

Exploratory, randomized, controlled, phase 2 study to evaluate the safety and efficacy of adjuvant fibrin sealant VH S/D 4 S-apr (ARTISS) in patients undergoing rhytidectomy.

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Abstract:

Background: Suction drains are commonly placed after rhytidectomy surgery to avoid seroma formation that may result from dead spaces between skin layers. Fibrin sealants promote tissue adherence by cross-linking with extracellular matrix proteins, which may reduce the dead space under skin flaps. Objectives: The authors evaluate the safety and preliminary efficacy of the fibrin sealant (FS) VH S/D 4 s-apr (ARTISS; Baxter Healthcare Corp, Deerfield, Illinois), added to standard-of-care (SoC) treatment, on tissue plane adherence and local hemostasis in rhytidectomy patients. Methods: In this phase 2, prospective, controlled, randomized, evaluator- and patient-blinded, multicenter study, 45 patients (of 56 possible enrollees) received SoC treatment on 1 side of the face and adjunctive FS VH S/D 4 s-apr treatment on the other side. Outcomes measures included visual assessments of ecchymosis (by blinded reviewers), grading of ecchymosis and edema, drainage volumes, occurrence of hematoma/seroma, safety evaluations, and patient-reported assessments of pain, numbness, and treatment preferences postoperatively. Results: Mean patient age was 55.1 years. Rates and grades of ecchymosis and edema were similar for the 2 treatments. The mean (SD) drainage volume 24 hours after surgery was 11.5 (13.7) mL from the FS VH S/D 4 s-apr-treated sides of the face and 26.8 (24.0) mL from the SoC-only sides ($P < .0001$). Patient assessments of pain, numbness, and preference favored treatment with FS VH S/D 4 s-apr. Adverse events were mild to moderate in severity. Conclusions: Adjuvant use of

FS VH S/D 4 s-apr appears to be safe and results in lower drainage volumes than SoC treatment alone. © 2013 The American Society for Aesthetic Plastic Surgery, Inc.