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Use of bioresorbable polymer sheet (SurgiWrap® Bioresorbable Protective Sheet) in liver transplantation – An early experience

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INTRODUCTION

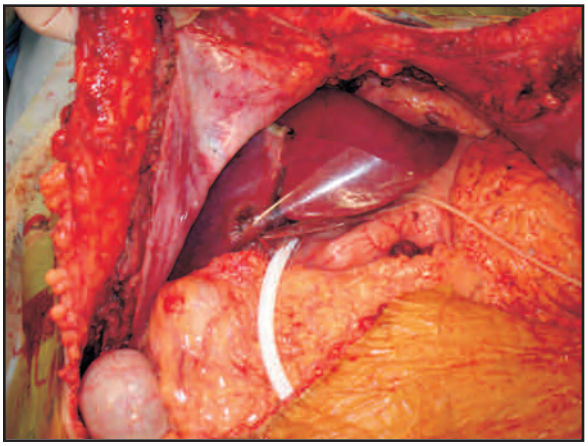
Intraperitoneal soft tissue attachments are a major source for morbidity and mortality following intra abdominal surgery. They are responsible for the majority of readmissions with small bowel obstruction following transperitoneal surgery[1]. Soft tissue attachments are also responsible for increased mortality and morbidity associated with re-exploration surgery. Difficulties in releasing soft tissue attachments are associated with an increase in inadvertent injury to abdominal structures resulting in prolongation of surgery and hospital course[2].

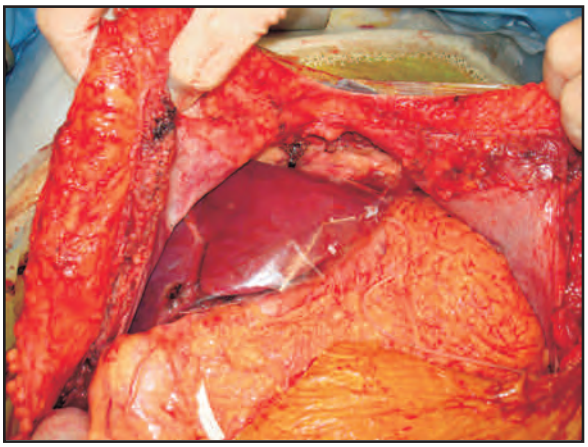
Injury to the peritoneum resulting in an imbalance in the coagulation/fibrinolytic system is postulated to be the cause of intra-abdominal soft tissue attachment formation[3]. Healing of the injured peritoneum and re-epithelialization occurs fairly rapidly and is complete within 5-7 days[3]. Separation of injured surfaces with a mechanical barrier during the healing period is one of the methods that has been proposed and used to prevent soft tissue attachments. Several such barriers have been evaluated and used with variable degree of success in the past decade[4,5]. The SurgiWrap® Bioresorbable Protective Sheet is a bioresorbable sheet made of a polylactide polymer of lactic acid. The SurgiWrap® sheets were developed to support and reinforce soft tissue, create a physical barrier, and minimize soft tissue attachments to the device when contacting the viscera which tend to develop during the post operative healing period. In the intra-abdominal setting this sheet retains its strength up to 6-8 weeks before it degrades by hydrolysis into carbon dioxide and water.

Liver transplantation is currently an accepted surgical intervention for the treatment of end stage liver disease. This complicated major surgical procedure is associated with significant morbidity and mortality. Re-exploration in the immediate post operative period and re-operation at later points in time for wound and biliary complications, can occur in up to 20-30% of liver transplant recipients[6]. Occasionally patients may need retransplantations. Reducing soft tissue attachment formation following the first surgical procedure would potentially help the re-exploration procedure and reduce the morbidity and mortality; with this intention, we have been using the SurgiWrap® sheets in liver transplant recipients. This report was prepared to share our preliminary experience with the use of the SurgiWrap® Bioresorbable Protective Sheets to support and reinforce soft tissue and minimize post operative soft tissue attachments to the device when contacting the viscera in patients undergoing liver transplantation.

METHOD

This is a retrospective review of experience with SurgiWrap® Bioresorbable Protective Sheets following liver transplantation performed by a single surgeon between 1/12/06 and 03/11/07, at a tertiary care academic center. The use of SurgiWrap® sheets was confirmed by review of the operating room records and procedure notes. Patient demographics, procedural details and postoperative follow up details were recorded from hospital and outpatient records. During each surgical procedure two or three sheets of SurgiWrap® 130mm x 200mm x 0.05mm were used. One or two sheets were used to separate the inferior surface of the right lobe of the liver and the inferior surface of the left lobe from the duodenum and colon and from the stomach respectively (Fig.1 and Fig. 2). One sheet of SurgiWrap® was used to cover the





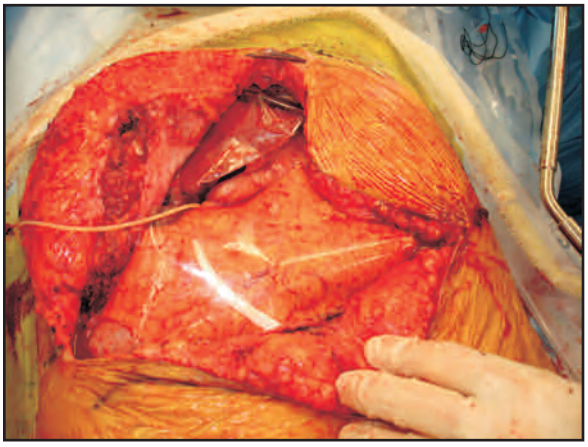


Figure 1 (top), Figure 2 (middle), Figure 3 (bottom)

anterior surface of the liver and colon to act as a barrier between the soft tissue and anterior abdominal wall incision. Currently we have standardized the procedure and routinely use three sheets of SurgiWrap® prior to closure (Fig 3).

RESULTS

Twenty one patients (16 males and 5 females) underwent 22 liver transplantations during this time period. One patient received a retransplantation on 4th postoperative day for primary non function of the allograft.

Two SurgiWrap® Bioresorbable Protective Sheets were used in 14 transplants and three sheets were used in 9 transplants. The follow up period ranged from 5 to 17 months with a median follow up of 12 months. One patient required re-explorations at day 3, 4 and 10 for open biopsy of the liver for suspected primary non function (PNF) followed by retransplantation and a further exploration for abdominal wash out and evacuation of hematoma respectively. The SurgiWrap® sheets were changed after the retransplantation and again after the exploration and abdominal wash out.

Two patients underwent hernia repairs at 7 and 10 months respectively. No soft tissue attachments were detected in either of these patients. One patient presented with lower abdominal pain at 28 days. A CT scan done for evaluation showed a small fluid collection with a small quantity of air in the area of the SurgiWrap® sheets but a subsequent ultrasound of the area for the purpose of aspiration failed to identify it. This patient underwent no further evaluation and recovered completely.

A small quantity of air was demonstrated in the area of the SurgiWrap® sheets in another patient undergoing a CT scan 2 ½ months later. Once again this finding did not merit any further work up. One patient presented with intraparenchymal hepatic artery aneurysm (2-3 months post biopsy) ten months following liver transplantation. This aneurysm was successfully treated with selective arterial embolization. One patient presented with a late bile duct stricture 4 months following transplantation that was treated with ERCP and stents.

Two patients underwent reoperations for hernia repairs. First patient was operated 7 months following liver transplantation for an incisional hernia. This patient had undergone a liver

retransplantation for biliary sepsis resulting from hepatic artery thrombosis that occurred several years after the first transplant. At the time of retransplantation the patient was on antibiotic coverage with multiple intrahepatic abscesses. She had a significant amount of ascities which interfered with wound healing in the post operative period resulting in the development of incisional hernia. During the hernia repair few soft tissue attachments were encountered between the bowel, the hernia sac and the abdominal wall. The second patient presented with an incarcerated Richter's type hernia in a small umbilical hernia defect. Again, few soft tissue attachments were encountered between the sac, bowel and anterior abdominal wall.

We have not had an opportunity to re-explore the field of the liver transplant in any patient. However, we have used the SurgiWrap® sheets in the setting of liver resection and found them to be useful in minimizing soft tissue attachments during re-exploration. Such an approach with other similar products have also been reported to be helpful in patients who undergo liver surgery who may need transplantation in the future as in procedures such as Kasai's performed for biliary atresia[7].

DISCUSSION

Our preliminary experience with the use of the SurgiWrap® Bioresorbable Protective Sheet has demonstrated a good safety profile in liver transplant recipients. No patient developed any immediate post operative complications attributable to the use of this product. This bioresorbable lactic acid sheet maintains its integrity in the tissues for 6-8 weeks. It is degraded by hydrolysis which results in production of CO2 and water. This was evident in two patients who underwent abdominal CT scan. Both CT scans showed tiny flecks of air that corresponded to the area of the SurgiWrap® sheets. One of the two patients had complaints of lower abdominal discomfort which was self limiting that could be attributable to the product undergoing hydrolysis.

One patient underwent re-exploration in the immediate post transplant period at 1, 3 and 5 days after the previous surgery. In each occasion we were able to demonstrate intact sheets providing evidence that the sheets created a barrier between soft tissues and minimized soft tissue attachments to the device allowing the healing process to be completed.

Though this experience is preliminary, it suggests that the product is safe in the setting of liver transplantation. With an increasing number of patients being transplanted for hepatitis C related liver problems, retransplant rates for this disease are on the rise. Similarly, it is not unusual to encounter significant problems due to soft tissue attachments while transplanting patients with previous liver surgery. An inexpensive, easy to use method to minimize soft tissue attachments would reduce the problems posed by complex soft tissue attachments encountered during re-operation. Such methods are a potential benefit for all upper abdominal surgeries to minimize soft tissue attachment related problems. We are currently in the process of developing a prospective trial using the SurgiWrap® Bioresorbable Protective Sheets in liver resections and liver transplantation procedures.

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