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Low Level Laser Technology and Your Practice

It's a great time to incorporate this technology into clinical practice.

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This article, written exclusively for PM, appears courtesy of the Institute for Podiatric Excellence and Development (IPED). IPED's mission is to motivate, inspire, and synergistically bridge the gap between students, residents, new practitioners, and seasoned veterans in the field of podiatric medicine. They are committed to the idea that mentors with passion to share and mentees eager to learn make a powerful combination that allows IPED to bring and renew a full life to podiatric physicians, their practices, and their well-being throughout the U.S. and beyond.

Editor's Note: *The Forum is an occasional PM feature that provides podiatrists with the opportunity to offer their personal perspectives on topics of interest to the profession. Readers should be aware that our publication does not endorse particular products or technologies. The opinions herein are the author's, and not necessarily those of PM.*

As physicians, we should never become complacent with the treatment protocols that we develop and incorporate into our practices. We are scientists at heart and strive to know the "how and why" a new treatment will work. We should be asking, "what is the mechanism of action here?" With a degree of certainty, we will initiate that new treatment regimen while delicately balancing the paramount goal of doing no harm to the patient.

One of the hallmarks of true learning is communication. Open lines of dialogue physician-to-physician is how we learn from one another. How else will we grow and share what our experience has taught us? With each day in practice, we continue to build a foundation of knowledge that helps us become better diagnosticians. There are many ways to communicate; some would argue there are too many ways these days with the advent of social media. Journal clubs, consensus boards, evidence-based research, practice management groups, blogs, and medical conferences are just a few of the common ways we tend to share our information with one another.

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There is a lot of value in attending medical conferences. At a central location, people from all over the country, and even around the world, meet with the sole purpose of sharing information about the different facets of practicing a particular profession. We gather for a few days of "super-concentrated podiatry." While sitting in the vast lecture halls, we discuss medical conditions, new surgical procedures, things to do, and things to avoid to better our outcomes. New research is discussed to help us decide what treatments are promising and what will fall out of favor. Roundtable discussions with industry experts help us form a consensus as to how we diagnose and treat many different conditions.

With great humility, some doctors will share their most challenging cases that led to failure or less than desirable outcomes. Why would anyone want to discuss these personally challenging cases, office visit by office visit, surgical failure by surgical failure? It is the most selfless reason of all: to prevent other practitioners from repeating those same errors. If they can inspire others to challenge themselves as to how they manage a particular condition, then they have done their job.

Inventor Thomas Edison made 1,000 unsuccessful attempts at inventing the light bulb. He was once asked by a reporter, "How did it feel to fail 1,000 times?" Edison replied, "I didn't fail 1,000 times. The light bulb was an invention with 1,000 steps." Learning how to do something correctly can sometimes involve 1,000 steps backward. Learning what not to do is just as valuable as

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learning what to do. Communication between us reinforces this. There is a learning curve for becoming seasoned and to having the experience to draw upon when we are trying to make a diagnosis. We need nurturing and support to keep us on the path.

Another appealing facet of a medical conference is the exhibit hall where we can shake off the uniformity of sitting for hours in upright chairs, listening intently to lectures, formulating ideas in our heads, and concentrating on photos, graphs, and x-rays that are presented to us. There is usually a buzz in the exhibition hall and everyone is enthusiastic to be there.

The exhibitors are excited to show their product line, eagerly pushing for sales. The doctors walk around looking for new ideas to incorporate into their practices. We sometimes know what we are looking for as if we are on a mission. Other times, we stroll up and down every aisle to make sure we don't miss something, that one thing that could change how we practice that could really make a difference to our patients.

Whether it is new diagnostic or therapeutic equipment, office or medical supplies, or needed subscription services, one can find it all under one roof in the exhibition hall. We have all jumped onto that one risky product or service thinking it would be a great idea but never really implemented it for one reason or another. We all have our trash heap of products that never make it into our practice; these mistakes can be very costly.

Risk is not something with which we all are comfortable. In fact, most of us are risk-averse. We are analytical beings weighing the pros and cons of how and when to jump into a new technology to treat our patients. Safety for our patients is paramount. Our reputation is equally as important. Our reputation is something we get only once. We guard it, grow it, and protect it because once it is gone, we can never get it back.

Risk is inevitable. However, the success or failure of our decisions isn't always our fault. Sometimes, changes in insurance coverage or reimbursement dictate the success or failure of a service. Other times it is our own doing. We may not effectively market this technology, train our staff to answer questions concerning it, or personally implement it. We need to be organized and deliberate in writing down our plan for incorporating new technology prior to acquiring it. We have to set ourselves up for success, while understanding that there may need to be some course corrections along the way.

We are currently in a health insurance climate where patients carry surgical benefits but with extremely high surgical deductibles. The high surgical deductibles we encounter are a relatively new burden to deal with. It used to be common for a surgical co-pay or deductible to run around $250, with 100% coverage thereafter. Now the deductibles can range from $3,000 to as much as $6,000 dollars annually. Of course, the monthly insurance premium to the patient is lower but patients do not typically weigh the probability of needing surgery when they shop for health insurance. Patients are rolling the dice and will generally just "deal with it" if they encounter the need for unexpected surgery.

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Patients who carry these high deductible plans are hesitant to pursue elective surgery, even when they are suffering from a painful condition. It can be challenging to get them to commit to surgery. They face the difficult financial challenge of being able to pay the surgical and anesthesia bills that used to be covered benefits. The long post-op recovery period can also be a huge detractor when trying to decide on whether to have surgery. Some patients are the breadwinners of the family or caretakers of children or elderly parents at home. Patients often times do not want to become outliers at work and fear the loss of their job if they are off for too long. "Light duty" assignments for many people is not always an option due to work-related constraints; therefore, family medical leave has to be undertaken, with the likelihood of not receiving any income. Thus, the *perfect storm* is created: an opportunity to incorporate cutting edge technology into our practice and treatment protocols, at a fraction of the cost of pursuing surgical intervention.

As students, we were taught to try all conservative measures prior to initiating surgical therapies. One viable alternative to surgery that we can offer our patients is a regenerative treatment that non-invasively heals the patient from the inside out and is called *Low Level Laser Therapy*. Low level laser therapy has wide-ranging applications from musculoskeletal conditions to fungal infections. Plantar fasciitis, Achilles tendonitis, posterior tibial tendonitis, and onychomycosis are just a few of the conditions that can be successfully treated with this modality. These treatments are not typically covered by health insurance plans and are fee-for-service arrangements.

Low Level Laser Therapy (LLLT) is a low-intensity laser light therapy that is non-invasive. The effect is photochemical, not thermal. It has been extensively documented that the laser energy that is absorbed triggers biochemical changes within cells, resulting in the physiologic changes we desire, such as pain reduction and decreased edema. Many of these new lasers are fully automated. The 635 nm wavelength has been found to be beneficial for plantar fasciitis, and the 405 wavelength effective against dermatophyte infections.

Clinically, low level lasers have been utilized in practice for over 30 years. In 1967, Mester, E, et al. was able to successfully demonstrate the phenomenon of "laser bio stimulation."[1]

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Subsequently, over the past 5 decades, 400+ Phase III randomized, double-blind, placebo-controlled trials have been published, with more than 4000 laboratory studies of LLLT available for our review. A laser is a device that emits electromagnetic energy in the form of a concentrated light beam. The beam is monochromatic and convergent. LLLT is the application of laser energy ranging from 10mW-500mW and has a typical wavelength in the red to near infrared region of the electromagnetic spectrum. This particular range of wavelength is employed because these wavelengths have the ability to penetrate skin and soft/hard tissues, and have been proven in clinical trials to have a good effect on pain, inflammation, and tissue repair. The hallmarks of LLLT are a reduction of swelling, enhanced pain relief, and accelerated tissue repair. For a fraction of the cost of their surgical deductible, the patient can undergo these treatments in our office without anesthesia. They go home weight-bearing the same day with no work missed. The only restriction is limiting high-impact exercising for a few weeks.

We are in the infancy of this "regenerative boom." Patients are very interested in being treated non-operatively with proven modalities that not only heal their specific condition but eliminate the down-time associated with the post-op period. There are also no narcotics to be prescribed, which is also beneficial to the patient, considering the opioid crisis we currently face. Patients fully understand that surgery is still a viable option if all conservative therapies fail.

Anyone contemplating the purchase of a laser should understand what the FDA-510 K approval process is and how it can benefit you. The advertising laws come into play when promoting these services and vary from state to state. How can we trust the science that we read and review? Lasers are a large investment. You want to be assured that the strictest of measures have been undertaken to ensure the device you purchase is safe and effective for your patient.

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The FDA clears for use medical laser devices along with many other products. During this process, the FDA will look at the laser's structure, the deemed risks and benefits, and other information in order to determine whether or not to approve or clear the device and with what designated indication. The first step in this process is for the manufacturer to file a *premarket notification,* also known as a PMN. The FDA then takes the next 90 days to review the application. During the 90-day review period, the FDA will also classify the device into one of three classes:

Class I devices are often OTC products.

Class II devices are considered medium risk, again not intended on treating potentially fatal conditions (LLLT falls into this category).

Class III devices are considered high risk devices. These are devices intended to support or sustain life.

With respect to podiatry lasers that are seeking FDA review through the pre-market notification process, the designation they seek is "FDA cleared" or "510K cleared," not "FDA approved." Once 510K cleared, the manufacturer can go straight to market. The reason for truly understanding this verbiage comes into play when you advertise these services for your practice. You don't want to get a letter from your state medical society saying you are violating advertising laws and are not in compliance.

When researching the laser market, ask the representative what conditions a device has been cleared to treat. Behind that answer should be years of evidence-based research and studies performed that demonstrate the laser's safety and efficacy. It goes back to efficacy and reputation protection being paramount goals. These treatments are unlikely to be covered by conventional insurance plans and are truly fee-for-service. Patients will not be happy if they do not work, as they are spending a lot of money for treatment.

Before making a purchase, there are some things you should do to make sure you hit the ground running. Buying the laser is the easy part, selling the idea to the patients and promoting it can present a new but manageable challenge. We have most of the tools already in place in our office to market these services without spending a lot of money.

Internal marketing is a great way to get started. From your EMR, you can run a report, with the name of every patient you ever diagnosed and treated for the specific pathological condition your laser can treat. Send these patients a letter stating that you have this great new technology in the office that can help with their problem, and that 10 years ago we did not have this technology. You will be amazed at how many people will call.

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Many of us still do not have a website. It is time to change that! It is time to think of a website as a "virtual employee" who is always ready and attentive to meet the needs of a potential patient searching for you. This "virtual employee" is always on time and never calls out sick. They work 24-7 and are a wealth of infor-

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mation, providing new patient paperwork ready to download, or to advertise patient testimonials or informative blogs. How much would you pay for someone to be in your office 24-7 to provide all of these services?

Today's patients use the Internet to research everything. Make sure your website is up-to-date and includes information about your new laser. You can even tag a YouTube video to demonstrate how it works. Your website is a reflection of you and the type of practice you run, so make sure it is professional-looking and functional.

Once a laser is purchased, there is no pressure to use it. Proceed at your own comfort level. You shouldn't be burdened with the stress of having to treat a certain volume of patients in a month. These are our patients who we see every day; they are not numbers or quotas, and we want them to be comfortable and confident in their decision to proceed. When selecting potential patients to treat with your laser technology, use the same clinical acumen that you have accumulated through years of practice, just as you would for selecting surgical patients to operate on. **PM**

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Reference

[1] Mester E, Ludány, G, Sellyei M, et al. The simulating effect of low power laser rays on biological systems. 1967, Laser Rev. 1:3.

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