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# TRUCAL<sup>®</sup> MILK CALCIUM SIGNIFICANTLY INCREASES BONE STRENGTH AND IMPROVES BONE BIOMARKERS *IN VIVO*

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## ABSTRACT

While calcium has been identified as the primary nutrient attributed to bone health, it is clear that the benefit of calcium is strongly influenced by other macro and trace minerals. A balanced mineral profile is critical when assessing the impact of a supplement on bone formation and mineralization. TruCal contains the correct balance of minerals required for maximum bone growth and maintenance.

TruCal<sup>®</sup> and calcium carbonate were evaluated for bioavailability in a rat model. Young growing wistar rats (10 per group) consumed standardized diets fortified with calcium for one month. After completion, bone density and bone tensile strength were measured. TruCal was more effective at increasing bone tensile strength and bone density in young growing rats than calcium carbonate.

In a separate study, the impact of TruCal and calcium carbonate on bone biomarkers was determined in a six-week human clinical trial. Results showed that TruCal caused a significant positive shift in bone biomarkers (urine helical peptide and bone alkaline phosphatase) compared to calcium carbonate and baseline values. TruCal was more effective than calcium carbonate at decreasing bone loss and building strong bones.

## INTRODUCTION

Milk and low-fat dairy products have long been recognized as the premier source for calcium and minerals. Obtaining calcium from milk is advantageous, because the balanced profile of milk may enhance calcium absorption and mineral retention. The consumption of milk provides a meal effect due to its balanced profile, fostering the absorption of calcium and phosphorus, which is critical for bone deposition<sup>1</sup>.

Young adolescents who do not consume milk or dairy products have lower total body mineral content and decreased bone density<sup>2</sup>. Milk also arrests bone loss in post-menopausal women<sup>3</sup>. The aforementioned advantages are associated with the balanced profile of milk, and can't be provided by calcium alone.

TruCal was developed to provide milk minerals in a form that could be used in a wide variety of applications. TruCal is the mineral fraction of milk that has been concentrated and spray dried into a powder. It includes both macro-minerals (Ca, Mg, K, P), as well as trace minerals (Cu, Zn, Fe), which are critical for optimizing bone health. The following two studies were conducted to evaluate the balanced profile of TruCal *in vivo*.

## MATERIALS AND METHODS

### *Wistar Rat Study*

Thirty young wistar rats were randomly assigned to three different groups. The groups included a control group (5% RDI), a calcium carbonate group (30% RDI), and a TruCal group (30% RDI). Macronutrients and micronutrients were standardized across all groups except the control group, which did not receive additional calcium. After one month, bone density and bone mineral content were measured. The study was approved by the Institutional Animal Care and Use Committee (IACUC).

### *Human Clinical Study*

Twenty females were randomly assigned to consume 700 mg of calcium from TruCal or calcium carbonate every day for six weeks. Calcium supplementation was consumed two times per day (350 mg twice per dose) with a meal. Urine helical peptide (UHP) and bone alkaline phosphatase (BAP) were measured at baseline and after six weeks of supplementation.

This study was IRB approved and was performed according to Good Clinical Practice Guidelines, the Declaration of Helsinki (2000), and US 21 CFR Part 50—Protection of Human Subjects, and Part 56—Institutional Review Boards.

## RESULTS

The present studies were designed to assess the impact of TruCal on bone formation and mineralization. Bone is a dynamic system consisting of living cells embedded in a mineralized matrix. This matrix is subject to breakdown, repair, and rebuilding, just like any other tissue in the body.

### *Wistar Rat Study*

Macro and trace minerals, as found in TruCal, are critical for the production of the mineralized matrix of bone. Deficiencies have been correlated with lower bone mineral density and strength.

Figure 1 shows the bone density at one month. TruCal subjects had a significantly higher bone density compared to the control and calcium carbonate groups.

**FIGURE 1: Rats consuming TruCal had a higher bone density (p<0.05)**

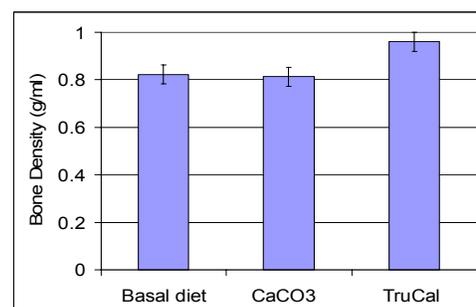
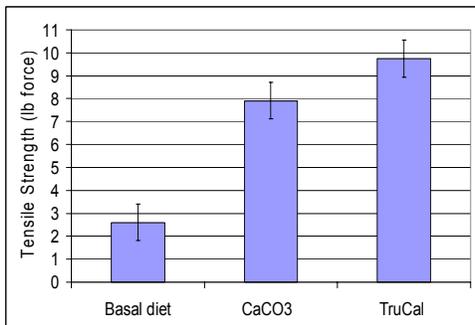


Figure 2 illustrates the superior performance of TruCal versus calcium carbonate on tensile bone strength for each group at one month.

**FIGURE 2: TruCal group had the highest bone tensile strength (p<0.05)**



**Human Clinical Study**

Remodeling consists of two stages: resorption and formation. During resorption, osteoclasts excavate areas of weakened bone. In bone formation, cells called osteoblasts lay down deposits of new bone. As we age, bone resorption exceeds formation. This amounts to a loss in bone mineral density. A higher rate of bone remodeling will lead to a more rapid loss of bone mass and thus more fragile bones.

We evaluated TruCal's impact on remodeling. UHP and BAP are sensitive biomarkers for bone resorption and bone turnover, respectively. Lower values for both biomarkers are critical, as this indicates a lower rate of bone remodeling. This results in a decreased loss of bone mass and thus stronger bones. Baseline values are shown in comparison to values after six weeks of supplementation with TruCal and calcium carbonate.

Figure 3 contains the measurements for urine helical peptide (UHP). Consumption of TruCal resulted in a significantly lower UHP value when compared to baseline and calcium carbonate, which is indicative of less bone mass loss. Calcium carbonate exhibited very little impact on UHP.

**FIGURE 3: TruCal significantly decreased urine helical peptide (p<0.05)**

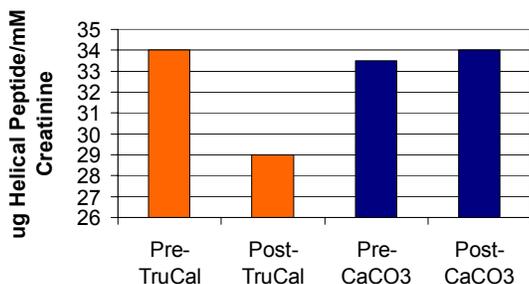
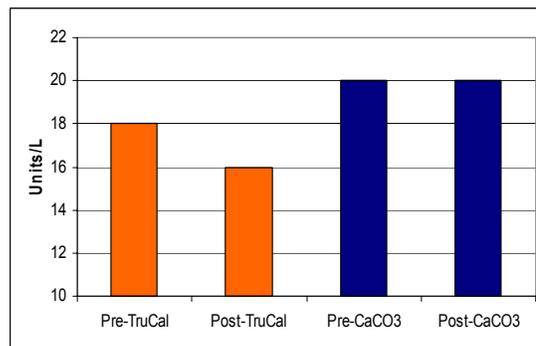


Figure 4 illustrates the results for bone alkaline phosphatase (BAP). TruCal showed a significant decrease in bone alkaline phosphatase activity when compared to baseline and calcium carbonate, which represents less bone turnover. Calcium carbonate had no impact on this biomarker.

**FIGURE 4: TruCal significantly decreased bone alkaline phosphatase (p<0.05)**



**CONCLUSIONS**

TruCal provides a bioavailable source of milk minerals that are absorbed and physiologically available for bone formation and mineralization.

TruCal was more effective at increasing bone tensile strength and bone density in young growing rats than calcium carbonate.

TruCal was more effective than calcium carbonate at decreasing bone loss and building strong bones during a six-week human clinical study.

TruCal delivers an excellent balance of calcium and other essential minerals critical for optimizing bone health.

TruCal is unique ingredient suitable for use in a wide variety of applications developed to help individuals optimize and maintain strong, healthy bones.

**References**

1. Guegen, L., et al., *The Bioavailability of Dairy Calcium*. J Am Coll Nutr, 2000. 19(2): p. 119S-136S.
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