

Safety and Performance Study of a Novel Fibrin Dressing for Cancellous Bone Bleeding Summary

This fibrin dressing controls arterial, organ, and cancellous bone bleeding (CBB) in various species. This study was performed to determine its efficacy on CBB in humans. Thirty patients were enrolled at 8 centers in the EU. Anatomical sites (AS) included posterior spinal fusion, iliac crest graft, and pelvic osteotomy. The dressing stopped CBB at 3 min in 74.3% and at 6 min in 92.3% of AS. Four patients had adverse events that may have been device-related, including one infection.

Hypothesis

A novel fibrin dressing (NFD) is safe and effective at controlling cancellous bone bleeding (CBB).

Design

Of 38 eligible patients, 30 who met the inclusion criteria were consecutively enrolled in this Level IV single-arm study in the UK and Norway. All 30 patients completed the 6-week follow up period.

Introduction

CBB is a significant source of blood loss in major spinal surgery. Current hemostatic methods are either ineffective or interfere with bone healing. The safety and efficacy of this NFD has been demonstrated in animals. This is the first safety and performance study of the NFD in humans.

Methods

Patients over 18 yr undergoing study procedures and willing to comply with the study protocol met the eligibility criteria. Anatomical sites (AS) studied were posterior spinal fusion (PSF), iliac crest graft (ICG) and pelvic osteotomy (PO). Exclusion criteria were extensive and included infection, bleeding disorder, revision fusion, allergy to test products, pregnancy, etc. Intraoperatively, the surgeon assessed the severity of CBB (pulsatile, flowing, oozing or none) and applied the dressing for 3 minutes. Bleeding was then assessed again and if it was not controlled (oozing or none) a second dressing was applied for an additional 3 minutes. If bleeding was not controlled after the second dressing application the surgeon used an alternative method. Patients were assessed at 24 hours and 6 weeks clinically (for hematoma, allergic reaction, etc.) and with laboratory analysis, including CBC, PT, aPTT and INR.

Results

Thirteen patients had PSF, 14 ICG and 3 PO. The dressing was used at 2 AS in 9 of the 30 patients. Of the 39 treated AS, bleeding was controlled at 3 min in 74.3% and 6 min in 92.3%. Three patients required alternative treatment. Adverse events (AE) possibly device-related occurred in 4 patients (13.3%). These included elevated ESR and eosinophilia in 1 patient, monocytosis in 1 patient, neutrophilia and monocytosis in 1 patient, and wound infection in 1 patient.

Conclusion

This NFD is efficacious and safe at controlling CBB in procedures related to scoliosis surgery (PSF, ICG, PO). A randomized, controlled FDA trial currently is underway.