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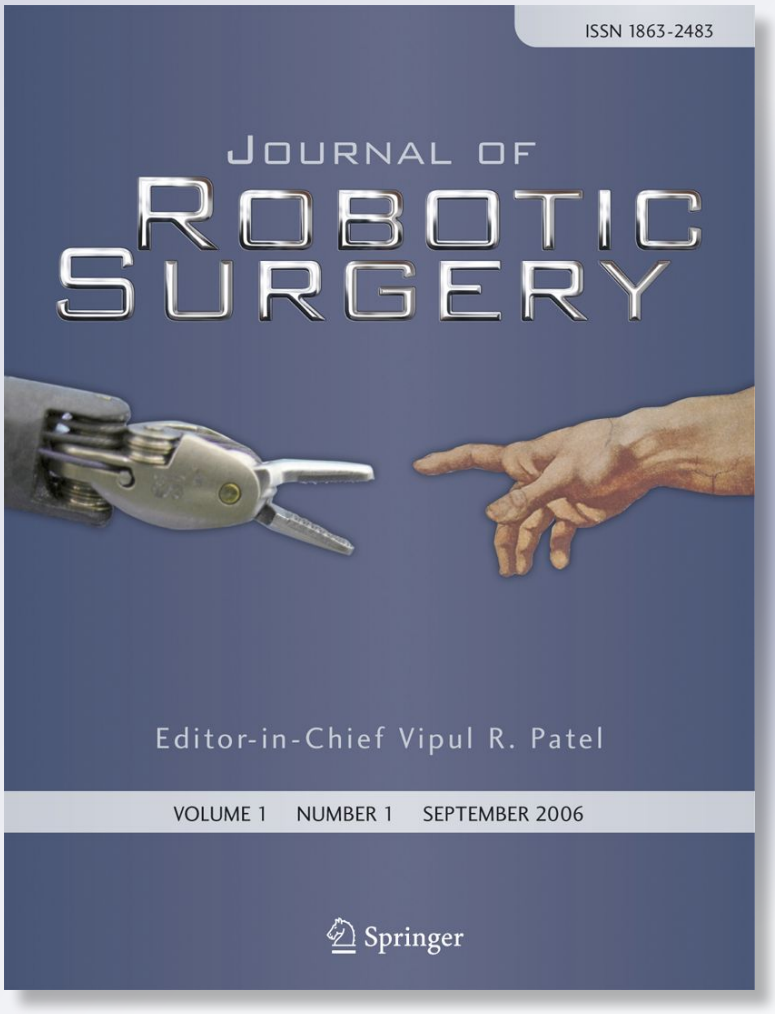

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ORIGINAL ARTICLE

Subjective and objective outcomes 1 year after robotic-assisted laparoscopic sacrocolpopexy

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Abstract We aimed to assess the subjective and objective outcomes 1 year after robotic sacrocolpopexy using a type I polypropylene mesh. This was a case series of 64 patients who underwent a robotic-assisted laparoscopic sacrocolpopexy using a type I monofilament polypropylene mesh coated with hydrophilic porcine collagen. Objective and subjective outcomes were assessed using the pelvic organ prolapse quantification (POP-Q), the short forms of the Pelvic Floor Impact Questionnaire (PFIQ 7) and the Pelvic Floor Distress Inventory (PFDI-20). Outcome measures were collected pre-operatively and 1 year post-operatively on all but one patient, who was lost to follow-up. Paired comparisons between pre- and post-operative outcomes were performed using the Wilcoxon signed rank test. At 1 year, POP-Q stage II or greater and loss of follow-up were considered to be surgical failure. The "surgical cure" rate was 89%. We observed three distal anterior failures, two distal posterior failures and one apical failure, and one patient was lost to follow-up. We found significant differences between pre- and post-operative POP-Q measurements ($p < 0.001$) and PFDI-20/PFIQ-7 total scores ($p < 0.001$). Robotic sacrocolpopexy using this polypropylene mesh resulted in significant improvements in subjective and objective outcome measures at 1 year.

Keywords Robotics · Sacrocolpopexy · Prolapse

Introduction

Pelvic organ prolapse is the descent of one or more of the anterior vaginal wall, the posterior vaginal wall, the uterus (cervix), or the apex of the vagina (vaginal vault or cuff scar after hysterectomy) [1]. The incidence and prevalence of pelvic organ prolapse in the general population is not well known [2]. However, in 1997 more than 225,000 women underwent inpatient surgical procedures for prolapse in the United States [2]. Unfortunately, up to 30% of these women will require a repeat operation [3]. Abdominal sacrocolpopexy is currently considered the "gold standard" operation for pelvic organ prolapse based on efficacy and long-term durability [4, 5]. A large proportion of the complications associated with an abdominal sacrocolpopexy are related to the laparotomy incision and resultant post-operative immobilization [6]. In an effort to decrease post-operative pain and recovery time, some surgeons have adopted the laparoscopic approach with comparative surgical outcomes [7]. However, the steep learning curve associated with advanced laparoscopic dissection and suturing has led to the slow and inconsistent adoption of such techniques. The development of the da Vinci robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA) provided surgeons with high-definition three-dimensional visualization and increased intra-corporeal dexterity with wristed instruments. Most of the available literature on robotic sacrocolpopexy is based on short-term outcomes or lacks subjective outcome measures [8–14]. The objective of this study was to assess the subjective and objective outcomes 1 year after robotic-assisted laparoscopic sacrocolpopexy using a type I monofilament polypropylene mesh coated with hydrophilic porcine collagen.

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Materials and methods

After approval by the Institutional Review Board at the Atlantic Health System (R09-02-007), we conducted a retrospective chart review of patients who had undergone a robotic-assisted laparoscopic sacrocolpopexy using a type I monofilament polypropylene mesh coated with hydrophilic porcine collagen (Pelvitex® CR Bard, Covington, GA, USA). Data were collected between May 2006 and May 2009 from patients seen in the Atlantic Health Division of Urogynecology and Reconstructive Pelvic Surgery in northern New Jersey. During the same study period we enrolled 120 patients in a randomized clinical trial (RCT) comparing organic and synthetic materials for laparoscopic sacrocolpopexy. Patients were included in this study if they declined participation in the RCT and had undergone a robotic-assisted laparoscopic sacrocolpopexy for pelvic organ prolapse.

Our surgical technique has been described in a previous publication [15]. We perform the entire dissection and suturing using the robot. A robotic-assisted supra-cervical hysterectomy is performed if a uterus is present, and then the cervix is grasped with a robotic tenaculum which is used to manipulate the vaginal tube. This allows full dissection and suturing without a probe in the vagina. In post-hysterectomy cases, a vaginal probe is used during dissection and suturing. The bladder is sharply dissected off the vagina to the level of the bladder neck distally and the rectum is dissected off the posterior vaginal wall down to the perineal body. This provides 4–6 cm of anterior coverage and 8–10 cm of posterior coverage. The mesh is sutured to the vagina and cervix (when present) using CV4 Gore-Tex suture on TH-26 needle (W. L. Gore and Associates, Inc. Medical Products Division, Flagstaff, AZ, USA), then configured into a Y mesh. The tail end is attached to the anterior longitudinal ligament at the level of the sacral promontory using two sutures of 0 Ethibond on SH needle (Ethicon, San Antonio, TX, USA) [16]. The peritoneum is reapproximated over the mesh using 0 Monocryl on CT-1 needle (Ethicon).

A total of 64 patients met the inclusion criteria; 41 patients underwent a supra-cervical hysterectomy at the time of surgery and the remaining 23 patients had post-hysterectomy procedures.

Outcome measures were collected pre-operatively and 1 year post-operatively for all but one patient, who was lost to follow-up. We assessed objective outcomes via the pelvic organ prolapse quantification (POP-Q) system, and subjective outcomes using the short forms of the Pelvic Floor Impact Questionnaire (PFIQ 7) and the Pelvic Floor Distress Inventory (PFDI 20) [1, 17]. Patients with any POP-Q stage II or greater were considered as "surgical failures". The rest were "surgical cures."

Additional data collected included estimated blood loss, operative time (skin to skin including concomitant procedures), anesthesia time, hospital stay, concomitant procedures, operative complications, mesh-related morbidity, and re-operations. We also collected surgical satisfaction surveys using a standardized non-validated questionnaire previously described by Murphy et al. [18].

Data were analyzed using SPSS 16.0 (SPSS Inc., Chicago, IL, USA) with Student's t test, the Mann–Whitney U test and Wilcoxon signed ranks test with the alpha value set at 0.05.

Results

The 1-year "surgical cure" rate was 89% (57/64 patients). We observed three distal anterior failures, wo distal posterior failures and one apical failure, and one patient was lost to follow-up. Patients' mean age was 54.4 (range 35–76) with a mean BMI of 25.6 kg/m^2 (range 19–35.8). Table 1 summarizes all the demographic data. Pre-operatively, 24 patients had POP-Q stage II (37.5%), 36 had POP-Q stage III (56.25%) and 4 had POP-Q stage IV (6.25%). Table 2 includes the operative outcomes. None of the patients required a blood transfusion. All but two patients were discharged home within 24 h; the remaining patients were discharged on the second post-operative day. Thirty-eight patients (59%) had a concomitant sling and one patient had a sling placed 2 months post-operatively for new onset stress urinary incontinence. One patient had mesh erosion (1.5%) at the vaginal apex which responded well to excision and closure. Another patient developed vaginal pain with trigger-point tenderness along the distal edge of the posterior mesh; she underwent partial excision of the posterior mesh with symptom resolution. None of the patients had post-operative deep vein thrombosis or pulmonary emboli and none had surgical infections. The only infectious episodes were related to simple urinary tract infections that were successfully treated with a course of oral antibiotics. We did not find any difference in 1-year outcomes between patients who underwent supra-cervical hysterectomy at the time of surgery and those who did not; thus we combined the two groups for this analysis.

We found statistically significant differences between pre- and post-operative POP-Q point C values (median pre-procedure = −1.00 vs. −8.00 post-procedure, $p < 0.001$); point Ba (median pre-procedure = 1.00 vs. −2.00 post-procedure, $p < 0.001$); point Bp (median pre-procedure = −1.00 vs. −2.00 post-procedure, $p < 0.001$); PFDI-20 total score (median pre-procedure = 91.67 vs. 8.33 post-procedure, $p < 0.001$), and PFIQ-7 total score (median pre-procedure = 61.84 vs. 0.00 post-procedure, $p < 0.001$) (Table 3).

Table 1 Demographics

Age (years, mean ± SD)	54.4	±12.1
BMI (kg/m^2, mean ± SD)	25.6	±4.0
Vaginal parity (median, range)	2	0–5
Menopause (number, %)	46	71.9%
Hormone replacement therapy (number, %)	6	9.4%
Prior hysterectomy (number, %)	23	35.9%
Prior surgery for incontinence (number, %)	15	23.4%
Prior prolapse surgery (number, %)	20	31.3%
Tobacco use (number, %)	4	6.25%
Race/ethnic group (number, %)		
White	57	89.1%
Hispanic	2	3.2%
African–American	1	1.5%
Asian	1	1.5%
Other	3	4.7%

Total number of women = 64

Table 2 Operative outcomes

Operative time (min, mean ± SD)	165.6	±23.0
Anesthesia time (min, mean ± SD)	190.9	±37.7
Estimated blood loss (ml, mean ± SD)	58.1	±55.9
Concurrent hysterectomy (number, %)	41	64.1%
Concurrent sling (number, %)	38	59.4%
Concurrent prolapse repair (number, %)	4	6.25%
Days in hospital (median, range)	1	1–2
Re-operation for sling take-down (number, %)	4	6.25%
Re-operation for sling placement (number, %)	1	1.5%
Re-operation for mesh erosion (number, %)	1	1.5%
Re-operation for prolapse (number, %)	2	3.1%

Total number of women = 64

The mean change in post-operative PFDI-20 and PFIQ-7 summary scores was 91 and 65 points, respectively. Table 4 shows the surgical satisfaction questionnaire results.

Table 4 Results from surgical satisfaction survey

Item	Number	Percent
Satisfaction with results of surgery		
Unsatisfied	0	0
Neutral	1	1.5
Satisfied	10	15.6
Very satisfied	53	82.9
Would go through the same surgery again?		
Do not think so	1	1.5
Unsure	0	0
Most likely	10	15.6
Yes	53	82.9
Recommend surgery to others?		
Do not think so	0	0
Unsure	1	1.5
Most likely	10	15.6
Yes	53	82.9

Total number of women = 64

Three sample questions from the surgical satisfaction questionnaire [18]

Discussion

Robotic-assisted laparoscopic sacrocolpopexy using the Pelvitex type I polypropylene mesh material resulted in significant improvement of subjective and objective outcome measures, an excellent "surgical cure" rate, and a low rate of complications. The strengths of our study include a 98% follow-up rate 1 year postoperatively. Patients completed the pre- and-post operative quality of life questionnaires at the time of their scheduled initial and post-operative visits, thereby minimizing the recall bias typically related to retrospective studies. Another strength of our study is the consistent use of the same surgical techniques, mesh material and suture materials throughout the study period.

Among the limitations of our study are the retrospective design and the lack of a control group. The post-operative POP-Q measures were taken by the treating physician and not a blinded observer, which is typical for retrospective studies. Another potential limitation is the inclusion of post-hysterectomy and concomitant supra-cervical hysterectomy in the same analysis. However, our surgical technique always includes vaginal dissection/suturing to the level of the bladder neck anteriorly and perineal body

Table 3 Paired comparison between pre- and post-operative scores

	Pre-operative			Post-operative (≥1 year)			*p* value
	Mean	Median	SD	Mean	Median	SD	
POP-Q							
C	−0.58	−1.00	3.6	−7.48	−8.00	0.8	<0.001*
Ba	1.85	1.00	2.3	−2.18	−2.00	0.7	<0.001*
Bp	0.08	−1.00	2.4	−1.93	−2.00	0.8	<0.001*
PFDI-20 score (n = 63)	104.38	91.67	54.8	12.50	8.33	9.8	<0.001**
PFIQ-7 score (n = 63)	72.58	61.84	60.2	7.81	0.00	14.2	<0.001**

Total number of women = 64

* Wilcoxon signed ranks test,
** Student's t test

posteriorly regardless of whether it is a post-hysterectomy or supra-cervical hysterectomy case.

Our objective results are similar to those reported by others [8–14]. Both subjective scales showed statistical and clinical significant improvement after robotic sacrocolpopexy. The minimum clinically important difference (MCID) represents the smallest change in score associated with a clinically meaningful change in quality of life. The published within-treatment MCID for the summary score of the PFDI-20 is 45 points (15%), and 36 points (12%) for the PFIQ-7 [17]. In our study, the mean changes were appreciably larger: 91 points for the PFDI-20 and 65 points for the PFIQ-7.

Conclusion

In summary, our retrospective study supports good long-term objective and subjective outcomes following robotic-assisted laparoscopic sacrocolpopexy. We look forward to prospective studies that would further address the long-term outcomes as well as the choice of mesh and suture materials.

Conflict of interest Dr. Salamon is a paid consultant for Intuitive Surgical. Dr. Culligan is a paid consultant for CR Bard and Intuitive Surgical.

References

1. Haylen BT, de Ridder D, Freeman RM et al (2010) An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Neurourol Urodyn 29:4–20
2. Jelovesk JE, Maher C, Barber MD (2007) Pelvic organ prolapse. Lancet 369:1027–1038
3. Olsen AL, Smith VJ, Bergstorm JO et al (1997) Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 89:501–506
4. Nygaard IE, McCreery R, Brubaker L et al (2004) Abdominal sacrocolpopexy: a comprehensive review. Obstet Gynecol 104:805–823
5. Culligan PJ, Murphy M, Blackwell L et al (2002) Long-term success of abdominal sacral colpopexy using synthetic mesh. Am J Obstet Gynecol 187:1473–1482
6. Diwadkar GB, Barber MD, Feiner B et al (2009) Complication and reoperation rates after apical vaginal prolapse surgical repair. Obstet Gynecol 113:367–373
7. Paraiso MF, Walters MD, Rackley RR et al (2005) Laparoscopic and abdominal sacral colpopexies: a comparative cohort study. Am J Obstet Gynecol 192:1752–1758
8. Geller EJ, Siddiqui NY, Wu JM et al (2005) Short-term outcomes of robotic sacrocolpopexy compared with abdominal sacrocolpopexy. Obstet Gynecol 112:1201–1206
9. Elliott DS, Krambeck AE, Chow GK (2006) Long-term results of robotic assisted laparoscopic sacrocolpopexy for the treatment of high-grade vaginal vault prolpase. J Urol 176:655–659
10. Elliott DS, Frank I, Di Marco DS et al (2004) Gynecologic use of robotically assisted laparoscopy: sacrocolpopexy for the treatment of high-grade vaginal vault prolapse. Am J Surg 188:52S–56S
11. Di Marco DS, Chow GK, Gettman MT et al (2004) Robotic-assisted laparoscopic sacrocolpopexy for treatment of vaginal vault prolapse. Urology 63:373–376
12. Ayav A, Bresler L, Hubert J et al (2005) Robotic-assisted pelvic organ prolapse surgery. Surg Endosc 19:1200–1203
13. Daneshgari F, Kefer JC, Moore C et al (2007) Robotic abdominal sacrocolpopexy/sacrouteropexy repair of advanced female pelvic organ prolapse (POP): utilizing POP-quantification-based staging and outcomes. BJU Int 100:875–879
14. Akl MN, Long JB, Giles DL et al (2009) Robotic-assisted sacrocolpopexy: technique and learning curve. Surg Endosc 23:2390–2394
15. Salamon C, Shariati A, Culligan PJ (2010) Optimizing efficiency with robot-assisted laparoscopic sacrocolpopexy. Female Patient 35(4):33–38
16. White AB, Carrick KS, Corton MM et al (2009) Optimal location and orientation of suture placement in abdominal sacrocolpopexy. Obstet Gynecol 113:1098–1103
17. Barber MD, Walters MD, Bump RC (2005) Short forms of two condition-specific quality of life questionnaires for women with pelvic floor disorder (PFDI-20 and PFIQ-7). Am J Obstet Gynecol 193:103–113
18. Murphy M, Sternschuss G, Haff R et al (2008) Quality of life and surgical satisfaction after vaginal reconstructive vs obliterative surgery for the treatment of advanced pelvic organ prolapsed. Am J Obstet Gynecol 198:573.e1–573.e7