

**Case Report**
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## 3D Printing Dressing in Treatment of Diabetic Ulcer: A Case-Series

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### ABSTRACT

Diabetic foot syndrome is defined as infection, ulceration, or destruction of deep tissues of the foot (including bones) in a patient with diabetes mellitus. Complex and multifactorial management of diabetic foot ulcer is necessary to reduce costs and ensure faster healing and avoid limb amputation. In this, dressings play a key role in stimulating tissue repair. In the case series we present we have experimented with the use of 3D printing resorbable biopolymers gauze in diabetic vascular ulcers.

In both cases the lesions healed with a period of around 3 months with signs of improvement in the bottom of the lesion as early as the fifteenth day.

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### Introduction

Diabetes mellitus is a common disease associated with a series of micro and macro vascular changes that manifest as a wide range of complications [1]. Diabetic foot syndrome is defined as infection, ulceration, or destruction of deep tissues of the foot (including bones) in a patient with diabetes mellitus [2]. Approximately 15% of diabetic patients developing foot ulcers during the course of their disease [3, 4]. The commonly identified risk factors predisposing to the development of foot ulcers include poor glycaemic control, peripheral neuropathy, peripheral vascular disease and immunosuppression.

Normally, wound healing is a process that transpires following breach of the skin barrier and is usually mediated by growth factors and cytokines released by different cells activated by the immune response, including fibroblasts, endothelial cells, phagocytes, platelets, and keratinocytes [5]. Inflammation, tissue hypoxia and extracellular matrix are wound persistence factors in diabetic patients that increase the duration of the injury.

Increasing evidence has shown that a complex and multifactorial management of diabetic foot ulcer like glycaemic control, pharmacological therapy, improving vascularisation, debridement, offloading, wound dressings, negative pressure wound therapy, growth factors and skin substitutes guarantees a reduction in costs and healin times [6, 7].

A multidisciplinary team approach is required to provide a comprehensive management of multiple aspects of diabetes care. Optimisation of clinical outcomes and a reduction in the risk of progression to amputation has been seen in patients with diabetic foot ulcers who have been cared for by a specialist diabetes foot care team.

### Wound Dressing

Dressing is a local approach to manage diabetic foot ulcer that offers an external protections and barrier to external forces and contaminants. Typically, wound dressings impregnated with antimicrobial agents are used. Simple gauze may actually damage the skin. Alginate and foam dressings provide high absorbency for moderate to heavy exudate. For a diabetic foot ulcer with dying tissue, hydrogels or dressings with collagen and silver are most effective. Most important is matching the absorptive ability of the wound dressing to the amount of wound drainage [8].

There has however been limited evidence to suggest that moist dressings are more effective than 'dry' dressings or vice versa [9]. Silver impregnated dressings have not been shown to be more effective in treating diabetic foot ulcers in randomised controlled trials than dressings for treating any other wound [10].

### Clinical Series

In this study the application of a new gauze dressing with polycaprolactone was tested in nonhealing wound in diabetic foot. Gauze is made up of resorbable biopolymers, polysaccharides and crosslinked fibrous structures. 3D printing allows to customize parameters such as porosity, degradation, thickness and shape. It allows to support adhesion and proliferation of fibroblasts and endothelial cells.

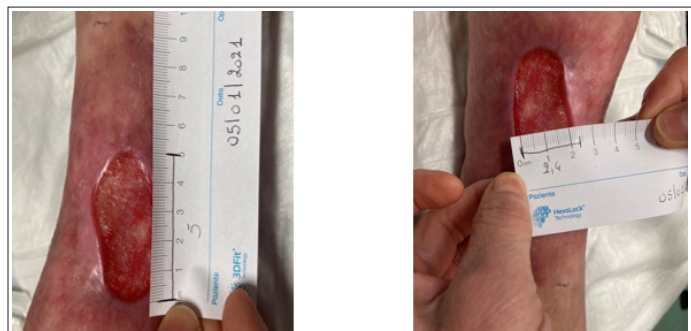
### Case 1

Woman 67 year old, history of depression, smoking, presumed Potus, diabetes mellitus with unknown onset date. Traumatic lesion of the right lower limb middle third external profile, which arose in June 2019, treated independently and subsequently taken over by the skin lesion center with flat dressing with greasy gauze. January

2021, given the poor progression of the lesion, it was decided to use the Polycaprolactone gauze with high porosity with a surface of 5cmx5cm and 1mm thickness (CHIRLAB BIOPOLYMER MD 2021).

At the first evaluation lesions measures 5cmx2.4cm, clear margins with crusty edge, fibrinous bottom, absence of clinical signs of infection, low exudate, erythematous periwound skin (Figure.1 and Figure.2).

Pain measured with VAS equal to 0, but presence of intense itching on the periwound cite. Performed dressing with active cleansing and pack with Prontosan® for 15 minutes; subsequently performed selective debridement and applied CHIRLAB - MD 2021 with simple closure and hyper oxygenated fatty acids on the periwound. It is decided to carry out the dressings twice a week



**Figure 1**

**First Evaluation**

**Figure 2**

At The first check-up after 7 days the lesion is reduced (dimensions 4.6cm x2.3cm). The fundus has more granulation tissue and good vertical response, absence of exudate. Reduced both the periwound erythema and the sharpness of the lesion margins. Still present slight itching in the periwound (Figure.3). Performed dressing with active cleansing and compress with Prontosan 15 minutes, subsequently performed selective debridement and applied dressing with simple closure and hyperoxygenated fatty acids on the periwound. It continues with dressings twice a week: one at our clinic and one at home .At the second check-up, after 7 days (from the previous one) the lesion is improved, both in terms of size and of granulation tissue, however there is still a slow progression: at the change dressing does not seem to have entered in complete synergy with the lesion (Figure.4). It was decided to lengthen the dressing change times: it will be performed only once a week. Before application, the biopolymer was activated with saline solution.



**Figure 3:** Check up 7 days after

Subsequent checks, performed weekly, show a progressive reduction in the size of the lesion and an increase in granulation of the fundus. Consequently to the improvements it was decided to further extend the dressing application time at 15 days (Figure.5).

In first day of April 2021 ulcer appears further reduced in size (dimensions: 3.1cm x1.2cm) with a 100% granular and well hydrated bottom, no sharp edges, with the beginning of reepithelialization starting from the margins (Figure.6). In last checkup ulcer appears almost completely reepithelialized (Figure.7).



**Figure 4:** Check-up at 15 days



**Figure 5:** Check-up further extend the dressing Application time

### Conclusions

A 70% reduction in wound size and an improvement in the wound fundus were found over a period of 109 days. These changes were more pronounced as the residence time of the dressing increased, before the next change. Complete reepithelialization was obtained at 4 months (Figure.7)



**Figure 6:** Check up at 1 April



Figure 7: Final Evaluation at 4 months

### Case 2

Man 78 years old, Type 2 diabetes, lower limb arterial disease treated with PTA and STENT on left Superficial Femoral Artery (2018), left transmetatarsal amputation (2019) following Texas University III B forefoot's ulceration.

In December 2020, 2 chronic lesions remain along the V ray and in the anterior area of the III ray.



Figure 8: First application of 3D printing dressing

The ulcer have a mixed bottom with necrotic area on the margins. No signs of infection are present in lightly exudative wound. Wounds treated with selective debridemen after pack of Prontosan® for 15 minutes and Iodipovidone gauze.

In June 2021 Prontosan ® detersion and Polycaprolactone dressing (high porosity, surface of 5cmx3cm and 0.5 mm thickness - CHIRLAB BIOPOLYMER MD 2021) with greasy gauze are applied. It combines protective offloading felt and the use of injury footwear (Figure.8). The checkup is scheduled after 7 days. Improvement in the lesion base was noted, with an increase in the granulation background and a reduction in the perilesional necrotic area (Figure.9).



Figure 9: Check-up at 7 days

Same treatment protocol for subsequent dressing was keep. One month later significant reduction of wounds necrotic area was observed.

In the following weeks there was a reduction in the size and a clear shift of the lesions towards reepithelialization (dressing performed once a week for 10 weeks).



Figure 10: Check-up 1 month later



Figure 11: Subsequent Check-up



Figure 12: Last Check-up

### Discussion

Polycaprolactone gauze has been shown to be effective in non-healed wounds in the diabetic patient. Healing times appear to be reduced from the second week of application. Degradation of the gauze does not complete after 7 days. This may depend on the vascular characteristic of the lesion. It can be inferred that dressing renewals can be done every 10-15 days in ischemic lesions. More data on neuropathic lesions are required.

Patients reports a pain's reduction of ulcerations while making the dressing change; presence of intense itching on the periwound was cite in first case. Comparing the photos you can see a reduction in the area of extension of the wound and an increase in granulation tissue in both cases 15 days after the first application.

In first case a 70% reduction in wound size and an improvement in the wound fundus were found over a period of 109 days. These changes were more pronounced as the residence time of the dressing increased, before the next change. Complete reepithelialization was obtained at 4 months Complete healing of the plantar ulcers in the second case occurred 10 weeks after the first application.

### Conclusions

In conclusion, we can therefore conclude that the use of 3D printing polycaprolactone gauze can improve healing times, dressing change pain and stimulate granulation tissue in diabetic patients with vascular complications in the lower limbs.

In plantar ulcerations use of diabetic shoes offloading have certainly contributed, together with the protocol therapy to a significant result. There were no cases of bacterial infection that required the intervention of systemic therapies during the experimentation. This is also because these dressings keep the oxygen permeability of the tissue in question constant and the presence in the gauze of low molecular weight chitosan, but above all of polyphenols and colloidal silver are essential to guarantee an antimicrobial value. Therefore, further research and experimentation is recommended in all pressure injuries and postsurgicals where tissue repair needs to be stimulated.

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Dressing's customization was carried out by CHIRLAB on the instructions of the medical team without being aware of any characteristics of the patients.

The authors have no conflicts of interest with this study.

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