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Prospective, multicenter study of laparoscopic ventral hernioplasty

Preliminary results

F. K. Toy,[1] R. W. Bailey,[2] S. Carey,[3] C. W. Chappuis,[4] M. Gagner,[5] L. G. Josephs,[6] E. C. Mangiante,[7] A. E. Park,[8] A. Pomp,[9] R. T. Smoot, Jr.,[3] J. F. Uddo, Jr.,[4] G. R. Voeller[7]

[1] Community Medical Center, 1800 Mulberry Street, Scranton, PA 18510, USA
[2] Allegheny University of the Health Sciences, Broad and Vine, Philadelphia, PA 19102, USA
[3] Nanticoke Surgical Associates, 900 Middleford Road, Seaford, DE 19973, USA
[4] East Jefferson General Hospital, 4224 Houma Boulevard, Metairie, LA 70006, USA
[5] The Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, OH 44195, USA
[6] Boston University Medical Center Hospital, 88 East Newton Street, Boston, MA 02118, USA
[7] University of Tennessee Memphis College of Medicine, 956 Court Avenue, Memphis, TN 38163, USA
[8] St Joseph's Hospital, 50 Charlton Avenue East, Hamilton, ON L8N 4A6, Canada
[9] Hotel-Dieu de Montréal, 3840 Rue St-Urbain, Montréal, PQ H2W 1T8, Canada

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Abstract
Background: A standard technique for laparoscopic ventral hernioplasty (peritoneal onlay using an expanded polytetrafluoroethylene [ePTFE] patch for hernias ≥ 4 cm^2) is being used in a prospective, multicenter, long-term study.
Methods: Demographic, operative, and postoperative data were collected and analyzed. Follow-up clinical evaluations were conducted 7–10 days, 4 weeks, 6 months, 1 year, and then annually after surgery in all patients.
Results: In the first 2 years of the study, 144 patients were enrolled; nine were lost to follow-up. The mean operating time was 120 min. The mean follow-up was 222 days (range 5–731). Postoperative complications were five infections, three cases of prolonged ileus, one bowel obstruction, 23 seromas (15 resolved without intervention), and six hernia recurrences. Hospital discharge occurred a mean of 2.3 days after surgery and return to normal activity a mean of 15 days postoperatively.
Conclusions: Laparoscopic prosthetic ventral hernioplasty avoids the large wound required in open repairs, with attendant complications and recurrences, and appears safe, especially if an ePTFE mesh is used. Compared with conventional open ventral hernioplasty, the laparoscopic technique may also allow shorter hospitalization and a quicker return to normal activities after surgery.

Key words: Laparoscopic hernioplasty — Ventral — Incisional — Expanded polytetrafluoroethylene — Peritoneal onlay — Multicenter study — Tension-free repair — Human

The repair of ventral hernias, including incisional, umbilical, epigastric, and spigelian defects, is a challenging surgical problem. About 13% of the hernia repairs performed in the United States, or approximately 90,000 repairs, are ventral repairs. Incisional hernias develop in about 2–11% of patients who undergo laparotomy [6, 21], although in patients in whom the surgical wound becomes infected postoperatively, the incisional hernia rate may be $\geq 40\%$ [13]. Open repair of ventral hernias is associated with substantial complications and recurrences. Recurrence rates as high as 30–50% have been reported, with the highest rates among patients in whom a prosthetic mesh was not used [10, 25]. On the other hand, use of a biomaterial in open ventral repairs carries a risk of wound complications. Stoppa [23], for example, reported an infection rate of 12% in a series of 466 open incisional hernia repairs that used polyester mesh.

Laparoscopic ventral hernioplasty may have a decreased risk of infections and resultant complications (including reherniation) compared with open repair because the prosthetic mesh is minimally exposed to the environment during implantation using laparoscopic techniques. Indeed, infection rates in the small series of laparoscopic ventral hernia repairs that have been reported [12, 18, 20] were all <10%. The choice of prosthetic material in ventral repairs may also influence the rate of wound complications. Expanded polytetrafluoroethylene (ePTFE) mesh is often employed in ventral hernioplasties in which the prosthetic material is placed in direct contact with bowel because it is less likely to

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Correspondence to: F. K. Toy

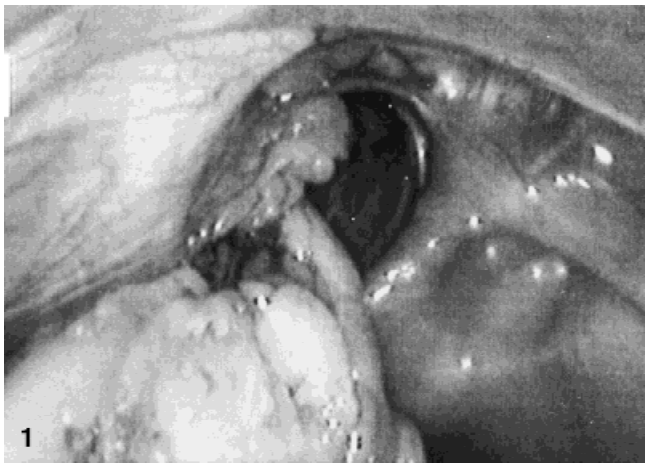


Fig. 1. Hernia defect with adhesions.

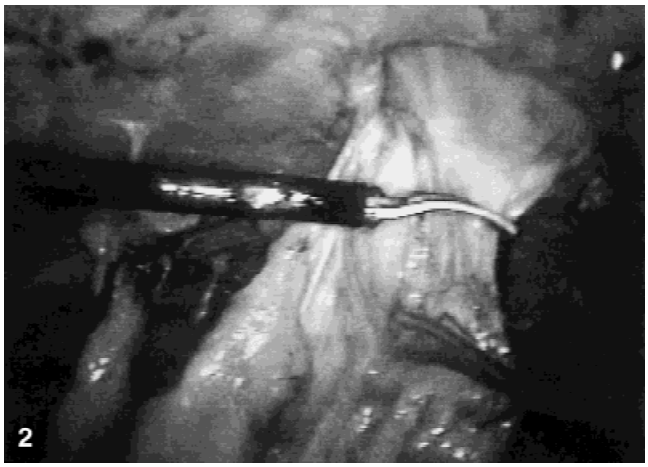


Fig. 2. Endoscopic shears being used to lyse adhesions.

adhere to the underlying viscera [24]. In addition, ePTFE has a lower rate of infectivity than other biomaterials [3].

Finally, laparoscopic ventral hernia repair may require a shorter hospital stay and allow a quicker return to normal activities than open repair, similar to what has been observed in randomized, prospective studies comparing open and laparoscopic inguinal hernia repairs [1, 19, 22].

To explore these issues, we are conducting a prospective, multicenter, 5-year study in which a standardized laparoscopic technique—peritoneal onlay with ePTFE mesh—is being used to repair primary and recurrent ventral hernias. Preliminary (2-year) results are given here.

Materials and methods

Approval for the study was obtained, as applicable, from the institutional review boards of the participating centers. Consecutive male and female patients >18 years of age presenting for ventral hernia repair at nine centers (12 surgeons) were considered for the study. Inclusion criteria included granting of informed consent to participate in the study and a willingness to return for postoperative follow-up examinations at several predetermined times. Patients were excluded if their wall defect was <4 cm^2 (sufficiently small to be repaired by primary closure), if they required emergency bowel resection for acute obstruction, if they had evidence of an abdominal wound infection, if conversion to open repair was required, or if initial exploration revealed no hernia.

Patients enrolled in the study underwent a tension-free peritoneal onlay laparoscopic ventral hernia repair using an ePTFE mesh (either GORE-TEX DualMesh Biomaterial or GORE-TEX Soft Tissue Patch, W.L. Gore & Associates, Flagstaff, AZ) fixed to the abdominal wall with both sutures and staples or tacks.

Operative technique

The procedure is performed with the patient under general anesthesia. Prophylactic antibiotic therapy is given. The bladder is decompressed with a Foley catheter; the stomach is decompressed with a nasogastric tube. A puncture site away from the hernia defect and any abdominal incisions is chosen. A skin incision is made and a Veress needle is inserted, or an open technique is used, and the abdomen is insufflated with carbon dioxide. A 30–45° laparoscope is introduced through the same incision. The abdominal cavity is explored, and the hernia defect and any adhesions are identified (Fig. 1). Under direct visualization, additional 11-mm trocars are inserted as far laterally as possible. Enterolysis is performed with endoscopic shears (Fig. 2). The contents of the hernia sac are reduced into the peritoneal cavity; the sac itself is left in situ (Fig. 3).

Additional 11-mm trocars are introduced on the opposite side laterally under direct vision; their number and position are individualized. The edges of the hernia defect are ascertained by direct vision and palpation and their location is drawn on the abdomen (Fig. 4). With reference to the defect drawing, the ePTFE mesh size is drawn so that when the mesh itself is cut to size, it will overlap the defect by $\geq$3 cm in all directions (Fig. 5). Nonabsorbable sutures (about 15 cm long) are placed at all four corners of the mesh.

The mesh is then inserted into the abdominal cavity. Meshes $\leq$10 cm $\times$ 15 cm can be introduced through an 11-cm trocar, whereas larger pieces require an 18-mm trocar. After introduction, the mesh is spread out in the peritoneal cavity. Small skin incisions (about 2 mm long) are made with an 11 blade scalpel, and an endoscopic suture passer is inserted through the abdominal wall. The suture passer is used to grasp the sutures at the corners of the mesh and pull them through the wall; the sutures are then tied (Fig. 6). This is done at all four corners of the mesh to hold it against the anterior abdominal wall. Circumferential securing of the mesh is achieved with nonabsorbable sutures placed about every 5 cm. The gaps between the sutures are closed by stapling or tacking the mesh to the transversalis fascia through whichever trocar is most convenient.

The security of the patch is verified (Fig. 7). Drains are not inserted unless the hernia is extremely large. Before the trocars are removed, nonabsorbable sutures are placed with the endoscopic suture passer. The pneumoperitoneum is released and the trocars are removed; the sutures are then tied to close the trocar defects. The skin is closed with absorbable subcuticular sutures.

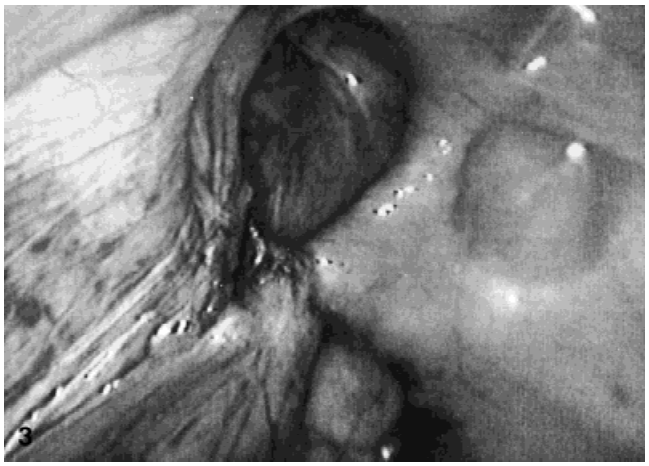
Postoperative evaluations and data collection

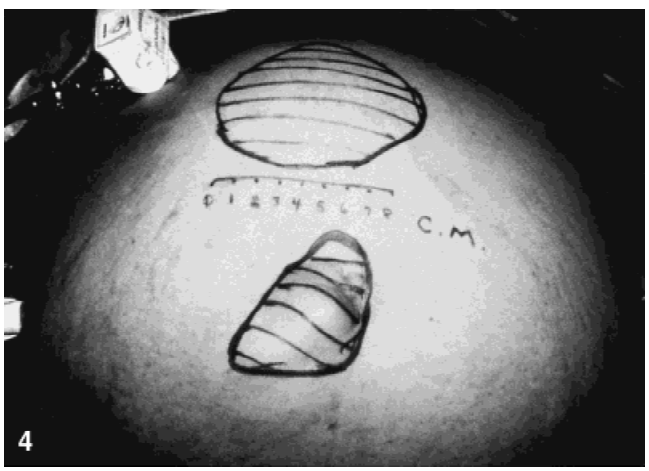
Patients underwent postoperative clinical examinations by their attending surgeon during the immediate postoperative period and 7–10 days, 4 weeks, 6 months, 1 year, and then annually after surgery. Standardized data forms were used to collect information on intraoperative, perioperative, and postoperative complications, including hernia recurrence; length of hospital stay; time of return to normal activities; and postoperative pain (McGill Pain Questionnaire). The data were entered into a computer database and analyzed at a central location.

Results

Characteristics of the 144 patients enrolled in the first 2 years of the study are shown in Table 1. About 26% of the patients were operated on for a recurrent ventral hernia. The four operative complications were treated successfully and there were no sequelae. Nine of the 144 patients were lost to follow-up. At 2 years after the first repair in this study (performed in February 1995), the mean time since surgery was 355.6 days (range 10–772). The mean follow-up time (days between surgery and most recent follow-up clinical evaluation) was 222 days (range 7–731).

Immediate and longer-term postoperative complications, including ventral hernia recurrences, are shown in





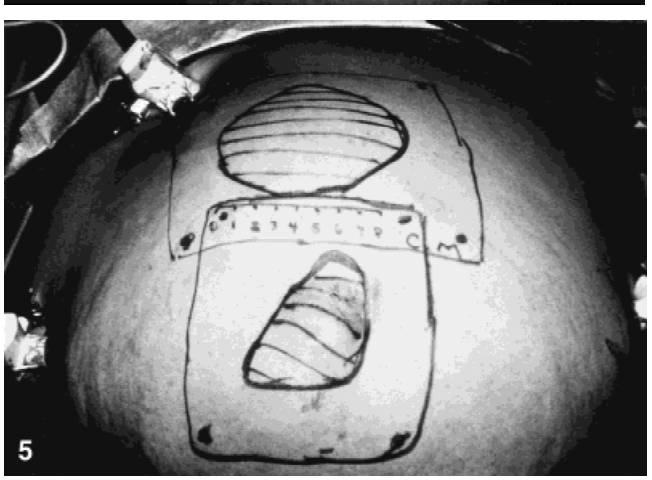


Fig. 3. Hernia defect with contents reduced.

Fig. 4. Hernia defects drawn on abdomen.

Fig. 5. Mesh size drawn on abdomen for orientation to corners.

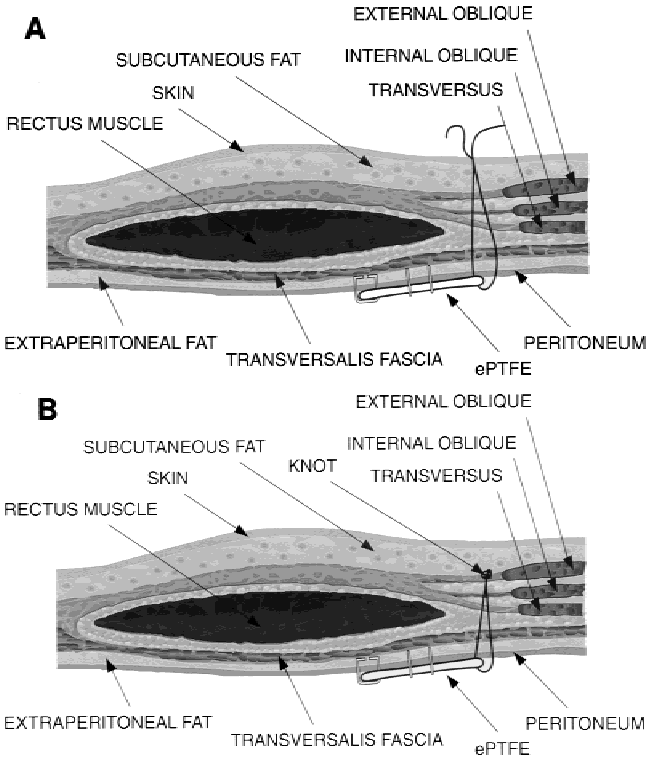


Fig. 6. Suturing of the mesh at four corners. Suture is passed through the wall (**A**) with a suture passer and tied (**B**).

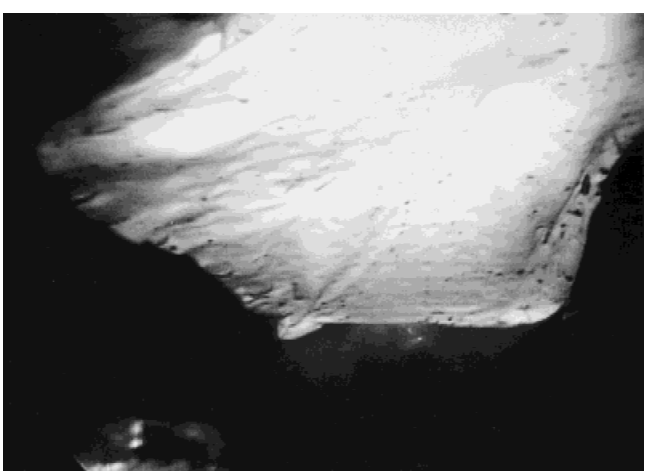


Fig. 7. Completed repair.

Table 2. Seromas occurred postoperatively in 16% of patients. Fifteen of the 23 seromas resolved without intervention within 30 days of surgery, two resolved without intervention after 30 days, and six resolved after aspiration. The two hematomas resolved uneventfully. There were five postoperative infections in the series—an infection rate of about 3%. Four of the infections began in a trocar site; three of these resolved after antibiotic therapy, whereas the fourth spread and eventually necessitated removal of the prosthetic mesh after a soft-tissue abscess developed. The remaining infection also involved the mesh and required mesh removal.

Six patients other than those from whom the prosthetic mesh was removed because of infection had recurrence of their ventral hernia, at about 3 months (two patients), 4 months (one patient), 7 months (one patient), and 9 months (two patients) postoperatively. Thus, the recurrence rate was about 4%. Three of the patients with recurrence had previous failures of ventral hernia repair.

Data on time to return of normal bowel function, duration of hospital stay, and return to normal activity are given in Table 2. Data from administration of the McGill Pain Questionnaire are not included in this preliminary report because they have not yet been compiled.

Table 1. Laparoscopic ventral hernioplasty at nine centers: patient characteristics and operative experience

Male/female	79/65
Mean (range) age in years	57.6 (24–87)
Type of hernia	
Incisional	92
Epigastric	11
Umbilical	23
Spigelian	2
Combination (>1 type) (No. of patients)	16
Recurrent hernias	38
Mean (range) defect size (cm^2)	98.3 (4–1,400)
Mean (range) patch size (cm^2)	215.9 (42–1,500)
Mean (range) operating time (min)	120.2 (40–310)
Operative complications	
Subcutaneous emphysema, increase in blood carbon dioxide level	1
Respiratory failure requiring reintubation	1
Enterotomy	2

Table 2. Laparoscopic ventral hernioplasty at nine centers: postoperative experience

Postoperative complications	
Seroma[a]	23
Hematoma	2
Infection	5
Prolonged ileus	3
Bowel obstruction	1
Recurrent hernia	6
Mean (range) return to normal bowel function (days)	1.8 (0–8)
Mean (range) duration of hospitalization (days)	2.3 (0–11)
Mean (range) return to normal activity (days)	15.3 (1–100)

[a] Fifteen seromas resolved uneventfully within 30 days; two resolved after 30 days; six resolved after aspiration.

Discussion

This report describes the preliminary (2-year) results of a multicenter, prospective, noncontrolled study of laparoscopic ventral hernioplasty that will eventually enroll >200 patients and attempt a 5-year follow-up by clinical examination in all subjects. Definitive conclusions cannot be drawn from the preliminary data, but a discussion of our experience so far, including some trends that have been observed, is appropriate.

We found laparoscopic ventral hernia repair to be safe and effective, with postoperative infection and recurrence rates that are lower than those generally observed in series of open repairs. Our infection rate of 3% compares favorably with the rates of 12–45% that have been reported in series of open repairs [7, 14, 23, 26]. We believe that the laparoscopic technique may have a decreased risk of infection compared with open repair because it avoids a wide dissection, with a long incision, raising of flaps, and exposure of the prosthetic mesh to skin flora, the primary source of contamination [7], at implantation. Clearly, a reduction in infection rate will in turn decrease the rate of hernia recurrence because most infections require removal of the prosthetic mesh, thereby allowing reherniation. Thus, the 4% recurrence rate in this series so far may have been at least partly due to the low infection rate.

The peritoneal onlay method itself may also have helped keep the recurrence rate low. This technique, which is based on the Stoppa-Rives method for open repair of ventral hernias [23], involves posterior patching of the defect with a large piece of prosthetic material. The large surface area of the mesh allows substantial ingrowth of tissue for permanent mesh fixation, and the intraabdominal pressure tends to hold the mesh in place apposed to the posterior fascia over the wide surface area (Laplace's law) [24]. The recurrence rate in our series may of course increase as patients are followed for longer periods. However, because the majority of recurrent incisional hernias appear within the 1st year after repair [10, 25] and the mean clinical follow-up time in our study is already 222 days, we are confident that our recurrence rate will not change a great deal.

The peritoneal onlay technique involves placing prosthetic mesh on the parietal peritoneum, where it is in direct contact with the abdominal viscera. Like others [2, 5, 12, 18], we believe that ePTFE mesh is the most appropriate material for this procedure because it evokes minimal inflammation and little foreign-body response and adhesion formation while allowing good tissue ingrowth [4, 11, 15]. In contrast, polypropylene mesh produces a strong inflammatory reaction that may lead to extensive adhesions, erosion into intraabdominal organs, or fistulization [9, 17, 27]. The form of ePTFE used in 88% of the repairs in the study (DualMesh) is particularly suitable for the onlay technique because of its two-surface nature. The surface that is placed against the bowel consists of a low-porosity membrane form of ePTFE that limits tissue attachment [4]. The ePTFE membrane has been used successfully to minimize adhesion formation after myomectomy [16] and initial surgery to repair congenital heart defects [8]. The opposite side of DualMesh consists of high-porosity ePTFE that provides strength and tissue ingrowth [11].

The method used to secure the ePTFE mesh has evolved. Initially, attempts were made to use staples only. When this method was found to provide inadequate fixation, we began to suture the mesh to the anterior fascial layer with a suture passer instrument and to insert tacks or staples in the areas between suture sites. The security of the fixation depends primarily on the sutures.

The rate of seroma formation in this study (16%) is similar to that reported by DeBord [5] in his report on open repair of ventral hernias using ePTFE mesh. Most of the seromas in our patients resolved without intervention within 30 days and none became infected. Six seromas were aspirated because of their size, at the patient's request, or because of suspicion of infection, but we try to avoid aspiration because of the risk of introducing bacteria into the seroma. We now routinely advise patients preoperatively that a seroma may develop, and we reassure patients with a seroma that the bulge is not a recurrence of their hernia.

No comparative studies of open and laparoscopic ventral hernia repairs have been done, although they are needed, especially investigations that address length of hospital stay, postoperative pain, and return to normal activity after these procedures. In fact, few noncomparative studies of ventral hernia surgery have provided information on these factors. Our current data on hospitalization, pain, and return to normal activity are too preliminary to allow definitive conclusions to be drawn from them. However, we believe that it is important to continue to track this information to permit eventual comparison with results of studies of open ventral repairs. Meanwhile, it seems reasonable to

assume that patients who do not undergo a wide abdominal dissection will have fewer perioperative and postoperative complications, less pain, and a quicker return to normal activities than those who do.

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References

1. Barkun JS, Wexler MJ, Hinchey EJ, Thibeault D, Meakins JL (1995) Laparoscopic versus open inguinal herniorrhaphy: preliminary results of a randomized controlled trial. Surgery 18: 703–710
2. Bauer JJ, Salky BA, Gelernt IM, Kreel I (1987) Repair of large abdominal wall defects with expanded polytetrafluoroethylene (PTFE). Ann Surg 206: 765–769
3. Brown GL, Richardson JD, Malangoni MA, Tobin GR, Ackerman D, Polk HC Jr (1985) Comparison of prosthetic materials for abdominal wall reconstruction in the presence of contamination and infection. Ann Surg 210: 705–711
4. Cristoforoni PM, Kim YB, Preys Z, Lay RY, Montz FJ (1996) Adhesion formation after incisional hernia repair: a randomized porcine trial. Am Surg 62: 935–938
5. DeBord JR (1995) Special comment: expanded polytetrafluoroethylene prosthetic patches in repair of large ventral hernia. In: Nyhus LM, Condon RE (eds) Hernia. 4th ed. JB Lippincott, Philadelphia, pp 328–336
6. Hesselink VJ, Luijendik RW, de Wilt JHW, Heide R (1993) An evaluation of risk factors in incisional hernia recurrence. Surg Gynecol Obstet 176: 228–234
7. Houck JP, Rypins EB, Sarfeh IJ, Juler GL, Shimoda KJ (1989) Repair of incisional hernia. Surg Gynecol Obstet 169: 397–399
8. Jacobs JP, Iyer RS, Weston JS, Amato JJ, Elliott MJ, deLeval MR, Stark J (1996) Expanded PTFE membrane to prevent cardiac injury during resternotomy for congenital heart disease. Ann Thorac Surg 62: 1778–1782
9. Kaufman Z, Engelberg M, Zager M (1981) Fecal fistula: a late complication of Marlex® mesh repair. Dis Colon Rectum 24: 543–544
10. Langer S, Christiansen J (1985) Long-term results after incisional hernia repair. Acta Chir Scand 151: 217–219
11. Law NW, Ellis H (1988) Adhesion formation and peritoneal healing on prosthetic materials. Clin Mater 3: 95–101
12. LeBlanc KA, Booth WV, Spaw AT (1994) Laparoscopic ventral herniorrhaphy using an intraperitoneal onlay patch of expanded polytetrafluoroethylene. In: Arregui ME, Nagan RF (eds) Inguinal hernia: advances or controversies? Radcliffe Medical Press, Oxford, pp 515–517
13. Mudge M, Hughes LE (1985) Incisional hernia: a 10 year prospective study of incidence and attitudes. Br J Surg 72: 70–71
14. Mueller CB (1974) Editorial: abdominal incisional hernia—the role of wound infection. Can J Surg 17: 195
15. Murphy JL, Freeman JB, Dionne PG (1989) Comparison of Marlex and Gore-tex to repair abdominal wall defects in the rat. Can J Surg 32: 244–247
16. Myomectomy Adhesion Multicenter Study Group (1995) An expanded polytetrafluoroethylene barrier (Gore-Tex Surgical Membrane) reduces post-myomectomy adhesion formation. Fertil Steril 63: 491–493
17. Nagy KK, Fildes JJ, Mahr C, Roberts RR, Krosner SM, Joseph KT, Barrett J (1996) Experience with three prosthetic materials in temporary abdominal wall closure. Am Surg 62: 331–335
18. Park A, Gagner M, Pomp A (1996) Laparoscopic repair of large incisional hernias. Surg Laparosc Endosc 6: 123–128
19. Payne JH Jr, Grininger LM, Izawa MT, Podoll EF, Lindahl PJ, Balfour J (1994) Laparoscopic or open inguinal herniorrhaphy? A randomized prospective trial. Arch Surg 129: 973–981
20. Saiz AA, Willis IH, Paul DK, Sivina M (1996) Laparoscopic hernia repair: a community hospital experience. Am Surg 62: 336–338
21. Santora TA, Roslyn JJ (1993) Incisional hernia. Surg Clin North Am 73: 557–570
22. Stoker DL, Spiegelhalter DJ, Singh R, Wellwood JM (1994) Laparoscopic versus open inguinal hernia repair: randomized prospective trial. Lancet 343: 1243–1245
23. Stoppa RE (1989) The treatment of complicated groin and incisional hernias. World J Surg 13: 545–554
24. Temudom T, Siadati M, Sarr MG (1996) Repair of complex giant or recurrent ventral hernias by using tension-free intraparietal prosthetic mesh (Stoppa technique): lessons learned from our initial experience (fifty patients). Surgery 120: 738–744
25. van der Linden FT, van Vroonhoven TJ (1988) Long-term results after correction of incisional hernia. Neth J Surg 40: 127–129
26. von Smitten K, Heikel HV, Sundell B (1982) Repair of incisional hernia by F. Langenskiold's operation. Acta Chir Scand 148: 257–261
27. Voyles CR, Richardson JD, Bland KI, Tobin GR, Flint LW, Polk HC Jr (1981) Emergency abdominal wall reconstruction with polypropylene mesh: short-term benefits versus long-term complications. Ann Surg 194: 219–233

Discussion

Dr. Katkhouda: Congratulations for this very interesting paper. I would like to ask you a question about the incidence of infection in cases where mesh is used. I know that this can be a big problem when doing a mesh repair. I noticed in your presentation that two of your meshes got infected and you had to remove them both. If you had done the operation open, maybe you would have been able to save the PTFE mesh and not had to go back and remove the mesh. When you had to remove the mesh, what did you do? What kind of operation did you do after removal of the mesh?

Dr. Toy: I personally did not remove these two, but I have had some earlier personal experiences. Early on, when we did not shave the patients adequately, hair got pulled down into the suture sites, and tracked down to the patch, and that in my opinion resulted in the infection. If they get infected and the patch gets involved, we perform an open procedure and remove the patch. The incidence of infection following open mesh repair of incisional hernias ranges from 12 to 45 percent and is, therefore, a considerable problem. We feel that our infection rates are going to be lower because we don't have direct communication with the skin or its flora when you do it this way. One situation where you may have a problem is if your trocar site was very close to the patch. If the trocar site got infected, it may form a subcutaneous abscess which can then migrate down and involve the patch.

Dr. Roll: Do you use a drain?

Dr. Toy: Except for extremely large hernias, we do not use drains. We have noted 23 seromas. Almost everyone will get some fluid within the sac, but it resolves spontaneously usually in 30 days; certainly by three months, so we recommend not aspirating and not draining, because that could potentially contaminate the seroma. We did have one giant seroma with a huge sac that we did drain, because when it filled with fluid the patient had much discomfort.

Dr. Roll: Why do you think your patients returned to work after 24 days. Why do you think it takes such a long time for the patients to return to work?

Dr. Toy: My large incisional hernias don't go back to work in seven days. Matter of fact, most of them, if you do them open, are still in the hospital at 6–7 days. It appears with this study that the pain is less, they're up moving around much quicker, they're only in the hospital an average of 2.3 days. The problem is that it is difficult to look at early convalescence and return to work, since it is very subjective, endpoint. Many patients want to stay out of work because they can stay out of work and get paid, so it's really a motivational problem and difficult to evaluate.