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ORIGINAL RESEARCH

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User acceptability and ease of use of the MedRing, a new personalized vaginal drug delivery and monitoring device

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ABSTRACT

Background: The MedRing is an innovative, flexible vaginal ring that, unlike other rings, allows personalized drug administration and monitoring. This study evaluated its user acceptability and ease of use.

Research design and methods: This was an exploratory, prospective, open-label, interventional, multicenter study. Twenty-one women (25 – 75 years) used the dummy/placebo MedRing for three weeks, with insertions/removals on day 1 and after weeks 1 and 3. Participants scored design, ease of self-insertion /removal, wearing comfort, and potential future use. They also kept a daily diary, rating comfort on a 10-point scale (1 = intolerable, 10 = no problem). In addition, physicians rated ease of use and complications on a 5-point scale (1 = no problem; 5 = problematic). Safety evaluations included vaginal examinations and adverse event (AE) monitoring. Data were analyzed descriptively.

Results: After three weeks, the median (min-max) overall acceptance score was 9.5 (5 – 10); insertion and removal scored 10 (8–10) and 9 (3–10), respectively. Median comfort scores ranged 8–10. The physician's ease-of-insertion/removal median score was 1 (1 – 5). Two participants discontinued due to AEs: inability to remove the ring and vaginal irritation.

Conclusion: The MedRing demonstrated high user acceptability and ease of use, supporting its use as a personalized, self-controlled treatment device across a wide age range.

PLAIN LANGUAGE SUMMARY

The MedRing is a new vaginal device designed for personalized drug delivery. In this study, it was well accepted by users, who rated it highly for comfort, ease of self-insertion, and removal.

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Vaginal ring; drug delivery device; personalized drug administration; acceptability; MedRing

1. Introduction

Vaginal devices have been used in gynecological practice for decades to treat various urogenital problems like urinary incontinence and pelvic organ prolapse (POP). These indications are all long-term conditions that require extended use of the product. The vaginal devices, mostly made of medical-grade silicone, are well tolerated, and their safety has been established [1].

The dense vascularization of the vaginal mucosa makes the vagina an excellent site for drug delivery [2,3]. Initially, vaginal drug formulations included suppositories, gels, foams, and tablets, while more recently vaginal rings have been introduced to the market. These vaginal rings are either aimed to achieve a local effect, such as the estradiol-containing vaginal rings to treat vaginal atrophy in menopause [4] and the dapivirine-containing vaginal ring for human immunodeficiency virus (HIV) prevention [5], or are designed for medication uptake to achieve a systemic effect, such as the contraceptive vaginal rings [6,7].

Compared to oral administration, the use of the vaginal route of administration for systemic drug uptake has several advantages, including sustained and prolonged drug delivery, which maintains consistent drug levels, avoiding peak and trough concentrations, and the need for daily drug administration. Additionally, the vaginal route of administration bypasses the hepatic first-pass metabolism [2,8]. In the currently available vaginal rings, the medication is dissolved or dispersed in the material of the ring, continuously releasing a fixed amount into vaginal tissue during use. These rings are not suitable for immediate or on-demand drug dosing, and do not offer the possibility for dose customization or personalization. Additionally, they are not designed to monitor drug delivery or other biometric signals.

The MedRing is a flexible vaginal ring with an innovative drug delivery system including a miniaturized drug reservoir coupled to a micropump, allowing programmed and personalized drug administration. The MedRing is suitable for drug delivery in complex dosing schemes, dose control, and compliance monitoring across various medical fields, and is designed for easy self-insertion and removal. It features a polyethylene body, a 2 mL medication reservoir to provide a total (guaranteed) dispensed volume of 1680 µL, and a pump for precise drug administration. It features a temperature sensor for monitoring compliance and body temperature changes, as well as a Bluetooth module for communication with the user's smartphone (Figure 1(A)). The microprocessor-

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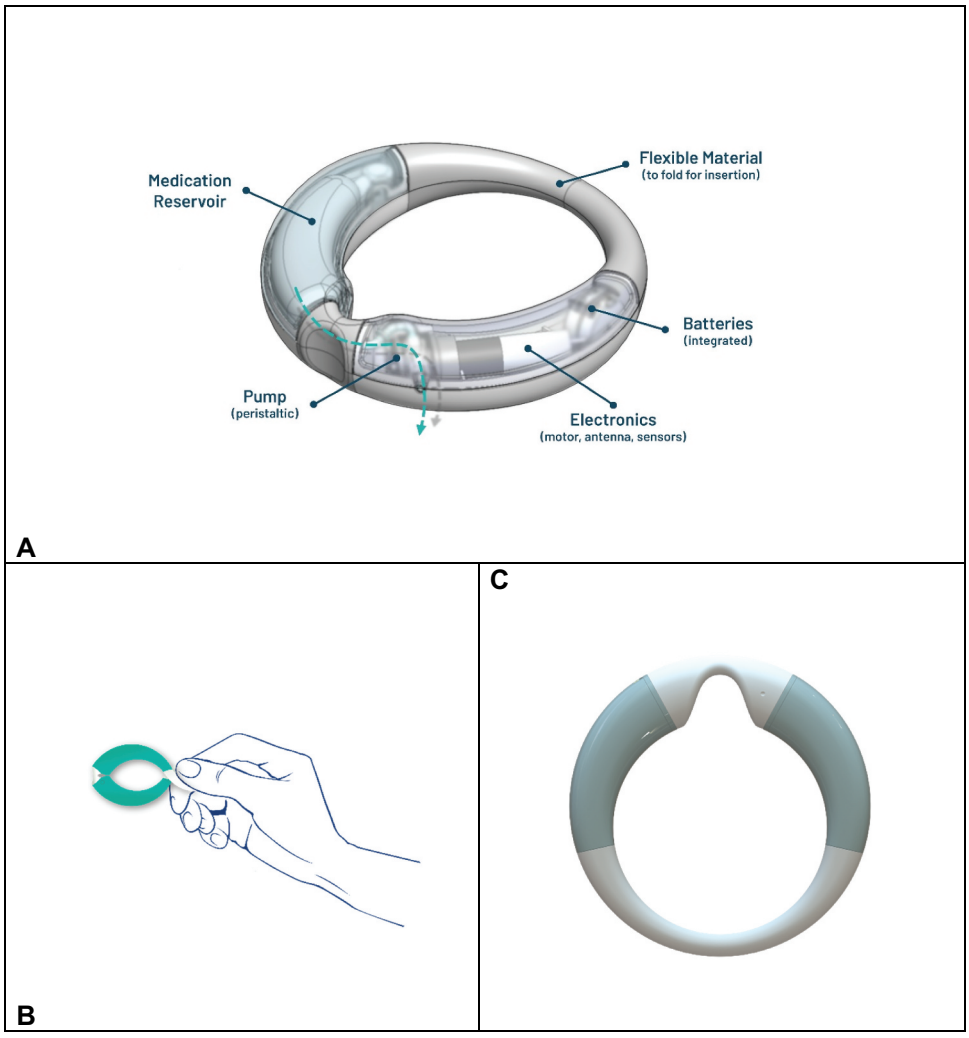

Figure 1. The MedRing. A: Technical drawing of the actual MedRing including components; B: Animation of the MedRing when 'squeezed' for insertion. The green side is the insertion side. C: The MedRing Dummy as used in this study.

controlled release system enables regular or pulsatile drug administration, which can be monitored via a smartphone. It supports various liquid formulations for a variety of therapeutic applications. The hinge allows the MedRing to fold and flex for easy self-insertion (Figure 1(B)), and it unfolds to fit securely once in place. The innovative design of the MedRing overcomes the limitations of current vaginal ring technologies by enabling controlled drug delivery, on-demand pulsatile dosing, and the potential for personalized patient treatment schedules.

The first-in-human study with the oxybutynin-filled MedRing in 8 healthy female participants demonstrated that the device successfully delivered oxybutynin at the prescribed volume, achieving plasma oxybutynin levels comparable to those of orally administered oxybutynin and significantly beneficially impacting the parent/metabolite ratio. Intravaginal administration of oxybutynin using the MedRing did not irritate the vaginal mucosa, and its use was well tolerated [9]. A second multiple-dose study in humans with the oxybutynin-filled MedRing, conducted in 24 healthy female participants, demonstrated that the device, with only 50% of the oral dose, achieved higher plasma levels, resulting in a 9.8-fold higher parent/metabolite ratio compared to oral medication. This confirms the benefits of vaginal administration [10].

Acceptability and tolerability are key to the successful, long-term use of vaginal devices. Poor user experience can lead to inconsistent use and reduced effectiveness. While the tolerability of vaginal rings is well established, data on MedRing acceptability is limited. This study aimed to evaluate its user acceptability and ease of use.

2. Participants and study methods

2.1. Study design

This was an exploratory, prospective, open-label, interventional, multicenter pilot study. The main objective was to assess user acceptance and ease of use of the MedRing. Additionally, we assessed physicians' opinions, device-related adverse events (AE), and damage.

The study lasted 4 weeks and included a screening visit, three in-person visits, and a follow-up phone call. Enrolled were women aged 25 to 75 years, who used adequate

contraception (if applicable) and had a normal result for cervical cancer screening within the last five years. Exclusion criteria were pregnancy, irregular bleeding, prior vaginal surgery, genital prolapse (POP-Q stage 2), known hypersensitivity to materials used in the MedRing, symptomatic vaginal discharge, and any ongoing illness that could affect the participant's health or the study results.

After screening (Visit 1), participants enrolled at the clinic were introduced to the MedRing for the first time and received usage instructions (Visit 2). They then inserted the ring, wore it for one hour, and performed removal, cleaning, and reinsertion. The MedRing was then worn for 1 week, followed by a clinic visit (Visit 3) to repeat the removal, cleaning, and reinsertion. Participants continued to wear the MedRing for an additional two weeks. At the final visit (Visit 4), they removed the MedRing, and a safety follow-up was conducted by phone 1 week later. A study physician performed vaginal inspections at each visit.

The study was conducted between January 2021 and October 2023 at three Dutch centers, by the principles of the Declaration of Helsinki, Good Clinical Practice regulations, and relevant local regulations. The center's ethics committee approved the study protocol and patient informed consent forms, and participants provided consent before study participation.

2.2. Study treatment

We used a dummy MedRing, similar in size, material, and consistency to the future MedRing but without the pharmaceutical content and lacking the internal functional components (Figure 1(C)).

2.3. Study assessments

At each visit, participants answered questions about the ease of insertion and removal, any irritation, whether they could feel the ring when it was in place, and overall tolerability (Supplemental Table 1). Before the first insertion at Visit 2, participants were shown the MedRing and asked about its appearance (design and material), as well as their confidence in their ability to insert it. All questions were scored on a 10-point scale ranging from 1 (completely intolerable) to 10 (not a problem at all).

Participants also maintained a diary (Supplemental Table 2), recording daily tolerability on a 10-point scale from 1 (completely intolerable) to 10 (not a problem at all). Additional questions addressing overall experience and perceived effects on bladder, intestines, and sexual intercourse were completed after 1 and 3 weeks of use (Supplemental Table 2).

Before the first insertion, physicians answered questions about anticipated problems with self-insertion. After insertion and removal at visits 2, 3, and 4, they completed questions on difficulties with self-insertion and self-removal, complications or bleeding, tolerability, preliminary removal, and any device damage. All questions were scored on a 5-point scale from 1 (not at all) to 5 (yes). More details were asked if a score of 5 was given (Supplemental Table 3). After the follow-up phone call, the physician recorded whether the participant had any vaginal or other complaints following Visit 4 (yes/no) and, if present, assessed their intensity (mild, moderate, severe).

Safety was assessed by reporting AEs during the period of use and by vaginal examinations on Visits 2 (baseline), 3, and 4. AEs were graded as mild, moderate, or severe, and their relationship to ring use was classified as not, probably, possibly, or definitely related.

2.4. Statistical analysis

Summary statistics (mean, median, standard deviation, and range) were calculated for questions related to tolerance, overall acceptance rate, and ease of use (insertion, removal, and comfort of wearing). The incidence of device-related AEs was summarized overall and by event type. Summary statistics were also provided for physician satisfaction questions and the number of damaged devices. Additionally, these statistics were broken down by subgroup of premenstrual and postmenopausal women.

3. Results

3.1. Study population and baseline characteristics

Twenty-one participants entered the study, with a mean age of 45.2 years (range 25 – 74 years). Among them, 13 were premenopausal, five were menopausal, and 3 had an unknown status (Table 1). Seven participants experienced involuntary urine loss, and two participants suffered from obstipation, one of whom had chronic obstipation (Table 1).

Out of 21 enrolled participants, 18 completed the study, including the follow-up phone call. Two participants discontinued due to AEs; one postmenopausal participant was unable to remove the MedRing after first insertion, and one premenopausal participant experienced vaginal irritation when using the MedRing. Follow-up information for one participant was missing.

3.2. Device performance and adherence

No damage to the MedRing was reported during the study, and none of them required replacement. One participant reported difficulty cleaning the MedRing during menstruation, while another noted discoloration of the MedRing during this time. One participant mentioned that the MedRing slid down during sports activities. Seven participants briefly removed the MedRing for various reasons, including sexual intercourse, cleaning, painful itches, sports, illness, frequent urinating, stomach cramps, and practicing removing and reinserting it.

3.3. Design and ability to self-insert

Participants rated the MedRing design with a median (range) score of 8 (4 – 10), and the material of the MedRing also received a score of 8 (6 – 10) (Table 2). The median (range) expectation for the ability to insert the MedRing was 9 (5 – 10). Overall, premenopausal women gave slightly higher scores than postmenopausal women (Table 1).

Table 1. Participant demographics and baseline characteristics.

		Premenopausal n = 13	Postmenopausal n = 5	Not known n = 3[a]	All participants n = 21
Age (years)	Mean (SD)	37.4 (8.35)	61.2 (8.64)	52.3 (3.21)	45.2 (13.01)
	Median	41	57	51	45
	(min-max)	(25–46)	(53–74)	(50–56)	(25–74)
Height (cm)	Mean (SD)	171.5 (6.83)	163.8 (9.99)	171.3 (5.13)	170.1 (7.96)
	Median	171	165	170	170
	(min-max)	(162–183)	(151–176)	(167–177)	(151–183)
Weight (kg)	Mean (SD)	72.1 (11.66)	72.2 (5.68)	73.3 (20.01)	72.3 (11.31)
	Median	70	74	74	72.5
	(min-max)	(55–92)	(64–78)	(53–93)	(53–93)
History of overactive bladder, n (%)		0	3 (60.0%)	1 (33.3%)	4 (19.0%)
Prior parity, n (%)		7 (53.8)	2 (40.0)	3 (100)	12 (57.1)
Pelvic surgery, n (%)		2 (15.4)	0	0	2 (9.5)
Prior pessary use, n (%)		0	0	1 (33.3)	1 (4.8)
Adequate contraception, n (%)		13 (100)	2 (40.0)	3 (100)	18 (85.7)
Prior history of obstipation:		1 (7.7)	0	1 (33.3)	2 (9.5)
Chronic obstipation, n (%)		0	0	1 (33.3)	1 (4.8)
Medication use, n (%)		0	0	0	0 (0)
involuntary urinary loss:		2 (16.7)[b]	3 (60.0)	2 (66.7)	7 (35.0)[b]
1 – 2 times per day, n (%)		2 (15.4)	0	2 (66.7)	4 (19.0)
3 – 5 times per day, n (%)			3 (60.0)	0	3 (14.3)

[a]For three participants, information on pre-menopause or menopause status could not be established. One participant had amenorrhea while wearing a contraceptive intrauterine device. For the other two participants, no data were available.
[b]For one participant, information on involuntary urine loss was not available.
Abbreviation: SD: standard deviation.

Table 2. Assessment of the appearance of the MedRing, before insertion.

		Premenopausal n = 13	Postmenopausal *n* = 5	Not known n = 3	All n = 21
Is the design of the MedRing appealing to you?	Mean (SD)	7.9 (1.26)	6.8 (1.92)	8.7 (1.15)	7.8 (1.48)
	Median (min-max)	8 (5–10)	7 (4–9)	8 (8–10)	8 (4–10)
Is the material of the MedRing appealing to you?	Mean (SD)	8.1 (1.2)	7.2 (1.64)	7.7 (0.58)	7.8 (1.21)
	Median (min-max)	8 (6–10)	7 (6–10)	8 (7–8)	8 (6–10)
Do you think you can insert the MedRing, yourself, after the explanation?	Mean (SD)	8.9 (1.24)	8.0 (1.87)	8.7 (1.53)	8.7 (1.42)
	Median (min-max)	9.5 (7–10)	8 (5–10)	9 (7–10)	9 (5–10)

3.4. User acceptability

3.4.1. Tolerability

The median (range) overall tolerability score, based on the question 'taking everything into account, how well did you tolerate the ring?' was 9 (3 – 10) after the first insertion and 9.5 (5 – 10) after three weeks of wearing it (Table 3). The lowest minimum score of 3 was reported among postmenopausal women after the first insertion, but this increased to 7 after three weeks of use (Table 3).

3.4.2. Ease of self-insertion

The median (range) ease of self-insertion score increased from 9 (7 – 10) for the first insertion to 10 (8 – 10) for the reinsertion after one week (Table 4) and was similar for premenopausal and post-menopausal participants.

3.4.3. Ease of self-removal

The median (range) ease of self-removal score increased from 8 (1 – 10) for the first removal to 9 (3 – 10) for the removal after 3 weeks of wearing (Table 4). The first removal score was lower in postmenopausal women (median 4; range 1–10) than in premenopausal women (median 8; range 5–10), but this difference disappeared by week 4, with both groups scoring a median of 9 (Table 5).

3.4.4. Wearing comfort

When asked whether they felt the MedRing during use, participants reported a median score of 9 after the first insertion and 1 hour of wear, which improved to 10 (range: 8–10) after 3 weeks of continuous use (Table 4). Scores were similar for premenopausal and postmenopausal participants.

Table 3. Overall tolerability of the MedRing.*

		Visit 2 After 1 hour	Visit 3 After 1 week	Visit 4 After 3 weeks
All (*n* = 21)	Mean (SD)	8.7 (1.62)	9.0 (1.18)	9.1 (1.32)
	Median (min-max)	9 (3–10)	9 (5–10)	9.5 (5–10)
Premenopausal (*n* = 13)	Mean (SD)	9.2 (0.60)	8.8 (1.3)	8.9 (1.38)
	Median (min-max)	9 (8–10)	9 (5–10)	9 (5–10)
Postmenopausal (*n* = 5)	Mean (SD)	7.4 (2.88)	9.3 (0.58)	9.3 (1.50)
	Median (min-max)	7 (3–10)	9 (9–10)	10 (7–10)
Not known (*n* = 3)	Mean (SD)	8.7 (1.15)	9.3 (1.15)	9.3 (1.15)
	Median (min-max)	8 (8–10)	10 (8–10)	10 (8–10)

*"All together, how did you tolerate the ring." Scored on a scale of 1–10 (completely intolerable-not a problem at all).

Table 4. Assessment of the ease of insertion of the MedRing.

			Visit 2 First insertion	Visit 2 Reinsertion	Visit 3
Was the insertion of the MedRing easy?[a]	All ($n = 21$)	Mean (SD)	8.8 (0.89)	8.7 (1.98)	9.4 (0.75)
		Median (min-max)	9 (7–10)	9 (1–10)[b]	10 (8–10)
	Premenopausal ($n = 13$)	Mean (SD)	9.0 (0.82)	9.3 (0.75)	9.5 (0.66)
		Median (min-max)	9 (8–10)	9 (8–10)	10 (8–10)
	Postmenopausal ($n = 5$)	Mean (SD)	8.6 (1.14)	7.6 (3.78)	9.8 (0.50)
		Median (min-max)	9 (7–10)	9 (1–10)[b]	10 (9–10)
	Unknown ($n = 3$)	Mean (SD)	8.0 (0.00)	8.0 (1.00)	8.7 (1.15)
		Median (min-max)	8 (8–8)	8 (7–9)	8 (8–10)
Did you feel the MedRing during use?[a]	All ($n = 21$)	Mean (SD)	8.9 (0.94)	8.5 (1.99)	9.2 (2.03)
		Median (min-max)	9 (7–10)	9 (1–10)[b]	10 (1–10)[c]
	Premenopausal ($n = 13$)	Mean (SD)	8.9 (1.04)	8.9 (0.95)	9.1 (2.47)
		Median (min-max)	9 (7–10)	9 (7–10)	10 (1–10)[c]
	Postmenopausal ($n = 5$)	Mean (SD)	9.0 (0.71)	7.6 (3.78)	9.8 (0.5)
		Median (min-max)	9 (8–10)	9 (1–10)[b]	10 (9–10)
	Unknown ($n = 3$)	Mean (SD)	8.7 (1.15)	8.3 (1.53)	8.7 (1.15)
		Median (min-max)	8 (8–10)	8 (7–10)	8 (8–10)
Did you feel irritation during use?[a]	All ($n = 21$)	Mean (SD)	8.8 (1.64)	8.5 (2.46)	8.6 (2.46)
		Median (min-max)	9 (4–10)	9.5 (1–10)[b]	10 (1–10)[c]
	Premenopausal ($n = 13$)	Mean (SD)	9.3 (0.75)	9.5 (0.67)	8.2 (2.95)
		Median (min-max)	9 (8–10)	10 (8–10)	10 (1–10)[b]
	Postmenopausal ($n = 5$)	Mean (SD)	7.4 (2.79)	5.0 (3.74)	9.5 (1.00)
		Median (min-max)	8 (4–10)	4.5 (1–10)[b]	10 (8–10)
	Unknown ($n = 3$)	Mean (SD)	8.7 (1.15)	8.3 (1.53)	8.7 (1.15)
		Median (min-max)	8 (8–10)	8 (7–10)	8 (8–10)

[a]Scored on a scale 1 – 10 (completely intolerable-not a problem at all).
[b]Score of 1 by a drop-out who could not remove the ring.
[c]Score of 1 by a drop-out due to vaginal irritation.

Table 5. Assessment of the ease of removal of the MedRing.

			Visit 2	Visit 3	Visit 4
Was removing the MedRing easy?[a]	All ($n = 21$)	Mean (SD)	7.5 (2.54)	8.1 (2.82)	8.1 (2.28)
		Median (min-max)	8 (1–10)[b]	9 (1–10)[c]	9 (3–10)
	Premenopausal ($n = 13$)	Mean (SD)	8.1 (1.44)	7.7 (3.33)	7.8 (2.59)
		Median (min-max)	8 (5–10)	9 (1–10)[c]	9 (3–10)
	Postmenopausal ($n = 5$)	Mean (SD)	5.4 (4.34)	8.8 (1.89)	9.3 (0.50)
		Median (min-max)	4 (1–10)[b]	9.5 (6–10)	9 (9–10)
	Unknown ($n = 3$)	Mean (SD)	8.3 (0.58)	8.7 (1.15)	7.7 (2.52)
		Median (min-max)	8 (8–9)	8 (8–10)	8 (5–10)
Did you feel irritation after the removal?[a]	All ($n = 21$)	Mean (SD)	8.6 (2.09)	8.6 (2.58)	9.4 (0.79)
		Median (min-max)	9 (1–10)[b]	10 (1–10)[c]	10 (8–10)
	Premenopausal ($n = 13$)	Mean (SD)	9.2 (0.90)	8.2 (3.11)	9.5 (0.67)
		Median (min-max)	9 (8–10)	10 (1–10)[c]	10 (8–10)
	Postmenopausal ($n = 5$)	Mean (SD)	7.2 (3.83)	9.8 (0.50)	9.3 (0.96)
		Median (min-max)	9 (1–10)[b]	10 (9–10)	9.5 (8–10)
	Unknown ($n = 3$)	Mean (SD)	8.3 (1.53)	8.7 (1.15)	9.3 (1.15)
		Median (min-max)	8 (7–10)	8 (8–10)	10 (8–10)
Was wearing the MedRing comfortable?[a]	All ($n = 21$)	Mean (SD)	9.0 (1.02)	NA	NA
		Median (min-max)	9 (7–10)	NA	NA
	Premenopausal ($n = 13$)	Mean (SD)	9.2 (0.80)	NA	NA
		Median (min-max)	9 (8–10)	NA	NA
	Postmenopausal ($n = 5$)	Mean (SD)	8.8 (1.30)	NA	NA
		Median (min-max)	9 (7–10)	NA	NA
	Unknown ($n = 3$)	Mean (SD)	8.3 (1.53)	NA	NA
		Median (min-max)	8 (7–10)	NA	NA

[a]Scored on a scale 1–10 (completely intolerable-not a problem at all).
[b]Score of 1 by a drop-out who could not remove the ring.
[c]Score of 1 by a drop-out due to vaginal irritation.
Abbreviation: NA: not applicable.

3.4.5. Irritation

The median irritation score during use and after removal was 9 (ranging from 4 to 10 and 1 to 10, respectively) at first use. It improved to 10 (ranging from 1 to 10 and 8 to 10, respectively) after three weeks of use (Tables 3 and 4).

3.4.6. Future use

Sixteen participants indicated they would choose the MedRing for future use, while two premenopausal participants were unsure. The participant who withdrew due to vaginal irritation stated that she would not use the MedRing. Two postmenopausal participants did not give their opinion.

3.5. Diary

3.5.1. Wearing comfort

Based on daily diary entries, the median comfort score ranged from 8 to 10 over the three weeks (Figure 2). Postmenopausal women rated comfort with a median score of 8 to 9, while premenopausal women gave a median score of 9 to 10. The lowest score of 3 was reported by a premenopausal participant who withdrew from the study on Day 12 due to vaginal irritation (Figure 2).

3.5.2. Bladder and bowel

Two participants had involuntary urinary loss at baseline; one of them was premenopausal and experienced an improvement, the other was postmenopausal, and she reported an increase in urine loss. Three participants reported an increased frequency of urination, increased bladder pressure (particularly during the first days of use), and decreased urinary force.

One participant with chronic constipation at baseline experienced an improvement while wearing the MedRing. Five participants each reported one of the following bowel effects: obstipation, darker stool color, abdominal cramps, less frequent defecation, and, in the first week, soft stools like those during menstruation.

3.5.3. Intercourse

Seven participants reported that the MedRing affected their experience during sexual intercourse. The participant who withdrew from the study due to vaginal irritation found sexual intercourse impossible while wearing the MedRing. This was also the case for one other participant, whose partner felt the ring during intercourse. Five other participants reported that either their partner (3), the participant herself (1), or both the participant and her partner (1) felt the MedRing during sexual intercourse.

3.6. Physician opinion

Before the first insertion, physicians expected no difficulties with self-insertion (median score of 1, range: 1 – 4). Hereafter, physicians also gave a median score of 1 (no problem at all) for all assessments (e.g. difficulties with self-insertion and self-removal, complications or bleeding, tolerability, preliminary removal, and early study termination). A score of 5 (worst case) for MedRing removal was given on four occasions: twice during Visit 2 for two postmenopausal participants and twice during Visit 3 for two premenopausal women. Two of these participants discontinued MedRing use.

3.7. Safety

Based on participant feedback, the MedRing was well tolerated. Five women reported mild AEs, all of which were assessed by the investigator as probably/possibly related to MedRing use. Two AEs led to discontinuation. The first discontinuation occurred on Day 1, involving a 66-year-old postmenopausal participant who was unable to remove the MedRing due to pelvic hypertonia, necessitating physician intervention for removal. The second discontinuation was by a premenopausal participant, 25 years of age, who removed the MedRing on Day 12 due to mild irritation of the vaginal wall. The other three AEs were vaginal discharge reported by a postmenopausal participant, and abdominal cramps and redness of the cervix/vagina reported by two premenopausal participants.

The vaginal inspections at each visit did not reveal any additional AEs. At follow-up, none of the participants reported any vaginal or other complaints.

4. Discussion

Systematic reviews underscore that the use of the currently marketed vaginal rings is generally well accepted, with rates ranging from 62% to 100% [11–13]. These rings typically

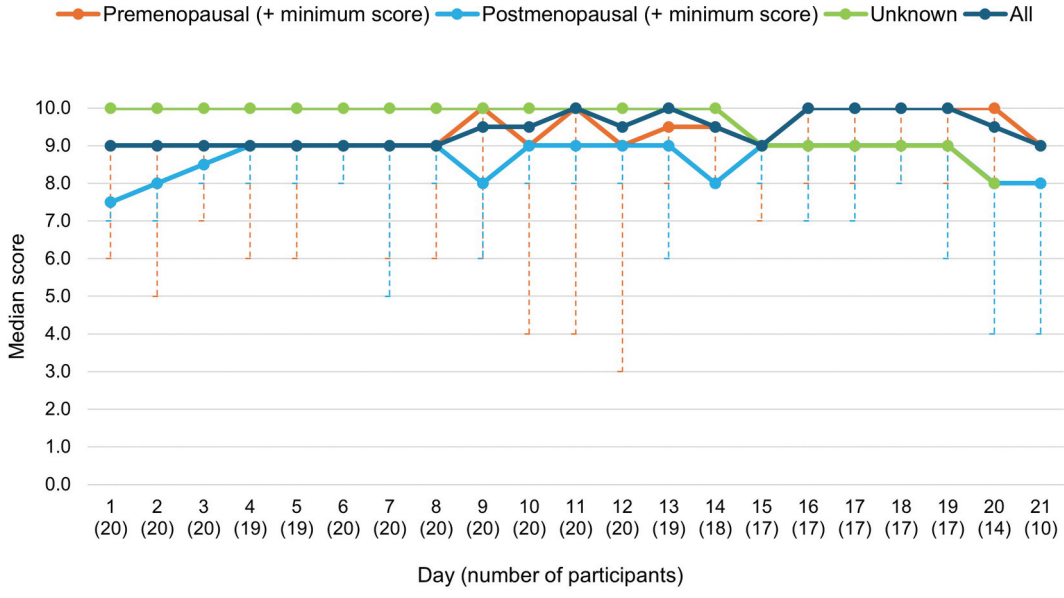

Figure 2. Comfort of wearing the MedRing based on diary entries.

feature polymeric or silicone bases that are soft and highly flexible, enhancing comfort during insertion and removal.

The MedRing is a vaginal drug delivery device with a polyethylene body and integrated microelectronics, which results in a thicker profile than conventional contraceptive or hormone replacement rings. Despite its added components, the MedRing remains thinner and more flexible than typical prolapse rings, which are designed for structural support and are therefore bulkier and more rigid. Although it is less flexible than traditional polymeric or silicone-based rings, the MedRing's unique shape allows it to be folded for easier insertion.

The MedRing can be used in a range of therapeutic applications, but its first application targets overactive bladder syndrome (OAB), aiming to deliver the individual's required dose of oxybutynin. Current oral treatments for OAB (e.g. oxybutynin) lead to side effects, resulting in low adherence and high discontinuation rates among patients [14]. While transdermal oxybutynin patches offer better tolerance, they can cause skin reactions [14]. The MedRing bypasses hepatic first-pass metabolism, thereby potentially minimizing anticholinergic side effects by reducing dose requirements and, more importantly, by reducing metabolism to N-desethyloxybutynin, a metabolite strongly associated with these side effects [10].

A short 6-hour pharmacokinetic study with the oxybutynin-filled MedRing already demonstrated good tolerability of the MedRing [9]. The current study assessed the acceptability of MedRing over a 3-week period, yielding a high median score of 9.5. Postmenopausal women initially rated acceptability lower (median score of 7), but it increased to 9 with extended use, suggesting familiarity enhances acceptability. Comfort ratings were high (median score of 9–10 in pre-menopausal women; 8–9 in postmenopausal women). Participants rated MedRing insertion and removal as easy (median scores of 10 and 9, respectively), contrary to their initial expectations. Some reported effects on nearby organs, such as the bladder and bowel, which diminished over time without causing discontinuation. Notably, symptoms of involuntary urine loss varied: one participant experienced worsening, while another saw improvement. Chronic constipation symptoms improved for one participant.

The presence of a vaginal device may also potentially influence sexual activity. Previous studies with contraceptive rings found that users or their partners sometimes feel the presence of the ring during sexual intercourse, but in general, this does not hinder their sexual activities [15]. Upon questioning, several participants or their partners indicated that they felt the MedRing during intercourse. For two participants, sexual intercourse was not possible during MedRing use; for one of them, this was due to vaginal irritation, and for the other, the reason was not specified.

Finally, the study physicians provided very positive feedback on the acceptability, ease of insertion, and removal of MedRing. This is important because the correct use and acceptance of new drug delivery systems, such as the MedRing, often require additional support and guidance from healthcare providers, who must trust the safety and efficacy of new medical devices before prescribing them, underscoring their crucial role in introducing these devices.

5. Conclusion

Overall, this study demonstrated that the MedRing was well-tolerated, highly accepted, comfortable to wear, and easy to insert and remove. Acceptability and comfort scores were comparable to those observed for currently available vaginal rings. Participants expressed satisfaction with MedRing's design, and nearly all indicated they would choose it in the future. Despite the study's small size and short duration, these findings are promising for the acceptance of the MedRing as a new vaginal drug delivery and monitoring system.

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Declarations of interest

C. van de Vaart was a study investigator at Bergman Clinics in Hilversum, the Netherlands; J. Veen was a study investigator at Máxima Medical Centre in Veldhoven, the Netherlands; M. Engberts was a study investigator at Isala Clinic in Zwolle, the Netherlands. M. Wiegerinck is an employee of LiGalli B.V., Leiden, the Netherlands. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Author contributions

All authors were involved in the design, analysis, and/or interpretation of the data and participated in drafting or revising the manuscript for intellectual content, and the final approval of the version to be published. All authors agree to be accountable for all aspects of the work.

Data availability statement

Any requests for data by qualified scientific and medical researchers for legitimate research purposes should be submitted in writing to LiGalli B.V., Leiden, the Netherlands.

Ethical statement

The center's ethics committee approved the study protocol and patient informed consent forms.

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