

CRT Opportunity



Extracorporeal High Intensity Focus Ultrasound

- Rapid and precise extracorporeal HIFU device
- Efficient tissue ablation demonstrated *ex vivo* and *in vivo* - 30 seconds to ablate 1cm³ lesion
- CRT seeks a partner to invest in further development of this device.
- The first generation device will be optimised to non-invasively treat patients with liver metastases with clinically feasible treatment times

MEDICAL DEVICE

October 2009

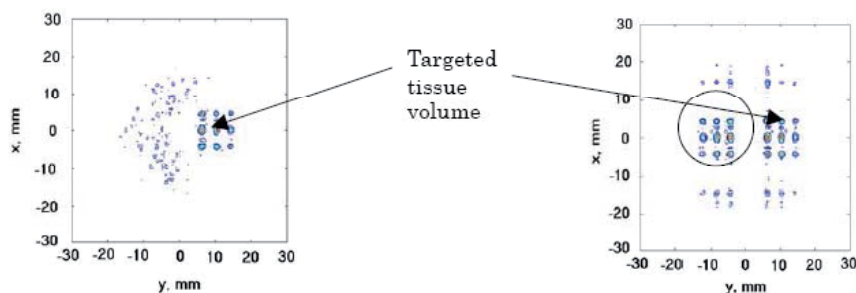
Therapeutic Rationale

While HIFU (a highly precise non-invasive medical procedure using high-intensity focused ultrasound to destroy pathogenic tissue) has been used to treat more than 80000 cancer patients to date, a number of factors have limited its wider uptake in the clinic as a standard of care treatment for patients with solid tumours. Current HIFU devices can require extensive treatment times that often exceed 4 hours and can result in significant collateral damage. To address these and other limitations a research team at Imperial College, London, have developed *Acublate*, a proprietary HIFU system, which addresses a number of the existing limitations of HIFU treatment to enable HIFU to become a more effective and economically feasible alternative to currently available procedures.

Technology

Acublate overcomes the shortcomings of existing HIFU applications through the safe use of proprietary random phased array technology which negates the risk of damaging non-targeted tissue adjoining the targeted tissue volume. Phased array technology involves the use of many small transducers that, with suitable electronic control, result in a focused beam that can be rapidly steered in 3-dimensions to targets within the body. The improved performance and greater safety of the *Acublate* device compared to a conventional phased array is demonstrated in Figure 1 which shows that the risk of damage to non-targeted tissue is very low when the *Acublate* device is used (Figure 1 a) compared to a conventional array (Figure 1 b).

Figure 1: Intensity distributions produced by the *Acublate* device compared to a conventional phased array

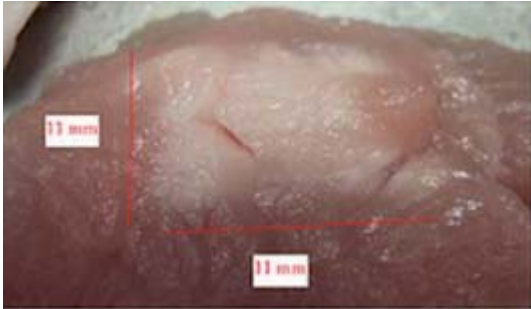


Comparative intensity distributions produced in the focal plane for the *Acublate* device (a) compared to a conventional array (b). The random distribution of localised (relatively low) intensity contours to the left of the targeted volume represents no risk to non-targeted tissue using the *Acublate* device as depicted in (a). The same focusing conditions were used for the conventional array (b). The intensity distribution at the target volume is mirrored on the left by a similar distribution of high intensity in non-targeted tissue (highlighted by the circle). The risk of damage to non-targeted tissue is very high in this case.

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The *Acublate* device has been successfully used to demonstrate *ex vivo* and *in vivo* ablation of tissue. Experiments in which meat was thermally ablated indicate that single and multiple foci lesions can be steered off and along the central axis of the array. Large contiguous lesions were produced with very short exposure times (typically 20-30 seconds for a 1 cm³ lesion) (Figure 2).

Figure 2 *Ex vivo* lesion produced using *Acublate*



An ablated lesion of approximately 2cm³ was generated using the *Acublate* device. No off target ablation was detected.

Applications

The *Acublate* technology has many applications including, but not limited to:

- curative or palliative ablation for primary or secondary cancer;
- ablation of uterine fibroids;
- other clinical applications including vascular, neurosurgery, cardiac, ocular, orthopaedic, and targeted therapy; and
- cosmetic correction.

The Imperial team are developing a clinical prototype device utilising the *Acublate* technology for the non-invasive treatment of colorectal liver metastases.

Colorectal cancer (CRC) accounts for approximately 10% of cancer-related deaths and it is estimated that there will be 150,000 newly diagnosed cases in the US in 2009. The US spends US\$8.4 billion per annum on CRC treatment. Approximately 50% of these patients will develop liver metastases (CLMs) and if left untreated their 5-year survival rate approximates zero. Surgical resection represents the only hope of cure; unfortunately only 15-25% of patients are suitable for such treatment. Invasive microwave and radiofrequency ablation therapies are used to treat patients with CLMs, however, the non-invasive application of the *Acublate* HIFU device offers clear advantages over these current therapies.

Commercial Opportunity

CRT is seeking a partner to enter into an investment and/or co-development arrangement to further develop the *Acublate* technology.

Intellectual Property

Patents protecting the “random” array technology have been filed in the major international healthcare territories relevant to the HIFU market. The patent has been granted in the US (2002), in China (2006) and in Hong Kong (2006). The patent is pending in Japan.

References

Hand JW *et al.* A random phased array device for delivery of high intensity focused ultrasound. *Phys. Med. Biol.* 2009;54:5675-5693

Gavrilov LR & Hand JW. A theoretical assessment of the relative performance of spherical phased arrays for ultrasound surgery. *IEEE Trans. Ultras. Ferroelec. Freq. Ctrl.* 2000; 47:125-139

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