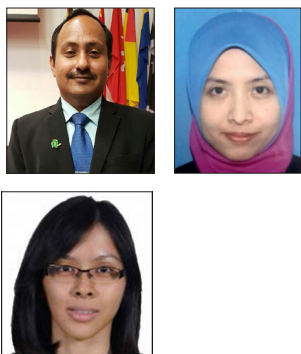


A novel approach to chronic wound management using a patented cream of silicon dioxide, silver ions, chlorhexidine and hyaluronic acid



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Chronic wounds with low healing rate generally lead to decreased in quality of life of patients, financial burden and increased morbidity rate (Järbrink et al, 2016). Thus, wound care management involving a patented 4-in-1 formulation is an aid in the management of chronic wounds. To demonstrate its efficacy, seven patients were chosen, four with a venous leg ulcer, two with a diabetic foot ulcer and 1 with a pressure ulcer. All the wounds were cleaned, debrided and then the silicon dioxide, silver ions, chlorhexidine and hyaluronic acid cream (KAdermin cream) was applied as the primary dressing, with a non-adhesive dressing as a secondary dressing. This case series demonstrates that the cream was able to reduce wound size significantly, while eliminating infection signs.

A chronic wound is defined as a wound that failed to proceed through an orderly and timely process to produce anatomic and functional integrity (Werdin et al, 2009; Malaysian Ministry of Health, 2014). These wounds can last from four weeks up to more than three months, and are often associated with complications due to comorbidities including diabetes, vascular disease and trauma. In developed countries, it is estimated that 1 to 2% of the population will experience a chronic wound in their lifetime (Gotttrup, 2004). These chronic wounds, which are difficult to heal, generally lead to a decrease in the patients quality of life, financial burden and increased morbidity rate (Järbrink et al, 2016; Yao et al, 2020). Based on a 2016 report from Wales, it is estimated that a 6% prevalence of chronic wounds attributes to 5.5% cost to the National Health Service (NHS) (Sen et al, 2019). Thus, modern wound care management is necessary to aid the healing of chronic wounds.

With great strides in technological innovation, a novel therapy was introduced. It provides a patented 4-in-1 solution for the treatment of a wide range of wound types (Nair, 2019). This wound care medical device has four main functions, disinfection, protection, wound hydration and restoration of the physiological condition of the area. The cream works by

exerting the antimicrobial effects of silver (Ag+) concurrently with the disinfection properties of chlorhexidine and the moisture-balance properties of hyaluronic acid (Lu et al, 2017; Li et al, 2019). Simultaneously, silicon dioxide (SiO₂) forms a protective barrier over the wound (Sood et al, 2014).

Methodology

Patients from Wound Care Unit of Hospital Kuala Lumpur with chronic wounds cases including four venous leg ulcers (VLU), two diabetic foot ulcers (DFU) and one pressure ulcer/pressure injury (PU/PI) were enrolled in this study by convenient sampling. They were treated with a cream of SiO₂ silver ions, chlorhexidine and hyaluronic acid (KAdermin, Y.S.P. Industries (M Sdn. Bhd.)). The delivery and application of KAdermin cream to wounds has been simplified since all the individual components are packed collectively in a specialised tube. Patient's details including age, past medical history, wound history and wound type were accumulated. Progress was recorded down by taking wound pictures and measuring wound sizes accordingly at baseline and the last observations.

In this case series, the wounds were cleaned and debrided where necessary. The cream was squeezed out onto a sterile surface and a layer of KAdermin cream was applied over the entire

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Table 1. Summary of patient data

Patient	Age	Gender	Comorbidities	Initial wound size (cm)	Final wound size (cm)
1	65	Male	Diabetes mellitus, hypertension	5 x 10	Fully epithelialised
2	65	Male	Diabetes mellitus	11 x 11	9 x 8
3	40	Male	Systemic lupus erythematosus	5.5 x 4	4 x 3
4	45	Male	Diabetes mellitus, hypertension	5.5 x 5	5.5 x 1
5	52	Male	Diabetes mellitus, hypertension	5.5 x 3	Fully epithelialised
6	55	Male	Diabetes mellitus, hypertension	7 x 7	5.5 x 4
7	41	Female	Diabetes mellitus, hypertension	1.5 x 4.5	Fully epithelialised

wound surface using a medical wooden spatula. The wounds were then covered with non-adhesive dressing. For highly exudative wounds polyurethane foam was used for absorption purpose. In all these cases, the wounds were bandaged and dressings were changed twice a week. All patients treated as per standard of care, DFU were offloaded, VLU were treated with compression bandage and pressure relief was provided for the PU (Malaysian Ministry of Health, 2014; Nair, 2017; Mani et al, 2018).

To measure the pain in all these cases, a Visual

Analog Score (VAS) with pain range from 0 to 10 where 0 indicated the absence of pain and 10 unbearable pain.

Results

Wound healing was observed and evidenced by the absence of infection, presence of granulation, reduction of pain as well as reduction of wound size (Frykberg and Banks, 2015). The patients' data and wound evaluation are summarised as in *Table 1* and *Table 2*. *Cases 1-7* show the individual patients.

Table 2. Wound evaluation based on observation of wound area and infection signs

Evaluated wounds (7 patients)	2 weeks after treatment	3 weeks after treatment	4 weeks after treatment
Area reduction (to >50%)	4/7 (57%)	1/7 (14%)	2/7 (29%)
Signs of Infection	none	none	none

Case 1. A bilateral venous leg ulcer over the calf

- A 65-year-old Malay male with diabetes mellitus, hypertension and a bilateral venous leg ulcer over the calf
- There was a significant restoration of blood supply and a reduction of the size of the wound area after 14 days of treatment, there was also presence of granulation
- At day 31 the wound had fully epithelialised.



	Day 0	Day 31
		
Wound size (cm)	5 x 10	Fully epithelialised
Area reduction (%)	-	100
Pain score	4	0

Declaration of Interest

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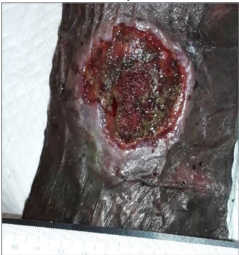

Case 2. A chronic venous leg ulcer of the left leg

- A 65-year-old Malay male with diabetes mellitus with a chronic venous leg ulcer of the left leg
- The ulcer had become chronic with the presence of moderate exudate and necrotic tissue
- At day 10 of treatment with the cream the wound size significantly reduced compared to day 0
- At day 63 all the infection signs had been eliminated and granulation was observed.

	Day 0	Day 63
		
Wound size (cm)	11 x 11	9 x 8
Area reduction (%)	-	40
Pain score	1	0



Case 3. A venous leg ulcer at the left leg

- A 40-year-old Indian male with systemic lupus erythematosus (SLE) and a venous leg ulcer at the left leg. The ulcer had become chronic with the presence of mild exudate
- After 34 days of treatment, there was a significant restoration of blood supply and reduction in the formation of necrotic tissue
- At day 48 the wound size was reduced to 4 x 3 cm, there was granulation tissue and no signs of infection.

	Day 0	Day 48
		
Wound size (cm)	5.5 x 4	4 x 3
Area reduction (%)	-	45
Pain score	0	0


Case 4. A venous leg ulcer of the right leg

- A 45-year-old Malay male with diabetes mellitus, hypertension and a venous leg ulcer of the right leg
- After 36 days of treatment, there was a significant reduction of the wound size as compared with the original size. There was also presence of granulation and absence of infections signs
- The wound size reduced progressively over a period of 50 days.

	Day 0	Day 50
		
Wound size (cm)	5.5 x 5	5.5 x 1
Area reduction (%)	-	80
Pain score	0	0

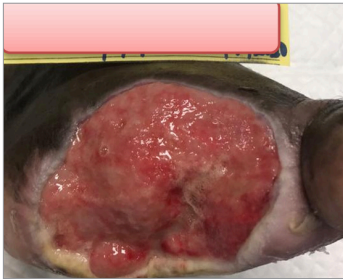

Case 5. A diabetic foot ulcer at the right leg

- A 52-year-old Chinese male with diabetes mellitus, hypertension and diabetic foot ulcer of the right leg
- Overtime, the ulcer had become chronic with moderate and clear exudate. After 24 days of treatment, there was a significant restoration of blood supply and a reduction of the wound size. There was also presence of healthy wound edge, granulation and the absence of infection signs
- At day 51 the wound had fully epithelialised.

	Day 0	Day 51
		
Wound size (cm)	5.5 x 3	Fully epithelialised
Area reduction (%)	-	100
Pain score	0	0

Case 6. A diabetic foot ulcer of the right leg

- A 55-year-old Malay male with a history of diabetes mellitus, hypertension and diabetic foot ulcer of the right leg. He had a subsequently undergone amputation of right toes
- At day 28 there was a reduction of wound size. A healthy wound edge and granulation were observed
- The reduction of wound size continued over a period of 64 days.

	Day 0	Day 64
		
Wound size (cm)	7 x 7	5.5 x 4
Area reduction (%)	-	55
Pain score	0	0

This case series consists of seven patients from Wound Care Unit of Hospital Kuala Lumpur was aimed to evaluate the efficacy of KAdermis cream. Among these seven patients, 57% of patients were older than 50 years old and 85% of all chronic wounds in this study occurred in the lower limb of patients, despite of the wound type variation.



After two weeks of treatment using the KAdermis cream, 57% of patients with chronic wounds were able to achieve an average wound reduction of more than 50%. 14% and 29% of patients with chronic wounds had the average wound reduction of more than 50% in 3 weeks and 4 weeks after treatment respectively.

Discussion

In all these patients, KAdermis cream creates a protective barrier with silicon dioxide to treat wounds, abrasions and minor burns, creating an environment protected from microbial aggression with silver as well as chlorhexidine and acting as a polymer film which favours the moisturising of tissues, thus accelerates granulation and physiological aspects of wound healing using hyaluronic acid (Lu et al, 2017; Li et al, 2019). The absence of infection signs was characterised by the absence of necrotic tissue, slough, pus and inflammation, while the moist wound healing method of KAdermis cream was demonstrated in the form of superficial epithelisation (Nair, 2019).

Case 7. A category II pressure ulcer

- A 41-year-old Malay female with a diabetes mellitus, hypertension and a category II pressure ulcer over the sacral area
- The patient was initiated on the following dressing regimen under home nursing care: cleaning with sterile water, bedside desloughing, novel cream followed by a non-adhesive dressing
- After 20 days of treatment, there was a significant reduction of 77% of wound size and granulation was observed. In 50 days, the wound had fully epithelialised.

	Day 0	Day 50
		
Wound size (cm)	1.5 x 4.5	Fully epithelialised
Area reduction (%)	-	100
Pain score	3	0

However, the sample size of this study was relatively small due to the limitation of subject availability. Thus, studies with larger sample size are needed to further support these observational findings.

Conclusion

The patented cream formulation of SiO₂- + Ag+ + chlorhexidine + hyaluronic acid was proven to be effective due to significant wound size reduction, absence of infection and presence of granulation as shown in current case series. The KAdermín cream exhibit broad spectrum antimicrobial properties of silver coupled with antiseptic properties of chlorhexidine, moisturising properties of hyaluronic acid as well as protective barrier of silicon dioxide (Nair, 2019).

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Acknowledgement

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