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The use of CAD/CAM technology in prosthetics and orthotics—Current clinical models and a view to the future

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Abstract—This report examines the current clinical uses of CAD/CAM in prosthetics and orthotics. We conducted interviews to contrast patterns of CAD/CAM use in different private practice settings, at two different teaching institutions, and within two large Prosthetic and Orthotic delivery systems. Investigation into these patterns of use has revealed several lessons. First, there currently exist several very different models of use in clinical practice and these different models will most likely continue. The clinical models range from all traditional techniques with no use of CAD/CAM, to full in-house suites of CAD/CAM equipment with extensive utilization, to a simplified office with minimal in-house equipment and minimal fabrication and a near total dependency on central fabrication. Second, a growing number of prosthetic and orthotic devices are successfully being fabricated and fit with CAD/CAM technology after starting the process with simple measurements instead of casted, scanned, or digitized exact anatomic data. Starting the CAD process with "by-the-numbers approach'' has revealed the reality that for some devices, the "input" needed to define the shape of the residual limb or torso, may not need to be as accurate as originally thought. Third, the fabrication techniques that are currently being used with CAD/CAM systems are still rather traditional techniques. Most devices are still laminated or formed over computer carved models. Although research continues into advanced fabrication techniques, the prosthetics and orthotics industry has not yet taken advantage of the possibilities in the computer-assisted manufacturing side of the equation. Finally, the business of manufacturing and selling up-to-date CAD/CAM equipment and software has a tremendous impact on how this technology is used in prosthetics and orthotics. The size of the prosthetics and orthotics industry and the potential number of customers for major equipment are relatively small. Being in the business of providing the advanced CAD/CAM systems of tomorrow is an expensive and difficult proposition. Current users of full in-house CAD systems have expressed concern that upgrading equipment and software might not be economical with today's decreasing revenues. For all of these reasons, many believe that the number of practitioners who use a central fabrication model will grow more rapidly than the number of practitioners who own and operate a full in-house system.

Key words: *CAD/CAM, orthotics, prosthetics.*

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INTRODUCTION

For centuries, the fabrication of the prosthetic socket has been a careful and handcrafted art attempting to create a comfortable, supportive, and functional socket for the residual limb. Through this socket, the body's weight is transferred to the remainder of the prosthetic device and to the ground. It is the single most important part of a prosthetic device, and the most individual and custom-made part of the prosthesis. As one would expect, there currently exists a tremendous range of techniques, styles, and philosophies on how to best create the socket.

An exact mold of the residual limb is not a good socket. The socket must be accurately indented in areas that can better tolerate the transfer of forces, and the socket must be relieved out away from the residual limb in areas that are less tolerant of force and pressure. These special areas of the socket that require modification are called regions.

Automated technology begins with obtaining an accurate and reproducible digital representation of the amputated limb, and transferring this digital image into a computer (1,2). Researchers still debate the ideal way to "digitize" the residual limb, whether the limb should be molded with a cast or not, and whether the anatomic data should be obtained while weight bearing or not. Also, the degree of precision of the input data continues to be debated. The first successful systems employed a hand-wrapped cast, which included some traditional molding and modification during the casting process by the prosthetist. This leads to some variation in the starting "digital" map. If a patient is casted ten times, each cast and, therefore, each digital map will be slightly different.

Once the digital representation of the residual limb is obtained, software is used to add the modifications that transform the digital shape from an exact mold of the amputated limb, to the shape of a functioning prosthetic socket. This process is called rectification and introduces indentations on regions that can tolerate more weight and relief in regions that cannot tolerate weight as well. Most software packages have templates that will identify these regions and add these modifications in a similar fashion even for different sized and shaped limbs. There are literally thousands of variations and theories about the exact location and shape of these regions and on how to describe the subtle details of gradual *versus* more abrupt modification, and the location of the apex and the magnitude of the change (3,4). Most software packages will allow an individual prosthetist to personally refine the rectification process. Prosthetists can create their own templates so that their favorite or most successful "rectifications" can be reproduced for other patients (5).

Once the rectification process is complete, a modified model is carved and a socket fabricated over this model (4–6). Again, there exist a variety of mechanisms for the fabrication of the socket and materials from which to fabricate the socket. While many prosthetists still insist on fabricating each socket within their own facility, the fabrication no longer needs to be done at the prosthetics office, and Central Fabrication sites exist to assist in the different stages of the rectification and fabrication process. Once the socket is delivered, minor modifications are often needed, with the grinding or padding of small areas. The socket then needs to be aligned to optimally position the residual limb in relation to the rest of the prosthetic device, the weight bearing lines of force, and the ground.

The 1985 Special Issue of Prosthetics and Orthotics International—CAD/CAM—Computer Aided Design and Manufacturing captures and highlights many of the original concepts and ideas from this era (1,4,6–11). George Murdoch outlined the possibilities of creating and fitting several sockets in a matter of hours, and how this technology will allow a practitioner and patient to explore different philosophies of socket design or new ideas. He commented on how this will increase productivity of a prosthetist and allow him to fit more patients in a given time. He also commented on how this technology will result in improving the lot of the disabled in the developing world: "there must be some reality in the dream that one prosthetist could measure, fabricate, and fit many, many patients in the space of a single day" (7).

Bo Klasson, also writing in 1985, provided an excellent introductory review of CAD/CAM and highlighted many of the applications and advantages of automated systems (8). Automated systems can avoid duplication of work, simplify studying three-dimensional geometry-avoiding physical models, simplify input of data for analyses and display of results, simplify documentation of the product, and store experience and information from previous designs. He pointed out that reproducibility will be an important aspect in the future and that the handcrafting fitting process is not reproducible. He also pointed out the potential impact on education by converting silent knowledge, which is gained by practice and experience but is hard to document, into articulated knowledge, which is explained and analyzed.

Klasson also discussed Gunnar Holmgren's handcrafted approach and philosophy: that modifying a socket is not a matter of adding or shaving away a few millimeters here or there; it is rather a matter of modifying the pressure distributions when making the cast (8). This debate on casting has continued. Klasson predicted a Computer Aided Stump Measurement Technique, where the measurement technique mimics the molding process, actively modifies the shape, and simulates the socket before the measurement occurs. This prediction has not yet become reality.

CURRENT USES OF CAD/CAM

Private Practice

In order to highlight the wide range of clinical uses of CAD/CAM in prosthetic practice, two facilities were chosen for in-house interviews. These two practices were chosen because they represent the ends of the spectrum of CAD/CAM use. One is a large group practice that utilizes a full suite of CAD/CAM equipment to optimize in-house fabrication; the second facility is of a solo practitioner who minimizes overhead with an extremely high use of central fabrication.

The large private practice group has two offices, six providers, and two residents. They own and operate a full in-house suite of CAD/CAM equipment and believe the use of CAD to be their most efficient model. The principle provider first purchased a full in-house CAD system in 1991. The following year, the group incorporated the use of a new digitizer, beta test version of new software, and a new carver. This system functioned well until the end of 1997, when the need to fabricate spinal orthoses led to the purchase of an extended carver, digitizer, and upgrade in software. This upgrade involved converting from a Macintosh system to a PC system. Unfortunately, the new upgraded system was not fully functional until early 1999 when this group traded to an even newer four-axis carver and a newer version of software. During this period of slightly over one year, the group returned solely to traditional fabrication methods.

The current system has been fully functional for over two years and is used for fabrication of 95 percent of the TLSOs, 70 percent of the transtibial prostheses, and 40 percent of the transfemoral prostheses. Partial foot, Syme, knee disarticulation, hip disarticulation, and all upper extremity prostheses are done by traditional hand methods. Transtibial prostheses start with a digitized hand cast, and each practitioner has his/her own set of templates that work well for him/her. While the different practitioners all cast with slightly different technique, their own internal consistency makes each practitioner very efficient with his/her own set of templates. For transfemoral prostheses, the ischial containment sockets and elastomeric suspension sockets are made off CAD, while quadrilateral sockets and true suction suspension sockets are made by hand.

This group fabricates approximately 30 TLSOs per month, and nearly all are made using the CAD system. Interestingly, nearly all TLSOs start with simple measurements, by-the-numbers technique. Seven medial/lateral caliper measurements, seven circumferential measurements, and six length measurements are taken. The landmarks are the navel (waist), xyphoid, nipple line, sternal notch, ASIS line, pubis, and trochanteric line. This by-the-numbers approach has resulted in a 95- to 98-percent successful first fitting, which is equal to the rate achieved with the more time-consuming prone and supine casting, and digitizing methods. The exact, anatomic digitized detail is simply not needed for successful fitting of TLSOs in this predominately adult and trauma population. This group is currently gaining some experience with the new scoliosis protocols that are based on simple measurements, but currently digitize a hand cast for all scoliosis TLSOs.

Finally, this group has emphasized the tremendous investment of time, energy, and resources that are required to upgrade to new equipment. Because of the complexities of a major upgrade, this large group hopes to use their current CAD/CAM system for many years to come.

A second practice model is that of a solo practitioner, who recently opened a new facility with the goal of minimizing office space, minimizing equipment costs, and simplifying fabrication of devices. This practitioner has developed a practice style that takes full advantage of the current central fabrication model. Transtibial limbs are made by starting with a hand cast, which is digitized, modified, and set by modem. Test sockets arrive in 24 hours, and definitive sockets arrive in 48 to 72 hours. Transfemoral socket and profiles are generated in software after starting with simple measurement methods (by-the-numbers), not with casts or anatomic digitization. All spinal orthoses are also based on simple measurement protocols, not casts or anatomic digitization. Again, 24- to 48-hour delivery from the central fabrication site is expected. By using this central fabrication CAD model, equipment needs have been limited to a small cast digitizer, sewing machine, drill press, trautman grinder, band saw, and dust collection system. There has been no need for fume hoods, exhaust fans, laminating equipment, ovens, or vacuum forming equipment. This practitioner has no need to employ a technician. The model has been successful, and this practitioner has maintained very good relationships with his patients and referring physicians.

University Prosthetic and Orthotic Teaching

The teaching of prosthetics and orthotics must also keep pace and evolve with the expanding technologies in fabrication, alignment, and delivery of devices. Alongside of the traditional fabrication techniques, students must also be taught about the benefits and drawbacks of central fabrication, on on-site CAD/CAM. They must understand how these systems impact the care of the patient, and the record of that care. The Prosthetics and Orthotics program at the University of Washington has incorporated CAD/CAM to a level that gives the students a good basic exposure, and a comfortable level of understanding. It does not strive for mastery of all the concepts and techniques. Students who graduate from the University of Washington will enter a wide range of clinical programs from no CAD and no central fabrication, to full in-house CAD/CAM, or to a practice with a large dependence on central fabrication. All students must have mastered the traditional techniques before graduation, but full mastery of CAD is not one of the goals. John Fergason, director of the program, believes that the CAD skills will be advanced through individual practices and continuing education.

At the other end of the spectrum is the prosthetics program at Hong Kong Polytechnic University. David Boone comments that the vast majority of students leaving this program will enter practice situations that are extremely geared towards CAD/CAM systems. There is an expectation that the students will have far more than just introductory exposure to CAD; they will have advanced exposure and be well on the way to mastering many of the techniques and practices. The curriculum is structured to provide a higher level of education and skills in CAD/CAM. These two programs illustrate how advanced techniques are being built into the teaching environment in response to the community needs and practices. Both programs still emphasize that CAD has not replaced the need for all students to learn and master the traditional techniques, at least not at this time.

LARGE SYSTEMS OF PROSTHETIC AND ORTHOTIC DELIVERY

Hanger Orthopedic manages approximately 650 prosthetic patient care facilities and currently runs seven central fabrication sites. All seven central fabrication sites produce lower-limb prosthetics, spinal orthotics, and general orthotics. Two of these sites (Anaheim, California and Apharetta, Georgia) have the added responsibility of specializing in upper-limb prosthetics. While a few of the Hanger facilities have full suites of CAD/CAM equipment and practitioners trained on the use of a full suite of equipment; these are the sites that had existing full suites of equipment when they were acquired by either Hanger or Novacare.

One major focus of Hanger has been in developing an extensive and optimal central fabrication system. According to Richard Mason, director of central fabrication, the goal is to have excellent central fabrication services available to all interested providers, within and outside of the Hanger group. Hanger wants to provide standard product with a very high technology and quick turnaround time. Check sockets are fabricated and shipped the same day data are received by modem, while transtibial definitive sockets are shipped within two days, and transfemoral sockets are shipped within three days. Richard Mason strongly believes that the central fabrication model will dominate CAD/CAM use well into the future.

The Veterans Administration Health Care system provides care to America's Veteran population through 172 in-patient medical facilities and over 400 outpatient facilities. There are currently 57 Prosthetic and Orthotic services geographically positioned throughout the country. In 1993 and 1994, the Veterans Administration made a major investment in CAD/CAM by providing equipment and training for 37 sites to become CAD/CAM sites. The training was performed in conjunction with Prosthetics Research Study in Seattle with an intense one-week lecture and hands-on course in Seattle, and follow-up on-site training at each center (12,13). Mr. Fred Downs reviewed the program after 18 months, and at that time, he estimated that the CAD/CAM program generated savings to the VA of just over five million dollars (14).

Currently the VA supports a wide variety of contract vendor services and practice styles for prosthetics, mainly: in-house traditional techniques, in-house CAD/CAM, outside contract vendors with both traditional and CAD/CAM protocols, and the use of central fabrication services. This wide mix of mechanisms is needed to provide optimum service for the large number of veterans with limb loss. Mr. Downs declares the experience with CAD/CAM to be an overwhelming success both within the VA and with the outside providers who utilize CAD/CAM strategies. He believes that CAD/CAM will continue to offer real savings for the VA Health Care System and very high-quality prostheses for the veteran amputee.

INTERNATIONAL AND DEVELOPING WORLD ISSUES

The use of CAD/CAM has also extended into prosthetic services for the developing world, and in general it has been largely very successful (15–17). It has been demonstrated that CAD/CAM can meet the goals of delivery of a large number of very high-quality limbs, to areas of large need, with relatively low cost. While the debate continues, in general, this use of CAD/CAM has proven more successful than first imagined. The demonstration clinic in Hanoi, Vietnam, sponsored by the Prosthetics Outreach Foundation (POF) has been one of the very successful centers. This clinic opened in July 1990 and is still providing high-quality CAD/CAM limbs at very reasonable cost (15–17). There has been ongoing collaboration and support between the clinic and POF to maintain training, supplies, and equipment. The efforts to make this clinic self-sufficient are proceeding rapidly and effectively.

There exist an overwhelmingly large number of individuals with limb loss throughout the world, and in relative terms, there exist too few clinicians trained in prosthetics. Most individuals involved in caring for the world's amputees now believe that some form of automated design and fabrication will by necessity have a major role in successful, large-scale solutions (7,17).

REALITIES THAT WERE NOT PREDICTED

During the early discussions of CAD/CAM in prosthetics and orthotics, many individuals were adamant in the belief that the input of anatomic shape into the system needed to be extraordinarily accurate. Huge investments were made in the research and development of a wide range of digitization methods such as large freestanding scanning systems, digitizers for casts, silhouetting, line stripping imaging, and handheld scanning and digitizing methods. In actuality, clinical practice has taught us that the input does not need to be as precise as originally believed. Also, it appears that different prosthetic or orthotic devices require different precision of input. For example, most spinal orthoses for trauma or adult spine fusion can be successfully made starting from basic measurements without incurring the time and expense of casts or scanned data. The TLSOs made from this simplified input, and improved templates have been used successfully in one of the nation's busiest trauma centers for several years now. Although many practitioners are still using casting for scoliosis patients, there are evolving protocols for also fabricating scoliosis TLSOs from simple measurements.

In prosthetics there also seems to be a difference in requirement for the input data between a transtibial amputee and a transfemoral amputee. A majority of CAD users still use cast digitizer systems to get the digitized geometry of the transtibial residual limb into the system. However, the transfemoral amputee has a larger volume of soft tissue covering and padding the bone. Because of this, and because of the more forgiving nature of transfemoral fitting, many practitioners are returning to simple measurements as the starting point for CAD/CAM protocols. Many prosthetists have abandoned the use of the digitized cast or complex directly scanned anatomical data as unnecessary. The current templates and modifications have been shown to allow successful fitting, without the added time and expense of more complex data gathering. This was not predicted.

Early discussions of CAD/CAM focused on the full-suite, in-house model. The concept was to see a patient and rapidly fabricate and fit multiple check sockets, and ultimately provide the limb all in the same day. As the complexity of owning, operating, and training staff for this equipment emerged and the cost and availability of "overnight delivery" improved, the central fabrication model has grown tremendously. This was not initially predicted.

ADVANCED FABRICATION

Fabrication technology for prosthetic devices has not enjoyed the same evolution as digitization and software design (10). Currently, many traditional fabrication methods are being used to fabricate devices over the CAD/CAM carved models. There has been research, and prototype systems that directly fabricate a prosthetic socket or orthosis from direct computer control and avoid the necessity of a positive model have been constructed. One prototype system has been the squirt shape technology (18,19). This CAM method directly fabricates the final socket, or orthosis, by squirting out plastic material under computer control and layering it up in a method that directly builds the socket or brace. No interim computer-carved plaster model is needed to then laminate over. Computer-assisted manufacturing systems still could provide many benefits of direct fabrication, including sockets with different mechanical properties in different locations of the socket. While none of the systems are in widespread use, these systems could dramatically change the fabrication processes used today.

THE FIRST YEAR OF CARE—HOW AUTOMATED TECHNOLOGY CAN IMPACT REHABILITATION

One concept, advanced by George Murdoch's discussion on the usefulness of CAD/CAM back in 1985, was the possibility that CAD/CAM could facilitate creating and fitting several sockets in a matter of hours (7). Thus the prosthetist and patient could explore different socket philosophies and designs and actually wear the various sockets and feel the difference on the amputated leg. Also, using automated technology, one could fabricate multiple sockets very efficiently over the early rehabilitation time, and thus keep up with the changing shape and volume of the residual limb during the first 12 to 18 months following amputation.

Although this concept was discussed in the early years of automated socket technology as one of the most wonderful virtues, it has not gained widespread use. One private group in the Seattle area does employ this strategy. This group has a full in-house suite of CAD/CAM equipment. They will fabricate a reinforced test socket and allow the patient to wear the test-socket limb for 2 to 10 weeks, while the dramatic changes in volume are occurring. As the residual limb changes shape, new test sockets are fabricated, either by software modifications alone, or by wrapping a new cast, digitizing, applying templates, and generating an entirely new test socket. The definitive socket is not fabricated until the volume of the residual limb has stabilized. This practice avoids two common pitfalls that occur early in the postoperative phase. In one, the provisional prostheses' fit deteriorates so rapidly that complications arise from the pressure points of bottoming out or too many socks. In the second example, the delivery of a definitive limb too early in the postoperative process is followed by the patient's residual limb shrinking down, and the patient not being able to get authorization for a new socket because of insurance timeline regulations. The system of multiple, CAD-generated, reinforced test sockets, used to allow weight bearing, has been received with great satisfaction by patients, physicians, and third-party payers. The young traumatic amputee program has seen tremendous benefit with this model for first-year care.

THE BUSINESS OF CAD/CAM EQUIPMENT AND SOFTWARE

The business of manufacturing the CAD/CAM equipment and writing updated software is a very complex issue. Because of the rapid pace of change in computers, operating systems, modems, and imaging technology, the business of providing updated equipment and software is a very large and expensive investment for such a small industry. Many of the experts who have been involved in the evolution of CAD/CAM for prosthetics wonder about the financial wisdom of trying to keep up with the rapid pace of change. The demand for new equipment and software is small on an annual basis, and when prosthetic facilities do make the large investment for this equipment, they hope for perhaps a decade of use, as opposed to the traditional 3-year functional lifespan of a computer. The current CAD/CAM systems were developed specifically for P&O, and this equipment has not found much use outside of the P&O industry. The decisions made by the companies involved in research, development, and sales of the equipment and software will have a tremendous impact on the patterns of use of that equipment by the industry. Low-cost equipment and software that requires little training leads to increased in-house use, while higher costs or more complicated training leads to central fabrication models. How improvements in the fabrication side of the equation will affect clinical behavior cannot be predicted at this time, but they will most likely be taken advantage of first in the central fabrication model. While the ideal system might allow seeing, molding, and fitting a patient all within one working day, the decision to offer this type of service will rest on whether the equipment needed to provide this service, and the volume of patients seen, make the entire package financially beneficial.

THE FUTURE

The future of technology in lower-limb prosthetics is exciting and invigorating. Automated fabrication of devices will continue to evolve (20–23). Techniques to improve the accuracy, reproducibility, and simplicity of the alignment process are being introduced and refined. New materials that can change their shape and material characteristics in response to sensory input will allow sockets that can adjust to the physiologic changes in the residual limb with walking and muscle activity. Sockets could adjust to the volume changes that occur throughout a day or with physical activity. Sockets may be able to automatically adjust to the changes that occur more slowly, such as with alteration in body weight, muscle hypertrophy, or muscle atrophy. Direct skeletal attachment of prosthetic devices is being reported from the work in Gothenburg Sweden, and the University of Surrey, England (24,25).

Components that adapt better to walking or running situations and adapt to surfaces that are not level are being made to adjust their position, resistance, and function range of motion for uphill, downhill, stairs, or sidehills. Microprocessor control can allow the components to respond and change automatically, and on the fly.

Adding muscle, force, and motor control into the prosthesis will help restore the muscular function lost in amputation. The average nonamputee/layperson often does not realize that current devices, while improved greatly from historical devices, do not have active muscles. The advances of elastic response materials and designs that deform slightly under the loads of walking do give a bit of spring or kickback to the amputee, as the weight is unloaded off the prosthesis. Amputees received these prosthetic components with tremendous enthusiasm, but this function is still not the same as active muscle function. Knee units for thigh-level amputees are still quite primitive. Although microchip technology has refined and advanced the way the pendulum swings (by slowing or assisting the pendulum motion), they do not replace the quadriceps or hamstring muscles. Cleaver design and technology can minimize buckling of the knee unit and can make the prosthesis safer and more stable, even when loaded in a bent-knee position. However, the current devices do not yet truly help power the amputee from the sitting to the standing position or elevate the body weight up onto the next step.

Advanced technology has improved the design, comfort, fabrication, and alignment of lower-limb prosthetic devices. Individuals with lower-limb loss have benefited greatly from all the advances to date, but much more can and will be done.

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