

# PROSPECTIVE OUTCOMES STUDY ON THE RESTORE® RECHARGEABLE NEUROSTIMULATION SYSTEM FOR NEUROPATHIC PAIN: A MULTICENTER STUDY

J. P. Van Buyten, MD<sup>1</sup>; S. Fowo, MD<sup>2</sup>; G. H. Spincemille, MD, PhD<sup>3</sup>; V. Tronnier, MD, PhD<sup>4</sup>; M. Schrey, MD<sup>5</sup>; G. Beute, MD<sup>6</sup>; J. J. Pallarés, MD<sup>7</sup>; H. Naous, MD<sup>8</sup>; F. Zucco, MD<sup>9</sup>; J. K. Krauss, MD, PhD<sup>10</sup>; U. Friess, MD<sup>11</sup>; J. De Andrés, MD, PhD<sup>12</sup>; E. Buchser, MD<sup>13</sup>; A. Costantini, MD<sup>14</sup>; Y. Lazorthes, MD, PhD<sup>2</sup>

1. Multidisciplinary Pain Center, AZ Nikolaas Hospital, Sint-Niklaas, Belgium; 2. CHU Rangueil, Toulouse, France; 3. Academisch Ziekenhuis Maastricht, Maastricht, The Netherlands; 4. Universitätsklinik Schleswig-Holstein Campus Lübeck, Lübeck, Germany; 5. Universitätsklinikum Heidelberg, Heidelberg, Germany; 6. St. Elisabeth Ziekenhuis, Tilburg, The Netherlands; 7. Hospital Universitario La Fé, Valencia, Spain; 8. Hôpital Neurologique et Neurochirurgical Pierre Wertheimer, Lyon, France; 9. AZ Ospedale Garbagnate, Garbagnate, Italy; 10. Medizinische Hochschule Hannover, Hannover, Germany; 11. Klinikum Mannheim, Mannheim, Germany; 12. Hospital General de Valencia, Valencia, Spain; 13. Hôpital de Morges, Morges, Switzerland; 14. Ospedale Clinicizzato SS. Annunziata, Chieti, Italy

## INTRODUCTION

A multicenter, prospective, open-label trial was conducted in 12 European centers using the Medtronic Restore® Neurostimulation System with the following characteristics:

- Rechargeable, implantable neurostimulation system
- Up to 9-year neurostimulator battery longevity
- Allows high energy output and sophisticated therapy, i.e., multiple programs and groups of programs
- Temperature of the recharge antenna is controlled for a safe recharging session



## METHODS

### Study Objectives

#### Primary Objective

- To evaluate the ability of patients to successfully recharge the Restore system using patient labeling and training

*Performance Requirement: The exact binomial 95% Lower Confidence Bound (LCB) on the proportion of patients that are able to achieve successful recharging must be greater than 75% with 80% power.*

#### Secondary Objective

- To characterize satisfaction with the neurostimulation system
- To characterize pain relief and quality of life

### Patient Selection

The Restore Study required that patients meet at least one of the following indication criteria for SCS implantation:

- Failed back surgery syndrome (FBSS)
- Chronic back and leg pain
- Complex regional pain syndrome (CRPS)

Excluded patients with a prior implanted neurostimulation system.

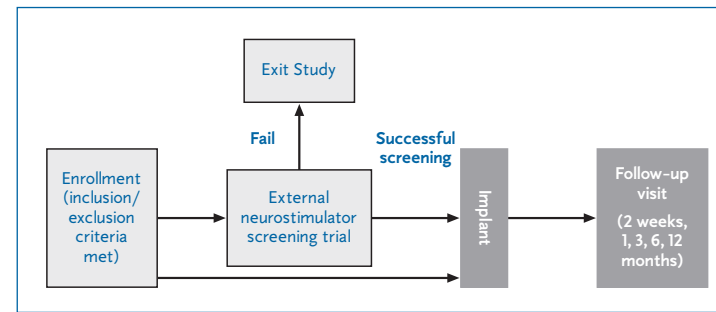


Figure 1. Study design flow chart.

### Follow-up Visits

- Two-week follow-up visit after wound healing to receive the recharger and recharging instructions
- One-month follow-up visit to assess patients' recharge ability
- Visits at three, six, and 12 months post-implant to assess outcomes
  - Pain Visual Analog Scale (VAS), Percent pain relief
  - Oswestry Disability Index (ODI), EQ-5D
  - Patient satisfaction with neurostimulation at three and 12 months

## RESULTS

### Demographics

- 45 patients enrolled; 42 patients implanted
- 41 patients followed for 12 months
- Age 51 ± 11 years (range 31 to 69)
- Gender: 67% female, 33% male
- Pain duration: 7.2 ± 6.9 years (range 0.7 to 30)

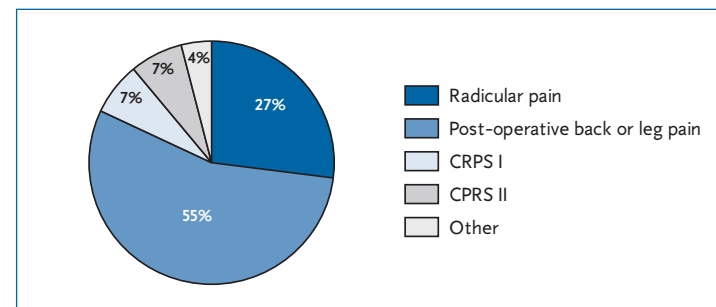


Figure 2. Etiology of pain at baseline.

### Primary Objectives

After one month, all patients (95% LCB = 93%) who met analysis inclusion criteria were able to recharge the system.

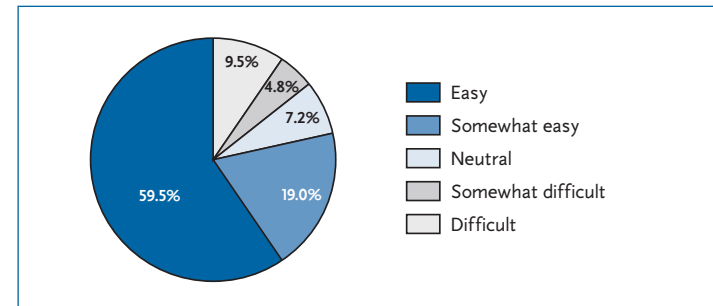


Figure 3. Patient rating of recharging at one-month follow-up.

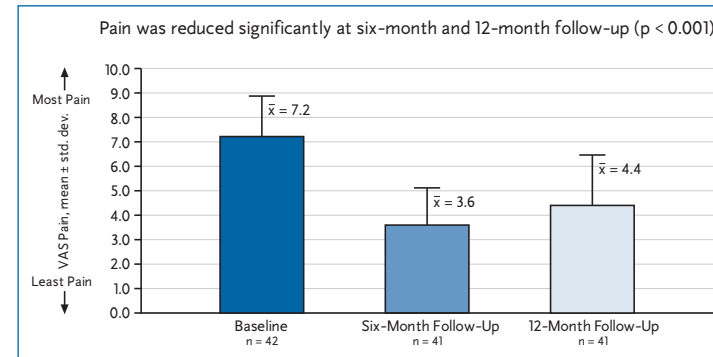


Figure 4. Pain assessment—VAS.

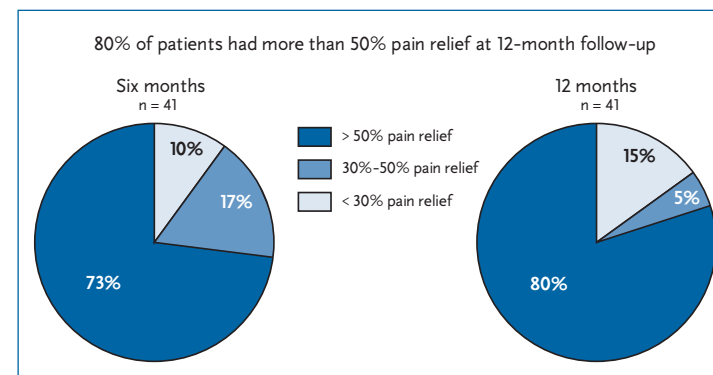


Figure 5. Percent pain relief—patient self-reported.

Quality of life increased significantly at six-month ( $p < 0.001$ ) and 12-month ( $p = 0.05$ ) follow-up

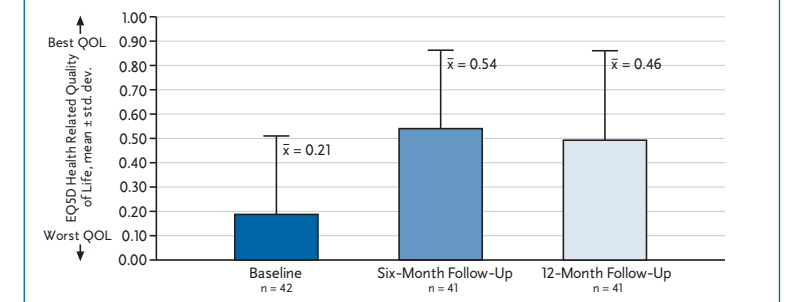


Figure 6. Quality of life—EQ-5D.

Functional disability decreased significantly at six-month and 12-month follow-up ( $p < 0.001$ )

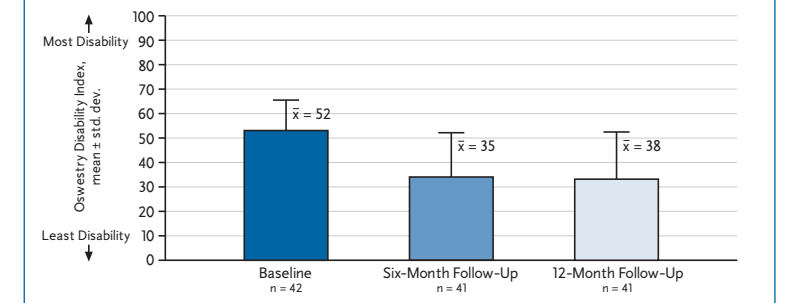


Figure 7. Functional disability—ODI.

## ADVERSE EVENTS

A total of 74 adverse events were experienced in 31 of the 45 enrolled patients. Of these, 41 events in 23 patients were device-related, with 11 rated as serious, requiring revision. The device-related events occurred during screening and during or after implant. They were mostly related to the lead (eight events), lead/extension tract (seven events), and neurostimulator pocket (eight events). No events were unanticipated, and no deaths occurred.

## CONCLUSIONS

The Restore study demonstrated that in patients with severe chronic pain:

- All of them successfully recharged the Restore neurostimulator battery
- The majority of patients (79%) rated the usability of the recharging system "easy" or "somewhat easy"
- Pain reduced significantly at 12-month follow-up
- Quality of life and functional status significantly improved at 12 months

#### NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

**Brief Summary:** Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure.

**Indication for Use** – Chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **Contraindications:** Diathermy. **Warnings:** Defibrillation, diathermy, electrocautery, MRI, RF ablation, & therapeutic ultrasound can result in unexpected changes in stimulation, serious patient injury or death. Rupture/piercing of neurostimulator can result in severe burns. Electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. **Precautions:** The safety and effectiveness of this therapy has not been established for: pediatric use, pregnancy, unborn fetus, or delivery. Follow programming guidelines & precautions in product manuals. Avoid activities that stress the implanted neurostimulation system. EMI, postural changes, & other activities may cause shocking/jolting. **Adverse Events:** Undesirable change in stimulation; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, & surgical risks. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at [www.medtronic.com](http://www.medtronic.com). **Rx Only.** November, 2007.