



# Use of Autologous Growth Factors to Heal Chronic Wounds

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There are approximately 6 to 8 million diabetics living in Germany. Based on demographic trends, this can be expected to increase to about 10 million by 2010. This increase can be regarded as the result of a higher economic standard of living and increased life expectancy. Roughly 15 % of diabetics have to deal with the development of foot lesions and thus with diabetic foot ulcers. Approximately 20 % of these cases are treated



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by amputation. Even today, about 70 % of all non-accident related amputations in Germany are performed on diabetics. The likelihood of developing diabetic foot ulcers increases with age. With a population in Germany of approximately 80 million, about 280,000 patients can be expected to suffer from diabetic foot each year. According to data from the General Regional Health Insurance Fund (AOK), 26,000 amputations were performed on patients with diabetes in 2001. Half of the amputations were above the ankle. A Swedish summary of data from 2001 showed the cost of treatment for diabetic foot to be approximately 17,500 USD per patient. When amputation was required, the costs increased to as much as 35,000 USD. Back in 1989, in the so-called „St. Vincent

Declaration“, which was signed by all of the European health ministers, an agreement was reached on a goal of halving the amputation rate within 5 years. This goal has still not been achieved today.

Chronic, slow healing wounds on the lower legs and feet play a major role, particularly in diabetics. Dressings must often be changed several times per week over a period of months (or even years in some cases). Those affected need to make frequent visits (in some cases up to three times per week) to the doctor's practice or have home visits by a nursing service.

Diabetes mellitus can, if persistent over an extended period and inadequately controlled, result in other diseases. In the case of diabetic foot, these concomitant diseases primarily include nerve damage and poor circulation (arteriosclerosis). Persistently elevated blood sugar levels result in broad metabolic changes. These changes cause elevated blood lipid levels, the consequences of which include the rapid progression of arteriosclerosis. In addition, high blood sugar levels lead to impaired nerve function.

This neuropathy, which is caused by dysfunction in the smallest blood vessels that directly supply the nerves, results in unnoticed abnormal stresses in the feet. These abnormal stresses can result in skin wounds or gradual progressive deformation of the feet. The resultant decubitus ulcers can develop bacterial infections. If these infections remain unnoticed due to a lack of pain perception, deeper structures within the foot (such as tendons, muscles and bone) can also become infected.

Poor arterial circulation in the legs may be present either on its own or in combination with nerve damage. If the blood flow is severely impaired, the result can be failure of the wounds to heal or even tissue necrosis in the foot. Open, chronic wounds also carry a high risk of infection for the affected patients. In most cases, hospitalisation or even amputations will no longer be avoidable if a wound becomes infected. In these cases, many hospital stays or amputations would be avoidable with early and correct treatment.

Today, a wide variety of dressing materials have been developed, the purpose of which is to create an appropriate environment in each case to enable optimal conditions to accelerate wound healing. However, these materials alone are frequently not sufficient.



Healing effect of Vivostat® PRF® treatment of lower leg ulcer on the inner ankle bone

In chronic wounds, there is an imbalance between “wound development” and “wound recovery” factors. In order to provide a chronic wound with greater wound healing activity, regular wound cleaning and wound refreshment (debridement, e.g. using a sharp curette) are necessary. In this way, wound secretion and necrotic wound detritus are removed. This helps promote granulation (tissue regeneration) and prevent infection.

### Special therapeutic procedures

In the Wound Healing Centre of the North Rhine Westphalia Heart and Diabetes Centre (HDZ NRW) in Bad Oeynhhausen, Germany, a variety of special procedures are used with the therapeutic goal of achieving wound closure. Innovative procedures include clinical treatment approaches to diabetic foot (DF) and poor leg circulation using autologous stem cells to regenerate blood vessels. An initial study showed treatment outcomes achieved using this procedure to be good. Wound closure was successfully achieved and leg amputation avoided in almost all of the patients parti-

cipating in the study. Therapeutic procedures to improve the flow properties of blood (fibrinogen apheresis) represent another approach to treatment. This involves the blood undergoing special fil-

tering and a specific proportion of the fibrin, which is largely responsible for the viscosity of the blood, being removed. The purpose of this method is to improve the flow properties of the blood,

Deep skin wounds that exhibit insufficient granulation tissue have to date been very difficult to treat. A modern procedure involving autologous blood from the patient makes effective treatment possible.

Growth factors and fibrin are both important components in wound healing. Platelet-rich fibrin contains concentrated growth factors embedded in a fibrin matrix.

The fibrin matrix acts as a carrier medium ensuring the steady release of growth factors into the wound over an extended period. The system can be applied directly and is easy to use, only requiring 120 ml of autologous blood to make 5 ml of platelet-rich fibrin (PRF®).

1. Prior to treatment, 120 ml of blood is taken from the patient and stored under sterile conditions.

2. The storage container filled with blood is placed in a fully automated processing unit, in which the platelet-rich fibrin is extracted.

3. The platelet-rich fibrin is applied directly to the wound to be treated as a spray.

The new therapeutic agent has been used with very good results in a number of different indications and is constantly being evaluated for additional potential medical uses in the treatment of chronic wounds.

## Case Study

The section that follows will describe the case of one patient treated in the Wound Healing Centre in the North-Rhine Westphalia Heart and Diabetes Centre in Bad Oeynhausen.

A system manufactured by Vivostat (Denmark) is used to make the blood platelet concentrate. After the blood platelets have been concentrated, they are applied to the wound and held in place by an autologous fibrin glue. This fibrin enables the Vivostat PRF<sup>®</sup> to be used to treat large surface lesions. This is often problematic to use growth factors, as it is difficult to hold blood platelet concentrates in place on wound surfaces without the fibrin concentrate.

The patient treated is 64 years old and suffers from diabetes mellitus. The patient has had an ulcer measuring approximately 12 x 6 cm on his right lower leg for about nine years. This has to date been treated without any success.

Various previous stays in specialised clinical institutions and several dressing changes per week were unable to heal or reduce the size of the wound. After preparatory measures (wound debridement, negative pressure therapy and dressings appropriate for the wound stage three times weekly), the patient had three treatments of platelet-rich fibrin (PRF<sup>®</sup>, Vivostat<sup>®</sup> system).

In order to maintain a moist wound environment, the wound was covered with an oil emulsion gauze dressing. The therapy was supported with compression stockings to prevent swelling. Using this procedure, almost complete wound closure was achieved within six months. There is currently a residual surface lesion measuring a few millimetres across, which is expected to be closed within the next few weeks.

The closure of the wound was highly important for the patient for another reason. A heart operation, which had long been planned and had to be postponed due to the major risk of infection from the lower leg ulcer, has now been performed successfully.



especially in the small blood vessels, in order to promote the wound healing process. The first patients are currently undergoing treatment using this procedure in the Wound Healing Centre at the North Rhine Westphalia Heart and Diabetes Centre in Bad Oeynhausen.

Special "negative pressure dressings", which should be pain-free when applied, are also used. With these dressings, the evacuation is individually adjusted and tissue regeneration achieved (e.g. for very deep wounds). The significantly more level lesion can then be closed by skin graft.

Another highly promising option is offered by therapy with autologous growth factors which can be found in the blood platelets. This procedure involves using an everyday autologous mechanism which targets minor injuries to blood vessels in the human body. The Vivostat<sup>®</sup> PRF<sup>®</sup> system is used to concentrate the blood platelets to 7 times the initial blood concentration. Alternative procedures for deriving growth factors from blood platelets will often only achieve a concentration of 1.5 – 4 times the initial level.

The high concentration of blood platelets achieved using the Vivostat<sup>®</sup> PRF<sup>®</sup> system allows the effect to be increased considerably and wound healing to be accelerated. For this approach, it is

important for the wound to be prepared properly to maximise the efficacy of the procedure. The North-Rhine Westphalia Heart and Diabetes Centre has long experience in the treatment of wounds with platelet-derived growth factors. For this treatment, 120 ml of blood is taken from the patient. An advanced process is then used to produce a blood platelet concentrate, which is used to treat the affected wound. The highly concentrated growth factors stimulate the wound

and this often results in a successful healing process in chronic wounds, which in individual cases had exhibited no healing tendency for years.

### Information

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