

ASX Announcement

28 March 2025

Outstanding Clinical Outcome Demonstrates Material Benefits for Patients Using NervAlign® Nerve Cuff

Highlights:

- Recently presented study demonstrates statistically significant benefits for patient outcomes when using the NervAlign® Nerve Cuff in peripheral nerve repair surgery.
- Patients undergoing peripheral nerve surgery that utilised the NervAlign® Nerve Cuff experienced a major decrease in post-surgery pain measures compared to patients whose surgery did not utilise the Nerve Cuff.
 - Mean post-operative pain scores decreased from 7.1 to 0.4 with the Nerve Cuff, compared to a reduction in scores from 7.1 to 3.3 without the Nerve Cuff.
 - Patients treated with the Nerve Cuff also reported higher satisfaction with their surgery compared to those that did not receive the Nerve Cuff (93% of patients with the Nerve Cuff said they would elect to have surgery again vs. 70% of patients without the Nerve Cuff).
- NervAlign® Nerve Cuff demonstrates clear benefits to patients' post nerve repair, leading to better patient outcomes.

ReNerve Limited (ASX:RNV) ("ReNerve" or "the Company"), a medical device company developing novel peripheral nerve repair products, is pleased to announce the highly positive results from a recent nerve repair comparative study. The results of the study show that patients benefit from the use of the NervAlign® Nerve Cuff compared to those who do not have the Nerve Cuff incorporated in their treatment, reporting significantly lower post-surgery measures of pain. Furthermore, as an indication of patient satisfaction post-surgery, patients who were treated with the Nerve Cuff were more likely to indicate they would have their procedure again than those that were not treated with the Nerve Cuff.

The study data has been presented this week at the American College of Foot and Ankle Surgeons (ACFAS 2025) Annual Conference in Arizona, in a presentation titled: Efficacy of a Porcine Pericardium Nerve Wrap in Peripheral Nerve Surgery. Namany et al. ACFAS 2025 (refer Abstract Ref ID Sci-743 on page 372 - Link: <https://www.acfas.org/admin/ACFAS/media/PDF/Abstract-Report-1.pdf>)

Commenting on the study's results and the improved patient outcomes resulting from use of the Nerve Cuff, ReNerve CEO, Dr Julian Chick, stated: *"These are very significant results for the development of ReNerve's products, as they highlight the utility of the NervAlign® Nerve Cuff in reducing patients' pain following peripheral nerve surgery. The results clearly demonstrate the patient benefits that follow from the proper repair and regeneration of a nerve that is returned to normal function post-surgery. The NervAlign® Nerve Cuff facilitates the patient's repair process is protected during the initial post-operative recovery and regeneration period. Thereafter, because the Nerve Cuff is absorbed naturally after six months, there is no longer a lasting 'foreign body' at the site of repair to create potential complications for the patient."*



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The NervAlign® Nerve Cuff

ReNerve's NervAlign® Nerve Cuff is designed for the protection of repaired and regenerating nerves during the healing process after peripheral nerve injuries or repair surgery. The product is unique as it protects the nerve while healing, but is also naturally absorbed within six months, leaving only regenerated and repaired tissue in the body. The medical properties of the NervAlign® Nerve Cuff mean that it is well suited for use in a wide range of surgical procedures.

Study Design: Efficacy of a Porcine Pericardium Nerve Wrap in Peripheral Nerve Surgery¹

The study examined the use of the NervAlign® Nerve Cuff in peripheral nerve repair surgeries and used two end points – the first being an independent pain score assessment using the Visual Analogue Scale (VAS) methodology, measured pre- and post-surgery; and the second being whether the patient would elect to have the procedure again following the surgery and their recovery period.

- **Study Size:** 13 with Nerve Cuff; 10 without Nerve Cuff
- **Gender:** 21 Female, 2 Male
- **Average Patient Age:** 53 years old
- **Follow-up:** 2 - 36 months; Average follow-up = 9.25 months.
- **Inclusion criteria:** foot or ankle pain that could be improved with peripheral nerve surgery (PNS).
- **Exclusion criteria:** patients with previous history of PNS in the same extremity.

Results²

The study¹ presented by Dr Adams demonstrates the significant benefits of using the NervAlign® Nerve Cuff in peripheral nerve repair surgery. Patients who underwent surgery with the NervAlign® Nerve Cuff experienced a significant ($p=0.021$) decrease in post-surgery pain compared to those who did not use the Nerve Cuff. These data show that there is a clear benefit to patients when their neurectomies (repaired nerves) are protected for the healing process using the NervAlign® Nerve Cuff. The use of post-operative pain scores as a clinical marker was useful in this study as every case was for a foot and ankle surgery. These regions take considerable movement and overall patient body weight compared to upper limbs and therefore nerve pain is correlated to the condition of the nerve and related nerve damage and recovery.

1, 2 "Efficacy of a Porcine Pericardium Nerve Wrap in Peripheral Nerve Surgery" March 2025 Namany et al. ACFAS 2025
(<https://imis.acfas.org/ACFAS2025/ACFAS2025/Abstracts.aspx?hkey=5209f2e8-69fc-4935-8823-799c8f5c2922>) Abstract Ref ID Sci-743

Clinical data

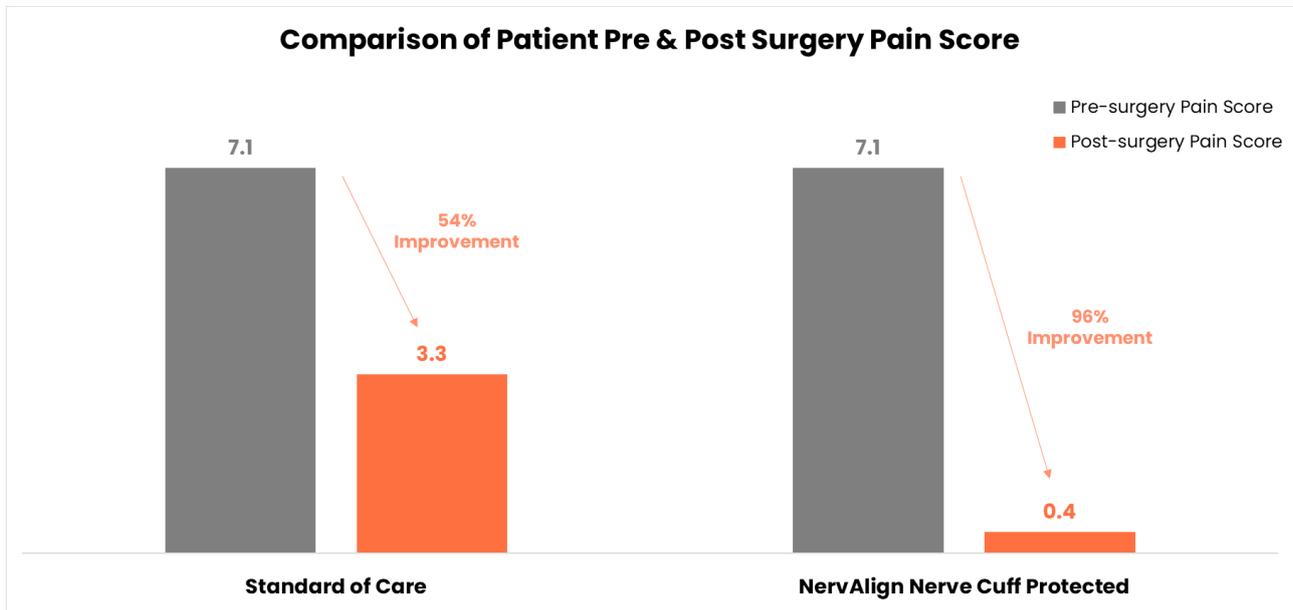


Figure 1. The comparison of pain scores between the two cohorts of patients

Independent Patient Pain Scores

	Standard of Care	Standard deviation	Protected with the NervAlign [®] Nerve Cuff	Standard deviation
Pre-surgery Pain Score	7.1	2.3	7.1	1.8
Post-surgery Pain Score	3.3	3.3	0.4	0.7

The pain score rating used in the study followed a standard pain score rating* such as:

- 0 = No pain.
- 1 = Pain is very mild, barely noticeable. Most of the time you don't think about it.
- 2 = Minor pain. It's annoying. You may have sharp pain now and then.
- 3 = Noticeable pain. It may distract you, but you can get used to it.
- 4 = Moderate pain. If you are involved in an activity, you're able to ignore the pain for a while. But it is still distracting.
- 5 = Moderately strong pain. You can't ignore it for more than a few minutes. But with effort you can still work or do some social activities.

- 6 = Moderately stronger pain. You avoid some of your normal daily activities. You have trouble concentrating.
- 7 = Strong pain. It keeps you from doing normal activities.
- 8 = Very strong pain. It's hard to do anything at all.
- 9 = Pain that is very hard to bear. You can't carry on a conversation.
- 10 = Worst pain possible.

* Taken from the Kaiser Permanente pain score - <https://healthy.kaiserpermanente.org/health-wellness/health-encyclopedia/he.learning-about-the-0-to-10-pain-scale.abs0043>

Percentage of patients that would elect to have their surgery again

	Would you elect to have surgery again	
	Yes	No
Standard of Care	70%	30%
Protected with NervAlign® Nerve Cuff	93%	7%

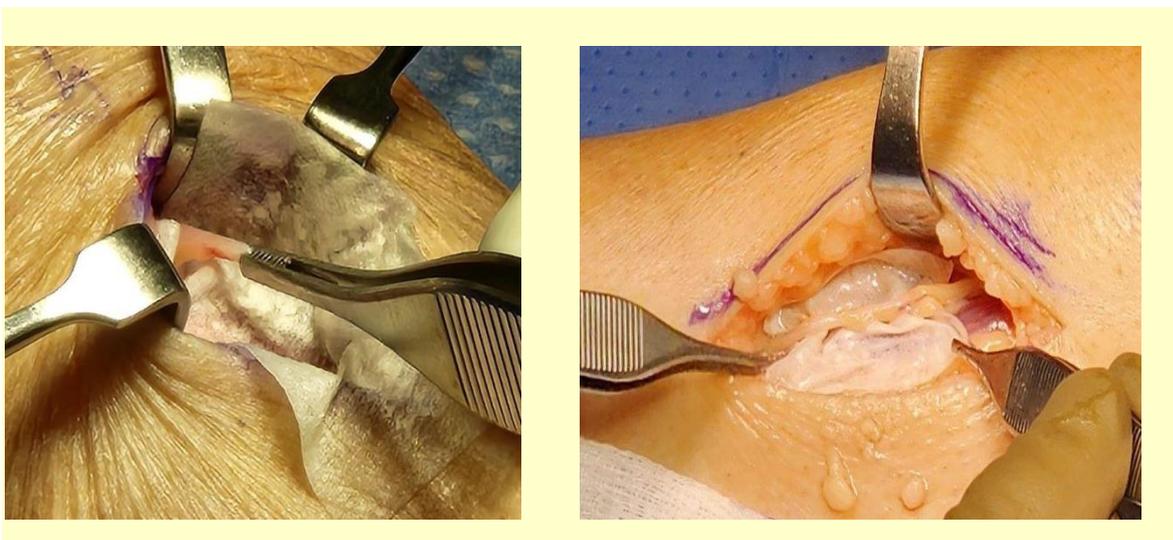


Figure 2. Patient Implants of the NervAlign® Nerve Cuff from the Study.

Conclusion

The results of this study illustrate the benefits to patient outcomes from the use of the NervAlign® Nerve Cuff as a protection for a recently repaired nerve after surgery.

This announcement has been approved for release by the Company's Board of Directors.

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About ReNerve Limited

ReNerve Limited (ASX:RNV) is a medical device company specialising in advanced nerve repair and regeneration solutions. The Company is focused on commercialising cutting-edge medical devices and tissue-engineering products that seek to address significant unmet needs for patients with peripheral nerve damage – a critical gap in healthcare. ReNerve aims to improve patient outcomes through scientifically backed products that have been developed to enhance the human body's natural healing process, while commercialising cutting-edge, scalable products for the healthcare market. ReNerve wishes to acknowledge AusIndustry's Accelerating Commercialisation program for its support through many of the activities required to commercialise the NervAlign® Nerve Cuff™.