RETROSPECTIVE STUDY OF THE ØREBLUE® METHOD ON A PROSPECTIVELY FORMED COHORT

ABSTRACT

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General Context

Environmental factors, such as noise disturbances, certain medications, genetic factors and especially age, contribute to the development of hearing impairments. Auditory system dysfunctions such as tinnitus or hyperacusis can appear independently from hearing loss. The deterioration of the auditory system causes hearing loss that, in some cases, fosters the development of these dysfunctions.

Tinnitus refers to noise heard continuously or intermittently "in the ear" or "inside the head", in the absence of any external sources. Tinnitus is the result of the interaction of several sub-systems of the nervous system. The auditory pathways play a role in the emergence of tinnitus as an auditory perception. Other systems, namely the limbic and autonomic systems, contribute to its continuation, and to the discomfort experienced by the patient. According to observational studies, approximately 15% of the general population suffers from tinnitus at some point in their lives[1].

Hyperacusis refers to a heightened intolerance to noise, even at low intensities that represent no risk for people with normal hearing. These noise levels, which cause no inconvenience to people with normal hearing, cause discomfort and pain in people suffering from hyperacusis. This can be qualified and quantified by a narrowing of the subject's dynamic range of hearing, which demonstrates an exaggerated auditory system reaction.

Negative impact

Tinnitus and hyperacusis have a negative impact on the quality of life of affected persons, which can include sleep problems, concentration problems, and disturbances to social and professional life. This negative impact can be very disabling. The auditory dysfunction is coupled with an increase in background noise, as well as emotional effects. It is therefore no surprise that tinnitus and hyperacusis are now seen as major public health issues.

The ØREBLUE® Method

The medical device used for the ØREBLUE® method is indicated for the treatment of tinnitus and hyperacusis. It is non-invasive and complies with Directive 93/42/EEC concerning medical devices[2] It is composed of an auditory stimulation unit connected to five software programs. This medical device transmits the patient's customized, targeted sound therapy treatment, contained in the chip card, via an audio headset.

Objective

The main objective of the study was to evaluate the effectiveness of the ØREBLUE® method in eliminating tinnitus and hyperacusis. The secondary objectives included improving the quality of life and sleep of treated persons, as well as determining the safety of the device.

The study was conducted in compliance with personal data protection regulations, and is registered with the CNIL[3] under declaration number 2173616 v0.

Method

This retrospective study used a cohort of 74 patients (Figure 1), the majority of whom were male (51 men – 23 women) with an average age of 51.1 (for the tinnitus sub-group [range: 23-83 years old] and for the hyperacusis subgroup [range: 19-72 years old]), formed prospectively between 2011 and 2015. The primary criterion was reduced discomfort by at least 5 points 1 month after the end of treatment using the ØREBLUE® method in relation to the initial score. Discomfort was measured on a numerical scale (Figure 2; NS) ranging from 0 "no discomfort" to 10 "maximum discomfort". The secondary criteria were the differences in quality of life and sleep scores 1 month after the end of treatment using the ØREBLUE® method in relation to the initial values.

Figure 1 – Patient cohort

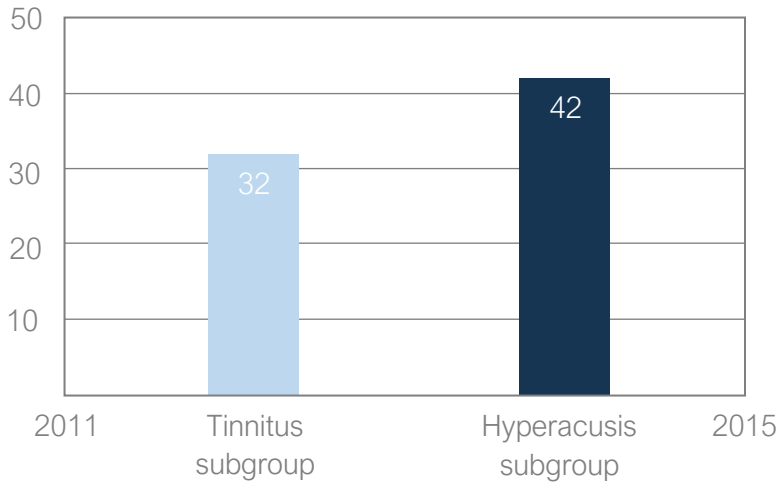
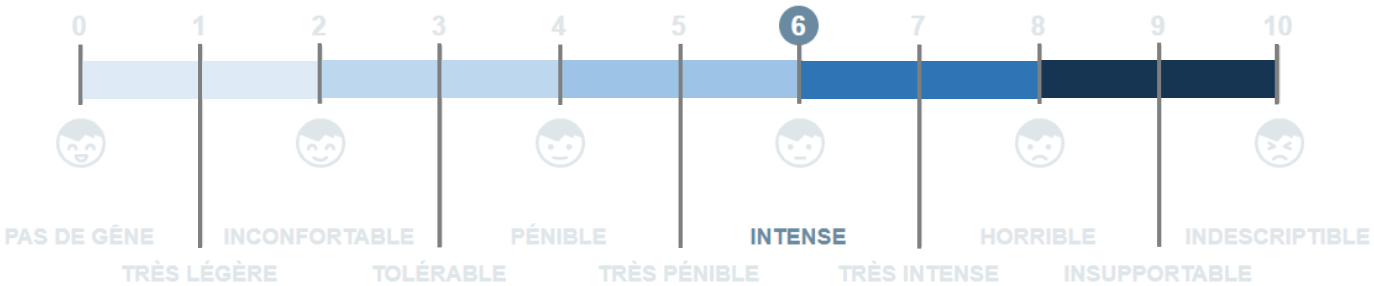


Figure 2 – Numerical scale (NS)



For patients suffering from hyperacusis, the level of discomfort for the frequencies studied was evaluated upon enrolment in the study and one month after the end of treatment using the ØREBLUE® method, and then compared to the Fletcher 115 dB isotonic curve for subjects with normal hearing (Figure 3).

Results

The cohort studied was composed of 74 patients, divided into two subgroups according to their symptoms on enrolment: the Tinnitus subgroup was composed of 32 patients, and the Hyperacusis subgroup, of 42[4].

Discomfort

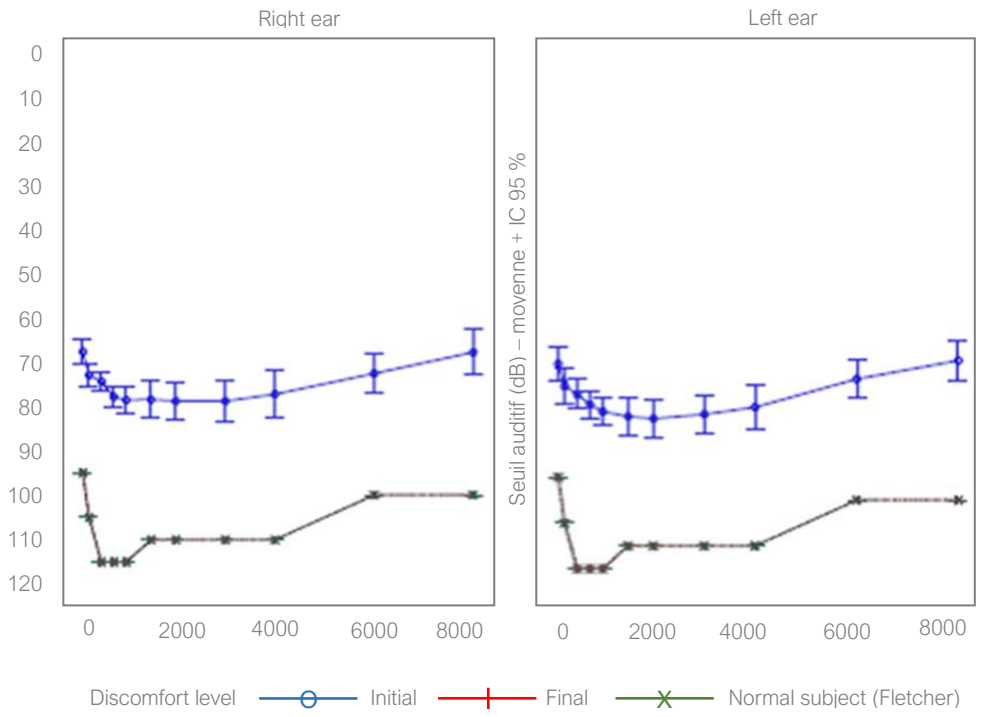
In the Tinnitus subgroup, 96.9% (range: 83.8-99.9%) of patients met the primary criterion, improvement of discomfort by at least 5 points on the numerical scale one month after the end of treatment using the ØREBLUE® method in relation to the initial values.

The proportion was 100% in the Hyperacusis subgroup, meaning an improvement of discomfort by at least 5 points on the numerical scale one month after the end of treatment using the ØREBLUE® method in relation to the initial values.

Level of discomfort

In the Hyperacusis subgroup, the discomfort level was superimposed on the Fletcher curve for all frequencies examined (Figure 3).

Figure 3 – Initial and final discomfort levels (dB) and 115 dB Fletcher curve of a subject with normal hearing.



Initial assessment on enrolment.

Final assessment 1 month after the last ØREBLUE® session.

Quality of life

The patients' quality of life saw a gradual, clear improvement throughout the treatment, with an average quality of life, on the numerical scale, of 7.9 (range: 7.3-8.5%) in the Tinnitus subgroup and of 8.6 (range: 8.3-9.0%) in the Hyperacusis subgroup on the final assessment. These scores indicate a good or very good quality of life.

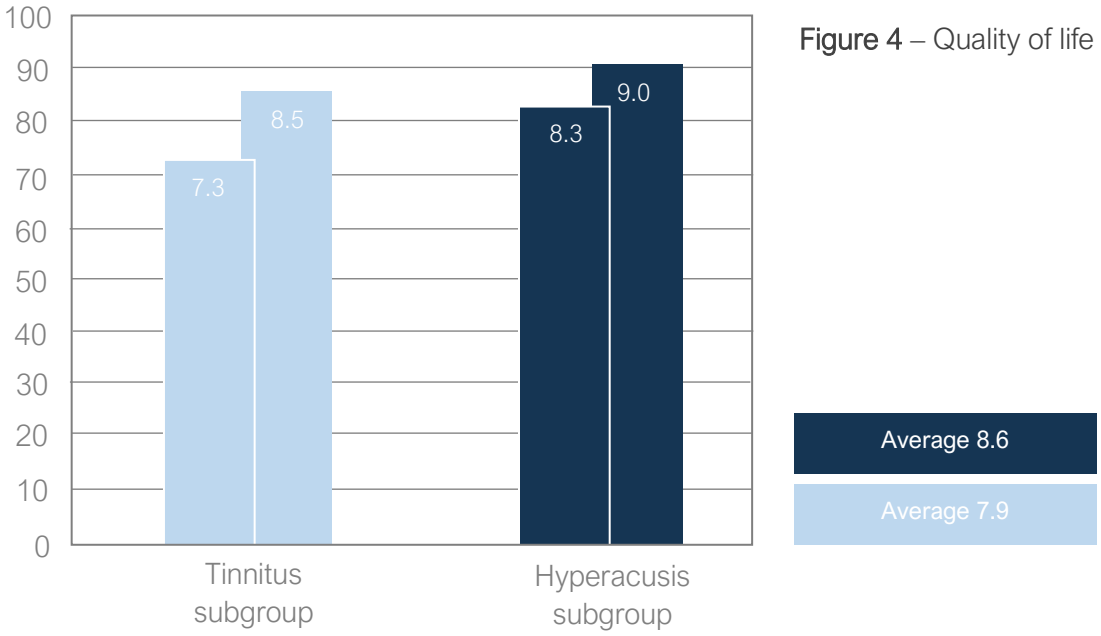


Figure 4 – Quality of life

Sleep

The effect on sleep was more moderate, with a final score, on the numerical scale, of 5.6 (range: 5.0-6.2%) in the Tinnitus subgroup and of 4.4 (range: 3.7-5.1%) in the Hyperacusis subgroup on the final assessment.

Safety

During the study, no side effects were observed that would cast doubt on the safety of the ØREBLUE® method.

Limitations of the study

The study's main limitation is its retrospective nature. The feasibility of prospective studies to corroborate these highly encouraging results is currently being examined with the help of a scientific committee.

Conclusion

No benefits are expected from the device used on its own, as its effects are indissociable from the use of the OREBLUE® method. This study demonstrates that the ØREBLUE® method effectively reduces patient discomfort due to tinnitus and hyperacusis. The analysis reveals a clear improvement in patient quality of life, with a more moderate impact on sleep. The device was very well tolerated.

Given the high prevalence of hyperacusis and tinnitus and their impact on quality of life and on the social and professional lives of affected persons, if the device being evaluated, in combination with the ØREBLUE® method of use, confirms its effects and goes into circulation, it could have a significant positive impact on public health.

References

1 McCormack A, Edmondson-Jones M, Somerset S, Hall D. A systematic review of the reporting of tinnitus prevalence and severity. Hear Res. 2016;337:70-9.
2 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
3 CNIL: French National Commission on Information Technology and Freedoms
4 Clinical evaluation report NCB#100, MAY001-CER001 v1