Bioengineered skin substitutes for the management of burns: a systematic review

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Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' objectives
The objective of this review was to assess the safety and efficacy of bioengineered skin substitutes in comparison with biological skin replacements and/or standard dressing methods in the management of burns, through a systematic review of the literature.

Authors' conclusions
On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of bioengineered skin substitutes for the management of burns:

Classifications Evidence rating: The evidence-base in this review is rated as average. The included randomised controlled trials were limited by small sample size and poor reporting of methodological detail. The numerous subgroup analyses and the diversity of skin substitutes limited the ability to draw any conclusions from it.

Safety: The evidence suggests that bioengineered skin substitutes, 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 as one study reported a high rate of infection and the trial was terminated early. The long-term safety of the use of bioengineered skin substitutes, with respect to viral infection and prion disease, could not be determined.

Efficacy: For the management of partial thickness burns, the evidence suggests that bioengineered skin substitutes, 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. For the management of full thickness burns, the efficacy of autologous skin could not be determined based on the available evidence. The efficacy of Integra could not be determined based on the available evidence.

Clinical and Research Recommendations
Additional methodologically rigorous randomised controlled trials would strengthen the evidence base for the use of bioengineered skin substitutes. However, it is acknowledged that it is unlikely that randomised trials of patients with large, deep burns will be carried out, as these burns are uncommon and usually involve complex clinical decision pathways and possibly the use of several products, which may differ between patients and make comparisons difficult. Therefore, it is recommended that randomised trials of patients with smaller burns be undertaken as these burns are more common and patient accrual should be easier. Furthermore, clinical equipoise should be more easily obtained in these less life-threatening situations. Additionally, studies with sufficient follow-up should be conducted to evaluate the long-term safety of bioengineered skin substitutes and future studies should define and document outcomes for partial and full thickness burns separately.

There is also a need for randomised controlled trials on cultured epithelial autograft, in particular cultured epithelial autograft suspensions, as there is a lack of evidence to support its safety and efficacy and its use largely based on
anecdote.

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