CUSTOMISED HEARING AIDS

Ear cavity shapes are unique as fingerprints, with the left cavity differing from the right one, for each individual. Therefore, it is not suitable to provide hearing aid users with earmoulds of a *'standard'* design. An improvement to providing hearing aid users with *comfortable* hearing aids in the minimum possible *time*, is much required in Malta. A *'customised'* solution, where the earmould is designed for the individual, is therefore much needed. The research work carried out investigated different *reverse engineering* techniques to design and fabricate customised behind-the-ear (BTE) hearing aids. *Time-compression technologies* which reduce a product's time-to-market, and which thus save on *time* and *money*, while at the same time improve the *quality* of products, were implemented.

<u>The 'Impression Approach'</u>

Only the first step of the Impression Approach, which is the method currently adopted by leading international hearing aid manufacturers such as Siemens, Phonak and Widex is carried out locally, whereas the other four steps are completed abroad. The research work investigated whether it is feasible to carry out all the steps locally with the resources available.

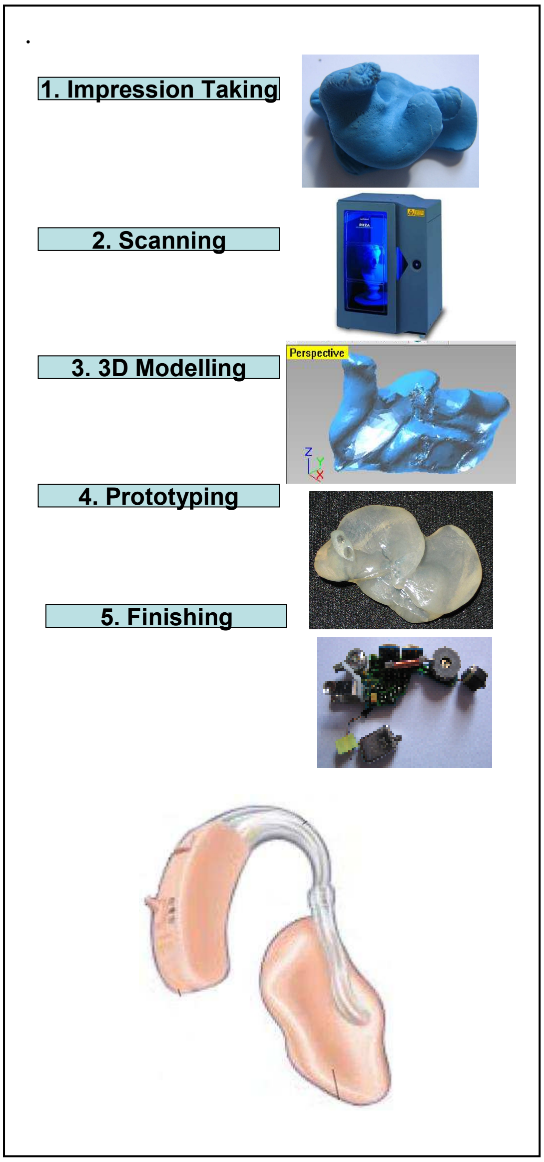
1) A material is syringed in the patient's ear in order to obtain an 'impression' (reverse) of the ear cavity geometry.

2) The 'impression' is scanned using a 3D laser scanner.

3) The output from the 3-D laser scanner is in the form of a *'cloud of points'*. These need to be converted into a *'mesh'* and then into a *'watertight solid'*. Some modifications to the model, such as filling gaps and subtracting features from the model to create space for holes for the vent[1] and tubing[2] are performed at this stage.

4) The solid model is saved as a *.stl file and is sent electronically and transferred to the rapid prototyping machine. Stereolithography (SLA) and selective laser sintering (SLS) are the two commonly used techniques to manufacture such medical devices. The earmould is fabricated layer by layer using a liquid epoxy resin which is cured by the laser beam. The part is further solidified by 'baking' it in a fluorescent ultraviolet oven.

5) The earmould prototype edges are grinded and the electronics are inserted in the shell and the tubing is connected.



[1] Vent – to equalize the air pressure and prevent whistling due to the response caused by the low frequency components
[2] Tubing - connects the shell to the earmould

Designed Experiments

Taguchi's one-factor-at-a-time experiments were carried out to determine the accuracy lost in dimensions when the impressions were scanned and then manipulated through the set of software programs. The dimensions of the impressions were taken using the Coordinate Measuring Machine (CMM) available at DME and a vernier calliper, before they were scanned. These were compared to the dimensions of the 'digital model' after each data conversion was performed, and the percentage error was calculated. The *One way ANOVA* and the *One Sample T-Test* were used to analyse the experimental results using the Statistical Package for the Social Sciences (SPSS). The fact that the dimensions of the 'digital' mould and the original impression were not drastically different implies that the earmould would fit well in the patient's ear, thus ensuring customer satisfaction.

CT Scan Approach

The second part of the research investigated the possibility of using a set of 2D CT slices, converting them to a 3D model and then fabricating the model using RP techniques. This approach was proposed to eliminate the impression taking stage in the 'Impression Approach', which may create inaccuracies due to shrinkage of impression material. However although an accurate 3D model of the ear was obtained using *3D Doctor,* when converting the mesh to solid some data was lost.

Conclusions

Time evaluations that were carried out for the 'Impression Approach' showed that if an enterprise were to invest in the equipment mentioned in this paper, and start to fabricate customised hearing aids, the lead production time may be reduced by nearly 10 months. However cost evaluations showed that since the local demand is low, it would take many years for the company to break-even. Both these feasibility studies reveal that it may be economical for Malta to join ventures with foreign clinics and hospitals to manufacture customised hearing aids for export. Malta's geographical position is ideal for easy collaboration with both European countries as well as Southern Mediterranean countries. It would be even more cost-effective if the same machine would be used to produce other prototypes for other biomedical engineering products.

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