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

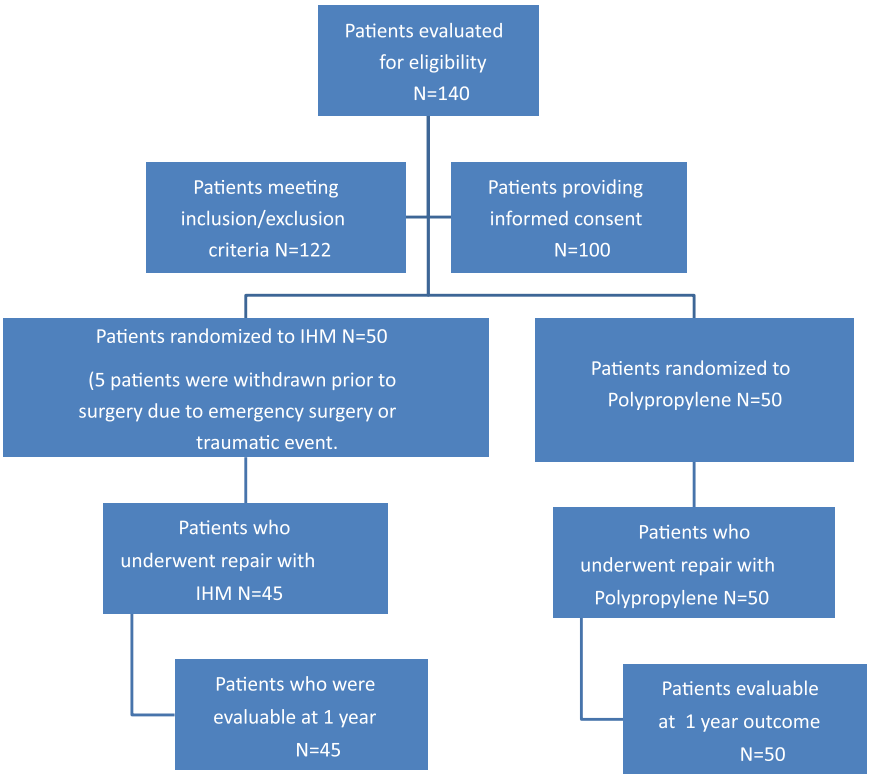

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

was administered at the first postoperative visit and then again at 3 months.[20] Patients were assessed for recurrence by an independent blinded surgeon (a surgeon other than the one who performed the operation) and the nurse coordinator at 3 months, 6 months, and 12 months. A recurrence was confirmed by repeat operation, ultrasonography, or CT scan.

RESULTS

One hundred patients were enrolled from March 19, 2007 through February 7, 2011. Please see Table 1 for a list of their demographics stratified by study group. There were no significant differences in age, body mass index, and American Society of Anesthesiologists class between the 2 groups. However, the IHM study group had significantly more patients with type 2 diabetes ($p = 0.05$) and were more likely to have a history of hyperlipidemia ($p = 0.03$). Five patients in the IHM arm were excluded before surgery, as they either became symptomatic between the time of consent and required emergent surgery or had another emergent procedure before their scheduled surgery that did not allow them to participate. See Table 2 for intraoperative characteristics. Most notable, there were no significant differences in the type of hernia (direct vs indirect and sliding vs nonsliding) and type of anesthesia used.

At the 1-year follow-up period, there were a total of 3 hernia recurrences diagnosed; all 3 were in the IHM group and were originally classified as direct hernias.

Table 1. Patient Characteristics and Preoperative Comorbidities Stratified by Study Group

	Study group		
	IHM	Polypropylene	p Value
Patients enrolled, n	50	50	
Age, y, mean (range)	64 (24–85)	59 (25–87)	NS
Ethnicity, n (%)			
Caucasian	26 (52)	16 (32)	0.04
African American	14 (28)	20 (40)	NS
Other	10 (20)	14 (28)	NS
Body mass index, mean (range)	26 (18–39)	25 (19–37)	NS
Comorbidities, n (%)			
Diabetes, type 2	6 (12)	1 (2)	0.05
Hypertension	13 (26)	7 (14)	NS
Hyperlipidemia	20 (40)	10 (20)	0.03
History of smoking	28 (56)	29 (58)	NS

IHM, Inguinal Hernia Matrix (Cook Medical).

Table 2. Intraoperative Information

Intraoperative information	IHM (n = 45)	Polypropylene (n = 50)	p Value
Type of hernia, n (%)			
Direct	20 (44)	21 (42)	NS
Indirect	26 (58)	29 (58)	NS
Sliding	24 (53)	19 (38)	NS
Nonsliding	26 (58)	31 (62)	NS
Presence of lipoma, n (%)	22 (49)	24 (48)	NS
Anesthesia, n (%)			
Epidural	0 (0)	1 (2)	NS
Spinal	4 (9)	6 (12)	NS
General	42 (93)	44 (88)	NS
Presence of Foley catheter	4 (9)	7 (14)	NS
Procedure time, min	134	115	NS

IHM, Inguinal Hernia Matrix (Cook Medical).

See Figure 2 as an example of a direct hernia diagnosed intraoperatively in the IHM group. Other risk factors for recurrence, such as diabetes and smoking, were not found to be significant risk factors for recurrence.

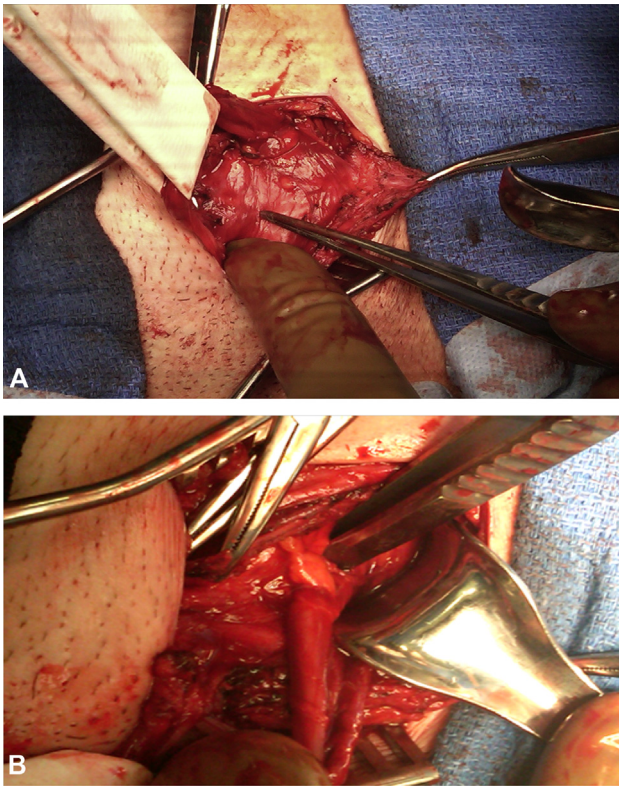

Figure 2. (A) Intraoperative photo demonstrating Inguinal Hernia Matrix (IHM; Cook Medical) 1 year post repair. It is virtually impossible to distinguish between native tissue and the remodeled IHM. (B) Intraoperative photo demonstrating a recurrence at the internal ring.

Complications

There were a total of 72 complications and 12 serious adverse events identified during the first year (see Tables 3 and 4). There was 1 death as a result of a myocardial infarction in the IHM group. Not surprisingly, pain at the 2-week follow-up period was the most common complication noted in both groups (n = 17), followed by neuralgia (n = 10), urinary retention (n = 9), and testicular problems (n = 9).

Patient-centered outcomes

Figure 3 illustrates the pain scores detailed by the VAS at 2 weeks, 3 months, and 12 months post surgery. There is no statistically significant difference between the 2 groups. Tables 5 and 6 demonstrate the results of the SF-36V2 at baseline and 3 months post hernia repair. Both groups demonstrated an improvement in their physical functioning and role. However, only the IHM group had a significant improvement in bodily pain ($p < 0.05$) and other mental health indicators (social functioning, mental health, vitality, and role emotional) ($p < 0.05$).

Surgeons' experience

We also performed a post-hoc evaluation of the association between surgeons' self-reported experience (the number of procedures performed previously and years out of training) and recurrence (Table 7). There were no significant differences in experience between the 2 groups. However, all 3 hernia recurrences occurred in patients who were operated on by surgeons who were in their first year post completion of residency/fellowship training.

Table 3. 12-Month Postoperative Complications

	IHM		Polypropylene	
Complications	n	%	n	%
Postoperative pain				
Immediate	0	0	0	0
At 2 weeks	9	20	8	16
At 1 year	2	4	3	6
Hematoma	6	13	1	2
Seroma	5	11	0	0
Neuralgia	4	9	6	12
Infection	0	0	0	0
Testicular problems	5	11	4	8
Urinary retention	6	13	3	6
Spermatic-cord injury	0	0	1	2
Orchitis	0	0	0	0
Incisional pain	2	4	4	8
Surgical site reaction	3	7	0	0

IHM, Inguinal Hernia Matrix (Cook Medical).

Table 4. Serious Adverse Events

Inguinal Hernia Matrix (Cook Medical)
Hematoma requiring hospitalization—unrelated to the device
UTI requiring hospitalization—unrelated to the device
MI resulting in death—unrelated to the device
Scrotal hematoma requiring hospitalization—unrelated to the device
Bradycardia during hernia repair—unrelated to the device
Right inguinal pain, inflammation, and tenderness requiring hospitalization—possibly related to the device
Left groin pain and scrotal swelling requiring hospitalization—possibly related to the device
Polypropylene
Diverticulitis and prostatitis requiring hospitalization—unrelated to the device
Substantial bleeding with central-line placement—unrelated to the device
Motorcycle accident resulting in death—unrelated to the device
Severe pain requiring hospitalization—unrelated to the device
Urinary retention requiring overnight observation—unrelated to the device

UTI, urinary tract infection.

DISCUSSION

Polypropylene continues to be the preferred prosthetic material for tension-free hernia repair because it handles well and becomes quickly integrated. However, complications such as postoperative pain, long-term discomfort, infection, intestinal obstruction, and fistulization, are still considered to be major concerns when using this type of mesh.[22-24] Therefore, PP should never be placed in direct contact with abdominal viscera and would need to be removed if it became infected.

In an effort to avoid the complications associated with using synthetic mesh, surgeons have been evaluating biologically derived hernia matrices in the past several years. Examples of these include, but are not limited to, acellular dermal products (eg, FlexHD, Strattice) and extracellular-derived matrix products (eg, IHM) derived from human and porcine materials. The main platform of these materials is that they act as a bioscaffold to support and enhance tissue repair. The IHM (derived from porcine small intestinal submucosa) has been FDA approved for more than a decade and has been used in a variety of areas, including inguinal and ventral hernia repair. Several studies have demonstrated that porcine small-intestine submucosa (IHM) is rapidly degraded when used as an in vivo bioscaffold, as fibroblasts migrate and proliferate, serving as scaffolding for new tissue growth. As organized tissue deposition occurs, IHM is gradually remodeled by the host, yielding a repaired tissue structure that is entirely host derived.[25,26] Therefore, theoretically, IHM should not erode or require removal if it were to become infected.

In this study, we evaluated the recurrence rates of a biologic inguinal hernia repair in a randomized trial compared with standard PP using the Lichtenstein technique. We chose the Veterans Affairs population for our trial, as this cohort of patients with the diagnosis of inguinal hernia has been well studied previously.[7,10]

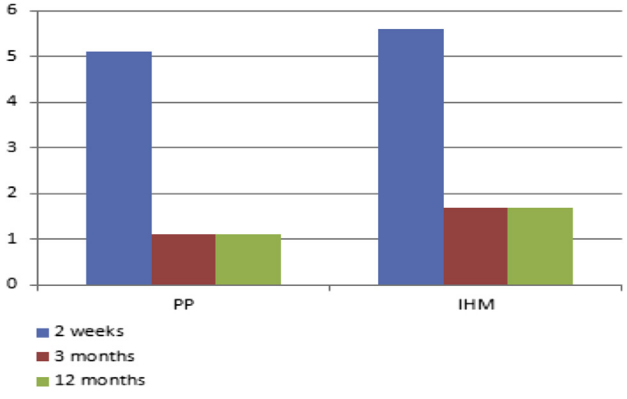

Figure 3. Pain scores at 2 weeks, 3 months, and 12 months. IHM, Inguinal Hernia Matrix (Cook Medical); PP, polypropylene mesh.

Table 5. Short-Form 36 Health Survey, Version 2 Scores of Polypropylene Arm

SF-36V2 category	Baseline, mean ± SD	3 Months, mean ± SD	Mean difference	p Value
Physical functioning	66 ± 29	81 ± 51	15	<0.05
Role physical	52 ± 28	68 ± 27	16	<0.05
Role emotional	68 ± 28	74 ± 25	6	NS
Vitality	60 ± 20	61 ± 19	1	NS
Mental health	69 ± 21	71 ± 19	2	NS
Social functioning	69 ± 23	73 ± 22	4	NS
Bodily pain	56 ± 26	58 ± 22	2	NS
General health	67 ± 17	72 ± 20	5	NS

SF-36V2, Short-Form 36 Health Survey, version 2.

Table 6. Short-Form 36 Health Survey, Version 2 Scores of Inguinal Hernia Matrix (Cook Medical) Arm

SF-36V2 category	Baseline, mean ± SD	3 Months, mean ± SD	Mean difference	p Value
Physical functioning	66 ± 28	77 ± 22	11	<0.05
Role, physical	68 ± 27	78 ± 24	10	<0.05
Role, emotional	74 ± 25	85 ± 21	11	<0.05
Vitality	61 ± 19	69 ± 18	8	<0.05
Mental health	71 ± 19	78 ± 15	7	<0.05
Social functioning	73 ± 22	84 ± 19	11	<0.05
Bodily pain	58 ± 22	77 ± 28	19	<0.05
General health	72 ± 20	72 ± 19	0	NS

SF-36V2, Short-Form 36 Health Survey, version 2.

Table 7. Surgeon Experience and Intraoperative Factors

Surgeon information	IHM	Polypropylene
Age of primary surgeon, y, mean (range)	37 (32−48)	37 (32−43)
No. of earlier hernia repairs, mean (range)	195 (0−1,600)	157 (0−1,300)
No. of years out of training, mean (range)	4 (0−12)	5 (0−12)
Level of frustration during the case, mean (range)	2 (1−5)	2 (1−4)
Level of difficulty of case, mean (range)	2 (1−4)	2 (1−4)

IHM, Inguinal Hernia Matrix (Cook Medical).

We controlled for several factors previously reported to be associated with recurrence, such as type of hernia and surgical experience. For example, Neumayer and colleagues concluded that the level of a surgeon's frustration during performance of an inguinal herniorrhaphy was a better predictor of outcomes of the operation than was satisfaction with the procedure.[10] In addition, the same authors reported that the age of the surgeon and level of experience in the operating room were also risk factors for recurrence.[10]

During this 1-year interim analysis of this 3-year study, 3 recurrences were diagnosed in the IHM arm and no recurrences were diagnosed in the PP arm. It is important to point out that all 3 recurrences occurred in hernia repairs performed by a junior attending (first year post graduation from residency or fellowship) and there have not been any recurrences diagnosed so far in patients repaired by the more experienced surgeons. This finding suggests that a biologic repair might require some added technical skill and experience, as there was no significant difference in the perceived complexity level and level of frustration reported by the operating surgeon. Patients randomized to the IHM arm experienced more early postoperative complications, including hematomas, seromas, and localized surgical site reactions (Table 3). These complications all resolved with conservative treatment and patients experienced no adverse sequelae.

With regard to pain, there were no statistically significant differences in pain scores as denoted by the VAS results between the 2 groups at 3 months and 1 year (Fig. 1). There was, however, a greater percentage of patients who reported persistent incisional pain at 1 year and neuralgia in the PP arm. Although not statistically significant, we will re-evaluate this at our subsequent analysis at years 2 and 3. As expected, the results of the SF-36V2 demonstrated that both groups had an improvement in physical functioning and role at 3 months post surgery. However, there was a significant improvement in perceived bodily pain in the IHM arm ($p < 0.05$) at 3 months only and not in the PP arm. In addition, the IHM group also demonstrated a significant improvement in the mental health components of the SF-36V2, as delineated by mental health, social functioning, and vitality scores ($p < 0.05$). This might be a direct result of the improvement in their overall perceived bodily pain.

CONCLUSIONS

We report our 1-year findings of this 3-year randomized trial. There were a greater number of recurrences in the biologic repair arm, however, this might be attributed to the inexperience of the surgeons who performed those hernia repairs.

Author Contributions

Study conception and design: G V Bochicchio, Turner, Ilahi, K Bochicchio

Acquisition of data: G V Bochicchio, Jain, McGonigal, Reese, K Bochicchio

Analysis and interpretation of data: G V Bochicchio, Jain, McGonigal, Reese, K Bochicchio

Drafting of manuscript: G V Bochicchio, Reese, K Bochicchio

Critical revision: G V Bochicchio, K Bochicchio, Reese

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Discussion

DR BARBARA BASS (Houston, TX): First, I really want to commend the authors in their persistence in contributing evidence to help guide our choices in treating this most common surgical condition. Clearly, this is an area in which dealer's choice is a very common approach in both materials and approaches that we take toward the groin. Dealer's choice reigns supreme here.

I do think we have gained evidence-based consensus that a tension-free repair is the optimal strategy. But after that, the data to support our choices on other aspects of inguinal hernia remain really quite thin. So I congratulate you on contributing with a randomized controlled trial comparing 2 widely used products to perform a Lichtenstein repair of primary inguinal hernia.

We all recognize that completing a blinded randomized surgical clinical trial is not an easy thing to do. And I am delighted to see that the Baltimore VA surgeons and research staff—although you've moved on now to Washington University now, Dr Bochicchio—continue to design and execute these studies.

This study compared a synthetic polypropylene mesh, a very inexpensive product, against a biologic mesh product, a rather pricey product created from the porcine small bowel submucosa, the first of biologic matrices to come to commercial production. We all know that synthetic mesh, polypropylene being 1 example, can be a very troublesome thing in years to come for some patients, occasionally causing pain and for others, dreaded infection. So, if we could prove that biologic substrates were equally effective in achieving our goal of durable hernia repair and eliminate those more troublesome effects of synthetic mesh, this would certainly be a laudable goal, and therefore, the very justifiable rationale for this randomized control trial.

The design and endpoints of the trial were thorough and rational and the trial was well executed. This study captured the outcomes and variables defined in the earlier VA cooperative study trials on inguinal hernia repair. These elements included the important outcomes of early and late wound complications, durability of repair, and assessment of meaningful contributing variables such as hernia anatomy, surgeon experience, and surgeon frustration as a potential contributor to outcomes.

The results of your 100-patient study at the 1-year interim analysis suggested that there is no statistically significant difference in these 2 approaches. Equivalency, we might say. However, several notable trends are evident that I would like you to expand on as part of the responses to my questions.

1. Did you do a power analysis when planning this study? How many patients really would you need to accrue to get to your endpoints of equivalency? What assumptions did you use in planning that power analysis?
2. The trends that you noted clearly showed more early postoperative complications, hematoma, seroma, and site inflammation in the biologic mesh group. Is this one of the prices we are going to pay for using biologic meshes?
3. What is the scale on your visual analog pain scale? Is it 1 to 6? 1 to 10? If it is 1 to 10, a difference of 1 to 1½ at 6 months, I must say, does not look terribly troublesome to me.
4. The table shows that 40% to 50% of your hernias were classified as sliding hernias. Is that really true? And, if so, how was the sac handled in those particular cases? That's an awfully high number of sliders for primary inguinal hernia.
5. The authors reported that the 3 recurrences could be linked to surgeon experience. They all, of course, also happened to have