

A comparison between the standard care of wounds with a soft silicone wound dressing * and the care with an elastic silicone-wound dressing **.

* Mepitel Mepitel[®] or One[®]

** Spycra Contact

Results of a cohort study:

Luc Gryson;

- Director Wound-Ex, the woundcare expert centre of the Vrije Universiteit Brussels (VUB). Luc Gryson is one of the leading authorities for woundcare in Belgium and a frequent speaker at international conferences and seminars
- CEO WZC 't Hoge – Alveringem
- Chairman EWMA

Design:

A comparative cohort study was set up in two nursing homes and one hospital in the period April 2013-April 2014. In this study, a standard care procedure using a soft silicone wound contact layer was compared with the use of a new elastic silicone wound contact layer. The following statement was examined: either there is no noticeable difference in use and appreciation of the wound contact layers Mepitel[®] and Mepitel One[®] (standard treatment) and Spycra Contact[®], either there is a difference between the standard treatment and Spycra Contact[®].

The study results were processed by institution and globally.

The institutions involved in the study were: WZC Meunickenhof, WZC 'Hoge and the Sint Franciscus Hospital in Heusden-Zolder.

Method:

In each institution, residents were selected when having wounds in the specified period. This study included 28 men and 61 women with an age between 80 and 89 years.

An brief overview of treated skin lesions:

- 1: skin tear class 2b
- 2: skin tear class 3
- 3: pressure ulcer
- 4: venous ulcer
- 5: arterial ulcer
- 6: mixed venous – arterial.
- 7: trauma
- 8: other

The wounds included in the study were primarily lacerations (Skin Tears) class 2b (more than 25% tissue loss) and lacerations class 3 (full tissue loss), pressure ulcers and small trauma wounds. A wound which required professional care appeared for the first time among 52% of the included residents/patients. The average treatment duration was 11.7 days with a minimum of 1 day and a maximum of 127 days.

The wounds were cleaned with either a physiological saline solution or with a wound cleanser (Sanoskin Cleanser[®]). In 29% of the cases, an additional Polyvidone Iodine aqueous solution or a Chlorhexidine aqueous solution was used to desinfect.

After cleaning the wound, the wounds were covered with Mepitel[®] (44.9%) or Mepitel One[®] (4.5%) -Molnlycke[®]- during the first testing period and with Spycra Contact[®] (50.6%) –Reskin Medical NV during the second testing period. The tested wound contact layers were used as a typical wound contact layer, sometimes in combination with an hydrogel, an algina enzyme gel or an honey gel (Melladerm Plus[®]). In all of the cases, the wound contact layer was covered with a secondary dressing (PU foam bandages, compresses,) as described in the IFU.

During the testing period, the estimated care time was recorded as well as the degree of itching and the evolution of the surrounding skin and woundbed. The duration of a wound care ranged between 3 and 15 minutes (median: 8 minutes). 80% of the residents/patients had no itching during the healing process. 46% of them had an initial intact skin and 34% had a ' parchment ' (very thin) skin. 28% of the residents had a visible skin redness before treatment.

Evaluation of the three wound contact layers used; Mepitel[®],

Mepitel[®] One[®] and Spycra Contact:

Various elements were independently measured: pain after application, comfort & easyness of applying the wound contact layer and influence of the wound contact layer on the mobility of the resident/patient.

Conclusion:

- All wound contact layers were equally good in regard to pain and pain relief. In general, there was almost no pain as such; only Mepitel One[®] tends to give more pain than the other wound contact layers.

- The three wound contact layers have no negative impact on the mobility nor on the comfort of the resident/patient.

Nurses experiences in regard to easyness of use:

The easyness of use was examined by evaluating different topics such as easyness of opening the packaging, the easyness of removing the liner – paper to facilitate the application-, easyness to apply the dressing, to cut the dressing and to reposition the dressing if needed. A 5 points scale was used whereas 5 was excellent and 1 very poor. The median score was 4 for the 3 wound contact layers.

The nursing evaluated the ease of use in general on a 10 points scale for the three wound contact layers equally ; median score 8. The nurses also stated that all three wound contact layers stayed equally well in place after applying. (median of 8 out of a 10 points scale); however a little preference was noticed for the Spycra Contact[®].

The study also evaluated the adherence strenght of the three wound contact layers onto the surrounding skin and the adhesiveness in the wound – adhesion to the wound bed-. The median score was 8 for three 3 wound contact layers.

The evaluation of the removal of the wound contact layer is a valuable tool as a method to determine whether any additional damage was caused to the wound. In 54% of cases, the skin was completely intact after removal (median 10 for all wound contact layers). Adhesive residu in the wound was observed in 7.7% after removing Mepitel[®] and in 4.4% after removing Spycra Contact

The study also evaluated the average wear time of both Mepitel, Mepitel One and Spycra Contact. The average weartime of Mepitel /Mepitel one was 3,42 days as for Spycra Contact 4,82 days. The maximum weartime observed during the clinical trial for Spycra Contact was 12 days. A little preference was noticed for the Spycra Contact[®] in regard to wear time.

Conclusion:

If we look at the Levene's test to verify if the variances are equal or not, we have to conclude that there are no significant differences. Also, the results of the T-test give no significant difference between the standard treatment and the treatment with Spycra Contact[®].

After statistical analysis of the results of the clinical trial comparing a standard treatment –using Mepitel/Mepitel One – and Spycra Contact on 89 residents/patients coming from three different health care settings, we have to conclude that no noticeable difference was observed in regard to easyness of use, wear time and general appreciation.