

Functional Outcomes of Titabon™ (Bovine Collagen Peptide): Insights from Clinical Trials on Osteoarthritis and Hair Health

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Abstract:

Background: Collagen Peptide (CP) specifically that of bovine origin has been studied to have antioxidant properties, promoting synthesis and regeneration of extracellular matrix. Bovine CP (BCP) has been proven effective in improving joint health, overall appearance of hair, owing to the triple helix protein structure that is a vital component of bones, skin, tendons and ligaments. Titan Biotech Ltd. has formulated their BCP Titabon™ to be available as a nutraceutical supplement for adults looking to improve general hair health and symptoms associated with osteoarthritis(OA). OA is a leading cause of reduced mobility, increasing pain that interferes with a person's everyday activities and diminishes their quality of life. The current clinical studies conducted on Titabon™ have shown promising results.

Materials and Methods: Two randomised, double blinded, placebo controlled clinical studies were conducted on Titabon™ of Titan Biotech Limited. 52 subjects were enrolled in each study randomised into those consuming Titabon™ or Placebo for a period of 12 weeks. OA study treated adults with 10g per day dose of Titabon™ and compared efficacy outcomes against the placebo group assessments such as WOMAC, Pain VAS, Global Impression of Change scale (GROC) and QoL Questionnaire. Volunteers in the Hair study were supplemented with 5g per day dose of Titabon™ vs Placebo. The efficacy outcomes were measured using the Hair Growth questionnaire. Clinical safety was assessed using hemogram, liver and kidney function tests at baseline and end of study.

Results: In both studies, results showed that Titabon™ was better than placebo with statistically significant results. Efficacy outcomes from the OA study such as WOMAC (40.77% vs 1.72%), Pain VAS (74.42% vs 4.21%), Quality of Life Questionnaire (22.87 scores vs 7.31 scores), GROC results (1.87 vs 4.38) proves that Titabon™ is effective in osteoarthritis. Results from the Hair study showed that Titabon™ improved dry hair (29.49% vs -61.11%), lifeless hair (32.05% vs -54.17%), hair fall (19.23% vs -66.67%), hair breakage (32.05% vs -66.67%), thereby improving overall hair health (33.33% vs -43.06%) compared to placebo.

Conclusion: The clinical studies have proved that daily supplementation with Titabon™ has been effective in improving symptoms of joint pain and stiffness as seen in osteoarthritis (10g dose) and in enhancing the appearance and general health of hair (5g dose). Both studies did not report any adverse events and no abnormalities were noted in the clinical safety blood tests, attesting to the safety of Titabon™

Keywords: Collagen peptide, Bovine Collagen, Collagen for Osteoarthritis, Collagen for Hair

I. Introduction

Osteoarthritis is one of the most prevalent sources of pain globally, which, if left unchecked, may ultimately result in disability. OA is a form of muscular skeletal disease that can arise from a variety of internal and external factors.¹ Topical treatments for OA aim to alleviate pain for a speculated time frame without addressing the underlying issues. Collagen peptides serve as the fundamental building blocks that constitute the triple helix structure of collagen proteins, a significant protein found in various connective tissues such as skin, bones, tendons, and ligaments. It is believed that collagen supplements can promote cartilage regeneration, thereby alleviating joint pain and inflammation, enhancing mobility, and potentially slowing the progression of OA². Collagen is a type of protein derived from animals, with a long-standing history of use by humans; its name is derived from the Greek word *kola*(gum) *gen* (producing). In recent times, collagen has gained interest as a nutraceutical for both beauty and health purposes³. Collagen peptides are mainly composed of three amino acids: proline, hydroxyproline, and glycine, and can be extracted from various sources, one of which is bovine. Numerous clinical trials have demonstrated its efficacy in promoting joint health as well as benefiting skin and

hair health. The fundamental structure of collagen aids in rejuvenation and supports the synthesis of collagen within the body. Bovine collagen, contains bioactive peptides that are readily absorbed and distributed, making it effective in restoring cartilage regeneration and serving as a powerful supplement for hair, skin, and nails. ¹ The objective of the clinical studies was to determine the efficacy and safety of Bovine Collagen Peptide-Titabon™ from Titan Biotech Ltd. in alleviating osteoarthritis symptoms and a nutraceutical supplement in improving hair health.

II. Material And Methods

Two randomised, double blinded, placebo controlled clinical studies were conducted on Titabon™ of Titan Biotech Ltd. The clinical trials were managed by Aurous Healthcare R&D India Pvt. Ltd (Chennai) between June 2019 to October 2019. The study was planned on a total 52 subjects (both male and females) for each study.

Study Design: Prospective, double blind, placebo controlled, randomised, comparative, interventional study.

Study Location: Raam Clinic, Kodambakkam, Chennai, Tamil Nadu, India.

Study Duration: June 2019 to October 2019.

Sample size: 52 subjects were enrolled for both treatment arms.

Sample size calculation: The sample size was estimated on the basis of the Sponsor's requirements.

Subjects & selection method: Adult subjects (both sexes and ages inclusive) between the ages of 30 and 65 years were screened for the OA study and adult volunteers aged between 18 and 45 years for the Hair study.

Subjects were randomised into two treatment arms in a 1:1 ratio using SAS generated alphanumeric blinded codes.

Treatment Arm I (N=26 Patients) – Titabon™ (10g for OA Study & 5g for Hair study)

Treatment Arm II (N = 26 Patients) – Placebo (10g for OA Study & 5g for Hair study)

Salient Inclusion criteria: OA Study

1. Subjects with Grade II or III of Kellgren Lawrence (KL) Grade.
2. Subject with pain (VAS score ≥ 4) on walking in one or both knees 24 hours prior to screening.
3. Subjects with BMI ≥ 35 at the time of screening.
4. Subjects who are ambulatory, requiring but not currently receiving or not satisfied with anti-inflammatory or anti-analgesic drugs.

Salient Inclusion criteria: Hair Study

1. Subjects with concerns of dry dull hair, hair fall, hair breakage.
2. Subject/LAR who is willing to give informed consent for participation, able to comprehend and understand the responsibilities during treatment period and follow up period.
3. Subjects who are willing not to participate in any other clinical trial during participation in the current trial.

Salient Exclusion criteria: OA Study

1. Subjects with known hypersensitivity to investigational product or its constituents.
2. Subjects with known hypersensitivity to NSAID, aspirin, COX-2 inhibitors and other analgesic medicine.
3. Subjects who have had hyaluronic acid injections, upto 6 months prior to enrolment.
4. Subjects who have had Intra-Articular Steroid, upto 3 months prior to enrolment.
5. Subjects with immunocompromised state complications.
6. Significant (requiring surgical correction) valgus or varus deformity of the knee, ligamentous laxity, or meniscal instability.
7. Concomitant inflammatory or any other disease/condition which may affect joints (e.g., rheumatoid arthritis, metabolic bone disease, psoriasis, gout, pseudogout, chondrocalcinosis etc.).
8. History of sepsis in any joint or any clinical concern for a sub-acute infectious process in the target joint.
9. History of surgery in the target joint.
10. Planned surgery on any lower extremity joint.
11. Any musculoskeletal condition that would impede measurement of efficacy at the target joint
12. Females who are pregnant or lactating or planning to become pregnant during the study period.

Salient Exclusion criteria: Hair Study

1. Subjects with known hypersensitivity to investigational product or its constituents.
2. Subjects who are on active treatments for hair conditions.
3. Subjects who have dyed their hair in the last 60 days.
4. Subjects with immunocompromised state complications.
5. Any significant medical condition (e.g., significant psychiatric or neurological disorders, active alcohol/drug abuse, etc.), any medical condition that is unstable/poorly controlled or other factor (e.g., planned relocation) that the Investigator felt would interfere with study evaluations and study participation.

6. Females who are pregnant or lactating or planning to become pregnant during the study period.
7. Subjects who mentally unable to comprehend the responsibilities and adhere to the stipulations of the protocol.
8. Subjects, who in the opinion of the Investigator or the Medical Experts are not eligible for enrolment in the study.

Procedure methodology

The OA study and the Hair study were designed and conducted by Aurous HealthCare Research and Development India Pvt. Ltd., Chennai. Tamil Nadu. Titabon™ was studied for 90 days in comparison with methylcellulose as the placebo in both studies. Both studies were provided ethical clearance by Universal Ethics Committee CDSCO (Reg no. ECR/125/Indt/TN/2013/RR-20) and OHRP, USFDA (Reg no. IORG0007234). The studies were also registered with ICMR Clinical Trial Registry of India - CTRI/2019/06/019856 (OA Study) and CTRI/2019/06/019857 (Hair study).

The clinical trial site was Raam Clinic and the studies were conducted in accordance with the ethical principles of Good Clinical Practices as laid down by The International Council for Harmonisation (ICH), Indian Council for Medical Research (ICMR) and CDSCO. The study is in compliance with CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Written informed consent was obtained before undertaking screening procedures. Demographic and anthropometric data is recorded at baseline. For the OA study, efficacy parameters were measured using standardized questionnaires like Western Ontario and McMaster Universities Arthritis Index (WOMAC) a 24-question scale for rating OA symptoms⁵, Pain - Visual Analog Scale (VAS) to numerically measure the pain level due to OA⁵ and Quality of Life Questionnaire to evaluate impact of OA on everyday life. These questionnaires were answered by the subjects on Day 1 (baseline), 45 days and 90 days (end of study) of everyday supplementation with 10g of either Titabon™ or placebo as per the randomisation schedule. The target joint was X Ray at the start and end of the study. The clinical improvement based on the X Ray was evaluated by the Investigator using Clinical Global Impression of Change.

For the Hair study, the improvement metrics were assessed using a well-designed questionnaire addressing concerns such as dry hair, dull hair, hair fall, hair breakage etc. Subjects self-evaluated the improvement in their hair health, 45 and 90 days upon supplementation with Titabon™ 5g or placebo 5g as per their randomisation.

Vital signs (pulse rate, respiratory rate, blood pressure, temperature) were assessed for every enrolled subject during all their visits to the clinic. Clinical safety was ensured using complete blood count, blood tests for liver and kidney function at the start and end of the study.

The OA study permitted the use of SOS medication. After commencement of the studies, there were no amendments to the study design, outcomes, end points. No interim analysis was conducted. Both studies were completed as per plan without any changes.

A few subjects were lost to follow up. At the end of 90 days, 23 and 25 subjects completed the OA study, 26 and 24 subjects completed the Hair study in the Titabon™ and placebo arm respectively.

Statistical analysis

The sponsor of the study Titan Biotech Limited decided on the sample size of 26 subjects per treatment arm. Generation of double blinded alphanumeric codes and statistical analysis was performed using SAS. The analysis was in compliance International Council on Harmonisation (ICH) E9 (R1) guideline for Statistical Principles for Clinical Trials. The improvement from baseline to end of study for each treatment arm was analyzed using one sample t-test and the comparative analysis between the Titabon™ and placebo treatment arms was evaluated using two sample t-test. Proportion tests were used to evaluate the percentage of subjects who had reached the end point at the end of the clinical study. All statistical analyses were performed at 95% significance level.

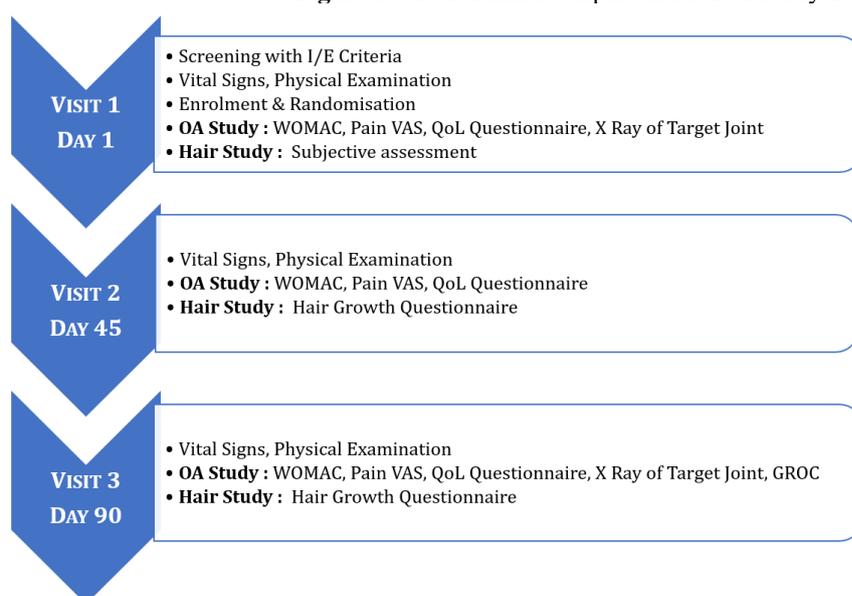
III. Result

Baseline data show that care was taken to ensure that there was no bias with enrolling the subjects into either of the treatment arms. Table 1 represents the demographics data of the population participated in the study which includes gender, age, height, weight and Body Mass Index (BMI).

Table No 1: Baseline demographic data of subjects in both treatment arms at the start of the study.

STUDY	OA Study		Hair Study	
	Titabon™	Placebo	Titabon™	Placebo
Gender	Female 15 (38%) Male 11 (28%) Total 26 (100%)	Female 12 (31%) Male 14 (36%) Total 26 (100%)	Female 15 (58%) Male 11 (42%) Total 26 (100%)	Female 8 (31%) Male 18 (69%) Total 26 (100%)
Age	44.23 ± 8.52	43.88 ± 8.93	36.58 ± 6.60	30.62 ± 7.84
Height	1.61± 0.07	1.64 ± 0.07	1.65± 0.08	1.66 ± 0.07
Weight	75.80± 5.06	75.96± 6.32	78.29± 6.75	77.47± 6.62
BMI	29.41 ±2.82	28.46 ±3.27	29.01 ±3.36	28.36 ±3.60
Where applicable, values are expressed as Mean ± SD				

Figure No 1: Schematic Representation of Study Design

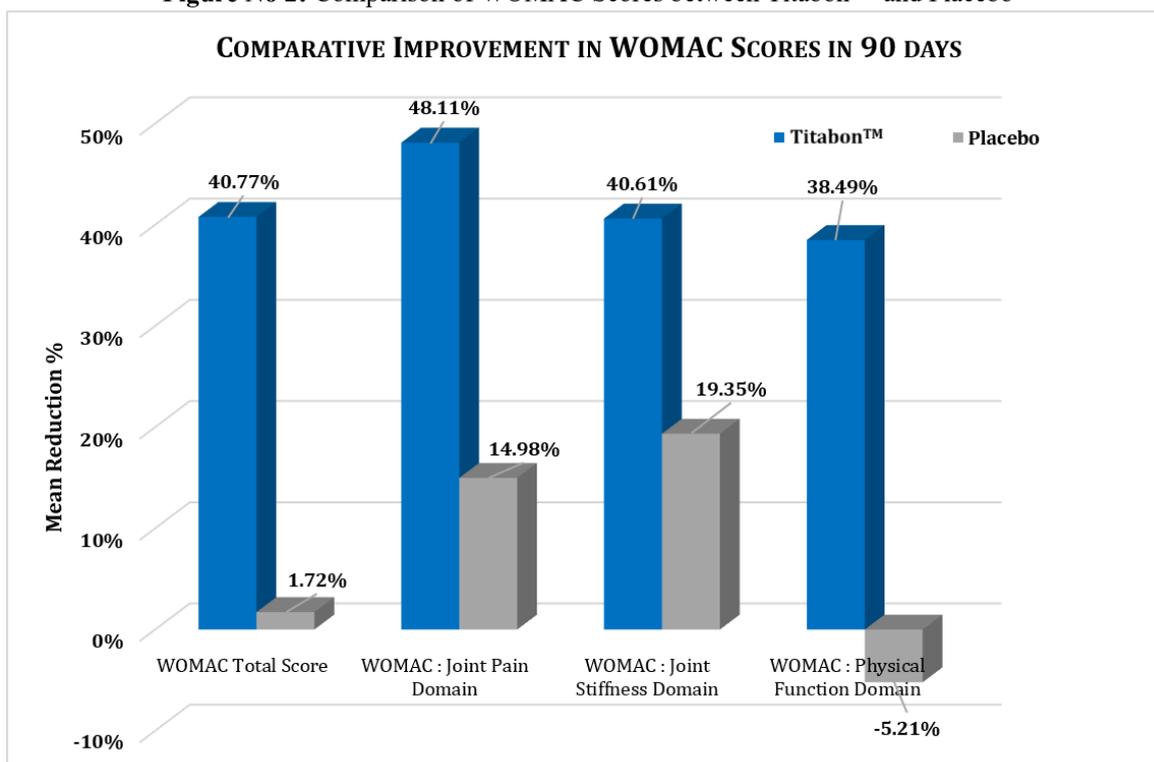


10g of Titabon™ showed remarkable results in the gold standard assessment of WOMAC with an improvement of 40.77% (SD 5.26%) vs 1.72% (SD 2.18%) in the placebo arm. (Figure 2). WOMAC consists of three domains assessing various symptomatic components of OA such as joint pain, joint stiffness and ability for physical function. 10g Titabon™ achieved 48.11% (SD 6.35%) reduction in joint pain, 40.61% (SD 12.63%) reduction in joint stiffness and 38.49% (SD 5.44%) improvement in physical function in 90 days compared to the placebo arm which shows results of 14.98% (SD 6.84%), 19.35% (SD 10.81%), -5.21% (SD 3.95%) respectively. (Table 2)

Table 2: OA Study : Results of 10g Titabon™ vs Placebo in 90 days : WOMAC Index

PARAMETERS	TITABON™	PLACEBO
WOMAC Total Score	40.77% (5.26%)	1.72% (2.18%)
WOMAC : Joint Pain Domain	48.11% (6.35%)	14.98% (6.84%)
WOMAC : Joint Stiffness Domain	40.61% (12.63%)	19.35% (10.81%)
WOMAC : Physical Function Domain	38.49% (5.44%)	-5.21% (3.95%)
Values are expressed as mean reduction % (SD%)		

Figure No 2: Comparison of WOMAC Scores between Titabon™ and Placebo



The Pain Visual Analog Scale (VAS) measured pain on a scale of 0 (no pain) to 10 (maximum pain). This was a subjective questionnaire aimed at evaluating the reduction in pain in 90 days. Subjects of the Titabon™ group showed a reduction of 74.42% (SD 6.85%) compared to 4.21% (SD 9.09%) in the placebo group. (Figure 3). Subjects reported enhanced everyday living as evident with the increase of scores in the Quality of Life (QoL) questionnaire from an average of 7.69 (SD 0.79) at Day 1 to 22.87 (SD 0.46) at Day 90 in the Titabon™ arm compared to scores of 7.46 (SD 1.07) at Day 1 to 7.31 (SD 0.74) at Day 90 in the placebo arm. (Figure 4) The investigator’s clinical global impression of change scale was based on the X ray of the target joint. Titabon™ reported a radiological improvement of 1.87 (SD 0.55) vs Score 4.38 (SD 0.50) in the placebo arm on a 7 point GROG scale where score 1 is interpreted as “very much improved” and score 7 is interpreted as “very much worse”. (Table 3) 69.57% of subjects in the Titabon™ reported to have “much improved” symptoms at the end of 90 days while 0% of the subjects reported improvement in the placebo arm. (p=0.0001 <0.05)

Table 3 : OA Study : Comparative Efficacy Results 10g Titabon™ vs Placebo in 90 days

PARAMETERS	TITABON™	PLACEBO
Pain Visual Analog Scale	74.42% (6.85%)	4.21% (9.09%)
Quality of Life Questionnaire Score	22.87 (0.46)	7.31 (0.74)
Global Rating of Change Scale Score	1.87 (0.55)	4.38 (0.50)
Values are expressed as Mean(SD)		

Owing to the inclusion of a placebo arm, all subjects started off the study with a standard background medication of Aceclofenac 100mg, paracetamol 500mg for the first 7 days after which the subjects only consumed 10g of Titabon™ or placebo. Subjects were permitted the use of SOS/rescue pain medications, which was available by subjects who upon unblinding at data analysis stage, were found to be of the placebo arm.

Figure 3: Comparison of improvement in Pain VAS between Titabon™ and placebo group

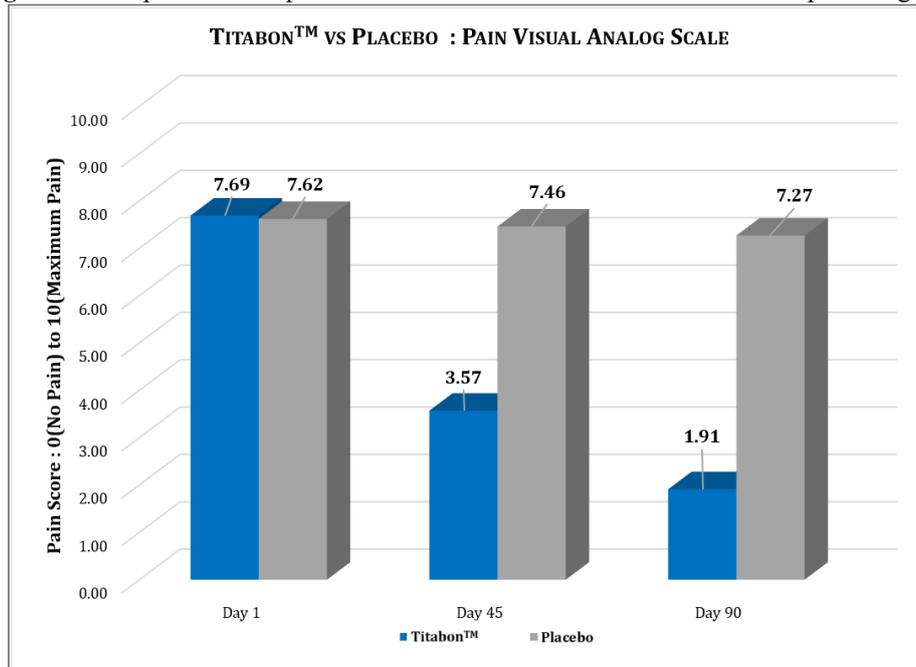


Figure 3 shows the effectiveness of Titabon™ in reducing pain associated with OA in 90 days compared to scores in the placebo arm which did not show much improvement. $p=0.0001 < 0.05$

Figure 4: Comparison of improvement in Quality of Life Questionnaire between Titabon™ and placebo group

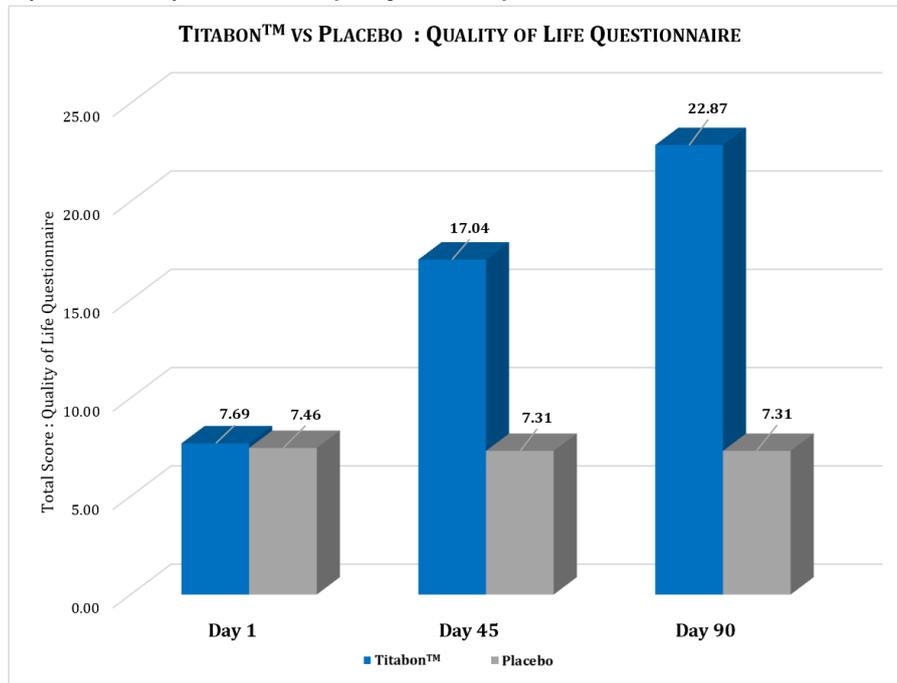


Figure 4 shows the increase in total scores of the Quality of Life Questionnaire from Day 1 to Day 90. The QoL Questionnaire captured the impact and improvement if any on the symptoms of OA on work, social life and overall impact on life. $p=0.0001 < 0.05$

Supplementation with 5g of Titabon™ for 90 days improved hair health. Subjects who consumed Titabon™ showed a 29.49% (SD 9.60%) reduction in dryness of hair, 32.05% (SD 6.95%) improvement in lifeless hair, 19.23% (SD 17.03%) reduction in hair fall, 32.05% (SD 6.95%) reduction in hair breakage and 33.33% (SD 10.05%) improvement in overall hair health. This was statistically significant compared to placebo, $p=0.0001 < 0.05$ (Table 3) (Figure 5)

Figure 5 : Improvement metrics in Hair Health : Titabon™ vs Placebo in 90 days

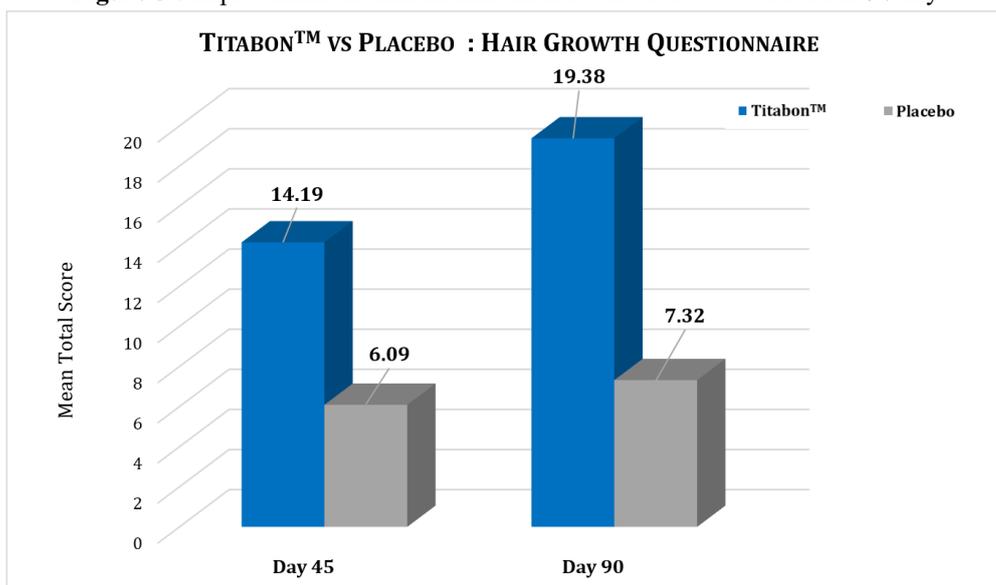
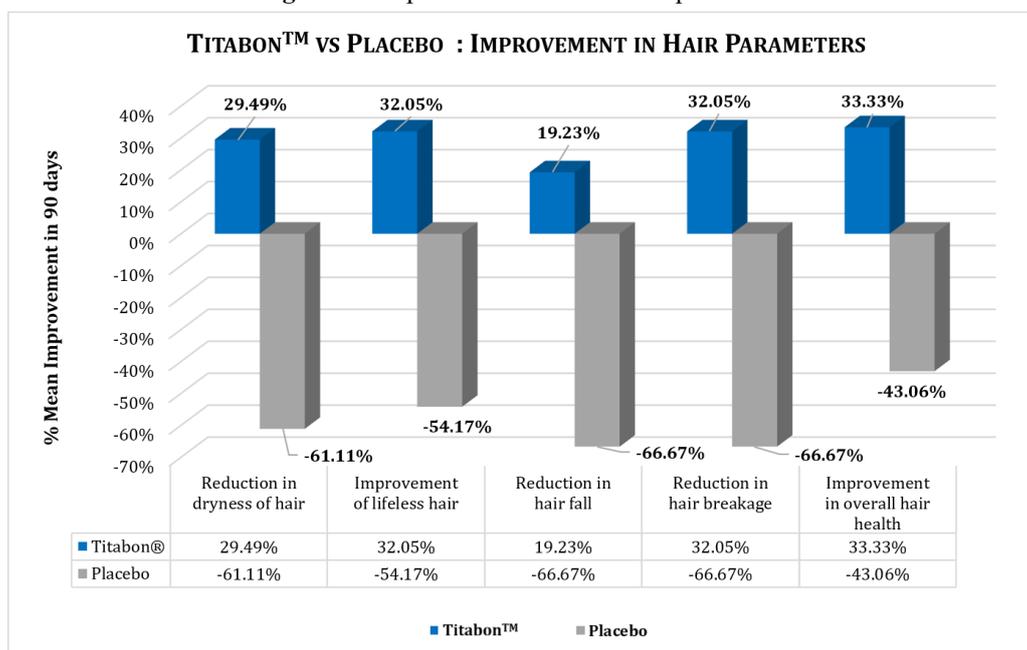


Figure 5 shows increase in total score of the Hair Growth Questionnaire at Day 45 and Day 90 of consumption of either 5g Titabon™ or placebo. This questionnaire focused on subjective self-assessment of dryness, dullness, hair fall, breakage and health of hair. Subjects rated the improvement on a scale of 1 (poor) to 5 (excellent).

Figure 6 : Improvement in hair health parameters



Both studies did not report any adverse events. There were also no abnormalities noted between the hemogram, liver and kidney function tests performed at baseline and end of study, thereby proving clinical safety of Titabon™ as a nutraceutical supplement.

Table 4: Hair Study : Improvement in Hair Health : 5g Titabon™ vs Placebo in 90 days

PARAMETERS	TITABON™	PLACEBO
Reduction in dryness of hair	29.49% (9.60%)	-61.11% (12.69%)
Improvement of lifeless hair	32.05% (6.95%)	-54.17% (16.48%)
Reduction in hair fall	19.23% (17.03%)	-66.67% (0.00%)

Reduction in hair breakage	32.05% (6.95%)	-66.67% (0.00%)
Improvement in overall hair health	33.33% (10.05%)	-43.06% (15.48%)
Values are expressed as Mean(±SD)		

III. Discussion

Collagen is emerging as one of the super food nutraceuticals which seems to have beneficial effects on the structure components of the body such as bones, tendons, skin, hair, nails and even ligaments. Collagen has been known to have anti-inflammatory and antioxidant properties as well as being able to stimulate collagen synthesis and in turn facilitate bone formation.⁶ Multiple studies have further reported a positive impact of collagen peptide in reducing OA related symptoms by increasing bone strength and reducing inflammation thereby impacting the indices and progression of OA⁷. In-vivo study by JunLi Liu et al. provided evidence that BCP increased osteoblast proliferation, played positive roles in osteoblast differentiation and mineralized bone matrix formation.⁸ The study by Jian-Xin Jiang on BCP supplementation for 6 months in elderly women significantly reduces joint pain and improves physical mobility which was assessed by two well established scoring systems (WOMAC and Lysholm score).⁷

Maryam Borumand et al., reported BCP consumption improving hair, skin and nail health, 52% subjects taking collagen reported that hair had become less brittle compared to placebo in 9 weeks.⁹ In another study on hair health by David M. Reilly et.al., clinical trichoscopy was measured in parallel to expert visual grading measures, recorded at baseline, week 6, and week 12 of collagen supplementation showed 11.0% improvement in scalp scaling and a 27.6% increase in the total number of hairs counted vs. placebo and was associated with a 31.9% increase in clinical grading score for hair healthy appearance ($p < 0.01$)¹⁰

We conducted two clinical studies to evaluate the efficacy, safety, and tolerability of Titabon™ of Titan Biotech Ltd in the management of OA symptoms and in improving hair health. Results have shown that Titabon™ performed statistically better than placebo in both studies. Pain is the first and most limiting factor associated with OA and Titabon™ has shown promising results in reducing pain and joint stiffness, thereby improving quality of life. As part of their study responsibilities and instructions, the subjects in the OA study were asked to refrain from making any life style changes such as diet modifications, exercise etc. to be able to evaluate the discrete effectiveness of Titabon™

Improvement in hair health seems to be significant, upon supplementation with 5g Titabon™ proving impact on the structural proteins and strengthening hair from the inside. The findings offer a clear perspective on the safety and efficacy of Titabon™ for everyday use. The trial was conducted without any changes to the participants' daily routines and limited the use of hair products that could potentially affect the study's outcomes. This approach yields real-time data free from external biases regarding the effectiveness of Titabon™ in enhancing OA and the hair health of the participants. The absence of adverse events supports the potential use of Titabon™ supplementation as a nutraceutical that alleviates pain and improves hair health from a matrix level.

The present research indicates a promising outlook for bovine collagen; however, the trial is constrained by a smaller sample size and a short treatment duration, which may not sufficiently evaluate the effects of the nutraceutical. Moreover, a thorough analysis of related biomarkers that is essential for a more in-depth understanding of the protective benefits noted in the OA study. Additionally, the Hair study did not include instrumental evaluations of hair and assessment nor did it take into account the hair growth rate which are considered as limitations of the study.

IV. Conclusion

The efficacy parameters show promising turn of data in 90 days. Clinical safety confirmed with blood tests established without doubt the safety of Titabon™ as a nutraceutical. Results are conducive to advocate for the use of Titabon™ the bovine collagen peptide from Titan Biotech Ltd. as a safe and effective nutraceutical supplement for management of OA and improving overall hair health.

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