A Prospective, Multi-center Cooperative Group Study to Evaluate the Effectiveness of Epidermal Grafting

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Introduction

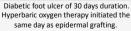
Epidermal grafting is an evidenced-based reconstructive option to promote healing in acute and chronic wounds. However, until recently, its use was limited to a few investigational trials because of the laborious and arduous harvesting techniques. Introduced in 2013 an automated epidermal harvesting device* produces more than 100 epidermal grafts at the bedside with minimal patient discomfort in 20 to 40 minutes.

Methods

This prospective, multi-center cooperative group study evaluated the effectiveness of epidermal grafting in the treatment of acute and chronic wounds of various origins (diabetic, venous, traumatic, pyoderma and post-surgical). Patients with granulating wounds, free of non-viable tissue, underwent one epidermal graft application. Wound assessment and planimetric measurements were performed weekly in the wound center for a total of four weeks.









One week post grafting



Two weeks post grafting



Complete healing at 4 weeks.

Results

24 patients from three geographically distinct wound centers with a variety of chronic ulcers underwent epidermal grafting micrografts harvested using the System*, 87.5% of the wounds demonstrated improvement with decreased wound surface area with four wounds achieving complete closure in four weeks. There were three wounds that either did not improve or worsened. All of the grafts were harvested from the inner thigh without anesthesia. There were no donor site adverse events with 100% healed during the trial. The one patient with pyoderma gangrenosum did not suffer from pathergy at the donor site. Approximately 50% of the wounds treated exhibited "graft take" to some degree. Those that did not, healed from the margins as is seen with other cellular and tissue-based products (CTP).

Conclusions

Epidermal grafting was effective in promoting healing of XX patient's chronic wounds. The results of this prospective series informed the ongoing randomized controlled clinical trial evaluating the efficacy of epidermal grafting in venous leg ulcers.

* CelluTome® - Epidermal Grafting



