

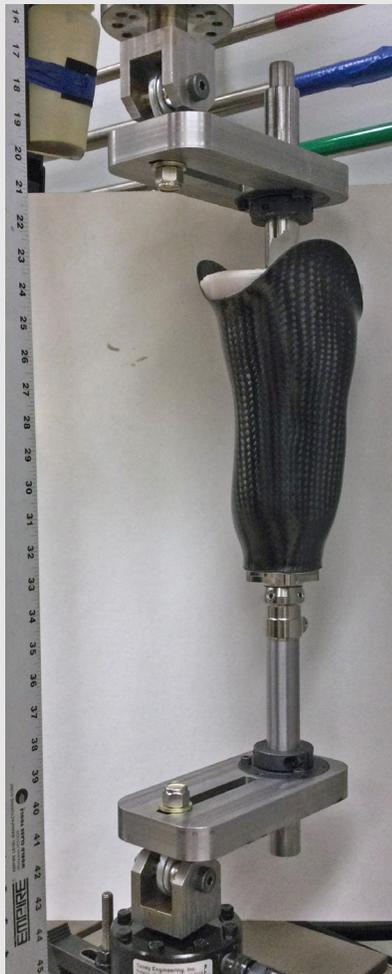
Carbon fiber vs. printed with HP Multi Jet Fusion (MJF) technology and HP 3D High Reusability (HR) PA12 material



Quorum



EMPIRICAL
TECHNOLOGIES



Introduction

Additive manufacturing (AM) has the potential to revolutionize the orthotic and prosthetic fabrication process by improving personal customization capabilities, reducing manufacturing time and waste, and ultimately, resulting in better overall outcomes.

A number of trials have been conducted in fabricating prostheses and orthoses using AM technology. However, there is a research gap in completed studies that test lower limb prosthetic sockets¹. This whitepaper study sought to highlight the significance of investigating the upper-bound mechanical test data limits for lower-limb prosthetic sockets, using AM technology.

In this context, HP aims to answer the following research questions:

- Is an additively manufactured socket printed with the HP Jet Fusion 3D 4200 Printing Solution and HP 3D HR PA12 material comparable to a conventionally manufactured carbon fiber socket?
- How can we determine and test if a socket printed with HP MJF technology is better or worse than a socket fabricated using traditional techniques?
- Can HP predict how and where a printed socket might fail?

Testing methodology: Exploring socket design through traditional methods vs. HP's MJF 3D printing

The testing approach of the study involved exploring socket design using traditional methods versus HP's MJF 3D printing technology. To effectively compare the two methods, HP collaborated with Quorum Prosthetics, a prosthetics company, and Empirical Technologies, a testing group (both based in Colorado, USA).

Testing apparatus

Quorum Prosthetics provided the carbon fiber sockets and their digital equivalents with minor differences in geometries. As you can see in Figure 1, the traditional carbon fiber lay-up socket (gray) features a slightly unique geometry, as traditional sockets often possess different geometries due to varying fabricator's lay-up techniques.

¹<https://www.sciencedirect.com/science/article/pii/S2095809920302575>

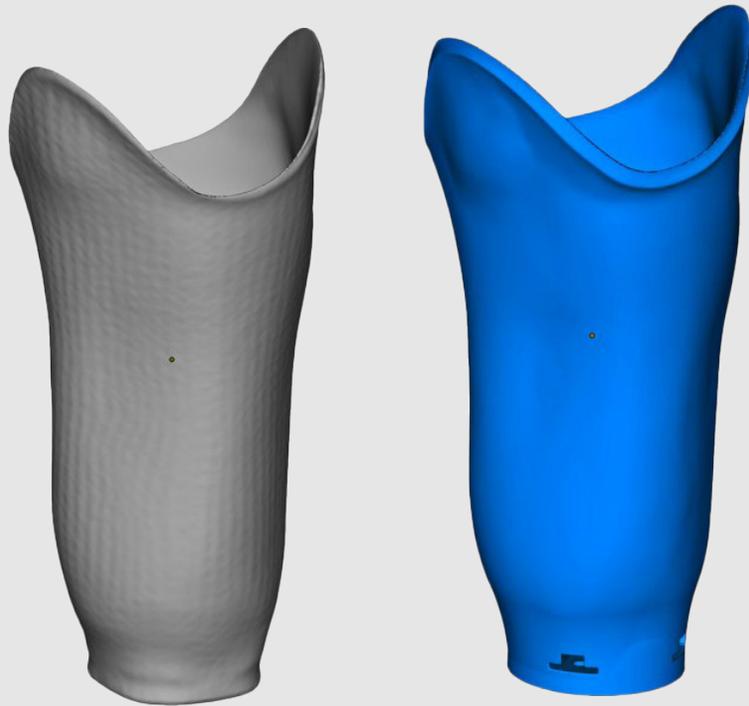


Fig. 1 - Note the cutouts in the blue 3D design as a way to attach a pyramidal adapter, whereas the gray design is the carbon fiber equivalent.

Both designs are a transtibial socket focused on mid-to-high activity level range. Quorum Prosthetics also stated that this design would be appropriate for the majority of their transtibial patients that they typically see in their clinic.

It's crucial to recognize the inherent variability, primarily, due to the layering process involved in the creation of carbon fiber sockets.

Typically, the wall thickness of the laminated sockets tends to be much less than 6 mm, usually closer to 2-3 mm, even with multiple layers of carbon, leading to slight inconsistencies in thickness across different areas of the socket.

The socket was designed for an individual who stands 5 feet 9 inches tall and weighs approximately 200 pounds (see 'Appendix' for a link to a video highlighting how the socket was made traditionally).

Quorum Prosthetics felt this design approach would be most conducive for a mid-activity level patient. Note that the metal baseplate is not represented in this digital equivalent of the carbon fiber design represented above in gray.

In contrast, the HP MJF printed sockets were crafted using the HP 3D HR PA 12 material. These sockets were specifically designed to have an average uniform wall thickness of 6 mm.

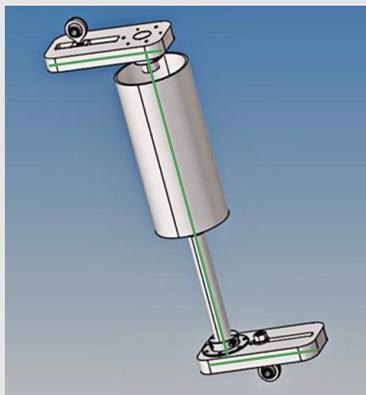
The design integrated four T-slots at the distal end, enabling a secure attachment of a baseplate to the bottom of the printed socket.

Early testing approach

The early testing approach aimed to evaluate the mechanical strength of a prosthetic socket, focusing on the socket itself rather than the hardware attached to it.

As a first step, ISO 10328:2016 was identified as the most suitable protocol for evaluating the mechanical properties of a prosthetic socket via both static and cyclic fatigue testing. Fatigue testing helps determine a material's ability to withstand cyclic loading conditions and assesses factors such as fatigue life, fatigue strength, and crack resistance when subjected to repeated loading and unloading cycles, until a specified number of cycles or failure occurs.

However, the test following this protocol did not produce a socket failure (Fig. 2).



Original test setup follows ISO 10328:2016



Results of test



Modified test setup doesn't follow ISO 10328:2016

Fig. 2

As a result, the test setup was modified (as shown above with the green lines for emphasis) to apply extreme force to induce failure in a socket, made using HP's Multi Jet Fusion technology. In this instance, the socket eventually failed at the T-nut section, but only after withstanding a force of approximately 4,000 newtons or 900 pounds (408 kg) (Fig. 3).

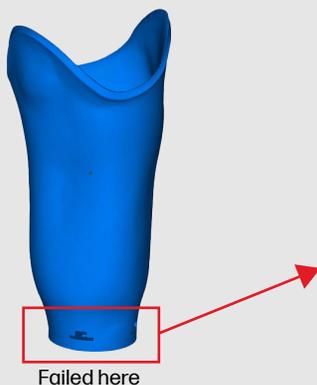
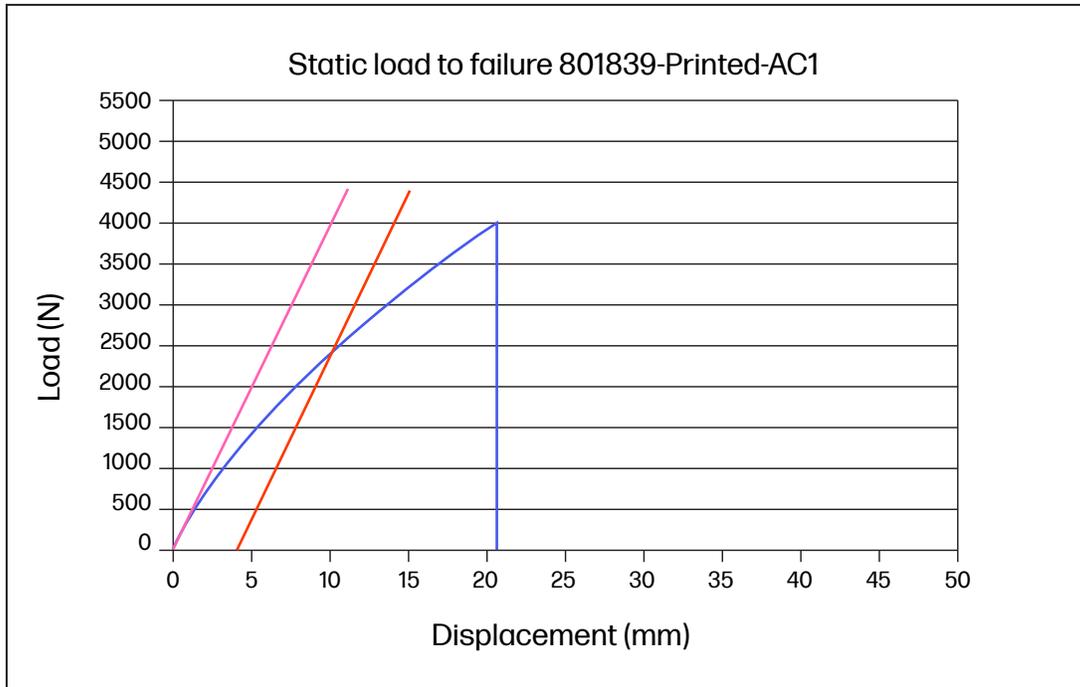


Fig. 3



Graph 1. Static load to failure: Specimen 801839-Printed-AC1

Note:

- Blue line: This signifies the raw data as measured (specifically measuring the force and displacement data).
- Pink line: This is the linear region where the stiffness is calculated, thereby indicating the material yield.
- Red line: This is the 2% offset from the pink line. This is used in testing because some materials are hard to pinpoint the exact point at which a material changes from elastic to plastic deformation.

Specimen #	Linear fit offset (mm)	Yield displacement (mm)	Yield load (N)	Stiffness (N/mm)	Ultimate load (N)	Ultimate displacement (mm)
801839-P-AC1	-0.03	10.17	2446	396	4003	20.61

As Quorum Prosthetics typically aims for a safety factor of 2x the body weight with their sockets, the company considered these results impressive, particularly given the worst-case scenario test setup approach.

Data collection and investigation

After determining a repeatable testing approach and collecting initial test data, HP conducted tests on three other MJF-printed and one carbon fiber lay-up socket. Interestingly, the data revealed that the three MJF sockets tested outperformed the single carbon fiber socket.

Following the modified test setup, as shown with the green lines in Figure 2 graphic above, there are a few points worth considering regarding the test data we gathered from both the printed and carbon fiber sockets.

First, a socket printed with HP’s MJF technology and HP 3D HR PA12 material can withstand a higher ultimate load (N) than a carbon fiber lay-up socket. However, given that this test methodology does not adhere to an ISO protocol (nor does one exist), HP cannot definitively determine whether the results are “good” or “bad.”

Table 1: Results of the static load to failure testing (traditionally manufactured socket)

Specimen #	Linear fit offset (mm)	Yield displacement (mm)	Yield load (N)	Stiffness (N/mm)	Ultimate load (N)	Ultimate displacement (mm)
801839-M-AC1	-0.04	8.73	2426	513	3335	13.11

Table 2: Results of the static load to failure testing (3D-printed Quorum prosthetic socket)

Specimen #	Linear fit offset (mm)	Yield displacement (mm)	Yield load (N)	Stiffness (N/mm)	Ultimate load (N)	Ultimate displacement (mm)
801839-M-AC1	-0.03	10.17	2446	396	4003	20.61
801839-M-AC2	-0.09	11.09	2728	385	4207	20.50
801839-M-AC3	-0.23	19.60	3760	241	5128	42.30
Mean	-0.12	13.62	2978	341	4446	27.80
Std Dev	0.101	5.196	691.9	86.5	599.2	12.556

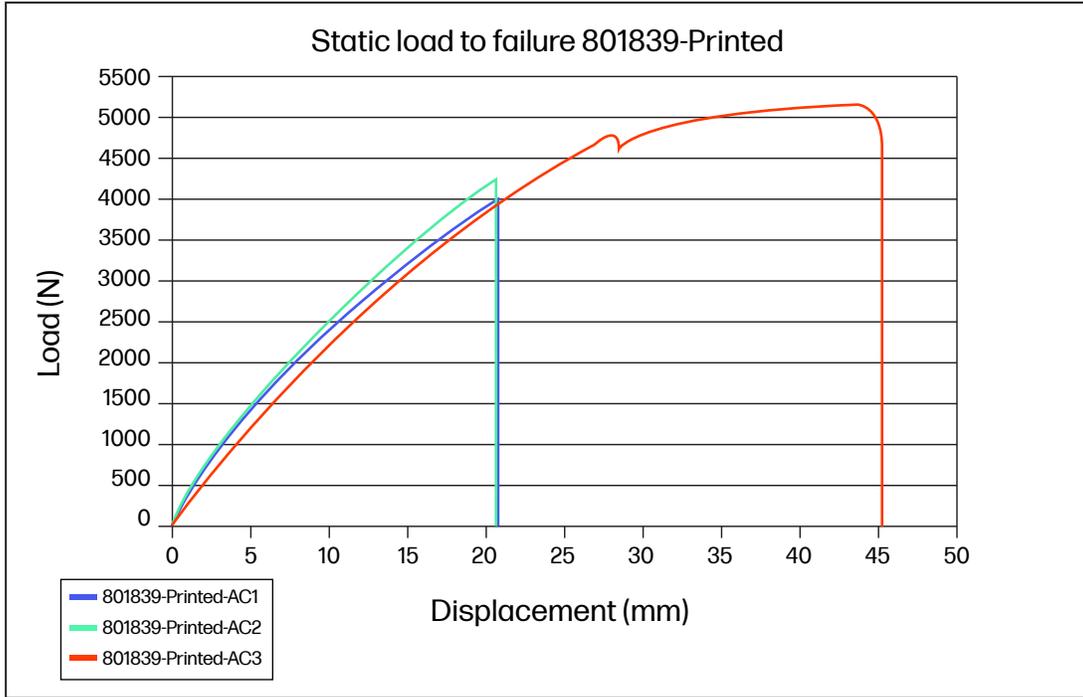
Note on results in tables 1 and 2:

The observed behavior of the PA12 and carbon in displacement and stiffness results provided insights into potential user experiences with an MJF vs. CF socket. The comparatively lower stiffness values of the MJF socket might align with the increased comfort some users report, describing a socket sensation akin to a "shock-absorber with higher energy return" (PA12), as opposed to a more jarring impact (CF).

This difference can be conceptualized as the experience of running or walking on concrete versus a rubberized surface. The higher displacement values of the MJF, relative to the CF, might also indicate advantages in certain failure scenarios, given the potential for greater elongation before breaking, which could absorb more energy as failure approaches.

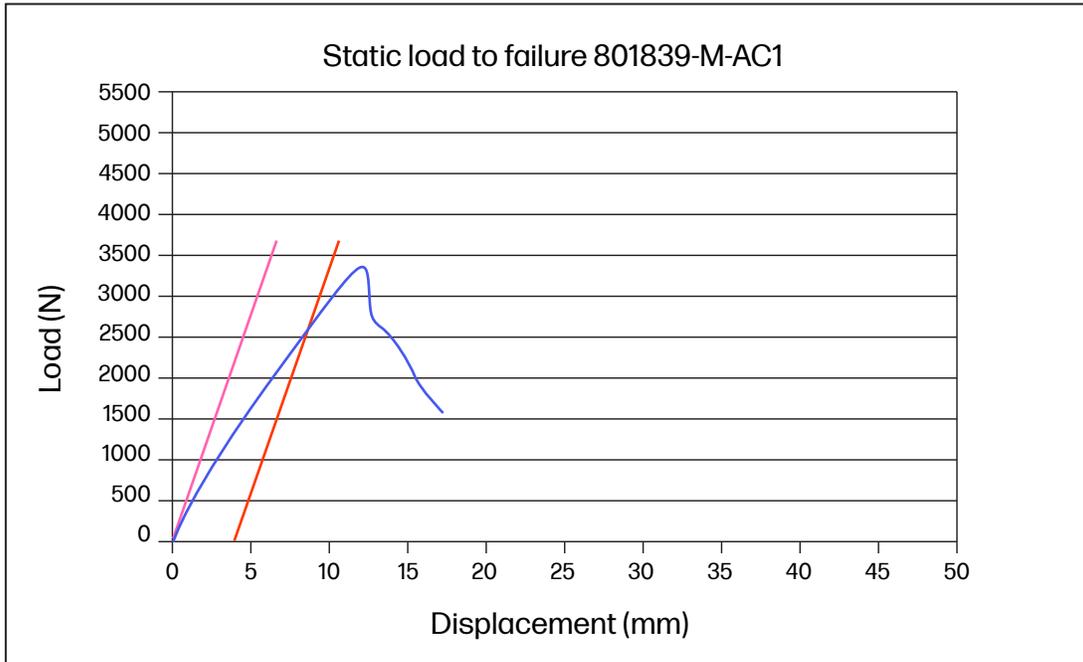
Furthermore, statistical evidence is pivotal in such analyses. As research expands to include larger sample sizes, it edges closer to allowing for claims backed by stronger statistical significance.

Printed with HP MJF technology and HP 3D HR PA 12 material



Graph 2. Static load to failure: 801839-Printed (All printed sockets)

Carbon fiber

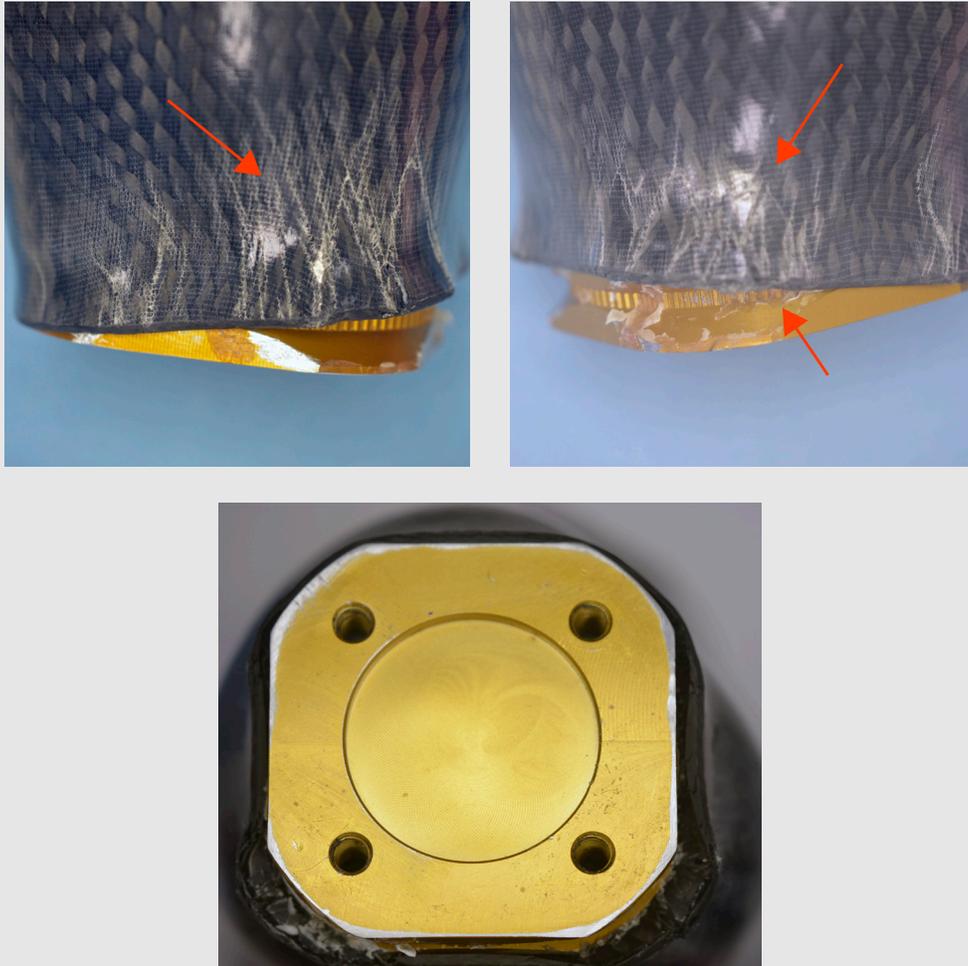


Graph 3

Note on Graph 3:

- Blue line: This signifies the raw data as measured (specifically measuring the force and displacement data).
- Pink line: This is the linear region where the stiffness is calculated, thereby indicating the material yield.
- Red line: This is the 2% offset from the pink line. This is used in testing because some materials are hard to pinpoint the exact point at which a material changes from elastic to plastic deformation.

Second, there was one MJF outlier (801839-P-AC3) that resulted from the testing hardware not being fully secured, leading to damage during testing as pressure increased. The non-outlier MJF socket (801839-P-AC2) failed at around the same ultimate load (N) as in the first test to failure (801839-P-AC1).



The carbon fiber socket failed at the distal end from stress fractures, which allowed the end plate to pull away from the socket.

Fig. 4

Last, HP initially planned to test two carbon fiber sockets. However, due to the failure of the initial test setup (bending of the metal rod as observed in results 1.1), only one CF socket was available for testing at that time.

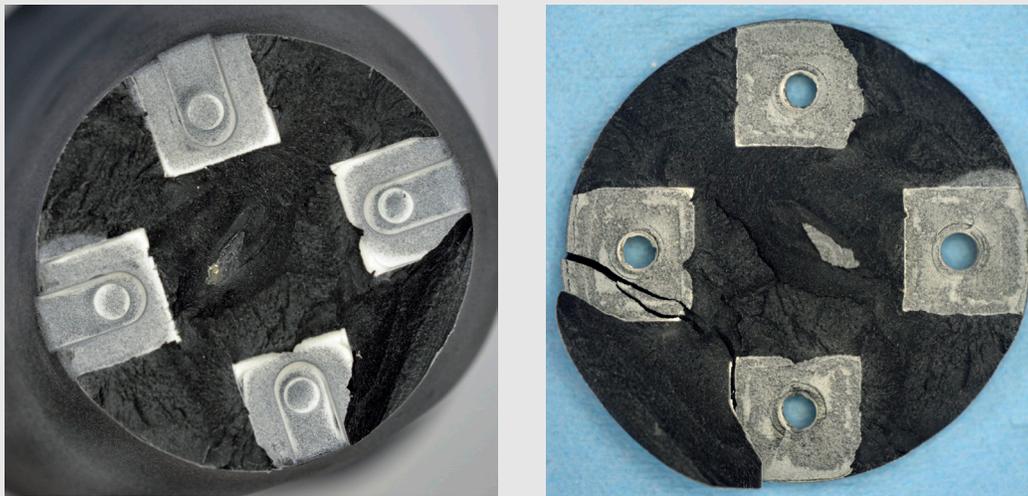


Fig. 5

As shown in Fig. 3, the MJF sockets separated at the T-slot where the baseplate attaches. The investigation of test-to-fail data was crucial in determining the strength of MJF and carbon fiber sockets. The data revealed that the MJF sockets outperformed the carbon fiber socket with this testing configuration.

Cyclic fatigue testing & evaluation

The cyclic fatigue test was undertaken to gauge the endurance of the sockets. During that period, there had been no prior research to establish the maximum mechanical capabilities of either printed or traditionally fabricated sockets. Hence, our team at HP created a unique scenario to expose these sockets to a cyclic fatigue test with gradually increasing force to evaluate the sockets' performance under accelerated testing conditions.

Scenario

Every 250,000 cycles, assuming no failure, an additional 500 N of force was added.

Cycles [x1,000]	Force [N]	Cycles [x1,000]	Force [N]
0-250	1,000	750-1,000	2,500
250-500	1,500	1,000-1,250	3,000
500-750	2,000	1,250-1,500	3,500

Carbon fiber evaluation



Fig. 6 These images show how and where the titanium pyramidal adapter failed

The Bulldog TCA-1S titanium female pyramidal adaptor failed twice (and was replaced each time) at cycle count 895,164 (fracturing 145,164 cycles into the 2,500 N step), and at cycle count 974,988 (fracturing at an additional 79,824 cycles into the 2,500 N step) with the carbon fiber socket. As a note, the Bulldog TCA-1S adaptor is rated to 300 lbs (136 kg).

Sockets printed using HP MJF technology evaluation



Fig. 7

At 17,343 cycles into the 2,000 N step, one of the bolts securing the pyramidal adaptor to the socket broke on an MJF printed socket. The bolt was replaced, and testing restarted. The socket later failed at the connection point between the baseplate and the MJF socket at cycle 812,944 (or 62,944 cycles into the 2,500 N step).

The cyclic fatigue test determined the durability of carbon fiber and MJF sockets. The data revealed that the carbon fiber socket failed twice, while the MJF socket failed once due to a bolt securing the pyramidal adaptor breaking.

Test findings and results

Static and cyclic fatigue results



Printed with HP's MJF technology and HP's 3D HR PA 12 material

Fig. 8

The static testing approach was developed with input from Quorum Prosthetics and Empirical Technologies to ensure a fair and replicable testing approach. Prosthetic components attached to a socket are normally tested following ISO 10328:2016 and typically undergo testing at approximately 1,950 newtons of force. Our extreme test setup resulted in the failure of both sockets at the following forces:

- Carbon fiber: 3,335 newtons
- HP MJF #1: 4,003 newtons
- HP MJF #2: 4,207 newtons

Given that the test is both extreme in nature and the results are 2x that of the ISO 10328:2016 protocol for socket attachments, HP views this as promising with regards to safety. It is encouraging to see the MJF sockets failing at similar force values as well. Interestingly, the MJF sockets sustained a higher load before failure compared to a carbon fiber lay-up socket. HP attributes this difference to HP MJF's relative flexibility compared to carbon fiber.

The baseplate at the distal end pulled away from the middle of the carbon fiber lay-up socket due to stress fractures in the carbon fiber, thereby inducing the failure. The socket printed using HP MJF technology failed where the baseplate attaches to the distal end of the socket at the T-nut attachment features. This suggests that if a higher failure force is desired for the printed socket, an alternative attachment method should be considered.

Similar to static testing, HP intentionally caused the carbon fiber and MJF sockets to fail during cyclic fatigue testing to better comprehend the upper limit of when and how a socket

might fail. Both HP & Quorum Prosthetics found it surprising to see both the carbon fiber and HP MJF sockets withstand the test for as long as they did, considering the extreme forces applied. Remarkably, the titanium pyramidal adaptors failed before the carbon fiber socket.



"This study was a significant and necessary step in the right direction for all industries involved: O&P, Additive Manufacturing, Engineering. We cannot disregard the study's limitations, but we cannot discount the results either. Many variables of socket design and fabrication, both from the "traditional" and "digital" methods, should be considered. We must acknowledge that these variables played a role in the MJF socket ultimately failing at a higher force value than the CF socket in the static test. If a different design and fabrication method had been used for each socket tested, these results could have easily been reversed.

Another significant variable to consider is the attempt to adhere to industry standards, i.e., ISO 10328. These standards apply to mass-produced, non-custom components of the overall device. Historically, there has not been a standard set to test socket design, material durability, strength, etc., in this category of custom total contact sockets; this is not without reason.

These types of sockets are custom to the individual and not an "off-the-shelf" product that is mass-produced in the same way or with the same level of control as the other components. This nature makes it impossible to standardize and regulate the design and fabrication of such products.

The thought of regulating socket design and fabrication could lead to further reducing access to these devices, in an economy that already struggles to give access to end users efficiently and economically. When carbon fiber sockets entered the market, there didn't seem to be as much scrutiny around the question we are facing today: "Are they strong enough?". This project is just the tip of the iceberg."

- Sean McClure, R&D Engineer and Director, Quorum Prosthetics



Images above are the failures endured after a cyclic fatigue test, as defined in the below chart. Image on the left shows the carbon fiber socket and image on the right shows socket printed using HP's MJF technology and HP's 3D HR PA 12 material.

Fig. 9

Cycles [x1,000]	Force [N]	Carbon fiber cycle failure	MJF cycle failure
0-250	1,000		
250-500	1,500		
500-750	2,000		
750-1,000	2,500	895,164	812,944
		974,988	
1,000-1,250	3,000		
1,250-1,500	3,500		

Note:
 The test was halted for both CF and MJF due to pyramidal adaptor failures. Given the recurring failure mode and constraints on time and resources, we opted not to repeat the test with the CF socket, having observed similar adaptor issues at this cycle count previously.

With the failure observed in the socket printed with HP's MJF technology, HP is optimistic about safety, as we do not believe the failure mode would pose a risk to the wearer. All printed sockets failed while under a load of 2,500 newtons (562 lbs/ 238 kg) in a worse case scenario testing setup.



"The testing process undertaken was an enriching experience for both our testing facility and the client. This project empowered us to craft tailored testing methodologies, enabling direct comparisons between diverse socket designs. These custom test methods pave the way towards standardizing procedures, a leap that could revolutionize the prosthesis industry by ensuring the continuous production of safe and reliable designs that enhance lives globally. We eagerly anticipate further opportunities to contribute to the expansion of this vital area of testing."

- Marcus Martinez, Senior Test Engineer, Empirical Technologies

The data collected from the static and cyclic fatigue testing approaches can help improve the design process with iterative structural testing, leading to sockets that last longer, necessitate fewer repairs and replacements, and potentially reduce time and costs.

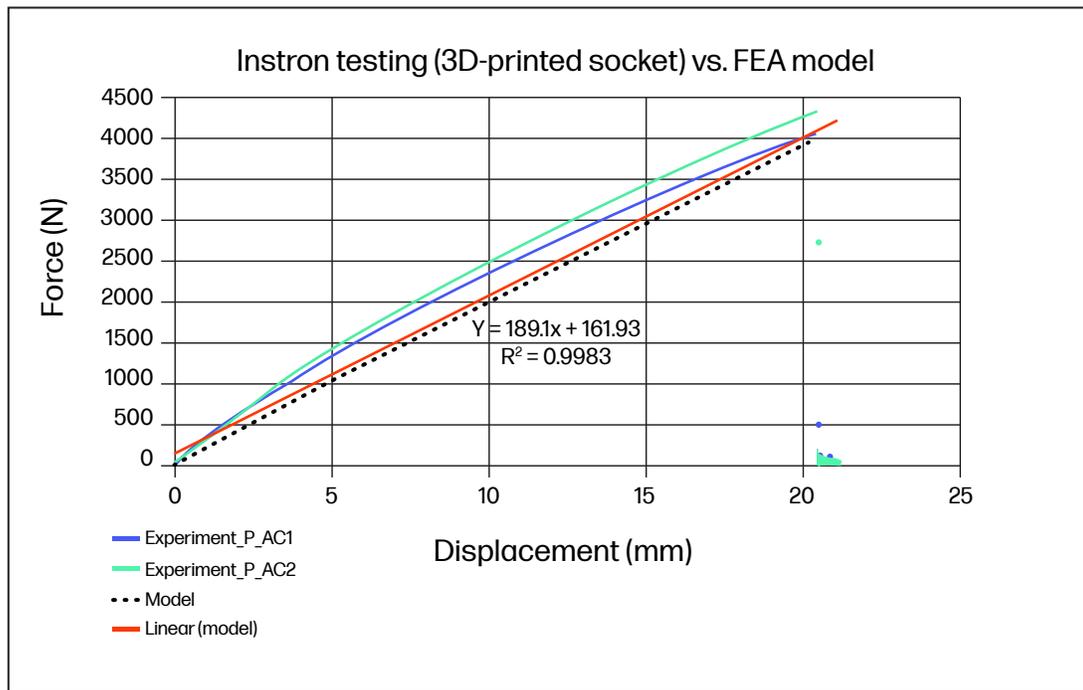
Manufacturing time: Time taken to make each socket

Manufacturing method	Day 1 (Fri)	Day 2 (Sat)	Day 3 (Sun)	Day 4 (Mon)	Total
Carbon fiber	Fabricate liner- 30 min. First lamination- 1 hour Alignment check Attach lamination plates Shape the foam- 30 min. Total: 2 hours	Bondo foam & sand Second lamination- 30 min. Finishing pass sanding- 30 min. Total: 1 hour	—	—	3 hours, over 2 days
HP MJF technology and HP's 3D HR PA 12 material	Scan model/limb- 15 min. CAD cleanup- 1 hour Prepped & began printing- 15 min. Total: 1.5 hours	Parts cooling	—	Parts retrieved & bead blasted- 1 hour Total: 1 hour	2.5 hours, over 4 days

FEA modeling results

Upon collecting technical data, HP sought to answer the question, "Can HP predict where/how a socket might fail?"

Force vs. displacement



Graph 4

The HP FEA team successfully developed a model trendline (black line) that closely matches the actual test data collected (blue & orange).

The data collected from the FEA modeling allowed HP to closely simulate the performance of a specific socket. While the data set is not yet comprehensive, HP believes it serves as a valuable starting point for guiding the design development process of prosthetic sockets in the future.

Conclusion

This investigation achieved the development of a testing approach that is equitable, consistent, and holds potential relevance for the industry to adopt as a method to test sockets.

Leveraging Quorum Prosthetics' expertise in the prosthetics field and Empirical Technologies' proficiency in testing, HP was able to address the questions they initially aimed to explore.

Is a 3D-printed socket printed with HP 4200 MJF technology and HP 3D HR PA12 material comparable to a conventionally manufactured carbon fiber socket?

A comprehensive evaluation was conducted comparing a 3D-printed socket, utilizing HP MJF technology and HP 3D HR PA12 material, to a conventionally manufactured carbon fiber lay-up socket. Despite the lack of universally accepted metrics for prosthetic socket performance, the data derived from our innovative testing approach—developed collaboratively with a leading testing and prosthetics company, yielded some significant insights:

- A 3D-printed socket printed using HP MJF technology and HP 3D HR PA 12 material performed better than a carbon fiber socket when put under extreme load to failure. This outcome might be attributed to HP's 3D HR PA12's inherent flexibility compared to carbon fiber's rigid material properties. Additionally, the sockets printed with HP's MJF technology failed at similar force values, demonstrating consistency in the results.
- A 3D-printed socket printed with HP MJF technology and using HP 3D HR PA12 material failed slightly before a carbon fiber socket when put under increasing load while experiencing cyclic fatigue. Notably, while stress fractures were observed on the carbon fiber socket, the repeated failures of the pyramidal adaptors around the same cycle count prevented further testing to the point of complete socket failure. The failure mode of the HP MJF socket suggested a reduced likelihood of presenting a sharps-related risk to the wearer, which is seen as a positive outcome. When comparing the two, the socket printed with HP MJF technology failed within 10% fewer cycles than the carbon fiber socket, before issues with the titanium attachment arose, indicating remarkable resilience.



“With the introduction of HP’s Multi Jet Fusion 3D printing technology, Quorum is able to deliver consistent, repeatable, and measurable results down to the layer line. Additive manufacturing allows for highly personalized and patient-specific socket designs, giving us the ability to create complex geometries and adapt the shape based on the individual’s unique anatomy. This method results in a better fit and improved comfort for the user.

Traditional approaches to O&P can take extended amounts of time to fabricate devices (especially based on the specialist’s experience level), and typically, have few official standards for customized devices. Comparatively, MJF speeds up the development process and reduces lead times, while simultaneously ensuring patients receive a device unique to their anatomy.

Additive manufacturing also enables us to create lightweight and structurally optimized socket designs. This not only enhances comfort for the user but also helps in minimizing material waste, thereby making the prosthetics fabrication process more energy-efficient overall.

As an amputee with millions of steps in my MJF-printed socket, I have several unique benefits that keep me moving. Plastic is much cooler in the summer and does not retain heat like carbon sockets. It also has more pliability for shock absorption, providing more durability and support. While the initial investment in 3D printing technology may be higher, the overall manufacturing costs can be reduced in the long run due to less waste and more efficient use of materials.

On a larger economic scale, we have noticed that the cost of 3D prints remain on a steady decline, while the cost of O&P fabrication continues to rise.

Each day we see lives being improved using this technology, and we are grateful to HP for developing such an incredible manufacturing platform!”

– Joe Johnson, CEO of Quorum Prosthetics

How can we determine and test if a socket printed with HP MJF technology is better than a socket fabricated using traditional techniques?

To answer this question, let's consider the benefits of HP's Multi Jet Fusion 3D printing technology. This technology offers design flexibility, breathability, light weighting, and customized fittings, which generally lead to higher device compliance by the wearer.

Additionally, it provides manufacturing benefits, such as ease of duplicating devices, ability to scale, less manufacturing space required for production, ability to differentiate in a highly competitive marketplace, ability to attract and retain talent via modern tool usage, and business resilience to pivot quickly, if required.

The promising mechanical test data suggests that there is a compelling reason to explore manufacturing prosthetic devices using HP's Multi Jet Fusion 3D printing technology.

Can HP predict how and where a printed socket might fail?

HP's innovative data collection and modeling have successfully simulated the performance of a specific socket. This approach will serve as a cornerstone for shaping the design and development process of future prosthetic sockets.

Limitations of the study and future considerations

During our testing process, we opted to use a testing limb made of dental cement. Given its unlimited stiffness, it likely resulted in socket failures that were premature compared to what a life-like limb would exhibit following the same testing methodology. As such, repeating this study with a life-like limb might yield better mechanical performance for both carbon fiber and the MJF printed socket.

For the purpose of establishing a baseline, we did not compare multiple designs or sizes of MJF or carbon fiber sockets in this study. Further testing will be required to understand how mechanical performance translates across different sizes and designs.

Due to the collaborative nature of this research on the part of both Quorum Prosthetics and HP, Invent Medical commissioned a study of their Augo socket design shortly after this one, which follows a similar patient characteristic (i.e., 200 lbs or 90 kg). Their study differs in the following ways:

- **Materials:** HP 3D High Reusability PA 11 & BASF Ultrasint® TPU01: These are the materials they currently use in production today
- **Socket design:** Utilizes their Augo design
- **Distal end attachment design:** Follows a standard 4-hole adapter
- **Testing approach:** Given Invent Medical's 20+ years of socket testing, like us, they attempted to follow ISO 10328 and attach the socket to the test setup in as realistic a condition as possible. In practice, however, they decided to modify their approach.

Further reading recommendation: For a comprehensive and deeper understanding of this topic, we highly recommend reviewing an associated whitepaper by [Invent Medical](#). This document offers pivotal insights and complements the findings presented here, ensuring readers gain a holistic view of the subject matter.

Access to the Invent Medical whitepaper can be obtained [here](#).

Appendix

Materials used for the socket fabricated using traditional techniques (i.e. carbon fiber lay-up)

Carbon weave	
Manufacturer	A&P Technology www.braider.com
Trade name	Sharx® Braided Biaxial Sleeving (W56L600R)
Raw material	Carbon G34-700 WD 12k (.014A)
Diameter	6.00" ID
Braid angle	+/- 45 degree
Braid yield	6.3 ft/lb
Areal weight	14.6 oz/sq yd, 495 GSM
Resin-cream hardener	Info via SDS sheet
Manufacturer	US Chemical & Plastics 330-830-6000
Trade name	Cream Hardener Red (27007)
Physical & chemical properties	
Boiling point	100°C (212°F)
Vapor pressure	2.3 kPa (17.5 mm Hg)
Relative density	1.19
Viscosity	Kinematic (40C (104F): >20.5 mm ² /s
Epoxy acrylic resin	
Manufacturer	Paceline Advanced Medical Solutions 800-443-1827
Trade name	NANO

The traditionally fabricated socket as created by Quorum Prosthetics was filmed and described in this video: <https://www.youtube.com/watch?v=5Bfj56xYBow>

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