Phonak
Field Study News

Lyric self-replacement: safety, efficacy and perception

While Lyric patients enjoy access to continuous amplification, they rely on recurrent provider visits to replace devices. The Sonova Silicon Valley R&D team conducted a pilot study to investigate a new device replacement procedure to offer Lyric patients and providers improved flexibility and reassurance by offering self-replacement at every other visit. With 20 participants – 10 in the control group and 10 in the self-replacement group – the study aimed to evaluate safety and efficacy of a controlled self-replacement model of care, where the provider assesses patient candidacy, teaches self-replacement and manages patient care. For both groups, safety and device efficacy were tracked over the course of approximately six months by monitoring ear health, insertion depth and aided test performance. Patient satisfaction and likelihood of pursuing a Lyric subscription were also assessed at the conclusion of the study.

Grace Gardner Branson / February 2021

Key Highlights

- No statistically significant differences were seen in safety or efficacy endpoints between the control group and the self-replacement group, indicating a robust candidacy criteria and self-replacement procedure.
- Favorable results in the pilot study led to an expansion of data collection across multiple clinics and Lyric providers.

Considerations for practice

- Participants in the self-replacement group rated overall satisfaction higher than the those in the control group.
- Participants in the self-replacement group were more likely to pursue a Lyric subscription than those in the control group.
- For approved candidates, self-replacement can offer improved flexibility and reassurance for Lyric patients and providers alike.

Introduction

With deep placement in the bony portion of the ear canal, Lyric is designed to optimize natural sound quality by leveraging the anatomical structures of the pinna and external auditory canal to minimize the occlusion effect and preserve sound localization cues. These benefits are largely dependent upon precise placement and position of the device, which is restricted to a trained Lyric provider under current indications for use. With the lifespan of a Lyric device limited by battery constraints and the ear canal's tolerance of continuous use, recurrent device replacement appointments may become inconvenient to some providers and patients.

The initial Lyric candidacy assessment, sizing and fitting procedures are always best performed by a trained Lyric provider, but the Lyric patient may hold an informed perspective on subsequent device replacement, due to the tactile and auditory feedback unique to device position in the ear canal. The experienced and attentive Lyric patient is often familiar with the expected feeling and sound of their Lyric devices, with slight changes in fitting precision prompting requests for adjustments to device placement.

While self-replacement is not appropriate for all Lyric patients, selective candidacy criteria, adequate Lyric experience, and provider-guided training and management have potential to establish a procedure for self-replacement that upholds the high standards of Lyric patient outcomes regarding safety and device performance.

This study aimed to investigate the impact on safety and efficacy of the self-replacement procedure, as compared to the standard best practice model of care. Safety was evaluated by tracking ear health and insertion depth, and device efficacy was evaluated by tracking aided audiometric performance. Patient satisfaction and plans for amplification were also evaluated.

Methodology

Participants

Study participants consisted of 20 first-time Lyric users between ages of 58-92. Ten participants were in the self-replacement group, including, including nine men and one woman, with an average age of 65.5 years, and a standard deviation of 4.2 years. Ten participants were in the control group, including four men and six women, with an average age of 81.5 years, and a standard deviation of 9.4 years. In the self-replacement group, nine participants had binaural fittings, and one participant had a monaural fitting. All ten participants in the control group had binaural fittings. All participants had audiometric thresholds falling essentially within the mild to moderately-severe hearing loss range. All participants were subject to a standard Lyric candidacy assessment prior to the first fitting, and commercially-available Phonak Lyric3 devices were used throughout the study.

Procedure

All study visits took place at Sonova Silicon Valley (Fremont, California), and participants were cared for by a dedicated audiologist with oversight by the Lyric Medical Director. Study participants attended five scheduled study visits over the course of approximately six months, with additional visits occurring on an as-needed basis for additional support for self-replacement and ear health concerns.

A strict candidacy assessment was conducted to qualify participants: intact cognitive function, adequate dexterity/mobility, and successful Lyric use for at least one month. Cognitive function was evaluated using a standardized screening tool, the Trail Making Test (parts A&B), as well as a medical history review. Dexterity was determined by clinician observation and medical history review. Successful Lyric use was determined by establishing one month of Lyric use without ear health issue presentation necessitating a rest period before device replacement.

Following candidacy assessment, the audiologist conducted initial sizing and fitting procedures according to standard best practice. Study appointments were scheduled for a device replacement approximately every 4-6 weeks across the study period. Ear health and insertion depth were tracked at each insertion and removal for both groups. Ear health status was classified as either mild (no rest required prior to device replacement) or significant (rest required prior to device replacement).

At the second appointment, baseline aided audiometric testing was completed for both groups, including aided thresholds and speech-in-noise testing. The control group continued to follow the standard model of care, with provider device replacements completed every 4-6 weeks throughout the study period.

Participants in the self-replacement group received self-replacement training and guided practice at the second appointment, followed by additional unguided practice at the third appointment after provider assessment of ear health condition and cerumen management, as needed. If the provider and participant were comfortable with the procedure after the unguided self-replacement practice,

participants were sent home with Lyric devices to self-replace prior to returning for the fourth study appointment. At the fourth study appointment, participants in both groups repeated aided audiometric testing. Self-replacement group participants self-replaced the devices again independently. At the fifth and final study appointment, all study participants completed a questionnaire designed to address satisfaction and intentions for purchasing hearing instruments.

Outcome Measures

Safety

Ear health issue presentation was recorded after each device removal and prior to device replacement. Ear health issues are known to occur occasionally with some Lyric patients in clinical practice. For the purpose of this study, ear health was classified into the following categories:

- No ear health issue
- Mild ear health issue: no rest required prior to device replacement (e.g., redness)
- Significant ear health issue: Rest required prior to device replacement (e.g., abrasion, hematoma)

Insertion depth was measured at the initial sizing appointment, and at each device insertion and removal. Change in insertion depth from the initial measurement is expected for some Lyric users over the course of Lyric wear. However, a significant change in the context of self-replacement may indicate a safety risk, as it may increase the likelihood of ear health issue presentation.

Efficacy

Device efficacy was measured by aided audiometric testing (thresholds, QuickSIN) conducted in the soundfield twice using the same device settings over the course of the study period. Aided pure tone average and SNR Loss were compared from the baseline (second appointment) to the test condition (fourth appointment) – following self-replacement for the experimental group. The control group followed the same repeated testing methodology (baseline and test condition) to evaluate changes seen with the standard Lyric replacement procedure for comparison. Pure tone average (PTA) was calculated by taking the average of aided audiometric thresholds at 500, 1000, and 2000 Hz, with the subject sitting one meter away from the speaker at 0° azimuth. Scores are reported in dBHL, with a lower score indicating better performance on the test. Speech-in noise testing was measured using the QuickSIN test, presented at 70dB, with the subject sitting one meter away from the speaker at 0° azimuth. Scores are reported in SNR Loss (dB), with a lower score indicating better performance on the test.

Results

Ear Health

Ear health issues were categorized by type (redness, moisture accumulation, hematoma, abrasion) and severity (mild, significant). Each ear was considered individually, for a total of 20 ears in the control group (10 binaural fittings), and 19 ears in the self-replacement group (9 binaural fittings, and one monaural fitting).

When comparing ear health issue presentation between the control group and the self-replacement group, data were examined across appointments 3-5, when the self-replacement group was actively practicing and using the self-replacement procedure. Baseline ear health information from the first two appointments was not taken into consideration, as all fittings from the first two appointments across both study groups were completed either by the audiologist using the standard fitting methodology, or with guidance and support for the self-replacement group.

Control group ears experienced a total of 15 ear health issues (eight total ears involved), while self-replacement group ears experienced a total of 16 ear health issues (ten total ears involved). Of the eight control group ears with health issues, four ears had significant ear health issues requiring rest before refitting. Of the ten ears in the self-replacement group with health issues, one ear had a significant issue requiring rest before refitting (figure 1).

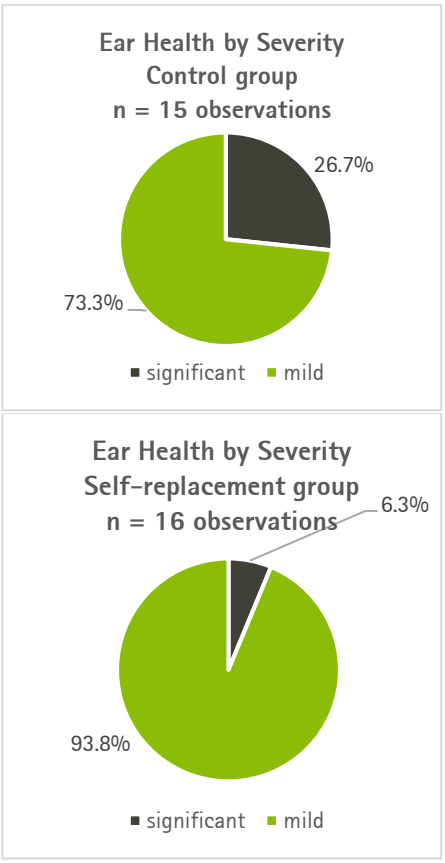


Figure 1. Ear health observations by severity

While the self-replacement group showed a slightly higher percentage of ear health issues among total device replacements, ear health issues in the self-replacement group were limited to three categories, with the highest percentage occurring was redness. The single significant ear health issue occurring in the self-replacement group was hematoma, which resolved within two weeks without medical intervention. The distribution of ear health conditions can be seen in Figure 2.

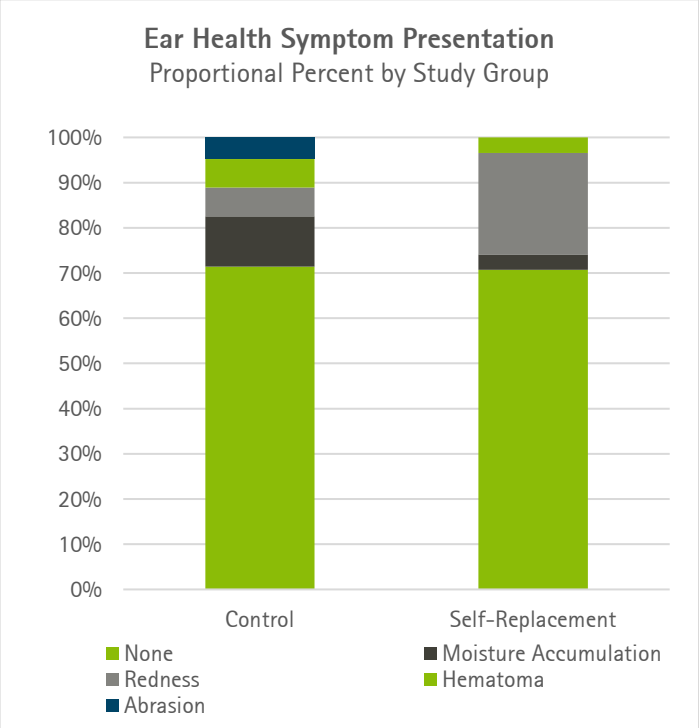


Figure 2. Ear health symptom presentation by study group

Insertion Depth

Insertion depth was measured across three device replacement appointments, and the average was compared to the measured insertion depth at the initial fitting. While the average difference seen in insertion depth for each ear was not statistically significant between the self-replacement group and the control group (p = 0.35, 95% CI), the self-replacement group showed a larger variance than the control group, when looking at the average of three refit events for each study ear. This indicated a wider range of insertion depths seen in the self-replacement group (SR group: F = 0.86; Control Group: F = 0.41), consistent with less precise placement. Positive numbers are consistent with a deeper insertion depth, while negative numbers are consistent with a shallower insertion depth. See Figure 3.

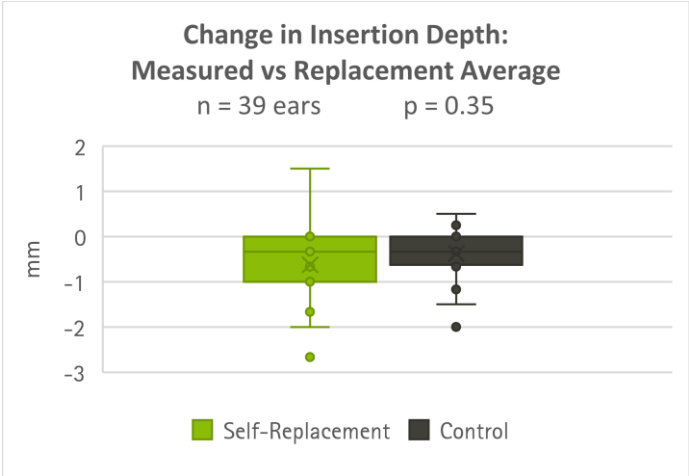


Figure 3. Average change in insertion depth: measured vs replacement condition

Aided Audiometric Testing

Results of pure tone averages and SNR Loss were compared between the baseline condition (second appointment), and at the fourth appointment with equivalent device programming.

One participant in the self-replacement group was unable to complete the task due to ear health issue presentation that prevented refitting at the time of testing. Paired t-tests revealed no statistically significant differences from the baseline condition (2nd appointment) to the test condition (4th appointment) for both the control group (p = 0.63, 95% CI), as well as the self-replacement group (p = 1.0, 95% CI). Given the limited number of test participants, statistical results should be viewed with caution (Figure 4).

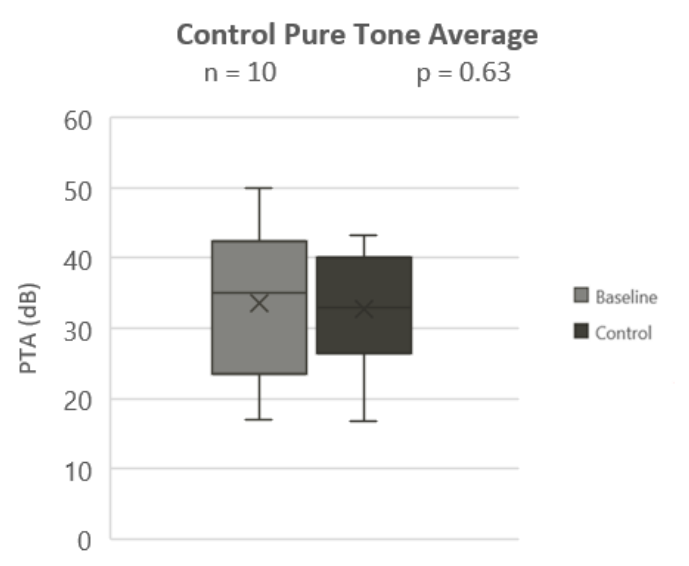


Figure 4. Efficacy results: pure tone average (PTA – dB HL)

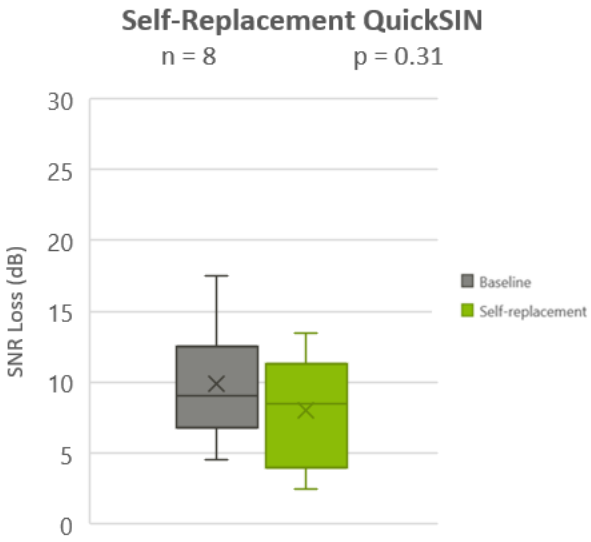
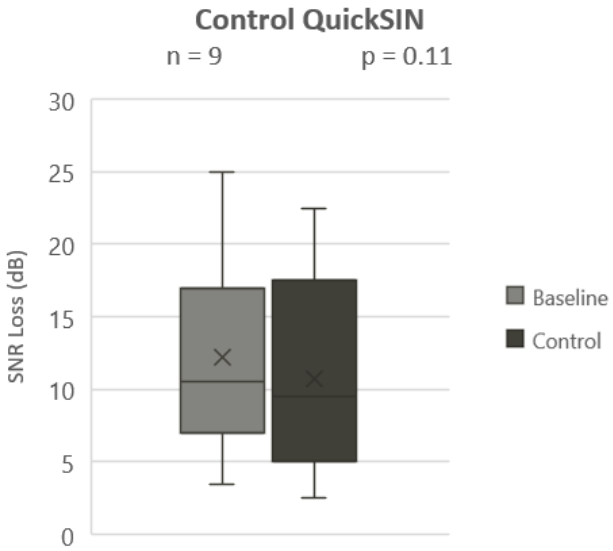


Figure 5. Efficacy results: QuickSIN

One participant in each test group was unable to complete the task. An additional participant in the self-replacement group was unable to complete the task due to ear health issue presentation that prevented refitting at the time of testing. Paired t-tests revealed no statistically significant differences from the baseline condition (2nd appointment) to the test condition (4th appointment) for both the control group (p = 0.11, 95% CI), as well as the self-replacement group (p = 0.31, 95% CI). Given the limited number of test participants, statistical results should be viewed with caution (Figure 5).



Participant Perception of Self-replacement

Outcomes were measured by assessing success with the self-replacement protocol, overall satisfaction with Lyric, and the participants' plans for amplification at the conclusion of the study.

While some self-replacement group participants needed more training and support than others, nine out of the ten self-replacement group participants, were able to successfully and comfortably insert the devices on their own after the second training. The tenth participant was able to complete self-replacement by the end of the study, although he was not entirely confident with the procedure.

Overall satisfaction was measured on a scale of 1-10 (10 = most satisfied) for all study participants. While the difference was not statistically significant (p = 0.06, 95% CI), the self-replacement group participants tended to have higher satisfaction ratings than the control group participants.

A survey designed to assess plans for amplification at the conclusion of the study was given to participants, where they were presented with a variety of different amplification options given a regionally-relevant price structure. Participants were asked to choose between Lyric, traditional daily-wear hearing aids, and no amplification. Based on these three options, more participants in the self-replacement group selected Lyric than in the control group (Figure 6).

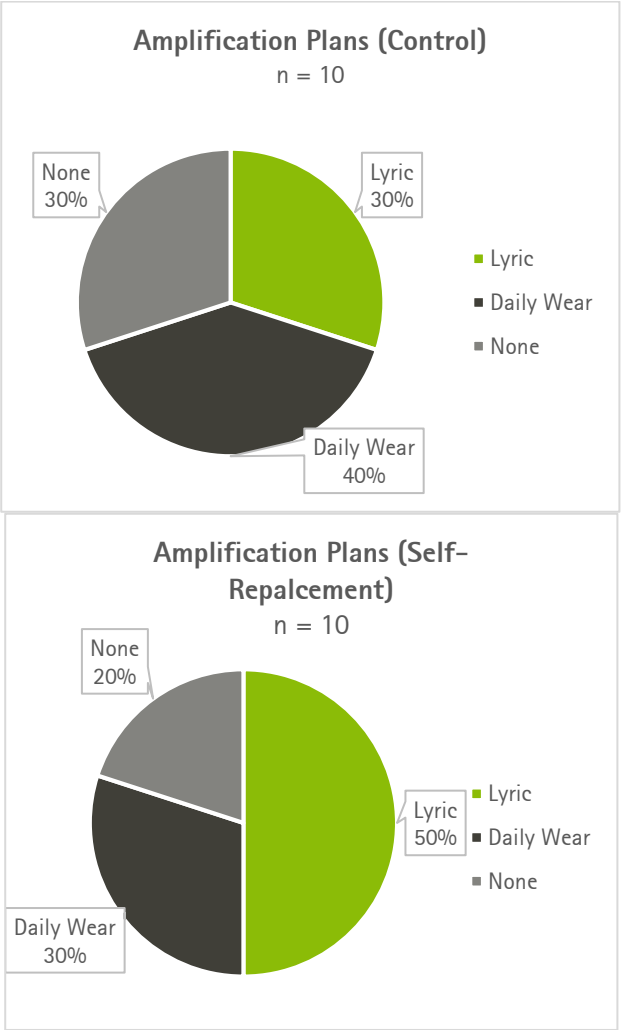


Figure 6. Amplification Plans: self-replacement vs control

Conclusion

The results of this exploratory pilot study support favorable patient outcomes for a controlled, provider-guided Lyric self-replacement procedure. The criteria used to select candidates for self-replacement upheld the safety and efficacy of the standard Lyric fitting procedure, and the training protocol was largely successful in preparing and instilling confidence in the majority of self-replacement candidates. Study participants cited greater satisfaction when using the self-replacement procedure, as well as a greater likelihood of pursuing a Lyric subscription. These early data have led to further clinical investigation of the self-replacement procedure across various Lyric clinics and providers, with the goal of implementation into wider clinical practice for improved flexibility and reassurance for Lyric patients and providers.

Authors and Investigators

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Grace Gardner Branson 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.

Dr. Jacob Johnson

Jacob Johnson is the Medical Director for Lyric. He has been a medical consultant for the Phonak team since 2010. He has supported Lyric development, clinical research, education and clinical monitoring since 2001. He received his MD with honors from Baylor College of Medicine in 1996 and completed his Otolaryngology Head & Neck Surgery residency at University of California - San Francisco (UCSF) in 2001. He is a president of San Francisco Otolaryngology Medical Group, Associate Clinical Professor at UCSF, president of San Francisco Audiology, Quality Committee member for Brown & Toland Medical Group, and Board member for UCSF Clinical Integrated Network.