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Elasticity Improvement and Water Loss Prevention in Vulvar Skin by Topical Nonhormonal Moisturizer

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ABSTRACT

Background: Postmenopausal vulvovaginal symptoms due to estrogen depletion are very common. Many women prefer over-the-counter (OTC), Nonhormonal products containing few or no additives.

Objectives: We investigated the effect of a topical Nonhormonal moisturizer containing just mineral oil, white beeswax, emollients, and water.

Methods: Vulvar skin on 20 menopausal, asymptomatic women were measured before treatment with topical nonhormonal moisturizer, after one application, and after application twice daily for 7 days. Trans epidermal water loss (TEWL), elasticity, pH, and erythema were all measured on the inside of labium majus.

Results: The moisturizer was well absorbed by the skin (90%). TEWL decreased significantly by up to 51% ($p = 0.00021$). Elasticity increased up to 21% compared to baseline measurements ($p = 0.0014$). No objective changes in erythema or pH were observed after 1 week ($p > 0.13$). The asymptomatic women reported both positive and negative effects, the latter mainly greasiness. In symptomatic women the moisturizer may relieve dry vulvar skin. Improved elasticity may reduce irritation, laceration and bruising during physical and sexual activity.

Conclusions: The tested nonhormonal moisturizer showed pronounced elasticity improvement and water loss prevention in vulvar skin with no clinically relevant side effects. The study protocol was approved by the Danish Research Ethics Committees (no. H23030347).

Trial Registration: H23030347.

1 | Introduction

Progressive postmenopausal vulvovaginal atrophy is often associated with symptoms of dryness, itching, burning, and decreased elasticity. Vulvovaginal skin dryness is found in 50% of postmenopausal women [1], the symptoms being related to decreasing levels of estrogen [2] having a negative impact on women's intimate life, enjoyment of sexual intercourse, and sexual spontaneity [3, 4].

Only a minority of menopausal women receives prescribed hormonal replacement therapy (HRT), either from lack of professional medical attention, or due to personal concerns about HRT [5, 6]. In a Spanish study, only half of the patients on intrauterine estrogen treatment were content with the results [4]. The use of over-the-counter (OTC), nonhormonal moisturizers, alone or together with an intrauterine estrogen product, is very common. Numerous products are marketed, but customers are often confused by type of product, content, additives, and chemical substances [7]. Preferably,

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the manufacturers should limit the number of ingredients and avoid parabens, glycols, and preservative ingredients. The purpose of the product being rehydration of the vulvar skin and reduction of friction, it should not alter vulvovaginal pH, or cause irritation of the vulvar skin [1]. Most effect-investigating studies used questionnaires collecting subjective statements from participants [8], and only a few were based on objective measurements [9].

In this study, we applied a nonhormonal moisturizer to vulva, containing very few ingredients and no additives. We examined vulvar absorption of moisturizer and measured trans epidermal water loss (TEWL), elasticity, erythema, and pH on the inner surface of the right labium majus.

2 | Materials and Methods

2.1 | Study Design and Test Person Recruitment

The purpose of this study was to examine the effect of a non-hormonal moisturizer on vulvar skin of healthy, asymptomatic, postmenopausal women (an imperative to avoid altered vulva conditions caused by e.g., the menstrual cycle). The study design was approved by the Danish Research Ethics Committees (no. H23030347).

Exclusion criteria: Substance abuse, dementia, genital complaints, gynecological disease, regular use of other skin moisturizers in the vulvar area.

We used “Dr. Warming Critical Care (WCC) Intim Creme,” a moisturizer with no additives containing only paraffinum liquidum (mineral oil), cera alba (white beeswax), cetyl palmitate (emollient), and water.

The following tests were performed on 20 healthy, asymptomatic, postmenopausal women, recruited via social media and personal contacts. All women completed the study.

Measurements on the inner surface of the right labium majus were performed by a trained nurse with the test person positioned on a gynecological examination bed.

2.2 | Test Scenarios

1. Examinations with no treatment or intervention for at least a week before study start (baseline measurements).
2. Effect of 1 application on the entire vulva, measured half an hour after application of 500 mg WCC.
3. Effect of home application of WCC on the entire vulva, twice daily for 1 week by the participants. A brand-new, sealed tube of WCC was weighed and subsequently handed to each participant.

2.3 | Methodologies

1. Measurement of mucus/moisture/WCC absorbable from vulva, using Whatman Grade 40 filter paper (Product No.

1440-090, Cytiva, Massachusetts, USA), placed between labia for 1 min and weighing the paper before and after application of WCC. In all three scenarios, this procedure was performed before all other measurements.

All measurements in Section 2, 3, 4, and 5 were performed on the inner surface of the right labia majora.

2. Measurement of erythema (increased erythema may indicate vulvar skin irritation caused by WCC) was performed as erythema index with a Colorimeter DSM-4 (Cortex Technology ApS, Aalborg, Denmark).
3. Measurement of trans epidermal water loss (TEWL) evaporation rate was performed with a DermaLab TEWL Probe (Cortex Technology ApS, Aalborg, Denmark).
4. Measurement of pH-value was performed with a DermaLab pH-probe (Cortex Technology ApS, Aalborg, Denmark), calibrated to pH 4, and pH 7, respectively.
5. Measurement of vulvar elasticity was performed with a DermaLab Elasticity Probe and a pump module for the DermaLab Combo 4 (Cortex Technology ApS, Aalborg, Denmark). The suction force to lift vulvar skin 1.5 mm from base level was measured with the detector fixed to the vulva with a sticker.
6. All participants stated their opinion on the negative and positive effects of one application, and again after 1 week of using WCC. We also asked if they wished to continue using WCC after study completion.

2.4 | Statistical Analysis

All comparisons between the three scenarios were done as nonparametric paired tests (Wilcoxon signed rank test) using SPSS for Windows, version 29. The relation between measured parameters were examined using Spearman's correlation. All measuring results are described with median and range (minimum – maximum) values. All tests are two-sided and p -values ≤ 0.05 are considered significant.

3 | Results

3.1 | Personal Characteristics

Participants' median age was 65.5 years (range 51–86), and median weight was 63.4 kg (range 50–76), corresponding to a median BMI of 23.3 (Table 1).

3.2 | Measurements and Test Results

We performed a series of measurements according to each scenario (Table 2).

Blotting paper was used to measure fluid, mucus, and excess WCC between the labia. Before treatment, the median absorbed amount was 5.0 mg (range 1–35). Half an hour after one application of 500 mg WCC the median absorbed amount was 56.5 mg (range 11–134), a significantly larger amount with

TABLE 1 | Personal, demographic, and clinical data on test participants and data from one week of treatment with WCC.

ID	Age	Weight	Height	BMI	Pregnancies	Estrogen treatment	Number of applications	Mg WCC per application	Hours from last application to measurements
1	61	52.5	158	21.1	0		14	210	10
2	65	71	171	24.3	3		14	220	9
3	54	62	163	23.4	2		14	440	8
4	60	66	163	24.9	5		14	640	10
5	64	59	169	20.7	3	X	13	690	18
6	55	76	163	28.7	2	X	14	640	9
7	51	70	162	26.7	2		14	220	6
8	59	75	174	24.8	2		14	360	10
9	86	51	154	21.5	2		14	860	8
10	80	62.5	165	23.0	2		14	360	5
11	71	65	160	25.4	1		15	330	1
12	72	62	171	21.2	1		14	290	4
13	53	57	166	20.7	1		14	570	10
14	74	55	160	21.5	2	X	14	640	6
15	74	50	156	20.6	4		16	380	8
16	68	69	160	27.0	2		12	420	8
17	67	57	167	20.5	2		14	500	6
18	66	66	169	23.2	1	X	13	540	8
19	59	67	162	25.6	2		15	870	4
20	67	75	175	24.5	3	X	11	730	9

applied WCC than before treatment ($p = 0.0000019$), despite being only 11.3% of the applied amount (Figure 1A).

During 1 week of treatment, the median amount of WCC per application was 470 mg (range 210–870), and median number of applications was 14 (range 11–16). Median measurement time after last application was 8 h (range 1–18), (Table 1).

The median amount absorbed by the blotting paper after 1 week of treatment was 9.5 mg (range 0–22). This was not significantly larger than before treatment which means that all WCC had been absorbed (Figure 1A).

A slight increase in erythema was seen from scenario 1 to 2 and from 2 to 3. There was only a significant increase between scenario 1 and 2 ($p = 0.039$), indicating minor or no irritation by WCC (Figure 1B).

Trans Epidermal Water Loss (TEWL) decreased significantly from 56.8 g/m²/h before WCC application to 27.7 g/m²/h after one application, and to 38.5 g/m²/h after multiple applications. All differences between medians were significant ($p \leq 0.00017$) (Figure 1C).

Acidity (pH-value) of the vulva was not affected by the treatments, pH-value was 5.8 before treatment, 5.7 after one treatment, and 5.6 after multiple treatments.

Elasticity increased after both one and multiple treatments, and the suction force needed to lift the skin of the vulva by 1.5 mm decreased. No significant difference in median values were found between single use (284 MPa) and multiple (261 MPa), ($p = 0.097$), but the force to lift the vulvar skin at baseline (before treatment) was significantly bigger (330 MPa). Elasticity was significantly improved after both single use ($p = 0.032$) and multiple use ($p = 0.0014$), (Figure 1D).

Test results are listed in Table 3.

3.3 | Measurement Correlations

No significant correlation was found between TEWL and elasticity. No significant correlation was found between age and TEWL, elasticity, erythema, pH, or weight of absorbed amount by the blotting paper. No significant correlation was found between weight of absorbed amount by the blotting paper after multiple use and time from last application of WCC. Number of previous pregnancies had no relation to TEWL and elasticity.

3.4 | Benefits

After using WCC, 9 women (45%) stated beneficial effects after one single use: 6 women stated a comfortable feeling from the fat content in WCC, 1 woman stated less itching, 1 woman

TABLE 2 | Clinically relevant individual measurements from the study on WCC. Before application of WCC (1), after one application of WCC (2), after treatment twice daily for a week with WCC (3). See method section, and median values in Table 3.

ID	1		2		3		1		2		3		1		2		3	
	Absorbed mg fluid/WCC	Absorbed mg fluid/WCC	Absorbed mg fluid/WCC	TEWL g/m ² /h	TEWL g/m ² /h	TEWL g/m ² /h	Elasticity MPa	Elasticity MPa	Elasticity MPa	Elasticity MPa	Elasticity MPa	Elasticity MPa	Erythema Arb. units	Erythema Arb. units	Erythema Arb. units	Erythema Arb. units	Erythema Arb. units	Erythema Arb. units
1	5	63	13	60.7	35.5	50.5	1027	3688	734	23.1	23.3	29.6						
2	2	66	2	35.5	30.0	33.6	1879	1778	1173	22.8	24.6	23.0						
3	35	121	13	70.1	25.9	55.8	2189	1790	265	26.7	30.7	33.8						
4	5	83	5	52.2	20.1	30.7	1374	743	260	28.1	32.0	30.2						
5	27	73	13	78.8	60.2	64.3	587	230	138	26.2	29.8	32.2						
6	14	134	11	24.5	18.8	29.8	284	260	261	31.2	32.5	36.5						
7	5	90	22	70.2	43.0	58.5	243	206	204	34.8	36.0	32.6						
8	4	15	6	46.4	19.1	47.4	159	155	125	30.8	31.1	31.6						
9	1	38	5	60.4	17.0	29.0	1573	750	665	26.3	31.0	27.6						
10	6	78	12	37.8	24.3	34.3	319	431	318	26.7	26.6	25.8						
11	5	58	14	25.4	10.9	32.5	303	155	273	34.5	38.1	28.7						
12	6	83	9	76.7	27.3	57.1	819	303	476	25.2	25.8	24.2						
13	5	44	19	63.9	29.9	37.3	172	152	275	35.9	33.7	32.8						
14	6	43	7	43.5	21.8	34.1	335	264	1168	24.6	25.5	31.5						
15	3	11	0	40.6	28.1	28.7	1344	624	198	33.7	32.9	30.6						
16	17	37	22	60.9	23.1	56.5	309	538	172	37.8	26.9	34.6						
17	4	15	5	53.2	40.4	47.6	206	190	196	30.2	29.2	35.8						
18	5	55	6	80.5	48.3	32.8	324	176	161	26.6	28.5	33.5						
19	4	18	6	69.3	37.7	63.0	1006	1037	223	22.6	26.3	21.6						
20	7	37	10	49.6	28.9	39.6	185	149	166	24.4	24.3	34.7						

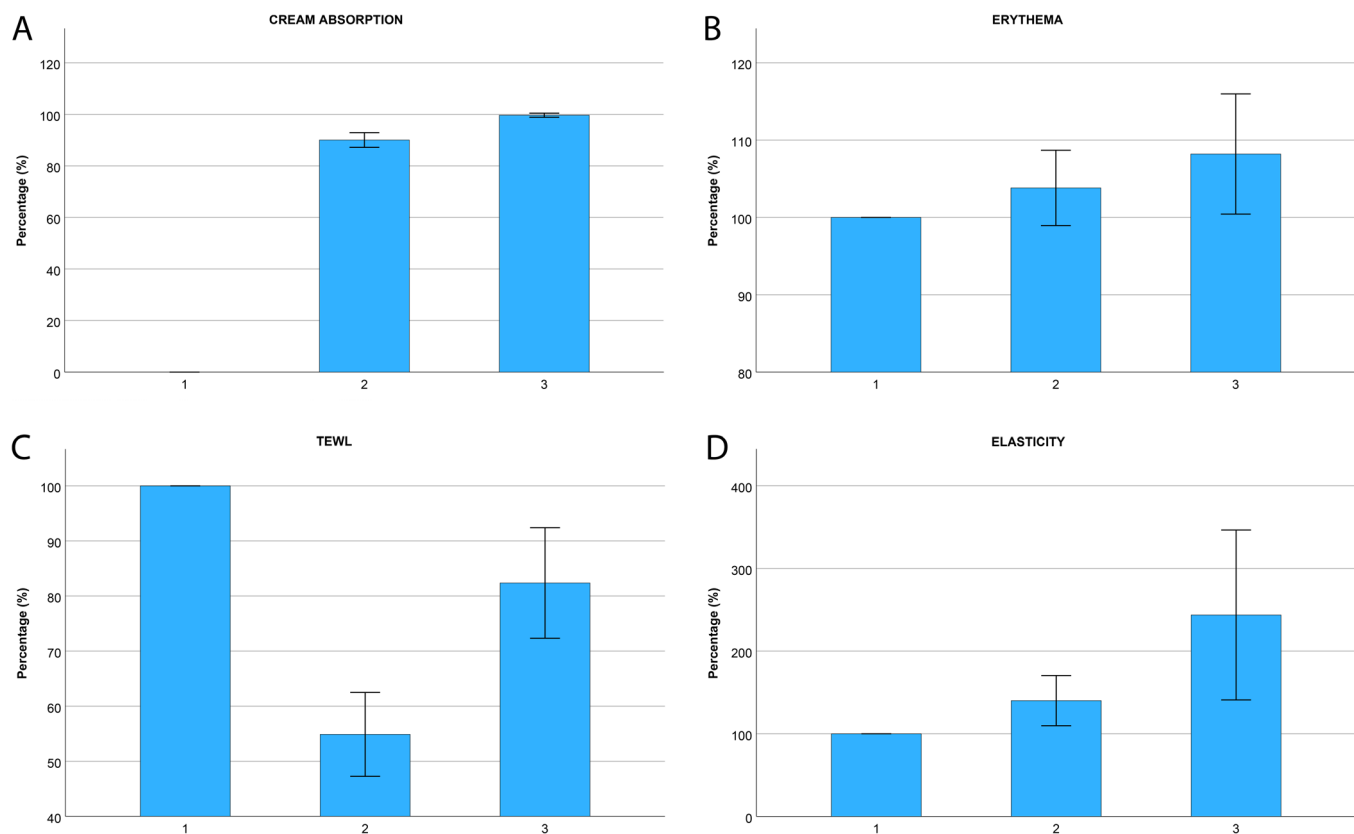


FIGURE 1 | (A) % of WCC absorbed, (B) Erythema compared to before treatment, (C) % reduction in TEWL, and (D) increase in vulvar skin elasticity compared to before treatment. Column 1: Before WCC application; Column 2: 30 min after one application; Column 3: 8 h after application twice daily for 1 week. Error bars 95% confidence interval. WCC, Dr Warming Critical Care Intim Creme; TEWL, trans epidermal water loss.

TABLE 3 | Median values for measurements during 3 different scenarios: (1) before treatment, (2) after one single treatment, and (3) after one week of treatment.

Order of measurements		Median			Statistics		
		1 No treatment	2 WCC × 1	3 WCC 7 days	<i>p</i> = 1–2	<i>p</i> = 1–3	<i>p</i> = 2–3
1	Blotting paper (mg)	5.0	56.5	9.5	0.0000019	0.11	0.0000019
2	Erythema index (Arb. Units)	26.7	29.5	31.6	0.039	0.13	0.36
3	TEWL (g/m ² /h)	56.8	27.7	38.5	0.0000019	0.00021	0.00017
4	pH (0–14)	5.8	5.7	5.6	0.86	0.20	0.20
5	Elasticity (MPa)	330	284	261	0.032	0.0014	0.097

Note: The *p*-values for significant differences between the scenarios are in bold. 1: Baseline. 2: Single treatment. 3: One week of treatment.

stated less friction, and 1 woman had a cooling effect, even though all women claimed to be asymptomatic at study inclusion. After multiple applications of WCC, 14 women (70%) stated beneficial effects: 7 women had less dryness/itching, 3 described a nice softness, 2 had less irritation related to bathing and towel-drying the area, and 1 experienced less friction.

3.5 | Side Effects

After one application, 5 of 20 women (25%) stated genital issues: 2 women stated a greasy, moist sensation, 1 stated a sensation of

warmth, and 1 stated a sensation of needles and pins, and 1 stated itching.

After 1 week, 8 of 20 women (40%) stated genital issues: 7 women stated a greasy sensation, and 1 woman stated a sensation of discharge.

After study completion, 14 women (70%) wished to continue with WCC: 2 women wished to continue application twice daily, 7 women once daily, and 5 women occasionally (preferably weekly). Six women (30%) wanted to discontinue the use of WCC.

4 | Discussion

This study applies a well-established methodology to examine changes in skin condition [10–12] but it has rarely been used to examine vulvar skin changes [9]. We examined the objective effects of a moisturizer with few ingredients and no additives, perfume, silicone, or preservatives, applied to skin on the inner surface of the labium majus. We investigated if objective effects could be measured after use of a basic, nonhormonal OTC product [1]. WCC was chosen on the assumption that moisturizers with a more complex composition might have a similar effect.

To minimize variables, we only included healthy, asymptomatic, postmenopausal women stating no vulvovaginal symptoms, assuming that an objective effect on this group would also be present in symptomatic women. We found significantly reduced TEWL, less dryness, and increased elasticity in our test persons, expecting a reduction of irritation, laceration, and bruising during physical and sexual activity in women with vulvovaginal complaints. It may also have a preventative effect on skin tearing during vaginal childbirth [13].

The moisturizer being non-irritative is vital to safety of use [1]. We measured posttreatment erythema of the vulva and found a small, immediate increase in erythema after a single application, but not after use twice daily for 1 week. Measurement of erythema depends on unaltered light penetration through epidermis which may have been affected when measuring on skin shortly after application of emollient, as shown by Berne et al. [14], although this fact has been disputed by Fetil et al. [5]. The faint increase in acute erythema may be caused by the manipulations of the skin area associated with baseline measurements before initial application of WCC.

To establish identical measuring conditions and gain insight into WCC absorption speed, excess moisture, mucus, and WCC were removed by blotting paper before all measurements. After half an hour 90% was absorbed, and after 8 h all WCC was absorbed. At this point of time, TEWL and elasticity were significantly improved. For data control, similar measurements were performed on a person's forearm for easy observation, and identical values were obtained, strengthening the finds on vulvar skin. Due to risk of infections, vulvar skin pH should not be affected by the product [15], and we found no change in pH levels during the study. This study provides knowledge about objective effects of emollients on vulvar skin and may be useful to practising clinicians when advising their patients seeking symptom relief from non-hormonal creams.

5 | Limitations

Women with vulvovaginal symptoms are not the focus of this study. Performing the measurements on asymptomatic women is a limitation to the study as the use of moisturizers will normally be motivated by some form of complaint. However, our participants may have had some unrecognized issues relieved by the WCC, agreeing with their wish to continue the use.

6 | Conclusion

The topical nonhormonal moisturizer investigated in this study did not alter pH levels. Both with single application and multiple use the WCC showed effect on elasticity improvement and water loss prevention in vulvar skin, and may relieve dryness, irritation and lacerations.

Author Contributions

Hans Christian Wulf planned and performed the study and wrote the manuscript. Peter Alshede Philipsen performed statistical analysis and evaluations. Catharina Margrethe Lerche planned the study and wrote the Danish Research Ethics Committees application.

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Ethics Statement

All participants in the study gave written informed consent to participate in the study and the use of their deidentified, anonymised, aggregated data. The study protocol was approved by the Danish Research Ethics Committees (no. H23030347).

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data available on request due to privacy/ethical restrictions.

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