Novel Multi-functional Films as Building Blocks for Advanced Wound Dressings

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Statement of Purpose
The complexity of the wound healing process and the variability of wounds are challenging for medical professionals and advanced wound dressing (AWD) designers. There is no “universal” dressing that can be used to treat all wounds, however AWDS utilize specific core characteristics in order to better manage wounds, such as maintaining optimal moisture balance, allowing gaseous exchange, conformability, and microbial protection. Moreover, recent advances indicate that delivering actives to the wound could significantly reduce bioburden, promote healing, and manage pain and odor.

We have developed a new class of multifunctional fluid absorbing films using proprietary thermoplastic polyurethane polymer blends that meet the requirements of AWDS. The films can be used alone or as building blocks for more complex dressings. Feasibility of pain and odor management drugs incorporation into films was demonstrated.

Methods
Proprietary thermoplastic polyether polyurethane polymer blends were developed at Lubrizol. Thin films of these polymer blends were prepared by solvent casting in water/organic solvents (e.g., tetrahydrofuran; alcohols). Single and bilayer films were draw down on polyethylene substrates using an automatic film applicator with vacuum plate (Bryo-drive, BYK Gardner, MD, USA) and dried at room temperature (Figure 1). Model drugs for pain management, antibiotics and odor control (Table 1) were incorporated in the polymer mixture at room temperature before solvent casting. Films were removed from the substrate and characterized for free swell absorptive capacity in simulated wound fluid (BS EN 13726-1:2002), dry film tensile strength, dry film % elongation (ASTM D882-12) and MVTR (Mocon® Permatran-W® 101K, Mocon Inc., MN, USA).

Mechanical properties of the hydrated films were measured using a texture analyzer (TA.XT plus, Texture Technologies Corp. and Stable Micro Systems Ltd., MA, USA) according to an in-house developed test.

For comparison, films from polyurethane polymers (PU1* and PU2*) used in commercial film dressings (www.lubrizol.com/medical) were prepared by a similar procedure. Polymer prototypes were also prepared by solvent cast. The bi-layer composite maintains the fluid absorbing capacity of the thin film dressing and a layer of the novel fluid absorbing component were also prepared by solvent cast. The bi-layer composite maintains the fluid absorbing capacity of the single layer hydrating film and a MVTR ranging from 3000 – 4000 g/(m² x day) as measured with a Mocon® Permatran-W® 101K, Mocon, Inc. The bilayer construct maintains integrity and does not de-laminate even when exposed to excess solution A for prolonged time.

Feasibility of pain, antibiotic and odor management drugs incorporation into the films was demonstrated. The drugs were incorporated at room temperature during the solvent casting process. Table 1 shows examples of drugs and level of drug incorporation into the films. Using methods well established in the Pharmaceutical Industry (USP dissolution Apparatus 5 or Immersion cell apparatus) we have demonstrated the release profile of drugs from the films. For example, the in-vitro release of ibuprofen from a 3.5 mil/88.9 microns ibuprofen/MPD00484A film using two different membranes demonstrates the potential use of these films for slowly releasing a pain management drug in a wound environment (Figure 6).

Conclusions
• Proprietary multifunctional, thin films with fluid absorption and high MVTR have been developed for applications in wound care.
• Fluid absorption, mechanical strength of the dry and hydrated film, as well as MVTR, can be dialed-in by adjusting the composition of the films.
• The newly developed films were incorporated in bilayer constructs to include bacterial/viral protection, while keeping absorptive and MVTR properties.
• Drug incorporation in developed films was demonstrated. Controlled release of drug from transparent, drug loaded films was demonstrated in-vitro.
• Innovative technology allows building in desired properties to design wound dressing films for a wide range of applications:
  • Multi-layer film composite with unique fluid absorption/MVTR
  • Drug loading and controlled drug delivery at the wound site.

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Footnote
* PU1 - Pellethane® 5863-90A; PU2 - Pellethane® 5863-80A, Lubrizol, USA.
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