Comparing the clinical performance of two selected mechanical wound debridement products in sloughy pressure ulcers

Background: Mechanical wound debridement is an essential intervention in the treatment of slough pressure ulcers. Therefore, a lot of products are presented in the current local market as effective tools to perform that procedure. There is a need to revise the clinical performance of the available used products in one of the biggest governmental hospitals in Saudi Arabia to support efficient resource utilisation and suggest clinical practice protocols for pressure ulcer treatment. **Objectives:** The current retrospective cohort study compares the clinical performance of two products regarding mechanical debridement for sloughy sacral and heel pressure ulcer. Methods: The researchers retrospectively cohort the progress of 32 patients with more than 50% slough pressure ulcer, received mechanical debridement by wound care nurse during hospitalisation in the same setting and using the same pressure ulcer treatment protocols, by using either monofilament debridement pads (Debrisoft®; Lohmann and Rauscher) (16 patients) or mechanical debridement by using impregnated sterile gauze monofilaments (UCS™; WelCare Industries S.p.A) for a period of three continuous weeks. The research used PUSH tools as a data collection tool. The Hospital Institutional ReviewBoard approved the study. Results: Both products show the positive progress of pressure ulcer healing status after 3 weeks of application (P<0.01). Also, the progress mean among the monofilament group was significantly higher than the progress mean among the impregnated sterile gauze (P<0.05). **Conclusion:** The study recommends monofilament debridement pads for mechanical debridement on sloughy (more than 50% of wound bed) pressure ulcers.

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ound bed condition is the leading factor in clinical decision making to choose the most suitable dressing procedures in the treatment of pressure ulcers (Swanson et al, 2015). The wound condition should be positively progressed under the healable status, if the initial interventions satisfied the needs of the wound bed (Schultz et al, 2003). For that, the dressing decision should be evaluated in a regular manner to observe the effects of the procedure (Bryant and Nix, 2015). In general, failure of healable pressure ulcer to progress requires further procedures.

One of the main conditions that slows down the healing process is the presence of unhealthy tissue on the wound bed, such as slough (Liu et al, 2015). Management of unwelcomed tissues is an important step to enhance pressure ulcer healing (Bale, 1997). Tissue management is presented in several studies as the debridement procedure (Hampton, 2011). Debridement is defined as the removal of foreign material and necrotic tissue from a wound bed to stimulate healthy proliferation (Ashrafi et al, 2016). There are several methods approved for the debridement of pressure ulcers, such as

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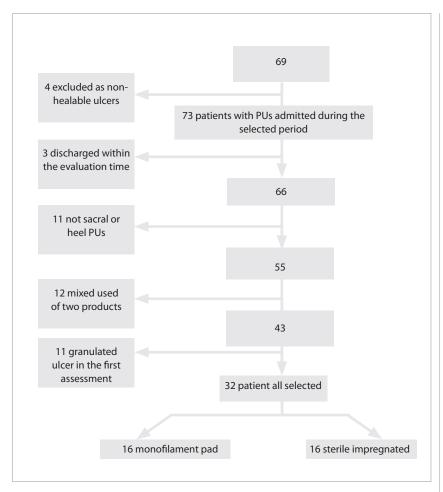


Figure 1. Selection of patients in the study.

surgical, mechanical, chemical and biological debridement (Young, 2012). Mechanical debridement is considered the most straightforward and lowest risk treatment on the patient in comparison with the other types, such as surgical debridement's, which might lead to unwanted complications (Meads et al, 2015). Nurses frequently prefer the mechanical debridement as the most accessible procedure for applying new dressings (Kelly, 2011). Mechanical debridement is widely used in the current clinical practice in King Saud Medical City.

There are several methods used to perform mechanical debridement in current practice. Wet-dry gauze, which may lead to significant wound bed injuries and delay the healing processes (Bale, 1997) and has been associated with severe pain while removing the gauze (Hampton, 2011). Monofilament debridement pads (Debrisoft®, Lohmann and Rauscher) (Meads et al, 2015) and impregnated sterile gauze monofilaments (UCS™, WelCare Industries S.p.A) (Elvin, 2015) are the two

available products used in the current wound care practice in King Saud Medical City.
Currently, there is a confusion among wound care nurses in the hospital relating to how to decide, which is the most appropriate product to be selected for mechanical debridement for pressure ulcers with the presence of slough.
Until now, the decision has depended on the individual opinion of the wound care nurse only. Therefore, there is an urgent need to evaluate the effects of both products on the overall healing process.

In summary, there is lack of available evidence comparing the clinical performance of these two wound care products in their use for the mechanical debridement of sloughy pressure ulcers. This study highlights the clinical effectiveness of mechanical debridement by using two different products. The result of the study will help the wound care nurses to select products based on evidence-based rationale, support the management leaders to formulate clear clinical practice dressing protocols and help the procurement departments to manage the available resources in the wound management practice. The study was conducted as a part of Wound Management Unit practice improvement in King Saud Medical City in Riyadh, Saudi Arabia.

Aim of study and research questions

This study aimed to compare the clinical effectiveness of two methods of mechanical debridement on changes in sloughy pressure ulcer healing statues. Therefore, the research question: "Was there a difference in the progress of healing status in sloughy pressure ulcers after perform the mechanical debridement by monofilament debridement pads (Debrisoft) compared to impregnated sterile gauze monofilaments (UCS) after 3 weeks of daily use?" The 3 weeks cut use as requirement of hospital policy to revise the treatment procedures for chronic wounds at a maximum of every 3 weeks.

Method

This was a cohort retrospect comparison study for 32 patient files with sacral or heel pressure ulcers admitted to a male medical ward in the hospital between the time from January 1 2017 until February 21 2017. The data collection took place from April 1 until May 15 2017 with patients entering the 3-week evaluation phase. Researchers evaluated the wound condition three times; on day 'zero' of diagnosing the pressure ulcer as a sloughy pressure ulcer (50% of wound bed slough or more) after 14 days

Table 1. Demographical patient information among the two groups						
	Monofilament pad Impregnated sterile gauze		Overall			
Age	60	62	61			
Length of stay	25 days	22 days	23 days			
Braden on admission	15.3	14.9	15			
Sacral ulcer	9	9	18			
Heel ulcer	7	7	14			
Initial primary dressing (silver)	8	8	8			
Initial primary dressing (Ringer hydro-clean)	6	3	4.5			
Initial primary dressing (honey)	2	5	3.5			
Initial PUSH mean score	14.81	15.6	15.02			

Table 2. PUSH score among the groups									
	Type of cle	Type of cleansing used							
	Monofilam	Monofilament pad (group 1)			Impregnated sterile gauze (group 2)				
	М	SD	n	М	SD	n			
PUSH score initial	15.38	1.9	16	15.63	1.78	16			
PUSH 3	3.87	1.25	16	10.67	1.70	16			

and after 21 days. Researchers transferred the narrative wound care note to a numerical scale by using Pressure Ulcer Scale of Healing (PUSH).

The hospital ethical committee approved the study. Researchers revised the wound care notes in a coherent, retrospective manner to recruit patients based on specific inclusion criteria. Patients eligible for the study were complaining of sacral or heel (or both), healable pressure ulcers based on the initial wound care nurse assessment. Also, patients had to be non-diabetic, with wounds containing more than 50% sloughy tissue in the initial evaluation by a wound care nurse and they must have received mechanical debridement at each dressing change by one of the selected products only.

Patients with a non-healable or chronic wound were excluded, as well as patients that were diagnosed as being diabetic or if their ulcer was clean with no signs of slough or necrotic tissue. Any patient who had received mechanical debridement using both products within 3 weeks was excluded. The exclusion criteria designed to eliminate the effect of any further factors on wound healing, such as the history of diabetes before the last admission, low nutritional profile and patients above the age of 70.

Patients were then divided into two groups; the first group of patients received mechanical debridement by using the monofilament debridement pad and the second group by using impregnated sterile gauze. All patients were treated using the same material for 3 weeks continuously. If any change occurred to this procedure in either group by using any other material, the results would be excluded from the study. The data collection took place from April 1 until May 15 2017.

The research team revised 73 patient files. Four patients were classified as non-healable wounds. Moreover, three patients were discharged within 3 weeks. Eleven patients did not complain of sacral or heel ulcers and, in 12 patients, the mechanical debridement management was mixed between both products. Finally, 11 patients had granulated ulcers without the presence of slough.

All patients were treated under European Pressure Ulcer Advisory Panel (EPUAP)/National Pressure Ulcer Advisory Panel (NPUAP) prevention guidelines (NPUAP, 2014). Repositioning was applied every 2 hours, supporting surfaces were employed as was nutritional follow up. Twenty patients were receiving regular dietary care from the hospital clinical dietitian; eleven of them in the sterile impregnated gauze group and nine in the monofilament pad group. There were also 12 patients initiated on the nutritional follow

Table 3. Paired t-test result among the groups								
	Paired differences							
	М	SD	Std. Error Mean	95% confidence interval of the differences		t	df	Sig
				Upper	Lower			
Pair (PUSH1st – PUSH 3rd) Monofilament Pad	11.5	2.19	0.54	10.3	12.66	20.99	15	0.00*
Pair (PUSH1st – PUSH 3rd) Impregnated Sterile gauze	2.62	2.18	0.54	1.46	3.79	4.8	15	0.00*
*P less than 0.001								

Table 4. Independent t-test						
	Group	N	Mean	Std. deviation	Std. error mean	
PUSH3	Monofilament	16	3.88	1.25	0.31	
	Impregnated	16	13.69	1.70	0.42	

up during the investigation period. *Figure 1* presents the flow chart for the patients' selection procedure.

All patient files were revised for wound care nurse notes and plan of care; all ulcers were treated based on the routine procedure in the hospital by applying hydrogel dressing depending on the moisture level of the wound. If the wounds still had slough tissue after 3 weeks maximum, then the wound care nurse used a ringer lactate dressing as treatment (TenderWet® plus, Hartmann). For treatment of infection, silver was the first option, and after 3 weeks without response, a polyhexamethylene biguanide (PHMB) dressing would be applied. If infection was still present after 3 weeks, then a honey dressing was the option. No patient within these groups was on any systematic antibiotics during the data collection period. Antibiotics are not routinely applied to treat any conditions related to the pressure ulcer.

Measurements

The PUSH Tool was used as the data collection indicator (Choi et al, 2016). PUSH is the most recommended tool used to evaluate the effectiveness of wound care practice among healable pressure ulcer (Liu et al, 2015; Choi et al, 2016).

To confirm the reliability, the research team divided into two groups, with two in each category and excluded the primary author. Each group was revised randomly selected file for total 18 for each of them. Reliability of the PUSH applications in the present study was

confirmed by randomly selecting 12.5% of the total patients in the study (four patients) and blindly re-transfering the reported note to PUSH sheet from different personnel. The patients with double evaluation matched together (total number of four patients had six separate PUSH sheet, presented to primary author from different group) The analysis for these selective PUSH sheet by using Cronbach alpha, the level of consistency between the 12 readings of PUSH (total 4 patients, each patient will have three PUSH equal 12 with another 12 from duplication means 24 PUSH sheet) revision = 0.96. The research team considered this to be a satisfactory consistency check.

Pressure ulcers were assessed and scored on the three elements of the PUSH tool after reading and then revised by the wound care nurse: Length x width -> scored from 0 to 10. Exudate amount --> scored from 0 (none) to 3 (heavy). Tissue type --> scored from 0 (closed) to 4 (necrotic tissue). The guideline for using the PUSH tool was taken from the NPUAP website (NPUAP, 2016).

Results

Demographical result

There were 32 patients (16 in each group) in total with all patients being male. In the impregnated sterile gauze group, eight patients had a hospital-acquired pressure ulcer, and in the monofilament debridement pad group, six patients had a hospital-acquired pressure ulcer [Table 1]. The average age was 61 years, while the average length of hospital stay was 23 days.

Table 5. Independent t-test for PUSH 3rd after three weeks of use						
	F	Sig	t	df	Sig (2-tail)	
t-test (PUSH 3rd)			-18.54			
Equal Variance			10.5 1			
assumed	4.20	0.047		20	0.00	
Equal Variance not	4.30	0.047		30	0.00	
assumed			-18.54	27.62	0.00	

The average Braden Scale score on admission was 15.14. Patients developed a pressure ulcer in the hospital (nine sacral and five heel ulcer – two were on the left side and three on the right side), and 18 patients had community-acquired pressure ulcers (nine sacral pressure ulcer and four left heels and five right heel ulcer).

Within group analysis

The data shows that among the monofilament pad group, the average of initial score of PUSH score was 15.38 with standard deviation (SD)=1.9. While the third-week PUSH score for monofilament pad shows a mean (m) of 3.87 with SD coming in at 1.25. On the other hand, the impregnated sterile gauze group shows initial PUSH score M=15.63 and SD=1.78. The mean of the third-week PUSH reached 10.67 with an SD=1.70. *Table 2* presents the summary of PUSH score results among the two groups.

Furthermore, there was a significant difference between the count of initial PUSH (M=15.3, SD =1.9) and the score of PUSH 3rd after 21 days of dressing (M=3.87, SD=1.25) conditions t(15) = 20.99 P=0.00 [Table 3]. There were strong similarities between the groups during the first week of treatment. Furthermore, the effect of each therapy seems to have a significant impact when comparing data between the first and third week.

Between group analysis

The result also presented a significant statistical difference in the PUSH score for Monofilament pad (M=3.88, SD=1.25) and Impregnated sterile gauze (M= 13.69, SD=1.70) condition t (30)=4.30, P=0.047 [Table 4 & 5].

Discussion

There is no doubt that wound mechanical debridement is a critical clinical procedure for slough pressure ulcers (Meads et al, 2015).

Nurses in clinical practice should focus more on the importance of conducting mechanical debridement whenever the status of wounds show the evidence for that. There are a lot of products and material presented in the current market in Saudi Arabia as a useful tool for the efficient mechanical debridement use.

Availability of both products in Ministry of Health Hospitals created the needs for making a comparison and evaluation. The present observational study provides an insight for experts and researchers and hints at a focus in this area in the management of sloughy pressure ulcer. Therefore, this study should be used by the clinical decision makers as an initial step for further clinical analytical evaluation for the effects of mechanical debridement products effects on the healing conditions of sloughy pressure ulcer.

The wound care nurses' key decision in King Saud Medical City (KSMC) was either to utilise the monofilament pad or sterile impregnated gauze without a clear practice guideline or logical clarifications for either of these two products. The current study facilitates the better understanding of the needs and useful utilisation in an area of providing the mechanical debridement for pressure ulcers with sloughy wound bed. The study is an observational study for the routine use of the products without interfering with the mechanism of work and the nature of mechanical debridement happen. But the observed difference might be supported by the role of monofilament pad in undertaking debridement which is consistent with wound bed preparation as a tissue management intervention (Meads et al, 2015). The Study also presents the need for further experimental investigations to clarify the differences between the two products. In summary, both products are recommended to be used in the wound care practice in King Saud Medical City with a

preference for monofilament use in pressure ulcer with slough.

Limitations

There were numerous limitations to this study. This is a descriptive cohort study with no interventions. Also, the sample size of the survey is not satisfactory to be representative and all patients were taken from the same unit and the care provided for them by the same wound care nurse during the study time. Furthermore, the study did not investigate the effects of the role of primary dressings and the consequence and frequency of dressing changes. These limitations could affect the generalisability of the results, and the study highlights the importance of further research in issues of mechanical wound debridement and the products applied for that purpose.

Conclusion

There appeared to be a significant difference in the effects of using different substances in the healing process for patients by choosing different mechanical debridement products. The results could be used as evidence to support the use of the monofilament debridement pad for all pressure ulcers with slough when applying debridement. In conclusion, mechanical debridement is an essential step in pressure ulcer care in the sacral and heel areas, and it is recommended to be conducted by using monofilament pad in case of slough or necrosis seen in the first assessment for the ulcer. Further randomised controlled trials will be favoured in future for better understanding of the mechanical debridement phenomena. WME

Conflict of Interest

The research team declares that there is no any conflict of interest in this study.

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