Observational Registry Study of Symbotex™ Composite Mesh in Ventral Hernia Repair

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Disclosures – Constantin Zaranis

- SymCHro study sponsorship, funding, and data analysis provided by Medtronic.
Symbotex™ Composite Mesh

- Mesh transparency for increased visibility during placement\(^1\)
- Green orientation marking for accurate positioning\(^1,2\)
- Abdominal wall side: monofilament 3D polyester textile
- Visceral side: hydrophilic collagen bioabsorbable film
- Large pore size: 3.3 mm × 2.3 mm

1. Covidien internal report 0901CR252a (June 2013)
2. Covidien design validation report 0901CR249a (June 2013)
Mesh Porosity Matters

Methodology: Preclinical study of PET mesh integration and shrinkage comparing mesh weight (HW vs LW), pore size (SP vs LP) and weave (2D vs 3D)

- Large pore mesh showed better integration than small pore mesh
- Lightweight small pore mesh exhibited the most shrinkage
- 3D mesh supported the highest collagen count and exhibited the least shrinkage

→ Mesh porosity is more important than mesh density for tissue integration
SymCHro Study Design

Observational registry study: the short- and long-term clinical outcomes following the use of Symbotex™ composite mesh.

- 100 consecutive patients reported in the Hernia Club database
- 2 Years Follow-up
- Inclusion Criteria:
  - ≥18 years of age
  - Ventral hernia: Primary or incisional
- Exclusion Criteria:
  - None
  - Surgical technique is left to the surgeon’s preference
Ventral hernia laparoscopic repair: Symbotex™ Composite Mesh after external defect raphy
Marc LEPERE / France - 2015
SymCHro Study Endpoints

Primary Endpoints:

• Peri-operative complications
• Post-operative complications (up to 2 year follow-up)

Secondary Endpoints:

• Operative time and hospital stay
• Quality of life and patient satisfaction
• Ease of use / mesh manipulability assessment by surgeons
SymCHro Patient Follow-Up
(as of January 2016)

- Surgery (N=100)
  - Month 1 (N=85)
    - Month 3 (N=22)
      - Month 6 (N=22)
        - Month 12 (N=27)

Completed Follow-Up: 46.5 (0 – 425) days

Theoretical Follow-Up: 360.5 (238 – 551) days
Patient Demographics & Risk Factors

**Risk factors related to healing (≥1)**
- Anticoagulant treatment or bleeding disorder: 32%
- Chemotherapy/immunosuppressive treatment: 18%
- Diabetes: 8%
- Daily / Regular Smoker: 7%

**Risk factors related to dissection (≥1)**
- Prior intraperitoneal surgery: 68%
- Mac Burney: 55%
- Prior extraperitoneal surgery: 16%
- Daily / Regular Smoker: 7%

**BMI range (kg/m²)**
- 10%
- 20%
- 30%
- 40%
- 50%
- 60%
- 70%
- 80%

- 17.8
- 28.7
- 48.1
Hernia Characteristics

Hernia Defect Area

- Primary Hernia (N=39): 5.2 cm²
- Incisional Hernia (N=63): 32.5 cm²

Multi-site hernias

- 19 patients (19%) with 1 site
- 83 patients (81%) with ≥ 2 sites

Hernia Symptoms (N=100)

- Asymptomatic hernia: n=7
- Discomfort/pain or dysesthesia: n=86
- Strangulated hernia with obstruction: n=1
- Incarcerated hernia (N=101): n=30
Operative Data

Surgical Approach

**PRIMARY Hernia**
- 37 (100%)

**INCISIONAL Hernia**
- 39 (66%)
- 20 (34%)

Operative Data

Operative Time

- **Laparoscopic**
  - Operative Time: 37 minutes (mean ± SD)

- **Open**
  - Operative Time: 77 minutes (mean ± SD)
Surgeon Satisfaction

- Mesh Flexibility
- Ease in Mesh Trimming
- Ease in Mesh Insertion
- Mesh Memory Shape
- Low visceral attachment

Surgeon Response (0% to 100%)

- Satisfied
- Unsatisfied
- Unknown
Patient Complications

- Few complications occurred; none required reoperation
- No recurrence, sepsis, nor serious adverse events were reported within 12 months

<table>
<thead>
<tr>
<th>Complication</th>
<th>Symbotex™ composite mesh (N=100)</th>
<th>Time of occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seroma¹</td>
<td>6/100 (6.0%)</td>
<td>1 perioperatively</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 within 1 month</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 within 2 months²</td>
</tr>
<tr>
<td>Transitory ileus³</td>
<td>3/100 (3.0%)</td>
<td>2 perioperatively</td>
</tr>
<tr>
<td>(Clavien 1 or 2)⁴</td>
<td></td>
<td>1 within 1 month</td>
</tr>
</tbody>
</table>

¹ All seroma were minor/required no medical treatment; none were mesh-related
² Already identified at 1 month, but asymptomatic and punctured at 2 months
³ Relation to mesh or procedure is unknown at this time
Post-Operative Pain

VAS Pain Assessment

P < 0.0001 for scores relative to baseline, based on Wilcoxon signed rank test (non-parametric) for paired data.
Conclusions

→ Only non-serious adverse events were reported

→ Post-operative pain decreased significantly

→ High rate of surgeon satisfaction regarding mesh handling

Intermediate results of this registry study support the use of Symbotex™ composite mesh in primary and incisional hernia repair. Two year patient follow-up is ongoing.