Is Nerve Regeneration after Reconstruction with Collagen Nerve Conduits Terminated after 12 months? The Long-Term Follow-Up of Two Prospective Clinical Studies

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Abstract

Background Long-term follow-up data of digital nerve reconstructions with nerve conduits are limited. Furthermore, it is not known whether nerve regeneration after tubulization is terminated after 12 months, or whether improvement can be expected after this period of time. Therefore, we present the long-term follow-up of two prospective clinical trials.

Patients and Methods We invited 45 patients who were enrolled in two prospective clinical trials for long-term follow-up. All patients underwent digital nerve reconstruction with conduits made from bovine collagen I due to a gap length of < 26 mm. Sensibility was assessed using static and moving two-point discrimination and monofilament testing. Follow-up data of 1 week, 3, 6, and 12 months, and the current examination were available. Improvement of sensibility was investigated by comparison of the American Society for Surgery of the Hand classification score at 12-month follow-up with the score raised at current examination.

Results We examined 20 reconstructed nerves in 16 patients with a mean follow-up of 58.1 months (range, 29.3–93.3 months). We found an improved sensibility at current follow-up compared with the 12-month follow-up in 13 cases. Three cases had the same values whereas four cases had worsened sensibility. Improvement of sensibility was associated with a significantly shorter nerve gap length with significantly better results if the gap length was < 10 mm.

Conclusion Our results provide evidence that the long-term recovery of sensibility after digital nerve tubulization depends on the nerve gap length with better results in those < 10 mm. Nerve regeneration after tubulization seems not to be terminated after 12 months.

Keywords
- nerve injury
- digital nerve reconstruction
- nerve regeneration
- nerve conduit
- collagen I conduit
- hand

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Injuries of peripheral nerves are common in trauma and hand surgery and appear more frequently if the upper extremity is affected.[1] In approximately 10% of all hand injuries that require surgical treatment, nerves are injured.[2] The consequences might be sensibility deficits and temporary or permanent paresis of the innervated muscles. Sick leave and partial or even permanent total employment disability may have severe socioeconomic consequences for the patient and society.[3,4] The proper and common digital nerves are the most frequently injured nerves if the upper extremity is affected.[2,5] The gold standard for nerve reconstruction after complete transection is the direct end-to-end coaptation of the nerve stumps, assuming it can be performed without tension. This accounts for approximately 82% of the cases.[6] In the remaining 18%, the gap between the nerve stumps is too wide for tensionless coaptation, necessitating nerve reconstruction by means of grafting or tubulization.

There are several studies on the conduit repair of digital nerve lesions that demonstrate good clinical outcomes.[7–11] Some of these studies have a mean follow-up of 20 to 31 months. However, most authors only present 12-month data. No long-term follow-up data of more than 31 months in average are available for patients who underwent digital nerve reconstruction with artificial hollow conduits. Furthermore, it is not clear if a longer follow-up can be associated with a better outcome.

We are presenting long-term results of two prospective clinical studies on digital nerve reconstruction with collagen nerve conduits with a mean follow-up of 58.1 months. The purpose of this study was to investigate whether nerve regeneration after tubulization is terminated after 12 months, or whether patients can expect further improvement after this period of time.

Patients and Methods

The study populations of two prospective clinical studies on digital nerve reconstruction with collagen nerve conduits were followed up in this study.[11,12] The first study included 15 nerve lesions in 14 patients, which were reconstructed between July 2004 and November 2006 at one institution.[12] The second study included 49 digital nerve lesions in 40 patients who underwent the same procedure between May 2007 and September 2011 in two study centers.[11] Only common and proper digital nerves of the hand with a gap length equal to or less than 26 mm were reconstructed. Both the studies were approved by the local ethical review boards. The inclusion and exclusion criteria are listed in the original publications.

Nerve Tubes

For both the studies, NeuraGen nerve conduits made from bovine collagen I were used (Integra Lifesciences, Plainsboro, NJ). Maximum conduit length of 30 mm and a minimum overlap of 2 mm on each side limited gap length to 26 mm. The semipermeable tubes are made from bovine tendon and are available in different diameters ranging from 1.5 to 7 mm. In both the studies, we only used conduits with an internal diameter of 2 or 3 mm. In a moist state, wall thickness is precisely 0.5 mm. Conduits are soft, pliable, and have shown to be completely degraded within 36 months after insertion in monkeys.[13] All operations were conducted by microsurgically trained plastic surgeons.

Operative Procedure

The operating microscope was used in all operations. The exposure of the severed nerve ends, as well as repair of concomitant injuries to the hand, was performed under tourniquet control. This had to be released (followed by meticulous hemostasis) before insertion of the nerve ends into the conduit to prevent bleeding into the lumen because the formation of a blood clot inside the tube might be detrimental to nerve regeneration. After accurate debridement, proximal and distal nerve endings were inserted into the conduit with an overlap of approximately 3 mm. To remove potentially remaining blood clots from the conduit, the lumen was rinsed with normal saline after each suture, which was usually performed with one 9–0 nylon suture in a horizontal mattress fashion through the conduit and epineurium at both sides. We administered a single-shot of 1.5 g cefuroxime intravenously to prevent infection. The adjacent joints were immobilized for 14 days. In the case of concomitant tendon repair, early mobilization was performed.

Patients

We invited all patients who were included in these two studies and had a 12-month follow-up documented (45 patients), for a follow-up visit. We were able to examine 20 reconstructed nerves in 16 patients who appeared for follow-up (9 nerves [8 patients] and 11 nerves [8 patients], respectively in the two centers; 3 nerves [3 patients] and 17 nerves [13 patients], respectively from study populations of the first and second study) (►**Table 1**). The mean follow-up time was 58.1 months (range, 29.3–93.3 months). The male-to-female ratio was 12:4 (75% male). The mean age at the time of operation was 40.0 years (range, 20–75 years). The dominant hand was affected in 15% of the cases. The index finger was affected most often (39%), followed by the thumb and ring finger (25% each) and the middle finger (11%). Cut injuries were reported in 75% and crush injuries in 25%. The mean gap length after debridement was 11.0 mm (range, 6–25 mm) and the mean distance of the proximal coaptation to the fingertip was 72.1 mm (range, 45–100 mm). We found a mean conduit length of 16.2 mm (range, 10–30 mm). The ratio primary versus secondary treatment was 85 to 15%.

Sensibility Testing

Sensibility was assessed by one examiner at each study center using static and moving two-point discrimination (s-, m2PD) and monofilament testing. For 2PD tests, we used the Mackinnon/Dellon Disk-Criminator (Mackinnon-Dellon Partnership, Baltimore, MD). Modified guidelines of the American Society for Surgery of the Hand (ASSH) were used to stratify the 2PD measurements (excellent, $<$ 6 mm; good, 6–10 mm; fair, 11–15 mm; poor, $>$ 15 mm; failure, anesthetic).[14] Furthermore, 2PD of the uninjured contralateral finger was

Table 1 Patient demographics, types of injury, treatment, and follow-up in our cohort of patients

Patient	Case	Sex	Age	Injured hand	Injured nerve	Gap (mm)	Tube (mm)	Type of injury	Distance FT (mm)	Treatment	Follow-up (mo)
1	1	M	42	L	4	10	14	Cut	55	Primary	75.5
2	2	M	38	R	3	8	12	Cut	65	Primary	77.1
3	3	M	38	L	3	15	25	Cut	70	Primary	74.8
4	4	M	22	L	6	25	30	Contusion	100	Primary	54.4
	5			L	7	15	20	Contusion	100	Primary	54.4
5	6	M	29	L	7	6	18	Cut	60	Primary	68.3
6	7	M	20	R	4	9	15	Cut	95	Primary	84.3
7	8	M	65	L	4	16	19	Cut	75	Primary	86.3
8	9	W	63	L	1	12	17	Cut	62	Secondary	93.3
9	10	M	30	L	3	9	15	Cut	75	Primary	31.3
10	11	M	30	L	1	8	13	Contusion	90	Primary	52.6
	12			L	2	12	18	Contusion	90	Primary	52.6
	13			L	3	8	16	Contusion	75	Primary	52.6
11	14	W	68	L	7	13	16	Cut	65	Secondary	41.4
12	15	W	25	R	8	10	10	Cut	45	Primary	30.7
13	16	W	73	L	6	7	11	Cut	60	Primary	47.9
14	17	M	28	L	1	6	12	Cut	50	Primary	29.3
	18			L	2	6	12	Cut	50	Primary	29.3
15	19	M	45	L	3	13	17	Cut	85	Secondary	65.1
16	20	M	75	L	7	11	15	Cut	75	Primary	61.6

Abbreviations: FT, fingertip; L, left; M, man; R, right; W, woman.
Note: Distance FT is the distance from the proximal coaptation to the fingertip.

assessed and the difference of injured and uninjured nerve was calculated to form a Δ2PD to avoid bias by interindividual differences in normal sensibility. A score developed by the authors was used to classify the Δ2PD values (excellent, < 3 mm; good, 3–7 mm; fair, 8–12 mm; poor, > 12 mm, but protective sensibility; failure, anesthetic). To develop this classification, we oriented ourselves by the stratification of the well-known ASSH classification and subtracted 3 mm in each category.

The three patients with three reconstructed nerves of the first clinical study had no 2PD of the uninjured contralateral finger documented at 12-month follow-up. Furthermore, those three patients had only the s2PD, but no m2PD documented.

Calculation of the changes in 2PD from 12 months to the current follow-up can be problematic if the 2PD is > 15 mm and thus not measureable. We therefore decided to compare the patient's ASSH classification score at the 12-month follow-up with the score raised at current examination.

The examiners at the 12-month follow-up visits were different from the examiners at current follow-up. Therefore, we performed the same analysis using the scores of Δ2PD values in the classification system described above with the idea of minimizing this potential bias.

Monofilaments with calibrated pressure of 0.07, 0.4, 2, 4, and 10 g were used (Touch-Test Sensory Evaluator, North Coast Medical, Inc., Morgan Hill, CA). For the lowest reported monofilament, inconsistent or consistent (100%) detection of monofilament touch was reported. Sensibility testing was performed without digital nerve block for the concomitant palmar nerve of each finger.

Statistics

The two-tailed unpaired *t*-test was used to calculate differences between the two groups of nerves with gap lengths under 10 mm and of 10 mm and above, respectively. The two-tailed paired *t*-test was used to calculate differences of classification system scores at different time points of follow-up. The exact Wilcoxon–Mann–Whitney rank sum test was used to look for significant correlation between possible influencing factors and outcome scores.

Results

When we compared s2PD values of the current follow-up with those of the 12-month follow-up, we found an improvement in static 2PD in 13 nerves (65%). The mean follow-up for these cases was 55.1 months (range, 29.3–84.3 months) and the mean gap length was 8.8 mm (range, 6–15 mm). The mean distance to the fingertip was 72.3 mm (range, 50–100 mm). The improvement of sensibility in these 13 cases, by means of the ASSH score, was statistically significant ($p < 0.001$).

Three nerves showed the same values for sensibility, four nerves demonstrated worsened sensibility (mean deterioration 1.75 mm; range, 1–3 mm) compared with the 12-month visit. In these seven cases who did not show improved values, the mean follow-up time was 63.7 months (range, 30.7–93.3 months). Interestingly, we found a significantly longer mean gap length of 14.9 mm (range, 10–25 mm) in these cases compared with the nerves with an improvement of sensibility ($p = 0.002$). The mean distance from the proximal coaptation to the fingertip was 71.7 mm (range, 45–100 mm), and therefore was comparable to the whole cohort and the cases with improved sensibility. The same applied to the mean age of the groups.

The mean s2PD of all 19 reconstructed nerves with measurable sensibility at current follow-up was 6.8 mm (range, 3–15 mm), one nerve had no measurable s2PD.

►**Fig. 1** shows the return of sensibility according to the modified guidelines of the ASSH using the static 2PD values of the 20 cases at different time points of follow-up.

Furthermore, we found the improvement of sensibility, by means of improvement in ASSH score, in nerves with a gap length under 10 mm ($n = 9$) to be significantly higher when compared with nerves with a gap length of 10 mm or more ($n = 11$) ($p < 0.001$). The mean distance of the proximal coaptation to the fingertip and the mean age of the cases with gaps less than 10 mm were 68.9 mm (range, 50–95 mm) and 34.0 years (range, 20–73 years), respectively. The same parameters for the other group were 74.7 mm (range, 45–100 mm) and 45.0 years (range, 25–75 years), respectively.

When we conducted the analysis using the static Δ2PD instead of the 2PD values, we found nine nerves (56%) with improved sensibility compared with the 12-month follow-up. The mean distance from the proximal coaptation to the fingertip was 68.9 mm (range, 50–90 mm). Mean follow-up for these cases was 49.7 months (range, 29.3–74.8 months) and the mean gap length was 8.9 mm (range, 6–15 mm). The improvement in these nine cases, by means of the change in the score in our Δ2PD classification (►**Fig. 2**), was statistically significant ($p = 0.003$). Three nerves showed the same sensibility values as 12 months after the operation and five nerves demonstrated worsened values (mean deterioration, 1.60 mm; range, 1–3 mm). These eight cases had a mean follow-up time of 56.4 months (range, 30.7–77.1 months) and a mean gap length of 12.8 mm (range, 8–25 mm). The mean distance from the proximal coaptation to the fingertip was 73.8 mm (range, 45–100 mm) in these cases.

►**Fig. 2** shows the return of sensibility according to our classification using the static Δ2PD values at different time points of follow-up.

►**Fig. 3** demonstrates the results of monofilament testing at different time points of follow-up.

The analysis using m2PD values did not provide further information. We did not observe significant differences in sharp versus crush injuries or the dominant versus nondominant hand involved. Furthermore, we did not observe a significant influence of patient's age, sex, smoking habits, study center, and primary versus secondary reconstruction.

Discussion

The direct and tension-free nerve coaptation is still the gold standard for reconstruction after complete transection of a nerve.[15] However, in some cases the gap between the nerve stumps is too long due to tissue loss or retraction of the nerve endings. These patients require alternative reconstruction

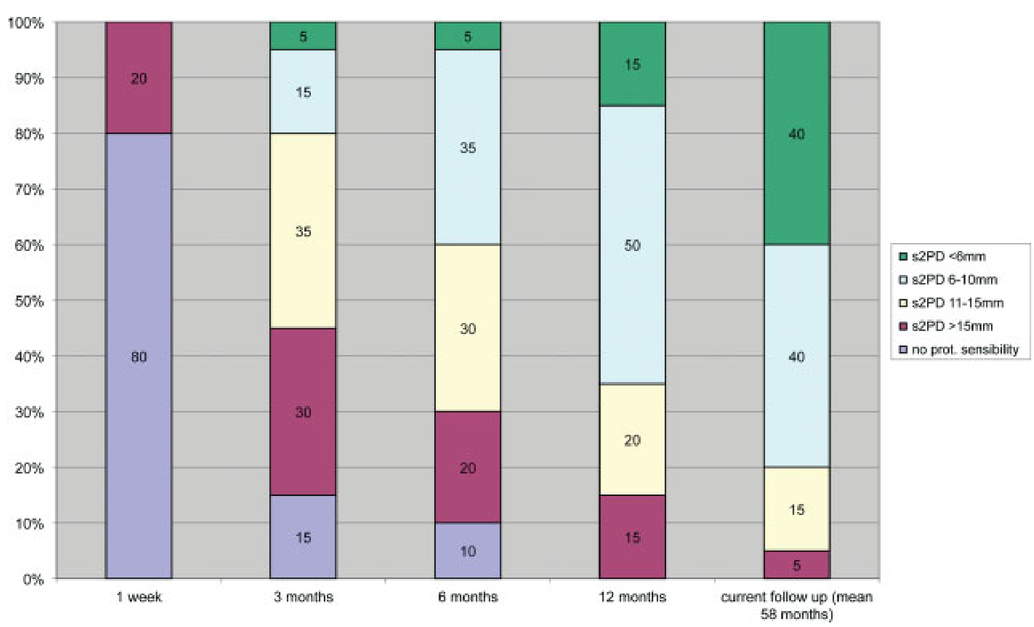

Fig. 1 Return of sensibility according to the modified guidelines of the American Society for Hand Surgery. Continuous progress is seen until the last examination at current follow-up. Note the increase in the percentage of cases with excellent sensibility (s2PD < 6 mm) between 12 months and current follow-up. prot, protective; s2PD, static two-point discrimination.

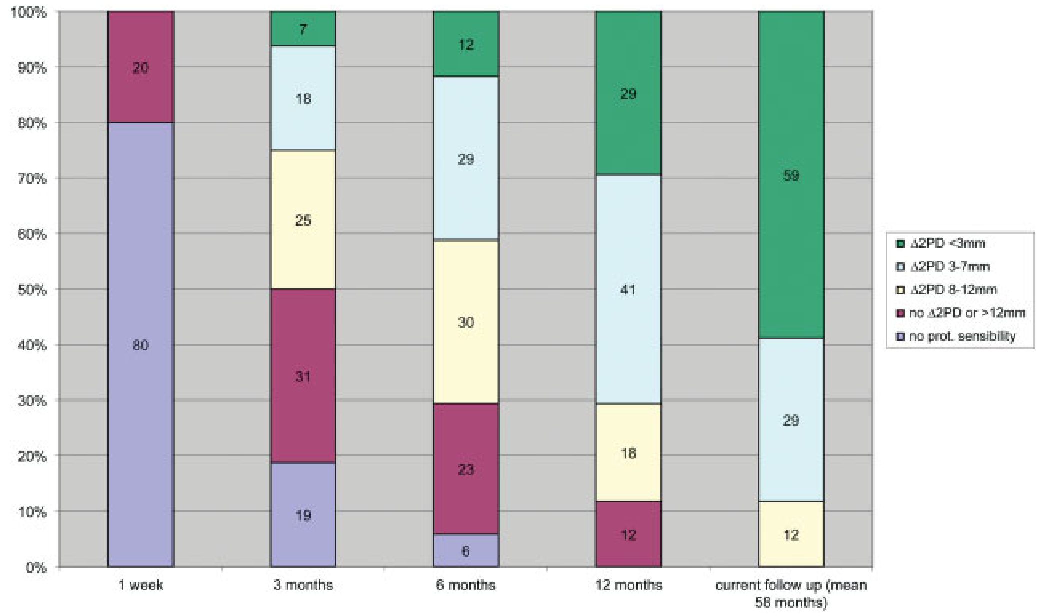

Fig. 2 Δ2PD (difference of the static 2PD of injured and uninjured contralateral digit) at the five follow-up visits. Results are classified in Δ2PD $<$ 3 mm, 3–7 mm, 8–12 mm, $>$ 12 mm with and without protective sensibility. Note the increase in the percentage of cases with excellent sensibility (Δ2PD $<$ 3 mm) between 12 months and current follow-up. prot, protective; 2PD, two-point discrimination.

techniques including the nerve autograft, which remains the gold standard for this indication.[16] However, the donor site morbidity caused by graft harvesting and the limited availability of suitable nerves necessitate alternative techniques. In the last 10 to 15 years, artificial nerve conduits have been established. Several studies have demonstrated favorable outcome of digital nerve reconstructions using different types of conduits.[7–11,17–22]

The return of sensibility after nerve reconstruction using collagen I conduits was investigated by Taras et al in 21 nerves.[7] The authors found an m2PD in all patients of at least 8 mm; the mean follow-up was 20 months.

In contrast to that, a recent study by Haug et al reports a high failure rate (static 2PD $>$ 15 mm) of 60% after nerve reconstruction with collagen I conduits (NeuraGen) in 42 patients with a follow-up of 12 months.[20]

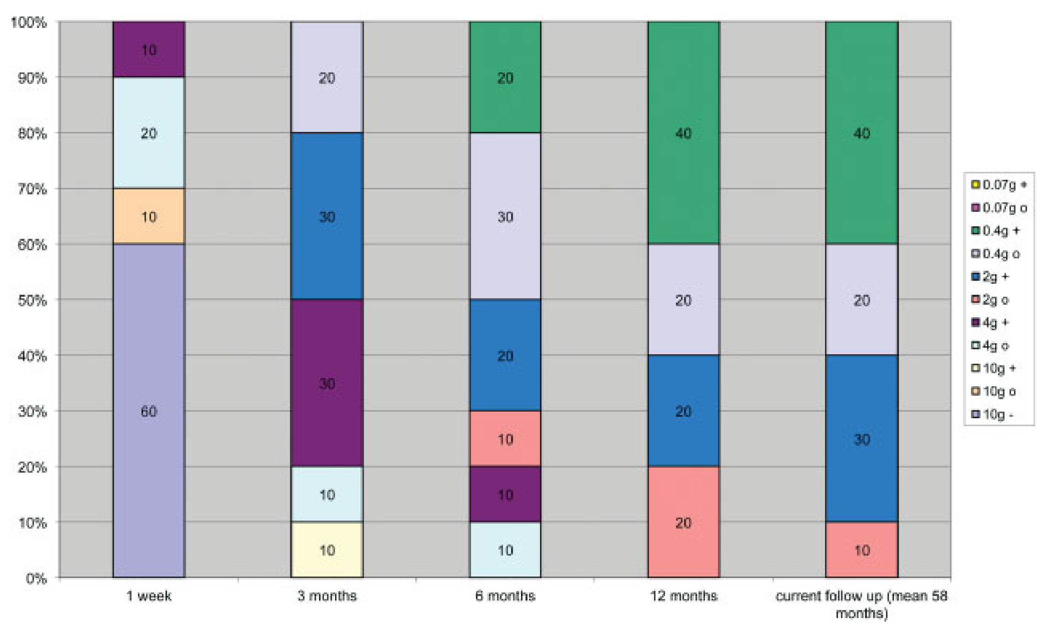

Fig. 3 Monofilament test results at the five follow-up visits. " $+$ " indicates that the specific stimulus is always recognized. "o" indicates that the stimuli are infrequently recognized. "-" indicates no recognition.

Lohmeyer et al reconstructed 49 nerves in 40 patients with the same collagen I conduit (NeuraGen) and recently published the 12-month follow-up results of 40 nerves.[11] The authors demonstrated excellent or good sensibility according to the ASSH classification in 20 reconstructed nerves. Five cases had fair, six cases poor, and nine cases had no sensibility. A gap length shorter than 12 mm was associated with significantly better sensibility in monofilament testing compared with gap lengths of 12 mm or more. The authors also reviewed and analyzed the literature and commented that 80% of the digital nerve repairs with artificial conduits recover some degree of sensibility.[11] These studies demonstrate that tubulization is one possible technique in nerve reconstruction for gap lengths of 5 to 25 mm. However, most of the studies present follow-up data of up to 12 months. Single studies report mean follow-up periods between 20 and 31 months.[7,10,19,23] To the best of our knowledge, there is no study available that followed up patients over a period of 50 months on average or more. Furthermore, it has not yet been specifically investigated if the status of sensibility 12 months after nerve conduit implantation is the final result of nerve regeneration, or if further improvement can be expected.

When we reviewed the studies that present outcomes after digital nerve reconstruction using nerve conduits, we found no clear relationship between the mean time of follow-up and the recovery of sensibility. Possible influencing factors such as mean age and gap length were comparable for most studies. Battiston et al presented a mean follow-up of 31 months after reconstruction of 18 digital nerves with polyglycolic acid conduits.[10] In six cases (33%), the authors found no measurable 2PD at the final follow-up visit. Chiriac et al found no measurable 2PD in six of eight nerves (75%), reconstructed with a conduit, after a mean follow-up of 27 months.[23] In this study, we found no measurable 2PD only in 5% of the patients.

Many of the studies reviewed have major limitations such as a small sample size. Thus, comparability of outcomes is difficult. Meek and Coert and Lohmeyer et al provide reviews over these studies, their outcome, and limitations.[11,21]

We present a cohort of 20 reconstructed digital nerves in 16 patients with a mean follow-up of 58.1 months to overcome these shortcomings.

Our study demonstrates that sensibility after digital nerve reconstruction with a collagen I conduit seems to continue to improve beyond 12 months in a majority of cases. We found significant improvement of static 2PD in 13 out of 20 reconstructed nerves between the 12-month and the current follow-up (mean, 55.1 months). Three cases experienced no change in sensibility and four cases had worsened sensibility in current follow-up. The reason for a decrease of sensibility in these cases is not clear. Two out of these four nerves had a worsening of 1 mm, which might be due to an assumed measuring inaccuracy of 1 mm. The two other cases experienced deterioration of 2 and 3 mm, respectively.

We observed a significantly higher improvement of sensibility in nerves with a gap length of less than 10 mm, compared with those having a gap of 10 mm and more. Accordingly, the 13 cases who experienced improvement of static 2PD between 12 months and the recent follow-up had a significantly shorter gap length than the seven cases who had equal or worse sensibility. Besides Lohmeyer et al, the group of Weber et al demonstrated decreased 2PD with increasing gap length.[11,17] Rinker and Liau were able to confirm a tendency for better results with gaps of < 10 mm versus ≥ 10 mm.[18]

►**Figs. 1** and **2** illustrate that the number of cases who regained excellent sensibility (2PD < 6 mm or Δ2PD < 3 mm, respectively) increased between the 12-month follow-up and the current examination. This might indicate that the maturation of the nerve after reconstruction with nerve conduits still takes place beyond 12 months postoperatively.

Interestingly, 3 out of the 20 nerves in our study had no measurable sensibility (2PD) at the 12-month follow-up. Of those, two cases with gap lengths of 7 and 6 mm, respectively, regained sensibility (follow-up 47.9 and 29.3 months). The case that still had no measurable sensibility at current follow-up (86.3 months) had a gap length of 16 mm.

Two grading systems are mainly used for the classification of sensibility after nerve reconstruction: the Medical Research Council[24] and the modified ASSH guideline.[25] However, we feel that these classifications might be problematic due to the fact that they do not take the patient's age into consideration. In a recent study, we found evidence that normal sensibility deteriorates with age and that interindividual differences are high, especially in seniority.[26] Therefore, we chose to include sensibility testing of the uninjured contralateral nerve and calculate the difference of the s2PD of the injured to the healthy contralateral side to form the static Δ2PD. The use of the Δ2PD might also minimize the bias of different examiners at different points of follow-up. Small differences in the way of 2PD testing might be of minor consequence if Δ2PD values are compared instead of 2PD values.

This study indicates that gap length may play an important role in long-term recovery after nerve reconstruction with nerve conduits. We assume that especially nerves with a gap length of < 10 mm might expect further improvement of sensibility 12 months postoperatively. We further found evidence that cases with short gap lengths, who have no sensibility 12 months after the tubulization, might expect to regain sensibility later.

Conclusion

This study provides evidence that the nerve gap length seems to be of importance for the long-term recovery of sensibility after digital nerve tubulization. Especially in patients with a nerve gap length of < 10 mm, who undergo digital nerve reconstruction with a collagen I tube, the recovery of sensibility may indeed not be terminated after 12 months.

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