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Dated Kiel 3<sup>rd</sup> January 2005

### **Analysis of observational study on the tolerability and combinability of Prontosan® Gel**

Sponsored by the company PRONTOMED Medizinprodukte GmbH, Am Bahndamm 70, 32120 Hiddenhausen, the wound outpatient unit of the Kiel University Dermatology Department carried out an analysis of case observations on the use of Prontosan®Gel in the cleansing and moisture retention of chronic wounds of varying aetiology and duration. In the following the cases observed are analysed.

#### Objectives and documentation procedure

##### *Objectives*

Using a retrospective analysis of documentation records from the wound outpatient unit of the Kiel University Dermatology Department the objective was to record the tolerability and combinability of Prontosan®Gel for chronic wounds, and their environment (n =31). The influence of Prontosan®Gel on wound odour was also to be evaluated.

##### *Procedure*

Documentation was carried out in December 2004. All patients cared for and whose progress was recorded at this time by the medical staff of the wound outpatient unit of the Kiel University Dermatology Department were included in the analysis.

Dressings were generally changed on a daily basis or at intervals of 2-3 days. At each dressing change the wound was irrigated with isotonic saline solution, Prontosan® W-Solution or tap water (“showered off”).

Evaluation was carried out with regard to:

- gender
- age
- primary disease
- result of application regarding compatibility of Prontosan® Gel with other products for modern moist wound care treatment
- undesirable effects with concomitant use of Prontosan® Gel and wound dressings

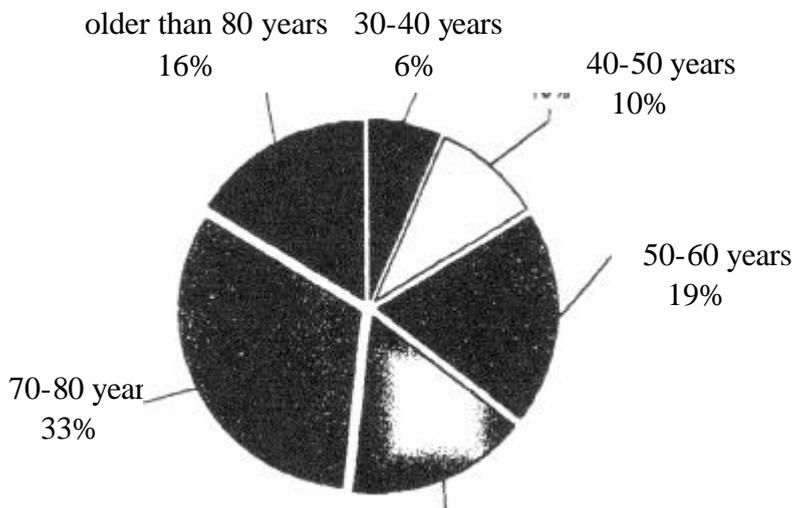
On the subject of compatibility of Prontosan® Gel with other products used in modern moist wound care treatment an assessment was made of whether any possibly negative parameters, i.e. influence on the structure, shelf-life and usability of the above-mentioned products were recorded when these were combined with Prontosan® Gel.

*Results*

Number of cases documented:

31 cases, of these

- 7 men
- 24 women

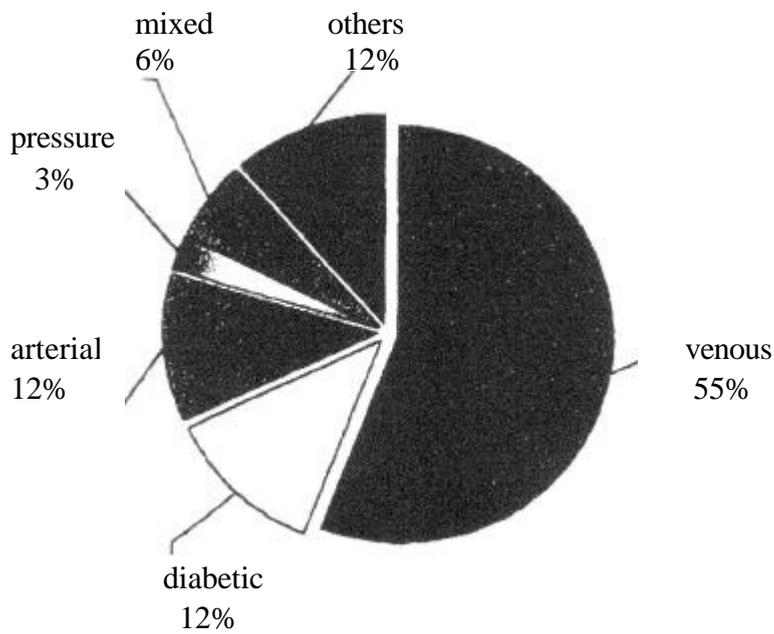


**Fig.1: Age of the patients**

## Aetiology of the wound

Aetiology of the wound was divided as follows:

Aetiology of the wound	Number
• arterial	4
• mixed arterial-venous	2
• diabetic	4
• venous	19
• pressure sores	1
• others	4



**Fig.2: Overview of wound aetiology**

## Analysis

### *Combination with products used in modern moist wound care treatment*

The combinability of Prontosan® Gel when used with products in modern moist wound care treatment was examined macroscopically.

There were no therapeutic problems at all when these products were combined. In particular no influences on structure were observed (loss of material structure, integrity of material and surface or material consistency).

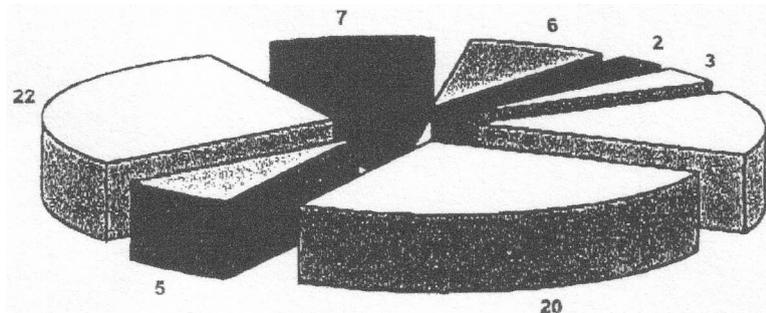
In detail combined application with the following products was recorded: (naming more than once/combined use possible):

The general term was selected for the products.

The following were used:

- Tielle product family (hydropolymers)
- Adaptic dressings (with an oil in water soaked viscose fibre)
- Mepilex (silicone layered foam dressing)
- Gauze dressing (cotton gauze)
- Allevyn product family (foam dressing)
- Paraffin dressings with a cotton base
- Silver dressings

**Fig.3:**



Tielle
Adaptic
Mepilex
Gauze dressings
Allevyn
Silver dressings
Paraffin dressings
Mepithel

*(Insert key)*

### **Combination of products used in modern moist wound care treatment**

## **Concluding evaluation, interpretation and conclusions**

Overall from our viewpoint the following conclusions can be drawn:

1. The results of topical treatment with products used in modern moist wound treatment in combination with the use of Prontosan® Gel are good to very good. In particular the wound cleansing properties and acceptance at the transition point wound / wound environment were good.
2. There was no structural change to the wound dressings used as a result of the effect of Prontosan® Gel (loss of material structure, integrity of material and surface or material consistency).
3. Clinical application showed that there was full compatibility with typical products used in modern moist wound care treatment. There is consequently no limitation on its use.
4. In the case of very odorous wounds there was a clear tendency for regular use of Prontosan® Gel to produce a marked reduction in odour. The reduction in odour contributed to an improved quality of life for the patient.
5. Provocation or intensification of negative wound margin and wound site reactions was not found in any of the cases documented.
6. Subjective tolerability (with regard to local reactions such as burning sensation, pain, itching) in the patient was overall very good.

Signed by Prof.Dr.med.Ulrich Mrowietz      Dated Kiel, 3<sup>rd</sup> January 2005  
Curriculum vitae Ulrich Mrowietz

(in English in original)