

# Femicushion™: a new pessary generation - pilot study for safety and efficacy

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**Abstract: Introduction and Objective:** Pelvic Organ Prolapse (POP) is a condition related to loss of anatomical support of pelvic organs. A non-invasive treatment option is a pessary, intravaginal device that provides anatomical support. Femicushion™ is a device that works as an external pessary and was developed for easier placement and reduction of complications that might happen from pessary use. Our aim is to assess the efficacy of Femicushion™ in the vaginal symptoms caused by prolapse and their impact in Quality of Life. Patients and method: We evaluated five women with symptomatic POP. The ICIQ-VS questionnaire was chosen for assessment of symptoms and Quality of Life impact caused by the prolapse. Patients were assessed at baseline and received the device and required use orientations. Femicushion™ was used for three months and patients were re-assessed after this period. **Results:** We observed a decrease in the ICIQ-VS score with the use of Femicushion™. The greatest differences were observed in question 1 (pain in lower abdomen), question 5 (lump or bulge presence) and question 6 (visual lump or bulge outside the vagina). After a period of three months of Femicushion use, we observed improvement in the vaginal symptoms and in the impact they cause in the Quality of Life of the patients. **Conclusion:** Femicushion™ was effective in the reduction of symptoms and impact in Quality of Life caused by pelvic organ prolapse.

**Key words:** Pessary; Femicushion™; Prolapse.

## INTRODUCTION

The aging process results from successive damage to the molecular structures of the body along time. An individual's aging speed is a direct result from molecular damage, maintenance and repair and is influenced by genetics, environmental factors and comorbidities.<sup>1</sup>

The increase of female longevity, observed as a trend lately, has led to an increase in pelvic organ conditions, affecting quality of life, family bonds, sexuality and self-esteem.<sup>2</sup>

It is estimated that a 79-year-old woman has a chance of 11 to 12% of undergoing surgery for prolapse correction or urinary incontinence, and the reoperation ratio is 29.2%.<sup>3</sup>

Prolapses are classified in anterior, posterior or apical and they are graded from I to IV. Usually symptomatic prolapses are the ones that reach (or go beyond) the hymen (Grade  $\geq$  II), observed during Valsalva Maneuver.<sup>4</sup>

Pessaries are indicated by over 85% of gynecologists and almost 98% of urologists. These devices provide anatomical support and may be used as a temporary treatment or provide a solution for women who do not have indication for surgery, as a conservative treatment option.<sup>5</sup>

In this project we assessed the efficacy of a novel external pessary (Femicushion™) in the vaginal symptoms caused by prolapse and their impact in Quality of Life.

## PATIENTS AND METHOD

We conducted a prospective trial to assess efficacy of a novel external pessary for conservative treatment of Pelvic Organs Prolapse. Following IRB approval and obtainment of informed consent, women were screened before enrollment. Inclusion criteria were: Women with POP grade II or above and presence of at least one of the following symptoms: pain or pressure in lower abdomen, vaginal soreness caused by POP, reduced sensation in or around vagina or feeling of loose vagina. Exclusion criteria were POP < II, vaginitis, tissue buildup and presence of lesions with suspected malignancy.

Vaginal symptoms and Quality of Life were assessed through validated Portuguese version of International

Consultation on Incontinence Questionnaire - Vaginal Symptoms (ICIQ-VS).<sup>6</sup> Questionnaires were filled during baseline assessment and three months after daily Femicushion™ use. This tool evaluates the vaginal symptoms caused by prolapse and its score is directly proportional to the symptom presence. It also measures Quality of Life impact in a scale of 0 to 10 (0 being not bothersome at all and 10 being extremely bothersome).

The ICIQ-VS consists of 14 questions, but only questions 1 to 8 were used in this study, since they are the ones related to vaginal symptoms. Questions regarding sexual activity were not completed since all participants reported not being active, due to advanced age or widowhood.

Femicushion™ is made of silicone and comes in three different sizes, to be chosen according to the size of the introitus (Figure 1 A). Upon size definition, the prolapse reduction is performed, inserting it into the vagina and placing Femicushion™ in the correct position (Figure 1 B).

The device is kept in place by a specific pad with Velcro that is attached to the adjustable underwear (Figure 2).

The correct placement of the device keeps the prolapse from descending beyond the vaginal introitus, as seen in Figure 3.

Following device placement, all participants were advised on hygiene and maintenance. They were instructed to wear the device during the day and remove it at night for cleaning. The product is made of a fast-drying material, which allows for use the following morning.

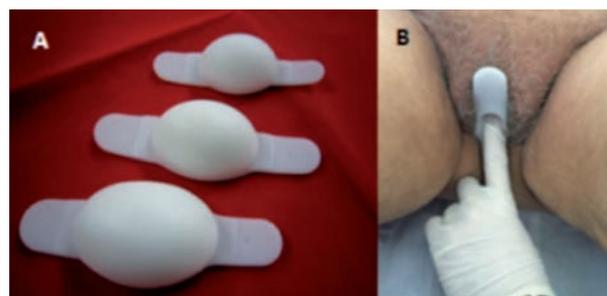


Figure 1. – A) Femicushion in 3 different sizes. B) Placement of Femicushion.



Figure 2. – Adjustable underwear.

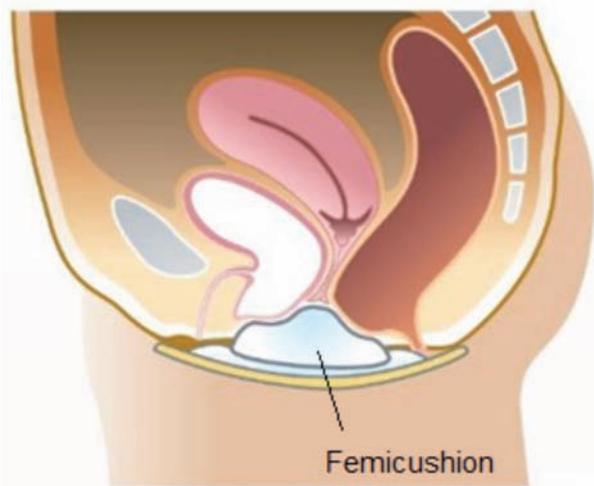


Figure 3. – Femicushion™ placement.

**RESULTS**

Five women aged 60 to 79 (average 71) were assessed. Four of them presented anterior prolapse grade IV. One woman presented associated posterior prolapse grade II and one of them presented posterior prolapse grade III.

At baseline, ICIQ-VS score varied from 10 to 44, as seen in Table 1.

The final assessment was performed after three months of daily Femicushion™ use. Participants reported improvement in vaginal symptoms, mainly regarding lower abdomen pain, descending lump and visualization of lump. ICIQ-VS score range was reduced from 10-44 to 10-22, as seen in Table 2.

All patients but one achieved a reduction in the total score, as seen in Figure 4. These results show great improvement in symptoms after Femicushion™ use.

The impact of symptoms in Quality of Life was reduced after three months of use, as seen in Figure 5. In two of the

TABLE 1. Baseline assessment: ICIQ-VS Score.

ICIQ-VS Question	Participants/Score				
	1	2	3	4	5
Q1. dragging pain in lower abdomen	2	4	6	0	0
Q2. soreness in vagina	0	2	0	2	2
Q3. reduced sensation or feeling in or around vagina	0	2	0	0	0
Q4. vagina too loose or lax	6	0	6	6	0
Q5. lump or bulge coming down	8	8	8	8	4
Q6. visualize lump or bulge coming out	8	4	8	4	4
Q7. vagina too dry	8	0	8	4	0
Q8. difficulty emptying bowels	0	0	8	0	0
Score	32	20	44	24	10

TABLE 2. Final assessment: ICIQ-VS Score.

ICIQ-VS Question	Participants/Score				
	1	2	3	4	5
Q1. dragging pain in lower abdomen	0	2	4	0	0
Q2. soreness in vagina	0	0	0	0	2
Q3. reduced sensation or feeling in or around vagina	0	2	0	0	0
Q4. vagina too loose or lax	6	0	6	6	0
Q5. lump or bulge coming down	4	4	2	2	8
Q6. visualize lump or bulge coming out	4	4	2	2	4
Q7. vagina too dry	8	0	0	0	0
Q8. difficulty emptying bowels	0	0	4	0	0
Score	22	12	18	10	14

patients, the impact degree was 9-10 and at baseline and at the final assessment it was reduced to 0.

Besides the symptoms assessed in ICIQ-VS, we observed that one participant who presented infravesical obstruction caused by the prolapse at baseline was able to pass urine normally at final assessment.

**DISCUSSION**

Pelvic Organ Prolapse is perceived as a very sensitive descending lump in the vagina. It worsens by the end of the day and improves when the woman lies down. Some patients refer pelvic or lower abdomen pain. Dyspareunia, vaginal bleeding and urinary symptoms such as infravesical obstruction or urinary incontinence have also been reported. Some patients also report difficulty emptying their bowels.<sup>2</sup>

Within three months of Femicushion™ use, a decrease in vaginal symptoms caused by POP was observed. The symptoms that presented the largest change in score were lower abdomen pain, feeling of descending lump in the vagina and visualization of descending lump outside the vagina.

In the present study mean age of participants was 71. In a retrospective epidemiologic study, Olsen *et. al.* have found a strong relation between POP and age, showing that 11% of females will be submitted to at least one surgical procedure for correction of pelvic floor defect. Relapse and need for reintervention reach 29.2% of these women and the period of time between interventions tends to be smaller as time goes by.<sup>7</sup>

Kapoor *et. al.* observed that when offered a pessary for initial treatment of POP, almost 2/3 of women have accepted it.<sup>8</sup>

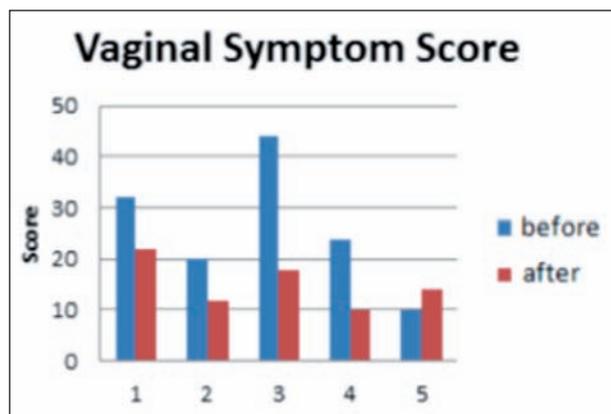


Figure 4. – ICIQ-VS score before and after Femicushion™ use, per patient.

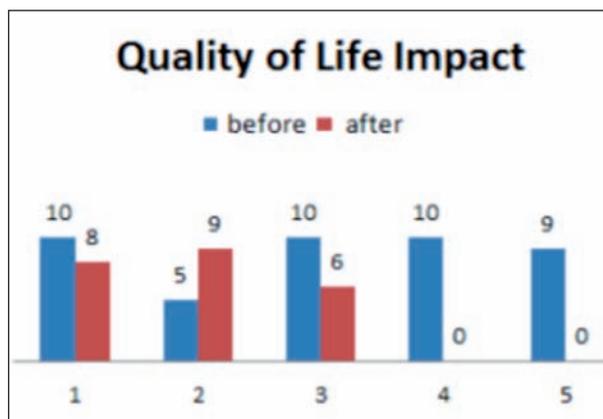


Figure 5. – Impact of vaginal symptoms in Quality of Life before and after Femicushion™ use, per patient.

In a systematic review from 2015, different complications due to the use of vaginal pessaries were observed: Vaginal discharge, bleeding and odor were the most frequent ones; however, rare cases of serious complications were observed, such as vesicovaginal or rectovaginal fistulae, difficulty emptying bowels, hydronephrosis and even death. It is estimated that 91% of the cases of serious complications are due to pessary negligence, and patients with dementia are at a higher risk.<sup>9</sup>

The use of Femicushion™ presents lower risk of complications when compared to pessaries, due to the fact that it is not placed inside the vagina and it is removed daily for hygiene, reducing the risk of infections and negligence. In the present study no complications were reported.

Studies with Pessaries have showed decrease in vaginal symptoms and improvement in Quality of Life.<sup>10,11</sup> Similar results were observed with Femicushion™.

Femicushion™ was developed aiming for better Quality of Life and decrease in vaginal symptoms in women with POP grades II or higher. These results are achieved by the use of the device, which keeps the prolapse inside the vagina, above the vaginal introitus. It is indicated for patients without surgical indication or for those who are waiting for the surgery. We have presented our preliminary results, and a longer follow-up time is needed, as well as a larger number of patients. In some cases, a decrease in prolapse degree was also observed, and more studies should be performed in order to investigate how this decrease happened. One of the hypotheses is the reflex contraction caused by the use of Femicushion™ and the absence of prolapse distension outside the vaginal introitus during daily activities.

## CONCLUSION

Femicushion™ has proven to be effective in the decrease of vaginal symptoms caused by Pelvic Organ prolapse. It has consequently reduced the impact of these symptoms in the Quality of Life of these women.

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### Multidisciplinary Uro-Gyne-Procto Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in Pelviperiology are commented on by **Urologists, Gynecologists, Proctologists/Colo Rectal Surgeons or other Specialists**, with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

**Rehabilitation...** Traditionally, vaginal pessaries are worn to contain prolapse of the organs in women who are too ill or who do not desire surgical repair. Pessaries are not used to control symptoms of bladder dysfunction and pain.

The Femicushion™ is an interesting evolution of this conservative treatment method. This pessary could be considered as a direct application of the Integral Theory which states that bladder, bowel and pain symptoms are mainly caused by laxity in the vagina or its supporting ligaments. The shape supports the bladder base and the apex of the vagina, in particular, loose cardinal (CL) and uterosacral (USL) ligaments which of course cause uterine prolapse. The initial data for pain relief, though in only 5 patients, is quite promising. We could anticipate that this pessary would substantially reduce other symptoms deriving from loose CL/USL ligaments, for example nocturia, abnormal bladder emptying, even some bowel symptoms such as obstructive defecation and fecal incontinence. However, more extensive studies will be required to establish its usefulness as regards symptom relief. I have some comments on its use in reducing pelvic organ prolapse. The traditional ring pessary works by over distending an already damaged vagina. Hence its long-term use is accompanied by vaginal ulcerations and even damage to the vagina. Larger and larger pessaries are required. The Femicushion™ avoids such problems but it requires an external support to keep it in place. We need to know how effective this would be in the longer term. In summary, this is an interesting and novel method which does not damage the vagina and uniquely addresses disturbing pelvic floor symptoms. I look forward to seeing its use in patients with minimal prolapse and major symptoms such as chronic pelvic pain, urgency, nocturia, especially in patients who do not respond to the squatting-based Integral System PFR methods (1).

#### REFERENCES

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**Urologist...** The authors report an interesting pilot study on an innovative pessary model based on an adjustable suspension system. Pessaries do not cure pelvic organ prolapse, but in selected cases they help slowing the progression of prolapse. With some risk of damaging the vaginal walls they add support to the vagina tightening tissues and pelvic muscles around it. From a urological point of view the Femicushion™ acts in comparable way to the most recent female or male slings whose action are related to the creation of a new biological system of urethral and pelvic floor suspension. In urodynamic practice the pessary is sometimes used to exclude an urethral obstruction during the analysis of voiding phase. In conclusion the use of the pessary in urological field is rare and when applied it is not free from complications. The traditional pessary should be limited to specific clinical cases in which the surgical reconstruction of pelvic floor is not possible due to the advanced age or bad general conditions of the patient. The the Femicushion may open new perspectives.

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Figure 1.

**Procto/Colorectal...** The term pelvic organ prolapse (POP) is widely used by uro-gynecologists for genital prolapse. Anal prolapse should be included in "POP" as well, being due to hemorrhoids, and mucosal or rectal descent outside the anal orifice. It affects negatively the quality of life, and patients fear the operation because of pain or considerable risk of relapse. A conservative approach would be highly appreciated when surgery is needed, but besides elastic band ligation of lower degrees (2nd, sometimes 3rd) of hemorrhoids and mucosal prolapse, nothing serious is available. An anal pessary does not exist and cerclage is the simplest procedure to avoid complete rectal prolapse. Treatment of vaginal prolapse with Femicushion is interesting because less invasive and non traumatic compared to the traditional pessaries. A similar solution has been proposed years ago in Italy for prolapsing 4th degree hemorrhoids with a so-called *Anti-hemorrhoidal Suspender* (Fig.1), a non-invasive mechanical barrier with suspenders resting on the shoulders. Its popularity has been short as it is now impossible to buy it anywhere. General surgeons have experience of patients with inguinal hernia using elastic pant with ball bearing top, instead of the trusses.

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# Preliminary program

## Wednesday 21 September

### 08:00-12:00 Workshops

08:00-09:00 Workshop registration

- 1 The Integral System - *Peter Petros*
- 2 Pelvic floor Ultrasound - *TBD*
- 3 Chronic Urogenital Pain (CUP), Diagnosis and treatment - *Marek Jantos*
- 4 Urology for urogynecologists
  - Fistula repair - *Dimitri Pushkar*
  - Male SUI - *TBD*
  - IC and Painful bladder - *TBD*
- 5 Colorectal surgery for urogynecologists - *Daren Gold*

Lunch

## ISPP Annual conference

14:00-15:00 Registration

15:00-15:15 Opening

15:15-18:00 First Plenary session - Chronic pelvic pain



## Thursday 22 September

10:30-11:00 Second plenary session - for Urology pain (OAB, IC)

11:00-13:00 Coffee break

13:00-14:00 Third plenary session - Posterior compartment

14:00-16:00 Lunch

16:00-16:30 Forth plenary session - Implants for POP and SUI repair

16:30-18:00 Coffee break

Fifth plenary session - Tips and Tricks in urogynecology

Gala dinner

## Friday 23 September

08:00-13:00 **Live surgery**

- \* Urinary incontinence - different TVT slings  
Emanuel Delorm & David Waltregny
  - \* Pelvic organ prolapse: vaginal mesh, Starr operation  
Michel Cosson & Antonio Longo
  - \* Lap Sacrocolpopexy  
Peter von Theobald & Joerg Neymeyer
  - \* Fistula repair  
Dimitri Pushkar
- Lunch

## Saturday 24 September

Jerusalem tour

