

A new developed surgical wound dressing* – Final data of a clinical study with 395 patients

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INTRODUCTION

For an optimal wound healing it is necessary to have a reliable protection of the wound. Therefore a surgical wound dressing has to be used, that fulfils this requirement. Being almost painless during dressing change and conformable for the patients is also a huge benefit. A new surgical wound dressing [Picture 1] has been developed to meet these properties. This study has been performed to evaluate the product in daily wound care. After showing the preliminary results last year, this poster presenting the final results of our study.

METHOD

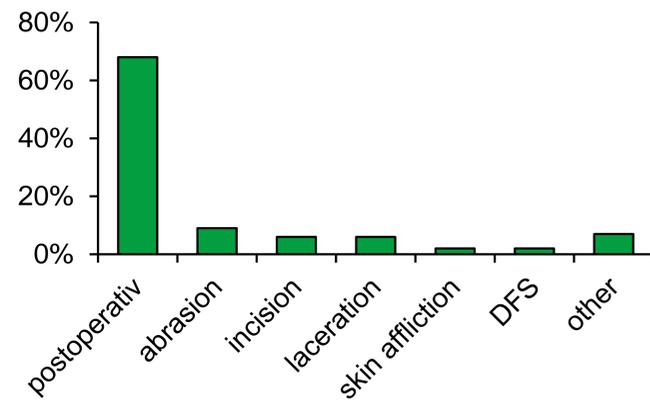
A multicentre, national Post-Market Clinical Follow-up-study (PMCF) has been performed. 46 professional users (medical doctors, nurses and healthcare specialists) were using the surgical wound dressing on 395 patients. For this study they have been asked to describe the performance of the product, the experience of themselves and the experience of patient while the treatment. The patients, were suffering on postoperative wounds, incisions, lacerations, abrasions, skin affliction and other types of wounds [Graph 1] at a variety of localizations [Graph 2]. For the treatment the professional users could choose between different product sizes from 7 x 5 cm up to 10 x 34 cm. The users were instructed to fill out a written questionnaire to document the results. The questionnaire was developed and provided by the sponsor of the study and used a six-point Likert scale (very good = 1, good = 2, satisfactory = 3, sufficient = 4, deficient = 5, insufficient = 6).

RESULTS

The adherence of the surgical wound dressing on the skin was rated as “very good”. The average application time was 1-3 days. The fit of the product to the treated localisation was rated as “very good” in general. Even at difficult localisations like foot, head, hand or knee the fit was rated as “good” or better. The germ-free application, the protection of the wound as well as the personal safety of the user was rates as “very good” [Graph 3]. More than 90% of the users rated the simplicity and the speed of the application as “very good” or “good”. More than 95% of the patients rated the wearing comfort as “very good” or “good” [Graph 4]. 88% of all patients experienced no pain during the dressing changes. The remaining 12% had average mild pain of 3 on the Numeric Rating Scale (NRS) [Graph 5].

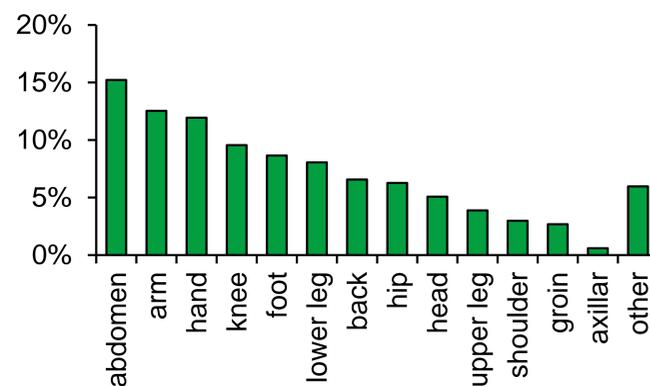
DISCUSSION

This study confirmed the suitability of the new surgical wound dressing for a variety of indications and localizations. The product was predominantly used for postsurgical wounds, but also for a variety of other acute wounds. Together with the fact, that there were no preferred localisation and the good assessment of the fitting accuracy, this shows the flexibility of the wound dressing. Due to the very good wearing comfort and the almost pain-free dressing changes the acceptance by the patient is very high. The wound dressing is also user friendly, due its simplicity and effectiveness. It also promotes wound healing by protecting it against contamination and mechanical damage.



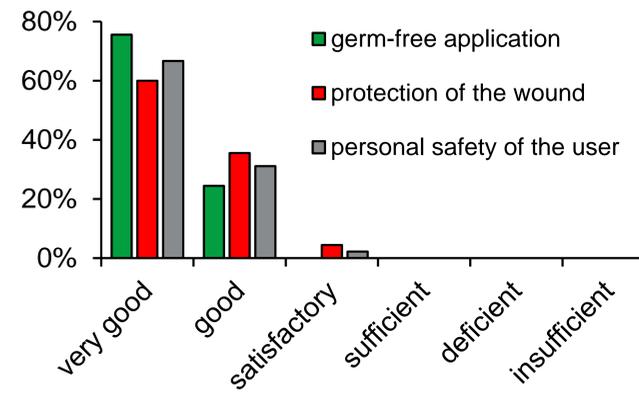
GRAPH 1: Type of wounds

68% of the wounds, that were treated in this study were postsurgical wounds. 9% were abrasions, 6% were incisions, 6% were lacerations, 2% were skin afflictions, 2% were DFS and 7% were other types of wounds such as ulcus cruris, secondary healing wounds or burn blisters.



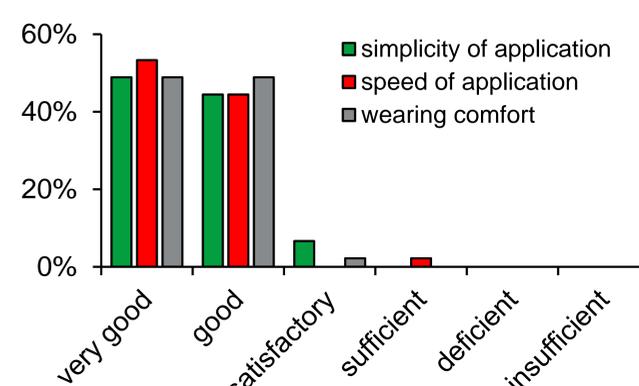
GRAPH 2: Localization of the wounds

The wounds, that were treated in this study, were localized at the abdomen (15%), arm (13%), hand (12%), knee (10%), foot (9%), lower leg (8%), back (7%), hip (6%), head (5%), upper leg (4%), shoulder (3%), groin (3%), axillar (1%) and other localizations (6%).



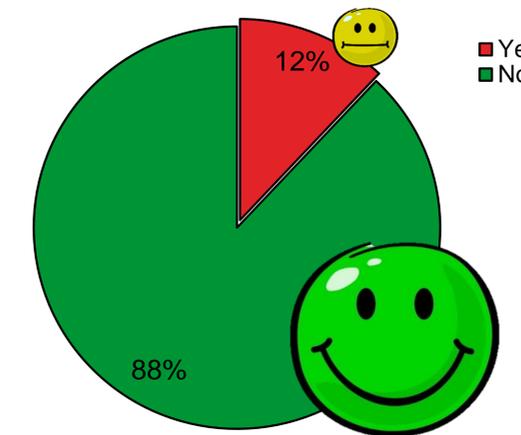
GRAPH 3: Safety

The germ-free application of the surgical wound dressing [green bars] have been rated with „very good“ ($\bar{x} = 1.24$). The protection of the wound [red bars] was also rated as “very good” ($\bar{x} = 1.44$), as well as the personal safety of the user [gray bars] ($\bar{x} = 1.36$).



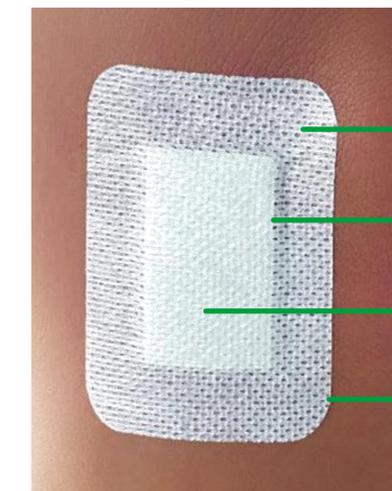
GRAPH 4: Fitting and handling

The users were asked to rate the simplicity of the application [green bars]. This was rated with “good” ($\bar{x} = 1.58$). The speed [red bars] of the application were also rated with „good“ ($\bar{x} = 1.51$), as well as the wearing comfort ($\bar{x} = 1.53$).



GRAPH 5: Pain

The majority of the patients reported to have no pain at all during the dressing changes (88%). 12% of all patients reported to have pain during the dressing changes. In average the pain was assessed with 3 on the NRS scale, this corresponds with mild pain.



PICTURE 1: The Dressing

- Polyester (nonwoven fabric)
- Polyethylene (wound contact layer)
- Viscose, polypropylene and polyethylene (dressing pad)
- Polyacrylate (adhesive)