A New Form Fitting Hybrid Hydrogel Facial Mask Which Stimulates Wound Healing in Facial Resurfacing

Marta I. Rendon-Pellerano, M.D.*, Brian Bucalo, M.D.*, Steven Davis**
* Cleveland Clinic of Florida, Department of Dermatology
** University of Miami School of Medicine, Department of Dermatology & Cutaneous Surgery

The duration of wound healing and the final outcome of facial resurfacing will be influenced not only by the modality employed but by the care of the skin before and after the chosen procedure. This paper is an effort to clarify which wound dressing actually accelerates wound healing and helps improve treatment outcomes.

Since control of evaporative water loss following skin injury is of major importance to the overall healing process, hundreds of clinical reports have appeared in various journals over the past thirty years verifying the value of various compositions of hydrogel wound dressings. In 1936, DuPont chemists synthesized poly-2-hydroxyethylmeth-acrylate, (the precursor to modern day hydrogels), but it was not until the 1950’s that Wichterle and his co-work first recognized the potential medical value of these unique hydrophilic polymers as a general surgical material.

Hydrogels are a three-dimensional network of hydrophilic polymers that are insoluble in water and are non-degradable. They interact with aqueous solutions by swelling to certain equilibriums dictated by their compositions, and thus, retain a significant proportion of water within their structure.

The data from previous clinical studies, concerning the physical requirements for wound dressings, emphasize the need for the following dressing characteristics:

♦ capable of keeping the wound moist, without excessive moisture;
♦ capable of absorbing excessive amounts of wound exudates;
♦ strong bacteriostatic action;
♦ able to remain on the wound for three to seven days, and sufficient strength to resist the pressure of added weight from fluid accumulation;
♦ non-traumatic to wound bed on removal;
♦ able to keep growth factors supplied to the wound bed and not absorb them;
♦ able to promote increased speed of epithelialization.

Previous investigations indicate that Dermaphase™ approaches these requirements. Editors Note: Elasto-Gel™ has been renamed Dermaphase™. Dermaphase™ is a blend of glycerine with synthetic hydrophobic polymers into a three-component system in which water enhances the compatibility and function of the dressing. Dermaphase™ utilizes a high concentration of glycerine (65%) as water soluble humectant in a mixture of 17.5% water and 17.5% of a polyacrylamide. Dermaphase™ is presented as a hydrogel because of its ability to absorb large quantities of fluids. (Hydrogels are the closest class of dressings with similar qualities.) Its protective properties are similar to other hydrogels, but, due to its high percentage of glycerine, it exhibits additional desirable properties, such as bacteriostatic action which is absent in other types of hydrogel dressings.

Due to its high permeability, water content, and acceptable pH, Dermaphase™ can reduce pain by protecting exposed neurons from dehydration. Other major characteristics of this dressing are its elasticity, strength, and durability which allow the dressing to remain in place for seven days. Nearly all documented clinical experiences show that occlusively dressed wounds heal more quickly and with less pain, tenderness, and swelling than undressed wounds. It has been hypothesized that wound dressings, by inducing a mild inflammatory reaction, enhance healing by activating cells, such as macrophages or fibroblasts, to produce growth factors and other mediators of the repair process.

Observations of the effects of hydrogel dressings at the molecular level through the use of reverse transcriptase/polymerase chain reaction have been used to evaluate effects on the expression of interleukin 8 (IL-8), basic
fibroblast growth factor (bFGF), granulocyte-macrophage colony-stimulating factor (GMCSF), epidermal growth factor (EGF), transforming growth factor betas (TGF-betas), and fibronectin. Results demonstrate significant increase in IL-8 and bFGF levels, thus, suggesting, that hydrogels augment collagenolysis via the promotion of inflammation. Results also demonstrate that there is evidence for extensive connective tissue remodeling occurring during occlusive dressing therapy. Early application of hydrogel dressings to a wound was accompanied by elevated collagenase activity and an increased inflammatory reaction to the dermis.

Previous research shows that Dermaphase dressings absorb greater quantities of wound exudates than other hydrogels and in doing so concentrate the growth factors and other valuable proteins in the wounds site. This means that the dressing does not take away from the wound the valuable factors produced within the wound but keeps them concentrated where they are needed most. The dressing never sticks to the wound and cannot dry out, thus eliminating the problems of keratinocytes attaching themselves to the interstices of the dressing and causing loss of epidermis when the dressing is removed.

Until the development of the Dermaphase facial mask, the question of how long to leave a hydrogel dressing on a wound was unclear since resurfacing wounds are very exudative and usually require more than one dressing change. Previously, prolonged use of some hydrogel dressing often exceeded the absorptive ability of the dressing resulting in leakage of the exudate and a break in the integrity of the dressing. Such a break in the dressing integrity can cause a change in the metabolic environment which predisposes the wound to infection.

In an independent laboratory test of absorptive properties the performance of Dermaphase was compared to other widely used wound dressing materials such as hydrocolloid, membrane, hydrogel and alginates. The test period covered a period of ninety-six hours, the absorptive properties were measure by evaluating the absorption of a .09% saline solution at room temperature. Each dressing was examined at various time intervals starting after the first half hour and continuing for a period of ninety-six hours. All but one dressing (an alginate) continued to absorb saline for the entire test period.

Within six hours, Dermaphase had absorbed eighty-five grams of fluid, out-performing all of the dressings tested.

1. The popular Vigilon wound dressing absorbed less than twenty grams of water for the entire ninety-six hours.
2. ClearSite, PolyMem, and DuoDERM absorbed less than thirty grams of fluid in the ninety-six hour period.
3. Polyderm appeared to reach peak absorption at 0.5 hours.
4. DuoDERM began to dissolve after twenty-four hours, so no further measurements were possible.
5. Restore absorbed less than seventy grams of fluid in ninety-six hours.
6. At one hour, Elasto-Gel had absorbed significantly more fluid than any other dressing except Kaltostat (alginate) which was expected.
7. At three hours Dermaphase had absorbed a similar amount of fluid to that of Kaltostat, but significantly more than all other dressings.
8. At six hours Dermaphase was the only dressing continuing to absorb significant amounts of fluids.
9. None of the test dressings absorbed more than seventy grams of fluid during the ninety-six hour period except Dermaphase which had absorbed 85.0 grams at six hours, 112 grams at twelve hours, 126 grams at twenty-four hours, 156.4 grams at thirty-six hours, and 173.0 grams at ninety-six hours.

Dermaphase’s high concentration of glycerine (65%) contributes to its antimicrobial properties. Several studies support the fact that Dermaphase does not support growth of any microbe tested and will kill bacteria that are able to survive on inert surfaces. Only Bacillus subtilus, a gram positive rod that can form spores, was not killed. Glycerine in high concentrations has a slight but definite anti-microbial action which accounts for the way bacterial growth will be hampered. It has been speculated that bacterial size should preclude penetration of the gel by any bacteria.
Glycerine also appears to have an immunomodulating effect which influences the inflammatory response to injury. The reaction of cultured human lymphocytes to foreign epidermal cells is inhibited in the presence of small amounts of glycerine.³ Glycerine’s strong negative charge binds to extra cellular matrix molecules, modifying their break down and subsequently modulating the inflammatory response³.

Various hydrogel constructions have been used on a wide range of wounds which respond favorably to occlusive dressings. This class of chemical compounds has a varying ability to absorb liquids from wound sites or to be an effective fluid donating agent¹⁹, making them truly unique as a dressing material. Hydrogels have been used successfully in skin resurfacing as a skin substitute, for skin ulcerations, pharyngocutaneous fistulas, the speed of re-epithelialization in surgical incisions, long-term chronic wounds, and a burn dressing.², 8, 9, 23 The virtues of Dermaphase™ in maintaining an ideal healing environment appears to be unsurpassed by any other modality.

The Dermaphase™ facial mask’s bilaminate construction provides an homogeneous hydrogel composite dressing deposited on a mechanically stable substrate. A knit stocking-like material fits comfortably over the head to create intimate contact between the gel and all facial surfaces. It thereby protects and promotes early healing to post procedural facial trauma created by laser, chemical deep peelings, derma-abrision, or surgical incisions. Bilaminate construction helps reduce the normally high-water-vapor transmission rates often associated with hydrogel dressings to much lower, clinically acceptable levels.²⁴ By maintaining a moist environment the mask decreases the chances of contamination and bacterial infection and initiates immediate pain relief. Mechanically, the Dermaphase™ mask’s layered construction protects the underlying hydrogel from tearing and puncturing while ensuring conformability to the wound site.

Laboratory tests indicate that this unique hydrogel mask can absorb substantial amounts of fluids from stimulated wet wounds as well as donate substantial amounts of fluids to dry or necrotic wounds, depending upon the moisture content and nature of the substrate to which it is applied.

References:
2. Queen, D; Gayton, JD; Evans, JH; Courtney, JM; Reid, WH: "The preclinical evaluation of water vapor transmission rate through burn wound dressings", Biomaterials 1987, 8:5 367-371.
4. Vandeputte, J; Gryson, L: “Clinical trial on the control of diabetic foot infection by an immunomodulating hydrogel containing 65% glycerine”.
11. Carver, N; Navsaria, HA; Green, CJ, Leigh IM: “The effect of backing materials on keratinocytes autographs...
13. Independent Laboratory Study. Title: "Saline Absorption Properties of Various Wound Dressings", NAmsA, 2261 Tracey Road, Northwood, Ohio.
14. Eglestein, HW; Mertz, DM; Davis, SC; Oliveria, MF: "Effects of Elasto-Gel™ on Pseudomonas aeruginosa - Proliferation in Burn Wounds", Unpublished data - University of Miami School of Medicine, available from the author.
15. Eglestein, HW; Mertz, DM; Davis, SC; Oliveria, MF: "Effects of Elasto-Gel™ on Pseudomonas aeruginosa - Proliferation in Burn Wounds Part II", Unpublished data - University of Miami School of Medicine, available from the author.
16. Eglestein, HW; Mertz, DM; Davis, SC; Oliveria, MF: "In Vitro Study to Examine the Effects of Elasto-Gel™ on Five Different Bacteria", Published data - University of Miami School of Medicine, available from the author.
17. Independent Laboratory Study "Bacteriostatic - Fungistatic Potential" #850911-202-6669 Physiological Research Laboratories, Coon Rapids, MN.
24. Queen, D; Evans, JH; Gaylor, JD; Courtney, JM; Reid, WH, " The physical effects of an adhesive dressing top layer on burn dressings", Burns Incl Therm Inj, 1986 Jun, 12:5, 351-6.

Dermaphase = Elasto-Gel™ = Novogel™

Manufactured by:
Southwest Technologies, Inc.
North Kansas City, MO 64116