Changing with the Times: Applying Digital Technology to Hearing Aid Shell Manufacturing

Digital technology, in the form of CAD/CAM shell-making, is now being implemented in several manufacturers’ products. Here’s what it means and how it will change your fittings.

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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.

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. 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 article addresses these questions using the CAMISHA (Computer Aided Manufacturing of Individual Shells for Hearing Aids) system, a laser-fit technology employed by Widex, as an example. It is important to note that, while this proprietary technology certainly has its own unique features/benefits, this article will try to point out the general attributes of CAD/CAM shell production anticipated throughout the industry.
Conventional Shell 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 (ie, CIC versus ITE):

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

2. **Trim.** The impression is then cut down to an appropriate size for the model ordered (Figure 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 are done.
3. **Wax.** The trimmed impression is now dipped into hot wax (Figure 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” (if any) 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 (eg, 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. Excess 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 #2.** The trimmed and waxed impression is now cast in hydrocolloid (Figure 1d). 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.

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

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 (Figure 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 (ie, 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.

7. **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 (Figure 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.

8. **Vent.** The vent is now installed (Figure 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, 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.

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 smooths 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 (Figure 1i).

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.

The CAD/CAM Method of Shell Manufacturing
Several hearing aid manufacturers have employed digital imaging technique in shell manufacturing. While there are differences among the systems used, they all include the same fundamental stages that are presented here. These stages include scanning, modeling, and printing.

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.
1. Scanning. A 3-dimensional picture of the ear impression is taken (Figure 2a). A 3D scanner scans the ear impression using a laser light source. Because a laser loses its effectiveness in marking the contour of the impression if it is transparent, powder and liquid impression materials should not be used to take an ear impression. Rather, an opaque substance, like silicon, should be used to take ear impressions. The color and viscosity of the silicon material, however, are less critical.

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. 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.

2. Modeling. Modeling is the process whereby the technician (or modeler) takes the virtual image of the impression to create a virtual hearing aid shell (Figure 2b). This is accomplished with 3D modeling software that allows the technician to modify the virtual impression as if it were a real object.

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 are 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 (ie, either rounded or left square). The height of the faceplate and the thickness of the shell is also specified. Afterwards, the technician experiments with different placements of the virtual components (to include IC chips, receivers, microphone, faceplate, vents, receiver tubings, 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.

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.

3. Printing. Printing is the term used for the actual production of the shell (Figure 2c). It is so called because the instructions generated during the modeling stage are now “printed” onto the material that is used to make the shell. There are at least two types of printers, each using a different type of material and process to make the shells:

- In the Stereo Lithographic Apparatuses (SLA) printer (3D System™), a photo-sensitive acrylic resin is used as the materials to make shells. Because this material is very similar to the UV-cured acrylic material used today for conventional shells, it has the advantage that the resulting shells may be modified and treated like any other acrylic shells.

  Figure 3. A tray of finished shells, including the support legs.

  During the printing process, the SLA printer uses a laser (that has a spectrum that includes the UV range) to harden the photosensitive resin into shells that have been modeled during the modeling stage. The laser outlines the shell according to the instructions specified during the modeling stage. Very thin layers of material (1/10 mm thickness) are hardened to form the shell. For example, a CIC shell that is 20 mm in total length will require 200 layers of material to be hardened. This will take approximately 2-8 hours to complete depending on the number and styles of hearing aids being made. To optimize the process, anywhere from 40 to 80 different shells can be printed at the same time in a production run (Figure 3).

  Figure 4. A shell showing an ID tag, vent, and module interface.

  To distinguish among these shells (for different wearers), each printed shell has an internal ID tag (Figure 4) and a faceplate interface in order to ensure that the faceplate is aligned correctly. After the shells are collected, they are cleaned and cured a final time in an UV oven before they are sent to have the faceplates and electronics assembled.

- In the Selected Laser Sintering (or SLS) printing process, nylon powder is used as the shell material. In this process, the software directs a laser source to first outline the shell, one layer at a time, each 1/10 mm thick (thus 200 layers for a CIC shell that is 20 mm in length). This forms a “ring.” Then the laser is directed through a carbon-dioxide (CO2) medium which melts the nylon powder around the ring and immediately cools and hardens it. Because of the melting and cooling, shells made with SLS have a slightly
rougher surface than those made with the SLA process. Furthermore, because nylon melts sooner than acrylic, care should be exercised when modifying (like buffing or drilling) shells made with SLS.

4. Installation. The technician aligns the faceplate and electronics module interface to the exact position specified during the modeling stage. The assembly process with CAMISHA shells is designed to be simpler and can be achieved more efficiently than with conventional shells because the vent, wax-guard, receiver tubing, etc, are already modeled into the shell during the modeling stage. The technician only needs to drill a hole in the faceplate for the vent opening. No buffing is required. Furthermore, the bushing for the wax guard is secured to the shell without adding any acrylic material. The receiver can simply be placed into the shell without any excavation of excess shell material. The electronics module and the battery/microphone assembly can be installed simply.

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. Figure 6 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.

Figure 7. Picture 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 7). 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.

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 earmold impression or an error by the technician during the modeling stage. 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 (eg, 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.

Advantages of CAM/CAD

Both conventional and CAM/CAD methods produce shells that fit patients’ ears. The main advantage of CAM/CAD processes, like CAMISHA, 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.

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 (see Figure 1c). In an internal study of 100 randomly sampled waxed ear impressions, the thickness of the wax varied from 0.54 mm to 1.01 mm on the same impression. 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 0.3 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. An internal study conducted at the Widex shell lab showed that, of 32 CIC conventional shells that were randomly selected and examined, the thickness of the shell wall varied from 0.1 mm in one CIC to 2.4 mm in another CIC. The shells varied by as much as 2.3 mm in thickness within the same CIC.

CAD/CAM systems allow the technician to specify the thickness of the shell wall during the modeling stage. Typically, a 0.7 mm thickness is specified to approximate the average thickness found in conventional shells. During the same internal study of CIC shells, 32 CAMISHA shells were found to vary by only 0.3 mm in thickness at different locations across shells. No shell walls were thinner than 0.7 mm and, on some CICs, the wall thickness was measured to be 1.0 mm.
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 (see Figure 1h). Any bending of the wire will result in a crooked vent tube. This could make cleaning of the vent, or the insertion of Select-A-Vent plug, difficult. 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 diameter 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. In the same internal study comparing CIC shells made with CAMISHA and with the conventional method, the new shells were lighter than conventional shells by about 30%. 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. Likewise, the metal bushing that holds the Ceru-stop wax guard (in CAMISHA) is simply put into place. 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.
More Available Gain Before Feedback. The more accurate fit and the better placement of the receiver would suggest that hearing aid shells made with this technology will allow wearers more available gain on the hearing aids before feedback occurs than shells made with a conventional method. To examine such a possibility, we conducted a small study where we compared the available gain before feedback on a Senso C+ ITE hearing aid with shells made three ways: 1) The conventional method; 2) CAMISHA using SLA technology (method adopted by Widex); and 3) CAMISHA using SLS technology. Earmold impressions were taken of 10 hearing-impaired subjects and the same impressions were used to make the three types of hearing aid shells. Other than the technology used to make the shells, all the hearing aids were identical in dimensions and similar in electroacoustic characteristics. (Authors’ note: Because the shells made with the conventional method were specially made for research purposes, the variability from shell to shell that may occur in real-life shells may not be reflected fully in this study. Thus, the results obtained with the conventional shells should be viewed as the “best case” scenario.)

Several evaluative measures that focused on the impact of the goodness of fit were applied. This included the in-situ thresholds measured with the hearing aid, available gain of the hearing aid before feedback, insertion gain for conversational sounds, speech recognition at a low input level, subjective comfort, and potential occlusion. Except for available gain measures, no significant difference was found among the hearing aids made with these three shell technologies. In other words, conventional shells (made for research purposes), shells made with SLA, and shells made with SLS did not differ in the in-situ thresholds measured, the amount of gain provided for conversational sounds, speech understanding at a low input level, occlusion, and real-life subjective preference.

However, the three hearing aids did differ in the amount of available gain before feedback. This index was determined during a feedback test whereby a soft, internally-generated complex signal was amplified by the increasing gain on the hearing aid until feedback was registered. The maximum gain level before feedback occurs was the “maximum available gain.” For hearing aids with the same coupler gain, the aids that have the least leakage have the highest maximum available gain before feedback. On a nonlinear hearing aid, this index reflects the gain available for low-input sounds.

Figure 5. Available gain in each of the low, mid, and high frequency channels among the conventional, SLA, and SLS shells.

Figure 5 compares the maximum available gain across the three frequency channels among the three shell technologies. For the low frequency channel, the SLS method yielded about 2 dB more gain than the SLA method, and as much as 6 dB more than the conventional method. On the other hand, for the mid- and high- frequency channels, the SLA method yielded about 3 dB higher gain than the SLS method, and 5 dB higher gain than the conventional method before feedback occurred.
Figure 6. Real-ear output of a hearing aid made with CAMISHA technology measured underneath the hearing aid and through the vent.

Conclusion

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.

Looking into the future, this technology will continue to refine itself in the complexity of the software manipulation, as well as the ease and accuracy in which the scanning is done. Regardless of how the hearing aid shell is manufactured (ie, conventional or digital), one must always remember that an accurate ear impression is the first crucial step in ensuring an accurately fit hearing aid shell.

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