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We are very pleased to have the lead article in this issue by our incoming ISHRS President, Dr. Sharon Keene. This article is the first of her three-part series on low level laser light therapy (LLLT): Part 1, "The Science of LLLT," Part 2, "Regulation of LLLT Devices from a U.S. and International Perspective," and Part 3, "Controlled Trials and Understanding the Methods for Accurate Hair Counts." —RHT

The Science of Light Biostimulation and Low Level Laser Therapy (LLLT)

Sharon A. Keene, MD, FISHRS Tucson, Arizona, USA drkeene@hairrestore.com

The use of light therapy from the sun can be seen illustrated long ago in ancient Egyptian hieroglyphics. Today, the critically important process of photosynthesis, or ability of sunlight to induce chemical changes in plants to consume carbon dioxide and produce water and oxygen, is considered basic science, and taught in elementary school classes. The concept of light-induced cellular chemical reactions is not new—but the acceptance of laser light to induce therapeutic chemical changes in human cells has been slow and gradual.

In the early 1960s, only a few years after their discovery, lasers were first introduced to the medical field for their ability to ablate, dissect, cauterize, or vaporize tissue. It was a serendipitous discovery in 1967 when Dr. Endre Mester, a Hungarian physician and surgeon, first observed the biostimulating or photomodulating effects of low level laser light on tissue. Dr. Mester applied a ruby laser beam of 694nm to the backs of shaved mice, seeking to evaluate potential carcinogenic changes, when he noted instead more rapid regrowth of hair.¹ Since that time, low level laser light has been studied in over 100 randomized, controlled trials and accepted as a therapeutic modality in many human tissues.² Ironically, it would take 40 years from the first observation of photostimulated hair growth in mice until the first low level laser therapy (LLLT) device would receive legal clearance in the United States for the treatment of androgenetic alopecia in humans.³ Since the first device clearance in 2007, other devices utilizing light from laser diodes, as well as light emitting diodes (LED), have been cleared by the FDA and introduced to the U.S. market; similarly, a myriad of devices used in Asia and around the world to treat hair loss have emerged, too.

It should be noted at the outset of this planned series of articles on LLLT to treat hair loss, that many questions remain about its true efficacy, and clinical studies have not addressed some of them. Clearly, there are patients who have tried some of these devices without benefit. The purpose of this series of articles will be to review the science that supports a potential benefit for LLLT to treat hair loss in some patients, as well as the practical limitations of current devices based on variations in hair characteristics and coverage—and certain properties of light in general, as well as device designs or use, in particular. Subsequent articles in this series will delve into what doctors need to know about medical and laser device regulation. In particular, how to determine whether the device your patient is using, or you are selling, is legal in your jurisdiction. Devices that haven't been approved by regulatory agencies may not have met requirements for safety, and may also pose issues of legal liability—which means they are not prudent for consumer use, and neither for a doctor's good reputation. Furthermore, there are now several randomized, controlled trials that support the use of LLLT to treat hair loss, and these will likely be used for marketing purposes, so doctors need to be familiar with them and their reported conclusions. Importantly, some of these studies appear to have substantive flaws in hair counting methodology raising critical questions of their validity and claims, and the correct method to gather and analyze this data will be reviewed. Issues pertaining to dosing or application of particular wavelengths and timing/frequency with a view to encouraging member participation in future clinical trials will also be discussed.

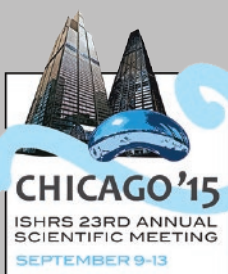
Low Level Laser Light and Mechanisms of Cell Biostimulation

Low level laser light is defined in part by its wavelength which is visible light in the 500nm-1100nm wavelength range, and this determines its properties of tissue absorption. The other characteristic is low power and low power density,

1mW-500mW (5W) and 1mW-500mW/cm², respectively, ensure a low thermal output and prevent tissue heating. Studies have shown a minimum of 13 W/cm² is required to cause first degree skin burns, and 24 W/

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www.ishrs.org/AnnualMeeting.html



Hair Transplant Forum International Volume 24, Number 6

Hair Transplant Forum International is published bi-monthly by the International Society of Hair Restoration Surgery, 303 West State Street, Geneva, IL 60134 USA. First class postage paid at Chicago, IL and additional mailing offices. POSTMASTER: Send address changes to Hair Transplant Forum International, International Society of Hair Restoration Surgery, 303 West State Street, Geneva, IL 60134 USA. Telephone: 1-630-262-5399, U.S. Domestic Toll Free: 1-800-444-2737; Fax: 1-630-262-1520.

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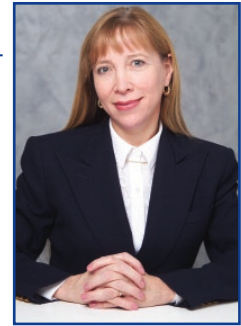
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President's Message

Sharon A. Keene, MD, FISHRS *Tucson, Arizona, USA* skeene@ishrs.org



As the incoming president of the ISHRS, returning home from the first annual meeting held in Asia, at the beautiful Shangri-La Hotel in Kuala Lumpur, I was filled with a sense of pride for the breadth and reach of our Society's international stature. The shared commitment among regional societies to the goal of providing hair restoration patients our "best practices" in order to achieve optimal outcomes was inspirational.

Those who attended received a superb educational experience under the guidance and planning of our esteemed scientific chairman, Dr. Damkerng Pathomvanich. Despite many challenges, the meeting was managed in a seemingly effortless fashion by our executive director, Victoria Ceh, and her staff.

There was cause for celebration on many fronts. First, not only did we exceed the number of expected attendees, we welcomed the largest number of first-time attendees in ISHRS history! From a program perspective, attendees witnessed a historic and important marriage of surgical techniques—the union and integration of the follicular unit micro-dissection strip harvesting and follicular unit extraction (FUE) methods. In fact, an entire panel was devoted to the video illustration of both techniques simultaneously in patients with extensive hair loss where maximal graft yield could not be obtained by either technique alone. Presenters shared their experience with how these techniques can be used to achieve optimal outcomes, with the caveat that both techniques inherently cause scarring, a risk for donor area shock loss, and, because of finite permanent donor hair, have their limitations. We look forward to the progress of the ISHRS's FUE Research Committee with IRB-approved studies to answer many of the questions about yield and methods to achieve optimal growth and patient selection. Of course, donor harvesting is but one aspect of graft yield; placement techniques and storage solutions remained hot topics of analysis and review. Many of the same questions and subjects have been investigated since we first began to perform follicular unit grafting in the 1990s, but they are now being revisited to ensure the safest and most effective use of FUE harvesting techniques, too.

On a related theme, we are receiving strong support from regional hair restoration surgery (HRS) societies for the ISHRS policies on ethics and best practices. Doctors in our field must be held accountable for wrongly delegating critical aspects of surgery to assistants. Furthermore, members have shared their concerns about websites and advertising that misrepresent techniques, outcomes, or credentials, and they are irate when they see doctors who claim membership in our organization when they do not have it. We are taking measures to address the legal aspects of these issues, however, no medical society can instill ethics. It is an individual doctor's character and commitment to doing what is right for patients, rather than what is easier or, perhaps, more profitable, that will set the ethical doctor apart. Policing is the job of medical boards and regulators, not a medical society. Nevertheless, we acknowledge reports that some doctors are being taken to task by medical regulators for allowing assistants to perform FUE, and we applaud this action. Furthermore, even though the ISHRS is not a regulatory body, as a medical society we are allowed to select and maintain as members only those who adhere to our policies, including best practices. With this in mind, we are expanding our Membership Committee and scrutinizing new applicants more carefully—and listening to regional HRS societies when determining membership approval.

As a medical society, we continue to build our reputation in the world, and want the public and our medical colleagues to recognize membership in the ISHRS will stand for those who strive to follow best practices that result in optimal patient care—and not simply what is legally allowed. Achieving and maintaining these standards includes diligent education and training in all surgical techniques so that a doctor is comfortable and competent to train their own staff and provide important options for informed consent. The ISHRS is committed to continuing medical education to assist in these competencies. We are also committed to providing education on evidence based medical therapies, and promoting research of novel therapies to establish

Co-editors' Messages

Mario Marzola, MBBS Adelaide, South Australia editors@ISHRS.org

Our 22nd Annual Scientific Meeting in Kuala Lumpur was an outstanding success on many fronts. The weather was nice, the hotel accommodation and conference facilities great, and as you will read elsewhere in this issue, Dr. Damkerng Pathomvanich and his Scientific Committee put on a great program. Our indefatigable leader, Victoria Ceh, and her helpers ran the meeting as smoothly as ever. Seamless was a word often used. Congratulations to all. If you weren't there, I'm sorry to say you missed something special. Forty-one percent of registrants were first timers, nearly double the usual number. That is healthy for the future of our Society. There were more attendees from Asia than ever before with America and India vying for first place with 58 each. Read in the Cyberchat column some lighthearted and entertaining banter between Drs. Wolf and Cole, and their take on the meeting. It's great reading.

I join with others who have congratulated our award winners, Dr. Ken Washenik with the Platinum Follicle and Dr. Jim Harris with the Golden Follicle. The highest award our Society can give is the Manfred Lucas award, and Australia is very proud of this year's winner, Dr. Russell Knudsen. We are also very indebted to Dr. Vincenzo Gambino for guiding our Society for this past year. Congratulations to all!

We have many interesting articles lined up for next year's issues of the *Forum*. We hope they will all be informative and fun to read, but we also hope that some will challenge the way we think of hair growth and hair loss. However, the first principle of publication is to give the readers what they want, so please

write to us at editors@ISHRS.org and let us know your wishes and we will try to write on the subjects that interest you.

Dr. Bernstein reminded us that in all of this afterglow, we still have many challenges ahead, and indeed we have. False advertising in the pursuit of market advantage has always been with us and we struggle to find ways to curb it. No doubt the doctors who rely on this to secure patients will end up in court being sued by their unhappy patients, but the damage has already been done. Similarly, the practice of medicine by unlicensed and unsupervised technicians who perform all the hair restoration procedure may be difficult to completely control, but the Board of ISHRS has taken strong steps in this direction this year. There is no getting away from the time-tested, traditional way of becoming a successful medical practitioner: do the time, be an apprentice with a helpful mentor, and avoid the avoidable complications and do no harm wherever possible. Not only will we be successful, but we will sleep better at night.

This is our last edition for 2014. My co-editor Dr. Bob True and I have enjoyed our first year in the job and hope you have enjoyed reading the *Forum*. As we head into the holiday season, it is good to reflect upon the year that has just passed. We hope that life has treated you well both personally and professionally and that enough time has been taken to spend with the ones we love. See you in 2015. ♦



Robert H. True, MD, MPH, FISHRS New York, New York, USA editors@ISHRS.org

As we come to the close of our first year of editing the *Forum*, I want to express my gratitude to all who have made contributions. I think we have had very interesting and relevant issues. Our columnists, Drs. Marco Barusco, Tim Carman, John Cole, Jeff Donovan, David Perez-Mesa, Nicole Rogers, Sara Wasserbauer, and Brad Wolf have done a great job and we look forward to more of the same in 2015.

I want to thank my dear friend, Dr. Vincenzo Gambino, for his courageous and steady service as our President this year. He smoothly took us through the difficulties of the change of meeting venue and in addressing the problem of unlicensed technicians. With Dr. Sharon Keene as our incoming President and Dr. Nilofer Farjo as the Scientific Program Chair, we should expect another great year in 2015.

The Kuala Lumpur meeting turned out to be a great success both in terms of attendance and program quality. Dr. Pathomvanich, Victoria Ceh, the ISHRS staff, and the Annual Meeting Committee members deserve hearty congratulations.

Our full meeting summaries will appear in the January/February 2015 *Forum*. In this issue, we feature the winners of the Poster Presentations, Dr. Haber reports on some surprising norms of practice as revealed by the Audience Response System (ARS) from the Kuala Lumpur meeting, and Drs. Wolf and Cole provide an entertaining discussion of highlights of the meeting in Cyberchat. Part of that discussion addresses the impact of various types and sizes of punches on the donor area in FUE and the best way to obtain single follicle grafts. I'd like to add to these

insights. In obtaining single-hair grafts with FUE, it is essential to do so in a way that preserves the donor area follicular architecture. The patchy appearance of the donor area after FUE is primarily related to the size of the area devoid of hair after extraction rather than the size of the punch site. As shown in Figure 1, taking the only follicle in the center of a field produces a much larger area of bald skin; whereas extracting the follicle adjacent to a group of follicles produces a very

⇒ page 205

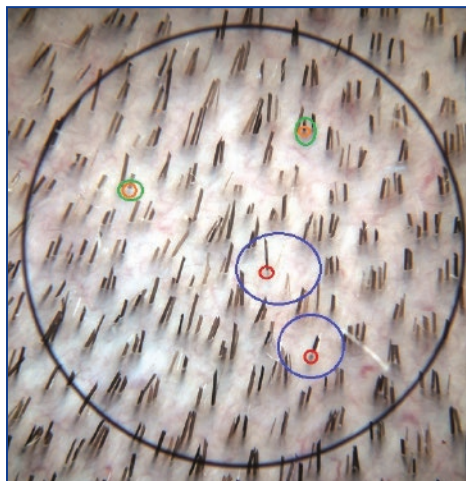


Figure 1. Red circles indicate follicles removed in the center of a field and blue circles the size of the hairless areas that result. Orange circles indicate follicles harvested adjacent to a group of follicles and green circles the size of the hairless areas that result.

INTERNATIONAL SOCIETY OF HAIR RESTORATION SURGERY

Vision: To establish the ISHRS as a leading unbiased authority in medical and surgical hair restoration.

Mission: To achieve excellence in medical and surgical outcomes by promoting member education, international collegiality, research, ethics, and public awareness.

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Editorial Guidelines for Submission and Acceptance of Articles for the Forum Publication

- Articles should be written with the intent of sharing scientific information with the purpose of progressing the art and science of hair restoration and benefiting patient outcomes.
- If results are presented, the medical regimen or surgical techniques that were used to obtain the results should be disclosed in detail.
- Articles submitted with the sole purpose of promotion or marketing will not be accepted.
- Authors should acknowledge all funding sources that supported their work as well as any relevant corporate affiliation.
- Trademarked names should not be used to refer to devices or techniques, when possible.
- Although we encourage submission of articles that may only contain the author's opinion for the purpose of stimulating thought, the editors may present such articles to colleagues who are experts in the particular area in question, for the purpose of obtaining rebuttal opinions to be published alongside the original article. Occasionally, a manuscript might be sent to an external reviewer, who will judge the manuscript in a blinded fashion to make recommendations about its acceptance, further revision, or rejection.
- Once the manuscript is accepted, it will be published as soon as possible, depending on space availability.
- All manuscripts should be submitted to editors@ishrs.org.
- A completed Author Authorization and Release form—sent as a Word document (not a fax)—must accompany your submission. The form can be obtained in the Members Only section of the Society website at www.ishrs.org.
- All photos and figures referred to in your article should be sent as separate attachments in JPEG or TIFF format. Be sure to attach your files to the email. Do NOT embed your files in the email or in the document itself (other than to show placement within the article).
- We CANNOT accept photos taken on cell phones.
- Please include a contact email address to be published with your article.

Submission deadlines:

December 5 for January/February 2015 issue

February 5 for March/April 2015 issue

April 5 for May/June 2015 issue

June 5 for July/August 2015 issue

August 5 for September/October 2015 issue

October 5 for November/December 2015 issue



President's Message *from page 202*

their legitimate use. As president, I encourage our members to actively investigate or learn about new therapies to ensure what we recommend is really beneficial to treating hair loss. Based on the lecture I gave in Kuala Lumpur on low level laser therapy (LLLT) to treat hair loss, I will be authoring a series in the Forum to encourage members to scrutinize studies and to know when this modality may benefit a patient, and when it is unlikely to do so.

When properly used, technology can provide advancements in surgical outcomes. But history has shown technology in medicine has risks and limitations, too. Our responsibility is to ensure that technological innovation in the field of hair restoration surgery is only recommended when it is advantageous to patient care and outcomes, and never simply for increased profits, realizing these are not necessarily mutually exclusive.

I also wish to express my gratitude to my predecessor presidents with whom I have worked these past 3 years on the executive committee—most immediately Dr. Vincenzo Gambino, and prior to him Drs. Carlos Puig and Jennifer Martinick—all of whom worked courageously and diligently to establish policies that support best practices—including active opposition to the

unlicensed practice of medicine. Their work included providing a way to recognize members who have made the extra effort to learn and teach, with the title of “Fellow” of the ISHRS. I encourage all members who wish to lecture and share their experiences to submit an abstract for the 2015 Annual Scientific Meeting in Chicago, Illinois.

Finally, we have responded to concerns that an onslaught of business forces threatened to turn the breadth of hair restoration science and surgery into a mere technical procedure for any medical practice. To allow this would disadvantage patient care and squash the progress ISHRS members have made toward developing and providing a comprehensive diagnostic and treatment program for men and women who suffer from hair loss—most of which appears to be hormonally and genetically mediated, but may have treatable accelerants. We will continue to educate the public about their options for treating hair loss. I encourage members to share their suggestions, questions, or concerns with me on issues they feel are important to our field. I also wish to thank my colleagues and fellow ISHRS members for placing their faith in me to lead us further toward our goals. My contact e mail address for my year as ISHRS president is skeene@ishrs.org. ♦

True Message *from page 203*

small increase in the size of the hairless skin. Being strategic in follicle selection and in partial harvesting of a group of follicles rather than removing all of the follicles in a group represents an important evolution of the FUE technique that does a better job of preserving the donor region appearance and supply.

Not all practices do so, but some of us do screen our patients for bloodborne pathogens prior to surgery. I have always felt that this is good practice and over the years I have made many

primary diagnoses of HIV and hepatitis. The good news is that the new technology HIV-1/2 Fourth Generation testing is significantly more sensitive and is able to detect infection 20 days earlier, so the window between virus acquisition and detection is shortened. Also, the new assays that have replaced the Western blot are able to give same day confirmation and detection of the virus even in the absence of antibodies. ♦

SEEKING PRACTICAL TIPS!

Do you have a practical tip for our readers:

- How you organize? • Tools you have invented? • Patient education aides? • Staff building?
- Post-op care? • Surgical technique?

It doesn't have to be a major discovery...sometimes even small tips can make a big difference.

Please contact Dr. Tim Carman, “How I Do It” column, at tcarmanmd@me.com and share your insights.



Notes from the Editor Emeritus

Robert S. Haber, MD, FISHRS *Cleveland, Ohio* HaberDerm@gmail.com



With a great meeting fresh on the mind, its time for a summary of the data collected by the ARS audience response system (ARS), some reflection, and perhaps a bit of curmudgeonly commentary. The 22nd annual meeting of the ISHRS in Kuala Lumpur was certainly a success, with credit to Damkerng Pathomvanich and the Scientific Committee team. Also much thanks must go to Vincenzo Gambino for his steadfast guidance during his presidency. And, of course, I'm so very pleased that my friends Jim Harris, Ken Washenick, and Russell Knudsen were deservedly honored with the Golden Follicle, Platinum Follicle, and Manfred Lucas awards, respectively.

These awards were witnessed by an unusually large number of new attendees and Asians, reflecting our first ever meeting in Asia. There was also the commensurate and unfortunate absence of some of our most familiar speakers, who I think will regret, if they had a choice, deciding to sit this one out.

I've had the opportunity to review the available data collected by the ARS over the past four years. Unfortunately, questions have been asked in different ways over these years, making comparisons difficult at times, and yet the data are indeed interesting. Looking first at the demographics, we can see in Figure 1 that since 2011, attendance by North Americans has declined each year. The precipitous drop this year is unlikely to continue for the Chicago meeting, but it will be interesting to see if the long-term dominance of the field by North Americans is coming to an end. Figure 2 reveals that while Dermatologists remain the most common specialty of our field, Plastic Surgery is gaining ground, while Family Medicine and other specialties are decreasing in dominance.

Figure 3 summarizes the attendees experience in the field, and is very reassuring. There is a consistent bump of attendees with less than one year of experience, presumably those sampling our field and our meeting, and a drop in experience for the next two years. The table then reveals a left leaning bell curve with the largest group having 3-5 years of experience, followed by a

slope consistent with aging and retirement. So it would appear that our long-standing concern regarding where the next generation of hair surgeons will be coming from may be moot. This table reveals that we have lots of relative newcomers in the field, with enough experience to suggest a long-term commitment. Figure 4 reveals that consistently 50% of attendees devote all or most of their practices to hair restoration, with the other half maintaining more diversity in their practices. And Figure 5 demonstrates that attendees are performing fewer procedures over time. This may be due to an increase in beginners or an increase in the average size of the procedure. Unfortunately, the data does not exist as yet to answer that question.

Analysis of ARS responses pertaining just to this meeting was revealing as well. The majority of all hair transplantation in the world is still performed by the strip technique (60%), but clearly the pendulum is swinging. Predictably, beginners (performing HT less than 3 years) are far more likely to primarily perform FUE than FUT (64%), while more established practitioners rely on strip harvesting. In addition, 40% of meeting attendees have been performing HT less than 5 years, 20% of attendees were performing surgery less than 3 years, and 5% for more than 25 years!

Also of note is that 90% of meeting attendees perform FUE at least occasionally, but only 30% perform FUE all or almost all of the time, and interestingly, only 30% felt that in five years, all or almost all of their HT cases would be with FUE, and only 10% felt that FUE would completely replace FUT. So strip surgeons can breathe a sigh of relief that we are not really endangered.

For FUE, almost 50% harvest with a motorized sharp punch and 11% use the ARTAS® robot. Only 4% report using the NeoGraft device, suggesting that most NeoGraft users are not ISHRS members. Also noted is that 60% of FUE grafts are extracted with punches .9mm or smaller in size, and the vast majority of FUE docs are willing to perform

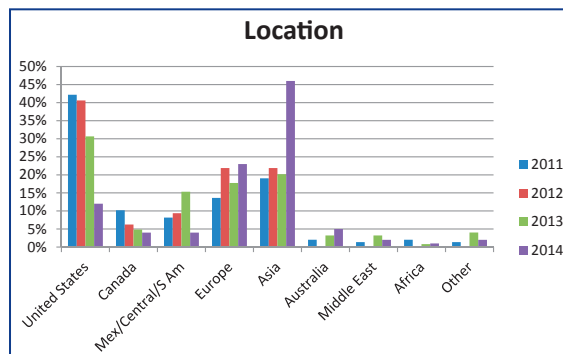


Figure 1

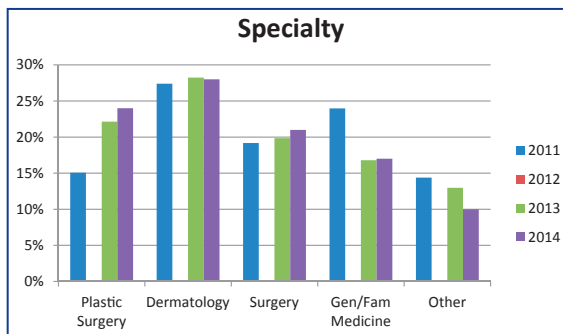


Figure 2

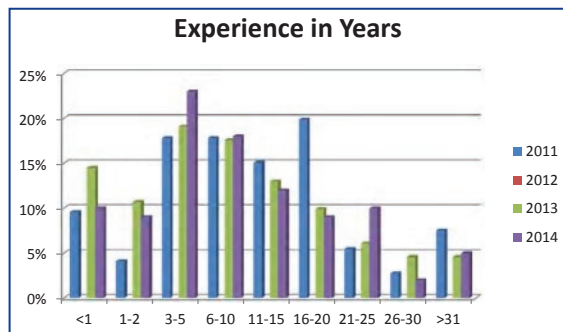


Figure 3

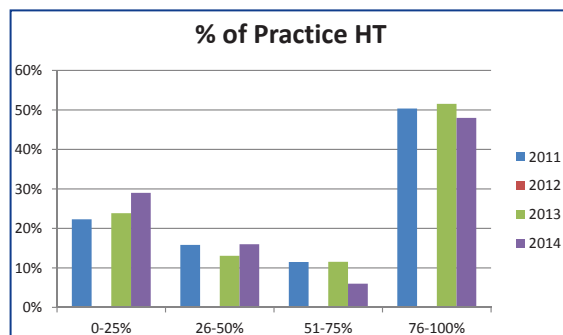


Figure 4

the procedure on women as well as men, and 90% felt that FUE and FUT were complimentary techniques, as opposed to only 11% who felt they produced the same results.

The vast majority (84%) always or almost always use scalp hair for HT. For those performing BHT, almost 60% use beard hair, 35% use torso hair, and only 7% use extremity hair. Of those responding, 82% felt that beard hair gave the best survival.

About one-quarter (24%) of attendees perform surgery very rarely (less than 1 per week), while 12% perform multiple procedures each day; the remainder perform 1-5 cases per week. Almost half of attendees devote all or almost all of their practice to HT, while 30% devoted less than 25% to HT. The majority of HT cases are under 2,000 grafts, perhaps because it's more difficult to extract larger cases using FUE. And finally, there was an even split between single- and double-layer closures, with the vast majority choosing to close with sutures.

The ARS system is a valuable tool for the ISHRS to learn about ourselves, review the past, and perhaps predict the future. I eagerly anticipate the gathering of more data.

And now for my curmudgeon side to emerge. Why is it that fully 50% of the presenters seem incapable of using a camera properly, and yet they expect us and their patients to believe they can wield a scalpel competently? How many lectures on photography will it take before we can look at photographs that are even remotely acceptable for a scientific meeting?

We hair surgeons are a conundrum. We invite and eagerly listen to scientific lectures of the highest quality, such as those delivered by Valerie Randall, Desmond Tobin, Rodney Sinclair, and Tom Dawson, yet we often follow the crowd without exercising our critical thinking skills. The most popular table by far at the Coffee with the Experts session was the platelet rich plasma (PRP) table, yet there remains an almost complete vacuum of scientific evidence supporting the efficacy of PRP in clinical practice.

We are our own worst enemy. I am proud to call myself a hair transplant surgeon, and have worked hard, like many of you, over the past 20 years, to elevate the reputation of our field that suffered so badly in prior years due to the actions of unscrupulous practitioners. And yet many of our most prominent and respected members engage in behaviors that call into question their true desire to represent themselves and our field ethically. One example is the widespread and pervasive misuse of initials after names to suggest credentials that do not in fact exist.

As professionals who have completed advanced study, and have passed rigorous examinations, we are privileged to add after our names our credentials. The initials MD, DO, FRCP, and PhD are internationally recognized, and are very meaningful. There are indeed laws that govern the use of such initials and serve to differentiate a "Lawn doctor" from a physician. Other legitimate initials include credentials that are granted after achieving additional certification. As a Board Certified Dermatologist, the American Academy of Dermatology grants me the title Fellow, and thus I am entitled to add the initials FAAD after my name.

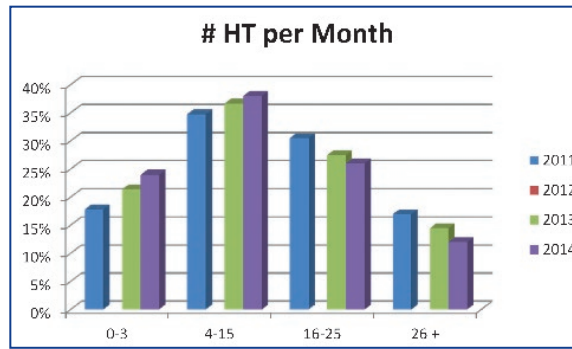


Figure 5

Organizations are not credentials, and yet a large number of my respected colleagues feel necessary to include organization acronyms after their names, including ISHRS, ABHRS, and others. While legitimately proud of these affiliations, this is unethical, deceitful, and misleading. The ISHRS has instituted the Fellow category partly to address this issue, and now those granted Fellow status can proudly use the FISHRS credential after his

or her name. Those who persist in using organization initials in place of or in addition to bona fide credentials simply reinforce our reputation as a field full of charlatans. And if this was only done by unknown individuals desperate for some sort of recognition, then perhaps I could understand, but well-known and respected men and women persist in adding these misleading acronyms after their name. On the website of the largest hair transplant chain in the world, almost 50% of the listed docs actually use the ISHRS initials after their names. Do none of those physicians have any legitimate credentials?

We have a choice. Either walk the walk, and truly attempt to elevate the reputation of our field by espousing the highest standards of conduct, which includes only using legitimate initials after our names, or give up such pretenses and do whatever it takes to convince prospective patients that we are the most amazing, innovative, respected, honored, and awarded physician since Hippocrates.

If we do not police ourselves, then the very privilege of adding initials after our names will become meaningless. If it's acceptable to add the initials of every organization we belong to after our names, virtually 100% of the population can use initials, and lots of them. So I challenge my respected colleagues to behave in the most ethical manner possible. Remove those misleading initials from your websites and your PowerPoint presentations and videos, and let your competence speak for itself.

Finally, what's happening to FUE? There was a time when strip surgeons were made to feel bad about our scars and threatened by FUE. We responded by improving donor closure techniques that now produce the best scars in our history. And now we are learning that in the interest of profit many FUE practitioners are turning over the most crucial portion of the harvest to unlicensed personnel, and many of those that do not are spending so much time harvesting that they neglect the most critical aspects of hairline design. Are we nearing the second Valley of Darkness for our field? Will we see our slowly burnishing reputation become tarnished once again? I certainly hope not. But as Murphy wisely stated: "Left to themselves, things tend to go from bad to worse," and it is up to each one of us to make sure our personal practices, our colleagues, and the entire field of hair restoration are carefully monitored and nurtured so that the future remains bright. ♦

Biostimulation and LLLT *from front page*

cm² for second degree burns.⁴ Maintaining low power in LLLT devices helps avoid thermal injury to tissue and allows the opportunity for photostimulation to occur. The first law of photobiomodulation states that a cell must have a chromophore or photoacceptor that absorbs light photons in order to stimulate a biologic response. The most common photoacceptors in tissue are melanin, hemoglobin (oxyhemoglobin and deoxyhemoglobin), and water. These are well known to doctors who may have lasers for hair removal or other cosmetic uses as these are targets for laser light. However, these chromophores actually have their lowest rate of absorption of light for the above range of wavelengths, thus creating what is referred to as the “optical window,” because with minimum absorption by these chromophores, the light wave can be absorbed elsewhere for its biostimulating effects to occur. Studies reveal the cellular organelles involved in low level laser biostimulation are the mitochondria. Specifically, a portion of that organelle’s energy and respiratory chain contains a chromophore called cytochrome c oxidase—it is the last step in the electron transport system of the mitochondria. Cytochrome c oxidase is reversibly inhibited by nitric oxide (NO) from performing its functions of electron transport and creating energy for the cell. Photons apparently are able to remove NO from cytochrome c oxidase, liberating it to perform other cellular functions. Among the functions cytochrome c oxidase is associated with are increased ATP production and modulation of reactive oxygen species, which can induce transcription factors that activate genes and produce proteins useful to the cell. The latter can result in increased cell proliferation and migration, production of growth factors (i.e., nerve growth factor), production of inflammatory mediators and cytokines, as well as increases in tissue oxygen.^{2,5} There is some evidence to suggest it may even play a role in modulating 5-alpha reductase. Specifically in regard to hair growth, it is postulated these cellular effects result in stimulation of anagen re-entry, prolongation of the anagen phase, proliferation of anagen hair follicles, and prevention of premature catagen.⁵

It has been observed that cells in tissue culture when stimulated with varying wavelengths of low level laser light produced four peaks of DNA production felt to be a reflection of increased cytochrome c oxidase activity. These wavelength ranges (to the nearest single digit) were 614-624nm, 668-684nm, 751-772nm, and 813-846nm.^{1,6} Remarkably, none of the published laser device studies to date conform to these wavelengths, raising the question of whether efficacy would be enhanced if they did.

Low Level Light Therapy as Medication and Dose

When considering low level light as medical therapy, it can help to consider the irradiance parameters as “the medicine.” The medicine, then, includes the wavelength, which determines which chromophores will offer the greatest absorption; and the irradiance, which in mathematical terms is the power (Watts) administered to a given area, or Watts/cm². Keep in mind that in the United States, LLLT devices are part of a laser class that allows a maximum power of 5mW or .005 watts.

The dosing of the “medication” adds in the element of time, or irradiation duration, known as energy. Energy is given by Watts × time (sec) = Joules. Fluence is Joules/cm². The dose is also affected by frequency of or interval between therapies.^{2,7}

Therefore, when using low level light as a therapy, the wavelength will determine a target for absorption, and the radiant energy that travels with it will determine the level of cellular excitation the light can create—meanwhile duration and interval will determine how long and frequent this excitation must occur for the desired cellular effect and clinical outcome.

Properties of Light Impacting Light Delivery and Effect on Cells

How Light Interacts with Tissue

Light interacts with tissue in the following ways: it can be reflected, transmitted, scattered or absorbed. Light wavelengths help determine the absorption of various chromophores as previously stated, but other tissue properties contribute to interactions that reduce absorption, too.⁸ For example, melanin is a known chromophore that absorbs light. Between the two types of melanin in hair, pheomelanin (blonde or red hair) and eumelanin (brown or black hair), the latter has one of the highest light absorption properties of any tissue. In fact, in a published bioengineering study using a computer simulation model to study the effect of hair color on low level laser light transmission (635nm, 5mW) for photodynamic therapy of the scalp, it was concluded that light transmission was reduced between 32-37% depending on hair color—blonde hair allowing greater light transmission than black hair. Importantly, this model assumed a hair length of only 2mm, and therefore did not consider how layering of hair would reduce transmission. Furthermore these numbers assumed a level of transmission into skin to be very superficial, only .08mm deep—less than full depth of the epidermis.⁹ When the model assumed greater skin depths of penetration, light transmission was reduced even further. One could assume transmission would be strongly impacted with longer hair lengths and layering of hair on skin—although the latter was not considered for this study. This strongly draws into question the benefit of beaming LLLT onto hair with hoods and helmets—where hair absorbs, reflects, and scatters light. The more hair present, the less likely it is that light will be transmitted to the scalp and absorbed by its intended target, in particular, follicle mitochondria.

The Inverse Square Law & Lamberts Cosine Law Effecting Light Transmission for LLLT devices

One of the physical properties of light that can affect light transmission and irradiance is referred to as the “inverse square law,” which states: intensity of radiation varies inversely with the square of the distance from the source, and is described in the equation $I = 1/d^2$. What this means is that light intensity is reduced based on the target’s distance from the source. For example, for a target (scalp) that is twice (2cm) the distance from the source, light intensity is reduced to one-fourth the intensity at 1cm, and a target 3 times (3cm) the distance from the source receives only one-ninth the light intensity. The inverse square law, however, assumes the divergent properties of a normal light beam. Laser light is collimated and coherent with substantially less divergence of the beam and when it hits a target has a spot size that influences its power and intensity. Laser diode beams are more oval in shape—and unless controlled by a focusing lens, they will still follow a modified inverse square law so that distance from the source is a factor impacting light intensity and transmission.

LED lights are not collimated or coherent, but provide less

beam divergence than regular light bulbs. Nevertheless, LEDs are more affected by a modified inverse square law effect because of their beam divergence. This means their beam may cover a larger area, distance from the source (light) can be expected to have an impact on intensity at their target (scalp), too. Ultimately, for LLLT devices, distance is a factor when trying to apply light at a particular dose for scalp absorption and therapeutic response.¹⁰ Devices (such as hoods or overhead apparatus) that beam light from a distance cannot claim comparable dosing, even when using the same wavelengths and treatment frequency, as a similar device that touches, or nearly touches, the skin.

Lamberts Cosine law of light states that a beam perpendicular to its target provides 100% irradiance, but is reduced at oblique angles as a cosine of the incident angle, because the light is spread over a wider area. The cosine law indicates that off angle beams at the most oblique angle can end up being completely reflected. Off angle light from hoods and overhead apparatus will result in reduced irradiance—presumably below therapeutic doses if calculated on the assumption of a perpendicular beam—especially one that touches the skin.¹⁰

Collimated and Coherent (Laser) vs. Non-coherent Light (LED)

Normal light bulbs, as previously noted, beam light in a variety of colors and wavelengths in all directions, which results in ambient lighting. This is remarkably different than laser light where each beam of light produced is monochromatic (same color and wavelength) and collimated and coherent, so that light waves move parallel to one another and in the same direction forming a “spot” at the target—described as “spot size” for purposes of calculating power density.

LED light, while also a largely monochromatic beam, may vary slightly in wavelength and is much more divergent (non-coherent) than laser light, as previously noted. Furthermore, it is not collimated, so LED beams do not run parallel to each other. LED light illuminates a larger area, but results in much lower light intensity than laser light. LED light in the visible/NIR spectrum has been deemed a non-significant risk by the U.S. FDA and cleared for human use.¹¹

The Arndt-Schultz Law or Biphasic Dose Response for LLLT

A biphasic dose response means that when low level laser light is applied at a wavelength and dose that is too low, no tissue response will occur. If it is applied at a dose that is too high, it can inhibit a tissue response. There is, for a given biostimulus, an optimal dose (timing and interval) where a maximal response is obtained. This has been seen in studies of wound healing where too low a dose did not have an impact, and too high a dose prolonged wound healing—while the optimal dose resulted in faster healing.²

The clinical significance of this property is important because until we study sufficient variations of dosing and wavelength, it may be difficult to know if we are actually in the peak dosing range. Furthermore, it begs the question as to whether there is a point at which the same effective dose and timing will achieve a maximal response, and then begin to cause an inhibitory response. Thus far, most clinical trials have lasted for only 6 months or less. There is no long-term follow-up data to indicate if tachyphylaxis or inhibition could or does occur.

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Part 2 of this series will deal with regulation of LLLT devices from both a U.S. and international perspective. This portion of the article will look at medical device categories and regulation worldwide, as well as laser device categories and regulation—and why they should/do exist for patient's safety. However, the effect of regulation on cost of device development, and how this may both impact and impede device innovation, will also be discussed. For those who wish to view an abbreviated review and update of LLLT as provided in a PowerPoint presentation at the 2014 ISHRS Annual Scientific Meeting in Kuala Lumpur, a copy of the recorded lecture can be accessed at the ISHRS website. ♦