Evaluation study of the UCS® Debridement medical device in the treatment of chronic skin lesions

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ABSTRACT

UCS® Debridement is a sterile system for the initial debridement and maintenance of chronic skin lesions and for the cleansing and hydration of the perilesional edges and the entire limb. The system is designed to improve and facilitate the cleansing and mechanical debridement phase. Recommendations for the management of a wound with the presence of biofilm include cleaning, debridement, and application of an appropriate dressing to keep the number of microorganisms to a minimum. The debridement activity should be started and undertaken regularly. The aim of this observational study is to demonstrate the effectiveness of biofilm removal by the medical devices used, reduction of pain during and after the procedure, reduction of operative times, reduction of bleeding, benefits to wound edges of the injury, and improvement of perilesional skin.

Introduction

Chronic skin lesions require careful preparation of the wound bed and a treatment protocol that can facilitate their path to healing. Cleansing and debridement are the first therapeutic acts in the management of skin wounds, which are crucial steps in creating an environment conducive to healing. Cleansing allows the removal of surface contaminants from the bottom of the wound and from the perilesional skin, and it reduces biofilm formation. Debridement refers to the mechanical removal of biofilm from the wound bed, devitalized tissue, debris, and slough through the use of the device, gauze, curette, surgical blades, or ultrasound. It also refers to the treatment of the edges and perilesional skin (hyperkeratosis).

Debridement can be defined as an integral part of wound management because biofilm is recognized as the primary barrier to healing in most chronic wounds.[1] Once the biofilm is removed, it can quickly reform within 48-72 hours.[2]

Debridement is, therefore, a procedure to be repeated at each dressing change - *maintenance debridement* - even in the presence of an apparently adequate wound bed. Among the various methods of debridement, *mechanical debridement* is carried out using the physical action of removal, using devices and/or dressings soaked in detergent solutions. It can be considered the oldest and most widely used form.

The various methods can be combined with each other depending on the injury, pain management, clinical conditions of the patient, and the care setting. Mechanical debridement is part

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of TIMERS, a model introduced by the WBPA Board to define the dynamic process of removing all obstacles that impede and slow down the healing process. Thus, this model identifies the critical areas: T (Tissue) for removal of devitalized tissue, I (Inflammation/Infection) for reduction of infection, M (Moisture) for reduction of exudate and odor, E (Edge) for stimulation of the perilesional edge and promotion of granulation tissue, R (Repair) for stimulation of the re-epithelialization process, S (Social and Patient Related Factors) for evaluation of social determinants. The TIMERS model recognizes the importance of debridement not only for the wound bed but also for the wound edges and the perilesional area through the removal of the main barriers to healing (biofilm, exudate, infection), and edge stimulation, necessary actions to promote the re-epithelialization process. Thus, the use of the UCS® Debridement system allows a complete implementation of the TIMERS model, and it simultaneously activates all the listed steps necessary for the healing process.

Description

The study is an observational study in which each patient was a case-control. The aim of the study is to demonstrate the effectiveness of the devices used in removing the biofilm, reducing pain during and after the procedure, reducing operating times, reducing bleeding, improving the peri-wound skin, and treating the wound edges.

The total enrolment was 40 patients with chronic skin lesions of various etiology, sizes, stages, and statuses (*Supplementary Table 1,2; Supplementary Figure 1,2*).

All patients were informed of the protocol in question, and after signing the informed consent form, they were included in the study. The average age of the total group was 62 years, with a range of 27/88 years. The male/female ratio was almost 1 to 1 (21/19), and the two groups were homogeneous.

Inclusion criteria: adults, patients with chronic skin ulcers for at least 8 weeks, able to attend checks, defined etiological diagnosis, life expectancy >6 months, not taking immunosuppressants and/or chemotherapy, not pregnant, acceptance of the informed consent.

Exclusion criteria: age under 18 years, skin lesions appearing less than 8 weeks ago, pregnancy, and patients who have participated in other studies within 60 days of enrolment or are in progress.

From a local point of view, the type of dressing was chosen for two weeks in accordance with the TIMERS guidelines, while the underlying pathology was treated according to the gold standards of the literature. After the Run-in period, the device in question in the form of a solution or cloth was inserted at the time of dressing. Dressing changes were managed based on exudate: daily change in exuding wounds and every other day with controlled exudate. Checks were carried out every other week. The parameters analyzed were Area (using the Wound Viewer© system), WBP (using the Falanga score), pain (using NRS score), infections (using Cutting and Harding score), and perilesional skin (descriptive system) (*Supplementary Tables 3-5; Supplementary Figure 3,4*). The following were evaluated: Erythema, Xerosis/Desquamation, Maceration, Inflammation, Bleeding during the procedure, and Procedural Pain (NRS score).

Run-in: observation at T0 and T14 administering the best treatments and medication procedures for the specific case.

Subsequently: treatment with debridement medical devices followed by dressing, as previously done during the Run-in, according to the needs of the case.

Observation: four checks scheduled (T0, T14, T28, T42), in forty-two days.

At each check, Area, VAS, WBP Score, Cutting and Harding, and perilesional skin were assessed (erythema descriptive system, Xerosis/Desquamation, Maceration, and Inflammation), Bleeding using an increasing scale from 0 to 10, where 0 represents no bleeding, and 10 represents profuse bleeding (this scale was created *ad hoc*, considering that there are no different validated scales).

Materials and Methods

No randomization criteria were applied. The dressing protocol during the Run-in was as follows: removal of the previous dressing, cleansing of the wound with saline solution, dressing with inert gauze (greasy gauze), positioning of the secondary dressing, and fixing of the dressing as required based on the site.

The dressing protocol during treatment was: removal of the previous dressing, cleansing with the UCS® Debridement system (cloth and solution), covering with dressing suitable for the case, positioning of secondary dressing if necessary, fixing of the dressing as required based on the site. In the treatment phase for cleansing and debridement, the following were used:

UCS® Debridement cloth: ready-to-use, individually wrapped, pre-soaked sterile gauze with allantoin and Aloe Barbadensis, class IIb Medical Device. It is recommended for debridement and cleansing of ulcers (venous, arterial, mixed, diabetic), decubitus (I-IV degree), burns, fistulae, abscesses, hydration of the perilesional area, and the entire limb, and for removal of hyperkeratosis. The cloth is soaked in a solution based on Poloxamer, a non-ionic surfactant, with a non-cytotoxic and non-damaging action on tissues, non-irritating, totally non-aggressive action, effective in breaking down and removing biofilm, fibrin, necrotic tissue and slough.

UCSol Debridement Solution: ready-to-use sterile solution, class IIb Medical Device. It is indicated for debridement of the wound bed and edges, cleansing and hydration of the perilesional area and the entire limb, and elimination of hyperkeratosis. Poloxamer-based solution with allantoin and Aloe Barbadensis disrupts biofilm, necrotic tissue, fibrin, and slough.

Active component specifications

Poloxamer (P188): P188 is a surfactant, belonging to the poloxamer family. It cleans deeply, breaks down biofilm structures, and removes necrotic tissue, allowing better penetration of other topical treatments such as antibiotic or antimicrobial solutions. It prevents biofilm reformation thanks to its long-lasting effect. Poloxamer has been shown to aid healing at the cellular level, and it is not harmful to healthy cells.[1] Numerous clinical studies have evaluated the pharmacodynamic characteristics of P188, demonstrating that surfactants belonging to the poloxamer family promote wound healing[2-5] by exerting a protective action against oxidative stress and inflammation in various experimental models of damaged tissues. The ability to promote the wound healing process can result from several activities, including aiding in

wound cleansing, suppressing aggregation and denaturation of proteins, repair of the tissue or cell membrane, and antimicrobial action. The P188 allows cleaning of the wound bed, facilitating debridement. Clinical practice has confirmed that P188, when included in the wound-washing protocol, allows the removal of debris present in the wound, creating a "rinsing" action.[6] P188 lowers the surface tension between the wound and the cleansing liquid, facilitating the separation of loose, non-viable tissues and microbial particles from the vital wound bed, promoting their eradication.[7] Furthermore, it acts on the proteases present in the wound bed with a drastic increase in the activity of gelatinases, a decrease in the action of collagenases, and stimulation of the MMP-2 and MMP-9 metalloproteinases, promoting autolytic debridement.[8] Surfactants can also suppress protein aggregation and contribute to the folding of denatured proteins by preventing persistent inflammation, which underlies delayed wound healing.[7]

Finally, poloxamer 188 has been shown to have an excellent safety profile, with low cytotoxicity on fibroblasts and keratinocytes, and to reduce inflammation by acting on bradykinins.[8]

Allantoin: is a well-known keratolytic (softens hard, dry hyperkeratotic skin) and continues to act after debridement, improving the integrity of the skin. It has a healing, hydrating, soothing, and anti-irritant action.

Aloe Vera Barbadensis: contains antioxidants, enzymes, vitamins A and C and has a highly anti-inflammatory and hydrating effect on the periwound skin.

Results

The results of the study are included in the Supplementary Tables and Figures (*Supplementary Tables 6-14; Supplementary Figures 5-16*).

Discussion

All the parameters analyzed showed concordant values with a significant and very significant improvement to the benefit of the overall clinical picture, with percentages even exceeding expectations. This is demonstrated by the diagrams resulting from the aforementioned surveys.

Area: during the Run-in, the improvement was 4%, while during the treatment (T0-T42) the area reduction was on average 62%. In all cases observed, the improvement was significant and in 37 cases out of 40 analyzed, the area reduction was greater than 50%.

Pain: in the Run-in period, the pain reduction was 9%, while in the treatment period, it was 43% at T14, 72% at T28, and 91% at T42. Note how the progression is linear here, too.

WBP score evolution: a notable difference was highlighted between the 14 days of Run-in, after which a 17% improvement was recorded, and the treatment period, which ended with an overall improvement of 78% at T42.

Cutting and Harding: the infection during the Run-in period decreased by 7%. During the treatment period, infections were eliminated in 32 out of 40 cases, with a 49% improvement already at T14. At T42, the overall improvement was 93%.

Xerosis/Desquamation: the results obtained from the use of the products on Xerosis/Desquamation were evident. The Run-in period ended with a minimum improvement of 8%, before reaching complete resolution at the end of treatment at T42.

Maceration: the results obtained on Maceration show a 15% improvement at the end of the Run-in period, which then increased to 100% at T42 of the treatment with the medical device used.

Inflammation: at the end of the Run-in period decreased by 16%. During the treatment period, the inflammation went from 63% at T14 to complete resolution with 100% at T42.

Bleeding: the Bleeding parameter, understood as an increase in bleeding caused by the cleansing/debridement procedure, highlights that during the Run-in, the reduction was 9% compared to 51% at T14 of the treatment, which becomes 84% at T28 and 95% at T42.

Procedural pain: the use of these systems allows the T phase of the TIMERS to be carried out adequately without "bothering" the patient too much. In fact, an 8% reduction in procedural pain was detected at T14 of the Run-in compared to a 45% improvement at T14 of the treatment, which increased to 81% at T28 and 98% at T42.

Therefore, correct cleansing and "continuous" debridement are useful and essential procedures for chronic skin lesions to proceed toward rapid healing. The correct management of the perilesional skin, the margins, and the edges of the lesion must be adequately stimulated. Medical devices containing surfactants and moisturizing principles useful for the peri-wound skin promote the faster resolution of vulnological pathology.

Conclusions

The medical devices studied have demonstrated significant effectiveness, beyond all expectations, for the progression of the ulcer toward healing.

All the parameters analyzed and in all phases of the survey carried out showed concordant results to be able to indicate the medical devices used as effective and advisable in the appropriate management and treatment of the chronic skin lesions of any etiology and in any state and stage of the lesion.

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Online supplementary material:

Supplementary Table 1. Patient data.

Supplementary Table 2. Patient data.

Supplementary Table 3. WBP rating scale.

Supplementary Table 4. Cutting & Harding rating scale.

Supplementary Table 5. Perilesional skin rating scale.

Supplementary Table 6. Evolution of the lesion area. During the Run-in, the improvement was 4%, while during the treatment (T0-T42), the area reduction was, on average, 62%. In all cases observed, the improvement was.

Supplementary Table 7. Pain assessment. In the Run-in period, the pain reduction was 9%, while in the treatment period, it was 43% at T14, 72% at T28, and 91% at T42. Note how here, too, the progression is linear.

Supplementary Table 8. WBP evolution. A noSupplementary Table difference was highlighted between the 14 days of Run-in, after which a 17% improvement was recorded. The treatment period ended with an overall improvement of 78% at T42.

Supplementary Table 9. Infection evolution. Infection during the Run-in period decreased by 7%. During the treatment period, infections were eliminated in 32 out of 40 cases with a 49% improvement already at T14. At T42 the overall improvement was 93%.

Supplementary Table 10. Evolution of xerosis/desquamation of perilesional skin. The results obtained with the use of the product on Xerosis/Desquamation were evident. The Run-in period ended with a minimum improvement of 8% and then reached complete resolution at the end of the treatment at T42.

Supplementary Table 11. Evolution of perilesional skin maceration. The results obtained regarding Maceration show a 15% improvement at the end of the Run-in period, which then increased to 100% at T42 of the treatment with the medical device used.

Supplementary Table 12. Evolution of perilesional skin inflammation. Inflammation at the end of the Run-in period decreased by 16%. In the treatment period, the inflammation went from 63% at T14 to complete resolution with 100% at T42.

Supplementary Table 13. Bleeding evolution. The Bleeding parameter, understood as an increase in bleeding caused by the cleansing/debridement procedure, highlights that during the Run-in, the reduction was 9% compared to a 51% reduction at T14 of the treatment, which becomes 84% at T28 and 95% at T42.

Supplementary Table 14. Evolution of procedural pain. The use of these systems allows the T phase of the TIMERS to be carried out adequately without "bothering" the patient too much. In fact, an 8% reduction in procedural pain was detected at T14 of the Run-in versus a 45% improvement at T14 of the treatment, which rose to 81% at T28 and 98% at T42.

Supplementary Figure 1. Sex and average age.

Supplementary Figure 2. Ulcer etiology.

Supplementary Figure 3. VAS pain rating scale.

Supplementary Figure 4. Bleeding rating scale.

Supplementary Figure 5. Evolution of the lesion area.

Supplementary Figure 6. Pain assessment.

Supplementary Figure 7. WBP evolution.

Supplementary Figure 8. Infection evolution.

Supplementary Figure 9. Evolution of xerosis/desquamation of perilesional skin.

Supplementary Figure 10. Evolution of perilesional skin maceration.

Supplementary Figure 11. Evolution of perilesional skin inflammation.

Supplementary Figure 12. Bleeding evolution.

Supplementary Figure 13. Evolution of procedural pain.

Supplementary Figure 14. Patient n.3. Evolution of mixed arterial/venous ulcer with UCS® Debridement treatment.

Supplementary Figure 15. Patient n.5. Evolution of mixed arterial/venous ulcer with UCS® Debridement treatment.

Supplementary Figure 16. Patient n.7. Evolution of mixed arterial/venous ulcer with UCS® Debridement treatment.