Nerve decompression for leprous neuropathy: A prospective study from Ecuador

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Summary

Objectives: Since the mid-1950s retrospective studies in leprosy have reported outcomes following decompression of single anatomic sites of compression (e.g., ulnar nerve at elbow). The purpose of this prospective study is to apply concepts developed from the successful treatment of diabetics, who have neuropathy and multiple sites of chronic nerve compression, to patients with leprous neuropathy (e.g., neurolysis of the ulnar nerve at the elbow and at the wrist).

Results: Eighteen of 19 patients returned for post-operative evaluation. There were no post-operative complications. At 2 years follow-up, 13/15 (87%) patients have sensory improvement as demonstrated by the Pressure-Specified Sensory Device™ (PSSD). Thirteen of 13 (100%) patients reported motor improvement and could demonstrate a voluntary muscle testing score of 4/5 or 5/5 on their most recent follow-up. Post-operatively, we observed significantly improved quality of life by RAND-36, \( P = 0.03 \) and significantly increased upper-extremity function by...
Q-DASH ($P = 0.02$). Among patients with severe pain, there was a significant decrease in pain by an average of 5.6 points ($P = 0.005$).

**Conclusions:** Application of the double crush concept to decompression of multiple peripheral nerves is feasible in the population with leprous neuropathy. In our cohort, neurolysis of the median nerve at the wrist and forearm, of the ulnar nerve at the wrist and elbow, of the tibial nerve in 4 medial ankle tunnels, and of the peroneal nerve at the knee, leg and foot gave increased quality of life, decreased disability, improved pain, and improved sensory and motor function in the majority of patients.

**Introduction**

Leprosy (Hansen’s disease) continues to burden communities across the globe despite advancements in medicine and public health. In 2014, at least 213,899 new cases were reported worldwide. According to the World Health Organization (WHO), a satisfactory diagnosis of Hansen’s occurs when at least one of three cardinal signs is present: loss of sensation in a hypo-pigmented or reddish skin patch; acid-fast bacilli in slit-skin smear; or thickened or enlarged peripheral nerve(s) concomitant with loss of sensation and/or muscle weakness in appropriate regions of innervation. Despite being one of the most treatable neuromuscular diseases, Hansen’s disease also continues to be a significant source of disability.

More than 4 million people worldwide suffer from disabilities due to Hansen’s disease; these disabilities include paresthesia, muscle paralysis (e.g. lagophthalmos, foot drop, claw hands), ulcers, and chronic osteomyelitis. Over several decades, emphasis has been placed on understanding, preventing, and treating leprous neuropathy as the source of these disabilities and deformities, and therefore as the root of the stigma associated with Hansen’s disease.

Despite the lack of rigorous study, surgical nerve decompression (ND), or neurolysis, has been employed for decades to treat leprous neuropathy. Various surgical approaches are available for ND for leprous neuropathy; some have even been used in randomised controlled studies (RCTs), although no good quality RCT exists in the literature to date. It can, therefore, be difficult to make conclusions about the impact of ND on motor and sensory function.

During the past 25 years, utilising an extension of the “double crush hypothesis”, a surgical approach to chronic nerve compression in people with diabetic neuropathy has been developed that employs the use of ND at multiple sites of known anatomic narrowing along multiple individual peripheral nerves during the same operation. In the present study, we apply the surgical approach resulting from the ‘double crush hypothesis’ to patients with leprous neuropathy when there are indications of nerve compression of one nerve at multiple levels. This approach involves a neurolysis of the ulnar nerve at both the wrist and elbow, the median nerve at both the wrist and forearm, the tibial nerve in the four medial ankle tunnels, and the peroneal nerve at the knee, leg and foot dorsum.

Historically, studies examining sensory function following ND for leprous neuropathy have generally used monofilaments and/or the ballpoint pen test (BPT) and have less frequently used nerve conduction studies. Previously, we have shown that the Pressure-Specific Sensory Device™ (PSSD) has superior sensitivity and specificity than the BPT and monofilaments at detecting neuropathy among Hansen’s patients. The PSSD also has greater sensitivity and specificity than nerve conduction studies at determining other sources
of neuropathy. Overall, the PSSD is a reliable tool for assessing peripheral nerve function in diverse clinical settings and has significant advantages over other forms of nerve testing (Supplementary Table 1).

Another significantly under-researched area in ND for leprous neuropathy is patient-reported outcomes (PROs). Generally little attempt has been made to use questionnaires to characterise PROs such as pain, disability and quality of life (QoL) changes due to ND; the single study regarding QoL and ND for leprous neuropathy reported only post-operative measurements without pre-operative measurements to compare.

Thus, in this study, we hypothesised that the PSSD could demonstrate sensory improvement after ND, and that PROs for strength, pain, disability, and QoL would improve after ND done at multiple sites of compression in both the upper and the lower extremities.

Patients and Methods

Inclusion Criteria for Patients

Patients were selected from those at Damien House Organization of Guayaquil, Ecuador. Inclusion criteria were (1) being more than 6 months out of multi-drug therapy and corticosteroid therapy for Hansen’s disease and complications (e.g. reactions, neuropathy); (2) not currently having an ongoing reaction (i.e. reversal reaction or erythema nodosum leprosum); (3) currently having either upper or lower extremity pain, numbness, weakness and/or deformity; and (4) presence of a positive Tinel sign at known sites of entrapment, or tender, thickened peripheral nerves.

Exclusion Criteria for Patients

Patients who underwent medical therapy with corticosteroids in the past 6 months, and patients with diabetic neuropathy or neuropathies other than leprous neuropathy, were excluded. Patients who had a previous peripheral nerve surgery were excluded. Patients with amputated digits or ulcers were excluded.

Surgical Technique

Patients were placed under general anesthesia and surgical decompression of the three nerves in an arm and three in the leg were done simultaneously using a 2-team approach. Patients were given intravenous cephalosporin prior to inflating the pneumatic tourniquets. Bipolar coagulators and 3.5 × loupe were also used. Our approach emphasised decompression of each nerve at each site in which it could be decompressed in that extremity (‘double crush’ concept). The ulnar nerve was decompressed at the elbow and at the wrist. At the cubital tunnel, the ulnar nerve was decompressed in situ; decompression at the Guyon’s canal included the sensory and motor branches of the ulnar nerve. The median nerve was decompressed at the wrist (open carpal tunnel) and forearm (proximal median nerve, specifically the anterior interosseous nerve) along a path starting 3 cm distal to the elbow flexion crease and terminating approximately 3 cm proximal to the medial humeral epicondyle. The superficial sensory branch of the radial nerve was also decompressed in the mid-forearm (Wartenburg release). The tibial nerve was decompressed at each of its branches in the medial, lateral, plantar, and calcaneal tunnels. The peroneal nerve was decompressed at
both the fibular neck and over the dorsum of the foot. Internal neurolysis was performed as indicated by intra-operative findings of firmness, intraneural fibrosis, and/or loss of perineurial markings. Oral cephalosporin was continued for 1 week post-operatively.

SENSORY AND STRENGTH TESTING

Sensory testing was conducted pre-operatively and 1 and 2 years post-operatively using the Pressure-Specified Sensory Device™ (PSSD). The PSSD incorporates a non-invasive and computer-based system that quantifies and records 1- and 2-point cutaneous pressure thresholds, which can then be compared to normative data in order to detect nerve function impairment. Testing with the PSSD revealed the cutaneous pressure required for the patient to determine 1-point stimuli as well as the cutaneous pressure and inter-prong distance necessary for the patient to determine 2-point stimuli apart from 1-point stimuli. Scoring tables used the PSSD results to determine nerve function impairment; each table was specific to a site used for cutaneous sensory testing (Supplementary Tables 2 to 7).

Strength testing was conducted 2 years post-operatively using voluntary muscle testing on a scale of 0 (no visible contraction) to 5 (normal). The following muscles and functions were tested when possible, and an average integer was reported per patient for hand and/or foot function: hand grip, opponens pollicis (opposes thumb), abductor pollicis brevis (abducts the thumb), adductor pollicis (adducts the thumb), opponens digiti minimi (opposes the little finger), abductor digiti minimi (abducts the little finger), third palmar interossei (adducts the little finger), foot dorsiflexion and plantar flexion. To partially remedy a lack of pre-operative strength testing, the patient was asked to recollect if their strength had improved since before surgery.

QUALITY OF LIFE, DISABILITY, AND PAIN QUESTIONNAIRES

Pre-operative and post-operative quality of life, disability, and pain were measured using appropriate translations of the RAND 36-Item Short Form Health Survey (RAND-36), the short-form of the Disabilities of the Arm, Shoulder and Hand questionnaire (Q-DASH), and the Numeric Pain Rating Scale (NPRS), respectively. These were collected at 1 year after surgery.

PATIENT DEMOGRAPHICS

Nineteen patients with a mean age of 56 years (standard deviation, SD = 13.3 years) received nerve decompression surgery. Seven patients (36.8%) were female, the average BMI was 26.6 (SD = 5.3), and the average number of years with an active diagnosis of Hansen’s disease was 12.8 years (SD = 9.7 years).

Eighteen patients (94.7%) underwent surgery on both upper and lower limbs. Among the 19 subjects who underwent surgery on any limb, 10 (52.6%) procedures were performed on the right upper extremity (RUE), eight (42.1%) procedures were performed on the right lower extremity (RLE), four (21.1%) procedures were performed on the left upper extremity (LUE), and 15 (78.9%) procedures were performed on the left lower extremity (LLE). In total, 88 nerves were operated upon: 19 median, 18 ulnar, 18 radian, 17 fibular, and 16 tibial nerves (both medial planter and medial calcaneal branches decompressed).
Patients included in this study either never received corticosteroid therapy or had failed corticosteroid therapy for the treatment of reactions and prevention of nerve function impairment. No adverse events occurred.

**STATISTICAL ANALYSES**

Quantitative and categorical variables are summarised using mean with associated SD and count with associated percentage, respectively. Percent improvement was calculated from summary statistics to quantify the pre- to post-operative improvement in quality of life. Pearson’s correlation coefficients were used to examine the linear association between measures of quality of life. Spearman’s correlation coefficients were also calculated to corroborate the robustness of the Pearson’s correlation coefficient’s assumption on linearity. The two sets of correlation coefficients are comparable, so only the Pearson’s correlation coefficients are reported. Paired t-test was used to compare pre- to post-operative changes in quality of life, disability, pain, and sensory scores measured by PSSD Survey results were complete from >80% patients. The analyses were done on all available completed data. The patient characteristics were not substantially different between those who did and did not complete the surveys. We stratified the analysis of sensory scores by site and nerve to investigate the post-operative outcome 1 and 2 years after surgery. All hypothesis tests were two-sided with significance level set at 5%. The analysis was performed using R Statistical Software, version 3.1.3 (R Foundation for Statistical Computing, Vienna, Austria). (R Core Team [2015]. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/).

**Results**

**QUALITY OF LIFE**

Fifteen patients completed pre-op and post-op RAND-36 surveys, for which higher scores indicate a more favourable health state. Overall RAND-36 scores improved 71 points after surgery ($P = 0.03$) (Table 1).

**Table 1.** Quality of Life (RAND-36) Outcomes Before and After Surgical Decompression

<table>
<thead>
<tr>
<th>Scale</th>
<th>Pre-Operative Score Mean (SD)</th>
<th>Post-Operative Score Mean (SD)</th>
<th>$p$-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>51.3 (22.0)</td>
<td>64.0 (22.5)</td>
<td>0.10</td>
</tr>
<tr>
<td>Role limitations due to physical health</td>
<td>30.0 (45.5)</td>
<td>41.7 (38.6)</td>
<td>0.39</td>
</tr>
<tr>
<td>Role limitations due to emotional problems</td>
<td>33.3 (43.6)</td>
<td>51.1 (35.3)</td>
<td>0.19</td>
</tr>
<tr>
<td>Energy/fatigue</td>
<td>60.7 (15.2)</td>
<td>62.3 (15.2)</td>
<td>0.62</td>
</tr>
<tr>
<td>Emotional well-being</td>
<td>61.9 (15.2)</td>
<td>64.5 (21.3)</td>
<td>0.58</td>
</tr>
<tr>
<td>Social functioning</td>
<td>68.3 (18.8)</td>
<td>71.7 (26.1)</td>
<td>0.51</td>
</tr>
<tr>
<td>Pain</td>
<td>50.0 (20.6)</td>
<td>64.0 (26.1)</td>
<td>0.12</td>
</tr>
<tr>
<td>General health</td>
<td>44.3 (22.5)</td>
<td>51.7 (16.4)</td>
<td>0.26</td>
</tr>
<tr>
<td>Overall</td>
<td>399.9 (142.0)</td>
<td>470.9 (147.0)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

†$P$-value is obtained from two-sample paired t-test.
All scales saw some improvement after surgery, with the greatest improvement on the pain scale (21·7 points) and a modest improvement in terms of energy/fatigue (1·6 points), for example.

DISABILITY

Thirteen patients completed pre-op and post-op Q-DASH surveys, for which a higher score indicates greater disability. The pre-op Q-DASH score mean was 43·9 (SD = 27·5) and the post-op Q-DASH score mean was 21·1 (SD = 23·7). After surgery, a 20-point (p = 0·02; 95% CI: 4 – 37) average improvement in disability was measured by the Q-DASH. 10 of these patients had also completed the optional Work module of the Q-DASH pre- and post-op; in the Work module, a higher score also indicates greater disability. The pre-op Work score mean was 41·3 (SD = 38·8) and the post-op Work score mean 34·4 (SD = 29·1). There was an average improvement of seven points, however this was not statistically significant (P = 0·31).

PAIN

Fourteen patients had both pre-op and post-op responses to NPRS, where 0 is no pain and 10 is most severe pain. Of these 14 patients, seven had a pre-operative pain rating of greater than 5, indicating pain severe enough to impact quality of life. Considering just these patients, there was a significant decrease in pain by an average of 5·6 points (P = 0·0049). Eight (57·1%) out of 14 patients reported a drop in pain intensity after surgery, one (7·1%) patient reported no change, five (35·7%) reported more severe pain after surgery. Trending evidence showed positive association between the Q-DASH and NPRS scores (Pearson’s correlation = 0·24).

MOTOR FUNCTION

After surgery, 13 patients returned for voluntary muscle testing. All 13 patients had hand and/or foot individual muscles and functions graded and had a 4 or 5 on the Medical Research Council (MRC) Scale for Muscle Strength (0 to 5; 5 signifying that the muscle contracts against full resistance.)

SENSORY FUNCTION

16 patients completed both pre-op and post-op PSSD testing at 1-year follow-up; 15 patients completed both pre-op and post-op PSSD testing at 2-year follow-up. In total, 18 patients returned for PSSD testing after surgery. At 1-year follow-up, 13 of 16 patients (81·3%) had sensory improvement, and at 2-year follow-up, 13 of 15 patients (86·7%) had sensory improvement.

Overall, there was a positive trend demonstrating, over the course of 2 years, greater proportions of nerves having improved sensation after receiving nerve decompression surgery (Table 2, Figure 1).

Here, sensory improvement was defined as progression to a lesser grade of nerve impairment on the PSSD scoring scale (Supplementary Tables 2 to 7) and/or a decrease of at least 2 mm (the minimally important difference) required for 2-point discrimination.
Among the nerves, the ulnar nerve innervating the pulp of the fifth finger had the least improvement and the medial plantar branch of the tibial nerve innervating the big toe pulp had the most improvement by 2 years after surgery (Figure 1, Figure 2).

When examining changes in nerve function from pre- to post- surgery using the PSSD grading scale (Supplementary Tables 2 to 7), there was an overall decrease of 0·5 grade at 1-year follow-up ($P<0·0019$, 95% CI [0·2 to 0·8]) and an overall decrease of 1·1 grade at 2-year follow-up ($P<0·0001$, 95% CI [0·7 to 1·5]) among all the nerves collectively. Interrogation of individual nerves revealed that there was a general trend demonstrating that after surgery, the severity of nerve impairment improves at 1 year after surgery and continues to improve at 2 years after surgery (Table 3).

At 1 year after surgery, none of the improvements were statistically significant. However, at 2-year follow-up, half of the nerves had statistically significant improvement compared to prior to surgery. The medial plantar branch of the tibial nerve, the median nerve, and the superficial radial nerve all demonstrated significant sensory improvement ($P = 0·0039$, $P = 0·01$, and $P = 0·035$, respectively).

### Table 2. Sensory Outcomes of All Nerves After Surgical Decompression

<table>
<thead>
<tr>
<th>Nerve</th>
<th># of Nerves</th>
<th># w/1 YR &amp; Pre-Op</th>
<th># (%) Improved Sensation @ 1 YR</th>
<th># w/2 YR &amp; Pre-Op</th>
<th># (%) Improved Sensation @ 2 YR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep fibular</td>
<td>16</td>
<td>16</td>
<td>3 (19)</td>
<td>10</td>
<td>5 (50)</td>
</tr>
<tr>
<td>Tibial n. medial plantar br.</td>
<td>15</td>
<td>14</td>
<td>2 (14)</td>
<td>11</td>
<td>8 (73)</td>
</tr>
<tr>
<td>Tibial n. medial calcaneal br.</td>
<td>15</td>
<td>14</td>
<td>5 (36)</td>
<td>11</td>
<td>6 (55)</td>
</tr>
<tr>
<td>Median n</td>
<td>18</td>
<td>15</td>
<td>7 (47)</td>
<td>15</td>
<td>10 (67)</td>
</tr>
<tr>
<td>Ulnar n</td>
<td>17</td>
<td>14</td>
<td>3 (21)</td>
<td>15</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Radial n</td>
<td>17</td>
<td>13</td>
<td>6 (46)</td>
<td>12</td>
<td>8 (67)</td>
</tr>
<tr>
<td>Overall</td>
<td>98</td>
<td>86</td>
<td>26 (30)</td>
<td>74</td>
<td>43 (58)</td>
</tr>
</tbody>
</table>

### Figure 1. Sensory Outcomes of All Nerves After Surgical Decompression.
Before nerve decompression, no significant difference in sensory impairment is present among the different nerves (ulnar vs median nerves, $P = 0.09$; radial vs median nerves, $P = 1$; peroneal nerve vs tibial nerve medial plantar branch, $P = 0.95$). At 1 and 2 years after nerve decompression, we found that no significant differences exist when comparing the sensory outcomes among different nerves to each other (1 year post-op: ulnar vs median nerves, $P = 0.30$; radial vs median nerves, $P = 0.59$; peroneal nerve vs tibial nerve medial plantar branch, $P = 0.36$; 2 years post-op: ulnar vs median nerves, $P = 0.40$; radial vs median nerves, $P = 0.26$; peroneal nerve vs tibial nerve medial plantar branch, $P = 0.71$).

We also found that at 1 year and at 2 years after surgery, no significant outcome difference existed when examining the variables of Hansen’s type (tuberculoid leprosy vs lepromatous leprosy), age, or sex (male vs female) (Table 4).

Eight out of nine (89%) of patients with lepromatous leprosy, 2/3 (67%) of patients with borderline leprosy, and 3/3 (100%) of patients with tuberculoid leprosy had sensory improvement as measured by the PSSD at 2 years post-op. A significant ($P = 0.008$) outcome difference appeared to be associated with BMI at 1 year after surgery, but this difference became insignificant ($P = 0.564$) at 2 years after surgery.

**Discussion**

*M. leprae* selectively targets superficial peripheral nerves. After bacterial colonisation and/or host reactions, the nerves are more likely to suffer ischemia from inflammation, trauma, and/or mechanical stress such as nerve compression at known sites of compression. 24–26

Here, we have presented long-term outcomes that support the effectiveness of nerve decompression at multiple sites along the peripheral nerve with leprous neuropathy.

Significant improvements are seen, after nerve decompression, in patients’ quality of life, disability of the upper-extremities, and sensory function of the peripheral nerves. Pain and motor function also appear to improve after surgery. To the best of our knowledge, we are the
Table 3. Sensory Outcome Scores of All Nerves Before and After Surgical Decompression

<table>
<thead>
<tr>
<th>Site</th>
<th>Nerve</th>
<th>Pre-Op Score</th>
<th>Post-Op Year 1 Score</th>
<th>p-value (Pre-op vs Year 1)</th>
<th>Post-Op Year 2 Score</th>
<th>p-value (Pre-op vs Year 2)</th>
<th>p-value (Post-op Year 1 vs Year 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsal Web Space 1/2</td>
<td>Deep Fibular</td>
<td>3.5 (1.6)</td>
<td>2.5 (1.9)</td>
<td>0.23</td>
<td>2.4 (2.2)</td>
<td>0.34</td>
<td>0.73</td>
</tr>
<tr>
<td>Great Toe Pulp</td>
<td>Tibial (Medial plantar br.)</td>
<td>3.5 (1.3)</td>
<td>3.1 (1.5)</td>
<td>0.51</td>
<td>2.1 (1.4)</td>
<td>0.004*</td>
<td>0.012*</td>
</tr>
<tr>
<td>Heel (Medial)</td>
<td>Tibial (Calcaneal br.)</td>
<td>3.3 (1.8)</td>
<td>2.6 (1.8)</td>
<td>0.23</td>
<td>2.4 (1.9)</td>
<td>0.14</td>
<td>0.27</td>
</tr>
<tr>
<td>Index Finger Pulp</td>
<td>Median</td>
<td>3.4 (1.7)</td>
<td>2.5 (1.3)</td>
<td>0.08</td>
<td>2.2 (1.2)</td>
<td>0.01*</td>
<td>0.39</td>
</tr>
<tr>
<td>Little Finger Pulp</td>
<td>Ulnar</td>
<td>2.3 (1.5)</td>
<td>2 (1.4)</td>
<td>0.2</td>
<td>1.8 (1.2)</td>
<td>0.11</td>
<td>0.27</td>
</tr>
<tr>
<td>Radial Hand Dorsum</td>
<td>Radial sensory</td>
<td>3.2 (1.7)</td>
<td>2.3 (1.7)</td>
<td>0.14</td>
<td>1.6 (1.4)</td>
<td>0.035*</td>
<td>0.18</td>
</tr>
</tbody>
</table>

1 Scoring was conducted using Supplementary Tables 2 to 7.
*Statistically significant at p = 0.05.
first in the Hansen’s community to report the detailed use of our sensory, quality of life, and disability assessment methodologies in this context.

Limitations of our study include a small sample size, a single-center design, and no control group. The lack of pre-operative muscle strength testing leads us to be cautious about our motor function conclusions. However, we are actively developing further studies to delineate motor function improvement after nerve decompression. Strengths include assessing sensory function, quality of life, and disability outcomes using established techniques, some of which are lacking in the literature related to using surgical nerve decompression to treat the sequelae of Hansen’s disease.

The lack of standardised study methods in the literature about this subject makes comparing our results difficult. In one descriptive cross-sectional study, only short-term (3 month) post-operative DASH scores were collected and analysed after 14 subjects underwent ulnar nerve decompression at the elbow with subcutaneous anterior transmission and median nerve decompression at the carpal tunnel. From their results, we can estimate their average post-operative DASH score to be 38·1 (SD 12·0). According to their categorisation of DASH scores, this average DASH score falls in the category of ‘mild limitation’. We can estimate our average pre-operative Q-DASH score to fall in the ‘mild limitation’ category and our post-operative Q-DASH score to fall in the ‘no limitation’ category. This appears to reaffirm that nerve decompression for leprous neuropathy relieves disability. In other clinical neuropathy settings, nerve decompression also significantly improved upper extremity disability.

Another descriptive cross-sectional study used the WHOQOL-BREF tool to measure quality of life following nerve decompression for leprous neuropathy in 33 patients. However, only post-operative measurements were taken, with a mean follow-up of 2·6 years. It is therefore difficult to make direct comparisons with our results; however, the study did observe that the physical domain of the WHOQOL-BREF was the lowest scoring domain. This domain takes into account conduct of activities of daily living, dependence on medicinal substances and medical aids, energy and fatigue, mobility, pain and discomfort, sleep and rest, and work capacity. Reis et al. observed that factors of a low scoring WHOQOL-BREF physical domain include dissatisfaction with dependence on medicinal substances and medical aids, decreased work capacity, and decreased ability to conduct activities of daily living.

We determined that, after surgery, the lowest scoring RAND-36 domain was the role of limitations due to physical health, even though this domain did improve greatly after surgery. Additionally, individual RAND-36 domains in our study improved to different extents after surgery. In other contexts with surgical nerve decompression, quality of life as measured by Short-Form 36, a tool very similar to RAND-36, also significantly improves.

Table 4. Multivariable Analysis of Scored Sensory Outcome

<table>
<thead>
<tr>
<th>Variable</th>
<th>Post-Op 1 Year</th>
<th>Post-Op 2 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>p-value</td>
<td>p-value</td>
</tr>
<tr>
<td>TL (ref = LL)</td>
<td>0.24</td>
<td>0.95</td>
</tr>
<tr>
<td>Age (years)</td>
<td>0.33</td>
<td>0.46</td>
</tr>
<tr>
<td>Sex M (ref = F)</td>
<td>0.91</td>
<td>0.83</td>
</tr>
<tr>
<td>BMI</td>
<td>0.01</td>
<td>0.56</td>
</tr>
</tbody>
</table>

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together, it appears that although quality of life can be significantly improved after nerve
decompression surgery for leprous neuropathy, other factors also influence quality of life,
including reactions, prejudice, stigma, economic status, gender, and education.\textsuperscript{32–36}

Our reported improvements in pain and sensory and motor function are consistent with
outcomes published in the scientific literature.\textsuperscript{10,11,37–42} In 1998, it was shown that neurolysis
could restore sensation in 50\% of cases of leprous neuropathy.\textsuperscript{37} Theuvenet \textit{et al.}
demonstrated a sensory improvement in 27\% and 66\% of operated nerves at 2 years after
surgery compared to 7\% of the non-operated nerves.\textsuperscript{42} Further, in 2001 and 2003, it was
found that neurolysis improved musculature and muscular function.\textsuperscript{11,38} In previous studies,
the limited tools to test sensation had restricted our ability to examine the process of sensory
and motor restoration after nerve decompression. It is clear that in order to support the
scientific evidence-base for nerve decompression, future studies should be conducted with
quantitative, objective measures to examine peripheral nerve function before and after nerve
decompression.

With regard to the observations relating to pain in this study, only 50\% of patients had a
level of pain impacting quality of life. After surgery, this group experienced significant
improvement in their pain related to release of their nerves. As the nerves regenerated
distally, some of the patients who did not have pre-operative pain, did experience pain after
surgery. This observation must be presented to patients prior to surgery to guide their
expectation and understanding of nerve recovery.

A Cochrane review on the effectiveness of surgical nerve decompression for leprous
neuropathy was recently undertaken and concluded that there was insufficient evidence to
make strong conclusions regarding the effect of nerve decompression surgery for leprous
neuropathy.\textsuperscript{6} The review examined data from the only two RCTs that exist, which are of very
low quality and did not report adverse events. The authors call for future well-designed RCTs
that examine not only clinical aspects of nerve decompression but also healthcare costs and
quality of life. Nickerson \textit{et al.} have also highlighted some necessary research developments
in this topic, including the need for randomisation, well-defined therapy, specific endpoints,
reporting of adverse events, long-term follow-up, and objective outcome measurements.\textsuperscript{43}
Objective outcome measurements include pinch and/or grip dynamometry and quantitative
sensory testing such as with the PSSD.

In conclusion, we have demonstrated that the ‘double crush’ concept, applied to surgical
nerve decompression for leprous neuropathy, significantly improves quality of life, disability,
and sensation. Pain and motor function also appear to improve following surgery. However,
there is great need for future well-designed RCTs in order to make stronger conclusions about
the effectiveness of nerve decompression surgery for leprous neuropathy.

**Competing Interest Statement**

Dr. Dellon holds a financial interest in the Pressure Specified Sensory Device\textsuperscript{™} described
in this paper. Dr. Wilton is the lead of Annie’s Angels Seacoast Medical Team, which
performed the surgeries described in this paper. All the other authors declare that the
answer to the question on competing interest form are all “No,” and therefore have
nothing to declare.
Ethics Approval

Ethical approval was obtained from the Institutional Review Board of the Johns Hopkins Medical Institutions in Baltimore, Maryland (IRB00045873).

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Contributors & Guarantors

PAB and JN obtained the initial pre-operative data. WBE and JPW conducted the surgeries. RMJ managed the patients clinically pre- and post-operatively. JN and ELW collected post-operative data. JN and RMJ were the collaborators from Ecuador. ELW and ALD planned the research, reported the work, and will act as guarantors of the paper.

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