White paper

Transforming prosthetics and orthotics production with HP Multi Jet Fusion technology

Baby helmet from Invent Medical

Ankle-foot orthosis from Invent Medical

Executive summary

The prosthetics and orthotics (P&O) industry is approaching a challenging time as the number of athletic injuries, the aging population, and instances of diabetes, cardiovascular disease, and amputations are increasing each year.[1] In parallel, the number of prosthetic and orthotic (P&O) technicians is declining, educational CPO programs are scarce, and P&O manufacturers are struggling to keep up with demand.

According to Alan Hutchison, CEO of ProsFit, there have been very few changes to the manufacturing of P&O devices in the past 10 years. **"Patients may report discomfort when wearing the devices and few experience the right fit the first time, potentially requiring multiple visits with clinicians and iterative modifications,"** Hutchison said. **"Increased productivity and consistent quality in P&O manufacturing are the keys to solving the current capacity constraints in the industry and to improve quality of life for patients."**

From left to right: 8Sole from Invent Medical; arm prosthesis and foot-leg orthosis from Invent Medical; helmet from Invent Medical; prosthetic socket from Hulotech

Moving personalized prosthetics and orthotics manufacturing into the future

The implementation of digital workflows in the P&O industry yields benefits across the entire value chain by:

- Simplifying manufacturing operations by increasing automation capabilities and output quality.
- Freeing up the schedule of the clinician who has more time to see patients rather than spending valuable time building molds and conducting re-fittings with traditionally manufactured molds.
- Enhancing the patient's quality of life by providing a perfect fit, a lightweight and slim device, and a modern, visually appealing design.

Adopting 3D printing for P&O manufacturing

From a business point of view, 3D printing in the prosthetics and orthotics industry presents myriad benefits when compared with traditional manufacturing. Specifically, HP Multi Jet Fusion (MJF) technology provides additional advantages in precision and quality to unlock the full potential of 3D printing. HP MJF's scalable platform that supports functional prototypes and final parts can contribute to business growth in a new era of digital manufacturing.

Making the switch from traditional to digital manufacturing will require staff to become familiar with three new aspects of the technology: 3D scanning, 3D design, and 3D printing.

3D scanning: Any part of the body can be 3D scanned in order to obtain a digital image of the desired area. This process allows clinicians to create a model to work with and/or to send the image directly to a central fabrication company.

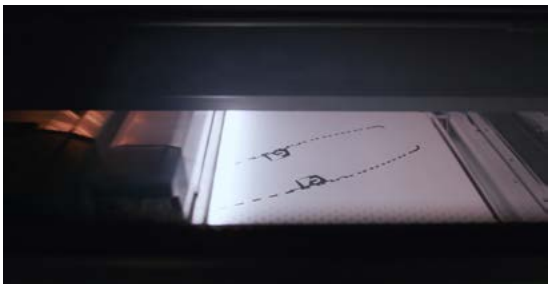
3D scanning process by Hulotech

3D design: The scan is then imported into an industry-specific CAD software, typically Vorum or Rodin4D. This will allow the technician to adapt the model and make changes just like they would with a physical mold.

The adjusted model is then sent to 3D design software, where a design and engineering team creates the 3D printed orthotic device around the modified 3D scan. There is a wide range of tools available on the market, the most popular of which are SolidWorks, Rhinoceros 3D, and Autodesk Fusion 360. This step can take several hours for a novice or just a few minutes of computer time for a professional if the workflow has been automated.


Left: Hulotech designing a prosthetic socket; Right: Invent Medical designing an orthotic helmet

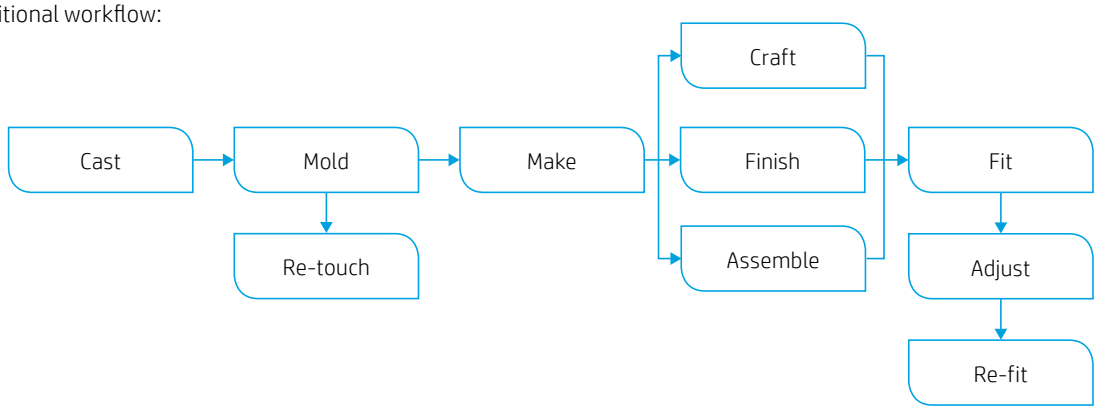
3D printing: Once the design is ready, it can be sent to the 3D printing queue with a batch of other parts to be printed together. For example, an HP Multi Jet Fusion 3D print build can produce about 60 pairs of insoles or multiple adult ankle foot orthotics (AFOs) in about 16 hours, without human supervision.



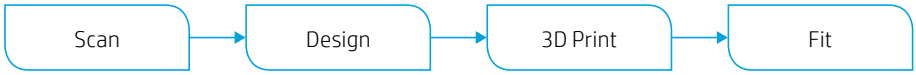

Left and Right: Hulotech – The printing process and final part

Traditional workflow vs. streamlined HP 3D Printing workflow

- Traditional workflow:



- Streamlined HP 3D Printing workflow:



The business and end-user benefits of 3D printing for P&O practices

- Switching from traditional manufacturing to 3D printing involves the transition from an "art" where clinicians keep paper or mental records of measurements and designs (and only digital copies of patient data) to an "industrial" process with high repeatability and **centralized knowledge via electronic records**, which can store patient and part specifications.

- Traditional molds are made by a Certified Prosthetist Orthotist (CPO) and multiple experts who may use their own methods, which can lead to inconsistent product quality, while 3D printed devices produced with HP MJF result in **consistent, industrial-grade quality**[2] parts.

- With traditional manufacturing, physical measurements are taken to create a plaster cast of the limb, and the original geometry may be lost after multiple manual adjustments of the mold, leading to suboptimal comfort and aesthetics due to design and product limitations. But 3D printing technology allows for the creation of a **3D digital model** which can be saved for comparative purposes and to support future treatment. The innovative design capabilities available with 3D printing turn prosthetics and orthotics into customized consumer products.

- A two-step process is involved with traditional manufacturing wherein the clinician typically fits the patient for a test device and then finishes the device with some adjustments; optimization requires manual work and multiple visits. 3D printing only requires a one-step process as **optimization occurs prior to manufacturing**, providing the right fit the first time.

How 3D printing will revolutionize the P&O industry

3D printing adoption is not only about creating a more efficient workflow, but it also offers the opportunity to re-think how P&O products function, perform, and look.

Successful P&O businesses are driven by innovation, investing efforts in research, development, and implementation of technology. When incorporating 3D printing into workflows, investments in product design and engineering are also required, as is a fresh perspective on design.

3D printing has the power to transform prosthetics and orthotics into a consumer goods industry without incurring additional costs. By applying design for additive manufacturing principles, the design and performance of P&O devices can be greatly improved. Some of the most relevant strategies to consider when 3D printing P&O products include:

Variable wall structures: Thanks to **variable-thickness walls** that can be generated by 3D printing, designers and manufacturers can control the stiffness and strength in every aspect of the final device. This enables P&O professionals to create much lighter devices with greater stiffness in areas where support is required and greater flexibility in other areas for improved comfort. In many cases, 3D printing can allow for the creation of devices that are thinner than thermoplastic or carbon fiber counterparts. Tailored stiffness, lighter weight, and **improved overall comfort lead to higher patient satisfaction and the potential for better treatment outcomes**.

3D printed foot-leg orthosis from Crispin Orthotics

Advanced structures: Specific design features such as lattices (a network of crosshatch sections) and meshes can modify the performance and material properties of a part by **increasing stiffness, reducing weight,** and **enhancing breathability**. These structures and patterns, which are only achievable with 3D printing technology, influence the behavior of a material through design.

3D printed helmet from Invent Medical

Part consolidation: Thanks to the nature of 3D printing, parts and mechanisms can be printed all at once by interlocking moving components and consolidating complex shapes. Part consolidation typically reduces weight, decreases the amount of assembly work and rework needed, and eliminates dependency on several suppliers.

3D printed foot orthosis from Crispin Orthotics

Branding and personalization: 3D printing allows clinicians and manufacturers to personalize products with a logo or a business's name. In addition, it makes it easy to tag items with a production order number to digitally track them through their lifecycle.

3D printed 8Sole (insole) from Invent Medical

Why HP Multi Jet Fusion technology?

3D printing with HP Multi Jet Fusion technology presents myriad benefits for manufacturers, clinicians, and patients, including:

- **Material properties.** The consistent industrial-grade qualities[4] of the materials used with HP Multi Jet Fusion (MJF) technology (such as HP 3D High Reusability [HR] PA 11) result in excellent impact resistance, ductility, and enhanced elongation at break.[3] In addition, HP 3D printing's materials have passed evaluations for irritation and skin sensitization; therefore, articles made from these materials, under similar conditions, will meet the compliance requirements of USP Class I-VI and FDA guidance for Intact Skin Surface Devices.[4]

- **Isotropic properties.** HP MJF is ideal for the production of orthotic and prosthetic devices because it can deliver enhanced isotropic properties[5] thanks to the proprietary fusing agents applied during the printing process.

- **Productivity.** HP MJF technology makes it possible for prosthetics and orthotics manufacturers to 3D print products up to 10 times faster.[6]

- **Sustainability and cost savings.** Printing with HP MJF technology can minimize waste thanks to industry-leading powder reusability.[7] In addition, unlike subtractive manufacturing processes like CNC machining, HP MJF (an *Additive* Manufacturing process) only uses the exact material required to "build" the device. For example, in the production of insoles, this can result in a 97% reduction of material waste.[8]

- HP MJF allows for the **consolidation of equipment into an all-in-one solution**. This scalable solution offers an optimal operator-to-machine ratio and can lead to an up-to **8-times reduction in manual labor time**.[9]

Applying HP MJF technology to real life

Since the launch of HP MJF technology, P&O pioneers have reaped the benefits that 3D printing can bring to their own manufacturing processes.

Crispin Orthotics

Crispin Orthotics provides orthotics solutions and products to the National Health Service as well as to private patients in the United Kingdom and across Europe.

With HP Multi Jet Fusion technology, Crispin experimented with complex geometries to produce more effective and more modern-looking devices for patients, such as their ankle foot orthosis (AFO). They also found that it cost 50% less to produce with HP MJF compared with carbon fiber.

"The industry for orthotics tends to be quite traditional in manufacturing," says Mark Thaxter, Managing Director of Crispin Orthotics. **"3D printing allows the creation of products that we've not been able to manufacture previously."**

Orthosis collar from Crispin Orthotics

OT4

OT4 Orthopädietechnik GmbH, based in Munich, Germany, develops, designs, and produces patient-specific orthoses with 3D printing technologies.

OT4 transitioned to HP MJF technology to produce its helmet, dynamic ankle foot orthosis (DAFO), and hand brace. With HP MJF technology, OT4 is now able to sell products without having to apply expensive post-processing.

"3D construction using HP Multi Jet Fusion makes it possible to produce completely new products with a functionality that wasn't possible until now," says Andreas Flamm, CEO of OT4. **"Before HP came onto the market with this new technology, we couldn't deliver a product with the same durability, the same quality, and in the same time."**

Hand orthosis from OT4

Invent Medical

Invent Medical transitioned from manufacturing with subtractive processes to HP Multi Jet Fusion technology to produce custom-made orthotics. Clinicians can take 3D scans of a body part and upload the scans to Invent Medical's website where they can choose and customize the final product to be 3D printed.

"With HP Multi Jet Fusion, we are able to design and directly print out the final product," says Invent Medical Chief Designer Ales Grygar. **"This allows us to deliver higher-performance orthotic devices that are lighter, more flexible, and more comfortable."**

HP Multi Jet Fusion technology has helped foster a relationship among patient, caregiver, and medical device manufacturer, and has allowed Invent Medical to scale its model on a global level.

Ankle-foot orthosis from Invent Medical

ProsFit

ProsFit is the international leader in providing below-knee 3D printed prosthetic sockets based on a quality-assured industrial solution, which provides clinics all over the world with software for clinicians to create robust and reliable prosthetic sockets.

HP Multi Jet Fusion technology allows for a fully digital "scan-to-print" solution, "virtualizing" socket design and fitting, and increasing productivity by a factor of at least 5. ProsFit Original sockets are sold in the EU as regulated custom-made medical devices, each according to the prosthetist's design and specifications.

"ProsFit is the first company in the prosthetics industry to have developed a fully digital solution for the design and manufacturing of prosthetic sockets," says Alan Hutchison, CEO of ProsFit. **"We see the role of HP as being very strong in the industry… and having access to that equipment that we know is consistent and of high quality is going to be very strong."**

Leg prosthesis from ProsFit

1. As reported in the following studies: Orthotic Devices Market: By Type; By Application; By Geography – Forecast (2018-2023) and Global Orthopedic Prosthetics Market 2017-2021.
2. Based on HP's unique Multi-Agent printing process. Excellent dimensional accuracy and fine detail within allowable margin of error. Based on dimensional accuracy of ±0.2 mm/0.008 inches on XY for hollow parts below 100 mm/3.94 inches and ±0.2% for hollow parts over 100 mm/3.94 inches, using HP 3D High Reusability PA 12 material, measured after sandblasting. See hp.com/go/3Dmaterials for more information on materials specifications.
3. Testing according to ASTM D638, ASTM D256, and ASTM D648 using HDT at different loads with a 3D scanner for dimensional stability. Testing monitored using statistical process controls.
4. For more information about the biocompatibility of HP's materials, please view the Biocompatibility Certificates for HP 3D HR PA 11 and HP 3D HR PA 12.
5. Based on the following mechanical properties: Tensile strength at 48 MPa (XYZ), Modulus at 1700- 1800 MPa (XYZ). ASTM standard tests with HP 3D High Reusability PA 12 material. See hp.com/ go/3Dmaterials for more information on materials specifications.
6. Based on internal testing and simulation, HP Jet Fusion 3D average printing time is up to 10 times faster than average printing time of comparable fused deposition modeling (FDM) and selective laser sintering (SLS) printer solutions from $100,000 USD to $300,000 USD on market as of April, 2016. Testing variables for the HP Jet Fusion 3D 4210/4200 Printing Solutions: Part quantity: 1 full build chamber of parts from HP Jet Fusion 3D at 20% of packing density versus same number of parts on above-mentioned competitive devices; Part size: 30 cm3; Layer thickness: 0.08 mm/0.003 inches.
7. Compared to PA 12 and PA 11 materials available as of June, 2017. HP Jet Fusion 3D printing solutions using HP 3D High Reusability PA 12 provide up to 80% post-production surplus powder reusability and HP Jet Fusion 3D printing solutions using HP 3D High Reusability PA 11 provide up to 70% post-production surplus powder reusability, producing functional parts batch after batch.
8. According to HP customer research, 97% of material used in the manual insole production process is wasted. An average pair of 77-gram insoles can produce 2100 grams of waste material using manual production methods. A pair of insoles produced with HP MJF can produce only 100 grams of waste.
9. According to HP customer research and inputs, HP MJF can result in reduction of manual labor time from 1 working day to 1 hour.

4AA7-4605ENW, September 2019