Efficacy of crosseal fibrin sealant (Human) in rhytidectomy.

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Abstract:

Objective: To examine the potential efficacy of Crosseal (the human protein, bovine component-free fibrin sealant) (OMRIX Biopharmaceuticals, Ltd, Brussels, Belgium) to reduce ecchymoses and hematoma formation in patients undergoing rhytidectomy. Methods: Before initiation of the study, approval was obtained from the US Food and Drug Administration for an Investigational New Drug Application and off-label use of Crosseal and from the Institutional Review Board of the University of California, Davis. Patients undergoing rhytidectomy with or without concomitant procedures were voluntarily enrolled without compensation in the study (N=9). Patients were randomized according to which side of the rhytidectomy the tissue sealant was placed. In all patients in the study, 1 side of the rhytidectomy was treated with Crosseal; the other, untreated side was used as a control. Before closure of the skin, 2 mL of Crosseal was sprayed through a pressure regulator under the skin flap of the dissected area of the rhytidectomy only on 1 side. The skin was pre trimmed before placement and closed in standard fashion. A pressure dressing was left in place for 3 days before removal. Nine patients were originally enrolled in the study. On postoperative days 3 and 7, photographs were taken of the patients. The photographs were judged by 5 independent reviewers who were blinded as to which side had been treated with Crosseal. The judges rated the degree of ecchymoses on a scale of 1 (minimal) to 10 (severe) and were asked their opinion as to which side of the facelift had been treated with Crosseal. These results were compared using statistical analysis. Also on days 3 and 7, patients were examined for seroma or hematoma formation on each side of the face. Results: Our study demonstrated efficacy of Crosseal in reducing ecchymoses and swelling in all patients. The mean score for ecchymosis on the Crosseal-treated side was 4.5 and on

the untreated (control) side was 6.2 (P<.01, Wilcoxon rank sum test). The rate of hematoma or seroma formation was 22% (2 of 9 patients) for the untreated side vs 0% (0 of 9 patients) for the treated side. This did not reach statistical significance (P=.43, Fisher exact test). Small hematomas developed in 2 patients on the control side, which were needle aspirated. There were no known long-term complications from either the use of Crosseal or the rhytidectomy. Conclusion: Crosseal is efficacious in reducing ecchymoses after rhytidectomy.