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Review Article

Rives-Stoppa Repair of Incisional Hernias Using PVDF Mesh: A 10-Year Experience of a Dedicated Surgical Team

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Abstract

Background: Ventral hernia repair is one of the most common operations in general surgery. However, the procedure can be associated with significant postoperative complications, especially in the case of incisional hernias. The purpose of this study is to investigate the outcomes of PVDF mesh in the Rives-Stoppa repair of incisional hernias.

Methods: This retrospective observational study, based on prospectively collected data, presents data from 115 patients with incisional ventral hernia who underwent elective Rives-Stoppa repair with PVDF mesh (DynaMesh®-CICAT or DynaMesh®-IPOM) between April 2009 and March 2020. The procedure was combined with component separation in 53 (46%) patients. Mean follow-up was 43 months.

Results: Early complications occurred in 10 (8.7%) patients, including 4 (3.5%) hematomas, 3 (2.6%) surgical site infections, 1 (0.9%) haemorrhage, 1 seroma and 1 death. All of these complications occurred in patients treated without component separation, except for one hematoma. 98 patients were included in the long-term follow-up. Late complications were recorded in 9 (9.2%) patients, including 6 (6.1%) cases of prolonged moderate pain and 3 (3.1%) recurrences. There was no mesh infection or ileus/obstruction. According to the Carolinas Comfort Scale (CCS), the patients' quality of life was high.

Conclusion: The results obtained with the Rives-Stoppa technique confirm its status as the gold standard for open incisional hernia repair, especially due to its good combination with component separation in complex cases. Anterior and posterior component separation provided similar results. The repair of incisional hernias with PVDF meshes (DynaMesh®-CICAT or DynaMesh®-IPOM) revealed low recurrence and overall low complication rates. Mesh-related complications did not occur during the follow-up.

INTRODUCTION

Repair of ventral hernias is one of the most common operations in general surgery. However, the procedure can be associated with considerable complications such as surgical site infection, hernia recurrence and reoperation, creating a vicious cycle of repair, complication, recurrence and re-repair, with each recurrence increasing the complexity of the subsequent repair [1]. For this reason, improving outcome should be a major concern when planning ventral hernia repair, especially for incisional hernias.

Mesh reinforcement in incisional hernia repair was popularised by Usher et al in the late 1950s [2]. The subsequent frequent utilisation of mesh techniques led to a significant reduction in recurrences after hernia surgery compared to primary suture repair [3-5]. Nowadays there is a wide range of different synthetic, biosynthetic and biological materials available. The choice of material usually depends on a variety of considerations, including the characteristics of the patient and the defect, the location where the mesh should be implanted (extraperitoneal or intraperitoneal) and the surgeon's preference. Polyvinylidene fluoride (PVDF), as a well-established synthetic polymer in medicine since the 1960s, has proven useful for the manufacture of suture material and surgical mesh as it has great biological, chemical and mechanical properties [6-8]. In particular, its high biocompatibility, high resistance to degradation and the unnecessity to supplement additives qualify PVDF as excellent biomaterial [7, 9-11].

Although the main goal of incisional hernia repair remains to reduce recurrences, early and late complications, including mesh-related complications, after surgery need to be considered as they may have a significant impact on the patient's quality of

life (QoL). QoL assessment is particularly useful to evaluate the success of the surgical intervention from the patient's point of view. QoL after hernia surgery was usually assessed with one of the existing validated generic QoL questionnaires as the SF-36 or the EQ-5D survey. These questionnaires, however, has been deemed too generic for patients undergoing hernia repair with mesh [12,13]. For this reason, a specific QoL survey considering mesh, the Carolinas Comfort Scale, was developed and validated to assess patient-perceived symptoms and satisfaction [13,14].

The purpose of the present study is to investigate the outcomes of PVDF mesh in the Rives-Stoppa repair of incisional hernias over a period of 10 years including the patients' QoL.

MATERIAL AND METHODS

All patients with primary or recurrent incisional ventral hernia who underwent elective Rives-Stoppa repair with PVDF mesh (DynaMesh®-CICAT or DynaMesh®-IPOM both from FEG Textiltechnik mbH, Aachen, Germany) between April 2009 and March 2020 were selected from the prospectively maintained database of the abdominal wall unit of Policlinico Umberto I – Sapienza University of Rome, Italy. All operations were performed by two experienced senior surgeons. Demographic and surgical data (Table 1) as well as early postoperative outcomes (Table 2) were obtained from the medical records.

Informed consent was obtained from all the patients before they were surgically treated.

According to the internal guidelines of the clinic, all patients were clinically examined 1, 3, 6, 12 months after surgery and then annually. In addition, patients were contacted by phone for the final follow-up of this study. A preliminary inquiry was carried out to determine the general state of health and the presence of complications related to the previous surgery. In case of positive or inconclusive answers, patients were invited for an additional clinical examination.

Following the negative inquiry or after the clinical examination, patients were asked to answer the Carolina Comfort Scale (CCS) questionnaire, a specific tool for assessing quality of life (QoL) after hernia surgery with mesh. The CCS is a 23-item survey that measures the presence and the severity of pain, mesh sensation and movement limitations on a 6-point Likert scale from 0 (= no symptoms) to 5 (= disabling symptoms) in 8 categories (while laying down, bending over, sitting up, performing activities of daily living, coughing or deep breathing, walking, stair climbing, and exercising). The CCS score results from the addition of the scores from each of the 23 items and ranges from 0 (best score) to 115 (worst possible score) (Figure 1,2) [13].

Statistical Analysis

Microsoft Excel was used to calculate the descriptive statistics; continuous variables are reported as mean (range) and categorical variables as absolute numbers (percent).

RESULTS

A total of hundred fifteen patients, 64 (55.7%) male and 51 (44.3%) female, were included in the study. Mean age was 62 years (range: 36-80 years) and mean body mass index (BMI) 27.0 kg/m^2 (range: 19.7-39.5 kg/m^2). A recurrent incisional hernia was diagnosed in 22.6% (n = 26) of cases. The most frequently observed comorbidities were 21.7% current smoker, 19.1% neoplastic disease, 13.0% BMI 30-40 kg/m^2, 12.2% dysmetabolic disease and 9.5% chronic respiratory disease. The mean size of the abdominal wall defect was 112.8 cm^2, ranging from 23 to 318 cm^2. According to the EHS classification, incisional hernias were classified most as M4 and M2 with 27.8% and 27.2%, respectively, followed by M3 with 20.0%, M5 18.3%, M1 and L2 each 2.6%, and L1 with 0.9%. One patient had a combined M4 and L3 hernia (Table 1).

DynaMesh®-CICAT was used in 60 (52%) and DynaMesh®-IPOM in 55 (48%) cases. The latter implant was only used in patients with particularly thin peritoneum. Depending on the size of the hernia defect and according to the physical characteristics of the patient, the mesh sizes ranged from 15x15 to 45x60 cm (Figure 1).

The surgical technique used in all cases was the Rives-Stoppa

Table 1: Demographic and surgical data of patients treated for ventral incisional hernias with Rives-Stoppa repair. Values are presented as absolute number (%) or mean (range).

	DynaMesh®-CICAT (n = 60)	DynaMesh®-IPOM (n = 55)	Total (n = 115)
Female	23 (38.3%)	28 (50.9%)	51 (44.3%)
Age (years)	60.7 (37-84)	63.4 (36-80)	62.0 (36-80)
BMI (kg/m^2)	27.5 (22.1-39.5)	26.4 (19.7-38.8)	27.0 (19.7-39.5)
Comorbidity			
Current smoker	12 (20.0%)	13 (23.6%)	25 (21.7%)
Neoplastic disease	17 (28.3%)	5 (9.1%)	22 (19.1%)
BMI (30-40 kg/m^2)	7 (11.7%)	8 (14.5%)	15 (13.0%)
Dysmetabolic disease	8 (13.3%)	6 (10.9%)	14 (12.2%)
Chronic respiratory disease	7 (11.7%)	4 (7.2%)	11 (9.5%)
EHS classification			
M1: subxiphoidal	2 (3.3%)	1 (1.8%)	3 (2.6%)
M2: epigastric	17 (28.3%)	14 (25.4%)	31 (27.2%)
M3: umbilical	12 (20.0%)	11 (20.0%)	23 (20.0%)
M4: infraumbilical	15* (25.0%)	18 (32.7%)	33 (28.7%)
M5: suprapubic	10 (16.7%)	11 (20.0%)	21 (18.3%)
L1: subcostal	1 (1.7%)	0	1 (0.9%)
L2: flank	3 (5.0%)	0	3 (2.6%)
L3: iliac	1* (1.7%)	0	1 (0.9%)
Recurrent hernia	14 (23.3%)	12 (21.8%)	26 (22.6%)
Component separation	30 (50.0%)	23 (41.8%)	53 (46.1%)
Carbonell Tatay [15]	24 (40.0%)	3 (5.5%)	27 (23.5%)
TAR [16]	4 (6.7%)	14 (25.5%)	18 (15.7%)
Carbonell [17]	2 (3.3%)	6 (10.9%)	8 (7.0%)
Mesh size (cm^2)	1190.2 (600-2700)	1092.3 (225-1350)	1141.2 (225-2700)
Average follow-up (months)	53 (9-132)	34 (1-108)	43 (1-132)

*One patient treated with DynaMesh®-CICAT had an M4 and L3 incisional hernia.

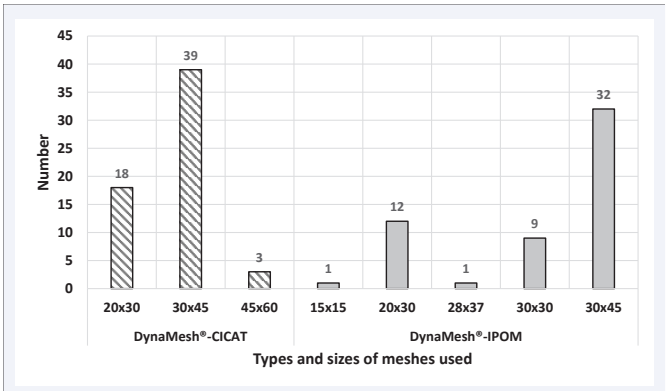

Figure 1 Mesh types and sizes used during the 10-year study period. Bars of DynaMesh®-CICAT are shown hatched. Since we select the mesh size according to the defect size, it can be seen that DynaMesh®-CICAT was used for larger hernias.

repair. In addition, a component separation technique (CST) was performed in 53 patients to achieve midline closure: anterior CST was realized in 27 (24%) cases according to Carbonell Tatay et al. [15], transversus abdominis release (TAR) in 18 (16%) cases according to Novitsky et al. [16], and in 8 (7%) cases reconstruction of the linea alba was achieved using posterior CST according to Carbonell [17].

Overall, the mean length of hospital stay was 10.1 days, with 9.1 days (range: 2-25 days) in the DynaMesh®-CICAT cohort and 11.2 days (range: 4-20 days) in the DynaMesh®-IPOM cohort (Table 2).

Early postoperative complications occurred in 10 (8.7%) patients, including 4 (3.5%) hematomas, 3 (2.6%) surgical site infections, 1 (0.9%) haemorrhage, 1 seroma and 1 death (Table 2). All of these complications occurred in patients treated without component separation, except for a hematoma in one patient who underwent TAR. In the DynaMesh®-CICAT cohort, the seroma and the two hematomas were surgically drained. All surgical site infections were conservatively treated with antibiotics and wound care, including negative pressure wound therapy. One patient treated with DynaMesh®-CICAT had postoperative haemorrhage requiring emergency surgery and one patient treated with DynaMesh®-IPOM died of a massive pulmonary embolism on the second postoperative day.

98 patients were reached by phone for long-term follow-up. 6 (5.2%) patients had died for reasons unrelated to the surgery and 10 (8.7%) patients could not be reached because they had either changed their address or phone number. Late postoperative complications were recorded in 9 (9.2%) patients, including 6 (6.1%) cases of prolonged moderate pain, 2 in the DynaMesh®-CICAT cohort and 4 in the DynaMesh®-IPOM cohort, and 3 (3.1%) recurrences in the DynaMesh®-CICAT cohort confirmed at clinical examinations 1 year, 2 and 8 years after surgery (Table 3). There was no mesh infection or ileus/obstruction.

The Carolinas Comfort Scale (CCS) questionnaire was well accepted by all respondents. Overall, the mean CCS score was 4.1

Table 2: Early postoperative complications. Values are presented as absolute number (%).

	DynaMesh®-CICAT (n = 60)	DynaMesh®-IPOM (n = 55)	Total (n = 115)
Length of stay (days)	9.1 (2-25)	11.2 (4-20)	10.1 (2-25)
Early complications	6 (10.0%)	4 (7.3%)	10 (8.7%)
Haemorrhage	1 (1.7%)	0	1 (0.9%)
Hematoma	2 (3.3%)	2 (3.6%)	4 (3.5%)
Seroma	1 (1.7%)	0	1 (0.9%)
Surgical site infection	2 (3.3%)	1 (1.8%)	3 (2.6%)
Mortality	0	1 (1.8%)	1 (0.9%)
Reoperation	3 (5.0%)	0	3 (2.6%)
Readmission	1 (1.7%)	0	1 (0.9%)

Table 3: Late postoperative complications. Values are presented as absolute number (%).

	DynaMesh®-CICAT(n = 60)	DynaMesh®-IPOM(n = 54)	Total (n = 114)
Reason for loss to follow-up			
Mortality	3 (5.0%)	3 (5.6%)	6 (5.2%)
Not reached*	4 (6.7%)	6 (11.1%)	10 (8.7%)
Late complications	5 (9.4%)	4 (8.9%)	9 (9.2%)
Recurrence	3 (5.7%)	0	3 (3.1%)
Mesh infection	0	0	0
Prolonged pain	2 (3.8%)	4 (8.9%)	6 (6.1%)
Ileus/obstruction	0	0	0
Reoperation	0	1 (2.2%)	1 (1.0%)

*Patients could not be reached because they had either changed their address or phone number.

and ranged from 0 to 40, with the highest score reported in the DynaMesh®-IPOM cohort. The mean CCS score in the DynaMesh®-CICAT cohort was 2.3 (range: 0-16) and in the DynaMesh®-IPOM cohort 6.1 (range: 0-40).

DISCUSSION

The goal of modern ventral hernia surgery, especially incisional hernia, is a low recurrence rate, a low complication rate in terms of surgical site occurrence (SSO) and surgical site infection (SSI) as well as the anatomical-functional restoration of the abdominal wall with a satisfactory aesthetic result. Therefore, the surgical strategy should take into account not only the surgical technique but also a multidisciplinary approach. It should include effective preoperative management aimed at correcting modifiable risk factors such as obesity, smoking, disturbed blood and nutritional parameters as best as possible. Nevertheless, the surgical technique plays an important role in the patient's outcome. In our experience, the Rives-Stoppa technique is the procedure of choice for repairing incisional hernias. The placement of the mesh in the retromuscular space achieves the best results in terms of recurrence and complication rates compared to other open mesh techniques for ventral hernias [18,19].

A pivotal point to achieve a better outcome in ventral hernia repair is the restoration of the linea alba, i.e. closing the midline [20]. Therefore, in cases where midline recuts fascia could not be reapproximated, a component separation technique (CST)

was performed. In our experience, the procedure of choice is the transversus abdominis release (TAR) according to Novitsky et al. [16]; a posterior CST technique that allows for the creation of a large, well-vascularised retromuscular preperitoneal space in which the mesh can be placed with great defect overlap. Maintaining vascularisation and innervation preserves the trophism of the abdominal wall [20].

The anterior CST described by Carbonell Tatay et al., is based on the same principles as the CST described by Ramirez, with the preparation of an avascular plane between the external and internal oblique muscles, extending to the costal plane superiorly and to the pubic symphysis inferiorly [15, 21]. In contrast to the traditional technique of Ramirez et al., the procedure of Carbonell Tatay et al., utilises mesh to reinforce the abdominal wall. The mesh, which slides with its upper margin under the ribs, is attached to the pubis and to the anterior wall. Finally, the external oblique muscle is fixed to the implant to limit its lateralisation and ensure wide mesh coverage to reduce postoperative complications [15]. In our clinical practice, we modify the original technique by fixing the mesh with non-resorbable sutures to the antero-superior iliac spine and bilaterally to the inguinal ligament, and with slowly resorbable sutures and fibrin glue to the costal plane and to the anterior wall. The CST technique of Carbonell Tatay et al., is a good alternative to posterior CSTs, especially when the retromuscular space cannot be used because of injury/violation by previous surgery, prostheses or fixation systems. It also may be indicated if abdominal dermolipectomy needs to be combined with ventral hernia repair. Moreover, in our experience, the learning curve for young surgeons proves to be easier compared to TAR.

Although Krpata et al., found posterior component separation to be superior compared to anterior component separation in terms of recurrence and SSOs [22], in our experience the results of anterior CST are comparable, which is in good agreement with others [23,24].

Among the many biomaterials currently available for hernia repair, the choice of mesh material may depend on several factors, including surgeon's preference, availability and cost. PVDF is a non-resorbable, highly non-reactive fluoropolymer with excellent mechanical, chemical and biological properties, introduced in 2002 for surgical meshes by Klinge et al., [7]. Meshes made of PVDF monofilaments have good biocompatibility. They elicit a minimal foreign body reaction and form much smaller foreign body granulomas compared to polypropylene surgical meshes [11,25,26]. Their high effective porosity reduces the risk of "bridging", i.e. complete filling of the mesh pores by fibrotic tissue and thus excessive scarring [25,26]. Studies on biostability/degradation have demonstrated that suture material and surgical meshes made of PVDF are still stable after several years and do not show any significant visual surface changes [8,10,27]. In the last decade, DynaMesh®-IPOM and DynaMesh®-CICAT have been our first choice for ventral hernia repair.

Some PVDF implants are also available as "visible" variants. These meshes contain a small proportion of triiron tetraoxide that is incorporated into the polymer matrix, enabling the mesh to be visualised in vivo using magnetic resonance imaging. In this way, the position and condition of the mesh can be accurately determined in vivo, facilitating planning and reducing unnecessary revision surgery [28,29].

DynaMesh®-IPOM is a mesh specifically developed for the intraperitoneal onlay mesh technique. It has a parietal and a visceral side; the parietal side consists of PVDF on the surface and a small proportion of PP, whereas the visceral side consist of PVDF on the surface. DynaMesh®-IPOM is intended for the surgical treatment of epigastric, umbilical or incisional hernias, and the treatment of parastomal hernias after ostomy surgery. Although there were some initial concerns about the intraperitoneal use [30-32], numerous studies have demonstrated good results [33-36]. A recently published large nationwide cohort study from the Danish Ventral Hernia Database comparing reoperation rates for recurrence of different mesh types in laparoscopic ventral hernia repair showed that DynaMesh®-IPOM performed best of all mesh types over a median follow-up of almost 10 years [37]. However, as we prefer extraperitoneal mesh placement, we show here the efficacy of DynaMesh®-IPOM in the retromuscular position. We use DynaMesh®-IPOM exclusively in patients with particularly thin peritoneum, which we believe favours the use of a two-sided mesh with a barely adherent material that produces a low inflammatory reaction (PVDF) facing in the direction of the peritoneum and a material that promotes rapid ingrowth (PP) facing away. As shown in Table 1, thin peritoneum was particularly common in patients undergoing TAR.

The other mesh that we routinely use is DynaMesh®-CICAT; a mesh intended to be used only in the extraperitoneal position for the surgical treatment of epigastric, umbilical or incisional hernias, and incisional hernia prevention. The mesh has an anti-slip surface that ensures stable positioning of the mesh and facilitates handling and fixation [38]. Its high effective porosity (~61%) allows for direct contact of tissues through the mesh's pores, promoting rapid incorporation while reducing mesh shrinkage and maintaining elasticity. DynaMesh®-CICAT is our standard mesh for ventral hernia repair. More recently, we have started to use DynaMesh®-CICAT visible which allows for better assessment of patient outcomes. In addition to the annual clinical examination, we now also perform an MRI (CT in patients with previous neoplastic disease) examination. In 19 patients, DynaMesh®-CICAT visible proved effective for controlling the position and condition of the implant, demonstrating surgical success (Figure 2).

Clinical controls at predefined time points (1, 3, 6, 12 months and then annually after surgery) allowed to follow-up more than 90% of patients over time, with only 10 patients lost to follow-up because of address or phone number changes.

Both DynaMesh®-CICAT and DynaMesh®-IPOM show good results in terms of early and late complications (Table 2 and Table 3), which is in concordance with others [33,37-39]. Overall, three (3.1%) recurrences were diagnosed 1, 2 and 8 years after

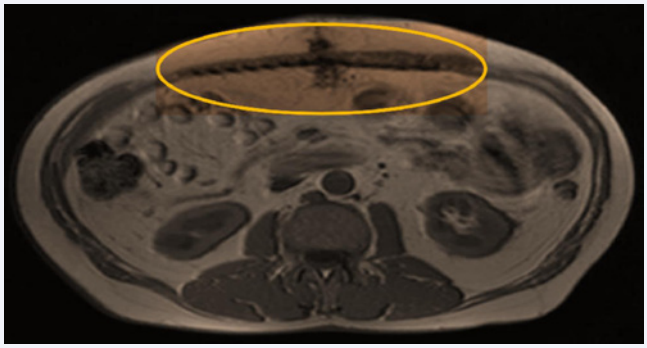

Figure 2 Magnetic resonance image (MRI) of DynaMesh®-CICAT visible in a patient one year after Rives-Stoppa repair with component separation. The hypo-intense "visible" filaments are clearly distinguishable from the surrounding tissues in the abdominal wall. The mesh follows the contour of the abdominal wall without visible folds, consequently there is no or minimal mesh shrinkage.

surgery: One patient was not treated because of exitus unrelated to the previous surgery, another with a previous liver transplant and gastric carcinoma refused further surgery, and the last patient had a recurrence due to a Pfannestiel incision to perform a hysterectomy for uterine cancer.

Our results using PVDF meshes in incisional hernia repair are very satisfying, as demonstrated by the overall low mean Carolina Comfort Scale (CCS) score of 4.1. The CCS questionnaire was well accepted by all patients, who showed high satisfaction and a slight decrease in compliance over time, although a good level was maintained. The results of the CCS show a slightly better quality of life (QoL) in the long term for DynaMesh®-CICAT (2.3 vs. 6.1 for DynaMesh®-IPOM), while QoL was similar in the period immediately after surgery. The reason for this may be the higher effective porosity of DynaMesh®-CICAT (~61% vs. ~43% DynaMesh®-IPOM), which reduces the fibrotic response; this is particularly important for meshes in an extraperitoneal position where tissue grows into the pores from both sides. Consistently, this is also reflected in the number of patients with prolonged pain (2 vs. 4). Our experience with the CCS questionnaire are in line with previous studies that have shown the survey to be an effective tool to measure patient-perceived outcomes after ventral hernia repair [13,14,40].

CONCLUSION

In conclusion, our experience with the Rives-Stoppa technique supports its status as the gold standard for open incisional hernia repair. The technique combined well with component separation in complex cases and allowed complete reconstruction of the linea alba in all cases. With regard to complications, both the anterior component separation according to Carbonell Tatay and the posterior component separation according to Novitsky (TAR) achieved similar results. The repair of incisional hernias with PVDF meshes (DynaMesh®-CICAT or DynaMesh®-IPOM) revealed low recurrence and overall low complication rates. Mesh-related complications did not occur during the follow-up. The Carolinas Comfort Scale proved its efficacy in determining patient-perceived symptoms and satisfaction after incisional hernia repair. The survey proved easy to use, provided reliable results and was well accepted by all patients.

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