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ORIGINAL ARTICLE

Robotic mesh-supported pectopexy for pelvic organ prolapse: expanding the options of pelvic floor repair

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Abstract

Pelvic organ prolapse affects 30–50% of the female population. For definitive treatment surgery is unavoidable. Sacrocolpopexy has been the gold standard for anatomical correction of pelvic organ prolapse since the 1990s. Recently, pectopexy has been introduced as a new surgical procedure to correct apical prolapse. We have translated the laparoscopic pectopexy into a robotic procedure. The charts of the first 30 consecutive patients who underwent robotic pectopexy at the department for robotic and pelvic floor surgery were reviewed. All patients were analyzed for estimated blood loss, operation time, as well as complications. Treatment success was evaluated after 3–6 months using a composite endpoint including anatomical and subjective components. Of the 30 patients analyzed, 18 underwent hysteropectopexy ($n = 18$), 6 patients underwent vaginopectopexy and 6 patients underwent cervicopectopexy. Additional procedures were performed in 14 patients, and this influenced operation time and intraoperative blood loss. No intraoperative complications were noted and no conversions were necessary. Treatment success according to the primary composite endpoint was achieved in 30 (100%) patients. Furthermore, neither de novo urgency nor obstructive bowel symptoms were noted in any of the patients treated with robotic pectopexy. Similar to SCP, pectopexy is designed for prolapse repair. The robotic technique for pectopexy capitalizes on the advantages of robotic surgery as compared to conventional laparoscopy since it allows for anatomical preparation and simplification of applying sutures and mesh material, reducing operating time and minimizing surgical trauma. The technique is safe, and anatomical outcomes are excellent.

Keywords Pelvic floor disorder · Pelvic organ prolapse · Pectopexy · Robotic · Surgery · Surgical mesh

Introduction

Pelvic organ prolapse (POP) affects 30–50% of the female population depending on definition [1, 2]. It refers to the downward displacement of the vaginal apex, uterus or cervix. Frequently, this also leads to displacement of the bladder and the rectum, resulting in protrusion of these organs into the vagina. Depending on the stage of the prolapse, organs may be displaced beyond the defined level of the introitus. Patients complain about various symptoms including intravaginal bulging, pelvic pain and downward pressure. Frequently, altered bladder and bowel functions can also be observed. Initial treatment is in most cases conservative, however, for definitive treatment to correct POP surgery is unavoidable.

Sacrocolpopexy (SCP) has been the gold standard for an anatomical correction of POP since the 1990s. The procedure can be carried out as open or minimal invasive surgery [3, 4]. Laparoscopic SCP has initially been described by Nezhat et al. [5], and since then has gained increasing popularity, albeit the procedure itself can be challenging. Briefly, the cervical stump or vaginal vault are elevated and held in place by a y-shaped mesh attached to the longitudinal ligament at the level of S1-S2. The feasibility of SCP as a robotic procedure was first addressed by Di Marco et al. [6] in a case series involving 5 patients. Since then, the

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procedure has been rapidly adopted by many surgeons using the da Vinci® system [7–9], and the advantages offered by the use of the robotic system support have become apparent.

Pectopexy is a new surgical procedure to correct apical prolapse. It uses the lateral parts of the iliopectineal ligaments for fixation and thus offers some advantages when compared to SCP, since the pelvis is not divided by mesh material, and bowel manipulation is not needed to complete the procedure. It can be conducted per laparotomy as well as laparoscopically. Laparoscopic mesh-supported pectopexy has been introduced by Banerjee et al. in 2011 [10]. This new method has now been increasingly added to the spectrum of pelvic floor reconstruction worldwide [11, 12]. In its original description, a pre-cut one fits all mesh is used (DynaMesh®PRP).

Although the minimal invasive approach makes it an ideal candidate for robotic surgery, the robotic approach to correct POP by pectopexy has not been previously described. We have used the da Vinci Xi® robotic system to translate the established laparoscopic procedure of mesh-supported pectopexy into a robotic approach. We present our preliminary results and technique of robotic pectopexy on the first 30 consecutive cases treated with this new surgical approach. The procedure was performed in three different settings: hysteropectopexy with intact uterus, cervicopectopexy combined with supracervical hysterectomy in the same session if uterine pathology was present, and vaginopectopexy in patients presenting after previous total hysterectomy.

Materials and methods

The present cohort study was conducted at the maximum care university women's hospital of Klinikum Nuremberg, Paracelsus Medical University in accordance with the ethical standards of the Declaration of Helsinki. The study was approved by the internal review board of the Paracelsus Medical University.

The first 30 consecutive patients who underwent robotic pectopexy to correct POP at the department for robotic and pelvic floor surgery during the time period from 1st January 2018 to 30th January 2020 were included into the study. The patients presented with symptoms related to apical prolapse, such as sensation of vaginal pressure, bulging and/or protrusion, lower back pain, dyspareunia, or associated urinary symptoms, such as incontinency, frequency, urgency and urinary retention. All demographic data (age, weight, and height), type of pectopexy performed as well as information on any additional surgical procedures performed during robotic pectopexy were taken from the patient chart.

The patients were preoperatively evaluated by a specialized team of pelvic surgeons. A problem-oriented history was taken and physical examination was conducted including a specialized vaginal examination to evaluate the status of the pelvic floor. All patients had a minimum apical prolapse of Baden-Walker grade 3. Patients with symptoms of incontinency received an urodynamic evaluation preoperatively. Exclusion criteria were previous operations for prolapse correction and previously identified or strongly suspected massive adhesions in the abdominal cavity.

All patients underwent surgery after their informed consent was obtained in standard general anesthesia. All cases were performed by the same team of two robotic and pelvic floor surgeons with ample experience in both disciplines, using the da Vinci Xi® surgical system. Postoperative ultrasound of bladder and kidneys was routinely performed on the first post-operative day to rule out urinary obstruction or retention.

Treatment success was defined as primary composite endpoint. For assessment, all patients were scheduled for a re-visit 3–6 months after surgery and evaluated for outcome of their pelvic floor repair, beginning in April 2018 and ending in July 2020. The composite endpoint was defined as previously published including anatomical and subjective components as well as the necessity for a repeated surgery due to POP recurrence [13], as follows:

1. A POP-Q stage of ≤ 1 for the leading edge of the anterior or apical vaginal wall,
2. Absence of a vaginal bulge symptom and
3. No need for repeated surgery for anterior or apical POP.

A subjective overall satisfaction assessment was taken with a simple yes or no answer. The objective outcome was assessed by physical examination and categorized following the POP-Q criteria as specified above.

For secondary outcome measures, all patients were analyzed in terms of estimated blood loss in g/dl (EBL, calculated as the difference between hemoglobin level at admission versus hemoglobin level on the first postoperative day), operation time in minutes (i.e. the time when surgical measures were carried out starting with vaginal examination and ending with the last suture applied), BMI in kg/m^2 (as calculated from body weight and body height according to standard formula), length of hospital stay (number of days from admission day including day of dismissal from the hospital), necessity of conversion, and postoperative complications as detected perioperatively during hospital stay or indicated by readmission within the following 2 weeks.

Surgical procedures

We used the da Vinci Xi® surgical system using a three arm reduced trocar setting with standardized horizontal trocar placement at the level of the umbilicus (Fig. 1). The patient was brought into a Trendelenburg position with a decline of 25 degrees. All necessary materials (mesh, stitching

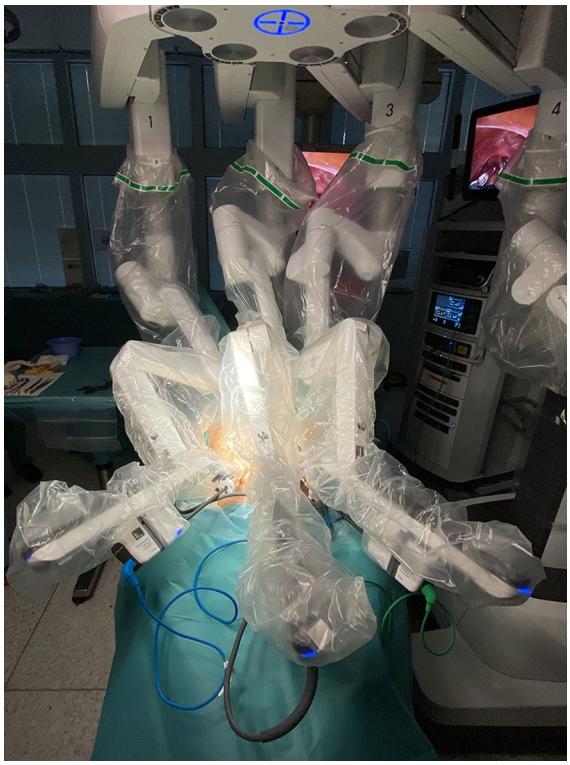

Fig. 1 Intraoperative positioning of the da Vinci Xi® for robotic pectopexy using the reduced trocar technique

material) were introduced through the 8 mm trocars. No additional trocars were applied.

Pectopexy was carried out according to the method described by Banerjee and Noe [10], with adaptations to optimize the technique in the robotic setting. The procedure was performed using pre-cut mesh (DynaMesh®PRP) in a standardized fashion by fixation of the mesh to the uterus, cervical stump or vaginal vault depending on the presentation of the case and to the pectineal ligaments on both sides. When uterine pathology was present, a standard supracervical hysterectomy in combination with the prolapse correction was indicated and performed.

Briefly, a peritoneal bladder flap was prepared and the cervix or vaginal apex with adjacent anterior and posterior vaginal wall was prepared for mesh fixation (Fig. 2a). The peritoneal incision was carried caudally of the round ligaments to the pelvic wall on both sides. The iliopectineal ligament was exposed adjacent to the insertion of the iliopsoas muscle. For bilateral mesh fixation, a standard polyvinylidene fluoride (PVDF) monofilament mesh (DynaMesh®PRP, 3 × 15 cm) was used in all cases. The mesh was sutured to the pectineal ligament using Ethibond 0 on both sides (Fig. 2b, c), and to the anterior cervix for hysteropectopexy (Fig. 2d), or to the cervical stump for cervicopectopexy or the apex of the vagina for vaginopectopexy. Finally, the peritoneal incision was closed using Vicryl 0.

If multiple pelvic floor defects were present, we performed simultaneous correction in the same operative

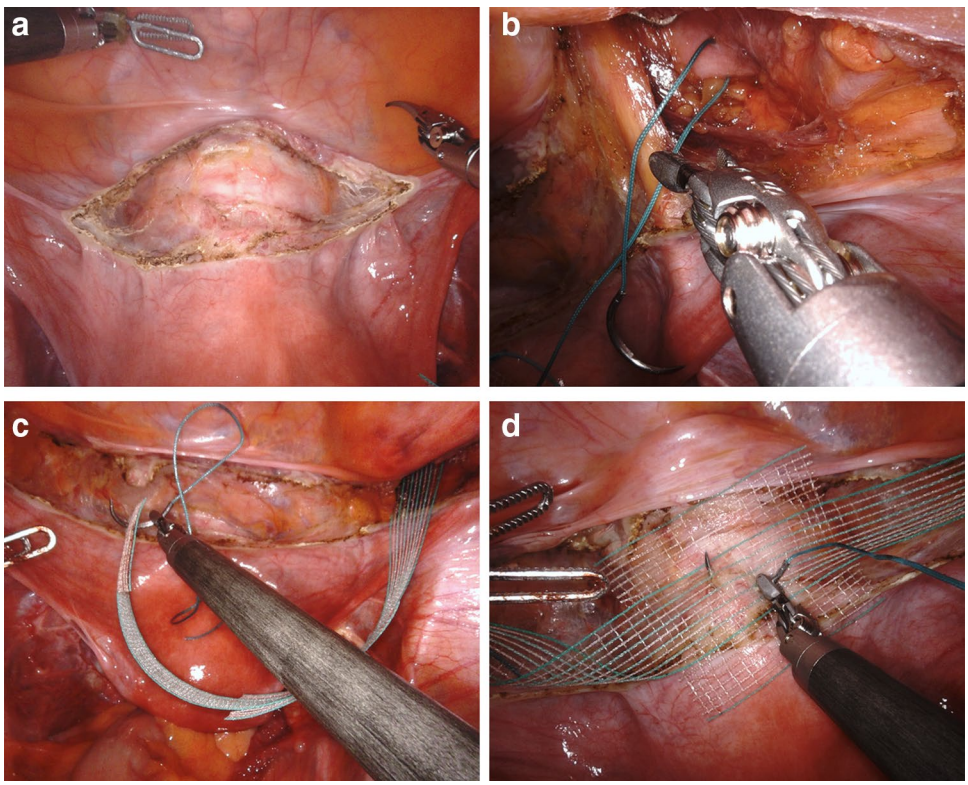

Fig. 2 Operative steps for robotic hysteropectopexy. **a** Preparation of the peritoneal bladder flap. **b** Placement of Ethibond suture to iliopectineal ligament on the right side. **c** Mesh placement to the iliopectineal ligaments. **d** Suturing of the mesh to the anterior cervix

session as necessitated. Additional surgical measures taken to optimize the anatomical results and/or necessary for other medical reasons are shown in Table 1.

Statistical methods

Data were checked for consistency and normality. Fisher's Exact test or Pearson's test were used to analyse cross tabulations. Generalized linear models with log-normal and Poisson distributions, repeated measures ANOVA, fixed factor ANOVA based on bootstrap simulations, Student *t*-tests based on Monte Carlo simulations, Kruskal–Wallis ANOVA together with LSD tests were used for to analyse continuously distributed variables. All reported tests were two-sided, and p values < 0.05 were considered statistically significant. All statistical analyses in this report were performed by use of NCSS (NCSS 10, NCSS, LLC. Kaysville, UT), STATISTICA 13 [14] and PASW 24 (IBM SPSS Statistics for Windows, Version 21.0., Armonk, NY).

Results

Demographic patient data

A total of 30 consecutive patients who received robotic pectopexy using the da Vinci Xi® system from January 2018 to January 2020 were included in this first analysis of a new surgical option for correction of apical prolapse. Mean patient age was 62.4 (std 14.7) years. Mean patient weight was 69.8 kg (std 10.6 kg) with a mean BMI of 25.8 kg/m^2 (std 3.56), range 17.3–35.2 kg/m^2. Mean length of hospital stay was 5.4 days (std 1.1) with a range of 3–8 days. No statistical difference was observed when comparing the length of hospital stay between the three different types of surgery.

Surgical procedures

Of the 30 patients analyzed, the majority underwent hysteropectopexy ($n = 18$), while 6 patients underwent vaginopectopexy and another 6 patients underwent cervicopectopexy. All patients undergoing cervicopectopexy underwent supracervical hysterectomy in the same operative session. Additional procedures were performed in 14 patients and included interventions either related to urogenital symptoms or were indicated by a variety of general gynecologic indications (Table 1). Of note, most additional procedures were performed in the cervicopectopexy group, with 19 additional procedures in 6 patients, while in the hysteropectopexy group there were 6 additional procedures in 18 patients, and in the vaginopectopexy group there were 2 additional procedures in 6 patients.

Thus, statistically, patients receiving cervicopectopexy had significantly more additional surgical procedures (mean 3.17, std 1.17; $n = 6$) than patients receiving hysteropectopexy (mean 0.44, std 0.7; $n = 18$) or vaginopectopexy (mean 0.5, std 0.83; $n = 6$) (Fig. 3a). When comparing cervicopectopexy to hysteropectopexy, this difference was highly significant ($p < 0.000003$) as determined by generalized linear model. Likewise, a significant difference was seen when comparing cervicopectopexy to vaginopectopexy ($p < 0.003$). No significant difference was seen when comparing hysteropectopexy to vaginopectopexy.

Additional procedures performed had a strong influence on operation time. Mean operation time for all procedures was 111 min ($n = 30$). Operation time in cases including supracervical hysterectomy was longer (176 min, std 51.3; $n = 6$) than in cases without supracervical hysterectomy (95 min, std 26.3; $n = 24$). This difference was statistically significant when comparing cervicopectopexy to hysteropectopexy ($p < 0.00002$) as well as cervicopectopexy to vaginopectopexy ($p < 0.00002$) (Fig. 3b) ($p = 0.86$).

Table 1 Additional surgical procedures performed with respect to type of robotic pectopexy (i.e. hystero-, cervico-, or vaginopectopexy)

	Hysteropectopexy ($n = 18$)	Cervicopectopexy ($n = 6$)	Vaginopectopexy ($n = 6$)
Supracervical hysterectomy	0 (0%)	6 (100%)	0 (0%)
Anterior colporrhaphy	1 (5.6%)	3 (50%)	0 (0%)
Posterior colporrhaphy	1 (5.6%)	3 (50%)	1 (17%)
Perineoplasty	1 (5.6%)	2 (33%)	1 (17%)
Burch colposuspension	0 (0%)	2 (33%)	0 (0%)
Sacrospinal fixation	0 (0%)	1 (17%)	0 (0%)
Salpingo-oophorectomy	0 (0%)	2 (33%)	0 (0%)
Salpingectomy	1 (5.6%)	0 (0%)	0 (0%)
Tubal ligation	1 (5.6%)	0 (0%)	0 (0%)
Cystoscopy	1 (5.6%)	0 (0%)	0 (0%)
Dilation and curettage	1 (5.6%)	0 (0%)	0 (0%)
Vaginal polyp resection	0 (0%)	0 (0%)	1 (17%)

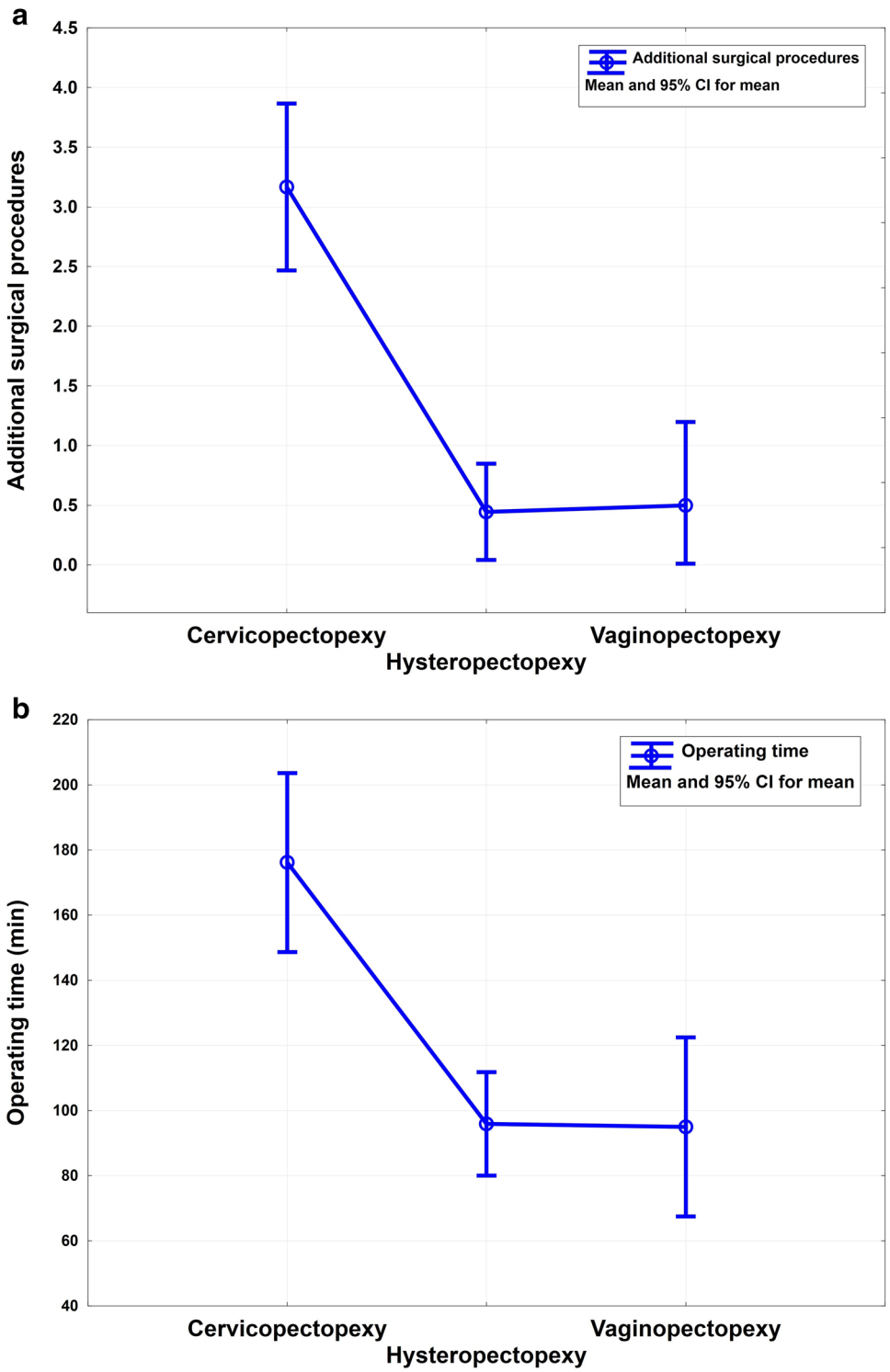

Fig. 3 Additional procedures and operating time. **a** Whisker plot of number of additional procedures in cervico-, hystero- and vaginopectopexy with means and 95% confidence intervals for means. **b** Whisker plot of operating time in cervico-, hystero- and vaginopectopexy with means and 95% confidence intervals for means

Influence of BMI on operative time

BMI ranged from 17.3 kg/m^2 to 35.2 kg/m^2, with a mean BMI of 25.8 kg/m^2. Operative time was not significantly correlated to BMI ($r = 0.17$, $p = 0.41$).

Estimated blood loss

Estimated blood loss was calculated from blood hemoglobin levels measured pre- and postoperatively. Mean hemoglobin levels were 13.21 g/dl before and 12.48 g/dl after surgery,

resulting in a mean decrease of 0.73 g/dl for the whole cohort. When comparing the three types of surgery, mean decrease in hemoglobin levels in the cervicopectopexy group was significantly higher than in the hysteropectopexy group (1.30 g/dl vs 0.60 g/dl, p = 0.028) and in the vaginopectopexy group (1.30 g/dl vs 0.57 g/dl, $p = 0.056$.) (Fig. 4). Of note, supracervical hysterectomy was performed in all cases of cervicopectopexy within the same operation.

Complications and conversions

Within the 30 cases reported, no conversions were necessary. No intraoperative complications occurred, in particular no organ, vessel or nerve injury or blood loss of > 200 ml. All patients received postoperative ultrasound of the kidneys and bladder to control for urinary obstruction and ability to completely empty the bladder. All postoperative controls were without finding. No complications directly related to the surgical procedure were noted in the perioperative phase.

There were 4 patients requiring medical intervention postoperatively. The problems observed were not directly related to the surgical procedure and of various nature in three of the four cases. All three cases were resolved without further intervention (Table 2). In one out of the 30 cases, postoperative stress urinary incontinence was diagnosed and treated conservatively by the use of a pessary. There were no readmissions due to any type of complication.

Postoperative results

To examine treatment success as our primary endpoint, patients were re-evaluated during a follow-up visit 3–6 months after surgery. Subjective satisfaction and clinical findings were recorded. The follow-up rate upon invitation for a follow-up re-examination was 100%. Using a simple yes or no format, all patients stated that they were satisfied with the post-operative result. No re-occurrence of apical prolapse was noted in any of the patients. The anatomical results were assessed using the POP-Q criteria and showed stage 0 or stage 1 in all patients. Repeated surgery therefore was not indicated in any of the patients. Treatment success according to the primary composite endpoint

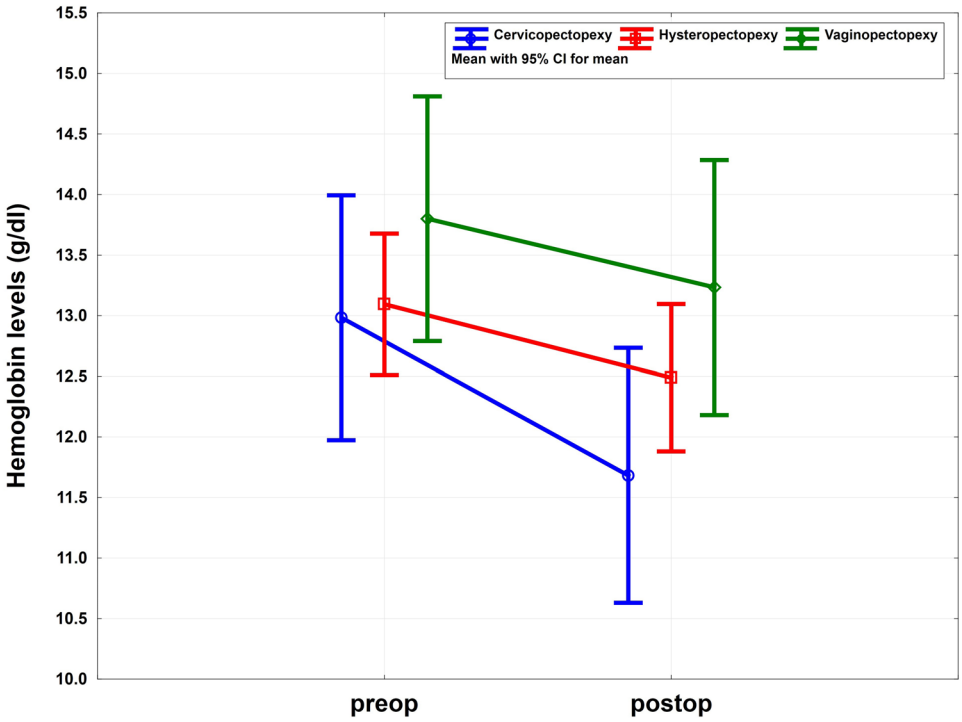

Fig. 4 Change in hemoglobin levels pre- and postoperatively in correlation to type of pectopexy. Whisker plot of hemoglobin pre- and postoperatively in cervico-, hystero- and vaginopectopexy with means and 95% confidence intervals for means

Table 2 Perioperative findings with robotic pectopexy necessitating intervention

Finding	Intervention	Status
Postoperative incontinence	Pessary use	Ongoing
Impairment of plexus brachialis	MRI: no morphologic correlate	Resolved
Elevated blood pressure	Additional medication	Resolved
Persisting head ache	CT scan	Resolved

was thus achieved in 30 (100%) patients. Furthermore, neither de novo urgency nor obstructive bowel symptoms were noted in any of the patients treated with robotic pectopexy. One patient was diagnosed with de novo stress urinary incontinence.

Discussion

In recent years, the increasing use of robotics has offered new opportunities to refine existing concepts of minimal invasive surgery. The range of robotic support is wide and includes for example the option of camera support by voice command or eye tracking, the facilitated movement of surgical instruments, stereotactic biopsy systems and other elements to optimize different kinds of surgical procedures. The da Vinci Xi® system has been established to improve minimal invasive surgery by excellent 3D vision, tremor elimination, motion scaling and a new generation of surgical instruments allowing unrestricted wrist movement, thereby increasing precision and reducing compromise caused by the limitations of straight stick conventional laparoscopy.

SCP has been the established gold standard for apical prolapse repair with a superior outcome relative to a variety of other procedures such as sacrospinous colpopexy, uterosacral colpopexy and transvaginal mesh [15]. It offers excellent anatomical and functional outcomes in long-term follow-up. However, care has to be taken to avoid damage to the sigmoid, the presacral veins, and the right ureter. In some instances, the promontory may not be reached due to severe obesity or bowel adhesions. Thus, alternatives were sought to facilitate apical prolapse repair with complex intra-abdominal findings, and pectopexy was introduced as an alternative to SCP, since it avoids the aforementioned difficulties [10, 16].

Similar to SCP it is an operative method designed primarily for apical prolapse repair, however in contrast to SCP, pectopexy uses the lateral parts of the iliopectineal ligament for a bilateral mesh fixation of the descended structures. Therefore, preparation of the sacrum is not necessary, and potential bowel obstruction as a long-term sequela of apex repair can be avoided. Importantly, iliopectineal ligament fixation does not change the physiologic axis of the vagina because S2 level is the anchor point for the physiological axis.

We have established a safe and reproducible approach to use this technique for robotic surgery. Within the first 30 cases conducted robotically, three different types of pectopexy were performed depending on the presentation of the case. They differed in regard to the median anatomical fixation point, namely the vaginal apex after previous total hysterectomy, the anterior isthmus in cases with intact uterus, or the cervical stump after supracervical hysterectomy in cases when hysterectomy was indicated due to uterine pathology.

Operation time

We observed longer operation time accompanied by slightly increased blood loss when supracervical hysterectomy was included into the procedure. Since the anatomical results were excellent in all cases done, care should be taken when indicating additional supracervical hysterectomy as opposed to perform a pure hysteropectopexy, leaving the uterus intact. As a principle, hysterectomy in cases of apical prolapse should only be performed with a clear indication to do so, e.g. fibroids, enlarged uterus or other uterine pathology.

Influence of BMI

BMI could not be shown to have a significant influence on operating time in this study. Other authors have found variable results when looking at the influence of BMI on operating time in robotic procedures. While Lagares-Garcia et al. [17] found a significant association of increasing BMI with longer operative time when looking at colorectal surgery, no such correlation was found for robotic surgery in endometrial cancer [18]. Likewise, robotic-assisted laparoscopic SCP showed no impact of BMI on operation time [19].

Since the overall patient number in this study was small, and subgroup effects on operating time were noted with respect to the type of pectopexy performed, the analysis of a potential influence of BMI on operating time did not yield any conclusive data. Possibly a discernable effect might become apparent with greater patient numbers for one defined procedure protocol, for example looking at hysteropectopexy only since it had the smallest number of additional procedures performed. On the other hand, it might be interesting to investigate a complex procedure such as pectopexy combined with supracervical hysterectomy for possible effects of BMI on operating time, since a correlation between BMI and operating time had been found in an earlier laparoscopic study looking at benign hysterectomy, including also robotic cases [20].

Length of stay

The mean length of hospital stay for pectopexy was 5.4 days. Of note, this included also patients who underwent supracervical hysterectomy together with pectopexy. Nevertheless, from our point of view the mean length of stay could be significantly reduced in an optimized environment, providing standardized and comprehensive ambulatory care during the perioperative period. Under such optimal circumstances, pectopexy could also be applied as a day-case surgery. To date, standard regulations within our health system have

posed multiple restrictions to the optimization of patient management for day-case surgery in cases with intermediate risk. Suitable ambulatory perioperative infrastructure and day-case concepts would need to be established.

Outcome

We had defined treatment success as our primary outcome measure for the study. When examining the outcome after prolapse surgery, it is important to differentiate the anatomical versus the subjective outcome. Anatomic outcome is generally reported using the Baden-Walker scale or POP-Q with the definition of a successful repair defined as Grade 0–1 or Stage 0–1 prolapse at the time of follow-up. We applied the POP-Q criteria in the setting of a composite endpoint of anatomical and subjective components as well as the necessity for repeated surgery due to POP recurrence [13]. In our case series, anatomic outcome stayed within the definition of a successful repair in all cases, as assessed using the POP-Q criteria, and no repeated surgery was necessary due to POP recurrence. Also, all patients reported their satisfaction with the operative result in a standardized follow-up interview on a simple yes or no basis.

One reason for good anatomic outcome may be the fact that pectopexy is a suitable means to reconstruct the physiologic axis of the vagina. In recent trials using pelvic MRI follow-up to compare postoperative results after various approaches for pelvic floor reconstruction, SCP as well as sacrospinous colpopexy have both been shown to deviate the vaginal axis in its medium and inferior portions [21]. In a similar study, vaginal axis after laparoscopic lateral mesh suspension surgery was likewise analyzed by MRI. As opposed to SCP and sacrospinous colpopexy, the vaginal axis was found to be near-normal in the patients who underwent lateral mesh suspension [22]. Thus, using a lateral anchor point in the pelvis for prolapse correction at the level of S2 appears to represent an ideal option for reconstructing the physiological axis of the vagina and may explain the excellent results observed in this study.

We used DynaMesh®PRP for all our procedures. This mesh is precut and comes ready to use. Therefore, rough edges are avoided. The fixation points display an anatomically adapted shape. Furthermore, the mesh characteristics are such that stretching and loss of shape are reduced to a minimum, while the durability and holding strength of the mesh have been proven to be reliable [23]. At present, there are only few alternatives to the use of precut mesh for this purpose. Mesh application has been increasingly questioned during the past years leading to complete market withdrawal of vaginal meshes in some countries. Careful new approaches to this problem have been made [24] and recommendations to treat mesh complications have been put forward [25]. In view of these developments, the option of mesh-free pelvic floor repair should always be considered when planning a procedure.

The use of robotic surgery has simplified the established laparoscopic procedure, thereby reducing operating time and minimizing surgical trauma. While surgical difficulty and complication potential have already been reduced by the laparoscopic pectopexy versus SCP, robotic pectopexy has allowed to abandon surgical compromise. Blood loss using the robotic technique is minimal due to the excellent visualization within the 3D console and optimal control of the wrist-like instruments. The technique is safe, and anatomical outcomes are excellent. No conversions were necessary, and there were no procedure-related intraoperative or postoperative complications. Using the same surgical team for all procedures performed, we have reduced potential error in the evaluation of our results to a minimum.

Limitations

The study is limited by its retrospective character. However, we sought to establish a defined laparoscopic procedure in the robotic setting. We provide the early results of the translation from the laparoscopic to the robotic method by initial analysis of outcome parameters. Further comparative studies are under way to analyze the procedure in the context of established types of robotic POP surgery.

In conclusion, the robotic technique for pectopexy capitalizes on the advantages of robotic surgery with anatomical preparation and simplification of applying sutures and mesh material as compared to conventional laparoscopy. It offers a safe approach to apical prolapse repair with respect to the intra- and perioperative management as well as excellent anatomical results. Due to short operation time and minimal trauma, it could also be offered in an outpatient setting. In future studies, we are planning to address the question of mesh versus no mesh in apical prolapse repair using the robotic approach.

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Declarations

Conflict of interest Authors D. Bolovis, W. Hitzl and C. Brucker declare that they have no relevant financial or non-financial interests to disclose.

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