

WHS
Wound
Healing
Society



Edward Stout, Ph.D

Submitted for publication May 10, 2011.

*Correspondence: Southwest Technologies, Inc., 1746 Levee Road, North Kansas City, MO 64116 (e-mail: amckessor@elastogel.com).

Abbreviations and Acronyms

FDA = Food and Drug
Administration

MRSA = methicillin-resistant
Staphylococcus aureus

Glycerin-Based Hydrogel for Infection Control

Edward I. Stout and Angie McKessor*

Southwest Technologies, Inc., North Kansas City, Missouri.

Problem: Infection is a major problem in the health and wellbeing of patients in hospitals, nursing homes, and other medical facilities as well as the homecare patients and the general public. According to Scientia Advisors, wound care costs the healthcare system over \$7 billion in 2009. After adding the cost associated with potential complications such as infections, extended physician care, and lengthy hospital stays, the annual wound care expenditures well exceeded over \$20 billion.¹ There are 20 million reported cases of diabetes per year and more every day. Because of the fact that leg ulcers are the number one health problem of men coupled with the rise in drug resistance of infections, the importance of providing the professional and the public with relatively simple and affordable wound care is of extreme importance. Often the wounds can become chronic wounds, which then result in long-term nursing expense in time and supplies or, worse yet, can result in expensive amputations ranging from \$5000 to \$40,000 per patient.

Solution: There are many dressing options now available for treating wounds with components such as glycerin, honey, salt, and many other natural products, with some dressings being more appropriate than others. In 1988, a patented glycerin-based dressing was introduced to the market, called Elasto-Gel™.²

New Technology: Elasto-Gel™ is a glycerin-based gel sheet (65%) combined with a hydrophilic polymer that causes the sheet to absorb the exudate from the wound and simultaneously release the glycerin from the gel, which adds many benefits to the wound for excellent healing outcomes. The gel sheet is 1/8th of an inch thick with a four-way stretch backing. It has the ability to absorb 3–4 times its own weight of fluids. The dressing will not dry out or allow the exudate to dry out, thus keeping the dressing from becoming bonded to the wound or the surrounding tissue. It does not have adhesive properties and, therefore, will not cause damage to the wound bed or periwound area upon dressing removal. Because of the thickness, the product provides excellent cushion and padding support. It has been also proven to be bacteriostatic/fungistatic. (Bacteriostatic is the ability to restrain the development or reproduction of bacteria.)³

Product Technology: Glycerin is a humectant by definition and has been recognized by the U.S. Food and Drug Administration (FDA). Humectants attract, bind, and hold moisture to the site of application. The actual concentration of glycerin in a wound dressing is indicative of the ability to absorb excess moisture. Exudate management is an important function of topical treatment. The ability to absorb drainage and prevent pooling of exudate in the wound or on the surrounding skin are attributes specific to high glycerin content. Perhaps, the most significant advantage of the glycerin-based hydrogel sheet is its impact on wound bioburden and pathogenic organisms.⁴ Glycerin is a simple three-carbon tri-alcohol and is a natural humectant. It is used as a carrier in many medicines and as plasticizer in gelatin gel capsules. Glycerin is a component of cosmetics, conditioners, soaps, foods, and other common products. It is a component of mono-, di-, and triglycerides naturally occurring in the body. These glycerides and glycerin

are constantly reacted with each other by the natural enzymes and reversed with the natural metabolic processes already present in the body. Any glycerin that may be absorbed into the body fluid is rapidly diluted in these fluids and is no longer toxic but is metabolized as another component of the food chain. It is well known that glycerin in high concentration will exhibit dehydrating effect on many systems including living cells by the commonly known process of osmosis. (Osmosis: the flow or diffusion that takes place through a semipermeable membrane, as of living cell, typically separating a solvent such as water, thus bringing about equilibrium conditions.⁵) It has been shown that glycerin at high concentration will be cytotoxic to all cells that have been tested if they are exposed long enough. These properties of glycerin have been recognized by the European Skin Bank, where they use 85% glycerin solutions to store cadaver skin at ~42F, and can be used for potential wound coverings. The cadaver skin that has been prepared by this method has been available since 1994.⁶ The concern for safety resulted in a three-day international symposium⁷ with emphasis on glycerin-preserved cadaver skin providing healthy environment for the preserved skin to be successfully accepted without rejection, having no complications of infection and providing excellent healing outcomes and minimal scarring. Additional research by Dr. David P. Mackie of the Red Cross Hospital, The Netherlands, reported that using 85% glycerin solutions had slow bactericidal effects and also showed virucidal activity on several types of viruses.⁸ Dr. Hoekstra has observed that within 2 hours after application of Elasto-Gel™, the inflammatory reaction is reduced.⁹ Vandeputte, Belgium, showed that wounds covered with Elasto-Gel™ had fewer myofibroblasts than those covered with hydrocolloid.¹⁰ It has been proposed that myofibroblasts in high concentrations contribute to the formation of hypertrophic and keloid scars. As noted earlier, there is less scar formation when glycerin-based gel sheets are used. The data cited here have shown that glycerin and glycerin-based products are effective antimicrobial agents with less side effects. Many verbal reports along with personal communications have indicated that applying glycerin-based gel sheets to stalled wounds, some 15–20-year-old chronic wounds, resulted in healing in 1–20 weeks (data/case studies on file).

Indications for Use: Elasto-Gel™ has been approved for all types of wounds, that is, pressure ulcers, acute and chronic wounds, diabetic wounds, traumatic wounds, dermatology wounds, cancer tumors, and first- and second-degree burns, to name a few. Because of the product's features and benefits, it may be used on a variety of wounds. Because of its padding properties, it may be also used as a preventative product over bony prominence areas so that wounds do not occur. The glycerin properties act as a skin substitute and may also be used for scar reduction.

Caution: Elasto-Gel™ is not approved for third-degree burns as no dressing has been approved by the FDA for this type of wound.

UNMET NEED

INFECTION can cause chronic wounds and morbidities. There is an epidemic of infections such as those by methicillin-resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa*, *Escherichia coli*, *Streptococcus pyogenes*, and others that cause delay in the healing process or even more severe, causing amputations, morbidities, and death.

Continued research into the influence and mechanism action of glycerin products may give us new insight and new tools to positively influence the healing process.

INNOVATION

Elasto-Gel™ has been proven to be bacteriostatic and fungistatic. Reduction of bioburden has less chance for an

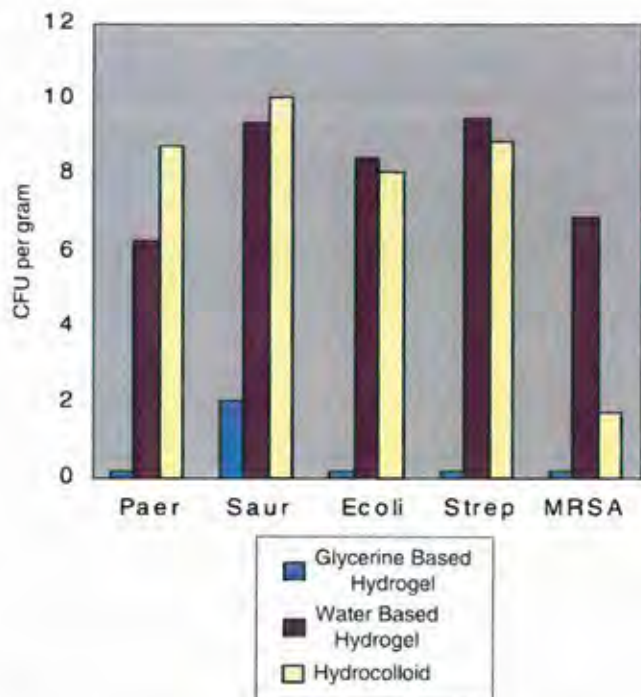


Figure 1. Independent study by University of Miami School of Medicine, Department of Dermatology, Miami, Florida by Patricia M. Mertz, B.A., Maria Oliveria-Gandia, D.V.M., and Stephen Davis, B.S. It is published in ref.¹¹ The effect of Elasto-Gel™ on a lawn of bacterial growth was evaluated. Agar plates were evenly streaked in three directions of the bacteria listed on chart figure were inoculated at 10,000 cfu and Elasto-Gel™ was placed over top of the agar. The plates were checked after 24 h, which showed no or very little growth of each bacteria under Elasto-Gel™.

infection at the wound site. Reducing the total bacterial count in the wound is clinically significant, because an excessive bioburden has been shown to impair wound healing and cause major problems including death. Controlling wound bioburden and infection is more challenging than ever due to the virulence of micro-organisms and the prevalence of multiple antibiotic-resistant organisms in all settings of patient care. Clinical studies have shown that glycerin, in a high concentration, creates a bacteriostatic environment, which decreases the number of microbes in the wound. This is a definite advantage when treating wounds and results in better healing outcomes.

PEER-REVIEWED DATA

Many comparison animal studies have been conducted on deep burn wounds showing the comparison of Elasto-Gel™-glycerin-based gel versus water-based hydrogels or hydrocolloid dressings (Fig. 1). Wounds were inoculated with *P. aeruginosa*, *E. coli*, *Str. pyogenes*, *Sta. aureus*, and MRSA, and it was shown that glycerin sheet reduces the microbes more than any other dressing.¹¹⁻¹³

Table 1. Independent study by Physiological Research Laboratories (Division of Medtronic, Inc.), with internal laboratory report support by Southwest Technologies, 1985—Bacteriostatic and fungistatic test results

	Viable Growth	Growth of Rinse	Growth Verified
Bacterial Plates			
Elasto-Gel™			
<i>Staphylococcus aureus</i>	No	No	
<i>Staphylococcus epidermidis</i>	No	No	
<i>Streptococcus faecalis</i>	No	No	
<i>Bacillus subtilis</i>	No	Yes	Yes
<i>Bacillus cereus</i>	No	No	
<i>Pseudomonas aeruginosa</i>	No	No	
<i>Klebsiella pneumonia</i>	No	No	
<i>Escherichia coli</i>	No	No	
Control			
<i>Sta. aureus</i>	No	Yes	Yes
<i>Streptococcus epidermidis</i>	No	Yes	Yes
<i>Str. faecalis</i>	No	Yes	Yes
<i>B. Subtilis</i>	No	Yes	Yes
<i>B. cereus</i>	No	Yes	Yes
<i>P. aeruginosa</i>	No	Yes	Yes
<i>Klebsiella pneumonia</i>	No	Yes	Yes
<i>E. coli</i>	No	Yes	Yes
Fungal Plates			
Elasto-Gel™			
<i>Candida albicans</i>	No	No	No
<i>Penicillium species</i>	No	No	No
<i>Aspergillus species</i>	No	Yes	Yes
Control			
<i>C. albicans</i>	No	Yes	Yes
<i>Penicillium species</i>	No	No	No
<i>Aspergillus species</i>	No	Yes	Yes

The Elasto-Gel™ seems to kill vegetative cells but does not destroy spores. It possesses bacteriostatic and fungistatic properties, but not sporicidal property.

In addition, an independent study conducted in 1985 by Physiological Research Laboratories/Medtronic, Inc., tested the following microorganisms (Table 1): *Sta. aureus*, *Str. pyogenes*, *Streptococcus faecalis*, *Bacillus subtilis*, *Bacillus cereus*, *P. aeruginosa*, *Klebsiella pneumonia*, and *E. coli*; and fungi: *Candida albicans*, *Aspergillus species*, and *Penicillium species*; the summary of the results by the investigator of the report was that Elasto-Gel™ did not support growth of any microbe tested. Seven of eight bacteria were killed when they were in contact with the glycerin gel sheet. The process of testing: Bacteria were spread onto the gel sheet, left for 24 hours, and then rinsed off the gel sheet and the rinse solution was tested to see which bacteria grew. One organism, *Str. pyogenes*, was able to survive on the surface. Elasto-Gel™ did not kill *B. subtilis*. This gram-positive rod is capable of forming spores, which are resistant to harsh environmental states. Elasto-Gel™ killed the *C. albicans* (yeast) but did not kill *Aspergillus niger* (mold). Molds form spores that are more resistant to destruction. *Penicillium species*

failed to grow.¹⁴ Southwest Technologies, Inc., has 30 years of clinical data on file of the use of Elasto-Gel™ on all types of wounds showing control of microorganisms in the wound bed.

CONCLUSION

Glycerin/Elasto-Gel™ sheets have been shown to be effective antibacterial agents. The gel sheets have exhibited many desirable properties that

contribute to a suitable wound healing environment. The use of glycerin sheets have been shown to inhibit bacterial growth and to result in better healing outcomes.

AUTHOR DISCLOSURE AND GHOSTWRITING

Edward I. Stout is the Owner, CEO, and Director of Research with Southwest Technologies, Inc. Angie McKessor is the ghostwriter who wrote this chapter.

REFERENCES

1. Scientia Advisors: *Industry Briefings, Wound Care Market*, 2009.
2. Edward I. Stout: Patent No. 4671267, June 9, 1987.
3. "bacteriostatic": Webster Medical Desk Dictionary, 1986, p. 63. Merriam Webster Inc, Springfield, MA.
4. Thimsen K and Motta G: *Moist Wound Healing: Cost Efficient Patient Care Using Glycerin-Based Hydrogel Technology*. Continuing education paper supported by Southwest Technologies, Inc. 2010–2011.
5. "osmosis": Webster Medical Desk Dictionary, 1986, p. 501. Merriam Webster Inc, Springfield, MA.
6. Burns: Glycerol (glycerine)-preserved donor skin. *J Int Society Burn Injuries* 1994; **20**(Suppl. 1).
7. *New Approaches to the Management of Chronic Wounds*. In: Proceedings of the European Wound Management Association, Spring Meeting, Milan, Italy, 1997, p. 4.
8. Mackie DP: *J Burn Care Rehab* 1997; **18**: PS7–PS9.
9. Hermann RP, Hoekstra MJ, Kropman GM, and Koendermok JA (Euro Skin Bank): *Annals Burns Fire Disasters* 1996; **9**.
10. Vandeutte J: Treatment variations in pressure ulcers between hospital and home care. *Br J Plast Surg* 1993; **46**: 585–589. Poster presentation.
11. Oiveria-Gandia M, Davis SC, and Mertz P: Can occlusive dressing composition influence proliferation of bacterial wound pathogens. *Wounds* 1998; **10**: 4–11.
12. Saegeman V, Ectors N, Lismont D, Verduyck B, and Verhaegen J: Short and long term bacterial inhibiting effect of high concentrations of glycerol used in the preservation of skin allografts. *Burns* 2008; **34**: 205–211.
13. Ectors NL: *Tissue Banks, University Hospital Leuven, Katholieke Universiteit Leuven, Leuven, Belgium*. Elsevier, 2007, pp. 305–4179.
14. Physiological Research Laboratories (Division of Medtronic, Inc.): *Internal Laboratory Report*. Southwest Technologies, 1985.