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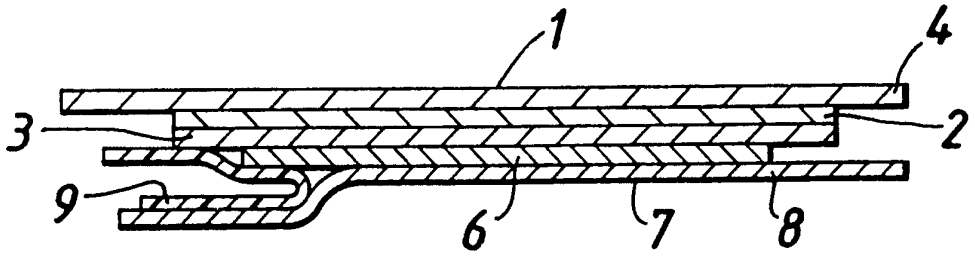

(57) Abstract

There is described an adhesive dressing (1) comprising a backing layer (2) having a pressure sensitive adhesive layer (3) over one surface thereof, a hydrogel layer (6) over part of the adhesive surface, a removable protector (7) which covers the exposed adhesive layer (3) and the hydrogel layer (6); and a continuous conformable support layer (4) which is reversibly attached to the non-adhesive surface of the backing layer and extends beyond the backing layer at one or more edges.

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WOUND DRESSINGS

This invention relates to a novel form of wound dressing and a novel method of treatment of wounds.

The accummulation of wound exudate in secreting skin wounds such as decubitus ulcers and surgical wounds promotes the growth of bacteria and other organisms which may delay healing of the wound and in some cases cause infection of the wound. It is well established that wound healing may be accelerated if the wound is kept in a 'moist condition' but that excess exudate must be removed from the wound.

Polyurethane films have been used as dressings in recent years, such films have a moisture vapour transmission rate (MVTR) which allows excess exudate to permeate whilst keeping a residual amount of moisture around the wound area. More recently hydrogel materials have been used, sometimes in conjunction with a polyurethane film dressing to further control the 'moisture' content of the wound.

However, the application of a hydrogel and subsequently a polyurethane dressing proves awkward to manipulate. A further disadvantage is that for fairly superficial wounds only relatively small amounts of hydrogel are required thus a sachet of hydrogel may only be part used and the remainder discarded.

Recent developments have sought to overcome this problem. For example, European Patent Application No.424165 describes a reservoir of a hydrogel in a vacuum formed well in a thin film dressing layer provided with an adhesive perimeter portion. The thin

film layer is provided with a support layer around the perimeter of the vacuum formed well. However, such dressings have only limited stability since the support layer does not add to the support of the hydrogel. In the embodiment described therein the dressing layer may be provided with a grid pattern to permit measurement of wound healing.

European Patent Application No.426422 discloses a number of hydrogel dressings which include;

(i) a hydrogel material maintained in a cavity formed in a flexible film membrane; and

(ii) a hydrogel layer maintained in position on a flexible film by a perimeter defining adhesive coated foam dam.

However, such dressings although advantageous over the methods of applying hydrogels and dressings separately, suffer from a number of disadvantages.

The foam dam dressings of the prior art have the disadvantage that the shoulder of the dam is aligned with the edge of the dressing, the shoulder easily catches when a patient moves, thus dislodging the dressing and/or causing discomfort to the patient. This is found to be a particular problem with sacral dressings. Moreover, it is common for the appearance of a small wound in the form of a pressure sore in the dermis or epidermis to merely be an indication of a much larger subcutaneous wound sore. Thus it may be undesirable to adhere a dressing to tissue directly adjacent to the visible wound.

Also, because of the need to create a vacuum formed well, particularly with the dressings of European Patent Application No.426422, the dressings of the prior art are difficult and expensive to manufacture and would tend to require a less conformable backing layer.

Although the dressings of the prior art are described as optionally having a grid marked on a backing in order to measure wound healing, this particular aspect of the prior art is disadvantageous since the grid cannot be easily entered into the patients records.

We have now found a form of dressing which overcomes or mitigates these problems.

According to the invention, we provide an adhesive dressing comprising a backing layer having a pressure sensitive adhesive layer over one surface thereof, a hydrogel layer over part of the adhesive surface, a removable protector which covers the exposed adhesive layer and the hydrogel layer; and a continuous conformable support layer which is reversibly attached to the non-adhesive surface of the backing layer and extends beyond the backing layer at one or more edges.

The amount which the support layer extends beyond the outer edge of the backing layer may vary according to the size and nature of the wound to be treated. However, in general we prefer the support layer to extend beyond the backing layer by approximately 1 - 5

cm, more preferably by 1 - 4 cm and most preferably by 1 - 3 cm. The support layer may extend over one edge, two edges or all four edges of the backing layer.

The pressure sensitive adhesive may be a continuous adhesive layer or may be non-continuous. In a preferred embodiement of the present invention the pressure sensitive adhesive layer is non-continuous, eg. a pattern spread adhesive. In particularly the portion of the backing layer around the periphery of hydrogel layer may be adhesive free. Such adhesive free regions may be manufactured by coating the backing layer with an adhesive in the presence of a template. The adhesive free region of the backing layer may be from 0.1 to 5.0mm wide, preferably from 0.1 to 20mm wide, more preferably from 1 to 10mm wide.

The hydrogel layer may optionally be provided with a support member. The support member may be integral to the hydrogel layer or may be adjacent the periphery of the hydrogel layer such peripheral support members may surround all or part of the hydrogel. Preferably, a peripheral support member is a foam dam member which preferably surrounds the whole of the hydrogel layer.

The dam member may surround the whole of the hydrogel layer. The exposed surface of the dam member may also optionally be coated with a pressure sensitive adhesive layer, but preferably, the wound facing side of the dam member is adhesive free.

The dam member may define any conventional shape, eg. circular, square or rectangular. Alternatively, the dam member may define an internal well which is different in shape to that defined by it's external walls. Thus the dam member may be rectangular shaped on it's external walls whilst defining a circular shaped well. When the outer walls of the dam member define a square or rectangular shape the corners of the dam member and/or the backing layer may be rounded in order to further alleviate the problem of the dressing, when applied, catching and causing discomfort to the patient. In addition, the shoulder of the dam member adjacent to the backing layer may be bevelled in order to alleviate 'dressing lift'. Such 'dressing lift' may also be alleviated by profiling the dam member such that it's thickness at it's outer edge may be less than that at its inner edge. In a similar fashion 'dressing lift' may be alleviated in the support free dressing by profiling the hydrogel layer. Thus, when the hydrogel layer is a square or rectangular slab, the corners of the slab may be of less thickness than the remainder. Alternatively, the whole of the outer edge of the slab may be of less thickness than the remainder. Such edge profiling would of course be applicable to all shapes of hydrogel layer.

When the hydrogel layer is provided with an integral support member, the support member may be a reticulated member, or may comprise a scrim or gauze of material. The integral support layer may be a scrim, gauze or net of material. The integral support member may comprise a conformable sheet, eg. a

plastics sheet provided with a plurality of apertures or, for example, a polyurethane net, eg. a **HYPOL** net. Further, the integral support member preferably comprises material which absorbs wound exudate, eg. cotton, although non-absorbent materials may also be used. The integral support member will be within the hydrogel layer but may be adjacent either the wound facing or the backing layer facing surface. It is preferable however that the integral support will lie substantially in the middle, measured by depth, of the hydrogel layer, that it is, substantially in equal proximity to the wound facing and the backing layer facing surface. The integral support preferably extends substantially to the edges of the hydrogel layer, although provided the hydrogel layer is sufficiently stable this is not essential.

Suitably the backing layer may comprise any of those materials which are conventionally employed to form thin film surgical dressing. Suitable materials include those described in UK Patent No. 1280631. European Patents Nos. 51935, 91800 and 178740. Particularly apt materials are polyurethanes, for example polyester or polyether polyurethanes known as Estanes (Trade Mark). Other apt materials are elastomeric polyether polyesters, for example those known as Hytrels (Trade Mark) and polyether polyamides, for example those known as Pebaxes (Trade Mark). Other favoured materials include hydrophilic polymers such as hydrophilic polyurethanes including those described in UK Patent No. 2093190B, especially the polyurethane described in Example 2 therein. Such materials will typically take up from 5 to 95% by

weight of water.

The materials employed in the dressings of the invention may be moisture vapour permeable. The moisture vapour transmission rate of the materials employed in the present invention may be measured by a procedure known as the Payne Cup method, which method is described in European Patent Application No. 360458. The method uses a cup 1.5cm deep with a flanged top. The inner diameter of the flange is such to provide an area for moisture vapour transmission of $10cm^2$. In this method 10ml of chilled water is added to the cup and a sample of the material under test, large enough to completely cover the flange, is clamped over the cup. The complete assembly is then weighed and placed in a cabinet where the temperature and relative humidity are maintained at 37^oC and 10% respectively. After 17 hours the cup is removed from the cabinet and allowed to cool at room temperature. After re-weighing, the mass of water lost by vapour transmission is calculated and the result expressed as in gm^{-2} $24hrs^{-1}$ at 37^oC at 100% to 105 relative humidity difference. Hereinafter the units for moisture vapour transmission will be abbreviated to gm^{-2} $24hrs^{-1}$.

More importantly, the overall moisture vapour transmission rate (MVTR) of the dressing should equate to 500 - 7000 gm^{-2} $24h^{-1}$ based on composite properties, ie in heavily exuding wounds the gel may act as a 'sink' and enable the moisture vapour permeable film to "flash off" excess fluid. In lightly exuding wounds the MVTR should be sufficient

to maintain a moist environment and prevent the wound drying out.

The backing layer may comprise a polyurethane film or alternatively the backing layer may comprise a HYTREL (TM). The backing layer may have a thickness of from 15 to 100μm, preferably 20 to 80μm and more preferably 25 to 50μm, for example 27.5μ, 30μm, 35μm, 40μm.

The pressure sensitive adhesive layer may be formed from an adhesive which is conventionally used for contact with the skin. Suitable adhesives include polyvinyl alkyl ether adhesive and acrylate ester copolymer adhesives. Suitable adhesives are described in UK Patent No. 1280631 and European Patents Nos. 35399 and 51935. Preferably the adhesive is a polyvinyl ether adhesive or an acrylate ester copolymer adhesive formed by the copolymerisation of 2-ethylhexyl acrylate, butyl acrylate and acrylic acid.

The adhesive layer may be from 15 to 65μm thick, for example 20 to 40μm thick and is applied at a weight per unit area of 10 to 75gsm, more suitably 15 to 65gsm and preferably 25 to 40gsm.

The removable protector is preferably a silicone coated release paper. Suitably the removable protector may have a weight per unit area of 100 to 140gsm, and preferably 110 to 130gsm, for example 120gsm. The removable protector may be divided into two or more pieces. Preferably at least one of the

protector pieces is significantly larger than the other or others and covers a major proportion of the adhesive layer. It is desirable that the stripping load of the support layer from the backing layer is greater than that of the protector from the adhesive layer otherwise there is a risk that the support layer would peel from the backing layer before the protector can be removed.

The hydrogel layer may be any polymer which is characterised by it's hydrophilicity and insolubility in water. Such polymers preferably comprise a cross linked macromolecular network. Such hydrophilic polymers may be amphoteric, eg. containing anionic and cationic monomers; anionic, eg. containing carboxylate, sulphonate, phosphonate groups; cationic, eg. containing quaternary ammonium ions; zwitterionic, eg. containing monomers with a cationic and anionic group; or non-ionic, eg. containing amide, hydroxyl, lactam, polyether, polyhydroxyethylmethacrylate or polyvinyl pyrrolidone (PVP) groups.

Preferred hydrogel materials are those containing polyethylene oxide or PVP. Such hydrogels preferably contain from 5 to 30% w/w of the hydrophilic polymer, preferably from 5 to 20% w/w, most preferably 5 to 15% w/w, eg. 10% w/w.

The hydrogel material may be an aqueous or a saline solution in a gel-like phase and may comprise from about 5% to about 30% by weight of a polyhydric alcohol selected from the group consisting of polypropylene glycol, polyethylene glycol and

glycerine.

The hydrogel may also contain from about 8% to about 14% by weight of an isophorone disocyanate terminated prepolymer, and, when saline, up to about 1% by weight of a salt such as sodium chloride, and the balance water.

The hydrogel comprises a water-insoluble, water-swellable cross-linked cellulose derivative, water and a polyol component and the cellulose derivative comprises less than 10% by weight of the gel.

In particular, hydrogels which may be mentioned include those described in patent application no. WO 92/16245. When the dressing according to the invention includes a support member, the hydrogel may be relatively more mobile than other preferred hydrogels although the less mobile hydrogels may also be used.

It is a further feature of this invention to provide an adhesive dressing as hereinbefore described wherein the removable protector extends beyond the backing layer at one or more edges, preferably at both edges and comprises first and second parts, the first part having a portion extending away from the adhesive surface and bent back to form a v-shape and the second part having a portion extending away from the adhesive and overlying the v-shaped first part.

According to a further feature of the invention the conformable support layer may be provided with a

grid marking in order to enable wound healing to be observed. The extensions of the conformable support layer beyond one or more edges of the backing layer are preferably non-adhesive and thus facilitate the removal of the conformable support layer from the backing layer.

In another aspect therefore the present invention provides a method of treating a wound which comprises applying thereto an adhesive dressing as hereinbefore described by removing the removable protector, applying the hydrogel layer to the wound and the exposed adhesive layer to the skin and then removing the continuous conformable support layer.

We further provide a method of manufacturing an adhesive dressing as hereinbefore described. This method comprises taking a backing layer provided with a support layer on a first side. The support layer preferably being provided with a grid pattern, a second side of the backing layer is coated with an adhesive layer and then a protector is applied to the adhesive using conventional methods known per se. In an automated process, the dressing may optionally be wound onto a reel. Subsequently, the reel is unrolled, the protector is removed from the adhesive layer, the hydrogel layer, which may be in the form of a 'slab' is positioned onto the adhesive. The protector is then reapplied and the dressings may be cut to size.

When the hydrogel layer comprises an integral support member the process of manufacture will be as

hereinbefore described. When the dressing according to the invention comprises a dam member, the dam member may be applied after the hydrogel layer or the hydrogel layer may be supported in the dam member prior to applying the supported hydrogel layer to the backing layer. Preferably however, the dam member is applied to the backing layer and then the hydrogel layer is applied.

The dressing may be placed in a bacteria-proof pack, sealed and sterilised by conventional methods, including, for example, using ethylene oxide or irradiation.

Preferred embodiments of adhesive dressings of the present invention will now be described by way of example only and with reference to the accompanying drawings, in which

Figure 1 is a cross section through an embodiment of a dressing according to the invention,

Figure 2 is an expanded perspective view of the embodiment of Figure 1.

Figure 3 is a cross section of an embodiment of the invention provided with a peripheral dam member,

Figure 4 is a cross section of a embodiment of the invention provided with an integral support member.

Figures 1 and 2 shows an adhesive dressing (1)

which comprises a backing layer (2) formed from a film of polyether polyurethane. The backing layer (2) has on one surface a pressure sensitive adhesive layer (3) formed from polyacrylate ester adhesive. On the non-adhesive surface of the backing layer (2) is a support layer (4). The support layer (4) may comprise a silicone or polyethylene coated paper or a transparent film of polyethylene or polypropylene. The support layer (4) is marked with a grid (5) to enable wound healing to be measured. A hydrogel (6) is attached to the adhesive layer (3). The adhesive layer (3) and the hydrogel (6) are provided with a protector (7) made from a silicone coated release paper.

The protector (7) comprises two components. A large protector (8) is essentially flat and overlaps the smaller protector (9) which smaller protector (9) is folded into a v-shape.

The support layer (4) is provided with edges (10) which extend beyond the edge (11) of the backing layer (2) and adhesive layer (3).

In Figure 3 the dressing is provided with a dam member (12) around the periphery of the hydrogel layer (6).

In Figure 4 the hydrogel layer (6) is provided with an integral support member (13) being a scrim.

In use the larger piece (8) of the protector is removed first and the dressing held by the overlying

portion of piece (9) and edge of the support layer (4). In such a case the larger area of the dressing is adhered to the skin, then the smaller piece (9) and the support layer (4) may be removed. Alternatively, the smaller protector piece (9) may be removed before application and the dressing handled asectically by the edges of the support layer (4) which project beyond the adhesive (3) and film (2) layers.

CLAIMS

1. An adhesive dressing comprising a backing layer having a pressure sensitive adhesive layer over one surface thereof, a hydrogel layer over part of the adhesive surface, a removable protector which covers the exposed adhesive layer and the hydrogel layer; and a continuous conformable support layer which is reversibly attached to the non-adhesive surface of the backing layer and extends beyond the backing layer at one or more edges.

2. An adhesive dressing according to claim 1 in which the support layer extends beyond the backing layer by 1-5cm.

3. An adhesive dressing according to claims 1 or 2 in which the adhesive layer is non-continuous.

4. An adhesive dressing according to claim 3 wherein the backing layer possesses an adhesive free zone around the periphery of the hydrogel layer.

5. An adhesive dressing according to claim 1 in which the hydrogel layer is provided with a support member.

6. An adhesive dressing according to claim 5 wherein the support member is a dam member.

7. An adhesive dressing according to claim 5 wherein the support member is a scrim.

8. An adhesive dressing according to claim 7 wherein the scrim is based away from the edge of the hydrogel.

9. An adhesive dressing according to claim 1 wherein the protector comprises first and second parts, the first part having a portion extending away from the adhesive surface and bent back to form a v-shape and the second part having a portion extending away from the adhesive surface and overlaying the v-shaped first part.

10. A dressing according to claim 1 wherein the backing layer is a hydrophilic polyurethane.

11. The use of a hydrogel in the manufacture of a dressing according to claim 1.

12. A method of manufacturing an adhesive dressing according to claim 1 which comprises taking a backing layer provided with a support layer on a first side, the support layer preferably being provided with a grid pattern, a second side of the backing layer is coated with an adhesive layer and then a protector is applied to the adhesive the protector is removed from the adhesive layer, the hydrogel layer, is positioned onto the adhesive and the protector is then reapplied, the dressings may cut to size.

FIG. 1.

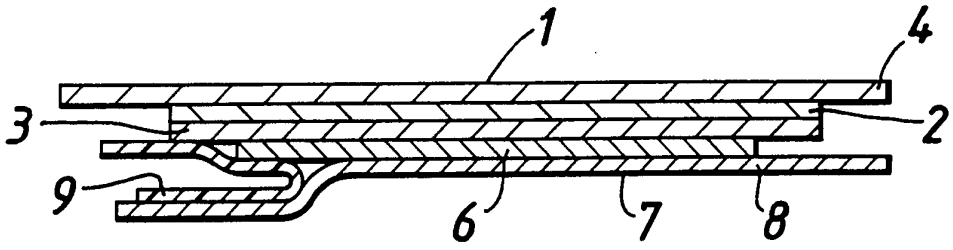


FIG. 2.

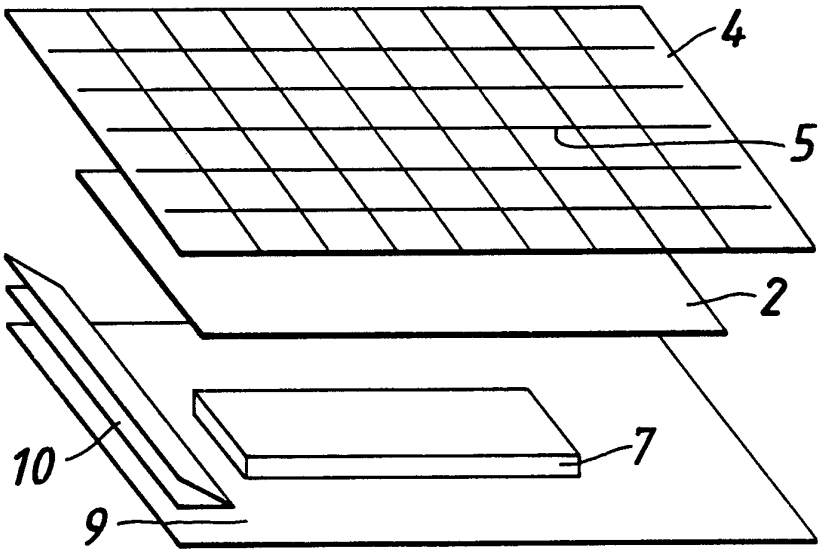


FIG. 3.

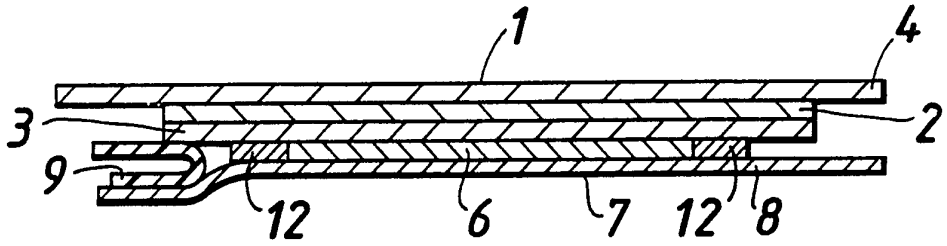
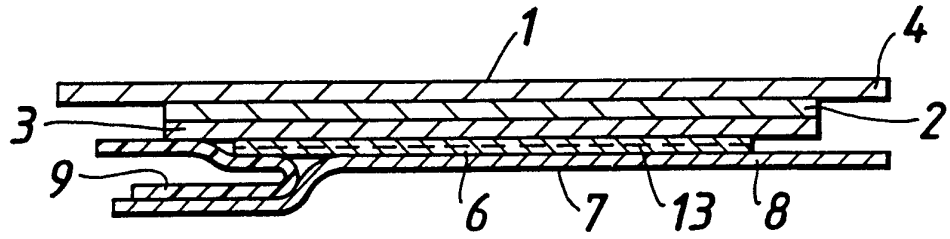


FIG. 4.



INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 93/02382

A. CLASSIFICATION OF SUBJECT MATTER

A 61 F 13/02, A 61 L 15/60

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A 61 F, A 61 L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5 160 328 (CARTMELL et al.) 03 November 1992 (03.11.92), the whole document. --	1,5,7, 8,10-12
A	EP, A2, 0 426 422 (NDM ACQUISITION CORP.) 08 May 1991 (08.05.91), the whole document (cited in the application). --	1,5,6, 10-12
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A	EP, A1, 0 360 458	1,9,10

☐ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
22 February 1994	15. 03. 94

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	(SMITH & NEPHEW PLC) 28 March 1990 (28.03.90), claims; figs (cited in the application). ----	

ANHANG — ANNEX — ANNEXE

zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

to the International Search Report to the International Patent Application No.

au rapport de recherche international relatif á la demande de brevet international n°

PCT/GB 93/02382 SAE 81908

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben. Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

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