A variant PDGF incorporated into fibrin sealant for treatment of burn patients undergoing autologous mesh skin grafting.

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Abstract:

Rationale: Assessment of safety, tolerability and efficacy of a variant PDGF covalently incorporated into fibrin sealant (KUR-212, Kuros Biosurgery AG) in burn patients undergoing autologous meshed skin grafting. Methods: KUR-212 was compared with staples in a phase 2a, multicenter, intra-patient controlled study. Eligible patients had thermal burns of 5-50% total body surface area (TBSA) with two comparable test sites each 1-2% TBSA. Ten patients were randomized and received a single topical treatment of KUR-212 (1 mug/mL) at one test site and staples at the other test site to affix skin grafts, meshed with ratio 1:1.5 to 1:3. Follow-up was 1 year post-surgery. Results: KUR-212 was found to be well tolerated. There were no treatment- related adverse events up to day 28 post-surgery (primary safety endpoint) or 1 year post-surgery. No patient developed hypergranulation, showed evidence of systemic absorption of PDGF or antibody formation against native or variant PDGF. The small sample size precluded statistical evaluation of efficacy. There was a notable difference in the time to full re-epithelialization between treatments for the 1:3 mesh ratio, with a shorter time to healing for the KUR-212 treated test sites (mean 17 days vs. 23.5 days). Vancouver scar scale assessments showed similar results for both test sites 1 year post-surgery. Humanistic outcome data indicated patient's and investigator's preference for KUR-212 over staples. Conclusion: KUR-212 applied as a single dose was well tolerated with no safety concerns raised. The data support further investigation of KUR-212 in burn patients undergoing autologous meshed skin grafting.