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Wound Care Department

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Effects of Hydrogel With Enriched Sodium Alginate in Wounds of Diabetic Patients

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Objective of this study was to evaluate the efficacy of the autolytic debridement promoted by hydrogel with sodium alginate enriched with fatty acids and vitamins A and E in the healing of foot wounds in diabetic patients. A clinical study was conducted at an outpatient clinic of medical specialties. The sample comprised 8 patients supervised for a 3-month period, from April to July 2017, by means of a clinical history, photographic record, planimetry, and classification of the wound severity by the Pressure Ulcer Scale for Healing (PUSH) system. Of the 8 patients supervised, 1 dropped out and 7 were followed up for 12 weeks. Only 2 had complete wound healing, but all presented a reduction of the lesion area of approximately 22.2% and PUSH score of 9.8 to 6.6. This study found that hydrogel showed good results for the treatment of diabetic feet, reducing the area and overall PUSH score of the wounds.

INTRODUCTION

Diabetes mellitus (DM) is a common condition in approximately 24% of the Brazilian adult population. Projections suggest that the worldwide diabetes prevalence may go up to 4.4% in 2030, which means that about 366 million people will be affected (Wild, Roglic, Green, Sicree, & King, 2004). It is estimated that the disease of the lower extremity is twice as much more common in people with diabetes compared with those with no disease. The diabetic individual may develop neuropathy or arterial vascular disease, which are risk factors for foot ulceration (Reiber et al., 1999), occurring in 15% of the diabetic population (Singh, Armstrong, & Lipskv, 2005). Between 1% and 4% of individuals with diabetes have wounds in their feet at a certain moment of their lives (Abbott et al., 2002).

A recent meta-analysis evaluating clinical assays, where patients with wounds caused by diabetes received adequate care, identified that only 24% of the ulcers healed completely in 12 weeks and 31% in 20 weeks (Margolis, Kantor, & Berlin, 1999). Besides, the risk of recurrence of ulcers is high. A British study estimates that 2% of diabetic patients develop new ulcers in their feet per year (Abbott et al., 2002). In 2005, reports showed that 62% of patients with ulcer (n = 231) had complete healing within 31 months, with a recurrence rate of 70% in a 5-year period (Dorresteijn, Kriegsman, & Valk, 2010).

The difficulty in repairing the tissues in patients' wounds with DM is justified by the transformation of the microenvironment of the wound bed from an acute to chronic condition. In addition to the reduction of the immunologic response intrinsic to diabetes, diabetic wounds do not heal for several reasons, such as local ischemia, presence of a great deal of necrotic tissue, and high bacterial load. These factors provoke a prolonged inflammatory response and delayed healing. (Mostow & Regulski, 2014).

According to concepts of preparation of the wound bed developed by Falanga (Panuncialman & Falanga, 2009), the cure of lesions depends on the removal of any obstacle that prevents cellular proliferation and formation of new tissue. The debridement of the necrotic tissue is an important component of the treatment of the diabetic foot. Several techniques can be used for the debridement, and the main options include surgical, mechanical, enzymatic, biologic, and autolytic methods (Falanga, 2002).

The autolytic debridement uses the capacity inherent to the organism for the removal of the necrotic tissue with endogenous enzymes or phagocytic cells. This approach

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The authors report no conflicts of interest.

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DOI: 10.1097/PSN.0000000000000228

is facilitated by dressings that retain moist, such as hydrogels. Moisture caused by such substances offers ideal conditions for cells involved in the healing process, as well as allows for autolytic debridement (Cardinal et al., 2009; Knox, Datiashvili, & Granick, 2007). This method is easily used, requires little technical ability, and involves minimum pain (Atkin, 2014; Knox et al., 2007).

Hydrogels are superabsorbent insoluble polymers, structured in the form of current, which links a relatively large volume of water. Its porous structure allows for fluids and cells to pass straight through its interior, without getting stuck (Holman, Young, & Jeffcoate, 2012). This water can then be donated to the wound to keep the environment moistened. In addition, as the matrix of hydrogel polymer is not totally hydrated, it can absorb some exudate with the purpose of optimizing humidity level (Dumville, O´Meare, Deshpande, & Speak, 2011).

Because of these advantages, hydrogel was thought to be associated with other products to increment its action. Alginates are polysaccharides derived from alginic acid, obtained mainly from marine algae of the *Laminaria* species. The sodium from the exudate and the calcium from the alginate suffer ionic exchange, forming a soluble gel of sodium alginate. This gel is not adhering to the wound. The generation of calcium-free ion amplifies the cascade of coagulation, instilling hemostatic property. It is indicated for exudative wounds because the exudate is necessary for transforming alginate into gel (Blanes & Baptista, 2004).

The association of hydrogen to alginate and essential fatty acids (Dersani) is actually a new therapeutic option, indicated to promote autolytic debridement and help healing in dry and exudative wounds, with necrosis or slough, of several etiologies, such as venous, arterial, by pressure, first-degree burns, abrasions, lacerations, and also to stimulate granulation and epithelialization.

In this way, the current study aims at evaluating the efficacy of debridement and stimulus to healing promoted by hydrogel with sodium alginate enriched with fatty acids and vitamins A and E in wounds in the feet of diabetic patients.

METHODS

Design of the Study

This is a clinical study of the series type of prospective cases, with a 12-week follow-up, evaluating the use of amorphous hydrogel, enriched with fatty acids and vitamins A and E, in the treatment of ulcers in lower limbs of diabetic patients. The study was conducted at an outpatient clinic of medical specialties, regarded as a reference for the eastern zone region of São Paulo city, Brazil. The research was carried out for a period of 6 months, from February to July 2017. It took place in accordance with the ethical precepts determined by the No 466/2012 resolution of the National Health Council and other regulations. It has also been analyzed by the Ethics Committee in Research of the Santa Marcelina Hospital, consolidated opinion of approval No 2.214.977, CAAE 65256817.0.0000.0066. Participation was voluntary, with no sort of financial refunding.

Participants

In this study, the following inclusion criteria were used: 18 years or older, from both genders, with medical diagnosis of DM types 1 or 2, at least one wound of neuropathic cause, absence of clinical signs of infection in the ulcer or in the periwound tissue, presence of pedis pulse, absence of ischemia signs or indication of revascularization of lower limbs, wound not healing 3 months prior to beginning of study, and absence of allergy to hydrogel. Besides being in accordance with the procedures of the study and signing the informed consent form, the following patients were excluded from the study: those using corticosteroids above 0.5 mg per day, those who had been subjected to surgical debridement 3 days or less prior to beginning of study, previous use of hydrogel, pregnant patients or breastfeeding mothers, and participation in other studies for evaluation of dressing with an interval of less than 30 days before recruiting.

Treatment Protocol

Eight participants were included in this study, and all of them, including their caretakers, received guidance on how to proceed in order to make dressings in a standard manner. The change of dressings was made daily, according to the following standard: cleansing with a saline solution 0.9%, application of amorphous hydrogel enriched with fatty acids and vitamins A and E (Dersani, Laboratório Daudt Oliveira Ltda, Rio de Janeiro, Brazil) only in the wound site, and avoiding contact with the skin around it. Subsequently, the nonadherent cellulose acetate-based dressing was applied, and then, the cotton gauze for secondary cover.

Dressings were changed daily, and all materials necessary for making the dressings at home were made available, with no financial expenses to participants. Patients attended the outpatient clinic for follow-up appointments every 4 weeks. The treatment was maintained for 12 weeks until healing of the wound was achieved.

Data Collection and Measurement of Outcome

On the first day of the study (D0), each participant had an interview for collecting a clinical history. At the occasion, other procedures were carried out: photographic register, planimetry (manual measure with metric ruler in the cephalocaudal and laterolateral directions) for calculating the area of lesion, and wound classification by the PUSH (Pressure Ulcer Scale for Healing—Portuguese version for

pressure ulcer) system. On the 12th week of treatment, all patients were reevaluated through the following procedures: photographic register, planimetry, and wound classification by means of the PUSH. The patients' follow-up was carried out by a nurse and a plastic surgeon specialized in the treatment of wounds.

The clinical evaluation allowed the collection of the following variables: age, gender, previous diseases, life habits, time of open wound, and previous treatments. The photographic register served as a calculus for the total area of the wound. The lesions were photographed by a digital camera at an average distance of 15 cm, and a ruler was used as a gauge, with no contact with the wound. Images were analyzed by the free program *Image J*—1.36b version (Wayne Rasband, National Institutes of Health, Rockville, MD), available at: http://rsbweb.nih.gov/ij/index.html.

The PUSH instrument was initially created and validated for evaluation of the pressure ulcer healing process by the PUSH Task Force of National Pressure Ulcer Advisory Panel (Choi, Chin, Wan, & Lam, 2016; Gardner, Hellis, & Frantz, 2011), but its use was validated for the evaluation of other types of wounds such as diabetic and venous (Hon et al., 2010; Ratliff & Rodeheaver, 2005). Three parameters for evaluation of the wound healing process and intervention result: wound area (score from 0 to 10 according to total area of lesion), quantity of exudate (score from 0 [absent] to 3 [large amount]), and appearance of the wound bed (score from 0 [healed] to 4 [necrotic tissue]). The subscores for these parameters or subscales, when summed up, generate a total score, whose possible variation is from 0 to 17. Higher scores indicate worse ulcer conditions, whereas lower scores show improvement in the healing process. Wound classification by the PUSH was carried out from photographs obtained and carried out by an enterostomal therapist nurse and a plastic surgeon, who had no contact with patients.

Statistical Analysis

The data were analyzed by means of descriptive ad inferential statistics. The continuous variables were presented in the form of average, median, and standard deviation, and the categories in frequency and percentage.

RESULTS

At first eight patients were selected to take part in this study, however, one gave it up as he was unable to attend follow-up appointments. This patient was excluded from the variable analysis and outcome studied. Among the seven patients who completed 12 follow-up weeks, only two achieved complete lesion healing, whereas the other five did not heal completely (Figure 1)

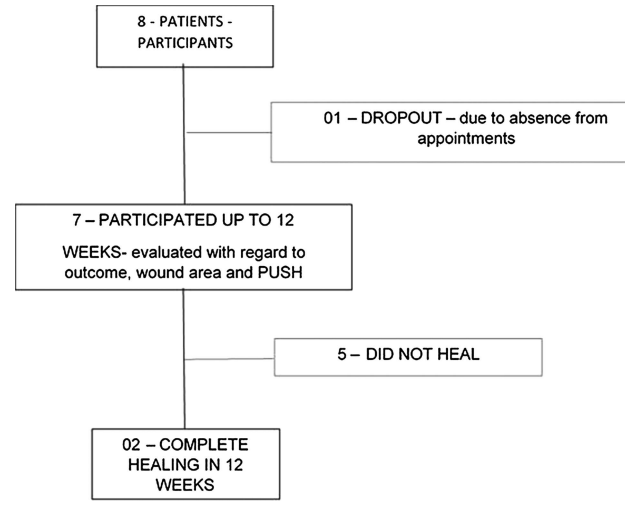

FIGURE 1. Participants fluxogram.

Considering only participants included in the analyses of outcome, the age range of the group studied was 68.9 years (*Mdn* = 73, *SD* =10.08), with an average time of open wound of 318.8 days (*Mdn* = 270, *SD* = 277.7). Of the 7 participants analyzed, females prevailed (71%). Most of them presented pathologies, such as systemic arterial hypertension (71%), DM (100%), heart disease (14%), and chronic renal insufficiency (14%). Several types of treatment had already been tested, such as collagenase, essential fatty acids, papain, omcilon, and recluse, with no apparent progression of the wound (Table 1).

The average area of wounds was of ±23.9 cm^2 in the first week, and after 12 weeks, the average was ±18.6 cm^2 (a decrease of ±5.3 cm^2, in other words, ~22.2% of reduction in average) (Table 2).

In relation to PUSH analyses, it was possible to observe a global improvement of the average of general score for wounds analyzed (Table 3).

When we analyze the results of the subscores, we notice that the main alterations occurred in reduction to length × width and type of tissue (Table 4).

DISCUSSION

Diabetes mellitus is a chronic disease that affects approximately 415 million individuals worldwide. The global prevalence of diabetes continues to increase, and in 2014, it was estimated that 9% of all adults would have the disease. Nontraumatic amputations of lower extremities are a common complication of this pathology. Approximately 85% of all amputations are associated to diabetic ulcers and occur in up to 25% of all people with diabetes. It is estimated that a lower extremity is amputated at every 20 seconds due to diabetes (Somayaji et al., 2017).

In this study, a new medication was tested (Dersani), which associated hydrogel to calcium alginate, essential

TABLE 1 Characteristics Related to Patients Studied

Patient Code	Age (Years)	Gender	Ethnicity	History	Wound Duration (days)	Previous Treatments
1	81	Female	Black	HAS	180	Fatty acids and collagenase
2	63	Male	White	-	720	Collagenase
3	67	Female	Black	HAS	360	Papain and collagenase
4	62	Female	White	–	30	Omcilon
5	81	Female	White	IRC + HAS	360	Fatty acids and collagenase
6	55	Male	White	Heart disease + HAS	720	Collagenase and recluse
7	70	Female	White	HAS	150	Collagenase

Note. HAS = systemic arterial hypertension; IRC, chronic renal insufficiency.

TABLE 2 Measures of Areas of Wounds in the Beginning and End of Treatment Analyzed by the Computer Program *Image J* (1.36b Version)

Patient Code	Area of Lesion, in the 1st Week of Treatment (cm^2)	Area of Lesion, in the 12th Week of Treatment (cm^2)	Percentage Reduction
1	66.2	56.3	15%
2	0.8	0.0	100%
3	51.9	57.7	0%
4	0.1	0.0	100%
5	29.4	2.0	93%
6	1.2	0.2	83%
7	17.8	13.8	22%
Average	23.9	18.6	22.2%
Mdn	17.8	2.0	
SD	26.6	26.7	

fatty acids, and vitamins A and E. The main action mechanism of this product is based on debridement, allowing the removal of the necrotic tissue and unfeasible senescent cells, and reducing the local bacteria cargo, thus opening way to the emergence of a new tissue with active and young cells, which stimulate tissue restauration.

With regard to the characterization of the sample, we notice that the age range of the group was rather high (68.4 years) and several comorbidities (hypertension, heart disease, and chronic renal insufficiency) were identified. Renal and cardiovascular alterations are frequent complications provoked by DM. With regard to time of the open wound, the average time was 318.8 days. In general, the microenvironment of ulcers in diabetic patients shows reduction of growth factors, reduction in the production of angiogenic factors and the action of macrophages, excessive accumulation of collagen, and predisposition to wound infection (Uccioali et al., 2015). All of these factors explain the prolonged time these wounds remain open. Besides, the older age is another element that prevents the healing process, due to the increase of cell senescence as time goes by (Zhao et al., 2017). Concerning diversity of previous treatments used, lack of consensus is evidenced with regard to the best treatment and difficulty of healing of these lesions. In this series of cases, the treatment of lesions in diabetic feet was

TABLE 3 PUSH Scale Showing Reduction on Scores and Improvement in Development of Lesion

Lesion	Total Average Score	Total Score *Mdn*	Total Score *SD*
1st week	9.8	8.5	5.7
12th week	6.6	6.0	6.2

TABLE 4 PUSH Scale Showing Reduction of Subscores and Improvement in Development of Lesion

Lesion	Length × Width			Quantity of Exudate			Type of Tissue		
	Average	*Mdn*	*SD*	Average	*Mdn*	*SD*	Average	*Mdn*	*SD*
1st week	6.6	9.0	3.8	0.7	0	1.3	2.7	2	1.0
12th week	4.9	4.0	4.7	0.4	0	0.8	1.3	1	1.1

followed up for 12 weeks, evaluating clinical factors of the wound.

In this series of cases, the treatment of lesions in diabetic feet was followed up for 12 weeks, when clinical factors of the wound were evaluated. Of the eight patients, one gave up the study, and among the remaining seven, there were only two completed healing of the wound. Debridement is considered a key primordial point for healing lesions; however, in long-term chronicity condition, most times the cleansing of the wound is not enough to stimulate the total process of cutaneous repair, which demands further therapeutics such as collagen-based dressings, which, in turn, maximize the formation of an extracellular matrix framework for the migration of keratinocytes (Donaghue, et al., 1998; Fernandes de Carvalho, Paggiaro, Isaac, Gringlas, & Ferreira, 2011).

In the analysis of the final area, after treatment with hydrogel, we noticed an average reduction of 22.2% of wounds (Table 2). This result coincides with the PUSH subscore, which evaluates length × width.

When we evaluate participants' average PUSH score, we notice that an initial average of 9.8, and after 12 weeks of treatment, a sound improvement of the wounds score, with an average of 6.6 (Table 3), indicating a global improvement in the severity of lesions.

With regard to extra subscores of the PUSH index, we notice a reduction in the amount of exudate, an initial average of 0.7 and drop to 0.4, and the improvement in the tissue of wound bed, with an initial average of 2.7 to 1.3, showing a decrease in the necrotic tissue and granulation increase. These results can be attributed to the action of hydrogel, which promotes absorption of exudate, providing a moist means in the wound bed, allowing for autolytic debridement and, at the same time, offers favorable conditions for the action of alginate and vitamins A and E, which stimulate the formation of the granulation and re-epithelialization tissue (Francesko, Petkova, & Tzanov, 2017).

Three studies carried out between 1997 and 1998 compared a hydrogel with conventional dressing. The first reports no statistically significant difference in the number of healed ulcers in the group treated with hydrogel compared with the conventional one (D´hemecourt, Smiell, & Karin, 1998). The second and third groups, on the other hand, report that there were more healed ulcers in patients treated with hydrogel compared with the control group (Jensen, Seeley, & Gillin, 1998; Vandeppute & Gylson, 1997).

Limitations

The main limitations of this research were the low number of cases and the lack of a control group to compare results. In order to suppress these problems, we suggest new studies of the type clinical assays to increase the evidence in the level of findings. However, this study shows that hydrogel enriched with alginate and vitamins A and E seem to be a promising drug in the arsenal from treating lesions in diabetic feet.

CONCLUSION

It was concluded that the combined intervention using the hydrogel, was effective in the treatment of seven diabetic foot wounds. After 12 weeks of treatment, a significant reduction in wound volume was observed with monitoring of the overall PUSH score.

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