Field Study News

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Titanium FitGuide – helping more than 50% of people get an even more discreet Virto B-Titanium

A recent study conducted at PARC (Phonak Audiology Research Center) in Warrenville, Illinois reveals the Titanium FitGuide (TFG) delivers deeper fitting custom hearing aids. Eighteen adults were screened, enrolled and fit with Virto B-Titanium in-the-ear hearing aids utilizing two methods, standard versus TFG. Use of the TFG resulted in more than half of participants receiving a deeper fitting device. The devices were, on the average, placed 2.9mm deeper in the ear, compared to the standard approach of modeling. Of those participants who benefited from the TFG, the majority expressed a preference for the hearing devices built based on TFG data, in regards to visibility.

Introduction

In 2015, Abrams and Kihm reported results from an online survey which revealed that, of the most common reasons why people do not buy hearing aids, financial constraints and lack of perceived need fall at the top. Once these are resolved, the stigma of hearing loss begins to surface. Typical explanations are that they are too young to wear hearing aids or that hearing aids are too embarrassing and unattractive.[1] With market analysis showing that 62% of potential first time users prefer an invisible hearing aid,[2] the introduction of smaller, in-the-ear devices has changed the industry.

Although this option created new opportunities and selections for end users, the process of obtaining invisible hearing aids is not always as straight forward as it seems. Due to anatomic limitations, building discreet in-the-ear devices has not always been feasible. One opportunity is to take into account the dynamic aspects of each individual ear canal. Traditional impression taking methods capture only the static status of the ear canal. One factor that can influence the dynamics of ear canals is skin texture, an aspect that goes unaccounted for in current custom product candidacy protocol. Pirzanski & Berge found, using a large data base of ears (n= 744), that up to 1 mm of widening can occur based on individual anatomical factors relating to ear canal texture and mobility. In addition, hearing care professionals (HCPs) were not able to accurately predict ear canal dynamics based on otoscopic examination.[3] This indicates that there is added value in capturing dynamic ear canal information.

One way HCPs try to capture this dynamic information is by taking a set of impression, with an open and closed mouth, utilizing bite blocks. This process takes valuable clinic time which is not always available. These factors may lead to issues with comfort, migration or feedback, but among the bigger initial disappointments is that the client ends up with hearing aids more visible than they would prefer.

The smallest custom hearing aid from Phonak, the Virto B-Titanium (see fig. 1), includes a titanium shell designed to allow for deeper fitting devices.[4]

Figure 1. Virto B-Titanium

As the titanium shell is 50% thinner than the traditional acrylic UV-shells for in-the-ear products, this creates up to 30% more room inside the shell. This additional space allows flexibility for either a deeper fit, larger receiver, or bigger vent depending on the client's needs.

The introduction of the patented[5] EasyView Otoblock (EVOB) allowed for deeper ear impressions and therefore the deeper fitting devices. It has a transparent lens at the end that allows full visualization during placement, enabling confidence in placing the otoblock past the second bend and attaining an average of 6 mm[6] deeper impressions. While this additional canal length information is invaluable, the HCP still does not have a reliable tool to assess the individual flexibility within the canal without taking multiple impressions.

The Titanium FitGuide (TFG) provides a new way to evaluate ear canal dynamics and get even deeper fittings for clients who desire super discreet hearing aids. The TFG (see fig.2) is a clinical tool for the hearing care professional (HCP) to use at the hearing aid evaluation. The tool consists of two different modular ends: one end for those who require a moderate receiver (M receiver) and the second end for a power receiver (P receiver). Each end represents the minimum space requirements for a Virto B-Titanium, considering a 1.4 mm vent. It is made from solid medical grade titanium. The audiologist inserts the appropriate module into the client's ear canal and notes the depth in millimeters, using the indicators that are etched on the stem of the tool. The HCP then provides this depth indicator on the hearing aid order form that accompanies the client's ear impressions.

With this additional information reflecting the dynamic tolerance of the client's ear canal, the modelling process of the titanium shell can be based on the additional information on the individual characteristics of the ear and can leverage this information to make the most discreet hearing aid possible.

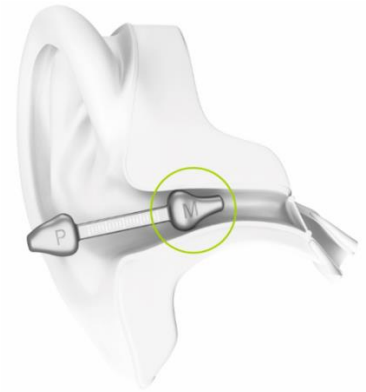

Figure 2: TFG, market ready configuration

Methodology

Twenty-six adults between the ages of 29 and 76 years (average 65 years) were recruited for this study. Twenty-three of these adults, who met study qualifications, were initially enrolled. Five participants were later excluded or withdrawn during the data collection period, resulting in a total of eighteen participants. Average hearing loss for these individuals was in the mild to moderate range.

The TFG procedure was completed at each participant's initial screening appointment and was repeated on the 20 participants who returned for the fitting appointment to evaluate the presence of a learning curve. The instruction for when to stop the insertion of the TFG specified that the deepest most comfortable depth should be collected. In other words, once the participant reported the TFG felt snug but comfortable enough to wear for at least 8 hours per day, the depth was measured by finding the indicator on the stem of the tool at the inter tragal notch. (For full instructions on how to insert the TFG, please visit phonakpro.com). Ear impressions were made using the EasyView Otoblock and a manual impression gun containing a low viscosity impression material.

Participants were fitted bilaterally with two sets of M receivers, Virto B-Titanium hearing aids: (1) "standard devices," modeled traditionally based on the ear mold impression (EMI) scans only, and (2) "TFG devices," modeled using the TFG measurements along with the data from the EMI scans. Participants wore both devices over the course of a one or two week home trial, and alternated the days during which they wore each set of devices. They were asked to document their experience and fill out a questionnaire directly comparing the TFG devices to the standard devices.

Results

In the initial screening appointment, the average TFG indicator was 11.8 mm. The procedure was then repeated at the following appointment, where the TFG indicator was found to be on average 13.1 mm. This difference in TFG value is likely attributed, at least in part, to both HCP and participant learnings as well as slight modifications to study protocol after the initial TFG insertions.

To determine how the TFG measurements translated to the in-ear depth of the devices themselves, removal filament lengths were used to approximate hearing aid faceplate depth in the ear canal. In the modeling rules for all Virto B-Titanium, the sphere of the RF is designed to sit directly in, or

as close as possible to the client's inter-tragal notch. Removal filament lengths of the TFG devices were modeled to match the TFG measurements for each participant, while the removal filament lengths of the standard devices were determined based on traditional modeling.

For the 23 participants originally enrolled, results from the screening/modeling portion of the study revealed that the TFG modeling yielded devices that were seated deeper in the ear canal for 26 of the 46 ears (57%). In one ear of one participant, this improvement was 11 mm, though this data point was deemed an outlier and was therefore excluded from further analysis. On average, the faceplate depth improvement was 2.9 mm (see fig. 3).

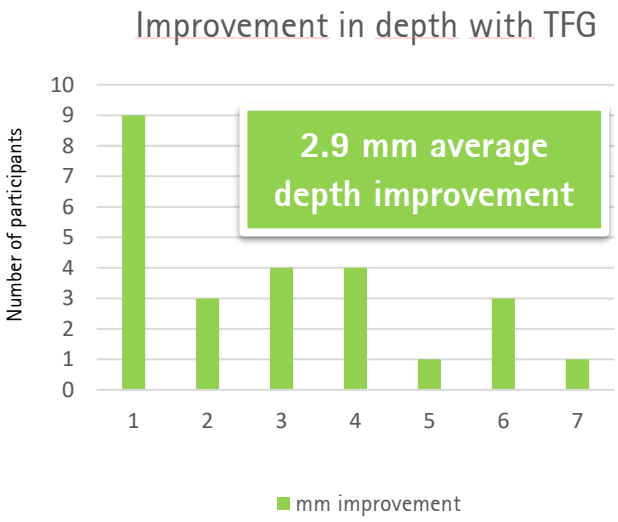

Figure 3: Average depth improvement for ears that had improved faceplate depth using the TFG.

Results of the home trial questionnaire directly comparing the TFG devices to the standard devices indicated that of those participants who received a deeper fitting device using the TFG, they preferred these devices with respect to visibility (see fig. 4). Thus, not only were the TFG devices deeper fitting from a modeling perspective, but the participants also could perceive the difference in discreetness.

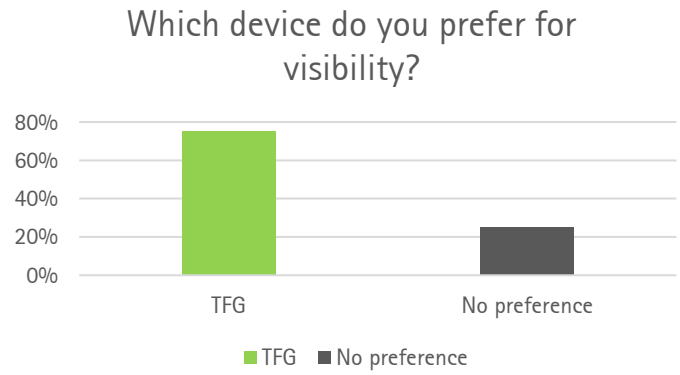

Figure 4: Outcome from questionnaire. Of participants who have deeper fitting with the TFG, 75% preferred them with respect to visibility, compared to standard devices. 0% preferred the standard devices for visibility.

Conclusion and Discussion

The use of the TFG leads to improvements in device size and perceived discreetness. Virto B-Titanium hearing aids were deeper for more than half of participants by an average of 2.9 mm compared to the standard approach of modeling. The TFG devices were also preferred by 75% of participants (with the other 25% reporting no preference) with respect to visibility. Further, this feasibility study resulted in several learnings regarding the benefit and implementation of the TFG.

There was a TFG insertion learning curve experienced by the investigator and participants - this should be accounted for prior to first use of the TFG in clinical practice. It is recommended that a clinical HCP collect 10-15 practice insertions with the TFG prior to using it on a client for the first time. It is also recommended that when using the TFG in the clinic, that the client has one practice insertion. This should be conducted with the P receiver regardless of the receiver strength needed (as the shape of P is wider and insertion can be more comfortable than the M) while navigating the TFG for the first time. Implementing this recommendation can help improve the test-retest reliability of the tool, the comfort level of the HCP and client.

Slight modifications to the TFG insertion protocol have been adopted to mitigate risk and ensure patient comfort and ear canal safety. The recommendation for TFG insertion depth is now to halt medial insertion when the module of the TFG is sitting past the first bend i.e. once you see that you will achieve invisible-in-the-canal depth, there is no added benefit to continuing deeper and the risk of harm and hearing aid insertion difficulties increases as you get closer to the client's tympanic membrane.

Finally, in 37% of the participants, the TFG hearing aids did not sit as deeply as the standard devices. For clients who receive a depth benefit of the TFG, the TFG value will be used when modeling their Virto B-Titanium hearing aids. In cases where the TFG value indicated a more visible, or larger device, the TFG value will be discarded. The TFG will only help to make Virto B-Titaniums more discreet. In the rare case in the field where a client experiences comfort or insertion challenges with the standard modeling (i.e. their TFG indicator was more lateral than standard modeling) a remake with special instructions to model specifically to the TFG value can certainly be requested.

While Virto B-Titaniums fit in this study had a moderate receiver configuration, the market ready TFG has separate modules for both moderate- and power receivers to improve ease of use for the HCP. Separate investigations conducted as this report was published included power receivers. The preliminary outcome of those fit rate investigations indicates that power receiver Virto B-Titanium devices will also receive similar discreetness benefits for around half of the population. These benefits are thanks to the Titanium FitGuide and an additional new modeling flexibility that allows for an alternative mounting option of our power receivers. With proper TFG implementation in the field, HCPs can expect that new Virto B-Titanium hearing aids (regardless if they have an M or P receiver) will have a deeper placement in the ear canal for around half of clients.

In this investigation the TFG helped to make the Virto B-Titanium even more discreet in over 50% of people by an average of 2.9 mm. Titanium shells allow for smaller and therefore more discreet devices, compared to those made from industry-standard acrylic. Results of this study suggest that with the addition of the TFG, clients will receive the exceptionally discreet hearing aids they are asking for.

For more information on how to use the TFG, please visit www.phonakpro.com

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