

The Institute of Physics and Engineering in Medicine President's Prize for best oral presentation at the 2017 Medical Physics and Engineering Conference, awarded to Cara Cooper.

Hear Glue Ear: Horizontal Innovation to provide hearing for children with Glue Ear

Background: By the age of 10 years, 80% of children will have had at least one episode of Otitis Media with Effusion (Glue Ear). Glue ear is a condition in which the middle ear becomes filled with fluid, preventing the ossicles to amplify sound for the inner ear. The condition is the most common cause of hearing loss [1] and is known to cause fluctuating mild to moderate hearing loss. However, due to spontaneous resolution in 95% of cases [2], treatments are only offered after extended periods of "watchful waiting" after diagnosis is confirmed through an audiology test. During this time, which can last up to 18months, hearing aid is rarely provided to the child and this in combination with the condition can result in speech and language problems.

We aim to transfer consumer bone conduction technology into a medical product which can provide hearing to the child at a low cost. Bone conduction technology by-passes the middle ear and provides sound to the cochlear directly, improving hearing for those with a conductive hearing loss, such as in Glue Ear. This project is targeting delivering a number of complete products which can be used in clinical evaluation as well as developing a technical file sufficient for regulatory approval.

Methods: To facilitate the design process the Hear Glue Ear product has been developed using a Healthcare Design Toolkit. This process seeks to explore needs, create concepts and then evaluate in a rapid and iterative cycle. An existing consumer technology had been identified by the clinician at the start of the project. Needs were explored with key stakeholders through design workshops, stakeholder meetings and regulatory analysis. These needs analysis sessions lead to the creation of a requirements specification covering a range of "must have" elements essential for the product and "nice to have" items which could be developed in future products.

Early risk analysis of the current consumer technology, using user failure mode effects analysis (uFMEA), has identified a number of key risks in the use of the products in a medical context. These risks have driven the design and concept workshops to innovate additions to the consumer product to provide safety features. Prototypes will then be made to establish viability before further development to produce manufacturable accessories to the consumer product.

These accessories, along with an instruction for use, will be packaged with the consumer technology to create the medical device pack. It is expected that this pack will then be made available through audiology as well as direct to consumer, due to an anticipated low cost.

Results: The healthcare design toolkit, along with risk management techniques have been effective for capturing user needs, developing specifications and understanding the risk profile of this class IIa medical device. This is leading to the development of concepts to extend the currently available consumer product to a medical use for paediatric patients with Glue Ear. The modifications are being developed using CAD and rapid prototyping techniques. The complete medical product will then go into a clinical investigation which will support the development of a technical file for regulatory submission.

Conclusion: A healthcare design toolkit and risk analysis tools have been used to facilitate in-house horizontal innovation in an NHS trust to provide a cheap hearing tool for children with Glue Ear diagnosis during the "watchful waiting" period.



Figure 1: Child hearing using bone conduction with microphone support at story time

References:

[1] Haggard M, Hughes G. Screening children's hearing. A review of the literature and the implications of otitis media. London: HMSO, 1991

[2] Zielhuis GA, Rach GH, Broek PV. Screening for otitis media with effusion in preschool children. Lancet 1989; 1: 311-4