

Are There Marketed Optimal Options for Female Sexual Pain? A Review and Preliminary Evidence of a New Water - Based Vaginal Lubricant



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Introduction

Female sexual pain (FSP) disorders are one type of female sexual difficulty that affects women's sexual and reproductive health and they are poorly understood and often misdiagnosed [1]. They have a significant negative impact on a woman's health, self-esteem, relationships, quality of life, and work productivity. It can be difficult to identify a definitive cause of pain. The aim of this review was to investigate recommendations of treatments for sexual pain caused by lack of lubrication and to present the results of an identified treatment developed in accordance with latest evidence from scientific societies.

Outcomes

FSP is a common, distressing complaint in women of all ages that is under recognized and undertreated [2]. Definitions and terminology for female FSP are currently being debated. While some authors have suggested that FSP is not per se a sexual dysfunction, but rather a localized genital pain syndrome, others adhere to using clearly sexually related terms such as dyspareunia and vaginismus [2]. Sexual pain can be mild to severe, generalized or localized and can be present for any amount of time. Reported prevalence estimates for female sexual dysfunction and pain are challenging to determine as study designs may be influencing and contributing to the wide variation in published estimates [3]. The population prevalence of painful sex (dyspareunia) is estimated to vary from 3 to 18% globally and lifetime estimates range from 10 to 28% and approximately 15% of women might finally develop chronic dyspareunia [4,5].

Decrease of vaginal lubrication is highly likely to be the main cause of dyspareunia when no other diagnosed vaginal related pathology is present. Reasons for such decrease are numerous and include advancing age, hormonal changes, menopause, breastfeeding, stress, other conditions, and iatrogenic causes such as radiation and chemotherapy treatment

and antidepressant use [6]. First line treatments would include vaginal moisturizers and lubricants [7]. Although lubricants and moisturizers have demonstrated effectiveness, they differ in terms of their composition, and certain individual components may be of concern in specific situations. Therefore, it is important to choose the most appropriate lubricant or moisturizer to best suit the needs of the individual patient [6]. Different types of lubricants might be used being water-based lubricants associated with fewer genital symptoms in women, compared with silicone-based as well as having the advantage of being non-staining [6].

Lubricants are effective in relieving discomfort and pain during intercourse. Vaginal lubricants ease sexual intercourse as they minimize friction during penetration and neutralize vaginal pH to help sperm survival. According to WHO, the pH of the healthy vagina is normally in the range 3.8-4.5 and ideally a vaginal lubricant should have a pH of about 4.5. The preservation of water-based lubricants is easier if the pH is maintained below 7. For these reasons the pH recommended for this type of lubricants is 7 or less [8].

Following WHO's review, it is remarked that most commercial lubricants have high osmolalities (2000-6000 mOsm/kg). By comparison, the normal osmolality of female vaginal secretions is 260-290 mOsm/kg and in human semen it is 250-380 mOsm/kg. Ideally, the osmolality of a lubricant should not exceed 380 mOsm/Kg to minimize any risk of epithelial damage. Given that most commercial lubricants significantly exceed this value, imposing such a limit at this time could severely limit the options for sourcing personal lubricants for sector procurement and a need of developing optimal treatments is foreseen [8].

A preliminary clinical study with a water-based vaginal lubricant (Suzanne Lubricante®/ Ainara Lubricante®), developed considering the above referenced specifications

(osmolality<380 mOsm/Kg and pH 6.5), was conducted in female adult subjects treated for 3 weeks. A total of 20 female subjects, aged between 18 and 70 years old, with dry intimate are and 100% of sensitive intimate skin were recruited. Treatment was applied by the subject herself before sexual intercourse and in case of failure to comply with 2 sexual intercourses in one week, the product was applied twice weekly. Clinical examinations by dermatologists and gynecologists on Day 1 and Day 22 as well as a questionnaire to be filled in by the subject on Day 22 evaluated the acceptability and tolerability of the product. Analysis of the results obtained revealed on the whole a very good acceptability

of the investigational product in all subjects as regards irritation or discomfort. No abnormal clinical sign was observed by the Dermatologists and/or Gynecologists, after 3 weeks of application. No subject indicated to have had or observed, during the study, any cutaneous reaction, irritation or discomfort. Itching in the intimate zone was also tested according to a scale from 0 (few itching) to 8 (lot of itching) together with dryness on the intimate zone scored from 0 (few dryness) to 8 (lot of dryness). Significant statistical decrease of both symptoms were observed between Day 1 and 22 as shown in Table 1 & 2.

Table 1: Itching on the intimate zone.

	n	Mean and Standard Deviation (S.D)		Probability P: Wilcoxon Test	Variation Percentage #
		D1 Initial value	D22		
Itching on the intimate zone	20	4.30±2.08	0.35±1.18	0.0001	-94%

In bold: Significant statistical probability: p<0.05.

Variation regarding the initial values

Table 2: Dryness on the intimate zone.

	n	Mean and Standard Deviation (S.D)		Probability P: Wilcoxon Test	Variation Percentage #
		D1 Initial value	D22		
Dryness on the intimate zone	20	5.70±1.22	2.15±1.90	0.0001	63%

In bold: Significant statistical probability: p<0.05

Variation regarding the initial values

Table 3: Efficacy and Acceptability.

Suitable product for the skin of the intimate area	100%
Pleasant application of the product	95%
Easy application of the product	95%
Pleasant texture of the product	95%
The product has a lubricant effect of the intimate zone	95%
The product helps to relieve the dryness of the intimate Zone	100%
The product acts as your natural lubrication	90%
Efficient product from the beginning	90%
The lubricant effect appears immediately after the application	100%
The lubricant effect duration is prolonged during all the sexual intercourse	90%
You would use this product in habitual use in your sexual intercourse	90%
The use of this product improves the sexual intercourse	95%
The product improves the penetration and it soothes the comfort during the sexual intercourses	95%
The product provides a comfort sensation	95%
The product provides a lasting comfort sensation	85%
The product does not stain on the clothes after its application	100%
Globally, I like the product	90%
Your partner likes the product from "a lot" to "enough"	85%
Your partner finds that the product is pleasant	85%
By comparing with the product generally used, the subject found her skin " just as good" to "better"	100%

The evaluation of the efficacy and acceptability questionnaire showed a positive judgement and a favorable appraisal of these subjects and their partners for all assessed criteria as shown in Table 3. Between its favorable effects, it must be outlined its immediate lubricant effect after application, together with its prolonged duration throughout all the sexual intercourse, particularities not always achieved by this type of products. Subjects were also asked about their partners' acceptability of the product, obtaining a very positive result.

Conclusion

This brief review highlights the importance of treating sexual pain associated with lack of lubrication with suitable products. Scientific societies have a view on this matter and identify certain characteristics in order to choose the most appropriate alternative. Currently there are many different options available on the market but it was addressed that many of them do not comply with their recommendations. The study describes a product, developed with ideal osmolality and pH, which provides a very good efficacy in improving symptoms like itching and dryness besides the optimal subject's acceptability.

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