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\$15,000 "Cure it!" Lemelson-MIT Student Prize Graduate Winner

The Cutaneous Mechanoneural Interface (CMI), a system to restore a sense of touch to patients with prostheses, and regenerative Agonist-antagonist Myoneural Interface (rAMI) to help patients with prostheses gain better mobility and sense of body position.

The Challenge: Patients who wear prostheses due to limb loss from amputation often experience a lack of sensation and reduction in mobility because of an inability to receive adequate sensory feedback from their prosthetic devices. A simple task like buttoning a shirt can be difficult for someone with a prosthetic arm because they may be unable to feel what they are touching or sense how the prosthesis is moving.

Current approaches for restoring the sense of touch to those with prostheses involve stimulating nerves or vibrating residual skin when the prosthesis touches objects. Patients commonly report that this approach leads to paresthesias or discomfort that feels like being poked by pins and needles. The existing synthetic approaches struggle to replicate the complexity of the nervous system and thus have not achieved widespread acceptance.

It is important for those who wear prostheses to have full mobility range and sensation so that their independence and productivity are not inhibited. However, many amputees opt for passive prostheses with no active movement, given the inadequate functionality of the current neural interfaces and challenges with conveying motor commands to advanced prosthetic devices.

The Solutions: Shriya's primary invention is called the Cutaneous Mechanoneural Interface (CMI) and it is a new amputation method that intends to restore a sense of touch to patients living with prostheses. When a patient has a below-the-elbow amputation, healthy skin, muscle and tissue from the fingers and palm are preserved such that the nerves and vasculature remain intact. Muscles are then wrapped around segments of the preserved skin to form new organ-like structures that can convey sensation. These structures are then implanted in the upper arm along with a wireless receiver and stimulator.

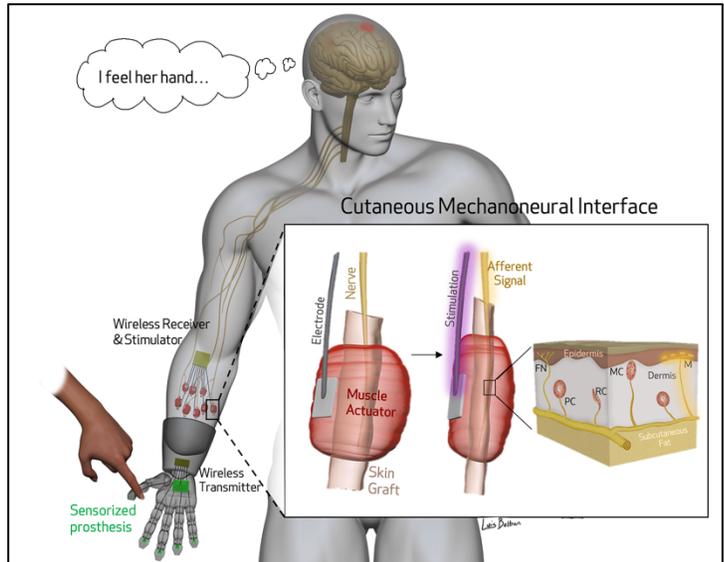


Figure 1: The Cutaneous Mechanoneural Interface (CMI)

During a patient's interaction with their environment, a specialized prosthesis would convey information from surface sensors to the implanted stimulator. Varied pulse sequences from this stimulator would activate the muscle graft, constricting or vibrating the skin at varying magnitudes and frequencies to provide independent and anatomically-specific feedback signals for each finger as well as the palm region. The patient will know that the fingers and palms on the prosthetic are moving because the brain will receive the signals via the original nerves that have been implanted in the residual limb.

In order to gain better mobility and proprioception, or awareness of body position in space, Shriya's second invention also involves a new kind of surgical technique for amputees. It's called the regenerative Agonist-antagonist Myoneural Interface (rAMI). During amputation or revision surgery, muscle grafts are placed on traditionally-orphaned nerves, amplifying their signals and providing commands to a prosthesis. Then, grafts for each extensor-flexor pair are connected to re-establish the agonist-antagonist relationship. When the user contracts an agonist muscle, the antagonist muscle undergoes stretch. Length and force

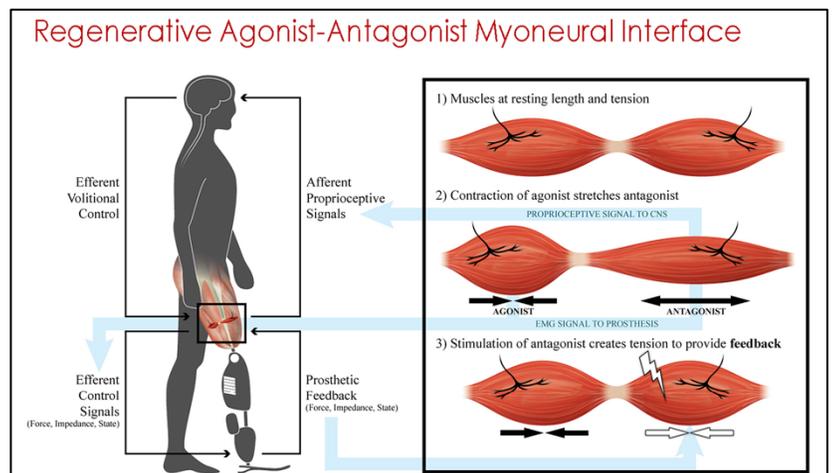


Figure 2: The regenerative Agonist-antagonist Myoneural Interface (rAMI)

information from the antagonist muscle, critical for joint stability and fine motor control, are conveyed to the central nervous system through afferent signaling pathways. Functional electrical stimulation is employed to provide feedback on the prosthesis' position and state. This surgical method can be performed in any type of amputation, with little tissue requirements and minimal tools for low-resourced settings.

By 'giving a voice' to traditionally neglected nerves and providing the anatomical facility for sensory feedback, the rAMI is currently the only method available to millions of existing amputees to 'upgrade' and achieve feedback signals and greater ease of mobility.

Commercialization: There are over two million amputees in the United States and that number is expected to double by 2050, costing U.S. insurance agencies \$12 billion a year.¹ A large fraction of the costs are attributed to the secondary medical and mental health complications that patients often experience.² These costs could be diminished by Shriya's inventions since they decrease limb pain, increase motor function and stability, and allow many amputees to return to the workforce.

Planning is already underway for a clinical trial of the CMI. Shriya has also applied for DARPA (Defense Advanced Research Projects Agency) funding to rigorously test her system and its ability to restore the sense of touch. Once efficiency has been established through the clinical trial, the CMI system could be adopted by clinicians across the country. Shriya plans to license the intellectual property for the CMI to various prostheses manufacturers so that patients can utilize their prosthesis of choice in conjunction with the CMI system.

The rAMI surgical technique is expected to help dozens of patients in the next two years through an ongoing clinical trial. Shriya intends to work with surgeons to modify the technique based on patient feedback. She is hopeful that this technique can be implemented in low-resource environments where specialty surgical centers and advanced prostheses are inaccessible. Implementation in low resource environments will help with future take-up in less affluent and under-resourced markets, often where amputation is more prevalent.

¹ <https://accessprosthetics.com/15-limb-loss-statistics-may-surprise/>.

² <https://journalofethics.ama-assn.org/article/ethics-rehabilitation-access-prosthetics-and-quality-care-following-amputation/2015-06>.