Comparison of Lichtenstein and Proflor™ Open Inguinal Hernia Repair in Regards to Immediate Post-Op Pain: A Randomized Double Blinded Registered Clinical Study

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Abstract

**Background:** With recent advances in inguinal hernia repairs recurrence is no longer the major consideration. Chronic groin pain is now the most commonly reported complication. Postoperative pain can be divided between immediate and acute post-op and chronic long - term with excessive immediate and acute short - term pain being an indicator for the development of chronic long - term groin pain.

**Material and Methods:** A randomized, double - blinded, registered clinical trial enrolling 48 patients was undertaken to compare the amount of immediate and acute short - term pain experienced by patients undergoing a ProFlor repair versus a Lichtenstein repair.

Randomization was carried out by the surgeon selecting a computer generated sealed envelope in the operating room. Neither the patient nor the follow - up data collector was aware of the procedure performed. The patients were between the ages of 18 and 65 and had similar demographics. Recorded Carolinas Comfort Scale, visual analog scale, operative time, return to work and medication consumption results were subjected to statistical analysis.

**Results:** The results show that using the ProFlor Dynamic Implant, which requires minimal dissection in the anterior space, avoids the placement of mesh in the anterior space, and requires no fixation, had a statistical difference in regards to Carolinas Comfort Scale and VAS scores, operative time and post - op medication consumption. There were no serious adverse events recorded during the trial period.

**Conclusions:** Proflor repair was superior the Lichtenstein Repair in regards to immediate post - op pain.

ClinicalTrials.gov identifier: NCT02240550.

INTRODUCTION

The use of mesh and mesh products in the repair of inguinal hernias has reduced the incidence of recurrence to the point that it no longer is a major consideration. Postoperative pain is now considered to be the major complication following inguinal hernia repair [1-6]. Postoperative pain can be divided into two phases, acute and chronic. It has been postulated that severe immediate pain may be a predictor in the development of chronic groin pain [7]. Chronic groin pain has been reported as high as 40% but a more realistic number would be 10-11 % [5-13]. With approximately 1 million hernia repairs done in the US annually, this equates to filling a major university football stadium each year with patients suffering from chronic groin pain. Many of these patients reported no pain complaints pre - operatively, but now may suffer pain for years or even for life after repair.

A number of procedure related factors may be responsible for significant acute postoperative pain and the subsequent development of chronic groin pain. These may include the entrapment of inguinal nerves or one of their branches, trauma to the nerves, both direct and indirect such as stretching, wide dissection of the anterior space, excessive traction of the cord structures, the use of excessive mesh, the type of mesh used, mesh impingement of the nerves, shrinkage of the mesh and fixation of the mesh to name a few.

As most of these factors are related to the anterior space it would seem preferable to minimize dissection in this space and perform as little manipulation of the nerves as possible [8-12]. By placing the flat mesh in the preperitoneal space and avoiding its placement in the anterior space the possible interaction between the mesh and the inguinal nerves can be reduced significantly.

The purpose of this study was to evaluate the immediate and short - term discomfort and pain following a ProFlor Dynamic Implant and Lichtenstein repairs.

MATERIALS AND METHODS

This study was designed as a randomized, double-blinded, registered controlled clinical trial performed at one surgical center by the authors. (Clinical Trials.GOV Identifier: NCT02240550)
The patients were randomized to a Lichtenstein or the ProFlor™ Dynamic Implant by a computer - generated scheme.

Eligible participants were over the age of 18 years, defect size 5mm to 35mm and with a clinical need for an open inguinal hernia repair. Exclusion criteria included infection, recurrent inguinal hernias, femoral or inguinoscrotal hernias, and a BMI > 35 kg/m². Informed consent was obtained from all participants. The study was approved by the ethics committee at the Healing Hands Clinic.

A total of 48 patients were enrolled in the study between September 1st and 30th, 2014. The patients were assigned to either the Lichtenstein or ProFlor group based on a computer-generated randomization scheme with the selection placed in a blinded envelope by an independent person. The surgeons opened the envelopes intra-operatively and the patients were assigned to the appropriate group at that time. This process ensured that neither the patient nor the post-operative interviewer were aware of the randomization allocation (Figure 1, Tables 1, 2).

Using a sample-size calculator and the power calculations, 25 subjects per treatment group were needed to achieve a statistical power of 90% with an alpha of 5%. The calculations were made using current published values of the Lichtenstein VAS scores at 7 days post-operatively. It was postulated that a 30% reduction in the score would be clinically significant. The values used in the calculations were a VAS of 2.4% (Lichtenstein) and 1.7% (representing a 30% reduction), 1.0 S.D., 0.05 alpha, and .90 power. This resulted in a sample size of 22 subjects for each group. Considering a 10% loss to follow-up, we determined 25 subjects to be an appropriate number of cases for each arm of the study.

The CCS (Carolinas Comfort Scale) questionnaire has 23 items for assessment of health related QoL after hernia repair with mesh. This results in a numeric maximum score of 115. The higher the score the lower is the health related QoL. These values can also be reported as a percentage of the maximum score. The VAS (Visual Analog Scale) was used to gauge patient pain intensity, ranging from 0 = no pain to 10 = worst pain ever. The VAS and CCS scores are presented by time with a statistical analysis of MEAN, MEDIUM and MIN & MAX values displayed. The CCS scores were calculated according to the CCS algorithm using SAS or similar methods. The Carolinas Equation for Quality of Life (Ce QOL) predicts the incidence of chronic discomfort following inguinal hernia repair. Users simply answer 19 simple questions about themselves, their hernia, and their current QOL status as it relates to their hernia, and a percentage chance of having some form of discomfort one year following surgery is produced and interpreted. This was used specifically in the male patients prior to surgery.

Results on continuous measurements are presented as mean ± standard deviation (SD) and results on categorical measurements are presented in number (%). The 2-tailed, paired t-test was used to compare the data sets (continuous variables) and the chi-squared test to assess associations between categorical data. A p-value of less than 0.05 was considered statistically significant.

Surgical technique

All procedures were performed under general anesthesia. Both groups received skin and subcutaneous injections of 0.5% lidocaine prior to skin incisions. A standard “time out” was performed prior to each procedure.

Lichtenstein procedure

Following the injection of 0.5% lidocaine in the skin and subcutaneous tissue a 2.5cm skin incision was made.

The Lichtenstein procedure was performed as described by Amid [14] using polypropylene mesh (Ethicon) secured by a 2-0 polypropylene suture. The mesh was trimmed to match the inguinal floor if necessary. After closure of the external oblique and Scarpa’s fascia, the skin was closed with a running 3-0 Prolene suture.

ProFlor™ dynamic implant procedure

The skin and subcutaneous tissue were treated in a similar manner as the Lichtenstein procedure and an identical sized skin incision made. The external oblique fascia was incised and dissection in the anterior space was carried out only to the
extent to allow identification of the hernia defect. The cord was left in place as much as possible in order to avoid disturbing the inguinal nerves. The inguinal nerves were identified but left in place. The preperitoneal space was entered for both an indirect and direct hernia by incising the transversal fascia at the base of the defect.

A preperitoneal space was developed by blunt finger dissection beneath the superficial epigastric vessels to expose both the medial and lateral triangles. The femoral space was explored to be certain there was no occult defect. This ensured that the myopectineal orifice was covered completely by the integrated underlay disc of the ProFlor. The underlying disc of
Table 4: Statistical Summary of CCS, OR Time, RTW, and Medication Consumption.

<table>
<thead>
<tr>
<th>Data</th>
<th>Time point</th>
<th>Lichtenstein Range</th>
<th>ProFlor™ Range</th>
<th>P-value</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCS</td>
<td>Pre-Op</td>
<td>7.46%</td>
<td>6.21%</td>
<td>0.166</td>
<td>p &gt; 0.05</td>
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<tr>
<td></td>
<td>POD1</td>
<td>33.36%</td>
<td>11.45%</td>
<td>5.15E-08</td>
<td>p &lt; 0.01</td>
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<tr>
<td></td>
<td>POD7</td>
<td>22.06%</td>
<td>6.04%</td>
<td>1.85E-08</td>
<td>p &lt; 0.01</td>
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<tr>
<td></td>
<td>POD14</td>
<td>13.58%</td>
<td>2.19%</td>
<td>3.08E-13</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td></td>
<td>POD28</td>
<td>8.82%</td>
<td>0.86%</td>
<td>2.01E-06</td>
<td>p &lt; 0.01</td>
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<tr>
<td>VAS</td>
<td>Post-op</td>
<td>3.13</td>
<td>1.84</td>
<td>3.51E-07</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td></td>
<td>POD1</td>
<td>3.22</td>
<td>1.68</td>
<td>1.82E-09</td>
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<td></td>
<td>POD7</td>
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<td>0.4</td>
<td>9.15E-10</td>
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<tr>
<td></td>
<td>POD28</td>
<td>0.1</td>
<td>0.04</td>
<td>0.48</td>
<td>p &gt; 0.05</td>
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<tr>
<td>OR Time (Minutes)</td>
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<td>0:43</td>
<td>0:24-0:55</td>
<td>0.24</td>
<td>0:16-0:50</td>
</tr>
<tr>
<td>Return to Work (RTW) (Days)</td>
<td></td>
<td>2.96</td>
<td>7-Jan</td>
<td>2.2</td>
<td>4-Jan</td>
</tr>
<tr>
<td>Medication (Tablets) Average</td>
<td></td>
<td>10.09</td>
<td>1.72</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 3 VAS results.

Figure 4 Comparative OR Times.
the ProFlor was then placed in the preperitoneal space extending to Cooper’s ligament and beneath the epigastric vessels. The core of the dynamic implant occupied the defect at the level of the transversal fascia and did not protrude into the anterior space. Because of the dynamic nature of the implant, which allows for inherent recoil, it requires no fixation. The external oblique fascia, subcutaneous tissue and skin were closed in a similar manner as the Lichtenstein.

The primary objective of the study was to determine if there was any statistically significant difference between the two procedures in regards to immediate and short-term pain. Pain was assessed by use of the Carolinas Comfort Scale and Visual Analog Scale. These were administered pre-operatively, immediately post-operatively, and on days one, seven, fourteen and twenty-eight days post-operatively. Secondary outcomes were operative time, return to work status, and consumption of pain medication post-operatively (Figures 2-5, Table 3).

RESULTS

The Carolinas Comfort Scale (CCS) was administered pre-op, day one, day 7, day 14 and day 28 to all patients and the percentage of maximum score recorded. Statistical analysis of the data depicted in Figure (1) revealed significant difference between the Lichtenstein and ProFlor repairs in regards to mesh sensation, movement limitation, and pain. The composite of all three measures (Total) show that the average score at 28 days of the Lichtenstein patients has not returned to pre-op levels while the average score of the ProFlor™ patients had returned to below pre-op levels by day 7.

The Visual Analog Scale was also administered immediate post-op, post-op day 1, 7, and 28. The results at post-op, POD1 and POD7 correlate well with the scores achieved with the Carolina Comfort Scale results and show a statistical difference between the two procedures (p < 0.01).

The average OR time for the Lichtenstein repair was 43 minutes. The average OR time for the ProFlor repair was 24 minutes. This represented an average reduction in skin-to-skin surgical time of 19 minutes or 43% and a statistically significant value of p<0.01. There was no statistical difference between the two groups in regards to return to work.

Pain medication consumption was shown to be statistically different between the two groups of patients (p < 0.01). It is also important to note that the ProFlor™ group required no pain medication past the 7th day while there were Lichtenstein patients still taking pain medication at 14 days (Table 4).

SUMMARY

Comparison of the two procedures shows statistical differences in regards to Carolina Comfort Scale scores, VAS, OR time, and analgesic consumption. Only in regards to return to work was no difference reported.

DISCUSSION

Synthetic mesh has been used in the repair of inguinal hernias for the past 40 years. It has been shown in randomized clinical trials to reduce the incidence of recurrence [14]. Post-op chronic groin pain is now considered to be the major complication following open inguinal hernia repair [1-6]. Post-operative pain can be divided into the immediate and acute post-op pain, lasting 7-10 days, and chronic groin pain lasting at least 3 months. It has been postulated that the more severe the immediate post-op pain the more likely the patient will develop chronic groin pain [7].

For this reason, a randomized double-blinded study was undertaken to compare the Lichtenstein procedure and ProFlor™ procedure in regards to immediate/short-term post-op pain. The term “mesh in guinodynia” was first purposed by Heise and Sterling in 1998 [16]. It was also discussed by Mazin who felt that it represented a major clinical problem [17].

A number of factors may be responsible for the development of chronic groin pain. Some we cannot control such as certain genetic and perioperative factors. Those that we can attempt to control through surgical technique may include the entrapment, trauma, and stretching of the inguinal nerves, wide dissection.

Figure 5 Comparative Return to Work Times.
and the use of excessive mesh in the anterior space, the use of heavy weight mesh, fibrosis, and shrinkage of the mesh, vascular injury and excessive fixation.

Present hernia systems for open repairs have several disadvantages. They are static, have excessive mesh in their design, one or more components of the system are placed in the anterior space, require extensive dissection in the anterior space and of the cord, and require some form of fixation. In addition, they do not allow for normal tissue in growth but rather form a regressive scar plate that depending on the amount of inflammatory response can be rather thick. The dynamic implant of ProFlor because of its movement within the defect induces near normal abdominal wall tissue with evidence of vessel and nerve growth as well as “soft” collagen deposition [18,19].

It may seem obvious, but an ideal hernia device should have little or no mesh in the anterior space, fill the actual defect with reinforced tissue, repair the hernia in the preperitoneal space, require minimal dissection in the anterior space and of the cord, leave the nerves as undisturbed as possible, cover the MPO and require minimal fixation. ProFlor™ was designed prospectively based upon failings of other implants to accomplish all of these factors.

CONCLUSIONS

By avoiding mesh in the anterior space and placing it with no fixation in the preperitoneal space, anchored by the dynamic implant, the possible interaction between the mesh and the inguinal nerves can be reduced significantly.

It would seem that most of the controllable factors that might lead to chronic groin pain are found in the anterior space and therefore it would seem preferable to minimize dissection in this area and to perform as little manipulation of the nerves as possible, reducing interaction between the mesh and inguinal nerves with mesh placement in preperitoneal space. The study shows that some patients who had a Lichtenstein procedure had a worse Quality of Life post-op than they did pre-operatively.

The results of the study show that ProFlor™ has statistically better VAS and CCS scores, a shorter operating time, and requires less pain medication and for a shorter length of time than does the Lichtenstein procedure.

ACKNOWLEDGEMENTS

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REFERENCES


