**Covidien Update: Clinical Study**

**Preliminary results of a clinical study involving Parietex ProGrip™ mesh.**

**TITLE**

Preliminary Results of a Comparative Randomized Study: Benefit of Self-Gripping Parietex ProGrip™ Mesh in Open Inguinal Hernia Repair.

**AUTHOR**


**JOURNAL**


**PURPOSE OF THE STUDY**

The Lichtenstein method is the gold standard for open mesh inguinal hernia repair with low recurrences. However, an unresolved problem is postoperative pain which may be related to mesh fixation. The aim of this test report was to compare the self-gripping Parietex ProGrip™ sutureless mesh repair against the Lichtenstein sutured mesh repair in a randomized study evaluating herniorrhaphy postoperative pain.

**METHODS**

From October 2008 to June 2010, 390 patients were randomized in 9 European centers and analyzed at three-month (among whom, 215 patients reached the one-year assessment). 197 patients were operated with the traditional Lichtenstein repair (L group) and 193 patients were operated with the self-fixating Parietex ProGrip™ mesh (P group) without fixation or with one absorbable stitch on the pubic tubercle. Patient pain measured by a visual analogue scale (VAS) and other outcomes were assessed (included wound complications, recurrence and surgery duration) from the preoperative visit to the one-year follow-up visit. Postoperative pain was analyzed using the difference between VAS score at each assessment and baseline.

**RESULTS**

Homogenous and comparable population in both groups (P and L) was observed in terms of demographics and risk factors data.

The VAS difference analysis showed:

- A lower pain in P than in L group at Discharge (respectively +2.57 and +10.41, p=0.05) and Day-7 (-1.37 vs +5.96, p=0.05)
- No pain difference at 1-month post-surgery or later.

According to the protocol, one resorbable stitch was allowed on the pubic bone to help Parietex ProGrip™ mesh positioning but 69% were placed without any suture.

Moreover, the VAS difference analysis showed that the pain was significantly reduced from discharge to one month in no fixation P sub-group compared to the L group:

<table>
<thead>
<tr>
<th>VAS difference (Post-operative VAS/Baseline)</th>
<th>Discharge</th>
<th>Day 7</th>
<th>1 Month</th>
<th>3 Month</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>No fixation (n=133)</td>
<td>-0.9</td>
<td>-3.5</td>
<td>-20.03</td>
<td>-23.21</td>
<td>-24.64</td>
</tr>
<tr>
<td>1 Stitch (n=60)</td>
<td>+10.1</td>
<td>+3.71</td>
<td>-7.89</td>
<td>-9.35</td>
<td>-18.63</td>
</tr>
<tr>
<td>p (t-test)</td>
<td>0.051</td>
<td>0.154</td>
<td>0.011</td>
<td>0.005</td>
<td>ns</td>
</tr>
</tbody>
</table>

Infection rates were 5.6% in L group (10 superficial + 1 deep) and 3.1% in P group (6 superficial), (p=NS).

Surgery duration was significantly shorter (-16%) in P than L group (34.4 min vs 40.7 min; p <0.001).

No recurrence was observed in P group although 1.6% was observed in L group.

**CONCLUSION**

These preliminary results show that surgery duration and early postoperative pain are significantly reduced with Parietex ProGrip™ compared to Lichtenstein repair. The use of Parietex ProGrip™ is simple and fast, providing some better outcome measures for patients compared with Lichtenstein. These promising results and trends need to be confirmed with longer follow up and on a larger population.