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First Clinical Observations with a new intraurethral Medical Device (Obtinu®) for Treatment of Female Stress Urinary Incontinence.

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Device

- Intraurethral valve catheter
- Disposable
- Made of soft silicone
- A malecot tip for bladder neck support
- A wide distal end

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Aims of study

Evaluate:
- efficacy
- comfort
- user satisfaction
- side effects

Patients

- 48 women with SUI participated in four clinical trials
- Trial I (N=10) focused on feasibility
- Trial II (N=10) tested different sizes and shapes
- Trial III (N=19) included extended activities like cycling
- Trial IV (N=9) involved home use for a longer duration

Outcome

- Two Standardized pad tests (cough and activity)
- Discomfort on 10-point Numeric Rating Scale
- 5-point PGI-I scale (1 = very much better, 5 = much worse)
- Asked if they would like to continue with Obtinu
- Asked if they would recommend to a friend

Figur 1

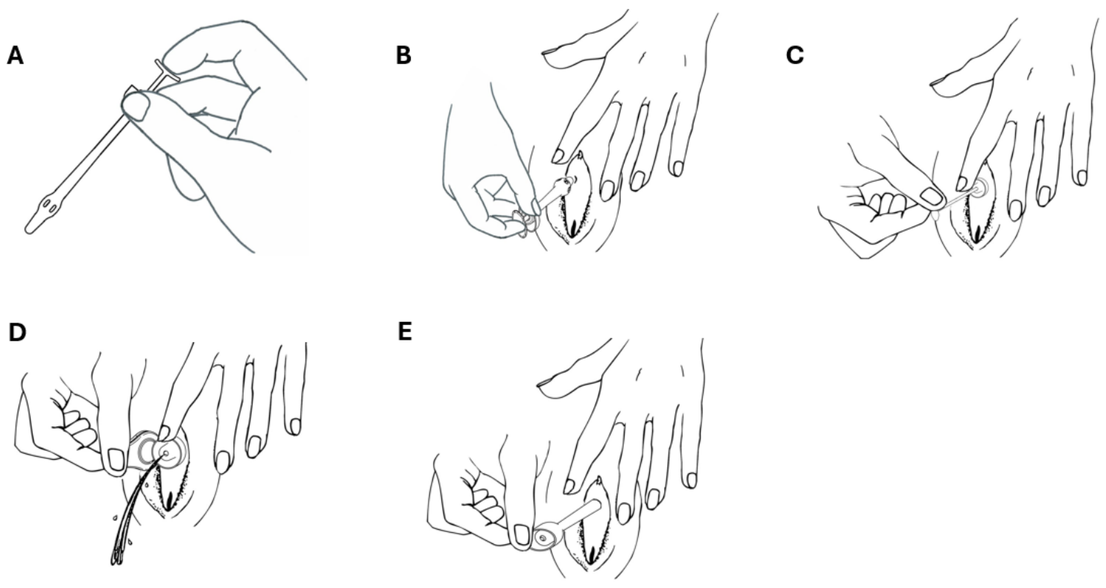


Figure 1: Placement, bladder emptying, and removal of the Obtinu catheter. To insert, the user elongates the malecot tip using an insertion pin and inserts the device into the urethra (A and B). The pin is then removed (C), allowing the malecot tip to re-form and the internal ball valve to close, preventing urine flow. For voluntary bladder emptying, the user applies a magnetic accessory near the device to open the valve (D). After emptying, removing the accessory automatically closes the valve. The device is then pulled out for removal (E).

Results

44 women completed the pad tests (Table 1).

Table 1	N	Without Obtinu	With Obtinu	P
Standardized Cough Pad test. Mean (range)	44	12.9 g (0-114)	0.6 g (0-6)	<0.001
Standardized Activity Pad test. Mean (range)	44	14.7 g (0-93)	0.4 g (0-6)	<0.001

•**Trial I (N=10):** Seven women wished to continue using Obtinu, and all 10 would recommend it.

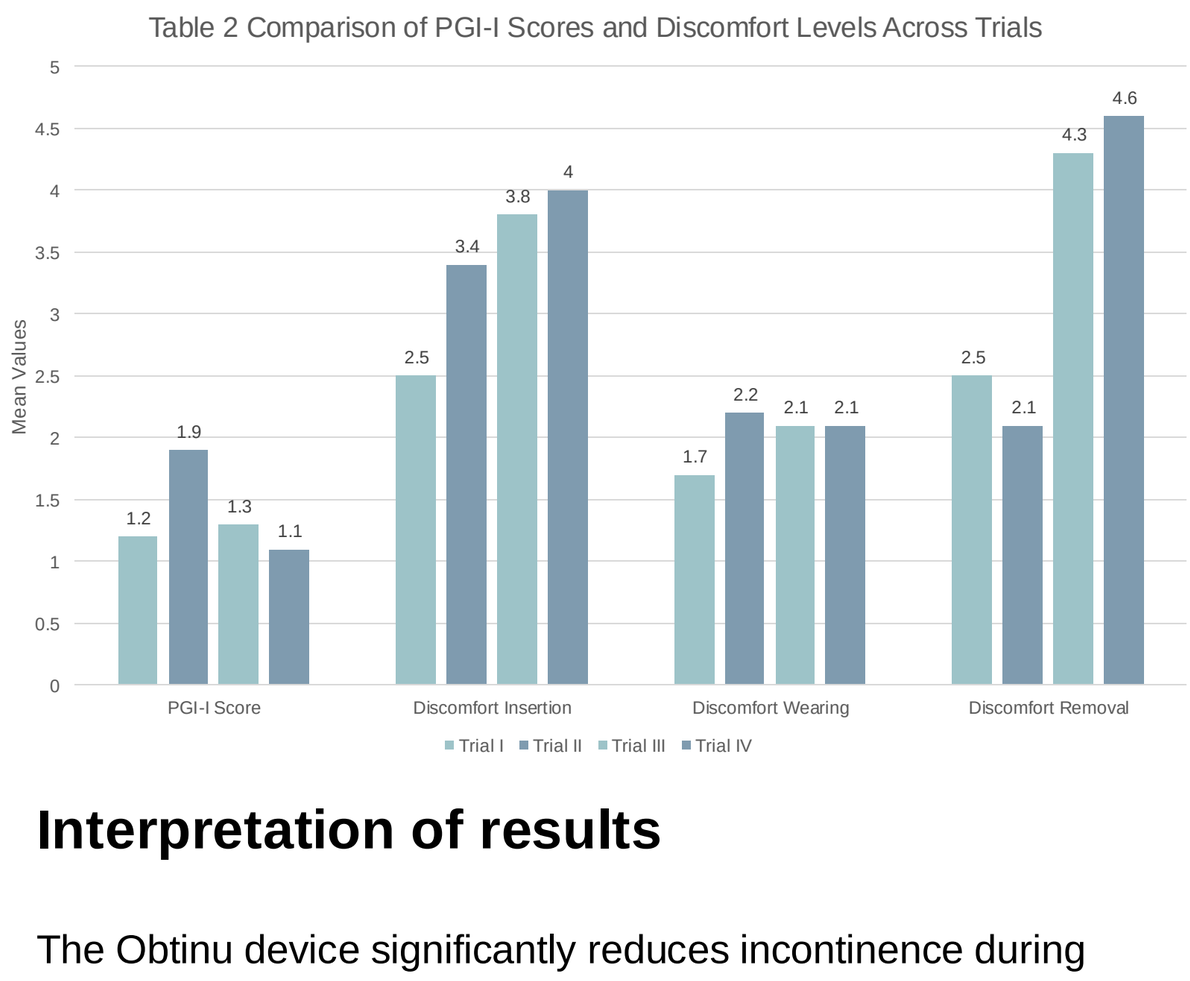
•**Trial II (N=10):** Six women wanted to continue, and 8 would recommend Obtinu.

•**Trial III (N=19):** Seventeen women wanted to continue, and 17 would recommend Obtinu.

•**Trial IV (N=9):** One woman withdrew due to pain. Two withdrew after one week. Four completed a 2-week test, and two completed a 4-week test. None wanted to continue, but 4 would recommend Obtinu.

Reported adverse events included dysuria (6), spotting (3), hematuria (4), and small tears during device removal (3). No urinary tract infections or device migration were observed.

PGI-scores are shown in table 2



Interpretation of results

The Obtinu device significantly reduces incontinence during standardized tests while allowing bladder emptying. Long-term discomfort may be attributed to the absence of a coating. A new hydrophilic coating has been added and is currently being tested in the final clinical trial (Trial 5).

Concluding message

Obtinu has demonstrated efficacy, tolerability, and safety in short-term clinical trials. However, long-term comfort was inadequate. A hydrophilic-coated version is now under evaluation in our final clinical trial (Trial 5).