

Field Study News

Lyric and safety

A study on the safety of Lyric and user satisfaction

Abstract

The following Field Study News article describes the results of an independent study on the safety of Lyric and users' satisfaction with the device. Lyric is inserted into the user's ear canal by a hearing care professional and worn constantly for up to 120 days. The data for this study was collected over a period of two years at a specialist hearing aid retailer in the USA. 364 customers (644 ears) were included retrospectively in the study with regard to ear health issues. It became apparent that 279 customers wore Lyric on a long-term basis, having worn it for up to two years (189 days on average) at the time of the analysis. None of the participants in the study developed any ear health issues that would have required otological treatment. It is evident that Lyric, like any other hearing aid, is not completely risk-free. However, by adhering to all of the selection and fitting criteria outlined in an extensive training program, these risks can be minimized. Furthermore, the innovative and unique design of the device helps to improve its safety. Lyric has already been on the market in the USA since 2008 and more than 5000 customers have already successfully been fitted with it.

Introduction

Lyric is worn deep in the ear canal, 24/7. It has been specially designed to be worn in this deep position and to remain in the ear canal for up to 120 days. It thus offers the user some unique advantages: no servicing or maintenance is required, there is no need to remove and insert the device on a daily basis, and a natural sound quality is guaranteed by the positioning of the microphone deep in the ear canal, etc. Lyric is inserted in the ear canal and wirelessly programmed by specially trained hearing care professionals. Lyric consists of two parts, connected by a flexible rubber joint, each enclosed in a soft foam cover. These parts conform optimally to the shape of the ear canal. To be eligible to wear Lyric, the ear canal must be of a specific length and minimum diameter. This is checked in a measurement procedure before the fitting. In addition, all relevant medical and general contraindications which could potentially give rise to ear health issues are enquired about in a preliminary consultation. A full otoscopy

is carried out to rule out any anatomical contraindications. Before each fitting, the ear canal must be completely clean and the skin and eardrum must be in perfect condition. The long duration for which Lyric is worn in the ear canal and its constant contact with the skin of the ear canal continually raises the question of whether the device is safe to wear. This was the motivation for the present study. Lyric is CE-certified and has been successfully approved in all of the countries in which it is available. Lyric is not subsidized by health insurance.

Aim of the study

Safety

The aim of the study was to demonstrate the safety of Lyric by means of a data analysis of a group of Lyric customers.

Satisfaction with Lyric

A sub-group of Lyric customers was asked about their satisfaction with Lyric in comparison with their own hearing aids.

Structure of the study

For the purposes of the study, the Lyric fittings for 364 customers of the Northern Valley ENT specialist retailer were analyzed retrospectively between 2007 and 2009. Before the fitting, Lyric was explained to all the participants in the study during a preliminary consultation, in which contraindications were enquired about. In addition, an in-depth otoscopy was carried out to determine the length and size of the ear canal, to rule out any possible anatomical contraindications. These include, for example, the ear canal being too short or too narrow, exostosis, and perforations of the eardrum. The data was collected over a period of up to two years. The ear canal was also examined every time the device was replaced to record any possible ear health issues. For collecting data on the topic of user satisfaction, a sub-group of 60 customers who were already wearing normal hearing aids were asked questions about their satisfaction with Lyric in comparison with their own hearing aids.

Test subjects

The participants included both customers who had already been provided with hearing aids and new customers who had never worn hearing aids before.

All of them were customers of the specialist retailer who had shown an interest in Lyric and were eligible to be fitted with Lyric.

The sub-group of 60 customers participating in the survey on user satisfaction in comparison with their own hearing aids was randomly selected from the study participants who had already been provided with hearing aids.

All initial and subsequent fittings were carried out in the same specialist retail establishment and the devices were worn until their functionality ceased. Standard Lyric hearing aids were used for all fittings.

Results I

Of the 364 customers who took part in the study, 18% (64 customers) returned their Lyric devices within 30 days. The main reasons cited for this were pain in the ear, irritation in the ear canal, occlusion or a build-up of moisture between the hearing aid and the eardrum. A detailed examination revealed local irritation or redness. In no case was there any sign of inflammation. The ear pain usually disappeared within one hour and all symptoms disappeared completely after a maximum of five days. In no case was any otological treatment required. Retrospectively, most of the ear canals showed a rather unfavorable geometry, e.g. with a curvature in the bony part of the ear canal or a narrow diameter. A further 21 customers stopped using Lyric at a later point. The reasons given for this were similar to those described by the previous group. The ear canals recovered quickly without any treatment and showed no more abnormalities after a few days.

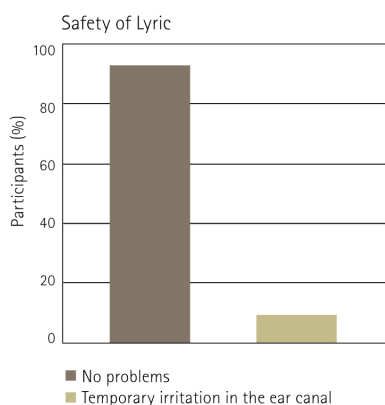


Figure 1: Proportion of study participants with no problems and with temporary irritation in the ear canal

The remaining 279 customers successfully wore Lyric and had worn their devices for an average period of 189 days at the time of the analysis. 91% of these customers wore Lyric without incident, while 9% temporarily experienced irritation in the ear canal which led to the device being removed for a period lasting 3 to 14 days. However, all customers were

subsequently able to continue wearing the device again. There were no cases of inflammation, eardrum perforation or sudden deterioration in the user's ability to hear.

Results II

The survey of a sub-group of the 364 participants revealed a very high level of satisfaction with Lyric in comparison with the hearing aids previously worn by the participants. As shown in Fig. 2, 90% on average preferred Lyric. The level of satisfaction with Lyric from a cosmetic perspective and when using the telephone was particularly high.

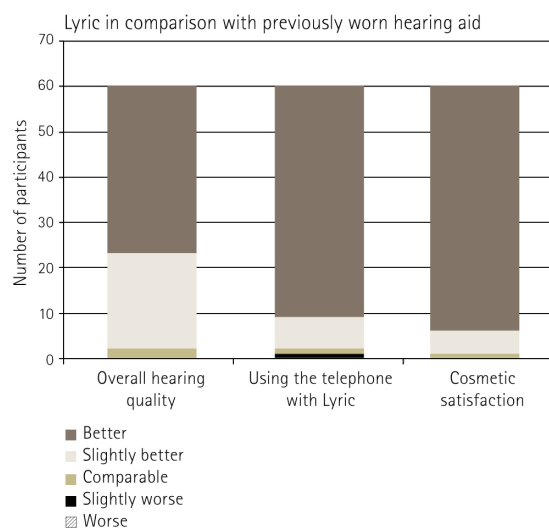


Figure 2: Satisfaction with Lyric in comparison with the previously worn hearing aid

Conclusion

Lyric is a safe hearing aid. Like any other hearing aid, it is not completely risk-free, but these risks can be minimized by adhering to all of the instructions given. None of the 279 participants in this study experienced any ear health issues that would have required otological treatment. It also became apparent that Lyric cannot be worn by everybody. All in all, 23% of the participants gave up using Lyric. The main reason for these withdrawals was pain in the ear caused by the geometry of the ear canal being unsuitable for wearing Lyric. This also shows how important it is for prospective Lyric users to undergo otoscopy and an assessment of the anatomy of the ear canal. The customers who were able to wear Lyric expressed a very high level of satisfaction with the device in comparison with the hearing aids they had previously worn, particularly from a cosmetic perspective and in terms of sound quality.

References

Scherl M, Szabo D, Desai N, Scherl S, Whichard S, Arbogast T. Real-world safety experience with a 24/7 hearing device. *Hearing Review*. 2011;18(1):18-23.

jens.tenholder@phonak.com