# OHSU, UCF launch first US clinical trial of 3D-printed prosthetics for children

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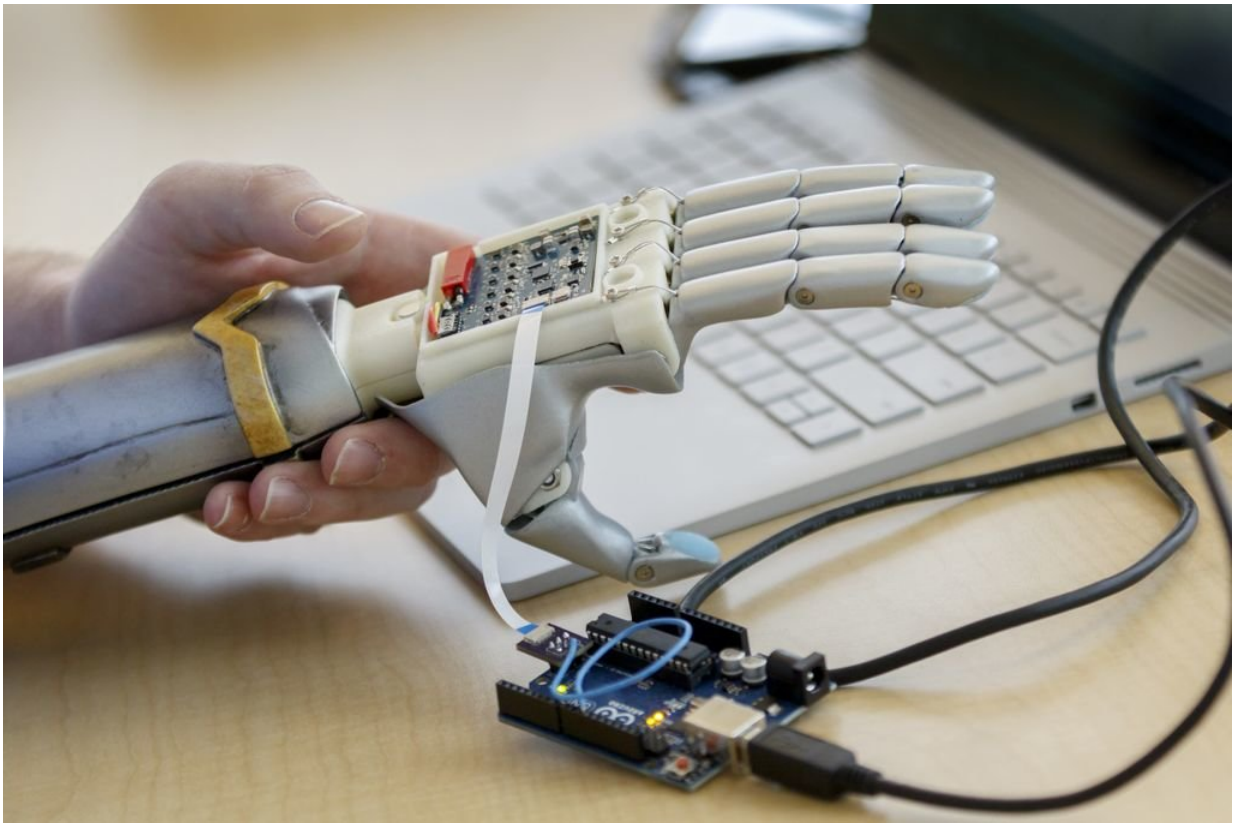

A new U.S. clinical trial will test bionic arms for children produced on 3D printers. The trial is a partnership between OHSU and a nonprofit based at the University of Central Florida in Orlando, Limbitless Solutions. Credit: OHSU/Kristyna Wentz-Graff

The first U.S. clinical trial of bionic arms for children produced on 3-D

printers is launching today thanks to researchers at OHSU in Portland, Oregon, and a nonprofit based at the University of Central Florida in Orlando.

Albert Chi, M.D., associate professor of surgery in the OHSU School of Medicine, will be the lead clinical investigator in collaboration with Albert Manero, Ph.D, the CEO and a co-founder of Limbitless Solutions, which creates bionic arms for children.

"Where this goes from here is going to be huge," said Chi, a national leader in advanced prosthetic technology. "It's my personal aspiration to provide advanced prosthetics to all those in need. Making it affordable and accessible is the goal, and I really do believe 3-D printing technology is the solution."

Thousands of children are born without arms each year. There are few good options for them. Between therapy and material, the combined cost of traditional prosthetics can easily exceed $100,000—prohibitively expensive for children who will quickly outgrow the devices.

"But our bionic arms can change all that," Manero said. "We hope our work will ultimately allow us to provide prosthetic arms to children at little or no cost. There is a real psychological-social aspect of having an arm they can customize and which reflects their personality. It allows kids to be kids and understand their opportunities are limitless."

Limbitless' myoelectric arms operate using a pair of leads placed on the skin which activate when children flex their muscles. These devices can be produced at a hardware cost of less than $1,000 each in the lab at UCF. The latest version of the arm includes multiple motors and smart phone technology to improve a child's ability to grip objects and use it for various gestures.

The clinical trial (link to site) will recruit 20 children, primarily from the Southeast and the Pacific Northwest, to be fitted with Limbitless' advanced custom-designed arms. The children will be trained to use them over the course of one year. Occupational therapy will be provided in Orlando and Portland as part of the study. The trial will test the functionality of the arms in children aged 6 to 17, gauge the effect on their quality of life, and determine how children are using the arm for specialized tasks.

The clinical trial will help to determine whether the Food & Drug Administration would approve the arm for market clearance, which would enable them to be covered by insurance. The Limbitless collaborators, which include surgeon and UCF College of Medicine professor Juan Cendán, degree, hope that this is the first of several trials across the nation and could establish a nonprofit model in which 3-D printing technology brings custom-designed prosthetics for children who need them.

"It's been a long journey, and we are so excited to see the trials start because we believe it will make a difference in children's lives," Manero said.

For UCF, this step is a good example of the power of higher education and partnerships.

"At UCF, we use the power of scale and the pursuit of excellence to impact tomorrow's greatest challenges and to make a better future for our students and society," said UCF President John C. Hitt. "As America's Leading Partnership University, we engage others of common cause to achieve what no one entity can accomplish alone. Limitless has taken these lessons to heart and is changing the lives of many."

OHSU is eager to see how the expertise of both partners impacts the

lives of children everywhere.

"Dr. Chi brings a rare combination of expertise as a surgeon and as a biomedical engineer, and OHSU is proud of his innovative work to improve the lives of patients affected by limb loss," said OHSU President Joe Robertson, M.D., M.B.A. "Advancements in 3-D printing technology make it possible to greatly expand the number of people who can benefit from advanced prosthetics, especially children. We're eager to see the results of this clinical trial, which could lay the groundwork for improving the lives of thousands of children in Oregon and across the country."

The bionic arm project began in 2014 when Manero, then a UCF college graduate student, and a group of his friends gathered around a kitchen table after a parent asked Manero to build her son an arm. Manero and his team built the first prototype that summer. The student group went on to establish a nonprofit at UCF that brings together elements of engineering, design, art, and even video game development to train children to use the devices. The team produced and distributed several prototypes. Actor Robert Downey Jr. helped deliver one arm to a 6-year-old Iron Man. In 2016, Limbitless and professors at UCF's School of Visual Art and Design teamed up and created fun video games to train children's muscles in anticipation of receiving bionic arms.

Chi has directed the Targeted Muscle Reinnervation program at OHSU since he arrived from Johns Hopkins University in 2016. Using cutting-edge technology funded in large part by the Department of Defense, Chi surgically reassigns nerve endings in such a way that patients control their prosthetics simply by thinking about the action they want their prosthetic hand or arm to perform.

The clinical trial is open to children nationwide, but proximity to the two trial sites is key to completing the year-long process. Families interested

in participating should visit 3DHope.com and sign up for more information.

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