

# The assessment of quality of life and satisfaction with life of patients before and after surgery of an isolated apical defect using synthetic materials

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## Research article

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# Abstract

*Background:* Pelvic floor static disorders constitute a significant clinical and social problem. The incidence of the problem increases with the age of female patients up to 80 years of age. Due to various methods of procedural treatment, eligibility for surgery should be carefully discussed with the patient. Ideally, the surgery should be effective and with the least possible number of complications. The objective of this study was to assess the quality of life of patients before and after the surgery of an isolated apical defect with the use of BSC mesh.

*Methods:* The study involved 60 patients who were diagnosed with pelvic floor static disorder on the basis of physical examination. Standardised questionnaires were used to assess the quality of life and satisfaction with life: the Perceived Quality of Life (P-QOL) and the Satisfaction With Life Scale (SWLS).

*Results:* The P-QOL results for each domain were higher in patients before surgery compared to the results obtained after the surgery. For almost all domains, the results obtained were statistically significant. The results obtained in the SWLS questionnaire in most answers also show that after the procedure there was an improvement in satisfaction with life in the examined female patients.

*Conclusion:* In most patients, surgical treatment of an isolated apical defect using BSC mesh results in the subsidence of bothersome symptoms and improves the quality of life.

## 1. Background

Pelvic organ prolapse (POP) constitutes a significant clinical and social problem. The symptoms worsen when intra-abdominal pressure increases, for instance during physical activity or coughing. The number of patients suffering from pelvic organ prolapse is not exactly known due to different definitions of the disorder and various systems of classification. According to the latest European data, the ailment concerns approximately 6-11% of women. American data suggest that the disorder is found in about 24% of women. The incidence of the problem increases with the age of female patients up to 80 years of age. In such cases, the need to perform surgery is determined in 20% of women [1,2,3].

Currently, the basic indication for surgical treatment is the occurrence of symptoms and ineffective conservative treatment. and the lack of consent of the patient for conservative treatment or ineffective conservative treatment. Surgery may be warranted if if there are symptoms associated with prolapse such as:

- strain and/or pain in the lower abdomen;
- urinary and/or faecal incontinence;
- recurrent bladder ailments (urinary urgency or pollakiuria);
- difficulty urinating and/or defecating;
- the need to change body position in order to urinate;

- limited sexual activity [4].

Due to various methods of procedural treatment, eligibility for surgery should be carefully discussed with the patient. Ideally, the surgery should be effective and with the least possible number of complications.

In 1990, A. Wattiez [5] performed the first laparoscopic sacrocolpopexy, which is a gold standard for treating pelvic floor static disorders. The surgery involves the reconstruction of pelvic fascia using an implant. The Y-shaped posterior mesh is attached to the puborectalis muscles and above, to the vaginal stump or the uterine cervix. While the front mesh is attached to the vagina to the level of the bladder trigone, pubovaginal fascia or vesicovaginal fascia Both mesh implants are joined and after opening the peritoneum they are stitched to the longitudinal ligament of the vertebral column. Then, the peritoneum is closed over the mesh [6].

The surgery gives very good treatment results in the absence of complications typical for vaginal mesh implants. Unfortunately, due to the fact that the patient is in the Trendelenburg position during surgery and on account of the long surgery time of approximately 180 minutes [7], laparoscopic sacrocolpopexy is not a solution that can be performed on every patient.

Therefore, new solutions have appeared, such as Noe's [8] pectopexy (the suspension of the Cooper's ligament) and the Dubuisson's laparoscopic lateral suspension [9].

Nevertheless, it seems that in the case of older patients with a history of internal diseases, for whom laparoscopic or abdominal surgeries under general anaesthesia may pose too high risks, the only alternative is transvaginal surgery. Afterwards, the vaginal suspension to the sacrospinous ligament, developed by Amreich in 1951 [10], and then modified by Sederl and Richter, [11] should be considered. This method involves putting stitches on the sacrospinous ligaments visualising them. According to the latest scientific reports, this method is as effective as any other vaginal approach for prolapse repair, but have a higher reoperation rate than sacrocolpopexy [12]. Therefore, it is necessary to find a method which would combine low invasiveness of transvaginal surgery with high efficiency.

Transvaginal surgeries performed under block anaesthesia, with the use of synthetic materials, giving good results in most studies [13], seemed to be a good solution.

However, due to the possibility of complications, such as mesh erosion and pain associated with its implantation, in 2011, the U.S. Food and Drug Administration (FDA) issued a warning, and in 2019 withdrew the vaginal mesh implants from the US market [14].

Complications related to the use of the mesh include the possibility of its erosion. The incidence or risk of mesh erosion is likely to be decreased by the use of small mesh implants with a monoporous texture that reduce the burden of biomaterials. What is more, mesh should be lightweight and macroporous. As a consequence of the preparation and attachment of the mesh near the pudendal nerve and pudendal vessels, the possibility of damage to the above structures, including neuralgia or haemorrhage may arise [15]. Pelvic organ prolapse significantly reduces the quality of life for women. The most common

problems include incomplete bladder voiding, chronic urine retention, interrupted or impeded urination, as well as the need to support urination by engaging the abdominal prelum or the need to change body position in order to urinate [16,17]. Nowadays, doctors not only focus on extending the life of their patients, but also on improving its quality. Contemporary medicine aims to improve the quality of life of the patient to the condition from before the disease. Therefore, researchers are increasingly interested in assessing quality of life of people affected by various diseases [18,19].

The objective of this study was to assess the quality of life of patients before and after performing the surgery of an isolated apical defect using BSC synthetic mesh.

## 2. Material And Methods

### 2.1. Design and data collection

The study involved 60 patients from the Gynaecology Department of the Hospital of the Ministry of Internal Affairs and Administration in Wroclaw, who were diagnosed with pelvic floor static disorders. The POP-Q scale and the modified classification of pelvic static disorders according to DeLancey were used to objectively assess the type and degree of the disorder (Table 1).

Table 1. Stages of POP-Q system measurement

Stage 0	no prolapse is demonstrated
Stage 1	the most distal portion of the prolapse is more than 1 cm above the level of the hymen
Stage 2	the most distal portion of the prolapse is 1 cm or less proximal or distal to the hymenal plane
Stage 3	the most distal portion of the prolapse protrudes more than 1 cm below the hymen but no farther than 2 cm less than the total vaginal length (for example, not all of the vagina has prolapsed).
Stage 4	vaginal eversion is essentially complete

[Persu C, Chapple CR, Cauni V. Pelvic Organ Prolapse Quantification System (POP-Q) - a new era in pelvic prolapse staging. J Med Life. 2011; 15 4(1): 79.]

All patients qualified for the study had an isolated apical defect POP-Q III C or POP-Q IV C. The vast majority were, however, patients with POP-Q III C. The aim of the study was to assess the quality of life in another less common group of patients. Before the beginning of the study, informed consent was obtained from all patients to participate in the study. All qualified patients completed the P-QOL and the SWLS questionnaires twice: before the surgery and 12 months after surgery. Patients were qualified for the study on the basis of specific inclusion criteria.

The inclusion criteria were the following:

- Patients with an isolated apical defect;
- Reproductive organ static disorder grade III or IV of the POP-Q scale;
- Level I defect on the modified DeLancey scale;
- Lack of consent to pessary treatment;
- Ineffective conservative treatment
- Age over 65.

All patients qualified for the project had a cervical or vaginal stump suspension procedure performed using the AMI BSC system. The BSC mesh is designed to induce neo-ligament formation by establishing a symmetrical, two-sided vaginal vault suspension from sacral cruciate ligament. The BSC mesh provides support that was previously provided by natural ligaments that no longer work [20]. In this case, the mesh is fixed with i-Stitch-sutured fixation directly to the sacrospinous ligament. The surgical technique used included:

- pre-operative treatment (estriol application - 4 weeks before surgery, antibiotic prophylaxis with a combination of cephalosporin and metronidazole application, vaginal disinfection, anus covering);
- incision in the posterior vaginal wall (3 cm distal to the vaginal apex);
- access to the sacrospinous ligament (a canal designated to admit the index finger of the surgeon is formed by advancing Metzenbaum scissors immediately under the vaginal wall horizontally in the direction of the pelvic side wall);
- dissection of a horizontal space under the cranial vaginal tissue (from the upper end of the longitudinal vaginal incision, the tissues of the rectovaginal septum are dissected off the posterior aspect of the vaginal wall);
- choosing the future fixation points for the BSC Mesh (it is a matter of personal preference, on which side the i-Stitch suture is placed first, the suture is advanced into the receiving groove, the sutures are not knotted but guided laterally to the thighs of the patient where they are held i.e. by short Kocher clamps);
- fixation of the tape to the underside of the vaginal apex or the posterior or anterior aspect of the cervix with 3 or 4 non absorbable polypropylene threads
- threading the sutures through the mesh (the prepositioned sutures are threaded through the mesh from posterior to anterior);
- Tying of the sutures and cut short, bringing the mesh in contact with the patient`s tissue for the first time, the vaginal incision is closed with the pre-positioned running suture);
- Preparation for postoperative care (insertion of estriol ointment into the vagina, weekly prescribing vaginal estriol applications) [21].

## 2.2. Measures

1. *The Perceived Quality of Life (P-QOL)* questionnaire is a generic instrument for assessing perceived QoL and the level of satisfaction with life. The questionnaire consists of 38 questions, of which the first twenty represent nine QoL domains (general health perception, prolapse impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy, and symptom severity measures). The next eighteen questions refer to the symptoms of pelvic organ prolapse. The responses range from 'none/not at all' through 'slightly/a little' and 'moderately' to 'a lot'. A four-point scoring system for each item was used to measure the severity of the urogenital prolapse symptoms. No combined score is calculated for this questionnaire. If a woman has only one affected life domain and another woman has another affected domain, they are both considered symptomatic, though in different aspects of QoL [22,23].
2. *The Satisfaction With Life Scale (SWLS)* questionnaire was developed by Diener et al., and a Polish adaptation was made by Juszczynski [24]. It is a tool used to analyse the satisfaction of the respondents with their current life. The questionnaire consists of 5 questions assessed on a 7-point scale. Values from 1 for "I strongly disagree" to 7 for "I strongly agree" were assigned to the answers to individual questions. The higher the score (min. 5 points, max. 35 points), the greater the feeling of satisfaction with life [25].

### 3. Statistical Analysis

The statistical analysis was carried out using the R programme. Descriptive statistics were applied to analyse the results obtained. The quality of life of patients from before the surgery and 12 months after the surgery was compared using the following tests: Wilcoxon matched-pairs test or the Fisher's exact test. The analysis was carried out both for the results obtained from the P-QOL and the SWLS questionnaires. The value of  $p < 0.05$  was considered to be statistically significant.

### 4. Results

60 women with diagnosed POP-Q III C and IV C were qualified for the project. The average age of the patients was 70.28 (the range of 65 - 87 years old). Assessment was performed before surgery and 12 months after surgery using AMI BSC. The P-QOL results for each domain were higher (i.e. worse) in patients before the surgery compared to the results obtained after the surgery. For almost all domains, the results obtained were statistically significant (Table 2). Most of the answers given in the P-QOL questionnaire, which concerned urinary tract and bladder symptoms, were also statistically significant as the quality of life in their functioning after the surgery has significantly improved (Tables 3 and 4). After the surgery, statistically significant changes in other symptoms assessed in the P-QOL questionnaire were also observed (Table 5).

Table 2. Domain scores of the PQoL questionnaire from women before and after surgery

	before surgery	after surgery	p-value
<b>General Health</b> n = 60	40 (0 - 80) 38.60 (17.67)	20 (0 - 80) 26.67 (17.86)	0.00002861
<b>Prolapse Impact</b> n = 60	50 (0 - 75) 38.60 (29.15)	0 (0 - 75) 18.86 (27.66)	0.000007581
<b>Role Limitation</b> n = 60	12.50 (0 - 75) 26.96 (30.60)	0 (0 - 75) 10.75 (23.79)	0.0001724
<b>Physical Limitation</b> n = 60	0 (0 - 75) 27.19 (30.26)	0 (0 - 75) 10.31 (21.54)	0.0001927
<b>Social Limitation</b> n = 60	0 (0 - 75) 19.30 (25.12)	0 (0 - 50) 7.02 (16.37)	0.0002904
<b>Personal Relationship</b> n = 60	0 (0 - 72.73) 17.53 (24.51)	0 (0 - 54.55) 7.31 (13.48)	0.01551
<b>Emotion</b> n = 60	0 (0 - 75) 26.17 (29.94)	0 (0 - 75) 12.72 (23.63)	0.00008613
<b>Sleep Energy</b> n = 60	25 (0 - 75) 24.12 (24.87)	0 (0 - 75) 13.60 (17.56)	0.001441
<b>Severity Measures</b> n = 60	13.33 (0 - 73.33) 19.42 (22.51)	0 (0 - 73.33) 9.47 (16.81)	0.0002301

Data are presented as median (range) and mean (standard deviation). n denotes size of each group. Given p-values are for the Wilcoxon test for dependent samples.

Table 3. Urinary symptom responses from PQoL questionnaire from women before and after surgery

urinary symptom	response	before surgery	after surgery	p-value
frequent visits to the toilet to urinate	does not occur	6	25	0.0004818
	not at all	6	11	
	a little	10	9	
	moderately	31	11	
	a lot	7	4	
sudden, very strong urge to urinate	does not occur	7	27	0.001219
	not at all	3	4	
	a little	16	15	
	moderately	22	10	
	a lot	12	4	
urinary incontinence associated with a strong need to urinate	does not occur	14	31	0.01085
	not at all	2	2	
	a little	15	10	
	moderately	13	10	
	a lot	16	7	
urinary incontinence associated with coughing	does not occur	18	31	0.1474
	not at all	3	3	
	a little	13	10	
	moderately	12	10	
	a lot	14	7	
weak urine flow	does not occur	18	39	0.002271
	not at all	11	5	
	a little	18	8	
	moderately	8	4	
	a lot	5	4	
strain when emptying the bladder	does not occur	28	46	0.01501
	not at all	10	4	
	a little	9	4	
	moderately	10	5	
	a lot	3	1	
dripping urine after emptying the bladder	does not occur	23	38	0.05322
	not at all	9	3	
	a little	12	7	
	moderately	12	10	
	a lot	4	2	

Data are presented as subgroups size. Given p-values are for the Fisher's exact test.

Table 4. Bowel symptom responses from PQoL questionnaire from women before and after surgery

bowel symptom	response	before surgery	after surgery	p-value
feeling of incomplete bowel emptying after defecation	does not occur	28	39	0.176
	not at all	10	3	
	a little	11	10	
	moderately	7	5	
	a lot	4	3	
constipation, difficulty in defecation	does not occur	32	41	0.4012
	not at all	10	6	
	a little	6	3	
	moderately	5	6	
	a lot	7	4	
strain accompanying the defecation	does not occur	31	41	0.4488
	not at all	13	9	
	a little	6	3	
	moderately	4	3	
	a lot	6	4	
use of fingers to defecate	does not occur	48	53	0.04262
	not at all	6	0	
	a little	2	5	
	moderately	1	0	
	a lot	3	2	
frequency of defecation	more than once a day	8	4	0.7779
	once a day	39	42	
	once every two days	6	8	
	once every three days	4	4	
	once a week or less	3	2	

Data are presented as subgroups size. Given p-values are for the Fisher's exact test.

Table 5. Other symptom responses from PQoL questionnaire from women before and after surgery

symptom	response	before surgery	after surgery	p-value
vaginal bulge disturbing in intercourse	does not occur	29	48	0.001898
	not at all	16	7	
	a little	4	3	
	moderately	7	0	
	a lot	4	2	
back pain occurring together with discomfort in the vagina	does not occur	36	49	0.03176
	not at all	6	2	
	a little	5	6	
	moderately	6	1	
	a lot	7	2	
vaginal discomfort	does not occur	26	44	0.007846
	not at all	6	5	
	a little	13	7	
	moderately	6	1	
	a lot	9	3	
bulge in a vagina	does not occur	33	48	0.03191
	not at all	4	3	
	a little	11	5	
	moderately	5	3	
	a lot	7	1	
heaviness or pressure in the vagina or down stomach at the end of the day	does not occur	32	48	0.03223
	not at all	2	1	
	a little	10	4	
	moderately	10	5	
	a lot	6	2	
thickening in the vagina making defecate difficult	does not occur	38	51	0.01145
	not at all	7	3	
	a little	11	3	
	moderately	0	2	
	a lot	4	1	

Data are presented as subgroups size. Given p-values are for the Fisher's exact test.

The results obtained after performing the SWLS questionnaire indicate that after the surgery, patients' satisfaction with life showed an upward trend (Table 6). The results did not obtain statistical significance, no less visible is the upward trend in the assessed aspect. Table 6 presents the results of individual questions in the questionnaire, including the number of people who provided the answer. No statistical significance was obtained for these data. Despite this, especially in questions number 3 and number 4 it is noticeable that after the surgery patients more often indicated that they were happier and could fulfill their life goals (Table 7).

Table 6. Domain scores of the SWLS questionnaire from women before and after surgery

	before surgery	after surgery	p-value
total score	23.5 (5 - 35)	30 (8 - 35)	0.5044
n = 60	22.92 (6.58)	23.72 (6.81)	

Data are presented as median (range) and mean (standard deviation). n denotes size of each group. Given p-value is for the Wilcoxon test for dependent samples.

Table 7. Responses from SWLS questionnaire from women before and after surgery

question	response	before surgery	after surgery	p-value
In most aspects my life is close to my ideal	I definitely agree	7	8	0.9279
	I agree	8	11	
	I rather agree	19	14	
	I neither agree nor I disagree	11	13	
	I rather disagree	3	3	
	I disagree	6	4	
	I definitely disagree	6	7	
The conditions of my life are perfect	I definitely agree	9	11	0.9889
	I agree	13	12	
	I rather agree	13	15	
	I neither agree nor I disagree	11	11	
	I rather disagree	7	5	
	I disagree	5	5	
	I definitely disagree	2	1	
I am happy with my life	I definitely agree	8	9	0.8119
	I agree	15	19	
	I rather agree	18	18	
	I neither agree nor I disagree	11	5	
	I rather disagree	2	3	
	I disagree	2	2	
	I definitely disagree	4	4	
So far, I achieve important goals that I want in my life	I definitely agree	5	9	0.8794
	I agree	13	16	
	I rather agree	16	11	
	I neither agree nor I disagree	14	13	
	I rather disagree	3	3	
	I disagree	1	1	
	I definitely disagree	8	7	
If I could live my life again, I would change almost nothing	I definitely agree	11	12	0.4445
	I agree	14	13	
	I rather agree	10	6	
	I neither agree nor I disagree	5	6	
	I rather disagree	3	9	
	I disagree	11	6	
	I definitely disagree	6	8	

Data are presented as subgroups size. Given p-values are for the Fisher's exact test.

## 5. Discussion

The main aim of this study was to assess the quality of life in patients before and after the surgery of an isolated apical defect. The results showed that after the surgery the quality of life of the patients improved significantly, as in most cases the symptoms which significantly limited the daily functioning of the affected women disappeared. Ellerkmann et al. [26], in the conducted study, observed the correlation between anterior wall prolapse and urinary incontinence as well as improved quality of life of patients after surgery. Clemons et al. [27], in their study, assessed the level of satisfaction and the changes in the degree of prolapse and the symptoms of urinary incontinence in patients with pelvic floor static disorders. All patients received a 2-month conservative treatment with the use of pessaries. After the end of the therapy, the improvement in the quality of life and the disappearance of the prolapse symptoms were observed in 92% of the patients. Also, Killinger et al. [28], on the basis of 6 questionnaires, assessed the changes in the quality of life in patients with pelvic floor muscle disorders who underwent a one-year

conservative treatment in the form of pelvic floor muscle training. The questionnaires performed indicated that in most women the symptoms subsided. Mirskaya et al. [29] conducted an online interview with patients after natural labour during which pelvic floor static disorder occurred. 33 women of childbearing age (24 - 45 years) were qualified for their study. The conclusions presented by the authors showed that, as a result of pelvic organ prolapse, the mental and physical lives of all patients qualified for the examination has worsened. Due to prolapse, the patients had to give up many daily activities, sex life, sports and even some parental responsibilities. Riss et al. [30] demonstrated that pelvic floor static disorder has a worse effect on the quality of life than stress urinary incontinence. Matanes et al. [31,32], in their studies, compared the efficacy of surgeries using mesh implants, which were performed by a surgeon or with the assistance of a robot. On the basis of several questionnaires, the change in the quality of life and sexual function of the patients in particular groups was assessed. The assessment was performed 6 weeks and 6 months after the procedure. The quality of life parameters in both groups improved at a similar level.

Rahkola-Soisalo et al. [33] also studied the role of the influence of the isolated apical defect surgery on the quality of life of the patients. 207 patients were qualified for their study, and they had an isolated apical defect procedure performed using the Vaginal Uphold™ system. 12 months after the procedure, they assessed the quality of life and sexual function of the patients using three standardised questionnaires. On the basis of the results obtained, the authors concluded that the quality of life of the patients improved significantly, while the sexual function deteriorated after the surgery.

Hüsch et al. [34] assessed the quality of life in patients after transvaginal pelvic floor static disorder surgery using mesh implants. The results obtained were compared with those of patients who did not show any symptoms of pelvic floor static disorder and who were in the same age group. A low complication rate as well as quality of life at a comparable level between patients undergoing the procedure and healthy women were found. Similar conclusions were reached by Fünfgeld C et al. [35], who assessed the efficacy of the procedure 12 and 36 months after performing the alloplastic mesh implantation. In their work, the authors focused more on functional assessment and anatomical repair of the defect. Quality of life assessment was an additional element.

Both this study and those cited above show the importance of assessing the quality of life in patients with pelvic floor static disorders. Effective surgical treatment not only eliminates the anatomical defect, but also improves the mental health of the patients. The results presented show that healthcare workers should assess and attempt to improve the quality of life of the patients. In addition to assessing the quality of life, an interesting issue may also be investigating the changes in the sex life of people undergoing POP surgery. This topic was not the subject of research in this article. Nevertheless, the authors recommend taking it in the future.

## 6. Conclusion

1. Pelvic organ prolapse significantly reduces women's quality of life.

2. Surgical treatment of an isolated apical defect using AMI BSC kit causes in most patients the regression of burdensome symptoms and improves their comfort of life.
3. The P-QOL questionnaire is a more useful tool for assessing the effect of treatment than the SWLS questionnaire and helps patients become aware of the improvement in their quality of life after the surgery.
4. Transvaginal surgery using BSC system, despite controversy associated with the number of complications and erosions, seems to be a reasonable alternative to laparoscopic surgery in a strictly selected group of patients with apical defect.

## Abbreviations

BSC	Bilater Sacrospinous Colposuspension
FDA	Food and Drug Administration
POP-Q	Pelvic Organ Prolapse Quantification System
P-QOL	Perceived Quality of Life
SWLS	Satisfaction With Life Scale
WHOQOL	World Health Organisation Quality of Life

## Declarations

### Ethics approval and consent to participate

The research was approved by the Bioethics Committee of the Medical University in Wroclaw. Before participating in the research, each participant signed a consent to participate in the project.

### Consent for publication

Not applicable.

### Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

### Competing interests

All authors declare that they have no competing interests.

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### Authors' contributions

MZ, GK, KN and WA performed the development of study design, and the original literature search, and participated in drafting the manuscript. ŁB and AM participated in the design of the study and performed the statistical analysis. MZ, GK, AM, KN, ŁB and WA participated in Data acquisition and analysis. All authors read and approved the final manuscript.

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