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외이 쉘 자동 제조를 위한 CAD/CAM 기법 적용

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고 정

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CAD/CAM Method Application for Ear Shell Auto-Manufacturing

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Graduate School of Chosun University

Information and Communication Engineering

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CAD/CAM 기법 적용

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7. 소속 대학의 협정기관에 저작물의 제공 및 인터넷 등 정보통신망을 이용한 저작물의 전송·출력을 허락함.

동의여부 : 동의(O)

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ABSTRACT

CAD/CAM Method Application for Ear Shell Auto-Manufacturing

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This thesis presents the engineering technique of the rapid hearing aid production with a rapid shell modelling (RSM) Computer Aided Design/Manufacturing (CAD/CAM). It will be worthwhile to describe how the virtual ear shell designed with RSM from an ear impression. And the virtual ear shell model is then used as the template to manufacture the actual ear shell by a Rapid Production (RP) machine. Some detailed description of the whole processing will be given in this thesis. The CAD/CAM method processing will enhance and provide outstanding, high-quality hearing aid shell production capabilities to customers. It reduces the time and the cost of designing products and facilitates direct and indirect manufacturing by creating actual parts directly from digital input. It determines that this

technique has made a large impact on hearing aid processing and fitting. The thesis also includes an arbitrary designing of BTE (Behind-The-Ear) type hearing aid model.

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I. Introduction

A. Research Background

Digital technology, in the form of CAD/CAM shell manufacturing, is now being implemented in several manufacturers' products. 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.

After the launch of the first digital 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.

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. 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.

Currently, there are only a few manufacturers who have introduced digital imaging technology in hearing aid shell manufacturing. 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. Conventional Ear Shell Manufacturing

In conventional hearing aid shell modelling processing there are 10 steps. Although slight differences occur between manufacturers, the same 10 steps need to be completed regardless of the style of the product:

Cast. A cast is a record of the ear impression made directly from the ear impression prior to any modification. 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.

Trim. 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 wearer’s ear. The model, hearing loss, and the dispenser’s request determine how much trimming and tapering be done.

Wax. The trimmed impression is now dipped into hot wax. 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.

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 (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.

Cast 2. The trimmed and waxed impression is now cast in hydrocolloid. This natural jell-like material is solid at room temperature, but liquifies 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.

Pouring of Shell Material. Room-temperature cured (RTC) or UV-cured acrylic is poured into the hydrocolloid cast to make the shell. 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.

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. 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 (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.

Trim 2. 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. A flat sanding wheel is used to trim the lateral end. The amount of trimming also determines the final profile of the hearing aid.

Vent. The vent is now installed. 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.

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 smoothes 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.

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.

II. Impression Techniques

As the hearing aid must be resemble the shape and the size of the patient's ear canal exactly.

No matter in traditional ways or in 3D rapid shell modeling, we should make the ear canal impression first.

Step 1 Otoscopic examination

A. The otoscope provides illumination and visual amplification of the ear. Grasp the top of the ear with your thumb and index fingers; press the remaining fingers against the head to control any sudden movements your client may make.

B. Carefully enter the ear canal with the specula portion of the otoscope while pulling up on the ear (pull down for children) so that the ear canal and eardrum are clearly visible.

Some problems that may encounter are:

Cerumen (Earwax). If the earwax is impacted, the wax must be removed before taking an impression.

Discharge of fluid. This is usually caused by infection. Do not take an ear impression until the infection has cleared.

Prolapsed canal. A flap of skin will close the ear canal opening. Pulling the pinna up and out the flap of skin will usually open the canal.

Foreign objects. Pencil erasers or any other foreign objects must be removed before taking an impression.

Enlarged canal. This condition is usually due to surgery. Many times the eardrum will be completely missing or perforated. Have medical clearance before taking the impression.

Malformations. Some ears have moles, stenosis, warts, pimples, and varios types of scar tissue or congenial deformities. If these are present, make sure your impression properly identifies them and alert the lab that this is a real anatomical variation and not an impression error.

Hair Growth. Hair growth at the opening of the canal should be trimmed away before taking an ear impression. Ear hair trimmers can be used to trim away excess hair.

Step 2 Examining the ear's texture

A. Using index finger and thumb grasp the auricle, bend forward, and then stretch slightly to check the ear's elasticity. If the ear is difficult to move the texture is hard, if it moves and stretches easily the texture is soft.

B. Pull up on the ear to see how the ear canal opens. If there is little movement of the opening, the texture would be considered firm. If the ear canal expands considerably from its relaxed position, the texture would be considered soft.

Fig. 2.1 Examining the ear's texture.

Step 3 Inserting the ear block

A pre-tied foam or cotton block must be placed into the ear canal before injecting the impression material into the ear. The purpose of the block is to cushion the eardrum from the impression material, to make sure the impression material fills the ear canal completely, and as a safety device in the event of impression material dislodging into the ear canal after removal. There have been cases of prolapsed and surgical ear canals where this has happened. If the broken material does not extract by pulling the block out of the ear canal by the block string, do not try to remove the material. Thus when choosing an impression material always follow the recommended mixing and setup directions, and make sure the impression material has a good tensile (tear) strength.

A. Start by placing the block at the opening of the ear canal using fingers or tweezers. Hold the light probe near the illuminated probe tip.

Fig. 2.2 Insert the ear block1.

B. Using probe light in one hand and holding the patient's head in the same manner discussed in the otoscopic examination, tap the block in small increments until the block is in place at or near the second bend of the ear canal. Do not drive the block into the canal. If the block is hardly visible with the probe light it can be assure we are at the right depth.

Fig. 2.3 Insert the ear block 2.

C. If the block is hard to insert cut some of the block fibers or switch to a smaller block so it will move down the ear canal. If the block inserts too easily or if there are visible gaps around the block and the tissue of the canal use a larger block. You do not want the material to flow around the block.
D. We using a foam block, it is important that the block is not compressed to tightly, as the block may slide or move from the foam expanding.

Step 6 Injecting material into the ear

Once the impression material is mixed, shape the material into the barrel of the syringe.

A. Before injecting the material into the ear, push the plunger forcing the material down the barrel until the material is 1/8 away from the tip of the nozzle of the syringe.

Fig. 2.4 Material in the syringe.

B. Place the nozzle of the syringe into the ear canal about ½ and slowly begin to inject into the canal. As the material begins to flow, slowly back the syringe out of the ear canal allowing the material to flow evenly with the tip of the syringe.

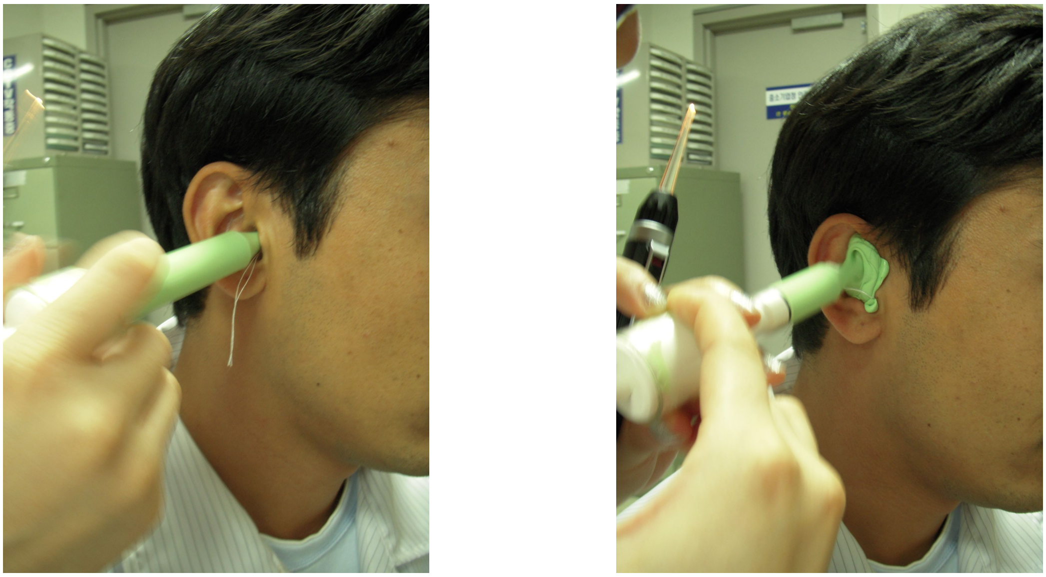


Fig. 2.5 Insert material into the ear step B.

C. Work the material down to the anti-tragus notch, around the concha and up through the helix area. Fill the remaining portion of the ear making sure the tragus portion is completely filled. Always use a steady, constant flow of material into the ear. Removing the syringe using stop and go motion can cause coiling or air gaps to the finished impressions. Use all of the material in the syringe.

Fig. 2.6 Insert material into the ear step C.

Step 7 Removal

A. Press the outer edges of the pinna towards the patient's head to break the material loose from the anti-tragus notch, concha, and helix area. With index finger pull up on the helix area to dislodge the material from the helix fold. Work the way down in the same manner to the anti-tragus notch.

Fig. 2.7 Remove the impression.

B. Grasp the anti-tragus notch area of the impression with thumb and the helix portion with index finger. In a single motion gently pull and slightly rotate the impression towards the patient's nose until the impression is removed from the ear.

Fig. 2.8 Ear impression.

III. 3D Rapid Production Of Hearing Aids Shell

The CAD/CAM method of shell manufacturing includes three stages:

- **Impression scanning (iScan)**
- **Virtual modeling**
- **Shell building**

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.

A. 3D Scanning of the ear canal impression-iScan

In the rapid shell modelling process, the patient's ear shell is designed from the 3D scanned ear canal impression. This virtual impression can be further manipulated using RSM to obtain the specifically designed ear shell model. The geometry of each hearing aid ear shell model is three dimensionally archived, so that it is immediately possible to reproduce an identical copy of the same ear shell model without physical re-collection of the patient's ear impression again.

Fig. 3.1 Digital image is formed.

The 3D scanner scans the ear impression using a laser light source. The ear impression is placed in the middle of the scanner. We start with the block being removed from the impression, and then the 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.

Through triangulation, thousands of data points can be generated from the digital images. These data points are connected by the computer, and a "point cloud" of the impression is generated.

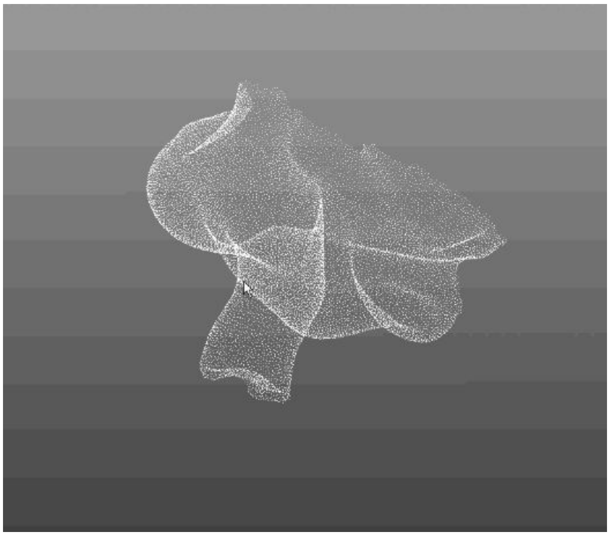


Fig. 3.2 Point clould

The computer interpolates data from the point cloud and creates a digital image of the impression.

B. Rapid shell modelling process with RSM

Modeling is the process where we modify the virtual model with software (here we use RSM) and creates a virtual hearing aid shell. There are a number of operations that we perform with the virtual impression to create the virtual shell.

RSM virtual modeling

1. Point Cloud Flowstep

We begin with the virtual impression in the form of a point cloud. There are the options to choose the virtual instrument and the receiver we use. And the style of hearing aids we are going to made: CIC, Mini canal, Canal, Half shell and Full shell.

In this flowstep we clean up the point cloud scan file: remove noise in the scan and open up the impression at the top (faceplate side).As indicated on the image below. Selected points are highlighted in red.

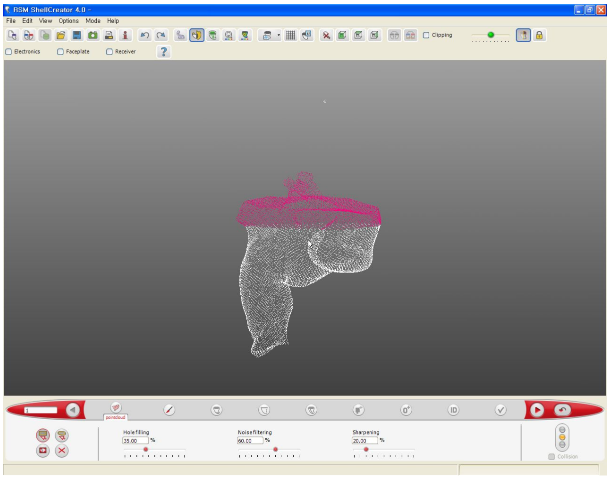


Fig. 3.3 Selected points are highlighted in red

The selected points will be removed and the point cloud is converted into a triangulated (*.STL) surface model.

2. Detailing flowstep

In a procedure called "Surface Offset", the entire impression, or parts of it, can be enlarged. Also parts of the virtual impression which are not necessary for the shell can be removed. This is similar to waxing with the conventional approach. The amount of the material added or removed is shown in colors to visualize the changing tightness of the shell.

The electrical components are positioned inside the impression in this step first, and then detail the impression around it.

The process includes **the faceplate side detailing** and **the tip side detailing**. When detailing the impression, we have many different tools for cutting and trimming to make the hearing aid shell smaller and more comfortable. And hole filling tools can make the impression surface easy for detailing. Meanwhile we use line cut to create space for a styled vent to be added later on.

a. Positioning the components

To avoid collisions, make sure the checkbox 

underneath the traffic light is selected. This way collisions are immediately detected by showing a red traffic light and coloring the colliding components red, like the figure shows below:

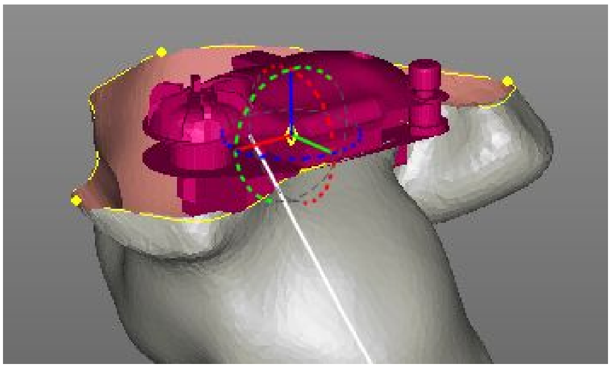


Fig. 3.4 Position the components-collision

The “component placement mode” can activate the component placement. The movement handlers (3 axes for translation, 3 circles for rotation) are added to the components. Use the **manual placement tools** for a further fine-tuning of the position. Grabbing the axes (blue, green & red line) will translate the component into a new position. Grabbing the circles (blue, green & red circles) will rotate the component into a new orientation.

After this step we obtain a collision free position, similar to the one below. Then position the receiver. The “receiver placement mode” can visualize the receiver and activate the receiver placement. Probably the receiver is partially hidden by the  faceplate assembly. The “transparency”

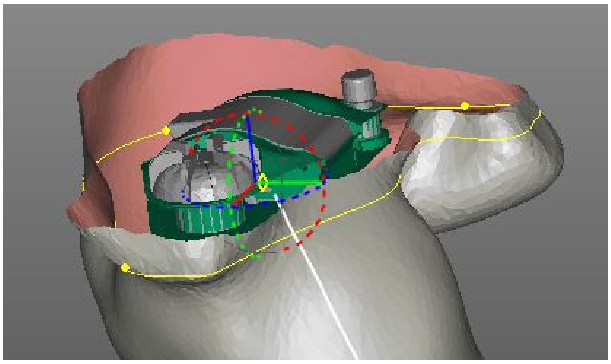


Fig. 3.5 Position the components-components placement

in the main toolbar can render the impression transparently. Fine-tuning of the placement is done by grabbing the axes or circles.

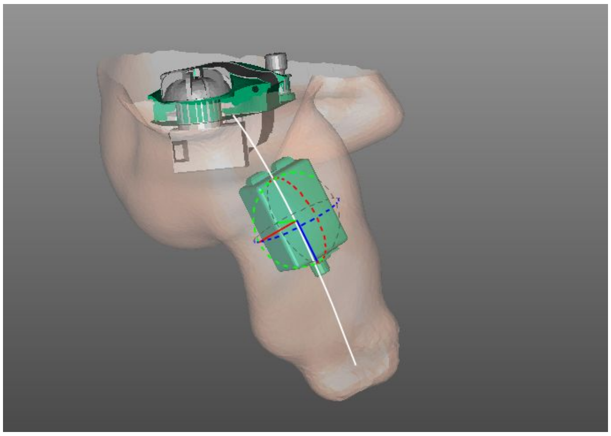


Fig. 3.6 Position the components-receiver placement

So that all the electrical components are positioned inside the impression, we can start detailing (cutting to size) the impression around it. First we will take care of the faceplate side.

b. Detailing the impression (faceplate side)

The impression is cut to the position of the faceplate by activating the “manual cutting mode” and using the “cut to faceplate option”.

The “show virtual cast” can be chose to get a good visualization of the result. We can use line cut to create space for a styled vent which will be added later on. The cutting line (cutting plane) should be more or less positioned as in the image below.

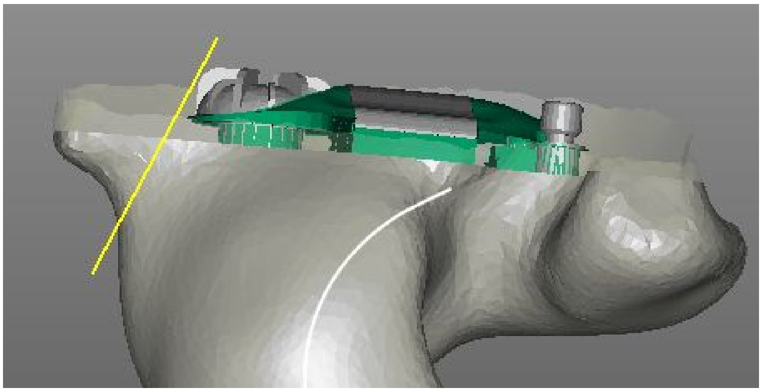
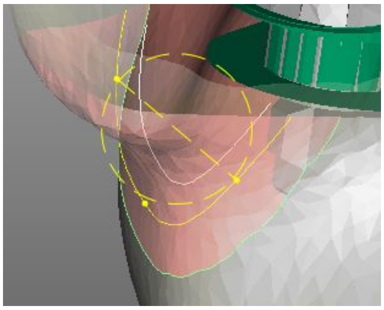


Fig. 3.7 Detailing the impression-faceplate side

The different “spider lines” give a good preview of the surface. Rounding and tapering are added to avoid sharp corners. To adjust these, drag and drop the green start and end curve of the preview or use the controls on the right side of the screen.



or

Fig. 3.8 Detailing the impression- spider lines

Choose the rounding and tapering in such a way that there will be enough space for a styled vent to be added later.

As the Bezier cut is a very flexible and powerful cutting tool.

This is the  “Bezier-cut tool”.

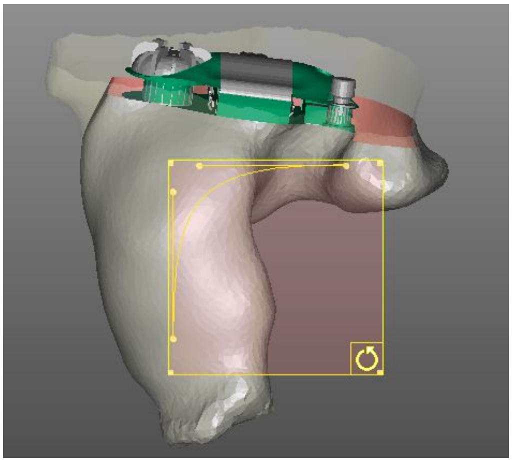


Fig. 3.9 Detailing the impression- Bezier-cut tool

Use the 4 points on the curve to modify the shape of the curve. The Bezier curve should be positioned as follows:

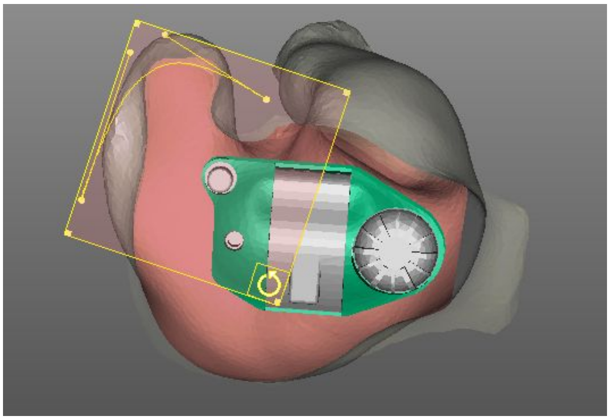


Fig. 3.10 Detailing the impression- Bezier-cut tool position

From the 3D spider preview we can adapt the rounding and tapering.

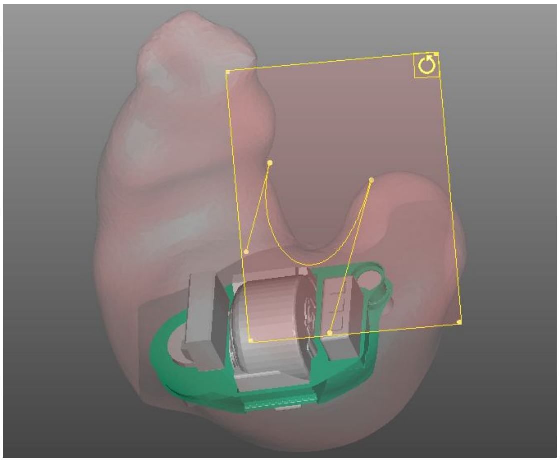


Fig. 3.11 Detailing the impression- rounding and tapering

While doing this we have to make sure the cutting plane stays clear from the components.

c. Detailing the impression (tip side)

To cut the tip of the impression, a simple line cut is used.

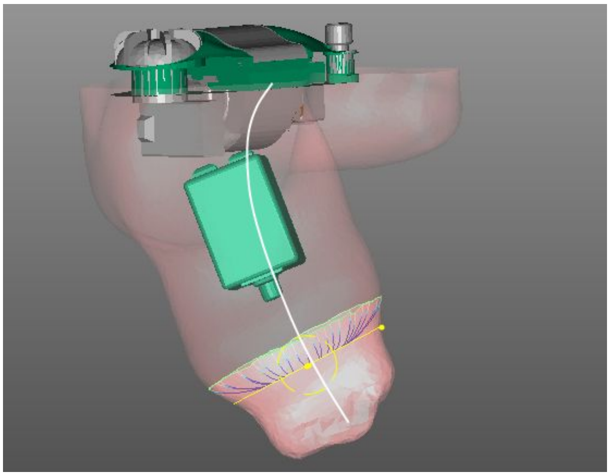


Fig. 3.12 Detailing the impression- tip side cutting

By dragging the yellow circle in the centre of the cutting plane, the orientation of the cutting plane can be easily changed.

3. Shell flowstep

We can select the wall thickness and the wax offset in the shell flowstep. Some part of the ear shell we need it be thicker, for example the bottom part and the entry point part of the vent. In this step we can make these parts thicker, the selected area is marked in yellow.

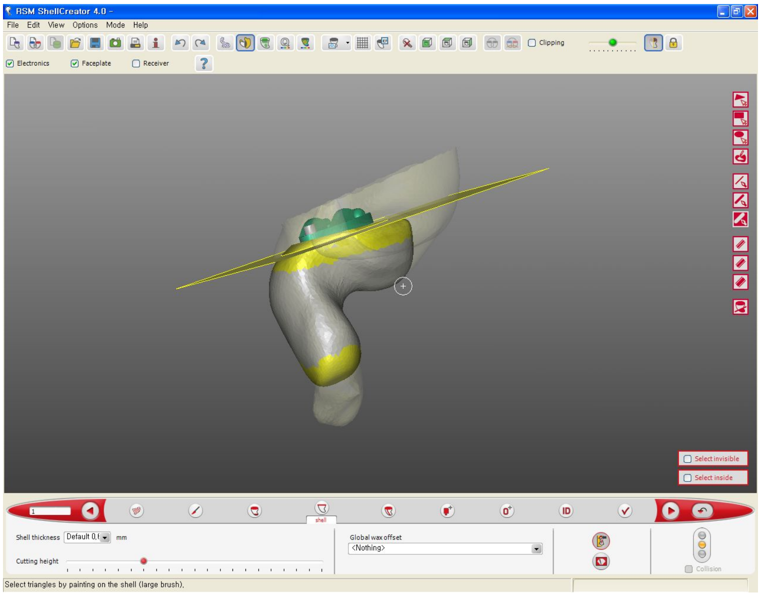


Fig. 3.13 Shell flowstep

4. Vent flowstep

In traditional ways the vent step (as the figure 3.14 shows) is really a time-consuming and troublesome step: **a coated wire should be inserted into the vent hole. Then liquid acrylic is poured over the wire and cured**

to make the vent channel. Once the curing is complete, the wire is removed.

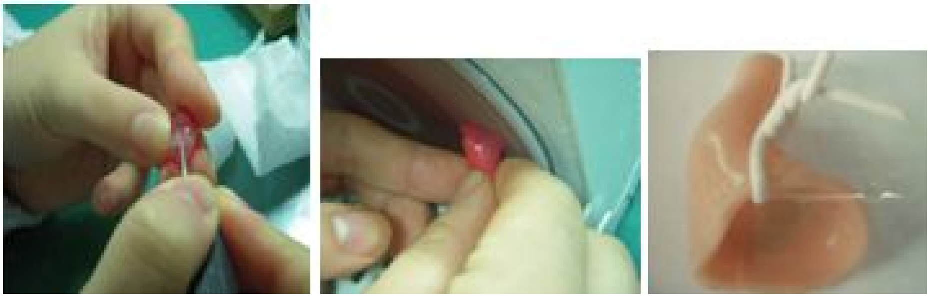


Fig. 3.14 Vent flowstep-conventional method

For CADCAM method, in the vent step we can style the vent path and the suitable place for the entry point is the styled surface we have created in the detailing step. This virtual vent will be realized with the ear shell in shell building stage. From doing this we can create the ear shell vents easily and fast.

Choose the diameter of the vent (0.5~2.0) and as style choose “styled” from the dropdown list.

Then placing the vent, we can switch off the straight vent run option so that the vent will follow the path of maximum curvature.

A red dot will indicate the entry point of the vent on the impression. The suitable place for this is the styled surface has been created in the detailing step.

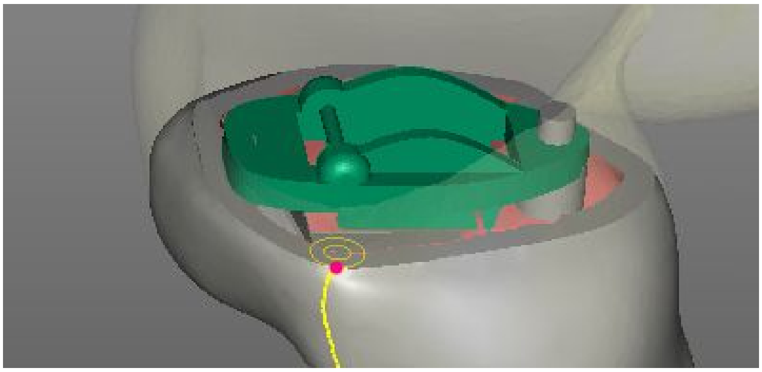


Fig. 3.15 Vent flowstep-entry point place

Next indicate the exit point on the tip side. The vent path will be automatically calculated and a preview is shown. The 4 red dots can be used to re-position the exit and entry point or to change their entry and exit angle. It is possible to change the path of the vent. The venting channel will now be created.

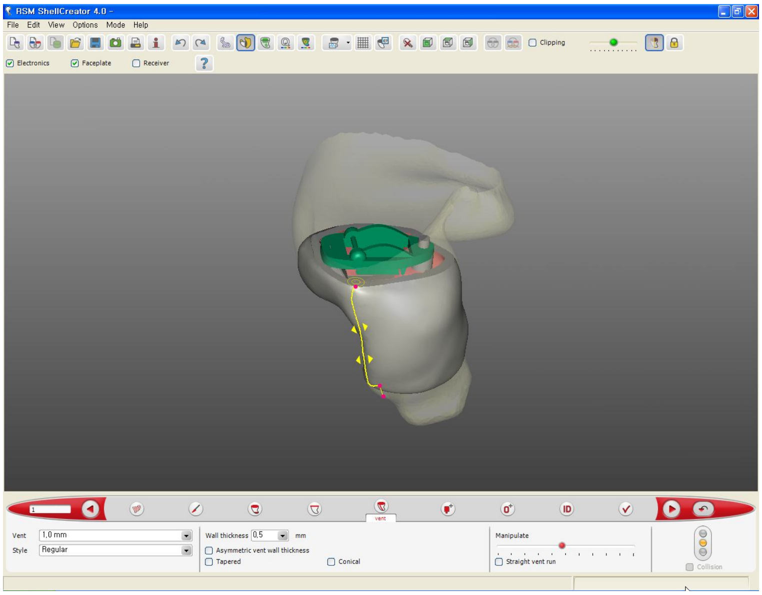


Fig. 3.16 Vent flowstep-vent path

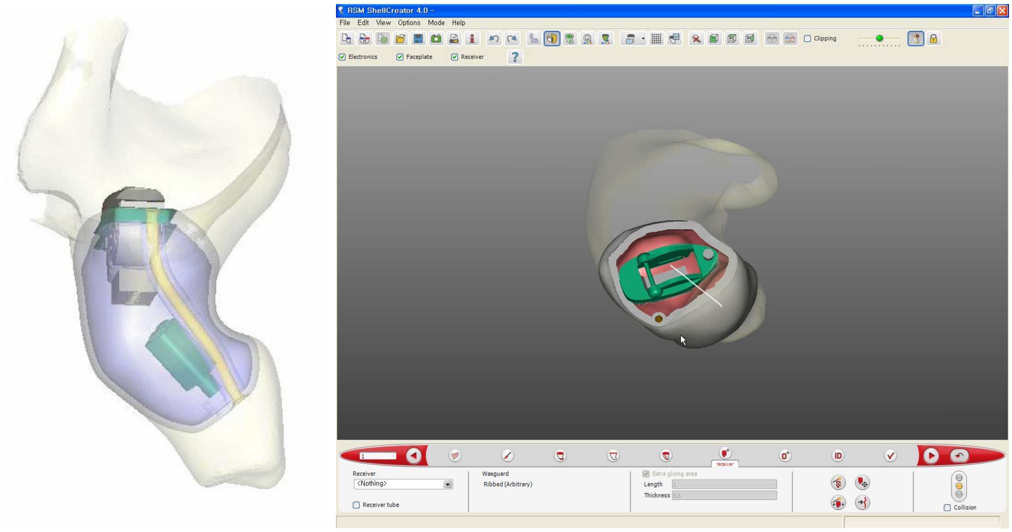


Fig. 3.17 Vent flowstep-finished vent

5. Receiver flowstep

In the receiver step we first indicate where the waxguard is to be integrated. To indicate this position simply on the tip, the waxguard geometry will be visualized. As this geometry gets (internally) integrated into the shell, only the internal part matters.

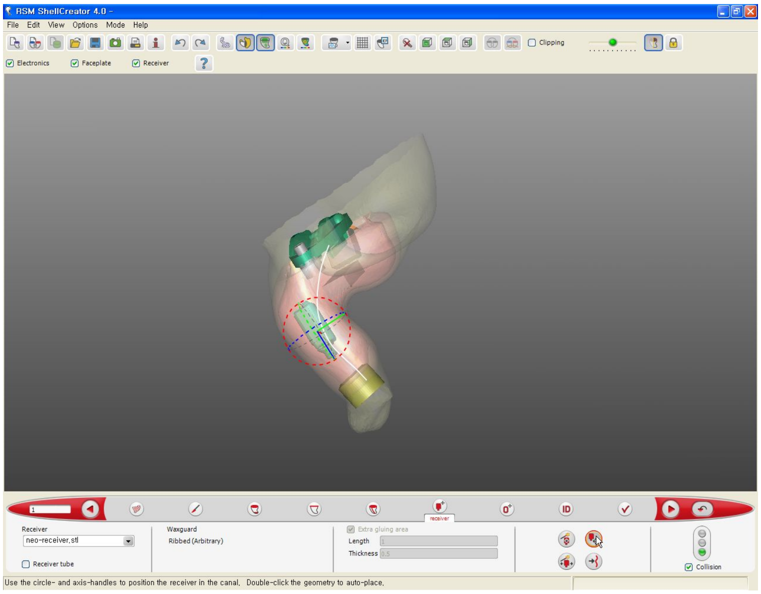


Fig. 3.18 Receiver flowstep-receiver position

By grabbing the red dot we can change the position, grabbing the yellow dot change the angle. To further fine-tune the position of the receiver, we can use the “manual placement” icon and the standard movement handlers.

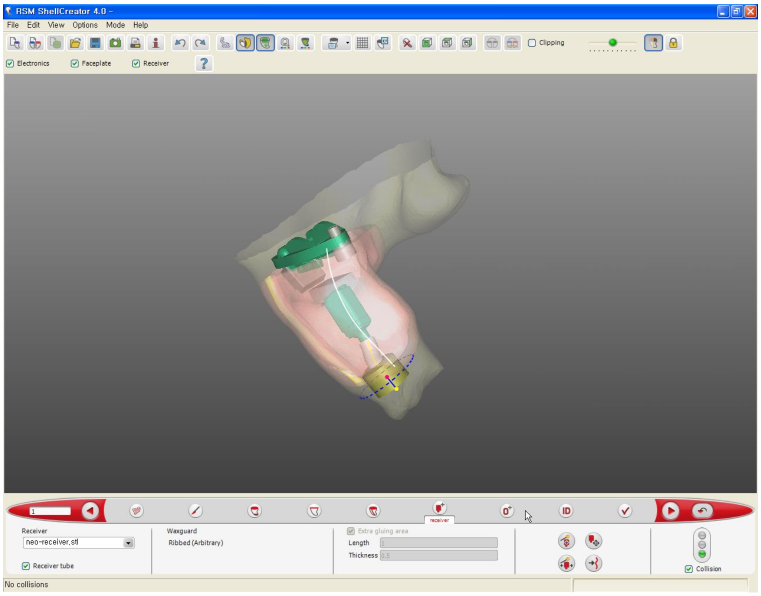


Fig. 3.19 Receiver flowstep-receiver tube position

The receiver tube option can visualize the run of the glue-in tube that will connect the receiver hole with the receiver itself. Red indicates that are certain bends too sharp, if this is the case change the position of the receiver.

6. Faceplate flowstep

In this step by selecting the “Extra gluing surface” from the dropdown list a green preview line will indicate the position up to which an additional “shoulder” is created. This shoulder will allow for a stronger gluing of faceplate to shell.

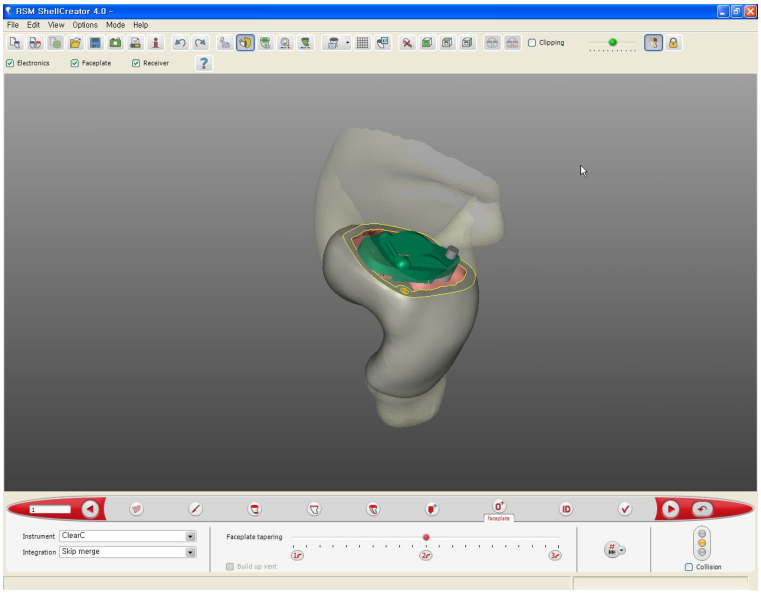


Fig. 3.20 Faceplate flowstep

7. Finish project flowstep

After all these key steps we can get the resulting STL geometry.

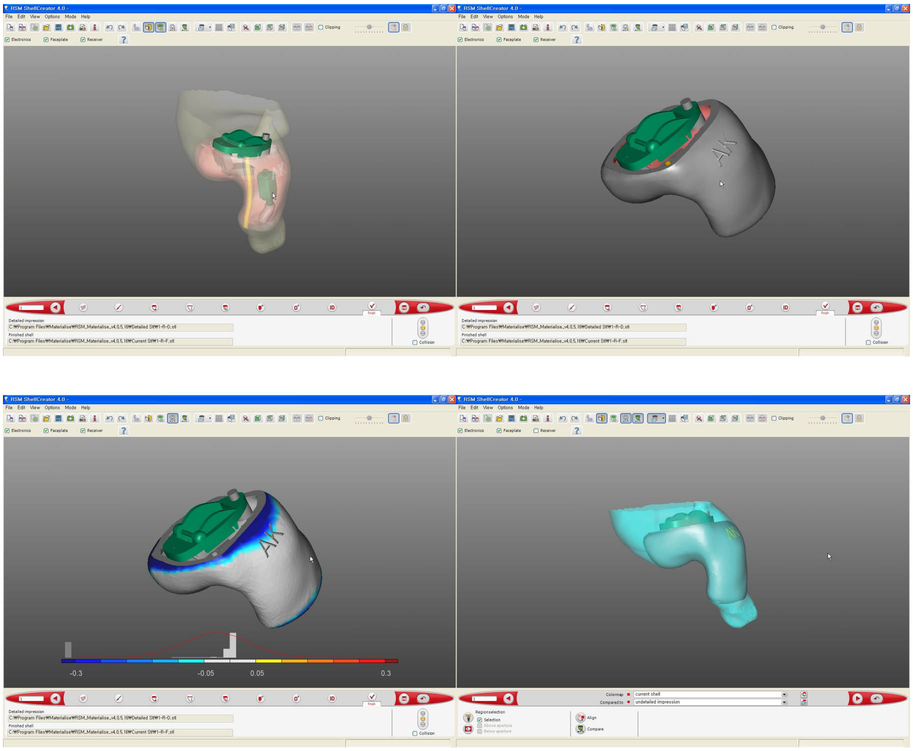


Fig. 3.21 Finished virtual ear shell

Advantages of RSM virtual modeling

Instead of the traditional methods of prepping the physical impression by trimming, waxing, hole filling, etc, we utilizes RSM to electronically detail the impression. What was once being done by hand is now done within the virtual world of the computer. This yields many advantages. For example, if a mistake is made and too much of the canal is trimmed, we should just clicks the “undo” button, rather than made a new impression.

At this stage, the components are virtually placed, venting is implemented, and the receiver opening is determined. This is all done on a computer so that we can have a 3D view of everything, allowing for easy customization to produce the optimum instrument design.
The process also utilizes “collision detection”, the button on the right bottom. This ensures all instrument components will fit as needed without any components interfering with each other. Therefore, the entire instrument is built first in the virtual world before it really gets fabricated.
Afterwards, we should experiment with the size of the shell and different placements of the virtual components (include IC chip, receiver, microphone, faceplate, vent, receiver tubing, wax guard, etc) into the virtual shell until the best possible placement is achieved.

C. The hearing instrument design

If we using machinery CAD/CAM software (here we use **Solid Works** and **Magics** for modify *.STL file) into this virtual sell design, the processing tends to extend to a more extensive extent. We can design the hearing instrument which we need by ourselves: the faceplates, the receivers, the microphones, and some different shape tubes.

1. **Receivers Receiver FFH-23373-I04**

a. **Receiver FFH-23373-I04**

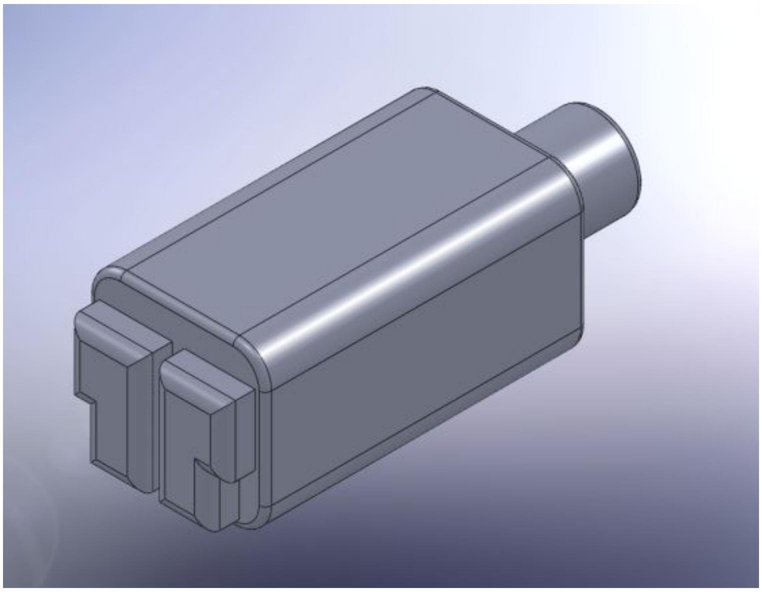


Fig. 3.22 Instrument design-receiver FFH-23373-I04 1.6mm

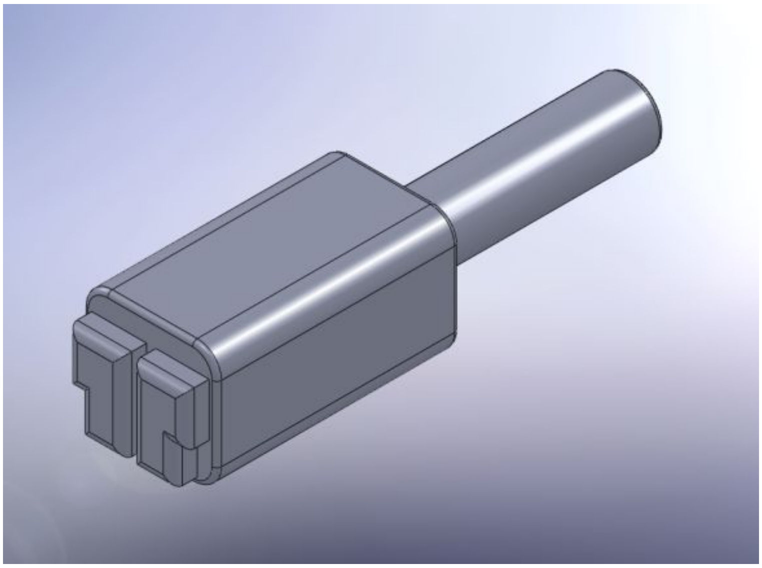


Fig. 3.23 Instrument design-receiver FFH-23373-I04 5mm

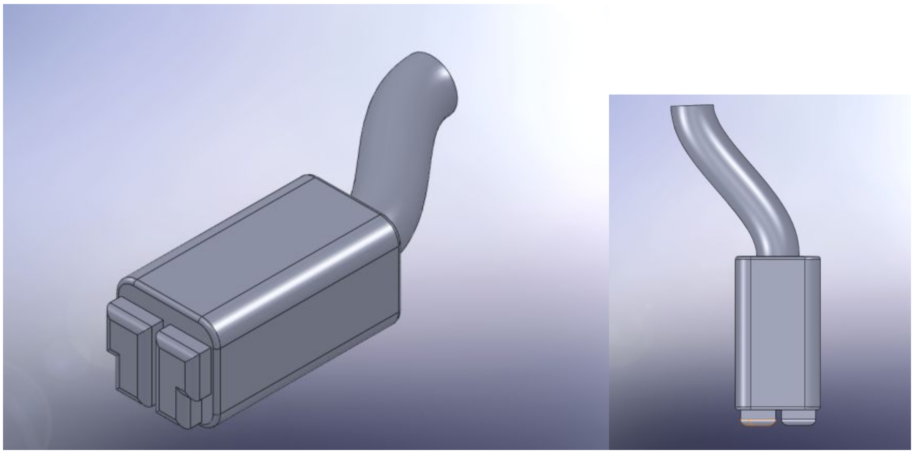


Fig. 3.24 Instrument design-receiver FFH-23373-I04 5mm curved tube

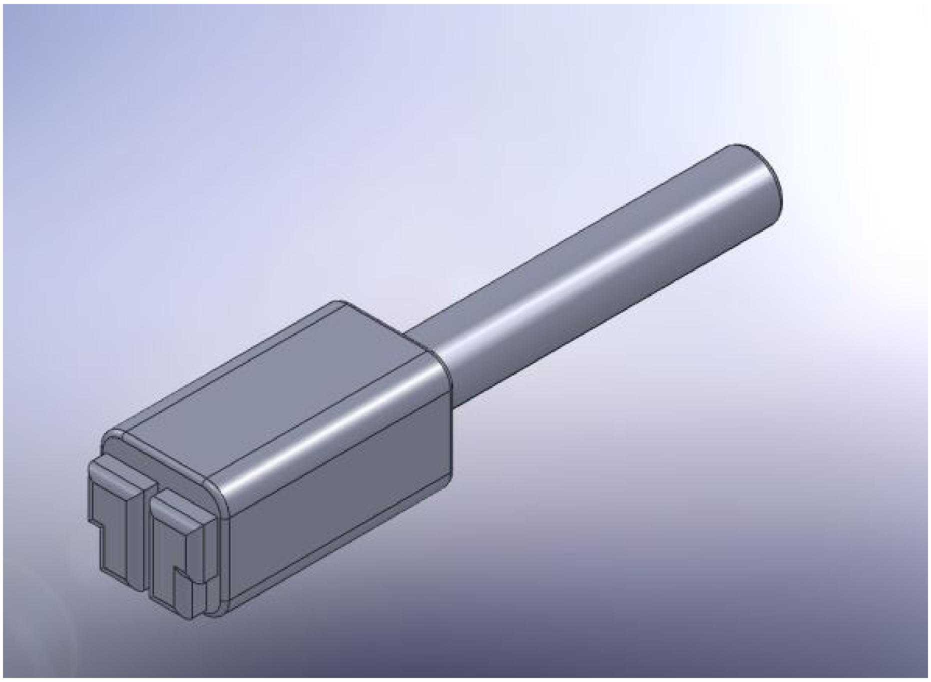


Fig. 3.25 Instrument design-receiver FFH-23373-I04 8mm

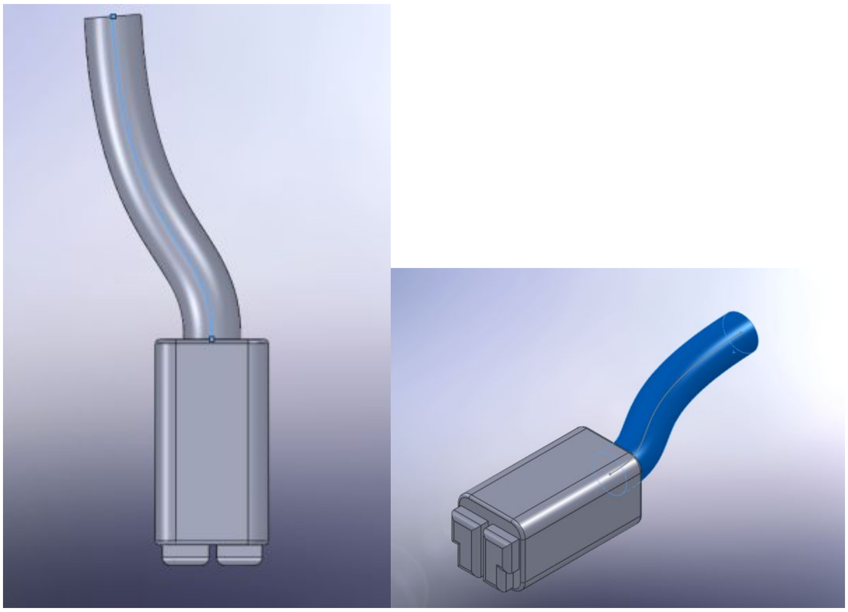


Fig. 3.26 Instrument design-receiver FFH-23373-I04 8mm curved tube

The shape of the tube can be design and changed

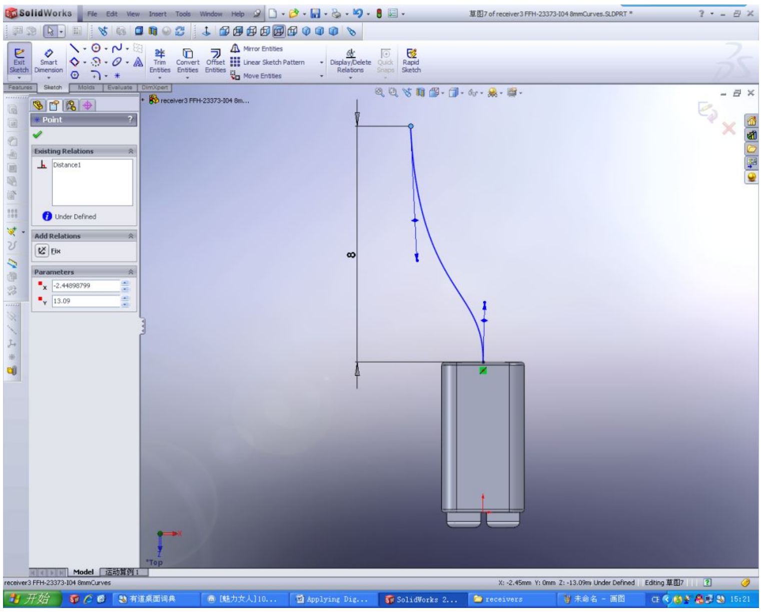


Fig. 3.27 Instrument design-receiver curved tube design

b. Receiver AK-R1

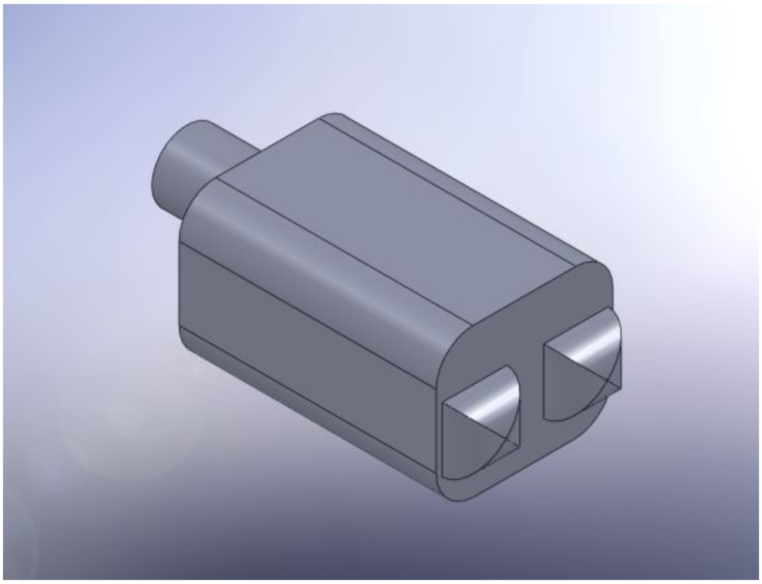


Fig. 3.28 Instrument design-receiver AK-R1 1.59mm tube

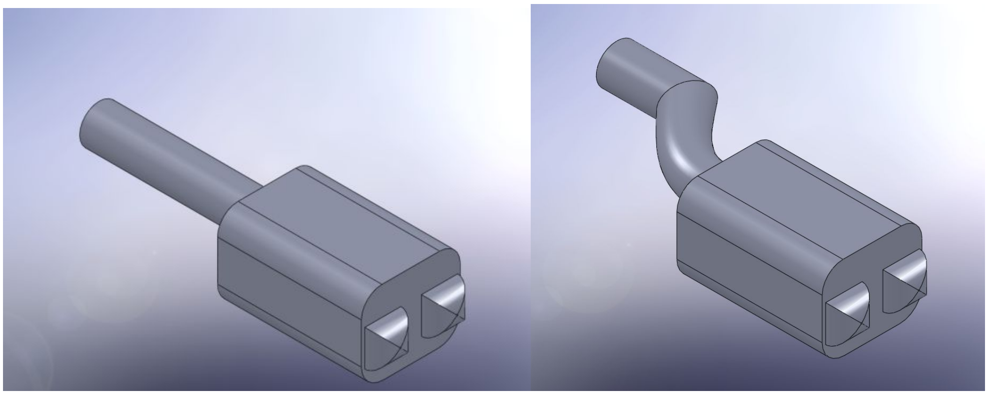


Fig. 3.29 Instrument design-receiver AK-R1 6mm and 6mm curved tube

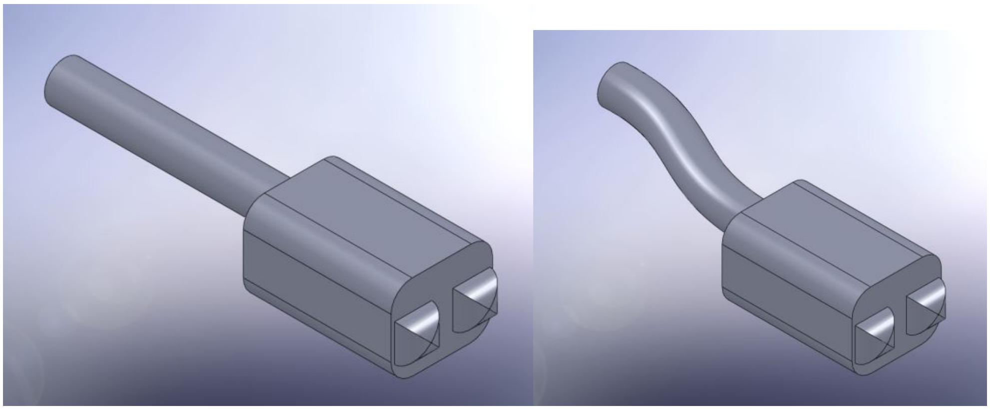


Fig. 3.30 Instrument design-receiver AK-R1 8mm and 8mm curved tube

c. Receiver 26A01B

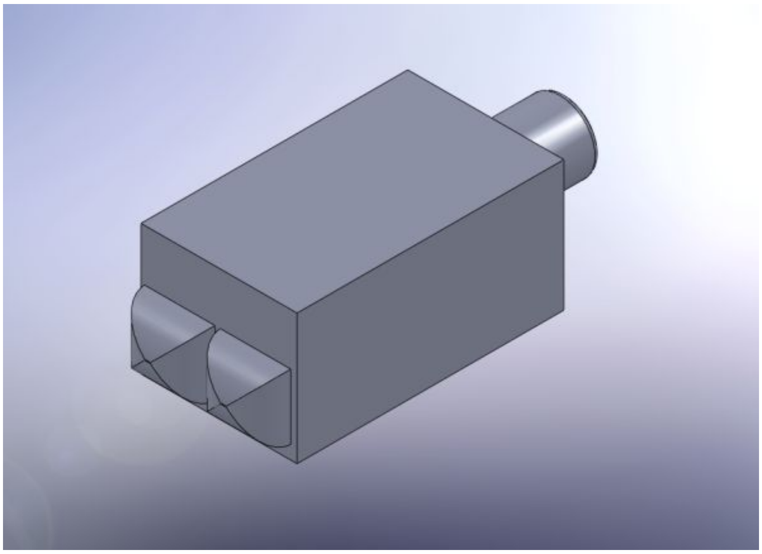


Fig. 3.31 Instrument design-receiver 26A01B 0.64mm

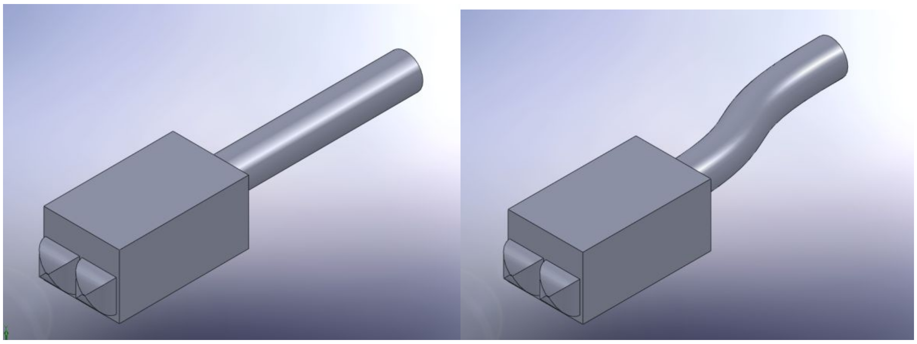


Fig. 3.33 Instrument design-receiver 26A01B 8mm and 8mm curved tube

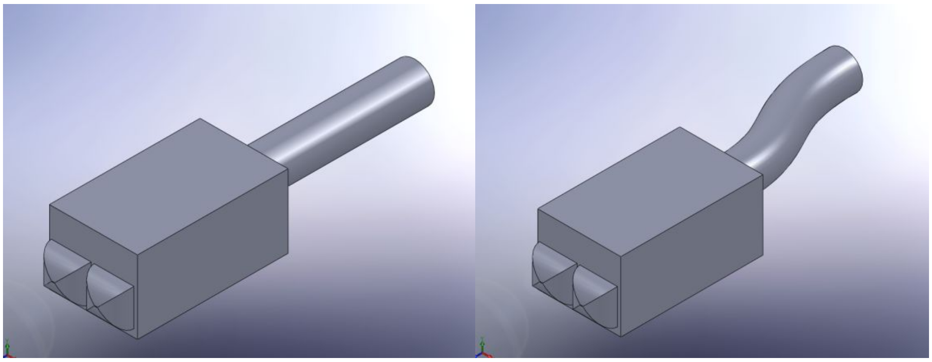


Fig. 3.32 Instrument design-receiver 26A01B 6mm and 6mm curved tube

d. Receiver PHF-23853-000

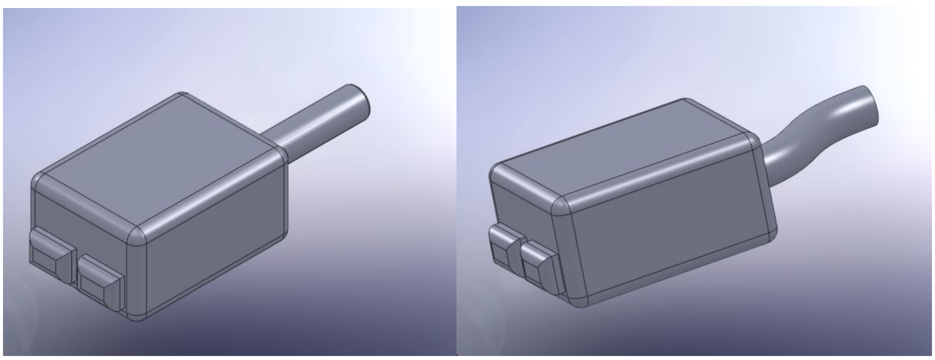


Fig. 3.36 Instrument design-receiver PHF-23853-000 6mm and 6mm curved tube

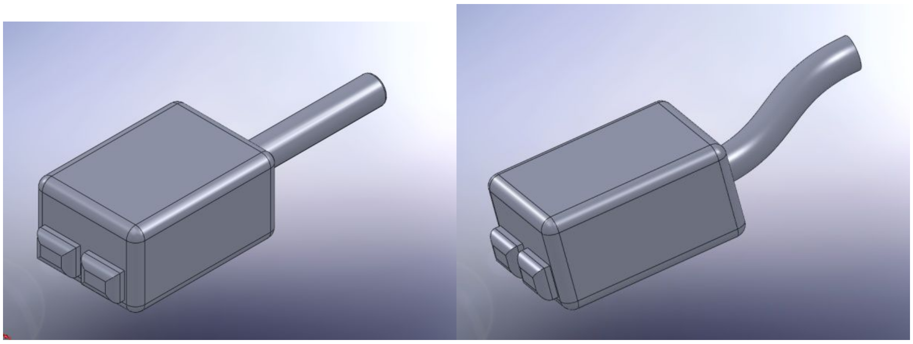


Fig. 3.37 Instrument design-receiver PHF-23853-000 8mm and 8mm curved tube

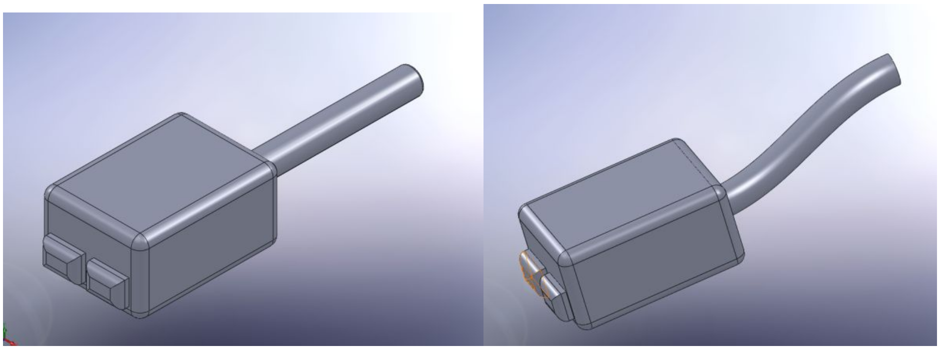


Fig. 3.38 Instrument design-receiver PHF-23853-000 10mm and 10mm curved tube

2. Microphones

a. TM-23568-C36

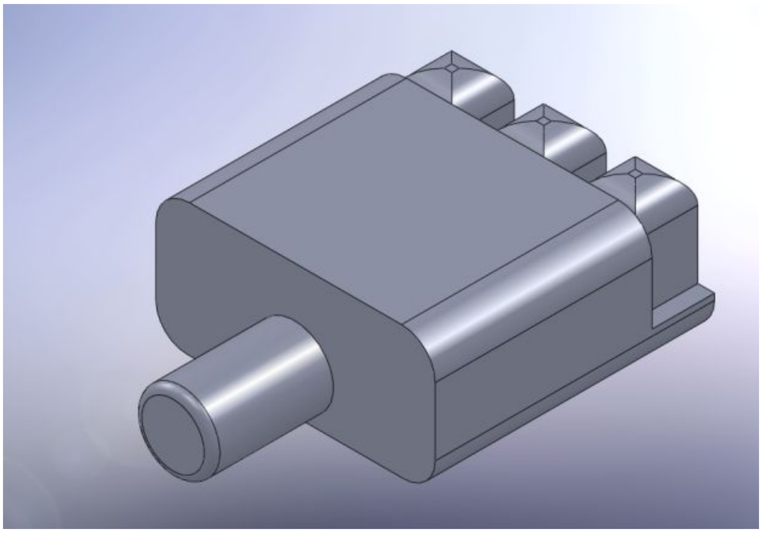


Fig. 3.39 Instrument design- TM-23568-C36

b. TO-24611-000

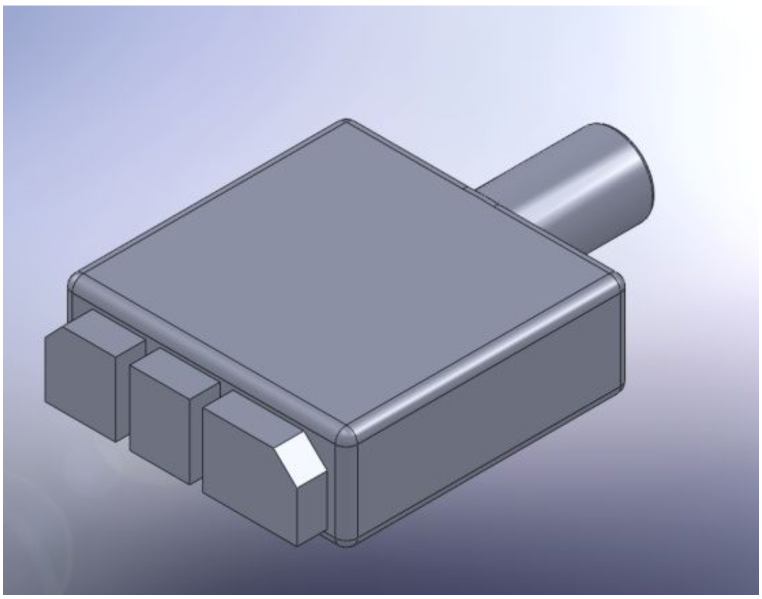


Fig. 3.40 Instrument design- TO-24611-000

c. AK-M3

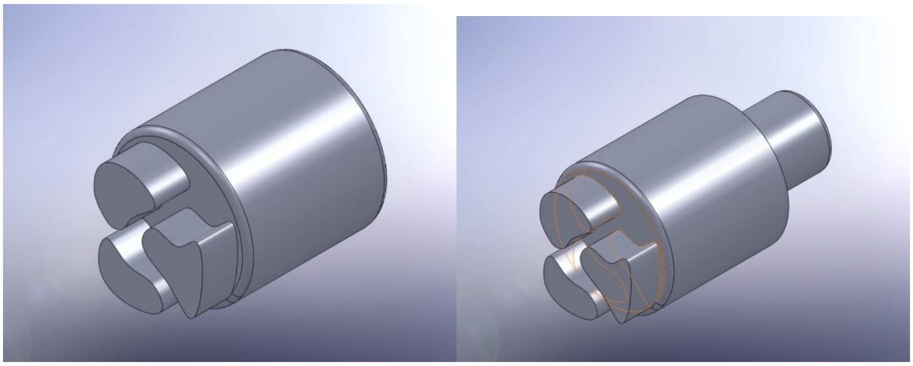


Fig. 3.41 Instrument design- AK-M3 and AK-M3 with 1.55cm tube

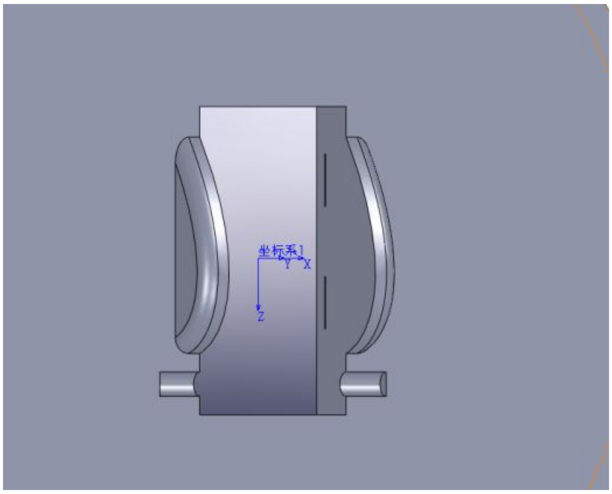


Fig. 3.44 Instrument design- faceplate cu10 detail

3. Faceplate-CU10

4. Different shape tubes

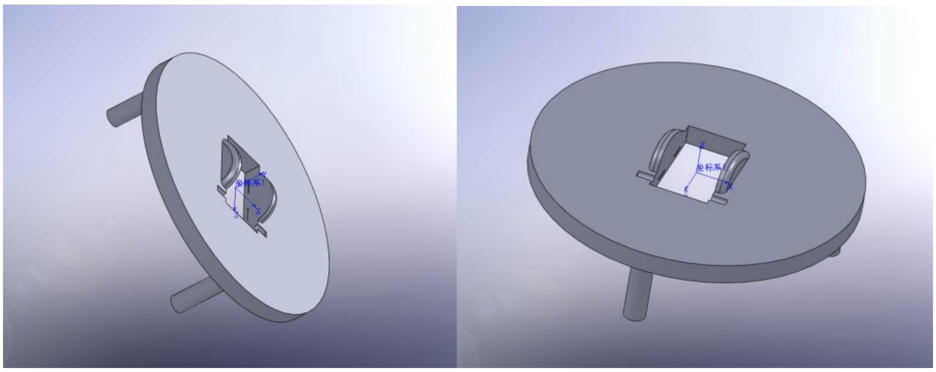
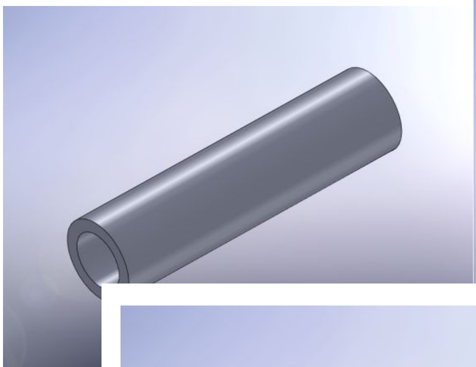
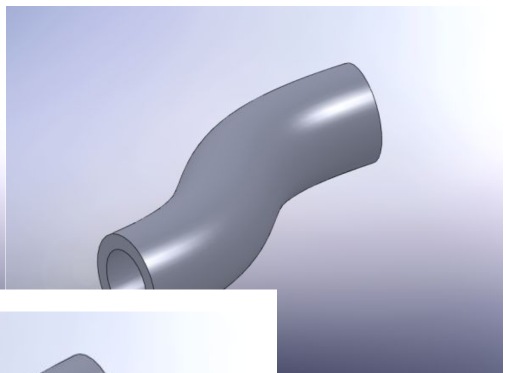


Fig. 3.43 Instrument design- faceplate cu10

5. **Battery door**

a. **10IS-batterydoor cs74**





rved tube

Fig. 3.46 Instrument design-8mm curved tube

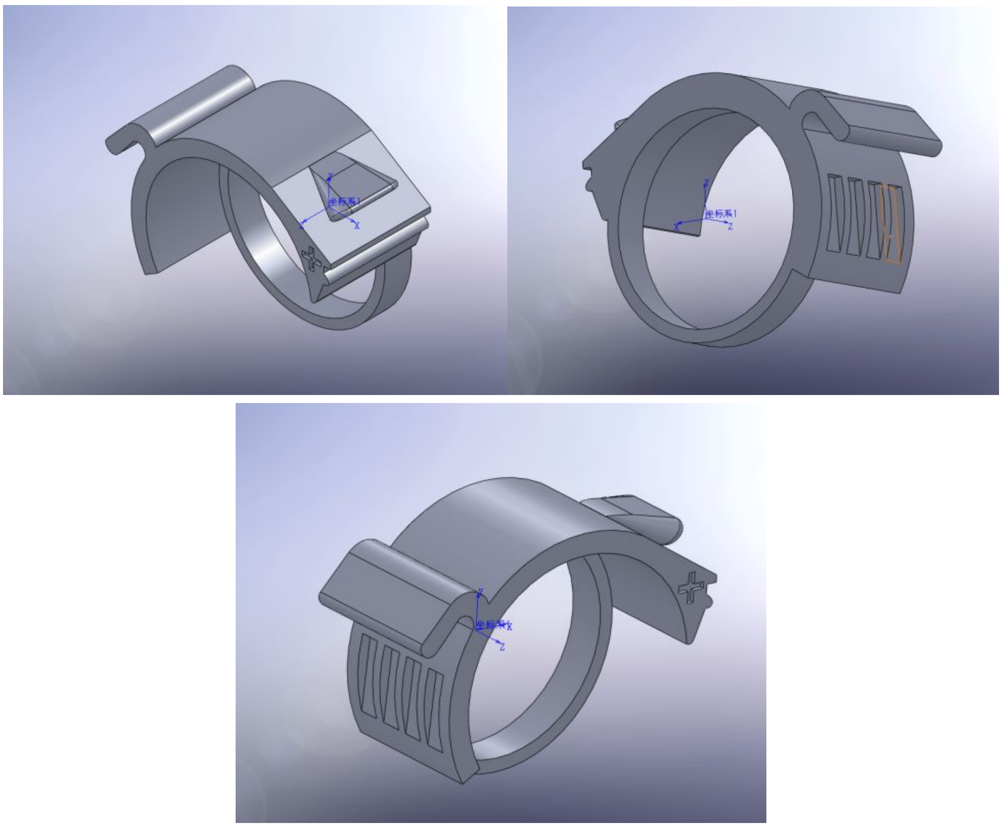


Fig. 3.47 Instrument design-10IS-batterydoor cs74

b. 12IS-batterydoor cs74

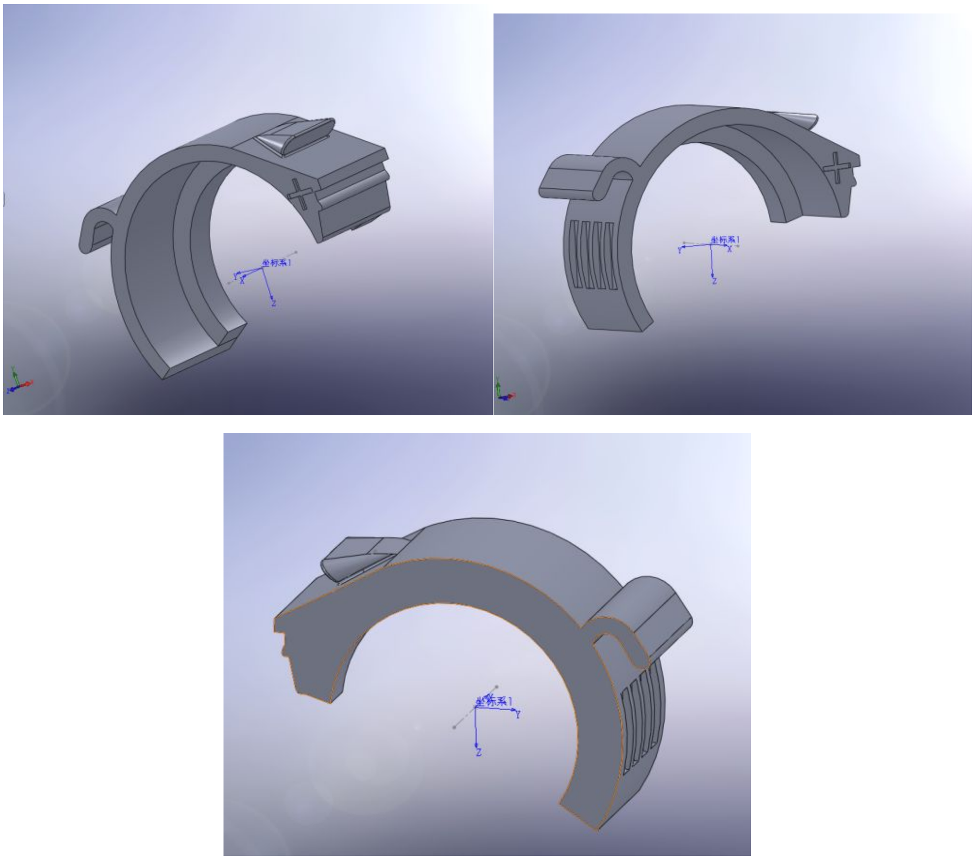


Fig. 3.48 Instrument design-12IS-batterydoor cs74

c. 13IS-batterydoor cs74

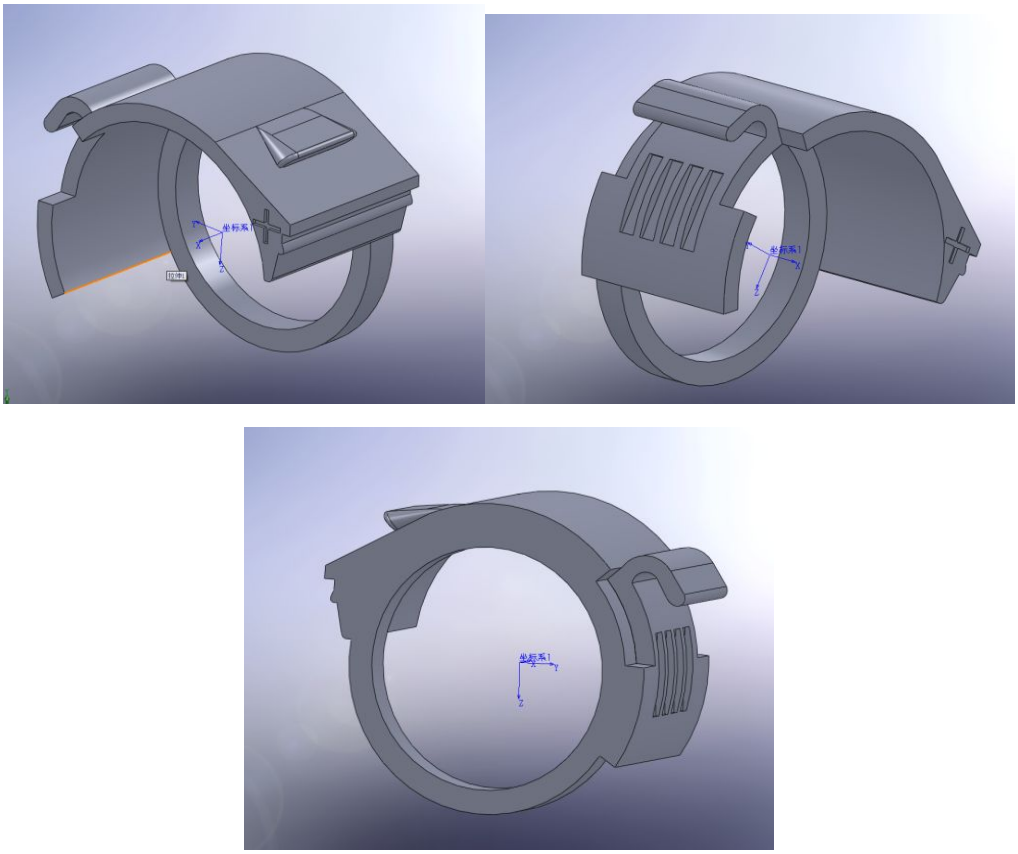


Fig. 3.49 Instrument design-13IS-batterydoor cs74

6. Receiver connector

Sometimes we need two receivers in one ear shell. We can design a connector.

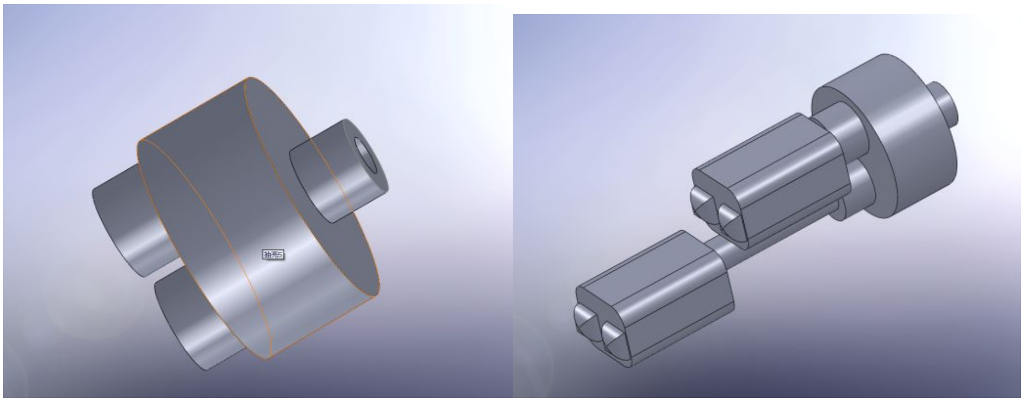


Fig. 3.50 Instrument design-receiver connector

And all these components can be used easily by RSM after copy the *.STL file into the RSM program file.

D. Ear Shell with Faceplate Design

Furthermore, RSM CAM can directly integrate the faceplate design into the shell, so it can be built as one single piece, when in other method the faceplate is still glued on.

Ear Shell with Faceplate Design-Lower Frame

Design a kind of component out of the frame-**lower frame,** and use it instead of the virtual faceplate. The figure below shows what the lower frame like.:

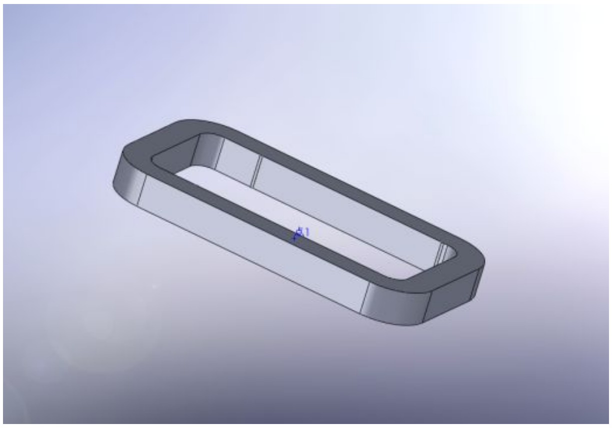


Fig. 3.51 Ear shell with faceplate design-lower frame

The lower frame is designed by **SolidWorks**.

And then using **Magics** to remove the lower frame outer wall, the **Magics** can make the surface open.

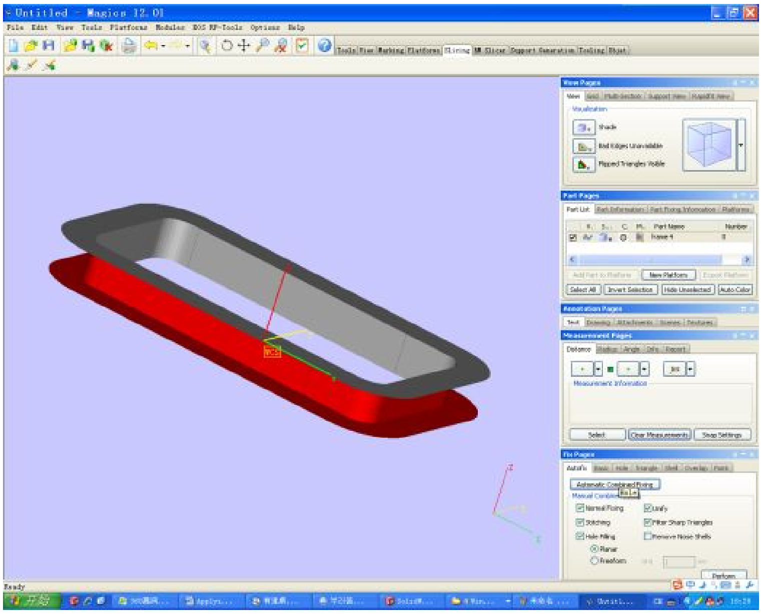


Fig. 3.52 Ear shells with faceplate design-outer walls remove using Magics

In RSM the faceplate step we can choose faceplate preserving merge in integration option. After that we can create a virtual shell which surface is closed to the lower frame, like the figure shows:

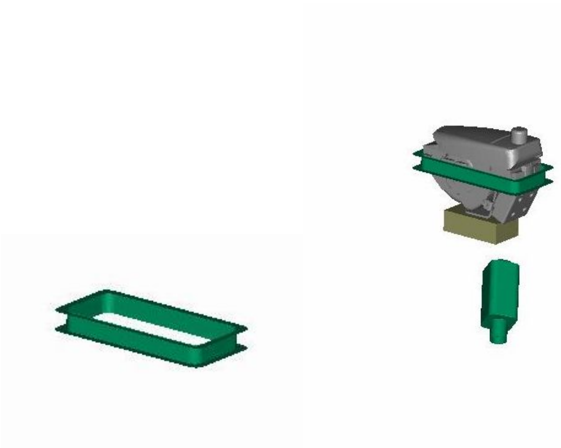


Fig. 3.53 Ear shells with faceplate design-lower frame and components

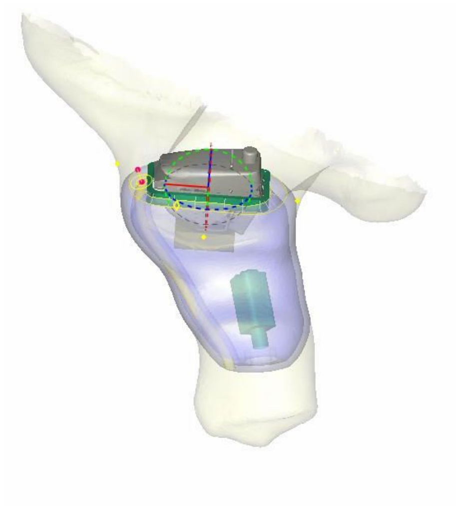


Fig. 3.54 Ear shells with faceplate design-lower frame in ear shell modelling

By using lower frame this virtual component, RSM can create an ear shell need not faceplate anymore. It’s a big improvement, because in traditional ways we need the faceplate parts and glue it to the ear shell like the figure shows:

Fig. 3.55 Ear shells with faceplate design-traditional method ear shell and the faceplate part

But by using the CADCAM method we just need to insert the other elements into the ear shell to finish the hearing aid, this is the virtual shell we finally got (the size and the shape refer to the cu10 faceplate):

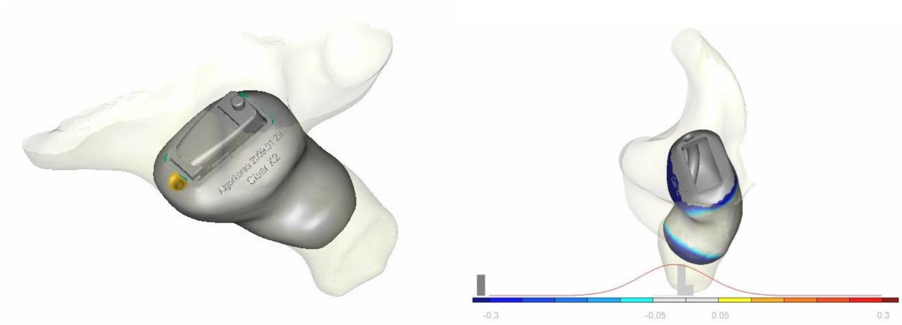


Fig. 3.56 Ear shells with faceplate design-CADCAM method ear shell with faceplate part

After doing that we can build the faceplate and the ear shell as one part. Most of these operations are aided by the CAD/CAM software RSM to make the modeling process easier and time effective.

Virtual modeling of an ear shell is faster and usually it takes only some minutes while the conventional processing consumed hours for that.

E. Shell Building -*Using Rapid Production (RP) Machine*

Printing is the term used for the actual production of the shell or ear mold. Once the virtual design is complete, the shell is produced via the RP machine, resulting in a smooth-textured acrylic shell. The virtual shell is used as the template to “print” the actual shell from liquid acrylic through a rapid prototype manufacturing process. The RP machine can building the shell layer by layer to precisely reproduce the digital impression.

During the printing process, the RP machine uses a laser to harden the photosensitive resin into shells that have been modeled during the modeling stage. The shells are printed in a pool of liquid UV sensitive acrylic along with the receiver bore and vent, and along with the support frame. Thin layers of the acrylic (1/10 mm thickness) are hardened to form the shell. For example: an ITC shell that is 20 mm in total length will require 200 layers. It takes approximately 4-8 hours to complete the printing. After printing, the shell is semi-rigid and requires a final cure under UV light. This process is carried out after the vent and receiver bore is cleaned from the remaining uncured liquid acrylic with a vacuum.

Fig. 3.57 Shell building - the final production hearing aid shell

IV. BTE (Behind-The-Ear) type hearing aid model design

A. Introduction

Digital hearing aids are available in two main types - behind the ear, or BTE where a mould sits inside the ear, connected to the main body of the aid which rests behind the ear; and in the ear, ITE, or in the ear canal, ITC, where the entire aid fits inside the ear. People with very severe hearing loss or narrow ear canals may not be able to use these.

Fig. 4.1 BTE type hearing aid (left) and ITE type hearing aid (right)

Behind-the-ear (BTE) hearing aids fit comfortably behind-the-ear and are attached to a soft custom earmold. With BTE hearing aids, the electronics are housed in a case that fits behind the ear. Sound is directed from the hearing aid, through the tubing, and through the earmold to the eardrum. These hearing aids can be modified with connections to external sound sources such as auditory training equipment, infrared listening systems or television.

BTE hearing aids can provide more amplification than smaller devices due to the stronger amplifier and the larger battery. This style is available in the programmable, digital, and conventional circuits, and in several colors for hair and skin tone matching.

B. BTE (Behind-The-Ear) type hearing aid model

BTE hearing aids have a main shell section, an earmold and a connecting tube. The main shell houses the electronics and the battery – the shell sits at the top of the ear and runs down behind. On the latest hearing-aids the tube that runs from the shell to the ear-piece is very thin and is almost invisible to the casual observer. The design of the earmold varies from model to model; in some it sits in the hollow of the ear, like an ITE; in others it fits more like a ITC aid.

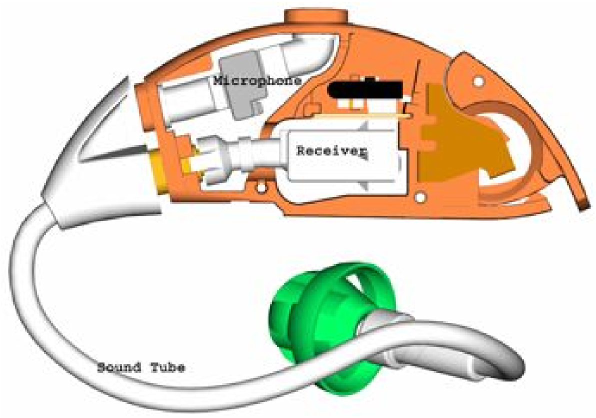


Fig. 4.2 BTE main shell and instrument

A hearing instrument consists of a microphone, amplifier/computer, and receiver, all of which sit behind the external ear. The microphone picks up sound and transmits it to the amplifier/computer, which simultaneously manages feedback suppression, speech enhancement, directionality improvement and noise suppression. The attenuated sound goes through the receiver into a sound tube and comes out through an internal earpiece (green).

C. Key steps of BTE type hearing aid model design

The design of three dimensional objects in a two dimensional medium has shaped products to a large extent. Many objects are designed a certain way simply because they can be drawn in plane views conveniently. This limitation imposes an artificial constraint on the design which can result in either a poor design or expensive experimental iteration.

Step 1: 3D Sketching with Planes

Create an industrial design model using a single 3D sketch and 3D sketch planes.

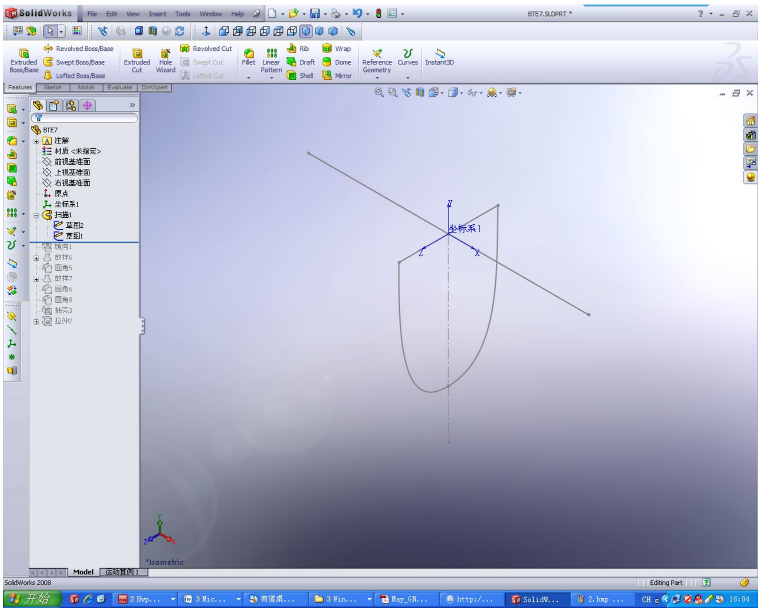


Fig. 4.3 3D Sketching with Planes

- Open a 3D sketch on a selected plane
- Use arcs in a 3D sketch

- Add relations between arcs, splines, and construction lines
- Create a surface loft from a single 3D sketch using contour select

Step 2: Sweep the sketch to build the main body

Use sweep option. This most common usage is in creating cuts around

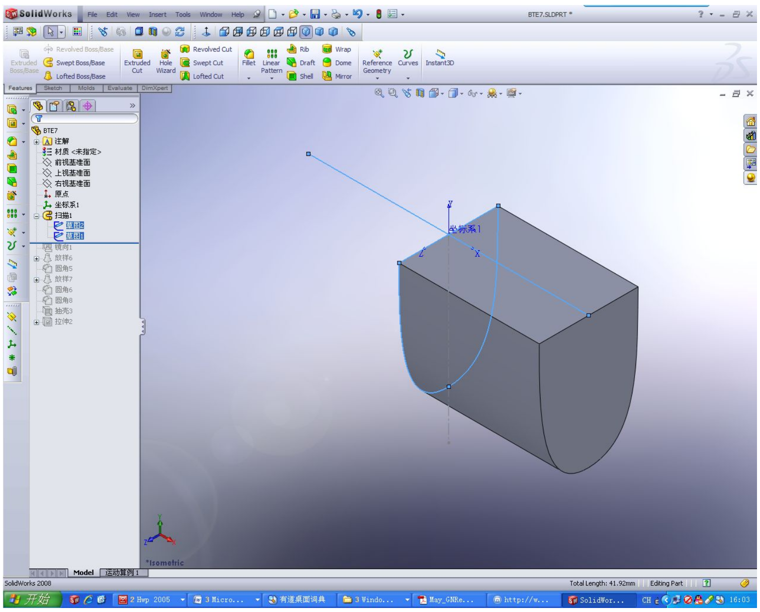


Fig. 4.4 Sweep the 3D Sketching with Planes

cylindrical bodies. This option would also be useful for end mill simulation. Chose curve line to be the profile, the straight line to be the path.

Step 3: Mirror the main body feature

Under Mirror Face/Plane, select the features in the graphics area.

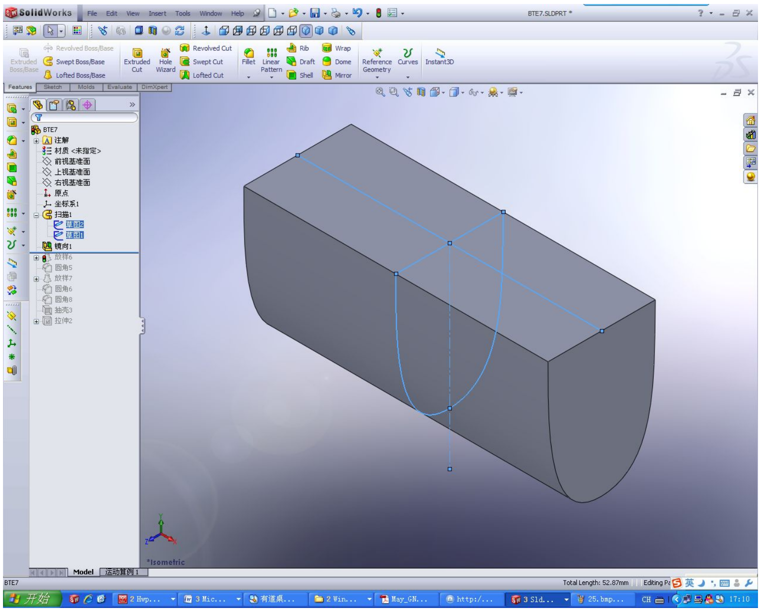


Fig. 4.5 Mirror the feature

Step 4: Make a loft to create the BTE afterbody

Loft creates a feature by making transitions between profiles.

Create the loft using two profiles: the first and the last profiles sketches. Draw a curve connect these two profiles, the curve line will be the path of the loft.

For a solid loft, the first and last profiles must be model faces or faces created by split lines, planar profiles, or surfaces.

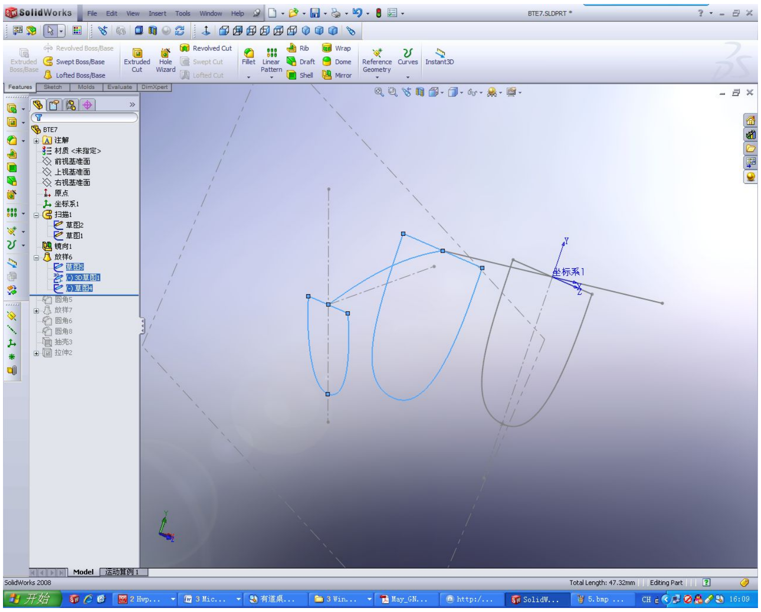


Fig. 4.6 Make a loft-profiles and path

These three blue lines shown in the figure is the profiles and path.

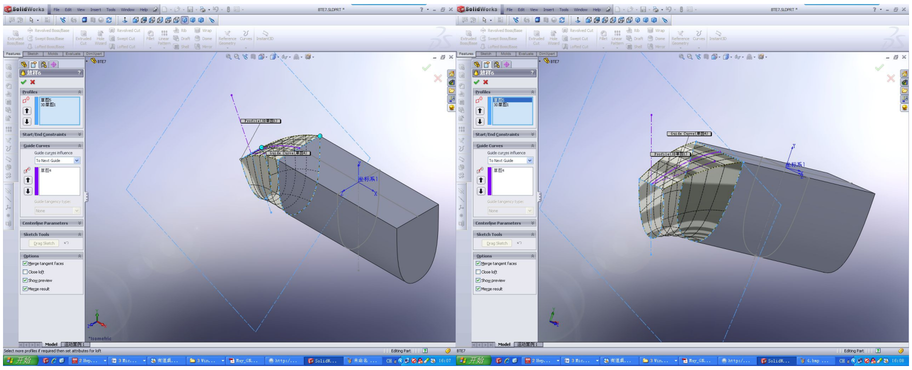


Fig. 4.7 Make a loft

Step 5: Fillet the edges

Chose the top planes edges and the fillet radius is 1mm.

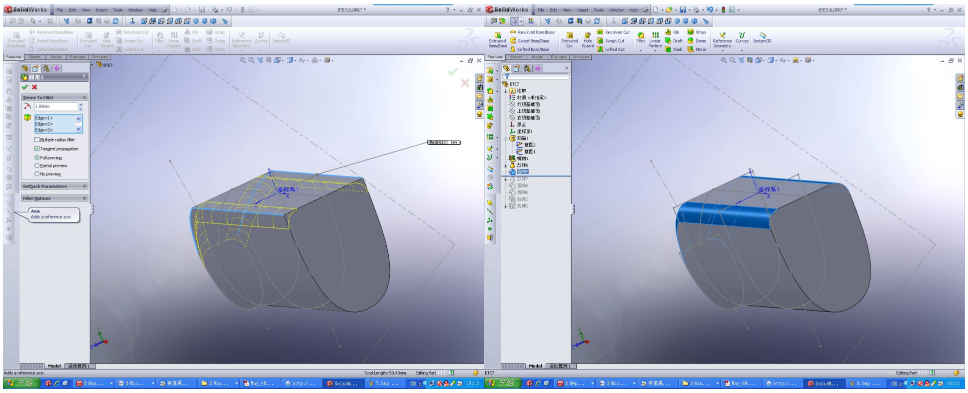


Fig. 4.8 Fillet the edges

Step 6: Make a loft to create the BTE ear holding part

Also we create the loft using two profiles and one path curve line.

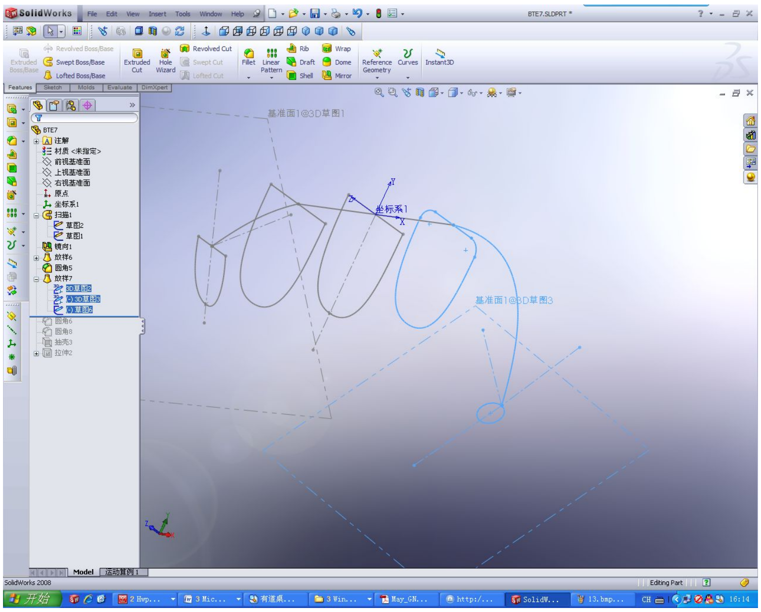


Fig. 4.9 Make a loft of holding part- profiles and path

These three blue lines shown in the figure is the profiles and path.

Draw the section plane of the main body and it is one profile. Draw a circle on a 3D sketch and it is the other profile. The loft path line is the curve which connects the profiles.

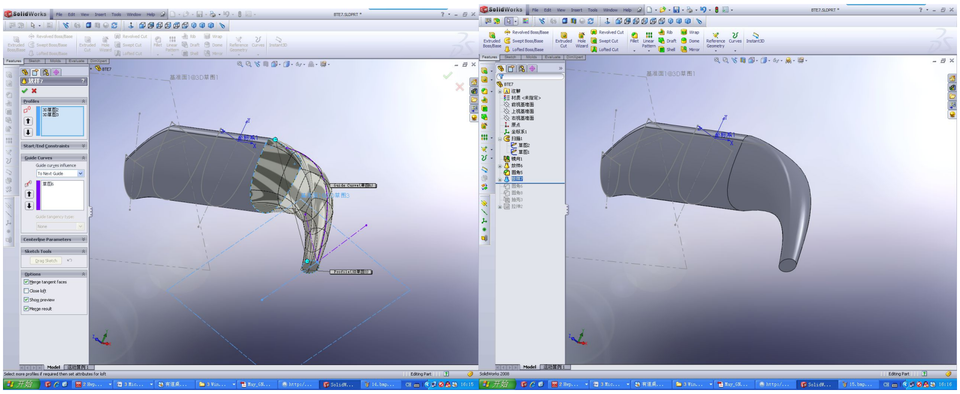


Fig. 4.10 Make a loft of holding part

Step 7: Fillet the edges again

Fillet the back edge and the holding part circle as the figures show:

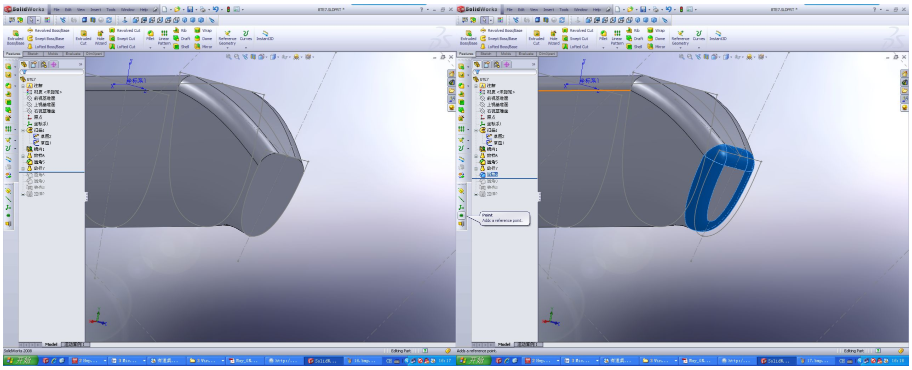


Fig. 4.11 Back edges fillet

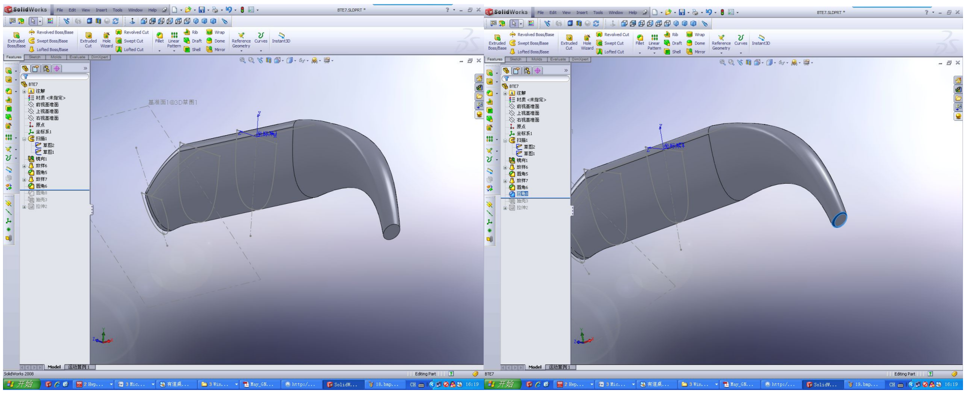


Fig. 4.12 Holding part fillet

Step 8: Shell Features

The shell tool hollows out the mold and creates thin-walled features on the remaining faces. After doing this we can shell a solid part, creating a closed, hollow model.

To create a shell feature of uniform thickness:

In Parameters, set Thickness is 1mm (to set the thickness of the faces).Select Shell outward to increase the outside dimensions of the part.

Step 9: Extruded cut

For this BTE type, there should be a door on the top side to insert the hearing aid instruments and this door also used as the battery door holding the battery. And on the holding part there should be a hole for the tube.

Use Extruded cut to form them.

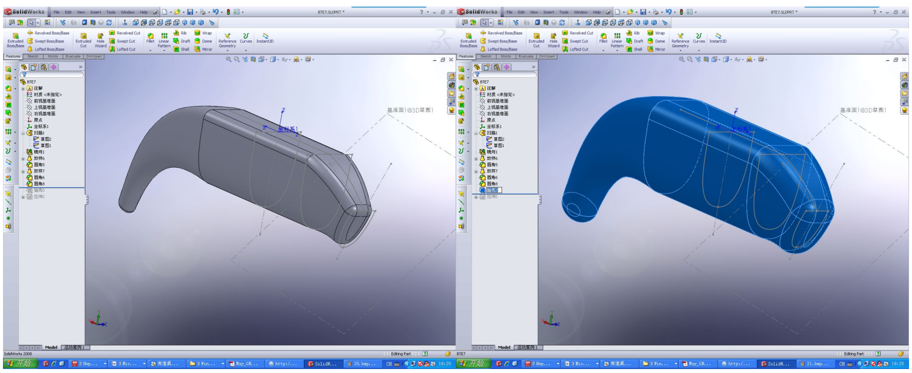


Fig. 4.13 Shell Features-original mold and after shelling

V. Advantages Of The CADCAM Method For Ear Shell Auto-manufacturing

Both conventional and CAM/CAD methods produce shells that fit patients' ears. The main advantage of CAM/CAD processes is the precision at which it captures and reproduces the shape of the ear impression so that the shell can be accurately rendered and efficiently manufactured. Because the shells are manufactured using the same criteria, high consistency can be expected. One can attribute these advantages to the fact that many of the shortcomings of the conventional method are bypassed with the new process.

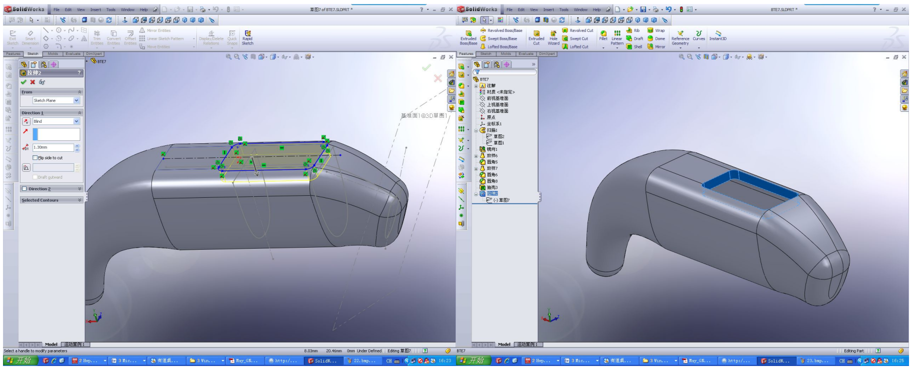


Fig. 4.14 Extruded cut

More Accurate Fit. It was indicated earlier that, because of the curvature of the ear impression and that different parts of it may be immersed in wax for different durations, wax thicknesses can vary. The end result is that, when the waxed impressions are made into shells, some parts of them may fit tighter than other regions. This could result in discomfort.

The advantage of CAM/CAD shells is that waxing is done in the modeling stage where a consistent 0.6 mm increase (or any other magnitude) in thickness is specified over the entire surface of the impression. Because of the consistent thickness, no buffing is necessary on these shells after they are printed. Without the unnecessary buffing and trimming, the retention between the first and second bends and the area medial to the second bend may be improved. This results in a more accurate fit.

Uniform Shell Thickness for Increased Durability. The “pouring” process associated with the conventional method may result in unpredictable thickness of the shell wall. Such variability occurs both within a hearing aid shell and among different hearing aid shells. CAD/CAM method allows the technician to specify the thickness of the shell wall during the modeling stage.

A hearing aid shell that has a uniform thickness increases its mechanical resistance to impacts and potential damage. These shells should break less frequently than conventional shells. This may reduce the number of repairs for broken shells, especially on the posterior wall of the conventional shell where it is typically thinner and more susceptible to wear and tear. If shell modification is necessary for the shells, the uniform thickness also allows the dispenser to apply the same pressure to all parts of the shell during its drilling/buffing without fear of accidental breakage. This should minimize the number of unnecessary repairs.

Consistent Vent Diameter: Vents in conventional shells are made by pouring liquid acrylic over a wire placed at the position of the intended vent in a finished shell. Any bending of the wire will result in a crooked vent tube. This could make cleaning of the vent, or the insertion of plug. Furthermore, incomplete coverage of the wire with the liquid acrylic may result in thinner vent walls along some parts of its length. This could result in breakage of the vent wall when one attempts to enlarge the vent, resulting in an unintentional anti-resonance cavity or a different feedback path that may suggest “internal” feedback.

The consistent wall thickness of CAD/CAM shells means that the walls of the vent have a consistent thickness as well. The diameters of the vents are consistent from the faceplate to the medial end. This ensures the intended performance of the vents and makes cleaning easier and modification less prone to unintentional breakage.

Physical weight/comfort. With a conventional shell, the technician has to excavate the excess acrylic materials on the inside of the shell to make room for the electronic components. This takes time, and the resulting shell may be thicker/thinner than it needs to be depending on the amount of excavated material.

A CAD/CAM shell is designed in the virtual environment during the modeling stage where all the components (eg, vent, ICs, microphone(s) and receiver opening, etc) are laid out for the best utilization of shell space. Thus, the technician working with the shells will not need to drill any holes or excavate any excessive acrylic. This makes the shells lighter. We believe this will contribute to wearer comfort.

Lower Chance of "Internal" Feedback Due to Receiver Placement. An advantage of the Modeling stage in CAD/CAM systems is that the technician visualizes the placement of different components, including the receiver. This minimizes the risk of the receiver pointing at the ear-canal wall (or being misdirected) which may result in feedback. Because the receiver opening has been specified during the modeling stage, the technician does not need to drill/create the receiver opening. An optimal placement of the receiver (and its opening) ensures a more stable position for the receiver. This could reduce the chance of internal feedback from receiver vibrations as a high output is generated.

VI. Conclusion

From the above we get that the conventional manufacturing is a very labour-intensive process, with little scope for automation or information technology. 3D rapid shell molding CADCAM changes this conventional problem by integrating advanced 3D design CADCAM and rapid prototyping technology into an automation process. We can now manufacture hearing aid shells semi-automatically with this technology.

Compared to conventional means of shell manufacturing, hearing aid shells made with 3D rapid shell molding CAD/CAM technology may be less prone to certain repair problems, minimize the need for taking extra ear impressions, and can be produced more efficiently and accurately. Like the application of DSP in hearing aids, this new technology could improve the quality of hearing aids dramatically.

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