ORIGINAL ARTICLE

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SUMMARY

It is known that collagen is a protein of great importance for bones, tendons, cartilage, muscles, skin, hair and nails. There are several types of collagen, and type II is the main component of the joint cartilage matrix and can help prolong the independent lifestyle of an elderly person, improving their quality of life. The research aimed to evaluate the effect of a collagen mix composed of peptides, type II collagen and nutrients involved in the joint bone metabolism of active elderly. Volunteers with a minimum age of 60 years and physically active participated in the research. This is a non-randomized clinical trial conducted with the gymnastics group of the elderly of an Activity Center in Florianópolis – SC. Oral supplementation with the collagen mix composed of bioactive peptides of hydrolyzed

collagen, intact type II collagen, silicon and nutrients involved in joint bone metabolism (Duo flex®) was administered for 90 days, and the next 30-day cycle of the supplement was always delivered before the end of the current cycle, so that the participants did not interrupt the treatment. These were also followed weekly via telephone contact to avoid withdrawal or interruption of treatment. Questionnaires were applied to evaluate symptoms related to sarcopenia, joint functionalities, characteristic skin, nails and hair health, and anthropometric measurements. The sample consisted of 50 elderly, most of them female (72%). Product consumption reduced pain, decreased stiffness and improved joint mobility according to the WOMAC questionnaire result. Duo flex® has significantly improved joint health and therefore can be an effective solution to delay joint manifestations. The results suggest that collagen mix can be used as a therapeutic approach for physically active elderly.

Keywords: collagen, elderly, osteoarthritis, body composition, aging.

1. Introduction

According to the United Nations (UN, 2017), health care systems around the world are working to promote healthy aging, prevent and treat chronic non-communicable diseases. The global population aged 60 and over totaled 962 million in 2017, more than double that in 1980, when there were 382 million elderly people worldwide. The number of elderly people is expected to continue to grow considerably by 2050, when it is expected to reach almost 2.1 billion.

The elderly individual may present clinical manifestations with several alterations that are part of natural aging even though they have a physically active life and healthy diet. With this occur gradual loss of muscle mass, degeneration in articular cartilages, aging of the skin, hair loss, weak nails, which can thus decrease life satisfaction and increase the mortality rate (CAI, 2016).

Articular cartilage is a well-organized tissue with remarkable durability, however, the damage can result in debilitating joint pain and functional impairment in the old person, worsening mobility (MORAN *et al.,* 2014; QUEIROZ; LEMOS; RAMOS, 2010). According to Bakilan *et al.* (2016), degenerative changes are observed in both articular and subcondral bone. The

imbalance between synthesis and degradation leads to its destruction. Therefore, numerous pharmaceutical and nutritional agents have been developed with the aim of slowing the progression of structural changes in Osteoarthritis (OA), such as collagen.

Collagen is a protein of structural function for cells and there are different types of collagen, depending on the tissues from which it originates. Type I is the most common, usually found in places that resist high strains such as tendons, dermis, bones and even cornea. Type II is found in structures resistant to high pressures, such as elastic cartilage and hyaline, intervertebral discs and eyes. Type III collagen is identified in the aorta artery, lungs, muscles of the intestine, liver, uterus constituting reticular fibers and type VI, is not associated with fibrils, has the function of support and filtration, present in the kidneys, basal lamina and crystalline capsule (GERMANO *et al*., 2016).

Collagen peptides (PC) have been proposed as nutraceuticals to improve joint health in patients with osteoarthritis. In a prospective, randomized, double-blind, placebo-controlled study in older women with mild to moderate knee osteoarthritis, it was demonstrated that oral intake of collagen peptides for six months significantly reduced joint pain and improved mobility assessed by two well-established scoring systems (WOMAC and Lysholm scores). This study confirmed that collagen peptides are highly efficient nutraceuticals to improve joint health, which can help maintain an active lifestyle throughout aging (JIANG *et al.,* 2014).

Since the body of the elderly individual needs care to minimize the aggressions to joint, bone and muscle tissues so that they have greater autonomy and better quality of life, the aim of this study was to evaluate the effect of a collagen mix, composed of collagen peptides, type II collagen, organic silicon and nutrients involved in the joint bone metabolism of the elderly.

2. DEVELOPMENT

2.1 METHODOLOGY

This is a non-randomized clinical trial, with participants who attended the gymnastics classes, volive class, multifunctional training and pilates in an Activity Center in the city of Florianópolis – SC. Individuals aged 60 years or older were recruited. The volunteers

participated in the study only after signing the Free and Informed Consent Form (TCLE) according to Resolution N°. 466/12 of the National Health Council, which was approved by the Research Ethics Committee (CEP) of the Estácio de Santa Catarina University Center, meeting the requirements of Resolution N°. 466/12, which describes the rights that are established for research projects involving human beings. Approved according to the process (CAAE: 96708718.0.0000.5357).

The study included 50 affected subjects with joint pain and/or self-reported diagnosis of bone and/or joint disease. The subjects began the 90-day treatment with the collagen mix composed of bioactive peptides of hydrolyzed collagen, intact type II collagen, silicon and nutrients involved in joint bone metabolism (Duo flex®) in order to evaluate the influence of this supplementation on the general state of the participants, especially on joint manifestations.

The research had the following exclusion criteria: participants who were using chondroitin and/or glucosamine, non-steroidal anti-inflammatory drugs (AINEs) and corticosteroids, but those who had been using these same drugs for more than 30 days and still felt pain were included. Participants who did not comply with the protocol or who modified eating and/or physical habits during the intervention could be excluded from the study. Those who had surgeries, intra-articular medication injections, or who had modified oral medication in the month prior to the beginning of the study would also be excluded. Participants with synovite and effusion in the knee, severe concomitant systemic diseases, peripheral or central neurological disorder, heart, renal, hepatic, or severe hematological disease were not accepted in the study. In addition to those who included medications such as chondroitin and/or glucosamine (AINEs) and corticosteroids during the study, they would also be excluded.

Data were collected at time 0, after 30, 60 and 90 days of intervention.

2.2 METHODOLOGICAL DESIGN

To trace the profile of the sample, the questionnaire adapted with variables such as age, gender, level of physical activity and anthropometric measurements was used (MOTA, 2017).

Regarding anthropometric data, the weight was measured by means of a transparent glass digital scale of the Powner® brand with a capacity of 150 kg. For height measurement, the compact 200 cm, wall-mounted, Slim Fit®. The nutritional status of the elderly was classified according to the Body Mass Index (BMI) and evaluated according to the cutoff points of the Pan American Health Organization (PAHO 2002), and the elderly were classified as underweight (BMI ≤23 kg/m²), normal weight (BMI ≥23≤28 kg/m²), overweight (BMI ≥28≤30 kg/m²) and Obesity (BMI ≥30 kg/m²).

To investigate the effect of supplementation on symptoms related to sarcopenia, the SARC-F + CP score (calf circumference) was applied, which contain 5 components that signify the letters of the name of this questionnaire in English, Strength, Walking Assistance, Get up from a chair, Climb stairs and Falls, and scores range from 0 to 10 for CP and from 0 to 2 points for each component that makes up the questionnaire. The score equal to or greater than 4 was predictive of sarcopenia (MALMSTROM *et al.*, 2016).

To measure the calf circumference, a measuring tape of the TBW brand ® flexible plastic, inelastic, auto retractable and graduated from 0 to 150 cm, measured in the most protuberant part, was used while the patient was seated, with the leg folded at an angle of 90 degrees. Calf circumference is a good parameter for evaluating muscle mass in the elderly and should be considered adequate to circumference equal to or greater than 31 cm for men and women (BRASIL, 2017).

The HAQ (*Health Assessment Questionnaire*) score assesses eight areas of habitual functional activities, with 20 questions about the patient's daily life. The patients answered the questions each with four possibilities of answers, being: no difficulty (score 0), with some difficulty (score 1), with great difficulty (score 2) and unable to perform (score 3). The arithmetic mean of the highest score of each of the eight areas evaluated was calculated and the final result was the HAQ score (FERNANDES, 2003).

The WOMAC score (*Westerm Ontario and McMaster Universities*) is divided by sections that question the intensity of pain in knee arthrosis, intensity of joint stiffness in the knee and ability to get around and to take care of themselves in daily physical activities, in which the responses can be "none", "mild", "moderate", "strong", "very strong". To analyze the data, these levels were transformed respectively into 0, 25, 50, 75 and 100. Therefore, used to

analyze the efficacy of supplementation in joint recovery (FERNANDES, 2003).

The Lequesne score was also used to analyze the joints and according to Marx *et al.* (2006), investigates whether the person feels pain, discomfort or does not feel pain during daily activities. It is a way to evaluate the functional improvement of a patient with osteoarthritis, where the subject reports his difficulties. Scores range from zero (without involvement) to two (incapable) and the sum of the score ranges from 1 to 4 (little involvement), 5 to 7 (moderate), 8 to 10 (severe), 11 to 13 (very severe), equal to or greater than 14 (extremely severe).

The usual day questionnaire described the daily meals of each subject to control eating habits during the study. Diets with values between 90 and 110% of the recommendation were considered adequate, insufficient when <90% and excessive when> 110%. In addition, an adapted questionnaire used to evaluate the health characteristics of the skin, nails and hair was applied as an indirect way to evaluate the possible benefits of collagen peptides and associations of the supplement on the health of body structures. After 30, 60 and 90 days of treatment intake, with questions that evaluated whether there was a difference in firmness, elasticity, hydration and general appearance of the skin, regarding the appearance, growth and strength of the nails (ADDOR, 2015).

2.3 INTERVENTION

Participants were instructed to ingest 12g of Duo flex brand Snella® (provided by Basecol Mix® – Botucatu – SP) daily for 90 days. They were instructed to dissolve the product in a glass of water, juice or vitamin or even, crumpled with fruits in one of the intervals between the main meals (snack). The individuals were instructed about the benefits of intake of the supplement and the need to maintain without changes the eating and physical habits, as well as the use of medications during the study.

The data were tabulated in the Microsoft Office Excel® program and analyzed with graphpad instat software with Student's T Test, being considered significant $p<0,05$. The results obtained were presented through tables and graphs.

2.4 RESULTS AND DISCUSSION

Of the elderly analyzed, the majority were female (72%). The mean age was 67 ± 5.2 years, with no significant difference between the sexes, with a mean of 67 ± 4.9 years in women and mean of 67 ± 6.3 years in men. The mean height of the volunteers was 1.61 ± 0.096 m and the average weight was 71 ± 12.7kg. Regarding the type of physical activity of the participants, 16% practiced gymnastics, 36% volleyball, 24% multifunctional training and 24% pilates. All participants remained physically active during the study and did not change their medications and/or diet.

The assessment of nutritional status (EN) of the participants showed that 16% were underweight, the largest share (58%) had normal weight, 12% were overweight and 14% were obese. The participants maintained the same EN until the end of the study.

In relation to EN, high weight (26% of participants), added to the natural processes and wear iness of aging, can interfere in the maintenance of health with the increase of joint pain, negatively influencing quality of life and morbidity and mortality (CHUMLEA, 1989).

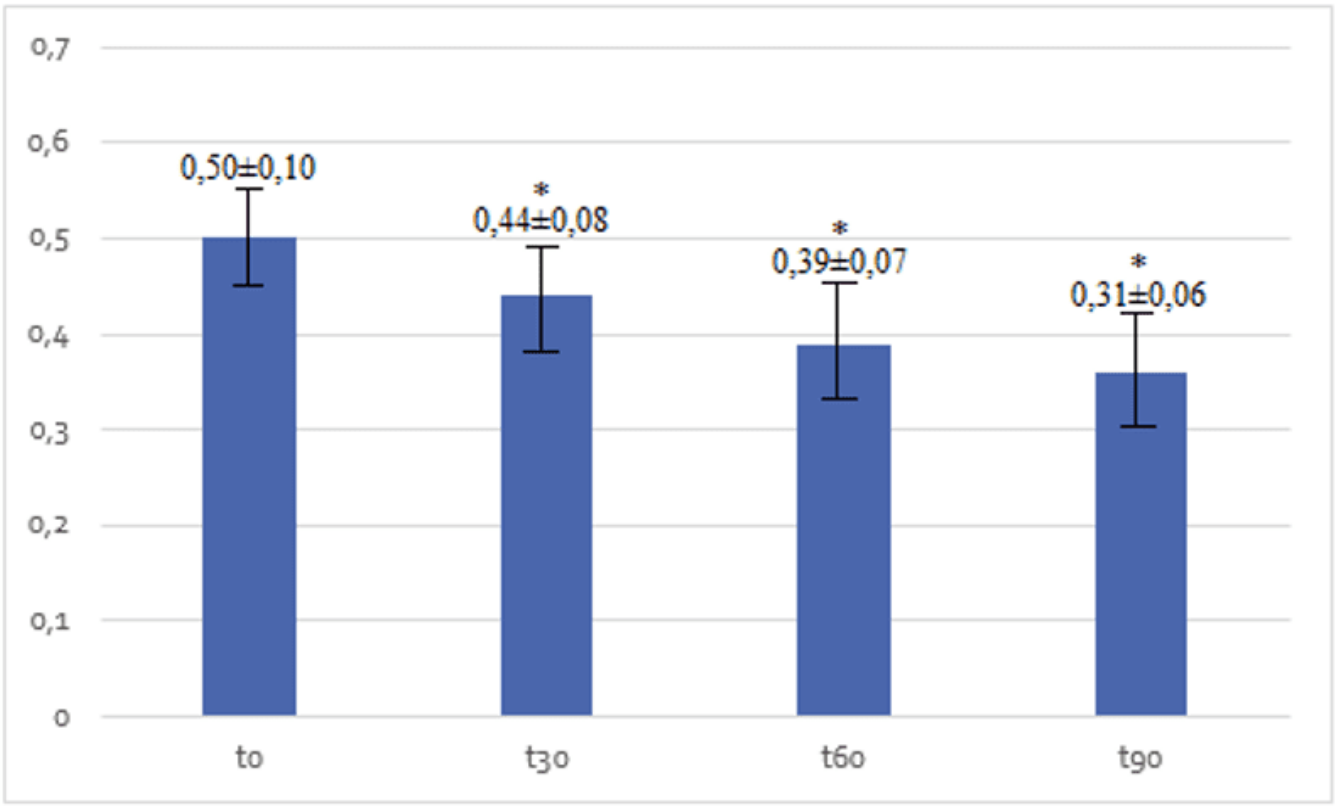
Another common complaint observed in the sample studied was regarding the health of the skin, nails and hair. It is known that the reduction of collagen, a common situation in senectude, not only worsens the health of osteoarticular structures, but is also shown in aesthetic issues. Regarding the evaluation of skin, nails and hair characteristics, there was a partial improvement of the nails in 32% of those analyzed; partial improvement of nails and hair (26%); partial improvement of skin and nail (4%); total hair improvement (10%); total improvement of hair, skin and nail (6%); and reported indifference (22%) of those studied. As age increases, there are changes that lead to a decrease in collagen in the general population, which are not yet fully understood. Aging can vary from person to person, lifestyle, current and established diseases, genetic and environmental influences (YAAR *et al.*, 2002), and the replacement of collagen peptides seems to bring beneficial results regardless of external factors, in the present study, seen in 78% of those analyzed.

To evaluate sarcopenia through the SARC-F + CP protocol, it was evidenced that 16% of the elderly started in t0 with sarcopenia, while in t30 they became 14% and at the end of the study it increased to 12%. Although supplementation did not have the main objective aimed

at improving lean mass, 4% of the participants showed these beneficial results at the end of the study. There were no new cases of sarcopenia during the research. The study by Zdzieblik (2015) was able to prove that individuals supplemented with collagen presented a greater increase in lean mass and muscle strength, which corroborates the results in question.

In addition to the analysis of lean mass, the functional status evaluated was performed by means of HAQ, where more than half (60%) they presented in the classification of mild deficiency, that is, that they are able to perform activities of daily living, however, there was a prevalence of 47% who reported pain or discomfort in the shoulder joint, and that according to Figure 1, performance is observed along t30 ($p = 0.0003$), t60 ($p < 0.0001$) and t90 ($p < 0.0001$) when compared to t0. Lately, collagen peptides have been vividly discussed as a symptom-modifying agent for osteoarthritis. Based on their application in functional foods as bioactive ingredients, they are thought to act in a phase before the disease, helping to prevent or delay the manifestation of osteoarthritis (VIJVEN *et al. 20*12), as in already established situations, bringing improvements.

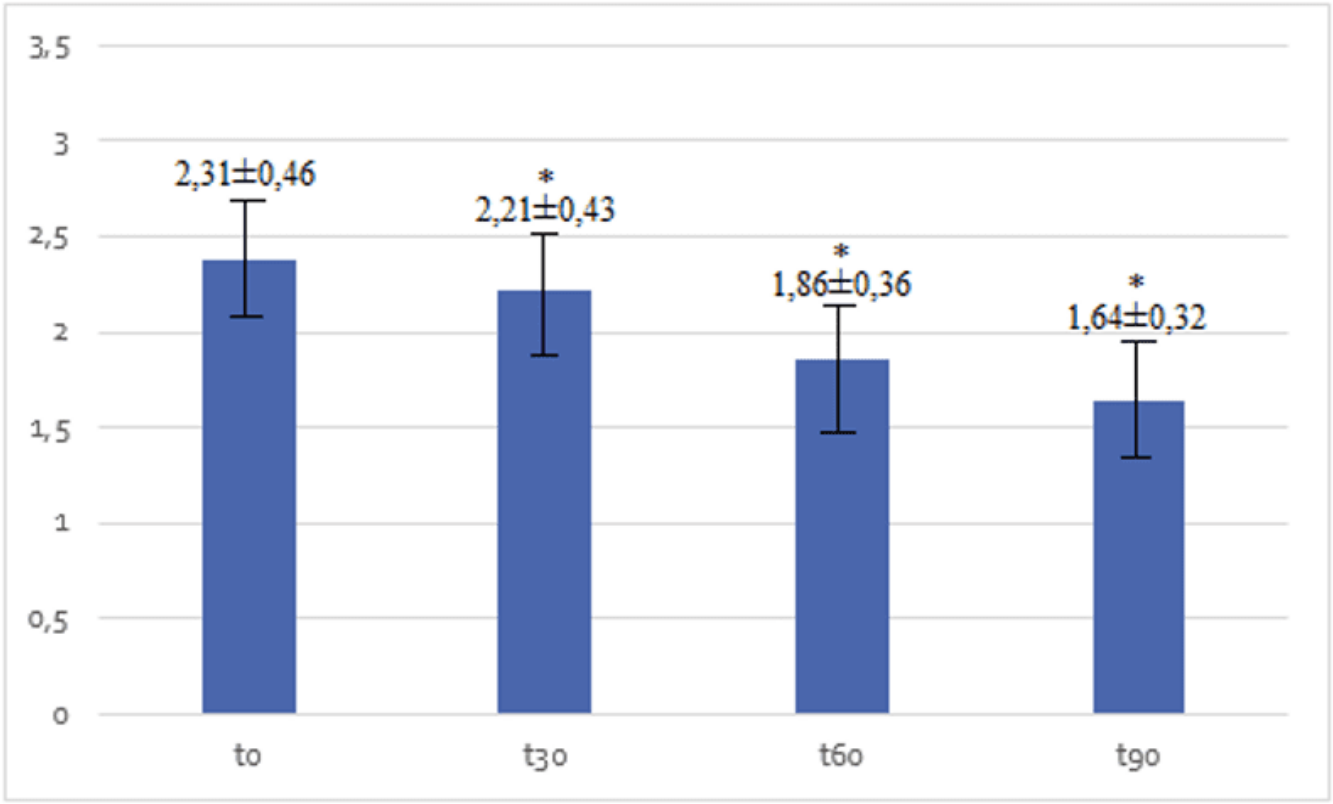
Figure 1 – Comparison of pain/discomfort measured by HAQ questionnaire (mean ± DP) during study times with collagen mix supplementation.



*Source: primary data (2018). Legend: *p < 0.05 when compared to t0.*

In the evaluation of the WOMAC protocol, it was observed that 58% of the volunteers had osteoarthritis in the knee or felt some discomfort related to symptoms. For the participants who answered this protocol, an improvement was obtained in the first month of treatment, as shown in Figure 2, with the improvement of functional capacity in t30 ($p=0.0001$), t60 ($p<0.0001$) and t90 ($p<0.0001$). These results corroborate the findings in the study Crowley et al . (2009) with the demonstration of the efficacy of treatment with type II collagen and reduction of the WOMAC score by 33% related to difficulties in the daily activities of individuals.

Figure 2 – Comparison of functional capacity measured by WOMAC (Mean ± DP) during study times with collagen mix supplementation.



*Source: primary data (2018). Legend: *p < 0.05 when compared to t0.*

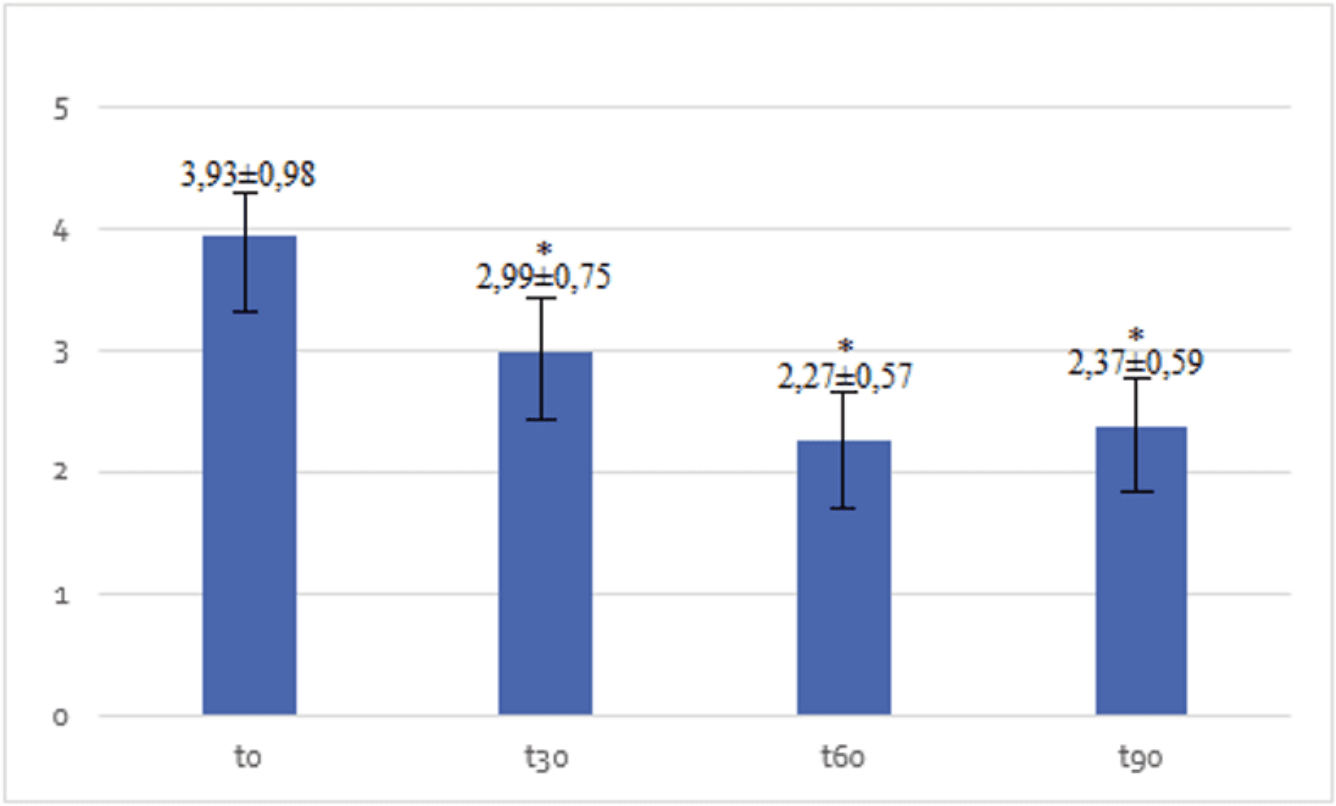
According to Lugo *et al.* (2015), also showed that individuals who consumed type II collagen showed better clinical results compared to those supplemented with placebo in this study. The analysis of WOMAC subscales showed that there were reductions in the three WOMAC subscales contributing to the improvement in the overall WOMAC score observed in individuals supplemented with type II collagen

It is known that with advancing aging, there is loss of trabecular bone. However, according to the study by Oftadeh *et al.* (2015), trabecular microarchitecture was improved after treatment with PC. This result clearly suggests that PCs are effective in improving the capacity of the trabecular network.

Regarding the pain classification of the Lequesne score, most males (71%) mean age 65 ± 5.2 years presented some difficulty in daily activity in relation to the knee and hip, and 30% were obese according to BMI, which may influence this result aggravating the injuries. According to figures 3, there was a reduction in pain/disonform in the hip in t30 ($p<0.0001$),

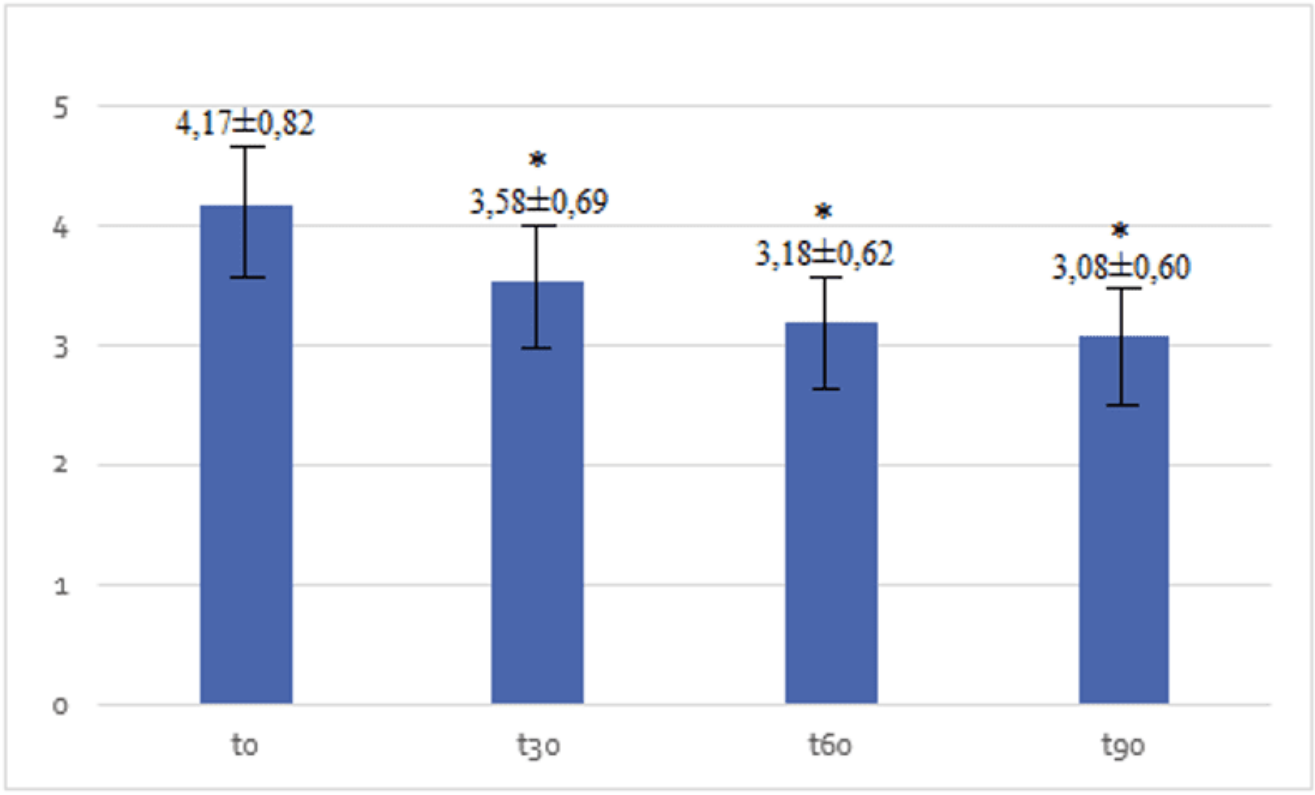
t60 (p<0.0001) and t90 (p<0.0001) and knee in t30 (p<0.0001), t60 (p<0.0001) and t90 (p<0.0001). The use of collagen can be used in the prevention and/or treatment of osteoarthritis and osteoporosis. A clinical study showed efficiency in reducing joint pain and improving patient mobilization when supplemented (ZIEGLER and SGARBIERI, 2009).

Figure 3a – Comparison of hip pain/discomfort measured by Lequesne (Mean ± DP) during study times with collagen mix supplementation.



*Source: primary data (2018). Legend: *p < 0.05 when compared to t0.*

Figure 3b – Comparison of knee pain/discomfort measured by Lequesne (Mean ± DP) during study times with collagen mix supplementation.



*Source: primary data (2018). Legend: *p < 0.05 when compared to t0.*

3. FINAL CONSIDERATIONS

The protocols used in this study were effective with results such as: improvement of muscle strength, reduction of pain and improvement of daily activities of patients with pain or some discomfort in the joints. It was observed that collagen mix can be a good alternative for joint problems for physically active elderly.

Based on the results obtained, it is concluded that the collagen mix supplement composed of bioactive peptides of hydrolyzed collagen, intact type II collagen, silicon and nutrients involved in joint bone metabolism (Duo flex® – Brand Snella) demonstrated efficacy in joint manifestations evidencing to be a good nutraceutical for the active elderly.

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