SCIENTIFIC ARTICLE

Use of Bioabsorbable Nerve Conduits as an Adjunct to Brachial Plexus Neurorrhaphy

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Purpose The use of bioabsorbable conduits in digital nerve repair has demonstrated increased efficacy compared to direct repair (for gaps ≤ 4mm) and nerve grafting (for gaps ≥ 8 mm) for sensory recovery in a level 1 human trial. Although nonhuman primate studies on mixed motor-sensory nerves have documented comparable efficacy of the bioabsorbable nerve conduits when compared to nerve repair or grafting, there is minimal human clinical data on motor recovery following bioabsorbable nerve conduit repair. This study investigates the outcomes of bioabsorbable nerve conduits in pure motor nerve reconstruction for adult traumatic brachial plexus injuries.

Methods Over a 3-year period, 21 adult patients had 1 or more nerve-to-nerve transfers for traumatic brachial plexus palsy performed using the operative microscope. Ten nerve transfers were performed by advancing the nerve ends into a semi-permeable type I collagen conduit stabilized with 8-0 nylon sutures (conduit-assisted neurorrhaphy). Twenty-eight concurrent nerve transfers were performed using standard end-to-end neurorrhaphy and 8-0 or 9-0 nylon sutures. Clinical evaluation using the Medical Research Council grading system (MRC) was performed at 1 and 2 years postoperatively. Postoperative electromyographic studies were performed in 28 of 38 transfers at final follow-up.

Results Thirty transfers (17 patients) were available for 2-year follow-up evaluation. All 10 transfers performed with nerve conduits demonstrated clinical recovery and electromyographic reinnervation at 2 years. Eighteen of 20 transfers performed without conduits demonstrated clinical recovery.

Conclusions Although no statistical difference in functional recovery was seen in nerve transfers performed with collagen nerve conduits or by traditional neurorrhaphy, this pilot series demonstrated clinical and electromyographic recovery in 10 of 10 motor nerve repairs performed using conduits. These findings warrant continued investigation into the efficacy of conduit-assisted repair for motor nerves, especially in regards to operative time, precision of repair, and speed of nerve recovery. *(J Hand Surg 2012;37A:1980–1985.*

Type of study/level of evidence Therapeutic IV.

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BIOABSORBABLE NERVE CONDUITS have been studied for sensory nerve repairs in humans and have demonstrated improved sensory recovery compared with direct nerve repair or nerve graft in a randomized prospective study.[1] Comparable efficacy of nerve conduits for mixed motor-sensory nerves has been documented in animal studies.[2–6] The data on the use of conduits for motor nerve repair in humans are sparse and have been mostly on mixed motor-sensory nerves.[3,7–11] To date, outcomes following the repair of pure motor nerves using nerve conduits have been reported in 3 case reports. Inada et al.[12] reported motor recovery in 2 patients with facial nerve injuries (frontal branch) using polyglycolic acid tubes coated with cross-linked collagen. Navissano et al.[13] used polyglycolic acid synthetic tubes (Neurotube, Synovis Micro Companies Alliance, Inc., Birmingham, AL) to repair injuries to the zygomatic and buccinator branches of facial nerve in 2 patients. Rosson et al.,[11] demonstrated recovery of a spinal accessory nerve repair performed with a polyglycolic acid nerve conduit. No comparative series have been performed on the use of conduits in motor nerves in the extremity or the brachial plexus.

Traumatic brachial plexus injuries cause devastating functional loss of the upper extremity. Various surgical techniques including neurolysis, direct nerve repair, nerve grafting, and nerve transfer are used to treat these injuries. Although direct nerve repair may be used for penetrating injuries or sharp brachial plexus lacerations, excess tension at the repair site that results from the primary closure of a gap between retracted nerve ends will compromise nerve regeneration.[14,15] Nerve grafting, which uses an autogenous donor such as the sural nerve, has the potential to provide a tension-free repair and functional reinnervation. However, nerve grafting has worse outcomes with longer graft lengths[16] as well as potential donor-site morbidity (eg, scarring, loss of donor site sensation, infection, neuroma formation, and increased operative and anesthesia time).[3,11,15,17,18] Nerve transfer provides an effective alternative in which an intact, undamaged motor nerve from one muscle is redirected to the distal, undamaged portion of a nerve from another. The technique has been widely accepted and expanded because it bypasses the injured proximal nerve segment, targets a single muscle for reinnervation, and provides a relatively short reinnervation distance to the denervated motor end plates.[15,19–22]

The theoretical benefits of using a nerve conduit to position sectioned nerve ends in close proximity include more rapid repair, decreased nerve handling, simplified coaptation of cables or multiple fascicles, enhanced potential for intrinsic nerve guidance, and ability to coapt nerves with size mismatch.[1,23–26] The purpose of this pilot study was to investigate the efficacy of conduit-assisted neurorrhaphy during motor nerve transfers for brachial plexus reconstruction.

MATERIALS AND METHODS

This institutional review board–approved investigation spanned a 3-year period beginning in 2006. Thirty-seven intraplexal nerve transfers[15,22] and 1 repair involving interposition graft were performed in 21 patients by a single surgeon at our institution. Intercostal nerve transfers were not included in the analysis, because 2 or 3 intercostal nerves are typically coapted to each recipient nerve. Ten transfers in 8 patients were performed by advancing the nerve ends into a semipermeable type I collagen conduit (Neurogen, Integra LifeSciences Corporation, Plainsboro, NJ) stabilized with 8-0 nylon sutures. Twenty-eight nerve transfers in 17 patients were performed during the same time period using standard end-to-end neurorrhaphy and 8-0 or 9-0 nylon sutures. Because this was a pilot study and there was no published experience on the use of conduits in adult brachial plexus reconstruction, the surgeon approached the use of these cautiously and made an attempt to use the nerve conduit technique in many different types of transfers, including 1 performed with an intercalated nerve graft, to best assess its efficacy. Four of the 8 patients for whom conduit-assisted neurorrhaphy was used also had 1 or more additional nerve transfers performed with traditional suture coaptation; in effect, these patients acted as their own controls. Fibrin glue (Tisseel, Baxter, Deerfield, IL) was routinely used to augment 25 of the 28 standard nerve repairs; fibrin glue was not used for conduit repairs. The study was concluded after 10 nerve conduit–assisted repairs had been performed in order to assess the pilot outcomes.

Data were collected on the 38 consecutive nerve transfers using a data registry that was compliant with the Health Insurance Portability and Accountability Act and our institutional review board policies. The nerve transfers studied included ulnar nerve to biceps (n = 1 for conduit-assisted, 14 for traditional neurorrhaphy), nerve of long head of triceps to axillary nerve (n = 3 for conduit-assisted, 2 for traditional neurorrhaphy), spinal accessory nerve transfer to suprascapular nerve (n = 5 for conduit-assisted, 12 for traditional neurorrhaphy), and sural nerve graft from C5 root to axillary nerve (n = 1 for conduit-assisted, 0 for traditional neurorrhaphy) (Table 1). Postoperative rehabilitation and follow-up were identical between groups. Clinical evaluation using the Medical Research Council (MRC)

TABLE 1. Summary of Patient Information

Patient Identification	Age	Gender	Smoking	Fibrin Glue	Time to Surgery (mo)	Intervention	1-Year Gross Motor	2-Year Gross Motor	Postoperative EMG	Time of EMG (mo)
Traditional Nerve Repair Group										
1	31	M	No	Yes	4.1	UTB	4	4	—	N/A
2	23	M	No	Yes	4.0	UTB	4	4	3	18
5	43	M	No	Yes	4.7	UTB	2	—	—	N/A
6	26	M	No	Yes	5.5	UTB	1	0	2	11
7	29	M	No	Yes	7.1	UTB	4	4	3	12
8	26	M	No	Yes	4.9	UTB	4	—	—	N/A
11	52	M	No	Yes	5.5	UTB	3	—	3	15
13	33	M	No	No	—	UTB	4+	4+	—	N/A
15	35	M	≤ 1PPD	Yes	5.7	UTB	1	2	3	11
16	24	M	No	Yes	5.0	UTB	4+	4+	—	N/A
17	29	M	No	Yes	4.8	UTB	3	4	3	16.5
18	35	M	≤ 1PPD	Yes	2.0	UTB	4	4+	4	9.5
19	40	M	No	No	4.0	UTB	4	4+	4	13
20	30	M	No	Yes	8.0	UTB	3	4	3	9
2	23	M	No	Yes	4.0	SAN-SSN	3	4	3	18
4	34	F	No	Yes	6.3	SAN-SSN	2	—	—	N/A
5	43	M	No	Yes	4.7	SAN-SSN	3	—	—	N/A
6	26	M	No	Yes	5.5	SAN-SSN	4	4	4	11
7	29	M	No	Yes	7.1	SAN-SSN	3	3	3	12
8	26	M	No	Yes	4.9	SAN-SSN	3	—	—	N/A
10	46	F	No	Yes	5.0	SAN-SSN	3	4	3	10
11	52	M	No	Yes	5.5	SAN-SSN	3	—	3	15
13	33	M	No	No	—	SAN-SSN	3	4	—	N/A
16	24	M	No	Yes	5.0	SAN-SSN	4	4	—	N/A
17	29	M	No	Yes	4.8	SAN-SSN	3	3	3	16.5
18	35	M	≤ 1PPD	Yes	2.0	SAN-SSN	2	3	4	9.5
3	37	M	No	Yes	3.7	LHTA	2	3	4	24
11	52	M	No	Yes	5.5	LHTA	4	—	3	15
Average	34				5.0	≥ M3 strength	22/28	18/20		
						≥ M4 strength	11/28	14/20		
						EMG recovery			17/18	
Conduit-assisted Nerve Repair										
9	80	M	No	No	3.7	UTB	4	4	3	9.5
9	80	M	No	No	3.7	SAN-SSN	2	3	3	9.5
14	46	M	No	No	6.4	SAN-SSN	0	3	3	16
15	35	M	≤ 1PPD	No	5.7	SAN-SSN	4	4	3	11
19	40	M	No	No	4.0	SAN-SSN	3	3	4	13
20	30	M	No	No	8.0	SAN-SSN	3	4	4	9
6	26	M	No	No	5.5	LHTA	4	4	4	11
9	80	M	No	No	3.7	LHTA	3	3	3	9.5
12	59	M	≤ 1PPD	No	10.9	LHTA	3	3	3	22
21	37	M	No	No	7.0	Ax-Ax	3	4	3	6
Average	51				5.9	≥ M3 strength	8/10	10/10		
						≥ M4 strength	3/10	5/10		
						EMG recovery			10/10	

Ax-Ax, sural nerve graft to axillary nerve; EMG, electromyographic; LHTA, long head triceps to axillary; N/A, not applicable; 1PPD, 1 pack per day; SAN-SSN, spinal accessory to suprascapular; UTB, ulnar to biceps.

grading system of muscle function was documented by the surgeon at approximately 1 and 2 years postoperatively when the surgeon and the physician who performed electrodiagnostic studies were blinded to the particular repair method performed. Postoperative electromyographic (EMG) testing was performed to evaluate for reinnervation potentials and was graded on a scale of 0 to 4 (Table 2). All the EMG reports were graded by an independent evaluator who was blinded to the repair method chosen.

Data collection

Data were collected prospectively in a web-based, password-protected database configured in the System for

TABLE 2. Evaluation System for Electromyographic Testing

Grade	Description
0	Chronic denervation, no reinnervation
1	Positive waves or fibrillations with no voluntary motor units
2	Presence of voluntary motor unit potentials with or without fibrillations
3	Reinnervation, voluntary motor units, recruitment, and nascent potentials
4	Normal

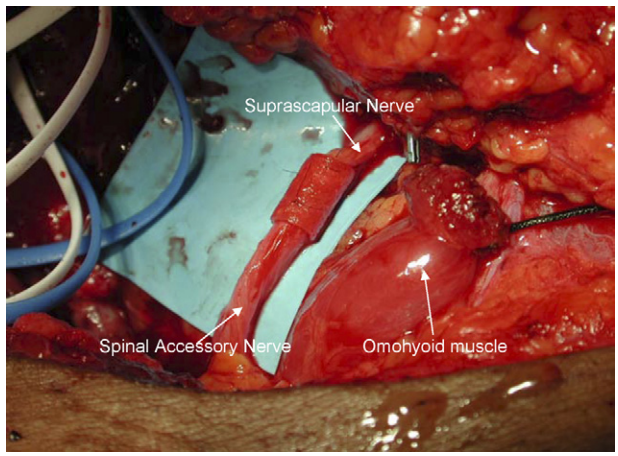

FIGURE 1: Conduit-assisted transfer of spinal accessory to the suprascapular nerve.

Collaborative Translational Research, a web-based, clinical research data entry application. Standardized data collection forms were used for each visit (eg, patient demographic data, injury details, surgical details, motor and sensory outcome, and EMG studies). In compliance with Health Insurance Portability and Accountability Act regulations, security features in the System for Collaborative Translational Research enabled the deidentification of patient health information. Deidentified data were exportable to Excel for statistical analysis.

Statistical comparisons

Demographic data for the 2 groups were compared by using independent samples Mann-Whitney U test (scale data) and Fisher exact test (ordinal data). The difference in the proportion of patients who attained useful clinical or EMG recovery (gross motor score of at least M3 and EMG score of 3 or 4) was assessed through the use of the Fisher exact test. The alpha level was set at $P = .05$.

Surgical technique: conduit-assisted neurorrhaphy

NeuraGen semipermeable collagen conduits (Integra LifeSciences Corporation, Plainsboro, NJ) were used for conduit-assisted neurorrhaphy. The conduits are fabricated from purified type I fibrillar collagen extracted from bovine flexor tendons. Nerve transfers were prepared by identifying the recipient and donor nerves; the recipient nerve was divided with sufficient length to ensure a tension-free junction and inspected under the operating microscope to ensure a healthy fascicular pattern, free of intrafascicular fibrosis. The nearby donor nerve or donor fascicles were selected (as has been previously described by Mackinnon et al.,[19] Oberlin et al.,[21] and Leechavengvongs et al.[27–30]) using nerve stimulation as necessary and to have sufficient length to ensure a tension-free junction to be as close to the recipient donor endplates as possible.[19,21,27–30] The nerve conduits were soaked in saline for 5 minutes according to the manufacturer's recommended technique. The diameter of the nerves was measured and, in the case of a discrepancy, the larger of the 2 nerves used to size the conduit. The conduit was chosen to be 1 mm larger than the diameter of the largest nerve. Conduit diameters ranging from 2 to 5 mm were used for nerve transfers. The conduit length was trimmed to 3 times the diameter of the nerve in accordance with the manufacturer's recommendations. Sequentially, each nerve end was introduced into the conduit using 2 horizontal mattress sutures of 8-0 nylon placed through the epineurium at 180° spacing. Both sutures were placed before advancing the nerve into the tube. In accordance to manufacturer's recommendation, care was taken to advance the nerve into the tube for a distance equal to the nerve diameter by placing the sutures at half of the diameter from the ends of the nerve and the conduit respectively (Fig. 1). By trimming the tube to a length of 3 nerve diameters, a gap of 1 nerve diameter was standardized within the tube. The traditional neurorrhaphies were performed in a standard fashion using 3 to 5 8-0 and 9-0 nylon epineural sutures under the operative microscope, and supplemented by fibrin glue (Tisseel, Baxter, Deerfield, IL).[15,21,27–30]

RESULTS

There were a total of 38 transfers in 21 patients with 1-year follow-up data. Of these 38 transfers, 28 were standard micro-neurorrhaphy repairs and 10 were conduit-assisted repairs. Of these 21 patients, 17 had 2-year data for strength testing, comprising 30 transfers, 10 of which were conduit-assisted transfers and the remaining 20 were traditional neurorrhaphies (Table 1). Of the 21 patients, 15 had 1 year or greater postoperative EMG

data, comprising 28 transfers, 10 of which were conduit transfers and the remaining 18 were traditional neurorrhaphies (Table 1). The mean time for EMG testing was 12 months in the conduit group and 14 months in the traditional neurorrhaphy group ($P = .12$).

The average age for nerve repair was 38 years (51 in the conduit group and 34 in the traditional neurorrhaphy group ($P = .01$). The average age was greater in conduit-assisted transfers and was skewed by the 3 transfers performed in an 80-year-old patient (Table 1). The average time to nerve repair was 5.2 months overall (5.9 months in the conduit group and 5.0 months in the traditional neurorrhaphy group ($P = .5$). There were 2 patients (2 nerve transfers) in the conduit group and 2 patients (3 nerve transfers) in the traditional neurorrhaphy group who smoked 1 pack of cigarettes or less per day ($P = .6$).

At year 1, 8 of 10 conduit-assisted nerve transfers demonstrated M3 or greater strength, and 3 of these were M4. Of 28 transfers in the control group after 1 year, 22 demonstrated M3 or greater strength, 9 had M4 strength, and 2 had M4+ strength (very strong, but asymmetric with respect to the opposite side). At year 2, all 10 of the 10 conduit-assisted nerve transfers demonstrated M3 or greater strength, and 5 of these had M4 strength. At year 2, 18 of 20 traditional nerve repairs had M3 or greater strength, 10 were M4, and 4 were M4+. One standard repair had no recovery, and one was M2. All 10 (100%) conduit-assisted nerve transfers showed M3 or better clinical recovery at 2 years compared with 18 (90%) of 20 patients in the control group ($P = .54$). All 10 (100%) conduit-assisted neurorrhaphies and 17 (94%) of the 18 traditional nerve repairs demonstrated EMG evidence of recovery ($P = .99$). The point estimate of the difference in proportions and the associated sample size was not sufficiently powered to detect a statistical difference.

DISCUSSION

Previous studies of nerve conduits for sensory nerve repair demonstrated their clinical utility. In 2000, Weber et al.,[1] in a study of 136 digital nerve transections in 98 patients, showed that the use of bioabsorbable polyglycolic acid conduits to repair nerve gaps of 4 mm or less resulted in improved sensory recovery compared with traditional methods of nerve repair (ie, direct repair or nerve graft). Motor nerve repair using nerve conduits has been reported in animal studies.[2–4] In a study of 15 median nerve repairs and 1 ulnar nerve repair performed on 8 monkeys, Archibald et al.[2] showed histological evidence of regenerated nerves in 5-mm nerve gaps repaired with collagen nerve conduits. The nerves repaired by collagen nerve conduits, which were completely reabsorbed, demonstrated comparable physiological recovery to direct repair and nerve graft control groups. In humans, reports on motor nerve recovery are sparse and must be teased out from mixed motor-sensory nerve repairs, predominantly in the forearm.[7,8,10,11,31] In 2004, in a study of 30 patients with median and ulnar nerve lacerations in the distal forearm that were repaired randomly with either direct coaptation or silicone tubes, Lundborg et al.[10] reported no significant difference in motor or sensory outcome between the groups. In 2005, Taras et al.[31] reported "favorable" results in 73 collagen conduit repairs in humans of various peripheral nerves including the median, ulnar, radial, and digital nerves; however, detail on motor strength, sensibility, EMG recovery, or percent success was not reported. Ashley et al.[9] used 5- to 7-mm-diameter collagen matrix tubes for mixed motor/sensory nerves with gaps 2 cm or smaller in 5 pediatric brachial plexus patients. The tubes were used as an alternative to a nerve graft from C5 and C6 to C5/C6/upper trunk/middle trunk in 5 infants with an average age of 8 months. Although 4 of the 5 patients were reported to have a "good" functional outcome at an average of 2 years, no comparable data on nerve grafts for these injuries were reported. Furthermore, EMG analysis was not documented, which is essential for motor recovery.

We are aware of 3 case reports of conduit-assisted repair of isolated motor nerve injuries in humans and none in adult brachial plexus injuries. Inada et al.[12] described the use of polyglycolic acid tube coated with cross-linked collagen in 2 patients with injuries to the frontal branch of facial nerve. Five months following surgery both patients showed symmetric eyebrow lifting. Electrophysiological testing revealed recovery of compound muscle action potential and distal latency on the affected side. Navissano et al.[13] used polyglycolic acid synthetic tubes (Neurotube) to repair the buccinator branch of the facial nerve in 1 patient and the zygomatic branch of the facial nerve in another. Both patients demonstrated "satisfactory" muscle recovery at 7 and 10 months of follow-up. Electrophysiological testing was not reported in either patient. Rosson et al.[11] used a bioabsorbable polyglycolic acid nerve conduit to repair a spinal accessory nerve 3 months following injury. Four months following surgery, the patient showed M3 shoulder abduction and EMG evidence of reinnervation.

Our study, all 10 conduit-assisted repairs demonstrated M3 or greater clinical recovery and EMG evidence of reinnervation at 2 years following repair. In the

traditional micro-neurorrhaphy group, 18 of 20 repairs demonstrated clinical and 17 of 18 demonstrated EMG evidence of recovery at 2 years. We showed no measurable difference in the clinical outcomes in the 2 groups; however, the analysis was limited by the relatively small sample size of our pilot study. Another limitation of the study was that the patients were not randomized, although an attempt was made by the surgeon to allocate conduit-assisted repairs to multiple different nerve transfers. Despite these limitations, the finding of 100% efficacy of conduit-assisted neurorrhaphy in adult brachial plexus reconstruction provides confidence to the surgeon in using this technique, should the clinical situation warrant, and provides the foundation for further, larger-scale study in the use of conduits for motor nerve reconstruction. There may be theoretical advantages for the use of nerve conduits over traditional nerve suture, including a potential reduction in operative time, a reduction in nerve handling, minimized suture use, improved coaptation of minute or multifascicular nerves, and the potential for enhancing axonal guidance by allowing regenerating axons to choose appropriate distal targets across a repair gap.[1,23–26]

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