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

Lubrizol LifeSciences
Polymers | Formulation | Manufacturing

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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 (Byko-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 were prepared by a similar procedure.

Drug assays and in-vitro drug release were performed using accepted pharmaceutical protocols (USP Dissolution Apparatus 5; Immersion cell apparatus; see USP 38 - NF 33 General Chapters <724> and <1724>).

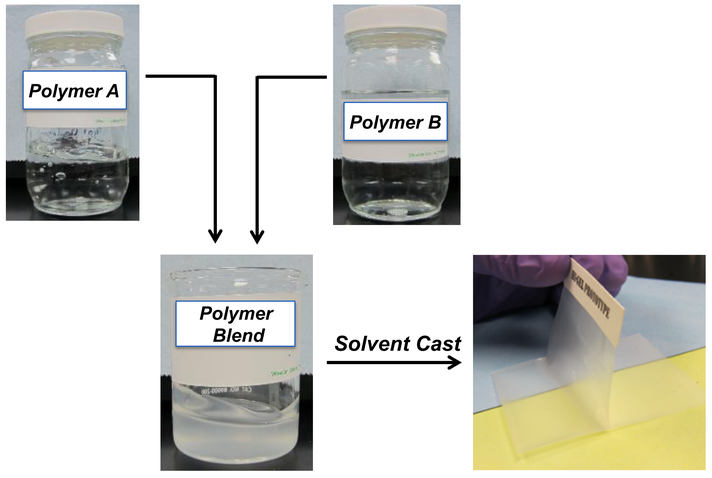


*Figure 1. Preparation of high absorption/high breathability films for wound dressing*

## Results

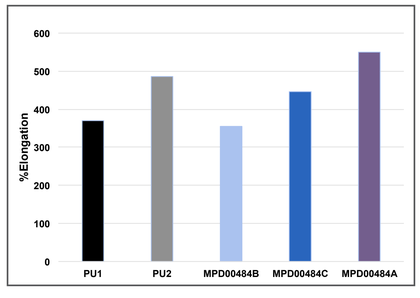


*Figure 2. %Elongation of novel polymer prototype films as compared with polymer films used in commercial film dressings*

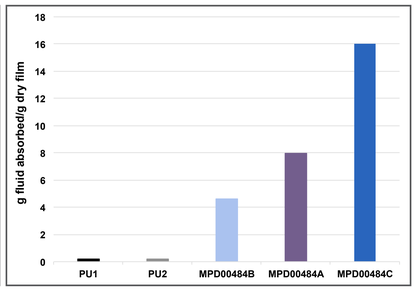


*Figure 3. Fluid absorbance of novel polymer prototype films as compared with polymer films used in commercial film dressings*

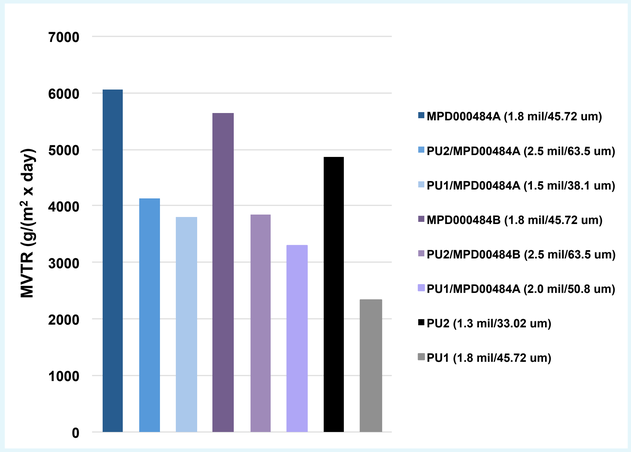


*Figure 4. MVTR for single layer MPD00484A & MPD00484B and bilayer films consisting of a backing layer (a polyurethane used in commercial film dressings) and MPD00484A and MPD00484B as a fluid absorbing component*

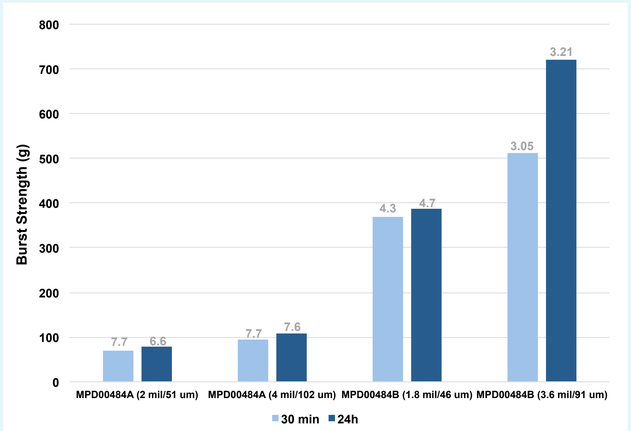


*Figure 5. Strength of hydrated single layer film prototype*

Table 1. Drug loading into prototype films – proof of concept

| Conditions associated with chronic wounds | Drugs incorporated in prototypes by a *solvent cast* process mg drug/g composite film |
|---|---|
| *Pain* | *Ibuprofen – 138 mg/g* |
| | *Lidocaine – 47.6 mg/g*<br>*Lidocaine HCl – 44.8 mg/g* |
| *Infection* | *Metronidazole# – 9.2 mg/g and 50 mg/g* |
| *Odor* | |

*#Metronidazole – antibiotic used for anaerobic bacteria and protozoa. Clinical data support use of topical metronidazole to decrease/eliminate odor and wound exudate in malignant fungating wounds and palliative care.*

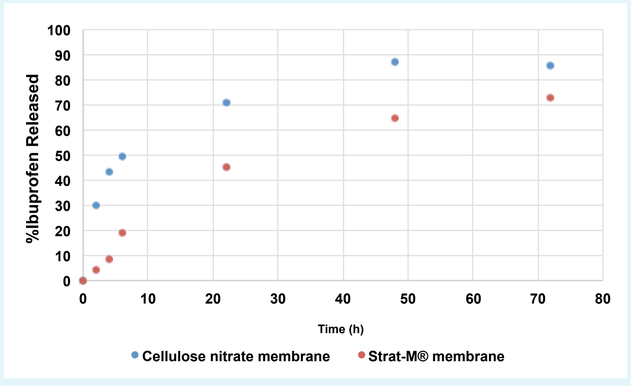


*Figure 6. Ibuprofen release from Ibuprofen loaded MPD00484A films (3.5 mil/88.9 microns). Films contain 138 mg Ibuprofen/g film composite.*

*Method: Immersion cells apparatus; 100 mL phosphate buffer saline pH 7.4; 32.5 °C).*

## Discussions

Thin films of proprietary polyurethane blends of approximately 1 - 5 mil thickness with fluid absorbing properties and high MVTR were developed by a solvent casting process. The films under study were chosen to demonstrate the range and combination of properties that can be built in, and to demonstrate a wide range of possible applications in the design of multifunctional wound dressings. Figures 2, 3 and 4 illustrate the properties of three film prototypes (MPD00484A, MPD00484B and MPD00484C), developed in our laboratory, in comparison with films prepared from polyurethane polymers used in commercial film dressings. The developed films in dry state have similar mechanical properties (e.g., % Elongation of 300-400) and exhibit more than twice the MVTR when compared with films prepared from polyurethane polymers used in commercial film dressings (PU1 and PU2). The increase in MVTR of the novel films is significant. These films allow more transmission of moisture through the dressing, which is critical to the overall fluid handling capacity of the thin film dressing.

The great benefit built in the developed films is the fluid uptake, which ranges from 400% - 3000% (referenced to dry film weight). Hydrated films of MPD00484A and MPD00484B have good mechanical strength as illustrated by values of measured burst strength ranging from 70 – 700 g (Figure 5). The strength of the hydrated films is related with the amount of fluid absorbed, however the composition and chemistry of the polymers plays a significant role. Solvent cast films prepared from polyurethane polymers used in commercial wound dressings do not have significant fluid absorption (Figure 3).

Bi-layer films consisting of a backing layer (a polyurethane used in commercial film wound dressings e.g., PU1 or PU2) 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 incorporated 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 transparent, 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 bi-layer 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.

## Acknowledgements

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## Footnote

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