AngioSculpt Pilot Study Summary

Restoring arteriovenous access: Pilot study using a scoring balloon in 50 patients

Study by Dr. J R Ross

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Key Takeaway:
- Results suggest that the AngioSculpt scoring balloon may be a viable treatment option for restoring stenosed arteriovenous (AV) fistula/graft access

Objective:
- Determine safety and efficacy of AngioSculpt PTA in restoring AV fistula/graft access and examine patency

Study:
- 50 patients with stenosed hemodialysis fistula/grafts treated with AngioSculpt
- Patients followed for six months
- Single-center prospective pilot study by Dr. Ross
- Lesions were short (mean: 4.56 mm)
- Investigator-initiated study, funded by Philips
- No randomized control groups

Results
- The study reported ~70% reduction of stenosis in AV fistulas/grafts immediately post-procedure
- Two- and six-month patency rates were 90.0% and 80.9%, respectively (studies for alternative forms of angioplasty report 50-60% patency rates)
- No slippage/dissections occurred
- No device- or procedure-related complications occurred through 30 days post-procedure

<table>
<thead>
<tr>
<th>Procedural characteristics</th>
<th>Average</th>
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<tbody>
<tr>
<td>Six-month patency</td>
<td>80.9%</td>
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<tr>
<td>Pre-procedure stenosis</td>
<td>78 ± 13.4</td>
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<tr>
<td>Post-procedure stenosis</td>
<td>7.2 ± 7.6</td>
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<tr>
<td>Dissections (%)</td>
<td>0 (0%)</td>
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<tr>
<td>Slippage (%)</td>
<td>0 (0%)</td>
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