

A Case-and-Control, Multisite, Positive Controlled, Prospective Study of the Safety and Effectiveness of Immediate Inferior Alveolar Nerve Processed Nerve Allograft Reconstruction With Ablation of the Mandible for Benign Pathology

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Purpose: This study determined whether immediate reconstruction of the inferior alveolar nerve with a long (>4.5 cm) processed nerve allograft (PNA) in conjunction with simultaneous ablation and reconstruction of the mandible would be effective in safely restoring subjective sensation and achieving functional sensory recovery.

Materials and Methods: Patients (5 to 70 yr old) requiring resection of the unilateral or bilateral mandible for benign pathology were included. The graft had to be longer than 4.5 cm. Results of sensory nerve tests and 3 different surveys (Direct Path, Numerical Rating Scale, Word Choice) were collected before surgery and at 3, 6, and 12 months after surgery. Safety data were recorded.

Results: Twenty-six patients participated in this study. Three patients served as positive controls (no nerve repair). Five in the repair group and 1 in the positive control group were lost to follow-up. Data during a 1-year period were collected on 18 patients (7 male and 11 female; mean age, 26.4 yr; range, 10 to 64 yr). The mean length of the PNA was 62.7 mm (range, 45 to 70 mm). Seventeen of 18 patients had S4 sensory scores preoperatively and the postoperative score was S4 at 3 months in 3, at 6 months in 3, and at 1 year in 12. Scores for positive control patients never exceeded S2. Numerical rating scales and word choices were not statistically different from presurgical scores at 6 and 12 months. There were no adverse events.

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Conclusions: The PNA is safe and effective when immediately inserted with resection and reconstruction of the mandible: 90% of patients achieved functional sensory recovery and reported similar sensations to preoperative subjective values.

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Ablation of the mandible for benign pathology requires the resection of bone, teeth, soft tissue when indicated, and the intraosseous component of the inferior alveolar nerve (IAN). IAN function is strictly sensory and provides unilateral innervations to the teeth, oral mucosa, vermilion of the lip, and skin of the chin. Loss of IAN function results in disturbance of normal functions such as speech, retention of saliva, self-induced injury from biting of the mucosa or lip, altered eating and chewing function, and diminished pleasures (kissing, etc).

Resection of the mandible for benign pathology results in intentional discontinuity injury to the IAN. Oral and maxillofacial and head and neck surgeons have developed excellent techniques to reconstruct the bony mandible, its associated soft tissues, and, in some instances, the replacement of teeth. However, restoration of IAN function has largely been ignored. There are few publications that have reported on the use of nerve-sparing methods¹⁻⁵ or immediate reconstruction with large autogenous (ie, sural nerve) grafts.⁶⁻⁸ Chow and Teh⁹ reported that some sensory recovery was discernible after ablation of the mandible for benign pathology even without IAN reconstruction, indicating the possibility of neural plasticity or habituation. However, their report on 10 patients showed that all had some degree of sensory loss and only 2 patients had 2-point discrimination, 4 had directional sensitivity, and 5 had pain responses, indicating that recovery was only functional in 2 of 10 patients.

In 2016, Salomon et al¹⁰ reported on a retrospective cohort study of 7 patients who underwent immediate reconstruction of IAN gaps of at least 50 mm using a processed nerve allograft (PNA) with resection of 6 benign tumors and 1 malignant tumor of the mandible. One patient did not have functional sensory recovery (grade S3 to S4 on the Medical Research Council Scale [MRCSS]), 5 had grade S3, and 1 had grade S4 at a mean follow-up time of 17.7 months (range, 10 to 27.5 months). No complications related to the nerve repair were reported. This proof-of-principle study showed that immediate repair of long nerve gaps with resection of the mandible for pathology can result in functional sensory recovery of the IAN.

The use of PNAs for nerve reconstruction was made available by AxoGen Inc (Alachua, FL) in 2008. Approved PNAs consist of decellularized nerve

allografts processed with mild detergent and treated with chondroitinase (AVANCE; AxoGen Inc). AVANCE grafts are provided in different diameters and lengths to match reconstructive needs. The 7-cm long × 3- to 4-mm graft is a perfect fit for unilateral IAN replacement associated with mandibular ablative surgery. Preliminary studies have reported excellent sensory regeneration to the level of functional sensory recovery of trigeminal nerve injuries independent of age, type of injury, or graft size variation.¹¹ Of patients who underwent PNA reconstruction of the IAN and were followed for 1 year, those who underwent immediate reconstruction of large (≥50-mm) nerve gaps actually had better functional sensory recovery grades compared with those with delayed (>3 months from injury) nerve repair. This finding was expected because the literature is replete with evidence that early repair results in superior recovery of sensory, motor, and mixed nerve function in non-trigeminal nerves¹² and trigeminal nerves.^{13,14} Recently, Bichanich et al¹⁵ reported that using acellular nerve allografts (ANAs), similar but not identical to PNAs, in rats did not support regeneration of nerve in grafts at least 50 mm in length. Sciatic nerves labeled with thymine-1 and green fluorescent protein showed robust axonal regeneration in the proximal portions of the ANA graft, with gradual tapering of regenerating fibers distally, and axons failed to grow beyond the graft of this length at 5 weeks. At 20 weeks, regeneration had dwindled and terminated within the 5-cm ANA grafts without neuroma formation.

The hypothesis that drove this study was 2-fold. First, use of the PNA to immediately reconstruct the IAN in conjunction with the simultaneous ablation and bone reconstruction of the mandible would be effective in restoring sensation of the lip and chin to functional sensory recovery and would be safe. Second, PNAs 4.5 to 7.0 cm in length would be capable of supporting functional sensory recovery in a purely sensory nerve, the IAN, when repaired immediately.

Materials and Methods

STUDY DESIGN AND SAMPLE

This was a case-and-control, prospective, multisite study of immediate reconstruction of the IAN with ablation of the mandible for benign pathology with immediate reconstruction of the bony mandible, its soft

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