Virtual Prototyping in the Development Process of Customised Hearing Aid Shells

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In the paper the author proposes a novel approach to design customised shells for hearing aids by means of techniques of virtual prototyping, used today in several fields of medicine. Digital technology is providing the technical platform to eliminate the need to take an ear impression, replacing the ear canal of a patient with a digital scan, but at present on the market there are still not systems able to perform in vivo scans of the human ear canal. Starting from CT (Computed Tomography) data of the external ear, adopting the powerful and quite easy to automate NURBS (Non Uniform Rational B-spline) modelling tools available in the commercial Rhinoceros® CAD system, the author uses a straightforward modelling procedure that by means of VBS (Visual Basic Scripting) tools, allows obtaining automatically and quickly the accurate CAD solid model of the customised hearing aid shell. Having the CAD model, then, it is possible to view and modify the shape in the three-dimensional space and so to design innovative acoustic prostheses completely internal to the ear canal to which they perfectly fit.

Moreover, the procedure followed in the paper, will allow, analysing the ear canal changes in response to normal jaw motion, to design the best shape of the hearing aid shell.

Keywords:

CT Data, CAD, STL Format, Hearing Aids Shell.

1. INTRODUCTION

A hearing aid is a small electronic device that the user wears in or behind his/her ear. It amplifies sound to provide speech information to listeners with a hearing loss. A hearing aid has three basic parts: a microphone, an amplifier, and a speaker. The hearing aid receives sound through a microphone, which converts the sound waves to electrical signals and sends them to an amplifier. The amplifier increases the power of the signals and then sends them to the ear through a speaker.

There are different basic types of hearing aids (Figure 1). The styles differ by size, their placement on or inside the ear, and the degree to which they amplify sound, based on the specific hearing loss.

A very important part of the hearing aids is the shell. Most users get a custom-made hearing aid shell for proper fit and function. Traditional production techniques require manual processing that are error prone and are not reproducible. This often results in a not perfect fit of the shell to the ear canal. In addition, it can cause an audio feedback (also known as the Larsen effect from the Danish scientist, Soren Larsen, who first discovered its principles) between microphone and amplifier, which does not allow the user to understand the conversation and the noise useful to orientate oneself.

The hearing industry and the audiological fields have made steady progress in diagnostics and amplification over the past 20 years. Today, there are products one could only have dreamed of in the 1980s. Unfortunately, the process of reproducing the external ear via ear impressions to make the shell has not changed substantially in the same 20 years. Digital technology is providing the technical platform to eliminate the need for an ear impression, replacing it with a digital scan of the external- and internal ear, which will capture the active area (jaw open vs jaw closed) of the ear canal, but at present there are only research activities with the aim to develop prototypes of three-dimensional scanning systems [1, 2, 3, 4].

In the paper the author proposes a new approach without using the ear impression. It starts from a set of 2D CT slices of an ear canal and through a modelling procedure with VSB tools, allows obtaining automatically the CAD models of the ear canal and of the customized hearing aid shell.

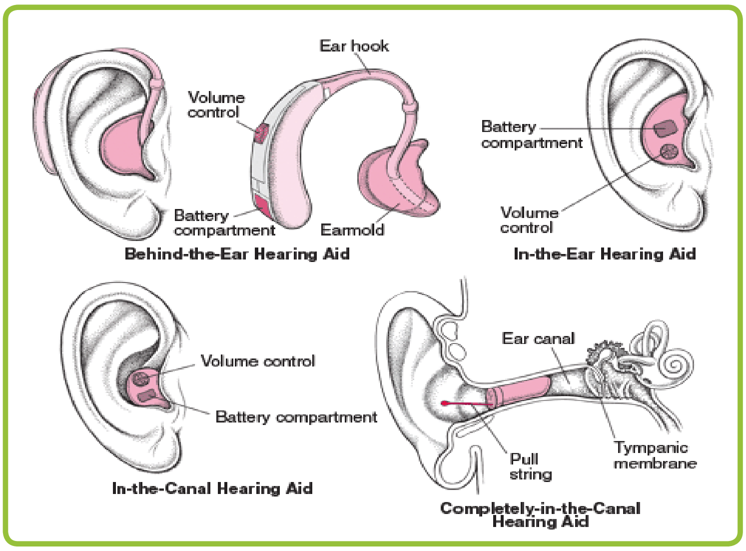

Figure 1:

Styles of Hearing Aids

2. TECHNIQUES FOR THE HEARING AID SHELL MANUFACTURING

2.1 TRADITIONAL TECHNIQUES

To obtain, by traditional technique, the hearing aid shell it is necessary to take an ear canal impression injecting into the canal an impression material. There are currently two main types of impression material in common use. Condensation silicon consists of a small amount of hardener added to a larger quantity of putty; additional silicon consists of two component materials mixed in equal parts (like in dentistry applications). Additional silicones are often preferred due to their easier mixing, better flow properties and long-term stability. The first step consists of inserting a small plug of cotton into the ear canal to protect the eardrum and of using a syringe to fill the ear canal and outer ear with the impression material. After several minutes the impression material is removed, and the ear impression is finished (Figure 2). Then the impression is cut and smoothed according to type of hearing aid to manufacture and is prepared for the gel cast from which, with a photo-sensible material, the shell is obtained [5,6].

The conventional method is very invasive and inaccurate. Impressions are a static measurement or "still snapshot" of the ear canal. It is critical to note, however, that the ear canal changes in response to normal jaw motion as well as head position and posture, time of day when the impression is made and whether the person is wearing a hearing aid immediately before the measurements are made. Changes in the position of the jaw can cause a variance in canal diameter of more than 30% in some people.

Another possible contributor to poor fit is poor laboratory replication of impressions due to the pressure on soft walls. All of these variables can contribute to problems of fit of the shell to the ear canal that determines unintentional, uncontrolled and variable venting and often leads to acoustic feedback.

Figure 2: Ear canal impression.

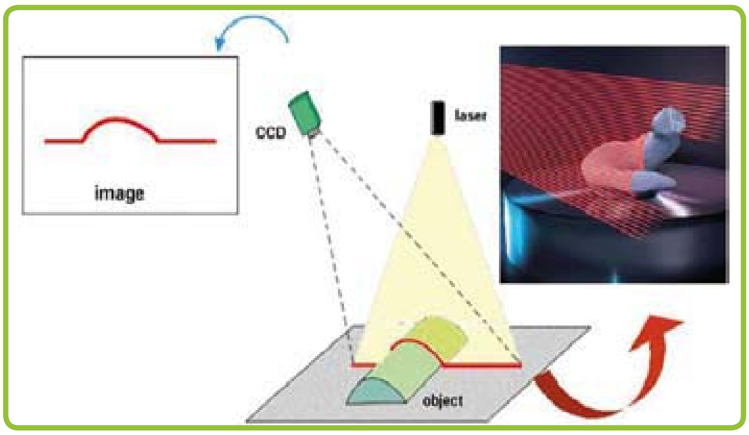

Figure 3 Triangulation

Principle to capture the point cloud of the ear impression by a 3D laser scanner.

2.2 DIGITAL DEVELOPMENT PROCESS

Currently, the process of digital mechanics to obtain a customized hearing aid shell, used by the main hearing companies, includes three stages: impression scanning, virtual modelling and shell manufacturing. The process begins with the digitization of the shape of the ear impression by using a no-contact Reverse Engineering system, a 3D laser scanner, based on the principle of triangulation (Figure 3).

The obtained point cloud (Figure 4) is accurate (50 ÷100 µm) and is taken in a few minutes [7]. Then a specific 3D modelling software is used to create the virtual shell that includes the functional structures, such as the shell thickness, venting paths, and mounting hardware for internal electronic components. The shell can be viewed and modified in the three-dimensional space before the manufacturing phase. This detailed impression is stored in a database, and the original impression is kept for future comparison and retrieval, to identify for example where discrepancies in the fit may occur.

This should remove some of the current "art" during the impression-making process and allow more decisions to be based on objective or scientific criteria. The computer aided design process allows the technician to see how all the components will fit into the shell before it is made. Therefore, the shell can be designed to produce the smallest instrument possible that will still accommodate all of the necessary components.

Once the virtual design is finished, a suitable Rapid Manufacturing (RM) technique completes the process for directly manufacturing, layer by layer, the shell in a bio-compatible material (Figure 5).

Both techniques for the hearing aid shell manufacturing, described in this paragraph, have the limit of starting from ear impressions and therefore they are very inaccurate and cause of problems of fit of the shell to the ear canal.

This limitation has prompted the author to consider a new approach to the problem without the use of the ear impression, starting from the anatomical shape of the patient canal.

3. A NOVEL APPROACH TO DESIGN CUSTOMISED HEARING AID SHELL

The digital technology is providing the technical platform to eliminate the need to take an ear impression but at present it is still not possible to obtain an hearing aid shell without it.

The author proposes a new approach without the use of the ear impression, with the aim to provide the opportunity to analyse exactly the ear canal changes in response to normal jaw motion, detecting the dynamic zones and static zones. It will be possible, in this way, to design the best shape of the hearing aid shell.

The main steps of the proposed procedure are as follows (Figure 6):

1. CT Data Acquisition (Dicom 3 format) of the ear canal;

2. 3D Reconstruction (STL model) of the ear canal;

3. STL to CAD format conversion;

4. Shell modeling;

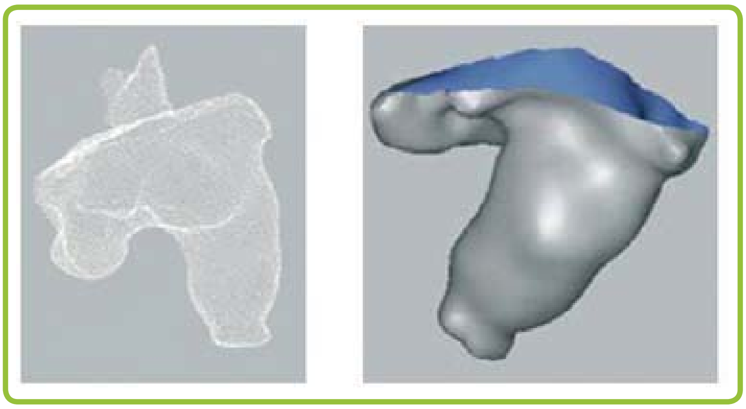

Figure 4

Point cloud (left) and CAD model (right) of the ear impression.

Figure 5

The shell is produced by a Direct Digital Manufacturing System in a bio-compatible material..

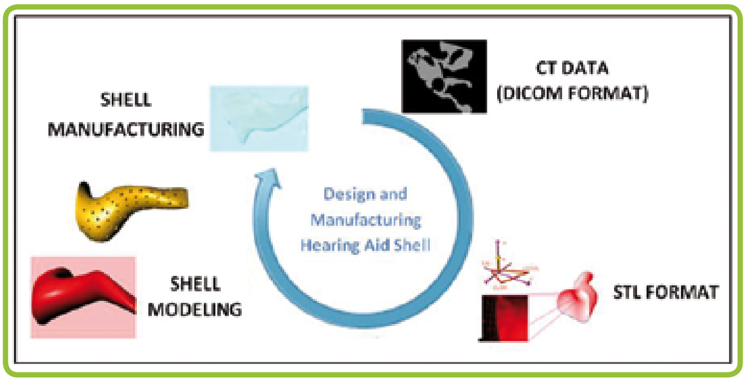

Figure 6:

Main steps of the proposed procedure.

5. Shell manufacturing by RM systems.

3.1 VIRTUAL MODEL OF THE SHELL

To obtain the virtual model of the hearing aid shell, the first phase of the proposed procedure consists of the acquisition of the ear canal radiological data by Computed Tomography (CT): the success of the whole process depends on the quality of these data.

Starting from spiral CT data, in DICOM 3 standard (slice thickness: 1,3 mm; spacing between slicing: 0,6 mm), related to a 25 years old female human skull, the 3D STL model of the external ear, including the ear canal till the tympanic membrane has been obtained, by combining both commercial software and customised algorithms developed in an open source software VTK (Visualization ToolKit) [8].

The STL Format consists of the description of 3-vertex facets including their normals, thus often the geometry is also called faceted or tassellated. The main restriction placed upon the facets in STL files is that all adjacent facets must share two common vertices.

This approximated description of the geometry may be converted to a math description of surfaces by fitting surface patches to point data. Some specific commercial software allows doing the point-to-surface operation, but this

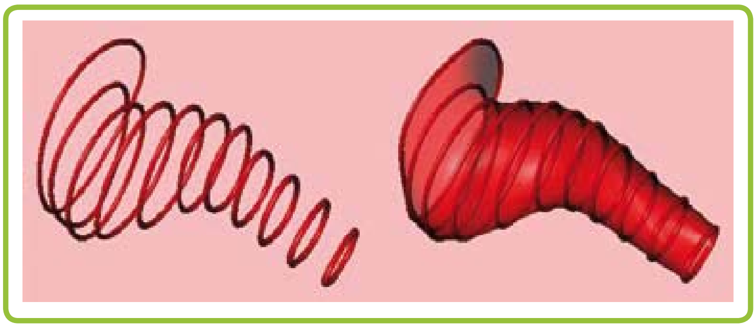

Figure 7:
Section curves and loft surfaces.

conversion is often time consuming and requires a trial-and-error approach to get a quite accurate surface model. When a satisfactory result is reached, the final model size is hard to handle in downstream applications.

More people, instead, use different approaches based on the extraction of planar curves intersecting the faceted model (or traced directly from the CT slices [9]), and then lofting (blending) a surface through those curves. The accuracy of the geometry depends on the distance between the cross section curves, on their accuracy, and mainly on the geometric modelling techniques used to create the loft surface. By using different parameterisation techniques in the loft direction, the effect of the surface obtained is different, and it may result very close to the original STL model or smoother and then a little farer.

By adopting the powerful and quite easy to automate NURBS modelling tools available in the Rhinoceros® CAD system, the author follows a straightforward modelling method defined in a previous paper [10] by Visual Basic Scripting tools: it makes use of section curves and loft surfaces (Figure 7), by controlling at every modelling stage, the deviation from the underlying point set to obtain a compromise between the closeness to original data and the smoothness of the surface obtained (Figure 8).

The method automatically quickly creates the solid model of the hearing shell which perfectly fits the ear canal.

Figure 9 shows the CAD model of the hearing shell (1 mm thick) within the STL model of the ear canal at 0.1 mm offset distance from it.

In table 1 and in Figure 10 the deviation check between the hearing shell CAD model and the STL model are shown. The greatest deviations are on the boundary of the shell.

Having the 3D CAD model it is possible to design innovative acoustic prostheses completely internal to the ear canal to which they perfectly fit.

The CAD model permits, in fact, to view and to modify the shape in the three-dimensional space; it is possible to modify the shell thickness, create different solutions for venting paths or define the best fit for the internal electronic components. For example, in Figure 11 a hearing aid shell with an innovative solution for venting paths is shown. The holes have been obtained automatically using the same VSB tools above considered.

Once the virtual design is finished, a suitable Rapid Manufacturing technique completes the process for directly manufacturing the shell, usually in a biocompatible hard material and today also in a biocompatible soft material [11].

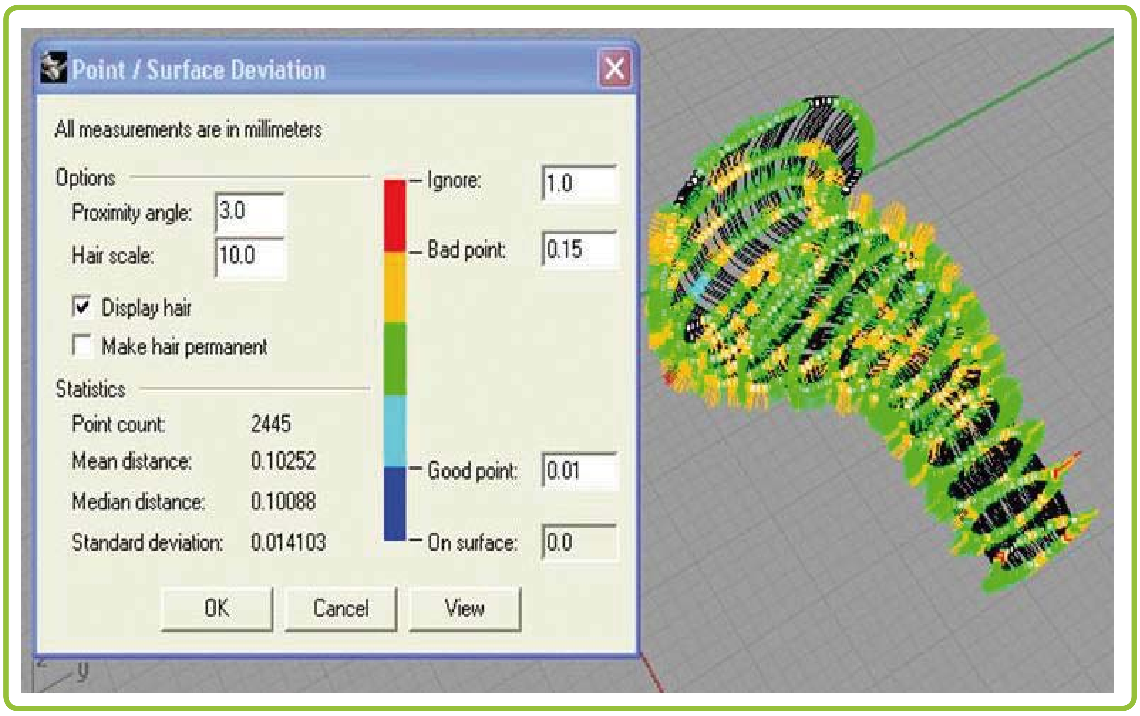

Figure 8:
STL-Surface deviation check.

4. CONCLUSIONS

Nowadays to obtain a customised hearing aid shell it is necessary to take an ear impression.

In the paper the proposed approach allows eliminating the ear impression in the design of a customised hearing aid shell.

Starting from STL model of the external ear (including the ear canal till the tympanic membrane), obtained from spiral CT-scan data, the author proposed a modelling method that automatically creates the CAD model of the hearing shell, which perfectly fits to the ear canal.

Particular attention has been posed to check the closeness of the CAD model to STL data.

The CAD modelling permits to analyse different and innovative solutions and so to design the shape of the hearing aid shell. Once the virtual shape is defined it can be directly manufactured by means of RM techniques, today also in a biocompatible soft material.

The proposed approach will also allow analysing exactly the ear canal changes in response to normal jaw motion, detecting the dynamic zones and static zones, designing, in this way, the best shape of the hearing aid shell.

	Parameter	Value(mm)
Statistics	Positive Maximum distance	0.1885
	Average distance	0.0163
	Standard Deviation	0.0238

Table 1:

Deviation statistics.

5. REFERENCES

[1] Prasciolu, M., 2007, 3D laser scanner based on surface silicon micromachining techniques for shape and size reconstruction of the human ear canal, Ph.D. Thesis - University of Trieste.

[2] Prasciolu, M., Malureanu, R., Cabrini, S.,Cojoc, D., Businaro, L., Carpentiero, A., Kumar, R., Di Fabrizio, E, 2005, Three-dimensional digital scanner based on micromachined micromirror for the metrological measurement of the human ear canal. Journal of Vacuum Science and Technology B: Microelectronics and Nanometer Structures. 23(6): p. 2990-2994.

[3] Prasciolu, M., Cabrini, S., Cojoc, D., Malureanu, R., Kumar, R., Businaro, L., Di Fabrizio, E., 2004, Fabrication through silicon micromachining of 3D scanner for optical determination of the ear canal. IFMBE Proceedings, Volume 6, Nov. 2004, MEDICON and HEALTH TELEMATICS 2004 "X Mediterranean Conference on Medical and Biological Engineering".

[4] Darkes, P., Voll, L., 2002, Shaping the Future of Shell Technology with Digital Mechanics, Hearing Review, Issue Stories, April 2002.

[5] British Society of Audiology, 2007, Recommended procedure for taking an aural impression, http://www.thebsa.org.uk.

[6] Widex, 2008, Making a hearing aid, at http://www.widex.co.za.

[7] Fabry, D., 2002, Hearing aid physical fit: the next revolution?, The Hearing Journal; Vol. 55: 46-50.

[8] The Visualization Toolkit User's Guide, 2006, Kitware, Inc., 5th Edition, 382 pages.

[9] Kawamoto, T., Sugahara, T., Ueno, T., Mizukawa, N., Sawaki, K., 2001, Stress analysis of artificial temporomandibular joint,

Figure 9:

CAD model of the hearing shell within the STL model of the ear canal..

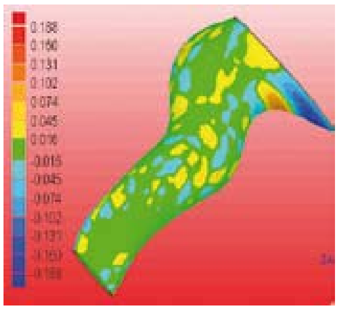

Figure 10:

Deviation plot

between the STL and CAD Models

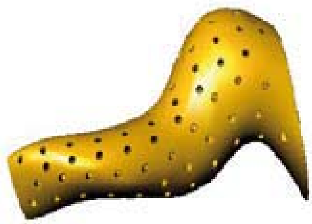

Figure 11:

Shell CAD model of an innovative solution for venting paths

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The 42nd Congress of Korean Association of Oral and Maxillofacial Surgeons, Taegu, Korea.

[10] Gerbino, S., Martorelli, M., Renno, F., 2004, Designing Acoustic Prosthesis by Virtual Reconstruction Techniques, Proc. of Medicon Conference: X Health Telematic Conference, July 31st-August 5th, Ischia, Italy.

[11] Turner, R. G., 2000, "Soft" hearing aids: The answer to some hard problems?, The Hearing Journal; Vol. 53: 10-18.