Nerve reconstruction

Results of a nerve generation guide from human umbilical cord vessels in the treatment of nerve sections in the hand

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Introduction

In peripheral nerve injuries with nerve gaps, the use of nerve allografts or neurotubes can be applied. NerVFIX® is an allograft of umbilical cord vessels that are turned inside-out, and have an inner coating made of Wharton's jelly, a gelatinous substance within the umbilical cord, rich in hyaluronic acid. The product is subjected to the AMTRIX process, combining chemical treatment, lyophilization and sterilization. The object of this multicentric and prospective phase II clinical trial, is to evaluate the nervous regeneration after nerve section in humans.

Materials and methods

The study was conducted in 5 centers in Belgium and France, between January 2018 and June 2019. Patients with a nerve section in the hand and a gap between 2 mm to 2 cm with subsequent loss of cutaneous sensitivity (static 2-point discrimination [s2PD] > 15 mm or a score of < S3 according to the Medical Research Council [MRC] scale of sensory recovery), were included. Baseline characteristics were s2PD, moving 2-point discrimination (m2PD) (MRC scale), nerve section symptoms: pain (visual analogue scale [VAS] 0 to 10), cold sensitivity, hyperesthesia, and numbness (score 0 to 4). Pressure sensitivity was evaluated with Semmes Weinstein monofilaments. Functional activity assessments were obtained by a QuickDash questionnaire. Follow-up occurred at 1, 3, 6, and 12 months post-surgery. The hypothesis of obtaining a s2PD < 8mm after 12 months, required an inclusion of minimum of 13 patients, based on a power-based sample size calculation.

Results

Eighteen patients were included between January 22nd, 2018 and March 30th, 2019. The mean age was 38 years (range 19-65), the average delay between injury and surgery was 9 days (maximum 92) and the nervous gap at surgery was 5.4 mm (range 2-20).
At the moment of inclusion, 47% of the patients were S1, 40% were S2, and 13% were S2+ (MRC score of sensory recovery). A mean pain intensity of 4.2 was assessed, using the VAS. All patients had numbness (mean of 3.19). Sixty-seven percent had hyperesthesia (mean 1.35) and 56% had cold sensitivity (mean 1.5) in the cutaneous area affected by the nerve section. Fifty-four percent of the patients were able to feel the monofilament of 200g, while 46% sensed a pressure of 4g.
s2PD (primary criterion) was significantly improved from the nerve section time to Month 12, ($p=0.0036$- Wilcoxon test for matched paired groups) with a mean of s2PD of 7.36 mm+/- 2.2 mm and improvement at 6 months ($p= 0.004$) with a mean of s2PD of 8.06 +/-1.69 mm. Pain (VAS < 0.5 $p<0.05$), numbness, hyperesthesia, cold sensitivity, and QuickDash activity (Mean score < 5, ($p=0.0069$) all improved. At sensory recovery measurement, a mean pressure of 0.2g was assessed ($p=0.013$). Two serious adverse events (SAEs) were reported: one early local infection, and one complex regional pain syndrome (CRPS). These two SAEs were not related to the graft. Sensory recovery was observed in these patients.

Conclusion
NerVFIX proved to be an efficient aid in nervous regeneration in the hand. No complications related to the nerve conduit, were objectified.