Summary
of the Combined Clinical Study Relating to Clinical Effectiveness of Zetuvit® Plus Silicone and Zetuvit® Plus Silicone Border

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Aim:

The aim of this study was to analyse the combined data from two separate studies that were originally undertaken to evaluate the effectiveness of the superabsorbent wound dressings Zetuvit® Plus Silicone (ZPS) and Zetuvit® Plus Silicone Border (ZPSB) in the management of patients with moderate to highly exuding wounds.

Background:

Managing wound exudate in patients with wounds that produce moderate to high levels of wound exudate is a considerable clinical challenge. Excessive exudate production can be associated with a wide range of problems: exudate leakage can lead to damage to peri-wound skin (e.g., maceration, excoriation, etc.), which may result in delayed healing or even wound enlargement. Over the past decade there has been the development of new dressings with the specific aim of managing this high level of exudate production and to reduce the detrimental effects on the wound and wound edge/peri-wound skin. For example, superabsorbent wound dressings have been developed that have the capacity to absorb large volumes of wound exudate. Importantly, scientific and clinical evidence also indicates that superabsorbent SAPs modulate the levels of damaging wound exudate components (e.g., proteinases and reactive oxygen species), reduce wound bioburden and enhance overall wound healing. The Zetuvit® Plus range of superabsorbent dressing (Zetuvit® Plus, Zetuvit® Plus Silicone and Zetuvit® Plus Silicone Border) have been developed by HARTMANN to manage high exudate levels and have been demonstrated to be very effective in a number of clinical studies (Barret et al., 2018; Atkin et al., 2020; Barret et al, 2020 for each of the above dressings respectively). This analysis combines the clinical data extracted from two separate clinical studies that investigated the clinical effectiveness of both ZPS and ZPSB in patients with a variety of acute and chronic wounds (with moderate to high levels of exudate).

Study objectives:

To evaluate the exudate handling capabilities of ZPS and ZPSB in the management of a variety of moderate to highly exuding wounds by combining the clinical data generated from the two clinical studies.

Primary clinical objective:

Both studies had a common primary objective: to evaluate the exudate handling capabilities of either ZPS or ZPSB for the management of moderate to highly exuding wounds

Secondary clinical objectives:

As with the primary objective, there were several common secondary objectives that were evaluated:

- The impact of exudate management on wound edge and peri-wound skin condition in terms of preventing skin damage (e.g., maceration, excoriation, etc.)
- The evaluation on wound bed preparation and healing progression, as measured by levels of devitalised tissue and change in wound area, respectively
- The impact of dressing use on signs of infection and odour
- The impact of the dressings on pain reduction (both at and between dressing changes)
- The physical handling attributes of the dressing will be assessed at each dressing change
- An overall assessment of dressing performance will be undertaken after the patients have completed their evaluation period

Study dressings:

Zetuvit® Plus Silicone and Zetuvit® Plus Silicone Border which are very similar in regards to their composition and structure but also in terms of their functionality and performance (absorption and retention capabilities). The primary difference is that Zetuvit® Plus Silicone Border has a silicone border so no additional dressings are required to secure the dressing. Both dressings are intended for use on the same types of wounds – moderate to highly exuding acute and chronic wounds.

Methods:

The collected data from both studies were combined and analysed to give an overview of the effectiveness of these superabsorbent dressings. The primary objective in both studies related to exudate management (assessed subjectively by the investigating clinician). Secondary objectives that related to exudate management included subjective assessment the effectiveness of the dressings in preventing damage to the wound edge or peri-wound skin.

Results

Baseline Characteristics

Table 1. Patient and wound characteristics

	Number of patients	Mean age (± SD) median age (years)	Mean wound area (± SD) (cm²)
Male	62	69.6 (± 12.5) 71	36.2 (± 76.8) 12
Female	39	77.7 (± 13.1) 78	28.3 (± 60.4) 12
Total	101	72.8 (± 13.3) 74	33.2 (± 70.7) 12

Total number of wound assessments – 494

- **Wound types evaluated:**
  A summary of the proportion of wounds assessed in this evaluation study (n=101), indicated Venous leg ulcer (27.3 %), mixed aetiology ulcers (27.3 %) diabetic foot ulcers (19.2 %), malignant wounds (7.1 %) and pressure ulcers (5.1 %). Most wounds had moderate levels of exudate production throughout the study (69 %). A significant proportion of the evaluations assessed exudate levels as 'high' (28 %), i.e., offering significant management challenges.
- **Wound duration prior to enrollment:**
  Showed that most wounds assessed were of long duration prior to participating in the studies. Forty percent of wounds had been present for 7–52 weeks, with 34 % of wounds having been present for more than a year.
- **Dressing types used prior to enrollment:**
  As part of the clinical history of each patient, the types of dressing used on the study wounds for 4 weeks prior to the commencement of the ZPS/ZPSB studies was noted. The results showed that SAP dressing (30 %) were the most frequently used dressings prior to enrollment followed by foam dressings (23 %), antimicrobial dressings (AM) (17 %) and alginates (8 %).
- **Dressing change frequency prior to enrollment:**
  Dressing change frequency prior to enrollment ranged from several times per day (4 %) to weekly dressing changes (2 %). Most dressing changes occurred every second or every third day (29 % and 39 %, respectively).

Primary Objective – Exudate Management

Figure 1. Summary of overall exudate management assessments

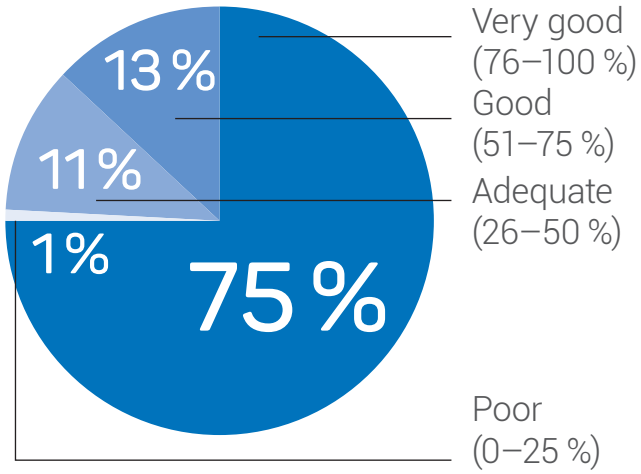
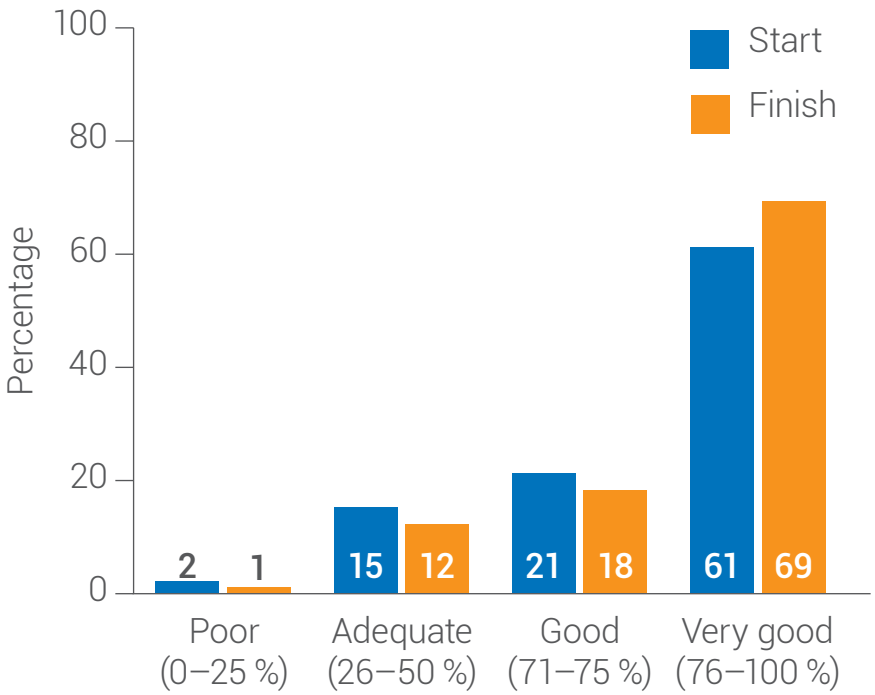


Figure 2. Exudate management rating at start and end of evaluation period



The clinicians rated the dressings as 'Very Good' or 'Good' for 88 % of all assessments (Figure 1). When assessing the exudate management performance of ZPS/ZPSB at the start of treatment versus the end of the treatment, the dressings were rated as 'Very Good' and 'Good' in the majority of cases (Figure 2).

Secondary Objectives: related to the wound exudate management effectiveness of ZPS/ZPSB is the impact on the wound edge and peri-wound skin, results appertaining to these parameters are presented here.

Wound Edge Response to Treatment with ZPS/ZPSB

Figure 3. Changes in wound edge skin condition response over the course of the evaluation period

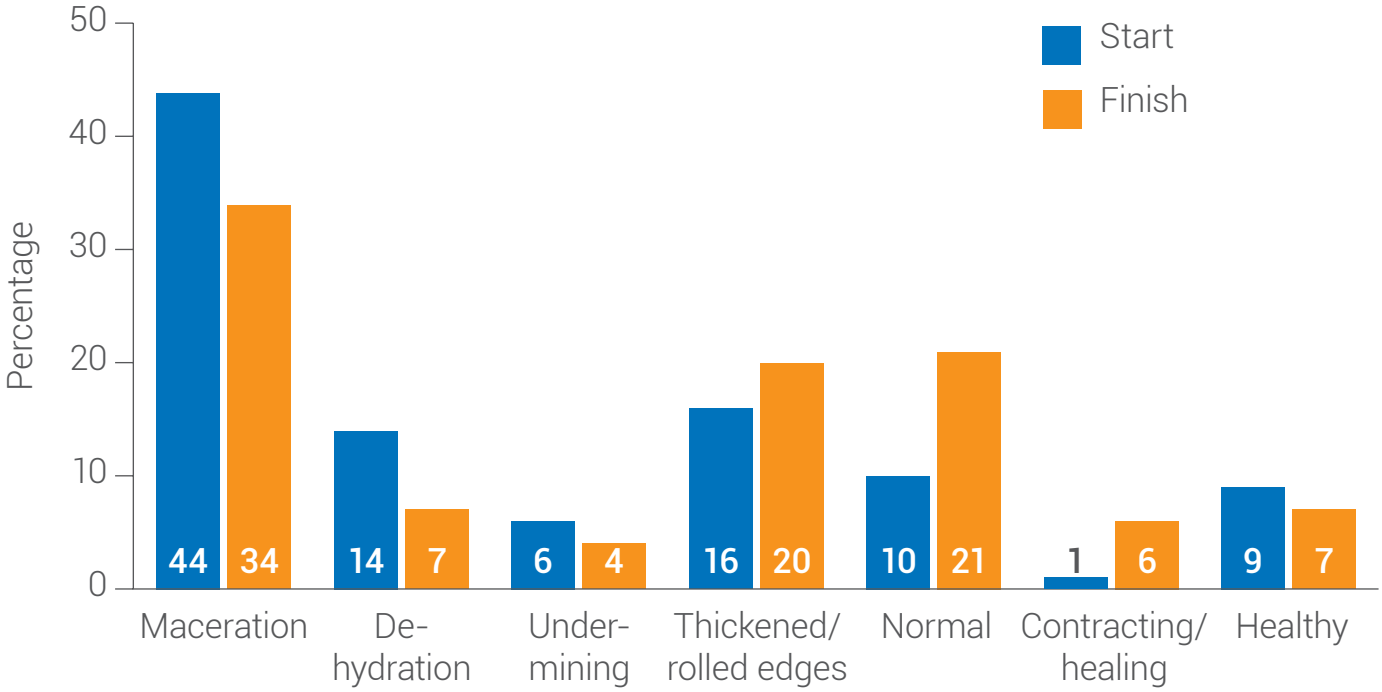
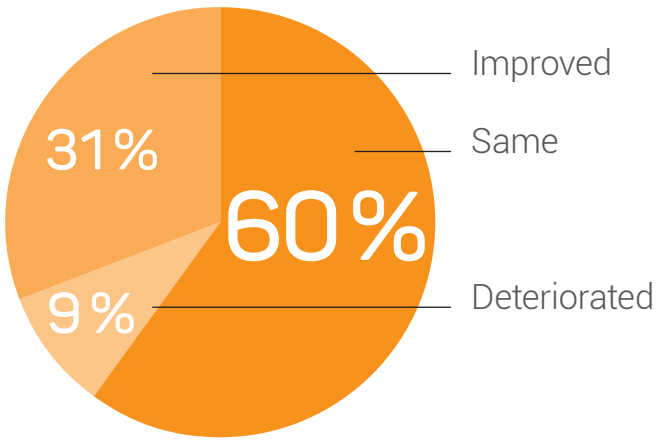


Figure 4. Assessment of change in wound edge skin condition



Wound Edge Skin Conditions:
The results show a wide range of skin conditions were present throughout the study, but that the poor skin conditions changed when treated with either ZPS or ZPSB for example. maceration reduced from 44 to 34 % conversely, "normal" wound edge skin increased from 10 to 21 % (see Figure 3). Additionally, each of the patients showed that 91 % of patients show the same level or improving skin condition (Figure 4).

Peri-wound Response to Treatment with ZPS/ZPSB

Figure 5. Changes in peri-wound skin condition response over the course of the evaluation period

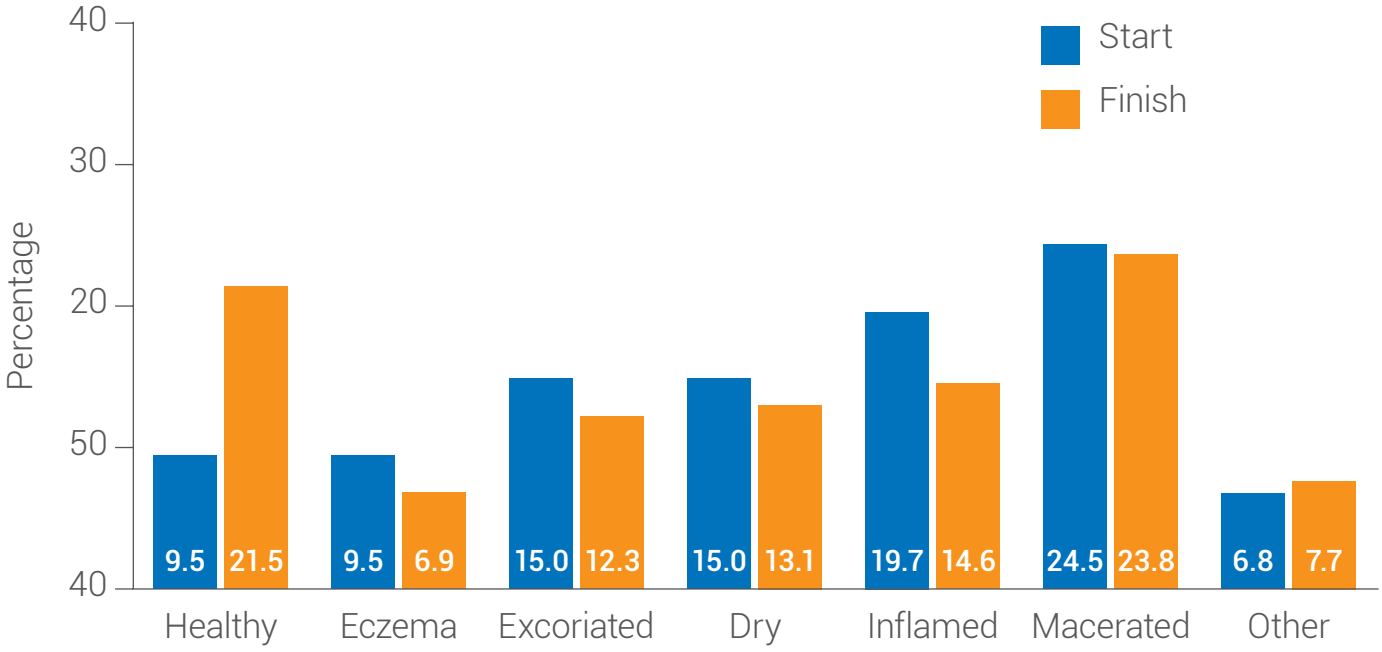


Figure 6. Assessment of change in peri-wound skin condition

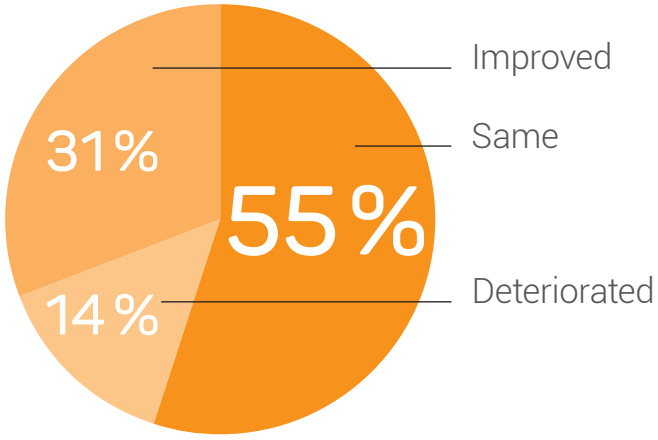
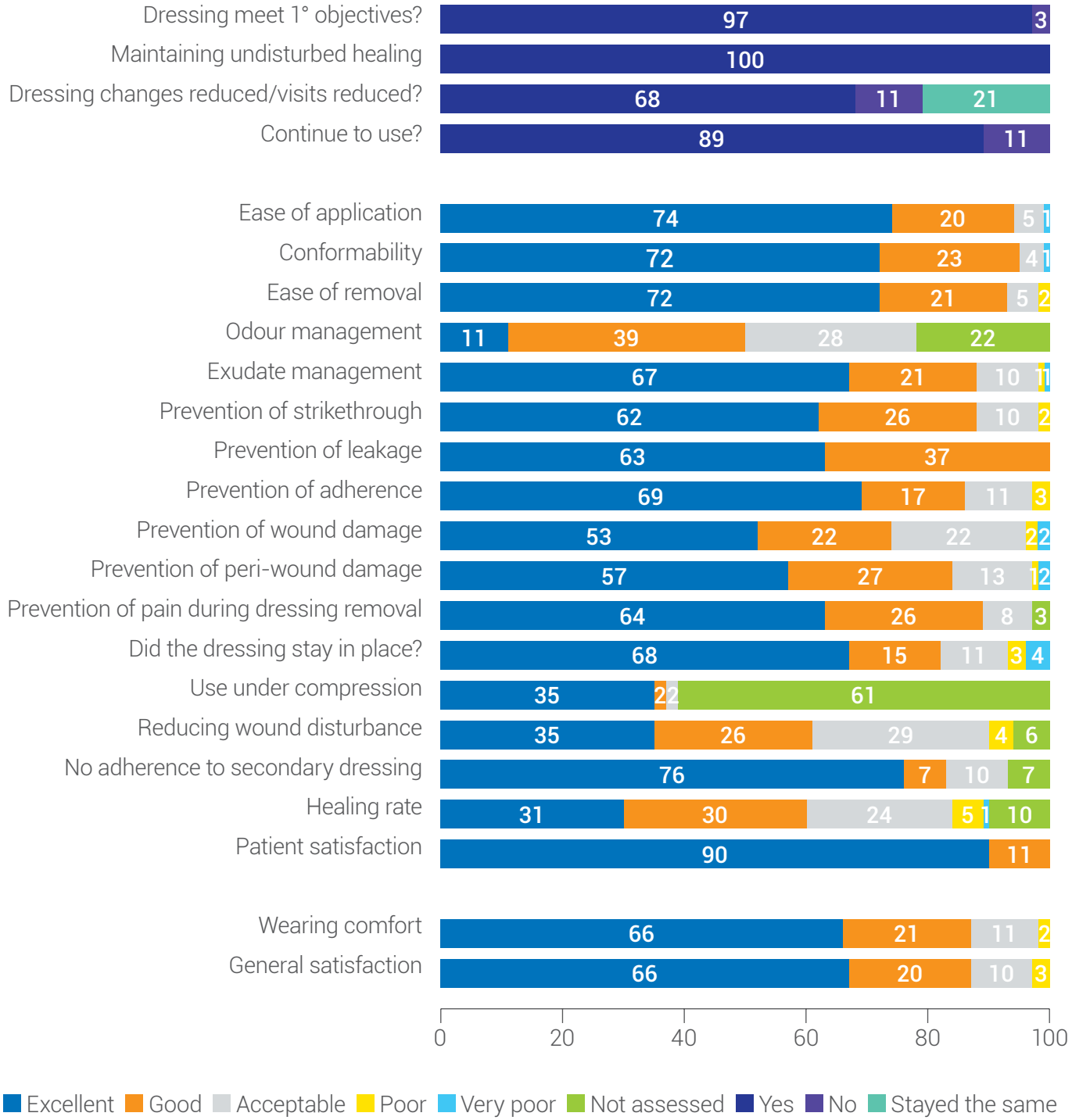


Figure 8. Overall assessment of ZPS and ZPSB



Conclusion:

The results from the combined data shows that the physical properties of both superabsorbent polymer dressings promote effective absorption and retention of wound exudate into the absorbent core of the dressings. Effective absorption of exudate aids in reducing the adverse sequale associated with poor exudate management (e.g., maceration and excoriation).