A multicentre clinical evaluation of Cuticell Contact silicone wound contact layer in daily practice

Abstract

Objective To evaluate clinically the performance of Cuticell Contact, a silicone-based primary contact wound dressing. **Background** Primary contact dressings that allow removal of exudate while protecting the wound bed during dressing changes are a key tool in wound management. Silicone dressings are of particular interest owing to their excellent conformability, pain-free dressing changes, and low toxicity. Cuticell Contact is a silicone-based wound dressing thought to provide these desirable benefits. **Method** In this evaluation, 38 patients with 40 wounds of a variety of aetiologies and anatomical locations managed with Cuticell Contact and secondary dressings were observed in 8 centres across Germany and the Netherlands. The observation period ranged from 2–42 days (mean 21 days, median 18 days). At the end of the observation, Cuticell Contact was evaluated for permeability to exudate, nonadherence to the wound bed, pain at dressing change, and overall performance. The condition of the wound bed, wound surface area, and levels of exudate were recorded at baseline, at each dressing change, and at the end of the evaluation, along with the condition of the wound edge and peri-wound skin. **Results** Wounds managed with Cuticell Contact showed improvement in the wound bed as evidenced by an increase in wounds with complete granulation from 12.5% (*n*=40) to 26.5% (*n*=34), and wounds with partial or complete epithelialisation from 35% to 82.4%. Cuticell Contact was assessed at the end of the evaluation as nonadherent to the wound in 91.2% of cases (*n*=34), and 93.3% of dressing changes (*n*=104) were deemed pain free. Wound surface area decreased by a mean of 19.9%. Cuticell Contact was rated satisfactory for permeability to wound exudate in 82.4% of responses and overall satisfaction with the dressing performance was also 82.4%. **Conclusion** Cuticell Contact is a soft silicone dressing that is easy to use, efficacious in supporting wound healing through protecting the wound bed, and facilitates atraumatic dressing changes.

Key words: Silicones Dressing Exudates Granulation tissue Pain measurement

The primary function of low-adherence wound contact layer dressings is to protect the wound bed from the risk of mechanical trauma, and thus reduce or eliminate pain at dressing change (White, 2005). Traditional wound contact layer dressings, such as paraffin-impregnated gauze dressings, that do not let exudate pass easily and may stick to the wound bed are being replaced by modern dressings. The modern dressings seek to combine protection with maintenance of an optimally moist environment in the wound bed, reducing the risks of maceration and hypergranulation. In addition to being low-adherent, these modern wound contact layers need to remain stable on the wound, that is, not slip off or cause the slippage of any secondary dressings, while allowing the easy passage of any exudate through to the secondary dressing, in order to avoid leakage and maceration of the peri-wound skin. Non-adherent wound contact layers permeable to exudate are proposed by the World Union of Wound Healing Societies (WUWHS) (2007) as one of the dressing types to be considered in combination

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with absorbent secondary dressings to reduce leakage and the consequent high frequency of dressing changes.

Cuticell Contact is a primary wound contact layer, consisting of an elastic, transparent, perforated polyurethane film coated with soft silicone. The thinness of the polyurethane film used allows it to be easily stretched two-ways and the weight of the silicone gel allows the product to conform to small irregularities resulting in it being highly conformable (BSN Medical, 2013). Its transparency allows easy inspection of the wound bed and the perforations allow exudate to pass through. Its design results in it adhering to the surrounding skin but not to the moist wound bed, thus greatly reducing the risk of painful dressing changes. The present product evaluation was undertaken to observe these performance characteristics of Cuticell Contact combined with various secondary dressings in the context of the day-to-day management of a variety of wounds of differing aetiologies and anatomical locations.

As this was an observational clinical evaluation of a medical device already in use, Ethics Committee approval was not required. Local institutional approval for the evaluation was granted, and informed consent was obtained from the patients.

Method

Patients with wounds of a variety of aetiologies and anatomical locations were observed at eight different centres across Germany and the Netherlands. Patients were included in the evaluation if their wound was indicated for treatment with Cuticell Contact according to the dressing's instructions for use. One dressing size (7.5 cm x 10 cm/3 inch x 4 inch) was available for evaluation; where wound areas to be covered were larger than the dressing, multiple dressings were used. All patients had their wounds assessed at baseline, at dressing change, and at final assessment. The clinician was free to decide on the length of time between dressing changes so that the performance of the dressing could be observed under normal clinical practice. Assessment included the evaluation of key parameters such as pain at dressing change, incidence of adherence of Cuticell Contact to the wound bed and/or the secondary dressing, degrees of granulation and epithelialisation, signs of infection, levels of exudate, and condition of the wound edges and peri-wound skin. Wound surface areas were calculated from the longest length and breadth measured by the investigator using a ruler. Photographs were taken at each dressing change. All wounds were then dressed with a Cuticell Contact dressing followed by an appropriate secondary dressing, most commonly gauze pads with a fixation bandage (*Table 1*). The final assessment was undertaken following the treatment period where the final wound condition, frequency of dressing changes, and an overall assessment of Cuticell Contact's performance parameters were assessed together with ratings for overall clinician satisfaction.

Table 1. Secondary dressing used at first application of Cuticell Contact (*n*=40)

Gauze pads	29
Sticking plaster	3
Superabsorbent	3
PU-Foam	5

Data analysis

Statistical analysis was performed using standard computer software (GraphPad Prism 6). Data were compared using t-tests. Where assessments of an individual data point were missing from the data collection forms, the patient was excluded from the analysis of that particular data point and percentages were calculated on the basis of the number of patients for whom data were available. Post-hoc analyses were performed to assess the relationship between exudate level and peri-wound skin condition at both baseline and end assessment, with particular focus on wounds that were highly exuding at baseline. However, missing data resulted in small sub-group sizes that made it unfeasible to draw conclusions.

Results

In all, 38 patients were recruited (28 males, 10 females) with an age distribution of 9–92 years (mean age: 62 years) and a total of 40 wounds. Patient demographic data is shown in *Table 2*. There were a variety of wound aetiologies among the patients

Table 2. Patient demographic data (*n*=38) and wound data (*n*=40)

Sex	Male	28 (73.7%)
	Female	10 (26.3%)
Age (Years)		62.2 ± 18.3 (Range 9–92)
Aetiology	Diabetic foot wound	11 (27.5%)
	Trauma	9 (22.5%)
	Leg ulcer	8 (20.0%)
	Postoperative	7 (17.5%)
	Other	5 (12.5%)
Compression Used	Yes	6 (15.0%)
	No	34 (85.0%)
Anatomical Location	Head	2 (5.0%)
	Arms/hands	4 (10.0%)
	Legs/feet	29 (72.5%)
	Truncus	5 (12.5%)
Wound duration (days)		94.3 ± 147.8 (Range 1–640)
Wound size (cm²)		15.4 ± 19.4 (Range 0.3–96)

Results are presented as number (%) or mean ± SD (Range)

Table 3. Intervals between dressing changes in days

Dressing changes	First	Second	Third	Fourth	Fifth
Wounds assessed per change	*n*=39	*n*=32	*n*=21	*n*=12	*n*=6
Intervals					
Mean	3.56	3.56	5.52	4.75	2
Median	6	12	15	2	1.5
***Mean excl. outlier values**		3	3.2		

*Exclusion of one reported interval at second dressing change of 21 days and of 2 reported intervals at third dressing change of 25 and 28 days. Dressing changes were carried out but not reported during these intervals.

including 11 diabetic foot ulcers (27.5%), 9 traumatic wounds (22.5%), 8 leg ulcers (20.0%), 7 postoperative wounds (17.5%), and 5 others (12.5%) of miscellaneous aetiology. Six leg ulcer patients wore compression bandages. Two of the patients with diabetic foot ulcers were recorded as being neuropathic in the lower limb. The majority of wounds were located on the legs/feet (*n*=29, 72.5%). The remainder of the wounds were on the trunk (*n*=5, 12.5%), arms/hands (*n*=4, 10%), and head (*n*=2, 5%). Wounds ranged in size from 0.3–96.0 cm^2, with a mean area of 15.4 cm^2 (*n*=34, baseline assessments were not recorded in 6 patients). Nonadherent wound contact layers were recorded as having been used previously in 30.3% of wounds (*n*=33).

At the start of the study, 85% (*n*=40) of the wounds received additional treatment or cleansing. From these, 40% of all wounds were treated with the antiseptic solution Octenisept (Schülke); 22.5% with the ionized seasalt solution ActiMaris (ActiMaris AG); and 15% with either Prontosan (B. Braun), Lavasept (B. Braun), or Ringer's solution. In addition, 10% of the wounds had been debrided, and 4 patients were receiving analgesics at the start of the evaluation.

The overall observation period as defined by the start of management with Cuticell Contact up to the date of the last dressing change ranged from 2–42 days (mean: 21 days, median: 18 days). The number of wounds assessed at each dressing change and the intervals between each dressing change are given in *Table 3*. In three cases, not every dressing change was recorded. In two cases, the investigator stated the dressing remained in place for a week at a time. In the third case, the patient removed the dressing themselves and missed clinic appointments, eventually presenting with an infected wound that led to the patient's withdrawal from the study.

At the end of the assessment on the overall use of Cuticell Contact, the investigators reported that 55.9% of the wounds had Cuticell Contact changed every 2–3 days and 58.8% had the secondary dressing changed every 2–3 days (*Table 3.1*).

Final assessments of the wound condition and use of Cuticell Contact were carried out on 34 wounds (85%). One patient's wound increased in size in the first week of the evaluation; hence, the patient was withdrawn. Another patient was referred to surgery and one patient was withdrawn because of infection and noncompliance with the treatment. In the remaining three cases, final assessments were not completed or were completed with insufficient data for analysis.

Table 3.1. Frequency of dressing change reported at final assessment

Frequency	Every day	2–3 days	>3 days	≥7 days	≥14 days
Cuticell Contact *n*=34	11.8%	55.9%	20.6%	11.7%	0%
Secondary dressing *n*=34	14.7%	58.8%	17.6%	8.9%	0%

Table 4. Reasons reported for individual changes of primary dressing (*n*=68)

Reason	*n*	%
Observation of wound not possible*	23	33.8%
Checking and cleaning the wound	11	16.2%
Routine	7	10.3%
Infection suspected (including 2 reports of pain)	7	10.3%
Confirmed infection	6	8.8%
Primary dressing moved	6	8.8%
Daily change or change due to volume of exudate	5	7.4%
Other	3	4.4%

Note: Scores are reported for the primary reason given for the dressing change. In two cases of dressing change, owing to suspected infection, the primary dressing was reported as having moved. Including these two cases would give an incidence of 11.8% for movement of Cuticell Contact as a reason for dressing change.
*'Observation of wound not possible' in practice meant that inspection of the wound bed was impaired to varying degrees. No graduated scale was used for assessing the ease of inspection of the wound bed.

Product assessment

Cuticell Contact was shown to have minimal wound bed adherence, being classified as 'nonadherent, to wounds in 91.2% of the investigators' final assessments of treatment (*n*=34). Reasons for all dressing changes are shown in *Table 4*, the most

common reason being the wish to observe the wound bed directly and/or cleanse it (50%, *n*=68).

'No Pain at dressing change' was recorded in 93.3% of the patient visits reported (97/104), with only two reports of tolerable pain and none of severe. The zero pain scores of the two neuropathic patients are excluded from the 'No Pain' scores above. The end of study assessment of pain was that 85.3% (29/33) of the patients had suffered no pain at dressing change, with only 6% reporting tolerable pain and the 2 neuropathic patients being excluded from the 'No Pain' score. There were no reports of severe pain. The four patients receiving analgesics at the start of the study were included in the 'No Pain' scores.

The passage of fluid through the dressing to the secondary dressing was rated as 'sufficient' in 82.4% (*n*=34) of cases. At the final assessment, 97% of responses rated Cuticell Contact as easy to use. In terms of overall performance, the dressing was rated as 'very good' or 'good' in 82.4% of cases, with the dressing rated as 'satisfactory' in the remaining 17.6%. Cuticell Contact was considered to have met practitioners' expectations in 85.3% of cases. In 84.3% (*n*=32), it did not stick to the secondary dressing used. Cuticell Contact was considered to be stable and without residue in 91.2% of end of study assessments (*n*=34).

There were two adverse events, both of which were not device related. These were two cases of wound deterioration: one idiopathic and one as a result of the patient performing excessive physical activity.

Wound bed and peri-wound condition

The overall wound bed condition improved at final assessment compared to baseline. The proportion of wounds with complete granulation increased from 12.8% (*n*=39) to 26.5% (*n*=34), partial epithelialisation increased from 38.9% (*n*=36) to 70.6% (*n*=34), and complete epithelialisation from zero to 11.8%. There were two incidents of hypergranulation attributed to the wound bed being too moist because of high levels of exudate and selection of an inappropriate secondary dressing.

Mean wound surface area decreased by 4.4 cm^2 (19.9%) (median: 1.9 cm^2, 33%). Signs of infection decreased at final assessment vs baseline from 35.3% (*n*=34) to 15.6% (*n*=32). Results for baseline and final assessment of granulation, epithelialisation, and exudation are shown in *Figures 1*, *2*, and *3*.

The condition of the wound edges improved between baseline and final assessment, with increased numbers of 'intact' (healthy) wound edges and a marked decrease in 'reddened', 'macerated', 'oedematous', and 'undermined' wound edges (*Figure 4*); however, there was a slight increase in the incidence of rolled wound edges (from 5 to 6).

The incidence of 'intact' peri-wound skin increased and that of 'reddened', 'macerated', 'oedematous', and 'dry/scaly' decreased at final assessment compared to baseline (*Figure 5*).

Limitations to the evaluation

The present evaluation was designed to observe the performance of Cuticell Contact without burdening the investigators with too extensive a collection of data. Visual analogue scales (VAS) were not used to measure the degree of pain experienced, and scales for assessing degrees of wound bed condition more precisely than 'complete' and 'partial' were not developed. Levels of satisfaction with aspects of dressing performance and the passage of exudate through the dressing had binary answers, and so degrees of performance could not be recorded. In three cases, not every dressing change was recorded. Types of secondary dressing and wound cleansing agents and antiseptics used were recorded only at the first application of Cuticell Contact, so it was not possible to track at every dressing change the correlation of volume of

Figure 1. Proportion of wounds graded 'none', 'partial', or 'complete' for levels of granulation at baseline and final assessment

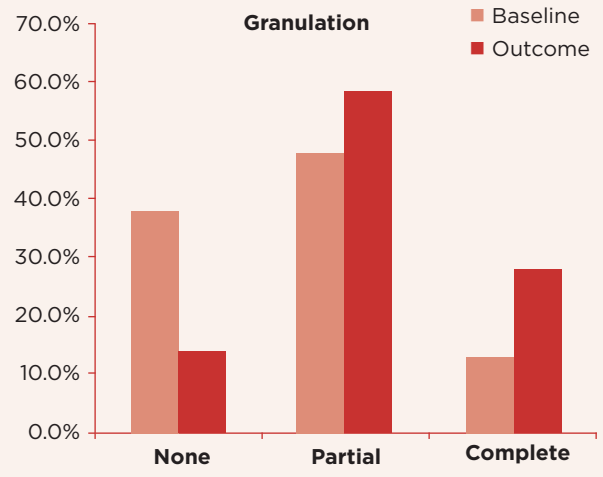


Figure 2. Proportion of wounds graded 'none', 'partial', or 'complete' for levels of epithelialisation at baseline and outcome

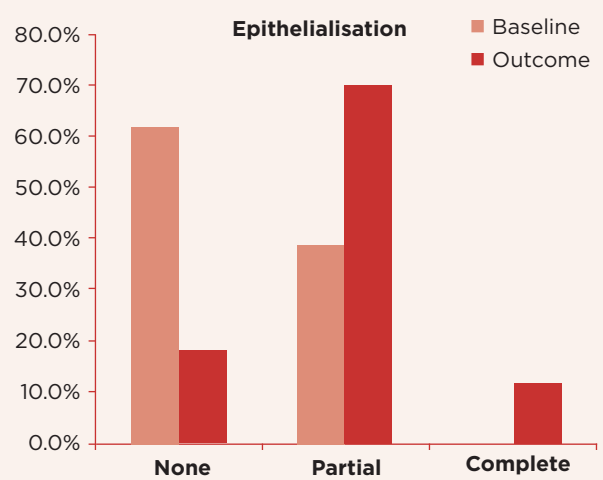


Figure 3. Proportion of wounds graded 'none', 'light', 'moderate', and 'heavy' for levels of exudation at baseline and final assessment

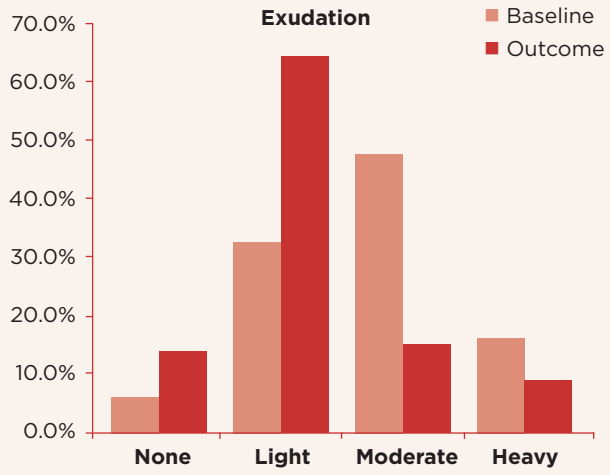


Figure 4. Number of wound edges that were 'intact', 'reddened', 'macerated', 'oedematous', 'dry/scaly', 'rolled', or 'undermined' at baseline and final assessment

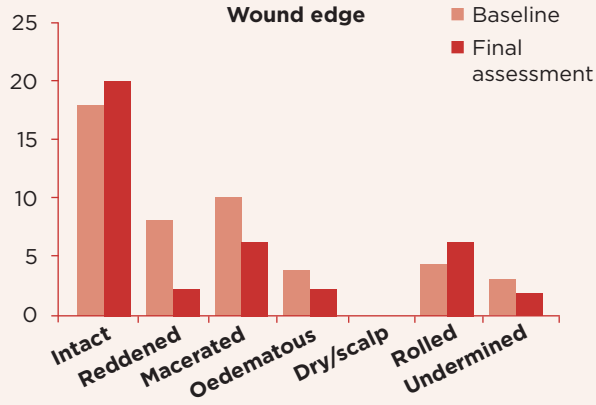
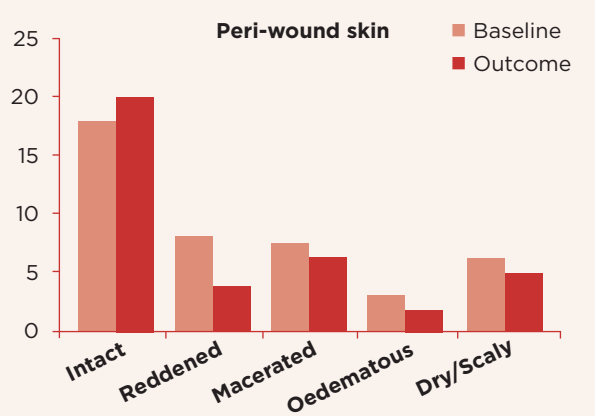


Figure 5, Number of wound edges that were 'intact', 'reddened', 'macerated', 'oedematous', 'dry/scaly' at baseline and final assessment



exudate, use of antiseptics, and wound bed condition with the frequency of change of Cuticell Contact, and thus indirectly its permeability to exudate.

The authors acknowledge that the evaluation would have benefited from mapping and recording the extent of granulation and epithelialisation as percentages of the wound bed surface area and of establishing and validating scoring systems for critical performance indicators such as permeability to exudate. The use of these systems is being taken into account for further observational studies.

Discussion

Soft silicone dressings are becoming increasingly relied upon to provide a dual-action wound dressing that provides a barrier to protect the wound from trauma during dressing changes and allows the passage of exudate to be freely absorbed by an absorbent secondary dressing. This evaluation assessed one such soft silicone dressing—Cuticell Contact—in terms of its performance as a primary contact dressing.

'No Pain at dressing change' was reported at 93.3% of patient visits, a promising finding that agrees with other studies that report the removal of silicone dressings to be relatively painless compared with the removal of other standard dressings (Gates, 2000; Meuleneire, 2002). The absence of pain at dressing changes is evidence of Cuticell Contact's effectiveness as a nonadherent dressing and highlights the potential benefit of using the dressing for non-healing wounds to minimise patient discomfort when frequent changes of dressings may be necessary.

Cuticell Contact was rated highly for ease of use and was nonadherent both to the wound bed and the secondary dressing in the majority of cases. Dressing changes due to slippage were rare. The use of the dressing provided an effective balance between minimal adherence and thus minimal trauma to the wound bed, remaining in place comfortably over long periods of time and enabling the passage of exudate to maintain optimum conditions over the wound bed.

The condition of the wound bed as measured by the proportion of the wound surface area covered by granulation and epithelialisation improved during management with Cuticell Contact. This supports the results of other studies that have demonstrated that silicone dressings support wound healing (Cooper et al, 2010; Patton et al, 2013).

Only one size of Cuticell Contact was available to the clinicians during this evaluation; therefore, when areas of wound bed larger than the dressing were to be covered, two dressings were used side by side. It was observed that the

KEY POINTS

- The use of Cuticell Contact dressing offers the patient pain-free dressing changes
- Cuticell Contact contributes to the maintenance of optimum conditions in the wound bed for healing by allowing exudate to pass freely through to the secondary dressing if the Cuticell Contact dressing is not overlapped, while protecting new tissue from mechanical trauma
- Cuticell Contact is considered simple to apply, with low adherence to the wound bed
- If several dressings are needed, care must be taken to not overlap Cuticell Contact dressings, in order to prevent obstruction of the pores of the wound dressing
- Caution should be exercised when using nonadherent wound contact layer dressings in moderately exuding wounds that may become heavily exuding, as this group of dressings is not designed to allow the easy passage of high volumes of exudate

movement of exudate to the secondary dressing was impaired when two Cuticell Contact dressings were overlapped, the mesh of one dressing blocking the pores of the other, reducing permeability to exudate and increasing the risk of hypergranulation. The incidence of maceration may be an indirect indicator of dressings being overlapped, but in the absence of a specific recording of overlapping at dressing change it was not possible to infer a direct relationship between them. The importance of choosing the correct size of dressings and of avoiding overlapping should be emphasised in training on the use of wound contact layers, as should the careful assessment of likely volumes of exudate.

In the final overall assessment Cuticell Contact was considered to have performed well as a wound contact layer, with practitioners rating the dressing as 'good' or 'very good' in 82.4% of cases and 'satisfactory' in 17.6% (n=34). Previous studies have shown that silicone dressings are considered very easy to apply and superior to other products when used in difficult anatomical locations (such as around the digits of the hands or feet), owing to their excellent conformability (Terrill and Varughese, 2000; White, 2005). In this study, Cuticell Contact was used on areas of mobility such as toes, fingers, a thumb, and the inner hand as well as on foot and ankle wounds. Cuticell Contact was scored positively for permeability to wound exudate in 82.4% (n=34) of final assessments and stable and residue free in 97% (n=33). It did not adhere to the wound bed, further enhancing patient comfort during dressing wear and dressing changes.

Table 5. Cuticell Contact dressing sizes available in the UK

Size	Pack Qty	BSN Code	NHSSC Code	PIP Code
5 cm x 7.5 cm	1 x 5	7268000	ELA677	388-6447
7.5 cm x 10 cm	1 x 5	7268001	ELA678	388-6454
10 cm x 18 cm	1 x 5	7268002	ELA679	388-6462
15 cm x 25 cm	1 x 5	7268003	ELA680	388-6470

Conclusion

The use of Cuticell Contact as a primary wound contact layer allowed the clinicians to select the secondary dressings for optimum management of exudate and frequency of inspection of the wound while leaving the wound bed and thus the progress of healing undisturbed. Cuticell Contact represents a useful addition to the wound care practitioner's options for protecting the wound bed of diverse acute and chronic wounds and maximising patient comfort while maintaining optimum conditions in the wound for healing. The flexibility in the choice of secondary dressings in combination with the ability to leave Cuticell Contact in place for up to 14 days could facilitate cost savings in comparison to alternative dressings. Cuticell Contact is available in the UK in a number of sizes (*Table 5*). **CWC**

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Note: The information in Table 5 is correct at time of publication.

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