



Increasing Efficiency, Repeatability, and Accuracy in Prosthetics and Orthotics Through the Use of CAD

Many functions in today's O&P office are performed by hand. These processes, such as fabricating prosthetic sockets and recording patient data, are often tedious and susceptible to human error. In some cases, they are inconvenient and even uncomfortable for the patient. Most of these processes can be improved through the use of a CAD (Computer Aided Design) system, allowing the prosthetist to spend more time on patient care and less time on tedious tasks.

Documenting

Many aspects of the creation of a prosthesis or orthosis involve recording of data. In most offices, measurements are recorded on a paper form, and information about the patient's condition is jotted down in a manila folder. When information must be transferred from one person to another, the potential for misreading a colleague's handwritten notes is always a possibility.

Some portions of the process are never recorded at all. Instructions given by the clinician to a technician for modifying the model are likely relayed verbally and never recorded in the patient's file, allowing for the possibility of misunderstanding. Complete and accurate information about a model shape is rarely measured and recorded.

A complete CAD system will allow the clinician to enter the patient's information directly into the software in a user-friendly, menu-driven format to reduce the possibility of errors. The shape of the model and a list of its modifications are stored in the computer for easy reference at any time. Requests for data from third-party payors, doctors, or other parties can easily be met with a few clicks of the mouse.

Measuring

The first step in creating a prosthesis or orthosis is to measure the patient. Typically the lengths and circumferences of the applicable body part are measured with a measuring tape. Depending on whether the tape is held loosely or tightly against the body, or whether the tape is held at a slight angle, these measurements can differ significantly. Two people can measure the same patient, one immediately after the other, and obtain different sets of numbers.

Without a consistent measurement system, it is difficult to achieve consistent outcomes. How is it possible to correctly assess changes in the patient's condition over time? What happens if a patient is seen by different clinicians from one visit to another, each of whom has a slightly different technique?

These human variables can be eliminated by obtaining measurements electronically through the use of a digital, three-dimensional shape capture system. The measurements are entered directly into the patient's record in the software, eliminating the possibility of writing down or copying the wrong numbers.

Measurements acquired through such a precise electronic method are much more repeatable and reproducible than those that are collected by hand. (A result is *repeatable* when, each time the clinician measures the same patient using the same equipment, the measurements are the same; a result is *reproducible* when the same measurements are obtained by different clinicians on the same patient using the same equipment.) Regardless of how many times a clinician measures the patient, or how many different clinicians measure the patient, the results are accurate every time. (Accuracy is how close the measured value is to the actual value.)

The importance of using accurate measurements cannot be overstated; if the process begins with inaccurate data, then there is little chance that the final product will fit properly. Time and effort will be required to address a problem that could have been avoided if a more accurate method had been used.

Casting

The process of accurately capturing the patient's shape is crucial for providing a comfortable prosthesis or orthosis. Just as measurements can vary depending on technique, so can a cast. The plaster casting material can be stretched loosely or tightly, and the prosthetist's hands can apply varying levels of pressure.

Casting is a lengthy process, requiring the patient to remain in one position for several minutes while the plaster is applied and then allowed to dry. The transfemoral (above knee) process can be particularly awkward, requiring the patient to stand with the residual limb inserted into a fixture until the plaster dries. The messy nature of plaster also means that, in addition to the

time required for taking the cast itself, there is also some time required for preparation and cleanup. The process doesn't end when the plaster cast is removed from the patient; the cast, which is a negative of the patient's shape, must then be used as the basis for creating a positive model out of plaster. The total time for the process is increased again as the plaster is mixed, poured, and allowed to dry.

With a successful CAD system, plaster is eliminated entirely. The time for the shape-capture process is reduced significantly; only a few minutes are required for the entire process. There is no preparation aside from perhaps applying a sock or other covering to the body, and there is no drying or cleanup required. There is no additional time required at this point for the creation of a positive model. The three-dimensional shape of the limb is created in the software almost immediately after it is captured.

As with the measuring process, the shape capture process becomes repeatable and reproducible through the use of CAD. The possibility that a particular clinician's casting technique could affect the outcome is no longer an issue.

Modifying the Model

The process of creating a prosthesis or orthosis always involves modifying the model to achieve the desired socket or brace design. The typical method involves using an assortment of tools such as a file, a piece of sandpaper, and even a tongue depressor to remove, apply, or shape plaster in specific areas to achieve the clinician's goals.

Applying/removing plaster by hand is extremely imprecise and tedious. For example, suppose a clinician needs to reduce a positive model by 5% in order to make a prosthetic socket for use with a specific type of socket interface. The prosthetist must shave plaster off of the model in a manner that is as symmetric as possible. He must stop periodically and re-measure the model (using that aforementioned measuring tape) to determine how close he is to his goal measurements, then repeat the process until the goal is achieved. An infinite number of different reductions of different amounts in different areas can result in the desired 5% reduction, with some areas being reduced more than 5% and other areas less than 5%. Quantification of the shape of a model is extremely difficult and is rarely even attempted.

If, in the course of making a particularly extensive modification, a clinician makes a mistake that cannot be easily corrected, he must start over by making a new positive model from plaster.

A user-friendly CAD system replaces the primitive plaster-related tools with electronic tools. The clinician is able to use his skill in determining the location and extent of the modifications, but he is able to obtain the result with a few clicks of a mouse instead of with the labor-intensive plaster process. The modifications are much more precise than they could ever be when performed by the human hand. A 5% volume reduction is accomplished in seconds, and it is exactly 5% over the entire model. Also, there is no chance of ruining a

positive model with an inaccurately performed modification; CAD allows you to simply erase a modification and try it again. A thorough CAD system also maintains a list of the modifications that are made, providing a record of each step that was used to design the orthosis or the socket for this patient.

Fabricating

Once a plaster positive model is modified to achieve the desired design, it is used as the basis for fabricating the orthosis or prosthetic socket. Depending on the facilities and workload of the clinician's office, this fabrication can be done in-house, or the plaster model can be shipped to an outside fabricating facility.

A prosthetist with a complete CAD system can either fabricate the device in-house by taking a few minutes to carve a foam positive model on a carving machine and producing the socket or orthosis from there, or he can e-mail the CAD file to a fabricating facility, in which case the file is delivered in seconds without the costs associated with shipping a plaster cast. Precise instructions for fabricating and shipping can be included along with the file.

If the clinician performs an initial fitting on the prosthesis or orthosis and finds that the fit is less than optimal, he can easily review both the modification steps and the fabrication instructions to determine where an error may have been made. Did he mistakenly enter the wrong amount of ply reduction? Did the C-Fab install the wrong distal adapter? Such items can easily be confirmed by consulting the patient's comprehensive electronic file.

Building a Prosthesis

Fabricating a socket, while crucial, isn't the only step in making a prosthesis. The prosthetist must also select all of the components that are attached to the socket to make the complete leg. Normally, a prosthetist would flip through catalogs, refer to charts to select appropriate weight and activity options, and jot down part numbers to give to his office staff so that an order can be placed. This method requires an investment of time to research the appropriate options for each patient and, as with the other manual processes described here, allows for the possibility of human error.

A truly effective CAD system will improve the efficiency and accuracy of not just the socket fabrication process, but of every step in the creation of the prosthesis -- including component ordering. Because all of the patient data that is required for selecting components is already entered into the software, it is a logical step to use that data for selecting components and submitting orders. The software should be able to rule out components that are unsuitable because the patient is too heavy, too active, or has too little space between the limb and the floor. The prosthetist is then able to use his expertise to select from a short list of appropriate components.

Monitoring the Fit After Delivery

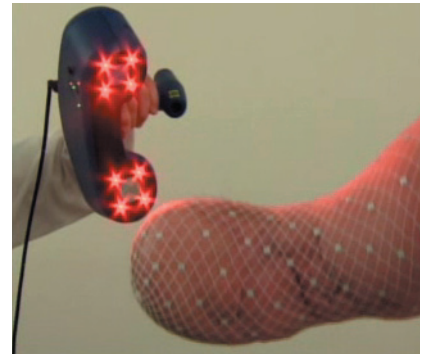
Most amputees experience a change in the shape and/or volume of the affected limb over time. Sometimes this change is minor enough to be addressed through a simple adjustment to the socket or brace, but in some cases the change is drastic enough that a replacement socket is required. It is critical that clinicians be able to clearly justify a socket or brace replacement based on exact patient information. Simple handwritten notes in a file do not accomplish this task, and certainly it is impractical to ship plaster models to prove a change in size or shape.

A well-designed CAD system allows the prosthetist to compare one file to another to show the change in the patient's shape over time. The required documentation can be easily printed out and submitted whenever justification is necessary for reimbursement. Although reimbursement is probably the most notable instance in which detailed documentation is required, most facilities will find that this level of record-keeping is invaluable in many aspects of their business.

The OMEGA Tracer System

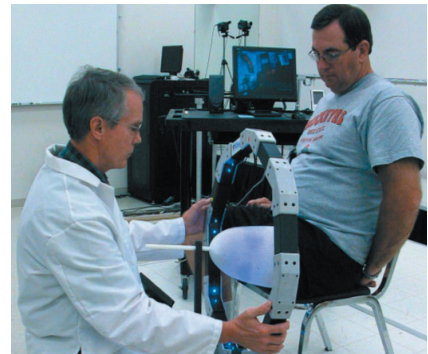
For business owners seeking to increase the productivity and performance of a prosthetic or orthotic facility, Ohio Willow Wood offers the OMEGA Tracer System. This CAD system provides all of the features described in this document that are necessary for increasing efficiency and accuracy in all aspects of prosthetic and orthotic care:

- The system provides a complete range of prosthetic functionality (transtibial, transfemoral, transhumeral, and transradial) along with spinal, AFO, and cranial orthoses capabilities.
- Patient data is entered directly into the software through a series of user-friendly screens, producing a standardized set of information and eliminating the need for handwritten notes.
- Once the data is entered, there is no need to record it again. Each process, from model creation through component ordering, references the same data.
- Three highly accurate shape-capture devices are available to the prosthetist for capturing a three-dimensional shape:
 - **OMEGA Scanner:**
 - non-contact, optical, hand-held laser scanner
 - accurate to +/- 0.5mm
 - provides a high level of detail for capturing deep scars and invaginations
 - designed for use with transtibial, transfemoral, transhumeral, transradial, and cranial shapes



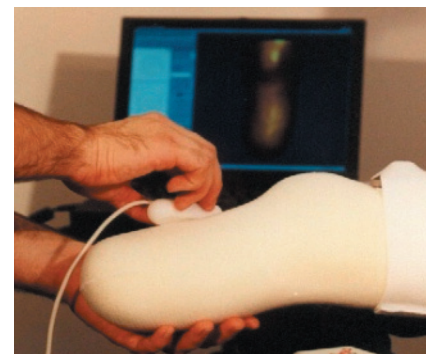
***How it works:** The OMEGA Scanner uses a pulsed crosshair laser to determine the contours of the surface being scanned. It also uses LEDs to illuminate reflective targets on the surface so that digital cameras in the scanner can record the position of the targets in space.*

- **OMEGA T-Ring:**
 - ring-shaped, non-contact, optical scanner
 - accurate to +/- 1.5mm
 - shape capture requires only a few seconds
 - designed for use with transtibial and transfemoral shapes



How it works: The OMEGA T-Ring projects lines onto a white sock on the patient's limb so that its four synchronized electronic imagers can "see" the lines and capture the 3-D shape.

- **Tracer Pen:**
 - used for "tracing" the shape of the limb
 - can also be used for tracing the shape of existing sockets for duplication
 - designed for use with transtibial and transfemoral shapes
 - with the caliper attachment, can be used to take and automatically enter measurements for the creation of an AFO



How it works: A transmitter sends a signal that is picked up by the Tracer Pen and by a sensor that is strapped to the patient's limb. As the clinician moves the pen over the surface of the limb, a control unit determines the location of the Tracer Pen in space and conveys this information to the software.

- All three hardware devices capture the entire three-dimensional surface of the limb in a fraction of the time that is required when using plaster.
- None of the hardware devices require the patient to stand; all can be used with the patient in either a sitting or a prone position. No uncomfortable fixtures are required.
- A “shape creation” method is also available, in which the software applies the patient’s measurements to a “template” to create a custom shape. This method of using software to calculate the model is applicable for spinal, AFO, and many above-knee shapes.
- The amount of time required for using plaster casting versus two of the OMEGA Tracer methods for AK and BK prostheses has been documented as follows:
Times include preparation, modification, and positive model fabrication.
 - *Below-knee prosthesis:*
 - Casting -- 70 minutes
 - OMEGA T-Ring -- 22 minutes
 - *Above-knee prosthesis:*
 - Casting -- 1 hour, 45 minutes
 - OMEGA T-Ring -- 40 minutes
 - AK By Measurements -- 35 minutes
- The software features an extensive set of modification tools to allow the clinician to make any necessary modification.
- In addition to basic tools that allow functions such as carving, building up, and smoothing, the software includes more than 70 other tools. Among them are:
 - *Adjust Tool:* allows adjustment of circumferences, volumes, APs, and MLs
 - *Alignment Tool:* allows bending, flexing, rotating, shifting, or tilting of the model
 - *Ply Tool:* adds or subtracts plies to the model
 - *Shift Area Tool:* works like a virtual heat gun to move a selected portion of the model
 - *Symmetry Tool:* copies, mirrors, or averages two sides of the model
 - *Trimline Tool:* allows you to draw a trimline on the model
- Many of the tools are specific to certain types of models (such as Lateral Support for AKs, and Plantarflexion for AFOs) and are grouped accordingly for ease of use.
- None of the software tools require more than a few clicks of the mouse to achieve the result. The three-dimensional model can be viewed from any angle and in a variety of modes (solid, wireframe, etc.) to suit the clinician’s needs.

- The software tools can be used to create any modification that is possible in plaster, and in some cases can be used for functions that are NOT possible in plaster.
- Logs of each modification of each model are automatically recorded, building a comprehensive record of every step taken to achieve the appropriate design.
- An “undo” button on the modification screen allows the clinician to immediately correct a modification that did not generate the desired result.
- Modifications are precise: the exact amount of increase/decrease, abduction/adduction, flexion/extension, etc. can be entered with the keyboard or selected with a slider bar.
- The “Dual Model View” tool allows prosthetists to easily compare one model to another to document any change in shape or size.
- Measurements, shape files, and other information can be quickly printed out and submitted for reimbursement purposes.
- Patient shapes are stored by saving the files in the computer, not by keeping bulky plaster models on shelves.
- Fabrication options include the OMEGA Fab facilities for outsourcing of fabrication needs, or the OMEGA Carver for in-facility use. The clinician is not required to use one specific Central Fab facility.
- When sending a file to a C-Fab, the clinician can include detailed fabrication and shipping instructions so that the C-Fab staff will have all the necessary information without having to call and confirm.
- Electronic component ordering allows the clinician and/or office staff to select products from menus to reduce the possibility of order errors. For example, the part number for a product contains various digits denoting size, color, thickness, and other options. With handwritten orders, digits can be transposed or written incorrectly. With OMEGA Tracer, the clinician simply clicks on the desired options from the menus, and the software builds the part number and enters the item into the user’s order.
- The software compares the available components with the patient’s clinical information and eliminates from consideration those that are unsuitable due to weight, activity, or clearance restrictions.
- If a check socket requires more modification than can be achieved with a quick shot of the heat gun, the prosthetist can quickly pull up the patient’s file and easily make the necessary changes to the shape.

- Component orders can be easily tracked, allowing the office staff to schedule appointments without having to make numerous phone calls to determine when the components will be available.
- For complete office-wide efficiency, the system can be integrated with administrative software solutions such as the OPIE Patient Management Suite.

Additional Benefit: Custom Components

The OMEGA Tracer System features another capability that sets it even farther apart from other CAD systems: it allows clinicians to create custom liner interfaces for their patients. In the case of a uniquely-shaped or hard-to-fit patient, the prosthetist can now design a liner to fit the exact shape that was captured with the system. The file can be e-mailed to Ohio Willow Wood, where the custom interface product is manufactured within 48 hours. These custom interfaces can be created for both lower and upper extremity amputees.

Summary

The OMEGA Tracer System is the solution for prosthetists seeking to increase the efficiency, repeatability, and accuracy of all aspects of their business. Designed to eliminate mundane tasks from each step of the process from data recording to model rectification to component ordering, OMEGA Tracer allows patients to receive their prostheses without spending hours away from home or work, and helps prosthetists to make productive use of their valuable time.

Ohio Willow Wood is an innovative industry leader in the manufacturing and distribution of prosthetic products, including the Alpha® family of liners and the Pathfinder® II foot. Founded in 1907, Ohio Willow Wood is headquartered in Mt. Sterling, Ohio. For more information about Ohio Willow Wood and its products, call 1-800-848-4930 or visit www.owwco.com.