# 830 nm light-emitting diode (led) phototherapy significantly reduced return-to-play in injured university athletes: a pilot study

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**Background and Aims:** For any committed athlete, getting back to conditioning and participation post-injury (return to play [RTP]) needs to be as swift as possible. The effects of near-infrared lightemitting diode (LED) therapy on pain control, blood flow enhancement and relaxation of muscle spasm (all aspects in the treatment of musculoskeletal injury) have attracted attention. The present pilot study was undertaken to assess the role of 830 nm LED phototherapy in safely accelerating RTP in injured university athletes.

**Subjects and Methods:** Over a 15-month period, a total of 395 injuries including sprains, strains, ligament damage, tendonitis and contusions were treated with 1,669 sessions of 830 nm LED phototherapy (mean of 4.3 treatments per injury, range 2 - 6). Efficacy was measured with pain attenuation on a visual analog scale (VAS) and the RTP period compared with historically-based anticipated RTP with conventional therapeutic intervention.

**Results:** A full set of treatment sessions and follow-up data was able to be recorded in 65 informed and consenting subjects who achieved pain relief on the VAS of up to 6 points in from 2-6 sessions. The average LED-mediated RTP in the 65 subjects was significantly shorter at 9.6 days, compared with the mean anticipated RTP of 19.23 days (p = 0.0066, paired two-tailed Student's *t* test). A subjective satisfaction survey was carried out among the 112 students with injuries incurred from January to May, 2015. Eighty-eight (78.5%) were either very satisfied or satisfied, and only 8 (7.2%) were dissatisfied.

**Conclusions:** For any motivated athlete, RTP may be the most important factor postinjury based on the resolution of pain and inflammation and repair to tissue trauma. 830 nm LED phototherapy significantly and safely reduced the RTP in dedicated university athletes over a wide range of injuries with no adverse events. One limitation of the present study was the subjective nature of the assessments, and the lack of any control groups. However, further controlled studies are warranted to enable confirmation and generalization of the very good results in the present study.

**Key words:** Low level light therapy (LLLT) • sports medicine • LED • pain; musculoskeletal injury • inflammatory mediators • inflammatory facilitators

### Introduction

Universities and Colleges today, alongside rigorous academic curricula for all students, also offer multiple

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sport programs for competitive student-athletes. The mission is clear in advancing learning upon graduation while developing leadership skills and fostering personal growth as a competitor both in and out of the classroom. The participating students are expected to excel in all aspects of their studies, including maintaining top athletic performance for whatever sport or

Received date: January 2nd, 2016 Accepted date: January 25th, 2016

sports in which they are participating. Athletes aim to be at peak performance through comprehensive conditioning programs for their respective sport although some involve some form of collision, contact or noncontact in nature, on the track, field, court or pitch. Injury surveillance programs have produced consistently greater amounts of injury-related data in contact sport activities or with frequency of participation as factors, at the same time noting that overtraining can also play a role in musculoskeletal or soft tissue injuries.

A small percentage of student-athletes go on to become professional athletes so any injury in student athletes has to be evaluated with at least the same care and detail as for a professional athlete. An injured athlete today upon evaluation will often approach the clinician with questions as to why an injury occurred, how can the injury be addressed and what will be the next step or steps. Managing treatment so as to ensure the fastest but safest return-to-play (RTP) is therefore of crucial importance. Although RTP is the accepted endpoint, in varsity-level sports the potentially conflicting wishes of a variety of individuals have to be dealt with: the athlete, his or her parents or guardians, the trainer, the coach, and the sports medicine team including clinicians, physiotherapists and so on, all of whom will have different expectations. 1) Taking this into consideration, and always noting the severity of the injury, providing communication linkage with all the interested parties in a team approach towards a treatment plan is a critical component which is always placed first by either the athletic trainer or physical therapist at the collegiate level. Evidenced-based protocols and the safest possible functional progression toward achieving RTP comprise the desired outcome, as this will minimize the time lost for the motivated athlete: however it must be accomplished without exacerbating the existing musculoskeletal injury.

Recently, low level light therapy (LLLT) with near infrared light-emitting diode (LED)-based systems (LED-LLLT) has attracted attention in acute and chronic pain relief and in many aspects of wound healing, particularly for pain control, blood flow enhancement and relaxation of muscle spasm. These aspects would have particular relevance in sports medicine to ensure alleviation of the pain and swelling associated with acute sports-related injuries while simultaneously enhancing the healing process so that not only the symptoms are being treated, but also the cause, which is of paramount importance in avoiding reinjury. The present pilot study was therefore undertaken to assess the role of 830 nm LED phototherapy in reducing the RTP period among injured student-athletes at a nationally recognized university (Lehigh University, Bethlehem, PA, USA) where both individual and team success is a byproduct of prevention and treatment of musculoskeletal and soft tissue injuries.

## Subjects and Methods

### LED System and treatment technique

The 830 nm LED-LLLT system used was the HEALITE II (Lutronic Corp, Boston, MA, USA and Goyang, South Korea, **Figure 1**). This system delivers 60 J/cm<sup>2</sup> of quasimonochromatic near-infrared non-ionizing light at 830 nm  $\pm$  7 nm in 20 min (irradiance of 50 mW/cm<sup>2</sup>). The freestanding unit sits on a lockable castered base, with "place and stay" friction hinges in both the articulated arm and 5-panel treatment head, and can be moved between treatment rooms. The hinged head panels enable the treatment head to be wrapped around a limb or a joint, or spread almost flat to treat areas such as the back in a hands-free manner. The head is set up around 3 – 15 cm from the target tissue.

Following the advice of the manufacturers for the treatment of acute injuries, we started treatment as soon as possible after injury, involving in principle three consecutive daily sessions, 20 min per session. Therapy sessions continued over one or two cycles (3 days LED-LLLT and 3 days recovery cycle) or until



**Fig 1:** The HEALITE II LED-LLLT system (Lutronic Corp., Boston, MA USA, and Seoul, South Korea) used in the present study. The 5-panel treatment head could be adjusted to fit the contour of any part of the body being treated.

marked improvement in the VAS were noted by the Sports Medicine staff (SM) and athlete.

## Subjects and injuries

From January 2014 till the end of May 2015, inclusive, a total of 395 injuries, comprising 53 injury types, was treated over 1,669 sessions (2 - 6 sessions, mean 4.6 sessions per injury) **(Table 1)**. The majority of the injuries comprised knee sprains (96, 26.2%), hamstring strains (35, 9.6%), Achilles tendonitis (30, 8.2%), intercostal strains (26, 7.1%) shoulder sprains (20, 5.5%), abdominal strains (20, 5.5%) and fractures of the foot (17, 4.6%). In general, two assessments were used: pain attenuation using a visual analogue scale (VAS) and the actual date of return to play (RTP) compared with the traditionally-based or anticipated RTP following conventional therapeutic intervention.

#### Results

The majority of student-athletes receiving 830 nm LED-LLLT indicated having achieved an excellent result,

**Table 1:** New injuries and treatments per month fromJanuary 2014 to May 2015, inclusive, and therunning total of treatments

Month (Year)	New Injuries	Tx /Month	Total Tx
Jan (2014)	33	136	136
Feb (2014)	32	134	270
Mar (2014)	27	100	370
Apr (2014)	27	123	493
May (2014)	6	12	505
Jun (2014)	0	0	0
Jul (2014)	5	22	575
Aug (2014)	29	126	701
Sept (2014)	31	148	849
Oct (2014)	41	181	1030
Nov (2014)	29	152	1182
Dec (2014)	23	99	1281
Jan (2015)	42	168	1449
Feb (2015)	27	77	1526
Mar (2015)	24	72	1598
Apr (2015)	19	89	1687
May (2015)	0	12	1699
Total injuries = 395		Ave. Tx/in	jury = 4.3

namely a reduction in pain and inflammation, while also noting pleasantly mild surface heating of the skin. In addition, there were no side effects or any increase in pain during the sessions throughout the pilot study. The sports medicine staff also agreed overall with the authors' opinion, that the hands-free application of LED-LLLT at 830 nm was less intensive than other modalities used in this field during clinic hours.

As noted earlier, student-athletes at higher levels of learning routinely have an academic course load that may not allow them to access the optimum regimen of LED-LLLT treatments, with restricted availability as a factor at times due to timetabling conflicts. It was therefore a strategic goal among SM staff to ensure inseason athletes received the highest priority during scheduling morning or afternoon sessions when treating with 830 nm LED-LLLT. Furthermore, it was apparent that the availability of a second unit would have dramatically increased the treatment availability and allowed compiling a more statistically significant body of data for the present pilot study.

We were able to accurately record consecutive treatment sessions and a follow-up of 1 - 4 months in 65 subjects, who therefore comprised the study group in the current article. All members of this group, having had the purpose of the study explained to them, gave written informed consent to participate in the study. The study itself was approved by the Research Committee of the Lehigh University Sports Medicine Department. The injuries treated were as follows: hamstring strain in 22 (19 mild, 3 moderate); knee sprain in 22 (14 mild, 1 moderate, 1 moderate-severe and 6 severe); ankle sprain in 15 (11 mild, 3 moderate and 1 very severe); costochondral sprain in 4 (3 mild, 1 severe); and hip pointer in 2 (1 mild, 1 severe). All injuries were treated in the acute phase, and received between 3 and 5 sessions (Table 2).

All 65 study subjects completed their assigned consecutive daily treatment sessions (2-6 sessions, **Table 2**) and the follow-up period (1 – 4 months, **Table 2**). On the VAS score, from 2 - 8 points improvement was achieved, with all subjects having a final VAS score of zero. The average LED-facilitated RTP in the 65 subjects was 9.62 days, compared with an anticipated average range of 14.8 to 24.9 days (mean 19.23 days) which was statistically significant (p = 0.0066, paired two-tailed Student's *t*-test, 95% confidence interval).

A subjective satisfaction survey was also carried out. There were 112 injuries in the January – May 2015 period, and the survey was carried out via a questionnaire in these 112 students, all of whom responded.

Damage assessment	Condition	Examined Cases (N = 65)	Average No of Tx	F/U (months)	Average RTP (days)	Expected RTP range (days)
1°	Hamstring Strain	19	4	2	7	10-14
1°	Knee Sprain (LCL, MCL)	14	3	1	5.75	7-10
1°	Ankle Sprain	11	3	2	3.6	7 -10
1°	Costochondral Sprain	3	4	2	5.5	7-14
1°	Hip pointer	1	3	2	4	7-10
1+	Ankle Sprain	3	3	3	7.3	10-14
1+	Hamstring Strain	3	6	3	19	14-28
1+	Knee sprain	1	4	4	10	12-14
1++	Knee sprain (LCL, MCL)	1	4	4	11	14-28
2°	Knee Sprain (LCL, MCL)	6	6	4	16	28-42
2°	Costochondral Sprain	1	5	4	17	28-42
2°	Hip pointer	1	5	4	7	21-24
2+	Ankle sprain	1	5	4	12	28-42
				Means ± SEM	9.62 ± 1.41*	19.23 ± 2.91

**Table 2:** Injuries, treatment numbers and actual RTP *vs* historically anticipated range of RTP in 65 consecutively-treated and fully followed-up subjects.

1° = mild; 1<sup>+</sup> = moderate; 1<sup>++</sup> = moderate/severe; 2° = severe; 2<sup>+</sup> = very severe. RTP = return to play; LCL = lateral collateral ligament; MCL = medial collateral ligament \*Statistically significant: P=0.0066 (Two-tailed Student's t-test, 95% confidence interval)

Table 3 shows the breakdown of these injuries by site of the body, sex of the student and the sport involved. Students were asked to rate their satisfaction with the treatment on a grade of 5 to 1, where 5 was very satisfied, 4 was satisfied, 3 was somewhat satisfied, 2 was somewhat dissatisfied and 1 was very dissatisfied. A section was allotted for comments. Thirty-eight subjects (33.9%) were very satisfied, 50 (44.6%) were satisfied, 16 (14.3%) were somewhat satisfied, and 4 each (3.6%) were somewhat dissatisfied or very dissatisfied, meaning that 76.5% of the subjects achieved a satisfactory result. Reasons for dissatisfaction were mostly concerned with the length of the treatment time (20 min per session), and interference with academic timetabling. Interestingly, lack of success in treating the injury was not cited as one of the reasons. Positive comments, apart from the efficacy of the treatment, included the ease of the treatment and the feeling of gentle warmth which was felt during treatment, which helped thr subjects to "feel that the treatment was working". In addition the good control of the inflammation was quoted as an important feature increasing student trust in the LED-LLLT sessions. It is currently the case, especially amongst the football and wrestling

Sport	Upper extremity		Lower extremity		Totals
	Female	Male	Female	Male	1 otais
Baseball		2		4	6
Basketball		1	2	5	8
Crew			1		1
Cross country					0
Field hockey					0
Football		2		8	10
Golf					0
Lacrosse		1	3	12	16
Soccer			3		3
Softball					0
Swimming/diving	5				0
Tennis					0
Track and field			7	3	10
Volleyball			3		3
Wrestling		17		38	55
Totals	0	23	19	70	112

**Table 3:** New injuries from January to end of May,2015, broken down by site of the injury, sexof the injured student and sport

student-athletes, that LED-LLLT is being more and more requested by these groups as the first line of therapy post-injury.

Of the three most common injuries in the 65patient study group, namely hamstring strain, knee sprain and ankle sprain, the hamstring strain and knee strain subjects took longest to reach a VAS pain score of 0 from an initial VAS score of 5-4 in the hamstring group, requiring from 4 to 6 treatment sessions. The initial VAS score in the knee group was from 9-4, and this injury required from 5 to 6 sessions to reach the zero score. Ankle sprains required fewer sessions, namely 2 to 3, to reach a VAS of 0 from an initial range of 8-4, with the exception of one sprain classed as very severe, which required 4 sessions.

#### Discussion

The growing awareness of the need for fitness or regular exercise in the general population has concomitantly increased the number of fitness-related injuries, whether from overtraining, joint trauma or simply contact during their activities. The data would also reflect a number of injuries occur in specific sports where collision and contact are inherent in both practice and competition. In fact, competition results produce higher injury rates and percentages in competition with American football, wrestling, ice hockey, soccer, basketball, lacrosse and gymnastics.<sup>2)</sup> The university in the current study, Lehigh University in Pennsylvania, USA, is a distinguished school of higher learning where the value given to both an excellent education and success in athletics is realized as a commitment continuum by student-athletes. The "work hard, play hard" ethos is applied in both academic and sports studies, with the "play hard" component connected with the almost inevitable occurrence of sports-related injuries. In the case of highly motivated student athletes, being back in competition or practice is paramount, taking into account the fact that their innate and developed behavioral traits such as work ethic, "team first attitude" and competiveness are vastly different from active participants in the general population.

The concept of return to play (RTP) has its own philosophy and rules, and must often be achieved with the understanding of several different viewpoints, <sup>1)</sup> starting with discussing the treatment plan and establishing short/long term goals, both of these depending on the severity of the musculoskeletal injuries. RTP refers to that point in recovery from an injury when an injured athlete, recreational athlete or simply weekend warrior is back in participation functioning once again at 100%, be it in a collegiate sport, recreational activity or fitness workout. If the injured athlete returns too soon, *i.e.* before adequate healing or recovery has taken place, there are strong risks regarding reinjury and possibly an even longer downtime.

Recognized sports medicine bodies, such as the American College of Sports Medicine (ACSM) and the American Orthopaedic Society for Sports Medicine (AOSSM) strongly advocate the PRICE approach for controlling the initial symptoms. The accepted conventional PRICE concept is as follows:

- Protect: Protect the affected area from further injury.
- Rest: Rest and protect the injured part to experience less swelling and a more rapid recovery.
- Ice: Put ice on the affected area to decrease swelling and help control pain. This is especially helpful in the first 48 to 72 hours after injury.
- Compression: Wrap or brace the injured part to allow for control of initial swelling and to decrease motion.
- Elevation: Elevate the injured part, especially if it can be held higher than the heart, as this helps decrease swelling and pain.

For almost 3 decades, near infrared low level laser therapy (LLLT) has been attracting attention for its effects in wound healing, inflammation and edema control and pain attenuation. 3) In 1998, the so-called "NASA LED" from Whelan and colleagues added lightemitting diodes (LEDs) as a clinically useful therapeutic light source, <sup>4)</sup> which led Professor Kendric C Smith, a leading and highly respected photobiologist from Stanford University, CA, to redesignate the acronym LLLT as low level light therapy. 5) Since then LEDs have found useful indications in many clinical fields, including sports medicine. A study in a sports medicine center on the efficacy of 830 nm LED-LLLT for injuries in sports professionals showed high efficacy in a variety of injury types, with 17 of the 29 athletes having an excellent response and only 2 showing minimal improvement. 6)

From the various sections above of the overall PRICE concept, the most important goal would appear to be to control and reduce the swelling, the body's natural splinting and immobilization mechanism. This has two aims: to help to decrease the pressure-associated component of the injury-related pain and to enable earlier return to obtaining preinjury range of motion, but without compromising the healing of the injured tissues. Encouraging lymphatic drainage has the double benefit of reducing swelling and allowing a fresh supply of lymphatic fluid to clean out the injured area, while carrying in reparative and protective cells and removing other cells such as macrophages complete with their internalized debris from the injured tissues. In a recent meta-analysis, moderately strong evidence supported the fact that treatment with 830 nm LLLT could significantly reduce severe postmastectomy lymphedema, showing a powerful capability to reduce swelling due to a build-up of lymph. <sup>7)</sup> These findings are potentially transferrable to postinjury edema in athletes. The same study also noted significant reduction of pain.

Studies at a cellular level, both in vitro and in vivo, have demonstrated a growing strong body of good evidence for significantly increased action potentials of the inflammatory and wound healing cells. An early in vitro study on macrophages showed much faster internalization of their target with a several-fold greater synthesis of fibroblast growth factor (FGF) following near-IR LLLT. 8) A more recent in vivo controlled study on human subjects by Calderhead and colleagues demonstrated swift degranulation of mast cells in 830 nm LED-LLLT-irradiated but otherwise unwounded tissues, and with significantly greater recruitment of neutrophils and macrophages at 48 hr after one singe 60 J/cm<sup>2</sup> irradiation <sup>9)</sup> In an *in vivo* animal model of acute joint inflammation, Alves and colleagues showed that near-IR LLLT significantly mediated inflammation-related cytokines and brought about a significant reduction in the inflammatory cells.<sup>10)</sup>

Several evidentially strong studies have shown the beneficial effect of near-IR LLLT on specific sites of injury. In a mixed methods study, Rowe and colleagues systematically reviewed the conservative management of midportion Achilles tendinopathy, and found medium-strong evidence for LLLT. 11) In an in vivo and in vitro immunohistochemical study in an animal model, Tsai et al. proved that near-IR LLLT caused the migration of tenocytes to the site of injury in tendons with up-regulation of dynamin II expression compared with control injuries. 12) Very recently, in a Critically Appraised Topic (CAT) study, Doyle and colleagues assessed a strong beneficial effect of LLLT on tendinopathy-associated pain, hypothesizing that LLLT increases cellular respiration and ATP synthesis which could enhance blood flow, and also reduces pain, resulting in a environment which would be beneficial for tendon repair. 13) Meniscal pathology was treated with near-IR LLLT in a double-blinded placebo-controlled trial by Malliaropoulos et al., who concluded that LLLT was a valid treatment option for patients with meniscal tears who were unwilling to undergo surgery. <sup>14)</sup> Other studies have shown that 830 nm LLLT aids in recovery from muscle fatigue and muscle injury 15, 16).

Although some of the LLLT systems used in the above-cited studies were laser diode-based rather than LED-based, the advantage of the LED system from the sports medicine standpoint was that it could be operated in a hands-free manner, without necessitating the point-by-point application of the laser diode handpiece. In addition, the treatment head in the system used in the present study was capable of enclosing an entire joint, or covering a large area of tissue in one treatment. Finally, with an irradiance of 50 mW/cm<sup>2</sup>, even though LEDs do not have the photon intensity of laser diodes and are quasimonochromatic (830 nm ± 7 nm, > 93% of photons at the rated wavelength according to the manufacturers) rather than truly monochromatic, because of the large area treated and enhanced scattering effect associated with near infrared light, the photon intensity within the target tissue is very high and the efficacy in the present study speaks for itself. An extra bonus associated with LED-LLLT is the systemic effect whereby tissues distant to the irradiated site also benefit from the LLLT effect. A recent study clearly demonstrated the powerful systemic effect of 830 nm LED-LLLT, whereby indirectly treated burn injuries distant to the actual irradiated area healed significantly faster than unirradiated controls. 17)

Taking the above evidence into consideration, together with the significantly decreased RTP we found in our results with the 65 subjects we were able to follow up comprehensively, we believe that 830 nm LED-LLLT is a valuable treatment method in the Lehigh University sports medicine facility, where a multitude of injuries among student-athletes have been and are treated daily. LED-LLLT not only typically reduces pain and swelling swiftly, but from the in vitro and in vivo evidence presented above it also works on the injured tissues themselves, not just on the symptoms associated with the injury, through photoactivation of the injured or compromised cells via absorption of the near-IR photons in the cellular membranes, leading to photoactivation of the targeted cells. This complementary repair process on both injury and symptoms is completely in line with an accelerated but safe RTP, as embodied in the following selection from the RTP guidelines from the American College of Sports Medicine:

- The injured player or athlete should have pain-free full range of motion. The injured body part should have full movement and flexibility with little or no discomfort.
- There should be return of strength: The injured body part should be approximately equal (90-95%) to the opposite side before returning to full activity.

• There should be minimal pain or swelling: Some mild discomfort, stiffness and/or swelling during or after exercise is to be expected during the initial return to activity.

The ACSM recommends that ice can be used to alleviate these symptoms, but we believe that 830 nm LED-LLLT will be even more effective than ice, because it is working from the inside of the injury outwards, with the deep penetration capability of the 830 nm wavelength ensuring photoactivation and repair of the compromised cells in the injured tissues. We also noted that the pain relief peaked during the "dark cycle", *i.e.* the period without treatment following the treatment cycle, giving a very good latency effect during the subsequent follow-up period in the 65 subjects for whom we were able to document a full follow-up. Karu has hypothesized that irradiated cells require this "dark stage" to interpret the information they have received during the irradiation, 18) and our findings certainly followed her concept.

The present pilot study has two limitations, firstly there was a small patient population of the central study despite the comparatively large number of injuries treated **(Table 1)**. This was due in part to not being able in every case to consistently and consecutively perform the ideal therapeutic LED-LLLT regimen due to academic restrictions associated with class timetabling, and commitment to the practice routine even as a sideline observer. This resulted in the data from affected student-athletes being excluded from the assessed pilot study data set because we were unable either to deliver the optimum treatment cycle, or perform a thorough follow-up, or both. Secondly, all

**Table 4:** Results of a subjective satisfaction surveyamong the 112 injured students in 2015.

Grade	Degree of satisfaction	Ν	%
5	Very satisfied	38	33.9
4	Satisfied	50	44.6
3	Somewhat satisfied	16	14.3
2	Somewhat dissatisfied	4	3.6
1	Dissatisfied	4	3.6
	Totals:	112	100

assessments were subjective in nature, and due to the problems with numbers and timetabling conflicts mentioned above, we were unable to include any control groups for non- or sham-irradiated subjects in the present study. We are hoping that the addition of a second LED-LLLT system will enable us to redress this lack of control subjects, as well as being able to minimize timetabling conflicts and include more subjects in our future studies.

The efficacy of the 830 nm LED-LLLT system used in the present study created a significant demand and fosters the probability for larger institutions/athletic programs of having more than one unit available to expedite care for injured student-athletes, which would be of great assistance in being able to amass a much larger number of injuries and athletes with a full-term follow-up, and institute a control arm for future studies for better and more transparent assessment of efficacy. The second point which would help with some of the problems we encountered in scheduling treatments would be to deliver the 60 J/cm<sup>2</sup> dose in a shorter period by increasing the intensity of the LEDs. This would definitely help to ease timetabling problems caused by the current 20 min treatment time.

#### Conclusions

830 nm LED-LLLT at 60 J/cm<sup>2</sup> safely and effectively decreased both inflammation and pain in injured student-athletes allowing a shorter return to participation in sports activities and training than is generally the case with musculoskeletal or soft tissue injuries. 830 nm LED-LLLT with the system used in the present study was easy to apply, was pain- and side effect-free and was well tolerated by all subjects. In addition, the Lehigh University Sports Medicine Center staff have gradually but firmly bought in to the concept of LED-LLLT, finding it easy to apply, safe and effective, with hopes for a second unit to allow 830 LED treatment in both Lehigh campuses. The authors believe that 830 nm LED-LLLT is a potentially valuable treatment modality to enhance the quality of care afforded to injured athletes in any Sports Medicine facility, whether a privately owned clinic, or in a professional or collegiate setting. Further controlled studies are, however, warranted to enable confirmation and generalization of the very good results achieved in the present study.

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#### [Acknowledgements]

The authors are very grateful to Lutronic Corporation, Goyang, South Korea, for generously supplying the HEALITE II system used in the present study. The authors declare the following information regarding potential conflicts of interest with the system used in the study.

JF and JB: None to declare

RGC: VP Medicoscientific Affairs, Lutronic Corporation.

DBV: Clinical Research Consultant for Lutronic