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CA 2140827 C 2006/02/28

(11)(21) **2 140 827**

(12) **BREVET CANADIEN
CANADIAN PATENT**

(13) **C**

(22) Date de dépôt/Filing Date: 1995/01/23

(41) Mise à la disp. pub./Open to Public Insp.: 1995/07/25

(45) Date de délivrance/Issue Date: 2006/02/28

(30) Priorité/Priority: 1994/01/24 (94 01279.6) GB

(51) Cl.Int./Int.Cl. **A61L 15/28** (2006.01),
A61L 15/60 (2006.01)

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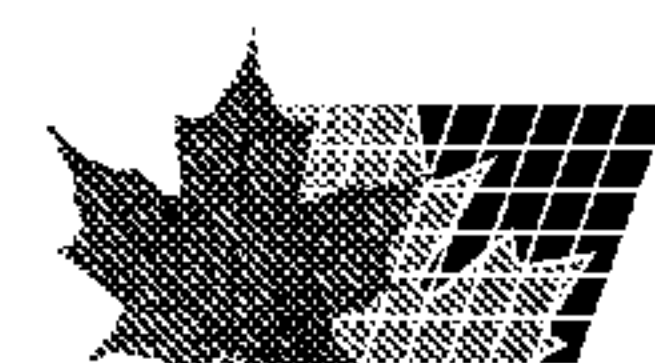
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(54) Titre : PANSEMENT ABSORBANT NON-ADHERANT

(54) Title: NON-ADHERENT ABSORBENT WOUND DRESSING

(57) **Abrégé/Abstract:**

The invention concerns a wound dressing comprising a fibrous material impregnated with a composition said composition comprising: (a) from about 0.05% to 10% by weight of a natural gelling agent; (b) from about 1.0% to 10% by weight of a hydrocolloid; (c) from about 5.0% to 30.0% by weight of an alkylene glycol and (d) at least 50% by weight of water. The dressing has the advantages of being convenient, non-adherent, and suitable for use on exudating wounds.



ABSTRACTNON-ADHERENT ABSORBENT WOUND DRESSING

The invention concerns a wound dressing comprising a fibrous material impregnated with a composition said
5 composition comprising:

- (a) from about 0.05% to 10% by weight of a natural gelling agent;
- (b) from about 1.0% to 10% by weight of a hydrocolloid;
- (c) from about 5.0% to 30.0% by weight of an alkylene
10 glycol and
- (d) at least 50% by weight of water.

The dressing has the advantages of being convenient, non-adherent, and suitable for use on exudating wounds.

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NON-ADHERENT ABSORBENT WOUND DRESSING

This invention relates to a wound dressing. More particularly, this invention relates to a wound dressing comprising a fibrous material coated with an impregnating composition, useful for treating wounds.

10 The invention also relates to a method of treating a wound comprising applying the dressing to a wound.

It is well known that the cleansing and debriding of wounds and the removal of wound exudate is important to the process of healing wounds. Commonly used wound dressings
15 comprise gauze, foams, sponges, cotton wads or other fibrous materials. Gauze and other fibrous materials absorb fluids by capillary action with the disadvantage that when new tissue is formed as part of the healing process, it engulfs the fibres and is torn when the
20 material is removed causing wound injury. Many fibrous products also have the disadvantage that they do not conform readily to the shape of the wound particularly if the wound includes a cavity.

Saline coated gauzes are known in the art but have the
25 disadvantage that the coatings are mobile and can be lost from the gauze and wound. In addition many of the coated gauzes cannot be used on exudating wounds as the coatings have limited absorbancy.

It is also known from EP 0 567 311 A2 (Queen/ER Squibb and
30 Sons) to use an absorbent gel to remove exudate from wounds. The gel is packaged in a tube and is applied to the wound from the tube. For some wounds this method of application has the disadvantages of needing a secondary dressing and being time consuming and messy.

We have now found that a dressing comprising a fibrous material coated with a composition applied as a particular gel, mitigates many of the above disadvantages.

Accordingly the invention comprises a wound dressing comprising a fibrous material impregnated with a composition characterised in that the composition comprises:

- (a) from about 0.05% to 10% by weight of a natural gelling agent;
- (b) from about 1.0% to 10% by weight of a hydrocolloid;
- (c) from about 5.0% to 30.0% by weight of a glycol and
- (d) at least 50% by weight of water.

The most preferred composition contains 0.1% pectin, 3.4% sodium carboxymethyl cellulose, 15% propylene glycol and 81.5% water.

The wound dressing is used to treat wounds and in a preferred embodiment, chronic wounds.

The natural gelling agent is preferably selected from pectin, alginic acid and salts thereof, carageenan, tragacanth, acacia, locust bean gum, guar gum, starch, agar and gelatin. More preferably the pectin is pectin with a high ester content derived from citrus peel consisting chiefly of the partial methyl esters of polygalachronic acid (approximately 65% of the carboxyl groups are esterified). Representatives of the pectin useful in the gel composition is that marketed under the name GENU^{*} pectin type VIS-L by Copenhagen Pectin. The natural gelling agent is preferably present in an amount from 0.05% to 1.0% by weight.

The hydrocolloid is preferably selected from sodium carboxymethyl cellulose, methyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl cellulose,

* trade-mark

hydroxymethylcellulose, hydroxypropyl cellulose, carboxyvinyl polymer and salts thereof, poloxamer for example Pluronic^{*} F127, xanthan gum, povidone, modified starches, and guar derivatives. The carboxymethyl cellulose is preferably sodium carboxymethyl cellulose present in an amount from about 2.0% to 4.5% by weight. The preferred sodium carboxymethyl cellulose is a high viscosity sodium carboxymethyl cellulose (typically in the range 2000 - 4500 cps as measured by Brookfield LV Viscometry of a 1% solution, oven dry basis, 25°C and spindle 4/30 rpm.

The glycol can be an aryl or alkylene glycol, preferably selected from the group of glycerol, polyethylene glycol, panthanol, and sorbitol. If the glycol is an alkylene glycol it is preferably propylene glycol present at from about 10.0% to 20.0% by weight.

The water used in the present invention is preferably purified and pyrogen free water and is present in an amount sufficient to bring the total composition up to 100% by weight.

Various optional ingredients can also be included in the final composition such as preservatives eg, methylhydroxybenzoate and propylhydroxybenzoate. In addition, the wound gel composition can, if desired, contain small amounts (effective amounts) i.e. less than 5%, of pharmacologically active ingredients. For example, an antibiotic or antimicrobial agent such as metronidazole, silver sulphadiazine, neomycin or penicillin, and antiseptic agent such as povidone iodine, and anti-inflammatory agent such as hydrocortisone or triamcinolone acetonide, or a skin protective agent such a zinc oxide can be included.

The composition used to make the dressing of this invention is prepared by mixing the natural gelling agent in water

* trade-mark

with heating (for example at a temperature from about 50°C to 60°C) to form a solution. Alkylene glycol is added while mixing and hydrocolloid gradually added while mixing to form a gel.

5 We have found that the wound dressing of the invention performs particularly well if the gel has a viscosity of from 50 to 800 Pas as determined by Viscolog^{*} model MRV8 viscometer and a helical drive unit and PD spindal rotating at 2.5 rpm. If this is achieved flow of the gel off the
10 gauze either in the packaging or at the wound site is reduced while conformity of the dressing to the surface of the wound is optimised. Since the gel has some wet tack the gauze stays in place more readily.

For certain types of wound treatment it is advantageous to
15 have a dressing comprising many layers of substrate. For such a dressing the impregnating composition needs to be more mobile than a gel to fully impregnate the substrate. This can be achieved with the present invention by sterilising a gel impregnated fibrous substrate by
20 irradiation which then destroys the gel-structure and renders the composition more mobile. The advantage of using a gel to impregnate the substrate is that the gel gives processing advantages in that it can be extruded onto the substrate and less coating is lost from the substrate
25 during packaging. The resultant, irradiated dressing comprises a composition which includes hydrocolloids which are able to absorb wound exudate. This is an advantage over known saline impregnated dressings which rely on the gauze to absorb exudate with the unwanted result of wound
30 re-injury.

The fibrous material of the invention may be selected from viscose, cotton and polyester in the form of a knitted, woven or non woven sheet or ribbon, but is preferably a

* trade-mark

knitted gauze. Most preferably the gauze is a knitted viscose being a warp knitted fabric using 220 Dtex, 40 filament Bright viscose yarn. For certain applications the substrate is preferably a multiplied plain woven cotton gauze.

The wound dressing of this invention is prepared by coating the fibrous material with the impregnating composition preferably by extruding the composition in the form of a gel through a nozzle onto both sides of the gauze. Preferably the coating density is from 750g to 2kg of gel per square metre of gauze.

The wound dressing may then be packaged in a moist state in a foil envelope and sterilized. Sterilization can be achieved either by autoclaving or by irradiating the envelope.

The invention will now be illustrated by the following non-limiting examples.

Example 1

A wound dressing was prepared by coating a 10cm square of gauze made from knitted viscose with the gel composition below to a density of 1kgm².

	<u>Gel composition</u>	<u>% by weight</u>
	Pectin	0.1%
	Sodium carboxymethyl cellulose	3.4%
25	Propyleneglycol	15.0%
	Purified water	81.5%

Pectin (0.2g) was added to purified water (163.0g) in a beaker and heated to 50 - 60°C with constant stirring until

the pectin dissolved. Propylene glycol (30.0g) was added and sodium carboxymethyl cellulose (6.8g) was gradually added with constant mixing. A hydrocolloid gel (200g) was produced.

- 5 The wound dressing was packaged in a foil envelope and sterilized by autoclaving at 121°C.

The handling characteristics of the wound dressing were evaluated in a full thickness wound model. The wound dressing of the invention was compared to Tricotex* (a non-adherent dressing ex Smith and Nephew) alone by applying the dressings under a secondary dressing of either Tricotex* or Op-Site* (ex Smith and Nephew) an occlusive dressing to a total of 18 wounds. Dressings were changed on days 3, 4, 7 and 9.

- 15 Generally when applying the dressings into the wound cavity, the wound dressing of the invention demonstrated superior handling characteristics in that it could easily be moulded to the shape of the wound. The Tricotex* gauze dressing on its own was difficult to apply to the wounds and did not conform at all to the shape of the wound. A subjective evaluation of the ease of removal of the dressings from the wounds demonstrated that generally the wounds treated with Tricotex* gauze under Tricotex* or Op-Site* showed poor removal. This was because the gauze appeared to adhere to the wound surface, and in some cases caused re-injury of the tissue on removal. The wound dressing of the invention was easily removed from the wound without causing re-injury of the wound and without the use of a saline wash, whether wound fluid was present or not.

30 Example 2

The rates of contraction of the wounds of Example 1 were measured as a percentage of wound area on day 0. All the

* trade-mark

wounds with dressings under Tricotex* followed a normal contraction curve. However the wounds with dressings according to the invention showed superior performance under Op-Site*, for example at day 11 Tricotex* under Op-Site* demonstrated 85% of the original wound area while the wound dressing of the invention under Op-Site* demonstrated 45% of the original wound area.

Example 3

A wound dressing was prepared by coating a 10cm square of gauze made from plain woven cotton multiplied to 8 to 12 ply, with the gel composition below to a density of 2kgm².

	<u>Gel composition</u>	<u>% by weight</u>
	Pectin	0.1%
	Sodium carboxymethyl cellulose	3.4%
15	Propyleneglycol	15.0%
	Purified water	81.5%

Pectin (0.2g) was added to purified water (163.0g) in a beaker and heated to 50 - 60°C with constant stirring until the pectin dissolved. Propylene glycol (30.0g) was added and sodium carboxymethyl cellulose (6.8g) was gradually added with constant mixing. A hydrocolloid gel (200g) was produced.

The wound dressing was packaged in a foil envelope and sterilized by exposure to gamma irradiation at 25K Gy. The irradiation destroyed the gel structure to allow penetration of the coating into the gauze.

* trade-mark

CLAIMS

US

1. A wound dressing comprising a fibrous material impregnated with a composition wherein said composition comprises:
 - 5 (a) from about 0.05% to 10% by weight of a natural gelling agent;
 - (b) from about 1.0% to 10% by weight of a hydrocolloid;
 - 10 (c) from about 5.0% to 30.0% by weight of an alkylene glycol and
 - (d) at least 50% by weight of water.
2. A wound dressing as claimed in claim 1 wherein the composition is in the form of a gel.
3. A wound dressing as claimed in claim 1 wherein the
15 natural gelling agent is pectin.
4. A wound dressing as claimed in claim 1 wherein the hydrocolloid is sodium carboxymethyl cellulose.
5. A wound dressing as claimed in claim 1 wherein the alkylene glycol is propylene glycol.
- 20 6. Use of the wound dressing of claim 1 to treat a wound.
7. Use of a fibrous material impregnated with a composition comprising:
 - 25 (a) from about 0.05% to 10% by weight of a natural gelling agent;
 - (b) from about 1.0% to 10% by weight of a hydrocolloid;
 - (c) from about 5.0% to 30.0% by weight of an alkylene glycol and

(d) at least 50% by weight of water
for use in the treatment of wounds.

8. Use as claimed in claim 7 wherein the composition is
5 in the form of a gel.
9. A wound dressing product comprising a sealed foil
envelope containing a wound dressing comprising a
fibrous material impregnated with a composition said
composition comprising:
- 10 (a) from about 0.05% to 10% by weight of a natural
gelling agent;
- (b) from about 1.0% to 10% by weight of a
hydrocolloid;
- 15 (c) from about 5.0% to 30.0% by weight of an alkylene
glycol and
- (d) at least 50% by weight of water.
10. A product as claimed in claim 9 wherein the
composition is in the form of a gel.
11. A method for making a wound dressing product comprising the
20 steps of:
- (i) impregnating a fibrous material with a gel said
gel comprising:
- (a) from about 0.05% to 10% by weight of a
natural gelling agent;
- 25 (b) from about 1.0% to 10% by weight of a
hydrocolloid;
- (c) from about 5.0% to 30.0% by weight of an
alkylene glycol and
- (d) at least 50% by weight of water;
- 30 (ii) sealing the impregnated fibrous material in an
envelope and
- (iii) sterilizing said envelope and contents.

12. Method as claimed in claim 11 wherein the sterilization is carried out by autoclaving.
13. Method as claimed in claim 11 wherein the sterilization is carried out by gamma irradiation.
14. Use as claimed in claim 7 wherein the wounds are chronic.