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Title **Bioengineered Skin Substitutes for the Management of Burns: A Systematic Review**

Agency **ASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures – Surgical**

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Aim

To assess the safety and efficacy of bioengineered skin substitutes (BSS) compared to biological skin replacements and/or standard dressing methods in managing burns.

Conclusions and results

This review included 20 randomized controlled trials (RCTs). Due to the diversity of skin substitutes, methods, etc, it was not possible to study the effectiveness of BSS in partial thickness vs full thickness burns, in pediatric patients vs adult patients, and for total burn surface area (TBSA). However, we could draw some conclusions on the different BSS reviewed.

For partial thickness burns (<15% TBSA), Biobrane® and TransCyte® appear to be more effective than silver sulfadiazine. Biobrane® may offer cost advantages over other BSS.

For burns between 20% and 50% TBSA, allogeneic cultured skin and Apligraf® combined with autograft both appear to be effective. Dermagraft® was also found to be effective for these burns (as effective as allograft), but the validity of this comparison is questionable.

No major complications were reported with BSS in managing burns or donor sites. The mortality rate was relatively high; however, it was unclear whether these deaths were due to the BSS or the actual burn injury. The evidence did not show the long-term safety of BSS as regards viral infection and prion disease. Hence, autograft remains the gold standard for excised burns.

Recommendations

The ASERNIP-S Review Group agreed on the following classifications and recommendations:

Evidence rating: Average.

Safety: BSS, namely Biobrane®, TransCyte®, Dermagraft®, Apligraf®, autologous cultured skin, and allogeneic cultured skin, are at least as safe as biological skin replacements or topical agents/wound dressings. The safety of Integra® could not be determined, nor could the long-term safety of BSS with respect to viral infection and prion disease.

Efficacy: In managing partial thickness burns, BSS, namely Biobrane®, TransCyte®, Dermagraft®, and allogeneic cultured skin, are at least as efficacious as topical agents/wound dressings or allograft. Apligraf® combined with autograft is at least as efficacious as autograft alone. In managing full thickness burns, the efficacy of autologous cultured skin could not be determined, nor could the efficacy of Integra®.

Methods

Search strategy: MEDLINE, EMBASE, the Cochrane Library, Science Citation Index and Current Contents were searched from inception to April 2006. Other electronic databases were searched in April 2006.

Study selection: Only RTCs in humans were included for review. Efficacy outcomes included wound infection, wound closure, wound healing time, and wound exudate. Patient-related outcomes included pain and cosmesis. Safety outcomes included complications and mortality.

Data collection and analysis: Data were extracted by one researcher using standardized data extraction tables developed *a priori* and checked by a second researcher. Statistical pooling was not appropriate due to the study and result heterogeneity.

Further research/reviews required

Rigorous RCTs would strengthen the evidence base, but RCTs are unlikely of patients with large, deep burns. Therefore, RCTs of patients with smaller burns should be undertaken. Studies should evaluate the long-term safety of BSS, and future studies should define and document outcomes for partial and full thickness burns separately. RCTs are also needed on cultured epithelial autograft, in particular cultured epithelial autograft suspensions.

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