (Bony Seal Tip) concept, which will be described in Part II of this article, is a continuation of the efforts to solve some of the fitting challenges associated with deep canal technology. In spite of the acoustical and cosmetic advantages provided by deep canal technology,^{7, 11, 13, 16, 17, 21, 22, 25, 26, 28, 29} the main sources of consumer and dispenser complaints continue to relate to the mechanics of fitting a hearing aid deeply within the auditory canal: comfort of fit, occlusion effect, feedback, cerumen protection, pressure relief, working itself from the ear canal, and the difficulty in taking appropriate ear impressions. The main challenge to the growth of deep canal fitting technology lies in solving those problems, while providing an acceptable physical and mechanical fitting of the instrument within the bony structure of the external auditory meatus.

A major issue that must be resolved in deep canal fittings relates to the mechanics associated with placing a foreign object more deeply within the auditory canal. Realizing the low tolerance to foreign objects acceptable within the bony canal, a series of approaches was investigated to determine a style, shell material composition and design that would be acceptable to not only the hearing instrument user, but also to the dispenser and the manufacturer. A satisfactory solution to the fitting challenges, while still maintaining

the advantages of peritympanic fittings, was sought, and found, in the BST® concept.

Deep Canal Hearing Aid Devices

Many dispensers confuse peritympanic hearing aids with CIC (completely-in-the-canal) hearing aids. For purposes of the remainder of this article, the following distinctions between peritympanic and CIC fittings occur: the term "deep canal" is generic and includes at least two types of hearing aid fitting applications: peritympanic and CIC.

A hearing aid prosthetic device can be classified as a peritympanic if the following conditions are met:

- The medial end of the instrument penetrates the bony portion of the external auditory canal sufficiently for the residual cavity to be approximately 200 mm³ (0.2-cc).
- This same medial end must provide a complete seal in the bony part of the auditory canal-making full contact with the bony canal wall.
- The microphone position should be flush with, or inside, the aperture of the external auditory canal.

A hearing device is classified as CIC if:

- The microphone position is flush with, or inside, the aperture of the external auditory canal.
- The medial end of the instrument extends 2-3 mm past the second bend of the canal.

The primary advantages and distinctions of peritympanic fittings to the hearing impaired are:

1 Peritympanic provides the greatest increase in SPL, especially in the high frequencies, mostly due to the very small volume of the residual cavity, but due also to a lesser extent to the microphone sound pick-up location.

2 Peritympanic eliminates, or reduces, substantially the occlusion effect, an extremely disturbing experience in which a person who wears hearing aids may hear his/her own voice at a very high level (their voice is described as being loud, in a barrel, full, bassy, etc.). This occurs when the instrument does not make full contact with the bony structure of the canal,^{11, 33, 34} or is it not possible to make the vent sufficiently large.

3 Deep positioning creates the greatest possible discretion, or even invisibility of the instrument while wearing, to others. The more deeply an instrument extends into the auditory canal, the greater the possibility of enhancing the cosmetics. Realistically, peritympanic and CIC instruments may be quite similar in their external cosmetics, mostly due to the rather severe second bend in the ear canal that often prevents the electronics from being inserted more deeply.

In spite of these advantages, actual experience with thousands of deep canal hearing aids has led to some fitting challenges (enumerated earlier in this article) for the consumer and the dispenser. Additional research with a goal of improving upon overall performance was, therefore, necessary. Part I presents a discussion of these issues. An explanation as to resolution of each through utilization of the new BST® concept will appear in Part II.

Issue 1: The Ear Impression

To take full advantage of peritympanic hearing aid fittings, appropriate instrument positioning requires a complete impression of the outer ear canal, including the location of the tympanic membrane. Because the end of the hearing aid terminates approximately 4 mm from the eardrum, a special liquid silicone impression procedure has been recommended.^{17, 22} This procedure requires more time, knowledge of the ear canal, and experience than other types of ear impressions. In spite of these potential limitations, this technique has been well accepted and will continue to be used by those individuals who are comfortable with the procedure. While thousands of ear impressions have been made using this procedure and have proven its ease and reliability,²⁴ it was found that this technique creates considerable apprehension for those who have never been trained in or exposed to it. The primary concern expressed is that the tympanic membrane may be more susceptible to trauma with this procedure than with previously existing impressions procedures. No clinical substantiation exists for this idea. Still, recognizing this as an obstacle to fitting peritympanic hearing aids, an alternate fabrication approach has been designed to fulfill peritympanic fitting requirements that allows for a "more conventional" impression technique. The BST® improvement to be described in Part II accepts a simplified impression that will still permit peritympanic application.

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The outer ear canal anatomy, physiology, and tolerances to a foreign object being inserted deeply into the ear require a closer examination of the canal's cartilaginous and osseous portions. Fortunately, the cartilaginous ear canal accommodates to, and tolerates, virtually everything placed in it within reason. Unfortunately, for deep canal fittings, the osseous portion has essentially no forgiveness and sometimes has difficulty accepting foreign objects, even those made of soft material.

Issue 2: Comfort

Of what significance is the mandibular movement to the taking of ear impressions and to the eventual fitting of deep canal hearing instruments? What is the impact on the fitting comfort of the ear impression and eventual fitting of the hearing aid to the cartilaginous canal?

To make this determination, a comparative dimensional study was conducted on 108 ears using two dif-

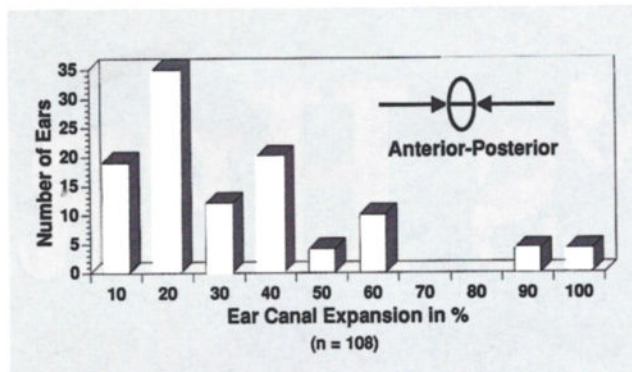


Fig. 1 Anterior-posterior expansion of the cartilaginous portion of the external auditory canal in percent. Measurements were recorded from ear impressions made with a silicone of 20 Shore (no expansion) and with 70 Shore (about the greatest expansion caused by a silicone ear impression material). $N = 108$ ears.²⁸

ferent ear impression materials.²⁸ Two impressions were made for each ear; one using a silicone liquid of 20 Shore (Shore refers to the hardness of the material. The higher the Shore, the more dense and harder the impression material and the greater the expansion of the finished impression) injected with essentially no pressure, and the second used a dense silicone paste (70 Shore) injected under 150 grams of pressure at the outlet of a standard silicone

syringe. The differences in dimension between the two completed impressions, and, therefore, the expansion that occurred within the cartilaginous ear canal are shown as percentages in Fig. 1.

These measurements show striking expansion of the cartilaginous ear canal for the majority of subjects with some showing a 100% expansion in the anterior-posterior dimension. Hearing aids made from expanded impressions would seem, therefore, to minimize any potential damping of jaw movements

in this dimension. The combination of a hearing aid made from an expanded ear impression and jaw movements has the effect of significantly changing the angle relationships between the first and second bends of the ear canal. The result is that, with instruments made from an expanded impression, jaw movement comfort against the hearing aid is limited to the maximum expansion conditions. Because jaw movement is not allowed to travel its normal anterior-posterior distance, those conditions where the mandible is intended to be in its posterior direction (including when at rest) cause the greatest discomfort.

On the other hand, an instrument made from a non-expanded impression will have a tendency to be "pushed" from the ear during mandibular movement. This sensation can be experienced by placing the small finger lightly into the ear canal (expanding the canal) and moving the jaw. The outward force created by the condyloid process of the ramus of the mandible can be felt easily.

The second issue requiring an answer relates to the bony part of the ear canal and its tolerance to pressure. Because the bony part of the ear canal is not flexible, as is the cartilaginous portion, much less tolerance to pressure is accepted. When a completed hearing instrument is enlarged by 0.1 mm in the bony section, enough pressure is created so that the instrument is not tolerated.²⁸ Although this tolerance to pressure varies among individuals, the sensation of discomfort was present for a pressure increase of only a few grams.

It is known that ear impression techniques that use a pressurized syringe and 40 Shore material have been shown to expand the ear canal and the polymerized ear impression itself. This mandates, in part, manufacturing and fitting practices in which the end of the

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instrument is tapered to compensate for comfort, especially when the instrument is made from a hard acrylic material. Clear ear shell acrylic is often used so that the canal portion of the instrument can be reduced without grinding into the electronics.

The results relating to tolerance acceptance differences between the bony and cartilaginous parts of the ear canal should not be surprising. The tissue of the cartilaginous part of the ear canal is generally considered to be about 0.5 to 1 mm in thickness and has a well-developed subcutaneous layer.²⁰ On the other hand, the underlying tissue of the osseous part is quite thin, about 0.2 mm, has no subcutaneous layer, is highly vascular, and is quite sensitive. Therefore, little or no tolerance for expansion exists, and when it does, discomfort and pain are readily noticed. Any deeply inserted instrument that is not consistent with the tolerances of the osseous part of the ear canal, or that does not compensate for the angle adjustments created between the first and second bends as a result of jaw movement, is, therefore, subject to rather severe wearing discomfort.

It would appear, therefore, that hearing aid shell materials that do not comply with the criterion of tolerable pressure within the bony segment should not be introduced into the ear canal. Reason dictates that no expansion should occur and that subsequent pressure by the finished product must be very low in order to be tolerable.

Issue 3: The Occlusion Effect

The occlusion effect is operationally defined as that sensation in loudness of one's own voice when the ears are plugged, such as occurs when wearing hearing aids. It is an increase in sound pressure level in the chamber formed in the ear canal between the occluding device and the tympanic membrane.

Supposedly resulting from vocal fold vibration spreading throughout the skull via bone conduction, a substantial part of the low frequencies of this vibration is transmitted through the soft tissues of the cartilaginous part of the ear canal and also from vibrations transmitted by the condloid process of the mandible which vibrates out of phase relative to the movement of the skull, and, therefore, sets up the sound pressure in the ear canal.²⁰ With an open ear canal (or with large vents), these pressure variations take the path of least resistance—into the larger volume of surrounding air, and are dissipated. When the ear canal is blocked with a hearing aid or other device, the path of least resistance, however, is now toward the tympanic membrane and the sound waves generated become an effective supplement to audition. The result

is an increase in bone-conducted sensitivity as high as 25 dB at 500 Hz and at even higher levels below 500 Hz.^{4, 6, 8, 9, 10, 15, 19, 27, 31}

Fig. 2 illustrates the acoustic pressure measured by real-ear probe microphone measurements for the phoneme (u) (shoe) spoken at a level of 70 dB SPL. The lower curve is the result as measured from an open ear canal (no hearing aid), and the upper curve from an ear blocked with a standard hearing aid terminating in the cartilaginous part of the ear canal, but with no amplification. The dramatic increase in low frequency overall SPL is readily noticed, and in this case shows an increase of 22 dB at approximately 350 Hz. This value can be higher or lower for other speakers and for other phonemes.

The negative impact of the occlusion effect on hearing aid wearers is well known and the phenomena itself was reported many years ago by Wheatstone.²² Historical attempts to reduce this effect have been to enlarge the vent in hearing aids or earmolds. However, when sufficient vent enlargement is not possible (due to the size and location of the hearing instrument), an alternate approach to solving the problem has been to terminate the instrument or earplug as deeply within the ear canal as possible.^{1, 2, 3, 11, 13, 21, 22, 25, 33} It is in this phenomenon that major distinctions between fitting approaches occur. General CIC approaches taper the tips of the hearing instruments such that a full fit deep within the canal is not as likely to occur. On the other hand, true deep canal fittings attempt to make full contact deep within the bony structure.

The question must, therefore, be asked, is a full seal within the bony part of the ear canal necessary?

Fig. 3 shows the results of the importance of a full fit in the reducing substantially the occlusion effect. The lower curve shows the results of a Philips XP peritympanic instrument with a soft shell of 25 Shore that provides a full seal in the bony part of the ear canal. The upper curve shows the results measured on the same instrument with its shell reduced by 0.1 mm in the bony segment. Note that a 20 dB increase in the SPL occurs at 500 Hz as a result of this minor adjustment. This supports other research that indicates that if the occlusion effect is to be minimized, full contact within the bony structure of the ear canal is required.^{21, 33, 34} This may explain why some CIC hearing instruments have not reduced the occlusion effect significantly.

A difficulty in solving this problem is that, to make a good seal, comfort is likely to be the limiting factor. In spite of this, experience has shown that some individuals are able to adjust very well to hearing aids having a full fit in the bony section. A "desensitization" seems to occur for many patients during a time period ranging from as few as a couple of days up to two weeks. It is important to note that this discomfort can occur even for soft shells made of 25

Shore silicone. This explains CIC practices of tapering the ends of hearing instruments, especially those made of hard acrylic material. The BST[®] has been designed to keep the occlusion effect to a minimum by providing a new approach to bony ear canal contact.

Issue 4: Feedback

Acoustical feedback is a historic problem with canal hearing instruments. Deep fitting aids, while being less susceptible, continue to show feedback as a limiting factor in many fittings. An evaluation of 796 peritympanic hearing instruments returned for repair or remake during a four-month period in late 1992 listed feedback as the cause in 9.92% of the instruments.¹⁷ It is for this reason that most deep fitting hearing aids (and CICs as well) now have the high frequencies rolled off somewhat and, if vented, use a size that facilitates pressure release only. Feedback increases as a problem with attempts to fit more severe hearing impairments.

Tapering and shortening of an instrument lead to greater feedback. Although waxing of the impression and expansion of the cartilaginous part of the ear canal by the hearing aid may help reduce feedback in some cases, a more logical approach to feedback control is to have a good seal in the bony structure where ear canal movement and leakage are minimized. This issue is addressed directly with the BST[®].

Issue 5: Cerumen Control

Canal hearing instruments often fail because of cerumen blockage of the sound bore. With deep canal instruments, this has been less of an issue because the instrument acts as a "cleaning rod" whenever it is inserted and removed, with a thin film of cerumen collecting on the sides of the instrument rather than at its tip. This cleaning action holds true for an individual who wears the instrument on a consistent basis. But, what about the individual who wears the instrument periodically and who produces large amounts of cerumen? An approach would be desirable that does not require these instruments to be returned to the manufacturer for cerumen removal should they be inserted into an ear having substantial cerumen. The BST[®] attacks this issue directly with a unique wax guard design.

Issue 6: Pressure/ Equalization/Aeration

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and the tympanic membrane, the issue of pressure equalization and of adequate aeration of the cavity with the external environment is sometimes raised. Lybarger¹² has suggested that pressure equalization can be achieved with a parallel vent of about 0.6 mm (0.025"). Although reported adverse effects of pressure equalization and of adequate aeration have not been high enough to be reported on reasons for remakes or returns for credit, it is believed to be an issue that should be addressed. The BST® addresses this issue directly in its design.

Issue 7: "Walking" of the Instrument

Mandibular movement frequently has the effect of causing the hearing instrument to work its way from the ear canal, breaking the seal that controls feedback, the occlusion effect, and in some cases, the overall SPL delivered to the ear. Often an outward movement of 1 to 2 mm is sufficient to create this problem. This condition appears to be more of an issue with individuals having "straight" ear canals than for those having "severe bends" to their ear canals. Preliminary results with the BST® concept suggests that it is a viable solution to controlling outward movement of the hearing aid created by mandibular movement.

The Situation

In spite of the fact that deep canal hearing aid fittings have substantial

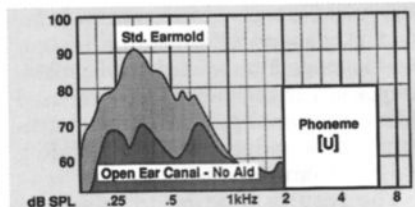


Fig. 2. Real ear probe microphone measurements of the magnitude of the occlusion effect in dB SPL for the phoneme (u), as in "shoe," when the ear canal is filled with a standard earmold terminating in its outer, cartilaginous portion (upper curve). No hearing aid amplification is present and the earmold does not have a vent.

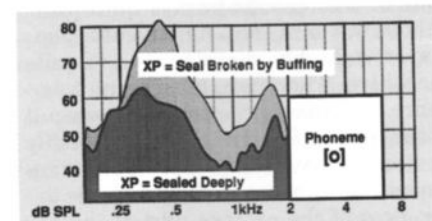


Fig. 3. The effect of an incomplete seal in the bony portion of the ear canal on the occlusion effect.

advantages, the critical tolerances required for good physical fit explains why several adjustment of the shell are often required to provide a satisfactory fit without sacrificing for feedback, comfort, high frequency increase in SPL, and reduction of the occlusion effect. An explanation as to the resolution of each issue through utilization of the new BST® concept will appear in Part II. ♦

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residents of the region. Hagen and his team fit 84 patients with hearing instruments that were supplied by members of the medical team and through a sizeable contribution from Unitron Industries. Additionally, the group performed hearing tests, repaired hearing instruments and made new earmolds.

Hearing care is not attainable for many in the poor region of Guaymas, where a typical behind the ear hearing instrument can cost the equivalent of one year's earnings. The problems for children with hearing deficiencies are compounded by their removal from normal education systems and placement in institutions

reserved for the deaf and learning disabled. Many of the patients treated by the team were underprivileged children who now look forward to the opportunities presented by their return to mainstream society.

This was the second consecutive year that Hagen and Bye traveled to Mexico to provide free hearing care. ♦

Correction

The Nov/Dec *Hearing Review* lists the 1995 Academy of Dispensing Audiologist's (ADA) convention as taking place on October 17-22 in Myrtle Beach, NC. This *should* read Myrtle Beach, SC.

Transient Sounds

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Solving Challenges

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This article was submitted by Henri Garcia, vice president, Marketing, Philips Hearing Instruments, Eindhoven, The Netherlands and Wayne Staab, PhD, special consultant to Philips Hearing Instruments on Peritympanic Hearing Instruments. Inquiries can be submitted to Staab at 602-942-4939.

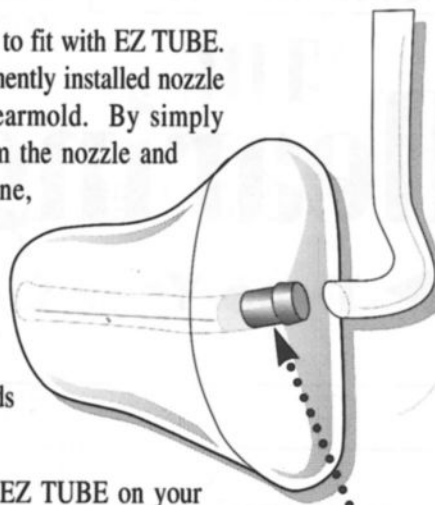
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Solving Challenges in Deep Canal Fittings, Part II

The Bony Seal Tip (BST®) in Hearing Instrument Fitting Applications

Part I of this article, which appeared in the January 1995 issue of *The Hearing Review*, defined deep canal devices and examined seven fitting issues that dispensers must cope with in fitting these types of hearing instruments: *The Ear Impression, Comfort, Occlusion Effect, Feedback Reduction, Cerumen Control, Pressure Equalization, and "Walking" from the Ear*. Part II discusses the Bony Seal Tip (BST®), a soft, pliable fitting tip that extends the length of a deep fitting hearing aid made from conventional deep impressions, and provides for a full, "active seal" in the bony part of the ear canal. It was developed by Philips Hearing Instruments to address these issues specifically.

Solution I: The Ear Impression

The use of the BST® (BST) concept allows peritympanic hearing advantages to be obtained from a conventional, deep ear impression. As an alternative, the original liquid silicone procedure required for the original XP hearing instrument² can be used and may continue to be desirable under certain conditions—especially when maximum depth is required.

When a conventional deep ear impression is taken, however, the procedure recommended is:

- Medical contraindications and cerumen management should be explored.
- A gauge (insert) can be used to determine if the ear canal size is sufficient for the electronics and for cosmetic acceptance (Fig. 4).
- A standard, commercially-available 40 Shore silicone impression material is recommended, using an appropriate silicone syringe.
- A cotton or foam block is used to keep the silicone impression material from the tympanic membrane.

- The impression must be complete to a length approximately 3 mm past the second bend so that the axis and direction of the bony canal can be perceived clearly (Fig. 5).

In using a conventional, deep impression, it is important to determine how peritympanic positioning can be achieved without completing the impression to the tympanic membrane. A solution was needed because conventional impressions are generally too short for the completed hearing aid to make full contact in the bony structure and for providing a very small residual cavity so that maximum high-frequency SPL increases would be generated.

Fig. 6 diagrams how a peritympanic fitting can be achieved with a "less-than-satisfactory," conventional ear impression. A peritympanic hearing aid shell fabricated from a conventional deep impression (solid line) is shown, the end of which terminates about 3 mm past the second bend of the ear canal. The final shell (dashed lines) that is derived from this impression has two modifications:

- 1 The hearing aid receiver extends medially from the impression about 4 to 5 mm, centered in the direction of the bony ear canal; and
- 2 This projection enables the shell to be shortened on the distal surface by a distance up to, but sometimes less, than the extended length, allowing for a cosmetic fit.

The minimum length for this electronics package is 15 mm with the receiver accounting for about half the length. Although the receiver can now be envisioned to be somewhat deeper within the ear canal, this diagram shows that full contact with the bony structure of the ear canal does not yet occur. Diagrams and explanations later in this article will help in understanding how full contact is achieved from this basic building block.

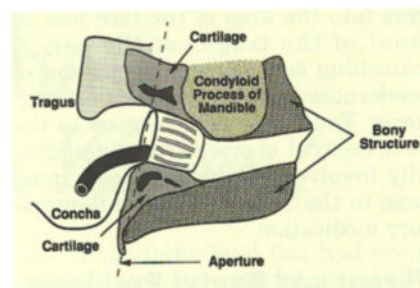


Fig. 4. An example using a gauge to determine if the ear canal is of sufficient size to accept the electronics of a deep canal hearing aid and to determine also if the depth will be cosmetically appealing.

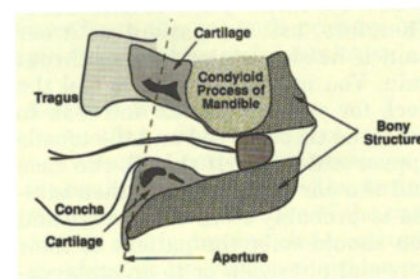


Fig. 5. Location of the ear impression block (2 to 3 mm beyond the second bend) to ensure adequate depth and knowledge of the direction of the bony portion of the ear canal.

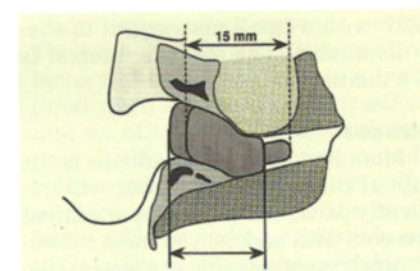


Fig. 6. Diagram showing how the BST concept will allow for deep insertion within the bony portion of the ear canal with the use of a "standard," but deep, ear impression. The tip must be added.

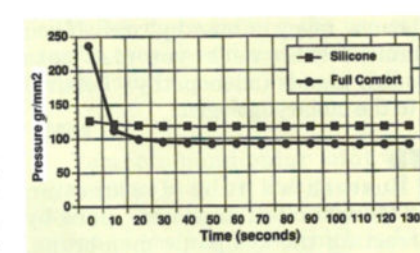


Fig. 7. Counter-force pressures comparing Full Comfort material with soft silicone material of the same 25 Shore hardness. This new material is able to be molded into another position and maintain that position with less counter pressure than silicone requires.

Solution 2: Comfort of the Hearing Instrument

One of the exclusive properties of the Full Comfort® (FC) soft shell material, a proprietary material developed by Philips for use with the XP peritympanic hearing aid, is its ability to memorize form. When this resilient material is compressed and maintained in its compressed condition, two pressures are differentiated: the pressure necessary for initial compression and that necessary for continued compression. Fig. 7 shows the results of these measured pressures on a compressed FC soft material sample compared with those obtained from a soft silicone material of the same Shore hardness (25 Shore). This soft shell material is more resistant to initial deformation, but after a few seconds, appears to memorize its new form. This results in a considerable decrease (2.5 times) of the counter-reaction pressure involved, and therefore, of the pressure required to maintain it in its new position. Silicones and rubber do not have this property, and their curve shows that for them the initial compression pressure is substantially the same as the maintenance pressure. They, resultantly, have a stronger, constant force trying to return them to their original positions—thus creating greater pressure and discomfort. Advantages of the FC property are:

- 1 That during the insertion of the instrument, this soft material holds its shape fairly well; and
- 2 With continued compression to its new state following insertion, the counter-reaction pressure to return to its original shape decreases, resulting in a more comfortable fit.

This unique shell material action allows the bony canal to be sealed with an insert cross-section that is larger initially than the ear canal (Fig. 8a), but when compressed (Fig. 8b), matches the contour of the bony ear canal with less pressure than other types of ear shell materials. The anterior-posterior pressure exerted on an ear shell by the cartilaginous canal walls during mandibular movement is 100 grams or more. It is not difficult, therefore, to imagine the discomfort that could be caused by a rigid shell penetrating deeply and fitting tightly in the bony canal.

The pressure required to be exerted on the bony ear canal by the "mushroom-shaped" BST device to maintain a seal and to provide comfort was determined experimentally on 20 ears. An added feature is the ability to use various sized "mushrooms" to help solve fitting problems related to the occlusion effect, the aid working its way from the ear canal,

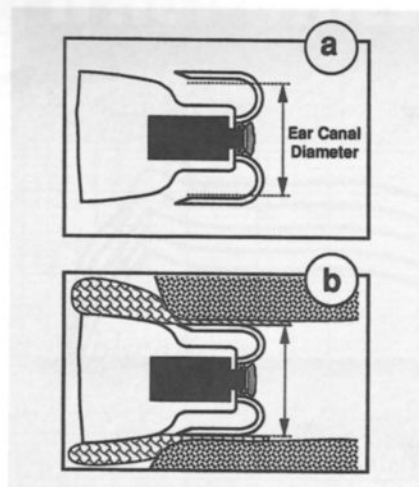


Fig. 8 a & b. Diagram of the BST extension showing (a) that its cross-section is slightly larger than the diameter of the bony auditory canal, but (b) that its design allows for a full seal under compression with substantially improved comfort.

feedback, comfort, etc. The actual pressure exerted is controlled by specifying the thickness of the FC material walls of the BST. Despite the flexibility of its walls, insertion is not difficult (Fig. 9) because the BST is an integral part of the body of the hearing instrument—at its tip and in its center. Additionally, it used the FC form memory property, providing a resistance of 2.5 times greater during the insertion state. The thickness of the walls is such that after a few seconds following insertion, and when the counter-reaction pressure has decreased, the BST stabilizes at its least reactance pressure for maximum comfort.

Fig. 10 illustrates the results of using the BST on 44 ears (30 individuals) to determine its comfort on a mixed group of new (10 ears) and previous hearing aid wearers (four BTE; Six ITE; 24 XP). Results suggest that the comfort factor goal is being met.

Solution 3: The Occlusion Effect

The BST concept, by extending the fitting mushroom more deeply into the bony canal with full contact and with the ability to maintain the full contact without discomfort, helps solve the problems related to the occlusion effect. In the event that the seal is not as good as desired, the BST concept allows for an exchange of the mushroom size. This is accomplished by the dispenser, who, in a simple procedure with proper in-office tools, can remove the fitting tip and replace it with one of another size. A special bayonet arrangement of the tip makes this possible.

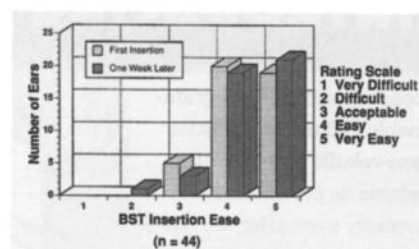


Fig. 9 Insertion ease during the first insertion, and for one week later, of the BST extension fitted to an XP peritympanic instrument.

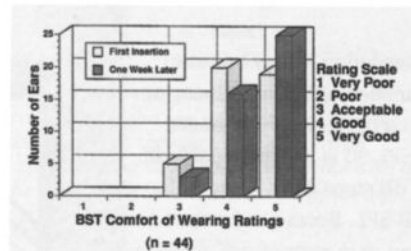


Fig. 10. Wearing comfort ratings of the BST during the first insertion and for one week later.

Solution 4: Feedback Reduction

Data to date proves that the BST arrangement allows for greater gain before feedback without any special electronic high-frequency roll-off than what has been measured previously on similar gain and response deep canal hearing aids. On 44 consecutive ears, user preferred gain was reached in all cases and in 34 ears, the instrument was advanced to full volume control rotation (22 to 32 dB peak 2-cc coupler gain) without feedback. Although experience to date is inconclusive, if feedback is a problem, a larger mushroom can be used when it can be tolerated. This unique design isolates feedback control to the bony section, the most critical area of the ear canal.

Solution 5: Cerumen Control

Although cerumen control has not been a major problem with peritympanic hearing instruments, potential difficulties can arise with patients who have not worn their instruments for some time or who insert them for the first time without cerumen management. It is for this reason that a cerumen wax guard system was sought that would make it very difficult for cerumen to enter the sound bore of the instrument. This system would involve essentially no additional physical space, and could be replaced/cleaned easily by the dispenser (and even by some users) without having to return the instrument to the manufacturer. This feature is built into the BST concept (Fig. 11). Sound is allowed to leave the sound bore through an indi-

rect route that prevents cerumen from entering the sound bore directly. The tip can be removed and cleaned by the user with a small washing device or placed into an ultrasonic cleaner.

Solution 6: Pressure Equalization/Aeration

The seal of the BST is such that it appeared desirable to provide a balancing (decompression) of the pres-

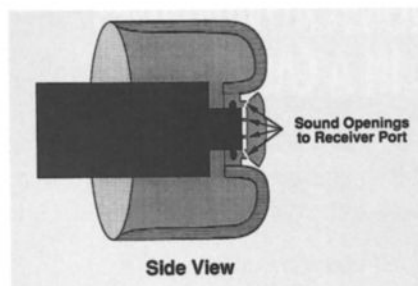


Fig. 11. The wax guard concept of the BST.

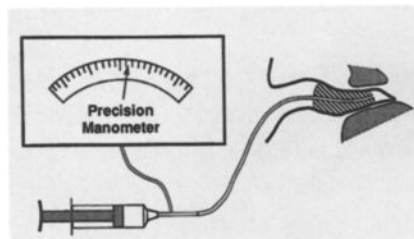


Fig. 12. Precision manometer arrangement used to define the optimal pressure equalization conditions of the BST size, shape and thickness.

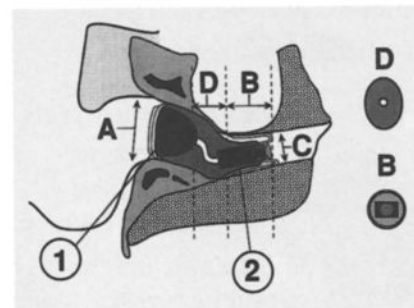


Fig. 13. Diagram showing how the BST performs to solve the difficulties of fitting a hearing aid to compensate for the articulation problems between the cartilaginous and bony portions of the ear canal during deep canal hearing aid fittings. (See text for explanation.)

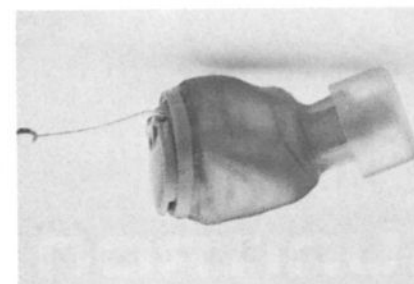


Fig. 14. Instrument with BST.

sure behind the seal in the residual cavity and to allow for aeration with the external environment. To achieve this by use of a conventional vent, the vent size would have to be approximately 0.6 mm.¹

The design of the tip precluded a standard parallel vent with which to achieve this pressure release. Pressure release was, therefore, designed into the fitting tip after careful study that recognized that to be able to maintain all the advantages of peritympanic application, the decompression (pressure release) function built into the BST had to have a high impedance to sound waves. The size of the decompression aperture in the tip was designed to be such that the return to pressure equalization or balance should be slightly larger than a period of the lowest frequencies applied. To facilitate making this determination, the instrument, illustrated in Fig. 12, was used to check the time constants required and to define the optimal pressure release size. An air volume of 2 cm³ was injected into the residual cavity by means of a tube connected to a syringe that was branched to a precision manometer. The functional aperture for pressure equalization was obtained when a brief pressure increase pulse, which disappeared immediately, was measured. A display of this pulse shows that a time constant does occur and that the system has considerable resistance to rapid pressure variations (sound waves).

Solution 7: Fit Without "Walking" From its Position in the Ear

A sufficient number of difficult cases having this problem has not yet been gathered. However, the following report from one patient (and similar comments from other patients) suggests that the design of the BST may be performing as was planned. "Wore aid for six hours, during work, during dinner, and for three hours while playing three sets of tennis in 85° temperature. The aid stayed in very well during the entire time. I did not have to push the instrument in for reseating although my other XP works its way out slightly."

Positioning

Fig. 13 shows the BST in position within the ear canal and Fig. 14 shows the complete instrument. The letters in Fig. 13 relate as follows:

A Inferior-superior movement to be absorbed (about 2 mm and accommodated for by the FC soft material of the shell).

1 The first non-flexible area of the XP hearing instru-

ment containing the battery, microphone, and electronics.

2 The second non-flexible area of the XP containing the receiver.

B So-called articulation area in which highly flexible, hollow FC material is used for the BST tip that has a flex pressure of only 10 to 15 grams (to accommodate up to 100% expansion in the anterior-posterior direction—mostly from mandibular movement).

C Any slight residual radial deformations will be damped by the suspended fitting of the BST because it is deformed at a pressure much lower than that of the discomfort tolerances of the bony ear canal.

D Transition to the so-called articulation area (accommodated for by the FC soft material of the shell).

Summary

The Bony Seal Tip concept is a new approach to solving some of the fitting challenges associated with deep canal hearing aid fittings. Although numerous acoustical and cosmetic advantages exist with deep canal fitting applications, the primary obstacles to expanded use are now understood to relate to consumer and dispenser complaints about the comfort of fit, the occlusion effect, feedback, cerumen protection, pressure relief, "walking" from the ear canal, and the difficulty in taking appropriate ear impressions.

The main challenge of any new deep canal technique understandingly lies in providing an acceptable physical and mechanical fitting of the instrument within the bony structure of the external auditory meatus. The Bony Seal Tip is designed to be an improved solution to these complaints, along with maintaining the advantages of peritympanic hearing aid fittings. ♦

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2. Philips Hearing Instruments, XP Newsletter Produced for XP Certified Dispensers, No. 2, January, 1992.

This article was submitted by Henri Garcia, vice president, marketing, Philips Hearing Instruments, Eindhoven, The Netherlands and Wayne Staab, PhD, special consultant to Philips Hearing Instruments on peritympanic hearing instruments. Inquiries can be submitted to Staab at 602-942-4939.