Standardization in the Golden Age of Medical Plasma: From Technical Device Requirements to Clinical Protocols

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ABSTRACT

Introduction: Despite the tremendous potential of cold atmospheric plasma (CAP) in wound healing, dermatology, and oncology, clinical translation is hampered by the lack of standardized protocols and device reproducibility. Over 200 research-grade plasma devices exist with vastly different physical parameters, making inter-study comparison and meta-analysis virtually impossible. This work proposes a four-layer standardization framework to bridge the gap between engineering innovation and evidence-based medicine.

Materials and Methods: A multilayer standardization model was developed, encompassing: (1) physical and technical standards (voltage, frequency, gas type, and electrode configuration); (2) dosimetry and calibration protocols, including colorimetric kits for clinical H_2O_2 and nitrite measurement; (3) biological efficacy endpoints (cytotoxicity, reactive species quantification, and antimicrobial activity); and (4) clinical protocol guidelines for specific indications. A consensus-based minimal protocol for diabetic foot ulcers was drafted: He:Air (1:1), 10 mm distance, 60 s/cm², two days per week.

Results and Discussion: Key technical requirements for medical CAP devices were identified: temperature control (<40°C t tissue surface), electrical isolation, ultraviolet filtration, ozone removal, discharge stability, and treatment uniformity. A national/international registry for plasma studies with mandatory parameter reporting is proposed. Draft protocols for basal cell carcinoma (ablative vs. immunomodulatory dosing) and diabetic wounds (TIME criteria-based assessment) were formulated. Emerging technologies—AI-driven dose optimization, real-time sensor-based applicators, and injectable plasma-activated fluids—were mapped on a 2025–2035 horizon.

Conclusion: Standardization is not a constraint but an enabler of clinical adoption, cost reduction, and improved patient outcomes. Iran has the opportunity to lead regional standardization efforts, transitioning from technology consumer to knowledge exporter. A national strategic roadmap for medical plasma standardization, developed through interdisciplinary collaboration, is urgently needed.

Keywords: Clinical protocol, Cold atmospheric plasma, Dosimetry, Patient safety, Reproducibility, Standardization

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