Case Studies with Revamil® Wound Gel, Carried out at Bronovo Hospital, The Hague, The Netherlands

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Abstract
A product trial was carried out at the wound management centre of Bronovo Hospital, The Hague, The Netherlands. During five months more than fifty patients with chronic and infected wounds were treated with Revamil® wound gel, a wound management product based on pure medical honey. The results of the trial are described in another article (Groenhard et al, WCS News 2006). This report describes several cases in more detail, to demonstrate the effectiveness of Revamil® to clean and treat difficult and infected wounds. In four representative cases as described here, Revamil® was effective to clean the wounds in short time, and to reach granulation and wound closure within reasonable times. The cases describe an acute infected wound, diabetic foot ulcers and chronic wounds that have been present for over six months. The trial shows that Revamil® is very effective in creating a moist and clean wound bed, facilitating granulation and wound closure. In some cases granulation stimulating products like Promogram® further enhance closing of the wounds after Revamil® has cleaned and calmed down the wounds.

Introduction

Beginning of January 2005 a patient trial was started to test in a hospital setting the product Revamil® for its effectiveness in a broad spectrum of wound healing. The trial was carried out at the Bronovo Hospital in The Hague, at the Centre for (diabetic) foot out-patient care. The trial took place under supervision of Mr. O. Groenhard, expert in wound management

Around 75 patients were treated with Revamil® to test its effectiveness in wound healing, its ability to give infection protection, its ability to effect wound cleaning and wound closure. The results of this study will be published shortly (Groenhard *et al.*, WCS News 2006).

This report describes several definite cases that are indicative for the effectiveness of Revamil® in wound healing, applied to a wide variety of wounds, such as acute infected wounds, diabetic foot and leg ulcers and other foot wounds.

The wounds were treated with Revamil®, a new wound management product, based on special medicinal honey, with a high enzyme level.

Wound healing, honey and Revamil®

The wound healing capacity of honey is not new. In history it is known that honey was used to treat infected and burn wounds. In the beginning of the 20th century, Russian soldiers used honey in the First World War. Honey was used for its antiseptic activity and its wound healing stimulating functionality. The development of antibiotics in the 20th century has moved interest from more traditional medicine (such as honey) to (at that time) modernized medicine. However, due to increased resistance to antibiotics honey has regained interest in the last decade of the 20th century. This interest was enhanced by the ability of, e.g., Bfactory to develop and produce enzyme rich, pure honey. This grade stands for guaranteed functionality, stability and consistency of its product. Furthermore, the production of honey can be scaled up almost without limit, so that industrial and medical safe production can be guaranteed.

The product Revamil® is developed for the treatment of infected and chronic wounds. Its indications are diabetic ulcers, infected acute wounds, ulcus cruris, burn wounds, decubitus wounds. Revamil® comes in a 18 gram tube (primarily developed for home care by the patient), and in hygienic single dose units for one-time usage (Revamil® Single Dose) (see Figure 1).

Figure 1. Pictures of the Revamil® products

The products are CE-classified as a medical device, class IIb, approved by DEKRA in Arnhem, The Netherlands. The approval process includes biocompatibility studies, batch (chemical) residue testing, functionality testing (pH, water content, presence and level of the enzyme glucose-oxidase). The biocompatibility studies showed that Revamil does not evoke any allergic or oversensitivity reactions on patients and all tests showed constant, high levels of compounds functional in wound repair.

Revamil® trial, Bronovo Hospital

The Bronovo Hospital was selected to carry out a trial of 75 patients with primarily foot and leg ulcers. Bronovo is specialized in treating (diabetic) foot ulcers and has an out-patient centre focused on foot ulcers. This centre has an important regional function, as all patients with difficult foot wounds (including diabetic wounds) are sent to Bronovo Foot Centre. The Foot Centre is headed by therapist Mr O. Groenhard, specialized in the treatment of difficult wounds, including infected wounds and chronic ulcers.

The trial was set up to answer the following questions:

- Is Revamil® effective in cleaning wounds in mildly to highly infected wounds?
- Is Revamil® effective in creating a calm wound environment in which granulation can take place?
- Is Revamil® effective in creating wound closure?
- Are there side effects of the use of Revamil® that are worth knowing?

To answer these questions, it was decided to work with a large variety of patients and wounds, rather than trying to identify similar patients and/or similar wounds. Identifying patients with similar wounds is, in the case of wound healing, extremely difficult and hardly ever carried out.

Overall results

The results of the Revamil® trial at the Bronovo Hospital are described in Groenhard *et al.* (in preparation). The main conclusions of this study are:

- In most cases (>80%) Revamil® creates a clean wound bed which reaches granulation phase.
- In case of the presence of an infection, application of Revamil® diminished and removed the infection so that the wounds reached granulation phase.
- In 50% of the cases, Revamil® was used until wound closure. In an additional 20% of the cases, wound closure was reached with a combination of Revamil® and another product, such as Promogram®.
- In 5% of the cases patients complained of a stinging sensation after application of Revamil®; approximately 1% complained of pain.

The conclusions demonstrate that Revamil® is effective in wound healing. Also, it shows that in some cases, wound closure can be enhanced with additional products such as Promogram®. A stinging-sensation is a well-known side effect with the use of honey-based products in wound healing. Also with Revamil®, stinging or pain is registered in a limited number of cases. Moisturizing of the wound prior to applying Revamil® reduced the occurrence of stinging sensations.

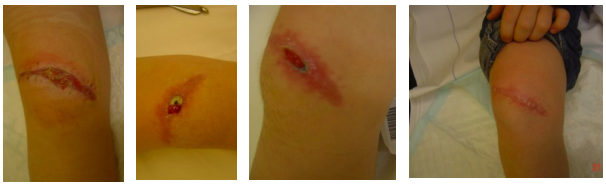
Case 1: Acute infected wound

This case concerns an infected wound, previously closed by stitches. Due to a fall, the wound had re-opened, and became infected. The patient was 9 years old, male, the wound was 3 mm deep, and had a surface of 50x10 mm^2. The infection showed a coloring of 40% yellow, and 60% red. The wound was treated with Revamil® in infected state on 16 March 2005. Within two weeks the wound was clean and the granulation phase was initiated. On 13 May, wound closure was observed, and on 21 May the treatment was successfully ended. Table 1 shows the main wound data, and Figure 2 shows the development of the wound during treatment.

Table 1. Case details Case 1

Birth year	1996	1st treatment	16/3/2005
Start Revamil	16/3/2005	Wound clean	1/4/2005
End Revamil	21/5/2005	Granulation phase	1/4/2005
Diabetic patient?	No	Wound closure	13/5/2005
Complications?		Wound depth	3 mm
% Yellow	40%	Wound surface	50x10 mm^2
% Red	60%	Remark:	12/3: wound burst open with infection
% Black	0%		

Figure 2. Wound development Case 1



18/3 1/4 30/4 21/5

Case 2: Diabetic foot wound

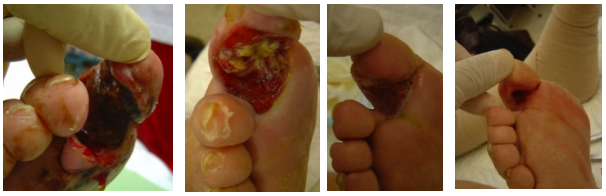
The second case describes a patient of 94 years old, female, suffering from Diabetic Mellitus, with neuropathy, and weak veins. Additional complications of this patient were heart problems, kidney failure, by-pass (leg). The wound concerns a diabetic toe, 12 mm deep, and a surface of 30x90 mm^2. The

wound consisted entirely of necrotic tissue, i.e. 100% black. The patient used pain relievers and antibiotics. The patient was admitted into the hospital on 8 March 2005, treatment started on 18 March with Maggots to remove the necrotic tissue. On 26 March Revamil® treatment was commenced (initiated). First the remainder of the necrotic tissue was removed, and the wound bed was cleaned in four weeks (20 April). Wound closure was achieved on 3 June. Data and wound development can be seen in Table 2 and Figure 3.

Table 2. Case details Case 2

Birth year	1911	1st treatment	8/3/2005
Start Revamil	29/3/2005	Wound clean	20/4/2005
End Revamil	3/6/2005	Granulation phase	20/4/2005
Diabetic patient?	Yes	Wound closure	3/6/2005
Complications?	See rem.	Wound depth	12 mm
% Yellow	0%	Wound surface	30x90 mm^2
% Red	0%	Remark:	Heart problems, kidney failure, by-pass on leg
% Black	100%		

Figure 3. Wound development Case 2



22/3 8/4 11/5 1/6

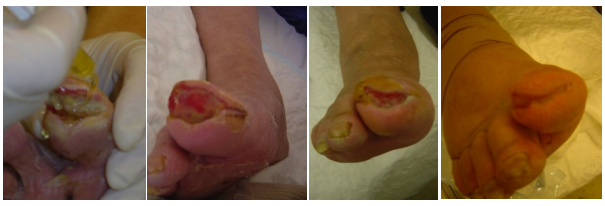
Case 3: Diabetic foot wound

The third case described here deals with a 84 year old male, suffering from Diabetic Mellitus, and is insulin dependent. Complications include weak veins and neuropathy. The toe wound was 5 mm deep, with a surface of 20x30 mm^2. The patient was admitted into the centre on 7 March 2005, the same date that the Revamil treatment started. The wound had a strong rotting odor and was infected, due to improper treatment. Amputation was near, unless treatment with Revamil® would be successful. The wound had a coloring of 80% yellow and 20% red. The wound was examined weekly and new bandages were applied every two days. In 60 days, the wound was clean and the granulation phase started. During this phase usage of Revamil® was continued. On 24 June, wound closure was reached, and amputation of the toe was prevented. See Table 3 and Figure 4 for case details.

Table 3. Case details Case 3

Birth year	1919	1st treatment	7/3/2005
Start Revamil	7/3/2005	Wound clean	13/5/2005
End Revamil	24/6/2005	Granulation phase	13/5/2005
Diabetic patient?	Yes	Wound closure	24/6/2005
Complications?		Wound depth	5 mm
% Yellow	80%	Wound surface	20x30 mm^2
% Red	20%	Remark:	Infection present due to poor wound treatment
% Black	0%		

Figure 4. Wound development Case 3



7/3 20/4 14/5 25/6

Case 4: Chronic wound, due to operation

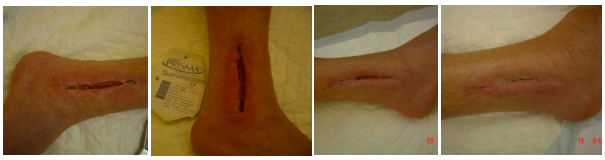
The fourth case, discussed here, deals with a female patient who suffered already more then six months from an open wound that failed to close after surgery. The wound was not particularly infected, but was stuck in a chronic state without any progress towards healing. After admittance in the centre in January 2005, treatment with Revamil® started on 14 April. At that time, the wound was 4 mm deep, and had a surface of 12x100 mm^2. The wound had a coloring of 10% yellow and 90% red. The wound

boundaries showed inflammation and irritation. The wound was examined twice a week, and Revamil was applied when bandages were exchanged every two days. On 27 April (after two weeks of treatment with Revamil®) the wound was considered clean, the chronic state was overcome and the granulation phases started. At this point, a combination treatment of Revamil® and Promogram® was started. After six weeks, on 17 June, wound closure was achieved and the treatment was terminated successfully. Table 4 and Figure 5 show the details of Case 4.

Table 4. Case details Case 4

Birth year	1945	1st treatment	6/1/2005
Start Revamil	14/4/2005	Wound clean	27/4/2005
End Revamil	17/6/2005	Granulation phase	27/4/2005
Diabetic patient?	No	Wound closure	17/6/2005
Complications?		Wound depth	4 mm
% Yellow	10%	Wound surface	12x100 mm^2
% Red	90%	Remark:	Revamil used for wound cleaning. On 27/4 combination Revamil / Promogram
% Black	0%		

Figure 5. Wound development Case 4



Conclusions

The case studies carried out with Revamil® at Bronovo Hospital show that Revamil® is effective in creating a clean wound bed, in arresting the chronic state of a wound, and in initiating the granulation phase. In addition, Revamil® stimulates wounds close, but combination treatments with other products can enhance granulation tissue formation and wound closure.

The demonstrated cases show that Revamil® is effective in a broad range of wounds, i.e. from acute infected wounds to difficult to heal wounds such as diabetic foot wounds.

Literature

Groenhard, O *et al.*, Treatment of seventy five (75) patients with medicinal honey, in preparation