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THE USE OF ELECTRIC STIMULATION AS A DIAGNOSTIC TOOL TO ASSESS FRACTURE HEALING AND NEW BONE FORMATION

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ABSTRACT

Repeated x-rays are required to confirm healing of fractures. Clinical assessment is also difficult in patients treated with Ilizaro rings. Electrical stimulation was earlier tried to speed the fracture union whereas it has not been tried as a method to diagnose healing of fracture. In this study we have tried electric stimulation as a method to monitor fracture healing. There is a comparative group followed with traditional method of x-rays and clinical assessment only.

Keywords: *Electrical Stimulation, Direct Current (DC), Fracture Healing, Monitoring, Radiation Hazard.*

1. INTRODUCTION

Ilizaro ring is a versatile device helping in managing complex bone problems. It is particularly useful in the treatment of open fractures. Generally in fractures treated by this method the healing is followed with x-rays and clinical assessment only. Though it is obvious that x-rays involve repeated radiation [1,2,3,4] some authors felt that it is not reliable also.[5,6]In this set up DEXA [Dual Energy X-ray Absorptiometry]and CT [Computerized Tomography]cannot be used continuously because of artifact production and radiation.[7,8,9,10]Ultrasound probe also cannot be used around the rings and if used over immature bone it can cause thermal effects, cavitations , and can even ionize. [11,12,13,14]

To accelerate fracture healing (in a curative aspect) fractures in animal and humans have been treated with electric stimulation and pulsed capacitatively coupled electric field. [15, 16,17,18,19]

We have earlier studied the diagnostic assessment of fracture healing by electric stimulation method using carbon ring fixator. [20,21,22,23].

Present study differs from our previous works in that this compares the time spent in Ilizaro ring by patients who were followed up with electrical conduction method and statistically analyses the results.

2. RESEARCH AIM

To find the time spent in Ilizaro ring if fractures are assessed by electrical stimulation method along with x-rays and clinical method than only with x-rays and clinical method.

3. METHODOLOGY

A prospective clinical case control study was done with a total of 12 tibial fracture cases. We included open fractures or bone defects of tibia of both sexes from fifteen to seventy years, with normal distal blood circulation. We excluded from the study closed fractures of tibia, those associated with fractures of femur, those which were treated with plate or nail [internal fixation], or coupled with arterial injury. These cases were divided into two groups of 6. In each patient of the both the groups the fractures were debrided and fixed with Ilizaro external fixator made up of carbon non conducting material in first group and with Ilizaro external fixator made up of
stainless steel in the second group . Tibia was chosen as it was one of the common bones to get fractured. It is obvious that in Ilizaro methodology

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of fracture fixation if carbon rings were used, there will be no conducting material across the fracture and electrical conduction across the fractured limb can be measured.

In the 1st group of 6 cases the fracture was fixed with carbon ring assembly and stainless steel K wires passed into the bone fragments above and below the fracture. In all these patients at the start, to verify the location of fracture fragments and wires, x-rays were taken. Direct Current voltage of 0.1V to 1.0V was applied between the wires on either side of the fracture from a small DC generator and resultant current was recorded as healing proceeded. The line diagram of the circuit used is seen in figure 1. The Carbon rings were manufactured by SSEPL® Sharma Surgical and Engineering corporation Private Limited,646,GIDC,Waghodia,Baroda,Gujarat– India 391760The Direct Current voltage generator , Scientech ® model ST4073 was manufactured by Scientech technologies private limited Indore - 452010 India. The direct current ammeter model DPM 04 was manufactured by EIC meters private limited, Bangalore 560062 India .A graph was constructed with current in y axis and number of treatment days in x axis. During this period simultaneously taken x-rays were studied for fracture healing and new bone formation and were compared with the conduction characteristics of the fracture cases. A patient of this group is shown in figure 2 and is illustrated below.

In the 2nd group there were 6 similar cases of fracture and bone defects but treated with stainless steel Ilizaro ring fixators and were followed up with x-rays and clinical methods only. These Stainless Steel rings were manufactured by Advance Ortho Tech, Kilpauk, Chennai 600010.

All the subjects gave informed consent to take part in the study and the study has been permitted by the ethical committee. All studies were carried out in accord with the World Medical Association Declaration of Helsinki. One case of each group is illustrated and observations noted are presented below.

4. GROUP 1

Of the total 6 cases one case is illustrated. A 40 year old housewife tripped and fell in her farm and injured her right leg.Initially for 3 months she was treated elsewhere with plaster of Paris immobilization. When she presented she had inability to bear weight on the right lower limb . Her xrays are seen in figure 2a show an oblique fracture of tibia. On 29-8-09 under spinal anaesthesia and tourniquet control when the fracture was opened there was a lot of fibrous tissue and over-riding of the fragments. The fracture was aligned and a 4 carbon Ilizaro ring construct was applied with K wires passed into the bone to fix the fracture with 2 rings proximally and 2 rings distally.2 units of blood was transfused.Patient was discharged on the 6th postoperative day after current recording and was periodically followed.She did not have any discomfort while any of the recordings.However she did have routine problems of the ilizaro ring like the pin tract infection which was managed with antibiotics.

5. OBSERVATIONS IN THE ILLUSTRATED CASE

The current was recorded for various DC voltages applied across the fracture and the variation of current output as fracture heals is shown in figure 2b. There were initial fluctuations from 1 -50 days with a maximum current flow of 240 mA on the 23rd day. This was followed by a gradual fall.100 days thereafter the current stabilized at a minimum of 130 mA. The concurrently taken x-rays are shown alongside the graph constructed indicated stabilization of current correlated with completion of the healing process as evident from new bone formation. Rings were removed and patient was put on walking plaster and later changed to a brace. At present she is walking unaided without any splint. She is seen standing in the figure 2c.2d shows her completely healed x-rays.

6. RESULTS AND DISCUSSION OF ALL THE CASES IN GROUP 1

Table 1

Patient	Age	Sex	Day current stabilized	days in ring	Number of x-ray views
SL	40	F	100	101	6
ST	25	M	78	83	6
SM	50	M	55	58	6
AN	26	M	260	275	24
SN	50	F	45	49	6
VN	39	M	236	244	20
Mean	33.16	4:2	129	135	16.6

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The results of group 1 cases are shown in table 1. In all these six cases there was initial irregularity followed by stabilization as the treatment progressed. There was difference in the days of stabilization of current between the patients. This is possibly be due to difference between the patients in the mode of injury , timing of surgery, presence of infection, repeated surgeries, associated soft tissue loss . In all these cases the current stabilized after a period and this corresponded with the healing as verified by x-rays, as shown in the figure 2c. Also in all these cases it was observed by the time when the current stabilized there was no pain and the patient was able to weight bear comfortably and the radiographs also showing signs of healing-matching the graph constructed. In an average the current stabilization occurred 6 days before the appearance of new bone in x-rays. The fresh finding is that stabilization of electric conduction indicates healing. The cause of disturbances during the initial period of treatment in all these cases is exactly not known and is possibly due to injury itself and endogenous electric potentials produced in these tissues which in preliminary stage of healing are still disorganized. The shear- stress and piezo-electricity in collagen fibres may be the cause of these currents. They may probably stimulate the connective tissue cells to form more extra cellular matrix[24,25].Similar work on skin healing was done by Burr et al and he noted that potentials recorded stabilizes when skin wound heal[26].

7. GROUP 2

One case from this group is illustrated. A 35 year old farmer was injured in a road accident. He had lacerations of 16x6x4cm depth in the right leg with bone fragments exposed through the wound. He had resuscitation and investigations. He had segmental fracture of right leg bones. On the day of admission under spinal anesthesia he had an emergency wound debridement and external fixator application on 5-5-07 [figure 3a] and skin grafting on 14-6-07. This was followed by a stainless ring fixator application on 20-6-07. His x-rays are shown in figures 4 a,b,c and d, He was examined clinically and radio logically with serial x-rays seen in figure4b,c,d e,f,g,h and i and assumed to have united and decided to remove the rings .

Thus after 4 months his rings were removed with a judgment that the fracture was united. Later when he was made to walk with support he found the fracture site was yielding. Further after 3 weeks the patient came with instability and findings of a nonunion when his plaster was removed on 26-10-07. His x-rays taken in October [26-10-07] and November [26-11-07] still showed atrophy at fracture site. These fresh x-rays are shown in figure 3 j and k and clinical examination also the fracture showed abnormal mobility [both the fragments were moving independently].This fracture was hence diagnosed as un united. [This again reiterates that the x-rays are unreliable]. Hence it was decided to re-do the Ilizaro procedure.

He again underwent ring fixator application for the second time on 12-3-08 [fig 3- l] and later to stimulate healing had autologous bone marrow injection on 8-5-08. The x-rays taken during this period is shown in the figures 4 m, n and o. Further x-rays taken are shown in figures 4 p, q r and s. Figure 3s is a close up view of fracture seen in fig 4 r. After [dynamization] loading the fracture gently by loosening the nuts gradually, the rings were removed. The final x-rays as shown in figure 4t, u and v show complete healing of the fracture.

8. OBSERVATIONS IN THE ILLUSTRATED CASE

During the treatment period of 400 days the total number of x-rays taken to assess union at fracture site for this patient was 32. Obviously there was difficulty in assessing the fracture whether united or not based on clinical examination and x-rays only. It was also difficult to convince the patient that the fracture has united after the second surgery. We feel possibly the decision to remove rings after the first surgery based only clinical and x-rays was erroneous.

9. RESULTS AND DISCUSSION OF GROUP 2 CASES

Table 2

Patient	Age	Sex	days in ring	Number of x-rays
Pen	27	F	360	44
Krn	40	M	350	26
Chn	37	M	350	32
Vnd	27	M	240	36
Rml	28	F	220	30
Etrj	40	M	200	16
	33.16	4:2	286	30.6

Table 2 showing cases treated with stainless steel Ilizaro rings for fracture healing or bone transport and followed up with x-rays and clinically only and

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the number of x-rays needed. All of them in this group have spent at least 200 days in rings with an average of 286 days. They have also underwent repeated radiological examination of at least 30 x-rays correlating well with other similar work using only x-rays to find out if fracture union is over.[1]

10. DISCUSSION OF OBSERVATIONS IN BOTH THE GROUPS OF PATIENTS

Six cases in each group and totally twelve cases were available till the very end of the study and had all the x-rays and could be compared.Comparing the tables 1 and 2 it is obvious that in both groups there are two females and four males. Also in both the groups there were 4 open fractures with no bone loss and 2 cases with bone defect. These bone defect cases were treated with corticotomy [a purposeful bone division] and bone transport. The average age of both the groups was 30-40 year range only. Thus in these two comparably matched groups there was reduction in the number of days in ring fixator by about 50% than the 2nd group. It is also evident that the number of x-rays taken during the treatment period in the first group is only around 50% of the 2nd group.

The comparatively faster removal of rings in the first group may be due to the identification of completion of healing faster which is deduced from the stabilization of electric current than in the second group. This may also probably due to electric stimulation causing faster bone formation in the first group as discussed in certain works .[15,16,17,18,19] Whatsoever the reason , from the patients' view point the method used with 1st group of patients relieves them from external fixator faster .The radiation dose for a view of leg is 1.54µSv [27]. For an antero posterior and a lateral view it will amount to 3.08 µSv .We have reduced at least 14 views per patient in group 1. This will amount to a reduction of 46.2 µSv per patient during the treatment period in an average in group 1.

11. LIMITATIONS OF THE STUDY

This study is done with a small group of patients and the results may not be directly generalized .A study with a larger number of patients is underway. This method is only a diagnostic method. The patients followed electric stimulation healed relatively faster. This was analyzed and the cause was searched. However there is no uniformity in total current dose. Although all these patients had a range of 0.1v to 1v DC voltage, the number of days differs between them as some patients healed faster within the group. In future standardization of the electrical dose is planned for all patients. We also had a limitation that the fracture in real patients can be varied and irregular in pattern and cannot be a clean division of bone as in animal models. We were only able to include open fractures presented to us consecutively in both the groups. However the corticotomy [a purposely made bone cut to produce new bone] made by us also showed a similar trend in electrical conduction of early irregularity followed by stabilization in patients 4 and 6 of group 1.

At present we do not claim that this method totally replaces the age old method of clinical examination in fracture assessment. However in patients treated with Ilizaro frame it is common place that we do have difficulty in assessing bending strength with the rings on. In such a circumstance we feel this method of electric stimulation can be definitely useful in assessing fracture union or new bone formation.

12. CONCLUSION

The irregularity of the current output in group 1 patients in the initial stage changes to a stable current as the fracture heals. This comparative study concludes that following up of fracture healing in patients treated with Ilizaro frame with electrical stimulation alongside clinical assessment and x-rays is useful. This not only reduces in days of treatment in ring fixator device but also reduces radiation exposure to the individual and the paramedic involved. At present this method will not altogether do away x-rays but will reduce the need once the bone fragment reduction and stability is ensured. However a larger trial is needed with this method before induction as a routine diagnostic method.

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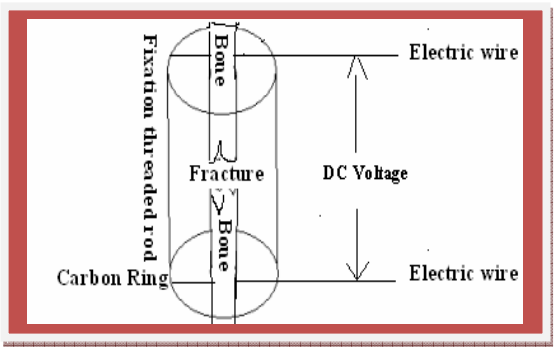

FIGURE 1

FIGURE 2A

FIGURE 2B

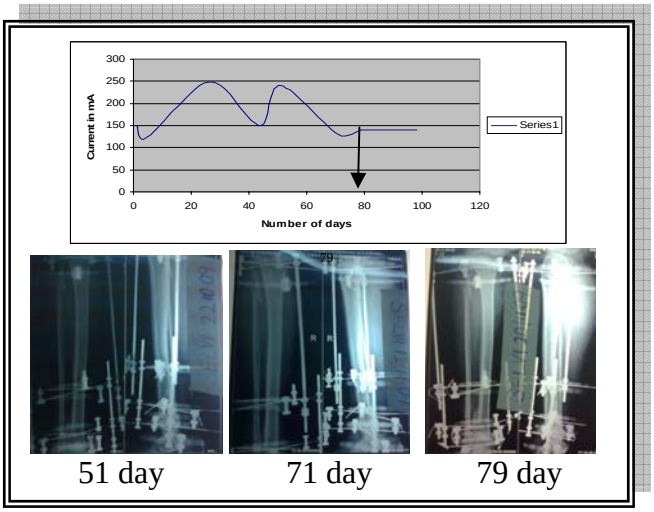

FIGURE 2C

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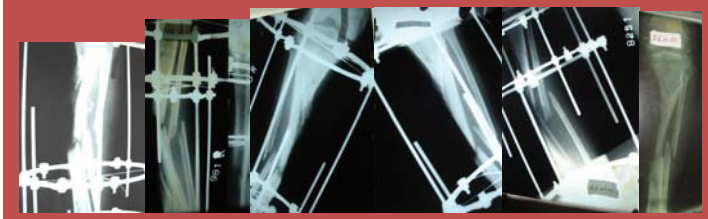
3 a


3b


3c


3d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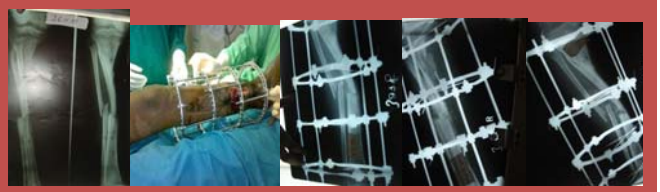
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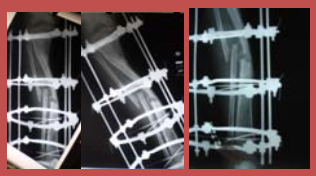
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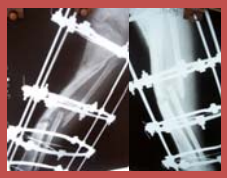
3p


3q 3r


3s


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3u 3v