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ORIGINAL ARTICLE

Retrospective comparison between the Prolift and Elevate anterior vaginal mesh procedures: 18-month clinical outcome

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Abstract
Introduction and hypothesis There are few direct comparisons between the first-generation trocar-guided and the second-generation single-incision mesh systems in the treatment of anterior pelvic organ prolapse (POP). Hence, the purpose of this retrospective review was to compare 18-month operative success in female patients who had undergone POP surgery with the anterior Prolift (n=52) or the anterior Elevate mesh (n=62).
Methods Subjective (bulge symptoms) and objective measures (absence of anterior or apical descent beyond the hymen, POP-Q anterior stage 0 or I, no retreatment for POP) were used as the measures of surgical efficacy. Postoperative pelvic floor pain, dyspareunia, de novo overactive bladder (OAB), de novo stress urinary incontinence (SUI), and mesh exposure were addressed as complications of POP surgery.
Results The two groups did not differ with regard to the subjective and objective measures of the operative efficacy. There were no between-group differences in the proportion of women reporting postoperative pelvic floor pain, dyspareunia, de novo SUI, and de novo OAB symptoms (all p values >0.05). The proportion of patients with postoperative vaginal exposure was significantly higher in the Prolift group (7.7 %) than in the Elevate group (0.0 %; p=0.02).
Conclusions In conclusion, our results suggest that the use of the Elevate system in patients with anterior compartment prolapse results in fewer mesh erosions, but similar efficacy, compared with the Prolift mesh.

Keywords Pelvic organ prolapse · Prolift mesh · Elevate mesh · Operative success

Abbreviations

CI	Confidence interval
OAB	Overactive bladder
POP	Pelvic organ prolapse
POP-Q	Pelvic organ prolapse quantification
SSLs	Sacrospinous ligaments
SUI	Stress urinary incontinence
TVL	Total vaginal length
TVM	Transvaginal mesh

Introduction

The use of polypropylene mesh for the transvaginal repair of pelvic organ prolapse (POP) has become a popular technique for improving outcomes of POP surgery [1]. Transvaginal placement of surgical mesh (TVM) may provide an anatomical improvement compared with the traditional POP repair without mesh, particularly in the anterior compartment [2].

The first-generation external trocar-based kits (e.g., Prolift) and subsequently single-incision vaginal approach grafts (e.g., Elevate) have already been described [3, 4]. A typical placement of the Prolift anterior requires 5 incisions, 1 anterior vaginal incision and 4 cutaneous incisions for the passage of superficial straps. The Prolift implant is held in place by friction acting on the associated straps passing through the

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obturator foramen [5, 6]. A typical placement of the Elevate mesh requires a single incision. In contrast to the Prolift, the Elevate system provides four-point fixation in the sacrospinous ligaments (SSLs) and the obturator internus muscles with plastic fixation tips [4]. Given the above differences in the placement method, certain differences in surgical and clinical outcomes may be expected between the Prolift and the Elevate mesh. It has been hypothesized that attachment of the Elevate to the SSLs might be associated with a better level I or apical support and less tissue dissection, and thus a lower risk of a nerve injury and postoperative pain [4]. Despite the clinical significance of the above hypotheses, there are insufficient data to guide treatment decisions and a choice between the first-generation (e.g., Prolift) and single-incision Elevate kits. McLennan et al. [7] reported the results of a retrospective analysis of their perioperative experience of POP repair with the Prolift and the Elevate vaginal mesh procedures. No differences in operative time, change in hemoglobin, pain score, narcotic use, and the rate of bowel and vascular injuries were noted between Prolift (n=143) and Elevate patients (n=77). The length of stay was slightly shorter in patients with the Elevate. However, according to the authors' interpretation, the difference could be related to more aggressive discharge planning [7]. In a single retrospective study with longer follow-ups, Shek et al. [8] observed 66 women with the Prolift and 91 women with the Elevate for ≥3 months (range: 0.3–5.6 years) following anterior mesh placement. Compared with the Elevate mesh, the Prolift mesh implantation was associated with a significantly lower risk of anchoring failure and POP recurrence [8].

The primary purpose of the present retrospective study was to compare 18-month operative success in patients who had undergone anterior POP surgery with the Prolift or Elevate mesh procedures. Both subjective (bulge symptoms) and objective (absence of anterior or apical descent beyond the hymen, POP-Q anterior stage 0 or I, no retreatment for POP) measures were used as the efficacy outcomes, as recommended by the international guidelines [9–11]. Rates of postoperative pelvic floor pain, dyspareunia, de novo overactive bladder (OAB), de novo stress urinary incontinence (SUI), and mesh exposure were used as the secondary outcomes.

We compared Prolift and Elevate mesh in the treatment of anterior POP with a comprehensive set of efficacy measures and complications addressed in line with international guidelines, which we feel contributes to the current literature.

Materials and methods

Study groups

The study was carried out in accordance with the Declaration of Helsinki of the World Medical Association (WMA). The study protocol was approved by the Ethics Committee for Human Studies at the Military Institute of Medicine, Warsaw, Poland. The study methods and definitions conformed to the standards jointly recommended by the International Urogynecological Association and the International Continence Society [10].

Medical records of women with an anterior vaginal wall prolapse admitted to the Department of Gynecology and Oncological Gynecology between January 2011 and December 2012 were reviewed. The study groups included patients with symptomatic anterior compartment prolapse, stages III and IV, based on the Pelvic Organ Prolapse Quantification (POP-Q) system [12], who had undergone standardized implantation of the Prolift mesh (Prolift Anterior™, Gynaecare Prolift Pelvic Floor Repair System, Ethicon, Somerville, NJ, USA), as described by Debodinance and co-workers [13, 14], or the Elevate anterior mesh (American Medical Systems, Minnetonka, MN, USA), as described by Moore et al. [4]. The patients had a primary anterior prolapse surgery or an anterior repair following a previous posterior repair. A concomitant procedure was performed, if necessary, including a cervical amputation (11 patients), posterior vaginal bridge repair (15 patients), with no significant differences between the study groups. Patients with genital anomalies or medical conditions that might render the interpretation of results difficult (e.g., cancer treatment, long-term steroid treatment, diabetes, severe neurological disorders) were excluded from the study. Women with previous anterior POP surgery were also excluded from the study.

Assessment of efficacy outcomes before and following the surgery

Efficacy outcomes (presence vs absence of the anterior or apical descent beyond the hymen, POP-Q anterior stage 0–I vs II–IV) [9, 11] were assessed using the patients' clinical records. Pelvic examination was performed with the patient in the dorsal lithotomy position. The POP-Q system was used to quantify the POP severity at a maximum Valsalva strain [12, 15, 16].

The vaginal bulge symptoms were assessed by asking a question selected from the Pelvic Floor Distress Inventory ("Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?") [17]. Patients scoring ≥1 were considered as having bulge symptoms. Retreatment for POP was defined as any repeat surgery for a prolapse arising from the same site [11] or the use of a pessary for recurrent anterior and/or apical descent [9].

Assessment of secondary outcomes before and following the surgery

The assessment of secondary outcomes was a part of standard follow-up. The patients were interviewed about SUI

symptoms using the Stamey Incontinence Score (grade 0 continent; grade 1: loss of urine with a sudden increases in abdominal pressure, such as coughing, sneezing, laughing; grade 2: leaks with lesser degrees of physical stress, i.e., walking, sitting up in bed; grade 3: urine is lost without any relation to physical activity or body position) [18]. The patients with grade ≥1 or showing a positive cough stress test were considered to have SUI. The OAB symptoms were assessed using questions selected from the Pelvic Floor Distress Inventory [16, 19] ("Do you usually experience frequent urination?", "Do you usually experience a strong feeling of urgency to empty your bladder?", "Do you usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?"). The patients who answered "yes" to any of the questions were considered to have OAB [16].

The patients were interviewed about postoperative pelvic floor pain and dyspareunia. The postoperative pain severity was estimated by the patient using a five-point scale based on the IUGA/ICS grading system for the assessment of mesh-related pain. The severity of pain may vary from 1 (asymptomatic, no pain), through 2 (provoked pain only during vaginal examination), 3 (pain during intercourse), 4 (pain during physical activities) to 5 (spontaneous pain) [20]. Patients were considered to experience postoperative pain if they rated the pain severity ≥2. Dyspareunia was assessed with the question "Do you have pain with intercourse?" [21].

Vaginal exposure following surgery was defined as a condition of a vaginal mesh visualized through a separated vaginal epithelium [20].

Statistics

Sociodemographic and clinical parameters were expressed as means (±SD) or proportions (*n*/*N*). The Prolift and Elevate groups were compared using Student's *t* test or the Chi-squared test. A probability level (*p*) less than 0.05 was considered significant. All statistical analyses were performed using the Statistica 5.0 software package (StatSoft, Tulsa, OK, USA).

Results

One hundred and thirty-one records initially qualified for the statistical analysis. Ten patients did not meet the inclusion criteria (and/or met the exclusion criteria). Seven patients were lost to follow-up. The final database contained pre- and postoperative records of 114 Caucasian women who fulfilled the inclusion criteria and did not meet the exclusion criteria and for whom full results of postoperative assessment were available.

Table 1 presents basic sociodemographic and clinical characteristics of the study groups, i.e., the Prolift (*n*=52) and the Elevate patients (*n*=62). For all the patients included in the database, a clinical follow-up assessment was performed at 18 ±2 months postoperatively. The two groups did not differ in age, marital status, the proportion of women with a university degree, height, weight, gravidity, vaginal deliveries, postmenopausal status, and smoking habits. Nor were there any differences between the two groups with regard to their preoperative SUI and OAB symptoms (all *p* values >0.05).

The two groups did not differ in the anterior and posterior POP-Q stages and the proportions of patients reporting preoperative pelvic floor pain and/or dyspareunia. Similarly, the proportions of women in the Prolift and Elevate groups who had undergone a previous posterior POP and/or SUI surgery did not differ (Table 1).

Table 2 shows the operative success rates in the Prolift and Elevate groups assessed 18±2 months following surgery. There were no between-group differences in subjective (bulge

Table 1 Basic sociodemographic and clinical characteristics of the study groups

Patient characteristics	Prolift (*n*=52)	Elevate (*n*=62)	*p* value
Age (years)	68.5±7.9[a]	66.1±7.4	0.1*
Married	44 (85 %)	47 (76 %)	0.2
University degree	13 (25 %)	22 (35 %)	0.2
Height (cm)	162.3±5.2	163.2±6.1	0.4
Weight (kg)	72.0±9.1	75.2±9.1	0.1
Body mass index (BMI)	27.3±3.0	28.3±3.3	0.1
Gravidity	2.3±1.1	2.3±0.9	0.9
Vaginal deliveries	2.0±1	1.8±0.8	0.1
Postmenopausal status	50 (96 %)	60 (97 %)	0.8
Current smokers	5 (9.6 %)	7 (11.2 %)	0.8
Stress urinary incontinence	23 (44 %)	21 (34 %)	0.2
Overactive bladder	12 (23 %)	15 (24 %)	0.9
Previous posterior POP surgery	13 (25 %)	16 (26 %)	0.9
Previous SUI surgery	14 (27 %)	15 (24 %)	0.7
Preoperative pelvic floor pain	5 (9.6 %)	6 (9.6 %)	0.9
Preoperative dyspareunia	8 (15 %)	7 (11 %)	0.5
Preoperative POP-Q anterior	3.2±0.4	3.1±0.3	0.4
Stage 0	0	0	0.4
Stage I	0	0	
Stage II	0	0	
Stage III	42	54	
Stage IV	10	8	
Preoperative POP-Q posterior	10.0±1.6	0.8±1.5	0.6
Interval from surgery to follow-up (months)	18.1±1.1	18.0±1.0	0.7

*The *t* test or Chi-squared test

[a] Mean±SD

Table 2 Operative success rates following the Prolift or Elevate vaginal mesh procedure

	Prolift (n=52)	Elevate (n=62)	p value
Postoperative POP-Q anterior	0.46±0.7[a]	0.56±0.8	0.5*
Stage 0	34	36	0.6
Stage I	13	20	
Stage II	4	3	
Stage III	1	3	
Stage IV	0	0	
Postoperative POP-Q anterior stage 0 or I	47 (90 %)	56 (90 %)	0.9
No descent beyond the hymen	51 (98 %)	58 (93.5 %)	0.2
Subjective cure/no vaginal bulge symptoms	38 (73 %)	47 (76 %)	0.7
No re-treatment for POP	52 (100 %)	60 (97 %)	0.2
Vaginal exposure	4 (7.6 %)	0 (0 %)	0.02
De novo stress urinary incontinence	6 (11.5 %)	9 (14.5 %)	0.6
De novo overactive bladder	1 (2 %)	0 (0 %)	0.3
Postoperative pelvic floor pain	6 (11.5 %)	7 (11.3 %)	0.9
Postoperative dyspareunia	6 (11.5 %)	7 (11.3 %)	0.9
Postoperative POP-Q posterior	0.50±0.9	0.45±0.9	0.8

*The t test or Chi-squared test

[a] Mean±SD

symptoms) and objective measures of operative efficacy (absence of anterior or apical descent beyond the hymen, POP-Q anterior stage 0 or I, no retreatment for POP). In line with the above, the mean anterior POP-Q stage of the two groups, assessed at the follow-up evaluation, did not differ (p values >0.05).

The Chi-squared test showed no between-group differences in the proportion of women reporting postoperative pelvic floor pain, dyspareunia, de novo SUI, and de novo OAB symptoms (p values >0.05). The proportion of patients with postoperative vaginal exposure was significantly higher in the Prolift (7.7 %) than in the Elevate group (0.0 %; p=0.02; Table 2).

Discussion

Our retrospective study based on medical case records showed the high and comparable operative success rates in two groups of women following the POP surgery with the anterior Prolift or Elevate mesh. Neither subjective (vaginal bulge symptoms) nor objective measures (absence of anterior or apical descent beyond the hymen, POP-Q anterior stage 0 or I, no retreatment for POP) [9–11] of surgical efficacy differed between the two study groups. In general, the present results provide a further support for studies showing relatively high objective and subjective success rates following both anterior Elevate [4, 22] and anterior Prolift mesh repair [6]. For example, recently published single-arm studies showed that the Elevate system was an effective procedure for prolapse repair, with an objective success rate in the anterior compartment of 88 % to 92 % [4, 22]. The latter findings are similar to the efficacy rates observed in the present study (>90 %).

In a retrospective study on the anchoring failure of anterior compartment mesh, Shek et al. [8] compared recurrence rates associated with an anchoring failure in patients who had undergone the anterior Prolift (n=66) or Elevate (n=91) mesh surgery. The follow-up in the latter study ranged from 0.3 to 5.6 years. The Elevate mesh was significantly more likely associated with an anchoring failure and cystocele recurrence compared with the Prolift mesh (the odds ratio: 12.61, 95 % CI: 4.5–35.0). In line with the report by Shek et al. [8], we found that the only two patients who required retreatment for anterior POP had been implanted with the Elevate mesh. Recently, Brennand et al. [23] visualized the placement of self-fixating anchoring tips of the Elevate mesh on magnetic resonance imaging. Interestingly, in 10 out of 20 insertion points, the anchors were unintentionally inserted into pelvic structures other than SSLs [23]. Taking into account the results of the present and previous studies [8, 23], it may be concluded that the single incision mesh approach (Elevate) and the first generation external trocar-based kits (Prolift) do not differ in terms of typical efficacy outcomes.

One may hypothesize that by avoiding trocar passes, the Elevate technique causes less postoperative pelvic floor pain and dyspareunia, and may lead to higher subjective success rates. In the present study, we found no differences in postoperative pain and dyspareunia between the Prolift and Elevate groups. Our results are in agreement with the findings of McLennan et al. [7] who reported no difference in pain scores in an immediate postoperative period between the Prolift and Elevate groups. It is worth remembering that pelvic floor pain following TVM includes a variety of pelvic symptoms (e.g., dyspareunia, obturator neuralgia, buttock pain, inner thigh pain) secondary to different mechanisms (e.g., nerve and/or muscle damage, postoperative infections, mesh overtension, mesh retraction) [24–26]. In the present study, postoperative pelvic floor pain and dyspareunia were observed in approximately 11 % of patients regardless of the use of the Prolift and Elevate mesh. Similar rates of postoperative pelvic floor pain were reported by other authors [26].

We found a significantly higher risk of vaginal exposure after the Prolift mesh implantation (7.7 %) compared with that with the Elevate mesh (0.0 %). This may be due to a larger size of the Prolift mesh resulting in insufficient intraoperative mesh spreading or mesh folding soon after surgery [25]. Our study differs from a report by Sirls et al. [27]. In the latter study, vaginal mesh exposure was identified in 27 (8.0 %) out of 264 women implanted with the Prolift and in 6 (8.5 %) out of 71 women implanted with the Elevate mesh.

There were no between-group differences in the rate of de novo OAB and SUI. The low rates of the de novo OAB in the present study are consistent with those in a report by Takahashi et al. [28]. The rates of de novo SUI in the present study (11.5 % in the Prolift group, 14.5 % in the Elevate group) were comparable with those reported by Vaiyapuri et al. [29] for patients implanted with the Prolift mesh.

The present study involves some limitations. We retrospectively analyzed a relatively small sample of patients diagnosed and treated in one tertiary-care urogynecological center. One should be aware that some of the between-group comparisons might have been underpowered. Although the questionnaires used in the study were translated into Polish by using a standard back-translation procedure, the Polish versions were not formally validated. Hence, the present findings should be treated as preliminary, and replicated in multicenter studies on larger samples of POP patients. In future studies, the use of other trocar-guided mesh systems (e.g., Gynemesh, Perigee) may be considered as the Prolift mesh has already been withdrawn from the market. Despite the withdrawal of the kit, women implanted with the Prolift mesh are still followed-up in many urogynecological centers. Our findings may have direct relevance to the further management of this group of patients.

In conclusion, our results suggest that the use of the Elevate system in patients with anterior compartment prolapse results in fewer mesh erosions, but similar efficacy, compared with the Prolift mesh. A similar conclusion has been drawn from a retrospective study by Larouche et al. [30]. The latter authors have reported that the use of trocar-guided Gynemesh and trocarless Polyform TVM systems resulted in comparable surgical efficacy and that the use of the Polyform mesh resulted in significantly fewer mesh exposures. Further longitudinal studies on the first-generation external trocar-based kits and second-generation single-incision vaginal approach grafts are needed to validate the results of the present and previous studies [8, 30].

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