THE MARKETECH GROUP MINUTE

INTERVIEW

MR guided Focused Ultrasound - The Fusion of Imaging and Treatment

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CR: InSightec is a great example of convergence between imaging and therapy, where imaging is the key instrument for treatment. As a former innovation manager at GE, can you explain what you like about the technology so much, and do you know other examples that confirm the convergence trend?

RN: Several years ago while at GE, a team of us including Morry Blumenfeld began looking seriously at image guided therapy. I believe the first meeting on the subject was in the spring of '90 in Boston. Actually, the idea was to take MR beyond conventional diagnostics. This was also about the time we began development of the SIGNA SP. In 1992 we worked with the Brigham and Women's doing research to determine whether or not we could use difference of temperature in the body as contrast. We also worked with laser, cryo as well as focused ultrasound as sources of 'MR compatible' heating for tissue ablation. Between 1993 and 1995 GE built 12 'double donut' magnets where the physician could operate in the MR imaging volume, and we looked at the various potential applications for this concept. By 1999, GE was not interested in pursuing a new therapy technology, so we combined what we had been doing with the developments of an ultrasound group in Israel, and spun this technology development into a unit dedicated to MR guided focused ultrasound, which became InSightec. I just had to follow the technology. We had just performed the first successful human clinical trials treating fibroadenomas and I couldn't leave at that stage of development. The idea of a completely non-invasive energy source for treatment, with MR for guidance and control was too exciting to drop.

CR: What are the other examples besides InSightec that confirm the convergence trend between imaging and therapy?

RN: The first real system like this I became aware of was the Robodoc system for hip implants. Other examples include any of several types of stereotactic techniques for biopsy, gamma knife technology and all the associated procedures with radiation therapy planning. Most radiation therapy facilities now have a dedicated CT networked to the radiation therapy device with a direct transfer of the images that allows the physician to see and to treat. Varian has a very well developed system like this. The integration of imaging and therapy is clear in many other interventional situations. We have today several methods of image guided biopsies and many types of vascular intervention using X-ray. There are also ultrasound guided procedures to guide RF ablation procedures - for example, using RITA or a Radionics device. CT is also used to help guide liver ablation procedures. The idea in the development of these types of technologies and integrating images into the treatment is really quite simple - get the images down off the wall. In one of my talks, I have the classic picture of the surgeon looking over his shoulder at an MR film on a light box and wondering what to do next. At InSightec we get the images off the wall and into the hands of the interventionalists, in real-time.

CR: So what has the percentage of growth been over time of these converging technologies? Have the number of procedures of technologies integrating imaging and treatment grown significantly and will they continue to grow?

RN: I have one more example of the integration of imaging and treatment if we look at this as a continuum. Both endoscopy and laparoscopy were implemented more or less mainstream in the early 1990s. This was the very beginning of using imaging and treatment technologies integrated into one device for procedures. Now we have the imaging diagnostic and treatment device completely integrated. To answer the question regarding growth, in

2000 there were only a few systems integrating imaging with treatment technology. One very dramatic example was Intuitive Surgical. They now do aortic valve bypass repair surgery and colorectal procedures through a keyhole approach. The guidance technology is endoscopy: but the surgeon controls a robot that directs both the endoscope and performs the procedure. There are many others.

CR: What are the drivers for this convergence?

RN: The lead driver is that these technologies transform invasive procedures into minimally invasive or non-invasive ones, minimizing the injury to surrounding tissue. This leads into the second driver, which is reduced hospitalization. The third is the minimization of lost work following the treatment. While this is not often measured as a cost benefit – by the insurance company – it certainly is a benefit to the patient, and the employer.

I would also say that there are three critical arenas for development in moving these ideas into regular clinical practice. The first is quantitative evidence of the safety and effectiveness – this is the one that everyone thinks about first because of FDA. The second key arena is reimbursement. The third arena revolves around the issues of combining the technologies in such a way that they can be used by 'normal' MD's – not just at the research centers. Image-guided therapy can be a disruptive technology to normal flow of patients through the various existing medical specialties. There are no image-guided therapists and no recognized sub-specialty called image-guided therapy. The Ob/Gyn community may certainly know a lot about uterine fibroids as well medical management of a patient, but they generally have little or no experience with diagnostic MR. Conversely radiologists know a great deal about MR and imaging technology, but do not necessarily have a much of experience of all of the issues of regular clinical care. So when we put something as complex as MRgFUS (Magnetic Resonance Guided Focused Ultrasound) into a hospital or clinic, we have not only the training issues developing an individual's expertise with the device, but we also have the issue of building a team, as well as identifying the proper medical resources and infrastructure to support the particular therapy.

CR: What challenges do you see in terms of practice and organizational changes, reimbursement, and liability/legalissues?

RN: No one has studied or performed focused ultrasound in residency - neither gynecologists nor radiologists do image-guided therapy in residency. I think that in 5 years time there will be a specialty called image-guided therapy or something of that nature. There will be a need for hybrid individuals or hybrid teams trained to perform these kinds of procedures and capable of understanding the merge of imaging technology and treatment. In the case of MRgFUS for uterine fibroids, this hybrid is the combination of skills from radiology and gynecology.

As far as reimbursement is concerned, we currently operate in a health care system where technology often evolves much faster than reimbursement structure. Often by the time a technology completes the path to reimbursement approval for the first generation, the company has already developed the third generation of that technology, if they have the cash to survive the intervening period.

CR: Will the use of these technologies be considered an adjunct or will there be a separate and distinct procedure code associated to these technologies?

RN: Reimbursement really involves 3 separate steps. The first is coding for the procedure, second is the petition of insurance companies for coverage, and third is establishing the appropriate level of reimbursement. For coding, someone needs to do a fair amount of research. There may be a CPT code already established for what you are doing, as well as proper reimbursement. However, the current code, or the reimbursement could be very inappropriate for the new procedure.

You cannot wait until you have FDA approval to start looking at the reimbursement strategy. Somewhere very far upstream in the technology development process, someone at the company must evaluate and plan for reimbursement approval in the same way you now evaluate the plan for regulatory approval. Our analysis indicated that there were no existing CPT codes that could be used for MRgFUS. For example, the code for ultrasound guidance for biopsy pays about $175 and there is a code for MR-guidance and that reimbursement rate is about $250. This level of reimbursement does not support a business models upon which to build the success of a new and separate technology along the lines of what we doing. Also, the therapy method we are using was not really well described in any of the existing CPT's. For the last 2 years, we have been working with a company called Healthcare Strategies on CPT codes. Two CPT codes were recently defined and approved for MR-guided focused ultrasound for ablation of uterine fibroids.

CR: And libability?

RN: This is a pretty complex topic. there is always insurance, but the most pro-active way to deal with this is to be sure that you provide appropriate training to new sites to they can identify paritents who are approrpriate for this type of treatment, and enable them to use the system in a safe and effective manner. IN Sightec has developed a significant training and credentialing program for its users. This intense training is not unique to this specific image-guided therapy, but applies to all new innovations.

JW: What catalysts will facilitate widespread adoption of telemedicine?

TN: Clearly, EMR, the electronic medical record, and telemedicine are linked. Availability, access and the exchange of information in the medical record represent a significant missing link to the efficient use of telemedicine. A telecommunication network, point of care testing, and small imaging devices such as portable ultrasound devices are all components of a fully developed telemedicine system in the future. Telemedicine today provides us with sight and sound, but no touch, and we need substitutes for that missing sense, although some tactile-based approaches are in development.

CR: Which companies will be in the driver's seat: imaging companies or surgical/medical device companies? So will it be imaging companies like GE or device companies such as Medtronic?

RN: I do not think that either has any inherent advantage. I do think the companies that will be in the driver's seat will likely be those that will grow up in between the two examples you just mentioned. For example, the minimally invasieve laparoscopic makret was kicked off by a little company (at the time) called U.S. Surgical. J&J then created Ethicon Endosurgery to compete. Multiple other new or existing companies soon joined the market to fill specific clinical needs.

CR: Which physicians will champion this evolution: radiologist or surgeons?

RN: What we have done is to target visionaries near the border on both sides. We have worked with radiologists that have significant interventional expereicne and an interest in clinical medicine; we have also worked with gynecologists with surgical experience and an interest in learning moreabout MR imaging. A previous example was the development of the interventional cardiology market. Initially most cardiac imaging/procedures were preformed by radiologists, but today lots of cardiologists perform their own procedures. For people who start from either the radiology or the clinical side, there's a lot of learning that has to happen. I think at some point, a new training curriculum will need to be established at medical schools in order to handle this new trend of image-guided therapy. As I said earlier, I believe image-guided therapy will become a subspecialty, but initially we will find people from both the radiology and clinical side interested in the technique.

CR: Is this a sustainable trend? Which applications do you think will be the most successful?

RN: I believe that image-guided therapy represents the only path to minimally or non-invasive therapy, so yes, this is definitely a sustainable trend. The only replacements for the surgeon's eyes and hands into an opening in the body are imaging systems and remote control of the treatment devices. One of the key applicaitons from a technology viewpoint will be focused ultrsound or other thermal therapy methods in combination with MR, ultrasound and endoscopy to convert open, invasive procedures to closed, minimally, or non-invasive procedures. Mass General Hospital and others are doing research combining diffusions and functional MR imaging with catheter delivery of drugs and devices to rapidly pinpoint the foci of a stroke and restore flow, and the development of this technology will significantly change how we manage strokes. We should also include what we are doing in the development of MR in the control of non-invasive thermal ablation, and we have touched on others. Extending these types of techniques to treatments in the breast, liver, prostate and brain are going to bring tremendous benefits to the patient, and transform the way we manage disease in the future. It is an incredibly promising field to be working in!