

# BioAstin helps relieve pain and improves performance in patients with rheumatoid arthritis

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## Introduction

Rheumatoid arthritis is a chronic destructive disorder. It is the most common form of inflammatory arthritis and has a substantial effect in terms of disability and productivity lost as well as cost. The disease is characterized by joint pain and swelling with progression to invasion of bone and cartilage. Without successful treatment it may lead to loss of function, disability and increased mortality. Patients with active disease require aggressive treatment. Although new treatments are constantly being developed, current therapy cannot reliably alter the long term outcome. Conventional treatments for rheumatoid arthritis present problems in terms of both safety and efficacy. A number of alternative therapies have been studied. The response to these treatments is variable and often unpredictable.

Preliminary anecdotal evidence showed that regular consumption of BioAstin, containing astaxanthin, may help symptoms of rheumatoid arthritis.

## Description of the study

We performed a pilot study to evaluate the efficacy of this product in the treatment of rheumatoid arthritis. The study product contained 460 milligrams high oleic safflower oil, 40 milligrams *Haematococcus* extract, 4 milligrams astaxanthin, 40 micrograms leutein, 65 International Units vitamin A (as beta-carotene), 50 International Units vitamin E (as d-alpha-tocopherol), gelatin and rosemary oil. The placebo contained food grade safflower oil.

The study was a single-center, double-blind, placebo-controlled, parallel design study of eight weeks' duration with a total of 21 subjects. A group of 14 randomized to BioAstin and

a group of 7 randomized to placebo. Subjects consumed three study product gelcaps daily, one with each meal, for eight weeks. Subjects were asked not to change any other medication that they were taking, either prescription or OTC. The subjects completed questionnaires (Appendix One) at the beginning of the study, at mid study (4 weeks) and after 8 weeks. The form used is in Appendix One.

## Results

The "VAS" pain scale (visual analogue scale) at the beginning, after 4 weeks and after 8 weeks was  $0.42 \pm 0.22$ ,  $0.38 \pm 0.21$  and  $0.27 \pm 0.25$  for the treatment group and  $0.48 \pm 0.23$ ,  $0.42 \pm 0.16$  and  $0.45 \pm 0.14$  for the control. The satisfaction score at the beginning, after 4 weeks and after 8 weeks was  $1.75 \pm 0.72$ ,  $1.50 \pm 0.76$ ,  $1.00 \pm 0.60$  for the treatment group and  $1.83 \pm 0.69$ ,  $1.50 \pm 0.96$  and  $1.67 \pm 0.94$  for the control group.

TABLE 1

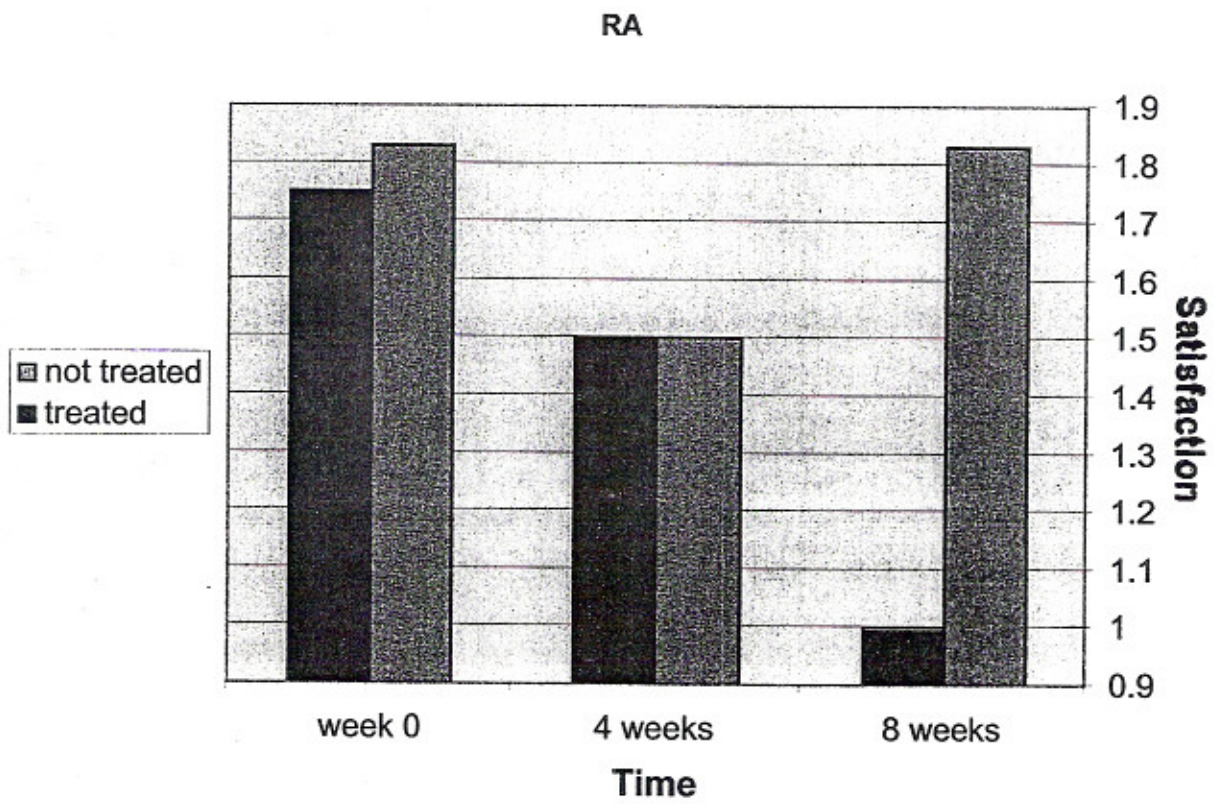
SUMMARY OF KEY RESULTS			
"VAS" PAIN SCALE			
	before	4 weeks	8 weeks
treatment group	$0.42 \pm 0.22$	$0.38 \pm 0.21$	$0.27 \pm 0.25$
control group	$0.48 \pm 0.23$	$0.42 \pm 0.16$	$0.45 \pm 0.14$
SATISFACTION SCORE			
	before	4 weeks	8 weeks
treatment group	$1.75 \pm 0.72$	$1.50 \pm 0.76$	$1.00 \pm 0.60$
control group	$1.83 \pm 0.69$	$1.50 \pm 0.96$	$1.67 \pm 0.94$
all values as means $\pm$ SD			

Figures 1 and 2 visualize the results. In both figures and in table 1 lower numbers mean positive results.

### Conclusion

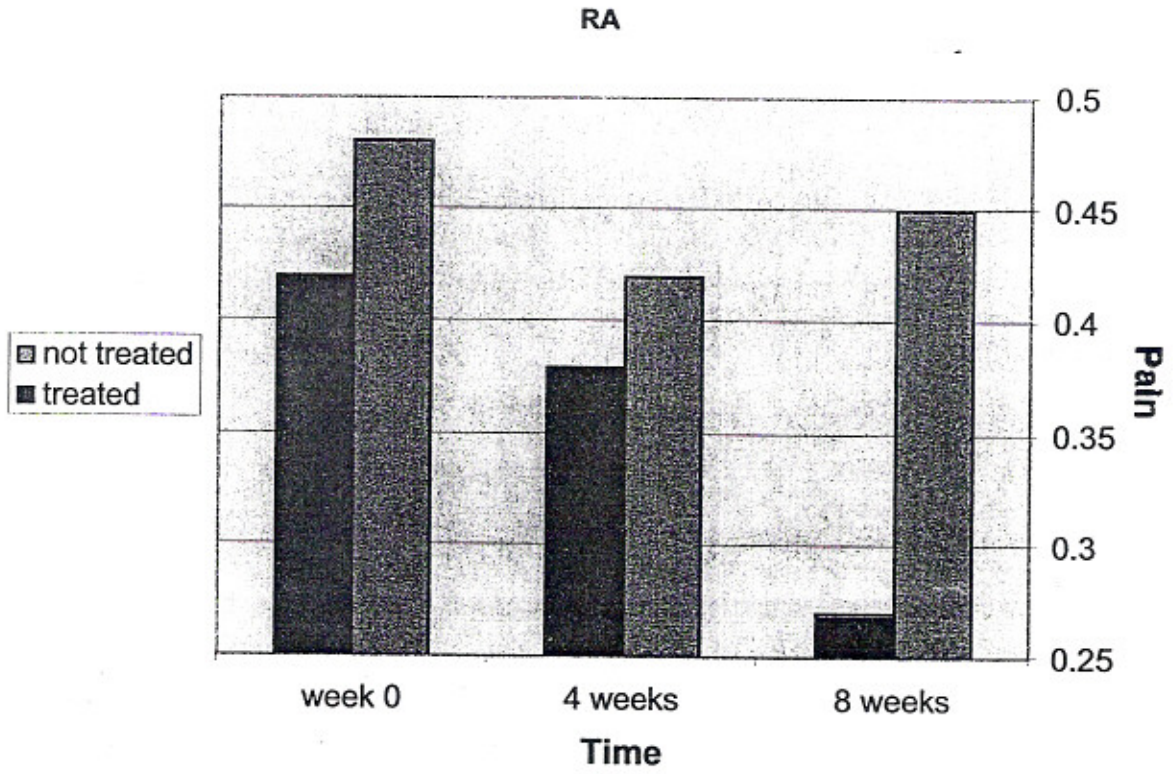
BioAstin or products containing astaxanthin may be an important addition to RA treatment allowing patients to have less pain and more satisfaction with their ability to perform their usual activities. Further study with larger study groups is needed.

Figure 1 - Satisfaction before and after BioAstin



Satisfaction scale is from 0 to 3, with zero being most satisfied and 3 not satisfied at all

Figure 2 - Pain before and after BioAstin



## Appendix One

Date \_\_\_\_\_

Print Name \_\_\_\_\_

## Kona Algae & Rheumatoid Arthritis Study

### *Health Assessment Questionnaire*

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

1. Please check (✓) the ONE best answer for your abilities at this time:

AT THIS MOMENT, are you able to:

	<u>without any difficulty</u>	<u>with some difficulty</u>	<u>with much difficulty</u>	<u>unable to do</u>
a. Dress yourself, including tying shoelaces and doing buttons?	___0	___1	___2	___3
b. Get in and out of bed?	___0	___1	___2	___3
c. Lift a full cup or glass to your mouth?	___0	___1	___2	___3
d. Walk outdoors on flat ground?	___0	___1	___2	___3
e. Wash and dry your entire body?	___0	___1	___2	___3
f. Bend down to pick up clothing from the floor?	___0	___1	___2	___3
g. Turn regular faucets on and off?	___0	___1	___2	___3
h. Get in and out of a car, bus, train or airplane?	___0	___1	___2	___3
i. Walk two miles?	___0	___1	___2	___3
j. Participate in sports and games as you would like?	___0	___1	___2	___3
k. Get a good night's sleep?	___0	___1	___2	___3
l. Deal with feelings of anxiety or being nervous?	___0	___1	___2	___3
m. Deal with feelings of depression or feeling blue?	___0	___1	___2	___3

2. How much pain have you had because of your condition OVER THE PAST WEEK?

Place a mark on the line below to indicate how severe your pain has been:

NO  
PAIN

\_\_\_\_\_

PAIN AS BAD AS  
IT COULD BE

3. Which of the following best describes you TODAY? Please check (✓) only one:

- a. I can do everything I want to do.
- b. I can do most of the things I want to do but have some limitations.
- c. I can do some, but not all, of the things I want to do, and I have many limitations.
- d. I can do hardly any of the things I want to do.

PLEASE TURN TO THE NEXT PAGE

4. When you get up in the morning, do you feel stiff? \_\_\_Yes \_\_\_No

If you answer "No" please go to Item 6.

5. If you answer "Yes," please write the number of minutes: \_\_\_\_, OR number of hours: \_\_\_\_  
until you are as limber as you will be for the day?

6. How much of a problem has unusual fatigue or tiredness been for you OVER THE PAST  
WEEK? Place a mark on the line below:

FATIGUE IS  
NO PROBLEM

\_\_\_\_\_

FATIGUE IS  
A MAJOR  
PROBLEM

7. How do you feel TODAY compared to TWO WEEKS AGO? Please check (✓) only one:

- a. Much better today than two weeks ago
- b. Better today than two weeks ago
- c. The same today as two weeks ago
- d. Much worse today than two weeks ago

8. How SATISFIED are you with your ability to do your usual activities? Please check (✓) only  
one:

- a. very satisfied
- b. somewhat satisfied
- c. somewhat dissatisfied
- d. very dissatisfied

9. Considering all the ways in which illness and health conditions may affect you at this time,  
please make a mark below to show how you are doing?

VERY  
WELL

\_\_\_\_\_

VERY  
POORLY

10. Did you miss taking any gelcaps during this 4-week period? No \_\_\_\_\_ Yes \_\_\_\_\_  
If yes, how many did you miss \_\_\_\_\_ and what was the reason \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

*Thanks for completing the questionnaire!*