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**LIMITED OBSERVATIONAL STUDY:
IMAGE MONITORED PEMF TREATMENT OF HYPERPLASIA**

Clinical performance test report by:
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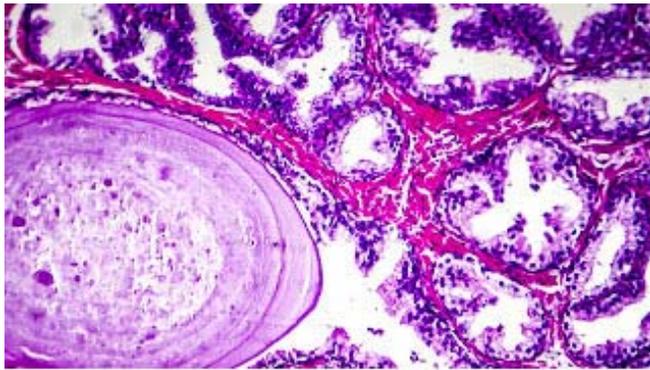
Disclaimer: The report is a private and independent pilot study about the use of PEMF/Pulsed Bioenergy technology on Prostate Hyperplasia (enlarged prostate) conducted by Dr. Robert L. Bard sponsored by the Integrative Health Research Center (NYC) and the AngioFoundation Research Institute. All results of this academic impartial study are submitted as academic data without any commercial influence by any outside parties. Any mention of technology (brands or models) applied in this study are strictly for reference and is not to be construed as commercial marketing in any way.

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2023 STUDY: IMAGE MONITORED PEMF TREATMENT OF HYPERPLASIA

ABSTRACT

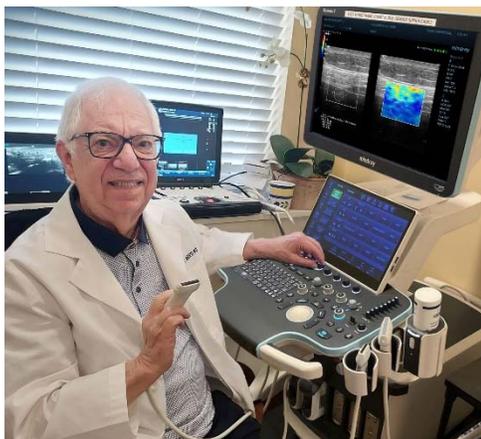
On average, the prostate is about the size of a walnut. It grows to roughly the size of a Ping-Pong ball, weighing 30 to 35 grams. Within a major portion of adult males, the prostate continues to grow even further up to the size of a tennis ball or larger. The normal prostate gland has measures $3 \times 3 \times 5$ 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].



Histopathology of prostate gland hyperplasia, light micrograph, photo under microscope

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

Since march of 2022, Dr. Robert Bard initiated a multi-pathology study of PEMF treatments. This specific study is a clinical evaluation of the PEMF treatments of four (4) volunteers @ the Bard Diagnostic 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.

IMAGE GUIDED APPROACH TO THE TREATMENT OF PROSTATE HYPERPLASIA

by: Robert L. Bard, MD

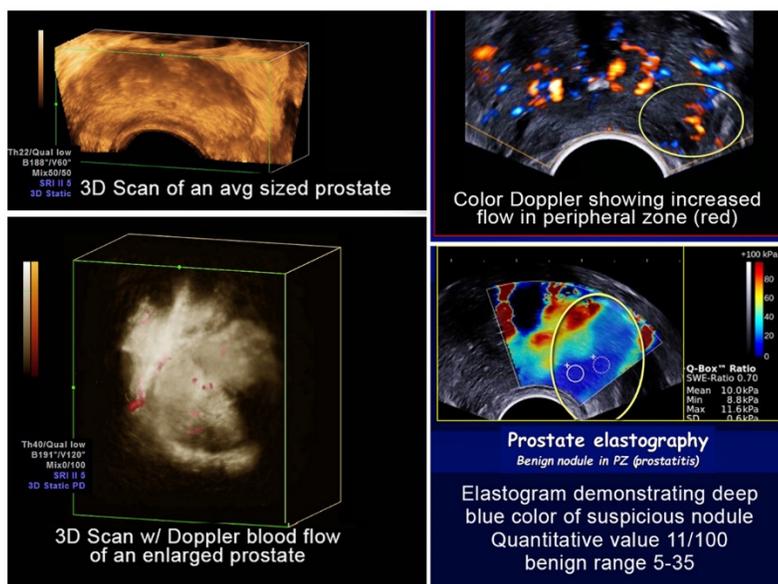
Procedurally, the best way to study an enlarged hyperplastic prostate gland is as a low grade inflammatory process, similar to women with fibrocystic breasts considered to be breast inflammation. [1] This does not need to be treated with antibiotics since this inflammation is often aligned with a chronic disease and requires a long-term treatment protocol. One example of this therapy is using a pulse electromagnetic applicator (PEMF) which can be applied over the groin area or under the pelvis (even in the car seat). For treatment applications, this protocol is recognized to be safe, painless, comfortable, and user-friendly on a long-term basis.

Reducing low grade inflammation can be managed with relatively low energy treatment over an extended yet controlled period of time. Daily application of energy therapy inducers to the prostate and bladder area has been proven to reduce bladder urge, the need to urinate and improve the urine flow out of the enlarged prostate. It also decreases the chance of incontinence because the bladder that is more easily emptied is less likely to overflow in an uncontrolled manner.

PSA READINGS vs IMAGING

In 1930, the PSA was developed by the University of Arizona as a rape test. It was accurate for finding and identifying semen in rape victims but it was never made to be diagnostic for prostate cancer. The 2004 Journal of Urology stated the PSA is 2% accurate in diagnosing prostate cancer definitively, which means that the digital

rectal exam is at least three times more accurate than the PSA blood test in finding clinical prostate cancer. Also, in benign diseases such as prostatitis or benign enlargement with older age, the PSA level automatically rises in most patients. Therefore, the PSA lifespan has ended, much like the x-ray has ended in the use of prostate disease because we use CT, MRI and ultrasound. CT and MRI are observed by the imaging community as being replaced (for many applications) by a trending substitute; the 3D Doppler and elastography to scan the prostate for prostate cancer aggression and capsule integrity worldwide [4].



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- 2) Ultrasound of the prostate – PMC : <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842183/>
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MONITORED PERFORMANCE REPORT (4 Case Studies)

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

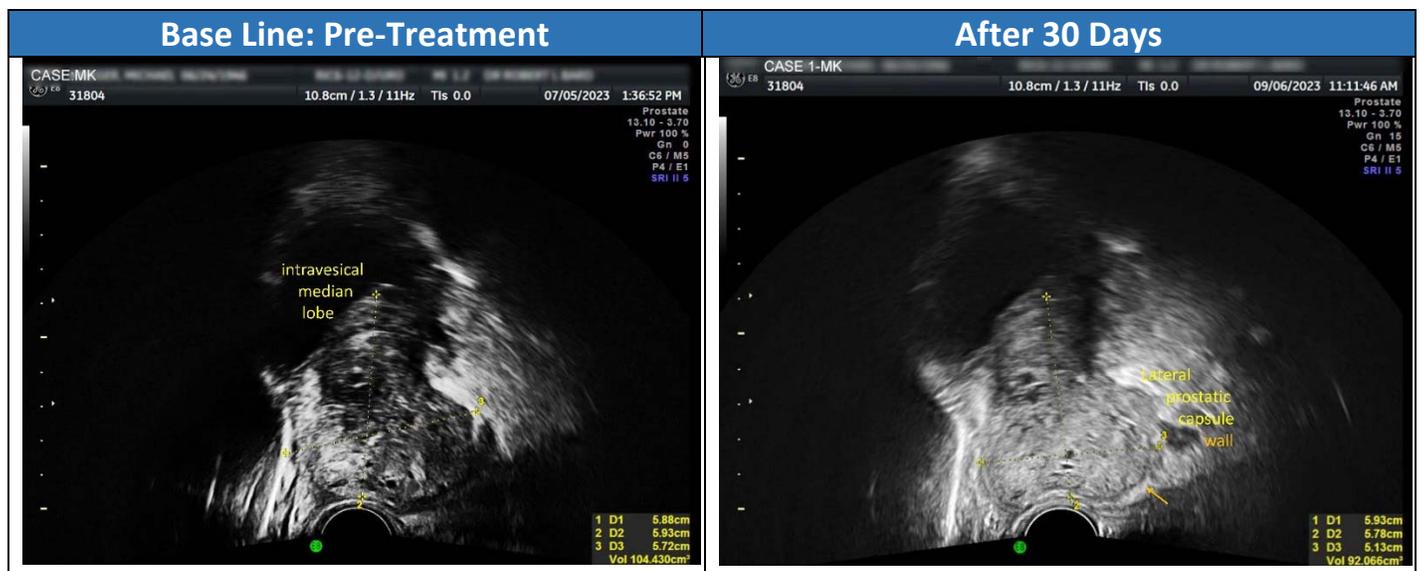
No adverse effects were reported in 4/4 subjects. 75% of the group had baseline and 30 day followup volumetric ultrasound with 3D high resolution probes and demonstrated variable volume loss. From 2 years of experience with the Aurawell device, it is understood that these technologies are not uniformly 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.



Case study 1: Caucasian male, 69 years old

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

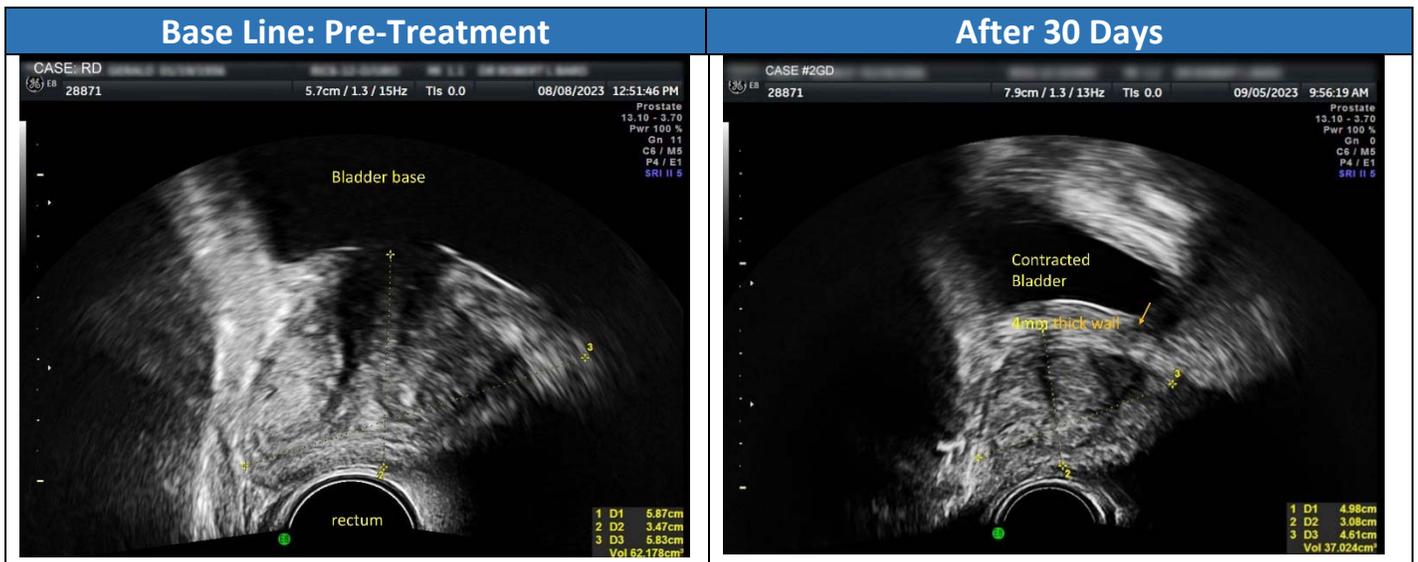
Time out: risks/benefits/possibility of false positives discussed

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 comparison (Reduction- 12cc)

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



Case study 2: Caucasian male, 87 years old

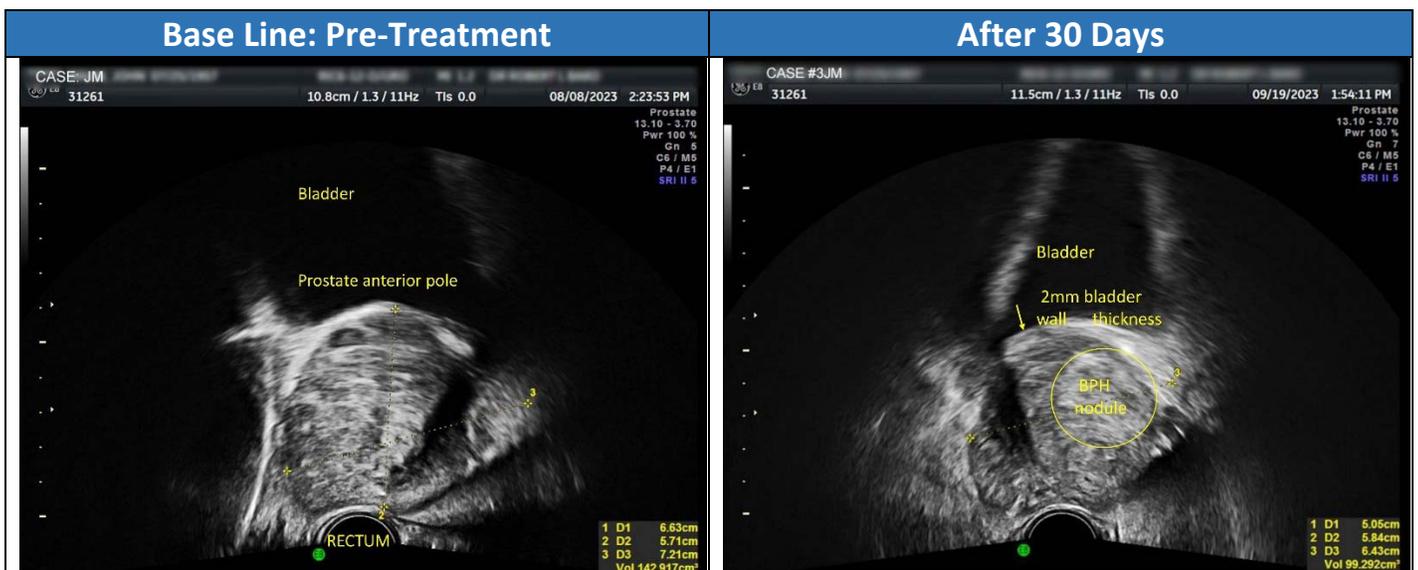
SONOGRAM BLADDER / PROSTATE

BLADDER-PEMF 1 month comparison 8/8/23

Prostate volume comparison (Reduction- 25cc)

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.



Case study 3: Caucasian male, 71 years old

SONOGRAM BLADDER / PROSTATE Comparison 8/8/23

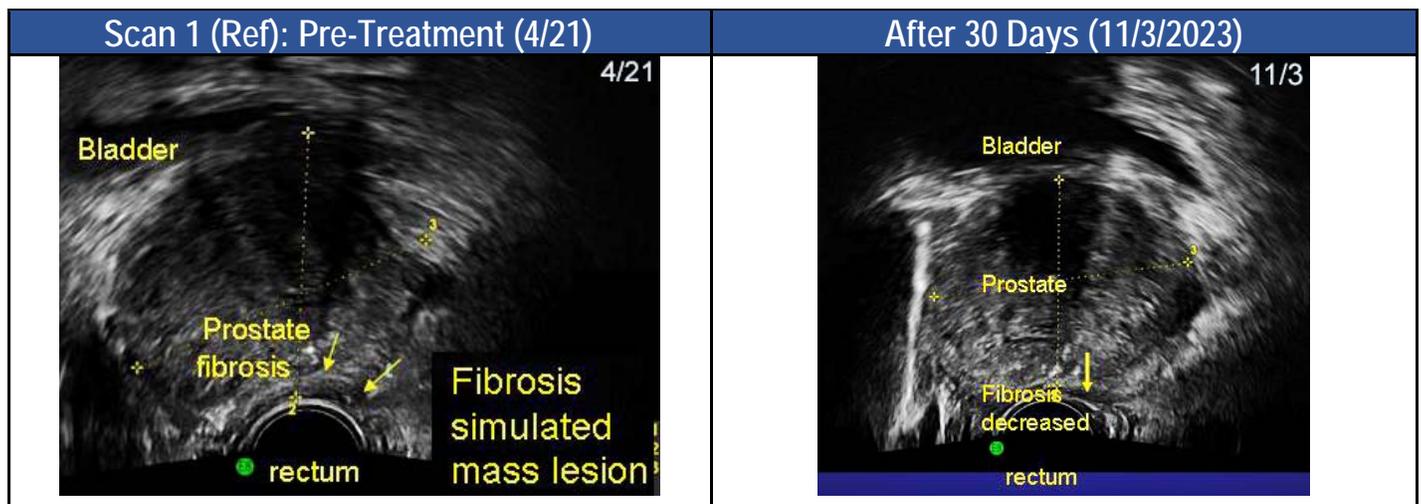
Hx: DRE +/- right midgland bph pemf

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.

Prostate volume comparison (Reduction- 43cc)

Pre-treatment prostate vol: 143 cc | 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.



Case Study 4: Caucasian male, 69 years old

Hx: dysuria comparison 9/22, 4/23 PEMF treatment | Urgency decreased flow increased

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.

DRE: Digital Rectal Exam: regular no mass noted. Vascular area: none. Avascular area: none

Prostate volume comparison (Reduction- 16cc)

Base line Protate volume: 100cc | Current Prostate volume: 84 cc

DOPPLER SPECTRAL: Prostatitis right>left diffuse decreased | Triphasic waveforms Peak vel 7cm/s

BLADDER – normal outline | 3D IMAGE RECONSTRUCTION: intact | SEM VESICLE –Symmetric

IMPRESSION: PROSTATITIS / BPH DECREASED

- No Vascular Lesion Normal Capsule On 4d
- Clinical Correlation Recommended
- Routine Follow Up 6 Months Recommended findings



Supplemental (Case #4): Subject's Background Prostate Study + MRI

PHYSICIAN'S NOTES: Subject #4 has been followed by MRI and Ultrasound Imaging for 6 years due to a history of toxic exposure from the 911 WTC event as a member of the FDNY. Inflammation (possibly from carcinogenic exposure, trauma or chronic infection) caused scarring of the prostate which produces tissue fibrosis that clinically felt like a firm mass in the gland on the examiners Digital Rectal Exam (DRE). MRI that is commonly used now instead of CT scans cannot differentiate inflammation from cancer- 3D Doppler sonogram is selected as optimal diagnostic option. (MRI taken 9/20/2023 (ref: Preno))

Notable success with non-invasive Pulsed Bioenergy Therapy (PEMF) indicated reduction in size and symptomatology within the last 2-year report w/c prompted this current study. The MRI and sonogram pre-treatment (above) reported the volume reduction from 110/100cc to 88cc after daily application of the PEMF device.

Also, the scar formation presented a reduction visually on the interval sonogram and appears to no longer be palpable on the DRE. Subject states urinary urgency and frequency are likewise decreased. Industry reports indicate the use of Doppler ultrasound is beginning to replace the hour long contrast MRI exam for the prostate in many areas without the possible side effects of potentially harmful Gadolinium dye injections. The possibility of non-invasive Bioenergy treatments reducing inflammation and cancer risk from chronic disease is expected to be the subject of future studies.

PHYSICIAN'S CONCLUSION STATEMENTS ABOUT THIS STUDY

By: Dr. Robert L. Bard

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 (Response Evaluation Criteria In Solid Tumors) 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.

PEMF FOR PROSTATE HEALTH

Current research reports show that PEMF is being applied clinically in prostate therapeutic treatments [8,9]. Under the philosophy of inflammation reduction, our pilot study was designed to test PEMF performance and the patient's physiological reaction before and after treatment as we are evaluating the treatment effect in real time. Because we are able to calibrate the strength of the prostate bioenergy entering the body by monitoring the autonomic nervous system we were able to fine tune the therapeutic process. So far we are having measurable success in positively addressing symptoms and (hopefully) will have proven over time a long term goal that reducing prostate inflammation also reduces the incidence of clinical prostate cancer.



Image courtesy of: Sal Banchitta / AuraWell PEMF

It is important to note that low grade inflammation is oftentimes a precursor or potentially mixed with cancers. The possibility of reducing prostate cancer risk by using post bioenergy noninvasive protocols is something that makes clinical sense and has been widely used in other countries [11,12]. Upon the strategic design of our current pilot study, we hope to expand the scientific findings of this protocol to lead to greater use of non-invasive pulsed energy solutions for prostate and allied health problems.



***For more information about this and other performance studies, visit:
www.AngioFoundation.org. All research inquiries, please contact BARD DIAGNOSTIC
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