

Field Study News

March 2017

Lyric™



Benefits of Lyric3 XXS and XXL

New sizes deliver comfort and acceptance

The purpose of the Lyric3 size study was to evaluate physical fit, acoustic fit and overall acceptance of the new XXS and XXL size offerings. Study participants were selected specifically for their potential candidacy for XXS or XXL. The hearing aid fittings, follow up and all data collection were conducted by hearing care professionals in a clinical setting over 8 weeks. Results show positive outcomes for both sizes in terms of comfort and feedback. Also, XXL was preferred by most candidates and XXS improved trial success rate. We conclude that, for persons with small or large ear canals, Lyric3 XXS and XXL are valuable additions to the product portfolio offering more fitting flexibility.

Introduction

Lyric is continuously evolving, with each generation bringing new features and added benefits.

Lyric is a unique hearing solution. When it launched in 2007, Lyric created a new, extended-wear hearing device category. "Extended wear" means that the device is worn 24 hours a day, 7 days a week for months at a time. Lyric provides amplification for individuals with mild to moderately-severe hearing loss. The device is inserted deeply into the ear canal using a non-surgical procedure and without anesthesia. The placement of Lyric in the ear canal is intended to make the device invisible, to require less gain, and to take advantage of the natural acoustic cues provided by the lateral portions of the external ear. Since its introduction, Lyric technology has undergone continuous product improvements – in power consumption, size, design, signal processing, etc.

The latest noteworthy enhancements to the Lyric3 portfolio feature the introduction of two new sizes, XXS and XXL. These new options are intended to yield benefits in comfort, feedback and Lyric candidacy.

The purpose of this study was to investigate patient outcomes with the new size offerings in Lyric3. Specifically, we set out to evaluate the physical fit, acoustic fit, and overall acceptance of Lyric3 among prospective XXS and XXL candidates.

Methods

The Lyric3 size study involved 6 hearing care professionals (HCPs) at 5 independent audiology practices around the United States. HCPs at study sites were asked to recruit prospective candidates for bilateral XXS or XXL use with the following guidance ...

- 1) Current Lyric3 XS or XL users who were dissatisfied with comfort, feedback or recurring ear health issues; or
- 2) Individuals who had previously tried and rejected Lyric3 XS or XL for the reasons described above.

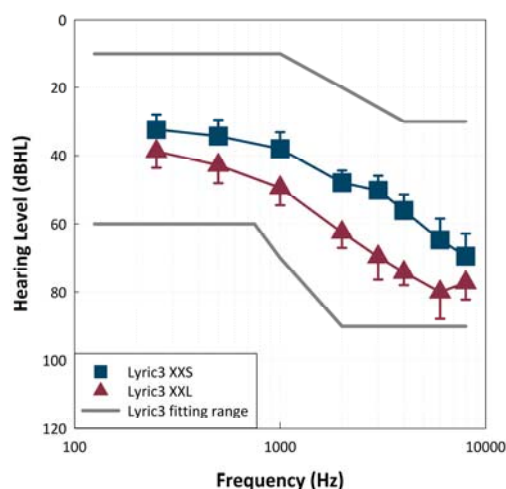


Figure 1: Mean (symbols) \pm 95% confidence interval (error bars) of audiometric thresholds for Lyric3 size study participants. The upper and lower limits of the published fitting range for Lyric3 are also shown for reference.

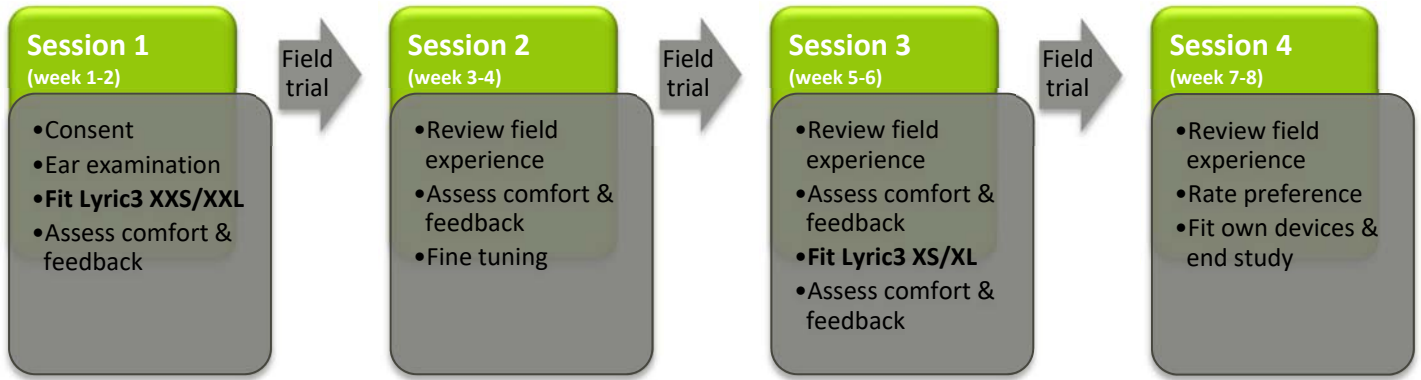


Figure 2: General sequence of study-related activities. Week designations for each session refer to the blocks of time set aside for the entire study. Sessions for individual participants occurred at 2-week intervals.

35 participants – XXS (n=19) and XXL (n=16) – were selected on the basis of their potential candidacy for the sizes under investigation, with no opportunity to specifically size ears for the XXS/XXL devices. Participants were aged 36–94 years (mean = 74 years) and 40% were female. Among study participants, 9 were current Lyric3 XS users and 15 were current XL users, together averaging ~4 years (range 0.2–8 years) of experience. All remaining participants (10 XXS users and 1 XXL user) had previously tried and rejected Lyric3. At the start of the study, all but one participant wore Lyric3 devices bilaterally during the study. Informed consent was obtained at the start of the study. Further, upon study completion, participants were returned to their own devices and paid a modest stipend for time and travel. This study was approved by an independent ethical review board.

Audiometric assessment revealed a good representation of hearing thresholds across the Lyric fitting range for both groups (Figure 1). Further, on average, XXL users had significantly poorer ($p < 0.05$) audiometric thresholds than XXS users.

An important aspect of the study is the cross-over design where all participants wore the new XXS/XXL size for 4 weeks followed by 2 weeks of wearing the standard XS/XL size, allowing comparison between the new and standard sizes. As shown in Figure 2, the study involved 4 visits to the study sites over a period of 8 weeks; additional interim visits were scheduled as needed on an individual basis. During each 2-week field trial, participants completed a diary on their experiences with Lyric during daily use.

16 participants (9 XXS users, 7 XXL users) discontinued during the study. The reasons for discontinuation were inability to comfortably wear the XXS/XXL device (~45%, mostly XXS users); inability to wear the XS/XL device due to comfort or feedback (~45%, mostly XXL users); and unknown (~10%). Of these discontinuations, 10 were bilateral (14 XXS ears, 6 XXL ears) and 6 were unilateral (2 XXS ears, 4 XXL ears). Because of the ear-specific nature of candidacy for device size, the opposite ear of the unilateral

discontinuations remained in the study. Unless otherwise specified, data for all ears are reported here.

Results

The objective of this study was to evaluate physical fit, acoustic fit and overall acceptance of the new XXS and XXL size offerings of Lyric3. Although various approaches were used to assess outcomes in each dimension, in the interest of brevity, only a representative sample of the results are discussed here.

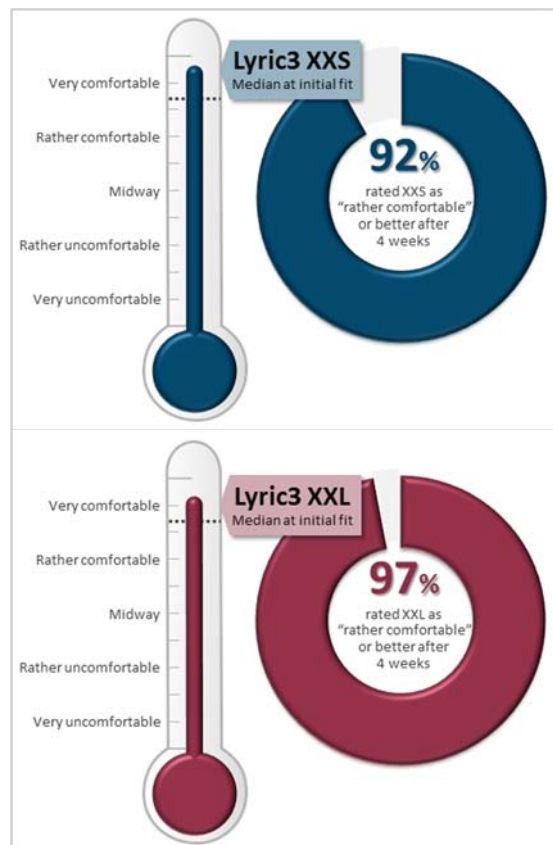


Figure 3: Comfort ratings at initial fit and after 4 weeks of use for Lyric3 XXS (upper panel) and Lyric3 XXL (lower panel). Dotted line shows benchmark for standard Lyric3 sizes (XS–XL). Refer to text for details.

Physical fit was evaluated by participants as comfort rating in the clinic. Following insertion of the XXS/XXL device and at each session, participants were asked to rate the physical comfort of the device in the ear. Ratings were provided on an 11-point scale from 0-10; in addition to numbers, descriptive labels were provided for 1 (=Very uncomfortable [poor outcome]), 3 (=Rather uncomfortable), 5 (=Midway), 7 (=Rather comfortable), and 9 (=Very comfortable [good outcome]). As shown in Figure 3, median comfort ratings of 9.5 and 9.0 were obtained at initial fit for XXS (n=37) and XXL (n=32) ears, respectively. These are comparable to benchmark ratings previously obtained for standard sizes of Lyric3. Further, among participants who used the Lyric3 XXS/XXL devices for the entire duration, 92% of XXS ears (n=22/24) and 97% of XXL ears (n=28/29) were rated as being "rather comfortable" or better after 4 weeks of device use.

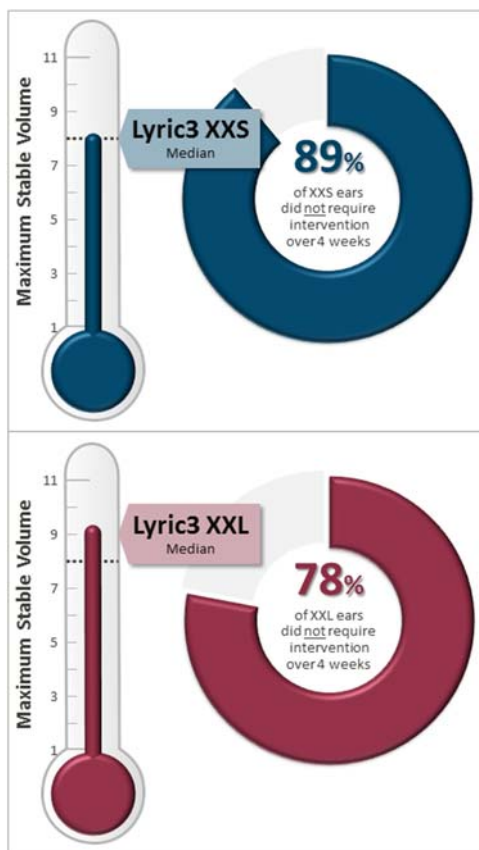


Figure 4: Feedback outcomes at initial fit and during 4 weeks of use for Lyric3 XXS (upper panel) and Lyric3 XXL (lower panel). Higher MSVs represent better outcomes. Dotted line shows benchmark for standard Lyric3 sizes (XS-XL). Refer to text for details.

Acoustic fit was evaluated by HCPs in two ways: maximum stable volume (MSV) and need for intervention. MSV refers to the highest volume setting that can be achieved without feedback, when performing various actions known to cause feedback (jaw movement, phone/hand at ear, etc.). Higher MSVs are desirable because they represent lower risk of feedback occurring during everyday use. [Refer to Banerjee

(2016) for a more detailed description of the MSV procedure and its implications.] As shown in Figure 4, median MSVs of 8 and 9 were obtained for XXS (n=37) and XXL (n=32) ears, respectively. These are comparable to benchmark MSVs previously obtained for standard sizes of Lyric3. At each session (and anytime in between), clinicians had the opportunity to address feedback complaints based on MSV and participant report. Over the course of 4 weeks of device use, no feedback intervention was required for 89% of XXS ears (n=33/37) and 78% of XXL ears (n=25/32). The higher prevalence of feedback requiring intervention for XXL, compared to XXS, may be attributed to the greater degree of hearing loss (and, therefore, greater gain requirement) for the XXL group in this study (as shown in Figure 1). For comparison, the benchmark of 83% not requiring feedback intervention for standard Lyric3 sizes and the average degree of hearing loss for those individuals lie between the intervention rates and degree of loss for the XXS and XXL groups in this study.

Overall acceptance was assessed on the basis of preference for the new size (XXS, XXL), standard size (XS, XL) or neither. At the end of the study, participants were asked to indicate their device preference. In addition, for participants who discontinued (n=27 ears), preference was assigned based on their specific circumstances. For example, for participants unable to wear XL due to intractable feedback, a preference for XXL was assigned based on successful use during the study. For participants who discontinued early because they were unable to wear XXS, preference was assigned as XS if they returned to wearing that size or as non-candidate if they were unable to wear Lyric at all.

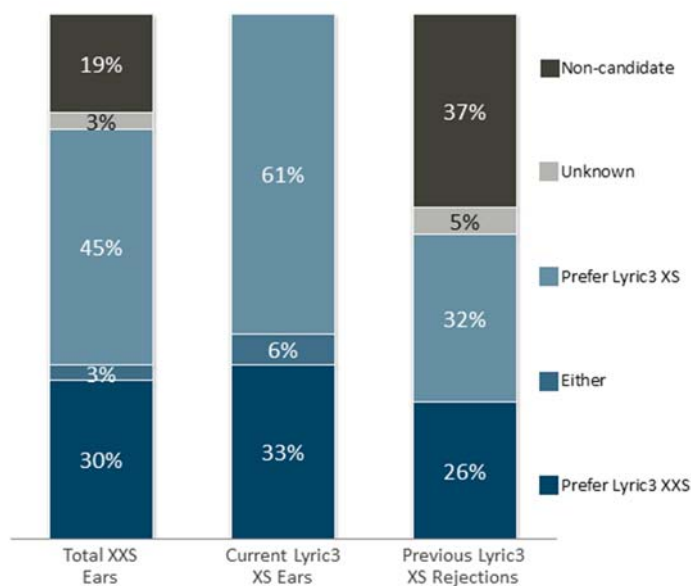


Figure 5: Lyric3 device size preference for XXS group. Previous Lyric rejections = previously tried and rejected Lyric XS; Either = no preference between XXS and XS; Unknown = data not available; Non-candidate = unable to wear Lyric.

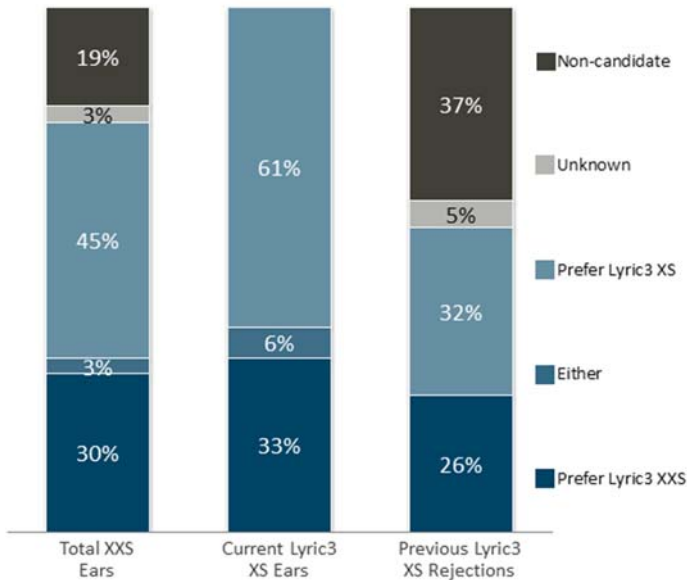


Figure 5 shows the final device size preference of the prospective XXS candidates who participated in this study. There are two main findings of note here. First, among the total pool of prospective Lyric3 XXS candidates, 19% (n=7/37 ears) were unable to wear Lyric at all. It is to be expected that, despite its smaller size, some ears will still be too small to accommodate a Lyric. The second notable finding is that, among persons who previously tried and rejected Lyric3 XS, 26% (n=5/19 ears) preferred XXS and 32% (n=6/19 ears) preferred XS. Anecdotal comments from HCPs suggest that the somewhat surprising preference for XS may have been related to the smaller XXS physically preparing the ears for the 24/7 nature of Lyric and subsequent acceptance of Lyric3 XS. Regardless of the underlying reason, the finding that ~60% of persons who previously rejected Lyric3 XS can now wear Lyric3, represents an ~36% increase in trial success rate (i.e., the percentage of Lyric trials that convert into subscriptions) for Lyric3 XS with the addition of Lyric3 XXS to the product portfolio. The most common reasons for rejecting XXS were discomfort, ear health and feedback.

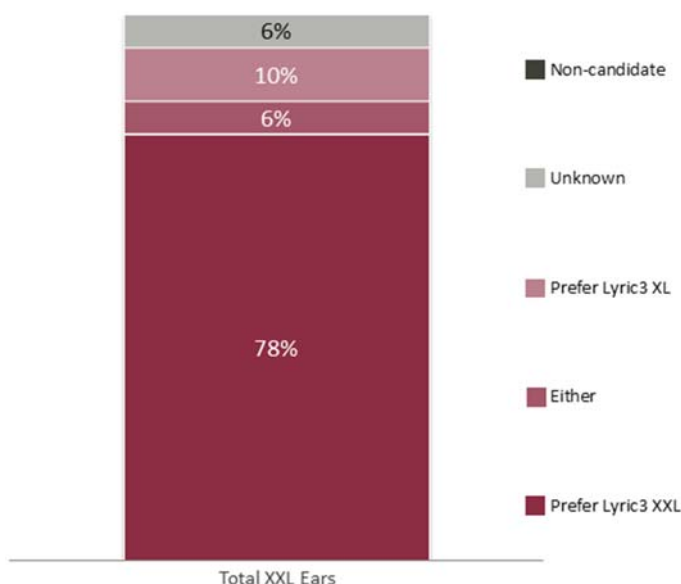


Figure 6: Lyric3 device size preference for XXL group. Either = no preference between XXL and XL; Unknown = data not available; Non-candidate = unable to wear Lyric.

The final device size preference of the prospective XXL candidates who participated in this study is shown in

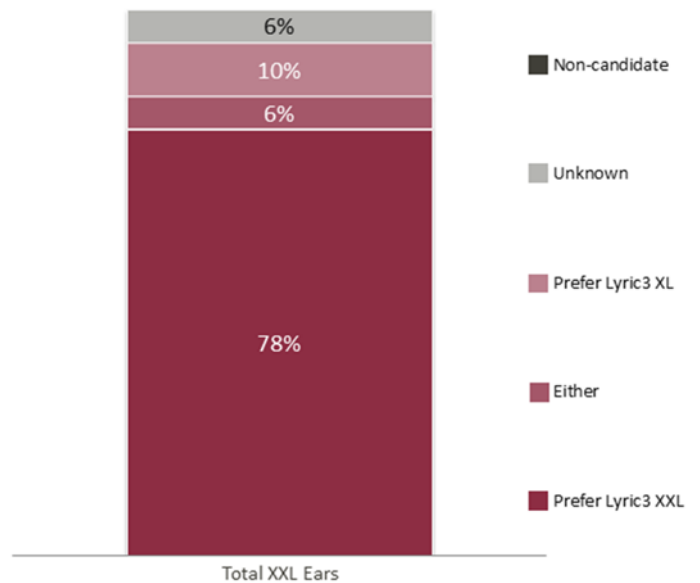


Figure 6. [Since all but two of the participants were current Lyric3 XL users, only the overall data are reported.] Among the total pool of prospective Lyric3 XXL candidates, 78% (n=25/32 ears) indicated a preference for XXL. Feedback was the most common reason for rejecting XXL.

The findings of the Lyric3 size study with XXS and XXL can be summarized as follows:

- Lyric3 XXS and XXL offer comfortable fits and freedom from feedback for most ears;
- Lyric3 is accepted by ~60% of persons who previously rejected Lyric3 XS, resulting in a ~36% increase in the trial success rate for Lyric3 XS; and
- Lyric3 XXL is preferred by 78% of prospective candidates (i.e., persons with large ear canals).

Conclusion

The results of the Lyric3 size study demonstrated positive outcomes for comfort, feedback and acceptance of the Lyric3 XXS and XXL sizes. The new sizes also enable more ears to be fit with Lyric. Further, HCPs felt that these benefits led to increased fitting efficiency. These findings lead to the conclusion that patients with small and large ear canals can successfully use Lyric3 XXS and XXL, respectively.

References

Banerjee S. (2016) Lyric3: Combating feedback. Phonak Insight January.

Author and Investigator



Shilpi Banerjee, PhD, studied audiology at Northwestern University, USA. She has extensive experience in hearing aid research, teaching Audiology, and speaking globally on a variety of topics. In her capacity as a consultant to Phonak, Shilpi has overseen clinical research on Lyric3 2017.

Acknowledgements

Phonak acknowledges participation of the following clinicians and clinics in the Lyric3 size study: Liz Tusler and Mark Christian of Audiological Associates of Deerfield, Deerfield, IL; Lori McCorry at Audiological Consultants of Atlanta, Atlanta, GA; Tamara Anderson at Better Hearing Center of Walnut Creek, Walnut Creek, CA; Donna Szabo at Innovative Hearing Solutions, Westwood, NJ; Connor Nelson at South Bay Hearing & Balance Center, Torrance, CA. We also thank Laura Jones, Laurel Gregory & Tori Haynes for their logistical and operational assistance with the study.