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(71) Applicant *(for all designated States except US):* SMITH AND NEPHEW ASSOCIATED COMPANIES p.l.c. [GB/GB]; 2 Temple Place, Victoria Embankment, London WC2R 3BP (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only) :* POTTER, William, Duncan [GB/GB]; 7 Carters Leys, Bishops Stortford, Hertfordshire (GB). RAWLINGS, David, Alan [GB/GB]; 14 Rainsford Road, Stansted Mountfitchet, Essex CM24 8DV (GB).

(74) Agent: COLE, William, Gwyn; Smith and Nephew Research Limited, Gilston Park, Harlow, Essex CM20 2RQ (GB).

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(54) Title: SURGICAL ADHESIVE DRESSING

(57) Abstract

A surgical dressing which consists essentially of a film which carries and adhesvie layer for securing the dressing to the body characterised in that (a) the film is continuous and comprises a polymer which in contact with water has a higher MVP than when in contact with moisture vapour but not water (b) the adhesive layer is adapted to allow access of water to the film when water is in contact with the adhesive layer so that (c) said surgical dressing has a MVP of not less than 2500g/m^2 when the adhesive layer is in contact with water and has a MVP of not more than 2000g/m^2 when the adhesive is in contact with moisture vapour but not water; whereby the dressing is suitable for use on exuding wounds and on non-exuding wounds.

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SURGICAL ADHESIVE DRESSING

The present invention relates to adhesive dressings for use on the human body. More particularly this invention relates to adhesive surgical dressings suitable for use on both exuding wounds and non-exuding wounds.

Moisture vapour permeable thin films coated with adhesive were disclosed in British Patent No. 1,280,631 and U.S. Patent No. 3,645,835 as being suitable for use as surgical dressings. In recent years one such film has come to prominence under the trade mark "Op-Site" and has found use as a surgical dressing, for example for covering burns, donor sites, surgical incisions, intravenous catheter sites and the like. The known dressings have proved useful because they keep out bacteria owing to the microscopically continuous nature of the film and adhesive layer but do not cause maceration of the skin to which it is applied because both the film and the adhesive layer have high moisture vapour permeability (MVP). One problem with presently available high MVP dressings is that

the MVP is not high enough for some uses such as covering exuding wounds when an unsightly blister can occur. However it has not been thought practicable simply to increase the MVP of the product overall since this would lead to drying out of some wounds with a consequent reduction in the rate of healing. It has now been discovered that it is possible to alleviate the known disadvantages of conventional surgical dressings by providing dressings which transmit substantially more moisture vapour when in contact with a wetter wound than they do when in contact with a dryer wound.

Accordingly the present invention provides a surgical dressing which consists essentially of a film which carries an adhesive layer for securing the dressing to the body characterised in that (a) the film is continuous and comprises a polymer which in contact with water has a higher MVP than when in contact with moisture vapour but not water (b) the adhesive layer is adapted to allow access of water to the film when water is in contact with the adhesive layer so that (c) said surgical dressing has a MVP of not less than 2500g/m^2 when the adhesive layer is in contact with water and has an MVP of not more than 2000g/m^2 when the adhesive is in contact with moisture vapour but not water; whereby the dressing is suitable for use on exuding wounds and on non-exuding wounds.

When used herein with reference to "contact" the term "water" means liquid water (as opposed to moisture vapour) unless otherwise specified. When used herein MVP units are $g/m^2/24hrs/37^oC/100-10\%$ relative humidity and are generally abbreviated to g/m^2.

Suitable test methods for determining the MVP of a dressing or its components are set forth in the Description hereinafter. When MVP values quoted hereinafter are referred to as "wet-MVP" they refer to values obtained with the adhesive face in contact with water and when referred to as "dry-MVP" they refer to values obtained with the adhesive face not in contact with water.

More suitably the dressing of this invention will have a wet-MVP of not less than $3000g/m^2$, most suitably will have a wet-MVP of not less than $3200g/m^2$ and preferably will have a wet-MVP of not less than $5000g/m^2$.

More suitably the dressing of this invention will have a dry-MVP of not more than $1500g/m^2$, most suitably will have a dry-MVP of not more than $1400g/m^2$ and preferably will have a dry-MVP of not more than $1200g/m^2$.

The film used in this invention may comprise any synthetic or modified natural polymer which has a sufficiently higher wet-MVP than dry-MVP to produce the desired MVP parameters in the dressing. The method set out

in the Descriptions may be employed to determine whether the film material exibits the desired MVP when in contact with water. Most aptly the film comprises a synthetic polymer although modified natural polymers such as regenerated cellulose or cellulose acetate may be employed if sufficiently plasticised to conform to the movements of the body when adhered thereto. Preferably the synthetic polymer employed is an elastomer so that it readily conforms to the movement of the skin when the dressing is in use.

Most suitably the film used in this invention will be hydrophilic, that is will absorb water when immersed therein. Aptly the film material when hydrated will contain 5% to 50% water (w/w at 20°C), more aptly from 10% to 40% of water and favourably from 20% to 30% of water.

Suitable hydrophilic film material will include polyurethanes, polyether polyamide block copolymers, polyether polyester block copolymers, cross-linked polyvinyl alcohols, acrylic copolymers, polyamides, regenerated cellulose, cellulose acetate and the like, provided said film material are highly conformable (whether per se or by plasticisation) and that the material used most suitably has the preceeding water contents when hydrated.

The film employed will be a continuous film, that is it will be free of holes (whether microporous or macroporous) which allow the passage of bacteria.

The desirable properties of this invention may be best obtained by employing a film of hydrophilic polyurethane in combination with an adhesive layer adapted to allow access of water to the film when water is presented to the adhesive face of the dressing.

Most suitably the film will be from 15 to 80 microns thick, will more usually be from 20 to 60 microns thick and will preferably be from 25 to 50 microns thick, for example 30, 35 or 40 microns thick.

Aptly the film will be formed from a hydrophilic polyurethane which when hydrated contains from 5% to 50% of water, more aptly from 10% to 40% of water and favourably from 20% to 30% water.

In order to enable visual observation of the wound it is desirable for the film used in this invention to be transparent. This in turn requires that the film should be capable of being self supporting, that is sufficiently coherent when wet or dry to be used without recourse to additional support such as a fabric, for example a gauze,

net or the like. It has been found that polyether polyurethanes are particularly suitable for use in the formation of such films. Favoured polyether polyurethanes are essentially free of reactive substituents such as hydroxyl or carboxyl groups. It has been found that certain apt polyurethanes for use in this invention are random polymers containing units derived from diolic compounds and di-isocyanates.

Suitable polyurethanes are disclosed in British Patent Specification No. 2093190A at page 3 lines 16 to 47 which are incorporated herein by cross reference.

The adhesive layer present on the body contacting surface of the film is favourably an interrupted layer so that areas of the film are free of adhesive, aptly 20 to 75% of the film is free of adhesive, more aptly 30 to 70% of the film face is free of adhesive and preferably 40 to 60% of the film face is free of adhesive. The use of an interrupted layer in such a manner has been found to be highly beneficial in allowing the desirable variability of MVP to be achieved.

The adhesive is generally employed at a mass per unit area of 10 to 80g/m^2, more aptly 20 to 45g/m^2 and favourably from 25 to 35g/m^2.

The adhesive may be applied around the periphery of the dressings, in lines over the face of the dressing (parallel, at right angles, forming diamond pattern or the like) or in combinations of such systems.

The adhesive is preferably one which itself transmits water vapour, for example one which if present as a film 25 microns thick would have a MVP of at least 300g/m^2, more suitably at least 500g/m^2 and preferably at least 700g/m^2. Such permeabilities may be achieved by using a non-porous or porous (including microporous)pattern spread adhesive but generally it is preferred to employ a non-porous pattern spread adhesive. Suitable adhesives include polyvinyl ethyl ether adhesive and acrylate surgical adhesives. Preferred adhesives include those described in European Patent Application No. 81300847 (Publication No. 0035399).

The dressings of the invention may be made by any convenient process, for example a film of, for example hydrophilic polyurethane may be roller printed or hand printed with a pattern of adhesive. Alternatively any other convenient method of providing a non-continuous adhesive may be employed. The coated films may then be cut, packaged and sterilised in conventional manner, for example by irradiation, heat or ethylene oxide.

In a favoured aspect this invention provides a dressing as hereinbefore described in sterile form. Most aptly the sterile dressing is packaged in a bacteria-proof package such as a paper or aluminium foil pouch.

Suitable polyurethane may be produced by the methods of British Patent Specification No. 2093190A and incorporated herein by cross reference are page 6 line 35 to page 8 line 41 thereof.

Normally the dressings are provided for use with a silicone release paper to protect the adhesive which protector is removed prior to use of the dressing.

The following Examples illustrate the invention:

Description

"Dry" MVP Determination

Discs of the material under test are clamped over Payne Permeability Cups (flanged metal cups) using sealing rings and screw clamps. The exposed surface area of the test sample is $10cm^2$. Each cup contains approximately 10ml. of distilled water.

After weighing the cups are placed in a fan assisted electric oven which is maintained at $37 \pm 1^{o}C$. The relative humidity within the oven is maintained at approximately 10% by placing 1Kg. of anhydrous 3-8 mesh calcium chloride on the floor of the oven.

The cups are removed after 24 hours, allowed to cool for 20 minutes and re-weighed. The MVP of the test material is calculated from the weight loss and expressed in units of grams of weight per square metre per 24 hours.

"Wet" MVP determination

The method described above is employed except that the Payne Cups are inverted in the oven so that the water within the cups is in contact with the test material.

Example 1

Preparation of Film

A solution of a hydrophilic polyurethane (of Example 2 of UK No. 2093190A) in industrial methylated spirits (18% solids) was cast using a doctor blade onto a silicone treated release paper to produce a coating weight after drying of 30 $\pm$ 3g/m^2. The cast film was dried at 80°C to remove solvent.

Pattern Spreading of Film with Adhesive

A solution of acrylic adhesive in acetone (solids content 35%) was coated directly onto the film of hydrophilic polyurethane using an engraved roller so as to produce a reticulated (cross hatched) coating of adhesive. After coating the adhesive was allowed to dy in air before a silicone treated paper protector was applied. The average weight of the adhesive coating was 30 $\pm$ 3g/m^2. The area of film covered by the adhesive was approximately 50% of the total available area. (The adhesive was that of Example 1 of European Patent Application No. 81300847.1).

The dry-MVP of the product of this Example was 1250g/m^2 and the wet-MVP was 3600g/m^2 (compare corresponding values of about 1100g/m^2 and about 1250g/m^2 for an analogous material which employed Estate 5714 - a non-hydrophilic polyurethane in place of the hydrophilic polyurethane).

Example 2

The product of Example 1 was cut into 10 x 10cm squares and sealed into pouches. The product was sterilised using ethylene oxide. The resulting sterile dressing may be employed to cover wounds.

Example 3

The procedures of Examples 1 and 2 may be carried out replacing the hydrophilic polyurethane by those of British Patent Specification No. 2093190A at page 6 line 35 to page 7 line 25. The resulting dressings are suitable for covering wounds.

Example 4

The procedures of Examples 1 and 2 may be repeated using a vinyl ethyl ether adhesive in place of the acrylic adhesive. The resulting dressings may be employed to cover wounds.

Example 5

A 25 micron film of polyether polyamide block copolymer (Pebax 4011 supplied by ATO Chemical Products, Newbury, UK) had applied thereto by roller a cross hatched pattern of polyvinyl ethyl ether adhesive. The adhesive covered about 75% of area of the film surface and the diamond shaped interstices accounted for about 25% of

the area of the film. The average weight of the adhesive layer was approximately 60gsm. The resulting material was cut into 15cm x 15cm squares, placed on silicone release paper (adhesive side to release layer), placed in pouches and sterilised using ethylene oxide.

The dressing had a dry-MVP of about 1800g/m^2 and a wet-MVP of greater than 5000g/m^2.

WHAT IS CLAIMED IS:

1. A surgical dressing which consists essentially of a film which carries an adhesive layer for securing the dressing to the body characterised in that (a) the film is continuous and comprises a polymer which in contact with water has a higher MVP than when in contact with moisture vapour but not water (b) the adhesive layer is adapted to allow access of water to the film when water is in contact with the adhesive layer so that (c) said surgical dressing has a MVP of not less than 2500g/m^2 when the adhesive layer is in contact with water and has a MVP of not more than 2000g/m^2 when the adhesive is in contact with moisture vapour but not water; whereby the dressing is suitable for use on exuding wounds and on non-exuding wounds.

2. A dressing as claimed in claim 1 wherein the MVP is not more than 1500g/m^2 when the adheisve layer is in contact with moisture vapour but not water.

3. A dressing as claimed in either of claims and 2 wherein the MVP is not less than 3200g/m^2 when the adhesive layer is in contact with water.

4. A dressing as claimed in any of claims 1 to 3 wherein the film comprises a hydrophilic polyurethane which when hydrated contains 5% to 50% of water and is from 15 to 80 microns thick.

5. A dressing as claimed in claim 4 wherein the film comprises a hydrophilic polyurethane which when hydrated contains 10% to 40% of water and is from 20 to 60 microns thick.

6. A dressing as claimed in any of claims 1 to 5 wherein the film is a hydrophilic polyurethane which is a hydrophilic polyether polyurethane.

7. A dressing as claimed in any of claims 1 to 6 wherein the adhesive is an interrupted layer which leaves 30% to 70% of the film free of adhesive.

8. A dressing as claimed in any of claims 1 to 7 wherein the adhesive comprises a polyvinyl ethyl ether or an acrylate surgical adhesive.

9. A dressing as claimed in any of claims 1 to 8 in which the average weight per unit area of adhesive is $20g/m^2$ to $45g/m^2$.

10. A dressing as claimed in any of claims 1 to 9 in sterile form packaged in a bacteria proof package.

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 83/00104

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[3]: A 61 L 15/06; A 61 F 13/02

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC[3]	A 61 L 15/06; A 61 L 15/01

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
P	EP, A, 0050035 (SMITH & NEPHEW) 21 April 1982, see page 2, lines 9-15; pages 12,13; claims 1,4-6,8,10,11 (cited in the application)	1-6
A	GB, A, 648733 (J.R. SQUIRE) 10 January 1951, see page 2, lines 67-75	1
A	EP, A, 0006714 (JOHNSON & JOHNSON) 9 January 1980, see page 2, lines 23-33; page 3, lines 1-24; claims 1,3	1
A	EP, A, 0028452 (SMITH & NEPHEW) 13 May 1981, see claims 1-4,10	1-10
A	US, A, 3526224 (R.M. POTTS) 1 September 1970, see column 1, lines 1-40; claims 1,2	1
A	US, A, 3579628 (R.J. GANDER et al.) 18 May 1971, see claim 1	1

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* Special categories of cited documents: [15]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [3]	Date of Mailing of this International Search Report [3]
18th July 1983	11 AOUT 1983
International Searching Authority [1]	**Signature of Authorized Officer [20]**
EUROPEAN PATENT OFFICE	G.L.M. Kruydenberg

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No [18]
A	FR, A, 2440380 (F.E. GOULD) 30 May 1980, see claims 4,12,13,70	1
A	GB, A, 761840 (BRITISH UNITED SHOE MACHINERY) 21 November 1956	1
A	US, A, 4061618 (H. STANLEY et al.) 6 December 1977, see claims 1,2 and examples 1,2	1

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/GB 83/00104 (SA 5033)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 10/08/83

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A- 0050035	21/04/82	WO-A-	8201306	29/04/82
		GB-A-	2093190	25/08/82
		AU-A-	7648781	11/05/82
GB-A- 648733		None		
EP-A- 0006714	09/01/80	US-A-	4181127	01/01/80
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US-A- 3579628	18/05/71	None		
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		GB-A-	1605080	16/12/81
GB-A- 761840		None		
US-A- 4061618	06/12/77	None		