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Effect of a Hydrolyzed Collagen, Vitamin, and Zinc Containing Nutritional Supplement on Telogen Effluvium

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ABSTRACT

Background: Telogen effluvium (TE) is a prevalent cause of diffuse, nonscarring hair loss, characterized by the premature entry of hair follicles into the telogen phase. Previous research from our group demonstrated the efficacy of a nutritional supplement containing hydrolyzed collagen, Group B vitamins, and zinc (Pilopeptan® Intensive) in improving the anagen/telogen ratio after a 1-month treatment. This study aimed to further assess and validate the sustained effects of this supplement in a larger cohort. **Materials and Methods:** A 1-month intervention with Pilopeptan® Intensive was administered to 343 TE patients, with assessments at baseline (T0), posttreatment (T1), and after a 30-day washout period (T2). Parameters evaluated included self-assessed hair thickness, hair amount, hair shedding, hair strength, hair brightness, hair softness, pull test results, subject-perceived improvement, treatment satisfaction, adherence, and side effects. **Results:** Out of 343 patients, 340 completed the second visit, and 330 completed all three visits. The participants, predominantly women (92.1%), had a mean age of 43.2 years. Significant improvements in all hair parameters were observed at T1 and T2 ($P < 0.001$). The pull test indicated reduced hair shedding, with sustained effects during the washout period ($P < 0.001$). Participants reported overall improvement and satisfaction with treatment. Mild side effects were reported by ten patients, with high adherence observed. **Conclusions:** Pilopeptan® Intensive showed promising effects in improving hair parameters for TE patients, with sustained benefits posttreatment. The study supports the potential role of nutritional supplements as nonpharmacological adjuvants for TE treatment. Further research, including randomized controlled trials, is warranted to validate long-term efficacy and safety.

Key words: Hair loss, hydrolized collagen, nutritional supplement, telogen effluvium, vitamins, zinc

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INTRODUCTION

Telogen effluvium (TE) is the most common cause of diffuse nonscarring hair loss, and occurs when follicles prematurely enter the telogen phase.[1-3] It poses significant distress for individuals and manifests as heightened hair loss observed during routine activities such as combing, showering, or sleeping. The majority of TE cases are subclinical, making its precise incidence unclear.[3] The condition does not exhibit a racial predisposition and impacts individuals of both genders, although it tends to occur more frequently in females.[4] TE can be classified as either transient or chronic, depending on whether it persists for less or more than 6 months, respectively.[1,4] Postpartum hair loss, also known as telogen gravidarum, is a variant of TE and one of the most common types of shedding.

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TE is a multifaceted condition with triggers encompassing lifestyle factors, seasonal changes, rapid weight loss, nutritional deficiencies, illness, infectious disease, surgery or trauma, and emotional stress, among others.[1-5] In addition, certain drugs may also induce TE.[6] Treatment approaches vary based on the type of TE. Acute TE, typically a self-limited condition, often requires no additional treatment if the underlying cause is identified and appropriately addressed.[4] If medication is identified as the culprit, discontinuing the medication often results in the resumption of hair growth. In cases where hormonal, dietary, or metabolic imbalances contribute to the condition, restoring balance in these factors will typically lead to the return of normal hair growth. Notably, hair transplantation is ineffective for treating TE.[4] For those cases requiring an active intervention, treatment options include oral minoxidil;[7] corticosteroids;[8] stem cell-conditioned media;[9] botulinum toxin,[10] mesotherapy combined with photobiostimulation;[11] or specific olfactory receptor agonist,[12] among others. Successful outcomes have also been reported in the treatment of TE using standardized botanical extracts, vitamins, and minerals delivered both systemically through nutritional supplements or topically via shampoos, conditioners, or serums.[13-17] Previous research from our group demonstrated the efficacy of a nutritional supplement containing hydrolyzed collagen, Group B vitamins, and zinc (Pilopeptan® Intensive) in improving the anagen/telogen ratio after a 1-month treatment period.[16] Accordingly, this study aims to further assess the effects of Pilopeptan nutritional supplement and validate sustained efficacy in a larger cohort.

MATERIALS AND METHODS

Study design

This research aimed to assess the sustained effects of an oral nutritional supplement (Pilopeptan® Intensive) on TE. The drinkable solution comprised hydrolyzed collagen (8 g), vitamin B5 (pantothenic acid), vitamin B6 (pyridoxine hydrochloride), and zinc sulfate. Participants orally consumed one sachet daily for 1 month, and assessments were conducted at three time points. During the baseline visit (T0), participants received study information, the supplement, and instructions. The second visit occurred at the end of the 30-day treatment (T1), followed by a third visit after a 30-day washout period (T2) to evaluate treatment durability. All data, parameters, and observations were meticulously recorded in an electronic Data Collection Logbook (eDCL). This study adhered to Good Clinical Practices for research involving human subjects.

Study population

Patients meeting all the inclusion criteria and none of the exclusion criteria were enrolled in the study. The inclusion criteria were age between 18 and 84 years and a recent TE diagnosis. Exclusion criteria included other alopecia types, pregnancy likelihood, concomitant diseases (inflammatory, vascular, cardiac, pulmonary, kidney or metabolic problems, immunodeficiency, and malabsorption syndrome) and hypersensitivity to any of the components of the product. Participants abstained from other nutritional supplement, drugs, or hair loss products 3 months before the study.

Outcome measures

To assess nutritional supplement effects, participants subjectively evaluated the visual appearance of their hair in terms of hair thickness, amount of hair, hair loss, hair strength, hair shine and softness. Each parameter was scored on a 5-point Likert scale (1= very little, 2= little, 3= normal, 4= quite a bit, and 5= very much). At the same visit, researchers objectively evaluated hair health by performing a pull test. For this purpose, a clump of 20–60 hairs was pulled and the number of hairs extracted was subsequently counted.[5]

Secondary outcomes included subject-perceived improvement and satisfaction with the treatment, which were assessed using 4-point Likert scale (1= no improvement, 2= slight improvement, 3= significant improvement, and 4= exceptional improvement and 1= very dissatisfied, 2= dissatisfied, 3= satisfied, and 4= very satisfied; respectively). Macroscopic photographs taken by the researchers were also analyzed and any adverse effects were recorded.

Statistical analysis

Descriptive statistics were used to analyze qualitative and quantitative variables using the nonparametric Wilcoxon test. Quantitative data were analyzed as median, first and third quartile (Q1, Q3), and minimum and maximum values. Statistical analysis was performed on SAS® 9.4 (SAS Institute Inc., Cary, NC, USA), and $P < 0.05$ was considered statistically significant.

RESULTS

Primary outcomes

From the 343 patients included in the study, 340 participants

successfully completed the second visit, and 330 participants concluded all three visits. The mean (standard deviation) age at onset (T0) was 43.2 (14.6) years, ranging from 18 to 84 years, with 50% aged between 32 and 53 years and 92.1% being women.

The analysis of self-assessed hair parameters revealed progressive improvements over time, with statistically significant increases from T0 to T1 and from T1 to T2 for parameters hair thickness [Figure 1a], amount of hair [Figure 1b], absence of hair shedding [Figure 1c], hair strength [Figure 1d], hair brightness [Figure 1e], and hair softness [Figure 1f]. In addition, the pull test demonstrated a consistent reduction in the number of extracted hairs between T1 and T0, T2 and T0, and T2 and T1 [Figure 2]. Specifically, the number of patients without any hair detachment increased from three at the initial visit (T0) to 80 after 1 month of treatment (T1) and further to 115 after the washout period (T2). Furthermore, the overall improvement was also visually evident in global macroscopic images captured at the baseline, 1-month, and 2-month visits [Figure 3].

Secondary outcomes

Overall, participants perceived a statistically significant improvement in their condition [Figure 4a], and expressed satisfaction with the treatment [Figure 4b]. Only 13 volunteers did not perceive any improvement in the second control from the beginning of the treatment, and four volunteers did not perceive any improvement in the third control since the commencement of the treatment.

Regarding treatment adherence, 79.4% of participants consistently consumed the drinkable solution daily during the treatment month without missing a dose. Only 10.3% did not take the supplement at the recommended time. Importantly, 91.2% of participants continued the nutritional supplement even if their hair showed improvement, and 95.9% persisted in taking the supplement even if their hair condition worsened.

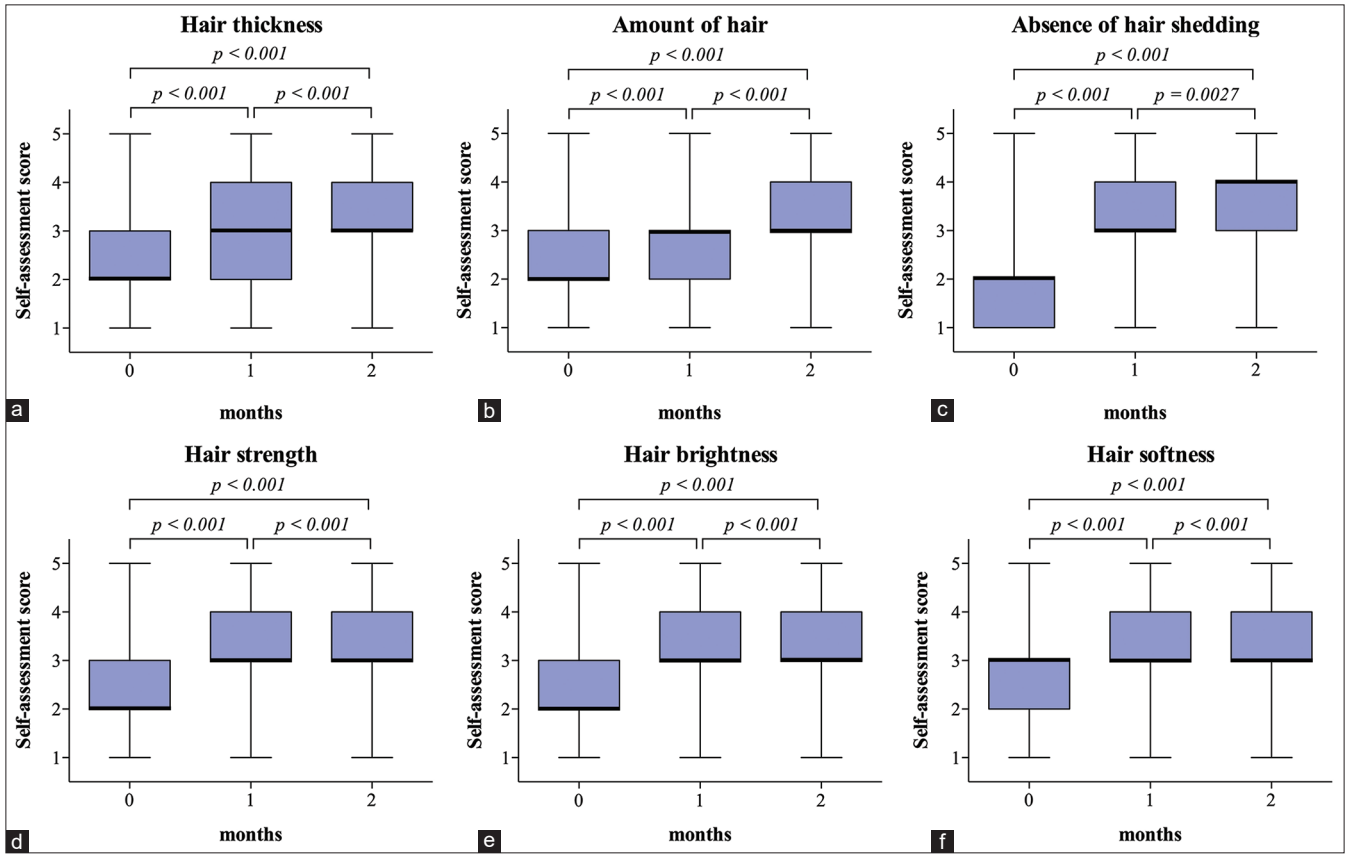

Figure 1: Improvement in Self-Assessed Hair Parameters Following Pilopeptan® Intensive Treatment. Self-perceived hair attributes were self-assessed at onset by a questionnaire in terms of hair thickness (a), amount of hair (b), absence of hair shedding (c), hair strength (d), hair brightness (e), and hair softness (f). Assessments were conducted at baseline (0 months), at the conclusion of the 30-day treatment period (1 month), and after a subsequent 30-day washout period (2 months). Each parameter was scored on a 5-point Likert scale (1= very little, 2= little, 3= normal, 4= quite a bit, and 5= very much). The results were graphically presented using Box–Whisker plots depicting medians (thick line within each box), first and third quartiles, and minimum and maximum values. $P < 0.05$ was considered statistically significant

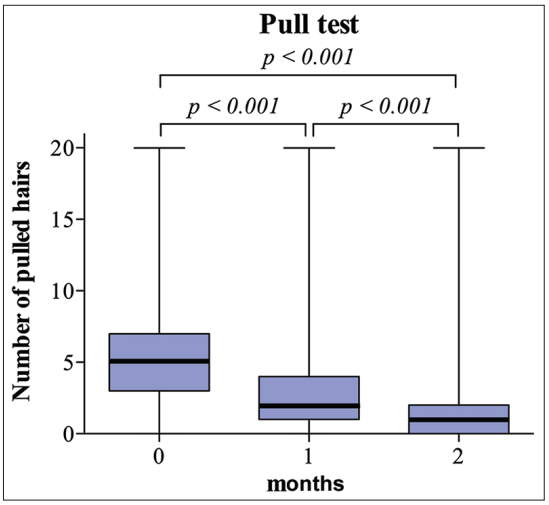

Figure 2: The number of pulled hairs was reduced after Pilopeptan® Intensive Treatment. Hair health was objectively evaluated by performing a pull test at baseline (0 months), at the conclusion of the 30-day treatment period (1 month), and after a subsequent 30-day washout period (2 months). The results were graphically presented using Box–Whisker plots depicting medians (thick line within each box), first and third quartiles, and minimum and maximum values. $P < 0.05$ was considered statistically significant

Side effects

Six patients reported minor undesired side effects during the treatment month, and an additional four patients reported such effects during the subsequent washout month. Remarkably, none of the individuals chose to discontinue product usage despite encountering these side effects. Primarily, the reported side effects were associated with digestive discomfort, specifically gastrointestinal reflux and gastric discomfort.

DISCUSSION

Hair loss due to TE poses a substantial emotional and psychological burden on individuals, impacting their social life and self-esteem.[1-5] In recent years, there has been growing recognition of the potential of nutritional supplements as safe and natural alternative treatments for different patterns of hair loss.[18] In this sense, previous research from our group has shown promising results on the use of Pilopeptan® Intensive, an intensive nutritional supplement, in managing TE.[16] Accordingly, this study aimed to further assess the effect of Pilopeptan® Intensive in TE treatment. The study's findings show that participants consuming Pilopeptan® Intensive for 1 month experienced significant improvements in self-assessed hair thickness, amount of hair, shedding, strength, brightness, and softness. Notably, a pull test revealed a quantifiable reduction in extracted hairs, indicative of improved hair retention. Moreover, these improvements were sustained after a 30-day washout period, indicating lasting effects.

The majority of patients seeking hair loss treatment are driven by underlying emotional or physiological motives.[19] Consequently, all patients seeking a solution for hair loss aim for self-perceived improvement. Therefore, the improvement of all self-assessed hair attributes observed after Pilopeptan treatment in this study serves as a compelling indication of the treatment's effectiveness, but also indicates a strong satisfaction with the treatment. While the aforementioned measures provide an important but subjective measure of the effects of the nutritional supplement, the pull test represents a valuable tool to objectively measure the improvement or worsening of TE. In acute TE, the hair pull test is strongly positive, with clumps of telogen hairs being extracted easily.[14] Accordingly, our results showed significant reductions in the number of extracted hairs at all assessment points. This indicates a tangible improvement in hair retention. In addition, the study observed high treatment adherence and only mild side effects were reported, with none of the patients discontinuing the product due to these side effects, indicating that the product was well-tolerated and easy to incorporate into daily routines. Overall, participants reported satisfaction with the treatment, as reflected in their ratings of effectiveness and satisfaction.

Despite their efficacy, conventional hair loss treatments like minoxidil or corticosteroids have associated adverse events.[8,20] Corticosteroid creams, for example, are generally avoided because they can make hair dirty, and lotions are hard to dose. Systemic corticosteroids, on the other hand, are discouraged due to prolonged treatment requirements and disproportionate side effects.[8] Furthermore, topical minoxidil carries the risk of irritant and allergic contact dermatitis, pruritus, scalp irritation, and facial hypertrichosis.[20] In contrast, nutritional supplements offer a compelling alternative, providing an effective, safe, and well-tolerated option for TE treatment.[18] This study introduces a nutritional supplement consisting of high-dose hydrolyzed collagen, vitamins B5, B6, and zinc. The hair follicle is characterized by a high metabolic rate, and B complex vitamins collectively play a crucial role in supporting metabolic functions, including the utilization of nutrients such as carbohydrates and amino acids. In the context of hair loss, insights into the impact of oxidative stress have unveiled potential intervention strategies. Notably, hair papilla fibroblasts exhibit heightened sensitivity to oxidative stress, particularly in cases of androgenetic alopecia.[21] Lastly, collagen's role in hair follicle aging is emerging, with research suggesting proteolysis of type XVII collagen linked to stem cell aging.[22] Hydrolyzed

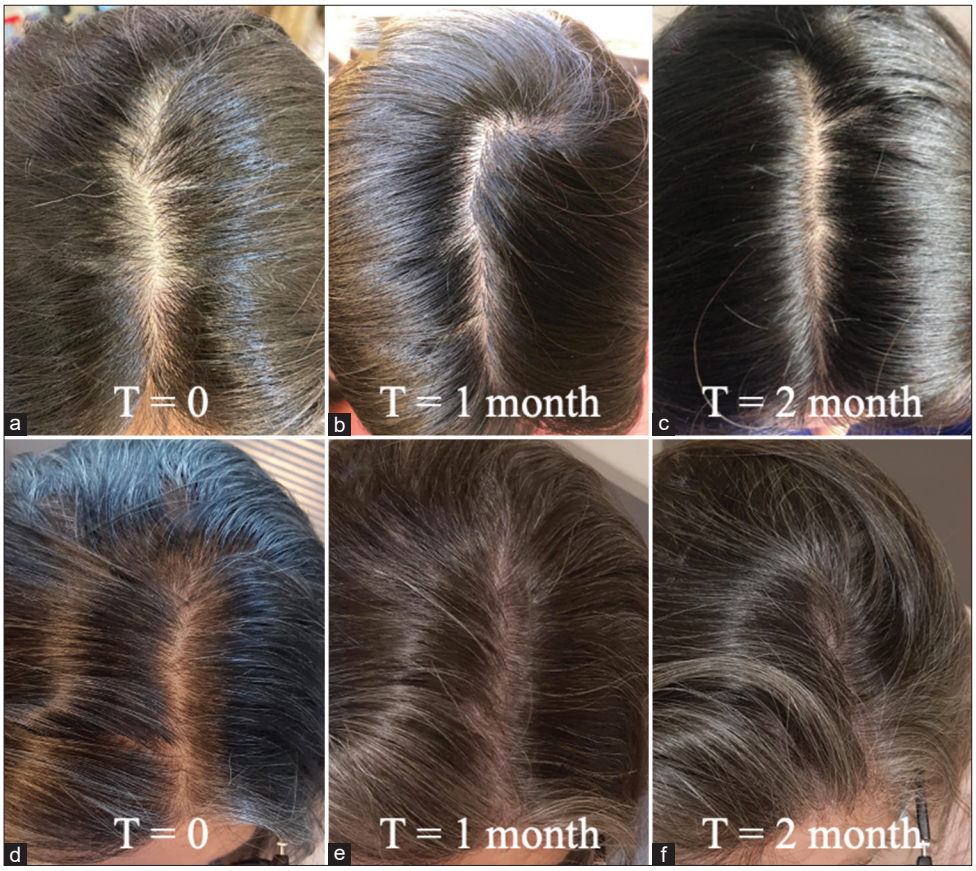

Figure 3: Global macroscopic images showing hair improvement after treatment with Pilopeptan® Intensive. Macroscopic photographs were taken at baseline (0 months), at the conclusion of the 30-day treatment period (1 month), and after a subsequent 30-day washout period (2 months). The effects of Pilopeptan® Intensive are shown for two patients: panels (a-c) represent one patient, and panels (d-f) represent the other

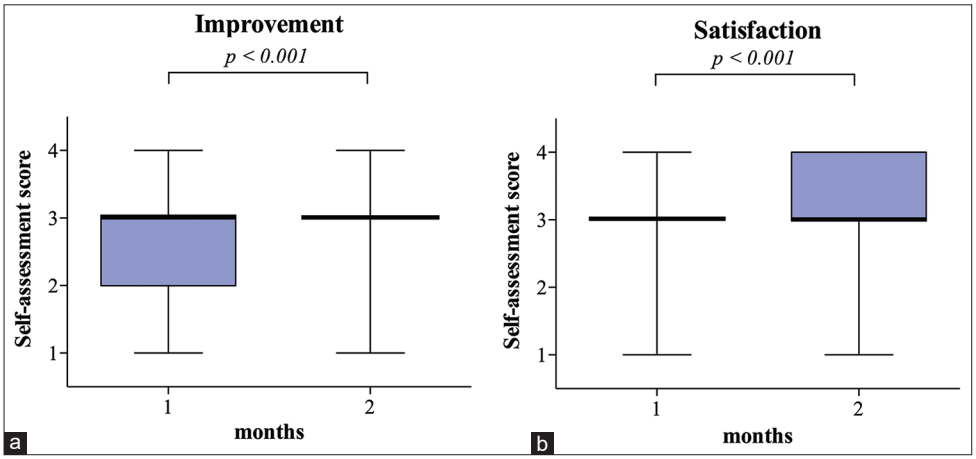

Figure 4: Patients treated with Pilopeptan® Intensive perceived a statistically significant improvement in their condition and expressed satisfaction with the treatment. The subject-perceived improvement (a) and satisfaction (b) with the treatment were assessed by a questionnaire using a 4-point Likert scale (1 = no improvement, 2 = slight improvement, 3 = significant improvement, and 4 = exceptional improvement; and 1 = very dissatisfied, 2 = dissatisfied, 3 = satisfied, and 4 = very satisfied; respectively). The results were graphically presented using Box–Whisker plots depicting medians (thick line within each box), first and third quartiles, and minimum and maximum values. P < 0.05 was considered statistically significant

collagen's bioavailability has been demonstrated in mice and humans,[23,24] with potential benefits for skin health, including increased collagen production and influence on fibroblast growth,[25,26] making it a promising area of study.

CONCLUSIONS

This study suggests that Pilopeptan® Intensive, an oral nutritional supplement containing hydrolyzed collagen,

Group B vitamins, and minerals like zinc, holds promise as a nonpharmacological adjuvant treatment for TE. Further research, particularly randomized controlled trials, is needed to confirm these findings and assess long-term efficacy and safety. This approach may offer a valuable addition to the management of TE and other forms of alopecia.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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