Australian Government

Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

National Horizon Scanning Unit
Horizon scanning prioritising summary

Volume 6, Number 7:

Dermagraft® : Dermal substitute wound cover for patients with Dystrophic Epidermolysis Bullosa

August 2004

AHTA

Adelaide Health Technology Assessment

Electronic copies can be obtained from http://www.horizonscanning.gov.au

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The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID: **000115**

NAME OF TECHNOLOGY: **DERMAGRAFT®**

PURPOSE AND TARGET GROUP: **DERMAL SUBSTITUTE WOUND COVER FOR PATIENTS WITH DYSTROPHIC EPIDERMOLYSIS BULLOSA**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☒	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	71133
☐	No	☐	Not applicable

This technology has been available in Australian hospitals for the past 5 years for the treatment of diabetic ulcers. Dermagraft® was approved for use in the United States for the treatment of DEB in July 2003 (American Food and Drug Administration, 2003)

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		
Australia	✓		

IMPACT SUMMARY:

Smith and Nephew provide Dermagraft® with the aim of treating skin lesions caused by dystrophic epidermolysis bullosa (DEB). This technology has been available in Australian hospitals for the past 5 years for the treatment of diabetic ulcers. Dermagraft® was approved for use in the United States for the treatment of DEB in July 2003 (American Food and Drug Administration, 2003).

BACKGROUND

Dermagraft® is a dermal substitute made from live human fibroblast cells placed on a dissolvable mesh material, which grow to form a skin substitute. The mesh is subsequently absorbed. The Dermagraft® dressing covers and protects the wound while providing an environment that facilitates healing (American Food and Drug Administration, 2003). Dermagraft® is supplied frozen in a clear bag containing one piece approximately sized 5cm x 7.5cm for a single-use application.

CLINICAL NEED AND BURDEN OF DISEASE

Epidermolysis Bullosa is a genetic disease that produces multiple skin blistering lesions either spontaneously or following trauma. The disease is categorised according to the severity of the lesions: simplex, junction and dystrophic (Komurcu et al 2004). The multiple blistering lesions occur as a result of a deficiency in the proteins that normally hold the layers of skin together. The disease occurs mainly in children. Patients with DEB often have chronic, wounds that are slow to heal at sites that are exposed to chronic trauma (Williamson et al 2002). It is estimated that there are approximately 1000 cases in Australia and 100 in New Zealand (Nu Skin Enterprises 2002). It was not possible to locate data for the number of hospital separations for epidermolyis bullosa as these data have not been published (AIHW 2004).

DIFFUSION

It is difficult to predict the likely diffusion of the new product given the low prevalence of the disease. The use of the Dermagraft® is currently limited and has not been reported to date in Australian peer-reviewed publications.

COMPARATORS

The management of inherited Epidermolysis Bullosa is tailored to the severity and extent of skin involvement and consists of supportive care, including wound management, surgical management when required, prevention and treatment of infections, and nutritional support (Bello et al 2003). Previously, various kinds of biological dressing, including autologous and allogeneic grafts, have been used to treat intractable ulcers in patients with recessive Dystrophic Epidermolysis Bullosa (Hasegawa et al 2004).

EFFECTIVENESS AND SAFETY ISSUES

The FDA assessment of Dermagraft® includes a description of a retrospective uncontrolled 6-patient case series (level IV evidence). This study recorded no adverse events associated with the use of Dermagraft® in these patients. In four patients the application of Dermagraft® to 22 persistent wounds resulted in 20% to 100% epidermal coverage in eight weeks of treatment (Williamson et al 2002). The table below includes patient data for these patients. Without a control group, it is unclear as to the benefit of Dermagraft® compared to usual supportive care.

Table 1. Results of patients with Dystrophic Epidermolysis Bullosa treated with Dermagraft®

Patient	Number of pieces of Dermagraft® applied	Number of body sites treated	Percentage of epidermal coverage after one to two weeks (mean percentage)	Percentage of epidermal coverage after eight weeks (mean percentage)
1	5	5	Unknown	50
2	5	5	80-100 (90)	100
3	3	3	80-100 (90)	50-100 (82)
4	12	9	80-100 (95)	20-100 (68)

Source: Williamson et al, 2004

Two of the patients in this series with exposed, non-infected bone experienced a 58% and 87% reduction in wound size respectively, after one year (Williamson et al 2004). The FDA concluded that there is insufficient data to establish safety and effectiveness for the treatment of DEB, but that it may be useful as an adjunct to other treatments (American Food And Drug Administration, 2003).

No other data on the effectiveness and safety of this product was identified.

COST IMPACT

The cost of the device is currently AUD$800 per application. In the case of deep, non-healing ulcers it is likely that a patient would require up to eight applications (personal communication, Smith and Nephew).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION

There is currently very limited and low-level evidence available on the effectiveness of the Dermagraft® for the treatment of wounds in patients with dystrophic epidermolysis bullosa.

HEALTHPACT ACTION:

ASERNIP-S are conducting a review on artificial skin. Therefore it is recommended that this technology be archived.

SOURCES OF FURTHER INFORMATION:

AIHW (2004). *Selected separation statistics* [Internet]. Available from: http://www.aihw.gov.au/publications/hse/ahs02-03/ahs02-03-xd08.xls [Accessed 7th July 2004].

American Food and Drug Administration (2003). *Summary of safety and probable benefit – Dermagraft®* [Internet]. Available from: http://www.fda.gov/cdrh/pdf3/H020004b.pdf [Accessed 4th August 2004].

Bello, Y. M., Falabella, A. F. & Schachner, L. A. (2003). 'Management of epidermolysis bullosa in infants and children', *Clin Dermatol,* 21 (4), 278-282.

Hasegawa, T., Suga, Y. et al (2004). 'Clinical trial of allogeneic cultured dermal substitute for the treatment of intractable skin ulcers in 3 patients with recessive dystrophic epidermolysis bullosa', *J Am Acad Dermatol,* 50 (5), 803-804.

Komurcu, M., Bilgin, F. et al (2004). 'Major surgery and anesthetic technique in epidermolysis bullosa', *Mil Med,* 169 (2), 125-127.

NU Skin Enterprises (2002). *Epidermolysis Bullosa Appeal* [Internet]. Available from: (http://www.nuskinenterprises.com.au/au/company/eb_appeal.shtml [Accessed 7th July 2004].

Williamson, D., Coutts, P., Sibbald, R.G. (2002). 'The role of dermal skin substitutes in the management of 'hard to heal', unusual wounds', *Can J Plas Surg,* 10 (Suppl A), 27A-30A.

Woodley, D. T. & Chen, M. (2004). 'Epidermolysis bullosa: then and now', *J Am Acad Dermatol,* 51 (1 Suppl), S55-57.

SEARCH CRITERIA TO BE USED:

Cells, Cultured
Epidermolysis Bullosa Dystrophica/ therapy
Fibroblasts/cytology/ transplantation
Skin Ulcer/complications/ therapy
Tissue Engineering
Wound Healing