Hypothesis: A modified technique for mesh-plug hernioplasty is a safe and efficacious option for primary unilateral inguinal herniorrhaphy.

Design: Prospective analysis of 1056 patients who underwent primary unilateral inguinal hernioplasty.

Setting: A private university medical center.

Patients: One thousand twenty-five men and 31 women (mean age, 49 years) with primary unilateral inguinal hernias that were surgically repaired between May 1, 1997, and November 1, 2001.

Intervention: We performed a modified technique using a mesh plug and local anesthesia with intravenous sedation. The modified technique consisted of placing the mesh plug into the preperitoneal space and suture fixation of the plug using the inner petals.

Main Outcome Measures: Surgical morbidity, hernia recurrence, postoperative pain medication used, and return to normal activities.

Results: We included 642 indirect and 414 direct hernias. Mean operative time was 25 minutes; mean recovery room time, 45 minutes. All procedures were performed as outpatient surgery. One thousand thirteen patients (95.9%) returned to normal activities within 3 days. All manual laborers returned to work on postoperative day 14. Only 169 patients (16.0%) required prescription pain medication. At 1-year follow-up, 1045 patients (99.0%) have been examined, and 1 recurrence (0.1%) has been detected. No mesh infection has occurred, and 19 hematomas spontaneously resolved. Five patients (0.5%) required treatment for persistent postoperative pain.

Conclusions: The modified mesh-plug hernioplasty uses a minimum of medical resources and is associated with a small amount of postoperative pain and an early return to normal activities and manual labor with a minimal documented early recurrence rate. The Millikan modified mesh-plug hernioplasty should be adopted as the gold standard for unilateral primary inguinal hernioplasty.

Arch Surg. 2003;138:525-530

Since Bassini described his primary inguinal hernia repair in 1890, many advancements and modifications of groin herniorrhaphy and hernioplasty have been described. Mesh repairs for inguinal hernias have become generally accepted as the solution to reduce tension on a repair during the past 2 decades. Mesh plugs were first introduced by Lichtenstein and Shore for femoral and recurrent hernias in the 1970s. Gilbert described a sutureless mesh-plug and patch repair for indirect hernias in the 1980s. Rutkow and Robbins followed this with a description of a mesh-plug and patch repair for all varieties of inguinal hernias in the early 1990s. Since then, Rutkow and Robbins have reported their repair results with a pre-made manufactured plug and patch.

Criticism of the mesh-plug hernioplasty by others who use alternative mesh repairs has surfaced during the past decade. Critics of the mesh-plug hernioplasty describe mesh shrinkage, erosion, and migration and chronic pain as reasons not to use mesh plugs in primary hernia repair. We modified the mesh-plug hernioplasty in 1997 to possibly eliminate previous criticism of the mesh plug and reported our early results in 2001. We have continued to use and prospectively follow this modification of the Rutkow and Robbins mesh-plug hernioplasty in an effort to determine its safety and efficacy in a large number of patients.

METHODS

We conducted a prospective analysis of 1056 patients with unilateral primary inguinal her-
Hernias undergoing a modified mesh-plug hernioplasty from May 1, 1997, through November 1, 2002, at Rush-Presbyterian-St Luke's Medical Center, Chicago, Ill. The study population consisted of 853 men and 31 women with a mean age of 49 years (range, 13-96 years). Four hundred sixty-five patients were manual laborers. Patients covered by worker's compensation were excluded from this study. Hernia type was determined at the time of operation. The following tabulation lists the types of hernias encountered according to the classification by Gilbert22:

<table>
<thead>
<tr>
<th>Hernia Classification</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect</td>
<td>642</td>
</tr>
<tr>
<td>Type I</td>
<td>78</td>
</tr>
<tr>
<td>Type II</td>
<td>506</td>
</tr>
<tr>
<td>Type III</td>
<td>58</td>
</tr>
<tr>
<td>Direct</td>
<td>414</td>
</tr>
<tr>
<td>Type IV</td>
<td>376</td>
</tr>
<tr>
<td>Type V</td>
<td>38</td>
</tr>
</tbody>
</table>

Pantaloon hernias were categorized by the dominant type of the 2 hernias present. Operating and recovery room times, return to normal activities, postoperative pain medication used, and return to manual labor were recorded into a data registry.

All procedures were performed by 2 of us (K.W.M. and A.D.). The operative technique was modified from the previous mesh-plug hernioplasty described by Rutkow and Robbin. For type I and II indirect hernias, the inside petals of a large plug were sutured to the internal oblique portion of the internal ring, allowing for the outer surface of the plug to form an underlay preperitoneal patch of the indirect defect (Figure 1). If the internal ring of a type II hernia is patulous, an additional suture is placed through an inside petal, securing it to the lateral shelving edge of the inguinal ligament. Absorbable suture material is used for plug fixation of types I and II hernias. For type III indirect and type IV or V direct hernias, the center inside fluted cone (petal) of an extra large plug was sutured to the Cooper ligament, the conjoined tendon, and the shelving edge of the inguinal ligament, allowing for the outer surface of the plug to form an underlay preperitoneal patch of the hernia defect (Figure 2). Monofilament permanent suture material was used for plug fixation of types III, IV, and V hernias. For types IV and V hernias, the transversalis fascia at the base of the hernia was circumferentially incised to allow the plug to be placed into the preperitoneal space. For types I, II, and III hernias, the indirect sac is highly dissected and placed into the preperitoneal space, allowing for the plug to subse-

RESULTS

There were 642 indirect and 414 direct hernias. Mean operative time was 25 minutes (range, 20-29 minutes). Mean recovery room time was 45 minutes (range, 25-59 minutes). All patients were discharged as outpatients. Of the 1056 patients, 887 (84.0%) required only over-the-counter pain medication postoperatively; 169 (16.0%) required prescription pain medication ranging from 2 to 10 days in duration; and 1013 (95.9%) were able to perform normal activities without prescription pain medication within 3 days. The remaining 4.1% of patients returned to normal activities within 10 days. All 465 manual laborers returned to work without restriction on postoperative day 14.

We recorded a total of 26 postoperative complications (2.5%). Nineteen postoperative hematomas were nonexpanding and were treated by observation. Seven patients returned with urinary retention and required catheterization. Two of these patients subsequently required transurethral resection of the prostate for significant benign hypertrophy of the prostate. No wound or mesh infections, orchitis, sinus tracts, or plug migration occurred.
At 1 year, 1045 patients have been examined, and 1 recurrence has been detected, for an overall recurrence rate of 0.1%. The patient with the recurrence had a type III scrotal hernia and returned at 4 months postoperatively complaining of a groin bulge. At reexploration, the mesh plug had pulled away from the Cooper ligament, resulting in a direct hernia recurrence. The patient required an onlay mesh repair. The remaining 1044 patients have been followed up for a mean of 22 months (range, 12-48 months) without a documented recurrence.

Five patients (0.5%) returned from 9 to 31 months postoperatively with significant groin and/or leg pain. Three of these patients responded to a series of local steroid injections. Two patients required anesthesia pain center nerve ablation, and both still have some residual pain that is related to position. However, both are able to maintain full-time employment. At present, no patient has required reexploration for mesh removal or nerve transection.

Mesh repairs for primary inguinal hernias have reduced the recurrence rate from greater than 10% in tissue-to-tissue herniorrhaphy to approximately 1%. The question in today’s surgical environment is not how to attain a tension-free repair with a 1% recurrence rate, but which mesh hernioplasty (Lichtenstein, Stoppa, laparoscopic, Kugel, or mesh-plug) is the simplest technique to master, has the lowest complication rate, has the shortest recovery or rehabilitation time, and is overall most cost-effective. Starting with reports in the early 1990s, Rutkow and Robbins have shown that the mesh-plug hernioplasty has less than a 1% recurrence rate, is technically simple, and can be performed in less than 30 minutes under epidural anesthesia as an ambulatory procedure, with more than 95% of patients fully recovered in 3 days. In an attempt to confirm and possibly improve on these excellent results, we switched from laparoscopic and Lichtenstein repairs to a modified mesh-plug hernioplasty in 1997. Our results in this series confirm that a modified mesh-plug hernioplasty can achieve less than a 0.1% recurrence rate with a 3-day recovery and minimal complications and can be performed with the patient under local anesthesia and intravenous sedation in less than 30 minutes on an ambulatory basis.

The history and principles behind mesh-plug hernioplasty span 3 decades, starting with Lichtenstein and Shore in 1974. They reported results of a cylindrical roll of polypropylene mesh placed in recurrent or femoral hernia defects. This technique was replaced by the onlay mesh repair popularized in the 1980s by Lichtenstein et al. Shocket in 1985 reported placing polypropylene preperitoneally to buttress primary inguinal hernia repairs. Gilbert used this principle to place a cone of mesh preperitoneally and allowed it to flatten out in this space for indirect hernias. Gilbert proposed that this repair was sutureless and did not require tissue-to-tissue approximation. The shortcoming of this repair was that it could only be used in indirect hernias, but on the other hand, Gilbert’s procedure confirmed that a mesh could be placed preperitoneally from a standard anterior inguinal approach. Rutkow and Robbins subsequently started using a cone similar to Gilbert’s repair for all varieties of inguinal hernias. They modified the technique by fashioning the size of the cone to the size of the defect and suturing the edge of the cone to the edges of the defect with absorbable suture material. An onlay mesh was also placed on the inguinal floor to reinforce adjacent areas of the inguinal floor not presently affected by the hernia. Since the plug repairs the hernia, no sutures are required in the onlay mesh to secure it to the inguinal floor other than the suture that approximates the tails of the onlay around the cord structures at the internal ring. The problem with the roll-your-own variety of plug used by Rutkow and Robbins was that it had a sharp point at the apex that potentially could erode into adjacent structures. Also, with the contraction of wound healing, the plug could shrink and possibly migrate into the inguinal canal. Realizing these shortcomings, Rutkow and Robbins modified the plug to smooth out the apex and imbricate the outer umbrella to have a plug much larger than the hernia defect and that could radially conform to the defect. They also added inner petals to the plug to act as filler bodies, which in theory should limit the amount that the plug could shrink and should decrease the possibility of plug migration.

We modified the Rutkow and Robbins technique by using the inner petals to fixate the plug with sutures to the anatomical structures used in most hernia repairs. For indirect hernias, the inner petals are sutured to the shutter mechanism (internal oblique muscle) medially of the internal ring, and in large patulous rings also to the inguinal ligament. This allows for the outer umbrella to open and flatten out in the preperitoneal space. This simulates the sutureless repair of indirect hernias by Gilbert. For direct hernias, the inner cone (petal) is sutured to the conjoined tendon medially and to the Cooper ligament and inguinal ligament laterally, allowing for the outer umbrella and the other petals to open and flatten out in the preperitoneal space similar to mesh placed in a Stoppa, laparoscopic, or Kugel repair. These modifications eliminate the possibility of plug migration or of the inner petals protruding into the inguinal canal. The sutured plug is completely preperitoneal in an almost flat configuration, with its structure allowing it to spring open and close like a fireplace bellows so that no tension is placed across the inguinal floor. In effect, this repair is the only true tension-free mesh hernioplasty, whereas the others, specifically the Lichtenstein repair, are not tension free, because a completely flat mesh fixed across the inguinal floor will become taut when a patient stands, coughs, or strains. This same effect occurs in a laparoscopically fixed preperitoneal flat mesh. We believe this tension-free modification reduces medial induced rectus muscle spasm, which accounts for most pain after inguinal mesh hernioplasty or tissue-to-tissue herniorrhaphy. Our 3-day return to normal activities and only a 16.0% use of postoperative prescription pain medication gives us proof of this hypothesis.

The procedure is performed with the patient under local anesthesia with intravenous sedation, which avoids the general anesthesia required in laparoscopic repairs. The fact that all patients are able to leave the ambulatory facility within 1 hour confirms the minimal effect...
of the anesthesia and surgical procedure on the patients. Patients are not restricted from any activities except heavy lifting of greater than 50 pounds for 2 weeks. Manual laborers are allowed to return to work without restriction in 2 weeks. We maintain that some collagen should be deposited to reinforce mesh position before heavy lifting is allowed. All manual laborers, with the exception of those covered by worker’s compensation, have returned to work without restriction after the 2-week waiting period.

Since an anterior approach is used for this technique, most surgeons should be comfortable with it. Deploying the plug directly into the hernia defect simplifies preperitoneal placement, which makes laparoscopic, Stoppa, and Kugel mesh placement more difficult to master. Fixing the plug to the same anatomical structures used in tissue-to-tissue repairs keeps an anatomical basis for this repair and also teaches our residents in training the appropriate anatomical landmarks of the inguinal region. Performing the procedure in less than 30 minutes keeps the operating room cost to a minimum. Using a 4- to 5-cm incision on patients of all sizes keeps the repair in the realm of minimally invasive surgery. Nearly a thousand surgeons have visited our facility for a 4-hour training course in the modified technique and have been able to adopt it without further training. We believe only a simple technique could have such a short learning curve.

Our complication rate is minimal. Hematomas are expected in small numbers after hernia repairs, and in this series they resolved without intervention. No infections occurred in this series, which may be a result of our use of intravenous antibiotics before the start of the procedure. A less than 1% urinary retention rate is also evidence of the minimal trauma to the groin that results after this repair. A less than 0.5% long-term pain rate is an indication that nerve entrapment is unlikely when the plug position is entirely preperitoneal. No plug to date has been removed for infection, pain, or migration. Our single recurrence was a type III scrotal hernia, which indicates that the plug in this case was not large enough to flatten out in the preperitoneal space with sufficient underlay to prevent recurrence. This type of hernia should be repaired with a large onlay mesh.

Cost can sometimes be very difficult to measure. If one accepts that hernia repairs should include mesh placement, then, other than the cost of the mesh, our procedure takes less than 30 minutes to perform under local anesthesia, with less than 1 hour of recovery room time as an outpatient procedure. These results are as cost-effective as a surgeon can achieve with regard to hernia repairs. Also, a procedure in which almost 96% of patients have fully recovered in 3 days and that allows manual labor in 2 weeks puts very little strain on our patients and their economic work status.

The modified mesh-plug hernioplasty technique solved or reduced many of the problems associated with other mesh-plug hernioplasties. The technique is simple and can be mastered by all general surgeons. Operating room and recovery room times are kept to a minimum. Pain and its required medication are reduced to a few days. Recovery and return to physical labor are at most extended for only 2 weeks. Cost is kept to a minimum. Early recurrence, as measured by results of the physical examination, is less than 0.1%.

CONCLUSIONS

The modified mesh-plug hernioplasty uses a minimum of medical resources, is associated with an early return to normal activities and manual labor, and has minimal complications with a low recurrence rate. We believe that this procedure should be adopted as the gold standard repair for unilateral primary inguinal hernias.

Accepted for publication January 23, 2003.

This study was presented at the 110th Scientific Session of the Western Surgical Association, Vancouver, British Columbia, November 20, 2002, and is published after peer review and revision. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.

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REFERENCES

Jeffrey Landercasper, MD, LaCrosse, Wis: I congratulate Dr Millikan and colleagues on completing a prospective evaluation of a modification of the mesh-plug technique for inguinal hernia repair. Their results are outstanding, and a few numbers deserve to be repeated. There were 1025 men and 31 women who underwent a primary unilateral inguinal hernia repair with suture fixation of the inner petals of a mesh plug into the preperitoneal space. The data collection was prospective. The mean operative time was only 25 minutes. Follow-up occurred in 90% of patients, and only 1 recurrence was detected at the 1-year follow-up visit. The authors conclude, “The Millikan modified mesh-plug repair should be adopted as the gold standard for unilateral primary inguinal hernia repair.” The authors’ conclusion is provocative, and I suspect it will generate some further discussion in the audience. I have some questions.

1. Please define further your criteria for patient inclusion and exclusion. You had 1 recurrent hernia in a patient with a scrotal hernia. Were there other patients with large hernias, scrotal hernias, and sliding hernias who were included and repaired successfully, or were the larger-hernia patients excluded from this trial? Were there any acute or incarcerated hernias?

2. Where are the women? You had more than 1000 men but only 31 women in the trial. The gender difference is 33:1 is not representative of the general population of patients with hernias. Did you exclude some women from this trial? If so, why? Did you exclude teenagers with small indirect inguinal hernias?

3. Did you include any patients with femoral hernias, perhaps discovered incidentally at the time of inguinal groin surgery? You described suture fixation of the inner petals of the mesh plug to Cooper’s ligament. Do you then have a transitory repair? We have always placed the onlay patch in women. Where are the women? We remove at least 4 of the 8 petals to reduce the outer umbrella to cover the femoral ring, but if we saw a football player, a junior in high school that came into the emergency room with an incarcerated or strangulated hernia, we would need to look for viability of the bowel. If there is any question of mesh failure, clinical concern and the bowel is viable, we do not place the onlay patch in a woman with an indirect hernia. I personally have never seen a woman with a direct hernia.

5. How quick is the learning curve? How many people advocate the plug repair to remove some petals? Am I assuming that you do not remove any petals in your technique? There are probably as many plugs now on the market as surgeons doing the plug repair. Do you think it makes any difference which brand or type of plug is used? (3) Finally, if you look at your excellent results, as good as they are, they are not all that much different from Lichtenstein’s original results with just an onlay patch. So what is the plug actually doing?

Jack Pickleman, MD, Chicago, Ill: I would like to quote from the Martha Stewart Book of Etiquette. Don’t you think it’s just a bit tacky, Keith, to name a new operation after yourself and immediately declare it the gold standard?

David R. Farley, MD, Rochester, Minn: The results are the best I have seen in the literature. I do this type of repair myself, but my patients have more problems with urinary retention than you report. I would really like some technical expertise on the local anesthetic that you use for these hernia repairs.

Dr Millikan: First, patient inclusion. All patients for this study with unilateral hernias were included except patients who came into the emergency room with an incarcerated or strangulated hernia, because we do these patients under a spinal or general anesthetic, and they were excluded. Also, it is my personal bias that if you have a strangulated or incarcerated hernia, you have to look for viability of the bowel. If there is any question of it, mesh should not be placed in those patients, and surgical residents and our surgeons should know how to do tissue-to-tissue repairs. So those patients were excluded.

Were there other scrotal hernias, sliding hernias? In my slide I categorized the different types of hernias. There were 38 type III by the Gilbert classification of hernias, which by description are sliding or scrotal hernias basically. We had 1 recurrence in that group. That’s about 2%. We thought that was unacceptable. Now, for that type of hernia, we recommend a large onlay repair, and that is one of the times that I would go back to the Lichtenstein repair. There were no acute or incarcerated hernias in this series.

Where are the women? I’m not sure, Dr Landercasper. Thirty-three to 1; I have always been told in the surgical literature it is a 20:1 ratio. Ours was higher, but this is what we saw. In our original study that had 283 patients, we had 10 women and 273 men, so it was 27:1 in that study. We are seeing even more men now.

Women with small hernias were not excluded. We do not place the onlay patch in a woman with an indirect hernia. I personally have never seen a woman with a direct hernia. I have seen femoral hernias and indirect hernias that have large rings, but I personally have never seen a direct hernia, so we do not place the onlay patch in women.

Do we exclude teenagers? There are different varieties and sizes of teenagers. My personal bias is if someone hasn’t gone through their growth spurt or reached puberty, mesh should not be placed. So we do not place mesh in young, small teenagers, but if we saw a football player, a junior in high school that was 210 pounds, and he had an inguinal hernia, we would place the plug and mesh in him.

What is the age range? It was 15 to 96 years. We did not find any incidental femoral hernias in this group. Now, it is a very small incision, and I can say we don’t look for incidental hernias like the laparoscopic surgeons do when they do their laparoscopic repairs. We have not found this to be a problem. We have not seen femoral hernias come back later on. We do not have a transition stitch. We place the first stitch in Cooper’s ligament so that the outer umbrella can actually cover the femoral space for direct hernias, but we do not place a transition stitch.

I have not had a deep vein thrombosis. I have had a few surgeons call me up who are using a plug technique who have described this. I believe that this comes from if you have a type 1 indirect hernia. We remove at least 4 of the 8 petals to reduce the bulk of the plug, because for a normal-size ring in a type 1 hernia, you do not need that bulky of a plug. There are smaller
plugs. I am cost conscious. We only keep large and extra-large on the shelf. So that’s why I would rather remove petals than have all of these different types of plugs on our shelf.

Is your technique easy to learn? Are your outcomes reproducible? One thing I didn’t mention is, on Monday hernia day, at least 5 to 10 surgeons come and visit for training. We have had 1000 surgeons in approximately 4 years come through our institution for training, and of that thousand, these were surgeons who did not know about the modified technique or were not using plugs at all. In a survey 6 months afterwards, 85% of them have adopted the technique as their standard procedure of choice now. I don’t have any outcome results on their reproducibility of this technique, but I can say if 85% changed their way of doing things in a 4-hour teaching session, it is very simple and easy to learn.

Dr DeBord, when do I remove petals? When I think the plug is too bulky for the internal ring. But that’s about the only time in small indirect hernias. We do not remove petals for any direct hernia, basically. The brand of the plug? This is the original plug that was on the market. I don’t like to be an advertiser for anything. People have mimicked the plug, and there are other types of plugs out there. This is the only one in my estimation that allows me to suture the inside petals and have an underlay preperitoneal that is not inverted. There is another type of plug that is inverted that to me would push right out of the preperitoneal space. Because of the plug being inverted like this, the pelvic pressures help the umbrella open up into a flat space.

Is this different from the original Lichtenstein repair? It definitely is. The pain reported with this is less. Also, in Dr Lichtenstein’s original article, he had 3125 patients; only 2300 of them were followed up, and there was a 0.2% recurrence rate. The question is, when you have 625 patients that weren’t followed, were the recurrent hernias in that group, because in most series the recurrences go to somebody else to be fixed, and you lose those patients to follow-up. Even if all 11 patients of ours had a recurrent hernia that we missed, we would only have a 1% recurrence rate in this series, basically.

Dr Pickleman, there are certain reasons for emphasis, and I have taken this after you, basically. If I didn’t put my name on it, no one would have really read the article seriously. This raises people’s eyes. I also wanted to separate it from Drs Rutkow and Robbins’ repair. I don’t want this to be considered their repair, because theirs is not truly a preperitoneal repair. To say it is the gold standard, I think at some point in time in hernia repair, in this year 52% of all hernia repairs in the United States will be done by the plug method. There are different types of plugs, but the plug method is becoming more than 50% of the market share in hernia repair. So at some point in time, we have to define a gold standard, and I decided to define that as now. That may not be correct.

Dr Farley, as far as local anesthesia goes, we use 1% Xylocaine [lidocaine hydrochloride] with bicarbonate, and I have excellent nurse anesthetists and anesthesiologists who use propofol. We call it IV sedation. It is really a light general. We also participated in a phase 3 trial recently of giving patients the night before Vioxx [rofecoxib] and then using a COX-2 inhibitor IV during the procedure and sending them home on a COX-2 inhibitor. That totally eliminates all narcotic medication. Now that phase 3 trial has just come to completion—and hopefully the COX-2 inhibitor IV will be on the market soon—and we will switch completely from giving patients prescriptions of Darvocet [acetaminophen and propoxyphene naprosinate] or Vicodin [acetaminophen and hydrocodone bitartrate] and totally just use COX-2 inhibitors in the future.

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**Announcement**

Online CME to Begin in Mid-2003

In mid-2003, online CME will be available for *JAMA*/*ARCHIVES* and will offer many enhancements:

- Article-specific questions
- Hypertext links from questions to the relevant content
- Online CME questionnaire
- Printable CME certificates and ability to access total CME credits

We apologize for the interruption in CME and hope that you will enjoy the improved online features that will be available in mid-2003.