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Development of an ear cap in chronic suppurative otitis media using additive manufacturing and TRIZ

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Abstract
The prevalence rate of chronic suppurative otitis media is high and its treatment continues to be a challenge for the otorhinolaryngologists. Due to middle ear infection, there may be pain, hearing loss and spontaneous rupture of the eardrum which results in perforation. Infections can cause a hole in the eardrum as a side effect of otitis media. The patients suffering from ear perforation or having a hole in eardrum require preventing entry of water in the ear. This article describes the development of ear cap using additive manufacturing and TRIZ (a collaborative tool) to prevent the entry of water in the ear during chronic otitis media.

Keywords
Otitis media, tympanoplasty, additive manufacturing, TRIZ, ear cap

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Introduction

Chronic suppurative otitis media (CSOM) is a highly prevalent disease. Despite all specific progress, it remains as an important public health issue. It causes great personal suffering and financial burden to the society.[1–3] A hole or rupture in the eardrum is called perforated eardrum. The causes of hole in eardrum are usually from injury, infection or chronic Eustachian tube disorders.[4,5] However, a vast majority of perforations due to infection are small and heal spontaneously; the recurrent infections may impair the regenerative process and result in chronic perforation.[6] The most common ear disease among indigenous children is otitis media (OM). Hearing loss associated with ear problems can lead to educational issues, social isolation, truancy, early school leaving and difficulties gaining employment.[7] The tympanic membrane is composed of collagen fibers that are exactly aligned to enable sound waves to be transmitted through the ear osssicles.[8] Tympanoplasty is one of the important surgical procedures mainly focused at restoring the hearing loss and eradication of middle ear disease.[3]

During the healing process, the eardrum must be protected from water and trauma. In preoperative evaluation, strict dry ear precaution is suggested by the doctors.[9] Presently, the devices available in the market that prevent the entry of water in the ear are earplugs and earmuffs. An improperly fitted, dirty or worn-out plug may not seal and can irritate the ear canal. Simultaneous use of earplug and muffs usually add more protection than used alone.[10] Protecting the ear from water during perforation is of primary interest. In this study, an innovative product is developed for protecting the human ear undergoing tympanoplasty and a novel approach to develop ear cap is presented and discussed.

Materials and methods

In the modern society, more and more attention is paid to the medical equipment or devices that have greater impact to improve quality of people's life. TRIZ offered a powerful technique for innovative idea generation. This technique can be used successfully in designing

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mechanical product. Subsequently, the applications of TRIZ in medical equipment design process grasp the researcher's attention. The additive manufacturing (AM) technology based on TRIZ can help the conceptual design of the new product. AM technology permits to develop a product with high level of geometrical complex shape and produce it as unique product by implying low cost and quick time production compared with other manufacturing processes. It is a faster method across various industrial disciplines to build functional, physical parts from computer-aided design (CAD) model. Freedom for design in product development is a new reality with AM.

Medical organizations explicitly need both creativity and innovations together. TRIZ was created by the former Soviet Union's patent reviewer, Genrich Altshuller. He derived the innovative principles by analyzing around 400,000 patents worldwide in 1950s. The theory systematically categorizes and includes innovations and problem-resolving methods.[11] Mawale et al.[12] represented the use of collaborative approach of TRIZ with AM. This approach provides realistic and systematic way to solve the innovative problems.

In their study, the authors had focused on 2010 expanded TRIZ matrix. It introduced 50 parameters and proved its high accuracy to match with the solutions of current invention.[13] Their initial analysis was connected with analyzing in-depth meaning and applications of all 50 parameters. This makes them to understand that out of 50 parameters, the 11 or 12 engineering parameters are often used in resolving contradictions of engineering problems. Hence, the focus was made on 14 engineering parameters.[14,15] An attempt was made to offer flexibility to the users working on mostly used mechanical engineering parameters by focusing on prioritization of most likely innovative principles used in engineering applications. In their study only 14 parameters from expanded TRIZ matrix were selected. Then, the 2010 expanded TRIZ matrix was reduced to 14×14 matrix and recommended innovative principles were selected. Further top 10 principles were selected based on their frequency of occurrence in 2010 expanded TRIZ matrix. The top 10 principles selected were parameter change, preliminary action, copying, segmentation, separation, periodic action, inversion, mechanical substitution, dynamicity and mediator (Figure 1).[12,16]

The work had been carried out of innovative design of ear cap. In this work, the requirement of new product was realized for the patients suffering from CSOM. Afterward, the engineering parameters from 2010 expanded TRIZ matrix concerned to those requirements were explored. The engineering parameters were selected for development of product, weight, volume, strength, reliability, manufacturability and harmful effects.[12] These selected engineering parameters were again prioritized and finally weight and manufacturability were chosen as important parameters. Using top 10 innovative principles and examining the above parameters, four inventive principles, parameter change, copying, segmentation and mechanical substitution, were selected (Figure 2).[12] Using collaborative approach, the inventive principles parameter change and copying were chosen as close relationship with the problem. The final prototype was developed using rapid prototyping (RP).

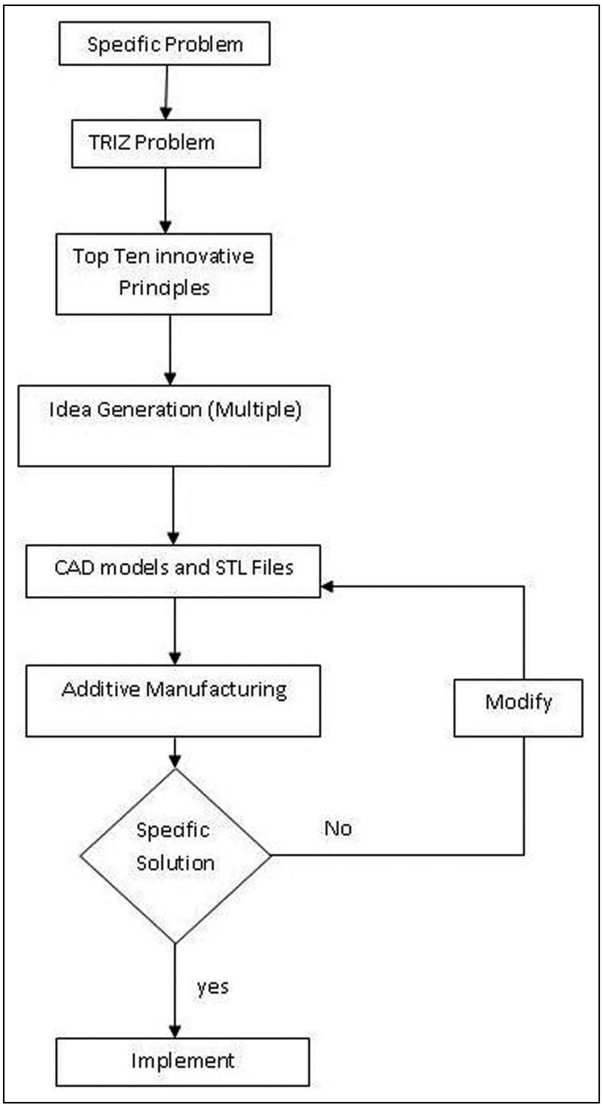

Figure 1. Use of top 10 innovative principles with collaborative tool (AM + TRIZ).

Design of the product

An ear cap is a medical device manufactured to protect the human ear from the entry of water during perforation. Traditional medical device manufacturing methods provide only standard parts in a standard shape and size. This implies that the medical device does not respond to the patient's specific needs, and the postoperative recovery is more difficult. What is important in medical device manufacturing is to provide customized devices for more comfort to the patients.

The medical device manufacturing was performed using a collaborative tool (AM + TRIZ) product

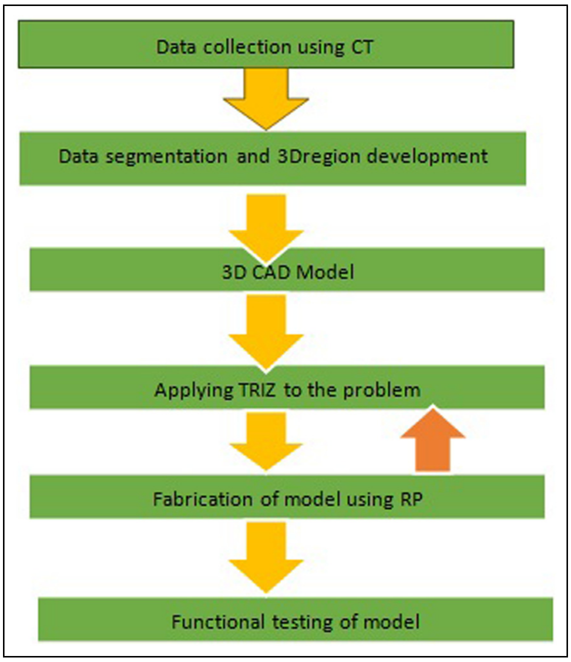

Figure 2. Approach for design and development of (RP + TRIZ) assisted ear cap.

development system which, besides geometry and topology, enables integration of product knowledge and applied technologies restrictions for some forms in a virtual model of a product.

Methods include the use of collaborative tool to design medical devices and these methods are based on the innovative principles recommended by TRIZ, ideas of otorhinolaryngologists and engineers. The basis for creating a prototype of ear cap was for its suitable fixation to the human ear.

The general engineering techniques for design, analysis and manufacturing of customized ear cap, for specific human ear, used in this research, include several tasks[17,18] (Figure 3):

1. Applying TRIZ to the problem (innovative principles).
2. Creating a three-dimensional (3D) model of a human ear using a computed tomography (CT) scan of the patient's skull.
3. Separating the ear from the skull using region separating tools.
4. Adjusting the geometry of the ear according to the requirements of the patient.

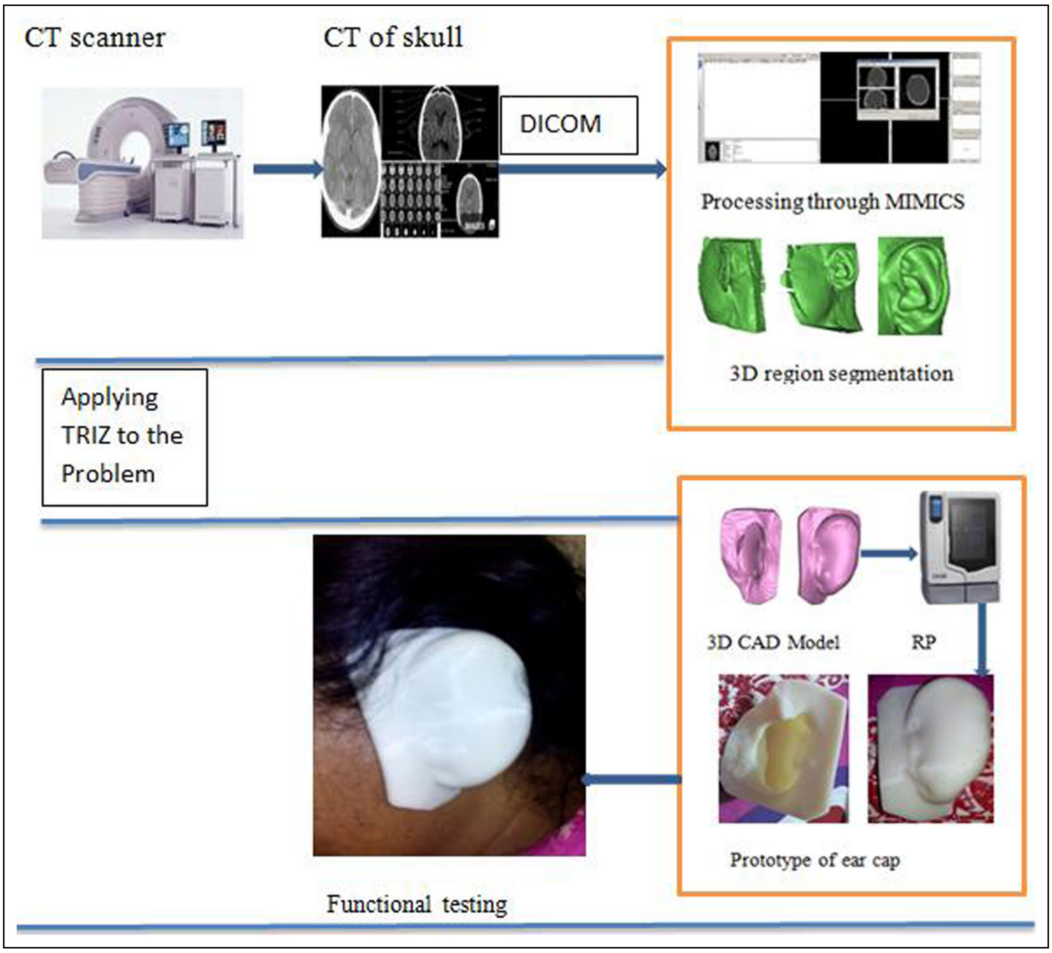

Figure 3. Phases of design and manufacturing of the customized ear cap.

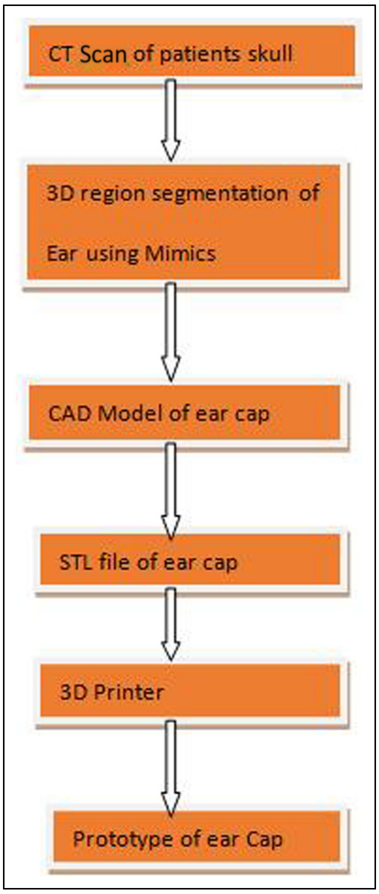

Figure 4. The process of reverse engineering for the ear cap.

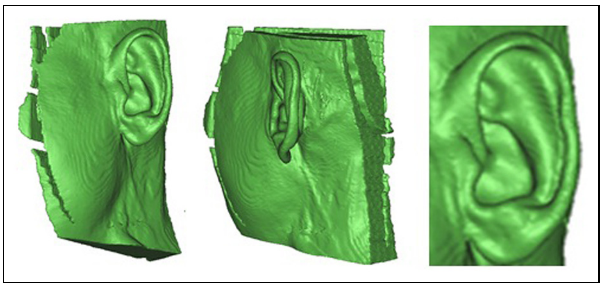

Figure 5. 3D ear models of patient's ear (MIMICS).

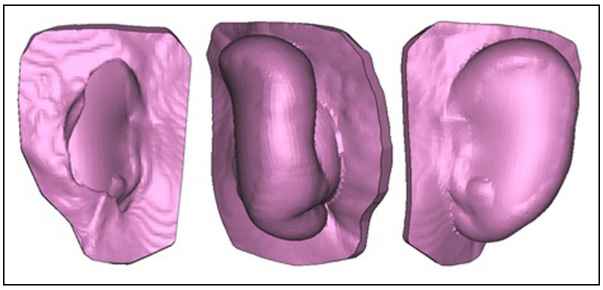

Figure 6. 3D CAD models of ear cap.

5. Creating a customized 3D model of the ear cap.
6. Analysis and optimization of the shape and size of the ear cap.
7. Creating a prototype of ear cap using AM.

The goal of this method is to create a patient's specific prototype of the ear cap using medical imaging techniques. With the application of this method, it is possible to create 3D models and prototype of the human organs.

Development of product

The use of CT and magnetic resonance imaging (MRI) with 3D representation of human anatomy has carved new revolution in the medical field.[19] Data acquisition using radiography techniques is a process of capturing the 3D shape of an existing anatomy using contact and non-contact measuring devices. Non-contact methods like CT, CBCT (conical beam computed tomography) and MRI are used for scanning purpose.[20] The image processing is performed on personal computers which require choosing an appropriate data interchange format. Most of the CT and MRI units have the ability of exporting data in common medical file format DICOM (digital imaging and communications in medicine).[21] In this study, a 60-year-old patient was considered. Patient was suffering from CSOM and having perforated ear with minor pain. Audiometry test recorded substantial hearing loss. The process used for the development of ear cap is represented in Figure 4.

A 3D CT scan of patient's skull in DICOM format was adopted with 0° gantry tilt with a slice thickness of 0.8 mm. Adopted pixel size was 0.3281 mm, number of slices 365, resolution 512×512 with a tube voltage 120 kVP and a tube current 200 mA. The medical image processing software (MIMICS 14.11, Materialise N.V) was used to process two-dimensional (2D) DICOM file by segmentation. In software, proper threshold values were selected to divide the soft tissues and bone structures. Afterward, required area was separated and 3D ear model was generated by region growing in highest possible quality STL file (Figures 5 and 6). The segmentation and editing tools enabled to manipulate the data to select bone, soft tissue, skin and so on.

Then, the STL file of ear model was imported to Catalyst Ex pre-processing software to link with RP machine (uPrint SE, Stratasys Inc., Ontario) for fabrication. The fused deposition modeling (FDM), a RP technique, was used to get biomodel made of acrylonitrile butadiene styrene (ABS) material (Figure 7). FDM technique was used for fabrication because of its minimum postprocessing requirements and superior mechanical properties like strength of the build material.[22] Finally, the functional prototype was manufactured for patient's ear (Figure 8). The prototype was tested to suit for its functionality by fixing it on patient's ear. It was found that the use of ear cap had served a purpose of preventing the entry of water in the ear during bathing. The patient was comfortable while using it.

Figure 7. Fabricated RP models of the ear cap.

Figure 8. Functional testing of prototype.

Conclusion

The patients suffering from the ear perforation or having a hole in eardrum require to prevent the entry of water in the ear. Again it is important to follow the dry ear condition for the patient, pre- and post-operatively undergoing tympanoplasty. The devices which are readily available in the market are having their own limitations and drawbacks. The proposed new device for protection of ear from water developed using AM with TRIZ will help the medical practitioners in rural and remote areas for the treatment of CSOM. It is easy to use and comfortable for patients.

Declaration of conflicting interests

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