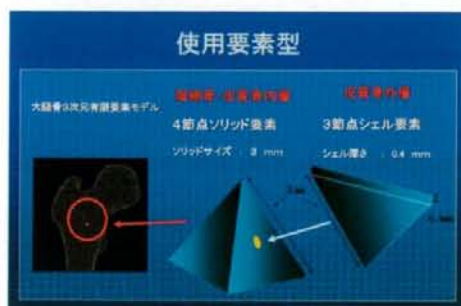


層に 0.4mm の 3 節点シェル要素を使用し、三次元骨強度解析モデルを作成した(図 1)。骨は不均質材料とし、重量密度は各要素に対して骨量ファントムの CT 値から換算式により計算した。材料特性は各要素の位置に対応する重量密度から個々に算出し、これに対応する要素の材料特性に割り当てた。ヤング率は Keyak (1994)ら、および Keller (1994)らの方法により設定した。ポアソン比は、0.4とした。非骨折側の三次元解析モデルを作成した(Bessho et al., 2007)。各要素の材料特性は各要素位置に対応する CT 値から骨密度を個々に算出し、骨密度に対応する材料特性を割り当てた。

(図 1) 使用要素型



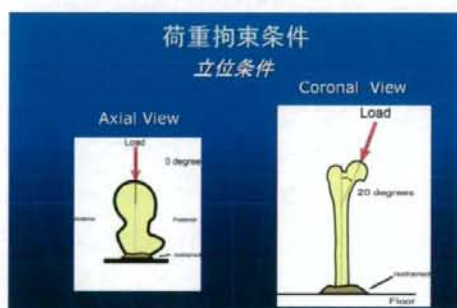
荷重拘束条件は、立位を模擬した条件(図 2)と側方転倒・後側方転倒を模擬した条件(図 3)を設定した。Newton-Raphson 法を用いた荷重増分法による非線形解析を行い、1 つのシェル要素の最大主応力がその要素の臨界応力を超える場合(クラック)、または、1 つのシェル要素の Drucker-Prager 相当応力が要素の降伏応力を超え、かつ最小主歪みが $-10000$  micro strain 以下の場合(圧潰)をそれぞれ骨折と定義した。1 要素以上の破壊を骨折と定義し、予測骨折荷重を解析した。

各荷重拘束条件の相違による強度の相違を比較した。統計処理は、Pearson's test、ANOVA 法、Post hoc test に Fisher's PLSD 法を用いた。有意水準を 0.05 以下とした。

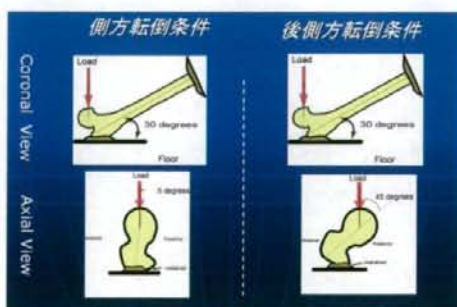
(倫理面での配慮)

CT 撮影に関しては、患者・家族同意の上で撮影を行った。CT データ・解析データは、暗号化を行った。

(図 1) 荷重拘束条件(立位条件)



(図 2) 荷重拘束条件(転倒条件)



### C. 研究結果

82 歳の大腿骨転子部骨折患者の解析例を提示する(図 3)。

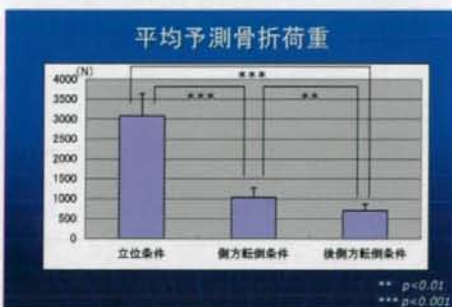
予測骨折荷重は、立位条件 3080 N(標準偏差(SD) 550 N)、側方転倒条件 1040 N(SD 236 N)、後側方転倒条件 700 N(SD 167 N)

であった。立位条件の予測骨折荷重は、側方・後側方転倒条件よりも有意に大きかった ( $p < 0.001$ )。側方転倒条件での予測骨折荷重は、後側方転倒条件よりも有意に大きかった ( $p < 0.001$ ) (図 4)。立位条件と側方転倒条件での予測骨折荷重の相関性は、 $r = 0.52$  ( $p = 0.01$ )、立位条件と後側方転倒条件では、 $r = 0.55$  ( $p = 0.006$ )、側方転倒条件と後側方転倒条件では、 $r = 0.67$  ( $p < 0.001$ ) であった。

(図 3) 予測骨折荷重・部位(白矢印の部分は、予測骨折部位)



(図 4) 平均予測骨折荷重



#### D. 考察

藤井ら (1987) は、Singh分類Ⅱ～Ⅲの骨粗鬆がある解剖用大腿骨を荷重方向を変えて各2検体ずつ計6検体行った結果を報告

した。それぞれ、立位荷重は2400 N、側方転倒条件では1400 N、後側方転倒条件では700 Nであった。立位条件、側方・後側方条件の順に強度は低下する傾向にあった。1検体につき、ある1方向からの骨折荷重しか求めることができず、同一検体における各荷重方向における骨折荷重の相関性は求めることができなかった。

Eksteinら(2002)の報告によれば、男女合わせた平均80歳の解剖用cadaverの大腿骨の垂直圧縮荷重の強度の平均3460 Nであった。

立位条件よりも側方転倒条件、側方転倒条件よりも後側方転倒条件が骨折危険度を高めた。また、各荷重・拘束条件間の予測骨折荷重の相関は有意であるが、相関性は低かった。大腿骨近位部の骨強度評価は、複数の荷重拘束条件から評価する必要があると示唆された。

#### E. 結論

三次元骨強度解析モデルを用いた大腿骨近位部の強度評価は臨床においても有用であると示唆された。

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## G. 知的財産権の出願・登録状況

(予定を含む。)

### 1.特許取得

なし

### 2.実用新案登録

なし

### 3.その他

なし

### Ⅲ 研究成果の刊行に関する一覧表



研究成果の刊行に関する一覧表

【H20. 4. 1～H21. 3. 31】

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
なし							

雑誌

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## IV 研究成果の刊行物・印刷



● *Original Contribution*

## A NEW METHOD FOR EVALUATION OF FRACTURE HEALING BY ECHO TRACKING

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TAKUYA MATSUMOTO,\* KOICHI MIYASAKA,<sup>†</sup> AKIMITSU HARADA,<sup>†</sup> SATORU OHASHI,\*  
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**Abstract**—Assessment of bone healing on radiographs depends on the volume and radio-opacity of callus at the healing site, but is not necessarily objective, and there are differences of judgment among observers. To overcome this disadvantage, a clinical system was developed to quantify the stiffness of healing fractures of the tibia in patients by the echo tracking (ET) method in a manner similar to a three-point bending test. The purpose of this study was to ensure that the ET system could clinically assess the progress, delay or arrest of healing. The fibular head and the lateral malleolus were supported. A 7.5-MHz ultrasound probe was placed on the proximal and distal fragments and a load of 25 N was applied. Five tracking points were set along the long axis of the ultrasound probe at intervals of 10 mm. With a multiple ET system, two probes measured the displacement of five tracking points on each of the proximal and distal fragments of the tibia, thereby detecting the bending of the two fragments generated by the load. ET angle was defined as the sum of the inclinations of the proximal and distal fragments. Eight tibial fractures in seven patients treated by a cast or internal fixation were measured over time. In patients with radiographically normal healing, the bending angle decreased exponentially over time. However, in patients with nonunion, the angle remained the same over time. It was demonstrated that the ET method could be clinically applicable to evaluate fracture healing as a versatile, quantitative and noninvasive technique. (E-mail: ohnishi-dis@h.u-tokyo.ac.jp) © 2008 World Federation for Ultrasound in Medicine & Biology.

**Key Words:** Ultrasound, Echo tracking, Fracture site stiffness, Fracture healing.

### INTRODUCTION

The most important issue in assessment of fracture healing is to obtain information about restoration of the mechanical integrity of the bone. In clinical practice, fracture healing is usually judged from serial radiographs. Assessment of bone healing on radiographs depends on the volume and radio-opacity of callus at the healing site, but is not necessarily objective, and there are differences of judgment among observers. In addition, radiographs cannot evaluate fracture site strength. In these respects, assessment of fracture healing by using radiographs is far from ideal.

The stated disadvantages of radiography for assessment of fracture healing have been pointed out in recent years, and various other methods of assessment have been developed. Jernberger (1970) devised an invasive

method for measuring the bending stiffness of healing fractures of the tibia. With his method, the proximal and distal bone fragments were fixed by screws that were connected to a specially designed beam, and a load was applied through a screw at the center of the fixing screws. The method was based on the principle governing the bending of two beams connected at the ends and subjected to a bending force applied at the midpoint. Burny et al. (1984) developed a method that used a strain gauge attached to a fixator shaft. With their method, the strain gauge readings were monitored over time during weight bearing, and the pattern of fracture healing was classified into seven categories (such as normal, delayed, arrested, etc.). Assessment using acoustic emission (AE) was developed by Nicholls and Berg (1981), who detected acoustic pulses generated by microscopic failure of the bone under loading. The investigation by Watanabe et al. (2001) revealed that AE signals occurred with the yielding of callus. However, the strain gauge method and the AE method have the disadvantage that both are limited to patients with external fixation, and both require the in-

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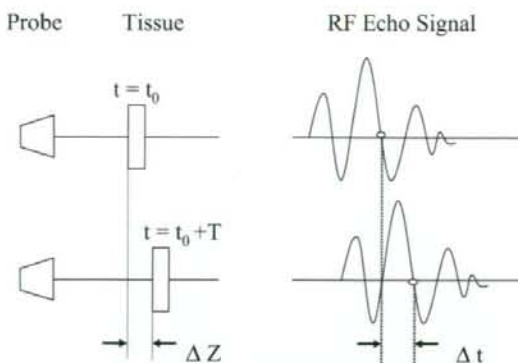


Fig. 1. The target tissue may move closer to or away from an ultrasonic probe over the distance  $\Delta Z$  during a pulse repetition time of ultrasonic waves ( $T$ ), causing phase delay of the RF echo signal ( $\Delta t$ ). The ET method measures the extent of this displacement by tracking the initialized phase pattern of the echo signal.

sersion of screw pins or wires. For these reasons, such methods have not been widely used and a new method is needed that is both noninvasive and widely applicable.

To overcome such limitations, we developed a new method for the noninvasive and quantitative assessment of fracture healing. Bone always undergoes deformation in response to an applied load. By quantitatively measuring this deformation, it is possible to assess the mechanical properties of bone and thereby estimate the strength of a fracture site. In this study, we attempted to noninvasively assess the bending stiffness of the healing fracture sites after applying a load. To measure bending stiffness, we focused on ultrasound because it is noninvasive. Precise measurement of the displacement of a specific point can be done by the echo tracking (ET) method. This method is a technique for measuring minute displacement of a certain point on a tissue by detecting a wave pattern in the radiofrequency (RF) echo signal reflected from the target tissue (Fig. 1) (Hokanson et al. 1972). To apply this technique for detection of bone deformation, we improved it so that displacement could be measured with an accuracy of  $2.6 \mu\text{m}$  (Matsuyama et al. 2006). We also developed a multi-ET system that was able to simultaneously track dynamic movement at multiple points on the bone surface. In our previous study of the three-point bending test using a porcine tibia, the strain gauge readings and the data from the multi-ET system showed an almost perfect linear correlation with the load ( $r = 0.998$ ). These results indicated the possibility of using the echo tracking method to detect bone surface deformation.

The purpose of this study was to determine whether our newly developed ET system could clinically assess the progress, delay or arrest of healing by detecting the

bending stiffness at the fracture healing site. Fracture healing was evaluated in patients with tibia fracture treated by a cast or internal fixation.

## METHODS

A clinical system was developed to quantify the stiffness of healing fractures of the tibia in patients by the ET method in a similar manner to a three-point bending test. Five tracking points were set along the long axis of the ultrasound probe at intervals of 10 mm. With a multiple ET system, two probes measured the displacement of five tracking points on each of the proximal and distal fragments of the tibia, thereby detecting the bending of the two fragments generated by the load. ET angle was defined as the sum of the inclinations of the proximal and distal fragments (Fig. 2). When callus was weak in the initial stage of healing, the tracked points were almost in a straight line and the inclination of the two fragments was calculated directly. However, when the callus was more rigid in the late stage of healing, the line connecting the points was curved and the inclination was obtained from the slope of the linear regression equation for the displacement of the points.

Before clinical application of this method, its accuracy was evaluated by measuring the inclination of the metal flat panel.

### Measurement of the accuracy of ET angle using an inclined flat metal panel

A flat stainless steel (SUS 420J) panel (length 270 mm, width 60 mm, thickness 5 mm) was used, which had a parallel accuracy and flatness variation of  $<2 \mu\text{m}$ . One end of the panel was attached to a magnet stand (DG, Noga Japan Ltd, Saitama, Japan), and the other side was attached to a goniometer (X13-001, Tsukumo Co. Ltd, Saitama, Japan) fixed to another magnet stand. Then, the

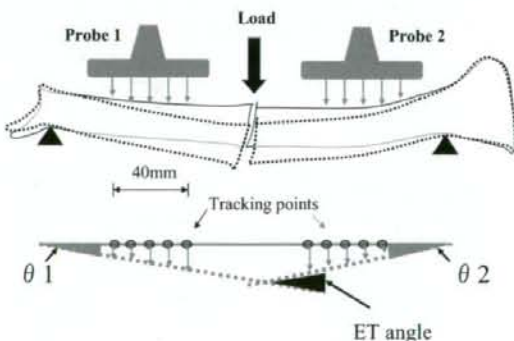


Fig. 2. Probes are set on each of the proximal and distal fragments of the tibia to detect the bending of the two fragments generated by a load. The ET angle is defined as the sum of the inclination of both fragments.



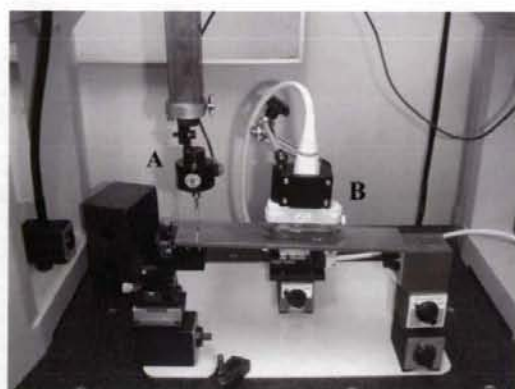


Fig. 3. The accuracy of the ET measurement was evaluated by measuring the inclination of the flat metal panel simultaneously using a 3-D measuring device. (A) 3-D measuring device; (B) 7.5-M Hz linear ultrasound probe.

metal panel was inclined by increasing the height of the goniometer stand. A 7.5-M Hz linear ultrasound probe (UST-5710-7.5, Aloka Co. Ltd., Tokyo) was set at a distance of 20 mm from the panel to measure the changes of displacement of each of five points on the panel (Fig. 3). Using these data, the ET angle of the panel was calculated. At the same time, the inclination of the panel was accurately measured using a 3-D measuring device (AE112, Mitsutoyo, Kanagawa, Japan) with an accuracy of 1  $\mu$ m. The panel was inclined by elevating the sliding mechanism of the stand by 0.4 mm and the inclination of the panel was measured 5 times, after which the mean and standard deviation were calculated. Accuracy was evaluated by calculating the standard deviation of the difference between the ET angle and the inclination measured by the 3-D measuring device in each of the measurement trials.

#### Clinical measurement of fracture site bending stiffness

Eight tibial fractures in seven patients with an average age of 37 y (range 24–69 y) were measured (Table

1). Two fractures of two patients were treated conservatively with a cast, and six fractures of five patients were treated by internal fixation (locked intramedullary nailing in 4, plating in 1 and screws in 1). The average measurement period was 40.8 wk (21–60 wk), and the average number of measurements was 7.5 (5–11).

Patients assumed the supine position with both knees extended, and the affected leg was held horizontal with the antero-medial aspect of the tibia upwards. The fibular head and the lateral malleolus were supported and held tight by a Vacufix (Murakami Medical Instrument Co., Ltd., Osaka, Japan) to avoid rotation of the leg during loading trials. Before measurement, B-mode images of the short axis of the proximal and distal fragments of the tibia were obtained to identify the center in both directions. By connecting both of the centers, the anatomical axis of the tibia was identified. A 7.5-MHz ultrasound probe was placed on the antero-medial aspect of each of the proximal and distal fragments in the long axis. Each probe was equipped with a multi-ET system with five tracking points at 10-mm intervals. The probes were set vertically on the skin of the leg and held tight with an articulated holder (DG61003, Noga Japan Ltd., Saitama, Japan). A load of 25 N was applied at a rate of 5 N/s and then reduced to 0 N at the same rate using a force gauge (DNP, Imada, Osaka, Japan) parallel to the direction of the probe at the most distal part of the proximal fragment adjacent to the fracture site (Fig. 4). For the initial measurement obtained in each patient, the loading point was set right on the long axis near the fracture site using a B-mode image as a guide. With this setup, the tibia was bent in the same way as for a three-point bending test in the direction of the ultrasound beam. In patients with oblique or spiral fractures, the loading point and the tracking points were set so that they did not cover the fracture site. In patients with a bone graft at the fracture site, the loading point was set on the graft, but the probes were placed so as not to cover it. In the patient with a plate, both the proximal and distal probes were set on the plate surface to measure bending of the plate. Using the multi-ET system, the probes

Table 1. Clinical cases of the tibial fracture

Case	Gender	Age	Limb	Treatment fracture healing	Measurement period (Initial-final)	Radiographic finding
1	F	24	L	Casting	4–47 wk	Normal
2	M	29	R	Casting	7–28 wk	Normal
3	M	23	R	Bone grafting	8–27 mo	Normal
4	M	31	R	Nailing	4–39 wk	Normal
5	F	57	R	Nailing	5–10 mo	Normal
6	F	57	L	Nailing	6–10 mo	Normal
7	F	26	R	Nailing	5 y 2 mo–5 y 7 mo	Nonunion
8	M	69	R	Plating	9–45 wk	Delayed

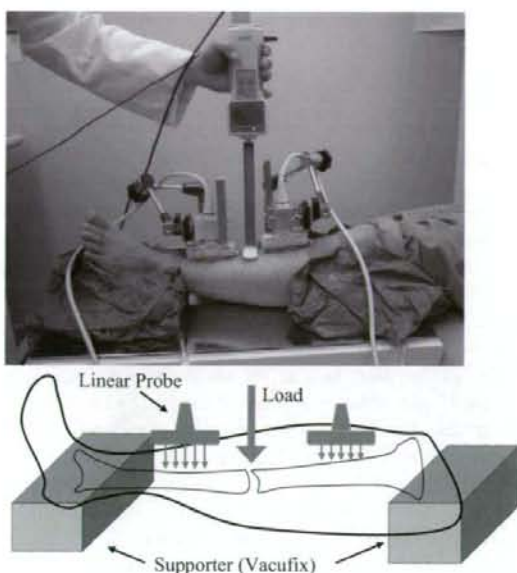


Fig. 4. The affected leg of a patient was held horizontal with the antero-medial aspect of the tibia upwards. The fibular head and the lateral malleolus were supported and held tight by a Vacufix. The probes were set vertically on the skin of the leg and held tight with an articulated arm. A load was applied using a force gauge parallel to the direction of the probe.

detected the angle between the proximal and distal fragments generated by the load. Measurement was repeated five times, and the mean and the standard deviation of the ET angle were calculated.

Fracture healing was assessed at intervals of two or three weeks until radiographic union or arrest of healing occurred. In each patient, the decrease of the ET angle was statistically examined to determine whether it decreased exponentially and whether the decrease was significant. To evaluate the changes of the ET angle over time, exponential regression analysis was performed, and the curve of the ET angle vs. time relation was drawn. Differences were considered significant when the  $p$  value was less than 0.05.

To investigate the influence of the position of the probes and the patient on the results, the precision of the method was evaluated by repeated measurement of the ET angle in a patient with a diaphyseal fracture of the tibia treated by a cast (case 2). In addition, the linearity of the relation between the load and the ET angle was assessed by incrementally increasing the load from 10 to 30 N. The ultrasound device (SSD 1000, Aloka Co. Ltd.) used in this investigation is used clinically and its safety has been established. The protocol of this investigation was approved by the ethics committee of The University of Tokyo Hospital, and the patients were enrolled after informed consent was obtained.

## RESULTS

### *Accuracy of ET angle measurement for a flat metal panel*

Measurement of the inclination of the flat metal panel showed that the average inclination was  $0.117^\circ$  and the standard deviation was  $0.002^\circ$ . The average inclination obtained with the 3-D measuring device was  $0.116^\circ$ , with a standard deviation of  $0.003^\circ$ . The standard deviation of the differences between the data obtained by the ET method and by the 3-D measuring device was  $0.002^\circ$ .

### *Clinical measurement of fracture site bending stiffness*

The average time required for measurement was 17 min (range 15–20 min). At each loading trial, none of the patients complained of pain and there were no complications related to measurement.

The precision of this method was evaluated by repeating measurement of case 2 (treated with a cast), with repositioning of the leg and the ultrasound probes. The mean and standard deviation of the ET angle were  $0.316 \pm 0.015$ , and the coefficient of variation was calculated to be 4.6%. The linearity of the relation between the load and the bending angle was very high, with a correlation coefficient of 0.997.

### *Cases presentation*

*Case 1: A 24-year-old-woman treated with a cast.* The patient sustained a spiral fracture of the proximal diaphysis of the tibia in a traffic accident, and a patella tendon bearing brace cast was applied. Healing was assessed by the ET method, as well as radiographs a total of 11 times from 4 weeks to 47 weeks after fracture. The fracture line became opaque and the callus volume increased from 4 weeks to 19 weeks, but after 26 weeks there was almost no change of the thickness of the callus. On the other hand, measurement showed that the ET angle was about  $1^\circ$  at 4 weeks, and that it decreased exponentially ( $y = 1.40e^{-0.105x}$ ,  $r = -0.975$ ,  $p < 0.0001$ ). The ET angles of both cases 1 and 2 treated with a cast decreased exponentially over time and they reached the level of the intact side by 22 weeks (Fig. 5a, b).

*Case 7: A 26-year-old-woman with a fracture of the diaphysis of the tibia treated by a locked intramedullary nailing.* ET measurement was performed five times from 5 y 2 mo to 6 y 7 mo after fracture. Her X-ray films showed hypertrophic nonunion, but judgment whether healing was proceeding was extremely difficult. ET measurement showed that there was no significant decrease of the angle over a period of 1 y and 5 mo ( $y = 0.264e^{0.002x}$ ,  $r = 0.238$ ,  $p = 0.700$ ) (Fig. 6a, b).



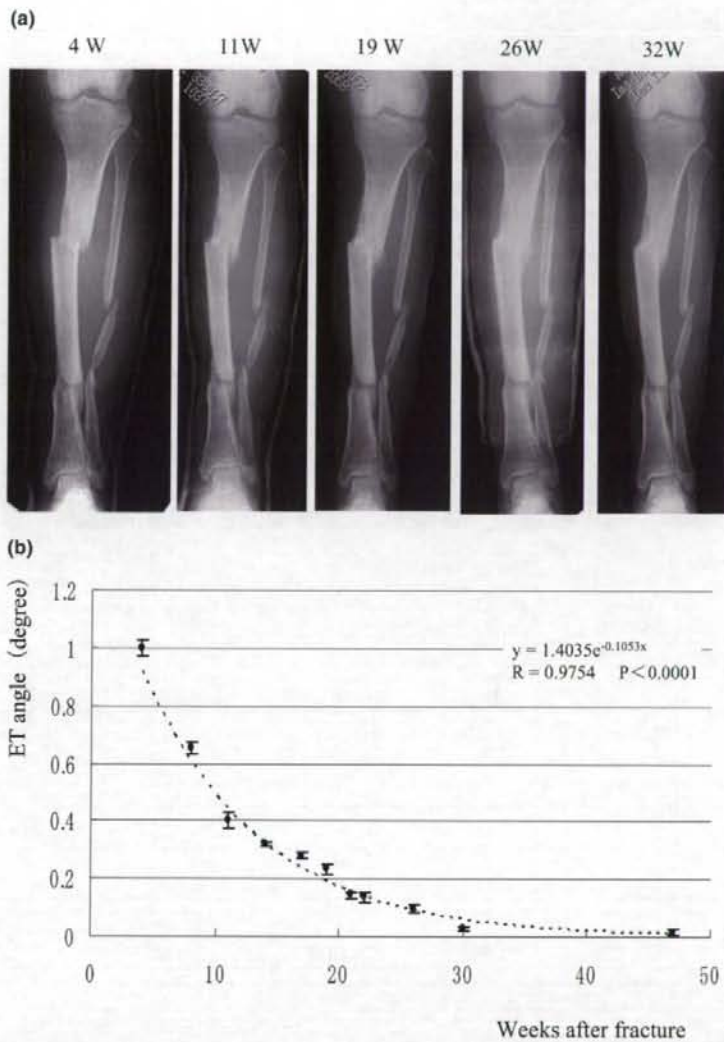


Fig. 5. (a) Time sequential change of the fracture site X-ray from 4 weeks to 32 weeks after fracture in case 1 treated with casting. The fracture site healed normally. (b) In the same patient, the ET angle was plotted. The ET angles decreased exponentially over time.

*Case 8: A 69-year-old-man with a long oblique fracture treated with a plate.* His X-ray films showed a long oblique fracture line extending for almost 80 mm. Measurement was performed 10 times from 9 weeks to 45 weeks after fracture, during which period almost no change of the fracture site or callus was recognized on X-ray films. The ET method measured the bending angle of the plate. The change was very slow, but the angle decreased significantly from 0.28 to 0.2 degrees, and then finally declined to 0.1 degree. The overall

change showed an exponential curve ( $y = 0.40e^{-0.030x}$ ,  $r = -0.895$ ,  $p = 0.0005$ ) (Fig. 7a, b). In patients with radiographically normal healing, the bending angle decreased exponentially over time (Fig. 8). However, in patients with nonunion, the angle remained the same over time.

#### DISCUSSION

Our method allows noninvasive assessment of bending stiffness at the healing site, so it can be appli-

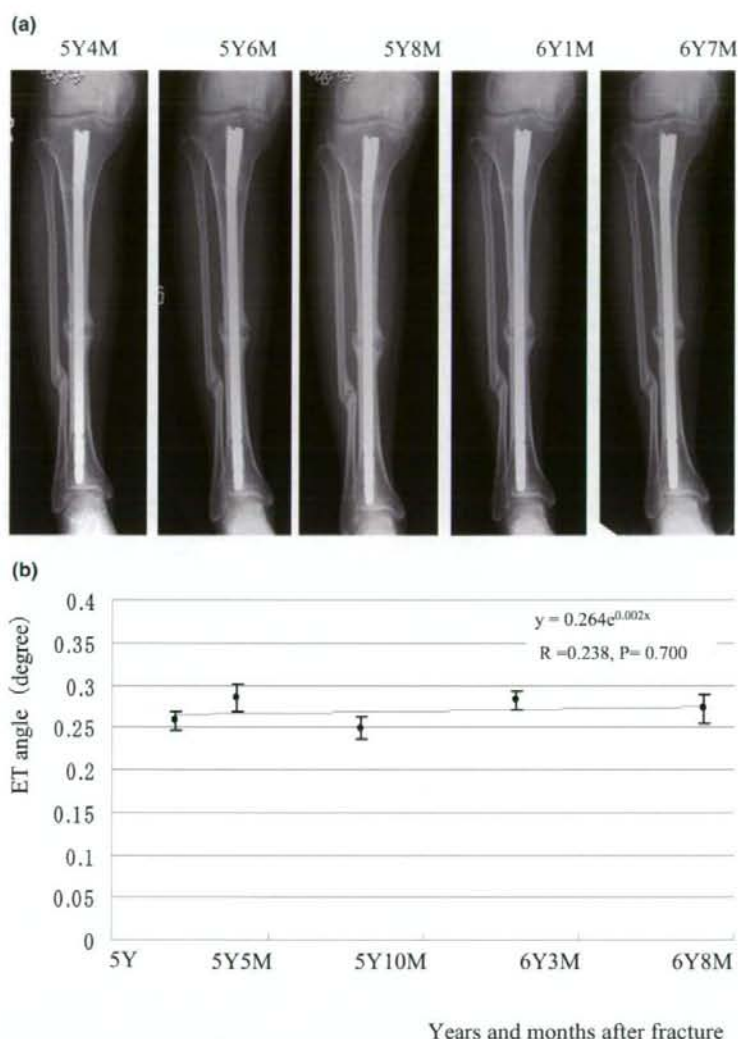


Fig. 6. (a) Time sequential change of the fracture site X-ray from 5 y 4 mo to 6 y 7 mo after fracture in case 7, treated with intramedullary nailing. The X-ray films showed hypertrophic nonunion, but judgment of whether healing was proceeding was extremely difficult. (b) In case 7, the ET angle showed no change over time and the regression lines showed no significant decrease.

cable to patients treated conservatively as well as those managed by surgical intervention with plating or intramedullary nailing.

In this study, the precision and reproducibility of the method were evaluated. The precision of measuring displacement by using the echo tracking system specially designed for bone surface measurement has already been assessed, and a precision of  $2.6 \mu$  was demonstrated in our previous study. However, the precision of measuring the bending angle has not been investigated before. We

obtained a precision of  $0.002^\circ$ , which was thought to be adequate based on the results of the study by Moorcroft et al. (2001) that evaluated fracture healing. They used the three-point bending test to generate angles of  $0.4$  to  $1.0^\circ$  in an *in-vivo* measurement trial and connected a goniometer to the bone fragment *via* screw pins fixed to a side bar of the external fixator to detect bending at the fracture site.

When estimation of the linearity of measurement was done in relation to the load, there was excellent



Fig. 7. (a) The X-ray films of case 8, treated with plating. No change of the fracture site or callus was recognized on X-ray films. (b) The ET method measured the bending angle of the plate. The change was very slow, but the angle decreased significantly from 0.28 to 0.2°, and then finally declined to 0.1°.

linearity between magnitude of the load and the ET angle ( $r = 0.997$ ), indicating that elastic deformation of the fracture site had occurred under a load range of 10 to 30 N. Therefore, measurement was shown to be noninvasive as well as safe, without causing any residual deformity.

Reproducibility of the measurement method was estimated to be  $0.015^\circ$ , which was adequate to evaluate fracture healing quantitatively, because the angle ranged from around  $1^\circ$  in the initial stage to about  $0.1^\circ$  in the final stage when it was almost equivalent to that of the intact tibia. However, we have to improve the reproducibility of measurement *in vivo*. The factors affecting reproducibility *in*

*vivo* include the position of the leg, loading direction and positions of the probes. Among these, the positioning or fixation of the leg seems to have the most influence on the reproducibility of measurement.

For clinical evaluation of fracture healing, data obtained by the ET method were compared with X-ray findings over time. In patients with delayed healing or nonunion, judgment of the healing process using X-ray films was difficult because the direction and conditions of obtaining images were not exactly the same every time, so the findings were not reproducible. In contrast, the echo tracking method evaluated fracture stiffness



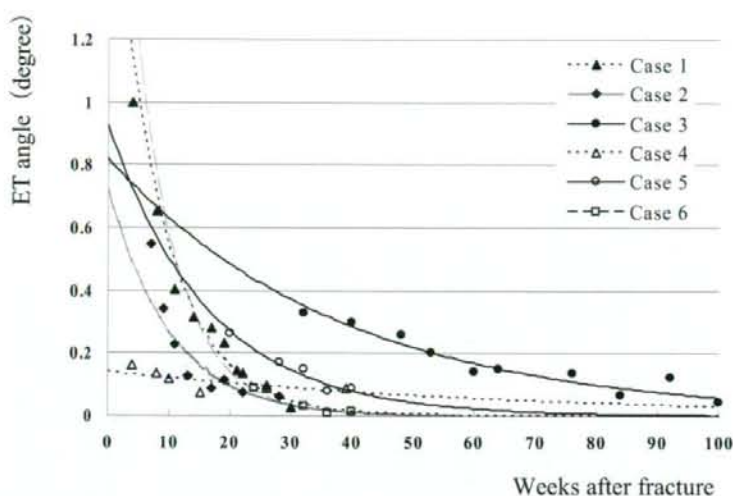


Fig. 8. In cases 1 through 6, the changes of the ET angle showed an exponential pattern. The correlation coefficients obtained by the regression equation for the ET angle and time were very high in these cases.

with considerable accuracy, sensitivity and reproducibility.

In patients with radiographically normal healing, the bending angle decreased exponentially over time. However, in patients with nonunion, the angle remained the same over time. According to the results obtained with previous methods such as the strain gauge method and the invasive method of Jernberger (1970), strain or deformation caused by loading at the healing site has been reported to diminish exponentially over time in patients with normal healing. Among these previous studies, Bourgois and Burny (1972) evaluated fracture healing in hundreds of patients treated with an external fixator that was instrumented with a strain gauge. They not only accumulated considerable clinical data on the strain readings over time, but also theoretically proved by mathematical simulation that the change of the strain over time during normal healing could be expressed as a typical hyperbolic curve. In addition to this, they proved that the time course of the change in strain could also be a hyperbolic curve by developing fracture simulation models with stabilization by intramedullary nailing, plating and external fixation. As a result, their clinical data were compatible with those for the theoretical model of external fixation. They classified the pattern of fracture healing into seven categories depending on the difference in the healing process. Among them, normal healing was defined as healing in which the strain reading vs. time curve reaches a plateau at 60 to 90 days after fracture. Slow healing was defined as healing in which the decline of strain was very slow compared with the

normal pattern but the healing process was progressive over time. Nonunion was defined as cessation of the progress of healing. In two patients treated with a cast in our study, the ET angle decreased rapidly until 10 weeks after fracture to a level twice that on the intact side, and then it decreased slowly. The exponential regression curve for the echo tracking angle vs. time showed a very strong correlation (case 1,  $r = -0.975$ ). Therefore, it can be concluded that the echo tracking method could be used to evaluate normal healing as proposed by Burny et al. (1984). As shown in Fig. 5, the progress of healing in patients treated with intramedullary nailing and bone grafting could be assessed by using the ET method. The ET angle vs. time relation in these cases was also expressed by exponential curves. However, the ET angle curve of patient 7 (Fig. 6b) did not show any significant decrease of the angle and there was no correlation between the ET angle and time. From this, the healing process was diagnosed as nonunion. The ET angle of patient 8, treated with plating, showed an extremely slow decrease over time from 9 weeks to 33 weeks, but reduction of the angle was statistically significant until 45 weeks, so the healing process was concluded to be delayed.

Fracture site stiffness was adopted as a parameter for evaluation that was thought to be correlated with strength of bone healing. In various earlier studies of fracture site mechanical properties, stiffness was measured to estimate the strength of the fracture site. However, stiffness is not necessarily correlated with strength. Chehade et al. (1997) investigated this relationship in 24



sheep. The tibia was stabilized with an external fixator and then osteotomy was done. Next, the tibiae were excised at 6, 8 and 10 wk after osteotomy and a 4-point bending test was done. As a result, in the initial stage of healing, stiffness showed a strong correlation with strength ( $r = 0.89$ ), but there was no correlation between them in the remodeling stage. However, as Chehade *et al.* (1997) stated, because the stiffness of the fracture site is strongly correlated with the strength until remodeling is initiated, it is clinically significant to monitor fracture site stiffness as a substitute for strength to determine the appropriate level of weight bearing so that patients can avoid refracture because of overloading the fracture site during postoperative management. In the remodeling stage, we need to pay special attention to the relationship between stiffness and strength, even if stiffness reached the same value as the intact side.

Fracture healing was evaluated quantitatively by the echo tracking method in patients treated conservatively as well as by internal fixation. All previous methods of assessment could only be applied to patients treated with an external fixator that required the insertion of wires or screw pins, and none of the methods could achieve evaluation in a totally noninvasive manner. The potential problem with evaluating patients treated with internal osteosynthetic devices such as intramedullary nails or plates is that the stiffness at the fracture site is the sum of stiffness for both the healing fracture and the implant. The stiffness of the implant is very high compared with that of the healing fracture because it is made of a metal such as stainless steel or titanium-aluminum-vanadium alloy. Therefore, the combined stiffness at the fracture site is usually very high compared with that in patients receiving conservative treatment by casting. In such patients with internal osteosynthetic devices, comparison of stiffness with the intact side does not have any meaning

for evaluation of fracture healing. Therefore, we have to be careful with interpretation of the changes of stiffness over time in such cases. How the implanted material and the configuration of stabilization affect fracture site stiffness should be investigated in the future so that we can assess fracture healing more precisely in patients with internal fixation.

In conclusion, it was demonstrated that the echo tracking method could be clinically applicable to evaluate fracture healing as a versatile, quantitative and non-invasive technique. Further development of this method should be performed so that it can be applied to other anatomical sites by improving accuracy and precision.

*Acknowledgements*—This work was funded in part by a grant from the Pharmaceutical and Medical Devices Agency of Japan.

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P91	<b>Prediction of strength and fracture location of the proximal femur by a CT-based nonlinear finite element method - Effect of load direction on hip fracture load and fracture site -</b>	<b>Masahiko Bessho, Isao Ohnishi, Matsumoto Takuya, Satoru Ohashi, Kenji Tobita, Juntaro Matsuyama, Koza Nakamura</b>
<p>Introduction: The aim of this study was to investigate the effect of load direction on fracture risk of the proximal femur. For this purpose, we evaluated changes in magnitude of strength for the proximal femur with changes in load direction by analyzing the contralateral femur in patients with hip fracture using a nonlinear CT/FEM.</p> <p>Materials and Methods: Twenty eight femora in female patients with contra-lateral hip fracture (age: 80 - 91, average: 85.2) (femoral neck fracture: 13 patients, trochanteric fracture: 15 patients). The study protocol was approved by our ethics committee and the patients were enrolled after giving informed consent. Axial CT images of the proximal femur of all patients were obtained as well as scans of a calibration phantom. The CT data were transferred to a workstation and 3D finite element models were constructed from the CT data using Mechanical Finder (Research Center of Computational Mechanics Inc., Tokyo, Japan) (Bessho et al., 2007). Force was applied to the femoral head at an angle <math>\gamma</math> to the shaft in the frontal plane and at an angle <math>\delta</math> to the neck axis in the transverse plane. For stance configuration (SC), <math>\gamma</math> and <math>\delta</math> were set at 160° and 0°. For fall configuration (FC), <math>\gamma</math> and <math>\delta</math> were set at 120° and 0° (FC1), 60° and 0° (FC2), 60° and 15° (FC3) or 60° and 45° (FC4), respectively. Predicted fracture load and predicted fracture site were analyzed. Predicted fracture type was compared with contralateral actual fracture type. Friedman test, Scheffe's post hoc test and Fisher's exact test were used for statistical analyses and the results were considered significant when p values were less than 0.05.</p> <p>Results: The average predicted fracture loads for SC was 3080 N (standard deviation (SD): 551 N), 2210 N (SD: 606 N) for FC1, 1047 N (SD: 236 N) for FC2, 970 N (SD: 199 N) for FC3 and 700 N (SD: 167 N) for FC4, respectively. The predicted fracture loads for FC2 were significantly higher than those for FC4 (<math>p &lt; 0.001</math>). The predicted fracture existed at sub-capital region in all patients for SC. The predicted fracture existed at the trochanteric region in all patients for all fall configurations except for FC1. On the other hand, the predicted fracture existed at sub-capital region or trochanteric region in all patients for FC1. For 20 patients, contralateral actual fracture type corresponded to predicted fracture type. Predicted fracture type corresponded significantly to contralateral actual fracture type (<math>p &lt; 0.01</math>).</p> <p>Discussion: If we assume that no morphological differences exist between right and left femora in each patient (Boston et al., 1982), the present study could contribute to providing us with useful information for the establishment of effective measures to prevent hip fractures.</p>		



第82巻

第3号

# 日本整形外科学会雑誌

NIPPON SEIKEIGEKAGAKKAI ZASSHI

The Journal of  
the Japanese Orthopaedic Association

Vol.82 No. 3 March 2008

Proceedings of the 81st Annual Meeting  
of the Japanese Orthopaedic Association



日整会誌

社団法人 日本整形外科学会

J. Jpn. Orthop. Assoc.

## 3-Po7-10

CT・CAD/有限要素法解析を用いた創外固定ピン  
応力の検討 —非対称ピンプロファイルはピンと  
骨の界面における応力集中を軽減する—

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創外固定ピンの loosening については、ピン-骨インターフェースの応力の集中が影響していることが示唆されている。単支柱式創外固定においてスレッド形状の異なるピンを用いた場合のピン刺入部の応力を検討するために、患者CTデータを基に有限要素法解析を行った。大腿骨変形治療患者に対して撮影したCT画像の健側大腿骨のデータを基に骨幹部中央を骨折部として骨欠損を作成した骨モデルと、CAD data を基に固定ピン4本(近位2本・遠位2本)を支柱により架橋する構造を創外固定モデルとを作成した。骨表面には0.4mm厚の3節点シェル要素を、骨内部、創外固定器およびピンには0.5-24mmの四面体要素を使用し、octree法によってmeshingを行った。骨は不均質材料とし、材料特性を各要素の位置に対応するCT値から個々に算出した。ピン、固定器はいずれも均質材料としてそれぞれチタン合金、ステンレス鋼の材料特性を割り当てた。3種類のピンを用いて2種類の固定モデルを作成した。1つはすべてのピンにスレッド形状が対称のピン( $\beta = \gamma = 22.5^\circ$ ) ( $\beta$ はピンスレッドのピン先端側の面とピン軸の垂面とのなす角、 $\gamma$ は同様にピンスレッドのピン尾側の面と垂面のなす角)を用いた対称ピン群モデルであり、もう一方は最近位および最遠位のピン(アウトターピン)にtype Aピン( $\beta = 40^\circ$ ,  $\gamma = 5^\circ$ )、骨欠損部に近接するピン(インナーピン)にtype B( $\beta = 5^\circ$ ,  $\gamma = 40^\circ$ )の非対称ピンをそれぞれ用いた非対称ピンモデルである。大腿骨頭より機能軸方向へ500N荷重を加え大腿骨遠位端を完全拘束し弾性解析を行った。両ピン群モデルにおいてピン刺入部の応力集中はアウトターピンでみられたが、最大相当応力は対称ピン群モデル(167.8MPa)よりも非対称ピン群モデル(137.6MPa)の方が低下していた。非対称ピンを最適位置に刺入することで個々のピンおよび創外固定全体の骨折固定力が向上すると考えられる。

東大大学院整形

## 3-Po7-11

CT/有限要素法による非線形解析を用いた大腿骨  
近位部の強度評価 —荷重・拘束条件の相違による  
予測骨強度・部位の相違について—

別所 雅彦 大西 五三男 松本 卓也 大橋 暁  
飛田 健治 松山 順太郎 中村 耕三

本研究の目的は、大腿骨近位部骨折患者の非骨折側の大腿骨近位部の三次元CT非線形有限要素解析を行い、荷重方向の相違による予測骨折荷重を定量的に予測し、同時にその骨折部位の局在を明らかにすることにより、本方法の有用性を検討することである。

対象は、女性の大腿骨近位部骨折患者28名(平均85.2歳)(頭部内側骨折13例、転子部骨折15例)。倫理委員会の承認のもと患者の同意を得て、定量的CTを撮像し、非骨折側の三次元骨強度解析モデルを作成した(Bessho et al., 2007)。骨頭への荷重方向は、前額面において骨軸から $\gamma$ 度、横断面において頸部軸から $\beta$ 度前方方向に傾斜した荷重をかけた。立位を模擬した条件( $\gamma 160^\circ \delta 0^\circ$ ) (立位条件)、転倒を模擬した条件、転倒条件1( $\gamma 120^\circ \delta 0^\circ$ )、転倒条件2( $\gamma 60^\circ \delta 0^\circ$ )、転倒条件3( $\gamma 60^\circ \delta 15^\circ$ )、転倒条件4( $\gamma 60^\circ \delta 45^\circ$ )を設定し、非線形解析を行い予測骨折荷重・予測骨折部位を解析した。予測骨折部位と対側の骨折型とを比較した。統計処理は、Fisher's exact testを用い、有意水準を0.05以下とした。

予測骨折荷重は、立位条件3080N(標準偏差(SD)551N)、転倒条件1、2210N(SD606N)、転倒条件2、1047N(SD236N)、転倒条件3、970N(SD199N)、転倒条件4、700N(SD167N)であった。骨折部位予測は、立位条件では全例に頸部骨折が発生し、転倒条件1を除く転倒条件では、全例に転子部骨折が発生した。転倒条件1では、頸部骨折と転子部骨折の両者が予測され、実際の骨折型と予測骨折型が一致したものは20例と、実際の骨折型と予測骨折型とにおいて有意な関連があった( $p < 0.01$ )。

大腿骨の形態学的特徴に左右差がない(Boston et al., 1982)と仮定すると、立位条件や転倒条件1を除いた転倒条件では、方向のみで骨折型が決定する可能性があった。一方、転倒条件1では、個々の患者の形態的相違によって異なる骨折型が発生する可能性が示唆された。本研究は、大腿骨近位部骨折をより効率よく予防する対策を確立するために資する知見を得ることに貢献すると考える。

東大整形