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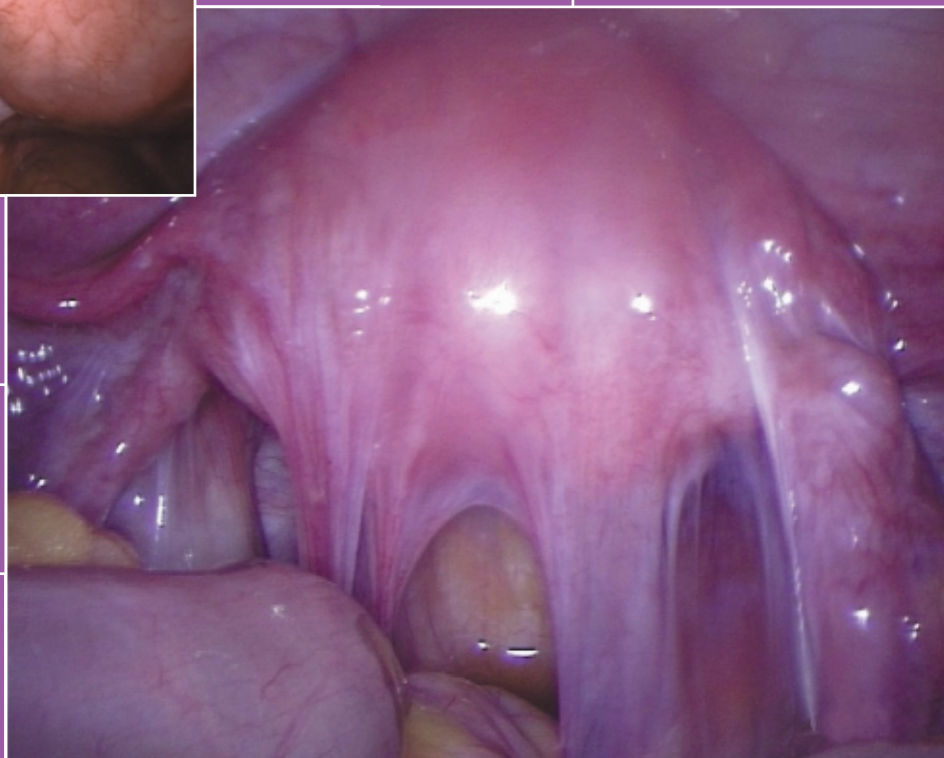
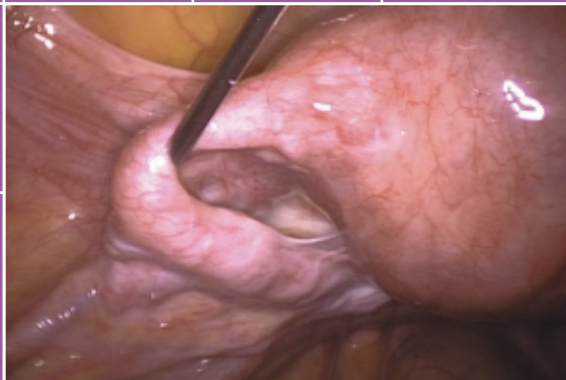
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## Consensus in adhesion reduction management

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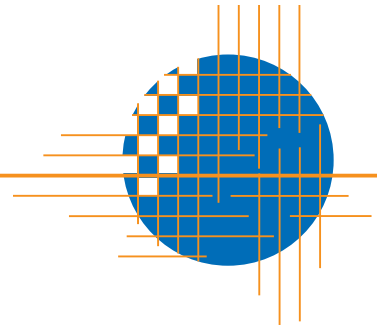
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## Consensus in adhesion reduction management

Adhesions are extremely common and occur after almost every abdominal surgical procedure. Although many adhesions have little or no detrimental effects for patients, a sizeable proportion of cases can lead to serious short- and long-term complications, including small bowel obstruction, fertility-related complications in women and chronic pelvic pain, requiring readmission to hospital and often additional surgery. Adhesion-related complications place a significant burden on patients, surgeons and the NHS, in terms of increased complications, additional and often more complicated and time-consuming surgical procedures and increased pressure on already limited healthcare resources. Recent epidemiological data have demonstrated the true extent of adhesion formation, showing that over one-third of patients who undergo open surgery are readmitted with adhesion-related complications within ten years. The data also revealed that laparoscopic procedures can be associated with a high incidence of adhesion-related readmissions and confirmed that certain open surgical procedures (e.g. ovarian, tubal and adhesiolysis) have a higher risk of adhesion formation. Clearly, to enhance good, safe medical practice, patients should be informed of the risk of adhesions, particularly before high-risk procedures. New epidemiological findings, coupled with an increase in research into anti-adhesion adjuvants have focused interest in this area once again. The adoption of effective adhesion prevention strategies will help to minimise the risk of adhesions following abdominal surgery and reduce complications, surgical workload and ultimately healthcare costs. Prevention strategies should include the adherence to good surgical practice alongside safe and effective anti-adhesion adjuvants. Any agent proven to be safe and effective should be used in procedures shown to have a high risk of subsequent adhesion-related complications. To help to address this issue, a panel of leading UK gynaecologists with a special interest in adhesions convened in December 2003 to discuss issues surrounding adhesion prevention and management. The aim of the meeting was to provide a forum for discussing the epidemiology and clinical implications of adhesions as well as current prevention strategies. This paper presents a summary of the topics discussed (including the epidemiology of adhesions, clinical implications and complications, medico-legal issues, adhesion prevention strategies) and the consensus points that were reached during the meeting. ■

### Introduction

It has long been recognised that postoperative adhesions are a complication of general and gynaecological surgery. Indeed, a fatal incidence of intestinal obstruction caused by adhesions during ovarian surgery was documented as far back as 1872.<sup>1</sup> The truth is that adhesions are extremely common and occur after almost every abdominal surgical procedure. The increase in the number of gynaecological and surgical procedures in recent years has seen a corresponding rise in the incidence of adhesion-related complications.

Adhesions are an almost inevitable consequence of peritoneal surgery and their management and prevention should be of great concern to surgeons and gynaecologists alike. The magnitude of the problem, however, has tended to be overlooked, largely due to a lack of awareness regarding the clinical significance and the true incidence of adhesions.<sup>2</sup> Consequently, gynaecologists have sometimes been slow to introduce comprehensive adhesion prevention strategies. Furthermore, if a woman is doing well in the early postoperative period and is discharged from hospital, the gynaecologist who treated her initially may not be part of her care team should any adhesion-related problems arise, months or even years later.

Although most adhesions have little or no detrimental effects for women, a sizeable proportion of cases lead to serious short- and long-term consequences, including fertility-related complications, chronic pelvic pain and, in some cases, small bowel obstruction. These often require readmission and additional surgical procedures. Adhesions can, therefore, place a significant burden on women, surgeons and health services, in terms of increased complications, additional surgical workload and pressure on an already stretched NHS. In 1994, in Scotland alone, the direct costs of adhesion related admissions were £6.1 million,<sup>3</sup> which would extrapolate to £67 million in the UK as a whole.

Publication of new epidemiological data has provided an insight into the incidence of adhesion formation following abdominal surgery.<sup>4,5</sup> These developments, coupled with the introduction of a range of anti-adhesion products, as well as increasing adhesion-related medico-legal claims, have raised interest in adhesion prevention. By adopting effective, comprehensive adhesion prevention strategies it should be possible to minimise the risk of adhesion formation following abdominal surgery and reduce morbidity, surgical workload and the burden on health services. ■

# Epidemiology of Adhesions

Adhesions are a widespread problem and develop following any type of abdominal or pelvic surgery. They have been shown to develop in up to 93% of surgical patients.<sup>6</sup> The incidence of adhesions has increased with the rise in surgical procedures, particularly gynaecological procedures.<sup>6</sup> It has been shown that between 60% and 90% of women suffer postoperative adhesions following major gynaecological surgery.<sup>1</sup> Although surgeons have been aware of adhesions for many years, it was not until the publication of data from the Surgical and Clinical Adhesions Reduction (SCAR) study in 1999 that the epidemiology of adhesions as an iatrogenic disease or the clinical burden of postoperative readmissions began to be better understood.<sup>4</sup>

## The Surgical and Clinical Adhesion Research Study (SCAR)

The SCAR study produced the first major epidemiological data on the impact of post-operative adhesions.<sup>4</sup> The research was conducted to investigate the extent of the problem of adhesions following open surgery, over a ten-year period, using validated data from the Scottish National Health Service Medical Record (SMR1) Linkage database. The database is unique in that it records all hospital admissions categorised by surgery and disease. This allows patients' hospital histories to be followed from the day of first admission. The Scottish database is ideal for epidemiological research as it represents a relatively stable population of 5.1 million people with a low annual migration (less than 1%). Through intensive quality assurance and annual audit, the accuracy of the database is maintained at 99%.

Using the Scottish database, a cohort of patients who underwent open abdominal or pelvic surgery in 1986 was selected. To limit the effect of previous surgery on adhesions (i.e. the influence of existing adhesions), patients who had undergone surgery within the previous five years were excluded from the study.

Adhesion-related readmissions were identified over the ten-year period using Office of Population Censuses and Surveys' third and fourth revisions of the Classification of Surgical Operations (OPCS-3 & OPCS-4) surgery codes and the International Classification of Diseases, ninth edition (ICD9) disease codes. Adhesion-

related readmissions were categorised as being:

- directly related to adhesions (adhesiolysis and nonoperative readmissions for adhesions)
- possibly related (selected gynaecological operations, selected abdominal surgery and selected nonoperative readmissions)
- readmissions potentially complicated by adhesions (leading to open or laparoscopic procedures).

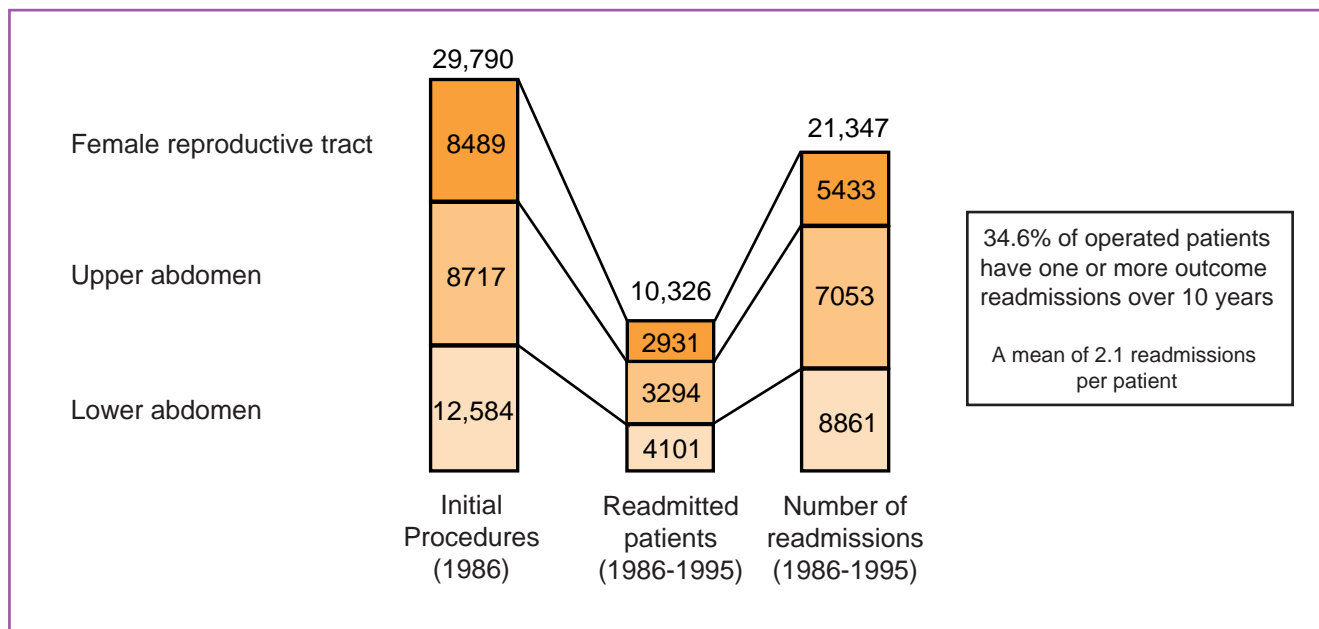
In this study, over one-third (34.7%  $n = 10\,326$ ) of the 29 790 patients who underwent open surgery were readmitted a mean of 2.1 times for complications directly or possibly related to adhesions, over the ten-year period (Figure 1). Of the total number of readmissions (21 347), 5.7% were directly related to adhesions. Importantly, 22.1% of all readmissions occurred within the first year but readmissions continued steadily over the ten years of the study.

## Adhesions in gynaecological surgery

A subanalysis of the SCAR study data was also performed. This analysis investigated the epidemiology of adhesion-related readmissions following gynaecological surgery only. A cohort of 8489 open gynaecological operations, categorised according to site (lower abdomen, upper abdomen, female reproductive tract), was also defined using the Scottish Database.<sup>5</sup> As for the previous analysis, all readmissions for potential adhesion-related problems in the subsequent ten years were reviewed.

Although the readmissions coded as directly related were 2.9/100 initial procedures, the overall readmission rate was much higher. Taking directly related, possibly related and operations potentially complicated by adhesions, the overall readmission rate was 64 readmissions for every 100 initial procedures. The ovaries and fallopian tubes were found to be particularly adhesiogenic

results for directly related, possibly related, potentially complicated by and total adhesion-related readmissions. After a rapid increase in adhesion-related readmissions over the first one or two years in all four groups, the rate of readmission continues to increase steadily. Previous studies have also shown that adhesion-related complications can occur ten years after the initial surgical procedure.<sup>6</sup>



**Figure 1.** Readmissions directly or possibly related to admissions ten years after abdominal or pelvic surgery

sites. The readmission rate increased to 106.4/100 initial procedures for operations on the ovary, with directly related adhesion readmissions occurring in every 7.5/100 initial procedures. The overall readmission rate for operations on the fallopian tubes was 80.5/100 initial procedures.

Clearly, from this study it can be seen that certain surgical procedures carry greater risk of adhesion-related complications. Surgical procedures on the ovary and fallopian tube were shown to have the highest risk of adhesion-related readmissions (48.1% and 41.2% of women readmitted, respectively).

In total, 34.5% of women were readmitted for complications directly or possibly related to adhesions or for further intra-abdominal surgery potentially complicated by adhesions (Figure 1). The number of readmissions increased steadily over the ten-year period, with 16% occurring within the first year after the initial surgical procedure (Figure 2).

One of the most important aspects of the SCAR study is the long-term perspective, which provides information on the timing of adhesion-related complications. Figure 2 shows the cumulative

### Surgical and Clinical Adhesion Research Study 2 (SCAR-2)

SCAR-2<sup>7</sup> was a study subsequently undertaken to assess the burden of adhesion related readmissions in more recent years than the original SCAR study.<sup>5</sup> Unlike the original SCAR study, SCAR-2 examined the overall extent of adhesion-related readmissions following laparoscopic gynaecological surgery as well as open gynaecological surgery (laparoscopic surgery was not widely used in 1986), thus allowing an examination of the risks for the two different types of surgery.

The study also used validated data from the Scottish NHS database. Three cohorts were identified, based upon when the original surgical procedure was performed (1996, 1997 and 1998). Each cohort was followed for two years and all readmissions reviewed for any potential relationship to adhesions. Women in the 1996 group (15 197 women undergoing laparoscopic and 8849 women undergoing gynaecological surgery) were followed up for four years. The cohorts were established using OPCS-4 codes. The laparoscopic cohort was subcategorised according to risk, i.e. high risk (adhesiolysis), low risk (tubal sterilisation) and medium risk (all other procedures). Surgical sites included in the open (laparotomy)

cohort were fallopian tube, ovary, uterus and vagina. Readmissions were identified using OPCS-4 and ICD 10 codes. The primary epidemiological outcome measures were one-year readmission rates, cumulative readmissions and time to first adhesion-related readmission.<sup>7</sup>

Laparoscopic procedures were not analysed by surgical site because the procedure codes for laparoscopic surgery are not extensive. It was not the intention of the study to compare 'like with like' open versus laparoscopic surgery, since the absence of laparoscopic codes made this impossible to achieve.

Gynaecological laparoscopy as well as open surgery was shown to carry significant risks of adhesion-related readmissions. Figure 3 shows one-year readmission rates by surgical technique.

At first sight, Figure 3 suggests that the burden of adhesions related to laparoscopic surgery is almost twice as high as that for open surgery. It is important to bear in mind, however, that nearly twice as many laparoscopic as open procedures are performed in Scotland. In the laparoscopic cohort, there were 0.7% readmission directly related to adhesions within the first year. This rose to 1.5% by year four. This compares with 0.7% and 2.0%, respectively, in the open surgery cohort. The overall laparoscopic directly/possibly related readmission rates were 6.3% and 17.6% at years 1 and 4 in the 1996 cohort (Figure 4). In the open surgery cohort, rates were 6.5% and 16.5%, respectively.<sup>7</sup>

### High-risk surgical sites

SCAR-2 confirmed that certain surgical sites are associated with increased risk of adhesions. The risk of readmission directly related to adhesions following high-risk, medium-risk and low risk laparoscopic procedures was shown to be one in 80, one in 70 and one in 500, respectively. The risk of readmission possibly related to adhesions was shown to be one in seven, one in ten and one in 40, respectively, in each of the laparoscopic groups. In the open surgery cohort, the risk of readmission directly related to adhesions following surgery of the ovary, fallopian tube and uterus was shown to be one in 50, one in 120, and one in 170, respectively. The risk of readmission possibly related to adhesions was shown to be one in six, one in seven and one in 20 in each of the open surgical groups, respectively.

It is interesting to establish whether these risks have changed over time by following the time to first directly or possibly related adhesion readmission between 1996, 1997 and 1998. Figure 5

compares the risk of directly or possibly related readmissions for gynaecological surgery, in the two years following initial surgery, conducted in 1996, 1997 and 1998 for high-risk laparoscopy and open surgery.

The readmission rates appear consistent in each of the years studied for open surgery indicating that any changes in surgical practice are having little effect on adhesion-related outcomes. There is a

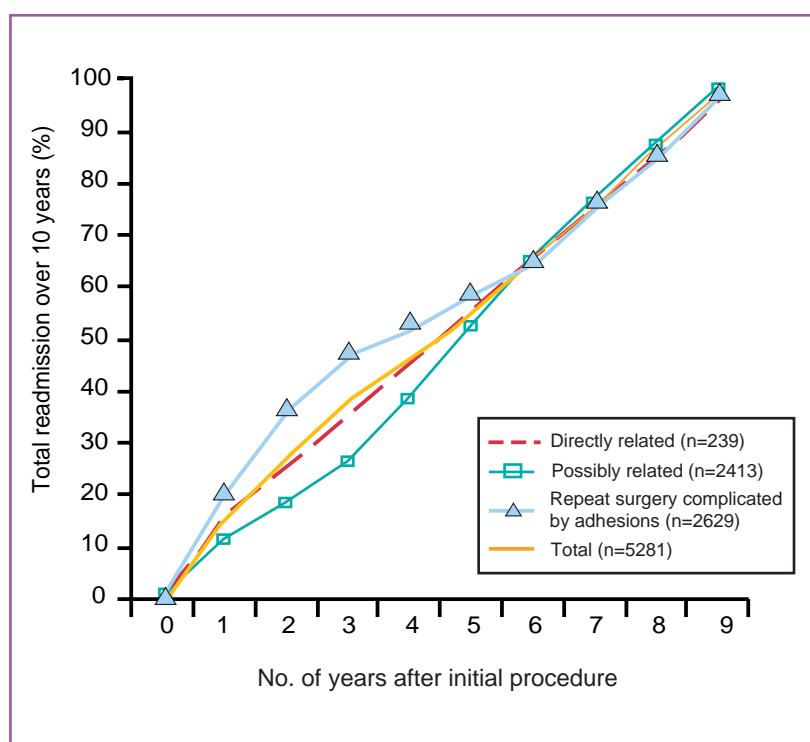


Figure 2. Analysis of readmissions over time; reproduced from Lower *et al.*<sup>5</sup> with permission

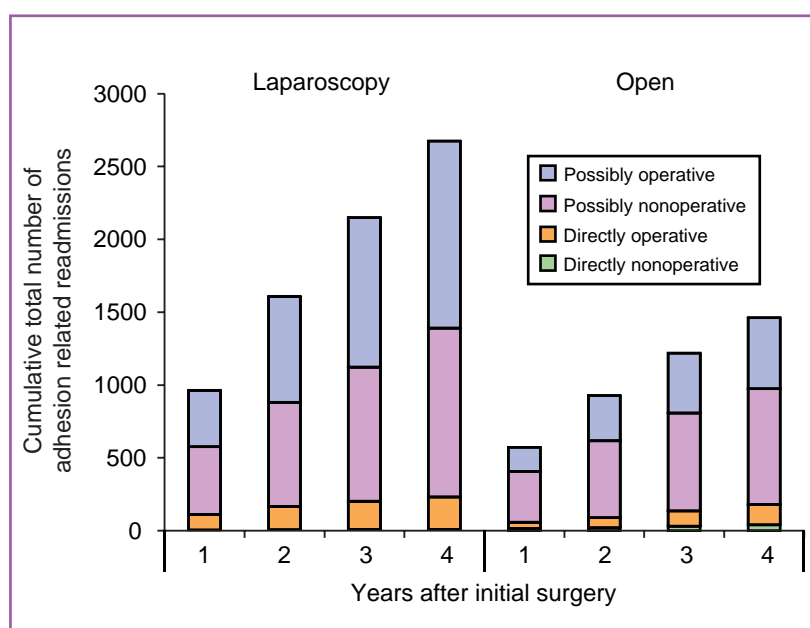
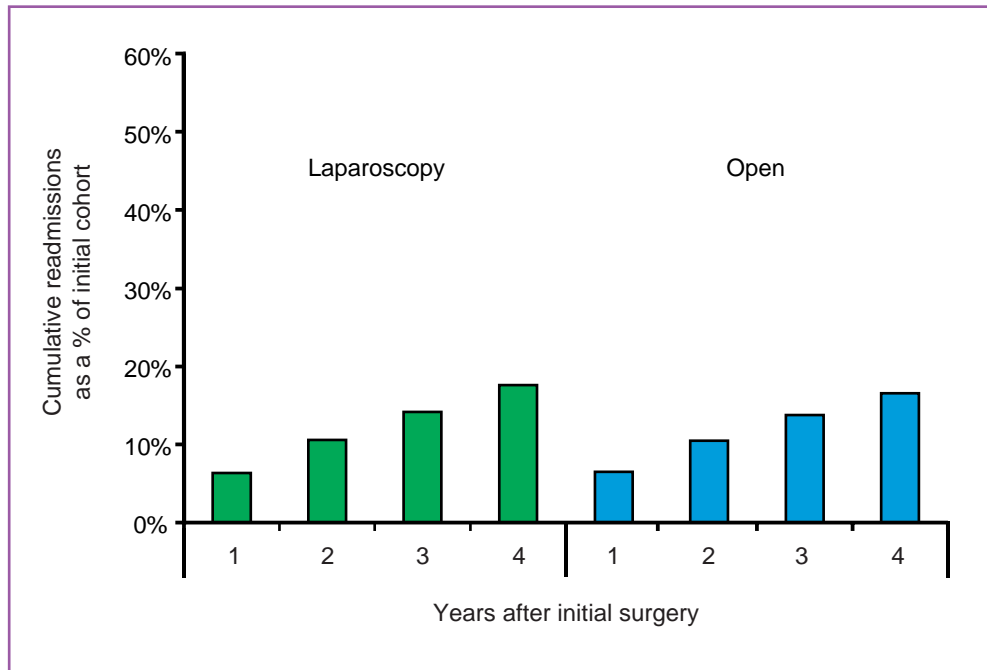


Figure 3. One-year readmission rates by surgical technique



**Figure 4.** Directly and possibly related readmission rates following laparoscopic and open surgery

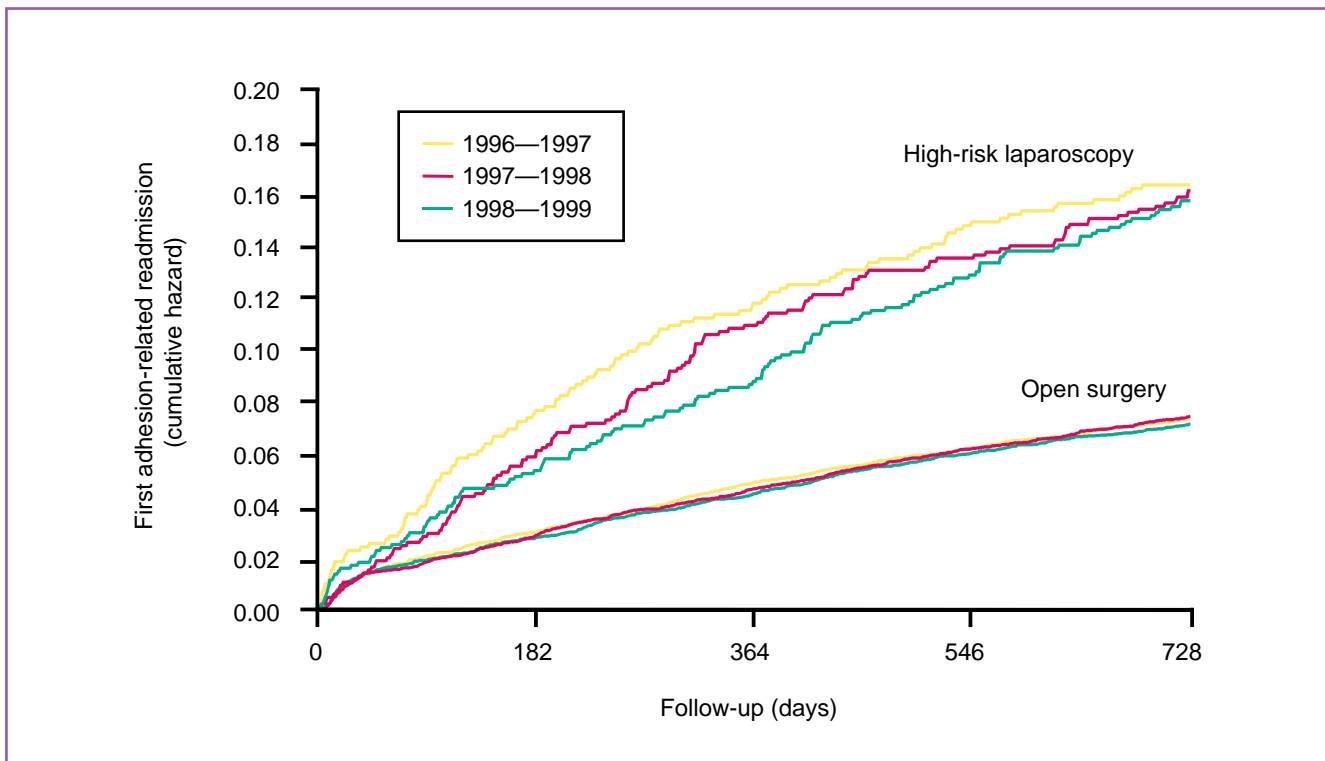
tendency towards an improvement with time in the high-risk laparoscopic group, but this probably reflects the smaller number of women in this cohort.

The SCAR study was the first major epidemiological study to examine the incidence of adhesion-related complications following open abdominal surgery. It showed that adhesion-related readmissions present a significant problem. The SCAR-2 study revealed that the overall risk

of readmission following either laparoscopic or open surgery is similar.

These epidemiological data show that adhesion formation results in a significant number of readmissions following both laparoscopic and open surgery and that the risk of adhesion-related complications extends for many years after the initial procedure. There is, therefore, a need for clinically and cost-effective strategies to help reduce the development of adhesions. ■

**Figure 5.** Relative risk of first adhesion-related readmission (cumulative hazard)



# The Consequences of Adhesions

Adhesions may be defined as abnormal attachments between tissues and organs (Figure 6). They can be either congenital or acquired.<sup>8</sup> Acquired adhesions develop in response to trauma to the peritoneum, either as a result of surgery or inflammation. There are a number of factors that influence adhesion formation during surgery. These include ischaemia, exposure to infection or intestinal contents, abrasion, desiccation, heat, light, electrocautery and suturing. Fibres and glove-dusting powder are also factors but these are largely no longer used during surgery.

Adhesion formation starts following localised injury to the mesothelial layer of the peritoneum (Figure 7). Bleeding and leakage of plasma proteins lead to fibrin deposits at the injury site, which is augmented by post-traumatic inflammation. Inflammatory cytokines, predominately interleukin-1 and interleukin-6, and tumour necrosis factor- $\alpha$  attract and activate macrophages to release vascular permeability factor. Simultaneous release of histamine and kinins increases the level of vascular permeability factor leading to inflammation and exudation with fibrin deposition on the peritoneal surface. The enlarging fibrin mesh may attach to an adjoining surface, a process that is counteracted by locally synthesised

fibrinolytic factors. Depending upon the local peritoneal conditions, the fibrin mesh can either be degraded, resulting in scarless repair, or transformed into an adhesion consisting of connective tissue. If the fibrin is degraded within a few days, the defect heals without scarring. If it is allowed to enlarge for a sufficient period of time, it will reach other tissue surfaces and form a bridge between them, transforming the initially reversible fibrous adhesion into a fibrous, collagen-containing structure. In a long surgical procedure it is possible to witness the adhesion formation process in action as it begins very shortly after injury.

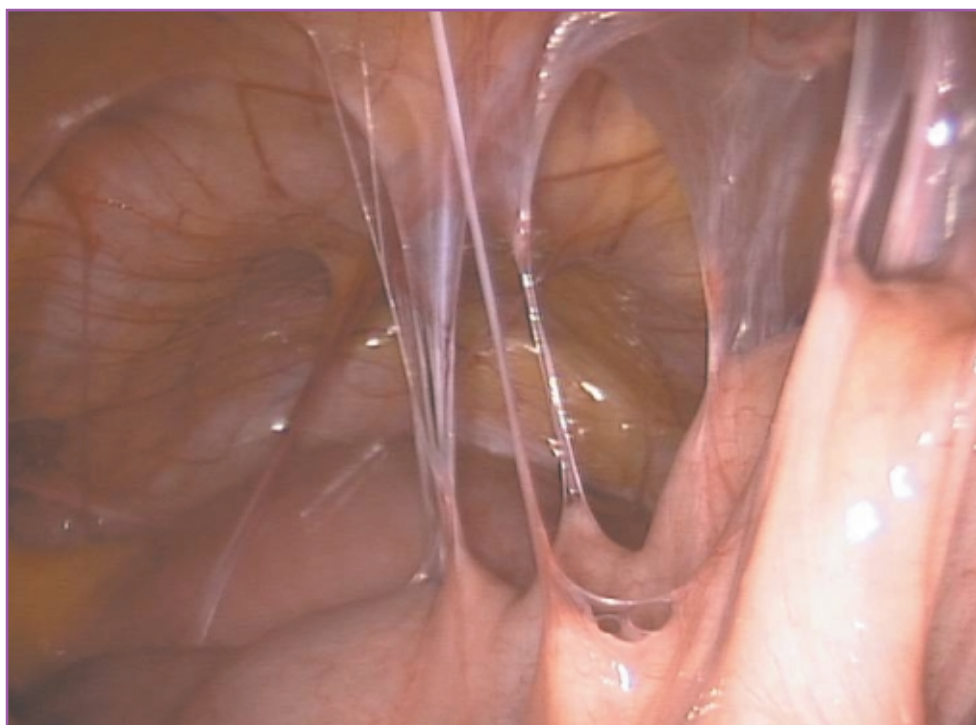
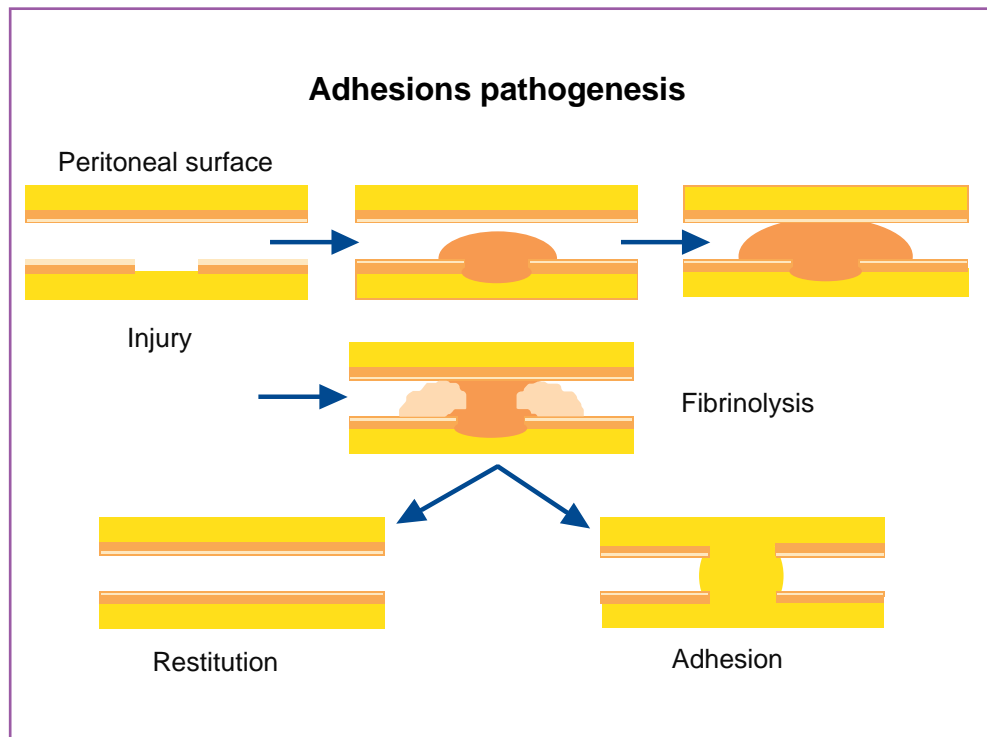


Figure 6. An adhesion



**Figure 7.** Adhesion formation process; reproduced with permission from Holmdahl, *Lancet*, 1999

### Clinical considerations of adhesions

Postoperative adhesions can result from all types of surgery and at any surgical site. As a consequence, adhesion formation can have a significant impact on women, surgeons as well as healthcare resources.

### Adhesion-related complications

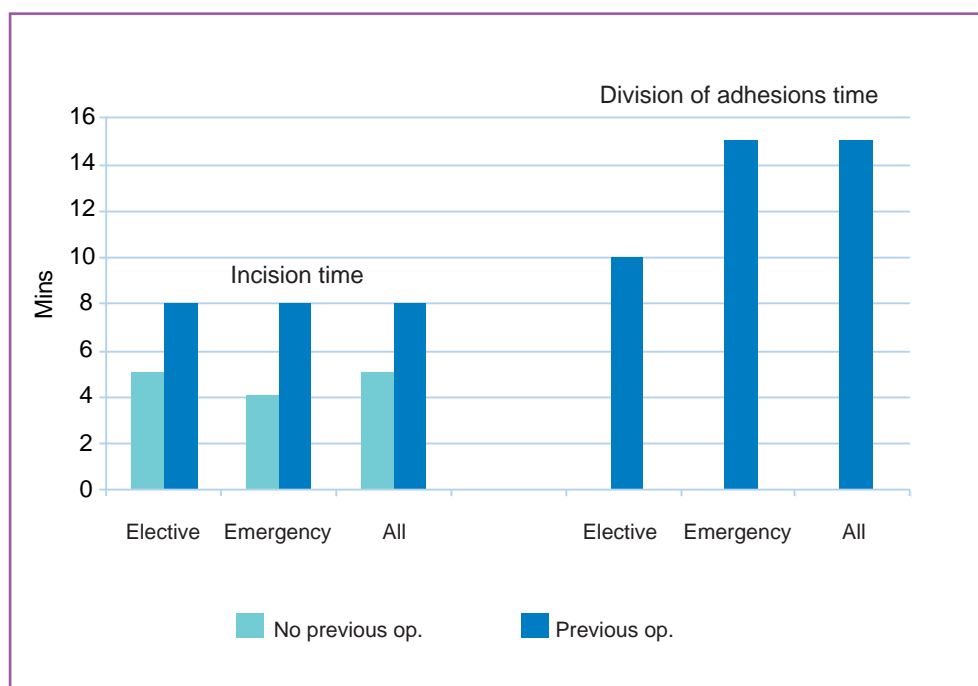
Post-surgical adhesions severely affect the quality of life of millions of people across the world.<sup>9</sup> Adhesions can have serious consequences including, fertility-related complications, chronic pelvic pain and, in some cases, bowel obstruction. These complications are often difficult to manage.

The majority (more than two-thirds) of cases of small bowel obstruction are adhesion related.<sup>10</sup> In addition, a large proportion (approximately 40%) of chronic pelvic pain cases are related to adhesions (e.g. endometriosis and pelvic inflammatory disease)<sup>11-13</sup> and 56% of repeat surgery is potentially complicated by adhesions.<sup>4</sup> Fertility-related complications are also common with 15-20% of secondary infertility in women being adhesion-related.<sup>14</sup> Infertility more commonly results from a change of the normal tubo-ovarian relationship, preventing ovum capture and transport. Interestingly, pregnancy rates have been shown to increase by up to 52% among previously infertile women following open adhesiolysis.<sup>9</sup> These adhesion-related complications result in women being readmitted to hospital, often on

more than one occasion.

Laparoscopic adhesiolysis to treat chronic pain is controversial and not necessarily evidence-based. A long-term review was conducted between 1998 and 2002 of women after laparoscopic adhesiolysis to relieve pain.<sup>15</sup> Hydroflotation with heparinised saline or icodextrin 4% was used to reduce adhesion reformation. Sixty-nine women were contacted via postal survey or by telephone using visual analogue scales to record pain scores. In total, 74% of women reported an improvement in symptoms, 38% felt that the pain was greatly improved and 17% felt that the pain had gone completely. This study, however, was retrospective, nonrandomised and unblinded. In addition, the use of telephone surveys can be questioned.

One study in 2003 evaluated whether laparoscopic adhesiolysis leads to substantial pain relief and improvement in quality of life in women with adhesions and chronic abdominal pain.<sup>16</sup> Women ( $n = 116$ ) underwent diagnostic laparoscopy for chronic pain attributed to adhesions. If lesions were found during the diagnostic procedure, women were then randomly assigned either laparoscopic adhesiolysis or no treatment. Both groups reported pain relief and significantly improved quality of life. However, there was no difference between the groups at 12 months. This seems to suggest that, although laparoscopic adhesiolysis relieves pain, the benefit is no more than with diagnostic laparoscopy.



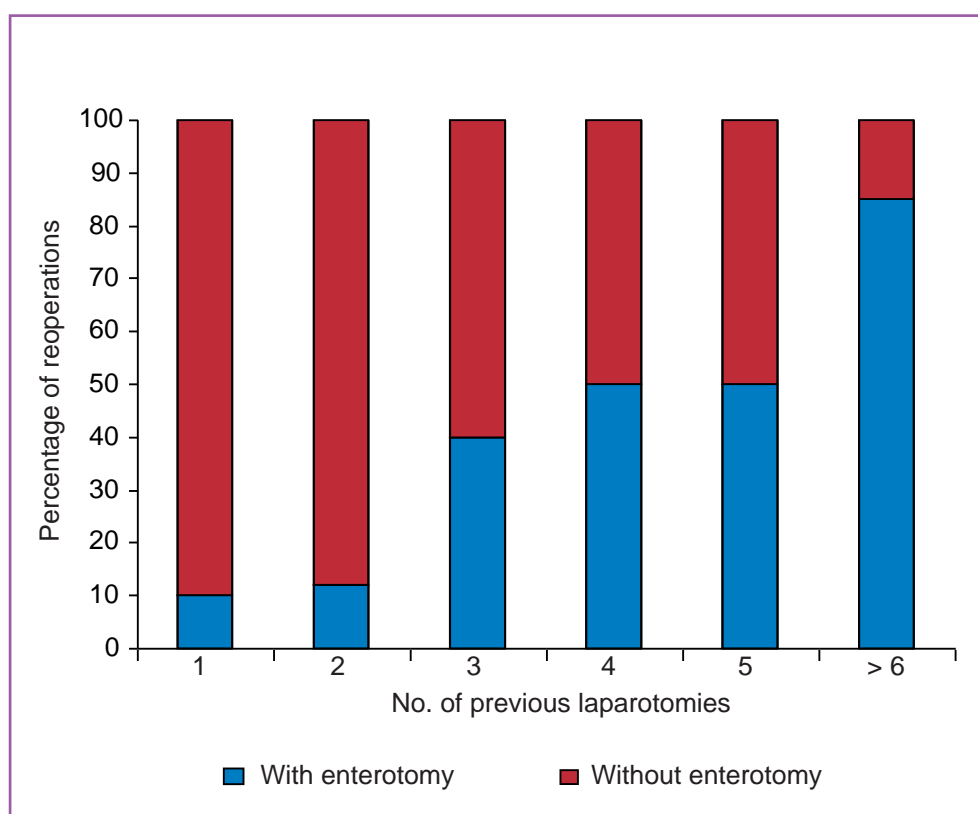
**Figure 8.** The effect of previous abdominal surgery on incision time and division of adhesions time for elective and emergency surgery and all cases; reproduced with permission from Coleman *et al.*<sup>18</sup>

### Increased surgical workload

For surgeons, postoperative adhesion formation complicates surgery by making it difficult to enter the peritoneal cavity, increasing the risk of perforations and extending operating, anaesthesia and recovery time.<sup>9,17</sup> Intra-abdominal adhesions make reoperation difficult and may increase the complication rate of further surgery. Prolonged operating times, substantial 'division of adhesion time', inability to use laparoscopy and inadvertent

enterotomy are all drawbacks of reoperative surgery directly related to adhesions.

The available data suggest that certain procedures are more likely to give rise to adhesions, e.g. ovarian cystectomy, endometriosis, myomectomy, adhesiolysis, tubal surgery including ectopic pregnancies and surgical treatment of pelvic inflammatory disease. For every 100 initial ovarian procedures there will be at least 7.5 readmissions within the first 12 months directly or possibly



**Figure 9.** Relationship between the percentage of reoperations with and without enterotomy and the number of previous laparotomies

related to adhesions.<sup>5</sup> For laparoscopic myomectomy this increases to 41 in every 100 procedures.<sup>18</sup>

The presence of adhesions from previous surgery has been shown to significantly increase operating time during subsequent surgery. One surgical study has evaluated incision time and division of adhesion time in 120 women.<sup>17</sup> Of these women, 51% of elective and 71% of emergency cases had previous abdominal surgery. Previous surgery prolonged median incision time from five to eight minutes and median division of adhesion time from 0 to 15 minutes (Figure 8). This represents a cumulative median increase of 18 minutes.

Inadvertent enterotomy is a risk when dividing adhesions during abdominal reoperation. It can lead to significantly more postoperative complications, higher rates of admission to intensive care and longer postoperative stay. In a study involving 270 women undergoing abdominal reoperation, one or more inadvertent enterotomies occurred in 19% of the patients.<sup>19</sup> Women with inadvertent enterotomy had undergone a mean of 3.3 previous laparotomies, compared with 1.7 in women without enterotomy. This suggests that each additional laparotomy induces *de novo* adhesions and adhesion reformation thereby increasing the risk of inadvertent enterotomy. Figure 9 shows the relationship between the percentage of reoperations with and without enterotomy and the number of previous laparotomies.

Clearly, adhesions caused by previous surgery can result in an increased enterotomy complication risk, both at the time of the insertion of a primary trochar and during the adhesiolysis procedure itself.

## Significant burden on healthcare services

Adhesions increase the chances of requiring reoperative surgery, leading to additional costs and burden on limited resources. Readmissions owing to adhesion-related complications have a tremendous impact in terms of both workload and costs. Adhesive small bowel obstructions have a particularly significant impact. One analysis has looked at the impact and costs of such obstructions.<sup>20</sup> In total, 298 admissions related to adhesive small bowel obstructions were monitored during 1996 and 1997, and 110 admissions were identified as being due to adhesions (41 treated surgically, 69 treated conservatively). The mean length of stay was 16.3 days for surgical treatment, and 7.0 days for conservative treatment. Inpatient mortality was 9.8% for the surgical group and 7.2% for the conservative group. The mean costs of both operative (£4,677) and nonoperative (£1,606) treatment estimated in this study were high and probably underestimated the real numbers. Bed stay for these women represents about 2% of the total bed occupancy per year.

It is clear that adhesions pose risks for women and major problems for surgeons, who may expect to encounter adhesion-related emergencies as often as one per month.<sup>21</sup> Treatment of small bowel obstruction due to adhesions occupies one surgical bed in a general hospital each day of the year plus two days of operating time.<sup>20</sup> The cost of adhesion-related readmissions in the UK for patients undergoing lower abdominal surgery one year after surgery is estimated at £24.2 million and £95.2 million, ten years after surgery.<sup>22</sup>

Adhesions clearly pose a major challenge. Effective adhesion prevention strategies, therefore, are needed to alleviate the considerable clinical burden they present. ■

# Quality Issues and Risk Management

There are a number of quality and risk management issues surrounding adhesions in surgery. The surgical speciality has given rise to the highest number and second highest value of negligence claims reported to the UK National Health Service Litigations Authority (NHSLA). The highest numbers of reported Clinical Negligence Scheme for Trusts (CNST) claims by speciality are:

- surgery: 3365
- obstetrics and gynaecology 2237
- medicine 1278
- accident and emergency 803.<sup>23</sup>

Increasingly, complications resulting from postoperative intra-abdominal adhesions have been the subject of medical negligence cases. These have included failure to diagnose adhesion-related problems, delay in diagnosis, bowel damage at adhesiolysis, adhesive intestinal obstruction, infertility or risk of infertility and failure to take precautions to prevent adhesions.<sup>24</sup> Between 1994–1999, for example, the UK Medical Defence Union received 77 adhesion-related claims that resulted in 14 out of court settlements in 11 years ranging from £7,960 to £124,261 (average £50,765 per case).<sup>24</sup> The Medical Defence Union is one of several insurers for the private sector; figures are not available for claims made by the National Health Service.

Anecdotal evidence suggests that the number of claims and out of court settlements has increased largely since then.

## Duty of care

There is a duty of care to provide careful advice and sufficient information upon which women can reach a rational, informed decision on whether to accept or refuse treatment. In negligence cases people usually claim that insufficient information was provided and that, if it had been provided, consent would not have been granted.

So how is negligence established? In order for this to be successful it is necessary to:

- 1) establish a duty of care
- 2) show a breach of this duty
- 3) demonstrate that this breach caused the injury.

All three aspects need to be present for negligence to be established. Recently, in addition to this, the UK Health Act has also established a duty of quality.

The Bolam test of negligence (1957) had for many years set the precedent in determining negligence. This ruling stated that practitioners are not negligent if they act in accordance with practice accepted by a responsible body of medical opinion. However, recent judgements suggest that judges are moving away from accepting what reasonable doctors might do, towards supporting what reasonable patients might expect. Recent case law suggests that the Bolam test is being modified to enable a court to reject medical opinion if it is not 'reasonable or responsible'.<sup>25</sup> Physicians are required to understand their obligations and have a duty to warn a patient of any material risk inherent in a proposed procedure, however small.

So how much should we tell patients? It is not necessary to canvass every risk. However, it is important to take account of the personality of the patient, the likelihood of misfortune and what in the way of warning is needed for the particular patient's welfare. Are gynaecologists and surgeons informing patients about the risk of adhesions? According to the International Adhesions Society Patient Survey, the answer is no. Results from this survey showed that adhesions were mentioned as part of the consent process in only 10.4% of cases.<sup>26</sup> In 14.4% of cases, adhesions were discussed but not as part of the consent process. For patients undergoing adhesiolysis procedures, 54% were given some information before surgery and 46% were given specific information about anti-adhesion agents. In nonadhesiolysis procedures only 10% of patients were advised about adhesions and only 6% were given information on anti-adhesion agents.

Negligence cases relating to adhesions are becoming more common. It is important to be aware that the law governing negligence has changed. Doctors are obliged to understand their obligations and this will mean warning of the risk of adhesions prior to abdominal or pelvic surgery ■

# Adhesion Prevention Strategies

Adhesions substantially increase workload and have a major impact on healthcare resources. With an increasing number of surgical procedures being performed, problems associated with adhesions are likely to increase. Adopting adhesion prevention strategies will help to address these problems. Clearly, certain procedures have a higher risk of causing adhesion-related readmission. Particular precaution should be taken in these 'high-risk' procedures.

The last consensus to be reached regarding adhesion formation and prevention was in 1997.<sup>8</sup> It recognised the need for good surgical practice and appropriate use of new anti-adhesion adjuvants. Despite these recommendations, the burden of adhesions remains. Interestingly, in a questionnaire study among Swedish obstetricians and gynaecologists, 40% of those questioned had never used any method of adhesion prevention.<sup>29</sup> In addition, there was generally a lack of interest and awareness of adhesion prevention strategies as well as large differences in surgical technique.

Since the 1997 consensus on adhesion prevention and treatment much has happened. The SCAR study and, most recently, the SCAR-2 epidemiological studies, have provided comprehensive data on the incidence of adhesion-related readmissions following lower abdominal or pelvic surgery. In addition, new and more effective anti-adhesion products are now becoming available. This coupled with a greater emphasis on quality and risk management issues has re-focused attention on adhesion prevention strategies.

## Approaches to adhesion prevention

A range of adhesion prevention strategies and techniques were reviewed by Risberg 1997.<sup>28</sup> Two major prevention strategies were identified: good surgical technique and the application of anti-adhesion adjuvants.

### Good surgical technique

Good surgical technique has been recognised as being particularly important for adhesion prevention. This should include:

- gentle tissue handling (minimal use of forceps, retractors and clamps on tissue not intended for removal)
- meticulous haemostasis (avoid blood in the peritoneum)
- irrigation to minimise serosal drying
- avoiding intraperitoneal infection
- minimising foreign bodies such as glove powder

Table 1. Adhesion reduction agents

Agent	Materials	Availability
<i>Site-specific</i>		
Preclude®	Expanded polytetrafluoroethylene Gore-tex® sheet	Generally unavailable
Interceed®	Oxidised regenerated cellulose fabric	
Seprafilm®	Hyaluronic acid carboxymethylcellulose film	
SprayGel™	Polyethylene glycol hydrogel	
Surgiwrap™	Copolymer 70:30 poly(L-lactide-co-D, L-lactide) sheet	
<i>Broad</i>		
Hyskon®	32% dextran 70 solution	Generally unavailable
Sepacoat®	0.04% hyaluronic acid-phosphate-buffered saline	Withdrawn
Intergel®	0.5% ferric hyaluronate gel	Withdrawn
Adept®	Icodextrin 4% solution	

- the use of fine nonreactive sutures
- taking care during cauterisation to prevent ischaemia.

## Anti-adhesion adjuvant solutions/drugs

Several adjuvant solutions and drugs have been used to prevent adhesions including nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids and fibrinolytics.<sup>28</sup> NSAIDs (e.g. ibuprofen, tolmetin, oxyphenbutazone) have been widely studied and can be administered systemically as well as intraperitoneally. The clinical efficacy of NSAIDs, however, is questionable.<sup>28</sup> Corticosteroids show poor efficacy and are associated with immunosuppression and delayed wound healing, such as infection, incisional hernia and wound dehiscence. Furthermore, corticosteroids do not remain in the peritoneal cavity for the duration of adhesion formation (four to five days post-surgery). Fibrinolytics are also used but there is a risk of impaired wound healing and/or bleeding by preventing or reversing fibrin deposition. Intraperitoneal or systemic tissue plasminogen activator (tPA), streptokinase and elastase have all undergone extensive clinical evaluation with conflicting results.<sup>28</sup> In some cases fibrinolytics have been associated with haemorrhagic complications. Their lack of efficacy may be attributed to rapid peritoneal absorption and clearance.

Clearly, these agents are far from ideal. To assess opinion on postoperative adhesions, two surveys were conducted at the European Society of Human Reproduction and Embryology (ESHRE 2002) and the European Association of Coloproctology (EACP 2002). According to

respondents, four main attributes are associated with an ideal anti-adhesion agent. A potential agent should be safe, efficacious (at the operation site and throughout the cavity), easy to use in all types of abdominal surgery (open and laparoscopic) and economical.<sup>29</sup>

Adhesion-reducing agents generally fall within two main categories:

- physical barriers, e.g. Preclude®, Interceed®, Seprafilm®, SprayGel™, Surgiwrap™
- solutions, e.g. crystalloid solutions including Ringer-Lactate/saline with or without heparin, Hyskon®, Intergel®, Sepracoat®, Adept® (Table 1).

Generally, the physical barriers tend to be site specific, whereas solutions have the advantage of providing broad coverage throughout the cavity.

Many of these agents, however, do not meet the four requirements for the ideal anti-adhesion agent. There are toxicity concerns with Hyskon® and Intergel®. While Hyskon® has been used it was not approved as an anti-adhesion agent; Intergel® was withdrawn in 2003. Preclude® and Seprafilm® are not easy to handle. Preclude® has to be sutured in place and should then be removed at a later date; it is rarely if ever used nowadays. It is difficult to use Seprafilm® laparoscopically and Interceed® is rendered ineffective in the presence of blood. SprayGel™ requires specialist equipment and technique to use and is under study. Surgiwrap™ is also under study. The physical barrier agents, while reducing adhesions where they are placed, have no effect on the development of adhesions throughout the pelvic cavity. The most widely used agents

**Table 2. Clinical development status of adhesion reduction agents**

Agent	Approved (Europe)	Safety profile	Limitations	Clinical studies <sup>a</sup>	Cost
<i>Site-specific</i>					
Preclude®	Yes	Yes	Suture in place	2	£££
Interceed®	Yes	Yes	Blood incompatibility	24+	£
Seprafilm®	Yes	Anastomosis?	Handling	4+	£££
SprayGel™	Yes	?	Complex and capital equipment	2 <sup>b</sup>	£££
Surgiwrap™	Yes	No	Suture in place but dissolves in one year	0	£££
<i>Broad</i>					
Hyskon®	No	Anaphylaxis	Toxicity	3	£
Sepracoat®	Withdrawn: FDA did not approve – poor efficacy				
Intergel®	Withdrawn: late-onset postoperative pain				
Adept®	Yes	38 000 patient-years 7.5% solution	Main studies continuing	4	£

<sup>a</sup> Continuing and complete; <sup>b</sup> Pivotal trial stopped owing to poor efficacy

Table 3. Cumulative cost of adhesion-related readmissions

Costs component	Mean cost of component per admission	
	Surgical (£)	Conservative (£)
Referral	70.97	77.79
Ward stay	3327.48	1267.92
Theatre	832.32	–
Diagnostics	282.73	207.33
Drugs (not intensive care unit)	133.90	28.29
Follow up	30.01	24.82
Total	4677.41	1606.15

provide broad coverage in the pelvic cavity. These include Adept®, crystalloid solutions and Sepracoat®. Adept® is becoming more widely used and looks promising; there are studies in progress to test the scope of its efficacy. Crystalloid solutions have been shown to be rapidly reabsorbed and ineffective in reducing adhesions.<sup>30</sup> Table 2 shows the clinical development status of adhesion reduction agents in the UK.

### Cost-effective solutions

The cost of adhesion-related complications is considerable. Adhesion reduction technologies may help reduce health costs associated by

minimising adhesion formation. Data from the lower abdominal surgery cohort from the SCAR study have been modelled to assess cost effectiveness.<sup>22</sup> It was determined that the routine use of adhesion reduction products costing £50 per patient will repay the investment cost after three years if adhesion-related readmissions are reduced by 16% (Table 3). Modelling of cost effectiveness has shown that products costing £200 or more are unlikely ever to pay back the direct costs. A cost comparison of current adhesion reduction products is shown in Figure 10.

Any agent proven to be safe and effective should be used in procedures shown to have a high risk of subsequent adhesion-related complications. ■

Figure 10. Cost comparison of current adhesion reduction agents



# Consensus and Recommendations

Epidemiological data from the SCAR study confirmed that adhesions still represent a major burden for patients, surgeons and healthcare resources.<sup>4</sup> The findings of the SCAR-2 study reaffirm the original SCAR findings and demonstrate that adhesions occur after both laparoscopic and open gynaecological procedures and can be associated with serious complications in a substantial proportion of patients. These studies also revealed that there are certain procedures that are associated with a high risk of adhesion formation.<sup>4,5,7</sup>

The panel conclusions, based on all the available data, were that the high-risk gynaecological procedures include:

- ovarian surgery
- endometriosis surgery
- tubal surgery
- myomectomy
- adhesiolysis.

The Scottish NHS Medical Record Linkage Database is one of the largest patient-linked databases.<sup>5</sup> It provides invaluable information relating to inpatient and outpatient admissions in Scotland. Currently, the surgical admission data collection in the rest of the UK is poor. Readmission rates need to be established for England, Wales and Northern Ireland but, firstly, many disease and surgery codes need to be reviewed and updated, particularly those relating to laparoscopic surgery. This task is likely to be driven by the newly formed National Patient Safety Agency (NPSA), whose remit is to develop solutions to improve patient safety.

The consequences of adhesions can be serious and include fertility-related complications, chronic pelvic pain and subsequent surgical complications, as well as small bowel obstruction in some cases.<sup>9-14</sup> The issue as to whether adhesions cause pain is contentious. It appears that some adhesions do and some do not. There is no doubt that adhesions around the ovaries, for example, are often associated with pain. The pain, however, may be secondary to the obstruction and effects on the functioning of the ovary rather than as a direct result of the adhesion itself.

Adhesiolysis should be undertaken to relieve the symptoms of adhesions only in selected cases.

Good results can be achieved with ovarian adhesiolysis in improving fertility in women. Division of adhesions around the ovary has been shown to increase pregnancy rates by over 50%.<sup>9</sup> The effectiveness of adhesiolysis in treating chronic pain is less clear.<sup>15,16</sup> From recent evidence, it would appear that adhesiolysis is no more effective in relieving pain than diagnostic laparoscopy, which therefore brings into question its efficacy in cases of chronic pain.<sup>16</sup> This is a significant finding as the majority of adhesion-related readmissions are associated with pain. In addition, adhesiolysis itself is associated with a high risk of adhesion reformation. Clearly, therefore, it is better to prevent adhesions forming in the first place rather than treat adhesions once they have occurred.

The latest epidemiological data suggests that patients who have had previous surgery have a higher risk of adhesion-related complications. As part of a quality and risk management strategy, therefore, patients should be informed of the risk of adhesions. This should form part of the process of informed consent and be included in the written information given to patients, particularly in 'high-risk' procedures (listed earlier). Adhesion reduction strategies should also be discussed with patients prior to surgery.

With the increase in negligence cases relating to adhesions being reported, surgeons and gynaecologists must be aware of the medico-legal consequences. Case law has changed and judges are moving away from accepting what reasonable doctors might have done to support what reasonable patients might accept. There is, therefore a duty to warn patients of all material risks (generally accepted as being 1% or greater) inherent in a proposed procedure.

It is essential to enhance good, safe medical practice and to reduce the risk of adverse events. Consequently, adhesion prevention strategies should be employed during all abdominal or pelvic surgery. This should include the adoption of good surgical practice as well as the use of safe and effective adjuvant anti-adhesion products.

The merits of good surgical technique are now well established. Surgical practices should include gentle tissue handling, avoiding exposure to intestinal contents, the use of irrigation to avoid desiccation, minimal exposure to foreign bodies and the avoidance of ischaemic suturing etc.

There are several promising new anti-adhesion products either available or in development. Available clinical data show encouraging results and larger studies are continuing. If an anti-adhesion agent is safe and cost-effective then its routine use should be supported during abdominal surgery, particularly during high-risk procedures. In the meantime, it is appropriate to use any agent that has been demonstrated to be effective. ■

## References

1. Monk BJ, Berman ML, Montz FJ. Adhesions after extensive gynecologic surgery: clinical significance, etiology and prevention. *Am J Obstet Gynecol* 1994;**170**:1396–403.
2. Diamond MP. Prevention of adhesions. In: Sciarra J, editor. *Gynaecology and Obstetrics*. Philadelphia: Harper Row; 1988. p. 211–22.
3. Parker M. The Economic and Practical Implications of Adhesive Small Bowel Disease. Abstract presented at the 'Adhesive small bowel obstruction following colon and rectal surgery: can we do better?' symposium at the American Society of Colon and Rectal Surgeons and Tripartite Meeting, 3 May 1999.
4. Ellis H, Moran BJ, Thompson JN, Parker MC, Wilson MS, Menzies D, et al. Adhesion-related hospital readmissions after abdominal and pelvic surgery: a retrospective cohort study. *Lancet* 1999;**353**:1476–80.
5. Lower AM, Hawthorn RJS, Ellis H, O'Brien F, Buchan S, Crowe AM. The impact of adhesions on hospital readmissions over ten years after 8849 open gynaecological operations: an assessment from the Surgical and Clinical Adhesions Research Study. *BJOG* 2000;**107**:855–62.
6. Menzies D, Ellis H. Intestinal obstruction from adhesions – how big is the problem. *Ann R Coll Surg Engl* 1990;**72**:60–3.
7. Hawthorn RJS, Lower A, Clark D, Knight AD, Crowe AM. Adhesion-related readmissions following gynaecological laparoscopy in Scotland, an epidemiological study of 24,046 patients. *Reviews in Gynaecological Practice* 2003;**3**(1) Supplement:1.
8. Holmdahl L, Risberg B, Beck DE, Burns JW, Chagini N, diZerega GS, et al. Adhesions: pathogenesis and prevention – panel discussion and summary. *Eur J Surg Suppl* 1997;**163**(577):56–62.
9. Liakakos T, Thomakos N, Fine PM, Dervenis C, Young RL. Peritoneal adhesions: etiology, pathophysiology, and clinical significance. *Dig Surg* 2001;**18**:260–73.
10. Menzies D. Postoperative adhesions: their treatment and relevance in clinical practice. *Ann R Coll Surg Engl* 1993;**75**:147–53.
11. Howard FM. The role of laparoscopy in chronic pelvic pain: promise and pitfalls. *Obstet Gynecol Surv* 1993;**46**:357–87.
12. Duffy DM, diZerega GS. Adhesion controversies: pelvic pain as a cause of adhesions, crystalloids in preventing them. *J Reprod Med* 1996;**41**:19–26.
13. di Zerega G. Biochemical events in peritoneal tissue repair. *Eur J Surg Suppl* 1997;**163**(577):10–16.
14. Hershlag A, Diamond MP, DeCherney AH. Adhesiolysis. *Clin Obstet Gynecol* 1991;**34**:395–402.
15. Ford J, English J, Giannopoulos T. Long-term follow up of pain and quality of life scores after laparoscopic adhesiolysis. Abstract 001. *Reviews in Gynaecological Practice* 2003;**3**(1) Supplement:1.
16. Swank DJ, Swank-Bordewijk SC, Hop WC, van Erp WF, Janssen IM, Bonjer HJ, et al. Laparoscopic adhesiolysis in patients with chronic abdominal pain: a blinded randomised controlled multi-centre trial. *Lancet* 2003;**361**:1247–51.
17. Coleman MG, McLain AD, Moran BJ. Impact of previous surgery on time taken for incision and division of adhesions during laparotomy. *Dis Colon Rectum* 2000;**43**:1297–9.
18. Dubuisson JB, Fauconnier A, Chapron C, Kreiker G, Norgaard C. Second look after laparoscopic myomectomy. *Hum Reprod* 1998;**13**:2102–6.
19. Van Der Krabben AA, Dijkstra FR, Nieuwenhuijzen M, Reijnen MM, Schaapveld M, Van Goor H. Morbidity and mortality of inadvertent enterotomy during adhesiolysis. *Br J Surg* 2000;**87**:467–71.
20. Menzies D, Parker M, Hoare R, Knight A. Small bowel obstruction due to postoperative adhesions: treatment patterns and associated costs in 110 hospital admissions. *Ann R Coll Surg Engl* 2001;**83**:40–6.
21. Ellis H. The clinical significance of adhesions: focus on intestinal obstruction. *Eur J Surg Suppl* 1997;**163**(577):5–9.
22. Wilson MS, Menzies D, Knight AD, Crowe AM. Demonstrating the clinical and cost effectiveness of adhesion reduction strategies. *Colorectal Dis* 2002;**4**:355–60.
23. NHS Litigation Authority. *Risk Management Objectives for the Surgical Patient Pathway*. London: NHS Litigation Authority; April 2003 [www.nhsla.com/docs/Pilot%20Version%20-%20Surgical%20Patient%20Pathway.pdf].
24. Ellis H. Medicolegal consequences postoperative intra-abdominal adhesions. *J R Soc Med* 2001;**94**:331–2.
25. Skene L, Smallwood R. Informed consent: lessons from Australia. *BMJ* 2002;**324**:39–41.
26. Wiseman D. Obtaining informed consent: patient awareness of adhesions. *Adhesions News & Views* 2003:10–12.
27. Sjosten AC, Blomgren H, Larsson B, Edelstam GA. Precautions taken to prevent adhesions – a questionnaire study among Swedish obstetricians and gynaecologists. *Eur J Surg* 1999;**165**:736–41.
28. Risberg B. Adhesions: preventative strategies. *Eur J Surg Suppl* 1997;**163**(577):32–9.
29. Cooke I. Gynaecology and Adhesions – the State of the Nation. Adhesions Workshop, 29th British Congress of Obstetrics and Gynaecology, 10–13 July 2001.
30. Wiseman DM, Trout JR, Diamond MP. The rates of adhesion development and the effects of crystalloid solutions on adhesion development in pelvic surgery. *Fertil Steril* 1998;**70**:702–11.

# **CONFERENCES**

## **BSGE – British Society for Gynaecological Endoscopy**

BSGE Annual Scientific Meeting

**7–8 May 2004**

The Alexander Hotel, Dublin, Republic of Ireland

## **ESHRE – European Society of Human Reproduction and Embryology**

20th Annual Meeting of the European Society of  
Human Reproduction and Embryology

**27–30 June 2004**

Berlin, Germany.

## **BCOG – British Congress of Obstetrics and Gynaecology**

30th British Congress of Obstetrics and Gynaecology

**7–9 July 2004**

Scottish Exhibition and Conference Centre (SECC),  
Glasgow, Scotland

## **ESGE – European Society of Gynaecological Endoscopy**

13th Annual Congress of the ESGE 2004, Evolution of  
Surgical Techniques to improve woman's health and  
reproductive function

**14–17 October 2004**

Cagliari, Sardinia, Italy

