



The opinions and views expressed by the author of this article are his own and do not reflect those of AAIM. This article is subject to open peer review, so readers are invited to respond with constructive thoughts and comments.

**A Medically Designed Synergistic Combination of Pro-hormones and
Pro-sexual Nutrients and Their Influence on Male Sexual Desire &
Potency: Preliminary Results**

Daniel S. Stein, M.D., F.A.C.O.G.,

Karen E. Engebretsen, Psy.D., PA, DABPS, DNBAE, DAPA, FACAPP, FAAIM,
DAC, CHT, CST, DABS

Nancy C. Bruemmer, Ph.D., M.D., F.A.C.O.G.

Beatrix Frasure, MSN, A.R.N.P.

Abstract

The supplement* evaluated is a medically formulated (formula by Daniel S. Stein, M.D., F.A.C.O.G.) combination of pro-sexual nutrients and pro-hormones. It was compounded with the objective of improving sexual function in normal men. A limited pilot study was performed to evaluate the potential effectiveness of the supplement's novel combination of male pro-hormones and pro-sexual nutrients and to provide the basis for the design of future studies.

Twenty volunteers were given one tablet daily of the dietary supplement for eight weeks.

A number of physical and perceptual assessments were performed in three sexual health domains: sexual desire/energy, sexual potency/performance and perceived overall sex life improvement.

The process of participant selection started with advertisements in local papers.

Specified criteria as to gender, age, and sexual interest were integrated in the randomized selection development. This study was conducted in a private medical clinic setting.

Based on the statistically significant enhancement of sexual health in all domains, preliminary clinical evaluation shows that the formulation concept of dietary supplementation with a combination of pro-hormones and pro-sexual nutrients appears to enhance sexuality in normal men.

*** The sexual nutrition dietary supplement studied is the proprietary formula of "ExtenZe™" brand, hereafter referred to as "the supplement."**

Literature Review

Sexual function is a fundamental part of a man's identity and how he feels about himself.

A man's sexual health (or dysfunction) has also been found to be a key factor in determining the capacity for maintaining healthy relationships. People with good sex lives live longer and healthier lives (Stein & Westoff, 2002). Erectile dysfunction (ED), in its different forms, threatens this capacity, and is thus an

increasingly important topic. In fact, the cost for various interventions can be staggering, both fiscally (Tan, 2000) and psychologically (Moore, Strauss, Herman, & Donatucci, 2003), and can have a considerable impact on quality of life (Sanchez-Cruz et al., 2003; Shirai, Sakimoto, Ishii, & Iwamoto, 2001). A preventative sexual health strategy employing dietary supplements might help reduce these costs and improve male wellness by reducing the incidence of ED, promoting longevity, and increasing sexual and global health. ED exists throughout the world and is especially prevalent in older men. Risk factors for ED overlap significantly with those for cardiovascular disease, sleep apnea, and complications from endocrine dysfunction (Arruda-Olson, Olson, Nehra, & Somers, 2003).

According to the most recently published literature, more than forty million men in the U.S. suffer from low levels of testosterone (Bunch, Abraham, Wang, & Meikle, 2002), which in turn can lead to ED. Other symptoms, such as general fatigue and depression (Nurnberg et al., 2002; Okulate, Olayinka, & Dogunro, 2003; Shabsigh, Zakaria, Anastasiadis, & Seidman, 2001), may be attributed to both the normal aging process and also to ED (Bacon et al., 2003). In addition, it has been shown that chronic illness (Marumo & Murai, 2001), obesity (Chung, Sohn, & Park, 1999), diabetes (De Berardis et al., 2002), hypertension (Burchardt M. et al., 2000), cardiovascular disease (Tan & Pu, 2003), and cigarette smoking (Mirone et al., 2002) contribute to developing ED. Other studies also mention prolonged stress, physical inactivity, and regular consumption of alcohol as factors that may play a role in the development of ED. Additional studies evaluating the prevalence of antidepressant-associated ED (Rosen & Marin, 2003) have found that ED in patients on antidepressant therapy may occur in up to 90% of men who take them.

A longitudinal study in 2000 by Johannes et al. looked at the incidence of erectile dysfunction in men 40 to 69 years old and showed that the rate for ED was 25.9 cases per 1,000 man-years (95% confidence interval [CI] 22.5 to 29.9). The annual incidence rate was found to increase with each decade of age. It was 12.4 cases per 1,000 man-years for men 40 to 49 (95%

CI 9.0 to 16.9), 29.8 for men 50 to 59 (95% CI 24.0 to 37.0), and 46.4 for men 60 to 69 (95% CI 36.9 to 58.4). Their research also suggested that the risk of ED could be estimated at about 26 cases per 1,000 men annually, and risk increased with age, lower education, diabetes, heart disease, and hypertension.

Another study evaluating a community-based sample of men 50 to 78 years old found that the prevalence of significant erectile dysfunction (defined as erections of severely reduced rigidity or no erections) increased from 3% in men 50 to 54 years old to 26% in men 70 to 78 years old and that the prevalence of significant ejaculatory dysfunction (as defined by ejaculations with significantly reduced volume or no ejaculations) increased from 3% to 35% (Blanker et al., 2001).

Interestingly, the researchers found that, generally, the men were more concerned about erectile dysfunction than about ejaculatory dysfunction. The number of men who reported being sexually active declined with increasing age. Sexual activity was lower in men with ED and in men without a partner.

In a cross-national community-based study evaluating the prevalence of ED in Brazil, Italy, Japan, and Malaysia (Nicolosi, Moreira, Shirai, Bin Mohd Tambi, & Glasser, 2003), ED was assessed, using self-reported data, as a subject's "inability to attain and maintain an erection satisfactory for sexual intercourse." Results indicated that the age-adjusted prevalence of moderate or complete ED was 34% in Japan, 22% in Malaysia, 17% in Italy and 15% in Brazil. The data also showed that the overall age-specific prevalence of moderate or complete ED was 9% for men aged 40 to 44 years, 12% for 45 to 49 years, 18% for 50 to 54 years, 29% for 55 to 59 years, 38% for 60 to 64 years, and 54% for those 65 to 70 years. As in other studies, they also found that there was an increased risk of ED associated with diabetes, heart disease, lower urinary tract symptoms, heavy smoking, and depression; however, their study also found that ED was inversely associated with education and physical activity.

Other studies have looked at the relationship between ED and depression, alcohol abuse, and panic disorder (Okulate, Olayinka, & Dogunro, 2003). They found that among those men identified as having ED, 10% were depressed, 10.3% had alcohol problems, and 0.6% had panic disorder. This study

found that age and depression were good predictors of erectile dysfunction, but not of alcohol abuse and panic disorder.

In a study evaluating the prevalence and severity of sexual dysfunction in combat veterans with and without post-traumatic stress disorder (PTSD), Cosgrove et al. (2002) found that patients with PTSD had decreased scores on overall sexual satisfaction and orgasmic function, and they showed trends toward less satisfaction with intercourse or erectile function, although there was no statistically significant difference in sexual desire. Results indicated that the rate of erectile dysfunction was 85% in patients with PTSD and 22% in non-PTSD subjects, suggesting that combat veterans with PTSD experience a significantly higher rate of sexual dysfunction than do veterans without PTSD. Although this research only evaluated the combat veteran population, it is important to consider these findings in relation to victims who experience other forms of severe stress, long-term stress, or trauma and their impact on emotional and sexual functioning.

An assessment of andropause awareness and ED among married men in Ile-Ife, Nigeria (Fatusi et al., 2003) revealed a high level of misconception about andropause with 38.9% indicating that it is a myth and another 23.6% attributing it to various causes other than a natural aging process. These authors stressed the importance of educating the population about the aging process and its relationship to male reproductive and sexual health.

Cerqueira, Moraes, and Glina (2002) conducted a study looking at the prevalence of ED and associated variables in patients with chronic renal failure. This study looked at age, education, income, race, period of dialysis, period of complaints of ED, etiology of ED, use of erythropoietin, presence of arterial hypertension and/or diabetes mellitus, use of antihypertensive drugs, use of cigarettes, and the psycho-emotional state of the patients. A multivariate analysis showed that the prevalence of ED in this population was 57.9%, and the main variables associated with ED were age, psycho-emotional state, and levels of

HDL-cholesterol, suggesting that factors such as age, anxiety and depressive complaints, and dyslipidemia seem to play an important role in the origin of erectile dysfunction in such patients.

Breau, McGrath, & Norman (2003) assessed the role of utilizing self-help issues for patients with prostate cancer, interstitial cystitis, ED, and urinary diversion. Results showed that patients with interstitial cystitis and ED reported having the greatest need for help, but they were least satisfied with the level of support and information they received. Inversely, patients with prostate cancer reported having the least need for help and were most satisfied with the self-help resources. The use and awareness of self-help measures were low in all groups, but it was speculated that this lack of utilization was likely due to a low percentage of patients being referred to self-help by their physicians.

Although the majority of the literature review has focused on the prevalence, etiology, and precursors of factors that may lead to ED, there is enough evidence to suggest that sexual functioning will decrease as part of the normal aging process. Moreover, there is ample data to suggest that optimal sexual health, at any age, is facilitative of optimal global wellness. It is to this issue that the current study is directed. While there are various forms of treatment available for sexual dysfunction, increasing numbers of individuals are seeking alternatives to doctor-regulated therapy and pharmaceuticals prior to symptoms severe enough to warrant a sexual dysfunction diagnosis. Multiple factors such as depression, pelvic or prostate surgery, negative mood, genital insecurity and lack of self-esteem, problems with relationships, or inadequate sexual experience can impact the actual *desire* for sex. Although some seek help, not every man may be a candidate for, or need, medical treatment. The current study asserts that it should not be necessary to wait for an inevitable age, stress or depression-related sexual decline, and its indirectly associated deteriorating effects on global wellness and self-esteem. Rather, a modern proactive strategy to empower natural health optimization through diet, exercise, and nutrition before sexual dysfunction is medically diagnosed is encouraged. Before clinically significant erectile dysfunction develops, there is an opportunity to employ a preventative “optimal health” strategy. This is where sexual nutrition supplements and pro-hormones may be of greatest benefit, given they are safe and likely to work.

This strategy would be especially effective if there were a medically plausible rationale for the efficacy of nutritional supplement in the treatment of ED. Health food stores and the Internet are filled with products boasting claims of increasing sexual performance and penile size with little evidence-based science to validate these claims. The following study was created to evaluate the effectiveness of the ingredients in “the supplement” and their effect on sexual functioning and sexual desire in a non-pathological sample. The formula was medically designed to enhance optimal normal male sexual function and to support optimum sexual desire and performance, erection, and pleasure. It is held that sexual nutritional supplements may help counter the cumulative negative effects of aging, andropause, atherosclerosis, depression, stress, and medication on health-promoting loving intimacy. They may help prevent the medical, social, and psychological issues associated with ED.

The Current Study

“The supplement” is a formulation medically designed with both pro-hormones (the nutritional building blocks of hormones) and pro-sexual nutrients. Some of the nutrients included have been used to promote sexual health and well-being for decades, and in some cases, for centuries; however, the addition of pro-hormones to promote optimal sexual health is novel.

The medical intention was to formulate a non-prescription pro-sexual herbal and male pro-hormone supplement to increase sexual desire and to enhance sexual health, penile size, and strength of erection. We hypothesized that—in addition to promoting sexual health, increasing penile size and strength of erection, and improving sexual performance—both the added sense of well-being from more (and more satisfying) sex and the increase in “testosterone effect” from the inclusion of nutritional pro-hormones DHEA and pregnenolone would have a positive effect on *desire* for sex. Since the market is flooded with herbal supplements claiming results that are physically and physiologically impossible to achieve, it was our intent to document authentic, experienced results on sexual intimacy from a clinical perspective. The study objective was to determine if the formula improves sexual functioning as defined by physical and

perceptual self-evaluations. The following are highlights of the rationale for medical inclusion of ingredients included in this product:

Pro-hormones: DHEA and Pregnenolone

DHEA, colloquially known as the “mother of all hormones,” is a pro-hormonal building block of natural testosterone and is the most important of all human pro-hormones. (Testosterone is known as “the hormone of desire” for both sexes.) Pro-hormones are the most important contributors to testosterone-related sexual arousal, desire, and response. DHEA (the pro-hormone that converts into testosterone in men) levels decrease linearly with age.

DHEA production peaks in a man’s early 20s and declines about 10% every 10 years.

Low levels of testosterone can lead to low sex drive and a smaller sex organ. DHEA is the nutritional precursor for testosterone and estrogen, which have also been reported to decrease with age (Morales, Nolan, Nelson, & Yen, 1994). Research shows that cortisol, the stress hormone, is elevated in major depression. DHEA has been found to counteract cortisol and improve depression.

DHEA supplements help those who have adrenal deficiency and low levels of DHEA (Araghinikam, Chung, Nelson-White, Eskelson, & Watson, 1996; Yen, Morales, & Khorram, 1997). The benefits from DHEA supplements (in those who are deficient) include improved sense of vigor and well-being, increased alertness and stamina, better memory, and enhanced sexual interest and performance.

Pregnenolone is colloquially known as the “grandmother of all hormones.” It is a vital hormone building block and arguably the most versatile pro-hormone in the cascade of molecular events which lead to testosterone, estrogen, and progesterone. Like freshly cut lumber, which can be processed into everything from home building materials to Kleenex®

(Wojtal, Trojnar, & Czuczwar, 2006), pregnenolone's final products perform a myriad of essential roles in the body (Brambilla et al., 2004). Certain steroids are produced from pregnenolone which may have powerful effects on the nervous system similar to those of neurotransmitters (Baulieu, 1991). Pregnenolone supports these neurosteroids and may increase tactile memory and peripheral neurosensitivity (Wu, Gibbs, & Farb, 1991). This enhanced neurosensitivity may reveal itself in a reduced threshold of genital sensitivity, thus enhancing the facility of arousal, erection, and orgasm as reflected in Quantative Genital Neurosensitivity Analysis, a quantitative technology (equipment by Medoc-Israel). Neurosteroid levels diminish with advancing age.

The human body either ingests pregnenolone or manufactures it from cholesterol and then uses it to make testosterone, progesterone, estrogen, DHEA, androstenedione, androstendiol, and all other pro-hormones and hormones in the "steroid" family. One reason for using DHEA and pregnenolone prophylactically is that the level of many of these hormones declines with age. By taking pro-hormone supplements, it is thought that their related hormonal metabolic end products may be maintained at more youthful levels.

Tribistol

Tribistol is the active ingredient in *tribulus terrestris*. *Tribulus terrestris* is a flowering plant in the family Zygophyllaceae, native to warm temperate and tropical regions of the Old World in southern Europe, southern Asia, throughout Africa, and in northern Australia. Tribistol is an herbal pro-sexual nutrient that has been demonstrated to increase the secretion of lutenizing hormone (LH).

Research suggests that LH stimulates the release of testosterone and enhances the level of natural testosterone production (Adaikan, Gauthaman, Prasad, & Ng, 2000; Li et al., 1998). It has been used for centuries in Chinese medicine to treat a variety of conditions including premature ejaculation, low libido, and male infertility.

Tongkat Ali

Tongkat Ali (*Eurycoma longifolia*) is a tree native to the jungles of Malaysia, Thailand, and Indonesia. Tongkat Ali is an herbal pro-sexual nutrient that has an ancient reputation as an aphrodisiac in Malaysia and Indonesia, where it is known as Pasak Bumi or “Ali’s staff,” a reference to its effects on male sexuality. A decoction of Tongkat Ali is used to increase stamina, energy, and vitality in men and for sexual connotations (penile firmness and strength). Tongkat Ali may enhance natural testosterone and cGMP production.

When optimal testosterone is achieved, sexual health and vitality are boosted. Tongkat Ali, with its widespread pro-sexual and healing properties, is believed to stimulate the natural defense mechanism of the body to all kinds of insults, thus increasing the body’s ability to protect itself. It is a clinically proven contributor to male sex drive and sexual stamina that is widely reported to heighten the urge for sex and prolong sexual activity before ejaculation. Of particular interest is the 1998 report on Tongkat Ali’s ability to increase sexual motivation in sexually naïve male rats published by the University Sans Malaysia (Ang, 1988). The study was designed to evaluate the aphrodisiac properties of Tongkat Ali. An electric grid separated sexually inexperienced male rats from estros-receptive females on the other side of the grid. One group of virgin male rats was treated with TongKat Ali; the other was not. Tongkat Ali caused the virgin male rats to hop across the electric grid to mount the receptive females and to ejaculate more frequently than the non-treated controls.

Eurycoma Longifolia Jack

Eurycoma longifolia jack is a small tree found in the jungles throughout Malaysia and Southeast Asia. Natives consider every part of the *Eurycoma longifolia* tree medicine.

Eurycoma longifolia jack is an herbal pro-sexual nutrient. Research has shown that

Eurycoma longifolia lack contains several phytochemicals that support healthy testosterone levels required for optimal male sexual functioning. It is also said to promote sexual health and sex drive in men

and to increase mental alertness (Ang & Sim, 1998). Results showed that repeated dosing of *Eurycoma longifolia* root extracts exerted pronounced stimulation of copulatory behavior in non-copulator male rats with high maintenance levels of both intromissions and ejaculations.

Yohimbine

Yohimbine is the name of the bark of a tall evergreen tree in western Africa known as *pausingystalia yohimbe* or *corynanthe yohimbine*. Yohimbine is an herbal pro-sexual nutrient made from natural yohimbe bark. It is the most important penile circulatory ingredient in the formula under study. As a drug, yohimbe HCl has been approved by the FDA as a vasodilator and for medical treatment of male impotence, whether due to vascular problems, diabetes, or psychogenic causes. It is said that the natives of West Africa used yohimbe bark extract for centuries during fertility ceremonies as a means of increasing libido, enhancing penis size, and improving sexual performance. Research has also demonstrated its use in the treatment of ED (Ernst & Pittler, 1998; Morales et al., 1987; Riley, 1994; Sonda, Mazo, & Chancellor, 1990; Vogt et al., 1997). Scientific studies on yohimbe conducted since the 1930s have confirmed that the herb has definite positive effects on aspects of sexual performance and have confirmed its ability to increase blood flow to the penis, cause erectile stimulation, and enhance penile size. “Long-term usage of yohimbe can result in erections that are firmer, larger, and longer lasting than normal and can encourage permanent gains in penis size,” (<http://www.herballove.com/library/resources>).

L-Arginine

L-Arginine is an amino acid present in the proteins of all life forms. It is best known as a growth hormone releaser. The decrease in growth hormone in the human body with aging is a major reason why muscle mass tends to decrease with age, body fat tends to increase with age, and why, in part, there is a slower rate of skin growth with aging (Kirk et al., 1993) which results in thinner and less flexible skin. L-Arginine is included in “the supplement” to enhance and compliment the effect of its other penile blood

flow enhancing ingredients and to compliment DHEA, pregnenolone, and its other longevity-, circulation-, and testosterone-promoting sexual nutrition ingredients. Several recent studies suggest a statistically significant improvement in sexual function associated with L-Arginine's clinical use (Barbul, 1986; Clarkson et al., 1996; Isdori, Lo Monaco, & Cappa, 1981).

Nitric oxide is formed from L-Arginine in the brain through an enzymic reaction similar to that in vascular endothelial cells (<http://www.pnas.org/cgi/content/abstract/86/13/5159>). Nitric oxide now also appears to be the neurotransmitter responsible for converting short-term memories to long-term memories in the brain. This is an ability that often declines with aging. Most important is its precursor role to nitric oxide, or NO, in the genitals. Nitric oxide plays a very important role in sexual function. It is an epithelial-derived relaxing factor, the chemical secreted by the lining of human blood vessels in the penis that causes the blood vessels to relax and dilate, and thus produces extra blood flow into the penis during the process of erection (Lerman et al., 1998). Adequate nitric oxide also helps to ensure that this allocation of blood flow to the penis is accomplished without undue increase in blood pressure.

Zinc

Zinc is an essential mineral required for the body to manufacture optimal testosterone levels in men. Men with zinc deficiency may have a problem with sexuality, and a shortage of zinc may induce a low sperm count, loss of sexual desire, and emotional problems. Lack of zinc may also cause swelling of the prostate gland, which will in turn slow sperm traveling up from the testes. This swelling may also diminish the release of prostatic secretions. Thus, zinc has a possible role in spermatogenesis and steroid genesis.

Zinc's low concentration in the seminal plasma of infertile male subjects is considered to be one of the factors responsible for their decreased testicular function. Zinc may also be helpful in fighting prostate infection and inflammation in older men (Ali et al., 2005).

Korean Ginseng

Korean ginseng is a perennial herb. The plant, with its typically light-colored fleshy root (the plant's nutritional part), is found in China, Korea, and Russia. Ginseng is classified as an *adaptogen* and is said to promote longevity, vitality, and act as aphrodisiac and sexual tonic. Research studies have found a slight connection between sex drive and consuming ginseng, although a direct link and the mechanism of action are still unknown (Murphy & Lee, 2002). Moreover, some tests with lab animals and ginseng have shown that Korean ginseng promotes the growth of male reproductive organs, increases sperm and testosterone levels, and increases sexual activity in laboratory animals. In general, scientists believe the link between ginseng and sex drive is due to ginseng's effect of strengthening overall health and balancing the hormonal system (<http://www.drugdigest.org/DD/DVH/HerbsWho/0,3923,552082|Korean+Ginseng,00.html>).

Method

Subject Selection

Subjects were solicited through local newspaper ads. The goal of this study was to obtain at least 25 participants of which 20 completed the 8-week study (n=20). Inclusion criteria included male gender, age between 18 and 65, a normal sexual history, and no erectile dysfunction (ED) or sexual dysfunction. Participants needed to agree to be reached by phone for the weekly evaluation of each measured variable. The study required a commitment to participate for at least 8 weeks. Subjects were also required to meet in person with the primary researcher in a private clinical setting at week 1 and at week 8.

Exclusion criteria included: 1) severe hypertension (whether or not pharmaceutically controlled) and 2) medically diagnosed impotence or sexual dysfunction due to physical/medical conditions. A medical doctor reviewed both criteria requirements.

Participants were instructed to take one tablet of the formula daily, at the same time each

day, to achieve a more controlled day-to-day level. Each subject received 60 tablets of the formula, and an availability day and time was agreed upon. To increase the likelihood of compliance with the research design requirements, a one year supply of “the supplement” was offered to each participant as an incentive to complete the study.

Measures

Questionnaire

Subjects were given a series of 13 questions to answer each week. Criterion validity of questions was assessed under three domains: 1) sexual desire/sexual energy/passion, 2) sexual power/pleasure/performance, and 3) overall sex life improvement. Limited to 7-day intervals, ratings were documented utilizing the Likert scale from 1 to 10. Results were obtained weekly (past seven days) through phone consultations using the same 13 questions each time.

Sexual Desire/Sexual Energy/Passion

The following four questions were considered under heading one:

- 1.) How many significant events have you had in the last week (i.e., vaginal intercourse, anal intercourse, masturbation, or oral sex)?
- 2.) How many times did you masturbate in the last week?
- 3.) How many times did you become hard or sexually aroused by erotic content in the last week (including all forms of media, internet, personal encounters)?
- 4.) How often did you sexually fantasize last week?

B. Sexual Power/Pleasure/Performance

The following six questions were considered under heading two:

- 5.) Was your confidence and ability to achieve and maintain a hard erection improved?
- 6) Did it take less stimulation to achieve a hard erection?
- 7.) Was your erection firmer, stronger, longer, or harder?
- 8.) How pleased were you with the improvement in your erection?
- 9.) Were you able to maintain a firm, hard erection longer during sex?
- 10.) Was the pleasure you got from your penis more than you previously experienced?

C. Overall Sex Life Improvement

The following three questions were considered under heading three:

- 11.) Were you more pleased with your sexual performance this week than last?
- 12.) Were you more pleased with your sex life as a whole this week than last?
- 13.) Has taking the formula (described in the study as “the pill”) contributed to an

overall improvement in the quality of your sex life?

There was a 99% improvement in sexual performance satisfaction after taking the formula for 8 weeks. These results provide evidence to conclude that when taking the formula, it is advisable to continue taking the pill for at least 8 weeks before the full effect can be noted.

Analysis did not show a statistically significant improvement between the first and the fourth week of taking the formula, but did show a highly significant improvement in increased sexual pleasure and performance by the time study participants had taken the formula for 8 weeks.

Penile Measurements

Penile measurements were also documented at week 1, week 2, month 1, and month 2. The study showed up to 50% improvement in flaccid and erect length. During the first interview, participants were asked to purchase a measuring tape, and the method of measurements was explained in detail to the participants. The demonstration of measurement requirements and procedure was then reviewed in private with each subject. Inconsistency of measurement could not be controlled using this design protocol method due to personal reasons (i.e., poor or inconsistent measuring techniques, shyness, lack of self-esteem, ego, size inadequacy, etc.). Despite these limitations, significant penile size enhancement in both length and girth was observed respectively in 50% and 45% of the participants. Future study might best be obtained by the direct objective measurement of erections and engorgement during nocturnal REM tumescence (nighttime sleep erections usually occur during dream sleep). This can and has been measured by the use of penile RigiScan™ monitor to record penile tumescence. The RigiScan™ attaches to the base and tip of the relaxed penis and connects via wires to a thigh-attached microprocessor (similar to the Holter monitor for the heart) that records penile engorgement or “rigidity” during sleep, thereby digitally documenting erection strength, frequency, timing, and duration. This would allow future studies to document reproducible objective clinical observations. RigiScan™ penile tumescence monitors have been used by scientists and doctors for decades to reliably document frequency and degree of penile erection (Murphy & Lee, 2002).

The new Uroan DIR501 might also be employed to document objectively reproducible penile erection information as they relate to pre- and post-supplement results. The DIR501 records penile axial rigidity in grams, relative intracavernous pressure, and duration of the erection.

Neither Rigiscan™ nor DIR501 measure actual penile length or girth in centimeters or inches. To our knowledge, no one else has addressed reproducible penile “size measuring” techniques with the intention of their being employed in scientific study. We attempted a strict protocol for flaccid and erect penis self-measurement. This study revealed encouraging overall perception of size and rigidity enhancement.

Unfortunately, size of penis issues, whether flaccid, erect, length, or girth, remain subjective as are the other self-evaluation parameters of this study. The fact remains that more than half of our patients and their partners thought, felt, and measured their penile erections as bigger, harder, and firmer.

Results

Analysis of Data

The results for each of the 13 questions had staggering similarities. Statistically significant improvement was noted in all subjective categories. A significance value (p-value) $< .05$ is called significant. A p-value $< .01$ is called highly significant. A p-value of $< .001$ is very highly significant. In every sub-heading category, “the supplement” showed statistically significant improvement in sexual health.

The questionnaire was comprised of 13 questions, which in turn were divided under three domains: sexual desire/sexual energy/passion, sexual power/pleasure/performance, and overall sex life improvement. Each question was rated by the participants on a Likert scale from 1 through 10.

Dr. Brian Garman, Professor and Chairman in the Department of Mathematics at the University of Tampa performed all statistical analyses on raw data. The psychosomatic effect of taking such sexual

enhancement drugs was taken into consideration and during questioning, attention remained focused on each participant's perception of improvement.

Sexual Desire/Sexual Energy/Passion

The following four questions were considered:

1. How many significant sexual events have you had in the last week (i.e., vaginal intercourse, anal intercourse, or oral sex)?
2. How many times did you masturbate in the last week?
3. How many times did you become hard or sexually aroused by erotic content in the last week (including all forms of media, internet, or casual encounters)?
4. How often did you sexually fantasize in the last week?

The overall p-value under this sub-heading is $p = .001$ and is therefore very highly significant. The results show a 99% level of difference between week 1 and week 8 utilizing a Fisher post-hoc paired t-test to see whether taking "the supplement" resulted in a week-to-week improvement. The results confirmed a significant improvement after 4 weeks. They also confirmed further significant improvement between the 4th and 8th week. It was clear that for optimum results, "the supplement" should be taken for at least 8 weeks. The increase in sexual thoughts and fantasies rose with statistical significance in all participants taking "the supplement" once a day.

Sexual Power/Pleasure/Performance

The following six questions were evaluated under sub-heading two:

5. Was your confidence and ability to achieve and maintain a hard erection improved?
6. Did it take less stimulation to achieve a hard erection?
7. Was your erection firmer, stronger, longer, or harder?
8. How pleased were you with the improvement in your erection?

9. Were you able to maintain a firm, hard erection longer during sex?
10. Was the pleasure you got from your penis more than you previously experienced?

The overall p-value under this sub-heading is $p = .05$ and was therefore statistically significant. The statistical analysis in this sub-category shows a 95% level of significant difference between starting “the supplement” and after taking “the supplement” for 8 weeks in the confidence of erection, ease of arousal to erection, firmness of erection, satisfaction of erection, and maintenance of erection, which in turn statistically increased the number of sexual events participants were able to enjoy.

Overall Sex Life Improvement

The following questions were asked:

11. Were you more pleased with your sexual performance this week than last?
12. Were you more pleased with your sex life as a whole this week than last?
13. Has taking “the supplement”™ (described in the study as “the pill”) contributed to an overall improvement in the quality of your sex life?

The overall p-value under this sub-heading was $p = .001$ and therefore very highly significant. There was a 99% improvement in sexual performance satisfaction after taking “the supplement” for 8 weeks. These results provide evidence to conclude that when taking “the supplement” it is advisable to continue taking the pill for at least 8 weeks before the full effect can be noted. Analysis did not show a statistically significant improvement between the 1st and the 4th week of taking “the supplement,” but did show a highly significant improvement in increased sexual pleasure and performance by the time study participants had taken “the supplement” for 8 weeks.

Interpretation of results

The following table is the results on a percentage basis:

Increase in weekly sexual events (Intercourse, masturbation, etc.)	18/20 = 90%
Increase in sexual desire	17/20 = 85%
Increase in sexual fantasies	20/20 = 100%
Improvement in confidence to achieve an erection	15/20 = 75%
Increase in penile sensitivity, less stimulation needed	13/20 = 65%
Increase in firmness of erections	18/20 = 90%
Increase in patient satisfaction with erections	18/20 = 90%
Increase in maintaining erection to complete intercourse	20/20 = 100%
Increase in overall pleasure	15/20 = 75%
Increase in personal sexual performance satisfaction	17/20 = 85%
Increase in satisfaction with sex life as a whole	16/20 = 80%
Increase in overall improvement including sexual activity, vigor and performance	20/20 = 100%

Conclusions

Results of this study suggest that sexual nutrition supplementation including both pro-hormones and pro-sexual nutrients can positively influence and enhance subjective

perception of sexual function in normal men.

The observed differences between week 1 and week 8 are statistically significant.

Based on these observations, similar larger studies with control groups are warranted. The authors recommend the inclusion of the following tests to help objectify the studies findings: sequential hormone analysis, serial Rigiscan™, serial Uroan DIR501 erection strength documentation, serial genital ultrasound confirmation of measured penile blood flow (with and without stimulation) to document the supplement's effect on penile blood flow in both flaccid and erect states, and serial quantitative neurosensory analysis (Medoc-Israel) or biothesiometry (Bio-Medical Instrument Company) to objectively document the supplement's subjective effect of enhanced penile neurosensitivity .

The current study results document the conclusion that when taking “the supplement” it is advisable to continue for at least 8 weeks before the full effect can be noted. This goes along with our current knowledge of pro-hormone activity and restoring optimal receptor saturation, blood levels, and end organ response for the supplement's pro-hormone support of their related steroid hormones. There was no difference in results trending with age.

Discussion

It was hypothesized that a sexual nutrition supplement containing both pro-hormones and pro-sexual nutrients could increase sexual pleasure and improve sexual performance naturally for adult men of all ages. As evidenced by the statistically significant data, subjects taking such a supplement experienced a dramatic increase in sexual desire unrelated to age. Also, regardless of age, the formula appeared to positively affect sexual stimulation and enjoyment and to contribute to longer-lasting, more frequent sex in 2 to 4 weeks. Based upon the subjects' self reports, there were neither adverse nor side effects. The supplement's formula appeared to offer a safe and effective natural organic alternative to standard pharmacological compounds currently in use. As evidenced in this pilot study, a combination

formula containing both pro-hormones and pro-sexual nutrients was shown to strengthen sex drive, enhance sexual performance, boost sexual ability, increase sexual stamina, increase penis size and strength of erection, and improve sexual self confidence which in turn, led to more frequent sexual contact and more gratifying and more rewarding intimate contact—all factors contributing to a better state of life and quality of health in general.

A 1997 study reported in the British Medical Journal by Smith G. Davey and colleagues examined the frequency of sexual intercourse and death in a sample of 900 men ages 45 to 59 over a period of 10 years. In the group having the highest number of orgasms, mortality rates were 50% lower than the group with the lowest frequency of orgasms. Interestingly, results were even more dramatic in those men with coronary heart disease. Those who had orgasms about twice a week had a 68% lower death rate than those who had them less than once a month. The researcher suggested that hormonal effects on the body resulting from frequent sex might explain the findings. While for men the number of times they had sexual intercourse affected their rate of longevity, in studies on women it was the quality of the sex they had that seemed more important in their longevity (Stein & Westoff, 2002).

The results of this study demonstrate improvement in both sex drive and sexual performance in normal men. The combination of pro-hormones and pro-sexual nutrients may reasonably be expected to have even more dramatic effects on men with weak libido or low sexual stamina. It is estimated that these symptoms occur in about 15 million American men and may be related to the natural hormone decline which begins at 20 years of age and continues in a downward decline. It may be associated with aging, stress, fatigue, and domestic and work place pressure.

Poor and declining genital circulation may also affect the vast majority of men. The formula's blend of herbal supplements previously studied in a variety of contexts has been shown to increase natural

genital blood flow. This improved circulation, leading to improved sexual appetite and performance, has related positive effects on mood and enjoyment of life.

Increased genital blood flow may be attributable to the synergy of pro-hormones and pro-sexual nutrients as well as the bio-enhancer effect of components of the formula which have specifically targeted fast absorption. Curiously, the observed increase in erect penile size, firmness, fullness, neurosensitivity, and function may well be due to the cumulative synergistic effects of the supplement's ingredients.

While the brain is stimulated by thoughts, fantasies (conscious and subconscious), and dreams, the penis is stimulated during dream sleep to become erect. In previous studies at the Foundation for Intimacy conducted by Stein et al., younger men with higher DHEA and testosterone levels were found to have an average of 3–5 nocturnal erections a night as measured by RigiScan™ testing. Younger men frequently awaken with a morning erection. These nocturnal dream and morning erections dilate and distend the spongy tissue in the corpora cavernosa and corpora spongiosa. With age, the nighttime sleep erections (and sometimes the testosterone-induced morning erections as well) decline in strength and frequency. The penile sponge (corpora cavernosa and corpora spongiosa) may become less pliable, similar to an old “forgotten sponge” that has become stiff and hard. Even when rehydrated, its absorbency and elasticity have been reduced.

Restoring optimal testosterone pro-hormone building blocks and nutritionally encouraging optimal genital blood flow and neurosensitivity, “the supplement” may help men keep penile spongy tissue expanded and readily distensible by promoting genital blood flow even during sleep (optimal testosterone promotes nocturnal penile tumescence, REM, or dream erections).

From a relationship standpoint, increased desire and sexual thoughts are implicated in better sexual communication, longer-lasting intimate encounters, and enhanced pleasure for both partners—all important in building and maintaining satisfactory relationships. As previous research has demonstrated, Viagra™ improves erection strength and has no direct effect on desire, pleasure, or overall virility. The formula in “the supplement,” as suggested in this study, positively impacts all four. Further, the herbal formula in “the supplement” not only has positive impact in the psycho-social arena, it also has economic impact as well. Because there are no healthcare provider costs; associated inconveniences connected with scheduling the doctor’s appointment necessary to obtain the prescriptions for Viagra™, Levitra™, or Cialis™; or embarrassment of being diagnosed with a sexual “problem” (whether erectile dysfunction or simply genital confidence and size insecurity) simply to get such a prescription, the ease of access of a pro-hormonal/pro-sexual nutrient combination with statistically significant male sexual enhancement effects may have added appeal.



The opinions and views expressed by the author of this article are his own and do not reflect those of AAIM. This article is subject to open peer review, so readers are invited to respond with constructive thoughts and comments.