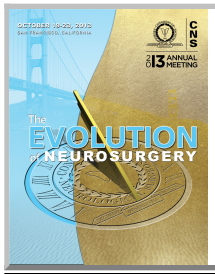

Novel Biocompatible, Biodegradable Surgical Hemostat for Intracranial Surgery

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Introduction

Control of bleeding in intracranial surgery with existing techniques and products can be time-consuming, uncertain and tedious. The most commonly used approach for the control of the low pressure bleeding is to apply manual pressure to occlude vessels and staunch bleeding, applied through absorbent dressing soaked in thrombin. Covering the bleeding site with a mixture of gelatin & thrombin, and manually adapting this covering to the site is also utilized. Both methods can be slow and uncertain in action, swell in place and obstruct visualization of the site, and incorporate blood and tissue derivatives. Slow action produces unnecessary costs, financial and clinical.

We have developed a patented surgical hemostat derived from plant sources to address multifocal, low pressure bleeding. The device forms a hydrogel in situ to staunch bleeding within seconds, works without manual pressure or adaptation, does not swell in situ, and is transparent. We provide our report of a first controlled in vivo trial that demonstrates the performance of this unique device and compares it to the current standard practice.

Opportunities for Improvement

- Speed and certainty of action
- No swelling after application
- Ease of use
- Transparent
- No blood or tissue components

Learning Objectives

1. Understand the necessary features of a surgical hemostat
2. Understand the basis for the technology presented

Improve Patient Care

Shorter procedures reduce hospital costs, post-op morbidity & possible infection

Technology

1. Patented system of 2 polysaccharides in aqueous solutions; no crosslinking agents or blood/tissue derivatives
2. Solutions are seamlessly mixed & sprayed onto bleeding site; form conforming hydrogel implant in situ within seconds to control bleeding; strong yet soft.
3. No swelling of implant; transparent; breaks down over time and is excreted via kidneys
4. No reconstitution or special storage

First Report of In Vivo Study Results

Method

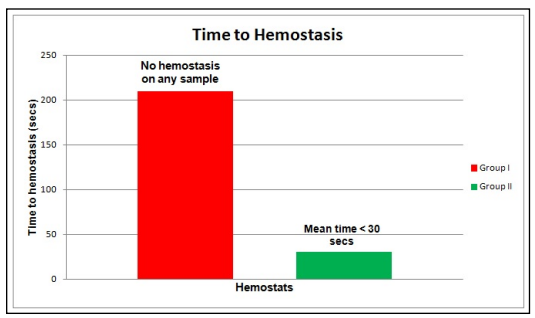
- Liver abrasion model in 2 adult Yorkshire pigs
- 20 standardized wounds, 2.0 x 1.0 cm, 2-3 mm in depth
- Steady, flowing bleeding observed in each wound prior to treatment
- Group I (control, n=4) - Gelfoam® + thrombin (5,000 units/ml) + standard pressure
- Group II (experimental, n=16) Treated with hydrogel alone, no pressure or adaptation
- Time to hemostasis measured for all wounds; all followed for 5 minutes post hemostasis to confirm function
- Group II also assessed for adhesion during blood flow and for persistence & transparency

Results

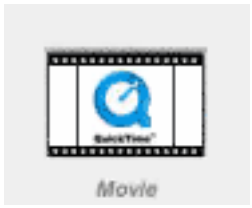
Group II - complete hemostasis achieved in all wounds

- Mean time to hemostasis – 29.94 ± 11.20 seconds {CI 95%]
- All adhered in place, transparent – allowed visualization of wound

Group I – all failed to achieve hemostasis within 210 seconds



Demonstration Video



Conclusions

In vivo results confirm lab data & demonstrate that novel device can provide hemostasis in about 30 seconds for low pressure, mixed venous and arterial bleeding – superior to current standard practice

References

hemostasis, hydrogel, hemostat

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