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YOU'VE GOT THE NERVE—THE AXOGEN AVANCE[™] NERVE GRAFT

*“To be, or not to be, that is the question:
Whether 'tis nobler in the mind to suffer
The slings and arrows of outrageous fortune,
Or to take arms against a sea of troubles
And by opposing end them.”*

Hamlet

William Shakespeare

When injury has taken the patient's nerve shall fate dictate “the slings and arrows of outrageous fortune?” Or, will you “take arms against a sea of troubles” and search for potentially a better nerve repair option for your patients? AxoGen offers peripheral nerve technologies to help you fight this worthy fight.

AxoGen, Inc. is pleased to offer you a groundbreaking technology: **Avance[™] Nerve Graft**—human allograft used for the repair and regeneration of peripheral nerves. With the recent introduction of this technology, AxoGen takes peripheral nerve repair options to new levels.

An autograft, as opposed to an allograft, employs tissue from the patient. Historically, autograft nerve has been the preferred option for nerve grafting. The autograft option uses a patient's own healthy nerve to repair a damaged nerve. However, the patient's existing nerves already have duties. To “reallocate” one nerve for a different task means the original function of the donor nerve will be lost. In some cases the sacrifice of a donor nerve may be warranted, particularly if the nerve needed is small and the function lost will be of perceived minor importance (such as a small area of sensory loss in a non-critical dermal area). Commonly-used autograft donor nerves include the sural nerve in the leg and the greater auricular nerve in the face. Yet, a patient may not wish to give up one function in order to gain another, or the patient

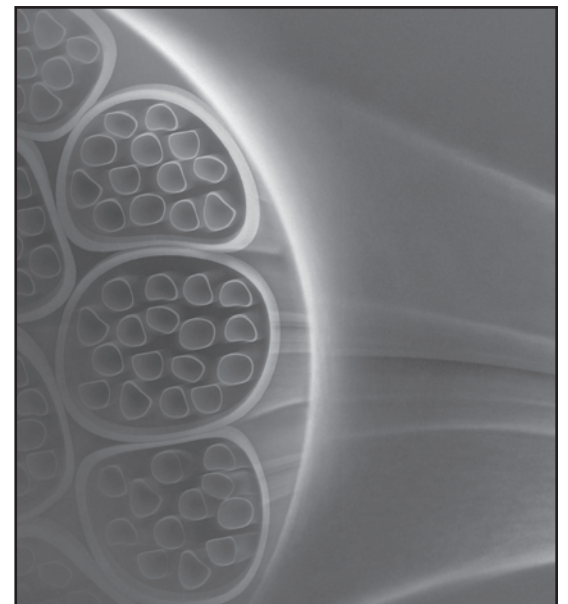


Figure 1. Artist's rendering of nerve architecture.

may not want to sustain an additional surgical injury site. And, suitable or sufficient autograft nerve may not be available. Therefore, where medical or social circumstances do not favor an autograft nerve, then an allograft nerve becomes a better option.

Nerve anatomy basically consists of axons within tubes within tubes. In the case of myelinated axons, each nerve fiber is surrounded by endoneurium. Groups of neurons are then, in turn, surrounded by a perineurium. This collection is a fascicle. Fascicles are collected into still larger groups defined by an epineurium.

This fundamental architecture is elegantly illustrated in Figure 1. And, this fundamental architecture is key to regrowth opportunities. In severe nerve injury (Sunderland IV and V classification¹) the “tubes” are disrupted. Without them, proximal sprouting axons cannot be guided to find the distal nerve fragment. A neuroma of collected terminal sprouts is a recognized complication.

Avance Nerve Grafts place the fundamental nerve architecture again within reach of the proximal sprouting axons.

Avance Nerve Grafts are minimally processed to preserve the three dimensional structure of the nerve basal lamina and the inherent growth promoters that lie within. The Avance Nerve Graft process decellularizes allograft human nerve to clear cells, cellular debris, and axons—leaving a sterile scaffold of nerve basal lamina which may serve to guide a patient’s regenerating axons.

The Avance Nerve Graft process goes further by clearing growth inhibitors. Functioning in its normal state, a nerve has inherent mechanisms to control its own cellular growth. Chondroitin sulfate proteoglycan appears to be among these. Dr. David Muir and colleagues (at University of Florida College of Medicine) found that pretreatment of nerve grafts with chondroitinase ABC “markedly enhanced nerve regeneration after grafting.” According to Muir, “In rodent models nerve regeneration fails in acellular nerve grafts greater than 2 cm in length.” In Muir’s 2007 study, reported in *Experimental Neurology*, eight of nine grafts 4 cm in length, which were pretreated with chondroitinase ABC, succeeded in demonstrating sciatic nerve regeneration by direct nerve pinch testing.² The Avance Nerve Graft process incorporates this innovative discovery and clears chon-

droitin sulfate proteoglycan.

Thus, Avance Nerve Grafts: 1) retain the architecture of nerve; 2) are predegenerated (cleared of cellular debris); 3) are cleared of inhibitors, and 4) retain growth promoters. Truly,

Avance Nerve Grafts provide a fertile field for nerve regrowth. Avance Nerve Grafts offer many features that are important considerations for nerve repair.

Where does all of this take us clinically? Steven L. Moran, M.D. (Associate Professor of Plastic and Orthopedic Surgery, Mayo Clinic Rochester) says he was an “early adopter” of Avance Nerve Grafts because “Preliminary research said sensory and motor recovery was equivalent or better than autograft in rat data.” Now, having used Avance Nerve Grafts clinically, he is very pleased. Dr. Moran says, “We may find it is as good as autograft. We have had very good results. We have had no episodes of infection or rejection. We do not need to use any form of immunosuppression.”

Because the Avance Nerve Graft process clears the cellular debris, immunosuppression is not required. This is always an advantage—particularly where other aspects of the patient’s illness might make immunosuppression specifically risky.

James G. Green, M.D., D.D.S. (Director of Residency, University of Florida, Gainesville) has also observed very good early results with Avance Nerve Grafts. He reports,

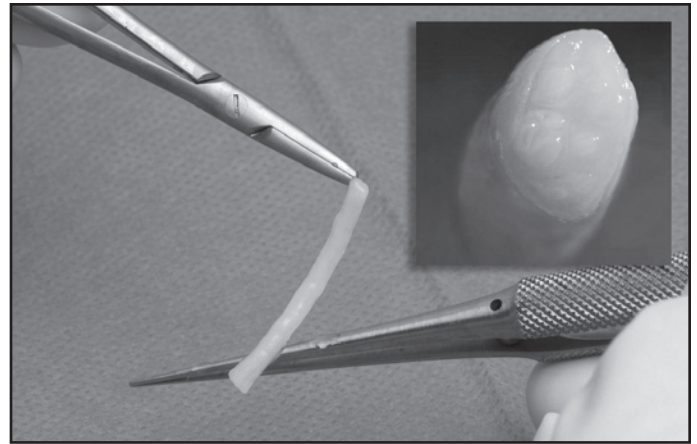


Figure 2. An Axogen Avance Nerve Graft.

“We’re now encouraging use of allograft because we don’t have to sacrifice other nerve.” At his institution, early benefits of Avance Nerve Grafts have been so promising that they keep a supply of grafts on hand for use by various departments.

Avance Nerve Grafts come in several sizes and lengths.³ This allows appropriate selection of tissue for the situation, minimizing tissue waste. The grafts are pliable, and handling is similar to autograft nerve. And finally, by avoiding a second surgery, Avance Nerve Graft can be cost-effective. ♦

To Learn More

Avance Nerve Graft³ can help your patient have more options for nerve repair. For more information, please call **AxoGen, Inc.** at 1-888-296-4361 (1-888-AXOGEN1); send email to customerservice@axogeninc.com; or visit the company’s Web site at www.axogeninc.com.

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1. Novak C. Peripheral Nerve Injuries. Emedicine. Available online at: www.emedicine.com/orthoped/topic537.htm. Accessed: 9/9/08
2. Neubauer D, Graham JB, Muir D. Chondroitinase treatment increases the effective length of acellular nerve grafts. *Experimental Neurology*. 2007 Jun; 207:163-170
3. See Avance™ Nerve Graft Instructions for Use for further information.