



## Autologus Platelet-Rich Fibrin for the treatment of hard to heal diabetic ulcers: A pilot study on three patients.

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### ABSTRACT

#### Introduction

Healing chronic wounds, especially the diabetic foot is not an easy job. Sometimes even after adequate infection control, after ischemia and edema has been adequately addressed and the patient is fully offloaded, still some of these 'lower-extremity hospice'-wounds will not heal. Besides removal of necrosis and bacteria, debridement has the benefits of making an acute wound from a chronic wound. Platelet's are held responsible for initial subsequent wound healing. However the number of platelet's in blood is only  $0.2 \times 10^6/\mu\text{l}$ . In Platelet-Rich Plasma the number of platelet's is  $>1.0 \times 10^6/\mu\text{l}$ .

#### Study

This study is a small pilot study of very hard to heal ischemic diabetic ulcers with Autologus Platelet-Rich Fibrin (PRF®) in order to see if this treatment is feasible and to see if a larger study is warranted. In Vivostat® PRF® autologous fibrin sealant and platelets are combined, thereby providing an easy-to-apply solution that polymerises immediately upon application.

#### Results

From september 2006 until the first of january 2007 (4 months) we treated three diabetic patients with a total of four ischemic wounds. One patient was admitted during the therapy. The first application was in september 2006. A total of 10 applications were applied (average 2.5 per wound). There were no complications observed. Blood (120 ml) was taken according to the manufactures advise. This was done in the outpatient department. All applications were done by the first author. It took an average of 90 minutes for the complete treatment (from taking the blood until the spraying). If possible two applications were planned on the same day (morning session). On average 6 ml's was collected, this was sprayed directly on the wound. This was covered with a Mepithel® dressing, which was subsequently covered with an absorbing dressing. This was replaced after 5 days. After 7-8 days the wound was rinsed with sterile water. It was then decided if another application would take place. Follow-up is short, but on the first of february 2007, two wounds were completely closed and two were less than 1/3 of original size and in a healing state. More patients are currently treated with this new method, prospective randomised trials are warranted.

#### Conclusion

Autologus Platelet-Rich Fibrin (PRF®) seems to be a promising new method for the treatment of hard to heal ulcers. The treatment is feasible in an outpatient setting, and seems to be a safe procedure. Prospective studies are warranted.



The system can be used in the outpatient department.



Application is easy using het spraypen.

### Case Study (patient 3)

This is a 42-year old diabetic patient with a below knee amputation of the left leg. She has a non-healing ulcer on the right leg, for which a fore-foot amputation was performed. Despite several treatment strategies including: maggot debridement therapy, vacuum assisted closure therapy, surgical necrotectomies, prolonged broad-spectrum antibiotic therapy, flammazine®, alginate dressing and hyperbaric oxygen therapy, the wound did not heal (see Figure 1)



The patient has open wounds on the affected leg for 16 months, the fore-foot amputation was performed two months earlier. At the same time the patient presented with a decubital ulcer of the below-knee amputation (Figure II) due to malfitting of the prothesis, with wich the patient was fully ambulated.



The vivostat applications were all performed in the outpatient department. The withdrawal of the blood, the cleaning of the wound and the application and subsequent dressing takes, on average, 90 minutes. The patients uses ascall® and plavix®. The first application was done after debridement, leading to local bleeding. Subsequent debridements were not performed when vivostat was applied. Application is done with the spraypen.



Table 1: Results of first three patients treated with Vivostat®

No	Sex	Age	Ipsilatera l leg	No of treatments	Outcome
1	M	60	BKA	1	Closed
2	M	65	AKA	4	<1/3
3	F	42	BKA	7	<1/3
				2	Closed

BKA= below knee amputation  
AKA= Above knee amputation

### Results

From september 2006 until the first of january 2007 (4 months) we treated three diabetic patients with a total of four ischemic wounds (see table I). A total of 10 applications were applied (average 2.5 per wound). There were no complications observed. Blood (120 ml) was taken according to the manufactures advise. On average 6 ml's was collected, this was sprayed directly on the wound. All patients had an contralateral major amputation, and presented with ischemic diabetic feet. After treatment of these wounds, 50% is closed (two wounds) and two wounds are almost closed. There were no complications observed.



About 6 ml of PRF is obtained from 120 ml of blood.



The PRF is covered with Mepithel®



After 2 applications the wound on the below knee amputation is closed and the other is after 7 applications almost closed. (now 4 months after starting with the treatment).

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