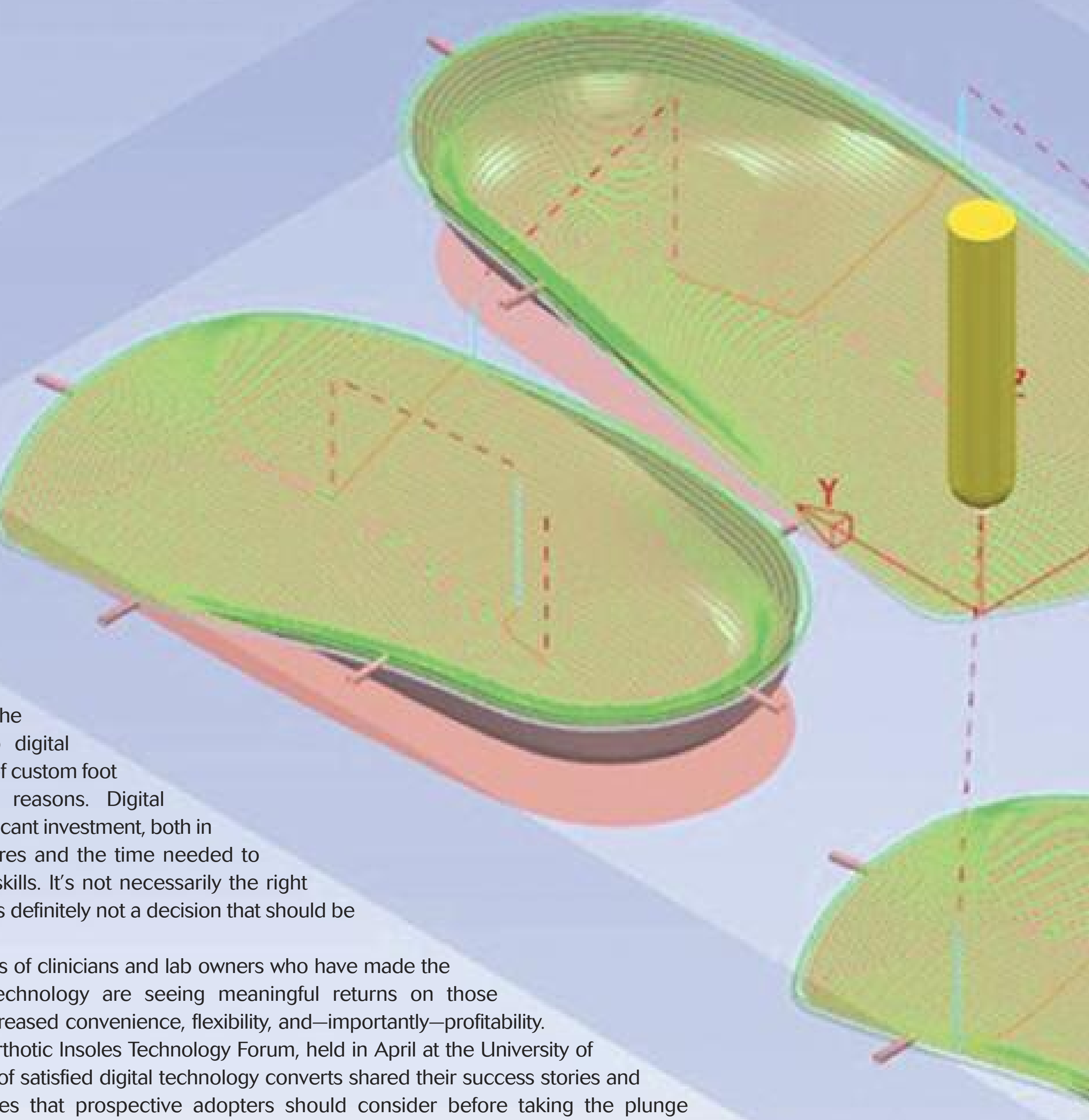
Custom Orthotic Insoles Technology Forum

By Jordana Bieze Foster



Many practitioners and orthotic laboratory owners are wary of making the switch from traditional to digital design and manufacturing of custom foot orthoses, and for good reasons. Digital technology requires a significant investment, both in terms of capital expenditures and the time needed to learn a whole new set of skills. It's not necessarily the right choice for everyone, and it's definitely not a decision that should be made lightly.

But increasing numbers of clinicians and lab owners who have made the leap to digital orthotic technology are seeing meaningful returns on those investments in terms of increased convenience, flexibility, and—importantly—profitability. At the inaugural Custom Orthotic Insoles Technology Forum, held in April at the University of Bath in the U.K., a number of satisfied digital technology converts shared their success stories and underscored the key issues that prospective adopters should consider before taking the plunge themselves.

Thinking critically

Perhaps the most predominant theme echoed by speakers at the conference was the need to understand and carefully weigh the pros and cons of investing in digital technology, as well as the pros and cons of different individual systems, to facilitate decision-making for individual situations.

"In general, digital technology offers a dramatic opportunity to increase our capacity and decrease our costs, but we need to be very critical about it," said Larry Huppin, DPM, medical director for ProLab Orthotics in Napa, CA, and a podiatrist with a private practice in Seattle, WA.

Not surprisingly, cost was the point of consideration cited most frequently during discussions about the choice to go digital, but it was far from the only one. Talking points also included convenience, learning curves and skill dependence, and operational flexibility.

Costs

Prices for optical scanners, design software, and CNC (computer numerical control) milling equipment range widely and, as with any technology, have gradually come down over time. And some orthotic labs provide practitioners with a scanner at no cost in exchange for that practitioner's orthotic business.

But for those looking to own their digital equipment, up-front capital expenses start in the thousands of dollars and can extend into tens of thousands. Plaster, by comparison, costs next to nothing. Other costs associated with digital technology include maintenance expenses and the time away from work required for staff to be trained in using the new systems.

The financial trade off is in the increased volume that digital systems make possible. Phil Wells, technical support manager at Salts TechStep in Birmingham, U.K., said with just five employees in the company's orthotic department, his laboratory's orthotic output increased from five pairs per month to 1000 pairs per month after making the switch to a digital system,.

When Colorado-based Mile High Orthotics Laboratory debuted in 2007, its founders decided that digital technology would be part of the company's start-up costs; they made back that initial investment in just three months, according to president Greg Armstrong. Mile High's customers have experienced corresponding increases in profitability as well.

"Every time we put a scanner in a practitioner's office, the number of orthotics we do for them doubles," Armstrong said.

If capital expenses are taken out of the equation, optical scanning is actually considerably less expensive than plaster casting, according to a 2007 cost-benefit study published in the *Australasian Journal of Podiatric Medicine* by Craig Payne, DipPod, MPH, a senior lecturer in podiatry at Latrobe University in Melbourne, Australia.

Payne, who presented his findings at the University of Bath conference, calculated that the cost of taking a plaster cast and

Going digital can increase volume by saving time.

preparing it for shipping ranged from $27.94 to $49.60 per cast, while the cost of optical scanning ranged from $3.30 to $10 (all amounts in Australian dollars). Costs included a podiatrist's hourly rate, materials, packaging, and postage.

The cost of a scanner, of course, can skew those figures considerably. But capital costs were not included in the analysis, Payne said, because of price variability related to the factors noted earlier.

Convenience

That increased volume is the direct result of time saved. The digital orthotic design and manufacturing process can save days on device turnaround, which means greater customer satisfaction. Labs can reinvest that time in generating even higher volumes; practitioners can use that time to get out of the lab and back to seeing patients or doing research.

That's what going digital has meant to the podiatrists at Aspetar Orthopaedic and Sports Medicine Hospital in Qatar, where, in 2006, the custom orthotic design process evolved from plaster to a contact digitizer and now is on the verge of transitioning to an optical scanning system. The amount of practitioner time required per pair of orthotics has been nearly halved since the first switch, according to Craig Tanner, head podiatrist at Aspetar.

The future of orthotic technology

Machining orthoses with desktop cryogenics, or using an open-source "3D printer" that not only replicates orthoses but can also replicate itself, may seem unattainably futuristic. But these technologies are on the verge of being ready for prime time, and attendees at the Custom Orthotic Insoles Technology Forum got a sneak peak.

Since 2004, mechanical engineers at the University of Bath in the U.K. have been developing and modifying a machine affectionately known as RepRap (short for replicating rapid-prototyper) that puts down layers of molten plastic to create 3D objects based on a digital design. Although other 3D printers have been available for nearly 30 years, the RepRap concept is unique in that it can essentially replicate itself by printing the majority of the parts needed to create a new machine. In addition, the software and instructions for assembly are open-source (available for free at reprap.org), and any parts that RepRap can't print itself are readily available at hardware stores or online. The total cost of assembly is estimated to be about $500.

"It's like MP3 music sharing, but for real solid stuff," said RepRap inventor Adrian Bowyer, PhD, a senior lecturer in the mechanical engineering department.

Current RepRap models are not large enough for custom orthotic device fabrication, but University of Bath mechanical engineering student Chris Hanton has made this challenge the focus of his senior thesis project. The result is a larger machine that can accommodate a pair of foot orthoses, which will make its public debut after Hanton gets his degree, Bowyer said. The device takes two to three hours to make a complete polypropylene insole, but since the machine itself can be replicated cheaply, multiple

It's no coincidence, Tanner said, that fellow Aspetar podiatrist Luke Kelly has published two articles in the last year, most recently a study on the effect of orthoses on neuromuscular control and aerobic costs in running that was e-published in May by *Medicine & Science in Sports & Exercise*.

"This is the kind of thing we can do when we have more time," Tanner said.

Digital scanning technology also obviates the storage headaches that accompany plaster-based systems. Storing plaster positive molds takes up real estate that could be used for other purposes. And because that space is limited, so too is the length of time that those positives can be stored. A digital scan can be used for a repeat prescription—or modified, if needed—years after a patient's initial visit, and long after that patient's positive molds would have been discarded to make space for others.

Skills

Knowing what constitutes an effective custom foot orthosis is essential to the design and manufacturing of that orthotic device regardless of the methods used. But digital processes take what has long been a very tactile experience and turn it into something more conceptual, and that transition necessarily comes with a learning curve.

That means going digital requires dedicating valuable staff time to training or hiring new employees who already have the necessary skills. Either way, a further concern is ensuring that those trained workers don't leave your fledgling digital orthotic business in the lurch by taking their newfound skills elsewhere.

Digital scanning obviates storage of plaster casts.

Flexibility

Labs or practitioners with an existing custom orthotic business need a digital system that will allow them to continue to produce the types of devices their customers have come to expect, and both existing and new businesses need a system that can handle requests their customers haven't made yet.

For a lab, maximum flexibility means being able to accept multiple file formats from customers, for a range of devices. For a practitioner, it might mean being able to send scans to multiple labs.

On the manufacturing side, direct milling offers the advantage of creating different degrees of thickness within a single device, whereas vacuum forming can achieve only a single thickness. However, certain orthotic modifications cannot be made digitally.

In addition, direct milling equipment does not employ an equal opportunity policy when it comes to materials. Many CNC machines that are designed for polypropylene and other relatively rigid materials will be more finicky when it comes to EVA (ethyl vinyl acetate), and vice versa.

Wells found this out the hard way, learning that the lab's new CNC machine was not designed for EVA use only after the machine had broken. Salts TechStep now has a dedicated CNC machine for all of its EVA milling, but Wells suggests that investing in material-specific equipment probably doesn't make sense for most operations.

"You've got to understand what you want to make and then go in one direction or the other," he said.

What it's about

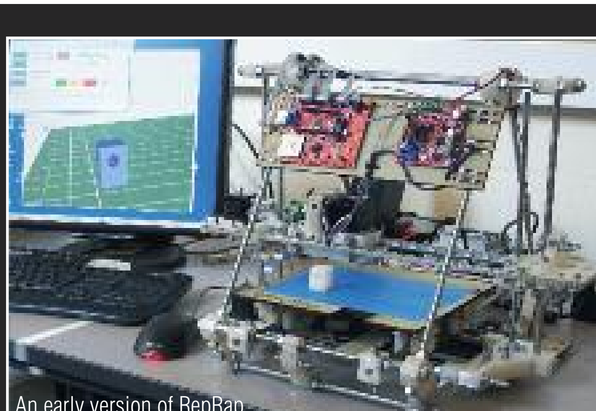
The ultimate clinical question, of course, is whether digital orthotic design and manufacture results in a custom device that is as effective as one made using traditional methods. But studies of such comparisons are in short supply, and advocates of the technology say they haven't noticed any difference in quality.

"It's not about that it's a better product. It's not about being better than a hand milled product," Wells said of the decision to go digital. "It's about speed, repeatability, material uniformity, material choice, and digital image capture." ler

machines working simultaneously can have the same output as a single faster machine.

Meanwhile, researchers in another corner of the same mechanical engineering department have developed a cryogenic process to facilitate the machining of soft elastomeric materials like EVA for such applications as customized athletic shoe outsoles.

The process involves freezing the material to below its glass transition temperature, or the point at which it becomes stiff enough for machining. In the case of EVA, that point is 120° K (-244° F).



An early version of RepRap.

Calculations built into the software also account for the fact that the material contracts when frozen and will expand again once fabricated.

Although cryogenic milling machines are currently quite large, researchers envision the evolution of desktop cryo-mills that can machine an orthosis directly from a digital CAD-CAM system, according to Vimal Dhokia, PhD, a knowledge transfer research fellow in the Innovative Manufacturing Research Centre of the mechanical engineering department.

"We see that happening within a year," Dhokia said. ler