

Targeted Muscle Reinnervation Treats Neuroma and Phantom Pain in Major Limb Amputees, A Randomized Clinical Trial

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Abstract

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.