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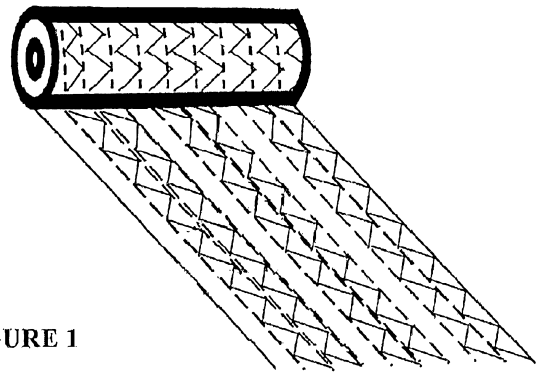

FIGURE 1

(57) Abstract: A wound dressing comprising a layer in the form of a strip and comprising gel forming fibres, the strip having longitudinal lines of stitches formed from a thread and transverse lines of stitches formed from a thread.

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WOUND DRESSING

This invention relates to a wound dressing, in particular to ribbon or strip dressing of the type composed of gel forming fibres in the form of a woven or non woven layer or layers. In particular the invention relates to dressings comprising gel forming fibres used in the treatment of sinus or cavity wounds or post-operative wounds.

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.

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 sinus or cavity wounds due to difficulty in removing the dressing from such a wound. The gel-forming fibres gel on absorption of exudate and consequently lose tensile strength once in a gelled state. This presents a problem when the dressing needs to be removed as removal generally is done by pulling the ribbon out of the wound from one end of the ribbon. The loss of tensile strength means that the dressing fragments on removal and has to be removed in many pieces or by flushing.

However it would be desirable to bring the advantages of gel forming fibre dressings to cavity wounds by having the dressings available in a

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strip form with sufficient tensile strength to enable the dressing to be removed in one piece from the wound once it has gelled and to be removed in one piece regardless of which part of the dressing is grasped in the removal.

It is known to form ribbon dressings with a reinforcing scrim in order to improve the tensile strength of the dressing. There are however disadvantages in doing so. The scrim detracts from the absorbency of the dressing and can create a physical barrier to absorption. The scrim also renders the dressing opaque which means that the wound and surrounding skin cannot be observed once the dressing is in situ.

It is known to increase the tensile strength of bandages by stitching the bandage along its length with one or more lines of stitching. However when longitudinal stitching is applied to a thin strip it gives strength only in the stitching direction and restricts how the dressing can be removed.

The discussion of the background to the invention included herein including reference to documents, acts, materials, devices, articles and the like is included to explain the context of the present invention. This is not to be taken as an admission or a suggestion that any of the material referred to was published, known or part of the common general knowledge in Australia or in any other country as at the priority date of any of the claims.

It would be desirable that the present invention provides an improved wound dressings which mitigates the problems associated with ribbon dressings in cavity or sinus wounds.

We have now found that it is possible to improve the tensile strength of strip dressings in a dry or wet (gelled) state.

Viewed from one aspect, the invention provides a wound dressing comprising a layer in the form of a strip and comprising gel forming fibres, the

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strip having longitudinal lines of stitches formed from a thread and transverse lines of stitches formed from a thread, which repeat to form a pattern stitch, wherein the transverse lines of the pattern stitch are made in columns joining at least two longitudinal lines of stitches and the transverse lines of the pattern stitch link the longitudinal lines of stitches to add strength to the dressing in a transverse direction, and wherein the dressing has a wet tensile strength in the transverse direction of at least 4 N/cm.

The longitudinal stitching is longitudinal in that it is generally parallel to the long dimension of the strip.

The transverse stitching is transverse in that it joins the longitudinal lines of stitches together and in some embodiments is generally perpendicular to the long dimension of the strip.

The thread may be a single filament or multiple filament yarn or a staple fibre yarn. The thread can be cellulosic, lycra, nylon, polyester or polyurethane. The thread can be impregnated with an active agent for example with an antimicrobial agent.

Such dressings are suited to treating sinus or cavity wounds, post operative or surgical wounds or any wound that needs to be packed.

The longitudinal stitching preferably passes through the whole thickness of the strip and can be visible on both sides of the strip. The transverse stitching may also pass through the whole thickness of the strip or may be present on one side only of the strip or both.

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 absorption

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).

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.

The dressing may for instance comprise non gel forming fibres and in particular may comprise lycra or other elastic fibre.

The dressing may be in the form of 0.5, 1, 2 or more metre lengths and be approximately 0.5 cm to 10cm wide, preferably from 0.5cm to 5cm wide. The longitudinal lines of stitching may be from 1 mm to 10 mm apart and preferably from 2 mm to 5 mm apart. The lines of longitudinal stitching may be a lock stitch and may typically be crochet or chain stitch but other stitch patterns may also be used. The rows of transverse stitching may be from 1 to 10 mm apart and preferably from 2 to 5 mm apart. The transverse lines of stitches form a pattern stitch. In some embodiments, the transverse lines of stitches may be crocheted or may be a basting stitch between two layers of superposed gel forming fibres. Preferably, the lines of stitching are made in a thread such as Tencel. The transverse stitches serve to link adjacent longitudinal lines of stitches together to add strength to the dressing in a transverse direction. The transverse lines of the pattern stitches are made in columns, which are preferably between pairs of adjacent longitudinal lines of stitches with stitch free gaps between the columns to allow a roll of stitched

gelling fabric to be slit in the gaps. This allows strips to be formed without creating loose ends of transverse stitching at the edges of the strip.

Preferably the transverse lines of the pattern stitch are made in a continuous zig zag between longitudinal lines of stitching. The transverse lines of the pattern stitch can be perpendicular to the longitudinal stitching as in the case of a zig zag castellated pattern or at an angle to it as in a continuous zig zag angled pattern.

The dressing comprises at least two longitudinal lines of stitching joined by the transverse lines of the pattern stitch that runs in a column between the longitudinal lines. This allows the dressing to be slit from a roll with minimal loose ends of thread. More preferably the dressing comprises at least four longitudinal lines of stitching arranged as two or more pairs of lines where the longitudinal lines of stitching in each pair are joined by a transverse line of stitching in the form of a column. This arrangement allows the user to further cut the dressing in the stitch free gap between the pairs of longitudinal lines of stitching to create a narrower ribbon.

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

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.

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.

Viewed from another aspect, the present invention provides a method of manufacturing a wound dressing for use in cavity or sinus wounds, the method comprising the steps of: (i) forming a roll of fabric comprising gel forming fibres; (ii) stitching the roll with longitudinal lines of stitching formed from a thread; (iii) stitching the roll with transverse lines of a pattern stitch from a thread, wherein the transverse lines of the pattern stitch are made in columns joining at least two longitudinal lines of stitches and the transverse lines of the pattern stitch link the longitudinal lines of stitches to add strength to the dressing in a transverse direction; and (iv) slitting the roll in a longitudinal direction between longitudinal lines of stitches; wherein the dressing has a wet tensile strength in the transverse direction of at least 4 N/cm.

The transverse lines of the pattern stitch are made in columns joining the longitudinal lines of stitching, such that stitch free gaps are created between the columns. In this way a ribbon can be slit from the roll in the gaps so that minimal loose ends occur at the edges of the strip which could otherwise be lost into the wound. Preferably the columns of transverse lines of the pattern stitch are secured so that there are no loose threads in the gaps between the columns and the edges of the ribbon or strip have no loose ends. Preferably the columns of transverse lines of the pattern stitch are a continuous line of stitching which zig zags between the longitudinal lines of stitches. In this way the columns have stitch free gaps in the space between the columns which allow the roll to be slit into strips with no loose ends at their edges.

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Preferably the dressing has several pairs of lines of longitudinal stitching with the lines in each pair joined by transverse lines of the pattern stitch in a castellated pattern to create stitch free gaps between adjacent pairs of joined longitudinal lines of stitches. This allows the dressing to be cut into thinner ribbons by the user.

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

Figure 1 is a view of a layer of gel forming fibres in the form of a roll with longitudinal lines of stitching joined by transverse lines of stitching in the form of an angular zig zag prior to slitting.

Figure 2 is a view of a layer of gel forming fibres in the form of a roll with longitudinal lines of stitching and transverse lines of stitching in the form of a castellated pattern prior to slitting.

Figure 1 shows a non woven roll of gel-forming fibres made by a needle felting carding technique to form a web. Optionally the roll can have an antimicrobial material incorporated into it and in particular silver by the method described in WO 02/43743. The roll is stitched in the longitudinal direction with lines of stitching in Tencel yarn. The longitudinal lines of stitches are supplemented by transverse lines of stitching in the form of continuous, angular zig zags which extend between adjacent longitudinal lines of stitches. In this way stitch free gaps are left between columns of longitudinal stitching. The roll is slit in the longitudinal direction in the stitch free gaps to form ribbons.

Figure 2 shows a non woven roll similar to that shown in Figure 1 except that the continuous zig zag of transverse stitches is made in a castellated pattern between the longitudinal lines of stitches and joins them together. The roll is slit in the longitudinal direction in the stitch free gaps to form ribbons.

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

Example 1

Dressing A

A wound dressing was made from a roll of gel forming fibres as described for the dressing of Figure 1. The roll had lines of longitudinal stitching spaced 5mm apart. The column width was 2.5cm. Ribbons were cut from each roll by slitting in a longitudinal direction at the gaps between the columns in the transverse stitching.

Dressing B

An alternative wound dressing was made by superposing two rolls of gel forming fibres as described for Dressing A and stitching as described for Dressing A.

Dressing C

An alternative wound dressing was made by eliminating the transverse stitching of Dressing A.

Dressing D

Was formed from 100gsm Aquacel a non woven dressing made from 20 fibres of carboxy methyl cellulose ex ConvaTec.

Test samples were cut from the stitched rolls to have the dimensions 25mm wide by 100mm long for the wet samples and 25mm wide by 75mm long for the dry samples. The tensile strength of the gelled and dry samples were measured in the longitudinal and transverse direction in the following manner.

Dry Tensile Testing

Samples were conditioned at 20°C ± 2°C and 65% 4RH for a minimum 30

period of 24 hours. The samples were secured in the pneumatic jaws of a Zwick U.T.M. fitted with a 100N load cell. The sample was elongated at a speed of 100mm/min until a 75% reduction in the samples' maximum force was measured.

Wet Tensile Testing

Samples were conditioned at 20°C ± 2°C and 65% ± 4RH for a minimum period of 24 hours. 2ml of a sodium and calcium chloride solution BP was dispensed via a pipette onto the centre of the sample and left for a period of 1 minute. The sample was secured within the pneumatic jaws of a Zwick U.T.M. fitted with a 100N load cell. The sample was elongated at a speed of 100mm/min until a 75% reduction in the samples' maximum force was measured.

The results are given below.

Property	Dry Tensile		Wet Tensile	
Measurement	MD N/cm	TD N/cm	MD N/cm	TD N/cm
Dressing D	5.33	16.19	**0.16**	**0.42**
Dressing B	8.04	20.82	**4.51**	**4.39**
Dressing C	13.51	15.75	**8.00**	**0.44**
Dressing A	12.19	30.78	**8.05**	**4.45**

These results show the improvement in tensile strength in transverse

stitched samples.

Example 2

Dressing A was used to pack a tracking wound. On removal from the wound the ribbon dressing was fully hydrated with wound fluid yet had maintained its structure. The dressing was easily removed from the wound in one piece.

Where the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the presence of one or more other features, integers, steps or components, or group thereof.

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The claims defining the invention are as follows:

1. A wound dressing comprising a layer in the form of a strip and comprising gel forming fibres, the strip having longitudinal lines of stitches formed from a thread and transverse lines of stitches formed from a thread, which repeat to form a pattern stitch, wherein the transverse lines of the pattern stitch are made in columns joining at least two longitudinal lines of stitches and the transverse lines of the pattern stitch link the longitudinal lines of stitches to add strength to the dressing in a transverse direction, and wherein the dressing has a wet tensile strength in the transverse direction of at least 4 N/cm.

2. The wound dressing of claim 1 for use in cavity wounds or sinus wounds.

3. The wound dressing as claimed in claim 1 or claim 2 wherein the longitudinal lines of stitching are from 1 mm to 10 mm apart and are parallel to a long edge of the strip.

4. The wound dressing as claimed in any one of the preceding claims wherein the dressing comprises a second strip, superposed over the first strip, and wherein the longitudinal lines of stitches join the two strips together.

5. The wound dressing as claimed in any one of the preceding claims wherein the transverse lines of the pattern stitch are stitched through the strip.

6. The wound dressing as claimed in any one of the preceding claims wherein the gel forming fibres are selected from a group including: spun cellulose fibres, chemically modified cellulosic fibres, pectin fibres, alginate

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fibres, chitosan fibres, hyaluronic acid fibres, other polysaccharide fibres and fibres derived from gums.

7. The wound dressing as claimed in any one of the preceding claims wherein the thread is selected from a group including: nylon, Tencel, polyolefin, polyurethane, polyester and cellulosic.

8. The wound dressing as claimed in any one of the preceding claims wherein the transverse lines of the pattern stitch are finished at the edges of the strip to reduce fraying.

9. The wound dressing as claimed in any one of the preceding claims wherein the transverse lines of the pattern stitch are in the form of a continuous zig zag that extends in columns between the longitudinal lines of stitching.

10. The wound dressing as claimed in any one of the preceding claims wherein the dressing is used as part of a composite dressing.

11. The wound dressing as claimed in any one of the preceding claims wherein the dressing comprises at least two longitudinal lines of stitching.

12. A method of manufacturing a wound dressing for use in cavity or sinus wounds, the method comprising the steps of:

(i) forming a roll of fabric comprising gel forming fibres;

(ii) stitching the roll with longitudinal lines of stitching formed from a thread;

(iii) stitching the roll with transverse lines of a pattern stitch from a thread, wherein the transverse lines of the pattern stitch are made in columns joining at least two longitudinal lines of stitches and the transverse lines of the pattern stitch link the longitudinal lines of stitches to add strength to the dressing in a transverse direction; and

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(iv) slitting the roll in a longitudinal direction between longitudinal lines of stitches;

wherein the dressing has a wet tensile strength in the transverse direction of at least 4 N/cm.

13. The method as claimed in claim 12 wherein the roll of fabric is formed by making a non woven web of gel forming fibres.

14. The method as claimed in claim 12 wherein the roll of fabric is formed by knitting a roll of gel forming fibres.

15. The method as claimed in claim 13 wherein the non woven web is made by hydroentangling a web of Lyocell fibres and carboxymethylating the so formed web.

16. The method as claimed in any one of the preceding claims wherein the method comprises the further step of treating the dressing with a source of silver to give antimicrobial properties to the dressing.

17. The method as claimed in any one of the preceding claims wherein the roll has a width and the transverse lines of the pattern stitch are made in columns less than the width of the roll.

18. The method as claimed in claim 17 wherein the roll has longitudinal edges and is slit between the columns of transverse lines of the pattern stitch so that the dressing has no loose thread from the transverse lines of the pattern stitch at its longitudinal edges.

19. The wound dressing as claimed in any one of the preceding claims, wherein the wound dressing has longitudinal edges and is slit between the columns of transverse lines of the pattern stitch so that the dressing has no loose thread from the transverse lines of the pattern stitch at its

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longitudinal edges.

20. A wound dressing or method for manufacturing a wound dressing, substantially as hereinbefore described with reference to any one of the embodiments illustrated in the accompanying drawings.

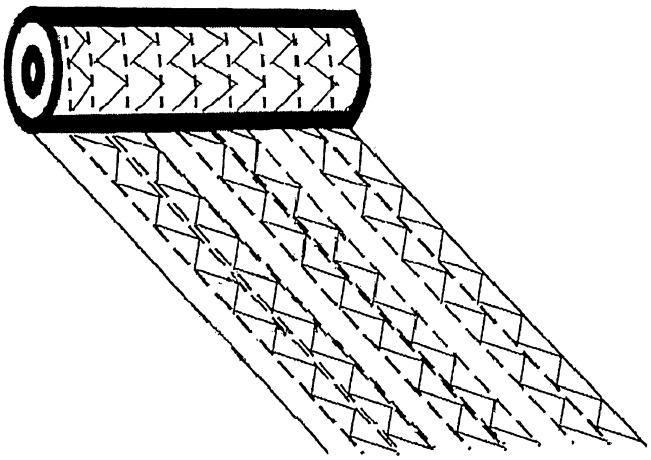

FIGURE 1

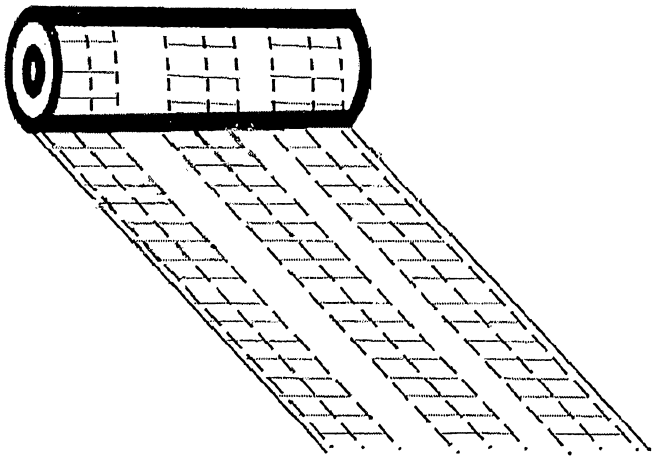

FIGURE 2