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Special Report

Stanching wounds

Other military branches question effectiveness of bandages Army issues to stop severe bleeding

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Sun Reporter

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The U.S. Army is launching a multimillion-dollar campaign to equip all its combat troops with a futuristic bandage designed to stop massive bleeding from battlefield injuries, despite doubts about its effectiveness and the development of a cheaper product that many scientists believe works better.

About 200,000 of the HemCon bandages, developed with the help of the Army's medical laboratory and the recipient of $29 million in Army purchase contracts and research grants, are to be distributed to every soldier in Iraq and Afghanistan within the next few months.

Army leaders, who deemed the bandage one of their "Top 10 Greatest Inventions" for 2004, call it a revolutionary step in treating severe hemorrhage, the leading cause of preventable death in combat. It is among the few nonsurgical methods developed to stop bleeding that is too severe to be controlled with a tourniquet or gauze.

Yet even as the Army's purchase order approaches 60,000 units a month and the HemCon bandage becomes increasingly prevalent throughout the military, doubts are rising from inside and outside the service that the bandage works as well as advertised - or at all.

Scientists working for the Navy have begun to question claims that HemCon possesses a unique blood-clotting ability, saying their studies show the dressing to be only slightly more effective than gauze. Some soldiers in Iraq say they have been discarding the $89 dressings unused because they don't consider the rigid bandages practical for combat injuries. One of the Army's studies, conducted last year and published in July, says the bandages are prone to slough off after an average of 49 minutes, allowing patients to bleed again.

Outside scientists say another product stops bleeding far more quickly and effectively: a granular substance called QuikClot, which costs the military $9.85 per bag.

Army medical officials acknowledge that HemCon isn't perfect, but they say it is the closest they've come to finding a safe treatment for the types of massive bleeding that have been killing wounded American soldiers for centuries. While the bandage might fall off, soldiers in modern combat are likely to be treated by a surgeon long before that happens, and the dressing can help keep them alive in the critical minutes after an injury, they say.

They agree that QuikClot works but say it can also cause burns - severe burns, according to the findings of the Army's medical laboratory at Fort Sam Houston in San Antonio. They have advised Army soldiers to avoid QuikClot and to await the stepped-up delivery of HemCon instead.

Officials with the Navy, the Marine Corps and the Air Force, meanwhile, consider that advice misguided. They have issued QuikClot to all of their combat forces, saying the potential for burns is an acceptable risk. Many of the Army's combat troops, having reached the same conclusion, are buying QuikClot for themselves despite the Army's recommendations.

Leaders of the Army's 101st Airborne Division ordered 4,000 packages of QuikClot when the unit began its second deployment to Iraq this fall. At a recent training session at Fort Dix, N.J., Army instructors urged soldiers headed for Iraq to add QuikClot to their combat gear even if they had to buy it themselves.

"What's worse, giving your buddy a little burn while you save his life or doing nothing and letting him die?" said Sgt. 1st Class Gregory Wilson, an Army medic who has trained thousands of soldiers at Fort Dix, the military's largest mobilization center. "Go back, talk to your supply folks and tell them to get this stuff for you," he told a class of soldiers deploying to Iraq and Afghanistan in June. "And don't let them tell you it's not available. Be aggressive. It can save your life."

Civilian doctors and researchers say the disagreements among Army and Navy scientists illustrate the complexities and the perils of operating on the leading edge of military medicine. Both services have pressed their preferred hemostatic agents into use faster than usual because they are desperate to give wounded soldiers and Marines the benefits of cutting-edge technologies, even as those benefits are still being explored and defined.

Politically charged

But civilian researchers in the burgeoning field of hemorrhage control also say the debate has become so politically charged, so clouded by institutional pride, that several of them have stopped cooperating with the military's research laboratories, saying the labs' results too often skew toward the products their respective branches endorse.

"We determined it was best to simply pursue other markets," said John Vournakis, a research scientist at the Medical University of South Carolina and executive in a company developing a trauma dressing called the Rapid Deployment Hemostat. "We've really not had a very happy and positive experience with the military."

"If the Army didn't invent it, they don't want it. I think that about sums it up," said Bob Harder, president and founder of the medical supply company H&H Associates, which manufactures and distributes products primarily to the Marine Corps and law enforcement agencies.

Medical officials in the Army say the perceived shortcomings of HemCon have been largely a problem of training. Their tests, performed on pigs at the Army's medical laboratory in San Antonio, showed HemCon to be extremely effective at stopping severe bleeding when properly applied, according to reports of the laboratory's studies published the past three years in the Journal of Trauma.

A survey of combat medics in Iraq also indicates the dressing is saving lives when used by soldiers who are trained to apply the dressing and maintain adequate pressure with their hands or another dressing, Army medical officials say. They are sending instructors and training materials to combat units to ensure soldiers understand when to use the battle dressing and how to apply it properly

"It has no known side effects, the performance is amazing in every study we've developed and the reports from people who actually use the product have been positive," said Col. John B. Holcomb, commander of the Army's Institute of Surgical Research. "There's no reason to field an alternative that has known complications."

But Holcomb's counterpart in the Navy reached a different conclusion.

"HemCon doesn't work," said Navy Capt. Peter M. Rhee, director of the Navy Trauma Training Center in Los Angeles and former head of the military's research laboratory in Bethesda.

"I've tried every one of these products, many times, on many different kinds of wounds," Rhee said. "I put HemCon on the side of a beating heart once, and it worked great. But for a large, open wound with a lot of bleeding, it's just not effective. For big-time bleeding - and that's what we're really worrying about here - HemCon doesn't work."

Looking for solutions

The Army's interest in stopping severe bleeding is as old as the service itself, but its push for innovative scientific solutions to warfare's most vexing medical problem was spawned 12 years ago by the deadly attacks in Mogadishu, Somalia. Holcomb, a Ranger doctor who treated casualties from the 1993 fight in which several soldiers bled to death, has focused much of his career on battlefield medicine and hemorrhage control since then.

One product of that effort has been a complete revision of the Army's recommended procedures for treating battlefield trauma, including greater emphasis on use of tourniquets and improved, combat-specific medical training for every soldier in the service. Whereas soldiers were once taught to use tourniquets as only a last resort, today they are trained to apply them as a primary treatment for combat injuries.

After an article in The Sun in March that detailed cases in which doctors questioned whether soldiers might have lived had they been equipped with the tourniquets Holcomb had been recommending since before the war, the Army issued 172,000 pre-made tourniquets to all of its uniformed personnel in Iraq and Afghanistan. Tourniquets have also been made standard-issue items for every soldier in the service.

Another advancement has been a succession of bleeding-control products developed or tested, with the help of several multimillion-dollar grants from the federal government, by the laboratory at Fort Sam Houston.

For much of the late 1990s, the Army's research efforts at the lab, which Holcomb oversees, centered on a bandage developed in cooperation with the American Red Cross that was treated with human blood proteins and is still regarded as one of the most promising blood-clotting agents ever devised. The Red Cross bandage, which showed a remarkable ability to coax human blood into forming a solid and stable clot, was distributed to special forces troops in Afghanistan as part of a large-scale trial in 2002.

But the trial was halted after one reported use - a successful one - and the program was mothballed because the dressing proved too unstable for mass production and too unconventional for easy approval by the Food and Drug Administration. It also cost roughly $1,000 apiece, though Army officials say the price never deterred their efforts to save lives.

Over the past decade, civilian researchers were also developing blood-clotting agents using such materials as potato starch and algae, and numerous scientists had been drawn to a substance called chitosan that is derived from the shells of insects and crustaceans. Perry R. Klokkevold, the director of postgraduate periodontics at the University of California, Los Angeles, worked with chitosan in the early 1990s as he searched for ways to control bleeding in dental patients, for instance, and he found that it appeared to promote clotting even in hemophiliacs.

"It's not a profound hemostasis - something you put on and the bleeding stops immediately," said Klokkevold, who halted the research when his commercial sponsor cut off funding. "But as an adjunctive treatment, it clearly had tremendous potential. I was very excited about it."

Around the time that Army researchers were struggling with the Red Cross dressing, scientists at the Oregon Medical Laser Center in Portland, Ore., developed a unique process of crystallizing chitosan from shrimp shells to form a flexible pad that seemed to have superior blood-clotting qualities. Army researchers flew to Oregon to watch the

scientists press their chitosan pads onto bleeding pig arteries and were impressed by the results.

"We were just as skeptical as always, and maybe more skeptical because we already knew about some chitosan dressings that didn't work," said Anthony Pusateri, a research scientist who leads the Army's hemostasis program at Fort Sam Houston. "But this one, even in its early prototypes did a phenomenal job of controlling hemorrhage."

The Oregon scientists were operating under more than $7 million in Army research grants to explore ways to close traumatic wounds with lasers. But hoping to capitalize on their dressing's promise, they formed HemCon Inc., teaming up with retired Army Col. William P. Wiesmann, who oversaw their earlier grants when he served as director of combat casualty care for the U.S. Army Medical Research and Materiel Command at Fort Detrick.

With help from a new $400,000 grant from Wiesmann's former agency, HemCon got expedited approval from the U.S. Food and Drug Administration in November of 2002. It won a $2.45 million grant from the Army soon after and began delivering the dressing in small batches just as troops were preparing for the invasion of Iraq in early 2003. As of today the company has received roughly $29 million in grants and purchase orders from the Army, its sole customer.

Another product

The Marine Corps, meanwhile, had committed to QuikClot, an inorganic mineral that is said to have emerged as a medical product in the 1990s after a scientist applied some to a cut on a whim. Similar to volcanic rock, with a consistency that Marines often compare to cat litter, it comes in 3.5-ounce bags and is poured into a wound. In studies at the military's research laboratory in Bethesda, sponsored by the Office of Naval Research, QuikClot saved the life of every animal it was applied to, according to accounts of those studies published in the Journal of Trauma.

QuikClot is the flagship product of Z-Medica Corp. in Wallingford, Conn., which worked closely with the Office of Naval Research to develop and package the product, and which will have received roughly $150,000 in Navy research and development grants by the end of the year. The company sells QuikClot to law enforcement agencies, foreign militaries and others, but the Marine Corps has been its primary customer.

From its earliest studies, QuikClot displayed an obvious drawback - its tendency to create heat when mixed with a liquid, such as blood. But scientists say it also shows a consistent and extraordinary ability to stop bleeding quickly.

James F. Drake, founder and chief scientist for the Minneapolis-based medical supply company Medafor Inc., is developing a blood-clotting agent for surgical use and has tested HemCon, QuikClot and other products in trials at the Mayo Clinic in Rochester, Minn. Each product has its strengths, he said. But if he were shot and was at risk of bleeding to death, he'd choose QuikClot over all the competitors, including his own,

Drake said.

"It might damage the surrounding tissue, and maybe some surgeon would have to dig it out of me later on, but I'd be alive," Drake said. "I guess if you had 30 guys hit and they all come in full of the stuff you'd have some problems. It's not right for routine injuries. But if the wound is potentially lethal, I'd have to go with the QuikClot."

The potential to cause burns is the first warning listed on QuikClot's packaging, but officials in the Navy, which provides medical care for the Marine Corps, consider it an acceptable risk. A survey of 68 reported uses, presented at a medical seminar last summer and using information compiled by Rhee, found six instances in which the patients complained of pain and two in which they suffered burns. One of those burns was serious enough to require a skin graft, though the survey also noted that the patient "may have died without QuikClot."

The Army and Navy have never been able to agree on the extent of the product's danger. When tested in the Army's laboratories, QuikClot got hot enough to scorch skin and kill tissue around the wound, and it required the scientists to wrap their hands in surgical tape and two pairs of gloves. In the Navy's studies it barely got hot enough to cause discomfort.

Scientists from the two services attribute most of the disparities to their different methods of experimentation, such as how each laboratory chose to mimic a severe battlefield wound on anesthetized pigs. Army scientists used an "X"-shaped clamp to inflict severe wounds to the animals' livers, while Navy scientists used a scalpel to create a deep groin injury, severing the femoral artery.

Yet even when the laboratories conducted virtually identical bench-top experiments - mixing equal amounts of blood and QuikClot in a beaker or petri dish - they reported vastly different results. Army scientists recorded a peak temperature of 140.4 degrees Celsius, well above the boiling point of water and hot enough to melt some plastics. Scientists working for the Navy measured 48 degrees Celsius, cooler than the hot water from most household faucets.

Rear Adm. Robert D. Hufstader, top medical officer for the Marine Corps, was so enamored of the product in the months before the Iraq war began that he requested enough to outfit every Marine headed for battle, roughly 80,000 bags. In a memo to Marine Corps leaders before the war, he called for an urgent approval, saying QuikClot "will save lives that might otherwise be lost."

Soon after the war began, the Air Force conducted studies of HemCon using bleeding pigs and concluded the dressing was "variable and inconsistent," and was least effective on deep, arterial wounds that are generally the most deadly. While noting that the dressing was far superior to gauze if it saved even one additional life, it recommended further studies and changes to the bandage's design before it was used in combat.

The Army, meanwhile, issued a warning to its service members that QuikClot can cause burns, and it continued buying the entire stock of HemCon as the dressings rolled out of the manufacturing facilities in Oregon.

By January of this year, when the U.S. Central Command issued a directive that every American service member should carry one of the two agents in combat, the situation had changed little. The Marine Corps was fully outfitted with QuikClot, while Army units awaited the gradually increasing shipments of HemCon. The Iraqi Ministry of Defense ordered 80,000 packets of QuikClot in April and distributed them to Iraqi Guardsmen.

The Army, meanwhile, continued to warn that QuikClot was dangerous, even as most of its soldiers in Iraq were equipped with neither of the two products, and today says it is appropriate for use only by trained medics. Units can buy it through the Army's supply chain, but it is not a standard-issue item like HemCon.

The Air Force decided in April to issue QuikClot to all of its airmen and other combatants, after concluding that "in practice, burns were not really a problem that seemed to change the management of the patient," according to Lt. Col. Joe Legan, chief surgery consultant to the Air Force surgeon general. QuikClot and a modern tourniquet are included in a new medical kit that the Air Force is distributing to about 25,000 service members.

The Air Force's special operations troops carry HemCon and QuikClot - the ideal solution, according to a multiservice committee that advises the Pentagon on combat casualty care. But none of the services considers carrying both dressings to be practical for the majority of its personnel.

"Both products can have a positive effect for a patient in combat, but QuikClot has the broadest range of effectiveness on different types of wounds," said Col. Jim McClain, chief of the Air Force's Global Medical Support division.

Statistics from the Pentagon show that the war in Iraq is one of the most survivable in history, with soldiers and Marines surviving injuries that would have killed them in prior conflicts. The percentage of wounded soldiers who have died is the lowest ever recorded in combat - 12.5 percent, compared with roughly 21 percent during the Vietnam War. It reflects improvements in body armor, blast protection and medical care, Army officials say.

The percentage of wounded soldiers who have died after reaching a medical facility has risen slightly, however, from 3.5 percent in Vietnam to 4.1 percent today. Army doctors say this shows that medics and frontline doctors are more proficient at keeping soldiers with complex injuries alive, thanks to rapid evacuation, increased use of simple tourniquets and airway tubes, and efforts to quickly control bleeding.

Anecdotal evidence

Evidence that HemCon and QuikClot are saving lives is elusive, however, consisting mostly of anecdotes.

An Army case study published this year summarizing 44 uses of HemCon in Iraq reported that the dressing stopped bleeding in 42 of them and failed in two because the site of the injuries - one a foot wound, the other a head wound - did not allow for proper adhesion.

Capt. Robert B. Fox, a physician's assistant with the Army in Samarra, Iraq, said HemCon has become an integral part of his gear.

"It's easier to manage as a bandage that is simply applied directly to the wound," Fox said, communicating by e-mail from Forward Operating Base Wilson. "It also seemed to work faster and has no exothermic reaction. They are expensive but worth every penny."

Aside from in the 68 cases of QuikClot use recounted in the Navy's case study, Rhee said he has used the substance in the Los Angeles emergency room, where he oversees the Navy's trauma training program. He recounted an incident several years ago during which an urban gunshot victim seemed certain to die, only to be saved by QuikClot.

"I tried everything known to man, and I was sure he was going to bleed to death," Rhee said. "So I ran to my office and got some QuikClot, scrubbed up and poured it in. And that guy walked out of here."

Some initial reports from Iraq were not encouraging for HemCon or QuikClot. A field report from the Marine Corps Systems Command in 2003 said QuikClot tended to be flushed out by spurting blood, leaving it "everywhere but the wound." Users are trained to cover the QuikClot with standard gauze and apply pressure after pouring it in, and the manufacturer has created a beanbag-like version in which the granules are contained inside surgical cloth.

An Army medical supply officer told The Sun that he stopped requesting HemCon bandages this year because soldiers and medics were discarding them unused, complaining that their rigid design made them unsuitable as a combat dressing. And early batches reported high instances of failure.

The manufacturer of HemCon says it has achieved a near-perfect manufacturing consistency in recent months that should eliminate any bad batches. And Army officials have begun training soldiers to check HemCon dressings for re-bleeding every half-hour, though wounded soldiers in Iraq are unlikely to wait even that long to receive medical treatment from a doctor or surgeon, they say.

Pentagon officials say official reports or statistics from Iraq indicating the value of hemostatic agents in the field are not available and will not likely be compiled from field reports for several years.

"There's no evidence one way or another, the real truth is," said Col. Philip Volpe, the Army's assistant surgeon general for force protection.

"Obviously, neither one of them is perfect," said Maj. Gen. Joseph Webb Jr., the Army's deputy surgeon general, at a congressional hearing last month.

Of HemCon, Webb added: "I think that we're all anxiously awaiting more data from theater to see how it actually works in combat situations. The limited data that we have back shows that it's worked very effectively."

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