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ORIGINAL ARTICLE

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The Contiform incontinence device – efficacy and patient acceptability

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Abstract A consecutive series of 59 women with urodynamic stress incontinence but no prolapse were offered treatment with Contiform (available in small/medium/large sizes). The 24-h pad test was the primary outcome measure. Of the 59 enrolled women, 41 (69%) completed the trial protocol. Median use was 21 days (IQR 10–24.5). Two severity groups were categorized based on pretreatment pad testing (mild <30 g/day $n=24$ patients, 59%) and moderate/severe >30 g/day, $n=17$(41%). Overall, loss was reduced by a median of 72% (5–92), $p<0.0001$, with the greatest reduction seen in the moderate/severe group of 85% (75–100) $p<0.0001$. No significant benefit on pad testing was noted in the mild group. Both groups showed significant benefit on the Incontinence Impact Questionnaire. The insertion technique was quickly learnt and the device well tolerated. A medium-sized Contiform was used by 33 (80%) women. No serious adverse events occurred.

Keywords Contiform · Stress urinary incontinence · Vaginal device

Introduction

The management of stress urinary incontinence has been traditionally undertaken by conservative pelvic floor muscle rehabilitation or by surgery. Nevertheless, some women who fail to respond to conservative therapy do not wish to have surgery. They may be frightened of the procedure itself, with its attendant hospitalization and anesthesia [1], or they may be concerned about the risks of voiding dysfunction or de novo detrusor overactivity.

In the last 20 years several vaginal or urethral devices have been developed to cater for the needs of such women. Some of these have failed to achieve a sustained place in a market economy, or have persisted to a limited extent [2, 3, 4].

For example, the bladder neck support prosthesis Introl, which was developed by an Australian gynecologist, provides continence in 86% of patients with stress incontinence who can be fitted [5]. The device is similar to a ring pessary but has two anterior 'prongs' that fit behind the pubic symphysis, hence it can elevate quite severe prolapse. This silastic device can be worn for up to 4 months, then sterilized and reused. Introl is available in 28 sizes to fit a range of pelvic anatomies; the fitting process can therefore be time consuming and requires the help of an experienced gynecologist or specially trained Nurse Continence Adviser.

The new Contiform device was developed by the same Australian gynecologist but is currently manufactured in only three sizes, to simplify the fitting process. It is shaped like a hollow tampon (Fig. 1) so that self-insertion by patients is feasible. The front arch sits underneath the urethra, creating a support in a similar fashion to a suburethral sling (Fig. 2a, 2b). Figure 2a demonstrates obvious descent of the bladder base, which is corrected after insertion of the Contiform (Fig. 2b). The device is made of Santoprene, which is a medical-grade non-allergenic thermoplastic rubber. It fulfills the FDA ISOI 0993 criteria for direct contact with body surfaces for 24 h to 30 days, and is non-carcinogenic, non-cytotoxic and non-hemolytic [6]. Santoprene is elastic but non-compressible (similar to silastic), hence once it is placed in the vagina it retains its shape and supports the urethra during episodes of varied intra-abdominal pressure.

The device can be worn continuously for 1 month. Unlike Introl, the Contiform is not suitable for use in patients with significant uterovaginal prolapse (who are generally not able to retain a tampon). We aimed to

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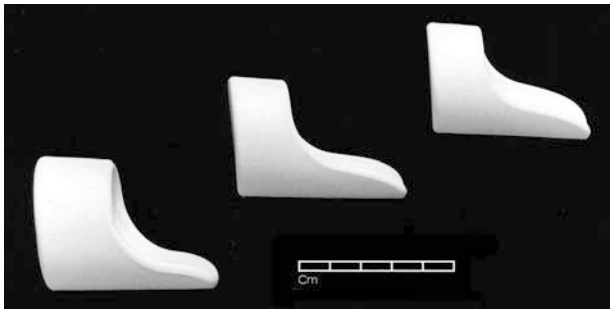

Fig. 1 The Contiform device: large (length of total shaft 55 mm x width of upper surface of ring 25 mm x diameter of ring 43 mm) medium (55×18×37) and small (52×18×35) sizes used in this study

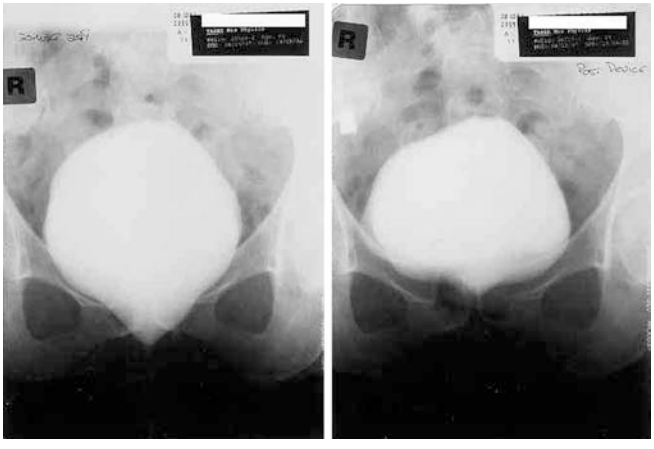

Fig. 2 Cystogram of bladder before (a) and after (b) insertion of Contiform, showing that the device supports the urethrovesical junction

assess the efficacy of this new device in correcting stress urinary leakage, and to measure patient acceptance, usability and the incidence of adverse events.

Patients and methods

A consecutive series of patients attending a tertiary referral urogynecology clinic, who were found to have urodynamic stress incontinence (USI) diagnosed by standard filling/voiding cystometry, were offered treatment with Contiform. A log was kept of all potential subjects. Exclusion criteria comprised detrusor overactivity, pelvic surgery within 3 months, previous pelvic radiotherapy, recurrent bacterial cystitis, hematuria, pregnancy, vaginal prolapse past the introitus, or obvious postsurgical narrowing of the introitus visible on simple inspection. All medications were noted, including whether postmenopausal patients used either systemic HRT or topically applied estrogens. No other treatment was initiated during the trial period. Medications already in use were not altered. We recruited only women who spoke English and could understand the written informed consent procedure, in accordance with local ethics committee approval. Patients were invited to join a study of this new continence device, among other options such as physiotherapy or surgery. They understood that they were under no obligation to continue with the device after 3 weeks if they preferred other treatment, and in fact some women agreed to enrol out of curiosity, rather than out of a desire to use the device long term.

Fitting of the device

Prior to fitting each individual was given the opportunity to view an instructional video. A brief questionnaire about attitudes to vaginal devices and previous tampons / diaphragm use was administered [7]. Patients who declined to continue with the device at this stage were noted. Initially fitting was with a medium-sized device, by a single individual (AM). If this was unsatisfactory then either a small or a large device was fitted as appropriate. Immediately thereafter, the patient removed and refitted the device herself. Correct positioning was then confirmed by vaginal examination by the doctor. If the device was incorrectly placed by the patient this was corrected and she was invited to remove and reinsert it again. Patients who were unable to self-insert the device were discontinued from the study at this stage.

On leaving the clinic, all participants were supplied with one device of each size (small, medium and large). Should they feel that they were not receiving adequate benefit from the device fitted in the clinic over the following 3–4 weeks, they were encouraged to try other sizes. Patients were also instructed to use a new device if any defect appeared in the Contiform they were currently using. Patients were allowed to leave the device in situ for the duration of the 3-week trial, or to insert/remove it on a daily basis, and were advised to remove it prior to sexual intercourse. A 3-week period was chosen as it was believed that this would allow sufficient time for each woman to become familiar with the device and to try the three different sizes if necessary. We anticipated that an appropriately sized device would reduce leakage promptly after fitting.

Assessment of efficacy

The primary outcome measure was the 24-h pad test. During the pretreatment test, patients were encouraged to undertake any activity that would normally induce stress leakage, and to repeat this same activity during the second pad test while wearing the Contiform. In order to determine whether the device was equally effective in mild or more severe leakage, these two groups were analyzed separately. A leakage of < 30 ml/24 h was categorized as 'mild loss' and > 30 ml was termed 'moderate/severe loss', as per O'Sullivan et al. [8]. An electronic balance accurate to 0.1 g was used to weigh all pads.

The definition of 'dry' on a 24-h pad test was not that published in 1986 [9] of up to 8.5 ml, but a more recent and stringent definition, based upon a larger study group of normal women [10], of 0.5 ml.

Short forms of the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire [11], as well as the Short Form 12 (SF12) [12], were administered to measure changes in quality of life. The SF12 comprises two components that measure physical (Physical Component Score (PCS)) and mental (Mental Component Score (MCS)0 health separately.

Patient acceptability was measured by a 10-point subjective rating scale depicting overall satisfaction and ease of use. A similar scale was also used to measure response to the question 'How comfortable would you feel with the idea of placing an incontinence device into the vagina' [7]. Five-point Likert scales were used to assess device usability and patients' willingness to 'recommend the device to a friend'. Both the number of days of use and the time taken to achieve a feeling of competence with insertion/removal were recorded. Previous experience with diaphragm or tampon use was noted, in relation to time to achieve competence [7]. After completing the study, further follow-up at 4–6 weeks in the Unit was undertaken, at which overall management was reviewed regarding desire to use the device long term.

Assessment of adverse events

The residual urine volume was estimated by using a handheld bladder scanner before and after device insertion. (BladderScan model BVI 2500 Diagnostic Ultrasound, USA). We recorded all episodes of vaginal discharge or pelvic pain associated with use of Contiform, as well as any episodes of a patient seeking treatment from another health professional because of other acute problems attributable to the device. Lastly, we asked participants to inform us of any defects appearing in Contiform, in particular any small fractures that might appear in the inner surface of the anterior aspect of the device when it is maximally compressed during insertion (Fig. 3).

Statistical analysis

All descriptive data are quoted as median value plus interquartile range, as the data were not normally distributed. Wilcoxon's and the Mann–Whitney *U* tests were used for paired and unpaired data, respectively. All definitions conform to those of the Standardization Committee of the International Continence Society [13] unless otherwise specified.

Fig. 3 Compression of the Contiform prior to insertion, showing the likely point of fracture (on the inner surface of the anterior aspect of the device) after multiple usage for more than 1 month

Results

During the recruitment period of 7 months, a total of 59 women with pure USI who had no prolapse or other exclusion criterion were offered Contiform. Of these, seven (11%) declined to participate because they were not inclined to use a vaginal device, and four (7%) withdrew prior to fitting, mainly because other commitments rendered the trial protocol too onerous. Three (5%) patients could not be fitted with any size of device, but they were encountered within the first month of the study. Two women had shortened vaginas and could not accommodate the smallest device. One patient could not retain the largest device because of a deficient perineum. Four (7%) were unable to fit and remove the device by themselves while in the Unit. Therefore, 41 of 58 (70%) individuals completed the trial protocol.

Of these, 24/41 (58%) patients had mild loss and 17 (42%) moderate to severe leakage. With the exception of parity, demographic data for the mild and moderate to severe groups were similar, as were quality of life indices (Table 1). Of the total group, 12 women (29%) were postmenopausal and, of these, 11 were receiving supplementary estrogens (92%).

As shown in Table 2, pad test loss for the total study sample was significantly reduced, by a median of 72% (IQR 5–92%), $P < 0.0001$. However, this was mainly due to the large reduction in loss noted for the 17 patients in the moderate to severely incontinent group, who experienced a median reduction of 85% (75–100%) from baseline. In comparison, the mild group exhibited a median reduction of 25% (−80 to +72). In this group the post-treatment change in pad tests did not reach significance because of the wide spread of baseline values and the wide variation in post-treatment data. Overall, eight patients (20%) were rendered dry, with no difference between groups (3/24 (12%) mild versus 5/17 (29%) moderate/severe, Fisher's exact test A = 3.31, $P = 0.21$).

The medium-sized device was fitted most frequently, in 34 (83%) patients. At completion of the trial, 33 (80%) women found this size the most appropriate, with six (15%) using the small device and only two (5%) requiring the large one.

Patients generally responded well to the suggestion of placing a Contiform device into their vagina (median score 7/10, IQR 4–10), and no difference was observed between severity groups ($P = 0.56$, data not shown). Overall, median usage for the whole group was 21 days (IRQ 10–24.5, range 1–36) with no difference between severity groups (21 (8–25) vs 21 (11–23), $P = 0.80$. The technique of insertion and removal was quickly learnt: 41 of 45 (91%) patients who were fitted with the device in the clinic were able to fit themselves prior to leaving. The median time to 'competency' (defined as having the confidence to reliably insert/remove the Contiform) was 2 days (IRQ 2–5) for the whole group. Of the 41 participants, 80% had used tampons and 34% a

Table 1 Demographic data

Parameter	Mild group ($n = 24$)	Moderate/ severe group ($n = 17$)	Significance
Age	46 (43–52)	47 (42–53)	$P = 0.94$*
Parity	2 (2–3)	2 (2–3)	$P = 0.2$*
BMI	26 (23–30)	26 (22–28)	$P = 0.51$*
Previous tampon use	20 (83%)	13 (76%)	A = 3.32 ≠ $P = 0.70$
Previous diaphragm use	9 (38%)	5 (29%)	A = 8.2 ≠ $P = 0.74$

*Mann–Whitney *U* test
≠ Fisher's exact test

Table 2 Pre- and post-treatment QoL and leakage data

Parameter	Whole Group			Mild Group			Moderate / Severe Group		
	Baseline	Post-treatment	Significance (P value)	Baseline	Post-treatment	Significance	Baseline	Post-treatment	Significance
Pad test	18.7 (5.8–53.9)	8 (1.9–14.2)	<0.0001	7.3 (4.5–10.8)	7.3 (2.1–9.2)	$P=0.5$	62.8 (43.5–107.3)	11.8 (0–26.2)	<0.0001
Residual Urine Volume	0 (0–49)	4 (0–61)	0.01	0 (0–13)	0 (0–78)	$P=0.21$	0 (0–0)	8 (0–66)	0.03
UDI	38.8 (28.3–56.9)	27.7 (16.7–49.9)	0.0054	33.3 (19–55.5)	28.5 (16.7–49.9)	$P=0.1297$	49.9 (33.3–61)	20.6 (16.7–49.9)	0.0266
IIQ	33.3 (15.5–57)	19 (10.3–40.4)	0.0029	33.3 (14.3–52.3)	19 (9.5–33.3)	$P=0.0384$	42.8 (26.7–58.2)	30.9 (11.3–47.6)	0.042

diaphragm in the past, with no significant difference between severity groups (Table 1). Those who had previously used a diaphragm found insertion no easier than those who had no such experience ($P=0.95$), nor did they achieve competence at insertion earlier ($P=0.71$). Tampon usage also showed no association with these parameters ($P=0.93$ and $P=0.64$, respectively).

Table 2 also indicates changes in quality of life indices. In those with moderate to severe loss both of the disease-specific questionnaires (the UDI and IIQ) demonstrated significant improvement after use of Contiform. A similar benefit was noted in the IIQ for those with mild loss, but not for the UDI. The only component of the generic test (SF12) that significantly improved was the physical score (PCS) in those with mild loss, baseline 52 (34.4–55.9) improved to 54.6 (45.8–56.6), $P=0.04$ (remainder of the SF-12 data not shown).

Despite an overall median 85% reduction in daily loss, 36% of those not rendered dry have elected to have surgery. In addition to this, two of eight (25%) with no loss on repeat pad testing also elected to have surgery. Although this is surprising, in that these individuals were cured while using the device, it was anticipated that some patients would elect to follow this course of action and was part of the explanation given at entry to the trial.

Adverse events

Although three women noted a subjective reduction in the volume of their urinary stream for the first 48 h, repeat uroflowmetry at the end of the study period did not show any evidence of reduced flow rate. Table 2 shows that residual volumes did increase very slightly with the Contiform in situ, but only six (15%) patients had a post-treatment residual greater than 50 ml.

Two women (5%) experienced acute bacterial cystitis during the trial period.

A small degree of fracture of the anterior curvature of the device was noted in nine instances (22%), although in no case was there any actual breakage of the device. Out-of-hours attendance at a medical facility was required by three (7%) participants, who had difficulty in removing the device at home.

Discussion

Unlike the Introl device, Contiform was designed for patients without significant uterovaginal prolapse who were sufficiently dexterous and mentally alert to be able to insert/remove the device themselves with little or no supervision.

Although three patients could not be fitted, these were among the first 14 patients recruited, suggesting that there is a steep learning curve regarding patient selection, and that clinicians treating incontinent women should be able to assimilate the technique rapidly.

Patients also appeared to have a short learning curve as regards insertion/removal technique, as they generally felt competent within 2–3 days. It is interesting to note that all patients elected to use it daily, rather than leave it in situ for prolonged periods, despite the product license that allows the device to be retained for up to 1 month. The fact that many of the patients had little leakage when resting at home or sleeping at night, and that (unlike a ring pessary) sexual intercourse is not possible with Contiform in situ, most likely accounts for this pattern of usage. However, although all participants had successfully inserted and removed Contiform themselves in the clinic, three had difficulty at home, resulting in out-of-hours attendance at a medical facility for its removal. None of these was associated with urinary retention or vaginal discomfort, but resulted simply from a desire to have it removed immediately, rather than waiting until the morning and phoning the Unit for advice or review. Interestingly (contrary to expectation), previous use of a diaphragm was not associated with either ease of use or time to competency, confirming the simplicity of the insertion/removal technique.

The 3-week duration of this study was designed for patient convenience, but in practical terms most patients

observed any benefit within the first week. Each woman was given one size of each of three devices to use for a maximum of 5 weeks in this study. We did not collect data as to the number of insertions and removals, and so we cannot judge whether the 22% rate of minor fracture per person is beyond expectation. The more frequently the device is removed and reinserted, the more likely it is to exhibit minor fracture.

The medium-sized device was used by 80% of women, the small version by 15%, and the large by 5%. Only five (12%) individuals who completed the trial changed the size after initial fitting. The majority of patients found it simple to use and would recommend it to a friend, whether or not it provided cure of incontinence. This reflected the simplicity of the device and the general ease with which it could be used – in essence, the majority felt they would 'have nothing to lose'.

Leakage for the whole group was significantly reduced, though this was driven by the reduction in those 17 patients with moderate/severe loss. We are unsure why those with mild loss should be relatively unaffected by Contiform, as they were anticipated as being most likely to achieve the greatest benefit. The overall dry rate was disappointing, but can be partially explained by our stringent definition of 'dry' based a recent study of the 24-h pad test in normal controls. Had we used the previously reported upper limit of 8.5 ml/24 h then the majority of patients in the mild group would not have been deemed to have been incontinent at all prior to enrollment, despite their attendance at our Unit complaining of urinary leakage.

The large device was too uncomfortable for almost all patients, but the low 'dry' rate suggests there is a place for an intermediate device, sized midway between the popular 'medium' device and the rarely used 'large' one. The slight increase in external diameter may give more support to the urethra, thereby enabling those who were almost dry to become fully continent. This device has now been developed and is undergoing clinical trials.

As with the Introl device, Contiform does not have a significant obstructive effect, although three individuals noted a significant reduction in the flow rate when using a new device – after approximately 48 h a softening of the device was noted and flow appeared to normalize thereafter. Fracture can occur on the underside of the superior aspect of the device when it is folded inwards prior to insertion (Fig. 3). We cannot comment on the efficacy of damaged devices, as if this occurred during the study patients were instructed to discard it and use a new one. However, such devices would be expected to continue to provide some support until the integrity of the anterior ring is completely breached – an occurrence that was not seen in this study.

In conclusion, Contiform appears simple to use and is well tolerated. The device offers an alternative to surgery, particularly in those who only leak during sport, or those who do not wish or have not yet completed their family. It provides a significant reduction of leakage in those with moderate to severe incontinence, but the newly developed medium–large device may provide greater overall efficacy. Clinical trials of this new size are in progress.

References

1. Holst K, Wilson PD (1998) The prevalence of female urinary incontinence and reasons for not seeking treatment. NZ Med J 101:756–758
2. Biswas NC (1988) A Silastic vaginal device for the treatment of stress urinary incontinence. Neurourol Urodyn 7:271–272
3. Moore KH, Simons A, Dowell C, Bryant C, Prashar S (1999) Efficacy and user acceptability of the urethral occlusive device in women with urinary incontinence. J Urol 162:464–468
4. Hahn I, Milson I (1996) Treatment of female stress urinary incontinence with a new anatomically shaped vaginal device (Conveen Continence Guard). Br J Urol 77:711–715
5. Moore KH, Foote A, Burton G, King J (1999) An open study of the bladder neck support prosthesis in genuine stress incontinence Br J Obstet Gynecol 106:42–49
6. FDA original master file 7760, 5600 Fisher's Lane, Rockville, Maryland 20857. www.fda.gov
7. Prashar S, Simons A, Bryant C, Dowell C, Moore KH (2000) Attitudes to vaginal/urethral touching and device placement in women with urinary incontinence. Int Urogynecol J 11:4–8
8. O'Sullivan R, Yoong W, Allen W, Buckland S, Moore KH (2000) The repeatability and definition of mild, moderate and severe on the 24 hour pad test in 96 incontinent women. Neurourol Urodyn 19: 481–483
9. Versi E, Orrego G, Hardy E, Seddon G, Smith P, Anand D (1996) Evaluation of the home pad test in the investigation of female urinary incontinence. Br J Obstet Gynaecol 103:162–116
10. Karantanis E, O'Sullivan R, Moore KH (2003) Normal values for the 24 hour pad test in continent women: the effects of exercise and hormonal status. Br J Obstet Gynaecol 110:649–657
11. Simons AM, Foote A, Moore K (2001) Quality of life assessment as an outcome measure in urinary incontinence research. A comparison of various quality of life and incontinence measures. Abstract. Int Urogynecol J 12 (Suppl. 3):169
12. Ware JE, Kosinski M, Keller SD (1996) A 12 item short form health survey. Construction of scales and preliminary tests of reliability and validity. Med Care 34:220–233
13. Abrams P, Cardozo L, Fall M et al. (2002) The standardisation of terminology of lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. Neurourol Urodyn 21:167–178

Editorial Comment

Intravaginal and intraurethral devices have been utilized with variable but only modest success in managing women with stress urinary incontinence. Although future studies might focus on a prospective randomized study design comparing this device to other devices used for incontinence, the authors took the first appropriate step in

prospectively determining the effects of the intervention both before and afterwards. It is interesting that only the group with more severe incontinence had an appreciable benefit. With the current study, this amounted to improvement in only 17 of the original 59 subjects, or 29% of subjects who used the device. None the less, the apparent ease of insertion and patient tolerance present this device as another possible option in the management of stress incontinence with minimal adverse effects.