ISSN: 2573-9506

Research Article

International Journal of Women's Health Care

Successful Management of Stress Urinary Incontinence in Women by a Contraceptive Device FemCap™ Pilot Study

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Submitted: 20 Sep 2020; **Accepted**: 06 Oct 2020; **Published**: 11 Oct 2020

Abstract

Background: *Women suffer silently from stress urinary incontinence (SUI). SUI is under-reported by women and under-diagnosed and treated by doctors. Treatment with pessaries is conservative and has significant limitations. These limitations include displacement, erosion, ulceration, and urethral obstruction. (SUI) is very prevalent among women of all ages, particularly menopausal women. The first line of SUI treatment is the ring pessary; however, more pessaries of different shapes and sizes have been introduced to achieve better results.*

Objectives: *To provide women with a safer, more effective device to treat SUI.*

Materials and Methods: *The FemCap combines the ring and space-occupying pessary features into one device, making it much more successful. The bowl of the dome of the FemCap covers the cervix and prevents it from prolapsing. The rim fits snugly into the vaginal fornices that support the bladder neck. The brim flares outward, pushing against the cystocele and the urethrocele anteriorly to restore the urethra and the bladder's anatomy. Forty-one women who had had significant SUI were recruited and asked to compare their experience for one week before using the FemCap and two weeks later. The FemCap was self-inserted and removed by the participants.*

Results: *Thirty-four women out of 41 were completely dry after two weeks of using the FemCap, while four women were partially dry, and three women did not notice any change. The participants reported no side effects, and pelvic examinations did not show any erosion or ulceration of the vagina.*

Conclusion: *The FemCap is safe and effective in restoring the bladder and urethra's anatomy, which could make it ideal for the treatment and prevention of mild to moderate SUI. More studies are warranted to prove the utility of the FemCap further to manage SUI.*

Keywords: FemCap, FemContinence, Stress Urinary Incontinence

Introduction

Stress urinary incontinence (SUI) is prevalent among women of all ages, particularly menopausal women. SUI is under-reported by women as well as under-diagnosed and treated by doctors. A woman using the FemCap for contraception reported that she had suffered from stress urinary incontinence, but her SUI subsided when using the FemCap (Figure 1,2,3) [1-8]. Thankfully, she shared her experience, which led me to investigate a new usage for the FemCap as an SUI pessary called FemContinence. The first line of therapy of SUI is pelvic floor muscle Kegel exercises and vaginal pessaries. (Figure 4). The most popular is the ring pessary (Figure 5); however, a variety of shapes and sizes (Figure 6, 7) are becoming available to achieve better results [9,10].

It should be noted that pessaries are NOT a cure but are safe and effective in treating mild to moderate SUI.

Figure 1

Figure 2

Figure 3

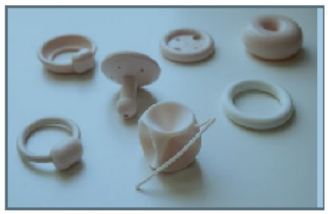

Figure 4

Figure 5

Figure 6

Figure 7

Pessaries are conservative alternatives to surgical repair, which is done with a sling for pelvic organ prolapse (POP) and SUI and (Figure 8).

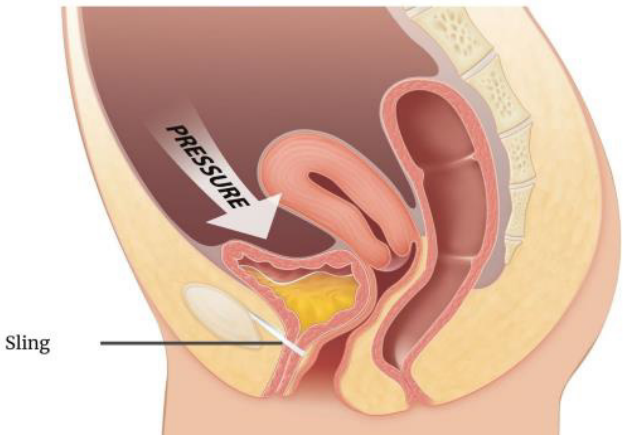

Figure 8

The surgical sling procedure's success rate is 80% at best, with a 30% risk of reoperation.

The leading causes of SUI include pregnancy, vaginal delivery, and pelvic floor muscles weaken, causing pelvic organs to prolapse. When the bladder prolapses (cystocele), it stretches, widen, and kinks the urethra, which leads to distortion of the urethral sphincters that become incompetent (Figure 9).

Therefore, anything that increases abdominal pressure, such as coughing, sneezing, bending over, lifting, or laughing, can pressure your bladder and cause urine leakage (Figure 10). Other factors that may worsen SUI include age, menopause, chronic coughing, obesity, jumping, and other factors. SUI causes emotional distress and embarrassment. It can disrupt work, social activities, relationships, and even sex life.

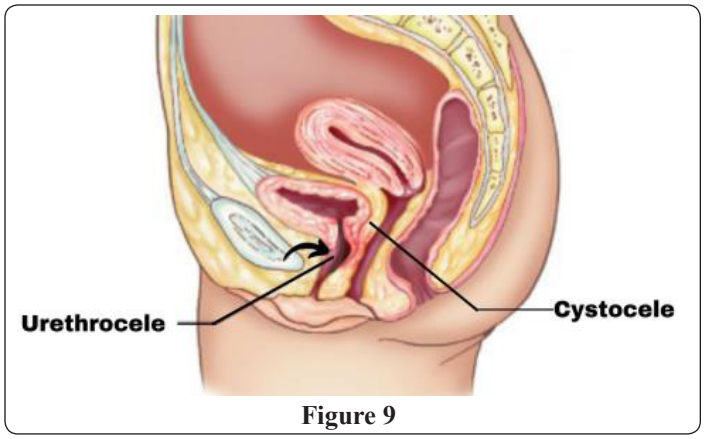

Figure 9

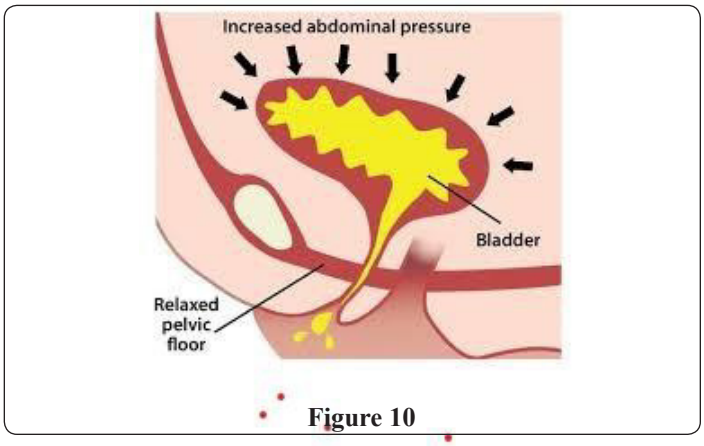

Figure 10

Materials

The FemCap combines the ring and space-occupying pessary features into one device, which makes it much more successful. Our investigation started by looking at the similarities between the FemCap and the ring pessary with support. The FemCap shows a marked resemblance to the ring pessary and the space-occupying

pessary. The Rim of the FemCap is similar in shape and function to the ring pessary that supports the bladder neck. The brim's outward flaring pushes the cystocele forward, which restores the anatomy of the bladder and urethra where they belong (Figure 11). The bowl of the FemCap supports the cervix and prevents it from descending, which provides further support (Figure 3).

The FemCap has been in use for 20 years without any significant reportable side effects.

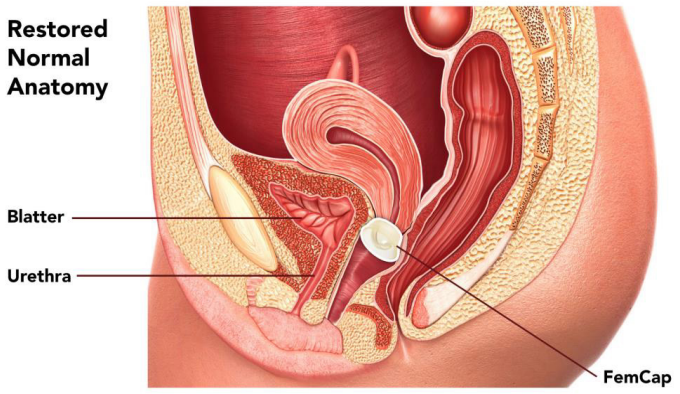

Figure 11

Methods

We recruited 41 women to be participants in a feasibility study for the management SUI. All the 41 women completed the protocol using the FemCap, to control their SUI for two weeks. We conducted an earlier pilot clinical trial to check the feasibility of the FemCap in controlling stress urinary incontinence [11].

The Protocol has the Following

Inclusion Criteria

a) women to be aged18 -75 old and
b) they must have at least two episodes of stress incontinence per day
c) they must be capable of inserting and removing the FemCap on their own, and
d) would be able to fill the Case Record Forms (CRF)

Exclusion Criteria

Women who had stage 3 or 4 prolapses, overactive bladder, overflow incontinence or pelvic infection or ulceration of the vagina

Study Procedures

Enrollment Visit

The investigator or his or her assistant explained the purpose of the study to the enrolee and how to fill the case record forms. If the enrolee is eligible for the study, the investigator performed a pelvic exam to rule out contraindications such as cancer, infection, or ulceration. If there is no reason for exclusion, the investigator showed her the FemCap and taught her how to insert and remove it. The investigator provided the CRF card and asked her to record any SUI episode and any side effects or problems.

Second or Final Visit

Interview the participant and checked the case records forms before using the FemCap (Figure 12) and after using the FemCap (Figure 13) to compare it to the previous CRF.

Risk Analysis

We did not anticipate any risk related to or from using the FemCap however; we ask all participants to report any issues they think may be related.

FemCap Stress Urinary Incontinence Study by Dr. Alfred Shihata

Questions? Call Us: (858) 922-7673

Name: Women from Sweden

Date Before using Femcap :

How many times per day you have stress incontinence, during the last week BEFORE using the FemCap you when you:

	Mon	Tues	Wed	Thurs	Fri	Sat
Cough	2	2	1	3	3	2
Sneeze	3	1	2	2	3	3
Laugh	1	2	1	1	1	1
Stand up	1	3	2	2	2	2
Get out of a car	1	2	3	3	2	3
Lift something heavy	1	2	2	2	1	2
Exercise	3	1	3	2	2	2
Do you wear a pad?	Yes	Yes	Yes	Yes	Yes	Yes

You should insert the FemCap first thing in the morning*. Don't remove it until bedtime and then wash and store it in container until you use it the next morning.

*If you are using FemCap for birth control use spermicide

*If you are using FemCap for incontinence only use with a water soluble lubricant.

Figure 12

Date After using FemCap :

How many times per day you have stress incontinence, during the second weeks while using the FemCap:

	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Cough	0	0	0	0	0	0	0
Sneeze							
Laugh							
Stand up							
Get out of a car							
Lift something heavy							
Exercise							
Do you still wear a pad?	Yes	Yes	Yes	No	No	No	No

1. Did have any side effects from the FemCap? No
2. Will you consider using the FemCap in the Future to control your (SUI)? Yes
3. Comments I didn't have leakage when jumping on the trampoline while using the FemCap, Coughing and sneezing no longer was an issue when I had a cold while using FemCap

Figure 13

Results

Thirty-four women out of 41 were completely dry after two weeks of using the FemCap, while four women were partially dry, and three women did not notice any change. The participants reported no side effects, and pelvic examinations did not show any erosion or ulceration of the vagina.

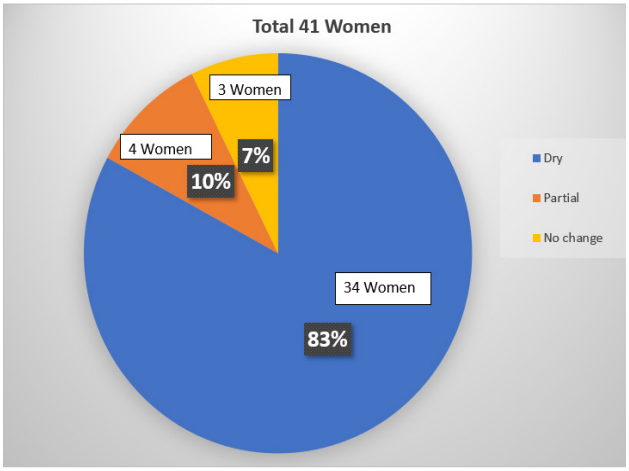

Figure 14

Conclusion

Currently, Stress urinary incontinence is an unspoken condition that women have to suffer silently with shame and embarrassment. The FemCap is safe and effective in restoring the bladder and urethra's anatomy, which could make it ideal for the treatment and prevention of mild to moderate SUI. More studies are warranted to prove the utility of the FemCap further to manage SUI [12-14].

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