# Clinical Experience with **AxoGuard® Nerve Connector** as a Coaptation Aid for Cable Grafting

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## Introduction

Cable grafting with autograft and/or allograft provides an option for the repair of large diameter nerves by providing scaffolding and support upon which axons can regenerate toward the target organ. However, the procedure can be technically challenging and time-consuming due to limited access to the patient's nerve and the amount of micro-suturing required. Use of a coaptation aid, such as the technique described here, can provide a method for rapid entubulation of cabled nerve grafts to create a construct that is more tightly packed and easier to implant compared to standard grafting techniques.

In the case described here, the patient had experienced a devastating soft tissue injury to the left brachium from a domestic farm animal attack. Initial treatment consisted of emergent brachial artery reconstruction, irrigation and debridement, and "tagging" of transected median and ulnar nerve defects. The nerve gap was reconstructed after delaying several weeks to allow demarcation of damaged nerve tissue and stabilization of the soft tissue envelope.

Note that the following is only an example of a surgical technique for using the AxoGuard® Nerve Connector. The methods described here should be adapted by the surgeon to fit the specific case being treated.

## Surgical Method

### Nerve exposure and assessment

1. A direct medial brachial approach was utilized incorporating previous traumatic and surgical scars. Tagged nerve endings were identified and trimmed to expose healthy viable fascicles. The resulting nerve gap was assessed with the arm extended, and it was determined that a 6 cm nerve graft would be required to reconstruct the deficit.

### Preparation of the Cable Graft

2. The sural nerve was harvested from the lower limb and cut into five stands measuring 7cm in length. The strands were assembled ex vivo as a cable graft approximating the cross-sectional area of the median nerve being reconstructed.

3. A small piece of esmarch was wrapped around a cable graft end while glue was slowly dripped on and around the stacked nerve strands. The esmarch was wrapped around the nerve/glue as a mold while the glue set (approximately 3 minutes). This same technique was used on the opposite end of the cable graft resulting in a stable construct. The excess glue and ends of the nerve grafts were sharply cut to expose a clean and even surface. See Figure 1.

### AxoGuard® Nerve Connector as a Coaptation Aid

4. Each AxoGuard® Nerve Connector is 10mm in length though diameter size is based on the largest diameter of the involved elements (either the patient's nerve to be repaired, or the cable graft). The size selected should be of sufficient diameter to account for normal edema following traumatic nerve injury and to allow easy insertion of nerve stumps into the lumen. Two 6mm (inner diameter) by 10mm (length) AxoGuard® Nerve Connectors were used in this case.

5. The AxoGuard® Nerve Connector was prepared by first peeling open the Tyvek® pouch and passing the tray into the sterile field. The product was hydrated in the pre-molded hydration reservoir of the packaging tray. Product hydration occurred just prior to implantation for approximately 10 seconds in sterile saline, as this was the hydration time that best suited the surgeon's handling preference.

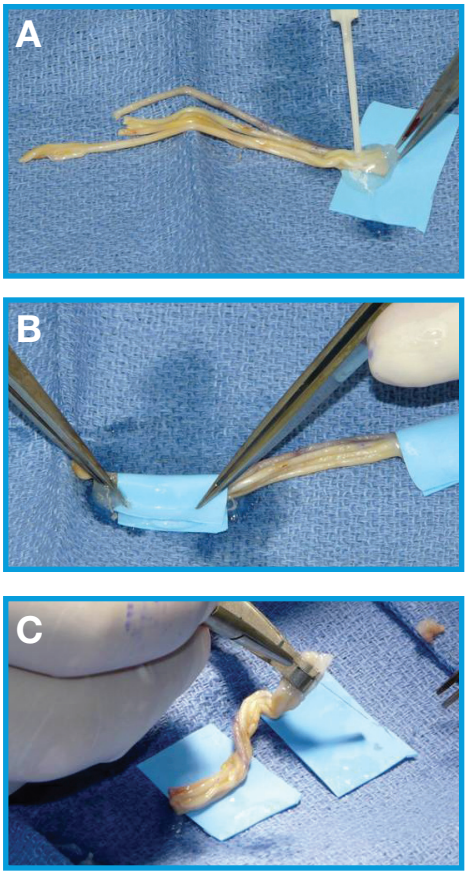


**Figure 1: Cable graft preparation.** Sural nerve autograft was laid side-by-side, and glue was used as a mild adherent to create a cable graft (A). A small piece of esmarch was used to maintain close proximity of the grafts while the glue dried (B). The resulting cable graft is shown in C.

6. Each cable graft end was inserted 5mm into an AxoGuard® Nerve Connector, as shown in Figure 2. Four or five simple stitches (utilizing 8-0 nylon cutting-edge needle suture) were placed through the wall of the connector and the epineurium of the nerve graft to maintain position. Note that it is important to suture through the epineurium and not only the surrounding glue. Asymmetric horizontal mattress sutures were applied to compensate for any size mismatch.

7. The cable graft construct was delivered to the operative field and interposed between the proximal and distal median nerve. Each stump was inserted 5mm into the corresponding connector and secured into place again using four or five simple sutures placed through the AxoGuard® Nerve Connector wall and the epineurium. The native nerve and the cable graft were approximated so that aligned fascicles were touching end-to-end. Glue was applied around both repair sites to reinforce and seal the repairs. See Figure 3.

8. Upon completion of the procedure, hemostasis was achieved and the incision was closed. Immobilization was maintained in 90 degrees flexion for three weeks.

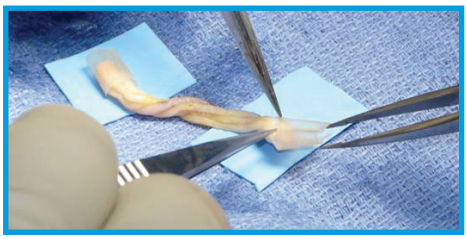

**Figure 2: AxoGuard® Nerve Connectors as coaptation aids.** Cable graft ends are entubulated to allow for easy implantation.

## Feedback on Intra-Operative Handling and Conclusions

The AxoGuard® Nerve Connector is an off-the-shelf option for closely approximating severed nerve stumps and bridging gaps up to 5mm. The device has excellent handling properties and is technically feasible for use as a coaptation aid in cable grafting. Noteworthy intra-operative handling properties include:

- Semi-translucence - allows visualization of the nerve during implantation
- Conformability - allows for custom fit onto nerve stumps, in particular when there is a size mismatch between the patient's nerve and the nerve graft
- Strong and flexible, plus easy to suture

In addition, AxoGuard® Nerve Connector incorporates the best attributes of a biologic material:

- Revascularizes – Encourages capillary ingrowth to bring vascularity to the repair site
- Remodels – Gradually incorporated with the patient's own cells to form a tissue similar to the nerve's epineurium
- Resists infection – Unlike type-1 collagen or synthetic materials, AxoGuard® is able to be used in a contaminated field

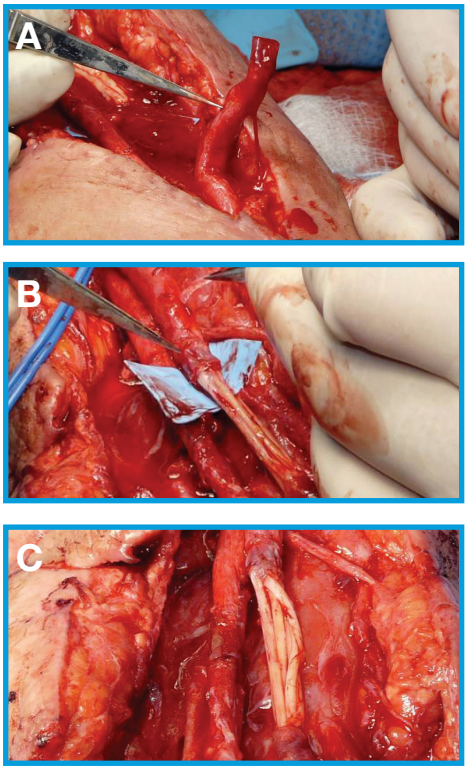


**Figure 3: Reconstruction of patient's nerve with cable graft construct.** The AxoGuard® Nerve Connector was used as a coaptation aid for close approximation of cable grafts and the injured nerve stump. The cable graft construct was inter-positioned within the nerve gap (A) and then secured in place with suture (B). Completed repair is shown in C.

For additional information on

AXOGUARD® Nerve Connector

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