OXFORD UNIVERSITY PRESS | BJS

Title: Outcomes of Posterior Component Separation with Trasversus Abdominis Release for complex abdominal wall hernia repair: an Italian Multicenter Cohort Study IMPACT study: Italian Multicentric Posterior-separation Abdominal Complex hernia Transversus-release

Journal:	*British Journal of Surgery*
Manuscript ID	BJS-2012-Oct-23
Manuscript Type:	Original Article
Date Submitted by the Author:	31-Oct-2023
Complete List of Authors:	PIZZA, FRANCESCO; ASL Napoli 2 Nord, General Surgery Maida, Pietro; Casa di Cura Privata Malzoni, Surgery Bertoglio, Camillo; ASST Ovest Milanese, Department of surgery Antinori, Armando; University Hospital Agostino Gemelli Marte, Gianpaolo; ASL Napoli 1 Centro, Department of General Surgery - Ospedale del Mare Sordelli, Ignazio; Private Hospital Malzoni Cerbara, Loredana; Institute for research on population and social policies National Research Council Mongardini, Federico ; University of Campania Luigi Vanvitelli School of Medicine and Surgery Alampi, Bruno; Magenta Hospital Morini, Lorenzo; Magenta Hospital Gili, Simona; ASL 3 Napoli Sud Docimo, Ludovico; Università degli Studi della Campania Luigi Vanvitelli Scuola di Medicina e Chirurgia Gambardella, Claudio; Università degli Studi della Campania Luigi Vanvitelli
Keywords:	Hernia, Plastic Surgery

Title: Outcomes of Posterior Component Separation with Trasversus Abdominis Release for complex abdominal wall hernia repair: an Italian Multicenter Cohort Study

IMPACT study: Italian Multicentric Posterior-separation Abdominal Complex hernia Transversus-release

Francesco Pizza[1]*, Pietro Maida[2], Camillo Bergoglio[3], Armando Antinori[4], Federico Maria Mongardini[7], Loredana Cerbara[5], Bruno Domenico Alampi[3], Lorenzo Morini[3], Simona Grimaldi[3], Gianpaolo Marte[5], Simona Gili[6], Ludovico Docimo[7] and Claudio Gambardella[7]

1 Asl Napoli2 Nord Department of Surgery, Hospital 'Rizzoli', Naples, Italy

2 Casa di Cura Privata Malzoni, Surgery Avellino, Campania, IT

3 Division of General Surgery, ASST Ovest Milanese, Hospital of Magenta, 20013 Magenta, Italy

4 Division of General Surgery, ASST Ovest Milanese, Hospital of Magenta, 20013 Magenta, Italy

5 Institute for Research on Population and Social Policies, National Research Council of Italy Rome

6 Asl Napoli3 Sud Department of Surgery, Hospital 'San Leonardo' Castellammare, Italy

7 Campania 'Luigi Vanvitelli', Naples, Italy 3Division of General, Mininvasive and Bariatric Surgery.

*Correspondence to: Department of Surgery, Hospital 'A. Rizzoli', Lacco Ameno, Naples, Italy (e-mail: francesco_pizza@libero.it)

Declarations

Conflict of interest: The authors declare no conflict of interest.

Ethical approval: Approval from the Institutional review board.

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.

Disclosure: The authors declare no conflict of interest.

Abstract

Background: Surgical management of large ventral hernias (VH) has remained a challenge. Various techniques like Anterior Component Separation and Posterior Component Separation (PCS) with Transversus Abdominis Release (TAR) have been employed. Despite the initial success, the long-term efficacy of TAR is not yet comprehensively studied. Authors aimed to investigate the early, medium, and long-term outcomes and health-related quality of life (QoL) in patients treated with PCS and TAR.

Methods: This multicenter retrospective study analyzed data of 308 patients who underwent open PCS with TAR for primary or recurrent complex abdominal hernias between 2015 and 2020. The primary endpoint was the rate of Hernia Recurrence (HR) and Mesh Bulging (MB) at 3, 6, 12, 24, and 36 months. Secondary outcomes included surgical site events and QoL, assessed using EuraHS QoL score.

Results: The average follow-up was 38.3±12.7 months. The overall HR rate was 2.9% and the MB rate was 3.9%. Most of the recurrences were detected by clinical and ultrasound examination. QoL metrics showed improvement post-surgery.

Conclusions: This study supports the long-term efficacy of PCS with TAR in the treatment of large and complex ventral hernias, with a low recurrence rate and an improvement in QoL. Further research is needed for a more in-depth understanding of these outcomes and the factors affecting them.

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

Title: Outcomes of Posterior Component Separation with Trasversus Abdominis Release for complex abdominal wall hernia repair: an Italian Multicenter Cohort Study

IMPACT study: Italian Multicentric Posterior-separation Abdominal Complex hernia Transversus-release

INTRODUCTION

The surgical treatment of large ventral hernias (VH) is challenging, even for experienced surgeons. Despite the high recurrence rate, the bridging repair is still a common surgical option for their treatment (1). Component separation, initially described by Ramirez et al, is a technique that includes the division of the posterior rectus sheath and, when necessary, the release of the external oblique aponeurosis (2). The so-called "Anterior Component Separation" and its modifications have been widely adopted in abdominal wall reconstruction. This technique involves the release of the external oblique muscle and fascia, but necessitates the creation of large skin flaps with significant associated wound morbidity (up to 63% in different series) (3–5).

The term Posterior Component Separation (PCS) was first introduced by Carbonell et al in 2008 (6), but it did not achieve great popularity, possibly due to the theoretical risk of injury to neurovascular bundles (6). The plane described in the original surgical technique, in fact, was between the transversus abdominis (TA) and internal oblique (IO) muscles. The Transversus Abdominis Release (TAR) for PCS was first described by Novitsky et al (7) in 2012 for the treatment of complex VH. The technique quickly gained popularity because it has proven to be highly useful in particularly demanding cases of abdominal wall reconstruction (7,8). This release allows midline closure for most large hernias that would otherwise require bridging. The significant space created between TA and the transversalis fascia (TF) enables the placement of a large mesh, reinforcing a weakened abdominal wall. Following this approach, an extensive retro-muscular and preperitoneal dissection can be performed to extend the mesh sufficiently to prevent hernia recurrence. The original description

initiates the dissection as far cranially as possible in the upper abdominal wall, achieved by incising the posterior lamina of the internal oblique aponeurosis (7).

To facilitate the execution of TAR dissection and achieve the accurate plane between the peritoneum and the transversalis fascia, García-Ureña et al (9) have proposed a modification of the technique called "down to up" (9). This modification describes a slight alteration of the TAR technique, beginning the dissection from the arcuate line in a downward-to-upward direction. However, although TAR has demonstrated early efficacy (8), the long-term clinical outcomes have not been comprehensively evaluated. Therefore, the aim of the current Italian retrospective multicenter study was to assess the early, medium, and long-term outcomes, as well as the health-related quality of life (measured using the EuraHS QoL score) (10) of patients who underwent open incisional or ventral hernia (IH) repair utilizing PCS with TAR.

METHODS

Study design

This study is reported according to the STROBE statement for cohort studies [11]. A retrospective multicentric study was conducted to analyze the surgical outcomes of patients undergoing open PCS with TAR for IH or VH. It was conducted according to the ethical principles stated in the Declaration of Helsinki. Written informed consent was obtained from all subjects. It was registered at Clinical.Trials.gov (NCT06111287).

Study setting and study population

From January 2015 and May 2020, all the patients affected by primary or recurrent complex abdominal hernias undergoing open PCS with TAR referring to 6 centers, were considered for the enrollment in the study. Inclusion criteria were age ≥16 years, primary or recurrent complex abdominal hernias with more than >10 cm midline defects Exclusion criteria were follow-up data

lower than 36-months, patients with a stoma for whom closure was not planned during the abdominal hernia repair.

Preoperative Evaluation

All subjects were preoperatively assessed during a specialized surgical assessment. Preoperative evaluation included anthropometric measurements (gender, height in cm, weight in kg, BMI in kg/m^2), ASA score, comorbidity analysis (HbA1c, chronic obstructive pulmonary disease (COPD), hypertension, cardiopathy, chronic use of corticosteroid, smoking, previous history of cancer). Preoperatively, all patients underwent a Computed Tomography (CT) scan to assess the size and location of the hernia and volume of sac. The presumed volume of the hernial sac was also estimated in all patients through longitudinal and sagittal reconstructions and collected in cm^3. Preoperatively, the quality of life, was evaluated via the translated version of EuraHS-QoL score (10) questionnaire. Hernia characteristics included location, European Hernia Society (EHS) classification (12), Ventral Hernia Working Group (VHWG) (13) classification, length in width of defect, area (cm^2) of defect Slater'classification (14). Moreover, wounds were classified into one of the four categories: clean, clean-contaminated, contaminated, and dirty-infected (13).

Clinical data were collected in a prospective maintain electronic database. Only patients actively followed up for at least three years, being invited to outpatient clinic by telephone or mail, were considered. The postoperative follow-up comprised a physical examination at 3 months, 6 months, 1 year, and then annually.

Surgical Technique

Midline laparotomy was performed and followed by complete lysis of adhesions. Retrorectus dissection was carried out by incising the posterior rectus sheath approximately 0.5 to 1 cm from the medial edge of the muscle. The retro muscular plane was developed laterally until the neurovascular bundles were visualized just medial to linea semilunaris, preserving the perforating neurovascular bundles to the rectus. In up to down technique, the ventral aspect of the posterior rectus sheath

(posterior lamina of the internal oblique) was incised approximately 0.5 to 1cm medial to the previously exposed perforators, medial to linea semilunaris, revealing the underlying fibers of the transversus abdominis muscle (TAM), that was then isolated and divided with cautery (TAR). In down to up technique, TAR technique starts the dissection from the arcuate line in a down to up direction. In this area, the preperitoneal fat can be detached from the posterior rectus sheath with blunt dissection, using the index finger placed under the arcuate line, extending the preperitoneal space dissection laterally and superiorly from the space of Bogros (the preperitoneal space lateral to the internal inguinal ring) (9).

The release of the muscle was carried out along the vertical plane in the caudal direction. Once completed along the length of the abdominal wall, using blunt dissection laterally, the plane between the TAM ventrally and the transversalis fascia/peritoneum dorsally was developed. This plane can be extended laterally towards the retroperitoneum and psoas muscle. Superiorly, the plane can be developed cephalad to the costal margin, as transection of the transversus abdominis allows for access to the preperitoneal plane of the diaphragm. The subxiphoid and retrosternal spaces were developed to expose the anterior aspect of the central tendon of the diaphragm, if necessary. Inferiorly, dissection was carried out within the space of Retzius, exposing myopectineal orifice, the pubic symphysis, and Cooper (7). This procedure was repeated on the contralateral side.

After complete PCS and TAR, the medialized posterior sheaths were reapproximated using a 2-0 running long term absorbable suture. For the reconstruction process, usually two large meshes are employed. The first is an absorbable biosynthetic mesh measuring 20 × 30 cm, supplied by WL Gore Associates, Inc, Flagstaff, AZ, under the product name GORE BIO-A® Tissue Reinforcement. The second is a permanent polypropylene (PP) mesh measuring 50 × 50 cm or polyvinylidene fluoride (PVDF) up to 60X45 cm. Both meshes are meticulously shaped to fit the surgical requirements and are positioned in the retromuscular space. Notably, the biosynthetic mesh is placed underneath the polypropylene mesh for optimal layering, fixed or not to both Cooper ligaments caudally, and to the upper insertion of the posterior rectus sheaths cranially. In cases when reapproximating was not

possible, the anterior rectal layers were sutured to mesh and covered by skin. Closed-suction drains were routinely placed above the mesh. For lateral incisional hernias (L1-L4 EHS classification)(12), a retromuscular preperitoneal dissection was performed to achieve a minimum of 10 cm dissection in all directions from the defect boundaries. When this dissection was insufficient to obtain the required 10 cm overlap, a TAR was performed from lateral to medial to create a wide preperitoneal retromuscular space. A reinforcement of anterior and posterior rectus sheath (AM and PM) was also used, similar to midline incisional hernias. The AM was placed without fixation, while the PM was secured cranially using one or two transparietal stitches in the intercostal spaces and inferiorly to the iliac crest and/or Cooper's ligaments. In most cases, the lateral muscle layers were closed using 2-3 rows of running sutures. A drain was routinely inserted. In contaminated or dirty fields, only absorbable mesh (AM) was placed, at the discretion of the surgeon.

EuraHS-QoL score

The EuraHS (European registry of abdominal wall hernias) working group proposes a new and open EuraHS-QoL score, specifically targeting patients that underwent abdominal wall hernia repair pre- and post-operatively. The EuraHS-QoL score is based on a Numerical Rating Scale for three dimensions: pain at the site of the hernia or the hernia repair, restriction of activities, cosmetic discomfort. The EuraHS QoL score has been validated by Filip Muysoms et al (10). EHS-QoL can be collected also via mail.

Outcome Measures

Mean operative time was evaluated in minutes. Mortality, length of hospitalization, and surgical reinterventions were recorded. Regarding the surgical procedure, the mesh type/size, the fixation or not (stiches), the type of technique (up to down/ down to up), the bridging (anterior or posteror), any associated surgery (i.e., resection or suture of small bowel, resection or suture of colon) and the blood loss (in ml) were recorded.

During each follow-up visit, anthropometric measurements were performed. Hernia Recurrence (HR) and Mesh Bulging (MB), was clinically and f clinical recurrence was suspected at any point during the follow-up period, a confirmatory CT-scan was performed.

In details, HR was clinically defined as any visible or palpable ‘‘blowout’’ in the abdominal wall. TC evaluation was carried out by a radiologist with 10 years of gastrointestinal TC experience. The criteria of HR were a visible gap within the abdominal wall and/or ‘‘tissue moving through the abdominal wall by Valsalva maneuver’’ and/or a detectable ‘‘blowout’’. Patients who had their intact midline repair violated during the 3-year follow-up period for reasons not related to the index hernia repair were excluded from the final recurrence analysis. HR was evaluated postoperatively at 3, 6, 12, 24 and 36 months. MB was defined as any clinically evident protrusion through the hernial defect causing swelling. It was well clinically evaluated at outpatient visit at 3, 6, 12, 24 and 36 months. In doubtful cases of clinically HR and MB, computerized tomography (CT) was performed.

Regarding the surgical site events, the classification of wound events was assigned according to the likelihood and degree of wound contamination at the time of the operation, as stated in the Centre for Disease Control and Prevention (CDC) wound classification (superficial, deep or organ space) (16). Surgical site occurrences (SSO)(16) (i.e., surgical site infection -SSI, seroma formation, wound dehiscence, hematoma, skin or soft tissue necrosis, enterocutaneous fistula, wound cellulitis) were reported according to the Ventral Hernia Working Group definitions (11). Surgical Site Occurrence Requiring Procedural Intervention (SSOPI)(16) were categorized as: antibiotics only, bedside wound interventions, percutaneous interventions, or surgical debridement. In cases where surgical debridement was necessary, the management of prosthetic materials was categorized as follows: no intervention, partial removal, or complete removal of the biosynthetic mesh.

Quality of life, analyzed according to EuraHS Quality of Life score (EHS-QoL) (Italian version), was evaluated preoperatively and at 3,6,12,24,36 months (10).

Study Endpoints

The primary endpoint was the evaluation of the rate of HR and MB at 3, 6, 12, 24 and 36 months in patients undergoing PCS with TAR. The secondary outcome regards the onset of SSO, at 30 days, and the QoL evaluated via EHS-QoL at 3, 6, 12, 24 and 36 months, determined during the outpatient visits.

Statistical Analysis

Descriptive statistics are reported as means with corresponding standard deviations for continuous variables and percentages for categorical variables. Additional analyses were performed to examine the rates and factors associated with the incidence of wound complications and hernia recurrences. Categorical variables were evaluated using the Pearson chi-squared and Fisher exact tests, as appropriate. Continuous and ordinal variables were evaluated using the Wilcoxon Mann-Whitney and the Kruskal-Wallis tests. Odds ratios with corresponding 95% confidence intervals are used to report the results of the logistic regression and Cox proportional hazards regression models. All reported p-values were two-tailed. The ANOVA Test was used to analyze the differences among the means of each domain of the EHS-QoL at 3, 6, 12, 24 and 36 months. All data were analyzed using Statistical Analysis Software (version 9.4, SAS Institute, Inc., Cary, NC). Multivariate analysis was performed to evaluate the independent association of variables with wound complications and hernia recurrence. The following variables were included in the analysis: BMI, gender, defect size, diabetes, smoking history, COPD, anticoagulants use, ASA score, anterior bridging evaluating their impact on Recurrence, SSO, SSI, and SSOPI. The quantitative variables were analyzed with a Student's t-test to assess differences in means among subgroups. The remaining variables were subjected to independent samples proportion tests with a Wald test for the null hypothesis.

RESULTS

Study Population

From January 2015 and May 2021 of 432 patients referred for IH, 308 met the inclusion criteria and received the PCS with TAR. The study design is summarized in Fig.1. Baseline demographic and pathological findings were detailed in Table 1. Mean age was 63.76±11.32 years with 58.4% of patients being male (Male/Female:180/128). The mean BMI was 29.31±4.72. 281 patients presented a IH (91.2%), while 27 subjects (8.7%) suffered of VH. Eighty-six patients presented a recurrent IH (27.9%; Table II) with 42 patients had undergone more than two hernia repair treatment. Mean hernia surface in the entire cohort was 321.18±89.22 cm^2 and 89.9% (277 patients) of the hernias were located in the midline. The pre-operative VHWG risk stratification classified the patients as follows: Grade 1 (Low risk) 30.2% (93 patients), Grade 2 (Comorbid) 64.3% (198 patients), Grade 3 (Contaminated) 5.5% (17 patients) (1). According to Slater's classification for complex abdominal wall hernia severity Authors found: Minor 3.5%(11 patients), 90.7% (279 patients), 5.8% (18 patients). The mean operative time was 280±112 min and Authors reported a mean 115±187 mL blood loss (Table 3). In 98 patients (31.8%) a double prosthesis was used. Most Patients required a bilateral PCS (81.4%). Closure of the anterior fascia was not possible, and a bridging technique was utilized in 64 cases (20.8%). Concomitant panniculectomy was performed in 19 (6.1%) of cases. Of the 24 patients with colostomy, 9 met the inclusion criteria for undergoing recanalization. Authors reported one gastric, 18 small bowel and two colonic partial thickness injuries during adhesiolysis; a single patient suffered full thickness small bowel injury requiring an intestinal resection. In 259 patients were used two mesh: polypropylene and BIOA. The average mesh area was 590.33±121.28 cm2, with overall patients receiving an average 1.74 polypropylene meshes, each measuring 50X50 cm. The intra- and per-operative findings were detailed in table 3. In 18 patients classified as "contaminated" and in 1 as "dirty", only absorbable mesh (AM) was used.

Primary Outcome

The mean overall follow-up time resulted 38.3±12.7 months. Table 4 showed the recurrence rate at each follow-up point Overall HR rate for the study population was 2.9% (9 patients at maximum follow-up observed) and the average time to recurrence was 23.2 ± 14.7 months (Table 4). In details, all the 9 patients who had developed a HR, were diagnosed by clinical examination confirmed by ultrasound examination. The first HR was identified at 5 months. Table 5 showed the prevalence of MB at each follow-up point Overall MB rate for the study population was 3.9% (12 patients at maximum follow-up observed) (Table 5). The first MB was identified at 1 month. All patients with MB underwent abdomen CT to confirm the diagnosis. In all patients treated with absorbable mesh (AM) alone (5.8%), there were no recurrences or wound complications, with morbidity rates not statistically significant compared to patients treated with dual mesh or permanent mesh (PM) alone. According to the multivariate analysis, the HR was significantly associated with elevated BMI (mean 32.00, $p<0.05$), preoperative smoking ($p<0.01$), and ASA Score>III ($p<0.05$). No association was found between HR and anterior bridging ($p=0.139$).

Secondary Outcome

Wound complications were observed in 65 cases (21.1%), and 3 patients in developed synthetic mesh infections (0.9%). No statistical difference was reported between complete closure and anterior bridging (20.9% vs 21.4%, $p=0.428$). Thirty-day readmission rate was 2.2% (7 patients). Longer hospital stays within the study group were largely due to SSOs and SSOPIs. Eighteen patients developed SSIs, of which 16 were superficial (5.2%). Authors suffered no organ space SSIs in this series. A subcutaneous seroma was reported in 25 patients (8.1%) with wound dehiscence occurring in 6 subjects (1.9%). Details of SSOs within the first postoperative month can be found in Table 7. Regarding, SSOPI the majority of cases were managed conservatively with one case (0.3%) requiring mesh removal for deep infection resistant to i.v. antibiotics and 6 cases (1.9%) requiring a superficial

surgical debridement [Table 8]. The multivariate analysis showed a significant association between SSO with diabetes ($p<0.001$). In details, SSI were significantly associated with an ASA score>III ($p<0.01$). Conversely, SSOPI were significantly associated with diabetes ($p<0.001$) and anticoagulants use ($p<0.01$). EuraHS-QoL score was collected in 108 patients (35.1%). Patients reported overall sustained improvement in health over the 36 months follow-up period as measured by the EuraHS-QoL score (Table 9). According to the ANOVA test, the increase from baseline on the EuraHS-QoL score was significant ($P<0.05$) at 3,6,12,24 and 36 months postoperatively for each domain of the score. There is no significant correlation between postoperative morbidity and anterior bridging ($p=0.358$).

DISCUSSION

The current is the first multicentric Italian national analysis on patients who underwent PCS with TAR for complex abdominal hernias. This innovative approach offers surgeons better opportunities to perform tension-free abdominal wall reconstruction for complex hernias (4, 11, 17), and numerous benefits compared to other hernioplasties for the treatment of complex abdominal hernias. Numerous studies have reported that utilizing sublay mesh reinforcement following the posterior components separation technique is a safe and effective approach, resulting in recurrence rates of less than 10% (9-11). In the current study, Authors observed a recurrence rate of 2.9% and an incisional hernia-related mesh infection rate of 0.6% during a follow-up period of 38.3±12.7 months. Multivariate analysis reveals that comorbidities, particularly BMI (mean 32.00, $p<0.05$), preoperative smoking ($p<0.01$), and ASA Score>III ($p<0.05$), were associated with HR. The limited recurrence rate in these series can probably related to the fact that Authors never positioned the mesh as a bridge on the posterior fascia; conversely, Authors consistently managed to close it. Moreover, no association was found between HR and anterior bridging ($p=0.139$) in these series. This aligns with what is documented in the literature, indicating one of the advantages of PCS over anterior component separation. The notable low recurrence rate in PCS with TAR is particularly remarkable considering

its application in patients with larger hernias compared to those repaired using the anterior component separation (ACS) technique. The absence of posterior bridging among the TAR population indicates a more efficient mobilization of the recti fasciae compared to ACS. Moreover, this technique allowed to use a larger mesh contributing to the reduced recurrence rate (4, 7). Petro et al. (23) reported seven cases of central mesh failure after ventral hernia repair using lightweight monofilament polyester mesh in the retro-rectus position with full anterior and posterior fascial coverage. A prospective randomized trial in clean or CDC class I wounds also suggested a potential trend (P=0.052) towards a higher recurrence rate with lightweight mesh (17%) compared to "standard" mesh (7%) for retro-rectus ventral hernia repairs (23). In the current study, Authors did not observe any case of central mesh breakdown, even when employing low-density permanent mesh. Additionally, the occurrence of Mesh Bulging was relatively infrequent in these series (3.9% at 38.3±12.7 months), in comparison to findings from other studies. This could be attributed to the combined use of two types of prostheses in the more complex cases: one absorbable and the other permanent, which might have had a favorable impact on this aspect. (5, 6, 12). In this study, a GORE BIO-A® prosthesis was employed, considering different theoretical advantages (14). During transversus abdominis release (TAR) surgery, peritoneal tears are frequent, even experienced surgeons characterize them as practically unavoidable (5,15,16). The challenge lies not so much in the visible tears that can be sutured, but rather in those that go unnoticed. Introducing the absorbable mesh (AM) between the permanent mesh (PM) and the peritoneum can potentially address all these concerns by establishing an extra barrier against intra-abdominal contents. It's important to emphasize that the AM acts as a tissue scaffold, reinforcing the posterior layer and covering inadvertent peritoneal tears, and should not be perceived as a conventional mesh. Furthermore, GORE BIO-A® possesses mechanical properties with tensile memory that offer substantial support to the PM, enhancing its stability upon placement. The AM scaffold is composed of glycolic acid and trimethylene carbonate, primarily degrading through hydrolysis, which promotes tissue regeneration and healing. Experimental studies have demonstrated these characteristics (17, 18). The Cobra study (19) demonstrated that the use of this biosynthetic

mesh in the single-stage repair of contaminated ventral hernias leads to low rates of recurrence and postoperative wound infections. In patients treated with absorbable mesh (AM) alone, the results are encouraging, although the sample size is small (18 patients) and not statistically comparable to the group with dual mesh, as already reported in other studies (19). In this multicenter national study, the majority of patients (80.5%) underwent the "Down to Up" surgical approach for abdominal wall reconstruction. While authors findings did not show statistical improvements in outcomes like recurrence or morbidity, the approach is popular in Italian surgical centers. This technique may offer benefits such as sparing muscle fibers and allowing for an integrated reconstruction with mesh. However, the absence of randomized trials comparing techniques means that these advantages are not yet confirmed, and choices often depend on individual surgeon preference. Novitsky YW et al (15), in a study of 428 patients who underwent complex abdominal wall reconstruction with PCS and followed-up for an average of 31.5 months, found that 18.7% developed surgical site occurrences (SSOs), and 9.1% experienced surgical site infections (SSIs). Procedural intervention was necessary in only 7.3% of cases, with 2.8% managed through bedside incision, drainage, and packing. Wound morbidity after elective TAR was notably lower than anterior component separation, primarily consisting of minor superficial infections treated with antibiotics. In cases of deeper infections, incision, drainage, and potential wound debridement were required, while mesh removal was infrequent (5, 6, 10, 20). Analysis reveals an incidence of wound morbidity associated of TAR, comprising 21.1% for SSOs, 5.8% for SSIs, and 9.6% for SSOPI. In this study, the majority of surgical site infections (SSIs) necessitated only antibiotics administration, and the rate of procedural intervention due to wound morbidity was consistent with literature findings for studies on elective TAR. However, significant wound complications leaded to 7 cases of readmission (2.2%) and one case of mesh removal (0.3%). It is worth noting that the increased incidence of wound events in this study could be attributed to various factors, including wound classification, bowel pathology, and the requirement for resection within a septic surgical field. The multivariate analysis showed a significant association between SSO with diabetes and obesity ($p<0.001$). In details, SSI were significantly

associated with an ASA score>III ($p<0.01$). Conversely, SSOPI were significantly associated with diabetes ($p<0.001$) and anticoagulants use ($p<0.01$). However, it is worth to comment that patient-related' risk factors like overweight (mean BMI of 29.31±4.72 kg/m^2), a history of surgical site infection (20.3%), previous mesh infections (0.9%), recent active smoking (38.6%) within one year of surgery, and diabetes (19.1%) might also contribute to heightened wound morbidity, as demonstrated in prior researches (20, 21). There is no significant correlation between postoperative morbidity and anterior bridging. Although the number of patients was limited, in these series the anterior bridging was not correlated to an increased risk of SSO (20.9% vs 21.4% for complete closure and anterior bridging, respectively; $p=0.428$). The inability to close the anterior fascia (20.8%), even though it never exceeded 120 cm^2, not appeared to impact the 30-day morbidity rate. Fixating the anterior fascia to the two prostheses and enveloping them with the sac, skin, and subcutaneous tissue could potentially act as a protective factor. Multivariate analysis also indicated that the use of anticoagulant drugs appeared to be associated with an increased risk of hematoma formation. However, only 3 out of the 12 cases requiring surgical drainage had this particular risk factor. Alkhatib et al (17) investigated the influence of comorbidities on postoperative outcomes after IH repair, discovering that an increasing number of comorbidities correlated with a significant rise in the 30-day wound morbidity rate. This underscores the crucial role of comprehensive preoperative patient optimization. In this study, some patients achieved smoking cessation (41 out of 119, 34.4%) and glycemic control targets (19 out of 59, 32.2%), but only 7 out of 64 obese patients (10.9%) reached a BMI below 30. Obesity stands as a notable risk factor for postoperative complications, making preoperative weight loss an imperative recommendation. Despite the challenges in patient optimization, it remains an integral aspect of abdominal wall reconstruction. Within this patient cohort, surgical treatment was often pursued despite the absence of weight loss, driven by concerns about potential legal issues. This aspect should potentially be clarified in guidelines. In this study, the EuraHS-QoL score was utilized, an instrument designed to assess the quality of life for patients undergoing ventral hernia repair. This score demonstrated sustained improvement in physical health

from before surgery to 3 and 36 months post-surgery. It is based on a Numerical Rating Scale measuring three dimensions: pain at the hernia site or the hernia repair area, activity limitations, and cosmetic discomfort. Unfortunately, only 108 out of 308 patients (35.1%) were able to complete the EuraHS-QoL score. Nonetheless, Authors observed an initial slow decrease in pain and restrictions domains at 3 months after surgery, potentially due to postoperative discomfort. Patients with a history of previous surgeries might have initially maintained cautious optimism following the operation, yet their hesitance to fully recover could stem from past issues. It's important to acknowledge that the definition of a successful outcome remains unclear, and patients might interpret outcomes differently from surgeons. However, this study has several limitations to address. It's retrospective rather than prospective, and the participating centers contributed varying numbers of patients, with some being high-volume centers and others being low-volume centers. Additionally, the enrolled patients exhibit diverse and often highly heterogeneous characteristics, which should also be considered a limitation of the study. The Component Separation Technique (CST) combined with Transversus Abdominis Release (TAR) served as an effective treatment approach for complex incisional hernias, demonstrating low rates of complications or recurrence and significantly improves quality of life, enabling a quick return to daily activities. Consistent with other research (9, 19, 22) Authors showed that using a combination of absorbable and permanent mesh in TAR effectively treats complex abdominal wall issues. It would be advisable to conduct a randomized multicenter study to compare the combined use of absorbable mesh and permanent mesh versus the use of permanent mesh alone.

Declarations

Conflict of interest: The authors declare no conflict of interest.

Ethical approval: Approval from the Institutional review board.

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.

Disclosure: The authors declare no conflict of interest.

References

1. Holihan JL, Askenasy EP, Greenberg JA, Keith JN, Martindale RG, Roth JS, Mo J et al; Ventral Hernia Outcome Collaboration Writing Group. Component Separation vs. Bridged Repair for Large Ventral Hernias: A Multi-Institutional Risk-Adjusted Comparison, Systematic Review, and Meta-Analysis. Surg Infect (Larchmt). 2016 Feb;17(1):17-26. doi: 10.1089/sur.2015.124. Epub 2015 Sep 16. PMID: 26375422; PMCID: PMC4742969.

2. Ramirez OM, Ruas E, Dellon AL. "Components separation" method for closure of abdominal-wall defects: An anatomic and clinical study. *Plast Reconstr Surg*. 1990;86:519–526.

3. Krpata DM, Blatnik JA, Novitsky YW, Rosen MJ. Posterior and open anterior components separations: a comparative analysis. Am J Surg. 2012 Mar;203(3):318-22; discussion 322. doi: 10.1016/j.amjsurg.2011.10.009. Epub 2012 Jan 12. PMID: 22244073.

4. Pauli EM, Rosen MJ. Open ventral hernia repair with component separation. Surg Clin North Am. 2013;93:1111–1133.

5. Lowe JB, Lowe JB, Baty JD, et al. Risks associated with ‘‘components separation’’ for closure of complex abdominal wall defects. Plast Reconstr Surg. 2003;111:1276 – 1283. quiz 1284 – 5; discussion 1286 – 1288.

6. Carbonell AM, Cobb WS, Chen SM. Posterior components separation during retromuscular hernia repair. Hernia. 2008 Aug;12(4):359-62. doi: 10.1007/s10029-008-0356-2. Epub 2008 Feb 22. PMID: 18293053.

7. Novitsky YW, Elliott HL, Orenstein SB, Rosen MJ. Transversus abdominis muscle release: A novel approach to posterior component separation during complex abdominal wall reconstruction. Am J Surg. 2012;204:709–716.

8. Wegdam JA, Thoolen JMM, Nienhuijs SW, de Bouvy N, de Vries Reilingh TS. Systematic review of transversus abdominis release in complex abdominal wall reconstruction. Hernia. 2019 Feb;23(1):5-15. doi: 10.1007/s10029-018-1870-5. Epub 2018 Dec 11. PMID: 30539311.

9. Robin-Lersundi A, Blazquez Hernando L, López-Monclús J, Cruz Cidoncha A, San Miguel Méndez C, Jimenez Cubedo E et al. How we do it: down to up posterior components separation. Langenbecks Arch Surg. 2018 Jun;403(4):539-546. 10.

10 Muysoms FE, Vanlander A, Ceulemans R, Kyle-Leinhase I, Michiels M, Jacobs I et al. A prospective, multicenter, observational study on quality of life after laparoscopic inguinal hernia repair with ProGrip laparoscopic, self-fixating mesh according to the European Registry for Abdominal Wall Hernias Quality of Life Instrument. Surgery. 2016 Nov;160(5):1344-1357. doi: 10.1016/j.surg.2016.04.026. Epub 2016 Jun 14. PMID: 27316825.

11. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007 Oct 20;370(9596):1453-7. doi: 10.1016/S0140-6736(07)61602-X. PMID: 18064739.

12. Muysoms FE, Miserez M, Berrevoet F, Campanelli G, Champault GG, Chelala E et al. Classification of primary and incisional abdominal wall hernias. Hernia. 2009 Aug;13(4):407-14.

13. Hodgkinson JD, Worley G, Warusavitarne J, Hanna GB, Vaizey CJ, Faiz OD. Evaluation of the Ventral Hernia Working Group classification for long-term outcome using English Hospital Episode Statistics: a population study. Hernia. 2021 Aug;25(4):977-984. doi: 10.1007/s10029-021-02379-8. Epub 2021 Mar 13. PMID: 33712933; PMCID: PMC8370963.

14. Slater NJ, Montgomery A, Berrevoet F, Carbonell AM, Chang A, Franklin M et al. Criteria for definition of a complex abdominal wall hernia. Hernia. 2014 Feb;18(1):7-17. doi: 10.1007/s10029-013-1168-6. Epub 2013 Oct 23. PMID: 24150721.

15. Pizza F, D'Antonio D, Lucido FS, Brusciano L, Mongardini FM, Dell'Isola C et al. IPOM plus versus IPOM standard in incisional hernia repair: results of a prospective multicenter trial. Hernia. 2023 Jun;27(3):695-704. doi: 10.1007/s10029-023-02802-2. Epub 2023 May 7. PMID: 37149818.

16. Knaapen L, Buyne O, Slater N, Matthews B, Goor H, Rosman C. Management of complex ventral hernias: results of an international survey. BJS Open. 2021 Jan 8;5(1):zraa057. doi: 10.1093/bjsopen/zraa057. PMID: 33609388; PMCID: PMC7893472.

12. Kanters AE, Krpata DM, Blatnik JA, Novitsky YM, Rosen MJ. Modified hernia grading scale to stratify surgical site occurrence after open ventral hernia repairs. J Am Coll Surg. 2012 Dec;215(6):787-93. doi: 10.1016/j.jamcollsurg.2012.08.012. Epub 2012 Sep 19. PMID: 22999328.

13. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol. 1999 Apr;20(4):250-78; quiz 279-80. doi: 10.1086/501620. PMID: 10219875.

14. Slater NJ, Montgomery A, Berrevoet F, Carbonell AM, Chang A, Franklin M et al. Criteria for definition of a complex abdominal wall hernia. Hernia. 2014 Feb;18(1):7-17. doi: 10.1007/s10029-013-1168-6. Epub 2013 Oct 23. PMID: 24150721.

15. Novitsky YW, Fayezizadeh M, Majumder A, Neupane R, Elliott HL, Orenstein SB. Outcomes of Posterior Component Separation with Transversus Abdominis Muscle Release and Synthetic Mesh Sublay Reinforcement. Ann Surg. 2016 Aug;264(2):226-32.

16. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol. 1992 Oct;13(10):606-8. PMID: 1334988.

17 Alkhatib H, Tastaldi L, Krpata DM, Petro CC, Huang LC, Phillips S et al. Impact of modifiable comorbidities on 30-day wound morbidity after open incisional hernia repair. Surgery. 2019 Jul;166(1):94-101. doi: 10.1016/j.surg.2019.03.011. Epub 2019 May 13. PMID: 31097319.

18. Grove TN, Kontovounisios C, Montgomery A, Heniford BT, Windsor ACJ, Warren OJ; AWR Europe Collaborative. Perioperative optimization in complex abdominal wall hernias: Delphi

consensus statement. BJS Open. 2021 Sep 6;5(5):zrab082. doi: 10.1093/bjsopen/zrab082. PMID: 34568888; PMCID: PMC8473840.

19. Rosen MJ, Bauer JJ, Harmaty M, Carbonell AM, Cobb WS, Matthews B et al. Multicenter, Prospective, Longitudinal Study of the Recurrence, Surgical Site Infection, and Quality of Life After Contaminated Ventral Hernia Repair Using Biosynthetic Absorbable Mesh: The COBRA Study. Ann Surg. 2017 Jan;265(1):205-211. doi: 10.1097/SLA.0000000000001601. PMID: 28009747; PMCID: PMC5181129.

20. Dewulf M, Hiekkaranta JM, Mäkäräinen E, Saarnio J, Vierstraete M, Ohtonen P, Muysoms F, Rautio T. Open versus robotic-assisted laparoscopic posterior component separation in complex abdominal wall repair. BJS Open. 2022 May 2;6(3):zrac057. doi: 10.1093/bjsopen/zrac057. PMID: 35748378; PMCID: PMC9227725.

21. Knaapen L, Buyne O, Slater N, Matthews B, Goor H, Rosman C. Management of complex ventral hernias: results of an international survey. BJS Open. 2021 Jan 8;5(1):zraa057. doi: 10.1093/bjsopen/zraa057. PMID: 33609388; PMCID: PMC7893472.

22. Pizza F, D'Antonio D, Arcopinto M, Dell'Isola C, Marvaso A. Safety and efficacy of prophylactic resorbable biosynthetic mesh in loop-ileostomy reversal: a case-control study. Updates Surg. 2020 Mar;72(1):103-108. doi: 10.1007/s13304-020-00702-z. Epub 2020 Jan 9. PMID: 31919832.

23. Petro CC, Nahabet EH, Criss CN, Orenstein SB, von Recum HA, Novitsky YW et al Central failures of lightweight monofilament polyester mesh causing hernia recurrence: a cautionary note. Hernia. 2015 Feb;19(1):155-9. doi: 10.1007/s10029-014-1237-5. PMID: 24659227.

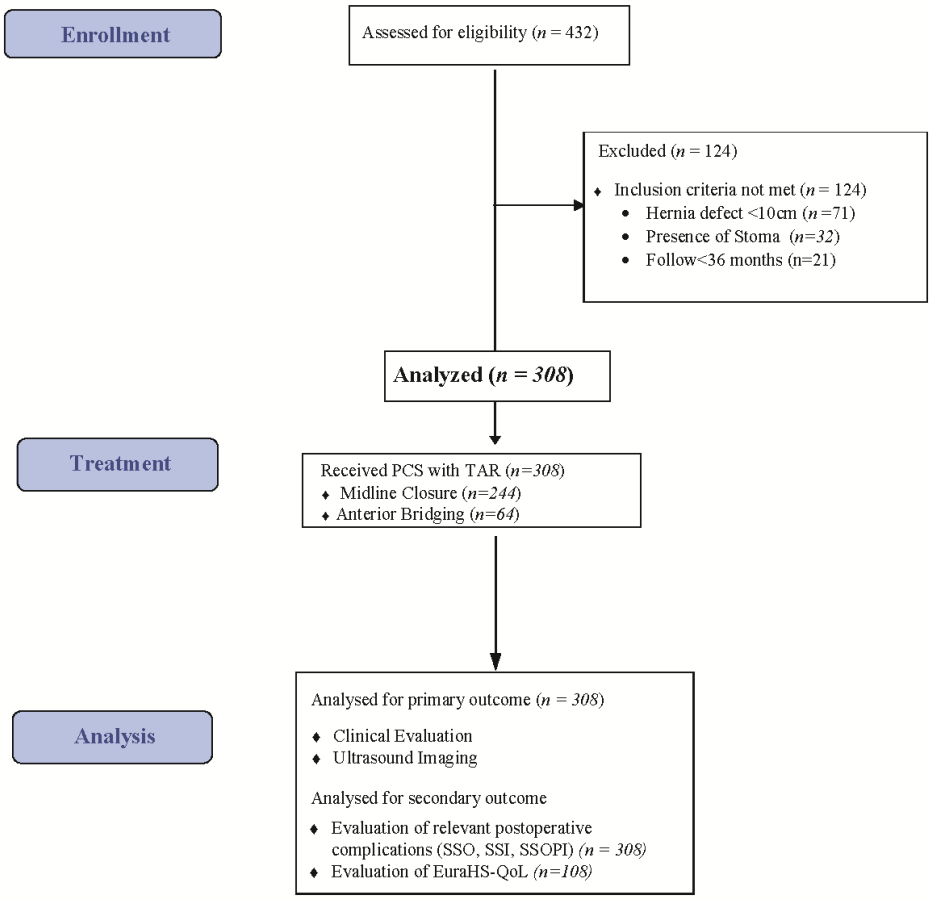

Fig.1 Study design Follow-up categorization.

Fig. 1 Study design Follow-up categorization.

157x159mm (200 x 200 DPI)

Table 1. Baseline demographic and pathological of patients undergoing Posterior Component Separation with Transversus Abdominis Release

	PCS with TAR *308 Pts*
Age°	63.76±11.32
Gender (Male/Female)	180/128 (58.4%/41.6%)
BMI°	29.31±4.72
Concomitant Ostomy	24 (7.8%)
Diabetes	59 (19.1%)
Smoking	119 (38.6%)
Chronic obstructive pulmonary disease	21 (6.8%)
Coronary artery disease	45 (14.6%)
Oncologic disease	99 (32.1%)
Anticoagulants use	87 (28.3%)
ASA Score III-IV	80 (25.9%)

Values are expressed as number of cases or means and standard deviation°.

BMI, Body Mass Index; ASA, American Society of Anesthesiologists; PCS with TAR, Posterior Component Separation with Transversus Abdominis Release

Table 2. Incisional Hernia and patients abdominal features of patients undergoing Posterior Component Separation with Transversus Abdominis Release

	PCS with TAR *308 Pts*
Abdominal Hernia ○ **Incisional Hernia** ○ **Ventral Hernia**	 214 (69.5%) 94 (31.5%)
VHWG risk stratification ○ **Low Risk** ○ **Medium Risk** ○ **High Risk**	 93 (30.2%) 198 (64.3%) 17 (5.5%)
Defect dimension (cm^2)°	321.18±89.22
Recurrent incisional hernia	86 (27.9%)
Concomitant Ostomy	24 (7.8%)
Preoperative CDC wound classification ○ **Clean** ○ **Clean-contaminated** ○ **Contaminated** ○ **Dirty-infected**	 243 (78.9%) 30 (9.7%) 34 (1.1%) 1 (0.3%)

Values are expressed as number of cases or means and standard deviation°.

VHWG, Ventral Hernia Working Group; CDC, Centre for Disease Control and Prevention; PCS with TAR, Posterior Component Separation with Transversus Abdominis Release

Table 3. Intraoperative outcomes and Mesh features in patients undergoing Posterior Component Separation with Transversus Abdominis Release

	PCS with TAR *308 Pts*
Operative Time (min)°	280±112
Blood Loss (mL)°	115±187
Bilateral PCS	251 (81.4%)
Visceral injury	21 (6.8%)
Number of mesh adopted	1.74
Mesh area (cm^2)°	590.33±121.28
Mesh Feature ○ **Permanent alone** ○ **Mixed (Permanent +Absorbable)** ○ **Absorbable alone**	49 (15.9%) 259 (84.1%) 18 (5.8%)
Fascial Closure ○ **Midline Closure** ○ **Anterior Bridging**	244 (79.2%) 64 (20.8%)
Surgical approach ○ **Up to down** ○ **Down to up**	60 (19.5%) 248 (80.5%)
Fixing technique ○ **Stiches** ○ **No Stiches**	131 (42.5%) 177 (57.5%)

Associated Surgery	33 (10.7%)
Hospitalization (days)°	7.39±6.73
Major Morbidity	5 (1.6%)
Mortality	2 (0.6%)

Values are expressed as number of cases or means and standard deviation°.

PCS, Posterior Component Separation; PCS with TAR, Posterior Component Separation with Transversus Abdominis Release

Table 4. Incisional Hernia Recurrence in patients undergoing Posterior Component Separation with Transversus Abdominis Release

	PCS with TAR *308 Pts*
3 months hernia recurrence	0
6 months hernia recurrence	2 (0.6%)
12 months hernia recurrence	3 (0.9%)
24 months hernia recurrence	8 (2.6%)
36 months hernia recurrence	9 (2.9%)

PCS with TAR, Posterior Component Separation with Transversus Abdominis Release

Table 5. Mesh Bulging in patients undergoing Posterior Component Separation with Transversus Abdominis Release

	PCS with TAR *308 Pts*
3 months mesh bulging	2 (0.6%)
6 months mesh bulging	5 (1.6%)
12 months mesh bulging	9 (2.9%)
24 months mesh bulging	10 (3.2%)
36 months mesh bulging	12 (3.9%)

PCS with TAR, Posterior Component Separation with Transversus Abdominis Release

Table 6. Multivariate analysis influencing the surgical outcomes in patients undergoing Posterior Component Separation with Transversus Abdominis Release

	Recurrence	p	SSO	p	SSI	p	SSOPI	p
Age*	63.95	0.121	63.77	0.497	63.52	0.058	63.55	0.138
	59.44		63.76		67.83		66.04	
BMI*	28.68	0.019	28.70	0.279	28.76	0.433	28.86	0.152
	32.00		29.12		28.96		27.88	
Gender (Male)**	0.579	0.300	0.587	0.433	0.576	0.111	0.577	0.182
	0.667		0.574		0.722		0.667	
Diabetes**	0.191	0.145	0.148	0.000	0.164	0.000	0.159	0.000
	0.333		0.407		0.667		0.556	
COPD**	0.071	0.203	0.068	0.434	0.066	0.233	0.068	0.455
	0.000		0.074		0.111		0.074	
Smoking**	0.377	0.008	0.382	0.363	0.376	0.064	0.374	0.070
	0.778		0.407		0.556		0.519	
ASA III-IV**	0.252	0.020	0.251	0.167	0.247	0.009	0.252	0.091
	0.556		0.315		0.500		0.370	
Anticoagulants use**	0.017	0.347	0.012	0.091	0.014	0.087	0.011	0.006
	0.000		0.037		0.056		0.074	
Anterior Bridging**	0.145	0.139	0.023	0.428	0.136	0.159	0.256	0.231
	0.347		0.051		0.267		0.359	

*Mean value between the subgroups. It was adopted a Student's t-test for the equality of means for independent samples under the assumption of unknown variances

** Proportion in subgroups. In this case, the test of proportions for independent samples was used.

Table 7. Surgical Site Occurrence in patients undergoing Posterior Component Separation with Transversus Abdominis Release

	Surgical Site Occurrence (SSO) *308 Pts*
Surgical site infection ○ **Superficial** ○ **Deep** ○ **Organ Space**	 16 (5.2%) 2 (0.6%) 0
Seroma formation	25 (8.1%)
Wound dehiscence	6 (1.9%)
Hematoma	12 (3.9%)
Skin or soft tissue necrosis	1 (0.3%)
Enterocutaneous fistula	0
Wound cellulitis	9 (2.9%)

SSO, Surgical Site Occurrence

Table 8. Surgical Site Occurrence Requiring Procedural Intervention in patients undergoing Posterior Component Separation with Transversus Abdominis Release

	Surgical Site Occurrence Requiring Procedural Intervention (SSOPI) *308 Pts*
Antibiotics only	19 (6.2%)
Bedside wound interventions	2 (0.6%)
Percutaneous interventions	2 (0.6%)
Surgical debridement	6 (1.9%)
Mesh removal	1 (0.3%)

SSOPI, Surgical Site Occurrence Requiring Procedural Intervention

Table 9. EuraHS-QoL score in patients undergoing Posterior Component Separation with Transversus Abdominis Release

EuraHS-QoL score *108 Pts*	**Preoperative**	**3 Months**	**6 Months**	**12 Months**	**24 Months**	**36 Months**	**p***
Pain domain	17.62 (12–25)	15.13(6-21)	10.31(6-21)	8.10(6-21)	7.05(3-21)	6.77(3-21)	0.032
Restrictions domain	23.23(13-36)	21.11(18-26)	14.22(14-26)	10.36(14-26)	8.36(4-24)	7.11(4-24)	0.017
Esthetical discomfort	12.12(4-18)	7.37(2-15)	4.28(2-15)	4.11(2-15)	3.18(2-15)	3.24(1-8)	0.041

Values are expressed means and range. *ANOVA test

QoL, Quality of Life