HAIR TRANSPLANT forum INTERNATIONAL

Volume 24
Number 6
November/December
2014

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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)

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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/cm$^2$, respectively, ensure a low thermal output and prevent tissue heating. Studies have shown a minimum of 13 W/cm$^2$ is required to cause first degree skin burns, and 24 W/

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