

CONFERENCE COVERAGE:

Orthotics Technology Forum 2012

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Orthotic laboratory managers, CAD-CAM technology experts, and lower extremity practitioners convened in Manchester, UK, in July to share ideas and experiences related to the automated design and manufacture of foot orthotic devices.

By Jordana Bieze Foster



Future of orthotic design will focus on practitioners

Foot orthotic laboratories have long been the principal players in the computer aided design and computer aided manufacturing (CAD-CAM) of foot orthoses. But practitioners are gradually starting to play a bigger role in the process—a development that dramatically enhances the potential for clinical creativity but also introduces an extra element of uncertainty.

The practitioner's role in orthotic CAD-CAM, particularly with regard to design, was a central theme of the second annual Orthotics Technology Forum, held in July at the University of Salford in Manchester, UK. In addition to the host university, event sponsors included Delcam Healthcare Solutions, Nora, Walking Mobility Clinics, e-Custom, SSHOES, and The SAVING Project.

Traditionally, the practitioner's role in the CAD-CAM process starts with a scan of the foot and ends with a prescription; all computerized design and manufacturing is handled by the orthotic lab. But some in the field believe that involving practitioners in the automated design process could result in a better product and also create efficiencies for the laboratory. These advocates include

Delcam, which is currently developing CAD software specifically designed so that laboratories can include practitioners in the design process to varying degrees.

"If the practitioner is responsible for the design, the laboratory can make orthotics cheaper and faster. The lab may be able to concentrate on milling efficiencies or add products and services. But ultimately the lab will be able to produce better performing orthotics more cheaply," said Dan Swatton, healthcare technical product manager for Delcam, during a presentation.

The key question—one that was enthusiastically debated by audience members at the conference—is just how much control over orthotic design a lab should be willing to give practitioners.

"Is it a good idea maybe to allow the practitioner to do eighty percent of the CAD design and then have twenty percent done by the lab?" Swatton asked. "Or might it be even better for the practitioner to do a hundred percent of the CAD so that the lab can just be a milling center or look into new markets for expansion?"

Pros and cons

Attendee concerns included the time and manpower needed for practitioner training, the inability to predict just how committed to

TIME SAVINGS WITH CAD-CAM

	Overall time (min)	Practitioner time (min)
Plaster	129	71
Transitional system	104	36
New system	44	35
Expected	24	15

These figures illustrate the time saved at Aspetar Orthopaedic and Sports Medicine Hospital in Doha, Qatar, after switching from plaster to a contact digitizer CAD-CAM system and, more recently, to a fully digital system.

the new automated protocol a practitioner might be, and the idea of adding a new channel through which errors could be introduced into the design process.

But attendees representing both the lab and practitioner sides of the equation also acknowledged the potential advantages of such a system.

"If I have a design team of six people and I can make two of those people technical support instead, then I can use those resources in other areas," said Philip Wells, BSc(Hons)Pod, technical support manager for Salts Techstep, a custom footwear and orthotic manufacturer in Birmingham, UK.

Craig Tanner, BPod(Hons), a podiatrist in the sports science department at Aspetar Orthopaedic and Sports Medicine Hospital in Doha, Qatar, noted that for many practitioners computerized design is a natural extension of conventional orthotic prescription.

"When you write a prescription, you *are* designing an orthotic," Tanner said. "I think it makes sense for practitioners to be able to see on the screen what it is they're prescribing. A lot of times a practitioner will ask the lab for things without really realizing what it is they're asking for."

The Qatar experience

Tanner, who also presented at the conference, knows firsthand what it's like for a practitioner to take responsibility for the CAD-CAM process. In his case, with an ever-increasing patient load and limited access to foot orthotic labs in the Middle East, Tanner has embraced CAD-CAM out of necessity. After several years using a contact digitizer-based orthotic system, Tanner switched last fall to 3D laser scanning, computerized design, and CNC (computer numerical control) machining.

There has definitely been a learning curve, Tanner said, but not an insurmountable one.

"I actually find it pretty cool learning about things like machining," he said. "I guess you can teach an old dog some new tricks."

In just a few months, the overall time needed to create a pair of orthoses has decreased dramatically (from 104 minutes with the old system to 44 minutes with the new system), though not quite to the level Tanner had expected. Surprisingly, he has found that the amount of time required of the practitioner has not changed significantly, but noted that practitioner time is now used much more efficiently since there is less travel back and forth between the lab and clinic.

Some of that is time Tanner has been using to explore the capabilities of his automated system, particularly those that don't correspond directly to traditional orthotic protocols.

OPTIMIZING ORTHOTIC MILLING

Computer aided manufacturing is anything but a one-size-fits-all proposition. Customers have a range of variables to choose from, and making the right decision in most cases depends on knowing what type of orthotic material the machine will be asked to handle. At the Orthotics Technology Forum in Manchester, Robin Smith, applications manager for Delcam, outlined some key factors to consider:

1 Materials. Different milling machines work better for some materials than others. Know the size and thickness of the material sheets you'll be working with, as well as the hardness.

2 Working envelope. This is the space required to accommodate the material, and is a key consideration when deciding between a router and a machine tool. Routers, which typically have a large XY envelope but not a lot of depth, are good for soft materials like EVA (ethylene vinyl acetate) and low to medium volumes of polypropylene. Machine tools, with a more 3D working envelope, are designed for "heavy" engineering.

3 Fixture method. The means of holding the material down while it's being cut depends, again, on the material. Believe it or not, double-sided adhesive tape works fine for low volumes of EVA. Vacuum tables work well for higher volumes of EVA, but the higher cutting forces required for polypropylene necessitate a fixture plate that is more secure.

4 Cutting tools. A rasp cutter is a good tool for cutting EVA but will "chew" polypropylene rather than cutting it cleanly. Sticky materials like polypropylene also can stick to the teeth of some cutting tools; using tools made of TiAlN (titanium aluminum nitride) is one way to help prevent this.

5 Ratser or offset cutting strategy. A ratser strategy is one in which the cutting tool passes back and forth along or across the material surface in parallel passes. An offset strategy, which follows patterns defined by the user, can help extend the life of the cutter and minimize sudden changes in cutting direction that will slow the feed rate.

6 Climb vs conventional cutting. Climb cutting, in which material is clawed away, works well for EVA. But conventional cutting, which pushes material away rather than pulling it, is more appropriate for polypropylene.

7 Waste extraction. Considerations include the size of the vacuum pipe, the availability of air flow to keep the cutting tool cool, and noise level.



One of the unanticipated challenges of switching to CAD-CAM encountered by Walking Mobility Clinics involved a hallway not much wider than the CNC router intended to be moved through it. Luckily, router and hallway both survived the ordeal. (Photo courtesy of Walking Mobility Clinics.)

"The key is that you've got two surfaces to work with. Either of those surfaces can be changed, either independently or together," he said.

One new application he's developed is a graduated extrinsic post, which is contoured in contrast to the traditional block shape, meaning less material is required. Another innovation involves increasing device stiffness in specific areas with a Y-shaped cross brace, which again allows the orthosis to be significantly thinner overall than it would be using conventional methods.

"We know CAD-CAM orthotics can be manufactured with superior efficiency. Now having experience with it, I can say it may also be superior when it comes to design," Tanner said.

Tanner is an example of a practitioner who is willing to change his way of thinking about foot orthoses in order to take advantage of what CAD-CAM has to offer. But other practitioners have found that a more conservative approach can also benefit from computerized technology.

The Ontario experience

Walking Mobility Clinics, a network of a dozen facilities in Ontario, Canada, is transitioning to the technology more gradually. Prior to investing in CAD-CAM technology, each clinic housed up to three pedorthists, two clinical coordinators, and an on-site lab with a technician. But the two clinics to open most recently are considerably smaller (1100 vs 2200 square feet) with just one pedorthist and one clinical coordinator, according to Ryan Robinson, CPed(C), CEO of Walking Mobility, who spoke at the conference. These changes have led to significant increases in gross profit and net income, Robinson said.

High-tech heel pad tissue analysis: Orthotic implications

The use of technology to improve orthotic design is not limited to CAD-CAM applications, as demonstrated by University of Salford researchers in two presentations at the Orthotics Technology Forum.

Daniel Parker, a doctoral student in the university's School of Health Sciences, and colleagues have developed a machine that replicates the forces that occur under the heel during the gait cycle and assesses tissue response to those forces.

The Soft Tissue Response Imaging Device, affectionately known as STRIDE, operates with the patient standing on a platform with his or her foot braced to limit motion. A cylindrical column positioned under the heel and driven by an actuator applies force to the tissue, and tissue changes are assessed using ultrasound and a linear variable displacement transducer.

Variables that can be measured or calculated from STRIDE data include stress, strain, compressibility, energy dissipation, and stiffness.

"The tissue characterization can be used to identify differences between individuals," Parker said. "We are currently looking at older versus younger individuals to see if there are tissue changes over time in people who don't have pathology."

Other potential applications include the ability to adjust the material properties of implants (to better mimic tissue) or orthotic devices (to improve tissue response) and to adjust the positioning of such devices to address key areas.

"The benefit is to inform the development of clinical or performance interventions," Parker said.

Additional applications may be possible by combining the benefits of STRIDE with those of finite element analysis (FEA), a type of computer modeling in which an object is segmented into elements so the model can calculate the effect of an applied force on each of those elements rather than on the object as a whole.

Nafiseh Ahanchian, also a doctoral student in the School of Health Sciences, has used some of the STRIDE findings to develop an FEA model of heel pad behavior. The initial model included anatomical data from magnetic resonance imaging scans about the different tissue structures within the heel and values from the medical literature for such variables as shear modulus and change in high-strain behavior. The calculated displacement was then compared to the actual experimental displacement and the relevant variables adjusted such that the model results better approximated the experimental results.

"This model can be used to examine a large number of footwear designs, without the burden of a high volume of experimentations, to predict stress in the heel pad under varied shoe or insole conditions," Ahanchian said. "Understanding the behavior of the heel pad might assist with investigating the mechanical functionality of the foot and the design of footwear."

Now all clinics have access to design software, three clinics have 3D laser scanners, and the purchase of a CNC router means that most of the orthotic fabrication happens in a central location. But the transition to computerized technology has been gradual, Robinson said.

Rather than scanning the foot directly, clinicians take a plaster slipper cast of the foot (as they traditionally have) and then scan the cast. They use the CAD software to make corrections and design each device. Devices are returned to the clinic from the central fabrication site approximately 90% complete, then are finished in a small "adjustments" lab with a small grinder and fume hood.

"We basically use the equipment to do what we were already doing, but in a digital sense," Robinson said. "We didn't have to abandon the way we did things. We just do it in a more efficient way."

The popularity of automated orthotic manufacturing in Canada has increased dramatically just in the last decade, said Robinson, who is also president of the Pedorthic Association of Canada. In a 2004 survey, 84% of Canadian certified pedorthists said they were making orthotic devices in-house; in 2009, that number had dropped to 68%. The association is planning a new survey soon, and they expect that trend will continue, Robinson said.

Whether clinicians actually want to be part of the CAD-CAM process, however, may depend to some extent on regional practice patterns, said Chris Lawrie, healthcare product manager for Delcam.

"In Holland, for example, practitioners are definitely doing CAD-CAM," he said. "But in the US, it's the reverse. It's mostly taking place in the lab."

Additive manufacturing inches toward prime time

The fledgling field of additive manufacturing is still somewhat fragmented, as evidenced by the fact that the same technology can be described as rapid prototyping or 3D printing. But additive manufacturing's profile is definitely on the rise, and its advocates are optimistic that lower extremity clinical applications are right around the corner.

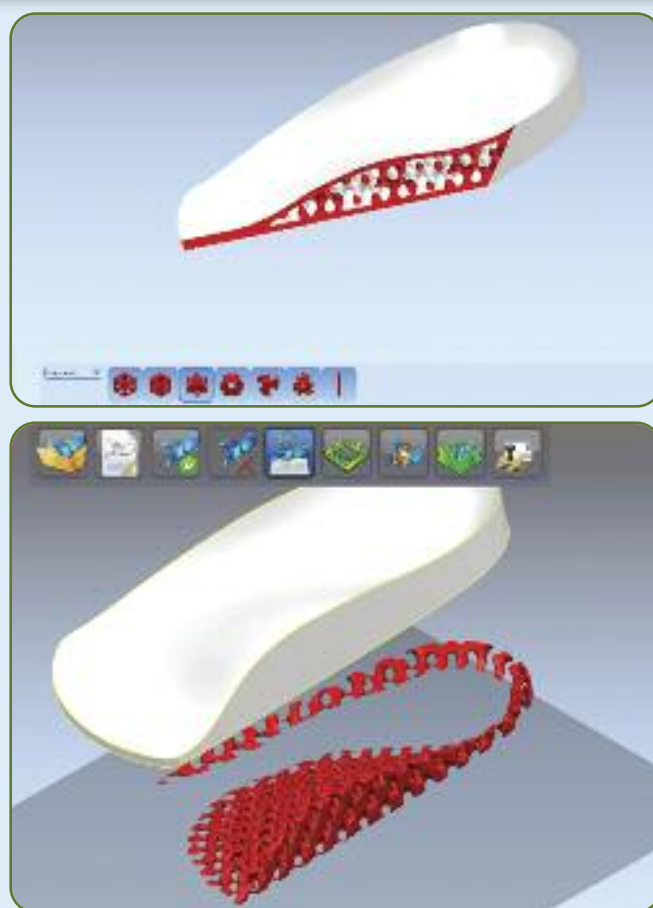
The technology, in which objects are built from individual layers of material stacked on top of each other based on a digital design, made headlines in early July with the unveiling of a prototype running shoe fabricated using only additive manufacturing. Luc Fusaro, a student at the Royal College of Art in London, designs each prototype based on scans of an athlete's foot as he or she performs different athletic tasks. All nonessential material is subtracted from the design, resulting in a latticed nylon shoe that weighs just 96 g, conforms precisely to the contours of the foot, and purportedly can improve sprinting performance by as much as 3.5%.

Two European organizations, e-Custom and SAVING (Sustainable product development via design optimization and Additive manufacturing) are also devoting resources to advancing the technology. But the biggest vote of confidence for additive manufacturing may have come from technology giant Hewlett Packard, which entered the additive manufacturing market last summer with its DesignJet 3D printer.

"If companies like HP are getting involved, it's not always going to be the small market it is today," said Graham Bennett, managing director of CRDM, a provider of additive manufacturing technology based in Hemel Hempstead, UK, that is a DesignJet reseller. Bennett was a presenter at the Orthotics Technology Forum in Manchester.

Additive manufacturing is ideal for implementing internal lattice structures, with which a hollow object can be made self supporting using less material than a solid structure, according to Chris Lewis Jones, manager of collaborative research projects for Delcam, who also presented at the conference. Other advantages include external lattice structures and the ability to grade materials for density or hardness.

"The whole thing gets built in one hit, so you don't have to turn things over or upside down. That means you can increase the complexity without needing additional setup," Bennett said.



Digital design of an internal lattice structure for orthotic additive manufacturing. (Photo courtesy of Chris Lewis Jones/Delcam.)

In addition to running shoes, lower extremity applications include corrective footwear, models for temporary prostheses, joint implants, and splints. Orthotic device fabrication can control material strength in specific directions, which could be used to limit motion and promote healing.

"What's missing now is education on how to design for additive manufacturing," Jones said. "But to be sure, it is going to be a part of our manufacturing future."