When time matters

Science matters

axiostat®
stops bleeding, instantly

Scientific Compendium
Axiostat® stops bleeding, instantly

**Advanced**
Haemostatic Dressing

**100%**
Chitosan

**Stop Severe**
External Bleeding

Award winning product Axiostat®, is a clinically validated sterile haemostatic dressing specifically designed to stop profuse bleeding instantly. Axiostat® is based on a patented novel biomaterial - chitosan, which has been proven as an excellent haemostatic agent. Axiostat® is your solution to severe bleeding in Emergency Trauma, Interventional Cardiology, Dental, Military bleeding situations.

Chitosan has been in use for medical applications since the beginning of the 21st century. Axio uses proprietary technology to filter and purify chitosan and the result is an end product without any variation in performance or safety features. Particularly, Axio technology uses low polydispersity, high molecular weight material and which is a pure, 100% chitosan, quick-acting haemostat.

Axio products are constantly benchmarked with globally harmonised standards. Our products comply with ASTM standards and are made n GMP, ISO 13485:2016 approved facilities.
Chitosan

Chitosan is a linear polysaccharide consisting of glucosamine and N-acetyl glucosamine chains and is derived mainly from shellfish. It has been used in many technical applications such as medical products, water purification, in cosmetics and as a fat-binding weight control product. Cationic nature of chitosan gives this polymer a mucoadhesive property which can be further activated for wound care applications.

Chitosan salts are used as a matrix or scaffold material as well as in non-parenteral delivery systems for challenging drugs.

Characteristics of Chitosan

- Biocompatible
- Bioadhesive
- 100% Natural
- 0% Protein
- No exothermic reaction
- Easily broken down to glucosamine
Chitosan as a Hemostatic Agent: Current State

European Journal of Medicine. Series B, 2015, 2,1

1 Maksym V. Pogorelov 2 Vitalii Z. Sikora

1 MD, Professor, 2 MD, Professor
Sumy State University, Ukraine
31, Sanatornaya Street, Sumy
E-mail: pogorelov_max@mail.ru

Abstract: Bleeding is the one of leading cause of death after civil and combat trauma and affective hemostasis is a key challenge for emergency medicine. Current review focused on modern topical hemostatic agents based on chitosan. This article prescribes mechanism of action of chitosan and its interaction with blood plasma, erythrocytes and platelets. Review classified all topical hemostatic agents and show advantage of chitosan-based dressing. Also it gives perspectives in hemostatic dressing research.

Chitosan - Derivatives as hemostatic agents: Their Role in Tissue Regeneration

Regenerative Research 1(1) 2012 38-46

Mercy HP1, Halim AS*1, Hussein AR2

1) Reconstructive Sciences Unit, School of Medical Sciences, Universiti Sains Malaysia, 16150 Kubang Kerian, Kelantan, Malaysia.

2) Department of Hematology, School of Medical Sciences, Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan, Malaysia.

Abstract: In a recent discovery in the field of tissue regeneration, chitosan, a natural polysaccharide, received attention as a hemostatic agent due to its character to function independently on platelets to achieve hemostasis. In our present review, we highlight the composition and chemical structure of chitosan and its application in the current medical breakthrough, its reactions on erythrocytes and platelets, and its use as a wound dressing to promote tissue regeneration.
Mechanisms of Poly-N-Acetyl Glucosamine Polymer–Mediated Hemostasis: Platelet Interactions

The Journal of Trauma, 2004, 57, S13-S21

Hemant S. Thatte, PhD, Sofija Zagarins, Shukri F. Khuri, MD, and Thomas H. Fischer, PhD

**Background:** Investigations were performed to determine whether poly-N-acetyl glucosamine (p-GlcNAc) induces hemostasis by the activation of platelets.

**Methods:** Platelets were isolated from human blood, fixed in the presence poly-N-acetyl glucosamine fibers, and visualized with scanning electron microscopy. Platelet activation surface markers were measured by fluorescence multiphoton microscopy. Platelet aggregation in the presence of p-GlcNAc fibers and integrin receptor blockers was measured.

**Results:** Scanning electron microscopy indicated that contact of platelets with poly-N-acetyl glucosamine fibers resulted in platelet activation. Fluorescent microscopy showed that contact of platelets with the marine polymer increased intracellular levels of free calcium and resulted in surface exposure of platelet phosphatidylserine, P selectin, and the $\alpha_{\text{Ib}$β3 integrin. Antibody inhibitors of the platelet $\alpha_{\text{Ib}$β3 integrin inhibited p-GlcNAc to stimulate fibrin polymerization.

**Conclusion:** Poly-N-acetyl glucosamine fiber material promotes hemostasis by the activation of platelets.

The Journal of Trauma, 2006, 60, 655-658

Ian Wedmore, MD, John G. McManus, MD, MCR, Anthony E. Pusateri, PhD, and John B. Holcomb, MD

**Background:** Hemorrhage remains a leading cause of death in both civilian and military trauma patients. The HemCon chitosan-based hemostatic dressing is approved by the US Food and Drug Administration (FDA) for haemorrhage control. Animal data have shown the HemCon dressing to reduce haemorrhage and improve survival. The purpose of this article is to report preliminary results of the hemostatic efficacy of the HemCon dressing used in the prehospital setting on combat casualties.

**Methods:** A request for case information on use of HemCon dressings in Operation Iraqi Freedom and Operation Enduring Freedom was sent to deployed Special Forces combat medics, physicians, and physician assistants.

**Results:** Sixty-eight uses of the HemCon dressing were reported and reviewed by two US Army physicians. Four of the 68 cases were determined duplicative resulting in a total of 64 combat uses. Dressings were utilized externally on the chest, groin, buttock, and abdomen in 25 cases; on extremities in 35 cases; and on neck or facial wounds in 4 cases. In 66% of cases, dressings were utilized following gauze failure and were 100% successful. In 62 (97%) of the cases, the use of the HemCon dressing resulted in cessation of bleeding or improvement in hemostasis. There were two reported dressing failures that occurred with blind application of bandages up into large cavitations injuries. Dressings were reported to be most useful on areas where tourniquets could not be applied to control bleeding. The dressings were reported to be most difficult to use in extremity injuries where they could not be placed easily onto or into the wounds. No complications or adverse events were reported.

**Conclusion:** This report on the field use of the HemCon dressing by medics suggests that it is a useful hemostatic dressing for prehospital combat casualties and supports further study to confirm efficacy.
Evaluating the effectiveness of Axiostat® hemostatic dressing material in patients on Oral Anti-Platelet Drugs

The Journal of Contemporary dental practice, 2017 Sep 1, 18(9), 802-806

Department of Oral & Maxillofacial surgery KLE VK Institute of Dental Sciences, Belgaum, Karnataka, INDIA.

Introduction: The study was conducted to find out the efficacy of Axiostat® in controlling bleeding after tooth extraction. Profused bleeding during tooth extraction in particular with cardiac patients when they are on Blood thinners is a challenge for any dentist to control. Conventional method to stop bleeding using ordinary cotton usually takes more than 8-10mins.

Method: This prospective study was conducted on 40 cardiac patients who had underwent either Interventional procedures or open heart surgery. The selection criteria was such that 2 tooth extraction was performed for each patient. At one site, Axiostat® was used to achieve hemostasis and on the other site conventional method of using normal cotton/gauze was used.

Results: Axiostat® dressing showed superior efficacy, compared to cotton gauze. The average time for hemostasis with cotton gauze dressing was about 13.5 minutes and with Axiostat® it was found to be 1.13 minutes. The findings from this study shows that novel hemostatic dressings made out of chitosan has the potential to be used as first intervention in acute haemorrhage during tooth extraction.

Conclusion: Results of this study demonstrated effective utilization of Axiostat on tooth extraction wounds.

Total time taken to stop bleeding was 1.13 minutes
Assessing the Efficacy of Haemostatic Dressing Axiostat® In Trauma Care at a Tertiary Care Hospital in India: A Comparison with Conventional Cotton Gauze

Indian Journal of Emergency Medicine, Volume-2, July - December 2016

Patel Ketan, Patel Anjali, Patel Jignesh, Patel Bhavika, Parmar Priyank, Patel Dev

Background:
Trauma in India is a significant issue, with alarming rates of road accidents contributing to at least thirteen deaths an hour. Fatalities due to road accidents are expected to increase by 150% by the end of year 2020. A major cause of death in trauma injuries is uncontrolled haemorrhage. Using haemostatic dressings as the first line of treatment before seeking further intervention is one of the methods to achieve haemostasis and haemodynamic stability. The aim of this study is to compare and evaluate Axiostat®, a chitosan based haemostatic dressing and conventional cotton gauze dressing to control bleeding from a wound.

Methods:
A group of 61 patients were randomly selected into two groups. Each group had patients of either sex, and aged 18 years or above with upper/lower extremity injuries. The first group received Axiostat®, a haemostatic dressing made from Chitosan. This dressing is highly adhesive, porous and works based on electrostatic interactions. It can easily be removed by using saline. In the other group, standard cotton gauze was used. The size of dressing in both groups was 5cm x 8cm. In both groups, the dressing was applied to cover the contour of the wound and manual pressure was applied until the dressing stuck to the wound. Time at which the blood oozing through the periphery of the wound stopped was noted as the time for complete haemostasis. Both dressings were kept on the wound for 30 minutes post haemostasis and then removed according to protocol.

Results:
Time taken to achieve haemostasis in group I (Axiostat®) was 2.125±1.35 minutes, where as in group- II (cotton gauze), it was 13.08±6.40 minutes. Rebleeding was observed in 5 patients in group I and 12 patients in group II. Group I showed minimum tissue reactions as compared to Group II. Patient and doctor comfort was deemed excellent in group I as compared to group II.

Conclusion:
The study data and comparative results of various parameters between both groups shows that using Axiostat® was better than using cotton gauze to control bleeding in minimum time, with less tissue reactions and with maximum patient and doctor comfort.
Chitosan based Axiostat Dental Dressing following Extraction in Cardiac Patients under Antiplatelet Therapy

Nishant Sinha, Alok Mazumdar, Jaydip Mitra, Gunita Sinha, Shalabh Baunthiyal, Sharda Baunthiyal

Background:
Haemostasis following tooth extraction could be challenging in patients taking anti-platelet drugs as these drugs may interfere with platelet aggregation reducing clot formation. Stopping the medication may increase the risk of thromboembolic events while altering the medication may cause excessive bleeding. Several haemostatic agents have been suggested to be used in patients without changing the anti-platelet drug regimen. One such agent is Chitosan, which, owing to its high molecular weight and positive charges on glucosamine units, induce clotting by platelet adhesion and aggregation. The article evaluates the effect of chitosan dressing Axiostat on patients taking anti-platelet drugs like Aspirin or Clopidogrel.

Methods:
50 cardiac patients either on single or dual anti-platelet therapy were considered for the study after examining their medical history and clinical parameters. Antibiotics were given to the patients preoperatively to minimise the risk of infections. Tooth extraction was performed under local anaesthesia. Axiostat dental dressing was placed into the socket and pressure was applied to secure the pack within the socket. Patients were observed for any immediate or secondary haemorrhage for 24 hours. Axiostat dressing was removed with saline irrigation and patients were recalled after one week to observe healing of the wound.

Results:
The average time taken for achieving haemostasis with Axiostat dressing was about 1.5 minutes. Upon placement, Axiostat formed a dense pack that adhered to the socket and gave sufficient pressure to enhance haemostasis. No bleeding was observed immediately or after 24 hours. Seven-day follow-up of the patients showed that Axiostat improved post-operative healing without any complications. No adverse reactions were reported for the study.

Conclusion:
The report suggests that Axiostat dental dressing is effective in cardiac patients undergoing tooth extraction. Use of Axiostat facilitates the continuation of anti-platelet drugs and minimises the risk of thromboembolic events.
Haemostatic Effect of Axiostat® Dressing on Radial Access After Percutaneous Procedures

Clinical trial registry: ClinicalTrials.gov Registry number: NCT02837744

Principal Investigator: Dr. Milan Chag
Study Status: Ongoing study
Site: Care Institute of Medical Sciences, Nr. Shukan Mall, Off Science City Road, Sola Ahmedabad, Gujarat, India, 380060
Contact: dharak.shah@cimshospital.org

Introduction: Uncontrolled bleeding from the arterial puncture sites is a common problem during trans-radial coronary intervention procedures. The problem is exaggerated because patients undergoing such treatments are often treated with heparin, an anti-coagulant agent. Conventionally, the bleeding from arterial puncture sites is controlled by applying manual compression for very long periods. The purpose of this study was to evaluate the haemostatic effectiveness of a 100% chitosan haemostatic dressing (Axiostat) in patients undergoing Coronary Angiography (CAG) and Percutaneous coronary intervention (PCI).

Methods: A total of 66 patients were enrolled in the study, out of which 46 underwent CAG and 20 underwent PCI. The CAG patients were administered a heparin dose of 5000IU, whereas in case of PCI patients, it ranged from 5000-12500 IU. The Axiostat with a secondary dressing was placed on the puncture site immediately after removing the sheath and was held in position by applying manual compression. Time at which blood oozing through or from periphery of the dressing stops, was considered as the time to achieve haemostasis (efficacy endpoint). Time to achieve haemostasis was confirmed by opening the secondary dressing and releasing pressure after 30 mins and 60 mins post application in CAG & PCI respectively. Axiostat was removed by applying saline/water and gently lifting it off after 60 mins & 120 mins from application in CAG & PCI respectively. Puncture site was checked for re-bleeding, skin irritation, swelling, vascular complication, allergy at the time of dressing removal & 60 min after removal. After removal of the dressing, the patients were further treated as per institutional standard of care.

Results: The average time to achieve haemostasis in CAG and PCI patients were 4.6 min and 6.7 min, respectively. The haemostasis time was minimized by about one-fourth times than the conventional method of applying manual compression, which usually takes minimum 15 minutes to achieve haemostasis. Axiostat was also found to be excellent in ease of application and ease of removal in majority of patient. Further, no re-bleeding, swelling, vascular complications or allergic reactions were observed after removal of Axiostat.

Conclusion: Axiostat is a safe and effective haemostatic dressing to control bleeding from arterial puncture sites in CAG and PCI patients. The quicker haemostasis offered by Axiostat may improve the patient compliance and reduce length of hospital stay in patients undergoing transradial coronary intervention procedures.
Pre-hospital hemorrhagic control, effectiveness of Axiostat® dressing versus conventional method in acute hemorrhage due to trauma

Mohamed Kabeer K. K, Subhash V.C and Venugopalan P.P

Department of Emergency Medicine, Malabar Institute of Medical Science, Calicut, Kerala, INDIA.

Abstract: Trauma encompasses one of the leading causes of death and disability in the world and in India, where trauma care is still in its infancy, it accounts for almost 10% of deaths every year. Lack of adequate pre-hospital care (golden hour) and uncontrolled bleeding from wound site is stated as one of the prominent reasons of trauma related death. In this study we investigated the efficacy of a new hemostatic dressing (Axiostat®, Axi Biosolutions, INDIA), which is made from a natural biopolymer chitosan; as an initial hemorrhage controlling device in pre-hospital scenario in India where a good material to prevent early blood loss is absent. This prospective study was conducted with the help of 35 EMCTs (Emergency Medical Care Technicians). A total of 133 patients with scalp wound injury were identified for the study of which 29 patients were excluded because they did not meet the criteria. Of 104 victims, 47 (45.2%) victims were treated with Axiostat® and 57 victims (54.8%) with conventional dressing, cotton gauze. All subjects needed suturing as the victims included in the study were brought with open scalp wounds. Axiostat® dressing showed superior efficacy, compared to cotton gauze. The average time for hemostasis with cotton gauze dressing was about 18.56 ± 5.04 minutes and with Axiostat® it was found to be under 5 minutes (4.68 ± 1.04 min), confirming the hemostatic potential of the novel chitosan dressing when compared to traditional dressings. The findings from this study show that novel hemostatic dressings made out of chitosan has the potential to be used as first intervention in acute hemorrhage conditions especially in the pre-hospital scenario.

Conclusion: Within the scope of this clinical trial which included only trauma cases that involved bleeding injuries to the scalp, we can conclude that the hemostatic dressing Axiostat® offers good hemostasis in prehospital scenario in India where an ideal hemostat to prevent early blood loss is lacking. On analyzing this study, it is evident that this dressing enables early hemostasis which prevents much blood loss and the wound becomes very clean on removal of dressing for later wound suturing when compared to normal cotton gauze. The Axiostat® is also very easy to apply on a bleeding wound with negligible side effects and having no allergic reactions. Hence, Axiostat® serves as a good hemorrhage controlling device in any prehospital health care systems especially in ambulances.
Axiostat becomes the first hemostat from India to get USFDA clearance

**CE CERTIFIED**

EC Certificate
Full Quality Assurance System

Certificate No.
INQ495127-01

Date of Issue
27 June 2018

This is to certify that the quality system of:
Axiostat Hemostatic Dressing
Axiostat Hemostatic Dressing Pvt. Ltd.
Pilot-16, Gujarat Pharma Techno Park,
Sanand, Ahmedabad 382223, Gujarat, India

For design, production and the product's inspection and testing of:
Chitosan Haemostatic Dressing

This has been assessed and found to comply with:

Further details of the products and conditions for certification are given on file.

Issued by

[Signature]

**ISO 13485 CERTIFIED**

Management System Certificate

Certificate No.
AXIO_1159_1

Date of Issue
27 June 2018

This is to certify that the management system of:
Axiostat Hemostatic Dressing Pvt. Ltd.
Pilot-16, Gujarat Pharma Techno Park,
Sanand, Ahmedabad 382223, Gujarat, India

This is assessed as being compliant with:
The requirements of

The Certificate is valid for the following scope:
Design, manufacturing and sales of chitosan haemostatic dressing

Issued by

[Signature]

**GMP CERTIFIED**

G.M.P. Certificate

Certificate No.
15063

Date of Issue
27 June 2018

This is to certify that Axiostat Hemostatic Dressing Pvt. Ltd., Pilot-16, Gujarat Pharma Techno Park, Sanand, Ahmedabad 382223, Gujarat, India

Is a G.M.P. Certified company as per the requirements of the G.M.P. standard as prescribed by the Indian Pharmacopoeia

Issued by

[Signature]

**UNIQUE PATENTED PRODUCT**
Control of Arterial Bleeding using Axiostat® dressing on Swine Model

Two adult white swines were selected to study the efficacy of Axiostat® hemostatic dressing in controlling arterial bleeding compared to cotton gauze. The study was based on US Army protocol for worst case scenario bleeding.

Arterial puncture was made on the femoral artery of swines and was allowed to bleed for 45 seconds. Axiostat was applied with pressure through a pool of blood. Hemostasis was observed after 5 minutes of using Axiostat. However, cotton gauze could’n’t control bleeding even after 15 minutes.

After achieving hemostasis, Axiostat was easily extracted through saline irrigation.
Toxicity and hemostatic potential of poly [β-(1,4)-2-amino-2-deoxy-D-glucosamine] based hemostatic material on albino rabbits

Toxicology Mechanisms and Methods, 2011; 21(1): 25–30

PV Mohanan 1, Leo Mavely 2, and Ashish Pandya 2

1) Toxicology Division, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Poojapura, Thiruvananthapuram, Kerela, India, and
2) Axio Biosolutions Pvt. Ltd, 411-A, Smita Towers, Ahmedabad - 380052, India

Abstract: The present study was designed to evaluate the haemostatic potential of poly [β-(1,4)-2-amino-2-deoxy-D-glucosamine] based haemostatic dressing material on albino rabbits. In vitro cytotoxicity study of poly[β-(1,4)-2-amino-2-deoxy-D-glucosamine] based haemostatic dressing samples was carried out with L929 cells, and the cytotoxic potential was evaluated at the end of 24 h. The skin irritation was carried out in albino rabbits. Extract of the material was applied topically and irritation response was evaluated up to 72 h. The haemostatic study was initiated in rabbits after general anesthesia with a mixture of ketamine and xylazine. Using a sharp surgical blade, a 1.0 cm longitudinal incision was made on the right (test) and left (control) marginal ear arteries. Through the resultant jet spray of blood, the right 1.0 cm long wound was immediately covered with a 2 x 2 cm2 piece of test material (poly [β-(1,4)-2-amino-2-deoxy-D glucosamine] of known weight (w1). Similarly the left wound (1.0 cm length) was covered with commercially-available bandage (control) of known weight (w2). Direct pressure was applied for 2 min and then the samples were removed and weighed immediately (w3 for test and w4 for control) after haemostasis. Blood loss (w3–w1 for the Test and w4–w2 for control) was calculated from the materials weight before and after absorbing blood. The result of the study indicated that the indigenously developed material has local biological activity in the form of haemostatic action and, together with its ability to activate macrophages, resulted in wound healing applications. Hence, the present study concluded that the poly [β-(1,4)-2-amino-2-deoxy-D glucosamine]-based haemostatic dressing material is non-toxic, non-skin irritant, and has better haemostatic potential than a commercially available material with enhanced haemostatic capabilities for various wound dressing.

Keywords: haemostatic; wound healing; skin irritation; cytotoxicity; SEM
**EMERGENCY**

Doctor: Ketan Patel  
Apollo Hospital, Ahmedabad

**Type of Injury:** Contused Lacerated Wound over high perietal with depressed skull  
**Bleeding Type:**  
- ☐ Mild  
- ☐ Moderate  
- ☠ Severe

**No. of Axiostats used:** 2  
**Pressure applied time:** 1.03 mins

**Rebleeding on removal of Axiostat:**  
- ☐ Yes  
- ☠ No

<table>
<thead>
<tr>
<th>Patient outcome with Axiostat</th>
<th>Ease of Application</th>
<th>Ease of Removal</th>
<th>Non-adherence to wound</th>
<th>Ability to manage exudates</th>
<th>Ability to manage odour</th>
<th>Conformability of dressing</th>
<th>Ability to remain in position</th>
<th>Patient comfort</th>
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**Time to achieve Haemostasis:** 1.03 minutes

**Nephrology**

Doctors: Mrs. Rupa / Dr. Vishwanath (Manipal Hospital, Bangalore)  
Dr. Padmanabhan (NU Hospitals, Bangalore)  
Mrs. Nirmala / Dr. Deepak (Columbia Asia Hospital, Bangalore)

**No of Patients under study:** 64  
**Average Age of Patients:** 57 years  
**Sex ratio (male : female):** 13 : 7  
**Average Heparin Dosage:** 6400 IU  
**AVF Access:** Brachial, Radial and Sub Clavian  
**Axiostat Variant:** N22

<table>
<thead>
<tr>
<th>Patient outcome with Axiostat</th>
<th>Ease of Application</th>
<th>Conformability of dressing</th>
<th>Adherence to wound</th>
<th>Ease of Removal</th>
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**Avg. Time to achieve Haemostasis:** 3.10 minutes
VASCULAR

Doctor:
Marykutti Chacko
Sanjeevani Hospital
Ahmedabad

Patient History:
46 year old Male undergoing Angioplasty having a history of Diabetes and Hypertension

Number of Axiostat used: 1
Total Procedure Time: <1 hour

Interventional Cardiology Procedure - Angioplasty
Heparin Dosage - 7000 IU
Loading Dosage - Inj. Cloxan 0.6 + Tab Plavix & Tab Aspirin
Sheath size - 7F (Artery) and 6F (Vein)
Usage of Secondary Dressing - Gauze piece

<table>
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<tr>
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<th>Ease of Application</th>
<th>Conformability of dressing</th>
<th>Adherence to wound</th>
<th>Ease of Removal</th>
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<td>Poor</td>
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Time to achieve Haemostasis: 5 minutes

DENTAL

Doctor:
Tejraj Kale
KLE VK Institute of Dental Sciences
Belgaum, Karnataka, India

Patient History: 48 year old Male undergoing 2 tooth extractions at same quadrant.

Dental Procedure: Tooth Extraction
INR: 2.20
Antiplatelet: Tab Ecosprin 325mg

Comparitive study was conducted for patients undergoing multiple tooth extractions at same quadrant. Extraction sites treated with Study Group (axiostat haemostatic dressing), achieved haemostasis earlier compared to Control Group (cotton gauze).

Postextraction pain was considerably lower and significant better healing was observed in the study group compared to the control group. Axiostat demonstrated to be an effective haemostatic agent that considerably lessens the bleeding time in patients on oral anti-platelet drugs, post extraction. In addition, it even offered minimal post-extraction pain and improved healing of the extraction wound.

Time to achieve Haemostasis: 1.50 minutes
Neck Trauma

At 11:40AM, the victim was brought in with severe lacerations on her chin and neck and was treated with multiple Axiostat® dressings.

Bleeding was stopped within 3 minutes and at 11:45AM, the dressing was removed for further treatment.

The lacerations required 75 external and 25 internal stitches.

Femoral Access Site Bleeding

Axiostat® vascular dressing used to control arterial bleeding quickly at femoral access site post removal of sheath during cathlab procedure. Axiostat® vascular dressings are very effective for patients on blood thinners and for different sizes of sheath.

CLINICAL DATA

<table>
<thead>
<tr>
<th></th>
<th>Haemostasis time in minutes</th>
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</thead>
<tbody>
<tr>
<td>Standard Gauze</td>
<td>13.08</td>
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<tr>
<td>Axiostat®</td>
<td>2.13</td>
</tr>
<tr>
<td>Cotton Gauze</td>
<td>18.56</td>
</tr>
<tr>
<td>Axiostat®</td>
<td>4.68</td>
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</table>

Clinical Study on Trauma Patients
Published in Indian Journal of Emergency Medicine
IJEM VOL.2 No.2 JULY-DEC 2016

Clinical Study on Trauma Patients
Malabar Institute of Medical Science,
Calicut, Kerala, India
# Global Haemostats Comparison

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Axiostat</th>
<th>Quik Clot</th>
<th>Celox</th>
<th>Surgicel</th>
<th>Spongostan</th>
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</thead>
<tbody>
<tr>
<td>Form Factor</td>
<td>100% chitosan sponge</td>
<td>Granules, Coated Gauze</td>
<td>Granules, Coated Gauze</td>
<td>Gauze</td>
<td>Sponge</td>
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<tr>
<td>Active Ingredient</td>
<td>Chitosan</td>
<td>Kaolin, Zeolite</td>
<td>Chitosan</td>
<td>OR Cellulose</td>
<td>Gelatin</td>
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<tr>
<td>Stop Bleeding capability</td>
<td>Moderate to severe bleeding</td>
<td>Moderate to severe bleeding</td>
<td>Moderate to severe bleeding</td>
<td>Mild bleeding</td>
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</tr>
<tr>
<td>Mechanism of action</td>
<td>100% active ingredient, Stuffable, No risk of emboli, Suitable for deep wounds</td>
<td>Irritation and Heat generation, Risk of emboli formation due to dispersion into blood.</td>
<td>Risk of emboli formation due to dispersion into blood.</td>
<td>Only suitable for surgical bleeding</td>
<td>Only suitable for surgical bleeding</td>
</tr>
<tr>
<td>Ease of removal</td>
<td>Easily removed using water/saline</td>
<td>Very difficult</td>
<td>Very difficult</td>
<td>Absorbed in the body</td>
<td>Absorbed in the body</td>
</tr>
<tr>
<td>Type of bleeding</td>
<td>External</td>
<td>External</td>
<td>External</td>
<td>Internal</td>
<td>Internal</td>
</tr>
</tbody>
</table>
AXIOSTAT v/s CHITOSAN HAEMOSTATIC GAUZE

The in vitro haemostatic efficacy of Axiostat is evaluated through the whole blood clotting time study. Axiostat and competitor chitosan gauze samples of same sizes are placed in test tubes and 1mL citrated blood is added to it. The formation of blood clot is confirmed by inverting the tubes. Axiostat quickly forms the blood clot and remains adhered to the test tube. Whereas, the competitor chitosan gauze does not form the blood clot, which is evident from unclotted blood flowing down the inverted test tube.

AXIOSTAT v/s COMPETITOR HAEMOSTATIC GAUZE

The strength of blood clot is visually evaluated by checking hemolysis in water. In this comparative study, Axiostat and competitor haemostatic gauze samples are placed in separate beakers and 1mL citrated blood is added. The samples are allowed to stand for 3 minutes and excess water is added to check the strength of the blood clot, the unclotted blood cells undergo hemolysis in water and give it a characteristic red color. Axiostat forms a very strong clot without any unbound blood cells and therefore doesn't show hemolysis. On the other hand, the competitor haemostatic gauze shows high degree of hemolysis indicating incomplete and poor clot formation.
INDICATIONS

• Arterial and Venous Bleeding • Scalp, Neck and Head Trauma

• Lacerations and deep cuts • Military gunshot wounds

• Interventional Cardiology procedures
  (Radial & Femoral artery)

• Haemodialysis procedure • Surgical procedures

• Puncture or stab wounds

• Dental bleeding during Maxillofacial trauma, surgeries, extraction and other dental procedures
**Introduction:** To determine the skin sensitization potential of the test item extracts using guinea pig maximization test (GPMT).

**Product Details:**

<table>
<thead>
<tr>
<th>Test Item Name</th>
<th>Non Absorbable Haemostatic Dressing (sterile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch / Lot No.</td>
<td>1039-014</td>
</tr>
<tr>
<td>Manufacture Date</td>
<td>September 2015</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>August 2018</td>
</tr>
<tr>
<td>Appearance</td>
<td>Chitosan sponge</td>
</tr>
<tr>
<td>Composition</td>
<td>Poly β-(1,4) - 2 amino -2 deoxy -D Glucosamine</td>
</tr>
<tr>
<td>Ingredients</td>
<td>Non-absorbable Chitosan</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in HCL, Acetic &amp; Nitric acid</td>
</tr>
<tr>
<td>Stability</td>
<td>37 °C</td>
</tr>
<tr>
<td>Condition</td>
<td>Sterile</td>
</tr>
</tbody>
</table>

**Methods:**

The method of administration is in line with the ISO 10993, Part-10 standard. For the induction phase intradermal injections and topical application was employed. The challenge phase was accomplished by topical applications.

**Results:** Chitosan Non-absorbable Hemostatic Dressing (Sterile) is considered valid, as the control animals showed no skin reactions; and no significant loss of body weight. No mortality occurred in control group animals.

**Conclusion:** Axiostat® dressing does not induce any hyper sensitivity reactions in the body.

**References:**
Introduction: To evaluate whether or not the test item Non Absorbable Hemostatic Dressing (sterile) induces cytotoxicity in Balb/c 3T3 cells using elution method.

Product Details:

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</tr>
<tr>
<td>Condition</td>
<td>Sterile</td>
</tr>
</tbody>
</table>

Methods:

Rationale for assay method

The NRU cytotoxicity assay procedure is a cell survival/viability chemo sensitivity assay based on the ability of viable cells to incorporate and bind neutral red dye. Specified in ISO 10993, Part-5 standard as an appropriate test to evaluate in vitro cytotoxicity of medical devices.

Results: Chitosan Non-absorbable Hemostatic Dressing (Sterile) is considered as non-cytotoxic to Balb/c 3T3 cell lines, under the conditions of the test.

Conclusion: Axiostat® dressing does not have any toxic effect on the mammalian cells.

References:
**Introduction:** To determine the acute systemic toxicity potential of the test item Non Absorbable Hemostatic Dressing (sterile) extracts in Swiss albino mice.

**Product Details:**
- **Test Item Name:** Non Absorbable Haemostatic Dressing (sterile)
- **Batch / Lot No.** 1039-014
- **Manufacture Date** September 2015
- **Expiry Date** August 2018
- **Appearance** Chitosan sponge
- **Composition** Poly {β-(1,4) - 2 amino -2 deoxy-D Glucosamine}
- **Solubility** Soluble in HCL, Acetic & Nitric acid
- **Stability** 37 °C
- **Condition** Sterile

**Methods:**
The extracts (Physiological saline and Cotton-seed oil) were administered without any dilution and the maximum dose volume used were 50 mL/Kg and 50 mL/Kg for IV and IP route, respectively. This is in line with the ISO 10993, Part-11 standard.

**Results:** Chitosan Non-absorbable Hemostatic Dressing (Sterile) is considered valid, as the control animals showed no biological reactions; and no significant loss of body weight. No mortality or abnormal behaviour such as convulsion or prostration was occurred in control group animals.

**Conclusion:** Axiostat® dressing did not show any Systemic toxicity and hence meets the requirements of ISO 10993, Part-11:2006 (E).

**References:**
**Introduction:** To determine the irritation potential of the test item extracts following intracutaneous injection into New Zealand white rabbits.

**Product Details:**

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</tr>
</tbody>
</table>

**Methods:**

The extracts (Physiological saline and Cottonseed oil) were administered intracutaneously without any dilution and the dose volume used was 0.2 mL per injection. This is in line with the ISO 10993, Part-10 standard.

**Results:** Chitosan Non-absorbable Hemostatic Dressing (Sterile) is considered valid, as the control animals showed no skin reactions; and no significant loss of body weight. No toxicity or mortality occurred in control group animals.

**Conclusion:** Axiostat® dressing did not show any intracutaneous reactivity and meets the requirements of ISO 10993, Part-10:2010(E).

**References:**

Axio envisages a future where contemporary knowledge of biomaterials, medicine and engineering will be integrated in designing novel solutions to address the huge unmet need in management of trauma and chronic-infectious wounds.

We are a deep science medtech company with extensive R&D expertise in biomaterials. Our platform-based approach enables us to develop medical products that are engineered to enhance its efficacy even at higher scale. With such a vision, we introduced our first line of haemostatic products that are probably one of the best available trauma heamostats in the market today.

Axio’s research philosophy is to translate the biomaterials research into real-world products and bring them to patients’ bedside at an affordable cost. Here innovation is a daily practice as we explore unchartered territories in novel materials and technologies. The research & development team at Axio is developing novel solutions that are smarter, friendlier and quicker than the conventional products.
MANUFACTURING FACILITY

Axio products are manufactured in ISO 13845 certified facility owned and operated by Axio.

- State of the art manufacturing facility is located in Pharma tech park at City of Ahmedabad, Gujarat, India.
- Custom built imported machinery with 75-80% automated processing.
- Minimal human intervention reducing handling errors.
- 5000sq.ft cleanroom area built according to cGMP, FDA guidelines under Class 10000 manufacturing area.
- Gamma sterilization done terminally. Full traceability from finished product to raw material source.

ISO 13485, GMP Certified

- All 3rd party vendors audited and qualified by EU notifying body.

We at Axio benchmark ourselves to global standards and follow appropriate regulatory guidelines in respective countries of operation. We follow a process that is based on a strong foundation of manufacturing quality standards, mutually beneficial relations with our customers, dealers and all professionals associated with us.
"We have used it topically on groin puncture up to 24 French sheath, where there is a small amount of bleeding after the use of closure devices, and also in rather unusual circumstances when we have had bleeding around sheaths- and have found that it works. It seems an interesting product and we would like to continue to trial it."

Mr Mansoor Ali Khan
PhD, FRCS, FEBS, FACS
Surgeon Commander, Royal Navy

"One of my colleagues used the product the other day, and it was very effective in achieving haemostasis. I do believe it is effective in stopping bleeding."

Dr. T S Srinath Kumar
President-SEMI
Consultant Emergency Department

"Axiostat® is a product which we used during trauma cases (laceration) and it has considerably reduced the bleeding per se. Thereby reduced the secondary insult to the patient and maintaining hemodynamic stability by reducing excess blood loss from the wound. I would like to recommend this product in trauma cases for external bleeding control."
Axioskat® Haemostatic pad is a novel device to get control of bleeding post sheath removal, specially from Femoral arterial puncture site. I have used the device successfully in my patients undergoing diagnostic and/or therapeutic Femoral cannulation.

Dhiraj Yadav
Cathlab Technologist

Bhakti Vedanta Hospital & Research Institute, Mumbai, India

This is to state that, I had the opportunity of using the Axioskat® hemostatic pad in the Department of Cardiology in our hospital for the interventional cardiology procedures. The Axioskat® Pad is a great help in stopping severe femoral bleeding within minutes of application. It is also observed that by using Axioskat® the loss of blood is minimal, thereby saving the time of technicians & supporting staff. I would recommend use of Axioskat® in all interventional procedures.

Axioskat® was used by para commandos in Surgical Strike 2016
www.youtube.com/watch?v=glb5pjiAxk

Scan to view
Q: What is Axiostat®?
A: Axiostat® is a sterile, non-absorbable haemostatic dressing intended to control profuse bleeding within minutes of application by providing an active mechanical barrier to the wound site. Axiostat® stops moderate to severe bleeding due to cuts, abrasions, lacerations, venous/arterial punctures and more.

Q: Why Axiostat®?
A: Conventional interventions as applying manual pressure, Cotton gauze etc. takes more than 10-15 minutes to stop profuse bleeding and in majority of cases they are incapable of controlling profuse bleeding. Axiostat® helps stabilize the patient immediately and also helps save time for caregiver to focus on severe injuries. Use of Axiostat® reduces blood loss, and thus the demand for blood transfusion products such as red blood cells or plasma.

Q: Is Axiostat® easy to use?
A: Axiostat® comes in sterile multi-layered pouches/blisters which can be easily opened using one hand. Axiostat® can be directly applied onto bleeding with palm pressure. It doesn’t require pre-mixing or preparation prior to use.

Q: How easy is it to remove Axiostat®?
A: Axiostat® can be removed using saline or water irrigation. It will turn into a gel that can be easily peeled away without causing any trauma to the wound. This is one major advantage in using Axiostat® as it can be completely removed from wound without dislodging the already formed clot.

Q: What precautions need to be taken while using Axiostat®?
A: Axiostat® has a higher affinity to blood and may stick to gloves if not dry. Axiostat® also needs adequate blood to wet & get activated to aid in quick control of bleeding.

Q: What is Axiostat® made of?
A: Axiostat® is made of a naturally occurring polymer known as Chitosan (Poly [β-(1,4)-2-amino- 2-deoxy- D-glucosamine],) which is a biocompatible polysaccharide extracted from endoskeleton of cephalopods like squid. They are rigorously processed and purified prior to fabricating into dressing and is terminally sterilized using Gamma irradiation.

Q: Is Axiostat® absorbable in the body?
A: No. Axiostat® is a non-absorbable dressing and is not an Implant. It should be removed prior to wound closure using water/saline.
Q: Can Axiostat® cause allergies?
A: There have been no known allergic reactions from the use of Axiostat® since 2011. Chitosan used in Axiostat® does not contain any protein or allergic components.

Q: How long can Axiostat® be kept on the wound?
A: Axiostat® can be kept on wound up to 48 hours.

Q: Is secondary dressing required after using Axiostat®?
A: Secondary dressing such as cotton gauze may be used to keep Axiostat® dry and in position. Axiostat® sticks to bleeding wound quickly and it eliminates the need for any other dressings.

Q: Will Axiostat® work on patients with bleeding disorders or who are on blood thinning drugs?
A: Axiostat® works independently of natural clotting mechanism and is based on adhesive property due to charge density of blood components.

Q: How do I justify the additional cost of using Axiostat® in my current procedure?
A: In an environment where critical care is being administered like an Emergency Room or Trauma Center, time becomes of prime importance. Any extra time spent in stoppage of bleeding with one patient is time that could be utilized with another patient in need of immediate attention. Stoppage of bleeding can also minimize the need for transfusion products, thereby reducing the risk of complications and additional cost. Overhead costs are also reduced when the turnaround time is decreased. Whether it is in emergency care or in a Cathlab, the shorter the procedure, the faster the bed can be turned around for the next patient. This translates directly into increased revenue as a result of additional patients served.

Q: How is Axiostat® different from other surgical haemostats?
A: Axiostat® works at the mechanical, electrostatic & biological level to effectively create a clot plug at an accelerated rate that cannot be matched by a non-active material such as cotton gauze. The haemostasis achieved is total and extends all the way to the blood vessel level.