

# Early Clinical Experience With Collagen Nerve Tubes in Digital Nerve Repair

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**Purpose** In cases of digital nerve injury in which nerve ends cannot be approximated without tension, autologous nerve grafts represent the most commonly used method for reconstruction. Recently, interest in synthetic nerve guides as an alternative to grafting has increased. Although several basic science studies have shown promise for collagen tubes, clinical studies of their success in humans are limited. The purpose of this study was to review our early clinical experience with collagen nerve tubes.

**Methods** The authors identified and followed all cases involving digital nerve repair at our institution over a 2-year period. Twelve patients had repair of a digital nerve with a collagen nerve tube during the study period. Two patients were lost to follow-up, and 1 patient had amputation of the grafted finger secondary to complications of other injuries. The primary outcome data points for the remaining 9 patients were the static 2-point discrimination (2PD), Semmes-Weinstein monofilament testing, and a Quick Disabilities of the Arm, Shoulder, and Hand (DASH) outcome survey at final follow-up.

**Results** Nine patients had follow-up of at least 1 year, with an average follow-up time of 15 months (range 12–22 months). There were no intraoperative or postoperative complications related to the nerve tubes. Using modified American Society for Surgery of the Hand guidelines, 2PD results were good or excellent in 8 out of 9 of patients. Semmes-Weinstein testing results were full in 5 patients, diminished light touch in 2, diminished protective sensation in 1, and loss of protective sensation in 1. Average Quick DASH scores for the group were 10.86 overall, 4.86 for the work module, and 23.21 for the sports/performing arts module.

**Conclusions** Although the patients in this study are still within the early follow-up period, our initial results compare favorably with those reported in the existing literature for various types of nerve repair and reconstruction, suggesting that collagen nerve tubes might offer a clinically effective option for restoration of sensory function. (*J Hand Surg* 2008;33A:1081–1087. Copyright © 2008 by the American Society for Surgery of the Hand. All rights reserved.)

**Type of study/level of evidence** Therapeutic IV.

**Key words** Collagen nerve tube, collagen nerve guide, digital nerve repair, nerve graft, nerve entubulation.

PERIPHERAL NERVE INJURY has posed an intimidating challenge to surgeons since Cruikshank first reported successful repair in 1795.<sup>1</sup> Modern

techniques for repair of peripheral nerves have evolved substantially since that time, and the best results are obtained when primary, tensionless repair of a single-function nerve (isolated motor or isolated sensory) can be achieved.<sup>2</sup> When gaps exist, however, tensionless end-to-end nerve repair may not be possible. Autogenous nerve grafting is often used to bridge these gaps.<sup>1,2</sup> However, the increased operating time and donor site morbidity associated with autogenous grafting have driven an interest in synthetic grafting materials as a potential alternative method to achieve tensionless repair.<sup>3</sup>

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Animal studies have demonstrated successful nerve regeneration through nerve tubes composed of a variety of synthetic materials.<sup>4–13</sup> Animal studies of collagen conduits have shown equivalent physiologic recovery as compared to autografts,<sup>5,7,8</sup> and a 2007 study actually found better results with collagen conduits than with polyglycolic acid (PGA) conduits.<sup>13</sup> The collagen guide's physiologic success is thought to be due to its semipermeable collagen framework, which allows molecular diffusion and controlled resorption.<sup>8,13</sup>

Despite these findings, literature regarding the clinical effectiveness of collagen nerve guides in humans remains scarce. Lohmeyer and colleagues reported 66% excellent results in a review of 6 patients 1 year after nerve reconstruction with collagen tubes.<sup>14</sup> Another anecdotal report has been published by Taras et al., simply stating that, in their experience, more favorable results were obtained using collagen tube repair of peripheral nerves than using direct repair or grafting.<sup>3</sup>

Polyglycolic acid conduits, on the other hand, have been documented several times in the clinical literature.<sup>9,15–20</sup> The best known paper on PGA conduits to date is a 2000 randomized trial by Weber et al., which demonstrated improved outcomes with PGA conduits than with end-to-end repair and autogenous nerve grafting in digital nerve reconstruction.<sup>9</sup> No such randomized trials have been conducted, however, to study the effectiveness of collagen conduits in humans.<sup>21</sup>

Since 2005, the senior author has used collagen nerve tubes for repair of appropriately indicated digital nerve injuries. Given the paucity of reports on outcomes associated with this specific type of collagen conduit, we sought to investigate, quantify, and report our early clinical experience by performing this case series.

## MATERIALS AND METHODS

All cases involving digital nerve repair with collagen nerve tubes performed by the senior hand surgeon at our institution (a level 1 trauma center) between January 1, 2005, and December 31, 2006, were identified and followed. The primary outcome data points for this study were static 2PD on physical examination of the involved nerve's sensory distribution, Semmes-Weinstein monofilament testing, and Quick DASH outcome survey scores. The Quick DASH is an abbreviated version of the full DASH, both of which have been validated as objective scoring systems for upper extremity surgery.<sup>22–25</sup> Scores range from 0 (no disability) to 100 (complete disability).

Tube use was indicated in any patient with a digital nerve injury with segmental loss of greater than 1 cm but less than 2 cm, where tensionless end-to-end pri-

**TABLE 1. Modified American Society for Surgery of the Hand Guidelines for Stratification of 2PD Results**

Rating	2PD Result
Excellent	<6 mm
Good	6–10 mm
Fair	11–15 mm
Poor	>15 mm or protective sensation

Adapted from Weinzweig, N. Crossover innervation after digital nerve injury: myth or reality? *Ann Plast Surg* 2000;45:509–514.

mary repair was not possible. Contraindications to tube use included active infection, considerable wound contamination, systemic instability of the patient, and digital nerve injuries permitting tensionless end-to-end primary repair. We set a minimum follow-up time of 12 months for analysis with Semmes-Weinstein testing and Quick DASH surveys and inclusion in the study group.

Postoperative examinations were performed by physicians and hand therapists blinded to the surgical status of the patient and the purpose of the research study. Static 2PD was measured with a Wartenburg Pinwheel Sensory Evaluator (North Coast Medical, Inc., Morgan Hill, CA), and modified American Society for Surgery of the Hand guidelines were used to stratify the results for static 2-point discrimination (Table 1).<sup>26</sup> Semmes-Weinstein monofilament testing was performed by a blinded hand therapist using the Touch-Test Sensory Evaluators Complete 5-Piece Hand Set (North Coast Medical, Inc, Morgan Hill, CA). The Quick DASH surveys were filled out individually by each patient.

Twelve patients who had repair of a digital nerve injury using a NeuraGen bovine collagen nerve tube (Integra Lifesciences Corporation, Plainsboro, NJ) were identified and followed (Table 2). There were 8 men and 4 women; the average age was 33 years (range 18–50). The injury involved the dominant hand in 50% of cases. A variety of digital nerves were injured by a variety of mechanisms. Four cases involved an isolated injury to a single digital nerve, whereas 8 other cases involved multiple traumatic injuries to the hand. All cases involved subjectively reported and objectively recorded loss of sensation in the distribution of the involved nerve at the time of injury.

Two patients lacked follow-up greater than 1 year, and 1 patient required digital amputation secondary to stiffness and pain related to multiple open fractures and tendon lacerations in the same finger. These 3 patients

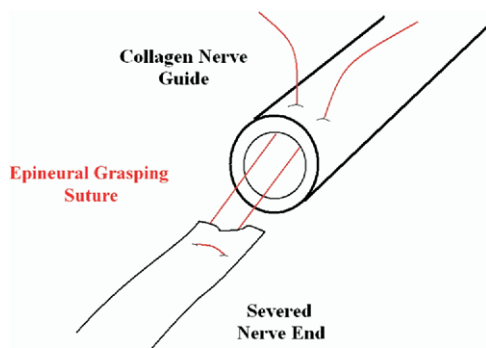
**TABLE 2. Nerve Repair Patient Data**

Number	Age	Gender	HD	Injured Nerve	Mechanism	Other Injury	Tube(mm)	F/U	2PD	S-W	DASH
1	18	M	R	L Index RDN	Circular saw laceration	FT	4 × 20	6	9	N/A+	N/A+
2	34	F	R	R Long RDN	Crushed in die-punch machine	OF, FT, ON	3 × 20	N/A*	N/A*	N/A*	N/A*
3	27	M	L	R Long RDN	Crushed between car jack and steel ramp	ET	2 × 20	7	5	N/A+	N/A+
4	45	M	L	L Index RDN	Crushed and lacerated in drill press	None	2 × 20	19	3	F	0/0/0
5	40	M	R	L Small UDN	Table saw laceration	OF, ET, NL	2 × 20	15	5	F	4.54/0/25
6	26	F	R	L Thumb RDN	Motor vehicle collision	OF	3 × 20	22	5	F	9.09/6.25/NR
7	49	F	R	R Thumb UDN	Puncture/laceration from rusty nail	None	3 × 20	14	13	LOSS PS	29.54/0/NR
8	29	M	R	R Index UDN	Table saw laceration	OF, FT, ET	3 × 20	14	7	DLT	9.09/18.75/25
9	50	M	R	R Ring UDN	Fell onto sharp edge of sheet metal	None	2 × 20	14	7	DLT	0/0/0
10	23	M	R	L Long UDN	Laceration from closing car door	None	3 × 20	13	5	F	11.36/6.25/18.75
11	39	F	R	R Long RDN	Crushed under heavy object	AMP	3 × 20	12	9	DPS	22.73/12.5/81.25
12	18	M	L	L Index RDN	Table saw laceration	OF, FT	3 × 20	12	8	F	11.36/0/12.5

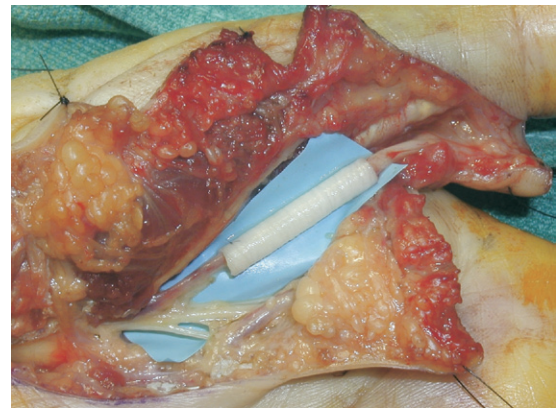
HD, hand dominance; F/U, follow-up time period in months; LTS, light-touch sensation results; S-W, Semmes-Weinstein monofilament testing results (>1 year); DASH, Quick DASH outcomes survey results (>1 year); RDN, radial digital nerve; UDN, ulnar digital nerve; AMP, partial amputation of other fingers; OF, open fractures; ET, extensor tendon lacerations; FT, flexor tendon lacerations; ON, other digital nerve injuries; NL, nailbed lacerations; F, full sensation; DLT, diminished light touch; DPS, diminished protective sensation; LOSS PS, Loss of protective sensation; NR, not reported; N/A, not included. Quick DASH scores: 0, normal; 100, complete loss of function; reported as overall score/work module score/sports and performing arts module score.

\*, patient had amputation of involved finger (excluded from analysis totals).

+, patient with less than 12 months' postoperative follow-up (excluded from analysis totals).



**FIGURE 1:** Suturing the nerve end into the collagen nerve tube. An epineural grasping suture is used to pull the severed end of the injured nerve into the nerve tube and secure it in place.



**FIGURE 2:** Completed repair. View of a collagen nerve tube used to repair a gap defect in a digital nerve of the left thumb.

were excluded from data analysis. For the remaining group of 9 patients with at least 1 year of follow-up, the average follow-up time was 15 months (range 12–22).

### SURGICAL TECHNIQUE

The choice of nerve exposure is based on surgeon preference and the presence of concomitant injuries such as additional nerve lacerations, tendon lacerations, fractures, pulley disruptions, and other problems. The ends of the involved digital nerve are then carefully dissected to evaluate the size of the gap and extent of devitalized neural tissue requiring resection. After debridement and irrigation of the wound, the ends of the injured nerve are freshened appropriately.<sup>27</sup> The gap and nerve width are measured, and an appropriately sized collagen nerve guide is chosen. The guide should be long enough to span the gap without tension on the nerve ends and wide enough to encircle the nerve without constriction. In our series, the diameter of tubes used ranged from 2 mm to 4 mm, depending on the surgeon's assessment of the size of the nerve at the time of surgery (Table 2). Longer tubes are available, but all of our patients received 20 mm tubes because no gap was larger than 2 cm in our series. The proximal end of the nerve is secured into the guide using a single 8–0 or 9–0 nylon suture in an epineural grasping stitch pattern, which helps “dock” the end of the nerve into the tube (Fig. 1).<sup>14</sup> The guide is then filled with saline, and the distal end is sutured in a similar fashion to complete the repair (Fig. 2). Some studies have also advocated injection of heparin into the tube to decrease clot and scar formation, but we chose to follow the manufacturer's recommended protocol of filling with saline alone. Additional injuries are addressed as needed, either before or after the nerve repair. The wound

is then thoroughly irrigated with saline, closed, and dressed appropriately.

Postoperative rehabilitation regimen depends on the spectrum of injury in each case. Range of motion, weight-bearing, active exercises, and other aspects of therapy were directly affected by the presence of concomitant fractures and tendon injuries. In general, however, we attempted to adhere to a standard sensory reeducation protocol. Upon return of protective sensation as assessed by Semmes-Weinstein monofilament testing, sensory reeducation therapy was initiated by certified occupational hand therapists. Therapists used moving or constant touch with a fingertip or pencil eraser. They also used objects of different textures and shapes (eg, coin, button, Q-tip, screw, paper clip). Patients were asked to identify the location of the stimulus and what it was they were feeling, first with their eyes open while touching the stimulus, then with their vision occluded, and last with eyes open to confirm what they were feeling. The therapists spent approximately 10 to 15 minutes on sensory reeducation 1 time per week for 4 to 6 weeks with each patient. Patients were also encouraged to perform these activities at home 2 to 3 times per day. Overall therapy regimens usually lasted about 3 months, again depending on the other injuries involved.

In our cases, the average tourniquet time for all cases was 80 minutes (range 43–155), and the average overall surgical time for all cases was 140 minutes (range 72–234). In cases involving other surgical interventions (such as flexor tendon repair or fracture fixation), these time measurements did not attempt to quantify the specific amount of time spent on each component procedure; only the entire time of tourniquet use or room-in to room-out surgical time was recorded. There were no intraoperative complications.

## RESULTS

All patients had results recorded at their most recent follow-up visit, with patients returning at 1 year or later undergoing evaluation with Semmes-Weinstein testing and Quick DASH surveys (Table 2). There were no postoperative complications or allergic reactions related to the nerve tube. Using the modified American Society for Surgery of the Hand guidelines for static 2PD, 4 patients (44%) had excellent results, 4 patients (44%) had good results, and 1 patient (11%) had fair results. Semmes-Weinstein testing results were full in 5 patients, diminished light touch in 2 patients, diminished protective sensation in 1 patient, and loss of protective sensation in 1 patient. The average Quick DASH survey scores were 10.86 for the overall score, 4.86 for the work module score, and 23.21 for the sports/performing arts module score.

## DISCUSSION

Our early experience with collagen nerve guides for repair of digital nerves has been encouraging. With an average follow-up time of 15 months, most of our patients have experienced complete or near-complete recovery of subjective light-touch sensation in the distribution of the affected nerves. The return of 2PD is also promising, with 89% of patients having good or excellent results. Semmes-Weinstein results likewise reveal good functional recovery, and validated survey-based scores also confirm good outcomes. Although we lack the sample size to exhibit a reliable statistical correlation, we have seen a trend toward improved sensory function with continued observation over time.

The findings of our study compare favorably with the existing literature on nerve repair in the setting of a pure sensory nerve deficit. Primarily, our findings provide clinical validation of the conclusions of the various basic-science studies describing successful use of collagen nerve guides in animal models.<sup>4,5,8,13,15,28–31</sup> Our results seem similar to those of several reports of primary repair of digital nerve injuries<sup>15,26,32–37</sup> and repair with autograft.<sup>15,20,33</sup>

Our findings also seem to compare well with the few well-described case reports and series on nerve tubes made from materials other than collagen. Case reports by Inada et al.<sup>16–18</sup> and Meek et al.<sup>20</sup> document successful clinical use of PGA and p(DLLA-epsilon-CL) tubes, respectively. In a 1990 analysis of 15 cases of secondary reconstruction of nerve gaps using PGA tubes, Mackinnon and Dellon found excellent 2PD results in 5 patients (33%) and good 2PD results in 8 patients (53%), representing an overall 86% good/excellent result rate, similar to our rate of 89%.<sup>19</sup> For

**TABLE 3. Battiston Modification of the Mackinnon-Dellon Scale for Stratification of 2PD Results**

Battiston Rating	Mackinnon-Dellon Score	2PD Result
Very good	S4, S3+	2–6 mm, 7–15 mm
Good	S3, S2+	>15 mm
Poor	S2 or worse	N/A

N/A, not included.

Reprinted with permission of John Wiley & Sons, Inc., from Battiston B, et al. Nerve repair by means of tubulization: literature review and personal clinical experience comparing biological and synthetic conduits for sensory nerve repair. *Microsurgery* 2005;25:258–267.

their study, however, the authors used a static 2PD stratification scale that included results up to 15 mm in the “good” category—a method less strict than the 1 we employed.

In a 2005 article, Battiston et al. reported their results using a modification of the Mackinnon-Dellon scale for sensory recovery (Table 3). In their analysis of 19 cases of digital nerve repair using a Neurotube (Neuroregen LLC, Bel Air, MD) bioabsorbable PGA conduit, they found 13 patients (76.5%) with “very good” results. Although the “very good” results of Battiston et al. are higher than our reported “excellent” results, we used the modified AHHS guidelines (Table 1), not the modified Mackinnon-Dellon scale. Using their modified Mackinnon-Dellon scale, we would have had 100% “very good” results—a figure that we felt overstated the success of the nerve tubes. Furthermore, Battiston et al. reported an average overall Quick DASH score of 9.30, to which our average score of 10.86 compares favorably.<sup>15</sup>

Our study results are also comparable to those reported in the currently most-definitive study of nerve tubes against other repair options. In the 2000 paper by Weber et al. involving PGA nerve conduits, 74% of patients had good or excellent results in analysis of stratified 2PD.<sup>9</sup> Under their rigorous study conditions, Weber et al. concluded that PGA conduits were superior to primary repair for gaps less than 4 mm and superior to autogenous nerve grafting for gaps greater than 8 mm.<sup>9</sup>

Finally, our study compares favorably to the recent report by Lohmeyer and colleagues on collagen nerve tubes.<sup>14</sup> They followed 11 patients having nerve reconstruction with the same NeuraGen tubes (Integra Lifesciences Corporation, Plainsboro, NJ, USA) that we used in our study. Although only 6 of these patients had follow-up of 12 months or greater, 4 of the 6 (66%) had

“excellent” 2PD of 7 mm or less. The other 2 patients had 2PD of 15 mm or greater. Detailed monofilament testing results were not provided, and no outcome surveys were performed in their study.

Our study did have some limitations. First among these was the small size of the study group and relatively short follow-up time. The smaller numbers of patients included might reflect the relative infrequency of this technique, but it also limits the analysis of the impact on outcome of factors such as patient age, severity of injury, and other comorbidities. We sought to report our results despite relatively short follow-up times, however, because of the limited clinical data available regarding collagen tubes. Given the small number of patients in both our study and the Lohmeyer study,<sup>14</sup> future investigators should seek to include larger numbers of patients and follow those patients for longer intervals.

Another limitation was the lack of a comparison cohort of patients undergoing primary repair or repair involving autogenous nerve graft. We have thus made comparisons to results reported in the literature for primary repair and for other graft options, as discussed earlier. Another weakness was the inclusion of patients with additional injuries other than their nerve injury. These additional injuries might alter the results of the nerve repair relative to cases in which only an isolated nerve injury was treated. By including these patients, however, our data perhaps more accurately reflect a generalizable target population for this technique.

Our findings indicate that collagen nerve guides can provide effective restoration of digital nerve function in the early postoperative period. Our clinical data corroborate the existing basic science data for collagen nerve guides and suggest that these guides perform equivalently to other synthetic conduits. This information can be used to generate larger studies into the effectiveness of various nerve conduits, cost analysis for purchasing decisions, and research into the broader applications of collagen nerve tubes.

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