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Biologically Important Non-Linear Optics Crystal Substitute For Tibia Fracture: Healing Diagnosis.

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ABSTRACT

Fracture healing prediction in a various type of fracture is a challenging task in medical field due to irregular fracture shape and variation of patient's age level with blood glucose level. The need for an accurate and appropriate online model to predict such nonlinear fracture is on huge demand now days, to avoid repetition of x-ray and complications in patient's side. In this work focuses on the use of load cell as a diagnostic tool to non-invasively measure fracture healing which can be confirmed with radiographs taken alongside. A load cell was used for this study for measurement of limb parameter. With and without tibia fracture leg. It was found that the difference between injured and injured limb values decreased as the week progressed and the healing took place. A ratio between injured limb and the patient's weight was calculated and it was found that the maximum loading capacity was roughly 8 to 12% of the patient's body weight.

Keywords: fracture healing; load cell; injured limb; uninjured limb, Tibia

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INTRODUCTION

Fractures are common nowadays due to aggressive lifestyles. The treatment of fractures is usually based on radiographic findings. Studies have proved that radiographic findings lag behind in assessing mechanical stability. Though there are varieties of fracture stabilization methods available to doctors for internal fixation, the inability to directly monitor healing remains a limiting factor when assessing patient's recovery.

Standard radiographic assessment lacks the sensitivity to directly detect small changes in fracture healing. A bone fracture is a medical condition in which there is a partial or complete break in the continuity of the bone.

A bone fracture may be the result of high force impact or stress or a minimal trauma injury as a result of certain medical conditions that weaken the bones. Tibial fractures are the most common bone fractures (36.7% of all bone fractures). Burney, Fet.al has discussed different modes of healing like normal, slow, delayed, breakage and so on. As the healing progresses, the bone participates more and more in weight bearing of the system and the rod deforms less. Hence it was inferred that the loading ability of a limb increases as the healing takes place and the patient can load the circuit without any difficulty after the complete healing of the bone.

Kumaravel et al explains the drawbacks of current clinical methods in monitoring the fracture healing process. It states that X-rays are not fully reliable since interpretation is highly dependent on experience with relatively poor interobserver and intraobserver reliability and partly because of the lack of an accepted definition of a radiographic union. Other methods like ultrasound cause in-vitro cell organelle destruction in human fibroblast. Degradation of ultrasound from patient to patient is limitations to its diagnostic use.

This process called cavitation can cause mechanical damage to the tissue and can even cause ionization. The probe of ultrasound cannot be moved between Ilizarov rings. Methods like computed tomography (CT) and radio nucleotide scan are very expensive and also involve radiation. After knowing the shortcomings, the load cell device was fabricated to overcome all the drawbacks. Cost estimation was made for both the current clinical methods and for the load cell circuit. It was found out that the circuit which was a one-time investment was much cheaper compared to the current clinical methods.

Richardson J.B et.al has explained about the fracture stiffness and how measuring the stiffness can define the healing of tibial fractures. It was considered that a stiffness of 15 Nm/degree in the sagittal plane provides a useful definition of the union of tibial fractures. As the bone heals, the load transfers from fixator to callus. Hence with this understanding, the measurements were taken from patients considering that the pressure exerted by the patient increases as the week progresses as the healing takes place.

A hypothesis was formulated wherein the patient was expected to load his injured limb without any pain after the complete healing of the fracture. The value of the injured limb reading is supposed to be equal to the uninjured limb reading after the complete healing of fracture which can be confirmed with radiographs taken alongside.

Hunter Pelham et.al explains about complications due to early or late weight bearing after a tibia fracture. While premature weight bearing can increase the rate of complications, unnecessarily delaying weight bearing results in additional burdens on the healthcare system. Identification of post-operative complications (non-union, infection, implant loosening, etc.) throughout the recovery process, while critical to effective treatment, is often difficult with existing internal fixation methods.

Recently, initial studies have been carried out with a group of four tibia fracture cases with electric stimulation in the diagnostic side to monitor fracture healing (Kumaravel et al. 2009). This has been followed up with studies in an increased group size of 12 cases where authors have looked upon the current stabilization alone. When the current is stabilized, with the help of x-ray fracture healing was diagnosed (Kumaravel et al. 2012).

Since X-rays lack the sensitivity to detect small amounts of fracture movement to directly measure fracture healing, the load cell circuit devised helps to be an effective tool to monitor bone healing after removing external fixation and could provide an objective clinical measure to return to weight bearing. Hence during follow-ups, the patients were asked to load the device and the values were tabulated with which their stage of healing was determined. Load cell have been used for assessing fracture healing of closed leg bone fractures and compared with radiographs. This work includes fracture treated with different operation methods and assessed only by load cell method.

In this work loading of uninjured and the injured limbs are compared, the uninjured limb's maximum limit (control) is taken as the ideal end-point of fracture union. With the obtained value from the circuit, the stage of the fracture healing is found out. Knowing the stage of healing is necessary since early weight bearing leads to more complications like bone non-union. The delayed weight bearing leads to stiffness of the bone. This device is used to test only patients with fractures in legs. If both the legs are injured, this method cannot be implemented as a standard value is needed (uninjured limb) for reference

EXPERIMENTAL

Fig 1 shows the experimental setup to study the dynamics of the fracture healing process. A Honeywell load cell sensor was used to monitor the change in pressure. A system with suitable interface was connected to the load cell for measurement of force value in terms of voltage.



Figure 1: Hospital set-up for taking measurement.

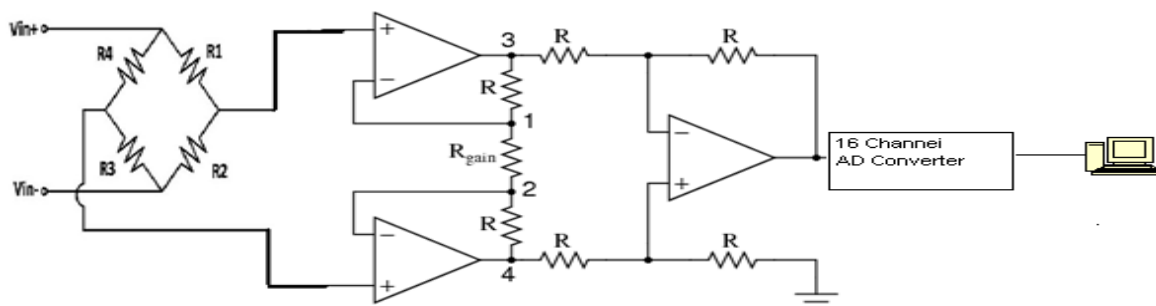


Figure 2: Wheatstone bridge configuration

Figure 2 shows the Wheatstone bridge configuration inside a load cell. An instrumentation amplifier is a special-purpose linear differential amplifier, used for the accurate amplification of the difference between two (often small) voltages, often in the presence of much larger common-mode voltage. The output of the instrumentation amplifier was connected to M/s AD Instrumentation 16 channel data acquisition card via., signal conditioning unit. The card was connected to the USB port of the Pentium processor with an in-built anti-aliasing filter. The card supports 16 ADC and DAC channels in the range of $\pm 15V$. Program was developed in 'C' language to read and display the patient's pressure force rating in terms of voltage. The graph was compared with the appearance of new bone formation in X-rays. The above methodology was carried upon twenty different patients at Thanjavur Government Medical College

to predict the exact instance at which a fracture has united completely. For all the twenty different patients same fracture healing pattern was obtained

RESULTS AND DISCUSSIONS

Fracture healing is an intricate process with most of the parameters unknown. In general, to Understanding of the physical process is the basis for making a decision on experimentation and statistical data collection, and the training of the data collected with appropriate machine learning makes the healing duration prediction close to the error free accuracy. In this work, based upon the analysis of tibia fracture healing, load cell model was developed and fracture healing prediction is demonstrated using, namely engineering approach for different difficult tibia fracture cases treated. The variation of pressure for an applied force in terms of voltage was measured and the response was plotted. The inference was validated with radiographs. The load cell device was tested with uninjured persons and their limb readings were noted(both left and right) along with their age, sex and weight it was shown in Table.1it was found that from the table 1 both the left and right side limb values were almost equal.

Table 1: loading ability of a limb

| S.No | Age | Sex | Weight | Limb Reading(Right leg)in KgF | Limb Reading (Left leg)in KgF |
|------|-----|-----|--------|-------------------------------|-------------------------------|
| 1 | 21 | F | 55 | 3.5 | 3.4 |
| 2 | 20 | F | 60 | 6.1 | 6.0 |
| 3 | 22 | F | 74 | 6.5 | 6.3 |
| 4 | 26 | M | 42 | 2.2 | 1.9 |
| 5 | 18 | M | 44 | 2.5 | 2.4 |
| 6 | 21 | F | 52 | 3.7 | 3.8 |
| 7 | 29 | F | 70 | 5.5 | 5.4 |
| 8 | 18 | M | 75 | 5.0 | 5.2 |
| 9 | 26 | F | 55 | 3.3 | 3.4 |
| 10 | 22 | F | 42 | 4.7 | 4.8 |

Table.2 shows the details of patients along with the case type and their loading values. Ratio between injured limb and the person’s body weight was found out. Even with different values of weight and age of person, it was possible to arrive to an average value of force which determines complete healing of the fracture. It varies from 8 to 12% of the body weight. It was found that even normal limb showed some element of fluctuation possibly due to difference in nutrition, fatigue ability, gain or loss of weight which in turn affects the loading capacity of normal limb. However since force of uninjured limb is taken as floating reference of union in case of every patient, there is no bias on basis of parameters such as sex, age and weight of the patient.

Table 2: Details of patients who underwent force measurement

| S.No | Case Type | Age | Sex | Weight (Kg) | Time in Weeks | Injured Limb loading(KgF) | Uninjured Limbloading(KgF) | Ratio(%) |
|------|------------------|-----|-----|-------------|---------------|---------------------------|----------------------------|----------|
| 1 | External Fixator | 13 | M | 40 | 1st | 1.6 | 4.4 | 11 |
| 2 | Tibia Nailing | 36 | M | 42 | 3rd | 3.4 | 4.8 | 11.42 |
| 3 | Tibia Nailing | 33 | M | 60 | 3rd | 4.5 | 5.2 | 8.6 |
| 4 | Ilizarov Ring | 62 | M | 58 | 4th | 3.1 | 4.8 | 8.2 |
| 5 | Tibia Plating | 10 | F | 25 | 4th | 1.5 | 2.8 | 11.2 |
| 6 | Tibia Nailing | 55 | M | 56 | 5th | 2.2 | 4.5 | 8.0 |
| 7 | Tibia Nailing | 44 | M | 59 | 1st | 2.2 | 4.9 | 8.3 |
| 8 | Tibia Nailing | 65 | F | 52 | 3rd | 2.9 | 4.3 | 8.2 |
| 9 | Ilizarov Ring | 49 | M | 55 | 1st | 1.6 | 4.2 | 8.1 |
| 10 | External Fixator | 76 | M | 39 | 1st | 1.2 | 3.5 | 8.9 |
| 11 | External Fixator | 40 | M | 35 | 2nd | 1.3 | 2.9 | 8.2 |
| 12 | Ilizarov Fixator | 60 | F | 49 | 3rd | 2.1 | 4.5 | 9.1 |

| | | | | | | | | |
|----|------------------|----|---|----|-----|-----|-----|------|
| 13 | Tibia Nailing | 50 | F | 51 | 4th | 1.9 | 4.6 | 9.0 |
| 14 | External Fixator | 10 | F | 26 | 5th | 1.5 | 2.8 | 10.7 |
| 15 | External Fixator | 35 | F | 36 | 3rd | 1.6 | 4.0 | 11.1 |

Each time the patients came for follow up, both the limbs were loaded as already explained and the values were tabulated for 3rd,5th and 8th week. Weekly variation of values can be seen in patients and it varies from patient to patient.

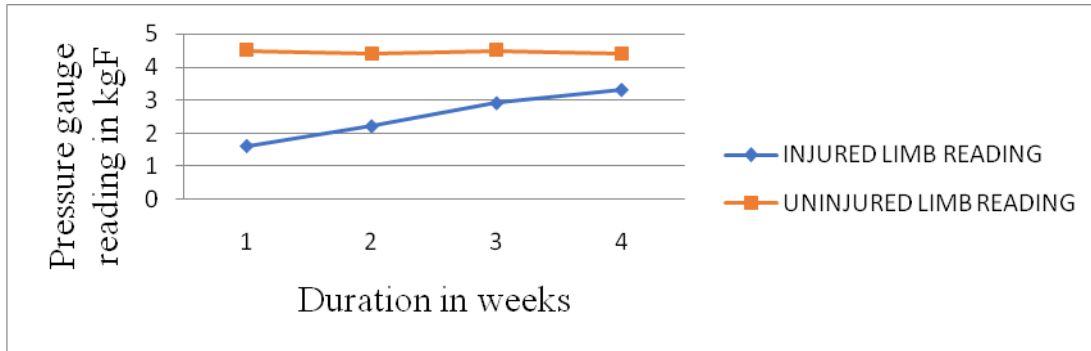


Figure 3: Graph of patient 1

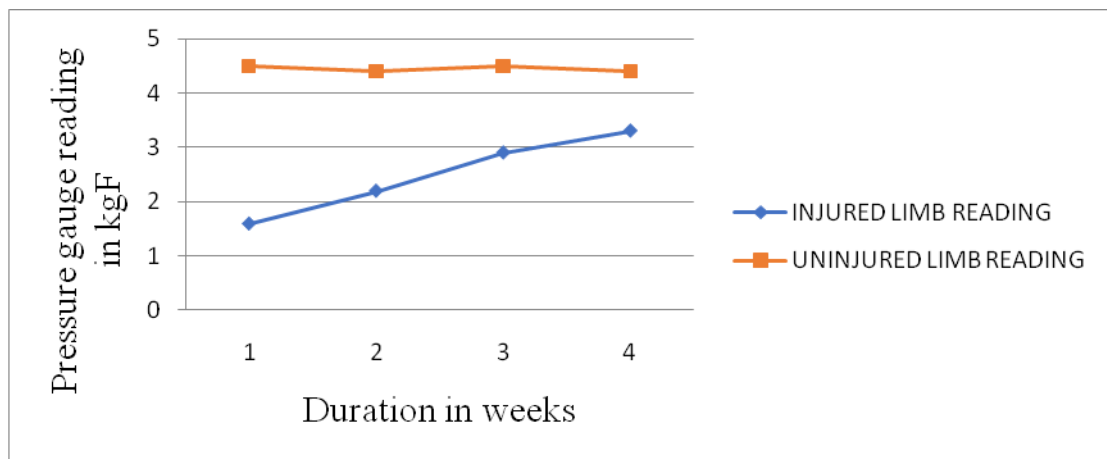


Figure 4: Graph of patient 7

DIABETIC PATIENT VS NON-DIABETIC PATIENT

On comparing the graphs of diabetic patient (patient 9) and a non-diabetic patient, it is found that the healing takes place slower in a diabetic patient as compared to a non-diabetic patient. In the case of a non-diabetic patient, both injured and uninjured limb values became equal towards the end of 8th week. Healing was slower in a diabetic patient and hence the curves of injured and uninjured limb reading did not merge at the end of 8th week.

Table 3: Load Cell reading of diabetic patient (patient 9)

| Week of treatment | Injured limb reading in KgF | Uninjured limb reading in KgF |
|-------------------|-----------------------------|-------------------------------|
| 1 | 1.6 | 4.5 |
| 3 | 2.2 | 4.4 |
| 5 | 2.9 | 4.5 |
| 8 | 3.5 | 4.4 |

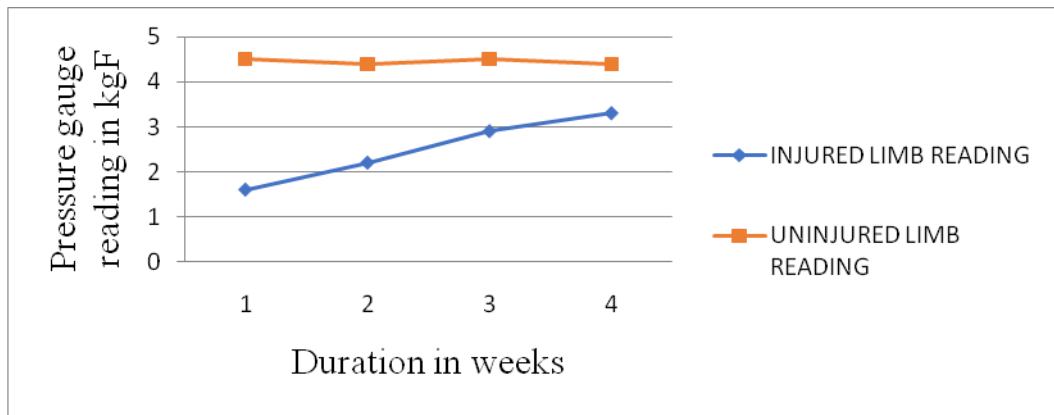


Figure 5: Graph showing values of injured and uninjured limb for a diabetic patient

CONCLUSIONS

The hypothesis was that the load cell reading of injured and uninjured limbs becomes equal after the complete healing of the bone. Hence the hypothesis was proved since the uninjured limb reading became equal to injured limb reading after complete healing of the bone which matched the fracture union in the radiography taken. In other words, when load cell readings of injured and uninjured limbs were plotted, merging or new callus formation can be seen in X-rays. In this work, normal limb was used as a control. It was found that even normal limb showed some element of fluctuation possibly due to difference in nutrition, fatigue ability, gain or loss of weight which affects the loading capacity of normal limb. However, the uninjured limb was taken as floating reference of union in case of every patient. This ensured that there were no bias on the basis of parameters such as sex, age and weight of the patient. Values for both the diabetic and non-diabetic patients were taken and it was found that the healing is slower in a diabetic patient as compared to the non-diabetic patients. On comparing the normal and injured side, it was found that 8 to 12% of individual's body weight was a consistent threshold value of ability to apply vertical force on the fractured limb. Since there are adverse effects due to radiography, this method can be used to reduce the effects and can be taken as a good control in future.

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