



# HerbClip™

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**FILE: ■Pycnogenol®**  
**■Maritime Pine Bark Extract (*Pinus pinaster*)**  
**■Erectile Dysfunction**

**HC050452-265**

**Date: September 30, 2004**

**RE: Pycnogenol® and Arginine Increase Erections in Uncontrolled Study**

Stanislavov R , Nikolova V. Treatment of erectile dysfunction with Pycnogenol and L-arginine. *J Sex Marital Ther.* 2003;29(3):207-213.

Male erections occur when muscle tissue in the penis relaxes and permits the organ to become engorged with blood. Nitric oxide (NO) is believed to be the primary mediator of this process by promoting dilation of blood vessels and acting directly on nerves in the penis. NO is produced from L-arginine through a series of enzymatic reactions. Pycnogenol® (Horphag Research, Ltd., Geneva, Switzerland) is a patented, standardized extract of French maritime bark (*Pinus pinaster*), and it has been shown to stimulate the production of NO. The purpose of this uncontrolled study was to determine if arginine plus Pycnogenol was effective in men with erectile dysfunction (ED).

The study was conducted in 40 men (aged 25-45 years) living in Sofia, Bulgaria. The men had confirmed functional ED. ED is typically characterized as either functional (psychological causes) or organic (physical causes). All the men in the study followed the same treatment schedule for 3 months. During the first month, the men took 1.7 grams of arginine each day in the form of Sargenor® (Sarget Pharma, Sedex, France). During the second month, the men took 1.7 grams of arginine plus 80 mg of Pycnogenol each day. During the third month, the men took 1.7 grams of arginine plus 120 mg of Pycnogenol each day. The men kept a diary of their sexual activity and completed questionnaires assessing their erections at the end of each month of treatment.

At the beginning of the study, no men reported having normal erections. After month one (arginine only), 2 of the 40 men (5%) reported normal erections. After month two (arginine plus 80 mg Pycnogenol), 32 of the 40 men (80%) reported normal erections. After month three (arginine plus 120 mg Pycnogenol), 38 of the 40 men (92.5%) reported normal erections. The changes from baseline to month 2 and to month 3 were statistically significant ( $P < 0.01$ ). No side effects were observed during the study.

The authors conclude that supplementation with arginine and Pycnogenol significantly improves sexual function in men with ED. However, certain aspects of the study need to be noted. The lack of a placebo group or control group is a significant weakness in the study design. Though, the low response rate during the first month, when patients received arginine only, should be taken into account. The low rate may indicate that the placebo effect was low. The results are based entirely on subjective measures (questionnaires and diaries); however, these are approved tools for investigating erectile function (studies of Viagra used these tools to confirm its efficacy). There is also no attempt to correlate improved erections with any clinical changes. Although there are well-controlled clinical trials using similar doses of Pycnogenol, the authors appeared to have not reviewed any such previous studies (at least previously published controlled trials are not cited) and did not mention if improved erections have been reported as a "side effect" in other trials. The 92.5% response rate is higher than the response rate reported for Viagra® (up to 80%). This high response rate and the complete absence of side effects are remarkable. A study with an improved design and additional participants to confirm the findings is needed.

—*Heather S. Oliff, Ph.D.*

The American Botanical Council has chosen not to reprint the original article.

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