Low Intensity Laser Therapy: The clinical approach

Fred Kahn
Meditech International Inc., 411 Horner Ave., Toronto, ON, Canada, M3W 4W3

ABSTRACT

Recently, there has been significant improvement in the process of research and application of Low Intensity Laser Therapy (LILT). Despite this positive direction, a wide discrepancy between the research component and clinical understanding of the technology remains. In our efforts to achieve better clinical results and more fully comprehend the mechanisms of interaction between light and cells, further studies are required. The clinical results presented in this paper are extrapolated from a wide range of musculoskeletal problems including degenerative osteoarthritis, repetitive motion injuries, sports injuries, etc.

The paper includes three separate clinical studies comprising 151, 286 and 576 consecutive patient discharges at our clinic. Each patient studied received a specific course of treatment that was designed for that individual and was modified on a continuing basis as the healing process advanced. On each visit, clinical status correlation with the duration, dosage and other parameters was carried out. The essentials of the treatment consisted of a three stage approach. This involved a photon stream emanating from a number of specified gallium-aluminum-arsenide diodes; stage one, red light array, stage two consisting of an array of infrared diodes and stage three consisting of the application of an infrared laser diode probe. On average, each of these groups required less than 10 treatments per patient and resulted in a significant improvement / cure rate greater than 90% in all conditions treated. This report clearly demonstrates the benefits of LILT, indicating that it should be more widely adapted in all medical therapeutic settings.

Keywords: Low intensity laser therapy, clinical, mobility, rehabilitation, treatment, pain reduction

1. INTRODUCTION

Low Intensity Laser Therapy (LILT), from both the clinical and research perspective has been scrutinized intensively during the course of its application over the past 30 years. Despite this extensive history, the utilization of lasers to heal tissue is a relatively new endeavor, particularly in North America. There are many reasons contributing to this situation:

- Lack of interest, as a preponderance of medical practice is based on the utilization of pharmaceuticals and surgical interventions.
- The majority of research papers and other publications emanate from Russian, Japanese and Eastern European laboratories, with minimal exposure in the western industrialized nations.
- Slow approval by regulatory bodies
- Non inclusion by today's gatekeepers i.e. HMO's, insurance companies, governments, etc.

This has resulted in a lack of acceptance by mainstream medicine which demands that more controlled double blind studies be carried out. The concept of curing pathologies with laser therapy has not fully made its impact in the practice of medicine. The majority of pharmaceuticals are not designed to heal the pathology but rather to modulate or mask symptoms. In contradistinction, LILT is designed to cure the pathology rather than to suppress symptoms.

Over the past three decades, many research groups have attempted to define the exact interaction between light and cells both in vivo and in vitro, including cell cultures of both the human and animal variety. A recent review of the literature comprising over 300 cited articles and abstracts attests to this fact (1). The majority of double blind clinical trials reveal an overwhelming amount of evidence supporting the positive effects achieved using LILT. Articles that are negative have generally failed in their approach owing to the use of poorly designed devices and the improper application of therapy. This includes lack of standardization, inadequate power, insufficient length of

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duration of treatment and utilizing incorrect protocols. Furthermore, most devices in the marketplace today are deficient in design, protocols are frequently selected at random and therapists are not provided with the proper education to operate the equipment. Moreover they generally lack a basic understanding of physiology, anatomy and physics. Academics over the past decade have continued to promote additional double blind clinical trials and this is certainly commendable; in actual fact however, minimal practical progress has been achieved from the clinical perspective.

The effectiveness of laser therapy has been much debated regarding the analysis of parameters (frequency, duty cycle, waveform, etc.), environmental setting, the accuracy of the pre-therapeutic diagnosis and numerous other factors. At Meditech, we recognized these problems 15 years ago at the inception of our research and this publication shares some observations in addition to the results achieved with our new clinical approach to healing.

2. METHODS

The outcomes in these studies are derived from the utilization of therapy delivered by the BioFlex Professional System manufactured by Meditech International Incorporated. This system was developed over the course of 16 years by a group headed by Dr. Fred Kahn. Over the course of time, valuable contributions were made by Professor Tiina Karu, Dr. Mary Dyson, numerous clinicians and the Engineering Department at Ryerson University in Toronto. Initially, 20 systems were developed for proof of concept purposes. The current system has been in operation in a clinical setting at Meditech's Treatment Centres and at numerous independent clinics in 22 countries throughout the world. Patients in our studies were carefully diagnosed by a small number of medical specialists and treatments were prescribed on the basis of Meditech's Clinical Users Manual directives and customized as clinically indicated. All therapeutic procedures were carried out in uniform fashion based on a combination of accurate diagnosis, clinical experience and the utililization of the correct protocols. Consistency was the keynote throughout the entire process. Changes in treatment procedure were based on clinical progress both positive and negative on each individual patient visit. In 70% of all patients treated, the protocols utilized were standard and customization was carried out in the additional 30%. This consistent methodology is felt to be essential in the achievement of superior clinical outcomes.

Primary objectives of the treatment were:

1. Elimination of pain.
2. Substantial increase in mobility and range of motion.
3. Cessation of the utilization of multiple medications (analgesics, NSAIDs and cortisone.)
4. Improvement of the patient's overall status (normal sleep patterns, activity levels, appetite and headache relief, etc.)
5. To enable the patient to resume normal work patterns and physical activities.

To reach these goals required an intense effort and close collaboration between the patient, physician and the therapist applying the treatment. This attention to detail is essential to the achievement of positive results in the preponderance of patients, the objective in all instances being a total cure.

Invariably the treatment regime utilized in these studies consisted of the three stage approach. Super luminous diode arrays and lasers from 660 to 840 nm wavelength were employed in individual arrays. In certain circles the debate of utilizing laser versus superluminous diodes remains controversial and we adhere to the dictum that the results speak for themselves. The major difference between these two types of light remains coherence. In the treatment of biological tissue this coherence is lost within the first 5 to 10 µm as it is differentially scattered. This clearly supports the use of superluminous diodes as being equally efficient in the treatment of cells. The singular advantage of using laser diodes is that the power output is generated in a confined area resulting in deeper penetration, useful in treating the primary focus of any pathology. The three stage approach that we utilize covers a wide range of varying penetration depths and chromophore absorption. The stages are delivered using the following arrays:

1. Red light (660 nm) using a 180 diode array of superluminous diodes.

2. Infrared light (840 nm) using a 180 diode array of superluminous diodes.
3. Infrared laser probe (830 nm) using a single laser source focused on the basic pathology.

Low Intensity Laser Therapy was utilized as the basic platform in the therapeutic program which was augmented in approximately 50% of cases by massage, thermal therapy and at the later stage exercise programmes. These are therapies that we use to speed up the process initially, particularly in acute and extensive injuries but were not felt to be essential to the treatment program.

It should be noted that over 60% of cases suffered from more than one medical problem and the majority of patients had undergone therapy varying from a matter of weeks to years under the direction of the family physician, physiotherapist, chiropractor, neurologist, rheumatologist, orthopedic surgeon or psychologist. Analgesics, anti-inflammatory medications and cortisone had been utilized extensively in the majority of the patient population and many surgical procedures had been carried out often with results that were less than desirable. It is not uncommon for a patient presenting at our clinic to indulge in the ingestion of over 30 analgesics on a daily basis. In our practice most pain can be explained applying the standard medical approach. We listen to the patient, perform a complete physical examination and utilize test procedures as indicated. Once this process has been completed, we initiate therapy, generally on the initial visit.

In all studies, a patient questionnaire was used to determine the percentage of improvement on discharge. This included a visual analogue pain scale ranging from 0 (no pain) to 10 (intolerable pain). This is seen in Figure 1.1.

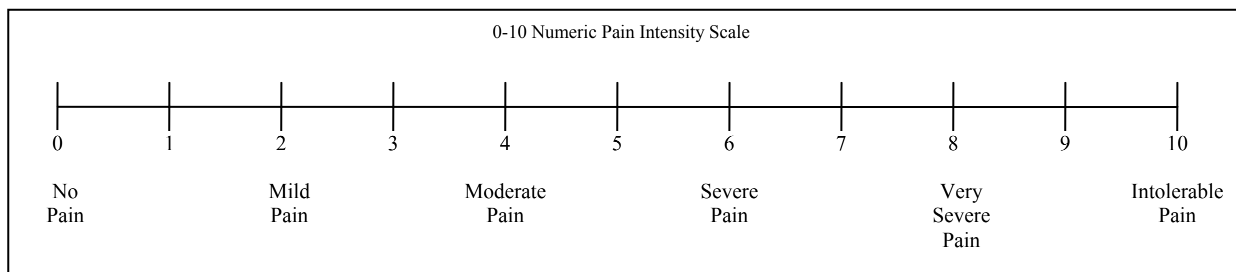

Figure 1.1: The visual analog scale used to determine patient pain intensity upon discharge.

This was followed by asking the patient to state the degree of overall improvement and was based on a scale from 0% (no improvement) to 100% (complete elimination of symptoms). The numbers of these questions were then averaged into five groups and are presented as a mean ± standard deviation. The groups consisted of degenerative pathologies, repetitive strain injuries, trauma, sports injuries and other pathologies that do not conform to the previous categories.

The following three sections are the separate clinical studies, comprised of 151, 286 and 576 patients. Each section contains both a summary of the patients treated as well as the results from the questionnaire that was competed at the last treatment session.

3. STUDY ONE

3.1 Patients:

One hundred and fifty-one patients (n=151); consisting of ninety-four males (n=94) and fifty-seven females (n=57) participated in the first clinical study. The average age of the patients was forty-six years (age=46±12 years). Separating the patients into distinct pathology groups resulted in 29% of the patients falling into the category of degenerative osteoarthritis. The majority of these involved the lumbo-sacral spine and over 60% of these were accompanied by degenerative disc disease, bulging discs, nerve root compression and/ or stenosis of the spinal canal or foramen. The percentage of different pathologies treated in this study can be seen in Figure 2.1.

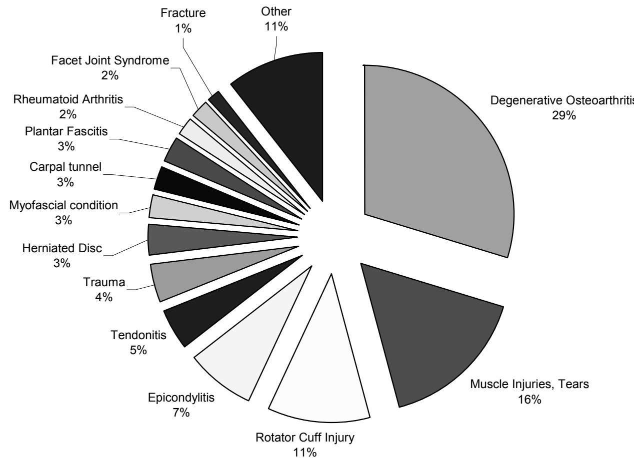

Figure 2.1. The percentage of each condition treated in the first study.

3.2 Results:

The results of the first clinical study were that patients had a 90.4% improvement over an average of 11 treatments. The average visual analog pain scale rating was 0.22 out of 10. The overall improvements for the different pathologies are presented in Table 1.

Table 1. Percentage improvement and average number of treatments for the different pathologies treated in the first clinical study.

Condition	Number of Patients	Average number of treatments	Percentage overall improvement
Degenerative	48	12.6	86.3
Repetitive Stress Injury	28	11.5	87.8
Trauma	36	10.7	95.6
Sports Injury	22	9.3	94.4
Other	17	11.2	90
Mean ± Standard Deviation	151	11.3 ± 1.0	90.4 ± 6.8

3.3 Discussion:

The results of this study are encouraging in the treatment of a range of pathologies with LILT. Further improvement of protocols throughout this study revealed a diminishing number of treatments and increased the overall improvement of the patients. This trend should continue as both the treatment experience and the refinement of protocols expand.

One patient particularly highlights the success in treating a variety of pathologies using LILT. The patient was an 86 year old podiatrist who had periphero-arterial occlusive disease that created a pre-gangrenous status in his feet. The problem had been complicated by severe frostbite of his toes during a prior skiing excursion. He was advised that partial amputation would be necessary. The patient decided to find alternative therapy and presented at our clinic. The first picture (Figure 2.2a) was taken on arrival prior to his first treatment; 6 months after he had initial symptoms in the foot.

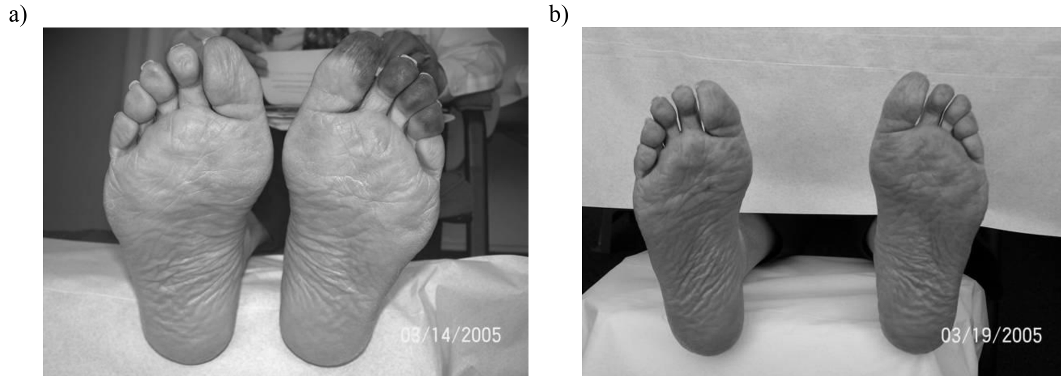

Figure 2.2 a) The initial picture before any treatment with LILT.
b) The final picture after 5 consecutive days of treatment with LILT.

After the first treatment he noted a reduction in pain and an increase in the temperature of the foot. Treatments were 60 minutes in duration and were administered daily for five days both locally and over the spinal cord and sympathetic ganglia. The improvement in temperature continued throughout the treatment and by the fifth day it had returned to normal; the pain and discoloration were completely gone (Figure 2.2b). The toes had regained normal function.

4. STUDY TWO

4.1 Patients:

Two hundred and eighty-six patients (n=286); consisting of one hundred and seventy males (n=170) and one hundred and sixteen females (n=116) participated in the second clinical study. The average age of the patients was fifty-three years (age=53±17 years). Separating the patients into distinct pathology groups resulted in 46% of the patients falling into the category of degenerative osteoarthritis, which is 17% higher than the first study. The segmentation of pathologies can be seen in Figure 3.1.

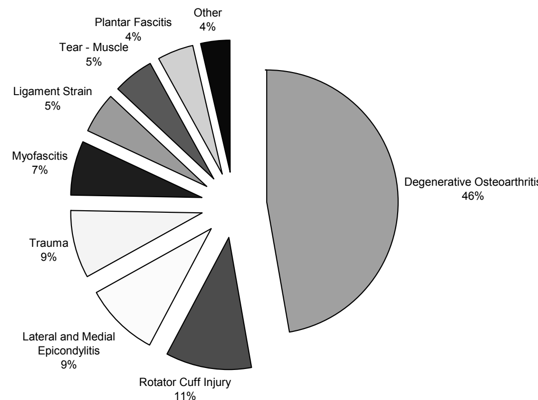

Figure 3.1 The percentage of each condition treated in the second study.

4.2 Results:

The results of this clinical study were that patients had a 91.1% improvement over an average of 9.7 treatments for all conditions. The average visual analog pain scale rating was 0.19 out of 10. The improvements for the different pathologies are presented in Table 2.

Table 2. Percentage improvement and average number of treatments for the different pathologies treated in the second clinical study.

Condition	Number of Patients	Average number of treatments	Percentage overall improvement
Degenerative	108	11.5	87.6
Repetitive Stress Injury	35	10.7	88.7
Trauma	48	8.9	93
Sports Injury	89	7.8	96
Other	6	11.1	91.1
Mean ± Standard Deviation	286	9.7 ± 0.96	91.1 ± 6.84

4.3 Discussion:

The results from this study show an improvement over the first study containing 151 patients. This improvement can be attributed to better knowledge including improved protocol selection, application and experience.

As the patient load increases, we note a commensurate increase in the number of back problems, degenerative arthritis, and sports injuries. Our surveys indicate that this is based on patient and physician referrals, the result of superior treatment outcomes. Moreover the athletes treated, both at the high performance amateur and professional level, are highly motivated to return to activity. This group has developed a dependence on this dramatic therapeutic approach to return them to action more quickly than conventional therapies. The majority of these sports injuries consist of trauma to muscles, tendons, ligaments and bone structures.

An example of these sports injuries is an athlete who had a partial tear of the left Achilles tendon. This resulted in the inability to plantar flex the foot as it was exceedingly painful (Figure 3.2a). The edema around the tendon is quite obvious and left untreated would heal with scar tissue formation and possible functional impairment. Incidentally this patient had rejected treatment of six weeks in a cast offered by her orthopedic surgeon, a customary method of therapy.

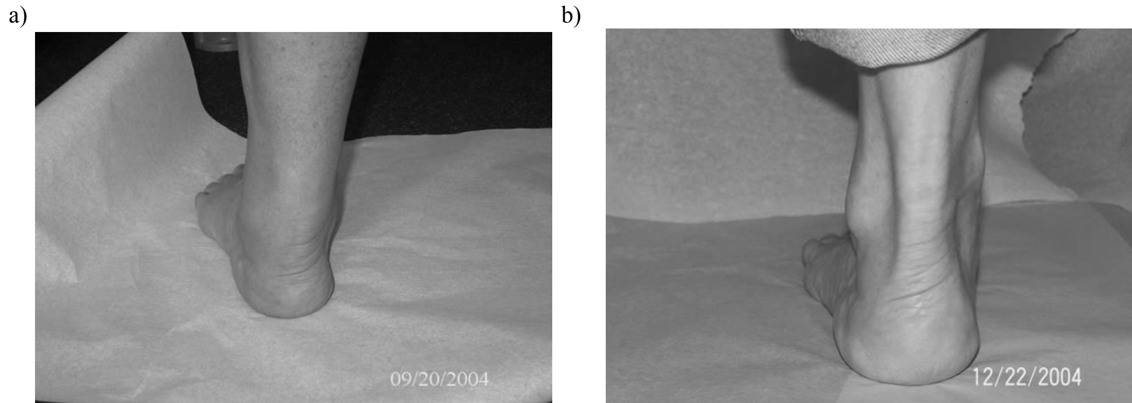

Figure 3.2 a) The initial picture before any treatment with LILT.
b) The final picture after 10 treatments over 3 months.

The superficial nature of the Achilles tendon makes it easy to treat. This patient received 10 treatments over 5 weeks and was able to return to competition. The reduction in the edema around the tendon is clearly evident (Figure 3.2b). At the end of the treatment the strength of the tendon had returned to normal accompanied by full function.

Once again, one can only state that Low Intensity Laser Therapy judiciously applied produces results unequaled by other technologies if the appropriate criteria are observed. Furthermore, it reinforces the fact that LILT is the therapy of choice in the treatment of musculoskeletal pathologies.

5. STUDY THREE

5.1 Patients:

Five hundred and seventy-six patients (n=576); comprised of three hundred and seventeen males (n=317) and two hundred and fifty-nine females (n=259) participated in the third clinical study. The average age of the patients was fifty-three years (age=53±16 years). The range of pathologies treated and the rate of occurrence can be seen in Figure 4.1.

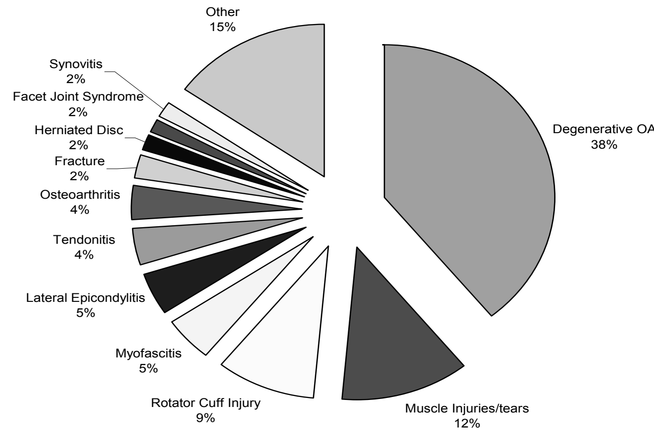

Figure 4.1. The percentage of each condition treated in the third study.

5.2 Results:

The results of the third clinical study were that patients had a 93.6% improvement over an average of 9.7 treatments for all conditions. The average visual analog pain scale rating was 0.16 out of 10. The improvements for the different pathologies are presented in Table 3.

Table 3. Percentage improvement and average number of treatments for the different pathologies treated in the third clinical study.

Condition	Number of Patients	Average number of treatments	Percentage overall improvement
Degenerative	140	11.3	88.3
Repetitive Stress Injury	93	9.6	94.3
Trauma	66	9.4	936
Sports Injury	258	9.2	96.1
Other	19	7.5	96.3
Mean ± Standard Deviation	576	9.7 ± 0.96	93.6 ± 6.84

5.3 Discussion:

The results from the third study show an improvement over the first two clinical studies containing 151 patients and 286 patients respectively. Again, there was an improvement in the cure rate as well as a reduction in the average number of treatments when compared with the two previous studies.

Throughout this study we continued to treat a number of chronic ulcers; the majority of these had existed over 6 months. The treatment of ulcers has been very challenging as the continued application of ointments, creams and dressings often increases the size of the ulcer. LILT when properly applied has an immense ability to heal lesions that would otherwise progress to more serious complications. An example of this was a patient who had thrombophlebitis of the left lower leg and multiple dermal ulcers of both extremities. This condition had been present for 14 months and

the patient had been hospitalized for 3 months without improvement. He discharged himself from hospital against medical advice. The leg was in jeopardy and clearly in danger of requiring amputation (Figure 4.2).

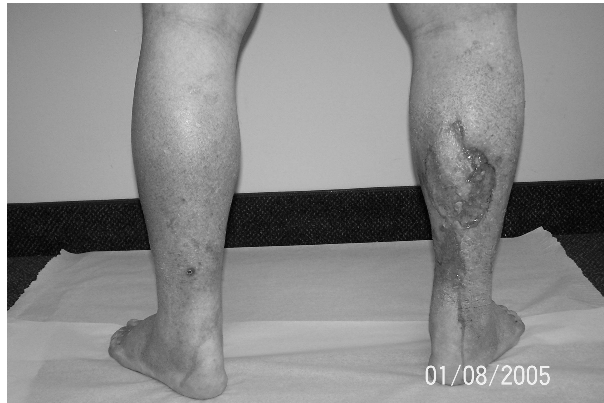

Figure 4.2. At the initial assessment the left leg has a large ulcer.

Prior to the initial treatment the diameter of the right calf was 6 cm greater than the left secondary to thrombophlebitis. The patient had 48 treatments over a period of 3 months owing to the severity of the condition and as it had been present for over 14 months before commencing LILT. The patient was placed on a regime of warm saline compresses, laser treatment on alternate days and the wounds were left open. His compliance with the outlined treatment was less than ideal. When the patient arrived he was unable to walk and had extreme pain suppressed by large quantities of analgesics. He was also on massive doses of a variety of antibiotics. Antibiotics were discontinued at the beginning of laser therapy and wounds were treated by open exposure. At the termination of his treatment (Figure 4.3) he was able to walk and had ceased to take any medications as he was pain free.

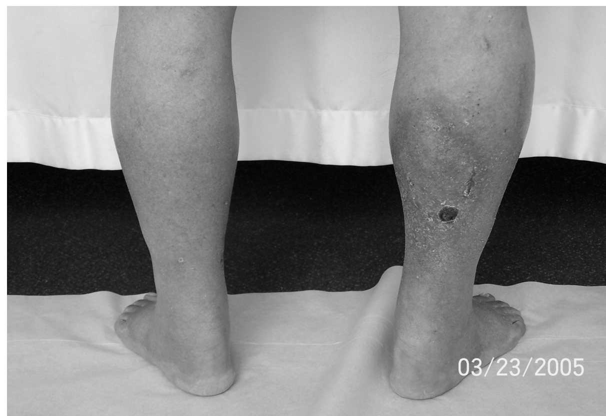

Figure 4.3. Near the final treatment the ulcer has fully healed over and the thrombophlebitis has been resolved.

A second patient in this study presented another therapeutic challenge. A 16 year old national caliber tennis player, who was riding his bike, caught the tire in the space between the sidewalk and the grass and was catapulted over the handle bars at high speed. This young man sustained spinal cord shock and a tear to the right brachial plexus. This injury was a serious threat to his tennis career as he was unable to move his arm. The initial assessment demonstrated severe loss of motor function of the muscles of the neck and of the right arm (Figure 4.4).

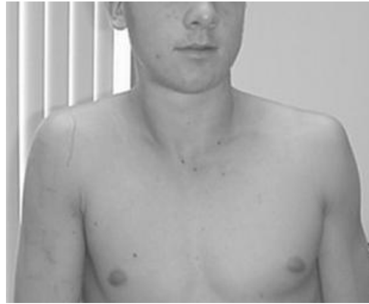

Figure 4.4. At the initial assessment the patient was unable to move his right arm and had limited movement of the neck.

He had extensive neurological work up at a major university hospital but no solutions were offered; moreover no improvement had occurred over a 4 week period prior to treatment with LILT. After the initial treatments, he gradually began to recover motor function (Figure 4.5).

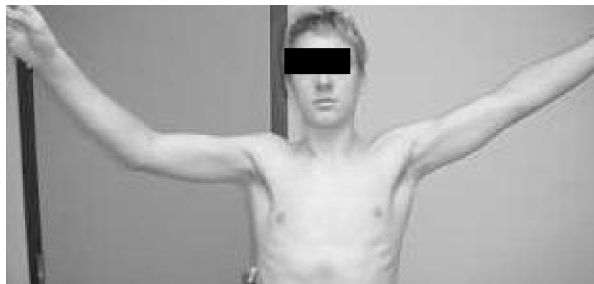

Figure 4.5. Halfway through treatment there was obvious improvement in the range of motion. The neck has resumed a more midline position. The abduction of the right are

The treatment continued over 8 weeks during which he received 15 one hour treatment sessions to the cervical spine and brachial plexus. LILT was augmented with massage therapy to help accelerate the healing process. At the completion of treatment he had regained complete power of the muscles along with a full range of motion of the arm and neck (Figure 4.6).

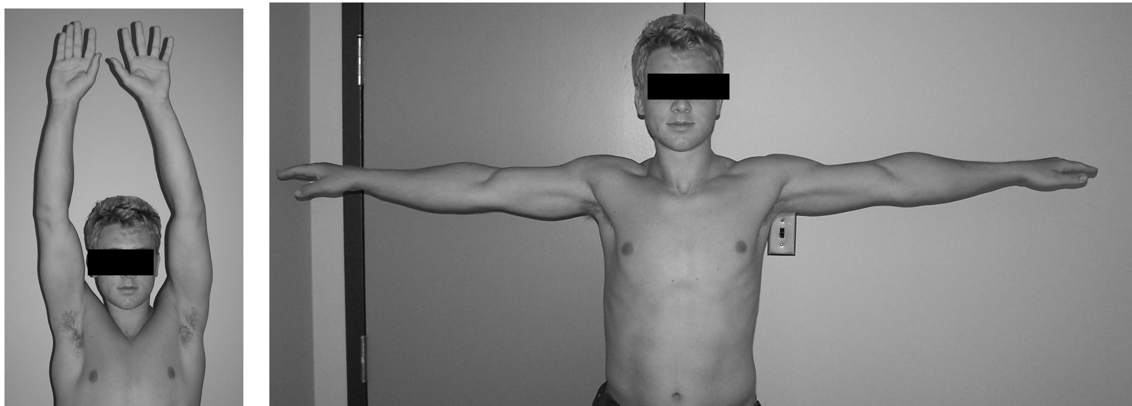

Figure 4.6. At the end of the treatment there is a full recovery with a normal range of motion.

Moreover he was able to accept a full tennis scholarship. This demonstrates the effectiveness of LILT in treating a wide range of conditions that might have otherwise been difficult to resolve.

6. CONCLUSION AND DISCUSSION

In these three studies we have demonstrated the effectiveness of treating a broad range of musculoskeletal pathologies with Low Intensity Laser Therapy. Each study revealed an improved cure rate with a concomitant reduction in the number of treatments required. This is clear evidence of the refinement of treatment protocol selection and application.

The four patients presented can be characterized as problematic therapeutic challenges and are a testimonial to the healing potential of Low Intensity Laser Therapy. Moreover, they should provide a stimulus to future research to enhance the understanding of the technology and its wider application.

7. REFERENCES

1. Turner, J. and L. Hode. *Laser therapy clinical background and scientific practice*, 13.3, Prima Books AB, Grängesberg, 2002.