

The Effects of ArginMax, A Natural Dietary Supplement for Enhancement of Male Sexual Function

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This study examines the role of ArginMax, a natural daily dietary supplement, on male sexual function. 25 subjects diagnosed with mild to moderate erectile dysfunction were evaluated over a 4-week period while on ArginMax. Of the 21 subjects that completed the study, 88.9% improved in ability to maintain erection during sexual intercourse and 75.0% improved in satisfaction with their overall sex life. No significant side effects were noted.

Introduction

It has been reported in the literature that dietary supplementation with certain botanical extracts, vitamins, or amino acids have led to modest improvements in male sexual function. No studies, however, have examined a systematically designed combination of natural products for the enhancement of male sexual function. Based on the proposed and elicited mechanisms of various natural products in the literature, we postulated that a combination regimen (ArginMax) could provide a major impact in support of male sexual function. First, a review of the supporting literature.

It is well established that nitric oxide (NO) is the key mediator for the up-regulation of cGMP which in turn mediates erectile function.¹ L-arginine is the precursor of nitric oxide. The conversion of L-arginine to nitric oxide is mediated by nitric oxide synthase (NOS). Increasing tissue L-arginine levels results in the increase of NO and

cGMP.^{2,3} Supplementation with L-arginine has been shown to be sufficient to restore endothelial-derived nitric oxide production in many disorders in which endothelial-derived nitric oxide is reduced or impaired including impairment resulting from diabetes and hypercholesterolemia.⁴⁻⁸ Studies also point to the role of L-arginine as not only a substrate for NOS in the up-regulation of cGMP, but also acts to reduce cell-mediated breakdown of nitric oxide.⁹

The efficacy of Korean ginseng (Panax Ginseng) in treating erectile dysfunction was recently demonstrated in a randomized controlled clinical trial involving a total of 90 patients studied over 3 months, 30 each receiving placebo, trazadone, or ginseng.¹⁰ Ginseng was the most efficacious treatment with improvements measured in erectile parameters such as girth, libido, and patient satisfaction. Frequency of intercourse, ejaculations, and erections did not differ among groups. In a controlled study with 66 patients, Panax ginseng was demonstrated to increase spermatozoa count and motility, testosterone, DHT, FSH, and LH levels in 66 patients with fertility problems.¹¹ Ginsenosides (the primary active component of ginseng) have been shown to increase NO production in endothelial cells.¹²⁻¹⁴ One observed mechanism for increase in NO production is up-regulation of NOS activity by ginsenosides.¹⁴ The effects of ginsenosides on NO production has implications for improved sexual function, and may partly account for the aphrodisiac effect of Panax ginseng used in traditional Chinese medicine.

Ginkgo biloba is well established to facilitate microvascular circulation¹⁵ which may physiologically lead to improvement of erections. In addition to ginkgo biloba's ability to facilitate microvascular circulation, potentially benefiting erectile function through enhanced vascular blood flow, there is evidence that ginkgo biloba extract may also directly elucidate smooth muscle relaxation in the corpus cavernosum, likely via effects on the nitric oxide pathway.^{16,17}

B-complex vitamins are important to the activity of hundreds of enzymes and in energy metabolism. Low levels of circulating folate and vitamin B6 confer an increased risk of peripheral vascular disease,¹⁸ leading to potential reduction of erectile function.

Zinc is a fundamental mineral in the maintenance of human reproductive function. Low levels of serum zinc has been shown to cause sexual dysfunction and is associated with infertility in males.^{19,20} Zinc deficiency during growth periods results in lack of gonadal development in males.^{21,22} Zinc deficiency leads to depletion of testosterone and inhibition of spermatogenesis.²³ Zinc is also thought to help extend the functional life span of ejaculated spermatozoa.²³

Selenium has a key influence on spermatozoa numbers and motility. It is an essential element in normal spermatozoa develop-

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ment. Selenium is incorporated in the sperm mitochondria capsule and may thus affect the behavior and function of the spermatozoon.²⁴ It has been shown that dietary supplementation with selenium-vitamin E statistically significantly increases sperm motility, percent live, and percent normal spermatozoa.²⁵

It is well established that one of the key roles of seminal plasma is the protection of spermatozoa against reactive oxygen species.²⁶ In a study of 101 patients seeking consultation for infertility and 15 fertile donors, a strong inverse relationship was found between total reactive antioxidant potential in seminal plasma and infertility.²⁶

ArginMax (The Daily Wellness Company, Mt. View, CA) is a natural dietary supplement which incorporates a highly standardized combination of ginkgo biloba (24% flavone glycosides, 6% terpene lactones), Korean ginseng (Panax Ginseng-30% ginsenosides), American ginseng (Panax Quinquefolius- 5% ginsenosides), L-arginine, along with B-vitamins 6 and 12, folate, antioxidant vitamins A, C, E, thiamin, riboflavin, niacin, biotin, pantothenic acid, zinc, and selenium. ArginMax was developed as a dietary supplement to support male sexual fitness. This paper reports our findings of a clinical pilot study of male sexual function using ArginMax as a daily dietary supplement in a group of men with mild to moderate erectile dysfunction.

Method

We recruited male subjects with mild to moderate erectile dysfunction through various medical clinics. Interested participants were enrolled at a test center located in a urology clinic at a University of Hawaii affiliated teaching hospital (Kuakini Medical Center). Subjects were enrolled in a consecutive manner until 25 patients had been enrolled for this pilot phase of the study. All interested participants were allowed to enroll regardless of etiology of erectile dysfunction. Initial work up consisted of a detailed patient past medical history including history and etiology of erectile dysfunction, treatment and medication history, and a physical examination including blood pressure, height, and weight. The subjects were then instructed on the use and a regimen of ArginMax as a dietary supplement and were requested to fill out a baseline SFQ (Sexual Function Questionnaire). Subjects started a twice-per-day regimen of ArginMax, once in the morning upon waking and once in the evening at bedtime. A 4-week supply of ArginMax was provided. After completing the 4-week regimen, patients were instructed to complete a 4-week SFQ and return to the test center for follow-up evaluation and examination.

The SFQ (Sexual Function Questionnaire) was used as the primary test instrument. The SFQ is a self-administered questionnaire beginning with the validated IIEF (International Index of Erectile Function used with permission) test instrument designed to measure changes in erectile function and sexual function.²⁷⁻²⁹ Following the IIEF questions, the SFQ included questions regarding subject's activities, condition during the trial period, and quality of life.^{30,31}

Subject Group Profile At Baseline

Total number of subjects-	25
Age range-	40 - 77
Number hypertensive-	19
Number diabetes mellitus-	4

Study Results

Sexual Function Improvements as Measured By SFQ

Patient responses to SFQ variables at 4 weeks were compared to SFQ responses at baseline. A comparison analysis was performed for those subjects whose degree of erectile dysfunction were mild to moderate as characterized by a minimal baseline score of 2 in comparison to their 4 week score on the same SFQ variable. The results were then pooled, summarized, and evaluated to reflect the percentage of subjects with improvement in each of the SFQ variables. The following are our findings showing the two highest and two lowest SFQ variable results:

88.9% of subjects showed improvement in the ability to maintain erection during intercourse, as measured by the following SFQ variable:

Over the past 4 weeks, during sexual intercourse, <u>how often</u> were you able to maintain your erection after you had penetrated (entered) your partner?	0 = Did not attempt intercourse
	1 = Almost never/never
	2 = A few times (much less than half the time)
	3 = Sometimes (about half the time)
	4 = Most times (much more than half the time)
	5 = Almost always/always

75.0% of subjects showed improvement in satisfaction with overall sex life, as measured by the following SFQ variable:

Over the past 4 weeks, how satisfied have you been with your overall <u>sex life</u> ?	1 = Very dissatisfied
	2 = Moderately dissatisfied
	3 = About equally satisfied and dissatisfied
	4 = Moderately satisfied
	5 = Very satisfied

20.0% of subjects showed improvement in number of orgasms, as measured by the following SFQ variable:

Over the past 4 weeks, when you had sexual stimulation <u>or</u> intercourse, how often did you ejaculate?	0 = No sexual stimulation/intercourse
	1 = Almost never/never
	2 = A few times (much less than half the time)
	3 = Sometimes (about half the time)
	4 = Most times (much more than half the time)
	5 = Almost always/always

12.5% of subjects showed improvement in the number of times attempted intercourse, as measured by the following SFQ variable:

Over the past 4 weeks, how many times have you attempted sexual intercourse?	0 = No attempts
	1 = One to two attempts
	2 = Three to four attempts
	3 = Five to six attempts
	4 = Seven to ten attempts
	5 = Eleven + attempts

Subjects Dropped

Of the 25 subjects enrolled, 21 were included in the scoring of the above shown results. Four (4) of the enrolled subjects were not included for the following reasons:

- Loss of sex partner resulting in major change in sexual activity. (1 subject)
- Did not complete study due to personal problems- unspecified. (1 subject)
- Did not complete 4 week regimen in entirety. (2 subjects)

Side Effects

Blood Pressure Changes: no significant change in blood pressure. Mean blood pressure at baseline: 135/82 (s.devs: 14.9/11.71). Mean blood pressure at 4-weeks: 139/85 (s.devs: 12.26/13.17).

No other significant side effects as noted. The following are net % of patients reporting increase or decrease of:

headaches:	4.8%
nausea:	-4.8%
stomach upset:	-14.3%
chest pain:	0%
dizziness:	0%
vision disturbance:	0%

Discussion

The role of natural dietary supplements for sexual health is an infrequently discussed yet extremely important subject. Our pilot study preliminarily addressed the role of a combinatorial natural product for the enhancement of male sexual health. The proposed mechanism by which ArginMax improves sexual health and erectile function is through increasing smooth muscle relaxation, enhancing vascular dilatation, and improving peripheral circulation. Based on review of the literature pertaining to the ingredients in ArginMax, it is likely that ArginMax enhances the NO-cGMP pathway by providing additional substrate for NOS, up regulating NOS activity, and decreasing the cell-mediated breakdown of cGMP. On a vascular level, ArginMax likely facilitates erectile function by increasing blood vessel dilatation and microvascular circulation.

It is important to recognize that this pilot study is a part of a larger scale ongoing clinical evaluation of the health effects of ArginMax. Although designed as an open-label, pilot study, the results of the SFQ survey demonstrate significantly greater improvements in variables relating to erectile function than in non-erectile function related variables. It is reasonable to conclude that if only a placebo effect was noted, all variables would be impacted in a similar fashion. The presence of major variations among the variables leads us to believe that there is a physiological effect at play. Our pilot study indicates that an expansion of our current study to a larger population with a placebo-controlled protocol is the logical next step in exploring the sexual function benefits of ArginMax.

It is important to recognize that as Americans develop an ever increasing interest in dietary supplementation and the concept of wellness, that the role of a supplement for one of the most important biological functions of life, sexual

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health, be clinically evaluated. After all, if we take a calcium supplement for our bones, and an aspirin for our blood, why not consider taking a supplement for our sexual health?

Conclusion

In a pilot clinical study of ArginMax (The Daily Wellness Company, Mt. View, CA), a natural daily dietary supplement developed to support male sexual fitness, significant improvements were noted in male sexual function after 21 subjects, ages 40-77, with mild to moderate erectile dysfunction, completed a 4 week regimen of ArginMax. 88.9% of the subjects experienced improvement in ability to maintain an erection during intercourse. 75.0% of the subjects experienced improvement in satisfaction with their overall sex life. There were no significant reports of side effects (headaches, nausea, stomach upset, chest pain, dizziness, vision disturbance, changes in BP). Based on the findings of this study, there appears to be strong indication that natural dietary supplementation (ArginMax) may play an important role in sexual health and erectile function.

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WHEN SMOKERS QUIT

Within 20 minutes of smoking that last cigarette, the body begins a series of changes that continues for years.

20 MINUTES

- Blood pressure drops to normal
- Pulse rate drops to normal
- Body temperature of hands and feet increases to normal

8 HOURS

- Carbon monoxide level in blood drops to normal
- Oxygen level in blood increases to normal

24 HOURS

- Chance of heart attack decreases

48 HOURS

- Nerve endings start regrowing
- Ability to smell and taste is enhanced

2 WEEKS to 3 MONTHS

- Circulation improves
- Walking becomes easier
- Lung function increases up to 30 percent

1 to 9 MONTHS

- Coughing, sinus congestion, fatigue, shortness of breath decrease
- Cilia regrow in lungs, increasing ability to handle mucus, clean the lungs, reduce infection
- Body's overall energy increases

1 YEAR

- Excess risk of coronary heart disease is half that of a smoker

5 YEARS

- Lung cancer death rate for average former smoker (one pack a day) decreases by almost half
- Stroke risk is reduced to that of a nonsmoker 5-15 years after quitting
- Risk of cancer of the mouth, throat and esophagus is half that of a smoker's

10 YEARS

- Lung cancer death rate similar to that of nonsmokers
- Precancerous cells are replaced
- Risk of cancer of the mouth, throat, esophagus, bladder, kidney and pancreas decreases

15 YEARS

- Risk of coronary heart disease is that of a non-smoker



Source: American Cancer Society, Centers for Disease Control and Prevention