Expert Report on the State of the Orthotic Industry

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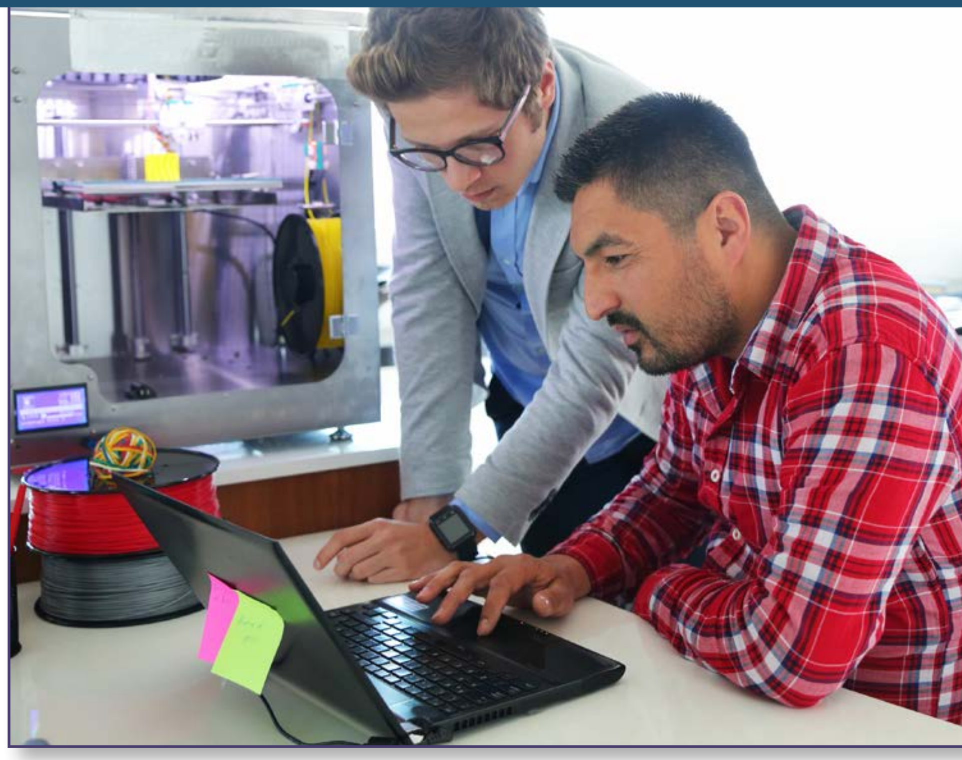
Collaborative Care for Better Outcomes

The Future of Orthotics Manufacturing



By Cary Groner

3D printing has been waiting to disrupt the orthotics market for years. Only time will tell if the pandemic's pause afforded clinicians the opportunity to understand the benefits this technology can bring to their practice and their patients.

Recent decades have seen a proliferation of technological advances that promise to transform traditional methods of fabricating in-shoe foot orthoses. One of the most innovative of these is additive manufacturing, otherwise known as 3D printing. A host of complicating factors have stalled acceptance and implementation of this approach, however, including a high cost of investment, molasses-slow production times, confusion about the most efficient workflows – and, as a result of such concerns, an understandable reluctance on the part of clinicians and fabricators to make the switch, or even to add 3D printing to existing manufacturing options.

That said, in the past couple of years a number of factors have begun to crystallize in a way that may finally contribute to significant disruption and change. These include falling equipment costs; further innovation in materials; an increasing consensus about what may be the most efficient and cost-effective production model; and most important, growing appreciation of certain advantages 3D printing offers that no other technology can match.

Where We've Been

To understand why it's been so hard to push 3D printing forward, it's helpful to remember where we've been. Stripped to essentials, the process of making an orthosis involves several steps:[1]

- An assessment of the patient's medical condition and needs, including diagnosis, pressure mapping, and gait analysis where indicated.
- The creation of a positive cast or digital image of the foot, using plaster casts, foam boxes, or 3D scanning
- Either vacuum forming thermoplastic over the cast or translating the scanned data into CAD/CAM processes, leading to subtractive milling
- Finishing, which may include customizations such as posting, padding, a topcover, and so forth.

Part of the problem with altering this approach is that some version of it has worked pretty well for decades. Moreover, aspects of the process – such as the initial patient assessment – are unlikely to change regardless of how the orthosis is made.

Recent advances allow for improved approaches to varying segmental stiffness.

"Right now, we have a bunch of labs that are very good at producing high-quality orthoses using either CAD/CAM or thermaforming techniques," said Kevin Kirby, DPM, who is in private practice in Sacramento, CA, and teaches at the California School of Podiatric Medicine in Oakland. "Large labs make eighty to a hundred orthotics a day, and compared to that, 3D printing has been much too slow."

But the existing method has limitations, as well. Plaster casting and foam boxes offer notoriously variable foot models, though the increasing acceptance and accuracy of direct 3D scanning of the foot will likely replace those methods within a few years.[2, 3] Subtractive milling results in significant amounts of wasted plastic in an age when recycling is tricky to verify and the oceans are already awash in plastic microparticles. Standard turnaround times are typically on the order of 2 to 3 weeks, and mistakes and redos due to misinterpreted specifications are common. Most important, however, is that because the process involves a lot of hands-on work, consistent repeatability is challenging;

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> ***– Kevin Kirby, DPM***

different workers make slightly different orthoses even when using identical specifications. All of these factors affect efficiency.

Where We're Going

By contrast, orthoses made with 3D printing are infinitely reproducible. The process is automated once a scan of the foot is made, so if the patient wants another pair, fabricators simply send the same order through and get an identical result. The only manual work is gluing on a topcover if one is needed.

By the same token, 3D-printed orthoses are easily customizable. Traditionally, to make adjustments, podiatrists or orthotists would add posting or other adjustments using labor-intensive methods such as forefoot wedging or heel skiving. In 3D printing, any such changes can be added directly to the design specs sent to the printer – and again, they would be identical on every orthosis made.

Most exciting to clinicians is that recent advances allow for improved approaches to varying segmental stiffness. Bruce Williams, DPM, defines this as evaluating the stiffness values of the lateral and medial forefoot, the range of motion of the first midtarsal joint, and those of the ankle joint and the midfoot.

"Once you know those segmental stiffness values, you can create an appropriate orthosis, and it's really important to be able to alter stiffness in different regions," said Williams, a Chicago-area podiatrist who was previously director of gait analysis at the Weil Foot & Ankle Institute. "Traditionally, if you wanted to alter stiffness, you had to increase or decrease the arch fill, or change the thickness of the plastic used."

For example, if a patient weighed 200 pounds, the clinician might prescribe a 4mm-thick polypropylene orthosis for relative stiffness, or a 2.75mm-thick one for more flexibility.

"The trouble is, not everybody's foot is the same size or functions the same just because they weigh the same," Williams continued. "Some people have more flexible arches than others, despite how much they weigh. But do we necessarily need to make the entire device more flexible, or could we just do that in one region of it? Ideally, 3D printing will allow you to control movement in some parts of the foot while encouraging mobilization in others."

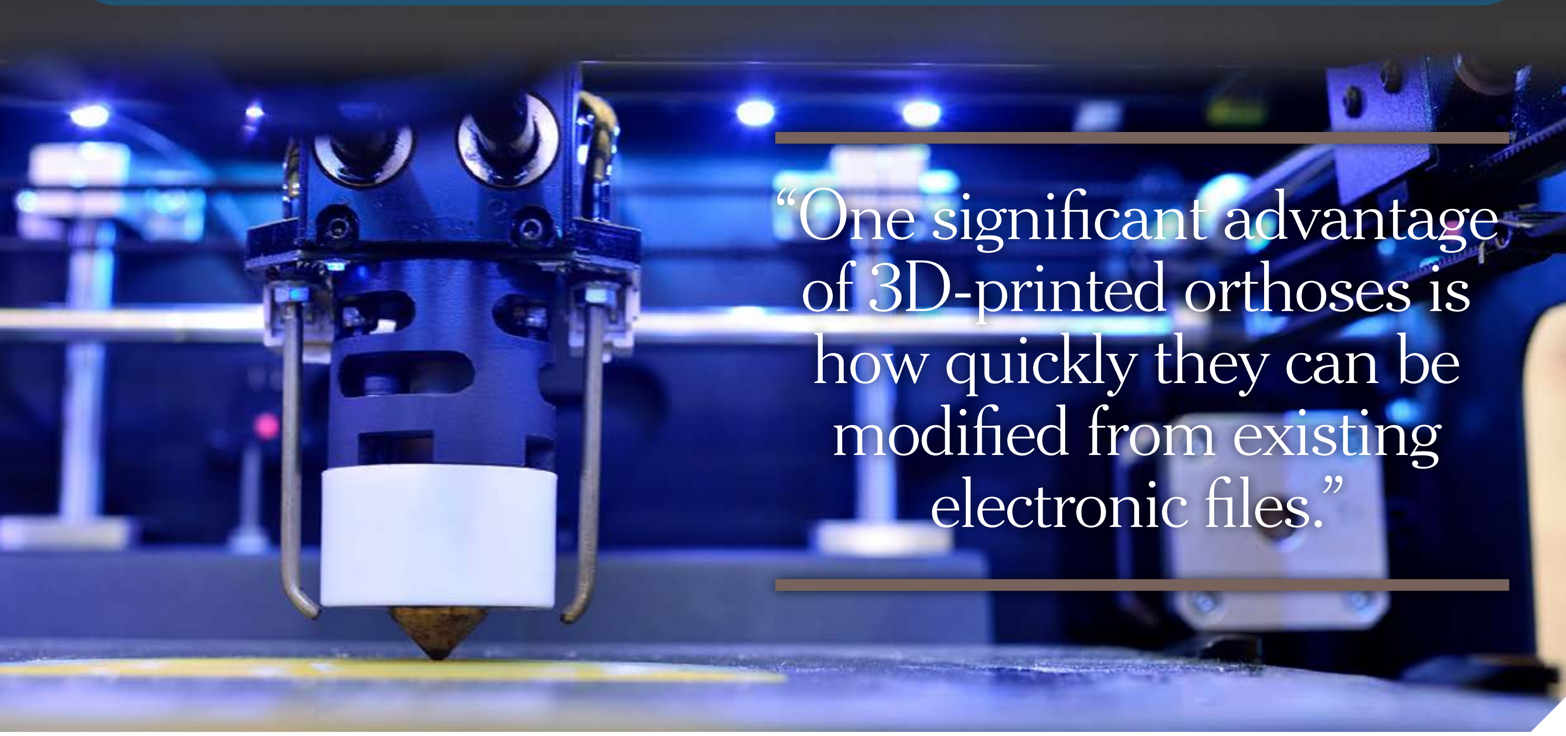
One unique advantage of 3D printing is related to how the process works. The 3 main approaches are selective laser sintering (SLS), stereolithography (SLA), and fused deposition molding (FDM). All of these allow the easy creation of detailed, geometrically complex objects requiring sub-millimeter resolution.[1] What this means in practical terms is that tiny lattice structures can be created within an orthosis, like three-dimensional honeycombs. Stiffness, then, can be adjusted by altering the design and shape of those lattices rather than by varying material thickness, as in traditional approaches.

I asked Williams about my own case – high-arched feet, but with a stiff right foot that's prone to fasciitis and a flexible left foot that isn't.

"That's just the kind of problem 3D printing is suited for," he said. "With traditional technology, the only way to address that would be with a thinner orthosis for the right foot, with arch fill, or with posting. 3D printing would let your podiatrist program more flexibility or other design features into the right orthosis, and it would be exactly the same every time you got a new pair unless you wanted to change it."

Diabetes

3D printing also holds significant potential when treating diabetes patients when peripheral neur-



opathy increases their risk of pressure ulcers, infection, and amputation. At Staffordshire University in the UK, Nachiappan Chockalingam, MSc, PhD, a professor of clinical biomechanics, uses multisegmental models to articulate the relationships between different areas of the foot such as the medial and lateral forefoot. Such data are extremely helpful in designing orthoses for these patients, he told *LER*.

"We are color-mapping segmental information specific to the particular patient," he said. "When we match the stiffness of the polyurethane orthosis materials to the stiffness of the patient's plantar fascial tissue, we reduce pressure better and improve outcomes."

In a study published in 2020, Chockalingam and his team created customized 3D-printed footbeds using FDM for diabetes patients deemed at high risk for developing their first foot ulcers. The footbeds used different infill patterns (matrices) to vary the density in distinct parts of the sole.[4] On average, the custom footbeds reduced plantar pressures 46%.

In another study published this May, Chockalingam and a colleague, Panagiotis Chatzistergos, MSc, PhD, reported that a 3D-printed insole comprising flexible thin-walled hexagonal structures functioned well as a low-cost, non-electronic pressure sensor for assessing overloaded areas of the sole in diabetic patients.[5] Because the insole's honeycomb structures exhibited different mechanical behavior for different magnitudes of compressive loading, they reliably detected areas of plantar overloading. The research served as proof of concept that in preventing diabetes foot ulcers, 3D printing may contribute to assessment as well as treatment.

John DesJardins, PhD, the Robert B. and Susan B. Hambright Leadership Professor of Bioengineering at Clemson University in South Carolina, has been working with similar concepts in diabetes patients for years.

"Our work has been fundamentally about being able to tune specific areas of an orthosis to allow for changes in pressure areas across the foot," he said.

One significant advantage of 3D-printed orthoses is how quickly they can be modified from existing electronic files, increasing the clinician's efficiency. "It's really important to be able to rapidly prescribe and produce an orthosis, then iterate that on a weekly or biweekly basis when the patient comes back in," DesJardins explained. "Most clinicians have a general idea that softer materials are better, but offloading effectively requires intensive changes to an orthotic, and they can't iterate quickly. Sometimes it takes two or three weeks, and once they have that one, they can't reproduce it. So those issues are what we're trying to target by just hitting the 'Print' button and changing how hard or soft the material is in certain locations."

Materials

DesJardins and his team have been working to adjust density not only with the void structure – the internal architecture – of orthoses, but also with the materials themselves.

"Some printers will create blends of different materials," he explained. "It's like having different inkwells on a color printer. They can take a hard material and a soft one and combine them to produce a range of different hardnesses."

Such materials tend to be proprietary and expensive, DesJardins noted, similar to the model by which inkjet manufacturers make a lot of money. The cost is a significant disincentive to large-scale production, but the strategy is well-suited to prototyping and similar uses. His team is hoping that the advent of printers that use different densities of silicone will widen the approach's appeal.

Bruce Williams said that polypropylene remains the industry standard by which other compounds are measured. "You want to make sure that your material has similar strength and flexibility, because that's what clinicians are used to," he explained.

Scott Telfer, EngD, the director of the Computational, Robotics & Experimental Biomechanics (CoRE) laboratory at the University of Washington in Seattle, agreed that 3D printing materials are continuously evolving.

"Each company has its own variations, and there are now hybrid versions of compounds we've had a long time, like PLA and ABS, mixed to be tougher or longer-lasting," he said. "Nylon 12 and its variations have been around for years and seem reliable. The most interesting technology I've seen, in terms of speeding up the process, is carbon 3D printing."

The Paradigm Shift

DesJardins, like many others in his field, has been waiting for 3D printing to take over, but it seems to be an ever-receding horizon.

"What will it take?" he asked. "I think the initial idea of a printer in every clinician's office is probably not the economic model that's going to work."

Given that 3D printers range in cost from roughly $4,000 to over a hundred times that – and that you pretty much get what you pay for – it isn't hard to see why. For DesJardins, the existing model of a central fabricator to which the clinician emails the design is more practical and scalable.

"They would be the ones that buy the 3D printer, because the infrastructure investment is severe," he said. "Also, you have to have the expertise, and these shops understand CNC [computer numerical control] and 3D printing."

DesJardins noted that as healthcare continues to consolidate, major health systems with thousands of patients may create their own in-house central fabrication facilities and either buy or lease 3D printers. Clemson, for that matter, leases the printers he and his team use. From the standpoint of both investment and maintenance, it's simply more efficient.

Back to Basics

Several experts *LER* spoke with for this article emphasized that regardless of the technology used to create an orthosis, the clinician will remain the critical link in the chain.

"The tools are only one part of the picture," Kevin Kirby said. "The rest is having the knowledge to design the orthosis better, regardless of how it's made. Podiatry is becoming such a surgical profession that the younger practitioners aren't getting the biomechanics education they need. But improving orthotics is a therapeutic goal, and podiatrists need to know how orthoses can be designed to optimize therapeutic outcomes for the patient."

"There are always those of us who want more control," agreed Bruce Williams. "I want to be able to see and understand the different modifications. But if you're going to innovate – to improve comfort, function, and fit – 3D is a better way to go."

DesJardins, too, emphasized the importance of clinical decision-making, and he has a relatively optimistic view of younger clinicians' capabilities.

"What you make affects the pressure on the foot, and that's where clinicians earn their money," he said. "There are all these questions that only the clinician can answer, so the more control you give them, the better. After you've done your scans and you have a digital model of the foot, the clinician needs to sit down with a nice piece of software and be able to draw where they want the offloading to be and reshape it."

Most clinicians aren't trained in that digital capacity yet, but the ones DesJardins has spoken to are excited about the possibilities for coupling better therapeutic outcomes with improved efficiency.

"They say, 'Man, if I could change just a specific part of the orthotic with a single mouse movement and add or subtract, or change the hardness here or there, I'd love it,'" DesJardins said. "And the younger ones are much more comfortable with that computational side of things." ler

Cary Groner is a freelance writer based in the San Francisco Bay area.

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