

EpiDex[®] Swiss Field Trial 2004–2008

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Key Words

EpiDex[®] · Skin substitute, autologous · Epidermal equivalent · Plucked anagen hairs · Outer root sheath keratinocytes · Cell culture · Wound healing · Leg ulcer · Venous ulcer · Field trial · Unselected consecutive case series

Abstract

Background: Approximately 20% of leg ulcers remain unresponsive to the best conservative standard of care. So far, these patients could either receive conventional skin grafts or had to accept their intractable wound. Skin substitutes from cell culture may represent a promising alternative to heal a major part of these patients on a non-surgical, potentially more cost-effective basis. **Objective:** To systematically evaluate the first 68 patients treated in Switzerland (Swiss EpiDex[®] field trial 2004–2008). **Methods:** Retrospective study on EpiDex treatment of a complete consecutive series of 68 patients with chronic wounds (66 chronic leg ulcers, 2 sores) unresponsive to best conservative standard of care. The primary end point was complete wound closure within 9 months after transplantation, the secondary end points change of wound surface area, pain reduction and overall judgement by the patient. Adverse effects were infection, dermatitis and others. Calculation of treatment costs was made. **Results:** By the end of the study, 50/68 (74%) of patients had their wound completely healed [venous 29/37 (78%); mixed 7/9 (78%); others 14/22 (64%)]; 10/68 (15%) had

the wound surface area reduced by >50%, and 8/68 (12%) did not respond to the EpiDex treatment. Wound pain disappeared completely in 78% and partially in 13%. Fifteen patients (22%) received antibiotics for wound infection, and 2 (3%) developed dermatitis (not related to the local therapy). Average treatment costs for venous ulcers amounted to EUR 5,357, compared to EUR 5,722–8,622 reimbursed according to the German DRG system (2010) for an in-patient skin graft. **Conclusion:** EpiDex may effectively heal up to three quarters of recalcitrant chronic leg ulcers. Thus, it represents an intermediate step to avoid costly in-patient split-skin mesh graft treatments. Patients remain mobilized, and a donor site is avoided. Large wound size or a necrotic wound bed limit the use of EpiDex. Otherwise, it offers the opportunity to avoid conventional skin grafts in a significant number of chronic leg ulcer patients. Copyright © 2010 S. Karger AG, Basel

Background

Leg ulcers represent a frequent and costly medicosocial problem [1–8]. They considerably impair the quality of life [9–11] and usually require 3–6 months to heal in 60–80% of patients, with approximately 20% remaining refractory

EpiDex is an acronym for an autologous epidermal equivalent of outer root sheath keratinocytes from plucked anagen hairs.