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The Efficacy in Minimizing Soft Tissue Attachment Using PLA Sheet™ Bioresorbable Sheets in Temporary Diverting Loop Ileostomy

Abstract

The formation of dense fibrous tissues following surgery is a common and irrepressible problem. The consequences of unwanted soft tissue attachments include chronic abdominal pain; intestinal obstruction; infertility; and heightened surgical risk during subsequent surgeries. Upon reoperation, the presence of unwanted fibrous attachments is known to prolong the operative time; increase the patient's risks to further injury; blood loss; and increase healthcare costs.

Techniques routinely used to minimize unwanted soft tissue attachments include proper wound irrigation; prevention of infection; careful hemostasis; and prudent tissue handling. Despite these precautions, approximately 93% of patients develop post-operative fibrous bands as part of the body's natural healing process. It has long been recognized that more than meticulous surgical technique is needed to prevent unwanted post-op soft tissue attachments. Various biomaterials have been evaluated for their potential as a physical barrier between opposing tissues.

The purpose of this prospective, randomized controlled, single-blinded study was to evaluate the efficacy of a bioresorbable physical barrier made of polylactide acid (PLA) on the incidence, extent and severity of post-operative soft tissue attachments in patients with the principal diagnosis of colorectal cancer or chronic ulcerative colitis who required a temporary diverting ileostomy or colostomy.

Twenty adults (n=20), with no prior history of abdominal surgery through the midline were scheduled for an open colorectal procedure, either a colectomy with ilioanal pouch anastomosis or low anterior resection. Both procedures included a

temporary diverting loop. Just before closing the abdominal wall during the primary procedure, patients were randomly assigned to either the Treatment Group to receive placement of the PLA mesh under the midline incision or the Control Group who did not receive any specific prophylactic treatment. Several weeks later, patients were re-admitted for closure of their temporary loop. During this second procedure, the peritoneal cavity was inspected by the principal investigator and videotaped for a third-party blinded assessment.

From December 2003 until January 2005, thirteen patients (8 men and 5 women), with either rectal cancer (n=10) or ulcerative colitis (n=3) were evaluated. No patient presented with pre-existing fibrin strands in the abdominal cavity during the first surgical procedure. The Control Group was composed of 5 patients and the Treatment Group was comprised of 8 patients. After a meantime of 13.2 weeks, the incidence, extent and severity of soft tissue attachments were evaluated during the second surgical procedure. The results are summarized in Tables 1-4.

Incidence of Attachment (Table 1):

Incidence	Treatment PLA (n=8)		Control (n=5)	
No Attachments	3	37.5%	0	-
Attachments Observed	5	62.5%	5	100%

Extent of Attachments (Table 2):

Extent	Treatment PLA (n=8)		Control (n=5)	
No Attachments	3	37.5%	0	-
Localized Attachments	4	50%	0	-
Moderate Attachments	0	-	0	-
Extensive Attachments	1	12.5%	5	100%

Extent of Midline Involvement (Table 3):

Extent	Treatment PLA (n=8)		Control (n=5)	
	n	Score	N	Score
No Attachments	3	3	0	-
Localized = <1/3 of the incision length covered with attachments (Score =4)	4	16	0	-
Moderate = 1/3 – 2/3 of the incision length covered with attachments (Score =8)	0	-	0	-
Extensive = >2/3 of the incision length covered with attachments (Score = 16)	1	16	5	80
Mean Score	-	4.3	-	16

Severity of Attachments (Table 4):

Extent	Treatment PLA (n=8)		Control (n=5)	
	n	%	N	%
No Attachments	3	-	0	-
Grade 1: Least Severe	2	25%	0	-
Grade 2: Moderately Severe	3	37.5%	0	-
Grade 3: Very Severe	0	-	5	100%

Use of a thin bioresorbable PLA mesh significantly reduced the incidence, extent and severity of unwanted fibrous attachments in the Treatment Group compared to the Control Group (p= 0.008, confidence interval >95%; using U-test of Mann-Whitnet or Uleman test). In clinical practice, the incidence, extent and severity of attachments seen in the Control Group are known to prevent free movement of organs and provide an environment for high-risk complications and chronic pain. Prophylactic placement of SurgiWrap® (MAST BioSurgery, San Diego, California) at the midline during the first surgical procedure provided an effective physical barrier between opposing tissues to support independent healing, as seen during the requisite second procedure to close the patient's temporary diverting loop.