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Article by Pitanguy et al., "Use of Cellulose Film (Biofill) as Biologic Dressing

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This declaration certifies the accuracy and precision of the translation from Portuguese into English of the above material and is an accurate reflection of the text as it appeared in Portuguese.

For the translator:

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USE OF CELLULOSE FILM (BIOFILL®) AS BIOLOGIC DRESSING

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SUMMARY

The authors report on their experience with 133 cases, treated at the Ivo Pitanguy Clinic and 38th Infirmary of the Santa Casa da Misericórdia General Hospital, in which the cellulose pellicle BIOFILL® was used as a biological dressing. The product was utilized in cases of dermabrasion, 2nd degree burns and partial skin graft donor areas. The indications, technical details and advantages are presented. The results obtained showed the efficacy of BIOFILL® in the treatment of the lesions above mentioned.

KEY WORDS: biological dressing; temporary skin substitute

Through the times, a large variety of substances and procedures have been used as protective agents in lesions characterized by skin loss. From the application of fresh meat and honey, as reported in the Ebers Papyrus of 1500 B.C., to the current autografts of cultured skin, diverse materials were used, such as: autologous grafts, sulfonamide films, plastics and porcine xenografts. Various procedures were also employed in the treatment of burns and cutaneous abrasions in general, among them, closed or open dressings, with or without topical drugs.[1]

Due to a better understanding of the physiology of healing, it was possible to establish the factors which play a relevant

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role in the microenvironment of the dressing.[2-3] This permitted the utilization of already existing materials and the development of new materials that may provide ideal conditions for healing.

In a didactic form, the temporary skin substitutes, or biologic dressings, can be classified in the following manner:

Biologics

- Homografts (Allografts)
  - Live donor
  - Fresh cadaver donor
  - Preserved cadaver donor
  - Amniotic membrane

- Heterografts (Xenografts)
  - Live donor
  - Preserved, irradiated, dry (lyophilized)

- Tissue derivatives
  - Collagen (sheet, sponge, etc.)
  - Fibrin

Synthetics

- Polymerized solid silicone membrane
- Various plastics
- Microporous materials
- Adherent materials

Composites

- Surface membrane (silicone, microporous, Hydron)
- Substrate adherents (collagen, gauze, composite polymers, Dacron flakes)

Although an ideal skin substitute does not yet exist, its characteristics have already been determined.[4]

1. Adherence
2. Permeability to water vapor

3. Elasticity
4. Durability
5. Bacterial barrier
6. Non-antigenic
7. Hemostatic
8. Easy to apply and handle
9. Low cost

Available skin substitutes, although they fulfill some of these items, are deficient in others.[5-10]

Our paper seeks to present the experience of the Ivo Pitanguy Clinic and of the 38th Ward of Santa Casa da Misericórdia of Rio de Janeiro with the use of the cellulose film - BIOFILL® - as biologic dressing in dermabrasions, second degree burns and partial skin graft donor areas.

MATERIAL AND METHODS

The cellulose film named BIOFILL® is formed by a micro-fibrillar mesh of homogeneous cellulose, produced by the biosynthesis of bacteria of the *Acetobacter* genus (Fig. 1A, B). Visually similar to human skin, it is semitransparent, with an average thickness of 0.05 mm and with selective permeability, making possible the passage of water vapor but blocking bacteria. The film is sterilized with ethylene oxide and packed in plastic, not requiring greater care in transport or packaging.[11]

It is easy to apply, principally when hydrated in normal saline, becoming flexible and adaptable to the receptor bed, the process being practically painless.[12]

The receptor areas were rigorously cleaned with iodopovidone and rinsed with normal saline. The films were applied over the entire lesion, extending 1 cm beyond the edge. In cases in which two or more films were used, they were overlapped by 1 cm on the ends. After placement, air bubbles were removed with the aid of forceps or fingers, in centrifugal movements. When application was complete, the areas were covered with dry gauzes and

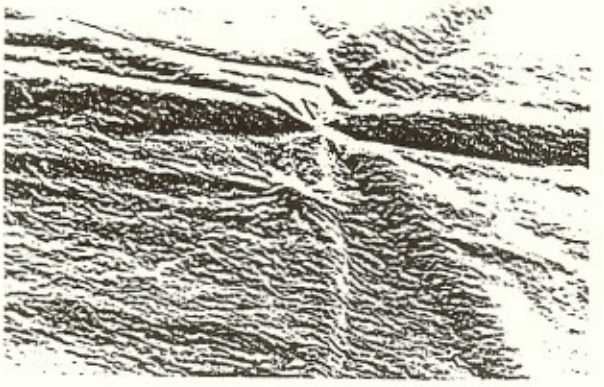

Fig. 1-A.

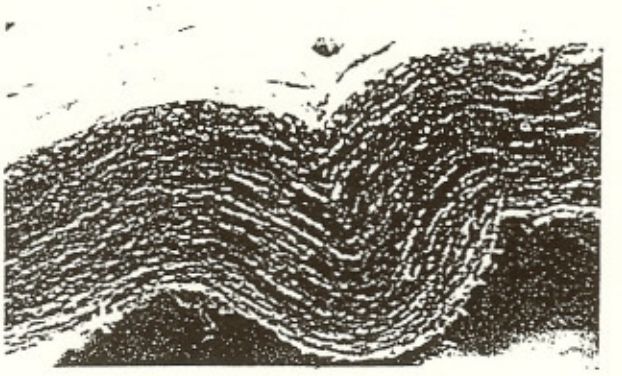

Fig. 1-B.

Fig. 1 - The cellulose film (BIOFILL®) under electron microscope: A - 1200 X magnification (front view); B - 5000 X magnification (sagittal cut).

bandages, seeking to protect them from abrupt movements or friction during handling and transport of the patient. This temporary dressing is normally maintained for three hours or until recovery from anesthesia. However, in cases of children, agitated adults or when the applications were done over areas of great mobility (joints), the dressings remained up to a maximum of 24 hours. In dermabrasions, the crust formed by the film was removed five to eight days after its application. In second degree burns and graft donor areas, spontaneous release was allowed, which occurred between the 6th and 17th days.

The film was used in the treatment of 133 patients, in accordance with three basic indications: dermabrasion, second degree burns and partial skin graft donor area. Of the total patients treated, 83 were females and 50 were males. The age varied from five to 68 years, with predominance in the age group of 30 to 40 years.

a) Dermabrasion: BIOFILL® was applied in 58 patients who underwent dermabrasion as the only procedure, combined with scar revision or rhytidoplasties. Good adherence of the film in the frontal, malar and nasal regions was observed, with a good

hemostatic effect and absence of discomfort or pain. In the perioral region, due to the intense mimic, good adherence of the film was not obtained. When applied over sutures, no alteration in its properties was observed (Fig. 2A-D).

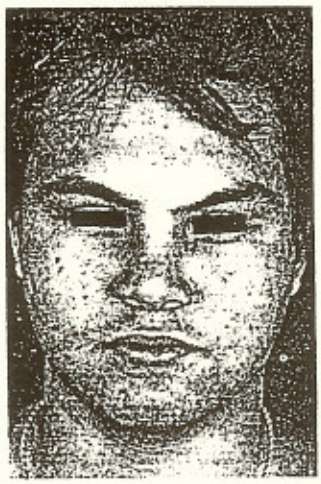

Fig. 2-A

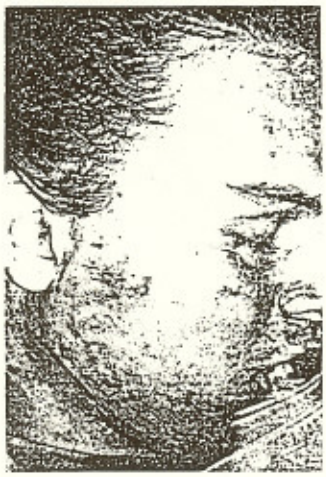

Fig. 2-B

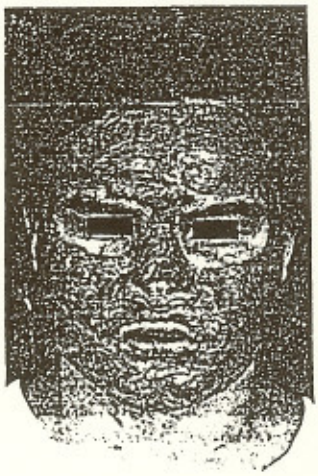

Fig. 2-C

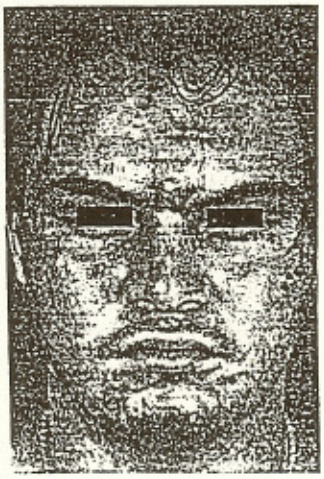

Fig. 2-D

Fig. 2 - 22-year-old patient, having acne sequela, who underwent mechanical dermabrasion combined with resection of scars: A - Preoperative; B - Intraoperative: BIOFILL® applied over dermabraded area, including small sutures; C - Appearance 24 hours after application of the film; D - One week after dermabrasion and one day before removal of the crust.

B) Second degree burns: The 31 patients treated had burns [ranging] from small to involvement of 20% of the body surface; there was also variation with regard to the depth of the lesion, etiologic agent and anatomic region. After complete debridement of the blisters and asepsis, BIOFILL® was applied at intervals that varied from 30 minutes to 8 hours after the burn (Figs. 3A-D, 4A-C and 5 A-B).

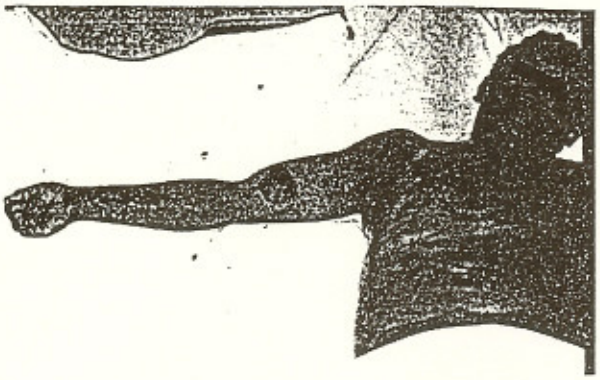

Fig. 3-A

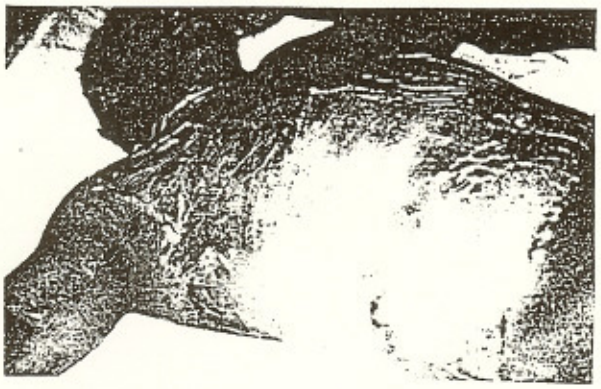

Fig. 3-B

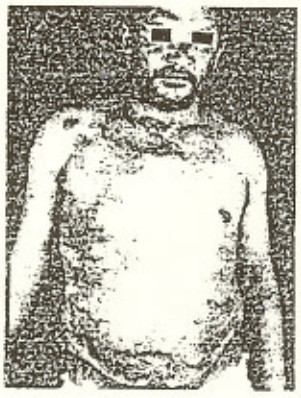

Fig. 3-C

Fig. 3-D

Fig. 3 - 32-year-old patient with burn caused by alcohol, five hours after the accident; A - second degree lesions on the face, cervical region, trunk and right upper limb, totalling approximately 20% of area burned; B - Appearance 24 hours after application of the film; C and D - Seventeen days after the accident, crust already detached.

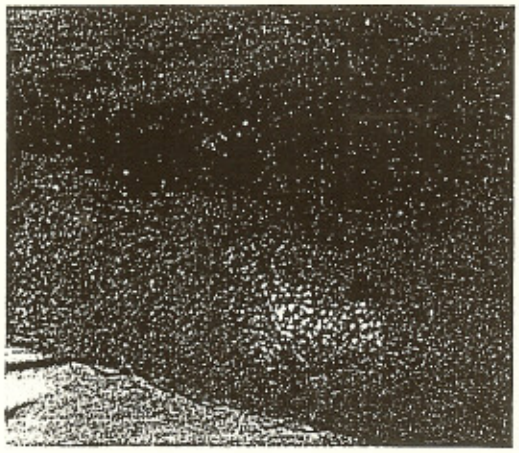

Fig. 4-A

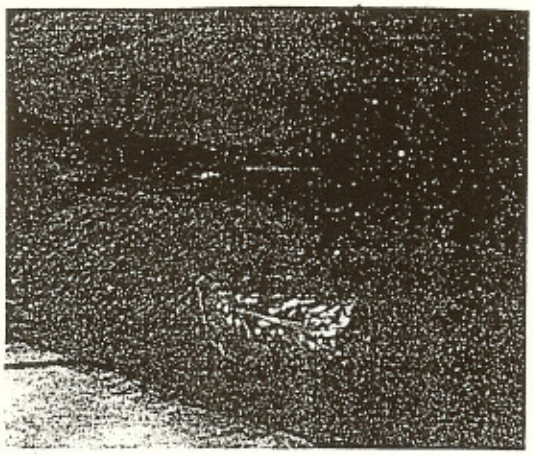

Fig. 4-B

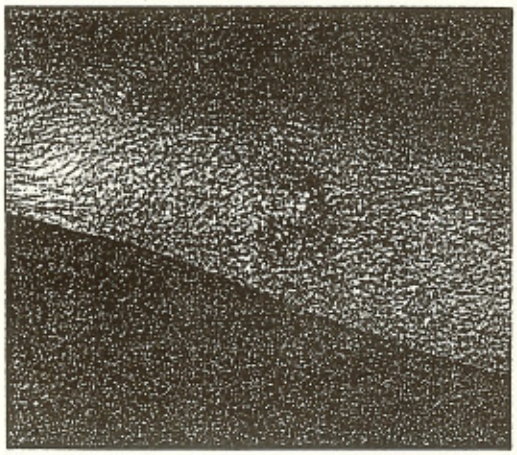

Fig. 4-C

Fig. 4 - 36-year-old patient with second degree burn due to chemical agent on the left forearm: A - Appearance of the lesion. B - BIOFILL® applied. C - Six days after the accident, already with elimination of the crust.

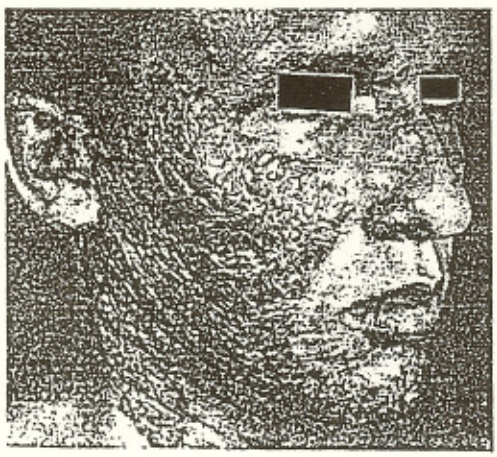

Fig. 5-A

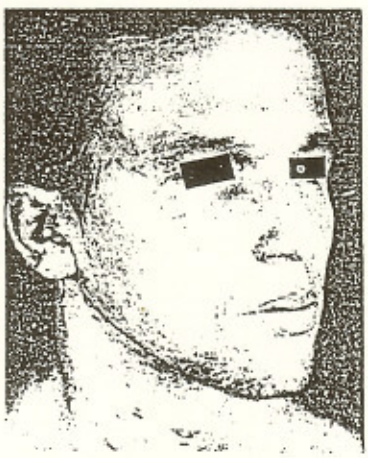

Fig. 5-B

Fig. 5 - 28-year-old patient, with second degree burn due to scalding, affecting face and right cervical region: A - Appearance immediately after application of BIOFILL®; B - Five days after the accident, crust already eliminated.

c) Graft donor areas: 17 patients, with ages varying from five to 22 years, had the lateral surface of the thigh removed as partial skin graft donor area (Fig. 6). Gauzes soaked in vasoconstrictor solution (adrenalin 1:200,000) were temporarily placed over the donor area. After their removal, BIOFILL was then applied, proceeding to remove air and/or blood bubbles. A light compressive dressing was maintained for 12-24 hours.

RESULTS

A) Dermabrasion: A variation was observed in results obtained according to the area of the face to which BIOFILL® was applied. In the temporal region, excellent adherence, good hemostatic function and little formation of bubbles was confirmed, with removal of the crust between the 5th and 8th days. In the perioral region, due to the great mobility of the area, there was little adherence, with wrinkling and early detachment around the 2nd day. The malar and nasal regions showed intermediate behavior.

In the cases in which dermabrasion was combined with resection of scars, good adherence of BIOFILL® to the sutures was confirmed, without compromising them (Fig. 7).

None of the patients reported local pain or symptoms associated with application of the membrane, at rest or during movement in the first days. There was no need to change the film, with just one application having been made. The sero-sanguineous collections were reabsorbed in the first 24-48 hours, causing thickening of the crust and decrease in the transparency of the film. No signs of infection were documented and there was no change in the total time of the re-epithelization process.

b) Second degree burns: The first factor observed after application of the film was the elimination of pain. Some patients reported initial mild to moderate burning, followed by immediate relief. Except when the burns involved very mobile areas (joints, hands, etc.), the temporary dressings applied over the BIOFILL® remained for less than 24 hours. During the time it

was in place, the dressing was inspected and after this period the film was left exposed. In some cases of small burns on flat surfaces, the temporary dressing can be removed in approximately three hours.

Two patients with burns due to scalding on the abdomen and face had infection. Blister formation was observed, on the 5th and 4th day respectively, with purulent contents, proving by means of culture the presence of *S. aureus*. The blisters were debrided and after cleaning, the areas were re-covered with BIOFILL® with resolution of the process. The average healing time, with detachment of the crust in second degree burns, was approximately 12 days.

c) Graft donor areas: The surface of the donor area (anterolateral region of the thigh) did not present difficulty in the application and maintenance of the film on the bed. In removing the partial skin graft, abundant local bleeding was confirmed, despite compressive dressings with vasoconstrictive solution. In six cases, there was a certain degree of sanguineous accumulation under the film, forming a dark chestnut-colored, nontransparent crust that detached around the 11th day (Fig. 8). No patient reported significant local pain.

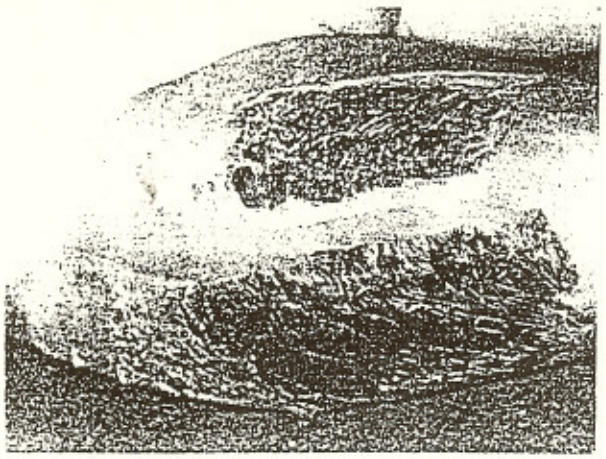

Fig. 6 - Detachment of the crust on the 11th day after application of BIOFILL® in partial skin graft donor areas (anterior and lateral regions of the right thigh)

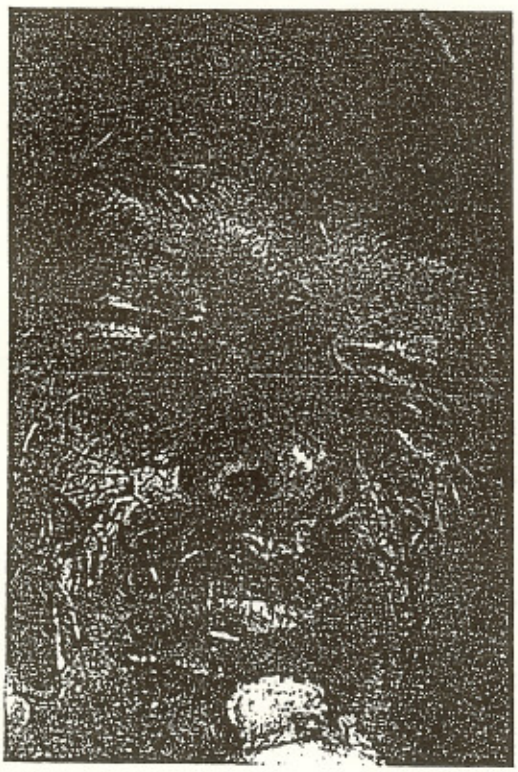

Fig. 7 - Detail of the application of BIOFILL® over sutures in case of mechanical dermabrasion combined with resection of scars.

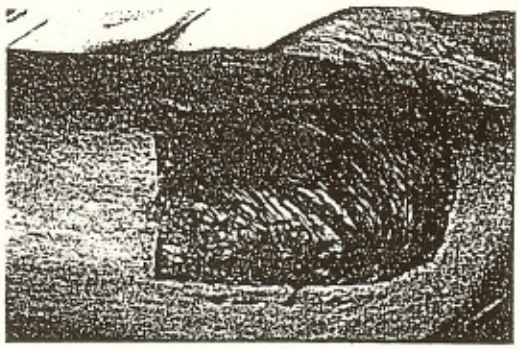

Fig. 8 - Partial skin graft donor area (lateral region of the left thigh), accumulation of blood under the film being observed.

Fig. 9 - Detail of the application of BIOFILL® over irregular surface. In this case of second degree burn, the film was recut and applied over the auricular pavilion. with good adherence.

Fig. 10 - Biopsy of segment of partial skin graft donor area, performed 24 hours after the application of BIOFILL.® H.E. 10 X, with infiltrate of macrophages between the dermis and the film being observed.

DISCUSSION

Although the causative agents, affected areas and conditions of the patients have varied, the basic lesion treated with BIOFILL® was the partial loss of skin. This condition permitted a more refined analysis of the product used, since the pathology was the same, and only the situations in which it was observed and treated varied. With the exception of elasticity, all the ideal properties of a temporary skin substitute were found in BIOFILL®. The small degree of elasticity was evidenced when the film was applied on areas of great mobility (e.g., perioral region), even compromising the remaining properties. When immobilization could be attained by means of compressive dressings and the patient cooperated in the sense of avoiding movement in joint areas, this deficiency was avoided with relative efficacy. In very mobile areas, such as, for example, the perioral region or the hands, the film was not maintained in the desired conditions, being in some cases replaced by another form of dressing (gauzes with Granúgena® paste).

Seeking to avoid the elasticity problem which impeded adherence of the film to irregular surfaces, BIOFILL® was recut into small segments and applied according to the routine (Fig. 9).

In areas in which great elasticity of the film was not required, BIOFILL® proved to be highly effective, eliminating pain almost immediately and providing early discharge of the patient to usual activities (walking, work, hygiene, etc.), with greater comfort than with other forms of dressing used by the Service.

The good adherence of the film, verified clinically, was studied with histologic technique (HE). In a partial skin graft donor area (inner surface of the thigh), BIOFILL® was applied and a skin biopsy performed 24 hours later. The infiltrate of macrophages, visible between the skin and the film, demonstrated the inflammatory reaction responsible for adherence which began within the first 24 hours (Fig. 10).

We observed that the use of BIOFILL® permitted, due to its transparency, the immediate visualization of complications (partial infection, seroma and hematoma) and consequent treatment by means of excision of blisters, local cleaning and application of a new film.

The costs of treatment with BIOFILL® were (approximately 30% lower in comparison to conventional treatments, since the hospitalization time is reduced, as is the number of dressings and frequency of medical care.

CONCLUSION

BIOFILL®, due to its characteristics, is shown to be an effective biologic dressing for lesions that are not very deep and areas of little mobility, proving to be fairly efficient in the treatment of partial skin losses. Despite its low elasticity, it has good adherence and durability, reasonable hemostatic capacity, permits vaporization of water, and is a good antiseptic, easy to apply and handle, eliminating pain almost immediately.

Due to its transparency, it makes possible constant inspection of the wound and prompt treatment in cases in which there may be complications. This procedure permits early discharge of the patient to normal activities. With a shorter hospitalization time and reduction in the frequency of dressings and medical treatment, we found that treatment with BIOFILL® reduced the costs by approximately 30% in relation to conventional treatments.

Bibliography

1. Guldlian J, Jelenko III C, Callaway D, Nicknight JT. A comparative study of synthetic and biological materials for would dressings. Trauma 1973: 13(1): 32-35.
2. Wayne MA. Clinical evaluation of epilick. A semiocclusive dressing. Ann Emerg Med 1985; 14(1): 20-34.
3. Varghese MC, Bajin AK, Carter DM, Caldwell D. Local environment of chronic wounds under synthetic dressings. Arch Dermatol 1986; 122: 52-57.
4. Tavis MJ, Thornton J, Doinet R, Barlett RM. Currend status of skin substitutes. Surg Clin North Am 1978; 58(6): 1233-1249.
5. Katz S, McGinley K, Leyden JL. Semi permeable occlusive dressings. Arch Dermatol 1986; 140: 58-62.
6. Alexander JW, Wheller LM, Rooney RC, McDonald JJ, MacMillon BG. Clinical evaluation ou epigard, a new synthetic for homograft and hetero graft skin. Trauma 1973; 13(4): 374-383.
7. Neal DE, Whalley PC, Flours MW, Wilson DH. The effects of an adherent polyurethane film and conventional absobent dressing in patients with small partial thickness burns. Br J Clin Pract 1981; 254-257.
8. Mariani U, Manna Filho, E, Agerami RE. Avaliação dos curativos absorventes como veículos de antimicrobianos. Rev Hosp Clin Fac Med São Paulo 1984; 39(4): 163-167.
9. Konberg I, Burns NE, Kajesjiab R, Barlett RH. Ultra thin silicone polymer membrane. A new synthetic skin substitute. A preliminary study. Trans Am Soc Atif Int Organs 1972; 18: 39-44.
10. Colocho G, Graham WP, Grrene AE, Matheson DW, Lynch D. Human amniotic membrane as a physiologic wound dressing. Arch Surg 1974; 109: 370-3.
11. Farah LFX. "BIOFILL" – Uma descoberta da ciência médica paranaense. JAMP 1986, março/abril.
12. Rebello C, Almeida DA, Lima Jr EM, Dornelas MP. Biofill, um novo substituto de pele: nossa experiência. Rev bras Cir 1987; 77(6): 407-14.