■ TRAUMA

Telemetric assessment of bone healing with an instrumented internal fixator

A PRELIMINARY STUDY

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In an interdisciplinary project involving electronic engineers and clinicians, a telemetric system was developed to measure the bending load in a titanium internal femoral fixator. As this was a new device, the main question posed was: what clinically relevant information could be drawn from its application? As a first clinical investigation, 27 patients (24 men, three women) with a mean age of 38.4 years (19 to 66) with femoral nonunions were treated using the system. The mean duration of the nonunion was 15.4 months (5 to 69). The elasticity of the plate-callus system was measured telemetrically until union. Conventional radiographs and a CT scan at 12 weeks were performed routinely, and healing was staged according to the CT scans. All nonunions healed at a mean of 21.5 weeks (13 to 37). Well before any radiological signs of healing could be detected, a substantial decrease in elasticity was recorded. The relative elasticity decreased to 50% at a mean of 7.8 weeks (3.5 to 13) and to 10% at a mean of 19.3 weeks (4.5 to 37). At 12 weeks the mean relative elasticity was 28.1% (0% to 56%). The relative elasticity was significantly different between the different healing stages as determined by the CT scans.

Incorporating load measuring electronics into implants is a promising option for the assessment of bone healing. Future application might lead to a reduction in the need for exposure to ionising radiation to monitor fracture healing.

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doi:10.1302/0301-620X.94B3.27550 $2.00

J Bone Joint Surg Br 2012;94-B:398–404.
Received 24 May 2011; Accepted after revision 17 November 2011

Modern advances in micro-electronics have enabled collaboration between electronic engineers and clinicians to develop an efficient low-cost small mechanical measurement system to use with an internal fixator.[1] As with every new development, it is necessary to define what clinically relevant information can be drawn from its application.

Bone healing is typically monitored by the evaluation of sequential radiographs. Clinical experience as well as scientific investigation has shown substantial inter-observer variability in judging healing.[2] In nonunions, variations in the radiological projections used can make it difficult to monitor bone healing; this can be overcome with CT assessment.[3] The main problem of all methods of imaging is that judgement is based on visible calcification, whereas the clinician needs information about the mechanical properties of the bone. As the stiffness of fracture callus increases over time,[4] one solution is to monitor this property.

The aim of our prospective study was to analyse the information gained by the telemetric instrumentation of femoral locked plates in nonunions and compare this with CT imaging, which is the current reference standard.[3] Our hypothesis was that measurements of stiffness would distinguish between the healing stages diagnosed on CT scans.

Patients and Methods

Technology of the fixator system. Telemetric measurement modules consisting of a strain gauge bridge and a 12 mm × 12 mm electronic circuit were mounted on a titanium internal fixator (Tifix; Litos GmbH, Hamburg, Germany). The strain gauges were sensitive to bending of the plate. In conjunction with a microprocessor and a coil for energy and data transmission, the strain gauges were encapsulated in an epoxy resin, certified for implantation. A dedicated external reader system was connected to a notebook PC. The reader system supplied the internal circuit with power by inductive coupling at a frequency of 125 kHz. The plate dimensions were 200 mm × 20 mm × 6.5 mm, with a central recess to carry the electronic module (Fig. 1). The screw-plate interface consisted of a threaded screw hole into which a thread on the screw head engaged to create a stable interface.[5] Four bicortical screws were used on each side of the nonunion gap.

Fig. 1

Photograph of the instrumented internal fixator, comprising a titanium locked-wave plate and an electronic unit encapsulated in epoxy resin.

Fig. 2

Photograph showing the measurement set-up, comprising an antenna

The biocompatibility and function of the system had previously been demonstr

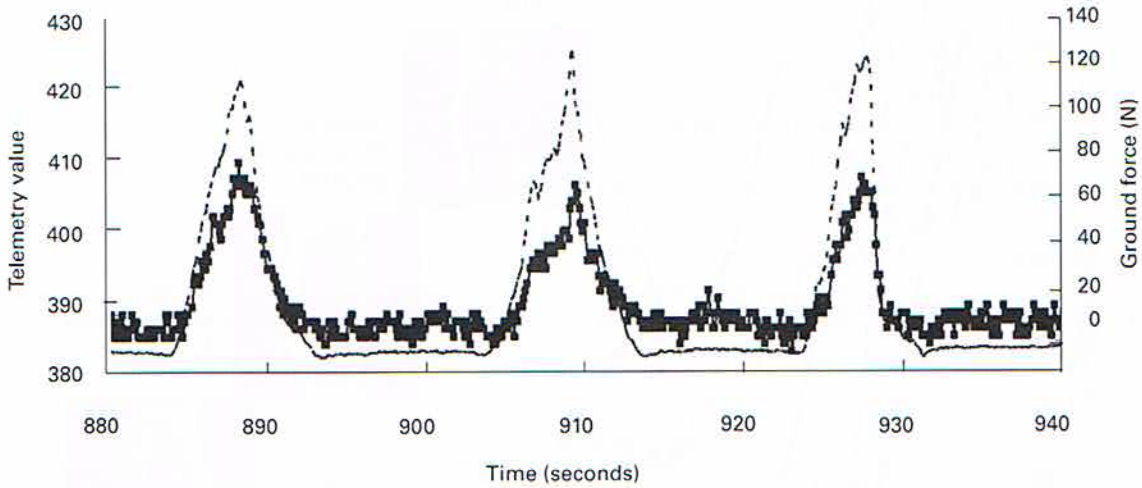

Fig. 3

Graph showing an example of the original recordings in a 20-year-old female patient. Calculating the regression between the load applied externally (dotted line) and the plate load measured telemetrically (solid line) enables determination of an elasticity value for the actual osteosynthesis.

consideration: first, healing begins in the most stable area, which is below the plate – this was observed in all patients; and second, biomechanically, any osseous support influences stability depending on its distance from the implant. Thus, any incomplete osseous bridging in the first third of the transverse location of the nonunion gap closest to the plate was defined as stage 1; in the second third, extending to the position of the medullary canal, was defined as stage 2; and in the final third opposite the plate was defined as stage 3. No osseous bridging at all was defined as stage 0 (Fig. 4). The nonunion gaps were evaluated three-dimensionally by manual scanning through the transverse slices and the reconstructions. Clinical union was defined as full weight-bearing in the absence of pain or tenderness.[2]

Statistical analysis. Considering the small sample sizes, non-parametric tests were chosen. The Kruskal-Wallis test was applied to compare independent samples. In order to test the difference between two samples the Mann-Whitney U test was used. All analyses were performed using the statistical package SAS (SAS Institute Inc., Cary, North Carolina).

Results

All nonunions, discounting two cases of implant failure, healed with a mean time to union of 21.5 weeks (13 to 37). In five patients telemetric measurements showed an initial increase in elasticity. During healing the relative elasticity decreased in all patients. This occurred without an abrupt change of elasticity at any specific time. The three slowest and fastest courses of healing are shown in Figure 4. The change was a reduction in the relative elasticity to 50% after a mean of 7.8 weeks (3.5 to 13) and to 10% after a mean of 19.3 weeks (4.5 to 37). At 12 weeks, a mean of 28.1% (0% to 56%) had been reached.

Plain radiographs showed a general course of healing parallel to the measurements (Fig. 5). However, owing to the irregular nonunion gap and the fact that radiographs are projections, a reliable evaluation of osseous bridging was not possible in most cases.

Comparison between the telemetric mechanical measurements and the CT images was possible at 12 weeks, as all patients received a scan at this time. Osseous bridging in the nonunion gap opposite the plate (stage 3) was related to relative elasticity values of $\leq 30\%$. When no healing signs were apparent (stage 0) values of $\geq 38\%$ were found. Bridging under the plate (stage 1) resulted in inconsistent changes in elasticity with no relevant difference to stage 0 from the median (Fig. 6). Osseous bridging at the side of the tubular bone (stage 2) gave rise to an intermediate elasticity measurement. The median elasticity values were significantly different between the healing stages determined on the CT scans at 12 weeks (Kruskal-Wallis test, $p = 0.007$), confirming our hypothesis that the stiffness of the fracture, indirectly determined by the reduction in the distortion of the plate, would reflect different stages of healing. The comparisons between the median values of elasticity for the healing stages revealed statistical significance, with the exception of the comparison between stage 0 and stage 1 (Mann-Whitney, $p = 0.43$), and stage 2 compared with stages 1 and 3 (Mann-Whitney, $p = 0.07$ and $p = 0.09$, respectively), probably owing to the small number of patients in the stage 2 group.

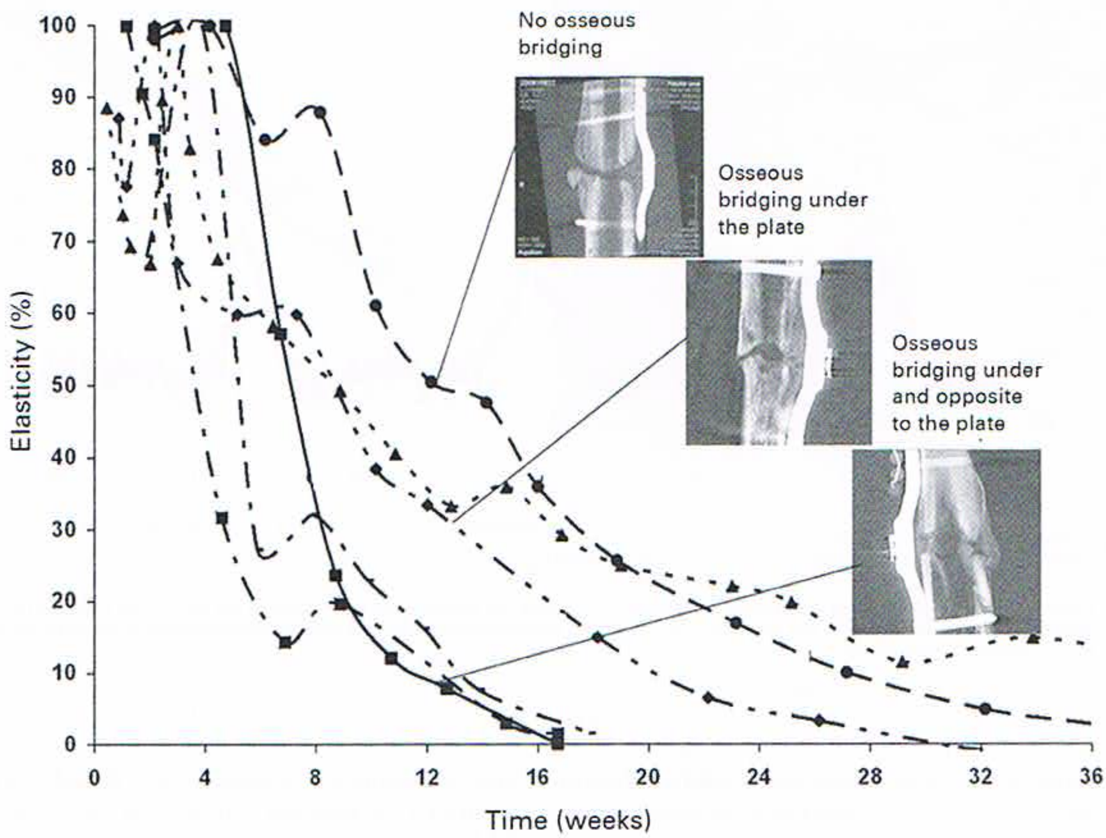

Fig. 4

Graph showing elasticity of the osteosynthesis as a function of the healing time. The curves of the three slowest- and three fastest-healing patients are shown alongside corresponding coronal CT slices at 12 weeks from three patients with different stages of healing.

Fig. 5

Series of plain radiographs of a 46-year-old man during treatment of nonunion. This healing is depicted by a curve in Figure 4 of fast healing (squares on a dotted line).

An important observation was that in the first weeks, well before any radiological signs of healing could be detected, a substantial increase in stiffness (decrease in the relative elasticity) was already evident. A level of 10% was reached by all patients during the final stages of healing, at a mean of 19.3 weeks. This period closely resembles that of clinical healing after 21 weeks.

No medical complications arose due to the presence of the electronic circuit. Two re-operations were necessary, one because of breakage of the implant through one of the

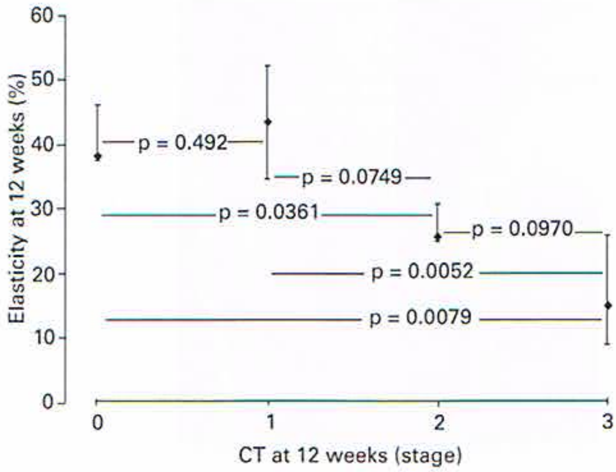

Fig. 6

Plot showing telemetrically measured elasticity *versus* the healing stage as diagnosed from CT at 12 weeks post-operatively. The median values are shown with interquartile ranges. p-values are shown for comparison between medians (Mann-Whitney U test).

screw holes, and one due to bending of the plate, with a resultant gross deformity. Both incidents could be related to severe accidental overloading by the patient. The reoperations were performed using an implant similar to the instrumented one but without telemetry. Uneventful healing resulted in both patients. Despite positive bacterial cultures in four cases, no infections or wound healing problems were observed. In one patient, one bead from the Septopal chain migrated into the knee and was removed arthroscopically.

As is to be expected with a newly developed system, a few technical problems occurred. In two patients it was not possible to make appropriate measurements, probably due to a partial loosening of the measurement circuit from the plate. One of these might have been related to traumatic overloading; an incident was reported by the patient. In four patients measurements could not be fully performed during healing, owing to a shift of the unloaded value out of the measurement range. As a consequence, the attachment to the plate was improved and the amplifier in the electronic circuit was modified to allow an extended range while maintaining the sensitivity necessary to detect changes in the later stages of healing.

Illustrative case. A 55-year-old patient with a subtrochanteric nonunion had undergone three previous operations (Fig. 7). Revision was performed including debridement of the nonunion gap, application of the instrumented fixator, cancellous bone grafting and the addition of a Septopal antibiotic chain. Measurements during physiotherapy two weeks after surgery showed considerable plate loading, which had to be related biomechanically to potentially harmful inter-fragmentary movements, probably related to the long lever arm of the leg with respect to the subtrochanteric region. Thus, as a security measure, for six weeks exercises were limited to passive movements. Fracture healing progressed slowly, and there were no radiological signs of healing after 24 weeks. Telemetric measurements with the fixator, however, revealed a constant, albeit very slow, decrease in elasticity. Accordingly, it was decided not to perform further bone grafting. After 34 weeks, signs of consolidation were apparent on the CT scan. The patient was permitted to bear full weight after 37 weeks and returned to his occupation as a construction worker. For security purposes, measurements were performed at four-week intervals with the intention of detecting any problems due to overloading at an early stage until full bone remodelling had taken place. No complications occurred. The telemetry-guided decision to not embark on further surgery was proved to be correct.

Discussion

It is difficult to assess the extent of fracture healing,[7] as there is a lack of consensus regarding its definition.[8] In addition to clinical examination, radiological criteria are predominately used; these include bridging the fracture site with trabecular bone or bridging of three cortices.[2] Inter-observer agreement for this assessment is low.[9] In nonunion it can be difficult to judge the extent of healing from the radiographs, and CT scanning may be required.[3]

Measurements using the instrumented implant revealed a significant relationship with CT findings. Because CT is the current reference standard,[3] the study shows that telemetric measurement could be a valid alternative in assessing bone healing.

It is difficult to correlate the radiological appearances with mechanical stability.[10,11] Clinicians cannot clearly determine the strength of the healing fracture on a basis of a single set of radiographs,[12] or rank radiographs of healing fractures in order of callus strength.[13] It seems clear that measuring the mechanical changes in the healing bone offers additional clinically relevant information. Our measurements showed that stability follows a continuous function, with changes beginning well before they can be detected by imaging.

Electronic measurements of fracture healing using osteosynthesis plates have been performed before.[4] The first description of internal telemetric measurements using ostoesynthesis implants was by Sommelet, Hummer and Ory[14] in 1976. However, after using the system in 14 patients they concluded that the measurements were difficult to interpret. Their findings contrast with the good agreement between the measurements and the progression of healing found in our study. A major difference between the systems is the application of angular stability.[15] The non-locked implants, which were the only type available to Sommelet et al[14] allowed relative movement between the screws and the plate and, in consequence, between the plate and the bone. Those movements are influenced by friction and are difficult to control. In addition, loosening may occur between the screws and the plate over time. However,

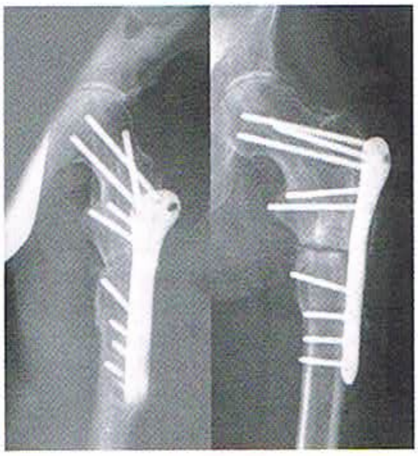

Fig. 7a

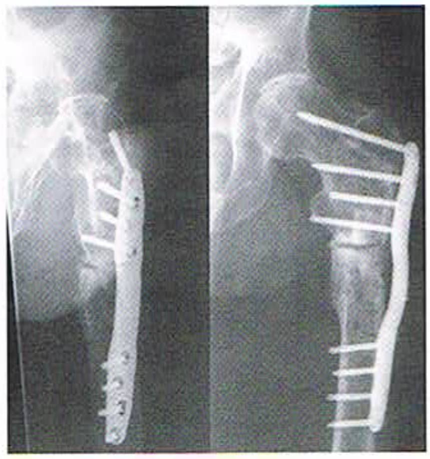

Fig. 7b

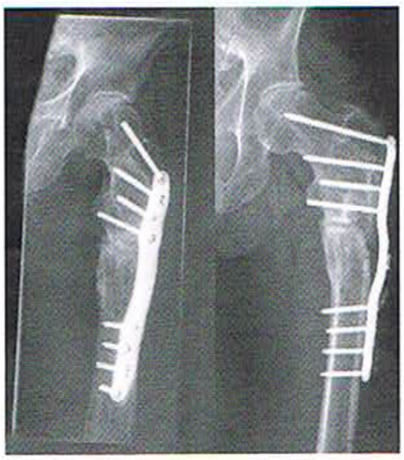

Fig. 7c

Fig. 7d

Axial and anteroposterior radiographs of slowly healing non-union in a 55-year-old man, a) pre-operatively showing the previous treatment, b) at 19 weeks after the application of the instrumented internal fixator, showing no radiological signs of healing, c) at 37 weeks showing the healed nonunion, and d) the final result at two years. This healing is depicted by a curve in Figure 4 of slow healing (triangles on a dotted line).

the application of angular stability seems to be an important factor for a telemetric implant.

Burny et al[16] investigated the possibility of measurements with proximal femoral plates, first using transcutaneous wires and later in some cases using telemetry. As in our study, a continuous decrease in the load acting on the plate was observed during healing. The reduction in the number of implant failures due to optimisation of weight-bearing through the use of telemetry has been studied with intramedullary nails, a spinal fixator and joint replacements in small numbers of subjects.[17,18]

Our device was produced at low cost using readily available electronic components. We anticipate that with further experience with this device it will be possible to define a healed fracture or one progressing towards nonunion based on the mechanical stabilisation progress. In patients who are healing quickly an accelerated approach to increased weight-bearing could be allowed. A further promising mode of application could be monitoring the load applied during physiotherapy in order to avoid harming the callus or the implant.

Further, the system might offer the chance to reduce the number of ionising exposures used during assessment of union. Finally, automated systems that evaluate the data could produce an alarm on the patient's mobile telephone when an overload or impending nonunion is detected, or suggest a faster increase in weight-bearing when appropriate.[19]

Supplementary material

A table detailing the history, clinical data and measurement values of all 27 patients treated with the instrumented internal fixator is available with the electronic version of this article on our website www.jbjs.org.uk

This work was funded by the Deutsche Gesetzliche Unfallversicherung (German Workmen's Compensation Insurance) and the Bundesministerum für Bildung und Forschung (German Federal Ministry for Education and Research).

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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