Adhesiolysis in Severe and Reccurent Cases of Adhesions Related Disorder (ARD) - A Novel Approach Utilizing Lift (Gasless) Laparoscopy and SprayGel™ Adhesion Barrier

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ABSTRACT

We investigated the feasibility and outcome of adhesiolysis in patients with severe and reccurent adhesions using lift (gasless) laparoscopy and a SprayGel™ adhesion barrier at the Institute for Endoscopic Gynecology (EndoGyn®). The design included a prospective evaluation of lift (gasless) laparoscopic adhesiolysis in combination with a SprayGel™ adhesion barrier. A new score for bowel adhesions was developed and applied. All 35 patients with severe and reccurent adhesions underwent a lift-laparoscopic adhesiolysis with the Abdo-Lift™ and SprayGel™ adhesion barrier, a second-look laparoscopy at Day 7 and, in case of continuation of pain, a third-look laparoscopy within 6 months after the initial surgery. All patients were operated upon without conversion to laparotomy. The reduction in the adhesion score of adhesions at the second-look laparoscopy was overall (sum) 89.8% (90.1% reduction in extent, 89.3% reduction in severity, and 89.9% reduction in grade). Five patients (14.3%) had a third-look laparoscopy

within 6 months after the initial surgery, in which four cases of adhesion reformation were confirmed. However, the scores were reduced compared to the initial surgery, especially in grade (94.2%) and severity (93.2%). In these analyses, SprayGel™ was uniquely effective in improving the success rates of adhesiolysis when combined with lift (gasless) laparoscopy and good hemostasis techniques. Adhesiolysis with Abdo-Lift™ and SprayGel™ had unparalleled efficacy in the adhesiolysis procedure even in those patients in whom other solutions have not worked. An overall reduction of adhesions by 89.9% at second-look laparoscopy was found. Even if five patients (14.3%) required a third-look laparoscopy where four cases of adhesion reformation were confirmed, the scores were reduced when compared to the initial surgery, especially in grade and severity

INTRODUCTION

Adhesions are recognized as long-standing, common, recurring postoperative complications in gynecological surgery. Previous studies have estimated postoperative adhesion formation to be anywhere from 55% to 100%, and adhesion reformation has been estimated to be equally high.[1] Additionally, the cascade of postoperative complications have been well described.[2] To date, patients affected by postoperative adhesions have undergone long and complex surgeries, suffered consequent morbidities, and do not know if future surgeries will even work due to a near guarantee that adhesion reformation will result.

Laparoscopy has been proposed and studied as a means for further reducing adhesion formation and reformation.[2,3] When accompanied by a variety of physical barriers or other agents, adhesion formation is reduced. Surgical adjuvants for adhesion reduction, their efficacy, and their drawbacks have been well documented by other authors.[1,4] These adjuvants include fibrinolytic agents, anticoagulants, anti-inflammatory agents, antibiotics, and mechanical separations (including a subclass of barrier agents). Of these agents, only a few are shown to be effective and often used in abdominal procedures: CMC sponges, polymer slab gel, Polyoxamers, Gore-Tex, Surgicel, Interceed TC7, and Seprafilm are a few examples.[4] However, even these adjuncts have proven to be less than ideal to use, inconsistent in their outcomes, expensive, or increase the risks of side effects.[1] Some of these side effects include mixed efficacies across trials, removal of barriers at a second-look laparoscopy (SLL) that cause adhesions, barrier materials becoming enveloped in membranes, and inefficacy in the presence of blood.[4] Little data exists regarding the outcomes when these products are used to prevent adhesion reformation.

SprayGel™ (Confluent Surgical, Waltham, MA, USA) is a new anti-adhesion barrier used in abdominal procedures. It is already proven to be effective in a wide variety of gynecologic procedures — both open and through endoscopic routes. A study by Johns et al. evaluated SprayGel™ in human laparoscopic ovarian surgeries (bilateral adnexal surgeries) in 14 patients. This study was a European, prospective, randomized, internally controlled, two-center study. Compared to the control (adnexa), adnexa randomized to SprayGel™ had a 71% reduction in frequency, a 69% reduction in extent, and a 43% reduction in severity of adhesions at second-look. No incidences of adverse effects associated with SprayGel™ were reported and it could be applied to all patients.[5]

From experimental studies, carbon dioxide is known to be a co-factor in adhesion formation and can lead to more adhesions.[3,6,7] With the duration of exposure to CO_2, more adhesions were shown to occur. Therefore, gasless laparoscopy might be indicated for adhesiolysis surgery. For the proceudure, we used lift laparoscopy, a new concept of gasless laparoscopy.

This analysis of the initial 35 patients presents a radically new approach to gynecological and bowel adhesiolysis by a single operator by evaluating the use of SprayGel™, lift (gasless) laparoscopy, and a second-look procedure at postoperative Day 7 in patients with multiple recurring postoperative adhesions after having undergone a variety of different previous abdominal and pelvic procedures, both open and laparoscopic, and several previous adhesiolyses procedures.

METHODS

In our analysis, most patients had bowel adhesions and multiple failed adhesiolysis procedures. This difficult set of circumstances was a distinct characteristic of our group that set it apart from other studies.[5]

The analysis included 35 patients from the U.S., the U.K., and Germany who underwent laparoscopic abdominal adhesiolysis from July 2002 to April 2004 in a single center in Seligenstadt, Germany. The age range was 23 years to 84 years of age and included 33 women and 2 men (Table 1).

The typical patient history included pain, bowel obstructions, infertility, and dietary restrictions as a result of abdominal adhesions from a long history of multiple surgeries.

Comprehensive Scoring System and Adhesion Evaluation

We established a comprehensive abdominal adhesion scoring system to maintain a set of measurement standards specific to abdominal bowel and

Table 1
Patient Population Overview

Seligenstadt, Germany. The age range was 23 years to 84 years of age and included 33 women and 2 men

Case	Age	Gender	Lapt	Lapsc	Findings	Relevant History
1		F	2		RU quad, B-AW, LL B-AW, Ov cyst	
2		F	1	2	L B-AW	
3		F	2		L Col-L AW	
4		F	1	1	RU quad, B-AW	
5		F	1	3	B mid-AW	
6		F	3	4	S and L B-AW	
7		F	1	1	B and Om-rib cage, L AW-B, salpingostomy	Could not lie down due to pain
8		F	3	3	RU quad, B and Om-AW	
9		F	1	1	RU quad, B, Om-AW, LU quad B, Om-AW, liver AL	No SG on liver
10		F	1	7	3rd quad compl ad, B and OM-AW	
11		M	1	1	LU quad near spleen	
12		F	1	4	4th quad full	
13		F	1	3	RU quad B, Om-AW very vascular	
14		F	2	3	Colon R side, Myo removed	
15		F	3	1	L side, both quad, B-AW	
16		F	3	3	B-L AW midline	26 years of surgeries for adhesions
17		F	1	3	Col-L AW, clip in adh, appendectomy site near liver	
18		F	1	3	R side AW, L side AW	
19	61	F		4	Liver-L AW, AW-liver	Chronic bloating and digestive problems
20		F	1	1	B-uterus and Ov, peritonitis	
21		F	1	3	3rd quad full adh, lysed lower half to band, SB lesion sutured	1 Lap AL with gas
22		F	1	3	1st quad, B-B, B-AW	Lap with gas
23	15	F	2		R side full, U-B adh, hysterectomy	
24		F	1		AL at midline, B-AW, left 1 adh over iliac art	
25		F		1	SB-AW obst	Due to give birth next week
26		F	2	1	3 quads full	
27		F	4	2	1 loop B-AW, R Om-AW	
28		F	2	4	Om-AW everywhere but edges, all quad	
29		F	1	2	B and Om-L AW, B and Om-R AW	
30		F		2	Liver and B-AW, L Ov-AW, B-Om-R AW	
31		F	2	3	Exten B and Om-AW, B enterotomy sutured	
32		F	2	5	B-midline, RU quad, B and Om-AW	
33	73	F	2		B-midline	
34		F	4		RU quad, B and Om-AW, LU quad, liver adh	
35		F	4		All quad, B and Om-AW, B had 7 injuries with sutures, B resect	

Abbreviations :

Adh = Adhesion
AL = Adhesiolysis
AW = Abdominal wall
B = Bowel
Col = Colon
Cyst = cystectomy
Gyn = Gynecological
L = Left
Lap = laparoscopy
LL = Left lower
LU = Left upper
Myo = Myomectomy
Om = Omentum
Ov = Ovarian
R = Right
RU = Right upper
S = Small
SB = Small Bowel
SG = SprayGel™
U = Upper
Lapt = Previous Laparotomies
Lapsc = Previous Laparoscopies

Table 2.
Extent of Abdominal Surface with Adhesions

Score	Definition
0	No adhesions
1	Less than 5 cm of adhesions
2	6 cm to 10 cm of adhesions
3	11 cm to 20 cm of adhesions
4	One abdominal quadrant
5	Two abdominal quadrants
6	Three abdominal quadrants
7	Four abdominal quadrants
8	Frozen abdomen

Table 3.
Severity Score

Score	Definition
0	No adhesions
1	Mild (thin, filmy, avascular)
2	Moderate (dense, minimally vascular)
3	Severe (thick, vascular)
4	Complete attachment

Table 4.
Adhesion Grades

Score	Definition
0	No adhesions
1	Avascular, easily lysed, fails to bleed
2	Vascular, easily lysed, bleeds at time of lysis
3	Thick, requires extensive sharp dissection
4	Requires excision of serosa or deeper layers of peritoneum
5	Requires bowel resection

pelvic adhesions. This system was developed to extend beyond the scope of several other widely recognized measure- ment systems proposed by Hulka, The American Fertility Society, and The Adhesion Scoring Group.[4] A detailed description of our system is available in the table below (Tables 2, 3, & 4):

About the Procedures

Because prolonged CO_2 contact can cause complications that lead to more adhesions, we used a gasless laparoscopic technique.[3,6,7] We used the Abdo-Lift™ (Karl Storz, Tuttlingen, Germany), a system that holds the abdominal cavity open without the use of CO_2 gas and valves.[8] Other advantages of this are realized — the use of valveless ports enables the practice of standard surgical techniques and conventional instruments from open surgery as well as laparoscopic instruments. The absence of gas in the abdominal cavity provides the surgeon with many advantages such as no gas leakage, simple suturing, and effective suction and irrigation.

Scoring System

The same operator scored the adhesions at the initial adhesiolysis as well as at the SLL. The scoring system was a combination of scores in the "extent," "severity," and "grade" categories and expressed as a simple arithmetic sum. For example, a patient with 11 cm to 20 cm of adhesions that were severe (thick and vascular) and required extensive sharp dissection would receive a score of 9 (3-3-3).

The Use of SprayGel™ in the Procedures

SprayGel™ is a synthetic, absorbable adhesion barrier for use in abdomino-pelvic procedures. SprayGel™ consists of two polyethylene glycol (PEG) solutions with complementary end-functional groups. It is prepared and applied to the surgical site through the SprayGel™ Laparoscopic Sprayer through a 5-mm wide applicator. One of the liquids contains a dilute concentration of methylene blue, allowing for visualization of the barrier when applied. When the SprayGel™ liquids are mixed, they form a biocompatible hydrogel within seconds. The sprayer used in laparoscopic procedures is single-use and disposable and has a unique venting capability for safety and a flexible tip for greater control. The hydrogel persists for about 1 week, after which it is degraded by hydrolysis and excreted via the kidneys.[9,10]

Operative Procedure

As a result of using the Abdo-Lift™ system, the SprayGel™ application occurred in an air environment. We also used specially developed instrumentation, like a bipolar clamp and scissor (Fig. 1), that allows coagulation and cutting at one step and thus avoids bleeding. These special instruments allow coagulation without danger to surrounding tisse (namely, the bowel) as the bipolar energy is applied only between the two jaws of the instrument without spreading. Excellent hemostasis was assured with the use of these bipolar scissors. We also consistently rinsed the bowels with Ringers solution and used a drain.

For the adhesiolysis procedures, we

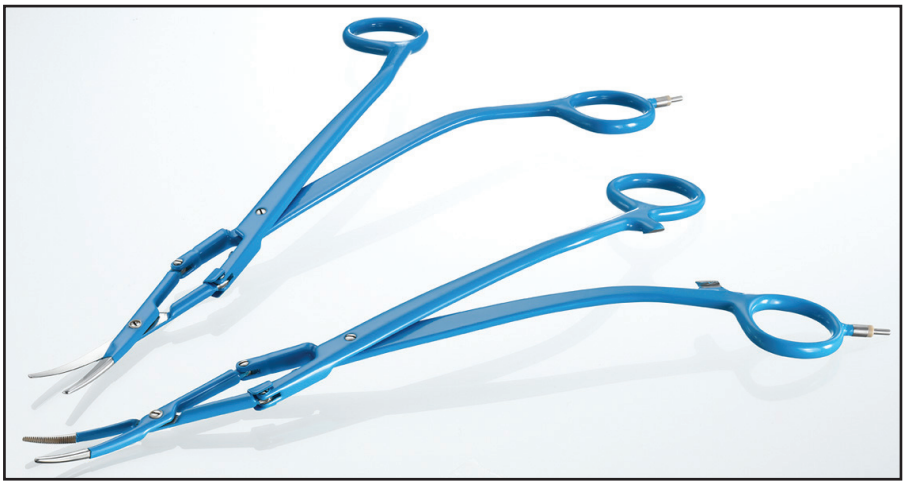


Figure 1. Bipolar scissors and clamps designed for gasless laparoscopy.

applied an average of 4.5 SprayGel™ kits (ranging from 3 to 8). Extensive photo documentation was done on each patient showing the progression and results of the surgeries (Fig. 2).

Representative Photo Documentation Table 2

Second-Look Laparoscopy (SLL) Evaluation

In our center, we followed up all surgeries with a SLL at 7 days to catch and lyse any reforming adhesions before they became vascular. SLL served as the second evaluation point for the effects of SprayGel™ on these adhesiolyses.

RESULTS

Three novel aspects are found in our approach: the use of SprayGel™, a gasless technique, and special instrumentation. Because SprayGel™ is colored a methylene blue, it enabled excellent visualization of the covered areas as well as a reference point to evaluate adhesion reformation during the SLL.

As mentioned previously, the adhesions were all scored by the same operator to ensure uniformity of the result assessment. Our analysis indicates a 90.1% reduction in extent, a 89.3% reduction in severity, and a 89.9% reduction in grade of adhesions at second look. The overall (sum) reduction was 89.8% (Table 6). The results at initial, SLL, and third-look laparoscopy (TLL) are shown in Tables 5, 6, and 7, respectively. Five patients (14.3%) had a TLL within 6 months after the initial surgery due to continuation of pain and discomfort. Four (11.4%) of these patients had reformed adhesions; however, the scores were reduced, especially in grade and severity, compared to the initial surgery (Table 6). The results of the TLL indicate a 87.7% reduction in extent, a 93.2% reduction in severity, and a 94.2% reduction in grade of adhesions. The overall (sum) reduction was 91.5% (Table 6). The surgical times for the initial procedure were an average of 256 min (ranging from 93 min to 780 min), 28 min (ranging from 17 min to 110 min) at SLL, and 67 min (ranging from 34 min to 163 min) at the TLL. The amount of SprayGel™ kits used were an average of 4.54 (ranging from 2 to 8) in the initial procedure, none at SLL, and 1.41 (ranging from 1 to 3) in the TLL. A follow-up questionnaire (Table 8) was sent to the patients via e-mail at 3 months, 6 months, and 12 months following the initial surgery.

DISCUSSION

Our analysis was set to evaluate patients with severe and reccurent of postoperative adhesions. Our research indicates that combining good hemostasis, the use of lift (gasless) laparoscopy, and the use of SprayGel™ as a surgical adjunct, we realized a high reduction in adhesion formation in these patients.

Multiple studies have been conducted to assess the efficacy of laparoscopy versus laparotomy, as well as to assess the efficacy of laparoscopic adhesiolysis. Gutt et al. conducted a comparative study to assess the benefit of laparoscopy based on published clinical and experimental data. Of 15 studies spanning 1987 to 2001, 9 concluded that fewer adhesions resulted from laparoscopies than laparotomies. Fewer adhesions to trocar sites than laparotomy sites were reported in 7 of these studies.[3]

A multicenter collaborative study of early second-look procedures after operative laparoscopy including adhesiolysis published by Diamond et al. described adhesion reformation and de novo adhesions to be frequent occurrences. At the second-look procedure, 97% were affected by reformed adhesions at 66% of the originally lysed sites. De novo adhesions occurred in 12% of patients.[2]

In another retrospective study to evaluate the degree of adhesion formation at laparoscopic surgery, Mettler et al. examined a subgroup of patients who had undergone previous surgery for adhesiolysis. Of this group, 24% showed a more severe adhesion score, 57% showed the same, and 19% showed less. These findings exceeded the severity of another group in the same study that did not have any pre-existing adhesions.[1]

One of the factors that has long been noted to cause peritoneal adhesion formation is tissue desiccation. The gas used to create a pneumoperitoneum has 0.0002% relative humidity and is delivered through trocars restricted with instruments, creating a forceful jet streaming effect.[15] This effect causes peritoneal cell vapor pressure changes, resulting in rapid surface drying of the peritoneum and an increase in solute concentration and in peritoneal fluid viscosity.[14] The "cold dry" gas alters peritoneal cell integrity and increases peritoneal cell trauma and death, which can lead to adhesion formation.[15] This principle is validated with a study that found fewer adhesions with extraperitoneal endoscopic surgery and more with intraperitoneal laparoscopic surgery.[14,16] Lift (gasless) laparoscopy is specially indicated for operations of long duration, interventions in high-risk patients, procedures requiring precise surgical technique, and procedures demanding complex suturing. Therefore, these patients were ideal candidates to use these techniques.

We observed that SprayGel™ persists in the body during the entire critical wound healing period (5 days to 7

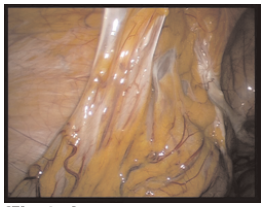
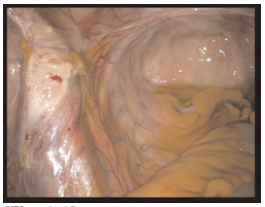
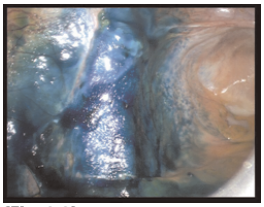
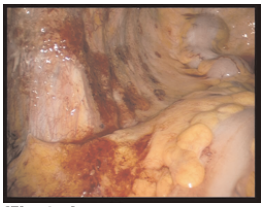
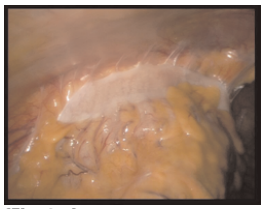
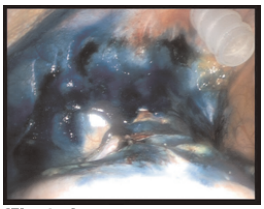
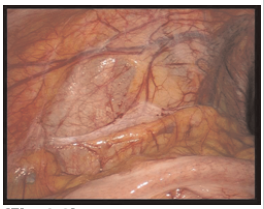
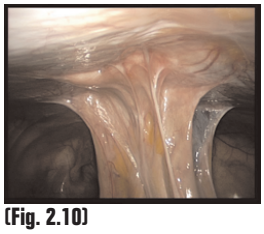
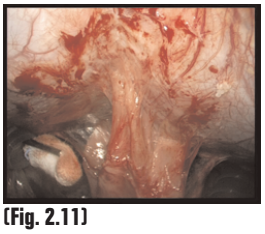
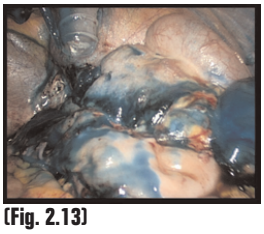
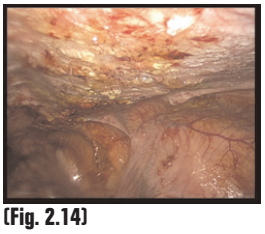
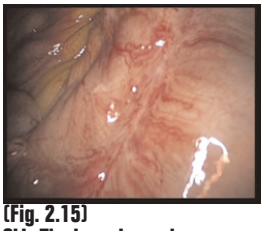
Initial	Following Adhesiolysis	Following SG Application	SLL at 1 Week	TLL
 (Fig. 2.1) Left pelvic brim and anterior abdominal wall, omental, and bowel adhesions.	 (Fig. 2.2) The left pelvic brim and the anterior abdominal wall after dissecting the adhesions.	 (Fig. 2.3) The left pelvic brim and the anterior abdominal wall after application of SprayGel™.	 (Fig. 2.4) The left pelvic brim and the anterior abdominal wall at the SLL on postoperative Day 7.	—
 (Fig. 2.5) Left pelvic brim with large bowel adhesions.	 (Fig. 2.6) Left pelvic brim after adhesiolysis.	 (Fig. 2.7) Left pelvic brim after application of SprayGel™.	 (Fig. 2.8) Left pelvic brim at the SLL (on postoperative Day 7), free of adhesions.	 (Fig. 2.9) Left pelvic brim at TLL 12 weeks after initial adhesiolysis. The peritoneum surface healed completety and no adhesions had reformed.
 (Fig. 2.10) Midline adhesions of the small bowel to the anterior abdominal wall.	 (Fig. 2.11) During the adhesiolysis, notice how near to the bowel serosa we need to cut, and even so no lesion appears with our special equipment.	 (Fig. 2.12) After the adhesiolysis, SprayGel™ must be applied on the abdominal wall and…  (Fig. 2.13) …on the bowel surface at the wounded area.	 (Fig. 2.14) The abdominal wall at the SLL, with only scar tissue and no adhesions.  (Fig. 2.15) SLL: The bowel area has already healed completely, with the new vessels (neoangiogenesis) in the wounded area aiding the healing process with a better blood and oxygen supply.	—

Figure 1. Bipolar scissors and clamps designed for gasless laparoscopy.

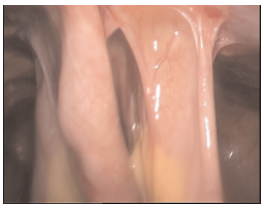
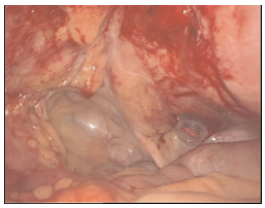
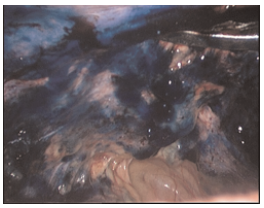
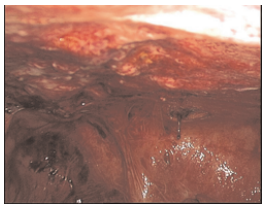
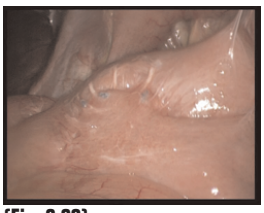
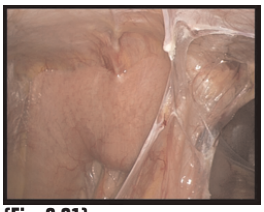
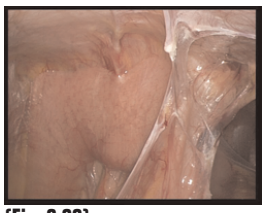
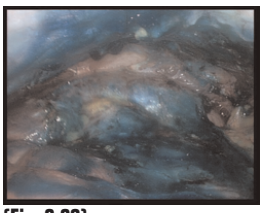
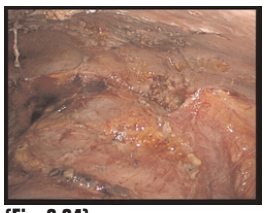
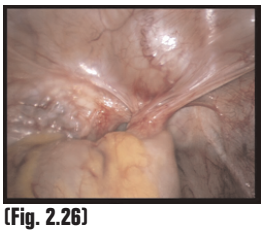
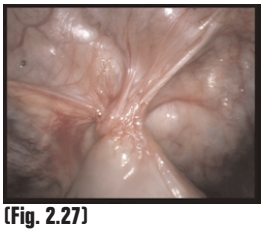
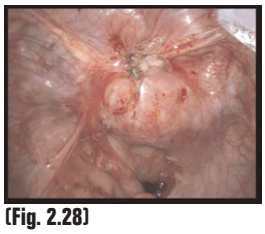
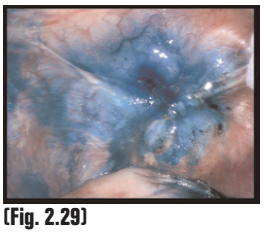
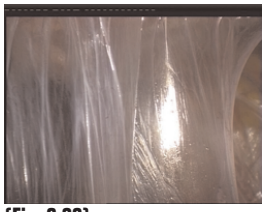
Initial	Following Adhesiolysis	Following SG Application	SLL at 1 Week	TLL
 (Fig. 2.16) Midline and left anterior abdominal wall with adhesions: Many loops of small bowel are attached to the abdominal wall.	 (Fig. 2.17) The abdominal wall after dissection of the bowel adhesions.	 (Fig. 2.18) The abdominal wall after dissection and after application of SprayGel™.	 (Fig. 2.19) The anterior abdominal wall at the SLL at postoperative Day 7, with the white spots representing the formation of scar tissue (normal healing) under SprayGel™.	—
 (Fig. 2.20) Upper left quadrant with adhesions after surgery with gastrojejunostomy.  (Fig. 2.21) Many loops are attached together and completely to the abdominal wall.	 (Fig. 2.22) The left upper quadrant after dissection of the bowel adhesions.	 (Fig. 2.23) The right upper quadrant after dissection of the bowel adhesions and application of SprayGel™.	 (Fig. 2.24) The right upper quadrant at the SLL at postoperative Day 7.  (Fig. 2.25) The peritoneum at the SLL shows neoangiogenesis and formation of white scar tissue.	—
 (Fig. 2.26) Adhesions in the left middle and lower quadrant, involving the large bowel.  (Fig. 2.27) Another view of the adhesions and a twisted bowel loop that was involved in the adhesions.	 (Fig. 2.28) The left lower quadrant after adhesiolysis.	 (Fig. 2.29) The left lower quadrant after application of SprayGel™.	 (Fig. 2.30) SLL: The adhesiolysis area and SprayGel™ covering this area.	 (Fig. 2.31) The adhesiolysis area at TLL: no adhesions reformed.  (Fig. 2.32) However, in another area in the middle abdomen filmy adhesions formed between the omentum and the anterior abdominal wall.

Figure 1. Bipolar scissors and clamps designed for gasless laparoscopy. (Cont)

Table 5.
Surgical Outcomes

Number of Patients	Patients without Adhesions	Patients with Adhesions
Initial surgery = 35	0 (0.0 %)	35 (100.0%)
SLL = 35	28 (80.0%)	7 (20.0%)
TLL = 5	1 (2.9 %)	4 (11.4%)

Table 6.
Comparison of Grades at Initial, SLL, and TLL

Scores at Initial Surgery			
Avg. Extent	Avg. Severe	Avg. Grade	Avg. Sum
5.14	4.60	4.83	4.85
Scores at SLL			
Avg. Extent	Avg. Severe	Avg. Grade	Avg. Sum
0.51	0.49	0.49	0.50
Reduction			
90.1%	89.3%	89.9%	89.8%
Scores at TLL			
Avg. Extent	Avg. Severe	Avg. Grade	Avg. Sum
0.63	0.31	0.29	0.41
Reduction			
87.7%	93.2%	94.2%	91.5%

Table 7.
Data from Initial, SLL, and TLL

	Avg. Surgical Time (range)	Avg. SG Kits Used (range)
Initial surgery	256 (93–780)	4.54 (2–8)
SLL	28 (17–110)	0
TLL	67 (34–163)	1.41 (1–3)

days postoperatively).[11] In addition, it is prepared quickly (within seconds), evolves no heat, degrades cleanly with a predictable rate, and is also useful in open procedures.[12,13] The PEG substrate also helps SprayGel™ not to promote or potentiate bacterial infection — a side effect that causes adhesion formation.[14] The methylene blue color of the product greatly helps with easy visualization during the adhesiolysis procedure.

We have determined that the seven-day period is the most optimal to check for adhesions because it allows enough time for de novo adhesions to form and is also at the point where SprayGel™ has undergone significant resorption. Alternately, adhesions that reformed could be removed very easy with aqua dissection without any bleeding. At our center, we perform SLL at 7 days postoperatively for all patients and provide on-site housing to facilitate this process. In our opinion, an early SLL is an important step in assuring a successful outcome. To offer a TLL for patients who continue to experience pain or discomfort offers the patient a reassurance to evaluate or to cure adhesion-related symptoms.

Although our initial results are very encouraging, we recognize that several limitations are present in this analysis. All procedures were done in a single center and monitored by a single reviewer, who was not blind to the patient treatment. No control group was used and long-term follow up of all patients has yet to be completed. We used more than one novel approach in these procedures - namely, a new adhesion barrier, SprayGel™, as well as a lift (gasless) technique, and other special instrumentation (bipolar scissors and clamps).

Because we observed SprayGel™ at SLL and adhesion reformation in some patients with a TLL, even though they were adhesion-free at the second look, we must evaluate whether adhesions would develop once the SprayGel™ completely dissolves. Finally, we recognize that with this type of analysis design, surgeon bias can creep into the analysis.

CONCLUSION

Our experience has shown that when compared to other surgical adjuncts, SprayGel™ is uniquely effective in improving the success rates of adhesiolysis when combined with lift (gasless) laparoscopy and good hemostasis techniques. This data demonstrates that SprayGel™ performs with unparalleled efficacy in abdominal adhesiolysis even in those patients in whom other solutions have not worked.

Our analysis indicates that even in severe adhesions where surgeons usually avoid surgery, a laparoscopic approach is reasonable. With lift (gasless) laparoscopy, a SprayGel™ adhesion barrier, and the concept of second- and third-look laparoscopy, we were able to reduce adhesions in a high percentage of patients (91.4% as an average of the scores of extent, grade, and severity). Thus, a reduction of adhesion reformation and associated symptoms such as pain and bowel obstructions with emergency surgeries results in a better quality of life for this group of patients. Further analysis, especially in a long-term follow up, is needed and will be reported. STI

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