Evaluation of a Non-Adhering Silicone Primary Wound Contact Layer

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ABSTRACT

To minimise tissue damage on dressing removal and to achieve optimal wound healing it is essential to protect the wound from dressing adherence. Preventing dressing adherence also minimises patient pain and trauma at dressing change. There are a number of wound contact layers commercially available that are designed to provide low trauma dressing removal by providing a low adherent contact surface with the wound and by providing a barrier between the wound and a secondary absorbent dressing such as a foam or an alginate, which can have a tendency to stick to the wound depending on the construction of the dressing.

Several wound contact layers were evaluated for their ability to provide low adherent properties in an *in-vitro* fibrin clot test method. An *in-vitro* fibrin adherence method was also used to assess the ability of the wound contact layers to prevent fibrin binding to a secondary dressing.

The data showed that the wound contact layers demonstrated low adherent characteristics in the *in-vitro* fibrin clot method and that a new non-adhering silicone primary wound contact layer was able to reduce the adherence of an alginate dressing by 92% and a foam dressing by 84% in an *in-vitro* adherence model.

Wound contact layers that provide low adherent properties are beneficial to the patient in reducing the potential for pain at dressing change, by lowering the risk of dressing adherence, and for protecting tissue from damage thereby optimising wound healing. It is also important to consider how the wound contact layer may function to prevent secondary dressing adherence and the impact on wound healing should an absorbent dressing be allowed to adhere to the wounds, either directly or through the pores of the wound contact layer.

BACKGROUND

The formation of granulation tissue is usually a good sign that a wound is entering the latter stages of its healing cycle. This extracellular matrix is composed of collagen and macro molecules that support a variety of cells such as fibroblasts, which are important for granulation tissue formation.

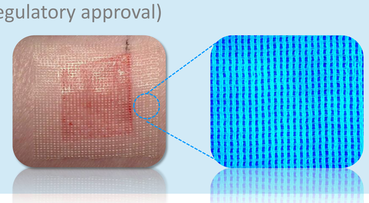
Adherence of the absorbent dressing to healing tissue
often causes damage to healthy regenerated granulation
tissue causing pain and lengthening the time to heal.
It is therefore imperative to try to preserve this healthy tissue
in order to reduce healing time, patient discomfort and overall costs.

In-vivo adherence of MEPITEL* to secondary dressing at day 3

Historically, absorbent materials were impregnated with hydrophobic oils such as paraffin to reduce adherence to the wound. More recent advances in non-adherent materials include:

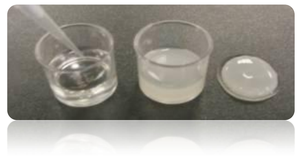
- Gel forming fibres such as alginates & carboxymethyl cellulose,
- Knitted materials such as cellulose acetate which may be impregnated with silicone or petrolatum,
- Perforated Ethyl Methyl Acrylate (EMA) films

ADAPTIC TOUCH™ consists of a flexible open mesh layer of cellulose acetate coated with a soft tack silicone (pending regulatory approval)



METHOD

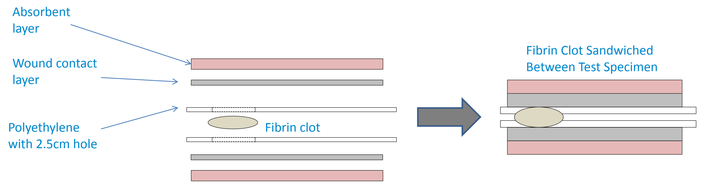
- Bovine serum albumin (20mg/ml) and plasma fibrinogen (6mg/ml) solutions were prepared in phosphate buffered saline solution (PBS) and mixed together with a 1:1 ratio. The clot was prepared by the addition of thrombin (25IU/ml) to the bovine serum albumin/fibrinogen mixture and incubating at 37°C for 1 hour for the clot to gel.



Fibrin Clot

- Dressing samples together with an absorbent layer behind (gauze in this instance) were cut into strips measuring 3cm wide and 6.5cm in length. In order to prevent the wound contact layer adhering to itself and to ensure accurate placement of the clot, strips of polyethylene were cut slightly larger and a hole of 2.5cm in diameter punched at one end of each strip for placement of the clot.

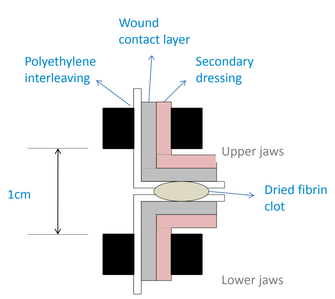
Assembly of Specimen



- On each strip of dressing/gauze sample, one piece of polyethylene was placed. Using a spatula the fibrin clot was placed into the hole of the polyethylene so that the full open area was covered with the clot. A further dressing /gauze/polyethylene strip was placed over the first ensuring the open hole area was placed directly over the fibrin clot. Sufficient weight was placed onto the dressing/fibrin clot ensemble to ensure contact of the layers was maintained. The test specimen was placed in a 37°C incubator for a further 24 hours.

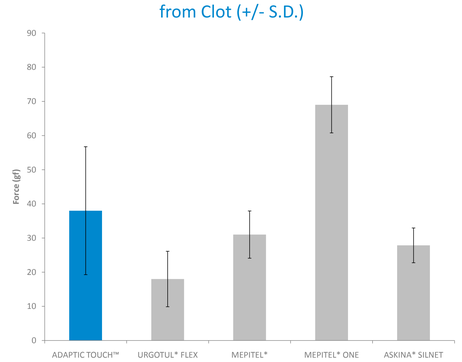
- The force required to remove the wound contact layer from the clot i.e. the adherence to fibrin clot was measured using an Instron Tensile Tester. The two layers were carefully peeled apart from the opposite end to the hole in the polyethylene strip, being careful to stop before reaching the fibrin clot. The upper and lower layers of the sample were placed into jaws of the Instron Tensile Tester to commence the test

Sample Placement into Jaws



RESULTS

Force Required to Pull Wound Contact Layer from Clot (+/- S.D.)

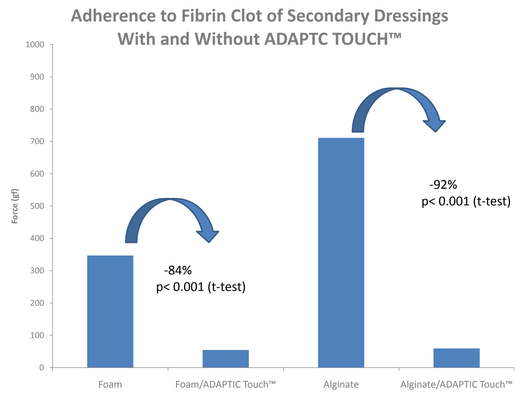


In this test when applying same test conditions,
Foam dressing adherence >300gf
Alginate dressing adherence >700gf

Adherence of Secondary Dressing in Combination With ADAPTIC TOUCH™

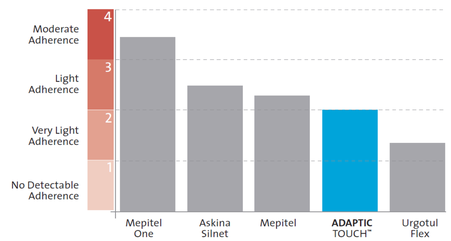
- Test method was conducted as previously described, using a foam and an alginate as the secondary absorbent dressing.

RESULTS



Addition of a non-adherent primary wound contact layer was seen to significantly reduce the adherence of secondary absorbent foam and alginate dressing *in-vitro*. This result was confirmed *in-vivo* as very light adherence.

Adherence of secondary dressing to the wound - Day 7
In vivo partial thickness model



CONCLUSIONS

Using a simulated adherence to fibrin clot test method, the non-adherent wound contact layer ADAPTIC TOUCH™ demonstrated low adherent properties. Furthermore, in the same method a foam and an alginate dressing adherence was significantly reduced in the presence of ADAPTIC TOUCH™ by 84% and 92% respectively.

Trauma to the wound bed is often caused by dressing adherence and by the removal of dressing fibres or residue left on the wound bed. Non-adherent wound contact layers are important in minimising the potential for mechanical trauma at dressing change and for reducing patient pain associated with dressing change

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