Updated December 6, 2017 (added studies/edits highlighted in yellow)

CLINICAL STUDIES - QuikClot® products are cleared for external use. Some of these publications describe clinical studies performed that do not describe cleared indications.

A novel technique for simultaneous hemostasis of ipsilateral radial and ulnar artery access sites.

Roberts JS, Niu J. A novel technique for simultaneous hemostasis of ipsilateral radial and ulnar artery access sites [published online October 17, 2017]. *Catheter Cardiovasc Interv*. doi:10.1002/ccd.27351

- This case study addresses the use of QuikClot® Radial™ and TR Band® on two patients in order to achieve simultaneous hemostasis of the radial and ulnar artery access sites post transradial artery (TRA) access.
- In both case studies, hemostasis was achieved at both the radial and ulnar arteries.
- The study reports that simultaneous hemostasis of both artery access sites can be achieved by using both a QuikClot® Radial™ and a TR Band®.

PILOT TRIAL COMPARISON OF A KAOLIN-BASED HEMOSTATIC PAD (QUIKCLOT® RADIAL™) VERSUS MECHANICAL COMPRESSION (TR BAND®) TO REDUCE COMPRESSION TIME FOLLOWING TRANSRADIAL ACCESS.

Roberts JS, Niu J. PILOT TRIAL COMPARISON OF A KAOLIN-BASED HEMOSTATIC PAD (QUIKCLOT® RADIAL™) VERSUS MECHANICAL COMPRESSION (TR BAND®) TO REDUCE COMPRESSION TIME FOLLOWING TRANSRADIAL ACCESS. *Poster* Presented at: ACC.17: 66th Annual Scientific Session & Expo; March 18, 2017; Hollywood, FL.

- The poster states that after transradial access (TRA) was performed on 30 patients, QuikClot® Radial™ and TR Band® were applied and hemostasis time was recorded and compared between the two products. The 30 patients were randomly split into 3 groups: 10 patients received medical compression with the TR Band, 10 received 30 minutes of compression with QuikClot Radial, and 10 patients received 60 minutes of compression with the QuikClot Radial.
- Hemostasis occurred more often with QuikClot Radial (100% versus 50%), and occurred more quickly with mean times of 30.7, 60.9 and 149.4 for the 30 minute, 60 minute and TR Band groups respectively.
- The poster concludes that "Application of the QuikClot® Radial™ hemostatic pad following TRA in this small pilot trial significantly shortened hemostasis times when compared with mechanical compression using the TR Band®. There was 100% successful hemostasis with both the 30- and 60-minute compression groups with the QuikClot® Radial™, with no increased complications noted."

The use of QuikClot combat gauze in cervical and vaginal hemorrhage.

Vilardo N, Feinberg J, Black J, Ratner E. The use of QuikClot combat gauze in cervical and vaginal hemorrhage. *Gynecol Oncol Rep*. 2017;21:114-116.

- This case series describes the use of QuikClot® in three cases of gynecological hemorrhage: vaginal cuff, cervical cone bed, and post-cesarean hysterectomy.
- QuikClot "remained in place for a mean time of 15 h with no adverse side effects observed" and was used to successfully achieve hemostasis in all three cases.
- QuikClot "as vaginal packing may provide an alternative option in the treatment of cervical and vaginal hemorrhage when other traditional conservative and surgical interventions fail or are unavailable."

Comparison of Hemostasis Times With a Kaolin-Based Hemostatic Pad (QuikClot Radial) vs Mechanical Compression (TR Band) Following Transradial Access: A Pilot Prospective Study.

Roberts JS, Niu J, Pastor-Cervantes JA. Comparison of Hemostasis Times With a Kaolin-Based Hemostatic Pad (QuikClot Radial) vs Mechanical Compression (TR Band) Following Transradial Access: A Pilot Prospective Study. *J Invasive Cardiol*. 2017; (10):328-334.

- QuikClot® Radial™ was compared to the TR Band® in patients undergoing coronary angiography and/or percutaneous coronary intervention treated via transradial access (TRA) in this prospective study (mean dose of heparin was 7117 ± 1054 IU, mean activated clotting time was 210 ± 50 sec)
- "Successful initial access-site hemostasis was achieved in all cases (100%) with use of QuikClot and failed in 5 cases (50%) with use of the TR Band (P<.001)."
- "Mean compression time for hemostasis with the TR Band was 149.4 min compared with 30.7 min and 60.9 min for the 30-min and 60-min QuikClot groups, respectively." The average recovery stay was slightly shorter in the QuikClot groups than in the TR Band group.
- "No [Radial Artery Occlusions] RAOs or major complications occurred in any subject at the end of this study."
- "Use of the QuikClot Radial pad following TRA in this pilot trial significantly shortened hemostasis times when compared with the TR Band, with no increased complications noted."

QuikClot® Combat Gauze® Use by Ground Forces in Afghanistan The Prehospital Trauma Registry Experience.

Schauer SG, April MD, Naylor JF, et al. QuikClot® Combat Gauze® Use by Ground Forces in Afghanistan The Prehospital Trauma Registry Experience. *J Spec Oper Med*. Summer 2017;17.2:101-106.

- This retrospective study compared outcomes between patients treated with QuikClot Combat Gauze® (QCCG) and those who were not (but were treated using other means) based on data from the Prehospital Trauma Registry (PHTR) and DoD Trauma Registry (DODTR).
- Hemorrhage was controlled 88.3% in the QCCG group. No statistical difference was seen in survival between QCCG and non-QCCG patients; however, QCCG patients had higher rates of gunshot wounds and more severe injuries or sickness than the non-QCCG group.
- The study concludes that the "success rates for hemostatic control compared with other published data support the use of QCCG in the prehospital combat setting".

Experience Using Kaolin-Impregnated Sponge to Minimize Perioperative Bleeding in Norwood Operation.

Shinkawa T, Holloway J, Tang X, Gossett JM, Imamura M. Experience Using Kaolin-Impregnated Sponge to Minimize Perioperative Bleeding in Norwood Operation. *World J Pediatr Congenit Heart Surg*. 2017 Jul; 8(4):475-479.

- This study was a retrospective analysis to assess the efficacy of a kaolin impregnated hemostatic sponge (QuikClot®) to reduce intraoperative blood loss in pediatric cardiac surgery.
- The study reviewed uses of QuikClot in patients (n = 15) who underwent Norwood operation in infancy between 2011-2016 and compared the results to patients treated with standard gauze (n = 16). There were no significant differences in preoperative profiles or cardiopulmonary bypass time between the groups. The results showed that, compared to standard gauze, the QuikClot treated group required significantly less:
    - Intraoperative platelet (55 ml vs. 72 ml, p=0.03)
    - Cryoprecipitate (10 ml vs. 15 ml, p=0.021)
    - Factor VII infusion (0 vs. 45 mcg/kg, p=0.019) compared to the standard gauze group. The incidence of bleeding complications was significantly lower in the QuikClot group (0%) compared to control (31%, p=0.043).
- The study concludes that QuikClot was "associated with reduced blood product use and perioperative bleeding complications in Norwood operation" at their institution.

Assessing Coagulation by Rotational Thromboelastometry (ROTEM) in Rivaroxaban-Anticoagulated Blood Using Hemostatic Agents.

Bar J, David A, Khader T, Mulcare M, Tedeschi C. Assessing Coagulation by Rotational Thromboelastometry (ROTEM) in Rivaroxaban-Anticoagulated Blood Using Hemostatic Agents. *Prehosp Disaster Med*. June 2017.19:1-8.

- This study compared the clotting times of rivaroxaban-anticoagulated blood (Xarelto) when treated with kaolin-based QuikClot® (n=8), chitosan-based Celox (n=8), or untreated control (n=8).
- Clotting time (CT), clot formation time (CFT), and maximum clot firmness (MCF) were all tested using rotational thromboelastometry (ROTEM). The results showed that anticoagulated blood treated with QuikClot improved CT, CFT, and MCF compared to control in 87.5%, 100%, and 75% of samples, respectively. Celox Gauze improved CT, CFT, and MCF in 75%, 32.5%, 62.5% of samples when compared with control, respectively. It should be noted that while Celox showed a reduction in CFT in 3/8 samples, the average effect over 8 samples was an increase in CFT, while QuikClot showed a reduction in CFT in all 8 samples.
- The researchers found that most QuikClot-treated samples trended "in a direction towards increased coagulability" in patients on rivaroxaban anticoagulants such as Xarelto.

Solimene F, Esposito F. Incidence of pocket haematoma associated with QuikClot administration in a high risk population receiving oral anticoagulation therapy. Unpublished Case Study. 2017.

- Twenty patients on oral anticoagulation therapy (either vitamin K agonists or novel oral anticoagulants) receiving cardiac implantable electronic devices were treated with QuikClot in the pectoral pocket at the time of device implantation.
- At 1-week follow-up, 5 patients (25%) had no hematoma, 13 (65%) had grade I, and 1 (5%) had

grade II hematoma. No patients treated with QuikClot presented with grade III.
- In comparison, retrospective data from 30 patients treated with standard gauze reported 3 patients with no hematoma (10%), 18 (60%) had grade I, 8 (26.6%) had grade II, and 1 (3.3%) had grade III. No reoperations, prolonged hospitalizations, or other complications were reported in patients treated with QuikClot.

Kaolin-containing Hemostatic Gauze Reduced The Re-bleeding Rate Following Catheter Ablation for Atrial Fibrillation.

Matsuda Y, Masuda M, Fujita M, et al. Kaolin-containing hemostatic gauze reduced the re-bleeding rate following catheter ablation for atrial fibrillation. Presentation at: American Heart Association's 2016 Scientific Sessions and Resuscitation Science Symposium;Nov, 2016;New Orleans, LA.

- QuikClot® Interventional™ (KG, n=235, 13.1% antiplatelet agents usage) was compared to standard gauze (n=190) in patients who underwent catheter ablation to treat atrial fibrillation.
- The rate of re-bleeding "was significantly lower in KG group than in normal gauze group (6.0% vs. 11.5%, P = 0.039). Notable, the efficacy of KG was more prominent in the reduction of re-bleeding events after the removal of gauze compression (0.4% vs. 5.7%, P < 0.001)."

Efficacy of Hemostatic Agents in Humans with Rotational Thromboelastometry: An in-vitro Study.

Lechner R, Helm M, Mueller M, Wille T, Friemert B. Efficacy of hemostatic agents in humans with rotational thromboelastometry: an in-vitro Study. *Mil Med*. 2016;181:907-912.

- The efficacy of QuikClot (CG), Celox (CX), QuikClot ACS+ (ACS+), and standard gauze (SG) were compared using rotational thromboelastometry (ROTEM) with blood from eight male volunteers who had no coagulation disorders.
- Clotting time, clot formation time, alpha angle, maximum clot firmness, and lysis index were all measured to quantify hemostatic efficacy of dressings that are used in the military setting. Nonactivated, intrinsically activated, extrinsically activated, and fibrin-based ROTEM were used to elucidate different mechanisms of action (e.g. the intrinsic & extrinsic pathways).
- With the exception of clot lysis, "CG achieved a significant improvement in all coagulation parameters in human blood…and significantly outperformed the other hemostatic agents in CT, α^{o}, and CFT".

Intra-abdominal packing with laparotomy pads and QuikClot™ during damage control laparotomy: A safety analysis.

Choron RL, Hazelton JP, Hunter K, et al. Intra-abdominal packing with laparotomy pads and QuikClot™ during damage control laparotomy: A safety analysis. *Injury*. Jan, 2017;48(1):158-164.

- This retrospective study included 68 patients (40 lap pad (LP) alone, 28 lap pad and QuikClot (LP+QC)) who underwent damage control laparotomy (DCL) at a Level -1 Trauma Center between 2011 and 2014.
- Of 28 LP+QC patients, Combat Gauze was used in 19 and TraumaPads were used in 9.
- "The surgeons at our institution now select augmented packing with QC for sicker patients, as we believe this may have additional advantage over standard LP packing."

A Multi-institutional Study of Hemostatic Gauze and Tourniquets in Rural Civilian Trauma.

Leonard J, Zeitlow J, Morris D, et al. A multi-institutional study of hemostatic gauze and tourniquets in rural civilian trauma. *J Trauma Acute Care Surg*. Sept, 2016;81(3):441-444.

- This retrospective study included patients across 10 institutions who were treated for hemorrhage in the prehospital setting using QuikClot (QC) or the Combat Application Tourniquet (CAT).
- Forty patients were treated with QuikClot on injuries that did not achieve hemostasis with direct pressure and were not amenable to tourniquet use. "QC was effective in 89% of cases."
- "QC and CAT are effective for hemorrhage control in the rural prehospital setting…but also medical causes of bleeding."

Tubeless percutaneous nephrolithotomy with non-absorbable hemostatic sealant (Quikclot®) versus nephrostomy tube placement: a propensity score-matched analysis.

Koo KC, Park SU, Jang HS, Hong C-H. Tubeless percutaneous nephrolithotomy with non-absorbable hemostatic sealant (Quikclot®) versus nephrostomy tube placement: a propensity score-matched analysis. *Urolithiasis*. 2015;43:527-533.

- This study compares "40 (35.4%) patients who received tubeless Quikclot® applied PNL and 52 (46.0%) patients who received nephrostomy placement PNL."
- The authors note that a number of negative side effects have been seen when using absorbable hemostats in this manner but that "Quikclot in tubeless PNL led to significant reductions in pain and analgesic requirements, without increased risks of postoperative bleeding and complications."
- "Tubeless Quikclot® PNL was safe and provided effective hemostasis of significant parenchymal bleeding."

Escott MA, Gleisberg GR, Anderson JL, Crocker KJ, Aiken MC. QuikClot Combat Gauze® for civilian prehospital external hemorrhage control. Poster Session Presented at: Texas EMS Conference;Nov, 2015;Dallas, TX.

- The study evaluated the effectiveness of QuikClot Combat Gauze® in 28 patients treated by EMS services compared to standard treatment.
- In the cases studied, 93% showed significant improvement to patient condition and bleeding compared to pre-treatment. 7% showed no significant change in these conditions. 0% showed negative responses to QuikClot use.
- Study concluded that the "patient data indicates superior improvement utilizing QuikClot Combat Gauze® for the management of hemorrhage control in EMS" and "early application of Combat Gauze may have a significant effect on patient outcomes and negative consequences of hemorrhagic shock."

Prehospital use of hemostatic dressings by the Israel Defense Forces Medical Corps: A case series of 122 patients.

Shina A, Lipsky AM, Nadler R, et al. Prehospital use of hemostatic dressings by the Israel Defense Forces Medical Corps: a case series of 122 patients. *J Trauma Acute Care Surg*. 2015;79(4):S204-S209.

- This study compiled 122 prehospital cases where QuikClot Combat Gauze® (QCG) was applied 133 times between January 2009 and September 2014 by the Israeli Defense Forces.
- Injuries were penetrating (85.2%), blunt (3.3%) and combined (11.5%).
- "Hemorrhage control with the hemostatic dressing was reported to be successful in 88.6% of junctional applications and in 91.9% of nonjunctional applications. These results suggest that the QCG is an effective tool for hemorrhage control in both junctional and nonjunctional injuries."

- "Of note, in five patients, successful [QuikClot] dressing application was used after tourniquet failure."

Hemostatic dressings in civil prehospital practice: 30 uses of QuikClot Combat Gauze.

Travers S, Lefort H, Ramdani E, et al. Hemostatic dressings in civil prehospital practice: 30 uses of QuikClot Combat Gauze. *Euro J of Emerg Med*. Oct, 2016;23(5):391-4.

- This prospective study collected questionnaire data from physicians and/or nurses following 30 prehospital uses of QuikClot Combat Gauze between June 2011 and May 2014.
- "For 26/30 uses, [QuikClot] hemostatic dressing was justified by the inefficiency of other hemostasis techniques. Those 30 applications were associated with 22 complete cessations of bleeding, six decreases of bleeding, and ineffectiveness in two cases." No side-effects were seen.
- The low usage (30) was due to the study design "to use hemostatic dressing only in case of failure or inability to perform other hemostasis gestures. The results of our study have since led us to expand the use of these [QuikClot] devices."

Prehospital Use of Hemostatic Bandages and Tourniquests: Translation from Military Experience to Implementation in Civilian Trauma Care.

Zietlow JM, Zietlow SP, Morris DS, Berns KS, Jenkins DH. Prehospital use of hemostatic bandages and tourniquests: translation from military experience to implementation in civilian trauma care. *J Spec Oper Med*. 2015;15(2):48-53

- This retrospective study highlights the use of 62 QuikClot Combat Gauze dressings in 52 patients. The injuries treated with QuikClot Combat Gauze were 50% head and neck, 35% penetrating wounds, and 15% other mechanisms of injury.
- QuikClot Combat Gauze "was highly successful at stopping bleeding, with 59 of 62 injuries (95%) achieving hemostasis."
- The use of tourniquets and hemostatic gauze in prehospital civilian care is safe and highly effective, with success rates of 98.7% and 95%, respectively." The authors note the importance of initial training and that skills are maintained at 98% in two years "despite infrequent use of only about two times per month."

A KAOLIN-BASED HEMOSTATIC GAUZE AS AN ADJUNCTIVE TOOL FOR BLEEDING CONTROL AFTER VASCULAR CLOSURE DEVICES USE IN TAVI PATIENTS.

Trabattoni D, Fabbiocchi F, Olivares P, Basadonna G, Callligaris G, Bartorelli A. A kaolin-based hemostatic gauze as an adjunctive tool for bleeding control after vascular closure devices use in tavi patients. *Int J Recent Sci Rsh*. March, 2015;6(3):2919-2921.

- The effectiveness QuikClot Interventional was investigated in controlling bleeding after vascular closure devices (VCDs) were used in patients undergoing transcatheter aortic valve implantation (TAVI). All patients were on anticoagulants ("aspirin (90%), LMWH (2.5%) or aspirin + clopidogrel (7.5%)").
- "QuikClot™ interventional gauze was firmly applied over the access site in all the 12 cases of minor bleeding after Proglide implantation, obtaining complete and fast bleeding control (mean compression time 2.3 ±1.8 min)."
- "QuikClot Interventional Hemostatic Bandage tested after transfemoral aortic valve replacement demonstrated to be safe and effective in reducing compression time and preventing oozing or

bleeding after large sheath removal with a suture vascular device."

Intraoperative Use of QuikClot During Adenotonsillectomy: A Prospective Pediatric Trial.

Derkay CS, Baydoun HA, Stone L. Intraoperative use of QuikClot during adenotonsillectomy: a prospective pediatric trial. *Ann Otol Rhinol Laryngol*. May, 2015;124(5):384-91.

- A prospective clinical trial including 100 children ages 0-16 receiving tonsillectomy or adenoidectomy procedures
- One 4x4 QuikClot gauze was formed into tonsil sponges or tonsillar packs
- The researchers found that "intracapsular microdebrider tonsillectomy with adenoidectomy utilizing QuikClot to enhance the hemostasis results in recover times better than previously reported for this common operation in children"

Plastini MA, Choron RL, Hamilton L, Capano-Wehrle L, Chovanes JC, Hazelton JP. A case series examining the use of Combat Gauze™ in hemorrhage control of penetrating wounds. Poster Session Presented at: New Jersey Statewide Conference on EMS;Nov 13-15, 2014;Atlantic City, NJ.

- This poster is a retrospective review of 5 patients with penetrating wounds (gunshot, knife stab, or impalement wounds) that were packed with QuikClot Combat Gauze between 7/1/2010 and 9/1/2014 at Cooper University Hospital
- "Combat Gauze controlled external hemorrhage in the acute setting for the patients identified through this study.
- There were no documented re-bleeds, and complex care (care beyond daily dressing changes) was not required for any wound site in which Combat Gauze™ was utilized.
- The cases reviewed for this study show that Combat Gauze™ has a role in the acute control of external hemorrhage from penetrating trauma."

Topic usage of kaolin-impregnated gauze as a hemostatic in tonsillectomy.

Chavez-Delgado ME, Kishi-Sutto CV, Albores de la-Riva XN, Rosales-Cortes M, Gamboa-Sanchez P. Topic usage of kaolin-impregnated gauze as a hemostatic in tonsillectomy. *J Surg Res.* Dec, 2014;192(2):678-85.

- The researchers studied the use of QuikClot or standard gauze following cold dissection tonsillectomy and ligature in 230 patients 3-20 years old
- Operative time, intraoperative blood loss, pain at 6 and 12 hours post-surgery, and use of analgesic medications were less with QuikClot than control gauze. QuikClot patients also returned to normal diet and activities faster
- "In addition to rapid bleeding control, the dressing causes minimal inflammation and pain and allows patients to quickly return to normal activities. This novel dressing is a promising tool for ear, nose and throat surgical hemostasis"

Intra-Operative Use of QuikClot During Adenotonsillectomy: Prospective Pediatric Trial

Derkay CS, Baydoun H. Intra-operative use of QuikClot during adenotonsillectomy: prospective pediatric trial. Poster session presented at: ASPO Combined Otolaryngology Spring Meetings;May 14-18, 2014;Las Vegas, Nevada.

- This is an abstract for a poster that was presented at 2014 COSM conference (Combined

Otolaryngology Spring Meetings)

- The group studied intra-capsular adenotonsillectomy performed in 100 children between the ages of 3 and 16 to see if they could reduce the use of cautery by using QuikClot. This in turn would improve outcomes (return to normal diet and activity and less use of narcotics for pain)
- They found that QuikClot "enhance[d] the hemostasis" which "result[ed] in recovery times significantly better than previously reported for this procedure"

Does a kaolin-impregnated hemostatic dressing reduce intraoperative blood loss and blood transfusions in pediatric spinal deformity surgery?

Abbott EM, Nandyala SV, Schwend RM. Does a kaolin-impregnated hemostatic dressing reduce intraoperative blood loss and blood transfusions in pediatric spinal deformity surgery? *Spine (Phila Pa 1976)*. Sep 1, 2014;39(19):E1174-80.

- 65 control patients received standard operative care with gauze, tranexamic acid (Pfizer), Gelfoam (Pfizer), thrombin packing, Surgiflo (Ethicon), or bonewax and 52 treatment patients received packing with QuikClot TraumaPads.
- The treatment group had 40% less intra-operative estimated blood loss than the control group (974 cc vs. 1620 cc, $p<0.001$). The treatment group also had 42% less total perioperative transfusion volume (499 cc vs. 862 cc, $p<0.01$)
- "The use of a kaolin impregnated intra-operative trauma pad appears to be an effective and inexpensive method to reduce intra-operative blood loss and transfusion volume in pediatric spinal deformity surgery"

Sharp Debridement in the Wound Center: Why Not?

Treadwell T, Walker D. Sharp debridement in the wound center: why not? Poster session presented at: SAWC Spring;April 23-27, 2014;Kissimmee, FL.

- "The new Kaolinite based dressings have been found to be most effective in controlling moderate to severe bleeding in the wound center, hospital, and field. We have had excellent results using these products to control moderate bleeding in our wound center"

Prehospital Use of Hemostatic Bandages and Tourniquets: Translation from Military Experience to Implementation in Civilian Trauma Care.

Zietlow JM, Zietlow SP, Morris DM, Berns KB, Jenkins DH. Prehospital use of hemostatic bandages and tourniquets: translation from military experience to implementation in civilian trauma care. Presented at: Minnesota Surgical Society Spring Meeting;April 14, 2014;Minneapolis, MN.

- Retrospective study reviewing prehospital use of tourniquets and hemostatic bandages in 125 patients (11/4/11-1/1/14)
- "Hemostatic bandage application was to the head and neck (50%), extremities (36%) and torso (14%) with a 95% success rate"
- "Application of tourniquets and hemostatic bandages in prehospital civilian care are highly effective with proficiency of skills maintained despite infrequent use"

Treadwell T, Walker D. Sharp debridement in the wound center: control of bleeding. Poster session presented at: SAWC Fall;October 16-18, 2014;Las Vegas, NV.

- Review and commentary of QC in the context of sharp wound debridement.
- Reports that there is data supporting that clotting times are significantly reduced with kaolin dressings compared to standard gauze, and that kaolin works well even in patients on anticoagulants.
- "The use of the Kaolinite dressings, QuikClot®, has been very useful in treating excess bleeding resulting from sharp debridement in the wound center setting"

Brindle CT. Safe and effective use of kaolin based hemostatic agent in wound and ostomy care. Poster session presented at: SAWC Fall;October 16-18, 2014;Las Vegas, NV.

- Todd reviews use of QuikClot in debridement, negative pressure wound therapy, ostomy care, and palliative care
- "Kaolin impregnated gauze is more cost effective, does not obscure the wound bed via the result of residual product adherence and stops bleeding without the need of chemical cautery which can damage healthy tissue. The ease of use and low side effect profile of these products allow for safe delivery of wound care, effective debridement with subsequent control of bleeding, and immediate response of clinicians and care givers to unexpected bleeding events."

Glassberg E. Pre-hospital use of hemostatic bandages by the Israeli Defense Force Medical Corps: a report of 31 cases. Presentation at: MHSRS;Aug 18-21, 2014;Fort Lauderdale, FL.

- Summary per notes provided by Anne McKeague.
- Dr. Glassberg outlined recent experiences that the Israeli Defense Forces (IDF) had with Combat Gauze (CG). Uses were noted as to the level of the provider, either Advanced Life Support (ALS) or Basic Life Support (BLS). This was in operational scenarios and a retrospective analysis of hemostatic dressings applied under operational conditions. 93% were ALS trained, and 6% were BLS trained. Any failures were due to technique of application.
- 92% success rate in extremity hemorrhage. Two successful applications following tourniquet failure. This was based on an N=55.
- Separate set of data reported in the last 4 weeks (that was just prior to Dr. Glassberg coming to MHSRS) in which 67 CG were applied due to the increased activity in that area. They recorded a 91% success rate.
- They noted they are satisfied with CG with no plans to change, but they would look at new evidence for a better hemostatic if there was one, but currently that doesn't exist so there are no plans for IDF to change from CG.

Effect of Short-Time Compression with Kaolin-Filled Pad on Radial Artery Occlusion After Transradial Acess Catheterization.

Chou MT, Chiang CY. Effect of short-time compression with kaolin-filled pad on radial artery occlusion after transradial acess[sic] catheterization. *Global Heart*. March, 2014;9(1):e207.

- "One hundred patients who received first time transradial catheterization (diagnostic or interventional) were enrolled." Fifty patients received short (15 minute) compression and fifty received long (2 hour) compression.
- "Early sheet removal and short time compression with QuikClot pad can reduce the rate of RAO [radial artery occlusion] after transradial diagnostic or interventional procedures."

From the battlefield to the palliative care arsenal: application of QuickClot Combat Gauze for

aggressive palliation of hemorrhagic shock in the setting of end-stage liver disease-associated compartment syndrome.

Gebauer S, Hoopes D, Finlay E. From the battlefield to the palliative care arsenal: application of QuickClot Combat Gauze for aggressive palliation of hemorrhagic shock in the setting of end-stage liver disease-associated compartment syndrome. *J Pain Symptom Manage*. Oct, 2013;46(4):e6-e8.

- A 36-year-old man with end stage liver disease (causing coagulopathy) received a fasciotomy of his right thigh due to compartment syndrome. Uncontrolled bleeding followed.
- QuikClot was used to stabilize the patient. The wound was packed with 3 packages of Combat Gauze. The patient later died due to liver disease.
- "From a systems perspective, the cost of QCG is far less (approximately $50.00 per roll12) than that of repeated transfusions of blood and blood products."
- "QCG is a unique treatment option to consider when providing palliative care to patients with coagulopathies."

Boston bombings: a surgical view of lessons learned from combat casualty care and the applicability to Boston's terrorist attack.

Caterson EJ, Carty MJ, Weaver MJ, Holt EF. Boston bombings: a surgical view of lessons learned from combat casualty care and the applicability to Boston's terrorist attack. *J Craniofac Surg*. Jul, 2013;24(4):1061-7.

- "Application of this kaolin-impregnated gauze helps to activate the clotting cascade and has been shown to be effective to staunch bleeding on the battlefield."
- "Tourniquets and combat gauze work quite effectively for extremity trauma"

Novel Use of a Hemostatic Dressing in the Management of a Bleeding Leech Bite: A Case Report and Review of the Literature.

Fedor PJ. Novel use of a hemostatic dressing in the management of a bleeding leech bite: a case report and review of the literature. *Wilderness Environ Med*. 2012;23:44-48.

- QuikClot was used on a man's leech bite that had previously been treated with "standard wound care" but continued to ooze. QuikClot "allowed for rapid hemostasis without rebleeding."
- "Leech bites are notorious for unstoppable bleeding." This is due to the anticoagulant and antiplatelet factors contained in leech saliva.
- "QuikClot is the most common and inexpensive" over-the-counter hemostatic dressing available to civilians.

Vascular site hemostasis in percutaneous extracorporeal membrane oxygenation therapy.

Lamb KM, Pitcher HT, Cavarocchi NC, Hirose H. Vascular site hemostasis in percutaneous extracorporeal membrane oxygenation therapy. *TOCSTJ*. 2012;5:8-10.

- The efficacy of QuikClot Combat Gauze® (QCG) was assessed when applied to bleeding from the femoral artery or vein, internal jugular vein, tracheostomy and gastrostomy in patients receiving percutaneous extracorporeal membrane oxygenation support
- QCG controlled bleeding at these sites within 24 hours, resulting in "a significant reduction in both localized bleeding complications and the need for blood transfusion"
- QCG "is the most cost-effective product compared to…other hemostatic products such as

Surgicel®, Gelfrom®, and Fibrillar®"

Vaginal Hemorrhage From Transobturator Sling Controlled with QuikClot Combat Gauze.

Patel SA, Martin M, Chamales I. Vaginal hemorrhage from transobturator sling controlled with QuikClot Combat Gauze. *Mil Med*. 2012;177(8):997-998.

- Combat Gauze was used in a single patient bleeding from the right dissection site during a transobturator sling procedure.
- When standard gauze was ineffective, "Combat Gauze was placed into the extravaginal/extraperitoneal and vaginal spaces and successfully controlled hemorrhage after 10 minutes of direct pressure."
- "Advanced hemostatic dressings such as Combat Gauze offer an additional option for the surgeon to utilize and may provide temporary or even definitive hemorrhage control with major vascular injuries."

A new kaolin-based hemostatic bandage use after coronary diagnostic and interventional procedures.

Trabattoni D, Gatto P, Bartorelli A. A new kaolin-based hemostatic bandage use after coronary diagnostic and interventional procedures. *Int J Cardiol.* 2012;156(1):53-54.

- QuikClot® Interventional™ (QCI) was evaluated for safety and efficacy in femoral artery closure following diagnostic or interventional procedures
- Patients treated with QCI achieved hemostasis in a mean time of 4.9 minutes allowing for early ambulation at 4 hours without any incidence of re-bleeding or hematoma
- QCI "allows for a shorter and painless hemostasis procedure"

Hama Yi. The usefulness of QuikClot® to treat femoral puncture sites following atrial fibrillation ablation. *Leading Innovation from Nihon Kohden*. Feb, 2012;13.

- This specialized study sought to determine the effectiveness of QuikClot® when applied to femoral puncture sites following atrial fibrillation ablation for 61 patients on anticoagulants (warfarin and heparin).
- Successful hemostasis without rebleeding was achieved in all but one of the cases (98.4%), with the subsequent case achieving hemostasis after a second application.
- The study concluded that even in patients on blood thinners, "QuikClot is a superior device that can ensure trouble-free hemostasis simply by applying pressure."

Rapid hemostasis at the femoral venous access site using a novel hemostatic pad containing kaolin after atrial fibrillation ablation.

Sairaku A, Nakano Y, Oda N, Makita Y, Kajihara K. Rapid hemostasis at the femoral venous access site using a novel hemostatic pad containing kaolin after atrial fibrillation ablation. *J Interv Card Electrophysiol*. Aug, 2011;31(2):157-64.

- Following atrial fibrillation, patients' femoral access sites were treated with either manual compression alone or with QuikClot® Interventional™. All patients were treated with warfarin pre- and post-procedure and heparin during the procedure.
- "Hemostasis time in the patients treated with kaolin-impregnated pads was significantly shorter than in those treated without (6.1±2.3 vs. 14.5±4.0 min;$p<0.0001$)."

- "Kaolin-impregnated hemostatic pads safely and effectively decreased hemostasis time for the femoral venous access site in patients undergoing AF ablation."

A new kaolin-based haemostatic bandage compared with manual compression for bleeding control after percutaneous coronary procedures.

Trabattoni D, Montorsi P, Fabbiocchi F, Lualdi A, Gatto P, Bartorelli AL. A new kaolin-based haemostatic bandage compared with manual compression for bleeding control after percutaneous coronary procedures. *Eur Radiol*. 2011;21(8):1687-1691.

- 200 patients treated with aspirin, clopidogrel, LMW Heparin or warfarin received randomized treatment with QuikClot® or standard manual compression following cardiac catheterization via the femoral artery
- QuikClot® significantly reduced the mean time to hemostasis to 5.4 minutes from 25 minutes in the manual compression group

Randomized clinical trial on short-time compression with Kaolin-filled pad: a new strategy to avoid early bleeding and subacute radial artery occlusion after percutaneous coronary intervention.

Politi L, Aprile A, Paganelli C, et al. Randomized clinical trial on short-time compression with Kaolin-filled pad: a new strategy to avoid early bleeding and subacute radial artery occlusion after percutaneous coronary intervention. *J Interv Cardiol*. 2011;24(1):65-72.

- Following a percutaneous procedure for radial artery access, 120 patients were randomized into 3 groups: QuikClot® Interventional™ compressed for 15 minutes and standard gauze compressed for 15 minutes and 2 hours.
- The study found that after 15 minutes the QuikClot® group achieved hemostasis 80% of the time while the standard gauze group was successful only 10% of the time. No patients in the QuikClot® group formed radial artery occlusions (RAO) while the standard gauze groups had 5% and 10% RAO respectively.
- QuikClot® "does not require a learning curve for the operator or cath lab personnel or a patient monitoring after removing at the end of 15 minutes [of] compression" which could reduce costs.

QuikClot® Interventional™ Hemostatic Bandage (QCI): a novel hemostatic agent for vascular access.

Pahari M, Moliver R, Lo D, Pinkerton D, Basadonna G. QuikClot® Interventional™ Hemostatic Bandage (QCI): a novel hemostatic agent for vascular access. *Cath Lab Digest.* 2010;18(1):28-30.

- Collected data on 243 clinical procedures at 15 centers that used QuikClot® Interventional™ (QCI) as an adjunct to manual compression.
- QCI successfully controlled bleeding in 97.12% of procedures done including those on anticoagulated patients.
- Physicians said "they were highly satisfied and would use product again."

QuikClot Combat Gauze use for hemorrhage control in military trauma: January 2009 Israel Defense Force experience in the Gaza Strip--a preliminary report of 14 cases.

Ran Y, Hadad E, Daher S, et al. QuikClot Combat Gauze use for hemorrhage control in military trauma:

January 2009 Israel Defense Force experience in the Gaza Strip--a preliminary report of 14 cases. *Prehosp Disaster Med*. Nov-Dec, 2010;25(6):584-8.

- QuikClot Combat Gauze "dressings were applied to injuries to the head, neck, axilla, buttocks, abdomen, back, and pelvis in 10 cases, and to extremities in four cases. In 13 cases (93%), injuries were caused by blast or gunshot mechanisms. The success rate was reported as 79% (11/14). Failure to control hemorrhage was reported in three cases in three different locations: neck, buttock, and thigh. All failures were attributed to severe soft tissue and vascular injuries. No complications or adverse events were reported."
- "This report on the clinical field use of the QCG dressing by ALS providers suggests that it is an effective and safe product, and applicable for prehospital treatment of combat casualties. This report further suggests that QCG should be issued to medics as well as ALS providers. Larger clinical investigations are needed to confirm these findings."

QuikClot Use in Trauma for Hemorrhage Control: Case Series of 103 Documented Uses.

Rhee P, Brown C, Martin M, et al. QuikClot use in trauma for hemorrhage control: case series of 103 documented uses. *J Trauma*. 2008;64:1093-1099.

- This study focuses on 103 cases where the zeolite version of QuikClot was used in military and civilian traumas.
- "QuikClot has been effectively used by a wide range of providers in the field and hospital to control hemorrhage."

Preclinical Studies – QuikClot® products are cleared for external use. Some of these publications describe preclinical studies performed in an animal model and do not describe cleared indications.

Garcia-Blanco J, Gegel B, Burgert J, Johnson S, Johnson D. The effects of movement on hemorrhage when QuikClot® Combat Gauze™ is used in a hypothermic hemodiluted porcine model. *J Spec Oper Med*. 2015;15(1):57-60.

- QuikClot Combat Gauze® (QCG) was compared to standard gauze in a porcine model of femoral artery and vein transection. Following the removal of 30% of the animals blood volume, induction of hypothermia, vessel transection and one minute of free bleeding, the wounds were packed with either QCG or standard gauze followed by petroleum gauze and standard packing materials.
- After the application of pressure and observation, the extremity was moved until rebleeding occurred. QCG "was able to tolerate movements more than the control group (p<0/0001)."
- "QCG produces a robust clot that can withstand significant movement."

The effects of QuikClot Combat Gauze on hemorrhage control when used in a porcine model of lethal femoral injury.

Johnson D, Westbrook DM, Phelps D, et al. The effects of QuikClot Combat Gauze on hemorrhage control when used in a porcine model of lethal femoral injury. *Am J Disaster Med.* 2014;9(4):309-315.

- A lethal femoral artery and vein transection model was used to compare QuikClot Combat Gauze (QCG) to standard pressure dressing (control).
- QCG was found to be much more effective than the control:
    - Initial success of hemorrhage control was higher for QCG
    - Prevention of rebleeding following both induced hypertension and large volume fluid resuscitation was higher for QCG
    - Absence of rebleeding following active range of motion testing (p = 0.0001) was higher for QCG
    - None of the swine in the QCG group rebled. Only one animal in the control group did not rebleed."
- "QCG is an effective hemostatic agent for use in trauma management. QCG is superior in controlling hemorrhage compared to standard pressure dressings."

The effects of QuikClot Combat Gauze on hemorrhage control when used in a porcine model of lethal femoral injury.

Gould J, Dubey D. Effectiveness of a kaolin-based hemostatic dressing in an anticoagulated porcine model. Poster session presented at: SAWC Fall;Oct 16-18, 2014;Las Vegas, NV.

- This study was performed by Z-Medica. Pigs treated with Coumadin (Warfarin) or Plavix (Clopidogrel) were studied. Injuries were made to the liver, spleen, and mesentery. Either QC or standard gauze was applied with pressure for 5 minutes. If bleeding ceased, a "pass" was recorded.
- In Coumadin treated animals, 95.83% of QC tests passed while only 23.68% of SG passed (p=0.000). In Plavix treated animals, 92.45% of QC tests passed while only 29.72% of SG passed (p=0.000).
- "In this study, the kaolin-based hemostatic dressing controlled bleeding in liver, mesentery, and spleen injuries more effectively in Plavix (clopidogrel) and Coumadin (warfarin) treated animals than SG."

The effects of QuikClot Combat Gauze® on hemorrhage control in the presence of hemodilution and hypothermia.

Johnson D, Bates S, Nukalo S, et al. The effects of QuikClot Combat Gauze® on hemorrhage control in the presence of hemodilution and hypothermia. *Ann Med Surg*. June, 2014;3(2):21-25.

- This porcine study compared the effectiveness of QuikClot Combat Gauze® (QCG) to control gauze on hemorrhage in a hemodiluted and hypothermic model.
- QCG was "more effective at hemorrhage control allowing more intravenous volume resuscitation to be administered before rebleeding compared to a standard pressure dressing."
- QCG reduced the overall hemorrhage volume compared to control gauze by an average of 92.5%, achieved successful hemostasis in 84.6% of trials vs. 30.8% for control gauze, and retained on average more than 4 times as much IV volume resuscitation as control gauze. The author establishes ideal qualities of hemostatic agents and states that "QCG meets each one of these criteria", and notes that the packaging makes the product quick and easy to use.

A pilot study of the use of kaolin-impregnated gauze (Combat Gauze) for packing high-grade hepatic injuries in a hypothermic coagulopathic swine model.

Sena MJ, Douglas G, Gerlach T, Grayson JK, Pichakron KO, Zierold D. A pilot study of the use of kaolin-impregnated gauze (Combat Gauze) for packing high-grade hepatic injuries in a hypothermic coagulopathic swine model. *J Surg Res*. Aug, 2013;183(2):704-9.

- Coagulopathic animals (60% exchange transfusion with Hextend) were injured with a grade V liver injury in the left middle hepatic lobe. After 30 seconds of bleeding, Combat Gauze or control gauze was applied. The abdomen was closed and animals were observed for 2 hours.
- Survival in the Combat Gauze group was higher than in the plain gauze group.
- "Animals treated with Combat Gauze maintained a higher MAP following injury…Most notably, animals in the CG group lost considerably less blood than those in the [plain gauze] group."

Long-term preclinical evaluation of the intracorporeal use of advanced local hemostatics in a damage-control swine model of grade IV liver injury.

Inaba K, Branco BC, Rhee P, et al. Long-term preclinical evaluation of the intracorporeal use of advanced local hemostatics in a damage-control swine model of grade IV liver injury. *J Trauma.* 2013;74.2:538-545.

- Evaluated the long-term safety and efficacy of QuikClot Combat Gauze®, Celox®, and Celox Gauze® versus standard gauze in a high-grade liver injury.
- Celox Gauze® had higher mortality at all time points, higher need for repacking at 48 hours due to rebleeding, more deaths by bleeding, and a higher incidence of deaths by small bowel obstruction than QuikClot Combat Gauze . All animals treated with Celox® products had adhesions.
- Combat Gauze® was found to be effective and created a durable hemostasis.

Hemostasis in a noncompressible hemorrhage model: an end-user evaluation of hemostatic agents in a proximal arterial injury.

Satterly S, Nelson D, Zwintscher N, et al. Hemostasis in a noncompressible hemorrhage model: an end-user evaluation of hemostatic agents in a proximal arterial injury. *J Surg Educ.* 2013;70(2):206-211.

- Celox®, ChitoGauze®, Combat Gauze®, and HemCon® bandages were applied to arterial injuries by participants including military personnel and physicians due for deployment.
- No significant difference in hemostasis was seen between the products used.
- Combat Gauze® was reported as being "the most effective at controlling hemorrhage" and was "rated as the easiest dressing to use by the soldiers."

The effects of QuikClot Combat Gauze and movement on hemorrhage control in porcine model.

Gegel B, Burgert J, Gasko J, et al. The effects of QuikClot Combat Gauze and movement on hemorrhage control in porcine model. *Mil Med.* 2012;177(12):1543-1547.

- QuikClot Combat Gauze® (QC CG) and standard packing (control) were assessed in a static and moving hemorrhage model to simulate military and civilian trauma.
- QC CG was found to be "statistically and clinically superior at controlling hemorrhage" over control standard packing and QuikClot Combat Gauze® "produces a more robust clot that can withstand significant movement."
- QC CG "is an effective hemostatic agent for use in civilian and military trauma management."

The effects of QuikClot Combat Gauze on hemorrhage control in the presence of hemodilution.

Johnson D, Agee S, Reed A, et al. The effects of QuikClot Combat Gauze on hemorrhage control in the presence of hemodilution. *US Army Med Dep J.* 2012;25(6):36-39.

- QuikClot Combat Gauze® was assessed for hemorrhage control in the presence of hemodilution in a lethal femoral injury (30% of blood volume was removed and replaced with fluids).
- Results indicate that there was significantly less bleeding in the QuikClot Combat Gauze® group compared to the control group in this hemodilution study.
- "The QuikClot Combat Gauze® was easy to open, simple to use to pack the wound, and did not require premixing."

The efficacy of Combat Gauze in extreme physiologic conditions.

Causey MW, McVay DP, Miller S, Beekley A, Martin M. The efficacy of Combat Gauze in extreme physiologic conditions. *J Surg Res*. 2012;177(2):301-305.

- The efficacy of QuikClot Combat Gauze® was assessed in a model of severe acidosis and coagulopathy to mimic a post-traumatic environment.
- Combat Gauze® had a higher success rate in achieving hemostasis at 89% for the first and 100% for the second application than standard gauze (0% for the first and 13% for the second application).
- Results indicate that Combat Gauze® significantly outperforms standard gauze dressings in this extreme physiologic model of a vascular injury.

Safety evaluation of new hemostatic agents, smectite granules, and kaolin-coated gauze in a vascular injury wound model in swine.

Kheirabadi BS, Mace JE, Terrazas IB, et al. Safety evaluation of new hemostatic agents, smectite

granules, and kaolin-coated gauze in a vascular injury wound model in swine. *J Trauma.* 2010;68(2):269-278.

- Kheirabadi, et al studied the safety of QuikClot Combat Gauze®, WoundStat®, and standard gauze in controlling bleeding
- WoundStat® severely injured vessels and could cause lung thrombosis
- Results indicate that Combat Gauze® is as safe as standard gauze

Determination of efficacy of new hemostatic dressings in a model of extremity arterial hemorrhage in swine.

Kheirabadi BS, Scherer MR, Estep JS, Dubick MA, Holcomb JB. Determination of efficacy of new hemostatic dressings in a model of extremity arterial hemorrhage in swine. *J Trauma.* 2009;67(3):450-460.

- This study evaluated the efficacy of QuikClot Combat Gauze®, TraumaStat™, Celox-D™, HemCon®, and standard gauze for traumatic injuries.
- "Combat Gauze® was the most effective dressing tested""and resulted in the highest survival rate."
- Kheirabadi, et al found "based on these results and similar findings by our colleagues at Naval Medical Research Center, the committee has recommended replacing HC bandage with the new dressing. The new Tactical Combat Casualty Care Committee guideline recommends using CG as the first line of treatment for life-threatening hemorrhage on external wounds that is not amendable to tourniquet placement

Arnaud F, Parreno-Sadalan D, Tomori T, et al. Comparison of 10 hemostatic dressings in a groin transection model in swine. *J Trauma.* 2009;67(4):848-855.

- A porcine femoral transection model was used to compare ACS+, Celox, Instaclot, WoundStat, Alpha bandage, BloodStop, X-sponge (CG), Chitoflex, HemCon, and Polymem FP-21.
- "It was found that three new types of hemostatic dressings, namely Celox, WoundStat, and X-Sponge, and a currently deployed product, ACS+, performed better than standard gauze in controlling bleeding and improving survival in pigs during a 3-hour observation period."

Johnson JE, Meyer M, Huebner R. Efficacy of a wound packing trainer with learner biofeedback to enhance training and assess procedure competency. Presentation at: SOMA Scientific Assembly and Exhibition 2013;Dec, 2013; Tampa Bay, FL.

- The study sought to determine the effect of a biofeedback system when used to enhance training and competency in a wound packing simulation trainer compared to training with no biofeedback.
- The study was conducted with previously untrained subjects (n=17) who first packed the trainer model without biofeedback, and then again with biofeedback. Success was based on building pressure to the minimum required threshold (10lbs), packing time, and holding minimum pressure for 2 minutes
- The results showed that without biofeedback, 0% of the trainees succeeded in achieving the minimum required threshold of pressure, or holding minimum pressure for the required time, compared to the 100% success rate when using biofeedback. The study concludes that training with biofeedback is effective and that "biofeedback training enhances procedure competency".

Johnson JE, Huebner R, McKeague AL. A bioprosthetic simulation wound packing trainer equipped for

learner biofeedback to enhance perishable skills and assess procedure competency. Presentation at: SOMA Scientific Assembly and Exhibition 2014;Dec, 2014; Tampa Bay, FL.

- The purpose of this study was to determine the impact of a real time pressure feedback display on learning enhancement and competency when training with gauze on a wound packing simulator.
- Trainees with prior advanced medical training were divided into three groups, those receiving verbal instruction and simulation training with biofeedback (n=8), verbal instruction and simulation training without biofeedback (n=5), and verbal instruction only (n=6). A pass was defined as building pressure to the minimum required threshold (10lbs) and holding minimum pressure for 2 minutes. Performance for each group was compared before and after training
- The results showed that 87.5% (7/8) trainees using biofeedback improved from a fail to pass after training, compared to 40% (2/5) for simulation without feedback, and 0% (0/6) for verbal instruction alone. The study concludes that the use of biofeedback significantly improved ability to reach and maintain adequate pressure on the wound for the required time, and is "likely to improve wound packing skills and the effective application of hemostatic gauze at the point of injury."