Prospective, Randomized, Controlled Clinical Evaluation of the Safety and Efficacy of PerClot™ Compared to SuperClot® and Arista® in Achieving Hemostasis

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Objective: The purpose of this prospective, randomized, controlled clinical evaluation was to demonstrate that the safety and efficacy profile of PerClot™ is non-inferior to the safety and efficacy profiles of SuperClot™ and Arista™ in the achievement of hemostasis when used in a variety of surgical procedures.

Methods: A total of 142 patients from two investigational sites undergoing a surgical procedure (60 orthopedic and 82 general surgery) in which pressure, ligature, and other conventional means were ineffective or impractical in the control of capillary, venous, or arteriolar bleeding were randomized to receive PerClot (n=44), SuperClot (n=54), or Arista (n=44) as an adjunct hemostatic treatment. The most commonly performed procedures were splenic, hepatic, biliary, gastric, and spinal in nature. The primary endpoint for this investigation was hemostasis within 3 minutes of hemostat application. Continued bleeding at the application site after 3 minutes following hemostat application was regarded as a failure. All patients underwent baseline examinations and were evaluated at 48 hours and 14 days postoperatively. Adverse events were documented for all treatment groups.

The study design was powered at 80% to allow for the determination of differences between treatment groups. Analyses were performed on the data collected from all enrolled patients. Statistical descriptions (mean, median, standard deviation, minimum value and maximum value) were generated for all continuous variables. Frequencies, percentages, etc. were calculated for categorical variables. A *p*-value of less than 0.05, using a two-sided T-test, was considered statistically significant.

Results: The three groups (PerClot, SuperClot, and Arista) were statistically homogeneous with respect to age, gender, height, ethnicity, occupation (manual vs. non-manual labor), medical history, and physical examination. There was no statistical difference in the amount of bleeding observed at each identified lesion prior to hemostat application. The mean lesion size was 8.81 cm^2, 7.49 cm^2, and 7.47 cm^2, respectively ($p = 0.1574$). Hemostasis was achieved in all patients and in all treatment groups by 3 minutes. None of the patients in the PerClot and Arista groups experienced any adverse events. A single patient in the SuperClot group (1.96%) experienced one adverse event (a fever that resided 24 hours after surgery) that was deemed unrelated to the hemostatic device.

Conclusion: The safety and efficacy profile of PerClot is non-inferior to the safety and efficacy profiles of SuperClot and Arista. PerClot was shown to be safe and effective in all procedures.

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