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# The effectiveness of a bioresorbable polymer sheet (SurgiWrap®) in minimizing Soft Tissue Attachments (STA) after major colorectal surgery: A randomized controlled pilot study

## Introduction

Surgical manipulation of the peritoneum or visceral tissues in abdominal surgery and laparoscopy commonly is followed by the formation of postoperative STA. As part of the body's natural healing process, this undesirable and seemingly uncontrollable phenomenon can lead to additional complications such as small bowel obstruction, intractable abdominal pain, and fertility impairment in women. In addition, post-operative abdominal STA are associated with significant morbidity and mortality, presenting a substantial burden on healthcare systems worldwide.

A bioresorbable sheet made of polylactide acid (SurgiWrap® MAST Bioresorbable Sheet) was developed to reinforce soft tissue and subsequently create a temporary physical barrier between opposing tissue during the critical period of visceral healing.

## Objective

The objective of this prospective controlled study was to assess the efficacy of SurgiWrap® STA sheet in reinforcing soft tissues and subsequently reducing postsurgical STAs in patients undergoing a major colorectal surgery. The results shall provide evidence about the efficacy and safety of the resorbable STA sheet compared to no device treatment.

## Methods and Material

The study was designed as a randomized, controlled, single-blinded study. Eligible patients with rectal cancer (LAR) or ulcerative colitis (IAPP) who met the inclusion criteria were enrolled in this study after informed consent was given. The study was accepted by the local ethics committee. Baseline measurements and medical history were recorded. At the end of surgery, just before closing the abdominal wall, the patients were allocated to either the treatment group in which the SurgiWrap® sheet was placed under the midline incision or to the control group who did not receive any specific device treatment. Standardized surgical technique was performed with regard to midline approach.

Uniform placement and fixation of the SurgiWrap sheet under the midline incision was required. After a mean of 14 weeks the patients were admitted for laparoscopic ileostomy closure. During laparoscopic intervention the incidence, extent and severity of post-surgical STA were determined. To minimize a BIAS introduced by the investigator a second assessment of the abdominal cavity was conducted by an independent surgeon on base of the video records, who was blinded for patients treatment status.

## Assessment criteria

Primary effectiveness endpoints were the extent and severity of newly formed STAs under the midline incision where the SurgiWrap® sheet initially was placed. Extent and severity of STA were graded according to published scores (Ref 1,2).

A total of 14 adverse events were reported in 10 patients. Eight serious events (SurgiWrap n=3, Controls n=5), presented as subileus/ileus symptoms, pouchitis and high stoma output. None

TABLE 1: Extent characteristics of STA

Criteria	Description
0	no STA
localized	less than 1/3 of the length is covered
moderate	between 1/3 to 2/3 of length is covered
extensive	more than 2/3 of the length is covered

TABLE 2: Severity characteristics of STA

Criteria	Description	Grading
Least severe	firmy thickness, avascular, translucent	Grade 1
Moderate severe	moderate thickness, limited vascularity	Grade 2
Very severe	dense thickness, highly vascularized	Grade 3

## Results

19 patients have completed the study between 2004 and 2007			
	SurgiWrap (n=10)	Control (n=9)	p-Value
Rectal Cancer (LAR)	8	5	0.51
Colitis Ulcerosa (IAPP)	2	4	0.51
Men/Women	5/5	7/2	0.2
Age (mean)	56 yrs	52 yrs	0.4
Weight (mean)	73 kg	83 kg	0.14
Time of Surgery (mean)	204 min	230 min	0.22
Blood Loss (mean)	715 ml	694 ml	0.93
Incision Length (mean)	19.3 cm	22.8 cm	0.059

Extent of STA's under Midline Incision		
	SurgiWrap	Control
no STA	5	0
localized	4	1
moderate	1	1
extensive	0	7
n=	10	9

Extent of STA's [ Grade 1;2;3 ]		
	SurgiWrap	Control
Mean	0.60	2.67
STDev	0.69	0.71
Min	0	1
Max	2	3
p-Value	0.0005	

**Extent characteristics were graded numerically as: no STA = 0; localized = 1; moderate = 2; extensive = 3.**

Severity of STA between Midline - Omentum		
	SurgiWrap	Control
no STA	5	0
least severe	2	1
moderate severe	3	1
very severe	0	7

Severity of STA between Midline - Omentum		
	SurgiWrap	Control
Mean	0.89	2.56
STDev	0.93	0.73
Min	0	1
Max	2	3
p-Value	0.0025	

**Severity of STAs were scored acc. to Becker et al. (1996): Grade 1: filmy thickness, avascular, translucent. Grade 2: moderate thickness, limited vascularity. Grade 3: dense thickness, highly vascularized. No STA's were scored as 0.**

Severity of STA between Midline - Small Bowel		
	SurgiWrap	Control
no STA	7	2
least severe	3	0
moderate severe	0	0
very severe	0	7

Severity of STA between Midline - Small Bowel		
	SurgiWrap	Control
Mean	0.30	2.22
STDev	0.48	1.32
Min	0	0
Max	1	3
p-Value	0.0051	

of those events were device related. There were 6 wound healing problems ( SurgiWrap n=2, Controls n=4) classified as non-serious events.

## Conclusion

This study achieved its primary objective in demonstrating that the use of the resorbable PLA sheet, SurgiWrap MAST Bioresorbable Sheet in abdominal surgery will lead to reinforced soft tissues and a true reduction of tenacious soft tissue

attachments immediately adjacent to the device. Moreover, when analyzing the extent and severity of STA observed at relook interventions, this effect is even more pronounced when compared to the routine treatment which does not foresee any prophylaxis. Even though the study population is small, this pilot study shows a statistical significance in reduction of postoperative STA which arise from the midline incision after major colorectal surgery.