Laparoscopic Inguinal Hernia Repair Using ProGrip™ Self-Fixating Mesh: Technical Learning Curve and Mid-Term Outcomes

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ABSTRACT

Purpose: Self-fixating mesh has been introduced to further improve the quality results already seen with laparoscopic inguinal hernia repair. An observational study was undertaken to evaluate the technical learning curve and mid-term outcomes associated with the use of ProGrip™ (Medtronic, Minneapolis, MN, USA) laparoscopic self-fixating mesh in transabdominal preperitoneal (TAPP) inguinal herniorrhaphy.

Methods: Patients who underwent elective laparoscopic TAPP inguinal herniorrhaphy by a single surgeon...
The laparoscopic approach for inguinal herniorrhaphy was first introduced more than two decades ago.\textsuperscript{1,2} Total extra-peritoneal (TEP) and trans-abdominal preperitoneal (TAPP) techniques are the mainstay of current minimally invasive options. These operations have undergone technical refinements and enjoy great success with regard to surgeon adoption and patient satisfaction. Efforts to improve technical aspects and training of surgeons have been mirrored by advances in quality, capabilities, and features of commercially available mesh and fixation products.

The laparoscopic approach to inguinal hernia repair has yielded low recurrence rates.\textsuperscript{3} Therefore, the current focus of research and innovation has been on decreasing rates of acute postoperative pain and chronic inguinaldynia associated with traditional fixation techniques. ProGrip\textsuperscript{TM} laparoscopic self-fixating mesh (Medtronic, Minneapolis, MN, USA) uses micro-grips to adhere to tissue without the use of tacks or glue. A major concern regarding the use of this product is the perceived burdensome intraoperative handling due to its self-gripping qualities. Despite the

**Results:** Forty hernias were repaired in 29 patients with a laparoscopic TAPP approach. The average MI-FP was 249.4 seconds for the first 20 repairs, and 118.6 seconds (p < 0.001) for the final 20. Minor post-operative surgical complications were reported by 13.8% of patients; there were no major surgical complications. The average pain score on a scale of 0 to 5 was 0.9 (SD = 0.67, range 0–3).

**Conclusions:** Surgeons with reasonable laparoscopic experience can expect to become fully proficient in the manipulation of self-fixating mesh after 15 to 20 repairs. Use of this product yielded low intraoperative and mid-term postoperative complication rates as well as low postoperative pain.

**Figure 1:** a) Laparoscopic visualization of a left inguinal hernia. b) Completed inguinal dissection and exposure. c) Final placement of self-fixating mesh. d) Reapproximation of peritoneal flaps.
benefit of substantially lower postoperative pain, the initial experience with manipulating the mesh represents a barrier for surgeon adoption. A prospective, observational study was undertaken (in a surgical practice experienced in TAPP) to evaluate the initial learning curve and early clinical outcomes for this product.

**MATERIALS AND METHODS**

This study was conducted at two facilities within the same health system; a university-affiliated tertiary-care medical center and a community-based hospital. Institutional Review Board (IRB) approval was obtained to designate and conduct the research as a quality-improvement initiative. Patients who underwent elective primary or recurrent laparoscopic TAPP repair during 12 consecutive months were included. These cases represent a single surgeon’s initial experience with ProGrip™ laparoscopic self-fixating mesh. Patients with prior lower abdominal or pelvic interventions, previous pelvic radiation, or large direct defects not amenable to light-weight mesh repair, and those who required emergency procedures for incarceration and/or strangulation, were excluded from the study.

A TAPP approach was adopted for all enrolled patients. The abdomen was routinely accessed in the left upper quadrant using a 5-mm optical trocar. For left-sided hernias, this trocar was used as the camera port with two additional trocars: 10-mm right mid-abdomen and 5-mm periumbilical region. For right-sided or bilateral hernia repairs, an additional 10-mm trocar was placed in the left mid-abdomen. The larger trocar on the contralateral side of the hernia facilitates mesh introduction and, more importantly, allows a convenient angle for peritoneal reapproximation at the end of the case. The peritoneum was incised laterally, using laparoscopic scissors, from the medial umbilical ligament to the anterior superior iliac spine. It was then carefully dissected inferiorly, reducing the hernia sac and exposing inguinal landmarks (Figure 1b). Once ample development of the space was obtained, the mesh was prepared, introduced and manipulated into proper position to provide sufficient overlap of the defect (Figure 1c).

The mesh was trimmed as needed and pre-fitted with three dyed 2-0 absorbable sutures to help with visualization and positioning. The mesh was then folded and introduced into the abdominal cavity and appropriately positioned over the defect(s) (Figure 2). At the conclusion of the case, peritoneal flaps were re-approximated using a clip applier (Figure 1d). The 10-mm trocar sites were closed at the fascial level using a transabdominal suture passer with 0 absorbable suture. All incisions were closed using 4-0 absorbable sutures in a subcuticular fashion. Upon discharge, patients were given prescriptions for narcotic pain medication, stool softeners and instructions for postsurgical activity and follow-up.

Demographic data including age, gender, American Society of Anesthesiology (ASA) score, and admission status were collected preoperatively. Intraoperative data including hernia type, laterality, estimated blood loss (EBL), concurrent operations, intraoperative complications, time from mesh introduction to final placement (MI-FP), and total operative time were collected. Postoperative data included admissions and readmissions, days to follow-up visit, days until return to work, patient call logs to the surgeon’s clinic, postoperative complaints, short-term complications (within the 30-day post-operative period), and patient-reported pain as described on the Wong–Baker visual analogue scale (VAS). Recurrences were monitored at 6 months.

Data were collected and tabulated using Microsoft Excel (Microsoft Corp., Redmond, WA). A statistical analysis was performed using independent samples (unpaired t-tests) to compare mean outcome variable scores between the
first 20 and last 20 repairs. Statistical significance was set at p < 0.05.

RESULTS

A total of 40 inguinal hernias were repaired in 29 patients (11 patients underwent bilateral repair). The male-to-female ratio was 26:3, and the average age was 58.6 years (SD = 15.50; range 18–88). A total of 4 patients were risk-stratified as ASA class 1, 16 were ASA class 2, 8 were ASA class 3, and 1 was ASA class 4.

The average total operative time was 49.4 minutes (SD = 19.30; range 24.3–98.2), including two patients who had concurrent operations in addition to bilateral inguinal hernia repairs (both laparoscopic umbilical hernia repairs). The EBL was less than or equal to 5 cc in 27 patients and 10 cc in 2 patients. There were 21 right-sided and 19 left-sided repairs. The classification and frequencies of repaired hernias are shown in Table I. All operations were scheduled as outpatient procedures and 1 (3.4%) patient was admitted overnight for observation post-operatively due to frailty (an elderly patient with multiple medical co-morbidities). There were no intra-operative complications or readmissions.

The overall average MI-FP was 184.0 seconds (SD = 124.10; range 60–742). The average MI-FP for the first 20 repairs was 249.4 seconds (SD = 145.02; range 75–742) and that for the last 20 patients was 118.6 seconds (SD = 39.70; range 60–205) (t = 3.89 and p < 0.001). A graph of MI-FP versus surgeon experience (as estimated by number of repairs performed) is shown in Figure 3.

Patients were followed-up in the clinic for an average of 12.5 days (SD = 3.29; range 10–24) after surgery. Six patients called the surgeon’s office before their first office visit. Inquires included scrotal swelling, insomnia, constipation, and requests for early return to work. None of the requests were for additional pain medication. A total of 4 (13.8%) patients experienced minor postoperative surgical complications. These included seroma (n = 2; 6.9%), constipation (n = 1; 3.4%), and urinary retention (n = 1; 3.4%). All complaints resolved at subsequent follow-up. The average pain score on a VAS of 0 to 5 was 0.9 (SD = 0.67; range 0–3). The average pain score for the first 20 repairs (15 patients) was 0.80 (SD = 0.56; range 0–2) and that for the last 20 repairs (14 patients) was 1.0 (t = 0.93 and p > 0.05) (SD = 0.78; range 0–3). For the 18 employed patients, the average time for return to work (light duty only) was 10.2 days (SD = 7.41; range 1–28) post-operatively. Patients rounded typical daily activity an average of 8.93 days (SD = 10.63; range 0–30) following the procedure.

DISCUSSION

The use of self-gripping mesh has been shown to result in notably low levels of recurrence and pain, and minor post-operative complication rates for both open and laparoscopic procedures. A multicenter randomized controlled trial comparing Lichtenstein repair with open repair using self-gripping mesh (with and without suture fixation) found substantially reduced post-operative pain scores, infection rates, operative times and no recurrences at three months in the self-gripping mesh group. This study found increased pain with suture fixation, which suggests that it is partially responsible for postoperative pain. A similar study found that the incidence of residual inguinal pain was 2.8% at 6 months following open repair with self-gripping mesh. The outcomes of 220 laparoscopic TAPP repairs using self-gripping mesh found a hernia recurrence rate of 1.4%, an incidence of severe pain of 1.2%, and an incidence of mild pain of 3.6% at follow-up 23 months postoperatively. We observed no early or mid-term recurrences, acceptable pain scores, and no major perioperative complications. Only 4 short-term complications (13.8%) occurred, consisting of constipation, urinary retention, and seroma (n=2), which all resolved at subsequent

Table I

<table>
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<tr>
<th>Classification of Hernias</th>
<th>(n = 40)</th>
<th>(%)</th>
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<td>Indirect</td>
<td>18</td>
<td>45%</td>
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<tr>
<td>Direct</td>
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<td>25%</td>
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<td>Direct/Femoral</td>
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<tr>
<td>Indirect/Direct/Femoral</td>
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<td>2.5%</td>
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Figure 3: Time from mesh insertion to final position (MI-FP) versus case number.
follow-up. The average pain score on a scale of 0 to 5 was 0.9, and only 1 patient had a VAS score of 3. This is important, as perioperative complications and severe pain in the immediate post-operative period are predictors of chronic inguinal pain after inguinal hernia repair.

The placement of tacks for fixation of mesh is believed to be one of the most common causes of bleeding and nerve irritation in laparoscopic and open repair. This has been shown in several studies aimed at determining the relationship between the fixation method and post-operative complication rates. Injury to the inferior epigastric vessels resulting from inadvertent fixation can lead to brisk and easily detected bleeding. Conversely, misguided fixation into low-pressure venous structures, such as the corona mortis, may remain unnoticed in the setting of pneumoperitoneum secondary to its tamponading effect. Tacks also impact postoperative and chronic inguinal pain as a result of unintentional injury to the major nerves in the triangle of pain (lateral femoral cutaneous, femoral, genitofemoral nerves) or associated branches. Tacks placed to secure mesh in very thin individuals may lead to advancement through the abdominal wall into the subcutaneous layer, causing cutaneous nerve irritation. Alternatively, surgical glues have been used to prevent some of the above-mentioned problems associated with penetrating tacking devices. These glues include both synthetic (n-butyl-2-cyanoacrylate) and biologic materials (fibrin sealants). Cyanoacrylate-based compounds work by creating a stable polymer similar to superglue, but are associated with local tissue damage resulting from the exothermic chemical reaction. Additionally, these glues have been associated with higher seroma rates compared with staple fixation.

The introduction of self-gripping mesh has provided an improvement in the above complications and provides a cost savings, since glues/staple fixators are not required for mesh implantation.

Technical Learning Curve

Practicing surgeons have been slow to adopt laparoscopic approaches due to their technical complexity and the scarcity of structured training programs. Even with young trainees, TAPP inguinal hernia repair is safe and reproducible under the supervision of experienced laparoscopic surgeons. For established surgeons who are switching to laparoscopic self-fixating mesh, the technical details of mesh manipulation represent the only learning curve to overcome, since there is no difference in access, exposure, or closure. Considering that the repairs in our study represented a single surgeon’s initial experience with the mesh, the overall average operative time of 50 minutes per case was acceptably low. The graph of MI-FP versus case number (a surrogate value for surgeon experience with the mesh, Figure 3) shows a clear decrease in both time and variability as the number of cases approaches 15 to 20. The MI-FP in the last 20 repairs (118.6 seconds) was significantly shorter (p < 0.001) than that in the initial 20 repairs (249.4 seconds). This difference is statistically significant (p<0.001) even when an outlier (Case #13) is omitted from the analysis. Case-by-case MI-FP variability decreased with experience, and there was a 72% difference in the standard deviation (141.35 vs 38.69 seconds) between the two groups. This difference is indicative of attained comfort with mesh manipulation and suggests that proficiency was achieved at 15-20 cases.

Technical Considerations

The mesh is designed to anatomically fit the myocutaneous orifice and is suitable for direct, indirect, and femoral defects (as well as any combination of these defects). The main obstacle for an experienced surgeon who is starting to use self-gripping mesh is the increased procedure time necessary to gain the experience needed to efficiently maneuver and manipulate the mesh to its final position. The decrease in MI-FP after 20 cases is believed to be due to increased experience and familiarity with the technical nuances of the product. Our study surgeon provided the following technical suggestions:

- In most patients, the standard size and shape of the mesh is large enough to allow for trimming for a particular defect. Not all hernias require a full-sized mesh. Attempting to duplicate the shape of the area needing reinforcement will allow for easier manipulation and movement of the mesh.
- Placement of two or three absorbable sutures on the medial, upper, and lateral aspects of the mesh (Figure 2a) will allow easy repositioning in the event that a mesh needs advancement, particularly at the medial aspect towards Cooper’s ligament.
- Tri-folding the mesh (Figure 2b) creates a synthetic barrier that prevents self-adhesion. Grasping the mesh at its medial aspect during introduction and directing it toward the medial aspect of dissection (near Cooper’s ligament) is optimal. Once acceptably positioned, the upper and lower thirds are carefully unfolded with gentle sweeping motions into its final position.
- To perform adjustments following unfolding, grasping the preplaced sutures with one hand aids in manipulation. Tissue that adheres to the self-gripping side should be gently swept off rather than pulling to prevent self-adhesion of the mesh.

Limitations

Limitations of this study include that it was an observational study in the context of a single fellowship-trained laparoscopic surgeon. This experience only evaluated the mesh with the TAPP approach, and further studies will be necessary to investigate the space-restricted TEP approach. While the sample size of 40 is small, it was deemed to be reasonable for an observational study aimed at evaluating the learning curve and mid-term perioperative outcomes in a mature laparoscopic practice.

CONCLUSION

Laparoscopic self-fixating mesh provides adherence to tissue and stability of the prosthesis without the potential drawbacks associated with tissue tackers and biologic glues. Surgeons with reasonable laparoscopic experience can expect optimal proficiency after 15-20 repairs with an average MI-FP of less than 2 minutes. Use of this product yielded low short- and mid-term postoperative complication rates as well as low postoperative pain. We advocate that the long-term benefits of self-fixating mesh outweigh the short-term frustrations and operative time required to become proficient manipulating the mesh.
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AUTHORS’ DISCLOSURES

AD is a key opinion leader for Medtronic (Minneapolis, MN, USA) and the founder and executive director of National Surgery Review (Sharon Center, OH, USA), which has received educational grant support from Medtronic.

REFERENCES