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TOWARD REMOTE TREATMENT OF CRITICAL INJURIES: ROBOTIC HIGH INTENSITY FOCUSED ULTRASOUND

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In battlefield and disaster response situations, first responders are often placed in danger while tending to the wounded. Robotic systems hold promise for extracting the wounded from hostile environments and providing critical care. Realizing this vision will require flexible systems capable of delivering specific medical treatments while operating safely in close proximity to humans. Exsanguination is a leading mode of death due to trauma and on the battlefield, and arresting bleeding from both internal and external wounds is critical. With the goal of keeping the wounded alive until they reach full medical care facilities, we are developing a remotely-operated system for cauterizing internal and external wounds using High Intensity Focused Ultrasound (HIFU). With high-level control from a remote operator, the system will be able to identify wounds using ultrasound imaging and cauterize vessels using HIFU. The system consists of a robotic manipulator, an applicator assembly containing a HIFU array and an imaging transducer, a detachable actuated end-effector for fine movements of the applicator, a HIFU therapy planning and control strategy, and a remote operator interface. In combination with developing robotic tools for casualty extraction, this system could preserve the lives of those critically wounded in combat or disasters.

I. INTRODUCTION

In their efforts to save the lives of the critically wounded, first responders to disasters and combat medics often place themselves in danger. The threats that cause wounds in such circumstances, including enemy fire, explosives, radiological or chemical agents, unstable structures, or other dangers, frequently persist into rescue operations. Rescuers can be particularly vulnerable as their attention is divided between self-protection and tending to casualties. Robots capable of extracting wounded victims from hazardous environments and providing critical trauma care would reduce the need to expose additional personnel to danger solely to rescue the wounded. The ultimate embodiment of such technology would be a single, fully autonomous, integrated system that could autonomously locate, identify, protect, and triage individual casualties, provide critical trauma care to prevent death and permanent disabilities, and transport victims to field hospitals or higher-level care facilities. This vision, which represents the ultimate goal of DARPA and the US Army's programs in Autonomous Combat Casualty Care, poses enormous technical challenges. Historically robots have demonstrated effectiveness in executing highly structured tasks. In the case of casualty care, each wounded individual can be different from all others, and the environment is often unknown and highly unstructured. An autonomous casualty care robot must apply critical thinking and respond to detailed and subtle sensory observations that incorporate not only knowledge of human physiology but also awareness of the surroundings and circumstances that may have led to the casualty. Dealing with such an unstructured set of problems poses a significant machine intelligence challenge. At perhaps a more basic level, the

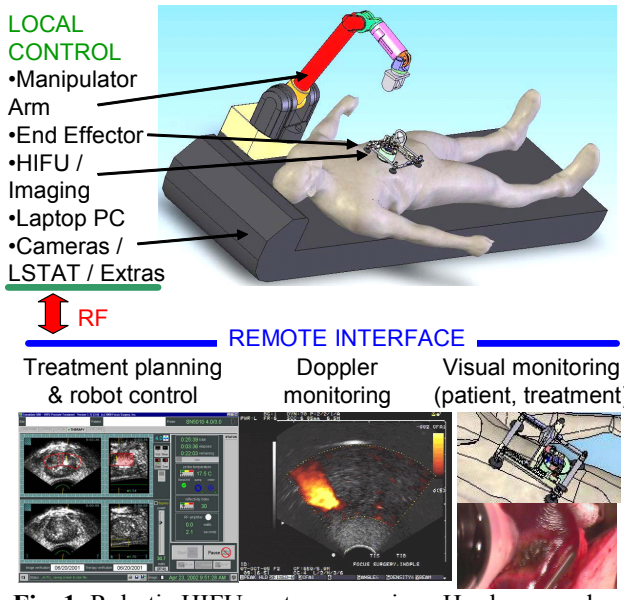

Fig. 1. Robotic HIFU system overview. Hardware and local control is concentrated at the point of treatment, while a remote operator controls high-level function.

problem also poses extreme physical challenges for robotics. Compared to robots, humans are extraordinarily versatile and dexterous, effective at traversing all types of terrain and able to execute extremely complex movements and object manipulations by using our large number of degrees-of-freedom. Any combat care robot must operate effectively in close proximity to and in significant physical contact with humans, with safety guaranteed. This need contrasts sharply with the historic safety paradigm that keeps humans out of the reach of robotic arms, and poses serious design challenges.[1] Further compounding the problem is the fact that the stakes are extremely high, as a combat care robot would literally hold lives in its hands.

Making progress against this overwhelming challenge requires addressing the problem in simplified parts. The Life Support for Trauma and Transport (LSTAT) system, developed for the US Army by Integrated Medical Systems (Signal Hill, CA), provides an integrated stretcher providing resuscitation and stabilization capability through a suite of devices including a ventilator, fluid and drug infusion, a defibrillator and other diagnostic and support systems.[2] Subsequent generations will be included in the Army's Critical Systems for Trauma and Transport (CSTAT) capability. Several Army-sponsored programs have focused exclusively on the casualty extraction problem.[3,4] A separate, DARPA-funded effort has worked toward an unmanned surgical suite to allow for the conduct of completely unmanned surgical procedures via teleoperation by incorporating such elements as a robotic scrub nurse, automated needle insertion, and advanced physiological monitoring.[5]

In this work we describe a system in development that specifically addresses the problem of exsanguination, or death by blood loss from internal or external wounds. Exsanguination is a major problem in combat trauma, and is the leading mode of death on the battlefield.[6] The system described is designed to be compatible with related technology under development and is intended as an important part of an overall strategy for care of combat or disaster casualties, or as a stand-alone solution for stopping blood loss from internal or external wounds.

The core technology leveraged by our system is High-Intensity Focused Ultrasound (HIFU) to non-invasively cauterize ruptured blood vessels, near the surface and at depth. HIFU has been used extensively to treat tumors through localized heating by the concentration of ultrasound waves,[7-9] but its use for cauterizing ruptured blood vessels is a more recent development.[10] Doppler sonography is used to image in 3D and locate ruptured vessels. The balance of the system consists of robotic elements and a control interface that positions the HIFU and imaging arrays to access the injured locations.

The approach taken is modular, allowing for the potential introduction of other hardware for other specific functions in trauma care (e.g. airway opening and maintenance, drug administration). Semi-autonomy is another guiding principle that provides efficient remote operator control and supervision while creating the infrastructure to permit the integration of increasing levels of autonomy as intelligence technology evolves. This approach strikes an appropriate middle ground between pure, low-level teleoperation, which can be extremely slow and inefficient, and full autonomy, which remains impractical, by endowing the system with the capability to execute intermediate-level "primitive" functions with high-level operator instruction and supervision.

The robotic HIFU system delivers stop-gap treatment that is intended to extend the lives of critically wounded patients long enough to allow them to be delivered to a higher level of care, and to prevent or minimize catastrophic injury tied to excessive bleeding. At least in initial deployed versions, the system will only be used in patients who are likely to die or suffer severe permanent disabilities without the treatment. The next section describes the configuration of the system and its elements, as well as its anticipated use. Section III describes the design and construction of the imaging and HIFU subsystems. Section IV describes the robotic elements of the system. Section V provides conclusions, current status and future plans.

II. SYSTEM OVERVIEW

The robotic HIFU system is summarized in Figure 1. The system mounts to an LSTAT or similar device. The HIFU array and imaging array are contained with an "applicator" assembly, shown within a motion stage termed the "end effector" in Figure 1. The end-effector provides fine motion control of the applicator, and is moved into gross position by a manipulator arm. Also

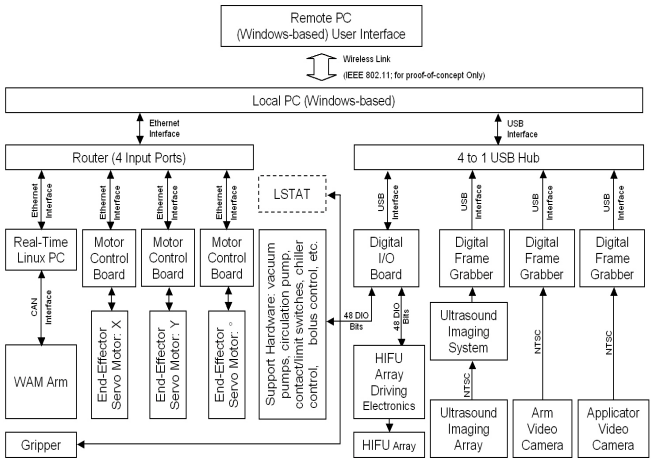

Fig. 2. Control architecture block diagram.

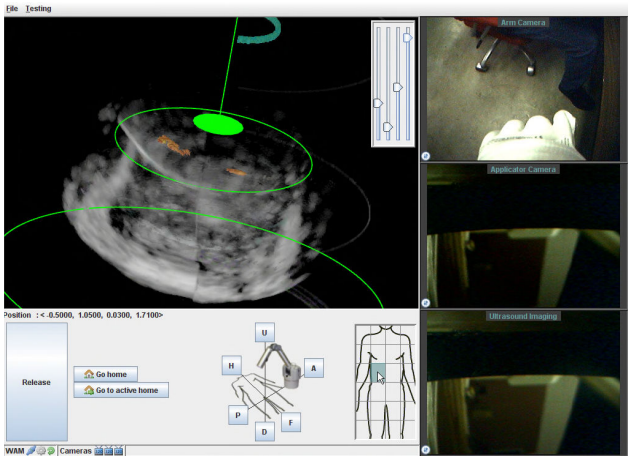

Fig. 3. Remote operator control interface. The top left panel provides Doppler imaging data and an interface for treatment planning. On the right are camera views at the point of treatment and around the LSTAT. On the bottom are movement controls for the manipulator arm.

local to the patient treatment location are several cameras, a control computer, and support hardware including electronics for the HIFU system, the imaging array, and the robotic systems, liquid systems for cooling, lubrication and coupling between the system and the skin, and a suction system for grasping the patient. Control systems for each element (HIFU array, end effector / applicator actuation, manipulator arm) have their own low-level controlling electronics. The local control computer directs high level functions by communicating with the lower-level control systems through Ethernet and USB. Figure 2 shows the structure of the control electronics and data protocols for the entire system in block diagram form.

Joined to this system by a wireless connection is a control station consisting of a computer that runs custom software. A remote operator has high level control over the system via a user interface shown in Figure 3.

Use of the robotic HIFU system begins once a patient has been placed on the LSTAT and any clothes or other obstructions in the vicinity of treatment have been removed. Based on visual inspection, reports from the patient or other personnel, or knowledge of the circumstances of the injury, an initial estimate is made by the operator of the approximate location of a wound. If the wound is in the torso, the end-effector system is used. The operator uses the interface to direct the manipulator arm to position the end-effector in the estimated wound location. The end-effector is then placed on the patient and held in place by the suction system. The ultrasound imaging system is used to take an initial 3D Doppler scan. If the wound is not found in this first image scan, the applicator is repositioned for another scan (for small movements, by actuating the end-effector; for larger movements, by moving the end-effector with the manipulator arm). Once the wound is located, the operator plans a HIFU treatment path and issues a command to execute. Location of ablation is controlled by actuating the end-effector and by phasing the HIFU array. The treatment is completed, and a follow-up scan is conducted to determine whether the flow has been eliminated. Further treatment is delivered if needed. Once treatment is successful, the manipulator retrieves the end-effector and the system returns to its "home" location.

If the wound is located on a limb, a similar procedure is conducted, except that the applicator is directly placed and moved by the manipulator arm, and the end-effector is not used. The reasons for this difference are discussed in Section IV. Design of the robotic HIFU system is complete, and prototype development is ongoing. The next two sections discuss the details of subsystem implementation for the imaging and HIFU system and the robotics.

III. IMAGING AND HIFU

The ultrasound components of the system are located in the applicator, shown in Figure 4. These consist of an imaging transducer (Sonosite C11) capable of taking Doppler data and a custom made HIFU array with 22 annuli. The commercial imaging transducer takes individual 2D slices. A small motor and worm gear located on the applicator rotate the transducer through 180º, and image slices are taken at fixed intervals. These slices are then assembled to form 3D volumes. The Doppler feature of the imaging system detects flow regions, which are depicted in color. Image processing algorithms are then applied to segment the color flow regions from the grayscale background imaging. An example data set, taken using a physically realistic flow phantom, is shown in Figure 5. The imaging transducer can penetrate a depth of more than 95 mm from its tip, or more than 75 mm of tissue depth. The transducer produces approximately triangular image slices; therefore the resulting volume effectively imaged in a single 180º sweep of the transducer is a cone at least 95 mm deep with a 120º cone angle.

The segmentation of the flow regions allows for either automatic or manual treatment planning. In either case, treatment planning consists of selecting volumetric sections to treat with HIFU, cauterizing tissue and stopping the flow. The HIFU array consists of a laser-patterned annular array made of high-power ultrasonic piezoelectric crystals. The array has a 74 mm radius of curvature and a 74 mm aperture. An opening in the center allows space for the imaging transducer. To provide coupling, the volume below the HIFU array is filled with water that is contained by a flexible polymer bolus at the contact surface with the skin. Focusing at specified depth is accomplished by phasing the 22 annuli of the array with

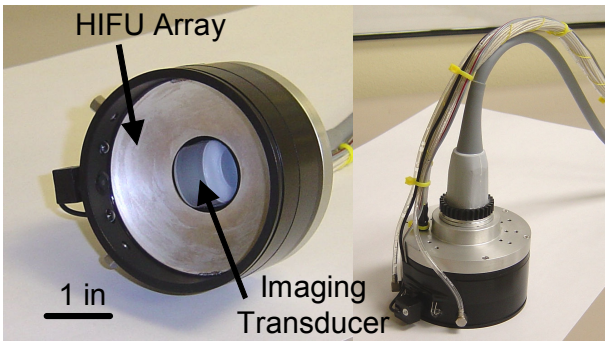

Fig. 4. The applicator houses an ultrasound / Doppler imaging transducer for diagnosis and the annular HIFU treatment array.

custom-developed electronics. The array can focus to depths ranging from 30 to 95 mm, and can deliver in-situ intensities of at least 1000 W/cm^2 throughout this range without exceeding 10 W/cm^2 at the crystal surface (permitting the use of available crystal technology). It is nominally situated 20 mm from the skin, permitting cauterization to depths of 75 mm. By increasing pressure in the liquid, the bolus can expand up to 10 mm vertically, pushing the array to 30 mm from the skin and enabling focusing on surface wounds. The details of the array design have been presented previously.[11]

We have fabricated the custom HIFU array and have demonstrated its operation with efficiency of approximately 44% operating at 2.18 MHz. Total acoustic power (TAP) levels produced exceed 120 W, while effective ablation of animal tissue (which requires similar intensities as cauterization, according to the literature) at depths ranging from the surface to 70 mm has been accomplished using TAP of less than 110 W, with HIFU

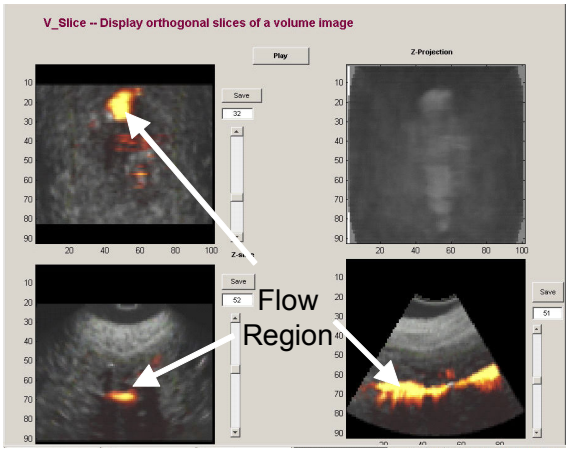

Fig. 5. Doppler image of a simulated wound using a custom-made phantom. Images shows are 2D slices of a 3D image constructed by a sweep. Flow regions appear in color, providing a basis for treatment planning.

applied for between 5 and 18 seconds. A sample of animal tissue ablated as desired with the new array is shown in Figure 6. The custom HIFU system also includes custom phased array electronics. These have been completed and individual channels have been impedance-matched to each annulus to accommodate for manufacturing variation in the array.

IV. ROBOTICS

While phasing of the HIFU array and inflation of the bolus control treatment depth, robotic elements are needed to provide other types of movement. Several distinct movement regimes are required. During treatment, the applicator must be moved through precise time courses in two approximately planar dimensions (along the patient's skin) with millimeter accuracy, to complement the depth of focus and treat three dimensional wounds. Before and after treatment, the HIFU applicator must be moved into and out of position against the skin in the appropriate location on the patient, through a workspace of several cubic meters. All systems must provide safety and performance in intimate contact with injured human subjects. Furthermore, it may be necessary to perform all system operations during transport over potentially rough terrain. Our solution to these challenges applies two key principles: modularity to accommodate different motion types and scales, and backdriveability over a large movement space to provide safe human contact. The system is also designed to operate in several different modes depending on wound location, providing the most precise motion control and superior isolation from disturbances for the most sensitive areas of the torso, and the greatest movement flexibility for the limbs.

Modularity is embodied in the use of the separate end-effector mechanism for precise, millimeter scale

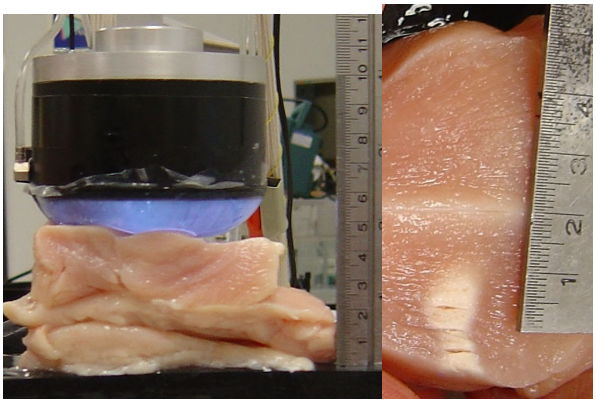

Fig. 6. Left: Setup for test ablation using applicator, with bolus partially inflated for increased standoff from skin. Right: Animal tissue ablated at 5 cm depth by prototype HIFU array.

movement against the skin. This specialized mechanism is placed and released by the manipulator arm and is registered to the patient's torso using suction. This approach accommodates relative movement between the patient and the robot base, as may be expected during transport or from other disturbances. Furthermore, by allowing the manipulator arm to move away from the patient during treatment, the amount of time that the arm must be in close proximity to the patient is minimized.

This is important because as the system is subject to disturbances (e.g. jostling), significant inertial and impact loads could result from close proximity between the arm and the patient. Once placed, the end-effector / applicator system becomes a self-contained (though tethered) motion control system. This option is expected to provide the best motion control performance, particularly in the presence of disturbances. This is especially important when treating the torso, as a slight deviation from the target treatment location could cause damage to organs or other important structures.

The design for the end-effector is shown in Figure 7. The system consists of a frame and two rotary motors that drive lead screws to produce 6 cm of linear motion in each of two axes (X and Y). Polymer bearings are used for the linear guides and are extremely quiet, require no lubrication, and operate robustly even in the presence of dirt and debris. The frame is attached to the patient using suction through four suction cups on the structure's legs. Suction comes from four small, independent vacuum pumps, each of which has been shown to support at least 20 N of tensile force at angles up to 30º when coupling between the suction cup and skin surface is strong. Each leg has 2 cm of passive, spring-loaded travel to accommodate the uneven shape of the torso and to allow for expansion of the bolus if needed. The entire end-effector assembly will weigh approximately 2.1 kg and measures 21 cm by 19 cm by 13 cm. Low level closed-loop control is accomplished directly through the motor controllers (Agile Systems), and higher level commands are issued via Ethernet from the controlling PC. The manipulator arm couples to the end-effector through a custom self-aligning interface that allows the arm to grasp the end-effector without precise positioning when the end-effector is retrieved.

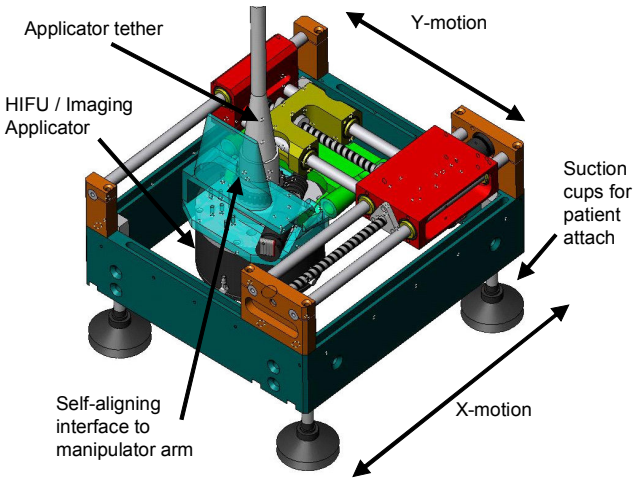

Fig. 7. Solid model of end-effector for planar motion registered to patient.

The manipulator arm, a 7 degree of freedom WAM arm from Barrett Technology[12] makes up the other aspect of the modular motion system, providing large scale movements with long reach and high dexterity. Unlike other commercial arms, the WAM is particularly well suited to operation in close proximity to humans thanks to its low endpoint inertia and friction, and its backdriveability along the entire length of its links, achieved with a specialized cable drive. The arm is also lightweight (27 kg) and has a very good payload-to-weight ratio (3 kg payload). The motor amplifiers are contained within the structure of the arm, so no separate cabinet is needed. The backdriveability and effective torque control make the arm suitable for the implementation of simple impedance control,[13] a proven strategy for safe and effective human-robot interaction.

The end-effector approach is poorly suited for certain wound locations, including certain locations on limbs. This is because there is insufficient surface area to allow the end-effector to be sturdily mounted, and the characteristic radius of limbs is generally too small. Instead, in these cases the arm can be used to directly control motion of the applicator during treatment. This is accomplished by using stiffness in an impedance controller to create a small, nearly constant force between the applicator and the skin. This approach introduces some risk for several reasons. If the system is subject to disturbances, the endpoint inertia of the manipulator would produce a change in force between the applicator and the skin that could cause relative movement during treatment. Nominally the arm can provide adequate motion control (nominal repeatability is sub-millimeter), but actual positioning accuracy is expected to be considerably worse when sliding against friction at the bolus / skin interface while the normal force is maintained. Nevertheless, this approach should provide an effective means of cauterizing key arteries if they are ruptured. Because of the slightly increased risk to surrounding structures, this approach is not as well suited to the torso, where many critical organs reside.

To use the system in this mode where the arm moves the applicator directly, the applicator is extracted from the end-effector while the system is in its home position. The mechanism by which the applicator attaches to the end-effector is completely passive, and does not require an actuator. The manipulator arm can grab the applicator from the home position in two orientations that differ from each other by 180º. In one orientation, the applicator

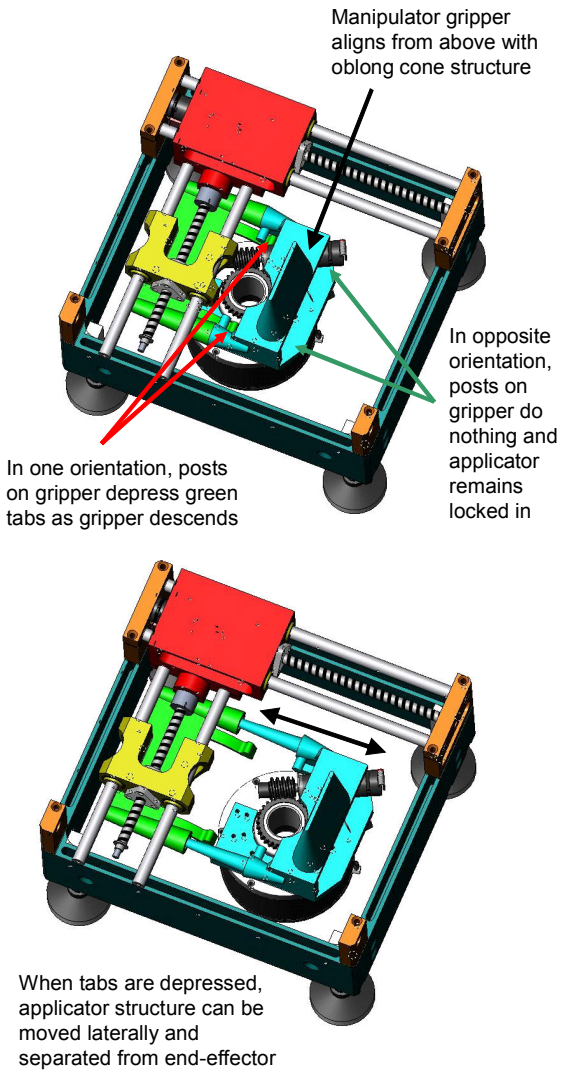

Fig. 8. Mechanism / procedure for separating applicator from end-effector. The mating "gripper" on the manipulator arm (not shown) aligns with the cone structure in one of two orientations. In one orientation, two posts on this gripper depress two tabs on the mating part of the end-effector. This releases a latch between the two parts, allowing the applicator to be slid out sideways by the arm, while the end-effector stays in place. In the other orientation, the posts do not contact anything and the assembly remains intact, so that the arm carries the entire assembly.

and end-effector remain coupled; in the opposite orientation, the applicator is unlatched from the end effector and the end-effector remains in the home position while treatment is applied. The mechanism that facilitates this process is depicted in Figure 8.

V. CONCLUSION

Fabrication of a prototype for our robotic HIFU system is ongoing. Most components have been fabricated and the process of integration is intensifying at the time of this writing.

The challenges to autonomous combat casualty care are sufficiently severe that we do not expect to see complete systems that fulfill the ultimate vision emerge in the near future. Instead, we expect such technology to emerge gradually through dedicated systems that perform specific, useful functions while embodying flexible architectures that can gradually be expanded to more advanced levels of care. Robots for homeostasis are an important early step. Although infection is the most common mode of death from combat, exsanguination remains the leading mode of immediate death on the battlefield. These types of casualties should be of paramount attention as automated systems first emerge. Even the earliest deployed trauma care robots will save lives that would otherwise be lost.

ACKNOWLEDGEMENTS

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