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Data courtesy of Footwork


Data Courtesy Twikit

DATA-DRIVEN EVALUATION OF 3D PRINTING AND TRADITIONAL METHODS FOR CUSTOM ORTHOTICS: **TEST METHODOLOGIES AND RESULTS**


Data Courtesy Inent Medical

Defining testing methodologies and criteria to study the impact of materials and print orientations on orthotic performance

Data Courtesy Inent Medical


Data Courtesy EXO-L

Introduction

Digital workflows hold immense promise for Orthotics & Prosthetics Clinics and Manufacturers. Additive Manufacturing offers productivity benefits while improving patient outcomes through personalization, customization, and integrated functions.

These productivity benefits reduce manual labor, waste, and manufacturing inefficiencies, allowing practitioners to showcase more innovative designs that help them stand out over the competition.

Data Courtesy Inent Medical

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The result: O&P Clinics and Manufacturers can offer differentiated products, which help open new avenues in scaling their business. These benefits outweigh upfront investment and adoption barriers in digitizing the production process.

However, clinicians and manufacturers must consider a few fundamental questions before investing in a digital orthotics and prosthetics workflow:

- Which material might be better suited for my device?
- What kind of performance do they provide to patients?
- How do they compare to traditional foot orthoses?

These critical questions have remained difficult to answer. The performance of an orthosis is evaluated based on how the end user "feels" rather than by quantifiable data. While highly technical, many traditional manufacturing methods still require an element of manual craftsmanship.

There is a need to devise a method to quantify comparative performance. Only then can we understand the comparative performance of orthoses created using Additive Manufacturing. This is vital before considering the potential deployment of such orthoses among patients.

Data Courtesy of Invent Medical

A New Paradigm to **Analyze Orthotics Performance**

In partnership with Biomechanigg Sport and Health Research, HP set out to develop a technical framework for quantifying device performance, specifically using foot orthotics, to:

1

Propose industry-wide criteria that could be used to compare device performance.

2

Develop a meaningful test methodology to evaluate material and design considerations.

3

Compare manufacturing methodologies using orthoses produced with HP Multi Jet Fusion technology and traditional CNC methods.

4

Develop a better understanding of optimal printing orientations and their impact on end performance.

While Biomechanigg helped guide and facilitate the development of these experiments, Solo Laboratories provided initial guidance by providing traditionally machined polypropylene insoles and an equivalent CAD model for testing purposes.

Defining the **Benchmarks**

To investigate relevant measures for orthotic performance, the team first explored historically accepted test criteria. This helped in expanding the scope to test the devices beyond the expected real-world use.

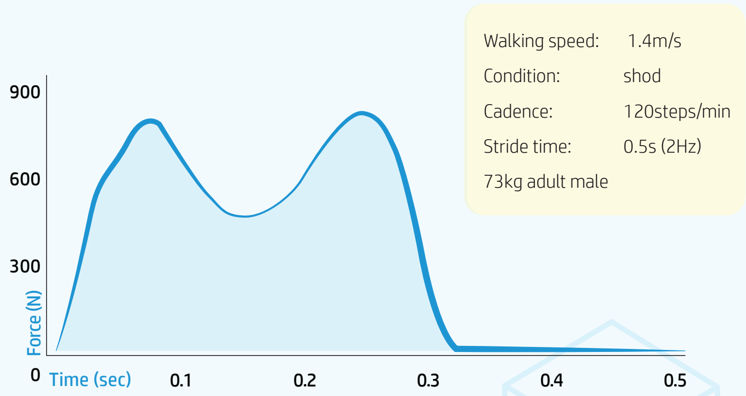
For instance, metatarsal phalangeal joint angle in studies[1] have shown 20-30 degrees flexion. To evaluate extreme deformation and stress, 60 degrees of flexion was used in our tests – far higher than would be experienced in a real-world setting.

Similarly, test parameters were selected to capture average step counts for individuals across age groups, average vertical ground reaction force (vGRF) while walking, levels of flex in arch compression, and the degree of insole deflection. [See Box 1]

Box 1

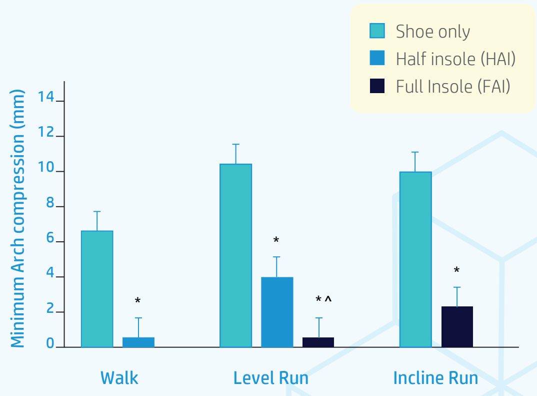
Average Number of steps per day:	
8-10 year olds	12,000-16,000 (less for girls)
Relatively healthy younger adults	7,000-13,000 (lower for women)
Healthy older adults	6,000-8,500
People with disabilities and chronic illness	3,500-5,500

*Based on a meta-analysis of 32 studies (Tudor--Locke and Myers, 2001)



Custom waveform of walking vertical reaction force used for cyclical loading of the orthotic samples. All walking trial vGRF values below the best test preload were changed to 20N.

*Yandell and Zelik, 2016



Stearne, 2016; Kuroyanagi, 2010

1. Cigoja, 2020, Kuroyanagi, 2010, Kelly, 2014, Kessler, 2019, Kelly, 2016

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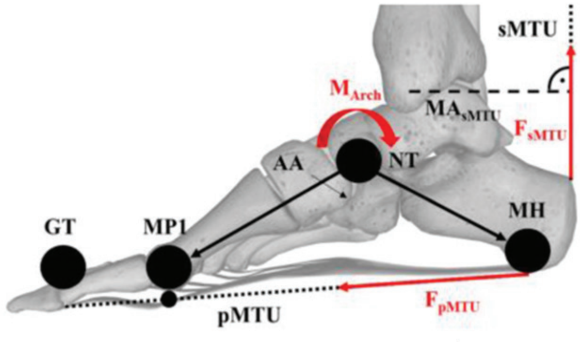
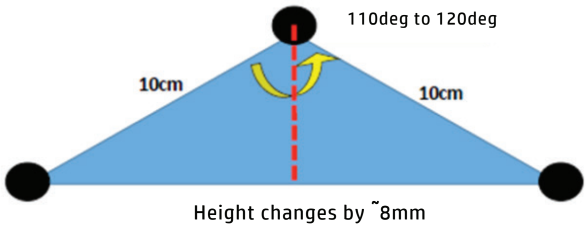
Although at the time of the study HP & Biomechanigg were not aware of any studies which define how much a typical foot arch may change, we were able to estimate that the height of an arch might change by as much as 8mm.

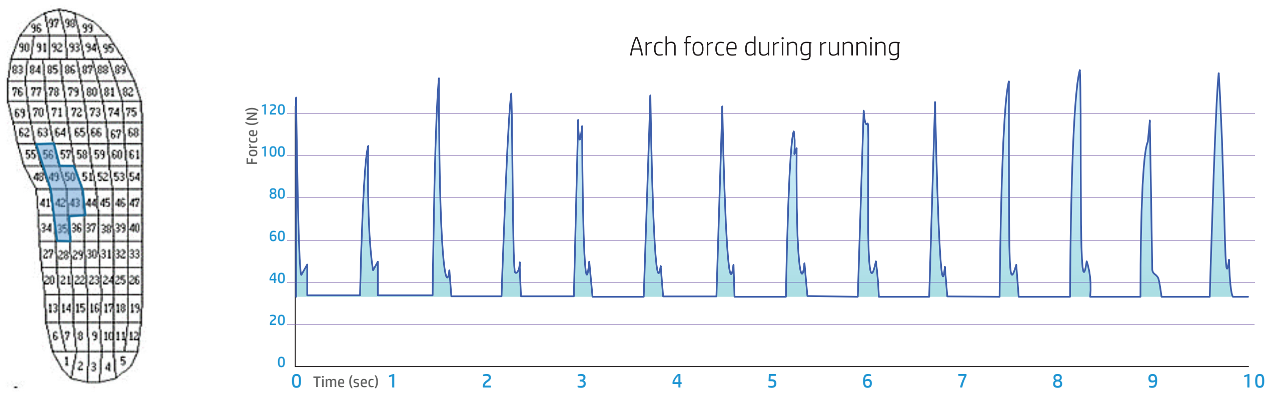


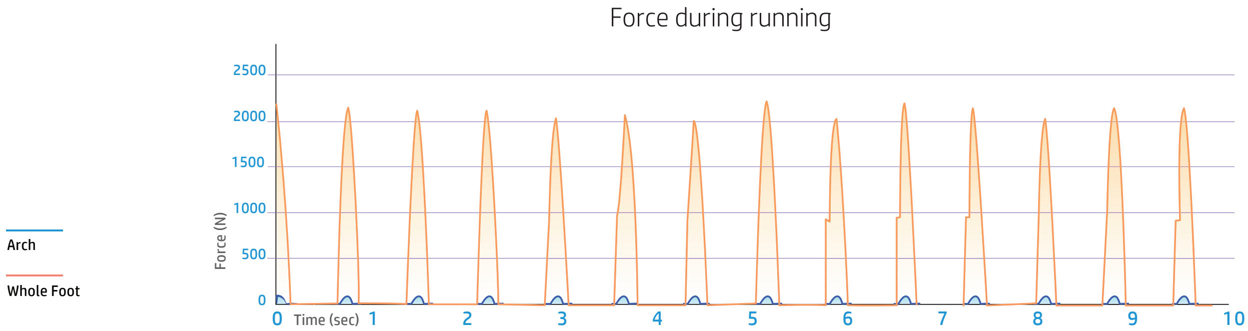
Arch angle



Based on previous work done by Biomechanigg, we were able to select the zones of the foot that we estimate our Instron machine exerted a force into (listed as “arch” in the chart). This helped us to better understand what a typical deflection force should be for this area of the insole. This background research helped guide how to structure an effective testing methodology.

Box 2





This groundwork helped lay a solid foundation to expand the quantification of foot orthotics performance and durability.

1. Cigoja, 2020, Kuroyanagi, 2010, Kelly, 2014, Kessler, 2019, Kelly, 2016

Formulating The Tests

Stiffness – Ramp Test

To evaluate stiffness, various orthoses were subjected to a 40mm displacement, at 1 mm/s. This is equivalent to 60 degrees of flexion. A force-deflection curve was generated for the foot orthoses.

In standard fashion, the slope of the stress-strain curve was used to determine arch stiffness. This illustrated the relative stiffness between different materials, geometries, and build orientations.

Durability – Displacement Control Test

The insoles were subjected to displacement cycling to estimate the impact of material selection and design on the durability of devices in terms of displacement, as would be expected in normal use.

During the test, the insole is cyclically fatigued – displacing samples by 5mm on each cycle. Studies indicated that average displacement of up to 2mm could occur in real-world conditions. The 5mm displacement was selected to test the insole well beyond the real-world use expectations.

The force deflected back by the insole is measured and an assessment of the durability can be made using the deflection force decay over subsequent cycles.

We also studied to determine if the insoles should be tested at 2 Hz or 4 Hz. Our investigation found that there were no significant differences in results as a function of frequency. Hence, we opted to conduct the tests at 4 Hz.

Specimens were subjected to a variety of cyclic fatigue – from 100K, 500K, 1 Million and 2 Million cycles. The 500K cycle test and the 2 Million cycle test showed similar data trends, which suggests that short-term testing could be used as a proxy to the longer-term, more expensive testing.

Durability – Force Control Test

This test was designed to estimate the impact of material selection and design on the durability of devices relative to applied force. The devices were subjected to accelerated failure and compared against expected use values.

The sample insoles were loaded with a force ranging between 10N to 110N – representing the highest and lowest forces recorded during a previous Biomechanigg running study. (See Page 6, Box 2, for the data)

The initial displacement [for the force control test] started at 5mm but increased over time as the cycle count ticked upward.
This progressive overload was intended to cause premature failure in the device.
The change in displacement was measured as a function of total cycles for comparison between materials, design, and manufacturing method.

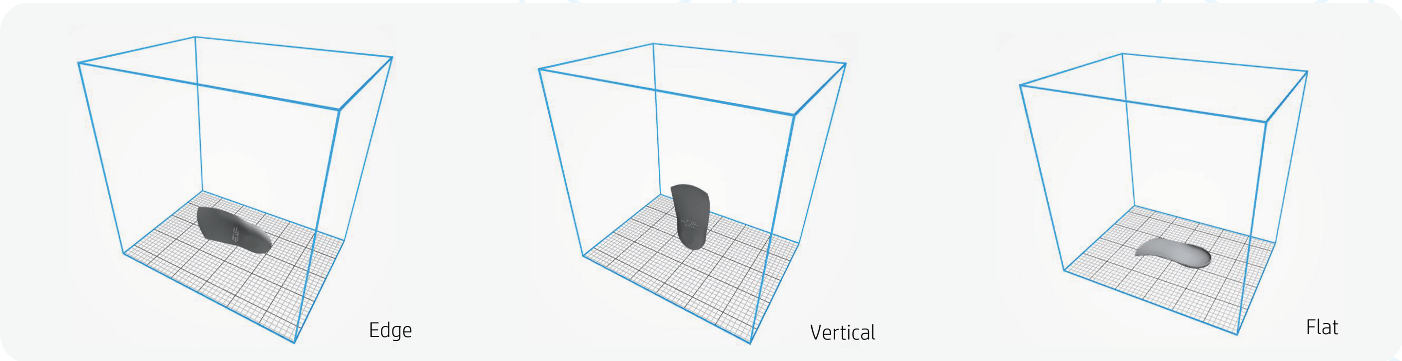
What the **Tests Revealed**

The sample insoles [files as provided by Solo Laboratories] were manufactured using HP's Multi Jet Fusion (MJF) technology.
Each sample was built using a particular material and printed in a particular orientation. The (MJF) materials used in the study were PA-11 and PA-12. The MJF insoles were built in Horizontal, Vertical and Edge orientations using each of these materials. We tested the MJF insoles against a Polypropylene CNCed traditional insole as provided by Solo Laboratories.

	Number of parts	Packing density	Build height
PA-12 Horizontal	94	9.89%	249.54mm
PA-12 Vertical	74	9.69%	200.68mm
PA-12 Edge	38	12.1%	99.46mm
PA-11 Horizontal	94	9.92%	249.54mm
PA-11 Vertical	74	10.15%	191.79mm
PA-11 Edge	38	12.1%	99.46mm

The thickness of the insoles was measured before and after testing in two places – heel and mid-sole to understand if thickness varied over time. Our measurements show that no meaningful difference occurred.

Additionally, each insole was weighed prior to testing to notate any significant variation. Again, no meaningful difference was observed. Lastly, the arch height for each insole was also recorded.



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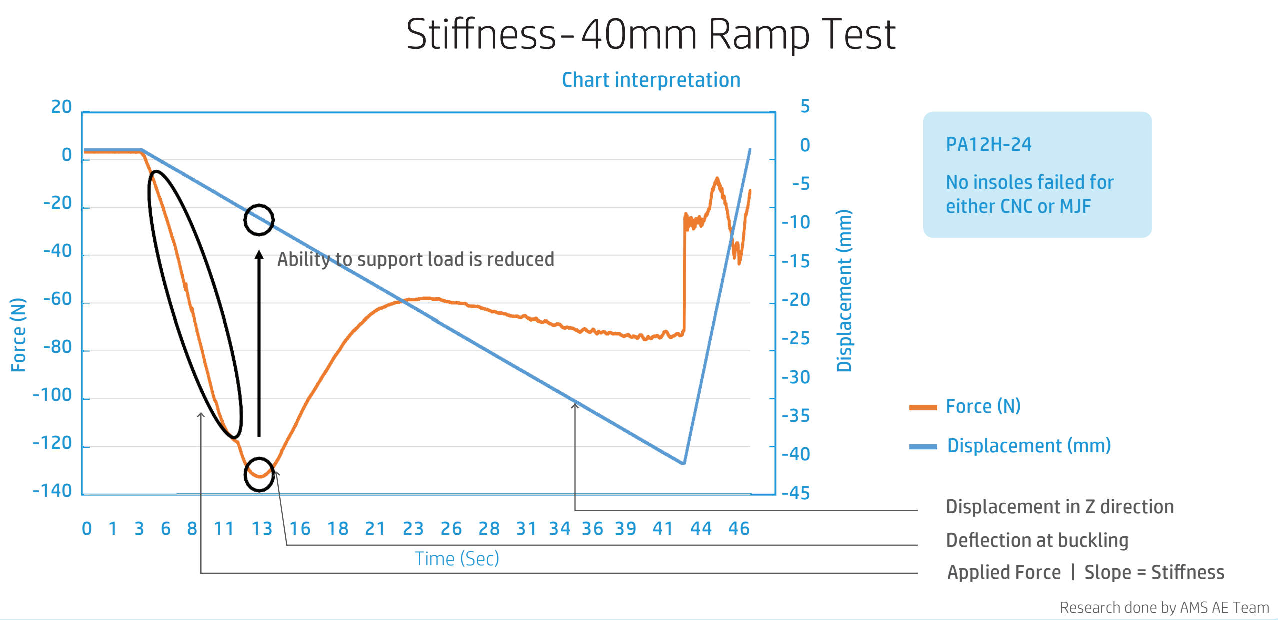
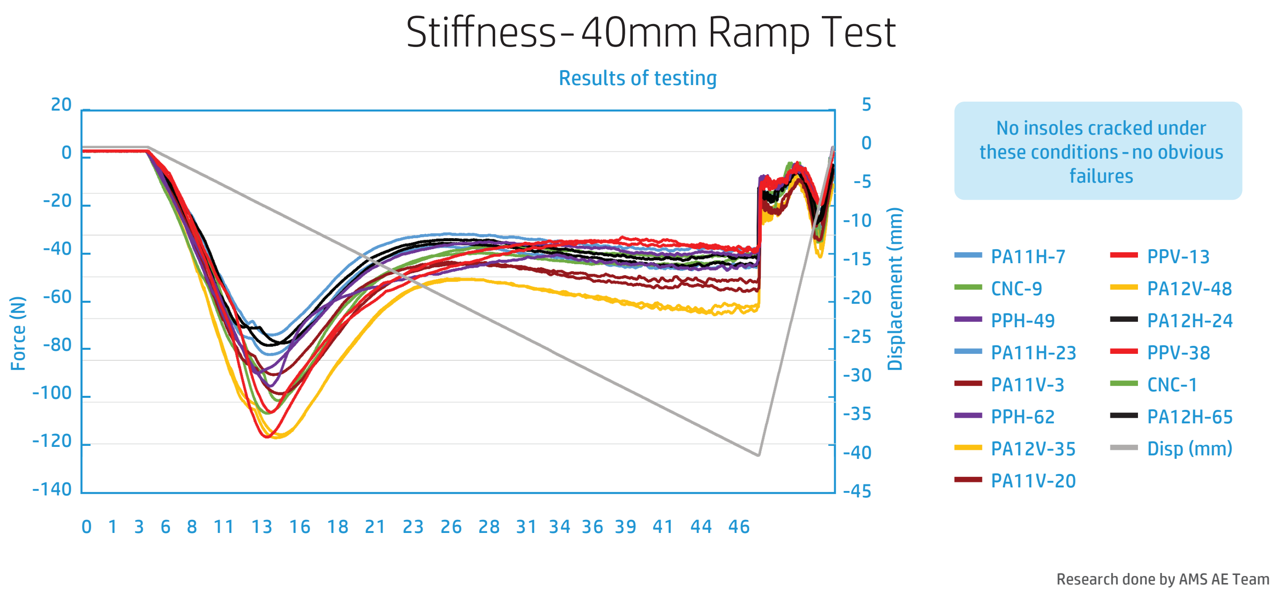
Stiffness

- **None of the insoles failed the Ramp Test.** The insoles printed by HP Multi Jet Fusion performed as well as those machined using CNC methodology.
- **Build orientation matters** since the stiffness and orientation of the orthosis affects the amount of force it can withstand before buckling. The orthosis manufactured using PA-12 in Edge orientation gave the most consistent performance and could withstand the highest forces.
- **Although stiffness varied minimally,** we believe the differences are so small that we don't expect a user to be able to "tell the difference" when wearing them. More studies would need to be performed to validate this conjecture.





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Stiffness-40mm Ramp Test

Results of final test- February 2021

	PA11E			PA12E		
Insole	32	31	27	22	23	33
Thickness	2.31	2.31	2.37	2.34	2.40	2.46
Max force (N)	-118.0	-102.3	-111.1	-129.8	-145.2	-146.4
Disp@ max force (N)	-10.2	-10.0	-10.7	-9.5	-8.9	-8.5
Slope	-11.5	-10.2	-10.4	-13.7	-16.3	-17.1
Normalized to thickness						
Max force (N/mm)	-51.1	-44.3	-46.9	-55.5	-60.5	-59.5
slope (N/mms)	-5.0	-4.4	-4.4	-5.9	-6.8	-7.0

Normalized to thickness calculations:

Max force (N/mm) = Max force (N) / Thickness (mm)

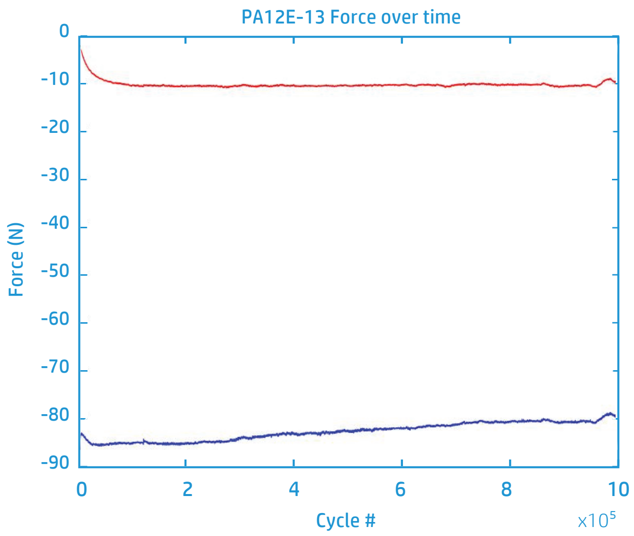
Curious obseration:

PA-12 & PA-11 Flexural modules (stiffness) is the same. 1800 Mpa.

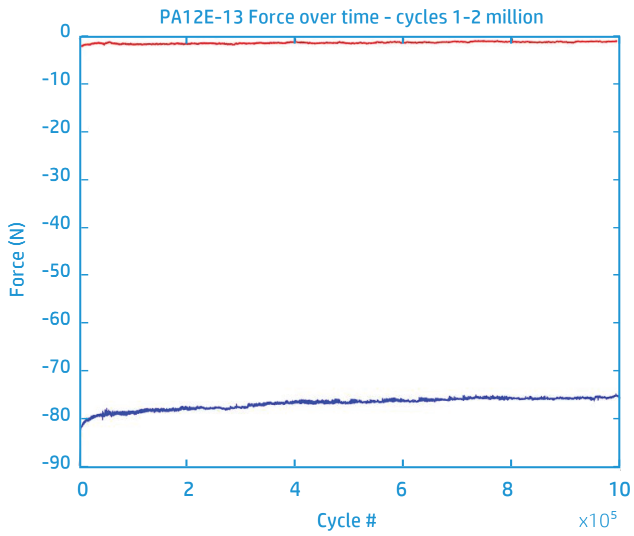
Durability

- There were no obvious failures while displacing the orthoses to double their normal conditions up to 1 Million and 2 Million cycles.
- The results of a single PA-12 MJF insole tested out to 2 Million cycles showed a similar performance change compared to what was observed in our 500K cycle test. Since our MJF insole and CNC insole tests performed similarly at 500K cycles, we believe that our tests show that MJF insoles performed similarly to CNC insoles. The results of a single PA-12 MJF insole tested out to 2 Million cycles showed a similar performance change compared to what was observed in our 500K cycle test. Since our MJF insole and CNC insole tests performed similarly at 500K cycles, we believe that our tests show that MJF insoles performed similarly to CNC insoles.

Cycles 0-1Million



Cycles 1-2Million



Taking a step towards **digital workflows with confidence**

While the experimental findings suggest quantifiable measures for the evaluation of 3D printed orthoses, there were several other key takeaways.

Data Courtesy of Crispin Orthotics

The study proposes industry measures for the analysis and discussion of orthotic performance in a scientific and quantifiable manner.

In combination with past research, this study formulates the test criteria for testing foot orthotics in terms of displacement, force, and cycle count.

Finally, the study discards non-relevant measures which have minimal impact on the performance outcomes of orthotics.

During our tests, foot orthoses of certain materials and printed using HP Multi Jet Fusion technology in particular orientations performed comparably to CNC orthoses, and they lasted just as long.

When samples were put through the testing methodologies formulated by this study, the insoles printed using PA-12 in Edge orientation were as durable as insoles manufactured using CNC methodology. Moreover, the relationship between end performance and mechanical testing suggested by this study may be extended to other geometries.

Orthotics clinics and manufacturers can thus offer products created using Additive Manufacturing techniques with confidence – knowing that the orthoses they deliver will perform as well as traditional ones. Having met this fundamental criterion, digital workflows can help open up new business opportunities. This means clinics can now design and fabricate complex, customized products that are impractical and inefficient to create with traditional methods, such as CNC. This will allow them to stand out from the competition – delivering a truly differentiated and superior experience to their customers and patients alike.

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