INAHTA Briefs

Issue 2006/125

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

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

PO Box 553 Stepney, Australia; Tel +61 8 83637513, Fax +61 8 83622077; college.asernip@surgeons.org

Reference ASERNIP-S Report Number 52. ISBN 0-909844-72-0.

Full text available: www.surgeons.org/asernip-s/ (publications page)

Aim

To make recommendations on the safety and efficacy of bioengineered skin substitutes for managing wounds.

Conclusions and results

Bioengineered skin substitutes (BSS) – epidermal, dermal, or both – were compared to standard care/dressings or autografts. The review included 23 RCTs (8 on venous leg ulcers, 6 on diabetic foot ulcers, and 9 on other wounds). Success was defined as complete wound closure across all studies. Other outcomes were not consistently reported, making comparisons difficult.

In venous leg ulcers, Apligraf®, cryopreserved cultured allografts, cultured keratinocyte allografts, Dermagraft®, EpiDex™, OASIS™ Wound Matrix, and Promogran™, were comparable with standard treatment in wound healing time, wound closure, and decreased ulcer area. No difference was found in pain, recurrence, and wound infection.

In diabetic foot ulcers, BSS showed an advantage over standard care. Wound healing time appeared to be better overall with BSS (Apligraf®, Dermagraft®, GraftJacket®, Hyalograft™ and Laserskin™, OrCel™ and Promogran™), and wound closure appeared to be favorable with Apligraf®, GraftJacket®, and OrCel™. Infection rates were lower, and where reported, there was no difference in recurrence.

Healing across different wounds was no better with BSS than the relevant comparator, although pain might be lower. The evidence suggested that Apligraf® for micrographic and postexcisional wounds produced similar results to standard therapy, and Biobrane® for donor sites was inferior to standard therapy. Evidence on Promogran™ in treating pressure sores suggested it equaled standard therapy, and cultured epidermal allografts were superior to standard therapy for wound healing time and pain, but in several studies the small samples may limit the validity of the conclusions.

Recommendations

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

Evidence rating: Average. Limited by small samples, short followup, and lack of rigor.

Safety: BSS are at least as safe as standard therapies for venous leg ulcers, diabetic foot ulcers, and other wounds.

Efficacy: Could not be determined based on the available evidence.

Methods

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

Study selection: Only RCTs in humans and only studies comparing a BSS as a physical layer that would integrate into the wound (not lysate) were included.

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

- Additional RCTs with longer followup periods of BSS, particularly in terms of recurrence.
- Development of standard outcome measures for consistent reporting of primary outcomes.
- Cost-effectiveness studies in an Australian health-care context.

Written by Ms Christine Barber et al, ASERNIP-S, Australia

ISSN 1654-501X