Hemofence

To demonstrate the non-inferiority of the novel hemostatic agent, Hemofence® (BMI Korea Co. Ltd., Jeju Korea, thrombin cross-linked sodium hyaluronate gel matrix) compared to the established agent, Floseal Hemostatic Matrix (Baxter, thrombin-gelatin matrix) in achieving hemostasis for spinal surgeries, with secondary objectives to assess additional efficacy and safety.

Methods: This clinical trial was a multicenter, randomized, subject-blinded, active-controlled, parallel-group, phase 3 study. Investigational drugs were administered to the first and second bleeding sites of each participant (or only to the first site if a second site was absent), evaluating hemostasis success rate within 10 minutes and the time to achieve hemostasis. Subsequent visits were conducted for safety assessments. For non-inferiority test, a 97.5% one-sided confidence interval was used; the test group was deemed non-inferior if the lower limit exceeded -10%.

Results: This trial showed a 97.10% success rate in the test group and 96.05% in the control group for primary efficacy. The 95% confidence interval (-4.90%, 7.44%) confirmed the test drug's non-inferiority. Time to hemostasis showed no significant difference between groups. All adverse events, adverse drug reactions, and serious adverse events were statistically similar between groups (p=1.0000, p=0.2427, and p=0.9663, respectively).

Conclusion: A novel hemostatic agent, Hemofence®, demonstrated an efficacy and safety profile comparable to that of Floseal [1)]

1)
An S, Kwon WK, Choi I, Lee JB, Kim J, Hur JW. Evaluating the Efficacy and Safety of Hemofence (Thorombin Cross-linked Sodium Hyaluronate Gel Matrix) in Hemostasis for Intractable Exudative Bleeding in Spinal Surgery: A Multicenter, Randomized, Phase III Clinical Trial. Neurospine. 2024 Apr 4. doi: 10.14245/ns.2448024.012. Epub ahead of print. PMID: 38575113.