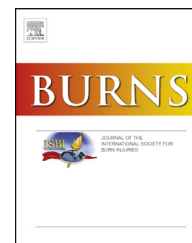


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# The use of Biobrane<sup>®</sup> for wound coverage in Stevens–Johnson Syndrome and Toxic Epidermal Necrolysis



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## ARTICLE INFO

Article history:

Accepted 19 March 2017

## ABSTRACT

**Introduction:** Published experience describing the use of Biobrane<sup>®</sup> for wound management in Stevens–Johnson Syndrome and Toxic Epidermal Necrolysis (SJS–TEN) is limited to case reports and case series involving ten or fewer patients. We have used Biobrane<sup>®</sup> in the care of SJS–TEN since 2000, and the purpose of this study was to review our experience with the application of Biobrane<sup>®</sup> for wound coverage in SJS–TEN.

**Methods:** A retrospective review of all cases of SJS–TEN admitted to an adult regional ABA-verified burn center between January 1, 2000 and June 1, 2015 was conducted. Biobrane<sup>®</sup> application was performed at burn center admission. Values are presented as the median (IQR), or mean  $\pm$  SD where appropriate.

**Results:** We identified 42 eligible subjects with SJS–TEN. Biobrane<sup>®</sup> was applied in 24 subjects. Biobrane<sup>®</sup>-treated subjects had an age of  $51.4 \pm 21.7$  years, with a %TBSA epidermal detachment of 39.5 (30–46), 63% were female and the admission SCORTEN was 3 (2–4, range 1–5). Biobrane<sup>®</sup> was applied at burn center (BC) admission in 18/24 subjects (82%), and between post admission days 1–4 in four subjects. Biobrane<sup>®</sup> was applied to 35 (22–40) % of the TBSA (range 7–90) involving all anatomic areas including the head and neck. There were no complications, infections, premature removals, or Biobrane<sup>®</sup>-associated sepsis in 24/25 applications (96%). In one subject a sheet of the TBSS was removed due to sub-Biobrane<sup>®</sup> fluid collection, but with negative microbiological cultures. Time to healing was 13 (12–16) days, and burn center length of stay was 34 (15.3–62.3) days. Subjects treated with dressings only (n=18) had a significantly smaller %TBSA epidermal detachment [10 (5–22),  $p < 0.001$ ], and were predominantly diagnosed with SJS (50%) or SJS–TEN overlap (33%). Time to healing among dressing-only subjects was not significantly different [12 (10–14.5) days] than among the Biobrane<sup>®</sup>-treated subjects, ( $p=0.127$ ).

**Conclusion:** Biobrane<sup>®</sup> was applied to SJS–TEN subjects with more extensive epidermal detachment, had no significant complications, and generally facilitated epidermal healing in under 2 weeks from application.

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<http://dx.doi.org/10.1016/j.burns.2017.03.016>

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## 1. Introduction

Toxic Epidermal Necrolysis Syndrome (TEN) is an exfoliative muco-cutaneous condition that is usually induced by a severe immune reaction to a medication, but may sometimes be associated with an infection or malignancy [1-3]. The most frequently implicated agents include allopurinol, anticonvulsants, non-steroidal anti-inflammatory drugs, and sulfonamide antibiotics [4,5]. TEN is part of a spectrum of diseases that are differentiated by the extent of epidermal detachment. These include Stevens-Johnson Syndrome (SJS), in which epidermal loss involves <10% of the total body surface area (TBSA), and SJS-TEN Overlap, where there is epidermal detachment from 10%-30% of the TBSA. In TEN, >30% of the TBSA must experience epidermal detachment to meet clinical diagnostic criteria [2]. The incidence of SJS is 1-7 cases per million of the population per year, while TEN occurs in 0.4-1.5 persons per million population per year [6]. The mortality rate for SJS is between 1% and 3% [7], while for TEN, the mortality rate is as high as 30%-50% [8,9]. Mortality rates specific to TEN treated in a burn center setting range between 20% and 32% [10-12]. A severity-of-illness score that estimates the risk of death in TEN (SCORTEN) has been developed [13] and validated [11].

The diagnosis of an exfoliative condition meeting the criteria for TEN warrants prompt referral to a burn center accustomed to managing critically ill patients with extensive wounds. Systemic manifestations may be significant, usually as a result of deranged thermoregulation, metabolism, fluid homeostasis and immunosuppression. The most frequently affected mucosal surface is the oropharynx, followed by the eyes and genitalia. A critical component of burn center treatment of TEN is the care of the skin, and particularly the management areas of raw exposed dermis. An important principle is to maintain viability of the remaining dermis in order to allow rapid re-epithelialization to occur [14,15]. One strategy to protect and preserve the dermis is to cover it with a temporary skin substitute, as opposed to a simple dressing. The potential advantages of using a skin substitute in this situation include prevention of desiccation of the wound, reduction of fluid and heat loss from the wound, establishment of a barrier to exogenous microbial contamination, and reduction in pain and facilitation of movement in the involved parts. Biological skin substitutes such as porcine xenograft have been used in TEN [14]. Biosynthetic skin substitutes such as Biobrane<sup>®</sup> have also been employed to cover wounds in TEN. Biobrane<sup>®</sup>, introduced in 1979, is a bi-laminar semisynthetic substitute composed of a nylon mesh and porcine collagen on the inner layer, and a silicone coating externally. It is a temporary substitute which adheres to the wound, but which ultimately detaches as epidermal re-population proceeds. Infection of Biobrane<sup>®</sup> is the most feared potential complication of its use.

The available descriptions of Biobrane<sup>®</sup> use in TEN in the literature are limited and involve case reports or small case series involving ten or fewer patients [16-22]. Since 1999, we have frequently used Biobrane<sup>®</sup> (Smith and Nephew Canada, Mississauga, Ontario) to cover the raw dermal wounds in patients with TEN treated at our burn center. The purpose of

this study was to review our experience with the use of this skin substitute in TEN. In particular we were interested in examining the time to wound healing and the rates of infection associated with Biobrane<sup>®</sup> use.

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## 2. Methods

This was an IRB-approved retrospective study conducted at an adult regional American Burn Association-verified burn center. The burn center's computerized database was used to identify all patients admitted to the burn center with the diagnosis of SJS, SJS-TEN overlap, or TEN, between January 1, 2000 and June 1, 2015. The medical records of these patients were then reviewed. We excluded any patients where a biopsy indicated a diagnosis other than SJS-TEN, or if the record was missing or incomplete. In general, we prefer to obtain biopsy confirmation of the clinical diagnosis in SJS-TEN, but this was not done in all cases. However, in the absence of biopsy confirmation, a patient was included for review as long as the clinical diagnosis was compatible with the clinical criteria stated by Roujeau and Stern [2].

The extent of %TBSA involvement was determined from the admission Lund and Browder diagram. We specifically documented the initial %TBSA of epidermal detachment at admission as well as the maximum %TBSA of epidermal detachment that occurred during the burn center stay. The difference between the two represented the %TBSA of progression of epidermal detachment. We determined the SCORTEN on the day of burn center admission and again on day 3 and day 5. We also documented any specific pharmacologic agents used to attempt to reverse the disease process [e.g. intravenous immunoglobulin (IVIG), Cyclosporine, Etanercept, or steroids].

Data pertaining to Biobrane<sup>®</sup> included the time of application relative to symptom onset and time of burn center admission, the %TBSA and anatomic locations covered with Biobrane<sup>®</sup> as documented in the procedural note by the attending surgeon, and a detailed day-by-day review of all medical progress notes and nursing notes while Biobrane<sup>®</sup> was on the subject, specifically looking for documentation of sub-Biobrane<sup>®</sup> fluid collection, lifting or detachment, or infection. We documented any situations where Biobrane<sup>®</sup> had to be removed either in part or in entirety due to non-adherence or infection. We also identified any instances when "windowing" of the Biobrane<sup>®</sup> was performed, whereby a hole was created in the material due to non-adherence to the wound or to facilitate drainage of an underlying fluid collection. If Biobrane<sup>®</sup> was not used, we documented the types of dressings that were applied, along with the %TBSA and anatomic locations over which the dressings were applied.

The outcome measures of interest were Biobrane<sup>®</sup> infection, Biobrane<sup>®</sup> sepsis, and time to wound healing, using the following a priori definitions: Biobrane<sup>®</sup> infection was defined as documentation of fluid or purulence beneath the Biobrane<sup>®</sup> necessitating part or complete removal of the sheet, with a positive microbiological culture of the fluid. Biobrane<sup>®</sup> sepsis was defined as a Biobrane<sup>®</sup> infection associated with a positive blood culture involving the same organism as cultured in the wound fluid. We defined the time of wound healing as the day

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