Salud Integral y Comunitaria. 2026; 4:270
doi: 10.62486/sic2026270

ORIGINAL

Ozone therapy as an adjuvant treatment for diabetic foot ulcers: a case series from Asunción, Paraguay

Efectos de la ozonoterapia como tratamiento adyuvante en úlceras del pie diabético: serie de casos en Asunción, Paraguay

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Cite as: Benitez Duarte J, Molas Florentín FJ, Da Silva MN, Poletti Duarte RE, Garlisi-Torales LD. Ozone therapy as an adjuvant treatment for diabetic foot ulcers: a case series from Asunción, Paraguay. Salud Integral y Comunitaria. 2026; 4:270. https://doi.org/10.62486/sic2026270

Submitted: 15-06-2025 **Revised:** 30-08-2025 **Accepted:** 16-11-2025 **Published:** 01-01-2026

Editor: Dr. Telmo Raúl Aveiro-Róbalo

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ABSTRACT

Introduction: diabetes mellitus is a major public health concern due to its chronic complications, including diabetic foot ulcers.
Method: this descriptive retrospective observational case series aimed to explore the potential effects of ozone therapy as an adjuvant treatment for wound healing in diabetic patients at the Centro del Pie in Asunción during 2023. A purposive sample of seven patients was analyzed through medical records using the Texas and RESVECH 2.0 scales.
Results: results showed complete healing in five patients, particularly those with less severe lesions (Texas II/B) and higher ozone session counts. Although a favorable clinical trend was observed, the small sample size and non-experimental design limit causal inference.
Conclusions: further controlled studies with greater methodological rigor are required to confirm the efficacy of ozone therapy and support its broader clinical adoption.

Keywords: Ozone Therapy; Diabetic Foot; Wound Healing; Adjuvant Treatment; Chronic Ulcers.

RESUMEN

Introducción: la diabetes mellitus representa un desafío creciente en salud pública por sus complicaciones crónicas, entre ellas el pie diabético.
Método: esta serie de casos observacional, de tipo descriptivo y retrospectivo, tuvo como objetivo explorar los posibles efectos clínicos de la ozonoterapia como tratamiento coadyuvante en la cicatrización de úlceras de pacientes diabéticos atendidos en el Centro del Pie (Asunción) durante el año 2023. Se incluyó una muestra intencionada de siete pacientes, cuyas características clínicas y evolución se evaluaron mediante revisión de fichas médicas, utilizando las escalas Texas y RESVECH 2.0.
Resultados: los resultados mostraron que cinco de los siete pacientes presentaron cicatrización completa, especialmente aquellos de menor severidad (Texas II/B) y mayor número de sesiones de ozonoterapia. Si bien se observó una evolución clínica favorable en general, el tamaño muestral limitado y el diseño no experimental impidieron establecer relaciones causales.
Conclusiones: la ozonoterapia podría ser una herramienta terapéutica complementaria prometedora para el pie diabético, pero se requieren estudios controlados con mayor validez externa para respaldar su implementación sistemática.

Palabras clave: Ozonoterapia; Pie Diabético; Cicatrización; Tratamiento Coadyuvante; Heridas Crónicas.

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease characterized by persistent hyperglycemia due to insulin deficiency or insulin resistance. According to the World Health Organization (WHO), this condition is among the leading causes of progressive damage to vital organs, including the heart, blood vessels, kidneys, eyes, and peripheral nerves. In 2021, an estimated 537 million people worldwide were living with diabetes. This represents an increase of more than 100 million cases compared to 2014. In addition, it was reported that one in two adults with diabetes remains undiagnosed (approximately 240 million people). This situation has had a substantial impact on health systems, generating an estimated global expenditure of $966 billion, with projections indicating that by 2030, expenditure will exceed $1 trillion.[1,2,3,4,5]

In Paraguay, the prevalence of DM in the adult population aged 18 to 69 was 10,6 %, according to the Second National Risk Factor Survey conducted in 2023. Likewise, the National Diabetes Program of the Ministry of Public Health and Social Welfare identified this disease as one of the five priority areas for intervention.[4] DM is a multifactorial disease. Its risk factors include both non-modifiable (family history, age, sex, history of gestational diabetes) and modifiable (obesity, sedentary lifestyle, poor diet, high blood pressure, dyslipidemia, smoking) factors. Early detection and proper management of these risk factors can modify the clinical course of the disease.[4,6]

In terms of classification, there are several types of diabetes: type 1 DM, which is autoimmune in origin and involves the destruction of pancreatic beta cells; type 2 DM, which is much more prevalent and is characterized by insulin resistance and progressive dysfunction of insulin secretion. In addition, there are less common forms, such as gestational diabetes, LADA (Latent Autoimmune Diabetes in Adults), and MODY (Maturity-Onset Diabetes of the Young), each with distinct pathophysiological mechanisms and therapeutic approaches.[1,7,8,9]

The classic symptoms of diabetes include polyuria, polydipsia, polyphagia, unintentional weight loss, blurred vision, fatigue, and delayed wound healing. However, a significant proportion of patients remain asymptomatic for years.[1,10] Chronic exposure to hyperglycemia is associated with macrovascular and microvascular complications that severely compromise quality of life, with diabetic foot being one of the most complex and frequent manifestations.[1,2,7,11]

Diabetic foot is a multifactorial complication that combines peripheral neuropathy, distal ischemia, and infection, conditions that favor the development of chronic ulcers that are difficult to resolve. The progression of these lesions generates a high risk of gangrene and non-traumatic amputations, representing one of the leading causes of prolonged hospitalization and morbidity in diabetic patients.[2,11,12,13] The traditional therapeutic approach includes measures such as debridement, antibiotic treatment, local wound care, strict glycemic control, and, eventually, surgical revascularization. However, in many cases, the clinical response is limited, prompting the search for adjuvant therapies with regenerative and antimicrobial potential.

In this context, ozone therapy has emerged as a complementary therapeutic alternative. Medical ozone acts as an antimicrobial agent, an oxidative stress modulator, and a stimulator of cellular metabolism, promoting angiogenesis and tissue oxygenation and accelerating the healing process.[2,11,13] It can be applied topically, which encourages wound cleansing, local infection control, and modulation of the body's redox state.[2,14,15]

Despite the background described above, there remains a gap in local clinical evidence on the use of ozone therapy for the treatment of diabetic foot, especially in primary care and outpatient settings. Although the international literature has described promising results, rigorously designed studies remain scarce, and no Paraguayan studies evaluating this intervention have been identified to date. Therefore, this research sought to answer the question: What were the effects of ozone therapy as an adjunctive treatment in the healing of diabetic foot in patients at a private medical center in Asunción during 2023? The starting point was the premise that ozone therapy, applied as an adjunct to conventional treatment, could promote ulcer resolution through biochemical and cellular mechanisms that reduce inflammation, optimize oxygenation, and modulate tissue response. The objective of this study is to evaluate the impact of ozone therapy in a real clinical context, to inform future research with more robust designs and a larger population.

METHOD

This study was an observational case series with a quantitative, descriptive, and retrospective design, conducted between May 2023 and February 2024. According to Sampieri et al.[23], exploratory-descriptive studies allow us to learn about phenomena that have been little addressed or are initially innovative, laying the groundwork for subsequent research with greater methodological depth.

The methodological objective was to observe and describe the clinical effects of ozone therapy as an adjunctive treatment in patients with diabetic foot ulcers at a private medical center in Asunción, Paraguay. There was no manipulation of variables or control group, as no intervention other than standard treatment was

applied; this absence of control is an inherent limitation of the non-experimental design.[23]

Sampling was non-probabilistic for convenience. All patients diagnosed with diabetic foot who received adjunctive treatment with ozone therapy during the study period and whose medical records contained complete follow-up data were included. Patients whose records lacked sufficient follow-up or failed to document the lesions' evolution in detail were excluded.

The variables analyzed were grouped into two main categories:

- Sociodemographic: age, sex, comorbidities.
- Clinical: classification of lesions according to the Texas Scale and healing progress according to the RESVECH 2.0 Scale.

Data collection was performed using a structured guide table (Appendix III) that integrated clinical data extracted from institutional medical records, together with assessments obtained using standardized scales. In particular:

- Texas Scale: used to classify the depth of the injury and the presence of infection/ischemia, assigning each ulcer a grade (0–III) and a stage (A–D) according to its severity.
- RESVECH 2.0 Scale: a validated instrument for assessing the evolution of chronic wounds, considering aspects such as size, granulation tissue, exudate, signs of infection, and edges; it assigns a cumulative score to reflect the status of the wound.

Data collection was authorized by institutional approval, ensuring legitimate access to clinical records in accordance with medical ethical principles. The information was processed in Microsoft Excel (Office 2019). The results were presented using basic descriptive statistics, including absolute frequencies, percentages, and measures of central tendency, summarized in tables and figures.

From a bioethical perspective, the principles of beneficence, non-maleficence, and justice were applied. Data confidentiality was protected, maintaining patient anonymity and the integrity of clinical records. The research did not involve direct intervention or pose any risk to patients, as it was exclusively a retrospective analysis of information already available in medical records. Likewise, informed consent was obtained from patients for the publication of clinical images, ensuring their complete anonymization. Finally, it was acknowledged that the small sample size, the absence of a control group, and the observational design limited the generalizability of the findings and the ability to infer causality. However, the results obtained were considered to provide a valuable clinical basis for planning future research with greater methodological robustness.

RESULTS

Table 1 summarizes the clinical and sociodemographic profiles of the seven patients included in the study. The patients' ages ranged from 44 to 92 years. Females predominated (4 of 7 cases), and the most common type of diabetes was type 2 (6 of 7 patients), which is consistent with the expected epidemiology of this disease in older adults.[2,4] An essential clinical finding was the high prevalence of hypertension, present in all patients, as well as the presence of overweight as an associated comorbidity in three of them. This pattern reflects the close relationship between metabolic syndrome and vascular complications in patients with diabetic foot. The number of ozone therapy sessions per patient ranged from 3 to 26, depending on the initial clinical severity and individual response to treatment.

Table 1. Clinical and sociodemographic profile of patients

Patient	Age (years)	Gender	Type of DM	Comorbidities	No. of ozone therapy sessions
1	63	Women	Type 2	Hypertension	9
2	49	Male	Type 2	Hypertension; Overweight	5
3	62	Male	Type 2	Hypertension; Overweight	3
4	92	Female	Type 2	Hypertension; Heart disease	10
5	65	Male	Type 2	Hypertension	9
6	44	Female	Type 1	Hypertension; Overweight	26
7	64	Female	Type 2	Hypertension	3

Table 2 shows the classification of each patient's lesions according to the Texas Scale, which assesses the degree of ulceration (0 = superficial lesion; I = skin tissue involvement; II = deep involvement; III = bone/joint involvement) and stage (A = no infection/ischemia; B = infection; C = ischemia; D = infection + ischemia). Most cases (5 of 7 patients) were classified as Grade II, Stage B, indicating deep ulcers with local infection (soft-tissue involvement) but without critical ischemia. Three patients (Nos. 2, 3, and 4) presented Grade III, Stage

D, implying the simultaneous presence of infection and ischemia; these cases were considered severe, with a high risk of requiring amputation.

Table 2. Classification of injuries according to the Texas Scale

Patient	Grade (Texas)	Stage (Texas)
1	II	B
2	III	D
3	III	D
4	III	D
5	II	B
6	II	B
7	II	B

Table 3 shows the evolution of ulcer healing status using the RESVECH 2.0 Scale, which gives an overall score from 0 (wound completely healed) to 35 (wound in deplorable condition). Six of the seven patients (86 %) achieved complete healing of their lesions, reaching a RESVECH score of 0 at the end of follow-up. Patient 2 obtained a final score of 9 and Patient 3 a score of 15; both corresponded to complex chronic lesions with slower evolution, which coincides with their more severe classification on the Texas Scale.[18]

Table 3. Evolution of lesions according to the RESVECH 2.0 Scale (final healing status and score)

Patient	Wound status	RESVECH 2.0 score (final)
1	Healed	0
2	Not healed	9
3	Not healed	15
4	Healed	0
5	Healed	0
6	Healed	0
7	Healed	0

Figure 1 shows the equipment used to administer ozone therapy in this study: a medical oxygen tank, an ozone generator, ozonated double-distilled water, and an *ozone bag* for topical applications. The ozone concentration used ranged from 5 to 60 µg/mL, in accordance with the therapeutic parameters described in the literature to ensure patient safety.[22]

Figure 1. Ozone therapy equipment used at the Foot Center (Asunción, Paraguay)

Figures 2, 3, and 4 illustrate the clinical progression of three representative cases. All of them show a photographic sequence from the initial presentation of the lesion to clinical resolution, evidencing the beneficial effects of ozone therapy as an adjunctive treatment. A notable reduction in necrotic tissue, the appearance of granulation tissue, and progression toward epithelialization were observed in the treated ulcers, supporting the quantitative findings described above.

Figure 2. Complete healing of plantar ulcer (Patient 1)

Foot Center, Asunción, Paraguay, 2023. Description: (a) Diabetic foot before starting treatment with ozone therapy. A fistula is observed in the region of the second to fifth metatarsals, with the presence of purulent secretion. (b) Surgical cleaning of the wound with opening and drainage of the abscess. (c) Intermediate evolution: presence of granulation tissue with well-defined edges of the ulcer. (d) Diabetic foot after 3 months of adjunctive treatment with ozone therapy. Signs of epithelialization and resolution of the lesion are observed.

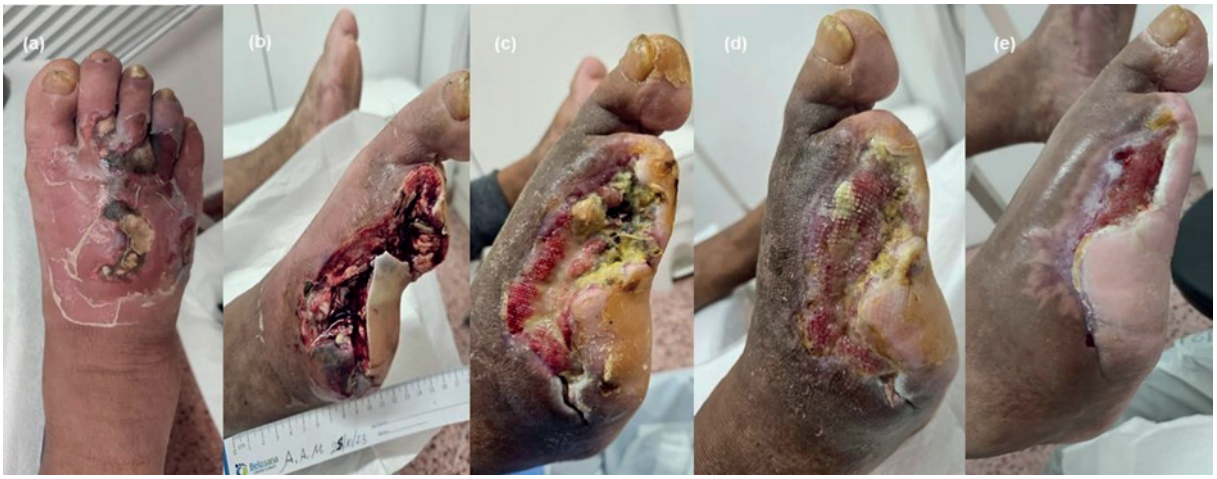

Figure 3. Significant improvement in ulcer with complications (Patient 2, history of amputation)

Figure 4. Complete healing in a 92-year-old patient (Patient 4)

Foot Center, Asunción, Paraguay, 2023. Description: (a) Diabetic foot lesion with marked signs of inflammation: presence of necrotic tissue and purulent secretion, with involvement of osteoarticular structures. (b) Surgical debridement with amputation of the second to fifth toes. (c) Early post-surgery: persistence of areas with infection and beginning of granulation tissue formation. (d) Repair phase: granulation tissue and progress of

epithelialization. (e) Lesion in the final phase of healing, with complete formation of epithelial tissue over the treated area.

Foot Center, Asunción, Paraguay, 2023. Description: (a) Diabetic foot at the start of ozone therapy treatment. Multiple lesions are observed on the toes of the right foot, with necrosis present on the big toe. (b) Initial surgical debridement of necrotic tissue. (c) Lesion in the final stage of healing after treatment. (d) Diabetic foot after 2 months of adjunctive treatment with ozone therapy. Signs of complete healing and resolution of the lesions are observed.

Additionally, table 4 summarizes the main characteristics of each patient and their therapeutic outcomes, including age, type of DM, clinical classification of the lesion (Texas), final score on the RESVECH 2.0 scale, number of ozone therapy sessions, total treatment time, and final healing status.

This analysis identified some relevant patterns: patients with less severe lesions (Texas II/B) who received a greater number of ozone sessions (more than nine sessions) achieved a higher proportion of complete healing. In contrast, those classified as Texas III/D, especially Patients 2 and 3, had fewer sessions and higher RESVECH 2.0 scores, reflecting a more limited clinical response in the period analyzed. Likewise, although the time of evolution of the lesions showed individual variability, a favorable trend was observed in those cases with good adherence to ozone therapy treatment, particularly in patients with less severe lesions.

Table 4. Demographic and clinical variables, treatment, and healing outcome for each patient

Patient	Age	Type of DM	Texas classification	Final RESVECH score	No. of sessions	Time (months)	Ulcer outcome
1	63	Type 2	II/B	0	9	3	Complete healing
2	49	Type 2	III/D	9	5	6	Partial healing
3	62	Type 2	III/D	15	3	4	Not healed
4	92	Type 2	III/D	0	10	2	Complete healing
5	65	Type 2	II/B	0	9	5	Complete healing
6	44	Type 1	II/B	0	26	13	Complete healing
7	64	Type 2	II/B	0	3	6	Complete healing

DISCUSSION

The objective of this study was to describe the effects of ozone therapy as an adjunctive treatment in the healing of diabetic foot ulcers in patients treated at the Foot Center in Asunción, Paraguay. This center has modern equipment for the safe and protocolized administration of medical ozone. Scientific literature has shown that ozone has antimicrobial and oxidative stress-modulating properties, contributing to local infection control, activating growth factors, and improving the tissue environment for healing.[2,13] According to the Madrid Declaration[22], the use of low therapeutic concentrations of ozone triggers significant biochemical responses at the cellular level, within safe margins.

The clinical and sociodemographic profile of the seven cases analyzed showed a predominance of older adults with long-standing type 2 diabetes mellitus, primarily women, and with multiple comorbidities. Hypertension was the most common comorbidity, followed by overweight and heart disease, which is consistent with well-established risk factors for the development and progression of ischemic and infectious lesions in the lower limbs.[2,4]

On average, nine ozone therapy sessions were administered per patient, with a treatment time of approximately 5,5 months. It was also identified that reduced mobility, poor therapeutic adherence, and poor metabolic control could negatively influence the evolution of some cases, consistent with the findings of Mandiola López et al., who identified these factors as determinants of clinical prognosis.[2]

Our findings are comparable to those of previous studies in the region. For example, a recent multicenter study by Carro et al.[12] in Argentina, involving 312 patients, reported a high prevalence of type 2 DM, hypertension, and overweight among those affected by diabetic foot, results similar to those observed in our series.[12] Similarly, a significant proportion of their patients had active infection and ischemia in the lesions, as evidenced in the cases classified as Texas III/D in our study. This reinforces the usefulness of the Texas Scale not only for stratifying ulcer severity but also as a guide for estimating the duration and complexity of the required adjuvant treatment. Indeed, in our series, patients with more severe lesions (Grade III, Stage D) required longer

recovery times and showed lower healing rates at the end of the observation period. This finding aligns with Stable's[20] description, which emphasizes that sustained hyperglycemia and tissue ischemia negatively affect the wound-healing process.

The objective assessment of clinical evolution using the RESVECH 2.0 Scale was instrumental, as it allowed the degree of healing to be quantified in a standardized manner. In our study, six of the seven patients achieved a final RESVECH score of 0, indicating complete healing. Similarly, Álvarez et al.[16] in Cuba reported that the addition of ozone therapy to conventional treatment resulted in improvements of more than 75 % over an average of 21 days, consistent with our results, which show a favorable evolution in most cases.

The treatment's beneficial effects were clinically evident across the classic phases of tissue repair (inflammation, proliferation, and remodeling/epithelialization), as documented in the follow-up images (figures 3–5). In particular, Patient 1 showed a remarkable response: after years of ulcer progression without improvement at other centers, the lesion completely resolved after nine ozone therapy sessions over 3 months. This improvement was likely facilitated by mechanisms such as neoangiogenesis, infection control, and modulation of oxidative stress, as suggested by Belo et al.[21] in their study on ozone therapy for refractory ulcers.

Although the results obtained are encouraging and consistent with the available literature, they should be interpreted with caution. The main limitations of this study include:

- Small sample size: only 7 cases were analyzed, which prevents robust statistical inferences or generalizing the findings to the entire population with diabetic foot.
- Descriptive and retrospective design: as there was no randomization or control group, it is not possible to establish direct causal relationships (as warned by Sampieri et al. for exploratory studies.[23]
- Potential information biases: derived from the variable quality and completeness of retrospective clinical records, which could influence the evaluation of results.

Despite these limitations, our findings are consistent with multiple previous studies that support the use of ozone therapy as a safe and potentially effective complementary intervention in the management of diabetic foot. In Cuba, for example, Álvarez et al. proposed using ozone as an adjunct to conventional antibiotic therapy.[16] In Brazil, ozone therapy was incorporated into the National Policy on Integrative Practices of the SUS in 2018, reinforcing its therapeutic relevance in complex clinical contexts.[2] This background, together with our results, suggests that ozone therapy may offer additional benefits in the healing of diabetic ulcers, provided it is used in a protocolized manner and as a complement to standard care.

CONCLUSIONS

Through this series of cases, preliminary observations were documented on the possible effects of ozone therapy as an adjunctive treatment in the healing of diabetic foot lesions. In patients treated at the Foot Center in 2023, a favorable trend in clinical evolution was identified, particularly in those with less advanced lesions and greater adherence to the proposed therapeutic protocol.

Although the number of cases included was limited and the methodological design does not allow for establishing causality or generalizing the findings, the descriptive results are consistent with international evidence on the potential benefits of ozone therapy in this clinical context. There is a clear need for further research, preferably with experimental or quasi-experimental designs, larger samples, and rigorous control of relevant clinical variables. Future studies of this type will allow for more robust validation of the efficacy of ozone therapy as a complement to conventional treatment of diabetic foot. They could facilitate its incorporation into national therapeutic guidelines if its benefits are confirmed.

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FINANCING

The authors did not receive funding for the development of this research.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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