EVALUATION OF A NEW MECHANICAL DEBRIDEMENT SYSTEM

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Introduction
Wound debridement is necessary to remove biofilm, fibrin, slough, and necrotic crusts, all of which prevent the tissue repair process to occur in chronic wounds.

The debridement can be autolitic, enzymatic, biological, mechanical or surgical; according to the type, the debridement process can be performed in a homecare setting, in a hospital out-patient clinic, or can require the surgical theatre.

Mechanical debridement in the homecare setting normally requires various devices, i.e., gauzes, liquid solutions, syringes. Ideally, the procedure performed in the home should be performed using just a single device.

Objective
Aim of study is the evaluation of the efficacy and safety of a single, new device (UCS™ Debridement) for the mechanical debridement of chronic ulcers regardless of their aetiology and stage exposure of the dermis, subcutaneous and muscular tissues to validate its use for the cleansing of the perilesional area and, specifically, the removal of hyperkeratotic plaque without the need of additional devices.

Study design
The evaluation of UCS™ Debridement consisted of the visual inspection of 55 wounds in three hospital wound out-patient clinics. The patients had been previously treated with mechanical debridement using the traditional methods: gauze and liquid solution, syringe, ringer. The perilesional area had been treated with moisturizing and hydrating creams.

The following parameters have been considered:

- Efficacy of mechanical debridement
- Level of pain perceived by the patient during the procedure
- Feasibility of using UCS™ Debridement on chronic ulcers regardless of their stage
- Time required for the procedure
- Adverse effects (increased pain after medication, allergic reaction)
- Learning curve (time) required by the personnel.

Materials and methods
UCS™ Debridement acts immediately. Therefore, it is not necessary to leave the premoistened gauze on the wound for several minutes before beginning the debridement procedure.

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The study included leg ulcers of different etiologies (vascular, diabetic)

Exclusion criteria:
- General patient’s condition that did not allow for treatment in the hospital out-patient clinic
- Neoplastic wounds
- Lesions at risk of hemorrhage
- Painful lesions

The observation begins at the dressing change.

No other device is used (saline solution, ringer, antiseptic). The gauze is positioned over the wound; then the edges of the gauze are gathered to form a tampon and the wound is debrided with circular movements. In order to clean and hydrate the perilesional area as well as the entire limb, use the other clean side of the gauze shaped as a tampon.

After debridement apply any advanced dressing.

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The study comprised of 55 chronic, non-healing ulcers, previously treated in our out-patient hospital centers.

- Average age 70.4 (from 55 to 88 years)
  - Associated pathologies:
    - 11 PAD,
    - 23 CVD,
    - 4 HCV correlated,
    - 3 rheumatoid arthritis
    - 2 osteomyelitis
    - 1 trauma

AETIOLOGY

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Stage: from 1 to 3 (Shea classification)

**SHEA Classification**

**STAGE 1:** Lesion limited to the epidermis (erythema, abrasion, blister)
**STAGE 2:** Lesion extends to the epidermis and dermis
**STAGE 3:** Lesion extends to the subcutaneous fat, possible eschar
**STAGE 4:** Lesion involves also the muscle, possibly affecting the bone and the joint

**Application technique**

Open the pouch and position the gauze, opened fully on the wound, pressing gently in order to moisten the wound tissue. Fold the four edges of the gauze to form a tampon and debride the wound bed with circular movements. Remove also the hyperkeratotic plaque.

Using the other clean side of the gauze, fold the edges to form a tampon and hydrate the perilesional area and the entire limb.

Do not apply moisturizing or hydrating creams. UCS™ Debridement hydrates the skin with lasting long-lasting affects.

The entire debridement procedure requires from 3 to 5 minutes, according to the size and condition of the wound.

**Results**

The efficacy of UCS™ Debridement in removing sludge and fibrin is comparable to the use of a traditional gauze but we have recorded a significant reduction in time required for the procedure and in the reduction of pain (VAS 0-1).

In a few cases, surgical debridement would have been the only efficacious alternative to the mechanical debridement with UCS™ Debridement in order to remove the fibrin. In only one case the general condition of the wound has required the use of an anesthetic ointment.

The time required for the procedure ranges from 3 to 5 minutes. One UCS™ Debridement gauze is sufficient for the procedure.

At the following dressing change, we asked the patients whether they desired the use of UCS™ Debridement again. Their response has been favorable.

**Conclusions**

UCS™ Debridement has been proven to be very efficacious. Brushing or surgical wound debridement have been the only alternative methods that obtain better results, but these methodologies were not included in this study objective.

The procedure may be slightly painful, within value 1 according to the VAS scale, but does not force the clinician to interrupt the maneuver.

No adverse effects were reported immediately following the procedure or on following days.

**Prospective use of UCS™ Debridement**

The device is a mechanical debridement system for chronic and acute wounds of any etiology. It does not damage the wound tissue. The wound progress is not negatively affected by UCS™ Debridement and is comparable to progress observed in wounds treated with other products.

The device can be used on wounds at any stage exposure of dermis, subcutaneous fat, muscle and joint/muscular structures.

The device is of significant value for use in hospital out-patient clinics or for homecare treatment, where it is significantly important to use efficacious, simple-to-use products.

The single, sterile packaging prevents the contamination of wounds.

It takes just a few minutes for personnel to learn how to use the product.

A single gauze is sufficient for treatment of wounds with a surface < 150-200 cm²

As with the other products currently available, the product is not indicated when a high risk of hemorrhage suggests not touching the wound bed.