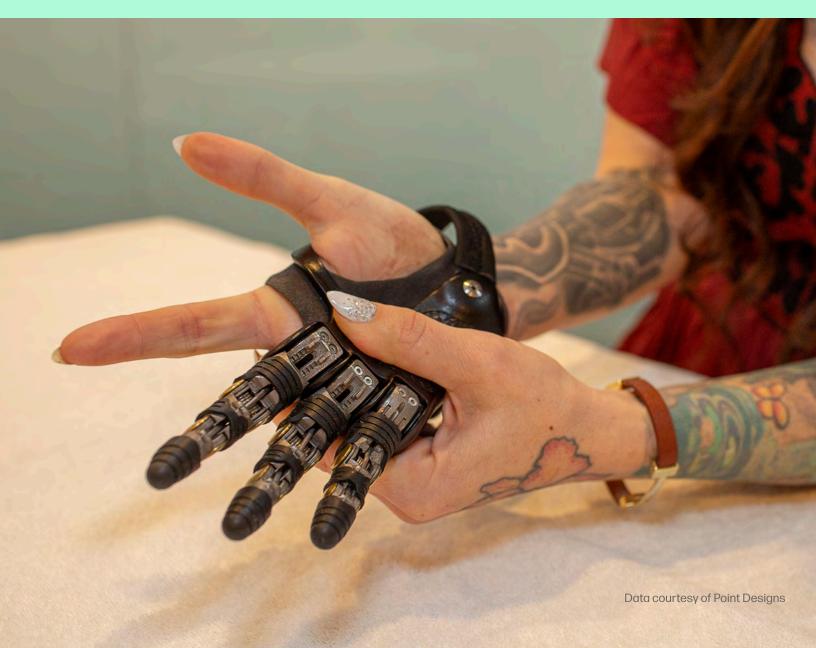


Point Designs Uses HP Multi Jet Fusion to Advance Partial Hand Prostheses

Working with DfAM design principles, HP Jet Fusion 3D Printing and HP's advanced materials, Point Designs develops new prosthetic devices that are strong, lightweight, durable and comfortable, improving outcomes for a large, underserved patient population





At a glance

Industry

Healthcare

Objective

Utilize DfAM, 3D printing and new materials to develop innovative partial hand prostheses that are strong, durable, and comfortable enough for skilled and manual labor

Technology Solution

HP Multi Jet Fusion

Sector

Orthoses and Prostheses

Approach

Leverage HP's Multi Jet Fusion unique technology and DfAM to develop strong yet flexible sockets that enhance performance, elevate adoption, and reduce repairs, improving patient outcomes

Material

HP High Reusability PA 12, enabled by Evonik BASF Ultrasint® TPU01



Introduction

"Additive manufacturing provides the tools and techniques needed to develop superior devices, especially for upper limb prostheses, including hands and fingers."

- Chris Baschuk, MPO, CPO, FAAOP(D) Director of Clinical Services, Point Designs

Getting people to try and ultimately adopt hand and/or finger prostheses can be difficult. If the device is uncomfortable, lacks functionality or is difficult to control they may not wear it, and if the prosthetic is too expensive, most can't afford it.

3D printing has ushered in a new wave of innovation with upper limb prostheses, especially with hands and fingers. Point Designs is on the forefront, improving patient outcomes and addressing an underserved market by blending leading-edge mechanical design and HP's Multi Jet Fusion (MJF) technology to develop highly advanced partial hand prostheses that are highly functional, user friendly and cost effective.



Background

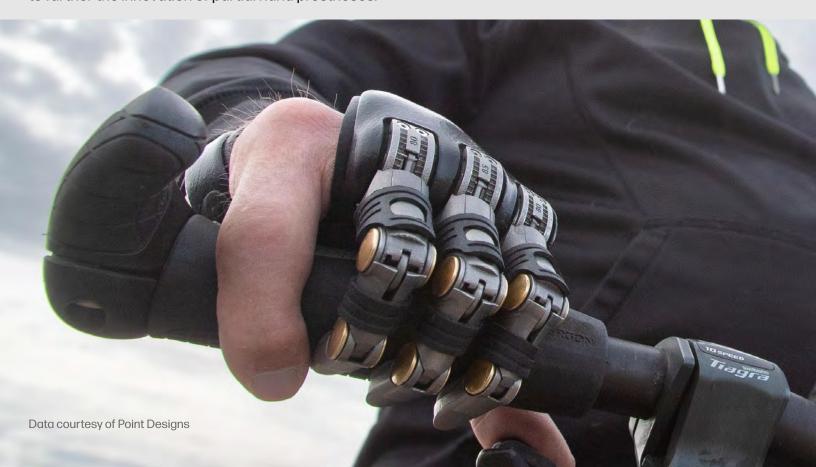
"We have an ambassador named Jeff," says Point Designs CEO and Co-founder, Levin Sliker, PhD. "He'd gone through several other finger prostheses and sockets before working with us. When he was fit with an additively manufactured socket, he was blown away by the differences. It was so much smaller and lighter, that he could actually walk into a store and buy one pair of gloves, instead of needing two different sizes. It brought him to tears."

Hand and finger prostheses are undergoing a revolution with a focus on improved functionality and user experience. While researchers are making exciting discoveries on neural interfaces and sensory feedback systems, advances in materials and manufacturing technologies are also fostering innovation, resulting in devices that are more comfortable, customizable, and affordable. With these new tools, companies are developing prostheses that empower users by seamlessly integrating into their daily lives and enabling them to do a wide range of tasks effectively.

Point Designs' Foundation

"Point Designs was founded in 2016 and sold its first product, the Point Digit, in 2017," says Ben Pulver, MS, Director of Product Development at Point Designs. "It's a mechanical, robust, articulating prosthetic finger. It was designed for patients with near metacarpophalangeal (MCP) level amputations, attaches at the knuckle, and features two additional joints."

Point Designs was founded by researchers from the Biomechatronics Development Laboratory at the University of Colorado. Specializing in the field of upper limb prosthesis design, professors Dr. Richard Weir and Dr. Jacob Segil have spent decades researching neural interfaces, myoelectric control algorithms, and upper limb prosthetic design. Along with co-Founders Dr. Levin Sliker and Stephen Huddle, MS, they created Point Designs to further the innovation of partial hand prostheses.





"Our product was developed out of real-world need," says Pulver. "Prosthetists came to our lab at University of Colorado and said, 'hey we need a really strong and robust device for this patient population, and nothing out there fits the bill. Can you make it?"

The dedicated and passionate team at Point Designs has significant expertise in additive manufacturing, mechanical design, and clinical care. Chris Baschuk, MPO, CPO, FAAOP(D) is the company's Director of Clinical Services. He is an alumnus of UT Southwestern Medical Center, where he earned his Master of Prosthetics and Orthotics. Chris has served as the Chair of the Upper Limb Prosthetics Society since 2017. His work has been published in many scientific journals and he has lectured at eminent institutions and conferences globally on topics related to upper limb prosthetic rehabilitation.

"Most prosthetists focus on lower limbs, but for the last 10 years, I've lived and breathed upper limb prosthetics," says Baschuk. "It's the space I knew I wanted to specialize in."

In his role at Point Designs, Chris is focused on integrating the capabilities of additive manufacturing and silicone customization into the company's line of hand and finger prostheses.

"My wife and I joined Point Designs two years ago to develop and provide a complete solution," says Baschuk. "Packaging the Point Designs Point Digit prosthesis with a custom silicone interface that we developed, along with innovative mechanical designs and professional clinical education which I provide, creates an ideal match."

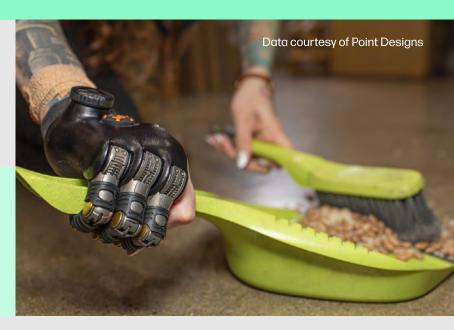




Problem

In the United States alone, there are over 45,000 finger amputations each year. Before their amputation, 68% worked in the trades and other physically demanding vocations, and 74% either switched jobs or retired because of their accident.

"Even though there are more hand and finger amputations than any other kind combined, 90% of prosthetists say they focus on lower limb, and it shows," says Baschuk. "For many years, well-meaning prosthetists have been trying to fit a leg socket on a hand, because that's all they know."



When it comes to assistive devices, finger amputees are faced with limited selection. Most prostheses focus on basic function and are not robust enough for the daily rigors of skilled or manual labor. The lack of choice can be frustrating for those who could return to work, if they had a more robust option.

Device cost and medical coverage

"The financial model is complicated and challenging for many reasons," says Sliker. "First, prosthetists are improperly classified as durable medical equipment suppliers. They go through a lot more training than the person selling canes and stand up chairs at a pharmacy. But prosthetists are limited in how they can bill for their services. Even though they spend time evaluating patients, fitting the prosthesis, and providing follow-up care to the patient for the life of the prosthesis, they can only bill for the device itself, so prices get inflated. But there are efforts underway, in part led by Chris, to create insurance billing codes for upper limb prostheses that are accurate and representative of the care provided by the prosthetist which will allow providers to serve a patient population which has largely been ignored."

Hand and finger prostheses, especially those with advanced myoelectric or osseointegrated features, can be incredibly expensive, ranging from several thousand dollars (USD) for a rudimentary non-moving device, up to \$100,000 or more for a motorized device.

"Every now and then you'll see a comparison of some home-built prosthesis that was made on a desktop 3D printer," says Baschuk. "They'll say it cost \$30 and try to compare it with a traditionally fabricated custom prosthesis costing multiple tens of thousands. What these comparisons don't account for is that a custom prosthesis is an FDA regulated medical device and as such is only provided under the prescription of a qualified medical provider. They ignore that included in the cost of the custom prosthesis is three to five years of prosthetic rehabilitation that goes along with the custom fabrication, delivery, and follow-up required to provision the prosthesis. The emphasis is too often only on the prosthesis, because that is what is most visible, and not on the care and rehabilitation surrounding it. A Certified Prosthetist Orthotist is the qualified healthcare provider that is specifically trained to make sure that the prosthesis is safe, functional, and effective for the patient."

Insurance coverage for prostheses varies significantly. This can be frustrating and challenging for patients to navigate. Many medical plans have restrictions on the quantity and types of prostheses that they will cover. When new technology is developed it will be labeled as experimental and investigational, or as exceeding the minimal functional need of the patient and therefore not medically necessary. To get a prosthesis approved can take an extended period of time, often involving a series of appeals before a prosthesis is approved. Those patients lacking coverage are faced with high out-of-pocket expenses, which can significantly impact their ability to regain mobility and independence.



Problems with traditional solutions

"I did a lot of my own fabrication with lightweight plastic thermoforming, lamination, and other methods," says Baschuk. "Much of it was done by hand, it took hours and hours, and if you made a mistake, most of the time you'd have to start over at square one."

Physical impressions

In the orthotics and prosthetics industry, impressions of the patient's body are typically taken with plaster, silicone or other materials. These casts or molds are used to shape the device to the user, creating a custom fit.

"The traditional prosthesis manufacturing model relies on a plaster cast or model to build the device," says Baschuk. "With lower limb prostheses, the shape is pretty cylindrical/conical and the socket is relatively easy to get off of the plaster model. With upper limb prostheses you're fighting gravity all of the time, which requires a prosthesis that is shaped to suspend off of the bones in the arm. The unique shape means that the plaster model is destroyed in the process of getting the prosthesis off of the model."

Plastic forming and lamination

Until recently, most prosthetic sockets were made with traditional manufacturing technologies like plastic forming and composite lamination. Techniques like drape forming use heat to wrap plastic sheets around the model. Afterwards, resin-soaked fabrics like fiberglass or carbon fiber are applied over the mold, creating a socket that is robust enough for ongoing use.

"To really serve this audience, you need a full product line with multiple devices and additional components," says Pulver. "When you add up all the different configurations, and combine them with the many levels of amputation, traditional fabrication becomes even more challenging."

Precision and repeatability are key

When developing a complex prosthetic device, the parts must fit and work together flawlessly. If the socket and prosthetic components don't align correctly, the device can malfunction. Also a patient may use the device for several years, and over that time the prosthesis may require repairs and replacement parts.



Data courtesy of Point Designs

Solution

Point Designs' approach

"A full service offering is helping us reach clinics who don't specialize in upper limb prostheses," says Pulver. "We're moving beyond the early adopters to the point where our solution is becoming an accepted standard of care."

Strong, durable, and capable hand and finger prostheses can be a game-changer for those who rely on manual and skilled labor for their livelihood, allowing them to perform their jobs effectively and reclaim their place in the workforce.

"We utilize additive manufacturing throughout our process," says Baschuk. "At the diagnostic phase we send clinicians a clear prosthetic socket made with PETG. They are familiar with that material and feel comfortable heating, grinding and modifying it."

Blending ingenious mechanical design with HP's Multi Jet Fusion 3D Printing technology, Point Designs manufactures high-strength prosthetic devices for people with partial hand or finger loss.

"We're not using lamination for our definitives anymore because we need variable wall thicknesses," says Baschuk. "HP's Multi Jet Fusion technology allows us to design parts that are rigid where we want them to be, yet still flexible in other areas. You just can't do that with traditional technologies."

Point Designs prostheses utilize patented technology to improve strength, durability and functionality. Their devices feature unique ratcheting, positionable digits that enable users to perform both heavy-duty manual labor and delicate tasks that require high dexterity. Users can lock the level of grip they need to perform a task and then automatically flex the finger back to its original state.

The prostheses offered by Point Designs also offer many other notable features:

- 150 pounds (68 kilogram) load capacity
- Titanium construction, allowing for low weight and high strength
- Anatomical flexion and rotation around the MCP and PIP joints
- Touch screen compatible and field replaceable fingertip pads
- One-handed operation

Product and process go hand-in-hand

"We have a well defined process and try to make it as easy as possible for our customers," says Sliker. "We start by sending them a kit which provides them with instructions on how to take an impression and ship it to us. From there we go through a diagnostic phase where we offer clinical support, checking the fit and trim lines, aligning the digits on the socket. Once that's done we take it to the last step when the approved device is delivered."

When it comes to prosthetic rehabilitation, a well-defined process is paramount. It's a collaborative journey involving the patient, physician, prosthetist and other members of the care team.

"With this patient population there is usually a care team, including the prosthetist, the surgeon, a physiatrist, hand therapist and others," says Baschuk. "The more we can interact with them the better. For example with amputations, surgeons are often taught to preserve as much viable tissue as possible to preserve as much length as possible.



We think that this school of thought should evolve to include thinking beyond the surgical procedure. We want surgeons to provide a good platform on which a prosthesis can be built. At the end of the day it's all about patient outcomes, whether or not they use a prosthesis. Giving them the choice is really important."

Process is also critical to ensuring that the prosthesis performs and fits as it should. The care team must consider the patient's lifestyle and activity level, and then select a prosthesis that offers the best combination of function, strength and aesthetics. During the fitting process, there are often ongoing adjustments, physical therapy, and patient feedback, which are critical to ensuring optimal comfort and long-term success with the prosthesis.

3D scanning and 3D printing are intertwined

The combination of 3D scanning and 3D printing is revolutionizing the way customized medical devices are designed and built. 3D scanning can capture the exact contours of a mold or even a patient's limb, with high precision. Digital data from the scans can be used to 3D print a personalized prosthesis.

"3D scanning and 3D printing are inseparably intertwined," says Baschuk. "Due to the nature of upper limb differences, we still need to utilize impressions from silicone, plaster and other methods, but scan them early in our workflow. This allows us to maintain the digital file and manufacture new molds whenever necessary."

DfAM unlocks innovation

"We've been able to change the lives of 1000's of patients because we've leveraged DfAM to make devices that are completely unique," says Baschuk. "They simply can't be made any other way."

Design for Additive Manufacturing (DfAM) principles unlock the full power of 3D printing. They are transforming the development of prostheses by enabling intricate designs that can't be manufactured any other way. DfAM also utilizes lattice structures, allowing for lighter and stronger parts. Additionally, DfAM enables customization by allowing designers to vary wall thickness for areas requiring flexibility or strength.

HP MJF is industrial 3D printing

HP's Multi Jet Fusion 3D Printing solution has emerged as a game-changer for the prosthetics industry. The incredible quality and smooth finish of MJF parts is ideal for prostheses and the system's high throughput allows companies to quickly scale their efforts.

"We've got our process dialed in to the point where we do one prototype and one final product," says Baschuk. "Occasionally we'll do a second prototype, but that's a rarity. We're very satisfied with the quality we get from MJF. It allows us to provide sockets with the same durability as our fingers."

Additive materials play a vital role

"Our customers have expressed to us that receiving a device made with PA 12 or PA 11 Nylon is a somewhat liberating experience," says Baschuk. "It's not as rigid as carbon fiber tends to be, allowing the socket of the prosthesis to move more naturally."

HP's Multi Jet Fusion technology utilizes biocompatible, Nylon-based materials like HP 3D High Reusability PA 12, enabled by Evonik and HP 3D HR PA 11. They offer excellent strength, flexibility, and durability, which are critical for prostheses that must withstand daily wear and abuse.



Benefits

"All parties are benefiting through our approach, but in the end it's all about patient outcomes," says Sliker. "With HP's 3D Printing Solution we've created a suite of devices for partial hand amputees that are lighter weight, minimalistic and low profile. We're trying to preserve sensation and range of motion as much as possible and with additive manufacturing and design principles we've developed we're close to achieving the end goal."

Many of Point Designs patients worked in heavy manual labor jobs before their amputation and aspire to continue serving their industries. The unique 3D printed prostheses offered by Point Designs are purpose-built for tough work environments.



Slimmer form factor

"Reduced build height is really impactful for patients," says Pulver. "With the curved track at the end of our finger, we were already lean, but by additively manufacturing the socket, we are reducing the device's form factor even further. Additionally, the flexibility of the socket is also vital. Traditional sockets are extremely rigid, and when you think about how you grab things, your hand is conforming to objects. The flexible socket feels more natural and allows patients to grasp things more easily."

By leveraging DfAM, HP MJF 3D Printing and advanced materials, the team at Point Designs is creating partial hand prostheses that are diminutive, yet strong and durable.

Better adoption

"When we've done our jobs well, our devices become invisible," says Pulver. "They become such an integral part of a patient's life. We get satisfaction out of that, knowing that we are enabling people to live easier."

3D printing plays an important role in helping patients adopt prosthetic devices. Unlike traditional fabrication, 3D printed prostheses can be exactly tailored to fit, which improves the likelihood of the device being worn. Also, the opportunity to customize design elements with colors, patterns, logos, and other features that complement the user's hobbies or professions can boost confidence and help further the likelihood of adoption.

Fewer repairs

"We're employing additive manufacturing across our entire range of products," says Sliker. "Even with a much wider offering, as we've improved our processes and technology, our service rate continues to decline. Currently less than 2% of our devices have been scheduled for repair. Considering the environments where they're used, that's pretty impressive. But even then, most of the repairs are from activities that were outside our daily recommended usage."



Traditionally, prosthetic repairs were time consuming and difficult. With HP's MJF 3D Printing Solution and its strong, durable and biocompatible materials, Point Designs has developed a device that is less likely to break and easier to repair, which ultimately lowers cost and increases a patient's time with their device.

Tighter control with in-house production

"We know the orthotics and prosthetics market is a big opportunity for HP," says Pulver. "We're on the front lines, showing them how valuable MJF can be in this market. They have the technology, and we're demonstrating how it can be used in the real-world. We hope it reinforces their value proposition and opens the door for additional collaboration."

Point Designs recently acquired HP's Multi Jet Fusion technology and is now producing sockets and other parts in-house. Having that capability not only fosters more frequent design iteration, it also enables faster turnaround times, especially for prototypes and replacement parts. Additionally, it provides the team at Point Designs with more control over material selection and quality assurance.

"Before we brought Chris and our Salt Lake City facility's fabrication services online, our biggest challenge was understanding the ultimate result," says Pulver. "Was the patient actually using our device? Our success was tied to several external parties. We found that we either needed to spend a lot of time educating, or steer customers to a third party lab we had already trained."

Point Designs can also better control their order workflow, from first patient visit, until the final prosthesis is produced and worn. By producing the sockets in-house, they eliminate the need for an outside fabricator, and all the training and communication challenges that go with it.

Scalability

"With our work on product and process, we've made the business scalable," says Baschuk. "We're extending our reach, now selling our fingers in over 30 countries and doing fabrication for clients in the U.S., Canada, and Australia. We're changing the global landscape for partial hand prostheses and that has been fundamentally possible because we're leveraging HP's MJF 3D Printing and DfAM to make genuinely innovative devices that lead to better patient outcomes."

3D printing has proven its ability to excel at low-volume, customized production. Recent advancements from HP and others have led to faster speeds, larger build areas, and more new materials. Further, new distribution models focus on shipping data, rather than finished products, as close as possible to the point of need. Together they enable a digital production network that allows products to be centrally designed and locally printed.

Time to execute

"The clinical work that Chris is spearheading and the research, development, and design work that Ben and Levin are doing, make selling this solution so much easier," says Mike Benning, MS, Director of Sales and Marketing at Point Designs. "Our team has so much to talk about. We present Point Designs as a thought leader, but also as a process and product leader. Our people can go out and sell with confidence, knowing our service rate is incredibly low and our team is delivering a cutting-edge solution."



Future plans

In addition to growing and scaling their business, the team at Point Designs has other future plans.

New product innovation

Point Designs recently developed a new shoulder prosthesis. Manufactured with HP's MJF, rigid PA 12 and flexible TPU materials, the device reduces bulkiness, weight and fabrication complexity, optimizing functionality and user comfort. It also includes advanced design features, such as hexagonal lattices for breathability and heat dissipation, and electronics integration to further improve the patient's experience.

The design was submitted to the Additive Manufacturing User Group's (AMUG) 2024 Technical Competition, where it won the award for Advanced Concepts.

With the award, the judges noted:

"Using additive manufacturing for prostheses is not new, but the methodology and attention to detail used in this entry are incredible. The forethought to incorporate lightweighting and DfAM to provide users comfort is impressive. The embedded electronics for movement were astounding and would improve the user's quality of life. This is a great additive manufacturing application to improve the human condition and an outstanding entry!"





Electronic integration

Electronic interfaces can provide additional functionality to prosthetic devices. Myoelectric control for example, detects muscle signals in the limb, and converts them into movement commands for the prosthetic. While this can provide amputees with greater dexterity, control and sensory feedback, it can be difficult to incorporate into a smaller form, such as a finger prosthetic.

But electronics can also serve other purposes, including supplying data about the patient's use of their prosthetic device.

"We know people are using their devices, but we don't have data on when, where or how they're using them," says Pulver. "While there are no electronics in our devices today, we are very interested in adding them to collect more data. We have a funded study in a pediatric population right now that's focused on activity tracking. It's an area we are very interested in and will continue to pursue."

Teaching and training

"The technology available in the additive space is way different than what it was 10 years ago," says Pulver. "One of our challenges is educating customers. The 3D printing technologies and materials are far superior to what they were then. It's a question of shifting mindsets from desktop 3D printing to additive manufacturing or digital fabrication. It's why we get the kind of outcomes we do. The technology and materials are more capable and they're at the point where they can really serve this patient population."

Beyond everyday work with prosthetists, doctors and patients, Point Designs is also talking with experts in other countries, learning about their needs and their approach to solving problems.

"I'm excited that Point Designs is sending me to Ukraine next month to teach, but I think there are also plenty of opportunities to learn," says Baschuk. "Going into it, we know they aren't going to have all the resources with 3D scanning and printing that we do here, but maybe we'll look at their methods and find additional ways to streamline our processes."

Learn more about Point Designs and their innovative prostheses by visiting: https://www.pointdesigns.com/en/

To discover more about HP Multi Jet Fusion 3D printing technology and how it is helping medical device companies develop strong, lightweight and durable prostheses, please visit us at:

https://www.hp.com/us-en/printers/3d-printers/products/multi-jet-technology.html

