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Abstract

Purpose

To investigate the outcomes of digital nerve repairs using processed nerve allograft for defects measuring 30 millimeters or less.

Methods

Seventeen patients with 21 digital nerve lacerations in the hand underwent reconstruction with processed nerve allograft. Outcome data for 14 patients with 18 digital nerve lacerations were available for analysis. Postoperative outcome data were recorded at a minimum of 12 months and an average of 15 months. The average nerve gap measured 11 mm (range, 5 - 30 mm). Outcome measures included postoperative sensory examination as assessed by Semmes-Weinstein monofilaments and static- and moving-2 point discrimination. Pain was graded using a visual analog scale throughout the recovery period. In addition, patients completed the Quick Disabilities of the Arm, Shoulder, and Hand survey pre- and postoperatively.

Results

Using Taras outcome criteria, 7 of 18 (39%) digits had excellent results, 8 of 18 (44%) had good results, 3 of 18 (17%) digits had fair results, and none had poor results. At final follow-up, Semmes-Weinstein monofilament testing results ranged from .08 grams to 279 grams. Quick Disabilities of the Arm, Shoulder, and Hand scores recorded at the patient's first postoperative visit averaged 45 (range, 2-80), and final scores averaged 26 (range, 2-43). There were no signs of infection, extrusion, or graft reaction.

Conclusions

The data suggest that processed nerve allograft provides a safe and effective alternative for the reconstruction of peripheral digital nerve deficits measuring up to 30 mm.

Type of Study/Level of Evidence: Therapeutic IV

Introduction

Restoration of peripheral nerve function continues to challenge surgeons despite advances in manufactured and traditional graft options and refined surgical techniques. (1,2,3) Segmental nerve loss often accompanies trauma to the hand making a tension-free, end-to-end repair impossible. In many cases, traumatic nerve injury requires debridement of the nerve ends, which further compromises tension-free repair. (4) In cases in which a secure, tension-free repair is not possible, the most common recommendation has been to graft the defect with a segment of autologous nerve. Autografts provide a reliable structure and environment through which axons can regenerate across a deficit. However, disadvantages include prolonged operative times, higher facility costs, and donor site morbidity which may include pain, scarring, neuroma formation, and sensory loss. (5,6,7,8)

Autograft alternatives include allografts and artificial nerve conduits, which eliminate donor site morbidity. Several clinical studies have documented the effectiveness of nerve conduits for short gaps (9); however, the clinical value of nerve conduits to bridge larger gaps remains unclear. (3,9) Recent advances in allograft tissue processing have eliminated the need for immunosuppression, and allografts are becoming an attractive alternative to autografts and conduits. (10,11,12)

Several authors have reported success with processed nerve allografts. (1,2,13,14) One such allograft is the Avance® processed nerve graft *(AxoGen, Inc., Alachua, FL)*. It consists of human nerve that has been decellularized, gamma irradiated, and subjected to enzymatic degradation of chondroitin sulfate proteoglycans with chondroitinase. As a result, the allograft is rendered nonimmunogenic while its 3-dimensional structure is maintained. (14,15) Animal studies have shown this material to mimic autografts in macrostructure, 3-dimensional microstructural scaffolding, and protein composition. Theoretically, these qualities render

allograft an effective material to span peripheral nerve defects. (1,4,16) A recent review of the literature, however, disclosed few clinical studies evaluating the efficacy of processed allografts to reconstruct digital nerve defects in the hand. (14,17) In a retrospective review, Karabekmez et al (14) reported on the efficacy of processed allografts for restoring adequate sensation in nerve defects ranging from 5 to 30 mm. Cho et al (17) reported on a subset of digital nerve defects up to 40 mm from an ongoing nerve registry.

The goal of this prospective study was to evaluate the clinical outcomes of digital nerve gaps in the hand measuring 30 mm or less reconstructed with processed nerve allograft.

Methods

After receiving institutional review board approval, a prospective study was conducted on patients older than 18 years of age with digital nerve lacerations not amenable to primary repair. (Table 1) Nerve reconstruction was performed using a commercially available processed nerve allograft (Avance® Nerve Graft, AxoGen, Inc., Alachua, FL)

Surgical Technique

When a nerve laceration was identified during surgery, the gap between the debrided ends was measured with the digits extended. If the gap was 5 mm or greater, then a nerve allograft was used to reconstruct the defect. The injured proper digital nerve's diameter was consistently 2-3 mm. Each processed nerve allograft was prepared following the packaged instructions for use. Under loupe magnification, the allograft was trimmed to match the defect, and 8-0 nylon suture was used to secure the graft junctures. Typically, 3 simple sutures secured each juncture. (Figure 1)

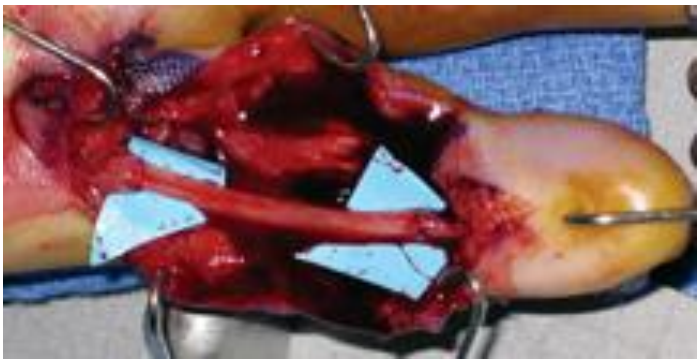

Figure 1. The completed nerve reconstruction with allograft in place.

Saline irrigation was used to clear the surgical field after release of the tourniquet and achievement of hemostasis. After wound closure, a plaster orthosis was applied over a sterile gauze bandage. After the first postoperative visit, the orthosis was discontinued, flexion as tolerated was allowed but extension was limited to neutral.

Outcome Measurement

Seventeen patients with 21 digital nerve reconstructions met this study's inclusion criteria. One hand surgeon performed all surgeries. One hand therapist who was not blinded recorded the outcome data. Final outcome data were recorded at least 12 months postoperatively. Primary outcome measures included postoperative sensory examination using Semmes-Weinstein, where lower values for touch-pressure detection thresholds indicate a less severe degree of nerve dysfunction (18) and static- (S2PD) and moving- (M2PD) 2-point

discrimination using the Disk-Criminator to assess sensibility *(Sensory Management Services LLC, Lutherville, MD).*

Patients completed the Quick DASH (Disabilities of the Arm, Shoulder, and Hand) (19) survey pre- and postoperatively to quantify their pain perception and functional impairment. Quick DASH scores range from 0 indicating no disability to 100 describing the most severe disability. Pain was recorded on a 10-point visual analog scale, where a score of 0 denoted no pain, and a score of 10 signified extreme pain. Secondary outcome measures included patient demographics, comorbidities, hand dominance, and location and mechanism of injury. Postoperative complications were reported. The Taras measurement outcome score was used to grade results as excellent, good, fair, or poor. (Table 2) (20)

The Taras scale attempts to account for outcomes in which either S2PD ***or*** M2PD is greater than 8 mm but is not a "Good" result. Taras et al stated that because digital width is finite, 2-point discrimination greater than 8 mm could not be determined accurately without entering the nerve distribution of the contralateral digital nerve and reported 2-point discrimination greater than 8 mm with a score of ">8". Moving- and static 2-point discrimination do not always recover synchronously to the same level; thus, the lesser of a nerve's 2 measurements was chosen to assign it to its appropriate group in the final statistical analysis.

Results

Seventeen patients with 21 digital nerve lacerations underwent digital nerve allograft reconstruction. Three patients did not complete the study's 12-month minimum follow-up

requirement. As a result, the study cohort included 14 patients with 18 digital nerve reconstructions. Ten men and 4 women with an average age of 39 years (range, 18–76 years) returned for follow-up examination and outcome reporting through at least 12 months after surgery. Eleven injuries involved the dominant hand, and 7 injuries affected the nondominant hand. Mechanisms of injury are reported in Table 1. There were concomitant fractures of the involved digit in 7 patients and 9 tendon lacerations in the involved digit in 7 patients. The average interval from injury to surgery was 29 days (range, 2–262 days). The average nerve defect measured 11 mm in length (range, 5 - 30 mm). The average time to final follow-up was 15 months (range, 12-20 months). At final follow-up, Semmes-Weinstein monofilament testing ranged from .08 grams to 279 grams. Average S2PD results were 7.1 mm (range, 5-8 mm), and average M2PD results were 5.4 mm (range, 2-8 mm).

Results were graded using the scale reported by Taras (20), a modification of the scale used by Weber (Table 2). (3) According to this scale, 7 of 18 (39%) digits had an excellent result, 8 (44%) had good results, 3 (17%) digits had fair results, and none had poor results. Using the Weber classification for comparison purposes, 7 of 18 (39%) digits had an excellent result, 7 (39%) digits had good results, and 4 (22%) had poor results. Initial Quick DASH scores recorded at the patient's first postoperative visit averaged 45 (range, 2-80), and final Quick DASH scores averaged 26 (range, 2-43). There were no signs of infection, extrusion, or graft reaction. Using the visual analog scale, pain averaged 2 at final follow-up compared to 5 initially. One patient underwent additional surgery for a 2-stage tendon reconstruction.

Discussion

Despite the options available to reconstruct nerve defects, treatment of peripheral nerve gap injuries remains challenging. Traditionally, nerve autografts have been advocated to reconstruct peripheral nerve defects not amenable to primary repair, but donor site comorbidities, increased operative times, and limited harvest sites have presented considerable limitations. (5,6,7,8) Early results of processed allografts have been encouraging and provide an attractive alternative to autografts. (1,17) Manufactured grafts eliminate donor site morbidity issues while retaining the elements that promote cell migration into the graft. (2,15,16)

Published studies have presented alternatives to autografts for nerve defects extending up to 20 mm. In 2000, Weber et al (3) conducted a randomized, controlled study to examine the outcomes of nerve conduits compared with direct suture and autograft for sensory digital nerve repairs. For nerve gaps 4 mm or less, they reported mean M2PD 3.7 +/- 1.4 mm for conduit repair and 6.1 +/- 3.3 mm for end-to-end repairs ($P = 0.03$). The mean M2PD for nerve gaps greater than 8 mm for conduits was 6.8 +/- 3.8 mm. Taras (20) et al also demonstrated the efficacy of purified type 1 bovine collagen conduits in a prospective study of 22 isolated digital nerve lacerations at a mean gap of 12 mm. They reported mean M2PD and S2PD of 5.0 and 5.2 mm, respectively, for digits with measurable recovery at the mean final follow-up 20 months (range, 12-59 months) after surgery; however, 6 nerve repairs failed to recover S2PD and were excluded from the mean analysis of S2PD. According to the grading criteria used in the Taras study, 13 of 22 (59%) digits achieved excellent results, 3 (14%) digits had good results, 6 (27%) digits had fair results, and there were no poor results. Rinker et al (21) showed no clinical difference between polyglycolic nerve conduits and autogenous vein grafts for repair of peripheral nerve defects at a mean gap of 10 mm. The Multicenter Retrospective Study of Avance® Nerve Graft Utilization, Evaluations and Outcomes in Peripheral Nerve Injury Repair represents the largest retrospective review of processed allografts to date. The multicenter,

multisurgeon review showed that use of processed allografts is a reliable method to restore nerve function across nerve gaps 5-50 mm in length. (1)

The current study presents the results of a prospective series demonstrating the clinical efficacy of processed nerve allografts to repair digital nerve defects measuring up to 30 mm (average 11 mm) in length. The results of the current study are similar to others in the literature (1,2,3,10,12,13,14,15,16,21) but are expanded to include the patient's perception of their functional limitations. In the current study, postoperative Quick DASH scores improved by an average of 18 points, representing a 42% reduction from preoperative scores. According to Hunsacker et al (22), a DASH score of 10 +/- 15 falls within normal limits for the US general population. Few studies to date have assessed the minimum clinically important difference (MCID) of the QuickDASH. Mintken et al (23) reported that the MCID was 8 points in shoulder patients. Sorensen et al (24) defined MCIDs for the DASH, Quick DASH, and Patient-Rated Wrist Evaluation questionnaires for group-level analysis of atraumatic conditions of the hand, wrist, and forearm, with the Quick Dash having an MCID of 14 points. For individual digits in the current study, the average difference between initial and final Quick DASH scores were thumb (n=7) 19, index (n=4) 12, middle (n=2) 28, ring (n=1) 48, and small finger (n=4) 12. A limitation of the QuickDASH rating instrument is that the score reflects concomitant injuries, which in many cases accounted for a greater degree of disability than did the nerve injury.

The correlation coefficients (r-values) for S2PD and M2PD were 0.36 and 0.74, respectively. The coefficients of determination (R Squared) for S2PD and M2PD are 0.13 and 0.55, respectively. The higher the coefficient of determination, the higher the proportion of variation of the dependent variable is interpreted by the independent variable. (25,26) For S2PD, this indicates a very poor correlation, and just 13% of the data is explained, which means that for recovery of sensibility, there is very little evidence to support a relationship between Semmes

Weinstein monofilament testing and 2-point discrimination. For M2PD, 55% of the variation in the dependent variable is explained by the independent variable. (Figure 2)

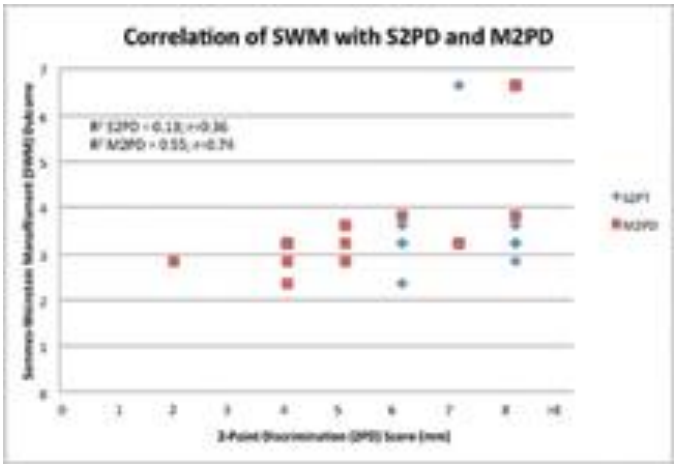

Figure 2. Comparisons of Semmes-Weinstein monofilament testing with static- and moving 2-point discrimination by repair. The linear coefficients of determination (R^2) for S2PD and M2PD were 0.13 and 0.55, respectively.

As anticipated the 2-point discrimination measures showed little correlation to the monofilament testing.

No postoperative complications such as infection or graft rejection occurred. One patient underwent an additional surgery for a 2-stage tendon reconstruction after failed primary tendon repair on the same digit as the nerve allograft, but the nerve allograft was not exposed during that procedure.

Debate exists about the best material and technique to repair digital nerve defects. One advantage of allografts compared to nerve conduits is the similarity between allografts and autografts in terms of 3-dimensional macro- and microstructure. Whitlock et al (16) compared Avance® processed allografts to type 1 collagen conduits and isografts (autograft) in a rat model. They demonstrated that processed allografts were superior to conduits for short (14 mm)

and long (28 mm) nerve gaps. Nerve conduit provides a hollow macrostructure and allows for collection of fibrin within the inner chamber to serve as the scaffold for axonal regeneration towards the distal stump. It lacks the internal microstructure and extracellular matrix of native nerve tissue. Whitlock et al (16) suggested that the basal laminal internal structure retained by advances in allograft processing enhances its nerve regeneration potential. A subsequent study quantified the nerve fiber density between allograft, nerve conduits, and isograft. Nerve conduits exhibited a consistent decrease in midgraft density compared to allografts and isografts for both short and long graft models. In addition, the nerve fibers were distributed in an unorganized pattern for conduits, whereas allografts and isografts demonstrated evenly distributed nerve fiber regeneration. (13)

One limitation of the current study is the small sample size. An unblinded, hand therapist collected all outcome data, thus, it is impossible to quantify the impact of observer bias on the results. Future investigation with prospective randomized studies to compare allografts to nerve conduits would further delineate the value of these techniques. In addition, the performance of nerve allografts to bridge motor nerve gaps longer than 20 mm would further delineate the indications for this type of graft.

Pricing for processed Avance® nerve allograft is comparable to hollow-tube collagen conduits and is less than the costs associated with autograft harvest (including additional operating room time, physician time, and anesthesia time). At one of the hospitals where this series' nerve reconstructions were performed, Avance® nerve graft cost approximately $1550 for all lengths, and the estimated cost of similar lengths of collagen conduit ranged from $1,385 to $1470. The added expense that autograft harvest adds to a procedure can easily exceed the cost of off-the-shelf processed nerve allograft or hollow-tube conduit. Estimated OR cost per minute varies greatly from hospital to hospital, but published costs of operating room time (27) ranges from $65 - $166 per minute exclusive of physician and anesthesia fees.

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Table 1. Nerve Repair Patient Data

Sex	Affected Side	Mech Inj	Digit	Nerve Injured	Gap Length (mm)	Final Follow-Up (mos)	S2PD	M2PD	SW (gm)	Initial Pain	Final Pain	Initial QuickDASH Score	Final Quick DASH Score	Difference in QuickDASH
male	Dominant	Ceramic	Thumb	RDN	10	25	8	4	.17	5	1	27.3	2.3	25.0
				UDN	10	25	8	4	.17	5	1	27.3	2.3	25.0
male	Nondominant	Knife	Small	UDN	10	15	5	4	.08	1	1	2.3	2.3	0.0
Male	Nondominant	Circular saw	Thumb	UDN	10	12	7	5	.17	2	1	65.9	43.2	22.7
Male	Dominant	Circular saw	Small	UDN	6	12	6	4	2.36	3	1	29.5	22.7	6.8
Male	Dominant	Saw	Long	UDN	17	23	8	8	279	5	8	79.5	50.0	29.5
Male	Nondominant	Circular saw	Small	UDN	28	13	8	8	.45	7	1	34.1	11.4	22.7
Male	Dominant	Sheet metal	Index	RDN	10	16	8	6	.45	3	3	56.8	43.2	13.6
Male	Nondominant	Table saw	Thumb	RDN	10	12	6	4	.17	3	1	43.2	36.4	6.8
				UDN	10	12	6	4	.17	3	1	43.2	36.4	6.8
male	Dominant	Glass	Thumb	RDN	10	12	8	5	.22	4	2	61.4	38.6	22.8
				UDN	10	12	6	5	.22	4	2	61.4	38.6	22.8
Male	Nondominant	Knife	Index	RDN	5	12	5	2	.08	8	1	11.4	6.8	4.6
Male	Nondominant	Glass	Ring	RDN	12	15	7	8	279	10	1	65.9	18.2	47.7
Male	Dominant	Tape measure	Index	RDN	7	17	8	7	.17	5	2	61.4	34.1	27.3
				RDN	5	17	8	7	.17	5	2	61.4	34.1	27.3
Male	Dominant	Steel cable	Index	UDN	30	12	8	8	279	4	4	29.5	27.3	2.2
male	Dominant	Glass	Small	UDN	5	12	8	5	.08	5	1	44.5	26	18.5
					11	**15**	**7**	**5**		**5**	**2**	**44.8**	**26.3**	**18.4**

Table 2.

Taras and Weber Grading Scales for 2-Point Discrimination

	Taras			Weber		
Grade	**Moving 2-Point Discrimination (mm)**		**Static 2-Point Discrimination (mm)**	**Moving 2-Point Discrimination (mm)**		**Static 2-Point Discrimination (mm)**
Excellent	≤ 4	or	≤ 6	≤ 4	or	≤ 6
Good	5 - 7	or	7	5 - 7	or	7 - 15
Fair	8	or	8			
Poor	>8	and	> 8	≥8	or	≥16