FESSH Clinical Research Grant recipient 2022

Targeted muscle reinnervation for the surgical treatment of painful neuroma in the upper extremity

Final Report

Researchers

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Grant name and year awarded:

FESSH Clinical Research Grant 2022

Project Title:

Targeted muscle reinnervation for the surgical treatment of painful neuroma in the upper extremity

Date of the grant period:

2022

Principal investigator:

Dr. J. Michiel Zuidam

Summary of progress and results:

After trauma or iatrogenic injury to peripheral nerves in the upper extremity, neuromas may develop. Up to 30% of neuromas develop painful symptoms. As described in our grant application, patients may experience considerable and debilitating symptoms, which significantly affect their daily lives. If conservative treatment fails, surgery can be necessary. Targeted Muscle Reinnervation (TMR) is a new treatment for nerve pain. During TMR, the diseased or damaged part of the nerve is removed, and the 'new' end of the nerve is spliced into a healthy donor nerve innervating muscle. Providing the damaged nerve with a target donor nerve to grow into and a target muscle to innervate, decreases pain, prevents formation of recurrent neuromas and hereby permanently mitigates symptoms. Our multicenter prospective study sought to research whether TMR is more effective in reducing pain than conventional neuroma surgery at 12 months postoperative.

The multicenter study started enrolling patients on January 1st, 2022, in the Erasmus Medical Center, Sint Franciscus Gasthuis, and Sint Franciscus Vlietland. In June 2022, inclusion commenced at HagaZiekenhuis. Finally, inclusion started at the Queen Elizabeth University Hospital in Birmingham in September 2022. To date, 65 patients have been included in the cohort, of which 38 have completed follow-up. Of patients who completed follow-up, 31 underwent TMR, and seven underwent conventional neuroma surgery. Considering that the seven conventional patients have not reached our required sample size of 23 patients per treatment group, we have not been able to compare results yet between treatment groups. Therefore, results for TMR patients will be presented below.

Results of TMR in the treatment of painful neuroma:

We would like to inform you that these results have not yet been published. Therefore, we kindly request that you treat this information as confidential until publication.

Thirty-one patients underwent TMR for a painful neuroma. The mean age at the time of TMR was 47.5 years. Nineteen out of 31 patients were female (61.3%). The most common mechanism of nerve injury was iatrogenic injury (35.5%), followed by limb amputation (32.3%) and traumatic nerve injury (32.3%). The mean time between nerve injury and TMR was 6.9 years, ranging from one to 35 years. The majority (54.8%) of patients had received prior surgical neuroma treatment for their neuropathic pain. There was one patient with a postoperative complication of wound dehiscence (3.2%).

Our primary outcome was pain score on the MHQ 10-point pain subscale (numerical rating scale of 0-10). Pain levels at rest improved for 22 out of 31 participants (71.0%). The mean

decrease in pain score for these patients was 4.1 ± 2.6 points. At twelve months follow-up, 54.6% of patients achieved a pain score of or below three. The mean pain score at rest preoperatively was 6.4 ± 2.1, which decreased to 4.3 ± 2.7 at three months follow-up and 3.7 ± 2.8 at twelve months follow-up The difference between the mean pain score at baseline and the end of follow-up was statistically significant ($p < 0.001$). The mean pain score during movement of the limb decreased from 7.8 ± 1.1 at baseline to 5.3 ± 2.4 and 5.2 ± 2.9 at twelve months follow-up. This decrease was statistically significant as well ($p < 0.001$). For five patients, pain levels remained constant (16.1%). For four patients, pain levels worsened (12.9%). For three of these patients, the increase in pain score was one point, and for one patient, it was four points.

Quality of life, measured as the EQ-index score on the EuroQoL EQ-5D-5L questionnaire, improved significantly for patients following TMR. The EQ-index score increased from 0.46 ± 0.23 at baseline (representing the health state's value on a scale ranging from 1 (indicating full health) to 0 (equivalent to being deceased)), to 0.59 ± 0.28 at twelve months postoperatively ($p = 0.011$).

The study is expected to conclude enrollment in December of 2024. However, a separate manuscript of our first 30 TMR patients will be submitted for publication in June 2024.

List of publications:

1. Targeted muscle reinnervation for the treatment of painful neuromas. Mirte Langeveld, Caroline A. Hundepool, MD, A.J.M. Teun Luijsterburg, Dominic Power, Liron S. Duraku and J. Michiel Zuidam. To be submitted for publication at Plastic Reconstructive Surgery 15-06-2024. Submittal is available to read on request.

List of presentations:

1. Oral presentation “Targeted Muscle Reinnervation: een nieuwe chirurgische behandeling van pijnlijke neuromen” (Translation: Targeted Muscle Reinnervation: a new surgical treatment of painful neuromas). Presented 08-11-2023 at the Dutch Association of Plastic Surgery (NVPC) conference. FESSH was accredited in the presentation.
2. Submitted for oral presentation at the 2025 IFFSH and IFSHT Triennial Congress, Washinton, the United States.
3. Oral presentation of research results at the FESSH 2024 Congress on June 27th, Rotterdam, the Netherlands.

FESSH was accredited in our presentation at the Dutch Association of Plastic Surgery (NVPC) conference. We will continue to acknowledge FESSH when papers and/or presentations from this research are published or presented.

Additional funding: we have not received nor applied for any additional funding for this project.

Calculation of Grant spending:

Personnel costs	**Fte**		**2022**
Primary Investigator, medical specialist	0.05	€	14,477.00
PhD student	0.80	€	42,007.00
Postdoc	0.10	€	8,838.00
Health Economist	0.05	€	5,842.00
Total personnel costs		€	71,164.00
Contribution of FESSH		€	-10,000.00
Contribution Department of Plastic, Reconstructive and Hand Surgery, Erasmus MC (Primary Investigator + Postdoc + Congress and publication costs)		€	-61,164.00