

# A COHORT STUDY ON THE TREATMENT OF DIABETIC FOOT ULCER PATIENTS USING A MONOFILAMENT DEBRIDER AND A COLLAGEN DRESSING

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## Introduction:

The diabetic foot ulcer is one of the major complications of Diabetes mellitus. It occurs in 15% of all patients with diabetes and precedes 84% of all lower leg amputations<sup>1</sup>. A major increase in mortality among diabetic patients, observed over the past 20 years is considered to be due to the development of macro and micro vascular complications, including failures of the wound healing process. Fibroblasts from the diabetic ulcer exhibit proliferative impairment that probably contributes to a decreased production of extracellular matrix proteins, delayed wound contraction and impaired wound healing<sup>1</sup>. The study evaluated efficacy of a treatment regime for twenty-five diabetic foot ulcer patients (grade A 1,2 and C1,2) including preventive measures, a \*monofilament fiber product for debridement and a \*\*collagen dressing (Table1). The collagen dressing has shown in vitro<sup>3</sup> to have a high binding capacity for different pro-inflammatory mediators, like proteases and cytokines. A clinical study<sup>4</sup> demonstrated the \*\*collagen dressing to help kick-start the stagnating wound healing process. The \*monofilament fiber product has been successfully used for debridement of various wound types and peri-wound skin<sup>5</sup>.

## Methods:

This observational study evaluated the debridement efficacy, safety, patient comfort and user satisfaction of the treatment regime. N = 25 Patients were followed during weekly visits for the first 4 weeks and during a follow-up period until ulcer healing. The \*debridement product was wetted with polyhexanide. After the procedure, the wounds were covered with a \*\*collagen dressing and a \*\*\*foam. Appropriate prevention measures, such as offloading were applied. Clinical outcome was scored by a trained clinician. Additionally, before and after photographs were assessed by one and the same clinician, who was blinded to the treatment given.

## Results:

Twenty-five patients were included in the study (Table 2). Debridement was shown to be effective in all of the sessions. In n=8 cases additional surgical debridement was performed to remove the thick callus at the ulcer edges. The mean time for each debridement session was 2.59 minutes ( $\pm$ SD 0.06). Visible debris, slough, hyperkeratosis and scabs were successfully removed with the \*monofilament fiber product. The \*\*collagen dressing was used for a maximum of three weeks after which the dressing was discontinued and the \*\*\*foam dressing was used as a primary dressing. No secondary infections occurred. N=18/25 ulcers healed within 16 weeks, n=2 required surgery and n=5/25 had not healed. A typical case is shown to illustrate the results (Fig 1a – Fig 1b).

Grade	0	1	2	3	4	5
A	Pre or post ulcerating foot	Superficial ulcer	Ulcer till the level of tendons or capsules	Ulcer till the level of bones or joints	Necrosis of foot parts	Necrosis of the entire foot
B	With infection	With infection	With infection	With infection	With infection	With infection
C	With ischemia	With ischemia	With ischemia	With ischemia	With ischemia	With ischemia
D	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia

Table 1: Diabetic foot syndrome - classification according to Wagner and Armstrong<sup>2</sup>

Variable	N=25
<b>Age, years</b>	
Mean ( $\pm$ SD)	60,3 ( $\pm$ 14,52)
Median (range)	61 (23 – 87)
<b>Sex</b>	
Male	16 (64)
Female	9 (36)
<b>Clinical characteristics</b>	
Diabetes mellitus: type 1	25 (100)
Charcot foot	1 (4)
Neuropathy	15 (60)
Ischemia	1 (4)
Amputation	2 (8)
<b>Ulcer location</b>	
Plantar	6 (24)
Heel	10 (40)
<b>Ulcer duration months</b>	
Mean ( $\pm$ SD)	10,74 ( $\pm$ 14,52)
Median (range)	4 (1 – 60)
<b>Ulcer size cm<sup>2</sup></b>	
Mean ( $\pm$ SD)	7,18 ( $\pm$ 6,09)
Median (range)	7,5 (0,16 – 9)
<b>Ulcer condition day 0</b>	
% Red tissue	
Mean ( $\pm$ SD)	36 ( $\pm$ 14,52)
% Yellow tissue	
Mean ( $\pm$ SD)	54 ( $\pm$ 1,32)
% Black tissue	
Mean ( $\pm$ SD)	10 ( $\pm$ 0,52)
<b>Ulcer condition end</b>	
% Red tissue	
Mean ( $\pm$ SD)	86 ( $\pm$ 0,52)
% Yellow tissue	
Mean ( $\pm$ SD)	14 ( $\pm$ 0,12)
% Black tissue	
Mean ( $\pm$ SD)	0 (0)

Table 2: Patient characteristics and ulcer details

### Case 1:



Fig 1a: Situation before debridement



Fig 1b: Situation after debridement with the \*monofilament product

### Case 1:

The 61 year-old male has DM type I since 2001. He has neuropathy, limited joint mobility and had a forefoot amputation six years ago. Visit to the clinic with a recurrent ulcer. (fig.1a) DM is controlled with insulin 4 times a day. Weekly callus removal with the \*monofilament product and offloading with padding material was performed (Fig 1b). \*\*Collagen was applied covered with a \*\*\*foam. Complete ulcer closure was achieved in 16 weeks. The patient was referred to an orthopedic shoemaker for footwear to prevent ulcer recurrence.

## Conclusion:

Results indicate the potential for this treatment regime and the added value of the \*monofilament fiber product to effectively and safely debride peri-ulcer skin and diabetic foot ulcers. Moreover the \*\*collagen dressing supported kick-starting the stagnating wound healing process.

## References:

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