### TITLE

## Effect of daily use of natural astaxanthin on symptoms associated with Tennis Elbow

# (lateral humeral epicondylitis)

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### ABSTRACT

Previous studies have provided data suggesting that daily use of a microalgal extract containing natural astaxanthin and marketed under the trade name BioAstin® can help alleviate pain associated with joint damage, specifically that seen in rheumatoid arthritis and carpal tunnel syndrome. For this study, the benefits of daily use natural astaxanthin provided by BioAstin® for the purpose of alleviating pain associated with Tennis Elbow (lateral humeral epicondylitis) was evaluated. It was found that grip strength measurements (GSM) for those on the active product were significantly improved by the end of the study. This correlation of improved GSM and use of natural astaxanthin may suggest that daily use can help alleviate pain associated with Tennis Elbow, and increase mobility. This improvement may greatly improve the standard of living for those who suffer from such joint disorders.

#### **INTRODUCTION**

In a pilot study conducted at the Health Research and Study Center, patients with Carpal Tunnel Syndrome receiving BioAstin<sup>™</sup>, an astaxanthin-containing extract of *Haematococcus* algae, showed a trend towards decreasing pain rate and duration. This study will investigate the effect of BioAstin<sup>™</sup> on the symptoms of Tennis Elbow (TE) and tendonitis using standard multidimensional health assessment questionnaires including Assessment of Pain (AP) and measurements including Grip Strength Measurements (GSM) and Maximal Grip Strength (MGS).

#### MATERIALS AND METHODS

#### Subjects

Subjects were recruited from the San Francisco Bay Area through newspaper advertisements and advertisements at local tennis clubs. Volunteers were admitted into the study if they qualified according to the following inclusion criteria: (1) men and women 40 to 60 years old, excluding pregnant and lactating women; (2) no diagnosis of cardiovascular disease, kidney disease, diabetes, or cancer; (3) on stable doses of medication, if taking any; (4) not participating in any other study that might conflict in some way with this one. Forty-two participants were selected according to the above criteria and agreed to participate in the study and thirty-three subjects (21 men and 12 women) completed the study (Table 1). The study protocol had been approved by an independent investigational review committee and was explained to each subject who then signed an informed consent.

#### **Study Design**

This single-center, double-blind, placebo-controlled study was conducted over an 8 week duration. Forty-two subjects began the initial stages of the study, with a total of thirty-three subjects completing all aspects of the study (21 in treatment group, 12 in placebo group). The teatment group consumed three BioAstin soft gelatin capsules, one with each meal. Each BioAstin soft gelatin capsule contained 4.0 milligrams of astaxanthin. The placebo group consumed three placebo soft gelatin capsules, one with each meal. The placebo gelatin capsules contained only safflower oil.

#### Device

A deluxe desk sphygmomanometer manufactured by Omron Healthcare, Inc. (serial #577207) was used to assess grip strength and maximum grip strength. Attached to the sphygmomanometer was a Marshall Tru-Gage Cuff.

#### Method

The participants met with the study coordinator individually for assessment. The participant was seated on a straight back chair with a seat height of 41cm, and was asked to extend the afflicted arm out, palm down, straight over the table in front of them at shoulder height. The table was constructed of wood, and had a height of 74 cm. All participants were able to extend their arm straight out without having contact with the table. The Omron sphymomanometer was on the table top near the participant, and was set up so that the Marshall Cuff was rolled up, the sphymomanometer was pumped to a pressure of 20 mmHg, and the rolled cuff was then placed in the palm of the participant, with the participant instructed to grasp the rolled cuff with their four fingers over the cuff, and their thumb under the cuff. The participant was then asked to squeeze the cuff until they first felt increased pain in their elbow. Once the participant indicated that they felt increased pain, the pressure reading at that time was recorded as their GSM (grip strength measurement). This process was done at the beginning of the individual assessment, at the middle, and at the end. The three numbers were averaged to find the mean. If no pain was felt throughout the assessment, "no pain" was indicated on their chart. In addition, at the end of

the assessment, the participant was asked to perform this process one last time, this time squeezing the cuff as hard as they could, regardless of pain. When the participant indicated that they could squeeze no harder, the pressure achieved was recorded as their Maximal Grip Strength (MGS).

### Protocol

Dr. Carter Multz of the Arthritis Care Center, located in San Jose, California, developed this protocol for the purposes of this test.

### **Statistical Analysis**

Changes in GSM, MGS, and AP were evaluated using paired *t*-tests. The level of significance was set at P < 0.05.

# RESULTS

Data are presented for 33 subjects.

Results of the grip strength measurements (GSM), maximal grip strength measurements (MGS), and assessment of pain (AP) at baseline and end of study are presented in the table below (mean  $\pm$  SD). GSM improved significantly (P< 0.05) in the treatment group but did not significantly improve in the placebo group. No significant changes were observed in MGS or AP in either group.

Group	GSM (mmHg)		MGS (mmHg)		AP	
	Baseline	End	Baseline	End	Baseline	End
Treatment	254 ± 321	493 ± 429 *	211 ± 91	215 ± 91	32 ± 28	$17 \pm 20$
Placebo	$190\pm270$	$352 \pm 401$	$146 \pm 66$	$238\pm251$	48 ± 29	26 ± 12

\* Significantly different from baseline (P<0.05).

# DISCUSSION

The group receiving BioAstin<sup>™</sup> had a significant increase in GSM when compared to the group receiving the placebo. No other significant changes were noted during the course of the study.

Effect of Bioastin on Tennis Elbow

This correlation of improved GSM and use of BioAstin<sup>™</sup> may suggest that daily use can help alleviate pain associated with Tennis Elbow, and increase mobility. This improvement may greatly improve the standard of living for those who suffer from such joint disorders.