# A Randomized, Split-side, Double-blinded, Placebo-controlled Trial on the Effectiveness of the Procapil Gel on Eyebrows Enhancement

Sirinya Chetanachan* and Sunatra Nitayavardhana

Division of Dermatology, Chulabhorn International College of Medicine, Thammasat University, Pathum Thani, Thailand
*Corresponding author, E-mail: sirinya711@gmail.com

**Abstract**

Eyebrows play a crucial role in both the visual aspect and functionality of the face, making them a particularly important facial feature. Insufficient eyebrow growth can significantly affect an individual's quality of life, especially in today's society where this issue has become a major concern from both social and aesthetic perspectives, regardless of gender. Currently, there is no standardized evidence-based treatment for eyebrow hypotrichosis. Procapil consists of a combination of Biotinoyl Tripeptide-1, Apigenin, and Oleanolic acid. Its primary aim is to address the root factors responsible for alopecia. However, the existing literature on the impact of Procapil on the development of eyebrow hair growth is limited. The main objective of this study is to investigate the effectiveness of Procapil gel compared to a placebo in stimulating eyebrow growth. Twenty-five participants within the age range of 18-60 years, with GEBA grade I, II, or III, were enrolled. Each participant received treatment with Procapil and a placebo on separate sides of their eyebrows, as determined through randomization. Throughout the course of the study, clinical outcomes were evaluated on Day 30, Day 60, and Day 90, by assessed on hair counts, GEBA scale assessments, photographic evaluation using a quartile grading scale, adverse events, and satisfaction survey. Upon completion of the 90-day treatment period, the results revealed that Procapil demonstrated a significant efficacy in promoting hair growth when compared to the placebo. The findings indicated a significant increase in eyebrow hair counts (*P*-value of 0.024) and a notable difference in the GEBA scale (*P*-value < 0.05) compared to the placebo group. Mild itching was reported in some cases, with no other signs of inflammation observed, and the difference was not statistically significant. Based on the study's findings, Procapil gel is a safe and effective treatment for individuals with inadequate eyebrow growth or eyebrow hypotrichosis.

***Keywords*****:** *Eyebrow Hypotrichosis, Procapil, Eyebrow Regrowth*

## 1. Introduction

Eyebrows serve multiple essential functions such as protecting the eyes, expressing emotions, and assisting with facial identification (Sadr, Jarudi, & Sinha, 2003). Some individuals may encounter insufficient eyebrow growth, known as eyebrow hypotrichosis, which can be idiopathic or secondary to underlying conditions. Various factors, including genetics, infections, trauma, stress, hormonal changes, immune system activity, nutritional deficiencies, and certain medications, can contribute to thin eyebrows (Velez, Khera, & English, 2007) with considerable social and aesthetic consequences, impacting the self-assurance of both women and men in the cosmetic industry. Currently, there is no standardized evidence-based treatment for eyebrow hypotrichosis. However, topical medications, surgical transplantation, and camouflage are commonly used methods to enhance eyebrow thickness.

Minoxidil, initially, was formulated as a potent vasodilator intended for treating severe refractory hypertension. However, individuals receiving oral minoxidil therapy exhibited hypertrichosis, leading to the development of a topical formulation for treating androgenetic alopecia (AGA) in both males and females with Food and Drug Administration (FDA) approval at a later stage. The mechanism of action of minoxidil involves prolonging the anagen phase, enhancing vasodilation to stimulate the microcirculation surrounding the hair follicles, initiating the expression of vascular endothelial growth factor (VEGF), and inhibiting the detrimental effects of androgen-mediated hair loss, thus facilitating hair growth (Badri, Nessel, & Kumar, 2021). The study conducted by Olsen et al. demonstrated that a higher dosage of minoxidil proved to be more efficacious in promoting hair growth compared to a lower dosage. Nevertheless, there is a higher occurrence of unpleasant effects like pruritis, itching, dryness, flaking, and other symptoms of scalp dermatitis with increasing doses (Olsen et al., 2002). Moreover, various studies and reports have provided evidence

demonstrating the safety and favorable outcomes of minoxidil in the promotion of eyebrow growth for treating eyebrow hypotrichosis (Gajbhiye, & Lamture, 2020; Worapunpong, & Tanglertsampan, 2017; Lee et al., 2014).

Procapil has also demonstrated positive results in promoting hair growth in both men and women who have androgenetic alopecia (AGA) (Garre, et al., 2018). It is derived from natural ingredients containing a combination of Biotinoyl Tripeptide-1 (a vitamin-enriched matrikine), Apigenin (derived from citrus plants), and Oleanolic acid (extracted from olive trees). The mechanism of action of Procapil focuses on addressing the primary causes of hair loss, specifically follicular atrophy caused by dihydrotestosterone (DHT), aging of the hair follicles, and inadequate blood flow to the scalp. Firstly, Oleanolic acid prevents the conversion of testosterone to DHT by blocking the enzyme 5α1,2-reductase in a dose-dependent manner and also stimulates the proliferation of dermal papilla cells, which are crucial for hair growth (Zhang et al., 2023). Additionally, the combination of Biotin and three amino acids (Glycine, L-histidine, L-lysine) in Biotinyl-GHK helps in the production of keratin in the hair bulb. This accelerates follicle growth, ensures strong hair attachment to the dermal follicles, and slows down premature hair loss. Lastly, Apigenin improves blood circulation to the hair follicles, supplying them with essential oxygen and nutrients, and inhibits the TGF-1 gene, which is known to induce hair loss by activating cell death, thereby preventing hair loss (Huh et al., 2009).

A previous study by Karaca and Akpolat compared the efficacy of topical 5% minoxidil to a combination of "Redensyl, Capixyl, and Procapil" in men with Androgenetic alopecia (AGA). The results demonstrated that the group treated with the combination showed significantly superior clinical improvement in terms of hair growth (Karaca & Akpolat 2019). Similarly, Garre et al. conducted a study investigating the effects of a hair lotion containing Oleanolic Acid, Apigenin, Biotinyl Tripeptide-1, Diaminopyrimidine Oxide, Adenosine, Biotin, and Ginkgo biloba on patients with androgenetic alopecia and telogen effluvium. The findings revealed significant improvements in the total amount of hairs and the proportion of anagen and telogen hairs, both in patients with AGA and those with TE (Garre et al., 2018) with no adverse events reported. However, as of now, there have been no studies conducted on the effects of Procapil specifically on eyebrow growth.

Procapil could be a potential alternative option for individuals with sparse brows or individuals with eyebrow hypotrichosis. However, the extent of research conducted on Procapil is currently not many, thus resulting in limited evidence supporting its safety, tolerability, and efficacy in stimulating eyebrow growth. Accordingly, this research aims to study the effectiveness of Procapil in promoting eyebrow growth in the hope of acquiring knowledge that can be utilized for future research, supporting the use of natural substances to enhance eyebrow growth while minimizing the potential for undesirable side effects.

## 2. Objectives

To evaluate the efficacy and safety of Procapil on eyebrow regrowth

## 3. Materials and Methods

An experimental study of a randomized, split-side, double-blinded, placebo-controlled trial was conducted at the Department of Dermatology, Benchakitti Park Hospital, Bangkok, Thailand. This research protocol was authorized by the Human Research Ethics Committee of Thammasat University (MTU-EC-OO-0-144/66).

### *3.1 Participants selection*

*Inclusion criteria:* eligible participants aged 18-60 years old with Grade 1, 2, or 3 on the Global Eyebrow Assessment (GEBA) scale.

*Exclusion criteria:* participants who have previously undergone eyebrow tattooing or transplantation, individuals displaying signs of irritation or infection around the eyebrow area, subjects who have received a Botox brow lift within the last three months, individuals currently taking medications or supplements that stimulate hair growth within the past six months, and those with any of the following medical conditions: alopecia areata, telogen effluvium, anagen effluvium, seborrheic dermatitis, atopic dermatitis, psoriasis, hypothyroidism, hyperthyroidism, trichotillomania, scars caused by injury, eyebrow tattoo removal, or chemical/thermal burns.

### *3.2 Study methods*

In this study, twenty-five participants who fulfilled the inclusion and exclusion criteria were enrolled.

They were provided with two identical packages of Procapil gel and placebo gel. The packaging was clearly labeled to indicate the side of the eyebrow where the gel should be applied. The side of the application differed for each individual with regard to randomization. All participants were instructed to apply the products twice daily for a period of 3 months. It was emphasized that they should not wipe or rinse the area after application, also the use of any other topical treatments on the treated area was prohibited throughout the trial. To monitor progress and gather data, follow-up appointments were scheduled at baseline, day 30, day 60, and day 90 for photo-documentation using a digital camera (Canon PowerShot G7 X Mark II, Canon Incorporated, Japan), photo of specific area of the brows using a digital handheld microscope (Dino-Lite Premier AM7013MZT) focusing on an area of 1 $cm^2$ in mid-pupillary line, satisfaction survey, and adverse events record.

### *3.3 Assessments*

The evaluation was conducted at baseline, day 30, day 60, and day 90 by two-blinded dermatologists and participants. The assessments consisted of two different types: objective and subjective evaluations. The objective evaluation involved counting the number of eyebrow hairs from photographs taken from specific areas of the brows. On the other hand, the subjective evaluation involved the global photographic assessment using a quartile grading system (grade 0 no change or worsened (0%), grade 1 slight improvement (1-25%); grade 2 mild improvement (26%–50%); grade 3 moderate improvement (51%-75%) and grade 4 significant improvement (>75%) and global eyebrow assessment (GEBA) scale (1 = very sparse, 2 = sparse, 3 = full, and 4 = very full) done by two-blinded dermatologists. As for participants, the assessment involved the global photographic assessment using a quartile grading system, adverse events, and satisfaction survey. The potential adverse events associated with the treatment were closely monitored and recorded at each follow-up visit. These events encompassed symptoms such as itching, erythema, dryness, burning sensation, scaling, or any abnormal hair growth.

### *3.4 Statistical analysis*

The SPSS program was used for statistical analysis. The statistical analysis including the mean, standard deviation, and minimum and maximum values was used to describe the overall characteristics of the sample. Additionally, comparisons between categorical variables, such as global photographic assessment, GEBA scale, satisfaction surveys, and adverse events, were made between the Procapil and Placebo groups using either a chi-square test or Fisher Exact test. To assess the difference in mean eyebrow hair counts between the two groups, repeated measure ANOVA statistics were used.

## 4. Results and Discussion

### *4.1 Study population*

A total of 25 participants, the majority of subjects were female (20/25, 80.0%), were enrolled and completed the study. The average age of the participants was 46.68 ± 11.90 years with ages ranging from 25 to 59. The eyebrow hair counts and global eyebrow assessment (GEBA) scale prior to treatment between the Procapil group and the placebo groups were not statistically different ($P$ = 0.751 for eyebrow hair counts, $P$ = 0.934 for GEBA scale)

**Table 1** Baseline demographics and other baseline characteristics of participants

| | n = 25 (%) | *P*-value |
|---|---|---|
| **Gender** | | |
| Female | 20 (80.0) | |
| Male | 5 (20.0) | |
| **Age (years)** | | |
| < 50 | 11 (44.0%) | |
| ≥ 50 | 14 (56.0%) | |
| Mean±SD | 46.68 ± 11.90 | |
| Median (min-max) | 53 (25-59) | |
| **Eyebrow hair counts** | | |
| Procapil group | 61.28±11.22 | *P* = 0.751 |
| Placebo group | 60.24±11.86 | (Procapil vs placebo) |
| **GEBA scale** | | |
| Procapil group | | |
| 1-Very sparse | 9 (36.0%) | |
| 2-Sparse | 10 (40.0%) | |
| 3-Full | 6 (24.0%) | *P* = 0.934 |
| 4-Very full | 0 | (Procapil vs placebo) |
| Placebo group | | |
| 1-Very sparse | 8 (32.0%) | |
| 2-Sparse | 10 (40.0%) | |
| 3-Full | 7 (28.0%) | |
| 4-Very full | 0 | |

### *4.2 Outcomes*

#### *4.2.1 Eyebrow hair counts*

According to the statistical analysis of the eyebrow hair counts at baseline (Day 0), it was found that there was no significant difference between the Procapil group and the placebo group ($P > 0.05$), the initial count was 61.28±11.22 and 60.24±11.86 respectively. However, on Day 90, there was a significant increase in the number of eyebrow hairs on the side treated with Procapil compared to the side treated with placebo, with a p-value of 0.024 (95% C.I. = 1.034-13.926).

**Table 2** Comparison of eyebrow hair counts on Day 0, 30, 60, and 90 between the Procapil-treated group and the placebo-treated group (n=25)

| Eyebrow hair counts | Procapil (n =25) | Placebo (n=25) | Difference | 95% CI of the Difference | | *P*-value |
|---|---|---|---|---|---|---|
| | Mean ±S.D. | Mean ±S.D. | Mean ±S.D. | Lower | Upper | |
| Day 0 | 61.28±11.22 | 60.24 ±11.86 | 1.040 ±6.308 | -5.525 | 7.605 | 0.751 |
| Day 30 | 63.56±11.03 | 61.36 ±11.95 | 2.200 ±6.904 | -4.339 | 8.739 | 0.502 |
| Day 60 | 66.96±11.48 | 61.48 ±12.59 | 5.480 ±8.699 | -1.371 | 12.331 | 0.114 |
| Day 90 | 71.28±11.10 | 63.80 ±11.57 | 7.480 ±7.292 | 1.034 | 13.926 | 0.024* |
| Delta change | 10.00±3.51 | 3.56 ±3.10 | 6.440 ±3.798 | 4.872 | 8.008 | <0.001* |

Day0-90: p-value from repeated measurement ANOVA and *post hoc multiple comparisons*: Bonferroni.
Different at 90 days: p-value from paired-samples t-test
* = significant at the 0.05 level.

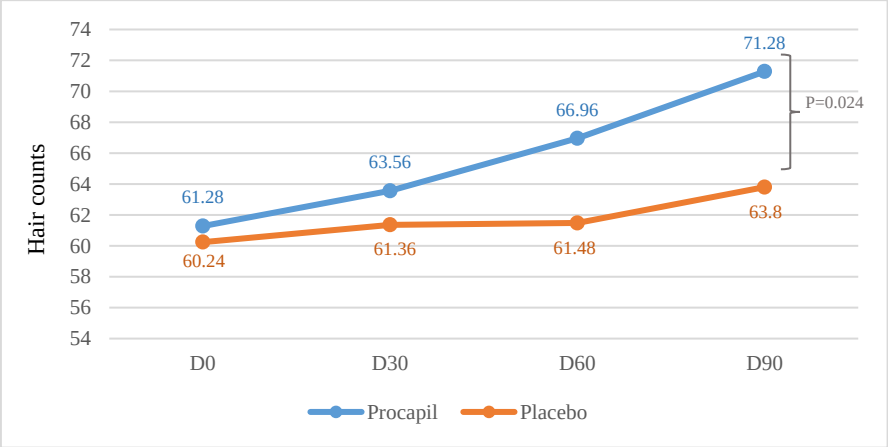


**Figure 1** The mean of eyebrow hair counts on Day 0, 30, 60, and 90 between Procapil-treated group and placebo-treated group

*4.2.2 Global eyebrow assessment (GEBA) scale and global photographic assessment scale*

Cohen's kappa statistic was utilized to assess the level of agreement between two-blinded dermatologists in their evaluations of the GEBA scale and global photographic assessment scale. The results indicated a strong level of agreement, with kappa values between 0.736 and 0.903 ($P < 0.001$).

Through a comparative analysis of data, the GEBA scale evaluated by dermatologists revealed the percentage of participants with at least 1-grade improvement in the GEBA scale from baseline was significantly higher in the Procapil group (92.0%) compared to the placebo group (48.0%) on Day 90. This difference was found to be statistically significant ($P < 0.05$) (Figure 2).

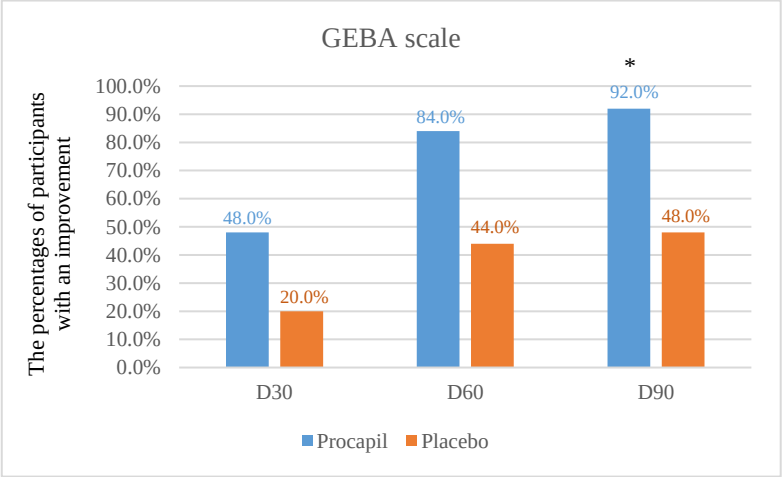


**Figure 2** The percentage of participants with at least 1-grade improvement in the GEBA scale from their initial assessment at each visit (* $P < 0.05$ versus placebo)

With regard to the findings of global photographic assessment using a quartile grading scale, the blinded investigator found a significant difference in efficacy between Procapil-treated and placebo-treated side on Day 60, with a *P*-value of 0.024, as well as on Day 90, with a *P*-value of 0.035. The participants themselves reported a significant improvement in the efficacy of the treatment on both Day 60 and Day 90, with a *P*-value of less than 0.001. On Day 90, the investigator rated 1 subject as having shown a greater than

75% improvement, 11 subjects as having a 51% to 75% improvement, 10 subjects as having a 26% to 50% improvement, and 3 subjects as having a 1% to 25% improvement. Meanwhile, on Day 90, participants rated 2 subjects as having shown a greater than 75% improvement, 8 subjects as having a 51% to 75% improvement, 12 subjects as having a 26% to 50% improvement, and 3 subjects as having a 1% to 25% improvement.

**Table 3** Comparison of global photographic assessment using quartile grading scale on day 0, 30, 60, and 90 between the Procapil-treated group and the placebo-treated group (n=25)

| Global photographic assessment | Dermatologist | | | | | |
|---|---|---|---|---|---|---|
| | Day 30 (n %) | | Day 60 (n %) | | Day 90 (n %) | |
| | Procapil | Placebo | Procapil | Placebo | Procapil | Placebo |
| 0% | 2(8.0%) | 5(20.0%) | 0(0%) | 0(0%) | 0(0%) | 0(0%) |
| 1-25% | 19(76.0%) | 17(68.0%) | 6(24.0%) | 14(56.0%) | 3(12.0%) | 10(40.0%) |
| 26-50% | 4(16.0%) | 3(12.0%) | 16(64.0%) | 11(44.0%) | 10(40.0%) | 11(44.0%) |
| 51-75% | 0(0%) | 0(0%) | 3(12.0%) | 0(0%) | 11(44.0%) | 4(16.0%) |
| >75% | 0(0%) | 0(0%) | 0(0%) | 0(0%) | 1(4.0%) | 0(0%) |
| *P*-value | 0.657 | | 0.024* | | 0.035* | |

The study found a significant difference in overall satisfaction levels among participants using Procapil compared to a placebo. This difference was observed after the 30, 60, and 90 days of use, with statistically significant *P*-values of 0.001 on Day 30 and less than 0.001 on Day 60 and Day 90. By the end of Day 90, 44% of Procapil users reported feeling highly satisfied, while 44% felt satisfied and 12% were slightly satisfied. Conversely, individuals using the placebo reported satisfaction levels of 40% satisfied, 52% slightly satisfied, and 8% neutral.

### *4.3 Adverse events*

Within each follow-up visit, 2-3 participants (8-12%) reported slight pruritus on either side of the eyebrow but was more prevalent on the side where Procapil was treated. This difference was not statistically significant based on Fisher's exact test for the significance of change. Regarding the two groups, no sign of any inflammation or significant adverse effects was reported.

## *Discussion*

Insufficient eyebrows have significant social and aesthetic implications, affecting the self-confidence of both women and men within the cosmetics industry. This condition can occur spontaneously or be associated with underlying medical issues; however, there is currently no standard treatment for eyebrow hypotrichosis.

Procapil is a botanical formula act by blocking the enzyme 5α1,2-reductase, which lowers the amount of testosterone that is converted to dihydrotestosterone (DHT) preventing hair follicle miniaturization (Maquart et al., 1999), stimulates the proliferation of dermal papilla cells (Patel, Swink, & Castelo-Soccio, 2017), and increase blood flow to hair follicles loss (Huh et al., 2009).

Previous studies on Procapil provide evidence for its effectiveness in promoting scalp hair growth. In vitro studies have shown that Biotinyl-GHK stimulates cell proliferation and improves hair anchoring to the follicular infundibulum by enhancing the expression of mitotic marker Ki-67, as well as collagen IV and laminin 5 synthase. Furthermore, a clinical trial conducted by Warson et al. observed a significant improvement in the anagen: telogen ratio in alopecia patients after using Procapil. Histologic observations on plucked hairs from the participants also confirmed the enhanced hair anchoring (Watson et al., 2008). Notably, a concentration of 2 ppm. resulted in a 583ijmj% increase in hair length, comparable to minoxidil, while a concentration of 5 ppm. achieved a 120% increase (Lintner, 2022). In the year 2018, Garre et al. conducted a study to examine the effectiveness of a hair lotion containing Procapil and other natural ingredients on 56 patients for a duration of 24 weeks. The results of the study indicated a notable improvement in the overall quantity of hair as well as the number of anagen and telogen hairs in both patients with androgenetic alopecia (AGA) and telogen effluvium (TE). Furthermore, no adverse events were reported throughout the study (Garre et al., 2018). Another study by Eslahi et al. investigated the efficacy of a treatment

called "Capixyl, Procapil, and rosemary extract (CPR)" for AGA, in comparison to a 2% minoxidil treatment. The findings of this study demonstrated the significant effectiveness of CPR in reducing hair loss when compared to the minoxidil group (Eslahi et al., 2022). Nevertheless, no research has been conducted specifically on the efficacy of these treatments for eyebrows.

In accordance with our research findings, Procapil has shown significant efficacy in promoting eyebrow regrowth compared to the placebo. The outcomes of this study were evaluated through methods of measuring hair counts, evaluating the GEBA scale, and conducting global photographic assessments. The results revealed a statistically significant difference between the Procapil-treated and placebo-treated groups. Specifically, there was a significant difference in hair counts and GEBA scale scores observed at Day 90, with a P-value less than 0.05. Furthermore, both dermatologists and participants reported significant improvements in global photographic assessments between Day 60 and Day 90, compared to the baseline. Furthermore, participants reported only minor pruritus on either side of the eyebrow, with a slightly higher prevalence noted on the side treated with Procapil. However, this difference was not found to be statistically significant.

## 5. Conclusion

In relation to the results of this research, it was found that Procapil demonstrated significant effectiveness in enhancing the regrowth of eyebrows, surpassing the effects of the placebo. The favorable tolerability of Procapil indicates that it has the potential to be a promising alternative for individuals with sparse eyebrows or eyebrow hypotrichosis.

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## Declarations

The author declares that they have no conflict of interest.

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