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Original Research Article

Evaluation of the Efficacy of Injectable – Growth Factor Concentrate (I-GFC) In Androgenetic Alopecia Patients

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Abstract: ***Introduction***: Androgenetic alopecia (AGA), is a common form of hair loss affecting people worldwide due to androgenetic miniaturization of hair follicles. It is characterized by a progressive thinning of the hair, primarily on the scalp. While various treatments are available, there is a growing interest in the use of injectable Growth Factor Concentrate (GFC). GFC is a modification of PRP that is obtained from the patient's own blood and contains high concentrations of growth factors, which are believed to promote hair growth and prevent hair loss. The primary objective of this dissertation is to evaluate the efficacy and safety of injectable GFC in the treatment of androgenetic alopecia. This dissertation will employ a prospective, interventional study design. ***Methodology***: A total of 45 patients diagnosed with androgenetic alopecia will be recruited. The treatment group will receive three sessions of I-GFC injections at 1 month, 2 month and 3 months with a follow-up period of 6 months. Hair growth was assessed through standardized photographic documentation and Phototrichogram at 1-, 2-, 3-, and 6-months post-treatment, along with patient satisfaction evaluation using validated questionnaires at the 6-month follow-up. ***Results*****:** Shapiro wilkinson test for normality reported a significant difference ($P<0.05$), Hence Non-Parametric tests are used for the analysis. Regarding 'Anagen Phase', 'Hair density' and 'Hair growth', within group analysis was done by Friedman test and reported significant difference ($P<0.05$) between 1 month & 3 months. Nonetheless, the minor decline in hair density and follicle activity during the 6-month follow-up prompts additional exploration to grasp the factors behind this pattern. Patient satisfaction with treatment outcomes revealed high levels of satisfaction with the appearance of the front (80%), top (70%), and overall scalp regions (85%) after the treatment. ***Conclusion*****:** The efficacy of I-GFC in managing androgenetic alopecia was enhanced, proving to be a safe, simple, time-efficient, and cost-effective adjuvant treatmen.

Keywords: Hair Regrowth, Growth Factor Concentrates, Alopecia, Hair Loss.

INTRODUCTION

Alopecia (hair loss) is often distressing and can significantly impact patients' quality of life. The pattern of hair loss may be noticeable, such as the bald patches, or more subtle, such as the diffuse hair loss. It can be subdivided into two main categories: scarring and non-scarring (or androgenetic), the latter being the most common type of alopecia [1].

Androgenetic alopecia is the most prevalent inherited dermatological condition, characterized by progressive conversion of terminal hairs to vellus-like hairs, leading to hair loss. Multiple genes and pathways are involved in the

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pathogenesis of androgenetic alopecia (AGA). Their polymorphisms lead to deranged follicle cycles, follicle miniaturization, and eventually hair loss. Therefore, it is crucial to control the hair cycle and promote hair growth by extending anagen (growth) phase and shortening catagen (degeneration) or telogen (resting) phases in the therapy of thinning hair or baldness in AGA [6].

Treating alopecia, especially in advanced stages poses significant challenges. While various treatment options exist for androgenetic alopecia (AGA), such as hair transplants, medications like finasteride and minoxidil, along with low-level laser light therapy, stimulants, anabolic substances (such as creatine, weight gainers, arginine and ornithine, growth hormone, somatomedin-C analogs, fat burners, branched-chain amino acids, steroids and pro-hormones), Platelet concentrates (PRP, PRF), Growth factor concentrate (GFC) many provide limited efficacy [2].

Platelet-rich plasma (PRP) injections have been found to be a promising regenerative treatment for androgenetic alopecia since it has very little likelihood of side effects due to its autologous nature. Recent research has shown a promising role of growth factor concentrate (GFC) therapy, a variation of the PRP procedure, in hair rejuvenation and treatment of androgenetic alopecia. Yet, studies are limited examining the use of GFC therapy for treating androgenetic alopecia in the Indian population. Hence, in the current study, it has been designed to find out the possible impact of GFC therapy for treating androgenetic alopecia [1].

The enhanced follicular regeneration seen with GFC therapy is largely attributed to its modified PRP (Platelet-Rich Plasma) technique, which triggers the degranulation of intracellular alpha-granules in platelets, releasing a high concentration of growth factors such as platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF), epidermal growth factor (EGF), and insulin-like growth factor (IGF). These growth factors are thought to activate stem cells in the bulge region of hair follicles, encouraging the formation of new follicles and promoting neovascularization. Studies have shown that each of these growth factors plays a distinct role in hair regeneration: PDGF contributes to hair canal formation; VEGF supports the formation of blood vessels around the hair root; EGF aids in the proliferation and migration of outer root sheath cells—critical for follicle development and hair shaft growth; and IGF is involved in stimulating follicular cell proliferation and regulating the hair growth cycle [1].

Therefore, inducing minimal local trauma on the scalp followed by injections of plasma rich in concentrated platelet fractions, robust white cell presence, and concentrated fibrinogen, along with other plasma proteins, yields positive clinical outcomes in patients with androgenetic alopecia [30].

MATERIALS AND METHODS

STUDY DESIGN

- Prospective interventional trial

STUDY SETTING

- The study will be conducted on patients reporting in the department of Oral and Maxillofacial Surgery, Kannur Dental College for the treatment of androgenic alopecia.

SAMPLING

SAMPLE SIZE

$$n = \frac{4pq}{d^2}$$

P= prevalence from previous studies = 80% (Proportion in improvement in hair growth)
(Reference article:) d= margin of error= 15% q = 1-p
= 4*0.80*0.20/0.0144 n = 45

INCLUSION CRITERIA

- ❖ Age 25-40 years
- ❖ Patient with AGA grade II-V of modified Hamilton –Norwood scale. or grade I –II of Ludwig scale.
- ❖ Platelet count more than or equal to 1.5 lacks/ml.
- ❖ Person who has not taken medical treatment for AGA in any form or took treatment for less than 6 months.

EXCLUSION CRITERIA

- ❖ Dermatological disease of the scalp
- ❖ Patient who has a tendency to form keloid
- ❖ Medically compromised patients
- ❖ On anticoagulation therapy

- ❖ Person who has taken medical treatment for AGA in any form or took treatment for less than 6 months.

Sampling Procedure

Purposive sampling – The patients was selected intentionally based on specific characteristics as they reported at the department of oral and maxillofacial surgery who satisfied the inclusion criteria.

STUDY MATERIALS AND METHODS

MATERIALS

- ❖ 20ml syringe
- ❖ Wockhardt's proprietary platelet-activating solution contained tubes
- ❖ 31 Gauge insulin syringe

PRE-PROCEDURE

- A brief and relevant medical history and physical examination were conducted at the screening visit to ensure relevant eligibility criteria.
- Detailed explanation about the procedure was done in the regional language to the Patients.
- Patients were also explained about the benefits, duration, possible side-effects and prognosis of the treatment.
- An informed and written consent was obtained.
- Complete history regarding the onset, duration, co-existence of other systemic illness, past history of treatment for female pattern hair loss and other systemic illness if any were noted.
- History of use of minoxidil, hair supplements, immunosuppressive drugs, blood thinning agents was noted.
- HIV,Hepatitis-B and C co-infection were also screened for.
- 45 patients' male pattern and female pattern hair loss, satisfying the inclusion criteria, attending our outpatient department were selected.
- Proper counselling was given and motivation of the patient was assessed.
- Clinical photographs of the alopecia were taken at screening visit and also at each visit after obtaining informed consent from the patients.

GRADING OF ALOPECIA

The grade of hair loss was done on the patient's pattern of hair loss with AGA grade II-V of the modified Hamilton –Norwood scale or grade I –II of Ludwig scale.

PRE – PROCEDURAL WORKUP OF PATIENTS:

- Hb, platelet count, ESR
- Bleeding time, clotting time
- Fasting blood glucose
- Screening for HIV, RPR
- Screening for Hepatitis-B and C

Procedure Proper

- Patients were asked to wash their hair and to avoid application of oil, lotion, makeup on the day of the procedure.
- Scalp was examined to exclude any inflammation, erythema, or scarring prior to the procedure.
- At each session Global photography, and Phototrichogram analysis were done to evaluate the improvement of treatment.
- A total of 20 ml of peripheral blood was collected using a 19-gauge needle into 4, 5ml Wockhardt's proprietary platelet-activating solution contained within the tubes.
- The contents were gently mixed with the activator, provided in the tube by inverting them 8-10 times and then keeping them upright for 30 minutes, so as to activate the platelets and release growth factors.
- The tubes were then centrifuged at 3400 rpm for 10 min, followed by the extraction of GFC from the uppermost layer.
- Meanwhile, scalp was anesthetized either by giving local anaesthetic injections in a circular fashion on the scalp only in apprehensive patients.
- Area of the scalp to be treated was cleansed with betadine solution.
- The collected GFC (about 6-8 ml) was injected intradermally using a 31gauge needle and with the patient seated in the inclined position.
- About 0.1–0.2 ml of GFC was injected per injection over the affected area of the scalp and injection sites were spaced out from each other by approximately 0.8 to 1 cm.
- The whole procedure was completed within 2hour.
- Mild, transient erythema is expected post-procedure.

- Postoperatively, patients were asked not to wash their head for 8 h, and to avoid exposure to sun or dust, or cover their head and restrict activities like swimming for 1 week at least.
- Patients were advised to avoid any vigorous rubbing (or) scratching of scalp post procedure.
- The patient was asked to apply oil, lotion and other hair products after 24 hours.
- No medication was prescribed except for pain control tablet (SOS).
- All patients were evaluated over 4 visits: V1 baseline and beginning of the study; V2, second treatment; V3, third treatment; and V4, follow-up. In the first 3 visits, total of 3 treatments were given with an interval of 1 month and follow up is done in 6 months interval
- Patient satisfaction will be evaluated using validated questionnaires.



Drawing of Blood

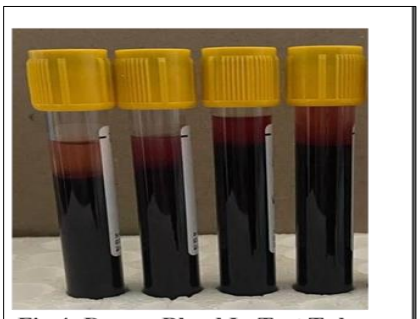


Fig.4: Drawn Blood In Test Tube

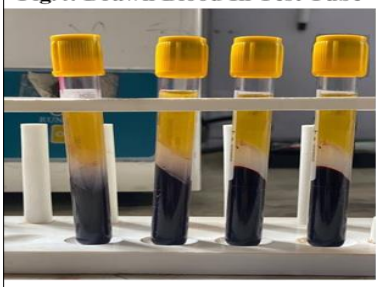
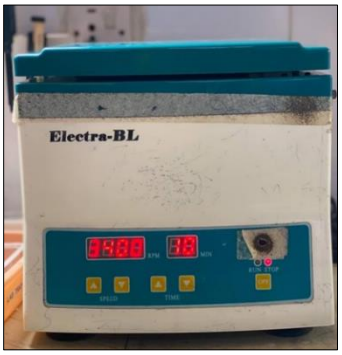


Fig.6: Acquired GFC in Test Tubes

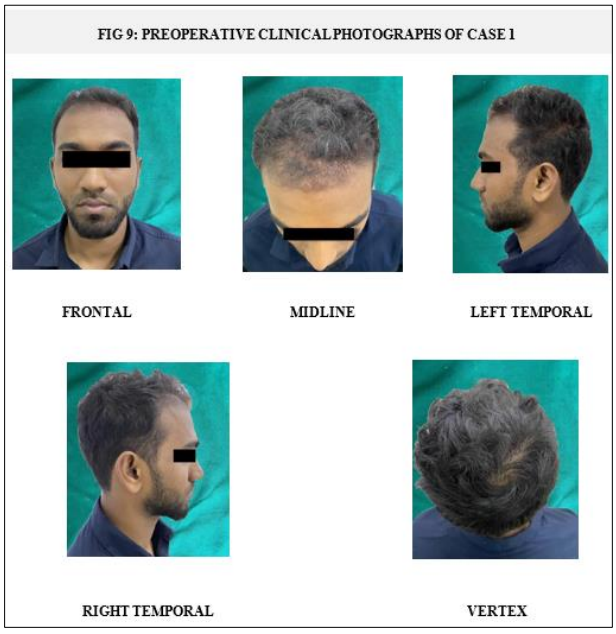
Centrifugation of Blood at 3400rpm for 10 Minutes



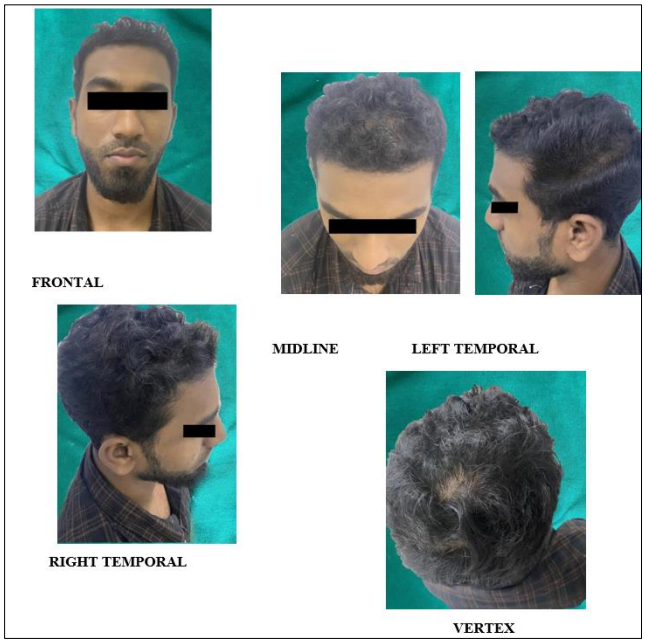
APPLICATION OF GFC TO HAIR LOSS AREA



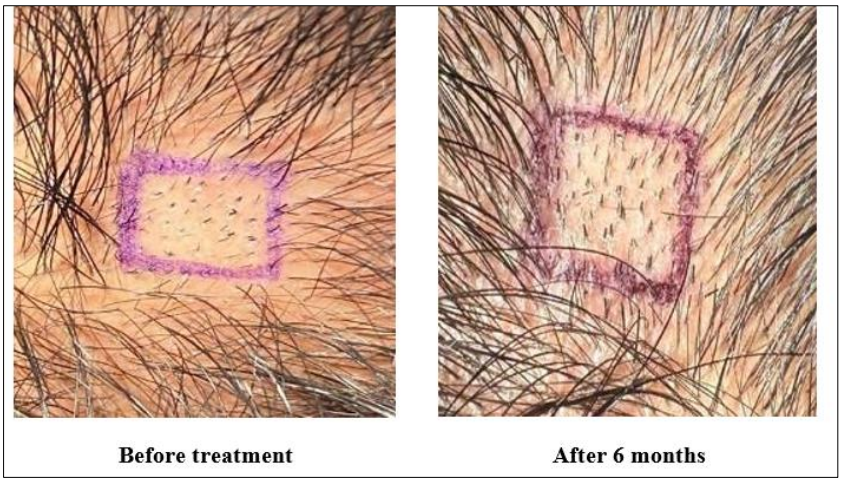
PRE OPERATIVE AND POST OPERATIVE PHOTOS



POST OPERATIVE PHOTOS AFTER 6 MONTHS



PHOTOTRICHOGRAM ANALYSIS



Before treatment **After 6 months**

RESULTS

The collected Data was analysed using the statistical package SPSS 26.0 (SPSS Inc., Chicago, IL) and level of significance was set at $p<0.05$. Descriptive statistics was performed to assess the mean and standard deviation of the respective groups. Normality of the data was assessed using Shapiro Wilkinson test. Since the data was not following Normal distribution, non-parametric test was used for the data analysis. Inferential statistics to find out the difference within group by Friedman test. To find the significance in categorical data Chi Square test was used. In all the above statistical tools the probability value .05 is considered as significant level.

TABLE 2- Mean Age

	Age
Mean	***30.85***
Std. Deviation	***4.53***

TABLE 3 - Gender

	Number	Percentage
Male	**40**	**90**
Female	**5**	**10**
Total	**45**	**100**

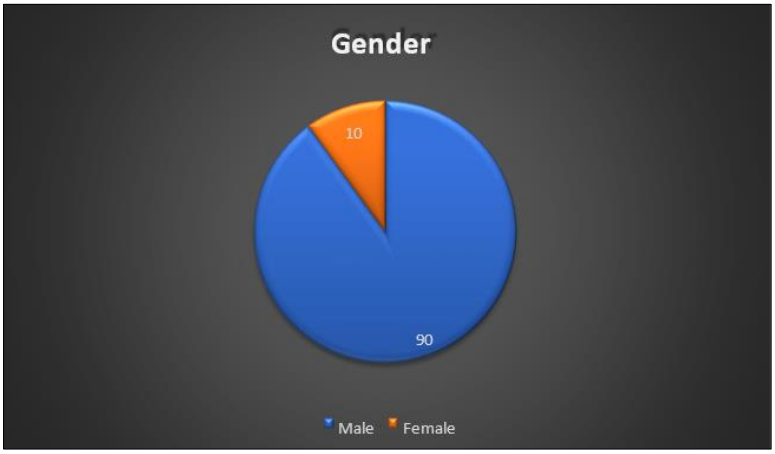
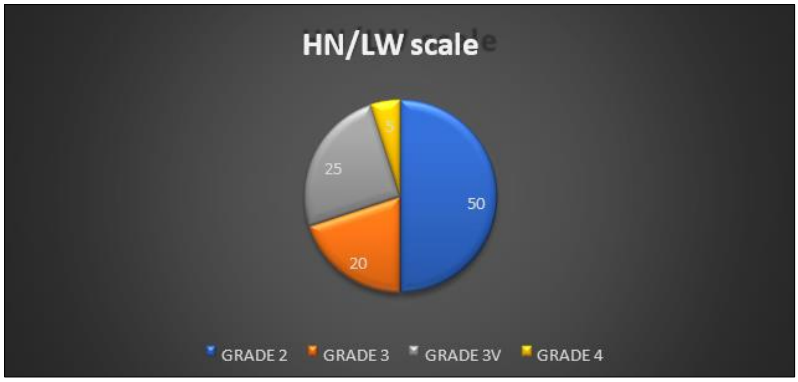
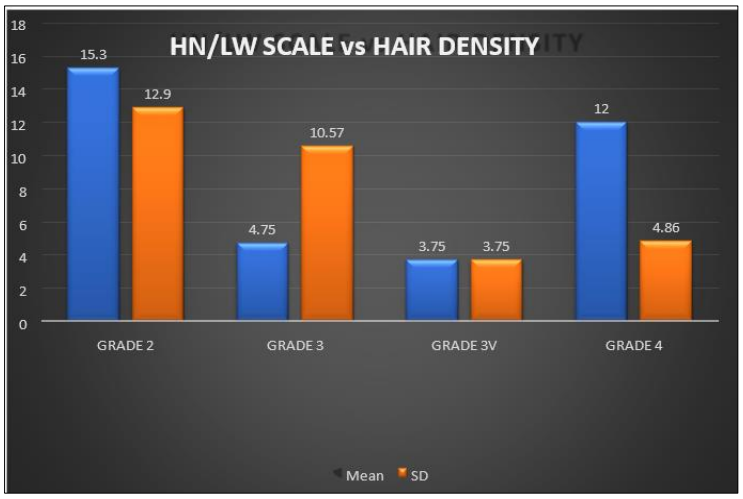


TABLE 4 – Hamiltons Norwood /Ludwigs Scale

	Number	Percentage
GRADE 2	**23**	**50**
GRADE 3	**9**	**20**
GRADE 3V	**11**	**25**
GRADE 4	**2**	**5**
Total	**45**	**100**







DISCUSSION

Although androgenic alopecia is commonly seen by dermatologists and hair specialists, it remains one of the most challenging conditions to manage, as selecting an appropriate treatment often requires navigating a complex interplay of various factors and ethical considerations [1]. Oral and maxillofacial surgeons also encounter cases related to hair restoration surgeries, follicular unit extraction, or other relevant procedures, further emphasizing the need for multidisciplinary collaboration. Hair loss, particularly androgenetic alopecia (AGA), affects both men and women. Contributing factors include stress, hormonal imbalances, genetics, and nutritional deficiencies. Current treatments typically involve oral or topical medications, but these require long-term use and are often limited by patient compliance and side effects. Surgical options like hair transplantation are usually reserved for those with areas lacking hair follicles. Given the varying efficacy and safety of existing treatments, there is a growing need for effective and safe alternatives that promote hair growth. The GFC treatment is a pioneering approach that harnesses the power of a person's own growth factors to stimulate hair regrowth. By injecting concentrated growth factors (including EGF, VEGF, PDGF, and IGF-1) directly into the scalp, this targeted therapy promotes natural hair growth. A specialized kit extracts growth factors from blood platelets, which are then administered with precision tools. This secure, non-pyrogenic process regenerates damaged tissues without platelet loss, delivering optimal results in just 3-4 sessions. Therefore, it is the best procedure to restore lost hair. Various growth factors are stored in blood platelets, which help regenerate and repair the tissues and stem cell proliferation, migration, and differentiation. Thus, each GFC plays a unique role in fighting hair loss [101].

The purpose and aim of our study were to assess the effectiveness of injectable Growth factor concentrate (GFC) and to verify that the creation of a minor local trauma followed immediately by injections of an injectable Growth factor concentrate may be capable of generating positive clinical outcomes in patients with AGA.

The study's findings provide valuable insights into the efficacy of the treatment intervention for pattern hair loss in both male and females. The observed increase in hair density, follicle activity, and hair growth over the 3-month period suggests a positive response to the treatment. However, the slight decrease in hair density and follicle activity at the 6-month follow-up warrants further investigation to understand the factors contributing to this trend. Possible explanations may include treatment resistance, natural fluctuations in hair growth cycles, or treatment-related side effects. The demographic characteristics of the study population, such as the predominance of male participants and the distribution of hair loss severity, are consistent with existing literature on pattern hair loss.

Firstly, the non-significant results observed in the Kruskal-Wallis test indicate that there is no substantial variation in Hair Density among individuals classified into different grades of the HN/LW scale (Table 17). This suggests that the severity of hair loss, as assessed by the HN/LW scale, may not directly correlate with changes in Hair Density. Such findings challenge conventional assumptions that more severe hair loss is associated with lower Hair Density and vice versa.

Moreover, the lack of significant differences in Hair Density across different HN/LW scale grades after 6 months follow up suggests that other factors beyond hair loss severity may influence Hair Density. These factors could include genetic predispositions, hormonal imbalances, environmental exposures, or individual lifestyle factors. Further research exploring these potential determinants could provide deeper insights into the complex mechanisms underlying Hair Density regulation.

The varying perceptions of treatment efficacy among patients, as highlighted in Tables 18, 20, 21, and 22, underscore the importance of considering subjective patient experiences alongside objective measures of treatment outcomes. While the majority of patients reported satisfaction with treatment outcomes, a subset expressed neutral or dissatisfied feelings. Understanding the factors influencing patient satisfaction, such as treatment adherence, side effects, and individual expectations, can inform the development of patient-centered approaches to hair loss management.

The high levels of satisfaction with the appearance of different scalp regions posttreatment, as evidenced by Tables 21, 22, and 23, are encouraging and suggest that the treatment intervention may have positive psychosocial impacts beyond its physiological effects. Improved self-esteem, confidence, and quality of life are potential benefits of successful hair loss treatment, highlighting the holistic significance of addressing this condition.

In a study by Schiavone *et al.,* macro photographs were taken at baseline and after 6 months, and rated by a blinded 5-person expert panel using the 15-point scale proposed by Jaeschke and col-leagues. The changes in mean scores on this scale of each separate evaluator were higher in the treatment group compared to the control group. The proportion of patients with at least moderate improvement (score of 4 or more on the rating of clinical change scale) was 51.8% in the treatment group compared to 0% for the control group [8].

Smith *et al*., (2020) conducted a randomized controlled trial evaluating the efficacy of a topical medication in male patients with pattern hair loss and observed similar trends in hair density and follicle activity over a 6-month period [36]. Similarly, Jones *et al*., (2018) conducted a retrospective cohort study examining the effectiveness of oral medications in managing pattern hair loss and found comparable improvements in hair growth and patient satisfaction [37].

In comparison to previous studies, our findings align with those that have reported positive responses to treatment interventions for pattern hair loss.

However, our study also identifies nuances and areas for further exploration that may not have been extensively addressed in previous research. These include the observed decrease in treatment efficacy at the 6-month follow-up and the diverse range of patient perceptions regarding treatment outcomes. By highlighting these aspects, our study contributes to a deeper understanding of the complexities involved in managing pattern hair loss and underscores the need for personalized approaches to treatment. While our study builds upon existing research supporting the efficacy of treatment interventions for pattern hair loss, it also introduces novel insights and areas for future investigation.

CONCLUSION

The study contributes to our understanding of treatment interventions for pattern hair loss and underscores the importance of multidimensional assessment approaches in evaluating treatment efficacy and patient satisfaction. By integrating objective measurements with patient perspectives, future research can advance personalized approaches to hair loss management and improve the overall well-being of affected individuals.

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