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ORIGINAL ARTICLE

The effects of Femore™ cream on sexual dysfunction in Turkish women

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Aims and objectives. To investigate the effects of Femore™ cream on sexual dysfunction in menopause and women's satisfaction levels.

Background. The recent interest of public and the world of medicine in female sexual function have led to a rapid increase in the number of studies on the subject.

Design. The study was designed as an observational intervention study.

Methods. The research data were collected by using a Women Information Form consisting of 13 items; a Sexual Function Index to measure sexual function; and a Satisfaction Determination Form to determine the level of satisfaction with the medical service the women received for the problems with their reproductive organs. The study was conducted with 29 menopausal women who complied with the inclusion criteria.

Results. It was found that women's average age was 52·6; that the average menarche age was 13·0; and that the average menopause age was 46·2. The major complaint of nearly all the women who were aware of their sexual dysfunction was vaginal dryness, and it was concluded that they took no precautions against this problem. The total scores obtained from the Sexual Function Index were reported to be an average of 18·8 ± 4·2 before use of Femore™ cream and an average of 42·3 ± 2·0 after use of Femore™ cream. The average score concerning satisfaction with the use of Femore™ cream was noted to be 9·06 ± 0·40.

Conclusions. The study results suggested that applying Femore™ cream had positive influences on sexual dysfunction and all subdomains.

Relevance to clinical practice. Women's sexual health can therefore be assessed at primary care centres, and it is considered that health professionals employed at these centres, a majority of whom are female nurses and obstetricians, can play an important role in guiding women on the issue.

Key words: menopause, sexual health, sexuality

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Introduction

The individual experience of menopause is the result of a complex interplay of biological, psychosexual and socio-relational factors, which influence the woman's ability to cope with a life period characterised by significant changes. The experience of climacteric symptoms and complaints may negatively affect the sense of physical and mental well-being together with changes in relationship, family and social life. Collectively, the menopausal transition is a turning point for many women with a potential impact on sexual attitudes and behaviour (Nappi & Lachowsky 2009).

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Female sexual dysfunction (FSD) is regarded as a major clinical condition, and it has a far reaching influence over many women's quality of life. FSD can be characterised with continuous or recurring reduction in sexual motivation, not enjoying sexual activity, arousal difficulty, difficulty in having orgasm as well as experiencing pain during intercourse. FSD is resulted from multidimensional reasons commonly associated with hormonal changes in the postmenopausal period and psychological problems like stress, fatigue and depression (Modelska & Cummings 2003). FSD is an age-related and progressive problem widely affecting almost 30–50% of women. In contrast to the advancements in the field of male sexual dysfunction, a well-established diagnostic classification for female sexual dysfunction has not been devised, and besides, the number of studies on the subject is limited. As a result, the path physiology, psychology and treatment regarding female sexual function have not been clarified yet. The recent interest of public and the world of medicine in female sexual function have led to a rapid increase in the number of studies on the subject (Guvel *et al.* 2003).

Results of a variety of studies on female sexual dysfunction conducted in Turkey and abroad are as follows: It was found that the prevalence of sexual dysfunction was below 50% on average (Cayan *et al.* 2001, Yeni *et al.* 2001, Laumann *et al.* 2005, Demirezen *et al.* 2006, Oksuz & Malhan 2006, Yánez *et al.* 2006, Avis *et al.* 2009, Verit *et al.* 2009, Maserejian *et al.* 2012). Verit *et al.* (2009) and reported that the levels of sexual dysfunction were low among postmenopausal women (16·3 ± 8·2) and premenopausal women (24·8 ± 8·0), but sexual dysfunction was more common among postmenopausal women comparatively (Verit *et al.* 2009).

The prevalence of sexual dysfunction is obviously affected by various factors (Laumann *et al.* 1999, 2005, Cayan *et al.* 2001, Yıldız 2002, Demirezen 2006, Yánez *et al.* 2006, Shifren *et al.* 2008, Avis *et al.* 2009, Maserejian *et al.* 2012), among which are age, marital status, level of education, ethnicity, stress, general health, socio-economic status, sexual experiences, obesity, hyperlipidaemia, high blood pressure, heart disease, use of alcohol/cigarettes and menopause. Women who suffer from sexual problems tend to share their problems with their partners rather than doctors or health professionals (Mercer *et al.* 2003, Nazareth *et al.* 2003, Moreira *et al.* 2005, Elnashar *et al.* 2007).

Research data on sexual problems among women in Turkey are limited, and there has been no wide-ranging research. Nevertheless, some clinical studies have shown that the issue is significantly widespread. Because sexuality is a taboo subject in society, the ability of women to express their complaints and to seek help is negatively affected. It is often emphasised in population-based studies that primary care centres can be key establishments in the collection of data. In our country, the services provided at primary care health centres are on the whole focused on women and children, and so these units are frequently visited by women. Women's sexual health can therefore be assessed at primary care centres, and it is considered that health professionals employed at these centres, a majority of whom are female nurses and obstetricians, can play an important role in guiding women on the issue (Demirezen 2006). Therefore, it is certainly believed that nurses can successfully inform and guide women with sexual problems when they are equipped with sufficient information about sexuality. Nurses are suggested to keep up with recent changes and adapt themselves to renovations in sexual health and consulting.

The study was designed as an observational intervention study to investigate the effects of Femore™ cream on sexual dysfunction in menopause and women's satisfaction with the use of the cream.

Methods

The study was conducted with women aged between 40–65 years who were registered at a Family Health Center in Manisa for one year. The population of the study was made up of 321 40–65-year-old women attending a Family Health Centre (ASM) in Manisa. At the first meeting, the women who agreed to participate were given two forms to fill in: the Women Information Form and the Index of Female Sexual Function (IFSF). The selected sample was composed of 36 women aged 40–65 years who attended the Family Health centre between the dates mentioned above. The participants were chosen from those who did not menstruate for at least one year and experienced sexual problems. The participants were also required to have at least a primary school degree. The women in the study were married and consented to participate in the study. Four women who did not want to participate in the post-test part of the study and three women who filled the data collection forms incorrectly or incompletely were later excluded from the study. The study sample, therefore, comprised of the remaining 29 women.

Application procedure and material

At the first meeting, the women who agreed to participate were given two forms to fill in: the Women Information Form and the IFSF. Women who were found to have prob-

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lems were given Femore™ cream and asked to use the cream at least three times a week for a period of four weeks. After each use of the cream, the women were requested to complete the Satisfaction Assessment Form, and the level of satisfaction was evaluated from the data thus collected. After the weekly application of the cream was specified, the completed forms were collected by home visits. After four weeks, the researchers asked the participants to fill in the IFSF and questioned about changes in their complaints. A separate control group was not used as the focus of the study was to compare IFSF point averages (before use of cream and after use of cream) of the women who experienced problems.

Femore™ is the result of a collaborative effort between medical professionals, women's doctors, medical research specialists and pharmacists who have sought to address the needs of women experiencing sexual dissatisfaction. Femore™ cream does not include any pharmaceuticals and hormones, and it is completely produced with natural ingredients proven to be safe and effective. Femore™ has been extensively tested among humans. Extensive research, patient interviews and product testing were conducted in order to provide the most safe and effective drug-free product that would richly enhance moments of intimacy for women. Gently massage product on the clitoris and adjacent area prior to intercourse. Femore™ is a nonprescription topical cosmetic cream that provides women with the opportunity to enhance intimate moments with greater intensity and pleasure within minutes of application and is effective up to one hour (Rite Care Pharmacy, Femore™ Intimacy Enhancement Cream For Women, 1999-2007, Cream Prospectus, CA)

Instruments

Main outcome measures used in the study were the Women Information Form consisting of 13 items and prepared in line with the literature to collect the data, the IFSF to determine the women's sexual functions and the Satisfaction Assessment Form to establish the level of the women's satisfaction with the methods used to examine the problems they experienced with reproductive organs. The 13 items in the Women Information Form inquired their age, level of education, features of the marriage, previous illnesses and operations, systemic diseases, use of cigarettes/alcohol, sexually transmitted diseases, age of first menstruation and menopause, pregnancy and birth. The IFSF was used to assess the women's sexual functions. The scale consists of nine items and questions women on problems experienced in sexual relations in the last four weeks. The maximum score in the scale is 49. The accepted cut-off value was found to be 30 for Turkey, and lower values were considered to signify sexual dysfunction. The scale has three subsections: the first is 'sexual fulfilment' and contains items 6, 7 and 8, the second is 'frequency of sexual relations/libido' and contains items 3, 4, 5 and 9, and the third is 'problems in sexual relations' and comprises scale items 1 and 2. The maximum score available in the first subsection is 16, in the second 21 and in the third 12. Higher scores are accepted as a more positive indication of sexual functions. The lowest point obtainable from the scale is approximately 9, whereas the highest point varies around 45. This index's validity and reliability studies were performed by Yılmaz and Eryılmaz (2004). The Cronbach's alpha reliability coefficient was found to be 0·82, and the index was considered to be suitable for implementation in Turkish society. The IFSF's Cronbach's alpha value was found to be 0·71 for the study population.

Visual Analogue Scale was used to grade women's satisfaction in Satisfaction Form to analyse the levels of satisfaction with Femore™ use. VAS evaluation is based on a ten-point grading: 1 and 2 too bad; 3 and 4 bad; 5 and 6 not bad; 7 and 8 good; 9 and 10 perfect.

Ethical approval

The necessary written permissions for use of the IFSF were obtained from Eryılmaz, who conducted the index's validity and reliability tests, from Ege University Nursing College Scientific Ethics Board and the relevant bodies associated with the establishment where the study was conducted. Before the meetings were held, the researchers informed the participants about the purpose, duration and practical benefits of the study, and the written consent of the participant was obtained accordingly.

Statistical analysis

Descriptive data are presented as number, percentage and mean. The data gathered from the groups were compared with Kolmogorow–Smirnow test, Wilcoxon signed rank test, paired smaple *t*-test and one-way ANOVA for repeated measures test. All analyses were carried out using SPSS for Windows, version 15.0 (SPSS, Inc., Chicago, IL, USA). A p value of $< 0{\cdot}05$ was thought to be crucial for all analyses.

Results

The analysis of personal information of women demonstrated that the age groups of participants were as follows: 10·3% in 43–47, 37·9% in 48–52, 41·4% in 53–57, 10·3%

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were over 58, and the average age was 52·62 ± 4·37. It was also reported that 75·9% of the women were primary school graduates, that 24·1% were secondary and high schools and that 75·9% were housewives. The analysis of the distribution of women according to their obstetrical and gynaecological features pointed out that the age of menarche was 11–13 for 69·0% of the women and the average age of menarche was 13·04 ± 1·44. The analysis also suggested that the age of menopause was 46–51 for 51·7% of the women and the average age of menarche was 46·24 ± 4·68. The results of the analysis further illustrated that 48·3% became pregnant for 1–2 times and 51·7% had given birth 1–2 times, while 89·7% had not had any miscarriages (Table 1). The major complaint of nearly all the women who were aware of their sexual dysfunction was vaginal dryness, and it was concluded that they took no precautions against this problem. The distribution of the IFSF and its subsections was analysed before the use of Femore™, and it was reported that the average scores of the sexual satisfaction subsection was 6·41 ± 1·86. The average score of the frequency of intercourse/libido subsection was 7·20 ± 2·38, while it was 5·24 ± 1·76 for the discomfort in intercourse subsection. The IFSF average score was 18·86 ± 4·28 (Table 2).

The distribution of scores in the IFSF and its subsections was also evaluated after the application of Femore™. It was concluded that the average score of the sexual satisfaction subsection was 12·24 ± 0·83, and the average score was 18·34 ± 1·56 for the frequency of intercourse/libido subsection. The average score was found to be 11·75 ± 0·43 for the discomfort in intercourse subsection, and the IFSF average score was 42·34 ± 2·05 (Table 2). The average subscale scores and average total scores of IFSF were compared before and after Femore™ use, which suggested a meaningful difference ($p < 0{\cdot}001$) (Table 3). The results also indicated that use of Femore™ cream positively affected sexual dysfunction problems and its subdomains.

The analysis of the satisfaction levels of the participant women illustrated that the average satisfaction score was 9·02 ± 0·66 in the first week, 9·04 ± 0·53 in the second week, 9·12 ± 0·59 in the third week and 9·09 ± 0·43 in the fourth week, while the overall satisfaction score was found to be 9·06 ± 0·40. The average scores were analysed with one-way ANOVA for repeated measures *t*-test, and it was noted that there was no difference between four measurements (Table 4), which confirmed that the participants were generally satisfied with the use of Femore™ cream and that the effect of Femore™ cream lasted as long as it was used.

There was a strong, positive and significant relation between women's IFSF average scores and their Femore™ application satisfaction average scores ($r = 0{\cdot}556$,

Table 1 Distribution of women according to their obstetrical and gynaecological features

Obstetrical and gynaecological features of women	Number of women	Percentage	Average
Age of menarche			
Between 11–13	20	69·0	13·00 ± 1·10
Between 14–15	9	31·0	
Age of menopause			
Between 34–39	4	13·8	46·24 ± 4·68
Between 40–45	8	27·6	
Between 46–51	15	51·7	
52 and above	2	6·9	
Number of pregnancies			
No pregnancy	2	6·9	2·55 ± 0·86
1–2 pregnancies	14	48·3	
3–4 pregnancies	8	27·6	
5–6 pregnancies	5	17·2	
Number of miscarriages			
Miscarriage	26	89·7	
No miscarriage	3	10·3	
Number of births			
No	2	6·9	
1–2	15	51·7	
3–4	7	24·1	
5–6	5	17·2	
Sexually transmitted diseases			
NA	29	100	
Awareness of sexual dysfunction			
Aware	5	17·2	
Not aware	24	82·8	
Total	29	100·0	

NA, not applicable.

Table 2 Distribution of points scored by women in the Index of Female Sexual Function (IFSF) and its subsections before and after the application of Femore™

IFSF and subsections	Number of items	Min–Max points scored	$\overline{X}$ ± SD
Before Femore™ application			
Sexual satisfaction	3	3·0–9·0	6·41 ± 1·86
Frequency of intercourse/libido	4	4·0–14·0	7·20 ± 2·38
Discomfort in intercourse	2	12·0–49·0	5·24 ± 1·76
Total IFSF	9	3·0–10·0	18·86 ± 4·28
After Femore™ application			
Sexual satisfaction	3	11·0–13·0	12·24 ± 0·83
Frequency of intercourse/libido	4	15·0–21·0	18·34 ± 1·56
Discomfort in intercourse	2	11·0–12·0	11·75 ± 0·43
Total IFSF	9	39·0–46·0	42·34 ± 2·05

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Table 3 Comparison of women's average Index of Female Sexual Function (IFSF) points before and after the application of Femore™

Femore™ application	Point average n	$\overline{X}$	Ss	t/z	p
Sexual satisfaction					
Before Femore™ application	29	6·41	1·86	−4·715†	0·000
After Femore™ application*	29	12·24	0·83		
Frequency of intercourse/libido					
Before Femore™ application	29	7·20	2·38	−4·711†	0·000
After Femore™ application*	29	18·34	1·56		
Discomfort in intercourse					
Before Femore™ application*	29	5·24	1·76	−4·731†	0·00
After Femore™ application*	29	11·75	0·43		
Total IFSF					
Before Femore™ application	29	18·86	4·28	−26·761‡	0·000
After Femore™ application	29	42·34	2·05		

*Kolmogorow–Smirnow test $p < 0{\cdot}05$.
†Wilcoxon signed ranks test, z value.
‡Paired smaple t-test, t-value.

Table 4 A comparison of average scores of satisfaction after Femore™ application

Femore™ application	Min–Max points scored	$\overline{X} \pm$ SD	F	p
First week	7·25–10·0	9·02 ± 0·66	–	–
Second week	7·75–10·0	9·04 ± 0·53	0·317	0·813
Third week	7·66–10·0	9·12 ± 0·59	–	–
Fourth week	7·75–10·0	9·09 ± 0·43	–	–
Overall satisfaction score average	7·60–10·0	9·06 ± 0·40	–	–

$p < 0{\cdot}001$) (Table 5). It was considered that the women's satisfaction with the use of Femore™ was related to the reduction in their sexual dysfunction.

Discussion

Female sexual dysfunction is regarded as a major clinical condition, which has a great impact on many women's quality of life. It can be described as a permanent or recurring reduction in sexual motivation or dislike for sexual activity, difficulty in achieving sexual arousal, inadequate orgasm achievement and pain during intercourse. FSD stems from multidimensional causes that include hormonal instabilities during the postmenopausal period and psychological factors such as stress, tiredness and depression. The National Health and Social Life Survey suggested that almost half of the female population has a dysfunctional sexual life in the United States (Modelska & Cummings 2003). Studies on the prevalence of female sexual dysfunction disorder affirmed that the percentages of women who experienced such problems have been specified by researchers as follows: the prevalence of sexual dysfunction ranged between 46–92% in several studies (Cayan *et al.* 2001, Laumann *et al.* 2005, Demirezen *et al.* 2006, Oksuz & Malhan 2006, Yánez *et al.* 2006, Avis *et al.* 2009, Maserejian *et al.* 2012). Although women with sexual dysfunction were included in the present study, it was also implied that only one-fifth of women were aware of this condition. The declining level of the serum oestrogen for women was reported to affect sexual response in the course of menopause. The decrease in oestrogen level causes vaginal atrophia, which leads to vaginal dryness and pain. This oestrogen decline among women in the course of menopause negatively affects sexual response which in turn increases the prevalence of sexual dysfunction (Gregersen *et al.* 2006, Howard *et al.* 2006). Verit *et al.* (2009) reported differences between the women's postmenopausal and premenopausal Female Sexual Function Index (FSFI) scores. Statistical differences were also found in this study between the pre- and postFemore™ use IFSF average scores of women with sexual dysfunction. An analysis of recent literature already maintained an increase in the prevalence of sexual dysfunction among menopausal women.

Table 5 Relational distribution of women's Index of Female Sexual Function (IFSF) and satisfaction point averages after the application of Femore™

$\overline{X}$	IFSF	Satisfaction point averages
X	42·34	9·06
Ss	2·05	0·40
n	29	29
r	0·556	
p	0·000 < 0·001	

Most of the studies are intended for diagnosis of the current situation rather than finding solutions to sexual dysfunction. This study, however, aimed at finding a solution for the relevant issue in the literature, which was considered to be achieved at the end of the study. The findings of this study comply with the relevant studies in the literature (Gregersen *et al.* 2006, Oksuz & Malhan 2006, Yánez *et al.* 2006, Shifren *et al.* 2008). Yánez *et al.* (2006) stated that there were more sexual dysfunction cases during the menopause period for women. Oksuz and Malhan (2006) concluded that menopause affects sexual dysfunction. The results of this study

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confirmed that all women complain about vaginal dryness but that they do not do anything to resolve the complaint. Elnashar *et al.* (2007) similarly acknowledged that 84·5% of the women do not receive any assistance for their sexual problems, and Nazareth *et al.* (2003) ascertained that 30% of the women consult a physician about their sexual problems, while Mercer *et al.* (2003) found that 21% of women with sexual problems seek assistance and 74·3% of these women consult a physician, with 4·8% visiting a gynaecologist's clinic. The fact that sex is a common taboo negatively affects women in terms of easily expressing their complaints and receiving assistance accordingly (Guvel *et al.* 2003). Social values and rules are important obstacles for women especially in raising their issues in this regard to healthcare professionals. Furthermore, these healthcare professionals overlooking this fact and not encouraging their patients to express their concerns lead to inadequate reporting (Yadav *et al.* 2001, Demirezen 2006).

It has been widely believed that sexual problems tend to increase with the decreasing levels of oestrogen in menopause. The results of our study affirmed that the use of Femore™ cream had positive influences on sexual dysfunction and its subdomains. It was also emphasised that the participant women were satisfied with the use of Femore™ cream and that its effect continued as long as it was regularly used. A woman's sexual dysfunction certainly influences her quality of life and constitutes a clinical case (Modelska & Cummings 2003). Both age and menopausal periods negatively affect a woman's sexual functions. It should not be forgotten that sex is a basic need of life. Failing to fulfil this need will result in the emergence of some psychological problems, a decrease in the quality of life, a poorer professional performance, in the severance of interpersonal contacts and in new health problems.

Conclusions

During the climacterium, women gained new experiences to reconsider their beliefs, to refuse or adopt taken for granted assumptions urged by other people, to enjoy a healthy relationship with their partners, to commit their energies to their families as well as raising awareness towards their rights as an independent person, which will certainly transform the way they perceive and manage their sexual life (da Silva Lara *et al.* 2009). In the light of the results of this study, it was reported that the use of Femore™ cream had positive effects on sexual dysfunction and its subdomains (Table 3). A positive, strong and significant relation between the average scores after using Femore™ and increasing levels of satisfaction indicated that the women's satisfaction with Femore™ was related to a decrease in their sexual dysfunction (Table 5). It was also shown that the participants were satisfied with the use of Femore™ and that its effect lasted as long as it was used (Table 4).

Currently in Turkey, primary healthcare services in our country are mainly focused on women and children, and therefore, these units are intensively visited by women. It is therefore thought that these primary healthcare services can be the place to assess women's sexual health, and all the female personnel (predominantly nurses and obstetricians) serving in these units can take an active role in guiding women on this matter. Therefore, it was concluded that nurses and midwives can find out the problems of sexual function by using IFSF and that they can provide guidance for women in case of sexual dysfunction by organising educational seminars or ensuring their transfer to healthcare centres. It is strongly recommended that initiatives on sexual dysfunction be integrated into women's health programmes to ameliorate sexual dysfunction among women, especially in traditional societies, like Turkey, where sexuality is still a taboo subject.

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Disclosure

The authors have confirmed that all authors meet the ICMJE criteria for authorship credit (www.icmje.org/ethical_1author.html), as follows: (1) substantial contributions to conception and design of, or acquisition of data or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, and (3) final approval of the version to be published.

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Conflict of interest

The authors declare no competing interests.

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