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Agonist-antagonist Myoneural Interface (AMI) and Pollex Grasp

The Challenge: The basic procedure for amputation surgery has not changed since the Civil War. When this surgical technique was developed, the primary goal was to remove the limb as quickly as possible and create a residuum that would sit comfortably within a prosthetic socket, with little or no thought given to what is today regarded as proper surgical handling of muscles and nerves. This standard amputation surgery is largely responsible for persons with amputation losing "proprioception," which is the sense of the relative positioning of one's body parts in space. For example, if a person with two intact limbs closes their eyes and tries to touch their fingers together, proprioception allows them to sense where their fingers are in space as they move them. Persons with amputation using even the most advanced commercial prostheses do not have this capability. Although typically it is not mentioned among the traditional five senses, proprioception is extremely important because the information it provides enables a person to interact with and understand the world. Studies have demonstrated that proprioception also plays a critical role in leg function, allowing humans to execute such tasks as catching themselves when they stumble unexpectedly, or sensing how hard they are pressing on an accelerator pedal.

In the United States alone, almost 2 million people live with the loss of a limb[1]. Because of the outdated standard amputation procedure, proprioception continues to be elusive for these patients. Unfortunately there is a stigma, for both doctors and patients, that amputation surgery is a last-resort option that represents a form of failure. Consequently, doctors and researchers have had little interest in working to improve the surgical process for amputation.

Furthermore, even the most advanced robotic prostheses currently available for amputees all fall short of fully replicating the biological control experience, because they do not provide proprioception to the central nervous system. This limitation is primarily a result of the outdated amputation surgery; during an amputation, operating surgeons tie down the muscles in the residual limb so that they cannot move. As a result, the brain is unable to interpret the

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[1] NLLIC Fact Sheet. Center for Orthotic and Prosthetic Care.

firing of these residual muscles as meaningful or useful proprioception. Without proprioceptive feedback, patients are unable to feel their prosthetic limbs moving, or determine their location without looking at them.

Another ongoing medical challenge is that each year more than 795,000 people in the U.S. suffer a stroke[2]. Upper extremity hemiplegia (paralysis of one side of the body) occurs in approximately 50% of stroke sufferers[2]. Research has found that repetitive motor-intensive activities can help hemiplegic patients reach partial or full recovery of motor function by retraining the parts of their brain that remain functional to appropriately control movement[3]. However, it is difficult to ensure correct exercise technique and motivate repetition when patients are outside of a clinical setting. The thumb in particular, due to its unique range of motion, presents an enormous challenge for successful rehabilitation.

The Solutions: Tyler's primary invention, the Agonist-antagonist Myoneural Interface (AMI), is a new way for surgeons to perform amputation surgery. Tyler worked with a team of surgeons, biomedical engineers, mechatronic technologists, and rehabilitation specialists to develop this new surgical paradigm. The AMI approach establishes two-way neural communication of joint position, speed, and force between the brain and the prosthetic limb. This connection allows persons with amputation to receive proprioceptive feedback, enabling them to feel as though their prosthesis is truly a part of their body.

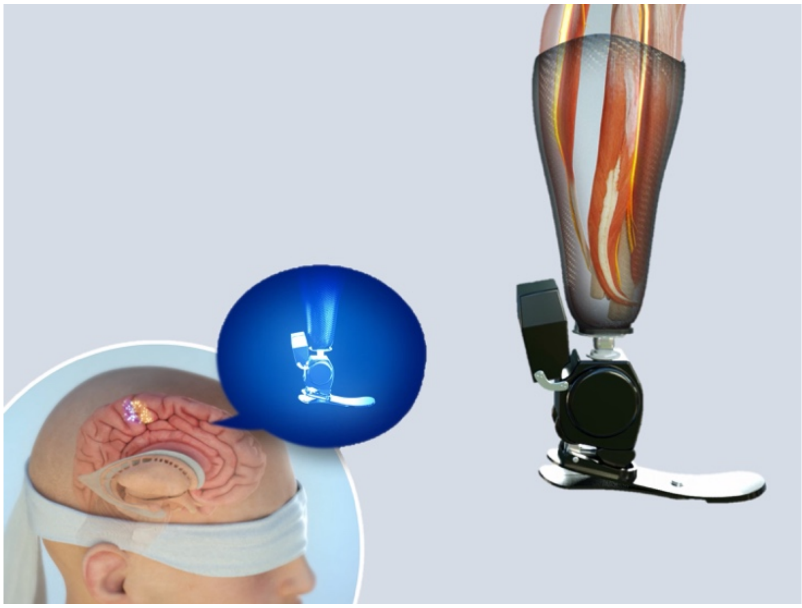

Figure 1: The AMI is designed to enable persons with amputation to feel their prosthetic joint, so that they know where it is in space without looking at it. Graphic excerpted from: https://www.brighamandwomensfaulkner.org/about-bwfh/news/ewing.

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[2] Benjamin EJ, Blaha MJ, Chiuve SE, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. *Circulation*. 2017; 135:e229-e445. Reported in https://www.cdc.gov/stroke/facts.htm.

[3] J. Ku, "Upper extremity rehabilitation of stroke: Facilitation of corticospinal excitability using virtual mirror paradigm," *Journal of Neuroengineering and Rehabilitation,* vol. 9, no. 71, 2012.

The AMI combines a restructuring of the amputation surgery with a complementary prosthetic control system, in the first stable method for providing natural proprioceptive feedback from a synthetic limb. An AMI is comprised of two muscles – an agonist and an antagonist – surgically connected in series, so that the contraction of one muscle in turn stretches the other. This connection preserves the dynamic muscle relationships that exist in native anatomy, thereby allowing proprioceptive signals from biological sensors within both muscles to be communicated to the central nervous system. What sets the AMI apart from other solutions is that it begins with a surgical restructuring of the residual limb, rather than relying on imperfect anatomy that is typically the result of standard amputation practices. In this way, the AMI allows engineering of both the biological body *and* the prosthetic leg, making it possible to create human-prosthetic interactions that far surpass what would otherwise be possible.

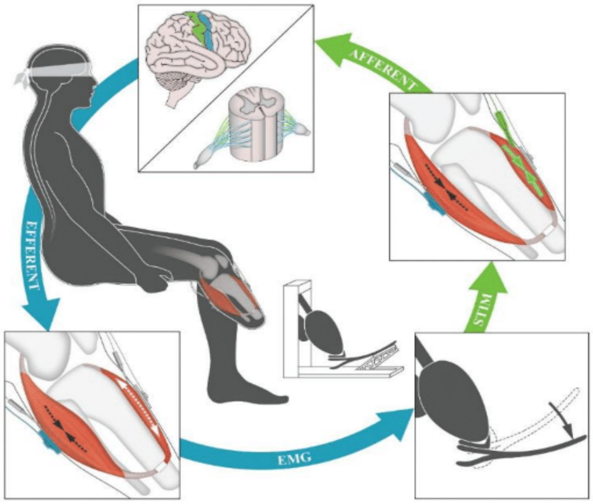

Figure 2: The AMI works in concert with an advanced prosthetic limb to allow a person with amputation to sense the torque that they are applying to an accelerator pedal.
Original artwork by Stephanie Ku, figure first appeared in Clites et al, Sci. Transl. Med. 10, eaap8737 (2018).

Validation of this invention began with patients who had undergone a specialized below-knee amputation surgery, in which AMIs were constructed in each of their residual limbs. In a preliminary study, three of these patients had the opportunity to interface with an experimental robotic prosthesis via the novel control system. When compared to persons with traditional amputation, these three AMI patients have a much higher level of control over a robotic prosthesis. Furthermore, they have healthier residual limb musculature, significantly reduced muscle atrophy, and no phantom limb pain. While controlling the experimental device, they are able to sense it moving as if it is their own biological leg, feeling like it has become “a part of them.” As one patient described, “it feels like…you put the bones back in my foot.” Tyler and his team are working to recreate the culture surrounding amputation surgery. They hope to help both doctors and patients learn to view amputation not as a last resort, but as a viable option that enables patients to return to full function in their lives.

Tyler’s secondary invention, Pollex Grasp, is an at-home, wearable, task-oriented therapy and assist device that improves and restores motor function, control, and dexterity of the thumb in people who suffered from stroke-related or other neurologically-caused hand disabilities. The principal feature of the invention is a specially-engineered soft robotic actuator, designed to closely mimic the motion of the thumb when it rotates to touch one finger. The actuator is made of a highly elastic rubber that is molded to capture a channel of air pressure. Expansion of the channel under air pressure is restricted by strategically-wrapped Kevlar fibers, such that pressurization of the channel causes a grasp motion of the thumb. The device could be worn to ensure proper thumb motion as it assists the patient in completing everyday tasks such as picking up and drinking from a cup or using utensils. Repeated, enforced correct movement, such as that offered by Pollex Grasp, helps to restore proper function to the thumb.

Figure 3: Example of a person wearing Pollex Grasp to complete an everyday task.

Commercialization: The adoption and commercialization of the AMI is to be carried out in two parallel and equally important efforts: (1) surgical adoption, and (2) commercialization of the robotic prosthesis and control system. The key to large-scale clinical adoption of the surgical practice is a compelling prospective clinical trial in a sizeable patient cohort. Tyler's clinical collaborators have recently been awarded a multi-million-dollar federal grant to carry out this effort. He is optimistic that surgeons will rapidly adopt the AMI due to early experimental results suggesting that the AMI surgery has significant benefits over standard amputation, even in the absence of an advanced prosthetic limb.

The AMI system reaches its fullest potential when implemented in tandem with a complementary control system running on an adequate robotic platform. All of the technology currently exists to advance a compatible robotic system to a point of commercial viability. Tyler envisions a paradigm in which hardware and control system designs are licensed to a large company, which has the resources to drive the technology through regulatory and reimbursement approvals and into the market.

Tyler's Pollex Grasp invention is optimized for quick market penetration. Due to its relevance as an assistive device, the first target will be an industrial setting in which workers perform repetitive grasping motions (e.g. assembly lines). From there, the expectation is that the device would have the backing and momentum to gain traction in spaces with greater direct clinical relevance, such as stroke rehabilitation. Pollex Grasp is made of relatively inexpensive materials; the majority of current cost comes in manufacturing, which can be significantly streamlined.