In vivo efficacy of a novel nerve coaptation device as a sutureless alternative for repairing peripheral nerve defects

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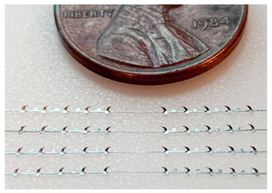
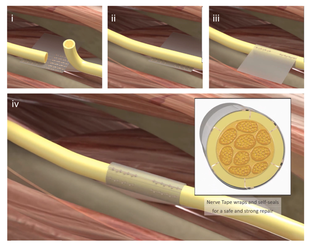
Introduction

- Over 2 million upper extremity injuries occur each year leading to a high volume of peripheral nerve trauma
- Microsuture Neurorrhaphy is the clinical standard for nerve repair, but
  - requires high microsurgical proficiency
  - often fails to provide adequate nerve approximation
- Entubulation using nerve conduits technically improve nerve alignment but still require microsuture placement
- Nerve glues risk dehiscence and lack control over application

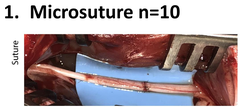
- Nerve Tape is designed to provide an efficient and technically easier, sutureless solution:
  - Arrays of Nitinol microhooks embedded in porcine small-intestine submucosa sheeting (SIS)
  - Microhooks grab outer epineurium to secure nerve ends
  - SIS backing wraps around and entubulates coaptation
- Provides stable, precise alignment

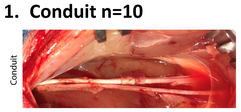


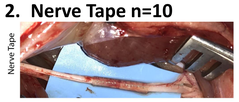


Methods

- Eighteen New Zealand White rabbits underwent *tibial nerve transection* and repair with
  1. Microsuture n=10
  1. Conduit n=10
  2. Nerve Tape n=10



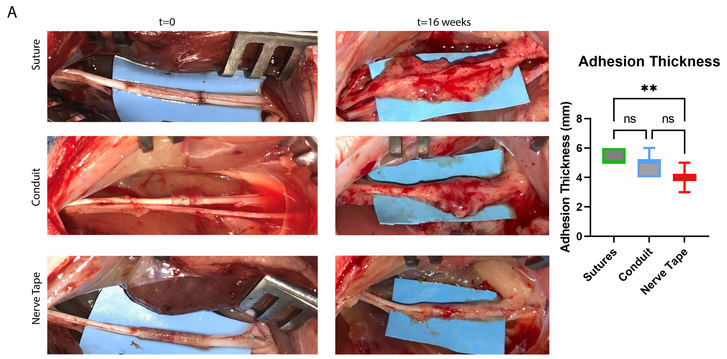




- At 16-weeks post-repair
  - Functional Testing
    - Nerve Conduction Velocity (NCV)
    - Amplitude
  - Muscle Morphology
    - Muscle Mass
    - Muscle Girth
  - Histology
    - Gross Inspection
    - Trichrome Staining
    - Toluidine Blue Staining
      - Axon counts and g-ratio
    - Immunohistochemistry
      - Neurofilament NF-200
      - Myelin P0
      - Macrophages MAC 387

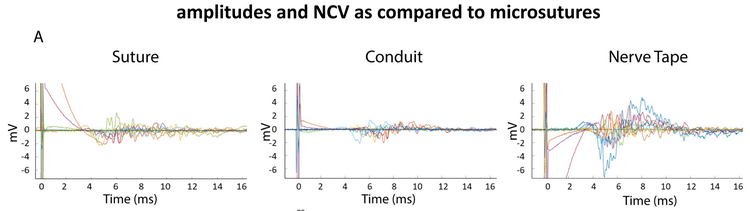
Results

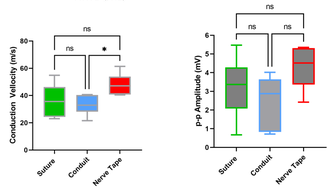
Adhesion response of the nerve tissue to conduit and Nerve Tape were similar, while microsutures induce significantly thicker adhesions as compared to the Nerve Tape



A) Surgical images of repaired nerves at the time of repair and at 16 weeks post-op. B) Adhesion data for repair site as observed at 16 weeks post-repair. (Suture: n=10, Conduit: n=9, Nerve Tape: n=10; ** p<0.01, pairwise w-test)

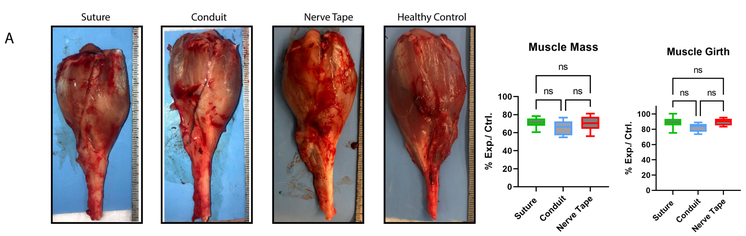
Nerve Tape provides significantly higher NCV than conduits, and similar amplitudes and NCV as compared to microsutures





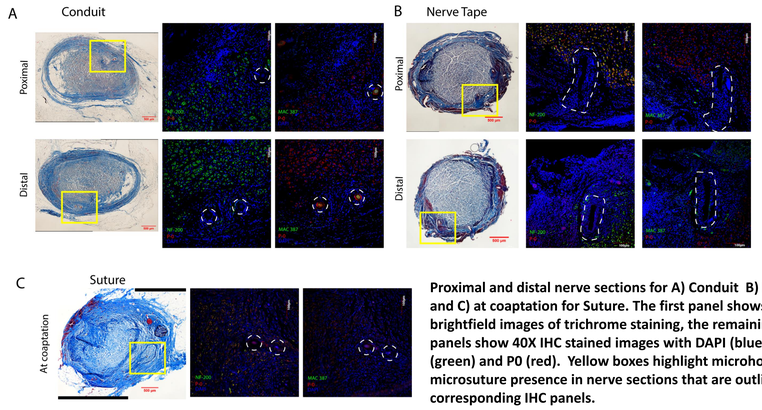
A) Sample compound action potentials seen at 16-weeks post repair. B) Conduction velocity and amplitude of action potentials recorded from different repair groups. * p<0.05

Muscle morphology was equivalent across the three groups



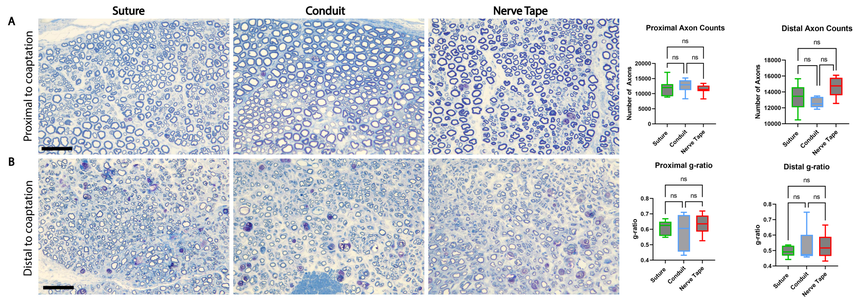
A) Representative gross images of gastrocnemius muscles at 16-weeks post-repair for each group B) Muscle mass and muscle girth comparisons between the repair groups. *ns-non significant*

Nitinol microhooks from Nerve Tape do not damage nerve fascicles, and provide similar axon growth across the coaptation site



Proximal and distal nerve sections for A) Conduit B) Nerve Tape and C) at coaptation for Suture. The first panel shows 4X brightfield images of trichrome staining, the remaining two panels show 40X IHC stained images with DAPI (blue, NF-200 (green) and P0 (red). Yellow boxes highlight microhook or microsuture presence in nerve sections that are outlined in the corresponding IHC panels.

Similar axon counts and g-ratio indicate equivalent axon regeneration in the three repair groups



Toluidine blue stained 40X images for nerve sections A)Proximal and B) Distal to the coaptation for the three groups. C)Axon counts and g-ratio was similar in the three groups at both the proximal and distal locations. Scale bar:50µm

Conclusions

- Nerve Tape supported effective nerve regeneration compared to conduit-assisted and microsuture repairs
- Nerve Tape's microhooks did not damage fascicles
- Nerve Tape provides a consistent, efficient means of sutureless nerve repair
- BioCircuit's microhook technology may be adapted for a range of other tissue repair applications (For MTEC teaming discussions, please contact Isaac Clements: iclements@biocircuit.com)

Acknowledgements

This study was supported by the NIH NINDS R44NS097113 grant. All animal studies were performed in accordance with the Institutional Animal Care and Use Committee (IACUC) at VCU.

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