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Placement of a Non–Cross-Linked Porcine-Derived Acellular Dermal Matrix During Preperitoneal Laparoscopic Inguinal Hernia Repair

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This retrospective chart review evaluated outcomes following laparoscopic inguinal herniorrhaphies with non–cross-linked intact porcine-derived acellular dermal matrix (PADM) by one surgeon in a community teaching facility hospital. Mesh was sutured and/or tacked in the preperitoneal space. Postoperative visits were scheduled at 2 weeks, 3 months, and 6 months, and then at 6-month intervals up to 2 years. PADM was placed in 14 male patients (mean age, 41.1 years). Seven patients had bilateral hernias. One patient required intraoperative conversion to open herniorrhaphy based on diagnostic laparoscopy findings. PADM sizes were 6 × 10 to 12 × 16 cm; mean operative time was 102 minutes. All patients were discharged on the day of surgery and resumed full activity. This treatment approach was effective, with no recurrence or complications during a median follow-up period of 18 months (range, 13–25 months).

Key words: Inguinal hernia – Laparoscopic – Herniorrhaphy – Tissue scaffolds – Surgical mesh – Non–cross-linked – Biologic matrix

Inguinal hernias are the most common type of abdominal wall hernia, with an estimated 20 million inguinal herniorrhaphy procedures performed worldwide each year[1] (approximately 770,000 annually in the United States,[2] 140,000 in France,[3] 70,000 in England,[4] and 30,000 in the Netherlands[5]). Open, tension-free inguinal herniorrhaphy remains the most commonly performed surgical approach, particularly for primary inguinal hernias. Laparoscopic repair, well described in the literature for ventral and inguinal herniorrhaphy, may result in shorter postoperative convalescence,[6–11] decreased pain,[6–9] and lower risk of infection[7–9] compared with open repair. Regardless of approach

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(*i.e.*, open or laparoscopic), effective, long-lasting repair is crucial because of the complexity of recurrent inguinal hernia management.[12]

Synthetic mesh is often used in conjunction with both open and laparoscopic inguinal herniorrhaphy and has been shown to significantly reduce the risk of hernia recurrence compared with primary repair without mesh.[9] However, synthetic mesh has been associated with postoperative complications such as infection, which can occur during the acute or long-term postsurgical period,[13–15] and longer-term complications such as chronic pain, fistula formation, and extrusion.[16–19] Infection following synthetic mesh insertion[19,20] often leads to explantation of the mesh, which may result in increased patient morbidity and use of health care resources.[20,21]

Biologic matrices support tissue revascularization and are thought to resist infection better than synthetic meshes.[13] Several biologic alternatives to synthetic mesh have been developed, including a non–cross-linked intact porcine-derived acellular dermal matrix (PADM; Strattice Reconstructive Tissue Matrix, LifeCell Corporation, Branchburg, New Jersey). The structure of PADM is strong and biocompatible, and it allows for cellular infiltration, vascularization, and tissue remodeling.[22] Clinical studies have shown the utility of PADM in several surgical procedures, including chest wall reconstruction,[23] breast reconstruction surgery,[24] and ventral herniorrhaphy.[25] To date, limited data have been reported about biologic matrix use in laparoscopic inguinal herniorrhaphy.[26–28]

To the author's knowledge, results from studies assessing the use of PADM in laparoscopic inguinal hernia repair have not been previously reported. This retrospective chart review evaluated the results of laparoscopic inguinal herniorrhaphy in 14 patients using a totally extraperitoneal (TEP) approach with placement of PADM. Postoperative recurrence and complication rates associated with this procedure were evaluated for a median follow-up period of 18 months (range, 13–25 months).

Patients and Methods

A retrospective chart review was conducted to identify patients who underwent elective laparoscopic inguinal herniorrhaphy with use of PADM performed by the author in a community teaching facility (Inova Alexandria Hospital, Alexandria, Virginia) from March 24, 2010, to October 1, 2012. Most of the patients who underwent laparoscopic repairs had chosen this technique over an open repair and had no history of failed prior laparoscopic repair with mesh. Further, patients with large inguinal sliding hernias were not candidates for laparoscopic repair and are thus not included in this series. All surgeries were performed at Inova Alexandria Hospital. Patients emptied their bladders prior to surgery, and no Foley catheter was used intraoperatively unless the patient had a history of urinary outflow obstruction. Perioperative antibiotics were administered per hospital protocol: cefazolin (or vancomycin in cases of cefazolin allergy) as a single intravenous dose $\leq$30 minutes before incision. General anesthesia was then administered.

Diagnostic laparoscopy was performed at the start of the surgery. Abdominal entry was made through a left subcostal incision using an Excel optical 5-mm port (Ethicon Inc, Somerville, New Jersey). A 0-degree, 5-mm camera was used to confirm the hernia as direct or indirect, and to inspect both inguinal regions intraperitoneally to rule out undiagnosed contralateral or femoral hernia. A photograph was taken and the abdomen deflated, with the port kept in place.

Laparoscopic herniorrhaphy was then performed. An infraumbilical skin crease cut-down was followed by a transection of the anterior rectus sheath on the side of the hernia, blunt dissection, and visualization of the retrorectus space. The retrorectal space was created using finger dissection; the rectus muscle was retracted laterally. A surgical balloon dissector (Covidien, Mansfield, Massachusetts) was used to insufflate the retropubic space (CO_2 insufflation up to 11 mmHg) using an 11-mm self-retaining trocar introduced into the retrorectus space. A 10-mm 0-degree scope was pushed into the balloon dissector system; the balloon was inflated to maximum capacity under direct vision and left in place for 1 minute to secure absolute hemostasis. The balloon dissector system was then removed and a self-retaining 10-mm trocar was introduced into the retrorectal space for inspection of the space and identification of anatomic landmarks, which included the inferior epigastric artery and vein on both sides, the symphysis pubis and internal ring on both sides, and both rectus muscles superiorly. After insufflation of the retropubic space, 2 additional short 5-mm trocars were placed along the midline between the umbilicus and the pubic bone. Dissection was started in the inguinal region on the side of the hernia. All fibroareolar tissue was dissected while avoiding injury to inferior epigastric vessels and nerves. The hernia sac was clearly identified between the cord structures and dissected free. If the sac was

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pierced during this dissection, it was closed using a looped 0 polydiaxanone (PDS) suture. If CO_2 entered the intraperitoneal space from the tear in the peritoneum during the sac dissection, the abdomen was vented through the subcostal port.

PADM was then used to support the repair. The PADM was prepared according to the manufacturer's instructions for use. Two 0 VICRYL (Ethicon) sutures, to be used as anchoring stitches, were placed in the PADM. Because the PADM was too thick to insert through the umbilical trocar, the trocar was removed and the PADM was introduced into the retropubic space using a grasper. The trocar was repositioned at the umbilical site, the retropubic space was reinsufflated, and the PADM was positioned to give maximum coverage to the hernia orifice at the internal inguinal ring. In the first two patients, PADM was placed using a Sorbafix tacker (Davol, Warwick, Rhode Island); however, it was observed that fasteners from this device were too short to penetrate the full thickness of the PADM and securely fixate the matrix. Also, there was very little room to manipulate this device in the retropubic space. In the remaining patients, PADM was secured using sutures. Anchoring stitches were pulled through the abdominal wall in the area of the right or left iliac region of the anterior abdominal wall using an endo-closure device, and the ends of the anchoring stitches in the mesh were pulled through the abdominal wall and tied loosely. The preperitoneal space was then deflated.

The peritoneal cavity was insufflated again through the subcostal port for reinspection of the inguinal region and PADM position prior to closure. Photographs were taken, the intraperitoneal space was deflated, and anchoring stitches were tied without tension. At closure, the anterior rectus sheath was approximated with absorbable 0 VICRYL sutures, and the port site incisions were closed with 4-0 MONOCRYL sutures (Ethicon).

Follow-up was scheduled at 2 weeks, 3 months, and 6 months, and then at 6-month intervals. Postoperative assessments included recurrence rates, complications, time to return to normal activity, and time to return to work.

Results

Among a total of 35 patients undergoing laparoscopic herniorrhaphy during the identified time period, 14 patients underwent repair using PADM and were identified for inclusion in this study (Table 1). All 14 patients were male, with a mean age of 41.1 years (range, 18–65 years). Most patients were white; mean body mass index was 34.4 kg/m^2 (range, 30–42 kg/m^2). One patient had a history of ischemic heart disease and atherosclerotic ischemic vascular disease.

Table 1 Patient demographics[a]

	Patients (N = 14)
Age, y, mean (range)	41.1 (18–65)
Male	14
Race	
White	13
Black	1
BMI, kg/m^2, mean (range)	34.4 (30–42)
History of smoking, yes	7
History of major/chronic diseases	1
History of chronic postoperative pain	1
History of inguinal herniorrhaphy	
No prior herniorrhaphy	9
Prior contralateral herniorrhaphy	2
Recurrent hernia	3

BMI, body mass index.

[a]Data are presented as number of patients unless otherwise indicated.

Patients had multiple reasons for selecting biologic matrix instead of synthetic mesh. The study included 2 patients with previous unsuccessful open repair attempts with synthetic mesh. One patient with a newly discovered hernia who had persistent pain and discomfort following a previous contralateral inguinal herniorrhaphy with synthetic mesh was also included. Several patients included in the study had a high level of physical activity and/or concerns about infertility.[29,30] One patient was concerned about adhesions that might be produced by a synthetic mesh and the potential for mesh-associated complications if robotic prostatectomy were to be needed in the future.

Details regarding the hernias are shown in Tables 2 and 3. All hernias were indirect and reducible. Two patients had failed previous inguinal herniorrhaphy via open repair using Prolene Polypropylene mesh (Ethicon). One patient had a history of chronic postoperative pain after inguinal hernia repair.

Thirteen patients were treated laparoscopically. One patient was converted to an open Shouldice repair with PADM because of a large sliding inguinal hernia containing the cecum and part of the ascending colon and intersac adhesions, with a wide internal ring defect discovered during diagnostic laparoscopy at the start of the procedure.

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Table 2 Hernia and matrix size

Location, initial/recurrent	No. of patients (N = 14)	Matrix size, cm (No.)
Bilateral		
Initial surgery bilateral	6	10 × 8 (2)
		10 × 16 (3)
		12 × 16 (1)
Right initial, left recurrent	2[a]	10 × 16 (2)
Unilateral		
Left, initial surgery	1[b]	10 × 6 (1)
Right, initial surgery	4	10 × 6 (3)
		10 × 10 (1)
Right, recurrent	1	10 × 16 (1)

[a]One patient with bilateral hernias and a recurrence on the left had a double hernia on the right side.

[b]Double hernia.

Table 3 Hernia and duration of surgery

Location, initial/recurrent	No. of patients (N = 14)	Duration of surgery, min
Bilateral		
Initial surgery bilateral	6	Range, 105–135
Right initial, left recurrent	2[a]	120,[a] 150
Unilateral		
Left, initial surgery	1[b]	60
Right, initial surgery	4	Range, 60–90
Right, recurrent	1	90

[a]One patient with bilateral hernias and a recurrence on the left had a double hernia on the right side.

[b]Double hernia.

Successful laparoscopic placement of PADM in the preperitoneal space occurred in 13 patients. The size of PADM used varied across patients (Table 2). For recurrent hernias, removal of synthetic mesh from prior open procedures was not required because the previous open surgery tissue plane was not exposed through the extraperitoneal approach. The mean length of surgery was 102 minutes, with a median of 105 minutes (range, 60–150 minutes). All patients were discharged on the day of surgery.

The median length of follow-up was 18 months (range, 13–25 months). Postoperative assessments showed no hernia recurrences and no complications (*e.g.*, hematoma, orchitis, nerve injury, seroma, chronic/persistent pain). The mean (SD) time to return to work was 3.0 (0.7) days; mean (SD) time to resumption of all normal activities was 12.7 (2.0) days.

Discussion

The results of this retrospective chart review demonstrate the successful placement of a non–cross-linked intact PADM in the preperitoneal space using a laparoscopic TEP approach. In the author's experience, the length of the procedure was not greater than that of laparoscopic inguinal herniorrhaphy with synthetic mesh. All patients were discharged on the day of surgery and had a rapid return to normal activity and work. There were no instances of hernia recurrence or other postoperative complications through a median follow-up period of 18 months. The selection of potential candidates for PADM or other biologic matrices in conjunction with laparoscopic inguinal herniorrhaphy is not well documented in the current literature. Extrapolation of data from other procedures, such as ventral herniorrhaphy, may not be valid and could unnecessarily limit candidates for PADM use in laparoscopic inguinal herniorrhaphy. In the author's experience, patient selection for PADM use in this setting should not be limited to contamination, infection, or certain comorbidities.

In this study, a wide range of patient types were successfully treated. Patients who favored biologic matrix versus synthetic mesh included some with previous unsuccessful open repair attempts with synthetic mesh, others with persistent pain and discomfort following contralateral inguinal herniorrhaphy with synthetic mesh, and young adults concerned about complications that could lead to infertility.[29,30] Some patients with a high level of physical activity chose laparoscopy and biologic matrix. Their decisions were based on the benefits of rapid return to activity associated with laparoscopic versus open repair and a desire to reduce the risk of chronic pain, which might be associated with synthetic mesh products.

Physician reports, literature reviews, and society guidelines have documented several advantages of laparoscopic repair versus open repair. Decreased postoperative pain,[7–9] lower incidence of wound infection and hematoma formation,[8,9] shorter hospital stays, faster recovery and return to normal activity,[7–11] and lower hospital costs have been reported, which may reflect improved cost-effectiveness for laparoscopic repair.[31–33] Laparoscopic technique also allows for both sides of the groin to be inspected/repaired without the need for additional ports or incisions,[34] and may be associated with fewer complications than performing the open procedure bilaterally.[6]

Limitations of laparoscopic techniques have also been described. Laparoscopic inguinal herniorrhaphy, particularly with the TEP technique, has a

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longer learning curve than open repair and may initially require longer operative time,[9] although operating time decreases with surgeons' experience.[32] Laparoscopic repair can be associated with a slightly higher rate of seroma relative to open Lichtenstein repair, and may also be associated with certain rare complications, especially during the learning period.[8,9,35] Contraindications for laparoscopic herniorrhaphy, including prior or planned pelvic operations and pelvic irradiation, or contraindication to general anesthesia, should also be considered.[34]

Open or laparoscopic inguinal herniorrhaphy are both recommended as good options for primary repair of unilateral hernias, whereas laparoscopic repair is usually recommended for bilateral or recurrent hernia, although the European Hernia Society and England's National Health Service National Institute for Health and Clinical Excellence guidelines agree that laparoscopic repair may reduce overall costs because of the decrease in long-term pain and more rapid return to work and daily activities.[9,35]

Both transabdominal preperitoneal (TAPP) and TEP procedures are used regularly for inguinal herniorrhaphy. In one controlled trial, Schrenk and colleagues[36] found no significant difference in operative time, hematoma, length of stay, or time to return to normal activity between the two procedures. Another prospective study reported by Feliu and colleagues[31] showed a shorter mean duration of surgery with TEP versus TAPP procedures. European Hernia Society guidelines and a Cochrane Database review found broadly consistent results showing a slight increase in injuries to internal organs and port-site hernias with TAPP, and more frequent conversions to other surgeries with TEP.[9,37]

Synthetic mesh is well established as an effective component of open and laparoscopic inguinal herniorrhaphy, but it is associated with several notable risks beyond those most commonly described. Chronic pain,[38,39] vas deferens injury and occlusion,[40] and enterocutaneous fistulae have been reported following synthetic mesh repair.[16] There have been some cases of infertility associated with insertion of synthetic mesh in the retropubic space,[30] and several studies have suggested that inadvertent injury to the vas deferens during laparoscopic herniorrhaphy may play a role in fibrosis formation around the spermatic cord.[29,30] With the recent advances in robotic prostatectomy, the presence of synthetic mesh in the retropubic space after hernia repair might prevent future minimally invasive prostatectomy; Tsivian and colleagues[41] describe problems with access and adhesions in the Retzius space that may affect the course of an individual urologic operation and contribute to an overall higher degree of operative difficulty.

Non–cross-linked intact PADM is designed to perform as a surgical mesh for soft-tissue repair while serving as a scaffold for the rapid ingrowth of host cells, collagen, and blood vessels.[42] The use of biologic matrix to reinforce tissue repair and maintain abdominal wall pliability in inguinal hernia repair might replace the "Iron Man" repair concept, which relies on strengthening the anterior abdominal wall with synthetic mesh and fibrosis.

In laboratory studies, PADM was found to be associated with rapid revascularization, white blood cell migration, and cell repopulation to support tissue regeneration[22]; it has also been shown to minimize occurrence of adhesions compared with synthetic mesh.[43] Clinically, PADM has been shown to focally integrate well in host tissue, with no adverse effects.[44] Also, based on studies of patients undergoing ventral hernia repair, biologic matrices (such as PADM) are thought to resist infection better than synthetic mesh products,[13] and use of biologics may minimize risk of inflammatory reactions.[22,45] These qualities support the concept of using a biologic matrix in inguinal herniorrhaphy to strengthen weak tissue while maintaining abdominal wall tissue elasticity that is sometimes diminished with synthetic mesh.

Results reported here demonstrate that TEP laparoscopic inguinal herniorrhaphy with PADM can be performed in an acceptable time frame and can result in definitive repair without significant morbidity. In the author's experience, there are several technical points that optimize use of PADM in the setting of TEP laparoscopic inguinal herniorrhaphy. Adequate trocar size (11 mm), proper rolling of the biologic matrix, and matrix fixation optimize results with this procedure. The author found PADM can be easily placed if it is first rolled over a laparoscopic grasper and slipped into the retropubic space through the retrorectal space without using a trocar; the mesh is slippery and has a memory recoil feature that makes it easy to unroll and manipulate into place during surgery. Placement of PADM in the patients in our case series was best accomplished through the use of absorbable sutures anchored to the anterior abdominal wall with an endo-closure device. The use of a tacker device proved difficult because of the thickness of PADM and lack of room

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for manipulation of the tacker in the retropubic space.

Additional data are needed to evaluate the use of PADM versus other types of biologic matrices or synthetic mesh during TEP, TAPP, or open inguinal herniorrhaphy. Large-scale studies to evaluate suitable patient types and the impact of postoperative complications on cost, patient productivity, and quality of life are needed to help improve long-term patient outcomes.

Conclusions

The successful outcomes recorded here demonstrate laparoscopic inguinal herniorrhaphy with non–cross-linked intact PADM in the preperitoneal space can be performed in an acceptable time frame with favorable outcomes.

The patients in this study experienced a rapid return to normal activity and to work, with no recurrence after a median follow-up of 18 months. Based on these data, this procedure, with appropriate patient consultation, can be offered to a variety of patients who might otherwise have been overlooked or excluded from consideration. Additional data are needed to elucidate outcomes relative to synthetic mesh and other biologic matrices in these procedures.

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