Long-term Outcome on the use of the Ventralight™ ST Hernia Patch in Laparoscopic Ventral Hernia Repair

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ABSTRACT

Background. Laparoscopic ventral hernia repair (LVHR) is a common procedure in abdominal surgery. Use of mesh has become the gold standard in the last decade because of significantly fewer recurrences. Subsequently, the attention shifted to reduce mesh related complications in the short- and long-term as well as to facilitate its handling and positioning.

In continuation of our previous study, we conducted a final analysis about the use of the Ventralight™ ST hernia patch (Davol Inc, Subsidary of C. R. Bard, Inc. Warwick, RI).

Methods. Prospectively collected data of 61 consecutive patients (men/women: 44/17) from July 2011 to October 2013 were analysed in this final study. Patients were evaluated clinically at four time points in total. At the final clinical check- up, 97% of the total study population was reassessed. The primary outcome parameter was recurrence. Secondary outcome parameters were described in terms of mesh related

complications, pain scores, and quality of life.

Results. Mean follow-up time was 23 months (range 16–44). Mean length of hospital stay was four days (range 2–17). There were no operative complications. Two patients (both > 80 years old) died more than one year after the procedure because of a cardiovascular event. One morbidly obese patient (2%) treated for a recurrent incisional hernia showed a second recurrence at the last follow-up visit. A clinical significant seroma was observed in two patients (3%) one month postoperatively. At last follow-up, two patients (3%) reported persistent mild discomfort at one specific spot. There was a significant reduction in the visual analogue scale (VAS) scores at the last follow-up visit compared to preoperative scores (3.01 vs. 0.27; P < 0.01). Quality of life measurements using the SF-36 questionnaire showed good results.

Conclusion. This final analysis of long-term follow-up results on the use of the Ventralight™ ST hernia patch in laparoscopic ventral hernia repair confirms our preliminary findings of the previous two reports. Use of the Ventralight™ ST hernia patch is associated with good short- and long-term outcomes and can be considered as safe and feasible in LVHR.

INTRODUCTION

Although laparoscopy is becoming the gold standard in most abdominal procedures, laparotomy is still frequently performed. Wide variance exists in reporting the incidence of incisional hernia after abdominal surgery. However, it is believed that 4% of all patients undergoing a laparotomy will need hernia surgery.[1] Whilst umbilical hernia is quite common, primary epigastric hernias only account for a small percentage of all hernias operated on.[2] Randomized clinical trials show a clearly significant advantage concerning the long-term outcome parameters (i.e., recurrence) for mesh repair.[3,4] Indeed, during the last decade, mesh repair has become the gold standard for any abdominal hernia repair. Being so, several companies started to focus on the development of the ideal mesh. Soon the attention shifted to reduce mesh related complications like seroma/hematoma formation, chronic pain, erosion, perforation, and adhesion formation.

The Ventralight™ ST hernia patch was first described in an animal study showing promising results.[5] We already reported twice on the preliminary results of our prospective study.[6,7] Here, we present the final results. Furthermore, the ST technology used within the Ventralight™ ST hernia patch beneficiate from proven results from previous generations of product, like the Seprafilm™ (Davol Inc., Subsidary of C. R. Bard, Inc. Warwick, RI) and the Sepramesh™ IP Composite (Davol Inc., Subsidary of C. R. Bard, Inc. Warwick, RI).[8]

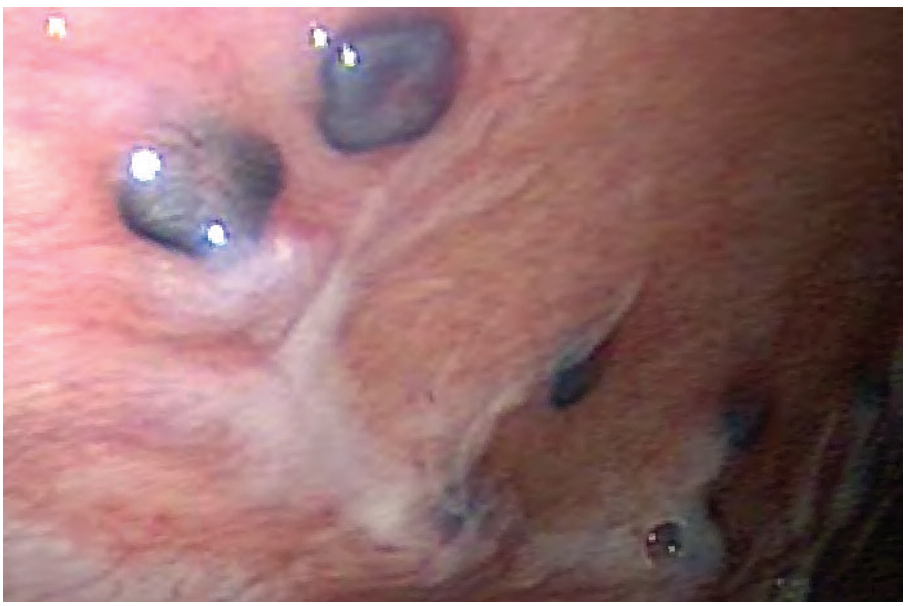

Figure 1. Completely ingrown Ventralight™ ST hernia patch with still visible Sorbafix™ tackers. No adhesion formation was observed.

MATERIAL AND METHODS

Study population

In total, 61 patients (men/women: 44/17) were included. Median age at the time of the procedure was 54 years (range 45–81). Relatively large hernias were treated with a mean hernia size of 6 x 5 cm (range 1.5 x 1.5 – 15 x 20). Incisional hernias accounted for 60% (37), epigastric hernias for 25% (15)

and umbilical hernias for 15% (9). Nine (15%) were operated on for a recurrent hernia. A unilateral inguinal hernia was performed simultaneously in three patients (5%). Median BMI was 23 kg/m^2 (range 21–40). All patients were treated in a single institution by one surgeon (TT).

Surgical technique

The Ventralight™ ST hernia patch is a bilayer medium-weight mesh that consists of two different layers, each with specific properties. The peritoneal side has an uncoated monofilament polypropylene surface, whereas the side facing the viscerae consists of reinforcing bioresorbable polyglycolig acid (PGA) fibers with a layer of a hydrogel barrier of chemically modified absorbable hyaluronic acid, carboxymethyl cellulose, and polyethylene glycol. This hydrogel barrier resorbs within 30 days. Those two layers are combined together using PGA fibers, giving 50% of thee added strength to the mesh for 15 days. Having these properties, it is believed that tissue ingrowth is enhanced and delamination is prevented while development of adhesion on the visceral side is minimized.[5]

LVHR is a very standardized procedure at our institution. A single dose of 2 grams of cefazolin is administered before induction of general anesthesia. After the pneumoperitoneum of 15 mmHg was set, three trocars were placed by the choice of the surgeon taking into account the anatomy of the hernia, mostly on the left flank. The fascial defect was closed with non-resorbable polypropylene sutures after the hernia sac was dissected and its contents were reduced. The size of the mesh (ranging from 15 x 15 cm up to 30 x 35 cm) was chosen in such a manner that an overlap of at least 5 cm with every side of the fascia defect was provided. To enhance mesh handling and positioning, a mesh with an EchoPS™ (Davol Inc., Subsidary of C. R. Bard, Inc. Warwick, RI) positioning system was chosen in cases of small intra-abdominal working space. This tool aids in proper intra-abdominal handling and positioning in LVHR like previously described.[7] Mesh fixation was performed in an onlay position by SorbaFix™ (Davol Inc., Subsidary of C.R. Bard, Inc. Warwick, RI) tackers in a double crown technique after proper positioning was ensured with non-resorbable polypropylene transfascial sutures in the cardinal positions. No wound drains were left in place. Defects in the fascia at the trocar sites were closed with a single polyfilament resorbable suture.

Before the end of anaesthesia, an abdominal binder was applied to provide counter pressure against high intra-abdominal pressures during awakening of the patient. During the hospital stay, patients received, on a routine basis, 1 gram of acetaminophen four times a day and 75 mg of diclofenac two times a day. In case of insufficient analgesia, 10 mg of piritramide was administered intramuscular or continuous perfusion of intravenous tramadol was started.

Patients were advised to use this binder and to avoid strenuous physical activity for six weeks.

Follow-up

Pre- and postoperative data were prospectively recorded in patient's electronic medical charts. During the whole follow-up period, assessments at four time points were organised: one month postoperatively, in April 2013, October 2013, and November 2014. Mean follow-up time was 23 months (range 16–44).

History taking, clinical examination, pain measurement using VAS, and quality of life assessment using the short-form health survey questionnaire (SF-36) were performed during the last three follow-up visits.[9] In case of uncertainty, an ultrasound or computed tomography was performed to rule out complications or recurrence.

Outcome measures

Recurrence was defined as the presence of a hernia in the region where the mesh was positioned.

Patients were observed for operative and post-operative complications like iatrogenic organ damage, seroma, and/or hematoma formation, wound or mesh infection, trocar site hernias, chronic pain, (sub) obstruction due to adhesions, or fistula formation.

Length of hospital stay and operation time (from first touch of the mesh until last tacker) were recorded.

The SF-36 health survey was used to measure quality of life. In one study about the use of quality of life measures, the SF-36 was, among the generic measures, the most widely evaluated one.[10] This validated health survey consists of 36 questions about the following eight sections: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. The weighted sum of the questions in each section yields eight scores which are directly transformed into a 0–100 scale on the assumption that each question carries equal weight. The lower the score, the more disability.[8] Mean SF-36 scores at one month and at the last follow-up visit were calculated and compared.

Preoperative VAS was compared with postoperative scores at the above mentioned time points.

Statistical analysis

Using the SPSS statistics software (SPSS Inc. Released 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc.) package, the paired t-test was applied for comparison of VAS and SF-36 scores and the difference in operation time between procedures with versus without the EchoPS™ positioning system.

Statistical significance was assumed if P values were smaller than 0.05.

RESULTS

Short-term outcome

Forty patients (66%) needed a patch of 15 x 20 cm. The 15 x 15 cm and 25 x 33 cm meshes were implanted in 10 patients (16%) and six patients (10%) respectively. Five patients (8%) had an implant of 20 x 25 cm. The EchoPS™ positioning system was used in 15 patients (25%). Last follow-up visit was performed in 97% of patients (59/61, two deaths).

Mesh introduction, proper positioning, and fixation had a mean duration of 20 minutes. Patients, in which the EchoPS™ positioning system was used, had a significant shorter mean duration of operation (14 vs. 26 minutes; $P < 0{,}001$).

The mean length of hospital stay was 4.4 days (range 2–17). No operative complications or mortalities occurred.

In the post-operative follow-up, we recorded two (3%) clinically significant seromas which were evacuated. These seromas did not recur.

At the last follow-up visit two

Table I
Mean VAS scores at different time points

Time point	VAS score	P value
Preoperative	3.01	
1 month postoperative	0.68	<0.01*
Last follow-up (4th time point)	0.27	<0.01**

* Comparison of preoperative vs 1-month postoperative values
** Comparison of preoperative vs last follow-up values

patients (3%) reported persistent very localized mild discomfort. In these patients, we successfully performed an infiltration with a combination of depomedrol and lidocain. They remained pain-free.

Long-term outcome

Two patients were lost in follow-up because of death due to a cardiovascular event more than one year after their procedures. They were both more than 80 years old. No mortalities directly related to the procedure occurred. At the last follow-up visit, no additional complications were observed.

One patient (2%) showed a clear relapse but remained asymptomatic. This female patient had a BMI of 39 kg/m^2 and had been operated on because of a recurrent 6 x 3 cm midline incisional hernia.

Three patients underwent an unrelated laparoscopy (cholecystectomy for symptomatic cholecystolithiasis) more than six months after their hernia surgery (all with a 20 x 25 cm mesh). During these procedures, no adhesions were observed in two of the patients. In the other patient, only one small part of the omentum was adhered to the mesh. This adhesion could be removed with simple blunt dissection that could therefore be classified as a grade 1 adhesion according to the Mazuji classification.[11] Complete tissue ingrowth of the mesh was observed in all patients. No trocar hernias were detected in these patients after the relaparoscopy.

Pain Scores and Quality of Life

Compared to preoperative values, postoperative VAS score was significantly better one month postoperatively as well as at the last follow-up (Table I). No significant difference in VAS scores existed along the patients with different sizes of meshes at the last follow-up ($P > 0.05$). The above-described patient with proven adhesion had a VAS score of 0.

The SF-36 questionnaire was completed at three time points (Table II). There was no significant difference between the SF-36 scaled scores at time point three versus time point four ($P > 0.05$).

DISCUSSION

Albeit in rare cases, LVHR can cause more severe complications (like iatrogenic bowel injury); however, it is proven to offer good results.[12-14] Indeed, a meta-analysis of randomized controlled trials reported a shorter mean length of hospital stay and fewer wound infections after the laparoscopic onlay mesh technique compared to the open sublay procedure without a difference in recurrence rates.[15]

In this final analysis of our prospective study, we evaluated the long-term outcomes on the use of the Ventralight™ ST hernia patch in laparoscopic ventral hernia repair, being the first one.

Primary endpoint was the recurrence incidence. Only one patient out of 61 relapsed (2%).

Compared to reported recurrence rates in older papers, this percentage can be considered as rather low. However, this rate is in line with reports in recent papers about ventral hernia repair and proves at least similar efficiency of this patch compared to meshes of the same generation.[16,17]

Because of this low recurrence rate, we did not perform a separate analysis about its predictors. The only patient who recurred had three risk factors as described in one study[17]: morbid obesity, large hernia (> 5 cm), and recurrent

Table II
SF-36 scaled scores at different time points

	PF	RP	BP	GH	VT	SF	RE	MH
O4/2013	88	96	89	76	80	95	100	84
10/2013	86	95	90	74	83	95	98	86
11/2014	82	97	88	85	80	91	94	79
P value*	> 0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

PF physical functioning; RP physical role functioning; BP bodily pain; GH general health perception; VT vitality; SF social functioning; RE emotional role functioning; MH mental health
* comparison of values at 10/2013 vs 11/2014

incisional hernia.

In the long-term follow-up, two patients died because of a cardiovascular event unrelated to the procedure as this occurred more than one year after the hernia procedure.

There is evidence that the ST™ technology (Sepra Technology) in the Ventralight™ mesh has advantageous properties with regard to adhesion coverage, mesh contraction, and inflammatory response.[18] Moreover, in a porcine model, Ventralight™ ST showed favourable strength of tissue ingrowth.[5] Despite it was not possible to evaluate this in all patients, we had the opportunity to observe positive results in three patients. Low pain scores in the whole population could also be an indirect evidence of low adhesion formation.

Ventral hernia repair is known to be a painful procedure.[19] We did not record VAS scores immediately postoperative because it is known that, in this period, patients have the most discomfort. In our experience, a combination of analgesics offers adequate analgesia in this period. One study clearly shows that pain sensation is quickly diminished after one week.[19] In a study with a population of similar mean age and also using double row tackers, patients reported similar VAS scores after three months.[18]

Our study population showed good SF-36 scores, including the physical functioning; physical role functioning, and bodily pain domains. These scores remained stable. Comparable scores were recorded in other studies after laparoscopic ventral hernia repair.[20-21]

CONCLUSION

This final analysis of long-term follow-up results on the use of Ventralight™ ST hernia patch in LVHR confirms our preliminary findings of the previous two reports. Use of the Ventralight™ ST hernia patch is associated with good short- and long-term outcomes and can be considered as safe and feasible in LVHR. STI

AUTHORS' DISCLOSURES

The authors have no conflicts of interest or financial ties to disclose.

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