Final outcomes of the initial 20 subjects reaching 2 year follow up in the BRAVO Ventral Hernia Study

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Introduction

The BRAVO trial was designed to evaluate the clinical performance of OviTex RTM (1S, Permanent), a novel reinforced tissue matrix in a variety of ventral hernia repairs. This abstract presents the final disposition of the initial 20 subjects reaching the 2-year follow-up post implantation.

Methodology

BRAVO is a prospective, single arm, multicenter study (ClinicalTrials.gov/NCT03074474). Most patients presenting with a ventral hernia were eligible, including those with recurrences and previous infections. Excluded were only those with a BMI > 40 kg/m2, CDC wound class Grade 4, and defects requiring implants larger than 20 x 20 or 18 x 22 cm. The endpoints studied are real and apparent recurrences and all post-operative surgical site occurrences (SSO), including wound related events. Patients with a clinically suspected recurrence were required to undergo a CT scan for confirmation. Any other complications occurring within the first three months following surgery were noted as well, whether related to the procedure or not. At each follow up timepoint patients completed Quality of Life (QoL) questionnaires and pain assessments. The patients are being followed for 2 years post-implantation.

Preoperative Variables, Comorbid Conditions, and Perioperative Variables	
Preoperative variables	24 Months
Subjects enrolled 92	
Subjects, n (%)	20 (22%)
Sex, n (%)	
Male	7 (35%)
Female	13 (65%)
Age (years), mean (range)	64.6 (47.0 - 84.8)
Body mass index (kg/m^2), mean (range)	31.1 (23.6 - 38.5)
Comorbid conditions	
Obesity, n (%)	14 (70%)
Patients with prior VH repairs, n (%)	7 (35%)
Number of repairs, mean	3
Prior SSI, n (%)	1 (5%)
History of surgical infection, n (%)	4 (20%)
Perioperative variables	
VHWG, n (%)	
Grade I	3 (15%)
Grade II	13 (65%)
Grade III	4 (20%)

Operative Characteristics	
Operative characteristics	24 Months
Hernia defect size (cm^2), mean (range)	131.3 (4-384)
Mesh size (cm^2), mean (range)	266.5 (30-400)
Approach, n (%)	
Open	14 (70%)
Laparoscopic	2 (10%)
Robotic	4 (20%)
Plane of placement, n (%)	
Retrorectus	11 (55%)
Intraperitoneal	5 (25%)
TAR	3 (15%)
Retrofascial/pre-peritoneal	1 (5%)
Onlay	0 (0%)
Primary closure, n (%)	18 (90%)
Component separation, n (%)	14 (70%)
Time in surgery (hours), mean (range)	2.53 (0.88-3.93)
Hospital stay (days), mean (range)	5.06 (0-9)

Primary and Secondary Endpoints: Adverse Events	
	24 Months
Total patients	20 (24%)
Hernia recurrence, n (%)	-
SSO (patients), n (%)*	5 (25%)
Seroma (requiring intervention)	-
Hematoma	1 (5%)
Wound dehiscence	-
Skin necrosis	-
Fistulae	-
Superficial infection	1 (5%)
Deep infection	3 (15%)
Organ space infection	-
Complications	
Bowel obstruction	1 (5%)
DVT/PE	1 (5%)
Ileus	3 (15%)
Malignancy	-
Other non-surgery or hernia related complications	6 (30%)
*Individual patients may have experienced more than one SSO	

Results

In total, ninety-two (92) patients were enrolled and underwent surgery. Twenty (20) subjects have now completed their two-year follow-up visit. In this group, the average BMI was 31.1, with 70% of the patients classifying as obese. Thirteen (13) of the 20 patients had a VHWG grade 2 and four (4) classified as grade 3. Five (5) subjects experienced SSOs, four (4) infections and one (1) hematoma, all of which had resolved at the time of first analysis at 30 days and did not require surgical intervention. No subject in this group has experienced a recurrence (0 of 20; 0%) through two years.

Conclusion

This first look at long-term outcomes in this prospective study with OviTex RTM demonstrates that in this group no further surgical procedures have been performed to treat either procedure related complications or recurrences. With the initial 20% of the intended patient population having reached the two-year follow-up, the observed absence of any recurrence is extremely encouraging.

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