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Axogen Announces Independent Publication of Comparative Nerve Gap Repair Meta-Analysis of 35 peer-reviewed studies of Allograft, Autograft, and Conduits

Study concluded allograft and autograft repairs delivered significantly better rates of meaningful sensory recovery in short gaps as compared to conduit repairs in a systematic meta-analysis including over 1,500 nerve repairs across 35 studies

ALACHUA, Fla. and TAMPA, Fla., Jan. 05, 2023 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced the independent publication of a comprehensive, retrospective clinical review comparing the meaningful recovery rates between allograft, autograft, and conduits using a meta-analysis methodology. The comparative peer-reviewed analysis was published online ahead of print by *Plastic and Reconstructive Surgery*. The publication, "*A systematic review and meta-analysis of nerve gap repair: Comparative effectiveness of allografts, autografts, and conduits,*" analyzed 35 peer-reviewed studies with a total of 1,559 nerve repairs including 711 nerve allograft, 670 autograft, and 178 conduit repairs.

- The analysis concluded that meaningful recovery rates for allograft and autograft repairs were comparable across all gap lengths up to 70 millimeters.
- There were no statistical differences between allograft and autograft outcomes for either short (5-30 mm) or long (31-70 mm) gap lengths for both sensory and motor repairs.
- Allograft and autograft repairs delivered significantly better rates of meaningful sensory recovery in short gaps as compared to conduit repairs; 87.1% and 81.6% vs. 62.2%, respectively, $p<0.05$.
- The cost analysis found that allograft does not represent an increased economic burden compared to autograft.

"The analysis found that meaningful recovery rates for allograft and autograft repairs showed no significant differences regardless of the gap length or nerve type; sensory, motor, or mixed, and both groups were significantly better than conduit repairs," said senior author Joseph Styron, M.D., Ph.D., Orthopedic Surgeon at the Cleveland Clinic.

Study authors also noted that, although autograft has been the historical standard of care for repairing peripheral nerve injuries, it is important to consider autograft donor site complications that may impact patient quality of life. These complications can include infection at the donor site or pain associated with neuroma formation.

“This paper provides the strongest clinical evidence to-date of the performance of Avance® Nerve Graft, the nerve allograft included in this study, across all gap lengths and nerve types. This comprehensive analysis of peer-reviewed studies illustrates that compared to autograft, Avance is just as effective, with similar procedure costs, while eliminating the potential for complications or reduced quality of life resulting from autograft nerve harvesting,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “With more than 50,000 implants since launch, Avance is a proven solution for providing patients the opportunity to achieve meaningful functional recovery without the need for autograft harvest.”

About the Study
The primary aim for the study was to compare the meaningful recovery rates of autograft, allograft, and conduit nerve repair alternatives. The clinical studies analyzed were found by screening publications from the last 40 years in the National Library of Medicine’s MEDLINE database while following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Two independent reviewers evaluated each study against inclusion criteria requiring nerve injury type, repair type, gap length, and outcomes reported using standard two-point discrimination, Semmes-Weinstein monofilament testing, and/or Medical Research Council Classification (MRCC) such that meaningful recovery rates (≥MRCC S3/M3) could be determined. For techniques with non-significant differences, an additional analysis was performed to assess procedural costs. This analysis was conducted using national Medicare hospital claims data for 2018. Axogen Inc. provided funding for the study. The paper can be accessed on the Plastic and Reconstructive Surgery website.

About Avance Nerve Graft
Avance Nerve Graft is a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site. Avance provides structural guidance for regenerating axons, and revascularizes and remodels into the patient’s own tissue. It is available in a variety of lengths and diameters.

About Axogen
Axogen (AXGN) is the leading company focused specifically on the science, development, and commercialization of technologies for peripheral nerve regeneration and repair. Axogen employees are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven, and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products,

including Avance Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard Nerve Connector®, a porcine submucosa extracellular matrix (ECM) coaptation aid for tensionless repair of severed peripheral nerves; Axoguard Nerve Protector®, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; and Axoguard Nerve Cap®, a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma. The Axogen portfolio of products is available in the United States, Canada, Germany, the United Kingdom, Spain, South Korea, and several other countries.

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