PROSTHETIC DEVICE FOR TYMPANOPLASTY RECONSTRUCTION

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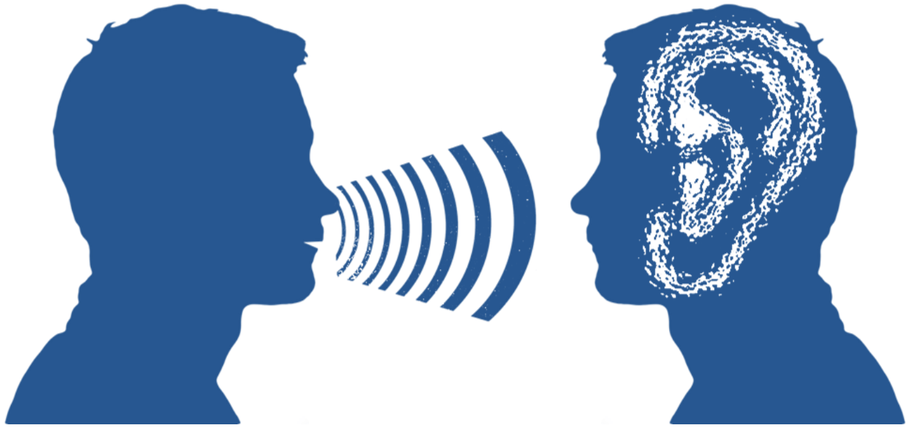
Invention

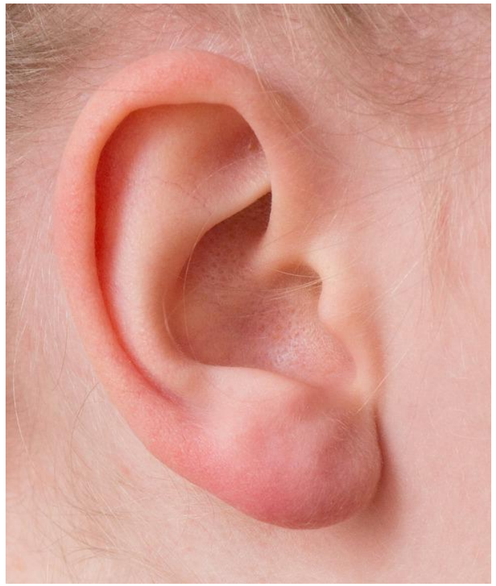
The present technology is a **prosthetic elevation device** that allows a fixation of the new tympanic membrane for the creation of a larger sounding (tympanic) box after tympanoplasty surgery, without damaging the facial nerve. Thus, the invention concerns the reconstruction of the posterior wall of the external ear canal.

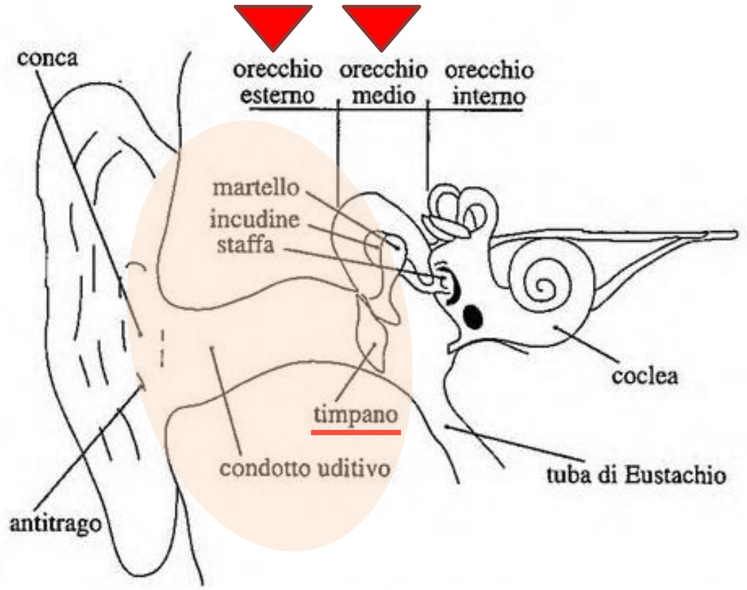
The chronicity of certain inflammatory states of the ear can lead to the **formation of cholesteatoma**, a type of expanded squamous epithelium that penetrates into the middle ear, causing damage and destruction of the fragile bone structures and the organ of hearing as well as a paresis of the facial nerve. In such cases, surgical treatment, so-called **tympanoplasty**, implemented on the tympanic cavity, is required, both at the level of the mid-ear bony structures and the mastoid.

This involves a severe destruction of the ear that operates the removal of part of the mastoid, destruction of the ear canal and middle ear structures. **Reconstruction is possible** only if the new cavity is smooth and well-ventilated and is done in the same surgery as the removal of the cholesteatoma. The **new tympanic membrane is larger** than its physiological size because, as the new cavity is totally smooth, anchoring it is difficult, creating a smaller tympanic case than the original one. This causes sound wave transmission problems and impedes the restoration of the patient full hearing function.

Drawings
& pictures







Industrial applications

The device is usefull in **tympanoplasty surgical treatments** to solve common problems due to difficult anchoring of the tympanic membrane.

The device would be of interest to Italian and international companies that commercialize devices for reconstruction of bone structures of the auditory system and prostheses for ossicular reconstruction.

The prosthetic device would bring great advantages in auditory reconstruction operations. The basic model showed already interesting results; further implementation of the prototype will be undertaken in order to:

- give o**ptimal support to the new tympanic membrane**, due to its placement in the posterior wall of the external ear canal;
- ensure that the stresses built up by the support do not directly discharge onto the bone canal covering the facial nerve;
- create a **resonance case** with a larger size than that obtained without the use of this device;
- reduce the **surgical operation time**.

A process for customizing the device can be implemented during surgery. This could recreate a sound wave transmission system increasingly similar to the physiological system of a healthy patient, thus improving the patient's hearing ability.

Possible developments

The design of the prosthetic device was conducted based on the hypothesis of anchoring on a bone rock of a reference adult patient.

The device meets three basic criteria: 1) ensuring support for the new tympanic membrane by adapting to the new anatomical region post-operatively; 2) reduced stress to the facial nerve; and 3) meeting biocompatibility criteria. To adhere to these specifications, the support was designed with a "C"-shaped structure of non-constant thickness, height, and curvature and with a groove at the bottom, of variable height, for adaptation of the support in the anatomical region. In order to meet the biocompatibility criterion, the device will be made of hydroxyapatite (HA). In fact, the use of this material promotes bone-integration with the anatomical structures, being one of the main constituents of the bone matrix.

The device was designed as part of the 2009 Toscana Salute Regional project, where Prof. Stefano Berrettini is in charge for.

The inventors are interested in future collaborations and licensing opportunities for the technology commercialization and dissemination in hospital departments specializing in **tympanoplasty**.

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