

Effect of ceramic dressings and silver-impregnated dressings on bacterial load and wound closure: a comparative study

Abstract: Wound healing is a series of complex and dynamic processes which occur in several stages. Optimal wound healing is essential for restoring the integrity and function of the affected area. Although medicated wound dressings have been extensively employed to control wound infection, the risks associated with antimicrobials make the use of non-medicated alternatives necessary. Nevertheless, the relationship between the concentrations of medicated wound dressings and their antimicrobial activities, along with their wound healing efficacies, still remains unclear. Non-medicated wound dressings are an alternative to dressings that contain active ingredients acting as antimicrobials or antiseptics. In the present study, the researchers examined the reduction of bacterial load as the primary endpoint and the healing rate as the secondary endpoint, comparing microporous ceramic dressings to silver-impregnated dressings in participants from two outpatient wound management clinics. The study included 25 participants in the silver-impregnated dressing (control) group and 28 participants in the ceramic dressing (study) group. The participants' wounds were

assessed through MolecuLight i:X (MolecuLight Inc., Canada) wound tracing and MolecuLight i:X fluorescence imaging to measure the wound size, as well as presence of a bacterial load of $>10^4$ colony forming units/g at weeks 1, 2, 3 and 4. The results indicated that there was a significant difference in the distribution over the categories of bacterial load cleared after weeks 1, 2, 3 or 4 in the two groups. Moreover, the bacterial load cleared significantly faster in the study group ($p=0.001$). Mean wound size was 10.93cm^2 (range: $0.10\text{--}37.95\text{cm}^2$) in the control group and 11.48cm^2 (range: $0.80\text{--}60\text{cm}^2$) in the study group. In the maximum likelihood regression analysis, the mean reduction in wound area for the study group was greater than that for the control group. The study concluded that the ceramic dressings could be an effective alternative to silver-impregnated dressings when treating infected wounds.

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bacterial load • ceramic dressings • fluorescence imaging • infected wounds • MolecuLight i:X • silver-impregnated dressing • wound • wound care • wound dressing • wound healing

The intact skin acts as a barrier to shield against invading pathogens. However, injuries that result in a wound can compromise this protection, significantly enhancing the risk of infection.^{1,2} Bacterial contamination is a natural occurrence in all wounds and does not inherently impede healing; in fact, the presence of skin microflora can even promote the healing process.^{3,4} The significance of wound bioburden in hindering healing becomes most apparent when contamination progresses to infection.

The International Wound Infection Institute Wound Infection Continuum (IWII-WIC)⁵ outlines the progressive stages of microbial presence in wounds, increasing in severity from contamination to colonisation, local infection (both covert and overt), spreading infection and systemic infection. As a practical resource, it integrates principles of antimicrobial stewardship (AMS) and biofilm-based wound care, aiding clinical

wound infection management at the bedside. The IWII-WIC removed the term 'critical colonisation', recognising that microbial burden evolves continuously without a precise tipping point. The continuum now includes the concept of covert local infection, characterised by subtle clinical indicators before overt signs of infection manifest, thus comprising five stages: contamination; colonisation; local infection; spreading infection; and systemic infection. However, prioritising the prevention of wound infection is deemed to be a crucial contributing factor in averting the transition of an acute wound into a hard-to-heal (chronic) wound.⁶⁻⁸

As a result, there are multifaceted research efforts to enhance therapeutic approaches for infection control and expedited healing of both acute and hard-to-heal wounds.⁹⁻¹² Silver is widely used in wound care for controlling infections. A significant rise in the use of silver-impregnated wound dressings has been witnessed over the last decades.^{13,14} Silver dressings are available in several different forms including: elemental silver (silver metal, nanocrystalline silver); inorganic compound (silver oxide, silver phosphate, silver chloride, silver sulphate, silver-sodium-calcium phosphate, silver zirconium compound and silver sulfadiazine) and organic complex (silver-zinc allantoinate, silver alginate,

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Febe A Bruwer,¹ PhD (UFS), Dr, Advanced Wound Nurse Specialist; **Rene Lessing**,² Sr, Advanced Wound Care Practitioner*

*Corresponding author email: wounds@hautecare.co.za

¹ Gauteng, South Africa. ² Haute Care & Centurion Clinical Research, Gauteng, South Africa.

silver carboxymethylcellulose).¹⁵ However, the relationship between different concentrations of silver in dressings, and their antimicrobial activities and wound healing efficacy remains unclear.¹⁶

Additionally, AMS principles have been advocated worldwide to mitigate antimicrobial resistance through the reduction in use of antimicrobial agents, thereby enhancing the safety and efficacy of treatments for infected wounds.¹⁷ A key goal of the various AMS programmes is to explore technologies for reducing bacterial load through the use of non-medicated wound dressings.¹⁷

Silver is increasingly used in wound dressings, and interacting with damaged and compromised skin.¹⁸ Several studies have identified that, as the use of silver increases, it is necessary that health professionals are aware of its potential side-effects, such as contact dermatitis and toxicity.¹⁹ While the silver ion has significant antimicrobial and bactericidal properties, evidence suggests that prolonged use (>2 weeks) or at concentrations >70 parts per million silver ions could influence fibroblast proliferation.^{20–23} Furthermore, applying silver-containing dressings to a wound can temporarily increase serum silver levels, potentially impairing wound healing, and prolonged use may lead to local and systemic absorption of silver, resulting in transiently elevated blood and urine levels, along with deposition in the lesion and other body organs.^{16,24}

Research indicates that non-medicated wound dressings offer an alternative to those containing active antimicrobial or antiseptic ingredients.²⁵ To effectively diminish the impact of microorganisms, a non-medicated wound dressing mostly operates through a mechanical mode of action (MoA).

A ceramic dressing, where the MoA is to absorb and sequester exudate while a charged surface on the ceramic has the potential to bind with the bacteria, is one such non-medicated dressing.²⁶ Briefly, the ceramic wound dressing consists of ceramic granules sealed in a sterile pouch. The microporous ceramic in the dressing absorbs excess wound moisture while microorganisms suspended in the moisture are adsorbed onto the surface of the ceramic. This helps to reduce the number of microorganisms and demonstrates antimicrobial properties. Furthermore, the adsorption and atmospheric oxygen on the clean and moist wound bed create ideal conditions for the increased demand of oxygen in injured tissue in order to maintain metabolic processes.²⁷

Several publications have provided data illustrating a direct correlation between bacterial load levels and wound inflammation.^{28,29} Research has also revealed a direct association between inflammation and the presence of endotoxins arising from the use of antimicrobial agents.^{28,29} According to Landén et al.,²⁹ the transition from wound inflammation to cell proliferation is regarded as a critical step in the wound healing process. Consequently, the successful reduction of bacteria through a non-medicated wound dressing should facilitate the advancement of cell proliferation,

fostering a favourable and conducive microenvironment on the wound bed, and thus promoting healing.

Therefore, the main objective of this study was to compare the efficacy of the ceramic dressing in reducing bacterial load over time, as visualised by the MolecuLight i:X device (MolecuLight Inc., Canada) on an infected wound, when compared to a silver-impregnated dressing. The reduction in wound size over a period of four weeks was also measured and compared.

Ethical approval

Approval for the study was granted by the Ethical Committee of Pharma Ethics, South Africa, with the assigned study number RBLCer-03 (approval number: 211124410). The authors of this article are not affiliated with the Sponsor (Cerdak) and possess independent expertise in advanced wound care practices. Written informed consent was obtained from all participants involved in this study, including for the publication of photographs of their wounds.

Methods

Trial design and participants

The study was conducted over eight months in 2022 in two advanced wound clinics in Gauteng, South Africa. Potential participants (age ≥18 years) with wounds with a high bacterial load (as indicated by fluorescence imaging) were invited to participate in the study. These included wounds caused by complications from trauma or surgery-related injury, hard-to-heal wounds not requiring debridement and hard-to-heal wounds after surgical debridement.

Participants with any known allergy to the dressing or its ingredients, known skin diseases or dermatosis (atopic dermatitis, psoriasis) were excluded from the study.

Medication related to topical or systemic antimicrobials were excluded from use throughout the study period. Prior to initiating any trial-related activities, written informed consent was obtained in accordance with the Declaration of Helsinki and the applicable laws of South Africa, from all eligible participants who met the inclusion/exclusion criteria and expressed willingness to participate in the study. The participants were provided with a copy of the subject information sheet.

The included participants were then randomised into two groups:

- Study group treated with ceramic dressing
- Control group treated with silver-impregnated dressing.

The reduction of bacterial load and healing properties were evaluated in both groups.

Materials

The non-medicated ceramic wound dressings, Cerdak Basic and Cerdak Aerocloth (used in different sizes), were acquired from the manufacturer, Cerdak (PTY) Ltd., South Africa. In the control group, dressing materials were randomly assigned to two subgroups:

Actisorb Silver 220 dressings (3M, UK) and Atrauman Ag dressings (Hartmann, Germany). In both the study and control groups, Zetuvit E (Hartmann, France) was applied as a secondary dressing when necessary. Noxmaria-stabilised hypochlorous acid (HOCl, at 330–370ppm) from Ultrapure (South Africa) was also used as a wound cleanser in both treatment groups.

Clinical procedure

Capture and analysis of wound imaging

The MolecuLight i:X device was used as per the manufacturer's instructions. The targeted wound area was irradiated with violet light (405nm).³⁰ Images of wound size assessment were taken and marked with the participant's unique study number (Fig 1). All images were saved without lines for area calculation and the bacterial fluorescence image of bacterial load was taken in the dark room. Finally, the images were stored, in accordance with data protection laws in South Africa, for further assessment.

Pre-study assessment and first visit

On the day of screening, the eligible participants were rechecked for inclusion/exclusion criteria and consent was obtained from those who met the criteria for inclusion. After randomisation to the two treatment groups, the participants were examined thoroughly for pre-morbid conditions and prior history of medications. The physical examination and vital signs (diastolic/systolic blood pressure, heart rate, temperature) were captured.

Wound assessments, which included tissue type and its percentage along with the signs and symptoms of infection, were performed. Sequentially, wound size imaging and bacterial fluorescence imaging were performed followed by pain score evaluation using a visual analogue scale (VAS, where 0=no pain to 10=worst pain imaginable). In addition, the dressings were changed when saturated and replacement time was dependent on exudate levels; indication for dressing change was 70% discolouration of the dressing. Participants were informed of these guidelines preemptively to facilitate immediate

visits to the study site in case dressing replacement was required due to emergencies. All the procedural details were properly documented, in strict accordance with the clinical trial protocol and good clinical practice guidelines.

Subsequent visits

Initially, frequency of visits was set at three days per week and could be relaxed to one or two days per week if the wound improved to a point that bacterial burden and wound size were substantially reduced. Wound size imaging and bacterial fluorescence imaging were performed. This was followed by the pain score evaluation, using VAS-related data, such as: dressing history since previous visit; wound assessment time; concomitant medication; and participants' assessment of any adverse events. All procedural details were documented, including washing and debriding of the wounds. Lastly, participants were notified of the scheduling of the next visit.

Criteria to determine outcomes

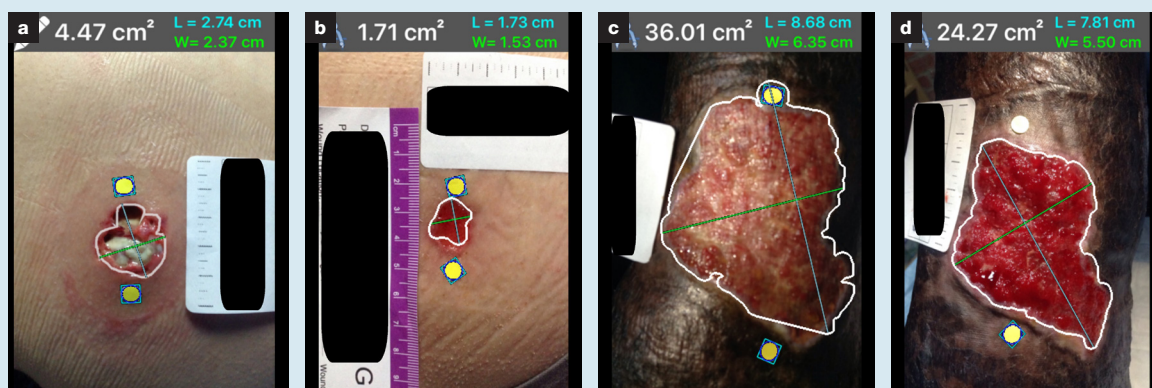
Primary study endpoint: zero visualisation of bacteria (at $>10^4$ colony forming units (CFU)/g) in wound area, as indicated by the MolecuLight i:X bacterial fluorescence imaging during the four-week study period, i.e., weeks 1, 2, 3 and 4.

Secondary study endpoint: the reduction in wound area, adjusted for the area at onset, as determined by the wound size calculation using the MolecuLight i:X.

Statistical analysis

Stata Statistical Software Release 18 (StataCorp LLC., US) was used for statistical analysis. The association between treatment groups (control and study) and the bacterial load reduction times (weeks 1, 2, 3 and 4) were assessed using a two-sided Fisher's exact test. The treatment groups were compared with respect to the change in wound area from onset to end of treatment using maximum likelihood regression. The wound area at onset was included as a covariate, with adjustments

Fig 1. Illustration of the imaging practices used to measure the size of the targeted wound area in the study. Images show the progression of wound healing over four weeks. A spider bite wound at baseline (week 0) (a); the same spider bite wound after four weeks of treatment (b); a venous ulcer at baseline (week 0) (c); the venous ulcer after four weeks of treatment (d)



made for the study sites. The predicted means along with 95% confidence intervals (CI) were also reported following the maximum likelihood (ML) regression. Statistical evaluation included means or medians and standard deviations (SD) or ranges of continuous or ordered variables. All statistical tests were considered statistically significant when $p < 0.05$.

Results

Demography of study participants

Data from a total of 53 wounds (in 53 participants) were coded (to prevent identification of patients) and analysed. Participants were randomised to a control group ($n=25$, of which 11 were treated using Atraumann and 14 were treated with Actisorb) and a study group ($n=28$). Participant demography is detailed in Table 1.

Additionally, the study noted that the predominant wound types were infected ulcers. Notably, 56% of these wounds were situated on the lower leg (Fig 2).

Bacterial load reduction

The distribution of the bacterial load reduction at weeks 1, 2, 3 and 4 of the two treatment groups differed significantly ($p=0.001$) (Fig 3). Data were assessed using two-sided Fisher's exact test. Initially, both groups demonstrated comparable bacterial load visibility percentages on day 0. However, there were notable differences in the bacterial load visibility between the two groups from week 1 onwards; the study group exhibited a significant increase in the reduction of bacterial load visibility. The findings presented in Table 2 and Fig 4 indicate that the study group demonstrated a more rapid reduction of bacterial load compared to the control group.

Reduction of wound size

The secondary aim of the study was to assess and compare wound healing times by analysing the change in wound area on weeks 1, 2, 3 and 4. Mean wound size was 10.93cm^2 (range: $0.1\text{--}37.95\text{cm}^2$) in the control group and 11.48cm^2 (range: $0.8\text{--}60\text{cm}^2$) in the study group.

In an ML regression analysis, the treatment groups differed significantly ($p=0.026$), and the mean change in wound area for the study group (predicted mean: 6.56cm^2 ; 95% CI: $4.29\text{--}8.83\text{cm}^2$) was greater than the control group (predicted mean: 2.81cm^2 ; 95% CI: $0.41\text{--}5.2\text{cm}^2$). Consequently, the results indicated that the treatment with ceramic dressing was more effective than treatment with the silver-impregnated dressing (Fig 5).

Discussion

Acute wounds heal within a predictable time period (1–12 weeks, depending on the nature of the wound); however, accelerated wound healing is desirable for recovery, overall health and cost.³¹ Hard-to-heal wounds do not heal in a predicted time period, are more susceptible to infection and are considerably more difficult to manage.³² Moreover, a wound is said to be infected when microbes enter through breached skin, leading to the accumulation of bacteria and slowing

Table 1. Sampling size, sex and ethnicity of participants

Sample size	Control group		Study group	
	25		28	
	n	%	n	%
Sex				
Male	15	60	15	54
Female	10	40	13	46
Ethnicity				
Black	9	36	9	32
White	14	56	17	61
Other	2	8	2	7

down the healing process.⁵

For infected wounds, topical antimicrobials are a rational alternative to systemic antibiotics. Silver-impregnated dressings are commonly used in infected or chronically colonised wounds. Among silver-impregnated dressings, Actisorb Silver 220 dressing has the lowest silver content and is specifically recommended for the management of malodorous, infected wounds.³³ However, the effect of such dressings on wound healing or wound healing trajectories is not

Fig 2. Distribution of wound types and their anatomical locations in control and study groups

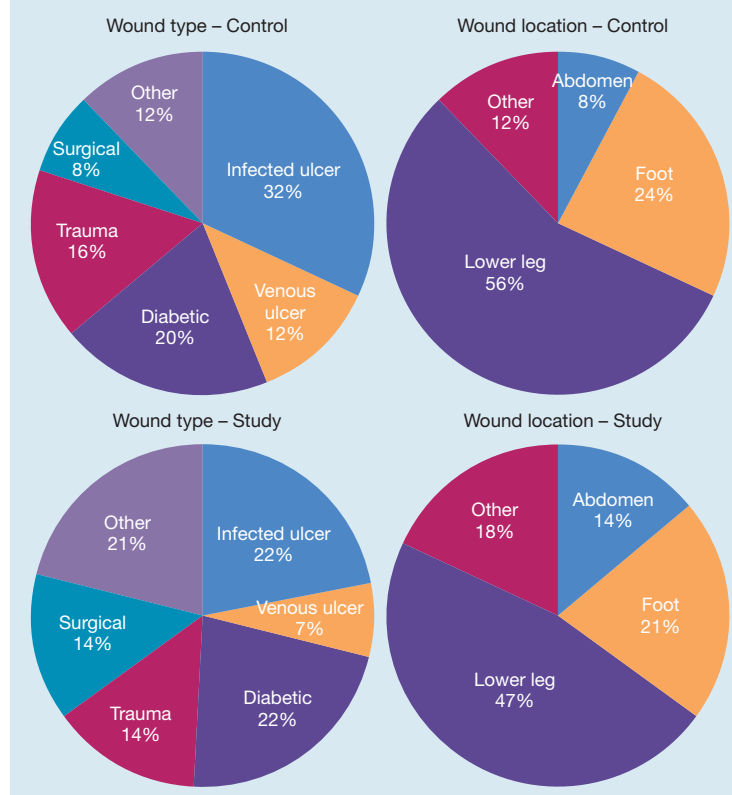
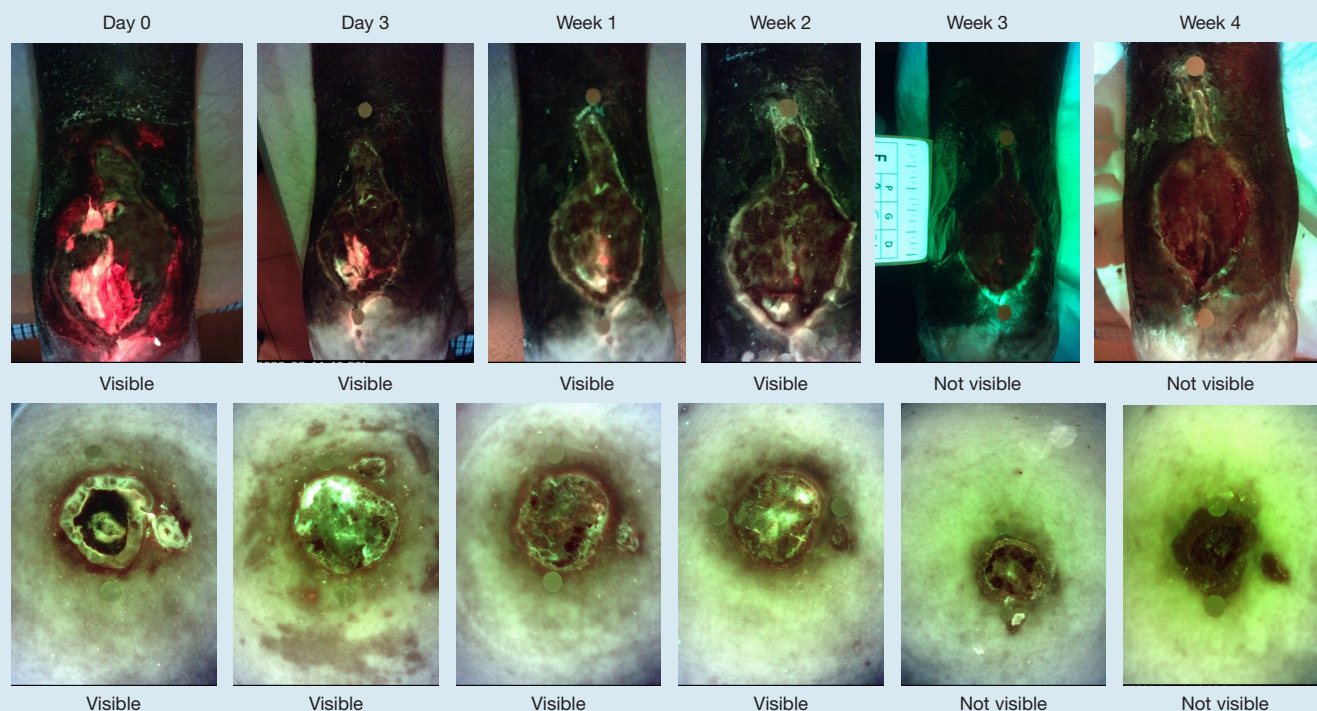


Fig 3. Fluorescence imaging of bacterial load by MolecuLight i:X device (MolecuLight Inc., Canada), with representation of bacterial load reduction distribution over 1, 2, 3 and 4 weeks. Images in the top row show the weekly progress of an infected traumatic injury on the lower right leg of a 55-year-old patient. Images in the bottom row show the weekly progress of a spider bite on the left glute of a 58-year-old patient. 'Visible' represents areas where bacterial load is evident, and 'non-visible' represents areas where bacterial load is not immediately apparent



known to any degree of certainty. Moreover, the use of dressings containing antimicrobial agents can lead to antimicrobial resistance and the presence of biofilms complicates treating the micro-environment of wounds.^{25,34} A review of the research carried out by White and Cutting,³⁵ indicated that there were three main factors which influenced the capacity for silver to produce toxic effects:³⁵

- The degree of absorption
- The capacity of the compound to bind to biological sites

Table 2. Reduction of bacterial load visible by fluorescent imaging on weeks 1, 2, 3 and 4. The distribution of the two groups over the categories of bacterial load reduction differed significantly ($p=0.001$)

Timepoint, weeks	Bacterial load reduction			
	Control group		Study group	
	n	%	n	%
1	2	8.00	11	39.29
2	0	0.00	5	17.86
3	5	20.00	5	17.86
4	18	72.00	7	25.00
Total	25	100.00	28	100.00

- The degree to which the silver compound ions were absorbed, metabolised and ultimately excreted from the body.

Hence, non-medicated ceramic wound dressings relying on physical properties to optimise wound conditions can serve as a valuable alternative for wound healing. These ceramic wound dressings, devoid of antimicrobial resistance, facilitate the mechanical elimination of proinflammatory substances. In brief, the non-medicated wound dressing's MoA comprises five distinct steps for infection prevention and management:³⁶

- Disruption of devitalised tissue
- Absorption of microorganisms
- Surface binding of microorganisms
- Microorganism immobilisation and isolation
- Microorganism removal within the dressing.

The non-medicated ceramic wound dressing used in the study group comprised a non-woven sachet filled with ceramic beads ($\approx 1\text{mm}$). The beads were porous which created a strong capillary force, ensuring permanent sequestration and removal of exudate and microorganisms. In addition, these positively charged ceramic beads possess the capability to attract and bind bacteria as well as other charged microparticles onto their surfaces. Moreover, the loosely packed beads facilitate an ample supply of oxygen to the wound, thereby promoting swift recovery.

The National Institute for Health and Care Excellence³⁷ provides guidance on hard-to-heal wound management, emphasising that simple, non-medicated dressings can be as effective as more complex alternatives, depending on the wound type and patient condition. This approach aligns with recommendations from the World Union of Wound Healing Societies,^{35,36} which also supports the use of non-medicated dressings when appropriate, highlighting their effectiveness in wound healing. These guidelines endorse non-medicated dressings as a viable and often preferable option in wound care, particularly when considering cost-effectiveness and ease of use.

The findings from this study suggest that the ceramic dressing outperformed the silver-impregnated dressing in reducing bacterial load in infected wounds. Additionally, the ceramic dressing demonstrated significant efficacy in reducing wound size over a four-week period. In a study by Hecker et al.,²⁶ wound healing, bacterial retention and diagnostic capabilities were evaluated. The study involved 20 patients with an average age of 64.6 ± 26.2 years and a total of 21 chronic (hard-to-heal) wounds. After a four-week treatment period, there was a significant reduction in median wound size from 1178mm^2 (range: $104\text{--}6300\text{mm}^2$) to 751.5mm^2 (range: $16\text{--}4819\text{mm}^2$) and improved overall wound scores. The sensitivity for detecting bacteria was 90.7% in sonication fluid from ceramic dressings compared to 76.9% in conventional wound swabs. These results suggest that ceramic dressings are a promising treatment for these types of wounds and could be valuable for microbiological diagnostics.

No published evidence was available, but the physical removal of bacterial load with the ceramic wound dressings to prevent wound infection or to treat contaminated and colonised wounds should be investigated. According to the IWII-WIC International Consensus Update 2022, contaminated and colonised wounds in general treatment will not be indicated for dressings containing antimicrobial agents.⁵

Limitations

Evaluating fluorescence images for visible bacterial load is a nuanced process. Wound conditions, lighting and device sensitivity can influence image interpretation, requiring investigators to use clinical judgement when decisions are marginal. In such cases, assessments relied on the expertise and discretion of the investigator. Future improvements could involve standardising imaging protocols and incorporating quantitative fluorescence analysis to enhance consistency, and allow for more objective and precise measurements.

Conclusion

The findings from this study indicated that the ceramic dressings could be effective in the reduction of bacterial load in infected wounds. This supports AMS principles and the search for solutions to prevent the development of bacterial resistance. Furthermore, the use of ceramic

Fig 4. Distribution of cases with visible bacterial load detected by fluorescence imaging at 1, 2, 3, and 4 weeks for the control and ceramic (study) groups. The columns represent the percentage of detectable bacterial load at each timepoint. A significant difference in bacterial load clearance was observed between the two groups (Fisher's exact test: $p=0.001$), with faster clearance in the ceramic group

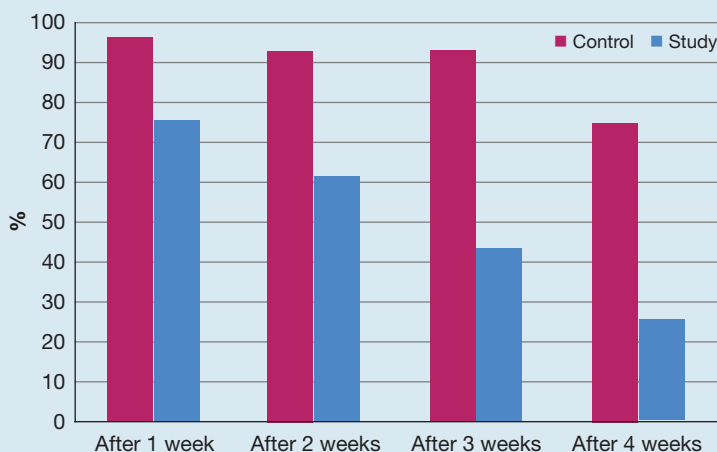
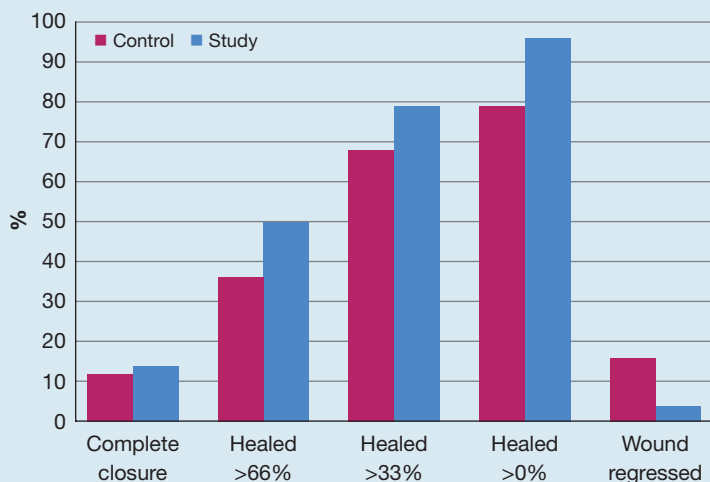


Fig 5. The reduction in wound area after a period of four weeks. The treatment groups differed significantly ($p=0.026$)



dressings in infected wounds resulted in a significant reduction in bacterial load and a significant improvement in wound healing over a period of four weeks. This may confirm the link between the effective removal of the bacteria rather than the bactericidal effect of the antimicrobial agent and an improved healing process. Besides, the availability of non-medicated dressings with both antimicrobial properties and improved healing properties can support the judicious use of antimicrobials and additional development of non-medicated dressings. **JWC**

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Reflective questions

- What are the unique properties of ceramic dressings in terms of adsorption and absorption?
- What are the advantages of using ceramic dressings in the treatment of infected wounds?
- How might the use of non-medicated dressings for the reduction of bioburden contribute to improved antimicrobial stewardship?

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