DEMO DAY WITH CALIBER-ID:
TEST DRIVING THE REFLECTANCE CONFOCAL MICROSCOPY

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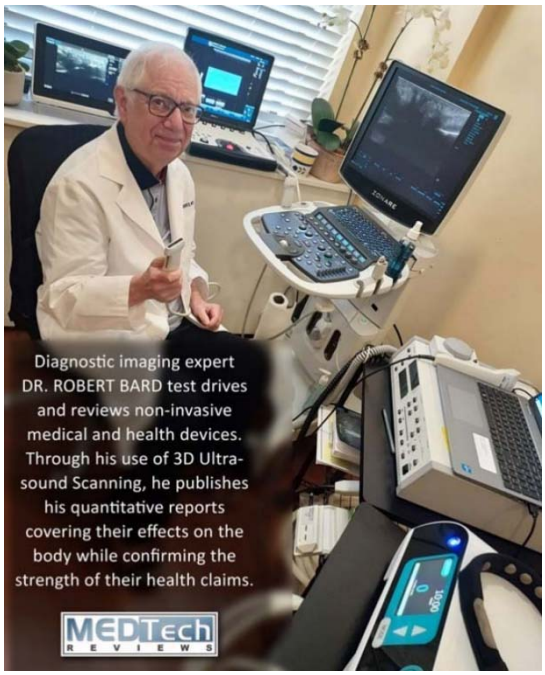
BACKGROUND



Since its official launch in Dec., 2001, the AngioFoundation (officially known as The Biofoundation for Angiogenesis Research & Development) was committed to conducting various disciplines of clinical research to support the advancement of technologies, treatment protocols and diagnostic science. Our funding supports research concepts and exploratory studies of minimally invasive modalities to treat cancer and inflammatory arthritis by analyzing "angiogenesis" or new blood vessel (angio) formation (genesis). The AngioFoundation's public mission is to advance image guided diagnostic and therapeutic technologies worldwide and supports teaching programs for physicians on new modalities to diagnose and deliver therapies for cancer and allied diseases including inflammatory arthritis.

THE ANGIOINSTITUTE VALIDATION PROGRAM:

Founder, DR. ROBERT L. BARD dedicated his life's work to the expansion of diagnostic imaging in the medical community. His undying commitment to clinical education, technical research and public advocacy of non-invasive protocols helped to forge The ANGIO INSTITUTE.

In support of the global movement of NON-INVASIVE medicine, this New York city-based diagnostic imaging validation lab is established to clinically identify the efficacy, performance and supportive claims set by non-invasive therapeutics and diagnostic solutions. The IHRC offers a non-profit, non-commercialized testing option for health-related innovations who seek an independent and impartial reporting through single-case pilot studies and reporting for public and industry education. IHRC employs credentialed medical professionals and specialists in clinical research whose experience contributes to the unique strategic approach of each test study.

HEALTHTECH REPORTER, IHRC (Integrative Health Research Center) and BARD DIAGNOSTIC IMAGING recently conducted a performance test drive of the VIVASCOPE 1500 reflectance confocal imaging system. CaliberID is recognized for a name in the imaging industry in support of dermatology. This innovation offers a non-invasive solution to analyzing and scanning information about the epidermis and the superficial collagen layers. The Vivascope is a low-powered laser providing real-time, high-resolution images, capturing the natural reflectivity of different cellular structures that can offer important information that may be useful in forming a clinical judgment.

RCM PERFORMANCE TESTING WITH ULTRASOUND COMPLEMENT

On March 25, 2024, Mr. Steven Ridge (VP Sales & Marketing) and Mr. Wes Young (Clinical Applications Mgr) presented a full-demo and contributed a 1-day test drive to Dr. Bard and select patients. They agreed to a full diagnostic performance review of the **Vivascope 1500** while Dr. Bard mirrors the process with his ultrasound probe(s).

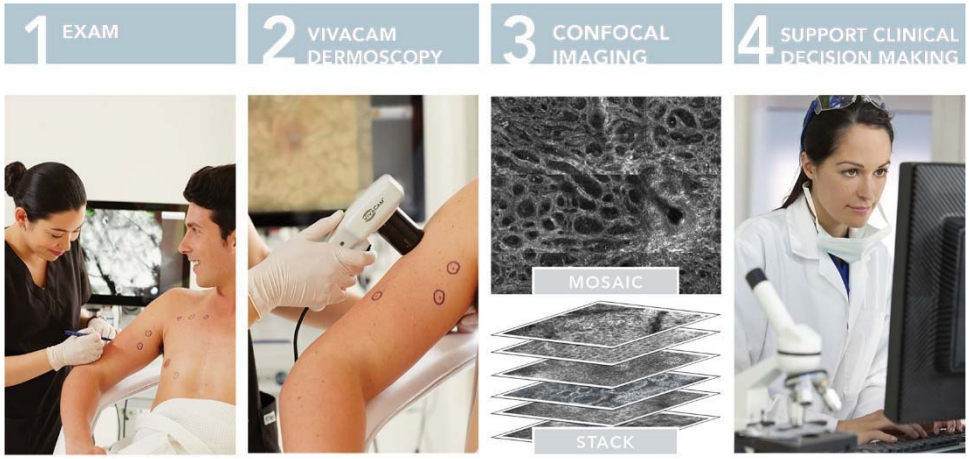
DEMO DAY at the Bard Diagnostic Imaging Center in NYC is a special event in support of clinical education and exploration about non-invasive technologies. Dr. Robert Bard (radiologist and clinical imaging specialist) supports the reporting of both therapeutic and diagnostic innovations that are currently on the market, or are close to deployment. Since the beginning of his career, Dr. Bard has highly supported the use of ultrasound technology for clinical use for its accuracy, quantifiable data collecting and accessibility. He also found the high value of ultrasound imaging to CONFIRM and VALIDATE therapies and therapeutic device performance. In the case of DEMO DAYS, Dr. Bard's research lab (121 E. 60th St. NYC) is the perfect setting for clinical research (trials), pilot studies and test drives of all medically approved technologies.

As a supportive imaging device for dermatologists, medical leaders and researchers alike have embraced the RCM as the "go to" solution for complex disorders like skin cancers, alopecia, melanoma, burns, scars etc. Meanwhile, use of medical imaging solutions such as the ULTRASOUND, gives us that objective and quantifiable data that we need to monitor therapeutic progress and measure the current state of a patient's pathology. Acquiring this form of data says, "this is where you were, this is where the treatment is, and this is where you are now!"

REPORTING TO SUPPORT THE NATIONAL COMMUNITY OF SPECIALIZED CLINICIANS

Since 1971, Dr. Bard's practice and research facility has been successfully positioned in the heart of the top medical centers in the US. As a cancer imaging specialist, he receives referrals from specialized departments at Mt. Sinai, NYU Langone, Lennox Hill, Northwell Health and Memorial Sloan Kettering. He has also built partnerships with many private practices whose interests are to collaborate with Dr. Bard's expertise in (function-based) exploratory imaging and quantitative diagnostic (second opinion) scanning. On a national scale, Dr. Bard is also a fellow of AIUM, a ranking member of the ARTHRITIS FOUNDATION and is a medical advisory board member and recognized keynote speaker for a major list of cancer organizations nationwide.

WHY RCM?



Historically, the advancement of REFLECTANCE CONFOCAL MICROSCOPY (or RCM) is identified as an optical imaging technique for increasing optical resolution and contrast of a micrograph by means of using a spatial pinhole to block out-of-focus light in image formation. Capturing multiple two-dimensional images at different depths in a sample enables the reconstruction of three-dimensional structures (a process known as optical sectioning) within an object. This technique is used extensively in the scientific and industrial communities and typical applications are in life sciences, semiconductor inspection and materials science.


Vivascope 1500 scan head (Gen 4)

As a life-long advocate for diagnostic imaging, Dr. Bard promotes non-invasive imaging to lead the future of clinical reporting and patient care evaluation. He supports the importance of RCM and its “remarkable strategic design” in and use of light and its ability to penetrate a skin specimen in a controlled depths.

THE FUTURE OF IMAGING

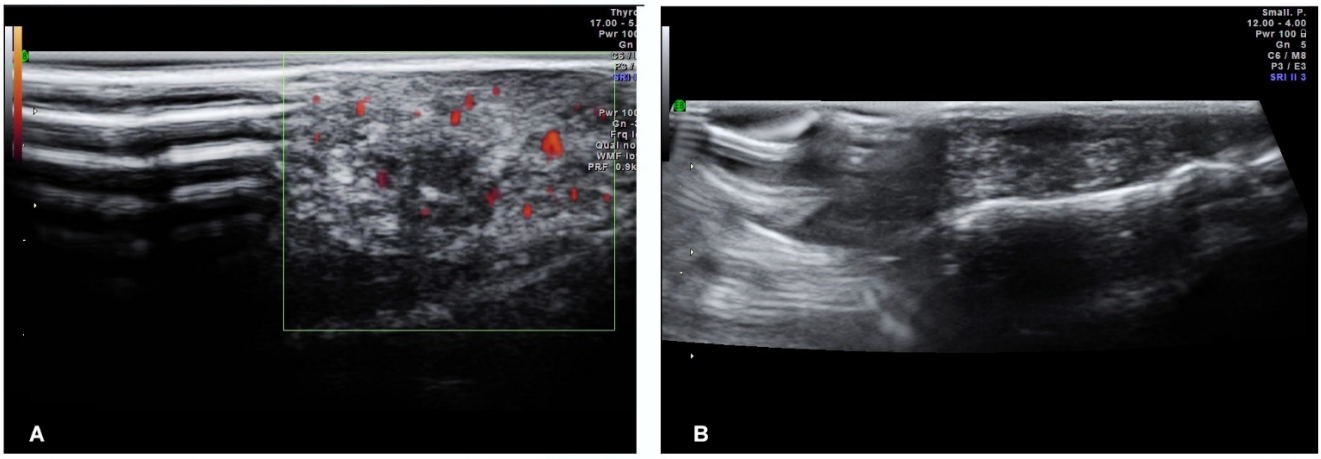
Imaging gives the patient confidence to continue the care knowing that our treatment is actually helping and that it's moving forward. It is also a blessing to physicians as it supports a safer intervention procedure, preventing potential 'land mines' and surprises. To know that it's not just psychosomatic, but they see data and what gets monitored and tracked and gets repeated. So that makes for a more compliant patient and then gets us a faster and better result.

Use of real-time monitoring through non-invasive innovations allow therapists to track the pre and post sessions as far as what's happening in in the tissue and what's happening with blood flow. We look at the imaging under the skin surface that normally people wouldn't be able to see. By this, we can track different things with light therapy, but on the average, most response happens over time. We don't have to wait till their next visit to identify response. We can adjust our treatment midflight- and change treats registered patients suffering from various chronic disorders (including a rotator cuff tear & other MSK joint injuries, psoriatic arthritis and psoriasis on the skin.

INITIAL REPORT ON RCM PERFORMANCE

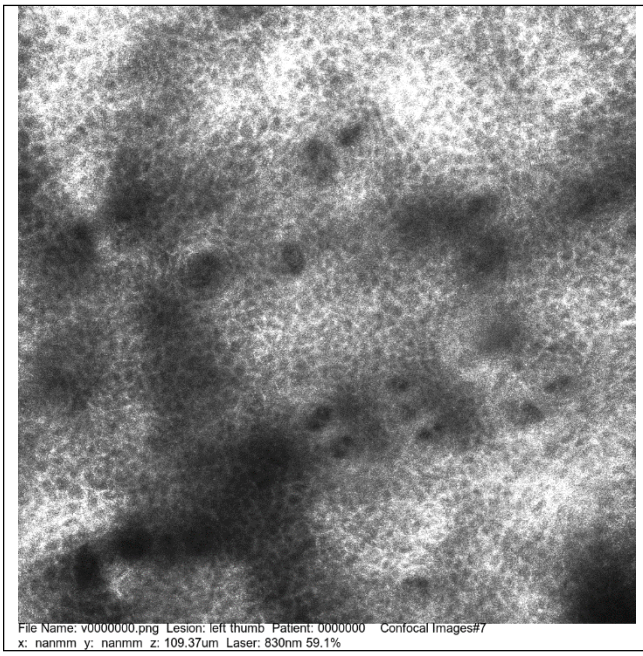
The following is an anecdotal performance report from an academic series of case studies of the CALIBER-ID Vivascope 1500- exploring the design concept, performance and science of Reflective Confocal Microscopy (RCM). This report is produced/collected under the medical supervision of BARD DIAGNOSTIC IMAGING. Quantitative imaging reports in this review were conducted strictly with the use of 3D Doppler Ultrasound imaging and are submitted by Dr. Robert L. Bard.

CASE 1 TREATED PSORIATIC NAIL



ULTRASOUND SCANS: 89 year old female with 40 year history of relapsing psoriasis with pain swelling and erythema of the thumb documented as non-infectious by 405 nanometer spectrometry. Patient received non-steroidal treatment with PEMF and NIR Red Laser weekly for 5 months and returned for follow up imaging including RCM.

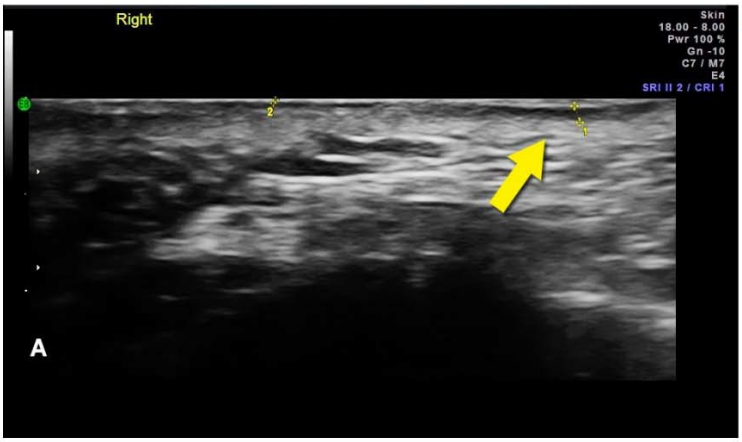
IMAGE A (pre-treated): Sagittal sonogram 18 MHx of thumb nail showing irregular outline of nail plates and thickened nail bed depth to 9 mm (normal 5-7mm) with central dark fibrotic area.
IMAGE B (treated): Transverse sonogram nail bed demonstrating normal vascularity and decreased fibrotic zone (dark region)

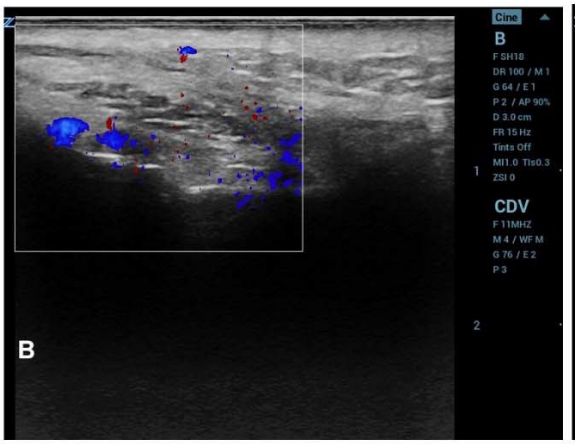


Reflectance confocal microscopy of normal skin shows regular honeycomb pattern of the epidermis and visible dermatoglyphs. Ultrasound shows homogeneous dermal echoes and 200 micron epidermal thickness which is contrasted with the pretreatment exam of 5 month prior demonstrating grossly abnormal dermal echogenicity with 900 micron epidermal thickness.

RCM is a clinically (FDA) approved device for the observation, display and transfer of in-vivo images of tissue, blood, collagen and pigment in exposed unstained epithelium and the surrounding stroma for review by physicians to form a clinical judgement. The in-vivo images of skin tissue provide clinical relevance to assessing various types of skin disorders below the skin surface, which can not be viewed by topical dermoscopy.

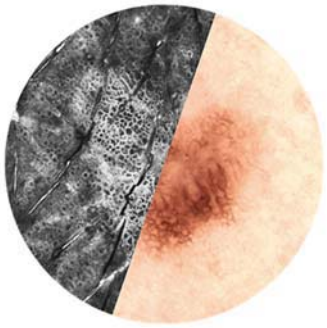
CASE 2 UNSUSPECTED PSORIATIC PATCH





ULTRASOUND: Sonography was performed in multiple scan planes with 20 MHz Zonal imaging, 18 MHz b scan and 17 MHz real time 3-D image analysis with power, color and spectral Doppler interpretation.
IMAGE A: Sonogram of the dermal and subcutaneous soft tissues performed in multiple scan planes with varying transducer frequencies. Epidermal depth 0.2mm. Maximum echopoor depth to 0.4mm with inflamed tissue dark band.
IMAGE B: Note hypermia in dermal band, subcutaneous tissue and frontalis muscle

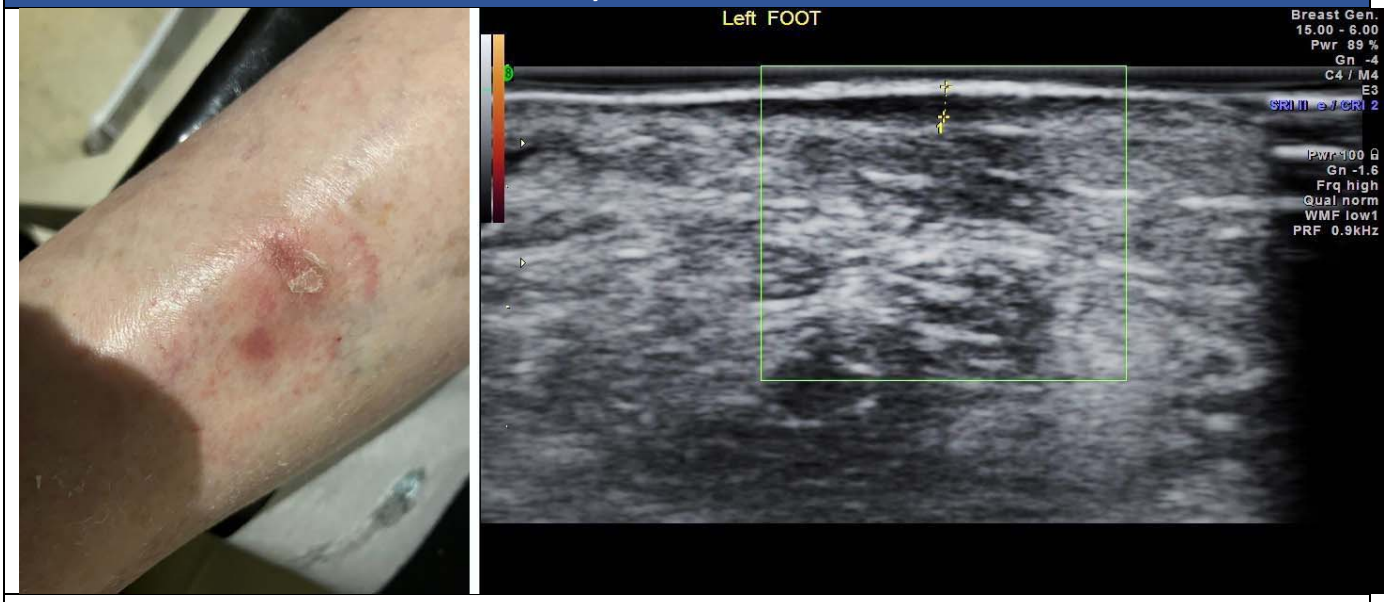
Reflectance confocal microscopy: See Beneath the Skin.



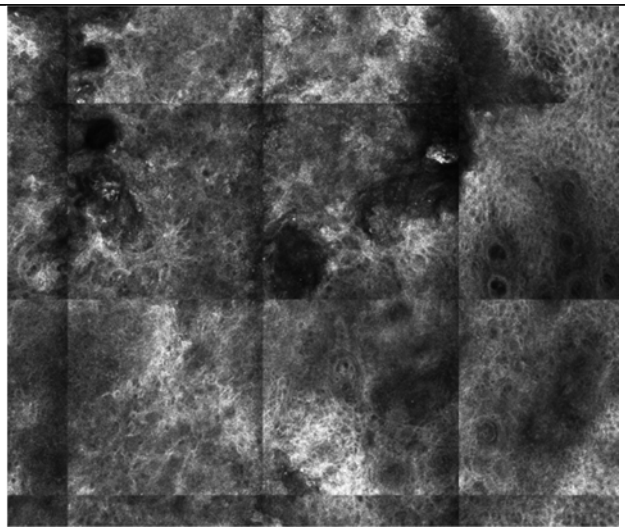
Instant Optical Biopsy –

- **Ideal for lesions on the body**
- Compare pictures over time to examine treatment.
- Easy, Fast and Simple handling to acquireimages for examination by your clinic or practice staff.

CASE 3: RED PATCHES - CANCER, SCAR OR INFLAMMATION



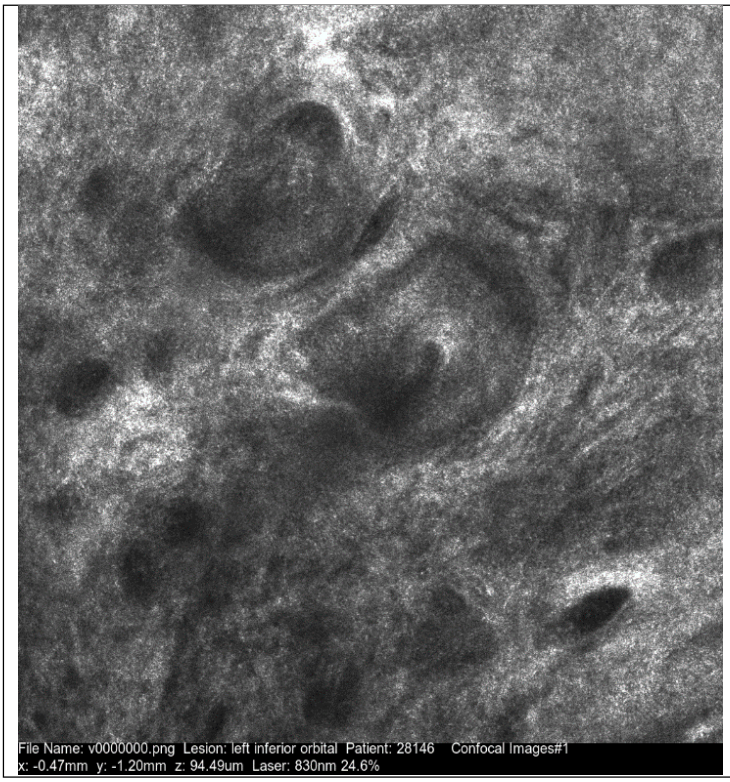
TIBIAL ERYTHEMA: Cephalad red focus is fibrotic region while distal site is healing burn in diabetic foot. Intact dermal papillae with readable well differentiated polygonal cells and normal real time circulation implying first degree burn. Conservative treatment recommended. Red scar with new tibial erythematous lesion.



Reflectance confocal microscopy shows irregular honeycomb pattern cellular and dilated vessels

CASE 4 DERMATOMYOSITIS

ULTRASOUND: 70 female with 15 year hx of biopsy proven autoimmune disorder and red eye lid. (Differential diagnosis). Sonogram left lid shows tissue edema (dark) with dilated vessels. B only. Note normal cornea and lens in image corner. Def: DERMATOMYOSITIS- a rare disease that causes muscle weakness and skin rash. Symptoms include a red or purple rash on sun exposed skin and eyelids, calcium deposits under the skin, muscle weakness, and trouble talking or swallowing. There is no cure, but treatment is done to reduce the symptoms.

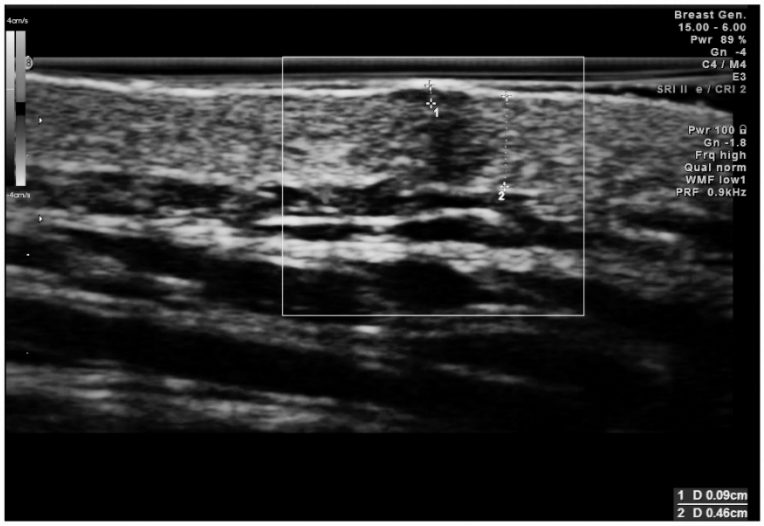


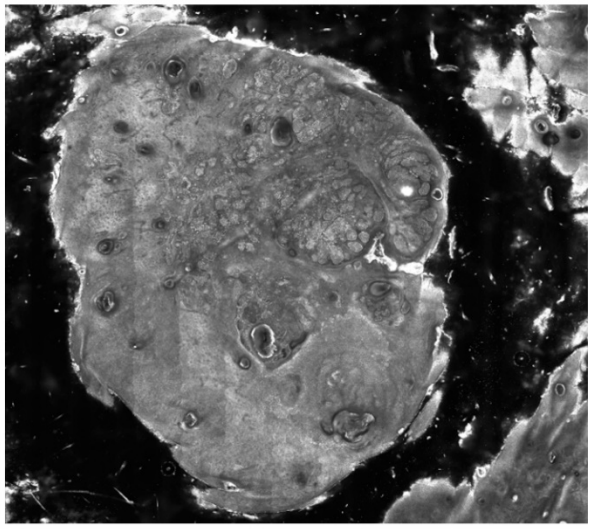
Reflectance confocal microscopy: Abnormal honey comb pattern and irregular cobblestone pattern d e r m a t o m y o s i t i s treated. DEJ and Dermis patterns show ringed (edged) patterns.

Cellular patterns are specific for each layer of the skin from the surface to the superficial dermis as observed by the penetration depth of the Reflectance Confocal Microscope (RCM). Disruption of these patterns by inflammation or disease states provides the dermatopathologists with valuable information to identify non-melanoma cancers and other types of inflammatory conditions.

The ability to '*View Under the Skin*' enables the Dermatologist to identify if a suspicious surface condition has disturbed patterns below the skin surface. These deeper layers help to identify if observation is needed or for more aggressive excision of the lesion.

CASE 5: BASAL CELL CARCINOMA





Ultrasound: HRUS (high resolution ultrasound) shows 600 micron depth of tumor. Patient followed with monthly scans to demonstrate 5-FU effect in cancer stability.	**Reflectance confocal microscopy** -BCC with bright and dark tumor lobules, streaming and palisading

Case 5 EXTRA
Direct observation of microvasculature within the skin layers below the surface provide evidence for normal skin circulation. However, with inflammation or BBC suspicion, these same vessels can also be convoluted and arranged in a tortuous pattern which provides evidence a tumor nest. RCM allows for in-vivo imaging and image capture without disturbance in the skin layer or the vasculature.

As the most common skin cancer the combination of accurate tumor stage is key to the least invasive treatment options. Visualization of this BCC limited to 1/8 of the actual dermal thickness permits initiation of non-invasive options without physical biopsy evidence. Frequent clinical and imaging (non-invasive RCM and high resolution microvascular ultrasound) allows cost effective management therapies for improved patient safety.

CONCLUSION: THE VISIONARY POTENTIAL OF RCM

Dr. Bard calls it “pushing the envelope”. As a seasoned radiologist, he sees the potential for all imaging to do “more” when it comes to detecting pathologies- and RCM is part of this future. The combined use of the science of Confocal Microscopy and sonogram holds the potential for supporting the HAIR REGENERATION community- a vastly active and lucrative society of specialists whose field of validation is typically limited to dermascope and trichoscope (magnification without penetration). In this treatment realm, “there is so much potential to better serve the hair regen and surgical aesthetics community if RCM pushed for approval in these areas… they’re missing out on a major market who direly needs more data to better navigate treatment strategies.”

Another roadmap for RCM that Dr. Bard is convinced could offer a major ‘game-change’ is revolutionizing the concerns and risks of BIOPSIES. Where Dr. Bard’s expertise falls in line with cancer care specialists, he subscribes to seeking solutions to avoid biopsies whenever possible. For the assessment of carcinomas, melanoma, Actinic keratosis, Skin lymphoma and other cancers, Dr. Bard sees the future of eliminating unnecessary ‘cutting’ through a viable diagnostic use of RCM and Sonography. “Understanding the depth of melanoma detected with imaging and generating quantitative reports through the high functioning devices available now allows virtual biopsy imaging as a precursor paradigm for upgraded diagnostics”

EPILOGUE

FREE PRESS FOR NON-INVASIVE HEALTH TECHNOLOGIES "THAT REALLY WORK!"

HealthTech Reporter™, an associated publishing resource of the AngioFoundation (501d1c3) and InterMedia Educational Press is proud to publish our latest test drive/performance reports of selected producers of health-related technologies. Our unique publishing force is an advocacy effort fostering specific non-invasive medical and wellness solutions that have achieved positive evidence of efficacy and health benefits to the end user (either by clinical validation, formal lab testing and/or FDA clearance).

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Our mission is the advancement of health or medical innovations. We support this by promoting the expansion of non-invasive modalities that treat disorders and fight disease without drugs or surgeries. Each time we publish an article or video about non-invasive solutions, we are helping to shape the future of healthcare and a smarter & safer way to address health disorders. That's the non-invasive movement.

Our collaborative network is comprised of both functional medicine and conventional doctors that support a wide range of wellness paradigms. The vast majority of our readers include the proactive wellness community dedicated to research better answers and exploring higher learning about alternative innovations. We call them the proactive "Googler".

GLOBAL SHARING NETWORK

Since 2007, our educational alliance was formed with the advancing interest in sharing useful information to our many health-related groups and associations. We also collaborate and share our news with individual health educators, medical directors, clinicians, researchers and patient advocates. Each news sharing partner is comprised of thousands (some have tens of thousands) of readers and the distributorship of our articles find their way through the power of social media. HealthTech Reporter™ is a public education resource pursuing the global distribution of current health or medical technologies and their advancement. We abide by journalistic standards of unbiased and impartial reporting.