

oe Pleban

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Talk to your doctor about your potential treatment options.

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TARGETED MUSCLE REINNERVATION:

Innovative Surgery Is Shown to Reduce Phantom Pain

By Gregory Dumanian, M

An innovative surgery originally developed for advanced prosthetics also significantly reduces amputee limb pain, according to a clinical study published in the peer-reviewed *Annals of Surgery*. The findings underscore the procedure's potential to revolutionize treatment and become the new standard of care for millions of amputees worldwide suffering from often-debilitating chronic pain.

The study – the first-ever published randomized clinical trial for the treatment of post-amputation pain in major limb amputees – found that a procedure called targeted muscle reinnervation (TMR) resulted in a significantly greater reduction in phantom limb pain and trended toward improved residual limb pain, compared to standard treatment for nerve and pain issues.

"This study proves what we've seen anecdotally – that TMR is the first major advance in the way we treat residual and phantom limb pain since the onset of amputations thousands of years ago," says Gregory Dumanian, MD, chief of plastic surgery at Northwestern University's Feinberg School of Medicine, lead researcher and study author, and originator of the TMR surgical procedure. "Respite from pain means freedom from narcotics, freedom to engage in physical activity, freedom to enjoy time with family and friends, freedom to pursue careers and much more."

Chronic pain is pervasive among the 2 million amputees across the U.S. and millions more around the world, often leading to reduced prosthetic function, poor quality of life, and dependence on opiates and other pain medication.

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A frequently cited survey published in 1983 showed that 85 percent of American military veterans reported significant amounts of phantom pain, noting that "few reported treatments were of any value." Other estimates suggest that as many as 76 percent of amputees experience residual limb pain, and as many as 85 percent suffer from phantom limb pain (PLP), which is the brain's perception of pain and discomfort seemingly originating in the absent limb.

In contrast, findings from the recent TMR study show that 72 percent of participants who underwent the procedure reported feeling mild or no phantom pain after 18 months, compared with just 40 percent who underwent standard neuroma excision and muscle burying for chronic post-amputation pain. Additionally, 67 percent of patients were free of or felt only mild residual limb pain following TMR, compared to 27 percent who received standard treatment.

The study, funded by the U.S. Department of Defense, included two sites: Northwestern University, led by Dumanian, and Walter Reed National Military Medical Center. led by Dr. Kyle Potter.



Keith Philizaire

"In addition to being effective, the beautiful thing about TMR is that there are low barriers to adoption – it requires little specialized equipment and can be performed in university hospitals, in military medical settings, and more," Dumanian explains. "With greater awareness and a little training, surgeons who treat amputees can ramp this up across the healthcare system, and they are doing so already."

One of the study participants treated at Northwestern, Keith Philizaire, says he lived through years of anguish and pain medication to address severe PLP following the amputation of his leg.

"If you can imagine, for two to three years it literally felt like my leg was being cut off, over and over again," Philizaire says. "Now, about a year after having TMR, I'm pain-free and I'm no longer using any medications. I'm able to take my daughters to the park and the movies, and I even rode a bike with my prosthetic leg."

Another study participant, Sarah Dean, is a registered nurse who lost her hand following a bus accident in Bolivia, where she was providing medical care for underserved communities.

"After my amputation, I experienced intense phantom limb pain and neuropathic pain – on a pain scale of one to 10, I was at a 20. It was like torture," Dean says. "After undergoing TMR, I still had some pain at first but I understood it was part of the healing process. Thankfully, after about four or five months it was manageable enough for me to go back to work. Now, I am proud to say that I am completely off all pain medications, I've earned my master's degree and have been working full-time at a hospital in the suburban Chicago area."

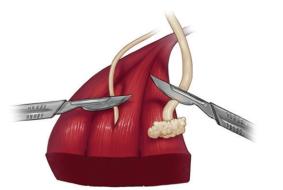
Perhaps the most well-known TMR patient is Joe Pleban, who received international attention in 2014 when he tattooed "Please cut here" on his left ankle and memorialized his limb's adventures on Facebook before amputation. Although he was not a study participant, he cites his TMR surgery performed by Dumanian as critical to reclaiming his active lifestyle.

"For me, TMR has been an amazing out from chronic pain," Pleban says. "Since the procedure, I've been able to start running, snowboarding, playing rugby, and it's just continued to go up from there. I started competing in World Para Snowboarding last season, which allowed me to travel around the world. Being a professional snowboarder has been a dream of mine since I was a little kid, and now I'm living that dream."

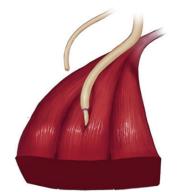
Residual limb pain is primarily caused by terminal neuromas, which are cut nerve endings encased in scars.



Sarah Dean







TMR dissects the amputated nerve – the "live wire" – and surgically reroutes it to reinnervate a nearby functionless muscle, thereby "closing the circuit."

Surgeons have devised numerous procedures to minimize or eliminate the painful symptoms of neuromas, but effective treatment has been largely elusive. Prevailing standard practice involves burying nerve endings from the amputated limb in a nearby muscle – essentially hiding a hot nerve ending, with limited success at reducing pain.

am absolutely committed to making sure every person living with an amputation and the doctors who treat them understand the potential of TMR to provide relief from chronic pain.

A related condition, PLP, is thought to be a complex interplay between painful neuromas and the central nervous system – and has proven even more difficult to prevent or reverse, with no treatment regarded as universally effective.

"Our nervous system is like an electric grid, and severed nerves are like live wires that cause pain," Dumanian explains. TMR dissects the amputated nerve – the "live wire" – and surgically reroutes it to reinnervate a nearby functionless muscle, thereby "closing the circuit." The reinnervation process allows the nerve to find end-receptors within the muscle, fooling the nerves into feeling "healed" and, more importantly, less painful.

"Simply put, TMR gives the nerves somewhere to go and something to do, a strategy absent from all other neuroma treatments," he says.

Dumanian was the first to perform TMR surgery in 2002 to enable patients to control advanced myoelectric (bionic) prostheses. While the procedure's implications for prosthetics drew international attention, Dumanian also observed that TMR patients experienced less pain, making it a potential treatment for a broader population of amputees. These observations were published in a retrospective study in 2014, but the latest findings are

the first to demonstrate significant improvements in a randomized, multi-center study.

In the recently published trial, 28 amputees with chronic pain were assigned to either standard treatment or TMR. Researchers gathered information including patient-rated pain scores, neuroma size and functionality data at six months, 12 months and 18 months post-procedure. Patients in the study did not know whether they had received TMR or standard treatment for a full year after surgery.

Notably, three study participants who originally underwent standard treatment opted to have TMR performed after the 12-month mark, including Philizaire. Eleven of the limbs treated with TMR had been amputated for five to 10 years or more.

"Critically, we found that there's really no shelf life on TMR," Dumanian says, also noting that there were no surgical complications to report. "It's not too late to have the procedure if you're more than a decade post-amputation, or if you've had nerve surgeries in the past, which is common among the amputee community."

Dumanian, a triple board-certified fourth generation Armenian-American surgeon, is on a mission to encourage the use of TMR to provide much-needed relief for amputees. As a plastic surgeon, he regularly lectures at medical conferences around the world, raising awareness about TMR among neurosurgeons and orthopedic surgeons who treat amputee patients in pain. Notably, he has no intellectual property rights and no commercial interests in the TMR procedure.

"I am absolutely committed to making sure every person living with an amputation and the doctors who treat them understand the potential of TMR to provide relief from chronic pain," Dumanian says. ©



Dr. Gregory Dumanian is chief of plastic surgery at Northwestern University's Feinberg School of Medicine. He is a surgical innovator who developed targeted muscle reinnervation for the treatment of painful nerve endings and for amputees to move bionic limbs. He also is the creator of Mesh Suture – the first new surgical suture design in 30 years. Dr. Dumanian performs the full range of cosmetic and reconstructive surgery procedures.