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# **Squirt Shape**

Development, Evaluation, and Use of a Computer-Aided Manufacturing Technique Based on "Rapid Prototyping" Principles

By Joshua Rolock, PhD. and Kerice Tucker



The "Squirt Shape" process developed at Northwestern University Prosthetics Laboratory and Rehabilitation Engineering Research Program provides a new method for the computer-aided manufacturing of sockets.

**Introduction:** The first displays of prosthetics Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) were in the early 1980s and the introduction of the first commercial CAD/CAM systems for prosthetics production was in the late 1980s and early 1990s. Since then, the clinical production of CAD-designed sockets has remained relatively unchanged, namely the carving of a socket mold and the forming of a plastic socket using that mold [Fig. 1].

While it is true that automated machinery is being used in this socket production, the task is actually only semiautomated. Two distinct steps involving labor intensive procedures or high cost have been necessary to reach the desired goal. The blanks needed for the prosthetics carvers must either be produced on-site in a labor-intensive procedure, or purchased at higher cost and stored as inventory in the prosthetics lab. The forming of the plastic sockets must be manually produced with high labor cost or use automated thermoforming methods which requires highcost preforms to be kept on inventory. With either forming method, the socket must be manually separated from the mold and the mold material is, in the end, discarded as waste.

In our lab, in cooperation with the VA Chicago Health Care System (Lakeside Division) we have developed an alternative means for producing sockets from CAD data. Rather than mimicking the procedure used in manual socket fabrication — as the current CAM techniques do — a new method has been developed which embodies the recent industrial concepts of "rapid prototyping" to produce sockets directly in a single-stage process.

A principal characteristic common to rapid prototyping processes is that parts are fabricated by the incremental addition of multiple layers of material which, when fused together, create the desired part shape. Typically, the material layers are thin and flat and stacked one upon another, and the process is almost exclusively an au-

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# "Squirt Shape" CAD/CAM

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tomated one. There are several different commercial implementations of rapid prototyping: Stereolithography, Laminated Object Manufacture, Selective Laser Sintering and Fused Deposition Modeling to name a few.

Industrial product development can be greatly accelerated using rapid prototyping, however, in prosthetics applications the commercial rapid prototyping systems are





Figure 1. Current methods for prosthetic CAM use a two-stage process of model carving (left) and socket molding (right).

not at all rapid. In early tests of Stereolithography it took 48 hours to fabricate a transtibial socket [Rovick, et al. 1992]. Using Laminated Object Manufacture it took 26 hours [Rovick 1994], and with Selective Laser Sintering it took 23 hours to fabricate a B/K socket [Anonymous 1992, Rodgers, et al. 1992]. Furthermore, the material strengths associated with many commercial, industrial rapid prototyping systems are insufficient for clinical prosthetics use.

Despite these limitations, rapid prototyping principles hold promise as a means for the CAM production of sockets. By tailoring a device specifically to the prosthetics application it has been found that socket production times can be reduced to a clinically-practical level and material strengths can be made comparable to other methods of socket fabrication. The applications are not limited to prosthetics. They are applicable to orthotics and may show promise for pedorthics as well.

**Method:** The applicable principles when applying rapid prototyping to prosthetics are, firstly, the conversion from CAD design to the final socket in a fully-automated, single-step operation, and secondly, the fabrication of the socket one layer at a time. With the computer it is easy to describe the socket as a layered object where each layer



Figure 2: The geometric shape of a limb or socket may be represented as stacked layers where each layer corresponds to a two-dimensional profile.

represents a flat, two-dimensional contour indicative of the socket perimeter at a given height level [Fig. 2].

The approach taken in this development project was to use a plastic deposition technique wherein melted plastic flowing from a nozzle is deposited in thin layers which then solidify. A solid, thermoplastic material such as polypropylene is fed into an extruder where it is melted and pumped through an orifice, nozzle or die [Fig. 3]. By moving the extruder as the plastic flows, a continuous bead of material may be laid down in a desired pattern.

### **Three Dimensional Socket Shape Control**

For precise, automated control, a computer-controlled motion carriage with sliding rails in the X-, Y-, and Z-directions and a rotational stage is used to direct the motion of the extruder [Fig. 3]. Coordinated motion of the sliding rails and the rotary stage allows contours of

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# **Promoting Active Learning in Prosthetic and Orthotic Education**

By Mark Edwards, CP Director of Prosthetics Education Northwestern University Prosthetic-Orthotic Center



Mark Edwards works with a patient model in a session to review an evaluation performed by a student.

Think back to when you were in school. What motivated you to learn the material being presented? Traditionally, universities use the lecture format as the dominant instructional method to teach. During traditional lectures, students sit, at times they listen — and they may take liberal notes. On the other side of the podium, instructors may view the students as empty receptacles, waiting to be filled up with the instructor's knowledge. Students are passive in this classroom setting, expecting the instructor to tell them all they need to know. The lecture has been and continues to be a familiar instructional style to most students and faculty. The role of each participant is well known. Does this scenario sound motivating and stimulating?

### **Students Must Become Involved in the Topic**

Students taught by lecture only may be able to recall a few specific facts or to briefly explain the meaning of a particular theory. At Northwestern University's Prosthetic-Orthotic Center (NUPOC), we feel that in order to truly learn, students must do much more than just listen. They must read, write, discuss, be actively engaged in solving problems.<sup>1</sup> The ability to use the knowledge, apply it to meaningful situations, and evaluate what has been learned is almost impossible in the traditional lecture scenario. The lecture in its most basic form relates only to the lowest levels of understanding. teaching techniques that allow students to use higher order thinking skills. One current philosophy in education is to engage the student in learning by promoting activity in the classroom. That means changing the

traditional ideas of teaching. This paradigm shift is often risky and costly. However, the advantages and results are well worth the initial risks and costs.

At NUPOC, students bring many different experiences with them when they come to our classrooms. Our students are required to have previous exposure to the prosthetic-orthotic profession. Many have worked as technicians in prosthetic-orthotic laboratories or as assistants to prosthetists or orthotists. They also have many different educational backgrounds. NUPOC requires that the student have a bachelor's degree. Degrees in allied health, engineering and various sciences are common. We use these diverse backgrounds as a resource in our learning program.

Active learning has always been a big part of the teaching philosophy at Northwestern. The faculty act as facilitators to learning, helping the students direct their learning by using the students' past experiences and relating it to the new information they are receiving in school. Students can actually test out the theories and ideas that are described in class in monitored clinical situations. The students are actively participating — passivity is not an option at NUPOC.

One method that obviously creates this active learning environment is the use of patient models. The students use what they learn from a lecture on patient evalua-

Researchers in education recommend the use of

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# **Childress Presents Lecture at UK Society, Dedicates Library in Scotland**

Dudley S. Childress, PhD, Director of NUPRL &RERP and Executive Director of NUPOC, presented the Brian Blatchford Lecture at the Silver Jubilee Meeting of the United Kingdom National Member Society of the International Society of Prosthetics and Orthotics (ISPO), October 25 at Scotch Corner in the North of England. His topic was "The Future of Upper Limb Prosthetics", which included a brief review of developments over the past 25 years. The Lectureship was established by the Blatchford Company, a well known British firm in the field of limb prosthetics. The lectureship was established to bring an international speaker to the UK meeting each year.

On October 27, following the ISPO meeting lecture, Childress formally opened the David C. Simpson Library at the Princess Margaret Rose Orthopaedic Hospital in Edinburgh, Scotland. Professor Simpson, who is now retired, is widely recognized for his work in control of upper limb prostheses using Extended Physiological Proprioception (E.P.P.). In fact, he developed the E.P.P. concept and applied it to the design of superb arm prostheses for children who were born without limbs because of Thalidomide. Childress has long been a proponent of Simpson's ideas and so it was appropriate for him to deliver the remarks that opened the library.

# NU PRL& RERP Staff Present at Two Conferences in November

NUPRL&RERP staff presented a number of reports on Northwestern research projects in prosthetics and orthotics at the 19th Annual International Conference of the IEEE Society Engineering in Medicine and Biology, held October 30 to November 2, 1997.

Richard F. *ff* Weir, PhD and Dudley S. Childress, PhD, presented two topics. "A New Method of Characterizing Gait Using a Portable, Real-time, Ultrasound Ranging Device" described the development and testing of the D.U.R.S. (see *Capabilities*, July 1997, p. 1). Weir and Childress also presented, "The Gait Velocigram (GVG): A Graphical Representation of Walking" at the Workshop on Human Motion Analysis at the IEEE conference.

Y. A. "George" Bertos, presented a report on the work conducted by Bertos, Craig W. Heckathorne, MSEE, Richard Weir, PhD and Dudley Childress PhD. Bertos' presentation was titled, "Microprocessor Based E.P.P. Position Controller for Electric Powered Upper-Limb Prostheses".

NUPRL&RERP staff also contributed to the Gait Symposium held in recognition of Susan Sienko Thomas, MS, by The Children's Memorial Medical Center Gait Analysis Laboratory. Steven A. Gard, PhD, presented, "The Effect of Stance-Phase Knee Flexion on the Vertical Displacement of the Trunk During Normal Walking". Richard Weir, PhD, discussed "The Gait Velocigram as a Tool for Evaluating Gait".

In another November presentation, Richard Weir was the invited speaker at the Friday Series Seminar of the Department of Biomedical Engineering, Marquette University, Milwaukee, WI. His topic was the design, development and use of a portable, real-time, ultrasound, ranging system for the analysis of gait velocity.

# Steven A. Gard, PhD, Conducts Grand Rounds at RIC

Physicians, residents and other medical personnel at the Rehabilitation Institute of Chicago and the Northwestern Memorial Hospitals heard Steven A. Gard, PhD, and staff member of NUPRL&RERP report results of his studies in Vertical Displacement of the Body During Normal Walking. The presentation was featured at the Grand Rounds Series Research Colloquium held Wednesday, November 26, 1997. The Grand Rounds Series is part of continuing education programs to assist Northwestern physicians to further their education. The lecture qualifies the attendees for one hour of Continuing Medical Education credits.

## NUPOC Faculty Member Wins O & P Almanac Article of the Year Award

Elaine Uellendahl, CP, recently won the 1997 *O & P Almanac* Article Contest. In addition to being published in the December issue of the *O & P Almanac*, Ms. Uellendahl received a plaque for her first place article, "Salary Survey". The inscription on the plaque notes that "The O& P Almanac is proud to recognize this article for its contribution to the body of knowledge available to orthotic and prosthetic professionals."

The award was presented on behalf of the American Academy of Orthotists and Prosthetists, the American Orthotic and Prosthetic Association and the American Board for Certification in Orthotics and Prosthetics, Inc. Ms. Uellendahl is Instructor of Prosthetics at NUPOC.

# Childress Elected to The Institute of Medicine of Chicago

David Cugell, MD, President of the Institute of Medicine of Chicago, announced on December 2, 1997 that Dudley S. Childress, PhD, was named a Fellow of the Institute of Medicine of Chicago. Fellows are elected by their colleagues in medicine in Chicago. The honor recognizes outstanding accomplishments in the fields of medicine and health care.

The Institute was founded in June of 1915 by a group of physicians to fill the need to have an independent society representative of all areas of medicine, health service delivery and public health.

### Promoting Active Learning in Prosthetics and Orthotic Education

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tion procedures to actually perform an evaluation, directly applying the knowledge they have acquired in a relevant clinical setting. They are formatively assessed on that particular patient evaluation and then a student/instructor dialogue can take place. This feedback is very important for reflective learning from the students' perspective, but it also allows the faculty to assess the level of learning that has taken place.

The lecture followed by practical application provides a strong learning experience. Students know that successful patient evaluations are relevant to their future careers as prosthetists and orthotists. At NUPOC, we have the luxury of providing sufficient clinical experiences that encourage this higher understanding and motivation to learn. Although arranging clinical experiences is costly, we find it is critical to the learning process.

Another common technique used at NUPOC is the case study approach. Students, who are working in groups, are given case scenarios with objective data concerning a specific pathology or clinical situation. The students must then use self-directed learning to find out additional information concerning this specific case scenario. They meet at a later date to discuss their findings. This small group discussion is very effective in producing attitude changes. Students also see that real life cases don't always have right or wrong answers. The student also hears other interpretations of the literature from the other members of the group. This technique is extremely useful in covering areas of the curriculum that cannot be covered by lectures due to time constraints.

The formal critique session has been one of the most effective learning techniques used at NUPOC. During this session, students present their assigned patient model in front of the class. The student proceeds to describe in detail the entire learning process of that specific fitting and clinical experience. The student is required to reflect, analyze their mistakes, and evaluate the result. After completion of the presentation, faculty and peers are able to ask direct or open-ended questions to the student. This questioning requires the student to communicate their knowledge of the information they have just presented. Gaps in knowledge or understanding become extremely apparent during these sessions. Faculty can clarify or emphasize knowledge gaps or errors and provide the student with an opportunity to redirect his or her own progress.

These are just a sample of the instructional methods that guide NUPOC's prosthetic and orthotic curriculum. The course goals are to produce life-long learners, who can think, problem-solve and be effective, compassionate practitioners.

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<sup>1.</sup> Bonwell, C. and Eison, J., "Active Learning: Creating Excitement in the Classroom", ASHE ERIC Higher Education Report No 1, 1991.

# Current Prostheses Incorporate State-of-the-Art Technology — But Can John Get One? Exploring the Picture

By Jan Little

Advanced electronics, lighter-weight, stronger materials and greater understanding of the principles of biomechanics are being incorporated into prostheses which are helping people with amputations regain a level of function previously unknown. Complex systems which combine mechanical and electric components aid people with bilateral, high-level upper-limb amputations to regain their independence. New designs and materials in prosthetic feet, knees, shock absorbing pylons and sockets contribute to the success of people with lower-limb amputees.

The increasing number of optimistic messages in the mass media about the improvement of quality of life through modern prostheses furthers acceptance of people with amputations in nontraditional roles. A young woman with bilateral lower-limb amputations, who competes in track for Georgetown University and won medals in the 1996 Paralympics, uses some of these components. She was featured recently on NBC's Dateline TV news magazine.

There are other media messages that are not so optimistic. These are the stories of people with amputations being denied funding for prostheses or having multiple barriers that prevent those people from obtaining the latest innovations in prostheses. It doesn't take much talking to people with amputations or reading publications aimed at consumers or mass audiences to gather stories such as these:

• A college student, whose leg was amputated below the knee following an automotive accident was forced to use \$7,000 of his funds saved for college because his HMO — one of the nation's largest — did not cover prostheses. He was luckier when he needed a new prosthesis. His student insurance policy covered 20% of the cost of the prosthesis most appropriate for his needs.

• A college student had both legs amputated as a result of a car accident. His orthopaedic surgeon refused to prescribe prostheses, noting in the case file that the student would never be able to achieve ambulation. The man, using two lower limb prostheses, walks so well with the aid of a cane that he is frequently perceived as having a sprained ankle.

• A 49 year old claims adjuster for the Social Security Administration had his leg amputated below the knee to halt the advance of an osteosarcoma. He found that his HMO plan excluded funding of prostheses. When he obtained the prosthesis he needed, he was able to return to his job.

It is not difficult to find anecdotal stories to illustrate the barriers between people with amputations and technological advancement. The more challenging task is to determine facts about the prevalence of the barriers, what creates them and what alternatives exist.

## How many people need specific types of prostheses?

One of the first tasks in assessing adequate access to new prosthetic technology is determining the actual number of people with amputations and specific information about the type of amputation they have experienced. The Disability Statistics Rehabilitation Research and Training Center at the University of California, San Francisco, is funded by the National Institute on Disability and Rehabilitation Research (NIDRR). Report 7, *Disability in the United States; Prevalence and Causes, 1992*, published in July 1996 by the Center, comments about the number of people with amputations in Section 3, "Conditions Causing Activity, Work and Self-Care Limitations". In this section, the Center states, "Absence or loss of upper extremity limits 102,000 people. The most common is loss of one or more fingers only (61,000); next most common is loss of one arm (25,000). Absence or loss of a lower extremity limits 256,000 people. The most common is loss of one leg (173,000); next is loss of only one foot or toes on one foot (50,000)."

Based upon amputee statistics from other countries

and based upon the number of prostheses (hands and feet) sold each year in the United States, we believe the statistics of this survey are conservative. The report itself says, "Although there is great demand for statistical information on the prevalence of disabling conditions, it should be noted that no truly accurate source of such information currently exists. A well-designed, population based survey could provide accurate information on the population prevalence of disabling conditions, but none exists."

Obviously the need for accurate statistics still exists. Until accuracy is achieved, the number of people who would benefit from prostheses is only an estimation. So, too, is the number of people who do not have access to the appropriate prostheses.

### What specific prostheses do people need?

To be of more use in establishing needs based on statistics, more refinement of the data will be necessary. If such data were available, further data about whether these people received prostheses and whether those prostheses were appropriate would be needed to complete the study. The newly established National Limb Loss Information Center, a cooperative program between the Centers for Disease Control and the Amputee Coalition of America recently received federal funding and may provide more statistical information about the demographics of amputation.

A major problem in determining what constitutes an "appropriate" prosthesis is the lack of definitive, long-term studies. "Efficacy" and "Outcome" are frequently discussed in professional and trade publications directed at those who prescribe and deliver prostheses, but methods of determining outcome are still being explored.

### Can we determine the role of funding in access to prostheses?

To obtain funding, the primary physician for the person with an amputation must write a rationale to fund a specific prosthesis. The primary physician may well not have extensive knowledge of rehabilitation medicine, prosthetics, and case studies of successful use of prostheses to guide him. In addition, he may well be limited to 15 to 30 minutes per patient and be expected to have knowledge of all areas from obstetrics to geriatrics.

Whether a person has health care funding and whether that funding covers prostheses are significant factors in whether or not the person with an amputation receives an appropriate prosthesis. Again, data is difficult to find.

The October 1, 1997 issue of *O & P Business News* included a study by Catherine Shin, a graduate of Califor-

nia State University-Dominquez Hills in Rehabilitation Engineering Technology and Prosthetics. Ms. Shin surveyed 49 prosthetics facilities in all parts of the country about a number of trends in their business. When asked about funding, respondents reported that 58% of their clients had their prostheses paid for by Medicare and Medicaid with another 18% funded by HMOs. Of the remainder, 19% were funded by private insurance and 5% paid for their own prostheses. No actual data about the level of reimbursement was included in the report. Anecdotal responses from those surveyed indicated that the reimbursement rates paid by Medicare, Medicaid and HMOs were considerably lower than those paid by private insurance. They also reported that Medicare, Medicaid and HMOs frequently required the prosthetic facility to submit competitive bids for services. ٠

### "Squirt Shape" CAD/CAM

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any shape to be formed and the stacking of multiple layers, one upon another, enables production of the three-dimensional socket shape.

A prototype of the device is shown in Figure 4 along



Figure 3: The Squirt Shape (extrusiondeposition)technique for socket production uses an extruder to melt raw plastic and a computercontrolled motion carriage to deposit precisely shaped profiles for each layer.

with a close-up view of the fabrication in process. The plastic is extruded through a shape-forming die which produces a flattened bead of material, and rapid cooling after deposition causes the melted material to return to solid form. As additional layers of material are added, the heat of the melted plastic results in thermal welding between the layers. Each deposited layer is 0.75 mm thick so a 225 mmlong socket would be composed of approximately 300 individual layers. Fabrication time for a socket of this size is about 45 minutes.

Material Strengths: Of concern with this method of socket production is the strength of the weld between



Figure 4: A prototype of the Squirt Shape fabricator. Profiles of extended plastic are successively deposited, layer by layer, to create the threedimensional socket shape. (Detail shown in inset.)

the individual layers of material and the potential for the "interlaminar notch" at the junction of the layers to act as a stress concentrator and a seed for material failure. To address this concern, mechanical tests were performed to determine the ultimate strength and the fatigue resistance of material specimens fabricated in this way [i.e. the extrusion-deposition technique]. Material test specimens conforming to ASTM standards were cut from "pseudo-sockets" fabricated with similar dimensions to actual sockets but having flat sides.

The specimens were pulled to failure in a material test machine while recording the load-displacement relationship. Failure stress was later computed using the ultimate failure load and the cross-sectional dimension of the test specimen.

The layered construct of these sockets may result in material anisotropies in which the mechanical behavior is different when stressed either parallel or perpendicular to the plane of the layer. To evaluate these differences, "pseudo-sockets" were also produced having sloped sides from which two alternative specimen types could be cut. Specimens cut from the standard "vertical" sockets would be pulled perpendicular to the layer planes whereas specimens cut from the "oblique" sockets would be pulled with a stress component either along the layer direction or across the layer width.

As a comparative reference, specimens were also cut from "pseudo-sockets" molded using customary, hand vacuum-forming techniques and from the "as delivered" sheet material used for hand thermoforming.



*Figure 5: Tensile strengths for polypropylene homopolymers. The first five categories are for the Squirt Shape technique and the final category gives a range of values reported in the literature.* 

Results of tensile strength testing for polypropylene homopolymer are presented graphically in Figure 5 and representative failed specimens are shown in Figure 6.



*Figure 6: Representative specimens after strength testing as detailed in Figure 5.* 

The first five categories in Figures 5 and 6 represent specimens fabricated using the extrusion deposition device. The next two categories represent traditional hand thermoforming (hand) and sheet material as delivered from the supplier (AD). The final category in the graph represents a range of strength values reported in the literature for polypropylene homopolymer.

Direct comparison between machine-fabricated sockets and hand-fabricated sockets could not be made since the material had come from different sources, however, it

Fatigue Performance		
Stress (MP	a) # Cycles	Failure?
	1,890,000	N
13	1,290,000	N
	1,340,000	Ν
	1,430,000	Ν
16	1,140,000	N
	5,810,000	N <sub>Eatique</sub>
	3 700	Limit
18.5	13,500	Ý
	. 5,000	•

**Table 1:** Fatique performance of Squirt Shape specimens. Tests at three stress levels (13, 16 & 18.5MPa) show a fatigue limit between 16 & 18.5 MPa. (Note: Estimated maximum stress for typical, active transtibial amputee is 12.5 MPa.) N=No, Y=Yes

is clear that the strengths are within the published range for this material. Furthermore it should be noted that failure of the specimens in general was not at the junction between the layers. Failure often crossed through multiple layers indicating a true weld at the layer junction.

To evaluate the durability of sockets exposed to repetitive loading, tensile fatigue tests were performed using type-B specimens manufactured with the extrusion deposition technique. Tensile loads with magnitude lower than the previously measured ultimate tensile strength were applied in a cyclic fashion. For a given loading level, the number of cycles required to cause failure was recorded. Tests were carried out at stresses of 13MPa (Mega Pascals), 16MPa and 18.5MPa. At 13 and 16MPa no failure occurred in well over one million cycles which represents the estimated yearly usage for an active individual [Table 1].

At a stress level of 18.5MPa, a significant reduction in the service life was seen, indicating that this stress level exceeds the fatigue limit for these specimens. The estimated maximum service stress for a typical transtibial amputee in moderate activity is 12.5MPa thus suggesting that no fatigue failure should occur in clinical fittings of these sockets.



Figure 7: Follow-up evaluation of the clinical test socket produced using Squirt Shape. After 20 months use, there were no visual signs of mechanical failure.

**Clinical Fittings:** At the time of this writing, three long-term clinical fittings for transtibial amputees have been made using sockets produced by the deposition fabricator. The longest running evaluation now exceeds 34 months

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with the prosthesis still in use. The amputee uses this limb exclusively and is an active individual with no restrictions in activity [Fig. 7]. The second longest evaluation now exceeds 17 months, although this is not the only limb used by the amputee. The third evaluation had a duration of 12 months but was discontinued after revision surgery on the amputee. Examination of the first socket performed at 20 months revealed no signs of mechanical failure.

**Summary:** A device and technique has been developed which converts CAD data into a final socket in a fullyautomated, single-step operation. The technique borrows principles from industrial rapid prototyping and manufactures sockets by the continuous deposition of multiple layers of extruded plastic.

The new technique differs from the current means of prosthetics CAM in that the separate steps of socket

mold carving and socket molding are now eliminated. The machine uses standard thermoplastics already common to prosthetics fabrication and can fabricate a typical below-knee socket in roughly 45 minutes. The strength and durability of the sockets are sufficient for long-term clinical use in lower-limb prostheses.

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# How People Are Obtaining the Appropriate Prosthesis

In the next issue of Capabilities, we will report some of the ways people are obtaining the prostheses they need through • building a rationale for funding

• receiving prostheses from some unique organizations

• having the advantage of recycling of components

Send us your story and comments



# Improving Patient Outcomes: VA Chicago Uses Orthotic Automation Technology

By Daniel Gnatz, MA

While foot problems are certainly not unique to the Chicago area, VA Chicago Health Care System's West Side Division has the busiest Podiatry section in the VA System and ranks third in outpatient encounters among all podiatry clinics in the country. To deal with an array of foot problems that keep our West Side Division hopping, the Prosthetic Treatment Center is using Computer Aided Design/Computer Aided Manufacturing (CAD/ CAM) technology to create custom insoles that match the unique contours of a patient's foot.

The orthotic fabrication system, created by AMFIT, Inc., has been in use at the West Side Division since 1992. It consists of a foot digitizer and a compact milling unit, each controlled by its own on-board computer. The digitizer was upgraded in 1996, and the milling machine underwent a major overhaul in 1997 to give the system its present capabilities.

### New Software Increased Versatility

While the 1992 system was DOS based and somewhat limited in the type and scope of adjustments that the operator could perform, the current system is Windows based and much more versatile.

By measuring the distance between a reference plane and points on the foot, the digitizer creates a topographic map of the foot with each elevation shown in a different color. By looking for low points, the operator can locate the pressure areas in the foot. These are potential problem areas.

Once located, relieving the pressure points is a matter of drawing in an area that will be cut lower by the milling machine. The mill creates an EVA (ethyl vinyl acetate) foot orthosis that is an impression of the patient's foot, while incorporating any modifications that have been made by the operator. The whole process, from foot scan to custom orthosis, can be completed in approximately 45 minutes. According to Christopher Winters, DPM, patients for whom Podiatry orders the custom orthoses are typically those who are experiencing chronic pain. "We are seeing approximately a 60% to 70% improvement in pain relief over and above our results using non-custom insoles."

"Many of our patients are diabetic or elderly," Winters continued. "Diabetics are prone to neuropathy and may experience breakdowns on the plantar surfaces of their feet. In elderly populations there is a depletion of the fat pad under the metatarsal heads which may also result in breakdown." These populations have shown improvement using the CAD/CAM orthoses.

The custom insoles have been applied to a range of diagnoses, such as diffuse calluses, fat pad deficiencies, and minor biomechanical problems according to Winters. The Podiatry and Orthotic staff at VA Chicago has innovated the use of certain topcovers with the EVA orthoses for different foot problems. "We use a thin layer of plastazote (1/16" to 1/8") for diabetic patients and an opencell, expanded poly material (PPT) cover for patients with fat pad deficiencies. PPT acts as a fat pad replacement", Winter continued.

#### Patient Satisfaction Level is High

Joseph Ridley, Orthotic Technician and primary operator of the orthotic fabrication system at the West Side Division, states that he has seen a great deal of patient satisfaction with the final product. "They seem to leave here jubilant — some of them practically in tears — saying that their feet haven't felt this good in years," said Ridley.

This technology is improving outcomes in a great many patients with chronic foot problems. The staff at VA Chicago is continually discovering new techniques to use with this equipment that will help still more patients. It is an excellent example of how the VA is reinventing government by using technology to improve patient care. *Capabilities* ISSN 1055-7156 Northwestern University Prosthetics Research Laboratory and Rehabilitation Engineering Research Program 345 E. Superior Street, Room 1441 Chicago, IL 60611-4496

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