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JMIG The Journal of Minimally Invasive Gynecology

Original Article

Mesh Exposure After Robot-Assisted Laparoscopic Pelvic Floor Surgery: A Prospective Cohort Study

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ABSTRACT **Study Objective:** To prospectively evaluate the mesh exposure rate after robot-assisted laparoscopic pelvic floor surgery for the treatment of female pelvic organ prolapse (POP) in a large cohort.

Design: Prospective observational cohort study (Canadian Task Force classification II-2).

Setting: Two large teaching hospitals with a tertiary referral function for pelvic floor disorders.

Patients: Patients with symptomatic POP and simplified POP quantification (S-POP) stage ≥2. Patients with a history of mesh repair or concomitant insertion of a tension-free vaginal tape were excluded.

Interventions: Robot-assisted laparoscopic sacrocolpopexy or robot-assisted laparoscopic supracervical hysterectomy with a sacrocervicopexy.

Measurements and Main Results: A blinded vaginal examination with the aid of a transparent speculum was performed to look for mesh-related complications. Mesh exposures were described following the International Urogynecological Association/International Continence Society classification system. One hundred and ninety-two patients were included, of whom 166 (86.5%) were seen for follow-up examination. The median duration of follow-up was 15.7 months (range, 8.2−44.4 months). Two vaginal mesh exposures (1.2%) were detected, both of which were treated in the outpatient clinic. One patient without any complaints had a suture exposure, which was removed in the outpatient clinic.

Conclusion: The safety of the use of mesh in pelvic floor surgery is a matter of debate owing to the occurrence of mesh-related complications. Based on the current literature, mesh-related complications seem to be lower in transabdominal mesh surgery than in transvaginal mesh surgery. In this study, a low mesh exposure rate was observed in robot-assisted abdominal pelvic floor surgery for POP. Journal of Minimally Invasive Gynecology (2019) 26, 636−642. © 2018 AAGL. All rights reserved.

Keywords: Mesh erosion; Pelvic organ prolapse; Sacrocervicopexy; Sacrocolpopexy

In 2008 and 2011, the US Food and Drug Administration (FDA) published a safety communication on complications related to the use of synthetic meshes [1]. The FDA based this warning on a systematic review showing a high incidence of mesh-related complications following transvaginal pelvic organ prolapse (POP) repair (10.3%; range, 0−29.7%; n = 11,785) [2]. Lower rates of mesh complications are seen after abdominal surgery using mesh, with a median mesh exposure rate of 4% within 23 months of surgery [1]. Owing to the vigorous debate on the consequences of vaginal mesh use and worldwide litigation, patients and doctors are becoming more reserved in the overall use of mesh, including in abdominal prolapse surgery. This may lead to suboptimal treatment of POP, resulting in a lower quality of life. Systematic reviews published after the FDA warning have reported a wide range of mesh exposure rates, including median rates of 2% in robot-assisted laparoscopic sacrocolpopexy (RASC; range 0−8%) and 3% in laparoscopic sacrocolpopexy (LSC; range 0−9%) [3,4]. However, these findings are based mostly on retrospective and/or

S.E.S.K. and I.A.M.J.B. serve as proctors for Intuitive Surgery. The remaining authors declare that they have no conflict of interest and nothing to disclose.

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Submitted March 6, 2018, Accepted for publication June 20, 2018.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ — see front matter
https://doi.org/10.1016/j.jmig.2018.06.015

small cohorts and may underestimate true mesh exposure rates. Given the increasing use of synthetic meshes due to a rising prevalence of female POP [2,5], determining accurate mesh exposure rates is important.

The use of robotics in place of straight stick conventional laparoscopy has been gaining popularity in pelvic floor repair because it may make complex minimally invasive procedures more facile [6]. The aim of this study was to determine the mesh exposure rate in a large cohort of patients undergoing robot-assisted laparoscopic prolapse surgery.

Materials and Methods

This prospective cohort study was performed in 2 large teaching hospitals with a tertiary referral function for patients with POP. Our series is part of the PARSEC database (Prospective Assessment of Robotic Sacrocolpopexy: a European Multicentric Cohort). All patients who underwent RASC or robot-assisted laparoscopic supracervical hysterectomy with a sacrocervicopexy (RSHS) at the Meander Medical Center (May 2011 to December 2015) and Rijnstate Hospital (September 2011 to June 2013) were consecutively included. The simplified Pelvic Organ Prolapse Quantification (S-POP) was used to determine the stage of prolapse [7]. S-POP is a validated short form of the standard POPQ, describing only 4 vaginal landmarks using 4 grades, making it more clinically accessible [8]. Inclusion criteria were symptomatic POP and S-POP stage $\geq$2 (i.e., descending from the given landmark of the S-POP at least 1 cm above the hymnal remnants or lower). Exclusion criteria were age $<$18 years, inability to undergo general anesthesia, and history of 3 or more previous laparotomies. Patients with a history of previous mesh procedures or with concomitant mesh procedures were excluded as well. The primary study outcome was mesh exposure.

All patients were counseled about alternative treatments and informed of the risks and benefits of the procedure. Patients who did not undergo a postoperatively vaginal examination were considered lost to follow-up. Mesh exposure was defined as any epithelial defect with visualization of the mesh through the vaginal or adjacent tissues. Protruding permanent sutures were scored separately. All exposures were described according to the International Urogynecological Association/International Continence Society classification system [9]. In this classification system, term exposure is defined as "a condition of displaying, revealing, exhibiting, or making accessible (e.g., vaginal mesh visualized through separated vaginal epithelium)." Patients underwent a routine follow-up examination at 12 months after surgery or when presenting with complaints. Follow-up examinations were performed by trained research fellows. Patients who did not attend the routine 1-year follow-up were invited a second time for postoperative evaluation in 2016.

All patients underwent a vaginal examination with the aid of a transparent speculum. When mesh-related morbidity was found or suspected, a second examination was performed by the urogynecologist to confirm the diagnosis. Patients completed a questionnaire before and after surgery to elicit information regarding their sensation of prolapse. The questionnaire also included questions regarding urinary, defecation, and sexual function, and quality of life. Patients who not wish to attend the 1-year consultation were invited to return the postoperative questionnaire by mail and asked about mesh-related complaints over the telephone.

The surgical technique was similar to the technique described by Clifton et al. [10]. The patient was placed under general anesthesia in a dorsal lithotomy position and given prophylactic intravenous antibiotics (1000 mg cefazolin and 500 mg metronidazole). All surgeries were performed with the assistance of the da Vinci Robot (Intuitive Surgical, Sunnyvale, CA). A peritoneal incision was made over the sacral promontory and extended distal to an inverted J-form, and an anterior and posterior dissection of the vaginal wall was performed. If the uterus was present, a supracervical hysterectomy was performed as the first step. Suspension was performed with polypropylene (type 1, macroporous polypropylene, weight 80$-$85 g/m^2; Prolene; Ethicon, Hamburg, Germany). A 22-cm-long, 30-mm-diameter vaginal probe (Meekers Medical, Utrecht, The Netherlands) was used to spread the mesh. Two meshes were sutured to the anterior and posterior vaginal walls and configured into an "Y" shape intracorporeally. The mesh was distally attached using nonabsorbable sutures (Ethibond; Ethicon) and anchored proximally to the sacral promontory using titanium tacks (Covidien Autosuture Protack 5 mm; Medtronic, Minneapolis, MN). The peritoneum was closed using a 23-cm Covidien V-Loc suture (Medtronic). Concomitant procedures were performed when clinically indicated.

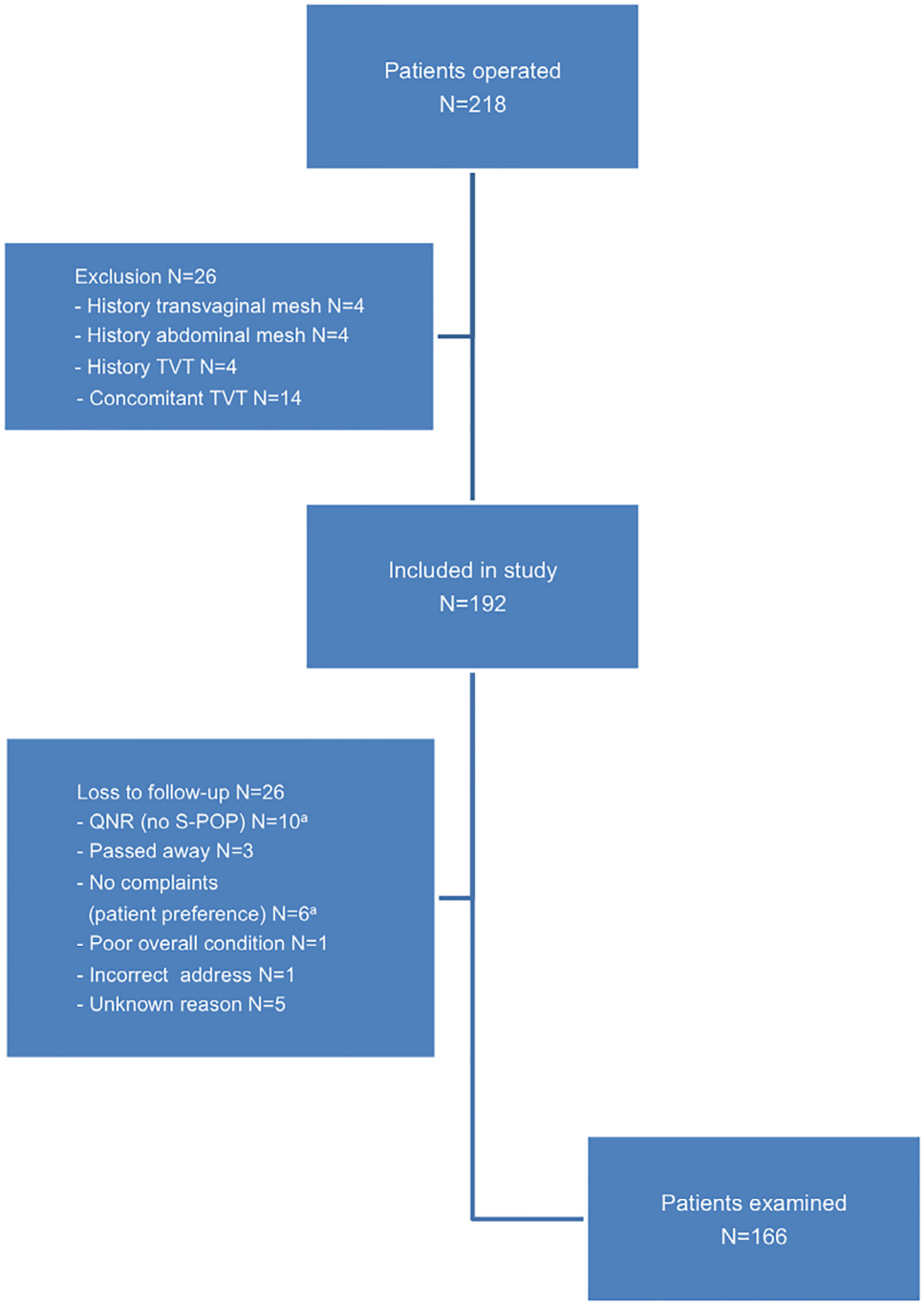
The PARSEC database is listed on ClinicalTrials.gov (identifier NCT01598467; registration, May 2012). The National Central Committee on Research Involving Human Subject ruled this study exempt, because it encompasses standard survey and interview research as required by Dutch law. Data were processed anonymously (F.v.Z./J. v.I.). Statistical analysis was performed using SPSS version 22.0 (IBM, Armonk, NY). Normally distributed values are presented as mean $\pm$ standard deviation; non$-$normally distributed values, as median and range. The independent-samples t test, Mann-Whitney U test, χ^2 test, and Fisher's exact test were used to compare continuous and nominal data as appropriate.

Results

A total of 218 patients underwent surgery during the study period. Twenty-six patients (11.9%) were excluded due to a history of pelvic floor mesh implants. Sixteen patients were lost to follow-up for various reasons (Fig. 1). Another 10 patients preferred to respond solely by mail with the postoperative questionnaire. A total of 166 patients (86.5%) were included in our analyses (Fig. 1). Sixty-six

Fig. 1

Flow chart of included patients. [a]Patients either reported to have no specific mesh-related complaints in their questionnaire or by telephone. N = number; S-POP = Simplified Pelvic Organ Prolapse Quantification; TVT = tension-free vaginal tape; QNR = questionnaire.



patients (39.8%) underwent RASC, and 100 patients (60.2%) underwent RSHS. Of the 66 patients undergoing RASC, 65 had a history of total hysterectomy and 1 had a history of supracervical hysterectomy. The baseline demographic data and surgical details of all patients by procedure are presented in Table 1. Compared with the patients who underwent RASC, those who underwent RSHS were younger, had a lower body mass index, and were less likely to be postmenopausal. This group underwent fewer previous POP/incontinence surgeries and had less severe prolapse to the posterior compartment. Among all patients, 3 patients (1.8%) used vaginal estrogens preoperatively. Postoperatively, 12 patients (7.2%) were prescribed or continued vaginal estrogens. The median duration of follow-up

Table 1

Demographics and surgical characteristics

Characteristic	All patients (n = 166)	RASC (n = 66)	RSHS (n = 100)	p value*
Age, yr, mean ± SD	61.3 ± 10.4	64.8 ± 8.4	59.0 ± 11.0	<.0005
BMI, median (range)	25.1 (17.9–44.1)	25.8 (19.8–38.3)	24.8 (17.9–44.1)	.022
Parity, median (range)	3.0 (0–7)	2.0 (0–7)	3.0 (1–6)	.764
Postmenopausal, n (%)	140 (84.3)	64 (97.0)	76 (76.0)	<.0005
ASA score, median (range)	2.0 (1–3)	2.0 (1–2)	2.0 (1–3)	.108
Diabetes mellitus, n (%)	14 (8.4)	6 (9.1)	8 (8.0)	.804
Preoperative vaginal estrogen, n (%)	3 (1.8)	2 (3.0)	1 (1.0)	.564
Smoking (current), n (%)				.185
Yes	27 (16.3)	11 (16.7)	16 (16.0)	
No	105 (63.3)	37 (56.1)	68 (68.0)	
Unknown	34 (20.5)	18 (27.3)	16 (16.0)	
History, n (%)				
Hysterectomy	66 (39.8)†	66 (100.0)†	N/A	N/A
POP/incontinence surgery	67 (40.4)	54 (81.8)	13 (13.0)	<.0005
Intra-abdominal surgery	68 (41.0)‡	36 (54.5)‡	32 (32.0)‡	.004
Preoperative S-POP, median (range)				
S-POP A	3 (1–4)	3 (1–4)	3 (1–4)	.548
S-POP B	2 (1–4)	2 (1–4)	1.5 (1–4)	.035
S-POP C	3 (1–4)	3 (1–4)	3 (1–4)	.102
S-POP D	2 (1–4)	N/A	2 (1–4)	N/A
Concomitant surgery, n (%)				
Oophorectomy§	9 (5.4)	2 (3.0)	7 (7.0)	.320
AC	15 (9.0)	4 (6.1)	11 (11.0)	.277
PC	2 (1.2)	0 (0.0)	2 (2.0)	.518
Other	5 (3.0)	3 (4.5)	2 (2.0)	.650
Conversion	2 (1.2)	2 (3.0)	0 (0.0)	.157

AC = anterior colporrhaphy; ASA = American Society of Anesthesiologists; BMI = body mass index; PC = posterior colporrhaphy; POP = pelvic organ prolapse; RASC = robot-assisted laparoscopic sacrocolpopexy; RSHS = robot-assisted laparoscopic supracervical hysterectomy with sacrocervicopexy; SD = standard deviation; S-POP = simplified Pelvic Organ Prolapse Quantification; yr = years.

* Comparing RASC with RSHS.

† Includes one supracervical hysterectomy.

‡ Excluding POP/incontinence surgery.

§ Single or bilateral.

was 15.7 months (range, 8.2–44.4 months) and was comparable for the 2 surgical techniques (RASC, 16.1 months [range, 8.9–42.9 months]; RSHS, 15.6 months [range, 8.2–44.4 months]; p = .865).

Mesh Exposure

Two patients (1.2%) were identified with mesh exposure, both ≤1 cm in diameter (Table 2). The incidences of mesh exposures after sacrocolpopexy and after supracervical hysterectomy and sacrocervicopexy were not significantly different (1/66 [1.5%] and 1/100 [1.0%], respectively; p = 1.000).

The first patient underwent a RSHS. She presented at 8 months after surgery with minimal vaginal and postcoital blood loss, without other complaints. Speculum examination revealed an exposition of the mesh (diameter, 0.5 cm) on the posterior vaginal wall (2BT3S1), which was excised under local anesthetic after consent in the outpatient clinic. The vaginal wall was closed with Vicryl Rapide suture (Ethicon) and supplementation with vaginal estrogens was started. At follow-up 13 months after removal, the patient exhibited no vaginal blood loss, no mesh exposure, or prolapse. The second patient, with a history of a supracervical hysterectomy, underwent a RASC. Nine months postoperatively at routine follow-up, 2 sutures in the fornix posterior surrounded by granulation tissue were detected (2AT3S1). The sutures were removed at the outpatient clinic, and the granulation tissue was treated with silver nitrate. Initially, this had the desired effect, but at 33 months after surgery she suffered from dyspareunia. A mesh exposure of 1 cm was now visible at the same location of the previous suture expositions (2BcT4S1). The mesh was excised in the outpatient clinic under local analgesia and treatment with vaginal estrogens was restarted. Further follow-up detected no recurrence.

Suture Exposure and Other Mesh-Related Complications

One patient (0.6%) was seen 20 months after RASC with no complaints of exposure but with urinary incontinence. On physical examination 1 transmural suture surrounded by granulation tissue was visible at the top of the vagina. This suture was removed, and silver nitrate was applied to treat the granulation tissue. Three patients (1.8%) complained of vaginal pain during examination. One patient had severe atrophy, and a suture was shimmering through the vaginal

Table 2

Overview of patients with mesh exposure

Previous surgery	BMI, kg/m^2	Associated risk factors	Procedure	Mesh exposure*	Time to exposure (months)
None	29.0	Smoking: no PMP: yes DM: no	RSHS	2BT3S1	7.6
Supracervical hysterectomy	21.6	Smoking: no PMP: yes DM: no	RASC	2AT3S1 2BcT4S1	8.9 33

BMI = body mass index; DM = diabetes mellitus; PMP = postmenopausal; RASC = robot-assisted laparoscopic sacrocolpopexy; RSHS = robot-assisted laparoscopic supracervical hysterectomy with sacrocervicopexy.
* CTS code: category (C), time (T), and site (S) classes.

wall without epithelial separation. In the other 2 patients, a prominence (i.e., a wrinkling or fold palpable without epithelial separation [9]) was found. Treatment with local estrogens was sufficient.

Discussion

To our knowledge, this is the largest prospective cohort study on mesh exposure after robot-assisted laparoscopic apical prolapse surgery reported to date. The low incidence of mesh exposure (1.2%) is in line with previously published systematic reviews (2%−3%) [3,4]. More recent publications on exposure rates with a minimum follow-up duration of 12 months and a physical examination included, showed rates of 4.5% for RASC (18/401; range, 0−7.8%) [11−18] and 1.4% for LSC (78/5755; range, 0−21.4%) [11−13,19−32]. The retrospective design of most of these studies and the high heterogeneity of definitions must be taken into account. Furthermore, some studies included concomitant total hysterectomy, which is associated with greater risk of mesh exposure [33]. A well- designed prospective study of 143 patients showed no mesh exposures [34]. Patients were objectively examined 1 year after RASC/RSHS, and a lightweight type 1 polypropylene Y-mesh (weight, 33.5 g/m^2) was used. Kenton et al. [13] conducted a randomized controlled trial with an ultra-lightweight mesh but with Gore-Tex sutures, which showed no mesh exposure in either arm (RASC, n = 33; LSC, n = 33). We chose to not change the type of mesh used (weight, 80−85 g/m^2), nor the (nonresorbable) suture type to evade heterogeneity. Further scientific evidence on lightweight mesh is scarce.

In studies with longer follow-up (≥ 3 years) and a substantial number of patients (n ≥50), mesh exposure occurred in 2.9% of RASC recipients (2/70; follow-up 72 months) [14] and in 2.8% of LSC recipients (11/398; follow-up range, 43−60 months) [23,28,35,36]. In all 5 studies, type 1 polypropylene mesh was used. Nygaard et al. [37] reported a high rate of mesh exposure after open abdominal sacrocolpopexy (10.5% after 7 years of follow-up). In this study, different types of mesh were used (Gore-Tex, Mersilene, biological material, and type 1 polypropylene). Gore-Tex and Mersilene are associated with higher mesh exposure rates, and biological material is associated with a high recurrence rate [38,39]. Given the possible increase of mesh exposure over time, studies with longer follow-up and examining a single implant type are of major importance. Our study group is currently researching mesh exposure after longer follow-up periods.

The exact etiology of mesh exposure remains unknown, with contradicting evidence published. However, based on the literature, the difference between the transabdominal route and transvaginal route is apparent. Opening the vagina carries a theoretical risk of inducing infection of the graft due to contamination from vaginal microbes [39]. Moreover, placing the mesh on newly created vaginal incisions could play a role in the occurrence of mesh exposure [40]. The literature shows that this technique eventually results in high mesh exposure rates [2]. In RASC and RSHS, the vaginal walls are not opened, and only precise dissections with minimal tissue damage are made. Other risk factors associated with transvaginal mesh surgery are patient age, smoking, operative technique, surgeon experience, previous prolapse repair, concomitant hysterectomy, mesh properties and load, inverted T colpotomy incision, sexual activity, and diabetes [2,41,42]. Risk factors for abdominally placed mesh are more difficult to identify; the use of polytrafluroethylene mesh, smoking, total hysterectomy (with opening of the vagina), or stage 3 or 4 prolapse have been reported [38,43]. Even when the vaginal wall is left intact, it may be thin and atrophic, especially in elderly patients. Treatment with vaginal estrogens can possibly prevent exposure. The use of mesh in other techniques, such as minimal invasive sacral hysteropexy, also show a low risk of mesh exposure. Gutman et al. [44] reported a mesh exposure rate of 2.7% after laparoscopic sacral hysteropexy in their 1-year prospective parallel cohort.

Strengths of the present study are the use of standardized surgical procedures, inclusion of a single mesh type, and thorough examination with a specific transparent speculum. Detection of rare complications requires evaluation of large cohorts. Randomized controlled trials, although considered

the gold standard, are often too limited in size. Prospective trials have the benefit of including all patients (solid denominator) and examining a large population [45]. Limitations of the study include the inclusion of solely tertiary referral hospitals for pelvic floor disorders. Some of the patients had complex pelvic floor disorders and/or an extensive history of pelvic floor surgery, which could possibly limit the generalizability of our findings. Another limitation is the loss to follow-up of 26 patients (13.5%), who were not physically examined at 12 months postprocedure. Sixteen of these patients responded either by questionnaire or by telephone, reporting no mesh-related complaints (Fig. 1). Finally, we examined patients who underwent sacrocolpopexy with and without a concomitant supracervical hysterectomy, which limited the homogeneity. However, in general practice, it is common to treat all posthysterectomy patients as patients with an intact uterus; therefore, both interventions were included in this study.

Comparing the abdominal use of mesh with literature on vaginally placed mesh, the abdominal route generated lower mesh exposure rates. These results are currently relevant owing to the public discussion on complications after mesh placement. Clear information about the safety or risk involved in the use of abdominal mesh has potential public health benefits by allowing doctors and patients to make informed decisions about the use of surgical mesh in prolapse surgery.

In conclusion, this large multicenter prospective cohort study shows a low incidence of mesh exposure after robot-assisted minimal invasive abdominal prolapse surgery.

Acknowledgments

We thank Peter L. Dwyer for language revision and Corinne C. W. Verduijn-Staal for study coordination.

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