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Loads acting in an intramedullary nail during fracture healing in the human femur

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Abstract

The form and function of the musculo-skeletal system is closely related to the forces acting in its components. Significant forces are present in the long bones, but their magnitudes have so far only been estimated from mathematical models. Fracture fixation by means of metal implants provides an opportunity to measure the implant-born forces and to estimate the long bone forces before healing occurs. The load changes during fracture healing may provide additional information. Therefore, a telemetrized, interlocking femoral nail for wireless transmission of forces and moments acting across the fracture site was developed. The design was based on the geometry and material of a 16mm AO nail with a circular, closed cross-section allowing full protection of the electronic circuits from the body fluids. After careful testing, it was implanted in a 33-year-old patient who had sustained a multifragmentary fracture of the left femur. Measurements at a rate of approx. 0.4 Hz were performed in different patient postures between the 2nd and 26th postoperative week. Significant axial forces and bending moments were measured during several activities such as sitting, unsupported leg elevation and partial weight bearing in a standing position. Forces orthogonal to the nail axis remained small. The reductions of the implant loads due to fracture consolidation were in the order of 50%. Dynamization of the nail did not change the forces. Even though the telemetry system did not allow for dynamic measurements and the results presented here provide data from one subject only, the new information will be useful with respect to implant design, biomechanics of fracture fixation and evaluation of healing progression. © 2001 Elsevier Science Ltd. All rights reserved.

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1. Introduction

Fracture treatment by means of intramedullary nails (Kuentscher, 1940; Alien et al., 1968) is an accepted and widely used method of treating transverse and short oblique, axially stable fractures of the femoral diaphysis. A low rate of complications and non-unions have been reported as well as an excellent and prompt return of function (Harper, 1985). The introduction of the interlocking nail allowed treatment of comminuted femoral fractures, because limb rotation and length can be maintained (Brumback et al., 1989; Kempf et al.,

1985; Wiss et al., 1986). In femoral nailing, two treatment modalities can be discriminated: Static locking connects the implants with the main proximal and distal bone fragments, securing their relative position and orientation. Dynamic locking with fewer connecting screws (King and Rush, 1981) should prevent rotation, but allow dynamic interfragmentary compression. Some authors (Kempf et al., 1985, Thoreson et al., 1985) recommend conversion from static to dynamic interlocking (dynamization) on a routine basis. In a prospective study of 100 femoral shaft fractures treated with static interlocking nailing (Brumback et al., 1988) 98% of the fractures healed without dynamization. This indicates, that conversion to dynamic fixation is rarely necessary. Nevertheless, it is of interest to know whether the nail is actually unloaded by dynamization and higher loads are carried by the fracture site.

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The function of an intramedullary nail to facilitate healing is secured by its stiffness, which is usually expressed according to load directions as bending or torsional stiffness. Nail stiffness has been determined in a large number of studies as reviewed e.g. by Eveleigh (1995). In a recent, more detailed comparative study, it was shown, that significant variations in bending rigidity exist between the proximal and the distal segment of certain nails, and that larger sizes do not always lead to increased stiffness (Wilkey and Mehserle, 1998). Nail design influences both bending and torsional stiffness. Important parameters are nail diameter, nail material, cross-section (open vs. closed) and design of the screw/ nail interface (Kyle et al., 1991). Nail strength is influenced by material, design and manufacturing properties. Failure of intramedullary nails is rare (Perren et al., 1988), but has been reported for the regular nail (Weinstein et al., 1981) and the interlocking nail (Buchholz et al., 1987). In vivo load data in all spatial components could provide important information for implant design both in terms of stiffness and strength.

Progress of fracture healing is usually monitored radiographically. This technique does not allow quantification of callus maturation in mechanical terms. Therefore, it is impossible to quantify the load sharing between implant and bone during fracture healing from standard radiographs, CT or MR scans. Postoperative patient management ranges from supplemental casting to immediate full weight bearing and depends on the severity of the fracture and the postoperative stability (Rockwood et al., 1991). Unfortunately, there is no in vivo data available quantifying the skeletal loads encountered during fracture healing as well as during different patient and physiotherapy activities. Such data would help to optimize postoperative protocols for proper fracture healing and implant protection.

Determination of lower extremity forces have been limited so far to in vivo measurements by means of instrumented joint prostheses and mathematical simulations. The hip joint reaction forces were measured in a variety of patient conditions in two subjects by Bergmann et al. (1993). He also provided a comprehensive review of this type of work of other authors (Bergmann, 1997). Taylor et al. (1998) used a telemetrized distal femoral replacement to derive the axial, shear and torsional loads during walking. Duda et al. (1997) included muscle force data from gait studies in their mathematical model of the femur and derived the internal forces and moments. But there is no study to measure the load supported by an intramedullary nail during the healing process.

The goal of this project was to measure the in vivo loads acting on an interlocking nail in a patient during the entire period of fracture treatment and to analyze these data with respect to (1) the forces acting in the femur, (2) the evolution of the healing process, (3) the significance of patient posture and physiotherapy, and (4) the effect of dynamization.

2. Materials and methods

2.1. The telemetrized nail

The design goal of the telemetrized nail was to continuously measure a complete set of strain values generated in the central cross-section of the nail and to transmit them from the patient to a laboratory computer system for calculation of the 6 force and moment components without disturbing fracture healing. An interlocked intramedullary nail will initially carry the entire load at the mid-diaphyseal cross-section in the case of a comminuted fracture. With progression of fracture healing, the load sharing between implant and bone will be changed.

The stiffness and strength of the telemetrized nail should be comparable to current implants on the market. Therefore, the material and outer dimensions of the nail were selected identical to the AO/ASIF universal nail (Zuber et al., 1988). It is made of stainless steel with a wall thickness of 0.9 mm and has a length of 400 mm, an outer diameter of 16 mm, and a radius of curvature of 1500 mm. The cross-section of the nail is circular (no cloverleaf) and there is no slot. This nail was manufactured from a curved tube which was first sectioned lengthwise by an electro-discharge milling process ("wire erosion") to allow the installation of the strain gauges and electronic components (Fig. 1). The tube segments, two end pieces and three smaller tubes connecting the holes for the interlocking screws were joined together by laser welding. Since the electronic circuitry is sealed hermetically from the patient tissues and fluids, long term function is possible. At the same time, leakage of non-biocompatible or toxic materials is prevented. The end pieces were necessary to allow use of the standard AO instrumentarium for implantation. The bending stiffness of the instrumented nail is comparable to the original implant. Due to the closed design, the torsional stiffness is 15 times higher than the universal nail, but still comparable to the properties of other (unreamed) nails used in clinical practice. The fatigue behavior of the implant was tested under bending and found to be similar to the universal nail (Schneider et al., 1988). Before insertion, the outside of the nail was sterilized by means of ethanol. The inside of the nail was disinfected additionally by submitting the welded nail to a temperature of 85°C for 24 h. Higher temperatures could not be used due to the sensitivity of the electronic components.

The demands on an implantable telemetry system are severe. Several systems used for measurements around
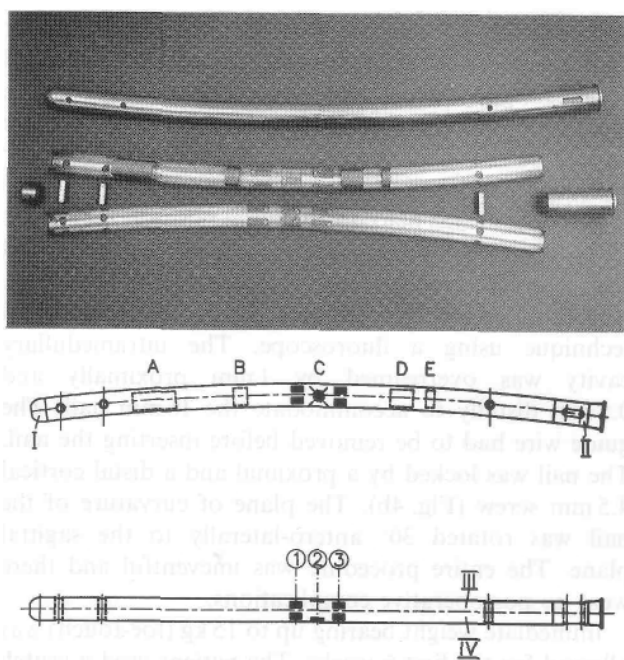
Fig. 1. Above: Photograph of open and completed nail. The location of the electronic components and the strain gauges is shown in the open nail. Below: schematic drawing of the nail consisting of the distal end (I), the proximal end for connection to the insertion instrument (II), and the tube segments (III, IV) in two orthogonal views. The nail contains the power transmission receiver coil (A), the data acquisition circuitry (B), the strain gauges (C), the data conversion circuitry (D), and the transmission circuitry and coil (E).
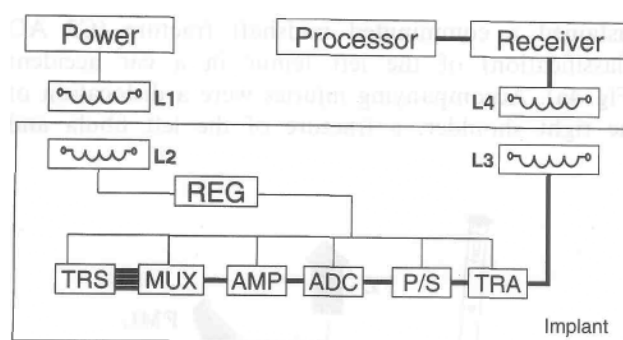

Fig. 2. Block diagram of the telemetry system (REG = Voltage Regulator, TRS = Strain Transducers, MUX = Multiplexer, AM-P = Amplifier, ADC = Analog/Digital-Converter, P/S = Parallel/Serial-Converter, TRA = Transmitter).

the hip are described in the literature (Carlson et al., 1974; English and Kilvington, 1979; Brown et al., 1982; Hodge et al., 1986; Bergmann et al., 1988; Davy et al., 1988; Taylor et al., 1997). None of them has the wide signal range needed in an instrumented intramedullary nail. Universal nails with a tight fit between implant and bone may be deformed significantly during implantation. Therefore, the resolution of the strain measurements must be higher than 12 bits. The requirement for space within the nail is not critical with exception of the inner diameter limited by the nail size. In order to avoid problems caused by the feed-through of the antenna, data need to be transmitted through the non-ferro-magnetic implant. Inductive powering is mandatory to avoid the problems related to implanted batteries. Finally, a digital data transmission scheme was introduced to avoid interference with other electro-magnetic radiation. The drift of the electronic components was shown to be smaller than 0.1% (Genge et al., 1988).

Strains were measured in 3 cross-sections 15 mm apart. Two strain gauges in a half-bridge arrangement at four locations each measured the bending moments in two planes rotated 45° with respect to the plane of curvature. Two gauges were used for torsional and one gauge for axial strain measurements. Calibration for determination of the force and moment components

acting in the central cross-section (6 x 6 element matrix) was performed in a water bath of 37°C. The major components of the telemetry system are shown in Fig. 2. Power for the eight channel telemetry system is provided by inductive energy transmission using the L1/L2 coil system at a frequency of 2 kHz and an internal voltage control. A multiplexer samples the eight data channels (6 channels for strain, 1 for temperature, 1 for supply voltage). The A/D converter (Intersil ICL7135) has 14 bits, which allows resolving the data into 16'384 increments and guarantees high accuracy. Data are encoded using pulse code modulation and transmitted by means of the L3/L4 coil system at a frequency of 100kHz. An external receiver amplifies the signal, decodes it by means of a microprocessor and delivers it to an RS232 serial port. The system allows for 3 strain measurements per second with an accuracy below 0.1%. This eight channel system therefore has a transmission frequency of 0.375 Hz. The linearity of the instrumented nail was found to be better than 2.5% for axial loads, 0.25% for bending and 0.6% for torsion loads (Schneider et al., 1988). The static telemetry system presented here has been described in detail by Genge et al. (1988).

Data acquisition, force and moment calculations, display and storage of the results were performed by means of a PC and special software developed in our laboratory. The nomenclature and coordinate system used for the forces and moments is shown in Fig. 3. In each patient position, 20 consecutive sets of the 6 load components were recorded. These 20 measurements were averaged to reduce the variations due to breathing or other muscular activities.

2.2. The patient and the surgical procedure

The instrumented nail was implanted in a 33 year-old male, subsequent to provision of extensive information and receipt of proper informed consent. He had

sustained a comminuted midshaft fracture (C3 AO Classification) of the left femur in a car accident (Fig. 4a). Accompanying injuries were a dislocation of the right shoulder, a fracture of the left fibula and
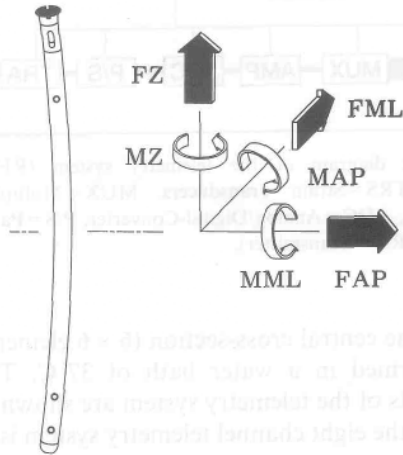

Fig. 3. Conventions used for assessing the three components of force: FZ points upwards in the axial direction, FAP from posterior to anterior and FML from medial to lateral. MZ, MML and MMAP are the corresponding moments. The coordinate system is fixed to the midpoint of the central cross-section of the nail.

contusions of the pelvis and thorax without cardiac or pulmonary involvement. Because the accident occurred in a foreign country and the patient wished to be repatriated, the fixation was performed 9 days after the accident. In the meantime, skeletal traction was used for stabilization.

The patient was placed in a lateral position. The point of insertion was prepared, the femoral cavity opened and a guide wire inserted for incremental reaming. Reduction of the fracture was performed by a closed technique using a fluoroscope. The intramedullary cavity was overreamed by 1 mm proximally and 0.5 mm distally to accommodate the 16 mm nail. The guide wire had to be removed before inserting the nail. The nail was locked by a proximal and a distal cortical 4.5 mm screw (Fig. 4b). The plane of curvature of the nail was rotated 30° antero-laterally to the sagittal plane. The entire procedure was uneventful and there were no postoperative complications.

Immediate weight bearing up to 15 kg (toe-touch) was allowed for the first 6 weeks. The patient used a crutch on his opposite side up to the 12th week, corresponding to approx. 35 kg of load and no crutch thereafter. Radiographs were taken postoperatively, after 6 and 10 weeks. Dynamization of the nail was performed by

Fig. 4. (a) Preoperative X-rays of the multifragmentary midshaft fracture of the left femur; (b) Postoperative X-rays with interlocking screws in place.

operative removal of the distal screw after 21 weeks. Physiotherapy was provided during the first 3 months.

2.3. The measurements

The measurements were performed with great care to ensure reproducible results. The patient was positioned on an investigational table, equipped with specific positioning, fixation and load application tools for the exercises in sitting or resting position. The supine position, with the patient completely relaxed, was used as reference for zero forces and moments. Each deviation from this standard position had significant influence on the reference. Three postures were measured in the supine position: "lifted" position (foot elevated by 20cm and 40cm above the bed) of the injured straight leg and "quadriceps training", i.e. maximal active isometric contraction of the quadriceps muscle. "Sitting" was measured with the patient having a horizontal distance of 20 cm between the patella and the edge of the bed, and with the foot being unsupported.

Six different positions were examined in an upright posture (Fig. 5): partial weight-bearing of 150 and 250 N (controlled by a scale), a "hanging leg" situation with the patient standing with his healthy leg on a small platform and an unsupported injured leg, a "touch ground" position where the patient was allowed to barely touch the ground with his injured leg and very little weight (<10N), the "two leg stance" position in which the patient tried to load both sides equally, and the "single stance" position in which the entire weight was born on the injured side. Torsion was measured in a prone position and the knee of the injured leg flexed at a right angle. The patient had to resist to an orthogonal force of 35N applied at the ankle and generating a torque of approx. 11 Nm around the long axis of the femur.

The first series of measurements was performed in the 2nd postoperative week. There were weekly intervals between the measurements up to week 15 and bi-weekly intervals up to week 26. In order to quantify the changes due to fracture consolidation, the early postoperative period including measurements of weeks 2-7 (pre-consolidation period) was compared to the late post-operative period including data of weeks 12-28. For each period, mean and standard deviations were calculated.

3. Results

The instrumented nail proved to function well and many more postures than the ones reported here were investigated. The nail ceased to transmit data after the 28th postoperative week, but healing had occurred
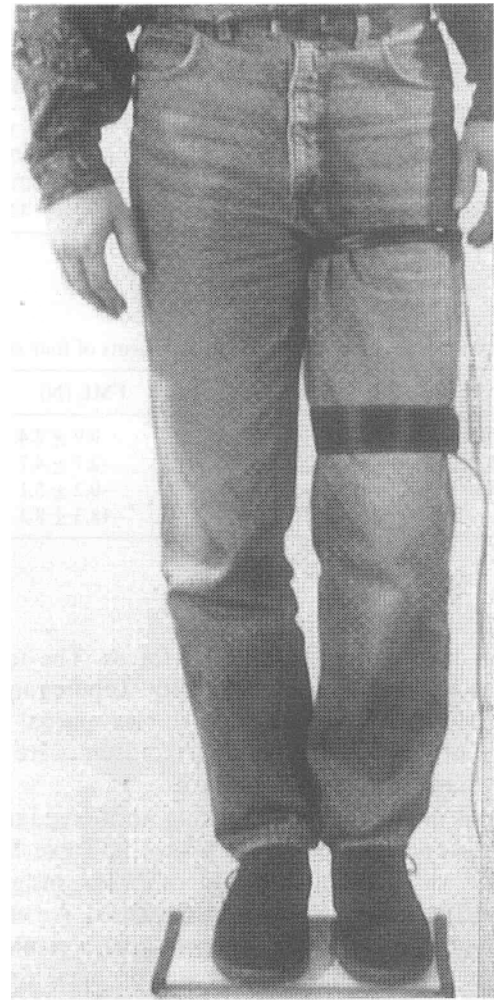

Fig. 5. Patient in standing posture during measurements. The proximal coil is used for power transmission (LI), the distal coil for data acquisition (L4).

clinically. Inspection after nail removal did not elucidate the cause of the failure. The system allowed continuous monitoring of the patient during the experiments, and invalid measurements due to motion artifacts could be rejected. The identical strain offset could be reproduced in the patient resting position in each experimental session and no drift was observed. The offset values in the resting position could be influenced markedly by the positions of both the lower and upper extremities.

The force and moment components for four common standing positions during the early postoperative phase are shown in Table 1. While the average axial components were always directed upwards, single measurements also showed negative values. In the "hanging leg" position, FZ was in the same order of magnitude as partial weight bearing of 150N. Partial weight bearing of 250 N generated a higher axial force in the nail than on the scale. In these postures, the transverse forces FAP and FML were always less than

Table 1
Magnitudes of the force and moment components of four different patient positions in a standing posture, average of the early postoperative period

Patient position	FAP (N)	FML (N)	FZ(N)		MAP (Nm)	MML (Nm)	MZ (Nm)
Touch ground	-1.3 ± 5.7	-3.0 + 14.5	51.9	± 77.3	-0.1 ±2.6	0.78 + 3.8	0.4 + 2.0
Hanging leg	12.4 ±9.8	17.2 ±4.3	107.3	± 180	4.7 + 2.4	-4.1 ±0.9	-2.6+ 1.1
Partial weight bearing 150N	-33.8 + 18.0	-21.7+ 19.1	149.4	+ 27.0	-9.9 + 4.0	6.8 ±4.6	3.4 ±2.1
Partial weight bearing 250 N	-61.9 ±20.8	-42.0 ±20.1	300.6	+ 26.7	-16.2 + 5.4	13.5 + 5.0	5.6 ±2.3

Table 2
Magnitudes of the force and moment components of four supine or sitting patient positions, average of the early postoperative period

Patient position	FAP (N)	FML (N)	FZ (N)	MAP (Nm)	MML (Nm)	MZ (Nm)
Lifted 20cm	0.6 + 3.5	0.9 + 2.4	0.0 + 16.6	-1.6 + 0.9	-1.1 +0.5	-0.1 +0.5
Lifted 40 cm	-2.3 ± 3.0	-2.7 ±4.7	38.2 ± 12.6	-2.1 ± 1.3	0.1 +0.8	0.3 ±0.6
Quadriceps	-3.4 ±4.1	-0.2 + 5.1	38.3 ±24.5	-1.1 + 1.2	0.0+ 1.2	0.1 ±0.4
Sitting	-16.2 + 8.9	-18.3 + 8.3	114.5 ± 120	5.4 + 1.5	6.8 + 1.4	0.5 + 0.6

20% of the corresponding axial forces. The torsional moment MZ was approx. 40% of the bending moments (MX, MY) and was highest during partial weight bearing of 250 N. The bending moments were always higher than the torsional moments.

Results of the supine and sitting positions during the early postoperative phase are shown in Table 2. When the foot was lifted to a height of 20cm, insignificant axial and transverse forces were measured. An elevation to a height of 40 cm however produced a similar axial force as in quadriceps training. The axial force FZ during sitting was approx. 3 times the value in quadriceps training. The transverse forces in the sitting posture were approx. 15% of the axial forces. In the supine and sitting positions, the torsion moments MZ always were below O.SNm. The bending moments were highest in the sitting position.

Partial weight bearing of 250 N proved to be a good exercise to monitor changes in implant load with time (Fig. 6). A major reduction of the load components occurred after week 7. This reduction was similar for all force and moment components. An increase in loading of the nail was noted between weeks 15 and 19, followed by another decrease. Fig. 7 depicts the axial force component generated in the nail by the voluntary "quadriceps training" exercise. The graph demonstrates that this component of force remains below 100 N in the first 10 weeks. Afterwards, the magnitude increases up to 250 N and is comparable to the same component during partial weight bearing at 20 weeks.

The average axial force FZ before and after fracture site consolidation (early vs. late postoperative period) is shown in Table 3 for partial weight bearing of 150 and 250 N, unsupported leg, and sitting. The reduction in implant loading (FZ) varied from 19% in partial weight bearing of 150 N to 88% in sitting. The moments MAP,
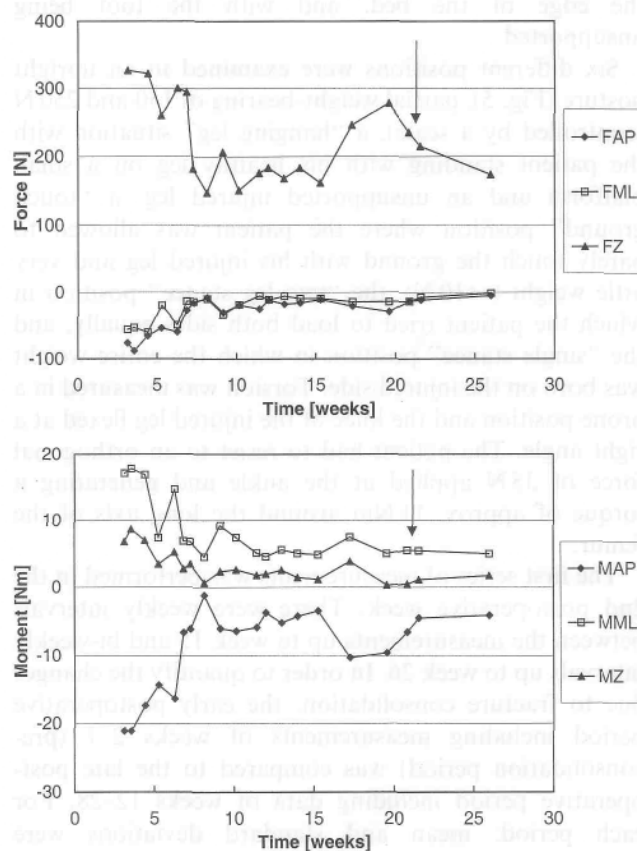

Fig. 6. Implant forces and moments vs. time in partial weight bearing of 250 N. The arrow indicates the time of dynamization of the interlocking nail. For clarity, no standard deviations are shown.

MML and MZ were reduced by 70%, 64%, and 79% in partial weight bearing of 150N.

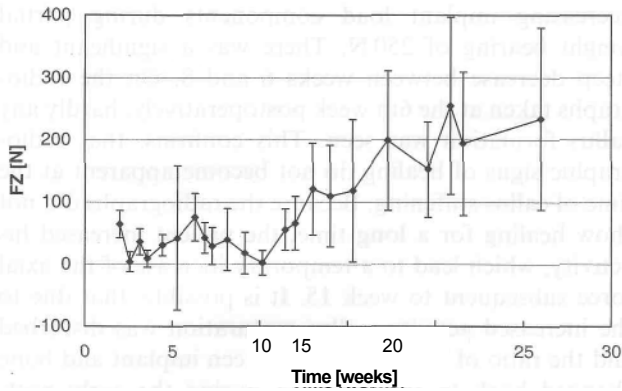The effects of dynamization can be seen in several graphs. No change of any of the load components

Fig. 7. Axial force component vs. time during maximum voluntary isometric contraction of the quadriceps muscle in the supine position.

Table 3
Four common patient positions for comparison of the axial force component at the early and late postoperative periods

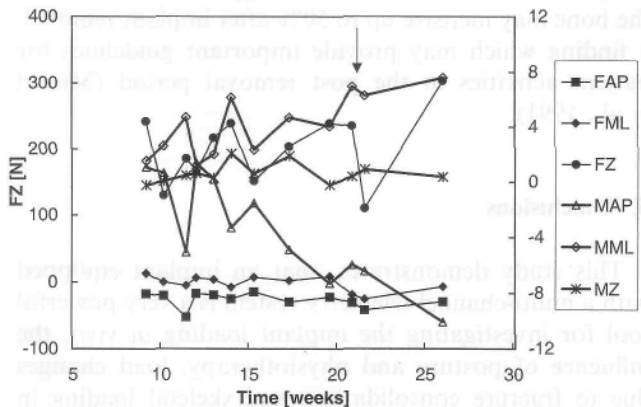| Patient position	Early phase (<7 weeks)	Late phase (>12 weeks)
Partial weight bearing 150 N	149.4 ± 27.0	121.3 ± 37.1
Partial weight bearing 250 N	300.6 ± 26.7	205.0 ± 40.5
Hanging leg	107.3 ± 180	−85.7 ± 55.4
Sitting	114.5 ± 119.8	13.0 ± 27.5

Fig. 8. Force and moment components during two leg stance. The arrow indicates the time of dynamization of the nail. For clarity, no standard deviations are shown.

occurred in partial weight bearing of 250 N (Fig. 6). None of the components changed in the two leg stance (Fig. 8) and the same was true for single stance (Fig. 9). In the axial torque MZ, however, (Fig. 10), a clear reduction was found.
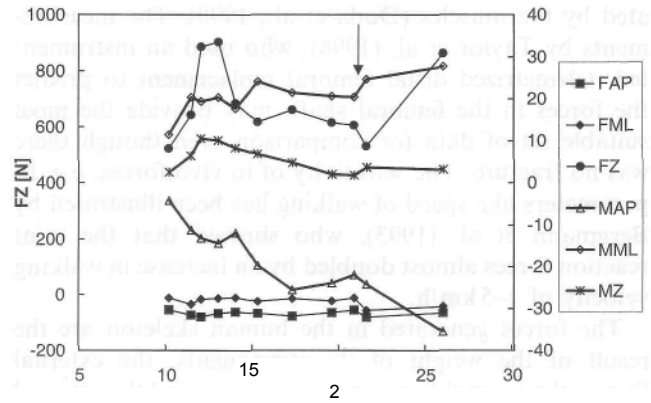

Fig. 9. Force and moment components of the nail in the single leg stance position. The arrow indicates the time of dynamization of the nail. For clarity, no standard deviations are shown.
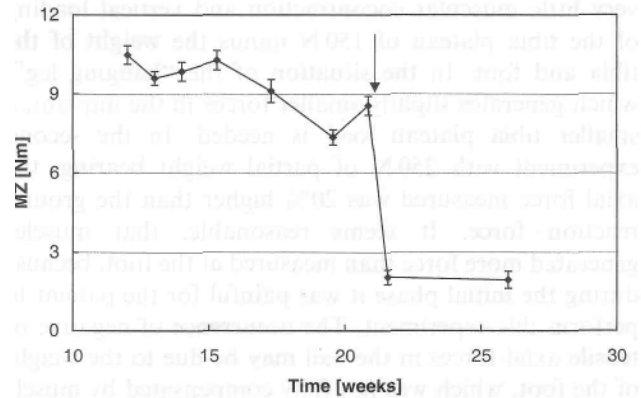

Fig. 10. Moment Mz during the torsion experiment before and after dynamization (arrow).

4. Discussion

The in vivo measurements reported here are unique and therefore cannot be compared directly with other literature data. Manley et al. (1982) measured the in vivo tensile and compressive loads in a canine femur. But he could not measure the complete set of load components, and the load situation in a quadruped is not comparable to the human situation. Obara (1979) measured the in vivo strains on an intramedullary nail during fracture healing in goats. He noted a decrease in implant strains due to fracture healing, but comparison of the animal with the human situation is again questionable. In vivo measurements of hip joint reaction forces were performed by English and Kilvington (1979), Hodge et al. (1986), Bergmann et al. (1993), and Davy et al. (1988). These data should not be used alone to predict the loads acting along the femur, because the strains present in the cortical bone depend significantly on the forces gener-

ated by the muscles (Duda et al., 1998). The measurements by Taylor et al. (1998), who used an instrumented, telemetrized distal femoral replacement to predict the forces in the femoral shaft, may provide the most suitable set of data for comparison even though there was no fracture. The sensitivity of in vivo forces, e.g. to parameters like speed of walking has been illustrated by Bergmann et al. (1993), who showed that the joint reaction forces almost doubled by an increase in walking velocity of l-5km/h.

The forces generated in the human skeleton are the result of the weight of its components, the external forces, the inertial forces due to motion and the internal forces due to muscle action. While the first three of them can be calculated or measured from outside the body, the muscle forces can only be estimated from in vivo measurements such as this. In the first experiment with partial weight bearing of 150N, the vertical force measured matched this value very well, probably with very little muscular cocontraction and vertical loading of the tibia plateau of 150 N minus the weight of the tibia and foot. In the situation of the "hanging leg", which generates slightly smaller forces in the implant, a smaller tibia plateau load is needed. In the second experiment with 250 N of partial weight bearing, the axial force measured was 20% higher than the ground reaction force. It seems reasonable, that muscles generated more force than measured at the foot, because during the initial phase it was painful for the patient to perform this experiment. The occurrence of negative or tensile axial forces in the nail may be due to the weight of the foot, which was not fully compensated by muscle action in certain situations. But in order to fully understand the generation of reaction forces such as this, more detailed measurements of implant, muscle and bone-to-bone forces would need to performed.

The sitting position can be used to further speculate about muscle action. If the weight of the unsupported lower extremity is assumed to be 100N (15% of the body weight of 75kg), there should be a bending moment of 20 Nm. The vector sum of the two bending moments in the nail, however, results in 8.7Nm only. This means, that more than 50% of the bending moment is compensated by muscular action. The weight of the unsupported leg would in addition generate a transverse force in the nail of 100N. But the transverse forces also remain small, which implies muscle action to avoid bending of the nail (and the femur). This can be achieved by quadriceps pull. It is interesting to note at this point, that partial weight bearing of 150N, the "hanging leg" and the sitting position generate similar amounts of axial loading, which might be a hint for admissible patient activities in the early postoperative phase.

Evolution of fracture healing or callus maturation by increasing stiffness can be observed in Fig. 6 by the decreasing implant load components during partial weight bearing of 250 N. There was a significant and steep decrease between weeks 6 and 8. On the radiographs taken at the 6th week postoperatively, hardly any callus formation was seen. This confirms, that radiographic signs of healing do not become apparent at the time of callus stiffening. Because the radiographs did not show healing for a long time, the patient increased his activity, which lead to a temporary increase of the axial force subsequent to week 15. It is possible, that due to the increased activity, callus maturation was disturbed and the ratio of load sharing between implant and bone changed back to the situation during the early postoperative phase. Dynamization of the interlocked nail at week 21 (Fig. 6) could not be distinguished from the decrease due to healing. In other experiments such as two leg stance (Fig. 8) and single leg stance (Fig. 9), it became apparent, that the load components did not change, with the exception of torsional loading (Fig. 10). These results show that interlocking does not inhibit axial and bending loads at the fracture site and therefore they support the clinical findings of Brumback et al. (1988), who showed that dynamization in interlocking nailing is only necessary for a few selected cases (Michel et al., 1993).

Fracture healing (Table 3) results in a large reduction of implant loads. However, even after fracture consolidation, the loads on the nail can be significant and are expected to increase with patient activities. These findings may thus help to explain reported nail failure several months after fracture consolidation (Perren and Baupre, 1984). Our results also suggest that loading of the bone may increase up to 50% after implant removal, a finding which may provide important guidelines for patient activities in the post removal period (Michel et al., 1991).

5. Conclusions

This study demonstrates, that an implant equipped with a multi-channel telemetry system is a very powerful tool for investigating the implant loading in vivo, the influence of posture and physiotherapy, load changes due to fracture consolidation, and skeletal loading in general. The results are limited by the fact, that measurements were performed in one patient, who sustained one specific multi-fragmentary fracture of his femur. It was found, that there were only small tensile forces in the diaphyseal fracture gap of the femur, that the loading in touch ground position was lowest, that even after fracture consolidation approximately 50% of the load was transmitted through the nail, that interlocking did not inhibit loading at the fracture site and that muscular activity plays an important role in fracture healing.

Acknowledgements

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