CLINICAL RESEARCH ARTICLE

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Effectiveness of bridge V.A.C. dressings in the treatment of diabetic foot ulcers

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***Objectives*:** This is a prospective study of the clinical efficacy of the V.A.C. Granufoam Bridge Dressing for the treatment of diabetic foot ulcers.

***Materials and methods*:** Five consecutive patients with diabetic foot ulcers were treated with V.A.C. Granufoam Bridge Dressings and studied over a period of 22–48 days. The indications for treatment included diabetic patients with open ray amputation wounds and wounds post-drainage for abscess with exposed deep structures. Clinical outcome was measured in terms of reduction in wound dimensions, presence of wound granulation, microbial clearance, and development of wound complications.

***Results*:** Our results showed that with V.A.C. therapy, wound healing occurred in all patients. The number of dressings required ranged from 8 to 10. The baseline average wound size was 23.1 cm^2. Wound areas shrunk by 18.4–41.7%. All subjects achieved 100% wound bed granulation with an average length of treatment of 33 days. Microbial clearance was achieved in all cases. All wounds healed by secondary intention in one case and four cases required split-thickness skin grafting.

***Conclusion*:** The V.A.C. Granufoam Bridge Dressing is effective in the treatment of diabetic foot ulcers. It promotes reduction of wound area, wound bed granulation, and microbial clearance. By allowing placement of the suction pad outside the foot, it allowed patients to wear protective shoes and to walk non-weight bearing with crutches during V.A.C. therapy.

Keywords: *diabetic foot, negative pressure wound therapy, ulcer, neuropathy*

Received: 5 December 2010; Revised: 19 January 2011; Accepted: 10 February 2011; Published: 4 March 2011

Foot ulcers affect 10–25% of diabetic patients (1). Management of a diabetic foot ulcer is often a challenging problem. Healing of these ulcers often takes a long time and may need one or more debridements. The treatment of such ulcers, therefore, needs time with a prolonged hospital stay, intensive wound management, and high hospitalization costs.

Large ulcers that do not heal adequately by secondary intention usually require split-thickness skin grafting for skin cover. However, the successful healing of such wounds depends mainly on the quality of wound bed preparation in promoting good granulation tissue.

Over the years several advanced wound care products have been developed, all with the aim of achieving wound bed optimization for eventual wound closure. In particular, negative pressure wound therapy (NPWT) using the Vacuum Assisted Closure (V.A.C.) Therapy System (Kinetic Concepts Inc, San Antonio, TX, USA) has gained increasing popularity for the treatment of chronic and complex wounds. The NPWT has been shown to accelerate wound healing by reducing local tissue edema, promoting granulation tissue formation, increasing local blood flow, and decreasing bacterial bioburden in both animal and clinical studies (2, 3). The efficacy of V.A.C. dressings has been demonstrated in several randomized controlled studies, which have shown significantly faster wound healing rates compared to conventional moist wound therapy (4–6).

V.A.C. therapy has been found to be useful for treatment of traumatic wounds, diabetic wounds (5, 7), pressure ulcers, and venous ulcers. As an extension to V.A.C. therapy, the Granufoam Bridge Dressing has been designed to allow patients to wear protective shoes and to allow early mobility with walking non-weight bearing with a pair of crutches. It also allows off-loading devices to be applied simultaneously.

This prospective study evaluates the efficiency of V.A.C. Granufoam Bridge Dressing in promoting wound bed granulation and wound closure for diabetic foot ulcers.

Citation: Diabetic Foot & Ankle 2011, **2**: 5893 - DOI: 10.3402/dfa.v2i0.5893

Materials and methods

A prospective case series of five consecutive patients was conducted by the National University Hospital, Singapore over a period of 22–48 days. The study population was made up of four male subjects and one female subject with a mean age of 58.8 years (range, 51–64 years). Inclusion criteria into this study consisted of open ray amputation wounds (three patients) and wounds post-drainage for abscess with exposure of deep structures such as tendon and fascia (two patients). Patients with previous V.A.C. therapy and those on other forms of advanced wound therapy like hyperbaric oxygen therapy, normothermic wound therapy, or growth factor therapy within 30 days of the study start date were excluded. Patients on corticosteroids, immunosuppressive agents, or chemotherapeutic agents and patients with poorly controlled medical problems were also excluded from the study.

The NPWT delivered by the V.A.C. Granufoam Bridge Dressing system consisted of the open cell polyurethane foam dressing, negative pressure generating unit with an attached disposable canister, and an encapsulated bridge dressing with an integrated suction pad that transmitted the negative pressure to the wound (Fig. 1). The V.A.C. dressings were applied by the medical officer intra-operatively during the debridement operation and post-operatively by trained staff nurses strictly according to the manufacturer's guidelines and a continuous pressure of −125 mmHg was delivered to all wounds. Change of dressing was performed every 48–72 hours and wound inspection was done at every dressing change. The wounds were examined for degree of granulation, reduction in size of the wound, and development of wound complications such as infection, tissue necrosis, and skin maceration. The reduction in the size of the wound was measured by placing two pieces of transparent plastic sheets directly on the wound and marking the outline of the ulcer with a permanent ink marker on the outer sheet. The inner plastic sheet was discarded. The outer plastic sheet with the ulcer outlined on it was placed over a calibrated graph paper. The area of the ulcer was then measured in square centimeters to the nearest square millimeter.

In all patients, the suction pad was applied on the lateral side of the leg proximally (Fig. 2). This allowed the patient, after application of the dressing on the foot, to wear protective shoes. All patients were allowed to mobilize early and walk non-weight bearing using a pair of crutches during the whole period of V.A.C. therapy. None of our patients had a neuropathic ulcer in the sole of the foot due to Charcot joint disease. No off-loading device was therefore needed in all patients.

The clinical endpoints of the study were complete ulcer healing by secondary intention and adequate optimization of wound bed permitting skin grafting (sufficient reduction in ulcer size, adequate wound granulation, and eradication of wound bed bacterial bioburden).

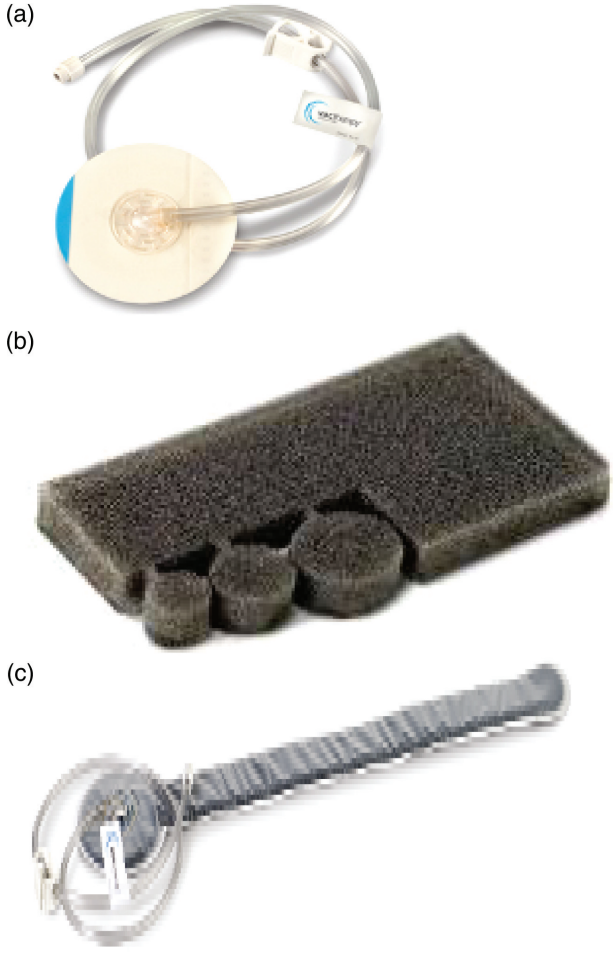

Fig. 1. (a) Suction pad, (b) polyurethane foam dressing, and (c) encapsulated bridge dressing.

Results

Table 1 summarizes the demographics and pre-treatment assessment of the study subjects. Three patients had reasonably well-controlled blood sugar levels with a HbA1c ranging from 6.7 to 8.7%; two had poorly controlled diabetes with HbA1c of 11.1 and 15.0% due to poor compliance to medications, but were subsequently counseled by the diabetic nurse educator and had their blood sugar levels optimized during their treatment period. Other significant co-morbidities include ischemic heart disease in two patients and end-stage renal failure requiring hemodialysis in one patient. All medical co-morbidities were well controlled throughout the duration of the study.

Table 1 showed that all the markers of infection were raised due to the infection present when the patients were first seen. Following V.A.C. therapy, all the markers have returned to normal showing that in all cases the infection

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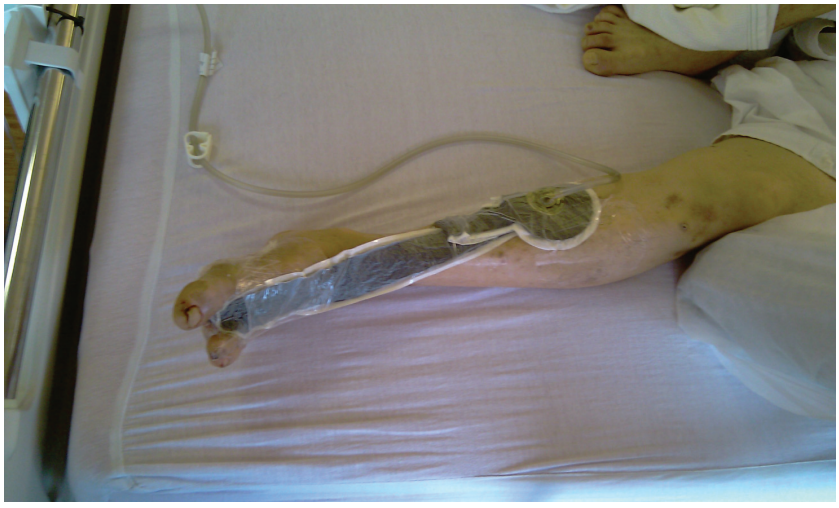

Fig. 2. Application of V.A.C. bridge dressing.

has been eradicated. Cultures of the wound swab grew *Methicillin-sensitive Staphylococcus aureus* in four cases and *Methicillin-resistant Staphylococcus aureus* in one case. All had polymicrobial infection indicating the presence of a severe infection, two patients having three organisms and another two patients having two organisms in the wound. All wound swabs taken after V.A.C. therapy was completed and indicated negative cultures.

The wounds in our study had a mean chronicity of 23.2 days (range, 7–60 days). Surgical debridement to remove all infected and necrotic tissue was performed prior to V.A.C. application to all wounds. Two patients underwent single ray amputations, two patients underwent abscess drainage and wound debridement, and one patient underwent three surgeries (first ray amputation, first ray amputation stump debridement, second ray excision arthroplasty) before starting on the V.A.C. therapy (Table 2).

Overall there was a reduction in the wound sizes of all five patients recruited into the study (Figs 3 and 4). One patient had complete ulcer closure by secondary intention with 100% re-epithelialization after duration of 42 days during which 10 V.A.C. dressings were applied. The average size of the wounds at the start of the study was

Table 1. Patient demographics, wound diagnosis and grading, infection markers, and wound cultures

						Infection markers (on arrival)			Infection markers (after V.A.C.)				
No.	Age (y)	Gender	HbA1c (%)	Wound diagnosis	Wagner grade	WBC	CRP	ESR	WBC	CRP	ESR	Wound swab (before V.A.C.)	Wound swab (after V.A.C.)
1	56	Male	7.1	Left second toe wet gangrene	3	17.35	67	121	9.40	18	25	Methicillin-sensitive *Staphylococcus aureus*, Group B *Streptococcus*	Negative
2	60	Male	6.7	Right heel abscess and cellulitis	3	15.43	63	98	6.25	12	35	Methicillin-sensitive *Staphylococcus aureus, Peptostreptococcus*	Negative
3	63	Male	8.7	Left first toe wet gangrene	3	20.19	83	55	9.56	16	22	Methicillin-resistant *Staphylococcus aureus*	Negative
4	64	Male	11.1	Right foot dorsum abscess and cellulitis	3	20.49	125	65	8.80	19	18	Methicillin-sensitive *Staphylococcus aureus*	Negative
5	51	Female	15.0	Left second toe wet gangrene	3	19.53	55	132	8.56	12	15	Methicillin-sensitive *Staphylococcus aureus*	Negative

Abbreviations: CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; WBC: white blood cell.

Table 2. V.A.C. therapy duration, change of dressings, number of surgical debridements, and time to complete microbial clearance

No.	Length of treatment (days)	No. of V.A.C. dressings used	No. of surgical debridements	Time to complete microbial clearance (days)	Surgical procedures done
1	22	8	1	20	Left foot second ray amputation
2	42	10	1	38	Right heel abscess drainage and wound debridement
3	34	10	3	31	1. Left foot first ray amputation 2. Left foot first ray amputation stump wound debridement 3. Left foot second ray excision arthroplasty
4	48	9	1	45	Right foot dorsum abscess drainage and wound debridement
5	31	9	1	29	Left foot second ray amputation

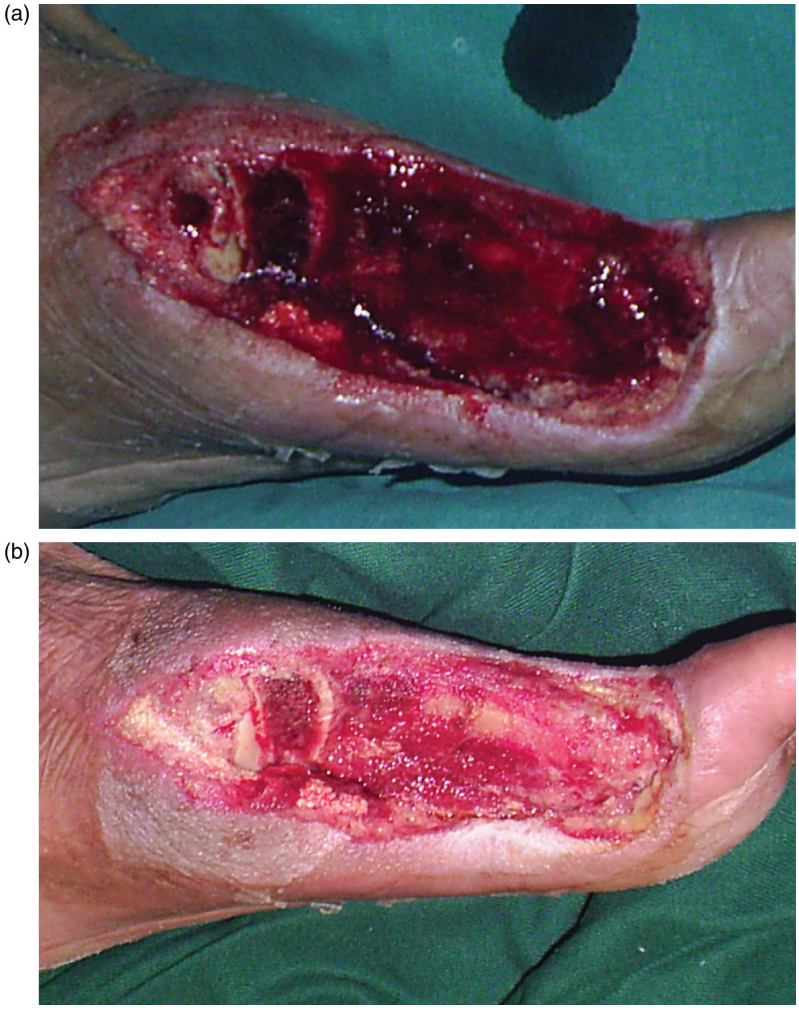

Fig. 3. (a) First ray amputation wound, day 1 post-operatively; and (b) wound appearance prior to split thickness skin grafting, day 34 post-operatively (after 10 V.A.C. dressings).

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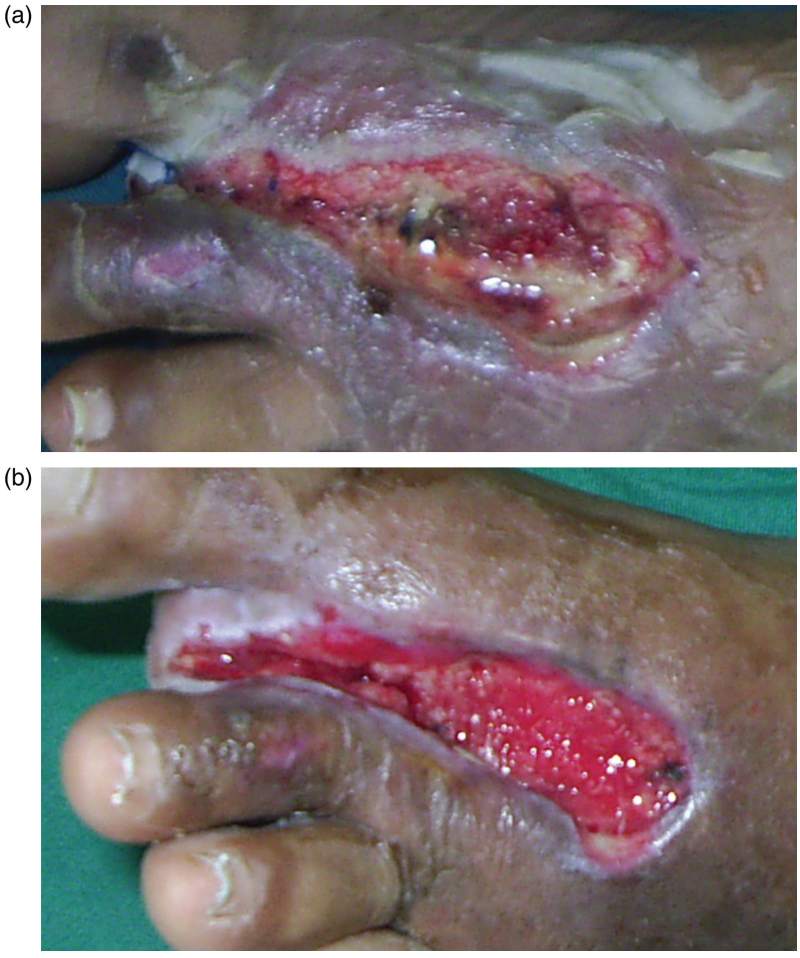

Fig. 4. (a) Second ray amputation wound, day 1 post-operatively; and (b) wound appearance prior to split thickness skin grafting, day 22 post-operatively (after eight V.A.C. dressings).

23.1 cm^2 (range, 9.8–35.8 cm^2), and by the end of the study the average wound size had reduced to 15.1 cm^2 (range, 6.3–23.0 cm^2). The mean percentage reduction in wound size was 32.8% (range, 18.4–41.7%). Table 3 clearly illustrates the progression of the wound areas for each of the five patients.

In addition to wound areas, all wounds were also clinically assessed for development of wound granulation and secondary wound complications. All five patients started showing signs of wound granulation within 4 to 8 days of starting V.A.C. therapy and all eventually achieved 100% wound granulation over a period of

Table 3. Wound progression and final outcome

No.	Wound area (cm^2)		Change in wound area		Time taken for appearance of granulation tissue (days)	Time taken for 50% granulation (days)	Time taken for 100% granulation (days)	Final outcome
	After final surgical debridement	End of study	Actual (cm^2)	Percentage (%)				
1	30	17.5	−12.5	−41.7	4	9	20	split thickness skin grafting
2	10	6.3	−3.7	−37.0	5	15	42	Secondary intention
3	35.8	23	−12.8	−35.8	6	13	30	split thickness skin grafting
4	29.8	20.5	−9.3	−31.2	8	19	45	split thickness skin grafting
5	9.8	8	−1.8	−18.4	5	13	28	split thickness skin grafting

20–45 days (mean, 30 days). Table 3 details the progression of wound areas and wound granulation of the five patients over the study period. None of the wounds developed frank clinical infection during the course of the treatment. There was no purulent discharge or wound bed necrosis in any of the wounds. All slough and biofilm that had accumulated in the wounds during V.A.C. treatment was thoroughly debrided in the ward prior to the application of the next V.A.C. dressing.

Wound swabs were also taken weekly for culture and sensitivity testing, and antibiotics adjusted accordingly. Initial wound swab growths are detailed in Table 1, but wound swabs of all five patients had no bacterial growth by the end of the study (i.e. at the point of skin grafting or complete re-epithelialization). The mean time to complete microbial clearance from the wounds was 32.6 days (range, 20–45 days).

In all five cases, no complication was seen at the site of the bridge dressing.

Discussion

This is the first study in Singapore evaluating the effectiveness of the V.A.C. Granufoam Bridge Dressing in the treatment of diabetic foot ulcers. The ability of regular V.A.C. dressings in promoting wound bed granulation and healing has been demonstrated in several studies (4–8), including one that was recently published by the first author of this paper (7). Wound bed optimization is crucial in preventing wound complications that may lead to higher amputations and for eventual wound closure by secondary intention or split skin grafting.

The V.A.C. Granufoam Bridge Dressing in our study showed comparable wound reduction capabilities as the regular V.A.C. dressings with an average wound size reduction of 32.8%. A randomized controlled crossover trial by Eginton et al. (8) achieved an average 59% wound volume reduction in patients on V.A.C. dressings, which was significantly greater than the 0.1% wound volume reduction achieved by moist wound gauze dressings, while Nather et al. (7) saw a mean wound area reduction of 24.9% in a local prospective case series on 11 patients.

Rate of wound granulation in our study was also comparable to that of published literature. Two large multicentric, randomized controlled trials conducted by Armstrong et al. (4) and Blume et al. (5) reported a median time of 42 days and 56 days, respectively, for 76–100% wound bed granulation using V.A.C. dressings for average wound sizes of 22.3 cm^2 and 13.5 cm^2, respectively, both of which were significantly faster than that for wounds treated by conventional moist wound therapy. The baseline average wound size in our study was 23.1 cm^2 and 100% wound bed granulation was achieved in all five of our study subjects with a median time to 100% granulation of 30 days.

Careful patient selection and meticulous wound bed preparation prior to V.A.C. application is crucial in ensuring good clinical outcome. Patients with untreated underlying wound infections and osteomyelitis were excluded from the study. All wounds were thoroughly debrided of infected and necrotic tissue before V.A.C. application. Nather et al. (7) showed the V.A.C. dressing to be effective for ray amputation wounds, wounds post-debridement for necrotizing fasciitis, and wounds for post-drainage for abscess with exposed deep structure such as tendon and fascia, although such ulcers can also be treated by conventional dressings. A proper randomized control study was needed to show whether V.A.C. dressings were significantly better than conventional dressings. In this paper, our indications include three ray amputation wounds and two post-drainage wounds for an abscess with exposed deep structure.

The main advantage of a Bridge V.A.C. Dressing is the ability to position the suction pad outside the foot or weight bearing area of the foot. In our patients the pad was applied on the lateral side of the calf. The application of the pad far away from the wound site has the benefit of preventing skin maceration around the wound. This complication can develop when the suction pad is applied directly over the wound. The other benefit is that the Bridge V.A.C. Dressing allows protective footwear to be worn after the V.A.C. application so that the patients can be mobilized early and walk non-weight bearing in the ward using a pair of clutches. All our patients were allowed to ambulate on the second post-operative day. The additional advantage of a Bridge V.A.C. Dressing is to allow off-loading devices to be applied simultaneously with the V.A.C. dressing. However, we were unable to experience this benefit as none of our cases were neuropathic sole ulcer due to Charcot joint disease to require off-loading treatment.

In the past when regular V.A.C. dressings were used for treating diabetic foot ulcers, we had on several occasions (three cases) improvised by positioning the suction pad outside the foot by creating bridges using additional material to allow patients to wear protective shoes and walk during the V.A.C. therapy. However, with the availability of a Bridge V.A.C. Dressing, this is no longer necessary. The use of the new custom-made dressing is not only convenient and saves time but also reduces wastage of resources. The new bridge dressing is designed for better function though it may cost slightly more.

The adding of a bridge in the new V.A.C. is not harmful and is not likely to cause any complication. It is possible that in some cases if the bridge is improperly bandaged to the leg (too tight), the suction may not function. Care must be taken to ensure that no unduly high pressure is applied anywhere along the bridge and also that the bridge must not have any kink.

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This is the first study performed on the effectiveness of V.A.C. Granufoam Bridge Dressing for the treatment of diabetic foot ulcers. We found the bridge dressing to be effective in promoting reduction of the wound size, wound bed granulation, as well as microbial clearance. Wound healing was successful in all five cases – one by secondary intention and four by split-thickness skin grafting.

Whilst our study of five cases showed the V.A.C. dressing to be effective in treatment of diabetic foot ulcers, a randomized controlled trial with a larger cohort of patients is needed to better establish the safety and efficacy of profile of this new bridge V.A.C. dressing. Patients treated by the bridge V.A.C. dressing could then be compared with diabetic ulcers treated by current conventional dressings (controls).

Conclusion

The new V.A.C. Granufoam Bridge Dressing was found to be effective in the treatment of diabetic foot ulcers. It promotes wound area reduction, wound bed granulation, and achieves microbial clearance. The placement of the suction pad outside the foot allowed the patients to wear protective shoes and to walk non-weight bearing with crutches during the V.A.C. therapy.

Conflict of interest and funding

The study was funded by KCI, Singapore, which sponsored the V.A.C. dressings for all the study subjects throughout the study period. They were not involved in the data collection, analysis or write-up of the paper and did not have editing rights to the paper. No benefits in any form have been or will be received by KCI, Singapore.

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