Intraperitoneal Tension-free Repair of a Small Midline Ventral Abdominal Wall Hernia: Randomized Study with a Mean Follow-up of 3 Years

HOCINE BENSAADI, M.D.,* LUCA PAOLINO, M.D.,* ANTONIO VALENTI, M.D.,* CLAUDE POLLIAND, M.D.,* CHRISTOPHE BARRAT, M.D.,† GÉRARD CHAMPAULT, M.D.*

*From *Paris XIII University–Hôpitaux Universitaires de Paris Seine Saint Denis, Hôpital Jean Verdier, Paris, France; and the †Department of Digestive and Metabolic Surgery, Bondy, France*

Funding received from Cousin Biotech, Wervicq Sud, France, and CR Bard Inc., Cranston, RI. **The aim of this prospective randomized study was to determine the long-term recurrence and complication rates after small abdominal wall hernia repair with two different bilayer prostheses. Hernia repair using prosthetic mesh material has become the preferred method of repair, because the recurrence rates are much lower than with conventional repair techniques. The use of a hernia bilayer patch, composite expanded polytetrafluoroethylene (ePTFE)–polypropylene, with intraperitoneal placement behind the hernia defect, through a small incision, may be efficient, safe, and cost-effective. This study is a randomized, single-institution trial, including 83 selected consecutive patients with primary (umbilical, epigastric) or incisional anterior abdominal wall defects from 2 to 5 cm. Hernia repair was performed by direct local access in ambulatory surgery; the prosthesis used was a circular bilayer with an inner face in ePTFE to avoid bowel adhesion. One group was treated with a Ventralex® Hernia Patch (Bard USA). The second group was treated with a Cabs'Air® Composite (Cousin Biotech France), which was delivered with two to four fixation sutures and a balloon to properly deploy the mesh intraperitoneally. Patients' characteristics and operative and postoperative data were prospectively collected. The primary outcome was late recurrence. Secondary outcomes included, pain, discomfort and quality of life before and after (3 months) surgery using the SF-12 questionnaire, patient–surgeon satisfaction, and early and late complications. Among 98 patients, 83 were included in the study protocol between January 2007 and August 2011. The two groups were comparable according to pre- and intraoperative data. According to surgeon experience, placement of the Cabs'Air® device was significantly faster (P = 0.01) and easier. At 3 months, there was significantly less pain and less discomfort for the Cabs'Air® group and patient satisfaction rate was higher. This was confirmed by all components of the SF-12 questionnaire. Long-term follow-up was available for 77 patients. The mean follow-up was similar for the two groups (42 months; range, 14 to 70 months). At this point, for the Ventralex® group, there were four recurrences (11.7%); one mesh infection; one small bowel obstruction; and six cases (15.7%) of severe pain resulting from a mass syndrome (shrinkage) with a sense of the presence of a foreign body. Six reoperations (15.6%) were required with explant of the prosthesis. There were no recurrences or late complications in the comparative group. The Ventralex® Hernia Patch is associated with inconsistent deployment, spreading, or shrinkage, which account for late complications and decreases the overlap, which contributes to the recurrence rate. The Cabs'Air®-associated balloon facilitates superior deployment of the prosthesis allowing for good fixation with four sutures.**

MIDLINE VENTRAL HERNIAS are common with the majority being parietal acquired defects (90%).[1] The etiology of umbilical herniation is multifactorial. Weakened fascial tissue as well as chronically increased intra-abdominal pressure is a major predisposing factor.[2] Umbilical hernias are often symptomatic and are prone to incarceration because of the adherence of omentum to the hernia sac.[2] There is no consensus on the best technique for the repair of ventral hernias. Increasing evidence[3] suggests that the use of a prosthetic

Address correspondence and reprint requests to Antonio Valenti, Chirurgie Digestive et Metabolique Hopital Jean Verdier, Bondy, ile de france, France. E-mail: antonio.valenti@jvr.aphp.fr.

mesh should be the preferred method of hernia repair, because recurrence rates after herniorrhaphy (suture repair) are high ranging from 11 to 54.5 per cent.

The current literature on umbilical herniation lacks objective data regarding treatment in relation to the size of the hernia. It is well established that a larger defect (greater than 3 cm in diameter) requires a prosthetic repair, particularly in obese and high-risk patients.[2–4] Questions remain as to whether defects smaller than 3 cm should be treated consistently with a prosthetic repair. However, because primary closure often fails and umbilical hernias are prone to complications, some evidence suggests that mesh repair should also be considered in these smaller hernias.[5–7]

For small and medium defects (2 to 5 cm), minimal skin access is needed and requires minimal dissection of the subcutaneous tissue and abdominal wall fascia, resulting in lower local complications such as wound infection and seroma formation. Placing the mesh behind the wall defect in a retrorectus extraperitoneal or, more frequently, peritoneal position is the foundation of modern hernia repair and results in lower recurrence rates.

In the literature, only the use of a Ventralex Hernia Patch® (Davol Bard, Cranston, RI) has been reported. This patch is a round dual-layer mesh device. The polypropylene side of the patch promotes tissue ingrowth and incorporation of the patch into the abdominal wall. The expanded polytetrafluoroethylene (ePTFE) side of the patch, which is placed in contact with the abdominal viscera, provides a permanent barrier and minimizes tissue attachment. The patch also has two polypropylene straps that facilitate placement, positioning, and fixation.[8]

To date, eight studies have evaluated the Ventralex® patch for repair of small midline hernias.[8–15] Five of these studies have shown that both short- and long-term recurrence (0 to 2.6%) and complication rates are low. Three studies reported higher long-term recurrence rates of 8.3 to 14.8 per cent.[8–15]

For Tollens[8] and Berrevoet,[13] findings at reoperation for recurrence, noted the device had very often stiffened up or shrunken in size. The most concerning reoperative finding was the device flipped down instead of spreading out well and aligning itself to the abdominal wall. This decreased the overlap and contributed to a higher recurrence rate. Reasons for these suboptimal findings are the lack of control of deployment when pulling the two straps as well as that the two heavyweight layers may cause significant foreign body reaction with consequent massive fibrosis and shrinkage.

A new device, Cabs'Air composite® (Cousin Biotech France), is also a round dual-layer mesh made of polypropylene and ePTFE. It is delivered with a balloon to properly deploy the mesh intraperitoneally and two to four fixation sutures.

We proposed to perform a randomized single-institution trial comparing Cabs'Air® with Ventralex® with long-term follow-up to evaluate recurrence and late complication rates.

Patients and Methods

Study Population

A total of 98 adult patients (18 years of age or older), undergoing umbilical, epigastric or small incisional hernia repair, were enrolled consecutively from January 2007 to August 2011 at a single institution. After informed written consent was obtained, the patients were randomized and underwent a prosthetic hernia repair.

Exclusion Criteria

Children (younger than 18 years), pregnancy, emergency case, associated surgery, body mass index greater than 35 kg/m^2, insulin-dependent diabetes mellitus, neoplastic disease, hepatocellular disease, drug or alcohol addiction, psychiatric pathologies, regular use of pain killers, steroids, immunosuppressant or anticoagulation therapy, and defects less than 2 cm or greater than 5 cm were considered exclusion criteria.

Preoperative data were collected, including management history, physical and professional activity level, American Society of Anesthesiologists score, the presence of comorbidities, and risk factors (e.g., arterial hypertension, prostatitis, smoking).

Surgical Technique

The choice of anesthesia was left to the discretion of the surgeon and anesthesiologist. Antithrombotic and antibiotic prophylaxis were used according to French healthcare recommendations (one dose of cephazolin routinely before surgery). In the majority of cases, the defect was exposed using an infra- or periumbilical approach. A small incision was made in the skin over the hernia and the hernia sac was dissected out and divided. The contents of the sac were then reduced into the abdomen and the redundant sac was excised. Adhesions from the peritoneal surface underlying the defect were removed. Fat tissue was then dissected off the underlying fascia to expose 3 to 5 cm of healthy fascia. The mesh patch, correlated to the size of the defect, with minimum overlapping (2 to 3 cm), was inserted through the defect and placed into the peritoneal cavity behind the wound. The prosthesis used was then fixed with nonabsorbable suture (Prolene®; Ethicon). The fascia was reapproximated with absorbable

sutures to protect the mesh from any potential wound contact. The wound was then closed using intradermal absorbable running suture and covered with an aseptic compression dressing. Once at home, patients were instructed not to lift heavy objects, to avoid strenuous activity for 6 weeks, and to wear an abdominal binder.

The Prosthesis

The Ventralex® Hernia Patch (Bard/Davol, Cranston, RI) is a composite circular bilayer prosthesis made of an outer heavyweight polypropylene monofilament mesh, promoting tissue in-growth and hence incorporation of the patch into the abdominal wall and an inner ePTFE surface placed in contact with the abdominal viscera, providing a permanent barrier and minimizing tissue attachment. The patch also has two polypropylene straps that facilitate placement, positioning, and fixation. The presence of the "pocket" on the top surface of this device allows the patch to be effectively sutured to the fascia of the defect. The patch should be placed in a retromuscular or intraperitoneal position. The Ventralex® Hernia Patch is available in three sizes: small (4.3 cm diameter), medium (6.4 cm diameter), and large (8 cm diameter).

The Biomesh Cabs'Air® Composite (Cousin Biotech Wervicq Sud France) is also a round dual-layer mesh polypropylene and ePTFE. It is delivered with two or four polyethylene terephthalate fixation threads, crimped of stainless steel needles at the cardinal points, and a balloon to properly deploy the mesh intraperitoneally. The implant expands and extends by inflating the balloon with air. Once the implant is fixed (sutured by two or four double threads), the balloon is removed by a central orifice of approximately 1 cm in diameter. The Biomesh Cabs'Air® Composite comes in three sizes of 5, 7, and 9 cm in diameter (the small one, without balloon) used for the intraperitoneal position (Fig. 1).

In this study, the size of the device used was determined by the surgeon performing the procedure and adapted to the defect: for less than 3-cm defects, the medium-sized Ventralex® (6.4 cm) and Cabs'Air® (7 cm) were used, and for defects equal or greater than 3 cm, the largest Ventralex® 8 cm and Cabs'Air® 9 cm were used.

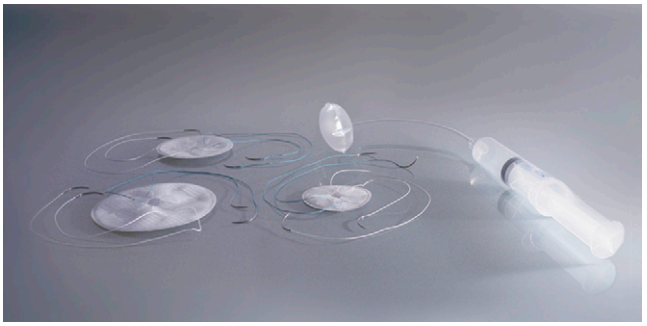

FIG. 1. Biomesh Cabs'Air Composite.

The Fixation of the Mesh

Ventralex® Hernia Patch

After placing the mesh in an intraperitoneal position, the two shapes were pulled up and fixated to the edge of the hernia defect with a nonabsorbable suture. The straps were then cut at the limit (5 mm) of the edge; the fascia was reapproximated with absorbable suture (Vicryl®; Ethicon).

Biomesh Cabs'Air® Composite

Before placing the mesh into the intraperitoneal cavity, the two (or four) double threads (nonabsorbable) were placed through the fascia, under view control, at the limits of the mesh (two or four cardinal points) to secure the entire deployment. Then, the mesh is introduced into the peritoneal cavity through the defect; the implant expands and extends by inflating the balloon with air. After removing the balloon (deflated) though the central small orifice, the fascia is sutured with absorbable suture.

The prosthetic patch used was selected at random the day before surgery. After the operation, patients remained in the surgery unit for up to 6 hours and were then discharged home.

Follow-up

Patients were systematically followed 1 week and 1 and 3 months after surgery (any complication at these time points was noted and treated). After 3 months, patients where then followed every 6 months. They were examined in the outpatient clinic by an independent surgeon (H.B.), who was blinded to the study randomization results. In cases in which the patient did not attend the follow-up visit, telephone interviews were conducted with the patient and their physician. These patients were also asked to complete and return a questionnaire by mail.

End Points and Data Analysis

The main end point of the study was recurrence at the mean long-term follow-up point. Recurrence was defined as a defect of the midline aponeurosis around the umbilicus at the site where the operation had been performed. For cases of incisional herniation, recurrence was defined as a defect of the abdominal wall after previous repair with one of the two meshes.

The second primary end points included the rate of early (at 3 months) postoperative complications (seroma,

hematoma, superficial wound infection, mesh infection) and the rate of long-term (at the later follow-up visits) complications (chronic pain, mesh infection, subobstruction) and rate of reoperation.

Additional End Points

Pain was evaluated by patient self-assessment preoperatively and at Week 1 (W1), Month 1 (M1), and 3 months (M3) after surgery using a visual analog scale (VAS). The VAS with O equaling no pain and 100 equaling the worst conceivable pain was presented to the patient, who selected a number on the scale that corresponded to the worst level of pain experienced during the period since the previous evaluation. Pain was classified according to the VAS into mild (1 to 30 mn), moderate (31 to 60 mn), and severe (greater than 60 mn). Absence of pain was defined as VAS = 0.

Discomfort was a more general term used to describe less severe pain. Discomfort is often used to describe a noncontinuous sensation in the hernia site that does not require analgesics. It was assessed preoperatively and at W1, M1, and M3 using VAS.

Quality of life (QoL) was measured using the Short Form Health Survey questionnaire, SF-12.[16] This is a self-administered 12-item questionnaire that measures health-related functions in eight domains: physical resulting from emotional problems, energy, fatigue, emotional well-being, social functioning, pain, and general health. Each scale was then standardized so that it ranged from 0 (lowest level) of functioning to 100 (highest level).

Evaluation of mesh placement including handling, quality, and time for placement was rated by the surgeon on a scale from 0 to 5 (excellent) and surgeon's satisfaction (from 0 to 100).

Duration of initial hospital stay and time to return to normal activities (physical, sport, and professional) were evaluated.

Use of World Health Organization (WHO) Class I to II analgesic drugs during the entire follow-up period were evaluated. Antalgic drugs, using the WHO classification, were offered to the patients and used if necessary. The protocol included Bi-profenid® (Ketoprofène, Laboratoire Sanofi Aventis France): 100 mg, one pill morning/evening and Ixprim® (Laboratoire Sanofi Aventis France) (Tramadol® + 325 mg Paracetamol): three pills/day 5/8 hours. Consumption evaluation scale was from 0 to 5 per day (number of pills).

Cost (in the French Health System) was evaluated.

Patient's satisfaction at 3 months as determined by the answer to the question: "Would you be willing to undergo the same type of operation again?" was evaluated.

Statistical Analysis

The minimum number of patients in each study group was calculated based on the assumption that reduction of recurrence incidence from 10 to 2 per cent or less (as observed in the literature with the Ventralex® Hernia Patch[8–15] after 42 months follow-up would be clinically significant. With this assumption, a test power of 80 per cent and an alpha level of 0.05, we calculated showing that 40 patients were needed in each group study. The final patient number per group was 42 secondary to anticipation of possible "losses." All statistical analysis were performed using the SAS (Version 9.2) software package. The results are reported with 95 per cent confidence intervals and a 5 per cent level of significance. No corrections for multiple testing were performed. Descriptive statistics were used to characterize patient groups, and mean (standard deviation) or median values (range of values) depending on the type of data and a normal data distribution in the interval scales. Qualitative data were summarized using frequency tables (frequency and percentages) and were analyzed qualitatively. Frequency distributions were compared with the χ^2 test. For SF-12 scores at baseline and after 3 months, the Student's t test for paired samples was used.

The study was approved by the hospital's Institutional Review Board.

Results

Patients

A total of 98 patients undergoing midline hernia repair were identified from the database. Fifteen patients did not agree to enter the trial and were excluded. Overall, 83 patients were included in the study. The population included 44 females (53%) and 39 males (47%) with a mean age at presentation of 42.6 years (range, 19 to 68 years). The average body mass index of this population was 28.4 kg/m^2 (range, 19 to 34 kg/m^2). The preoperative comorbidity prevalence rate was 38.5 per cent (arterial hypertension [7.2%], chronic respiratory diseases [1.2%], diabetes mellitus [7.2%], tobacco use [25.3%], and constipation [7.2%]). Twenty-four patients (32.5%) reported no professional activity (retired 21.6%, unemployed 8.6%), 27 (32.5%) were manual workers, and 31 (37.3%) engaged in sedentary professional activity. Fourteen patients (16.8%) reported active participation in sports.

Surgery

Three types of abdominal wall hernias were repaired: umbilical, n = 68 (82%); epigastric, n = 7 (8.4%); and small incisional, n = 7 (8.4%). A total of 76 patients

TABLE 1. *Preoperative Data (demographics)*

	Ventralex®	Cabs'Air®	*P* value
Number	41	42	
Male/female	21/20	18/24	NS
Mean age (years) (range)	42 (19–64)	37 (21–68)	NS
Comorbidity (prevalence, %)			NS
Patient-related risk factors	5/41 (36.5%)	7/42 (40.4%)	
Diabetes mellitus	3	4	
Lung disease	0	1	
Arterial hypertension	3	3	
Tobacco use	11	10	
Constipation	3	4	
ASA Score I	18 (44%)	22 (52%)	NS
Score II	23 (56%)	20 (48%)	
BMI index (kg/m^2), range	30.4 (19–34)	29.6 (24–34)	NS
Professional activity (prevalence, %)			
No (retired/jobless)	14 (26.8)	13 (31%)	NS
Manual work	13 (31.7)	14 (33.3%)	NS
Sedentary	15 (36.5)	15 (36%)	NS
Sport (active) (no.; %)	8 (19.5%)	6 (14%)	NS
Type of hernia (percentage)			
Umbilical	34 (83%)	34 (81%)	NS
Epigastric	4 (9.7%)	4 (9.5%)	NS
Incisional	3 (7.3%)	4 (9.5%)	NS
Mean duration of hernia (years)	1.8 (0.3–8)	1.4 (0.6–7)	NS
Pain (VAS), range	30 (0–40)	26 (0–55)	NS
Discomfort (VAS), range	37 (10–60)	30 (0–52)	NS

ASA, American Society of Anesthesiologists; BMI, body mass index; VAS, visual analog scale; NS, nonsignificant.

(91.6%) presented with a primary (first) hernia and seven (8.4%) were treated for a recurrent hernia (all hernias had previously been treated with suture repair). The mean duration of the hernia was 1.6 ± 3.9 years. Forty-nine patients (59%) had a hernia defect that was greater than 3 cm in diameter, whereas 34 defects (41%) were less than 3 cm in diameter. All the patches were placed intraperitoneally (100%). No anesthetic complications and no surgical deaths were reported.

Comparisons between the two groups are reported in Table 1 (preoperative data) and Table 2 (preoperative SF-12 questionnaire). Operative data are reported in Table 3. The median size of the incision was similar for the two groups (4.6 cm [3 to 7] *vs* 4.3 [3 to 6]). The mean collar diameter of the hernias was comparable (3.6 ± 1.7 cm). The size of the patch used was also comparable: medium: Ventralex®, n = 17; Cabs Air®, n = 17; and large: Ventralex®, n = 24, and Cabs Air®, n = 25. The difference in size between the two prosthetic patches accounts for the difference of mean overlap found for the two groups (2.3 ± 0.6 *vs* 3.4 ± 0.8, P = 0.001). No patient had concomitant surgery. The mean "skin to skin" operating time was significantly reduced in the Cabs'Air® group (25 ± 3.7 *vs* 34 ± 4.2 minutes, P = 0.01). Early postoperative data are reported in Table 4. Seventy-nine patients (95.1%) were discharged 3 to 5 hours after surgery, and no patient required readmission to the hospital. At 30 days, the morbidity was low for the two groups: 0 per cent for Cabs'Air®, one hematoma, and one case of wound sepsis in the Ventralex® group (4.8%) requiring explantation of the mesh. There was no difference concerning analgesic consumption during a mean period of 2.2 ± 1.3 days. There was also no difference concerning return to physical, professional (14.8 ± 7.6 days), or athletic (23.4 ± 5.4 days) activities. Evaluation of pain and discomfort using the VAS scale is reported in Table 5.

There was a statistically significant difference in favor of the Cabs'Air® group at 1 and 3 months for pain and at 3 months for discomfort. QoL improved significantly from the preoperative visit to 3-month postoperative in all domains for the SF-12 questionnaire (Table 6) for patients in the Cabs'Air® group. Theses results support the finding that at 1 month after surgery, 94 per cent of the patients in the Cabs'Air® group and 73 per cent in the Ventralex® group reported that they were very satisfied with the procedure and would choose the same operation again ($P = 0.01$). The surgical cost was similar for the two groups in the French health system.

The mean follow-up was 42 months (range, 14 to 70 months). It was similar for the two groups (Table 7). Six patients were lost to follow-up (three in each group). All further reported observations are based on 77 patients who underwent long-term follow-up physical examination (n = 48 [(62.3%]; 25 *vs* 23) or completed the postal questionnaire (n = 17 [22.1%]; nine *vs* eight) and a telephone interview (n = 12 [15.6%]; six *vs* six).

At long-term evaluation, 10 patients (19%) reported discomfort in the umbilical region in the Ventralex® group; one patient (5.4%) had a mesh infection (one at 3 months after delayed skin ulceration by the straps and one after bowel adhesion at 8 months of follow-up). One acute bowel obstruction (2.6%) was reported at 13 months as a result of bowel incarceration between the mesh and the wound, and six cases of severe pain, VAS greater than 60, (mean, 8 months; range, 3 to 15 months) correlated with a subcutaneous mass sensation and/or feeling of a foreign body (15.7%), especially in slim athletic female patients. Six reoperations were required ($P = 0.01$) during follow-up: one for mesh infection, three for recurrences, one for bowel obstruction, and one a "meshoma" mass. In these cases,

TABLE 2. *Preoperative SF-12 Quality-of-life Domain Measurement*

SF-12 Domain	Ventralex® (n = 41)	Cabs'Air® (n = 42)	*P* Value*
Physical functioning	62.46 ± 34.75	59.64 ± 43.84	NS
Role limitation as a result of physical health	64.47 ± 24.46	64.32 ± 38.22	NS
Bodily pain	62.58 ± 23.84	62.34 ± 28.76	NS
General health	66.74 ± 18.15	65.48 ± 34.15	NS
Vitality	47.25 ± 19.74	47.44 ± 24.37	NS
Social functioning	76.45 ± 25.48	72.71 ± 29.46	NS
Role limitations as a result of emotional problems	72.22 ± 24.37	73.29 ± 31.18	NS
Mental health	65.34 ± 17.84	69.36 ± 28.3	NS
Physical component +	0.67 ± 0.82	0.68 ± 0.43	NS
Mental component +	0.23 ± 0.44	0.24 ± 0.84	NS

* Mean ± standard (Student's *t* test).
NS, nonsignificant.

three suture repairs were performed (sepsis, bowel obstruction) and three Cabs'Air® mesh repairs were used (Table 7). The overall late complication rate was significantly ($P = 0.01$) higher in the Ventralex® group (21%). The risk of recurrence was significantly ($P = 0.01$) lower for Cabs'Air® (0%) than for Ventralex® (n = 4 [11.7%]).

DISCUSSION

Midline ventral hernias are common in adults. In the Danish Ventral Hernia Data Base,[17] 5629 elective ventral hernias: umbilical 45 per cent, incisional 33 per cent, primary epigastric 16 per cent, trocar site 2 per cent, and other rare or nonclassified hernias, were registered during a 2-year follow-up. The concept that primary and recurrent ventral hernias are best repaired with abdominal wall reinforcement is supported by several studies,[18, 19] although several other publications indicate that suture repair remains a valid option for many patients.[20, 21] If mesh is used, it can be positioned underneath the rectus muscles in a preperitoneal or intraperitoneal position.[22] Mesh with a dual layer has been developed to inhibit the formation of adhesions of the viscera to the mesh being positioned inside the peritoneum. The design of these meshes as used in our study, developed for the specific indication of a small ventral hernia, allows introduction through a small incision with a mesh of appropriate size to cover the hernia defect (not larger than the hernia defect itself). Most of these mesh devices have a built-in system of expansion to keep the mesh flat after introduction, and therefore, it appears that these meshes do not need fixation at the edge of the mesh to maintain postimplantation deployment of the mesh.[23]

Different mesh devices are available for repair of small hernias: Proceed® Ventral patch (Ethicon, Johnson & Johnson Sommerville, NJ) is a self-expanding, partially absorbable flexible laminate mesh; C Qur® V. Patch (Atrium Medical Corporation, Hudson, NH) is a round mesh that combines polypropylene mesh with an all natural pharmaceutical-grade omega-3 fatty bioabsorbable coating; and Cabs'Air® composite (Cousin Biotech Wervicq Sud France) is a round dual-layer mesh device made out of polypropylene and ePTFE delivered with two to four fixation sutures at the cardinal points and a balloon to properly deploy the mesh intraperitoneally. There have not been any prior medical

TABLE 3. *Operative Data*

	Ventralex®	Cabs'Air®	*P* Value
No.	41	42	
Anesthesia:			
General	40	40	
Local	1	2	NS
Skin incision (cm), mean (range)	4.6 (3–7)	4.3 (3–6)	NS
Mean collar diameter (cm)	3.7 ± 1.6	3.4 ± 1.9	NS
Size of the mesh (cm) (%)			
Small, n = 0 (0%)	0	0	NS
Medium, n = 34 (41%)	17	17	NS
Large, n = 49 (59%)	24	25	NS
Mean overlap (cm)	2.3 ± 0.6	3.4 ± 0.8	0.01
Mean operative time (minutes)	34.6 ± 11.7	25.7 ± 14.2	<0.01
Surgeon satisfaction (%)	62%	95%	0.02

NS, nonsignificant.

TABLE 4. *Early Postoperative Course (1 month)**

	Ventralex® (n = 41)	Cabs'Air® (n = 42)	*P* Value
Hospital stay (hours)	8.6 (4–36)	8.4 (3–48)	NS
Ambulatory	40 (97%)	39 (92.8%)	NS
Wound healing			
Hematoma	1	0	NS
Seroma	0	0	NS
Sepsis (1 month)			
Wound	1	0	NS
Mesh	0	0	NS
Reintervention required	1	0	NS
Return to normal activity (days)			NS
Daily (n = 83)	(n = 41) 2.6 ± 1.4	(n = 42) 2.3 ± 1.6	NS
Work (n = 58)	(n = 29) 14.3 ± 6.7	(n = 29) 15.4 ± 8.6	NS
Sport (n = 14)	(n = 8) 24.2 ± 4.6	(n = 6) 21.3 ± 6.7	
Cost (in Euros) (mean) (French healthcare system)	1700	1700	NS
Patient's satisfaction (%)	73%	94%	0.01

* There was also not any difference concerning return to daily professional (14.8 ± 7.6 days) or sport (23.4 ± 5.4 days) activities.
NS, nonsignificant.

publications on the use of these three devices. Eight studies evaluating the Ventralex® Hernia Patch (Davol Bard, Cranston, RI) have been published.[8–15] Five of these studies have shown that recurrence and complication rates are low. In one study of 51 patients, only one recurrence (2%), two minor wound infections, and one seroma were observed after 1 month of follow-up.[9] Similarly, in a retrospective analysis of 88 patients, there were no recurrences and a low (4.5%) complication rate after a median follow-up of 27 days.[10] A prospective study (101 patients) showed a recurrence and complication rate of 2 per cent after 28.5 months of follow-up,[11] whereas a retrospective review of 152 patients revealed a recurrence rate of 2.6 per cent and a complication rate of 11.8 per cent after a mean follow-up of 15.6 months.[12] The last study (51 postmenopausal women) showed a 36-month recurrence rate of 0 per cent.[14] Conversely, three other studies reported higher long-term recurrence rates. In a first study of 28 patients, Berrevoet[13] reported a recurrence rate of 0 per cent after 1 month of follow-up but 14.8 per cent after a median follow-up of 25 months. The same author, in another study[15] of 60 patients, reported a recurrence rate of 8.3 per cent after a mean follow-up of 31 months. This high recurrence rate (8.9%) was confirmed by Tollens[8] in a prospective study of 135 patients followed for 49 months (range, 13 to 70 months). Its findings were correlated with those obtained by Berrevoet.[15] At reoperation for these recurrences, very often, the device was stiffened up, shrunken in size, and almost concerning, flipped down instead of spreading out well and aligning itself to the abdominal wall. This decreases the overlap and contributes to the high recurrence rate. Reasons for this outcome are the lack of control over deployment when pulling the two straps as well as the fact that two heavyweight layers may cause a significant foreign body reaction with consequent massive fibrosis and shrinkage.[24] Tollens[8] has remarked, during reoperation, that intra-abdominal adhesions were fixed onto the polypropylene side of the mesh. He suggests that when the surgeon holds the Ventralex® Hernia Patch and pulls the straps, the patch flips together and exposes the heavyweight polypropylene layer. High recurrence and late complication rates correlated with the Ventralex® Hernia Patch seem to be associated with a lack of control over deployment. Our study confirmed this finding; short-term results and patient satisfaction were favorable for the two groups. The lack of control over deployment with the Ventralex® Hernia Patch can explain the number of complaints reported regarding discomfort during the mid- and long-term follow-up time points. The high recurrence rate in this group could also be explained by a lower overlap rate for the mesh resulting from a difference in size of the devices (6.4 to

TABLE 5. *Evolution of Pain and Discomfort (comparison of the two groups at Week 1, Month 1, Month 3)*

		Ventralex® (n = 41)	Cabs'Air® (n = 42)	*P* Value
Pain (VAS)	W 1	(n = 41) 23 (0–46)	(n = 42) 17 (0–35)	NS
(mean range)	M 1	(n = 41) 16 (0–52)	(n = 39) 10 (0–21)	0.01
	M 3	(n = 37) 21 (0–67)	(n = 39) 8 (0–14)	0.01
Discomfort (VAS)	W 1	(n = 41) 16 (0–30)	(n = 42) 18 (0–32)	NS
(mean/range)	M 1	(n = 41) 23 (0–51)	(n = 39) 14 (0–42)	NS
	M 3	(n = 37) 26 (0–64)	(n = 39) 14 (0–41)	0.02

W, week, M, month, NS, nonsignificant.

TABLE 6. *Quality-of-life (3 months) SF-12 Domains (means ± standard deviation)**

	Ventralex (n = 34)			Cabs'Air® (n = 36)		
	Preoperative	3 Months	*P*	Preoperative	3 Months	*P*
Physical functioning	62.46 ± 34.75	68.8 ± 33.0	NS	59.64 ± 43.84	77.6 ± 32.5	0.001
Role limitation resulting from physical health	64.47 ± 24.46	61.3 ± 23.1	NS	64.32 ± 38.22	78.1 ± 20.4	0.01
Bodily pain	62.58 ± 23.84	72.0 ± 24.3	NS	62.34 ± 28.76	83.0 ± 21.3	0.001
General health	66.74 ± 18.15	68.4 ± 16.4	NS	65.48 ± 34.15	70.0 ± 19.5	0.01
Vitality	47.25 ± 19.74	51.0 ± 1.9	NS	47.44 ± 24.37	55.0 ± 21.4	0.5
Social functioning	76.45 ± 25.48	76.9 ± 26.3	NS	72.71 ± 29.46	87.1 ± 18.8	0.001
Role limitation resulting from emotional health	72.22 ± 24.37	75.1 ± 23.1	NS	73.29 ± 31.18	83.5 ± 18.9	0.001
Mental health	65.34 ± 17.84	71.4 ± 18.3	NS	64.34 ± 16.7	72.9 ± 18.8	0.01
Physical component	0.23 ± 4.4	0.66 ± 0.81	NS	69.36 ± 28.3	0.76 ± 0.68	0.001
Mental component	0.67 ± 0.82	0.24 ± 0.91	NS	0.68 ± 0.43	0.36 ± 0.74	0.001

* Comparison between the two groups of patients (SF-12 domains) comparing preoperative visit and Month 3 using Student's *t* test.
NS, nonsignificant.

8 cm *vs* 7 to 9 cm). The placement of the Cabs'Air® mesh appears easiest and quickest ($P = 0.01$), which supports the high surgeon satisfaction rate. At 1 month of follow-up, there was less pain and discomfort ($P = 0.01$) in the Cabs'Air® group with a higher patient satisfaction rate (94 *vs* 83%) confirmed in all domains of the SF-12 questionnaire. The mean follow-up of the study was 3 years. The majority of Ventralex® complications occurred after 1 year. They can be attributed to the characteristics of the device: smaller size, lack of deployment, and poor or no fixation. According to Muyssoms,[23] recurrences should be correlated with shrinkage of the mesh. He reports a case in which the Ventralex® Hernia Patch had a dimension of approximately 3.0 cm in diameter. This correlates to shrinkage from a starting diameter of 6.4 cm (77.9%). The advantage of the Cabs'Air® device (complete deployment with the balloon; peripheral fixation with two or four sutures, absence of straps for positioning the device) accounts for the easy, quick, and secure placement and deployment. Fixation avoids shrinkage and perfect spreading avoids adhesion to the peritoneal viscera. The difference between results for the two study populations appeared at 3 months of follow-up: less pain, less discomfort, and better QoL when measured by the SF-12 questionnaire. The difference between the two devices compared in this study increased with the follow-up time: three recurrences at 2 years, four recurrences at 3 years, and 21 per cent of late complications with six cases of explantation. We do not have any experience and there is no publication concerning the use of new Ventralex™ ST (Davol Inc.), which is an all lightweight polypropylene mesh with composite Seprafilm® coating.

The main limitation of the present study included the small patient population (n = 83) although findings were statistically significant. In addition, recurrence may be asymptomatic and, consequently, only detectable during ultrasound examination. Because six (7.2%) patients did not attend follow-up visits, it is possible that some recurrences were not detected.

Conclusion

The results of this study show that use of the bilayer dual round prosthesis with open limited access offers a simple and efficient means of repairing small abdominal wall hernias. The early results are favorable. The use of a device as Cabs'Air®, which allows the balloon for controlled deployment and good fixation, increases at 3 months (pain, discomfort and QoL and decreases the risk of late recurrences or complications). It has been shown that the high percentage of recurrences and the late complications rate with the Ventralex® Hernia Patch are the consequence of poor spreading, associated with shrinkage that accounts for the associated severe pain, mass syndrome, feeling of a foreign body, adhesion, mesh infection, and a higher rate of recurrences. The characteristics of the Cabs'Air®

TABLE 7. *Complication during Follow-up*

	Ventralex® (n = 38)		Cabs'Air® (n = 39)		*P* Value
Mean follow-up (months)	36	(10–54)	36	(8–53)	NS
Mesh infection	1	(2.6%)	0	0%	NS
Bowel obstruction	1	(2.6%)	0	0%	NS
Severe pain (VAS > 60)	6	(15.7%)	0	0%	0.01
Mass sensation	6	(15.7%)	0	0%	0.01
Feeling body foreign	6	(15.7%)	0	0%	0.01
Total comorbidity	8/38	(21.05%)	0/39	0%	0.01
Recurrence	4	(15.7%)	0	0%	0.01
Reoperation (explantation)	6	(15.7%)	0	0%	0.01

VAS, visual analog scale; NS, nonsignificant.

device help to avoid these complications and thus should be preferred to the Ventralex® Hernia Patch.

Acknowledgments

We thank Adriana Torcivia, Andrea Lazzati, and Nabil Rizk for their participation in the study. The definitive version was rewritten by Jacklyn Jeruss, Assistant Professor, North Western University Chicago. The statistical analysis was controlled by the University Statistical Unit.

REFERENCES

1. Rosenthal RA. Small bowel disorders and abdominal wall hernia in the elderly patient. Surg Clin North Am 1994;74:261–91.

2. Rodriguez JA, Minder RA. Surgical management of umbilical hernia. Oper Tech Gen Surg 2004;6:156–64.

3. Schumacher OP, Peiper C, Lörken M, Schumpelick V. Long term results after Spitzy's umbilical hernia repair. Chirurg 2003;74: 50–4.

4. Witherspoon P, O'Dwyer PJ. Surgeon perspectives on options for ventral abdominal wall hernia repair. Results of a postal questionnaire. Hernia 2005;9:259–62.

5. Arroyo A, Garcia P, Peres F, et al. Randomized clinical trial comparing suture and mesh repair of umbilical hernia in adults. Br J Surg 2001;88:1321–3.

6. Sanjay P, Reid TD, Davies EL, et al. Retrospective comparison of mesh and sutured repair for adult umbilical hernias. Hernia 2005;9:248–51.

7. Arroyo Sebastian A, Perez F, Serrano P, et al. Is prosthetic umbilical hernia repair bound to replace primary herniorrhaphy in adult patient? Hernia 2002;6:175–7.

8. Tollens T, Den Hondt M, Devroe K, et al. Retrospective analysis of umbilical, epigastric and small incisional hernia repair using the Ventralex™ hernia patch. Hernia 2011;15:531–40.

9. Hadi HIA, Maw A, Sarmah S, Kumar P. Intra peritoneal tension free repair of small midline ventral abdominal hernia with a Ventralex® hernia patch: initial experience of 51 patients. Hernia 2006;10:409–13.

10. Martin DF, Williams RT, Mulrooney T, Voeller GR. Ventralex® mesh in umbilical epigastric hernia repairs: clinical outcome and complications hernias. Hernia 2008;12:379–83.

11. Vychnevshaia K, Mucci-Hennekine S, Casa C, et al. Intraperitoneal mesh repair of small ventral abdominal wall hernias with a *Ventralex*® hernia patch. Dig Surg 2010;27:433–5.

12. Iversen E, Lykke A, Hensler M, Jorgensen LN. Abdominal wall hernia repair with a composite ePTFE/polypropylene mesh: clinical outcome and quality of life in 152 patients. Hernia 2010; 14:555–60.

13. Berrevoet F, Van den Bossche B, de Baerdemacker L, de Hemptine B. Laparoscopic evaluation shows deficiencies in memory ring deployment during small ventral hernia repair. World J Surg 2010;34:1710–5.

14. Tinelli A, Malsavi A, Manca C, Alemanno G, Bettochi S, Benhidjeb T. Post laparoscopic mesh in post menoposal umbilical hernia repair: a case series. Minim Invasive Ther Allied Technol 2011;20:290–5.

15. Berrevoet F, D'Hont F, Rogiers X, et al. Open intraperitoneal versus retromuscular mesh repair for umbilical hernias less than 3 cm diameter. Am J Surg 2011;201:85–90.

16. Ware JE, Snow KK, Kosinski M, Gaudek B. SF36 Health Survey Manual and Interpretation Guide. Boston, MA: New England Medical Center, The Health Institute, 1993.

17. Helgstrand F, Rosenberg J, Bay Nielsen M, et al. Establishment and initial experiences from the Danish Ventral Hernia Data Base. Hernia 2010;14:131–5.

18. Burger JW, Roland J, Luijendijk RW, et al. Long term follow up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg 2004;240:578–85.

19. Stabillini C, Stella M, Frascio M, et al. Mesh versus direct suture for repair of umbilical and epigastric hernias. Ann Ital Chir 2009;80:183–7.

20. Halm JA, Hersterkamp J, Veen HF, Werdema WF. Long term follow up after umbilical hernia repair: are there risk factors for recurrence after simple suture and mesh repair. Hernia 2005;9:334–7.

21. Courtney CA, Lee AC, Wilson C, O'Dwyer PJ. Ventral hernia repair: a study of current practice. Hernia 2003;7:44–6.

22. Millikan KW, Baptista M, Amin B, et al. Intra peritoneal underlay ventral hernia repair utilizing bilayer expanded poly tetrafluoroethylene and polypropylene mesh. Am Surg 2003;69:287–91.

23. Muysoms FE, Bontinck J, Pletincks P. Complications of mesh devices for intra peritoneal umbilical hernia repair: a word of caution. Hernia 2011;15:463–8.

24. Bringman S, Louze J, Cuccurullo D, et al. Hernia repair: the search of ideal meshes. Hernia 2010;14:81–7.