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FEMALE SEXUAL FUNCTION

# Female Sexual Functioning in Women With a Symptomatic Pelvic Organ Prolapse; A Multicenter Prospective Comparative Study Between Pessary and Surgery

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## ABSTRACT

**Background:** Female pelvic organ prolapse (POP) has a negative effect on female sexual functioning and with an increasing life expectancy female sexual dysfunction caused by POP will be an arising global issue.

**Aim:** Improvement in female sexual functioning, measured with the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire IUGA-Revised (PISQ-IR), 24-months after pessary or surgery, for both sexually active (SA) and sexually inactive women (NSA) presenting with POP.

**Methods:** A multicenter prospective comparative cohort study was conducted in 22 Dutch hospitals. Women referred with moderate to severe POP symptoms and POP stage $\geq 2$ were included and chose either pessary therapy or surgical intervention. The PISQ-IR was filled in at baseline and 24-months, the delta of change was calculated and compared between both groups. Multivariate linear regression was performed to adjust for potential confounding factors in the association between the summary score of the PISQ-IR and therapy.

**Outcomes:** Change in PISQ-IR between pessary and surgical intervention.

**Results:** The delta of change at 24-months was calculated for 198 women in the pessary group and 129 women in the surgery group. SA women in the surgery group reported statistically significant more improvement on the condition-specific (-0.19 95%CI -0.35; -0.03, $P = .02$), and condition-impact (-0.48 95%CI -0.69; -0.28, $P < .001$) domains as well as on the summary score (-0.15 95%CI -0.23; -0.08, $P < .001$) as compared to the pessary group. No significant differences between pessary and surgery were found on the domains for NSA women. After controlling for potential baseline confounders, surgery still had a statistically significant effect on the summary score (B = 0.08; 95%CI interval 0.007−0.15, $P = .03$). Women having surgery had 2.62 times higher odds of changing from NSA to SA than pessary therapy.

**Clinical implications:** SA women who clearly express that POP-related symptoms limit their sexual functioning should be counseled that surgery results in a more remarkable improvement.

**Strengths & Limitations:** Our strengths include the large sample size, long-term follow-up, the use of the PISQ-IR as a validated outcome tool evaluating both SA and NSA women, and this study reflects real-life clinical practice that enhances the external validity of the findings. A limitation of our study is the considerable proportion of non-responders at 24-months follow-up.

**Conclusion:** Sexual function in SA women with POP is superior in case surgery is performed as compared to pessary therapy. **van der Vaart LR, Vollebregt A, Pruijssers B, et al. Female Sexual Functioning in Women With**

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KEY WORDS: Pelvic Organ Prolapse; Sexual Dysfunction; Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire IUGA-Revised (PISQ-IR); Pessary; Prolapse Surgery; Female

## INTRODUCTION

Female pelvic organ prolapse (POP) can affect daily life by causing numerous symptoms related to the abnormal descent of the pelvic organs from their normal position.[1] Symptoms include vaginal bulging and dysfunction of micturition and defecation.[1−3] Additionally, POP has a negative effect on female sexual functioning (FSF), and with an increasing life expectancy, female sexual dysfunction caused by POP will be an arising global issue. [4] Sexual function is affected by anatomical and functional integrity of the pelvic floor, and women's social, general physical and psychological well-being.[5,6] Literature has shown that women affected by POP have a more negative body image, feel less feminine and may feel ashamed about the appearance of POP, and are bothered by the presence of POP-related symptoms during sexual activity such as urinary- and/or fecal-incontinence.[7,8]

Current treatment options for a symptomatic POP include pelvic floor physiotherapy, pessary use, and surgery. Studies on pessary therapy as a treatment for FSF in women with POP show conflicting results; some studies show a pessary to be effective, whereas another study showed no significant improvement of FSF.[9−11] Surgical intervention was associated with significant improvement in FSF in women with POP.[12−15] However, due to study heterogeneity and different outcome measures, these results should be interpreted with caution.[15]

Comparative studies between pessary and surgery as a treatment for FSF in women with POP are sparse, show conflicting outcomes, have large variations in study design, and relatively short follow-up periods ranging from 3- to 12-months. [9,10,16,17] Furthermore, the outcome tools vary between studies and usually focus on dyspareunia and anatomical outcomes, and to a lesser extent to sexual functioning as a whole.[18] Finally, when assessing outcomes of treatments, it is also essential to include sexually inactive women since POP could be the cause of sexual inactivity, and interventions may alter that. [19]

Therefore, there is a need for a large, long-term comparative study between pessary and surgery as a treatment for FSF in women with POP, using a validated and reliable outcome tool that focuses on both sexually active and sexually inactive women. In this multicenter prospective cohort study, we compared FSF 24-months after surgery or pessary in sexually active and inactive women with a symptomatic POP.

## MATERIALS AND METHODS

### Study Design and Participants

The PEOPLE project was initially designed as a randomized controlled trial (RCT), comparing (cost-) effectiveness between pessary and surgery in women with symptomatic POP. During the inclusion period, we noticed that after counseling for the RCT, many women were reluctant to participate as they wanted to make their own treatment choice. Therefore, we set up an observational cohort study alongside the RCT. At first, women were asked to participate in the RCT. After 1 week, the woman was contacted by her gynecologist. If she was willing to participate, but preferred to choose either treatment, she was included in the observational cohort, which is subject of this paper. Both for the RCT and the observational cohort, identical primary and secondary outcomes were used. The primary outcome was subjective improvement measured with the Patient Global Impression of Improvement scale. This paper focuses on a planned secondary analysis, namely the effect of pessary and surgery on FSF in women with POP. This study was approved by the Medical Ethical Committee of the UMC Utrecht (protocol nr. 14-533/M) and funded by ZonMw, a Dutch organization for innovation and research in health care. The trial was registered at the Netherlands Trial Register (NL4756).

Twenty-two Dutch hospitals participated in this study. Women who were referred to the hospital by their general practitioner with a symptomatic POP, defined as POP stage $\geq 2$ of any vaginal compartment according to the POP-Q system, accompanied by moderate to severe POP bother (prolapse domain score > 33 on the original Urinary Distress Inventory) were included.[20] Exclusion criteria were insufficient knowledge of the Dutch language, prior pessary use, prior prolapse and/or incontinence surgery, probability of future childbearing, co-morbidity causing increased surgical risk (at the surgeon's discretion), and major psychiatric illness. All patients offered written informed consent (IC).

Patient data were collected in an electronic Case Report Form (OpenClinica version 3.6). Limesurvey (version 2.6.7) was used to store the questionnaire responses digitally.

### Interventions

All participating gynecologist did perform at least 100 surgical POP procedures and fitted 100 pessaries before the start of this study. Supportive and occlusive pessaries were allowed since

both are proven to be effective.[21] All surgical procedures were as per our national guidelines. The gynecologist decided which technique was used. Cystocele- and rectocele repairs consisted of conventional anterior- or posterior colporrhaphy respectively. Uterine sparing techniques and vaginal hysterectomy were allowed for uterine descent since recent studies showed similar effectiveness on anatomical and functional outcomes.[22–25]

A 6-week and 24-months follow-up visit were planned as part of the study protocol. Women were instructed to return to the hospital in case they experienced any complaint. Preferably, women were instructed to perform self-management of cleaning their pessary, and intervals should not exceed 4-months. If this was neither possible nor preferred, women returned to the hospital or general practitioner every 4-months for pessary cleaning and vaginal inspection.

## Outcome

Our primary outcome was an improvement in FSF at 24-months follow-up, measured with the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR). The PISQ-IR is a validated, reliable, and responsive tool evaluating FSF in women with POP and validated in the Dutch language.[19,26] In addition, the PISQ-IR allows the evaluation of both sexually active (SA) and sexually inactive (NSA) women, making it unique in its design.[19,27,28] The PISQ-IR comprises of 10 domain-specific subscales, 6 for SA women, where a higher score indicates better sexual functioning, and 4 for NSA women, where a higher score indicates a greater impact of POP on sexual inactivity.[19] Additionally, a summary score for SA women could be calculated to provide an overall effect on FSF in assessing the clinical management of POP.[29] All patients were asked to complete the PISQ-IR questionnaire at baseline and 24-months follow-up.

Secondary outcomes included the difference in sexual activity based on pessary used and frequency of pessary removal, the development of de novo dyspareunia, and change in sexual status (ie, NSA to SA or vice versa). Since women could to cross over from pessary to surgery, we also evaluated the difference in scores between pessary only, surgery after pessary, and primary surgery.

## Study Size

We decided to include women in this cohort until both groups had reached the minimum number of women, calculated as the sample size for the RCT. The sample size calculation for the RCT was 198 women per group and was based on the primary outcome Patient Global Impression of Improvement scale.

## Statistical Analysis

The analysis was performed based on the initial treatment received. Our primary goal was calculating mean scores for each domain-specific subscale and summary score for SA women at baseline and 24-months follow-up for both groups separately.[30] Summary scores were calculated according to the IUGA guidelines by summing the valid responses to items in the scale and then dividing the results by the number of items with valid responses.[29] Differences (delta) between baseline and follow-up within groups were calculated, and the delta of change was compared between groups. In addition, because some women had surgery after initial pessary therapy, we also evaluated the change in PISQ-IR score at 24-months follow-up between pessary only, surgery after pessary, and primary surgery. Multivariate regression analysis was performed to adjust for potential confounding factors in the association between the summary score of the PISQ-IR and therapy. Baseline characteristics with a $P$-value $\leq$ .1 in univariate analysis and prolapse stage were included in this model. Prolapse stage was included irrespective of baseline differences since we expect this to influence FSF.

Since no cut-off value for improvement on the domain-specific subscales of the PISQ-IR is available, we decided to calculate effect sizes (ES) for the changes within groups in case there was a statistically significant difference. The ES allowed us to assess the strength of the effect which is generally considered a measure of clinical relevance.[31] In general, an ES of 0.8, 0.5, and 0.2 represents a large, medium, and small effect size, respectively.[32]

For our secondary outcome we analyzed differences between sexual activity and pessaries used. We used question 1 of the PISQ-IR, asking if the respondent was "sexually inactive" or "sexually active with/without a partner," and compared this between the pessaries used. To define de novo dyspareunia, we used question 11 of the PISQ-IR, "how often do you feel pain during intercourse?." De novo dyspareunia was consequently defined if women answered "never" or "rarely" at baseline and "sometimes," "usually" or "always" at follow-up. Change in sexual status was measured with PISQ-IR question 1 at baseline and follow-up, asking whether the respondent was "sexually inactive" or "sexually active with/ without a partner." Change in sexual status was defined if the respondent answered "sexually inactive" at baseline and "sexually active" at 24-months, or vice versa.

Descriptive statistics were used to analyze baseline data. Categorical data were presented as numbers with percentages and analyzed using a Chi-Square test. Continuous data (means with standard deviations or medians with interquartile ranges) were tested using the (un)paired-samples $t$-test or Mann-Whitney U-test depending on normality distribution. Ordinal data were presented as median with interquartile ranges and analyzed using the Mann-Whitney U-test.

IBM SPSS statistics version 27 was used, and a $P$-value $\leq$ .05 was considered statistically significant.

# RESULTS

## Study Population

Between February 2016 and December 2017, we included a total of 539 women in 22 Dutch hospitals. Three hundred

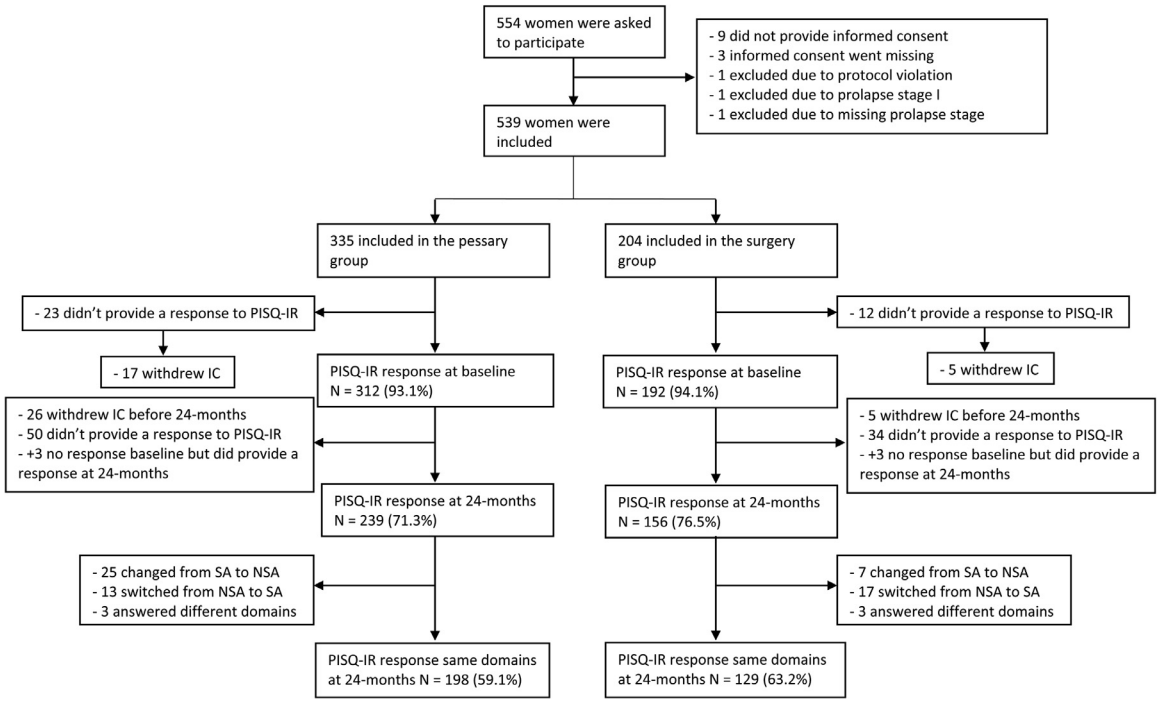


**Figure 1.** Flow-chart study population.

thirty-five (62.2%) women were included in the pessary arm and 204 (37.8%) in the surgery arm. Figure 1 shows the flowchart of the study. At baseline and 24-months respectively, 312 (93.1%) and 239 (71.3%) women in the pessary group and 192 (94.1%) and 156 (76.5%) women in the surgery group answered enough questions to calculate at least one PISQ-IR domain. Demographic data are shown in Table 1. Women in the surgery group were significantly younger, had a higher body mass index, had more often delivered by cesarean section, and were less often postmenopausal.

## PISQ-IR Outcomes

At baseline (Table 2), women who were SA and opted for surgery as primary treatment reported statistically significantly more impact of POP on the condition-specific and condition-impact domains and worse overall FSF (summary score) as compared to the pessary group. The NSA women in the surgery group reported statistically significantly more impact of POP on the condition-specific and condition-impact domains than the pessary group. For the partner-related domain of NSA women, women in the pessary group reported statistically significantly more impact on being sexually inactive; 53.8% reported that not having a partner contributed to being NSA as compared to 35.5% in the surgery group ($P$ = .02).

At 24-months (Table 3), SA women in the surgery group reported statistically significant improvement on the following domains: condition-specific, condition-impact, and overall FSF (summary score), with respectively a small (0.41), high (0.84), and moderate (0.63) ES. A deterioration was found in the global-quality rating domain for SA women with a small ES of 0.21. NSA women in the surgery group reported a statistically significant improvement on the condition-specific domain with a moderate ES of 0.49. For SA women in the pessary group, statistically significant improvement was found on the condition-impact domain, but a statistically significant deterioration was reported on the global-quality rating domain, with small ES of 0.32 and 0.23, respectively. In NSA women in the pessary group, a statistically significant deterioration was found on the global-quality rating domain with a small ES of 0.29.

We also compared the 24-months change in FSF between both groups (Table 3). Sexually active women in the surgery group reported statistically significant more improvement on the condition-specific (-0.19 95%CI -0.35; -0.03, $P$ = .02), and condition-impact (-0.48 95%CI -0.69; -0.28, $P$ < .001) domains as well as on the summary score (-0.15 95%CI -0.23; -0.08, $P$ < .001) as compared to women in the pessary group. No significant differences between pessary and surgery were found on the domains for NSA women.

The multivariate linear regression analysis demonstrated that surgery still had a statistically significant positive effect on the summary score (B = 0.08; 95%CI interval 0.007−0.15, $P$ = .03).

When comparing women who retained a pessary vs switchers to surgery vs primary surgery, no additional benefit of having surgery after pessary therapy was found on any PISQ-IR domain (Supplementary appendix 1), in fact, primary surgery

**Table 1.** Baseline characteristics

| Baseline characteristic | | Pessary group *N = 335* | Surgery group *N = 204* | *P* value |
|---|---|---|---|---|
| Age | | 62.8 (±9.6) | 59.3 (±9.6) | **<.001** |
| BMI (kg/m$^2$) | | 24.5 (22.9 – 26.6) | 25.4 (23.3 – 28.6) | **.001** |
| Smoking | | 45 (13.5%) | 30 (14.9%) | .67 |
| History of gynecological surgery | | 55 (16.5%) | 42 (20.6%) | .23 |
| Diabetes | | 14 (4.2%) | 12 (5.9%) | .38 |
| Chronic pulmonary disease | | 16 (4.8%) | 12 (5.9%) | .58 |
| Family history of prolapse | | 145 (43.4%) | 105 (51.7%) | .06 |
| Anti-depressants | | 16 (4.8%) | 11 (5.4%) | .76 |
| Parity | | 2.0 (2 – 3) | 2.0 (2 – 3) | .76 |
| Mode of delivery | | | | |
| Caesarean section | | 7 (2.1%) | 12 (5.9%) | **.02** |
| Vacuum assisted delivery | | 29 (9.9%) | 12 (6.9%) | .27 |
| Forceps delivery | | 11 (3.8%) | 13 (7.6%) | .08 |
| 3rd/4th degree perineal tear | | 24 (8.9%) | 15 (9.2%) | .90 |
| Topical estrogens | | | | |
| Starting | | 55 (16.6%) | 19 (9.4%) | **.02** |
| Continuation | | 21 (6.3%) | 15 (7.4%) | .63 |
| Menopausal state | | | | |
| Premenopausal | | 40 (12.5%) | 41 (21.8%) | **.005** |
| Postmenopausal | | 281 (87.5%) | 147 (78.2%) | |
| Duration of complaints in months | | 11 (3 – 24) | 12 (3 – 36) | .37 |
| Vaginal atrophy | | 100 (33.8%) | 53 (30.5%) | .46 |
| Prolapse stage | Stage | | | |
| | II | 141 (42.1%) | 89 (43.6%) | .73 |
| | ≥III | 194 (57.9%) | 115 (56.4%) | |
| Sexually active | | 203 (64.2%) | 127 (65.8%) | .72 |
| Type of pessary | | | n/a | |
| Ring | | 170 (50.6%) | | |
| Ring with support | | 155 (46.3%) | | |
| Cube | | 8 (2.4%) | | |
| Gellhorn | | 2 (0.6%) | | |
| Type of surgery* | | n/a | | |
| Anterior compartment | | | 21 (10.3%) | |
| Posterior compartment | | | 26 (12.7%) | |
| Apical compartment | | | 28 (13.7%) | |
| Anterior + posterior compartment | | | 11 (5.4%) | |
| Anterior + posterior + apical compartment | | | 32 (15.7%) | |
| Anterior + apical compartment | | | 78 (38.2%) | |
| Posterior + apical compartment | | | 8 (3.9%) | |

*P* values in bold are significant. Outcomes are based on available data (81–100%).
*Anterior compartment includes anterior colporrhaphy, posterior compartment includes posterior colporrhaphy, apical compartment includes sacrospinous hysteropexy, Modified Manchester-Fothergill, vaginal hysterectomy and laparoscopic sacrocolpopexy.

significantly improved the condition-impact as compared to surgery after pessary failure.

## Pessary Use at 24-Months

Details on pessaries used at 24-months can be found in Table 4. No statistically significant differences were found in sexual activity between pessaries used ($P$ = .25). Regarding pessary management, most patients (>60% in each pessary group) performed self-management at 24-months follow-up.

## Change in Sexual Status and De Novo Dyspareunia

At 24-months follow-up, women in the surgery group had 2.62 times higher odds (95% CI 1.1–6.0, $P$ = .02) of changing

**Table 2.** PISQ-IR at baseline for both groups

| | Pessary* Score ± SD | Surgery* Score ± SD | *P*-value |
|---|---|---|---|
| PISQ-IR domains for sexually active women† | | | |
| Global quality rating§ | 2.59 ± 0.68 | 2.62 ± 0.64 | .77 |
| Condition specific§ | 4.55 ± 0.59 | 4.36 ± 0.70 | **.01** |
| Condition impact¶ | 3.43 ± 0.71 | 3.06 ± 0.78 | **<.001** |
| Partner-related¶ | 3.46 ± 0.63 | 3.49 ± 0.49 | .59 |
| Arousal/ orgasm§ | 3.55 ± 0.69 | 3.47 ± 0.69 | .27 |
| Desire§ | 2.82 ± 0.62 | 2.84 ± 0.69 | .77 |
| Summary score | 3.37 ± 0.28 | 3.27 ± 0.30 | **.002** |
| PISQ-IR domains for sexually inactive women‡ | | | |
| Global quality rating§ | 2.29 ± 0.59 | 2.37 ± 0.51 | .42 |
| Condition specific¶ | 1.59 ± 0.77 | 2.11 ± 0.88 | **<.001** |
| Condition impact¶ | 1.47 ± 0.75 | 1.95 ± 0.97 | **<.001** |
| Partner-related¶ | 2.77 ± 1.02 | 2.37 ± 1.04 | **.02** |

*P* values in bold are significant.
*Baseline scores could be calculated for 312 women in the pessary group and 192 women in the surgery group.
†A high score indicates less impact of POP on sexual activities and better sexual function.

from NSA to SA and women in the pessary group had 2.61 times higher odds (95% CI 1.1−6.3, $P = .03$) in changing from SA to NSA (Table 5). De novo dyspareunia could be evaluated for 115 women in the pessary group and 94 in the surgery group: respectively 13 (11.3%), and 13 (13.8%) women developed de novo dyspareunia ($P = .49$).

## DISCUSSION

### Main Outcome

This study showed that surgery, compared to pessary therapy, resulted in statistically significantly greater improvement on the condition-impact and condition-specific domains of the PISQ-IR at 24-months for sexually active women. Additionally, the odds of becoming sexually active are 2.62 times higher after surgery than pessary therapy. For sexually inactive women, no differences were found between pessary therapy and surgery. The benefits of surgery for sexually active women persisted after controlling for potential baseline confounders.

### Interpretation

Women opting for surgery report a higher impact of POP on FSF in SA and NSA women compared to women choosing pessary therapy. Since women who opted for surgery were significantly younger, with no difference in prolapse stage as compared to the pessary group, their expectations about the effect of therapy on urogenital and sexual functioning can differ. Kapoor et al. reported that women choosing surgery perceived prolapse interfering with sexual satisfaction as a severe problem.[33] Thus, the physician needs to ask whether a patient is sexually active or inactive and also discuss how important it is for her to improve her sexual life.

### Surgical Intervention

At 24-months postoperatively, the summary score of the PISQ-IR significantly improved in the surgery group with an ES of moderate clinical importance (0.63). When looking at the subdomains that provide the summary score, improvements on

**Table 3.** PISQ-IR within- and between groups at baseline and 24-months follow-up

| | Pessary* | | | Surgery* | | | Mean difference in † between groups (95% CI) | *P*-value |
|---|---|---|---|---|---|---|---|---|
| | †change | *P*-value | ES‡ | †change | *P*-value | ES‡ | | |
| PISQ-IR domains for sexually active women¶ | | | | | | | | |
| Global quality rating | -0.14 ± 0.59 | **.009** | 0.23 | -0.14 ± 0.66 | **0.04** | 0.21 | 0.004 (-0.16; 0.17) | .96 |
| Condition specific | 0.07 ± 0.58 | .19 | | 0.26 ± 0.62 | **<0.001** | 0.41 | -0.19 (-0.35; -0.03) | **.02** |
| Condition impact | 0.22 ± 0.68 | **<.001** | 0.32 | 0.70 ± 0.83 | **<0.001** | 0.84 | -0.48 (-0.69; -0.28) | **<.001** |
| Partner-related | -0.06 ± 0.51 | .23 | | -0.02 ± 0.53 | 0.67 | | -0.04 (-0.18; 0.11) | .64 |
| Arousal/ orgasm | 0.02 ± 0.61 | .67 | | 0.11 ± 0.61 | 0.07 | | -0.09 (-0.25; 0.07) | .26 |
| Desire | -0.04 ± 0.53 | .39 | | 0.05 ± 0.59 | 0.45 | | -0.09 (-0.23; 0.06) | .25 |
| Summary score | 0.03 ± 0.29 | .33 | | 0.18 ± 0.29 | **<0.001** | 0.63 | -0.15 (-0.23; -0.08) | **<.001** |
| PISQ-IR domains for sexually inactive women** | | | | | | | | |
| Global quality rating | 0.19 ± 0.68 | **.03** | 0.29 | 0.13 ± 0.56 | 0.23 | | 0.07 (-0.22; 0.35) | .65 |
| Condition specific | -0.02 ± 0.95 | .85 | | -0.42 ± 0.86 | **0.02** | 0.49 | 0.40 (-0.03; 0.83) | .07 |
| Condition impact | 0.03 ± 0.77 | .76 | | -0.20 ± 0.58 | 0.09 | | 0.23 (-0.10; 0.57) | .17 |
| Partner-related | -0.12 ± 0.85 | .27 | | 0.14 ± 0.78 | 0.31 | | -0.26 (-0.63; 0.09) | .15 |

*P* values in bold are significant.
*Change in scores between baseline and 24-months follow-up could be calculated for 198 women in the pessary group and 129 women in the surgery group.
†Indicates the difference in score between baseline and 24-months follow-up.
‡ES = effect sizes (Cohen's d).
¶For the SA domains, an increase in the delta of change indicates less impact on FSF and better sexual functioning.
**For the NSA domains, a decrease in the delta of change indicates less impact of POP on sexual inactivity.

**Table 4.** Pessary use at 24-months

| | Ring | Ring with support | Cube | Gellhorn | Shelf | *P*-value |
|---|---|---|---|---|---|---|
| Sexual status 24-mo* | | | | | | |
| Sexually active | 68 (66.7%) | 72 (59.0%) | 7 (50.0%) | 1 (100%) | 0 | .25 |
| Sexually inactive | 34 (33.3%) | 50 (41.0%) | 7 (50.0%) | 0 (0%) | 1 (100%) | |
| Pessary management at 24-mo† | | | | n/a | n/a | |
| No self-management | 26 (38.8%) | 31 (38.8%) | 2 (33.3%) | | | .96 |
| Self-management | 41 (61.2%) | 49 (61.2%) | 4 (66.7%) | | | |
| Daily | 8 (19.5%) | 2 (4.1%) | 3 (75%) | | | |
| Weekly | 7 (17.1%) | 10 (20.4%) | 1 (25%) | | | |
| 1x/2 wk | 2 (4.8%) | 3 (6.1%) | | | | |
| 1x/4 wk | 3 (7.3%) | 12 (24.5%) | | | | |
| 1x/2 mo | 1 (2.4%) | 3 (6.1%) | | | | |
| 1x/3 mo | 3 (7.3%) | 1 (2.0%) | | | | |
| 1x/4 mo | 6 (14.6%) | 11 (22.4%) | | | | |
| 1x/6 mo | 2 (4.9%) | 1 (2.0%) | | | | |
| Unknown | 9 (22.0%) | 6 (12.2%) | | | | |

*Sexual status and pessary used could be calculated for 148 sexually active women and for 92 sexually inactive women in the pessary group.
†Data on pessary management was available of 153 women in the pessary group.

the condition-impact and condition-specific domains were responsible for improving the summary score. Thus, this implies that women in the surgery group experience a clinically relevant reduction (ES 0.84) of the impact of POP symptoms and a moderate reduction in perceived severity of symptoms (ES 0.41). For NSA women, POP-related symptoms were significantly less often the reason for sexual inactivity after surgery, and of moderate clinical importance (ES 0.49).

Other studies also found a positive effect of surgery on FSF.[13,14,34,35] One study did not detect improvement of FSF after POP surgery.[36] However, this study only had a follow-up of 6-months which might be too short to allow for complete resolution of symptoms and bother. This is supported by the high incidence of de novo dyspareunia in contrast to our study (42% vs 13.8%), possibly because of scar tissue formation and the healing process of surgery.[36] In our study, POP surgery had a slightly negative effect with a small ES (0.21) on global quality and did not affect specific aspects of FSF such as partner-related issues, arousal, and desire. Since we have shown that especially a reduction of POP symptoms, and thus less perceived impact, improves sexual functioning, the sexual response cycle is not affected. Another study that concluded that POP had no negative effect on certain aspects of FSF, such as arousal and satisfaction, supports this.[37] In conclusion, the improvement after surgery can be explained by multiple factors: improvement in body image, which is suggested by the relatively high rate of women becoming SA at 24-months (34%), and the anatomical repair leading to physical cure and lesser avoidance of sexual activity.

**Table 5.** Change in sexual status at 24-months

| | Pessary* | Surgery* | Odds ratio (95% CI, *P*) |
|---|---|---|---|
| NSA at baseline | 79 | 50 | |
| Remained NSA | 66 (83.5%) | 33 (66%) | |
| Change from NSA to SA | 13 (16.5%) | 17 (34%) | 2.62 (1.1–6.0, **.02**) |
| SA at baseline | 158 | 104 | |
| Remained SA | 133 (84.2%) | 97 (93.3%) | |
| Change from SA to NSA | 25 (15.8%) | 7 (6.7%) | 2.61 (1.1–6.3, **.03**) |

*P* values in bold are significant.
*Change in sexual status could be calculated for 237 women in the pessary group and 154 women in the surgery group.

## Pessary Therapy

In our pessary group, the impact of POP on sexual activity in SA women (ie, the condition-impact domain) improved significantly after 24-months. For example, less sexual inferiority, less avoidance of sexual activity due to POP-related symptoms, and less anger about their sexual life. However, at baseline, these women already reported minor impact of these problems on FSF, and women reporting more impact of their condition on FSF tended to opt for surgery. Additionally, with an ES of 0.32, this improvement is of relatively small clinical importance. Global quality, that is, sexual satisfaction and confidence, decreased significantly at 24-months for both SA and NSA women. One explanation is that SA women feel less satisfied with a pessary in-situ during sexual activity or feel the need to remove the pessary before or during sexual intercourse for partner considerations.[38] Unfortunately, no information on how many SA women had intercourse with the pessary in-situ was available in this study. In case the pessary is not removed before intercourse, the expectation is that intercourse may be more feasible with a supportive instead of an occlusive pessary.[39] However, Meriwether et al and Rantell et al showed that not all

women remove their pessary prior to intercourse and even advise that if the pessary fits well and causes no discomfort, it should not obstruct intercourse.[38,39] An explanation for the deterioration of global quality for NSA women could be because 16% of women who were sexually active before the start of pessary therapy switched to a sexually inactive status. This could imply that a pessary affects patients' satisfaction and frustrates women regarding their sexual life. Thus, there is a need for more studies examining whether impaired sexual functioning and the removal of a pessary prior to intercourse are reasons for the discontinuation of pessary therapy.

In contrast with our findings, one study found no changes in sexual function, except for a slight decrease in FSF related to the sexual partner.[38] However, this study only had a follow-up of 3-months. On the other hand, Kuhn et al and Fernando et al found a significant improvement in FSF and reported an increase in the frequency of sexual activity.[11,40] However, they used the Female Sexual Function Index (FSFI) and Sheffield pelvic organ prolapse symptom questionnaire (SPS-Q), which are not exclusively designed to relate POP and FSF. Additionally, both studies had a short-term follow-up of less than 4-months and a small sample size of 31 and 26 women, respectively. Furthermore, Kuhn et al used a pessary combined with local hormonal therapy, which might affect the results since it can positively affect lubrication and improve the pessary's tolerance due to stimulation of the vaginal epithelium to generate a thick layer of mature superficial cells.[11,41]

### Strengths and Limitations

One of the strengths of this study is the large sample size and multicenter participation across the Netherlands. The large sample size increases the generalizability of our findings. Additionally, with this large sample size we were able to perform a multivariate linear regression analysis with this large sample size since the reliability of estimates declines when observed outcomes or predictors are spars.[42]

Another strength is using the of the PISQ-IR as a validated outcome tool evaluating both sexually- active and inactive women since a POP can result in sexual inactivity.[4,19] Current studies on pessary or surgery for FSF in women with POP use questionnaires only applicable for sexually active women, namely the Pelvic Organ Prolapse−Urinary Incontinence Sexual Function Questionnaire short version (PISQ-12), FSFI, and the International Consultation on Incontinence Questionnaire Vaginal Symptoms Module (ICIQ-VS).[9,11,16,17] Additionally, the PISQ-IR is the only condition-specific questionnaire especially developed to estimate FSF in women with POP.[43] To our knowledge, this is the first comparative study between pessary and surgery for FSF in women with POP using the PISQ-IR, with such a large sample size and a follow-up of 24-months.

Another strength is that by allocating intervention based on shared decision-making, our study reflects real-life clinical practice, enhancing the finding's external validity. However, this is inherently a limitation since an observational study design cannot prevent selection bias and confounding. In order to minimize bias, we performed a multivariate linear regression analysis to correct for potential baseline confounders.

A limitation of our study is the considerable proportion of non-responders at 24-months follow-up. The overall response at 24-months was still relatively high (73.3%). However, change in domain scores could only be calculated for 198 (59.1%) in the pessary group and 129 (63.2%) in the surgery group. Lukacz et al, who also reported at a follow-up of 24-months, were able to calculate the change in scores on the PISQ-12 for 124 (67.7%) women. However, they only evaluated women who underwent surgery and could not evaluate sexually inactive women.[13] Women switching form sexual status could be an explanation for our lower follow-up rate. At present, no calculation formula is available comparing the PISQ-IR SA and NSA results.[44]

Another limitation is that we could not examine differences between supportive and occlusive pessaries in relation to different aspects of sexual (in-)activity measured with the PISQ-IR due to the small sample size of women using an occlusive pessary in this study (3%).

## CONCLUSION

Sexual function in sexually active women with POP is superior if surgery is performed compared to pessary therapy. The improvement mainly depends on the decreased impact of POP symptoms on sexual functioning. Sexually active women who clearly express that their sexual functioning is bothered by POP-related symptoms should be counselled that surgery results in more remarkable improvement. For sexually inactive women, a superior treatment could not be demonstrated. However, although the differences in PISQ-IR scores between pessary and surgery for NSA women were not statistically significantly different, significantly more NSA women in the surgery group changed their sexual status to sexually active compared to pessary therapy. This information, including balancing the benefits and risks of pessary and surgery, must be discussed with the patient to make a balanced decision.

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## STATEMENT OF AUTHORSHIP

LV was the main author of this manuscript. Conceptualization; AV, ALM, ALJ, JPR and CHV. Methodology; LV, AV and CHV. Formal analysis; LV, AV and BP. AV, ALM, JPR and CHV included patients. Writing, review- editing: all authors. Supervision: AV and JPR. Project administration: LV and AV. Funding acquisition: AV and CHV.

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## SUPPLEMENTARY MATERIALS

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