

An Absorbable and Soluble Haemostatic Gauze---BloodSTOP

Yan Yin

YY Labs, Medical , P.O.Box 597, Fremont, CA 94537

March. 2005

Abstract

BloodSTOP™ [1] haemostatic gauze has been widely used in many countries for several years. Millions of patients have used it. It has been well received by the market. BloodSTOP™ is a 100% natural substance created from chemically treated cellulose. It is an effective, patented, hemostatic agent registered with the FDA to help control bleeding from open wounds and in body cavities (mouth, ears, nose, throat, vagina, anus). The material contains no chemical additives, thrombin or collagen and is hypoallergenic. When it comes in contact with blood, it converts to a gel, which dissolves over several minutes time into glucose and saline. Because of its purity and the fact it simply degrades to these end products, and because it seals and protects the wound, it actually expedites healing. This paper describes how it works, and gives a comparison between this product and the other similar products, and provides customers with best application examples and testimonies.

Introduction

Wound care is a specialized field with a very long history. The speed of stopping bleeding, risk of infection, speed of healing, and side effects are the four important issues for wound care, and they are also the criteria for judging a wound-care product.

The traditional methods to stop bleeding are mainly applying pressure, closing the wound by suture, and filling with dressing. Since during operation, or serious wounds, sometimes some patients may have a problem with stopping bleeding, so that activating the coagulation factor becomes very helpful. The wound dressings developed these years have been seeking a better solution to this problem.

Wound dressings have usually been classified according to their material, mechanism of functioning, and their reaction with the human body. They can be also divided into two large categories: water soluble and not soluble. The research has found that water-soluble wound-care materials work much more efficiently than the others. The reason for this is related to the haemostatic mechanism.

BloodSTOP™ water-soluble gauze has a haemostatic effect through three channels: 1) **Physiological**. It activates the coagulation factor and accelerates the formation of thrombin in the human body, 2) **Physical**. When BloodSTOP™ contacts a wound in the human body, it will first absorb a great amount of water content from the blood, as so to increase the concentration and viscosity of the blood, and decrease the speed of blood flow, meanwhile, the product swells up quickly and produces a colloid after absorbing water, covering the wound and blocking the end of the blood capillary. The ability to absorb water, therefore, is very important to the haemostatic materials, 3) **Chemical**. BloodSTOP™ has the function of coagulating the platelets. The gauze dissolves, then

adheres to the thrombocyte and makes the red blood cells collect and activate the blood coagulation factor to facilitate forming the thrombus, and healing the wound.

Since the BloodSTOP™ may activate the coagulation factors and promote the formation of thrombin in the human body, BloodSTOP™ may result in a satisfactory haemostatic effect for the patients who suffer from deficiency of blood coagulation.

The water-soluble capability brings another advantage. It is easy to remove. It turns into a gel, and just washing it with clean water, the surplus gauze will be removed. The portion of gauze that is incorporated into the scab will remain to protect the wound and encourage healing. There will usually be no re-bleeding problem as regular gauze does.

This soluble material, therefore, is much more potent than other insoluble substances on the market.

Comparison of wound-care materials and products

There are various wound-care materials and products, which can be summarized in the following table

Components	Name of product	Material	Soluble	Absorbable	Allergenic	Efficiency
Pure cotton fabric		natural	No	No	No	poor
Styptic cellulose		natural	No	No	No	poor
Gelatin sponge	Gelfoam	Collagen, bio-material	No	No	Possible	low
Oxidized, regenerated cellulose fabric,	Surgicel	botanic	No	Yes	No	high, and can be used internally
Oxidized, partially regenerated cellulose fabric,	BloodSTOP™	100% natural	Yes	Yes (90%)	No	high, can be used externally
Oxidized and etherized regenerated cellulose fabric	BloodSTOP™ Ex	100% natural	Yes	Yes	No	very , high, can be used internally
	Quikclot	volcanic rock	No	No	No	--
Alginate	Hemo	sea weeds	No	No	-	low

BloodSTOP™ has two categories. They are BloodSTOP™ regular (simplified as BloodSTOP™) and BloodSTOP™ Ex. BloodSTOP™ is 99% absorbable, therefore, only for external use. BloodSTOP™ is 100% absorbable, therefore, can be left inside the body. It will be absorbed by human body, and then excreted by the body in few weeks.

Animal tests

Tests of haemostatic effect have been conducted on rabbits [2].

The bleeding models are respectively obtained from the liver, the kidney, the subdural space, the coeliac artery, the vein and the soft tissue of the rabbit. Four similar bleeding wounds were prepared for a same organ, then their bleeding controlled with BloodStop and BloodStop Ex, Gelfoam and styptic cellulose, observing the time of stopping the bleeding and the bleeding amounts. The results are summarized in the following Figures.

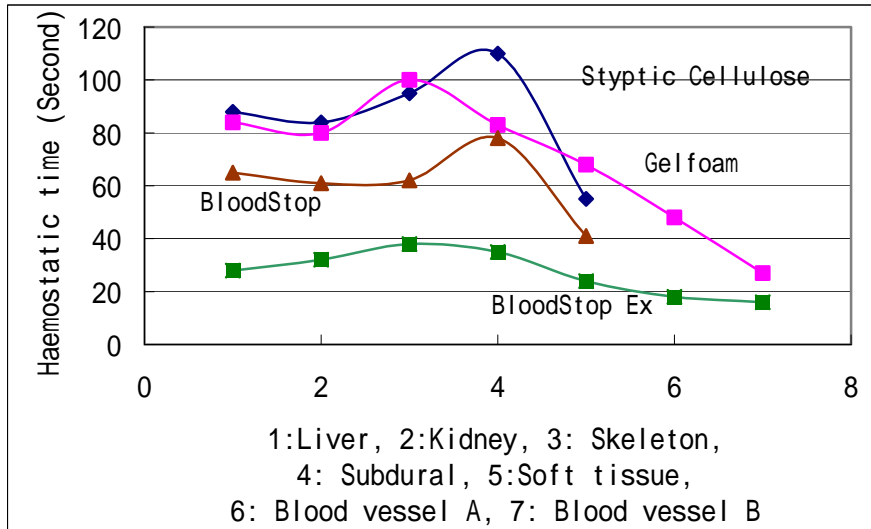


Figure 1. Haemostatic Time

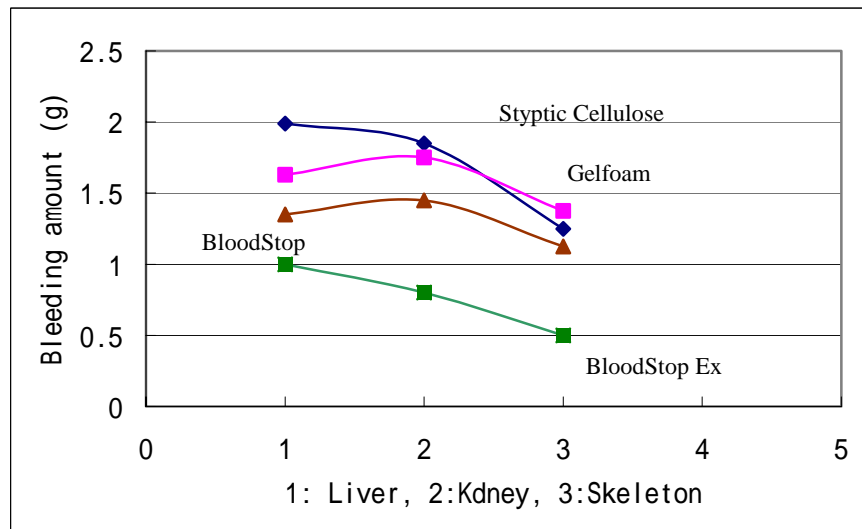


Figure 2. Bleeding amount

Figure 1 and 2 show that BloodSTOP™ and BloodSTOP™ Ex are clearly much better haemostatic materials than the others.

Clinic test results

More than 10,000 cases of clinical use have been recorded in continuing surveillance in China. The products have been tested in the following surgeries: BloodSTOP™ EX. The conclusion is the product indeed stops bleeding, fast, efficiently and reliably. There are no toxic effects and there is no irritation to the body from its use. The products have been tested in the following surgeries: Neurosurgery; Thoracic Surgery; Abdominal and Gastro-intestinal surgery; Bone surgery; Plastic Surgery; Treatment of Burns; Oral and Ear Nose and Throat Surgery (ENT); Obstetrics and Gynecology; Colon-rectal surgery; Surface biopsies.

The following is the report from the Clinic test data:

Summary of Use of BloodStop EX in Oral Surgery and Dental Surgery.

(Beijing Hospital and Beijing Medical University)

The report [3] listed 100 patients with age and diagnostic detail. These include gum surgery, wisdom tooth extraction, and other extractions. All required special attention because of bleeding.

Of the 100 patients 91 stopped bleeding immediately after application of BloodSTOP™ EX. Nine patients had a short history of capillary bleeding before bleeding stopped. There were no failures to stop bleeding.

There was no difference in the success with immediate response in regards to age or sex.

Neurosurgery

(Beijing Xuanwu Hospital and Beijing TianTan Hospital, 1987)

This hospital had 20 patients treated with BloodSTOP™ EX to control bleeding [4]. There were 16 males and 4 females. The age range was from 4 years to 58 years. On the average 1 – 2 pieces of BloodSTOP™ EX are used and the bleeding stops between 1 and 2 minutes. The average surgery time is 3 hours.

A case history:

A 58 year-old man had developed loss of vision in both eyes over 5 years. In the surgery on April 28, 1987 a large tumor was removed. There was post surgical bleeding, and on re-operation numerous small cut pieces of BloodSTOP™ EX were placed on the raw edges of the tumor resection. All the bleeding stopped within 6 minutes. There were no complications during the remaining hospital stay of 8 days, at which time the external sutures were removed.

The biggest brain tumor removed and bleeding controlled with BloodSTOP™ EX was 100 grams in weight.

From 1987 to 1990 all patients with surgery using BloodSTOPTM EX had follow-up for 2 ½ years. Recovery was very good, there were no side effects, and no toxic effects. Since 1990, BloodSTOPTM EX has been used routinely in this neurosurgery section.

Applications

While BloodSTOPTM EX has been used widely in surgeries as described above, two specific applications for BloodSTOPTM need to be mentioned here, they are: 1) General Dental, Oral Surgery, Endodontal and Periodontal Procedures, 2). Dialysis.

Bleeding in the mouth is a common problem for dentists, because the oral surgery often requires many procedures creating open wounds. Furthermore, It is a highly vascular area, which is also difficult to apply direct pressure in the mouth. It is important to stop bleeding and expedite the healing process, because tongue and eating irritate wounds, salivary enzymes can lysis clots before they have a chance to organize.

The dentist, therefore, often needs something that can be applied directly and locally to wounds that will aid hemostasis. The current substances are not ideal due to the high cost, or less efficiency, difficult to use. They may delay the healing. BloodStopTM Hemostatic Gauze is a product that meets the surgical needs in dental practices whether a general or specialist (oral and maxillofacial surgeon, periodontist or endodontist). The gauze applies to extractions, periodontal surgery, apicoectomy and retrofill, pre-prosthetic surgery, Orthognathic surgery, tumor excision, dry socket prevention and other selected procedures.

Dialysis patients face the bleeding problem almost every day. The common procedure of dialysis requires two large needles, one for artery, one for vein. The procedure requires Heparin to be injected into the blood to reduce viscosity of the blood, which also causes bleeding more easily. After the procedure, therefore, hemostasis becomes the most important task. Sometimes, some patients may have bleeding even hours after the procedure. An economic, easy to use, effective haemostatic material will be very helpful for the patients.

Examples

BloodSTOPTM has also received very good responsesTM from customers. The common comment is: “ This is really a marvelous product!”

Here are two examples.

One is a Dialysis patient in Hawaii. After the dialysis procedure, with all regular procedure trying to stop the bleeding, in few hours, the wound was still bleeding. Then the patient cut a 1 in. square [of BloodSTOP] and applied it to the wound. It stopped bleeding in a few seconds. An hour later the patient washed the arm, and the surplus gauze washed away, leaving a dime-sized crust. At night the patient washed the arm again, and the crust floated away.

The other one is a California customer. The customer recently had a fairly deep cut that bled profusely. He used a whole piece of paper towel and it did not stop the bleeding. He then used a double layer of BloodSTOP™ and the flow of blood stopped within seconds. CM Los Gatos, California

Conclusion

BloodStop™ hemostat is a sterile, traumatic wound treatment that rapidly arrests high-volume blood loss and achieves hemostasis in large wounds, arresting the hemorrhage before the casualty goes into shock. BloodSTOP™ affects coagulation in moderate-to-severe wounds.

Hemostasis is achieved through extremely rapid adsorption of water content in the blood in and around the wound, much like a super sponge, activates the coagulation factor of the patient. Then the gauze turns into gel to seal the wounds. It makes healing faster. The process represents a new approach to hemostasis, which typically involves adding clotting factors rather than extracting elements to halt bleeding.

It reduces the volume of liquid, thus concentrates clotting factors and dramatically accelerating haemostasis. BloodSTOP™ hemostat creates a stable, powerful clot that stays firm.

BloodSTOP™ hemostat is a gauze substance. BloodSTOP™ hemostat is 100% natural. It eliminates the danger of an allergic reaction or transmission of disease. It is safe to leave in the wound.

BloodSTOP™ delivers a unique combination of effectiveness, absorbability, solubility, and bactericidal protection.

Effective, soluble, fast haemostasis, it is easy to use, does not stick or fall apart, and it optimizes applications according to surgical and anatomic need. BloodSTOP™ Ex is the only soluble haemostatic gauze on the market.

The absorbable, plant-based product eliminates the possibility of animal or human-borne contaminants.

The product is economical, comparing favorably with the similar products on the market, which are as expensive as \$2.71/cm² (such as Surgicel). BloodSTOP™ is only \$0.22/cm², and BloodSTOP™ EX is \$0.31/cm². BloodSTOP™ products thus are 90% less expensive, which will greatly reduce patients' medical expenses, and can reduce the obligations of medical health insurance companies.

BloodSTOP™ has received FDA class 1 approval.

Author

Yan Yin, Professor of the University of Science and Technology of China, was working at Stanford Linear Accelerator Center, Stanford Synchrotron Radiation Laboratory,

TRIUMF of University of British Columbia, Vancouver, Canada; Founder of YY Labs, and principal investigator for several DOE SBIR Phase I and Phase II projects.

References

[1] Manufactured by Reginald Medical Solutions, Inc. DBA: Life Science Plus

[2] Bangwen Xu, Ningxing Zhou, “Applications of BloodSTOP Ex in Liver Surgery”, published in “BloodSTOP and BloodSTOP Ex Clinic Test Data Collection,” by Beijing Textile Institute, P9, 2000.

[3] Jiangkang Cao, Zhiming Zhang, “Applications of BloodSTOP Ex in Oral Surgery,” published in “BloodSTOP and BloodSTOP Ex Clinic Test Data Collection,” by Beijing Textile Institute, P21, 2000.

[4] Jinghong Dong, “Applications of BloodSTOP Ex in Neurosurgery,” published in “BloodSTOP and BloodSTOP Ex Clinic Test Data Collection,” by Beijing Textile Institute, P17, 2000.