Student Start-up Aims to Make Low-Cost Prosthetics for Those Who Need Them Most

UMass Lowell grads want to deliver durable, easily adjustable prosthetic legs – and eventually arms & hands – for just $20 per device

By Robert Grace

When Erin Keaney offers someone a helping hand, or a leg up, she means it. Literally. As in a prosthetic limb.

The 26-year-old plastics engineer, who just completed her Ph.D. at the University of Massachusetts Lowell, is co-founder and chief operating officer of Nonspec Inc., a six-person company that has pioneered the development of very low-cost, modular prosthetics targeted at developing countries such as India. At the moment, Nonspec is working on adjustable, lower-leg prosthetics that will cost just $20 per device.

The company, which she started in 2013 along with recently graduated fellow UMass Lowell student and mechanical engineer Jonathan Perez de Alderete, began as a class project. The two first met as freshman at the college.

Erin Keaney and Jonathan Perez de Alderete met as freshmen at UMass Lowell and have turned a student project into a company that aims to help hundreds of low-income individuals in India to regain mobility using their low-cost prosthetic legs.
Courtesy of Nonspec Inc.

"In our first class as engineers," Perez de Alderete has recounted, "one of the many hum-drum assignments provided was to provide a 'new' solution to an existing problem. It was at this point that our project initial began – a small (and rather heinous) rendering of a series of tube-like fingers attached to a square block powered by (impractical) micromotors."

The effort became a pet project for Perez de Alderete. The goal, over the course of the next four years, was to create a dexterous, fully functioning human hand that was capable of meeting or exceeding normal industrial procedures.

"Like many freshman dreams," Keaney said, "this was doomed to never fully come to realization, but Jonathan's persistent approach ended up yielding a very different result."

In his final semester of engineering, Perez de Alderete asked his professor if he – as his so-called "capstone project" – could form a team to take the very rudimentary robotic hand he had been developing to the next level.

The hand was to contain all the components required for modern hand functionality. The electronics, motors, cables, and controller all had to fit into the palm and fingers. Beyond this, because the project did not receive the larger industrial funding that is the norm for higher-profile projects, Perez de Alderete said, the device was made for the "difference between my paycheck and my rent."

The resulting device, he noted, included "a scavenged children's toy EEG [electroencephalography] interface, pins and bearings used in toy cars, servos from various hobby shops, and half a square foot of aluminum plate. The final bill of materials for the device was under $100."

During the course of this project, Perez de Alderete came to realize there was a real market need for a low-cost prosthetic. He broadened his team to become more multidisciplinary, and four years ago brought aboard plastics engineer Keaney, then a senior at UMass Lowell.

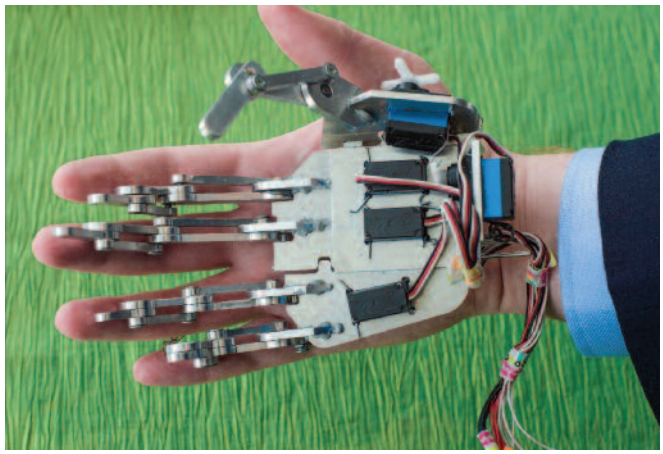
The university in 2013 was just launching a new competition – the DifferenceMaker™ Idea Challenge – to promote cross-functional, entrepreneurial student endeavors at the school. Perez de Alderete, Keaney and six other students called themselves the "Developing Nations Prosthetic" team, entered the contest, and won. That allowed them to gain $5,000 in funding from alumni to continue developing the project. Over the summer of 2013, the team worked to develop a simpler, more modular design.

As time went on, it became apparent that the student-budget-oriented project could be stripped of its electronics and turned into a highly customizable, adjustable prosthetic with a little work. About two years ago, the team pivoted from developing arm and hand prosthetics to lower legs.

"We wanted to make sure that our design could be converted to lower-extremity prosthetics, because everyone needs to walk," Keaney explained. "No portion of the device was to have only a solitary function."

As time went on, they applied the term "nonspecific" to many of the components. "Eventually, the moniker stuck to our approach," she said. "We are now Nonspec, a company providing a technical solution that could fit anyone while still being mass producible in nature. We are currently focused on getting below-knee limbs to clinicians in India," a largely underserved market.

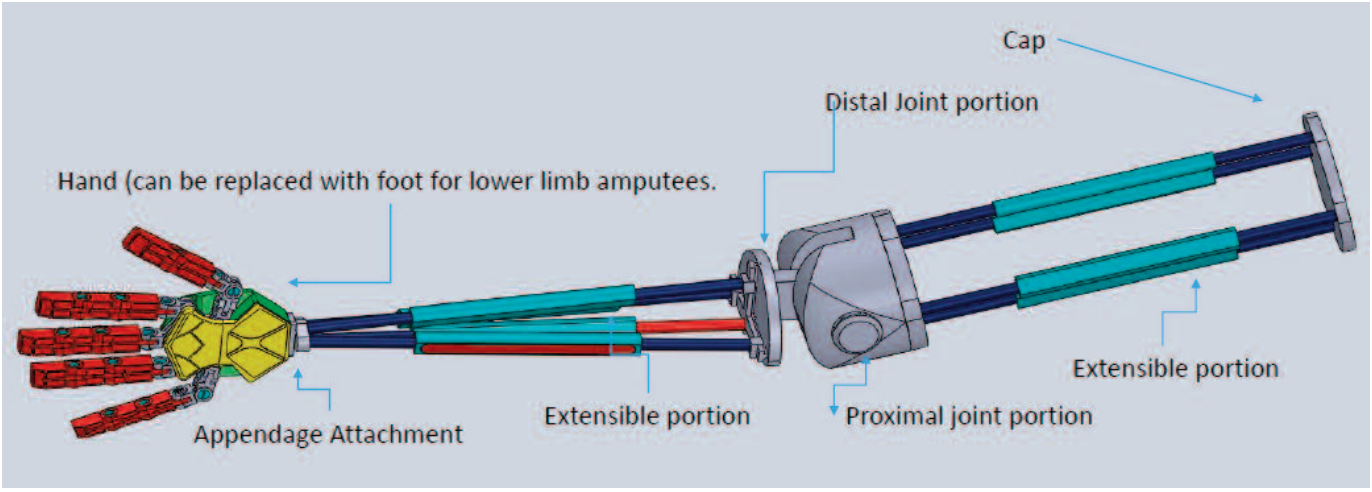
There are 54 million amputees worldwide, Keaney noted, and 45 million of them live in developing countries. Of the 3 million new amputees this year, one in five will live in India. In pediatric cases of amputation, this is compounded by the regular need for new prosthetics as the child grows. However, while the need for limbs is apparent, it is difficult to address due to the scale of the production required to provide everyone with what they need. Fast-growing kids need to change – or at least adjust – their leg prosthetics as frequently as they need to change shoe sizes (roughly every six to eight months).



Perez de Alderete's "capstone project" as a college senior focused on developing a functional robotic hand. He said total material costs for the first iteration of his device was "under $100."

The Nonspec team now consists of three U.S. members – the two co-founders (president/CEO Perez and VP Keaney), plus engineer Brendan Donoghue – and three members in India.

"Over the past three years, we have raised $300,000 in non-equity-based grants and competitions, have fit 10 patients with our below-knee limb in India, and have gotten a letter of intent for 750 devices from an Indian clinician," Keaney said. "Three of our first patients have successfully walked on



Though now somewhat dated, this drawing illustrates the technology the team developed for an adjustable arm and hand. Nonspec is currently focusing on lower leg prosthetics, but it still foresees potential in further developing upper limbs.
Images courtesy of Nonspec Inc.

our limb for a year and a half now with positive results. We are currently seeking funding to move the device forward and begin sales in 2018.

"Right now," she noted, "our core technology is the pylon system, which connects the socket that the patient wears, and the foot. That piece is Class 1 exempt [in terms of relevant medical regulations], so it does not have to go through [the Food & Drug Administration]; we just have to register it and follow Good Manufacturing Practices."

Additionally, she noted, "there is no regulation for our device in India, but globally prosthetics need to meet a specific ISO standard, so we've been ensuring that we meet that, so [our product] is marketable worldwide." Nonspec's lower-leg prosthetic meets the ISO requirements that Keaney says makes its durability comparable to competitive, $30,000 devices on the market. Nonspec recommends that patients using one of their products go see a doctor at least every four years, but "we've really designed it for infinite life."

A key goal of their design was to make a leg prosthetic for growing children that could be easily adjusted at home. Their product can be expanded by up to at least 4 inches in height. Bilateral amputees – those missing both legs – initially start with much shorter than normal legs, to allow them to regain their center of gravity, Keaney said. But the Nonspec prosthetic then can be extended easily as the patient gets his or her balance.

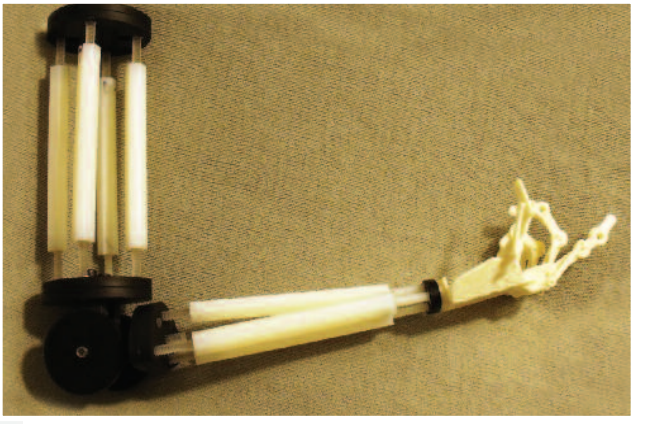
Nonspec's technology also can work for above-knee prosthetics, she said, but they just need a functioning knee joint to connect the two components. It also can work, on a smaller scale, for upper-body prosthetics (arms and hands).

"We wanted to keep it as simple as possible, so that anyone with very minimal training could make adjustments. We started by trying to meet pediatric needs," Keaney noted, "but we then realized that for adults, every single prosthetic is custom made. … Our device works off the shelf, and can be adjusted for height, width and angle to fit any patient, no matter what their age is."

Keaney and Perez de Alderete assumed that others must be doing what they were doing, because they felt their concept was so obvious, but were "shocked" to discover that was not the case. And they then realized that they needed to patent their technology. In January 2015 they secured a U.S. utility patent that covers adjustable prosthetics for both upper and lower limbs.

UMass Lowell does not offer any industrial design classes, so there was no designer on the Nonspec team. Keaney leveraged her plastics engineering knowledge to focus on ensuring the low-cost, high-volume manufacturability of the product. While they 3D-printed some of their early prototypes, the end product is designed to be injection molded, likely from polycarbonate. She acknowledges that her company needs to look into involving a designer to help refine their final product, to include developing a "skin" to cover their core technology.

Perez de Alderete and Donoghue, meanwhile, both expanded their business knowledge by getting their Master of Science in Entrepreneurship degree from UMass Lowell, a program



Left: Nonspec's patented pylon system adjusts for height, width and angular adjustment to perfect a patient's gait while they are wearing the prosthetic. Above is an early version of Nonspec's prosthetic arm and robotic hand. Photos courtesy of Nonspec Inc.

the school says "provides engineers, business majors and scientists with the skills and knowledge required to drive innovation in today's collaborative, global workforce."

Via an exchange program, all three U.S.-based partners went to India for the first time in January 2015, for about a month. They went to an engineering school in Hubli, in southwest India, and also visited a medical clinic there, where they got to fit their first patient. They returned to India in January 2016 for another month.

"We need to go back soon" to India, Keaney said in June, but they need to juggle their schedule to accommodate the fact that Nonspec recently got accepted into MassChallenge, a competitive accelerator program in Boston for start-ups. Nonspec is one of 128 teams chosen to participate out of more than 1,500 that applied. The top 26 teams will compete for shares of more than $200,000 in equity-free awards.

The firm is looking to secure more funding to help it build out its network and raise its profile. "We want to finish our R&D, start scaling up manufacturing, and build out our team," Keaney said. "We really need more people" – particularly people who can help Nonspec with marketing, sales and deployment, in both India and the U.S., and eventually other markets. The firm would like to hire three of four more people in India, she said, to secure more letters of intent from potential customers, and then to increase production to meet those needs.

Nonspec also wants to beef up its R&D team, "so we can get our full kit out there." The company is trying to get its pylons into the market first, but is getting request for other components, such as above-knee prosthetics, as well as a lightweight foot design.

Nonspec currently is "in transition" as regards its manufacturing. Right now, Keaney explained, they mostly buy stock polycarbonate and mill out the materials to make their components. "We just cut our first low-volume injection mold, to confirm that everything will work the same – or better – when we move to that process." The company currently has some fasteners made of metal that Keaney says they need to convert to plastic, to keep the weight down.

In the early days of this project, there was only one 3D printer on the UMass Lowell campus. Back then, they paid the school to 3D print some initial prototypes. Now the Nonspec team has 3D printing and CNC machining capabilities in the office space it rents in the school-affiliated Innovation Hub across town.

As regard its product plans, Nonspec set its pricing target at $20 per device. "People said we were crazy to say that publicly," Keaney noted, but she said that price point is affordable to 80% of the world's amputees – "and we really want this to be an accessible device. … Right now, we're making them for about $5 [per device], in-house."

Nonspec's research indicates that any one medical clinic

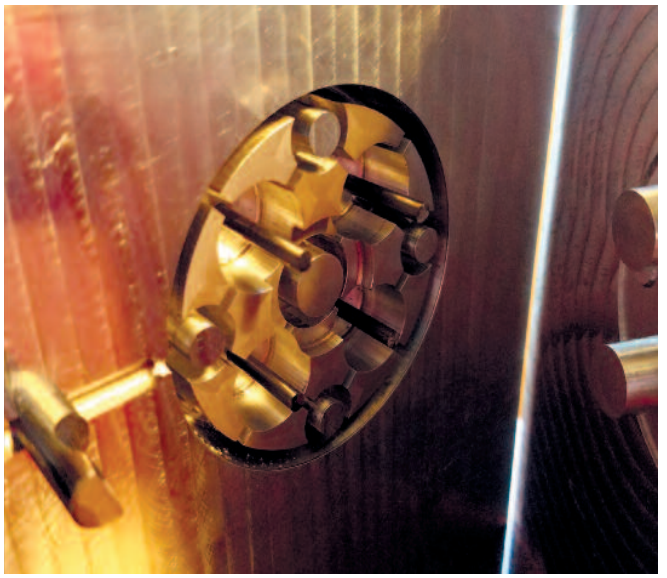
Left: After being fit with his new leg, Nonspec's first patient in India (above) used the gait training room at the local clinic. He then returned to farming after the team helped to treat his gangrene infection. Right: This woman – Nonspec's third patient (right) – works at the Mahaveer's Limb Centre in Hubli, India, where she was fit with her new leg. "She was very excited to prove to us that she can do all her day-to-day tasks right away after being fit with our limb," Keaney said, "including walking up and down stairs and walking around with heavy objects" such as this jug on her head. Photos courtesy of Nonspec Inc.

in India will see about 1,500 patients needing prosthetics on average per year, whereas in the U.S., the average clinic will see only 100-200 such patients. A lot of established prosthetic suppliers tend to avoid the developing countries, because they can't make enough money there.

But by breaking into the India market first, Keaney said, if Nonspec can reach supply agreements with just 15 or so clinics there, by year two it will already be one of the world's largest suppliers of prosthetics – "which is crazy," she said. Having so many devices fitted on patients in the market also will provide the data necessary to help the firm launch into new markets, including the U.S.

Upper-body prosthetics remain on Nonspec's radar, as well. "We actually open-sourced our hand design to e-Nable (www.enablingthefuture.org), a group that describes itself online as follows: "The e-NABLE Community is an amazing group of individuals from all over the world who are using their 3D printers to create free 3D printed hands and arms for those in need of an upper limb assistive device."

Nonspec also wants to create a nonprofit charity – the "Give a Hand Foundation" – to assist those who can't afford even their very low-cost limbs. Keaney said they've toyed with a "buy one, give one" concept, but added that many people urged them first to focus on getting their technology into the market, to those who need it.



Made just a few months ago, this is the first low-volume injection mold insert that Nonspec had produced to test the mold design of one of its lower limb plates.
Courtesy of Nonspec Inc.

Running a charity is a whole other business, so for now the firm is looking to partner with existing charities and perhaps become a supplier to such groups that already have distribution networks in place.

With a patent now in place, Nonspec also has interest in potentially engaging in discussions with medical device makers that may wish to license their technology, perhaps to serve the U.S. market, while the original team focuses on developing countries.

In India, Keaney and Perez de Alderete are seeking to work with more clinics as well as with university hospitals, which tend to train the clinicians who then fan out into various regions across the country. "There are 20 or so that we're targeting in India now, and we're already working with three of them."

Nonspec plans to make all its products in the United States, and has a goal of deploying about 2,000 devices in India in 2018. A key now is to establish consistent, frequent communication with its partners and customers in India, to ensure they get good feedback and can continue to fine-tune and improve their product.

Nonspec has access, at a discounted fee, to on-campus injection molders in the UMass Lowell network, but Keaney recognizes that the firm will need to find a steady molding partner in order to scale up production. The company also is working with the Massachusetts Manufacturing Extension Partnership (MassMEP), which should be able to help in this regard.

The company's name may be Nonspec, but it's clear that Keaney, Perez de Aldrete and their colleagues have a very specific goal for their innovative product – to help thousands of children and others to regain mobility and limb functionality, regardless of their income or position in life.

ABOUT THE AUTHOR

Robert Grace began his B2B journalism career with Crain Communications Inc. in 1980 in Akron, Ohio, and worked for Crain for seven years in London, England, before returning to Akron in 1989 as the founding editor of *Plastics News*. He also served as *PN*'s associate publisher, conference director and business development director. In May 2014 he launched RC Grace LLC, and in July 2016 became managing editor of *Plastics Engineering.* Contact him at bob@rcgrace.com.