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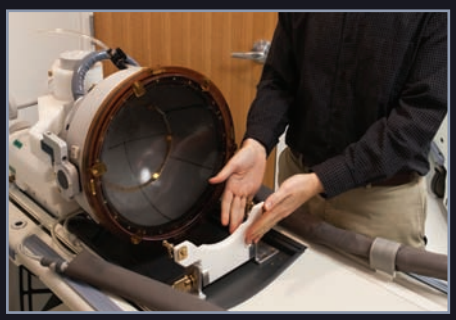

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Distinguished Professor of Neurosurgery at the University of Virginia

Focused Ultrasound Surgery Foundation

Leading the worldwide movement to revolutionize the field of medicine

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Focused Ultrasound Surgery Center of Excellence

Leading the worldwide movement to revolutionize the field of medicine

BY JOHN KELLY · PHOTOGRAPHY BY DAN ADDISON

Tucked up against the University of Virginia Medical Center is an utterly unremarkable one-story white building, a sort of modular architectural afterthought that looks as though it might have been built to provide overflow office space.

Looks can be deceiving. The building is actually the home of the $9 million Focused Ultrasound Surgery Center of Excellence, a first-of-its kind facility for a treatment that some think may be one of the most exciting and important medical advances of our time.

Focused ultrasound surgery has been hailed as the ultimate in non-invasive treatment and is the subject of a worldwide movement that has the potential to change the medical landscape and impact millions of lives, and to do so within the next decade. And the epicenter of that movement, thanks to internationally-acclaimed neurosurgeon Neal Kassell, is right here in Charlottesville.

A Distinguished Professor of Neurosurgery at the University of Virginia and the former co-chair of that department, Kassell is the founder and Chairman of the Focused Ultrasound Surgery Foundation (FUSF). It's a not-for-profit organization that is dedicated to shortening the time from technology development to patient treatment, developing new applications, and accelerating the worldwide adoption of magnetic resonance-guided focused ultrasound therapies.

The technology, which Kassell says is potentially the most important therapeutic technology since the invention of the scalpel, represents the innovative marriage of focused ultrasound and magnetic resonance imaging (MRI). Multiple intersecting beams of ultrasound energy are used with extreme precision to target tissue as small as one millimeter in diameter, leaving the surrounding healthy tissue and organs unaffected. Think of it like the classic magnifying glass experiment, focusing multiple beams of light onto a single point. The MR component pinpoints the tissue you are looking to treat in real time with immediate confirmation of the effectiveness of the therapy.

While it is currently approved for use treating uterine fibroid tumors and bone metastases, Kassell says we are less than a decade away from using the treatment to battle, and perhaps eradicate, some of today's most vexing and deadliest diseases, including breast, prostate, and pancreatic cancers,

Parkinson's Disease, stroke, and other brain conditions, such as lethal blood clots.

And it can all be done on an outpatient basis with minimal recovery time.

Even in our hyper-speed technological age, it sounds like a delicious bit of science fiction. But it is very real. And it does not stop there. Focused ultrasound, Kassell says, also has the potential to complement, or even replace, the need for most radiation treatments. In addition, it can transform drug therapy by allowing drugs like antibiotics and chemotherapy agents to be delivered directly to the area where they are needed, thus avoiding systemic toxicity and debilitating side effects.

One recent afternoon in the Foundation's downtown offices, Kassell explained his commitment to a complex treatment by using some simple math.

"Through my practice I get to affect about six hundred lives a year. By virtue of the research that I have been doing since 1962, I have impacted the lives of several thousand patients per year. Focused ultrasound has the potential to affect millions of lives around the world with a very broad spectrum of serious medical disorders."

Focused ultrasound's impact, he said, could very well mirror that of MR imagery. "Thirty years ago nobody foresaw how pervasive MR scanning would become. The MR scan has revolutionized diagnosis, and ten years from now everyone we know will have either been treated with focused ultrasound or will know somebody who has. And that includes our friends, our families, and ourselves. No one is immune from a disease that could benefit from this treatment."

Focused ultrasound is hardly Kassell's first trip to the front lines of medical technology. He has made a home there throughout his career, including playing a pioneering role in the adoption of the use of the Gamma Knife, a revolutionary tool first introduced in the 1970's that brought neurosurgery out of the era of frontal lobotomies and psychotropic drugs. He created the second Gamma Knife surgical center in the country here at the University of Virginia, now an internationally-acclaimed facility that has treated more than six thousand patients from around the world.

Still, the potential for and the excitement around focused ultrasound treatment has him more energized than at any point of his nearly fifty years in the field. It also has him more frustrated.

"As time goes on, the potential of focused ultrasound to help millions of people becomes more real and more solid. But at the same time, the gap between where we are and where we could be becomes more apparent. Knowing that we could close this gap if more money was available makes you nuts. Every day, we get calls from patients who could be helped if focused ultrasound treatments were available. I know in time we will definitely be able to help them, and that the time would come sooner if we had more money for research and development. The more real the potential of this technology becomes, the more frustrating it is that it is not available right now."

Kassell's energy and frustration act as key drivers for the current and future success of the Focused Ultrasound Surgery Foundation. He formed the foundation in 2006, two years after first being introduced to the idea of using ultrasound to treat brain issues by a colleague who was experimenting with similar technology on the heart.

"I was in the operating room and the neuroanesthesialogist, Marcel Durieux, said he was doing some research with a cardiologist using microbubbles and ultrasound." What Durieux and his colleagues were doing was injecting the microbubbles into the body, which would go into the heart where they would burst them with ultrasound, then watch them clear. The speed with which they clear is related to the blood flow in the heart. He thought it was something Kassell might want to consider for the brain.

Or had he? "It took me about fifteen minutes to get home, and I went on the internet and found focused ultrasound treatments were already under development. So, yes, it was a Nobel Prize-winning idea. It just wasn't mine."

He flashed back to the time when he was introduced to the Gamma Knife. "I knew it was going to be huge, and I thought this could be an order of magnitude bigger. So, I got really excited and got on the phone with the people at InSightec, which was the only company involved in the game at the time."

Kassell didn't stop there. In fact, he has spent endless hours since working the phones and traveling around the globe as the focused ultrasound's greatest champion and most tireless ambassador. And in a classic nod to one of the things that makes this region of ours truly special, his efforts began right here at home. He put together a series of meetings that brought together various medical industry stakeholders as well as leaders in the area's famously vibrant philanthropic community.

"I said, 'Look, this is interesting. It's like getting a window into MR when it was in its infancy twenty-five to thirty years ago.' We went to Edgar Bronfman's house for lunch, and people got really fired up. I said, "I'd like to create the world's leading Focused Ultrasound Center at UVA."

The question was, how?

"There was a lot of enthusiasm from people in the community, and a number of people said, 'Yes, let's do this.' They had the money and wanted to give it to us, but there was no mechanism at UVA, and I wanted to get going."

Focused ultrasound has the potential to affect millions of lives around the world with a very broad spectrum of serious medical disorders.

"I thought it was a terrific idea," he said. "And one day later in the month I was particularly frustrated with some complications we were having from Gamma Knife treatments, including benign tumors at the base of the skull that were too large or too complicated to treat with the Gamma Knife. I remember leaving the hospital and driving home, and I had one of those 'eureka!' moments. I said, 'I'll bet we can use ultrasound and microbubbles to somehow treat brain tumors.'"

He quickly imagined the implications of his so-called discovery. "I said to myself, 'I have been doing research since 1962, and now in 2004 I finally have come up with my Nobel Prize-winning idea.'"

It was local business leader Bill Crutchfield who suggested that the answer might lie in creating a foundation. And it was another influential business leader and entrepreneur whose commitment to the project truly got the ball rolling. "Ted Wechsler is the guy who really jump-started this," Dr. Kassell said. "I went to him to present the concept back in 2004, and he was the first one to say, 'You need some money. Here is a check.'"

For Wechsler, an investment professional well versed in the art of the pitch, this one

seemed to have it all. "Neal is one of those special people. He's a brilliant doctor. He's got this terrific ability to connect people, and he's got just tireless energy…energy beyond normalcy. Then you couple all this with the technology and his passion for it, and him being somebody who has the gravitas in the scientific community to make it happen—you kind of realize that you really can change the world."

The fact that you can work to change the world from right here in Albemarle County is particularly exciting, Wechsler said. "I always refer to this as a town that is long on intellectual capital. We have a lot of smart people that end up here for whatever reason, which is really fun because we end up being an incubator for all these different ideas."

Another of those smart people Kassell reached out to right in our own community was his longtime friend John Grisham.

"Neal is pretty persistent," Grisham said. "And over the past number of years this has become the only thing he talks about. So eventually my wife and I saw the presentation and began talking to Neal about how we can help. At some point several years ago he suggested that perhaps I can help raise money, which is one of the main functions of the foundation, among many others, to raise as much money as possible in as short a time as possible to crank up the research and make this surgery become a reality."

Soon after signing on with the foundation, an event in Grisham's personal life further clarified its mission and potential. "My mother was diagnosed with cancer of the uterus. That was the first big cancer scare in our family, and it kind of put things in perspective. We are all going to be faced, or already have been faced with that situation, whether it involves ourselves, our families, or our close friends, so that really drives it home."

He joined the Foundation's board three years ago and has had what he called "a delightful time" raising money for its efforts. "I can't think of anything else I can do as a philanthropist or as a fundraiser or as a pseudo-celebrity or whatever you want to call it, than to devote my energies to something that will so positively impact so many people for a long period of time."

Dan Jordan, who recently stepped down as the President of the Thomas Jefferson Foundation, shares these sentiments. "I am proud to be on the Board and have the greatest admiration for Dr. Kassell. The case for focused ultrasound is clear and urgent. How often do you have the opportunity to be part of an initiative that will save millions of lives and reduce pain, discomfort, and disability in tens of millions more?"

In July of 2008, Dr. Kassell went to see the late Frank Batten, founder of Landmark Media Enterprises and one of America's most legendary philanthropists. His long list of gifts, many to leading educational institutions, includes donations of more than $180 million to the University of Virginia.

"Now remember, on the one hand, that Frank had at this point had three cancers; he had had chemotherapy, radiation therapy and surgery, and all sorts of complications from all sorts of other medical problems. On the other hand, he had never given any money to medical research or medical causes because he just couldn't understand it. I showed him the presentation and he said, 'Here is $5 million. I am giving this to you because this is the first time I have seen in my life an opportunity where I could personally potentially help millions of people.'"

Watching the devastating effects of the disease on her father, and particularly the treatments meant to fight it, played a major role in Dorothy Batten's involvement in the foundation. "For me, seeing him go in and out of hospitals, his quality of life was just so poor after that. So when Dr. Kassell told me about focused ultrasound, and particularly its targeted drug delivery capability, I just thought it was a no-brainer. The fact that you can use really highly concentrated but tiny doses of chemotherapy and deliver them directly where they are needed without affecting the rest of the cells in the body just sounded incredible to me."

that brought together some three hundred medical experts from more than twenty-two countries. "It was," Dan Jordan said, "a complete validation of the efficacy of MR-guided focused ultrasound."

The Focused Ultrasound Surgery Foundation is dedicated to educating both clinicians and patients as a key component of its effort to bring this technology to millions. It provides fellowships to train physicians and scientists, creates and conducts training courses for physicians, establishes standards for training and credentialing, and more. It maintains a website that serves as the ultimate resource for the latest information and provides a place for all stakeholders to share their thoughts and experiences.

At the same time, the foundation presents and supports programs that increase awareness among all groups who are critical to its success, including patients, doctors, regulatory agents, and the insurance payers whose support of the technology in many ways holds the key to its future. "It could be a great treatment," Kassell said, "but if nobody offers reimbursement for it, who cares."

The organization's out-of-the-box approach can perhaps best be seen in the way it tackles research, Kassell said. "We are taking a sort of twenty-first century, iconoclastic, Internet-era approach, instead of the closed approach we have had in the past. Everything we do is open and shared with all researchers in a collaborative manner.

The foundation is a catalyst. Not only are we setting the agenda for the field, but we are in large part moving the direction of the field.

The foundation is, in many ways, defined and driven by its founder's trademark persistence. It has become a true global force, the center of a global network of more than one hundred scientific and medical centers devoted exclusively to the technology and its implications.

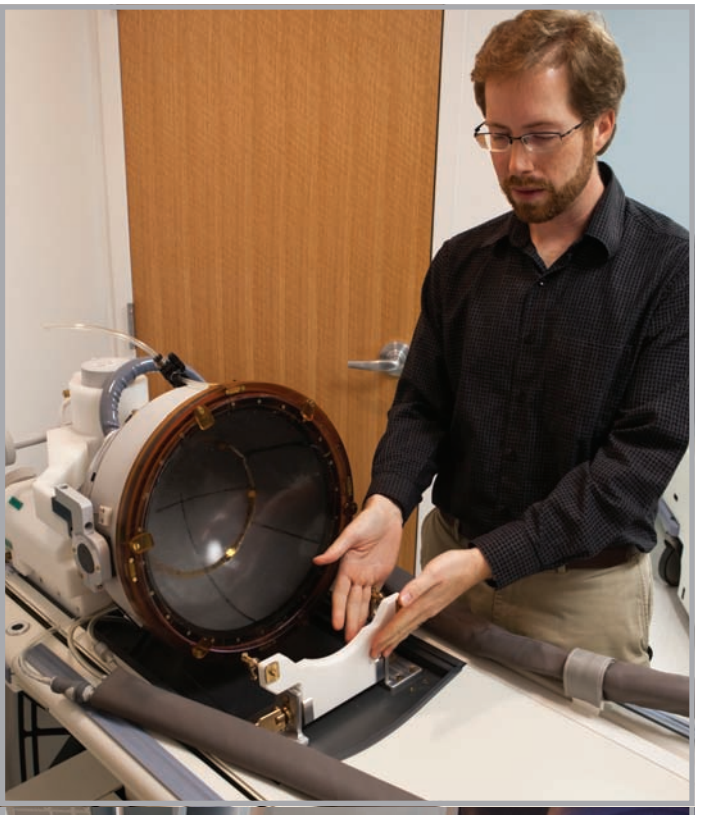
It's most high-profile mark of success thus far came in 2009 with the opening of the UVA facility. "It was a dream of ours to create a Focused Ultrasound Center that was at the same level as the original Gamma Knife Center at UVA," Kassell said. The center is a truly interdisciplinary effort that brings together some of the top medical and research minds at the University and currently hosts both research and therapeutic endeavors.

Recently, the foundation extended its reach even further by hosting its second international symposium in Washington, D.C.

This can give some researchers indigestion because they are more interested in glory and promotion than they are in seeing the end result. But everything we do is oriented toward the rapid development of a reimbursable treatment. We are not interested in science for science's sake."

What Kassell *is* interested in is results, which is why he is very careful about how he refers to his organization. "To me, 'not-for-profit' can sometimes mean 'not-for-performance.' There is sometimes no accountability. What we are is a tax-exempt organization defined by high performance and populated by mostly young, smart, unbounded professionals. The number of degrees that people have here is incredible. Everyone is highly educated and highly motivated, and they all could be working elsewhere."

The FUSF is the first organization of its kind dedicated to the adoption of a de-



Magnetic resonance image guided focused ultrasound (MRgFUS) can lead to profound changes in the way surgeries are performed by allowing incisionless operations, removing diseased tissues and tumors from outside the body with high-frequency ultrasound waves. This type of surgery requires no anesthesia and has no or a greatly reduced risk of infection and a low rate of complications. It can also be performed on an outpatient basis.

How MR-Guided Focused Ultrasound Surgery Works

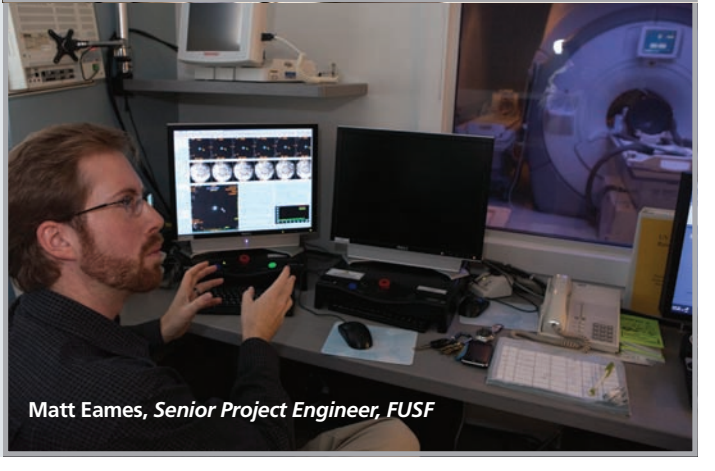
MR-guided focused ultrasound surgery is a breakthrough technology resulting from the innovative marriage of:

- **Focused ultrasound**, the concentration of multiple intersecting beams of ultrasound energy with extreme precision on a target tissue as small as one millimeter in diameter, much like a magnifying glass can focus multiple beams of light on a single point.
- **Magnetic resonance imaging**, used to identify and localize the tissue to be targeted and treated interactively in real time, to provide immediate confirmation on the effectiveness of the therapy, and provide feedback of temperature levels within the tissue in order to insure a safe and effective treatment of the area.

For more information

Focused Ultrasound Surgery Foundation
www.fusfoundation.org

Focused Ultrasound Center at UVA
www.healthsystem.virginia.edu/internet/fus



Matt Eames, *Senior Project Engineer, FUSF*

vice, versus to the fight against a particular disease or condition. "Instead of being like the American Cancer Society or the American Stroke Association, which just fund research, we positioned the foundation at the nexus of all the stakeholders from the very beginning. We looked at all the steps you have to go through before a device actually treats a patient, looked at where the chokepoints were, and that is where we are putting our effort."

So far, he said, the FUSF has exceeded expectations. "The foundation is a catalyst. Not only are we setting the agenda for the field, but we are in large part moving the direction of the field."

Today, Kassell said, the foundation finds itself at what he calls a "magic moment."

"It's a nice stage because if somebody said 'Here's a billion dollars, develop a cure for Alzheimer's Disease in the next five years,' that would be impossible. There is too much that is unknown, too much research that has to be done, and too much that is undiscovered. With focused ultrasound we are at a magic moment where the brute force application of money will translate into enormous progress. If somebody said, 'Here is a million dollars over five years, develop good therapies for Parkinson's, epilepsy, stroke, brain tumors, liver, prostate and breast cancers, and so on,' there is a ninety-five percent chance you can do it. There is not a lot to be discovered. It's sort of blocking and tackling. It's engineering versus research and development."

So far, according to officials, the Focused Ultrasound Surgery Foundation has received commitments of nearly $30 million. Over the next three to five years, Kassell said, it could efficiently use another $30-50 million to achieve what it has set out to do, with the money going into research and other patient-oriented programs dedicated to the advancement of the overall effort.

Others surrounding the project have mentioned the idea that this is a legacy project for Kassell, the perfect way to cap off an extraordinary career. He, however, has little time for such talk. There is too much work to be done.

"Having stumbled into this—and it was luck—it gives me something important to do for the rest of what I hope will be a long life. We are at the very beginning, which is the exciting time to be involved with this. But the closer we get, the more frustrated I'll be. The more real it is, the more frustrating it is that it is not available right now." ***a***

John Kelly is a Charlottesville based writer and PR/Marketing Consultant.

Focused Ultrasound Surgery Foundation

"This is the first time in my life I have seen an opportunity where I potentially could personally help millions of people."

The late **Frank Batten, Sr.**, philanthropist and former Chairman and CEO of Landmark Communications, Inc.

"The procedure itself was very successful! I would heartily recommend others to consider focused ultrasound."

Doris McArdle, an 89-year old patient who traveled from Chicago to London for the treatment of a benign pancreatic tumor.

"My work has focused on evolving surgical techniques through new technologies. The Foundation is championing a technology that could have dramatic impact on minimally-invasive surgery, radiation therapy and drug delivery."

Frederic H. Moll, M.D., Co-founder and Executive Chairman of Hansen Medical, and Co-founder of Intuitive Surgical, Inc., developer of the da Vinci Surgical System

"Like the Foundation, I am committed to accelerating the development and adoption of innovative treatments that save and improve lives."

Andrew von Eschenbach, M.D., President of Samaritan Health Initiatives, former Commissioner of the U.S. Food and Drug Administration, and former Director of the National Cancer Institute

giving hope | alleviating pain | saving lives

highly precise . effective . safe

"The potential to use a proven, safe technology like ultrasound to revolutionize the way so many diseases and conditions are treated is what personally and professionally motivates me. Philips Healthcare is extremely excited to be involved in this dynamic field. We have an opportunity to improve life for millions of people on a global scale."

Steve Rusckowski,
CEO of Philips Heathcare

"I can't think of anything else I can do as a philanthropist or as a fundraiser or as a pseudo-celebrity or whatever you want to call it, than to devote my energies to something that will so positively impact so many people for a long period of time."

John Grisham,
Author

"Having focused ultrasound was life changing. You can tell such a difference. My abdomen went down as soon as I had the procedure, so that was very cool. I was back to work and working out within three days, which was wonderful. I'm back to a sense of just being normal, being a full woman. I don't have any concerns and it's just great."

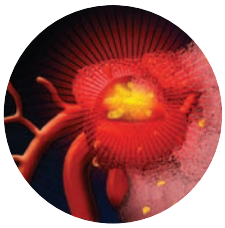
Frances T.,
a 35 year-old woman whose uterine fibroids were successfully treated with focused ultrasound. Approximately two years after her treatment, Frances delivered a beautiful baby girl.

"Focused ultrasound is a big idea whose time has come. The facility at the University will become a leading center for translational research, education and patient care in the new and rapidly evolving field of MR-guided focused ultrasound."

Arthur Garson, Jr., M.D.,
Executive Vice President and Provost of the University of Virginia

advocacy | collaboration | reseach | awareness



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giving hope | alleviating pain | saving lives