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(54) Benævnelse: **SÅRFORBINDINGSMATERIALE**

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EP-A- 0 642 779
WO-A-00/01425
WO-A-93/11805
WO-A-94/17837
WO-A-98/46818
US-A- 5 807 295

DESCRIPTION

[0001] This invention relates to a material according to claim 1 suitable for forming into a wound dressing, in particular to bandages of the type in which the wound-contacting surface is composed of gel forming fibres in the form of non woven layer. In particular the invention relates to bandages comprising gel forming fibres used in the treatment of burns or skin graft sites. US 5 807 295 relates to a bandaging material comprising two layers spaced apart by strands. The interstisial space may be filled wim a harderable resin and/or pharmacologically active agent. WO 98 468 18 relates to a wound dressing comprising a knitted fabric of support yarn and in-laid yarn, me support yarn being substantially fall of gel-forming fibres.

[0002] It is known to use carboxymethylated cellulosic materials in situations where a high degree of exudate absorption is required. For example, WO 93/12275 describes the production of various absorbent products capable of absorbing many times their own weight of water. This causes the carboxymethylated fibres to form a gel. WO 94/16746 and WO 00/01425 describe the use of carboxymethylated Lyocell materials in wound dressings where the advantages of gel formation in preventing adherence and therefore reducing wound damage and pain on removal are discussed.

[0003] Known wound dressings comprising gel forming fibres are essentially flat, rectangular and fairly small, typically 20cm X 15cm. The usefulness of *such* dressings is limited in respect of large-scale wounds such as can occur on the chest or limbs due partly to the contraction of the dressing on gel formation and partly to the difficulty in maintaining close contact with the wound.

[0004] For example, wounds to an extensive area such as the chest or limb are presently treated using many overlapping patch type dressings. The contraction on the absorption of exudate is accommodated by overlapping the dressings. This then presents a problem in fixing the dressings and maintaining contact with the wound. Even if the dressings were made in larger sizes the problem of contraction would remain.

[0005] However it would be desirable to bring the advantages of gel forming dressings to such burns by having the dressings available in bandage form. This is not however a simple matter. The current gel forming dressings, if presented in a strip form would contract, which if allowed to occur unchecked, could apply compression to the burn. The patient's natural acute wound response is to cause a burned area to swell.. Contraction of the dressing works against this response and is thus undesirable.

[0006] In addition most gel forming dressings are made from non-woven fabrics. Such fabrics have poor integrity in tension. In applying a bandage it is often desirable to apply slight tension in order to obtain conformity between the bandage and the skin. This would not be possible with a bandage made from a non woven fabric according to existing technology. The bandage when gelled may also not have sufficient integrity to maintain contact with the wound and may be difficult to remove in one piece.

[0007] The present invention therefore seeks to provide an improved material for use in wound dressings which mitigates the problems associated with patch dressings on extensive wounds.

[0008] We have now found that it is possible to restrict the contraction of dressings comprising gel forming fibres and improve their tensile strength in a dry and gelled state.

[0009] Accordingly the invention provides a material for use as a wound dressing the material being in the form of a roll and comprising gel forming fibres, characterised in that the gel-forming fibres are in the form of a non woven mat and the material has lines of longitudinal stitching made in nylon or polyolefin yarn.

[0010] The stitching is longitudinal in that it is generally parallel to the long dimension of the roll. The material is particularly suitable for forming bandages.

[0011] Such bandages are suited to dressing extensive areas as the bandage can be easily placed in intimate contact with the wound and surrounding skin. As the bandage can be applied under mild tension the bandage is maintained in contact with the wound. On absorption of exudate the gelled bandage is supported by the lines of stitching which are preferably made in nylon or polyolefin yarn or any yarn able to withstand gamma irradiation.

[0012] Preferably the material comprises a wound contacting surface made from gel forming fibres and an outer surface made from textile fibres. In this manner the bandage has an inner layer which gels on contact with exudate and an outer layer which does not gel but remains as a fabric much like a conventional secondary dressing. The stitching preferably passes through the whole thickness of the material. This has the advantage that the dressing may not require a secondary dressing to keep it in place and the outer textile layer gives the garment sufficient integrity to be removed from the wound in one piece without portions

of the dressing being shed into the wound.

[0013] By gel forming fibres is meant hygroscopic fibres which upon the uptake of wound exudate become moist slippery or gelatinous and thus reduce the tendancy for the surrounding fibres to adhere to the wound. The gel forming fibres can be of the type which retain their structural integrity on absorbtion of exudate or can be of the type which lose their fibrous form and become a structureless gel. The gel forming fibres are preferably spun sodium carboxymethylcellulose fibres, chemically modified cellulosic fibres, pectin fibres, alginate fibres, chitosan fibres, hyaluronic acid fibres, or other polysaccharide fibres or fibres derived from gums. The cellulosic fibres preferably have a degree of substitution of at least 0.05 carboxymethyl groups per glucose unit. The gel forming fibres preferably have an absorbency of at least 2 grams 0.9% saline solution per gram of fibre (as measured by the free swell method).

[0014] Preferably the gel forming fibres have an absorbency of at least 10g/g as measured in the free well absorbency method, more preferably between 15g/g and 25g/g.

[0015] The material for instance comprises non gel forming fibres and in particular may comprise lycra or other elastic fibre.

[0016] The material may be in the form of 1, 2 or more metre lengths and be approximately 30cm wide. The lines of stitching may be from 1mm to 10mm apart and preferably from 2mm to 5mm apart. The lines of stitching are typically crocheted and have the appearance of a chain stitch but other stitch patterns may also be used. Preferably, the lines of stitching are made with the fabric under slight tension so that a small amount of elongation of the material is possible. More preferably, the lines of stitching are made in a yarn which contracts on the application of heat. In this way the bandage may be stitch bonded and then heated to contract the stitching. The bandage thus becomes slightly puckered which enables the bandage to elongate on application to the patient giving the advantage of close conformity with the wound. In general, elongation is is limited to around 30% as it is not intended to apply compression with the bandage.

[0017] The bandage may comprise one or more medicaments. For example an antimicrobial agent, or an antibiotic, or an anaesthetic on an anti-inflammatory agent or a skin protective agent or an odour absorbing agent.

[0018] Carboxymethylation can be achieved, for example, by sequential or simultaneous treatment of the cellulosic material with a strong alkali, such as aqueous sodium hydroxide, and monochloroacetic acid or a salt thereof. The appropriate reaction conditions will depend upon the composition of the fabric and the degree of carboxymethylation required and will be readily apparent to the person skilled in the art. They may be identical or similar to those described in WO 93/12275, WO 94/16746 or WO 00/01425 to which the reader is directed for further detail.

[0019] Desirably the carboxymethylation is carried out in the presence of industrial methylated spirits (IMS), and IMS is preferably also used in a subsequent washing step, suitably along with water, as a cleaner and steriliser. The degree of carboxymethylation is desirably such that upon absorption of exudate the fibres at the skin-contacting surface of the bandage form a gel.

[0020] In a further aspect the invention provides a method of manufacturing a material as defined in claim 1 for use as a wound dressing characterised in that the method comprises the steps of:

1. (i) forming a roll of fabric comprising gel-forming fibres and
2. (ii) stitching the roll with lines of longitudinal stitching.

[0021] Such a material is suitable for forming three dimensional garments preferably for use in the treatment of burns. We have found that it is possible to cut shapes from the material and join those shapes together by stitching to form a three dimensional garment such as a glove for burns to the hand. An advantage of such garments is that they do not suffer contraction on gelling to the degree of known materials and thus do not constrict the burnt area. As it is possible to cut the garment, it can be tailored to the patient's needs. For example with a glove, some of the fingers can be removed to allow visual inspection of the patient's fingers.

[0022] In a further aspect the invention provides a three dimensional garment formed from a material in the form of a roll, the roll comprising gel forming fibres, the material having lines of longitudinal stitching.

[0023] We have also found that it is possible to cut lengths of the roll material and join those lengths together along their longitudinal edges for example by stitching, to increase the width of the material. Preferably the lengths are overlapped slightly

along their long edge and joined by stitching. In this way a flat seam is made which does not irritate the wound. Joining lengths together allows relatively large shapes to be cut from the material, for example the parts needed to make a vest to cover the torso of a patient with burns to the chest.

[0024] Preferred embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 not part od the invention is a view of a bandage made from knitted gel forming fibres; and

Figure 2 is a view of a bandage made from non woven gel forming fibres.

[0025] Figure 1 shows a knitted bandage incorporating lycra in the knit to give elongation. The stitch bonding can be seen in the form of lines of stitches along the length of the bandage.

[0026] Figure 2 shows a non woven bandage made by forming a web of Lyocell which is then either hydroentangled or needlefelted. The web is then carboxymethylated by sequential or simultaneous treatment of the cellulosic material with a strong alkali, monochloroacetic acid or a salt thereof, and then stitch bonded to give elongation and strength to the bandage. Optionally the bandage can have an antimicrobial material incorporated into it and in particular silver by the method described in WO 02/43743.

[0027] Preferred embodiments of the invention will now be described with reference to the following examples:

Example 1

[0028] A material in the form of a roll was made as described for the bandage of Figure 2. A roll was also made in the same manner except that the stitch bonding was omitted. A dressing was cut from each roll of size 8cm X 8cm and each was wetted with 7.5mls of water. The gelled dressings were then measured to give the results below.

	Stitched Dressing	Unstitched Dressing
	cm^2	cm^2
Dry	64	64
Wet	56.2	46.9

[0029] These results show the contraction of a dressing made from a small , unstitched quantity of material. The dressing made from stitched material suffered far less contraction.

Example 2

[0030] A roll of material was made by the method described for the material of Figure 2 above. The roll of material was 20cm wide and was cut into lengths 40cm long. Those lengths were joined together at their long edges by overlapping the edges and stitching through both thicknesses. Shapes suitable for making garments were then cut from the material and sewn together to make three dimensional garments such as gloves, vests and face masks particularly for use on burns.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US5807295A [0001]
- WO9846818A [0001]
- WO9312275A [0002] [0018]
- WO9416746A [0002] [0018]
- WO0001425A [0002] [0018]
- WO0243743A [0026]

PATENTKRAV

1. Materiale til anvendelse som en sårforbinding, hvilket materiale er i form af en rulle og omfatter geldannende fibre, kendetegnet ved, at de geldannende fibre er i form af en ikke-vævet måtte og materialet har langsgående stikningslinjer fremstillet i nylon eller polyolefingarn.

2. Sårforbindingsmateriale ifølge krav 1 i form af en bandage omfattende geldannende fibre, kendetegnet ved, at bandagen har langsgående stikningslinjer fremstillet i nylon eller polyolefingarn.

3. Materiale ifølge krav 1 eller krav 2 kendetegnet ved, at de langsgående stikningslinjer har en afstand på 1 mm til 10 mm og er parallelle med en lang kant af materialet.

4. Materiale ifølge et hvilket som helst af de foregående krav kendetegnet ved, at de geldannende fibre er udvalgt fra gruppen af spundne cellulosefibre, kemisk modificerede cellulosefibre, pectinfibre, alginatfibre, chitosanfibre, hyaluronsyrefibre og andre polysaccharidfibre og fibre afledt af gummi.

5. Materiale ifølge et hvilket som helst af de foregående krav kendetegnet ved, at materialet har en maksimal strækning på 30 % som målt ifølge ISO 9073-3.

6. Materiale ifølge et hvilket som helst af de foregående krav kendetegnet ved, at materialet omfatter mere end ét lag, hvor laget i sårkontakt omfatter geldannende fibre.

7. Materiale ifølge et hvilket som helst af de foregående krav kendetegnet ved, at stikningen går gennem hele materialets tykkelse.

8. Fremgangsmåde til fremstilling af materialet ifølge krav 1 til anvendelse som en sårforbinding kendetegnet ved, at fremgangsmåden omfatter følgende trin:
(i) dannelse af en rulle stof omfattende geldannende fibre;
(ii) stikning af rulle med langsgående stikningslinjer.

9. Fremgangsmåde ifølge krav 8 kendetegnet ved, at den ikke-vævede bane er fremstillet ved hydrosammenfiltring af en bane af Lyocell-fibre og carboxymethylering af den således dannede bane.

10. Fremgangsmåde ifølge krav 9 kendetegnet ved, at fremgangsmåden omfatter det yderligere trin med behandling af bandagen med en sølvkilde for at give bandagen antimikrobielle egenskaber.

11. Fremgangsmåde ifølge et hvilket som helst af de foregående krav kendetegnet ved, at stikningen er fremstillet i et varmefølsomt garn og bandagen opvarmes efter stikning.

12. Fremgangsmåde ifølge krav 8 kendetegnet ved, at fremgangsmåden omfatter følgende yderligere trin:
(iii) skæring af længder fra rullen og
(iv) samling af længderne med hinanden langs deres kanter for at øge materialets bredde.

13. Fremgangsmåde ifølge et hvilket som helst af de foregående krav kendetegnet ved, at fremgangsmåden omfatter det yderligere trin med skæring af former fra rullen.

14. Fremgangsmåde ifølge krav 13 kendetegnet ved, at fremgangsmåden omfatter det yderligere trin med samling af formerne med hinanden for at danne et tredimensionelt klædningsstykke.

15. Anvendelse af et materiale ifølge krav 1 i fremstillingen af et tredimensionelt klædningsstykke, hvor materialet er til anvendelse i behandlingen af forbrændinger.

16. Anvendelse af et materiale ifølge krav 1 i fremstillingen af en sårforbinding, til anvendelse i behandlingen af forbrændinger.

DRAWINGS

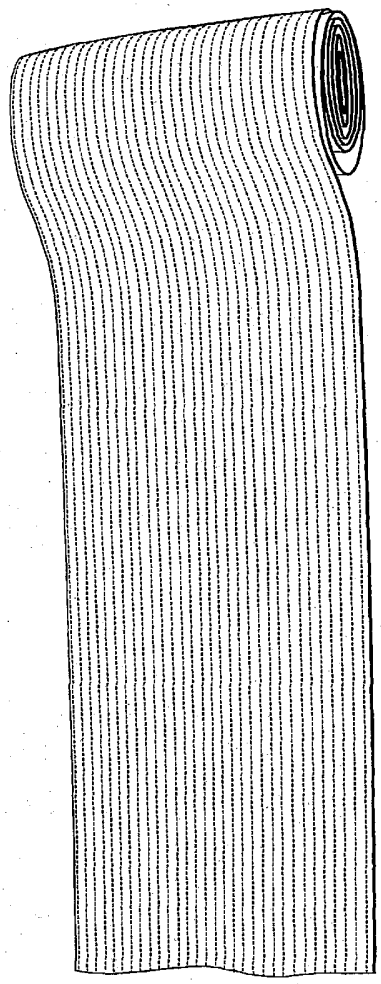

Fig.1

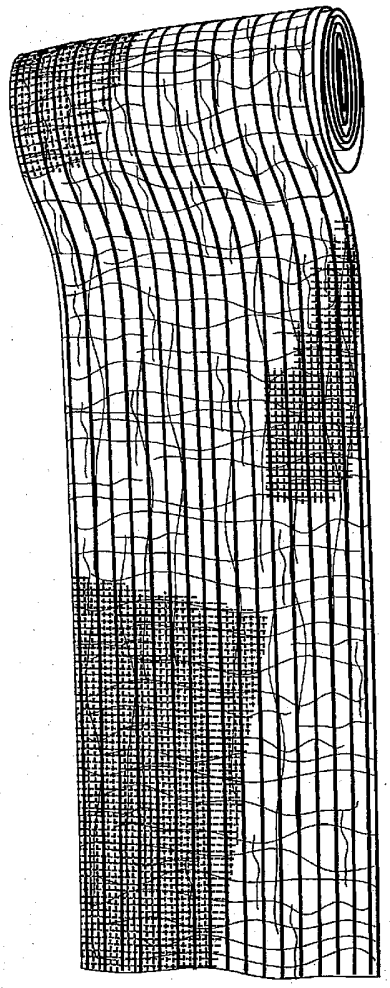

Fig.2