

PURPOSE: Optimal patient results in facial rhytidectomy (facelift) can be compromised by the formation of hematomas and seromas. The skin flap must adequately adhere to underlying tissues, and the dead space created during surgery, minimized. Fibrin sealant with four units/mL thrombin, vapor-heated, solvent detergent-treated (FS VH-S/D-4-s-apr) was evaluated for effectiveness in improving adherence of these skin flaps.

METHODS/MATERIALS: In two multicenter, prospective, controlled, randomized, clinical studies, 120 subjects received FS VH-S/D-4-s-apr (ARTISS [Fibrin Sealant (Human)], Baxter Healthcare Corp, Westlake Village, CA) on one randomly-assigned side of the face and standard of care (SoC) on the other, such that each subject served as her/his own control. Drains were utilized for 24hr post-surgery and drainage volumes were measured for each side. Hematomas or seromas were diagnosed clinically and treated in accordance with severity (from conservative treatment to surgical intervention) during multiple post-operative visits, up to day 14, and combined data, analyzed. Ecchymosis was analyzed separately.

RESULTS: A total of 7 hematoma/seromas were observed in 5 subjects (4.2%) on the FS VH-S/D-4-s-apr side of the face vs 17 in 17 subjects (14.2%) on the SoC side (proactive and frequent follow-up during clinical trials may influence rate of diagnosis). Two subjects (1.7%) presented with hematoma/seromas on the treated side only, 14 (11.7%) on the SoC side only, and 3 (2.5%) on both sides. The 95%CI for the difference of the paired proportions of subjects with hematoma/seromas occurring only on treated sides vs only on SoC sides ranged from 0.035 to 0.172, indicating significantly fewer hematoma/seromas on treated sides. Concomitantly, total drainage volumes were statistically significantly lower on the FS VH-S/D-4-s-apr sides in both studies. A mean \pm SD total volume of 11.5 \pm 13.7mL drained at the treated sides of the face, and 26.8 \pm 24.0mL drained at SoC sides ($p<0.0001$) in the Ph2 study ($n=45$); 7.7 \pm 7.4mL drained at the treated sides of the face, and 20.0 \pm 11.3mL drained at SOC sides ($p<0.0001$) in the Ph3 study ($n=75$).

CONCLUSION: In these studies, hematoma/seromas appeared less often with FS VH-S/D-4-s-apr use than with SoC alone. This, coupled with the statistically significant reduction in drainage volume, indicates that adjunctive use of FS VH-S/D-4-s-apr may improve the flap adherence, thereby reducing localized fluid accumulation through full-surface flap adherence, and eliminating dead space between the wound bed and tissue flap.