



By Jerod Prindable

On February 24, 2010, Midwest RF in partnership with Life Physics International, received FDA marketing approval for the MEP-90 Hair Growth Stimulation system. The indications were for the treatment of Androgenic Alopecia in women that met certain criteria of the Ludwig, Savin and Fitzgerald scales. Heartfelt congratulations go out to the two men behind this triumph, Don Osendowski and Helmut Keidl.

Laser Hair Therapy, known also under the aliases of cold laser therapy, laser hair restoration, photobiomodulation, laser biostimulation, and low level laser therapy (LLLT), has had a colorful history. Now, when I say colorful history, I am not referring to its technical beginnings so much as the up and down path it has traveled through the Hair Loss industry. It has been both a darling and a pariah depending on whom you ask. Oftentimes, these opinions were determined by whether they used the therapy in their salon themselves or considered it a threat to their existing services. The amazing thing is not that the treatment suffered poor word of mouth from the threatened and ill-informed, that in and of itself is not novel to our industry. The amazing thing is that while this treatment has been in fairly wide use for over a decade, we still find that most of the people in our industry are in the dark as to the effectiveness of the treatment and the viability of laser hair therapy as a revenue generating service. How is it that a therapy that has made several laser service providers wealthy, spawned many lawsuits, and treated tens of thousands of hair loss sufferers, still such an enigma? Other than Lexington's landmark research on laser therapy in men and the resulting FDA clearance for their Hairmax comb, it almost seemed as if laser manufacturers and practitioners alike were afraid to do research for fear of extinction. Luckily for us, two brave souls accepted the challenge and risked much to bring laser hair therapy, pardon the pun, into the light.

My own personal journey in laser hair therapy began roughly six years ago, and much like the industry, I spent the first year or so wavering between skepticism and revelation. A project to provide custom imaging solutions to a successful laser therapy provider was my first experience with the devices, and my own thinning hair was the driving force for my desire to learn more about the technology. Over the long course of that project and several that followed for that same provider, I watched diligently as clients marched in and out, the majority exuding satisfaction with their results. However, as most of you realize, no-one is more vocal than a dissatisfied hair loss client,

THE LONG PAINFUL ROAD TO VALIDATION

(and FDA approval)

and I was equally amazed at the tirades of some patrons. It was these perceived 'failures' that made me hesitant to fully accept the treatment's authenticity. That along with the fact that everywhere you turned there were hair transplant physicians (with absolutely no clinical data to back up their claims) decrying laser therapy as simply a scam. My confusion was made worse by the fact that some of the clients who complained actually appeared to me to have had decent results. This, along with the fact that treatments were improving the quality of my own hair, led me to believe that their dissatisfaction was due to unreasonable expectations. Why else would someone be unhappy when they were actually regaining hair? One day, as I watched a client who had what I would call significant improvement chastise the poor girl at the front desk, the answer dawned on me. I would see these people only every few months when I was on site, the differences that were so apparent to me after months away were lost to eyes that failed to notice minute changes every day in the mirror. This epiphany would lead me deeper into the industry where I would spend the next few years devising a software package to track changes in hair count and condition of the treated hair in order to show the client improvement in an empirical way. During the course of the software's development, I met with many providers and industry experts and eventually ended up at the door of Don Osendowski, who is likely the single largest contributor to the success of commercial laser therapy in the US. Don, whose Scalplaser, Inc. is the oldest, and most trusted manufacturer of commercial hair therapy lasers in the industry, was an ardent believer in the inexplicable healing power of lasers. In fact, so sure was he that the lasers he produced grew hair, that he risked everything to prove it.

Consider for a minute, you own a solid, lucrative business, but are constantly harassed by those that claim your technology is a hoax. Do you ignore the criticisms and collect the checks from those that know better? Or do you risk your entire life's savings and the very premise of your existing business to defend your beliefs? Osendowski, true to his convictions, began making preparations to provide the proof that would validate laser hair therapy once and for all. Typically such an undertaking would be impossible for a small company. Lexington, who I mentioned was the first to undertake a study that resulted in an FDA acceptance, was a much larger company at the time they made this type of commitment. Plus, Mr. Osendowski was determined to have the study conducted by an impartial 3rd party facility that would provide the objective evidence that the industry needed. While it seemed an insurmountable task to Don, help was on the way in the form of Helmut Keidl, CEO of the well-known medical manufacturer Midwest RF. Midwest RF had been manufacturing parts for Scalplaser on and off for several years, and Helmut, while unfamiliar with the tech-

nology, was a believer in Don. The Midwest RF team, under Don's guidance, devised a new medical laser, and together the partnership commissioned a study of unprecedented scope in the industry. What's more, they decided that since Lexington's study focused on men, they would concentrate on trying to address what they knew to be a horrible and psychologically devastating problem, androgenetic alopecia in women. Commencing the project in August of 2007, these gentlemen began traveling down the long, and often painful, road to validation...

The first step of the project was hiring a consultant and devising a clinical strategy in coordination with Dr. Grant Koher, a physician with over 20 years experience in hair restoration surgery. It was understood that Dr. Koher would not be paid for his services, nor were any of the test subjects, which would allow for complete impartiality. Dr. Koher deserves the industry's thanks for his selfless contribution of time and materials in the name of science. This first step alone took over 6 months and culminated in acceptance of their clinical strategy by the Western Institutional Review Board (WIRB), which is a committee that provides critical oversight functions for research conducted on human subjects that are *scientific, ethical, and regulatory*.

The research itself was conducted at the Koher Center for Hair Restoration, by Dr. Koher and his assistant Natasha Achterburg. The subjects consisted of an ethnically mixed group of females, all diagnosed by Dr. Koher and staff as suffering from androgenetic alopecia. I plan to provide a comprehensive analysis of the results in the next issue of The Journal, but just as a teaser for that article, it suffice to say that the success rate was almost universal, and the actual rate of regrowth, while varying amongst individuals, was astounding. In fact, the results pointed to females benefitting in some ways more than their male counterparts. While I found that tidbit surprising, my friend Dr. Michael Hamblin, a Harvard professor and principle investigator at Wellman Center for Photomedicine, remarked that he had somewhat expected that. Hopefully we will be able to get Dr. Hamblin to expound on his declaration in our next installment. In any case, the Koher team and management overcame many hurdles typical to research studies of this magnitude.

With test results in hand, the team hoped for a quick response from the FDA. But the FDA, always deliberate in their determination of viable medical devices, proceeded to lead the team through an ulcer-inspiring process which consisted of question, reply, wait up to 90 days, repeat... This time was trying for Don and Helmut, as they realized that even with the convincing evidence that they had in hand, one non-compliant answer or overlooked detail could derail the whole process. Finally, in the midst of this deliberation, a bit of good news finally

hit home. Dr. Koher, who had long since completed the research, was chosen to present the evidence of his findings at the International Society of Hair Restoration Surgery convention in Amsterdam. In my role as technical consultant, I represented Life Physics International at the convention and had the opportunity to congratulate Dr. Koher on behalf of the organization. While watching the open sessions based on the presentations on laser therapy, I noted the myriad of ingrained opinions formed long before Dr. Koher came to the podium. In fact, immediately prior to Dr. Koher's address to the body, the attendants were polled as to their personal belief in the effectiveness of laser hair therapy. The computer tabulated results were almost split evenly between those who believed in light therapy and those that did not. How amazing that a treatment could be so polarizing! I dare say that after Dr. Kohers' eloquent presentation, a re-polling would have shown a swing in favor of laser therapy. For certain though, the question and answer session immediately following the speech generated the liveliest discussion of all topics at the conference. The general consensus was that the subject definitely merited more directed study to determine proper 'best treatment' scenarios such as suitable dosage, most beneficial wavelength and such. It finally appeared as if we were beginning to move beyond the question of whether the treatment worked, and towards the more poignant questions regarding the most effective practices in use. Mission accomplished Don.

Now all that remained was whether Life Physics International would have the fortune to present to the world the first FDA approved medical device for treatment of female alopecia. November turned to December, December to January, and still no definitive word. Even the process of checking the mail every day to see if they received an answer became an exercise in frustration. Much like Pavlov's dog's reaction to the bell, Don would sigh wearily at the mere sight of the postman delivering the mail.

On Feb. 24th, 2010, Midwest RF, and Life Physics International received word of the acceptance of the 510k premarket approval of the MEP-90 Hair Growth Stimulation system. A long and sometimes tortuous road had come to an end. The feelings of relief, vindication, and joy in the room were overwhelming. The joy was directed not only at the opportunity to market a sure-to-be-lucrative new product, but also joy in the hope that a new day of validation for the entire laser hair therapy community had begun. With each wall that is knocked down, we are that much closer to public acceptance of that which many of us know to be true. Laser Hair Therapy is real, it works, and soon it will be available at physician near you.

Jerod Prindable is President of Prevail Technologies, a leader in innovative hair loss consultation software and laser hair therapy equipment. Jerod is also a technical consultant for LIFE PHYSICS INTERNATIONAL, distributors of the newly FDA approved MEP-90 Hair Growth Stimulation system.