

Original Research Article

Titagen® for total wellness: results from a randomised, placebo controlled clinical study on adults for osteoarthritis, improvement in skin, nail and health

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ABSTRACT

Background: Fish collagen has been vital in functional food with natural bioactive compounds to offer potential therapeutic benefits. Titan biotech limited (TBL) has studied Titagen® as a nutraceutical to evaluate improvement in adults looking to improve skin, hair, nail health and osteoarthritis.

Methods: Two randomised, double blinded, placebo controlled clinical studies were conducted on Titagen® of TBL. 48 adults were studied in each of the studies for a period of 90 days. Study 1 (SHN study) was conducted on adults looking to improve skin, hair and nail health with Titagen® dose of 5g per day for 3 months-assessed, using assessments and questionnaire to evaluate skin improvement, hair growth and nail health. Study 2 (OA study) was conducted on adults with osteoarthritis with Titagen® dose of 10 g per day for 3 months-evaluated using assessments and questionnaires.

Results: Results showed that Titagen® was better than placebo with statistically significant results in skin health (59.72% vs -51.39), 60 second hair comb test (27.15% vs 2.35%), hair health (18.06% vs -43.06%), nail health (62.50% vs -33.33%), Western Ontario and McMaster universities arthritis index (WOMAC) parameters (39.73% vs 1.72%), pain VAS (70.86% vs 4.21%), quality of life questionnaire (20.83 scores vs 7.31 scores), global impression of change scale results (2.75 vs 4.40). There were no adverse events related to Titagen® and is deemed safe for daily consumption.

Conclusions: The clinical studies proved 5 g Titagen® for 90 days improved skin, hair and nail health, 10 g Titagen® for 90 days reduced pain, stiffness in joints and improved quality of life living with osteoarthritis.

Keywords: Collagen peptide, Fish collagen, Collagen for osteoarthritis, Collagen for skin, Collagen for nails, Collagen for hair

INTRODUCTION

Nutraceuticals have gained tremendous popularity among the public because of the increased awareness towards preventive healthcare, lifestyle-related disorders and trend of supplementation. Public demand and increased scientific interest have resulted in the more rigorous clinical trials for said nutraceuticals. Research trends indicate a transition from traditional nutrition concepts to evidence based therapeutic applications in immune-

mediated diseases, metabolic diseases and aging. This synergy between the attention of the public and the validation of science is transforming medical management around the world.

Nutraceutical functional food market in United States is 250 billion US\$ while drug market is 150 billion US\$. Each year about 1000 new products coming in market, and about 29,000 dietary supplements available in US Nutraceutical functional food market has seen tremendous

growth in the past decade estimates at around 250 billion USD compared to the 150 billion USD drug market.¹

Collagen is one of extracellular matrix proteins, which is essential in most multicellular organisms including human beings, and functions to maintain cytoskeleton. It has also been used to treat proteins that promote cell and tissue regeneration as a scaffold, wound dressing, or dietary supplement due to its biocompatibility.^{2,3}

The bioactive proteins and peptides obtained from marine life are generating considerable amount of interest from the nutraceutical, pharmaceutical, and cosmeceutical sector due to their broad spectrum of bioactivities, which include antioxidant, antibacterial, and anti-aging benefits. Recently, cosmeceuticals containing collagen peptide from marine fish have shown promising outcomes in terms of antioxidant advantages, skin health, including anti-aging effects, and bone health.⁴ “Blue resources” are now being increasingly studied and promoted as an all-rounder nutraceutical for its multitude of benefits such as reduction in joint pain, improvement in skin health, better hair and nails and overall general health.⁵

Supplementation with fish collagen peptide has shown tremendous promise in preclinical research in improving markers associated with osteoarthritis.⁶ Fish collagen with its bioavailability and effectiveness had proved in several studies, across age groups to improve the aesthetic aspects of skin structure. Fish collagen has also been studied to improve bone mineral density and osteoblastic activity, thereby protecting against degeneration of bone.⁷ This accumulation of collagen peptide in cartilage is correlated with several studies that report improvement in symptoms of osteoarthritis like reduction in joint pain, improvement in joint mobility and physical function.⁸

TBL has developed their fish collagen Titagen® with the aim of a comprehensive and effective nutraceutical that would aid with improvement in skin, hair, nail health and joint health (osteoarthritis). TBL has conducted two clinical studies in this regard designed to evaluate the effectiveness of 5 g OD dose in healthy volunteers looking to improve skin, hair and nail health (SHN study) and a 10 g OD dose of Titagen® in patients with osteoarthritis (OA study).

METHODS

Both the SHN study and OA study were designed as a double blinded, randomised, placebo-controlled studies that were designed and conducted by Aurous healthcare research and development India Pvt. Ltd in Chennai. Titagen® was studied for 90 days from July 2019 to October 2019 with day 1 as baseline and day 45 as improvement metrics. Methylcellulose was used as the placebo comparator in both studies.

The studies were reviewed and approved by universal ethics committee, a Chennai based independent ethics

committee registered with CDSCO (Reg no. ECR/125/Indt/TN/2013/RR-20) and OHRP, USFDA (Reg no. IORG0007234) before the conduct of the studies. In compliance with national clinical trial mandates, the studies were also registered with ICMR Clinical Trial Registry of India holding registration numbers and CTRI/2019/06/019857 dated 26-Jun-19 for SHN and CTRI/2019/06/019856 dated 25-Jul-19 for OA studies respectively.

The study was conducted at Raam Clinic, Chennai; in accordance with the ethical principles as laid out in the current version of the Declaration of Helsinki, The The International Council for Harmonisation (ICH) Harmonized Tripartite Guideline—Guideline for Good Clinical Practice E6 (R2), and Indian council for medical research (ICMR) Ethical Guidelines for Biomedical Research on Human Participants and New Drugs and Clinical Trial Rules. The study is CONSORT (Consolidated Standards of Reporting Trials) compliant.

Each study enrolled 48 subjects according to participant criteria, The SHN study focused on adult individuals aged between 18 and 45, encompassing all skin types, who presented at least one concern related to hair, skin, or nails, such as wrinkles, dry or dull skin, or brittle nails. However, individuals who had dyed their hair within the last 60 days, those with skin conditions that could compromise the study's outcomes, and those undergoing active treatments for skin and/or hair issues were excluded. As for OA study included Adults between 30 and 65 years of age with confirmed diagnosis or known history of osteoarthritis with grade II or III of Kellgren Lawrence (KL) grade and pain (VAS score=4) on walking in one or both knees 24 hours prior to screening, subjects with hyaluronic acid injections, Intra-Articular Steroid, valgus or varus deformity of the knee, ligamentous laxity, or meniscal instability any other disease/condition which may affect joints were excluded. Subjects meeting these criteria were included in the study and randomised into either of the treatment arms-Titagen® or placebo based on alphanumeric codes that were generated via SAS. These double blinded codes were printed on similar sachets containing 5 g and 10 g of Titagen® for SHN and OA study respectively. There was a designated personnel who had the alphanumeric codes and the corresponding treatments for emergency unblinding in the event of any serious adverse event (SAE). SOS medication was permitted in the OA study, however was not applicable for the SHN study.

No changes were made to the study design or outcome measures after the commencement of the study. Both studies were not interrupted interim and was completed per plan.

Day 1

Informed consent was obtained from the subjects before screening procedures were undertaken for the subjects.

The patient information sheet and informed consent document was available in English and Tamil (local vernacular language) for the ease of understanding. It was ensured that vernacular document was a true, accurate and impartial translation of the English documents. The same was also done for questionnaires to be answered by the subjects. Such translations were reviewed and approved by the ethics committee.

Subjects were screened and enrolled into the study-24 subjects in each treatment arm; based on the inclusion and exclusion criteria designed for the study. The baseline assessments for the SHN study included 60 second hair comb test, skin improvement questionnaire, hair growth questionnaire and nail health questionnaire.⁹

For the OA study, baseline assessment included X ray of target joint, WOMAC scale, pain scale VAS, quality of life questionnaire.^{10,11} WOMAC has 24 questionnaires designed, developed and validated to measure the status of symptoms associated with osteoarthritis in three domains-pain, physical function and joint stiffness. PAIN VAS is a numerical indicator of current pain on a scale of 0 (no pain) to 10 (extreme pain).¹² Subjective quality of life questionnaire was assessment to evaluate improvement in symptoms and their impact on everyday life. This was correlated with global rating of change scale evaluated by the investigator using X ray of the target joint demographic details, anthropometric measurements along with vital signs (pulse rate, respiratory rate, blood pressure, temperature) were also recorded as baseline parameters for both studies. Hemogram, liver and kidney function tests were assessed as clinical safety reference point. On day 1, the subjects were provided with Titagen® or placebo-5 g for SHN study and 10 g for OA study.

Day 45

On day 45, improvement metrics and compliance to the product was measured. The assessments were administered for repeated measures. Vital signs were measured. The subjects were provided with investigational product per the randomisation schedule.

Day 90

End of study (EOS) evaluations were assessed for both studies along with hemogram, liver and kidney functions for EOS clinical safety. Subjects who has used SOS medication in the OA study were listed. No subjects withdrew due to adverse events or safety concerns.

Statistical methods

The sponsor of the study TBL decided on the sample size of 24 subjects per treatment arm. The statistical analysis was performed in accordance with International Council on Harmonisation (ICH) E9 (R1) guideline for statistical principles for clinical trials, using SAS (Version 9.4). Statistical tests were carried out at 95% level of

significance. The intra analysis for results between baseline and EOS was assessed using one sample t-test. The comparative inter analysis between Titagen® and placebo was assessed using two sample t-test.

RESULTS

Efficacy results

The SHN study, conducted on healthy volunteers looking to improve the health of the skin, hair, and nails were administered an OD dose of 5 g Titagen® or placebo based on their randomisation schedule.

The skin health of the volunteers were analysed based on a questionnaire that covers the following parameters (Figure 1)-improvement in skin hydration (40.28% vs-63.89%), improvement in skin tightness (50% vs-63.89%), improvement in skin wrinkles (44.44% vs-66.67%), improvement in skin glow (61.11% vs -66.67%) and overall skin health (59.72% vs -51.39%) in the inter group analysis between Titagen® vs placebo arm.

The 60-second hair count test (60SHCT) showed significant reduction in hair fall 27.15% vs 2.35% $t=4.67.9208$, $p=0.0001<0.05$ attributed to Titagen® and placebo respectively. This was correlated with the hair growth questionnaire results (Figure 2) which reported 25% improvement in dry hair, 23.61% improvement of lifeless hair, 1.39% reduction in hair breakage and 18.06% improvement in overall hair health in the Titagen® arm compared to -61.11%, -54.17%, -66.67%, -43.06% for the same parameters in the placebo arm (Figure 3).

Titagen® also reported statistically significant results compared to placebo in the enhancement of nail health (Figure 4). Strength of nails improved 62.50% in the Titagen® compared to -33.33% in the placebo arm. Subjects on the Titagen® reported an improvement of 37.5% compared to -54.17% in the placebo in nail thickness. Titagen® aided with 51.39% reduction in nail chipping, 47.22% improvement in nail texture and 62.50% improvement in overall nail health compared to -66.67%, -66.67%, and -33.33% in the placebo arm (Table 1).

In the OA study, the OD dose of 10 g Titagen® for 90 days in the management of osteoarthritis has shown very promising results (Table 2). In the WOMAC assessment, Titagen® showed an improvement of 39.73% (SD 5.92%) vs 1.72% (SD 2.18%) in the placebo arm. The results of the three domains of WOMAC were also between the two groups as 46.25% (SD 10.04%) vs 14.98% (SD 6.84) in the pain domain; 39.16% (SD 10.96%) vs 19.35% (SD 10.81%) in the joint stiffness domain and 37.75% (SD 4.69%) vs -5.21% (SD 3.95%) in the physical function domain between Titagen® and placebo respectively (Figure 5). Subjects reported 70.86% (SD 8.08%) reduction in pain in the VAS scale in the Titagen® arm compared to 4.21% (SD 9.09%) reduction in the placebo arm (Figure 6). Subjects reported statistically significant

improvement in quality of life upon consuming Titagen® for the management of osteoarthritis-score improvement of 20.83 compared to 7.31 in the placebo arm (Figure 7). ($Z=4.90$, $p=0.000<0.05$). The investigator's clinical global impression of change scale was based on the X ray of the target joint. Titagen® reported a radiological improvement of 2.75 (SD 0.44) vs Score 4.40 (SD 0.50) on a scale of -7 to +7 denoting "very much worse" to "very much improved" respectively (Figure 8).

Safety results

No adverse event was reported as related to the investigational product. Clinical safety was also confirmed with no significant/ abnormal clinical difference from baseline to the end of the studies in hemogram, liver and kidney function tests. Titagen® is thus deemed safe as a nutraceutical.

Table 1: Summary of efficacy scores: SHN study.

Assessments	Visits	Titagen®	Placebo
60 second hair count test	Day 1	49.42±9.46	45.05±7.12
	Day 45	40.52±7.66	42.66±7.46
	Day 90	36.20±7.16	44.24±7.04
Skin improvement questionnaire	Day 1	3.00±0.1	3.00±0.3
	Day 45	16.88±1.19	5.59±0.67
	Day 90	22.67±0.56	7.32±0.48
Hair growth questionnaire	Day 1	2.99±0.3	2.98±0.7
	Day 45	16.79±0.93	6.09±0.97
	Day 90	22.79±0.66	7.32±0.48
Nail health questionnaire	Day 1	2.97±0.3	2.96±0.7
	Day 45	16.83±1.09	5.55±0.74
	Day 90	22.83±0.64	7.41±0.50

Table 2: Summary of efficacy scores: OA study.

Assessments	Visits	Titagen®	Placebo
WOMAC score	Day 1	74.25±4.19	77.00±3.92
	Day 45	56.17±8.19	75.69±3.70
	Day 90	44.75±3.12	75.62±3.59
Pain VAS	Day 1	7.35±0.80	7.62±0.64
	Day 45	4.44±0.51	7.46±0.51
	Day 90	2.13±0.68	7.27±0.60
Quality of life questionnaire	Day 1	7.54±0.81	7.46±1.07
	Day 45	15.20±1.29	7.31±0.88
	Day 90	20.83±1.09	7.31±0.74
Clinical global impression of change	Day 90	2.75±0.44	4.40±0.50

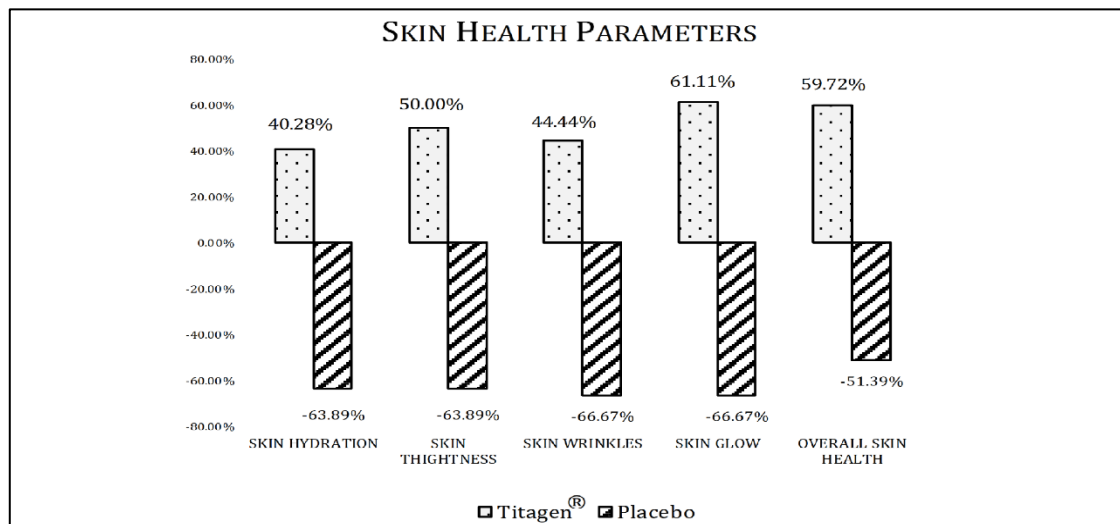


Figure 1: Comparative changes in skin health parameters: 5 g Titagen® vs placebo.

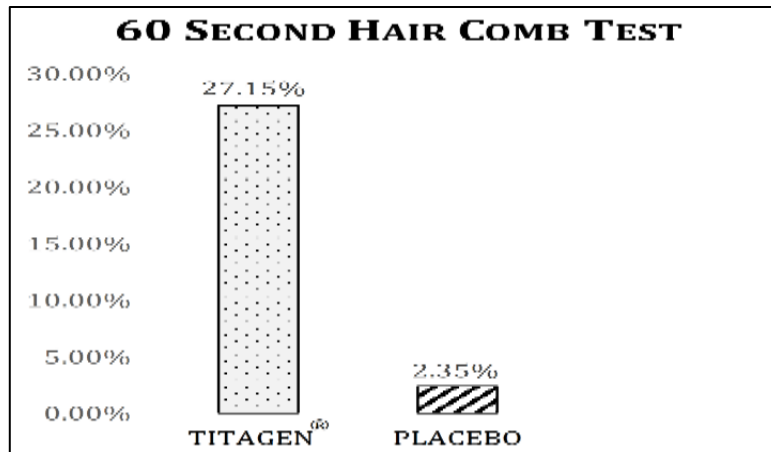


Figure 2: 60 second hair comb test: reduction in hair fall in 90 days: 5 g Titagen® vs placebo.

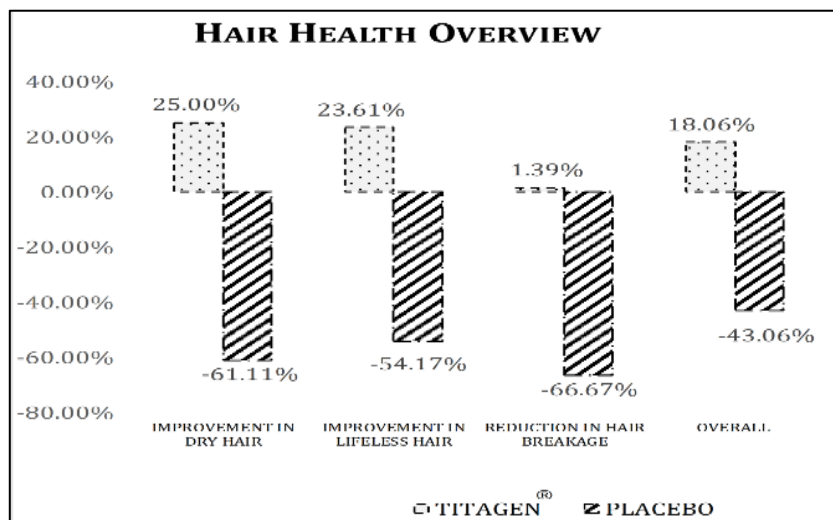


Figure 3: Comparative changes in hair health parameters: 5 g Titagen® vs placebo.

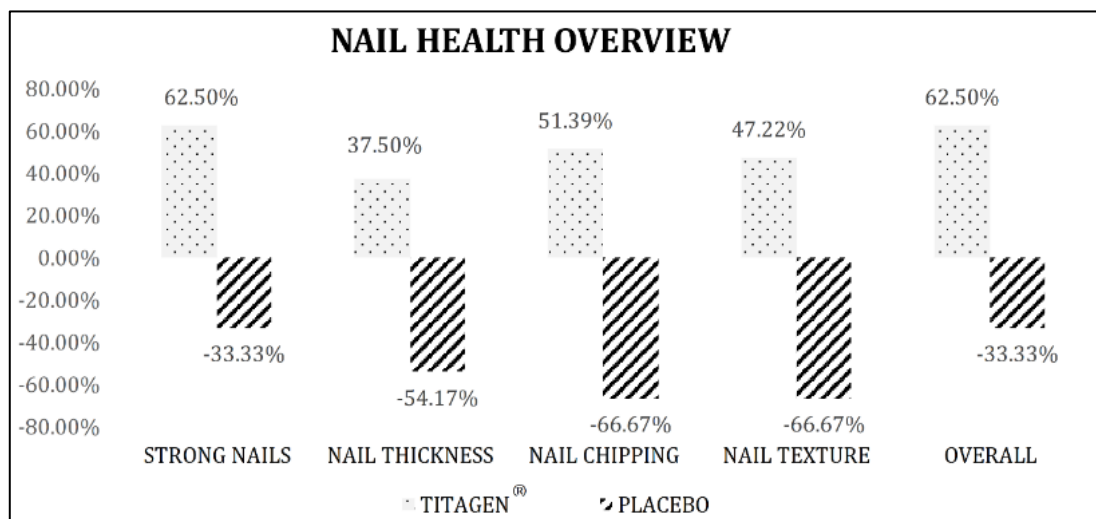


Figure 4: Comparative changes in nail health parameters: 5 g Titagen® vs placebo.

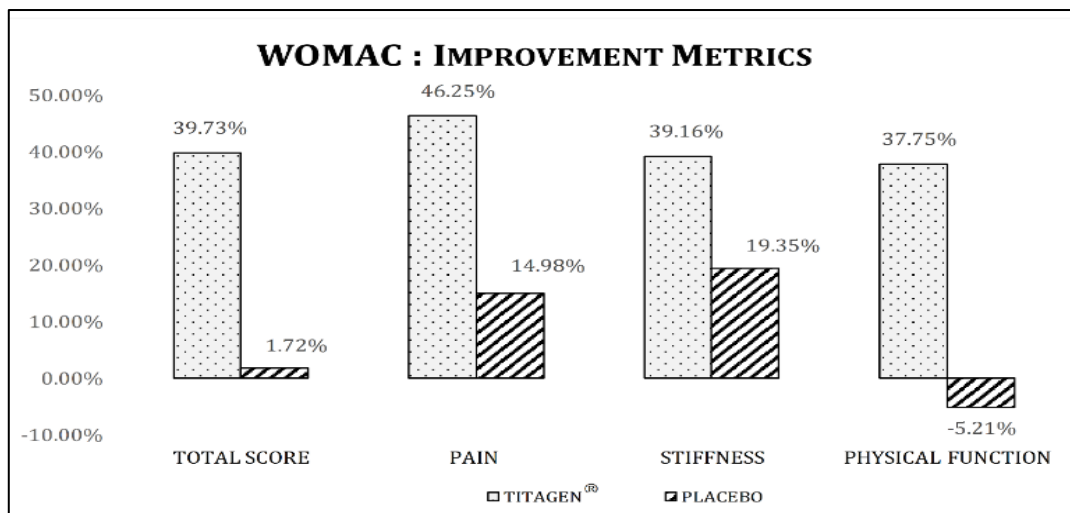


Figure 5: WOMAC improvement metrics: Titagen® vs placebo.

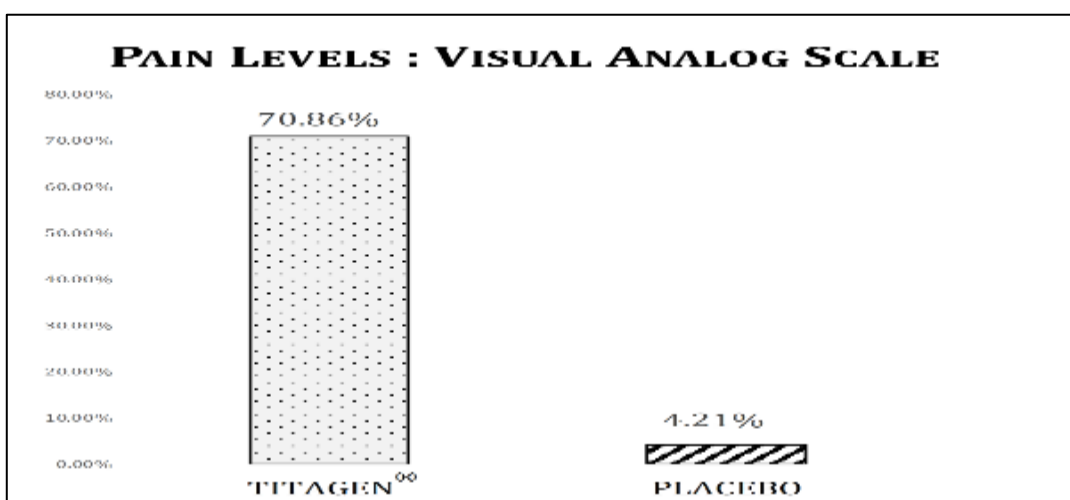


Figure 6: Pain VAS: reduction in pain levels: Titagen® vs placebo.

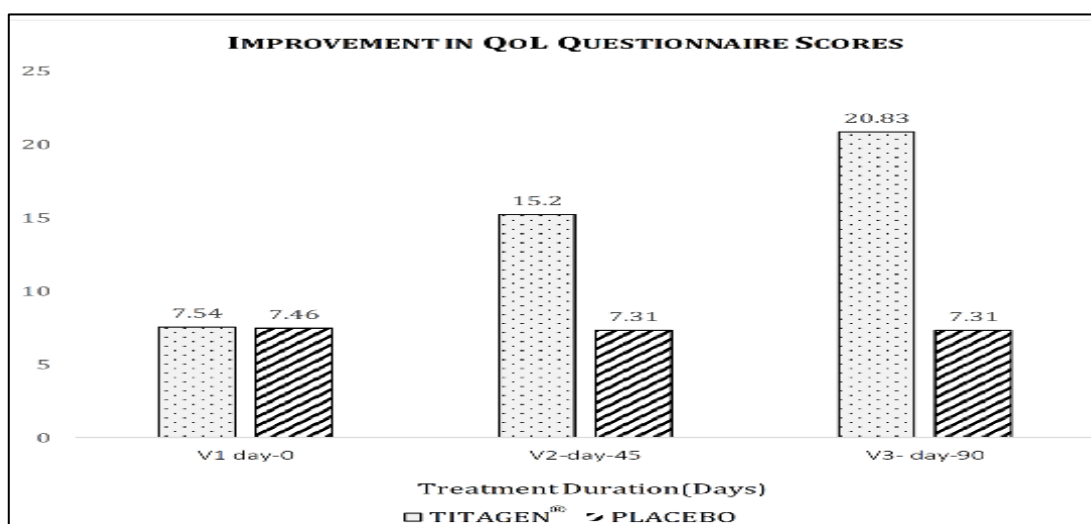


Figure 7: Improvement in quality of life: Titagen® vs placebo.

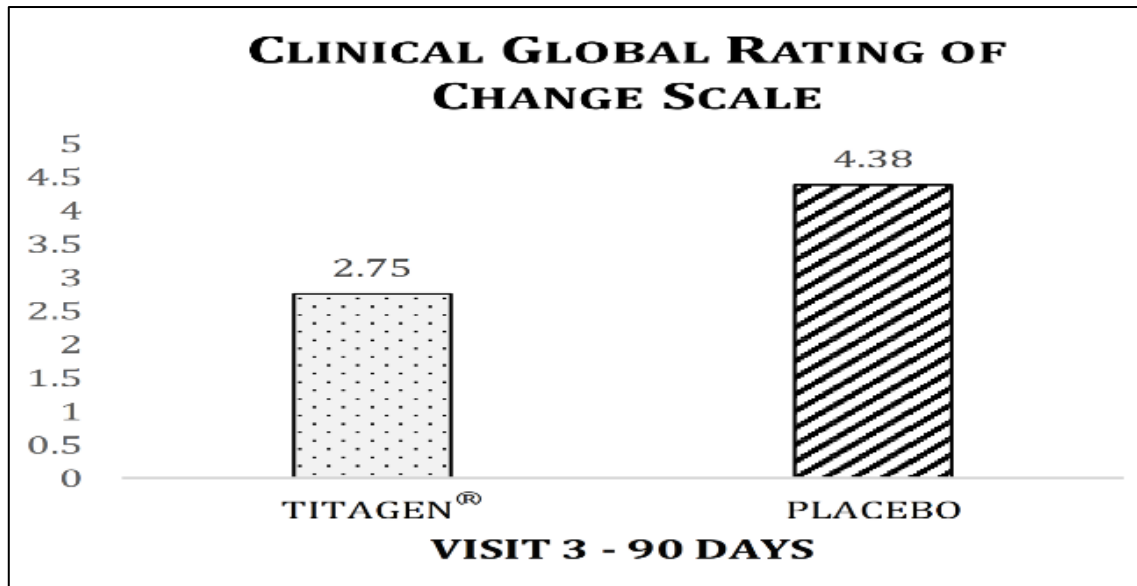


Figure 8: Clinical global rating of change based on X-ray.

DISCUSSION

Collagen promotes skin hydration and moisture retention, potentially support hair growth by improving collagen in the scalp and hair follicles, and work on brittle nails by strengthening nail beds and making them less prone to chipping.¹³ Collagen peptides are also understood to alleviate joint pain and inflammation, improve mobility, and support the regeneration of cartilage. Research has identified cellular mechanisms through which collagen peptides exert their positive effects on reducing pain and enhancing joint health in knee osteoarthritis. These mechanisms involve the anti-inflammatory and antioxidant properties of collagen peptides, as well as their ability to stimulate collagen synthesis and facilitate bone formation.¹⁴

Due to collagens high bioavailability of peptides and their impact on cellular and extracellular matrix have made it a great supplement for improving OA, hair, skin and nail.

Similar studies on collagen for OA by Oesser et al showed overall of 38% improvement in 12 weeks, Jiang et al study on collagen improvements on physical mobility using WOMAC confirming the effect of collagen peptide on OA.^{15,16} A study on collagen bio-markers by Scarpellini et al showed radiographs, assessments and bio-markers after 6 months and 1 year of treatment VAS, uCTX-I and uCTX-II mean values were significantly lower than the baseline for 57 were treated with type II collagen, similar improvement matrix is seen in skin hair and nail collagen peptide studies.¹⁷⁻¹⁹

The two studies were designed to establish and confirm the same for the fish collagen peptide namely Titagen® of TBL. The results show that Titagen® performed better in all assessments parameter ($p < 0.05$) than placebo in both the SHN and the OA study.

Healthy volunteers looking to better their skin, hair and nail health reported significant improvement with an OD dose of 5 g Titagen® in just 90 days.

The WOMAC is a validated and widely recognized tool used to evaluate key symptoms of osteoarthritis, especially in the hip and knee. It consists of 24 questions divided into three sections: pain (5 questions, total score range 0-20), stiffness (2 questions, score range 0-8), and physical function (17 questions, score range 0-68). Alongside WOMAC, the pain VAS is often employed in research to measure the intensity of pain at a specific point in time, using a scale from 0 (no pain) to 10 (worst possible pain). Pain is the foremost limitation in living with osteoarthritis, and the results of the OA study after administering Titagen® would indicate a positive therapeutic response.

Subjects reported that supplementation with 10 g of Titagen® for 90 days improved their quality of life by managing the symptoms of pain, joint stiffness and physical function associated with osteoarthritis. The absence of adverse events supports the potential use of Titagen® supplementation as a nutraceutical aid to, improve skin, hair, nail health and manage OA.

The sample size considered for the two studies may be considered a limitation however the studies serve their purpose as proof-of-concept studies for a nutraceutical. Addition of biomarkers such as serum CTX, ALP for the OA study and objective dermatological based investigations for the SHN study along with a larger sample size could have potentially added more value to the study results.

Throughout the study, the subjects were instructed to continue with the same lifestyle without making any significant dietary changes, exercise regimens, or routines as before enrolment in this study to be able to evaluate the

real-time effectiveness of Titagen®. The study has no sources of potential bias, imprecision, and multiplicity of analyses. The study inclusion and exclusion criteria have been designed to include subjects within a wide age range, including subjects of all genders, socio-economic status, and demographics, in an attempt to be objective and yet external validity, generalizability, and applicability.

CONCLUSION

Two discrete clinical studies were designed as a double blinded, placebo-controlled studies to prove beyond doubt and bias, the effectiveness of Titagen® as a therapeutic nutraceutical. The studies were conducted for a period of 12 weeks with 24 subjects in each treatment arm. Results of the SHN study has shown that 5 g of Titagen® in 12 weeks promises significant changes in skin, hair and nails. The efficacy parameters were studied using standardised and validated assessments like WOMAC, pain VAS, GROG and quality of life questionnaires. The 10 g for 90 days proves that Titagen® is a strong supportive nutraceutical to help with the symptomatic management of OA. The sample size, though small serves as base for a proof-of-concept study for establishing the therapeutic value of Titagen® as a nutraceutical. Clinical safety was confirmed with hemogram, liver and kidney function tests at the start and the EOS with no clinically significant changes establishing beyond doubt, the safety profile of Titagen®

With such encouraging results, it is safe to say that Titagen® supplementation as part of everyday life would replenish the natural collagen depleting with age and help manage symptoms of osteoarthritis and rebuild the skin's structural integrity along with improving hair and nail health.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee Universal Ethics Committee (CDSCO Registration Number: ECR/125/Indt/TN/2013/RR-20).

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