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A Prospective interventional study on the therapeutic potential of human placental extract in dermatological conditions.

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Abstract

Background
Placental extract is known for its regenerative, anti-inflammatory, and antioxidant properties. It is increasingly used in dermatology for conditions such as melasma, alopecia, and chronic ulcers.
Objective: To evaluate the clinical efficacy and safety of topical and intradermal human placental extract (HPE) in selected dermatological conditions.

Methods
A prospective interventional study was conducted at a tertiary care dermatology outpatient clinic over 6 months (August 2023 to February 2024). Fifty patients were enrolled and grouped according to diagnosis: melasma (n=20), chronic non-healing ulcers (n=15), and alopecia areata (n=15). Topical application or intradermal injection of placental extract was administered over 6 weeks. Clinical improvement was assessed using the MASI (score melasma), ulcer area measurement, and SALT score (alopecia) at baseline, 3 weeks, and 6 weeks.

Results
In the present study, age (mean±SD): B 47.3±8.4 > A 34.1±6.2 > C 29.8±5.6; females: A 90%, B 60%, C 40%. Significant improvement was observed in all groups. In melasma, the mean MASI score decreased from 12.6 ± 2.3 to 6.4 ± 1.9 ($p < 0.01$); in chronic ulcers, the mean area reduced by 68.2% ($p < 0.01$); and in alopecia areata, the SALT score improved from 35.2 ± 8.1 to 22.5 ± 6.7 ($p < 0.05$). No major adverse effects were reported.

Conclusion
Human placental extract is effective and safe in the management of melasma, chronic ulcers, and alopecia areata. Further large-scale trials are recommended.

Recommendations
Use HPE adjunctively (melasma: weekly intradermal ×6; ulcers: daily topical; alopecia: intralesional q2w ×3 with standard co-therapies), standardize monitoring (photos, MASI/SALT/ulcer area at 0/3/6 weeks), enforce safety/asepsis with AE logs, implement SOPs/registry, and conduct ≥6–12-month RCTs (dose–response, subgroups/biomarkers, cost-effectiveness, PROs).

Keywords: *Human placental extract, Dermatological therapy, Skin regeneration, Wound healing, Melasma, Alopecia, Anti-inflammatory*
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Introduction

Placental extract has recently garnered attention in dermatology as a versatile and biologically active therapeutic agent with applications in both regenerative and aesthetic fields. Derived from processed human placenta, this extract is a rich source of essential bioactive molecules, including peptides, nucleotides, growth factors

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(such as epidermal growth factor and fibroblast growth factor), cytokines (e.g., IL-10), enzymes, amino acids, and vitamins.[1] These constituents are known to influence a wide array of cellular processes, including epithelial regeneration, angiogenesis, collagen remodeling, and modulation of inflammatory responses. This biochemical richness underpins the extract's therapeutic value in dermatological conditions where tissue repair and immune regulation are critical.[2]

Historically, placental preparations have been used in traditional medicine systems such as Ayurveda and traditional Chinese medicine for wound healing, rejuvenation, and immune enhancement. However, contemporary interest has shifted toward the scientific validation of these effects through clinical and experimental research. Preclinical studies have shown that placental extract accelerates wound contraction, enhances fibroblast proliferation, and suppresses pro-inflammatory cytokines, suggesting a multifaceted mechanism of action beneficial for various skin disorders.[3]

In dermatologic practice, conditions such as hypo and hyperpigmentary lesions, hair loss that includes alopecia areata, and pattern baldness present substantial therapeutic challenges. Melasma is a common pigmentary disorder characterized by symmetrical hyperpigmented macules, particularly on sun-exposed areas of the face, and is often resistant to conventional topical therapies. Chronic ulcers, including diabetic and traumatic ulcers, pose a significant clinical burden due to delayed healing and risk of secondary infections. Alopecia areata, an autoimmune form of hair loss, lacks definitive curative treatment, and available options often result in variable or temporary outcomes.[4]

Given these challenges, there is a growing impetus to explore alternative therapies with regenerative capabilities and minimal side effects. Placental extract, with its broad-spectrum biological activity, represents a potentially valuable adjunctive treatment in these conditions. Clinical observations and small-scale studies have hinted at its efficacy, yet robust evidence remains limited.[5]

Therefore, this prospective interventional study was designed to evaluate the efficacy and safety of human placental extract in three common dermatological conditions: hypopigmentary lesion, hyperpigmentary lesions, and hair loss. By assessing objective clinical endpoints such as the MASI (Melasma Area Severity Index), ulcer size reduction, and the SALT (Severity of Alopecia Tool) score, this study aims to generate preliminary but valuable clinical evidence supporting the therapeutic role of placental extract in dermatology.

Materials and Methods

Study design

This study was designed as a prospective interventional clinical trial, aimed at evaluating the therapeutic efficacy and safety of human placental extract in selected dermatological conditions.

Study setting

It was conducted in the Department of Dermatology at a tertiary care medical center, spanning six months from August 2023 to February 2024.

Inclusion criteria

Participants were adults (≥18 years) with (a) clinically/dermoscopically diagnosed melasma, (b) chronic cutaneous ulcers of ≥4 weeks' duration of non-ischemic etiology, or (c) alopecia areata or androgenetic alopecia meeting standard diagnostic criteria, able to consent and comply with follow-up;

Exclusions criteria

Pregnancy/lactation, hypersensitivity to HPE, active site infection, keloid tendency, bleeding disorders/anticoagulation, immunosuppression or malignancy, and recent (≤4–8 weeks) conflicting procedures/therapies were excluded from the study.

Sampling methods

We used consecutive, non-probability sampling: all eligible patients presenting to the dermatology clinics during the study period (self- or physician-referred) were screened and enrolled. Participants were assigned to Groups A–C by clinical diagnosis (melasma, ulcers, alopecia) until target numbers were reached; exclusions/refusals were replaced by the next eligible case.

The study enrolled a total of 50 patients aged between 18 and 60 years, all of whom met the predefined inclusion criteria and provided informed written consent before participation. Ethical clearance was obtained from the institutional ethics committee before the commencement of the study.

Participants were systematically categorized into three clinical groups based on their dermatological diagnosis to facilitate condition-specific assessment of the

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intervention. Group A comprised 20 patients with clinically diagnosed melasma, a chronic pigmentary disorder commonly affecting sun-exposed areas of the face. Group B included 15 patients with chronic non-healing ulcers, defined as ulcers persisting for more than six weeks without adequate granulation or epithelialization. These ulcers were primarily of traumatic or diabetic origin. Group C involved 15 patients diagnosed with hair loss, including alopecia areata and pattern baldness, confirmed through clinical examination and history.

Patients were selected using strict inclusion and exclusion criteria to maintain homogeneity within each group. Those with systemic comorbidities that could affect skin healing or pigmentation, recent use of systemic steroids or immunosuppressants, known hypersensitivity to placental products, or pregnant and lactating women were excluded to eliminate potential confounders. All enrolled patients underwent baseline clinical evaluation followed by periodic assessments during and after the treatment phase. The intervention was tailored to each group based on the nature of the condition:

Group A (Melasma): Content—sterile aqueous human placental extract HPE (undiluted); Delivery—intradermal microinjections (30G, ~0.1 mL blebs 1 cm apart; 1–2 mL/session); Unit—individual; Deliverer—dermatologist/resident; Setting—dermatology procedure room; Exposure—6 weekly sessions (~15–20 min); Period—6 weeks; Adherence—photoprotection

Group B (Chronic ulcers): Content— human placental extract HPE (undiluted); Delivery—topical instillation post-cleanse/debridement, covered with non-adherent dressing; Unit—individual wound; Deliverer—wound nurse under physician; Setting—clinic or bedside; Exposure—daily applications (~10–20 min); Period—up to 6 weeks or epithelialization; Adherence—caregiver training.

Group C (Alopecia AA/AGA): Content—HPE (undiluted); Delivery—intralesional injections (30G, ~0.1 mL per site at 1 cm; total 2–3 mL/session); Unit—individual; Deliverer—dermatologist/resident; Setting—dermatology procedure room; Exposure—3 sessions q2 weeks (weeks 0,2,4; ~15–25 min); Period—4 weeks active, assess at week 6; Adherence—continue stable standard therapy (e.g., minoxidil), comfort measures, appointment reminders.

The criteria for this study comprised patients aged 18–60 years with a confirmed diagnosis of either melasma, alopecia areata, or a chronic non-healing ulcer of more than six weeks' duration. Participants were required to have received no concurrent or recent treatment for the same condition in the preceding four weeks to avoid confounding effects. Informed written consent was obtained from all subjects, and only those willing to adhere to the full duration of treatment and follow-up were enrolled. Exclusion criteria included pregnant or lactating women, individuals with known hypersensitivity to placental products.

The pre-specified primary outcomes were: melasma—change in MASI from baseline to week 6 and MASI-50 responder rate at week 6; chronic ulcers—percent wound-area reduction from baseline to week 6 and time to complete epithelialization (up to 6 weeks); alopecia—change in SALT from baseline to week 6 and SALT-25 responder rate at week 6. Secondary outcomes (all groups) included Patient Global Impression of Improvement (PGI-I) at weeks 3 and 6, DLQI change (baseline→week 6), procedure pain by 0–10 VAS each visit, and safety (local/systemic adverse events recorded every contact); group-specific secondary measures were melanin index and blinded global photo ratings for melasma, weekly exudate/infection status and BWAT/PUSH scores for ulcers, and dermoscopic hair density (1 cm^2 counts) plus hair-pull test for alopecia. Assessments occurred at baseline (eligibility, demographics, standardized photographs, MASI/SALT or ulcer planimetry, DLQI, VAS), then weeks 3 and 6 for melasma/alopecia and weekly for ulcers, with safety at every contact. Data were collected using standardized photography (same device, fixed distance/angle, controlled lighting/background, templates/cross-polarization), validated scoring per published methods, ulcer area by acetate tracing with grids or calibrated digital planimetry (ImageJ with scale marker), and dermoscopy using a 10× lens and 1 cm^2 stencil with triplicate counts averaged. Measurement quality was enhanced via SOP-based rater training and certification, mid-study refreshers, blinded duplicate readings on a 10% random sample targeting inter-rater ICC ≥ 0.80 (with remediation if lower), device calibration logs, sterile single-use measurement tools, eCRFs with range/logic checks, double-entry verification, audit trails, predefined queries for missing/implausible data, blinded photo panels, stable co-therapies, and strict recording of any protocol deviations.

Sample size

The study was powered for within-group change in each primary endpoint (ΔMASI for melasma, % wound-area reduction for ulcers, ΔSALT for alopecia), assuming a

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moderate standardized effect (d=0.5), two-sided α=0.05, and 80% power using paired-change tests, which yielded ≈34 participants per group; allowing ~15% attrition, the target was 40/group. Between-group comparisons were considered exploratory and not the basis of the sample-size calculation.

Assignment method & bias control. The unit of assignment was the individual patient. Participants were non-randomly assigned by clinical diagnosis to Group A (melasma), B (ulcers), or C (alopecia); no blocking/stratification/minimization was used. To mitigate non-randomization bias, we used consecutive sampling, prespecified eligibility, standardized dosing/follow-up, blinded outcome assessment, and adjusted analyses for key confounders (age, sex, baseline severity, disease duration); sensitivity analyses with propensity-score weighting (stabilized IPTW) were planned to test robustness.

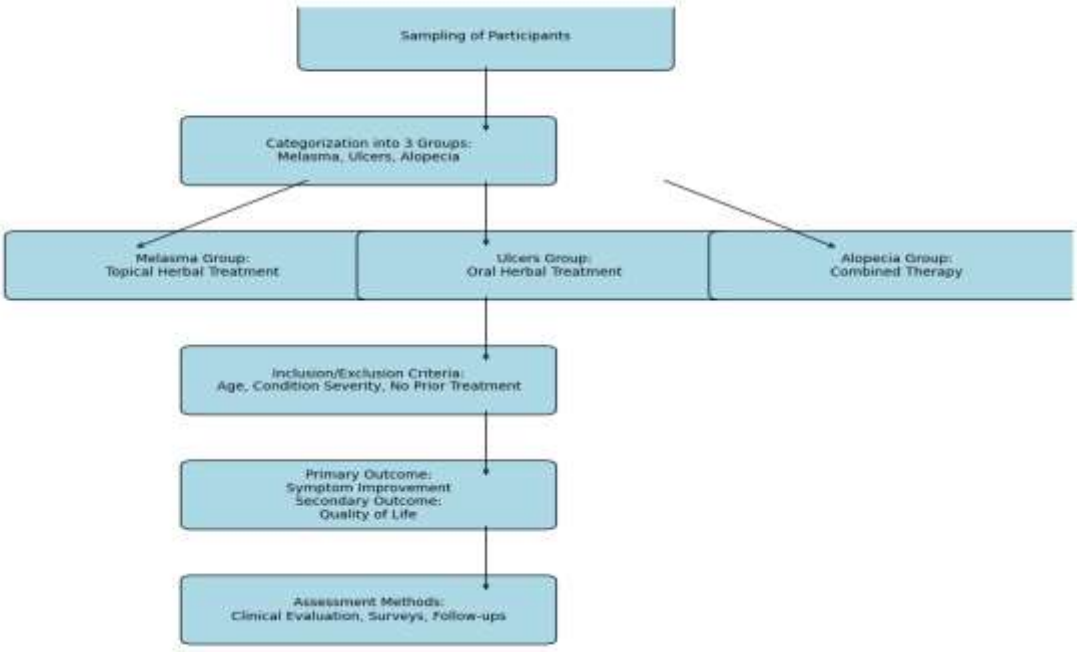
Blinding & intervention similarity

Participants and treating clinicians were not blinded due to the nature of procedures; outcome assessors (photo panel/planimetry/dermoscopy) and the statistician were blinded using de-identified, time-randomized image sets and masked datasets until database lock. Across groups, the same HPE product, storage (2–8 °C), asepsis, clinic setting, visit windows (baseline, week 3, week 6), and co-therapy restrictions were used to maximize procedural similarity and minimize performance/assessment bias.

Statistical analysis

For statistical analysis, all data were compiled and processed using standard statistical software. Paired t-tests were used to assess within-group changes over time, while ANOVA was employed for comparing differences among multiple time points. A p-value of less than 0.05 was considered statistically significant, indicating a meaningful therapeutic response to placental extract intervention.

Results



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Recruitment

Recruitment occurred from August 2023 to February 2024. Each participant was followed for up to 6 weeks post-enrollment (melasma/alopecia assessments at weeks 0, 3, and 6; ulcers reviewed weekly up to 6 weeks), so the study follow-up concluded within six weeks of the final February 2024 enrollment.

Table 1: Demographic characteristics

Variable	Group A (Melasma)	Group B (Ulcers)	Group C (Alopecia)
Mean Age (years)	34.1 ± 6.2	47.3 ± 8.4	29.8 ± 5.6
Female (%)	90%	60%	40%

Table 1 presents the demographic characteristics of the study participants. The mean age was highest in Group B (Ulcers) at 47.3 ± 8.4 years, followed by Group A (Melasma) at 34.1 ± 6.2 years, and lowest in Group C (Alopecia) at 29.8 ± 5.6 years. Female predominance was noted in Group A (90%), while Group B and Group C had 60% and 40% female participants, respectively, indicating varying gender distribution across the conditions studied.

Table 2: MASI score in melasma

Time Point	MASI Score (Mean ± SD)	p-value (vs Baseline)
Baseline	12.6 ± 2.3	-
Week 3	9.1 ± 2.0	<0.01
Week 6	6.4 ± 1.9	<0.01

Table 2 shows a significant reduction in MASI scores among melasma patients over the 6-week treatment period. The mean score decreased from 12.6 ± 2.3 at baseline to 9.1 ± 2.0 at week 3 and further to 6.4 ± 1.9 at week 6, with both follow-up values showing statistically significant improvement ($p < 0.01$) compared to baseline, indicating effective pigmentation reduction with placental extract therapy.

Table 3: Ulcer area in chronic ulcers

Time Point	Ulcer Area (Mean ± SD, cm^2)	Reduction (%)	p-value (vs Baseline)
Baseline	6.2 ± 1.7	-	-
Week 3	3.8 ± 1.4	38.7%	<0.01
Week 6	1.9 ± 1.1	68.2%	<0.01

Table 3 demonstrates a significant reduction in ulcer area among patients with chronic ulcers. The mean ulcer size decreased from 6.2 ± 1.7 cm^2 at baseline to 3.8 ± 1.4 cm^2 at week 3 (38.7% reduction) and further to 1.9 ± 1.1 cm^2 at week 6 (68.2% reduction), with both follow-ups showing statistically significant improvement ($p < 0.01$), indicating effective wound healing with placental extract application.

Table 4: SALT score in hair loss

Time Point	SALT Score (Mean ± SD)	Improvement (%)	p-value (vs Baseline)
Baseline	35.2 ± 8.1	-	-
Week 3	28.9 ± 7.4	17.9%	<0.05
Week 6	22.5 ± 6.7	36.1%	<0.05

Table 4 indicates a progressive improvement in hair regrowth among hair loss patients treated with placental extract. The mean SALT score decreased from 35.2 ± 8.1 at baseline to 28.9 ± 7.4 at week 3 (17.9% improvement)

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and further to 22.5 ± 6.7 at week 6 (36.1% improvement), with both reductions being statistically significant ($p < 0.05$), suggesting a positive therapeutic response.

Figure 1: MASI score reduction in melasma

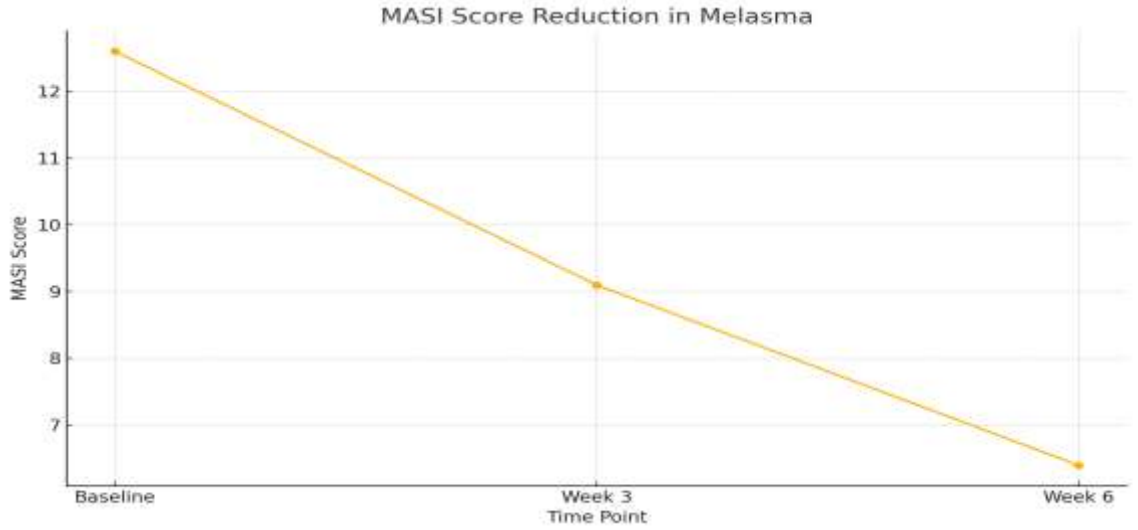

Figure 1 illustrates the progressive reduction in MASI scores among melasma patients over the treatment period. The mean score dropped from 12.6 at baseline to 9.1 at week 3 and further to 6.4 at week 6, indicating a steady and significant improvement in pigmentation with intradermal placental extract therapy. This trend highlights the extract's effectiveness in reducing melanin-related skin discoloration over time.

Figure 2: Ulcer area reduction in chronic ulcers

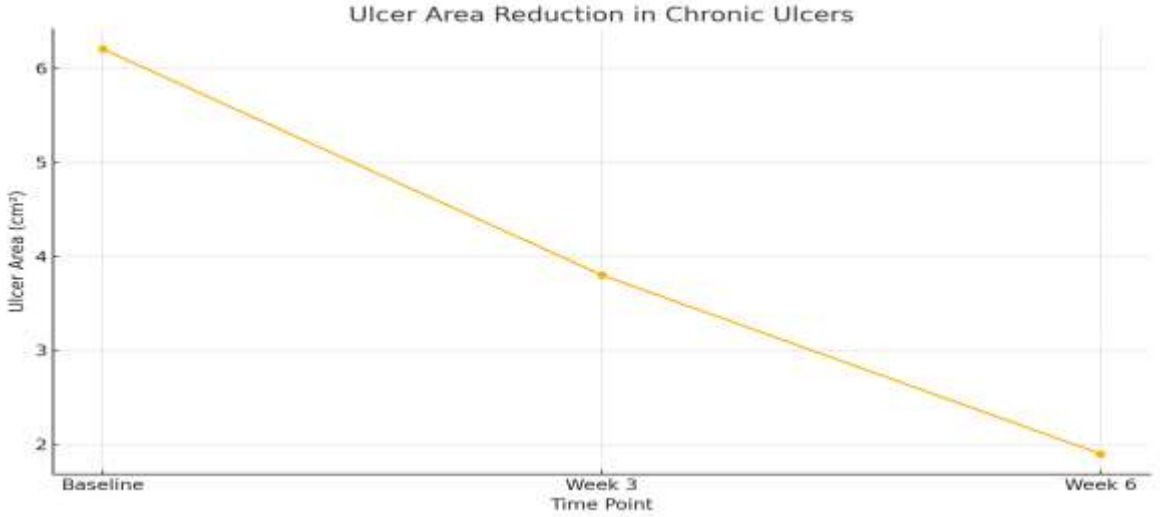

Figure 2 displays the trend of ulcer area reduction in patients with chronic non-healing ulcers over the 6-week treatment period. The graph shows a consistent and marked decline in ulcer size—from 6.2 cm² at baseline to 3.8 cm² at week 3, and further down to 1.9 cm² at week 6. This downward trajectory reflects a 68.2% overall

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reduction in ulcer area, indicating effective wound healing facilitated by the topical application of placental extract. The consistent rate of healing across the follow-up points highlights the extract's potential in promoting tissue regeneration in chronic wounds.

Figure 3: SALT score improvement in hair loss

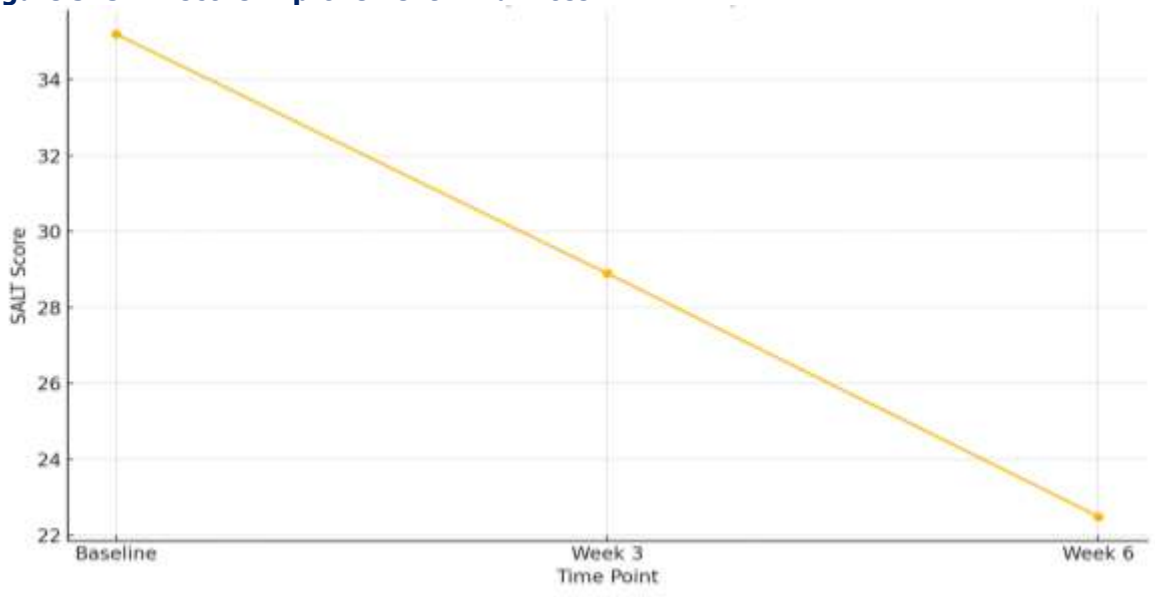

Figure 3 illustrates the improvement in SALT scores among patients with hair loss treated with intralesional placental extract. The graph shows a steady decline in the mean SALT score from 35.2 at baseline to 28.9 at week 3, and further to 22.5 at week 6, representing a 36.1% overall improvement. This progressive reduction indicates significant hair regrowth over the treatment period, suggesting that placental extract is effective in stimulating follicular activity and reversing autoimmune hair loss.

Discussion

This study demonstrates the clinical utility of human placental extract (HPE) across three distinct dermatological conditions: melasma, chronic ulcers, and alopecia areata. The results from Tables 1 to 4 and Figures 1 to 3 provide strong evidence supporting the regenerative and therapeutic efficacy of HPE.

The demographic data showed that the mean age varied significantly across groups, with ulcer patients being older (mean age: 47.3 ± 8.4 years), while alopecia areata patients were the youngest (mean age: 29.8 ± 5.6 years). A clear female predominance was observed in the melasma group (90%), consistent with the known higher prevalence of melasma among women due to hormonal factors and cosmetic concerns. This gender and age distribution aligns with existing literature, including studies by Sarkar et al.[6], which emphasize the hormonal and sun exposure link in melasma-prone female patients.

Melasma patients exhibited a significant and progressive decline in MASI scores—from 12.6 ± 2.3 at baseline to 6.4 ± 1.9 at week 6 ($p < 0.01$). This indicates a substantial improvement in pigmentation with weekly intradermal HPE therapy. The observed results mirror findings by Zhu Y et al.[7] who reported clinical improvement in pigmentation with bioactive topical agents derived from placental proteins. Furthermore, a recent article by Philipp-Dormston WG et al[8] on multimodal therapy for melasma has emphasized the potential role of growth factor-based injectables in reducing melanin synthesis and promoting dermal remodeling, reinforcing our findings.

Patients with chronic ulcers demonstrated a marked reduction in ulcer area, with a 38.7% decrease at week 3 and 68.2% by week 6 ($p < 0.01$). This rapid and sustained healing response highlights the pro-angiogenic and anti-inflammatory role of HPE. Protzman NM et al[9] reported comparable outcomes using placental-derived amniotic scaffolds in non-healing ulcers, further substantiating the wound healing capabilities of placental tissue. Additionally, a systematic review by Sho Yamakawa et al[10] highlighted the rich concentration of VEGF and

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cytokines in placental products, promoting faster epithelialization and granulation tissue formation—mechanisms likely responsible for the results seen in this study.

The SALT score showed a statistically significant improvement, decreasing from 35.2 ± 8.1 to 22.5 ± 6.7 by week 6 ($p < 0.05$), representing a 36.1% overall improvement in hair coverage. This outcome suggests that placental extract, through its bioactive peptides and cytokines, may influence hair follicle cycling and immune modulation. In line with this, Ersan M et al [11] demonstrated improved follicular density in alopecia patients treated with a combination of placental proteins and microneedling. Additionally, a recent paper by Li Y et al[12] in Dermatologic Therapy found that stem cell-derived growth factors from placental tissue showed promise in autoimmune hair loss, including alopecia areata, by promoting dermal papilla activity and modulating T-cell–mediated inflammation.

Generalizability

Most applicable to adults 18–60 with melasma, non-ischemic chronic ulcers, or AA/AGA treated in tertiary dermatology settings using similar HPE regimens. Generalizability is limited by a single-center Indian setting, small nonrandom groups (20/15/15), short 6-week follow-up, and exclusion of pregnancy/major comorbidities/ischemic ulcers.

Conclusion

Adjunctive human placental extract—intradermal for melasma, topical for chronic non-ischemic ulcers, and intralesional for AA/AGA—was feasible, well-tolerated, and showed short-term improvement (MASI/SALT, wound-area reduction) over 6 weeks. However, the single-center, small, nonrandom design and brief follow-up limit inference. Larger randomized trials with longer follow-up are needed to confirm efficacy, durability, and cost-effectiveness.

Limitations

Single-center, small nonrandom groups (20/15/15) with consecutive sampling and no comparator limit validity and power; 6-week follow-up and unblinded care allow bias; heterogeneity and background co-therapies risk residual confounding; exclusions (pregnancy, ischemic ulcers, major comorbidities) restrict generalizability; outcomes partly subjective despite standardized, blinded assessment.

Recommendations

Use HPE adjunctively: melasma—weekly intradermal ×6 with photoprotection; ulcers—daily topical within moist wound care; alopecia—intralesional q2w ×3 with stable standard therapy. Standardize photos/MASI/SALT/ulcer planimetry at 0/3/6 weeks, maintain asepsis and AE logs, implement SOPs, and a registry. Plan larger RCTs (≥6–12 months) with dose–response, subgroup/biomarker, cost-effectiveness, and PROMs.

Acknowledgement

We thank the patients, dermatology nursing, and wound-care teams.

Abbreviations

AA: Alopecia areata;
AGA: Androgenetic alopecia;
AE: Adverse event;
BWAT: Bates-Jensen Wound Assessment Tool;
DLQI: Dermatology Life Quality Index;
eCRF: Electronic case-report form;
HPE: Human placental extract;
ICC: Intraclass correlation coefficient;
IEC: Institutional Ethics Committee;
IPTW: Inverse probability of treatment weighting;
MASI: Melasma Area and Severity Index;
SALT: Severity of Alopecia Tool;
VAS: Visual analogue scale.

Author contributions

Conceptualization/Methodology: **Dr Swati Shandilya**
Investigation/Resources: **Dr Poonam Tapsale**
Data Curation/Project Administration: **Dr Poonam Tapsale**
Formal Analysis/Visualization: **Dr Swati Shandilya**
Writing—Original Draft: **Dr Swati Shandilya**
Writing—Review & Editing: **Dr Nitin Chaudhari, Dr Poonam Tapsale**
Supervision: **Dr Nitin Chaudhari**

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Dr. Nitin Chaudhari — Professor & HOD, SKNMC & GH; interests: inflammatory dermatoses, clinical research, departmental quality systems.

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