A multicenter clinical trial to evaluate the topical hemostatic efficacy of fibrin sealant in burn patients.

Authors: Nervi C, Gamelli RL, Greenhalgh DG, Luterman A, Hansbrough JF, Achauer BM, Gomperts ED, Lee M, Navalta L, Cruciani TR

Publication Date: 2001

Abstract:

Current surgical management of deep partial-thickness and full-thickness burn wounds involves early excision and grafting. Blood loss during these procedures can be profound, thus prompting the use of topical hemostatic agents to control and minimize hemorrhage during grafting. The primary endpoint of this multicenter trial was to evaluate the efficacy of fibrin sealant as a topical hemostatic agent during skin grafting. The secondary endpoint was to obtain data to support the existing safety profile of a human fibrin sealant (FS) in participating patients as indicated by the type, severity, and frequency of any adverse events within the 24-hour postoperative period. A multicenter prospective, open label, Phase III multicenter, randomized, comparative clinical trial evaluated the use of fibrin sealant in burn patients undergoing skin graft procedures. Each patient served as his or her own control in this randomized, unblinded study of the effect on time to hemostasis in donor sites treated with the investigational FS product. At operation, 1 contiguous donor skin harvest site was bisected into 2 equal halves, 1 of which was then randomly selected and treated with fibrin sealant. At the end of the fibrin sealant application, the time to hemostasis in each of the donor site halves was identified by the operating surgeon and recorded by the research coordinator. The use of any other topical hemostatic agents was prohibited. A significant difference ($P < .001$) was demonstrated in the mean time to hemostasis between the fibrin sealant treated donor sites when compared painwise to the control sites. The significant difference was consistent across the 6 participating study centers. There were no adverse events associated with the use of fibrin sealant. The

investigational FS product was shown to be efficacious, because it significantly decreases the time to hemostasis at the donor skin harvest site in patients undergoing skin grafting and was noted not to cause any adverse reactions.