Quantitative Model for Decompression Surgery in Bell's Palsy

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Introduction

- Acute entrapment of the facial nerve in the narrow confines of the temporal bone secondary to viral inflammation may result in high grade neural injury and subsequent aberrant neural regeneration
- Such injury occurs in 15-30% of Bell's palsy patients, resulting in irreversible post-paralysis facial palsy (Fig. 1)
- Clinical data varies regarding efficacy of decompression surgery on facial outcome
- No animal model examining facial nerve entrapment and subsequent decompression has been described

Figure 1. *Post-paralysis right facial palsy.* A: Involuntary eye closure with pucker. B: Neck contraction with smile. C: Impaired oral commissure excursion and involuntary eye closure with smile.

Device Design and Manufacture

- A fully implantable device to induce compression around rat facial nerve was designed for wireless, long-term implantation (Fig. 2)
- Wirelessly relays pressure data hourly to external receiver
- Receiver logs data into SD card or directly to computer, can record multiple device inputs simultaneously.
- All components integrated onto a single printed circuit board (PCB), coated in medical-grade silicone , and gas sterilized (EtO)
- Combined with existing rat model for evaluating facial nerve function based on whisker movements

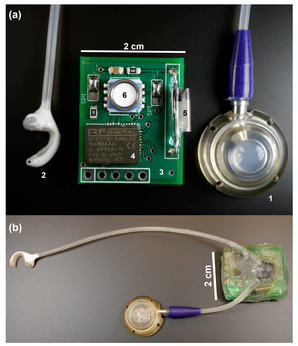

Figure 2. (a) Implant deconstructed without silicone encasement, showing (1) subcutaneous injection port, (2) hydraulic cuff, (3) printed circuit board with (4) microcontroller (Simblee), (5) magnetic switch, and (6) pressure sensor. (b) Implant with parts assembled and encased in silicone. Final weight 10-15g.

In Vivo Validation

- Three animals implanted and pressures maintained in low (0-100mmHg), medium (200-300mmHg), and high (300-500mmHg) ranges for 5 days before decompression, followed for 10 weeks post-decompression or until full recovery observed. Animals sacrificed for nerve staining at 10 weeks.
- No pressurization during first 3 days post-implantation, demonstrated no functional impairment from device placement
- Low-pressure animal maintained full function of nerve, no change in axon count or thickness in nerve proximal, within, or distal to cuff
- Medium-pressure animal showed gradual loss of > 50% function within 1 day of pressure exceeding 250mmHg, with full functional recovery after decompression. Histology suggested partial axonotmesis and regeneration
- High-pressure animal immediately lost function throughout compressive period and only recovered to ~50% function after 10 weeks. Histology showed complete neurotmesis and pervasive regeneration

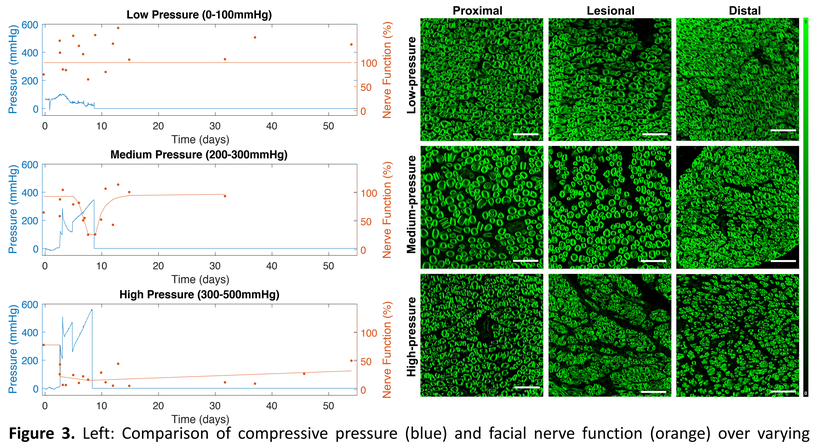

Figure 3. Left: Comparison of compressive pressure (blue) and facial nerve function (orange) over varying applied compressive forces. Low pressure (0-100mmHg) compression did not result in facial nerve functional impairment, while high-pressure (> 300mmHg) showed immediate loss of facial nerve function with significant remaining impairment after 6 weeks of recovery. Gradual, > 50% reduction in facial nerve function was seen at ~250mmHg compression, with full recovery after decompression. Right: Confocal fluorescence imaging of rat facial nerves exposed to low, medium, and high-pressures from implanted pressure cuff. Facial nerve axons exposed to low-pressures showed relatively unchanged axon caliber along the length of the nerve. Medium-pressure application revealed increased axon caliber variability with greater number of regenerating, small caliber axons. With high-pressure, near-complete axonal regeneration is suggested as the vast majority of stained axons are small, regenerating fibers.

Device Validation *Ex Vivo*

- Pressure accuracy and precision within desired range (Fig. 4)
- Device lifespan of more than 9 weeks with 12mm coin cell battery
- Cuff pressure induced and maintained with hypertonic solution injection in subcu port

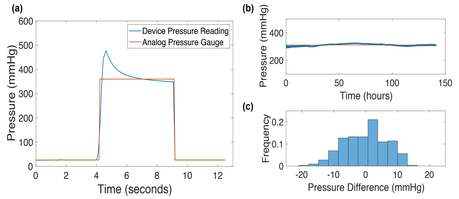

Figure 4. (a) Dynamic pressure monitoring shows return to baseline within two seconds of rapid pressurization. (b-c) Static pressure monitoring held over multiple days (b) shows error less than 20mmHg from analog pressure values (c).

Device Implantation and Removal

- Surgical implantation described in Figure 4. Implant tolerated > 3 weeks without extrusion, inflammation, strong foreign body response, autotomy, or device failure
- Device removed at desired timepoint to simulate decompression surgery

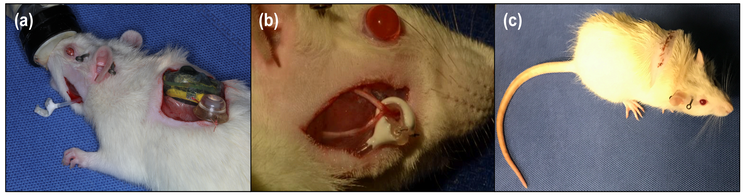

Figure 5. (a) The cuff and device in place before suturing closed, showing device sitting in pocket above scapulae and cuff tunneled through to whisker pad incision. (b) Placement of the cuff around the marginal and buccal branches of the facial nerve. (c) Animal 3 days post-operatively with implant visible on back.

Conclusions

- A low-cost implantable device to apply and monitor extrinsic pressure on a nerve trunk to model entrapment neuropathy has been described
- Quantitative measure of neural compartment pressure *in vivo* may be compared against function in real-time using the rat facial nerve model
- Model able to recapitulate Bell's-like phenomenon in rats, showing both full recovery and poor recovery outcomes