



Research Journal of Pharmaceutical, Biological and Chemical Sciences

A Perspective on Studies Which Tried Electrical Method as a Diagnostic Tool for Measuring Fracture Healing.

Shanmugasundaram Kumaravel^{1*}, and Srinivasan Sundaram²

¹Professor, Department of Orthopaedics, Thanjavur Medical College Thanjavur, Tamil Nadu, India

²Director, PRIST University, Thanjavur, Tamil Nadu, India.

ABSTRACT

We analyzed the articles on the assessment of fracture healing using electricity. These include two animal experiments and two human fracture studies. Of the two human studies one was our work using rings with body oriented fibres which was though empirical, found that conduction across fractured limb stabilizes as the fracture healed. In another study, claims of measuring induction with insulated fixator, healing without producing X-rays; piezo-electric effect in wet bone; LRS Q meter values are accurate; non-fractured part of the tibia can be taken as control; exact conducting portion of the Schantz screws in bone are not reasonable. In general, isolated human fracture bone resistance *in-vivo* is difficult to measure and such studies till date are empirical.

Keywords: parasitics, stability, fixator, conduction, induction, insulation, prognosis, LRS Q

***Corresponding author**

Email: drskumaravel@gmail.com

INTRODUCTION

Using electric current to monitor fracture healing instead of radiological method is fascinating. Few articles [1-4] on this aspect of assessment of fracture healing using electricity are reported in literature. This review is mainly on those studies that were using electric current as a tool to study healing of fractures. The real situation the difficulties and limitations are analysed.

In 1981 Gupta RC [1] et al published their interpretation of animal experiments on the "Changes in electrical resistance of bone after fracture and during healing" [1] In 2009, Yoshida [2] et al reported "Measurement of bone electrical impedance in fracture healing "in rabbits. [2] In 2012, Kumaravel S et al [3] published their article "Monitoring of fracture healing by electric stimulation, A new diagnostic tool". This is the first human study of diagnostic application of electric current in fractures while the two previous were animal experiments. ³ In 2013, Gupta K et al [4] published their article "Change in electrical properties of bone as diagnostic tool for measurement of fracture healing" which is also an attempt on the application of using the electric current.

The present article in a general overview of all these articles [1-4] but the main comment is on the last article [4]. The review will be along the following lines 1. A brief comment on the work [2]. Selection of the cases, significance and relevance of the study [3]. Insulation of the fixator 4. Induction and Errors in Measurement [5]. Stability of the apparatus 6. Carbon and conduction 7. Empirical nature of such studies 8. AC or DC 9. General defects and 10. Suggestions.

A brief comment the last work

Gupta K et al [4] have reported using insulated fixators for measuring electrical properties by LCR Q meter. Inductance, Conductance and Impedance were reportedly monitored in the fractured and normal segments of human Tibia. They have also claimed in their paper that the pins and rods were coated by an insulating polymer complying with USP Class VI biocompatibility standards for medical devices and implantation which did not permit conduction from skin and soft tissue. This coating was claimed to be absent inside the bone permitting movement of current and measurement of the electrical properties of bone devoid of noise from skin and soft tissue as the healing progresses. The patients who had compound fracture (Gustillo grade I & II) were treated with this electrically non-conductive fixator. [4] They have also claimed to have summarized all attempts that have been made in the direction comprising electrical parameters and also tried to suggest directions in which research should progress in this field. However we have found major defects in the paper and also feel that the authors have not fully read all the articles in the references, especially other papers [3] and have partially quoted or misquoted the ideas of the cited authors. ¹ and 2]

Selection, significance and relevance of the study

The fourth study is an analysis of the results from a very small sample size of 14 cases.[3] As the authors themselves have accepted, they need a larger sample size before any generalization. They could not calculate a 'p' value as such. They could instead have used an ANOVA.[5] They have only retrospectively analyzed and compared the data and cases which has low level of evidence (a prognostic case study). [4] However in Kumaravel S et al [3] study, conduction of fractures were studied and side by side were compared with simultaneous X-rays. With only 12 cases, Kumaravel S et al [3] have not tried any statistical analysis. However Gupta K et al [4] with less (14) cases (30 cases is minimum significant number [5] has tried statistical analysis.

Gupta K et al [4] have kept the fixator for an arbitrary period of 70 days for all cases on basis only known to them. They also claim there is no gold standard for fracture healing assessment, still use RUST score and affirm their result is significant.[4] If they do-not know and were blinded, how they will know the type of union eg a case is a normal union. They have not mentioned how the delayed union group behaved. They also say there was a re-injury. There is so much confusion whether this was due to another fall or due to poor fixation.

In Gupta K et al's study [4], the main issue was the selection process of cases. Were the cases routinely included as consecutive patients unmindful of comminuting, bone loss etc. For example there will be an element of bias, as only the person who sees and judges the shape of the fracture can decide the fixator. Or else, if it was done unmindful of any fracture configuration and application of same fixator in a routine fashion, then it turns out to be unethical. So it is only mandatory to describe who selected the cases and who operated and who followed up. This is the difficulty in human studies e.g. in bone substitute studies one cannot leave a patient (control) with same non-union potential without grafting. Imagine the plight of a fracture patient, one doctor examines him, some other sees his X-ray, and another person operates on him with his routine fixator unmindful of the fracture pattern.

Instead we feel that the study [4] shall be of the clinical side and instrumentation side also. In the clinical-side, the same surgeon examines the patient, analyses the X-ray uses appropriate fixator and follows up till union with X-rays. In the instrumentation side a bio-med engineer records the current unmindful of the clinical and radiological outcome of the study till the above surgeon asks the latter to stop. This means that at least one should have a control of the well being of patients.

Especially in open fractures the parameters of soft tissue, skin etc like wound size, volume of wound, grade of compounding differ from patients to patients affecting generalizability of electrical data. One would feel that a stratified analysis is required. However in Kumaravel S et al's study, [3] given the less acceptability of the ring fixator [7] one will appreciate that such stratified analysis is only theoretical. In Kumaravel S et al [3] s' work the ring was introduced to the patient and he was explained in detail about the DC current

application which did not involve any additional electrode inserted (since the wire was our electrode still was invasive anyway). This is vital especially with illiterate population. [8]

Insulation

Gupta K et al [4] work on impedance measurement [4] claims to have insulated their pins and rod type external fixator with a coat preventing conduction in soft tissue. Let us consider this. In this fixator, the anchorage of the fixator on bone is by the Schantz pins and the linkage of these pins is by the rods and clamps But from the figures available, (at least as we could make out), it appears they [4] have used only regular rods. There is no mention of the exact thickness of the coatings. The fixator has multiple components which even if at all they have insulated, one should agree that, the film should thin enough to allow the rods to slide in and out as they are being inserted into the clamps. Such a thin insulation coating can easily get peeled away and also cannot withstand the shear and stress while pins being passed into the clamp; tightening of the clamps and that of double staking (an attempt to increase the stiffness of the assembly putting a lot of stress on the multiple components causing the short circuiting. (See figure in Gupta K et al [4])

How would one ensure that the insulating film has not peeled away at even one place during the procedure. The precise diameter of the clamp holes, diameter of the rods is very important. Smearing of blood and serum on the pins clamps and fixator which will form a layer is unavoidable in operating on living humans. This will effectively increase the diameter of the rods causing further stress and resultant peeling off of the layer of insulation while inserting the external fixator rods into the clamps. Thus the effectiveness in insulation of the entire fixator assembly remains disputed and the results cannot be assumed to have not been influenced by the stainless steel fixator rod.

Gupta K et al [4]'s work claims that conduction occurs in the bone only. Surgeons who operate on real human fracture patients will accept that, the diameters of the shaft of the bone are different. Then how will anyone know the exact diameter of the bone to adjust the conducting length of the ready-made Schantz screw that will conduct. How will anybody stop the conduction from happening in the soft tissues? Moreover these coatings are radiolucent to be seen by an image intensifier. This proves the claim, that the current indeed flow only in the bone, is not perfect.

Even prior to Gupta K et al's work [4] the insulation of the external fixators with anodic oxide coating was performed in rabbits by Yoshida. [2] This insulation is done between the pins. They have also given small incisions before inserting the pins possibly to reduce conduction into the soft tissues.[2] However, Gupta K et al's work [4] has not mentioned this prior insulating aspect of Yoshida's[2] animal experiment [2] in their work. [4]

In Kumaravel S et al [3] s' work, they have categorically accepted that "In this study, at this point of time, there is difficulty in insulating the soft tissues from conducting. Hence, it can

be considered as a conduction study across the fractured limb.[3] Thus, in real human conditions insulating the fixator is never possible.

Induction and Errors in Measurement

In Gupta K et al [4]'s work the measurement is done by the LCR Q meter. Insulation does not prevent induction occurring in the apparatus. This is absolutely not possible. Induction will occur in the apparatus used by Gupta K et al [4] also even after insulation. The apparatus used is not a single piece device but has multiple components. The clamps, pins and rods, though if at all insulated, can still cause induction between each other. Thus measuring the inductance only across the fracture, the aim of that particular study is not possible. [4]

The measurement of the LCR Q is assumed to have perfectly arisen from only the fracture site. [4] But there have been occasions where 1) one DUT (device under test) measured with two different LCR –Q instruments giving two different results or 2) even measuring the same DUT with same measurement (LCR-Q) device getting different results. Thus the value one measures with the LCR Q meter is not automatically the one that is actually wanted. Further measurement errors are introduced by the instrument and its accessories. It is scientific to understand that essentially there are no such perfect purely-resistive or reactive devices. All components of LCR-Q have parasitics like unwanted series wire inductance and resistance, unwanted resistance and capacitance across the dielectric. Thus in any LCR circuit, the precise measurements of components are difficult. Also LCR Q uses AC, which itself is frequency dependent. Impedance is the total opposition a device or circuit offers to the flow of a periodic current. There can be real R and even an 'imaginary component' in the reactance. The reason for the measurement discrepancies are the frequency, level of test signal DC bias, voltage and current. This measurement can also be affected by humidity and temperature of the environment and even aging of the instrument. The ESR (Equivalent Series Resistance) of electrolytic capacitors increases with time and higher temperature exposures. At higher frequency these capacitors begin to function as an inductor. Electrical properties of a dielectric material of capacitor, the capacitance varies with the applied AC test signal. DC biasing can also change the component value in LCR-Q. Care should be exercised in handling these LCR-Q devices to prevent massive discharge of charges to the front of the device.[9,10] Thus Gupta K et al [4] have not taken these details into account before supporting the cause of the impedance measurement. Thus the LRS Q measurement is not scientific. Also when such an article is heavily written on the engineering side no authorship is given to the engineering colleagues. [4]

Stability of the apparatus

Conventional half frame external-fixators are not rigid enough to hold unstable fractures. To be mechanically effective the stiffness of the fixator frame should match the forces and moments at the fracture site. The fixator apparatus is applied anterior because the sagittal bending moments in the leg are two to five times larger than those in the coronal plane .[11] In any construct of external fixation like the one described, all half pins (Schantz pins)

should have a bi-cortical purchase i.e. cross the cortex. [12] Gupta K et al [4] in their attempt to reduce soft tissue conduction, have not crossed the second cortex. In the illustrated X-ray also in figure 1 [4], two pins were seen just touching the inner side of the far cortex. Thus the stability of the Gupta K et al [4] s' external fixator apparatus construct is dubious.

It is not surprising that actually two of their cases suffered injury again at second and fourth week (which might have been re-angulations on loading or even movement of the limb) and one suffered pin loosening with infection. It also gives an impression that the authors only wanted to collect the patients' data, details and leave him and are not interested in the treatment outcome of the patient. The current consensus in using the rod type of external fixator in the treatment of open fractures is only as a temporary stabilization as a spanning construct in physiologically unstable patients. Care is needed to avoid the sites of possible incision over the fracture.

Generally the healing time of the fractures is longer especially in adults. [11] Immobilization for only 8 -10 weeks is inadequate for a fracture of tibial shaft to heal. If ordinary external fixators are maintained longer, then the pins will loosen. It may result in mal-union, non-union, loss of function .The pin bone interface problem is very common. [13] If delayed unions were included in the series then these patients already would have spent a lot of time after their injury. They need stronger fixation devices and not the type tried by the authors. Conversion of an early stabilizing external fixator to (nailing) internal fixation within 2-3 weeks is also another option. If expected to go for a longer time with the fixator itself then currently an Ilizarov ring apparatus or Limb Reconstruction System are preferred. [1,4]

The pins near the fracture should be closer to the fracture. [13] In the figure illustrated by the authors [4] the pins are far apart i.e. the pins near the fracture. The loosening of such a fixation (non locking option) is not surprising. If the pin is loosened then where is the conduction.

Further Gupta K et al [4] claim that they have done redesigning of external fixator rods and pins. The sharp edge of the pins were filed and made blunt to prevent them from emerging through the second cortex when inserted. However in reality such blunt pins are already available. ¹³ There is no mention of the diameter of the pins used. [4] The staking to increase stiffness (already described) will not be an excuse for not using a full bi-cortical purchase. .Such use of a less stiff, temporary type external fixator is controversial and should have been explained to the injured human patients. This is vital .There is no mention about the type of consent taken because in India, we have a highly illiterate population.[8] In such a case study care shall be exercised. Such consents are difficult to obtain in places with low literacy. Data should be collected without affecting the patient's benefit from any intervention on him. This is the very basics of any human study. Just because one did not want a full two cortex purchase one cannot leave an open fracture with a potential of a delayed union fixed with gross instability. The pre-operative state of fractured fragments shall become osteoporotic leading to loss of purchase and re-fractures which have been already mentioned in the work ^[4]. From the

point of Helsinki declaration all these facts should have been told to the patients and they should be aware.[15] Even in animal experiments stronger fixators were used.[2]

Carbon and the conduction

Vertical or body orientation of fibers will affect their conduction properties. [16] The conduction also is different if the material in question has been in a sandwich arrangement. In Kumaravel S et al's work [3] they have studied electrical changes during the fracture healing using carbon rings with body oriented fibres in a sandwich structure with epoxy resin according to reference[17] cited by us in their paper. [3] Other works have reported that there is high electric resistance to amorphous carbon and tetrahedral amorphous carbon 'Ta C'. 'Ta C' exhibit insulating properties also. It is only when carbon film is arranged in a particular fashion then the conduction can occur. Even in graphite the anisotropic nature of the material results in interesting electrical properties. The carbon film is conductive in plane direction because of vast electron delocalization with the carbon layers but highly resistant in out of plane direction. The electric resistance of amorphous carbon is high. ¹⁶ The resins are also found to have insulating properties. Conductivity is frequency dependent. In certain frequencies the conduction reduces. [18] Carbon fibre material are regarded as non conductive [19].The polymers epoxy which is used in the carbon ring was highly resistant 10^{10} - 10^{13} [13. 20]

Empirical nature of such diagnostic electrical studies in fractures.

ECG is not exactly scientific but only empirical. According to D.J. Rowlands 'In excess of 100 million 12 lead ECGs are recorded annually world-wide , a fact that would surely would have astonished Waller (Augustus Désiré Waller 1856-1922) who made the first electrographic recording of the human heart in 1887 and expressed the view that it was unlikely that such recording would be of much use in clinical practice. This view was however not shared by Einthoven (1860-1927 who was awarded the Nobel Prize in 1924 for discovering ECG). Electrocardiography developed empirically and its basics diagnostic criteria remains empirical.' [21] Kumaravel S et al [3] have compared ECG with their work and mentioned the above lines in the last paragraph of page [3]88. This was possibly overlooked by Gupta K. [4] while citing Kumaravel S et al [3] . Kumaravel S et al [3] have also accepted the difficulty in completely insulating the electrodes. [3] The claim of Gupta K. [4] about insulation is not foolproof as discussed earlier. The above lines of Rowland's are indeed farsighted. [21]

For those who feel Kumaravel S et al [3] work is not comparable with the ECG of the heart, it is clearly said "In this study, at this point of time, there is difficulty in insulating the soft tissues from conducting. Hence, it can be considered as a conduction study across the fractured limb. In the present study, the issue is where actually the electrical conduction is taking place. To appreciate this, an example of an ECG may be considered. The ECG leads are kept on the chest wall and not directly on the heart and the resultant wave is inferred to have arisen from the heart. This is only because the pattern of waves matches with the contraction of heart, e.g. p wave synchronizing with atrial contraction. Likewise, if the conductivity of other tissues except the bone is assumed to be the same before and after healing, then the dynamically

changing tissue is only the fractured bone as evaluated by clinical examination and radiology. Hence, these changes observed in the graph constructed with resistance versus days for definite voltage should have arisen from events in the healing of fracture tissue only” [3] To add, carbon is a non living thing and whatever is its conduction is constant. The change that is seen in graphs matching the radiographs must have arisen from changes in the fracture limb.

Kumaravel S et al [3] also further wrote “As we see that there are different tracings in each graph, it is evident that we are not taking a particular reading of resistance as the endpoint. Instead, the changes in the resistance were correlated with radiological signs of healing as the endpoint, i.e. the stability of recording (with similar consecutive readings during follow up visits) is taken as the endpoint of healing which is correlated with radiological evidence of healing.” There is no end point day as such but there was a series of same readings causing a stable graph coinciding with simultaneous X-rays. ^[3] We feel Kumaravel S et al’s study [3] though empirical, reduced the radiation and kept it ALARA(As Low As Reasonably Achievable).[22]

Nowadays it is obvious that Ilizarov’s method comprehensively addresses the injuries of all the tissue and is not specific only to the bone, hence correctly termed as Ilizarov histogenesis, not only osteogenesis. The tension stress and loading will cause all the tissues to heal. ^{2[3]} Thus Kumaravel S et al [3] are scientific in telling about the electrical property changes in the whole injured limb. Nowhere in the world the resistance of live intact bone and fractured bone alone (it is with some soft tissue connection around as it is only possible) is available in literature. (see figure 1)

Unlike in the animal experiments, we feel in humans it is unethical to cut the skin, keep two electrodes across and record the current across the fracture and remove the electrode and suture the wound each time the recording was done. Thus we reiterate that the changes in our study [3] are basically of the entire fractured limb (un-insulated wires) indicating healing of all tissues and not only bone. [3] A model where ‘isolated fractured bone ‘can be studied during the healing process is yet to evolve. We reiterate, apart from assumptions and animal experiments, nowhere is there a definite recorded human bone resistance except one work on medullary conduction. [2,4]

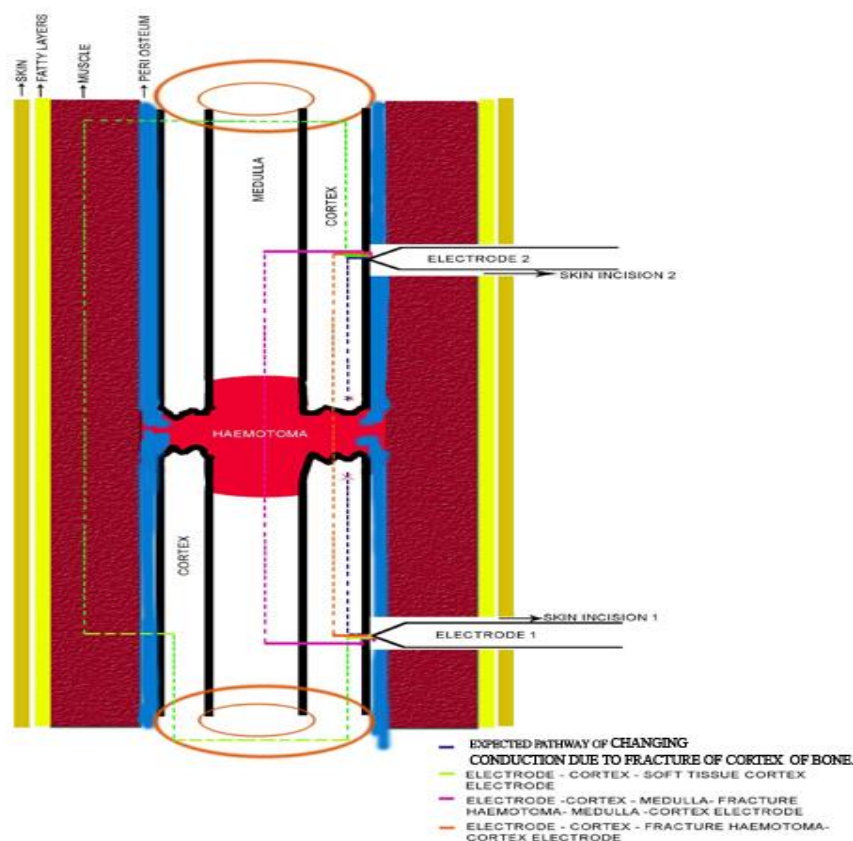


Figure 1: If one think he can prevent soft tissue conduction by a small incision at the level of the pins .Even in this method there will be conduction in the alternate pathways of Current conduction from electrode 1 to electrode 2 other than the broken path way at fracture site (cortex to cortex conduction) which is interrupted by the fracture. There can be conduction from

Electrode - bone cortex-soft tissue- bone cortex electrode →dotted green line

Electrode -Bone Cortex-Medulla- Fracture hematoma - Medulla- Bone cortex – Electrode →dotted violet line

Electrode -Bone Cortex- Fracture hematoma -Bone cortex –Electrode→ dotted brown line

Expected pathway of changing conduction due to fracture of cortex of bone→ dotted blue line

Skin, sutaneous fatty tissue , muscles periosteum are also shown.

AC or DC ,Which to use?.

The idea that Piezoelectric and junction-diode effects are responsible for electrical signals in bone [4] and these signals may interfere with DC currents, therefore their stabilization by AC currents is necessary is interesting. Gupta K et al s' [4] work is directly on an assumption that the two fracture fragments will behave as two electrodes. However such a PN junction diode like effect is reportedly assumed only between the collagen and the hydroxy-apatite in the intact bone and not at the fracture. [25] One may assume piezo electric currents are present in the wet and live bones also. In reality 'the electromagnetic effect observed in the

wet bone is not piezoelectric effect. The piezo -electric moduli evaluated in the uniaxial compression by Fukada and Yasuda (1957), Liboff and Shamos (1971), combined with an expression derived by Williams and Breger (1974, 1975) for the voltage expected across a homogenous piezo -electric beam under cantilever bending did not describe the response of biological tissues, neither quantitatively or qualitatively. The results of the experiments on wet bone show in contrast to dry bone, the piezo-electric effect in wet bone is insufficient and irrelevant. When bone, tendon and cartilage are subjected to mechanical forces under physiological conditions, piezo electric signals are not usually measured as induced polarization is rapidly neutralized by ions in the bulk fluid.' Thus the concern that that DC will be interfered by the micro currents is irrelevant. In reality, these are very low currents to interfere. [26]

Because AC depend on the frequency and can change, it cannot predict what changes have happened at any single point of time in the fractured limb. It is ideal to keep at least one factor constant and to observe change the other. Changing current and measuring a changing fracture electric behavior is obviously unscientific. Even a work [1] a 1.5 volt battery was used and which is obviously a DC source and had measured resistance (and not impedance as claimed by Gupta K et al [4])

One main concern is the safety of using AC and DC .The high electrical resistance of human skin makes it a dielectric with the sub-cutaneous tissue and metal plate on either side acting as plates of a capacitor. In cases of electrocution by DC voltage source, this capacitive property is of little importance. But if electrocution is by AC voltage source, the natural resistance of the epidermis is reduced allowing the current to bypass that resistance of the part of the body in contact causing reduction in the total resistance. The danger of the electrocution depends on the amount of current passing through the body .Thus when the resistance is reduced, the current passage is more. So AC is hazardous than DC. [27] Gupta K et al [4] have used AC and Kumaravel S et al [3] have used DC respectively in their work. [3]

General problems in these studies

Gupta K et al [4] have used un-injured metaphysis of the injured leg as control for the fractured site. The non-fractured part of the tibia cannot be taken as control obviously because the properties are different in different parts of the bone like mid-shaft (diaphysis) and ends of the long bones (metaphysis) as the authors themselves agree in their paper[4]. If one considers the following two statements in the paper [4] itself- in one place, it reports "Metaphysis was negatively charged in relation to the diaphysis'. While in another place it says "these two electrical parameters (impedance and conductance) are dependent on the cross section area and volume and BMD of that particular bone. The proximal and distal segments are not similar in cross section area and volume and BMD as evident from the structure of the tibia bone and difference in the density of metaphysis & diaphysis " [4] If so, how can one conclude that a diaphyseal fracture still can be compared with a metaphyseal and intact (un-fractured part)bone. This is also not scientific. In Kumaravel S et al [3]'s work is a case study only as humans controls are obviously difficult to get.

Gupta K et al [4] have not produced even a single case X-ray series with healing (from initial X-rays to completed healing) weakening the study. This they could have even done, well after the study is over. For the delayed- unions they have not mentioned procedures like bone marrow injection or bone grafting that were needed in these cases. If Gupta K et al [4] claim they did not want to get biased then this should at least be written as a limitation section. One is not sure as to what is the exact period the patient was kept in the hospital as an in-patient? The Gupta K et al [4] paper presents just 2 tables with few data. They have not given a master chart for all the 17 cases or 14 cases. They have also not mentioned the age of the patients studied, as age will affect healing.

If the presented work is on the diagnosis, then it should identify adequate strengthening of the fracture tissue to allow the loading of the limb. There is no mention of a follow up after 5 months. [4] There is naturally re-fractures. Such re-angulations can even occur after 6 years. [28] Thus this is only a prognostic study.

Given different shapes of actual fractures, there cannot be any fixed distance between the pins and fracture line. For e.g. the oblique fracture one side is closer to the pin and another side is away.

Gupta K et al [4] have not mentioned similar study on measurement of bone electrical impedance in fracture healing [2] as an inspiration. Instead they in their introduction feel they have improved the prior work of Yoshida et al [2] and later say that their own future aim is to use an oscilloscope as Yoshida et al [2] did. One wonders if Gupta K et al [4] were inspired by the work of Yoshida et al [2] or not? A neutral observer who sees a similar diagram of circuit of Yoshida et al [2] should appreciate that the same method (animal experiment [2]) is applied in humans in Gupta K et al study [4] sans the oscilloscope in Yoshida et al 's experiment.[2] A similar type set-up [2] is used by Gupta K et al [4] . Gupta K et al have claimed that differentiation between the normal and delayed union could be predicted even at the time of starting antibiotic protocol. [4] We also wonder what is the time of instituting the antibiotic. Is it after the external fixation device is applied? The common rationale is to immediately institute an antibiotic even before any procedures. [2.9]

Also to tell the time taken is 5-15 minutes more for applying their novel fixator [4] than the routine is vague and is as though from a personal experience (a poor level of evidence). [6]

Even while claiming that X-rays are not gold standard, Gupta K et al [4] have used them. [4] We feel even with some deficiencies like radiation hazard at present, , X-rays still have wide role , for example loss of reduction or bone loss or implant loosening cannot be predicted by the method that is proposed by Gupta K et al [4]. The X-rays are needed but could be kept ALARA (As Low As Reasonably Achievable).[22] The authority with which Gupta K et al [4] claim about the Radiographic Union Scale of Tibia itself is questionable since the work introducing RUST itself accepts it is only a preliminary work [30]. Because no "gold standards" currently exist against which rust can be compared, this study provides only the initial step in the score's full validation for use in a clinical context. It also did not correlate well with HUI

Health Utility Index.[30,31] HUI provides comprehensive, reliable, responsive and valid measures of health status for subjects in clinical studies.[32]

Blinding may reduce bias, but will not improve any single individual's observational skills. Studies show that there can be [3] groups fast normal, slow normal and slow healing [33]. Radiologic appearance is a factor of past osteogenic activity in the tissue and not due to current histology. The mere radiographic persistence of a fracture line does not invariably indicate non union. This means X-rays are not fully reliable. [34] There is also a lack of consensus in the assessment of Fracture-healing among orthopaedic surgeons. [35] Use of X-ray equipment is often not handy and the analysis unclear. [36] With radiographs, more inter observer variation and irrespective of whether the general appearance or the number of cortices united were found comparing stiffness measurement. [37] Use of RUST is not fool-proof for all cases.

Suggestions

By this communication, we are not discouraging anyone from doing such work. We value all these works and understand the pains the researchers might have undergone. We want readers to understand the empirical nature of these studies [3] which Kumaravel S et al [3] have accepted in the 5th paragraph of their discussion. We want every single work properly acknowledged e.g. insulation of pins by another author [2]. Any method of studying fracture healing should be useful to the patient avoiding potential late side-effects. This particular work of Gupta K et al [4], we feel should not stop at this level, but the directions of the research needs to be modified to 'Prediction of delayed unions in early phase of fracture healing using recording of electric parameters' preferably avoiding LCR Q if possible. Because only early stages of fracture healing is researched here in Gupta K et al's work [4].

There might be doubts as if all resistances bone, soft tissue carbon rings that are being measured are arranged in parallel therefore the combined resistance $R = [1/r \text{ of bone}] + [1/r \text{ of soft tissue}] + [1/r \text{ of fixator with carbon rings}]$. However Kumaravel S et al [3] have considered the resistance of the limb as a whole and not separately and in the figure the components are in series only. Kumaravel S et al [3] have not drawn a voltmeter or an ammeter in that figure. Obviously there are other figures also in their paper [3] e.g. a block diagram showing that the circuit is in series only. However whatever is the calculation, ultimately it is the pattern that is important, than the actual values since we are in no position to insulate the bone alone from soft tissues. [3] Kumaravel S et al [3] have told this in their paper as 'we are not measuring some actual value we are taking a series of readings and coming to a pattern.' Having not insulated the fixator the change should be obviously from the living tissue and not carbon rings. The change Kumaravel S et al [3] have told is due to the change in the fractured limb. One may feel that bone is bad conductor but soft tissues and fixator with carbon rings are good conductors. Resistance of bone is much higher than that of soft tissue and carbon rings thus during measurement, some amount of current passed through the carbon rings and soft tissue along with bone. However Kumaravel S et al [3] have already mentioned that they are unable to insulate the apparatus or the wire and have accepted the empiricity.[3] If in general the

resistance of intact bone is imagined to be more, then such resistance falls on bone being fractured and conduction happening through the fracture hematoma (see figure 1). As healing occurs there is a change in the conductive property of callus. As cortex regains continuity the resistance is regained. It strengthens Kumaravel S et al [3] hypothesis, and the result of their work.^[3] The empirical change in the resistance must be from the change in the callus and surrounding soft tissue fracture environment. To repeat, it is only scientific to accept that these changes cannot happen in non-living things like carbon ring etc.

SUMMARY

In summary in the first work cited Gupta RC et al [1] tried applying current above the recommended level of 1.0 volt by Libolff. [24] Libolff had told above 1.0 V electrolysis occurs. Gupta RC et al [1] also used DC and is not sure what are the readings that they actually measured in the last para of their work¹. They have mentioned both resistance and impedance (what resistance is for DC, impedance is for AC). Yoshida et al's work gives an insight into the fracture assessment in animals [2]. Kumaravel S et al [3] s' work is on human tibial fracture patients with definite indications of stabilization of current showing union, though empirical, is the first human study on Ilizarov patients.

However Gupta K et al [4] s' work, where effective conducting length of the Schantz pins cannot be monitored or adjusted, with coatings already potentially becoming peeled off while being insertion, as different shaft diameter to be adjusted with any imaging technique^[4] with inadequacies of LCR-Q meter, doubtful insulation, even the unpreventable induction between components even if insulated their inferences are questionable. The same is the objection to Gupta K et al [4] s' advocating AC when there is enough evidence of no piezo electric effect in wet and live bone. [26]

The main point in the treatment of any fracture is to identify the end-point of union as well as progress of fracture towards union which is vital to enable an orthopaedic surgeon to intervene in the form of bone grafting and at the end point of union to remove the fixator. It should not stop at an early stage and handicap the surgeon. When not many tibial fractures will unite within 5 months especially if it is open and the results of the Randomized Control Trials only apply to patients without signs of healing for 9 or 12 months, [38], Gupta K et al [4] s' study is silent in the later stages of fracture healing.

We also feel that Gupta K et al [4] method only flimsily fixes the fracture (uni-planar and no full cortical purchase), collects data which is questionable as induction cannot be prevented by insulation, with inadequacies of LRS-Q, removes the fixator in all cases at 10 weeks (even by not knowing radiological appearance) while healing takes longer time and concluded they can predict (only a prognostic study and not diagnostic) in the initial period only whether the fracture can heal normally or will go for delayed union. This study depends again on the X-rays which they claim as not dependable. We feel the work can be substantially improved.

To conclude, any single scientific work cannot address all problems of using electrical method to diagnose fracture healing. For once when particles faster than photons were detected, Einstein's $E=mc^2$ was immediately challenged. Science evolves. Man evolved from a single cell. [39]

REFERENCES

- [1] Gupta RC, Buttani KK, Mittal KK, Khanka B Changes in electrical resistance of bone after fracture and during healing. Indian J Orthop. 1981 ; 15(2): 228–33.
- [2] Yoshida T, Kim WC, Kawamoto K, Hirashima T, Oka Y, Kubo T Measurement of bone electrical impedance in fracture healing. 2009 J Orthop Sci ; 14(3):320-9.
- [3] Kumaravel S, Sundaram S. Monitoring of fracture healing by electric stimulation, Indian J Orthop. 2012 ; 46(4): 384–390.
- [4] Gupta K, Gupta P, Singh GK, Kumar S, Singh RK, Srivastava RN. Change in electrical properties of bone as diagnostic tool for measurement of fracture healing. Hard Tissue. 2013 Jan 21;2(1):3.
- [5] Kothari CR Research Methodology- Method and Techniques 2nd edition, Wishwa Prakashan New Delhi p212-4.
- [6] Wright JG, Marc F, Swiontkowski MF, Heckman, JD. Introducing levels of evidence to the journal. J Bone Joint Surg 85-A · 1 2003 Editorial,
- [7] Kulkarni GS. Biomechanics of Ilizarov fixator, in Text Book of Orthopedics and Trauma 1st edition New Delhi : Jaypee brothers 1999, p1490
- [8] Illiterate patients: greater care and caution required in the Indian context. Med law cases doct, vol 5 issue page 180.
- [9] Precision instruments for testing and measurements -LCR measurement primer 2012, pub IET labs Inc, pages 46 -61 available at http://www.ietlabs.com/pdf/application_notes/030122_IET_LCR_PRIMER_1st_Edition.pdf
- [10] Amarose G. LCR/Impedance Measurement Basics in '1997 Back to Basics Seminar', available at https://docs.google.com/viewer?a=v&q=cache:X6t_8HGE-gkJ:citeseerx.ist.psu.edu/viewdoc/download?doi%3D10.1.1.202.8586%26rep%3Drep%26type%3Dpdf+LCR/Impedance+Measurement+Basics&hl=en&gl=in&pid=bl&srcid=ADGEEShiHQnzRTKCRqjcxnWlZGIXAIJV0XK67GEICA3m0gMDh2igIK1rNQFn3DqSe4BvbdTYkVT hZRbG_4OcR2CkRS4hgkMIUV8c1_6MJpt_gn6CLbuuVrSU-iCxhT2Dgbu-NalQ61Y&sig=AHIEtbSbXmSvg_RUNVu4jfc9TvbJ7Q1YhA.
- [11] Behrens F, Searls K External fixation of the tibia J Bone Joint Surg 68 B (2) 1986;P246-54.
- [12] Robert C S, Dodds J C, Perry K, Beck D, Seligson D, Voor MJ. Hybrid external fixation of the proximal tibia : strategies to improve frame stability J.Orthop .Trauma,2003 17(6)415-20.
- [13] Ong A, Hayda R. Principles of External Fixation.- Orthopaedic Trauma Association March 2004 available at https://docs.google.com/viewer?a=v&q=cache:ttbMt-E_oROJ:www.ota.org/res_slide%2520iii/General/G11%2520Ex%2520Fix%2520Principles%2520JTG%2520rev%25202-4-10.ppt+Principles+of+External+Fixation.-+Orthopaedic+Trauma+Association&hl=en&gl=in&pid=bl&srcid=ADGEESgPPEiD1jNkRyj5JgTdNW3X248Y2QEag4BMo0rxgS7-oFfkDuamjQS6WLMFuHFq7rWgqF5rCBjMe9sAv6Oufkyccusa

- [26] Telega JJ, Wojnar R. Piezo Electric Effect in Biological Tissues. *J of Theoretical and Applied Mechanics* 2002 :3: 40, 723-59
- [27] Q & A: The Human Body's Resistance ,Ask the Van Department of Physics University of Illinois at Urbana-Champaign <http://van.physics.illinois.edu/qa/listing.php?id=6793>
- [28] Van Linge JH, Bessems G,P Bos PK. Refracture of the tibia 6 years after bilateral tibia nail removal in a patient later diagnosed with osteopetrosis. *Open Access Surgery* 2010;3 93–98.
- [29] Cross WW, Swiontowski MF. Treatment principles in the management of open fractures *Indian J Orthop* 2008 42(4):377-86
- [30] Whelan DB, Bhandari M, Stephen D, Kreder H, McKee MD, Zdero R, Schemitsch EH. Development of the radiographic union score for tibial fractures for the assessment of tibial fracture healing after intramedullary fixation. *J Trauma*. 2010 Mar;68(3):629-32. doi: 10.1097/TA.0b013e3181a7c16d.
- [31] Bhandari M, Kooistra BW. Bussehttp://www.bjjprocs.boneandjoint.org.uk/content/93-B/SUPP_IV/575.2.abstract - target-1 J, WalterSD , Torretta III P Schemitsch EH.1 108 – Radiographic Union Scale for Tibial (R.U.S.T.) Fracture Healing Assessment : Preliminary Validation
- [32] John Horsman, William Furlong, David Feeny, and George Torrance. The Health Utilities Index (HUI[®]): concepts, measurement properties and applications. *Health Qual Life Outcomes*. 2003; 1: 54. Published online 2003 October 16. doi: 10.1186/1477-7525-1-54.
- [33] Marsh D. Concepts of fracture union, nonunion and delayed union., *Clin Orthop Related Research* 1998: 355; S22-30.
- [34] Connolly JF. Selection, evaluation and indications for electrical stimulation of un united fractures (1981) *Clin. Orthop*. 39-53.
- [35] Bhandari M, et al A lack of consensus in the assessment of Fracture-healing among orthopaedic surgeons. *Journal of Orthopaedic Trauma* 2002;16:562-6.
- [36] Ryder D M, King S L, Olliff C J, Davies. “A possible method of monitoring bone fracture and bone characteristics using a non-invasive acoustic technique”. *Acoustic Sensing and Imaging* ,29-30 March 1993,Conference Publication No 369,© IEE,1993 page 159
- [37] McClelland D. Fracture healing assessment comparing stiffness measurement using radiographs *Clin. Orthop* 2007;457 :214-19.
- [38] Bauke W Kooistra et al. Electric stimulation : Non unions ,*Indian J Orthop* 2009; 43(2) : 149-55.
- [39] Jain AK. Innovations in Orthopaedics: Hypothesis to publication. *Indian J Orthop* 2012;46:605-7.