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NON-INVASIVE DETERMINATION OF TIBIA FRACTURE HEALING USING LOAD CELL

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ABSTRACT

Background: Radiographs are normally used to assess union of fractures. The current study focuses on use of load cell assessment as a diagnostic tool to non-invasively assess fracture healing and new bone formation in closed tibia fractures managed conservatively which can be confirmed with radiographs taken alongside.

Material and Methods: In a pilot study 15 closed fractures of tibia treated with functional cast bracing plaster were evaluated. Their healing was followed with clinical assessment and periodical radiographs till the endpoint of fracture union and then the functional cast bracing was removed. Besides, all these cases also had load cell assessment. The load cell assessment is done for the uninjured limb also. The readings of the injured and uninjured were plotted as a graph for the entire period of fracture treatment and their characteristics were studied. These graphs of the fractured and uninjured limbs were compared with the appearance of new bone at the fracture site in the radiographs.

Results: except 2 cases which were lost for follow up in all other cases, when the loading curves of the injured and uninjured limbs are merging, the radiographs showed healing (bridging callus) matching the graph and the patient was able to comfortably load the limb. The day of this merging was different for individual cases. All available patients had fracture healing at the fixed period of 12 weeks and were allowed full weight bearing without braces.

Conclusion: In this non invasive method, if the loading curves of the injured and uninjured limbs are merging, we can predict that the fracture tissue had strengthened. This matched the patients' ability to painlessly load the fractured limb .The radiographs also showed bridging callus. The maximum loading capacity was roughly 15 % of his body weight. If this is used as a parameter for fracture healing assessment in future, then the need for radiographs and resultant radiation will be less.

Keywords: load- cell, conservative, normal limb, comparison, fracture healing, radiographs

INTRODUCTION

Traditionally the stability or union at the fracture site is assessed by the clinical methods and is correlated with periodical radiographs of the fractured limb. Fractures take a long time to heal hence more number of radiographs are needed. They can depress the bone marrow cell production and can even cause leukemia.[1-3] The reliability of the radiographs are poor as there is no specific definition of a fracture union and has relatively poor inter observer and intra observer reliability.[4,5] Also quantitative radiologic assessment of healing is difficult because varying patterns of bone bridging can occur, including periosteal, endosteal, and inter-cortical patterns. [6] These radiographic findings lag behind mechanically [4] If ultrasound is used for the assessment of fracture healing, cavitations and also even ionization are problems [7,8,9] Quantitative computed tomography (QCT) and radio-nucleotide scans also involve radiation.[10-13]

As such fractures need not always be operated including the closed segmental fractures. After the initial pain is over immediate loading of the tibia bone fracture with suitable splints, is found to produce new bone. In this method the final shortening and angulations observed in most of the fractures are minor deviations from the normal.[14] we must optimise the fracture healing milieu than looking at mechanical integrity alone**.**[15.] In this aspect longitudinal loading in plaster is good condition to heal a tibia fracture and causes no translational shear on the fracture.

So to assess the fracture healing other non-invasive methods of fracture analysis need to be developed taking advantage of the early loading if the fracture as seen above.. In an animal study bending stiffness of fractures were compared with optical densitometry [16]

Other authors had studied bending stiffness in humans [4,6,17.] In one of these studies non union, delayed union and union are defined as amount of pressure that can be exerted by the fractured limb. [6] These studies are correct by principle but anthropometrically cannot be applied to all [18]. Also, there is no comparison with normal limb in the above studies. Our hypothesis was that when loading of limbs are compared, the counterpart uninjured limb's maximum limit (control) and can be taken as the ideal end-point of fracture union. As tibia is a commonly injured bone that can be controlled in plaster and can be loaded when the initial pain of the fracture settled, it was chosen. This is also because closed un-displaced or minimally displaced fractures are also expected to unite conservatively.

The basis of this study is that the force applying capability of patients can be empirically related to the stage of fracture healing. It aims to prospectively analyze the range of pressures in the tibia bone fracture patients as measured by the load cell during the treatment period and hence to assess the fracture union. The loading ability of the fractured limb is also compared with the uninjured side limb. The aim was to find if regular load cell assessment during the treatment period of tibial (leg bone) fractures can be used as a tool to study fracture healing. This can be verified with radiographs taken side by side.

METHODOLOGY

A pilot clinical study was done in the department of orthopaedics in a government medical college after ethical committee clearance. Fifteen patients (12 men and 3 women in the age group of 18 to 65 years) with closed fractures of middle third of the leg in acceptable position were included in the study. They were injured in different vehicular accidents. Most of their fractures were radiographically stable. Their blood parameters including their blood sugar taken after food, were normal. All patients were explained and they consented for treatment with plaster and consequent weight bearing and also for testing their fractured limb with load cell.

On the day of injury, after confirmation with radiographs, the patient's fractured lower limb was placed in a well padded plaster of Paris slab from the toes to above knee. After this, radiographs were taken to establish the position of fracture fragments. For pain relief drug like oral Paracetamol tablets were given from the third day onwards. Patient is discharged from the hospital after two weeks. After four weeks when the patient comes for follow up, when the swelling settled an another plaster cast is applied from the knee cap to the toes allowing flexion of the knee and loading of the knee, patella tendon bearing plaster application, before being taken up for this study. They were asked to put weight on their injured limb and asked to load the load cell and included in the study. The reading of the pressure gauge directly gives the reading as KgF. In all these cases, the fracture union was assessed clinically and also with radiographs taken periodically till the fracture union. After this, the immobilization was removed. Besides the fractured limbs, normal side lower limb of all these cases were tested in the same manner using the load cell for comparison.

We excluded if both side legs were fractured, as there is no control; if same side thigh bone fracture as the loading is affected; if operated s plate and screws will affect loading across the fracture; fractures in polio limbs or if the other limb had poliomyelitis as the loading is affected or cannot be compared; spinal injury or pelvic injury patients as they could not sit for loading of the fracture; open fractures as the intra-cavitary pressure will be less also plaster treatment is not advisable for them; fractures of tibia in unacceptable positions like gross overriding as the final union will not be as expected; fractures of upper shaft and lower shafts as it would be difficult to control them in a plaster.

Designing the load cell device

The hardware developed to be programmable capabilities and real-time debugging. The mount on which the load cell is fixed was made from L-angle mild steel bar, 6 mm thick, 45mm wide and 1.5 meter long. (Figure 1) This bar was cut into four equal sections (cross ends) and welded to create the load cell mount. (Figure 2). Holes of 9mm threads were drilled on the mount and a load cell-CZL

601-(figure 3) (Green lable with 40 kg loading capacity .Guangdong South China Sea Electronics) was fastened using mild steel bolts of 6 mm diameter. (figure 4) Exactly over this load cell on its load application point, a square shaped force- application surface made up of plywood -perfectly matching the metallic mount dimensions was attached (figure 5). A full bridge Wheatstone configuration inside the load cell gives maximum sensitivity for its output. The lead wires of this load cell are connected with circuitry consists of two individual components – the amplifier circuit (Fig 6) and the arduino uno controller.(Fig 7)(Arduino. Italy) which was programmed. (simple programme is provided in appendix 1) The amplifier circuit was built from scratch on a general circuit board. Amplification is based on non-inverting common mode design. Differential mode amplification was avoided to reduce error signal amplification which was observed in the latter. The circuit is based on utilizing one amplifier available from the four, present in LM324 IC. (Texas Instruments Incorporated) Amplification factor of 300 is attained with resistances 300 kilo Ohms and 1 kilo Ohm. We had difficulty in designing such a circuit, operating on very low input voltages. This was countered by utilizing optimal value grounded resistors. The amplified signals from the amplifier circuit reach the analog pin A2 of the arduino controller (figure 7). Analog to digital conversion happens inside the microcontroller, after which, values are digitally displayed in the LCD module (Fig 8). Robot -electronics.co.UK The digital voltage values generated by the Analogue to Digital Converter (ADC) in the microcontroller, are mapped to their corresponding force values. This mapping has been possible after analyzing the threshold sensitivity and careful calibration of the load cell circuit. The major advantage of using an arduino-LCD combined module is that live monitoring of all parameters is possible, which makes debugging easier and faster.

When the patient loads the load cell, a change in pressure occurs which is sent as an output from the load cell as a small current through the wire leads and given as inputs to the amplifier circuit. The output from amplifier circuit is given as analog input to the arduino controller. Analog to digital conversion, followed by voltage-force mapping occurs in the arduino controller and final force values are displayed in real-time in the LCD module. The working is described in detail in the figure 9 and its legend. The exact arrangement is as shown in figure 10

Device employment in hospital

The criteria for selecting patients were already discussed. During the first visit the patient's height, blood pressure and blood sugar were recorded. During every visit the patient's weight is recorded in a weighing scale while still supported on a walker. These are tabulated in the table 1. Now the patient is asked to sit erect on a chair with arms resting on the arm-rest of the chair and to put his foot of uninjured limb on the gauge and load the load cell vertically with a standard predetermined 90 degrees flexion of knee for 5 seconds. Figure 11. Their hands should never rest on or press on the thighs, indirectly assisting the loading they should not stoop forward to observe the reading on the gauge out of anxiety. Before loading the reading in the LCD screen is adjusted to zero to adjust the sheer weight of the limb, before the patient is asked to press the cell. Now with the reading is adjusted at zero, the patient is asked sit erect on the chair and to push as hard as he can on his foot exert full pressure on the load cell force plate for 5 seconds with his knee bent to 90 degrees. The output of the load cell goes into the microcontroller as a small current, gets processed and is fed into the LCD display as shown in Figure 10. The same was repeated for the injured limb after negating the weight of the plaster the resultant reading was measured (Figure12). Thus for all the cases the loading cell reading were measured for both the injured and uninjured limbs. The total time taken to record current output for a single patient was 10 minutes. The load cell reading was done when the patient came for weekly follow-ups. The amount of load that is exerted by the patient in both the normal limb for comparison and their fractured limb were noted(figure 11 and 12) and was plotted as two graphs (, i.e. for the injured and the uninjured limb) for the period of fracture treatment and their characteristics were studied. During every visit the power of loading of the injured limb and the uninjured limb were measured. Initially, in 4 cases an anteroposterior and a lateral radiographs were taken to establish the position of the fracture fragments and repeat radiographs taken every 2 weeks. Later, when it was seen that the reading of the injured side limb became equal to the uninjured limb matched the fracture union in the radiographic studies, in our other cases, we took radiographs after the load cell reading of the injured side limb became equal to the uninjured limb to substantiate the fracture healing. The loads exerted by the patient in the fractured limb during the days of treatment graph were compared with the appearance of new bone in the radiographs, which is the standard reference tool at present. All 15 patients were there till the end point of the study i.e. fractures union and had all the radiographs and could be compared with the loading graphs. There was no discomfort while the patients loaded on the load cell.

RESULTS

Two of the cases were lost for follw up. In all the available 13 cases, when the fracture limb loading-reading was nearing that of the uninjured limb loading, the radiographs also showed healing. (In these cases studied, the loading fluctuated during the healing phase and became stable when the fracture was healed.) The result of measurement of force applying capability of different cases is presented in table 1..Comparing the measurements of the force bearing capability of different patients were being made .Even with the different values of weight and age of the person, it was possible to arrive at an average value of force which would determine complete healing of the fracture. It is more than 15% of the body weight. Actual values can vary between individuals. However in our study force of the uninjured limb is taken as the floating reference of union in case of every patient. This could ensure that there was no bias on the basis of parameters such as age and weight of the patient.

Data from a typical patient is illustrated in the above [Table 2] figure and his loading reading is put as graph in figure 13. He had a load cell reading on the fourth week to find the starting reading. Then on weekly recordings were done for him up to 12 weeks. Each time the patient presented himself for review, both his limb were loaded as already described and readings was taken, i.e. at 8^{th}, 10th and 12^{th} week and was compared with radiographs taken during these visits. Weekly variation in loading force for this patient is seen in figure 12. But at 12 weeks, the readings of the injured and uninjured limb were same and the plaster of this patient was removed. The radiographs of this patient are presented serially alongside the expanded graphs in figure 14. Clinical examination and radiographs also showed this fracture has started to unite after 12 weeks. The figure shows the merging of the loading reading of the injured limb and the uninjured limb matched the healing process as evidenced by new bone formation in the radiographs. Comparable results were obtained for fractures which were subjected to load cell evaluation. The day of union differed based on the nature of fracture, but were confirmed with radiographs. Figure 15 shows the same patient's radiograph after the removal of plaster splintage and shows the healing of the fracture.

The routine use of radiographs is done nowadays to look for healing, and if necessary to intervene. For all the cases, the radiographs were taken every 2 weeks. We observed in this study that the loading cell readings of the injured and uninjured limbs merged when the fracture healed and hence we changed the protocol. For later 4 cases, final radiographs were obtained only when the loading curves of the injured and uninjured limbs merged in the graphs and Radiographs were later taken to confirm the healing.

Table 1: Details of patient who underwent force measurements

S. No	Age in years	Sex	Blood sugar level in mg/dl	Body weight	4th week of treatment		12th week of treatment		Ratio between the injured side loading and the body weight
					injured side loading in KgF	Un injured side loading in KgF	injured side loading in KgF	Un injured side loading in KgF	
1	18	M	90mg/dl	48kg	4	13.5	13.2	13.4	27.55%
2	40	M	120mg/dl	49kg	6.5	13.4	13.2	13.4	27.33%
3	60	F	136mg/dl	50kg	4	9.4	8.4	9.4	16.80%
4	60	F	121mg/dl	34KG	2.8	6	lost for follow up	lost for follow up	lost for follow up
5	42	M	114mg/dl	43.2KG	2	6.5	lost for follow up	lost for follow up	lost for follow up
6	29	M	86mg/dl	75kg	8.6	10.8	11.2	11.1	14.90%
7	57	F	96mg/dl	68kg	9.6	13.9	14.4	14.9	21.10%
8	38	M	70mg/dl	70kg	8.5	11.1	10.5	10.8	15%
9	47	M	105mg/dl	68kg	7.6	10.2	9.6	9.9	14.11%
10	63	M	110mg/dl	58kg	6.2	9.4	8.7	9.2	15%
11	56	M	100mg/dl	78kg	8.1	12.5	12.5	12.6	16%
12	43	M	120mg/dl	69kg	8.5	12.4	11.8	12.1	17%
13	62	M	140mg/dl	73kg	8.1	11.4	11.6	11.8	16%
14	46	M	130mg/dl	76kg	7.3	11.1	10.7	11.2	14%
15	32	M	118mg/dl	84kg	8.5	13.5	13.5	13.8	16%

Table 2: Load cell reading of the injured and uninjured lower limbs as the days proceeded for patient 1

Week of treatment	Injured side limb reading in KgF	Uninjured side limb reading in KgF
4	8.3	10.4
5	10.2	12.2
6	10.8	12.3
7	11.1	11.9
8	12.8	13.1
9	12.2	12.8
10	12.7	13.1
11	12.8	12.9
12	13.2	13.2

Figure 1: L-Angle bars after saw cutting

Figure 2: Load Cell Mount

Figure 3: Single point load cantilever type load cell. 9-12 V input range battery

Figure 4: The load cell being fixed on the steel mount.

Figure 5: A rectangular plywood is placed on the load cell and the above are separated using nuts and spiral washers to permit even loading of approximately 40kg load was applied only on a single point without damaging the crystal inside the load cell thereby not affecting the readings

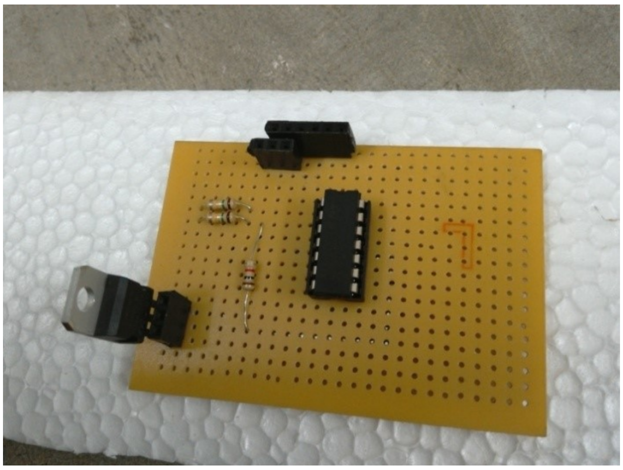

Figure 6: Amplifier Circuit

Figure.7: Arduino Controller Board was chosen as it can integrate the display and signal processing into a single unit, and make the complete force gauge less complex in circuitry.

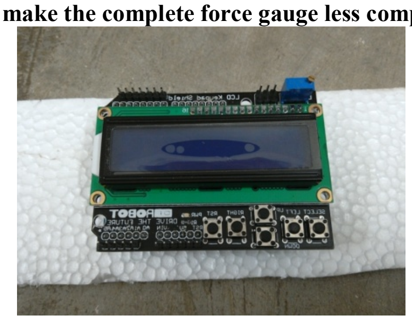

Figure 8: LCD 1602 Module

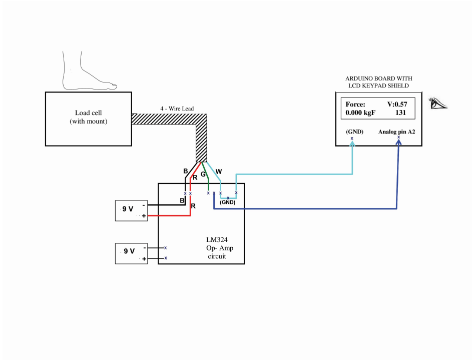

Figure 9: Experimental setup of the assembly of the loading cell its electric source and the display .A 4 wire lead attached to load cell with wires marked black, red, green and white. A 9V battery provides power through the black (-) and red (+) wires. The green (+) and white (-) wires carry the output of the load cell. They are given as input to the amplifier circuit (pins 3 and 11 of the microcontroller. The amplifier circuit is driven by another 9V battery regulated by a 7805 voltage regulator (5V). This arduino board with LCD keypad shield is powered by a separate 5V USB power supply

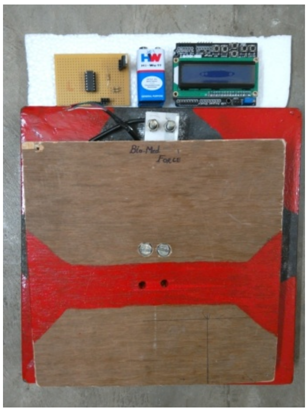

Figure 10: The arrangement used is shown complete with the loading surface , circuitry, power sources and display

Figure 11: A patient having closed fracture of tibia treated with a PTB plaster is allowed to load the normal limb for comparison. The arms are resting on the arm chair.

Figure 12: the same patient shown in figure 11 is allowed to load the load cell with his limb treated in plaster with care not to exert any extra load. The arm is resting on the arm chair. The other limb is not on ground

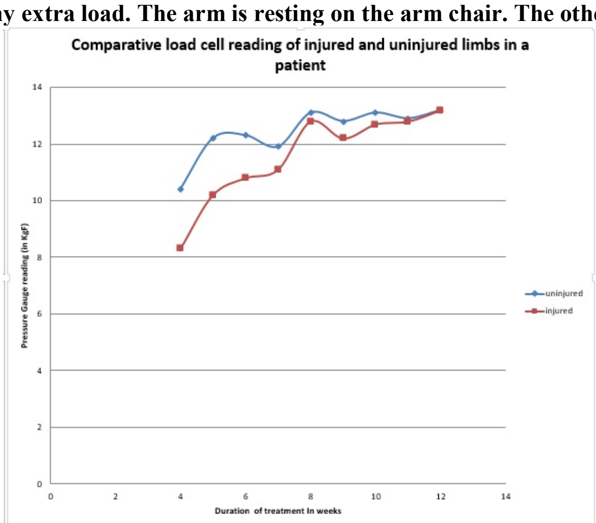

Figure 13: Reading of the load cell when the injured and uninjured limbs were loaded versus days curve for patient 1

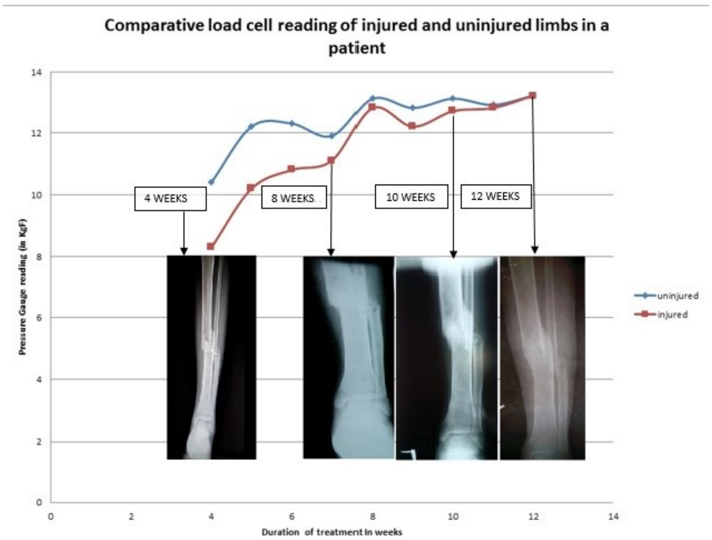

Figure 14: Progressive radiographs with the number of weeks of patient 1 with the exact period marked with a pointing arrow

Figure 15: The same patient's radiograph (Antero Posterior and lateral views) after the removal of the plaster. The site of fracture is completely united

DISCUSSION

Even though there are adverse effects of radiographs by exposure, there has been no non-invasive method to largely replace the former. To quantize the level of fracture healing, in this clinical non-invasive method .an indigenously developed force gauge was used to measure the ability of tibial fracture patients to apply force on their limb for fracture union analysis. Though this method needs further development, on the logical stand, this method stands correct in respect of developing a technique to quantitatively measure the level of fracture union. Routine clinical method by attempted shear between fractured fragments will affect healing during early period of fracture healing. In our study we have used data from pressure gauge reading with the radiographic methods. Studies had assesses bending stiffness of during the period of healing of the fractured limb only. [4,6,17] But we have compared the uninjured limb in the same patient along with fractured limb. This can be taken as a good control in future. In this study, fractures can present in different age groups , the pattern of load cell output stabilization as far as the present set of patients was the same. In regular weighing scales the loading plate is larger ; pressure is given in two places; even a small error will get magnified and create erroneous sounds ; an error of 3 kg goes even without pressing in such scales; precision of two decimals cannot be achieved.

In these cases as such pain in the fractured limb is expected to lessen as the fracture heals.

In this study, the normal limb is used as a control. During the course of treatment it is normally expected that as such the loading capacity of a normal limb must not vary. But we felt that, 1. there may be a difference in nutrition of the patient like him gaining or losing weight during the course of the treatment and 2. there can also be fatigue in the patient which is related to the time of the day when the loading is done. Both of these will affect the loading force. So only we have compared the normal side limb throughout the study period.

Though internal fixation is a procedure of choice for patients with multiple ipsilateral fractures, segmental fractures and fractures with comminution, patients with single, closed fracture of tibial shaft with good alignment with minimal or no displacement can be treated conservatively. We have included such cases. In such cases, this method can be useful.

SUMMARY

In an outpatient set up with non invasive load sensing method, comparing the normal and uninjured side, it was found that more than 15 percent of individual's body weight was a consistent threshold value of ability to apply vertical force on the fractured limb in our patients and it indicated leg bone union in radiographs also.

The scope for future study is to improve the threshold value by considering a large number of cases that include different types of fracture and pattern of injury.

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Annexure 1

ARDUINO PROGRAM CODE

```
#include<LiquidCrystal.h>
LiquidCrystal lcd(8,9,4,5,6,7);
int potPin = 2,setval=0,val=0;
float fixV=0.00,curV=0.00,a,b,c,d,h;
long int e,f,g;

void setup()
{
 lcd.begin(16,2);
 lcd.print("Force:");
 setval=analogRead(potPin);
 a=setval*5;
 b=a/1023;
 e=b*1000;
 lcd.setCursor(12,0);
 lcd.print(b);
 lcd.setCursor(10,0);
 lcd.print("V:");
}

void loop()
{
 val= analogRead(potPin);
 c=val*5;
 d=c/1023;
 f=d*1000;

 {
  g=f-e;
  h=g/12;
  h=h/10;
 lcd.setCursor(0,1);
 lcd.print(h);
 lcd.setCursor(5,1);
 lcd.print("kgF");
 lcd.setCursor(12,1);
 lcd.print(val);
 }
}
```

The arduino programme code