0022-5282/87/2702-0155$02.00/0
THE JOURNAL OF TRAUMA

Vol. 27, No. 2
Printed in U.S.A.

Biosynthetic Skin Substitute versus Frozen Human Cadaver Allograft for Temporary Coverage of Excised Burn Wounds

GARY F. PURDUE, M.D., JOHN L. HUNT, M.D., ROBERT W. GILLESPIE, M.D., JOHN F. HANSBROUGH, M.D., WILLIAM J. DOMINIC, M.D., MARTIN C. ROBSON, M.D., DAVID J. SMITH, M.D., BRUCE G. MACMILLAN, M.D.,† J. PAUL WAYMAC, M.D., DAVID N. HERNDON, M.D., MANU DESAI, M.D., BOYD E. TERRY, M.D., ARNALDO BENDLIN, M.D., FREDERICK A. DECLEMENT, M.D., ARTHUR M. KAHN, M.D., MARELLA L. HANUMADASS, M.D., AND TAKAYOSHI MATSUDA, M.D.

During the past 2 years a multicenter study was performed comparing Biobrane (Woodroof) and frozen cadaver allograft as temporary dressings on freshly excised full-thickness burns before the application of autograft. Each biologic dressing was evaluated with respect to the other on the same patient.

Seventy-one patients were evaluated. The mean burn size was 35 ± 20% with a mean full-thickness burn of 28 ± 20%. Mean patient age was 34 ± 21 years. Overall survival was 82%. The mean time of wound coverage was 10.2 ± 6.7 days.

There was no significant difference in the number of dressing changes, area changed, purulence, autograft take, and final results between allograft- and Biobrane-covered sites. There were no complications following use of either Biobrane or allograft. We conclude that Biobrane is as effective as frozen human cadaver allograft for the temporary coverage of freshly excised full-thickness burn wounds before autografting.

Aggressive management of large full-thickness burns by early removal of eschar requires temporary coverage of the excised areas until autograft donor sites become available. This has led to increased interest in the use of biologic dressings and synthetic skin substitutes for such coverage. The primary functions of these dressings are protection of the wound (preventing bacterial penetration and desiccation, and decreasing pain, heat, and loss of water), maintenance of microbial control, and more rapid wound maturation (5) until such time as autografts become available to permanently close the wound.

The ideal wound dressing should encompass the following characteristics: adherence, water vapor transport, elasticity, durability, creation of a bacterial barrier, absence of toxicity and antigenicity, antiseptic, hemostatic, ease of application and removal, long shelf life, minimal storage requirements, and low expense relative to the alternatives (6). Adherence to the underlying wound bed

Author's affiliations:
Gary F. Purdue, M.D., Assistant Professor of Surgery, University of Texas Health Science Center, Dallas
John L. Hunt, M.D., Associate Professor of Surgery, University of Texas Health Science Center, Dallas
Robert W. Gillespie, M.D., Associate Professor of Surgery, University of Nebraska Medical Center, Lincoln
John F. Hansbrough, M.D., Associate Professor of Surgery, University of California at San Diego Medical Center
William J. Dominic, M.D., Clinical Burn Fellow, University of California at San Diego Medical Center
Martin C. Robson, M.D., Division Chief, Plastic & Reconstructive Surgery, Wayne State University, Detroit
David J. Smith, Jr., M.D., Associate Professor of Surgery, Plastic Surgery Section, Wayne State University, Detroit
† Bruce G. MacMillan, M.D., Former Chief of Staff, Shriners Burn Institute, Cincinnati
J. Paul Waymack, M.D., Staff Surgeon, Shriners Burn Institute, Cincinnati
David N. Herndon, M.D., Chief of Staff, Shriners Burn Institute, Galveston; Professor of Surgery, University of Texas Medical Branch, Galveston
Manu DeSai, M.D., Assistant Chief of Staff, Shriners Burn Institute, Galveston; Associate Professor of Surgery, University of Texas Medical Branch, Galveston
Boyd E. Terry, M.D., Associate Professor of Surgery, University of Missouri, Columbia
Arnaldo Bendlin, M.D., Associate Director Burn Center, St. Agnes Medical Center, Philadelphia
Frederick A. DeClement, M.D., Director Burn Center, St. Agnes Medical Center, Philadelphia
Arthur M. Kahn, M.D., Attending Surgeon, Brotman Medical Center, Culver City, California
Marella L. Hanumadass, M.D., Clinical Director, Burn Center, Cook County Hospital, Chicago
Takayoshi Matsuda, M.D., Director Burn Center, Cook County Hospital; Assistant Professor of Surgery, University Illinois College of Medicine, Chicago
† Deceased.
Address for reprints: Gary F. Purdue, M.D., Department of Surgery, UTHSCD, 5323 Harry Hines Blvd., Dallas, TX, 75235.
Presented at the Eighteenth Annual Meeting of the American Burn Association, 9-12 April 1986, Chicago.

is the most important property of a biologic dressing, and is primarily dependent upon the creation of a fibrin bond (1). Because fibrin preferentially binds to collagen (2), collagen has often been incorporated as the basis of attempted ideal biologic dressings.

To date, allograft skin is the most frequently used and most effective biologic dressing. It forms the 'gold standard' by which all other dressings are evaluated (5). While allograft may be obtained from another family member or any suitable living volunteer, it is most commonly harvested from cadavers. The primary limitations of allograft are its mechanical characteristics (varying quality, thickness, and width), limitation of an adequate supply, limited shelf life (in the fresh form) or the need for special low-temperature storage (in the frozen form), and relatively high cost ($280–550 per square foot). In addition, accurate application of allograft to large areas requires substantial time.

Desire to overcome the shortcomings of natural biologic dressings has led to increased interest in the development of synthetic substitutes. These materials must meet two conflicting requirements. They must have water vapor permeability characteristics similar to those of skin (to prevent either submembrane accumulation of fluid or desiccation of the underlying wound bed), while also having a pore size of about 80 micrometers (μm). The latter physical property permits the ingrowth of fibrovascular tissue necessary for adherence to the wound. At the present time these requirements cannot be met by a single-layer material, but necessitate a two-layer composite of materials, each with a different pore size.

Biobrane (Woodroof Laboratories, Santa Ana, CA) is a bilaminate biosynthetic dressing. It is composed of a thin (about 6 μm) flexible silicon membrane bonded to a layer of nylon fabric mesh 360 μm thick. Both layers are covered with a monomolecular layer of porcine collagen (Type I collagen) which provides a hydrophilic coating for fibrin ingrowth. Water vapor transmission is slightly higher than that of skin, while flexibility and elasticity provide excellent conformance to the wound bed. A number of clinical trials have shown Biobrane to be an effective biologic dressing for the treatment of donor sites, partial-thickness burns, and as a temporary covering over widely meshed autograft (2, 3, 8, 9).

The purpose of this study was to compare the safety and efficacy of Biobrane and frozen human cadaver allograft (FHCA) as temporary biologic dressings on freshly excised full-thickness burn wounds. Comparison with FHCA was chosen because of its known efficacy, and its ready availability.

MATERIALS AND METHODS

During the past 2 years, a prospective study was conducted at ten burn units. Selection of investigators from different geographic areas, different unit sizes, and minimal stipulation of methods of handling the wounds provided a cross-section of burn care in the United States. Investigative protocols were submitted to the respective Institutional Review Boards for approval before the beginning of the study and informed written consents were obtained from the patients or their families.

The initial criteria for inclusion in the study limited the maximum burn size to less than 40% TBSA full-thickness and 50% total body burn, without an associated inhalation injury. These patient limitations were later revised upward to include any burn size, because of the limited number of appropriate patients who could be studied under those restrictions. The use of the protocol in children was included at some units.

Evaluation of the safety and efficacy of Biobrane was accomplished by direct comparison with FHCA on each patient. All patients entered in the study were to receive at least two operative procedures. The first was burn wound excision and application of the biologic dressings. This was followed at a later date (usually less than 2 weeks) by removal of the biologic dressings and application of autograft.

The FHCA was obtained from each burn unit's usual supplier and was prepared and applied in the manner already established for that institution. Regular (Blue Label) Biobrane was applied as directed on the package instructions.

Following excision of the burn wound (by either sequential tangential excision to viable tissue or by full-thickness excision to fascia), hemostasis was achieved. Biobrane and FHCA were then applied to equivalent areas of the excised wound. (One institution performed all sequential excisions with tourniquet control of bleeding, immediate application of the biologic dressings and compressive wraps, and then removal of the tourniquets with no attempt at local hemostasis.)

Following application of the biologic dressings, both the FHCA and Biobrane were treated in exactly the same manner, the routine used at each individual institution. When adequate donor sites were available, patients were returned to the operating room, both the Biobrane and FHCA were removed, hemostasis obtained, and autograft applied. The autografts over both experimental sites were then treated in the same manner (determined by each institution).

TABLE I
Patient characteristics

Mean total burn size	39.5% (range, 4–91)
Mean full thickness	29.0% (range, 4–77)
Mean patient age (yrs)	34.4 (range, 2–91)
Children	8 (11.9%)
Males	50 (74.6%)

TABLE II
Mortality

Patients	13 (18.3%)
Mean total burn size	47.9%
Mean full thickness	41.8%
Mean age (years)	56.1
Males	6 (46%)

TABLE III
Comparison of allograft and Biobrane experimental sites

	Site Equivalence	Final Results
Both areas equal	61 (88.1%)	57 (83.6%)
Allograft better	6 (8.7%)	5 (7.2%)
Biobrane better	2 (3.1%)	7 (10.2%)
Significance	None	None

Research evaluation protocols were completed at the time of excision and application of the biologic dressings, at serial evaluations of the experimental sites, at the time of removal of the biologic dressings, and at 2 weeks and 1 month after autografting.

Evaluations were accomplished by comparing the site covered with Biobrane with the site covered with FHCA. Comparisons were made with regard to the following criteria: equivalence of the respective sites (would the biologic dressing and later autograft be expected to perform equally at both sites), complications, adherence, accumulation of fluid beneath the biologic dressing, presence of subdressing infection, signs of rejection, and the proportion of each material that had to be replaced before autografting. Autograft evaluation included per cent autograft take, systemic complications attributable to either dressing, amount of autograft replaced, and the appearance of the autografted areas at 2 weeks and 1 month after application. Data were evaluated by the test of two proportions for statistical significance (4).

RESULTS

Seventy-one patients have been evaluated. Patient characteristics are seen in Table I. Thirteen patients died (Table II). No deaths were related to the biologic dressings. Five of these patients were able to be evaluated with autograft in place.

Excision and application of the biologic dressings was performed a mean of 6.0 ± 6.7 (range, 1–23) days after the burn. The total areas covered with Biobrane and allograft were 6.4 and 6.0%, respectively. Both biologic dressings were left in place a mean of 5.6 ± 4.9 (range, 1–27) days before removal and the application of autograft.

Purulent fluid collections were noted in ten (15.4%) of the Biobrane-covered sites and in 11 (16.9%) of the allograft sites. Seven of these purulent collections were in the same patients. The Biobrane required changing in 21 patients; the allograft was changed in 23 patients. Seventeen per cent of these changes were in the same patients. The average amount of dressing changed was 14.9% for Biobrane and 18.4% for allograft. None of the above data are significantly different.

At the time of the initial application of the biologic dressings, the experimental sites were judged as to their equivalence. Site equivalence and the final results are shown in Table III. There were no significant differences between Biobrane and FHCA. In addition, there were no complications of either biologic dressing and no rejection of either dressing was noted.

DISCUSSION

Widespread clinical usage of a biologic dressing requires that it be easy and rapid to apply, have minimal special storage requirements, and be cost effective in addition to being at least as effective as the presently accepted method of temporary wound coverage. The present study has shown that Biobrane is an effective biologic dressing for the temporary coverage of freshly excised full-thickness burn wounds before autografting.

REFERENCES

1. Burleson, R. L., Ennulat, N.: Fibrin adherence to biologic tissues. *J. Surg. Res.*, **25:** 523–529, 1978.
2. Frank, D. H., Wachtel, T., Frank, H. A., et al.: Comparison of Biobrane, porcine, and human allograft as biologic dressings for burn wounds. *J. Burn Care Rehab.*, **4:** 186–190, 1983.
3. Hansbrough, J. F., Zapata-Sirvent, R., Carroll, W. J.: Clinical experience with Biobrane biosynthetic dressing in the treatment of partial thickness burns. *Burns*, **10:** 415–419, 1984.
4. Hines, W. W., Montgomery, D. C.: *Probabilities and Statistics in Engineering and Management Science.* New York, Wiley, 1980, pp. 297–299.
5. Pruitt, B. A., Levine, N. S.: Characteristics and uses of biologic dressings and skin substitutes. *Arch. Surg.*, **119:** 312–322, 1984.
6. Tavis, M. J., Thornton, J., Danet, R., et al.: Current status of skin substitutes. *Surg. Clin. No. Amer.*, **58:** 1233–1248, 1978.
7. Tavis, M. J., Thornton, J. W., Harney, J. H., et al.: Graft adherence to de-epithelialized surfaces: A comparative study. *Ann. Surg.*, **184:** 594–600, 1976.
8. Tavis, M. J., Thornton, J. W., Bartlett, R. H., et al.: A new composite skin prosthesis. *Burns*, **7:** 123–130, 1980.
9. Wachtel, T. L., Sanders, R., Inancsi, W., et al.: Biological membranes as temporary wound dressings over meshed autograft (abstr). Presented at the Thirteenth Annual Meeting of the American Burn Association, April 2–4, 1981.