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A novel debridement device for the treatment of hard-to-heal wounds: a prospective trial

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A novel debridement device for the treatment of hard-to-heal wounds: a prospective trial

Objective: Debridement, the removal of nonviable tissue, forms the foundation of wound care practice. Clinicians have a variety of debridement methods at their disposal: sharp, biologic, enzymatic, autolytic and mechanical. The choice of debridement technique depends on the patient care setting, ulcer type and the clinician's experience, training, comfort level and licensure. This prospective study evaluated a novel debridement instrument, EZ-Debride (MDM Ventures, US). Cutting flutes on the head of the tool permit uniform removal of dead tissue while lessening the risk of deeper injury. It may also minimise pain during the debridement procedure.

Method: Subjects with hard-to-heal wounds, drawn from a single wound care centre, participated in this institutional review board-approved prospective clinical study. Pain was measured before, during and after debridement using a numerical scale. Assessment of bacterial burden using fluorescence imaging (MolecuLight, Canada) was performed before and after debridement.

Results: Enrolment of 10 male and 12 female subjects, with a total of 28 wounds, was carried out over a two-month period by two investigators at a single institution. The average age of subjects was 64 years (range: 22–95 years). The average wound duration was 29 weeks (range: 6–142 weeks). Wound types included diabetic foot, venous leg and pressure ulcers, post-surgical and traumatic wounds. The average pain score at the time of enrolment was 3.9. Subjects reported an average increase in pain with debridement of 0.6 points (range: 0–8). Fluorescence imaging demonstrated a reduction in bacterial load in 69% of cases, with complete resolution in 19% of wounds. Haemostasis was achieved with direct pressure in all cases and the only adverse event was a wound infection that occurred four days after debridement.

Conclusion: The results suggest that this novel debridement tool can safely remove nonviable tissue with minimal discomfort and reduce bacterial burden similar to results achieved by sharp debridement.

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bacterial burden • chronic wound • debridement • diabetes • fluorescence imaging • hard-to-heal wound • infection • ulcer • wound • wound pain

Hard-to-heal wounds are characterised by the presence of nonviable tissue and biofilms that impede wound healing.[1] Debridement, removing dead material and disrupting biofilms in the wound bed, is a hallmark of good wound care practice.[2] The importance of debridement was first demonstrated in diabetic foot ulcers in the late 1990s: patients treated with the growth factor becaplermin (Regranex, Smith+Nephew, US) healed 80% faster if the ulcer was debrided before applying the growth factor.[3] A large retrospective study of more than 300,000 hard-to-heal wounds confirmed the importance of debridement in hard-to-heal wound care and established that weekly debridement is the preferred frequency for the procedure.[4]

Clinicians can select from a wide variety of debridement methods: sharp, enzymatic, larval, autolytic and mechanical.[5] There are few studies comparing the effectiveness of the various debridement techniques. As a result, clinicians choose a method based on the care setting, wound type, the patient's pain level and the experience, training, licensure and comfort level of the clinician.[6] Sharp debridement using a scalpel or curette is common in the outpatient wound clinic; however, not all wound care practitioners receive formal surgical training and many practice in care settings in which aggressive sharp debridement is unsafe and impractical. Controlling procedure-related pain can also limit the use of sharp debridement techniques in the outpatient or post-acute setting.

This prospective trial evaluated a novel debridement tool, EZ-Debride (MDM Wound Ventures, US), designed as an alternative to traditional sharp debridement. The head of the instrument has cutting flutes that permit uniform removal of nonviable tissue from the wound bed and the periwound skin, lessening the risk of deeper injury. It has a flexible neck and a handle for stable gripping (Fig 1). It is US Food and Drug Administration (FDA) cleared for the mechanical debridement of all types of hard-to-heal wounds.

In a large multicentre clinical trial conducted at 14 sites in the US, fluorescence imaging (MolecuLight,

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Canada) identified bacteria at levels (>10^4 colony forming units (CFU)/g) that inhibit wound healing.[7] These findings were confirmed by quantitative tissue culture.

Sharp debridement has been shown in some cases to reduce bacterial load; however, it is unusual for a single debridement procedure to lower the bacterial burden below the 10^4CFU/g threshold.[8] In this study, we evaluated the ability of this mechanical debridement tool to reduce bacterial burden after a single debridement.

Methods

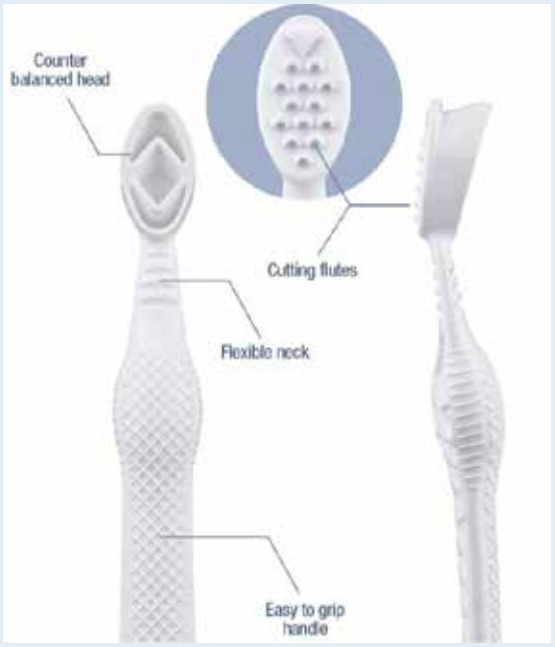
This prospective clinical trial was registered on ClinicalTrials.gov (NCT04342767). Adult subjects were recruited and treated at a single wound research centre in Pittsburgh, Pennsylvania. Subjects with acute or hard-to-heal wounds present for a minimum of four weeks were included. Subjects with multiple wounds had the option of enrolling more than one wound. Patients were excluded from the trial if they had a contraindication to debridement (for example, arterial ulcer, pyoderma gangrenosum) or any condition that, in the opinion of the investigator, would jeopardise patient safety.

After signing a Western Institutional Review Board (WIRB)-approved informed consent form, a history and physical examination were performed. The subject's wound pain level for the week before enrolment was recorded using the Pain, Enjoyment and General Activity (PEG) pain assessment tool.[9] This validated pain scoring system consists of three 1–10 rating scales: a standard numerical scale, an enjoyment of life scale and a general activity scale.[9] The wound was then undressed, photographed and measured digitally. A pre-debridement fluorescence image was obtained using a dark drape to block ambient light. Xylocaine gel 2% was applied to the wound bed for five minutes before debridement. The wound was then debrided using the mechanical debridement tool (Fig 1). Debridement was performed by two investigators, only one of whom was surgically trained, working separately in the same setting. In addition, a wound-certified nurse preformed debridement under the direction of the principle investigator. The subject was asked to rate the maximal pain experienced during the debridement procedure. Haemostasis was achieved with direct pressure. A second fluorescence image was obtained post debridement. At 10 minutes following the procedure, the patient again rated his or her pain on a scale of 1–10. The active portion of the trial was now complete. Patients were advised to contact the site if they experienced any adverse events in the next 30 days.

Results

The trial comprised 22 subjects (10 male patients and 12 female patients) with a total of 28 wounds. The average age of patients was 64 years (range: 22–95 years). The average wound duration was 29 weeks (range: 6–142 weeks). Wound types included diabetic foot ulcers, venous leg ulcers and pressure ulcers, post-surgical and traumatic wounds. Patient demographics are summarised in Table 1.

Fig 1. Debridement tool



The wound pain level reported by subjects for the week before enrolment averaged 3.9 and ranged from 0 to 10. The PEG assessment for the enjoyment of life and general activity scales were 3.0 and 3.8, respectively, each with a median score of two (Table 2). Subjects reported an average increase in pain with debridement of 0.6 points (Table 3). When the four patients with diabetes who reported having neuropathy were removed from the analysis, the pain score with debridement increased slightly to 0.75. The range of procedural pain extended from zero to eight; however, only 10% of patients reported an increase in pain of >2 points with wound debridement.

The investigators reported that the device was easy to use and effectively removed slough and necrotic material (Fig 2). The investigators did not need to supplement their debridement with a scalpel blade or curette in order to achieve a clean wound bed. There were no differences in pain scores based on the clinician performing the debridement. Haemostasis was achieved with direct pressure in all cases and the only adverse event was a wound infection that occurred four days after debridement. The investigator noted that it was unlikely that the adverse event was related to the procedure.

Pre-debridement fluorescence imaging revealed that 59% of wounds had red or cyan fluorescence, indicating a bacterial load ≥10^4CFU/g. In the wounds positive for fluorescence pre-debridement, the post-debridement fluorescence images showed: 19% were negative for bacterial fluorescence (an example wound is shown in

Table 1. Patient demographics

Subject	Patient age (years)	Sex	Ulcer duration (weeks)	Comorbidities (major conditions listed)
001-001	57	Male	129	Chronic venous insufficiency, venous leg ulcer
001-002	62	Male	20	Lymphoedema, chronic venous insufficiency, venous leg ulcer
001-003	72	Male	20	Coronary artery disease, hypertension, venous insufficiency, right lower leg venous ulcers, lymphoedema of leg, chronic venous insufficiency
001-004	Wound #2	Male	25	
001-005	Wound #3	Male	20	
001-006	Wound #4	Male	25	
001-007	Wound #5	Male	20	
001-008	59	Female	6	Anxiety, depression, psoriasis, hyperlipidemia, hypomagnesemia, diabetes type 2, gastroesophageal reflux disease, chronic venous insufficiency, chronic obstructive pulmonary disease, hypertension
001-009	52	Female	35	Abdominal wound, diabetes type 2, hypertension
001-010	55	Male	8	Hypertension, chronic venous insufficiency
001-011	81	Male	12	Diabetes type 2, hypertension, hypokalemia, hyperlipidemia
001-012	63	Male	30	Hyperlipidemia, chronic pain—general body, hypertension, lymphoedema, peripheral neuropathy, gastroesophageal disease, diabetes type, chronic venous insufficiency
001-013	49	Female	20	Morbid obesity, hypothyroid, hypertension, osteoarthritis, depression, chronic venous insufficiency
001-014	Wound #2	Female	8	
001-015	85	Male	8	Peripheral neuropathy, diabetes type 2, hyperlipidemia, benign prostatic hyperplasia, epilepsy, hypertension, history of deep vein thrombosis, chronic pain—general body, glaucoma
001-016	76	Female	24	Diabetes type 2, Parkinson's disease, hypertension, hyperlipidemia, chronic kidney disease, anxiety, anaemia, obesity, sleep apnoea, peripheral vascular disease
001-017	94	Female	41	Hyperlipidemia, hypertension, depression, atrial fibrillation, pressure ulcer, non-ambulatory
001-018	72	Female	68	Chronic renal disease, gastroesophageal reflux disease, hypertension, spinal stenosis, chronic pain—general body, hypothyroid, overactive bladder, depression, morbid obesity, pressure ulcer, lymphoedema, neuropathy, anxiety, diabetes type 2, chronic venous insufficiency
001-019	67	Female	20	Quadriplegic, epilepsy, iron deficiency anaemia, osteoarthritis, hyperlipidemia, pressure ulcer, dysphagia, heart disease (unspecified)
001-020	79	Female	142	Dysphagia, insomnia, general body chronic pain, diabetes type 2, asthma, hypertension, hyperlipidemia, hypothyroid, depression, peripheral vascular disease
001-021	66	Female	8	Lymphoedema, chronic obstructive pulmonary disease, hypothyroid, hypertension, diabetes type 2, anaemia, chronic pain—general body, urinary retention, peripheral vascular disease, congestive heart failure
001-022	77	Female	24	Oedema, hypertension, chronic pain—bilateral feet, peripheral arterial disease, chronic venous insufficiency
001-023	85	Male	8	Neuropathy, diabetes type 2, hyperlipidemia, benign prostatic hyperplasia, epilepsy, hypertension, history of deep vein thrombosis, chronic pain—general body, glaucoma
001-024	45	Female	45	Diabetes type 2, Charcot foot, neuropathy, anxiety, hypertension, gastroesophageal reflux disease, arthritis, bilateral first metatarsal amputation
001-025	22	Male	52	Bilateral trochanteric pressure ulcers, paraplegia
001-026	Wound #2	Male	47	
001-027	69	Female	45	Muscle spasms, oedema, chronic pain—bilateral legs, chronic venous insufficiency, peripheral arterial disease, chronic obstructive pulmonary disease
001-028	79	Male	6	Hyperlipidemia, hypertension, oedema, history of deep vein thrombosis, gastroesophageal disease, reflux disease, neuropathy, chronic obstructive pulmonary disease

Table 2. PEG Pain assessment scores at the time of enrolment

Pain assessment indicators	Median	Mean
What number best describes your pain on average in the past week?	4	3.9
What number best describes how, during the past week, pain has interfered with your enjoyment of life?	2	3.0
What number best describes how, during the past week, pain has interfered with your general activity?	2	3.8

PEG—Pain, Enjoyment and General Activity (PEG) pain assessment tool[9]

Table 3. Pain before, during and after debridement

Pain assessment indicators	Mean score
Pain before debridement	1.8
Pain during debridement	2.3
Pain after debridement	1.5

Fig 3), 50% of the images had less bacterial fluorescence (25%–75% reduction), 19% were unchanged and 3% had increased bacterial fluorescence (an example wound is shown in Fig 4).

Discussion

The old surgical adage: 'If you can't cut, you can't cure', rings true in the practice of wound care: 'If you don't debride, the wound won't heal.' Debridement is an essential procedure in the treatment plan for hard-to-heal wounds: it removes slough and necrotic material and disrupts bacterial biofilms. A large clinical trial evaluating more than 300,000 patients demonstrated that weekly debridement promoted wound healing better than less frequent or no debridement.[3] Recent admonitions for clinicians to practice biofilm-based wound care include frequent debridement to break up biofilms that stall wound healing.[10] Sharp debridement using a scalpel or curette is a frequent choice in the outpatient wound clinic; however, not all wound care clinicians feel comfortable wielding a scalpel or performing aggressive procedures in nursing facilities or at a patient's home.

There is evidence for the use of enzymatic debridement in hard-to-heal wounds,[11] but its use is often limited by concerns over cost and the time required to achieve a clean granulating bed. Larval therapy has also been shown to be effective;[12] however, it is impractical in many settings. In this study, a novel mechanical debridement device was shown to effectively remove nonviable tissue from the wound bed with minimal patient discomfort, no difficulties with bleeding and few adverse events. Clinicians looking for an alternative to sharp debridement, or practicing in home health or skilled nursing facilities may wish to incorporate this debridement technique into their wound care practice.

The results of fluorescence imaging before and after a single mechanical debridement in this study are similar to previous publications, and the observations from the FLAAG clinical trial.[7,8] The advent of fluorescence imaging is reshaping theories on debridement and its effect on bacterial burden. Results from this trial suggest that the mechanical debridement tool decreased bacterial load in most cases (69%); however, following a single debridement, 81% of wounds continued to have a bacterial load that inhibited healing. This suggests that a single debridement may not lower the bacterial burden to a level at which healing will proceed unimpeded. This may explain why weekly debridement

Fig 2. Pre- (**a**) and post-debridement (**b**) standard images

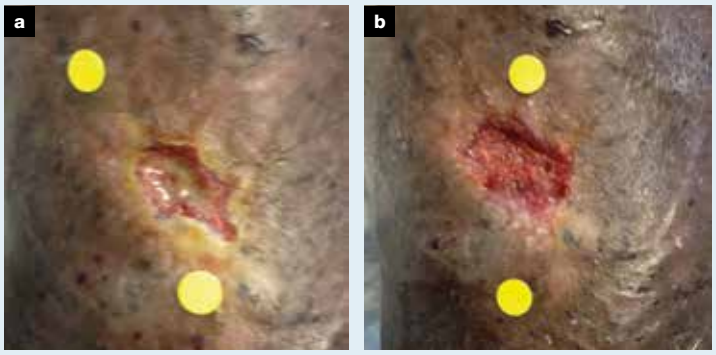


Fig 3. Pre- (**a**) and post-debridement (**b**) fluorescence images demonstrating elimination of bacterial fluorescence after debridement

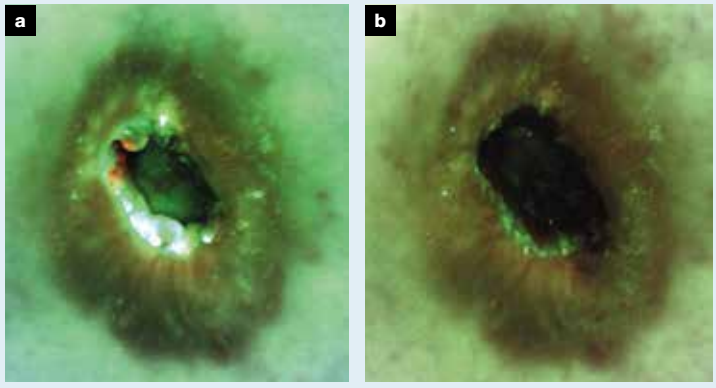
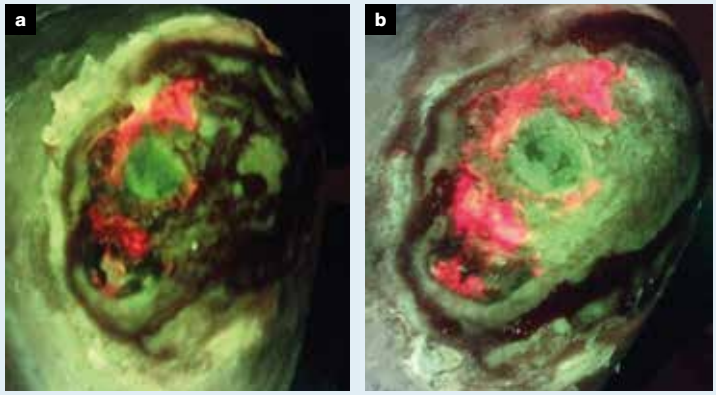


Fig 4. Pre- (**a**) and post-debridement (**b**) fluorescence images demonstrating increased bacterial load following debridement



has been shown to facilitate wound closure. Further research into the role of debridement in treating bacterial load and comparative effectiveness studies between debridement techniques is needed.

Limitations

The limitations of this study include the small sample size of 28 wounds, the lack of a control group, and its single-day design. All patients were debrided with the device and imaged. There was no comparator. The trial was conducted on a single day. Future trial designs will include longer follow-up. Future study designs will also include correlating debridement with reduction in surface area at four weeks and complete healing at 12 weeks. In addition, longer follow-up with fluorescence imaging will hopefully determine the number of debridement procedures required to reduce the bacterial load below the 10^4CFU/g mark.

The subjective nature of pain makes it difficult to study. This study allowed patients with low pain scores to participate. Future studies evaluating pain associated with debridement may wish to consider inclusion criteria with a minimal baseline pain value because it was difficult to fully evaluate the impact of the procedure on pain in some of the patients in this study due to a low baseline pain score. In addition, longitudinal studies using the PEG pain assessment tool may be of value in assessing pain over a period of time.

Conclusion

The novel mechanical debridement tool evaluated in this prospective study removed slough and necrotic material with minimal discomfort and adverse events. In the majority of cases it reduced bacterial burden as demonstrated by fluorescence imaging. It will not replace sharp debridement but is a viable option for wound clinic practitioners who are uncomfortable with sharp debridement, and for clinicians practicing in care settings in which sharp debridement is not a practical option. JWC

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Reflective questions

- Is it possible to have different debridement tools for different patient care settings?
- Can some debridement techniques result in less patient discomfort?
- Does a single debridement procedure remove all of the clinically significant bacteria?