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CASE REPORT

Potent Antimicrobial properties of a Biodegradable Medical Device in the treatment of Diabetic Foot

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ABSTRACT

There is an urgent need for effective antimicrobial agents to treat infected diabetic foot ulcers (DFUs), which are associated with debilitating symptoms, high rates of amputation, long-term disability, elevated mortality, and significant healthcare costs. This need is even more critical in the era of increasing antimicrobial resistance (AMR). Recent IWGDF/IDSA international guidelines recommend "avoiding antibiotics unless there is confirmed bacterial infection and demonstrated susceptibility to the prescribed agents."

Introduction:

According to the U.S. Centers for Disease Control and Prevention (CDC), over 12% of U.S. adults are affected by type 2 diabetes (T2DM), and more than one-third of adults are obese or prediabetic.[1] Treatment outcomes for diabetic foot (DF) are frequently poor due to neuropathy, impaired healing, immune dysfunction, vascular insufficiency, and renal complications. In low- and middle-income countries, delays in accessing specialized care further compromise multidisciplinary management.[2]

Methods:

Over the past several years, the antimicrobial efficacy of a non-antibiotic, non-toxic topical medical device — CPZO (Carbohydrate Polymer with Zinc Oxide, Pebisut®) — has been demonstrated through in vitro and in vivo preclinical studies in rodent models at the Experimental Laboratory of Anahuac University.[3] Clinical trials in adult patients with chronic venous ulcers at Juarez Hospital of Mexico have also shown promising outcomes.[4]

The formulation demonstrated potent antimicrobial and anti-inflammatory effects, even against multidrug-resistant bacterial strains.[5-7]

Further microbiological evaluation was performed at the National School of Biological Sciences (ENCB-IPN), assessing CPZO's bactericidal activity against three biofilm-forming bacteria: methicillin-resistant *Staphylococcus aureus* (MRSA), *Escherichia coli*, and *Pseudomonas aeruginosa*, using bacterial suspension, biofilm disruption, and an in vitro wound biofilm model.[7] Separate studies at Juarez Hospital also evaluated the product's efficacy against MRSA and *P. aeruginosa*.[7]

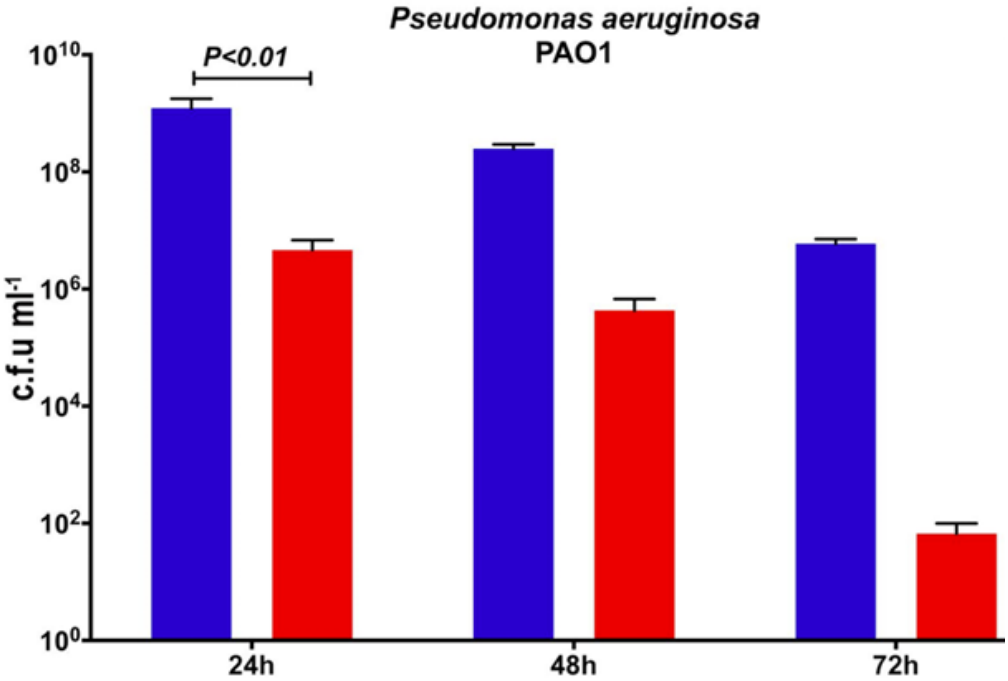


Figure 1. In vivo bacteriological results of CPZO vs. Pseudomonas aeruginosa.
Adapted from Bello-Lopez, et al., 2020. In Vitro Bactericidal Activity of a Carbohydrate Polymer with Zinc Oxide for the Treatment of Chronic Wounds. J Med Microbiol. 2020;69(5):874-880. (Red column: Pseudomonas growth. Blue column: control).

Results:

In rodent studies, both acute and chronic models showed that CPZO was well tolerated and fully resorbed within 6 days.[3] In clinical trials involving patients with venous ulcers, diabetes, obesity, and hypertension, no adverse effects were observed. Within 3–5 days of topical CPZO application, patients reported resolution of pain, burning, exudate, and insomnia.[4-7]

Subsequently, 102 patients with advanced DFUs were treated across four hospitals, including emergency admissions. Most patients showed significant improvement or complete healing. Surgical intervention was required in a limited number of cases: two above-the-knee, four below-the-knee, four transmetatarsal amputations, and 25 toe excisions. Importantly, no patient mortality was recorded.

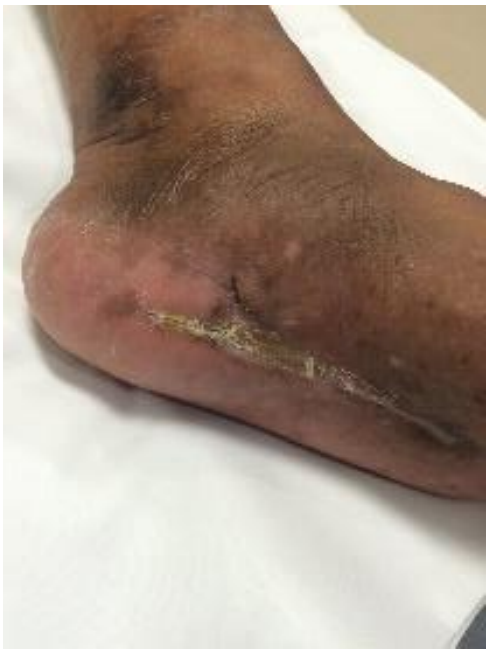


Figure 2. Male patient treated elsewhere initially, 56 y.o., DM2.

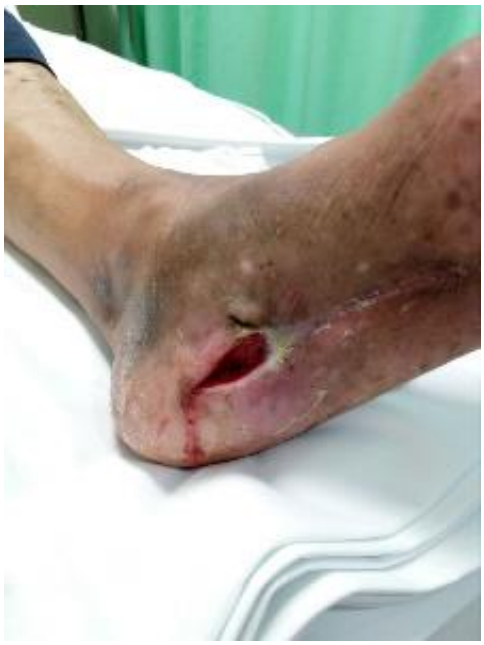


Figure 3. Complete wound healing in 7 weeks.

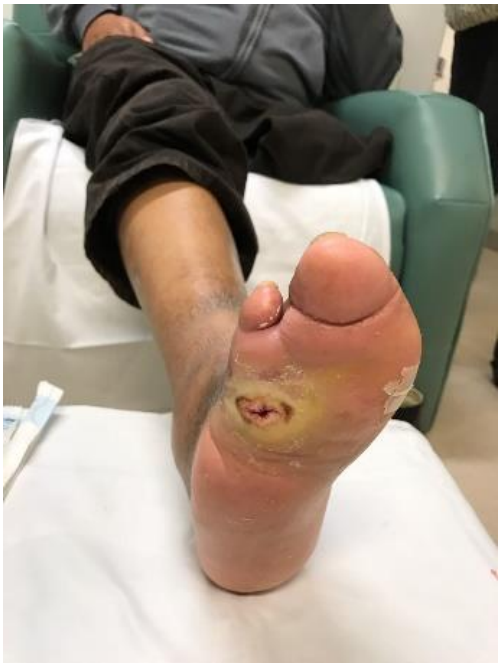


Figure 4. Male patient, 37 y.o., DM2 treated elsewhere initially.

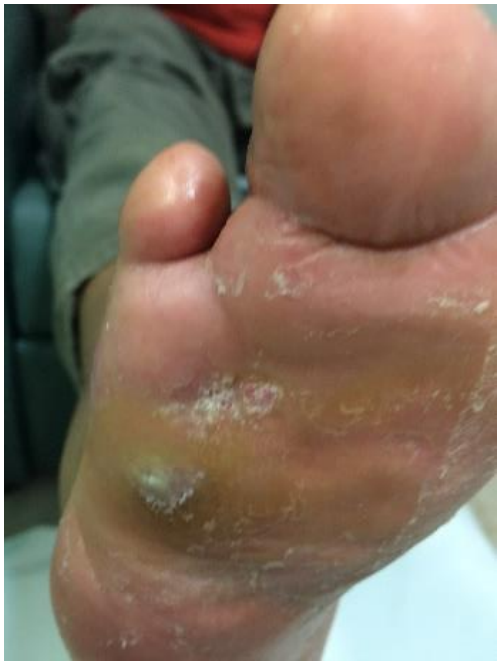


Figure 5. Foot ulcer healing was achieved in 8 weeks.

Discussion:

CPZO is environmentally friendly, requires no refrigeration, and has shown no evidence of toxicity or inflammation in animal studies.[3,5,6] Histological analysis revealed no signs of acute or chronic inflammation or infection. In clinical trials, no adverse effects were noted, and CPZO significantly accelerated healing in chronic venous ulcers compared to control groups.[4]

Since its approval for clinical use over six years ago, CPZO has been adopted by public and private healthcare institutions in Mexico, including the ISSSTE, with no reports of toxicity, allergy, or adverse reactions.

The morbidity and mortality associated with diabetes and DFUs continue to rise, possibly due to increased life expectancy and childhood obesity. Global obesity rates have more than doubled in adults and quadrupled in adolescents since 1990.[11,12]

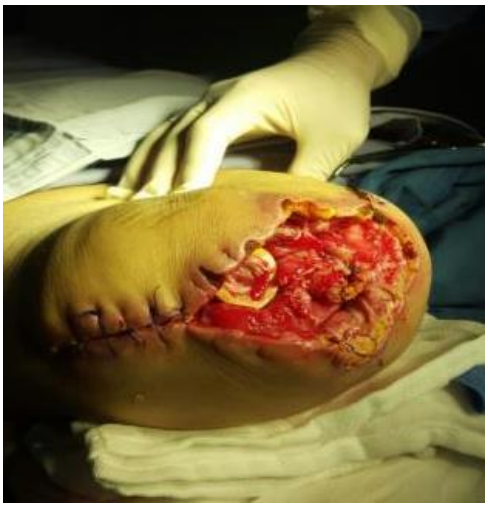


Figure 6. Male patient, 68 y. o., DM2, treated elsewhere for diabetic foot, very complicated, 3 previous amputations failed.

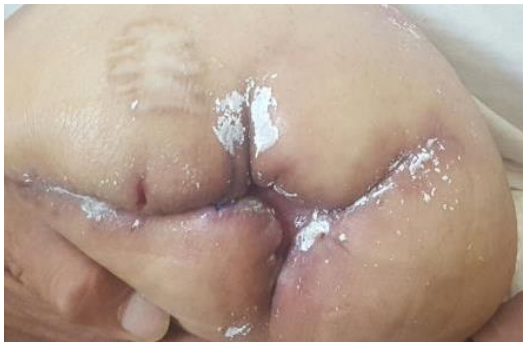


Figure 7. Rx. healing occurred 28 days after treatment with CPZO.Our Group received an emergency call requesting immediate delivery of 12 jars of CPZO to be sent to a mountain clinic in Jalisco area.

Extensive research by Moreno et al. confirmed CPZO's anti-inflammatory activity in rodent models, including reduced cytokine release and histological evidence of healing.[3] These findings correlate with the rapid clinical improvement observed in patients, typically within 3–4 days of application.[4]

Although other studies have shown that maltodextrins and zinc possess antimicrobial effects,[13,14] the most comprehensive evidence comes from the work of Bello-López et al. and Aparicio et al.,[7] demonstrating CPZO's potent bactericidal action against MRSA and P. aeruginosa in both experimental models and clinical settings, without toxicity.

These results are especially relevant given the global threat of AMR. According to the WHO, antimicrobial resistance contributed to 4.95 million deaths in 2019.[16]

The 2023 IWGDF/IDSA guidelines emphasized prudent antibiotic use, reinforcing the importance of alternative therapies such as CPZO.[15]

Conclusion

CPZO demonstrates potent bactericidal and anti-inflammatory properties without toxicity, offering a promising first-line treatment for DFUs, venous ulcers, and other complex chronic wounds. Its ability to prevent and control infections while accelerating healing makes it a valuable asset in managing difficult-to-treat lesions.

Case Report (Juarez Hospital).

M, 58 y.o. with T2DM, cellulitis, and a fistula extending from the dorsum to the sole of the foot. After 8 months of unsuccessful treatment, the patient was scheduled for infra-condylar amputation.

(Figures 8 and 8.2).

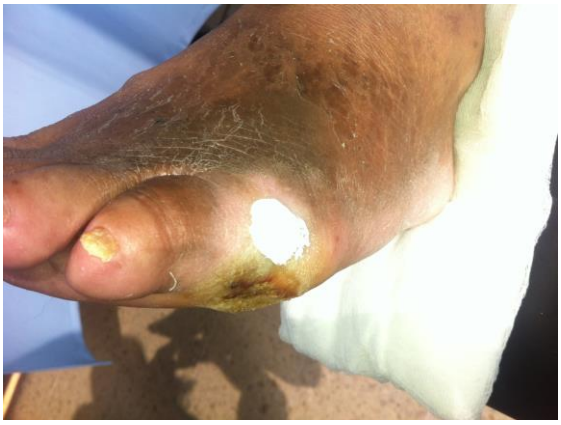
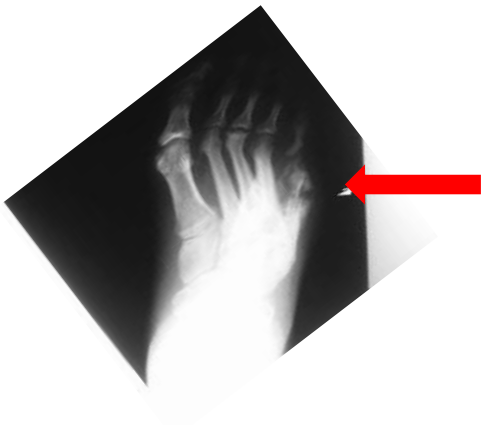


Fig. 8



Osteomyelitis.

Fig. 8.2

Treatment: Topical CPZO
Outcome after 72 days: Complete healing, (figures 9 and 9.2).

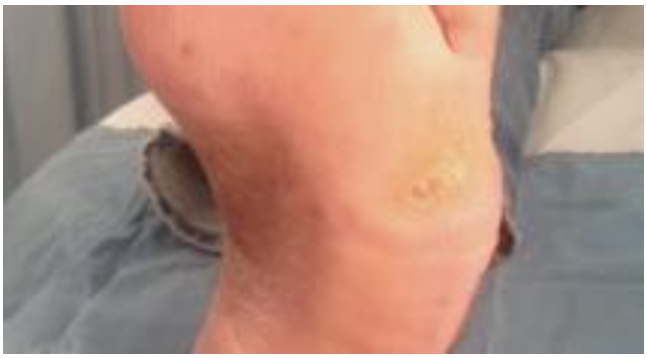


Fig. 9

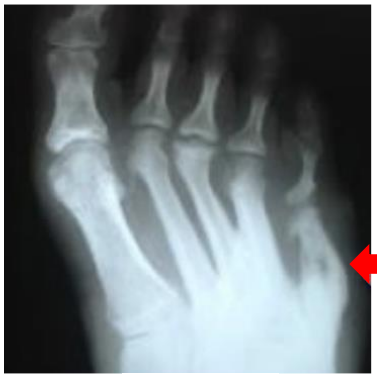


Fig. 9.2

Conflict of Interest:

Author J. Cueto holds patents related to the external application of CPZO described in this study. The remaining authors declare no conflicts of interest.

Patents: USPTO #8,252,333 and #9,808,484;Canadian #2,661,686 and #2,926,115; European #2,062,602; Mexican #280,754 and #350080.

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