TITLE: Biological Mesh: Clinical Effectiveness, Cost-Effectiveness, Indications, and Guidelines

DATE: 14 October 2010

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of biological mesh products?
2. What is the cost-effectiveness of biological mesh products?
3. What are the clinical indications for biological mesh products?
4. What are the evidence-based guidelines regarding the use of biological mesh products?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID MEDLINE, PubMed, the Cochrane Library (Issue 10, 2010) University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between January 1, 2005 and October 6, 2010. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic studies and guidelines. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS:

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented...
first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

Three systematic reviews, nine randomized controlled trials, and one guideline regarding biological mesh products were identified. Due to the large volume of relevant literature, non-randomized and dental studies are located in the appendix. Additional articles of potential interest are also located in the appendix.

OVERALL SUMMARY OF FINDINGS:

There are a number of clinical indications for the use of biological mesh products including surgical management of pelvic organ prolapse,\(^\text{1,3,4,11-13}\) surgical treatment of recurrent cystocele,\(^\text{7}\) post-mastectomy breast reconstruction,\(^\text{2}\) closure of graft harvest site for substitution urethroplasty,\(^\text{6}\) surgical hernia repair,\(^\text{5}\) diabetic foot ulcer repair,\(^\text{9}\) onlay graft during hemicraniectomy,\(^\text{8}\) and sandwich bone augmentation.\(^\text{10}\) Table 1 summarizes the results of the included studies. Additional clinical indications, including dental applications, are provided in the appendix.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Citation</th>
<th>Study type</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic organ prolapse</td>
<td>Marh et al. (2010)(^\text{1})</td>
<td>SR</td>
<td>Use of surgical mesh, including absorbable porcine dermis, at the time of anterior vaginal wall repair may reduce the risk of recurrent cystocele.</td>
</tr>
<tr>
<td></td>
<td>Sung et al. (2008)(^\text{3})</td>
<td>SR</td>
<td>There was insufficient data to accurately assess the efficacy of biologic graft use.</td>
</tr>
<tr>
<td></td>
<td>Hviid et al. (2010)(^\text{4})</td>
<td>RCT</td>
<td>Use of Pelvicol graft (porcine collagen) did not improve POP-Q stage.</td>
</tr>
<tr>
<td></td>
<td>Meshcia et al. (2007)(^\text{11})</td>
<td>RCT</td>
<td>Pelvicol graft (porcine collagen) can be used to easily to reinforce anterior colporrhaphy. Prolapse recurrence rate was lower in patients receiving the graft.</td>
</tr>
<tr>
<td></td>
<td>Paraiso et al. (2006)(^\text{12})</td>
<td>RCT</td>
<td>Patients undergoing repair with biological graft had significantly higher anatomic failure rate than comparison groups. Proportion of functional failure was similar among groups (15%).</td>
</tr>
<tr>
<td>Recurrent cystocele</td>
<td>Natale et al. (2009)(^\text{7})</td>
<td>RCT</td>
<td>Anatomical outcomes were similar between the groups receiving synthetic and biological mesh (Pelvicol). Mesh erosions were observed only in the synthetic mesh group.</td>
</tr>
<tr>
<td>Post-mastectomy breast reconstruction</td>
<td>Technology Assessment Unit of McGill University Health Centre</td>
<td>SR</td>
<td>Use of AlloDerm and DermaMatrix in post-cancer breast reconstruction procedures with implant was assessed. Complication rates were similar in reconstruction studies with and without biological mesh. There is no evidence to suggest biological mesh increases complication rates. Biological mesh provided good aesthetic results and a low</td>
</tr>
</tbody>
</table>

Biological Mesh
Table 1: Results of included studies

<table>
<thead>
<tr>
<th>Indication</th>
<th>Citation</th>
<th>Study type</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closure of graft harvest site for substitution urethroplasty</td>
<td>Jamal et al. (2010)⁵</td>
<td>RCT</td>
<td>No significant differences were observed between patients receiving AlloDerm-assisted closure versus primary closure of oral harvest site. Authors concluded the use of AlloDerm was unnecessary as primary closure without mesh was quite successful.</td>
</tr>
<tr>
<td>Surgical hernia repair</td>
<td>Ansaloni et al. (2009)⁶</td>
<td>RCT</td>
<td>A significant decrease in postsurgical pain and discomfort were observed in patients undergoing repair with Surgisis matrix compared to polypropylene repair. The authors conclude the use of Surgisis for hernia repair is safe and effective.</td>
</tr>
<tr>
<td>Diabetic foot ulcer repair</td>
<td>Reyzelman et al. (2009)⁸</td>
<td>RCT</td>
<td>Acellular matrix was compared to standard of care for diabetic foot ulcers. After adjustment for initial ulcer size, the odds of wound healing were 2 times higher in the study group. The authors concluded that a single application of acellular matrix is supported for treatment of diabetic, neuropathic ulcers.</td>
</tr>
<tr>
<td>Onlay graft during hemicraniectomy</td>
<td>Horaczek et al. (2008)⁹</td>
<td>RCT</td>
<td>Use of the collagen matrix during hemicraniectomy reduced operating time and cerebrospinal fluid loss. Use of the matrix was reported as easier to use than the usual procedure by 85% of surgeons.</td>
</tr>
<tr>
<td>Sandwich bone augmentation</td>
<td>Park et al. (2008)¹⁰</td>
<td>RCT</td>
<td>Bone defects were covered with bovine collagen membrane, acellular dermal matrix, or no membrane. After six months, there was no significant difference in defect height between groups. Absorbable membranes enhanced bone thickness.</td>
</tr>
</tbody>
</table>

RCT = randomized controlled trial; SR = systematic review

One systematic review² reported the cost of AlloDerm and DermaMatrix to be $1920 per procedure. No further cost information was identified. One evidence-based guideline¹³ was identified regarding the use of grafts in the surgical treatment of pelvic organ prolapse. The guideline authors were only able to present weak recommendations for the use of grafts in vaginal surgery due to the low quality of the available evidence.

Biological mesh products are used for a variety of clinical indications. The included studies found biological mesh to be effective,¹²,⁶,⁸,⁹,¹¹,¹² not significantly different than the comparator,⁴,⁵,¹⁰ or the authors were unable to present a conclusion regarding its effectiveness.³ Negative effects associated with the use of biological mesh were reported in only one included study.¹² Limited cost data and guidelines were identified from the literature.
REFERENCES SUMMARIZED:

Health technology assessments
No literature identified.

Systematic reviews and meta-analyses


Randomized controlled trials


Economic evaluations
No literature identified

Guidelines and recommendations


PREPARED BY:
Health Technology Inquiry Service
Email: htis@cadth.ca
Tel: 1-866-898-8439
APPENDIX – FURTHER INFORMATION:

Systematic reviews and meta – analyses – dental


Randomized controlled trials – dental


Non-randomized studies


Dental studies


Safety studies


Clinical practice guidelines


Clinical indications

   Note: Dermagraft indications

   Note: Surgisis and DuraForm indications


Review articles


Additional references