Bringing artificial limbs to patients who need them

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Garibaldi helps a patient adjust his prosthetic leg. Credit: University of California, San Francisco

After Johnny Matheny lost his left arm to cancer in 2008, he was determined to find a worthy replacement. But he eventually had to

choose between giving up on available prosthetic arms, which were uncomfortable and caused severe skin problems, or betting on a new technology that hadn't yet been approved by the Food and Drug Administration (FDA).

In 2015, with the FDA's blessing, Matheny became the first American to receive an upper extremity osseointegration implant, a surgically-implanted titanium joint that allows an amputee to wear an artificial limb without suction cups or irritating straps. But few patients actually have access to these new technologies.

Studies show that nearly 50 percent of upper-arm amputees don't end up using a prosthetic arm. For Leslie Wilson, Ph.D., an expert in patient preferences in health care, that's not surprising. As cases like Matheny's show, available prostheses don't really cut it for many patients, and newer devices can linger in FDA limbo for years.

Wilson, a faculty member in the Department of Clinical Pharmacy, UCSF School of Pharmacy, is talking to patients about what they actually want in artificial limbs and what risks they're willing to take to get them, with the aim of improving and speeding the FDA approval process.

With the FDA poised to vet a slew of new prosthetic devices in the next few years, Wilson and her colleague, Matthew Garibaldi, MS, director of the Orthotic and Prosthetic Center in the UCSF Department of Orthopaedic Surgery, are creating hard data on patient preferences for these devices. The two hope their work will enable more patients to benefit from ongoing advances in the field of prosthetics.

"A prosthetic limb can be a highly personal treatment for a patient," Wilson said. "We want patients to have access to artificial limbs that they will actually use."

Failure to launch

The next generation of surgically-implanted devices will get amputees closer to the full functionality of their lost limbs than ever before. Some of these devices snap on quickly and securely to an extension of a patient's existing bone, thanks to osseointegration implants. A technology called myoelectric control gives amputees fine control over individual fingers, or even some degree of sensation, using implants that link up with a patient's nerves.

Despite these advances, the options available to patients in the U.S. remain limited, due at least in part to the FDA's cautious approach to approving devices that require surgical implantation.

Wilson, a health economist, is an expert on the costs and benefits of different types of medical care. She works with experts across medicine, government, and industry to understand why different treatments take off or fail. Patient preferences play a big role in the adoption of new medical treatments and Wilson explores how patients weigh risks and benefits when they make health decisions. Since the FDA's adoption of a patient preference guideline in 2016, she has focused some of her efforts on developing standards for measuring what patients want in medical devices.

Wilson's interest in prosthetics and patient preferences led her to Garibaldi, who, over the last 20 years, has helped hundreds of amputees choose between different prostheses and manage them effectively.

Garibaldi thinks that some patients may come around to these newer, surgically implanted devices when they become readily available.

"A second surgery might not be very appealing to a patient who has just received an amputation," said Garibaldi. "But after seeing a prosthetist a

couple times a month for years to make necessary adjustments to a traditional device, patients may now want to try something that would let them easily click on a prosthesis at the beginning of the day and click it off before they go to bed."

Measuring what patients want

In Wilson's study, patients choose between two hypothetical artificial limbs that vary in terms of risks, like infection or needing additional surgeries, and in terms of benefits, like independence in cooking dinner or development of finer tactile sensation. Wilson also tests whether patients are more accepting of risks when they see a video clip of a prosthesis in action.

"For some, just taking the survey has been enough to change their overall willingness to consider a new prosthesis," Wilson said. "The video, in particular, seems to make preferences stronger when it comes to opening patients up to these technologies."

Conversely, some patients may value their current abilities with limb loss without a prosthesis. The titanium joint of an osseointegration implant may be easy to use, but it may not withstand the impact of a serious fall or the threat of pathogens in a public pool, for example, making it a tougher sell for some athletes.

Wilson's study vets two broad categories of prosthetic technology—osseointegration implants and myoelectric control—rather than any particular product. The data promises to help manufacturers, private and public, who are trying to strike a balance between durability, safety, functionality, and appearance in the new devices. It will also help the FDA with their approval decisions.

Ensuring a brighter future for amputees

Less than a year after Matheny received the first experimental upper extremity osseointegration device in the U.S., the FDA approved the surgery for experimental trials, and UCSF became the first U.S. institution to offer the procedure to amputees.

Matheny continues to try out experimental robotic arms, snapping them onto his osseointegration device, and providing invaluable information to developers. Just this year, he was able to bring one of these advanced arms home for the first time—something he hopes every patient can do in the coming years.

"These new prosthetic innovations bring back so many natural movements, even something as simple as scratching your back," said Matheny. "It's an exciting time for patients."

While Matheny helps engineers iron out the kinks in these futuristic arms, Wilson and Garibaldi are making sure the FDA will be ready to include the patient's perspective when they test and approve them. As their study progresses over the next four years, with support from the Burroughs Wellcome Fund, they also intend to follow up with patients who go on to receive these newer devices in UCSF's osseointegration program, to see if they think the surgeries were what they expected.

"Every patient with limb loss deserves access to the best in prosthetic technology," said Wilson. "We are determined to make our patients' voices heard."

More information: Katherine A. Raichle. Prosthesis use in persons with lower- and upper-limb amputation, *The Journal of Rehabilitation Research and Development* (2009). DOI: 10.1682/JRRD.2007.09.0151

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