FOCUSED ULTRASOUND FOUNDATION

PROGRESS REPORT
FALL 2015

Dear Friends,

During the past few months, the pace of progress in focused ultrasound has quickened. Here at the Foundation, we've gained valuable new insight with the addition of Charles Steger, Former President of Virginia Tech, to the Council. This fall, we began convening minds to chart a path forward for Alzheimer's and immunotherapy. Across the field, the logjam of laboratory and clinical studies in the growing pipeline is breaking, evidenced by a number of clinical firsts - including Parkinson's and depression. We anticipate more exciting milestones as we finish out the year.

Highlights

- **Depression and Parkinson's disease trials get underway**
- **Seminars feature leaders in regenerative medicine and neuromodulation**
- **Alzheimer's workshop helps define roadmap toward clinical trials**
- **Foundation sets target for end of year giving**

FOCUSED ULTRASOUND FOUNDATION

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Creating Knowledge: Research Milestones

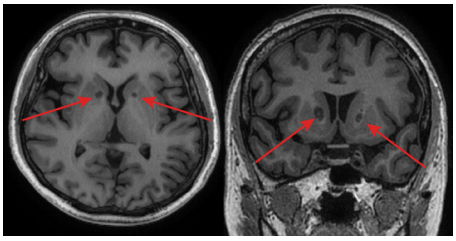
FIRST US PARKINSON'S DYSKINESIA PATIENTS TREATED

Researchers at the University of Maryland and the University of Virginia have performed the first focused ultrasound treatments in the US for dyskinesia associated with Parkinson's disease. These treatments are part of an international pilot study of 40 patients to assess the feasibility, safety, and preliminary efficacy of MR-guided focused ultrasound pallidotomy for treatment of dyskinesia. The Foundation partnered with the Michael J Fox Foundation to fund the study.

Once an avid biker, Kimberly's Parkinson's had made it impossible for her to balance safely. She was forced to turn to stationary bikes until she became the first patient treated at the University of Maryland. Now she's back on her bike and even running!
Read her story >

FIRST DEPRESSION TRIAL BEGINS IN KOREA

The first patient with severe depression has been treated with focused ultrasound. This procedure marks the beginning of a 10-patient pilot clinical trial to determine the feasibility and safety of using MR-guided focused ultrasound to non-invasively destroy a small volume of tissue deep in the brain related to depression. In the initial patient, the target was successfully ablated without complications. If successful, this trial, which is being supported by the Foundation, could lead to a larger pivotal study.



IMMUNOTHERAPY PROGRAM GAINS MOMENTUM

Immunotherapy has emerged as a key player in cancer treatment, and we have taken notice. Over the past few months, we established an Advisory Board of experts in cancer immunotherapy and focused ultrasound and are designing pre-clinical and clinical trials. One such trial is a collaboration between the Foundation, the Melanoma Research Alliance, and the Cancer Research Institute on a study investigating immunotherapy and focused ultrasound to treat brain metastases.

Research Program Update

The Foundation funded two new research projects this fall.

Histotripsy* to Treat Renal Carcinoma

University of Washington

Pediatric Bone Tumor Patient Data Registry

The Hospital for Sick Children, Toronto

*Histotripsy is a non-thermal use of ultrasound to destroy tissue that could significantly improve accuracy and speed of treatments.

FIELD REPORT ADVANCES IN THE FOCUSED ULTRASOUND COMMUNITY

- **Pancreatic cancer study in Barcelona shows potential survival benefit**
- **Researchers at Stanford perform the world's first FUS treatment for bone metastases on a patient with orthopedic hardware**
- **Insightec announces bone metastases treatment will be reimbursed in 18 additional states**
- **Theraclion will begin commercial treatments in Europe for thyroid nodules**
- **Profound Medical partners with Philips on a device to treat prostate cancer**

Increasing Awareness

FOUNDATION HOSTS SEMINARS ON EMERGING APPLICATIONS OF FUS

Joseph Frank, MD, from the National Institutes of Health, discussed using focused ultrasound to boost stem cell homing – a technique that could transform regenerative medicine.

Jean-Francois Aubry, PhD, from Institut Langevin in Paris spoke to the various effects that can be induced in the brain using ultrasound-induced neuromodulation, such as opening the blood-brain barrier and tissue displacement.

Both presentations were broadcast as interactive webinars and can be viewed on our website.

MEDIA COVERAGE REFLECTS ACCELERATION

This fall, exciting research breakthroughs in Parkinson's and depression spurred an uptick in media coverage as many major news outlets reported on these successes.

Medscape

THE BALTIMORE SUN
baltimoresun.com

NEUROSCIENCE NEWS.com

HUFFPOST LIVING

4 The Foundation hosted four awareness events this fall. These gatherings allow us to spread the word about the technology and our work.

VIRGINIA REPRESENTATIVES SUPPORT FOCUSED ULTRASOUND

US Congressman Robert Hurt and State Delegate Steve Landes visited the Foundation to learn about the promise of focused ultrasound and our mission. The staff shared the latest research developments to come out of the University of Virginia and around the globe.

I commend the Foundation for its leadership and innovation in bringing academic research, treatment facilities, and capital resources all together to collaborate in the best interest of the patient. -Congressman Hurt

Aggregating and Sharing Knowledge

FUS BIOLOGICAL EFFECTS FEATURED ON SITE

We have updated the Mechanisms of Action section of our website and a comprehensive White Paper is now available for download that includes illustrations for each mechanism - thermal ablation, opening the blood-brain barrier, and mechanical tissue destruction, among others. All illustrations can be freely used by the community.

Focused ultrasound can induce **18** different bioeffects when it interacts with tissue.

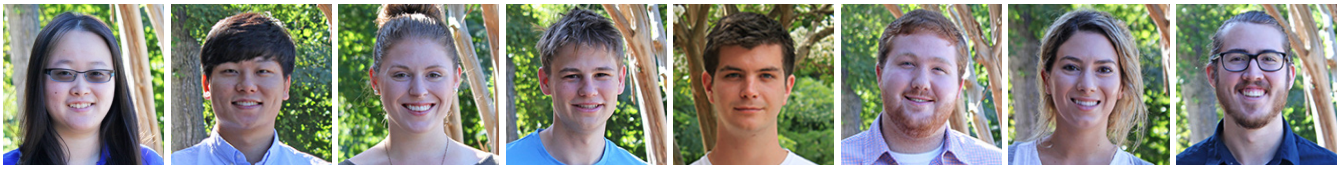
READERSHIP AT ALL-TIME HIGH

The Foundation's communication channels bring our audience - including researchers, clinicials, industry, and patients - abreast of happenings in the field. This fall, our website viewership hit record numbers of views, and our newsletter now reaches more than 8,100 people.

Cultivating the Next Generation

SUMMER INTERNS TACKLE DIVERSE PROJECTS

Eight students spent time with the Foundation team this summer, working on projects spanning from technical research to communications to assessing how the technology fits into the evolving health care environment. Three of the 2014 interns remained with us over the year to delve deeper into their projects.



Convening the Community

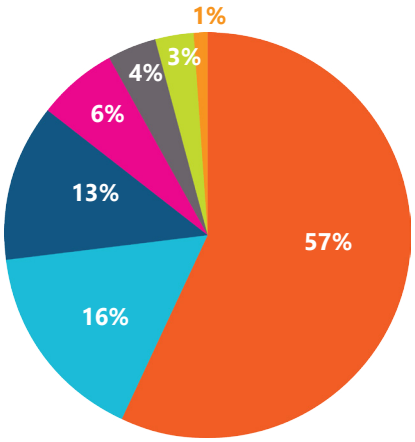
ALZHEIMER'S WORKSHOP TO DEVELOP RESEARCH ROADMAP

The Foundation hosted a workshop to discuss the state of the field, current challenges, and future research directions for using focused ultrasound to treat Alzheimer's disease. Participants included technical experts, leading Alzheimer's neurosurgeons, neurologists, neuroscientists, neuroradiologists, and representatives from FDA, medical research foundations, and industry. A White Paper summary of the outcomes is available.

Finances

ALLOCATION OF FUNDS

2015 YEAR TO DATE: $3,779,000



	ACTUAL YTD	BUDGET YTD
RESEARCH	$2,157,000	$3,694,000*
FUNDRAISING	$607,000	$776,000
COMMUNICATIONS	$476,000	$600,000
SCHOLARS PROGRAM/ FELLOWSHIPS	$238,000	$212,000
EXTERNAL RELATIONS	$149,000	$166,000
REIMBURSEMENT/ FIBROID RELIEF	$111,000	$221,000
SYMPOSIA/MEETINGS	$41,000	$39,000

*Research spending has been low due to delays in starting a number of clinical trials. We expect this number to rise significantly in the coming months.

The Foundation's 2014 Audited Financial Reports are available on the website.

FUNDING GOALS ON TRACK

Thanks to our generous donors, the Foundation raised a total of $5.6 million thus far in 2015. We hope to round out the year strong and raise an additional $2.4 million, to meet our target of $8 million. We appreciate your support of our mission to bring this technology to patients in the fastest time possible!

If you would like additional information or want to discuss how you can support our mission, please contact:
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