An Evaluation of Healing Metrics Associated with Commonly Used Advanced Wound Care Products for the Treatment of Chronic Diabetic Foot Ulcers

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Background

- As rates of diabetes escalate worldwide, diabetic foot ulcers are an increasingly significant public health problem.
- Approximately one-quarter of people with diabetes will develop a foot ulcer over their lifetime.1
- Many diabetic foot ulcers will not heal with conventional therapy.
- The Wound Healing Society guidelines recommend consideration of advanced wound therapies if a diabetic ulcer does not reduce in size by 40% or more after 4 weeks of standard therapy.2
- Advanced wound therapies that promote rapid and complete healing, thus reducing the risk for infection and amputation, can substantially improve quality of life while decreasing financial burdens to the individual and health care system.
- Clinical trial results have shown that bioengineered skin substitutes, such as Apligraf®, Dermagraft®, and Epifix® promote wound closure, resulting in more frequent and rapid healing of diabetic foot ulcers when compared with standard therapy.3,4,5
- Comparative effectiveness research offers an opportunity for improved clinical outcomes and quality by providing more complete information on how products perform, which in turn may reduce health care costs.

Purpose

Our purpose is to compare standardized healing metrics in patients with diabetic foot ulcers treated with 3 widely used advanced wound healing products.

Table 1. Product comparisons.

<table>
<thead>
<tr>
<th>Product description</th>
<th>Apligraf®</th>
<th>Dermagraft®</th>
<th>Epifix®</th>
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</thead>
<tbody>
<tr>
<td>Neocel fibroblasts cultured in bovine collage matrix overlaid with neonatal keratinocytes</td>
<td>Neocel fibroblasts cultured in polygalactin mesh</td>
<td>Dehydrated human amnion/chorion membrane allograft</td>
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</table>

Results

- Complete wound closure within 12 weeks of treatment initiation occurred in 56%, 30%, and 92% of Apligraf®, Dermagraft®, and Epifix®-treated ulcers, respectively.
- Epifix®-treated ulcers had the shortest time to healing (median 14 days) and least amount of graft material used (14 cm²) vs the Apligraf® and Dermagraft® groups.
- The differences observed in the published literature suggest that treatment with Epifix® results in the most rapid improvement and resolution of diabetic foot ulcers.

Methods

- Retrospective analysis of data collected and reported in published randomized controlled trials, physician product prescribing information, and pre-market approval summary documents from the US FDA.
- Rates of complete wound closure within 12 weeks, time to healing, number of graft applications to wound closure, duration of healed wounds, and safety were examined for patients with diabetic ulcers treated with Apligraf®, Dermagraft®, or Epifix®.

Included

- Included for analysis were only data from patients with type 1 or type 2 diabetes, adhered to the protocol, and had complete wound closure, recurrence were excluded.

Treatment

- Treatments consisted of Apligraf® (up to 5 weekly applications), Dermagraft® (up to 8 weekly applications), and Epifix® (weekly or every two weeks) applied until wound closure or up to 12 weeks, whichever came first.
- In all studies standard principles of diabetic foot care were adhered to.

Conclusions

The differences observed in the published literature suggest that treatment with Epifix® results in the most rapid improvement and resolution of diabetic foot ulcers.