

# Case studies using

Mepilex<sup>®</sup> Lite

This compendium contains:

Four cases from an ongoing clinical investigation on the management of diabetic foot ulcers, utilising a new soft silicone dressing: Mepilex<sup>®</sup> Lite.

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## **Clinical investigation**

The four cases presented in this compendium are from an ongoing open non-randomised case study with Mepilex® Lite. The aim is to evaluate the comfort, conformability and overall experience of Mepilex® Lite when used on patients with a diabetic foot ulcer.

Only patients with a foot ulcer, graded as I or II according to Wagner's classification\* with little or no exudate and no clinical signs of infection participated in the investigation. ing non-infected wounds participates in the investigation.

The investigation is a two-centre investigation with one centre in Sweden and one in Germany. The investigation will include a total of 20 patients and is planned to be finalised during year 2004. All four cases presented here are from the centre in Sweden.

## **Conclusions**

After treatment with Mepilex® Lite the following observations were made:

- The dressing proved to provide good or very good comfort and conformability.
- Patients experienced little or no pain during dressing removal.
- Mepilex® Lite caused no trauma to wound bed or surrounding skin upon dressing removal.
- Because the dressing was thin it was suitable to use under off-loading devices such as castings and orthopaedic shoes.
- Mepilex® Lite made the dressing changes easier and several of the patients could manage the dressing changes themselves.

## **\*Wagner's Classification**

- Grade 0: Pre-ulcerative lesion, healed ulcers and/or presence of bony deformity.
- Grade I: Superficial ulceration without involvement of the subcutaneous tissue.
- Grade II: Penetration through the subcutaneous tissue (could include exposure of bone, tendon, ligament or joint capsule).
- Grade III: Osteitis, osteomyelitis or abscess
- Grade IV: Gangrene of the forefoot.
- Grade V: Gangrene of entire foot.

## Patient #1

A 66 year old man with an 8 year history of diabetes type II, was treated for a malleolus foot ulcer rated as Wagner I. The ulcer had previously been treated with Aquacel and Solvaline.

Treatment with Mepilex® Lite commenced on October 21<sup>st</sup>. Over the following three weeks the dressing was changed twice per week. The patient finished the investigation on November 11<sup>th</sup> at which point the foot ulcer had healed.

### Evaluation

The patient rated the dressing's functionality as 'good'. In particular he appreciated the fact that it was thin, comfortable and unobtrusive to wear.

The nurse rated the dressing's conformability as 'very good'. One of the benefits she saw with the dressing was the fact that it made it easy for the patient to do the dressing changes himself.

### Comments

During the study period Mepitac™ soft silicone tape was used as additional fixation.

No type of off-loading technique was used on this patient.



Baseline photo of ulcer on October 21<sup>st</sup> 2003.



Demonstrating how Mepilex® Lite and Mepitac™ could be used to protect the ulcer.



November 11<sup>th</sup> 2003, the ulcer is almost healed.

## Patient #2

A 35 year old man with a 19 year history of diabetes type I, was treated for a foot ulcer rated as Wagner I, between digitalis IV and V. The ulcer was the result of a debridement performed on August 29<sup>th</sup>, 2003. The ulcer had previously been treated with Aquacel and Solvaline.

Treatment with Mepilex® Lite commenced on October 22<sup>nd</sup>. Over the following three weeks the dressing was changed twice a week. When the patient finished the investigation On November 12<sup>th</sup> the ulcer had almost healed.

### Evaluation

The patient rated the dressings functionality as good. He had previously received treatment for foot ulcer with another product. In comparing Mepilex® Lite to the product previously used, the patient found Mepilex® Lite to be very soft, thin and comfortable.

The nurse rated the dressing's conformability as very good. One of the benefits she saw with the dressing was its ability to fit in between the toes without increasing the pressure on the ulcer. She also appreciated that the dressing easily adhered to the skin.

### Comments

During the study period Mepitac™ soft silicone tape or a gauze wrap was used as additional fixation.

The patient used the smallest sized Mepilex® Lite and cut it to fit the ulcer.

The patient used orthopaedic shoes (therapeutic) to off-load pressure from the ulcer.



Baseline photo of foot ulcer on October 22<sup>nd</sup> 2003.



Mepilex® Lite demonstrating good conformability.



November 12<sup>th</sup> 2003, the foot ulcer is almost healed.

## Patient #3

A 64 year old man with a 22 year history of diabetes type II, was treated for a foot ulcer rated as Wagner I, on the plantar surface. Treatment with Mepilex® Lite commenced on November 4<sup>th</sup>. The patient used a total contact cast over the dressing to off-load pressure from the ulcer. During the investigation the dressing was changed approximately once a week. When the patient finished the investigation on January 13<sup>th</sup> the ulcer had healed.

### Evaluation

The patient rated the dressings functionality as good. What he liked most with the dressing was the fact that he did not feel it under the cast. He also pointed out that this was the first time in almost 9 years that the foot ulcer was completely healed.

The nurse rated the dressings conformability as very good. One of the benefits she saw with Mepilex® Lite was that because it's thin it reduces the risk of the dressing causing pressure on the ulcer when used under the cast.

### Comments

During the study period, Mepitac™ soft silicone tape was used to fixate the dressing.

The patient used Mepilex® Lite 5x7cm, cut to fit the ulcer.

The patient used a total contact cast to off-load pressure from the ulcer.



Baseline photo of foot ulcer on October 22<sup>nd</sup> 2003.



Total contact cast made on December 11<sup>th</sup> 2003.



December 19<sup>th</sup> 2003, showing Mepilex® Lite and Mepitac™ after one week under the casting.



January 13<sup>th</sup> 2004, the foot ulcer is healed.

## Patient #4

A 78 year old woman with a 23 year history of diabetes type II, was treated for a foot ulcer rated as Wagner I, on digitalis II. The ulcer was the result of osteitis and a debridement performed on January 18<sup>th</sup>, 2002. The ulcer had previously been treated with Aquacel and Solvaline.

Treatment with Mepilex® Lite commenced on November 4<sup>th</sup>. Over the following six weeks the dressing was changed once a week. When the patient finished the investigation on December 16<sup>th</sup> the ulcer had healed.

### Evaluation

The patient rated the dressings functionality as very good. She had previously been treated for a foot ulcer with another product. In comparing Mepilex® Lite to the product previously used, she thought Mepilex® Lite made it easier for her to do the dressing changes herself. She liked Mepilex® Lite because it was thin, comfortable and had the ability to stay in place.

The nurse rated the dressings conformability as very good. She found it easy to shape the dressing around the toe. Both the nurse and the orthopaedic technician appreciated the fact that the dressing was thin and easy to use with the orthopaedic shoe.

The thin dressing made it easier for the technician to position the off-loading device.

### Comments

Mepitac™ soft silicone tape was used on a couple of occasions during the investigation period to fixate the dressing.

The patient used the smallest sized Mepilex® Lite and cut it to fit the ulcer.

The patient used orthopaedic shoes (therapeutic) to off-load pressure from the ulcer.



Baseline photo of ulcer, November 4<sup>th</sup> 2003.



Mepilex® Lite demonstrating good conformability.



December 16<sup>th</sup> 2003, the ulcer is healed.



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