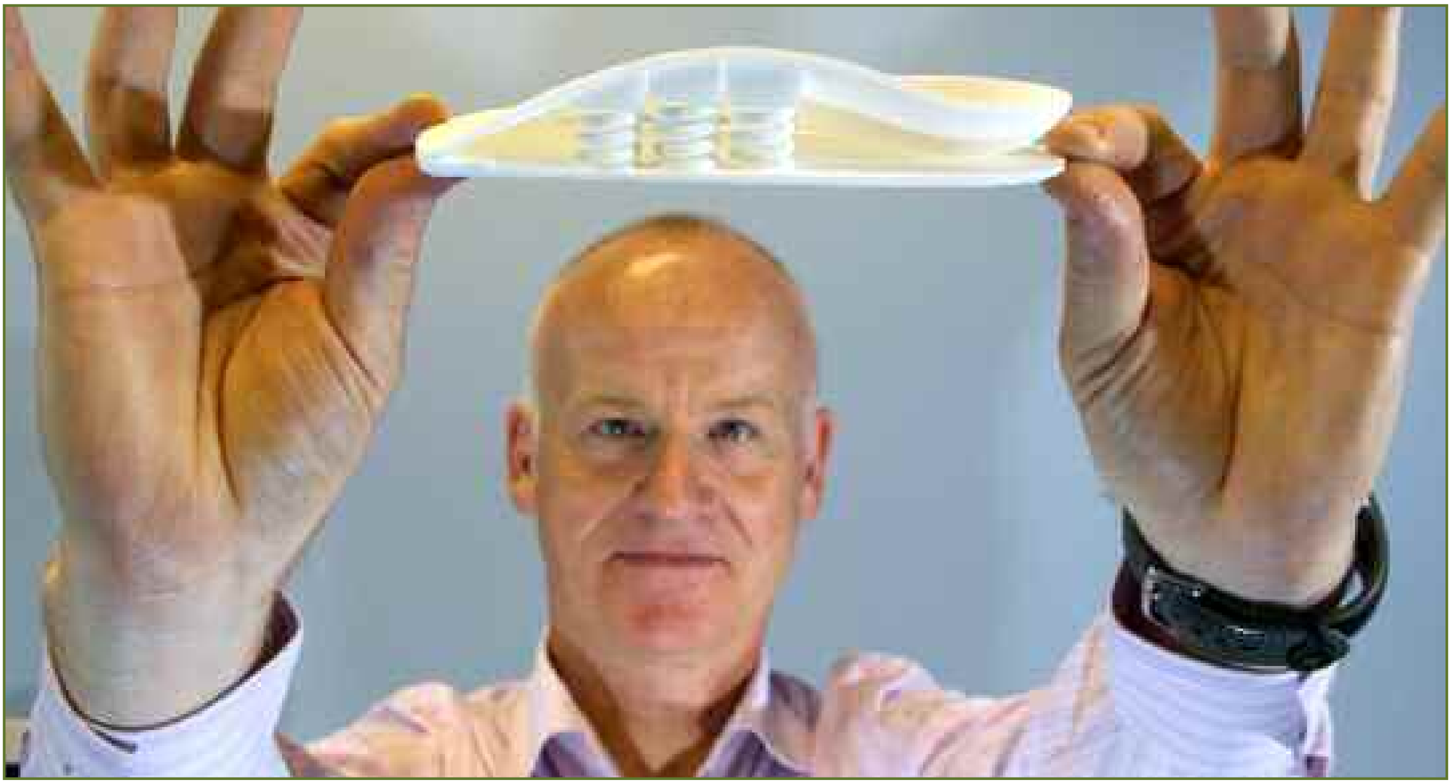
CONFERENCE COVERAGE: Orthotics Technology Forum 2013

Sponsored by an educational grant from... Delcam Healthcare Solutions

In late May lower extremity clinicians, orthotic lab owners and managers, and technology experts gathered at the Georgia Institute of Technology in Atlanta for a discussion of digital technology in orthotic application, design, and manufacture.

By Emily Delzell



An image of the future shown at the 2013 OTF: A 3D-printed model of the human foot, part of the A–FOOTPRINT project (see "3D printing," page 40). (Photo courtesy of Peter Devlin.)

High-tech path leads to the future of improved orthotic prescription

One of the most-talked-about images from the 2013 Orthotics Technology Forum (OTF) depicted 11 custom foot orthoses made by 11 experienced orthotists and podiatrists for a single patient. All 11 practitioners had been given the same information about the patient's condition, yet all 11 orthoses were distinctly different (see figure, page 40).

The image, part of a presentation by Nachiappan Chockalingam, MSc, PhD, CEng, CSci, underscored the opportunity for advanced technology to take the guesswork out of orthotic prescription—a theme that was repeated throughout the OTF, which was held in late May at the Georgia Institute of Technology in Atlanta.

More than 80 attendees enjoyed several days of presentations, conversation, and a tour of Georgia Tech's clinical biomechanics labs and the associated Global Center for Medical Innovation. In addition to host university Georgia Tech, event sponsors included Delcam Healthcare Solutions, Freedom Machine Tool, nora systems, SureFit, Mile High Orthotics Lab, Walking Mobility Clinics, Acor, Kiwi, and Kintec.

Drilling down into foot function

Chockalingam, professor of clinical biomechanics at Staffordshire University in Stoke-on-Trent in the UK, and others in his lab are combining plantar pressure and imaging data to develop patient-specific modeling to make orthotic prescription more accurate.

"[We can] provide more detail about foot function through mathematical models that could keep things like this from happening," he said, pointing to the image of the 11 different orthoses.

His team looks at both static and dynamic measurements using motion-capture systems and marker sets; force plates; in-shoe and mat plantar pressure systems; and systems that use interdigital sensors to measure dynamic plantar pressure. They also use ultrasound and magnetic resonance imaging to look at changes in foot tissue under different conditions.

"We also use multisegmental foot models to measure relationships between different foot segments rather than measuring simple angles and range of motion," he said. "For example, we'll look at the relationship between the medial forefoot and the lateral forefoot, the forefoot and the rearfoot, the rearfoot and the shank."

Chockalingam and his colleagues have developed a device that combines ultrasound with dynamometry to measure mechanical response to plantar loading. His team developed this as part of its involvement with DiaB-Smart (development of a new generation of diabetic footwear using an integrated approach and smart materials), an international effort funded by the EU.

Differences in orthotic training and approach result in highly variable prescriptions using traditional methods. (Image courtesy of Nachiappan Chockalingam, MSc, PhD, CEng, CSci.)

They found normal pressure differential gradients were 6.25 times higher in patients with diabetes than in controls, a factor that may be an independent predictor in diabetic foot ulceration, Chockalingam said.

"Physiological changes can affect mechanics, and various technologies can help us develop patient-specific and predictive models that can alter the orthotic prescription and process," he said.

A closer look at tissue behavior, stiffness

In his Georgia Tech lab, research scientist Géza F. Kogler, PhD, CO, is also combining imaging and pressure measurement tools to produce unique data on tissue behavior and stiffness characteristics of the foot.

"There are all these different soft tissues through which you're having to transfer a load [when an orthosis is used], and if I want to transfer a load I need to know what those tissues are and what their different the compositions and mechanical properties are," he said in an OTF presentation.

Kogler, who is director of Georgia Tech's Clinical Biomechanics Laboratory, and his team have developed test apparatuses to quantify plantar midfoot soft tissue stiffness properties and behavior in nonweight-bearing and weight-bearing conditions to provide perspective on the diversity of tissues.

"We had a fairly simple hypothesis; that plantar midfoot tissues would be stiffer in weight bearing than in nonweight bearing be-

3D printing: The shape of things to come

The Orthotics Technology Forum presentation given by Ben Boyer, CPed, was as much about what the speaker was wearing as what he was saying. Boyer, who is the lab manager at Kintec in Vancouver, Canada, wore a product he thinks may represent part of the future of orthotic design and manufacture—orthoses he'd printed with a hobbyist-level desktop 3D printer.

Boyer assured the audience that 3D printing (also called rapid prototyping, additive manufacturing, and mass customization) has become more accessible and cost effective, and will soon change the orthotic industry in the same way digital technology has changed media consumption.

"3D printing takes a physical object and makes it a digital commodity that anyone can produce anywhere, anytime," said Boyer, who made his orthoses using a free downloadable project from thingverse.com. The site allows users to share CAD designs, which others can download, customize, and print.

Boyer was quick to note his printed devices, designed by a layperson, were "pretty horrible" and coming apart after a few months.

"The life span of materials used in 3D printing can be short, and materials that work well for production scale are currently cost-prohibitive," he said, but added, "It is a product and may be good enough for some patients to try. And it's only going to get better."

Large labs will use 3D printing to improve production efficiency, he predicted.

"There will be no grinding, no cutting, it'll come out and you'll add a topcover, and that's it," he said. "As multimaterial printers get more sophisticated you'll be able to print the shell, padding materials, and topcover all a once."

In his presentation Boyer discussed podiatrist James Woodburn, MPhil, PhD, FCPodMed, professor of rehabilitation sciences at Glasgow Caledonian University in Scotland, who is now using a 3D printer in his clinic to print orthoses and other devices. Woodburn is also leading the A-FOOTPRINT project, an international consortium that will commercialize fully integrated, cost-effective 3D-printed foot orthoses with a 48-hour manufacture time.

Chris Lawrie, Delcam's business development manager for healthcare, pointed out that Woodburn had attended the first OTF, held in 2011 in Bath, UK, and expressed interest in an early model 3D printer.

"This shows the technology forum works," said Lawrie, who noted it's the exchange of ideas in settings like the OTF that puts advances into practice.

Woodburn's current printer cost about $3000, which Boyer says is typical for a consumer-level machine. Production-grade printers can cost anywhere from $10,000 to $600,000.

Where does all this leave labs and practitioners who make orthoses?

"Maybe it's a change in what we do," Boyer said. "We will still do the clinical work, but then perhaps provide a high-quality design file and sell that. We can also provide follow-up care when patients do make their own orthoses."

Other paradigms might include creating apps that make orthoses, he said. (ler) cause, when we load the foot, its structures become tense," he said. "Most tissue studies have been done at the heel, but most of the control in an arch mechanism is at the midfoot, so we started there."

They took measurements from a halfway point between the metatarsal heads and the posterior aspect of the calcaneus under weight-bearing and nonweight-bearing conditions, using ultrasound to quantify tissue displacement.

"We proved our intuitive hypothesis, that tissues were stiffer under weight-bearing than nonweight-bearing conditions, and also saw that tissue behavior and stiffness varies in individuals due to BMI and individual differences in tissue structure," said Kogler, who had tested 25 healthy volunteers at the time of the OTF (the study is ongoing).

"What we're really after is the clinical application [of this research], and to get to where we can determine what that stiffness value is in a particular foot and how we might use that to our advantage to control the movement with an orthosis, which means we need to alter the shape and perhaps the density of the material," he said.

Kogler also discussed pilot study data that showed an orthosis changed the stiffness properties of plantar tissues compared with a barefoot condition.

"We've used a rigid device that changes shapes and manipulates stiffness, and also changed the alignment of this person's foot structure from pes planus to one that has a slight arch. So, as orthotists, we have huge control capabilities—we can control skeletal structure and stiffness by changing shape, and we may be able to make similar changes by changing materials."

Lean manufacturing transforms orthotic fabrication

The need to replace entrenched processes and thinking with fluid, fast-moving orthotic design and manufacture that minimizes errors and maximizes resources was highlighted by several speakers at the Orthotics Technology Forum, including Jarret Eschenburg, CPed, director of operations at Allentown, PA-based SureFit, a subsidiary of Hanger.

Eschenburg made a distinction between simply "having technology" versus "using technology" in an optimal way—one that facilitates continual change and improvements in orthotic fabrication and results in an enhanced bottom line for lab owners.

This effort to make the most of expensive technology—SureFit invested in CAD-CAM in 2005, adding two mills to its lab—resulted in a reengineering process that streamlined the fabrication workflow and reduced workforce from 30 to 17 and turnaround times from 14 days to seven.

From clutter to clean: The tracing library before and after SureFit's process-flow *kaizen*. (Photos courtesy of Jarret Eschenburg, CPed.)

With new technology in place, Eschenburg continued his quest for *kaizen*, a Japanese term for continuous improvement, by embracing lean manufacturing, defined as "a manufacturing philosophy that shortens the time line between the customer order and the product shipment by eliminating waste using continuous improvement techniques."

The first step to getting "lean," he said, is standardizing work. A review of SureFit's lab processes showed each employee did the same task slightly differently, from the orthotic gluers and grinders to the certified pedorthists who analyzed orders. The review also identified sources of waste, Eschenburg said, which in orthotic fabrication often involve quality issues, such as reworking orders, and workstation delays that cause bottlenecks.

"Wait times between processes eat up time. You may say it takes only about 45 minutes to actually make an orthotic, when in reality, it takes all day," he said.

"Key lean concepts are using your current resources, and changing from the bottom up, not from the top down. It's hands-on workers who really know what the issues are and can best suggest ways to improve," he said. "Once processes are standardized you can implement crosstraining in which, ideally, every worker can do every job."

Eschenburg next focused his continuous change efforts on three areas in orthotic manufacturing: reducing distances traveled by reducing the lab's footprint, standardizing jobs to increase speed, and setting up a pull system to lower WIP (work in process) in the target area (postmill to grind finish).

"When orders get backed up you have increased WIP and work time. At this time we had a WIP of 400 orders—when I said we were aiming for 20 we almost had a revolution. We had a two-day turnaround in that area; we wanted it done that same day," he said.

Every employee took part in the brainstorming that resulted in a new floor plan and a standard workflow for every operator—about 175 action items in all.

It took about three months to identify and implement changes, but the end results were worth it, Eschenburg said. SureFit reduced its lab footprint by 30% and achieved other efficiencies, such as setting up a standardized gluing process and simplifying tracing (see figure above).

"I regard SureFit's progress merely as a means to do more. It's an indication that we have reached a place where we might begin to improve again," Eschenburg said.