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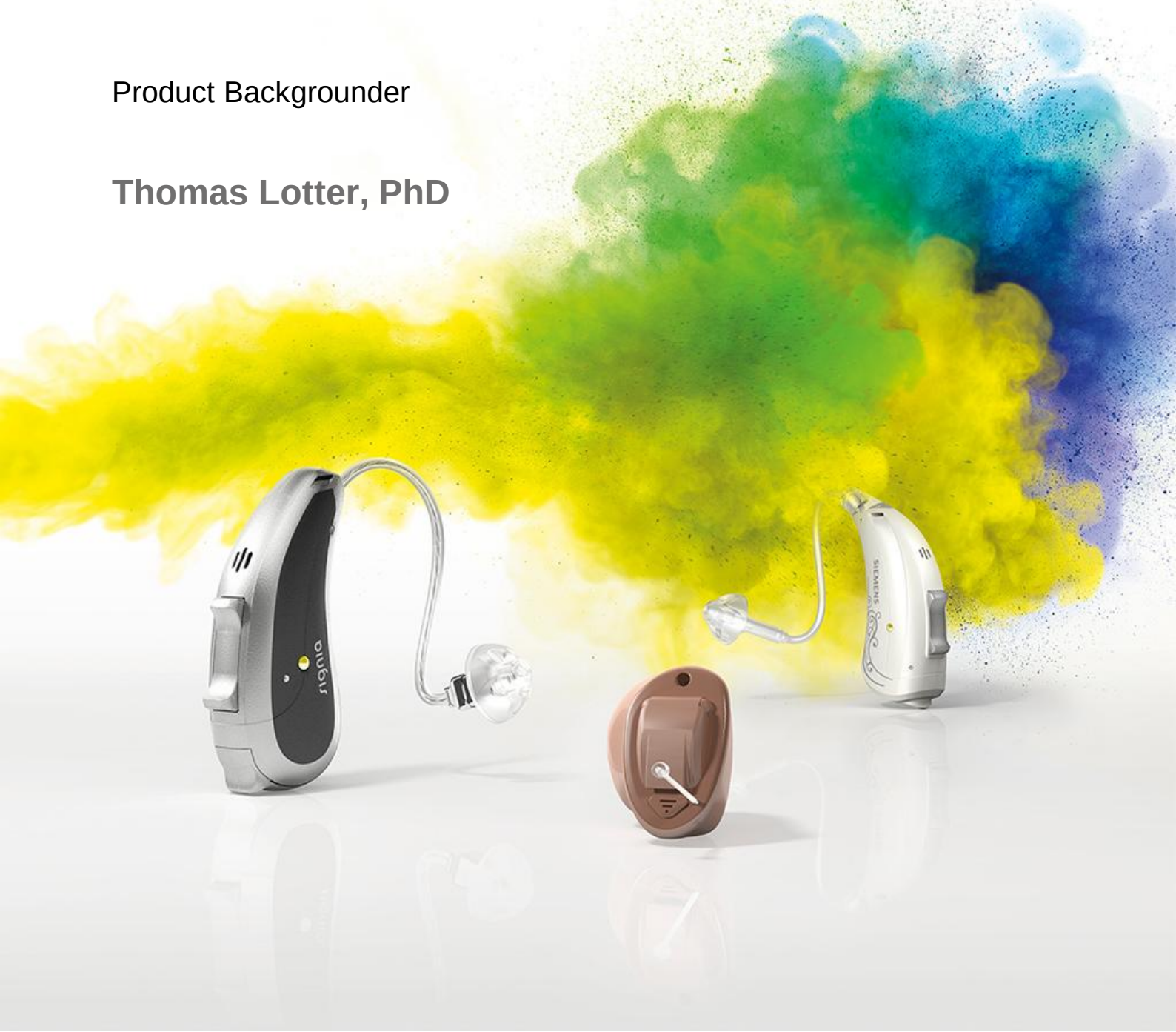
Silk and Click Sleeves – A New Concept for In-the-Ear Fittings

Product Backgrounder

Thomas Lotter, PhD



Silk and Click Sleeves – A New Concept for In-the-Ear Fittings

Motivation and Idea

In-the-ear (ITE) hearing instruments, especially those completely in the canal (CIC), provide a number of patient benefits [1]. One of the greatest advantage is the discreet cosmetics; they are essentially invisible for some fittings. Usability, such as ease of insertion and removal, or being able to use the phone like everyone else, is among other reasons for choosing an ITE. Furthermore, the placement of the microphone recessed in the ear preserves natural directivity and reduces wind noise significantly.

From a technological viewpoint, miniaturization of hearing components is a key enabler for continued improvement in ITE solutions. It has been only since the 1960s that miniaturized transistors enabled the first fully-in-the-ear products, and it was not until the 1990s that component size reductions and other factors enabled products to be fitted completely in the ear canal. In recent years, miniaturization has advanced further, allowing for completely invisible products that are fitted deeply in the ear canal and can be worn for months. However, those later niche products fail to be of significant relevance in hearing aid provision due to various reasons such as wearing comfort, or the need for a complicated and consequently error-prone fitting process, which is unpractical for a majority of hearing care professionals.

While these smaller custom products once had a high market share, mini-BTE receiver-in-the-canal (RIC) products have grown to 65% market share in places such as the U.S in recent years. The reasons for this success include the soft ear canal couplings that often provide the patient improved sound quality, and extended comfort. Also, the selection of ready-made tips and domes is very useful in the professional work environment, particularly when available fitting time is a limiting factor.

We have designed a new innovative ready-made ITE product called Silk. Along with this product is the introduction of especially designed click sleeves. This new product capitalizes on the successful components of the RIC fittings, so that similar patient benefits can be obtained with ITE products.

Silk and click sleeve concept

This completely-in-the-canal system is achieved with a non-invasive miniaturized instrument and a set of soft sleeves. By utilizing only ready-made parts, difficulties from impression taking and hard shell manufacturing are avoided. The mechanical tasks of ear canal coupling to achieve comfort, retention, and a target venting depending on the hearing loss fall on the soft earpiece alone.

The design of a miniaturized instrument, which fits in the majority of ear canals, is not a new task, and various solutions already exist. Requirements for ready-made soft earpieces are, however, more challenging compared to the application in RICs, where the RIC tube itself often pushes the silicone tip in the ear canal, and optional silicone locks in the concha can be used to ensure retention. Signia, therefore, now introduces click sleeves, for the purpose of ear coupling with the ready-made instrument Silk. Figure 1 and 2 show the conceptual approach of the click sleeves in combination with a Silk instrument.

Retention and sealing of the ready-made ear pieces is enhanced compared to conventional RIC domes, with the sleeves in contact with the ear canal wall tangentially over a comparably large surface. To maximize the contact surface, the click sleeve cross-section is oval shaped to mirror the ear canal geometry.

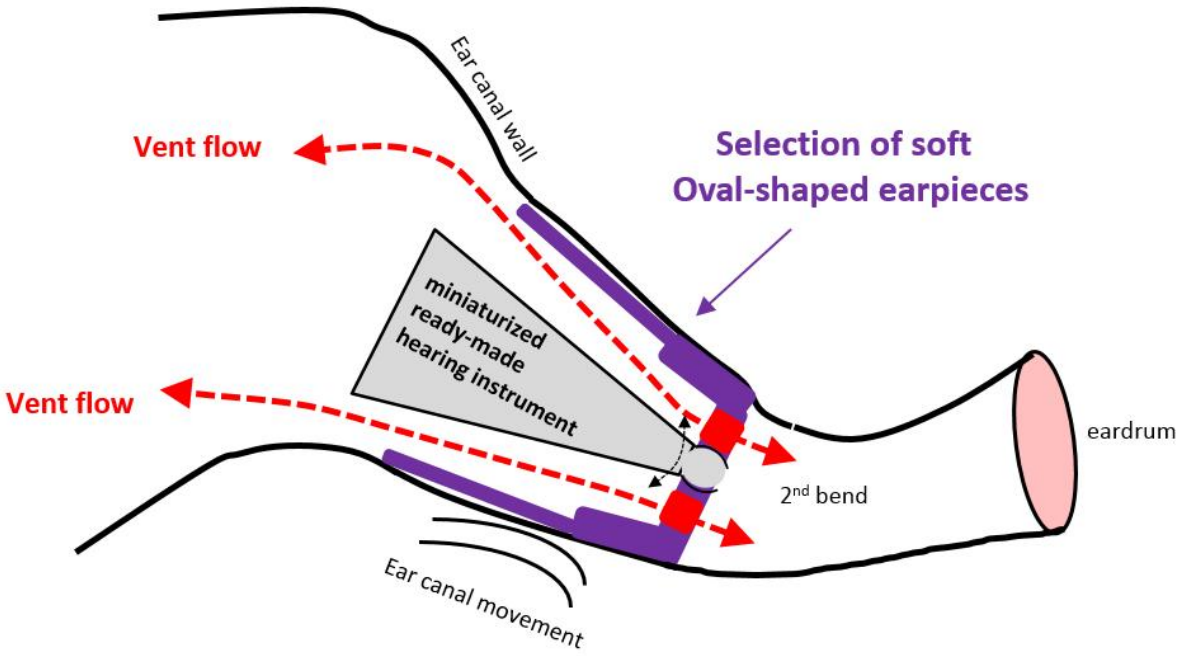


Figure 1: Concept of the Silk ready-made hearing instrument combined with the click sleeve ear coupling.

The ready-made hearing instrument is placed inside the click sleeve using the Signia click connection system as is in use with RIC instruments.

The ability to adapt to the individual ear canal shape is provided by various features. First, by the flexibility of the sleeve itself. Secondly, the hearing instrument inside the sleeves can be tilted relative to the sleeve by means of the ball joint, and finally, the sleeve joint is flexibly held in the silicone also.

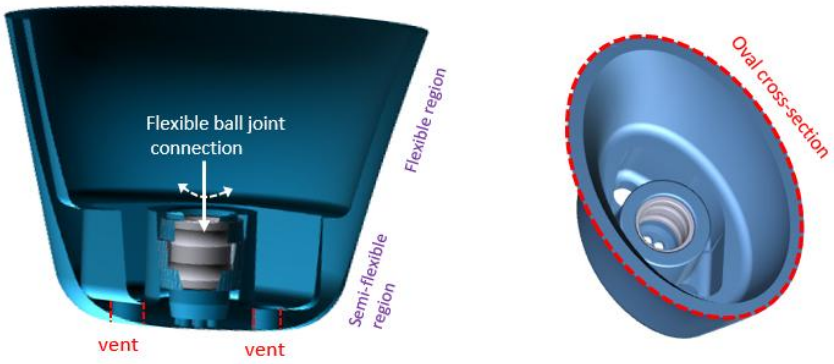


Figure 2: Design details of click sleeves showing components to maximize compatibility with a variety of ear canals.

The click sleeves are composed of two functional regions. A fully flexible portion for maximizing canal shape adaptability, retention, and acoustic sealing. A second semi-flexible portion helps with placement in the ear canal. Given that the hearing instrument is smaller than the sleeve, different vents can be realized via holes at the tip. The vent flow is then guided through the inside of the sleeve.

Silk and click sleeve product

Figure 3 shows a picture of Silk and the variety of click sleeves available.

Figure 3: Silk product and click sleeve types S/ M / L

To account for the different sizes of ear canals, three click sleeve sizes S, M, L are offered. To take different amplification needs into account, all three sizes are available in both closed and vented versions. In the closed version, used for higher amplification needs, a small vent of 0.8mm diameter and 4mm length realizes an equivalent vent size of 1.6mm diameter and 16mm length. In the vented types, two short openings are incorporated on both sides, providing an equivalent vent size of 16mm length and >4mm diameter.

By serialization and miniaturization of Silk, we are able to provide a very small but feature-rich form factor, eliminating the need to compromises between functionality and cosmetics. Notably, Silk includes connectivity features such as binaural directional microphones [2], TV streaming, and direct remote control from a smart phone [3]. It features an ample fitting range for moderate hearing losses with a peak amplification of 50dB in the 2cc coupler.

Venting concept efficacy

We know that one downside of ITE fittings in general is the occlusion effect. It is caused when vibrations from the ear canal cannot escape, and it can be resolved to a large extent with venting. To assess the venting efficacy of click sleeves, the occlusion effect was measured using the procedure described by Mueller et al [4]. Silk product with M size click sleeves of both closed and vented types were measured with 14 subjects with medium to large ear canal, and compared to the ear canal SPL when the canal was open. Patients were asked to vocalize an “e” at a defined level with the ear canal open, and with Silk using both closed and vented click sleeves placed in the canal; the hearing aid was *turned off*, to ensure that the measure was directly related to the occlusion effect. The output of the vocalization in the ear canal was assessed using probe-microphone equipment, with the probe tube tip placed approximately 5mm from the eardrum. Figure 3 compares the sound pressure levels at the ear drum for the three different conditions.

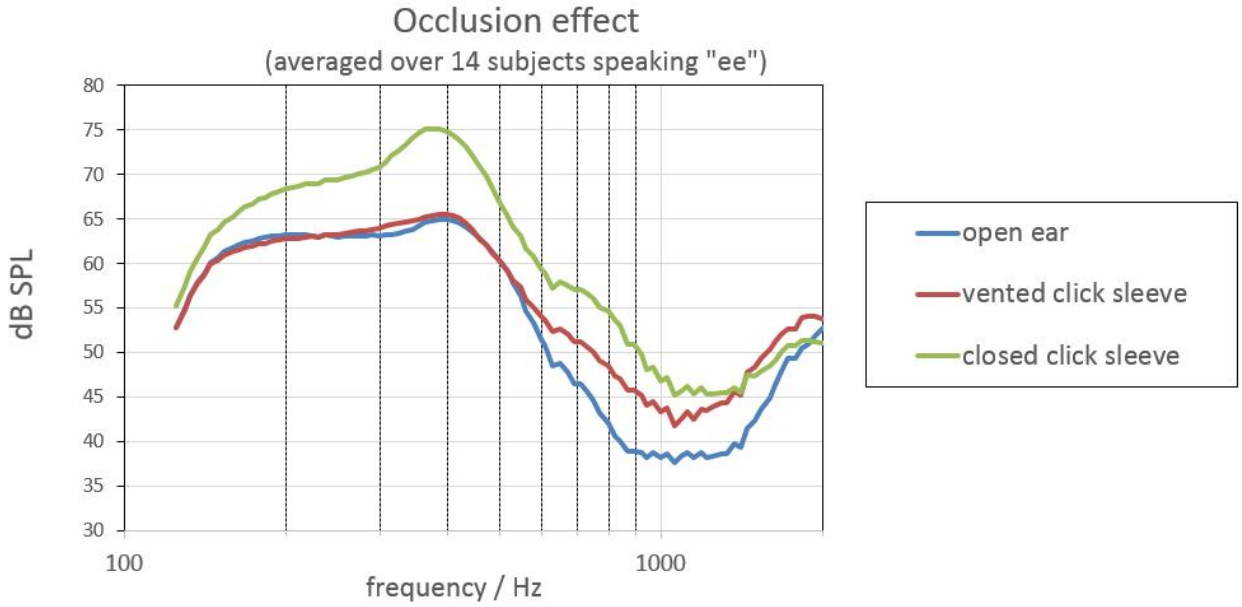


Figure 3: Occlusion effect of Silk with different ear coupling when pronouncing “e” (averaged curves for n=14).

Observe that the average data for the vented sleeve (red line) show an output essentially identical to the open ear (blue line), indicating no occlusion effect. This is consistent with occlusion effect research using the open fitting tips of RIC instruments [5]. As expected, there was some occlusion effect for the closed click sleeve (green line) of about 5 to 10 dB compared with the open ear. These sleeves, however, typically are used for patients with greater hearing loss, who tend to be less annoyed by occlusion. Overall, this indicates that the concept of click sleeve technology does provide a sufficiently large vent in a variety of ear canals.

In order to take individual variations into account when these instruments are programmed and fitted, probe-microphone measurements can be used. In this situation, the vented click sleeves allow an easy placement of the measurement tube through the venting hole. However, an alternative is now available with the new Connexx feature “effective coupling estimation,” which is a part of the critical gain measurement. It measures the patient’s individual ear canal acoustics, compares it against statistical values used in Connexx, and automatically adjusts the acoustic properties used for primaxFit accordingly for each individual patient.

Concept assessment in fitting environment

To assess the feasibility of the new product concept for professional fitting practices, a field study in 6 independent hearing care facilities in Germany and France was conducted. Twenty-two patients were fitted with Silk. Audiologists used their customary fitting procedures for selecting gain and output, and their typical counseling process.

Patient Selection:

In the field study, most patients chose this product because of cosmetic reasons. A secondary reason was wearing style. For example, the patient did not want a device hanging behind the ear due to occational requirements. By the nature of the product and its appeal to new users, 16 out of the 22 patients selected were first time hearing aid wearers. The average age of the patients was 62 years, with the averaged four-frequency (500, 1000, 2000 and 4000Hz) average hearing loss of 41dB and a maximum of 64dB. Compared to a reference commercial sales test with a RIC primax product (average age 72 years, 48dB average hearing loss), patients of younger age with less hearing loss chose the Silk product.

Satisfaction Results:
Satisfaction ratings were obtained from patients using a four-point continuum: very satisfied-satisfied-unsatisfied-very unsatisfied. Table 1 provides the overall results. Eighteen of the 22 patients used Silk with click sleeves for the duration of the field trial. For 4 patients, the ear canal was too small for click sleeves and a 4mm or 6mm click dome was chosen. Those 4 fittings, however, resulted in unsatisfied patients after home trial with problems in wearing comfort and sound quality. Typical problems included: the device slipped out of the ear, felt uncomfortable or whistled. These four patients were not used in the final analysis.

	After Fitting			After Home Trial		
Category	Overall	Wearing Comfort	Sound Quality	Overall	Wearing Comfort	Sound Quality
Very Satisfied & Satisfied Ratings	100% (18/18)	89% (16/18)	94% (17/18)	88% (15/17)	88% (15/17)	88% (15/17)

Table 1: Satisfaction for important categories in the field study. (Original n=22, dropout of 4 patients who needed to use small click domes, 1 patient did not complete the home trial questionnaire)

As shown in Table 1, fittings with Silk and click sleeves resulted in high satisfaction ratings, both immediately after first fit and after the home trial. In fact, at the initial fitting, the overall satisfaction would have been 100%, except for two patients being not being satisfied with wearing comfort.
More importantly, the high comfort and satisfaction ratings remained after the home trial, indicating that the high ratings were not related to the novelty of the fit, but rather a sustainable benefit. Also, it is interesting to note that sound quality ratings were high after initial fit and after the home trial.

Summary and Discussion

The Silk product using the click sleeves concept provides an alternative to RIC or CIC fittings. It applies some of the benefits of RIC products such as soft ear coupling and fitting flexibility with ready-made earpieces to CICs. The key advantages of small ITE products, such as cosmetic attractiveness and ease of handling, are maintained. A laboratory and a field test show that the product is especially attractive for first time users, and with the exception of very small ear canals, provides a sustainably satisfying solution.

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Thomas Lotter, PhD, has been with Sivantos GmbH (former Siemens Audiologische Technik GmbH) in Erlangen, Germany since 2004. His most recent work there has focused on the product definition of various innovative hearing systems such as Aquaris, the first digital waterproof system, or the Pure micon, and the Silk primax.

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