

New monofilament-fibre debrider lolly*

Experience in daily practice on 170 patients with acute or chronic wounds

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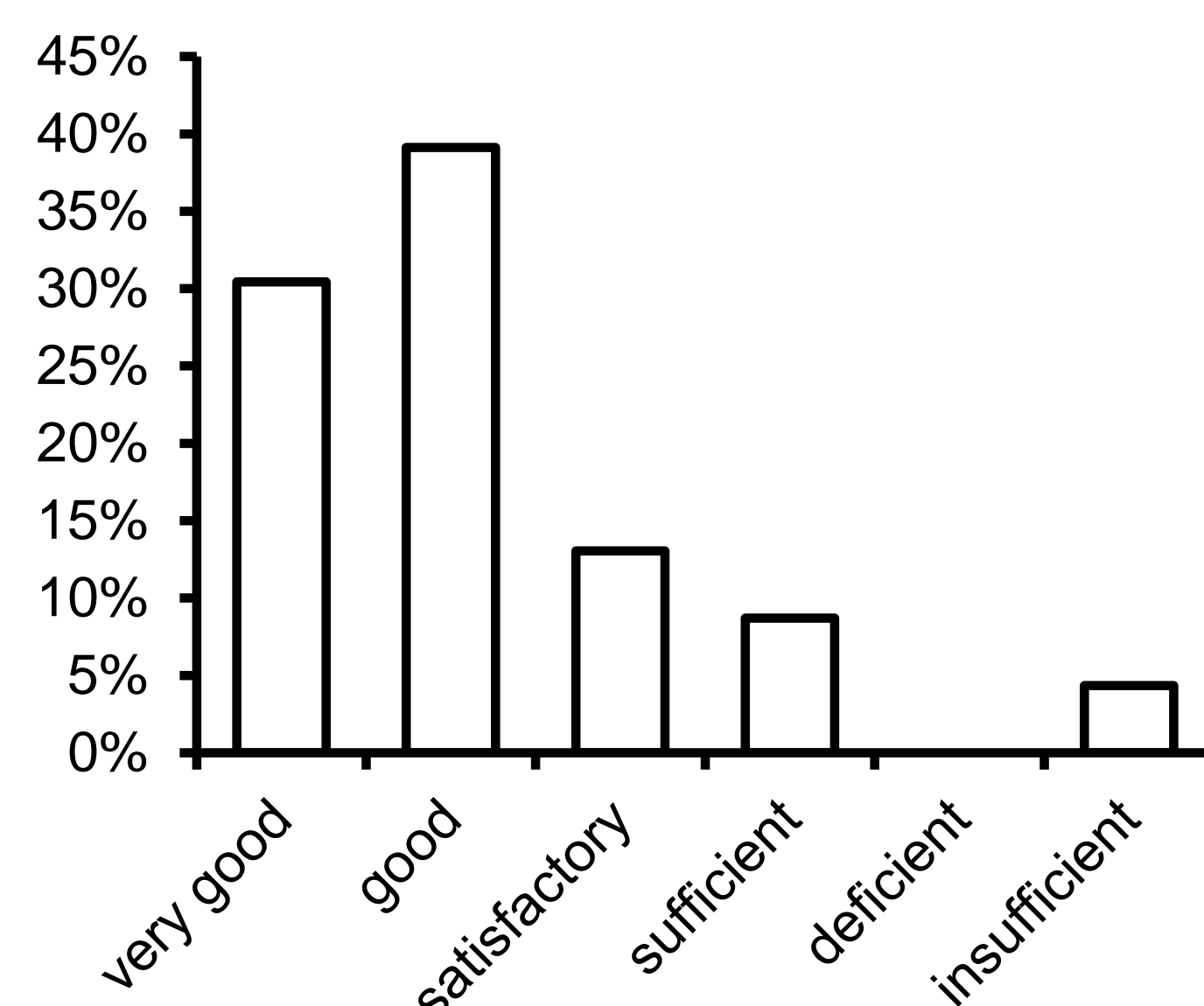
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INTRODUCTION:

The Debrisoft monofilament fibre pad has been implemented successfully within clinical practice as a very useful wound debrider for superficial acute or chronic wounds. It has been modified in its dimensions, provided with a X-ray contrast strip and connected to a handle. The newly developed product, Debrisoft Lolly, is indicated for debridement of acute and chronic, superficial to deep wounds and invasive surgery procedures.

METHOD:

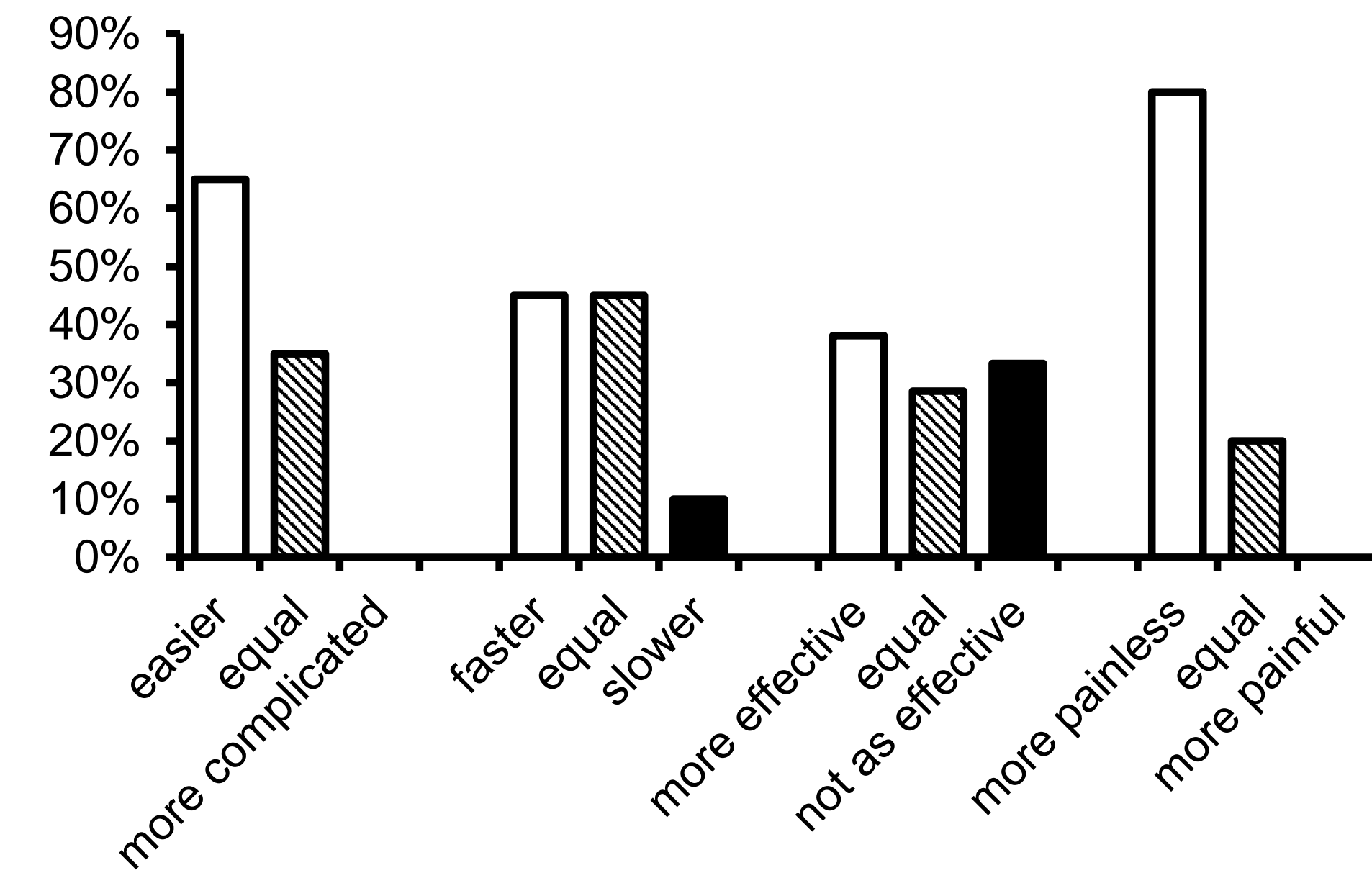
An international user test in 23 centers in Germany (17) and UK (6) was performed by nurses, wound experts, surgeons, dermatologists and phlebologists. The aim was to evaluate suitability of Debrisoft Lolly in different indications, wound locations, depths, user/patient satisfaction, ergonomic handling, usability and tolerability/safety. The product was used in 1-23 patients per center and the documentation was done on a pre-determined evaluation tool summarizing the experiences. Furthermore it was retrospectively compared with the standard method of the center.



GRAPH 3: How do you assess the application of Debrisoft Lolly when used in difficult locations?

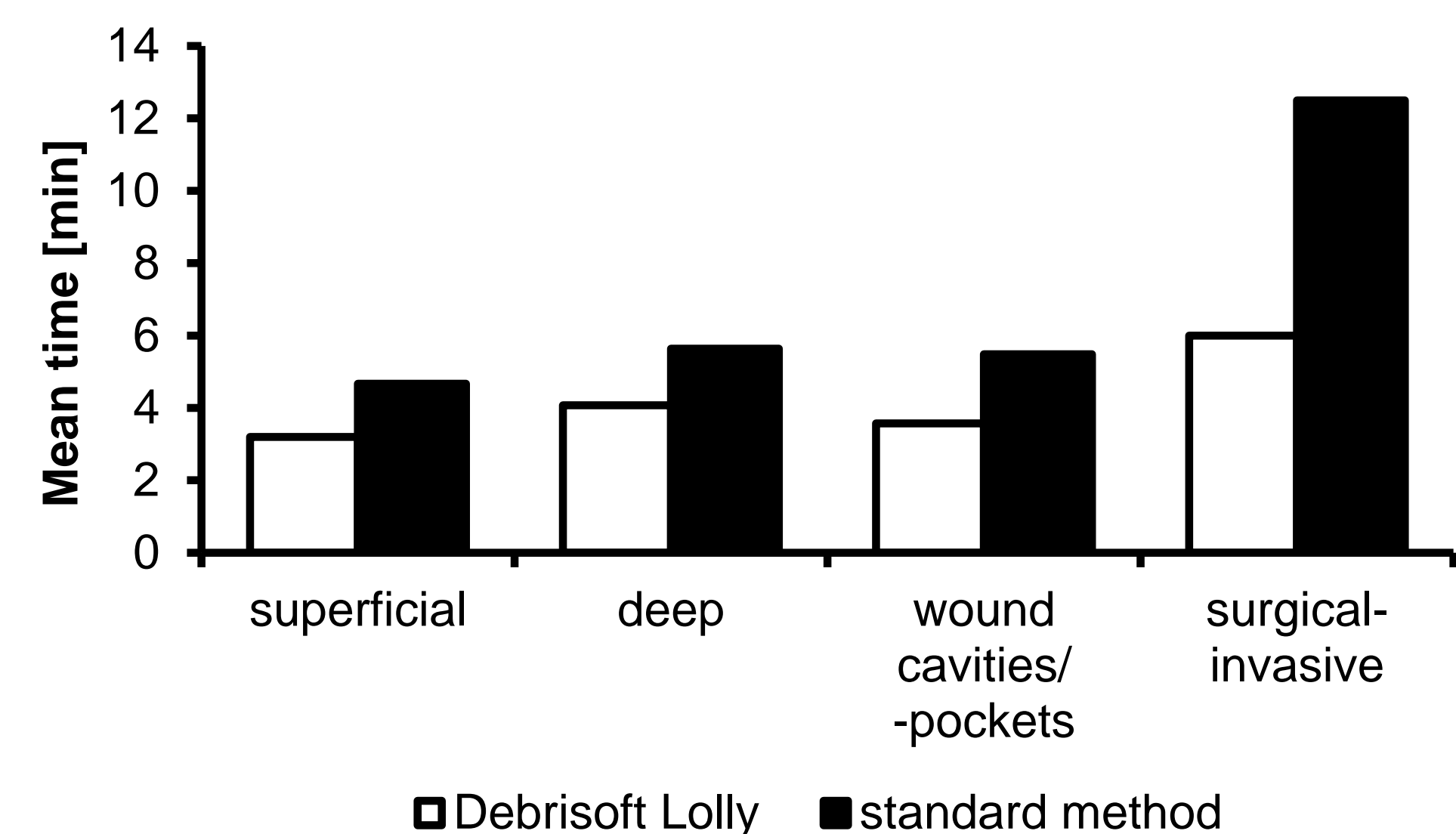
30% of the users rated the application of Debrisoft Lolly at difficult locations as "very good", 39% as "good", 13% as "satisfactory", 9% as "sufficient", 0% as "deficient" and 4% as "insufficient".

The mean value was 1.96. This correlates to the rating "good".



GRAPH 1: Comparison to the standard therapy

65% rated the wound cleansing as "easier" and 35% as "equal" in comparison to the standard therapy that is used normally by the individual user. 45% rated the wound cleansing as "faster", 45% as "equal" and 10% as "slower" in comparison to the standard therapy. 38% rated the wound cleansing with the Debrisoft Lolly as "more effective", 29% as "equal" and 33% as "not as effective" in comparison to the standard therapy. 80% rated the pain during wound cleansing as "more painless" and 20% as "equal" in comparison to the standard therapy.



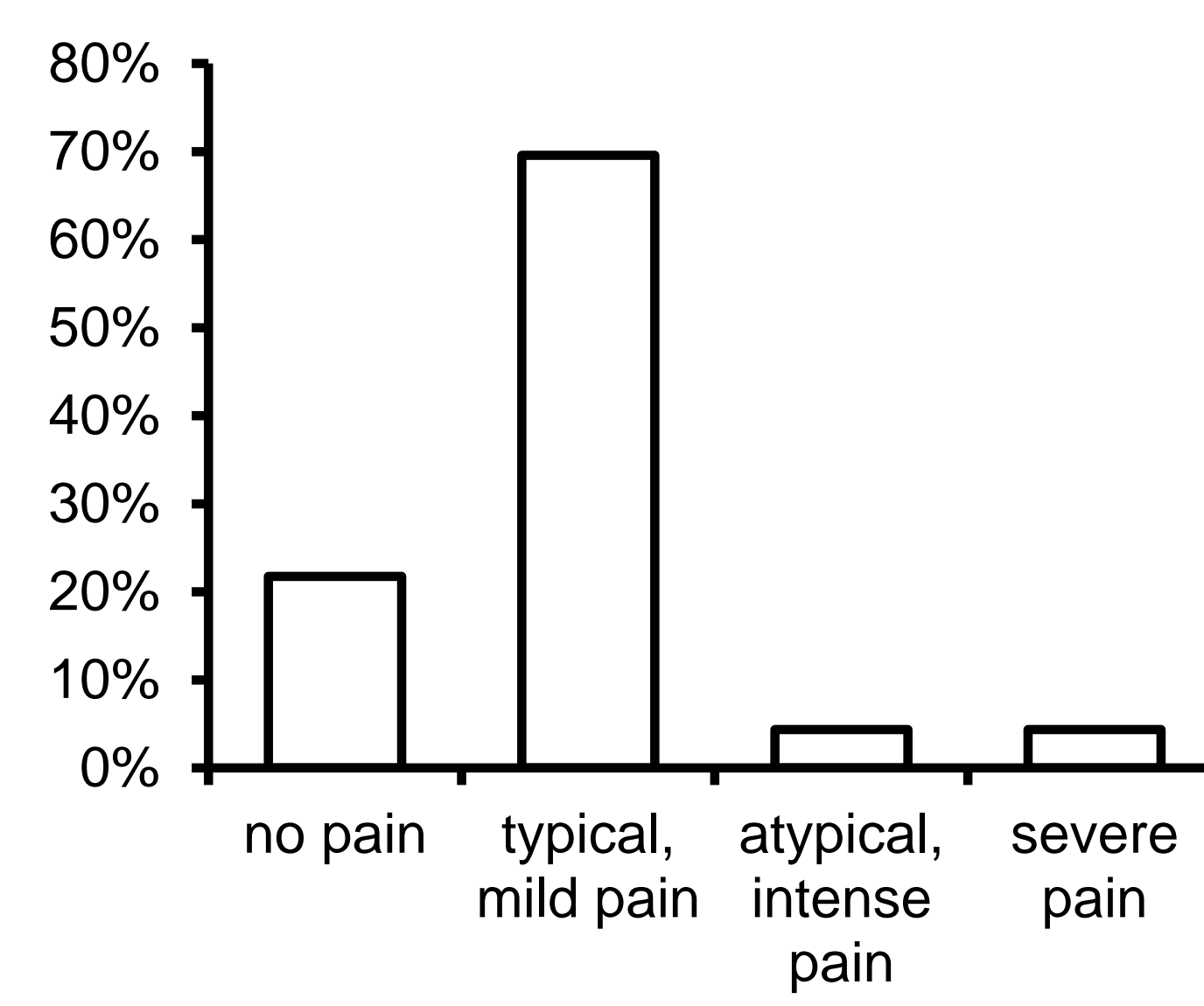
GRAPH 2: Required time in regard to the wound depth.

Comparison between the time needed for a wound cleansing with the Debrisoft Lolly [open bars] and the standard method [closed bars].

For superficial wounds the mean time for the Debrisoft Lolly was 3 min and for the standard method 5 min. For deep wounds the mean time was 4 min and 6 min. For wound cavities/-pockets the mean time was 4 min and 5 min and for surgical-invasive wounds the mean time was 6 and 13 min.

GRAPH 4: How do you assess the pain experienced by the patient during debridement with Debrisoft Lolly?

22% of the users assessed the pain of the patients as "no pain" at all. 70% assessed "typical, mild pain", 4% assessed "atypical, intense pain" and 4% assessed "severe pain".



92% of all users assessed only mild pain or even no pain at all for the patients.

RESULTS:

Debrisoft Lolly was used in 170 patients with wounds of different aetiologies (81 leg ulcer, 32 pressure ulcer, 28 diabetic foot ulcer, 8 surgical invasive, 21 other) by 23 users. The "other" category included post-operative wound healing (10), degloving injury with fibrin layer (1), tumour wound (1), abscess wound (2), chilblains (1), extravasation injury (1), haematoma (1), infected skin tear (2), lip lymph oedema (1) and pyoderma gangrenosum (1); 31 of these wounds were cavity wounds. In comparison to standard methods (surgical, mechanical, autolytic, larvae, enzymatic) the product was found to be easier, more painless and effective [Graph 1].

The required time of debridement was rated better than good (mean value: 1.95). The mean procedure time (0.5 - 10 min) using Debrisoft Lolly was always less than with the standard method used by the user. The highest saving of time was reported for surgical invasive wounds (difference of 7 min). Superficial wounds were nearly the same (2 min difference) [Graph 2]. The size of the tip was perceived as good or better by 68% and the length of the handle as good or better by 91% of the users. 56% of the users commented on some limitations related to the size of the device - especially for very small wounds. The usability was considered to be very good or good by 87% of the users (mean 1.74). The absorption capacity of the device was rated as very good to good by 74% of the users. The wound debridement with Debrisoft Lolly was perceived as more comfortable for the patient than with other methods and good or better by more than 95% of the users. Debrisoft Lolly was assessed as very compatible for the wound and the wound surrounding skin. 21 users rated the pain for their patients as painless or typical mild [Graph 4]. No adverse events or side effects were reported by the users. 96% of the users said that they would use the device again because it was easy to handle, saved time and provided very good debridement results.

DISCUSSION:

Debrisoft Lolly can be used in a variety of wound aetiologies especially at difficult body localisations [Graph 3] or skin conditions with need for debridement. It showed good results in wound cavities and also the surgically-invasive indication could be successfully proven. In comparison to common used methods - assessed retrospectively - Debrisoft Lolly was more painless, effective and easier which can be explained by proven efficiency of the monofilament fibres and the special form of the device.

The duration of debridement was lower for all indications, the highest saving of time was reported for surgical invasive approach (difference of 7 min). Superficial wounds were nearly the same (2 min difference) which indicates the usability especially for difficult to reach wounds. In contrast to the current standard therapy Debrisoft Lolly seems a very effective, safe, not as painful, ergonomic alternative for debridement.

CONCLUSION:

Debrisoft Lolly met the needs of the users for short term effective debridement, almost painless and therefore an improvement of Quality of Life, very skin and wound compatible, safe, very good ergonomic properties for debridement. Users were satisfied with the debridement results, reported similar or less painful for the patients when compared to other methods and found the device particularly appropriate for wounds with cavities. A few users proposed a second device with smaller dimensions.

Overall, the Debrisoft Lolly is an additional option in the debridement of a wide range of chronic wounds of different etiologies, including invasive-surgical wounds. The concept of the Debrisoft Lolly is ergonomic, useful, and highly evaluated by the users.