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Anti-Aging MEDICAL NEWS

2012 Winter Official Show Handbook

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Featuring:

Abraham Morgentaler *MD, FACS*
Expert Urologist from Harvard Medical School

In this Issue:

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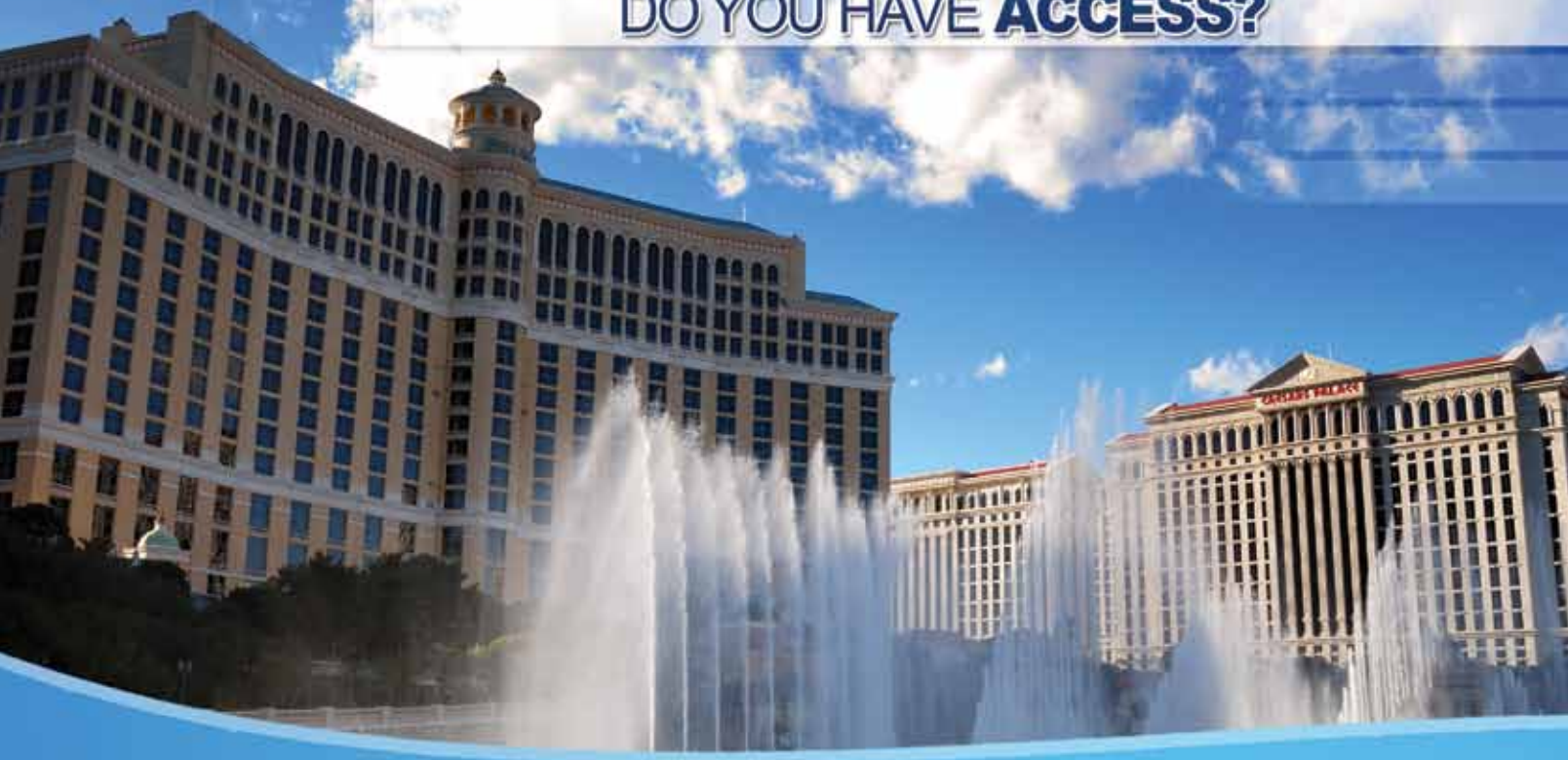

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Now in its third decade of educational service, the A4M's scientific educational programs have trained over 100,000 medical professionals worldwide. Your continued support allows A4M to expand the availability of advanced biotechnologies and leading-edge preventive healthcare throughout the world.

Advancement in medicine has allowed the population, worldwide, to live longer, therefore making the popularity of anti-aging medicine to grow exponentially. Around the world, people are seeking medical guidance for ways to stay healthy, active, and vital well into their older years. As a result, the principles of the anti-aging medical model are gaining rapid and widespread acceptance as a framework for lifelong habits for healthy living.

Founded in 1992, the A4M serves as an advocate for the new clinical specialty of anti-aging medical science and acts as a conduit to physicians, scientists, and the educated public who wish to benefit from the almost daily breakthroughs in biotechnology which promise both a greater quality as well as quantity of life. For twenty years, we have led the way in expanding the acceptance, awareness, and availability of anti-aging medical therapeutics worldwide. We commend you for attending this Congress, and your support of our educational endeavors enables us to continue in our leadership role in this innovative medical specialty.

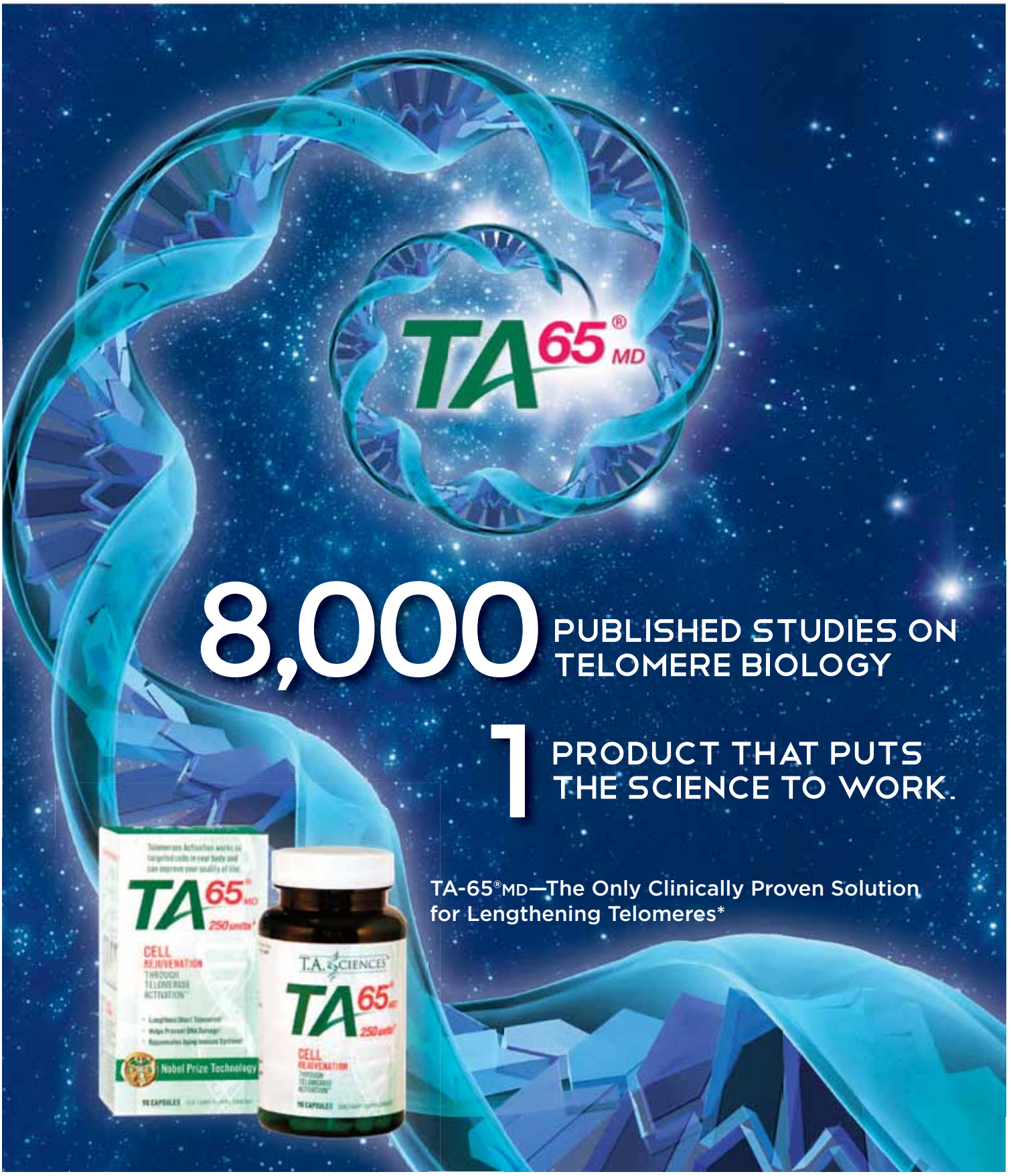
With warm regards,

Ronald Klatz

Ronald Klatz, M.D., D.O. FAASP
President, A4M

Robert Goldman

Robert Goldman, M.D., Ph.D., D.O., FAASP
Chairman, A4M



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SCHEDULE at-a-Glance

Wednesday, December 12, 2012

A4M PRE-CONFERENCE WORKSHOPS

9:00am – 5:00pm	Testosterone Deficiency and Therapy in Men Presented by: Abraham Morgentaler, MD
8:00am – 5:00pm	Advanced Expert Facial Injectables Presented by: Sharon McQuillan, MD
9:00am – 7:00pm	Nutritional/Weight Management Presented by: Expert Faculty
9:00am – 5:00pm	Marketing Tips and Strategies for Your Success Presented by: Manon Pilon, Medical Spa Expert
9:00am – 4:30pm	Your Practice and the Law Seminar *(Non-CME) Presented by: Yvonne Grassie, JD
9:00am – 5:00pm	The Nuts & Bolts of Nutritional IV Therapy *(Non-CME) Presented by: Guy DaSilva, MD

A4M BOARD CERTIFICATION

6:30pm- 9:30pm	ABAAHP Written Examination

Thursday, December 13, 2012 - Exhibit Hall Hours 11:00am – 6:00pm

GENERAL SESSION

7:00am – 11:00am

FAARM FELLOWSHIP – Modules I, V, XV (D), XVI (D), XVIII, XXIII(C)

7:30am – 6:00pm	Module I: A Metabolic, Anti-Aging and Functional Approach to Endocrinology
7:30am – 6:00pm	Module V: Clinical Intensives
7:30am – 6:00pm	Module XV (D): Brain Fitness Therapies
7:30am – 6:00pm	Module XVI (D): Cardiovascular Health D
7:30am – 6:00pm	Module XVIII: Neuropsychiatry
7:30am – 6:00pm	Module XXIII(C): Lifestyle Health Coaching

AESTHETICS FELLOWSHIP

8:00am – 6:00pm	Module XVII: Medical Hair Restoration

CONFERENCE TRACKS

1:00pm – 4:00pm	Track 1: Matters of the Heart
1:00pm – 4:00pm	Track 2: A Practical Application of Treating Adult Hormone Deficiency
1:00pm – 4:30pm	Track 3: Advances in Anti-Aging Medicine
1:00pm – 4:00pm	Track 4: Lab Testing Panel
1:00pm – 4:00pm	Track 5: Aesthetic Medicine

A4M BOARD CERTIFICATION

9:00am – 5:00pm	ABAARM Oral Exam
6:30pm – 9:00pm	Evening Workshops

Friday, December 14, 2012 - Exhibit Hall Hours 11:00am – 7:30pm

GENERAL SESSION
7:00am – 11:00am

FAARM FELLOWSHIP – Modules I, V, XV (D), XVI (D), XVIII, XXIII(C)
7:30am – 6:00pm Module I: A Metabolic, Anti-Aging and Functional Approach to Endocrinology
7:30am – 6:00pm Module V: Clinical Intensives
7:30am – 6:00pm Module XV (D): Brain Fitness Therapies
7:30am – 6:00pm Module XVI (D): Cardiovascular Health D
7:30am – 6:00pm Module XVIII: Neuropsychiatry
7:30am – 6:00pm Module XXIII(C): Lifestyle Health Coaching

AESTHETICS FELLOWSHIP
8:0 0am – 6:00pm Module XVII: Medical Hair Restoration

CONFERENCE TRACKS
1:00pm – 4:00pm Track 1: Mind Over Grey Matter
1:00pm – 4:00pm Track 2: A Practical Application of Treating Adult Hormone Deficiency
1:00pm – 4:30pm Track 3: Women and Sex
1:00pm – 4:00pm Track 4: The Hidden Environmental Stressor You Must Know About to Remediate Cancer, Heart Disease, Multiple Sclerosis, Diabetes, Mood Disorders, Chronic Fatigue and Failing Health
1:00pm – 4:00pm Track 5: Aesthetic Medicine

A4M BOARD CERTIFICATION
9:00am – 5:00pm ABAARM/ABAAHP Oral Exam

NETWORKING RECEPTION
6:00pm – 7:30pm – Networking Reception in the Exhibit Hall

FELLOWSHIP GRADUATION CEREMONY
7:30pm – 9:00 pm - Fellowship Graduation Ceremony, *By Invitation Only*
Sponsored by: BodyLogicMD and University Compounding Pharmacy

Saturday, December 15, 2012 - Exhibit Hall Hours 11:00am – 3:00pm

GENERAL SESSION
7:00am – 10:30am

FAARM FELLOWSHIP – Modules I, V, XV (D), XVI (D), XVIII, XXIII(C)
7:00am – 5:00pm Module I: A Metabolic, Anti-Aging and Functional Approach to Endocrinology
7:00am – 5:00pm Module V: Clinical Intensives
7:00am – 5:00pm Module XV (D): Brain Fitness Therapies
7:00am – 5:00pm Module XVI (D): Cardiovascular Health D
7:00am – 5:00pm Module XVIII: Neuropsychiatry
7:00am – 5:00pm Module XXIII(C): Lifestyle Health Coaching

AESTHETICS FELLOWSHIP
8:00am – 6:00pm Module XVII: Medical Hair Restoration

CONFERENCE TRACKS
1:00pm – 4:00pm Track 1: Advances in Anti-Aging Medicine
1:00pm – 4:30pm Track 2: Innovations in Anti-Aging Medicine
1:00pm – 3:00pm Track 3: Innovative Protocols in Regenerative Medicine
1:00pm – 4:00pm Track 4: Aesthetic Medicine

A4M BOARD CERTIFICATION
9:00am – 5:00pm ABAARM Oral Exam

EXHIBIT HALL
12:00pm **YOU CAN WIN – Enter your Passport to Prizes to Win a Cadillac**
Car Giveaway to be held on Saturday, December 15th at approximately 12:00 PM in the Exhibit Hall

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THURSDAY, DECEMBER 13, 2012
SPONSORED WORKSHOPS:

Improving Clinical Outcomes by Addressing NeuroEndocrine Imbalances
Presented by: Complementary Prescriptions
Time: 6:30pm – 9:00pm **Speaker:** Chris D. Meletis, ND and Jack Monaco, MD

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Integrate Metabolic HCG and Supplement Programs into Your Anti-Aging and BHRT Practice
Presented by: Homefirst
Time: 6:30pm – 9:00pm **Speaker:** Mayer Eisenstein, MD, JD, MPH

Validated In-Office Stem Cell Therapy: How to Ensure Regulatory Compliance
Presented by: Ageless Regenerative Institute
Time: 6:30pm – 9:00pm **Speaker:** Sharon McQuillan, MD and Kristen Comella

JOIN BodyLogicMD: An exclusive opportunity for you to join the nation's largest and most successful network of BHRT physicians
Presented by: BodyLogicMD
Time: 6:30pm – 9:00pm **Speakers:** Jennifer Landa, MD, Patrick Savage, Greg Pippert, MD, Bob Ghelfi, MD, Robert Porzio, DO, and Anita Petruzzelli, MD

Why the local health food store can't help your patients get well…and how you can solve this dilemma
Presented by: Green PolkaDot Box
Time: 6:30pm-9:00pm **Speakers:** Rod Smith, CEO

In Office Screening Ultrasound
Presented by: Radiologist.com
Time: 6:30pm-9:00pm **Speakers:** Andrew Rosenson, MD and Aldo Ruffolo, DO

Lyme & Autoimmune Disease: Solutions for Today
Presented by: Ondamed
Time: 6:30pm- 9:00pm **Speakers:** Silvia Binder, ND, PhD, Allan Magaziner, DO, PC and Perry Fields, Elite Athlete and Author

TBA
Presented by: MFIII/LabDom
Time: 6:30pm – 9:00pm **Speaker:** TBA

Management and Networking Reception:
6:30 pm – 9:00 pm **Presented by:** Manon Pilon

FRIDAY, DECEMBER 14, 2012

Networking Reception in the Exhibit Hall: We invite you to join us for cocktails and Hors D'oeuvres in the Exhibit Hall
Room: Exhibit Hall
Time: 6:00 – 7:30 pm

SATURDAY, DECEMBER 15, 2012

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The Future Role of Testosterone in Treating

Prostate Cancer

By: Edwin Lee, M.D., F.A.C.E. 9/27/2012

AFTER MORE THAN 70 YEARS, the use of testosterone replacement in men is still overshadowed by the fear that testosterone may cause prostate cancer.

On the basis of one article in 1941 by Dr. Charles B. Huggins - in which one of three men with prostate cancer was treated with testosterone and it made the prostate cancer worse - many doctors have been trained to believe that giving testosterone can increase the risk of prostate cancer.

An interesting medical finding regarding eunuchs has contributed to the myth that testosterone can cause prostate cancer. It was found that eunuchs (boys who undergo castration before puberty) do not develop prostate cancer because they have no source of testosterone production. Even the US Food and Drug Administration stated that, "Known or suspected carcinoma of the prostate is a contraindication for testosterone products."

Even as late as 2001, the then director of the National Cancer Institute in the United States refused to fund a large testosterone replacement trial by stating that he was, "Concerned that testosterone could spur the growth of prostate cancer among some men in the study."[1]

The origin of Huggins' original article - and the first association of testosterone with prostate cancer - began in 1940 when Huggins, a urologist from Chicago, was working toward understanding what causes the prostate to grow. He was interested in shrinking the prostate, or treating benign prostate hypertrophy. He worked on dogs since dogs have a prostate gland. Dogs also develop benign prostate hypertrophy and, unfortunately, also prostate cancer.

Because his work had shown that castration in dogs with an enlarged prostate had caused a reduction in prostate size, he made the connection that testosterone had a role in prostate growth. By luck, one of his dogs had prostate cancer, and he noted that after castration the prostate cancer was cured. Huggins published his findings in the 1940 issue of the Journal of Experimental Medicine.

Then, in 1941, Huggins used androgen deprivation therapy (either with castration or estrogen therapy) in men with metastatic prostate cancer and showed a rapid reduction of markers of prostate cancer in acid and alkaline phosphatase (markers of prostate cancer in the 1940s).

At the time, men with metastatic prostate cancer had a very high mortality rate, and it was apparently associated with significant pain of the bones. By having his patients consent to castration for the treatment of metastatic prostate cancer, Huggins showed that it significantly helped reduce mortality, and that it helped with the pain. The tradeoff of having low testosterone was worth the sacrifice, at that time, to live longer and to reduce the pain. This connection - that castration and lowering the testosterone level to zero - was the beginning of androgen deprivation therapy. Fortunately today, there are better ways (LHRH, Luteinizing Hormone Releasing Hormone) to achieve this without undergoing surgical castration.

During his clinical studies, Huggins had three men with metastatic prostate cancer undergo surgical castration, and receive testosterone replacement therapy. Of those three, the data on patient one was lost, patient two had an equivocal result, and patient three (with only 18 days of testosterone replacement) had worsening of his condition. Huggins reported that one man's testosterone treatment caused an elevation of a blood test called acid phosphatase, and then he concluded that testosterone causes prostate cancer. That was the beginning of the theory that testosterone replacement causes prostate cancer.[2] Unfortunately, mainstream medicine has since embraced this as gospel.

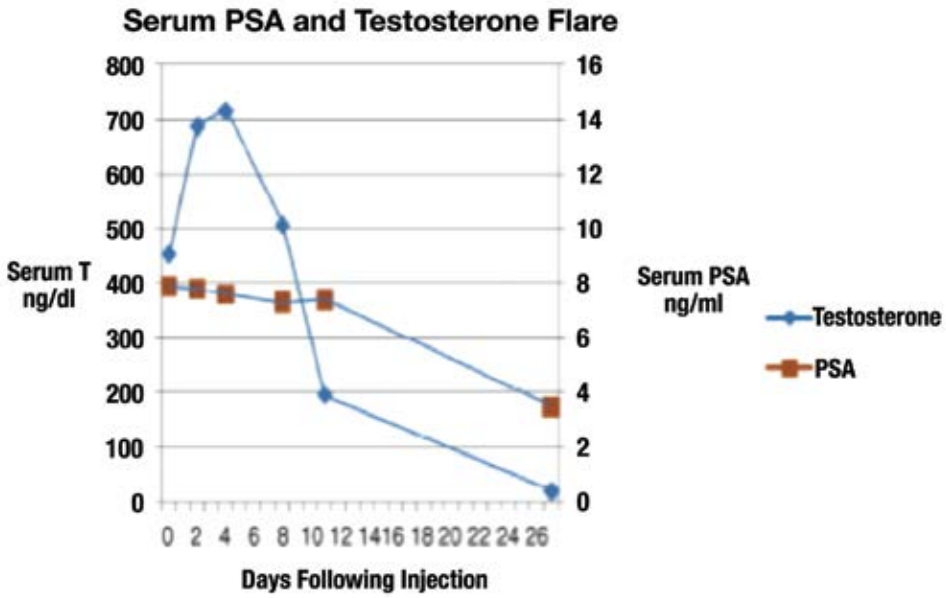
It is interesting to note that when Huggins received the Noble Prize in 1966 for his discovery that there is a chemical modulator for cancer, his Noble Prize was based on androgen deprivation therapy helping patients with prostate cancer. He also made the claim that testosterone aggravates prostate cancer based on only one patient after receiving 18 days of testosterone replacement. Then, in 1967, only one year later, there was a study published in which 26 patients with

The Future Role of Testosterone continued on page 14

The Future Role of Testosterone continued from page 13

advanced prostate cancer were given testosterone replacement after receiving androgen deprivation therapy. The patients did not show any progression of the cancer (several patients even reported an improved sense of well-being, increased appetite and decreased bone pain) with testosterone replacement.[3]

Millions of men suffer from prostate cancer, and have been told that testosterone replacement will make the prostate cancer worse. However, if that is true, and higher testosterone levels are indeed linked to prostate cancer, then why is that we see prostate cancer mostly in the elderly (when testosterone levels are low), and prostate cancer rarely occurs in the youth (when testosterone levels are high)?



Tomera et al. J Urol 2001;165(5):1585–9

In regard to the myth that testosterone causes prostate cancer, there have been many studies in different urology journals unable to support this theory. In a study of 75 men with a high risk of prostate cancer (prostatic intraepithelial neoplasia) and with low testosterone, the men were treated with testosterone for one year. None of them experienced an increased incidence of prostate cancer.[4] Also, to date, there is absolutely no data supporting the theory that restoring testosterone increases prostate cancer.[5] In addition, a large meta analysis of 19 prospective double-blind randomized placebo controlled studies showed that testosterone replacement showed the re was no significant difference for men receiving testosterone, versus the placebo group, in developing prostate cancer.[6]

For over 20 years now, Dr. Morgentaler from Harvard University has been questioning the validity of the testosterone/prostate cancer myth. Morgentaler best summarizes the many mutations of the myth in this way: In 1941, Huggins concluded in one case that testosterone activates prostate cancer. In the 1980s, it was believed that higher testosterone levels were risky for prostate cancer. In the 1990s, it was believed that high testosterone stimulated growth of existing prostate cancer. Now, in the 2000s, high testosterone levels over a period of time increase the risk. Despite the fact that all of the above theories have been disproved with medical studies published in peer reviewed journals.[7]

The Journal National Cancer Institute looked at 3,886 men with prostate cancer and found no association with testosterone, or with free testosterone, with prostate cancer.[8] In a study that looked at men being treated with LHRH (medical castration) for prostate cancer, the LHRH will eventually cause the testosterone level drop to a castration level; however, during the first seven days of being treated with LHRH, there is a flare (or rise) of testosterone level before the level drops. It has been shown in this study that even with that rise in the testosterone level, the PSA does not change or increase with the rise of the testosterone level,[9] as illustrated in the following graph.

In addition it has even been shown that low testosterone levels are associated with an increased risk of prostate cancer, and have a higher Gleason scores. [10]

As for the rate of prostate cancer being published in testosterone replacement trials at approximately one percent,[11] the rate is similar to the cancer detection rate in prostate cancer screening trials. While this is the current data we have about prostate cancer rates, a large and long-term study of testosterone replacement therapy will be needed to confirm this rate.

In addition, Morgentaler has also noted a paradox of testosterone and prostate cancer: While men treated with castration (medical or surgical) do receive a benefit from castration, higher testosterone levels do not increase prostate cancer growth. So, if higher levels of testosterone do not cause prostate cancer to grow, then what is the saturation or plateau level?

Such a saturation model of testosterone on the prostate gland has been theorized, and Morgentaler says, "Testosterone receptors in the prostate are completely bound at low levels of testosterone by dihydrotestosterone. By increasing the serum testosterone level, no changes occur due to the fact the receptors are saturated." An analogy of the saturation model that of giving water to a dying plant. Once the plant's "thirst" has been quenched, the additional water has no further effect.

Recently, Muller and his colleagues proved this saturation model with their study published in the 2012 Journal of European Urology. In the study, there were 3,255 men undergoing regular biopsy of the prostate. The men were followed over time, and it was found that there was no association between prostate cancer with testosterone

The Future Role of Testosterone continued on page 16

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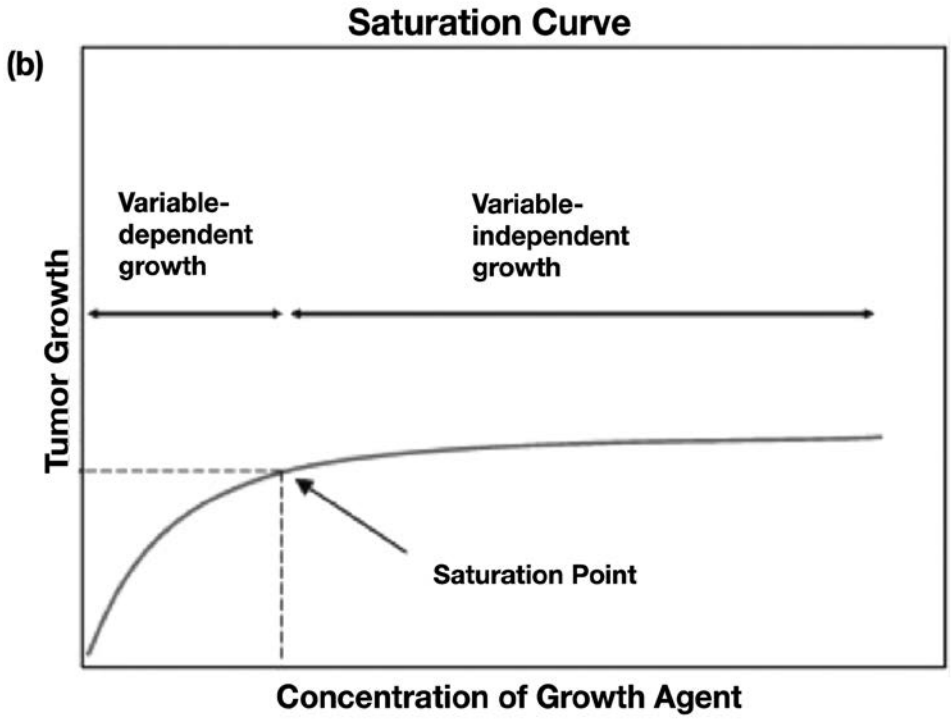
The Future Role of Testosterone continued from page 14

and dihydrotestosterone. It was also shown that low testosterone levels increased the risk, and that prostate cancer declines with the upper testosterone levels,[12] The following graph is the saturation model described by Dr. Morgentaler.

to a low vitamin D level, low insulin growth factor binding 3 (IGF BP-3), damage to any cancer suppressor genes, genetic defects in the prostate, high insulin levels, environmental toxins, or nutritional deficiencies. In regard to Huggins case, I suspect that all his



Morgentaler A, et al. European Urology 2009,55: 310--320

The saturation model does support the original finding by Huggins that prostate cancer is dependent of testosterone at low levels; however, his claim that higher testosterone levels activate prostate cancer is no longer supported by any medical studies. Having higher levels of testosterone does not increase the risk or stimulate the growth of prostate cancer.

It is important to mention that prostate tissue - whether it is benign or malignant - is exquisitely sensitive to changes in low levels of testosterone. According to Morgentaler, "The androgen receptor in the prostate is maximally bound with testosterone at 60-90 ng/dl. Higher levels of testosterone have no effect on the prostate gland whether it is benign or malignant."[13]

In conclusion, the development of prostate cancer is multifactorial. It may be linked patients had low testosterone before being diagnosed with prostate cancer - and they may also have had low Vitamin D, low IGF BP-3, high insulin levels, environmental toxins and nutritional deficiencies.

I believe that future long-term studies on using testosterone replacement in treating early hypogonadal men will most likely show reduced rates of prostate cancer. In fact, I predict that if you are able to maintain optimal testosterone levels with testosterone replacement — while maintaining low insulin levels, optimizing vitamin D, optimizing IGF BP-3, optimizing the liver to detox well (or improving phase 1 and phase 2 of the liver detoxification system) - then you will have a low chance in developing prostate cancer. I look forward to future studies showing that early replacement therapy with testosterone will decrease the risk of prostate cancer.

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IMPACT OF DYSFUNCTIONAL TELOMERES ON AGING AND CANCER

By: Sandy Chang, MD PhD
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ABSTRACT

Telomeres are repetitive DNA sequences that cap the ends of all eukaryotic chromosomes. Telomeres, complex with unique protein components, solve two important problems at chromosome ends: the end replication problem and the end protection problem. Numerous human diseases are associated with defects in telomere end protection, leading to proliferative failure of stem cells, onset of bone marrow failure syndromes and with increased cancer incidence. Telomere length serves as a reliable biomarker for the proliferative history of somatic cells, and is therefore a marker of biological, and not necessarily chronological, aging. While proper telomere maintenance requires the coordinated activities of the enzyme telomerase and associated protein complexes, environmental and lifestyle factors such as diet, nutrition, smoking, exercise (or the lack of) could negatively impact upon telomere length and the rate of telomere loss. Therefore, the ability to monitor telomere length, especially short telomeres, in individual cells should be an important component of the current revolution in personalized medicine. The seminal discovery that the proliferative capacity of somatic cells in mice with short telomeres could be increased by the activation of telomerase offers the possibility that mammalian lifespan could one day be therapeutically manipulated by modulating telomere length.

TELOMERES ARE NEEDED TO MAINTAIN CELLULAR FUNCTION. More than 50 years ago, Dr. Leonard Hayflick conducted a ground breaking experiment (1). He took primary human diploid fibroblasts and continuously passaged these cells in culture. What he found greatly surprised him - his cells would invariably stop dividing after 60-70 passages (now named the Hayflick limit). This result suggested that human primary fibroblasts cannot divide forever (they are mortal), and that they contained a signal telling them to stop dividing after a defined number of cell divisions. His data contrasted with those observed in human cancer cell lines, which do not display this growth checkpoint. Cancer cells are immortal and could be passaged indefinitely, while normal somatic cells experience cellular aging, or replicative senescence, after a set number of divisions. It was a great puzzle, then, as to why these two cell types were so different.

It is now known that telomeres, protein-DNA complexes that cap the ends of all chromosomes, serve as mitotic clocks that keep track of the number of cell divisions during a cell's lifetime. Because the DNA polymerase machinery cannot completely replicate lagging chromosome strands, each cell division results in progressive erosion of chromosomal ends. It is estimated that up to 200 base pairs of genomic DNA are lost with each round of DNA replication, resulting in a total loss of ~10 kb of DNA over the lifetime of long-lived organisms like humans. This degree of erosion could result in the loss of vital genetic information, eventually adversely affecting cellular homeostasis. So how do cells protect important genes from being lost through erosion?

The DNA portion of telomeres consist of long stretches of TTAGGG repeats that act as a buffer of non-coding sequences that prevent more important genes from being lost. Most importantly, higher eukaryotes have an enzyme called telomerase that functions to add TTAGGG repeats to chromosome ends, preventing them from being whittled away. Telomerase is a unique ribonucleoprotein complex that includes an RNA template (TERC) and a reverse transcriptase catalytic subunit (TERT). Telomerase therefore solves the "end replication problem" that plagues all organisms carrying linear chromosomes. Telomerase is expressed only in certain cells in our body, including stem cells. They are also highly expressed in most human cancer cells. Telomerase-positive cells therefore do not experience telomere shortening with increased cell division, making them immortal. Somatic cells, on the other hand, do not express telomerase. Their telomeres gradually shorten with each round of cell division, until their telomeres become so short that they are no longer protective. These "dysfunctional" telomeres act as damaged DNA, which in turn activates a potent p53-dependent cellular DNA damage response (DDR) to stop further cell division. These results indicate that continued maintenance of telomere length by telomerase is essential for cellular immortality. In addition, dysfunctional telomeres often stick to each other, resulting in increased chromosomal fusions and the formation of an unstable genome that promotes cancer initiation and progression (2).

MANY PROTEINS ARE REQUIRED FOR TELOMERE FUNCTION. Besides telomerase, maintenance of telomeres also require six telomere-specific binding proteins which forms a complex, termed Shelterin, that protects telomeres from inappropriately activating DDR checkpoints (Figure 1)(3). Three proteins, TRF1, TRF2 and RAP1, bind specifically to the double-stranded portion of telomeres. In addition, the protein POT1 binds to the very ends of telomeres, which exist as single-stranded DNA. POT1 forms a heterodimer with another protein TPP1, and this complex in turn interacts with TRF2 through the adapter protein TIN2. Deletion of these telomere binding proteins results in the rapid activation of a DDR and end-to-end chromosome fusions that result in genome instability. In addition to telomerase and shelterin, several other accessory proteins are required for the maintenance of telomere homeostasis. While it is not possible to document them all in this brief review, the STN1-TEN1-CTC1 protein complex has been shown to be required to recruit telomerase to telomeres, and is also critically important for telomere replication (4). Therefore, the maintenance of proper telomere function requires the orchestration of a large number of proteins at the ends of our chromosomes: telomerase to elongate telomeres after each round of cell division, CST complex to replicate telomeres, and shelterin to constantly stand guard and protect telomeres from being recognized as broken DNA by our DNA damage surveillance machinery.

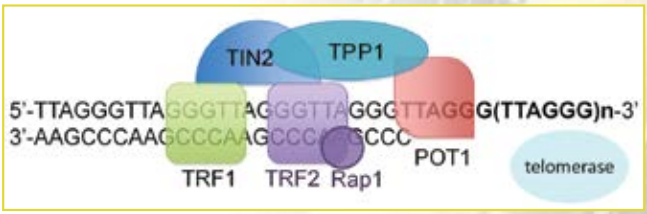

Figure 1. Schematic of a telomere. The telomere repetitive DNA sequences, six telomere binding proteins and telomerase are illustrated.

DYSFUNCTIONAL TELOMERES PROMOTE HUMAN DISEASES. Given the large number of essential proteins required for telomere maintenance, it should not come as a surprise that several human diseases are due to mutations of these proteins. Accumulating evidence show that defects

Impact of Dysfunctional Telomeres continued on page 22

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Impact of Dysfunctional Telomeres continued from page 19

in telomere maintenance contributes directly to several inherited human hematopoietic disorders (5). Critical telomere shortening results in proliferative defects in hematopoietic stem cells, leading to the onset of bone marrow (BM) failure syndromes. The best studied of these diseases is Dyskeratosis congenita (DC), a multisystem disorder characterized by the presence of dysplastic nails, BM failure, skin pigmentation abnormalities, hair greying and increased cancer risk. Autosomal dominant and recessive forms of this disease are due to mutations in the TERC and TERT components of telomerase, respectively, while X-linked DC is a result of mutations in DKC1, a gene encoding a small nuclear RNA protein that interacts with TERC (4, 5). Mutations in the gene encoding the shelterin component TIN2 results in a very severe form of DC, with severe telomere dysfunction, premature BM depletion and ultimately BM failure in patients as early as 10 years of age. Although mutations in POT1 has not yet been associated with DC, mouse models have revealed that deletion of the POT1 protein results in phenotypes highly reminenscent of human DC (6).

Recently, whole exome sequencing resulted in the discovery of a new player in inherited BM failure syndromes. Coats plus is an autosomal recessive disorder characterized by bilateral retinal exudative retinopathy (Coats disease), intracranial calcifications, osteopenia, hair graying, BM failure and the presence of critically short telomeres (4). Whole-exome sequencing of Coats plus patients revealed the presence of biallelic missense CTC1 mutations. Coats plus patients display clinical phenotypes that overlap with several other human BM failure disorders resulting from telomere dysfunction, including DC. Hoyeraal-Hreidarsson syndrome mainfests as developmental delay, intracranial calcifications and is due to mutations in DKC1, TINF2 and TERT. Patients with Revesz syndrome also exhibit developmental delay, with exudative retinopathy and intracranial calcifications as characteristic features. As this disease progresses, characteristic features of DC emerge, including BM failure and telomere shortening. Therefore, despite their broad clinical spectrum, DC, Hoyeraal-Hreidarsson syndrome, Revesz syndrome and Coats plus are all telomere biology disorders unified by the common molecular pathology of telomere dysfunction and shortening (7).

What are the molecular mechanisms underlying these telomere disorders (termed telomopathies)? Stem cells lacking functional telomerase are just like normal somatic cells, with limited replicative potentials, resulting in the progressive telomere shortening with each cell division and the eventual generation of dysfunctional telomeres. We know that a single shortest telomere in a cell could trigger a robust DDR in the setting of an intact p53-dependent DDR pathway (8). This in turn leads to the activation of apoptotic and/or cellular senescence programs, two potent cellular growth suppressor mechanisms to stop further cellular proliferation (2). The decline in proloferative capacities of stem cells (especially in highly proliferative compartments like the BM) results in progressive BM failure and onset of disease phenotypes. While studies of human telomere disorders have shed light on how dysfunctional telomeres negatively impact upon stem cell proliferative capacity, the use of mouse models of telomere dysfunction have been instrumental for our understanding of the impact that dysfunctional telomeres play in compromising highly proliferative cellular compartments. For example, mice engineered not to have any telomerase activities display defects in highly proliferative tissues, including the appearance of erosive dermatitis, reduced proliferation of T and B lymphocytes upon mitogenic stimulation, splenic atrophy and complete infertility at late generations due to defects in reproductive germ cells. These results suggest that telomere maintenance is vital in long-term stem cell survival and organ homeostasis. Progressive BM failure, the hallmark of BM failure syndromes, has been observed when we deleted POT1 or CTC1 function in mice (6, 9). These results reinforce the notion that mouse models of telomere dysfunction are extremely valuable for the understanding and future treatment of human telomopathies.

PROGRESSIVE TELOMERE SHORTENING IS A CONSEQUENCE OF NORMAL HUMAN AGING. Humans in developed countries are living longer, with increased life expectancies coming from improved sanitation, childhood vaccinations and the use of modern pharmaceutical drugs. However, our limiting telomere length ultimately restrains how long we could live. Increased aged-related cellular decline due to telomere attrition could be found in stem cells and tissues with high rates of proliferative capacities in normal people who live to an exceptionally old age. For example, an increased incidence of immunological deficiencies due to decreased T and B-cell function, chronic ulcers, diminished vascular endothelium function leading to arteriosclerosis, proliferative decline of retinal pigmented epithelial cells leading to age-related blindness and cancer have all been attributed to progressive telomere attrition. In addition, exposure to environmental and life-style factors such as cigarette smoking, reduced exercise, and excessive drinking could directly lead to increased telomere erosion, exacerbating cellular proliferative defects. While we cannot yet slow down normal telomere attrition in humans, a recent report suggesting that turning on telomerase in mouse cells with short

telomeres could actually rescue their proliferative defects gives us great hope that we could one day slow down or even reverse telomere shortening in aging human tissues (10). This intriguing possibility makes it imperative to have proper tests available to allow accurate telomere length measurements in human tissues. In addition, knowing one's overall telomere length could lead to lifestyle modifications that reduce/eliminate the contributions of environmental factors' adverse impact on telomere length.

ASSAYS TO MEASURE TELOMERE LENGTHS. Several different methods exist to measure telomere length. The oldest is the terminal restriction fragment (TRF) assay, a test that relies on size fractionation of telomere fragments and Southern blotting with a telomere probe to detect telomeres. This qualitative test is not scalable for high throughput analysis and is often hard to interpret due to the heterogeneity of telomere length in human cells, appearing as a smear of variable intensity. In a mixed cell population, it is not possible to tell which cell types have the shortest telomeres. Despite its shortcomings, TRF Southerns are routinely performed on human samples due to its simplicity. A modification of the TRF assay using a dot blot approach is even more problematic than the TRF method, in that it does not provide visualization of the range of telomere lengths (Figure 2). Neither the TRF nor dot blot method provides information about the shortest telomeres in individual cells.

The quantitative PCR method of telomere detection is fast and scalable for high throughput analysis. Its main disadvantage is that it gives information only as an average of telomere lengths and provides no information on the length of the shortest telomeres. Two companies (Telomehealth.com; Spectracell.com, Figure 2) provide this technology commercially. Another PCR-based approach is called STELA (single telomere length analysis). This is very low through put method that analyzes telomere lengths from only a few specific chromosomes. However, it has the advantage that it can provide information on the shortest telomeres in a population of cells. It is not yet a viable commercial test due to the long turnaround time, and it cannot provide information about the shortest telomeres in individual cells.

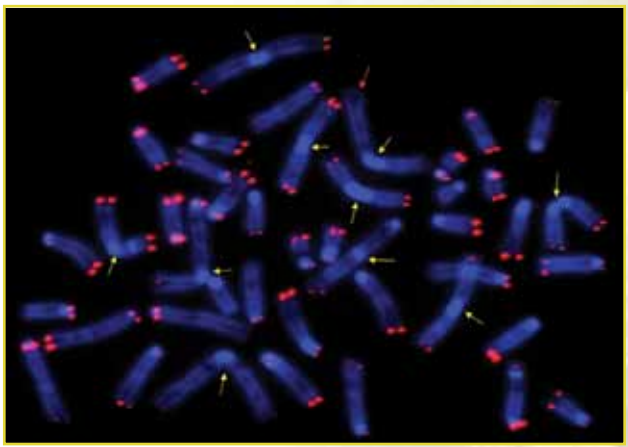
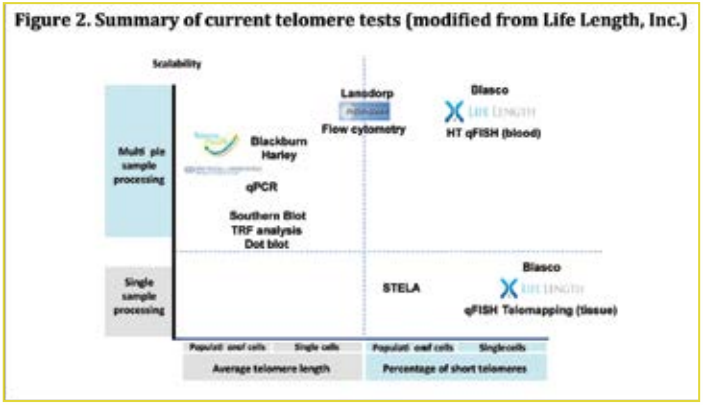


Figure 3. Q-FISH analysis of a metaphase spread from mouse spleen cells genetically engineered to possess dysfunctional telomeres. Red dots mark telomeres, while the blue dye stains chromosome bodies. Arrows point to sites of chromosome fusions due to telomere dysfunction. Several chromosome ends have very short telomeres, visualized as very small telomere signals at chromosome ends.

The flow-FISH (fluorescence in situ hybridization) method uses a FACS (fluorescence activated cell sorter) to analyze telomere length in a cell population after hybridization with a fluorescence telomere probe. This method provides only the averages of telomere lengths and not telomere lengths within individual cells. It almost exclusively uses lymphocytes, so is not designed to analyze telomere lengths from solid tissues. Flow-FISH is offered commercially (Repeatdiagnostics.com; Figure 2), and is CLIA certified for measuring telomere lengths as part of genetic counseling.

The high throughput microscopic quantitative (Q)-FISH method is a highly reliable approach to measure telomere lengths. This approach visualizes telomere lengths of hundreds of individual metaphase spreads or cells under a microscope so one can distinguish between subsets of cells containing very short telomeres from those with long telomere lengths and has the advantage over other methods of providing not only average telomere length per cell, but also the number and distribution of the shortest telomeres in individual cells (Figure 3) (11, 12). A commercial test (high throughput Q-FISH) was developed the Dr. Maria Blasco at the Spanish National Cancer Research Center and licensed to Life Length (Figure 2). With the exception of HT Q-FISH, no other commercial laboratory method is available which can distinguish a single critically short

Figure 2. Summary of current telomere tests (modified from Life Length, Inc.)



Impact of Dysfunctional Telomeres continued on page 24

Impact of Dysfunctional Telomeres continued from page 22

telomere within one cell that may be triggering a DDR. This approach has recently been commercialized into a high throughput method with an accuracy of 5% between tests (www.lifelength.com). Life Length also developed a technique called Telomapping (US Patent No 8,084,203 B2). This is similar to HT Q-FISH but determines the telomere lengths on chromosomes from tissue sections, thus maintaining the spatial topology of the samples. The advantage of this method is that archival formalin embedded paraffin sections can be used to determine if specific cell types within a tissue have short telomeres. This is likely to have important implication in the precancerous detection field. This method is more time intensive and is not scaled up to high throughput analysis at the present time.

In conclusion, reliable telomere tests are now available commercially. While there several options, one needs to ask if the method delivers results that provide measurements of the number of individual cells bearing critically short telomeres, which are universally regarded as the principal cause of replicative cell aging and age-related diseases (4, 8).

SUMMARY AND FUTURE CHALLENGES. The proper maintenance of telomere function is important to delay human cellular aging and prevents the initiation of cancer. Since cancer cells require a high level of telomerase for telomere length maintenance, drugs to inhibit telomerase activity may have some utility in cancer therapeutics. In human diseases of high cellular turnover, for example in inherited BM failure syndromes, reduced telomerase activity resulting in very short telomeres have been found. Therefore, the ability to lengthen telomeres in BM stem cells by reactivating telomerase might be a therapeutic approach to treat DC patients. Both of these approaches would benefit from the ability to accurately determine telomere length in cells. While the normal aging process is complex and certainly cannot be explained solely on the basis of telomere biology, there is a growing consensus that telomere status plays a fundamental role in determining how an organism ages. Certainly in mouse experimental systems, manipulation of telomere lengths in vivo has shown that decreased telomere length promotes the onset of premature aging phenotypes, while telomere lengthening results in a more robust and fit mouse. In humans, it is hoped that telomere length measurement tests may offer clinicians another piece of data to gauge the health of individual patients. For example, patients with a young chronological age but an advanced biological age, as determined from the increased number of very short telomeres in somatic/stem cells, could lead the physician to recommend behavior modifications to reduce adverse environmental factors such as smoking, which compromise telomere length. While we cannot yet manipulate telomere length in humans, the hope is that future drugs/supplements might offer us this ability in a controlled manner. The challenge will be to increase telomere length in somatic cells to delay cellular aging in humans without increasing cancer initiation.

CONFLICT OF INTEREST:

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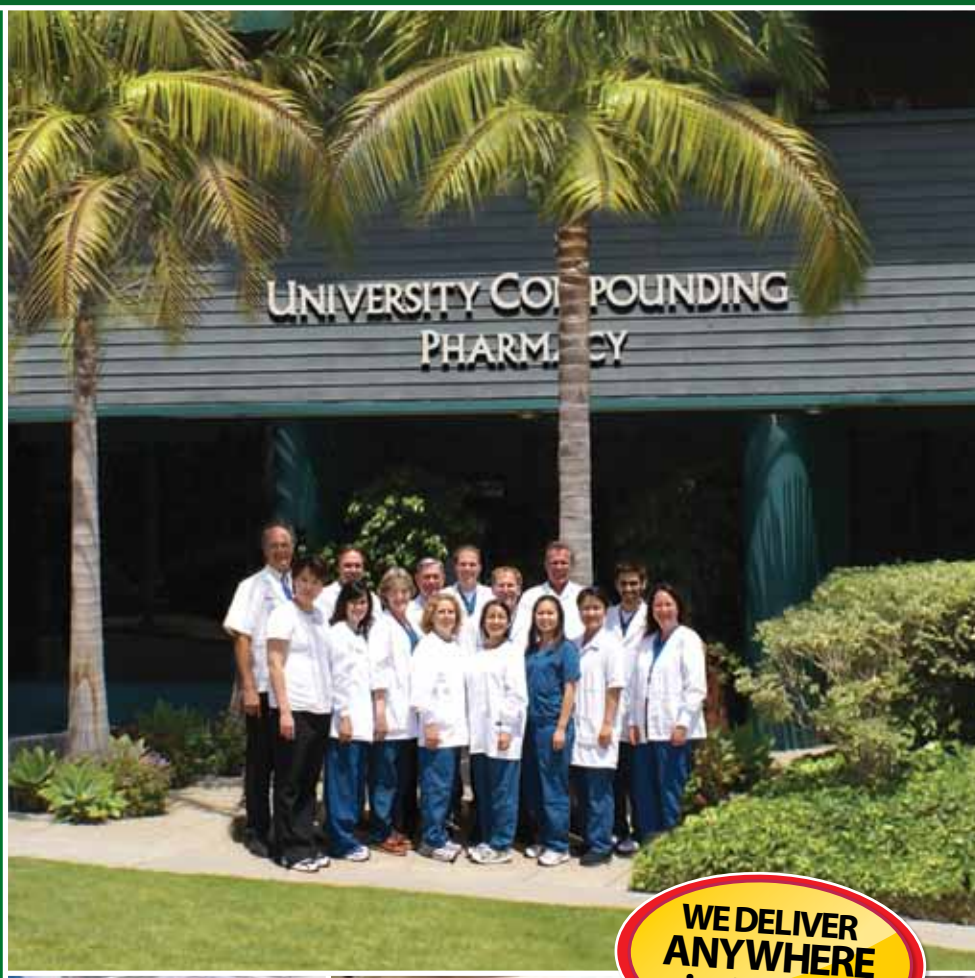

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Stem Cell Treatments:
Hope, Hype, or True Regenerative Medicine

By: Sharon McQuillan, MD and Kristin Comella, MS

THROUGH THE USE OF ADULT STEM CELLS, regenerative medicine is a revolutionary approach to treating many degenerative conditions that occur with age. This field joins nearly all disciplines of science and holds the realistic promise of repairing damaged tissue by harnessing the body's ability to heal itself. As with any major scientific breakthrough, the market has become inundated with "stem cell treatments" and stem cell products that promise to do everything from cure disease to provide cosmetic enhancement. The following is a guide for consumers interested in safe and efficacious treatment.

Adult stem cells are found in every part of the body and have the potential to develop into many different cell types. As a stem cell divides, each new cell has the ability to either remain a stem cell or become another cell type with a more specialized function. Stem cells are characterized by two functions from other cell types. First, they are unspecialized cells capable of renewing themselves by cell division. Second, they have the ability to become specialized cell types. Unlike embryonic stem cells, which are derived from human embryos, adult autologous stem cells are harvested from a patient's own tissue, such as adipose (fat) tissue or bone marrow.

Stem cells derived from a patient's own fat are referred to as adipose-derived stem cells. Adipose-derived stem cells or ADSCs have been shown clinically to differentiate, or become different cell types including cartilage cells, bone cells, nerve cells, skeletal muscle, and adipocytes (fat cells).[1] Several beneficial effects have been associated with adipose-derived fat cells, including the ability to reduce inflammation and promote tissue healing through the secretion of growth factors and signaling molecules (cytokines), which recruit stem cells to facilitate repair and healing of the affected tissue. Additionally, these cells provide a network for blood supply while the tissue heals.[2]

We first became interested in adult stem cells with the scientific discovery of the existence of adult cells contained in adipose tissue. This discovery led to the development and validation of a method for harvesting and isolating stem cells from fat for therapeutic use. Using this method, we are able to provide treatments in the area of regenerative aesthetics, orthopedics, and more.

Stem cells can be harvested and separated from adipose tissue under local anesthesia in a medical office setting. This procedure should be performed under sterile conditions under a doctor's supervision. The accepted method of adipose-derived stem cell harvesting involves tumescent liposuction. The fat is then processed to separate the stem cells from the adipose tissue using a special enzyme along with centrifugation and filtering processes to provide the final stem cell product, often referred to in the medical community as the stromal vascular fraction.

The stem cell isolation process should be a validated method that provides a consistent cellular product and is compliant with current regulatory guidelines. This means that studies should be conducted to test the procedure used to ensure that it is safe, provides a predictable amount of stem cells, and results in a purified and effective product for patient's use. In our clinics we utilize materials that are produced according to Good Manufacturing Practices (or cGMP) set forth by the FDA. We are collecting approximately one million cells per cc of fat extracted. This procedure consistently produces pre-determined acceptance criteria, making it easy to duplicate in a medical office setting and has been validated via reproducibility and robustness analysis. Obtaining a cellular product that is capable of proliferating and dif-

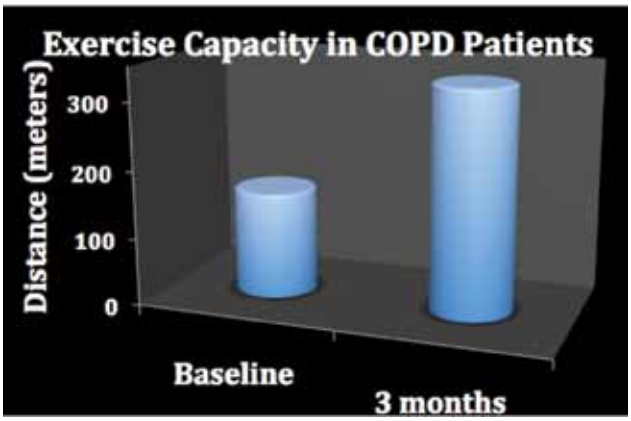
ferentiating requires detailed analysis and this is critical to ensure reliable patient outcomes.

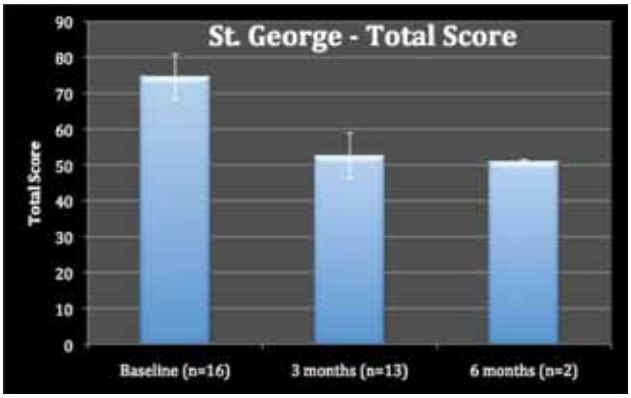
Offering stem cell therapies to patients not only requires procedural competence, but a thorough understanding of the regulatory considerations involved. Any technique employed to obtain stem cells must adhere to the current code of federal regulations for use in a physician's practice. The method previously described meets the federal code of regulations concerning tissues used at the point of care during the same surgical procedure into the same individual; therefore, it is not regulated by the FDA, but rather considered the practice of medicine. Additionally, the cells used must be minimally manipulated, meaning that the method of processing does not alter the relevant biological characteristics. What this means to patients and consumers is that the stem cells need to be removed, processed and reinjected in the same procedure and the product should not at any time be sent out of the clinic for processing. Additionally, the cells cannot be cultured, grown, or multiplied before re-administering to the patient. There have been numerous actions by the FDA on physicians and stem cell companies for violating the aforementioned regulations.

The validity and success of this cell isolation method is not just limited to the Ageless Institute. We have trained hundreds of physicians in the responsible aspects of stem cell treatments so that they can provide a safe and effective treatment to their patients. In conjunction with both the Regenerative Medicine Institute (RMI) and Bioheart, Inc., the Ageless Regenerative Institute (ARI), is conducting clinical trials for many degenerative diseases using adipose-derived stem cells. There are approximately thirty protocols that have been approved by the Institutional Review Board of Hospital Angeles, Tijuana, a JHACO-certified, state of the art private specialties hospital providing high quality chronic disease treatments with a patient-centered focus. Many of these protocols can be found at www.clinicaltrials.gov and include treatments for congestive heart failure, myocardial infarction (heart attack), ischemic limb disease, diabetes, and chronic pulmonary obstructive disease (COPD).

Early results are promising for the clinical trials being conducted in conjunction with our scientific partners for chronic obstructive pulmonary disease (COPD), congestive heart failure, and ischemic limbs.

Outcome measurements for the COPD study include safety, exercise capability, and quality of life assessment. Thus far, 35 patients have been treated and results demonstrate an increase of 174 meters in a six-minute walk test when compared to baseline at three months. These results are further substantiated by positive patient testimonial and 83% statistically significant improvement in quality of life. This represents a new breakthrough for COPD patients who often suffer a progressive decline in health following diagnosis.



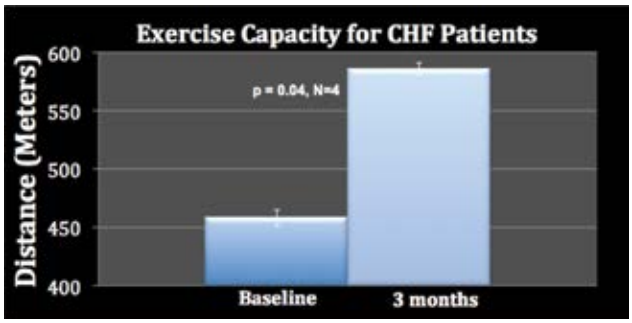


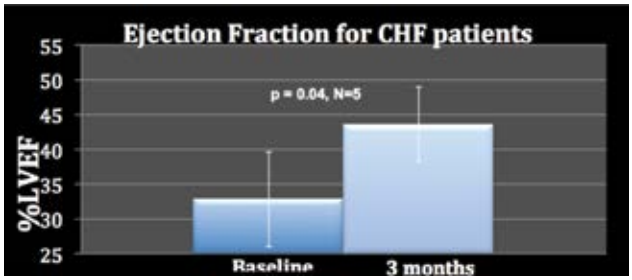
In a protocol focused on congestive heart failure, fifteen patients have been successfully treated with adipose-derived stem cells. Outcome measurements for this study include safety, changes in left ventricle ejection fraction, exercise capability in terms of a six-minute walk test, and quality of life assessment. In these treatments, autologous stem cells are harvested, processed, and delivered to the damaged area of the heart muscle via catheter.

Study patients have demonstrated on average, an absolute improvement of 11 percentage points in injection fraction and an increase of 128 meters over baseline in their six-minute walk test at their six-month follow-up. This means that the patient's heart appears to be functioning better on an echocardiogram. In addition, the patients' exercise capacity has improved, which allows for a more active and normal lifestyle.

Stem Cell Treatments continued on page 30

Stem Cell Treatments continued from page 29

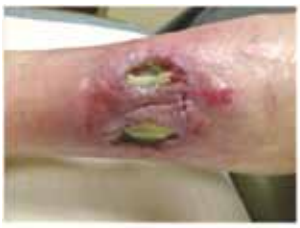




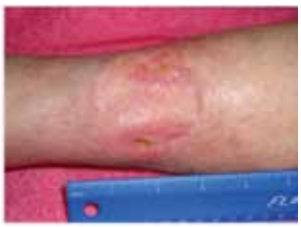
This data is in agreement with many years of pre-clinical animal studies completed by ARI and Bioheart, demonstrating the safety and efficacy of this therapy; including a study led by Keith March, MD, PhD, director of the Vascular and Cardiac Center for Adult Stem Cell Therapy at Indiana University. The results of these studies showed the tendency of adipose stem cells toward heart muscle regeneration and growth of new blood vessels.[3,4,5]

This action by the adipose-derived stem cells makes them the perfect therapy from ischemic tissue. Critical limb ischemia is condition where the blood supply is compromised to the lower limbs, causing tissue death and often results in amputation. Hundreds of patients have been successfully treated with adipose-derived stem cells for limb ischemia with end results being limb salvage due to increased blood flow to the area, a result of the development of new, healthy, functioning blood vessels in the affected area.

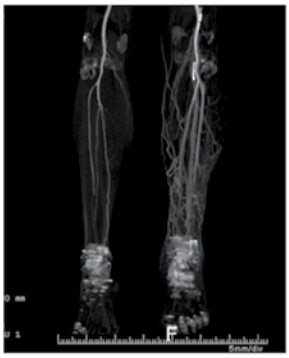
We have recently developed a protocol for treating patients that have non-healing ulcer wounds due to radiation. In the case study presented below, we delivered stem cell in and around the wound due to radiation necrosis. This patient had attempted several traditional therapies including a skin graft which was not successful. ADSCs promoted the growth of new blood vessels and promoted healing of the tissue. After 6 months, the wound has completely healed and the patient has resumed normal activities. In addition, the angiogram demonstrates the formation of new blood vessels in the effected leg.



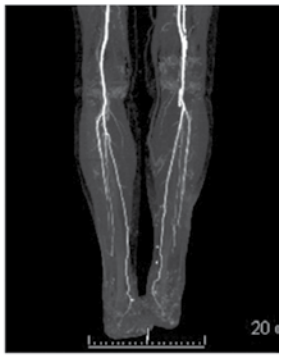
Pre-stem cell therapy



7 months post stem cell therapy



Pre-stem cell therapy



8 months post stem cell therapy

In the area of regenerative orthopedics, the treatment technique involves using adipose-derived stem cells combined with platelet rich plasma (PRP), which is injected into the affected area using sterile technique. This treatment is appropriate for patients with degenerative orthopedic conditions and musculoskeletal injuries. Average improvements following stem cell/PRP injections over baseline, using a visual analog scale, pain scale, and range of motion scale show an 80% improvement in 200 knee treatments, 75% improvement in 175 hip treatments, and 70% improvement in 50 shoulder treatments. The Ageless Institute is currently conducting these treatments under Independent Review Board (IRB) studies in the US to further study the long-term effects of these results for orthopedic conditions.

As the data suggests, stem cells possess enormous regenerative potential. Adipose stem cells can be obtained from the patient easily, abundantly, and with minimal patient discomfort. The potential applications are virtually limitless. Clinical applications for patients can be performed in a medical office setting safely, legally, and ethically using autologous adipose-derived stem cells. Before undergoing any stem cell treatments, patients should use the following checklist as a guide to determine if the treatment is the best option for them:

Stem Cell Treatments continued on page 32

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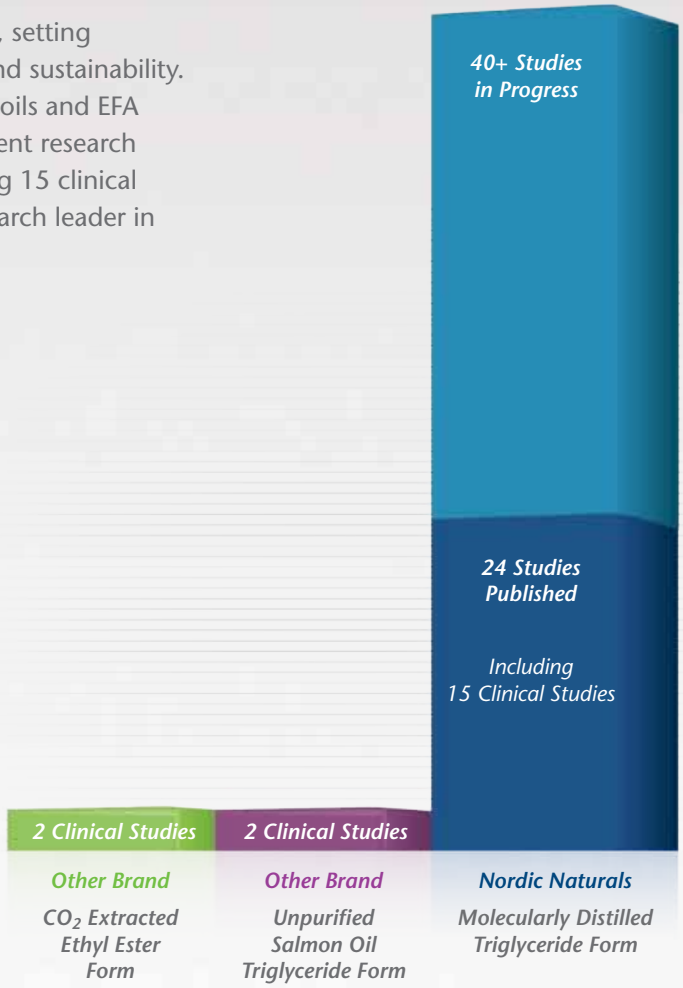

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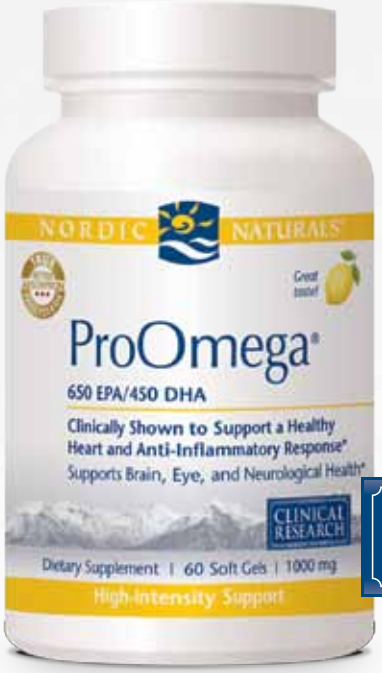

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Stem Cell Treatments continued from page 28

- **Physician's credentials and experience: how long have they been performing these treatments, what training/education/experience do they possess.**
- **Has the physician been sanctioned by their State Medical Board or any other regulatory agency?**
- **Method of obtaining the stem cells: is it a validated method? Can they provide you statistics to support this?**
- **Will the cells be harvested, processed and reimplanted in the same setting?**
- **What research or statistics can be provided on the success of the treatment?**
- **What are the possible complications/adverse effects of the treatment?**
- **How many treatments has the physician performed?**

Patients should only receive cutting edge treatments that are safe, compliant, and efficacious. One day, stem cell treatments will be the gold standard of care for the treatment of most degenerative diseases. Until then, patients should be diligent and fully research and understand the procedures they are choosing to undergo. Remember, if it sounds too good to be true, it most likely is not effective.

For additional information, contact info@agelessregen.com or (855) 274-2355.

[1] Rehman J, Traktuev D, Li J, Merfeld-Clauss S, Temm CJ, Bovenkerk JE, Pell C, Johnstone B, Considine RV, March KL. The Secretion of Angiogenic and Anti-Apoptotic Factors by Human Adipose Stromal Cells. Circulation. Mar 2004; 109(10): 1291-1298.

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[5] Houtgraaf JH, den Dekker WK, van Dalen BM, Springeling T, de Jong R, van Geuns RJ, Geleijnse ML, Fernandez-Aviles F, Zijlsta F, Serruys PW, Duckers HJ. J Am Coll Cardiol. 2012 Jan 31;59(5):539-40. First Experience in Humans Using Adipose Tissue-Derived Regenerative Cells in the Treatment of Patients With ST-Segment Elevation Myocardial Infarction.

For more than twenty years, **DR. SHARON MCQUILLAN** has been at the forefront of Aesthetic, Anti-Aging, and Regenerative medicine. Early in her career as a board-certified family practitioner, she focused on preventive medicine, exercise physiology, nutrition, bio-identical hormone replacement, and the mind-body connection long before holistic medicine was mainstream. As a practicing physician she quickly realized that a healthy self-image is a critical component of optimal health and longevity. She sought out the education of Drs. Jean and Alistair Carruthers, the pioneers of Cosmetic Botox and Aesthetic medicine.

Dr. McQuillan quickly became one of the leading aesthetic practitioners in Central Ohio and was one of the first physicians to offer the full spectrum of health, wellness, and beauty. Dr. McQuillan's passion for teaching and commitment to superior patient outcomes led her to the formation of The Ageless Aesthetic Institute, a hands-on training company for medical professionals seeking to learn aesthetic procedures. Dr. McQuillan has educated thousands of medical professionals in the art and science of aesthetic, anti-aging, and regenerative treatments for over a decade. Dr. McQuillan's ultimate goal is to standardize and advance Aesthetic Medicine into a nationally recognized subspecialty.

Dr. McQuillan relocated her practice to Florida, where she developed the Ageless BodySculpture technique. After years of performing BodySculpture, it became apparent that there were regenerative stem cells in the fat being removed from her patients during BodySculpture procedures. In 2009, she formed The Ageless Regenerative Institute in conjunction with an international team of experts from the medical, legal, biotechnical, and manufacturing arenas. Additionally, Dr. McQuillan in collaboration with Ageless Regenerative Institute's Chief Scientific Officer Kristin Comella, has authored over thirty clinical trials which harness the patient's own healing power of their stem cells to treat various degenerative conditions.

Some of Dr. McQuillan's prestigious titles include Medical Director of the Aesthetic Anti-Aging Fellowship for the American Academy of Anti-Aging Medicine (A4M). In addition to being the medical director of the Ageless Institute, she is a national speaker and educator for Allergan, Medicis, Merz Pharmaceuticals, ConBio, Sciton, Deka Medical, BTL Aesthetics, and Curamedix.

KRISTIN COMELLA

Ms. Comella has over 14 years experience in corporate entities with expertise in regenerative medicine, training and education, research, product development, and senior management. Ms. Comella has been a member of the Bioheart Inc. senior management team since 2004 and is currently serving as the Chief Scientific Officer. Bioheart is a publically traded company focusing on the discovery, development and commercialization of autologous cell therapies for the treatment of chronic and acute heart damage and peripheral vascular disease. Ms. Comella was appointed as Bioheart's Vice President of R&D and Corporate Development in December 2008. Since joining Bioheart in September 2004, she has played a major role in managing the product development, manufacturing and quality systems. In addition, Ms. Comella is currently and actively serving on multiple boards in the stem cell arena. She is co-founder and Chief Executive Officer of Stemlogix, LLC and Chief Scientific Officer of the Ageless Regenerative Institute. The Ageless and Stemlogix Programs involve education, training, technology and support in delivering regenerative medicine to clinicians and veterinarians. Ms. Comella has over ten years of cell culturing experience including building and managing the stem cell laboratory at Tulane University's Center for Gene Therapy. She also developed stem cell therapies for osteoarthritis at Osiris Therapeutics. Ms. Comella holds an M.S. in Chemical Engineering from The Ohio State University and a B.S. in Chemical Engineering from the University of South Florida.

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Subject A

• Before • After 10 min • The following day

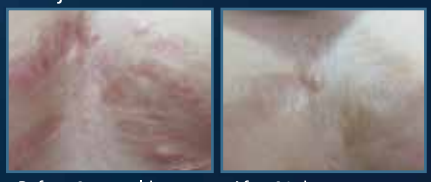
Subject B

• Before • After 10 min

Subject C

• Before • After 1 week • After 2 weeks

Subject D



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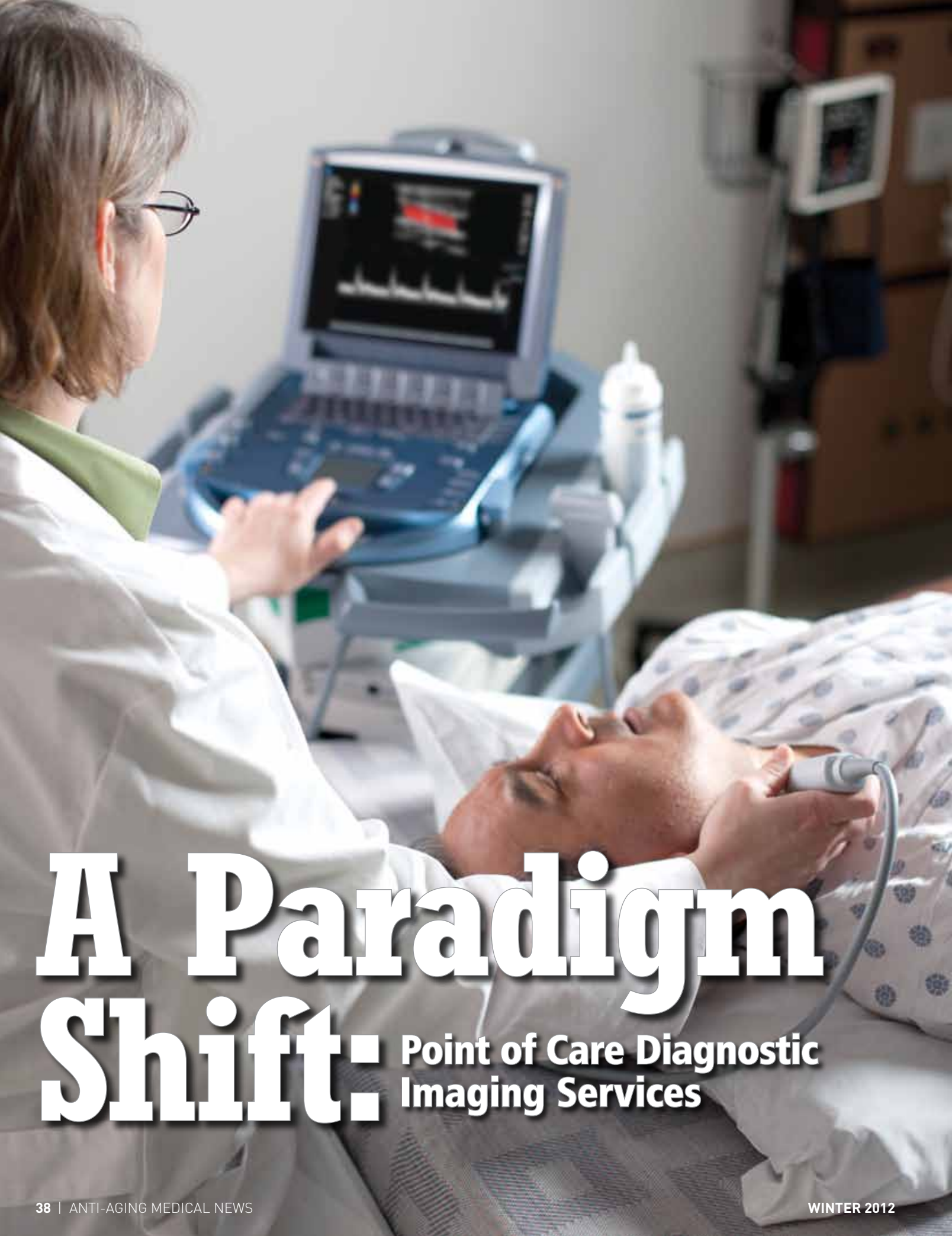


A Paradigm Shift:

Point of Care Diagnostic Imaging Services

By: Dr. Andrew Rosenson, M.D.

THE TIME HAS COME FOR A PARADIGM SHIFT in how diagnostic imaging services are provided. In the traditional model of diagnostic imaging, services were provided by radiologists located in a diagnostic imaging facility or department. Historically, this was a very reasonable model. Expensive radiology equipment could be centrally located in a single facility and used by multiple, unrelated, referring physicians, thus maximizing its use by spreading the cost for equipment over more patients than any one physician referred. No single medical practice would bear the high cost of radiology equipment with relatively few patients utilizing it. Moreover, the interpreting radiologist was located at the site of the equipment. This, of course, facilitated the radiologists reading for multiple referring physicians. Once the exam was interpreted, a centralized transcription service would type the reports and give them to the radiologist to sign, before sending them back to the referring physician. The process may have been somewhat tedious by today's standards, but it accomplished the goal of getting the radiologist's interpretation to the referring physician. In addition, the radiologist provided on-site supervision and oversight of quality assurance for exams performed.

Prior to recent advances in technology, this was the most effective and common model. Over the past few years, however, developing technology has led to a rapid stream of game-changers for diagnostic imaging. First, teleradiology allowed radiologists to leave the facility and read from any location – remote offices, home or at a conference. Today, improved technology allows the radiologist to read exams on a tablet or iPad, and, most recently, on a hand-held smart phone. Voice recognition now allows for faster reporting. Additionally, new software programs permit more standardized quality control and assurance.

None of these technological breakthroughs have given patients or their referring physician adequate control over the process by which they get their diagnostic imaging studies. Although the turnaround time for reporting is dramatically improved by voice recognition, the time that it takes for patients and their primary care physician to get that diagnostic information has often, paradoxically, increased. After a physician orders an exam, the patient still has to wait for an available appointment time at the designated imaging facility, travel to that facility, and take the test. The patient then waits for results to be sent to the referring physician. Typically, over the next few days, the patient will call the physician several times looking for results. When the results arrive, the physician's office may need to call the patient several times until they make contact. Then, in many instances, the patient will need to return to the physician's office to learn the results and discuss appropriate management. This scenario assumes, of course, that the patient's third-party payor, e.g., the insurance company, agreed that the test was justified. If not, there may have been further delay while the managing physician and insurance company's designee discussed the clinical appropriateness of the exam. Physicians are frustrated. Patient anxiety is increased. Clinical management is delayed. Treatment is delayed.

In order to avoid these obstacles for providing prompt patient service, one solution is to provide diagnostic services in the physicians' offices, at the point of care. This works well for many diagnostic tests such as rapid strep tests and urinalysis. These lab tests are evaluated with standardized equipment. They do not require the ordering physician to obtain extensive training or certification. A throat swab is taken and the swab is placed in a container where the solute reacts with it. A urine sample is obtained and it reacts with a series of reagents designed to give simple immediate diagnostic information. Can the same principles be applied to diagnostic imaging?

There are several obstacles to providing a high quality diagnostic imaging program in the primary care physician's office. The three biggest obstacles are cost, expertise and liability. With new applications of current technology, these obstacles can be overcome.

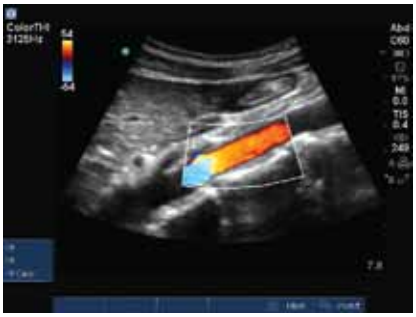
The cost of imaging equipment is usually too high for the limited volume of a single practice. In addition, the volume of patients in a particular physician's office is generally not enough to justify having a full time technologist to provide the on-site imaging.

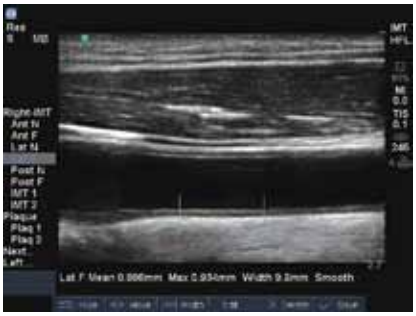
A Paradigm Shift continued on page 40

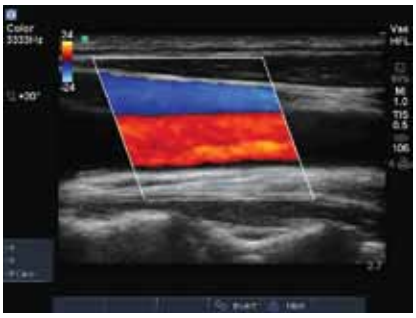
As a medical community, we need to provide patients with quality diagnostic studies in a timely way so clinical management can be implemented promptly and efficiently.

A Paradigm Shift continued from page 39

The expertise required for diagnostic imaging is extensive. It requires broad, complex skill sets and training that most non-radiologists lack. Although there are many one to three day courses designed to train physicians in the use of imaging modalities, there is no data showing that the competency of those physicians completing these courses would satisfy the requirements of recognized medical boards. In order to rein in the cost of health care and provide assurance of quality, insurance and government programs are increasingly setting applicable board certification requirements as a prerequisite to reimbursement.







Without that certification, many primary care physicians are concerned about the accompanying liability. Progressively more regulations require physicians to maintain quality assurance programs to monitor the quality of imaging exams. The government and third party payors increasingly require that facilities be certified for providing imaging services, as well as requiring that the physicians are certified for interpreting them.

As a medical community, we need to provide patients with quality diagnostic studies in a timely way so clinical management can be implemented promptly and efficiently. How do we overcome the obstacles of cost, expertise and liability to accomplish this with diagnostic imaging? We propose a paradigm shift in the way in-office diagnostic imaging is provided. We propose creating a new collaboration between referring physicians, diagnostic radiologists and equipment manufacturers – Comprehensive Point-of-Care Imaging Services.

Comprehensive Point-of-Care Imaging Services is a model that provides services to patients with their primary care physician and radiologist working together. Using state-of-the-art technology to overcome the obstacles described above, we can bring patient service to a new level. Creating this collaboration brings down the cost of equipment for the physician and, in turn, the cost of service for the patient. Implementation includes appropriate, focused, step-by-step training; and integrating the training with the expertise of the collaborating radiologist will assure quality and manage liability.

Although comprehensive point-of-care imaging services can apply to various types of imaging, ultrasound is an ideal modality for this program. To lower the cost of equipment, the physician must first identify how the equipment will be used for his or her specific practice. The physician's office is not a broad, full-service imaging facility. It needs to provide only those exams most often needed by the majority of its patients. Therefore the equipment does not have to be as robust – or as costly – as that used in a full-service imaging center. Working with the manufacturers, we can lower the cost of equipment by customizing it to the needs of the primary care physician's office.

Similarly, in defining the training needed for performing an exam, we first need to understand the goal is not to make the primary care physician into a radiologist or an imaging technologist. The objective is not to try moving all imaging into the physician's office, but rather to bring some imaging procedures into the physician's office and to create customized training programs to teach the health care provider how to perform some specific exams, such as a screening carotid ultrasound. This idea is no different than the way primary care physicians currently practice clinical medicine. For example, a primary care physician will treat some cardiac problems, while referring others to the cardiologist. Similarly, we need an imaging system that allows the physician to perform those studies that he or she is trained to do while referring out those requiring more complex training and skills.

Once an exam is performed, we can use state-of-the-art technology to bring the radiologist virtually into the physician's office. As the exams are performed, they are sent to the radiologist for immediate review and interpretation. This accomplishes multiple goals. The radiologist can now provide quality control review of every exam before it is interpreted. If an exam does not meet quality standards, the health care provider performing the exam receives immediate feedback and guidance to complete the exam.

After the exam is completed, it can then be interpreted by the board certified radiologist. With appropriate technology and workflow, a final report can be provided to the physician before the patient is ready to leave the office. Thus, clinical decisions can be made and management plans implemented without waiting for appointments at outside facilities, without enduring multiple phone calls, and without waiting for follow-up appointments.

A Paradigm Shift continued on page 42

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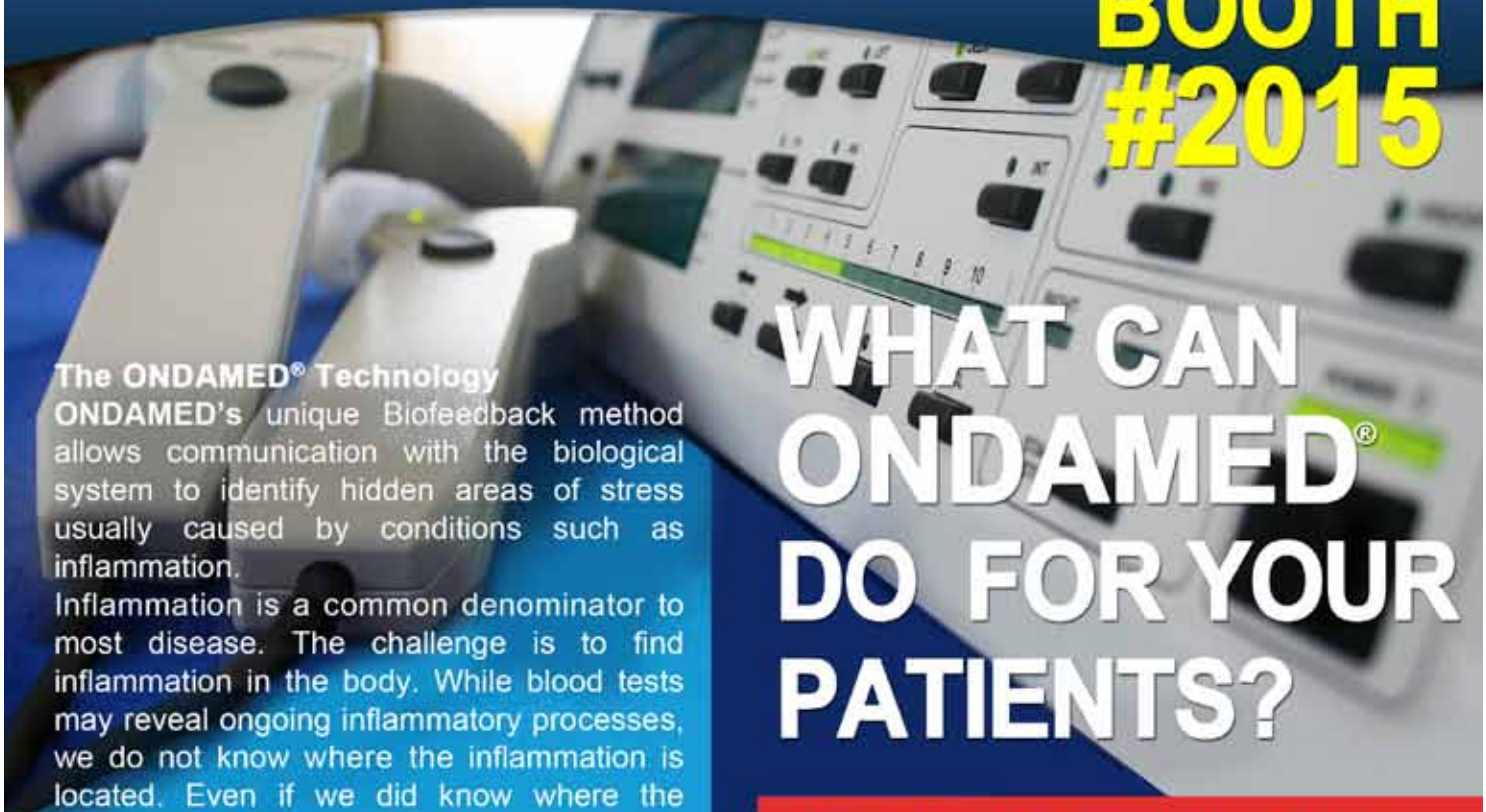

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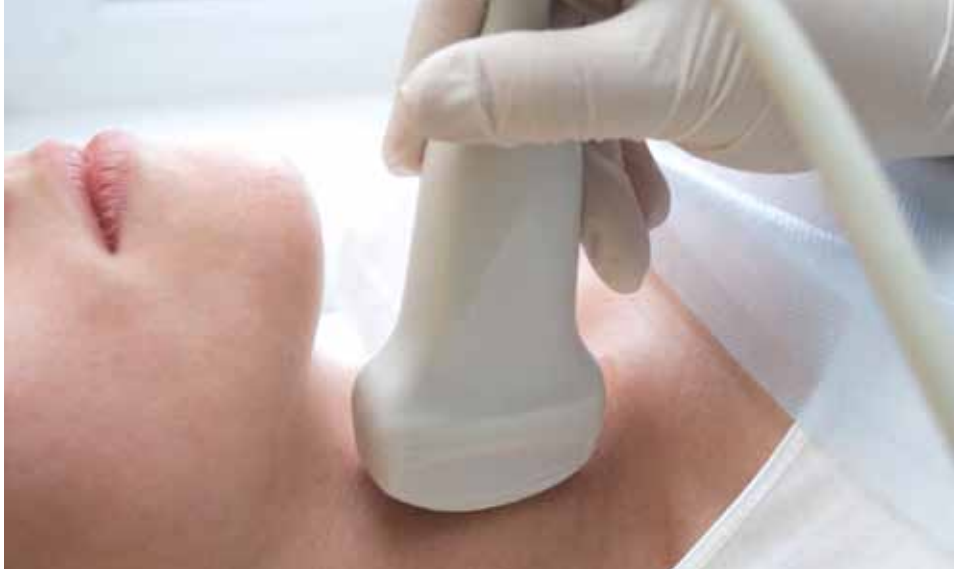
A Paradigm Shift continued from page 40

This program is easily adapted for ultrasound. Ultrasound machines can be manufactured at a lower cost when the functionality is limited. Health care providers can learn to perform the exams when the scope of exams is limited. Each exam requires its own specific training module based on its complexity. Every exam is reviewed and interpreted by a board certified radiologist. If needed or if requested by the health care provider, additional, supplemental training is available to maintain the quality of the exams. An appropriate work flow is established for reviewing and interpreting exams; a work flow designed to coincide with the physician's work flow and thus provide final interpretive reports to the physician while the patient is present.

The time has come for this paradigm shift in health care. It is time for the medical community to give patients the service level that this collaboration will allow. Patients no longer need to endure the anxiety of waiting for results. Physicians do not have to spend time pursuing the results. Most importantly, patient care and management can be implemented at the Point of Care.



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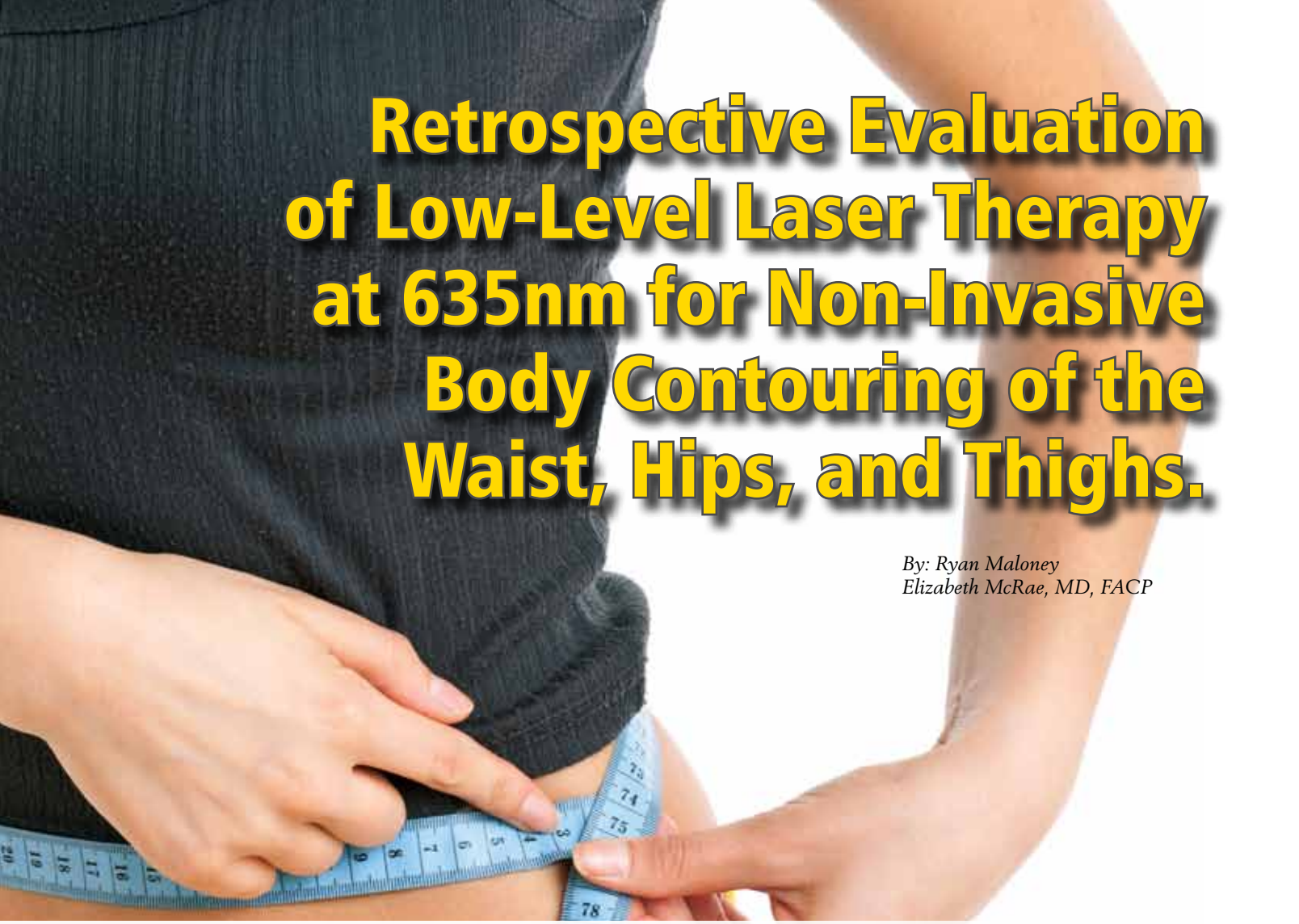


Retrospective Evaluation of Low-Level Laser Therapy at 635nm for Non-Invasive Body Contouring of the Waist, Hips, and Thighs.

By: Ryan Maloney
Elizabeth McRae, MD, FACP

INTRODUCTION

Current non-invasive body contouring technologies have catalyzed the growth in non-invasive tightening procedures by 20% from 2010 to 2011 [1]. Contributing directly to the growth of the non-invasive segments is low-level laser therapy at 635nm (LLLT-635nm). Studies have demonstrated that the delivery of a 635nm, 17.5mW line-generated laser beam activates secondary cascades within adipocytes triggering the formation of transitory pores within the cell's membrane [2-19]. The newly formed pores act as an egress, allowing the stored intracellular lipid material to vacate adipocytes, which, in turn, causes the enlarged (hypertrophic) adipocytes to collapse [2-19].

Modulating intracellular reactions with LLLT-635nm requires, first, activation of a photoreceptor molecule, which is a chemical structure able to absorb discrete colors of light [12, 16, 21]. A well-studied photoreceptor is the terminal enzyme of the respiratory chain, known as cytochrome c oxidase (CCO) [22-30]. Laser therapy activates CCO, in turn, increasing the synthesis of adenosine triphosphate (ATP) and reactive oxygenspecies (ROS) [32]. As a result, increased ATP and ROS production directly affects secondary signaling cascades, cascades that influence the overall function and behavior of the treatment cell. The mechanism of LLLT-635nm is analogous to the agonist effect of a certain class of pharmacological agents. Agonist pharmacological agents introduce a specific molecular configuration that, when absorbed, seek out and bind with a specific molecular receptor. When the receptor is bound to the drug, the receptor triggers a cascade within the cell that affects cell function and behavior. Conversely, LLLT-635nm affects overall cell physiology by using laser energy to target and activate a photoreceptor molecule instead.

To validate the clinical utility of LLLT-635, two placebo-controlled, double-blinded, multi-centered clinical studies were peformed [12-16]. Jackson et al. (2009) reported a combined circumferential loss of 3.5 inches (8.9 cm) for the waist, hips, and thighs after two weeks [12]. Nestor et al. (2012) treated upper extremities with LLLT-635nm and reported a combined loss of 3.7cm after two weeks [13].

To further validate the utility of LLLT-635nm, we performed an independent, retrospective investigation to examine the objective findings of 86 subjects who underwent LLLT-635nm for non-invasive body contouring of the waist, hips, and thighs.

Methods:

Eighty-six participants were retrospectively assessed at an individual clinic in the United States. Participants were excluded if they presented with a chronic, progressive medical disorder or were not considered of overall good health.

All subjects received treatment with a multiple head low-level diode laser consisting of five independent diode laser heads with each emitting a 635nm wavelength with each diode producing an output intensity of 17.5mW (The Erchonia® Zerona Laser, McKinney, Texas 75069). Subjects were informed that the device was FDA cleared for non-invasive body contouring of the waist, hips, and thighs.

Study Design

All subjects had their waist, hips, and individual thighs measured at baseline. In lieu of using anatomical landmarks (i.e. iliac crest, navel, or pubis), patients were asked to stand adjacent to a height chart to identify where their greatest accumulation of subcutaneous fat was located. Once the measurement points were identified, the patient was circled at each measurement point using a pressurized tape measure. Circumference was measured at two separate evaluation points: pre-procedure and one-week post-procedure.

In addition to the treatment laser, supplements were used to facilitate fat metabolism. The following supplements were used during the study: 100mg of niacin, 100mg of niacinamide, 100mg of L-carnitine, 880mg of omega-3 fish oil, 60mg of ginkgo biloba, and 200mg of decaffeinated green tea extract. Additionally, subjects consumed 2.0L of water per day to maintain proper hydration. The treatment administration phase consisted of six total laser treatments delivered every-other-day for two weeks. A single treatment included concurrent treatment of the waist, hips, and thighs - 20 minutes of anterior stimulation and 20 minutes of posterior stimulation.

Results:

Compared with baseline circumference measurement, an overall circumference change of -2.99 inches (or -7.59cm) was reported **(Table 1)**.

Table 1: Mean total circumference change for waists, hips and thighs (n=84)

	Mean (ins.)			2-tailed P	Pr > |t|
	Pre-Procedure	Post-Procedure	Difference		
WHT	123.38	120.39	2.99	P <0.0001	<0.0001
Standard Deviation	12.03	11.89	2.04		

For the entire treatment population, circumference measurement changes demonstrated had the greatest density between -4.0 and -2.0 inches **(Figure 1)**.

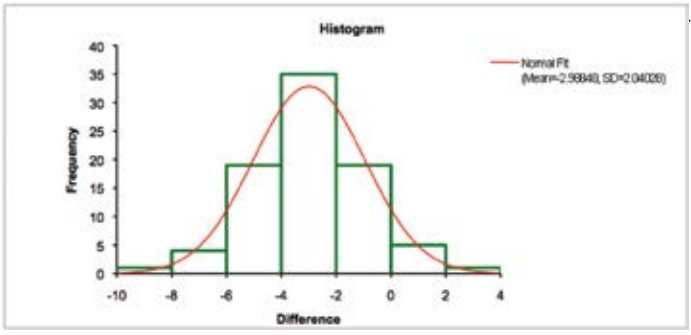


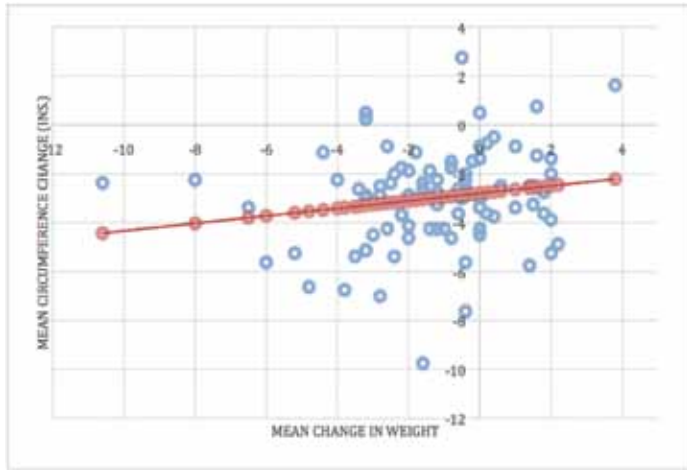
***Figure 1:** Probability distribution for the mean change in total combined circumference for waist, hips and thighs*

When the measurement points were assessed individually, a statistically significant change was observed **(Table 2)**.

	Mean (ins.)			37.28
	Pre-Procedure	Post-Procedure	Difference	
Waist Only	37.28	36.16	-1.12	P <0.0001
Standard Deviation	4.97	4.9355	1.11	
Flanks Only	40.955	40.186	-0.,769	P <0.0001
Standard Deviation	4.156	4.420	1.051	
Thighs Only (Left + Right)	45.28	44.11	-1.17	P <0.0001
Standard Deviation	4.97	4.44	1.42	

To assess the role weight played in the reported circumferential change, a linear regression was plotted to assess the correlation coefficient. Comparison of the independent mean weight change and the independent waist, hips, and thighs mean circumferential change reported a correlation coefficient of 0.179, which evidenced a weak correlation. **(Figure 2)**

***Figure 2:** Comparison of the independent mean weight change and the independent waist, hips, and thighs mean circumferential change*



Discussion:

These data demonstrate the clinical utility of LLLT-635nm for non-invasive body contouring of the waist, hips, and thighs. Additionally, our reported results reinforce preceding studies. Collectively, the clinical studies focused on elucidating the clinical benefit of LLLT-635nm for non-invasive body contouring aptly demonstrate its effectiveness and safety. Nevertheless, as a retrospective study, our study does present with limitations; this includes the lack of a control population. However, the purpose retrospective studies are not to prove the effectiveness of a therapy; that is the responsibility of a randomized, controlled study. Instead, retrospective studies determine whether previously reported results are reproducible outside of a clinically controlled environment. Nestor et al. (2012) and Jackson et al. (2009) have already published two separate placebo-controlled, randomized, double-blinded studies that appropriately revealed the overall clinical utility of LLLT-635nm. Therefore, our study was performed in an attempt to reproduce their reported outcomes within a broader, more diverse patient base.

Retrospective Evaluation of Low-Level Laser Therapy continued on page 48

Retrospective Evaluation of Low-Level Laser Therapy continued from page 47

The use of supplements also presents another limitation in our study. A retrospective study published by Jackson et al (2012) used supplements as a means to equate a multifarious population to mitigate the risks nutritional deficiency may cause [14]. In fact, studies have reported nutritional deficiencies increase the likelihood of being overweight and obese by 80% [33, 34]. Accordingly, we elected to use supplements because previously Nestor (2012) and Jackson (2009) did not employ supplements, and consequentially, serve as a baseline for LLLT-635nm as a standalone technology.

Conclusion

Histological and clinical data have substantiated LLLT-635nm mechanism and efficacy for non-invasive body contouring of the waist, hips, and thighs. This independent, clinician-led study provided an unbiased assessment of LLLT-635nm for non-invasive body contouring of the waist, hips, and thighs. Additionally, we provided empirical evidence that LLLT-635nm produces meaningful and statistically significant circumferential changes in two weeks without inducing an adverse event.

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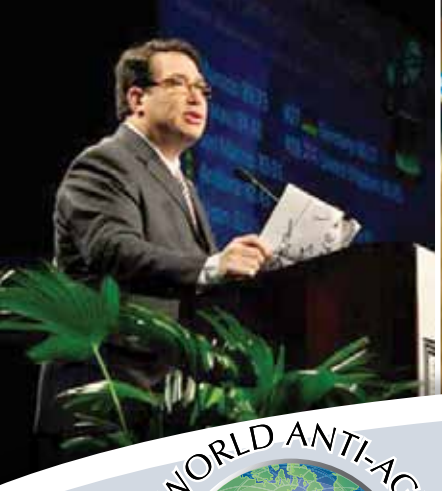

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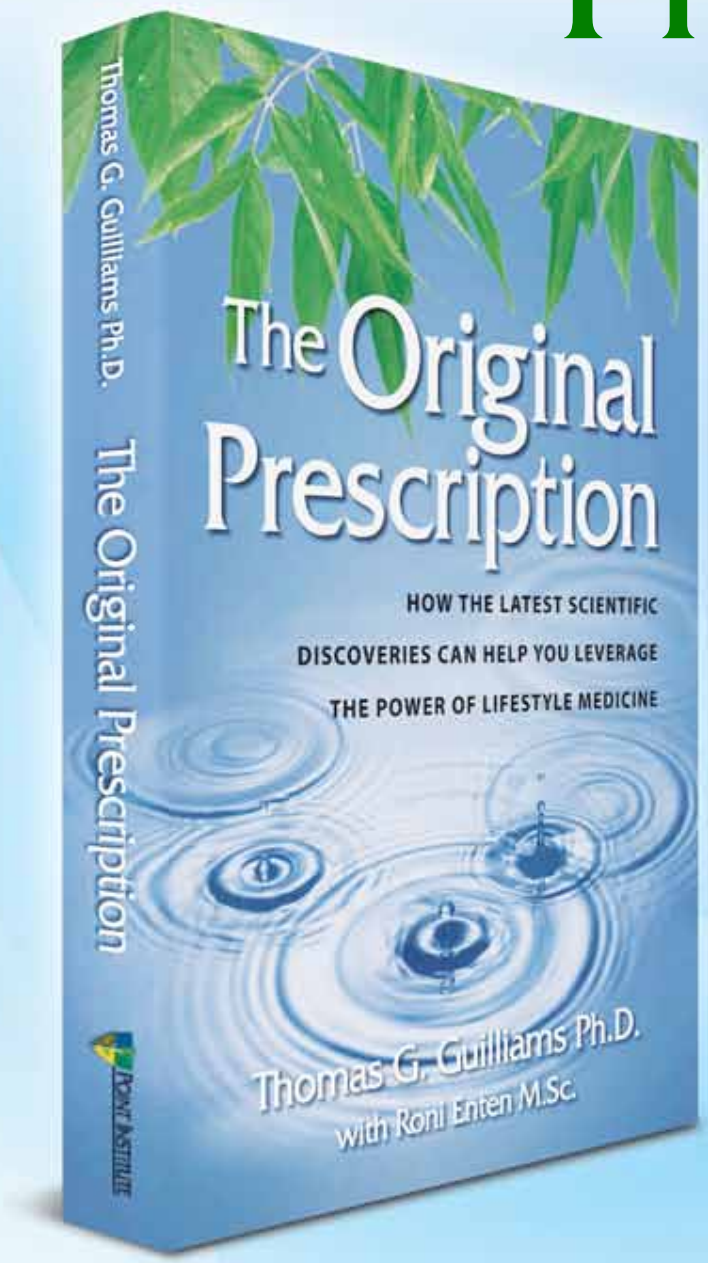

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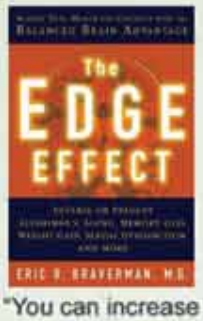

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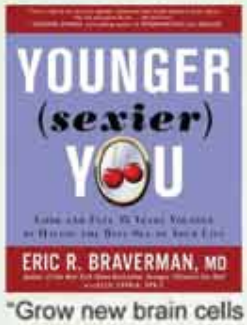

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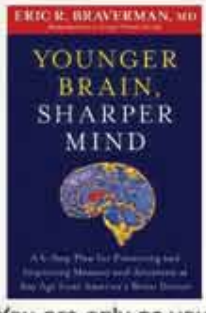

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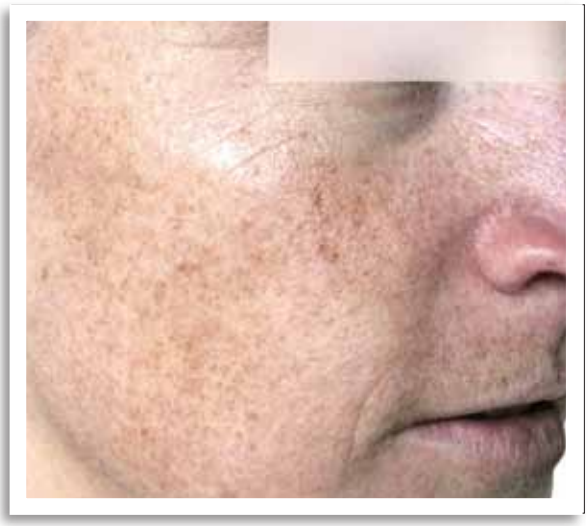

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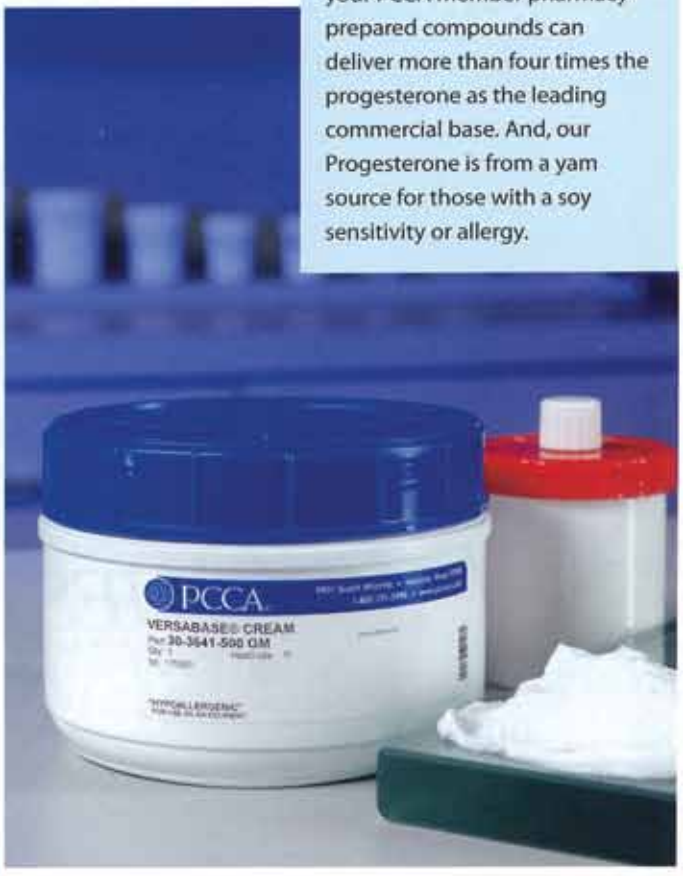

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Date	City	ABAARM Exam	ABAAHP Exam
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Feb 14	Mexico City, Mexico	*Written*	*Written*
May 5	Kuala Lumpur, Malaysia	*Written*	*Written*
Apr 10 & Apr 11-13	Orlando, Florida	*Written & Oral (11th-13th)*	*Written*
Aug 22 & Aug 24-25	Melbourne, Australia	*Written & Oral (24th-25th)*	*Written*
Sept 6-8 & Sept 9	Bangkok, Thailand	*Written & Oral (6th-8th)*	*Written*
Sept 18 & Sept 19-21	Boston, Massachusetts	*Written & Oral (19th-21st)*	*Written*
Sept 21	London, England	*Written*	*Written*
Oct 18-20	Bali, Indonesia	*Written (20th) & Oral (18th-20th)*	*Written*
Dec 12 & Dec 13-15	Las Vegas, Nevada	*Written & Oral (13th-15th)*	*Written*

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EN MEDÍCINA ANTI-ENVEJECIMIENTO Y REGENERATIVA

FEBRERO 15, 16 Y 17 DE 2013

UNIDAD DE CONGRESOS DEL CENTRO MEDICO NACIONAL SIGLO XXI

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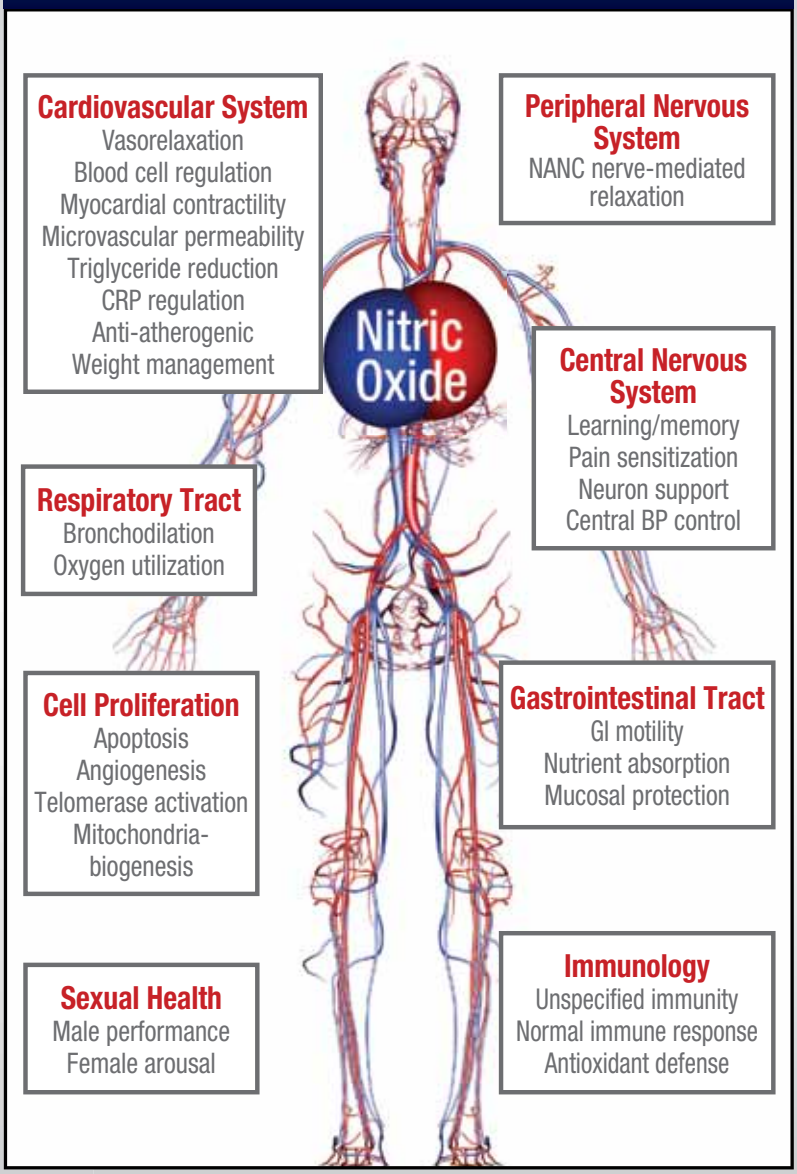

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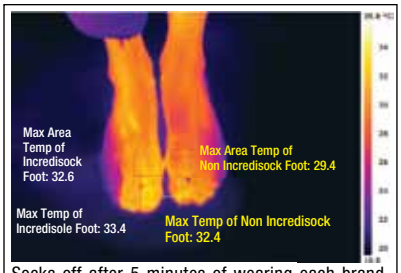

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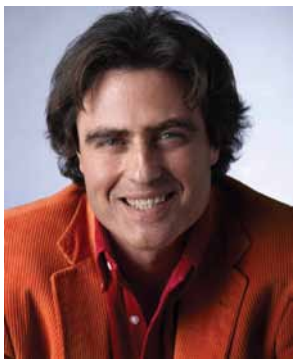
2013 CONFERENCE KEYNOTE SPEAKER

Prof Dr Thierry Hertoghe, MD



Dr Hertoghe, a world renowned endocrine expert & practicing physician, is internationally recognised as a leading specialist in Adult Hormone Deficiencies Therapies.

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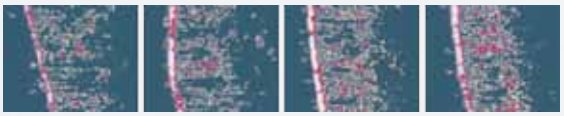

Day 0 | **Day 28** (+8% density) | **Day 56** (+26% density) | **Day 84** (+40% density)

(Source: Double-blinded placebo-controlled clinical studies at the Clinical Skin Testing Department).

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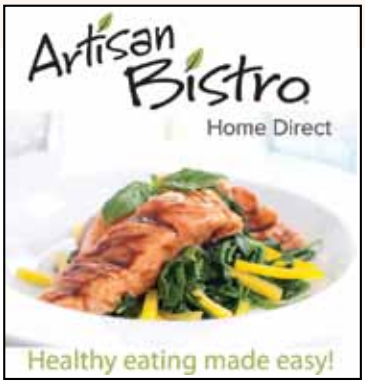

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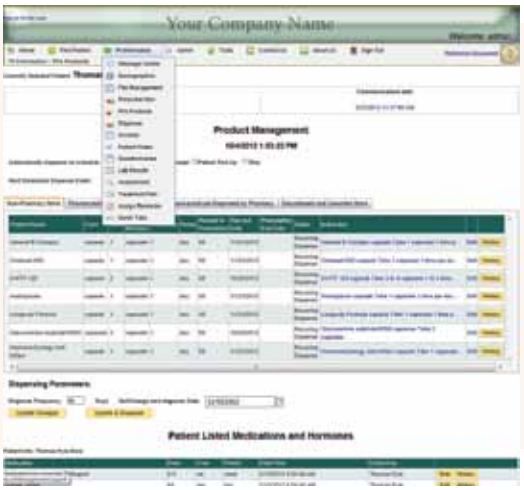

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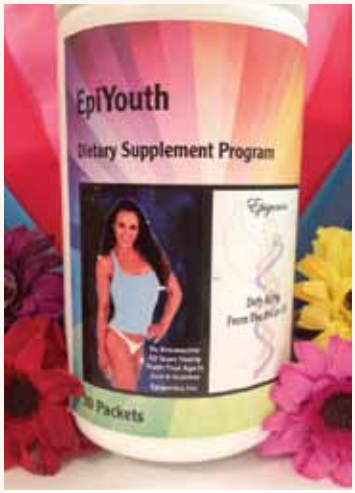

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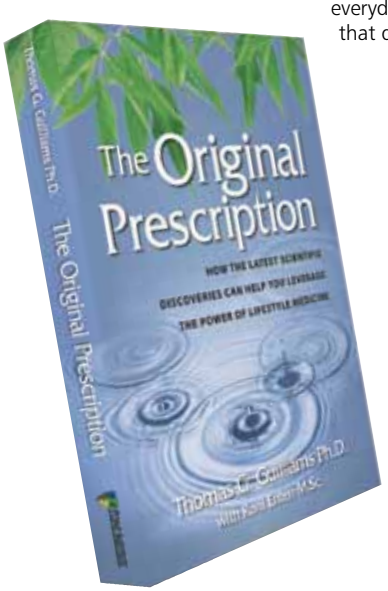

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