Rapid communication

A new nonabsorbable adhesion barrier for myomectomy

Marco A. Pelosi, II, M.D.*, Marco A. Pelosi, III, M.D.

Pelosi Women’s Medical Center, 350 Kennedy Blvd., Bayonne, NJ, USA

Manuscript received June 14, 2002; revised manuscript July 20, 2002

Abstract

Background: A pilot study was made to assess the efficacy and safety of a new nonabsorbable adhesion barrier (Shelhigh Dome Pericondial Patch No-React Treated) in reducing adhesion after extensive myomectomy by laparotomy with a planned second-look laparoscopy.

Methods: In 20 patients after extensive myomectomy and full thickness uterine wall reconstruction, the patch was sutured over the uterus. Second-look laparoscopy was performed 6 weeks postoperatively. Third-look laparoscopy was done in 3 patients.

Results: Surgeries were completed without intraoperative or postoperative complications. No problems related to the patch were encountered including the need for its removal. At laparoscopy no adhesions between the abdominal wall, bladder, small bowel, or sigmoid colon to the uterus were noticed. A thin layer of the omental edge covered the patch that was securely anchored to the uterine fundus. The mean follow-up was 13 months.

Conclusions: These findings suggest benefits with this new bovine/porcine pericardial adhesion barrier for myomectomy. Controlled clinical trials are warranted. © 2002 Excerpta Medica Inc. All rights reserved.

Keywords: Myomectomy; adhesion barrier; postmyomectomy adhesions; adhesion prevention

Laparoscopic and laparotomic myomectomies are associated with a high rate of postoperative de novo scar formation—approximately 50% to 90% of patients [1,2]. Such adhesion formation after myomectomy may result in bowel obstruction, chronic pelvic pain, infertility, and technical difficulties for reoperation. To date no preventive measures have proven to be uniformly effective for preventing postoperative adhesion formation after pelvic surgery. The use of pharmacologic agents such as corticosteroids, nonsteroidal anti-inflammatory drugs, calcium channel blockers, recombinant tissue plasminogen activated, tolmentin, and heparin irrigation, or the use of liquid adhesion barriers such as crystalloid substances or 32% Dextran 70 have not had any proven effectiveness.

Currently available solid adhesion barriers create a mechanical barrier between damaged tissues in an effort to prevent the formation of permanent fibrous bridges. They include absorbable oxidized regenerated cellulose (Intercade; Ethicon, Sommerville, New Jersey); Seprafilm (Genzyme, Cambridge, Massachusetts), an absorbable barrier composed of hyaluronic acid and carboxymethylcellulose; and Preclude (Preclude Surgical Membrane; W. L. Gore, Flagstaff, Arizona), a nonabsorbable barrier made of expanded polytetrafluoroethylene (ePTFE). These adhesion barriers have proven to be only partially effective—postsurgical adhesions are still formed in at least 20% to 50% of cases [3].

Intergel (Intergel prevention solution; Ethicon, Sommerville, New Jersey), a 0.5% ferric hyaluronate gel, has been recently introduced as an adhesion prevention solution in patients undergoing conservative pelvic surgery by laparotomy. In a study after conservative gynecologic surgery by laparotomy that included myomectomy the Intergel solution reduced postsurgical adhesions by up to 59% [4].

In an effort to overcome the biological and clinical limitations of current adhesion barriers, a 12 cm diameter No-React treated bovine/porcine pericardial patch (resembling the shape of a dome) was developed as a nonabsorbable permanent barrier for complex myomectomy. This pilot study aimed to evaluate the safety and effectiveness of the patch in preventing the formation of adhesions after extensive myomectomy with full thickness uterine wall reconstruction.
Patients and methods

This series is composed of 20 consecutive symptomatic patients who requested primary myomectomy as an alternative to hysterectomy. The mean age of the group was 32 years, ranging from 22 to 48 years of age. All patients were fully informed of the aim of this study and written consent was obtained. The surgeries were performed by the authors using a similar technique of myomectomy for all of the cases [5].

All patients received prophylactic antibiotic therapy before, during, and after surgery. The operations were performed under general endotracheal anesthesia. The patients were placed in a semilithotomy position, and the bladder was emptied by either a straight or indwelling catheter. A uterine manipulator was placed transcervically to create an effective uterine mobilization and tension.

A 4 cm to 6 cm suprapubic incision was made, the skin and subcutaneous layers were opened transversely, and the rectus fascia and peritoneum were incised vertically. A soft, self-retaining abdominal retractor (Protractor, Weck Closure Systems, Research Triangle Park, North Carolina; Mobius Retractor, Apple Medical, Marlboro, Massachusetts) was placed through the cruciate abdominal wall incision. The myomectomy consisted of three basic steps: (1) intraperitoneal reduction of uterine size by selective myomectomy, (2) delivery of the debulked uterus through the abdominal retractor, and (3) extracorporeal completion of myomectomy and uterine reconstruction. In all instances the uterine incisions and myomectomies were preceded by the injection of diluted vasoconstrictor solution into the superficial myometrium and serosa overlying the incision lines to decrease blood loss. When feasible, myomas were removed through a single midline anterior uterine incision. Efforts were made to minimize the number of uterine incisions. Mechanical vascular occlusion with a rubber tourniquet and clamping of the infundibulopelvic ligaments withatraumatic vascular clamps were routinely employed to tempo-

rarily occlude uterine blood flow. The entries in the uterine cavity were closed with sutures placed in the underlying supporting myometrium. Dead spaces at the base of the uterine defects after enucleation of myomas were obliterated with purse-string sutures. The defects in the uterine wall were closed in two layers using interrupted, delayed absorbable sutures. Any redundant myometrium was excised to help restore the normal shape of the uterus and to better approximate the uterine serosa. The serosa was closed using microsurgical techniques to minimize trauma to the peritoneal surfaces.

The Shelhigh Dome Pericardial Patch No-React Treated (Shelhigh, Millburn, New Jersey) is made of bovine/porcine pericardium treated with glutaraldehyde and heparin processed using a proprietary method named No-React Treated rinsing. Extensive experience with this material in cardiovascular surgery has demonstrated its safety and effectiveness when used as a permanent pericardial substitute. In such studies the patch has been shown to exhibit strong biocompatibility and antidegenerative properties and resistance to calcification and adhesions, and does not adhere to the heart or chest wall, even in pediatric patients. Its effectiveness and safety in neurosurgery for permanent dura repair has also been documented [6–10].

The Dome Pericardial Patch has a unique design, resembling the shape of a dome 12 cm in diameter. The shape enables the patch to conform to the uterine fundus and body, thereby achieving full coverage of the uterus, including myomectomy sites and adnexa (Fig. 1). The patch was designed to isolate the pelvic organs from adjacent tissues and bowels to prevent pathologic adhesions between the injured tissue surfaces during the most critical time for postmyomectomy adhesion formation (1 to 7 days). Because the patch is made from a nonabsorbable biocompatible material, it does not require removal but rather acts as a permanent protective cover (Fig. 1).

Technique

The patch is kept in an antibiotic solution prior to placement (Kanamycin Sulfate; Kantrex). After the completion of the myomectomy and uterine closure, the patch (with its smooth side facing the peritoneal cavity) is then placed over the uterus. The patch is soft, thin, and pliable, resists shrinkage, and adheres well to moist tissue surfaces. Its placement does not require complete hemostasis or removal of all irrigation fluid and instillates from the peritoneal cavity.

The Dome Pericardial Patch is secured in place using one nonabsorbable suture at the dome of the uterus. Four monofilament absorbable sutures are placed around the circumference of the patch to maintain adequate positioning of the patch. The uterus is then returned to the peritoneal cavity and the edges of the patch are allowed to conform to the shape of the pelvis (Fig. 2).

In an effort to further isolate the uterus and adnexa from bowel, omentum, and the abdominal wall, four absorbable
Patients who presented with pelvic or abdominal infection, diabetes, hematologic or coagulation disorders, autoimmune disease; those receiving chemotherapy, anticoagulants, or thrombogenic agents at myomectomy; and patients with known sensitivity to products of porcine or bovine origin were excluded from this study. Also, patients undergoing transvaginal myomectomy procedures, patients receiving any additional adhesion prevention alternative, and patients in whom absorbable hemostatic materials were left at myomectomy sites were also excluded.

Results

Myoma size ranged from 5 cm to 20 cm. The largest number of myomas removed from a patient was 15. The combined weight of myomas per patient ranged from 500 to 2,572 g. All operations were successfully completed without intraoperative or postoperative complications. Blood transfusions were not required in any of the patients.

No problems related to the patch were encountered, including the need for its removal. Postoperative infections, pelvic pain, or need for later surgery due to adhesion complications were not encountered. In all patients second-look laparoscopy was performed 6 weeks postoperatively, and third-look laparoscopy was carried out in 3 patients at 18, 20, and 24 months postmyomectomy. Several investigators have found that routine second-look or even third-look postmyomectomy laparoscopic prophylactic adhesiolysis is a valuable alternative in reducing the severity and number of postoperative adhesions and improving fertility [2].

At second-look laparoscopy a consistent pattern was found in all cases. No adhesions were found between the abdominal wall, bladder, small bowel, sigmoid colon, and the uterus or adnexa. In all cases a thin layer of the omental edge covered the Dome Pericardial Patch. This omental tissue was easily separated by hydrodissection and gentle tissue traction. In all cases the pericardial patch was securely anchored to the uterine fundus by the nonabsorbable sutures. Only minimal adhesions to the ovaries and tubes were found in patients who had posterior uterine wall myomectomy (7 patients). The patch was easily separated from the uterine surface with no evidence of adhesion formation.

It was of interest to note that in the majority of cases the uterine surface was not completely healed at 6 weeks. Removal of the patch was not considered necessary in any of the cases.

Biopsy of the pericardial patch at second-look laparoscopy showed excellent preservation of the collagen, and there was no tissue attachment to the material or foreign body reaction. In the 3 patients who underwent third-look laparoscopy, the appearance and findings of the pelvis and the patch were the same as that observed during their second-look procedure. Histological examination of the third-look laparoscopy revealed similar findings to that of the second-look laparoscopy. At 8 to 34 months of follow-up no

sutures placed at the edges of the patch are fixed to the healthy parietal peritoneum anteriorly, laterally, and posteriorly (Fig. 3). The abdominal incision is then closed.

Fig. 2. A. The myomectomy has been completed. Notice the soft abdominal retractor. The patch is applied to the uterus. B. One nonabsorbable suture is placed to the apex of the patch. A few absorbable sutures are then applied around the circumference of the patch to secure it to the uterine surface. The free edges of the patch are pushed in first, followed by the uterus. In the pelvic cavity four additional absorbable sutures are placed at the edges of the patch and fixed anteriorly, laterally, and posteriorly to the healthy peritoneum.

Fig. 3. Lateral view of the Dome Pericardial Patch with sutures in place.
complications related to the patch or need for its removal have occurred. Two patients subsequently had uncomplicated pregnancies and were delivered by cesarean section. The pericardial patches were easily removed after the cesarean delivery.

Comments

Each year more than 2 million abdominal procedures are performed in the United States [8]. Intra-abdominal adhesions have proved to be the most common surgical complication of laparotomy, with an incidence of greater than 90%. Such adhesions can result in bowel obstruction, chronic pain, infertility, and difficulties with reoperations. These complications result in more than 400,000 adhesiolysis procedures per year in the United States alone [11,12]. Adhesion formation-reformation is encountered in 55% to 100% of patients after reproductive surgery [13,14]. The economic impact of treating adhesions has been estimated at $1.2 billion annually [15]. Commercially available liquid and solid adhesion barriers have been unable to eliminate the problem of postmyomectomy surgical adhesion formation [16].

Ideally, a barrier for adhesion prevention after myomectomy should not affect healing or support bacterial growth. It should persist during the critical stages of reepithelialization, cover the traumatized area completely, and be a totally biocompatible, permanent or semipermanent membrane that does not require subsequent removal. The Shellhigh Dome Pericardial Patch fulfills the above criteria. Further, its value as a permanent replacement for pericardium after cardiovascular procedures and for dura repair in neurosurgery are well established [6–10,17].

Our preliminary experience with the pericardial patch in patients undergoing complex myomectomy and extensive uterine reconstruction consistently demonstrated the efficacy of the patch in preventing the formation of post surgical adhesions. In the majority of cases the uterine surface at the myomectomy sites was not completely healed at 6 weeks. This finding is probably the result of the extensive uterine reconstruction procedures performed in these patients that may require additional uterine serosal healing time. The possibility that the presence of the patch created a temporary delayed healing of the myomectomy sites needs to be considered. Although removal of the patch at the second- and third-look laparoscopic procedures was not considered necessary in any of the cases, cutting the sutures and withdrawing the patch through a laparoscopic port would have easily accomplished its removal.

The unique configuration and size of the Dome Pericardial Patch are features that clearly differentiate the patch from other solid barriers such as Interceed, Seprafilm, and Prelude. The patch is soft, thin, and pliable and adheres well to moist tissue surfaces. Because of its size and shape, the patch eliminates the need to predict the most vulnerable potential sites of adhesion formation and reduces the possibility of de novo adhesion at areas remote from the myomectomy sites. The pericardial patch shape conforms to the uterine fundus and body, and because of its size, covers the uterus and adnexa and extends to the lateral pelvic walls, bladder, and rectosigmoid. This enables it to effectively isolate the reproductive organs during the critical phase of peritoneal healing.

Interceed requires a blood-free incision, complete hemostasis of the surgical site, and complete removal of intraperitoneal irrigants. Its use in complex myomectomy is limited because absolute hemostasis is often difficult to achieve at sites of extensive myomectomy. In addition, Interceed migration may occur after application of large pieces [16–18]. Seprafilm and Prelude need to be trimmed to the desired size and shape in order to cover and overlap the edges of the repair site. Significant adhesion formation at the edges of these barriers frequently occurs and their placement in patients with posterior uterine incisions usually results in adhesion formation with undesirable involvement of the adnexa. Drawbacks of Seprafilm include its brittle membrane that has a tendency to fracture when bent at sharp angles, making it unsuitable for laparoscopic use. The material can also adhere to surgical gloves, resulting in displacement of the barrier, and it is cumbersome because it requires the removal of paper backing on the film. The shortcomings of Prelude include the potential development of fibrosis, mechanical impairment of organ functions or adverse biocompatibility complications if the Prelude is left in place. Furthermore, if it is sized too large, excessive wrinkling may occur, resulting in undesirable tissue attachment. Because the long-term effects of Prelude in the pelvis are unknown, its removal in a second procedure is routinely performed, limiting its clinical usefulness. No clinical data are available on the long-term use of the Prelude in patients undergoing myomectomy [11,19–23].

Intergel is marketed for use in only those patients undergoing open conservative gynecologic surgery [4]. The manufacturer states that the safety and effectiveness of Intergel solution has not been established in patients undergoing laparoscopic procedures. Clinical studies have not been conducted in pregnant women or women who have become pregnant within the first month after exposure to Intergel.

The Shellhigh Dome Pericardial Patch can be safely used in patients considering future pregnancy after extensive myomectomy. After reabsorption of the absorbable sutures, the patch does not interfere with uterine expansion when pregnancy occurs. At the same time the nonabsorbable suture at the top of the uterus prevents patch detachment.

In the present study, our predictable laparoscopic findings suggest that, in asymptomatic patients, routine second- or third-look laparoscopy for the sole purpose of prophylactic adhesiolysis and removal of the patch is not necessary. Although the duration of this trial was relatively short, there is reason to believe that late complications such as obstructive symptoms would be unlikely. This is because
the patch is a permanent biocompatible barrier approved for soft tissue repair that prevents the direct contact between the bowel and pelvic structures.

The scope of this study was the use of the patch for complex myomectomy procedures. Therefore, similar studies are needed on other surgical procedures, such as bowel surgery, to further validate its usefulness and safety.

Our early experience so far in using the Dome Percardial Patch for adhesion prevention in patients undergoing extensive laparoscopic myomectomy (4 patients) shows its suitability for laparoscopic use. Because of its pliability and thinness, the patch is easily rolled like a cigar to allow its easy placement into the pelvic cavity through a laparoscopic port. The patch is then unrolled in the pelvis and placed on top of the uterus, allowing the edges of the patch to conform to the shape of the pelvis. The patch is secured in place using laparoscopic suturing similar to the open myomectomy patch placement technique.

Conclusion

The results of this pilot study strongly suggest that there are significant benefits to be realized when using the Dome Percardial Patch in patients undergoing complex myomectomies where a significant amount of adhesions is anticipated. The biological and physical characteristics of the patch make it an ideal adhesion barrier alternative to current available materials for use in attempts to reduce the incidence and severity of postmyomectomy adhesions. Clinical trials are warranted.

References