Covidien Summary: Clinical Paper

Covidien provides the following synopsis of a clinical publication involving the use of Permacol™ surgical implant for reconstruction of acute and chronic abdominal wall defects.

**Title**
“Experience with Porcine Acellular Dermal Collagen Implant in One-stage Tension-free Reconstruction of Acute and Chronic Abdominal Wall Defects.”

**Authors**
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**Journal**

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**Purpose of the Study**
To review the use of porcine acellular dermal collagen implant in elective and emergency abdominal wall defects (AWD).

- **Format**: Prospective study of reconstruction of large AWD with Permacol™ surgical implant (porcine acellular dermal collagen [PADCI]) in emergency and elective surgery.
- **Number of Patients**: 20
- **Follow-Up**: 18 months

**Methods**
- Twenty consecutive patients (12 chronic, 8 acute) with large AWD (defined arbitrarily as defects measuring 12cm x 8cm or greater) were enrolled between January 2002 and June 2005
- All patients were evaluated by full history and physical examination where site and size of defect was assessed
- All patients received pre-operative thromboprophylaxis and broad spectrum antibiotic
- Patients were assessed for immediate post-operative complications and followed-up at six weeks, 3 and 6 months
- Incidence of complications was determined using homogenous definitions:
  - Seroma – fluid collection that required drainage or caused symptoms
  - Wound infection – clinical signs of infection and/or microbiological culture
  - Recurrence – any abnormal protrusion at the repair site

**Results**
All defects were successfully closed without tension using Permacol™ surgical implant
- Twelve patients (60%) had an uneventful recovery and were discharged within 7 days
- One patient (77 year-old) died from multiple organ failure 6 days after surgery. Patient had a history of congestive heart failure and steroid-dependent chronic obstructive airway disease.
- Seven patients (35%) developed complications:
  - Two seromas
  - Two wound infections
  - One wound haematoma
  - One wound edge skin necrosis
  - One superficial wound dehiscence
  - One wound sinus
- After a median follow-up of 18 months, three recurrences were reported (one at 3 months, 2 at 6 months). One patient declined further intervention; the others were asymptomatic and did not warrant further surgery
- No difference was noticed in terms of complications rate with the use of single sheet versus multiple sheets.

<table>
<thead>
<tr>
<th>Complications</th>
<th>Chronic abdominal wall defects (n=12)</th>
<th>Acute abdominal wall defects (n=8)</th>
<th>Total (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Seroma</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Wound Infection</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Wound Haematoma</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Wound Edge Skin Necrosis</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Wound Dehiscence</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Wound Sinus</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lower Respiratory Tract Infection</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td></td>
<td>1</td>
<td>1</td>
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<tr>
<td>Multiple Organ Failure</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Recurrence</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>10</strong></td>
<td><strong>15</strong></td>
</tr>
</tbody>
</table>
DISCUSSION

- Based on this data, biological grafts compared to synthetic meshes showed interesting results regarding erosion, infection, extrusion and rejection
- Unlike polypropylene mesh, PADCI does not form a biofilm, and can therefore be used in direct contact with the bowel wall
- Medium-term recurrence rates in this study are comparable to other literature reports:
  - Reasons for recurrence in the study are not clear as no patient underwent further surgery allowing investigations
  - Implant diastasis secondary to the stretching of the implant itself may be a cause and should be examined in future long-term studies

CONCLUSION

- PADCI has the potential for reconstruction of large acute and chronic AWD
- PACDI is particularly useful where delayed wound healing is anticipated, or when large quantities of prosthetic material are required
- Medium-term recurrence rate is comparable to synthetic mesh repair

**This concludes the clinical synopsis of this publication**