StrataGraft® Skin Tissue as an Alternative to Autografting Deep Partial-Thickness Burns

This study is currently recruiting participants.

Principal Investigator:	James H. Holmes, IV, MD
Sponsor:	Stratatech Corporation
Participating Sites:	Wake Forest Baptist Medical Center University of Colorado Hospital University of Wisconsin Hospital & Clinics Arizona Burn Center U.S. Army Institute for Surgical Research University of Texas Southwestern Medical
ClinicalTrials.gov Identifier:	NCT01437852

Purpose:

The proposed study is designed as a phase Ib open-label, dose-escalation, multicenter study evaluating the safety, tolerability, and efficacy of StrataGraft skin tissue in promoting the healing of the deep partial-thickness component of complex skin defects. The proposed study population will include patients with 3-49% Total Body Surface Area (TBSA) complex skin defects including a deep partial-thickness component resulting from thermal injury. The study has been designed to focus on the evaluation of safety and tolerability of prolonged exposure to increasing amounts of a single application of StrataGraft skin tissue. The potential for StrataGraft tissue to promote healing of the deep partial-thickness component of these complex skin defects as an alternative to donor site harvesting and autografting will be assessed. Targeted enrollment for this study is up to 20 patients with complex skin defects due to thermal burns which require surgical excision and autografting. Subjects will be sequentially enrolled in two cohorts of increasing treatment area receiving StrataGraft skin tissue.

Objectives:

Primary Outcome Measures:

- Wound closure of the treatment sites at three months
- Percent area of the StrataGraft treatment site requiring autografting by day 28

Eligibility:

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Inclusion Criteria:

- Men and women aged 18-65 years, inclusive
- Written informed consent
- Sufficient healthy skin identified and designated as a donor site in the event that the StrataGraft treatment site requires autografting
- Complex skin defects of 3-49% TBSA requiring excision and autografting
- Total burn may consist of more than one wound area
- Deep partial-thickness thermal burn(s) with total area of 88 to 880 cm2 requiring excision and autografting

- First excision and grafting of treatment sites

Exclusion Criteria:

- Pregnant women and prisoners
- Patients receiving systemic immunosuppressive therapy
- Patients with a known history of malignancy
- Preadmission insulin-dependent diabetic patients
- Patients with concurrent conditions that in the opinion of the investigator may compromise patient safety or study objectives
- Expected survival of less than three months
- Participation in the treatment group of an interventional study within preceding 90 days prior to enrollment
- Full-thickness burns will be excluded as treatment sites
- Chronic wounds will be excluded as treatment sites
- The face, head, neck, hands, feet, buttocks, and areas over joints will be excluded as treatment sites
- Treatment sites adjacent to unexcised eschar
- Clinical suspicion of burn wound infection at the anticipated treatment sites

Enrollment Information:
Estimated Enrollment: 20
Study Start Date: September 2011
Estimated Primary Completion Date: December 2012
Estimated Study Completion Date: September 2013