

Opportunities and Obstacles with Engineered Human Skin

Steven Boyce, Ph.D.; University of Cincinnati and Shriners Burns Hospital, Cincinnati, OH, USA

Translation of technologies for tissue engineering of human skin may be considered a long-term process involving discovery, development and delivery of advanced therapies for multiple medical indications for wound closure. Discovery requires understanding of a disease mechanism, formulation of a hypothesis for intervention, experimentation and design of preclinical prototypes, protection of intellectual property (IP) and standardization. For engineered skin (CSS) for wound closure, discoveries in preclinical studies have shown expression of epidermal barrier, stem cell phenotypes, basement membrane, and angiogenic factors to stimulate rapid vascularization. Development typically requires establishment of clinical and regulatory protocols, assurance of regulatory compliance, demonstration of safety, and feasibility for clinical efficacy at a single performance site. Clinical studies in extensive burns have shown greater wound coverage (ratio of closed wound to donor areas) with CSS (~60) than with meshed split-thickness skin graft (≤ 4) which reduces morbidity from harvesting of donor skin. Delivery usually requires IP licensing, establishment of manufacturing systems, a multi-center study of efficacy, marketing permission from FDA, and CMS coding for medical use and reimbursement. Factors that impact the resources available to complete these requirements include the acuity, incidence and prevalence of the disease, and the magnitude of the benefit of the advanced therapy compared to the prevailing standard of care. Transfer of the CSS technology was accomplished by licensing from the academic sponsors to a start-up company which was acquired by an established manufacturer of biopharma products and emerging cell therapies. Together, translation of technologies for engineered skin comprises a diverse and challenging set of requirements which are satisfied by sharing a common vision among the academic (NIH, NSF, research), standards (NIST/ASTM), regulatory (FDA, CMS), practice (AMA), and industrial communities for improvements in patient outcomes. Upon completion of translation of the CSS model of engineered skin from the laboratory to the clinic, it is expected that new standards for burn care will be established which reduce morbidity and costs, and contribute to an improved quality of life for patients.