

# Laparoscopic Herniorrhaphy with Porcine Small Intestinal Submucosa: A Preliminary Study

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## ABSTRACT

**Introduction:** Using mesh or a synthetic prosthesis during the laparoscopic repair of inguinal hernias has been demonstrated to be safe and effective. A new material, porcine small intestinal submucosa (SIS mesh), has been successfully used in canine and rodent animal models with excellent results. This mesh is degradable and resorbable with a marked decrease in the possibility of becoming infected. However, the amount of fibroblast ingrowth is equal to that with polypropylene mesh.

**Methods:** A comparison was made between this new SIS mesh to repair 15 inguinal hernias in 12 patients and polypropylene mesh used in 12 similar patients. A preperitoneal approach with balloon dissection was used in all patients.

**Results:** Demographics were similar in both groups. The results were excellent and compared equally. Complications (seroma, discomfort) were minimal in both groups and were similar.

**Conclusions:** Porcine small intestinal submucosa, SIS mesh, can be used for laparoscopic repair of inguinal hernias. Long-term follow-up will be necessary to confirm these preliminary results.

**Key Words:** Small intestine submucosa, Mesh, Laparoscopic hernia repair, Herniorrhaphy.

## INTRODUCTION

Mesh is now commonly used to repair inguinal hernias, and its use in laparoscopy is no different. Presently, polypropylene (Prolene or Marlex) or polytetrafluoroethylene (PTFE - Gor-Tex) are the 2 most commonly used prosthetics. They work well but have their drawbacks. The ideal prosthetic material for hernia repair should be inexpensive to produce, easy to use, promote host tissue ingrowth, result in a healed repair with equal strength to normal tissue over extended periods of time, provide resistance to infection, elicit little or no inflammatory response, and inhibit adhesion or fistula formation.

SIS mesh is a new material that initially was used as a graft material for arteries, veins, ligaments, dura, wound coverage, and urinary bladders. Recent animal investigations have shown that SIS is effective in repairing abdominal wall hernias. The mesh has been approved by the FDA. The purpose of this research was to evaluate the short-term results of laparoscopic inguinal hernia repair with porcine small intestinal submucosa.

## METHODS

Patients were seen and interviewed because of a suspected inguinal hernia. If a hernia was confirmed after a history and physical examination, patients were asked to participate in this investigation of a new type of mesh to repair their inguinal hernia. Patients were excluded from participating in the study if their hernias extended into the scrotum or were larger than 4 centimeters in size. All hernias were per-primum. The first 12 patients to agree to have surgery are included in this preliminary study. The first patient underwent hernia repair on August 19, 1999 and the last patient on November 6, 2000.

Laparoscopic hernia repair was performed with a totally extraperitoneal technique (TEPP)<sup>1</sup> in 11 of 12 patients. A balloon was used to dissect the peritoneum away from the anterior abdominal wall down to below the pubic bone. An 11-mm Hasson cannula was used in the fascia, just lateral to the umbilicus on the same side as the hernia. Two 5-mm cannulas were used in the midline above the pubic bone and midway between the umbilicus and pubis. The mesh, measuring 7 x 10 centimeters, was

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placed, uncut, over the myopectinate orifice. Five tacks were placed into the mesh into pubic bone (Cooper's ligament) in the midline, lacunar ligament and superiorly in the transversalis fascia. One patient was treated with a transabdominal preperitoneal repair (TAPP) because the hernia was incarcerated and could not be reduced before surgery. Patients were seen postoperatively at 2 weeks, 6 weeks, 3 months, and 6 months. A phone call interview was performed at 1 year.

Over 600 laparoscopic inguinal hernia repairs have been performed at The Gallbladder & Laparoscopic Surgery Center since 1992. Patients in the SIS group were matched to patients operated upon at the same time and dates. All demographics were matched equally. The patients in the control group had the same preperitoneal laparoscopic hernia repair except a polypropylene mesh was used for the repair. Mesh was placed uncut over the myopectinate space and tacked to the Cooper's ligament, inferiorly, and to the transversalis fascia, superiorly. The mesh size did vary depending on the patient. A 15 x 15-cm mesh was used and then cut down to a slightly smaller size if the patient's weight, body habitus, and hernia defect required a smaller than 15 x 15-cm mesh size.

## RESULTS

Seven women and 5 men were enrolled in the study. Ages ranged from 21 to 69 years. Mean age was 41.7 years. Operating time ranged from 25 minutes to 40 minutes. The average operating time was 31.5 minutes. Anesthetic techniques included general endotracheal in 6 patients, laryngeal mask with local infiltration of 30 cc of 1/2% bupivacaine in 5 patients, and epidural in 1 patient. Operative findings were direct hernias in 2, indirect hernias in 12, and a pantaloon hernia in 1 patient. All patients were discharged home the same day of surgery.

Complications were minimal. Three patients had a seroma (25%) and all resolved. In 2 of those patients (15%), the seroma was tender for 1 month. One patient had a temporary, intermittent dysuria for 2 weeks. No recurrent hernias have been noted.

In comparison, the control group had the same results and findings. The demographics were the same, as well. Complications were no different, and there were no recurrences.

## DISCUSSION

The use of mesh to repair inguinal hernias is now accepted as the standard of care by many surgeons whether the repair is performed openly or laparoscopically. Recurrence rates are low when mesh is used and are reported to be between 3% and 6%<sup>2-4</sup> for laparoscopic herniorrhaphy. The goal of hernia repair is to relieve the discomfort and to prevent the strangulation of intestine through the reconstruction of the inguinal floor. The fact that so many types of hernia repairs are described in the literature speaks to the fact of the difficulty in achieving this goal. Laparoscopic hernia surgery has been shown to have a short hospital stay, cause minimal pain, and offer improved convalescence.<sup>2-5</sup>

Small intestinal submucosa (SIS) was first investigated as a vascular graft substitute in dogs in 1989.<sup>6</sup> The uses of SIS have exploded over the past few years and include urinary bladder substitute, urethral grafts, Achilles tendon replacement, dura graft, skin covering, and, now, most recently, abdominal wall repair. Prevel in 1995<sup>7</sup> studied the use of SIS mesh to repair a 2 x 2-cm hernia defect in Sprague-Dawley rats. This study found that no abdominal wall hernias had developed, and minimal intraabdominal adhesions were observed. No evidence existed of graft versus host rejection.

Clarke, the following year, reported a pilot study in dogs with SIS mesh to repair full-thickness abdominal wall defects.<sup>8</sup> The SIS implants were completely replaced by host tissue at 4 months. Again, no evidence of implant failure was found. Their results confirmed rapid host tissue ingrowth with SIS maintaining sufficient strength.

Small intestinal submucosa is found between the mucosal and muscular layers of the small intestine. The submucosa provides strength to the intestine and is predominantly a complex matrix of collagen. The submucosa is also a reservoir for cytokines that guide the repair and replacement of intestinal epithelial cells. SIS works by providing a natural, extracellular matrix and acts as a scaffold for host cell incorporation and tissue remodeling.

## CONCLUSION

SIS is a natural, acellular biomaterial that supports tissue repair. It has been used in animal models with excellent results. This preliminary report shows that porcine SIS mesh

can be used for laparoscopic inguinal hernia repairs. Long-term follow-up will be necessary to confirm these preliminary results.

**References:**

1. Voeller GR, Mangiante EC, Wilson C. Totally preperitoneal laparoscopic inguinal herniorrhaphy using balloon dissection. *Surg Round.* 1995;3:107-112.
2. Liem MS, Graaf YV, Steensel CJ, et al. Comparison of conventional anterior surgery and laparoscopic surgery for inguinal hernia repair. *N Engl J Med.* 1997;336:1541-1547.
3. Brooks DC. A prospective comparison of laparoscopic and tension-free open herniorrhaphy. *Arch Surg.* 1994;129:361-366.
4. Payne JH, Grininger LM, Izawa MT, Podoll EF, Lindahl PJ, Balfour J. Laparoscopic or open inguinal herniorrhaphy? *Arch Surg.* 1994;129:973-979.
5. Kozol R, Lange PM, Kosir M, et al. A prospective, randomized study of open vs laparoscopic inguinal hernia repair. *Arch Surg.* 1997;132:292-295.
6. Badylak SF, Lantz G, Coffey A, Geddes LA. Small intestinal submucosa as a large diameter vascular graft in the dog. *J Surg Res.* 1989;47:74-80.
7. Prevel CD, Eppley BL, Summerlin DJ, Jackson JR, McCarty M, Badylak SF. Small intestinal submucosa: utilization for repair of rodent abdominal wall defects. *Ann Plastic Surg.* 1995;35:374-380.
8. Clarke KM, Lantz GC, Salisbury SK, Badylak SF, Hiles MC, Voytik SL. Intestinal submucosa and polypropylene mesh for abdominal wall repair in dogs. *J Surg Res.* 1996;60:107-114.

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