Zinc Ion Embedded Nylon Antimicrobial Technology for Non-Skin Irritation Compression Devices

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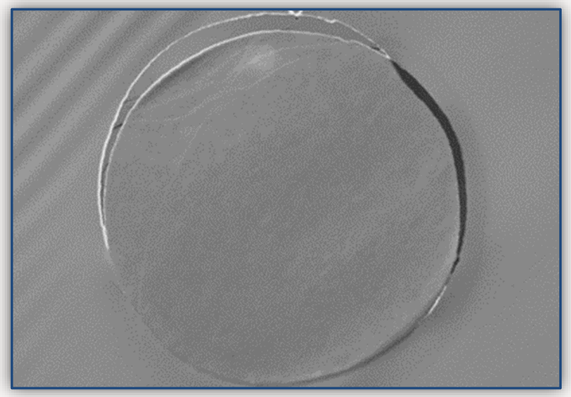
Purpose

Medical compression therapy is commonly used as either first line of defense or treat various stages of venous and lymphatic diseases. However, adverse events and contradictions have been reported related to compression therapy. In a recent review article,[1] these adverse events are categorized as non-severe and severe. Skin irritation, allergic skin reaction, discomfort and pain, forefoot oedema and lymphoedema, bacterial and fungal infection were described as non-severe adverse events. While soft tissue damage or necrosis, nerve damage, arterial impairment, venous thromboembolism, as cardiac decompensation, were described as severe events. Majority of these events were found to be occurring very rarely (<1/10,000 cases), except skin irritation and discomfort & pain which were reported as common incidences (≥1/100 to <1/10). Developing a comfortable and non-skin irritation materials to be used for compression devices could offer solutions to avoid these common adverse effects. A novel polymer based on high performance nylon which incorporates and maintains zinc in its ionic form at molecular level was developed (Fig 1). The polymer was converted into different forms that can be used for different functions in compression devices and were evaluated by dermatologist.

Figure 1: Novel zinc polymer



Materials

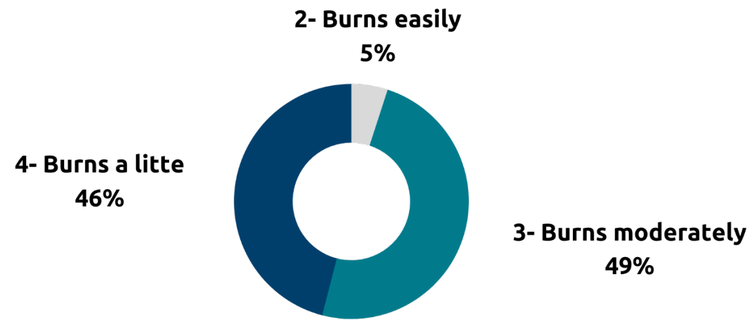
Zinc was introduced during the polymerization of nylon creating a novel zinc polymer. Two circular knits were produced using standard textile manufacturing process using (1) 100% of the yarn from this novel polymer (CK1) and (2) 92% of the yarn from this polymer and 8% Spandex (CK2). A spunbond nonwoven structure (SB) is formed using melt spinning directly from the polymer.

Methods

- Three independent Repeat Insult Patch Test were conducted for these three materials; SB, CK1, and CK2; on 183 humans (male - 30, female – 153) subjects (Fig 2).
- The Fitzpatrick Skin Type assessment[2] was utilized prior evaluation indicating that most of the skin burn moderately and burn a little (Fig 3).
- This protocol was repeated until a series of nine consecutive 24-hour exposures, three times a week for three consecutive weeks.
- Prior to each reapplication, the test sites were evaluated by trained laboratory personnel and results were overseen by a dermatologist.

Figure 2: Picture of circular knit and spunbond made with zinc embedded polymer

Figure 3: Fitzpatrick Skin Type Assessment



Results

100% of subjects scored 0, which is negative or no reaction according to the international Contact Dermatitis Research Group scoring scale[3]. Under the conditions of this study, there was no indication of potential to elicit dermal irritation or sensitization (contact allergy) noted.

Conclusion

Substrates made with novel zinc ion embedded nylon antimicrobial technology were "dermatologically tested". This technology has the potential to reduce the common adverse events associated with compression devices, while providing odor protection and keeping products clean from bacteria. Further study to show significance against a control in a clinical setting is advised.

References:

[1]Rabe, et al. Phlebology, 2020, 35(7), 447-460.
[2]Agache P, et.al. Measuring the skin, Springer-Verlag Berlin Heidelberg, 2004, p473
[3]Rietschel, R.L, et.al. Fisher's Contact Dermatitis 4th ed. Baltimore, Williams & Wilkins, 1995

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