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Exploratory Evaluation of an Exosome-Based Formulation for Skin Quality Improvement: A Case Series

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Abstract

Background: Exosomes are small extracellular vesicles involved in cell-to-cell communication and have gained attention in regenerative and aesthetic dermatology. Their bioactive components are thought to support skin regeneration, helping improve skin quality and visible signs of aging. **Objectives:** This paper aims to explore the clinical outcomes and safety of an intradermally administered exosome-based formulation for improving skin quality, radiance, and wrinkle appearance in multiple anatomical regions. **Methods:** This prospective observational case series included eight healthy adults (seven women, one man; median age 49.5 years) presenting visible signs of skin aging. Participants received intradermal microinjections of an exosome-based formulation to the face, neck, décolleté, and hands over four consecutive weeks. Efficacy was assessed using standardized wrinkle and radiance scoring systems, the investigator- and subject-rated Global Aesthetic Improvement Scale (GAIS), and paired statistical analyses. Safety and tolerability were evaluated at each visit. **Results:** Progressive improvements in wrinkle severity and skin radiance were observed across treated areas, with trends toward improvement from Week 2 onward. Both investigator and participant GAIS scores indicated consistent aesthetic improvement, reaching mean values of 1.63 at the final visit, indicating consistent improvement over time. The treatment was well tolerated, with only mild transient erythema reported at each session and one instance of minor microbleeding. **Conclusions:** Intradermal administration of an exosome-based formulation was well tolerated and associated with visible improvements in skin quality and radiance. These preliminary findings suggest potential clinical benefit of exosome-based formulations in aesthetic dermatology. Larger, controlled trials are warranted to confirm efficacy, optimize treatment protocols, and investigate long-term outcomes.

Keywords

Exosomes, Extracellular Vesicles, Aesthetic Dermatology, Skin Rejuvenation, Intradermal Microinjection, Skin Aging

1. Introduction

Cutaneous aging is a multifactorial biological process resulting from the interplay of intrinsic and extrinsic factors [1] [2]. Increasing evidence suggests that environmental exposures, collectively known as the exposome, can accelerate biological aging [3]. Intrinsic determinants such as genetic predisposition, metabolic activity, and hormonal changes, combined with extrinsic influences, including ultraviolet (UV) radiation, environmental pollutants, and chemical or toxic exposures, lead to progressive structural and functional deterioration of the skin [4]-[6]. These mechanisms involve degradation of dermal collagen and elastin, reduced dermal thickness and elasticity, impaired hydration, and altered extracellular matrix (ECM) remodeling [7]-[9]. Clinically, they manifest as wrinkles, irregularities in pigmentation, laxity, and enlarged pores, which impact both aesthetic appearance and psychosocial well-being [1] [9]-[13].

The growing demand for aesthetic improvement has fueled rapid advances in medical aesthetics, particularly in approaches designed to mitigate visible signs of aging [14]. Research has explored antioxidants, cytokine modulation, and gene-based biotechnologies [15]-[18].

In recent years, regenerative aesthetics has aimed to enhance cosmetic outcomes through biologically active interventions such as polydeoxyribonucleotide (PDRN) treatments [19] [20], photobiomodulation [21] [22], bioactive peptides [23], anti-senescence strategies [24] [25], and exosome therapies [26]-[28]. Among them, exosomes have attracted particular attention as a cell-free, biologically potent alternative to conventional regenerative therapies.

Exosomes are nanosized (30 - 150 nm) lipid bilayer vesicles secreted by multiple cell types that act as mediators of intercellular communication. They transport bioactive molecules, including proteins, lipids, and nucleic acids, that regulate key cellular functions such as proliferation, differentiation, migration, and apoptosis. Exosomes are characterized by conserved markers including tetraspanins (CD9, CD63, CD81), heat shock proteins (HSP70, HSP90), and biogenesis-related proteins (ALIX, TSG101) [29]-[31].

Recent studies highlight the potential of exosomes as innovative, cell-free therapeutic agents in dermatology and aesthetic medicine. Their bioactive cargo modulates pathways involved in extracellular matrix (ECM) remodeling, inflammation, and collagen synthesis [29]. In experimental and clinical models, exosomes derived from dermal fibroblasts and mesenchymal cells have been shown to enhance collagen production, reduce matrix metalloproteinase activity, and improve skin elasticity and texture [29] [32]. Topical and injectable formulations have also

demonstrated protective effects against UV-induced damage, stimulation of fibroblast proliferation, and promotion of angiogenesis in aged skin [26] [27] [33]. Beyond skin rejuvenation, exosome-based therapies show promise for scar modulation, pigmentation disorders, alopecia, and overall improvement in skin radiance [34]-[38]. Collectively, this growing body of evidence supports the regenerative and rejuvenating potential of exosomes in aesthetic medicine.

The present study aimed to evaluate the clinical effects of an exosome-based medical formulation (SIMILDIET EXOS ANTIAGING, Simildiet Laboratories, Spain) on the skin of the face, neck, décolleté, and hands. Specifically, it assessed changes in wrinkle severity and skin radiance to determine the formulation's potential benefits in improving overall skin quality and visible signs of aging.

2. Materials and Methods

2.1. Study Design

This exploratory study was not designed to provide definitive efficacy conclusions but to generate preliminary clinical observations. Each participant received intradermal injections of the formulation in four anatomical regions: the face, neck, décolleté, and hands. The study consisted of five consecutive visits over a 4-week treatment period (V1 - V5).

Visit 1 (baseline) included screening and eligibility procedures. Treatment sessions were performed at Visit 2 (Week 1), Visit 3 (Week 2), Visit 4 (Week 3), and Visit 5 (Week 4). Follow-up assessments were conducted to monitor local tolerance, safety, and treatment efficacy. The study was conducted in accordance with the principles of the Declaration of Helsinki, and all participants provided written informed consent before enrollment.

No formal sample size calculation was performed, as the study was intended to be exploratory.

2.2. Participants

Participants were recruited between November 1 and November 15, 2024, at a single private aesthetic dermatology clinic. Subjects were enrolled consecutively upon presentation and after meeting eligibility criteria. A washout period of at least two weeks prior to inclusion was required for any aesthetic procedures or topical treatments that could potentially influence study outcomes.

Eligible participants were healthy adults presenting visible signs of skin aging, including fine lines, wrinkles, and reduced radiance on the face, neck, décolleté, or hands. Exclusion criteria included pregnancy or lactation, active dermatologic diseases in the treatment areas, recent use of aesthetic procedures (e.g., fillers, botulinum toxin, resurfacing), or any condition that could interfere with the study outcomes or safety assessments.

2.3. Treatment Protocol

Exosomes are nanometer-sized vesicles (30 to 200 nm) containing proteins, lipids,

and genetic material (mRNA and miRNA), released by various cell types through the endosomal-lysosomal pathway. These units play a fundamental role in intercellular communication, intervening in key biological processes such as tissue repair and immune system modulation.

In the field of aesthetic medicine, the formulation SIMILDIET EXOS ANTI-AGING (Simildiet Laboratories, Spain) stands out, a commercial product that combines these extracellular vesicles with biomimetic peptides, hyaluronic acid, magnesium-associated collagen, and dimethylaminoethanol (DMAE), ensuring high biological potency by containing 15 trillion exosomes per vial.

Each participant received intradermal microinjections of the exosome-based formulation, performed by an experienced physician under aseptic conditions. Injection volumes were approximately 3 mL for the face, 1.5 mL for the neck, 2 mL for the décolleté, and 3 mL for the dorsal hands. Injections were performed using a 34 G needle for superficial intradermal administration, delivering small aliquots of approximately 0.02 mL per point, spaced at approximately 1 cm intervals. Participants were instructed to avoid makeup for 12 hours post-treatment and to refrain from exposure to sunlight, UV light, or extreme temperatures for two weeks following each session.

2.4. Assessments

Efficacy and safety evaluations were performed at each visit. Skin quality improvement was assessed through standardized clinical scales and photographic documentation under controlled lighting and positioning conditions.

Wrinkle severity was assessed using a standardized photonumeric clinical scoring system (Universal Wrinkle Score), applied across all treated regions, with lower scores indicating less severe wrinkling. Skin radiance was evaluated using a clinical scoring system assessing brightness and uniformity (0 = no radiance; 3 = high radiance), with higher scores reflecting improvement.

Décolleté aging was additionally assessed using the Landau photonumeric grading scale (0 - 5), which evaluates wrinkle severity at rest and during movement, with lower scores indicating less wrinkling [39].

Global aesthetic improvement was evaluated using the Global Aesthetic Improvement Scale (GAIS), a 5-point scale rating overall change compared with baseline (−2 = worse; +2 = very much improved), completed independently by both the investigator and each participant [40].

Safety Evaluation: Adverse events and local reactions were recorded at each visit.

Clinical assessments were performed by the treating physician at each visit. GAIS evaluations were completed independently by the investigator and each participant.

2.5. Statistical Analysis

Descriptive statistics were used to summarize all outcomes. Paired comparisons from baseline were performed using a two-tailed paired Student's t-test and are reported as exploratory, unadjusted analyses. Safety data were summarized as fre-

quency and percentage of subjects experiencing adverse events.

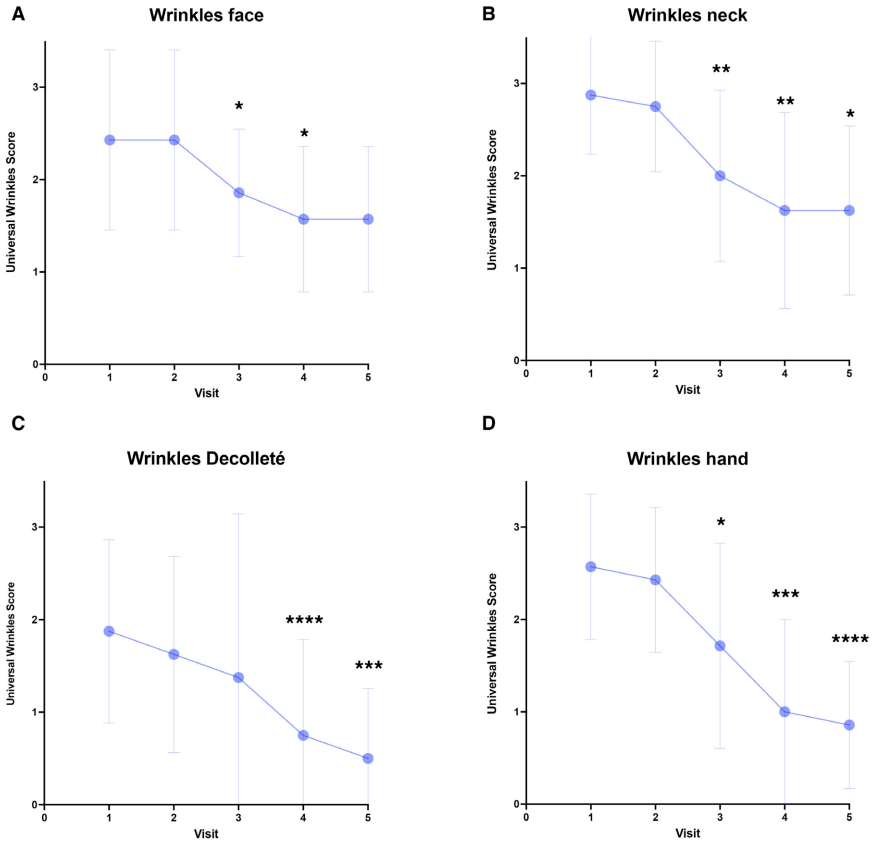
3. Results

Given the exploratory nature and small sample size, results should be primarily interpreted descriptively.

Eight participants (seven women and one man) were included in the clinical evaluation. The median age was 49.5 years, with an average height of 164.7 cm and a mean body weight of 69.4 kg. All subjects completed the study and received the exosome-based formulation administered to the face, neck, décolleté, and hands. Clinical assessments were performed over five consecutive visits (V1 to V5). The analysis focused on changes in wrinkle severity and skin radiance, as evaluated by standardized scoring systems and paired statistical comparisons to baseline values.

3.1. Wrinkle Assessment

A progressive and consistent reduction in wrinkle severity was observed across all treated regions (Figure 1).



Universal Wrinkles Scores for the face, décolleté, neck, and hands assessed from baseline (Visit 1) to follow-up visits (Visits 2 - 5). Data are presented as mean ± SD. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$.

Figure 1. Clinical wrinkle assessment.

On the face, the mean wrinkle score remained stable between Visit 1 and Visit 2 (2.4 at both timepoints) but showed a reduction to 1.9 at Visit 3 ($p = 0.030$) and 1.6 at Visit 4 ($p = 0.0167$). The mean score remained at 1.6 at Visit 5, with a p-value of 0.078, indicating maintenance of the improvement achieved by mid-treatment (**Figure 1(A)**).

In the neck, a similar trend was documented. The mean wrinkle score decreased from 2.9 at baseline to 2.0 at Visit 3 ($p = 0.0062$) and 1.6 at Visit 4 ($p = 0.0053$). The score remained stable at 1.6 at Visit 5 ($p = 0.0112$), showing a consistent improvement over time (**Figure 1(B)**).

For the décolleté, the mean wrinkle score declined progressively from 1.9 at baseline to 1.6 at Visit 2 and 1.1 at Visit 3 ($p = 0.381$). A marked and statistically significant improvement was then observed, with scores of 0.8 at Visit 4 ($p < 0.0001$) and 0.5 at Visit 5 ($p = 0.0001$), reflecting a pronounced reduction in wrinkle visibility (**Figure 1(C)**).

Wrinkle scores on the hands also decreased significantly over time. The mean value fell from 2.6 at baseline to 1.7 at Visit 3 ($p = 0.0167$), 1.0 at Visit 4 ($p = 0.0002$), and 0.9 at Visit 5 ($p = 0.0010$), demonstrating a steady improvement in skin texture and smoothness across visits (**Figure 1(D)**).

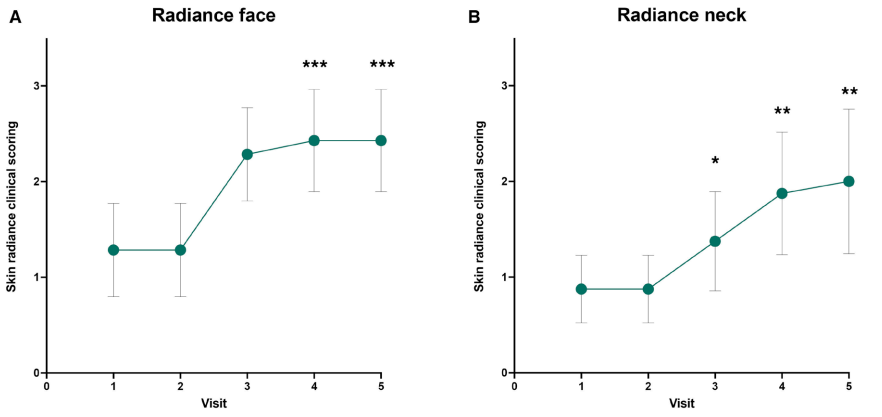
3.2. Radiance Assessment

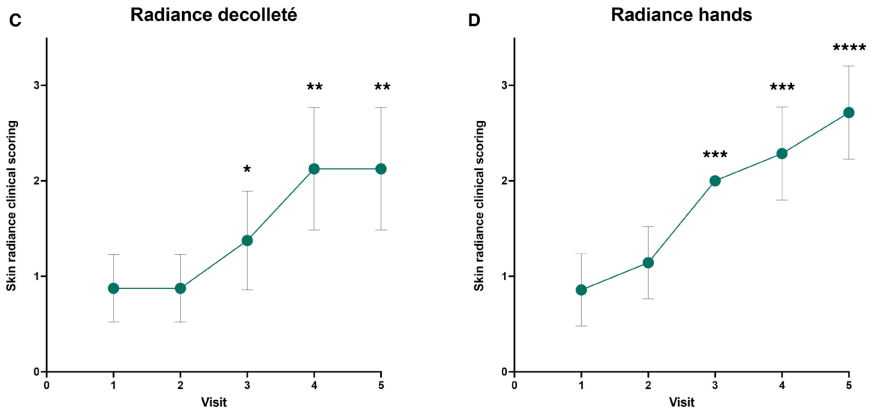
Skin radiance improved significantly and progressively in all treated areas (**Figure 2**).

On the face, mean radiance increased from 1.3 at baseline to 2.4 at Visit 4 and Visit 5 (both $p = 0.0002$), indicating a marked enhancement in luminosity and overall skin quality (**Figure 2(A)**).

In the neck, radiance improved from 0.9 at baseline to 1.4 at Visit 3 ($p = 0.033$), 1.9 at Visit 4 ($p = 0.0011$), and 2.0 at Visit 5 ($p = 0.0016$), showing a statistically significant and continuous improvement across visits (**Figure 2(B)**).

The décolleté followed a comparable pattern, with radiance scores rising from 0.9 at baseline to 1.4 at Visit 3 ($p = 0.033$) and 2.1 at both Visit 4 and Visit 5 ($p = 0.0016$ for each), reflecting progressive and sustained enhancement (**Figure 2(C)**).





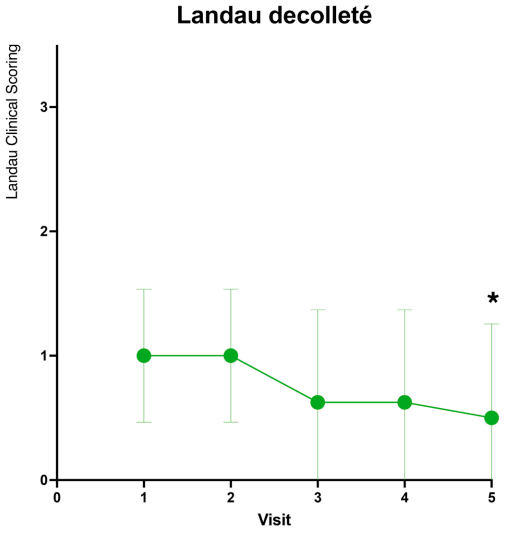
Skin radiance clinical scores for the face, décolleté, neck, and hands measured at baseline (Visit 1) and follow-up visits (Visits 2 - 5). Data are shown as mean ± SD. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$.

Figure 2. Clinical skin radiance evaluation.

For the hands, radiance increased from 0.9 at baseline to 1.1 at Visit 2 ($p = 0.172$, not significant), then showed significant improvement at Visit 3 (2.0; $p = 0.0002$), Visit 4 (2.3; $p = 0.0004$), and Visit 5 (2.7; $p < 0.0001$), demonstrating a clear cumulative effect of the treatment (**Figure 2(D)**).

3.3. Landau Décolleté Score

The Landau clinical score for the décolleté area decreased from 1.0 at baseline to 0.6 at Visits 3 and 4 (both $p = 0.079$, non-significant trend) and reached 0.5 at Visit 5 ($p = 0.033$), showing a consistent improvement over time (**Figure 3**).

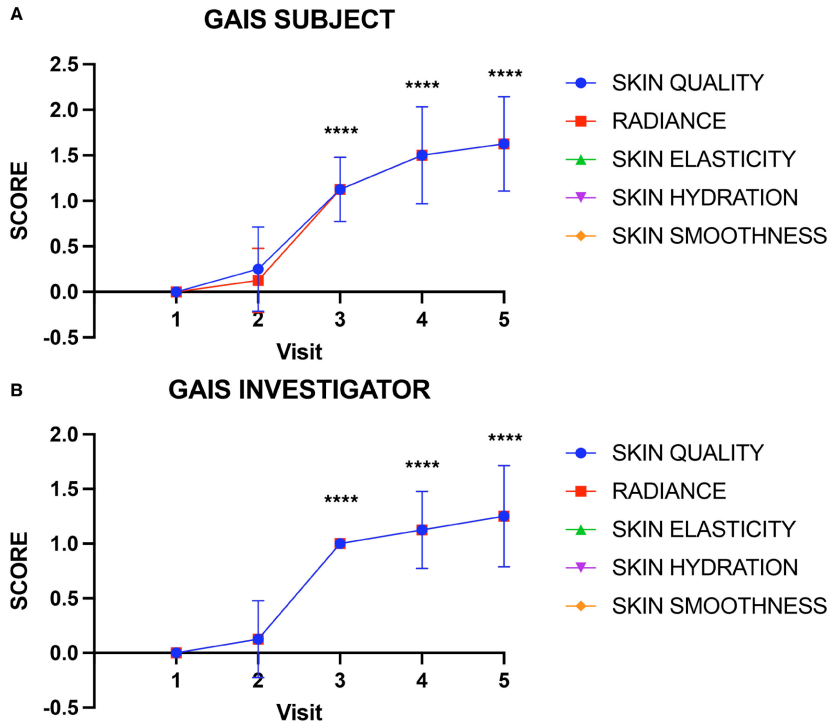


Landau clinical scores of the décolleté evaluated from baseline (Visit 1) through Visits 2 - 5. Data are presented as mean ± SD. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$.

Figure 3. Décolleté Landau score.

3.4. Global Aesthetic Improvement

Global Aesthetic Improvement Scale (GAIS) scores, evaluated independently by both the investigator and the participants, showed a consistent and progressive improvement in all assessed parameters, including skin quality, radiance, elasticity, hydration, and smoothness (Figure 4).



GAIS scores assessed by subjects (A) and investigators (B) for skin quality, radiance, elasticity, hydration, and smoothness across Visits 1 - 5. Data are shown as mean ± SD. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$.

Figure 4. Global Aesthetic Improvement Scale (GAIS).

At baseline (V1), all scores were 0, serving as the reference values for subsequent evaluations. By Visit 2, slight increases were recorded across all domains (mean GAIS range 0.12 - 0.25), reflecting early but modest perceptible changes. A marked and statistically significant improvement ($p < 0.0001$) was observed starting at Visit 3, with mean GAIS scores of approximately 1.1 for both investigator- and subject-rated evaluations. Scores continued to increase at Visit 4 (mean 1.5) and reached their highest values at Visit 5 (mean 1.63), demonstrating sustained enhancement over time.

The concordance between investigator and participant assessments was high throughout the study, with nearly identical mean scores at each time point. Both evaluators reported the greatest improvements between Visits 2 and 3, corresponding to the mid-treatment phase. These findings confirm a statistically significant and progressive aesthetic improvement in overall skin quality, radiance, elasticity, hydration, and smoothness following repeated treatment sessions.

3.5. Safety

The treatment was well tolerated by all participants. Mild erythema at the injection sites was observed in every participant at each treatment visit. The erythema was transient, resolving spontaneously and without requiring any intervention. One instance of microbleeding occurred in a single participant during the first treatment session (Visit 2); it resolved without sequelae. No edema, bruising, infection, or other adverse reactions were reported throughout the study period. Overall, the exosome-based formulation demonstrated a favorable safety and tolerability profile.

4. Discussion

In this exploratory case series, repeated intradermal administration of an exosome-based formulation was associated with visible and progressive improvements in overall skin quality. Reductions in wrinkle severity and increases in skin radiance were observed across all treated areas, with consistent trends over time. Both investigator- and participant-rated GAIS assessments suggested a sustained improvement throughout treatment.

These observations suggest improvements in skin smoothness, elasticity, and hydration associated with the treatment, contributing to a more uniform and luminous appearance. Improvements were noted across multiple anatomical areas, including the face, neck, décolleté, and hands. The concordance between the investigator's and subject's assessments further supports the consistency of the observed changes.

The treatment was well tolerated, with only mild and transient local reactions reported, supporting a favorable safety profile under the conditions of use.

Given the small sample size and absence of a control group, these findings should be interpreted with caution and considered preliminary. In addition, no formal sample size calculation was performed, as the study was intended to be exploratory.

However, these findings are consistent with the growing interest in exosome-based approaches in aesthetic dermatology. Previous clinical studies have further supported their clinical relevance. In a randomized split-face trial, Park *et al.* demonstrated that treatment with adipose stem cell-derived exosomes combined with microneedling significantly improved wrinkle appearance, elasticity, hydration, and pigmentation compared with control ($p = 0.005$), with no adverse events reported [28]. Likewise, Proffer *et al.* evaluated a platelet-derived exosome serum applied topically for six weeks and observed significant improvements in overall skin health, including reductions in wrinkles, redness, and melanin content, together with increased luminosity and color evenness ($p \leq 0.001$) [41]. Both studies reported excellent tolerability, supporting the growing body of evidence that exosome-based formulations can be safely used to enhance skin quality and radiance in clinical settings.

The findings of this study should be interpreted in light of several limitations.

The small sample size, the absence of a control group, and the short follow-up period limit the generalizability of the findings and preclude definitive conclusions regarding efficacy. In addition, the absence of objective instrumental measurements and histological evaluation limits the ability to fully characterize the treatment's biological effects. Future studies should include objective biophysical assessments, such as profilometry, elasticity measurements, or instrumental radiance analysis, to provide quantitative confirmation of clinical outcomes. Larger, randomized, controlled trials with extended follow-up are needed to validate these results and to define standardized treatment protocols.

Despite these limitations, this case series provides preliminary clinical insights into the potential role of exosome-based formulations in aesthetic dermatology and may serve as a basis for future controlled studies.

5. Conclusion

This exploratory case series provides preliminary clinical observations supporting the potential use of exosome-based formulations in aesthetic dermatology. The treatment was well tolerated and associated with visible improvements in overall skin quality. These findings contribute to the growing body of evidence on the use of exosome-derived products for skin rejuvenation. Further controlled studies with larger populations and longer follow-up are warranted to further evaluate efficacy, establish optimal treatment protocols, and clarify the underlying mechanisms of action.

Ethics Statement

This case series was conducted in accordance with the ethical principles of the Declaration of Helsinki (World Medical Association, 1964 and its subsequent amendments). Written informed consent was obtained from all participants for the use and publication of their clinical data and images.

All procedures were performed as part of routine clinical practice. Data were collected prospectively and analyzed retrospectively in an anonymized manner.

No potentially identifiable personal information is disclosed in this report.

Consent

Informed consent was obtained from all participants before inclusion in the study.

Conflicts of Interest

Dr Aznar is an employee of Simildiet. Dr Philippe Hamida-Pisal has no conflicts of interest to declare.

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