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Case Study

Clinical Case Studies in Managing Diabetic Foot Ulcers by Using Stabilised Hypochlorous Acid Wound Cleaning and Irrigation Solution

Gurmeet Singh A/L Sewa Singh[1*], Narinder Singh A/L Joginder Singh[2], Muhammad Hanif Bin Mahamad[3], Ravindraa A/L Thaigaraja[3], Pavethiran Pillai A/L Nallamuthu[3]

[1]*Department of Orthopedics, Hospital Seberang Jaya (HSJ), Seberang Jaya, 13700 Perai, Pulau Pinang, Malaysia*

[2]*Department of Wound Care, Hospital Seberang Jaya (HSJ), Seberang Jaya, 13700 Perai, Pulau Pinang, Malaysia*

[3]*Hospital Seberang Jaya (HSJ), Seberang Jaya, 13700 Perai, Pulau Pinang, Malaysia*

[*]*Corresponding Author's Email: gurmeet1968@moh.gov.my*

Abstract

Diabetic foot ulcers (DFUs) are an increasingly health concern and pose a significant burden on healthcare providers and patients equally. Managing this chronic wound needs to take into consideration the choice of wound care solution that is not only effective but also provides a safe healing environment without causing any adverse effects on healing tissues. This case series focuses on the use of stabilized super-oxidised hypochlorous acid in wound cleaning, debridement and irrigation in the managing of DFUs and assessing of the wound healing progress. A total of three patients with diabetic foot ulcer were subjected to wound cleansing using stabilised super- oxidised hypochlorous acid solution throughout the study period, detailing wound progression, treatment protocols, and healing outcomes. Results show that the use of stabilised HOCl (Hypochlorous acid) wound irrigation solution prevented risk of infection in these chronic wounds thus allowing natural wound healing to take place without any adverse effects. These findings support the integration of HOCl-based wound care into standard DFU treatment practices. Adherence to follow-up care and complete wound management strategies is crucial, and the positive outcome seen in these cases highlights the potential relevance of stabilised super-oxidised HOCl wound cleaning solution in the management of diabetic foot ulcers.

Keywords: *Attitude; Cone Beam Computed Tomography; Dental Students; Knowledge*

Introduction

Diabetic foot ulcer is a breakdown of the skin and sometimes deeper tissues of the foot that lead to sore formation. It is thought to occur due to abnormal pressure or mechanical stress chronically applied to the foot, usually with concomitant predisposing conditions such as peripheral sensory neuropathy, peripheral motor neuropathy, autonomic neuropathy or peripheral arterial disease. It is a major complication of diabetes mellitus, and it is a type of diabetic foot disease. Secondary complications to the ulcer, such as infection of the skin or subcutaneous tissue, bone infection, gangrene or sepsis are possible, often leading to amputation. The International Diabetes Foundation estimates that 40 million

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to 60 million people globally are affected by DFU, a marked increase from 2015 estimates that ranged from 9 million to 26 million. Like incidence, prevalence estimates vary widely and are influenced by differences in definitions of DFU, the approach to surveillance, completeness of follow-up, and the definition of and approach to defining diabetes. A recent meta-analysis found a 6.3% global prevalence of DFU among adults with diabetes, which equates to approximately 33 million people affected by DFU (McDermott et al., 2023). In Malaysia, National Diabetes Registry reports that 1.2% of the diabetic patients have diabetic foot ulcers and 0.9% of them have previous amputations (Ministry of Health Malaysia, 2014). This is lower than the estimated 15-25% of diabetic patients having diabetic foot ulcers and 4.3% of diabetic patients having had lower leg amputations.

Various types of wound cleansing solution are being used worldwide, which includes conventional solutions such as povidone iodine, hydrogen peroxide, saline, and modern wound cleansing solutions such as super-oxidised HOCl solution, PHMB, octenidine dihydrochloride and silver-based solution. However, despite having antimicrobial efficacy claims, many of these solutions are known to have certain limitations on their safety profiles. This is primarily because certain wound cleansing solutions are known to be associated with toxicity and irritation towards normal healing tissues (Wolcott & Fletcher, 2008). Therefore, it is imperative that any choice of wound cleansing solution needs to be selected on its clinical safety first prior to determining antimicrobial efficacy as any solution that poses risk to healing tissue may impair wound healing (Britto et al., 2024).

Hypochlorous acid (HOCl) – Mode of action and microbiological data

Hypochlorous acid is a weak acid that is naturally produced by white blood cells (neutrophils) and is an essential part of the immune system. Neutrophils, a subset of white blood cells, produce hypochlorous acid (HOCl) through a mechanism known as the respiratory burst in the human body. HOCl is released from activated leukocytes via a hemi enzyme, myeloperoxidase (MPO), which generates HOCl from hydrogen peroxide and chloride, O2 →→ H2O2 +Cl- → HOCl. Therefore, HOCl has an important function in the innate immune response (Natarelli et al., 2022).

Upon contact with microbes, neutrophils release a burst of bactericidal substance including its most powerful oxidising agent HOCl that disrupts the cell wall of microbes. The neutral hypochlorous acid attacks the negatively charged cell wall of the microorganism and increases its permeability. A hypotonic solution causes water to flow into the cells to equalise the osmotic gradient. This leads to osmosis; the increasing internal pressure causes the cell to burst which kills the microbe (da Cruz Nizer, Inkovskiy & Overhage, 2020). Generation of this similar HOCl for wound care applications, are done using electrolysis process of purified water and purified salt.

Because of its antibacterial properties and ability to encourage wound healing while being safe for wounds, it has been extensively researched and utilised in wound care (Wang et al., 2007). Hypochlorous acid possesses antibacterial properties against a variety of pathogens, such as bacteria, fungi, and viruses. When administered topically, it is expected to have no adverse effect towards healthy cells since HOCl is produced endogenously in mammalian cells. Antimicrobial studies conducted via in- vitro study using ASTM E2315 Standard Guide for Assessment of Antimicrobial Activity using a Time-Kill Procedure, (Report no.: R (RD) 026-24). It is an in-vitro test consists of directly inoculating the product with a high concentration of test microorganisms and then determining the percentage killed over time. The time kills results on common microbes found in wound shows when exposed to super-oxidised solution, ranges from 99.9999% within 1 minute for bacteria and 99% within 3 minutes for fungi and yeast (Table 1).

Table 1: The Exposure Time and Percentage Reduction of Test Microorganisms

Test Microorganism	Exposure Time (minute)	Percentage Reduction (%)
Escherichia coli ATCC 8739	1 minute	99.9999
Salmonella typhimurium ATCC 140028	1 minute	99.9999
Staphylococcus aureus ATCC 6538	1 minute	99.9999
Methicillin resistant *Staphylococcus aureus* ATCC 33592 (MRSA)	1 minute	99.9999
Klebsiella pneumoniae ATCC 700603	1 minute	99.9999
Pseudomonas aeruginosa ATCC 9027	1 minute	99.9999
Enterococcus faecalis ATCC 29212	1 minute	99.9999
Bacillus subtilis ATCC 6633	1 minute	99.9999
Aspergillus niger ATCC 16404	3 minutes	99.0000
Candida albicans ATCC 10231	3 minutes	99.0000

In a 2016 study published in the National Library of Medicine, researchers compared the efficacy of hypochlorous acid and sterile saline as debridement solutions in chronic wound treatment. Researchers concluded that while both solutions initially reduced the bacterial count present in the wounds, by the time of definitive closure, the saline-irrigated wounds had bacterial counts back up to 10^4 whereas the HOCl–irrigated wounds remained at 10^2 or lower (Robson et al., 2007). Hypochlorous acid (HOCl) emerges as a powerful conjunctive therapy in the treatment of diabetic foot ulcers, and related multi-drug-resistant pathogens due to its balance between safety and efficacy. Moreover, HOCl demonstrates inflammation modulation, which aids in the wound healing process (Roos, 2022). Hypochlorous acid appears to be a safe component of wound care for a wide range of dermal lesions, Including chronic non-healing wounds. The Application states that there are no reports of adverse reactions to topical applications by these methods based on the US EPA's Toxicology Database DSSTox, the US CDC Toxic Substances and Disease Registry, nor at either the Development and Reproductive Toxicology Database, or the European Bioinformatics Institute of EMBL. Studies on humans or animals did not report biological toxicity or toxicity due to inhalation or irritation or other types of toxicity. In terms of safety and toxicity owing to the potential direct contact with ocular, skin and respiratory systems, stabilised hypochlorous acid has been found to be non- irritating and non-sensitizing (WHO, 2025).

Management of Diabetic Foot Ulcer

Diabetic neuropathy and vascular disease are known to be common risk factors for DFU formation. These conditions impede the healing process and raise the possibility that wounds will become chronic. Infection and biofilms can also affect the speed at which wounds heal. Microbes that cause disease penetrate bodily tissues and cause infection. An increased risk of hospitalisation and poor clinical outcomes, such as an increased risk of lower-extremity amputation, a decreased quality of life, and an increased risk of mortality, are often linked to diabetic foot infection. Thus, it's critical to avoid infections or, in the case that they do occur, to treat them promptly. Infection is one of the important factors that delay wound healing, thus good wound care is critical for normal wound healing. Hypochlorous acid is a relatively new alternative to conventional cleansing solutions such as standard saline solutions, hydrogen peroxide and povidone-iodine for wound irrigation and managing complex, hard-to-heal wounds. Its unique mechanism of action, which includes both bactericidal and anti-inflammatory effects, makes it an effective solution for wound management (Armstrong et al., 2015). Effective wound care for individuals with diabetes requires an antiseptic and wound dressing regimen that not only fights infection but is also non-toxic to cells and promotes healing.

Methodology

This clinical case series evaluated the use of commercially available stabilized super oxidised hypochlorous acid (HOCl) solution (ELECTROCYN Soma, manufactured by V3Bio), an electro-activated water-based solution (EASW), for wound cleansing, irrigation, and debridement. Gauze was used as a secondary dressing in all cases. Patients were selected according to specific inclusion criteria, and the progression of wound healing was monitored throughout the treatment period. Patients eligible for the study must provide written informed consent and be aged between 18 and 70 years, physically comfortable without significant pain, and able to comply with weekly or monthly clinic visits. They should have diabetic foot ulcers classified as Grade 1 to Grade 3, according to the University of Texas Wound Classification System (Stages A or B), with a wound surface area ≤ 75 cm² suitable for coverage with a 10 cm × 10 cm dressing. Exclusion criteria include wounds exceeding 75 cm², significant comorbidities such as congestive cardiac failure, renal failure, or fulminant hepatic failure, or a current or past diagnosis of malignancy, regardless of remission status. Patients participating in another clinical trial or those unwilling or unable to provide informed consent will also be excluded. Wound photographs were taken at various stages to document the healing process. Wound assessment followed the TIME framework—Tissue, Infection/Inflammation, Moisture balance, and Edges/Epithelial advancement which is a well know tool for wound assessment. Tissue was categorised based on colour: epithelial tissue (pink or pearly white), granulating tissue (red and moist), slough (yellow, brown, or grey), and necrotic tissue (black and dry). Infection and inflammation were monitored, as these factors can impede healing. Moisture balance was carefully managed, as both excessive exudate and insufficient moisture can adversely affect healing outcomes.

The wound dressing procedure adhered to a standardised protocol. Dressing changes were performed every other day, with weekly follow-up assessments. Initially, the old dressing was removed, and the wound was cleansed with the super-oxidised HOCl wound cleaning solution. Gauze was soaked in the solution and placed onto the wound for approximately 10 -15 minutes to facilitate the softening and removal of necrotic tissue. The soaking time also allows longer antimicrobial exposure to reduce wound bed bioburden. Once the wound has been cleansed, a secondary gauze dressing was applied to cover the wound. All dressing procedures commenced with thorough hand hygiene, followed by preparation of sterile supplies, including gloves, ELECTROCYN soma solution, gauze pads, and securing materials. The wound was cleansed with super-oxidised HOCl wound cleaning solution, avoiding direct scrubbing to prevent tissue damage. Any visible debris or dried blood was gently removed with gauze, being careful not to damage healthy tissue. Wound inspection was conducted to detect signs of infection, such as erythema, swelling, or discharge. In the presence of any concerning symptoms, medical intervention was sought.

Wound healing was regularly monitored using the TIME framework, with particular attention paid to the edges of the wound, which were observed for signs of epithelial advancement. Advancing wound edges were characterised by pink tissue, indicative of healing, while non- advancing edges were marked by raised, rolled, or discoloured tissue. Pain assessment was also conducted before, during, and after each dressing change, as pain may reflect complications or insufficient wound management. Once the wound was adequately cleansed, a thin layer of hydrogel was applied to maintain hydration for the wound, prior to securing the wound with dressing. Wound rulers have been used in these cases to measure and monitor the wound surface area till the final week. Dressing changes were scheduled according to clinical guidelines or whenever the dressing became wet or soiled. The wound photos were taken using a mobile camera throughout the treatment period for observation purposes. Throughout the wound healing period, ongoing monitoring ensured timely detection of any signs of infection or complications, with appropriate adjustments made to the treatment regimen as needed.

Result

Clinical Findings and Patient Information

This case study series consists of three cases of diabetic foot ulcer which used a stabilised super oxidised hypochlorous acid based wound cleaning solution to treat the wound. All the three cases achieved positive results in the wound healing process with no signs of infections or adverse effects reported to the patients.

Case 1

Patient Age: 54 Patient Sex: Female

Underlying Disease (if any): Diabetes Mellitus Type II

Type of wound: Diabetic Foot Ulcer over Right Foot: Post Wound Debridement

The patient is a 54-year-old female with a medical history notable for diabetes mellitus, hypertension, and bronchial asthma. She presented with a puncture wound after allegedly stepping on a nail. Following the trauma, she developed swelling in the right calcaneal area. An initial incision and drainage procedure was performed; however, the wound deteriorated, as noted during a follow-up on October 5, 2023. Subsequently, she was admitted to the ward on the same day for further surgical intervention. Presence of pus discharge in calcaneal area. Warmth and erythema. Tenderness upon palpation. The patient was diagnosed with a right infected diabetic foot ulcer and underwent surgical wound debridement in the right calcaneal area. The patient received advanced wound management, which includes cleansing with super oxidised HOCl solution. She was monitored under the care of the wound team from week 1 to week 19. During this follow-up period, the wound exhibited significant improvement in terms of absence of infection and rapid reduction in wound size, ultimately achieving complete wound closure by the time of discharge (Table 2, Figure 1).

Table 2: Case 1, Diabetic Foot Ulcer over Right Foot: Post Wound Debridement

			
Week 1	Week 8	Week 12	Week 19
Wound Size: **56.0 cm^2**	Wound Size: **25.4 cm^2**	Wound Size: **13.3 cm^2**	Wound Size: **0**

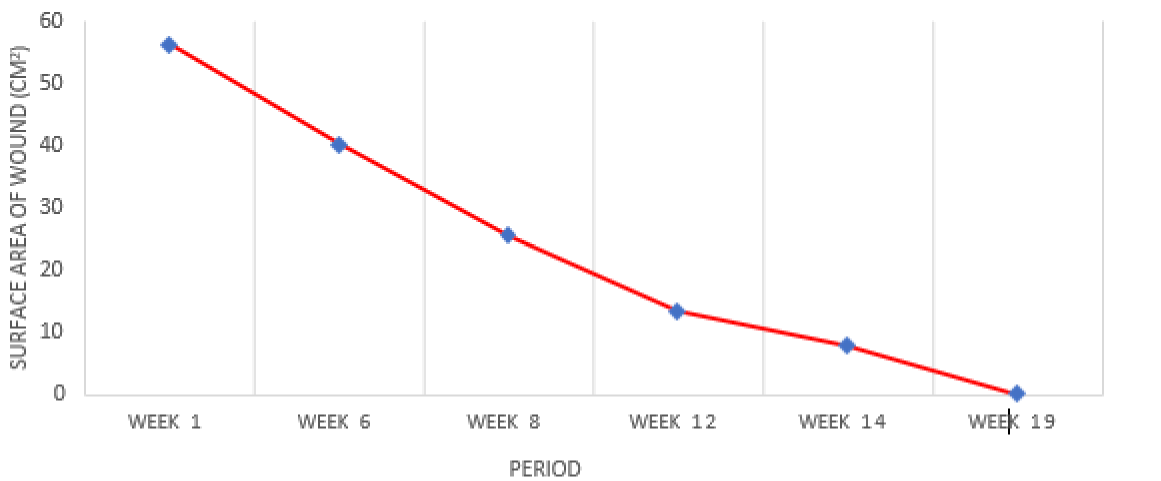

Figure 1: Wound Surface Area Monitoring Chart for Case 1

Case 2

Patient Age: 49

Patient Sex: Male

Underlying Disease (if any): Diabetes Mellitus Type II

Type of wound: Right Below Knee Amputation complicated with Wound Breakdown

The patient is a 48-year-old male with a medical history significant for diabetes mellitus and hypertension. The patient was diagnosed with an infected diabetic foot ulcer and left midfoot Charcot neuroarthropathy. Nine years prior, he underwent incision and drainage for a right foot plantar abscess at HPP. In 2021, he was presented with a diabetic foot ulcer on the right big toe, which progressed to impending necrotising fasciitis. As a result, he underwent disarticulation of the right big toe; however, the wound subsequently became infected. On September 14, 2023, the patient was presented with an infected wound over the left ankle, accompanied by deformity. Clinical examination revealed a wound over the left lateral malleolus measuring 3x3 cm, exposing subcutaneous tissue with serous discharge. The dorsalis pedis artery (DPA) and posterior tibial artery (PTA) were not palpable, though sensory function in the foot remained intact. Considering the infected wound and Charcot neuroarthropathy, the patient underwent a right below-knee amputation in 2023. Following the surgical procedure, he experienced complications related to stump breakdown. The case was subsequently referred to the wound care team on October 17, 2023. The patient received advanced wound management, which included cleansing with super-oxidised HOCl wound cleaning solution. The patient was monitored under the care of the wound team from week 1 to week 9. During this follow-up period, the wound exhibited significant improvement in terms of absence of infection and rapid reduction in wound size, ultimately achieving complete closure by the time of discharge (Table 3, Figure 2).

Table 3: Case 2, Right Below Knee Amputation complicated with Wound Breakdown

			
Week 1	Week 5	Week 7	Week 9
Wound Size: **18.2 cm²**	Wound Size: **17.0 cm²**	Wound Size: **0.3 cm²**	Wound Size: **0**

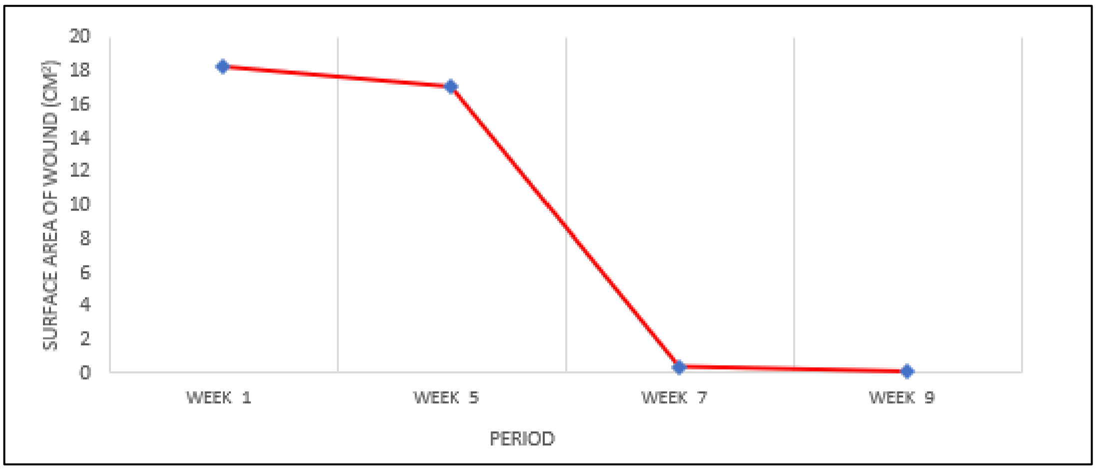

Figure 2: Wound Surface Area Monitoring Chart for Case 2

Case 3

Patient Age: 38

Patient Sex: Male

Underlying Disease (if any): Diabetes Mellitus

Type of wound: Post surgery extensive wound debridement and 3rd, 4th toe ray amputation for Right foot neurofibromatosis

A 38-year-old Malay gentleman with a documented history of diabetes mellitus was presented to the emergency department with right foot wounds that had persisted for three weeks. He reported a progressive enlargement of the wounds, accompanied by purulent discharge and a notably foul odour. The onset of fever on January 30, 2024, prompted his visit. Prior to this presentation, the patient had been under the care of a general practitioner. Upon examination, the patient's vital signs were stable. A comprehensive assessment of the right foot revealed a necrotic wound on the plantar aspect, measuring approximately 2x2 cm, characterised by foul-smelling purulent discharge and crepitus noted over the dorsal surface. Capillary refill time for all toes was less than 2 seconds, indicating adequate perfusion, while intact distal pulses suggested preserved arterial flow. The patient was subsequently admitted for further management and underwent surgical interventions on February 2 and February 6, 2024, aimed at debridement and management of the infected tissue. Following these procedures, he was discharged with detailed instructions for wound care and scheduled for follow-up at a specialised wound clinic. In the wound clinic, the patient received a comprehensive treatment regimen, including electrosurgical management utilising the super-oxidised HOCl wound cleaning solution. Regular follow-up appointments were conducted from week 1 to week 14, during which the wound exhibited significant improvement. By the final follow-up appointment, the wound had completely healed, resulting in the patient's discharge from the clinic with recommendations for continued monitoring and management of his diabetes. This case highlights the complexities inherent in managing diabetic foot infections and the necessity for prompt surgical intervention in conjunction with comprehensive wound care. The integration of the super-oxidised HOCl wound cleaning solution into the wound management protocol demonstrated notable benefits, including enhanced healing, preventing infections, and the maintenance of an optimal wound environment, all of which contributed to a positive clinical outcome (Table 4, Figure 3).

Table 4: Case 3, Post surgery extensive wound debridement+ 3rd, 4th toe ray amputation for Right foot neurofibromatosis

			
Week 1	Week 8	Week 12	Week 14
Wound Size: **50.0 cm^2**	Wound Size: **9.12 cm^2**	Wound Size: **1.92 cm^2**	Wound Size: **0**

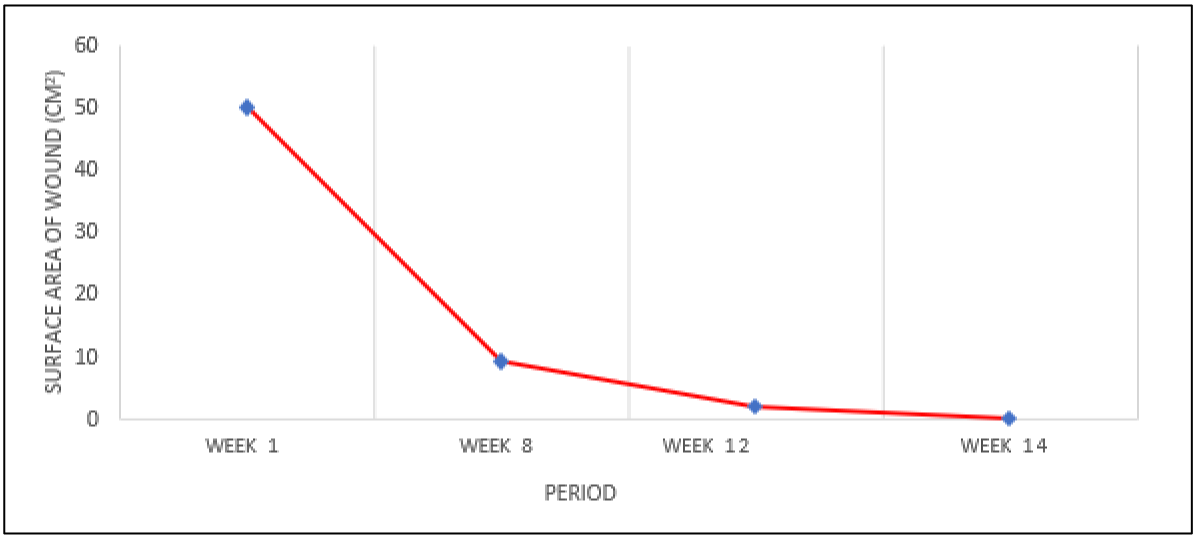

Figure 3: Wound Surface Area Monitoring Chart for Case 3

Discussion

These case studies highlight the potential of stabilised super-oxidised HOCl wound cleaning solution in treating DFUs effectively, while promoting stronger patient outcomes through continued care and medical monitoring. This approach could potentially save time and cost, and most importantly, may improve patient treatment compliance and overall quality of life. The stabilised super-oxidised HOCl wound cleaning solution which has been used in these cases helped in the healing of wound efficiently. Using this stabilised form of HOCl, the potent antimicrobial activities of HOCl are demonstrated against a wide range of microorganisms.

Chronic wound healing is primarily impeded by biofilm, which creates a physical barrier to bacteria from the surrounding environment, facilitates bacterial communication, increasing virulence and antibiotic resistance, and shields bacteria from immune recognition (Wolcott & Fletcher, 2008). It was observed that throughout the study, no biofilm was observed in any of the cases. Time kill is an in vitro measure of how fast a given antimicrobial can kill test bacteria. Based on a report on the efficacy of HOCl against biofilm from *Pseudomonas aeruginosa* in a contact time of 15 minutes, it was possible to obtain a long 2.3 reduction against *Pseudomonas aeruginosa* biofilm, which corresponds to a reduction of 99.4% (Report no.: R (RD) 026-24). This shows that the super-oxidised HOCl wound cleaning solution is effective in preventing the formation of biofilm. By eliminating bacteria that are accumulating on wounds the use of super-oxidised HOCl wound cleaning solution as a cleansing agent in wound care can reduce the rate of bacterial accumulation and lowering wound bed bioburden (Robson et.al, 2007).

On the safety aspects, the patients in this study had also reported that they had very minimal or no irritation upon applying super-oxidised HOCl wound cleaning solution on the wound. As per the ISO 10993- Biocompatibility testing of medical devices, the biocompatible and neutral nature of this super-oxidised HOCl wound cleaning solution played a significant role in ensuring no irritation after application and toxicity towards sensitive or healing tissues. This will be a crucial point to take note of, especially when dealing with chronic wounds that normally require prolonged treatment.

These three cases highlight the importance of timely intervention and the role of the super- oxidised HOCl wound cleaning solution in managing diabetic foot ulcers. The positive outcomes observed suggest its efficacy as a part of a comprehensive wound care protocol. Continued patient adherence to follow-up appointments is crucial for sustaining these healing outcomes. The successful application of super-oxidised HOCl wound cleaning solution in these instances suggests its potential as a valuable adjunctive therapy in the treatment of diabetic foot ulcers.

Conclusion

The positive outcomes observed in this case series underscore the clinical potential of stabilised super-oxidised hypochlorous acid (HOCl) wound cleaning solution in the effective management of diabetic foot ulcers (DFUs). The solution demonstrated notable antimicrobial activity, excellent biocompatibility, and significant enhancement in wound healing outcomes without causing irritation or cytotoxic effects to surround tissues. Its inclusion as a standard component in wound management protocols could improve patient compliance, reduce infection rates, and lower the burden of chronic wound care on healthcare systems. Future research should focus on conducting large-scale, randomised controlled trials to further validate the efficacy and safety of stabilised HOCl in diverse patient populations and various clinical settings. Comparative studies with other modern wound care agents can provide deeper insights into cost-effectiveness and clinical outcomes. Additionally, investigating its potential in treating other types of chronic wounds such as pressure ulcers, venous leg ulcers, and surgical site infections may broaden its applicability. Exploring the molecular mechanisms behind its anti-inflammatory and tissue-regenerative properties could also unlock new therapeutic pathways in wound care and tissue repair.

Conflict of Interest

The authors declare that there has no conflict of interest.

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