Published in final edited form as:

J Minim Invasive Gynecol. 2016 ; 23(6): 917–921. doi:10.1016/j.jmig.2016.05.001.

Cosmetic Appearance of Port Site Scars One Year after Laparoscopic vs. Robotic Sacrocolpopexy: A Supplementary Study of the ACCESS Clinical Trial

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Abstract

STUDY OBJECTIVE—To prospectively measured trocar site appearances 1-year following surgery in women participants in the Abdominal Colpopexy: Comparison of Endoscopic Surgical Strategies (ACCESS) Trial, a 2-center randomized surgical trial (NCT01124916).

DESIGN—Supplementary analysis of a surgical trial that randomized women to a robotic or laparoscopic sacrocolpopexy

DESIGN CLASSIFICATION—I. Evidence pulled from a properly designed, randomized controlled trial

SETTING—Operative trial

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Conflicts of Interest

Anger JA: Investigator ASTORA Women's Health LLC; investigator/expert witness for Boston Scientific

Breese C: Nothing to disclose

Kenton K: Grant from Boston Scientific

Mueller ER: Nothing to disclose

Tarnay C: Nothing to disclose

Clinical Trials.gov Identifier: **NCT01124916**

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PATIENTS—Women undergoing a clinically indicated sacrocolpopexy for symptomatic stage II POP and were randomized to a laparoscopic (LASC) or robotic (RASC) technique. Trocar skin incision closure was standardized by using Dermabond.

MEASUREMENTS—Photographs of all incision sites were taken at baseline (immediately), 6 weeks, 6 months and 1 year after surgery. Study coordinators scored each incision with the validated Stony Brook Evaluation Scale (SBES), a 5-point wound evaluation scale. We calculated the average of all scars scores per case to determine the percent of optimal wound healing (0 to 100%) for each case as well as the proportion of cases meeting 100% wound repair scoring. Wound repair scores across groups were tested with the Wilcoxon rank-sum test. The overall proportion of cases in each group meeting “optimal” wound recovery (scores of 100%) was tested with the Fisher’s exact test.

RESULTS—78 women with a mean age of 59 years (range 26–79) were randomized: LASC (n=38) and RASC (n=40). We did not detect significant differences in baseline characteristics or rates of drop-out between the two study groups (5 in LASC and 7 in RASC, $p=0.60$). Pain in the initial post-operative period was higher in the robotic arm, although groups were similar at two weeks. Nearly all cases (75/78) contributed wound repair data (36 laparoscopic, 39 robotic). Laparoscopic surgeries require significantly fewer incisions (median 4, range 4 to 6) than robotic surgeries (median 5, range 4 to 6; $p<0.001$). SBES scores at 6 weeks were not different for LASC and RASC ($p=0.426$). By 6 months the scores were better in the LASC group ($84.8\pm 8.8\%$ vs. $78.5\pm 7.2\%$, $p=0.031$) and this finding remained at one year ($93.4\pm 7.2\%$ vs. $85.9\pm 8.8\%$, $p=0.001$). The proportion of cases with optimal wound repair (score of 100%) was higher in the laparoscopic arm at one year (12/27 vs 4/33 $p=0.008$) one year after surgery.

CONCLUSION—Wound appearance using the SBES was better in the LASC group suggesting that there may be alterations in the mechanism for wound initiation and/or healing based on the minimally invasive route used for sacrocolpopexy.

Keywords

Robotic; Laparoscopic; Sacrocolpopexy; Scar; Wound Healing

Introduction

Minimally invasive surgical approaches to conventional surgery confer many well-described patient benefits, including less pain, shorter convalescence, and quicker return to function(1–4). In addition to functional outcomes, abdominal wall cosmesis is important to woman. In a study using photographs, women between ages 20–40 years, were asked to rank a representative photo marked with incisions for a Pfannenstiel (15cm), a mini-laparotomy (5 cm), conventional laparoscopy (5 small incisions) and robotic-assisted laparoscopy (5 incisions). Based on “cosmetic appeal” alone, 74% chose the 5cm mini-laparotomy as most popular, and traditional laparoscopy was preferred by the remaining 26%. Robotic-assisted laparoscopy was least favored by 42%(5). The limitation of this study was that it was a photo survey based on incision size and placement.

There is limited information about the measurable differences in wound and scar appearance between conventional laparoscopy and those from robotic assisted laparoscopy. Technical

differences between the two approaches vary and can include trocar size, the number of incisions, incision placement and the force generated on the patient's skin. We sought to evaluate wound cosmesis as a supplementary study of Abdominal Colpopexy: Comparison of Endoscopic Surgical Strategies (ACCESS). ACCESS is a randomized trial comparing 6-week cost effectiveness and surgical outcomes of robotic and conventional laparoscopic surgery for pelvic organ prolapse,

Methods

The Abdominal Colpopexy: Comparison of Endoscopic Surgical Strategies (ACCESS) Trial was a two-center randomized comparative trial conducted at UCLA and Loyola University Medical Center (Chicago, IL)(3,6). IRB approval for this study was obtained at each site. The primary aim was to compare cost effectiveness and outcomes of robotic versus laparoscopic sacrocolpopexy(3,6). Participants with symptomatic stage II POP were randomized to a laparoscopic (LASC) or robotic (RASC) abdominal sacrocolpopexy. The randomization assignment was revealed to the treating physician the morning of the surgery by having the surgeon dial into a randomization center and entering a code specific to the patient. The patient and the study coordinators were blinded to the assignment for the first 6 weeks. The randomization was done by block and was based on whether or not a concomitant hysterectomy was performed. The robotic procedures were performed using the DaVinci S and Si. The procedures were standardized for technique and trocar-cannula type. Concomitant surgeries, including hysterectomy, posterior repair, and retropubic midurethral synthetic slings, were allowed. In women undergoing LASC, 4 ports were used including camera (12 mm) and 3 ancillary ports (two 5 mm and one 12 mm). For the RASC group 5 ports were utilized including camera (12 mm) three ancillary (8.5 mm robotic-specific cannulas) and assistant port (12 mm). The robotic ports were placed using a W configuration and the laparoscopic port configuration was more of a hockey-stick configuration. All trocar skin incisions were closed at the time of surgery with Dermabond (Ethicon, Bridgewater, NJ). All incisions > 10mm also had a fascial closure suture.

The study coordinator at each site took a photograph and completed a scar evaluation at 6 weeks, 6 months and 1 year after surgery. Each incision was rated based on the in-person evaluation using a 5-point scale using the Stony Brook Evaluation Scale (SBES) – a validated wound evaluation tool designed to assess appearance of healed scars (7)(See Appendix 1). The scale has five dichotomous measures evaluating scar width, height, color, presence of suture marks and overall appearance. To adjust for the different number of incision sites per patient, we calculated the average of all scars scores to determine the percent of optimal wound healing (0 to 100%) for each case, as well as the proportion of cases meeting 100% wound repair scoring.

Demographic data were tested using Student's t-test (continuous data) or Chi-square test (categorical data). Average wound scores were tested across groups over time using a mixed model regression, and p-values were adjusted for multiple comparisons with the stepdown Bonferroni method. Wound score data was log-transformed prior to analysis to meet requirements for parametric assessment. The overall proportion of cases in each group meeting "optimal" wound recovery (scores of 100%) was tested by way of a Fisher's exact

test. Data are presented as means and standard deviations unless otherwise noted. Differences were considered significant where $p < 0.05$. Analysis was performed using SAS v9.3.

Results

Seventy-eight women with a mean age of 59 years (range 26–79) were randomized: LASC (n=38) and RASC (n=40). There were no significant differences in the age, race, BMI, previous or concomitant surgeries of the women randomized to a laparoscopic or robotic approach (Table 1). There was no difference in the rates of drop-out between the two treatment arms (5 patients in LASC group and 7 patients in RASC group, $p=0.595$). As previously described, pain in the initial post-operative period was higher in the robotic arm, but pain did not differ amongst groups by two weeks(3).

Seventy-five cases (96%) had data available to calculate a wound repair score (36 laparoscopic, 39 robotic). Laparoscopic surgeries had a median of 4 incisions with wound repair data (range 4 to 6), while robotic surgeries had a median of 5 incisions (range 4 to 6) ($p < 0.001$). Mean total wound repair scores at 6 weeks were not different for LASC (74.5% $\pm$ 11.9%) and RASC (72.8% $\pm$ 9.2%) ($p=0.426$; Figure 1). By 6 months, LASC group had higher (better healing) total wound repair scores (LASC: 84.8 $\pm$ 8.8%; RASC: 78.5 $\pm$ 7.2%; $p=0.034$) and this continued at one year (LASC: 93.4 $\pm$ 7.2%; RASC: 85.9 $\pm$ 8.8%; $p=0.001$). The proportion of cases with optimal wound repair (score of 100%) was higher in the laparoscopic arm at one year (12/27 vs. 4/33, $p=0.008$).

Sub-analysis of the individual items within the Stony Brook Evaluation Scale indicated the difference in total scar scores between LASC and RASC groups was largely due to better outcomes in overall scar color for the LASC group. At 6 months LASC patients had an average of 0.46 $\pm$ 0.35 points per incision on the color item while RASC patients had 0.22 $\pm$ 0.23 points ($p=0.003$) indicating the RASC patients had scars that were darker than the surrounding skin. This continued at 12 months with LASC averaging 0.82 $\pm$ 0.26 points and RASC averaging 0.54 $\pm$ 0.33 points ($p=0.002$). A representative example of differences in wound appearance is found in Figure 2.

Discussion

Our findings suggest that cosmetic outcomes at 6 months and 1 year after laparoscopic ASC may be superior to those after robotic ASC using the SBES as an objective measures of wound appearance. It is likely that port size played a role in the wound appearance. A study of 80 patients undergoing laparoscopic cholecystectomy addressed port size and cosmesis(8). One group was randomized to one 5mm port and three 3 mm ports and the second group to one 10mm port and three 5 mm ports. The primary cosmetic outcome was assessed at 6 months by the patients using a validated questionnaire. Bignell reported significantly better cosmetic outcome scores in the women with the smaller ports. In our study, the robotic ports were larger (8 mm) than the laparoscopic ports (5 mm) and this variable could account for the lower wound repair scores seen in the incisions of the women randomized to robotic access.

One variable we did not measure, but that likely influenced wound appearance, was the increased pressure placed on the robotic ports by the robot. With traditional laparoscopy, one can feel the resistance of an instrument against a port, and therefore modify the torque or excess pressure against the port. However, the robotic instruments are controlled from the console, and there is no feedback provided to the surgeon regarding the amount of force placed on the robotic ports.

The strengths of our study include the use of the Stony Brook Evaluation Scale (SBES) to evaluate the incisions. The SBES is an accurate clinical outcome measure with good to high inter-observer or inter-rater reliability or consistency on repeated testing and the US Food and Drug Administration adopted a version of the SBES as one of the required outcome measures of wound repair in clinical trials(9). We selected the SBES as it contained many measures relevant to scar evaluation. It is credible, comprehensive, sensitive, accurate, feasible, and makes biological sense(7). Another strength of our study was the 1-year data on the scar appearance. The data allows us to counsel patients undergoing sacrocolpopexy that 40% of women undergoing a laparoscopic approach and 12% of women undergoing robotic surgery will have a “perfect” wound repair at 12 months.

This study has limitations. First, although we found a statistically significant difference in the SBES, we do not know if this difference is clinically meaningful. Minimally clinically important difference (MCID) is a statistical model that tries to define the smallest change in a treatment outcome that a patient would identify as important(10). No MCID exists for the SBES. A second limitation is that we did not report patient-reported measures of wound appearance and satisfaction, which are ultimately the most important outcomes for patients, which would have aided our understanding of the MCID. Finally, the clinical observers who rated the wounds were not blinded to the randomization simply because of the number of trocar sites. Robotic procedures had a total of 5 trocar sites (camera and 4 ports for the robotic arms) while laparoscopic procedures had 4 trocar sites (camera and 3 ports for instruments). We did consider evaluating the incisions using the photographs that were taken however the photographic technique (light, angle, image size, white-balancing) could not be controlled for. Surgeons, however, were not involved in assessing wound outcomes to minimize biases. Despite these limitations, this study demonstrated an objective difference in wound appearance between robotic and laparoscopic port sites.

Conclusions

Our findings suggest that cosmetic outcomes after laparoscopic ASC may be superior to those after robotic ASC using objective measures of wound appearance, which surgeons may consider discussing with patients when planning a minimally invasive ASC. The degree to which objective wound healing translates to patient satisfaction, however, warrants further investigation.

Acknowledgments

Funding: National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Recovery Act Limited Competition: NIH Challenge Grant 1 RC1 EB010649-01 (JA, KK, EM)

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Appendix

Table 1

StonyBrook Scar Evaluation Scale

Scar Category	# of points*
Width	
>2mm	0
<2mm	1
Height	
Elevated or depressed in relation to surrounding skin	0
Flat	1
Color	
Darker than surrounding skin	0
Same color or lighter than surrounding skin	1
Hatch marks or suture marks	
Present	0
Absent	1
Overall appearance	
Poor	0
Good	1

* Total score = sum of individual scores. Range 0 (worst) to 5 (best)⁷

Figure 1.

Mean wound repair scores at 6 weeks, 6 months and 12 months following surgery based on the Stony Brook Evaluation Scale

Figure 2.

Representative incision photographs of 2 study participants at 6 weeks, 6 months and 12 months. Sub-analysis of the individual items within the Stony Brook Evaluation Scale indicated the difference in total scar scores between LASC and RASC groups was largely due to overall scar color demonstrated in these images (see Appendix).

Table 1

Patient characteristics.

	Robotic	Laparoscopic	P-Value
Age <i>Mean±SD</i>	58.5±10.5	60.6±9.2	0.35
BMI <i>Mean±SD</i>	28.3±6.6	27±4.7	0.29
Race			
Caucasian	88%	95%	0.68
African American	10%	3%	
Prior UI surgery	13%	18%	0.54
Prior POP surgery	21%	20%	0.99
Prior Hysterectomy	35%	50%	0.25
Concurrent procedures at surgery			
Hysterectomy	53%	63%	0.49
Retropubic midurethral sling	55%	65%	0.49
Anterior or posterior repair	11%	3%	0.20