Randomized, controlled, phase 3 study to evaluate the safety and efficacy of fibrin sealant VH S/D 4 s-apr (Artiss) to improve tissue adherence in subjects undergoing rhytidectomy.

Authors: Hester T.R., Shire J.R., Nguyen D.B., Gerut Z.E., Chen A.H., Diamond J., Desmond J.C., Silvati-Fidell L., Abrams S.Z., Rohrich R.J.

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Abstract:

Background: Suction drains are commonly placed after rhytidectomy to avoid seroma formation that may result from dead spaces between skin layers. Fibrin sealants promote tissue adherence by crosslinking with extracellular matrix proteins, which may reduce the dead space under skin flaps. Objectives: The authors evaluate the safety and 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, in improving flap adherence and reducing dead space in patients undergoing rhytidectomy. Methods: Patients with planned facial rhytidectomy were enrolled in this phase 3, prospective, controlled, randomized, patient-blinded, multicenter trial. They received SoC treatment on 1 side of the face and adjunctive FS VH S/D 4 s-apr on the other. Results: Seventy-five patients completed the trial. The mean (SD) drainage volume was 7.7 (7.4) mL from the sides treated with sealant and 20.0 (11.3) mL from the SoC-only sides ($P < .0001$). Rates of hematoma and seroma were similar for the 2 treatments, as were changes in postoperative skin sensitivity. Adverse events generally were mild; 2 serious adverse events were reported (wound abscess, dehydration). Conclusions: Adjunct use of FS VH S/D 4 s-apr in rhytidectomy was proven safe in this study. It significantly reduced drainage volumes without increasing the incidence of hematoma or seroma, which suggests that it eliminates dead space through improved flap adherence. © 2013 The American Society for Aesthetic Plastic Surgery, Inc.