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DECLARATION OF ACCURACY AND PRECISION

Re: Translation from Portuguese

Article by Capelo & Alves, "A new temporary skin substitute (Biofill)

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

Translator

11/11/90

Date

A NEW TEMPORARY SKIN SUBSTITUTE (BIOFILL®)

EXPERIENCE IN THE BURN UNIT OF THE COIMBRA PEDIATRIC HOSPITAL (C.P.H.)

by

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SUMMARY:

The authors present their experience with a new temporary skin substitute--a cellulose membrane (BIOFILL®)--in the Burn Unit of the C.P.H., used in 36 children with 2nd- and 3rd-degree burns varying between 6 and 25%. Also conducted was a case by case comparative study between 13 children treated conventionally and 13 children treated with Biofill® according to defined criteria. It was shown unequivocally that the second method of treatment is the most effective, not only because good results were obtained within a shorter period of time and with more convenience for the child, but also because of economic advantages.

INTRODUCTION:

Over the last decades, innumerable investigations have taken place with the goal of finding temporary skin substitutes (T.S.S.), biological or synthetic,[1-5] able to lessen the

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fateful consequences of the loss of the cutaneous covering, primarily in cases of extensive burns[5] (Fig. 1).

Tavis established what are the ideal properties of a T.S.S.[7] (Fig. 2), stressing that good adhesion reduces pain, limits infection, and protects natural tissue recovery.

The present study was carried out in the Burn Unit of the C.P.H., which, over the last few years, has recorded a frequency in hospitalizations ranging from 80 (1988) to 88 (1987), with the mean hospitalization time fluctuating between 25 (1988) and 16 (1989) days. (Fig. 3)

In this Unit the conventional treatment with closed dressings applied daily or on alternate days was customarily used. From the 2nd trimester of 1989 on, we had the opportunity of using a T.S.S.--BIOFILL®.

Our objective is to communicate the results obtained with the use of Biofill® and to compare them with those of the previous method of treatment.

MATERIAL AND METHODS:

Biofill® is defined by the manufacturer as being a biosynthesized membrane consisting of a net of pure cellulose microfibrils, semipermeable and semitransparent, homogeneous, with a mean thickness of 0.05 mm, resistant to traction and devoid of adhesives. Each membrane is supplied in a unit package sterilized (and resterilizable) with ethylene oxide.

It was used between 3/1/1988 and 5/31/1990 in 36 children under 10 years of age, 22 male and 14 female (Fig. 4). The percentage of burned area was less than 10% in 11 children and more than 20% in 6; 30 children exhibited 2nd-degree burns, 4 had combined 2nd- and 3rd-degree burns, and 2 exhibited 3rd degree burns over the whole burned area (Fig. 5).

Biofill®, applied twice under general anesthesia (G.A.) and as first dressing, was normally applied in the other cases on the 2nd day of hospitalization, in our bandaging room under aseptic

conditions. With the manufacturer's indication in mind, Biofill® was applied so as to exceed the burned area by 1 cm, and also overlapping the membranes 1 cm (this measurement was increased in articular regions). The dressing was kept closed for 24 hours, and exposed after that. Sometimes the Biofill® had to be repositioned over small areas left uncovered through slight slipping of the membranes; at other times, discontinuities had to be covered with Biofill®, especially in areas of membrane superposition.

During the rest of the hospitalization period, the child's Biofill®-covered burned area remained exposed without any dressing, which allowed normal daily activity, including the general hygiene bath.

Given the semitransparency of Biofill®, small serous collections were easily detected, which necessitated drainage only if there was a progressive increase. This drainage was performed by simple crosswise incision over the original membrane, this small area being covered with a patch of Biofill®. This second membrane was dried rapidly by a gentle stream of air at room temperature, with no need for a closed dressing.

We do not use Biofill® on the face or the perineum.

Whenever infection of the burned area was suspected, collections were made for bacteriologic examination. In some children, antibiotic therapy was administered while awaiting the results of the bacteriologic examination, or in order to treat intercurrent conditions.

From the conventionally treated children hospitalized in 1988, we chose 13 children comparable case by case with another 13 children treated with Biofill®, in accordance with the criteria shown in Fig. 6. We then verified the time of antibiotic therapy and the number of surgical interventions under G.A. for each "pair."

RESULTS:

We classified the adhesion of Biofill® into 3 grades:

a) Ineffective - less than 70%
b) Partial - between 70 and 90%
c) Total - more than 90%

Of our 36 cases, adhesion was considered to be ineffective in 4 cases, partial in 7, and total in 25 cases (Fig. 7). It should be stressed that of the 4 cases with ineffective adhesion, 2 were cases of exclusively 3rd-degree burns, and 2, of combined 2nd- and 3rd-degree burns.

The mean hospital stay for the 36 burned patients was 18 days. But, if we exclude the 6 burned patients (mean hospital stay 44 days) with 3rd-degree burns (2) and 2nd- and 3rd-degree burns (4) in whom Biofill® had an adhesion considered ineffective, or functioned as provisional treatment until the application of epidermal grafts, the mean hospital stay of the remaining 30 falls to 13 days.

In the cases treated exclusively with Biofill® (n = 30), the "ad integro" recovery proceeded rapidly, the temporary skin substitute falling away spontaneously as soon as the repair was complete, leaving slightly depigmented elastic skin.

The semitransparency of Biofill® allowed us in 7 cases to suspect the existence of underlying purulent collections. Bacteriologic examinations were all negative.

The comparative study of each conventionally treated burn patient with his corresponding Biofill®-treated "peer" can be summarized as follows:

	Treatment with Biofill® (n=13)	Conventional treatment (n=13)
1 - Days of hospitalization	169 (mean 13)	288 (mean 22)
2 - Days of antibiotic treatm.	62 (mean 5)	160 (mean 12)
3 - Surgical procedures	--	11

As for the aesthetic result, although difficult for us to quantify, our impression was that of a distinct advantage for the burn patients treated with Biofill®.

CONCLUSIONS:

Despite the small number of burned children in this study, it seems to us that it is warranted to conclude as follows:

The use of Biofill®, in contrast to the conventional method, permits burned children a life much closer to normal. Its adherence and some elasticity permit the children to move and thus, in relation to other patients, allows play activities, and the daily hygiene bath. The only slight elasticity of Biofill® was the sole unfavorable factor we detected; however, it was overcome by overlapping of the membranes, as well as the support on the skin surrounding the burn.

It prevents the physical and psychologic trauma encountered with conventional dressing, which is so familiar to anyone coping with burn patients.

The reduction of the infection factor and the absence of hypersensitivity reactions permit more rapid and aesthetically more favorable repair of the tissues involved.

It decreases the days of hospitalization and the treatment becomes easier--namely, in terms of the need for antibiotic therapy and of surgical procedures. It is our impression that this hospitalization time might be distinctly shortened if our patients were able to have effective care at home.

It shortens the duration of the upset incurred by the family due to the accident (burn), which is still considerable, given the geographic and socioeconomic conditions of our external milieu.

Beyond these benefits, the considerable reduction of hospital costs, so high in Burn Units, and which exceed by far the cost of the product, must be valued also.

To the nursing team of our Burn Unit we express our very sincere gratitude for the overall enthusiasm exhibited in carrying out their functions; the use of this new synthetic skin substitute was meticulously recorded, permitting the report presented here.

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1.	GOOD ADHESION
2.	PERMEABILITY TO WATER VAPOR
3.	ELASTICITY AND DURABILITY
4.	ANTIBACTERIOLOGIC BARRIER
5.	NONTOXIC; NOT HYPERSENSITIZING
6.	HEMOSTATIC
7.	EASY APPLICATION AND REMOVAL
8.	EASY STORAGE AND LOW COST

Fig. 2: Ideal properties of a temporary skin substitute (Tavis, 1978)

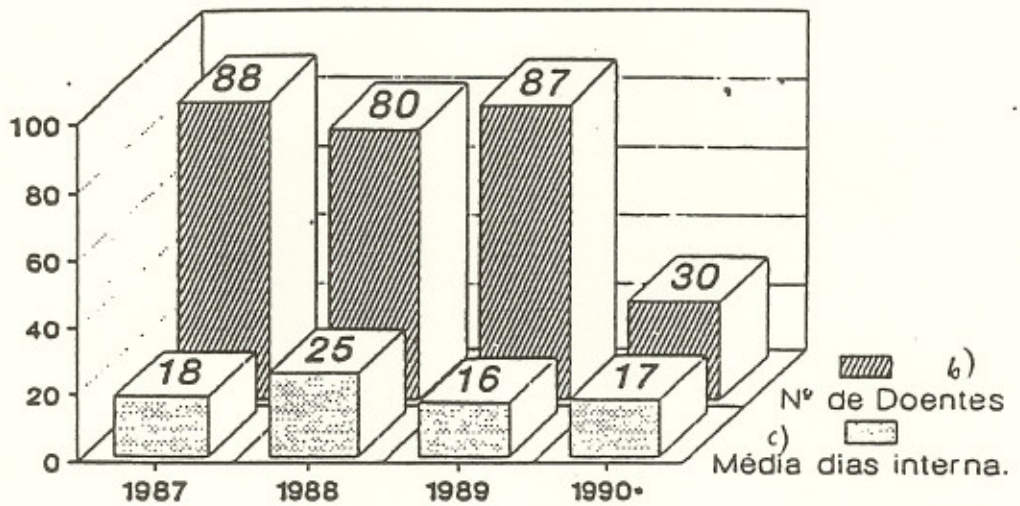

Figure 3: Burn Unit Movement in last years - Coimbra Pediatric Hospital

Key: a) Up to 5/31/90; b) No. of patients; c) Mean days of hospitalization

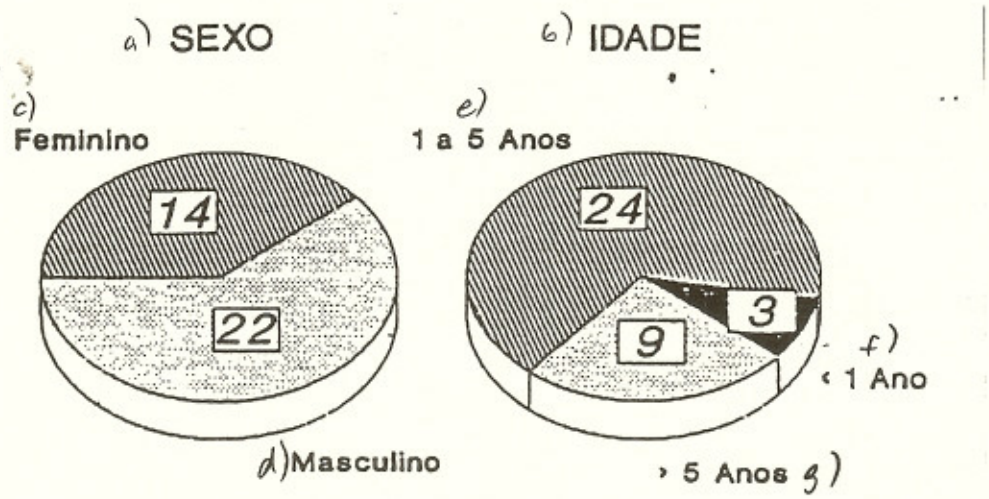

Figure 4: Distribution by sex and age (36 children).

Key: a) SEX; b) AGE; c) female; d) male; e) 1 to 5 years old; f) < 1 year old; g) > 5 years old

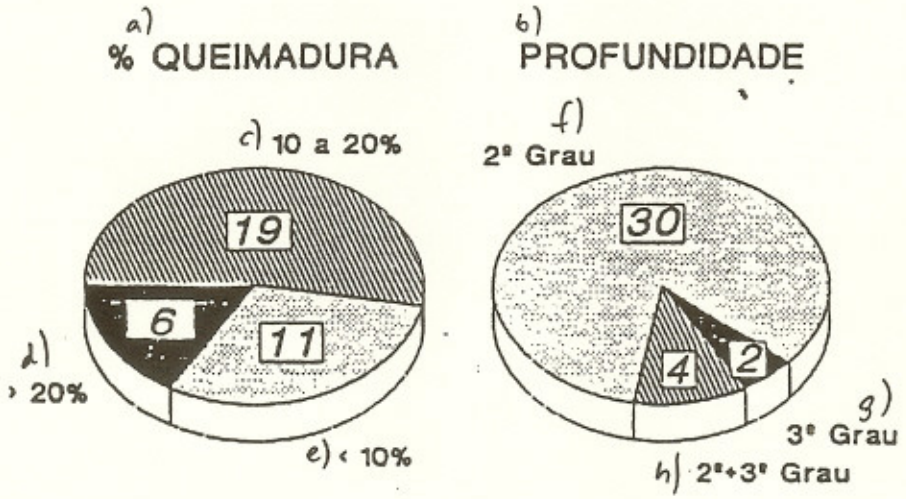

Figure 5: Distribution in % and depth of burn (36 children)

Key: a) % BURN; b) DEPTH; c) 10 to 20%; d) > 20%; e) < 10%; f) 2nd degree; g) 3rd degree; h) 2nd + 3rd degree

AGE -	MAXIMUM DIFFERENCE - 7 MONTHS (17 to 24 months)
AREA -	MAXIMUM DIFFERENCE - 2%
DEGREE -	SAME
AGENT -	VERY HOT LIQUIDS
AREAS -	TRUNK AND/OR LIMBS

Figure 6: Criteria for comparison between conventional treatment and treatment with Biofill

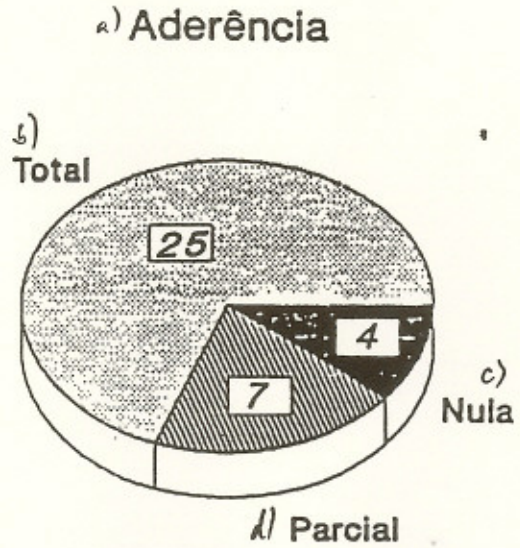

Figure 7: Results in terms of adhesion

Key: a) Adhesion; b) total; c) ineffectual; d) partial