A CLINICAL MULTI-CENTER REGISTRY STUDY ON DIGITAL NERVE REPAIR USING A BIODEGRADABLE NERVE CONDUIT OF PGA WITH EXTERNAL AND INTERNAL COLLAGEN SCAFOLDDING

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BACKGROUND

In this study, we evaluated the clinical efficacy of a biodegradable nerve conduit constructed of polyglycolic acid (PGA) tube with external and internal collagen scaffolding (Nerbridge®, Toyobo Co., Ltd, Osaka, Japan) for digital nerve repair.

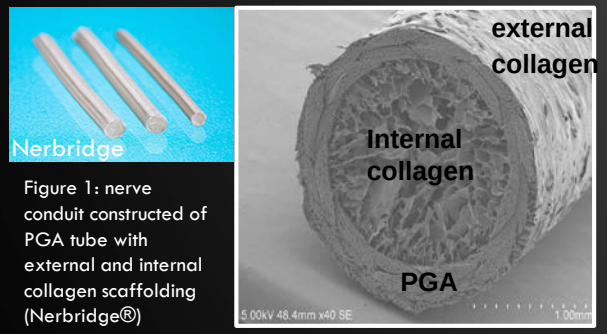
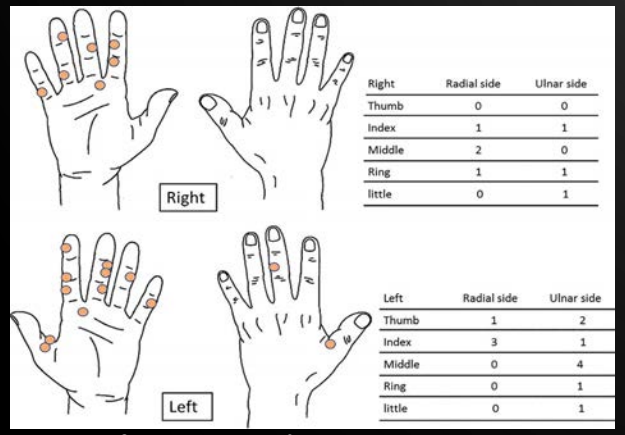


Figure 1: nerve conduit constructed of PGA tube with external and internal collagen scaffolding (Nerbridge®)



Right	Radial side	Ulnar side
Thumb	0	0
Index	1	1
Middle	2	0
Ring	1	1
little	0	1

Left	Radial side	Ulnar side
Thumb	1	2
Index	3	1
Middle	0	4
Ring	0	1
little	0	1

Figure 2: Distribution of nerve injury site

PATIENTS AND METHODS

A multi-center registry study was conducted in 11 locations between July 2013 and May 2016. Multiple mechanisms of injury included clean-cut (12 patients), crush (5 patients), and avulsion (3 patients) types of injuries. These patients underwent nerve repair with a biodegradable nerve conduit, with 9 patients having a primary repair and 11 patients having delayed repair. Average nerve gap was 16.7 mm (range: 1–50 mm). An average of 13 months follow-up (range: 12–15 months) was available including sensory assessments.

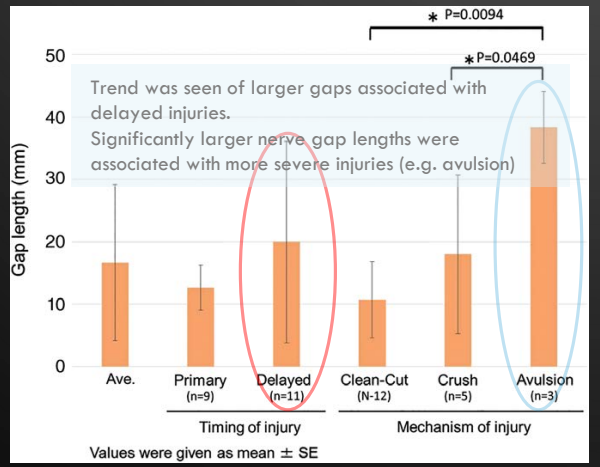


Figure 3: Graph of nerve gap lengths

RESULTS

Improved s2PD was found with less severe injury as in clean-cut (7.5 ± 1.5 mm), which was statistically significant in comparison to those in crush (9.8 ± 1.9 mm, $P = .0384$) and in avulsion (10.7 ± 4.7 mm, $P = .0013$) type injuries.

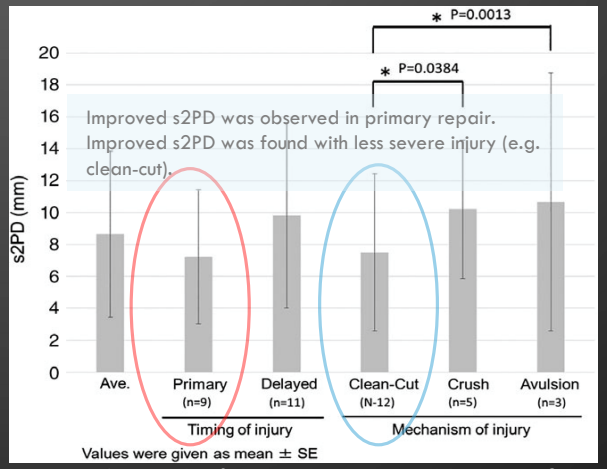


Figure 4: Graph of outcomes measured by static 2PD

A meaningful recovery (S3+ or S4) was observed in 90% of the 20 digital nerve repairs with a biodegradable nerve conduit of PGA with external and internal collagen scaffolding. Avulsion injuries had significantly lower levels of meaningful recovery (67%) in comparison to those of clean-cut ($P = .0291$) and crush ($P = .0486$) types of injury. No adverse effects were reported postoperatively.

Table 1: Meaningful Recovery Rate (≧S3+: s2PD=7-15mm)

Average	90%
Timing of nerve repair surgery	
Primary	100%
Delayed	82%
Mechanism of injury	
Clean-cut	92%
Crush	100%
Avulsion	67%

These outcomes were attained despite the high incidence of complex injuries (5 crushes, 3 avulsions) and 11 delayed nerve repairs, which are associated with poorer outcomes.

CONCLUSION

These results indicate that a biodegradable nerve conduit of PGA with external and internal collagen scaffolding is suitable for digital nerve repair of short nerve gaps with high levels of sensory recovery as measured by two-point discrimination that yields potentially superior results in comparison to previous hollow biodegradable nerve conduit constructs (Battiston et al., 2005; Lohmeyer et al., 2014; Weber et al., 2000), and equivalent results to those using processed allogenic nerve graft materials (Cho et al., 2012; Rinker et al., 2015).