3D CAD/CAM Manufacture of Autologous Otologic Grafts: Human Cadaver Trials

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Abstract

Objectives: Conventional middle ear prosthetics, including total ossicular replacement prostheses (TORPs) and partial ossicular replacement prostheses (PORPs), are expensive, require large inventories for otologic surgery services, and carry the risk of extrusion. Autologous bone and cartilage can be used for many of these applications, but they require expensive operating room time for carving to the appropriate shape and size. Computer assisted manufacture on demand in the operating room (subtractive 3D CAD/CAM) can quickly produce accurate bone and cartilage autografts on demand, resulting in significant cost savings. Such a technology can save money by reducing operating room time and reducing the need for expensive inventories of various shapes, sizes, and types of prosthetic devices. Since autologous materials are less likely to extrude or cause other problems such as infection, this could also reduce costs. We undertook this study to build on our previous experiences with machinist's wax and bovine bone materials.

Study Design: Prospective human cadaveric laboratory study.

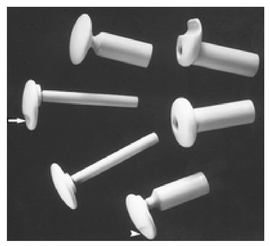
Methods: The methods of our previous study with machinist's wax and bovine bone were adapted to the present study. A Roland MDX-40A 3D milling machine (Roland DGA, Irvine, CA) was utilized. The CNC-RP approach features completely automated fixture planning, tooling and setup planning for creating a part directly from a CAD file. The use of a fourth (rotation) axis eliminates the need for reclamping of the part. For each orientation, all the visible surfaces are machined while a set of sacrificial supports keeps the part connected to the uncut end of the stock material. Once all the operations are complete, the supports are severed and the part is removed. In the present study, cadaveric human occipital bone was utilized. A Richards PORP was selected as an initial example to demonstrate the process. The dimensions of the Richards PORP were imported into an .stl file. The .stl file was opened in the SRP player software included with the MDX-40A machine. The SRP player software orients the part, generates toolpaths and sends it to the MDX machine. The part is then milled by subtraction. Cadaveric occipital bone was selected because it is inexpensive and commercially available. It has similar machining characteristics to cadaveric temporal bones but is less costly and more available.

Results: Cadaveric human occipital bone utilization resulted in reliable production of prototype middle ear prosthetics, in this case a Richards PORP. The size of the implant was varied to show how the implant can be customized.

Conclusions: Subtractive 3D CAD/CAM can potentially produce accurate autografts in the operating room environment. This subtractive technique differs from additive 3D printing in that the material is carved down from an initial block of material, rather than being printed by additive application of materials such as resin or plastic. This technology can save money on prosthesis costs, reduction of inventory, reduction of operating room time and reduction of complications. Autografts are less likely to cause extrusion or infection. Further research on prospective surgical trials is indicated.

Conventional Middle Ear Prosthetics

- Expensive
- Hospital Inventory
- Extrusion/Infection
- Cartilage layer often needed

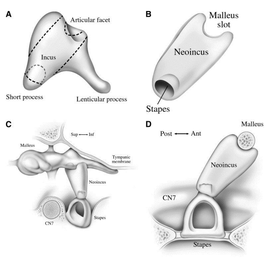


Homograft Materials

- Cadaveric sources
- ?risk of infectious disease transmission (controversial)
- Expensive
- Limited supply
- Proper storage before use

Autologous Bone and Cartilage

- No need for inventory
- Free
- Less extrusion and infection
- BUT need expensive O.R. time for carving/cutting/ fabrication
  *(?implantation cholesteatoma)



3D CAD/CAM Can Save Money

- No hospital or surgicenter inventory required
- Reduced OR time
- Reduced extrusion/infection rates so fewer revision surgeries
- *Can possibly also produce additional revenue - ?new CPT code 20900-xx: "Computerized Bone Graft"

Methods

- Roland MDX milling machine
- Now being used for production of orthopedic allografts
- Machinist's wax and human cadaveric occipital bones used for proof of concept

Subtractive Rapid Prototyping (SRP)

- 3 axis CNC milling machine
- 4th axis for multiple orientations
- Creates a part directly from a CAD file
- Dimensions are imported into an .stl file
- .stl file opened with SRP player software
- SRP player orients the part and generates toolpaths
- Sent to MDX machine
- Part is milled by subtraction

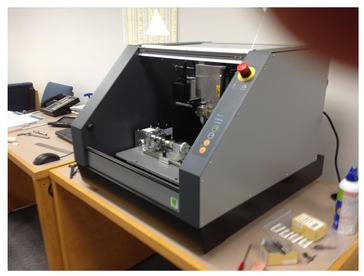


Figure 1.

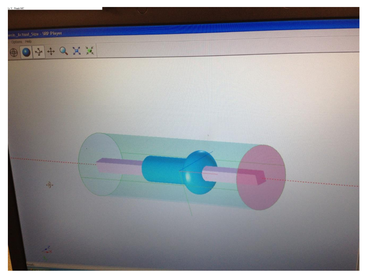


Figure 2.

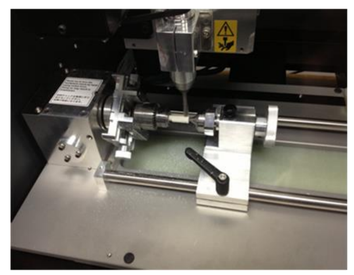


Figure 3.

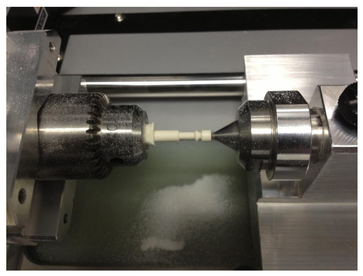


Figure 4.

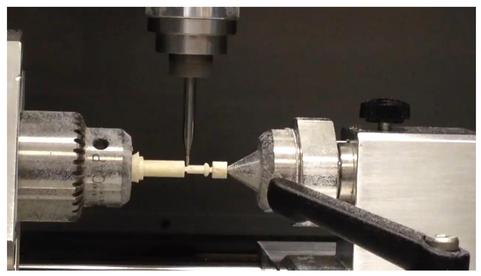


Figure 5.

Figure 6.

Results

- Machinist's wax and human cadaveric occipital bone utilization resulted in reliable production of prototype middle ear prosthetics for proof of concept (Figure 6).
- "Ultra-smooth" surfaces suggest that lower resolution can be used which would be even faster.

Conclusions

- Subtractive 3D CAD/CAM can produce accurate autografts in the OR environment
- Technology can save money on prosthesis costs, reduction of inventory, reduction of OR time and reduction of complications
- Less likely to cause extrusion or infection
- Further research on human cadaveric materials and prospective surgical trials
- Smooth surfaces from computerized milling may address "implantation cholesteatoma" (controversy)

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Disclosure

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