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(54) **WOUND DRESSING COMPRISING AN ANTIMICROBIAL COMPOSITION**

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(57) **ABSTRACT**

Methods, processes and compositions are provided for improved wound dressings comprising an antimicrobial composition. The wound dressings maintain conformability and strength, as well as antimicrobial performance, upon use after storage.

WOUND DRESSING COMPRISING AN ANTIMICROBIAL COMPOSITION

CROSS-REFERENCE

[0001] This application claims the benefit of priority of GB 1308770.5, filed May 15, 2013, which is herein incorporated by reference in its entirety.

BACKGROUND

[0002] This invention relates wound dressings which comprise an antimicrobial composition where the dressing can be applied to skin, wounds, cuts, abrasions or burns for the prevention or treatment of infections. More particularly the invention relates to a dressing capable of providing effective antimicrobial activity while at the same time avoiding wound and skin irritation and retardation of wound healing. In particular the invention relates to a dressing comprising chemically modified cellulosic fibres comprising an antimicrobial composition where the dressing properties are not compromised by the addition of the antimicrobial composition.

[0003] Overuse of antibiotics and the associated increase in bacterial resistance is impacting the efficacy of antibiotics in the treatment of wound infection. Effective alternatives to antibiotics are thus desirable.

[0004] Topical antimicrobial materials and preparations containing them have long been recognised as playing an important part in minimising the opportunity for skin and wound infections. Non-antibiotic antimicrobials are non-selective chemical agents that can be safe to use on living tissue. Molecular iodine, ionic silver and oxidising agents such as sodium hypochlorite and chlorine dioxide have been recognised as antimicrobial agents with effectiveness against a wide range of micro-organisms. There are however several barriers to making an effective antimicrobial composition for application to wounds based on such agents. One barrier is that these antimicrobial agents tend to react with organic materials found in the wound other than the intended microbial targets. This means that to be effective, antimicrobial agents need to be included in treatment compositions at high levels, which may cause undesirable side effects with prolonged use such as cell toxicity, hypersensitivity reactions, skin staining and systemic effects. Such side effects are further described in "In vitro cytotoxity of silver: implication for clinical wound care". Poon V K, Burd A. Burns. 2004 March; 30(2):140-7, "A review of iodine toxicity reports". Pennington J A. J Am Diet Assoc. 1990 November;90(11):1571-81 and "Topical antimicrobial toxicity". Lineaweaver W, Howard R, Soucy D, McMorris S, Freeman J, Crain C, Robertson J, Rumley T. Arch Surg. 1985 March;120(3):267-70.

[0005] A further barrier is in the delivery of the antimicrobial composition to the wound. If the composition is to be delivered from a wound dressing, it is preferable that the dressing be sufficiently usable such that the antimicrobial wound dressing is conformable, in its dry state, so that a close contact between the wound bed and the dressing is obtained, that the antimicrobial wound dressing maintain its form and structure upon storage and that sufficient strength is maintained in the dressing. If the dressing is stiff, it is possible that not only will the dressing not conform to the wound site on the patient but also will not conform to the contour of the wound bed. In that circumstance, voids can exist between the dressing and the wound which allow bacteria to grow. If large enough, those voids will not be closed even when the dressing is hydrated (on absorbtion of exudate) allowing the spread of bacteria under the dressing. Dry conformability in the dressing is therefore desirable as is close contouring of the dressing to the wound when hydrated. Jones, S A, Bowler P G, Walker, M., "Antimicrobial activity of silver-containing dressings is influenced by dressing conformability with a wound surface" Wounds 17:263-270 (2005); Bowler, P., Jones, S., Towers, V., Booth, R., Parsons, D., Walker, M., "Dressing conformability and silver-containing wound dressings" Wounds U.K. 6:14-20 (2010).

[0006] There is also a need for a means to make treatment compositions effective without simply increasing the level of antimicrobial agent included in the composition. It has also been recognised that wound bacteria often exist in biofilms and that these are more difficult to treat than their planktonic counterparts.

SUMMARY/DETAILED DESCRIPTION OF THE INVENTION

[0007] It is known to increase the effectiveness of antimicrobial metal ions by including a quaternary cationic surfactant in the formulation. WO 2012/136968 discloses an antimicrobial composition suitable for use on skin and wounds comprising a source of antimicrobial metal ion and a quaternary cationic surfactant.

[0008] The presence of the quaternary cationic surfactant enhances the effect of the antimicrobial metal ion so that the performance of the antimicrobial metal ion is improved. For instance the presence of the quaternary cationic surfactant can increase the rate at which the antimicrobial metal ion exerts its antimicrobial effect. The composition preferably also comprises ethylenediaminetetra-acetic acid (EDTA). EDTA is preferably present as the di-, tri- or tetra-basic salts of EDTA. We have found that these salts enhance the antimicrobial effect of the ionic metal in disrupting biofilm.

[0009] While the presence of the quaternary cationic surfactant enhances the effect of the antimicrobial metal ion, when that metal ion is being applied to a wound from a wound dressing, the presence of the surfactant can affect the drying properties of the dressing so that dressing performance is affected and the wound dressing is sufficiently usable. Treatment with a quaternary cationic surfactant can especially affect the rate of drying of the dressing, increasing it so that the resulting dressing is stiff and does not conform well to the wound.

[0010] It is known to make wound dressings from chemically modified cellulosic fibres. For instance GB-A-2220881 and GB-A-2094802 describe the production of carboxymethylcellulose fibres from regenerated cellulose fibres (viscose rayon) fibres or from cotton. It is also known that carboxymethylcellulose fibre of greater absorbency and strength can be produced from solvent-spun cellulose fibre. Such fibres are described in EP 0616650 and are manufactured by reacting solvent spun cellulose fibre with a strong alkali and a monochloroacetic reagent. It is also known that alternative chemical modification of cellulose fibres is possible and also has the effect of increasing the absorbency of the cellulose fibre. The cellulose fibre can for instance be modified by sulphonation, for example by substitution with an alkyl sulphonate at one or more of the hydroxyl groups on the anhydroglucose monomers that make up the cellulose backbone forming ether linkages. Modified cellulose of this type is

known as cellulose sulphonate or cellulose alkyl sulphonate some of the insoluble forms of which are described in WO2012/061225.

[0011] Modifying the cellulose fibre requires the fibre to be exposed to one or more reagents which modify the cellulose by substitution, the degree of substitution determining the absorbency and solubility of the fibre.

[0012] Once the modification has taken place, the fibres are washed to remove any unreacted alkali, chloroacetate, alkylsulphonate, other modifying agent or any by-products such as sodium chloride or sodium glycollate. An aqueous wash is generally used initially, preferably a mixture of water with a water-miscible organic solvent such as water and IMS (industrial methylated spirit), the major portion of the wash being organic solvent. After washing, the fibres can be treated with the antimicrobial composition including an antimicrobial metal in a manner such as those described in EP1318842, EP1425050, EP1882482, EP1343510 or EP2262545.

[0013] Following this the fibres are dried at low temperature for instance as described in EP 0680344, by forced air drying or radiant heat drying.

[0014] As the washing step or steps and the treatment steps, to which the fibres are subjected following modification, involve the use of relatively high percentages of organic solvents such as IMS, the drying of the fibres requires the solvents that are released to be managed from an environmental and safety perspective.

[0015] We have also found that the treating modified cellulose fibres with an antimicrobial composition comprising a cationic surfactant can result in fibres that have different drying characteristics than untreated fibres, and lead to decreased usability of the resulting wound dressing. For instance, for fibres with an increased rate and/or extent of drying insufficient moisture can lead to embrittlement which in turn leads to fibre breakage on opening, carding and needling and the formation of dust. The subsequent reduced length staple fibre may then produce a weaker and lighter fabric with less loft, and lower absorbency. More importantly, the conformability of the dressing can be affected which itself can lead to poor antimicrobial performance as the dressing is not in close contact with the wound.

[0016] We have now found that it is possible to mitigate the problem of decreased usability, such as a lack or decrease of conformability of wound dressings comprising modified cellulosic fibres treated with an antimicrobial composition comprising a quaternary ammonium surfactant by controlling the moisture content of the wound dressing at the time of packaging and maintaining that moisture content in the dressing until the time of use.

[0017] Accordingly, the invention provides a wound dressing comprising modified cellulosic fibres treated with an antimicrobial composition comprising a source of an antimicrobial metal ion and a quaternary cationic surfactant, the dressing having a moisture content of at least 10% or at least 10.5%, 11%, 12%, 13%, 14% or 15%, more preferably between 10% and 20% by weight at the time of packaging in a sealed package to maintain the moisture content in that range until the time of use of the dressing.

[0018] By the term antimicrobial is meant a substance that inhibits the growth of, or kills, micro-organisms from the taxonomical kingdoms of bacteria, fungi and protozoa. An effective antimicrobial composition is therefore one which is used to reduce and prevent the spread and proliferation of micro-organisms in a specific application. In wound care this can be interpreted in terms of control of cross-infection, prevention or elimination of infection and the reduction of recalcitrant bioburden that can cause delayed healing and chronicity.

[0019] The dressing according to a first aspect of the invention comprises an antimicrobial agent, preferably a metal ion for example the transition metals, antimony, silver, iron, nickel, copper, chromium, manganese, gold, gallium, germanium, mercury, arsenic, aluminium, lead, zinc, bismuth, tin and palladium. Preferably the metal ion is silver. The antimicrobial agent is preferably included in the dressing at a level of from 0.01% to 10% by weight, more preferably 0.1% to 5% and even more preferably 0.5% to 1.5% by weight or 1% to 5%. If the composition is in aqueous solution the antimicrobial metal ion is preferably in an aqueous solution comprising from 0.00001% to 1.0% by weight or more preferably 0.0001% to 0.1%, even more preferably 0.0001% to 0.02% by weight or 0.001% to 1.0% by weight.

[0020] The dressings according to the invention comprise a cationic surfactant. The cationic surfactant can be a quaternary ammonium salt, an alkyl pyridinium salt, an alkyl imidazolium salt, an alkyl morpholinium salt, a benzethonium salt or an ethoxylated quaternary ammonium salt or mixtures thereof. Preferably where the salt is a quaternary ammonium salt, it is selected from the group of monoalkyl trimethyl ammonium salts, dialkyl dimethyl ammonium salts and monoalkyl monobenzyl dimethyl ammonium salts. Preferably the cationic surfactant is a quaternary cationic surfactant and more preferably a quaternary ammonium surfactant. Preferably the cationic surfactant is selected from the group of benzethonium, benzalkonium, dimethyldialkylonium, alkylpyridinium and alkyltrimethylammonium cations with any counter ion, for example: bromide, chloride, acetate or methyl sulphate. Preferably the quaternary cationic surfactant is present at a level of more than or equal to 0.025% by weight, more preferably from 0.05% to 4% by weight and more preferably from 0.1% to 2% by weight.

[0021] The dressing preferably comprises a metal chelating agent, for example a citrate or polyphosphate or ethylenediaminetetra-acetic acid (EDTA). EDTA is preferably present as the di-, tri- or tetra-basic salts of EDTA. We have found that these salts enhance the antimicrobial effect of the ionic metal in disrupting biofilm.

[0022] The pH of the composition is preferably between 4 and 8, more preferably between 4 and 6 and most preferably between 4.5 and 5.5. The desired pH may be achieved by incorporating buffering agents in the composition. Examples of buffering agents which may be included are citric acid/disodium hydrogen phosphate, citric acid/sodium citrate, acetic acid/sodium acetate. The buffering agent may conveniently be present in an amount of about 0.5% to 2% by weight of the composition so as to provide an isotonic composition.

[0023] The antimicrobial compositions may be in the form of a solution which can be used as a spray to be applied to the dressing or a solution dip into which the dressing can be immersed. Preferably the pH of the formulation is buffered at around 5.5 as this does not alter the pH balance of the peri-wound tissue and therefore protects it. EDTA is preferably present in the compositions at a level of 0.1% to 4% by weight of the composition, more preferably less than 2% by weight, more preferably 0.2 to 1% by weight.

[0024] The dressings according to the invention can be made by modifying cellulosic fibres for instance by the methods described in EP 0616650 or WO 2012/061225 to obtain a

fibre which is capable of gelling on the absorption of exudate from the wound. The antimicrobial metallic ion can then be added to the fibres by an ion exchange process in a largely organic solvent followed by washing in an aqueous organic solution which also comprises an optional salt for photostabilising the metallic ion if appropriate and the optional metal chelating agent. The fibre is then washed again in an organic solvent wash and warm air dried. The fibre can then be processed to form a dressing by conventional means. The optional photostabilising agent can be added as described in EP1343510.

[0025] The moisture content of the dressing is between 10% and 20%. Preferably the moisture content of the dressing is between 11% and 18%, more preferably it is between 11.5% and 15% by weight and most preferably it is between 11.5 and 13% by weight. In some embodiments, the moisture content of dressing is at least 10% or at least 10.5%, 11%, 11.5%, 12%, 12.5%, 13%, 13.5%, 14%, 14.5% or 15%. A moisture content of 12% or 12.5% is particularly preferred. The moisture content of the dressing may, amongst other techniques, be measured indirectly by measuring conductivity of the resulting wound dressing. In other embodiments, the moisture content of the dressing may be measured by measuring the loss on drying of the manufactured dressing. In still other embodiments the moisture content may be measured by titration techniques (Karl Fischer) which is done by solvent extraction of the water in the dressing or by oven heating followed by water capture by solvent chemicals. The method of measuring moisture content in a dressing is not limited to the above, but may be accomplished using other techniques and/or by other technologies known in the field.

[0026] The moisture content of the dressings provided herein may be maintained by controlling environmental conditions during manufacturing. For example, cleanrooms may be employed during manufacturing controlling several environmental factors, including air pressure, air flow (including directional flow), air quality (including filtration) and humidity (including room temperature and pressure). All of these environmental factors may contribute to the establishment of the required moisture content of the dressings as disclosed herein. For example, temperature control is typically maintained at 18° C., +2° C., preferably +1° C. Relative humidity is typically maintained at pre-determined levels, including at least at 50% RH, 55% RH, 60% RH, 65% RH, 70% RH, 75% RH, 80% RH, 85% RH +5% RH, and preferably at +3% RH, depending upon the moisture content of the fibre being processed. These environmental factors may also be adjusted against each other in order to achieve the moisture content desired as disclosed herein.

[0027] Moreover, dressings that are further processed (for example, textiled or conditioned) and/or stored are first packaged in moisture impermeable packaging material or film and sealed prior to movement or storage of the dressings. Examples of moisture-impermeable packaging material include polyethylene, aluminium, polyester, mixtures thereof or any other suitable material or mixtures thereof, including a trilaminate film of polyethylene, aluminium foil and a polyester that ensures protection from light, oxygen and moisture transmission.

[0028] In some embodiments, the improvement in usability of wound dressings comprising surfactants as described herein results in the substantial maintenance of conformability as compared to a wound dressing without surfactant present. In other embodiments, the improvement in usability of wound dressings comprising surfactants as described herein results in a measurable improvement in tensile strength as compared to wound dressings with a moisture content of less than 10%. In yet other embodiments, the improvement in usability of wound dressings comprising surfactants as described herein results in a measurable improvement in tensile strength as compared to wound dressings stored at ambient temperature or in zero humidity conditions. In still other embodiments, the improvement in usability of wound dressings comprising surfactants as described herein results in the substantial maintenance of wound dressing structure, including lack of dust formation, as compared to wound dressings stored at ambient temperature or in zero humidity conditions.

EXAMPLES

[0029] The following examples are illustrative of the present invention.

Example 1

[0030] Effect of moisture content on the tensile strength of silver containing wound dressings according to the invention.

[0031] Dressings according to the invention were prepared modification of solvent spun cellulose tow to a degree of substitution of 0.3 to form carboxymethylcellulose, neutralising to a pH of 5.5 with an organic acid. Adding 1.2% cationic silver by an ion exchange process in a largely organic solvent such as by the process described in EP1343510, washing in an aqueous organic solution containing sodium chloride and di-sodium EDTA for light stabilisation and to entrain approximately 0.4% EDTA. Followed by washing in organic solvent wash containing fibre finishing agents including tween 20 and benzethonium chloride (to give 0.135% benzethonium chloride on the finished product). Warm air drying, cutting to staple and processing into a nonwoven felt by carding and a needle punching process. The dressings were cut to size from the felt and packaged in a light, moisture and vapour impermeable heat sealed foil pouch.

[0032] The dressings were removed from the packs and then subjected to various controlled environments.

Controlled Environments

[0033] Ambient as packed, tested without any preconditioning;

[0034] Zero humidity: Stored in a square desiccator with 3 perforated perspex shelves above a layer of silica gel desiccant, conditioned for a minimum of 5 days;

[0035] and the following by storing in humidity controlled rooms (Source Bioscience Ltd.) for a minimum of 6 days:

[0036] 25±2° C./60±5% RH

[0037] 30±2° C./65%±5RH

[0038] 40±2° C./75%±5 RH.

[0039] Samples (ambient as packed) were tested immediately after opening the packs. Samples removed from the other environments were sealed into plastic bags during removal, and then tested immediately. The plastic bags (also preconditioned in corresponding controlled environments) were used to maintain the humidity of the environment of the samples until the point of testing.

Loss on Drying (LOD)

[0040] LOD of the samples was determined using the Ohaus moisture balance MB23 operated in accordance with

the instruction manual. A sample mass of greater than 1 gram was used. Samples were cut to fit within the weighing pan, ensuring there was adequate clearance from the heating element. A standardised method was used with a maximum temperature limit of 110° C. The endpoint was determined automatically when the sample mass stopped reducing and was stable. Under these conditions the fabric did not char. Typically, samples would be subjected to a 10 minute cycle.

Fabric Thickness (Loft)

[0041] Samples were tested using the Hampden Soft Materials Thickness Gauge, Model FMTml-4D, S/N 14082. Fabric thickness (sometimes referred to as loft) was determined for 6 dressings per batch.

Fabric Dry Tensile Strength

[0042] 2.5 cm×7.5 cm rectangular strips were cut from along the length (machine direction) and across the width (transverse direction) using a ribbon cutting die and press. Samples were conditioned as described in the table. The peak force and the extension at which that force occurred were recorded when a 50 mm test length was stretched at a constant separation rate of 100 mm per minute.

Results

[0043]

Relationship between absolute and relative humidity

	Pre-Conditioning				
	Dry	Ambient	25° C./60% RH	30° C./ 65% RH	40° C./ 75% RH
Moisture (g/m^3)	0.00	9.50	13.81	19.71	38.29
Thickness (mm)	0.170	0.190	0.198	0.183	0.202
LOD %	9.28	11.93	14.17	15.27	18.10
Tensile Machine (N/cm)	3.10	5.19	5.80	5.36	7.75
Tensile Transverse (N/cm)	5.15	6.53	11.12	10.23	14.28

[0044] Loss on drying is the summation of all the volatile substances that can be removed by heating at 110° C. These include ethanol, water and to some degree acetic acid.

[0045] It is believed that water is the most critical of these to the successful production of gelling fibre products. Insufficient moisture leads to embrittlement which in turn leads to fibre breakage during fibre processing and the formation of dust. The subsequent reduced length stable fibre can then produce a weaker and lighter fabric with less loft which in turn leads to a lower absorbency product.

[0046] For this particular fibre, for this example, textile trials have shown that fibres for use in wound dressings according to the invention can be successfully textiled between 42% and 50% RH at around 18 to 20° C. Trials suggest that fibres with 10.5% to 11.5% w/w moisture content can be carded efficiently.

[0047] The results show that tensile strength, loft and LOD are all functions of equilibrium moisture content. The results suggest that fibres with a moisture content of greater than 10.5% will be able to be textiled to produce dressings suitable for use in the present invention.

Example 2

[0048] Effect of moisture content on conformability of examples of silver containing wound dressings according to the invention

Materials:

Test Dressings:

[0049] AQUACEL Ag, commercial product, absorbent, gelling, fibrous-felt dressing containing 1.2% w/w ionic silver.

[0050] Lot 1G 00157 5 cm×5 cm

[0051] Lot 1H 03025 10 cm×10 cm

[0052] Lot 1E 02908 15 cm×15 cm

[0053] AQUACEL Ag treated with an antimicrobial composition comprising di-sodium EDTA and benzethonium chloride during the addition of silver to the fibres.

[0054] Lot 1H 01291B 5 cm×5 cm

[0055] Lot 1H 01302B+C 10 cm×10 cm

[0056] Lot 1H 01303D 15 cm×15 cm Lot 1H 01251C+D 20 cm×30 cm

Methods:

[0057] The samples of AQUACEL Ag according to the invention, that is those treated with an antimicrobial composition comprising di-sodium EDTA and benzethonium chloride were produced by the method of example 1.

[0058] The resulting dressings were conditioned in a laboratory environment maintained at an average temperature of 20° C.±2° C. and an average relative humidity of 65% RH±4% for at least 24 hours prior to testing. The dressings had a moisture content as shown below.

[0059] Lot 1H 01291B 5 cm×5 cm LOD 12%

[0060] Lot 1H 01302B+C 10cm×10 cm LOD 11%

[0061] Lot 1H 01303D 15 cm×15 cm LOD 11%

[0062] Lot 1H 01251C+D 20 cm×30 cm LOD 11%

[0063] The AQUACEL Ag dressings were similarly conditioned and packaged.

[0064] Dressing conformability was assessed using a panel of three laboratory staff who were given six samples each of the dressing according to the invention and correspondingly sized AQUACEL Ag as a comparator (or control). They wrapped each dressing around their forearm (in the dry state directly from the packaging) and scored how well each dressing conformed to the shape of the arm using a comparative score based on a five point system.

[0065] (A) much better than the comparator

[0066] (B) better than the comparator

[0067] (C) the same as the comparator

[0068] (D) worse than the comparator

[0069] (E) much worse than the comparator.

[0070] The results are given in the following table.

	Flexibility Score				
Sample Details	A	B	C	D	E
Lot 1H 1302B			6		
Lot 1H 1302C		1	5		
Lot 1H 1302D			6		

[0071] These results show that the dressings according to the invention were either equal to or better than the AQUACEL Ag which is known to have good conformability.

What is claimed is:

1. A packaged wound dressing comprising modified cellulosic fibres treated with an antimicrobial composition comprising a source of an antimicrobial metal ion and a quaternary cationic surfactant, the dressing having a moisture content of between 10% and 20% by weight.

2. A wound dressing as claimed in claim **1** wherein the package maintains the moisture content of the dressing in the range of 10% and 20% until the point of use.

3. A wound dressing as claimed in claim **1** or claim **2** wherein the antimicrobial metal ion is selected from the group of the transition metals but particularly silver, iron, nickel, copper, chromium, manganese, gold, gallium, mercury, lead, aluminium, lead, zinc, bismuth, tin and palladium or combinations thereof.

4. A wound dressing as claimed in any preceding claim wherein the metal ion is silver.

5. A wound dressing as claimed in any preceding claim wherein the metal ion is included in the dressing at a level of from 0.01% to 10% by weight, more preferably 0.1% to 5% and even more preferably 0.5% to 1.5% by weight.

6. A wound dressing as claimed in any preceding claim wherein the quaternary cationic surfactant is a quaternary ammonium surfactant.

7. A wound dressing as claimed in any preceding claim wherein the cationic surfactant is selected from the group of the salts where the cation is benzethonium, benzalkonium, dimethyldiakylonium, alkylpyridinium and alkyltrimethylammonium.

8. A wound dressing as claimed in any preceding claim wherein the dressing further comprises a chelating agent for example, EDTA present as the di-, tri- or tetra-basic salts of EDTA.

9. A wound dressing as claimed in claim **8** wherein the metal chelating agent is present in the dressing at a level of 0.1% to 4% by weight, more preferably less than 2% by weight, more preferably 0.2 to 1% by weight.

10. A wound dressing as claimed in any of the preceding claims wherein the moisture content is between 11% and 18% by weight.

11. A wound dressing as claimed in any of the preceding claims wherein the moisture content is between 11.5% and 15% by weight.

12. A wound dressing as claimed in any of the preceding claims wherein the moisture content is between 11.5% and 13% by weight.

13. A process for preparing the wound dressing as claimed in any of the preceding claims.

14. A method for maintaining conformabilty of a wound dressing comprising providing a wound dressing as claimed in any of claims **1** to **12**.

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