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Monitoring and healing analysis of 100 tibial shaft fractures

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Abstract *Background:* We assessed the value of measuring biomechanical stiffness by assessing the fixator's external deformation as an objective means for monitoring fracture healing and determining the postoperative treatment regime, as compared to clinical and radiographic means of evaluation. *Patients and methods:* One hundred patients with tibial shaft fractures managed by unilateral external fixation had their fracture stiffness monitored. Stiffness was measured and clinical and radiological examinations were performed every 3–4 weeks. *Results:* The time required for healing as indicated by stiffness measurement was an average of 2.5 weeks earlier than by radiological assessment. Eighty-two patients healed within 19 weeks (12.1±3.3 weeks) and ten patients in the following 6 weeks (24±4.3 weeks). Eight patients did not show an increase in fracture stiffness and received intramedullary nailing at a second operation. The average healing time was 11.3±4 weeks for type A, 13.1±3.6 weeks for type B fractures, and 15.1±5.9 weeks for type C fractures. The healing time for closed fractures was 11.3±3.2 weeks and for open fractures 14±4.9 weeks. *Conclusions:* The measurement of fracture stiffness allows the detection of patients at risk for nonunions. The healing time increased with increasing fracture gap size and was less in patients with younger age, less complex fractures, and lesser degrees of soft tissue damage.

Keywords Fractures · Monitoring · Healing

Introduction

The assessment of fracture healing is subjective, and neither radiology [1] nor manual [2] examination allows a reliable determination of bone healing. An objective determination of the biomechanical stiffness of the healing bone would be a very appropriate measure of fracture healing status. The measurement of fracture stiffness is feasible particularly for fractures treated operatively by external fixation. In contrast to internal fixation techniques by plates and interlocking intramedullary nails, the axial interfragmentary movement is not blocked by implants which cross the fracture site.

Several methods of fracture stiffness measurements under external fixation have been reported by several groups [3, 4, 5, 6, 7]. The principle of this measurement is based on an applied load which is transmitted through the fixator and the bone healing region. As the fracture heals, more load is transferred by the bone and less by the fixator, leading to a reduced load at the fixator. In contrast to this indirect measurement of fracture stiffness, other groups have removed the fixator for each measurement and measured the fracture stiffness by applying a load to the bone, measuring the deflection [8] and calculating the stiffness. They found that no refracture or angulation occurs when the fracture stiffness exceeds 10 Nm/degree [8] and proposed a bending stiffness of 15 Nm/degree as a safe threshold value at which the fixator can be removed and the leg functionally loaded. However, this measurement technique is time- consuming, not possible in the first weeks after fracture, and impractical under routine clinical conditions.

In addition to enabling the monitoring of fracture healing, an objective method for the assessment of fracture healing would allow the analysis of the effects of various factors on the fracture healing process and would be helpful in determining the best postoperative treatment regime. The aim of our multicenter study was to answer the following questions: Does the healing time determined by clinical and radiological assessment differ from the healing time determined by stiffness measurement? Is it possible to detect early whether the healing process of a fracture is delayed when using external fixation? What is the effect of the quality of reduction of the fragments on the healing time? What is the effect of the complexity of the fracture and the severity of the soft tissue damage on the healing time?

Patients and methods

This prospective multicenter study included 130 patients with fractures of the tibial diaphyses managed by unilateral external fixation (University Hospital in Ulm, Military Hospital in Ulm, BG Trauma Clinic in Ludwigshafen, and St. Georg Hospital in Hamburg, Germany). Patients with infected fractures and pathological fractures were excluded. The severity of the injuries was classified for the type of fracture (Association for the Study of Internal Fixation classification) [9] and soft tissue damage (Gustilo and Anderson classification [10]).

Several different external fixation systems have been used at the ventral or ventromedial site of the tibia, particularly the Arbeitsgemeinshaft für Osteosynthesefragen (AO) tubular system and the Unifix (both from Synthes, Chur, Switzerland) and Orthofix (Orthofix Srl, Bussolengo, Italy). Fixators are usually applied on the day of injury and in a few cases within the first week after injury.

The patients were followed up with measurements of the fracture callus stiffness for up to 24 weeks. External fixator frames were removed when radiological and clinical findings were considered to show union.

Complete data on 100 patients could be recorded and evaluated. Twenty-five patients did not attend follow-up because their final treatment and removal of the external fixator frame were carried out in other hospitals, and five patients showed significant loosening of Schanz' screws which made the measurement impossible. Of the 100 patients 37 had type A, 45 type B, and 18 type C fracture [9]. There were 39 closed fractures, 21 open I, 28 open II, and 12 open III fractures. In 80 patients the fibula was fractured in addition to the tibia. In 36 (45%) of these patients the fibula was stabilized by a plate. Seven patients had sustained multiple injuries as well as the tibial fracture, and six developed a compartment syndrome. Nine patients received an autogenous bone graft in a second operation. The main reason for this operation was a large fracture gap (mean 8.6 mm).

Radiography was performed approximately every 3–4 weeks in the sagittal and frontal planes and analyzed by two experienced surgeons from each clinic independently of each other. The fracture was defined as radiologically healed when three of four cortices in the two radiographic planes were bridged by callus formation. The reduction of the fragments was determined with regard to the angulation of the fragments in the frontal and sagittal planes. Slides from radiographs of both plans of the fracture were projected to obtain a of ×5 of the fracture zone. The gap size at the location of the largest gap between two cortices and the ad latus displacement was measured using a ruler.

Measurement of stiffness

The stiffness of the fracture site was measured indirectly from the deformation of the external fixator under load [6]. With a fresh fracture involving a fracture gap the load is mainly carried by the external fixator system which leads to a certain deformation. This deformation can be measured using a special electromechanical device (Fraktometer FM 100, Hug, Freiburg, Germany) with a digital electronic gauge and a peak value memory [6]. With increasing callus formation and bone healing more load is transferred by the fracture site, and consequently the load at the fixator decreases. This leads to a decrease in the signal measured by the Fraktometer. Thus the decreasing Fraktometer signal indicates an increasing fracture stiffness.

If the fracture ends were not ideally reduced or associated with a fracture gap, an axial load of 10–30 kg (depending on the fracture fixation stiffness) was applied for the measurement and then kept constant for all measurements (Fig. 1). If the fracture ends were in contact, the fragments could transfer loads and would show only very small signals on the measuring device. In these cases a bending moment was applied to create an opening of the fracture site and a deformation of the external fixator. The bending moment was created by lifting the leg about 15 cm at the heel, with the patient lying on his/her back. The measurements were performed approximately every 3 weeks. The measurements were performed three times, and the mean of the three measured signals was used for the study. For graphic presentation (Figs. 2, 3, 4, 5, 6) of differences between groups the individual healing times of patients were grouped into healing periods of 3 weeks each. The numerical results of the measurement under standardized loads depended on the stiffness of the fixator and ranged between 0.15 and 0.9 mm. However, the measurement must always be taken between the same pins and at the same location to avoid differing signals. This repeatability was ensured by special clamps connected at the pins and allowing standardized application of the Fraktormeter during the whole monitoring period.

To compare the measurements for the different patients the first postoperative signal was defined as 100% and the following signals measured during the healing process were expressed as a percentage of the postoperative value. Fractures were defined as

Fig. 1 Axial loading of a tibial fracture stabilized by an Unifix external fixator instrumented with a Fraktometer FM 100 for measurement of fixator deformation (indirect measurement of fracture callus stiffness)

clinically healed when the fixator was removed and as healed by stiffness measurement when the signal was below 10% of the initial postoperative signal. The 10% threshold was chosen because calculation regarding load sharing between fixator and fracture healing zone showed that the sensitivity of the measured signal declines when the fracture stiffness reaches high values. However, when the initial postoperative signal was small, the 10% treshold would be below the accuracy of the Fraktometer. In this case 0.05 mm was chosen as a threshold because this was the accuracy of the measuring device.

Fractures which did not heal within 19 weeks were defined as delayed.

Clinical treatment

The general treatment regime allowed partial loading of the operated leg using crutches for the first 2 weeks. Increasing load was then advised for the patients and should have led to full load bearing after about 4 weeks. One hospital (BG Ludwigshafen) removed one tube of the double-tube unilateral AO fixator after 4 weeks to achieve a lower stiffness of the fixator and a higher loading of the fracture sited (dynamization). For this group of patients the measurement of fracture stiffness was performed with one fixator tube unlocked for the time of measurement to achieve comparable mechanical condition before and after the removal of the second tube. After the fractures were united by clinical definition, the fixators were removed, and the patients were encouraged to ambulate normally. In nine cases a brace was applied after fixator removal to protect the healed fracture from overloading.

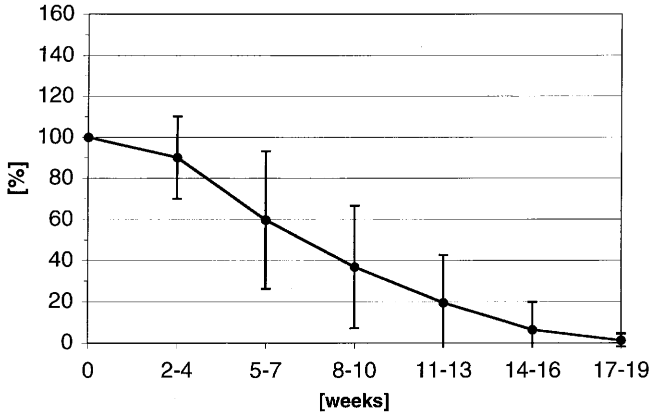


Fig. 2 Decrease in fixator deformation with healing time (corresponding to increase in fracture stiffness) of the "normal healing population" (n=82, mean values, standard deviation for the various healing periods)

Statistics

Mean and standard deviations were calculated. The Wilcoxon test was used to identify significant differences between two groups (Stat View, Abacus, Calif., USA). The level of statistical significance was set at P=0.05.

Results

There was a strongly positive correlation between the measured healing time and the clinically assessed healing time (r=0.83). The time for healing indicated by the stiffness measurement was an average of 2.5 weeks earlier than by clinical assessment. The difference in time defined by clinical and radiological assesment vs. by stiffness measurements ranged from 0 to 11 weeks. Eighty-two patients healed within 19 weeks (normal healing population, average healing time 12.1±3.3 weeks) and 10 more patients in the following 6 weeks (delayed healing population). The course of the measurement signal for the "normal healing population" is shown in Fig. 2. After 3 weeks a steady decrease in the fixator signal was seen which indicates a steady increase in fracture stiffness (n=82). The "delayed healing population" (n=10) still showed after 18 weeks an average signal of about 30% of the postoperative values after 19 weeks. However, they healed within the following 6 weeks (average healing time 24±4.3 weeks, Fig. 3).

Eight patients were operated on for a second time by intramedullary nailing because they did not demonstrate significant radiological signs of healing, and the stiffness measurements did not show a significant increase in fracture stiffness. The operation was performed between the 12th and 21st postoperative weeks. These eight patients can be subdivided in two groups. One group of five "nonresponding" patients showed only little changes

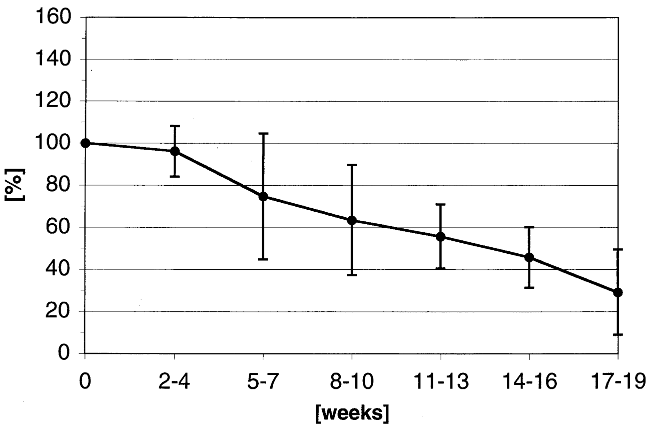


Fig. 3 Course of fixator deformation with healing time for the "delayed healing population" (*n*=10, mean values, standard deviation for the various healing periods)

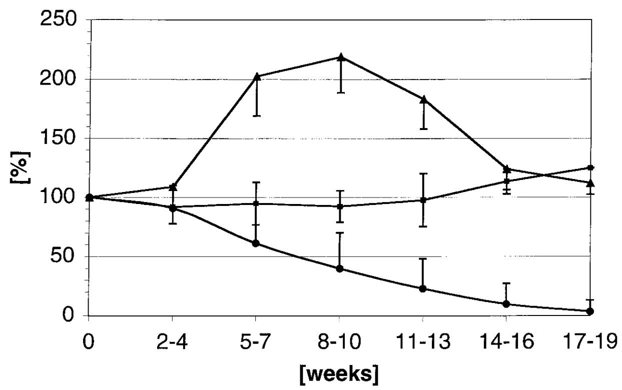


Fig. 4 Comparison of the fixator signal for all patients healed under external fixation (*n*=92, bottom curve), the "nonresponder group" (*middle curve*, *n*=5) and the patients with significant increase in fixator signal (*top curve*, *n*=3) (mean values, standard deviations for the various healing periods)

in the measured signals, and this group on average did not decrease from the initial postoperative signals (Fig. 4). The other group of three patients showed a significant increase in the signal (decrease in fracture stiffness) from week 5 to week 13 (Fig. 4) and a signal which remained above the initial postoperative values even after 17–19 weeks of treatment. Their individual signals after 5–7 weeks (150%, 211%, 246%) were above the 95% confidence interval (2 SD) of the normal healing group, the signal of the delayed healing group, and the signal of the "nonresponder" group.

Of the 92 patients who healed under external fixation treatment (average healing time 12.9±4.4 weeks) the average healing time was 11.3±4.0 weeks for type A fractures, 13.1±3.6 weeks for type B fractures, and 15.1±5.9 weeks for type C fractures. The healing time, however, differed substantially in individual patients. This was demonstrated by the frequency distribution of the healing times for the various fracture types (Fig. 5). The majority of type A fractures healed within 8–16 weeks and most of the type B fractures within 11–19 weeks. However, there were seven patients with type A and eight patients with type with B fractures who needed even more than 19 weeks. Type C fractures showed a shift of seldom the frequency distribution towards the longer healing periods. The very rapidly healing fractures were mostly those of young patients. There was, however, no statistical correlation between healing time and age of the patients. For a group of 13 young patients with an age of 14 years or younger (mean 11.8), the healing time of type A and type B fractures averaged 9.4±2.3 weeks, whereas a group (n=11) of patients aged over 50 years (mean 57.2) showed an average healing time of 11.8±1.8 weeks (P=0.013).

The healing time for all 92 healed fractures was 12.9±4.4 weeks, and for the 79 patients aged over 14 years 13.5±4.4 weeks. The healing time of all closed

Fig. 5 Frequency distribution of healing times for various types of fractures

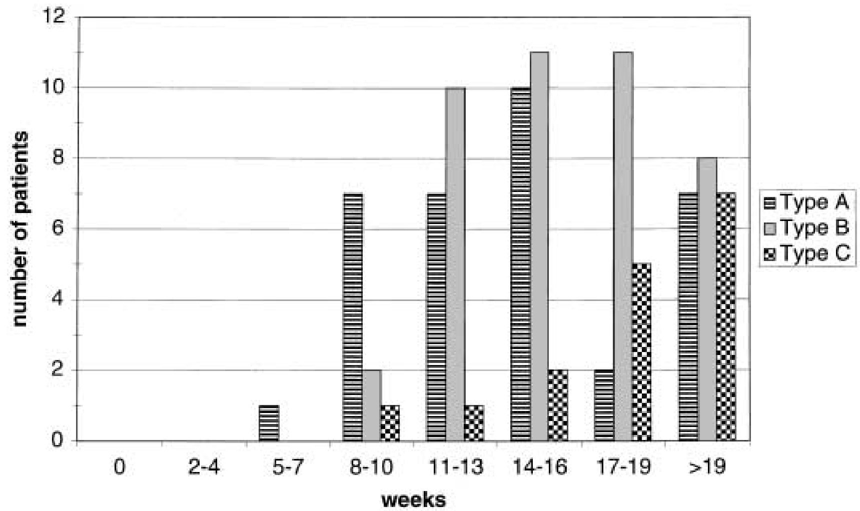


Fig. 6 Healing time for groups of different fracture type and soft tissue damage

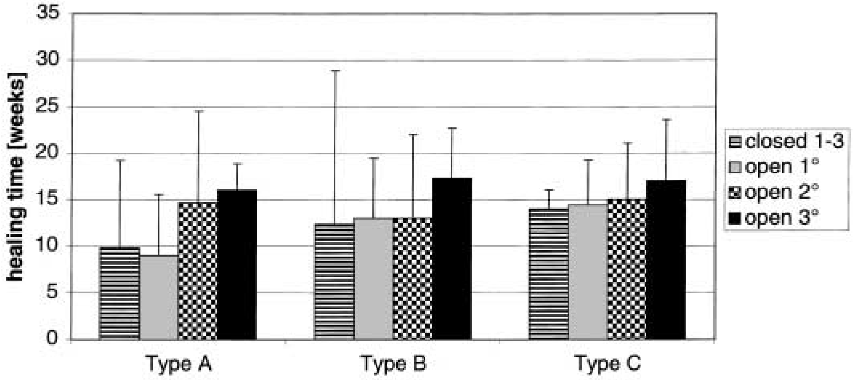
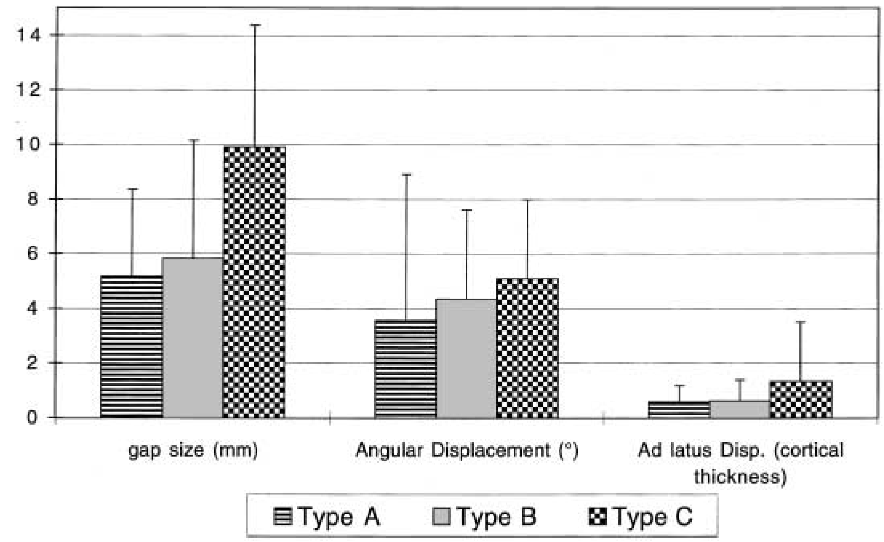


Fig. 7 Reduction of the tibial fractures for type A, type B, and type C fractures



fractures was on average 11.3±3.2 while the average healing time of all open fractures was 14.0±4.9 weeks. However, it was only for the simple type A fractures that there seemed to be a tendency of increasing healing time with increasing severity of soft tissue damage (Fig. 6) while this tendency was not observed for type B and C fractures.

The average reduction of the fractures with regard to the axial alignment and the lateral displacement is shown in Fig. 7 and was more precise for the simple type A fractures than for complex type C fracture. However, the maximal fracture gaps showed surprisingly large values (Fig. 7) for some of the patients, even for the simple fractures. The wide individual variations did not allow the finding of a statistically significant correlation between the healing time and the fracture gaps. However, there was a tendency to increasing healing time with increasing fracture gap size, and most of the rapidly healing fractures never had larger fracture gaps. The largest fracture gaps were found for the type C fractures (Fig. 7). When we excluded these severe injuries and selected the type A and type B fractures with gaps of 3 mm or less (n=19) and those of 10 mm or more (n=10), we found a significant differences (P=0.02, Wilcoxon test) in healing time. The average healing time was 12.3 weeks for fractures with gaps of 3 mm or less (n=10) and 20.0 weeks for the fractures with gaps of 10 mm or more (n=10).

Discussion

The measurement of fracture stiffness by determining the fixator's external deformation using the Fraktometer FM 100 is an easy and objective method for monitoring the healing process under clinical conditions. In contrast to most of the other systems which require strain gauge instrumentation of each individual fixator an amplifier and main electrical supply, one Fraktometer can be used for all fixators; it is easy to clamp on and is cordless (battery).

The method of stiffness measurement revealed the healing on average about 2.5 weeks earlier than the radiological assessment. The use of the stiffness measuring technique would therefore allow shortening the treatment time, which might be useful for the patient and the overall costs for the treatment. The typical course of fracture healing was indicated by a steady decrease in fixator deformation starting about 3 weeks postoperatively, which corresponds with an increase in fracture stiffness. A prediction as to whether a fracture will heal or is likely to develop a nonunion appeared to be possible at about weeks 5–7 ($P<0.05$). From this time onward the values of the three patients with increasing signals (Fig. 4) were always above the 95% confidence level (2 SD) of all groups which healed. This allows the decision as to whether the fracture would heal under external fixation, or whether the type of fixation, i.e., an intramedullary nailing, should be changed. The five "nonresponding" patients (Fig. 4) showed a different course of the signals than the "normal healing" group (Fig. 4). Differences between these two groups, however, occurred only from weeks 8 to 10 onwards at a confidence level of 66% (1 SD).

Such predictions could avoid extremely long treatment times which, however, will ultimately not lead to a fracture healing under external fixation. However, most surgeons today prefer an early change in treatment to avoid pin tract infections. Unfortunately, within the first 3 weeks of healing the measured signals of the normal healing population and the other patients (Fig. 4) did not show any difference and cannot be used for making an early decision. Therefore the measurement of fracture stiffness makes sense only if the healing under external fixation is the primary aim. When this strategy was chosen, however, 92% of the patients healed under external fixation within a reasonable period (in average 12.7 weeks). Most of the eight patients who underwent a second operation would probably have healed under external fixation in a reasonable time if an early reduction of large fracture gaps (average 8 mm) or an early autogenous bone grafting had been performed. The importance of the fracture gap for the healing time was demonstrated in an animal study recently [11]. For large fracture gaps a normal healing rate was achieved neither under flexible nor under stable fixation conditions [11]. Although the linear correlation between gap size and healing time was not statistically significant, the differences between groups of small and large gap sizes were statistical significant ($P<0.02$). It is clinically well known that bone defects (fracture gaps) delay bone healing.

This experimental and clinical evidence suggests that a good reduction of the fracture fragments is important. A possible explanation of the remarkably large fracture gaps in some patients is that external fixators are most often applied in emergency patients with multiple other severe injuries with a higher priority in treatment. The most frequently used AO double-tube external fixation system used in this study did not allow a secondary reduction of the fragments after the operation. Contemporary external fixators with hinge or ball joints would allow such a postoperative reduction.

When comparing studies on fracture healing under external fixation, it is important to assess the different proportions of fracture types, soft tissue damage, and other injuries described for each study. However, studies of similar proportions of about two-thirds of open fractures show similar or longer healing times of 16.7–26.5 weeks [12, 13, 14]. In our study the average measured healing time was 12.7 weeks, and 15.3 weeks by clinical and radiological assessment. The proportion of fractures with healing times longer than 16 weeks was 15% in our study and 10–17% in other studies [12, 13, 14]. In these studies the proportion of nonunions (more than 8 months treatment time) was 2–8.8%. In our study the 8% of patients who did not respond or showed an increase in signal were operated on before an 8-month period. Therefore it is not clear whether all of them would have developed nonunions. The increase in healing time with increasing complexity of the fracture (type A, 11.3 weeks; type B, 13.1 weeks; type C, 15.1 weeks) was similar to that reported by other authors [13] when we take into consideration that our measured data indicated the healing about 2.5 weeks earlier than the data achieved by radiological assessment. We found a healing time that averaged 2.7 weeks longer for open fractures than for closed fractures, which is comparable to the findings of another study [13] which found a 3-week difference.

Although the Fraktometer measuring system is a very helpful tool for the objective determination of the fracture healing process, there are also some limitations. The main limitation of the measurement system is the possible loosening of the pins chosen for the Fraktometer application. Five patients had to be excluded from the study because of this complication. Whether a pin becomes loose, however, can be tested and erroneous signals excluded. If the Fraktometer is applied with the leg in an unloaded position, manual bending of the pin leads to a significant Fraktometer signal if the pin is loose. Another limitation is that the system allows a sensitive determination of fracture stiffness in the early healing phase but not in the late healing phase. In the late healing phase the fracture stiffness is high and only small loads/deformations occur at the fixator. However, the steady decrease in signals even in the late healing phase and the good correlation between measured healing periods and radiologically and clinically assessed healing periods indicate a sufficient sensitivity. Very stiff external fixator arrangements may lead to larger measurement errors in the determination of the healing time because the 10% Fraktometer signal used for prediction of the healing time might be below the accuracy of the measurement system (0.05 mm). In general it is not the absolute value of the Fraktormeter signal but the course of the changing signal that is the best indicator of the healing process.

As with all clinical studies, we found great individual differences in the healing course. This can be explained by the fact that healing process is affected by a number of factors that differ from one patient to another. However, this study allows us to draw some conclusions. If it is planned to treat the fracture with external fixation, the indirect measurement of fracture stiffness by measurement of external fixation deformation is possible and allows the detection of patients with a risk for nonunions. The measurement signals give objective data and detect a healing to have occurred earlier than with the use of radiological assessments.

The main factor that affected the time of healing, and that can be influenced by the surgeon is the fracture gap, which remains after attempted reduction of the fragments. Large fracture gaps which delay the healing process can be avoided by using contemporary types of fixators which allow a better reduction of the fragments. This would significantly reduce the relatively long healing times for some of the patients and the necessity of reoperation.

As found in other studies, the more complex fractures and the more severe soft tissue damage increased the healing time. Our findings indicate that the number of reoperations after external fixation could be reduced if a better reduction of the fragments could be achieved. If the number of reoperations can be reduced, and the healing time is similar for the intramedullary nailing and external fixation [14], the question remains open whether there is a need to perform an intramedullary nailing so soon after an external fixation.

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