LIMITED OBSERVATONAL STUDY:
IMAGE MONITORED PEMF TREATMENT OF HYPERPLASIA

Clinical performance test report by:

Dr. Robert L. Bard

121 E60th St. #6A New York, NY

212.355.7017

Disclaimer: The report is a private pilot study about the use of Pulsed Bioenergy technology on Prostate Hyperplasia (enlarged prostate) conduced by Dr. Robert L. Bard under direct support of the Integrative Health Research Center (NYC) and the AngioFoundation Research Institute. All results of this independent and impartial study are submitted as academic data and is produced by the clinical research team from the aforementioned agencies. This report is established without any commercial influence by any outside parties and any mention of technology (brands or models) applied in this study are strictly for reference and is not to be construed as commercial or marketing in any way.

LIMITED OBSERVATONAL STUDY:
IMAGE MONITORED PEMF TREATMENT OF HYPERPLASIA

ABSTRACT

On average, the prostate is about the size of a walnut. It grows to roughly the size of a Ping-Pong ball, weighing 30 to 35 grams. In many men, it continues to grow even further, to the size of a tennis ball or larger. The normal prostate gland has measures 3 × 3 × 5 cm approximately or a volume of 25 ml. [1,2] According to statistical reports by Yale Medicine, About 50% of men between the ages of 51 and 60 have BPH, and that number jumps to 70% among men aged 60 to 69 and around 80% of men over 70 years of age [3].

Complications of benign prostatic hyperplasia (or enlarged prostate) include: acute urinary retention, chronic, or long lasting urinary retention, blood in the urine, urinary tract infections (UTIs), bladder & kidney damage or bladder stones.[4] The most common solution (thus far) to address this condition is medicinally with Alpha blockers. This is recognized as the recommended first-line treatment for men with mild to moderate symptoms. It is noted that alpha blockers carry a variety of side effects including dizziness and low blood pressure.[5] There are also invasive solutions to enlarged prostate including laser therapy, microwave heat, or prostate tissue compression. Partial prostate removal and full removal are more invasive but may be necessary for extremely large prostate glands.

As the medical community is (now) pursuing non-invasive alternatives for the many health conditions, addressing hyperplasia continues to be a significant interest in the medical community. Bard Diagnostics and Wellness Now, under a joint study under the AngioFoundation(501c3) is conducting a preflight study of the effects of Pulsed Bioenergy Therapeutic innovations. This Image-Guided program employs the use of **PEMF (Pulsed Electromagnetic Frequency) technology**, or neuromagnetic stimulation to address symptoms of enlarged prostate.

EFFICACY REVIEW

Dr. Robert Bard leads the clinical evaluation of the PEMF treatments of four (4) volunteers @ Bard Diagnostics clinical facility at 121 E. 60th St. NYC. In pursuit of the many reports of Electromagnetic Stimulation providing significant success in inflammation reduction, applying the effects of the cellular regenerative properties of neuromagnetic field directly on a pre-confirmed enlarged prostate gland dictates the same logical path of size reduction in an enlarged prostate.

Supervised exposure shall be provided by Dr. Bard and his research team through the use of real-time 3D Doppler Ultrasound and other non-invasive imaging devices. The initial (Image Guided) treatment shall be conducted @ the NYC clinic where Dr. Bard shall establish base line studies and regular (bi-weekly) PEMF treatments and ultrasound scans under periodical comparative imaging. In addition, each volunteer will take home a personal PEMF device for use twice a day at a given power setting and dosage duration. This preflight study is a one month (30 days) micro-review of the PEMF's function and a logging of the volunteer's exposure response via imaging. Dr. Bard shall record any and all progress within the time allotted- collecting any/all quantifiable data about the state of the volunteer's prostate size and health. Any progress is identified by a reduction in size, blood velocity (flow) within the immediate prostate area as well as the elasticity or firmness of the prostate tissue. This information is often collected by the diagnostic imaging technologies selected for this study at Dr. Bard's scanning devices.

PERFORMANCE REPORT

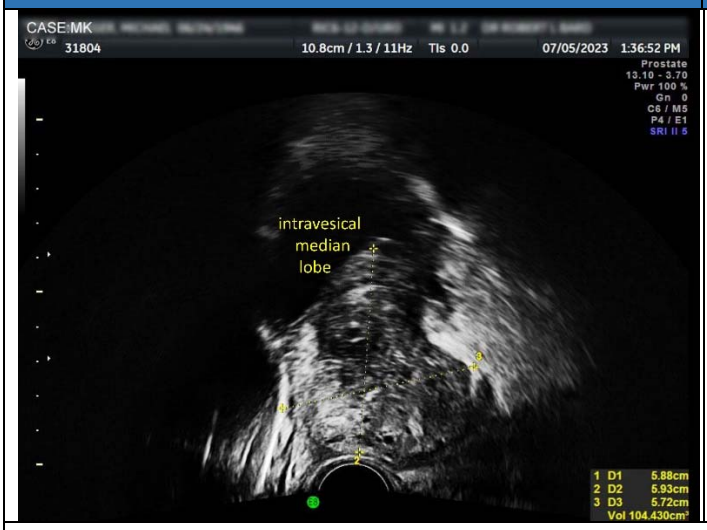
The objective of this limited study was 2 fold: To assess for any unexpected side effects and demonstrate physical changes in the treated gland with at home PEMF treatment. Patient parameters: printed

Results
No adverse effects were reported in 4/4 subjects. 75% of the group had baseline and 30 day followup volumetric ultrasound with 3D high resolution probes and demonstrated variable volume loss. From 2 years of experience with the Aurawell device, it is understood that these technologies are not uniformly adaptable to all patient types with the uniform probe positioning for this study and limited length of time for the procedure.

A full clinical trial with standard urologic measurements and ultrasound measurements of:

1-blood flow perfusion of inflammatory microcirculation
2-elastography of physical characteristics-scarring or fibrosis
3-presence of macrocalculi or change in microcalculi
4-presence of bladder pathology (stone, tumors, postvoid residual, hypertrophy)

Overview of therapy
Both benign enlargement and increased incidence of cancer are associated with micro inflammation. PEMF therapy may result in a reduction in kidney obstruction, a decrease in urinary symptoms and a reduced incidence in cancer as a benefit of routine use may be forthcoming.

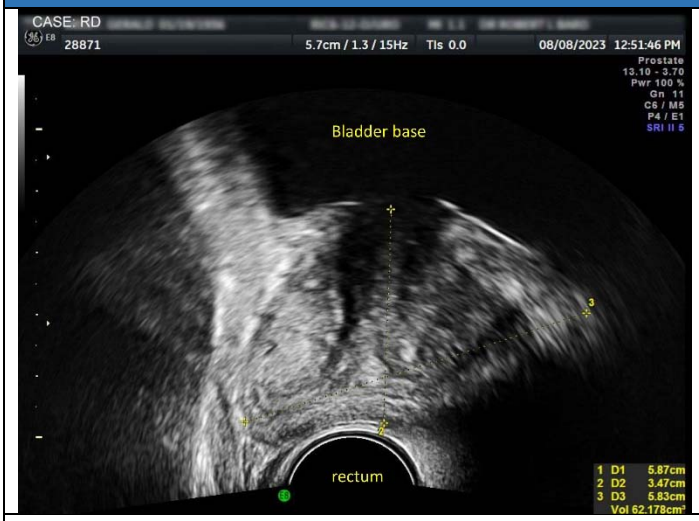
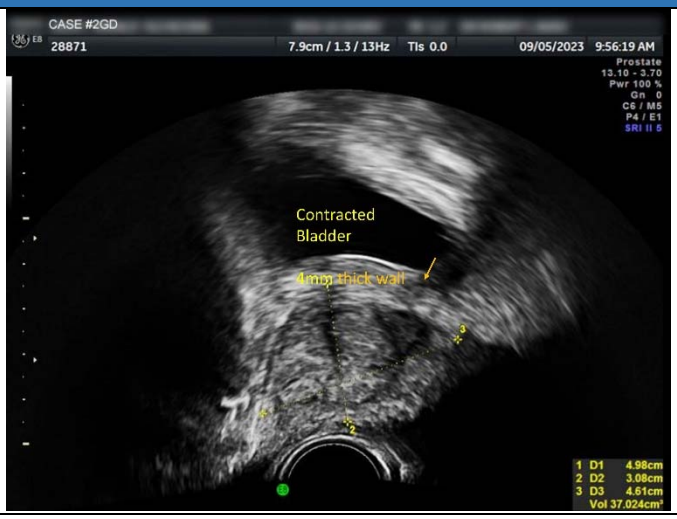
BASE LINE: PRE-TREATMENT	AFTER 30 DAYS
	

Case study 1: Caucasian male, 69 years old

SONOGRAM: RE+ right psa elevated Comparison 7/5/23 1 month PEMF

Time out: risks/benefits/possibility of false positives discussed
Prostate, bladder and pelvic paraprostatic spectral Doppler vascular study was performed using transrectal 4D real time b mode examination, power Doppler, spectral flows and 3D workstation analysis. This report sequence was limited to volumetric changes based on non invasive therapies. Dre=+/- left

Prostate volume:
Previous pre-treatment prostate vol: 104 cc
Current post treatment prostate vol: 92 cc
Vascular area: r lateral 9x7 prev 9x7 mm. VI=1% unchanged Vessel Index is a quantitative measure of inflammatory or malignant vessels. Note the absence of increased vascularity in the 9x7 mm focus signifies no evidence of abnormally induced vessel related adverse effects over the one month study period

BASE LINE: PRE-TREATMENT	AFTER 30 DAYS
	

Case study 2: Caucasian male, 87 years old

SONOGRAM BLADDER / PROSTATE

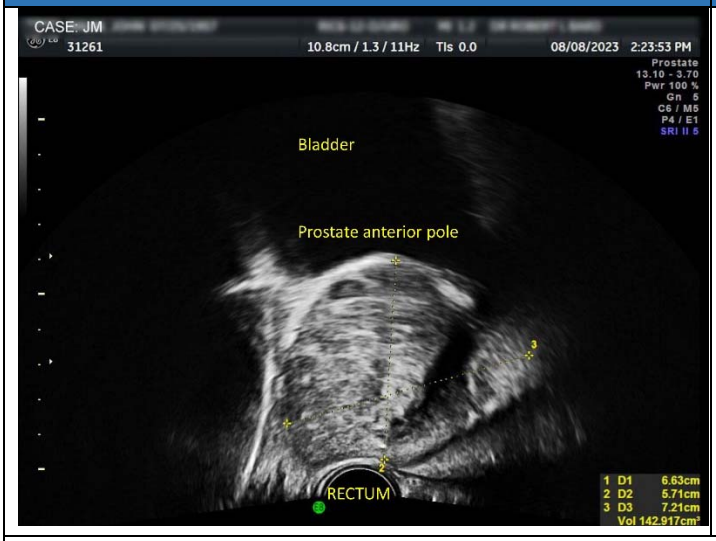
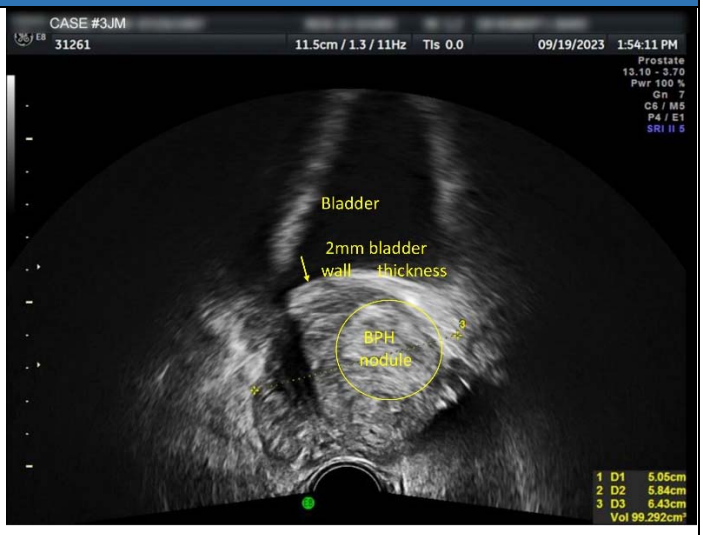
BLADDER-PEMF 1 month comparison 8/8/23

Previous pre-treatment prostate vol: 62 cc

Current post treatment prostate vol: 37cc

Volume measurements of the gland are influenced by bladder wall thickness as the tissues are adjacent.

The use of 3D multiplanar real time imaging permits clear delineation of these structures.

BASE LINE: PRE-TREATMENT	AFTER 30 DAYS
	

Case study 3: Caucasian male,71 years old

SONOGRAM BLADDER / PROSTATE

Comparison 8/8/23

Hx: DRE +/- right midgland bph pemf

Time out: risks/benefits/possibility of false positives discussed

Prostate and pelvic paraprostatic spectral Doppler vascular study was performed using transrectal 4D real time b mode examination, power Doppler, spectral flows and 3D workstation analysis.

Previous pre-treatment prostate vol: 143 cc

Current post treatment prostate vol: 100 cc

As the benign glandular hypertrophy and/or inflammatory findings respond to therapy additional pathology may be discerned, ie, in this case a 2cm echogenic benign nodule is clearly identified.

PHYSICIAN'S CONCLUSION STATEMENTS

Advanced imaging capabilities on ultrasound diagnostics permit real time image guided treatment options with today's non invasive and minimally invasive therapies which began in 1998 with hemodynamic observations of tumor activity and the treatment response to thermal therapies. The global RECIST study highlighted the problem with tumor volume decrease as an absolute marker of therapeutic success since the influx of immunologic cells, fluid from tumor necrosis and benign tissues may enlarge a malignancy in the short term. Vessel density of inflammatory or cancerous tissues is now a reliable radiographic parameter of therapy response as is decrease of the physical elasticity of desmoplastic infiltration quantifiably measures in kiloPascals by shear wave elastography.

1) *Average size prostate: https://utswmed.org/medblog/what-we-know-about-your-prostate/#:~:text=On%20average%2C%20the%20prostate%20is%20about%20the%20size%20of%20a%20walnut.&text=It%20grows%20to%20roughly%20the,weighing%2030%20to%2035%20grams.&text=In%20many%20men%2C%20it%20continues,a%20tennis%20ball%20or%20larger.*
2) *Ultrasound of the prostate – PMC : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842183/*
3) *Enlarged Prostate (Benign Prostatic Hyperplasia) https://www.yalemedicine.org/conditions/enlarged-prostate-benign-prostatic-hyperplasia-bph*
4) *Prostate Enlargement (Benign Prostatic Hyperplasia): https://www.niddk.nih.gov/health-information/urologic-diseases/prostate-problems/prostate-enlargement-benign-prostatic-hyperplasia*
5) *Alpha Blockers for the Treatment of Benign Prostatic Hyperplasia - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2213889/*
6) *Prostate resection - minimally invasive - https://medlineplus.gov/ency/article/007415.htm*