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ORIGINAL ARTICLE

Update: the "Contiform" intravaginal device in four sizes for the treatment of stress incontinence

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Abstract The aim of this study was to evaluate the efficacy of the Contiform intravaginal device for stress incontinence after the addition of a fourth size. We offered the device to a cohort of 73 women with a main complaint of stress incontinence but no prolapse. Of the 73 women invited to participate, 65 enrolled, of whom 52 were fitted. Of these 52 women, 37 (71%) completed the study protocol. Outcome measures were the 24-h pad test, St George score, and quality of life tests. Urine loss on pad test was significantly reduced from a median 6.6 g (interquartile range [IQR]=4.3–22.6) to 2.2 g (IQR=0.5–8.2; P=0.0016) after 4 weeks with significant benefit seen on the Incontinence Impact Questionnaire and Urinary Distress Inventory. The insertion technique was quickly learnt, and the device was well tolerated. The recently developed medium/large size of Contiform was used by 6/37 (16%) women.

Keywords Contiform · Stress urinary incontinence · Vaginal device

Introduction

In patients with stress incontinence who do not want surgery but still leak despite pelvic floor muscle retraining, an intravaginal device may be useful. Some women are reluctant to consider surgery due to the small risks of voiding dysfunction or de novo detrusor overactivity or they may be planning to have more children by the vaginal route.

The 'Contiform' intravaginal device is shaped like a large, hollow tampon made of Santoprene, a nonallergic thermoplastic rubber [1]. The device sits behind the pubic bone and supports the urethra during episodes of increased intra-abdominal pressure. The device is not designed to elevate prolapse (i.e., patients with prolapse usually cannot retain a tampon). Its tampon-like shape was partly designed to facilitate self-insertion/removal by patients (Fig. 1). Initially, the device could be purchased by patients directly from proprietary chemists in England and Australia, although presently, it is fitted by continence advisors or physiotherapists with appropriate patient supervision.

The clinical efficacy of Contiform was first reported in 2003 [1] when the device was only available in three sizes (small, medium, and large). In that study, significant benefit was achieved overall but only 20% were completely dry on the 24-h pad test. Subsequently, these authors requested that the manufacturer generate a fourth size ("medium/large") to fill the gap in the range of sizes identified by their previous study. The aim of our present study was to reevaluate Contiform efficacy once the four sizes had become available.

Materials and methods

Subject selection

Patients who presented to a tertiary urogynecology unit with the main complaint of stress incontinence were invited to consider the Contiform device. Other entry criteria included sufficient manual dexterity to insert and remove

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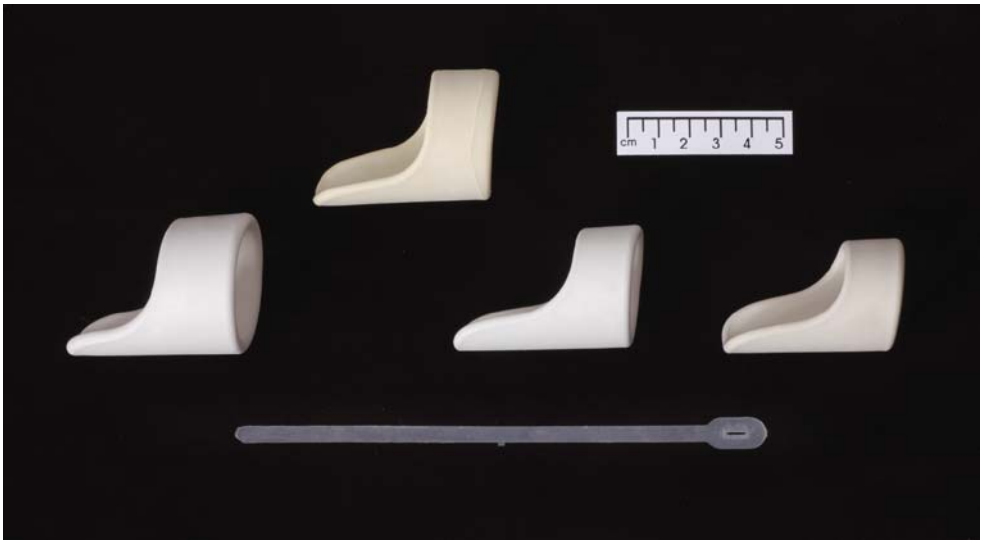


Fig. 1 The Contiform device: large (length of the total shaft, 55 mm×width of the upper surface of the ring, 25 mm× diameter of the ring, 43 mm), medium/large (55×20×39 mm), medium (55×18×37 mm), and small (52×18×35 mm) sizes used in this study with plastic removal strap

the device and ability to speak English and understand written informed consent as per local ethical committee approval. Urodynamic testing was not required as this device was originally designed to be used in the community. Exclusion criteria were: prolapse beyond the introitus, a main complaint of urge leak, bacterial cystitis (symptomatic or proven UTI) at the time of insertion, recent pelvic surgery within the last 3 months, previous pelvic radiotherapy, or pregnancy. Any demonstrable constipation on history or examination was treated before fitting the device.

Patients were asked to use the device for 4 weeks and to become comfortable with self-insertion and self-removal. All postmenopausal women were given topical vaginal estrogen therapy before or on the day of fitting. Throughout the study period, no changes or additions were made to current medications or other treatment.

Patients were offered the Contiform device and invited to join the study as one treatment option for their stress leak. Other options included physiotherapy or surgery. It was made clear to the patients that if they were not happy with the Contiform treatment, they could withdraw from the study at any stage. We did not attempt to persuade patients to continue with Conform to the end of the study if they preferred to pursue other treatments. No remuneration for time or transport expenses was provided.

Fitting of the device

After initial explanation, the same nurse continence advisor (NCA) examined and fitted all patients with a Contiform device. Once fitted, the patient was asked to cough in the supine position and then jump while standing to ensure the device did not move. Self-removal and self-insertion training was given. The NCA confirmed that the patient had correctly positioned the device on vaginal examination. If the device was not correctly placed, the NCA gave further instructions and the patient tried again. This was repeated two to three times until the patient was comfortable with both self-insertion and self-removal of the device. Some patients needed to use a plastic strap to assist in the removal of the device (similar to a tampon string; Fig. 1). Patients who were unable to insert or remove the device were withdrawn from the study at this stage (Fig. 2).

We asked the patients to inspect the device before each insertion to check for any fracture lines and to use a new device if a defect was found. Participants were advised to insert/remove the device on a daily basis and before sexual intercourse. We asked the patients to wash the device in hot soapy water after each removal, as per manufacturers' instructions. Patients were instructed to contact the NCA if they had any difficulties with the device. An instructional video about the Contiform device was given.

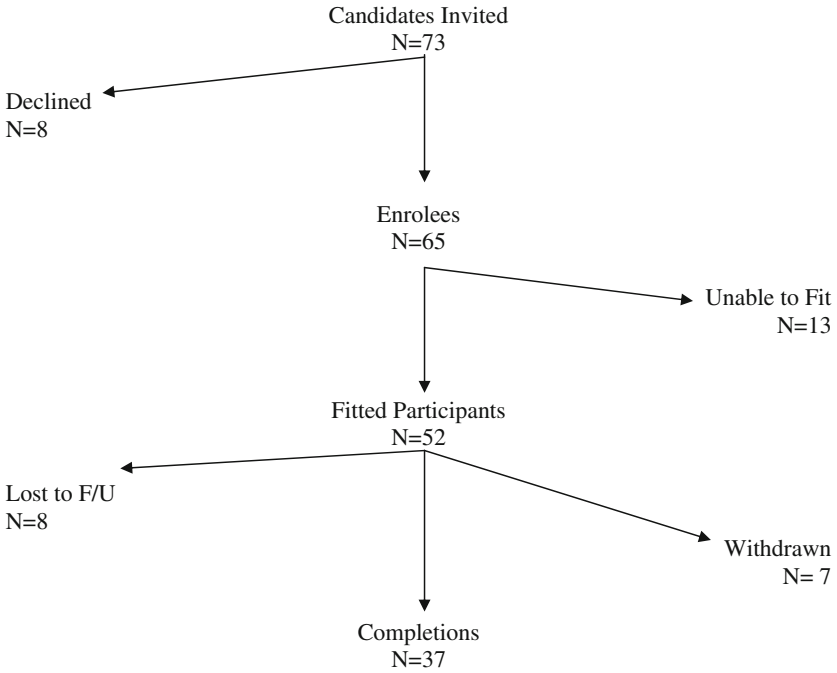
Assessment of efficacy

The main outcome measure was the 24-h pad test, which the patients performed at baseline and 4 weeks [2]. An electronic balance accurate to 0.1 g was employed to weigh all pads with "dry" equal to <2 g [2]. Patients were instructed to undertake the same activity at each of these pad tests that would normally cause them to have a stress leak, e.g., running, playing tennis, etc. The short forms of the Urinary Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ), and the St George score (20-point index scale of incontinence) [3] were also completed.

Assessment of adverse events

Once fitting was completed and the patient successfully inserted and removed the device, ultrasound of post void

Fig. 2 Trial overview



residual volume (PVR) was done to ensure that the device was not associated with voiding difficulty. Pre and post device PVR was not compared in this study as it was not clinically significant in our previous study [1]. As mentioned, the patient regularly inspected their device for fracture lines; any queries were immediately shown to the NCA. At the 4-week review, the NCA asked the patients whether they noted any feeling of incomplete emptying, pain/discomfort, urgency, bowel symptoms, or hemoserous staining/discharge.

Statistical analysis

All data are described as the median value plus the interquartile range (IQR), as the data were not normally distributed. The Mann–Whitney *U* test was used for paired data. All definitions conform to those of the Standardization Committee of the International Continence Society [4], unless otherwise specified.

Results

Over the 7 months of recruitment, 73 women with a main complaint of stress incontinence who satisfied the inclusion/exclusion criteria were offered the Contiform device (see Table 1 for the demographic data; all were sexually active to a varying degree, in keeping with their median age). Of these 73 women, 3 declined the device as they had marked benefit from PFME and a further 5 declined because they did not want to use/insert a vaginal device. Of the 65 enrollees, 13 (20%) were unable to be fitted with the device due to small introitus or shortening/narrowing of the vagina ($N=7$, from previous gynecological surgery) or the device was extruded with coughing ($N=6$). These 13 women never wore the device home. Of the 52 participants, 7 were withdrawn due to difficulty in removing the device despite repeated attempts while in the unit. Another eight participants were lost to follow-up despite repeated phone calls and letters. One month data was collected for 37

Table 1 Demographic data of the 37 participants who completed 1 month

	Median	IQR
Age	45	41–54
Body mass index	25	22–28
Parity	2	2–2
Menopausal (%)	12	32
Topical estrogen (%)	12	32

Table 2 Change in size of the Contiform device

No.	Original size	New size
6	Small	Medium
1	Medium	Small
1	Medium	Large
1	Medium/large	Small
1	Medium/large	Medium

Table 3 Outcome measures

Outcome measure	Pre Contiform pad test	IQR	Post Contiform pad test	IQR	*P* value
24 h pad test	6.6	4.3–22.6	2.2	0.5–8.2	0.0016
UDI	44	39–61	17	11–50	<0.0001
IIQ	38	33–52	14	5–33	<0.0001
St George score	10	8–13	4	2–7	<0.0001

(57%) of the 65 enrollees (or 37 (71%) of the 52 participants) who completed the study (see Fig. 2).

Of these 37 women, 13 (35%) were fitted with small size Contiform, 15 (40.5%) were fitted with medium size, 6 (16.2%) were fitted with medium/large size, and 2 (5.4%) were fitted with large size. Ten (27%) participants returned within 1 week to change the size of the device (as shown in Table 2) because of limited efficacy (too small) or pelvic discomfort (too large).

Of the 37 trial completions, 20 women (54%) were dry (<2 g) on the 24-h pad test. Further outcome data are given in Table 3. The use of the strap (Fig. 1) to assist in the removal of the device was required by 10 participants.

At completion, 8 (22%) of the 37 participants opted to have surgery for their stress leak, 4 of whom were dry with Contiform in situ but did not find it a suitable long-term solution. The remaining 29 participants wished to continue using the Contiform device long-term (Fig . 3).

Adverse events

Of the 37 women who successfully inserted and removed the device, 20 (54%) had nil residual, 9 (24%) had 49 ml or less, 6 (16%) had between 50 and 99 ml, and 2 (5.4%) had 100 ml or more residual. These two patients were advised to use the device for exercise only, and then remove the device to ensure that they could empty their bladder. All other patients were advised to monitor their bladder symptoms and to contact the NCA promptly if they felt their bladder was not emptying or had any pain or discomfort. The only other adverse event reported by the participants was the difficulty in insertion and/or removal of the device (n=7), these patients had to be withdrawn despite repeated instruction (as previously described). All remaining patients denied any problems emptying, pain/discomfort, urgency, bowel symptoms, or hemoserous staining at 4-week follow-up visit. Throughout the study, there were no episodes of the device fracturing nor did any patient complain of vaginal discharge.

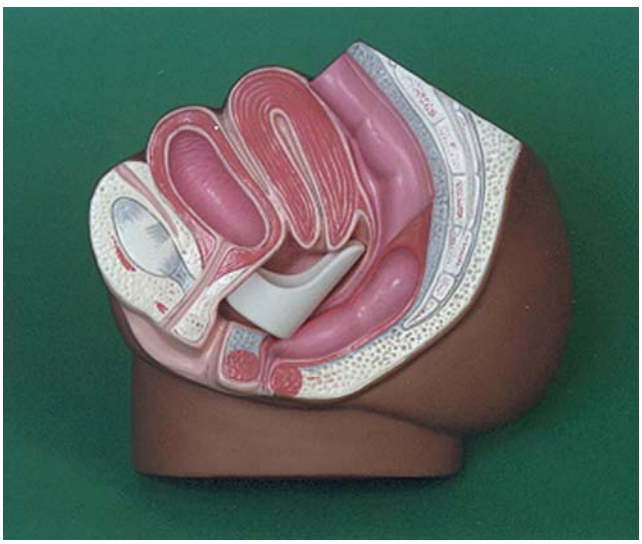


Fig. 3 The Contiform device in situ: the upper ring behind/underneath the urethra and the tail of the shaft behind the cervix

Discussion

This study attempts to present a "real-life" picture of the efficacy and user-friendliness of the Contiform device. Patients were asked to join the study for 4 weeks, but there were no funds provided to encourage them to persist with the device if they were otherwise inclined. In this context, it was not surprising that 8 of the 52 participants were lost to follow-up. The finding that 20% of the enrollees could not be fitted due to a small introitus or vagina was in keeping with the tertiary referral status of the unit, e.g., that many women had undergone previous continence and/or prolapse surgery but were referred as they were still wet. We suspect that the applicability of the device would be greater in the primary care setting, i.e., NCA or physiotherapy departments.

In this study, we employed the newly created medium/large size Contiform device. The percentage of "dry" participants was 54% in this cohort, as opposed to the cure rate of 20% seen when only three sizes [1] were available (χ^2=10.08, P=0.0015). The methods of fitting and follow-up were identical in the two studies. Note that the definition of "dry" (<2 g) was based on a large recent study of continent women [2] and was not the 8–10 g cut-off frequently employed in the literature. Had we used this less stringent definition, 75% of our patients would have been "dry" (IQR=0.5–8.2 g).

Of the 52 patients, 7 (13.5%) were withdrawn due to insertion/removal difficulties, most could readily insert the device but removal tended to be more problematic.

When comparing the cure rate of Contiform with other devices, the success of Contiform is similar to that of the Introl device (52% continent on the 1-h pad test), superior to that of Conveen Continence Guard (41–46% dry on the 24-h pad test), and similar to the Femassist (25–49% dry on the 1-h pad test) [5].

A final noteworthy aspect of this device is that it appeared to be economically worthwhile to the participants. The price of $21.50 Australian dollar (13.30 euros 2007) per month was not considered a financial burden to our patients. The manufacturers recommend using a new device every 45 days to prevent fracture lines. In fact, we found no episodes of stress factures in this study. Patients who only used the device for intermittent sporting activities reported that they often used the device for more than 1 month with continued efficacy, hence extending the economic life of the device.

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Note: Contiform does not currently have FDA approval, but is available from Contiform International EShop in Australia

Conflicts of interest None.

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