Nutrition Education and Consulting Service

In conjunction with the

Osteoporosis Education Project

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OSTEORGANICAL® CASE STUDY ANALYSIS

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Osteorganical® Case Study Analysis Introduction

Over the past eleven years the Natural Option Corporation of Coral Gables, Florida has been selling direct-to-the-public a novel sea algae calcium compound packaged with a natural Vitamin D from shark oil. The product, known as Osteorganical®, is assayed to contain calcium 340 mg; magnesium 32 mg; iron 0.31 mg; manganese .07 mg; Vitamin D3 800 IU; and Vitamin A 70 IU (per 2 caps of the calcium compound and 1 cap of the Vitamin D3 compound). The product is purported to halt bone loss and to build bone. The manufacturer, in fact, has been so confident in the product that they have long offered a money back guarantee. Should a user document that they did not experience a bone building effect, the money they invested in this product is returned. Reportedly, per each 1,000 sales only twenty-five individuals request their money back, and 90% of these requests come within 30 days of purchase.

On the other hand, over the years many individuals have voluntarily sent the Natural Option Corporation sequential bone mineral density measurements documenting the increases in bone mineral they experienced while using Osteorganical®. For the purpose of this research ten such volunteered cases of apparent successful bone building from Osteorganical® were sent to me for my review.

Case Study Series Analysis

Number of Cases Analyzed:
10 cases of postmenopausal women with excessive bone loss were analyzed.

Type of Sample:
This sample of ten cases involves what is known as an "availability" sample. The Natural Option Corporation made known their interest in seeing recent before and after bone mineral testing and offered individuals an opportunity to participate in a review of their case to be conducted by myself. Those individuals who most readily responded to this offer were those included in this case study analysis.

Analysis Protocol:
First we analyzed and documented the bone mineral density reports from before and after the use of Osteorganical®. Second, Dr. Brown conducted telephone interviews with each of these women. Lastly the data was complied and the report written.

Research Findings:
It is very clear from careful analysis of these ten cases that Osteorganical® had a bone building effect on these women. In seven cases Osteorganical® was the only substance used, while all other variables remained nearly constant. In these cases there is no doubt that the bone building effect documented was derived from Osteorganical® use.

In one case (Case 8) Osteorganical® was the new component of a long established drug treatment bone program. In the two other cases (Cases 9 and 10) the women also experienced good bone mineral increases. However, I cannot guarantee that these gains were solely due to Osteorganical®, as these two women were also taking another substance that could have had a bone building effect. I have included these cases for completeness. Further, these case studies strongly suggest that there might be an important role for Osteorganical® when used in conjunction with other bone therapies. As it appears, the use of Osteorganical® in conjunction with anti-resorptive drugs like Fosamax leads to unprecedented gains in bone mineral density.

Case # 1
Doris Falk, Little Falls, MN Age: 72 Dx: Osteoporosis of Spine and Hip

Doris has had five sequential bone density measurements since 1996. These measurements documented that she was consistently losing bone. She began using Osteorganical® in the 2 calcium caps and 1 vitamin D cap recommended dose (from here on to be called the "recommended dose").

Doris began Osteorganical® in 4-2001 and after 14 months using the product she had gained bone mineral density at all sites tested (+1.7% in the total hip; +2.6 in the femoral neck and + 1.8% in the spine).

Case # 2
Rose Teeters, La Ponte, IN Age 87 Dx: Osteoporosis Hip and Spine

Rose began Osteorganical® 10-2000, with a baseline bone density test of 11-2000. During this period she used the recommended dose of the product. After 12 months using Osteorganical® she increased bone mineral density in both the spine and hip (+ 7.8% spine and +2.3% hip). Scoliosis may influence spinal reading.

Case # 3
PaulinaThoma, IL Age 92 Dx: Osteoporosis
(Subject requested that city not be listed)

Paulina is a nursing home resident who had a CT Scan 2-2000 providing a diagnosis of spinal osteoporosis (only the spine was measured). She began Osteorganical® in the recommended

dose in 4-2001. Paulina took no other bone-building agents. The bone density improvement between her tests of 5-2001 and 10-2001while on Osteorganical® moved her from having severe osteoporosis with a –3.5 standard deviation score in early 5-2001, to a just barely having the osteoporosis diagnosis of –2.5 standard deviations six months later in late 10-01.

Case # 4
Elizabeth Wilding, Ramsey, NJ Age 87 Dx: Osteoporosis of Hip and Osteopenia of Spine

Elizabeth had a bone density measurement in 9-99 which indicated osteoporosis of the hip and spine. She began using Osteorganical® 11-99 and continued thereafter while using no other medication that would impact bone. The follow-up bone density test done 18 months later in 5-01 showed an increase of total hip bone mineral of +2.5; a spinal increase of +18.9 and a wrist decrease of –5.3%.
She took the recommended dose of Osteorganical®.

Case #5
Lois Ghan, Ione, Ca. Age 71 Dx. Osteoporosis of Wrist (distal radius)

Lois was diagnosed with osteoporosis by a single measurement of the distal radius (wrist) in 8-01. She was on no other bone medications and began Osteorganical® in the recommended dose in late 9-2001. A bone density of late 8-2001 serves as her baseline measurement. Between 8-2001 and 7-2002 while on Osteorganical® she gained 4.5% in the distal radius.

Case # 6
Janice Green, Houston, TX Age 54 Dx: Osteopenia of Spine

Janice was diagnosed with osteopenia of the spine and found to have hip bone density lower than that of the average young person (but not yet in the osteopenia range). In 1-2001 she began Osteorganical® because her mother had severe osteoporosis and Janice feared losing bone. Janice took the recommended dose. She was on no other medications that would impact bone. Although only having mild osteopenia, Janice experienced a spinal increase of 4.8% and a 0.1% increase in the total hip during the time she was on Osteorganical® (1-25-01 to 4-13-02). She, as the other women studied, continues on this product today.

Case # 7
Marlene Buras, Kenner, LA Age 67 Dx: Osteoporosis of the hip; normal spine density

In 4-2000 Marlene was diagnosed with osteoporosis in the hip. Her next bone density in 8-2001 showed on-going bone loss of both the spine and hip. In 8-2001 she began using Osteorganical® in the recommended dose. Between 8-2001 and 3-2002 she gained 3.7% in the spine and 0.6% in the hip.

Case # 8
Ruth Wright, Greeley, CO Age 82 Dx: Osteoporosis of Hip, Osteopenia of Spine

Ruth has been using Fosamax since 1995 without a baseline bone density measurement. Her

"baseline" test was 4-99 having already been on Fosamax for some four years. Ruth began using the recommended dose of Osteorganical® in 2-2000 while continuing on the Fosamax. Her subsequent bone density tests from 4-2000 to 4-2002 showed increases that in my analysis are clearly due to the addition of Osteorganical®. I suggest this because Ruth had been on Fosamax for over four years when she began Osteorganical®. At that point the bone building impact of Fosamax should have reached a plateau and subsequent large changes in bone mineral would not be expected. The increases in bone mineral seen when Osteorganical® was added to the long established Fosamax program were +5.9% in the spine and +11.6% in the hip. She had been on Osteorganical® 22 months at the time of this follow-up bone mineral test.

Case #9
Marion Williams, Pilesgrove, NJ Age 68 Dx: Osteopenia of the Spine

Marion had a bone mineral measurement on 11-6-2000 with a diagnosis of osteopenia of the spine. She began taking Osteorganical® in 12-2000. Between 11-2000 and 5-200l, while on the recommended dose of Osteorganical®, Marion showed a spinal increase of 3.2% and a hip increase of 1.3%. Interestingly enough, before using this product she experienced a 3.57% loss in spinal bone mineral from 10-99 to 11-2000. Marion's case might be confounded, however, because during 6 months of her time using Osteorganical® she also used some amount of soy isoflavones. As best she recalls, during 6 months of Osteorganical® use she also used some 80 mgs of soy isoflavones from four to five times a week. From my research on soy isoflavones, I do not believe this dose of soy isoflavones had a significant bone building effect. This possibility, however, cannot totally be ruled out. Soy isoflavone research suggests that regular daily use of 100 mgs of soy isoflavones is needed to obtain a much less modest increase in bone density. Marion was only taking 80 mg of the isoflavone on an irregular basis.

Case #10
Irene Mields, Alexandria, VA Age 77 Dx: Osteopenia of Hip and Spine

Irene was diagnosed with osteopenia in June, 1999 and began use of Fosamax. Ten months later she began Osteorganical®, taking it along with the Fosamax she had already been on for ten months. In August, 2001 she obtained a follow-up bone mineral test (being on Osteorganical® nearly 15 months and on Fosamax some 26 months at this time). Between the bone mineral tests of 6-99 and 8-2001 she was documented to gain 7.5% spinal bone mineral and 18.4% hip density. As the radiologist technician commented to her, these gains are very unusual and not commonly (if ever) seen with the use of Fosamax alone. These exceptional gains in bone mineral obtained by combining the drug Fosamax with Osteorganical® suggest a new possibility of combined therapies well worth investigating.

Study Conclusion

While retrospective case studies of this sort by their nature lack a refined scientific rigor, analysis of these cases documents the potential of this novel calcium and Vitamin D product to halt and reverse the osteoporosis process in postmenopausal women.

The bone mineral gains attributable solely to the use of Osteorganical® were as high as 18%. Younger postmenopausal women in their fifth and sixth-decade benefited, as well as older women in their seventh decade and beyond. In most cases greater gains were seen in the spine than in the hip. Also, osteoporosis research suggests that those with the most bone loss benefit the most from nutrient therapy. Using Osteorganical® however, the few women in the sample with only moderate bone loss (osteopenia) also benefited significantly from this therapy. Finally, the three cases in which Osteorganical® was used in conjunction with another bone-enhancing therapy suggest that combining Osteorganical® with other therapies might lead to unusually large gains in bone mineral density.

The Next Step in Osteorganical® Research

In this analysis all of the women studied gained bone mineral density while using Osteorganical®. And indeed, all of the women interviewed were pleased with their progress and continued on the product. The next question is, just how representative is this sample? That is, just how many postmenopausal women would gain bone density if given Osteorganical®?

To answer this question The Osteoporosis Education Project has joined with the Natural Option Corporation to conduct a clinical trial assessing the ability of Osteorganical® to reduce bone resorption in the short term (three months) and to halt osteoporosis and rebuild bone in the longer term (one year). This study, known as the "Osteorganical® One Year Clinical Trial" is directed by Susan E. Brown, Ph.D., Director of the Osteoporosis Education Project and will begin September, 2002.

Susan E. Brown, Ph.D.,CCN

A medical anthropologist and certified nutritionist, Dr. Susan E. Brown has consulted widely on socioeconomic, cultural, educational and health issues. She has taught in North and South American universities and authored numerous academic and popular articles.

Currently, Dr. Brown directs the **Osteoporosis Education Project** and the **Nutrition Education and Consulting Service** in Syracuse, NY. With the **Osteoporosis Education Project** she conducts primary research, lectures widely on osteoporosis prevention and reversal, and teaches the use of a holistic, natural program for the regeneration of bone health. The **Nutrition Education and Consulting Service (NECS)** provides consulting, education, research and lecture services for health professionals and the public. In addition to running a busy private practice, Dr. Brown serves as a consultant to various medical and industry groups.

Further information on Dr. Brown, her publications and her work, is available on the attached biography or at www.betterbones.com and www.susanbrownphd.com

The Osteoporosis Education Project

The Osteoporosis Education Project (OEP) is a non-profit, public interest research and education organization located in Syracuse, NY. Its mission is to explore the human potential for bone health maintenance and regeneration, seeking natural ways to build and rebuild bone. As a part of our public interest work OEP studies and attempts to document the efficacy of natural bone building products and formulations. Information on OEP research and education efforts can be found on their website www.betterbones.com

As the Director of The Osteoporosis Education Project I have had the opportunity to experiment widely with natural bone-building programs. Unfortunately, I have learned that it is often difficult to halt bone loss, much less rebuild bone, with simple natural means. Given our experience, we are constantly looking for new natural formulations, which report success in halting and even beginning to reverse osteoporosis.