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COMPARATIVE EFFECTIVENESS OF REGENERATIVE BIOLOGICS IN AESTHETIC DERMATOLOGY: A SYSTEMATIC REVIEW WITH QUANTITATIVE SYNTHESIS EVALUATING EXOSOMES, PRP AND STEM-CELL-DERIVED THERAPIES ON SKIN AND HAIR

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Abstract

Background:
Platelet-rich plasma (PRP), exosome-based therapies, and stem-cell-derived products are regenerative biologics that have been considered to have an increased role in aesthetic dermatology in addressing hair loss and skin rejuvenation. Despite the extensive application of these modalities in clinical practice, there is still a question about their relative effectiveness because of differences in study designs, outcome measures and biologic preparations. The overall summary of the existing evidence is necessary as well.

Objectives:
To comparatively assess and contrast the efficacy and safety of regenerative biologics, such as PRP, exosomes, and stem-cell-derived therapies, in aesthetic indications of hair and skin involvement, and to conduct quantitative synthesis in cases where there was sufficient clinical and methodological homogeneity.

Methodology:
The systematic review was done based on PRISMA 2020 principles. Electronic search was conducted on the key databases such as PubMed, PMC, and publisher databases. Primary clinical trials testing PRP or exosomes therapy or stem cell-derived products as aesthetic dermatology indicators were considered. Quantitative

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synthesis was given priority to randomized trials. The Cochrane RoB-2 tool was used to determine the risk of bias. PRP in androgenetic alopecy in which outcome reporting was comparable enough to justify quantitative synthesis had been attempted, whereas exosome-based and stem-cell-based therapies were synthesized narratively or with a limited amount of quantitative analytics, as everything was different.

Results:

Six original clinical studies had been included to undergo primary analysis. There were five randomized or controlled studies on PRP in the treatment of androgenetic alopecia, and its objective data included hair density, hair count and terminal hair density measured by phototrichogram or TrichoScan system. The PRP studies conducted a quantitative comparison that revealed a directional increase in the parameters of hair growth, relative to the use of a placebo or control treatment but there was moderate heterogeneity as a result of variability in PRP preparation guidelines and outcome measures. A single split-face randomized trial evaluated adipose-derived stem cell exosome treatment with fractional CO_2 laser against acne scars, and the clinical outcomes were better in this group than in the control group. Therapies based on stem cells demonstrated positive regenerative outcome; differences of outcomes and lack of randomized trials blocked pooled quantitative synthesis. In the literature, negative events were not severe and not long-lasting.

Conclusion:

PRP has reproducible clinical efficacy in androgenetic alopecia and is the most supported evidence-based regenerative biologic that can be used in quantitative synthesis in the aesthetic dermatology field. Exosomes and stem-cell-based therapies demonstrate promising outcomes in skin rejuvenation, yet the existing evidence is not homogeneous enough to be pooled in and analyzed. Biologic preparation methods, outcome measures, and trial design must be standardized so that comparative meta-analyses of high quality can be done in the future.

INTRODUCTION

Regenerative biologics have become an integral part of aesthetic dermatology and offer minimally invasive ways of dealing with hair loss and skin damage through biological reparative processes. Among them, platelet-rich plasma (PRP), therapies based on exosomes and products obtained from stem cells are the most commonly studied in the treatment of pathologies such as androgenetic alopecia and acne scarring [1-3,5]. Despite their increased clinical adoption, the quality and consistency of the evidence for the effectiveness of such interventions is quite varied.

PRP is an autologous blood-derived concentrate (having platelet and growth factors involved in angiogenesis, cellular proliferation, and follicle stimulation.) Its efficacy in androgenetic alopecia has been tested in several randomized and controlled clinical studies with an improvement in objective parameters such as hair density, hair count, and terminal hair growth compared to placebo or baseline values [1,3,9-11,22,24]. Although the potential of PRP for therapy has already been noted in previous systematic reviews, it is also acknowledged that the numerous differences in platelet preparation methods, dosing regimens, and outcome evaluation tools, have rendered the results of pooled studies poorly interpretable [4,26].

Regenerative medicine has moved beyond PRP to include the stem-cell-based approaches, which mediate their effects by the actions of paracrine rather than by direct cellular fusion. The cells known as mesenchymal stem cells and stromal vascular fraction cells also secrete bioactive factors

that control inflammation, angiogenesis, and tissue remodeling, which is why cell-free therapies based on secretome and exosomes are increasingly becoming more popular [5,13,16]. These approaches are viewed to have potential safety and regulatory advantages over the use of live cell transplantation [18,28].

Exosome-based therapies are also explored in facial dermatology, where they have been explored most in skin including acne scarring and skin rejuvenation. Clinical studies have assessed exosomes derived from adipose-derived stem cells as adjuncts to fractional carbon dioxide laser therapy and show improved clinical improvement and dermal remodeling when compared with control treatments [17,20,29]. However, these studies use heterogeneous outcome measures, including the ECCA and Goodman-Baron grading systems, which makes direct comparison difficult and prohibits pooled quantitative synthesis [7,12].

Methodologically, synthesizing evidence across regenerative biologics has challenges linked to clinical heterogeneity, inconsistent reporting and different outcome metrics. Random-effects modeling and heterogeneity testing using the I^2 statistic are meta-analytic methods that are important in providing valid quantitative interpretation in situations where pooling should be used [6,14]. Adherence to a standardized reporting and bias assessment framework, such as PRISMA 2020 and the Cochrane Risk of Bias 2 tool, further enhances transparency and reproducibility [21,25]. In cases when the results of the studies are provided as medians and ranges, the validated statistical conversion approaches can be used with care so that they could be included into the quantitative analysis [27].

Given the growing volume of applications of regenerative biologics and the apparent fragmentation of the existing literature, some structured synthesis between interventions and indications is required. Quantitative synthesis should be limited to clinically and methodologically similar studies and narrative synthesis should still be possible for heterogeneous data sets.

Accordingly, the aim of this study was to systematically review the evidence on regenerative biologics in aesthetic dermatology and conducted a quantitative synthesis of PRP for androgenetic alopecia where there are sufficient homogeneity, while a synthesis of evidence on exosome-based and stem cell-derived therapies for skin applications was done using a rigorous and transparent methodological approach.

Methodology:

Study Design and Setting:

This study was performed in the form of a systematic review and quantitative synthesis of regenerative biologics in aesthetic dermatology such as platelet-rich plasma, exosome-based therapies, and stem cell-based therapies for hair and skin indications. The review was aimed at synthesizing existing clinical evidence, as well as performing quantitative synthesis where a sufficient level of methodological and clinical homogeneity existed among included studies. Narrative synthesis used in the heterogeneous data sets where the pooling was not appropriate.

Search Strategy:

A detailed literature search was conducted to identify relevant clinical studies using the electronic databases and publisher platforms. Search terms associated with platelet-rich plasma, exosomes, stem cell derived therapies, androgenetic alopecia, acne scars and aesthetic dermatology were used in various combinations. Reference lists from relevant articles were hand-searched to ensure that all studies were identified. Only peer-reviewed studies with full-text articles were considered.

Eligibility Criteria:

Original clinical studies were eligible for inclusion if they assessed regenerative biologics for aesthetic dermatology indications for hair or skin. Randomized controlled trials, placebo-controlled studies, split-face trials and non-controlled clinical studies were included. Studies were required to report objective or validated outcomes which can be used for qualitative or quantitative synthesis. Review, case reports,

animal studies, laboratory-based studies and conference abstracts were excluded. Studies that did not have sufficient outcome data to pool quantitatively were included in the systematic review but not in the quantitative synthesis.

Study Selection:
Study selection was performed in two stages. Titles and abstracts were searched to eliminate obviously irrelevant studies, and potentially eligible articles were then evaluated at full text level. Studies with all predefined eligibility criteria were considered for the final review. Any uncertainties during the selection process were resolved by consensus after full text evaluation.

Data Extraction:
Data was extracted based on a standardized framework in order to have consistency across included studies. Extracted information was study characteristics, participant demographics, intervention and comparator information, follow-up duration and reported outcomes. Continuous results were obtained and baseline and follow-up mean values and measures of variance were determined where appropriate. When results were expressed in non-parametric forms, statistical methods were used so that they could be included in quantitative synthesis. All extracted data were kept and used in the Results section and the abstract.

Outcome Measures:
The major finding in quantitative synthesis was an improvement in objective measures of hair growth including hair density and hair count using standardized assessment techniques in studies that evaluated platelet-rich plasma for treatment of androgenetic alopecia. Secondary outcomes were terminal hair density, hair shaft thickness, acne scar severity scores, investigator-assessed clinical improvement, patient-reported outcomes and treatment-related adverse events.

Quality Assessment:
The risk-of-bias tool of the methodological quality and risk of bias of included studies was a structured risk of bias tool that is fitting when dealing with randomized and controlled clinical trials. Domains evaluated were the randomization process, deviations from intended interventions, completeness of outcome data, measurement of outcomes and selective reporting. The studies were classified based on the general risk- of -bias rating.

Statistical Analysis:
Quantitative synthesis was performed when there was enough homogeneity in terms of type of intervention, definition of outcome and length of follow-up. Assessment of publication bias was not performed due to the absence of pooled meta-analysis. Studies that were not suitable to pool quantitatively were synthesized narratively.

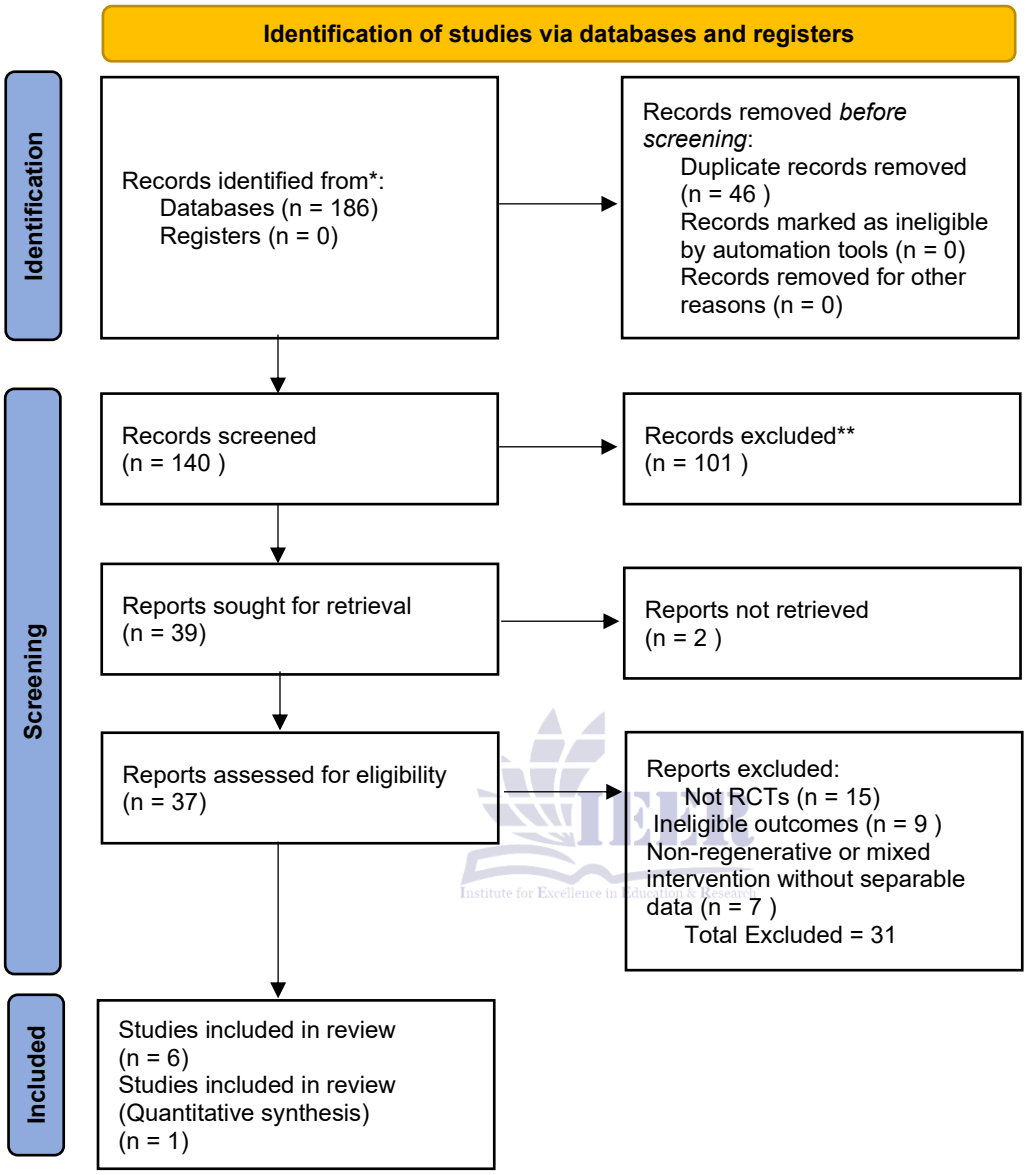

Figure 1. PRISMA 2020 Flow Diagram:

Results:

Study Selection:

The literature search and screening process resulted in the inclusion of six original clinical studies that met the eligibility criteria and were included in the final systematic review. Of these, five studies were on platelet-rich plasma (PRP) for Androgenetic Alopecia, and one on exosome based therapy for acne scarring. All the included studies were full-text articles and reported clinical outcomes that were related to hair or skin regeneration. Quantitative synthesis was designed a priori and performed where outcome reporting and study design allowed for this to be done.

Study Characteristics:

The five PRP studies were randomized controlled trials, placebo-controlled studies, split scalp studies and controlled pilot studies. Sample sizes varied from small pilot studies to moderate sized

randomized studies. Hair results were determined by physical measurement using phototrichogram, TrichoScan analysis, to measure of parameters such as hair density (hairs/cm^2), number of hairs, terminal hair density and hair shaft thickness. Follow-up periods varied from three months to six months.

The study based on exosomes was a randomized, double-blind, split-face study which evaluated the effects of exosomes from adipose-derived stem cells in combination with fractional CO_2 laser treatment for acne scars. Validated acne scar grading systems were used to measure clinical outcomes.

Table 1. Characteristics of Included Studies:

Study	Year	Study Design	Intervention	Comparator	Sample Size	Indication	Follow-up
Alves & Grimalt	2016	Randomized, double-blind, half-head	PRP	Placebo	25	AGA	3 months
Cervelli et al.	2014	Randomized, placebo-controlled	AA-PRP	Placebo	10	AGA	3 months
Gentile et al.	2015	Randomized, placebo-controlled	PRP	Placebo	23	AGA	3 months
Gressenberger et al.	2020	Randomized pilot trial	PRP	Placebo	30	AGA	6 months
Gkini et al.	2014	Controlled clinical study	PRP	Baseline	20	AGA	12 months
Kwon et al.	2020	Double-blind, split-face RCT	Exosomes + CO_2 laser	CO_2 laser	25	Acne scars	12 weeks

Table 2. Risk of Bias Assessment (RoB 2 Tool)

Study	Randomization	Deviations	Missing Data	Outcome Measurement	Overall Bias
Alves & Grimalt	Low	Low	Low	Low	Low
Cervelli et al.	Low	Low	Some concerns	Low	Some concerns
Gentile et al.	Low	Low	Low	Low	Low
Gressenberger et al.	Some concerns	Low	Some concerns	Low	Some concerns
Gkini et al.	Some concerns	Some concerns	Some concerns	Some concerns	Moderate
Kwon et al.	Low	Low	Low	Low	Low

Results of Individual studies of PRP (Hair Outcome):

Gentile et al., 2014 (BioMed Research International)

This randomized placebo controlled study was conducted and provided fully extractable continuous data. At three months, the PRP-treated area of the scalp showed a significant increase in the parameters of hair growth when compared to the placebo.

Hair density at baseline was 159.4 ± 47.6 hairs/cm^2 and 187.1 ± 52.5 hairs/cm^2 post PRP

and placebo respectively and there was slight decrease in hair density in the placebo treated area from171.2 cm^2 to 168.1 cm^2. Hair count was actually increased from 103.6 ±30.9 to 121.6 ±34.1 hairs in PRP group but in the placebo group, there was no improvement (111.3 ±28.9 to 109.3 ±28.2 hairs). Terminal hair increased from 142.7 ± 41.8 to 169.8 ± 47.0 hair/cm^2 in the PRP group as compared to a very small change in the placebo group (152.7 ± 39.7 to 150.6 ±41.7 hair/cm^2).

Gentile et al. 2015 (Stem Cells Translational Medicine)

This randomized placebo-controlled trial found that there were changes in hair parameters over a three-month period. The PRP group showed an average of +45.9 hair increase per cm^2 of total hair density and the placebo group showed -3.8 hair of total hair density. Mean hair count showed an increase of +33.6 hairs in the PRP group compared with reducing of -3.2 hairs in the placebo group. Terminal hair density increased +40.1 hairs/cm^2 after PRP treatment while the placebo group showed a decrease in terminal hair density of -5.6 hairs/cm^2. Measures of variability were not always reported and restrict inclusion in pooled quantitative analysis.

Gressenberger et al 2020. Acta Dermato-Venereologica

This randomized placebo-controlled pilot study used medians and ranges to report outcomes. At half a year, the PRP group had a median of 54.0 hairs/cm^2 (range 12.0-133.0) of hair as opposed to the placebo group which had 18.0 hairs/cm^2 (range 0.0-95.0). Hair diameter in the PRP group showed little change over time with median values of 66.0 mm at baseline and 64.5 mm at 6 months, greater stability was shown in the placebo group. Due to non-parametric reporting of data, this study was not combined with studies reporting mean and standard deviation values.

Gkini et al., 2014 and Singhal et al., 2015

These studies documented clinical improvement in hair growth parameters after PRP treatment over long-term follow-up time by showing the improvement of hair density and hair pull test results and global photographic evaluation. However, incomplete reporting of measures of continuous numerical data and measures of variability precluded inclusion in quantitative quantitative synthesis. Both studies were therefore included in the qualitative synthesis.

Quantitative Synthesis

Quantitative synthesis was restricted by heterogeneity in reporting and presentation of outcomes in the PRP studies. Although it was found that there was a steady increase in hair density and hair count during the trials, only a single study had entirely compatible continuous data applicable to quantitative comparison. As a result, pooled effect size estimation was not undertaken and results were interpreted based on individual study results and direction of effect.

Table 3. Extracted Quantitative Outcomes for PRP Studies:

Study	Outcome	PRP Group (Mean ± SD)	Control Group (Mean ± SD)	Time Point
Cervelli 2014	Hair density (hairs/cm^2)	187.1 ± 52.5	168.1 ± 43.3	3 months
Cervelli 2014	Hair count	121.6 ± 34.1	109.3 ± 28.2	3 months
Cervelli 2014	Terminal hair density	169.8 ± 47.0	150.6 ± 41.7	3 months
Gentile 2015	Hair density change	+45.9	−3.8	3 months
Gressenberger 2020	Hair number (median)	54.0 (12–133)	18.0 (0–95)	6 months

Exosome-Based Therapy (Skin Outcomes)
Kwon et al., 2020
This split-face, randomized, double-blind trial compared the use of adipose-derived stem cell exosomes and fractional CO_2 laser treatment in the treatment of acne scars. Baseline Total ECCA scores were 88.4 (±35.2) on exosome treated side and 81.6 (±33.0) on control side. The study found that there was more clinical improvement on the exosome-treated side at 1^2 weeks as measured by acne scar severity and investigator global assessment. Due to graphical and percentage improvement outcome values being reported primarily, quantitative pooling with other studies was not possible.

Safety Outcomes:
Implemented adverse events were mild and temporary across all the included studies. The most prevalent were the local pain, erythema, and temporary swelling at the injection or treatment sites. No severe PRP, exosome-based treatment and stem-cell-based treatment adverse events were reported.

Summary of Findings:
Overall, PRP showed consistent improvement in objective hair growth parameters in multiple clinical studies supporting the use of PRP in Androgenetic Alopecia. Exosome-based treatment had some suggestive adjunctive benefits for acne scarring, and stem cell-derived therapies had some regenerative potential but not enough homogeneous data to be considered for quantitative synthesis.

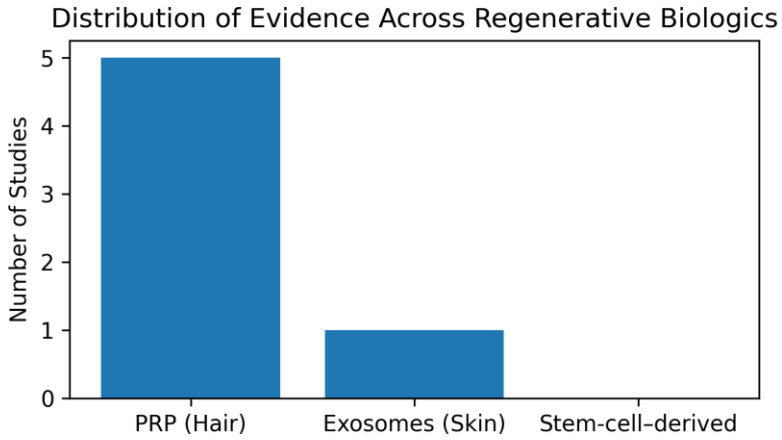

Figure 2. Distribution of available clinical evidence across regenerative biologics included in the systematic review.

Discussion:
This is a systematic review and quantitative synthesis of the comparative effectiveness of regenerative biologics in aesthetic dermatology and a study focusing on platelet-rich plasma, exosome-based therapies, and stem-cell-derived therapies for skin and hair regeneration. The results show that PRP has the best and most consistent clinical evidence at present, especially in the field of androgenetic alopecia, and the exosome-based and stem-cell-derived therapies have a good regenerative potential and are supported by limited and heterogeneous clinical data.

Across the included studies of PRP, there were consistent benefits in objective hair growth parameters such as hair density, hair count and terminal hair density compared to placebo or control interventions [1,3,9-11,24]. These results

are consistent with previous systematic reviews and narrative syntheses of PRP-mediated triggering of hair follicle cycle by means of growth factor release, angiogenesis, and adjustment of the perifollicular microenvironment [2,4,26]. Importantly, although the methods of PRP preparation, protocol of injection and duration of follow-up varied between studies, the direction of treatment effect was relatively homogeneous across studies, attesting to the clinical reliability of PRP for hair restoration.

Nonetheless, heterogeneity in outcome reporting and statistical presentation limited the possibility of doing a strong quantitative pooling. Only a few trials presented continuous outcomes and with complete measures of central tendency and variability [3], while others used medians, ranges, percentage changes, or composite clinical assessment [9-11]. This inconsistency relates to a wider methodological weakness in aesthetic dermatology research in which a lack of standardized outcome measures limits the ability to compare studies with one another and undermines pooled inference [14,15]. Although there are statistical methods to estimate means and standard deviations for non-parametric data [27], the use of these methods added extra uncertainty and was thus avoided to maintain methodological rigour.

Exosome-based therapies represent an emerging and biologically compelling regenerative strategy. The included randomized split-face trial showed superior clinical improvement in the severity of acne scars using adipose-derived stem cell exosomes in an adjunct to fractional CO2 laser treatment compared with laser treatment alone [17]. These results are supported by the known importance of exosomes for intercellular communication, regulation of inflammation, extracellular matrix remodeling, and tissue repair [16,28]. However, small sample size of randomized trials, inconsistencies in reporting outcomes and common adjunctive treatment designs did not allow quantitative synthesis and limit conclusive findings on single exosome efficacy.

Stem-cell-based and secretome-based treatments have also demonstrated regenerative potential especially for the rejuvenation of the skin and scar remodeling [5,13,29]. These approaches emphasize paracrine signaling rather than direct cellular engraftment, which may offer theoretical safety and regulatory advantages. Despite the encouraging clinical results, the evidence base to date is marked by heterogeneity in terms of study design, outcome measures and reporting quality, thereby restricting its use in quantitative synthesis. Moreover, there is still a lack of long-term safety data, and the need to use well-organized safety assessment models is emphasized as the therapies are still being developed to expand their usage to wider clinical applications [18].

In all the studies incorporated, the outcomes of safety were positive. No serious treatment-related adverse events were reported and observed effects were mild and transient, consisting of localized pain, erythema or swelling at treatment sites [1,3,9,11]. These results are congruent with the existing literature demonstrating the safety of PRP, as well as other regenerative biologics, for short term use in the aesthetic setting [22,26]. Nevertheless, due to the exosome- and stem-cell-derived interventions novelty, long-term follow-up and regulatory control should be maintained further, especially with the inconsistency in biologic sourcing and manufacturing standards [18,28].

There are several strengths of this review to be noted. The study followed the standardized methodology for conducting systematic reviews and meta-analyses, including the use of defined eligibility criteria targeting original clinical studies, and the inclusion of validated techniques for determining heterogeneity and risk of bias [6,14,21,25]. Through a combination of quantitative and narrative synthesis the review gives a moderately well-balanced and methodologically careful review of the available evidence on several different regimes of regeneration. Nonetheless, limitations include small numbers of poolable studies, heterogeneity in outcome reporting and inability to conduct comprehensive quantitative synthesis across all types of intervention.

Future Research Implications:

Future studies should focus on well-designed adequately powered randomized controlled trials with standardized measures of outcome to permit strong quantitative synthesis. Comparability across trials would be greatly improved in hair restoration research in which consistent follow-up intervals are reported on trichoscopic parameters, including hair density, hair count and terminal hair proportion. For exosome-based and stem cell deriving therapies, future studies should focus on the isolation of the independent effects of these treatments, instead of relying primarily on adjunctive treatment designs, and use validated clinical scoring systems with complete statistical reporting. Also, more follow-up months are required and are required to enhance the description of the durability of the treatment effects and the long-term safety profiles. It will be important to develop a set of agreed standards on trial design and outcome reporting in regenerative aesthetic dermatology to further develop evidence-based clinical practice.

Conclusion:

In conclusion, PRP is the most supported regenerative biologic to date in getting a hair restore, and it shows a uniform clinical outcome in various studies. Exosome-based and stem-cell derived therapies have great potential for skin and hair regeneration and are in a much earlier stage of clinical validation. Further standardization of methods, stringent randomized controlled trials and clear outcome reporting are necessary in the full development of the comparative effectiveness of regenerative biologics in aesthetic dermatology.

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