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CYSTOCELE REPAIR BY AUTOLOGOUS RECTUS FASCIA GRAFT. THE PUBOVAGINAL CYSTOCELE SLING

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Autologous Pubovaginal Cystocele Sling is a safe surgical technique to correct cystocele, with or without stress urinary incontinence, delivering successful anatomical and functional outcomes.

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Abstract

Purpose: The autologous rectus fascia pubovaginal sling has been a safe and effective means of correcting stress urinary incontinence (SUI). In this study we tested the feasibility of using a larger graft for correcting cystocele with or without SUI.

Materials and Methods: between January 2006 and October 2010, thirty patients with symptomatic cystocele underwent the Pubovaginal Cystocele Sling (PCS) procedure; 14 were with concomitant SUI and 16 without. The technique is a modification of the standard pubovaginal sling procedure. A large trapezoidal (major base 6cm, minor base 4cm, height 5cm) rectus fascia graft is used, with four instead of two sutures to suspend the graft corners. The two sutures at the level of mid urethra are tied above rectus muscles in a tension-free manner, whereas the two at the level of the cervical fold are tied with tension. Data on anatomical outcomes (Baden-Walker classification), functional outcomes (Pelvic Floor Impact Questionnaire, PFIQ-7-short form), postvoid residual urine volume (PVR), and urinary tract infection (UTI) were prospectively collected.

Results: At mean follow-up of 62.6 months (range 46-98 months), there was no recurrence in anterior compartment but one involving both apical and posterior compartments. All patients reported a statistically significant improvement in PFIQ-7 score. When present preoperatively, PVR, UTI, and SUI ceased in all cases. There was only one complication, a donor-site wound dehiscence without fascial involvement.

Conclusions: The autologous PCS seems to be a safe and effective technique for correcting cystocele, with or without SUI.

Introduction

Pelvic organ prolapse (POP) is a significant health issue in females worldwide.[1] In the United States, more than 300,000 surgeries for POP are performed each year, with anterior colporrhaphy (AC) being the most common operation for cystocele/anterior compartment prolapse repair.[2] However, failure rates of 40 to 60% have been reported following this procedure, as it uses weakened tissue and addresses only midline defects with no apical support.[3] To avoid failures related to the use of a weak native tissue, synthetic grafts have been introduced and the abdominal mesh sacral colpopexy (AMSC) procedure has gained popularity. AMSC provides the highest cure rates for apical/vaginal vault prolapse but this benefit must be balanced against a long operating time, a long time to return to activities of daily living, and a nearly 20% risk of *de novo* stress urinary incontinence (SUI).[4,5]

Following the success of AMSC for apical prolapse repair, transvaginal mesh surgery (TMS) has increasingly been used for cystocele repair. In comparison with AC, TMS has higher short-term rate of successful treatment but also has a higher rate of surgical complications and postoperative adverse events, the latter mainly due to mesh exposure. [4,5] As a matter of fact, in 2008 and in 2011 the United States Food and Drug Administration issued two Public Health Notifications on serious complications associated with TMS; the latest update warns that surgical meshes represent a source of concern as serious complications associated with their use for transvaginal POP repair are not rare.[6]

The ideal procedure for cystocele repair should therefore avoid the use of weakened autologous tissues but also of synthetic meshes, and should be able to correct SUI, when present, rather than causing *de novo* incontinence. With this in mind, we tested the possibility to correct cystocele, with or without SUI, using a modified pubovaginal sling procedure that involved a large trapezoidal autologous rectus fascia graft.

Materials and Methods

Between January 2006 and October 2010, thirty consecutive patients referred to one of us (LC) for surgical correction of grade 2 to 4 (Baden Walker halfway classification system – HWS) symptomatic cystocele were scheduled for the PCS procedure. Nineteen patients had a pure cystocele/anterior compartment defect, ten had a combined anterior and apical compartment prolapse, and one had a prolapse of all three compartments but the posterior defect was minor (HWS degree 1) thus requiring no treatment. The HWS classification of prolapse was carried out with the patient having a full bladder and placed in gynecological position. Before surgery, all patients underwent urodynamic testing, with and without cystocele repositioning.

All surgical procedures were performed under spinal anesthesia. The patient was placed in the dorsal lithotomy position and both suprapubic and genital areas were draped. A Foley catheter was inserted and an inverted-U colpothomy carried out on the anterior vaginal wall, approximately 1 cm from the urethral meatus. The plane between the pubo-cervical fascia and the anterior vaginal wall was developed by blunt and sharp dissection till reaching the cervical fold medially and the paracervical spaces laterally (Fig. 1). Meanwhile, another surgeon harvested, through a Pfannenstiel incision, a large trapezoidal (major base 6cm, minor base 4cm, height 5cm) rectus fascia graft (Fig. 2). Care was taken to obtain a mobilization of the rectus fascia from the overlying tissue wide enough to leave at least 3 cm from the edges of the graft as this allowed an easier sliding of the major base towards the minor one during closure. An even wider mobilization of the major base side, particularly on the midline, was noticed to be useful to make the sliding process easier. Conversely, there was no need to mobilize the fascial edges from the underlying muscles. The Retzius space was entered and the endopelvic fascia cleaned bilaterally in order to pass the Raz needle under direct vision, thus avoiding the large veins underneath (Fig. 3). The surgeon's index finger kept at the level of mid urethra and, subsequently, of the paracervical space, indicated the place for correct passage of Raz needle. Four instead of 2 woven polyester 1/0

stitches were passed; the proximal part (with the needle) was kept on the vaginal side to anchor the four corners of the graft (Fig. 4) while the distal part was passed above rectus muscles before closing their fascia. The gap in rectus muscles fascia was closed starting from the two corners of the major base; the two sutures were tied together in the midline and the remaining vertical gap was closed with one of these two sutures, thus resulting in a figure of Y closure (Fig. 5). Such closure reduced tension in the cranio-caudal direction. Meanwhile, cystoscopy was performed to rule out bladder or urethral perforation. Using 3/0 polyglactin stitches, the apical part of the graft was fixed to mid urethra whereas the basal one was fixed at the level of the cervical fold (Fig. 6). A size 10 Hegar dilator was introduced into the urethra; the two apical (mid-urethral) stitches were tied together above the rectus fascia in a tension-free fashion, whereas the two basal ones were tied together above the rectus fascia with tension in order to suspend the cervical fold. Straightening of the Hegar dilator (Fig. 7) indicated adequate suspension. A 20Fr Foley catheter and a vaginal iodized pack were left in place; the pack was removed on first postoperative day while the catheter on second. The patient was discharged after a successful voiding trial; lifting of objects greater than 3 kg and sexual intercourse were forbidden for the first 4 weeks.

Subjective outcome was assessed by the International Continence Society-recommended disease-specific questionnaire for quality of life (Pelvic Floor Impact Questionnaire short form, PFIQ-7),[7] whereas objective outcome was assessed by the Baden Walker HWS, the post-void residual urinary volume (PVR), the urinary tract infection (UTI) rate, and the number of pads per day in those with SUI. The PVR was measured by ultrasound; a PVR ≤20 ml was considered as no PVR, thus categorized as 0 ml. UTI was defined as the occurrence of at least two episodes of symptomatic UTI with positive urine culture over a year. All data were prospectively recorded. The study was approved by the local ethical committee and all patients had to sign an informed written consent to be enrolled.

Statistical Analysis

Continuous data are reported as means ± standard deviations (SD); those with normal distribution, according to the Skewness and Kurtosis test, were compared by Student's t-test for paired or unpaired data, whereas those with a non-parametric distribution were compared by the Mann-Whitney U-test for independent groups. Differences in rate were compared by the Fisher's exact test or the χ^2 test, as appropriate. A two-sided $p<0.05$ was considered statistically significant. Statistical calculations were carried out using the MedCalc 9.2.0.1 (MedCalc software, Mariakerke, Belgium) and PASW 18 software (PASW 18, SPSS, Chicago, Ill, USA).

Results

Of the 30 patients who underwent the PCS procedure, 10 complained also of SUI and, as matter of fact, were found with SUI clinically and urodinamically confirmed; 4 patients did not have complaints of SUI but were found to have SUI at cystocele repositioning during urodynamic testing, thus making a total of 14 patients diagnosed with cystocele and concomitant SUI. The remaining 16 patients had cystocele without subjective or objective SUI.

Patients' characteristics and surgical data are listed in Table 1. There were no intraoperative complications. The urethral catheter was removed on second postoperative day and the patient discharged 24 hours later in case of successful voiding. Postoperative complications included 9 cases of transient urinary retention upon catheter removal, which were successfully treated with a mean of 4 days (range 3-5) of self clean intermittent catheterization. As expected, transient urinary retention was more common in patients without than in those with SUI (37.5% vs. 21.4%; p=0.44). Most cases however occurred in the early phase of our experience; it is likely that tying with tension the two stitches at the level of the cervical fold caused further tension on the two stitches at the level of mid urethra, thus resulting in transient urinary retention.

There was no donor-site complication except for one case of superficial wound dehiscence not involving the rectus fascia in a diabetic patient. It was successfully treated by surgical toilette and

re-suturing.

Patients were seen at 1, 3, 6 and 12 months postoperatively and then yearly. Mean follow-up was 62.6 months (range 46-98 months). All patients experienced a statistically significant reduction in their PFIQ-7 score; as expected, those with SUI had, on average, a greater reduction than those without SUI (Table 2). Interestingly, the PCS procedure benefit all three domains of the PFIQ-7, including the bowel domain (Figure 8, panel A). Again, in patients with SUI the benefit was greater and involved all three domains, whereas in patients without SUI the benefit was lower, remaining significant only in the bladder and vagina domain (Figure 8, panel B and C).

Objectively, the PCS corrected the cystocele in all cases as well as the apical compartment defect when present (Table 3). One patient, the fourth of this series, reported cystocele recurrence. At physical examination, however, she had a floppy and redundant anterior vaginal wall not passing the hymeneal ring (HWS degree 1) with and without straining; conversely, adequate bladder base suspension could be felt during straining. This finding was attributed to insufficient anterior vaginal wall resection during surgery. The patient refused surgical excision. Another patient presented 66 months after surgery with a de novo symptomatic grade III apical (uterine) and grade II posterior prolapse which were not seen at the 5-year follow-up visit. PVR and UTI, when preoperatively present, disappeared in all cases (Table 3). No patient leaked urine when examined with a full bladder in gynecological position and none reported pad usage; the occasional use of safety panty-liners reported by four patients was considered as no need for pad usage.

Discussion

Chapple et al.[6] recently pointed out the expanding phenomenon of litigation, up to class-action suits, against Companies producing kits for TMS and surgeons implanting them, as well as the consequent emerging trend, among United States physicians, to opt for non-mesh surgery for POP. In this scenario of “uncertainty for mesh use in surgery”, a potential way forward was seen in

research directed towards synthetic absorbable materials and tissue regeneration techniques but also towards novel native tissue-based repair techniques.[6] The pubovaginal sling procedure, described in the early 20th century and popularized by McGuire in the late 1970s, has stood the test of time, demonstrating to be a safe and effective native tissue-based technique for treating SUI with excellent outcomes.[8] Consequently it appears logical to modify the technique to correct cystocele as well.

The described PCS procedure provided anatomical success in 96.7% (29/30) of cases, as only one patient had a *de novo* apical and posterior compartment defect 66 months after surgery. All patients had functional improvement in PVR, UTI, and SUI when present. Current literature suggests defining success after POP surgery on the basis of urological symptoms and patient's satisfaction rather than on anatomical correction only.[9] According to PFIQ-7 scores, the PCS provided significant symptoms improvement in all patients; also in the patient with postoperative redundant vaginal wall had a significant, though lower, reduction in PFIQ-7 score. Complications were only minor, as we had a 30% rate of postoperative urinary retention that, however, disappeared within one week, and no case of *de novo* detrusor overactivity/urge incontinence.

The possibility of successfully correcting concomitant cystocele and SUI with a PCS has already been described by Chung et al. [10] using a cadaveric dermal allograft. At mean follow-up of 28±4 months, one (5.3%) of their 19 patients had graft infection resulting in graft removal, one (5.3%) developed *de novo* detrusor instability, successfully treated with anticholinergics, and two (10.5%) had asymptomatic grade I and II recurrent cystocele. Also the possibility of successfully correcting cystocele with an autologous tissue has already been described by Raz et al. [11] Their "four-corner" transvaginal needle suspension operation provides effective repair of anterior vaginal wall prolapse by elevating both bladder neck and base in the high retropubic position but could open an apical defect for the future.

Like the "four-corner" transvaginal needle suspension, the PCS could theoretically expose to the

risk of opening an apical compartment defect for the future. In our series, however, the incidence of *de novo* apical compartment defect was very low (3.3%), probably due to the fact that we used a stronger tissue (rectus fascia rather than vaginal wall). Moreover, since the *de novo* apical compartment defect occurred more than 5 years after surgery, it is possible that it was due to vaginal wall laxity rather than the PCS having created space for it.

Our PCS procedure has several strengths. Like TMS, it seems to provide successful long-term results in terms of both subjective improvement and objective correction of cystocele with or without SUI; in addition, it has the advantages of preventing the costs and, most important, the complications related to synthetic as well as allograft meshes. In comparison to AMSC, it is able to cure rather than causing SUI.

The use of any autologous substitute may be limited by the possibility of donor-site complications. Risks potentially associated to the creation of a large fascial defect could have been difficulty in fascial closure, postoperative pain and wound dehiscence. Fortunately, there was none of these problems and the case of wound dehiscence was probably due to patient's risk factors (diabetes mellitus) rather than the procedure itself. It is likely that a wide and accurate mobilization of rectus muscle fascia and closure of the isosceles trapezoid fascial gap into a figure of Y were effective in reducing tension up to preventing significant postoperative pain and fascial dehiscence. Interestingly, previous abdominal surgery with incision of the rectus fascia, including 8 cases of abdominal hysterectomy and 2 of cesarean section, did not hamper on the procedure. The previously incised rectus fascia did not appear weak but rather fibrotic, thus providing a graft robust though slightly more difficult to harvest.

A potential study limitation is not having used the Pelvic Organ Prolapse Quantification system (POP-Q) that certainly is more accurate than the common HWS, but also more complex and not worldwide accepted/routinely adopted. Another potential study limitation is not having planned a comparison with another procedure commonly used for cystocele repair, but this was beyond the

scope of a “pilot” study aiming to evaluate feasibility, efficacy and safety of this novel procedure. Finally, we acknowledge that the use of validated questionnaires for incontinence, voiding dysfunction, and sexual function would have provided further strength to our study.

Conclusions

The PCS proved to be an effective and safe technique for the correction of cystocele, with or without SUI. Using a robust native tissue, it avoids complications related to the use of non-autologous meshes.

Acknowledgments

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References

1. Beer M, Kuhn A. Surgical techniques for vault prolapse: a review of the literature. Eur J Obstet Gynecol Reprod Biol 2005; 119: 144-155.

2. Shah AD, Koduri S, Rajan SS et al The age distribution, rates, and types of surgery for pelvic organ prolapse in the U.S. Int Urogynecol J Pelvic Floor Dysfunct 2008; 19: 421-8.

3. Maher C, Baessler K. Surgical management of anterior vaginal wall prolapse: an evidence based literature review. Int Urogynecol J Pelvic Floor Dysfunct 2006; 17: 195-201.

4. Maher C, Feiner B, Baessler K et al. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2013 Apr 30; 4:CD004014.

5. Altman D, Vayrynem T, Engh ME et al. for the Nordic Transvaginal Mesh Group. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 2011; 364: 1826-36.

6. Chapple CR, Raz S, Brubaker L et al. Mesh sling in an era of uncertainty: lessons learned and the way forward. Eur Urol 2013; 64: 525-529.

7. Barber MD. Symptoms and outcome measures of pelvic organ prolapse. Clin Obstet Gynecol 2005; 48(3): 648-661.

8. Chaikin DC, Rasenthal J, Balivas JG. Pubovaginal fascial sling for all types of stress urinary incontinence: long term analysis. J Urol 1998; 160: 1312-6.

9. Barber MD, Brubaker L, Nygaard I et al. Pelvic floor disorders network. Defining success after surgery for pelvic organ prolapse. Obstet Gynecol 2009; 114: 600-609.

10. Chung SY, Franks M, Smith CP et al. Technique of combined pubovaginal sling and cystocele repair using a single piece of cadaveric dermal graft. Urology 2002; 59: 538-541.

11. Raz S, Klutke CG, Golomb J. Four-corner bladder and urethral suspension for moderate cystocele. J Urol 1989; 142(3): 712-5.

Figure Legends:

Figure 1: Following an inverted-U colpothomy, approximately 1 cm from external urethral meatus, the plane between pubo-cervical fascia and anterior vaginal wall is developed by blunt and sharp dissection till reaching the cervical fold medially and the paracervical spaces laterally.

Figure 2: A large trapezoidal (base 6cm, apex 4cm, height 5cm – picture in picture) rectus fascia graft is harvested through a Pfannenstiel incision.

Figure 3: The left endopelvic fascia is cleaned and the Raz needle passed under direct vision to avoid the large veins underneath. Thin arrow shows the apical stitch; large arrow shows the Raz needle perforating the endopelvic fascia to pass the basal stitch.

Figure 4: On the vaginal side, the four corners of the graft are anchored using the proximal part of the 4 woven polyester 1/0 stitches passed through the endopelvic fascia.

Figure 5: Y closure of rectus muscles fascia.

Figure 6: Using 3/0 polyglactin stitches, the apical part of the graft is fixed to mid urethra whereas the basal one is fixed at the level of the cervical fold.

Figure 7: Straightening of the Hegar dilator indicates adequate vaginal wall suspension.

Figure 8: Changes in the 3 domains of the PFIQ-7 questionnaire in the overall population (panel A), as well as in patient with SUI (panel B) and without SUI (panel C).

Table 1. Patients' characteristics and surgical data

	Overall population	**Pts. without SUI**	**Pts. with SUI**
Patients	30	16	14
Age (y)	61 ± 8.67	61.6 ± 9.50	60.4 ± 8.85
BMI (Kg/m^2)	30.2 ± 1.74	29.7 ± 3.59	31.6 ± 2.20
Previous hysterectomy (%)	30 (9/30)	37.5 (6/16)	21.4 (3/14)
Previous POP repair (%)	30 (9/30)	37.5 (6/16)	21.4 (3/14)
POP (# and HWS* *degree*)			
Anterior vaginal defect	30/30 3.3 (range: 2-4)	16/16 3 (range: 2-4)	14/14 3.6 (range: 3-4)
Apical vaginal defect	10/30 1.9 (range: 1-3)	6/16 2 (range: 1-3)	4/14 1.9 (range: 1-2)
Posterior vaginal defect	1/30 HWS 1	1/16 HWS 1	0/14
Preoperative PVR (mL)	56 ± 48.12	90 ± 37.41	22 ± 30.33
Previous UTIs (%)	30 (9/30)	37.5 (6/16)	21.4 (3/14)
Pads/day (#)	NA	0	3.2 ± 1.30
Operative time (min)	87.7 ± 16.8	86 ± 8.66	89.5 ± 24.74
Blood transfusion rate (%)	0	0	0
Postoperative hospital stay (days)	4.1 ± 0.9	4.2 ± 1.1	4.0 ± 1.0
Postoperative urinary retention (%)	30 (9/30)	37.5 (6/16)	21.4 (3/14)
Wound dehiscence (%)	3.3 (1/30)	6.2 (1/16)	0

Data expressed as mean±standard deviation or rate.

*HWS: Half Way Classification System.

Table 2. PFIQ-7 scores outcome data.

	Overall population	**Pts. without SUI**	**Pts. with SUI**	**p-value[1]**
Patients	30	16	14	-
Preoperative	193.5 ± 45.66	179.2 ± 54.2	207.8 ± 35.2	*0.35*
Postoperative 1 year	38.2 ± 37.29	54.2 ± 48.01	22.2 ± 13.5	*0.18*
Postoperative last follow-up	36.2 ± 21.14	55.1 ± 49.2	21.5 ± 12.5	*0.17*
p-value[2]	*<0.0001*	*<0.0001*	*<0.0001*	

Data are expressed as mean ± standard deviation.

p-value[1] : with vs. without SUI;

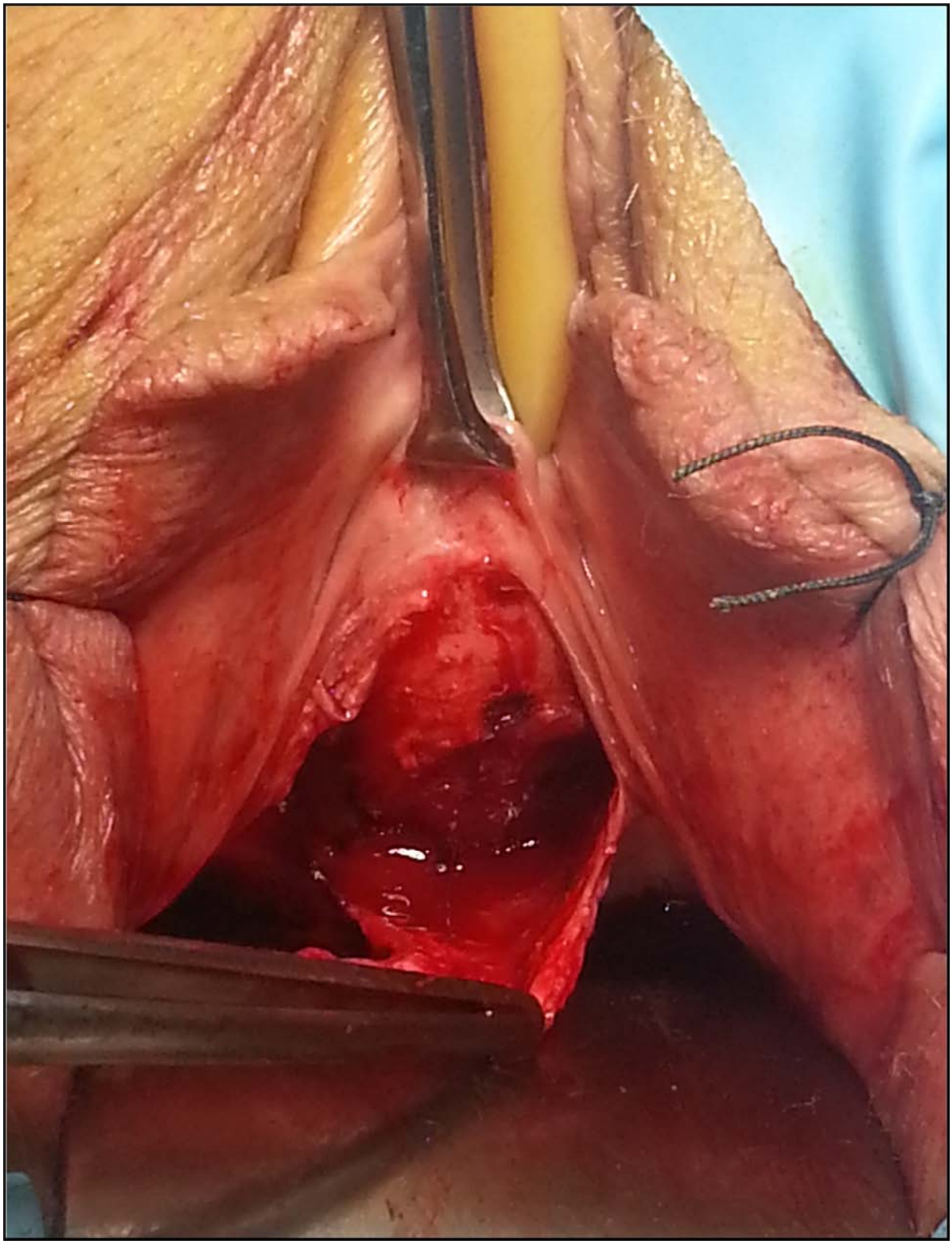
p-value[2] : preoperative vs. postoperative last follow-up

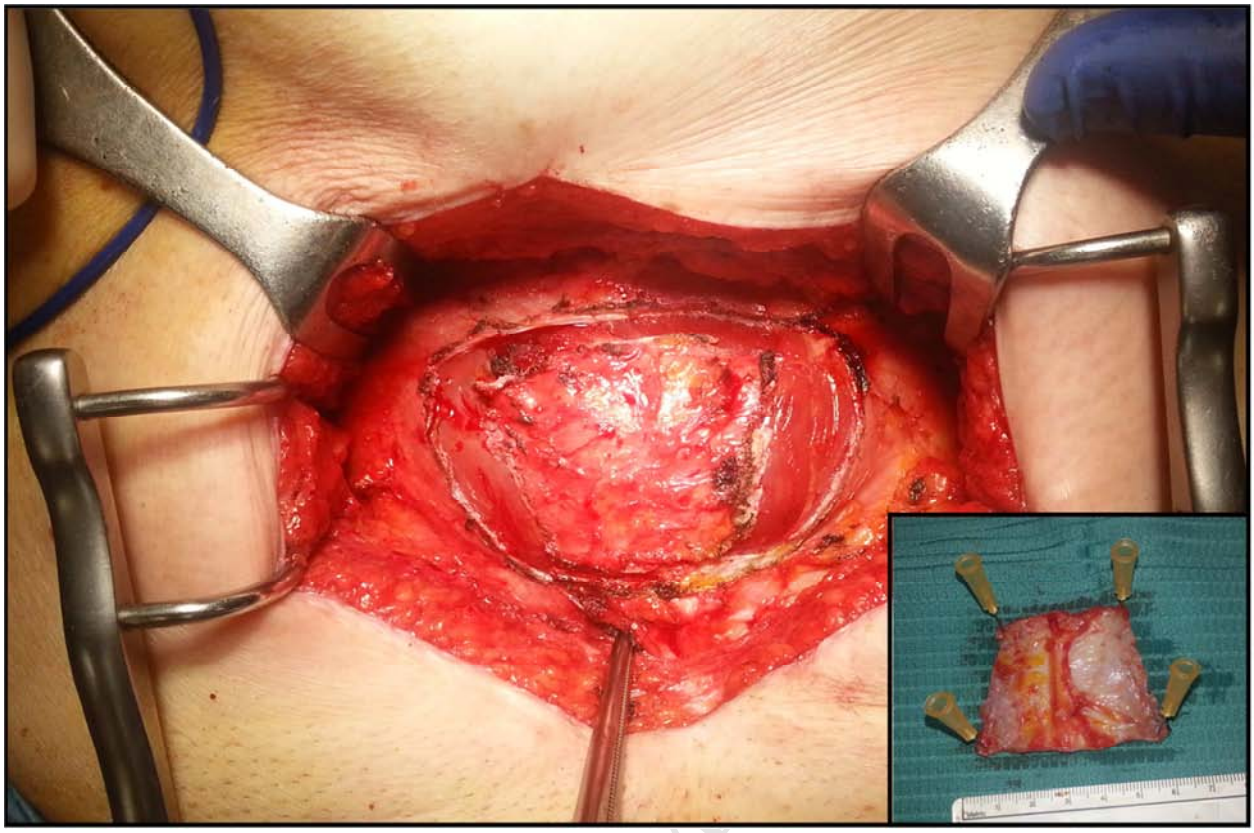
Table 3. Objective outcome data

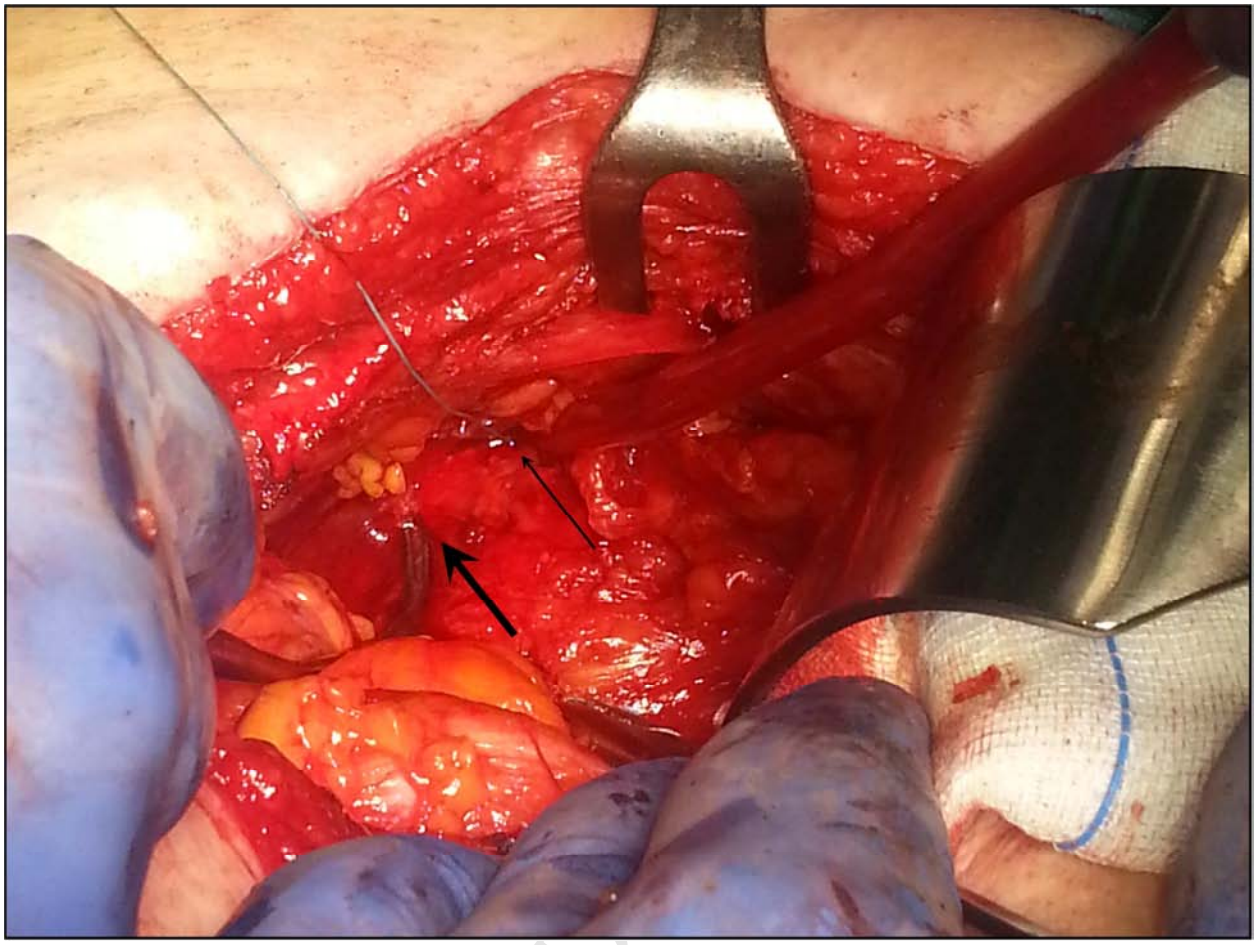
	Preoperative	Postoperative 1 year	Postoperative last follow-up	p-value"
POP (# and HWS* *degree*)				
Anterior vaginal defect	30/30 3.3 (range: 2-4)	1/30^ 1	1/30^ 1	*<0.001*
Apical vaginal defect	10/30 1.9 (range: 1-3)	0/30	1/30 3	*0.007*
Posterior vaginal defect	1/30 1	1/30 1	2/30 1.5 (range: 1-2)	*0.9*
PVR (mL)	56 ± 48.12	0	0	*<0.001*
UTIs (%)	30	0	0	*0.2*
Pads/day§ (#)	3.2 ± 1.30	0	0	*<0.0001*

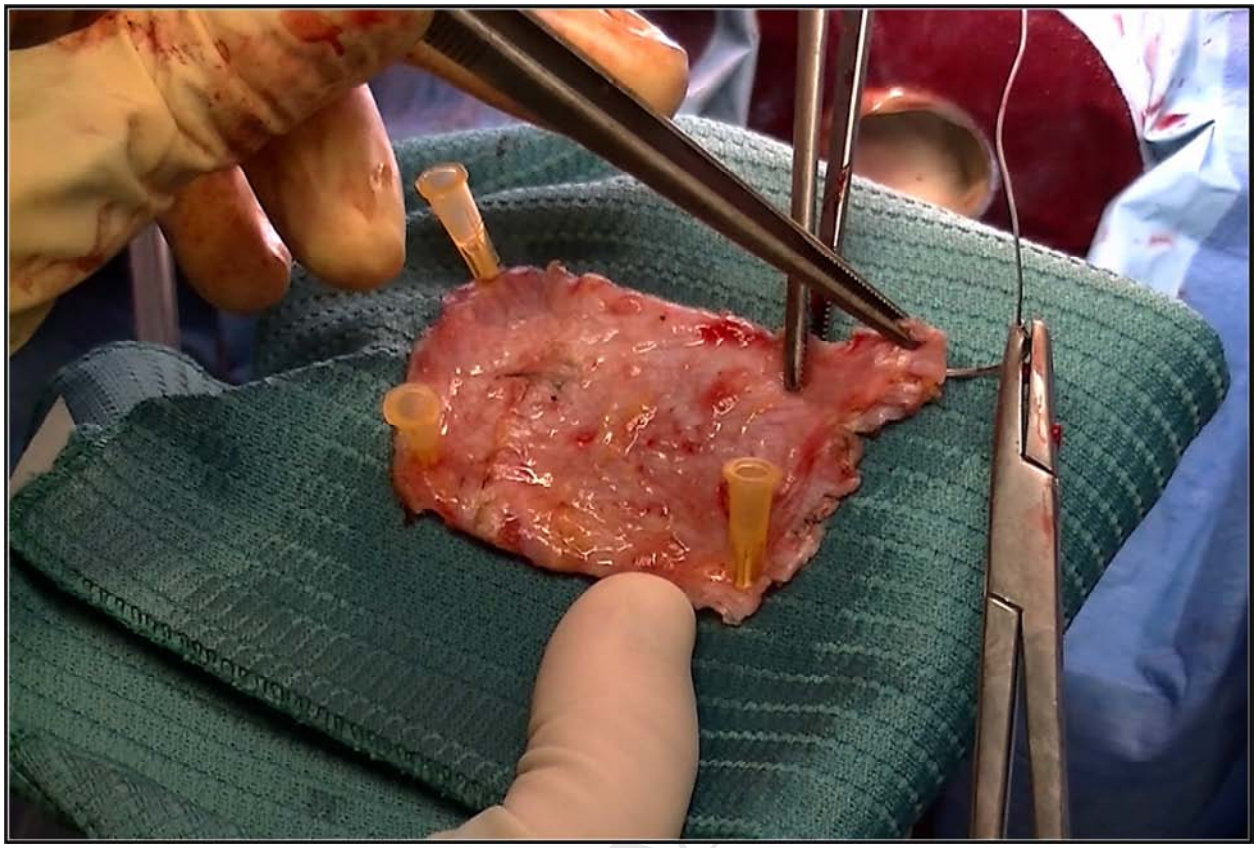
Data are expressed as mean ± standard deviation or rate.

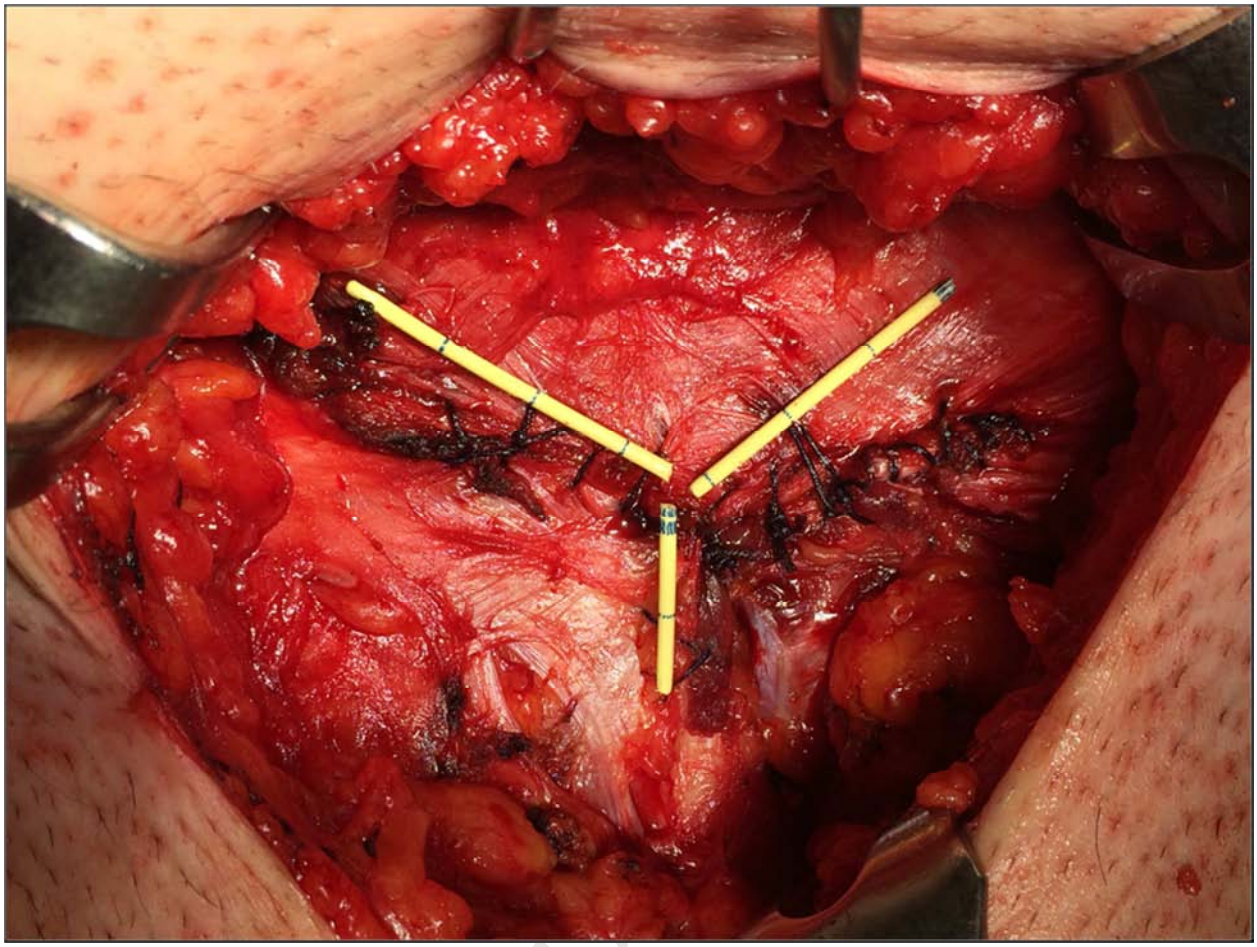
§Patients with SUI. *HWS: Half Way Classification System. ^Redundant vaginal wall rather than recurrent prolapse. '' Preoperative vs. postoperative last follow-up.

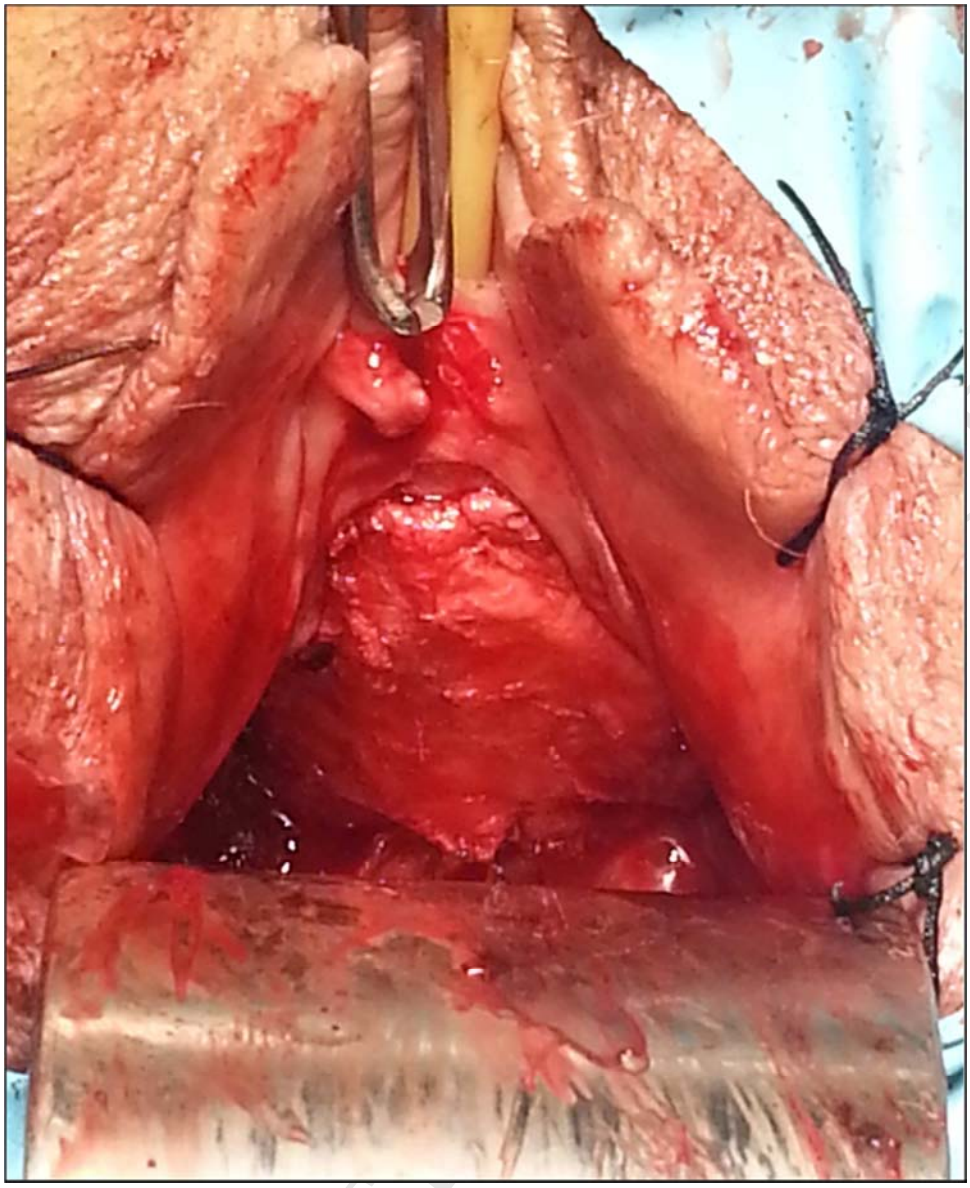


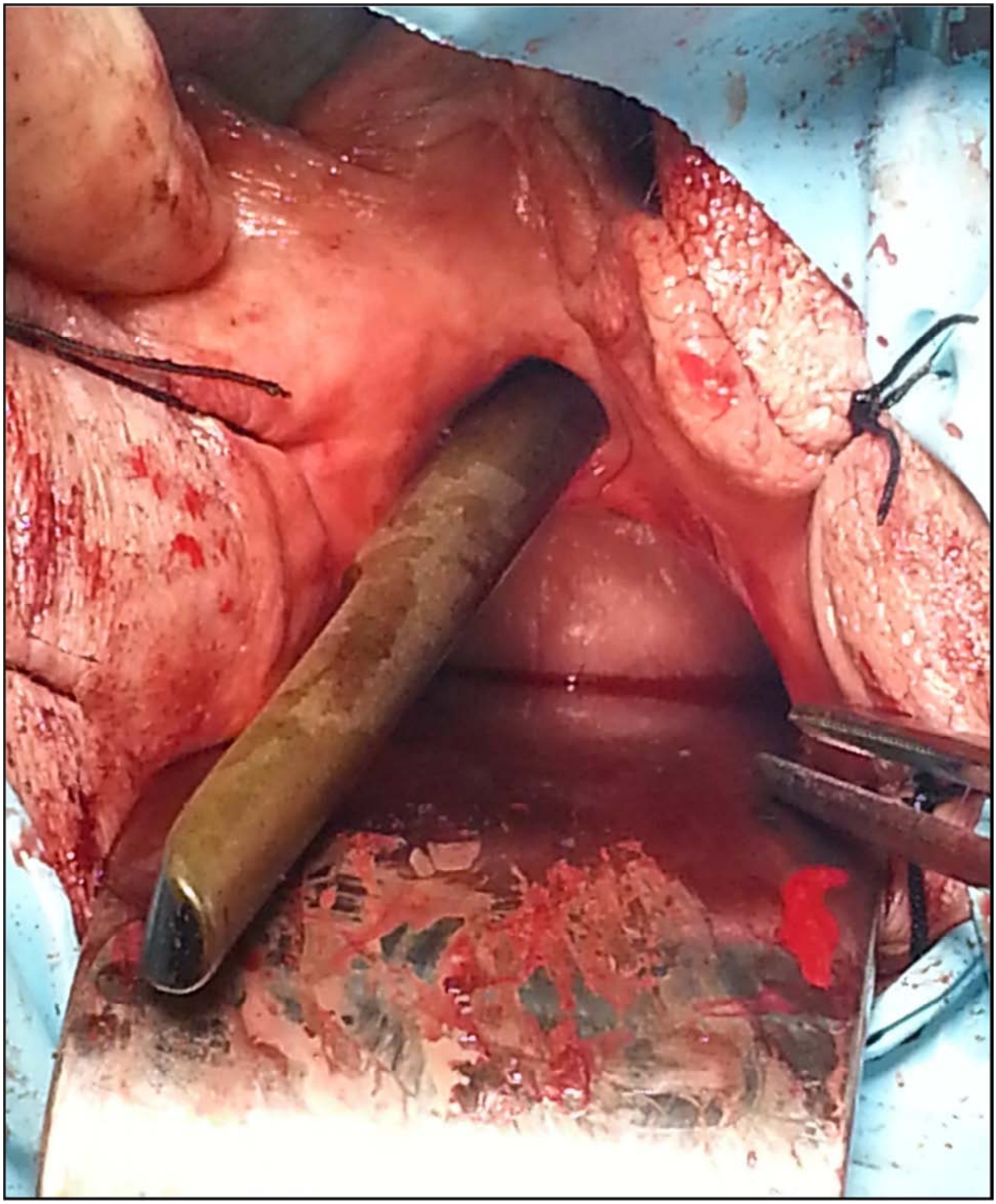


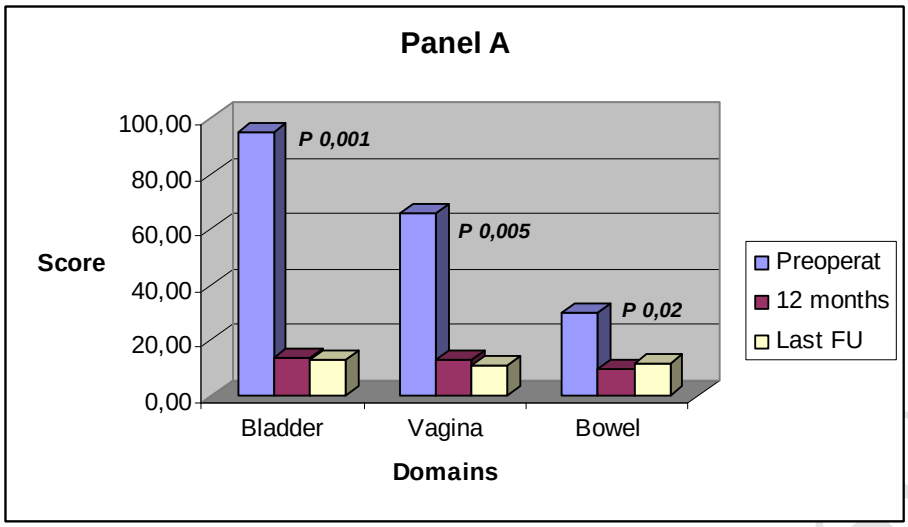








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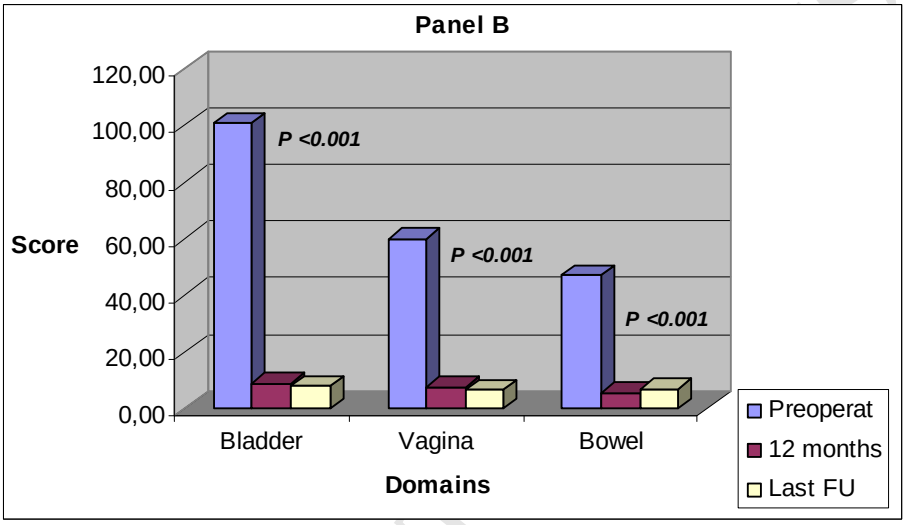
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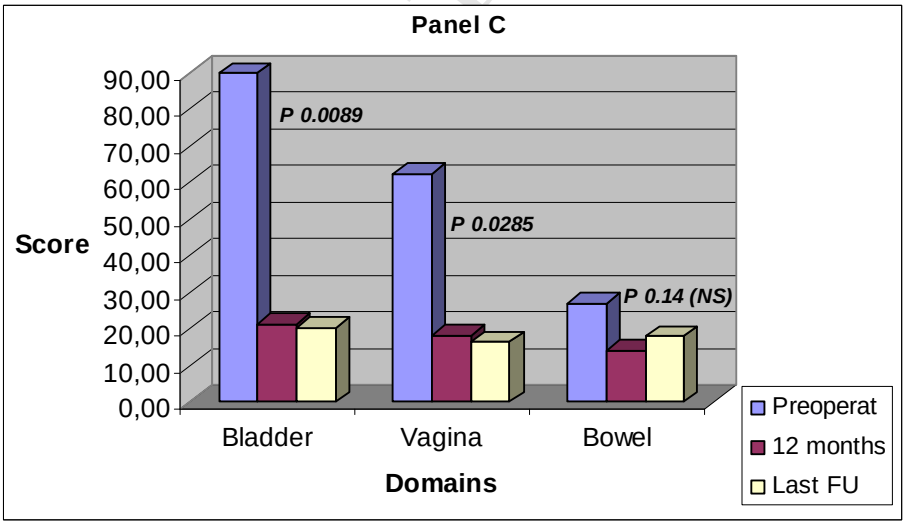
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Bladder
Vagina
Bowel
Domains
Preoperat
12 months
Last FU

Abbreviations and Acronyms

SUI = stress urinary incontinence
PCS = pubovaginal cystocele sling
PFIQ-7 = pelvic floor impact questionnaire 7 short form
PVR = postvoid residual urine volume
UTI = urinary tract infection
POP = pelvic organ prolapse
AC = anterior colporrhaphy
AMSC = abdominal mesh sacral colpopexy
TMS = transvaginal mesh surgery
HWS = Baden Walker halfway classification system