SUMMARY

Processed nerve allografts have shown clinical benefit in studies for peripheral nerve reconstruction. There are several benefits of this nerve repair option:

- The 3-dimensional structure inherent to the nerve is maintained to provide structural support for regenerating axons.
- The extracellular matrix becomes revascularized and remodeled into the patient’s own tissue.
- Flexibility to choose the appropriate diameter and length to allow for customized peripheral nerve repairs.
- Commercially available, without the complication, expense, and morbidity of nerve autograft.

The benefits and limitations of processed nerve allograft should be carefully evaluated when selecting treatment options for peripheral nerve injuries. Ultimately, clinical judgment should be used to select the method with which a nerve is repaired.

### Historical Literature Reference

<table>
<thead>
<tr>
<th>Study</th>
<th>Year Published</th>
<th>No. of Repairs</th>
<th>Nerve Injury Types</th>
<th>Test Article</th>
<th>Gap Length (mm)</th>
<th>Positive Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wangenstein and Kallioinen²</td>
<td>2001-06</td>
<td>52</td>
<td>Sensory, Mixed Motor</td>
<td>Neurotube¹, Exane Ex Whit C Collagen Tube</td>
<td>2.5-20 (avg. 12.6)</td>
<td>43%</td>
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<tr>
<td>Kim et al.¹⁶</td>
<td>2000-06</td>
<td>52</td>
<td>Mixed</td>
<td>Autograft</td>
<td>2.5-20 (avg. 12.6)</td>
<td>43%</td>
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<tr>
<td>Frykman and Gramyk²</td>
<td>1991</td>
<td>90</td>
<td>Sensory, Mixed Motor</td>
<td>Autograft Direct Suture</td>
<td>—</td>
<td>67-80%</td>
</tr>
<tr>
<td>Frykman and Gramyk²</td>
<td>1991</td>
<td>107</td>
<td>Sensory</td>
<td>Autograft</td>
<td>—</td>
<td>67-80%</td>
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<tr>
<td>Weber et al.³⁷</td>
<td>2000</td>
<td>62</td>
<td>Sensory</td>
<td>Neurotube¹, Exane Ex Whit C Collagen Tube</td>
<td>0-30 (avg. 7.0)</td>
<td>80%</td>
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<tr>
<td>Kallio et al.²⁵</td>
<td>1993</td>
<td>254</td>
<td>Sensory</td>
<td>Autograft Direct Repair</td>
<td>0-30 (avg. 4.3)</td>
<td>74%</td>
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<tr>
<td>Kallio et al.²⁵</td>
<td>1993</td>
<td>254</td>
<td>Sensory</td>
<td>Autograft Direct Repair</td>
<td>10-70</td>
<td>70%</td>
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<tr>
<td>Lohmeyer et al.²⁴</td>
<td>2009</td>
<td>12</td>
<td>Sensory</td>
<td>Neuroflex², Type I Bovine Collagen Tube</td>
<td>6-18 (avg. 12.5)</td>
<td>75%</td>
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</tbody>
</table>

References


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13859 Progress Blvd., Suite 100, Alachua, Florida 32615
**Processed Nerve Allografts**

- Decellularized, cleansed and sterilized extracellular matrix from human peripheral nerves.

**HOW PROCESSED NERVE ALLOGRAFTS WORK**

- **Hours**
  - When implanted, the body begins to revascularize and repopulate the extracellular matrix (ECM) of the processed nerve allograft with cells.

- **Days**
  - Axons begin to cross the ECM scaffold of the processed nerve allograft toward the distal nerve stump. The advancing axons become remyelinated by the Schwann cells.

- **Months**
  - The processed nerve allograft remodels into the patient’s own tissue as the axons continue to move toward their distal end targets.

- **Years**
  - Within the remodeled scaffold, the axons finish their maturation process.

**CLINICAL STUDIES OF PROCESSED NERVE ALLOGRAFTS**

**Brooks et al. Study**
- 12 sites; 25 surgeons; 132 nerve injuries in adult patients
- Largest multicenter study for nerve allograft and peripheral nerve repairs
- Assessed sensory, mixed and motor nerves in gaps between 5 and 50 mm

**Repairs Reporting Recovery by Nerve Type**

- **Sensory**
  - Meaningful Recovery 88.6%

- **Motor**
  - Meaningful Recovery 85.7%

- **Mixed**
  - Meaningful Recovery 77.0%

**Repairs Reporting Recovery by Gap Length**

- **5-14 mm**
  - Meaningful Recovery 100%

- **15-29 mm**
  - Meaningful Recovery 76.2%

- **30-50 mm**
  - Meaningful Recovery 90.9%

**Karabekmez et al. Study**
- 10 nerve injuries
- Static and moving two-point discrimination tests were used to evaluate functional recovery

**Clinical Studies Conducted with Processed Nerve Allograft**

<table>
<thead>
<tr>
<th>Study</th>
<th>Year Published</th>
<th>No. of Repairs</th>
<th>Nerve Injury Types</th>
<th>Test Article</th>
<th>Gap Length (mm)</th>
<th>Meaningful Recoverya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brooks et al.1</td>
<td>2011</td>
<td>132</td>
<td>Sensory Mixed</td>
<td>Avance® Nerve Graft</td>
<td>5-50 (avg. 22)</td>
<td>87%</td>
</tr>
<tr>
<td>Karabekmez et al.2</td>
<td>2009</td>
<td>10</td>
<td>Sensory Avance® Nerve Graft</td>
<td>5-30 (avg. 22)</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Shanti et al.3</td>
<td>2011</td>
<td>1</td>
<td>Sensory Avance® Nerve Graft</td>
<td>—</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

* Mackinnon modification of the Medical Research Council grading system used for evaluation of sensory and motor recovery. Meaningful recovery was defined as S3 / M3 – S4 / M5.

**Study Findings**

- Processed nerve allografts have been shown to be a safe and effective option for nerve reconstruction.1,2,3

- No graft related rejection or infection have been reported in multiple studies.1,2,4,6

- "The outcomes...compare favorably with those reported in the literature for nerve autograft and the processed nerve allograft returned a higher rate of meaningful functional recovery than those reported in the literature for nerve conduits." – from Brooks et al. 20111

**CLINICAL EXAMPLE**

- Reconstruction of the ulnar and radial digital nerves with processed nerve allografts (stars).

  Image courtesy of Darrell N. Brooks, M.D.

**CLINICAL EXAMPLE**

- Image courtesy of Darrell N. Brooks, M.D.

  The Buncke Clinic