Quantification of Regenerative Peripheral Nerve Interface Signal Transmission

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PURPOSE: Amputees prefer body-powered, cable operated prosthetics over those with advanced technology. Our solution is to surgically construct an interface at residual peripheral nerves endings. Regenerative peripheral nerve interface (RPNI) devices are composed of: a) host muscle freely grafted to the residual stump area, b) residual peripheral nerves for neurotizing the muscle, c) implanted recording electrodes, and d) decellularized small intestine submucosa (SIS) wrap. This study's purpose is to quantify signal transmission at RPNI devices in the rat. The hypothesis is: RPNI devices communicate peripheral nerve signaling with capacities approaching Sham devices.

METHODS: F344 rats (n = 29) were randomized into 3 groups. During Sham surgeries, the right soleus muscle was exposed (Sham, n=11). For RPNI not neurotized (RPNI-NN, n=9) and neurotized (RPNI+N, n=9) devices, the left peroneal nerve was divided and the right soleus muscle was transferred to the left thigh simulated residual limb area. For the RPNI+N device, the divided left nerve was used to neurotize the soleus. SIS was wrapped around all devices. Electrodes were implanted at evaluation. Measurements included nerve conduction, force capacity, and histology after 1 or 3 months of convalescence.

	Sham (n=7)	RPNI-NN (n=6)	RPNI-N (n=6)
CMAP Amplitude,(mV)	8.4 ± 2.8 <b>†</b>	1.7 ± 1.0*	4.2 ± 3.4
Stimulus Threshold, (V)	0.41 ± 0.05	1.28 ± 0.71*	1.10 ± 0.66
Area CMAP, (mV*msec)	21.8±8.7	3.1±2.7*	12.8±13.7
Гetanic Force, (mN)	586 ± 166	358 ± 295	789 ± 296 <sup>†</sup>
RPNI mass, (mg)	153 ± 18	111 ± 15*	143 ± 34
Motor Units,(#)	8.3 ± 2.6	3.3 ± 1.7	8.4 ± 6.8
NMJ Density counts/mm2	4.13 x 10 <sup>4</sup>	7.11 x 10 <sup>4</sup>	17.44 x 10 <sup>4</sup> *

RESULTS: Comparisons of RPNI compound muscle action potentials (CMAP), muscle mass, and stimulation thresholds between months 1 and 3 indicated ongoing regeneration and reinnervation. At 3 months, RPNI+N CMAP amplitude, CMAP area, device force, and motor unit number were 50% to 100% those of Sham devices (Table 1). RPNI-NN values were significantly lower than Sham (p<.05). Histology showed RPNI+N contained healthy axons with robust myelination that were organized with muscle fibers.

CONCLUSION: Successful peripheral nerve interfacing which approached sham functioning was achieved through neurotization of regernerative peripheral nerve interface (RPNI) devices.

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