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Peer Review

Review of: "Evaluation of Ozonized Fibrin-Rich Plasma as a Therapy for Facial Rejuvenation: A Clinical Case Study"

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Looking at this preprint study on ozonized fibrin-rich plasma (I-PRF) for facial rejuvenation, several significant methodological and scientific concerns emerge that limit the validity and reliability of the findings.

The study design represents one of the most fundamental weaknesses. This is purely an observational case series without any control group, randomization, or blinding, which makes it impossible to attribute observed changes specifically to the treatment rather than natural variation, placebo effects, or other confounding factors. The small sample size of only five patients severely limits statistical power and generalizability of results. Additionally, the heterogeneous patient population (ages 25-70 with varying baseline conditions) makes it difficult to draw meaningful conclusions about treatment efficacy across different demographics.

The methodology for outcome assessment is particularly problematic. The authors rely heavily on subjective visual assessment and photographic comparison without employing standardized, validated measurement tools. There are no objective metrics such as skin elasticity measurements, collagen density assessments, or standardized skin scoring systems. The photographs, while numerous, lack consistent lighting, angles, and positioning that would be necessary for reliable before-and-after comparisons. The evaluation appears to be conducted by the same investigators who performed the treatment, introducing significant observer bias.

The statistical analysis is entirely absent. The study presents no quantitative data analysis, confidence intervals, or statistical tests to support claims of "significant improvement." Without proper statistical

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methodology, the clinical significance of any observed changes cannot be determined. The authors make broad claims about treatment efficacy based purely on subjective impressions rather than rigorous data analysis.

Safety reporting is inadequate given the novelty of combining ozone with I-PRF. While the authors mention no adverse effects were observed, there is insufficient detail about systematic safety monitoring, follow-up duration, or potential delayed reactions. The long-term safety profile of ozonized I-PRF remains unknown, yet the authors present this as a viable clinical option.

The literature review, while comprehensive in citing relevant I-PRF and ozone therapy studies, fails to adequately address the lack of evidence specifically supporting the combination treatment used in this study. Most referenced studies examine I-PRF or ozone therapy separately, not the combined approach being investigated. The authors extrapolate benefits from individual treatments to justify their combination without sufficient mechanistic or clinical evidence.

The treatment protocol lacks standardization that would be necessary for reproducibility. While the authors describe the ozone concentration and I-PRF preparation method, there are variations in application sites and techniques that are not well-controlled. The 30-day interval between treatments appears arbitrary without justification for this specific timing.

Patient selection criteria are too broad and poorly defined. Including patients with such diverse ages, skin conditions, and baseline characteristics makes it impossible to determine which patients might benefit most from this treatment. The exclusion criteria, while reasonable, do not adequately account for factors that might influence treatment response.

The discussion section oversells the clinical implications of these limited findings. The authors conclude that ozonized I-PRF is "promising" and "effective" based on this small, uncontrolled case series. Such strong conclusions are not supported by the level of evidence presented and may mislead clinicians and patients about the treatment's proven efficacy.

From a regulatory and ethical standpoint, promoting a novel combination treatment without proper clinical trial evidence raises concerns about patient safety and informed consent. The study was approved by an ethics committee, but it's unclear whether patients were adequately informed about the experimental nature of this combined treatment approach.

The study also lacks economic analysis or consideration of cost-effectiveness compared to established facial rejuvenation treatments. Without demonstrating superior efficacy or safety, it's unclear what

advantage this treatment offers over existing options.

In conclusion, while the concept of combining ozone therapy with I-PRF for facial rejuvenation may have theoretical merit, this study fails to provide convincing evidence of its safety or efficacy. The methodological limitations are so significant that the findings cannot be considered reliable evidence for clinical practice. Before this treatment can be recommended, properly designed randomized controlled trials with adequate sample sizes, objective outcome measures, standardized protocols, and rigorous safety monitoring are essential. The current study should be viewed as preliminary observations that may inform future research design rather than evidence supporting clinical implementation.

Declarations

Potential competing interests: No potential competing interests to declare.