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ORIGINAL ARTICLE

Long-term outcomes of Madrid approach after TAR for complex abdominal wall hernias: a single-center cohort study

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Abstract

Purpose Undeniably, in the last 2 decades, surgical approaches in the field of abdominal wall repair have notably improved. However, the best approach to provide a durable repair with low morbidity rate has yet to be determined. The purpose of this study is to outline our long-term results following the Transverse Abdominis Release (TAR) approach in patients with complex ventral hernias, focusing on the incidence of recurrence and overall patient satisfaction following surgery.

Methods This is a retrospective study on 167 consecutive patients who underwent TAR between January 2015 and December 2021 for primary or recurrent complex abdominal hernias. Of these, 117 patients who underwent the open Madrid approach with the use of a double mesh (absorbable and permanent synthetic mesh) were selected and analyzed. A quality of life questionnaire (EuraHS QoL) comparing the preoperative and the postoperative status was administered.

Results Between January 2015 and December 2021, we successfully treated 117 patients presenting with complex ventral defects using the double mesh technique (absorbable and permanent synthetic mesh). Of these, 26 (22.2%) were recurrent cases. At a median follow-up period of 37.7 months, there had been 1 (0.8%) case of recurrence and 8 cases (6.8%) of bulging. The QoL score was significantly improved when compared to the preoperative status in terms of cosmesis, body perception, and physical discomfort.

Conclusions The Madrid approach for posterior component separation is associated with both a low perioperative morbidity and recurrence rate. In accordance with other studies, we demonstrated that the TAR with reconstruction according to the Madrid approach provides excellent results in the treatment of complex abdominal wall hernias, even at long-term follow-up.

Keywords Abdominal wall reconstruction · Incisional hernia · Transversus abdominis release (TAR) · Complex ventral hernia · Madrid technique

Introduction

As surgical procedures continue to be performed with a midline incision, incisional hernias become more frequent [1]. Today, the risk of incisional hernia formation is quoted as high as 20%, increasing with patient risk factors such as age, obesity, tobacco abuse, diabetes mellitus, poor nutrition status and development of Surgical Site Occurrences (SSO) and Surgical Site Infections (SSI) [2]. In the last 2 decades, surgical approaches in the field of abdominal wall repair have notably improved. Nevertheless, complex ventral hernias remain one of the most challenging problems for the surgeons due to the high perioperative morbidity and recurrence rates. Hernias with loss of domain, parastomal hernias, non-midline and close to bony landmark hernias, and recurrent hernias are examples of challenging cases. The best approach to provide a durable repair with low morbidity rate has not been determined. Yet, there are a variety of possible approaches, types of meshes available, and possible locations of mesh placements [3].

In 2012, Novitsky et al. described the transversus abdominis release (TAR) approach in combination with posterior component separation (PCS) [4]. This technique allows wide mesh overlap with nearly any type of abdominal wall defect while affording an extended myofascial release

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to increase the intra-abdominal volume, thus preventing abdominal compartment syndrome and improving the chance of defect closure compared to Rives–Stoppa technique [5, 6]. Furthermore, it preserves rectus innervation by perforating neurovascular bundles and avoids the consequent problems of skin flaps and cutaneous devascularization, that can overcome after the PCS technique described by Carbonell et al. in 2008 [7] or after the anterior component separation technique described by Ramirez et al. in the 1990s [8]. It also creates a functional abdominal wall reconstruction widely reinforced with mesh in a retromuscular, sublay space. The mesh is placed extraperitoneally, preventing contact with abdominal viscera and hence, the development of adhesions. It can be performed even in reconstruction of complex hernia defects, including those close to bones and non-midline hernias, when all the other techniques fail. [2, 9–11].

Due to its visible benefits, TAR gained more and more popularity over time, but it requires anatomical knowledge and meticulous surgical technique.

The aim of this study is to describe our long-term results of TAR in patients with complex hernias using the combination of an absorbable and permanent synthetic mesh as previously described [12], focusing on the incidence of recurrence and patient-reported outcomes.

Methods

This a retrospective study on 117 patients who underwent TAR using the Madrid approach reconstruction between January 2015 and December 2021 for primary or recurrent complex abdominal hernias. Patient's characteristics, perioperative data, length of hospital stay, complication and recurrence rate were retrospectively analyzed from our prospectively collected database.

The defects were classified according to the European Hernia Society (EHS) classification and divided in lateral, medial and combined [13].

Inclusion criteria were patients treated with TAR with the combination of absorbable and permanent synthetic mesh. Exclusion criteria were age < 18, BMI > 40, presence of ileostomy or colostomy and contaminated field type Centers for Disease Control (CDC) III and IV [14, 15]. These patients were excluded because in contaminated fields the wall reconstruction was accomplished with biosynthetic mesh alone. Patients treated by robotic approach (robotic TAR) were also excluded.

All patients underwent a preoperative abdominal computed tomography (CT) at rest and after Valsalva maneuver. During preoperative workup, all patients were invited to optimize any modifiable risk factor (e.g., obesity, diabetes mellitus, smoking). Physical activity was encouraged to reduce body mass index (BMI) if needed [5, 16]. Compression stockings were applied before surgery to prevent deep vein thrombosis (DVT) and a second generation cephalosporin was administered. A TAP block was also performed. Postoperatively, low molecular weight heparin was administered and early mobilization was encouraged. All patients were mobilized on postoperative day (POD) 2 with an abdominal binder and started oral food intake according to Enhanced Recovery After Surgery (ERAS) protocol. The use of an abdominal binder was recommended for at least 1 month and a mild physical activity was allowed at least 3 months after surgery.

All patients were assessed with a clinical examination after discharge at POD 7 with regular clinical follow-up scheduled at 1 month, 6 months, and 1 year after surgery. All patients were invited to contact the surgeon at any time if any problem occurred or every 2 years.

From January to April 2022, patients were contacted by telephone and invited to perform a clinical examination and answer a quality of life questionnaire in which pain, cosmesis and physical discomfort were investigated (EuraHS QoL) comparing it with the preoperative status. If clinical recurrence was suspected at any point during the follow-up period, a confirmatory CT-scan was performed.

Surgical technique

The surgical technique has already been described in previous literature [9, 13, 17]. A midline laparotomy is performed and a complete adhesiolysis is carried out to allow total release of the posterior rectus sheath. The hernia sac is opened and preserved. If an intraperitoneal mesh is present, as much of it is removed as possible.

A large sterile green towel is then placed intraperitoneally above the abdominal viscera and tucked all around. This technique is used to protect the viscera and bowel during TAR and to better identify any minimal perforation in the posterior sheath.

The posterior rectus sheath is incised at the linea alba and the retrorectus space is dissected vertically from superior to inferior. Care is taken in identifying and preserving the neurovascular bundles. Along the arcuate line it is important to preserve the deep inferior epigastric vessels which run along the posterolateral surface of the rectus abdominis muscle. Inferiorly the space of Retzius is exposed with the pubis symphysis and Cooper's ligaments.

To access the TAR space, an incision is performed 0.5 cm medial to the lateral border of the posterior rectus sheath. Dissection is carried out from the arcuate line to the costal insertion of the muscle. The TAR dissection is continued laterally to reach the border of the psoas muscle with blunt dissection and superiorly the central tendon of the diaphragm.

Any accidental perforation of the transversalis fascia/peritoneum is repaired with a PDS 3/0 suture at the end of the retromuscular dissection. The posterior rectus sheaths are approximated to the midline with a number of 4–6 continuous, slowly absorbable sutures.

Two large meshes are used for reconstruction as previously described. A 20 × 30 cm absorbable biosynthetic (GORE BIO-A® Tissue Reinforcement-WL Gore Associates, Inc, Falgstaff, AZ), and a permanent 50 × 50 cm macroporous mid-density polypropylene mesh (Dipromed®; Dipro Medical devices SRL, Torino, Italy). The meshes were properly shaped and placed both in the retromuscular space with the biosynthetic located under the polypropylene. The polypropylene mesh was secured to the subxiphoid area and to the Cooper's ligament bilaterally with three slowly absorbable sutures. Two suction drains were placed on top of the mesh to avoid dead space. Furthermore, we laterally secured the transversus abdominis margins to obtain a more esthetic result. Tissucol (Tisseel; Baxter SPA, Rome, Italy) is spread over the polypropylene mesh. Finally, closure of the anterior rectus sheath is completed with continuous, slowly absorbable sutures. If the fascia cannot be appropriately approximated, we use the hernia sac as a bridge, to complete the closure of the anterior rectus sheath. One or two suction drains are placed in the subcutaneous space to prevent seroma formation. In the last years, we have implemented the use of Negative Pressure Wound Therapy (NPWT) on closed skin wounds (Prevena™ 3 M™, Italy) on patients with higher risk of SSO [18].

Statistical analysis

Statistical analysis was conducted using Statistical Package for Social Science SPSS®ver.22.0.0 software (IBM, Armonk, New York, USA). $P < 0.05$ were considered as statistically significant. Data are presented as number of cases (*n* or %) or mean (range), as appropriate. Student's t test was used to evaluate differences between pre and postoperative scores in the sections of the QoL questionnaire. The ANOVA Kruskal–Wallis' test was used to compare differences in the continuous variables between groups.

Results

A total of 117 patients underwent TAR with the double mesh reconstruction. All of them were evaluated at POD 7, at 1 month, 6 months, and 1 year after surgery, except for one patient who died on the 46th POD. In general, prior to Covid, the follow-up evaluation was done every 2 years or if any problem occurred. Due to the pandemic, the subsequent follow-up after 1 year was suspended for non-malignant diseases in our department, according to the Hospital policy. Once the severe phase of the pandemic was over, we contacted all 116 patients between January and April 2022 to resume a systematic follow-up. At this time, 74 patients (63.2%) actively participated to the follow-up by performing a clinical evaluation and responding to the EuraHS QoL questionnaire.

For the remaining 42 patients (35.9%) who were lost at telephone follow-up at the beginning of 2022 for several reasons (death, unreachable telephone calls, refusal for fear of COVID and because they were feeling well), their last clinical visit was considered as the last follow-up time.

Demographics, surgery outcomes, length of stay and defect characteristics are described in Table 1, according to the EHS classification [19].

Most of the patients (116 cases, 99.1%) had an incisional hernia and only one (0.8%) presented with a primary lumbar hernia. 26 patients (22.2%) had recurrent incisional hernias after abdominal wall surgery and, among these, 21 (80.7%) patients had a previously implanted mesh (12 intraperitoneal, 5 retromuscular, 2 preperitoneal, 1 onlay, 1 inlay). According to CDC wounds classifications [15], all cases were classified as clean or clean-contaminated wounds.

SSO occurred in 31 cases (26.5%). SSI occurred in 8 (6.8%) patients: in 4 (3.4%) of these, a partial dehiscence of the midline wound with positive cultures and mesh exposure was observed. A negative-pressure wound therapy (NPWT) was applied for a mean time of 20 days, until complete wound healing in all patients with partial dehiscence. In two of these cases, the partial dehiscence was due to a subfascial hematoma which drained spontaneously, in the third case, a surgical treatment at bedside was needed. No mesh removal was needed. One (0.8%) liver transplanted patient-reported skin necrosis and died at POD 46 for liver failure. Overall seroma rate was 17% at 6 months and no patient required surgical treatment. No seroma was observed at 1-year follow-up (Table 2).

At time of the last follow-up, a suspicion of clinical recurrence was detected in 9 cases (7.7%) and patients were invited to perform an abdominal CT-scan without contrast, at rest and after Valsalva maneuver, for a radiological confirmation of the clinical suspicion. Only in 1 patient (0.8%) a radiological recurrence was confirmed. Bulging was observed in the remaining 8 (6.8%) cases (Table 2). Length of follow-up is reported in Table 3.

Of the 74 patients who actively participated at recall between January and April 2022, 41 (55.4%) patients responded to the EuraHS QoL questionnaire for the pre- and postoperative time. The QoL score was significantly improved compared to the preoperative one in terms of cosmesis, body perception and physical discomfort. In addition, there was a significant reduction in reported pain, with improvement in daily and sport activities (Table 4).

Table 1 Patients' demographics

Cases			% Total 117
Mean age Years (range)		62.4 (29–87)	
Gender	Male Female	72 45	61.5 37.8
BMI Kg/m^2 (range)		29.2 (21–40)	
ASA	I II III	20 82 15	17.2 70.0 12.8
Comorbidity:			
	Obesity*	44	37.6
	Diabetes	17	14.5
	Smoke	33	28.2
	Quit smoking	39	33.3
Previous abdominal surgery		116	99
	Recurrent hernia	26	22.2
	Multiple recurrences	4	3.4
Hernia location	*Midline* M1 M2 M3 M4	68 12 21 17 18	58.1 10.2 18.0 14.5 15.4
	Lateral L1 L2 L3 L4	17 4 7 4 2	14.5 3.4 6.0 3.4 1.7
	Combination	32	27.4
Number of defects	*N1 (single)* *N2 (double)* *N3 (multiple, swiss cheese)*	54 31 32	46.1 26.5 27.4
Hernia width	*W1 (< 4 cm)* *W2 (4–10 cm)* *W3 (≥ 10 cm)*	0 21 96	0 17.9 82.1
Operative time min, mean (range)		169 (80–370)	
Concurrent abdominal surgery		11	9.4
	Inguinal hernia repair	8	6.7
	Cholecystectomies	3	2.5

BMI: body mass index; ASA: American Society of Anaesthesiology;
*Defined as BMI between 30 and 40 kg/m^2

Student's t test and ANOVA test have been used to statistically evaluate the difference in quality of life before and after surgery, dividing the patients in three classes based on the scores recorded on the test (Tables 5, 6).

Discussion

The treatment of complex ventral hernias is technically demanding, and no surgical approach or choice of mesh has been standardized yet. In 2019, the group from Madrid, in a multicenter prospective study, described for the first time the reconstruction after TAR using the double mesh in the same retromuscular position (Madrid Approach) [12]. APPROACH stands for Absorbable Posterior Reinforcement of Permanent mesh Of a Complex Hernia. Later, they have confirmed positive results in other abdominal wall reconstructions [20–24]. We started our experience in complex surgeries for abdominal hernia repairs using this double mesh technique in 2015, and then progressively standardized our technique as described above.

The absorbable mesh used is made of a biosynthetic polyglycolide-trimethylene carbonate copolymer. This tissue reinforcement is a 3D web of completely absorbable synthetic polymers that has shown in experimental and clinical data that is replaced by soft tissue over 6 months

Table 2 Postoperative outcomes

Cases			% Total 117
SSO	Seroma	31	26.5
	Hematoma	20	17
	Wound cellulitis	3	2.6
	Skin necrosis	0	0
	Wound dehiscence	1	0.9
	SSI	4	3.4
		8	6.8
Other complications			
(Clavien Dindo)	I	5	4.3
	II	1	0.8
	III	1	0.8
	IV	0	0
Death		1	0.8
Reoperation during hospitalization		1	0.8
LOS days, mean (range)		8 (4–47)	
Recurrence			
	Clinical (bulging)	8	6.8
	Radiological	1	0.8
Follow-up		37.4 (1–87)	
Months, mean (range)			

SSO surgical site occurrence, *SSI* surgical site infection, *LOS* length of stay, *FU*: follow-up

Table 3 Follow-up

		Cases (Total 117)	%
Length of follow up (months)	≤ 12	20	17.1
	> 12	16	13.7
	> 24	46	39.3
	> 48	13	11.1
	> 60	22	18.8

[22, 25]. The Cobra study, showed that, using this biosynthetic mesh for reinforcement of the midline closure in the single-staged repair of contaminated ventral hernias, relates to low recurrence and postoperative wound infection rates [26]. This tissue scaffold may also work as mechanical barrier between intra-abdominal contents and the permanent synthetic mesh, avoiding potential adhesions to bowel [22, 27]. As the Madrid group defended, we have checked that its initial rigidity provides a mechanical support to the extension of the permanent mesh, avoiding wrinkling and folding of the large PP mesh fixed cranially and caudally but not laterally, as the original description, in which transparietal fixation were used to extend and fix the mesh [4].

In the last 80 cases, we also reimplanted the lateral border of the dissected transversus abdominis muscle to the mesh to obtain a more physiological reconstruction. This re-attachment of the transversus may avoid subsequent atrophy and lateralization of the muscle usually observed after TAR [28].

Another additional advantage of using the double mesh is that, in case of recurrence requiring a redo surgery, the permanent mesh can be easily peeled off from the fibrous tissue on the peritoneum, so the retromuscular space can be dissected again [29].

In this study, we reported a seroma rate of 17% at 6 months. All patients were treated conservatively and no seroma was present at 1-year visit. This might be explained by the fact that the biosynthetic mesh is completely absorbed. In our series, 8 cases had SSI and 4 cases were treated with NPWT with or without instillation. In these 4 cases, we performed a surgical revision of the wound which is opened bedside to debride and expose the suspect for infection mesh. The treatment can be performed in the operating room or bedside in sedation with the use of local anesthetic. With this treatment, the mesh is saved in the majority of cases, even if it requires several dressing changes.

Regarding our long-term results, we have seen 0.8% recurrences at a mean follow-up time of 37.7 months.

The recurrence rate described by Novitsky in his standard technique was 4.7% with a higher rate of postoperative pain, SSI and SSO (23.8%) at a mean follow-up of 26.1 months [4]. The recurrence rate for the TAR approach reported by Pauli is quoted between 3 and 5% [30]. Krpata et al. reported

Table 4 Quality of life evaluation

			Scores	Cases	% Total 41
Pain	At rest	Pre op	0–3	3	7.3
			4–7	8	19.5
			> 7	30	73.2
		Post op	0–3	39	95.1
			4–7	2	4.9
			> 7	0	0
	In activity	Pre op	0–3	2	4.9
			4–7	5	12.2
			> 7	34	82.9
		Post op	0–3	39	95.1
			4–7	2	4.9
			> 7	0	0
	in the last week	Pre op	0–3	2	4.9
			4–7	11	26.8
			> 7	28	68.3
		Post op	0–3	41	100
			4–7	0	0
			> 7	0	0
Activity limitations	At home	Pre op	0–3	0	0
			4–7	8	19.5
			> 7	33	80.5
		Post op	0–3	40	97.6
			4–7	1	2.4
			> 7	0	0
	Outside	Pre op	0–3	0	0
			4–7	8	19.5
			> 7	33	80.5
		Post op	0–3	41	100
			4–7	0	0
			> 7	0	0
	Sports	Pre op	0–3	0	0
			4–7	11	26.8
			> 7	30	73.2
		Post op	0–3	39	95.2
			4–7	1	2.4
			> 7	1	2.4
	Hard works	Pre op	0–3	1	2.4
			4–7	7	17.1
			> 7	33	80.5
		Post op	0–3	38	92.7
			4–7	3	7.3
			> 7	0	0
Esthetics	Abdominal shape	Pre op	0–3	0	0
			4–7	6	14.6
			> 7	35	85.4
		Post op	0–3	37	90.2
			4–7	4	9.8
			> 7	0	0
	Hernia site	Pre op	0–3	0	0
			4–7	5	12.2
			> 7	36	87.8
		Post op	0–3	35	85.4
			4–7	6	14.6
			> 7	0	0

a recurrence rate of 3.6%, with a 25.5% of wound complications at a mean follow-up of 6.3 months [31].

The encouraging results of Madrid approach reconstruction compared to other series with a single synthetic mesh, could be explained by the use of the combination of BIO-A and polypropylene mesh. However, there is lack of evidence able to explain the specific mechanism according to which the use of the double mesh results in less recurrences and SSOs, as reported in the mentioned literature and in our series. Given that to date there is no sufficient evidence to support the superiority of the double mesh technique using the BIO-A and given the bias of the retrospective nature of our study, we hypothesize that the specific characteristics of this mesh (mechanical support to the extension of the permanent mesh which is substitute in 6 months with a tissue scaffold that may also work as mechanical barrier between intra-abdominal contents and the permanent synthetic mesh), could explain the better results and therefore we suggest its use in selected cases.

It is clear that further randomized studies, to better assess the superiority of a technique over the other, are needed.

A correct diagnosis of recurrence vs bulging must be made during follow-up. We distinguish the bulging, which is an area of weakness or asymmetry in the exploration of the abdominal wall without any visible defect at the CT-scan, from the recurrence itself, in which the defect can be detected both on physical examination and CT-scan. The timing of recurrence is between 6 and 12 months. In our study, we observed 8 cases of bulging (6.8%). These data are similar to the results of other studies analyzing recurrence after TAR [3, 9, 23, 32].

No case of bulging required reoperation. The only patient who had both a clinical and radiological recurrence was reoperated in another institution.

It is important to note that the recurrent case was a strong smoker obese patient who developed a necrotic skin flap.

The quality of life after surgery was defined as good by most of the 41 (55.4%) patients who answered the questionnaire. Regarding the pain at rest or during the lifetime activities, all the patients described a reduction of this symptom after surgery and the relief increased over time. In our experience, we did not have any case of chronic pain after TAR, in clear opposition to what described in 2016 by Blair et al. [33] who found a percentage of 50% of postoperative pain after 6 months, decreasing at 37.5% 1 year after surgery. No patient complained about difficulties in everyday life activities and all of them admitted an improvement in their capacities in movement comfort after surgery. Many of them restored a regular physical activity and actually play sports.

This study has an important limitation that prevents from drawing any evidence-based conclusion. It is only a cohort study and there is no group of comparison. Ideally, a multicenter RCT should be designed and performed in order to

Table 5 Student's *t* test: evaluate and postoperative scores about QoL

	Mean of difference	Standard dev.	Mean std. error	*t*	Significance (*P*)*
Pain at rest: pre vs. post op	7.195	2.722	0.425	16.924	< 0.05
Pain in activity: pre vs. post op	7.463	2.237	0.349	21.362	< 0.05
Pain in the last week: pre vs. post op	7.341	2.341	0.366	20.080	< 0.05
Activity limitation at home: pre vs. post op	8.000	1.924	0.300	26.631	< 0.05
Activity limitation outside: pre vs. post op	8.073	1.822	0.285	28.373	< 0.05
Activity limitation in sports: pre vs. post op	7.463	2.063	0.322	23.168	< 0.05
Activity limitation in hard works: pre vs. post op	7.610	2.048	0.320	23.793	< 0.05
Esthetics of abdominal shape: pre vs. post op	7.683	1.836	0.287	26.790	< 0.05
Esthetics in hernia site: pre vs. post op	7.293	1.847	0.288	25.279	< 0.05

Pre op preoperative, *Post op* postoperative

*P value < 0.05 is considered statistically significant

Table 6 ANOVA test: compare the differences in pre- and postoperative score about QoL in three groups of patients

	Scores	Cases	Mean	Standard dev.	*F*	Significance (*P*)*
Pain at rest	0–3	3	1.00	1.732	26.471	< 0.05
	4–7	8	5.50	1.414		
	> 7	30	8.27	1.893		
	Total	41	7.20	2.722		
Pain in activity	0–3	2	1.00	1.414	25.892	< 0.05
	4–7	5	5.60	0.894		
	> 7	34	8.12	1.552		
	Total	41	7.46	2.237		
Pain in the last week	0–3	2	1.50	0.707	42.244	< 0.05
	4–7	11	5.36	1.748		
	> 7	28	8.54	1.170		
	Total	41	7.34	2.341		
Activity limitations at home	0–3	0	0	0	33.593	< 0.05
	4–7	8	5.38	0.916		
	> 7	33	8.64	1.517		
	Total	41	8.00	1.924		
Activity limitations outside	0–3	0	0	0	58.527	< 0.05
	4–7	9	5.44	0.882		
	> 7	32	8.81	1.230		
	Total	41	8.07	1.822		
Activity limitations in sports	0–3	0	0	0	14.151	< 0.05
	4–7	11	5.73	1.272		
	> 7	30	8.10	1.936		
	Total	41	7.46	2.063		
Activity limitations in hard works	0–3	1	2.00	0	21.955	< 0.05
	4–7	7	5.14	1.464		
	> 7	33	8.30	1.425		
	Total	41	7.61	2.048		
Esthetics of abdominal shape	0–3	0	0	0	6.753	0.01
	4–7	6	6.00	1.095		
	> 7	35	7.97	1.790		
	Total	41	7.68	1.836		
Esthetics in hernia site	0–3	0	0	0	5.295	0.03
	4–7	5	5.60	1.140		
	> 7	36	7.53	1.812		
	Total	41	7.29	1.847		

*P value < 0.05 is considered statistically significant

demonstrate the potential superiority of the posterior layer reinforcement with an absorbable mesh.

To conclude, in accordance with other studies, we demonstrated that TAR using the combination of absorbable and permanent mesh (Madrid Approach) provides excellent results in the treatment of complex abdominal wall, with very low recurrence rate and a significant improvement of quality of life, with fast return to normal daily activities. In addition to this, in recent years, the use of robotic platforms in abdominal wall surgery is showing promising results and opening new scenarios in this field yet to be explored [34].

Declarations

Conflict of interest SC, TE, GL, MML, DAG and CD declare no conflict of interest.

Ethical approval Approval from the Institutional review board was not required for this study.

Human and animal rights This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this study, formal consent is not required.

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