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Original Article

Poly–D,L–lactic acid (PDLLA) scalp microinjection protocol with optional light microneedling priming for non–scarring alopecia: A prospective pilot case series

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ABSTRACT

Background: PDLLA demonstrates angiogenic and regenerative properties that may support hair regrowth by enhancing perifollicular perfusion. Objective: To evaluate clinical improvement after PDLLA scalp microinjection in 20 patients using standardized photography and Global Aesthetic Improvement Scale (GAIS) rated by two independent physicians.

Methods: Twenty adults with non scarring alopecia received PDLLA scalp microinjections at baseline and week 4 (optional booster at week 8). Optional light microneedling priming (0.5–0.8 mm) was performed immediately before PDLLA injection in 14/20 patients to

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facilitate distribution. Primary endpoint was physician rated GAIS at week 12; secondary endpoints included patient GAIS and safety. Images were acquired with fixed camera to scalp distance and lighting.

Results: Physician GAIS improved in 90% of patients at week 12 (mean ± SD 3.3 ± 0.6) and was maintained at week 24 (3.1 ± 0.7). Patient reported GAIS was 3.2 ± 0.7 at week 12. No serious adverse events occurred.

Conclusions: In this pilot uncontrolled case series, PDLLA scalp microinjections were associated with physician–rated GAIS improvement over 12–24 weeks with favorable short–term tolerability. Given the subjective endpoint, the absence of a comparator arm, and optional microneedling priming in a subset of patients, the findings are preliminary and require confirmation in controlled studies with objective trichologic measurements and longer follow–up.

Introduction

Microneedling (MN) has emerged as a promising minimally invasive intervention for hair loss, with systematic reviews demonstrating that microneedling monotherapy significantly increased total hair count more than topical minoxidil 5% alone, while combination treatment was even more effective than microneedling alone.[1] The procedure's mechanism involves creating controlled micro-wounds that stimulate Wnt protein expression (Wnt3a and Wnt10b) in hair follicles, encouraging stem cell differentiation and proper hair cycle regulation while simultaneously triggering scalp revascularization. Poly-D,L-lactic acid (PDLLA), a biodegradable and biocompatible polymer, has garnered attention for its unique angiogenic properties that promote blood vessel formation through upregulation of heat shock protein 90 (HSP90), hypoxia-inducible factor-1 alpha (HIF-1α), and vascular endothelial growth factor (VEGF), ultimately leading to enhanced perifollicular vascularization.[2–4]

The theoretical foundation for combining microneedling and PDLLA rests on their complementary mechanisms of action and temporal profiles, where microneedling provides immediate mechanical stimulation and creates microchannels that improve transdermal delivery by increasing sulfotransferase activity by 37.5% over 21 days, while PDLLA offers sustained angiogenic support between treatment sessions. The spherical and foamy outer structure of PDLLA microparticles, combined with their patented reticular and porous inner design, enhances biocompatibility while minimizing tissue damage, making them ideal for delivery through microneedling-created channels[5,6] Despite promising theoretical rationale, clinical evidence for the combined use of microneedling and PDLLA in hair loss treatment remains limited, with current microneedling research suffering from significant heterogeneity across protocols and relatively low-quality data preventing meta-analysis and establishment of best practices.[6]

The combination of microneedling and PDLLA offers a promising dual-mechanism approach to treating hair loss by addressing both mechanical stimulation and vascular regeneration. Microneedling creates controlled micro-wounds that stimulate Wnt protein expression (Wnt3a and Wnt10b) in hair follicles, promoting stem cell differentiation and proper hair cycle regulation while simultaneously triggering revascularization of the scalp.[1] This mechanical stimulation creates an ideal foundation for PDLLA's angiogenic properties, as the biodegradable polymer promotes blood vessel formation through upregulation of VEGF, HIF-1α, and HSP90, leading to enhanced perifollicular vascularization that is essential for healthy hair growth during the anagen phase.[2,4] The microchannels created by

microneedling could facilitate improved delivery of PDLLA microparticles to target follicular areas, while PDLLA's sustained biodegradable action provides continuous angiogenic support between microneedling sessions.

The therapeutic rationale for this combination is strengthened by their complementary temporal profiles and delivery mechanisms. While microneedling provides immediate growth factor release and improves transdermal delivery by increasing sulfotransferase activity by 37.5% over 21 days, PDLLA offers prolonged angiogenic stimulation through its sophisticated molecular pathway involving VEGF upregulation.[2,6] Since hair growth fundamentally depends on perifollicular angiogenesis and adequate nutrient delivery to follicles, the VEGF-mediated vascular enhancement from PDLLA could significantly amplify microneedling's revascularization effects.[3] Both treatments demonstrate favorable safety profiles, with microneedling showing no serious adverse events across 657 subjects and only mild, transient side effects, while PDLLA's biocompatible properties and successful use in cosmetic applications suggest minimal risk of adverse interactions.[6,10]

Here, we report a 20–patient prospective pilot case series evaluating a PDLLA scalp microinjection protocol for non–scarring alopecia, in which optional light microneedling priming was performed in a subset of patients to facilitate product distribution. Outcomes were assessed using standardized photography and physician–rated GAIS as pragmatic clinical endpoints. We acknowledge that GAIS is subjective and that this study was not designed to isolate the independent effect of PDLLA from microneedling priming or other background therapies.

Materials and methods

Study design and participants

Prospective, single–center case series approved by the local IRB with written informed consent. This study was designed as an exploratory pilot case series; therefore, no formal a priori sample size or power calculation was performed. The sample size reflects a convenience cohort of eligible patients treated within the study setting to generate preliminary effectiveness and short–term safety signals. Twenty adults (12 men, eight women; mean age 38.9 $\pm$ 9.1 years) with non–scarring alopecia (AGA or chronic telogen effluvium) were enrolled. Key inclusion: stable medical therapy $\geq$3 months, Fitzpatrick I–IV, and photographic compliance. "Stable medical therapy $\geq$3 months" was defined as no initiation, discontinuation, or dose change of hair–loss–related medical therapy during the 3 months prior to baseline by patient report. Detailed concomitant medication types and doses were not systematically recorded for analytical adjustment in this pilot series. Exclusions: active scalp infection, autoimmune cicatricial alopecia, anticoagulation, pregnancy, or prior scalp fillers.

Intervention: PDLLA preparation and delivery

Commercial PDLLA microspheres suspended per manufacturer instructions were further diluted with 0.9% saline and 1% lidocaine to yield a final concentration of 40 mg/4 mL per session. Using a 30 G needle, micro–aliquots (0.02–0.04 mL) were deposited intradermally/subdermally in 1–1.5 cm spacing across thinning zones (total 3–4 mL/session, Juvelook, VAIM, Seoul, Korea). All patients received treatment at baseline (week 0); 18/20 received a booster at week 4; 10/20 opted for an additional booster at week 8 based on early response and tolerance.

Optional microneedle priming

To facilitate distribution, optional light microneedle priming (0.5–0.8 mm) was performed immediately before PDLLA in 14/20 patients; no topical actives were applied. Microneedling priming was optional and not randomized; therefore, this study was not designed to isolate the independent effect of PDLLA from procedure-related effects of microneedling.

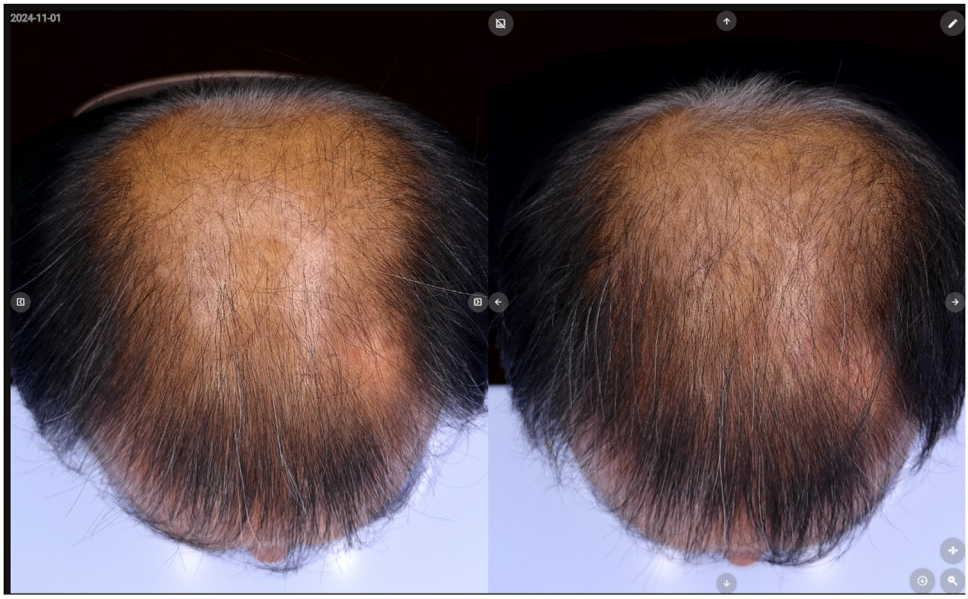

Figure 1. Representative patient with androgenetic alopecia treated with PDLLA scalp microinjections (with optional light microneedle priming where applicable). Baseline and follow–up photographs were obtained under standardized conditions (fixed camera–to–scalp distance and lighting).

Outcome measures and photography

Primary outcome was **physician–rated GAIS** (5–point scale: 1 = worse, 2 = no change, 3 = improved, 4 = much improved, 5 = very much improved) at week 12 based on standardized global–scalp photographs obtained at each visit (tripod–mounted camera, fixed distance (with attempted consistency), cross–polarized and parallel–polarized lighting). GAIS and standardized photography were used as pragmatic clinical endpoints in this pilot series. Objective microscopic trichologic measurements (e.g., phototrichogram/digital trichoscopy or tricogram) were not collected; therefore, conclusions regarding true follicular regeneration cannot be made. Two independent, blinded physicians (dermatologic surgeons) rated pairs (baseline vs. follow–up); disagreements >1 point were adjudicated by consensus. Secondary outcomes included patient GAIS and adverse events (pain, erythema, nodules, pruritus, infection) (Figures 1–3). Despite standardization efforts, residual variability in scalp parting and illumination may remain; photographic comparisons should be interpreted as qualitative supportive evidence rather than a primary objective endpoint.

Statistical analysis

Given the pilot nature of the study and the ordinal, subjective nature of GAIS, analyses were descriptive. Continuous variables are reported as mean ± SD (or median [IQR] where appropriate), and categorical data as *n* (%). No formal hypothesis testing was prespecified.

Results

Study cohort and treatment exposure

A total of 20 patients were included. All participants completed the week 12 assessment, and 19 patients completed follow-up at week 24. The mean injected volume per treatment session was

Figure 2. Representative patient with female–pattern hair loss treated with PDLLA scalp microinjections (with optional light microneedle priming where applicable). Baseline and follow–up photographs were obtained under standardized conditions.

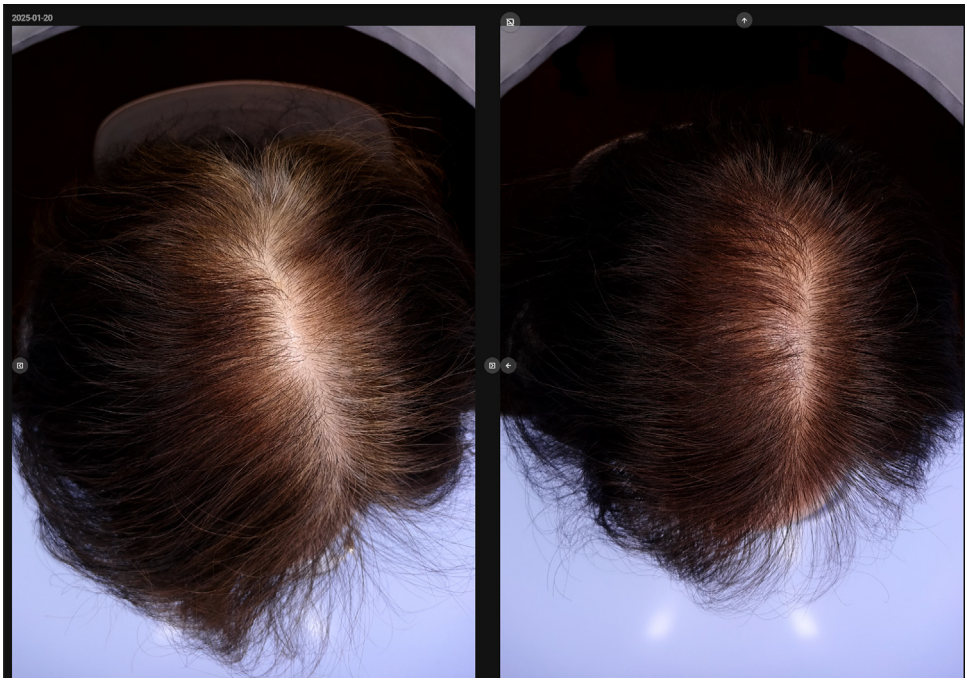

Figure 3. This figure illustrates the comparative efficacy of Poly-D,L-Lactic Acid (PDLLA) micro-injections in treating hair thinning. The comparison highlights changes in hair density and scalp coverage between the baseline condition and the post-treatment follow-up.

Table 1
GAIS outcomes over follow-up.

Timepoint	Improved or better (*n*/total)	Mean physician GAIS ± SD	Mean patient GAIS ± SD
Week 12	18/20 (90%)	3.3 ± 0.6	3.2 ± 0.7
Week 24	17/19 (89%)	3.1 ± 0.7	3.0 ± 0.7

3.5 ± 0.6 mL. Over the 8-week treatment period, patients underwent a mean of 2.4 ± 0.7 treatment sessions.

Primary outcome: physician-rated GAIS

At week 12, 18 of 20 patients (90%) were rated as “improved” or better by both physicians. The mean physician GAIS score at week 12 was 3.3 ± 0.6. At week 24, improvement was maintained through week 24 in 17 of 19 patients (89%), with a mean physician GAIS score of 3.1 ± 0.7 however, longer follow–up is needed to assess durability across hair–cycle dynamics and late–onset adverse events.

Patient-reported outcomes were consistent with physician assessments, with mean patient GAIS scores of 3.2 ± 0.7 at week 12 and 3.0 ± 0.7 at week 24 (Table 1).

Safety

No serious adverse events were observed. Procedural pain was mild (median VAS 2, IQR 1-3). Transient erythema occurred in seven of 20 patients (35%) and resolved spontaneously. No delayed nodules, infections, or telogen effluvium flares were reported through week 24.

Discussion

Hair loss, or alopecia, is broadly classified into two main categories: non-cicatricial and cicatricial types. Non-cicatricial alopecia is more common and involves hair shedding without permanent follicle damage, allowing for potential regrowth when underlying causes are addressed. This category includes androgenetic alopecia (AGA), the most prevalent form affecting up to 50% of women and 80% of men, characterized by progressive thinning due to DHT influence on genetically susceptible follicles. Other non-cicatricial conditions include alopecia areata (an autoimmune disorder causing patchy hair loss), telogen effluvium (diffuse shedding following physiological stress), and trichotillomania (compulsive hair pulling). In contrast, cicatricial alopecia is less common but more severe, involving irreversible follicle destruction and scarring that leads to permanent hair loss. These are classified by inflammatory cell type and include conditions like Lichen Planopilaris, Frontal Fibrosing Alopecia, and Folliculitis Decalvans. Diagnosis relies on comprehensive patient history, physical examination, and trichoscopy, with scalp biopsy recommended when cicatricial alopecia is suspected.[7]

Treatment approaches are tailored to the specific diagnosis and disease activity. For androgenetic alopecia, topical minoxidil remains the primary treatment (5% for men twice daily, 2% for women twice daily), with oral anti-androgens like finasteride and dutasteride effective for DHT inhibition. Additional options include prostaglandin analogs, platelet-rich plasma injections, and hair transplantation. Alopecia areata management focuses on immunosuppression through corticosteroids and topical immunotherapy, with newer JAK inhibitors showing promise for severe cases. Telogen effluvium treatment primarily involves identifying and eliminating triggering factors. For cicatricial alopecias, the goal is controlling inflammation to prevent further follicular destruction, using systemic corticosteroids for rapidly progressing cases, hydroxychloroquine and cyclosporine for resistant lymphocytic forms, and antibiotics with oral isotretinoin for neutrophilic variants. Early diagnosis and prompt treatment initiation are crucial for optimal prognosis and preventing irreversible hair loss.[7] Comparative context is limited in the present study because outcomes were based primarily on GAIS and standardized photography rather than objective trichologic endpoints (e.g., hair density or shaft diameter). Therefore, the magnitude of improvement cannot be directly benchmarked against established therapies such as topical minoxidil, oral 5α-reductase inhibitors, or PRP, which are often evaluated using quantitative measures. Future controlled studies incorporating objective endpoints are required for comparative effectiveness assessment.

In hair loss treatment, microneedling specifically increases expression of Wnt proteins (Wnt3a and Wnt10b) in hair follicles, encouraging differentiation of hair follicle stem cells and proper regulation of the hair cycle by the dermal papilla. Additionally, the procedure triggers revascularization of the skin, providing better nourishment to hair follicles similar to how minoxidil works as a vasodilator.[1,8]

Research showed that microneedling monotherapy significantly increased total hair count more than topical minoxidil 5% alone, while combination treatment of microneedling with topical 5% minoxidil was even more effective than microneedling alone.[1] Across 17 investigations involving 911 androgenetic alopecia subjects, microneedling improved hair parameters when paired with 5% minoxidil, growth factor solutions, and/or platelet-rich plasma, particularly in subjects whose hair count changes had plateaued for $\geq$6 months on other treatments.[6]

One of microneedling's key advantages is its ability to enhance the efficacy of topical treatments, particularly minoxidil. The procedure creates microchannels that improve transdermal delivery, with studies showing that microneedling led to a median increase in sulfotransferase activity of 37.5% over 21 days.[6] This is particularly significant because sulfotransferase enzymes are responsible for converting minoxidil to its active metabolite, minoxidil sulfate.[1] Additionally, microneedling with 5% minoxidil upregulated the expression of Wnt pathway proteins more than either treatment alone, suggesting that the combination amplifies the effects of minoxidil on hair growth signaling pathways.[6,9]

Despite promising results, the current evidence has significant limitations. The data are of relatively low quality with substantial heterogeneity across interventions, comparators, and microneedling procedures, preventing meta-analysis and establishment of best practices.[6] Most studies are small, often non-randomized, and frequently combine microneedling with other therapies without adequate controls for microneedling monotherapy.[1] Large-scale randomized controlled trials are needed to de-

termine optimal protocols, establish long-term safety data, and better define microneedling's role as both a standalone and adjunct therapy for hair loss treatment.[6]

Poly-D,L-lactic acid (PDLLA) is a biodegradable and biocompatible polymer that demonstrates significant potential for hair care applications through its unique structural properties. PDLLA-based resin microparticles feature a distinctive spherical and foamy outer structure combined with a patented reticular and porous inner design that enhances biocompatibility while minimizing tissue damage.[5] These nano- and micro-particulate systems offer superior delivery and stability compared to traditional formulations, providing controlled release and enhanced penetration of active ingredients essential for optimal scalp and hair follicle health. The material is suitable for numerous cosmetic applications, including hair care products such as shampoos, conditioners, hair oils, and hair color agents.[10]

PDLLA operates through a sophisticated mechanism involving controlled inflammatory responses that lead to beneficial tissue remodeling. When immune cells recognize PDLLA as a foreign body, they trigger subclinical inflammatory reactions that ultimately stimulate PDLLA-induced collagen synthesis through monocyte recruitment and differentiation into macrophages.[11] The key mechanism involves promoting M2 macrophage polarization, which is essential for anti-inflammatory and pro-regenerative responses. PDLLA achieves this by increasing IL-4 and IL-13 levels and upregulating TGF-β expression through the PCK2/AMPK/mTOR signaling pathway.[11,12] This process orchestrates a carefully controlled cytokine cascade, transitioning from initial activation involving IL-1, IL-6, and TNF-α toward M2-mediated secretion of IL-10 and TGF-β, creating a microenvironment conducive to tissue repair.[11,13]

The connection between PDLLA and angiogenesis represents a crucial aspect of its regenerative potential. PDLLA promotes angiogenesis in aged skin through a sophisticated molecular pathway that begins with macrophage activation and culminates in enhanced blood vessel formation. The treatment stimulates the expression of heat shock protein 90 (HSP90), hypoxia-inducible factor-1 alpha (HIF-1α), and vascular endothelial growth factor (VEGF) in senescent macrophages, with HSP90 playing a crucial role in preventing HIF-1α degradation and enhancing gene transcription.[11] This upregulation leads to increased VEGF secretion, which activates endothelial cells through VEGF receptor 2 binding and triggers downstream signaling cascades involving PI3K, AKT, and ERK1/2 pathways, ultimately promoting endothelial cell proliferation, migration, and tube formation. Mechanistic interpretations are extrapolated from prior PDLLA biostimulatory and animal/dermal studies; no scalp biopsy, histology, or biomolecular assays were performed in this series to confirm pathway activation in human alopecia.

The relationship between angiogenesis and hair growth is fundamental, as hair growth is intrinsically linked to perifollicular angiogenesis, which is highly active during the anagen phase.[4,14] VEGF serves as a critical factor in this relationship, promoting angiogenesis during the anagen phase and increasing the supply of nutrients and oxygen-rich blood to hair follicles, thereby facilitating hair growth by increasing follicle diameter.[3,4] The stimulation of angiogenesis through VEGF mechanisms, mediated by matrix metalloproteinases like MMP-2, enhances the delivery of growth factors and cytokines to hair follicles, establishing PDLLA's potential for hair regeneration applications.

Future research directions for PDLLA applications appear promising, with multiple avenues for therapeutic enhancement. Understanding the PCK2/AMPK/mTOR signaling pathway opens possibilities for combination therapies that could enhance this pathway or incorporate other regenerative factors.[12] PDLLA's ability to modulate immune responses and reverse age-related changes in immune cell populations suggests potential applications in autoimmune conditions where inflammatory microenvironments contribute to tissue degradation. Additionally, PDLLA's controlled biodegradation patterns and specific surface morphologies that favor M2 polarization could be combined with drug loading to create materials providing both structural support and controlled anti-inflammatory therapeutic delivery, positioning it as superior to other dermal fillers in promoting angiogenesis and tissue rejuvenation.[11]

Optional microneedling priming was performed in a subset of patients in this series to facilitate PDLLA distribution, and both microneedling–related wound–healing responses and PDLLA biostimulatory effects may plausibly contribute to observed changes. However, because microneedling priming was not randomized and the study lacked a comparator arm and objective trichologic endpoints, the independent contribution of PDLLA and any potential "synergistic" effect cannot be established. These results should therefore be interpreted as preliminary and hypothesis–generating, supporting

the need for controlled designs (e.g., split–scalp or intra–individual comparators) with quantitative measurements and longer follow–up.

Limitations

This study has important limitations. First, it is an uncontrolled pilot case series with a small sample size and without an a priori power calculation; therefore, the observed improvement rate may overestimate the true effect size. Second, outcomes relied on standardized photography and GAIS, which are subjective and susceptible to evaluator bias despite independent physician rating. Third, optional microneedling priming was performed in 14/20 patients without randomization, creating potential confounding and preventing isolation of the independent effect of PDLLA. Fourth, detailed baseline severity grading, disease duration, race/ethnicity, Fitzpatrick distribution, and concomitant medication histories were not systematically captured for analytical adjustment, limiting generalizability. Finally, follow-up to 24 weeks is insufficient to evaluate durability across full hair-cycle dynamics and potential late-onset adverse events; longer follow-up ($\geq$12 months) is warranted.

Conclusion

In this 20–patient prospective pilot case series, PDLLA scalp microinjections (with optional light microneedle priming in a subset of patients) were associated with physician–rated GAIS improvement over 12–24 weeks and favorable short–term tolerability. However, due to the uncontrolled design, small sample size, reliance on subjective outcomes (GAIS and standardized photography), and potential confounding from optional microneedle priming and concomitant therapies, these findings should be interpreted as preliminary and hypothesis–generating. Controlled studies incorporating objective trichologic endpoints and longer follow–up are needed before definitive claims regarding follicular regeneration, durability, or comparative effectiveness can be made.

Ethical approval

Approved by the local IRB.

Informed consent

Informed consent was obtained from all participants, with full disclosure of the study's purpose, risks, and confidentiality.

Author contributions

All authors have reviewed and approved the article for submission. Conceptualization, Kyu-Ho Yi, Olena Sydorchuk. Writing-Original Draft Preparation, Kyu-Ho Yi; Isabella Rosellini. Writing-Review & Editing, Kyu-Ho Yi; Jong Keun Song, Nilesh H. Pawar, Han Earl Lee. Visualization, Kyu-Ho Yi; Isabella Rosellini; Jino Kim. Supervision, Kyu-Ho Yi; Massimo Vitale.

Financial disclosure

There is no financial disclosure to report.

Declaration of competing interest

The authors declare that they have no conflicts of interest to disclose.

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This study was conducted in compliance with the principles set forth in the Declaration of Helsinki.

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