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보청기 이어쉘 제작 공정의 형상 연구

조선대학교 대학원

전자정보공학과

이 언 박

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지도교수 장 순 석

이 논문을 공학 석사학위신청 논문으로 제출함

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전자정보공학과

이 언 박

이언박의 석사학위논문을 인준함

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Table of Contents

List of Tables

List of Figures

ABSTRACT

Study of hearing aid ear shell manufacturing process improvement

Li Yanbo
Advisor: Prof. S.S.Jarng
Department of Information and Communication
Graduate School of Chosun University

디지털 기술은 보청기 및 보청기 휘팅에 큰 영향을 가져왔다. 그리고 현재는 보청기 쉘제작에까지 영향을 주고 있으며, 본 연구에서는 전통적인 방법과 CAD/CAM 을 이용한 방법의 차이점 및 CAD/CAM 방법을 설명한다. 플라스틱 물질에 UV 에 경화하는 경화제를 첨가하게 되면, UV 레이저를 이용하여 정밀한 조형물을 만들 수 있으며, 이때 컴퓨터를 이용하여 UV 레이저를 제어 하게 된다. 이때 Stereo Lithographic Apparatuses (SLA) 과 Selected Laser Sintering

(SLS)이 사용된다.

이 기술은 ITE 보청기에 1996 년 최초로 적용되었으며, 현재는 큰 환기구를 만드는데 시도 되고 있으며, CAD/CAM 기술은 현재 보청기 쉘 제작에 넓은 부분에 적용되고 있다.

본 논문은 RSM 을 이용하여 보청기의 쉘을 제작하는 CAD/CAM 기술을 포함하고 있다. 보청기 제작에 쾌속조형(RP)을 사용하는 것은 전통적인 방법과는 많은 다른 점을 포함하고 있다. 본 논문은 실제 사람의 귓본을 활용하여 CAD/CAM 과 전통적인 방법의 접근방법의 차이를 설명한다. 보청기에 적용된 CAD/CAM 기술은 서양사람의 귀를 바탕으로 발전된 기술이기 때문에 동양인의 귀에는 적합하지 않다. 따라서 본 논문에서는 동양인의 보청기 쉘을 제작 함에 있어 CAD/CAM 기술이 어떻게 변경되어야 하는지를 귓본의 크기와 형태에 따라 정량적인 분석을 하며, 귓본의 표준 형태를 보여준다.

Digital technology has made a large impact on hearing instrument processing and fitting, and it is now making a large impact on hearing aid shell manufacturing. A comparison of conventional shell-making and the new Computer Aided Design and Manufacturing (CAD/CAM) processes is offered, including a review of the two major methods of CAD/CAM printing: Stereo Lithographic Apparatuses (SLA) and Selected Laser Sintering (SLS). The new CAD/CAM methods offer many benefits. However, dispensing professionals may need to consider the way in which they obtain probe-tube measurements and make shell modifications when using these new shells.

To say that digital technology has revolutionized the hearing healthcare industry is an understatement. After the launch of the first digital ITE hearing aids in 1996, the hearing health care industry is now poised for another big event—the widespread application of digital imaging or Computer Aided Design and

Manufacturing (CAD/CAM) technology in the manufacturing of hearing aid shells.

Currently, there are only a few manufacturers who have introduced digital imaging technology in hearing aid shell manufacturing. This list will likely expand when its cost becomes more affordable. For a dispensing clinician, it will be worthwhile to understand the differences in the processing between hearing aid shells made with conventional and digital imaging technology; how shells made with these two approaches compare; and what considerations are necessary when working with hearing aid shells made with this new technology.

This thesis presents the CAD/CAM technique of the hearing aid ear shell production with a rapid shell modeling (RSM) software. The rapid production using the CAD/CAM technology is quite different from the conventional manufacturing method. This thesis shows the differences between the two approaches (CAD/CAM method & conventional method) in regard of the detailed impression management and analyzes these differences I practice. This thesis figures out where and how to cut the ear impression that will systematically give help to the hearing aids manufacturing and the thesis emphasizes the improved CAD/CAM method to be fitted better for particularly Asians' ears than ordinary CAD/CAM method. The size and the shape of the ear shell were thoroughly investigated in quantitative analysis, so that the thesis could show some standardized dimensions of the ear shell.

I. Introduction

A. Research background

Digital technology has made a large impact on hearing instrument processing and fitting, and it is now making a large impact on hearing aid shell manufacturing. A comparison of conventional shell-making and the new Computer Aided Design and Manufacturing (CAD/CAM) processes is offered, including a review of the two major methods of CAD/CAM printing: Stereo Lithographic Apparatuses (SLA) and Selected Laser Sintering (SLS). The new CAD/CAM methods offer many benefits. However, dispensing professionals may need to consider the way in which they obtain probe-tube measurements and make shell modifications when using these new shells.

To say that digital technology has revolutionized the hearing healthcare industry is an understatement. After the launch of the first digital ITE hearing aids in 1996, the hearing health care industry is now poised for another big event—the widespread application of digital imaging or Computer Aided Design and Manufacturing (CAD/CAM) technology in the manufacturing of hearing aid shells.

Currently, there are only a few manufacturers who have introduced digital imaging technology in hearing aid shell manufacturing. This list will likely expand when its cost becomes more affordable. For a dispensing clinician, it will be worthwhile to understand the differences in the processing between hearing aid shells made with conventional and digital imaging technology; how shells made with these two approaches compare; and what considerations are necessary when working with hearing aid shells made with this new technology.

B. Research overview

This thesis presents the CAD/CAM technique of the hearing aid ear shell production with a rapid shell modeling (RSM) software. The rapid production using the CAD/CAM technology is quite different from the conventional manufacturing method. This thesis shows the differences between the two approaches (CAD/CAM method & conventional method) in regard of the detailed impression management and analyzes these differences I practice. This thesis figures out where and how to cut the ear impression that will systematically give help to the hearing aids manufacturing and the thesis emphasizes the improved CAD/CAM method to be fitted better for particularly Asians' ears. The size and the shape of the ear shell were thoroughly investigated in quantitative analysis, so that the thesis could show some standardized dimensions of the ear shell.

C. Thesis Contribution

The characteristics parts of the carried research work are summarized under the title of the thesis contribution. They are as follows.

Like the application of DSP in hearing aids, this new technology could improve the quality of hearing aids dramatically, especially since over 75% of the hearing aids manufactured in the US are custom products.[1] Compared to conventional means of shell manufacturing, hearing aid shells made with digital imaging technology are more comfortable to the ears (acoustically and physically), allow more usable gain before feedback, may be less prone to certain repair problems, minimize the need for taking extra ear impressions, and can be produced more efficiently and accurately.

D. Thesis Organization

The content of this thesis is organized in modular chapters. Chapter 2 is devoted to brief overview of conventional shell manufacturing. Related works are also included in this chapter along with the description of the limitations of the conventional shell manufacturing. In chapter 3, proposed CAD/CAM method is presented. Over view the whole process of CAD/CAM shell manufacturing. In chapter 4, the comparison of the conventional shell manufacturing and CAD/CAM shell manufacturing is presented. And the related occlusion affect is also presented. Then the last chapter concludes the thesis with wrapping text for the summary of the carried research and possible future works.

II. Conventional Shell manufacturing

A. Introduction

How Manufacturers Make Conventional Ear shells

When ear shells are made, the oto-block is removed from the impression and the lateral process is cut to make a base. Silicone material is poured over the impression to make a cast called the control mold, which is a record of the ear impression made prior to any modification. The impression is then cut down to an appropriate size for the model ordered. It is also tapered and detailed so that the finished shell can be easily inserted into the client's ear.

The model, hearing loss, and the impression size and shape determine how much trimming and tapering are done. The trimmed impression is dipped into hot wax or lacquered. The number of times it is dipped and the temperature of the wax determine the thickness of the coating. In general, the severity of the hearing loss or the clinician's request for shell tightness will determine the extent to which the impression is built-up. [2]

B. The process of ear shell conventional manufacturing

There are 10 steps that are followed by most companies when producing a hearing aid shell using the conventional approach. Although slight differences occur between manufacturers, the same 10 steps need to be completed regardless of the style of the custom product (i.e., CIC versus ITE):

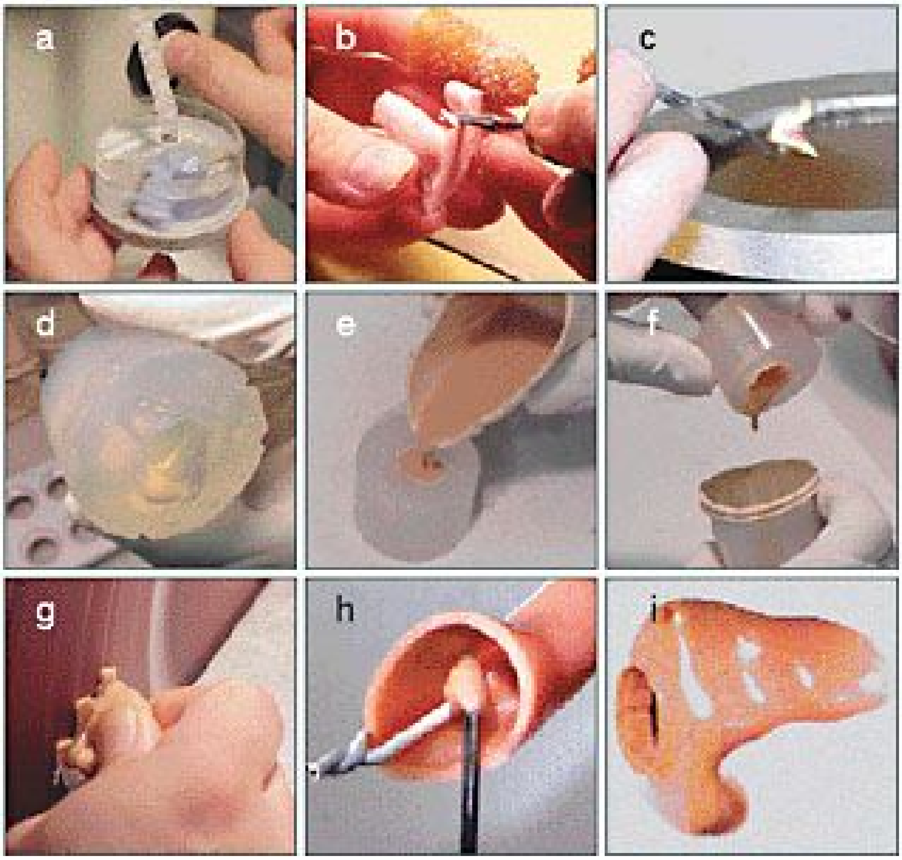


Figure 2 - 1 the 9 steps in making a conventional hearing aid shell (prior to assembling electronic components): a) A cast of the

impression is made; b) The ear impression is trimmed to the model size; c) The impression is dipped in wax; d) A hydrocolloid cast of the impression; e) Acrylic resin is poured into the hydrocolloid cast; f) Excess acrylic resin is drained from the hydrocolloid cast; g) The faceplate end of the shell is trimmed; h) The vent is laid into the shell; i) The finished shell is ready for electronics.[3]

1. Cast. A cast is a record of the ear impression made directly from the ear impression prior to any modification (Fig. 2- 1a). The oto-block is removed and the lateral process is cut to make a base. Silicon material is poured over the ear impression to make this cast which, when completed, is called the investment.

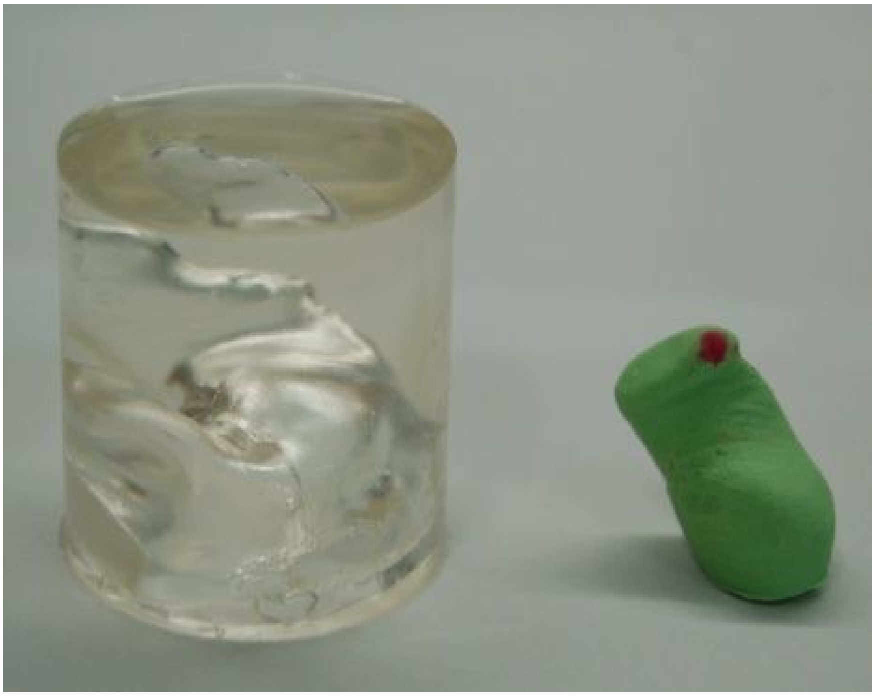


Figure 2 - 2 the investment and the trimmed impression

2. Trim. The impression is then cut down to an appropriate size for the model ordered (Fig. 2-1b). It is also tapered and detailed so that the finished shell can be easily inserted into the wearer's ear. The model, hearing loss, and the dispenser's request determine how much trimming and tapering is done.

Figure 2 - 3 the trimmed impression; it is called detailed impression also. The shape of the shell is decided by this detailed impression.

3. Wax. The trimmed impression is now dipped into hot wax (Fig. 2-1c). The number of times it is dipped and the

temperature of the wax determine the thickness of the wax on the impression. In general, the severity of the hearing loss and the dispenser's request for shell "tightness" will determine the amount of wax buildup.

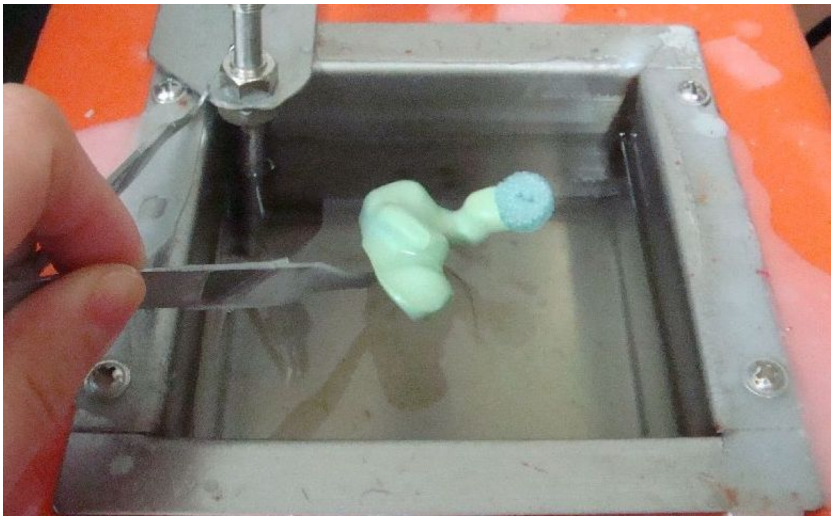


Figure 2 - 4 wax coating process. Dip the ear impression into the wax container.

Despite all the precautions, wax adheres in different thickness at different points of the impression. This is because the impression is curved and thus retains wax differently at various locations. For example, a concave surface (e.g., posterior of first bend and anterior of second bend) accumulates more wax than a convex surface. Also, the part of the impression that stays in the wax the longest will have the most wax accumulation. For example, the base of the impression will have a thicker layer of wax if one removes the canal portion of the impression first from the wax. This could distort the true shape of the ear-canal. The result is that the shell may be too loose or too tight, yielding pressure points that cause discomfort. Excess wax around the canal aperture will affect the retention and seal of the hearing aid. Extra wax on the posterior side of the first bend can affect receiver direction. Thus, the skill of the technician is extremely important in ensuring an even coating of wax on the impression.

4. Cast. The trimmed and waxed impression is now cast in hydrocolloid (Fig. 2-1d). This natural jell-like material is solid at room temperature, but liquefies when heated slightly. The hydrocolloid liquid will not melt the wax on the impression, and once it has hardened, an accurate casting of the impression is formed.

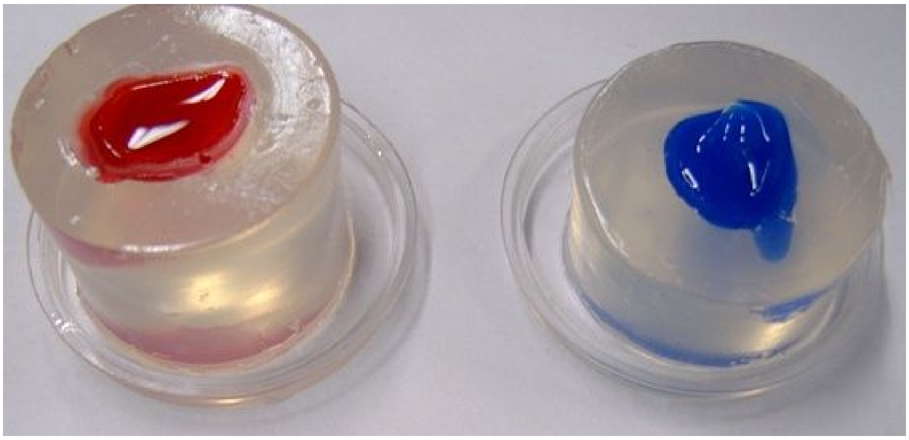


Figure 2 - 5 fill the investment with the shell material. Usually the blue color shell material is used for the left ear sell and the red color shell material is used for the right ear shell.

5. Pouring of Shell Material. Room-temperature cured (RTC) or UV-cured acrylic is poured into the hydrocolloid cast to make the shell (Fig. 2-1e). The color of the acrylic is selected before pouring. The acrylic is allowed to cure slightly. The curing process starts from the outside and progresses towards the core of the shell.

Figure 2 - 6 the curing process. First, pour the shell material into the investment; second, cover the investment with a black cap; then, put

the investment into the UV machine. The whole process will take about 5 minutes.

6. Drain/Drip. With the acrylic hardening on the outside and the liquid acrylic still on the inside, the cast is turned over in order to drip the excess liquid acrylic out (Fig. 2-1f). This creates a hollow shell that is a replica of the trimmed impression.

Shells made with this method may have different thickness. This is because portions of the shell where the liquid acrylic stays the longest (i.e., the pouring area) will have the thicker shell, and areas where it is farthest from the pouring area will have the thinnest shell. This uneven thickness will result in some regions of the shell more likely to need repairs because they are thinner and less resistant to constant abrasion.

Figure 2 - 7 completely pour the shell material from the investment to make the strong and thin ear shell.

7. Trim. The shell that has just been formed will have excess acrylic on its lateral (usually faceplate) end from the dripping out

of the hydrocolloid cast. This end must be flattened before the faceplate can be attached (Fig. 2-1g). A flat sanding wheel is used to trim the lateral end. The amount of trimming also determines the final profile of the hearing aid.

Figure 2 - 8 size down process. Grind the bottom edge of the ear shell using the grinder. The exact size of the ear shell is helpful to make the minimized hearing aid.

8. Vent. The vent is now installed (Fig. 2-1h). The vast majority of vents are internal channel vents. The diameter of the vent is determined by the hearing loss, available space, and the dispenser's request. The technician drills a hole in the shell at the receiver end, and then runs a wire of the desired diameter through the shell at the target location. Liquid acrylic is poured over the wire to make the channel vent. Once the acrylic has

cured, the wire is removed and the vent is ready.

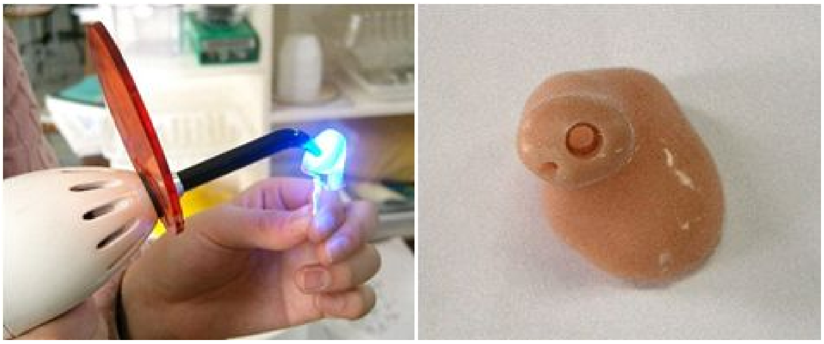


Figure 2 - 9 the process of making vent by hand

9. Attaching Faceplate and Buffing Shell. The technician aligns the faceplate over the shell, glues it in place, and then trims and rounds out any sharp corners in the faceplate. Once glued and assembled, the shell is buffed using a mild abrasive.

Buffing smooth out rough edges and gives the shell a pleasing finish. However, it is sometimes difficult to control how much distortion is introduced to the shell by buffing. The speed of the buffing wheel, the duration of the buffing, the pressure applied by the technician, the width of the buffing wheel, and the amount and concentration of abrasive in the buffing wax all affect the amount of distortion. Thus, the technicians need to be skilled; they need to verify that no gaps or pressure points are present by placing the finished shell into the silicone investment that was made previously. The shell is now ready for electronics (Fig. 2-1i).

Figure 2 - 10 the polishing machine. The polishing machine is used for smoothing the ear shell and making the shell shinning.

10. Assemble Electronics. The internal cavity of the shell is examined by the technician and excess acrylic is excavated using burrs. This step is necessary in order to give the technician room to properly position the receiver in order to minimize the risk of internal feedback. Installation of a wax guard system in the shell may require additional acrylic onto the shell. Once the electronic module and the battery/microphone assembly are installed, the custom hearing aid is ready for quality assurance testing.

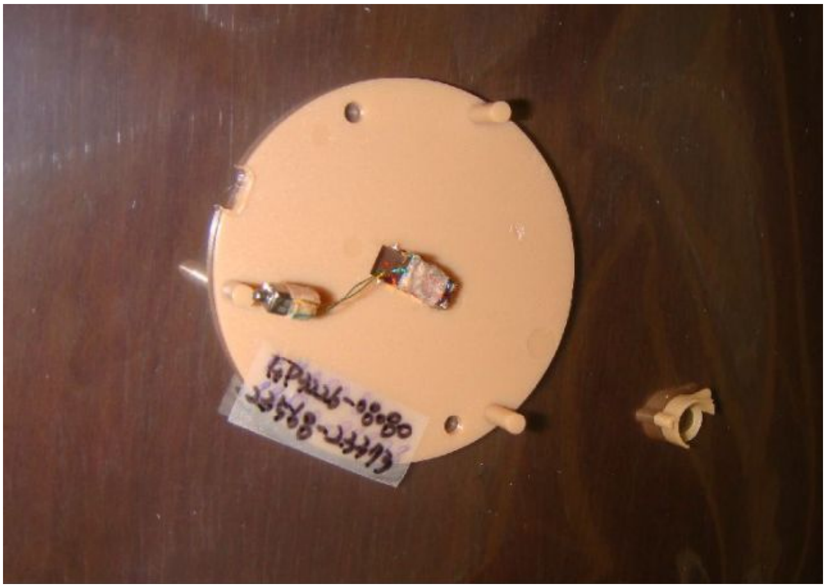


Figure 2 - 11 the finished faceplate. When the ear shell completely made, you can bound the faceplate and the ear shell to make the hear aid.

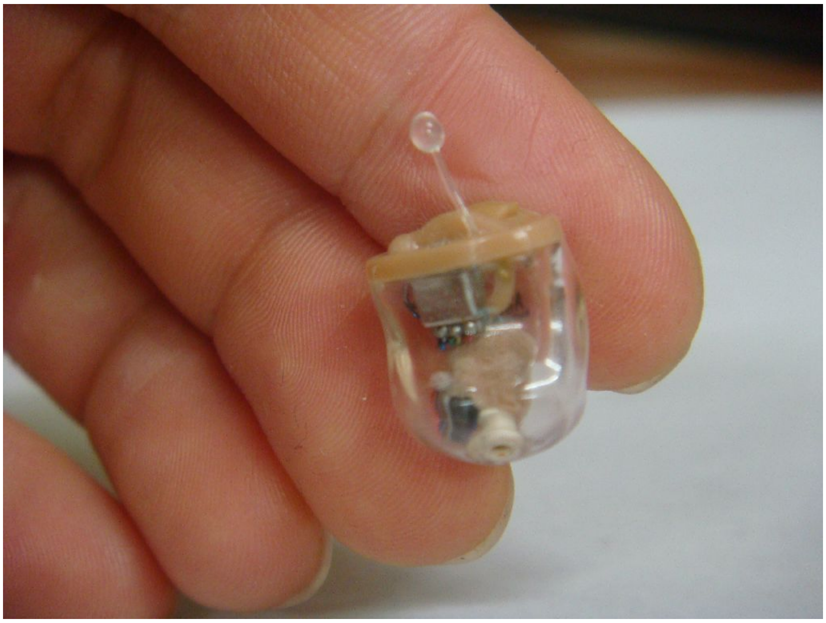


Figure 2 - 12 the complete hearing aid.

III. CAD/CAM method ear shell manufacturing

A. Introduction

The Computer Aided Design and Manufacturing (CAD/CAM) method of shell manufacturing includes three stages: impression scanning, virtual modeling, and shell printing. The three stages are linked to a computer server that integrates the data from each stage to create the final hearing aid shell. Data collected at each stage remain independent of the other stages. Any necessary changes may be made at any stage without affecting the integrity of the data stored during previous stages.

B. The process of CAD/CAM method ear shell manufacturing

The three stages are linked to a computer server that integrates the data from each stage to create the final hearing aid shell. However, data collected at each stage remain independent of the other stages; necessary changes may be made at any stage without affecting the integrity of the data stored during the other stages. Furthermore, once an appropriate impression is scanned and stored, no more new impressions will be needed if a new hearing aid or an alternate style is required for the wearer. Nonetheless, an accurate ear impression is still necessary to make an appropriate hearing aid shell. [4]

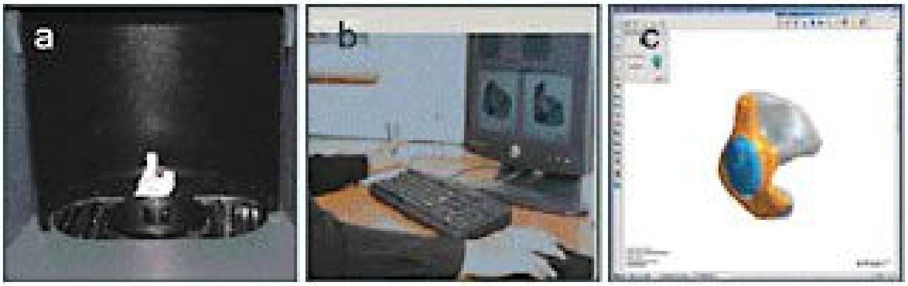


Figure 3 - 1 The 4 steps in manufacturing a CAD/CAM hearing aid shell (prior to final "printing" and assembling electronic components): a) An ear impression in a 3D scanner; b) The modeler makes changes to the virtual shell; c) View of the finished virtual hearing aid.

Step 1: The Impression. The process begins with an impression. Since the impression is the foundation of any custom-manufactured shell, it remains the key component for a proper fitting hearing instrument. Although this is an area that will see radical changes in the future, the impression-taking process remains the same at this time.

After the foam stop is removed from the impression, the impression is placed in the middle of the scanner. The door of the scanner is closed to seal out any light that could weaken the intensity of the laser. No other light source is allowed in the closed scanner.

The ear impression is photographed by several digital cameras angled at various locations inside the scanner box. As the narrow laser beam scans across the impression, the digital images that are formed are processed by the scanning computer. [5] Through triangulation, thousands of data points can be generated from the digital images. These data points are connected by the scanning computer, and a “wire-frame” of the impression is generated. The computer interpolates data from the wire-frame and creates a digital image of the impression.

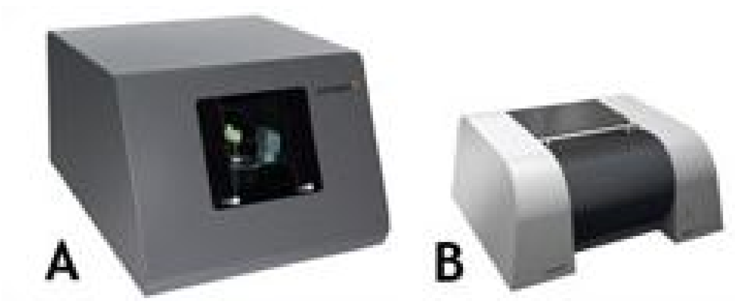


Figure 3 - 2 an industrial impression scanner, the 3Shape S-200 (left), and an in-office impression scanner, the 3Shape Legato (right)

Step 2: 3-D Laser Scanning. Currently, the digital mechanical processing starts with the digitization ear impression of the shape. Using advanced laser-scanning methods, it is possible to produce an extremely accurate three-dimensional replica of the ear impression. The ear impression is scanned using lasers with specially created high-end optics that scan the impression, taking up to 100,000 data points, with precision on the level of microns. The shape of the impression is reconstructed in software, and these measurements are then transferred to a permanent database for storage.

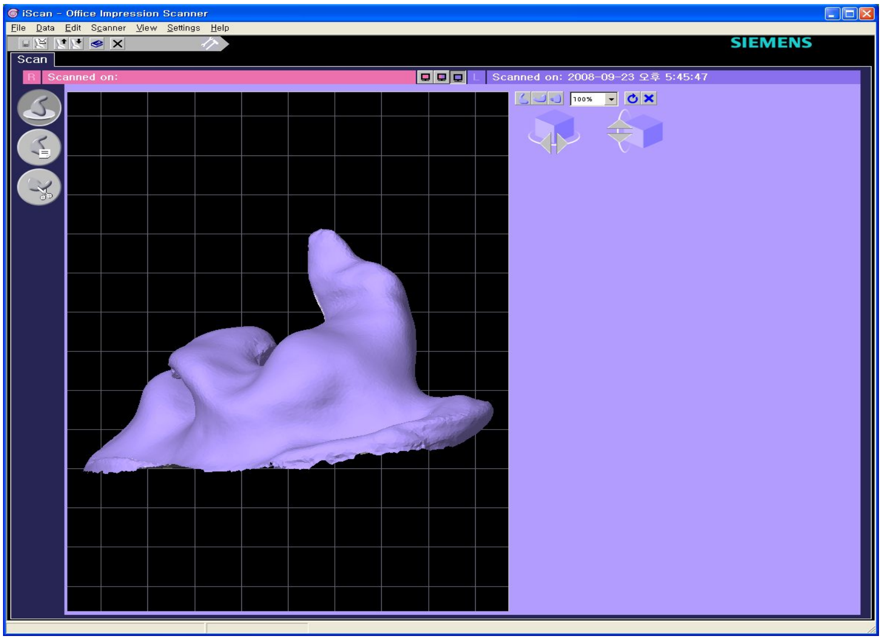


Figure 3 - 3 the digitized impression is finished on-screen using a digital model of the shell.

Step 3: Modeling. Modeling is the process whereby the technician (or modeler) takes the virtual image of the impression to create a virtual hearing aid shell (Figure3-4 and fig. 3-5). This is accomplished with 3D modeling software that allows the technician to modify the virtual impression as if it were a real object.

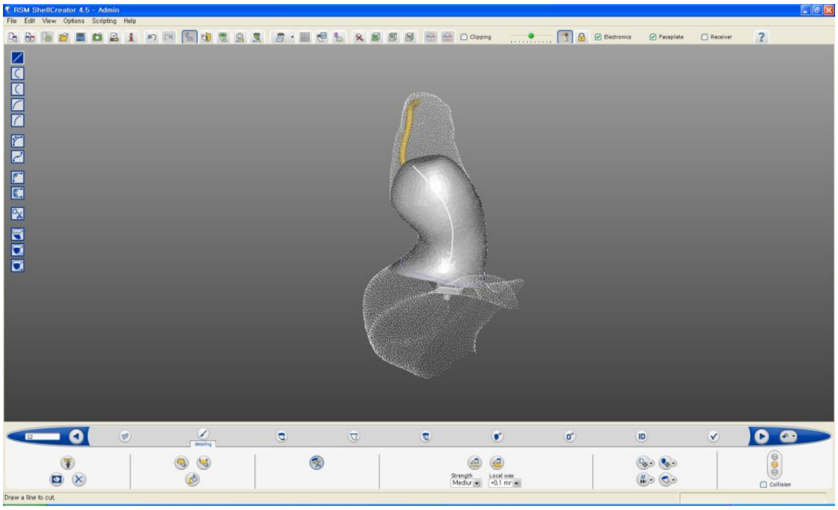


Figure 3 - 4 modify the shell by the cutting tool

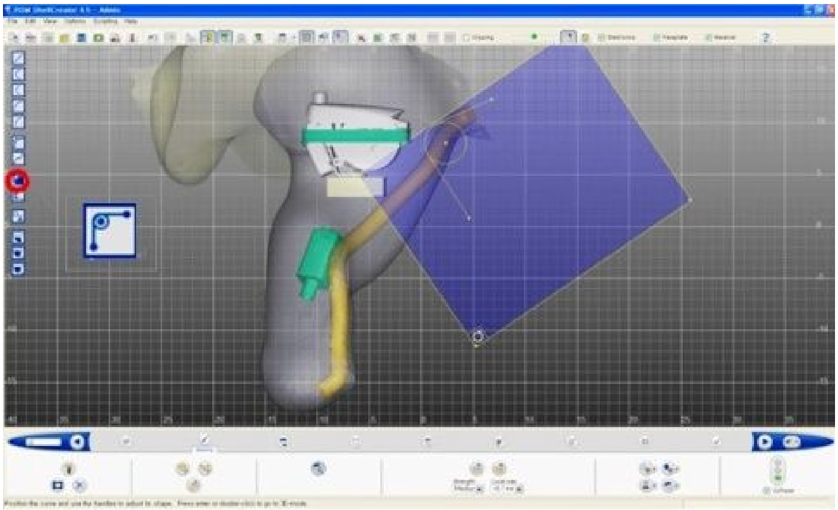


Figure 3 - 5 takes the virtual image of the impression to create a virtual hearing aid shell

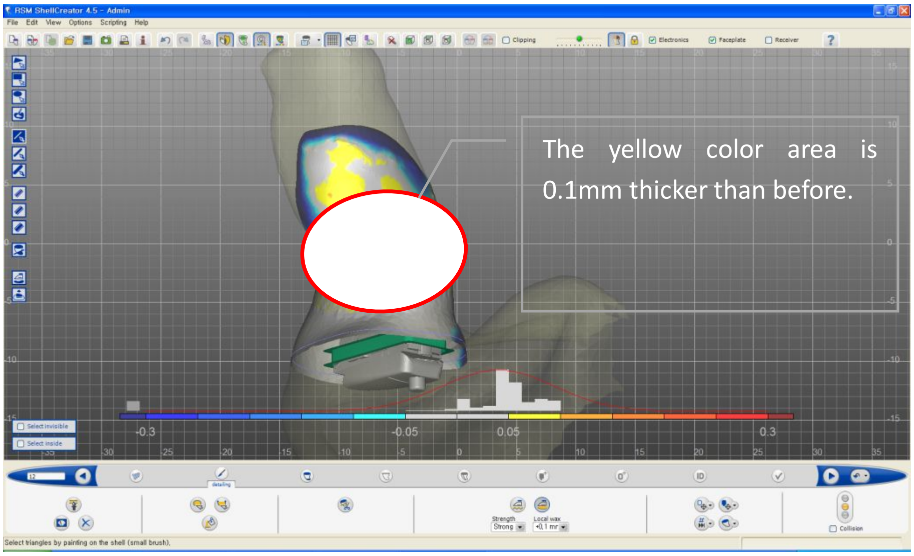


Figure 3 - 6 the new shell-making process allows recognition of factors, such as tightness of fit and points of irritation, before the shell is made.

There are a number of modifications that the technician can and should perform with the virtual impression to create the right virtual shell. Parts of the virtual impression that is not necessary for the hearing aid need to be removed. The technician then adds material to the virtual impression to fill in blemishes or imperfections. This is similar to waxing with the conventional approach. The receiver end of the shell is specified (i.e., either rounded or left square). The height of the faceplate and the thickness of the shell are also specified. Afterwards, the technician experiments with different placements of the virtual components (to include IC chips, receivers, microphone, faceplate, vents, and receiver tubing, wax guards, etc) into the virtual shell until the best possible placement is achieved. In this way, the technician can be certain that all the parts will fit into the shell during final assembly and that the hearing aid is cosmetically acceptable.

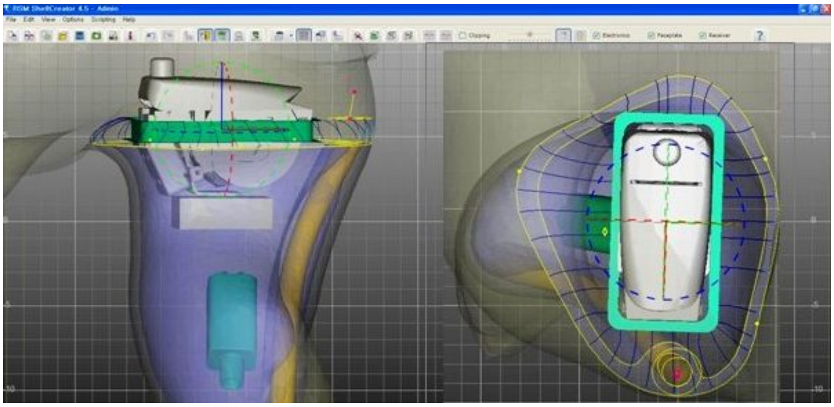


Figure 3 - 7 modify the shell according to the inside components. Making good use of the inside space, and make the hearing aid shell minimized and customized.

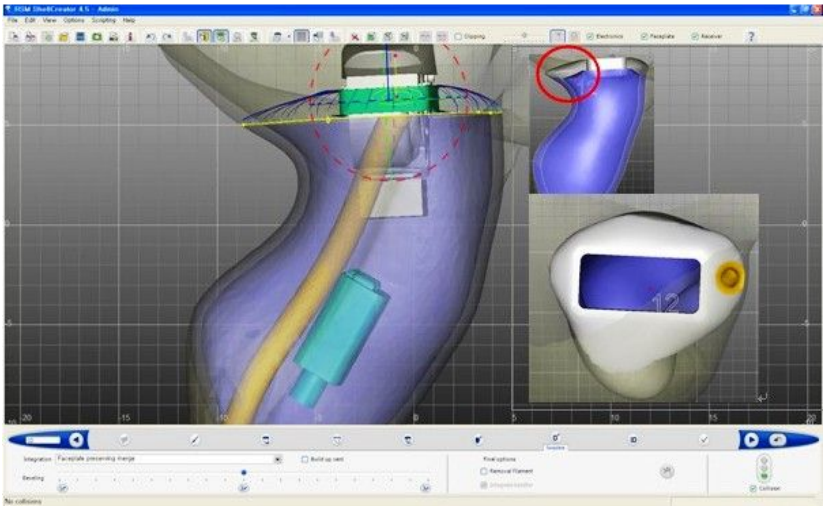


Figure 3 - 8 more humanity designing, such as the faceplate integration and the acoustic sealing area.

The main advantage of the modeling process is that the modeler can try out different modifications or layouts of the electronics before settling on the final plan. That is, all changes are reversible until the modeler approves his/her actions. In addition, all changes—including the exact amount of material added or removed from the virtual impression—are recorded in the computer for later retrieval and analysis

The shell can be viewed and modified in a three-dimensional space before manufacture. This detailed impression is stored in a database, and the original impression is kept for future comparison and retrieval.

Afterwards, the technician experiments with the size of the shell and different placements of the virtual components (chip, receiver, microphone, faceplate, vent, receiver tubing, wax guard, etc) into the virtual shell until the best possible placement is achieved. Most of these operations are aided by the software to make the modeling process easier and time effective.

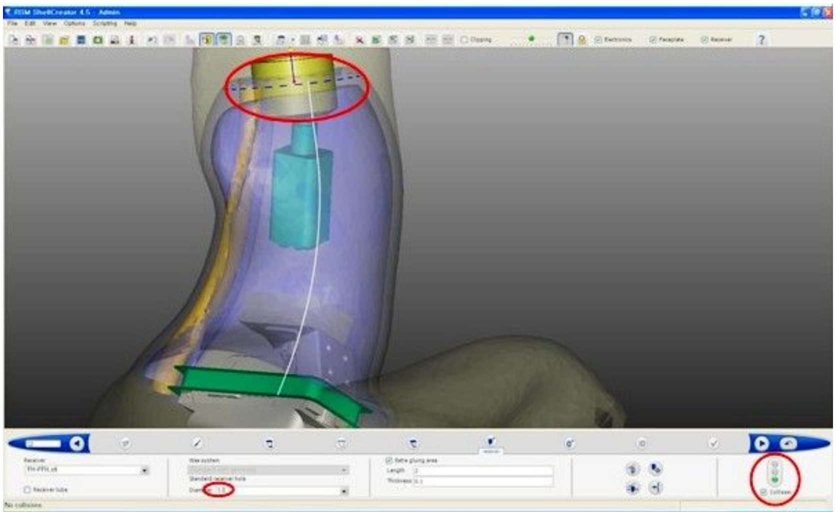


Figure 3 - 9 the virtual components can be placed into the shell to check the inside shell space.

Step 4: Shell Fabrication. The shell itself is produced by first heating a biocompatible nylon powder just below its melting temperature, and then a precise, computer-guided laser melts the contours of the shell, layer-by-layer (Fig. 3-10). This technique is called laser sintering. This form of computer-aided manufacturing is designed to produce a shell of consistent thickness that is a perfect replica of the original impression. As with current shells, the shell material may be modified in the dispensing professional's office. [6]

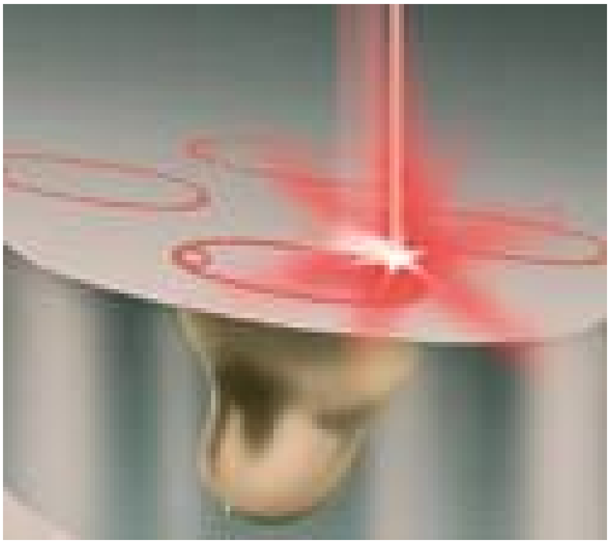


Figure 3 - 10 the shell is produced by laser sintering. Thin layers of plastic are solidified with a laser.

Step 5: Surface Finish. The surface of the shell is matted to provide a skin-like texture (Fig. 3-11). This textured finish provides a firm, comfortable fit with suitable retention in the ear. Yet, the material is not porous and it is designed for easy cleaning.

Figure 3 - 11 the outer surface is completed with a textured finish.

C. Present and Future Benefits

There are several advantages to this new shell-making procedure: Easy Reproduction, Comparison, and Replacement. Since the shell is made from a computerized three-dimensional representation, the data can be stored for later use. Remade shells can be compared to the original to identify 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. In addition, this information will allow knowledge-based and expert systems to be developed.

Lost instruments can be remade to original specifications from stored data. No new impressions are necessary.

Comfort and Fitting Issues. The shells are made from a hypoallergenic, medical-grade plastic. Its textured surface is designed to increase wearer comfort and to reduce slippage.

D. Practical Tips for Working with CAD/CAM Shells

The precision of CAM/CAD shells may require initial adjustments for some dispensing professionals. During the course of the laboratory study, we discovered that CAMISHA shells yielded different in-situ output from conventional shells at the same hearing aid setting. Because of the accuracy of the shells, no unintended leakage between the ear canal and the shell walls was available. This compressed the probe-tube that was used for the probe-microphone measurement, resulting in spurious and uninterpretable results. Fig. 3-12 compares the real-ear output of the same CAMISHA hearing aid measured with the probe-tube placed underneath the hearing aid and through the vent. [7]

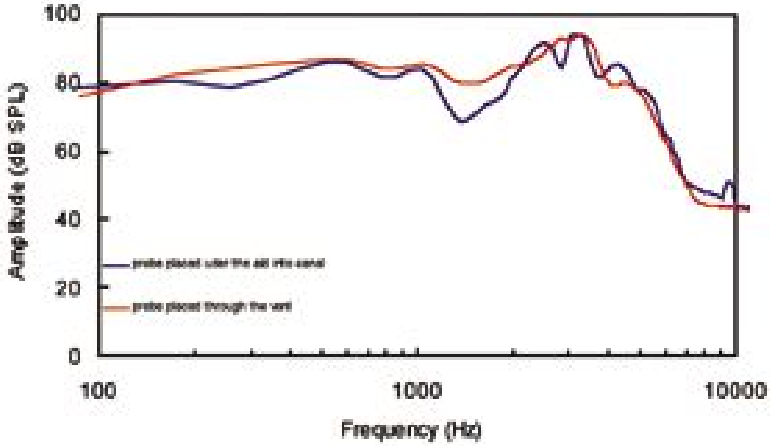


Figure 3 - 12 Real-ear output of a hearing aid made with CAMISHA technology measured underneath the hearing aid and through the vent.

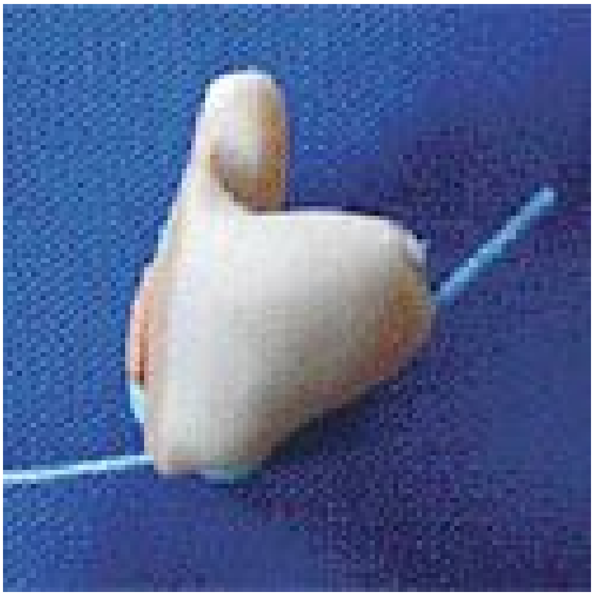


Figure 3 - 13 Pictures showing the direction of probe tube upon exiting vent.

Attempts to insert the probe-tube through the vent for the in-situ measurement were not without difficulty. Because the vent ran along the dimension of the tapered and upward-pointing canal, the probe tube that was fed through the vent had a tendency to point upward and hit the upper canal wall upon exiting the vent (Figure 3-13). This led to the unreliable in-situ output depending on the placement of the probe-tube. A final solution was to install a probe-vent in the shells for in-situ measurement. This has proven to be both necessary and effective. [8]

Another consideration when working with CAD/CAM shells is shell modification. Because the shells are made more accurately than conventional shells, it is less likely that they will require shell modification by dispensing professionals. Any required modification may have stemmed from an imprecise ear mold impression or an error by the technician during the modeling stage. [9] This means that any physical discomfort or issues that would have led to shell modification with the conventional method would require a new impression, a re-scanning of a new impression, or a re-modeling of the same impression and not a shell modification. As with conventional shells, an accurate ear impression is still necessary to create a properly fitting hearing aid shell with digital technology.

One should be careful during shell modification, as well. Because the shell has a uniform thickness (e.g., 0.7 mm for

CAMISHA), care should be taken not to buff or grind the shells in the same way one may be accustomed to with conventional shells. One reason is that the new shells do not vary in thickness as much as conventional shells. Another reason is that different materials used for the digital shells (i.e., SLA vs. SLS) react differently to shell modification. Because nylon melts easier than acrylic, one needs to be careful when working with nylon shells (from SLS process) and apply either less pressure or a slower speed during the shell modification to avoid damaging the hearing aid shell. We have found that, once properly instructed, most dispensing professionals are able to modify their procedures. [10]

E. Clinical Trial Results

A clinical trial of the Nanotech shells is now under way. Pilot study data have been returned on 50 hearing instrument wearers and these data are summarized below.

The objective of the clinical trial is to compare existing UV shell technology with the new shell technology. Subjects were recruited based on their experience with hearing instruments. Since the goal is to evaluate the materials, the comparisons were made between shells that were identical in every way, except for the material and process used in manufacture.

The subjects for the clinical trial included 50 experienced hearing instrument wearers. All were wearers of custom hearing instruments, either full-shell or canal models. To be eligible for the study, they had to be wearing their hearing instruments successfully for at least 1 year. Although both monaural and binaural wearers were eligible, approximately 75% of the participants wore binaural amplification.

Each of the 50 subjects, via their hearing care professional, agreed to send their current hearing instruments to Phonak for duplication. The current hearing instruments were scanned, and exact replicas of the shells were manufactured using the digital shell-making process. Every attempt was made to accurately duplicate the electro acoustic characteristics of the original instruments. Both the old instruments and the new were returned to the wearer.

Wearers were instructed to complete a questionnaire regarding their current hearing instruments. They were asked to rate their satisfaction with their current hearing instrument shell on the following factors: ease of insertion, ease of removal, comfort at time of insertion, comfort after 1 to 2 hours, comfort after 4 to 8 hours, irritation, security, sound of their own voice, feedback, general appearance, and overall satisfaction. The rating used a 5-point Lickert scale: 1 was very dissatisfied, 5 was very satisfied. [11]

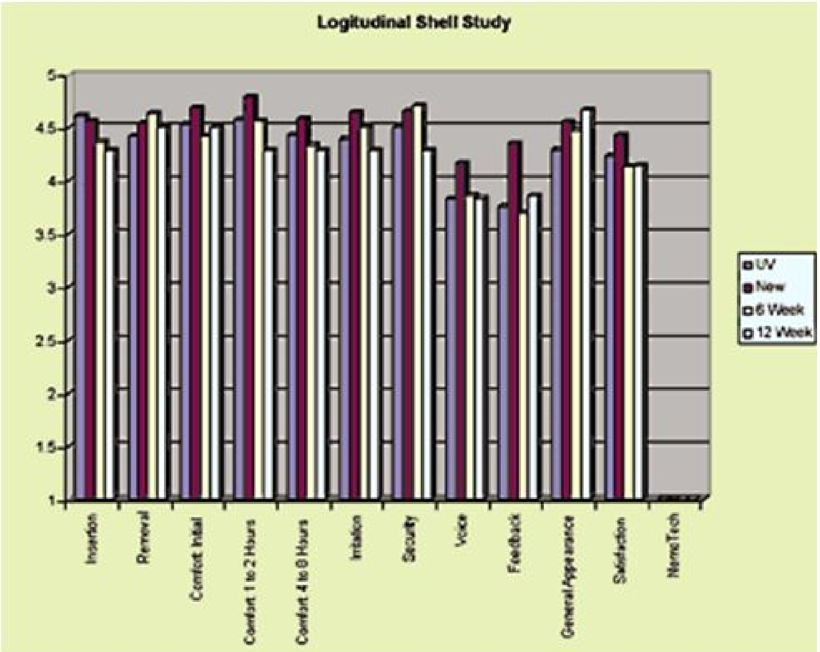


Figure 3 - 14 Results from the pilot test of wearer acceptance of the shells. The new shell manufacturing technology produced results that were similar or superior to the UV manufacturing method: 84% of wearers chose to keep the new shells rather than the UV shell.

Upon being fit with the Nanotech shell, the subjects rated their satisfaction on these items. The survey was repeated after 6 and 12 weeks (Fig.3-14). Although the initial acceptance was good, the overall scores show little difference between the traditional UV shells and the new shell technology. [12]

Assessing the Future of the Virtual Impression

This type of shell-making technology holds some fascinating possibilities for the not-too-distant future. As software algorithms are improved, additional refinements of the virtual shell will allow for an even more accurate fit of the hearing instrument. Software algorithms will allow for simulations of insertion and removal, as well as simulations of the dynamics of the ear canal during jaw movement when speaking or chewing. [13]

Will it be possible to eliminate the ear impression completely? Research efforts are underway on scanning the ear directly as a means to create a virtual impression. It may be possible in the future to eliminate the physical impression, transferring all the necessary patient data directly to the manufacturer via the Internet.

However, one possible interim step is a portable desktop LasR scanner that scans the impression in the dispensing office. The data file of the scan is attached to an electronic order form and transmitted to the manufacturer instantaneously, eliminating shipment requirements. Siemens and other manufacturers are now producing a significant percentage of custom hearing instruments using the virtual impression-taking process.

IV. Comparison between the conventional method and the CAD/CAM method

A. The characteristic of the CAD/CAM method

Accuracy. Digitizing the image of the ear impression allows for a more accurate representation of the impression in the final shell. Assuming that the impression is accurate, the end result should be a more comfortable, better fitting instrument.

Durability. The plastic used in the sintered shell is designed to be much stronger than the material used in traditional shells. The medical-grade nylon material has been developed so that it will not wear thin or crack, even after several years of use.

Design Optimization. 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 [14].

B. Experiment1: accuracy

1. Prepares an impression:

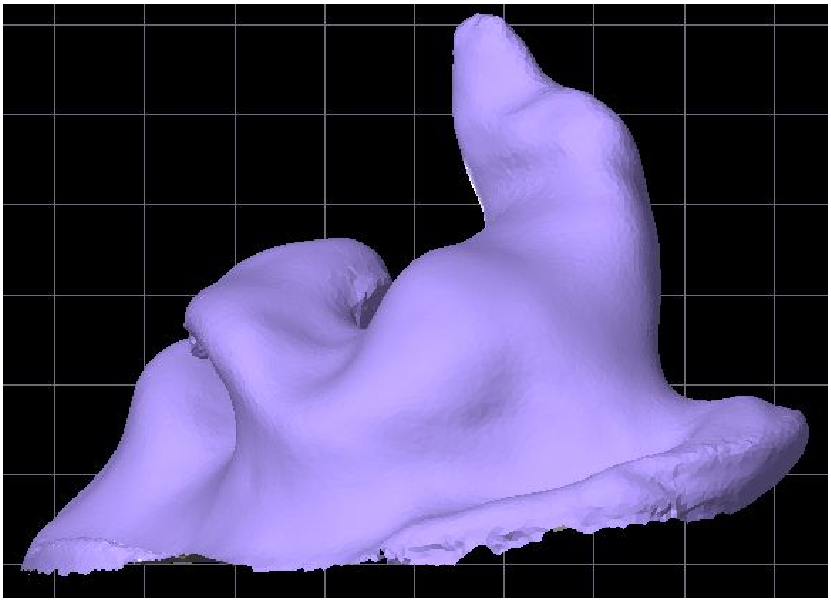


Figure 4 - 1 the image of the scanned ear impression

2. Scan the detailed impression

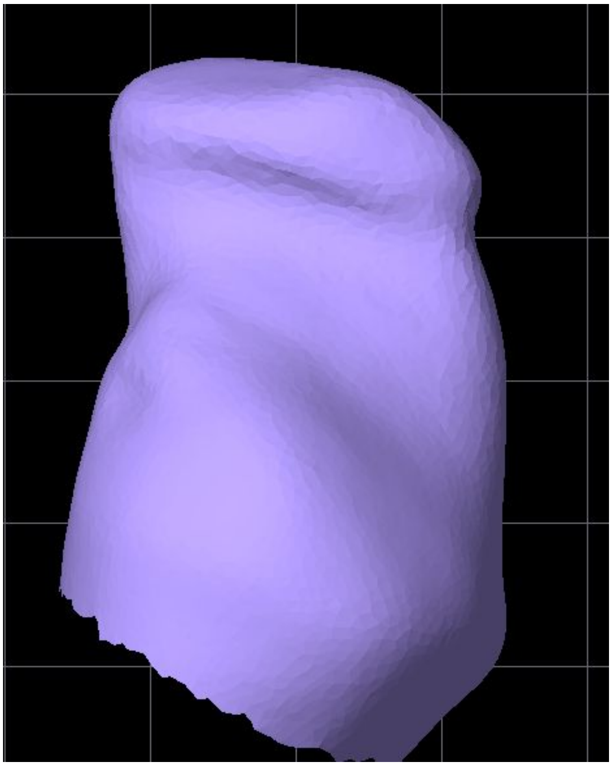


Figure 4 - 2 the image of the handy making detailed impression

3. Make a CAD/CAM shell using the same impression and get the detailed impression in *.stl file.

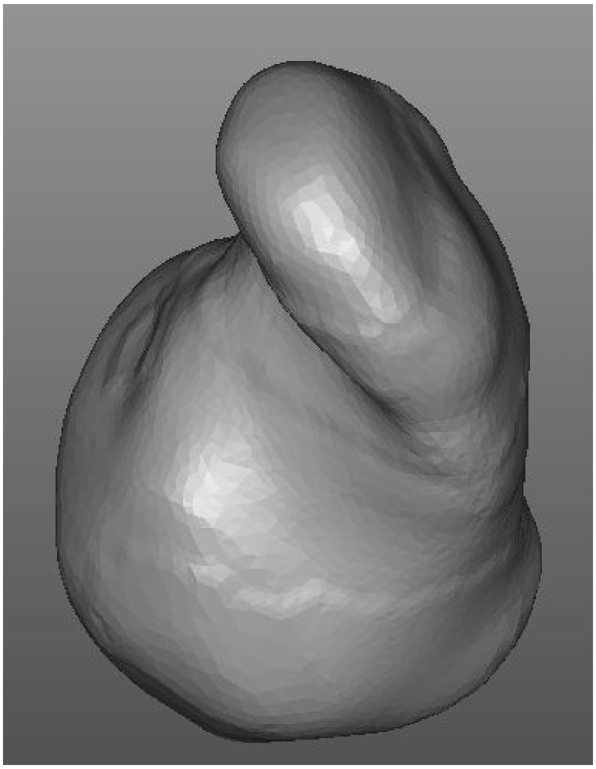


Figure 4 - 3 the virtual shell designed by the RSM software

4. Compare the 2 shells by Rapid Form software, and find the differences between the 2 shells.

Step 1: Choose 3 points from the 2 shells or choose parts of the 2 shells. (Similar positions/parts of the 2 shells) The blue one is handy making shell and the red one is designed by RSM software.

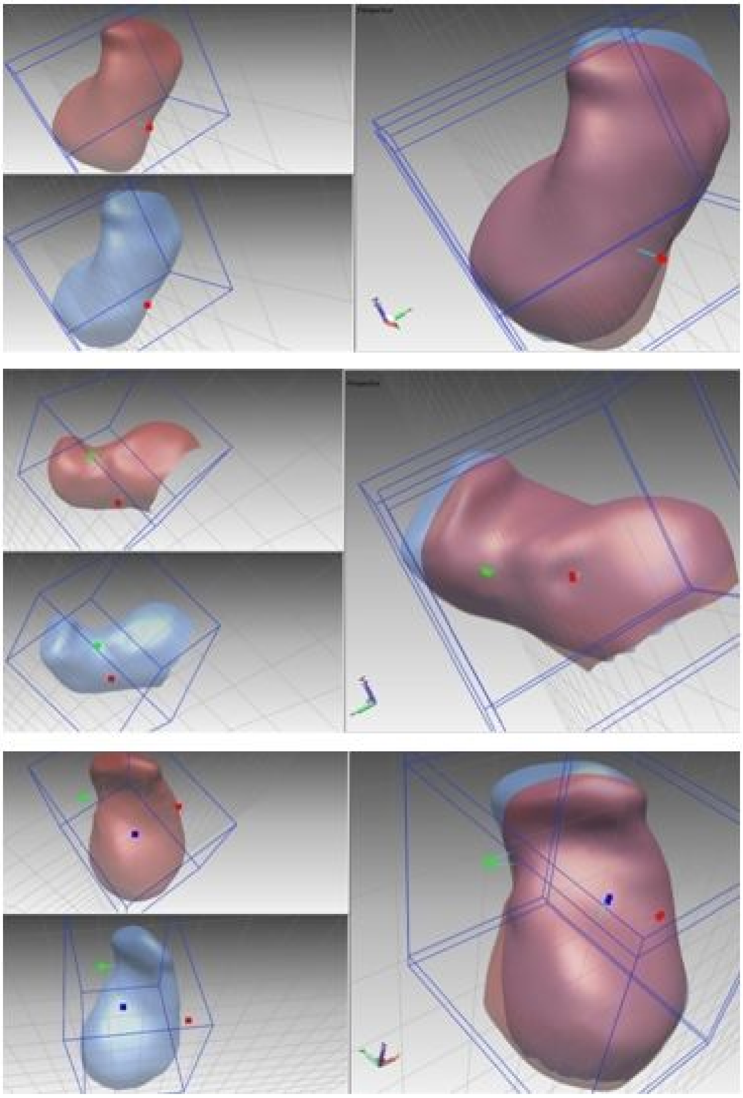


Figure 4 - 4 the method of comparing the 2 detailed ear impression by the software (Rapidform). Choose 3 points on the 2 different detailed ear impressions, and use the register function of the Rapidform, then you can get the comparison of these 2 impressions.

Step 2: Register the 2 shells, you can get the result.

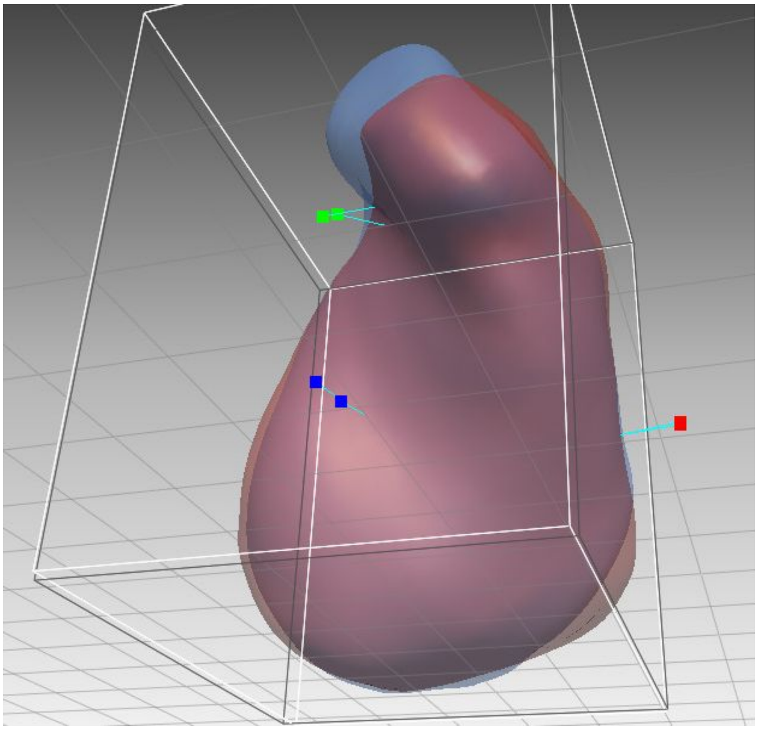
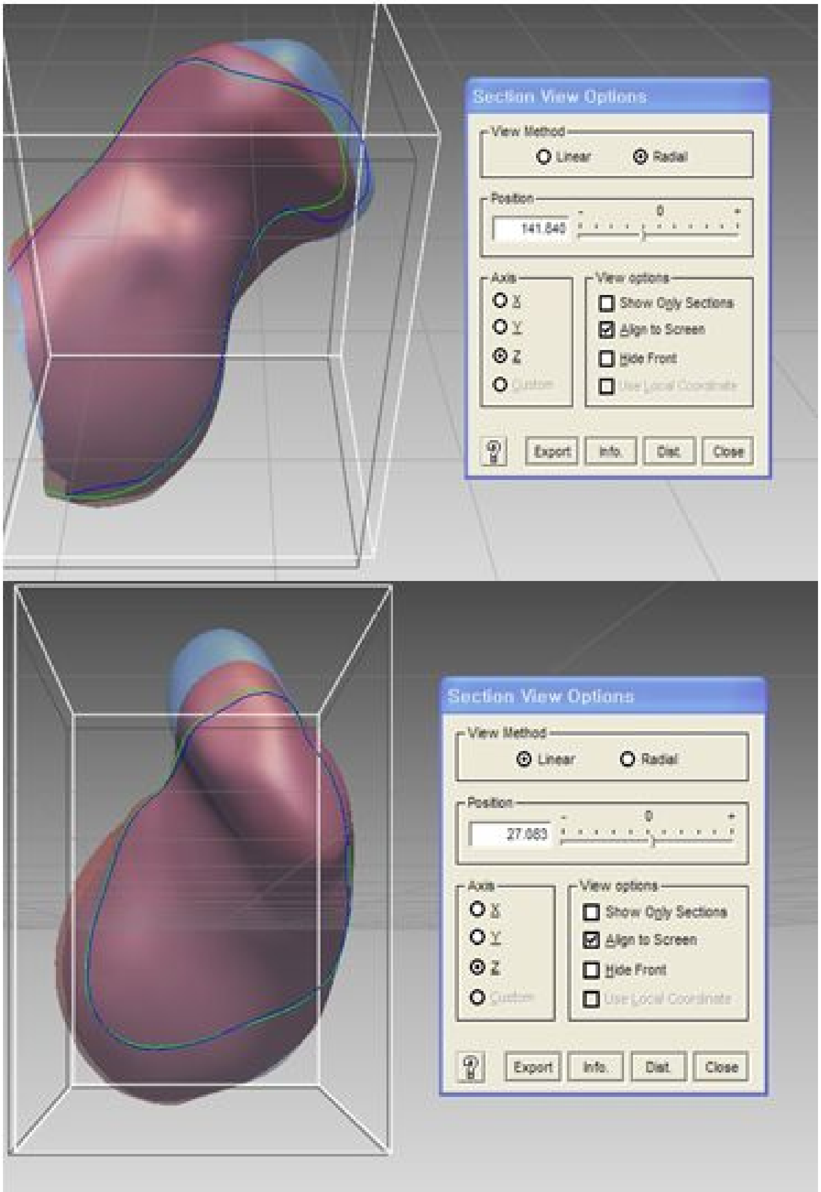


Figure 4 - 5 the result figure of the comparison. There's gap between the 2 virtual shells.

Step 3: Analyze the differences between the 2 shells.



1

Figure 4 - 6 analyze the comparison by comparing the sections of these 2 detailed ear impressions. The upper figure and the lower figure show different viewpoints of the same section comparison.

The green line describes the section of the red shell, and the blue line describes the section of the blue shell. There's slightly a difference between the 2 shells.

The figures show the differences between the 2 shells, the color bar means that the length is getting bigger from blue color to red color.

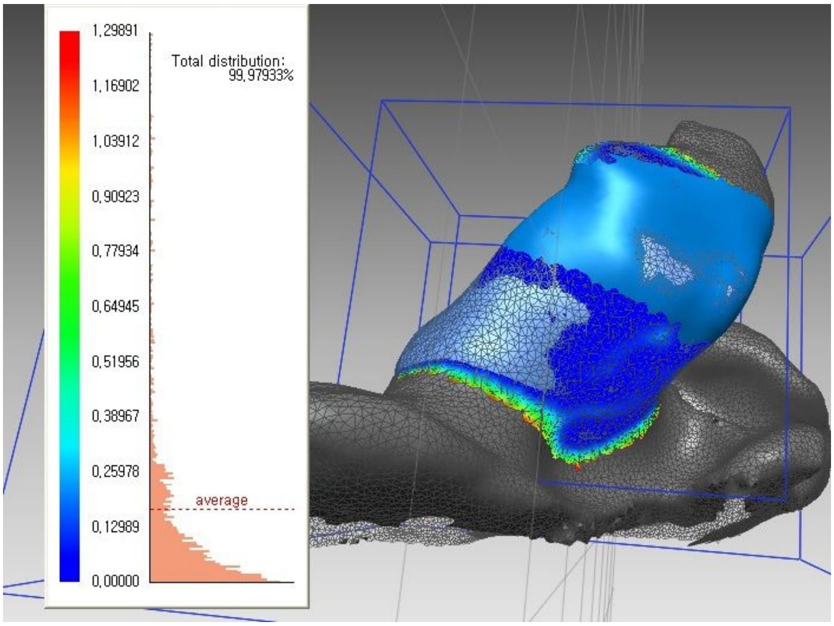


Figure 4 - 7 the handy making impression compares with the original impression. The overlap ratio of the 2 shells is 99.97933%.

Compare the handy making detailed impression and the original impression. The total distribution is about 99.97933%, almost the same with the original ear impression but the size of the gap which between the 2 impressions is not very small; the average size is about 0.16mm.

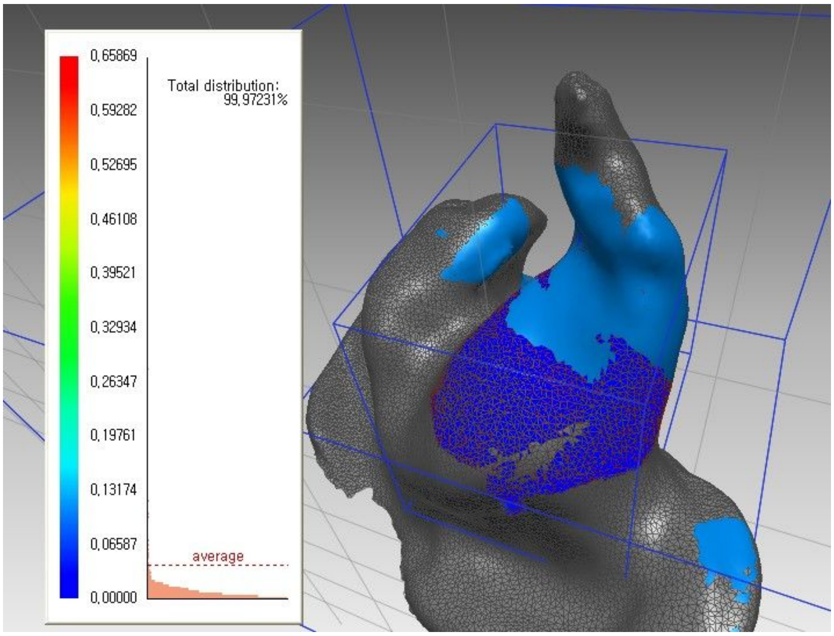


Figure 4 - 8 The RSM detailed impression Compares with the original impression and the overlap ratio of the 2 shells is 99.97231%

Compare the detailed impression designed by the RSM software and the original impression. The total distribution is about 99.97231%, almost the same with the original ear impression but the size of the gap which between the 2 impressions is very small; the average size is about 0.04mm.

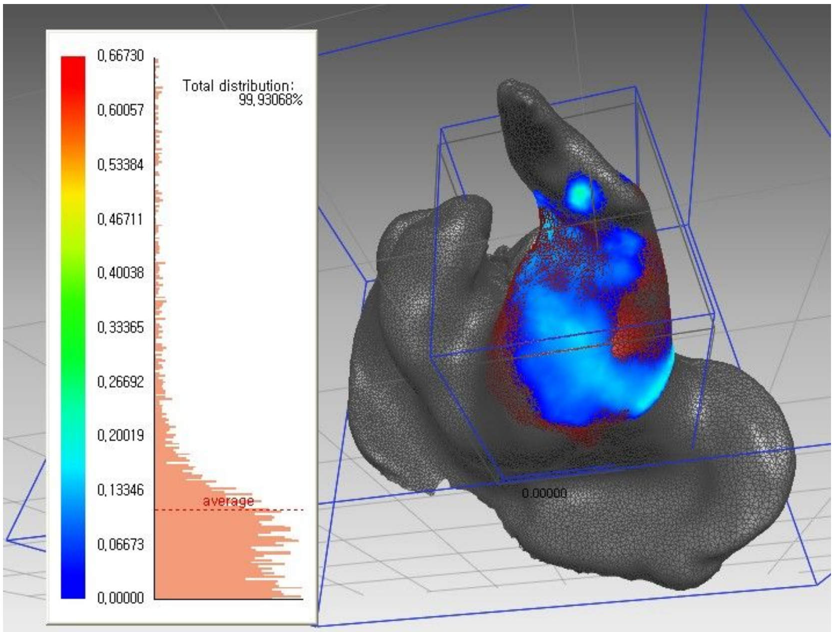


Figure 4 - 9 the figure as shown, the region between the 1st band and the 2nd band of the 2 shells are in register (the light blue color).The total distribution is 99.97362% and the average value is less than 0.1mm.

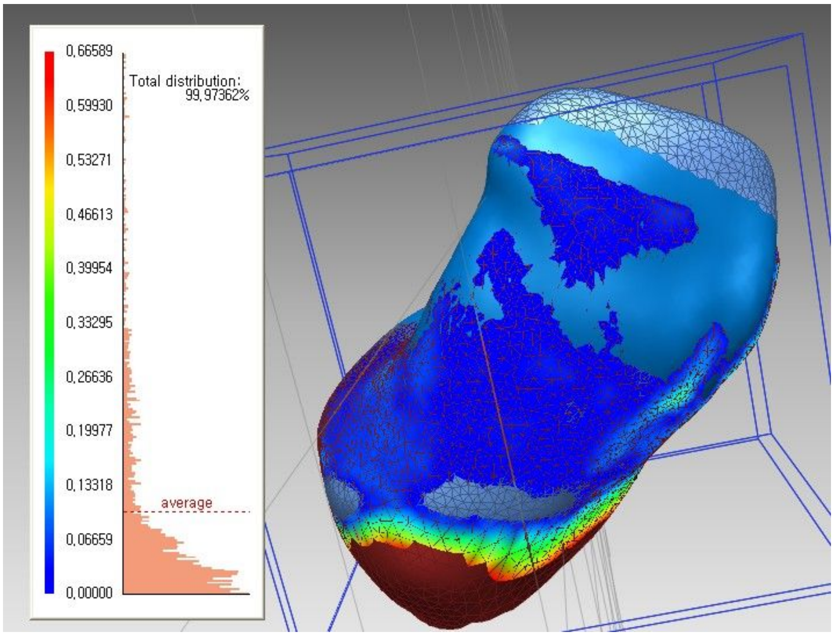


Figure 4 - 10 compare the detailed ear impression designed by the RSM software and the handy making detailed ear impression.

The result of this experiment shows that there exist differences between the 2 technologies. And the RSM software is more accuracy than the conventional shell manufacturing technology.

C. Experiment 2: Durability (The shell thickness plot)

i. The thickness of the shell

When design the shell by the RSM software, the thickness of the shell is set as 0.6mm. This figure shows the thickness of the final shell. The average of the thickness is about 0.61mm. The green sections show the areas which are thinner than the grey area. The printed shell will not change the shell thickness which you set already, that means you can get the shell with the uniform thickness.

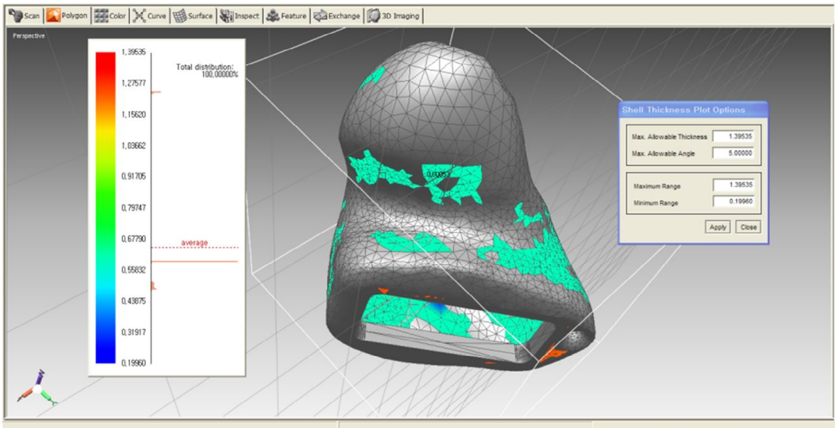


Figure 4 - 11 the total distribution of the shell is about 100%. And the average of this shell thickness is about 0.6mm. The thickness of this shell is set as 0.6mm. But there's part thinner than other parts, the thickness is about 0.5mm, shown as the blue color.

The shell needs uniform thickness, but not the whole shell. The top canal area and the bottom area, the thickness needs to be increased. These 2 parts are connected with other components; the thickness makes the connection more strong.

The face angle plot in handy making process, the shell thickness is hard to control.

Reason:

1. The shapes of the canals are different. The curing time and the negative form are all hard to control because every person has different shape ear canals. the surface of the shell

2. The bottom area and the top canal area problem. You have to modify the shell on the top canal and bottom area. Because when you pour the shell material from the negative form, the top canal area is getting thinner. Then you have to add some shell material to get the thickness.

ii. Color bar: reference coordinates—faceplate

Step 1: Create new reference coordinate
Step 2: Check the faceplate angle plot

The color bar shows the angle between the point and the bottom area. In handy making process, the low angle area is hard to curing

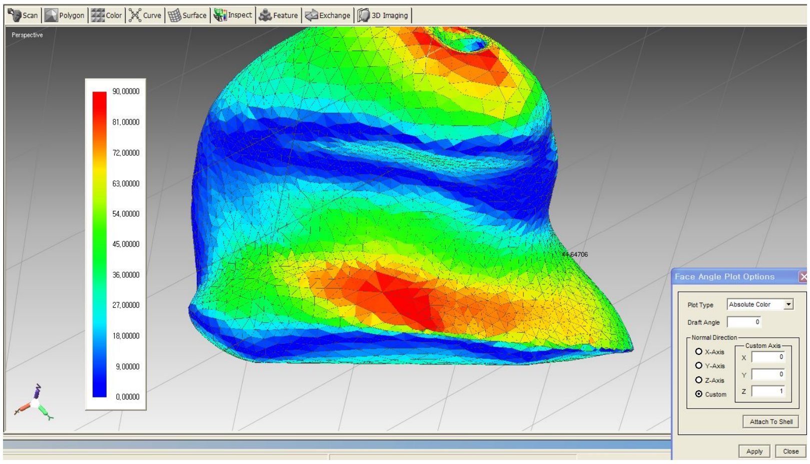


Figure 4 - 12 different angle will coursed different shell thickness. The small angle part will be made thinner than the bigger angle part. The blue color stands for the small angle part, and the red color stands for the bigger angle part.

Check the thickness of the final shell in Rapid Form software

Step 1: Select a section in the low angle area

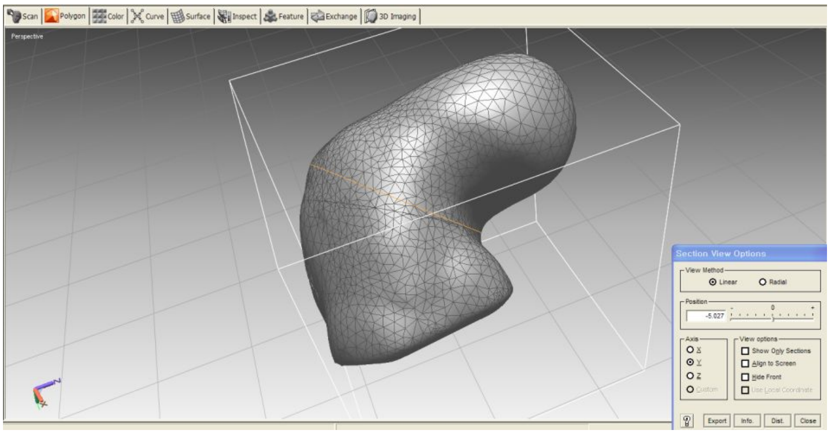


Figure 4 - 13 select the section in low angle area

Step 2: Measure the distance (thickness) of the section

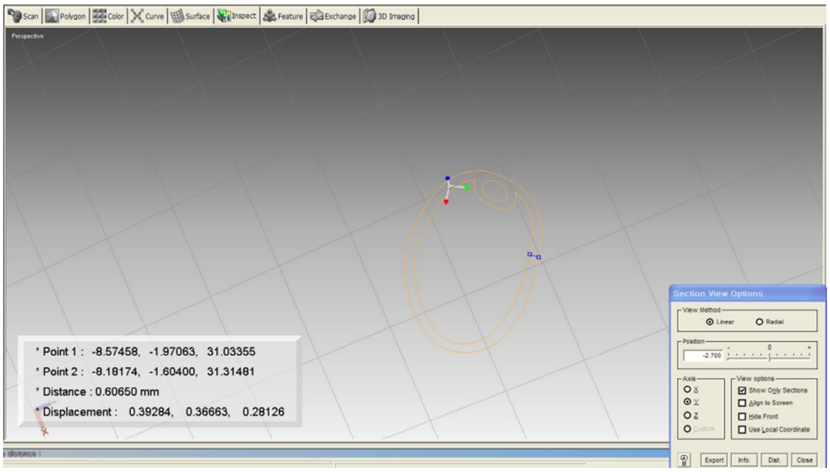


Figure 4 - 14 show only section part, measure the smallest distance of this section, this distance stands for the thinnest part of this shell section.

The thinnest thickness of this section is about 0.6mm.

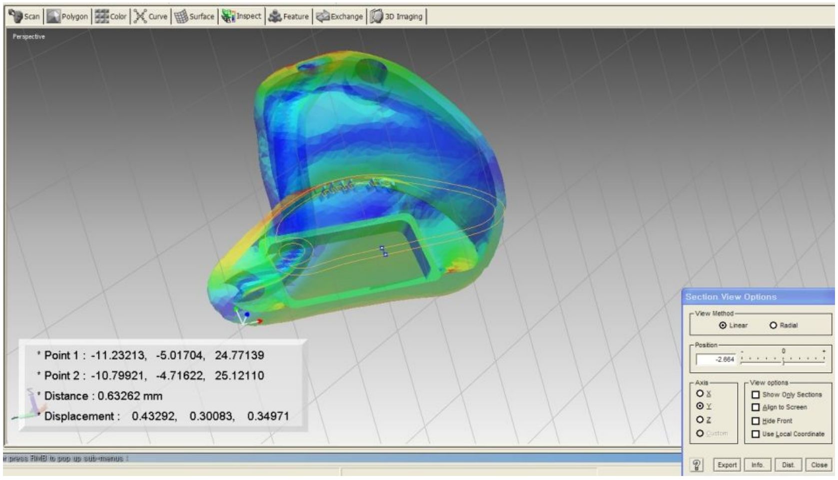


Figure 4 - 15 choose 2 points on the section; these 2 points are all in the small angle area. But this distance is not thinner than other parts; the thickness is about 0.63mm.

Result:

The thickness of the main part is uniform. And then, check the

top canal area. The bell canal makes the shell stronger than before, and the bell canal save the inside space of the shell;
So the CAD/CAM method ear shell is stronger than the conventional shell manufacturing. It's a more efficiency technology in hear aid ear shell manufacturing.

D. Experiment 3: Design Optimization (volume)

The accuracy of the wax guard system can affect the volume of the whole shell of the instrument.

Moisture and cerumen are detrimental to the performance of receivers and, consequently, to hearing instrument performance. Some sound may be impeded or distorted, and the increased demand on the receiver when trying to achieve usable gain can increase battery drain. So, sometimes the wax guard system is needed.

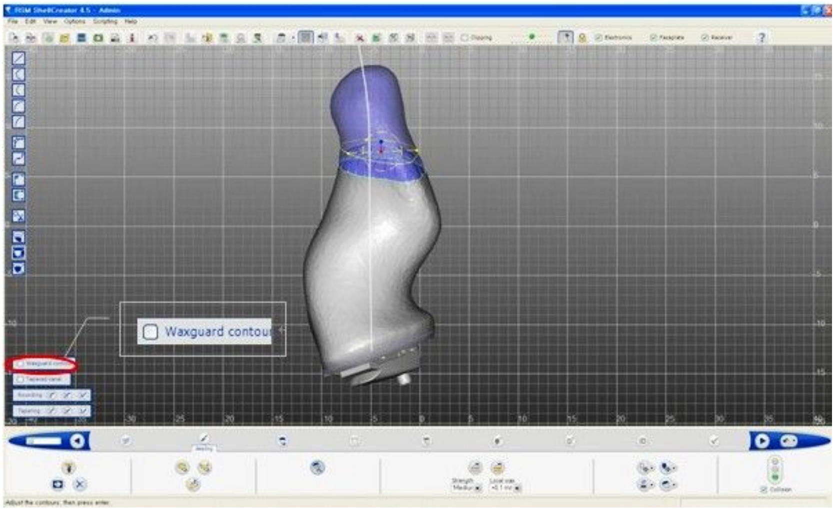


Figure 4 - 16 the wax guard designed by the RSM software.

Sometimes the wax guard is needed. And then use this option. There're 2 kinds of wax guard: bell canal and open cut.

In bell canal mode, there're 5 different styles, every style has its own feature. You can design the different style wax guard system according to the different ear impression.

Select the wax guard system style and bell canal option, and then click on the shell, try to modify the shape, size and the direction of the bell canal.

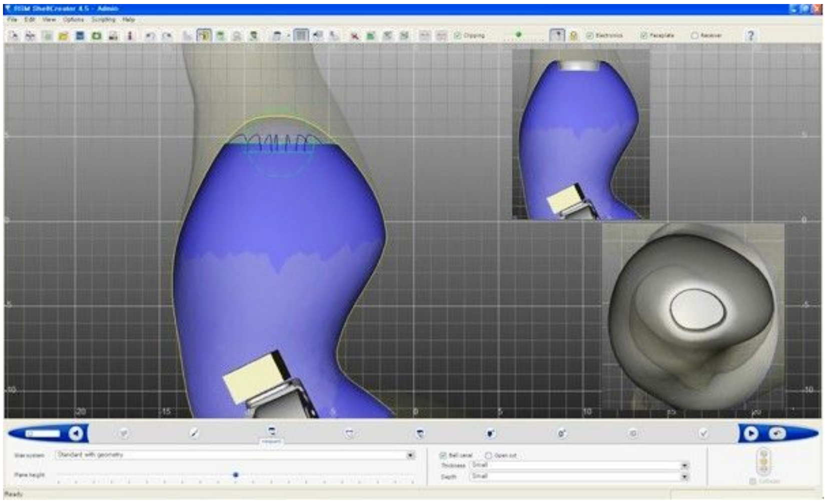


Figure 4 - 17 different styles of the wax guard. This style wax guard area is easy for bounding receiver tube.

The thickness of top canal area is increased because of the bell canal shape.

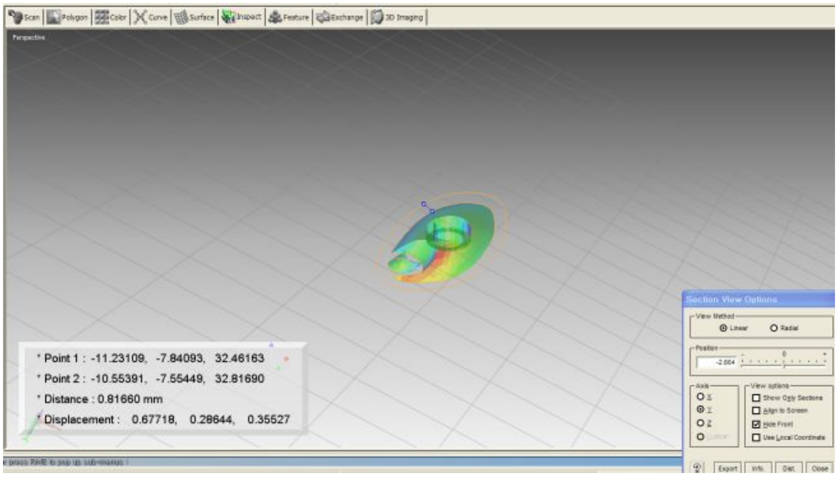


Figure 4 - 18 the shell thickness of the bell canal part is increased to the 0.81mm.

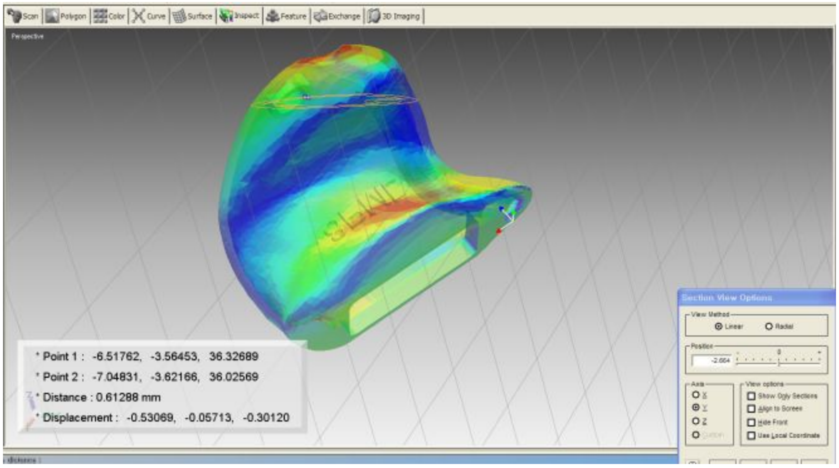


Figure 4 - 19 measure the small angle area thickness, the thinnest area is about 0.61mm.

In Conventional shell manufacturing process, it's hard to control the shell thickness.

From the shell information you can get the volume of the volume of this shell (402mm^3). The thickness of the shell is set as 0.6mm. Compare with the volume of the impression (1721mm^3).

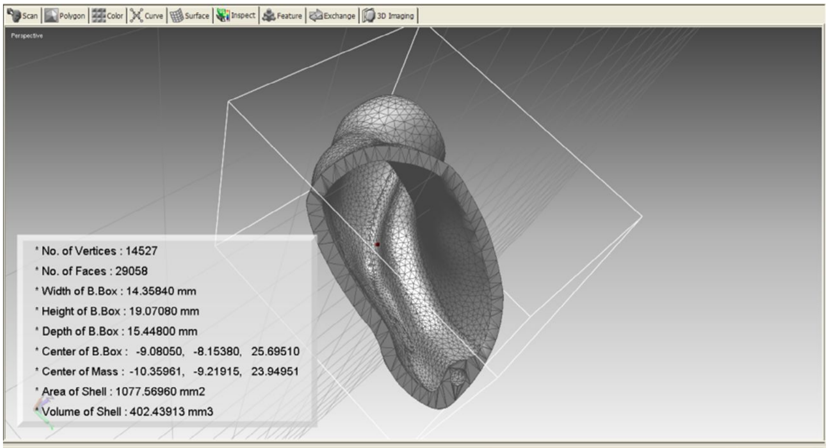


Figure 4 - 20 the volume of the inside shell space is about 402.43913mm^3

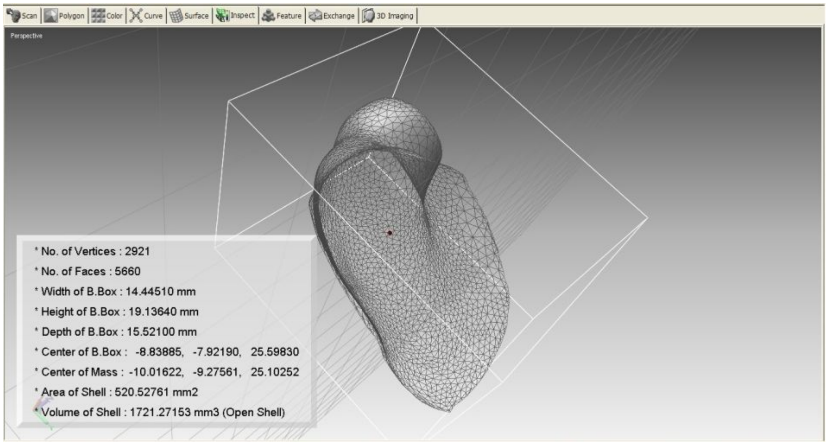


Figure 4 - 21 the volume of the detailed ear impression is about

1731.27163 mm^3

When designed the ear shell, the shell thickness is set as 0.6mm. Than the inside volume decreased 1329mm^3.if you set the shell thickness as 0.8mm. The inside space will decreased.

Step1: measure the volume of the vent

The length of the vent: 23mm

$$A = \pi r^2$$

The area of the cross section： $=0.6*0.6*\pi$ mm^2

The volume of the vent inside space: $0.6*0.6*\pi*23= 26mm^3$

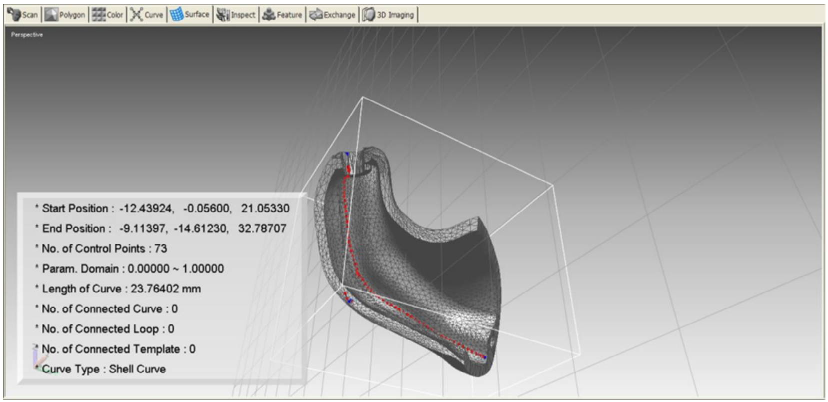


Figure 4 - 22 the length of the vent is about 23.76402mm^3

The volume of the inside components

Microphone: $17.3mm^3$

Hybrid: $30mm^3$

Receiver: $38.3mm^3$

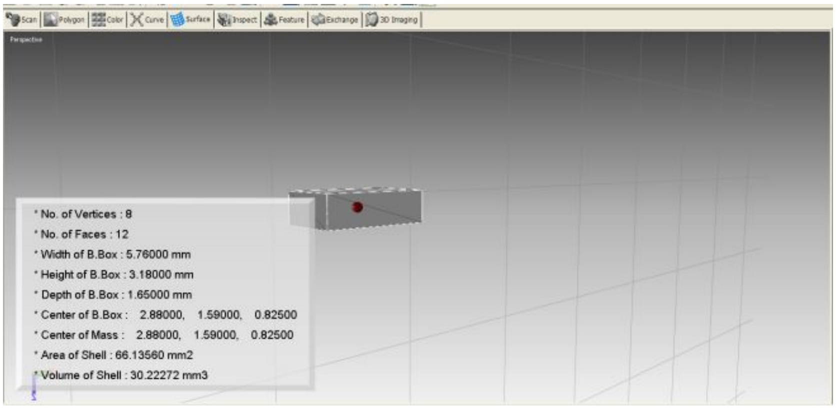


Figure 4 - 23 measure the volume of the inside components. The volume of the chip is about 30.22272mm^3

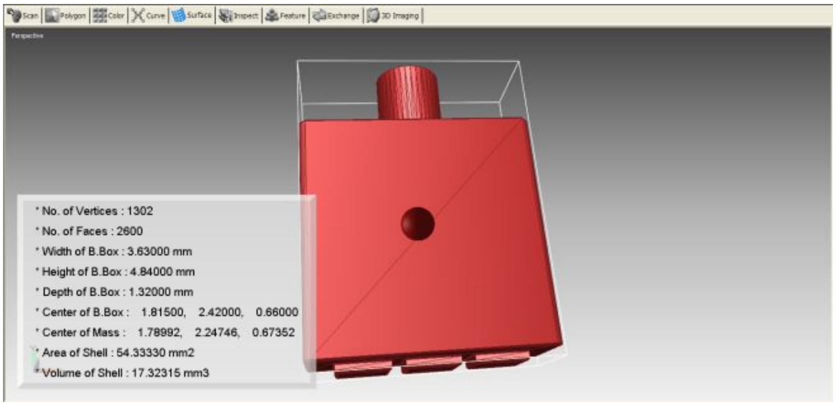


Figure 4 - 24 measure the volume of the inside components. The volume of the microphone is about 17.32315mm^3

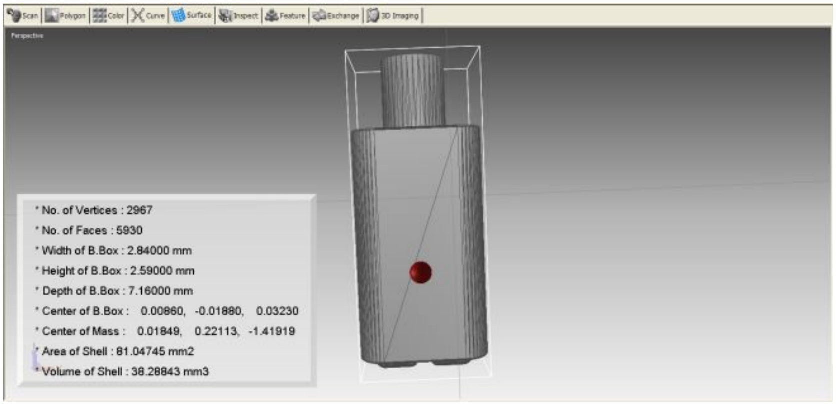


Figure 4 - 25 measure the volume of the inside components. The volume of the receiver is about 38.28843mm3

Electronics: 116mm^3 + Receiver: 38.3mm^3= 154.3mm^3

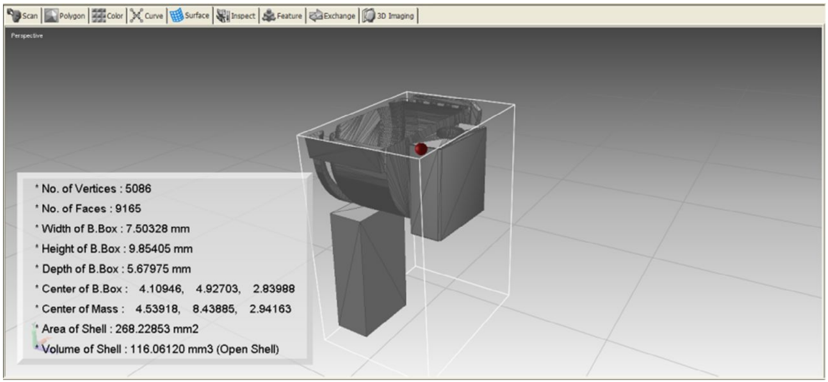


Figure 4 - 26measure the volume of the inside components. The volume of the electronics, the microphone and the chip is about 116.06120mm3

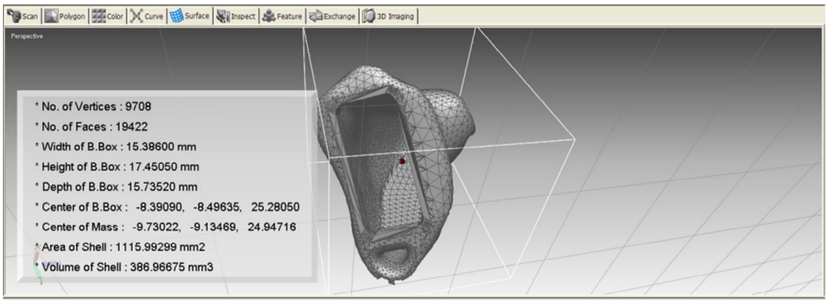


Figure 4 - 27 measure the length of the D-shape vent. The volume of the inside space of the shell is about 386.96675mm3

So when you design the ear shell by the RSM software

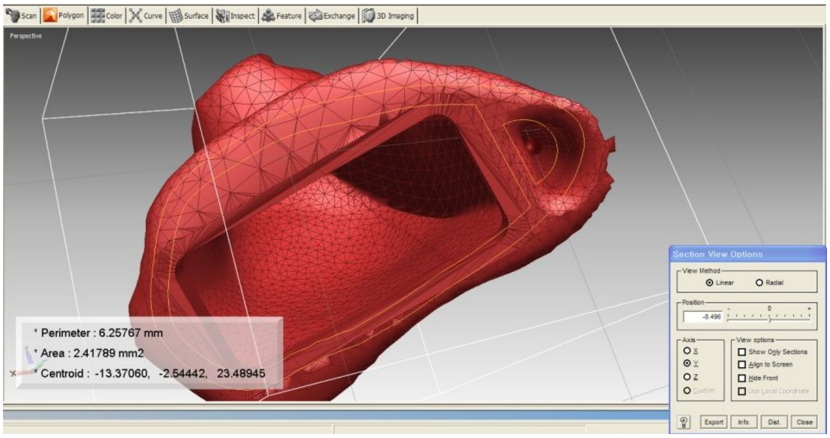


Figure 4 - 28 measure the vent section perimeter, the D-shape vent perimeter is about 6.25787mm, the area of the vent section is about 2.41789mm^2.

The volume of the D-shape vent is about:

2.41788*18= 43.533mm^3

	Regular	D-shape
length	23.76042	18
section area	1.131	2.41789
volume	26	43.533

Table 1 the comparison of the regular vent and the D-shape vent

.

Result:

The volume of the vent is bigger than the regular vent, the length is shorter than the regular one, and it's more efficient. Choose the same location and different style you can get the different result.

The regular style vent stands for the handy making vent, and the D –shape vent stands for the new technology vent.

E. Occlusion effect

Occlusion is an age-old problem. When dispensing professionals face the problem of occlusion, they are offered a variety of choices—some of which are contradictory. Sometimes increasing the low frequency gain helps; sometimes decreasing the low frequency gain helps. Frequently, shortening the length of the vent or enlarging the width of the vent helps. Sometimes increasing the SSPL 90 helps; sometimes increasing the TK helps. And the HAO effect is a distinctly different phenomenon from the threshold occlusion effect for at least four reasons [15].

The conventional definition of the occlusion effect is a resulting increase in the bone conduction thresholds for frequencies below 1 kHz when the ear is covered with an earphone. This effect has been attributed to the out-of-phase vibration of the mandible relative to the vibration of the skull for low-frequency sounds. While this may be helpful in understanding threshold measurements, it does not adequately explain the occlusion effect induced by a hearing aid.

We typically consider sounds at the eardrum to be a function of the output of the hearing aid moderated by the residual volume between the tip of the hearing aid/ear mold and the eardrum. To a large extent, this is true for an occluding hearing aid (one without any vents or leakage) and when the wearer listens to sounds from their environments. On the other hand, with a vented hearing aid and when the wearer talks, the overall sound pressure level at the eardrum also includes direct sounds that enter (or leave) through the vents (and any unintentional leakage) and bone-conducted sounds generated from the wearer’s voice. The contribution of each source varies depending on the state of the wearer (speaking versus listening) and the size of the leakage (or venting), in addition to the gain settings on the hearing aid. Fig. 4-29 shows a simplified diagram of the three sources of sound.

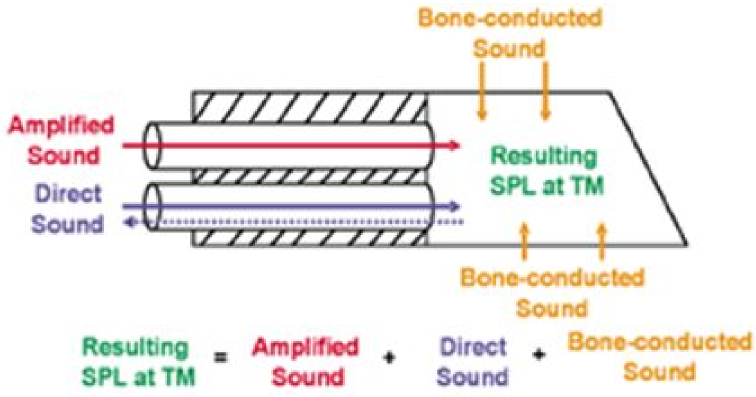


Figure 4 - 29 Sources of sound at the eardrum. [16]

In the extreme case of someone with a high frequency hearing loss who is speaking while wearing a closed ear mold, the low frequency SPL at the eardrum is dominated by the bone-conducted sounds.1 In an open-fitting situation, sounds entering directly through the vent opening will have a larger contribution to the SPL at the eardrum. [17]

Sounds Leaving the Ear

Low frequency output: The effect of venting on the acoustic output of a hearing aid is well documented. Fig. 2 shows the effect of vent diameter and vent length on the output frequency response. A straight line at “0” would suggest no change to the output relative to measurement made with an occluding ear mold; data above “0” suggest a gain increase (from resonance) while that below “0” suggest gain reduction with the specific vent dimension (length and diameter).

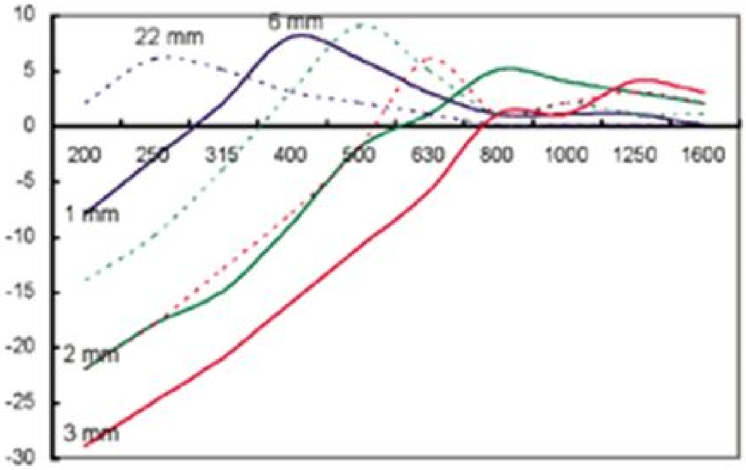


Figure 4 - 30 Effect of vent length on low frequency output for three vent diameters (1 mm in blue, 2 mm in green, and 3 mm in red).

The solid line shows the result of a 6 mm-long vent, while the dotted line shows that of a 22 mm-long vent. A straight line at "0" would suggest no change to the output measured with an occluding ear mold; data above "0" suggest a gain increase (from resonance) while that below "0" suggest gain reduction with the specific vent dimension (length and diameter).[18]

The solid line shows the result of a 6 mm-long vent, while the dotted line shows that of a 22 mm-long vent. For both vent lengths, one sees more low-frequency gain reduction as the vent diameter increases. For example, one sees that the output at 200 Hz is reduced by 7-8 dB with a 1 mm vent diameter, but as much as 28 dB reductions with a 3 mm vent diameter. Thus, an increase in vent diameter leads to a reduction in low frequency output below 1000 Hz.

A vent is a tube. As such, it is subject to tubing resonance. Fig. 4-30 also shows that a change in vent diameter leads to a shift in the vent-associated resonance. For the 6mm-long vent, the resonance peak occurs at around 400 Hz when the vent diameter is 1 mm. It becomes 800 Hz and 1200 Hz when the diameter is 2 mm and 3 mm, respectively. The real-ear SPL is higher than the coupler response measured at the same frequencies when a vent is used.

Fig. 4-30 also shows the effect of vent length on the low frequency output. The longer vent (e.g., 22 mm) differs from the shorter one (e.g., 6 mm) in two aspects. First, the longer vent has the vent-associated resonance at a lower frequency. In this case, the resonance is at 300 Hz for the longer vent and 400 Hz for the shorter vent when both have a 1 mm vent diameter. Second, the longer vent is less effective than the shorter vent in reducing low frequency output. [19]

In summary, as vent diameter increases, real-ear low frequency output decreases, and the frequency at which vent-associated resonance occur increases. In contrast, as vent length increases, gain reduction in the low frequency decreases and the frequency at which vent-associated resonance occur decreases.

V. Conclusion and Future Work

Here, it's easy to find the areas where should be modified during the CAD/CAM process. Nowadays, the CAD/CAM method is still not fit for us; the technology has not been extended around us.

The application of digital technology to shell manufacturing has increased the accuracy and consistency in which hearing aid shells are made. For the manufacturers, this increases the efficiency and accuracy in which hearing aid shells are made. Furthermore, it integrates all record-keeping within the computer database, negating the need to store processed ear impressions or the need to request new impressions for remakes. For the wearers, shells made with digital technology are more comfortable to wear and may allow the wearers to use more of the available gain from the hearing aids. So we have to dissemination this new technology.

The hearing industry and the audiological fields have made steady progress in diagnostics and amplification over the past 20 years. Today, we have products that could only have been dreamed about in the 1980s: CICs, digital instruments, and remote control devices that are housed in watches.

Unfortunately, the process of reproducing the external ear via ear impressions to make the ear mold or ITE housing (shell) has not changed substantially in the same 20 years. However, the process will change, and a custom ITE—without taking an ear impression—will someday become a reality.

The same digital technology that gave us digital hearing instruments is also providing the technical platform to eliminate the ear impression, replacing it with a digital scan of the external ear, which will capture the active area (i.e., jaw open vs. jaw closed) of the ear canal. Scanning the ear was always a dream in the hearing care profession, and we are now moving closer to the day when it will be a reality.

Although scanning the ear canal is still in the future, it is possible to start taking advantage of digital mechanics within the shell-making process today.

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