Highly Compliant Drug Eluting Absorbable Spray Bandage - An Initial Report

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Statement of Purpose: Liquid bandages were developed to replace rigid bandages used on highly mobile skin surfaces such as knees and elbows. While viscoelastic polymers as skin protectants are not novel, we sought to develop a spray-able liquid gel bandage having the flexibility to adhere and protect often in-congruent skin injuries with the potential for topical delivery of antibiotics and anesthestics. We present a concept that allows for the use of this liquid bandage on flexible surfaces and the release of drugs loaded into the film for therapeutic effects. In addition, the polymer matrix, SVG12 is composed of a biocompatible polyaxial co-polymer and acts as a protectant and/or simple skin approximating agent. Another shortcoming of other liquid bandages is the pain of application. Many use ethyl acetate and alcohols as the volatile solvent which causes burning. The reviewed system does not use ethyl acetate or alcohols which in theory will reduce the pain of application.

Methods: The technology of liquid bandages is based on a polymeric film precipitating from a volatile solvent as the solvent evaporates. SVG12, the polymer chosen for this project, allows for drugs to be loaded into the solution solution and diffuse out of the polymer matrix after application thereby creating a therapeutic effect. MTS tensile strength testing has been performed on multiple film samples of SVG12. These tests allow us to quantify the elasticity of our matrix. Zone of inhibition testing has also been performed that quantify the ability of loaded drugs to diffuse out of the matrix and inhibit the growth of microbes.

Results: The drugs that have proven effective are typically hydrophobic to increase solubility with our hydrophobic solvents and matrix including lidocaine, ciprofloxacin, clindamycin, sulfamethoxazole, trimethoprim, itraconazole, metronidazole, fluconazole, ketoprofen, leflunomide, and ketoconazole. Tensile tests have been performed on multiple film samples of SVG12.

Property	Result
Thickness	0.5 mm
Peak Stress	5.2 MPa
Tensile Modulus	8.9 MPa
Strain at Break	484%

Table I. Mechanical properties of SVG12

The polymeric matrix, SVG12, has been tested for cytotoxicity and has been shown to be compatible with L929 fibroblasts. Inhibition studies have been performed on a number of drug/polymer combinations as a bench-top effectiveness test. One such test (SF61) included the combination of a topical local anesthetic (lidocaine) with Bactrim (sulfamethoxazole and trimethoprim), an antifungal agent (itraconazole) and an antibiotic (metronidazole). Drugs were loaded at clinically-relevant levels, as directed by possible predicate devices. Films were tested in the presence of *Staphylococcus aureus* and *Candida albicans* as a measure of bacterial and fungal efficacy, respectively. Results, as represented in Figures 1 and 2, indicate the drug-loaded film as effective against *S. aureus* and *C. albicans*.

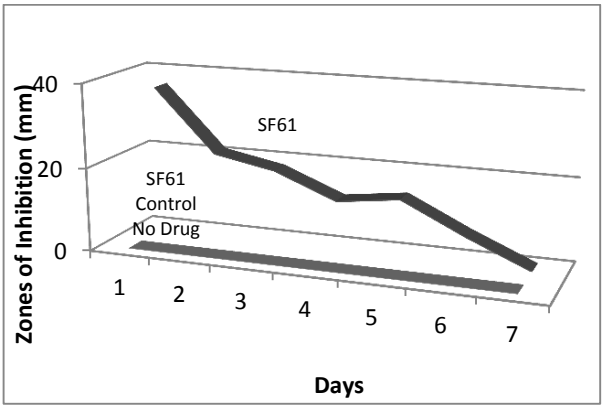

Figure 1. Antibacterial effectiveness of SF61with a zone of inhibition protocol using *Staphylococcus Aureus*.

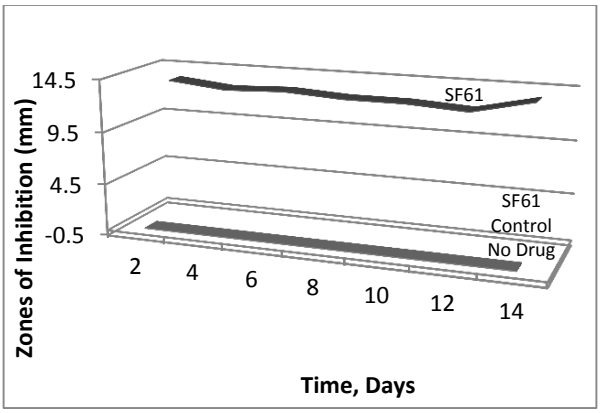

Figure 2. Antifungal effectiveness of SF61with a zone of inhibition protocol using *Candida albicans*.

Conclusions:

This viscoelastic film can stretch to over 400% of its original dimensions before a defect which offers a significant advantage over standard rigid bandages. Based on this example of drug loading, this particular liquid bandage should reduce the number and severity of infections due to topical lacerations or abrasions to human skin. This spray-able film concept is a platform technology that allows for the loading of a wide variety of drugs to meet a desired therapeutic outcomes.

References:

1. US Patent 7,070,858, published 7/4/2006
2. US Patent 6,794,485, published 9/21/2004
3. US Patent 6,462,169, published 10/8/2002
4. US Patent Application 20070077382
5. US Patent Application 61/337295