Tricol
BIOMEDICAL INC

2022 COMPENDIUM

Published Articles & Studies

1. Misgav M., Lubetszki A., Brutman-Barazani T., Martinowitz U., Kenet G. "The hemostatic efficacy of chitosan-pads in hemodialysis patients with significant bleeding tendency." J Vasc Access. 2017 May 15;18(3):220-224. doi: 10.5301/jva.5000707. Epub 2017 Apr 28.
   Summary: A prospective, randomized, cross-over, cohort study in 15 patients on chronic dialysis with acquired coagulopathy. Bleeding from arterial and venous needle sites was controlled with HemCon Bandage or standard gauze and pressure as the control. A total of 288 applications, 144 for each type of pad, were performed in 15 patients. The average time to hemostasis for the entire group was significantly shorter with the chitosan pads compared to the gauze. The average time to hemostasis for the entire group was significantly shorter with the chitosan dressing compared to the pad gauze ("arterial" point 3 vs. 18.5 min, p<0.001 "venous" access 2.8 vs. 13.2 min, p<0.001, respectively). Use of HemCon dressing saved patient time from roughly 30-60 minutes per visit
   FOCUS: DIALYSIS

2. te Grotenhuis, R., van Grunsven, P., Heutz W., Tan E "Use of Hemostatic Nasal Plugs in Emergency Medical Services in the Netherlands: A Prospective Study of 33 cases". J of Prehospital Emergency Care 2017; 0:1-7
   Summary: This study demonstrated that HemCon Nasal Plug is an effective adjunct in the prehospital treatment of severe and uncontrolled epistaxis. HemCon Nasal Plug effectively stops severe nose bleeding, also on anticoagulated patients; effectively stops severe nose bleeding, also when Merocel fails to stop the bleeding; are well-tolerated by patients due to the small size, compared to other nasal tampons; are relatively inexpensive and much less expensive than Merocel; are very easy to use.
   FOCUS: EPISTAXIS / EMS (M.DOC)

3. te Grotenhuis, R., van Grunsven, P., Heutz W., Tan E "Prehospital use of hemostatic dressings in emergency medical services in the Netherlands: A prospective study of 66 cases". Injury, Int. J. Care Injured 47 (2016) 1007–1011.
   Summary: From June 2012 to December 2014, all ambulances of two emergency medical services in the Netherlands were equipped with ChitoGauze, total of 66 cases were reported on. Of the 66 patients, 26 were treated with ChitoG auze after conventional treatment (standard gauze and manual compression) failed to work, and for 32 of the patients conventional therapy wasn't expected to work. This is the largest prospective study in civilian healthcare and the second largest case series with prehospital use of hemostatic dressings. It demonstrated that ChitoGauze is an effective and safe adjunct in the prehospital treatment of massive external traumatic hemorrhage. In 70% of the subjects treated with ChitoGauze the severe bleeding stopped within 60 seconds of treatment.
   FOCUS: TRAUMA / EMS

4. Morimoto, Y., Sugimoto, T., Haba, F., Sakahira, H. "A new hybrid sutureless patch repair utilizing chitosan for left ventricle rupture after myocardial infarction: A case report". International Journal of Surgery Case Reports 26 (2016) 131–133.
   Summary: A single case use of two sheets of 5cm x 5cm HemCon Bandage to treat a 1cm long tear in the left circumflex artery in an area of myocardial necrosis approximately 4cm x 5cm. The chitosan dressing application successfully controlled copious bleeding from the left ventricle free wall rupture. After achieving complete hemostasis, the dressing application was moistened with saline allowing the chitosan to be peeled off the site without further bleeding and the site to be inspected. A Tachosil biological dressing could then be applied over the site and the thoracic cavity closed. Echocardiography was performed every day for one week and detected no signs of re-rupture or pseudo-aneurysm. One month later, the patient had no complications at his postoperative follow-up visit. Morimoto et al. conclude that this is the first report of a hybrid patch repair utilizing chitosan-based sheets for left ventricular rupture after myocardial infarction. The procedure was demonstrated as safe, easy and

effective. Further studies are necessary to evaluate the short- and long-term efficacy of this procedure, and these results must be compared with those of classical surgical repairs

FOCUS: HEMOSTATIC EFFICACY

5. Pippi, R. "The effectiveness of a new method using an extra-alveolar hemostatic agent after dental extractions in older patients on oral anticoagulation treatment: an intrapatient study." Oral Surg Oral Med Oral Pathol Oral Radiol. 2015 Jul;120(1):15-21
   Summary: A prospective, paired, randomized trial of oral bleeding control in non-surgical extractions. Twenty patients on oral anticoagulant therapy (OAT) with an INR 1.6 - 3.5 with extraction of two teeth. test site – HemCon Dental Dressing (HDD) Tricol, control site, CollaPlug, Zimmer Dental. The mean application time was significantly lower in the HDD than in CollaPlug and this difference is statistically significant. The mean postoperative pain was significantly lower and post-extraction socket healing was significantly better with HDD than with CollaPlug. Safe procedure without discontinuation of the OA regimen. The HDD seems to reduce postoperative side effects and obtain rapid soft tissue healing

   FOCUS: DENTAL / ORAL SURGERY

6. Bulger EM, Snyder D, Schoelles K, Gotschall C, Dawson D, Lang E, Sanddal ND, Butler FK, Fallat M, Taillac P, White L, Salomone JP, Seifarth W, Betzner MJ, Johannigman J, McSwain N Jr. "An evidence-based prehospital guideline for external hemorrhage control: American College of Surgeons Committee on Trauma." Prehospital Emergency Care. 2014 Apr-Jun; 18(2):163-73.
   Summary: An expert panel was convened by the American College of Surgeons Committee on Trauma EMS Committee to include nationally recognized experts in prehospital trauma care, in addition to available literature review, for a comprehensive review of available hemorrhage control tools including tourniquets and hemostatic devices (to include HemCon) in military and civilian EMS settings.

   FOCUS: HEMOSTATIC EFFICACY – EMS

7. Eldibany, R.M. "Platelet rich fibrin versus Hemcon dental dressing following dental extraction in patients under anticoagulant therapy." Tanta Dental Journal 11 (2014) 75-84
   Summary: A prospective, randomized, open-label study *performed to evaluate the use of Platelet Rich Fibrin (PRF) and Hemcon dental dressing (HDD) in cardiac patients taking Warfarin following dental extraction.20 patients with (INR) <3.5. Complete hemostasis was achieved in all cases with no delayed bleeding. Patients in group A (PRF) showed minimal pain and accelerated healing, while those in group B showed pain on the first few days following extraction and retarded healing. HDD has excellent hemostatic properties and can be used safely in such patients but drives key element that HDD has to be used in small amounts and not to overpack the socket to avoid higher pain scores.*

   FOCUS: DENTAL / ORAL SURGERY

8. CAPT Brad L. Bennett, PhD, USN (Ret.), CDR Lanny F. Littlejohn MD, USN, Dr. Bijan S. Kheirabadi, PhD, CAPT Frank K. Butler, MD, USN (Ret.), COL Russ S. Kotwal, MD, USA, Dr. Michael A. Dubick, PhD, COL Jeffrey A. Bailey, MD, USAF. "Management of External Hemorrhage in Tactical Combat Casualty Care: Chitosan-based Hemostatic Gauze Dressings" TCCC Guidelines Change 13-05. 16 April 2014
   Summary: A review of clinical and pre-clinical data of chitosan dressings in military and civilian prehospital use. The review concludes that after a decade of clinical use (since 2003), there is a benefit and a good safety record for using chitosan-based pre-hospital dressings. For these reasons, many militaries, and emergency medical services (EMS) and law enforcement agencies have implemented the widespread use of chitosan-based hemostatic dressings. Based on the past battlefield success, the report recommended the addition of ChitoGauze to the TCCC guidelines. The TCCC Guidelines are consulted by militaries and by law enforcement agencies around the world to select hemostatic dressings for controlling pre-hospital hemorrhage.

   FOCUS: HEMOSTATIC EFFICACY – MILITARY/PRE-HOSPITAL

9. Susumu Oozawa, Teiji Akagi and Shunji Sano. “A New Hemostasis Tool after Percutaneous Angioplasty: The Hemcontm Pad Hemostasis Device.” J Vasc Med Surg 2014, 1:125.
Summary: A prospective single center, investigation compared the use of HemCon™ pad versus conventional manual compression (control) in 50 consecutive patients undergoing interventional procedures for peripheral artery disease (4-6F). Successful hemostasis in 48 of 50 patients (96% success); two patients had been converted into over size sheath (10Fr) during catheter procedure. The average time to successful hemostasis following sheath removal was significant shorter with the HemCon™ pad by 53% compared to the conventional manual compression, with no thromboses in access site artery. The HemCon™ pad is effective at decreasing average time to hemostasis.

FOCUS: HEMOSTATIC EFFICACY - CATH LAB

10. Rall JM, Cox JM, Songer AG, Cestero RF, Ross JD. “Comparison of novel hemostatic dressings with QuikClot combat gauze in a standardized swine model of uncontrolled hemorrhage.” Journal of Trauma Acute Care Surg. 2013 Aug; 75(2 Suppl 2):S150-6.
Summary: Study aimed to determine the efficacy of currently available hemostatic dressings (HCG - HemCon ChitoGauze; QCX - QuikClot XL, CEL - Celox Gauze, CTG - Celox Trauma Gauze) as compared to the current Committee for Tactical Combat Casualty Care Guidelines standard of treatment for hemorrhage control (QCG - QuikClot Combat Gauze) in the DoD consensus model of swine femoral uncontrolled hemorrhage.). QCG performed poorly on most variables, where the other products performed well in wound packing time, time to hemostasis, blood loss, resuscitation fluids, coagulation profile and histology. These results suggest that the current standard for point-of-injury hemorrhage control (QCG) may need to be re-evaluated or alternatively the standard of care expanded to include HCG, QCX, CEL and CTG.

FOCUS: IN-VIVO HEMOSTATIC EFFICACY

11. Mudi Misgav, MD, Gili Kenet, MD, and Uriel Martinowitz, MD. “Chitosan-based Dressing for the Treatment of External/Accessible Bleedings in Children With Bleeding Tendency.”J Pediatric Hematolgy and Oncology. 2013;00:000- 000.
Summary: A case series of use of HemCon Bandage chitosan dressings to control external accessible bleeding in 2 adults and 5 children with severe bleeding disorders who suffered 9 bleeding episodes. The inherited bleeding disorders were, Glanzmann thrombasthenia (1), Hemophilia A (4), Hemophilia B (1) and von Willebrand Disease (1) The HemCon™ dressings were used either after failure of extensive systemic therapy or as first choice. In 7 of 9 episodes the bleeding ceased immediately. There was no rebleeding after removal of the HemCon Bandage after several hours and up to 4 days use. There were no reported adverse events or local skin reactions. The use of HemCon dressings in patients with bleeding tendencies was encouraged.

FOCUS: HEMOSTATIC EFFICACY / BLEEDING DISORDERS

12. Kale, T.P., et al., “Effectiveness of Hemcon Dental Dressing versus Conventional Method of Haemostasis in 40 Patients on Oral Antiplatelet Drugs.” Sultan Qaboos University Med J, August 2012, Vol. 12, Iss. 3, pp. 330-335, Epub. 15th Jul 12
Summary: A prospective, randomized, open-label study with 40 subjects with 80 hemostatic treatments comparing the post extraction bleeding control of HemCon Dental Dressing (HDD) versus standard gauze. The 40 participants remained on oral antiplatelet therapy (OAT) throughout the study. All HemCon treated sites achieved hemostasis sooner than the control sites, HDD proved to be an excellent hemostatic agent that significantly shortened the bleeding time following dental extraction in patients on OAT. Additionally, HDD offered significantly improved post-operative healing of the extraction socket and less postoperative pain.

FOCUS: DENTAL / ORAL SURGERY

13. Schwartz MD, Reynolds MD, Shiver MD, Lerner PhD, Greenfield DO, Solis DO, Kimpel DO, Coule MD, McManus MD. "Comparison to Two Package Hemostatic Gauze Dressings in a Porcine Hemorrage Model." Prehospital Emergency Care. Vol. 15, No. 4. October/December 2011.
Summary: A study was conducted to compare the efficacy of ChitoGauze to Combat Gauze when controlling arterial hemorrhage in a swine model. A femoral arterial injury was created using a 6-mm vascular punch, then allowed to free bleed for 45 seconds. Direct pressure was applied for 2 minutes with hemostatic agent. It was appeared that ChitoGauze and Combat Gauze were equally effective at achieving hemostasis.

FOCUS: HEMOSTATIC EFFICACY

14. Waibel, Kirk H., Haney, Brian, Moore, Merrideth, Whisman, Bonnie, Gomex, Robert. "Safety of Chitosan Bandages in Shellfish Allergic Patients." Military Medicine. Vol. 176, October 2011.
Summary: A prospective randomized study assessing the safety and efficacy of HemCon chitosan, derived from shrimp shells, on patients with known shellfish allergies. 19 participants were enrolled; 10 completed the study. 9 reported shrimp allergy history and 5 reported multiple shellfish allergies. No participant had a positive skin prick test (SPT) to chitosan powder or experienced an adverse reaction during HemCon bandage challenges. No protein bands were visualized during gel electrophoresis analysis of chitosan powder.

FOCUS: SHELLFISH ALLERGIES

15. Azargoon H., et al. "Assessment of Hemostatic Efficacy and Osseous Wound Healing Using HemCon Dental Dressing" JOE — Volume 37, Number 6, June 2011
Summary: evaluate the hemostatic effect of HemCon in osseous wound sites and evaluate the wound healing potential and percentage of new bone formation in osseous crypts treated with HemCon. A split-mouth design in 12 rabbits. HemCon or 15.5% ferric sulfate. Histologic evaluation. No statistical significant difference in hemostatic efficacy or wound healing between HemCon and ferric sulfate, HemCon group showed a significantly higher percentage of new bone deposition compared with the controls showing promise as an adjunct to the endodontic surgical armamentarium.

FOCUS: DENTAL / ORAL SURGERY

16. Arbel MD, Joel; Rozenbaum MD, Eliezer; Reges MPH, Orna; Neuman MD, Yoram; Levi MD, Alex; Erel MD, Jacob; Haskial MD, Abdel R.; Caneti MD, Menachem; Sherf MD, Michael; Mosseri MD, Morris FESC. "USage of Chitosan for Femoral (USF) Haemostasis After Percutaneous Procedures: Comparative Open Label Study." EuroIntevention 2010; Apr ; 6 (9):1104-9. Also presented at Annual Meeting of the Israel Heart Society, April 2009 and at EuroPCR2009, Spain, May 2009
Summary: A prospective, randomized, single center clinical trial to evaluate the hemostatic efficacy and safety of HemCon Bandage for femoral hemostasis post coronary angiography as an adjunct to manual compression control in anticoagulated individuals. The HemCon chitosan pad significantly decreased the time to hemostasis compared to a regular pad. The HemCon pad also reduced the total incidence of hematoma.

FOCUS: HEMOSTATAIC EFFICACY / CATH LAB

17. MacIntyre, Allan D. D.O., Quick, Jacob A. M.D., Barnes, Stephen L. M.D. "Hemostatic Dressing Reduce Tourniquet Time While Maintaining Hemorrhage Control." The American Surgeon. Vol. 77, No. 2. February 2011
Summary: This case studied the efficacy of a tourniquet in conjunction with a hemostatic dressing. 4 hemostatic agents were compared; standard gauze, HemCon, ActCel, Celox, and QuikClot. Standard gauze had 100% failure rate, Celox was effective 60%, Quikclot was 80%, ActCel was 90%, and HemCon was successful and maintained hemostasis 100%.

FOCUS: - HEMOSTATIC EFFICACY

18. Alan H. Shikani, M.D., F.A.C.S., Karim A. Chahine, M.D., and Mohannad A. Alqudah, M.D. "Endoscopically guided chitosan nasal packing for intractable epistaxis." American Journal of Rhinology & Allergy. January–February 2011, Vol. 25, No. 1
Summary: A prospective clinical study of the use of HemCon ChitoFlex chitosan dressing wrapped around a polyvinyl acetal (PVA) nasal sponge to control intractable epistaxis in 20 patients, 16 of whom were on anticoagulation therapy. All subjects had failed to respond to traditional anterior–posterior nasal packing. Chitosan packing was performed under endoscopic guidance with 19 / 20 (95%) of subjects achieving immediate hemostasis (3.6 ± 2.2 minutes). 1 subject with persistent bleeding after the first packing attempt was successfully repacked within 30 minutes. The dressings were removed at 48 hours with no evidence of rebleeding on removal or any side effects such as adhesions, scarring or infection. Endoscopically guided chitosan packing is a safe, effective and well tolerated outpatient method to treat intractable epistaxis.

FOCUS: EPISTAXIS

19. Mabry, Robert, John McManus. "Prehospital advances in the management of severe penetrating trauma" Critical Care Medicine Journal. Vol. 36, No. 7 (Suppl.). September 2008.
Summary: Discusses hemostatic and hemorrhage control agents that are currently in use by the military Highlights the efficacy, portability, and durability of HemCon bandages as well as their strong distribution to the military throughout Iraq and Afghanistan.

FOCUS: BATTLEFIELD TECHNOLOGY

20. Burkatovskaya, Marina, Ana P. Castano, Tatiana N. Demidova-Rice, George P. Tegos, Michael R. Hamblin. "Effect of Chitosan Acetate Bandage on Wound Healing in Infected and Noninfected Wounds in Mice". Wound Repair and Regeneration (Mar 2008).
Summary: *In vivo* study of effect of HemCon Bandage on healing of excisional wounds that were or were not infected with *Staphylococcus aureus* (MRSA). Chitosan acetate bandage reduced the number of inflammatory cells in the wound at days 2 and 4, and had an overall beneficial effect on wound healing especially during the early period where its antimicrobial effect is most important.

FOCUS: WOUND HEALING

21. Malmquist, J.P., et al., "Hemostasis of Oral Surgery Wounds with the HemCon Dental Dressing." J Oral Maxillofac Surg 66:1177-1183, 2008
Summary: A randomized, 4-center, open label, split mouth (paired) clinical study to investigate the use of HemCon Dental Dressing (HDD) versus gauze to control bleeding from molar extraction sites. The study included 17 subjects each with two to four 3rd molar extraction surgical sites. The subjects had a total of 74 HDD applications on one side of the mouth and 52 standard gauze applications on the other. All HDD surgically treated sites, including all from patients taking oral anticoagulant therapy, achieved hemostasis in less than 1 minute and control wounds in 9.53 minutes. Sites treated with HDD showed better healing compared with control sites, no control sites healed faster than those treated with HDD.

FOCUS: DENTAL / ORAL SURGERY

22. Brown, Mark, Mohamud R. Daya, Joseph A. Worley. "Experience with Chitosan Dressings in a Civilian EMS System" The Journal of Emergency Medicine (Nov 2007).
Summary: *Final paper of the TVF&R abstract and poster presentation. A prospective trauma study design with chart review of completed HemCon Bandage use for the control of severe bleeding by trained emergency medical services (EMS) personnel in 37 patients with 34 outcomes recorded. The study demonstrates how the HemCon® Bandage, which was originally developed for military trauma use can be successfully incorporated into the civilian EMS system. The chitosan-based HemCon Bandage is beneficial in stopping uncontrolled external hemorrhage when traditional methods such as pressure and gauze fail. Proper training in the use of the bandage is essential because user error was a contributing factor in most of the documented failures.*

FOCUS: EMS

23. Gustafson, Scott B., Pam Fulkerson, Robert Bildfell, Lisa Aguilera, and Timothy M. Hazzard. "Chitosan Dressing Provides Hemostasis in Swine Femoral Arterial Injury Model." Prehospital Emergency Care 11 (2007) 172 – 178.
Summary: *Efficacy data comparing HemCon vs. Gauze in 2.7 mm arterial punch in inguinal femoral arteries. Pressure to injury 3 minutes. Dressings have to hold hemostasis for 30 minutes, if failed, second attempt. HemCon® Bandage provided superior hemostasis to gauze.*

FOCUS: HEMOSTATIC EFFICACY

24. Bachtell, Nathan, Teresa Goodell, Gary Grunkemeier, Ruyun Jin, Kenton Gregory. "Treatment of Dialysis Access Puncture Wound Bleeding with Chitosan Dressings." Dialysis & Transplantation Nov. 2006: 1 – 6.
Summary: *Bleeding in hemodialysis patients. 50 patients received both HemCon Bandage (HB) and conventional gauze dressings in random order on 2 successive visits. Safety and efficacy comparison between HemCon® Bandage and conventional gauze. Compared time to hemostasis and compression strap usage. A compression strap was used if dressing application was not successful at 4 minutes. Hemostasis analyzed at 2 and 4 minutes after application. Hemostasis was achieved in 2 min in 30% treated with HB versus 38% treated with gauze. Hemostasis was achieved in 4 min in 86% treated with HB versus 72% treated with gauze. Compression strap usage was reduced by 50% with the HB.*

FOCUS: HEMODIALYSIS

25. Burkatovskaya, Marina, George P. Tegosa, Emilia Swietlik, Tatiana N. Demidova, Ana P. Castano, and Michael R. Hamblin. "Use of chitosan bandage to prevent fatal infections developing from highly contaminated wounds in mice." Biomaterials 27 (2006) 4157 – 4164.
Summary: *Ability to rapidly kill bacteria in vitro and in mouse models of infected wounds was tested. HC was more adhesive to the wound and conformed well to the injury compared to alginate. The data suggests that chitosan acetate rapidly kills bacteria in the wound before systemic invasion can take place, thus due to its chemical structure the HemCon® Bandage is antimicrobial and is superior to alginate bandage and silver sulfadiazine that may both encourage bacterial growth in the short term.*

FOCUS: ANTIBACTERIAL

26. Belman, Alec, Mohamud Daya, Mark Stevens, and Joseph Worley. "From The Battlefield To The Street – Experience Of A Suburban Fire/EMS Agency With Chitosan Dressings." Emergency Medicine and Critical Care Review. June 2006.
Summary: T*he HemCon® Bandage can be successfully incorporated into the civilian EMS system. When properly applied, the HemCon® Bandage stops uncontrolled external hemorrhage when conventional methods fail.*

FOCUS: HEMOSTATIC EFFICACY

27. Pusateri, Anthony E., John B. Holcomb, Bijan S. Kheirabadi, Hasan B. Alam, Charles E. Wade, and Kathy L. Ryan. "Making Sense of the Preclinical Literature on Advanced Hemostatic Products." Journal of Trauma: Injury, Infection and Critical Care 60 (2006): 674 – 682.
Summary: *Analyze the current literature pertaining to four of the most promising products (dry fibrin sealant dressing, Rapid Deployment Hemostat, HemCon chitosan dressing, and QuikClot). Conclusions show that the first advanced hemostatic dressing used in situations in which severe external bleeding cannot be controlled by standard methods should be the HemCon Bandage.*

FOCUS: HEMOSTATIC EFFICACY

28. Wedmore, Ian, John G. McManus, Anthony E. Pusateri, and John B. Holcomb. "A Special Report on the Chitosan-based Hemostatic Dressing: Experience in Current Combat Operations." Journal of Trauma: Injury, Infection and Critical Care 60.3 (2006): 655 – 658.
Summary: *A retrospective case review of 64 uses of the HemCon Bandage in its first year of use on the battlefield. This report was the first report of the efficacy of the HemCon dressing for the control of severe bleeding in a pre-hospital setting on the battlefields of Iraq & Afghanistan. HemCon Bandage successfully controlled severe hemorrhage in 62 out of 64 uses (97%).*

FOCUS: MILITARY HEMOSTATIC EFFICACY

29. Acheson, Eric M., Bijan S. Kheirabadi, Rodolfo Deguzman, Edward J. Dick Jr., and John B. Holcomb. "Comparison of Hemorrhage Control Agents Applied to Lethal Extremity Arterial Hemorrhages in Swine." Journal of Trauma: Injury, Infection and Critical Care 59.4 (2005): 865 – 875.
Summary: *Comparison between QuikClot, HemCon and Fibrin Sealant Dressing on severe extremity arterial hemorrhage. 6mm aortic punch, free bleeding for 45 seconds and 3 minute compression with hemostatic agent. Animals observed for 180 minutes or until death. FSD was superior to others. HemCon showed hemostatic benefit. BC significant exothermic reaction.*

FOCUS: COMPETITION / EFFICACY

30. McManus, John, and Ian Wedmore. "Modern Hemostatic Agents for Hemorrhage Control – A Review and Discussion of Use in Current Combat Operations." Business Briefing: Emergency Medicine Review June 2005: 76 – 79.
Summary: Comparison of hemostatic agents – TraumaDex, QuikClot, Dry Fibrin Sealant, Rapid Deployment Hemostat and HemCon Bandage on Price, ease of use, effectiveness against severe bleeding, durable, minimal risk, little training.

FOCUS: COMPETITION / EFFICACY

31. Alam, Hasan B., Zheng Chen, Amin Jaskille, Racel Ireneo Luis C. Querol, Elena Koustova, Ryan Inocencio, Richard Conran, Adam Seufert, Nanna Ariaban, Kevin Toruno, and Peter Rhee. "Application of a Zeolite Hemostatic Agent Achieves 100% Survival in a Lethal Model of Complex Groin Injury in Swine." Journal of Trauma: Injury, Infection and Critical Care 56 (May 2004): 974 – 983.
Summary: Test of effectiveness of QuikClot with a change in residual moisture content to decrease heat generation (several formulations), also tested HemCon, TraumaDex, Fast Act. Groin injury in proximal thigh and complete division of femoral artery and vein. 3 minute bleed causing high drop in mean arterial pressure. Mortality rate, blood loss and wound temperature were registered. HemCon performed well on all, QuikClot SD 1% RM zeolite hemostat 3.5 oz had a 100% survival rate, but still exothermic reaction.

FOCUS: HEMOSTATIC EFFICACY

32. Pusateri, Anthony E., Simon J. McCarthy, Kenton W. Gregory, Richard A. Harris, Luis Cardenas, Albert T. McManus, and Cleon W. Goodwin, Jr. "Effect of a Chitosan-Based Hemostatic Dressing on Blood Loss and Survival in a Model of Severe Venous Hemorrhage and Hepatic Injury in Swine." Journal of Trauma: Injury, Infection and Critical Care 54 (2003): 177 – 182.
Summary: Severe liver injuries, 30 second bleed, dressing apple and resuscitation initiated. HemCon vs. Gauze. HemCon dressing reduced hemorrhage and improved survival after severe liver injury in swine.

FOCUS: HEMOSTATIC EFFICACY

33. Dailey, Roger A., Chavez, Mauricio R. and Dongseok Choi "Use of a Chitosan-Based Hemostatic Dressing in Dacryocystorhinostomy." Ophthalmic and Plastic Reconstructive Surgery (March 2009) Volume 25, Issue 5: 350-353

Summary: *A retrospective comparative case series study of HemCon ChitoFlex for hemostasis in dacryocystorhinostomy surgery against a standard of care dressing (collagen absorbable hemostat, Instat). 35 dacryocystorhinostomy procedures (procedure to create a new tear drain between eyes and nose) were performed on 26 subjects who were treated with ChitoFlex and 35 procedures were performed on 27 subjects who were treated with Insat an absorbable collagen hemostat from J&J (standard of care). The primary outcome measures were postoperative bleeding and the need, or lack thereof, of anterior nasal packing. Postoperative bleeding occurred in 2/35 in the group treated with HemCon versus 12/35 in the group treated with collagen dressing. Although ChitoFlex appears to be more effective as a hemostatic agent in cases involving turbinectomies, the sample size did not provide enough statistical power to claim clinical significance*

FOCUS: PLASTIC RECONSTRUCTIVE SURGERY

Abstracts

1. James Jones, Jack Lazar, Meihua Zhu, Lisa Buckley, Jason C. Hedges, Hua Xie. "Preclinical safety and efficacy of a chitosan-based hemostatic device to control and prevent hemorrhage after transurethral prostatic surgery". Presented at American Urological Association Meeting, Chicago, Illinois, May 3-6, 2019
   The hemostatic capability of the CEHD was determined by superior performance during splenic bleed testing. Overall, this study demonstrated that the CEHD hemostatic device could provide safe and effective control of bleeding in a porcine transurethral bladder neck bleeding model, including delivery, deployment, hemostatic efficacy, biocompatibility, and full clearance after 7 days.

   FOCUS: HEMOSTATIC EFFICACY

2. LCDR Ryan Buckley, DO; LCDR Sean Conley, DO; LCDR Gordon Markham, MD; LCDR Sean Stuart, DO; LCDR Austin Yoder, MD; Gregory Zarow, PhD. "Efficacy of Two Novel Hemostatic Agents in a Coagulopathic Model of Severe Hemorrhage." Combat Trauma Research Group, Naval Medical Center Portsmouth, Virginia. Presented at MHSRS2016, August 2016.
   Summary: ChitoGauze is a leading hemostasis product and outperformed Celox Rapid and Combat Gauze. ChitoGauze had the highest observed survival rate (100% animal testing); ChitoGauze had the least amount of blood loss and no re-bleeds; 60% of the animals reached hemostasis successfully after 3 minutes of compression. Many of our competitors are not as effective for severe hemorrhagic coagulopathy as shown in this study.

   FOCUS: HEMOSTATIC EFFICACY

3. K. Mat Nor, O. Nawawi, K. Rahmat, K. A. Abdul Kadir, F. Fadzli. "Achieving haemostasis of femoral artery puncture post angiographic procedures by manual compression. A comparison study between gauze pad and HemCon pad." Presented at European Society of Radiology (ECR2013), Vienna, Austria, March 7-11, 2013.
   Summary: 80 patients. Interventional and diagnostic. Time to hemostasis was significant shorter with the HemConTM pad by 53% compared to the conventional manual compression with no complications. This device may save the time for physician and the cost for hospital. Furthermore, this device can contribute to patient comfort, reduce the time to compression, and promise to a planned discharge

   FOCUS: CATH LAB

4. Kazuhiko Shibata, Tamio Iwamoto, Tomoyuki Murakami, Syuji Ono, Tomoko Kaneda[2], Eri Ikeda, Tadashi Kuji, Seiiti Kawata, Hidehisa Satta, Kouichi Tamura, Yoshiyuki Toya, Mai Yanagi, Satoshi Umemura and Gen Yasuda. Japan. "Randomized Trial comparing New Chitosan-Based Bandage with Kaltostat Hemostatic Dressing to Control Bleeding from Hemodialysis Puncture Site". Presented at 49th ERA-EDTA (European Renal Association – European Dialysis and Transplant Association Congress), Paris, France. May 24-27, 2012.
   Summary: 23 or 450 patients with arteriovenous fistula in the upper extremity that were not able to achieve hemostasis within 30 minutes, were randomized to receive either a chitosan based dressing (pressure for 2 minutes) or an alginate dressing (pressure for 4 minutes). Chitosan dressings controlled bleeding in ≤ 3 minutes 100% of the time, whereas alginate dressing only controlled bleeding in 4 minutes 50% of the time. Study suggests that the chitosan-based bandage is a safe and more effective hemostatic agent than hemostatic alginate dressing to stop severe, prolonged post-hemodialysis puncture site bleeding.

   FOCUS: DIALYSIS

5. McGrath, Barbara; Genco, Jenn; Kuhn, Sam; Donnellan, Peter; Buergi, Simona; Xie, Hua. "Hemostatic Performance Of GuardaCareXR Surgical In Two *in vivo* Surgical Injury Models In Swine." Presented at 71st Annual Meeting of the American Association for the Surgery of Trauma (AAST), September 12-15, 2012
   Summary: HemCon GuardaCareXR Surgical used on spleen and liver in-vivo models showing faster hemostasis compared to controls (lap pads, quikclot ED and gauze) and reduced the amount of total blood loss.
   FOCUS: SURGICAL ORGAN

6. JYuichi Kikuchi, Tsuyoshi Aono, Shinichirou Masuda. Department Of Cardiovascular Medicine, Miyagi East Cardiovascular Medicine "Clinical Experience Of A New Chitosan-Based Hemostatic Device (HemCon Patch®) After Femoral Approach Sheath Removal". Presented at 21st Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT2012), Niigata Japan - July 12-14th, 2012
   Summary: Ninety six patients who used HemCon Patch for hemostasis after femoral approach sheath removal were evaluated for efficacy of hemostasis and vascular complication in Japan. The clinical experiences of HemCon Patch usage showed only one vascular complication. Its rate as 1.04% is equal to or better than published reports
   FOCUS: CATH LAB

7. Baron J . Md, Kesus R. Md, Yaniv S. Md, Regev A. Md, Dvir A. Sherf M. Md. Novack V. Md, Phd, Wiznitzer A. Md. "The Efficacy And Safety Of Hemcon® Guardacare®XR Surgical Following Surgical Repair In Management Of Postpartum Bleeding Due To The Multiple Vaginal Lacerations." Presented at Soroka Medical Center OBGYN Congress, Israel, January 12, 2012
   Summary: assess the safety and efficacy of the HemCon® compared to standard bandaging in subjects with post-partum hemorrhage as a result of cervical and vaginal lacerations. The primary endpoint was a cessation of bleeding at 30 minutes after insertion of the device. HemCon GuardaCareXR was more efficacious than standard of care.
   FOCUS: SURGICAL OB-GYN

8. Shibata, Kazuhiko; Iwamoto, Tamio; Murakami, Tomoyuki; Ono, Syuji; Kaneda, Tomoko; Kuji, Tadashi; Kawata, Seiiti; Satta, Hidehisa; Tamura, Kouichi; Toya, Yoshiyuki; Umemura, Satoshio, Yasuda, Gen. "New Chitosan-Based Bandage Stops Severe Bleeding from Hemodialysis Puncture Site in 2 Minutes." Presented at The 56th Congress of the Japanese Society for Dialysis Therapy. June, 2011.
   Summary: Zeria tested the efficacy of HemCon's Strip by selecting 6 individuals, out of 150 patients with arterio-venous fistula and who have difficulty coagulating after 30 minutes of pressure. Before implementing the use of the Strip compression time ranged from 15-60 minutes, once the Strip was employed that time was reduced to 2 minutes.
   FOCUS: HEMODIALYSIS

9. Schwartz, Richard B, Shiver, Steven, Reynolds, Bradford, Xie, Hua, Lerner, Brooke, Federico, Massimo, McManus, John. "Comparison of HemCon ChitoGauze and QuikClot Combat Gauze for Hemorrhage Control in a Swine Model – A Meta-Analysis. Presented at Advanced Technology Applications for Combat Casualty Care (ATACCC 2010). August 2010.
   Summary: Compares the effectiveness of ChitoGauze to Combat Gauze in controlling arterial hemorrhage. It was concluded that ChitoGauze controls bleeding more rapidly than Combat Gauze, and results in less blood loss.
   FOCUS: HEMOSTATIC EFFICACY

10. Schwartz, Richard, Shiver, Steven, Kimpel, Nicholas, Greenfield, Erich, Solis, Ricaurte, Lerner, Brooke, Vecchio, Paul, Reynolds, Bradford, Coule, Phillip. "Comparison of ChitoGauze and Combat Gauze for Hemorrhage Control in a Swine Model". Presented at Academy of Emergency Medicine, May 2010. Vol 17, No. 5, Suppl. 1
    Summary: Compares the effectiveness of ChitoGauze to Combat Gauze in controlling arterial hemorrhage. It was concluded that ChitoGauze controls bleeding more rapidly than Combat Gauze, and results in less blood loss.
    FOCUS: HEMOSTATIC EFFICACY

11. Xie, Hua, Lucchesi, Lisa, Teach, Jeffrey, Gregory, Kenton, Buckley, Lisa, Real, Keith. "Comparison of Hemostatic Efficacy of ChitoGauze and Combat Gauze in a Lethal Femoral Arterial Injury in Swine Model" Presented at NATO Research and Technology Symposium -Use of Advanced Technologies and New Procedures in Medical Field Operations. April 2010.
    Summary: HemCon's ChitoGauze was used in comparison to Z-Medica QuikClot Combat Gauze for a femoral arterial injury to test the hemostatic efficacy. Both products are efficacious and have similar ease of application however ChitoGauze had greater success at achieving immediate hemorrhage control and with less blood loss than Combat Gauze.
    FOCUS: HEMOSTATIC EFFICACY

12. Xie, Hua, Lucchesi, Lisa, Teach, Jeffrey, Gregory, Kenton. "Comparison of Hemostatic Efficacy of ChitoGauze and Combat Gauze in a Lethal Femoral Arterial Injury in Swine Model." Presented at Advanced Technology Applications for Combat Casualty Care (ATACCC 2009). August 2009.
    Summary: HemCon's ChitoGauze was used in comparison to Z-Medica's QuikClot Combat Gauze for a femoral arterial injury to test the hemostatic efficacy. Both products are efficacious and have similar ease of application however ChitoGauze had greater success at achieving immediate hemorrhage control and with less blood loss than Combat Gauze.
    FOCUS: HEMOSTATIC EFFICACY

13. Krol, Julie M, Schierle, Clark F, Galiano, Robert D. "Use of Chitosan-based Hemostatic Dressings Facilitates Safe, Thorough Debridement of Chronic Wound Eschar at the Bedside". Study conducted by Division of Plastic and Reconstructive Surgery, Department of Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois. September 2008. Presented at Diabetic Foot Global Conference (DFCON2009). March 2009 and Symposium of Advanced Wound Care (SAWC2009). April 2009.
    Summary: Chitosan based dressings were used in bedside wound debridement. The assistance of chitosan bandages controlled bleeding and complications to a degree that the procedure could occur without a trip to the operating room. All patients were successfully debrided at the bedside without electrocautery.
    FOCUS: WOUND DEBRIDEMENT

14. Pavcnik, Dusan P. Kranokpiraksa, H. Kakizawa, Y.H. Kim, B. Uchida, F.S. Keller, J. Rösch. "Hemostatic Efficacy of Chitosan Based Bandage for Closure of Percutaneous Arterial Access Sites An Experimental Study in Heparinized Sheep". Presented at Society of Interventional Radiology Annual Meeting (SIR2009). March 2009.
    Summary: HemCon Patch was applied externally following the removal of an 8F femoral arterial sheath puncture model. The HemCon Patch was able to achieve hemostasis in less time than the control side, on an average of 6 minutes compared to an average of 9.5 minutes in the control group.
    FOCUS: CATH LAB

15. Heart Lab at St. Elizabeth Medical Center in Youngstown, Ohio. “Cath Lab Case Study of HemCon® Bandages”. Jan – Dec. 2008.
Summary: Post sheath removal HemCon dressings were applied with manual compression. The average time to ambulation was 95 minutes, adverse outcomes, such as minor hemotomas, were low, as well no major complications occurred with the HemCon dressings.

FOCUS: CATH LAB

16. Pappas, Mary, Tiana Riley, Thomas Matella, Shari Slyder, Alexandra Martyniuk, Kathleen Nolan, Christian Spies. “Initial Experience with the HemCon Bandage for Vascular Access Management in a Diverse Pediatric and Adult Congenital Hearth Disease Patient Population”. Presented at Pediatric and Adult Interventional Cardiology Symposium (PICS-AICS2007). July 2008.
Summary: HemCon Bandage was used at Rush Center for Congenital and Structural Heart Disease in Chicago, IL and results of the study show shorter manual compression and ambulation time compared to institutions current protocol when using the HemCon Bandage.

FOCUS: CATH LAB

17. Wardeh, A.J., C. Dille-Amo, H. Ramanna. “HemCon® Bandages Prevent Arterial Bleeding After Transradial Coronary Angiography”. Study conducted at Haaglanden Medical Center, The Hague, The Netherlands. June 2008.
Summary: Coronary angiography was performed using 5F catheters on 79 patients. Once the sheath was removed a HemCon Bandage was place on the puncture site with manual compression for the duration of 2 minutes, another minute was applied if needed. Hemostasis was achieved 100% of patients, no major arterial bleedings occurred in the angioroom or during follow-up.

FOCUS: CATH LAB

18. Misgav, Mudi, Gili Kenet, Dalia Bashari, Jacob Luboshitz, Uri Martinowitz. “Chitosan-Based Dressing for Treatment of External Bleedings Resistant to Systemic Hemostatic Treatment”. Presented at Hemophilia World Congress. June 2008.
Summary: Examines patients with hemophilia that lack response to recombinant activated factor VII; when HemCon’s chitosan dressings were applied and bleeding ceased immediately without rebleeding.

FOCUS: DIALYSIS

19. McManus, John, Angel Delgado. “Preliminary Screening of a New Hemostatic Product, ChitoFlex®, in a Lethal Arterial Hemorrhage Model in Swine”. Presented at International Congress of Emergency Medicine (ICEM2008). April 2008.
Summary: *Test of ChitoFlex to determine effectiveness for severe arterial hemorrhage in a swine model. Dressing resulted in 100% survival at 60 minutes in this model of lethal hemorrhage*

FOCUS: HEMOSTATIC EFFICACY

20. Misgav, Mudi, Yafa Peleg, Aaron Knecht, Uriel Martinowitz. “Chitosan-Based Dressing Decreases Bleeding Time From Hemodialysis Access Puncture Wound Bleeding”. Presented at Advanced Technology Applications for Combat Casualty Care (ATACCC 2007). August 2007.
Summary: 288 treatments (144 for each dressing) in 15 HD patients. Hemostasis achieved in 2 min 78.4%. 4 min 98.6%. no late out-of-hospital bleed. Avg. time to hemostasis improved to 2.9 vs. 18.6 minutes on arterial access site and 2.7 vs. 13.4 min for venous access site. The current study demonstrates the efficacy of the chitosan compared to a regular pad gauze with a significant decrease in time to hemostasis at dialysis puncture access sites.

FOCUS: HEMODIALYSIS

21. Horesh, A., R. Miler, and Z. Feigenberg. Pre-hospital use of the HemCon® Bandage. Paramedics of Magen David Adom the Israeli national EMS system. Ed. Medical Division, Magen David Adom in Israel. Presented at the 15th World Congress on Disaster and World Medicine. May 2007.

Summary: 8 cases – mostly skull, neck, groin and lower extremities bleeding during the second Lebanon war. All successful uses and stopped bleeding within 3-5 minutes.

FOCUS: HEMOSTATIC EFFICACY

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