The Vivostat System for the Automated Preparation of Autologous Fibrin Sealant

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Background: Fibrin sealant is used in cardiovascular and thoracic surgery as a hemostatic and adhesive agent and as a sealant of pulmonary air leak. Conventional fibrin sealants based on human fibrinogen prepared from pooled plasma donations and thrombin have not been licensed in several countries including the US because of concerns about infection.

Methods: The Vivostat system is a new medical device for the preparation of an autologous fibrin sealant in the operating room. The system is fully automated and microprocessor controlled and incorporates three components: an automated processor unit, an automated applicator unit, and a disposable, single patient use unit which includes a prep set and a spraypen applicator. The biochemical process is initiated by batroxobin, which acts upon fibrinogen from the patient's plasma. The completion of the process depends entirely on endogenous thrombin in producing the sealant. No exogenous thrombin is added.

Results: The preparation process was completed in 30 min. From 120 ml of the patient's blood the yield was 4.5 +/- 0.3 ml (mean +/- standard deviation) of fibrin sealant.

Conclusion: It is possible to prepare autologous fibrin sealant with the Vivostat system in 30 minutes. No exogenous thrombin is added. The sealant can be used in cardiovascular surgery.

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Key words: Autologous fibrin sealant, batroxobin, cardiovascular surgery, hemostasis, fibrinogen, microprocessor, thrombin.

Introduction

The Vivostat™ system is a medical device for the preparation of an autologous fibrin sealant in the operating room in less than 30 minutes. The sealant has successfully been used for the first time in man in cardiac surgery. The continued concern over safety and the increased emphasis on autologously sourced materials has led to this innovation in biochemical and electromechanical engineering. It is a novel approach to overcome the potential infective and antigenic risks associated with the use of currently available fibrin sealants. The purpose of this paper is to describe the Vivostat system and the fibrin sealant it produces.

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Materials and Methods

The Vivostat system incorporates three components:

- Automated processor unit: (fig. 1) a non-sterile, reusable, fully automated, microprocessor controlled, electro-mechanical device which drives and controls the biochemical process which takes place within the disposable preparation unit (prep set). It is that biochemical process which prepares a concentrated fibrin I solution from whole blood.
- Automated applicator unit: a non-sterile, reusable, electromechanical device, which houses the fibrin I and buffer cartridges and feed those solutions into the application pen via a multilumen catheter.
- A disposable single patient use unit: a disposable single use patient kit which contains everything needed to prepare and apply the Vivostat sealant. This includes a prep set into which blood is collected and in which the biochemical process which produces the fibrin I solution takes place, and an application pen (fig. 2) through which the fibrin sealant is dispensed onto the tissues being treated.

The Process

From the time the patient's blood is drawn directly into the prep set until the sealant is ready for use, the process is fully automated and microprocessor controlled.

The novel biochemical process for the preparation of fibrin sealant, and the characterization of that sealant, has been previously described by members of the Vivostat development team and others (1-5).

120 ml of the patient's blood is drawn and mixed in the prep set with 17 ml of 4 % sodium citrate USP for anticoagulation. Rapid cycle centrifugation™ results in the isolation of about