



TenderWet plus

Therapeutic effectiveness, compatibility and handling in the daily routine of hospitals or physician's practices



Summary

In a multi-centre observational study the wound healing-promoting effect, compatibility and handling of the new TenderWet plus wound dressing pad in the daily routine of hospitals or physician's practices were investigated. 170 patients, suffering from predominantly chronic wounds such as leg and decubital ulcers, were treated. The wounds had persisted for five months on average at the inclusion examination. An improvement in the wound status was already observed after an average of eight days of treatment. The proportion of fibrin coatings and necroses decreased during the treatment, whereas granulation tissue increased. At the same time infections and wound pain decreased. Overall, the treating persons and patients were very satisfied with the treatment with TenderWet plus. The treating persons overwhelmingly evaluated the product properties as "good" or "very good". TenderWet plus kept even dry wounds sufficiently moist over an average wearing duration of three days and was easy to remove. 88% and 96%, respectively, of the treating persons evaluated these properties as "good" or "very good". Patient acceptance of treatment with TenderWet plus was also very high. Thus, 87% of the treating persons and 84% of the patients said their overall impression of the treatment was "very good" or "good" and in most cases, they saw their expectations of the product fulfilled or even exceeded. TenderWet plus was suitable in the study into the treatment of partially infected and necrotic, fibrinous wounds in which wound cleansing and the production of a moist wound environment for promoting granulation are the forefront.

Introduction

The essential difference between a chronically and normally healing wound consists in the lack of integrity of the extracellular matrix and an increase in the activity of inflammatory processes. Accordingly an excess of matrix-degrading proteases, the activity of which in chronic wounds is up to 30 times greater than in acute wounds (1), and increased inflammatory activity frequently caused by infection is seen as one of the main reasons for disturbed wound healing.

Just as on intact skin, bacteria are also present in open chronic wounds. Only through proliferation do they disrupt the healing process, which is frequently called critical colonisation or infection. Often this initially occurs without any signs of a clinical infection. The inflammatory response to an infection is an influx of neutrophilic cells which releases cytotoxic enzymes, free oxygen radicals and other inflammatory factors which can bring about an increase in the activity of matrix metalloproteinases (1, 2). The protein-degrading enzymes break down the matrix proteins and growth factors necessary for the healing process and create a new wound environment which favours bacterial growth and prolongs the inflammatory stage (3).

Within the context of phase-adapted wound treatment, numerous wounds have been treated with the TenderWet wound dressing pad over the past years. The super-absorbent polymer in the core of the wound dressing is saturated in Ringer's solution which is continuously released into the wound so that coatings are softened and detached. Inversely, cell debris and healing-inhibiting factors are taken up into the wound dressing and stored in the core of the wound dressing pad. This exchange is possible as the superabsorber has a greater affinity for the protein-containing wound exudate than for the salt-containing Ringer's solution (Fig. 1). In this way, the activity of harmful matrix metalloproteinases in the exudate is demonstrably reduced (4). They are bound by the superabsorber and removed from the wound when the dressing is changed. In the core of the wound dressing pad the new TenderWet plus contains polyhexanide in bound form, one of the most promising antiseptics in terms of its efficacy, safety and clinical application (5). It can kill germs stored in the wound dressing pad so that recontamination of the wound is prevented. For this reason the new TenderWet plus actively removes healing-inhibiting factors

such as germs and MMPs and provides a wound environment in which build-up of granulation tissue is promoted. The flexible covering film prevents evaporation of the fluid stored in the wound dressing pad and allows it to stay on the wound for three days without the wound drying out. Silicone strips on the side facing towards the wound prevent adherence to the wound. Because of its high retention capacity TenderWet plus is also suitable in combination with compression therapy.

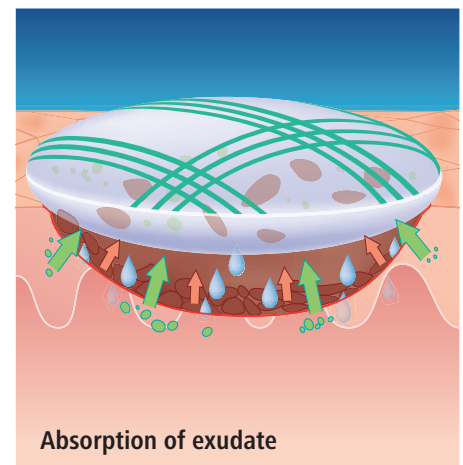
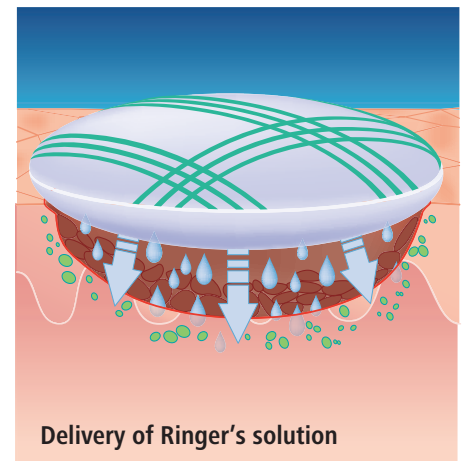


Fig. 1: Absorbing and rinsing effect of TenderWet plus.

Multi-centre study with 170 patients

In an observational study in which totally 170 patients with wounds of various geneses took part, the effectiveness, compatibility and handling of the new TenderWet plus were investigated. The treating persons documented the course of therapy for an average period of eight days or over three dressing changes, respectively, as a dressing change interval took three days on average (see Fig. 2)

The average age of the patients was 75 years. In most cases of patients (60%), the therapists evaluated the general condition as "good" and in 8% of cases even as "very good".

In 32% of cases, the general condition was rated as "reduced".

The most part of patients suffered from leg and pressure sores (Fig. 3). Of the decubital ulcers 6% were in decubitus stage II, 68% were in stage III and 23% were in stage IV (Fig. 4). Decubitus stage III is characterised by the loss of all skin layers and damage or necrosis (dead tissue) of the subcutaneous tissue which can extend to the underlying muscle. In stage IV muscles and supporting structures can already be affected. Bones and tendons are visible or palpable (6). Among the non-chronic wounds, 5% were caused by a trauma and 11% were of other origin such as post-operative wounds.

The patients had had their wounds for an average of 5 months whereby some of the wounds had been present for several years (20 years and more) and had been treated with a lot of wound dressings without success. In 29 % of the patients accompanying compression therapy was carried out and in 51% of the patients additional pressure-relieving measures were taken, such as changing position for example. In some cases TenderWet plus had additionally been covered with another wound dressing mostly an absorbent dressing pad.

Moist wound environment supports formation of granulation tissue

The backing film protects against evaporation of the fluid stored in the wound dressing pad. In combination with the high absorption capacity, the wound was thereby kept sufficiently moist and the cellular healing processes were supported.

Using a points scale, the treating persons evaluated the condition of the wound at the start and at the end of the observational study. At the start more than half of the wounds were covered with necroses and fibrin coatings, which decreased during the course of the treatment, necroses from 17% to 10% and fibrin coating from 41% to 33 %. Inversely, the proportion of granulation tissue increased from 35% to 46% and the proportion of epithelial tissue increased from 6 % to 11% (Fig. 5).

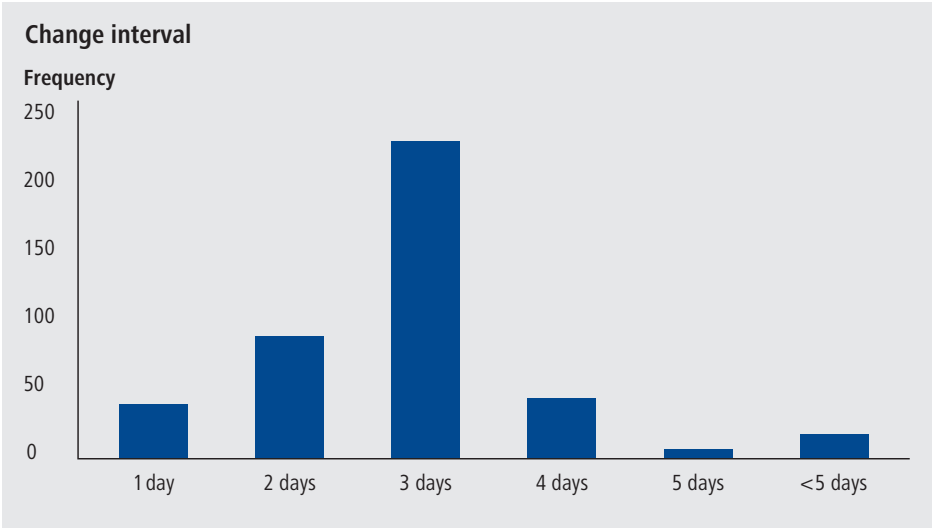


Fig. 2: TenderWet plus has been changed on average every three days.

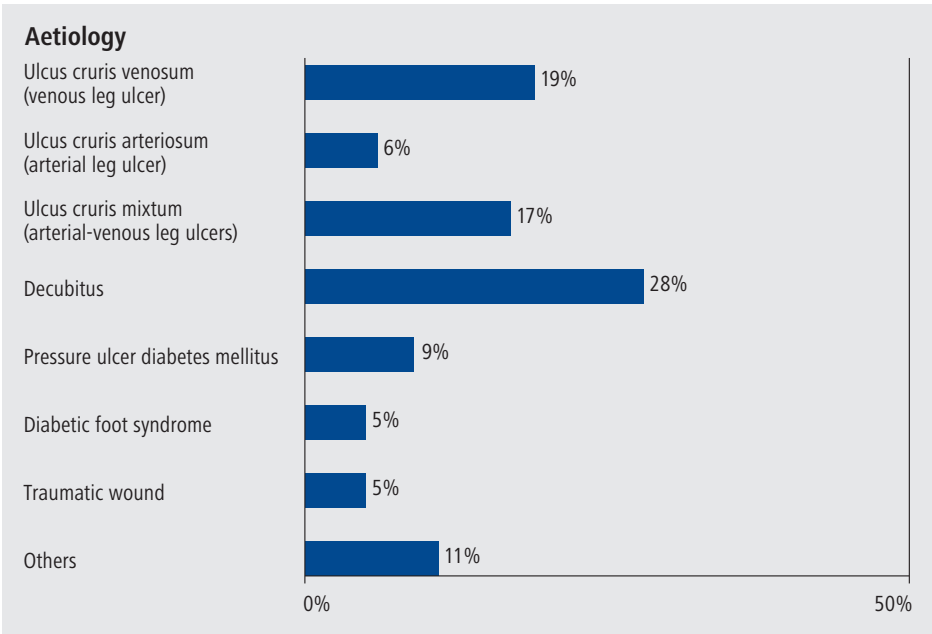


Fig. 3: More than 80 % of patients suffered from chronic wounds.

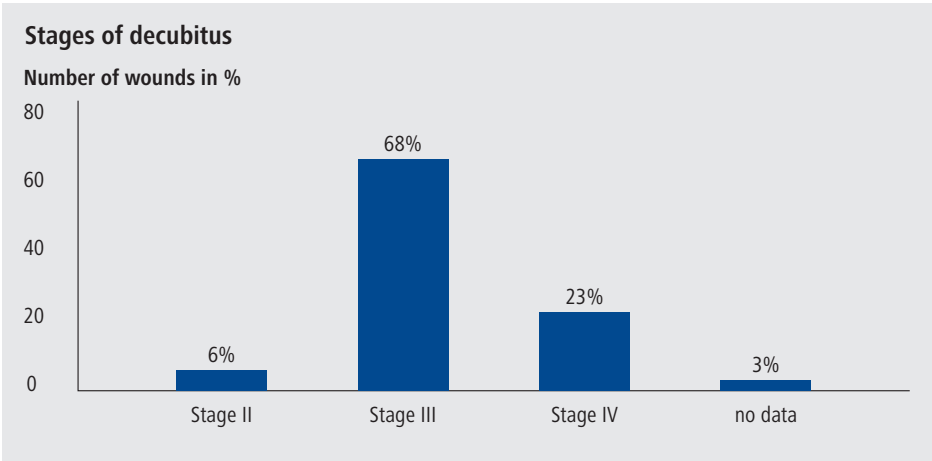


Fig. 4: The most decubital ulcers were in stage III.

TenderWet plus protects the wound margins

The high absorption and retention capacity of the polyacrylate contained in TenderWet largely prevents the wound fluid re-emerging from the wound dressing pad under pressure as used in compression therapy. This protects the surrounding tissue from protease-rich wound exudates so that wound margins recovered during the course of the therapy. At the start of treatment, 71% of the wounds had conspicuous wound surroundings, after the observation period the figure was only 62 %.

No recontamination as germs are killed in the wound dressing pad

The polyhexanide contained in the wound dressing pad kills the germs present in the wound fluid. Together with the high retention capacity of TenderWet plus this therefore prevents recontamination of the wound and infections, which was also reflected in the decline in infections during the treatment. The proportion of wounds with clinical signs of an infection reduced in the course of therapy from 24 % to 17 %.

Pain decreased with the improvement in the wound status

In slowly healing wounds, a persistent inflammatory reaction can lead to increased sensitivity of the wound and surrounding skin. During the course of the study, there was a reduction in pain with increasing improvement of the wound (Fig. 8). At the start of the treatment, 35% of patients were suffering from moderate to severe wound pain, whereas at the end of the study the figure was now only 19%.

In parallel to the wound pain the proportion of moderate to severe pain decreased during dressing change from 28% at the start to 11% at the end of treatment.

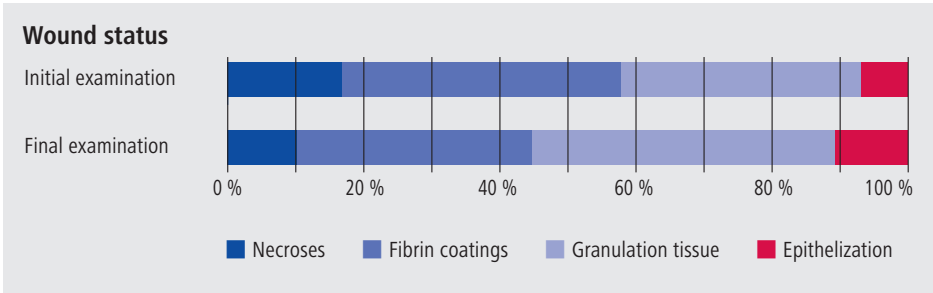


Fig. 5: Formation of granulation tissue increased.

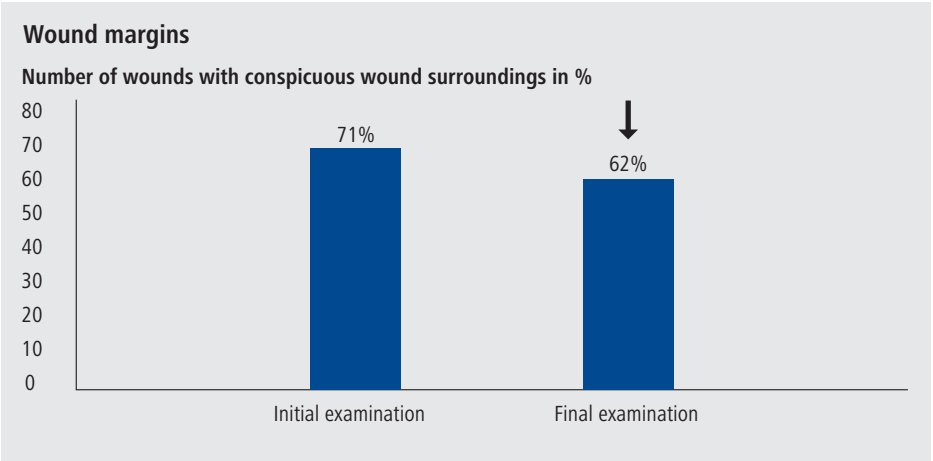


Fig. 6: Damages of the wound margins decreased.

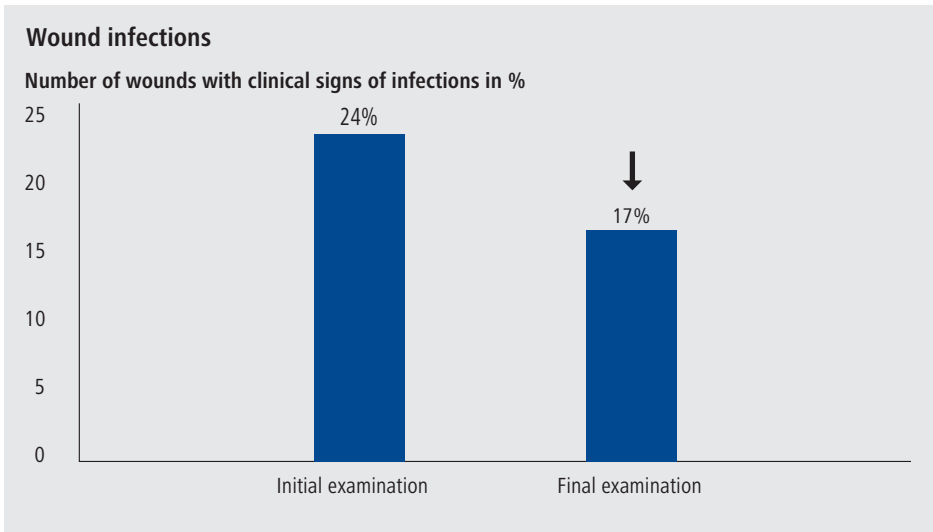


Fig. 7: During the course of the treatment, there were no new infections and the number of wounds with clinical signs of infection decreased.

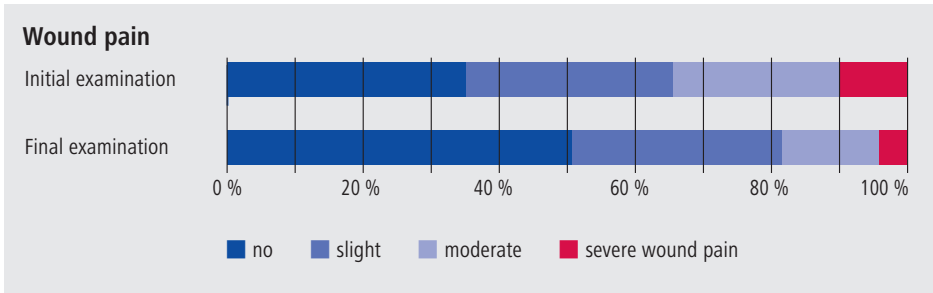


Fig. 8: Wound pain decreased during course of treatment.

Waterproof backing film improves the moisture retention capacity of the wound

The high absorption capacity of the super-absorber contained in the wound dressing pad, in combination with the protection against evaporation provided by the waterproof backing film on the side facing away from the wound, allowed an adequately moist wound environment even in the case of dry wounds. There were no cases of drying out of the wound dressing pad after an average wearing duration of three days. 80% and 88%, respectively, evaluated the absorption capacity and the moisture retention capacity of TenderWet plus as "good" or "very good".

No adherence to the wound

The large volume of Ringer's solution bound in the superabsorber produces a moist wound surrounding and together with the hydrophobic surface made of polypropylene ensures that the wound dressing does not adhere to the wound and wound surroundings. The silicone strips on the side of the wound dressing pad facing towards the wound make removability easier and protect the wound and wound surroundings against mechanically caused skin irritations. The treating persons evaluated the removability and the skin compatibility in 96% and 86% of the cases, respectively, as "good" or "very good".

Good draping capability with backing film

The flexibility of the backing film and the soft material enable good draping capabilities of the wound dressing pad in wounds of different depths and therefore also ensure good contact to the wound bed. These properties were evaluated in 74% and 80% of the cases, respectively, as "good" or "very good".

Good response among the treating physicians

In 92% of the cases, the treating persons had a "good" to "very good" overall impression of the course of therapy. Altogether, respondents found that the product fulfilled or even exceeded their expectations in 52% and 24% of cases. In response to the question of whether they would use TenderWet plus in comparable wounds again, 64% answered "very definitely" and 32% answered "possibly". Only 4% were certain that they would not use the product again.

Pain during dressing change

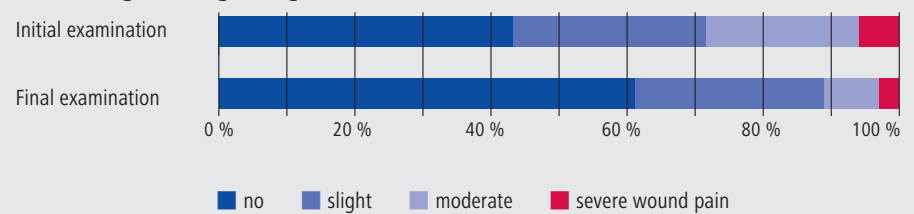


Fig. 9: Dressing changes were increasingly free of pain.

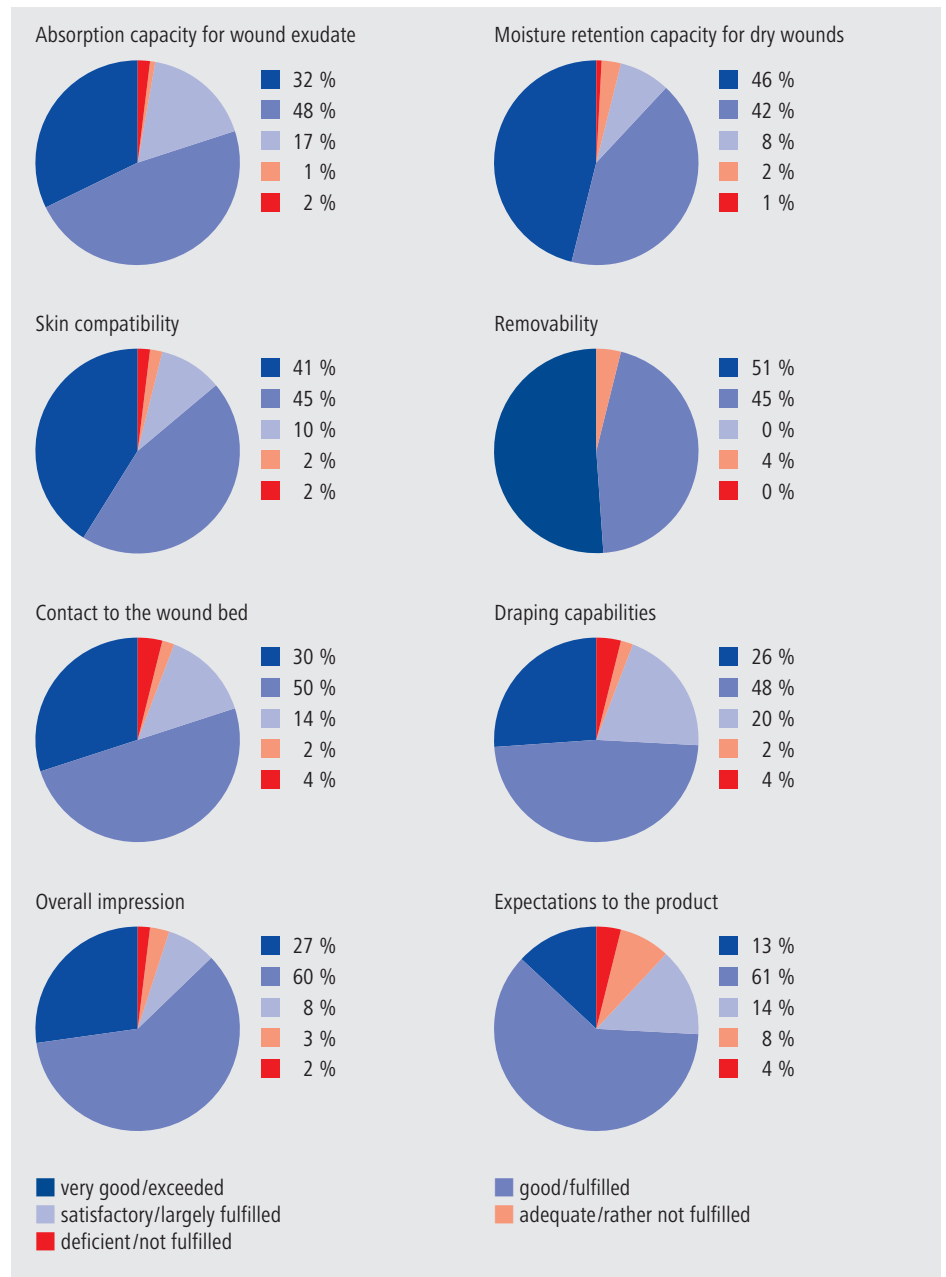


Fig. 10: Product evaluation by the treating persons.

Positive feedback from patients

Patients' degree of acceptance with treatment with TenderWet plus was also very high (Fig. 11). 87% and 83% of the patients, respectively, found that the product was "good" or "very good" on wearing comfort and compatibility. Therefore 62% of the patients found their expectations "fulfilled" and 15% even "exceeded".

Discussion

- The wound condition of the mostly chronic wounds, some of which had existed for several years, improved after an average treatment duration of eight days. TenderWet plus removed coatings and supported the reduction of already existing infections. These results confirm in vitro findings which have demonstrated that TenderWet binds harmful proteases in the core of the wound dressing pad and therefore reduces protease activity in the wound up to 88% (4). In addition, the polyhexanide contained in the wound dressing pad kills germs also bound by the super absorber in the wound dressing pad, which leads to a relevant reduction in the common wound bacteria *Staphylococcus aureus* and *Pseudomonas aeruginosa* in the wound (7).
- The quantity of Ringer's solution contained in the wound dressing pad and the evaporation protection by the covering film kept the wounds sufficiently moist the way that formation of granulation tissue was promoted. On average TenderWet plus could be left on the wound three days without drying out the wound dressing pad.
- With the improved condition of the wound and the wound surroundings, the wound pain decreased. The high moisture content prevents adherence of TenderWet plus to the wound so that pain during dressing changes was also reduced.
- The retention capacity of the superabsorber allowed TenderWet plus to be used with concomitant compression therapy which forms the basis of non-invasive treatment of venous ulcers (8).
- The ease with which it can be removed and the good compatibility resulted in physicians and patients having a positive overall impression of the treatment with TenderWet plus which largely fulfilled or even exceeded their expectations.

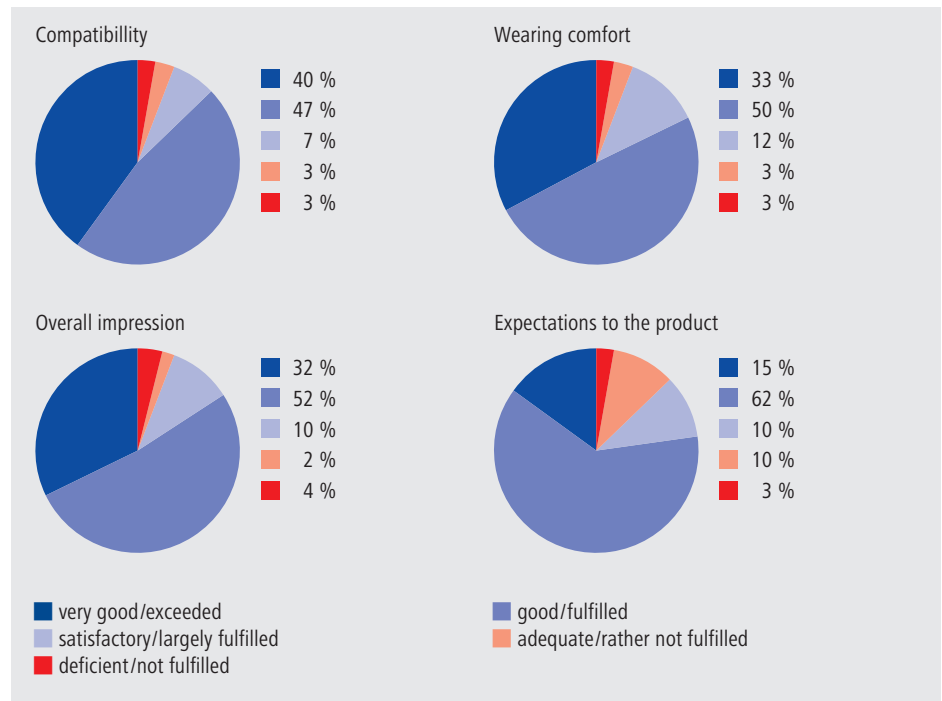


Abb. 11: Patient judgement.

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