Use of Novel Placental-derived, Conformable Allograft in the Treatment of Non-Healing Chronic Wounds

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Overview:

In the US, chronic non-healing wounds affect approximately 6.5 million adults with the associated cost of $25 billion annually to treat the wound and the associated complications[1]. The majority of these chronic wounds (CWs) in the form of ulcers are associated with peripheral arterial disease (PAD), peripheral venous disease (PVD), neuropathic/diabetic conditions or a combination thereof[2]. The comorbidities associated with these conditions are numerous and cause significant impairment in the wounds' ability to respond to standard and good wound care (SWC/GWCP) practices. The etiologies associated with non-healing wounds in the lower extremities present additional challenges; all of which are associated with increases in infection, amputation, morbidity, and mortality[3].

To date, SWC and GWCP approaches are inadequate to heal many CWs, which tend to progressively worsen under these conditions[3,4]. In these cases, surgical procedures for revascularization are the prominent options for CW patients as an effort to restore tissue formation[5]. These procedures have a success rate for wound closure of approximately 45%[3]. Those that fail typically require amputation, which carries a 5-year mortality rate of >50%[6].

In recent history, advanced wound care products (AWCPs) have emerged in the marketplace to promote wound closure. Many of these products are derived from placental tissue, synthetic and synthesized scaffolds (with and without viable cells) and growth factor-based therapies[3,4,6-8]. These approaches have shown promise where other treatments have failed in their ability to close non-healing wounds with a reduced recurrence of the ulcer in subsequent months. However, current AWCPs require multiple applications, rely on an extended timeframe and are often used under circumstances where the patient is being monitored in a specialized wound clinic.

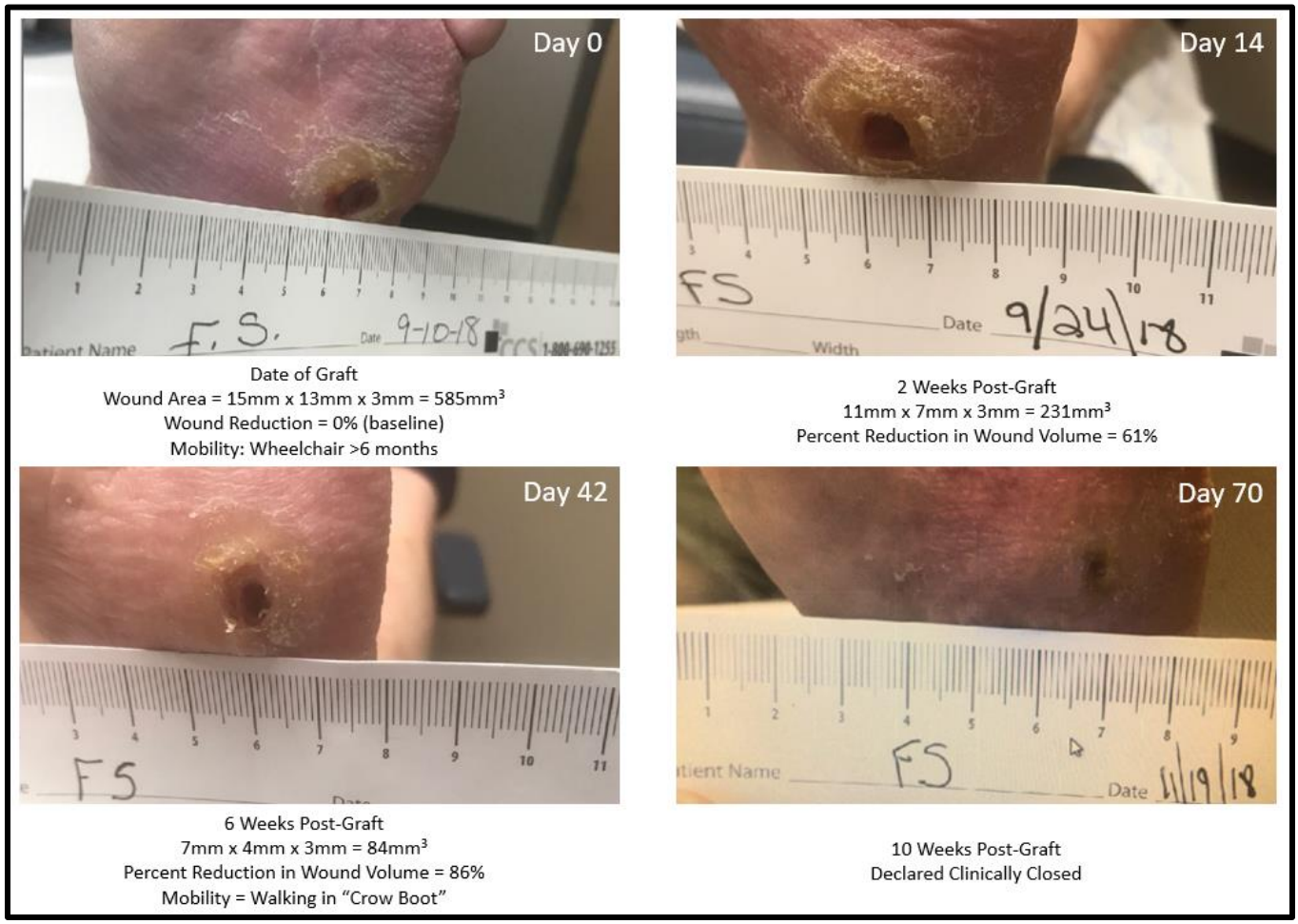
In the following case study, we are evaluating Procenta; a new product that provides a sterile, acellular, orientation free, hydrophilic, fully conformable wound barrier. The allograft is composed of natural connective tissues derived from placental material in a near-native state.

Patient Case:

The following patient suffers from ulcers of the lower extremities and is denoted as FS. In this case, the wound has been active for >4 months and unresponsive to GWCP. The application of alternative products failed to stall wound progression. The patient was a candidate for amputation.

- **FS*** – An 81-year-old male with a diabetic foot ulcer beneath the foot in the median aspect. The ulcer presented as being free of exudate without tissue sloughing. The patient was confined to a wheelchair for >6 months, due to the inability to bear weight on the leg. Procenta was applied to the ulcer on September 10th, 2018 which measured 1.5cm x 1.3cm x >0.3cm (LxWxD) at the time of the graft. A single application of Procenta was used at Day 0 and the wound was then covered with a 4"x 4" non-adhering, impregnated dressing (Adaptic Gauze) and Coban. The wound was not debrided at the time of the graft application. Patient follow-up and data collection were at day 14, 28, 42 and 70 post-grafting where wound closure was 61%, 72%, 86% and complete closure respectively (Figure 1).

FIGURE 1



Date of Graft
Wound Area = 15mm x 13mm x 3mm = 585mm^3
Wound Reduction = 0% (baseline)
Mobility: Wheelchair >6 months

2 Weeks Post-Graft
11mm x 7mm x 3mm = 231mm^3
Percent Reduction in Wound Volume = 61%

6 Weeks Post-Graft
7mm x 4mm x 3mm = 84mm^3
Percent Reduction in Wound Volume = 86%
Mobility = Walking in "Crow Boot"

10 Weeks Post-Graft
Declared Clinically Closed

Discussion:

This patient had a significant full-thickness diabetic neuropathic ulceration submetatarsal 5 secondary to a rigid plantarflexed deformity with cavus foot and equinus deformities. Several different forms of offloading the ulcer were used, including orthotics, forefoot offloading shoe, CAM boot, and CROW boot. All attempts of offloading failed to achieve complete wound closure and continued to deteriorate over time. The patient had significant comorbidities limiting aggressive surgical options although it was presented as an option. Procenta was applied to the ulceration with concomitant offloading. Procenta showed progress within the first two weeks of application with increased granulation tissue and decreased wound drainage. It appeared to be rapidly absorbed and maintained a favorable moisture balance within the wound bed. The wound bed was not debrided following application. By six weeks, the wound made a significant improvement in diameter, depth, and health of the wound bed of the ulceration. At 10 weeks, the wound was clinically closed with complete epithelialization. The patient was protected for a few more weeks with offloading in the CROW boot. The patient was then transitioned to an orthotic with plastizote inserts without re-ulceration at 6 months. Chronic wounds are an extremely

challenging issue in an otherwise healthy patient. Patients with significant comorbidities add increased variables to the wound healing process. Procenta has shown great promise to convert the chronic wound environment to complete wound closure in an expedited fashion. This case study is an example of a diabetic ulcer but the application can be relevant to other chronic wounds such as arterial and venous ulcerations of the lower extremity.

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