P#02

Abstract Title:	**Clinical Evaluation Of A Viable Engineered Skin Tissue* (VEST) For Severe Burns: Post Hoc Analysis Of A Phase 1b Randomized, Controlled, Clinical Trial**
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Objective:	1) Describe that StrataGraft skin tissue is a bi-layer 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 promoted substantial wound closure in both treatment-size groups 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 in burn centers 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). Here we report a post hoc analysis that evaluated outcomes stratified by the size of the VEST* treatment area (<200 cm2 vs ≥200 cm2). **Results/Findings:** By Day 28, no subject in any cohort underwent autografting at the VEST* treatment site. By 3 months, the mean percent of the VEST* treatment site that received autograft was 1.7 ±6.5% and 7.1 ±26.7% (<200 cm2 and ≥200 cm2 groups, respectively). By 3 months, 100% (15/15) of the subjects in the <200cm2 group and 86% (12/14) of the subjects in the ≥200 cm2 group achieved wound closure.

	Mean percent re-epithelialization of the VEST* treatment site was not statistically different from the autograft control site in both treatment-size groups by Day 28 (P≥0.25). **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* results in substantial wound closure without autograft at 3 months. A phase 3 open-label, controlled, randomized study (NCT03005106) is ongoing. *StrataGraft®, Stratatech, a Mallinckrodt Company, Madison, WI.