



## Targeted Muscle Reinnervation (TMR)

A Novel Approach for Prevention  
and Treatment of Postamputation  
Neuroma and Phantom Limb Pain



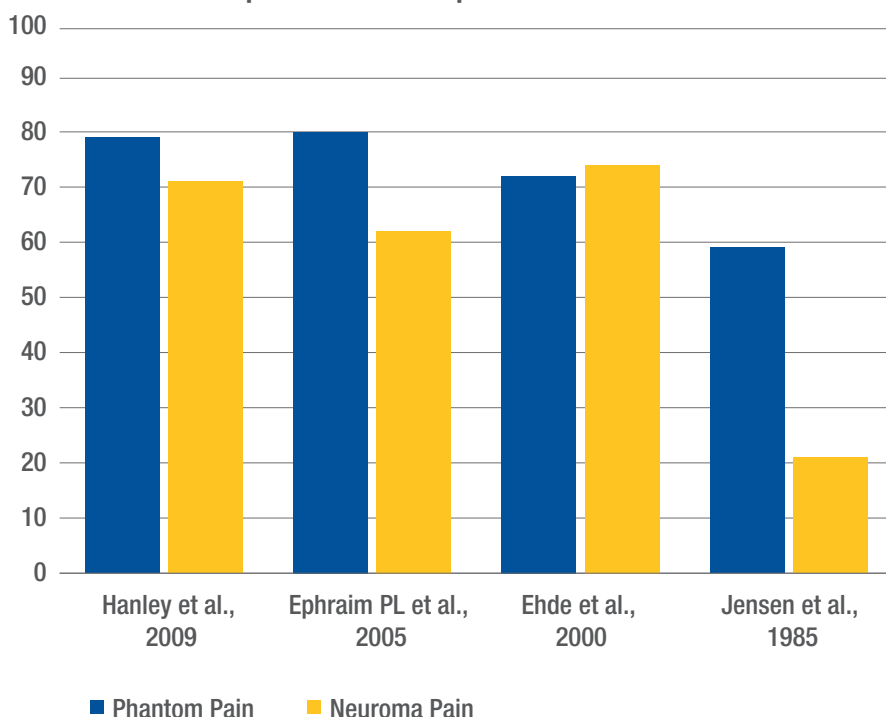
Approximately 185,000<sup>1</sup> limb amputations are performed annually in the U.S., and the Amputee Coalition estimates 2.1 million Americans are living with limb loss.

### Up to 80% of Amputees Experience Residual Limb or Phantom Limb Pain

Residual limb neuroma pain and phantom limb pain are serious consequences of amputation, limiting prosthetic device use and increasing disability, depression and dependence on opioids and other pain medications. Painful neuromas affect up to 74% of patients while up to 80% experience phantom limb pain.<sup>2,3,4,5</sup>

Despite numerous surgical procedures proposed in the literature, a consistently effective surgical approach to prevent and treat amputee pain has proven to be elusive.

Amputation Pain Reported in the Literature



<sup>1</sup>Dumanian GA, Potter BK, Mioton LM, Ko JH, et al., Targeted Muscle Reinnervation Treats Neuroma and Phantom Pain in Major Limb Amputees: A Randomized Clinical Trial. *Ann Surg.* 2018 Oct 26.

<sup>2</sup>Hanley MA, et al., Chronic Pain Associated with Upper-Limb Loss, *Am J Phys Med Rehabil.* 2009 September; 88(9): 742–779.

<sup>3</sup>Ephraim PL, Wegner ST, MacKenzie EJ, Dillingham TR, Pezzin LE, Phantom pain, residual limb pain, and back pain in amputees: results of a national survey. *Arch Phys Med Rehabil.* 2015 Oct;86(10): 1910-9

<sup>4</sup>Ehde DM, Czerniecki JM, Smith DG, et al. Chronic phantom sensations, phantom pain, residual limb pain, and other regional pain after lower limb amputation. *Arch Phys Med Rehabil.* 2000;81:1039–1044.

<sup>5</sup>Jensen TS, Krebs B, Nielsen J, Rasmussen P., Immediate and long-term phantom limb pain in amputees: incidence, clinical characteristics and relationship to pre-amputation limb pain. *Pain.* 1985 Mar;21(3):267-78.

<sup>6</sup>Dumanian GA, Valerio IA, Souza JM, Tintle SM, Ko JH, Loeffler BJ, Shores JT, Eberlin KR, National Targeted Muscle Reinnervation Board Meeting, ASSH Annual Meeting, Sept. 13, 2018

# Targeted Muscle Reinnervation Treats Neuroma and Phantom Pain in Major Limb Amputees

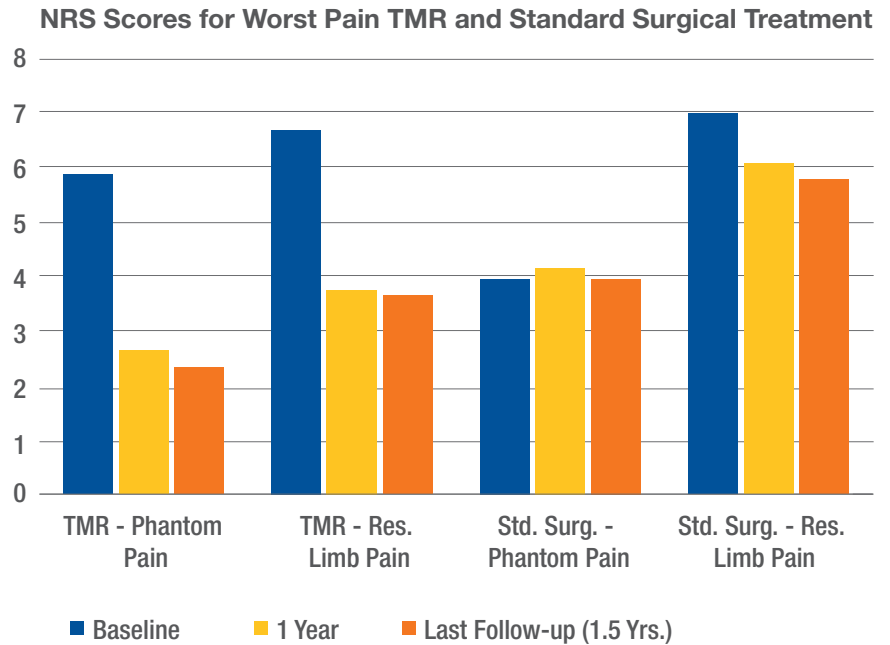
## A Randomized Clinical Trial

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## TMR Shown to Provide Clinically Significant Pain Relief

A recent prospective randomized clinical trial for the surgical treatment of postamputation pain in major limb amputees reported that TMR procedures decreased phantom limb NRS pain scores ( $P=0.03$ ) compared to standard surgical treatment (neurectomy with nerve buried into muscle).<sup>1</sup> The study also reported a trend toward improvement in residual limb pain in the TMR group compared to standard surgical treatment.



## The Checkpoint® Stimulator is an Enabling Tool for TMR

Surgeons performing TMR report the Checkpoint® Stimulator is designed to be an essential instrument for the most technically challenging step of TMR. Specifically, localizing the recipient motor nerve branches within targeted muscle tissue close to the motor endpoints.<sup>6</sup> Using the Checkpoint Stimulator may facilitate adoption of TMR as the primary surgical approach for the prevention and management of postamputation residual limb pain and phantom limb pain.

Visit [www.checkpointsurgical.com](http://www.checkpointsurgical.com) to learn more about the TMR procedure and access educational materials and resources.

## Randomized Controlled Trial:

**Objective:** To compare targeted muscle reinnervation (TMR) to “standard treatment” of neuroma excision and burying into muscle for postamputation pain.

**Summary Background Data:** To date, no intervention is consistently effective for neuroma-related residual limb or phantom limb pain (PLP). TMR is a nerve transfer procedure developed for prosthesis control, incidentally found to improve postamputation pain.

**Methods:** A prospective, randomized clinical trial was conducted. 28 amputees with chronic pain were assigned to standard treatment or TMR. Primary outcome was change

between pre- and postoperative numerical rating scale (NRS, 0–10) pain scores for residual limb pain and PLP at 1 year. Secondary outcomes included NRS for all patients at final follow-up, PROMIS pain scales, neuroma size, and patient function.

**Results:** In intention-to-treat analysis, changes in PLP scores at 1 year were 3.2 versus  $-0.2$  (difference 3.4, adjusted confidence interval (aCI)  $-0.1$  to 6.9, adjusted  $P = 0.06$ ) for TMR and standard treatment, respectively. Changes in residual limb pain scores were 2.9 versus 0.9 (difference 1.9, aCI  $-0.5$  to 4.4,  $P = 0.15$ ). In longitudinal mixed model analysis, difference in change scores for PLP was

significantly greater in the TMR group compared with standard treatment [mean (aCI) = 3.5 (0.6, 6.3),  $P = 0.03$ ]. Reduction in residual limb pain was favorable for TMR ( $P = 0.10$ ). At longest follow-up, including 3 crossover patients, results favored TMR over standard treatment.

**Conclusions:** In this first surgical RCT for the treatment of postamputation pain in major limb amputees, TMR improved PLP and trended toward improved residual limb pain compared with conventional neurectomy.

**Trial Registration:** NCT 02205385 at ClinicalTrials.gov.

**For additional information and surgical videos visit [checkpointsurgical.com](http://checkpointsurgical.com).**

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**RX Only**

The Checkpoint Stimulator is a single-use, sterile device intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability. Do not use this Stimulator when paralyzing anesthetic agents are in effect, as an absent or inconsistent response to stimulation may result in inaccurate assessment of nerve and muscle function. For a complete list of warnings and precautions regarding the use of the Stimulator please see [www.checkpointsurgical.com](http://www.checkpointsurgical.com)