



# Prospective observational study of abdominal wall reconstruction with THT technique in primary midline defects with diastasis recti: clinical and functional outcomes in 110 consecutive patients

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## Abstract

**Introduction** Surgical treatment of diastasis recti is still a matter of debate. Open approaches such as abdominoplasty, which offer the possibility to combine reparation of the diastasis with abdominal cosmetic surgery, are challenged by the emerging less-invasive laparoscopic or robotic techniques that offer shorter recovery for patients. However, evidence in favour of one of the two approaches concerning both short- and long-term complications and functional results is still lacking. In this paper, we analysed clinical and functional results of a new endo-laparoscopic technique for midline reconstruction (THT technique) in patients with primary abdominal wall defects associated with diastasis recti.

**Methods** Prospective observational study on 110 consecutive patients was submitted to endo-laparoscopic reconstruction of the abdominal wall with linear staplers. Morbidity and relapse rates with clinical and radiological follow-up were recorded at 1, 6, 12, and 24 months after the operation. Data regarding the impact of surgery on patients' quality of life (EuraHSQol) on chronic low back pain (Oswestry Disability Index, ODI) and urinary stress incontinence (Incontinence Severity Index, ISI) were gathered.

**Results** After a mean follow-up of 14 months, the morbidity rate was 9.1% and no recurrences were recorded. 6-month follow-up ultrasound showed a rectus muscles mean distance of 6.7 mm; EuraHSQol, ODI, and ISI scores significantly improved in 93%, 77%, and 63% of the cases, respectively.

**Conclusions** The THT technique proved to be a feasible, safe, and effective alternative for corrective surgery of primary midline hernias associated with diastasis recti. Short- and mid-term results are encouraging but need to be confirmed by further studies with longer follow-up. The achieved midline reconstruction offers a significant improvement of patients' perceived quality of life through reduction of abdominal wall pain, bulging, low back pain, and urinary stress incontinence.

Keywords THT technique · Abdominal wall repair · Midline hernias · Rectus diastasis · Stapled repair

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Diastasis recti or rectus abdominal diastasis (RAD) is an underestimated but extremely common disorder, with a significant negative impact on patients' quality of life (QoL). It is estimated that one out of three women after pregnancy and one out of two after 50 years of age show RAD [1, 2]. Abdominal swelling, dyspepsia, low back pain, and urinary stress incontinence are the most frequent symptoms associated with RAD [3, 4]. Despite the high incidence of this disease, still there is no consensus regarding surgical indications, the most appropriate approach and functional results of surgical repair. In this paper, we present the evaluation of a prospectively maintained database regarding 110 consecutive patients affected by midline primary hernias (MPH) associated with RAD, submitted to endo-laparoscopic midline reconstruction with linear stapler [THT technique [5]], by analysing clinical, radiological and functional outcomes up to 24 months after surgery.

## **Materials and methods**

Double-centre prospective observational analysis of 110 consecutive patients with MPHs associated with RAD, enrolled between April 2018 and September 2019. Primary endpoints of the study were to verify the technical feasibility of the THT technique for surgical repair of both MPHs and RAD, evaluating its morbidity (relapses, hematomas, seromas, infections, postoperative pain) at 7 days, 1-6-12 and 24 months after surgery. Secondary endpoints were to evaluate quality of life [EuraHSQol [6]] and RAD-related symptoms regression (abdominal bulging (EuraHSQol), back pain [Oswestry score [7]], and urinary stress incontinence [ISI score [8]] before surgery and at 1 and 6 months after surgery (8 months for patients prepared with chemical component relaxation). All patients were preliminarily examined with an abdominal CT scan. Inclusion criteria were age 18–65 years, BMI < 35 kg/m<sup>2</sup>, presence of at least one primary midline defect with a diameter  $\geq 10$  mm associated with a RAD  $\geq$  30 mm on CT scan, more than 1 year from the last delivery, and no intention of further pregnancy. Pregnant patients, patients within 1 year from the last pregnancy, cancer patients, and patients with previous abdominal midline surgery and with general contraindications to laparoscopy were excluded. Informed written consent was obtained from all participants before inclusion. The study protocol underwent institutional board revision and was approved by the Regional Ethics Committee, (Rep. Int. 2562) and registered in accordance with the declaration of Helsinki in the Research Registry (ID n. 4458).

#### Patient preparation to surgery

Smokers were asked to stop smoking at least thirty days before surgery. Patients with BMI  $\geq$  30 kg/m<sup>2</sup> were submitted to nutritional counselling in order to reduce visceral fat and abdominal circumference. Patients with midline defects greater than 6 cm in females (4 cm in males) and all patients with BMI still > 30 kg/m<sup>2</sup> after preoperative nutritional counselling were submitted to chemical component relaxation (CCR) through local injection of 500 Ul of Type A botulin toxin (Dysport®, Ipsen SpA, Italy), one month before surgery. Abdominal muscle toning with hypopressive gymnastics in preparation for surgery with appropriate physiotherapeutic support was suggested in every patient.

#### Surgical technique

The procedure is performed under general anaesthesia. The patient is positioned supine with the right arm open, the left one closed, split legs, the first operator standing in between, the second operator by the left side of the patient, and the nurse positioned between the two surgeons (Fig. 1). Through a lower periumbilical incision, the umbilicus is disconnected, and the anterior rectus sheaths (RS) are isolated. A small incision, performed along the medial margins of the two RS, allows access to the retromuscular space (Fig. 2). A transversal incision of the anterior fascia from the left to the right RS, preserving the integrity of the peritoneum and passing through the umbilical port is then performed. Two traction stitches help to join the RS facilitating the stapler insertion. An accessory trocar is then introduced on the left side to create a pneumoperitoneum at 12 mmHg, visualizing the abdominal cavity and staging the wall defects. Any adhesion between abdominal omentum/ viscera and the abdominal wall may be resected, adding one or more 5 mm trocar/s. The two branches of a linear stapler (stapler reload length 75-100 mm; open staples height 3.8-4.8 mm) are inserted into the retromuscular spaces towards the sternum to tighten the medial margins of the rectus muscles and close the umbilical hernial defect between them. A transperitoneal visual inspection allows to check the correct positioning of the stapler and the closure of the wall defect (Fig. 3). The RS are then sutured on two lines: an anterior one, where the medial fibres of the rectus abdominis muscles (RAM) are tightened, and a posterior one. A second stapler charge is positioned through the same umbilical access with the branches toward the pubis. Again, the two muscular sheaths are sutured to continue the two lines, one front and one rear. The procedure is then continued endoscopically through a single port device inserted within the umbilical incision. The axial adhesions between the RAM and their posterior sheaths are dissected gently up to the lateral neural-vascular pedicles of the RAM, creating a retromuscular plane to allocate the prosthesis. One to three endo-stapler reloads (stapler reload length 60 mm; open staples height 3.0-4.0 mm) are used to suture the RS cranially up to the costal margins and caudally up to a distance of at least 5 cm from the umbilicus, or until obtaining a space exceeding the defect by at least 5 cm cranio-caudally to house the mesh (Fig. 4). In case of sub-umbilical diastasis or hernia, it is possible to proceed with the stapler below the arcuate line accessing the Retzius space up to the pubis. At this point, a tailored synthetic prosthesis is positioned into the retromuscular space. After a last transperitoneal check of the result, the trocar/s on the left side is/are removed and the umbilical

## Fig. 1 Patient positioning

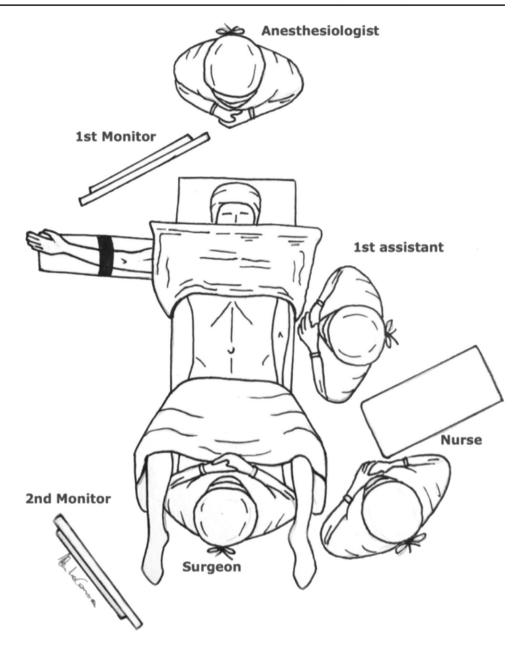




Fig. 2 Access to the retromuscular space



Fig. 3 Intraperitoneal view of the stapler closure

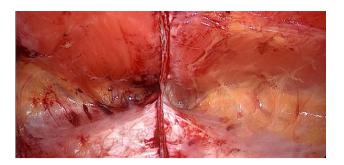


Fig. 4 Final view of the retromuscular space

access is sutured with resorbable sutures, obtaining finally a four-layer suture: posterior rectus sheaths, mesh, rectus muscles, and anterior rectus sheaths. The previously removed umbilical scar is then reattached to the anterior sheath with a single PDS stitch. Pain control is achieved through a preoperative TAP-block with 0.5% ropivacaine, 15–20 mL each on either side [9]. Participants received a total dose of 3 mg/kg of ropivacaine. All patients were treated with paracetamol 1 g every 8 h for the first 2 postoperative days; ketoprofen 160 mg iv or morphine 10 mg iv was used as rescue dose.

#### **Postoperative care**

Postoperative pain was evaluated by using a visual analogue scale (VAS) from 0 to 10, identifying 0 as "no pain" and 10 as "worst imaginable" pain. Patients were instructed to wear an abdominal elastic binder for 14 days after surgery and to avoid heavy physical work (> 10 kg) and sport activities for the first 30 days following the procedure. Just a light aerobic activity (4–5 km of trekking daily) was encouraged 14 days after the surgery. Follow-up visits were scheduled at 7 days, 1–6-12–24 months after surgery. Data about postoperative pain, evidence of haematomas, seromas, surgical site infections, and recurrences were collected on an online shared database postoperatively and at the time of the follow-up visits. Functional results of the abdominal wall reconstruction were studied using specific scoring systems preoperatively and at 1 and 6 months after surgery (1 and 8 months for

patient submitted to CCR). The EuraHSQol scoring system [6] was used to register data about the cosmetic result as well as the abdominal pain and the restriction to daily activities. The Incontinence Severity Index (ISI) [8] and the Oswestry Disability Index (ODI) [7] scoring systems were used to investigate stress incontinence and back pain, respectively.

### **Statistical analysis**

All quantitative values were presented by their mean  $\pm$  standard deviation (SD), median and 95% confidence intervals (95% CI), and categorical data by percentages. Univariate analyses for primary discrete outcomes were performed using the chi-square and/or the Fisher exact tests for categorical data and paired t-test or non-parametric Mann–Whitney *U*-test when the dependent variable was not normally distributed for continuous and discrete variables. For all statistical tests, the significant level was fixed at *p* < 0.05. Statistical analyses were carried out using SAS<sup>TM</sup> System 9.1.3 (SAS Institute Inc., Cary, NC, USA) statistical software.

## Results

Women represent 93% of present series (102/110), with a mean age of 43 years and BMI of 21.7 kg/m<sup>2</sup> (Table 1). In all patients, one or more midline primary hernia(s) associated with RAD were present, located in the umbilicus in 94% of cases (M3, W1, L1, 6 according to the European Hernia Society Classification) [10]. Preoperative chemical component relaxation was performed in 15 (13.6%) cases.

Technical data of the operations and early postoperative results are depicted in Table 2; a synthetic mesh was positioned in 86 cases (77.3%), while a biosynthetic mesh (Phasix®, BD) was used in the remaining 24 cases. Rescue analgesics (28.7% NSAIDs and 9.5% opioids) were administered in 42 (38.2%).

Overall morbidity rate was 9.1%, including 5 cases of haematoma (4.5%), 4 cases of SSI (3.6%), 1 case of seroma (0.9%), and 1 case of internal hernia due to laceration of the posterior RS suture (0.9%). No recurrences were detected (Table 3). The mean  $\pm$  SD inter-rectus distance at 6 months

Table 1	Patients and abdomin	al
wall def	ects data	

Variable	Mean	SD	Median	95% CI	Minimum	Maximum
Age (years)	43.1	8.9	41	41.5-44.9	27	81
BMI (Kg/m <sup>2</sup> )	21.5	2.6	21.3	21.1-22.0	17.5	30.5
RAD width (cm)	4.9	0.9	5	4.7-5.1	3	8
RAD length (cm)	18.6	1.5	19	18.4–18.9	15	22
MPH width (cm)	1.6	0.7	1.5	1.4–1.7	1	7
MPH length (cm)	1.4	0.8	1.0	1.2-1.5	1	6
Follow-up (months)	14.4	4.7	14	13.6–15.4	7	24

Table 2 Technical data of the procedure and early postoperative (in-hospital) outcomes

Variable	Mean	SD	Median	95%CI	Minimum	Maximum
Operative time (mins)	82.4	14.4	80	79.7–85.2	55	120
Stapler reloads	5.5	1.0	5	5.4-5.7	4	7
mesh width (cm)	11.3	1.2	12	11.1-11.5	10	15
mesh length (cm)	21.7	2.3	21	21.3-22.1	18	30
Mesh overlap (cm)	5.5	0.6	5	5.4-5.6	5	7
Postoperative pain (VAS)	4.4	1.7	4	4.1-4.6	1	9
Length of Hospital stay (days)	2.1	0.4	2	2.0-2.1	2	5

Table 3 Morbidity data

Complication	7 days	1 month	6 months	12 months	24 months	Total	%
Recurrence	0	0	0	0	0	0	_
Hematoma	4	1	0	0	0	5	4.5
Seroma	1	0	0	0	0	1	0.9
Infection	0	4	0	0	0	4	3.6
Other	1	0	0	0	0	1	0.9

#### Table 4 Functional data

	Mean	SD	Median	95%CI	Range	р
EuraHSQoL						
Before surgery	28.2	18.2	24	24.8-31.7	3–79	0.0811 <sup>a</sup>
1 month after surgery	25.5	17.4	22	22.3-28.8	1-70	$< 0.0001^{b}$
6-8 months after surgery	7.6	11.0	4	5.5-9.7	0–68	< 0.0001 <sup>c</sup>
Oswestry disability index (OI	OI) <sup>d</sup>					
Before surgery	11.5	4.5	8	10.5-12.5	5-22	$< 0.0001^{a}$
1 month after surgery	4.3	5.4	2	3.1-5.6	0–24	$< 0.0001^{b}$
6-8 months after surgery	2.6	3.1	1	1.9-3.3	0-14	0.0017 <sup>c</sup>
Incontinence severity index (I	SI) <sup>e</sup>					
Before surgery	3.6	3.0	2	3.0-4.2	0-12	< 0.0001 <sup>a</sup>
1 month after surgery	0.9	1.5	0	0.6-1.2	0–6	$< 0.0001^{b}$
6-8 months after surgery	0.7	1.5	0	0.4–1.0	0–8	0.3052 <sup>c</sup>

<sup>a</sup>Before surgery vs 1 month after surgery

<sup>b</sup>Before surgery vs 6-8 months after surgery

<sup>c</sup>1 month vs 6–8 months after surgery

<sup>d</sup>Available in 75 cases after exclusion of grade 0 patients before surgery

<sup>e</sup>Available in 90 cases after exclusion of grade 0 patients before surgery

and 12 months was  $0.69 \pm 0.82$  cm (median 6.0; 95% CI 0.63-0.74 range 0.2-2). All data concerning functional results are reported in Table 4.

## Discussion

MPHs are one of the most frequent abdominal wall defects in the adult population and in roughly half of the cases, they are associated with RAD [11-13]. These abdominal wall defects must be considered in a general impairment of the midline [14]. As already demonstrated [13] surgical repair of MPH without treating the associated RAD implies a fourfold relapse risk compared to the combined repair of both defects. To date, surgical reconstruction of the midline can rely on a wide range of materials and an even wider range of open and minimally invasive techniques. However, classic open repair according to Rives Stoppa and IPOM laparoscopic repair are the most used techniques offering the same short- and long-term results [15–17]. On the other hand, both approaches entail different drawbacks: generally, open repair may be affected by a higher incidence of seromas and infections, with longer recovery time, whereas IPOM laparoscopic repair has a definite higher risk of bowel injury

and bowel obstruction [5]. In order to overcome these limits and to combine benefits of both open and minimally invasive repairs, recently several new midline repair techniques have been suggested, with mesh positioning mainly outside the peritoneal cavity: eTEP, TESAR, MILOS, EMILOS, and SCOLA [14], [18, 19] to name a few.

Following this trend, in 2018, we developed the THT procedure a new endo-laparoscopic technique for the reconstruction of the midline in primary defects with RAD (named from the Trentino Hernia Team, our regional group of surgeons dedicated to abdominal wall surgery). This procedure combines the advantages of minimally invasive surgery with those of a Rives Stoppa abdominal wall reconstruction, eliminating at the same time the risk of complications related to a totally transperitoneal procedure such as post-surgical adhesions or visceral lesions. The THT technique approaches the retromuscular space through a single umbilical access, similarly to that described in the MILOS [20, 21] and EMILOS [22] technique. The use of a linear stapler is derived from the work of Costa T [23], allowing a fast and safe mechanical suture of the rectus sheaths. The combination of these two technical aspects allows easier and faster access to the retromuscular space, suturing at the same time the anterior and posterior rectus sheaths. The use of a 10-cm length linear cutter instead of an endoscopic stapler for the first two stapling, directly from the umbilical incision, further enhances these advantages; it significantly shortens the operative time, making the procedure easily reproducible.

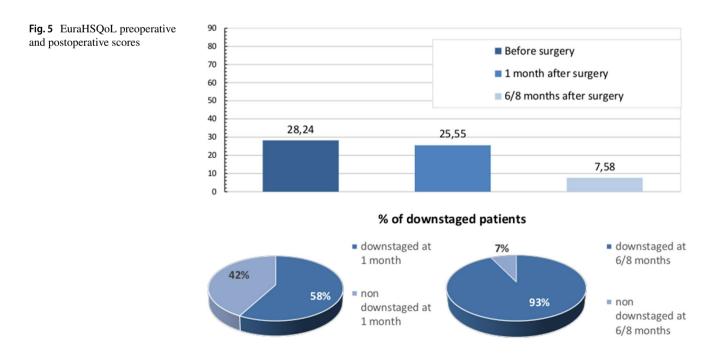
The main limitation of the THT technique is represented by the presence of excessive skin folds, especially in wide postpartum RADs, that are not manageable with this approach: THT has no aesthetic purposes but aims to repair abdominal wall defects, and we usually do not suggest to correct the skin excess at the same time of the abdominal wall reconstruction. 4–5 months after surgery, the skin folds are often reduced due to the reconstruction of the abdominal wall shape and the scars' remodelling, and, in our opinion, surgical correction of any skin excess should be postponed to that time in order not to be under- or over-treated.

Nevertheless, in selected patients with very large skin folds (post-bariatric patients with large RAD and huge pendulous abdomen), the abdominal wall reconstruction with THT technique was completed by a bikini line abdominoplasty in a traditional way.

Notwithstanding this proliferation of new techniques, the first consideration is that, unfortunately, the Italian National Health System—as well as in many other countries, does not include RAD into the list of diseases whose treatment is reimbursable, unless when it is associated with at least a MPH. Consequently, the international surgical community historically failed to consider RAD as a disease entity, deeming it as a physical conformation and/or a cosmetic defect rather than an effective healthcare issue. Nevertheless, patients with RAD are very often deeply frustrated, seeing their condition underestimated, or, even worse, considered merely a cosmetic issue. As a general rule, these patients continue to consult urologists, physiotherapists, neurosurgeons, orthopaedics, and osteopaths trying to find a solution to their urinary incontinence and low back pain, completely ignoring the connection between these problems and RAD. Recently, there has been a growing interest in RAD in the surgical community. Papers which recognize RAD as an important element in the origin of symptoms such as low back pain or urinary stress incontinence have been published [3], [24–27]. The German Hernia Society (DHG) and the International Endohernia Society (IEHS) proposed a new classification of rectus diastasis [28]. Olsson et al. published on BJS a study in which the effects of surgical repair of RAD with "open" approach on a series of 60 female patients were analysed [4]. The authors conclude that surgical repair of RAD results in significant improvement of the abdominal trunk function, urinary incontinence, and QoL.

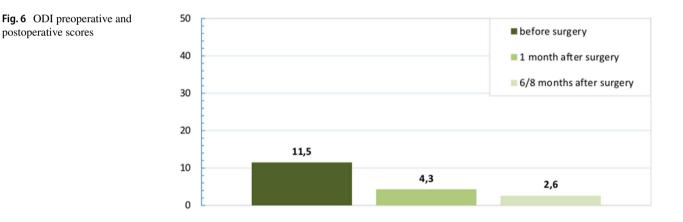
In our prospective series of 110 consecutive patients, all operations were performed by members of the THT in three hospitals of the autonomous Province of Trento. All the surgeons carried out the technique following the same steps and using the same materials and instruments. The mean duration of the operation was 82.4 min. No complications, which would have led to a laparotomy conversion or a change in the surgical programme, were reported. Postoperative pain (average VAS 4.4) was controlled by the use of paracetamol, while in 38% of the cases, the use of NSAIDs or opioids as rescue analgesics was necessary. The mean hospitalization was of 2.1 days. Based on this data, we believe that the THT technique can be considered as a feasible and safe solution to treat primary midline hernias associated with RAD. The use of CCR [29] in preparation for surgery in cases with defects greater than 6 cm helped to reduce midline tension allowing RAD correction with THT technique also in patients with defects up to 10 cm wide. The clinical and functional outcomes in the subgroup of patients pretreated with CCR (n. 15) after 6 months from the injection of Botox were consistent with those of the remaining portion without significant statistical differences. There were no significant differences in the outcomes both in the 86 patients who were given a synthetic prosthesis in the retro muscular space, as well as the other 24 patients who were given a poly-4-hydroxybutyrate biosynthetic prosthesis (P4HB) (Phasix®, BD). However, the limited follow-up of our study (average of 14 months), if compared to average reabsorption time of P4HB used by us (16–18 months), does not allow to draw conclusions regarding recurrence rate [30]. Considering the primary objectives of this study, the rate of short and mediumterm postoperative complications (up to 24 months) was consistent with other studies of abdominal wall surgeries with laparoscopic or robotic techniques [14], [31-37]. The rate of hematomas, seromas, and SSI complications were, respectively, 4.5%, 1.8%, and 1.8%. In one case 0.9%, a laceration in correspondence of the mechanical suture of the rear rectum fascia occurred, which caused an internal hernia that required a re-operation. It is important to underline that, during the second surgery, surgical suture staples in correspondence of the fascia laceration were perfectly closed. This means that the complication was due to an intrinsic weakness of the posterior rectus sheaths and not to the opening of the staples. Considering post-surgery recurrence of RAD as inter-rectus maximal distance (IRMD) between rectus muscles of more than 3 cm, in our work neither hernias nor RAD recurrences were registered after a mean clinical follow-up of 14 months (range 7–24). This figure was confirmed by an ultrasound of the abdominal wall performed 6-12 months after surgery, confirming a mean IRMD of 0.68 mm (range 0.2-1.4 cm). The functional effects of RAD corrective surgery deserve a separate mention. Several studies have shown how the disruption of the abdominal wall midline leads to an unavoidable abdominal core impairment. Therefore, it is understandable how RAD can lead to disabling consequences such as difficulty in performing sports and physical strains, lower back pain, abdominal relaxation associated with pain of the wall, dyspepsia, and urinary stress incontinence [3], [26, 27], [38, 39]. This complex characteristic of such diverse symptoms constitutes what could be defined as a syndrome, which could be defined as abdominal core dysfunction syndrome (ABCDS). However, studies that can quantify the functional effects of corrective surgery of RAD are missing in the literature. The correlated functional deficits of RAD are not easily measurable because of ordinal qualitative variables.

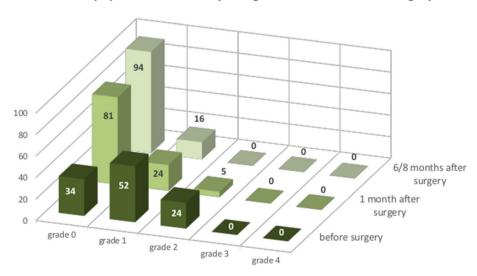
We chose to analyse the effects of THT surgeries on correlated functional deficits of RAD, by referring to the most used scoring systems in scientific studies and validated by international scientific societies. Abdominal bulging and correlated RAD wall pain, which are present especially during physical activity and episodes of abdominal overdistension, were analysed with EuraHSQol [6]. This scoring system was published by the European Hernia Society (EHS); it consists in 9 questions, measured by an analogical scale from 0 to 90 of pain in the defect wall, limited daily activities connected to the pain, and aesthetic discomfort of the abdominal shape. Given that in the EuraHSQol zero is considered the best score and 90 the worst, the average preoperative value of the population in our study was 28.2 (SD 18.3). This value decreased to 25.5 (SD 17.4) and 7.6 (SD 10.9), respectively, at 1 and 6 months from the surgery. The percentage of patients who reported an improvement of their EuraHSQol, was 53% at 1 month (p = 0.08) and 93% at 6 months from the surgery (p < 0.0001) (Fig. 5). It is important to underline that during the first month after surgery, approximately one-half of the operated patients reported an unpleasant abdominal swelling. This finding that strongly affected the EuraHSOol score at 30 days is likely referred to a temporary reduction of abdominal muscle tone, due to the reconstructive surgery of the abdominal wall and the use of an elastic corset for the first month. Actually, such effect regressed with the progressive recovery of muscles tone in the majority of the patients, until reducing to approximately 7% of the population at 6 months. Obviously, in patients treated with



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presurgery CCR, abdominal swelling was expected until the prescribed period of the botulinum toxin effects on lateral muscles (4-6 months) ended, and thus EuraHSQol evaluation was postponed to 8 months in this specific subgroup of patients. It is fair to point out how other factors such as RAD can generate abdominal swelling. These include relaxation and total elongation of the abdominal wall, accumulation of perivisceral adipose tissue, and meteorism connected to digestive disorders [40]. In our case studies 7% of patients found no benefit from physical therapy rehabilitation and restrictive dietary regimes on abdominal swelling up to 6 months after surgery. Based on these considerations, we believe it is right to explain to patients the possibility, though limited, of unsuccessful impact of surgical repair on abdominal swelling. Another important feature that conditions the QoL of patients affected by RAD is low back pain (LBP). In our study, this occurred in approximately 70% of the cases affected by primary hernias and RAD. The ODI [7] was used to quantify the impact of LBP on patients' lives. ODI is a validated, 10-point patient-reported outcome questionnaire. It is considered the gold standard for measuring disability and quality of life impairment for adults with LBP. The 10 factors that constitute the ODI criteria for assessing patients' functional impairment are pain intensity, ease of personal care, lifting, working, sitting, standing, sleeping, sex life, social life and travelling. The final score is on a cumulative scale from zero to 50, divided into 5 progressive levels according to the severity of the symptoms. Average ODI of our case study which was evaluated presurgery and at 1 and 6 months post-surgery, was 11.5 (SD 4.4) (mild disability), 4.3 (SD 5.4) (no disability) and 2.6 (SD 3.1), respectively. (Fig. 6). One month after surgery, 62% of patients had a downstaging of ODI level (p < 0.0001); this rate rose to 79% (p < 0.0001) after 6 months from surgery. In view of such evident downstaging effect in terms of QoL, one could argue that the advantages are quite limited considering such a low average ODI value of the population before surgery (11.5-mild disability). Nevertheless, it must considered that even though ODI is probably the most reliable and validated tool in literature for measuring the severity of low back pain, it does not take into account the variable of time. It is clear that a non-particularly sever but chronically persistent pain





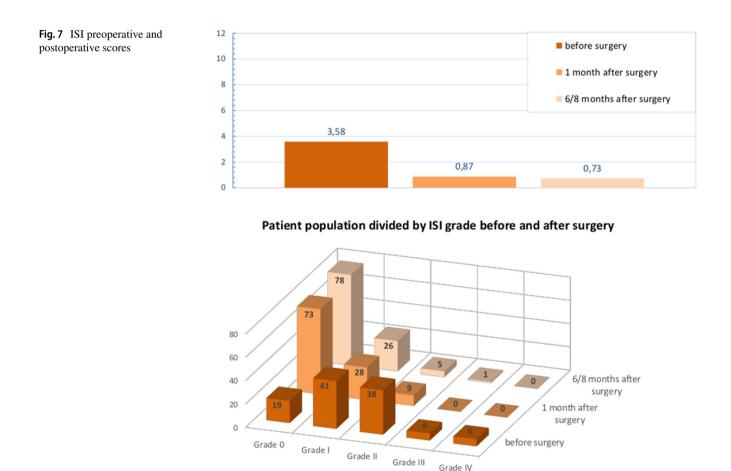
Patient population divided by ODI grade before and after surgery

can be more invalidating for a person's life rather than an intense pain that only manifests itself in isolated moments of the day. The situation reported to us by our case study patients during the preoperative meeting was a QoL significantly worsened by a "bearable" pain throughout the day even during the most mundane daily activities. It is appropriate for us to underline that the majority of our patients, during the 6-month checkup, identified regression of low back pain as the most appreciated result for QoL improvement.

A third RAD-related, yet often underestimated, aspect is stress urinary incontinence. In order to quantify stress incontinence, we elected to use the ISI [8], a widely used scoring system, based on two simple questions with a cumulative scoring from zero to 12 (zero being the absence of incontinence and 12 the highest level of urine leakage). Approximately 83% of patients in our study had an ISI grade 1 or higher before surgery. This percentage decreased to 34% at 1 month and 30% at 6 months after surgery (Fig. 7), with a parallel decrease in mean ISI score from 3.0 to 0.7 and 0.6 at 1 and 6 months after surgery, respectively. Stress urinary incontinence is known as a multifactorial problem affected by anatomy, pelvic floor function, urogenital apparatus, and abdominal core physiology; it is obvious that in our study, the corrections of RAD were able to offer a significant

benefit to patients by reducing, or in many cases, eliminating the issue. Therefore, according to our results, it is important to treat the abdominal wall defect, which requires surgical correction anyway, in order not to risk complications on the hernia or progressive worsening of RAD. After at least 6 months, one must evaluate the actual benefits from ABCDS symptoms in order to run a specialist visit (either orthopaedic, physiotherapy, urological, or gastrointestinal) only for patients who continue having problems after RAD surgery (7-30% of the cases in our study). The limits of our study are the lack of a control group and the short followup (mean 14; range 7-24 months). Other functional aspects of RAD such as breathing difficulty or dyspepsia were not evaluated in this study, even though many patients informally reported improvements of these functions after RAD corrective surgery.

In conclusion in this prospective study, the THT technique proved to be a safe and feasible technique for the repair of primary midline defects associated with RAD, offering effective treatment of ACDS. The low rate of major complications and the absence of recurrences are very promising but needs to be tested on a longer time-span. Functional aspects connected to corrective RAD surgery such as low back pain and urinary stress incontinence partially or totally



regressed, and QoL significantly improved for the majority of our patients. These results further support the hypothesis that the impairment of the midline abdominal wall is not merely an aesthetic problem but needs surgery because of heavy functional and QoL consequences that it entails.

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**Data availability** Anonymized participant-level datasets are available upon reasonable request by contacting the corresponding author.

#### **Compliance with ethical standards**

**Disclosures** Carrara Alessandro MD, Catarci Marco MD, Fabris Luca MD, Zuolo Michele MD, Pellecchia Luigi MD, Moscatelli Paolo MD, Dorna Adriano MD, Motter Michele MD, Pertile Riccardo PhD, Tirone Giuseppe MD have no conflicts of interest or financial ties to disclose.

**Research involving human participants and/or animals** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study protocol underwent institutional board revision and was approved by the Regional Ethics Committee (Rep. Int. 2562) and registered in accordance with the declaration of Helsinki in the Research Registry (ID n. 4458).

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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