ACOUSTIC HEMOSTASIS AND HEMORRHAGE CONTROL IN COMBAT CASUALTY CARE

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ABSTRACT

High Intensity Focused Ultrasound (HIFU) is a new treatment modality that shows great promise for hemorrhage control and hemostasis in trauma applications. This paper discusses our multi-center, multi-disciplinary effort to develop intraoperative and transcutaneous, ultrasound-image-guided, acoustic hemostasis treatment systems for use in combat casualty care.

1. INTRODUCTION

Since the Crimean War, the mortality rate for battlefield injuries has improved only marginally [Zajtchuk and Sullivan, 1995; Bellamy, 1984]. Although there has been some reduction in mortality for those combatants reaching the medical system, there has been little improvement for those who do not. The principal reason for this lack of improvement is that for severe wounds, there is a limited time in which medical care can be effective. The so-called “golden hour” may even be an exaggeration in the combat casualty care environment. Indeed, Zajtchuk and Sullivan [1995] have shown that ~67% of the mortality occurs within the first 10 minutes after injury; an additional 28% die within an hour, and only ~5% of the deaths occur after the first hour. These data suggest that immediate medical care is required if significant reductions in mortality are to be expected. Thus, a concept of the modern battlefield is to bring advanced technology to the battlefield, rather than to evacuate the wounded soldier to a technically sophisticated medical care unit. An important aspect of medical treatment is to diagnose quickly and correctly the life-threatening condition so that remedial therapy can address this condition. We are developing a self-contained technology to utilize ultrasound to image a site of bleeding and then to apply High Intensity Focused Ultrasound (HIFU) to this site to induce cautery and to terminate/control the bleeding. We call this approach “Image-guided Acoustic Hemostasis”.

2. METHODS AND RESULTS

There are three major components of a successful effort to use Image-guided HIFU therapy to control bleeding: (1) to detect that bleeding has occurred, (2) to target the bleeding site, and (3) to apply sufficient levels of HIFU to induce hemostasis. We examine each of these tasks individually.

2.1 Detection of bleeding

Current diagnostic ultrasound imaging systems range in size from a small refrigerator to a shoebox, and in cost from on the order of $300k to less than $10k. We were involved in the development of a small portable unit [Hwang et al., 1998] that has had much success in emergency care [Funk, 2004]. We have used these portable “hand-held” devices, such as the SonoSite 180, for bleeding detection in our laboratory. This device, and/or similar versions, has Doppler imaging capabilities. Doppler can be used in a “color-flow mode” to detect a site of bleeding for which a major vessel is breached and significant flow is occurring. Doppler can also be used in a “power Doppler” mode in which any form of fluid motion is detected. In this mode, we often look for sites that show a lack of perfusion, indicating that a particular
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region of tissue is ischemic and showing little or no perfusion to this area. Bleeding can also be detected by searching for hypoechoic as well as hyperechoic regions. As a pool of blood ages, it can change from hypoechoic to hyperechoic. We have learned that a rapid scan of the pouch of Douglas or Morison’s pouch can indicate if internal bleeding is occurring.

Fig. 1 shows an example of the use of Color Doppler to detect bleeding in a lacerated femoral artery of a pig, while Fig. 2 shows a region of a porcine kidney that is ischemic and shows a lack of perfusion to a particular region. In this latter case, Color Power Doppler was used to examine a region of the kidney in which 2 major vessels supplying blood to a particular region of interest was damaged, thus starving that particular region of perfusion.

2.2. Targeting of the bleeding site

Once a bleeding site, such as that shown in Fig. 1 is identified, the next task is to ensure that the HIFU to be delivered to induce hemostasis is directed exclusively to that site; accordingly, it is important to have some targeting system or approach that ensures that the powerful HIFU beam is accurately directed. We have discovered that low-level HIFU induces spontaneous out-gassing of the tissue being insonified and permits us to identify in real time if our therapy beam is properly placed [Vaezy, et al., 2001]. This out-gassing results in a hyperechoic region in the ultrasound image, thus permitting one to identify the location of focus of the therapy beam. Shown in Fig. 3 is an example of this hyperechoic region during HIFU exposure to a porcine liver.

2.3. The application of therapy

Although the present implementation of Image-guided Acoustic Hemostasis seems better suited to intra-operative applications (the major thrust of our present research), we have made significant progress and have high expectations that the necessary targeting and therapy-guidance capabilities can be developed over the next several years to permit transcutaneous therapeutics to be used by a properly trained medic. The main cause of death from both military and civilian trauma is blood loss [Anderson,
2002; Zajtchuk and Sullivan, 1995]; there are innumerable applications wherein an appropriately and well-targeted application of HIFU could save lives by effecting hemostasis, especially if it could be used in the remote and unsanitary conditions where the military needs are greatest. Such a system might be deployed locally under the direction of a physician, or used as part of current efforts to deliver care remotely via telerobotic surgery. Thus, we are currently investigating the technology and the biophysical mechanisms through which ultrasound can be used for determining a site of bleeding, through which it can be used to target that site, and finally through which it can be used to induce hemostasis, or at least, hemorrhage control. As indicated above, the technology currently exists in COTS hardware that permits bleeding detection and localization to be performed with portable, lightweight instruments that are currently being deployed in forward echelons of combat casualty care. The major challenge is whether appropriately directly HIFU can be used to induce hemostasis, or at least retard bleeding rates to an acceptable level. We turn now to our efforts in developing the technology of bleeding control.

We have followed two approaches to the use of HIFU for acoustic hemostasis. As a first step, we have constructed intraoperative acoustic hemostasis devices that can be used to treat visible bleeding [Cornejo et al., 2004; Crum et al., 1998; Curra et al., 2003; Martin et al., 1998, 1999, 2003; Vaezy et al., 1997; 1998a; 1998b; 1999].

This approach has enabled us to learn much about the basic physics and biology of HIFU-induced hemostasis and has permitted us to advance to image-guided approaches with more confidence. An example of an intraoperative acoustic hemostasis device is shown in Fig. 4.

The (time-averaged) intensity levels used in diagnostic ultrasound imaging are quite low when compared with those used for therapy—say, 300 mW/cm² for imaging and 3000 W/cm² when used for therapy, a difference of 4 orders of magnitude. Accordingly, different transducer technologies are used for the delivery of these two different types of ultrasound energy [Kaczkowski, et al., 2003]. Actually, one could probably use the same transducer array to do both, but this is a level of complexity that we have not yet achieved. In our current system, we have separated the imaging and therapy transducers, although they are tied together mechanically so that coplanar applications can be achieved. Shown in Fig. 5 is an example of one of our combined imaging/therapy systems.

![Fig. 4. The components of an intraoperative acoustic hemostasis device. One of the more important components of this device is the coupling element that transfers the acoustic energy from the transducer to the tissue. Various embodiments are used, including metal cones and biocompatible hydrogels.](image1)

![Fig. 5. This photograph shows an image-guided therapy system that uses a Philips C9-5 imaging transducer combined with a single-focus HIFU therapy transducer. With the mechanically coupled system used, the transducers are coplanar, which permits real-time image guidance of the therapy.](image2)

In the system shown in Fig. 5, the HIFU focus can be mechanically steered along the transducer axis, which enables a bleeding vessel to be identified with the imaging transducer in the imaging plane, and then targeted with the therapy transducer so that a specific vessel or bleeding region can be treated.
3. RESULTS

We have been successful in demonstrating hemostasis in two different approaches:

- Using an intraoperative HIFU transducer, we have been able to treat visible bleeding sites and induce hemostasis [Martin et al., 1998; 1999; 2003; Vaezy et al., 1997; 1998a; 1999] and
- Using an image-guided HIFU therapy system, we have been able to successfully treat occult bleeding and to induce hemostasis [Cornejo et al., 2004; Vaezy et al., 1998b].

3.1. Intraoperative acoustic hemostasis

We show in Fig. 6 an example of the application of an intraoperative acoustic hemostasis device to the treatment of bleeding in a transected porcine liver. Organs such as the liver and the spleen are highly perfused organs and consequently, when damaged, are sites of major internal bleeding. Currently popular hemostasis devices, such as electrocautery, are marginally successful in treating bleeding in such organs. In the example shown in Fig. 6, we demonstrate how our version of an acoustic hemostasis device can rapidly induce cauterization to some depth, because the acoustic field can penetrate into the tissue, thus providing “volume cauterization”, unlike electrocauterity, which can produce only surface cauterization.

![Image of HIFU device and liver](image)

Fig. 6. An example of the use of an intraoperative HIFU device for the induction of acoustic hemostasis of visible bleeding. In this case, a portion of the liver of a pig was transected, and the HIFU applied directly to the site of bleeding in the liver.

3.2. Image-guided transcutaneous acoustic hemostasis

The most attractive use of image-guided acoustic hemostasis is the far forward echelons of combat casualty care in which exsanguination can typically occur within a few minutes of injury, and before the combatant can reach a higher level of medical care. For those injured who reach the operating room, very high rates of survival are now occurring [Holcomb et al., 1999a; 1999b]. Although constructing a device that would be used in these far forward echelons presents a major challenge, we believe that we have demonstrated many important components of this goal and with the appropriate dedication of effort and resources, such a device could be constructed, tested and utilized.

Our approach would probably follow that of Asensio [Asensio, 1990; Asensio et al., 2000; 2001; 2003a; 2003b; 2004a; 2004b] who has published extensively on the topic of advanced trauma care, particularly to Grades IV and V injuries to the liver. This form of trauma is fatal in approximately 50% of cases and proceeds so rapidly that it duplicates similar advanced trauma under battlefield conditions [Beal, 1990; Beal et al., 1996; Beitsch, 1994; Hoyt et al., 1994; Patcher and Hofsetter, 1995; Sauaia et al., 1995; Shackford et al., 1993]. Asensio’s approach is to perform rapid embolization of the vessels that are supplying the sites of hemorrhage. This embolization must be done under fluoroscopy, and normally in the “cath lab”. Since most patients suffering severe trauma are first treated in the operating room, a major cause of mortality is the lack of proactive care in the transit from the operating room to the cath lab.

We have developed a technological approach that we believe will enable trauma surgeons such as Asensio to perform an effective vessel occlusion while in the operating room. Our system is similar to that shown in Fig. 5, in which we have constructed an imaging array tied mechanically to a therapy transducer that provides sufficient levels of HIFU so as to rapidly induce vessel occlusion.

Our approach, demonstrated successfully in large animal models, thus follows a protocol that we have demonstrated successfully in a number of animal models. This protocol also follows our general approach of bleeding detection, localization, and hemorrhage control. An example of the application of this protocol to a porcine model is shown in Fig. 7.
We can express this protocol explicitly as follows:

- Some form of trauma is induced in the liver of a pig,
- the vessels leading to this hemorrhaging area of located with a Doppler ultrasound device,
- HIFU is supplied to these vessels proximal to the site of trauma,
- the flow in these vessels is monitored by color Doppler, and
- HIFU is supplied to these vessels until the color Doppler indicates that total vessel occlusion has occurred.

4. FUTURE PERSPECTIVES

We have demonstrated that image-guided transcutaneous acoustic hemostasis devices can be utilized to identify a site of bleeding, to target it, and with the appropriate application of HIFU therapy, induce hemostasis or at least a comfortable level of hemorrhage control. The devices that we have developed in our laboratory are not yet at a level of technical sophistication that they could be converted into engineering prototypes.

We anticipate that for a device to be attractive to the combat medic, or battalion aide physician, it would need to be lightweight and portable, and require only modest levels of training. Such a device can be envisioned. It would contain the following components:

- A lightweight, handheld imaging system capable of both color flow and color power Doppler, in addition to normal B-scan,
- an annular array for application of the HIFU therapy, so that one could electronically direct the therapy at any depth,
- a simple human interface system that contained artificial intelligence that would seek sites of bleeding and automatically target vessels leading to this site of bleeding, thus permitting rapid and direct deployment of the therapy to an injured combatant.
We show in Fig. 8 an example of such a system.

**Fig. 8.** Potential configuration of an image-guided, transcutaneous acoustic hemostasis system.

5. CONCLUSIONS

We have made considerable progress in our extensive preliminary studies in laboratory animals and have demonstrated that HIFU can induce hemostasis in a variety of bleeding scenarios. We have also demonstrated that HIFU can be combined with an ultrasound imaging system to perform image-guided acoustic hemostasis of occult bleeding. Further developments of this technology offer promising approaches to critical combat casualty care issues.

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