

International multicentre application study to assess a polyester-tulle primary wound dressing with hydrocolloid particles* in terms of usability as well as user and patient satisfaction

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Introduction:

The aim of this clinical investigation was to assess the usability as well as user and patient satisfaction of a polyester-tulle wound dressing with hydrocolloid particles* in the daily routine.

Methods:

An international multicentre (11 centres), post marketing surveillance study was carried out to observe the application of the wound dressing on 53 patients with superficial, acute, and chronic wounds (Fig. 5) for up to 30 days of treatment (4 visits/V1-V4).

Dressing Change	
Quartil1 = Q,25	2,33
- Max	11,00
- Min	1,00
- Median	2,67
Quartil3 = Q,75	3,50

Fig. 1: The majority of the dressing changes (271 dressing changes in total), was between 2-4 days.

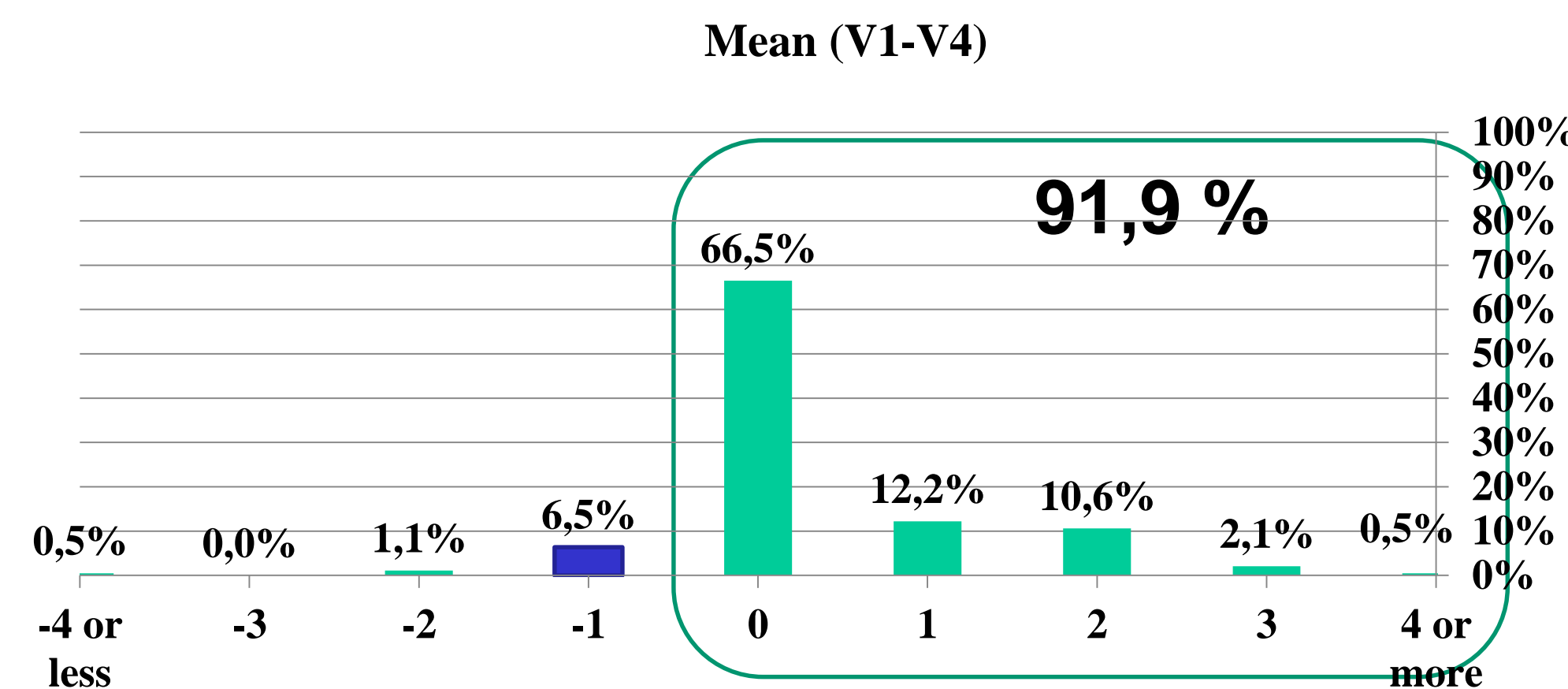


Fig. 2: Patients were interviewed regarding pain before and after wound dressing changes (VAS) and the results were subtracted. Values greater than zero show that the pain was reduced.

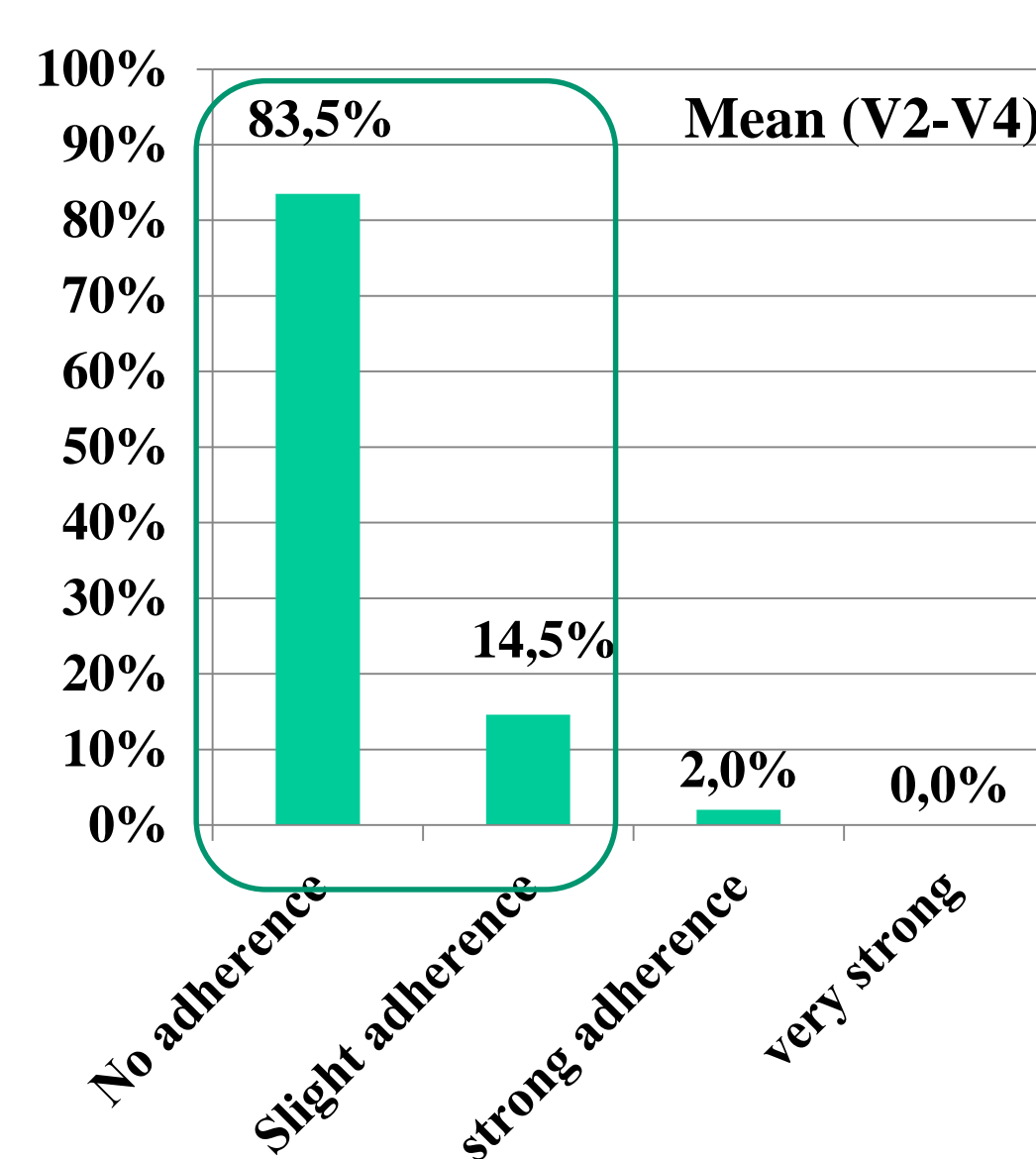


Fig. 3: During 97.2% of the removals of the wound dressing (mean V2-V4), there weren't any or only slight adherences to the wound.

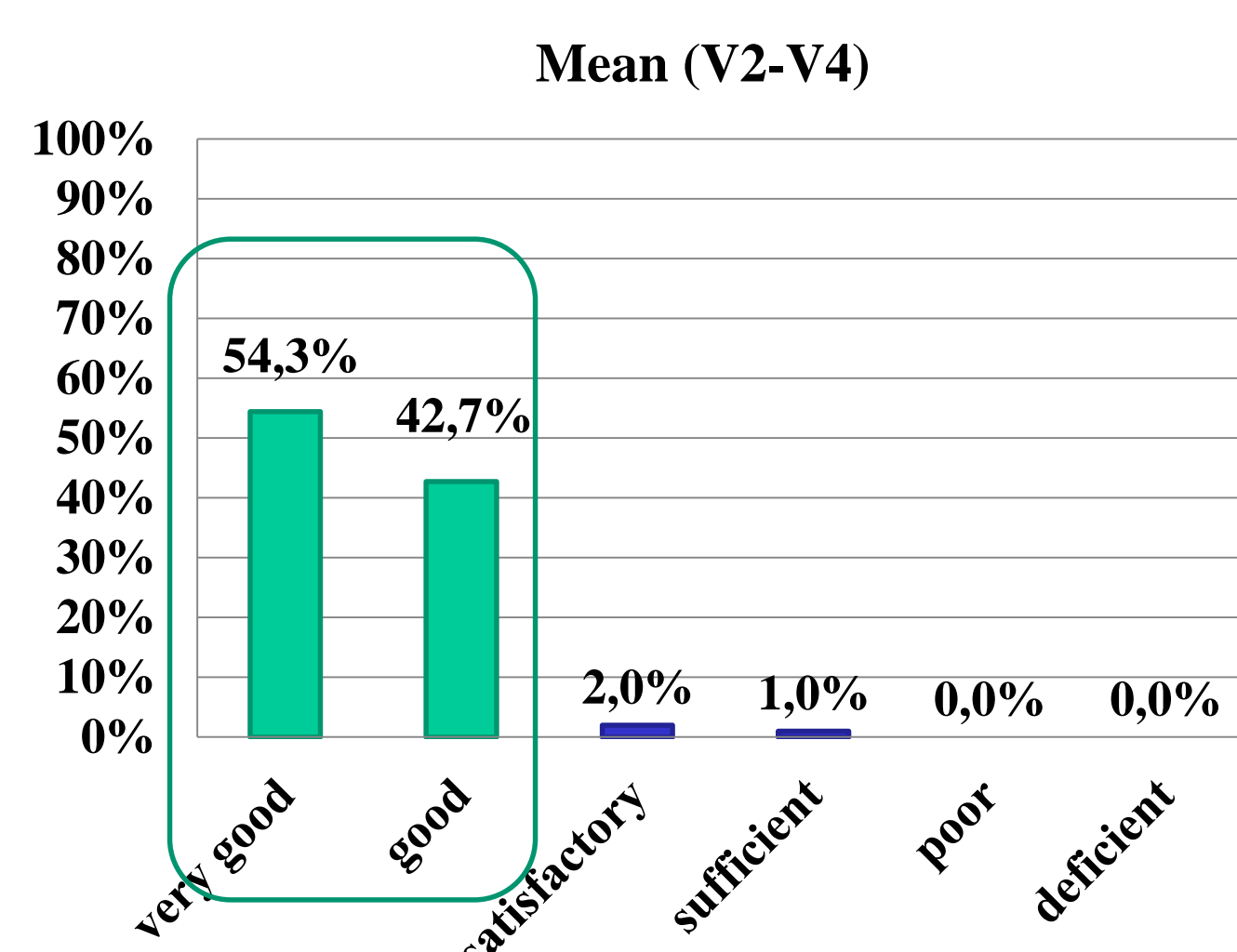


Fig. 4: The removability without causing trauma was rated as "good" to "very good" in 97% of the cases (mean V2-V4) by the users.

Results:

The usability of the polyester-tulle wound dressing with hydrocolloid particles* for the treated wounds was rated as "very good" to "good" in 93.9% of the cases (mean V1-V4) by the users. The majority of the dressing changes (271 dressing changes in total), was between 2-4 days (Fig. 1). The analysis of the dressing changes with respect to the duration between the dressing changes shows the whole spectrum of modern wound management and the reality of treatment of different wounds. The exudation degree was found to be medium for 49,1% of the cases, 37,7% of the cases mild and 13,2% of the cases severe.

The removability without causing trauma was rated as "very good" to "good" in 97% of the cases (mean V2-V4) by the users (Fig. 4). Patients assessed the removal as painless or even as a subjective reduction of pain (91.9% of the cases/ mean V2-V4; assessed by Visual Analogue Sore) (Fig. 2), they rated the wearing comfort as "very good" to "good" (94% of the cases/ mean V2-V4).

During 98% of the removals of the wound dressing (mean V2-V4), there were no or only slight adherences to the wound (Fig. 3).

Users rated the exudate drainage into the secondary dressing as "very good" to "good" (96.1% mean V1-V4) (Fig. 6).

The overall usability for the users was attested by indications as "cover film easily removable" (99.3% "very good" to "good"), ability to cut to size (81.3% "very good" to "good"), usability on both sides (100% "very good" to "good"). The combination with secondary wound dressings was "very good" to "good" (98.6%, mean V1-V4).

No medical device related adverse events (as allergic reactions or skin irritations) were reported by the investigators.

Conclusion:

The current data demonstrates the usability and performance of this wound dressing for various superficial, acute, and chronic wounds.

Wound type	number
Ulcus Cruris	23
Post traumatic (incl. cuts & abrasions)	10
Post-operative (incl. skin graft transfer)	11
Decubitus	4
Burn 2nd degree	1
Diabetic foot ulcer	1
Others, unspecified	3

Fig. 5: The treated wound types.

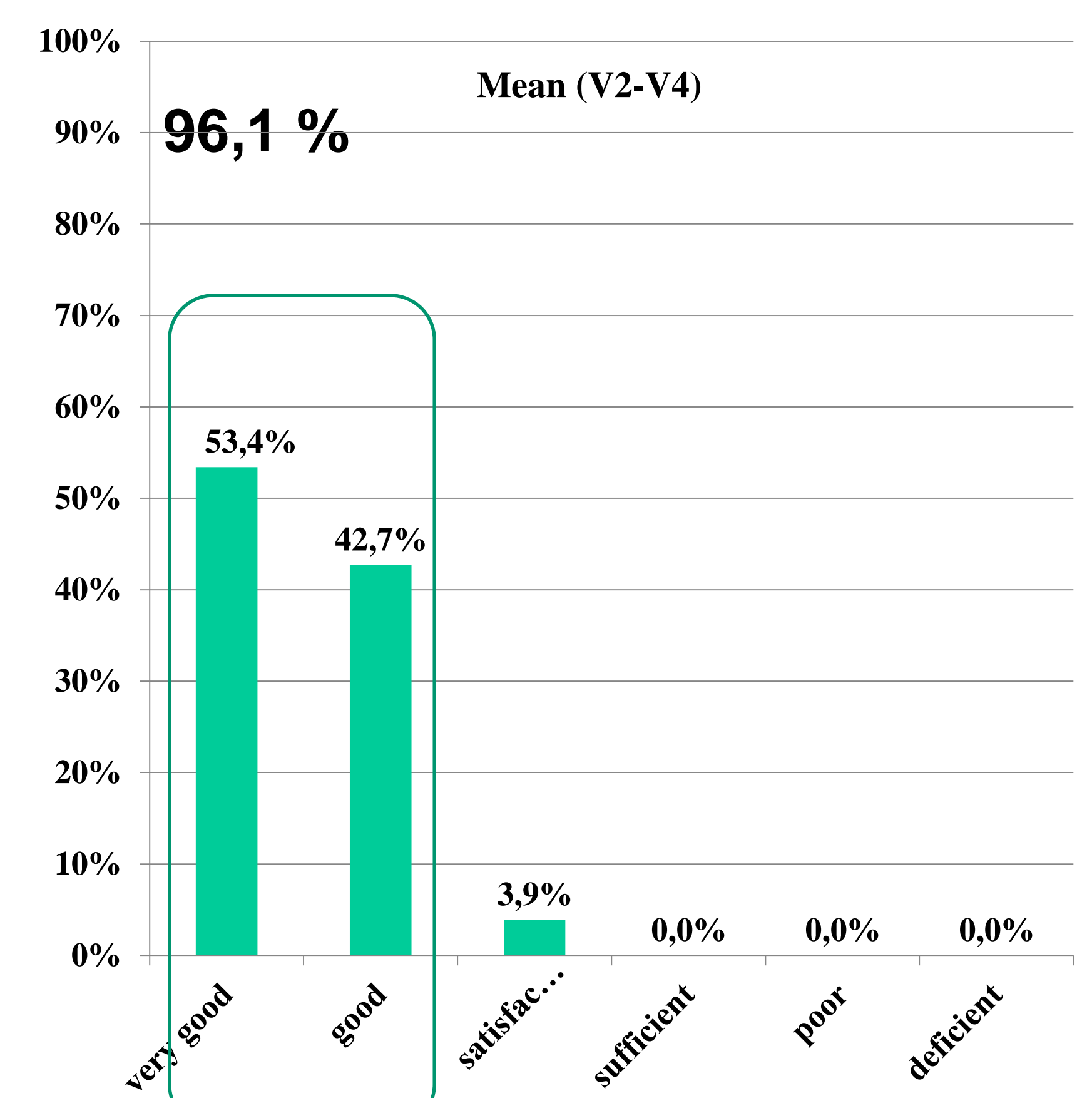


Fig. 6: Exudate drainage into the secondary dressing was rated as "very good" to "good" (96.1% mean V1-V4).

Pic. 1: Day 1



Pic. 2: Day 7



Pic. 3: Day 14



Pic. 4: Application of polyester-tulle wound dressing with hydrocolloid particles



Case study:

Male patient (age 80) suffering from Ulcus cruris venosum, age of wound is 6 months. Wound was previously treated with an antimicrobial PU foam dressing. Wound status at day 1 is granulating with moderate secretion and serous exudate. Pain level (VAS) 4 (Pic. 1)

Treatment: 14day application of polyester-tulle wound dressing with hydrocolloid particles* and a compress** (cleaning of a wound using a physiologic saline rinsing solution) (Pic. 4).

Wound status at day 7 is epithelisation with mild degree of secretion and serous exudate. Pain level (VAS) 2 (Pic. 2), pain during application of dressing is 2 (VAS).

Interval of dressing changes: 2 times/week. The user states that the dressing can easily be removed without causing trauma, there is no adherence to the wound and the exudate drainage into the secondary dressing is good.

The combination with secondary wound dressings is easy. Patient rates the wearing comfort as very good. No macerations or allergic reactions were reported. Wound is healed at day 14, pain level (VAS) is 1 (Pic. 3).