# Biologic vs Synthetic Inguinal Hernia Repair: 1-Year Results of a Randomized Double-Blinded Trial

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**BACKGROUND:** Various surgical meshes are used in the repair of inguinal hernia and are associated with numerous complications. Our main objective in this study was to determine whether a biologic hernia matrix is equivalent to polypropylene mesh in an open inguinal hernia repair using the Lichtenstein technique.

**STUDY DESIGN:** A prospective, randomized, double-blinded, single-center trial was conducted to evaluate the efficacy of a biologic Inguinal Hernia Matrix (IHM; Cook Medical) compared with polypropylene (PP) mesh using Lichtenstein's inguinal hernia repair in a 3-year outcomes study. Patients were evaluated for recurrence and complications by a blinded surgeon at 2 weeks, 3 months, 6 months, and 1 year post procedure. Patient demographics, including comorbidities and nutrition status, were recorded. Intraoperative information including hernia type and location, procedure time, level of difficulty, degree of surgeon frustration, and surgical experience were collected.

**RESULTS:** One hundred male patients provided informed consent and were randomized into the study in a 1:1 fashion. There were no significant differences in degree of difficulty and level of frustration between the 2 groups. At 1-year follow-up, 3 recurrences were diagnosed in the IHM group as compared with none in the PP group ($p = 0.11$). Persistent pain trended higher in the PP group (6% vs 4%). All 3 recurrences occurred in the direct inguinal hernia group and were performed by attendings in the first year post training (3 different attendings). No recurrences occurred in patients operated on by more senior surgeons.

**CONCLUSIONS:** The IHM hernioplasty compares favorably with PP mesh at 1-year follow-up with similar recurrence rates and complications. Surgeon experience appears to be a major factor affecting successful outcomes. (J Am Coll Surg 2014;218:751−759. © 2014 by the American College of Surgeons)

Inguinal hernia repair is the most common surgical procedure performed in the United States, with >600,000 performed on an annual basis.[1] However, despite how frequent this procedure has become with technical advancements occurring during the last several decades, the recurrence rates have been reported to remain as high as 15%. In addition, persistent postoperative pain and discomfort are commonly reported.[1-7] Several factors have been reported to be associated with these high recurrence and complication rates, which include (but are not limited to) the surgeon's age and experience, level of intraoperative frustration during the procedure, as well as level of experience of the surgical assistant.[7-10] In addition, the type of procedure performed (open vs laparoscopic), as well as the type of mesh (synthetic vs biologic), play integral roles in a patient's recovery and long-term outcomes.

After the introduction of tension-free surgical repair with the use of prosthetic mesh, recurrence rates were reported to be <5%. and patient comfort was reported to be substantially improved compared with that obtained by the traditional, tension-producing techniques.[11,12] Despite this new information, the debate about the use

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**Abbreviations and Acronyms**

IHM = Inguinal Hernia Matrix
PP = polypropylene
SF-36V2 = Short-Form 36 Health Survey, version 2
VAS = Visual Analogue Scale

of synthetic mesh continues as studies have noted their association with numerous complications, including persistent pain, infection, adhesions, bowel erosion, shrinkage, and inflammation.[13-15] In addition, concerns about the impact of synthetic mesh on azospermia as a result of vas deferens obstruction remain.[16,17] Such issues become even more important to consider when selecting the type of material to implant for an inguinal hernia repair in a young male patient in whom mesh might remain in place for several decades.

Biologic graft products, such as the Biodesign Inguinal Hernia Matrix (IHM; Cook Medical) are designed with the strength needed to reinforce soft tissues in the inguinal floor to repair inguinal hernias. The advantage of biologic graft is that they are nonpermanent (absorbable) and act as a scaffold for tissue regeneration. A nonpermanent graft would be a valued option in patients because, theoretically, many of the persistent complications associated with synthetic mesh, such as pain due to the mesh rubbing etc, would be temporary, as the mesh would eventually biodegrade. However, due to added complexities, biologic graft implantation might require added skill or technical expertise. Therefore, the objectives of this study were to evaluate whether there is are differences in recurrence and complication rates in patients who undergo an open Lichtenstein inguinal hernia repair using a synthetic (polypropylene [PP]) mesh compared with a biologic hernia matrix (IHM).

## METHODS

### Study population, recruitment, study interventions, and follow-up

Men presenting to a general surgery clinic at the Veterans Affairs medical center who were 18 years of age or older, had a diagnosis of unilateral inguinal hernia, and provided written informed consent were eligible for random assignment to open tension-free repair with PP mesh or IHM (Fig. 1). Patients in American Society of Anesthesiologists class IV (ie, those who had systemic disease that is a constant threat to life) or class V (ie, those who were unlikely to survive for 24 hours, with or without an operation) were excluded, as were those who had contraindications to general anesthesia, bowel obstruction, bowel strangulation, peritonitis, bowel perforation, local or systemic infection, a history of inguinal hernia repair with mesh (on same side as incarcerated hernias, unwillingness to receive a porcine-derived product, planned surgery), or with a life expectancy of <3 years. Patients who were participating in an investigational trial were also excluded. Randomization was 1:1 and was carried out using an interactive voice recognition system. After randomization and before intervention, patients were asked to complete a baseline Short-Form 36 Health Survey, version 2 (SF-36V2), an instrument designed to measure health-related quality of life. The patients were also asked to complete a pain score measured using a Visual Analogue Scale (VAS). The study was approved by the University of Maryland School of Medicine Institutional Review Board.

### Intervention

During the implementation phase of the trial, a training session was conducted with all of the surgeon investigators to ensure that each was thoroughly trained on the protocol. All surgeon investigators agreed on standardization of herniorrhaphy techniques and were also trained on the manufacturer's instructions per each specific hernia mesh. Consensus on all aspects of perioperative patient management (including postoperative patient instructions, follow-up schedules, definitions of recurrence, and complications) was obtained.

The Lichtenstein procedure, as described in the video produced by the Lichtenstein Clinic in 1997 and described by Amid, was used.[11,18] Also, the local anesthetic technique of Lichtenstein was chosen as the local anesthetic method for open repairs performed without general or spinal anesthesia. The exact size of mesh and placement and type of sutures were standardized. The participating surgeons' self-reported experience and age were recorded at the beginning of each operation, as well as the postgraduate year of their assistant. The presence of the attending surgeon at the operating table throughout the procedure was required. In addition, the level of frustration and difficulty of each case was detailed at the completion of each procedure by the operating surgeon.

### Data collection and follow-up

Intraoperative data were recorded at the time of operation, including size of mesh, adverse, or serious adverse events and Nyhus classification of the hernia.[18] Immediate postoperative (within 14 days) and early postoperative (within 6 weeks) complications of herniorrhaphy were recorded at routine postoperative visits.

Patients completed a VAS for pain every day after surgery and at each follow-up visit.[19,20] The SF-36V2