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Near Adhesion-Free Reconstructive Pelvic Surgery: Three Distinct Phases of Progress Over 23 Years

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Abstract

Background: A somewhat pessimistic view on the prevention of postsurgical adhesions has developed over the years because rigorous surgical approaches may still result in the formation of postsurgical adhesions. In addition, postsurgical adhesion formation is associated with a significant degree of long-term morbidity. In this article, a surgical technique is presented which allows patients with the most extensive form of pelvic adhesions to undergo reconstructive pelvic surgery with a near-adhesion-free postoperative outcome. Purpose: This study was undertaken to assess the effectiveness of a comprehensive, well-defined set of surgical techniques, with well-defined additions and subtractions in surgical technique over a period of 23 years and three distinct phases of implementation. This work was a systematic comparison of three case-series evaluated sequentially over time. The three surgical protocols were each completely standardized. Materials and Methods: This was a systematic comparison of three distinct case series of patients who had extensive pelvic adhesions. Three distinct and standardized surgical protocols were prospectively introduced and adhesion scores before and after surgical treatment were assessed and statistically compared for each of the three case series. Results: Ninetyfive (95) patients with extensive pelvic adhesive disease due to endometriosis or pelvic inflammatory disease participated in this assessment. They were chosen because of the extensive nature of their pelvic and adnexal adhesions. There were 26 patients in phase I (1987–1993), 44 patients in phase II (1994–2005), and 25 patients in phase III (2006–2009). Using the American Fertility Society scoring system for adnexal adhesions, the total adhesion score decreased from 33.8 to 18.1 in phase I, from 33.3 to 6.0 in phase II, and from 33.2 to 2.5 in phase III. Each decrease was statistically significant within each phase (P < 0.001). Further, a statistically significant decrease in subsequent adhesion scores (P < 0.01) was observed at the time of second-look laparoscopy, when comparing phases I to II, II to III, and I to III, with the lowest scores obtained with the phase III surgical techniques. Conclusions: With the use of a comprehensive, well-defined set of surgical antiadhesion techniques, it is possible to perform adhesion-free or near adhesion-free reconstructive pelvic surgery. (I GYNECOL SURG 26:31)

Introduction

DHESIONS ARE said to occur in 55%— 100% of women as a result of pelvic surgery.^{1,2} After surgical lysis of adhesions, the recurrence rate is approximately 85%.2 The consequences of such adhesion formation include subfertility or infertility, small bowel obstruction (SBO) and injury, chronic pelvic pain, dyspareunia, and difficult reoperative surgery.³ A somewhat pessimistic view on the prevention of postsurgical adhesions has developed over the years, because rigorous surgical approaches may still result in the formation of postsurgical adhesions.^{4,5} In addition, with the widespread utilization of in vitro fertilization procedures, there has been a decreased emphasis on surgically treating women with extensive pelvic adhesive disease, latestage endometriosis, and so forth, while maintaining or enhancing fertility.

There continue to be, however, married and single women who would like the underlying problems associated with their infertility and/or pelvic pain to be addressed and treated. In fact, many patients do not wish to be involved in *in vitro*-type procedures because of their view that these procedures are either unethical or immoral. As a result, this group of patients presents a specific challenge at trying to identify the underlying causes of their infertility and then treat them in such a way that this can successfully assist them in achieving pregnancy from using a natural procreative technology. This approach, called NaProTECHNOLOGY (natural procreative technology), has been described elsewhere in extensive detail.⁶ A component of this approach utilizes surgical procedures designed to reduce the formation of pelvic adhesions while, at the same time, tackling the most difficult, complex patients with extensive endometriosis and/or pelvic inflammatory disease associated with pelvic adhesions. The aim of this report is to present

the results of an ongoing 23-year, threephase research project on three surgical approaches that were specifically aimed at reducing or eliminating postsurgical pelvic adhesions and eventually performing adhesion-free or near adhesionfree reconstructive pelvic surgery.

Materials and Methods

Patients who were entered into this evaluation were distinctive because they exhibited the most extensive pelvic adhesions due to late-stage endometriosis and/ or pelvic inflammatory disease. They were entered into the study based upon the extensive nature of their pelvic and adnexal adhesions. Each of these patients underwent a preoperative diagnostic laparoscopy, followed by a laparotomy for lysis of adhesions and removal of the endometriosis (if present) and reconstruction of the pelvis. Approximately 10 days following the abdominal procedure, a second-look laparoscopy was performed to either lyse the adhesions that had formed or remove a mechanical antiadhesion barrier. This program, to date, has undergone three distinct phases, and thus, the effectiveness of the antiadhesion strategies could not only be measured, but could also be quantified and statistically compared.

Each of these patients' before and after diagnostic laparoscopies were performed by using a "near contact" technique, and they were videotaped and kept permanently. The videotapes were reviewed for the scoring of the adhesions that would be present at the time of the major abdominal surgery and the subsequent second-look laparoscopy. Scoring of the adhesions was done according to the American Fertility Society (AFS) scoring system for adnexal adhesions. Adhesions for the right adnexal area, the left adnexal area, and the total adnexal adhesion score were calculated. The numerical scores were then statistically evaluated by using the NCSS Biostatis-

Table 1. Standardized Antiadhesion Techniques Used Over the Three Phases of Study

Meticulous hemostasis with entry incision Intermittent irrigation Suture selection Microcautery and/or CO₂ laser as cutting instrument Appropriate technique for closing intra-abdominal surface tissues Uterine suspension (when indicated) Meticulous hemostasis at conclusion of procedure-completely clear irrigating fluid Closing parietal peritoneal surfaces Phase II All phase I techniques Hydropacks for packing the bowel away (replacing lap packs) Use of ePTFE as adhesion barrier Phase III All phase I and II techniques Application of CoSeal® Surgical Sealant as a spray-on antiadhesion adjuvant prior to placing the ePTFE adhesion barrier and intraperitoneal instillate

tical Package (NCSS 2000, Statistical System for Windows; NCSS, Kaysville, UT).

The three phases of antiadhesion techniques that were employed in this evaluation are listed in Table 1. Each of these techniques were standardized for each of the three series and are briefly described below.

Phase I

All surgical procedures for the lysis of adhesions were performed by laparotomy, usually through a Pfannenstiel incision. In the first phase of this study, which was conducted from 1987 to 1993 (n = 26), the bowel was packed away by using standard lap packs. Other techniques and their description are discussed below.

Meticulous hemostasis with entry incision. At the time of the skin incision and entry into the abdominal cavity, meticulous hemostasis was undertaken, so that during the course of the surgical procedure, back bleeding into the pelvis would not occur or would be limited.

Intermittent irrigation. During the course of the procedure, an irrigating

fluid was hung and administered through a urology tubing so that, intermittently, the pelvis could be irrigated of all blood products. The initial liter of this contained Ringer's lactate with 5000 units of heparin and 1 g of Solu-Cortef (hydrocortisone). Subsequent irrigation contained either Ringer's lactate alone or Ringer's lactate with 5000 units of heparin.

Suture selection. The use of suture is important because some suture materials are quite adhesiogenic (e.g., chromic cat gut). In these cases, a polypropylene suture (Prolene; Ethicon, Somerville, NJ) with an RB-1 needle was used for closing all exposed surfaces during the course of the surgery. A 4-0 polypropylene suture was used on peritoneal surfaces, a 5-0 polypropylene suture was used on ovarian surfaces, and a 6-0 polypropylene suture was used on the fallopian tube.

Microcautery and/or CO₂ laser as cutting instruments. Either microcautery or a CO₂ laser were used during the course of the procedures as cutting instruments. These are associated with the least amount of collateral damage to tissues. When using microcautery, a microcautery needle is used at a setting of 10–15 watts of power. With the CO₂ laser, a super-pulse mode is often utilized in power settings of between 3 and 30 watts.

Technique for closing intra-abdominal surface tissues. In closing the peritoneum, the ovarian surface, or the serosa over the myometrium (e.g., following myomectomy), the tissue edges are inverted. This leaves smooth, nonirritated, and nonabraded surface tissue exposed, along with an inert suture material.

Uterine suspension (when indicated). When the uterus was markedly retroflexed or retrocessed at the beginning of the surgery and especially when dissection occured in the posterior cul-de-sac or along the posterior wall of the uterus, a uterine suspension was performed. A simple plication of the round ligaments, using either a 2-0 Prolene or 2-0 PDS (polydioxanone) suture, was done.

Meticulous hemostasis at conclusion of the procedure: Completely clear irrigating fluid. Before the abdomen was closed, the surgical areas were closely inspected to make sure that there was no bleeding coming from any of the areas. The goal of the final irrigation fluid is to have it completely clear.

Use of intraperitoneal instillates at the conclusion of the procedure. Thirty-two percent (32%) dextran-70 in dextrose (Hyskon; Hospira, Inc., Lake Forest, IL), usually in the amount of either 100 or 200 cc, was placed within the abdominal cavity as an instillate, which would attract fluid into the peritoneal cavity and create a hydroflotation effect with the various organs.

Closing the parietal peritoneum. In closing the parietal peritoneum, the edges of the peritoneum were everted externally toward the anterior abdominal wall and a relatively inert, absorbable suture (2-0 PDS) was used. This also creates a smooth, nonabraded closure of the parietal peritoneum and significantly decreases adhesions to the undersurface of the abdominal wall.

Second-look laparoscopy. An early second-look laparoscopy (8–10 days following laparotomy) was instituted during phase I of this study, with the aim of reducing the long-term occurrence of pelvic adhesions by laparoscopically lysing any adhesions that had formed since the laparotomy. The optimal time for a second-look laparoscopy is in the range of 8–10 days following laparotomy, and some have reported up to 4 weeks. Adhesions observed later than these time

intervals are often thick and highly organized, making laparoscopic adhesiolysis difficult and traumatic.³ All laparoscopies were videotaped and kept on permanent file.

Phase II

In phase II (n = 44), all of the phase I techniques were utilized, except for the use of lap packs. In addition, the following were added, as described below.

Hydropacks for packing the bowel away. In phase II, the use of lap packs was abandoned and replaced with hydropacks made from Biogel® nonlatex, powder free, surgical gloves in 7½ to 8 size (Biogel Skinsense Gloves, Norcross, GA). These gloves were filled with Ringer's lactate and tied at the wrist. This "balloon" was then placed within the abdominal cavity and held there by fastened retractors. This can significantly reduce the amount of microabrasion to the bowel.

Use of ePTFE as an adhesion barrier. In these patients with extensive pelvic adhesions, there continues to be some degree of abrasion that is present in the pelvis either with the uterus, tubes, ovaries, peritoneum, or all of the above. This was protected by placing an ePTFE adhesion barrier (Preclude peritoneal membrane; W.L. Gore Associates, Inc., Flagstaff, AZ) over all of these tissues and securing it in position with interrupted 5-0 Prolene sutures or hemoclips. The adhesion barrier was removed at the time of the second-look laparoscopy.

Phase III

In phase III (n = 25), all of the phase I and II techniques were utilized. In addition, the following was added: Application of CoSeal[®] Surgical Sealant (Baxter Health Corporation, Hayward, CA) as a spray-On antiadhesion adjuvant prior to placing the ePTFE barrier and the intra-

peritoneal instillate. CoSeal was used as a spray-on anti-adhesion, absorbable hydrogel. This was the only addition to the techniques that were utilized during phase II.

Results

A total of 95 patients were entered into this evaluation between 1987 and 2009. There were 26 patients in phase I, 44 patients in phase II, and 25 patients in phase III. Phase I ran from 1987 to 1993, phase II from 1994 to 2005, and phase III from 2006 to 2009. There were no statistically significant differences in the age or gravidity between the different groups of patients.

This study was a systematic comparison of three case series evaluated sequentially over time. The three surgical protocols were each standardized. This study was ambispective. The standardized protocols were introduced at the beginning of each of the three phases, and the evaluation with the adhesion scores was introduced midway through the evaluation for comparison purposes. Each patient completed and signed informed consent papers.

The length of time between the laparotomy for lysis of adhesions and the second-look laparoscopy for all patients in phase I was 9.8 days (95% confidence level, CL: 7.9–11.6). The length of time between the laparotomy and the second-look laparoscopy for the patients entered in phase II was 10.1 days (95% CL: 7.4–10.8), and in phase III, the length of time averaged 10.1 days (95% CL: 9.6–10.7). There was no significant difference in this factor between the three phases.

The total adhesion scores for phases I, II, and III before the lysis of adhesions and at the time of second-look laparoscopy are presented in Table 2. At the time of surgery for the lysis of adhesions, the total adnexal adhesion scores were 33.8 (95% CL: 27.3–40.3), 33.4 (95% CL: 28.8–37.8), and 33.2 (95% CL: 27.5–39.0) for

phases I, II, and III, respectively. At the time of the second-look laparoscopy, the total adhesion scores were 18.1 (95% CL: 10.7–25.4), 6.0 (95% CL: 4.4–7.6), and 2.5 (95% CL 1.2–3.7), respectively. The differences between the adhesion scores at the time of the laparotomy to lyse the adhesions compared to the time of the second-look laparoscopy were statistically significantly different, when compared within each of the same phases. However, the total adnexal adhesion scores prior to pelvic reconstruction at laparotomy for phases I, II, and III were not different statistically. There was a statistically significant decline, however, in the total adhesion scores, when comparing the adhesion scores at the secondlook laparoscopy for phase I (total AFS mean, 18.1) and phase II (total AFS mean, 6.0). Further, the difference between the

Table 2. Total Adnexal Adhesion Score (TS), Right and Left Adnexal Adhesion Score (RA and LA) Comparing Adhesions at Beginning (1) to Those at Second Look Laparoscopy (2) by Phase of the Study^a

Phase of study	$TS-1^1$	$TS-2^1$	$RA-1^2$	$RA-2^2$	LA-1 ³	$LA-2^3$
I	33.84	18.1 ⁵	15.04	$7.8^{6,8}$	18.89	10.7 ^{10,12}
II	33.3	6.0°	16.0	2.70,	17.4	3.3 ^{10,11}
III	33.2^4	2.5°	15.9^4	1.77,8	18.0^{9}	$0.8^{11,12}$

^aFor 95% confidence intervals, see text.

 ^{1}P < 0.001 when comparing TS-1 to TS-2 scores within each of the three phases, respectively (Wilcoxon rank sum tests).

 2P < 0.001 when comparing RA-1 to RA-2 scores within each of the three phases, respectively (Wilcoxon rank sum tests and t-tests for difference between means).

 3P < 0.02 to P < 0.0001 when comparing LA-1 to LA-2 scores within each of the three phases, respectively (Wilcoxon rank sum tests and t-tests for difference between means).

⁴Not statistically significantly different when comparing phase I to II, II to III, and I to III (equal variance *t*-test).

⁵P < 0.01 when comparing phases I to II, II to III, and I to III (Wilcoxon rank sum test).

 $^6P\,{<}\,0.02$ when comparing phase I to II (Wilcoxon rank sum test).

 7 Not statistically significant when comparing phase II to III (Wilcoxon rank sum test). $^{8}P < 0.01$ when comparing phase I to III (Wilcoxon rank

 8P < 0.01 when comparing phase I to III (Wilcoxon rank sum test).

 9 Not statistically significant when comparing phases I to II, II to III, and I to III (Wilcoxon rank sum test). $^{10}P < 0.005$ when comparing phase I to II (Wilcoxon rank

sum test).

11 P < 0.02 when comparing phase II to III (Wilcoxon rank)

sum test). $^{12}P < 0.0001$ when comparing phase I to III (Wilcoxon rank sum test).

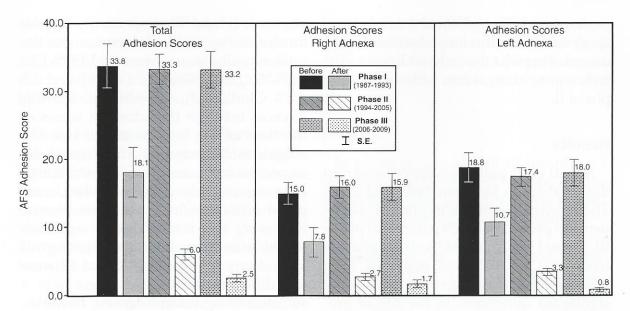


FIG. 1. Advancement in the prevention of postoperative adhesion formation during three distinct chronologic phases of improvement: phase I, 1987–1993; phase II, 1994–2005; and phase III, 2006–2009.

adhesion scores at the time of the second-look laparoscopy for phases II and III were also significantly decreased, from 6.0 to 2.5 (see Figure 1).

The adhesion scores for the right and left adnexa before the pelvic reconstruction with lysis of adhesions and at the time of the second-look laparoscopy are also shown in Table 2. There was a significant decrease observed in the adnexal adhesion scores from the time of the lysis of adhesions until the time of the secondlook laparoscopy during all three phases of the study. However, the adhesion scores at the time of the second-look laparoscopy were higher during phase I, lower during phase II, and again lower during phase III. Along each step, the reduction in adhesion formation was statistically significant, except for one comparison—the right adnexal adhesion score between phases II and III (2.7–1.7). This is all shown graphically in Figure 1.

A comparison of the percentage of patients who had minimal pelvic adhesions following reconstructive surgery (a score of 5 or less in the AFS classification, which is consistent with minimal adhesions) between the three phases is shown in

Table 3. The phase III techniques were significantly more likely to result in either adhesion-free or near adhesion-free (minimal) outcomes than were either the phase I or II techniques (P < 0.003).

Discussion

The formation of adhesions following abdominal and pelvic surgery is often considered to be a foregone conclusion. Further, there are significant sequelae that come as a result of postoperative adhesion formation. In 2001, for example, it has been reported that 2200 people died in the

Table 3. Number and Percent of Cases at Second Look Laparoscopy with Total Adnexal Adhesion Score ≤ 5 or $\geq 6^a$

Phase of study	Total adnexal adhesion scores							
	<u>≤</u> 5		≥6		Total			
	n	%	n	%	n	%		
I	9	34.6	17	65.4	26	100.0		
П	23	52.3	21	47.7	44	100.0		
Ш	22	88.0	3	12.0	25	100.0		

^aThe score of ≤5 is consistent with "minimal adhesions," as defined by the American Fertility Society Adnexal Adhesion scoring system.⁷ Chi-square analysis: I versus II, P = 0.1519, NS; II versus III, P = 0.0027; I versus III, P < 0.0001.

United States due to complications of small-bowelobstruction. In addition, there were 67,000 hospital admissions for adhesive small-bowel obstruction, with the length of hospital stay averaging 9.8 days. It has been estimated that \$5 billion annually are spent in the United States with adhesion-related hospital admissions. ¹¹

With specific relation to the formation of postoperative adhesions in the pelvis, significant implications exist for their effect on future fertility. This has led many gynecologic surgeons to avoid surgical procedures on the pelvis in conditions that would normally be considered surgical diseases (e.g., endometriosis and pelvic adhesive disease). Further, with the development of the artificial reproductive technologies (i.e., in vitro fertilization) reconstructive pelvic surgery for the specific purposes of enhancing procreative function or pelvic pain relief has been deemphasized. This has, to some extent, effected progress in this area and the training of future reconstructive surgeons.

At the present time, the best approach to the prevention of pelvic adhesions includes attention to surgical detail, adherence to microsurgical techniques, and principles such as gentle, noncrushing tissue handling, creating and maintaining a continuous humidified peritoneal environment, as well as judicious and meticulous use of energy sources. 1 Such meticulous attention to detail still often results in the formation of pelvic adhesions and has led, at times, to a somewhat pessimistic view of reconstructive pelvic surgery. ^{2,4,5} To a great extent, this is due to the adhesiogenic nature of pelvic surgery. It has been my view that no single approach can be considered effective in preventing pelvic adhesions, although, at times, there has developed a sense that a greater reliance on intraperitoneal instillates will solve the problem.1 In reality, no one approach, at the present time, can be considered highly effective. Thus, in this study, a comprehensive, antiadhesion surgical approach was utilized and developed to be highly effective over time.

This study represents a very unique evaluation of surgical technique in a group of patients over a period of time in which the foundational approaches were standardized. The surgical techniques utilized during the first phase of this evaluation (1987–1993) were also used in the second (1994–2005) and third (2006–2009) phases (with the single exception of the use of lap packs). At the same time, the patients involved in the first phase

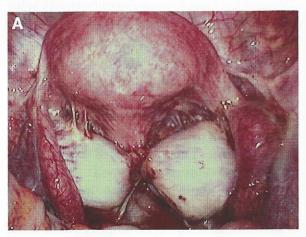




FIG. 2. (A) Laparoscopic photograph of the pelvis in a patient with advanced-stage endometriosis with bilateral endometriomas and extensive periovarian adhesions and right peritubal adhesions. (B) Use of three distinct pieces of ePTFE antiadhesion barrier are shown.

could be independently evaluated and compared to the patients involved in the second phase, because the phase II patients also became a distinct group with the supplementation of two additional techniques. These included packing the bowel away with hydropacks made up of fluid-filled Biogel gloves and the introduction and application of ePTFE antiadhesion membrane. The ePTFE antiadhesion membrane (Gore-Tex Preclude Peritoneal Membrane Gore Associates) is a nonabsorbable membrane which is 0.1 mm in thickness with a pore size of < 0.001 mm. It has been shown to be associated with a decrease in de novo adhesion formation following abdominal myomectomy and has also been shown to reduce adhesion reformation after laparotomy for adhesiolysis. The presence of residual blood does not compromise its efficacy, such as with other mechanical adhesion barriers.¹² The principle of adhesion prevention with the use of ePTFE involves the mechanical separation of traumatized surfaces, allowing each surface to heal independently. 13-15 ePTFE barriers have been previously examined histologically, and no adhesions to either surface of the material were identified.2 This material has also been found to be biologically compatible with gametes and the embryo. 16 Some have viewed its use as somewhat limited, because it is sutured into place and has to be removed by a subsequent laparoscopy. 12

Expanded polytetrafluoroethylene resists both chemical and biologic degradation, even after years of *in vivo* application. Using small patches (4×6 cm) is approved for permanent installation. In this series, the ePTFE adhesion barrier was used as a "blanket" over the uterus, fallopian tubes and ovaries. It was best applied with the use of a 15×19 cm piece divided into three separate sections (see Fig. 2A and 2B). Each of the adnexal areas, including the fallopian tube and ovary, had a single piece placed over them to protect them in

the early healing phase. The third piece was placed over the posterior uterus, the fundus, and the anterior uterus. While this type of placement does require a second-look laparoscopy for the removal of the ePTFE membrane, the results are so dramatically good, in terms of adhesion prevention, that it becomes rightfully justifiable. At the same time, it has been clinically observed that the second-look laparoscopy is well tolerated by this group of patients and does not appear to significantly delay their overall recuperation from the initial surgery.

In this series of patients, an instillate of 32% dextran 70 was added at the conclusion of the surgical procedure as a final component of the adhesion-prevention strategy. This product (Hyskon, Hospira, Inc.) has recently been discontinued, apparently because of the lack of availability of the raw products necessary to manufacture it. Thus, an appropriate substitute may need to be found. Recently, the U.S. Food and Drug Administration has approved a peritoneal irrigation and postoperative instillate for adhesion prevention, which is a clear, iso-osmotic solution of 4% icodextrin (Adept; Baxter Healthcare Corp., Deerfield, IL). 17 It may be that this fluid will need to be used as a replacement for 32% dextran 70 (it is only labeled for use, however, in patients who are undergoing laparoscopy).

One aspect that was not utilized in this series was the use of humidified laparoscopic gas at the time of the laparoscopic portions of this procedure. It has recently been shown that as little as a 30-second exposure to dry gas can result in loss of peritoneum. The effects of desiccation and peritoneal damage is prevented, however, by 95% relative humidity at 35°C warmed gas.¹⁸

CoSeal is a sprayable polymeric matrix that was originally developed and used as a vascular sealant in cardiac surgery. It consists of two solutions of highmolecular-weight polyethylene glycol

(PEG) in a liquid sodium phosphate buffer. Because it was observed to reduce pericardial adhesions at resternotomy, it has been used in cardiac surgery, even in pediatric cases. 19,20 It has also been shown, in a 71-patient study, to reduce adhesions following myomectomy in a way that is both safe and effective.²¹ At the time of administration, the mixed PEGs and solutions form a hydrogel that adheres to tissue. Its main indication is to achieve adjunctive hemostasis by mechanically sealing areas of leakage. This sealant swells up to 4 times its volume within 24 hours of application, and additional swelling may occur as the gel resorbs. 22 It resorbs over a 30-day period following its application.

When phase II was begun with the addition of hydropacks and ePTFE antiadhesion membrane, it was observed that bowel adhesions to the pelvic tissues were significantly decreased. With the previous use of lap packs to pack the bowel away, bowel adhesions to the uterus, tubes, and ovaries were quite common. However, if the ePTFE membrane was placed over the uterus, tubes, and ovaries with three separate small "blankets," as seen in Figure 2B, we would still occasionally see the omentum or a small portion of bowel adhesing to the tissues between the ePTFE applications. Once the PEG hydrogel was placed, nearly all of these small adhesion problems disappeared.

Conclusions

A question continues to remain as to whether or not adhesions will form following the removal of the surgical membrane. The Myomectomy Adhesion Multi-Center Study Group had the opportunity to evaluate this issue in a small group of patients who underwent a laparotomy for unrelated conditions within 18 months following the removal of the surgical membrane. It was noted that adhesions did not reform. ¹³ I have had

the opportunity to also view the pelvis in a small group of patients in phases II and III 1–2 years later. In each case, no adhesions were found to form.

Disclosure Statement

No competing financial interests exist.

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