Periwound skin management of chronic lower-limb wounds with use of a novel multi-ingredient skin cleanser: a single-centre study

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The condition and moistness of periwound skin has been directly linked to the success of wound bed preparation and wound healing. This study investigates the use of a novel skin cleanser designed to enhance periwound recovery, in a population of 61 patients seeking outpatient care at the wound clinic of Kuala Lumpur General Hospital for lower limb wounds. All patients underwent baseline assessment of their wounds using the TIME assessment technique for the wound bed and the Harikrishna Periwound Skin Classification for periwound skin, followed by treatment with the skin cleanser as well as the appropriate dressings and treatment adjuncts. Of the 61 patients assessed on periwound condition during the 7-month observation period, 3 patients had complete wound healing, 50 patients progressed to healthy wounds, 4 patients had macerated periwound skin and another 4 patients had dry periwound skin after the completion of the trial. All patients with wounds exhibiting inflammation with or without superimposed infection experienced resolution of these issues following use of the skin cleanser.

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The periwound skin is an important component of the triangle of wound assessment, which is a three-pronged approach to wound management. (Dowsett and von Hallern, 2017). It has been defined as an area of skin up to 4 cm from the wound edge, although this area may be expanded to include any area of skin extending outwards from the wound which is at risk of damage. (Dowsett, 2015). This area is often under threat from maceration due to excessive exudate, dry skin, hyperkeratosis and excoriation from trauma or dressing removal, and the resultant periwound skin damage may prolong wound healing time and impact a patient's quality of life (Cameron, 2006).

The TIME framework is a well-established tool used by clinicians to structure an approach to wound management, by categorising the wound according to four principles: presence or absence of nonviable tissue, presence or absence of infection, moisture balance of the wound, and whether the edges of the wound are undermined or non-advancing (Dowsett and Newton, 2005). These principles serve to aid health professionals in removing barriers to wound healing in hard-to-heal wounds. Protection of the periwound skin is an integral part of this strategy, and the hitherto lack of a standardised assessment tool for evaluation of the periwound area led to the development of the (Nair, 2019; Nair et al, 2020). The HPSC is a validated clinical tool for assessment of both the wound bed and periwound skin health on a scale of 0 to 5, with Class 0 being normal skin, Class 1 denoting fibrous tissue or tissue otherwise at risk, Class 2 being wounds with exudate, and Classes 3 and 4 being inflamed wounds without and with infection respectively. Class 2 exudative wounds are further divided

Table 1.Harikrishna Periwound Skin Assessment

Class	Subtype	Periwound condition
0		Normal
1		Fibrous tissue/tissue at risk
2	A	Exudate centred with desiccation
	B	Exudate centred with maceration
	C	Exudate centred with allergy
3		Inflammation without infection
4		Inflammation with infection
5		Atypical (senescent cells/ cancer/subcutaneous emphysema)

in Class 2A for those centred with desiccation, Class 2B for those centred with maceration, and Class 2C for those centred with allergy. Class 5 is a separate category for wounds with atypical cells, for instance pre-cancerous wounds or active carcinoma, or subcutaneous emphysema. (Nair et al, 2020) The HPSC thus serves both as a useful clinical assessment tool as well as an objective method for evaluation of the efficacy of measures to protect the periwound skin *(Table 1)*.

Methodology

Patients were selected via convenient sampling from the patients attending the wound care outpatient clinic at Hospital Kuala Lumpur for wounds of the lower limb from June 2020 to January 2021. These included patients with diabetic foot ulcers (DFU) and venous leg ulcers (VLU), with or without inflammation and infection. Informed consent was obtained for all patients (both verbal and written) for participation in this study, use of the skin cleanser, and medical photography for documentation and study purposes. All patients were treated for a standard duration of 12 weeks and reassessed with measurement of wound size, photography, and evaluation of healing.

All wounds were assessed upon recruitment using the TIME framework as well as the HPSC method. All patients subsequently underwent mechanical debridement via sterile gauze soaked in a diluted solution of the cleanser (Botrem Restoractiv INTENSIVE intricate care wash skin cleanser) as per manufacturer's instructions. The appropriate dressings were applied along with any specific treatment such as topical or systemic antibiotics.

Results

We recruited 61 patients for this study, about half (29 out of 61) had wounds with fibrous tissue or tissue otherwise at risk fitting HPSC class 1 at baseline *(Figure 1)*. Of the remainder, 25 patients had exudative wounds (defined as HPSC Class 2) with 16 patients fulfilling the criteria for HPSC Class 2A, 8 patients for HPSC Class 2B, and 1 patient for HPSC Class 2C. There were four patients with inflamed wounds without infection (HPSC Class 3) and three patients had inflammation with infection (HPSC Class 4)

Figure 1. Periwound condition on recruitment

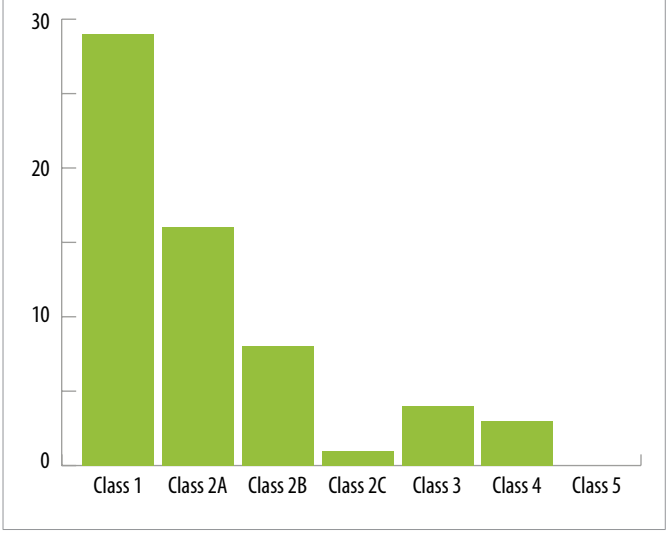
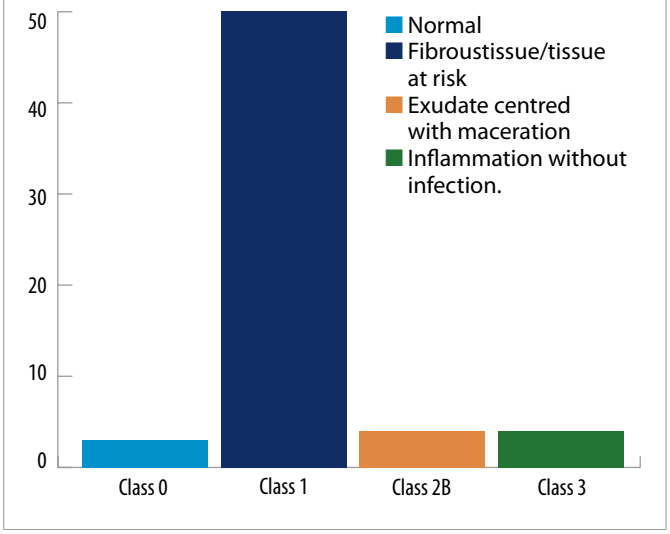


Figure 2. Periwound condition on last study date



Key words:

- *Bacteria*
- *Garcinia mangostana*
- *Wound healing*
- *Wound infection*

Figure 3. Venous leg ulcer Harikrishna Periwound Skin Assessment Class 1 (fibrous tissue) showing complete healing after 46 days of treatment with skin cleanser

Day 1: 9cm x 5cm	Day 46: Wound healed
	

Figure 4. Harikrishna Periwound Skin Assessment Class 4 wound (inflammation with infection) showing resolution of infection and inflammation and reduction in wound size by 75% after 27 days of treatment

Day 1 10cm x 10cm	Day 27 5cm x 5cm
	

(Figure 1). None of our study patients had atypical wounds with carcinoma or pre-cancerous tissue (HPSC Class 5).

Following treatment with the novel skin cleanser over three months, the majority experienced favourable outcomes from use of the cleanser *(Figure 2)*. There were three patients who had complete healing with wound closure, whereas 50 patients had healthy wounds by the end of the study period without superimposed infection or inflammation. However, four patients had dry periwound skin (HPSC Class 2A) and another four had macerated skin (HPSC Class 2B) at the end of the treatment period *(Figure 2)*. This could be accounted for by multiple patient factors including suboptimal :nutrition, poor personal care, or complicated wounds requiring treatment modalities beyond the scope of the

Figure 5. Patient with Harikrishna Periwound Skin Assessment Class 2C wound at baseline, showing dry periwound skin at the end of the treatment duration

Day 1 15cm x 10cm	Day 147	Day 174 6cm x 4cm
		

methods of this study. No allergic reactions to the skin cleanser were reported throughout the study period.

Figure 3 shows a 46-year-old male with a VLU and a Harikrishna Periwound Skin Assessment Class 1 (fibrous tissue). On presentation the VLU was 14 days old wound with comorbidities of diabetic mellitus on OHA. The wound was cleaned with normal saline until patient was referred to wound care unit. After 46 days of treatment with skin cleanser the wound completely healed.

Figure 4 shows a 39-year-old male infected eczema wound and a Harikrishna Periwound Skin Assessment Class 4 wound (inflammation with infection). On presentation the wound was 10 days old with and the patient was disabled. He went for treatment at emergency department for cellulitis and after that was referred to wound care unit for further management. The infection and inflammation resolved, and the wound size reduced by 75% after 27 days of treatment.

Figure 5 shows a 47-year-old male with VLU wound and a Harikrishna Periwound Skin Assessment Class 2C. On presentation the wound was 30 days old and the patient had hypertension, diagnosed in 2017, and was on antihypertensive treatment. The patient went for treatment at nearest district clinic and wound was cleaned with normal saline, he was referred to wound care unit because wound was getting bigger. On day 1 the wound, measured 15cm x 10cm. The wound reduced in size throughout the treatment and on day 174, it was 6cm x 4cm with dry periwound skin.

Discussion

DFUs and VLU being hard-to-heal wounds, have many factors affecting the wound healing rate. Vasculopathy, neuropathy and dermopathy cause poor lower limb circulation necessary for recovery, requiring an adjunct treatment approach to augur improvement. Early stage wounds with exudate and inflammation are often compounded by skin dryness and bacterial infection compromising the healing process. These factors need to be managed holistically effectively for symptoms reduction to ensure improved recovery of the wound bed.

Periwound moistness, as an enabler can improve the ability of the surrounding skin to channel nutrients to the wound bed aiding its recovery, notwithstanding the use of other treatment adjuncts.

This single-centre study reinforces the link between optimal management of the periwound area and favourable wound healing, as validated by the TIME method as well as the HPSC. Previous studies have shown a link between a moist periwound area and increased wound bed recovery, attributed to the improved channelling of micronutrients to the wound bed and prevention of wound desiccation.

The application of the novel skin cleanser to the wound bed and periwound area has thus been shown to result in optimal wound recovery in the vast majority (53 out of 61) of our study patients. It is notable that resolution

of inflamed wounds with or without infection was achieved for 7 patients with HPSC Class 3 or four wounds within 12 weeks duration. Among the ingredients used in the novel skin cleanser are those shown *in vitro* and *in vivo* studies to be bacteriostatic and/or bactericidal, and may theoretically improve bacterial balance in wound bed preparation (Hosseinpour et al, 2012; Zhang et al, 2016; Anzaku et al 2017; Koskovac et al, 2017; Lim et al, 2019; Matulyte et al, 2020; Nair, 2019 Rembe, 2020; Suryani et al 2020). These include virgin coconut oil, marine collagen, sea buckthorn oil, super-oxidised sodium hypochlorite and hypochlorous acid and *Acacia Senegal* gum. Although our study population is not sufficiently large to conclusively attribute any resolution of infection and inflammation to the usage of these natural antimicrobials, these encouraging results are grounds for further study.

No allergic reactions to the skin cleanser were reported throughout the study period. However, at least one patient with an exudative wound complicated with eczema (HPSC Class 2C) reported dry periwound skin at the end of the treatment period despite regular use of the skin cleanser. Various factors may account for this outcome including concurrent use of topical emollients, flare of the underlying eczema, or compliance to moist dressing. Nevertheless, a reduction in wound size by 84% (15cm x 10cm at recruitment, 6cm x 4cm at end of treatment) was reported for this patient, indicating an overall positive outcome for wound healing. Further study into the daily use of diluted washes in the management of chronic dermatological conditions is encouraged.

Limitations

The cleanser has an allergy disclaimer. Ingredient descriptions are on the label for those sensitive to its use. Furthermore, larger studies would are required to confirm these results.

Conclusion

This study shows that use of the Botrem Restoractiv INTENSIVE intricate care wash skin cleanser improves periwound moisture and wound recovery. Areas of further study include the recruitment of a larger patient population and a wider range of wounds including pressure injury, surgical wounds, and vasculopathic ulcers. Thus far it has been proven to be a safe and non-detrimental adjunct to wound management in our diabetic foot patients and an effective complement to our daycare treatment. WAS

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