

***Elasto-Gel™* Risk Analysis**

Sterile Products

(Sterility)

Introduction

Elasto-Gel™ products are formulated with a high glycerine content and a high absorbent polymer base. Glycerine is known to be a bacteriostatic agent and at concentrations of 85% has been shown to be bactericidal and shows antiviral activity¹

Animal Studies and Clinical Results with Elasto-Gel™

Elasto-Gel™ is formulated with a 65% glycerine content and has been shown to be bacteriostatic in a number of laboratory and animal studies.

A laboratory study on a number of common microorganisms was conducted in 1985 by Physiological Research Laboratories/Medtronic, Inc. These microorganisms included the following: Bacteria – Staphylococcus aureus, Streptococcus pyogenes, Streptococcus faecalis, Bacillus subtilis, Bacillus cereus, Pseudomonas aeruginosa, Klebsiella pneumoniae and Escherichia coli. Fungi – Candida albicans, Aspergillus sp., and Penicillium sp. The summary of the results by the investigator of this report² was -- “The material did not support growth of any microbe tested. The material killed 7 of 8 bacteria which are able to survive on inert surfaces. (One organism, streptococcus pyogenes, was able to survive on the inert surface.) The material did not kill Bacillus subtilis. This gram positive rod is capable of forming spores which are resistant to harsh environmental states. The material killed the Candida albicans (yeast) but did not kill the Aspergillus niger (mold). Molds form spores which are more resistant to destruction. The penicillium species failed to grow.”

More recent animal studies conducted in the laboratories of Dr. Bill Eaglestein, Pat Mertz and Steve Davis showed that the total bioburden of burn wounds after 48 hours, which had been inoculated with Pseudomonas aeruginosa at a level of approximately 10^5 , was dramatically reduced. See attached report I. An extended study of burns on an animal again inoculating with Pseudomonas aeruginosa at 10^6 compared ***Elasto-Gel™*** with two other dressings and showed that the number of microorganisms under ***Elasto-Gel™*** was significantly less than the number under the other two dressings when the wounds were examined over a nine-day period. See attached study II. A third study by Mr. Davis, et al³, showed that the growth of five different microorganisms inoculated on blood agar medium was dramatically more inhibited by ***Elasto-Gel™*** than by two other popular wound dressings. These findings are consistent with the clinical observations by numerous doctors and nurses from around the world.

In a study involving 29 patients with diabetic foot ulcers, Jan Vandeputte⁴ applied ***Elasto-Gel™*** to 15 patients and compared them to 14 patients treated with dry gauze and irrigation twice a day with chlorhexidine solution. The patients were randomly assigned the dressing treatment. Patients with diabetic foot ulcers of all types were included, such as infected, neuropathic or necrotic ulcers, and patients with previously amputated toes, but excluded patients who were being treated with systemic antibiotics. This study showed only one patient had an infection in the experimental group (it was badly infected when he started the study), but 7 patients in the control group had infections.

Applications of ***Elasto-Gel™*** to patients with first and second degree burns by R. Anderson and C. Wilkening⁵, showed no evidence of any infection during the healing process, even without using any additional antibiotics or antiseptic solutions. J. Matta⁶ reported that ***Elasto-Gel™***, applied to a wide variety of eschar-covered wounds that could not be surgically debrided gave clean wounds that “healed without amputation, scarring or follow-up corrective surgery that is usually required”. Many infants with special needs, micro-preemies, newborns with birth defects, infants with acute infections and children with graft versus host disease have been treated with ***Elasto-Gel™*** by K. Morse⁷ and she reported that those children did not experience the infections normally observed when other types of dressings were used.

This was observed even when wounds such as an open spinal wound on one patients was encountered on six different occasions within the first year of his life.

Anderson and Wilkening⁸ also reported that treatment of “gaping infected wound with extensive edema, eschar and slough on a young boy’s leg caused by a motorcycle collision . . .” which had been treated for three weeks with antibiotic ointment and petroleum dressing, was relatively quickly brought under control and continued to give a nearly scar-free healed wound after approximately four months. E. Siibrands-Standaart⁹ have covered radiation induced skin reaction (radiation burn) in cancer patients with a combination of calcium alginates and **Elasto-Gel™** and report that his protocol has shown superior results compared to the standard treatments previously used. H. Hoekstra¹⁰ an expert in the use of glycerine in skin preservation and wound treatment, states that “glycerine seems to have a modulating effect on the accompanying inflammation reactivity. **Elasto-Gel™** has shown to reduce the inflammation reaction nearly instantaneously. Diminishing of pain, a cooling effect, reduction of erythema and edema and a less outspoken pigmentation of the skin can be observed. “ Dr. Hoekstra had previously reported the absence of microbial cultures in burn wounds on animals.

At the recent meeting of the European Wound Management Association in Milan, Italy, J. Vandeputte¹¹ reported the results of a comparative study of burn wounds on a Duroc pig, that showed essentially no microorganisms in the wounds covered with **Elasto-Gel™** in contrast to those wounds covered with DuoDERM® (a hydrocolloid) which showed a total coverage with microorganisms. At the same meeting in Milan, Dr. Joseph Baksa¹², Head of the Department of Pediatric Surgery and Burn Unit of St. Janos Hospital in Budapest, Hungary, reported the effectiveness of **Elasto-Gel™** to prevent infections in severe third degree burns as well as its effectiveness in the prevention and treatment of scars. Nurse I.A. Oduogi¹³ of the Ministry of Health in Kenya also gave a report at the Milan meeting in which she reported that application to an abrasion which had been treated with savlone antiseptic and gauze for one week and remained in poor condition, was totally healed in 7 days after applying a single **Elasto-Gel™** wound dressing. She also reported that applying **Elasto-Gel™** to diabetic wounds reduced the odor, stopped the drainage of pus, and “was good for dirty, infected, diabetic wounds”. In another application to a chronic wound of about one year duration was essentially healed after 1½ months after treatment with **Elasto-Gel™**.

Dr. Joseph Baksa¹⁴⁻¹⁵ has reported additional examples of reduction and prevention of infections in wounds of all kinds that he has treated over a 3 year period. M. Halvorson and J. Kertz¹⁶⁻¹⁷ presented the application of **Elasto-Gel™** to wounds of many types, including non-healing wounds of malignant tumors in which the odor in such wounds was nearly eliminated within a few days and the pain was greatly reduced. They reported no infection with the use of **Elasto-Gel™** wound dressings.

All of above cited reports leave little doubt that **Elasto-Gel™** can be safely applied to highly contaminated wounds and, in many cases, has been safely applied to “infected” wounds. A more formal study is under way in which **Elasto-Gel™** is applied to non-healing cancer wounds and again the odor is being eliminated and the pain reduced¹⁸, which indicates the reduction of growth of bacteria in the wound site.

Conclusions

All of this data supports the concept that even if **Elasto-Gel™** were contaminated with the common microorganisms, it would not be a serious problem. Therefore, it would follow that if one of the pouches of **Elasto-Gel™** was not sealed or became unsealed, it would not create a serious health risk, especially if the product remained in the pouch. It would certainly be safer than even sterile gauze when applied to an open wound, since gauze is an open weave material and allows microorganisms to freely pass through the gauze into the open wound. The data indicates sterilization may not be necessary, but Southwest Technologies chooses to do so for safety in case of the development of a resistant microorganism and for marketing purposes.

¹ David Mackie, MD, **J. Burn Care & Rehabilitation**, Volume 18 #1, Part 2, Supplement, Jan/Feb 1997, pp. S7-s9 and references therein.

² Morris Cowan and Karen Miller, Report from Physiological Research Laboratories attached.

³ Stephen Davis, Patricia M. Mertz, PhD, Maria F. Oliveira, DVM, and William H. Eaglstein, MD, “*In Vitro Study to Examine the Effect of **Elasto-Gel™** on Five Different Bacteria*”, presented Advances in Wound Healing, Burn Care, Infection Control, International Burn Foundation, meeting February 17-21, 1997, Maui, HI.

⁴ Jan Vandeputte

⁵ R. Anderson and C. Wilkening

⁶ J. Matta

⁷ K. Morse

⁸ Anderson & Wilkening

⁹ E. Siibrands-Standaart

¹⁰ H. Hoekstra

¹¹ J. Vandeputte

¹² Joseph Baksa

¹³ I.A. Oduogi

¹⁴ Dr. Joseph Baksa

¹⁵ Dr. Joseph Baksa

¹⁶ M. Halvorson & J. Kertz

¹⁷ M. Halvorson & J. Kertz

¹⁸ Odor and Pain