Phonak Field Study News.

Safety and Effectiveness of the Phonak Lyric Self-Replacement Procedure

A large-scale study was conducted examining the safety and effectiveness of the Lyric Self-Replacement procedure compared to Hearing Care Professional (HCP)-replacement. The study included fifty-seven experienced Lyric users across eight clinic sites. Study participants were trained to independently conduct self-replacement and were followed for three subsequent self-replacement opportunities in this clinical investigation.

Wiebke, M. & Branson, G. April 2024

Key highlights

- All participants who were eligible for HCP led self-replacement training were successfully able to prove proficiency and advance to independent self-replacement.
- No meaningful or systemic increase in safety concerns were noted with the Lyric Self-Replacement procedure as compared to the HCP-replacement procedure.
- The findings in this study were the foundation for FDA 510k clearance of the Lyric Self-Replacement procedure and support that Lyric with self-replacement is as safe and effective as HCP-replacement.

Considerations for practice

- For approved candidates, self-replacement can offer improved flexibility and reassurance as well as reduced clinic visits.
- For Lyric clinics, reduced refit visits can translate to the potential for increased profitability and flexibility.
- The potential reduction of in-clinic visits and the resulting increase in convenience for the HCP and the patient far outweigh any risks or burdens uncovered in this clinical investigation.

Introduction

Lyric fittings

Lyric is an extended wear hearing device that provides amplification for individuals with mild-to-moderately severe hearing loss. Lyric is fit by Certified Lyric Fitters, who have undergone training and received certification to fit Lyric. The device is designed to be worn continuously in the external ear canal for up to 120 days before being replaced.

When compared to daily wear devices, extended wear devices pose a distinct set of advantages and challenges. With deep placement and intentional sealing in the bony portion of the ear canal, Lyric optimizes natural sound quality by leveraging the anatomical structures of the pinna and external auditory canal to minimize the occlusion effect and preserve interaural timing and intensity differences, which carry sound localization cues (Ross M., 2004). Proximity to the tympanic membrane also enables the device to utilize less gain, while creating an exceptionally discreet hearing solution for the end user. Additionally, the amplification strategy behind an extended wear device provides the opportunity for the user to experience a robust, continuous pattern of auditory stimulation, with the intention of approximating the stimulation pattern of a natural, intact auditory system 24/7.

Lyric is sold as a subscription-based model, and device fitting is performed by a Certified Lyric Fitter. Lyric fitting and care require a substantial time investment by the HCP to offer continuous care for device replacement and ear canal health maintenance, as well as a commitment by the patient to return to the HCP's office approximately every ten weeks.

During the initial Lyric fitting, the HCP carefully reviews candidacy considerations and completes ear canal measurements and sizing procedures followed by eventual device placement for appropriate candidates. This initial evaluation and placement are integral parts of determining Lyric candidacy and promoting the patient's success and comfort with the device. Once this process has been completed, device replacement visits are less complex, generally involving a simple exchange for a new device using the pre-determined measurements established at the initial fitting, along with an ear health check and cerumen management, as needed.

Self-replacement methodology

Reports from HCPs in the field have anecdotally supported the success of an HCP-guided Lyric Self-Replacement (SR) procedure, which prompted the initiation of a pilot study investigating safety and efficacy of this experimental SR procedure in 2018. Results from this pilot study showed favorable patient outcomes from a controlled, provider-guided Lyric SR procedure (Gardner, 2019). The criteria for self-replacement established in the pilot study were the foundation for this larger, cross-site investigation, which aimed to determine if the SR procedure yielded comparable outcomes for safety and efficacy as compared to the standard best practice model of care, HCP-replacement (HCPR).

SR does not replace the initial sizing procedure or fitting of the device, which are always performed by the Certified Lyric Fitter. However, once the patient becomes accustomed to wearing a properly programmed and positioned Lyric, they develop an exclusive perspective to confirm proper device placement, including tactile feedback and auditory perception unique to the fit of the device. Based on device placement, some patients may be able to confirm sound quality and comfort, which can prompt adjustments at the time of placement.

Following the patient's initial period of device wear, the Lyric HCP and the patient can discuss the option of SR. Interested patients who have worn Lyric for three months successfully can be assessed for SR candidacy, which includes ear health history, cognitive ability, and dexterity. For candidates, the HCP provides SR training, including comprehensive training on device storage, insertion, and inspection upon removal. Following training, both the patient and the HCP agree on readiness to move forward with independent SR, prior to sending a device home for independent SR. Only one device per ear should be provided at a time, which ensures that the patient returns to the clinic every other replacement for a thorough ear health examination.

The HCP remains a key partner in the Lyric hearing process for each patient conducting SR, as the patient continues with visits to the HCP for ear health checks, device programming, and cerumen management (as needed), although ideally, the number of HCP visits should be halved. At any time, if the HCP or patient determines that the SR procedure is no longer a good option for the patient, typical HCPR can resume. Ultimately, implementing a SR methodology presents an area of opportunity to make Lyric more accessible and manageable to patients and HCPs alike.

Methodology

Participants

Fifty-seven experienced Lyric users (22 female, 35 male) were enrolled in the study, across 8 clinic sites in the United States. The average age of all participants was 63.6 years (ranging between 38 and 86 years) and the average duration of Lyric device use was 4.0 years. All Lyric device sizes (XXS – XXL) were represented in the study.

Of the 57 participants enrolled, 44 were bilateral Lyric users and 13 were unilateral users (7 left, 6 right). Average unaided audiometric thresholds for all enrolled participants are shown in Figure 1.

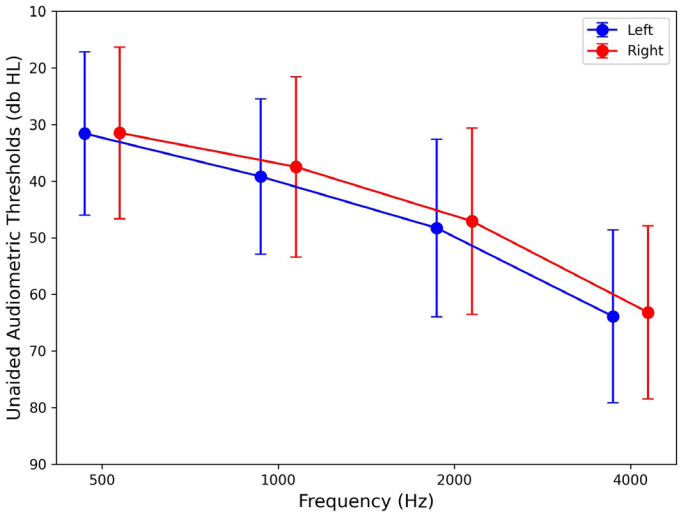

Figure 1. Unaided audiometric thresholds of the study participants n=57

Equipment

Participants were fitted with Phonak Lyric™4 devices. Devices were programmed consistently for each individual participant across all study visits.

Procedure

This study was a multi-center, longitudinal clinical investigation with a repeated-measures design, in which a cohort of experienced Lyric4 hearing aid users alternated between HCPR and SR approximately every two weeks over a minimum of 8 and a maximum of 10 pre-scheduled study visits. For each study participant, the duration of participation was approximately 14-18 weeks. Unscheduled study visits outside the pre-determined study visit schedule were incorporated for device issues and ear health management on an as-needed basis.

The self-controlled study design was selected, as it mimics the intended clinical use case for SR, in which the SR procedure is only offered to eligible, experienced Lyric users at every other device replacement per ear. Lyric SR is not intended to replace the HCPR model of care entirely. Rather, it is intended to be used intermittently, as guided and recommended by the Certified Lyric Fitter, at every other device replacement. Study activities represented this intended use by including HCPR every other time within the SR model of care. During the course of this clinical investigation, the HCP was responsible for assessing SR candidacy, completing SR training, replacing devices at every other visit, and managing overall hearing care.

Total study visits for each eligible participant included an initial study visit (where SR candidacy was assessed), and a minimum of one and a maximum of three SR training visits. Individual participant training needs were determined by the HCPs using the Lyric Self-Replacement proficiency checklist (Phonak, 2020). Participants who passed the proficiency evaluation by training attempt three, were eligible to complete individual visits for each device replacement condition.

Regarding SR training, of the 57 enrolled participants, 56 entered SR training. Fifty-six passed the training and were deemed proficient for SR by the HCP, with 52 passing on the first attempt, three passing on the second attempt, and one passing on the third attempt (Figure 2).

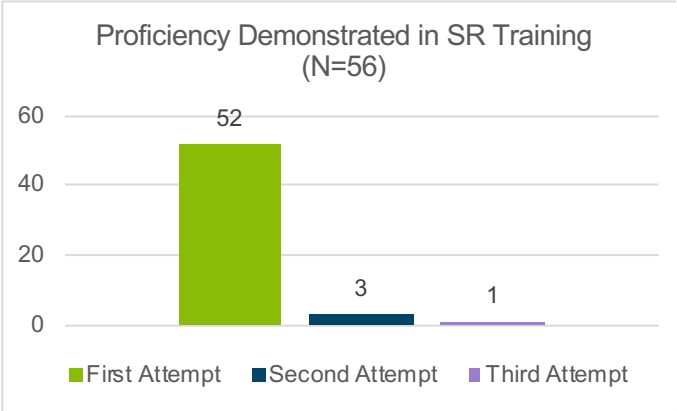

Figure 2. Number of participants who passed proficiency for independent SR on the first, second or third attempt.

For all participants, study visits proceeded in the following sequence: HCPR, SR training, SR, HCPR, SR, HCPR, SR, Final (end of study) (Figure 3). Outside of the training visit, SR was conducted independently, with observation in the clinic at visit 3, and in the home environment at visits 5 and 7.

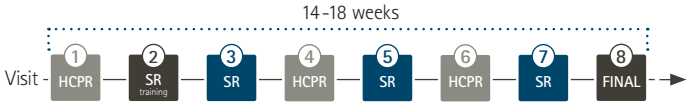

Figure 3. Sequence of study visits.

Assessments

The following assessments occurred at each study visit:

Visit 1:

- Baseline audiometric assessment (unaided thresholds and QuickSIN)
- Ear-health assessment
- SR candidacy assessment

Visit 2 and 4 through 8:

- Device position assessment (device position and measured insertion depth)
- Aided audiometric (thresholds and QuickSIN) assessment
- Ear health assessment

The presence of persistent, bothersome acoustic feedback and the need for HCP support were tracked throughout the study from visit 1 onward.

Achieved insertion depth, a measurement of the distance between the device and the ear canal opening following device placement was measured by the HCP for all replacement conditions with standard Lyric placement equipment. Device position and ear health assessments were conducted with the aid of standard equipment used in audiological care to observe the ear canal (i.e., otoscope), and investigators were provided with checklists to guide and standardize their observations for these assessments.

Aided audiometric testing was conducted in an ear-specific manner using standard audiometric equipment (audiometer and TDH-39 headphones). For each ear, audiometric thresholds were collected at the following frequencies: 500Hz, 1000Hz, 2000Hz, 4000Hz.

Speech-in noise testing was measured using the QuickSIN test (Etymotic Research, 2006), presented at 70dB, in an ear-specific manner using standard audiometric equipment. For each ear, 2 lists of 6 sentences were presented, and a signal-to-noise ratio (SNR) loss score was computed for each list. The final SNR loss score was the average of the 2 individual SNR loss scores.

Outcome measures

Effectiveness

For statistical comparison of effectiveness outcomes for SR, there is no inherently "good" or "bad" value; therefore, the outcomes must be evaluated in comparison to the outcomes of the HCPR condition for each ear under test. In order to achieve this in the study, data were aligned in paired instances of replacement (Figure 4).

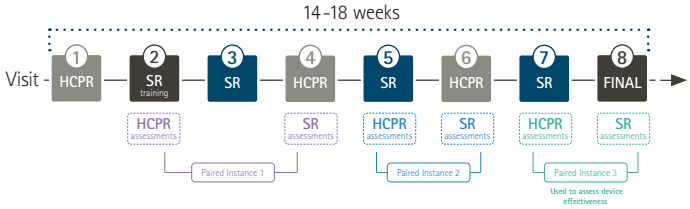

Figure 4. Sequence of study visits with paired instances of replacement.

Due to the anticipated learning effect associated with the SR procedure, evaluation of the effectiveness acceptance criteria took place at the third paired instance. To establish comparability between outcomes of self-replaced and HCP-replaced devices, the burden of responsibility defined in the clinical investigation and statistical analysis plan required successful achievement of effectiveness outcomes for left and right ears separately, for all effectiveness endpoints.

The primary effectiveness endpoint was achieved insertion depth, and co-secondary effectiveness endpoints were ear-specific aided audiometric thresholds (including 4 separate frequencies tested) and ear-specific aided speech-in-noise testing SNR loss.

Safety

The primary safety endpoint was incidence of ear health issues requiring medical referral and related to device placement. Utilizing a pre-defined ear health checklist at each study visit, the HCP indicated the presence of each ear health event (e.g., hematoma, bleeding), its relatedness to device placement, and whether or not it required a medical referral. This endpoint applied to both HCP-replaced devices and self-replaced devices. Safety data was tracked at and between all study visits.

Results

Data collected from this study supports the audiometric benefit of Lyric (Figure 5 and Table 1).

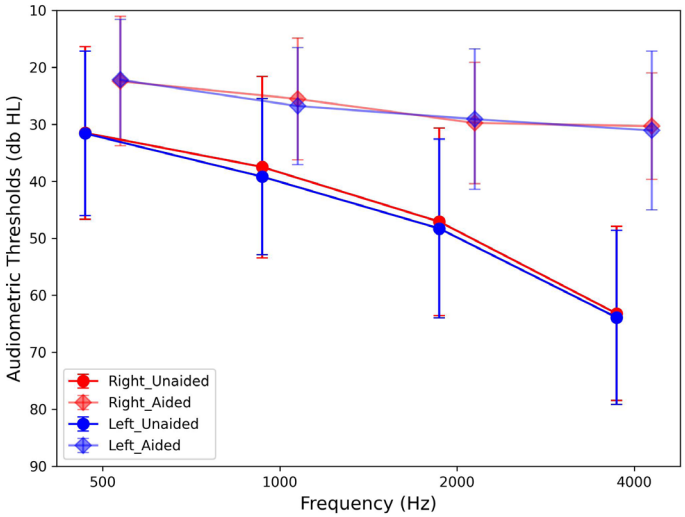

Figure 5. Mean aided audiometric benefit (left ears N=50; right ears N=49)

Speech-in-Noise Testing SNR Loss improvement (dB)			
	Unaided	**Aided, 3rd instance SR**	**Improvement**
Left Ears (N=45)	9.80	6.22	3.58
Right Ears (N=45)	9.70	6.54	3.16

Table 1. Mean aided speech-in-noise improvement: Left and right ears

Effectiveness

Differences are expressed as SR-HCPR, so a lower difference indicates that the outcome was, on average, in better agreement between SR and HCPR conditions, whereas a higher difference indicates less agreement between the two conditions.

Achieved insertion depth (mm)

The established non-inferiority criterion for achieved insertion depth is 2mm, applied at the 3rd paired instance of replacement (SR-HCPR). The non-inferiority margin of ±2mm is supported by post-market fitting data reported and analyzed from over 12,000 replacements from January 2020 to December 2020, indicating 90.9% of devices inserted by HCPs were within ±2mm of the target depth measured at the initial fitting (Assal, 2021).

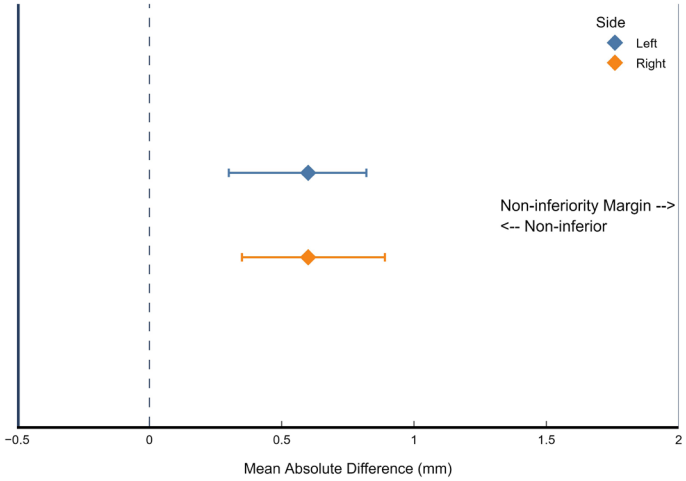

Figure 6. Mean absolute difference between SR and HCP-replacement in achieved insertion depth at 3rd instance

As seen in Figure 6, the upper 95% confidence limit of the mean absolute difference between the SR and HCPR conditions at the third instance in the left and right ears was well below the established non-inferiority margin. While the acceptance criterion was set for the third instance of paired replacement, all instances also fell well below the non-inferiority margin (Tables 2 and 3). With a statistically significant p-value calculated for the third paired instance of replacement, we conclude non-inferiority.

Achieved Insertion Depth left ears, n=50		
Paired instance of replacement	**Mean absolute difference (95% C.I.)**	**Non-inferior p-value**
Instance 1	1.0 (0.68, 1.36) mm	n/a
Instance 2	0.9 (0.50, 1.21) mm	n/a
Instance 3	0.6 (0.30, 0.82) mm	<.0001

Table 2. Achieved insertion depth left ears, all instances

Achieved Insertion Depth right ears, n=49		
Paired instance of replacement	**Mean absolute difference (95% C.I.)**	**Non-inferior p-value**
Instance 1	0.9 (0.52, 1.19) mm	n/a
Instance 2	0.9 (0.48, 1.25) mm	n/a
Instance 3	0.6 (0.35, 0.89) mm	<.0001

Table 3. Achieved insertion depth right ears, all instances

Aided audiometric thresholds (dB HL)

The established non-inferiority criterion for aided audiometric thresholds is 10 dB HL, applied at the 3rd paired instance of replacement (SR-HCPR). The non-inferiority margin of +10dB was chosen as an increase of 10dB HL or more equates to less sensitive hearing abilities. Additionally, current guidelines from the National Institute of Occupational Safety and Health (NIOSH) define a significant threshold shift as a change of 15dB HL or more at any test frequency from 500 through 6000 Hz across two consecutive audiometric tests (NIOSH, 2018). In the context of this study, audiometric thresholds were measured in 5dB HL steps, therefore, the non-inferiority margin was set at an increase of 10dB HL at any of the following frequencies: 500, 1000, 2000, 4000 Hz.

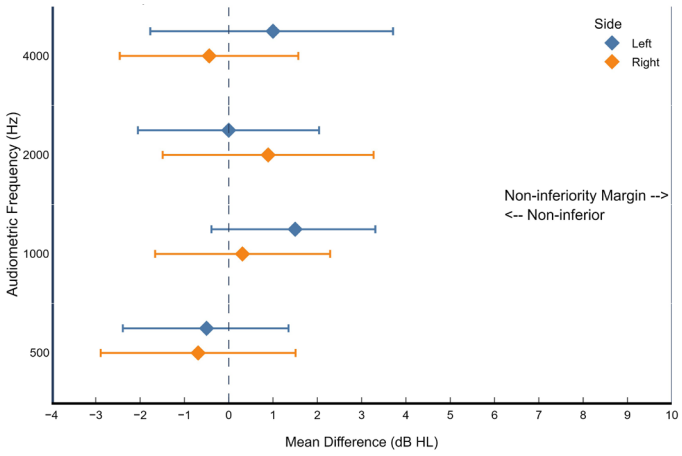

Figure 7. Mean difference between SR and HCP-replacement in aided audiometric threshold at 3rd instance by audiometric frequency, computed as self-HCP

A multiple imputation method was used where missing values occurred, enabling the calculation of an estimated difference across all study participants. As seen in Figure 7, the upper 95% confidence limit of the estimated difference between the SR and HCPR conditions at the third instance in the left and right ears is well below the established non-inferiority margin for this endpoint for all 4 frequencies tested. While the acceptance criterion was set for the third instance of paired replacement, all instances were well below the non-inferiority margin (Appendix Tables 1 and 2). We conclude non-inferiority as the p-value calculated for the third paired instance of replacement was statistically significant, at less than .0001.

Aided speech-in-noise testing SNR loss (dB)

The established non-inferiority criterion for aided speech-in-noise testing SNR loss score is 5 dB, applied at the 3rd paired instance of replacement (SR-HCPR). According to the QuickSIN user guide, beta testing completed across three test sessions using individuals with simulated hearing impairment revealed a standard deviation of 1.3 dB SNR loss across combined individual test-retest scores (Etymotic Research, 2006). The non-inferiority margin of +5dB was selected as it is more than three times the observed standard deviation in test-retest scores.

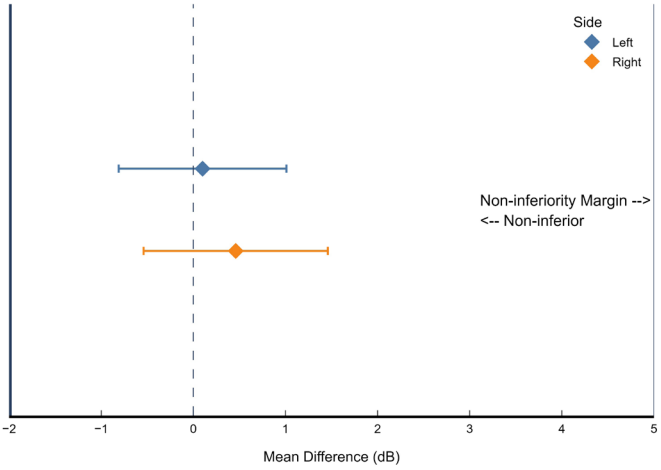

Figure 8. Mean difference between SR and HCP-replacement in aided speech-in-noise SNR Loss at 3rd instance, computed as self-HCP

As seen in Figure 8, the upper 95% confidence limit of the estimated difference seen in SNR loss scores between the SR and HCPR conditions is well below the non-inferiority margin of 5 dB. While the acceptance criterion was set for the third instance of paired replacement, estimated differences at all instances also fall well below the non-inferiority margin (Tables 2 and 3). With a statistically significant p-value calculated for the third paired instance of replacement, we conclude non-inferiority.

Safety

Safety was monitored throughout the study, across all study visits, assessed according to the following endpoints.

Incidence of ear health issues requiring medical referral and related to device placement

Across over 550 device insertions that occurred in this study, there was one instance of an ear health issue related to device placement that required medical referral. This issue occurred as a result of cerumen impaction, for which the resolution was cerumen management.

Incidence of treatment emergent adverse events (TEAE)

The overall incidence of adverse events (AEs) was similar when comparing the SR and HCPR conditions. A total of 13 participants experienced TEAEs attributed to the SR model of care, and 17 participants experienced TEAEs attributed to the HCPR model of care. A total of 12 participants experienced

adverse device effects (ADEs) attributed to the SR model of care, and 16 participants experienced ADEs attributed to the HCPR model of care. This indicates that virtually all reported AEs were device-related.

Incidence of TEAE types		
	Self-replacement condition	**HCP-replacement condition**
TEAE	**Number of participants**	
Redness of tissue	6	10
Blood/bleeding	1	3
Cerumen impaction	3	0
Swelling of clotted blood below tissue (bruise)	1	2
Excess fluid collection on tissue	1	1
Sore or ulceration of tissue	1	1
Medial bluge/growth	0	1
Sudden drop in hearing	1	0
Other (mild soreness/ discomfort or no cause found	6	5

Table 4. Incidence of TEAE types

Table 4 provides detail of the types of TEAEs observed in the study. The high number of TEAEs classified under the category 'Other' was primarily a reflection of a limited choice of ear health-related adverse event options in the pre-defined list, that did not include the relatively common symptom of mild discomfort or soreness.

One report of a sudden drop in hearing was related to a decrease in device output as opposed to a biological etiology. One AE was reported with a severity rating of 'Severe' under the SR condition. This AE was for the condition of cerumen impaction, which is not typically considered severe. The AE was resolved the same day it was reported, by a visit to the HCP, where cerumen management was conducted by an HCP in office, and no medical referral or treatment was required. Additionally, no rest was needed prior to Lyric replacement. All other AEs reported were classified as mild.

Additional outcome measures

Additional outcome measures were tracked throughout the study to evaluate additional areas of clinical impact related to the self-replacement procedure.

Incidence of gross placement errors during self-replacement

Device orientation within the ear canal was assessed by the presence or absence of a gross placement error, as judged by the HCP. There were no instances of gross placement errors observed during SR.

Support needed related to device or ear health concerns

Clinical support needed between study visits (e.g., phone calls or spontaneous visits) was tracked throughout the study. Overall, support contacts for device or ear health concerns were rare in this population, occurring in less than 10% of participants. During the course of the study, a total of five participants contacted the site for support for device or ear health concerns in the SR condition, and a total of four participants in the HCPR condition. All contacts made under the HCPR condition were device-related, whereas under the SR condition, contacts were made for device issues, ear issues, and issues with the SR process. None of the issues underlying any support contacts required medical care or resulted in medical referrals.

Incidence of persistent, bothersome acoustic feedback at the time of device replacement

The incidence of acoustic feedback occurring within 30 minutes of device replacement was tracked across all device insertions throughout the study. Across over 550 device insertions that occurred in this study, persistent, bothersome acoustic feedback was a rare event, occurring five times in the left ears (four times under the SR and once under the HCPR condition) and four times in the right ears (twice in each of the replacement conditions).

Conclusion

The success of the SR training protocol administered by the HCPs, along with the procedural execution by study participants, was evident by achieving effectiveness outcomes with results comparable between the SR and HCPR conditions. The absence of gross placement errors and the comparable Achieved Insertion Depths observed when comparing SR to HCPR supports that patients can position devices effectively in their own ears.

Proficiency in self-replacement training was easily achieved within 3 training attempts by all 56 participants who entered training, with only one participant requiring a third training attempt. This supports that HCPs who offer SR to their patients will not generally require extensive clinical training sessions in order to see patients achieve proficiency.

While a learning curve across the three paired instances of replacement was expected for the SR effectiveness outcome measures, all measures exceeded the established noninferiority criteria at the first instance of paired replacement. This suggests that HCPs can feel confident that, when prescribing SR as directed by Phonak, outcomes will be similar to those achieved with HCP-replaced devices.

No meaningful or systemic increase in safety concerns were noted with the SR procedure as compared to the HCPR procedure. While some increases were seen in the need for support and the incidence of persistent, bothersome feedback under the SR condition, both occurred rarely during the study. Ultimately, the burden of these instances did not seem to outweigh the potential benefit of the SR procedure, including potentially significant reductions of in-clinic visits and the resulting increased convenience for the HCP and the patient.

This study supports the conclusion that Lyric with self-replacement is safe and effective for appropriately selected and trained Lyric patients. Phonak intends to use the results of this study to support the launch of Lyric with self-replacement in the US market, where self-replacement is a discretionary option that can be offered by the HCP for eligible patients who feel comfortable replacing their Lyric devices every other time on their own.

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Michelle is the Lyric Audiology and Education Manager at Phonak. She has supported Lyric since 2010 when she joined InSound Medical as a Clinical Trainer. Following Sonova's acquisition of InSound Medical, Michelle transitioned to the Phonak team and has been with the company in various roles since. In her current role, she supports the clinical and audiological needs for Lyric, across training, marketing, research, and education.

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Grace is a Research and Development Audiologist with the Sonova Silicon Valley team located in Fremont, California, where she focuses on exploratory clinical research and product development. She joined the Sonova Silicon Valley team in 2017, following an internship with Advanced Bionics in 2016. Grace has a Doctor of Audiology degree from Pacific University in Oregon, as well as a background in language studies, linguistics, and speech and hearing science.

Appendix

Aided audiometric thresholds left ears, N=50			
	Instance 1 (dB HL)	**Instance 2 (dB HL)**	**Instance 3 (dB HL)**
500 Hz	-1.1 (-3.09, 0.99)	-1.7 (-4.01, 0.63)	-0.5 (-2.39, 1.35)
1000 Hz	-0.2 (-2.15, 1.65)	0.3 (-1.60, 2.27)	1.45 (-0.39, 3.31)
2000 Hz	-1.1 (-3.57, 1.31)	-1.1 (-3.88, 1.63)	0.0 (-2.05, 2.04)
4000 Hz	-3.6 (-7.15, -0.05)	-1.7 (-4.88, 1.48)	1.0 (-1.77, 3.71)

Appendix Table 1. Aided audiometric thresholds, left ears, all instances

Aided audiometric thresholds right ears, N=49			
	Instance 1 (dB HL)	**Instance 2 (dB HL)**	**Instance 3 (dB HL)**
500 Hz	0.52 (-1.49, 2.54)	-0.33 (-3.26, 2.97)	-0.69 (-2.89, 1.51)
1000 Hz	0.67 (-1.69, 3.04)	0.67 (-2.10, 3.43)	0.31 (-1.66, 2.29)
2000 Hz	-0.06 (-2.89, 2.77)	0.13 (-2.91, 3.17)	0.89 (-1.49, 3.27)
4000 Hz	-0.80 (-4.33, 2.73)	-2.08 (-5.31, 1.16)	-0.44 (-2.46, 1.57)

Appendix Table 2. Aided audiometric thresholds, right ears, all instances

Aided Speech-in-Noise SNR Loss			
	Instance 1 (dB)	**Instance 2 (dB)**	**Instance 3 (dB)**
Left ears (N=50)	-0.19 (-1.22, 0.83)	-0.78 (-1.82, 0.25)	0.10 (-0.81, 1.01)
Right ears (N=49)	-0.60 (-1.60, 0.41)	-1.02 (-2.24, 0.20)	0.46 (-0.54, 1.46)

Appendix Table 3. Aided speech-in-noise SNR loss, all instances