

Pioneering
Non-Invasive
Surgery



MEET THE EXPERT

Dr. David Brenin

Chief of Breast Surgery and Co-director of UVA Breast Center

University of Virginia, Charlottesville, USA

***“We will soon begin a trial combining
echotherapy and immune therapy to treat
stage 4 breast cancer.”***

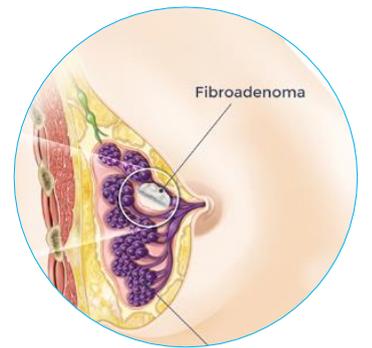
Dr. Brenin, can you please describe your institution?

The University of Virginia (UVA) is an academic medical center. The study of health and medicine has been central to UVA since its founding. Today, the University is a leader in the advancement of health sciences, basic and translational research, the training of medical and nursing professionals and the delivery of world-class health care. I am co-directing the UVA Health System's Breast Care Program, which offers preventive, diagnostic and therapeutic breast disease services.



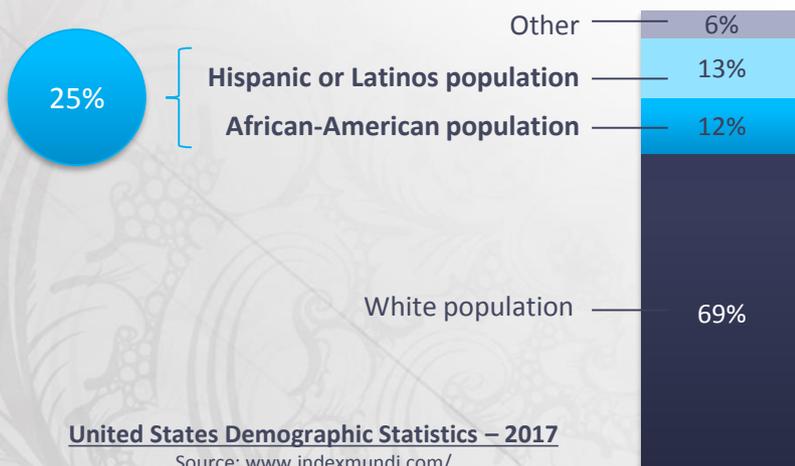
Why and when is it necessary to treat a breast fibroadenoma?

It is necessary to treat a breast fibroadenoma when it is so big that it is causing the skin on top of the fibroadenoma to be compromised or when it induces pain. However, many women are bothered by the fibroadenoma because it is a lump in the breast and most people really find it very alarming and rightly so. They wish **to be relieved of the symptoms of the fibroadenoma; in other words, not be able to feel the tumor or pain anymore.**



A quarter of the American population is Hispanic or African-American, are there any specificities regarding breast fibroadenoma in these population? Is having a non-invasive method particularly relevant for these populations?

That's a good question. **Fibroadenomas are very common in Latinas** typically born in Central and South America **and** are also common **in African-Americans**. One of the important aspects of a non-surgical treatment for these patients is that they are more likely to develop keloids so **the ability to avoid any incision like with echotherapy** in a patient who is predisposed to develop a keloid **is of great value.**



United States Demographic Statistics – 2017
Source: www.indexmundi.com/

"Patients who have darker skins are more likely to develop keloids."

Could you tell us the reason why you, as a surgeon, considered a non-surgical method?

The only treatment for fibroadenoma without focused ultrasound ablation is surgery. When we do surgery, we make an incision over the top of the fibroadenoma and we remove the fibroadenoma. After the surgery, the lump is gone. The shape of the breast is usually preserved without any difficulties but we need to make an incision and whenever we make an incision, there is going to be a scar. So, that is really the main difference between these two treatments. It is our hope that echotherapy may allow us to treat a fibroadenoma without an incision and for patients to go back to their daily activities with minimal interruption.

“The ability to avoid any incision like with echotherapy is of great value.”

You are the principal investigator of the echotherapy FDA study for fibroadenoma. Why do patients participate in the study ?

Patients participate in studies for many reasons. For instance, patients participate in breast cancer studies and in breast tumor studies because they really want to be part of the advancement in the field. Specifically, for this study using echotherapy in the treatment of breast fibroadenomas, **the patients are motivated by the idea of being able to get rid of the lump in their breast and the pain that this lump is causing without a scar.**



Inclusion Criteria

Palpable fibroadenoma

Fibroadenoma size $\geq 0.2\text{cc} - \leq 10\text{cc}$

Patient candidate for surgery

Pain $\geq 30\text{mm}/100\text{mm}^*$

Anxiety $\geq 30\text{mm}/100\text{mm}^*$

*measured on VAS as a maximum level during the last 30 days

Could you please describe your experience so far with echotherapy?

My experience in the trial today has been that we have been able to use the device with great ease. Preliminary findings from our first single arm, feasibility study of female patients diagnosed with palpable breast fibroadenomas showed that all **patients reported that they would recommend the procedure to a friend or family member.** Reduction in the size of the palpable mass was reported by both the patient and evaluating team in all cases. Data showed that treatment with the echotherapy device was well-tolerated by patients with minimal discomfort. (Data presented during FUS Symposium 2016)



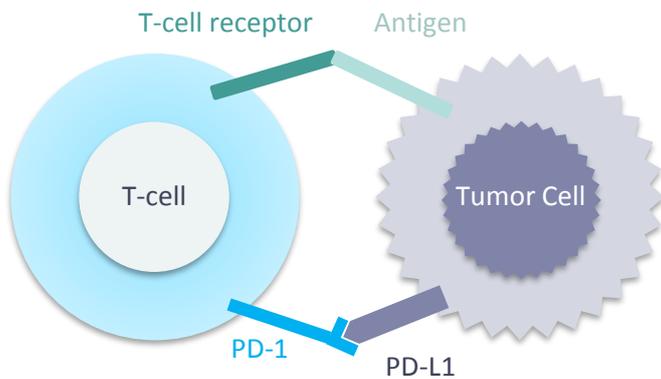
What could for you be potential new application areas for echotherapy?

Well it is my hope to apply echotherapy not only to the treatment of benign tumors in the breast but really continue to move it forward to treat malignant tumors. At the University of Virginia, we are actively pursuing that, **we will open a trial in the very near future using echotherapy in combination with immune therapy to treat patients with stage 4 breast cancer.** And then, depending on the results of that trial, hopefully, we could move forward to treating patients with breast cancer with earlier stage tumors.

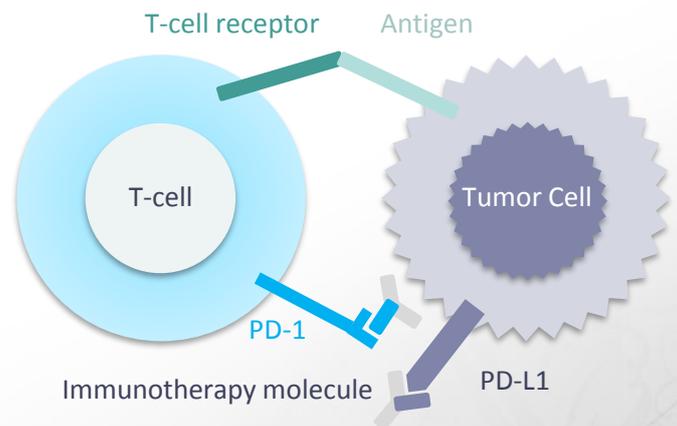


Why do you think echotherapy could be effective in breast cancer?

Immune therapy stimulates the body's own immune system to fight tumor cells. **Focused ultrasound** has also been demonstrated to induce an immune response. It is our hope that when delivered as a combined treatment **the two together may potentiate the immune response against the tumor.** Echotherapy could be used to pre-treat a tumor in order to shrink the overall volume and, perhaps more importantly, allow the patient's own immune system to access and recognize the malignant cells.



Deactivated T-cell (cancer cell can evade immune attack)



Activated T-cell coordinating an immune attack

Echopulse® is a class IIb medical device (according to Directive 93/42/EEC) designed and marketed by Theraclion. Echopulse® has received CE-mark for non-invasive treatment of breast fibroadenomas and thyroid nodules – CE n° 0120. Not covered by statutory health insurance schemes in Europe (with the exception of Germany where it is covered by several insurance companies). Before use, read the instruction for use carefully.

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