P#03

Abstract Title:	**Clinical Evaluation Of A Viable Engineered Skin Tissue* (VEST) For Severe Burns: Post Hoc Cohort Analysis Of A Phase 1b Randomized, Controlled Clinical Trial**
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Objective:	1) Describe that StrataGraft skin tissue is a bilayer human skin substitute being developed to reduce or eliminate the need for autograft in the treatment of thermal burns. 2) Explain that a proof-of-concept clinical trial in subjects with deep partial-thickness burns supported the safety and efficacy of StrataGraft. 3) Describe the results of this post hoc analysis that demonstrated that StrataGraft skin tissue, stored refrigerated or cryopreserved, promoted substantial wound closure without autograft at 3 months.
Abstract:	**Introduction/Background:** Excision and autografting is the standard-of-care for many burns. A viable engineered skin tissue* (VEST) is being developed to reduce or eliminate the need for autograft in the treatment of thermal burns, thereby decreasing donor site morbidity. **Methods/Design:** To evaluate the safety and efficacy of a VEST,* a clinical trial (NCT01437852) was conducted involving 30 subjects with deep partial-thickness (DPT) burns. Comparable burns on each subject were randomized to receive either VEST* or a control autograft following excision. Subjects were enrolled in 3 cohorts: Cohorts 1 and 2 (n=10 each) received refrigerated VEST* (≤220 cm2 and ≤440 cm2, respectively); Cohort 3 (n=10) received cryopreserved VEST* (≤440 cm2). Coprimary end points were the percent area of VEST* treatment site that received autograft by 28 days and wound closure by 3 months. **Results/Findings**: In this post hoc analysis of outcomes by cohort, no VEST* treatment sites underwent autografting by Day 28. Mean percent re-epithelialization (±SD) at VEST* treatment sites at Day 28 were 83.0% (±28.7) for Cohorts 1/2 and 98.9% (±3.3) for Cohort 3 (P=0.37). Of sites treated with refrigerated or cryopreserved VEST,* 90% (18/20) and 100% (9/9), respectively, were closed by month 3. There was no

	difference in mean Patient and Observer Scar Assessment Scale (POSAS) total scores between the VEST* and autograft control treatment sites by month 12, irrespective of assessor (clinical observer or subject) or tissue-storage method (refrigeration or cryopreservation). **Conclusions/Implications:** A novel VEST* has the potential to promote wound healing in patients with DPT burns without the need for autografting. This post hoc analysis demonstrated that use of VEST,* stored either refrigerated or cryopreserved, results in substantial wound closure without autograft at 3 months. A phase 3 open-label, controlled, randomized study (NCT03005106) using cryopreserved skin tissue* is ongoing. *StrataGraft®, Stratatech, a Mallinckrodt Company, Madison, WI.