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Original Articles

A Clinical Trial on Low Level Laser Therapy as a Pain Control Modality

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INTRODUCTION

Hypothesis: Reduction in the perception of pain can be achieved with specific applications of Low Level Laser Therapy (LLLT) at ML830nm® for certain conditions.

The study is a pilot project and was not considered by an IRB for the initial phase. Continued investigation is suggested. The equipment for the study was provided by MicroLight Corp of America and the treatment delivered in the study was done so according to the manufacturers recommendations. No fees for treatment were charged to any patients and no subjects were paid to participate in the study.

REVIEW OF THE LITERATURE

There are a multitude of studies on LLLT. Over 2500 published articles appear in a search with over 370 in the dental field alone. The clinical value of LLLT appears to be validated but those that exist rarely distinguish between the various wavelength devices. I have mentioned a few items here up front for consideration and then later on, I have provided a very brief synopsis of the prevailing literature for consideration.

According to the Swedish Medical Laser Society LED units are heating devices and seem to take around 2x the incident dose of LED to produce the effect of the Laser probe and then to a much shallower depth of penetration. Both LEDs and LASERs work, but more research must be carried out with LEDs. There is very little scientific research. LLLT research cannot be used to justify LED equipment, or to infer the benefits of LED therapy (this could apply equally to pulsed v continuous wave lasers). There are still no investigations showing that LEDT (Light Emitting Diode Therapy) is as effective as LLLT although many comparisons have been made, also with a different dose. The depth of penetration depends primarily upon the wavelength and power density of the beam incident to the tissue, and the absorption/reflection characteristics of the irradiated tissue.

FDA Classification

Another key point is that LED devices are classified by the FDA with a product code **ILY**. The Device is a **lamp, infrared.** The Device Description is Infrared lamp. True laser devices have a product code of **NHN**. The Device is a **lamp, non-heating, for adjunctive use in pain therapy.**
The Device Description is also Infrared lamp.

LED devices heat tissue and sellers of LED devices must warn customers of the hazards of heat generated by their modality, unlike low-wattage lasers that heal without heating human tissue. With laser devices I found there are no contra-indicators except for the eyes.

There are herein sited 51 abstracts indicating some interest in this concept and a continued search for alternatives to pain medication. The articles with a brief synopsis are listed at the end with the reference. The primary clinical point of the literature review is that certain light therapy seems to be a leading cause for remission of pain generation or of pain perception in both acute and chronic situations. There is also some evidence of tissue healing rate affectivity. In conclusion from analyzing these articles, LLLT is not well understood by those who have investigated the variety of frequency responses and expectations. As in most clinical experiences, it appears that proper application may be a significant variable.

CURRENT RESEARCH

A trial was designed to measure the patient's perception of pain and relative improvement on various conditions that cause pain or have pain associated with them. Patients who had reported persistent pain were notified of the project and invited to participate. Other providers of physical medicine were notified as well and encouraged to have patients with similar painful conditions inquire. All patients admitted to the study had a history of pain with multiple episodes of chiropractic manipulation and physical therapy with various degrees of limited success.

METHODS

A combination Visual Analogue Pain scale and pain drawing was used to measure an intake score for each patient and document the location and type of pain.

The Treatment Protocol was the same for each patient, only the location of the treatment differed based on the reported area of pain. Only one area of pain per patient was treated. Depending on the tissue to which the treatment was applied, three techniques were used: Rotation on thicker muscular tissue, Alignment on tendons and ligaments and Pivot on combination areas.

In this study, there were 4 men and 7 women ranging in age between 15 and 83 years of age.

Intake measurements include a visual analogue pain scale from 0 to 10 with 0 representing no pain and 10 representing the most pain. Patients were asked to complete the VAS prior to the beginning of the first treatment session and at the conclusion of the last treatment session.

Determination was made as to the chronicity of the condition being measured. Patients with complaints of less than 6 weeks onset were considered in the acute group and those of more than 6 weeks were in the chronic group.

THE PROCEDURE

The intake physician determined each of the following items prior to beginning any treatment: Treatment foci, the number of foci per complaint, the nature of the treatment protocol, rotational, alignment or pivot application of the laser instrument depending on the tissue being measured. These each remained constant throughout the

course of treatment. Each focus was treated with 4 joules per centimeter squared. Patients were positioned with treatment as closely horizontal to the heart as possible. Patients not treated face down were obliged to wear safety glasses.

RESULTS

11 patients were ultimately considered in the study results. Three patients were eliminated due to conditions that did not have pain associated with them and/or did not complete at least four sessions of treatment.

The average intake score was 7.18, and the average exit score was 2.91 on a scale of 0-10 with 0 being no pain and 10 being most pain.

The average intake score of the chronic group was 6.83 and the average exit score was 3.33 showing a measured average change of 3.5 that equates to an improvement quotient of 51.2%.

The average intake score of the acute group was 7.6 and the average exit score was 2.4 showing a measured average change of 5.2 that equates to an improvement quotient of 68.4%.

Pain Area	Diagnosis	Chronicity	Intake	Exit	Change	% change	# of Treatments
Wrist	Carpal Tunnel	acute	8	3	5	0.625	6
Hip	DJD	acute	9	1	8	0.88888889	6
Ankle	Post Surgery	acute	5	2	3	0.6	6
Right heel	plantar fascitis	acute	7	1	6	0.85714285	6
Knee	medial collateral sprain	acute	9	5	4	0.44444444	3
Wrist	Carpal Tunnel	chronic	9	6	3	0.33333333	6
Knee	DJD	chronic	9	2	7	0.77777778	3
Left Elbow	Tendonitis	chronic	5	4	1	0.2	5
Both Wrists	DJD	chronic	5	3	2	0.4	4
Neck	Cervical Disc	chronic	7	3	4	0.57142857	
thumb	DJD	chronic	6	2	4	0.66666667	6
		Chronic	6.8333	3.33333	3.5	0.51219512	
		Acute	7.6	2.4	5.2	0.68421052	

DISCUSSION

It is noted that every patient in the study perceived some reduction in pain. It was evident to the staff that the perception of pain was reduced in most patients after 1 or two sessions of treatment. It seemed as though the chronic group noted the most significant changes most rapidly even though their overall change was less than the acute group; but no measurements were made to corroborate this. It would be wise in a future study to have the patients complete a Visual Analogue Pain scale after each session to see when the most benefit was derived and to determine if 6 sessions were actually necessary to produce the remission of pain. It seemed that chronic patients needed less sessions to respond than did the acute group. This would be very interesting to bear out with future study as it seems to be opposite of the response to typical non-drug and non-surgery physical medicine modalities.

Drug use or pain medication was not considered in the intake measurements. This should be done in a future study in order to determine if ML830nm® Cold Laser Treatments could replace or reduce the use of pain medication for certain conditions. Perhaps patients who are on regular medication for control could receive benefit by reducing or eliminating the need for regular medication for pain.

Patient coincidentally reported a general feeling of more motion. This was not anticipated to be a part of the study and no measurement tools were used. It may be coincident to reduced feelings of pain, which may have allowed for more freedom of movement or actual improvement of motion due to tissue healing could be a consideration. In a study this brief, the former is suspected.

CONCLUSIONS

The ML830nm® cold laser treatment delivered in the protocol described above produces a consistent reduction in the perception of pain at various foci in patients with a variety of diagnoses. This may be temporary or permanent, this study could not determine any long term benefits. Follow-up and additional measurements in functionality changes are indicated to determine tissue healing, rehabilitation or recuperation as a result of this modality.

The other literature referenced herein shows a wide variety of responses. This study specifies one wavelength device and measured its effect on pain perception. It can be considered that many forms of light therapy have been studied on the surface and that an equally wide spectrum of response can be expected. Under controlled protocol for specific pain relative to a variety of conditions, the ML830nm® Cold Laser device can produce a consistent remission of pain perception in both acute and chronic situations. A review of the other current literature will bear this out.
Additional study is indicated to 1) follow-up on patients whose pain is reduced to see if there is a lasting effect; 2) measure functionality as a part of the initial considerations; and 3) measure timing of response to treatment by considering use of the pain tools on each visit rather than just intake and exit.

A BRIEF SYNOPSIS OF RESEARCH ON LLLT

1. Effects of low-power laser irradiation on cell locomotion in protozoa. Photochem Photobiol. 2004: 80 (3): 531-534. Irradiation at 830 nm laser compared to 650 nm resulted in a markedly higher response in Tetrahymena. Values remained increased after irradiation was discontinued.

2. Pugliese LS, Medrado AP, Reis SR, Andrade Zde A. **The influence of low-level laser therapy on biomodulation of collagen and elastic fibers.** Pesqui Odontol Bras. 2003; (4): 307-313. Low-level laser therapy contributed to a larger expression of collagen and elastic fibers during the early phases of the wound healing process.

3. Medrado A R, Pugliese L S, Reis S R, Andrade Z A. **Influence of low level laser therapy on wound healing and its biological action upon myofibroblasts.** Lasers Surg Med. 2003; 32 (3): 239-244. Treatment with dosage of 4 J/cm2 was superior to that with 8 J/cm2.: Laser therapy reduced the inflmatory reaction, induced increased collagen deposition and a greater proliferation of myofibroblasts in experimental cutaneous wounds.

4. Hopkins J T, McLoda T A, Seegmiller J G, Baxter G D, **Low-Level Laser Therapy Facilitates Superficial Wound Helaing in Humnas:** A Triple-Blind, Sham-Controlled Study. J Athl Train. 2004:39 (3): 223-229. Data indicate that LLLT is an effective modality to facilitate wound contraction of partial thickness wounds.

5. Lizarelli R F, Marcello O Mazzetto M O, Bagnato V S. **Low-intensity laser therpy to treat dentin hypersensitivity: comparative clinical study using different light doses.** Proc. SPIE. 2000; Vol. 4422. Double blind study showed for use of 660 nm laser therapy, doses of 0.13 to 2.0 J/cm2 were more efficient in treating dentin hypersensitivity.

6. Corona S A. Nascimento T N, Catirse A B, Lizarelli R F, Dinelli W, Plama-Dibb R G. **Clinical evaluation of low-level laser therapy andflouride varnich for treating cervical dential hypersensitivity.** J Oral Rehabil. 2003:30 (12): 1183-1189. Fluoride varnish and LLLT may be effective in decreasing cervical dentinal hypersensitivity. The GaAlAs laser showed improved results for treating teeth with a higher degree of sensitivity.

7. Marsilio AL, Rodrigues JR, Borges AB. **Effect of the clinical application of the GaAlAs laser in the treatment of dentine hypersensitivity.** J Clin Laser Med Surg. 2003; 21 (5): 291-296. GaAlAs laser therapy was statistically significant in treating dentinal hypersensitivity and after follow-up of 60 days.

8. Kawalec J S, Hetherington J, Pfennigwerth C et al **Effect of a diode laser on wound healing by using diabetic and nondiabetic mice.** Journal of Foot and Ankle Surgery. 2004; 43 (4): 214-220. LLLT shows a beneficial effect on wound healing in diabetic mice and does not have a detrimental effect in non-diabetic mice.

9. Cho H J, Lim SC, Kim S G et al. **Effect of low-level laser therapy on osteoarthropathy in rabbit.** In Vivo. 2004;18 (5):585-591. Data suggests LLLT is effective in the treatment of chemically-induced osteoarthropathy.

10. Irvine J, Chong S L, Amirjani N, Chan K M. **Double-blind randomized controlled trial of low-level laser therapy in carpal tunnel syndrome.** Muscle Nerve. 2004;30 (2): 182-187. There were no adverse effects of LLLT to patients with CTS. There was a significant symptomatic difference in both the control and treatment group but no significant difference in any of the outcome measures between the two groups.

11. Lapchak P A, Wei J, Zivin J A. **Transcranial infrared laser therapy improves clinical rating scores after embolic strokes in rabbits.** Stroke. 2004; 35 (8): 1985-1988. Laser treatment improved behavioral performance if initiated within 6 hours o fan embolic stroke and the effect of laser treatment is durable.

12. Brown S A, Rohrich RJ, Kenkel J et al. **Effect of low-level laser therapy on abdominal adipocytes before lopoplasty procedures.** Plast Reconstr Surg. 2004; 113(6):1796-1804; discussion 1805-1806. Data do not support the belief that low-level laser therapy treatment before lipoplasty procedures disrupts tissue adipocyte structure.

13. Gaida K, Koller R, Isler C et al. **Low Level Laser Therapy – a conservative approach to the burn scar?** Burns. 2004; 30 (4): 362-367. A correlation between scar duration and improvement through LLLT could be found. No negative effects were reported.

14. Zinman L H, Ngo M, Ng E T et al. **Low-intensity laser therapy for painful symptoms of diabetic sensorimotor polyneuropathy: a controlled trial.** Diabetes Care. 2004; 27 (4): 921-924. Although an

encouraging trend was observed with LLLT, the study results do not provide sufficient evidence to recommend this treatment for painful symptoms of DSP.

15. Ozkan N, Altan L, Bingol U et al. **Investigation of the supplementary effect of GaAs laser therapy on the rehabilitation of human digital flexor tendons.** J Clin Laser Med Surg. 2004; 22 (2): 105-110. Significant improvement in edema reduction improves rehabilitation of human flexor tendon injury. Supplementary applications had no effect on other functional recovery parameters.

16. Cruz D R, Kohara E K, Ribeiro M S, Wetter N U. **Effects of low-intensity laser therapy on the orthodontic movement velocity of human teeth: a preliminary study.** Lasers Surg Med. 2004; 35 (2):117-120. LLLT accelerates human teeth movement and could considerably shorten the whole treatment duration.

17. Wenzel G I, Pikkula B, Choi C H, Anvari B, Oghalai J S. **Laser irradiation of the guinea pig basilar membrane.** Lasers Surg Med. 2004; 35 (3): 174-180. LLLT may have therapeutic benefits for patients with high frequency sensorial hearing loss.

18. Gur A, sarac A J, Cevik R, Altindag O, Sarac S. **Efficacy of 904 nm gallium arsenide low level laser therapy in the management of chronic myofascial pain in the neck: a double-blind and randomize-controlled trial.** Lasers Surg Med. 2004; 35 (3): 229-235. Short-period application of LLLT is effective in pain relief and in the improvement of functional ability and quality of life in patients with myofascial pain.

19. Zati A, Fortuna D, Valent A, Pulvirenti F, Bilotta T W. **Treatment of low back pain caused by intervertebral disk displacement: comparison between high power laser, TENS and NSAIDs.** Medicina Dello Sport. 2004; 57 (1): 77-82 Higher power LLLT had better results than TENS and NSAIDs with longer duration from the laser effects.

20. Stergioulas A. **Low-level laser treatment can reduce edema in second degree ankle sprains.** Journal of Clinical Laser Medicine & Surgery. 2004; 22 (2): 125-128. RICE accompanied by LLLT presented a statistically significant edema reduction in ankle sprains.

21. Tascioglu F, Armagan O, Tabak U, Corapci I, Oner C. **Low power laser treatment in patients with knee osteoarthritis.** Swiss Medical Weekly. 2004; 134 (17-18:254-258. LLLT shows no effect on pain in patients with knee osteoarthritis.

22. Giuliani A, Fernandez M, Farinelli M, Baratto L et al. **Very low lwevel laser therapy attenuates edema and pain in experimental models.** Int J Tissue React. 2004; 26 (1-2): 29-37. LLLT reduced edema and induced analgesia in experimental plantar pain in rats and that LLLT increased the mRNA leveling single neurons.

24. Burduli N M, Aksenova I Z. **[Platelet aggregatory impairments in chronic obstructive bronchitis and a role of laser therapy in their correction].** Klin Med (Mosk). 2004;82(8):34-7.[Article in Russian] Intravenous blood laser irradiation is an effective technique in correcting thrombocytic dysfunction in chronic obstructive bronchitis.

25. Nussbaum E L, Lilge L, Mazzulli T. **Effects of low level laser therapy (LLLT of 810 nm upon in vitro growth of bacteria: relevance of irradiance and radiant exposure.** J Clin Laser Med Surg. 2003; 21 (5): 283-290. LLLT has immediate relevancy for infected wounds and could potentially benefit wounds infected with P. aeruginosa.

26. Lin Y S, Huang M H, Chai C Y, Yang R C. **Effects of helium-neon laser on levels of stress protein and arthritic histopathology in experimental osteoarthritis.** Am J Phys Med Rehabil. 2004;83 (10): 758-765.

The extragenic production of SP is well correlated with the therapeutic effect of LLLT in preserving chondrocyes and the repair of arthritic cartilage in rats.

27. Zalewska-Kaszubska J, Obzeta D. **Use of low-energy laser a s adjunct treatment of alcohol addiction**. Lasers Med Sci 2004;19 (2):100-104. Laser therapy may be useful as an adjunct treatment for alcoholism.

28. Wozniak P, Stachowiak G, Pieta-Dolinska A, Oszukowski P. **Laser acupuncture and low-calorie diet during visceral obesity therapy after menopause.** Acta Obset Gynecol Scand. 2003; 82 (1): 69-73. Laser acupuncture plus low-caloric diet shows significant results as a means of reducing body weight, body mass index and waist-to-hip ratio for women.

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34. Ng G Y, Fung D T, Leung M C, Guo X. **Comparison of single and multiple applications of GaAlAs laser on rat medical collateral ligament repair.** Lasers in Surgery and Medicine. 2004; 34 (3); 285-289. Multiple laser therapy improves the normalized strength and stiffness of repairing rat MCLs at 3 weeks after injury. Multiple treatments seem to be superior to a single treatment when the cumulative dosages are comparable between modes of application.

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Stadler I, Lanzafame R J, Oskoui P, Shang R Y, Coleman J, Whittaker M. **Alteration of skin temperature during low-level laser irradiation at 830 nm in a mouse model.** Photomedicine and Laser Surgery. 2004; 22 (3): 227-231. Smaall temperature increases at the surface were seen in white mice compared to black. Data suggests thermal effects of color should be considered, particularly at higher influences.

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cellular redox state, which plays a pivotal role in maintaining cellular activities, leads to photobiostimulative processes.

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ATTRIBUTION

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Reprints & Abstracts

Informed Consent

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The level and rapid growth of evidenced-based knowledge relating to chiropractic manipulative therapy is encouraging. Chiropractic orthopedists relate great difficulty in keeping up with the advances in his own profession especially with the problems of the era of managed care and assimilation of available information as it relates to medicolegal issues (e.g. negligence) as negligence is not the ONLY example of medicolegal issues).

There has been an astonishing rise in malpractice actions in the last thirty years which led to the refinement of informed consent. This doctrine enables the patient to receive compensation for complications of therapeutic or diagnostic procedures that have not been adequately disclosed to the patient before the procedure is performed. Even though the procedures have been performed in a non-negligent manner. (this is not a sentence JM) There

has been cases involving chiropractic diplomates based on failure to provide informed consent and a CCE college on their alleged failure to teach this doctrine.

In this age of consumer participation, patients want to be informed to a greater degree than in prior times. Medical negligence can be avoided if the chiropractic orthopedist realizes that it is the patient who accepts or refuses treatment. An orthopedist may accept or refuse to accept any patient and the doctor/patient relationship begins when the doctor renders services to the patient after their expressed or implied request for treatment.

Informed consent is the process by which fully informed patients can participate in choices about their health care. It originates from the legal and ethical right the patient has to direct what happens to their body and from the ethical duty of the chiropractic orthopedist to involve the patient in their health care.

What are the elements of full informed consent?

The most important goal of informed consent is that patients have an opportunity to be an informed participant in his health care decisions. It is generally accepted that complete informed consent includes a discussion of the following elements:

1. the nature of the decision/procedure
2. reasonable alternatives to the proposed intervention
3. the relevant risks, benefits, and uncertainties related to each alternative
4. assessment of patient understanding
5. the acceptance of the intervention by the patient

In order for the patient's consent to be valid, he must be considered competent to make the decision at hand and their consent must be voluntary. It is easy for coercive situations to arise in medicine or chiropractic. Patients often feel powerless and vulnerable. To encourage voluntariness, the chiropractic orthopedist can make clear to the patient that they are participating in a decision, not merely signing a form. With this understanding, the informed consent process should be seen as an invitation to them to participate in their health care decisions. The chiropractic orthopedist is also generally obligated to provide a recommendation and share their reasoning process with the patient. Comprehension on the part of the patient is equally as important as the information provided. Consequently, the discussion should be carried on in layperson's terms and the patient's understanding should be assessed along the way.

This doctrine has been an aspect of the chiropractic practice for quite some time. In a booklet entitled, "Chiropractic Physician's Guide to Clinical Malpractice" distributed by the National Chiropractic Mutual Insurance Company during 1983; informed consent is well outlined and a sample consent form is offered. Further investigation revealed informed consent as a policy of the ACA (adopted July 1975), discussed in the Basic Chiropractic Procedural Manual (1980), Basic Chiropractic Paraprofessional Manual (1978) and ICA malpractice alert (1982). This may be a rude awakening to you since many feel that we are not well versed in this doctrine during our chiropractic careers.

Any chiropractic orthopedist who renders professional services to a patient without having the patient's authority to do so can be charged with assault and battery. Any chiropractic orthopedist who administers treatment without a patient's consent, except in dire emergency, expressed or implied, is liable for damages.

How much information is considered "adequate"?

How do you know when you have said enough about a certain decision? Most of the literature and law in this area suggest one of three approaches:

1. Reasonable physician standard: what would a typical physician say about this intervention? This standard allows the physician to determine what information is appropriate to disclose. However, it is probably not enough, since most research in this area shows that the typical physician tells the patient very little. This standard is also generally considered inconsistent with the goals of informed consent as the focus is on the physician rather than on what the patient needs to know.

2. Reasonable patient standard: what would the average patient need to know in order to be an informed participant in the decision? This standard focuses on considering what a patient would need to know in order to understand the decision at hand.

3. Subjective standard: what would this patient need to know and understand in order to make an informed decision? This standard is the most challenging to incorporate into practice, since it requires tailoring information to each patient.

There are two rules that outline the standards of disclosure within a certain state:

A. The majority rule (reasonable physician standard) sets the standard of disclosure of risks as that which other chiropractic orthopedists practicing under similar circumstances will consider necessary to tell the patients. The standard must be established by expert testimony and is the traditional medical standard. Remember, if you hold a chiropractic diplomate, you will be judged as a specialist and not as general practitioner.

B. The minority rule (reasonable patient standard) is that a chiropractic orthopedist must give the patient material information necessary to enable him to make a decision. Expert testimony is not needed to establish a failure to perform to the level of that standard and is appropriate in at least fourteen states or jurisdictions. Those chiropractic orthopedists who are under minority rule should be aware that they are subject to a strict rule of risk disclosure.

Please do not be misled that the doctrine of informed consent does not apply to manipulative therapy or rationalize that the other health care professionals do not use informed consent (ie., when prescribing drugs). They must also abide by the statutes in their particular state in which they are licensed.

The best approach to the question of how much information is enough is one that meets both your professional obligation to provide the best care and respects the patient as a person with the right to a voice in health care decisions. Most states also have legal cases that determine the required standard for informed consent. We must emphasize that each chiropractic orthopedist must keep informed as to the laws and their interpretation in their particular state of practice. The following is an example of a review decision of a court of appeals case involving a chiropractic provider.

We have included a summary of a chiropractic malpractice case issued by the WI Supreme Court on June 29, 2005. The central issue is whether chiropractors have the same duty of informed consent as physicians.

Gary Hannemann v. Craig Boyson, D.C. 2003AP1527

On June 29, 2005, the Wisconsin Supreme Court issued its decision in the case of Hannemann v. Boyson, a chiropractic malpractice case. The Court held oral argument in the case on February 2, 2005. The key issue in this case is whether a chiropractor owes a duty of informed consent to chiropractic patients that is similar to the duty that physicians owe their patients. The Court concluded that chiropractors are obligated to inform their patients of the risks and benefits of chiropractic treatment, similar to the informed consent given by physicians to their patients.

Facts

Gary Hannemann received regular chiropractic adjustments from a chiropractor, Craig Boyson. On August 21, 1997, Boyson adjusted Hannemann's spine with a move that included a neck twist. Hannemann was in pain following the procedure and, the next day, one of his legs started to "act up." He called Boyson and went in for another adjustment. The following morning, Hannemann awoke to find that he was paralyzed on one side. A neurosurgeon determined that he had had a stroke, which left him permanently and significantly disabled.

Experts who testified during the trial gave different opinions about the cause of the stroke. Hannemann's expert witnesses attributed the stroke to the chiropractic adjustment while Boyson's expert witnesses testified that an earlier bout with meningitis was the cause of the stroke. The experts testified that there is a well-known relationship between chiropractic adjustments and neurovascular injuries including stroke. However, they disagreed on the size of the risk. Some experts estimate that injuries might occur in 55 out of 177 patients and others assert that one in 400,000 patients or even fewer might experience a neurovascular injury. At the start of the chiropractic relationship, Boyson explained the treatment and some of the risks associated with treatment. Hannemann signed a written consent form. However, the parties agree that Boyson never informed Hannemann that there was a risk of stroke associated with cervical spine adjustment. Boyson testified that he did not disclose the risk of neurovascular injury to patients because he did not believe that there was a definitive correlation between chiropractic adjustment and neurovascular injury and because "the risk of that is so astronomical that it wasn't a major factor."

Decision

The Court noted in its decision that the Wisconsin Administrative Code § Chir 11.02 requires that chiropractic records include documentation of the patient's informed consent or the consent of the parent in cases of a minor, for examination, diagnostic testing and treatment. The chiropractic rule does not impose any parameters on a chiropractor's duty to obtain informed consent, unlike Wis. Stat. § 448.30, which imposes specific requirements upon physicians. The Court gave a detailed discussion of a physician's duty of informed consent and concluded that the principles of informed consent developed for physicians should apply equally to chiropractors. The Court noted that chiropractic practice is separate and distinct from the practice of medicine, but chiropractors are health care providers involved in the diagnosis and treatment of patients.

The Court acknowledged that Wis. Stat. § 448.30 is a statute that applies specifically to physicians. However, the Court noted that § 448.30 embodies the common law (several court decisions) that requires physicians to inform patients about the availability of all alternate, viable medical modes of treatment and about the risks and benefits of those treatments. According to the Supreme Court, the common law applies to chiropractors. The Court stated:

We conclude that although the practice of chiropractic and the practice of medicine are distinct health care professions, the obligation of the practitioners of both to disclose the risks of the treatment and care they provide should be the same. While the actual disclosures will inevitably vary between doctors and chiropractors, the nature of the duty and limitations thereon should be the same. A patient of chiropractic has the same right as a patient of medical practice to be informed of the material risks of the proposed treatment or procedure so that he may make an informed decision whether to consent to the procedure or treatment. As such, we hold that the scope of a chiropractor's duty to obtain informed consent is the same as that of a medical doctor.

The Supreme Court concluded that the circuit court should have submitted a special verdict to the jury on the issue of informed consent. Because the circuit court's failure to give a special verdict on the issue of informed consent was a significant (prejudicial) error, the Supreme Court returned the case to the circuit court for a new trial.

Justice Butler issued a dissenting opinion. While he agreed with the other Court members about the duty of informed consent that a chiropractor owes to his patients, he disagreed that the error was prejudicial and requires a new trial.

We offer the following recommendations for consideration:

1. Please be advised that the legal liability of the chiropractic orthopedist and the standard by which his actions in informing the patient are significantly different depending upon the rule (majority or minority) followed in the state where he practices. It is the responsibility of the chiropractic orthopedist to inform the patient, in non-technical terms, of all anticipated practices and procedures and to receive the patient's informed consent prior to examination and therapeutic procedures. The patient should be informed of all significant potential consequences so that consent is given with full knowledge of any inherent dangers to which the patient may be exposed. The chiropractic orthopedist may not need to disclose (state dependent) all possible or remote risks or consequences of a procedure or treatment, however, this “good intention" may be most difficult to prove in court at a later date.

2. All chiropractic colleges should continue to teach the concept of informed consent on the undergraduate level and emphasize the concept within the confines of the college clinics and post-doctoral classes. Malpractice companies, national and state trade chiropractic organizations should participate in the educational process at the colleges (ie., formulate a state specific informed consent form) and advise the future and practicing practitioner of basic prevention and defensive procedures. This
would be of great benefit to all involved parties.

3. It is advisable to utilize an informed consent form in each chiropractic office (utilizing a form that states that the provider does not diagnose conditions does not release the provider from their legal obligation). No form is a satisfactory substitute for a personal discussion with the patient in securing a fully informed consent. Discussion and the patient's consent should be noted in the patient's record in the progress notes (risks, options and alternatives discussed). This procedure is not fool-proof because the patient may later deny it but it is better than the signed form itself.

4. The chiropractic profession should realize that manipulation has its indications, contraindications and risks as does any diagnostic or therapeutic procedure (remember what has happened to our colleagues in Canada). Please do an internet literature search or review the latest Turrett manuscript. You will see that there appears to be sufficient literature indicating possible risks with manipulation especially relating to the cervical spine. Remember these are only the cases that have been published. How many incidents have actually occurred?

It is always the individual chiropractic orthopedists prerogative as to how they should run their practice and deal with patients. The status of the doctrine of informed consent as it applies to the chiropractic profession has been identified and superficially discussed. The doctrine has opened an avenue of legal recovery allowing the patient to recover for injuries resulting from risks that were inadequately disclosed and may be not as a result of negligent medical performance. Considering how the doctrine of informed consent affects chiropractic orthopedists in their daily work; the implications are great. Informing the patient in the spirit of concern for his well-being and the appreciation and respect of his intelligence strengthens the doctor-patient relationship and leads to a greater respect and cooperation between the doctor and his patient.

Forensic Pearls

1. We are living in a generation when patients are well informed about health. It is not unusual to meet a patient who has done a literature search, scanned the internet, made their own provisional diagnosis and knows what they want from their chiropractor. Their understanding may be imperfect, they may have little knowledge of treatment options and outcome, but they already have some information and they want more.

2. They also want to be involved in making decisions about their management.

3. Patients believe that good information means "honest, unbiased, up-to-date" information about their illness, its likely outcome and the risk and benefits of different interventions. They want help to identity and secure their treatment preferences.

4. When uncertainty exists it should be discussed, not omitted or glossed over, and advice should be explicitly supported by the best available evidence.

5. It is hardly surprising that when this information is denied them, and when things go wrong, patients are inclined to sue. The most common cause for patient dissatisfaction is not clinical competency but communication, a failure to receive sufficient information about the manipulative procedure and its risks.

6. At the present time most chiropractors agree that prior to manipulation every patient must know the risks and benefits of the manipulative procedure (especially of the neck).
The College on Forensic Sciences (CFS; http://www.forensic-sciences.org), a subsidiary of the Council on Chiropractic Orthopedics (CCO), offers additional training in medicolegal issues (online at http://www.ChiroCredit.com). Their examining board (American Board of Forensic Professionals) extends advanced standing to those holding chiropractic diplomate status towards the forensic subspecialty DABFP). For additional information contact us at 770-740-1999 or go to their website at http://www.forensic-sciences.org

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Sleep More, Stay Slim
By Pete Bils

Here is proof that every once in a while, life hands us a break. Getting enough sleep each night – the ultimate luxury – can actually help maintain a trim waistline, according to a recent study conducted at the University of Chicago. Hearing this, you may feel like you just picked up the Monopoly Chance card: "Bank Error in Your Favor, Collect $200."

The study shows that sleep deprivation could contribute to overeating and weight gain. So, the next time you hear someone brag about pulling an all-nighter to impress the boss, remind yourself that an all-nighter would make it that much harder to shed those pesky extra pounds you've been meaning to lose. This latest discovery in the land of sleep research means that nobody should feel guilty when they make time for a good night's sleep.

Here is what this new study means and how you can avoid triggering sleep deprivation and weight gain.

Sleep Deprivation, Appetite Control
The hormone leptin communicates satiety or fullness to the brain. When your leptin levels are high, your brain knows you are satisfied or full. When leptin levels are low, your brain thinks the body needs nourishment. The

newly published study suggests that not sleeping long enough at night causes decreased levels of leptin. You feel hungry, regardless of whether the body actually needs more sustenance, according to Eve Van Cauter, Ph.D., professor and sleep researcher at the University of Chicago and member of the Sleep Advisory Board℠ at Select Comfort.

The study participants were restricted to four hours of sleep per night and their food intake and activity levels were strictly monitored. After only six nights of sleep deprivation they demonstrated a leptin decrease ranging from 19 to 26 percent. The participants with the greatest decrease in leptin reported feeling the most hungry and craved carbohydrate-rich foods. The participants with less significant leptin decreases reported being the least hungry.

The bottom line: If you aren't getting enough sleep, you will probably have a very difficult time controlling your appetite and will be at increased risk of overeating.

Avoiding Leptin-Triggered Overeating
The good news is that a well-balanced lifestyle is still your best bet for achieving and maintaining a healthy physique. Here are some tips to keep you on the right track.

- **Make Sleep A Priority**
  Get serious about dedicating eight hours a night to sleeping. Remind yourself that getting a good night's rest will help you control your appetite and prepare you for a productive day. Set a timer to remind yourself to prepare for bed if necessary.

  If you think your mattress is keeping you from sleeping well, investigate newer bedding technologies like The Sleep Number Bed by Select Comfort™, which can be adjusted at the touch of a button to an individual's preference for comfort, firmness and support. In clinical studies, test subjects reported back pain relief and improved sleep quality when sleeping on a SLEEP NUMBER® bed, compared to their own innerspring mattress.

- **Sharpen Your Time Management Skills**
  Find a time management technique that works for you and stick with it. By becoming more organized, you'll be less likely to have to sacrifice sleep or time at the gym in order to meet deadlines. If you need inspiration, purchase a new daily planner or ask colleagues what works for them.

  When things get busy at the office, resist the urge to call for pizza delivery and hunker down for an all-nighter. Instead, plan on spending an extra hour or two at the office each night for a week.

- **Cut Yourself Some Slack, Occasionally**
  Your office in-box will never be empty, and there will always be more dirty laundry to wash tomorrow. Don't let life overwhelm you. Create realistic standards for your life and make time for fun.

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Pete Bils is the chairperson of the Sleep Advisory Board at Select Comfort, the nation's leading bed retailer and creator of the Sleep Number® bed.

Photo caption: The Sleep Number Bed by Select Comfort™ can be adjusted at the touch of a button to an individual's preference for comfort, firmness and support. In clinical studies, test subjects reported back pain relief and improved sleep quality when sleeping on a Sleep Number® bed, compared to their own innerspring mattress.

Case History

A Metatarsal Occult Fracture Which Became An Insufficiency Fracture

Rick Corbett DC, F.C.C.R.(C), F.C.C.O.(C.)

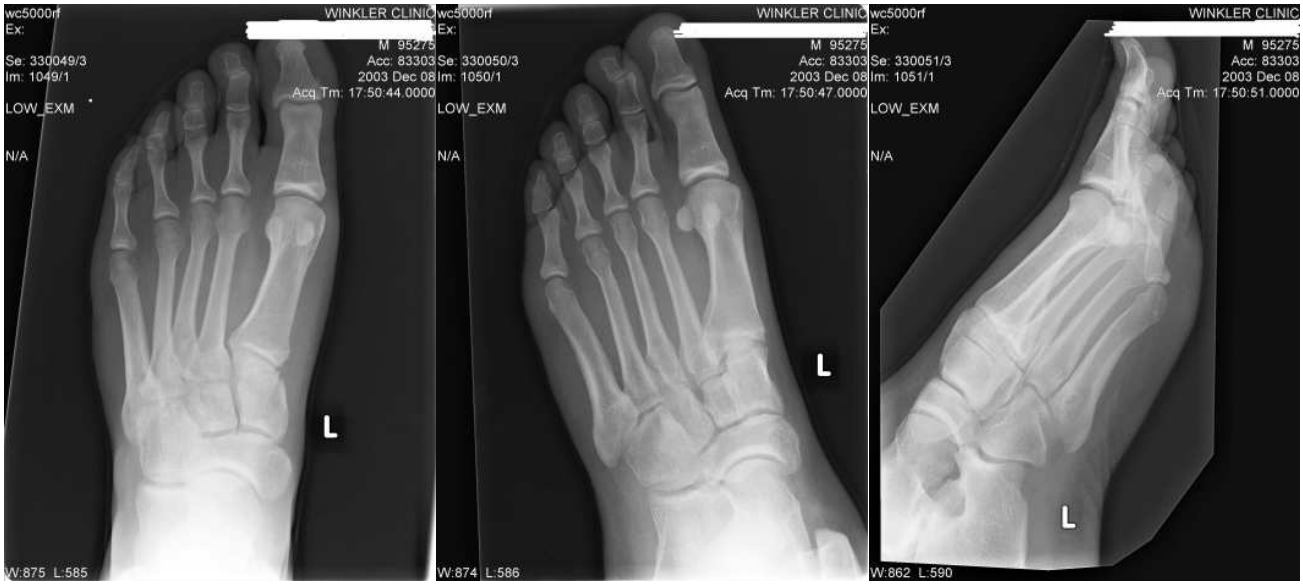
History

A 19 year old male presented with a chief complaint of foot pain.

He reported that he had been at work when he had dropped a pallet on his foot 2 days ago, and experienced immediate pain in his left foot over the 2nd and 3rd metatarsals.

Management 2 Days Ago

He presented to the local walk-in medical clinic, where 3 views were taken of his foot:
an A/P, an oblique and a lateral. See Image 1, 2, and 3.



Radiology Report

The films were read as negative for fracture, and in retrospect, I cannot see a fracture line.

2 Days later

The patient, reported that on leaving his house to go to work that morning, he had simply taken a normal walking step, and "felt something pop" in his foot. He reported that his foot pain was immediately worse.

Consultation

He located a "sore" feeling in his left foot dorsum.

He rated the pain as 7 out of 10 on a numerical rating scale

Interesting...

I asked him how bad the pain was compared to when he had dropped the pallet on his foot, and he stated "About the same: maybe a little less than today."

Aggravators

Weight bearing

Relievers
Diclofenac

Observation
The patient had a moderate limp on left weight bearing

Inspection
There was spongy inflammation over the dorsum of the left 2nd and 3rd metatarsals.

Palpation
There was moderate tenderness over the left foot dorsum at the left 2nd and 3rd metatarsals.

In particular, there was severe point tenderness over the diaphysis of the left 2nd metatarsal.

Impression
The findings were not inconsistent with a contusion, or a soft tissue crush injury.

Differential:
Sprain, strain. Could this be a fracture?

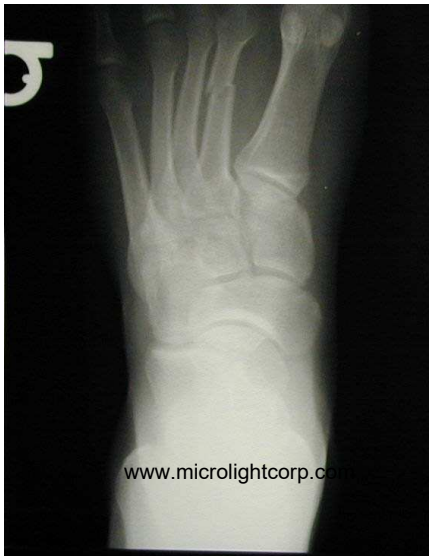
What to do?
Should we re-x-ray or not?

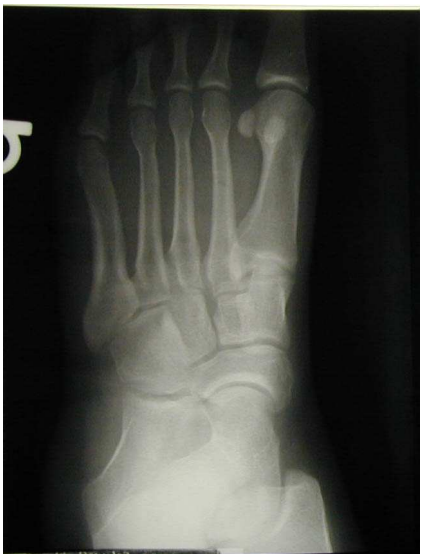
Arguments Against Re-X-Ray:
He just had films 2 days previously and there is no evidence of fracture on these films.
The patient has had no new significant trauma.

Arguments For Re-X-Ray:
- Spongy inflammation;
- Increase in severity of pain, although not a dramatic increase;
- Severe point tenderness;
- The patient "felt something pop".

Decision:
My gut feeling was that this was unusual. I elected to re-x-ray.

X-rays On Day of Re-injury
The A/P and oblique clearly showed that the patient now had a fracture at his left 2nd metatarsal





See Images 4 and 5.

Definitions
Occult Fracture:
Yochum and Rowe state "An occult fracture represents a special presentation whereby the fracture gives clinical signs of its presence without any radiological evidence."

Insufficiency Fracture (AKA Pathological Fracture)
Yochum and Rowe further define the insufficiency fracture **or** pathological fracture as
"a fracture through a bone which is weakened by a localized or systemic disease process."

Resnick states "Insufficiency fractures occur as a result of normal physiologic stresses on abnormal bones having deficient elastic resistance."

Both an Occult and Insufficiency Fracture
This fracture has characteristics of both an occult fracture and an insufficiency fracture.
In essence, we have an occult fracture which became an insufficiency fracture.

Lesson Learned
A reason to re-x-ray:
New trauma, with a "pop" sensation felt by the patient, an increase in pain severity, and severe point tenderness.

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Clinical Pearl

Review of the Literature

Current Events

Attribution
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