Laboratory Report

CASE STUDY

FEMINOL™

Test Units:

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Sponsor:

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EFFICACY AND SAFETY OF ORAL FEMINOL™ IN WOMEN WITH SEXUAL DYSFUNCTION
(AN OPEN-LABELED, FLEXIBLE-DOSE STUDY)

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Introduction

Although male sexual problems have long been the subject of intensive medical research, the equivalent problems in women have received relatively little attention until recently. The tremendous commercial success of the drug Viagra has prompted pharmaceutical companies to focus considerable attention on finding a comparable treatment for women.

Loss of libido, painful intercourse, and difficulty in achieving orgasm have troubled many women. Possible physical causes include side effects from drugs such as antidepressants or sedatives, hormonal insufficiency, or adrenal insufficiency.

Current conventional treatments for sexual dysfunction depend on its cause: counseling when the cause is psychological; switching or reducing dosage of drugs when they are at fault; hormone replacement therapy when there is a deficiency; treating the cause of painful intercourse; and correcting adrenal insufficiency. Drugs for sexual dysfunction are currently under active investigation.

Natural Sensation is the natural and safe way to assure optimal female sexual satisfaction every time. Orgasms occur much more easily, more quickly, more naturally and with much greater intensity without the pre-planning and negative side effects often associated with prescription drugs.

Female sexual response is heightened when blood flows into the genital tissue, particularly the clitoris and g-spot areas. This blood flow is naturally under the control of nitric oxide. The active ingredients of Natural Sensation, FEMINOL™ contains the same substance used by the body itself to produce nitric oxide which in turns improves and heightens female sexual response.

The natural FEMINOL™ is delivered to the genital tissue. this brings about increased blood flow resulting in heightened sensation in the clitoris, the g-spot and other female genital tissues. The result is all sexual chemistry in motion.

The role of nitric oxide in controlling blood flow was only recently discovered in 1998 resulting in a Nobel Prize for scientific discovery. From this discovery, researchers further discovered that the application of L-Arginine (Nitric Oxide) through Natural Sensation results in the production of a natural and optimal female and male sexual response.

To examine the effect of FEMINOL™ a open-labeled case study performed on 25 individuals along with questionnaire on to determine the efficiency of these products.

SUMMARY

OBJECTIVE: To evaluate the efficacy and safety of FEMINOL™ in an open-labeled pilot study in women with sexual dysfunction of broad-spectrum etiology with more than 3 months duration. METHOD: 25 women were enrolled in a 12-week prospective, open-labeled, flexible-dose study. Each woman received 1 capsule of FEMINOL™ in the morning every day and, as needed, took 1-2 capsules at night approximately 30 minutes to 3 hours before engaging in sexual activity. Efficacy was determined by the responses to question 3 (sexual desire), question 6 (sexual pain), question 9 (orgasm function) and question 13 (overall satisfaction of sex life) of the 14-item questionnaire. Other measures of efficacy and safety included the questions about the patient's medical history and questions about FEMINOL™. RESULTS: At the end of the study, there was a statistically significant improvement in 4 descriptive evaluations of the 14-item questionnaire. FEMINOL™ significantly increased the patient's sexual desire ($p<0.01$), orgasm function ($p<0.01$) and overall satisfaction ($p<0.01$) and decreased the pain during sexual activities ($p<0.05$). 68% of the patients reported an improvement in sexual arousal. No side effects were reported during this 12-week study. CONCLUSIONS: This study suggests that FEMINOL™ is an effective, well-tolerated alternative treatment for women with sexual dysfunction.

BACKGROUND

Many women suffer from Female Sexual Dysfunction (FSD). According to the *Journal of the American Medical Association*, more than 43% of American women (approximately 40 million women) experience some form of sexual disorder at some point in their lives. Physicians and other healthcare providers recognize FSD as a medical condition. It includes a variety of disorders that are related to the desire for sex (also called libido), arousal during sexual activity, problems with orgasm and pain during sexual activity. Since ancient times, there have been many types of folk medicines and pharmacological remedies focusing on men's sexual functions, but there has definitely been a lack of products and treatments for women's sexual functions. As a booster of sexual function especially designed for women, FEMINOL™ has increasingly become a popular product on the market. FEMINOL™ is a combination of botanical extracts using a proprietary, patent-pending technology called "Bio-Enhanced Extraction, (B.E.E.™)", from sweet potato B.e.E, myrtleB.E.E, cinnamon, palm dateB.E.E, damiana B.E.E,and passion flowerB.E.E, which specifically is designed to improve a woman's sexual function. FEMINOL™ has been on the market in the United States and in other countries for more than 3 years and has fully earned its users' confidence. In order to evaluate the efficacy and safety of FEMINOL™, we designed and performed this pilot study. In this report, we are presenting an open-labeled study involving 25 subjects who were given FEMINOL™ for a period of 12 weeks. The analysis of the data was based on 4 specific questions completed by these subjects at the beginning of the trial and also at intervals of 4, 8 and 12 weeks after taking FEMINOL™ initially.

MATERIALS AND METHOD

Subjects: 25 subjects (all females, ages: 26 to 68) were enrolled to participate in this study.

Selection criteria included:

1) Females 18 years and older

2) Having at least one of the symptoms of Female Sexual Dysfunction related to sexual desire, arousal during sexual activity, orgasm and/or pain during sexual activity.

Exclusion criteria included:

1) Currently dealing with uncontrolled, severe medical conditions, such as hypertension (SP >160mmHg and DP >100mgHg) and/or clinical cardiovascular disease (myocardial infarction, angina pectoris, coronary revascularization, stroke, and/or transient ischemic attack).
2) A history of clinical cardiovascular disease (myocardial infarction, angina pectoris, coronary revascularization, stroke, and/or transient ischemic attack).
3) A history of psychiatric or other medical conditions that may jeopardize compliance
4) Currently participating in another clinical trial.

Methods and Procedures:

After the R&D department of Hamida Pharma, Inc. approved the protocol of the study, the subjects were recruited from advertisements in the local community. Subjects were screened first with Questionnaire 1 (SEXUAL FUNCTION ASSESSMENT IN WOMEN AT THE BEGINNING OF THE STUDY OF FEMINOL™) (see attachment-1). An informed consent form was obtained from each subject before the beginning of the study, the procedures of the study were explained and a medical history review was completed. All the female subjects are patients currently coping with some type of sexual dysfunction. Based on information from Questionnaire-1, 72% (18/25) of the subjects had very low sexual desire or no sexual desire at all, 64% (16/25) of the subjects had low or very low genital sensation (sexual arousal) during sexual activities, 48% (12/25) of the subjects only achieved orgasm a few times or never had an orgasm and 36% (9/25) of the subjects had very severe or severe pain during sexual activities. 80% (20/25) of the subjects were “dissatisfied” or “very dissatisfied” with their overall sex life. 36% (9/25) of the subjects had sexual concerns of a psychological nature and 40% (10/25) of the subjects had sexual concerns of a physical nature. The other subjects’ situations were uncertain.

At the beginning of the study, each subject was given open-labeled FEMINOL™ product and instructions on how to take FEMINOL™ as well as recommendations on their overall lifestyle. Each subject took 1 capsule in the morning daily for 12 weeks and, as needed, took 1-2 capsules approximately 30 minutes to 2 hours before engaging in sexual activities.

Each subject finished and submitted Questionnaire 2 (SEXUAL FUNCTION ASSESSMENT IN WOMEN AFTER THE ACTUAL TRIAL OF FEMINOL™) (see attachment-2) separately at the end of 4 week, 8 week and 12 week intervals after taking FEMINOL™ initially,

RESULTS

The compliance of this study and the acceptance of FEMINOL™ were satisfactory. 25 subjects completed the 12-week trial period. 22 subjects took FEMINOL™ every morning for 12 weeks without interruption and also took 1-2 capsules before engaging in any type of sexual activity. 3 subjects (3/25) took FEMINOL™ inconsecutively, 2 of them took FEMINOL™ only before engaging in sexual activities and the other 1 subject took FEMINOL™ before engaging in activities, but she also took 1 capsule in the morning intermittently. All 25 subjects reported no side effects during the 12-week study. The effects of FEMINOL™ in the women’s sexual desire, orgasm function, pain level during sexual activities and overall satisfaction of sex life were evaluated statistically and the results are shown on Table 1 to Table 4.

Table 1. Sexual desire

Scores\Time	Before	After		
	Baseline	In 4 weeks	In 8 weeks	In 12 weeks
1. Very low or none at all	6	0	0	0
2. Low	12	6	2	1
3. Moderate	5	14	18	14
4. High	2	5	4	6
5. Very high	0	0	1	4
Mean scores ± S.E.	2.12±0.18	2.96±0.14**	3.00±0.13**	3.52±0.16**

n=25, **P<0.01 (Significant difference compared with baseline)

Table 1 shows the changes in the sexual desire reported by 25 subjects. 6 subjects reported "very low" desire and 12 subjects reported "low" sexual desire at the beginning of the study. At the end of 12-week study, only 1 subject reported "low " sexual desire. 24 subjects reported "moderate", "high" or "very high" sexual desire. The mean score increased from 2.12 at the beginning of the study to 3.52 at the end of 12-week period. The increase of scores at the end of 4, 8 and 12 week periods were statistically significant compared with the baseline value ($p<0.01$).

Table 2. Frequency of sexual orgasm

Scores\Time	Before	After		
	Baseline	In 4 weeks	In 8 weeks	In 12 weeks
1. Almost never or never	4	3	3	2
2. A few times (less than half the time)	8	3	2	2
3. Sometimes (about half the time)	11	12	9	5
4. Most times (more than half the time)	4	7	9	14
5. Almost always or always	0	0	2	2
Mean scores ± S.E.	2.52±0.19	2.92±0.19	3.20±0.22*	3.48±0.21**

n=25, *P<0.05, **P<0.01 (Significant difference compared with baseline)

Table 2 shows the change in frequency of sexual orgasm during sexual stimulation or intercourse by all 25 subjects. 4 subjects reported "never or almost never" having feelings of orgasm and 8 subjects reported having feeling "a few times". Only 4 subjects reported that they had orgasms most of the time at the beginning of the study. At the end of 12 weeks, 4 subjects "almost never or never" had an orgasm or had an orgasm only "a few times". 16 subjects reported that they had an orgasm most of the time or always when they had sexual activities. The mean scores increased from 2.52 at the beginning of the study to 2.92, 3.20 and 3.48 at the end of 4, 8 and 12 week periods. Compared with the baseline value, the changes at the end of 8 and 12-week periods were significant ($p<0.05$ & $p<0.01$).

Table 3. Sexual pain during sexual activities

Scores\Time	Before	After		
	Baseline	In 4 weeks	In 8 weeks	In 12 weeks
1. Very severe	3	2	1	2
2. Severe	6	3	1	2
3. Moderate	6	5	7	9
4. Light	5	7	6	4
5. Very light or not at all	5	8	10	9
Mean scores ± S.E.	3.12±0.27	3.64±0.26	3.92±0.22*	3.64±0.26

n=25, *P<0.05, (Significant difference compared with baseline)

Table 3 shows the changes in sexual pain during sexual activities reported by the 25 subjects. 9 subjects reported “very severe” and “severe” sexual pain during sexual activities at the beginning of the study. At the end of 4-week study, 5 subjects reported” very severe” and “severe” painexisted during sexual activities. At the end of 8-week study, 2 subjects reported “very severe“and “severe” pain existed during sexual activities. At the end of 12-week study, 4 subjects reported “very severe” and “severe” pain. The results show the improvements in reducing sexual pain at the end of 4, 8 and 12-week study. The mean score increased from 3.12 at the beginning of the study to 3.64 at the end of 4-week period, 3.92 at the end of 8-week period and 3.64 at the end of 12-week period. The increase of scores at the end of 8 week periods were statistically significant compared with baseline value ($p<0.05$).

Table 4. Overall satisfaction of sex life

Scores\Time	Before	After		
	Baseline	In 4 weeks	In 8 weeks	In 12 weeks
1. Very dissatisfied	10	3	2	2
2. Moderately dissatisfied	10	4	5	2
3. Equally satisfied & dissatisfied	3	6	3	3
4. Moderately Satisfied	2	9	10	11
5. Very satisfied	0	3	5	7
Mean scores ± S.E.	1.88±0.19	3.20±0.24**	3.38±0.25**	3.76±0.24**

n=25, **P<0.01 (Significant difference compared with baseline)

Table 4 shows the changes in the overall satisfaction of the subjects’ sex life. Only 2 subjects reported that they were “moderately satisfied” with their overall sex life at the beginning of the study. At the end of 12-week period, 18 subjects reported that they were “moderately satisfied” or “very satisfied” with their overall sex life. The mean score was 2.07 at the beginning of the study and at the end of the 4, 8 and 12-week periods, reached 3.07, 3.54 and 3.79. The increase of the mean scores were significant compared with the baseline value. ($p<0.01$)

DISCUSSION

The compliance of this open-labeled study and acceptance of FEMINOL™ were satisfactory. All 25 subjects completed this study.

Female Sexual Dysfunction (FSD) is defined as a disorder of sexual desire, arousal, orgasm and/or sexual pain, which results in personal distress and has an impact on the quality of life and interpersonal relationships. It is a compilation of problems that has both biological and psychosocial components and is multifactorial in etiology. Normally, when a specific etiology of FSD is discovered, most doctors recommend a "basic treatment". Basic treatments include educational interventions, enhanced stimulation and elimination of routine (e.g., use of erotic books or videos, varying positions, use of vibrators, etc.), provision of distraction techniques (e.g., background music, encouragement of fantasies, etc.), encouragement of non-coital behaviors (e.g., sensate focus exercises, sensual massage) and techniques to minimize dyspareunia (e.g., change in position, topical lidocaine, lubricants, etc.). In addition to basic treatments, alternative medicine has become one of the most important approaches to replace the pharmacological remedies. FEMINOL™ is a combination of botanical extracts that may play an important role in naturally increasing the level of testosterone that can be effective transdermally. Abundant clinical literature has shown that testosterone levels directly or indirectly influence the fundamental components of both male and female sexual function, including genital development, sex drive, sexual sensation and orgasm. FEMINOL™ might play another important role by increasing the blood flow to the vagina and clitoris thus increasing the sensitivity in the genital region and promoting lubrication and wetness. The exact mechanism of FEMINOL™ is still not completely clear; further research may be required.

CONCLUSION

This open-labeled study evaluated the effects of FEMINOL™ on a woman's sexual function including sexual desire, sexual orgasm, pain during sexual activities and overall satisfaction of sex life. The results showed a significant improvement on forgoing aspects. No significant side effects were reported during this 12-week study. This study indicated that FEMINOL™ is an effective, well-tolerated alternative treatment for women with female sexual dysfunction.