Primary stability of various forms of osteosynthesis in the treatment of fractures of the proximal tibia

The treatment of fractures of the proximal tibia is complex and makes great demands on the implants used. Our study aimed to identify what levels of primary stability could be achieved with various forms of osteosynthesis in the treatment of diaphyseal fractures of the proximal tibia. Pairs of human tibiae were investigated. An unstable fracture was simulated by creating a defect at the metaphyseal-diaphyseal junction. Six implants were tested in a uniaxial testing device (Instron) using the quasi-static and displacement-controlled modes and the force-displacement curve was recorded. The movements of each fragment and of the implant were recorded video-optically (MacReflex, Qualysis). Axial deviations were evaluated at 300 N.

The results show that the nailing systems tolerated the highest forces. The lowest axial deviations in varus and valgus were also found for the nailing systems; the highest axial deviations were recorded for the buttress plate and the less invasive stabilising system (LISS). In terms of rotational displacement the LISS was better than the buttress plate.

In summary, it was found that higher loads were better tolerated by centrally placed load carriers than by eccentrically placed ones. In the case of the latter, it appears advantageous to use additive procedures for medial buttressing in the early phase.

Intramedullary stabilisation procedures have been established for many years as reliable methods for the treatment of fractures of the tibial shaft. This has been verified by the good results achieved in numerous studies.1-9

In fractures of the proximal shaft of the tibia the range of indications has been extended as far as the metaphyseal border. Clinical assessments have shown complications of fracture healing and axial malalignment. There are several studies that demonstrate a high percentage of axial deviations of >5°.10

There are some anatomical peculiarities of the proximal tibia that are responsible for the axial deviations. Anterior curvature malalignment is encouraged by a tibial plateau that is directed posteriorly between 3° and 7° and also by the insertion of the patellar ligament into the tibial tuberosity. Secondary malalignment is also promoted by a dorsally displaced axis of loading. Medial tilting of the proximal fragment is created by a medially located axis of loading. In an attempt to avoid primary malalignment after intramedullary nailing, the nail should be inserted at the correct site. Lang et al10 showed that a slight displacement of the site of insertion in the anteroposterior or lateral planes led to tilting of the proximal fragment.

Although paying special attention to the site of insertion and to correct operative technique can reduce the incidence of primary and secondary malalignment, the problem of relative instability and the consequent disorders of fracture healing remain.11,12 The relative instability of the proximal fragment is shown by a widening of the proximal medullary cavity. Once this occurs there is no longer pressfit congruency of the nail and the bone and the stability of the proximal fragment depends on the locking screws.

Alternative procedures to intramedullary (IM) nailing include osteosynthesis using a buttress plate or external fixation. A hybrid fixator might also be applied. The LISS (less invasive stabilising system), an internal fixation system with fixed-angle screws, has been developed for the treatment of fractures of the proximal tibia. This system can be introduced using small incisions, thus conserving soft tissue. So far, there are only a few publications reporting clinical results using this implant.13,14

Although numerous clinical studies have described the treatment of fractures of the proximal tibia by means of IM nailing, biomechanical investigations have been under-
taken only recently.\textsuperscript{15-17} We aimed to identify what levels of primary stability could be achieved in the treatment of fractures of the proximal tibial shaft using the available methods of osteosynthesis.

**Materials and Methods**

The investigation was performed on pairs of human tibiae which had been kept refrigerated. Pre-operatively, bone density was determined by computer tomography (High-resolution Spiral CT, GE Medicalsystems, Cedex, France). The specimens were divided equally into different test groups with reference to bone density measurements. Five tibiae were used for each construct. Each tibia was used only once since plastic deformation could not be excluded after quasi-static, destructive testing.

Measurement of the bone mineral density (BMD) of the specimens, and even dispersion between the groups, was regarded as essential for the mechanical testing. Bone density was determined for each tibia using the built-in BMD measuring function of the spiral CT. The CT-based measurement of BMD is known to provide accurate, reproducible and reliable values.\textsuperscript{18-21} The region of interest was defined as starting 10 mm below the medial tibial plateau. The specimens were grouped into five BMD classes. Even dispersion of specimens with different BMD was ensured using an incomplete, balanced block design through a randomisation program based on Excel. The comparison of the characteristic group variables (mean, range and mean error of BMD) showed no differences between the six implant groups.

Each specimen underwent one testing. All measurements were taken from this single testing. The specimens were instrumented while still intact in order to eliminate the possibility of primary axial malalignment. After instrumentation, the metaphyseal-diaphyseal junction was identified according to the AO classification. A transverse osteotomy was performed at the junction and a defect of 10 mm created by removal of bone.\textsuperscript{22} This simulated a complex diaphyseal transverse fracture of the tibia, AO classification 42 C3.3.\textsuperscript{22} The following implants were tested:

1) unreamed tibial nail (UTN; Synthes, Oberdorf, Switzerland): 8 mm, proximal nailing with two transverse screws and additional 45˚ oblique locking; 2) cannulated tibial nail (CTN, Synthes): 12 mm, proximal locking with two transverse screws and additional 45˚ oblique locking; 3) lateral tibial head buttress plate (LPO, Synthes): 4.5 mm, titanium, 9-hole, 5 screws in the proximal fragment, three of which were cancellous bone screws; 4 cortex screws in the distal fragment; 4) less invasive stabilising system-proximal lateral tibia (5-hole) (LISS, Synthes): This is a newly developed implant designed in accordance with the principles of the internal fixator. The anatomically pre-contoured plate has specially designed screw threads in the plate holes. These permit anchorage of the screw head in the plate in a position of angular stability. The entire implant can be inserted using small incisions, thus conserving the soft tissue. Bi-

cortical screws are used in the metaphysis and monocortical screws in the diaphysis; 5) external fixator (EF, Synthes) (Fig. 1): external stabilisation with an external fixator applied in a V-configuration and 6) hybrid fixator (HF, Synthes) (Fig. 2). External stabilisation by means of a hybrid fixator with half-ring tensioned wires in the metaphyseal fragment and Schanz screws in the shaft fragment.

Before biomechanical testing, the proximal and distal ends of the specimens were embedded in cylinders of acrylate (Beracryl, Troller Kunststoffe, Fulenbach, Switzerland). The physiological site for the application of force on the articular surface of the proximal tibia was selected on the basis of 3-D finite element analysis.\textsuperscript{15} Force was applied proximally through a ball-and-socket joint. Distally, the tibia was held in the testing device by a universal joint so that it was free to move. Testing was performed in a uniaxial testing device (Instron, Canton, Massachusetts), quasi-static and displacement-controlled and the force-displacement curve was recorded (Instron, Type 4302, resolution of +/- 1%, accuracy of 0.1 mm). A test distance of 9 mm at a constant speed of 10 mm/min was set for an osteotomy gap of 10 mm. Recording generally took 54 seconds per specimen. Failure of the implant or overloading of the test apparatus at 10 kN was defined as premature termination of testing. The distance tested and the force applied were determined digitally using a frequency of 10 Hz.
The relative movements of the fragments and the implants were recorded by a video-optical system. To this end the fragments and implants were equipped with reflecting spherical markers functioning as optical markers whose movements were recorded by two video cameras and then processed digitally (3-D-MAC-Reflexsystem, Qualisys, Gothenburg, Sweden) (Fig. 3). The measured variables were the relative movements of the fragments in six degrees of freedom defined in terms of angulation and translation (Fig. 4). The following variables were statistically evaluated: maximal applied load (Maxload); relative movement of the fragments towards varus or valgus (alpha angle) at 300 N; relative movement of the fragments in terms of anterior and posterior tilt (beta angle) at 300 N; and relative movement of the fragments in terms of rotation (gamma angle) at 300 N.

The maximum applied force was the maximal force applied to the specimen. Two criteria were defined in order to end a test: either a maximal load of 10 kN or closing of the fracture gap of 10 mm (stop after 9 mm). Since there was great variation in the stiffness of the implants, the plate-like implants stopped after displacement of 9 mm and most nails at 10 kN. The characteristic stiffness in the linear part of the curve was calculated for better comparison between the implants. The displacement value at 300 N was chosen to assess movement of the fragment under partial weight-bearing.

Statistical evaluation. The relative movements and stiffness in all three planes were compared by analysis of variance for all the different types of implants. Bone density was taken into account as a block effect. All group comparisons were adjusted in accordance with the Tukey-Kramer test.

This block model assumes normal distribution. The distribution was evaluated by means of box plots and, in particular, QQ plots. In addition, Tukey-Anscomb plots were produced in order to evaluate the homogeneity of scatter. To evaluate the relationships between the different target variables (displacement, maximal force) and/or influencing variables (bone density), the Pearson correlation coefficient was calculated and the significance tested. The level of significance was set at 5%. The results are also expressed with the 95% confidence interval (CI).
Results

Maximum force applied. The maximum force which could be applied to an instrumented specimen varied considerably between the different implants. For the analysis, the maximum possible force was achieved either when the bone could be loaded over the entire distance with a continuously increasing force, or when the implant-bone construct yielded under a specific applied force and started to give way jerkily with a simultaneous drop in the applied force. The highest mean applied force was 1.4 kN (standard error (SE) 1.14; all estimates are back-transformed by power exponentiation) and occurred for the CTN. A lesser maximum applied force was seen for the UTN at 0.96 kN (SE 1.16). A much lower force was recorded for both fixator systems, at 0.66 kN (SE 1.63) for the V-fixator and 0.49 kN (SE 1.14) for the hybrid fixator. Loading capacity was comparably low for the buttress plate at 0.54 kN (SE 1.14) and 0.57 kN (SE 1.14) for the LISS (Fig. 5).

The regression model yielded substantial differences among the six implant groups (Type III effect, p = 0.0002). The CTN showed by far the highest forces. The mean difference between the CTN and the LPO was 0.4 kN (95% CI, 0.22 to 0.72; p = 0.0011). The CTN also showed higher values with respect to the hybrid fixator (mean difference 2.79; 95% CI, 1.53 to 5.07) as well as both the LISS (mean difference 2.40; 95% CI, 1.32 to 4.36) and the external fixator, respectively (mean difference 2.1; 95%, CI 1.10 to 3.91).

No significant differences were found between the CTN and the UTN (p = 0.5) but the latter differed significantly from the hybrid fixator (p = 0.03; mean difference 0.51; 95% CI, 0.27 to 0.96). No significant differences were found in relation to the other implants (CTN, LPO, LISS, external fixator).

Relative movement of the fragments in a varus direction (alpha angle) at 300 N. The mean values for the alpha angle excursions indicated clear differences, depending on the implant, as shown in Figure 6. First, it is apparent from the truncated curves that the different implants were exposed to different maximum forces to yield or to the end of the 9 mm distance. The greatest degree of tilting in the frontal plane occurred for specimens that were stabilised by means of eccentric load carriers (LPO and LISS). Here, mean values of 6° to 7° maximum excursion were reached at a load of 400 N. The intramedullary load carriers and the external fixator systems proved to be more stable in the frontal plane. The analysis of relative movements of the fragments in a varus direction at 300 N is shown in Figure 7. The least
movement of fragments was found for the CTN at 0.51˚ varus (SE 0.50˚). The external fixator also produced a low alpha angle excursion value of 0.57˚ varus (SE 0.51˚). The highest values were recorded for the buttress plate and the LISS at 4.17˚ varus (SE 0.50˚) and 4.57˚ varus (SE 0.50˚), respectively. The regression analysis showed a significant variation between implants (Type III effect, p < 0.0001). The LISS appeared to be different from the CTN (mean difference 4.07; 95% CI, 1.96 to 6.17), the external fixator (mean difference 4.0; 95% CI, 1.62 to 6.37), the hybrid fixator (mean difference 2.88; 95% CI, 0.59 to 5.16) and the UTN (mean difference 2.74; 95% CI, 0.54 to 4.93), respectively.

Relative movement of the fragments with regard to anterior and posterior alignment (beta angle) at 300 N. The mean values for beta angle excursions depended upon the implant. Initially, it was apparent from the truncated curves that the different implants could be subjected to different maximum forces before they yielded or before the distance of 9 mm was completed (Fig. 8). The most unstable implants in the sagittal plane proved to be the UTN and hybrid fixators. Only the curve up to 440 N could be analysed for the hybrid fixator. The curve for the UTN rose steeply and reached a mean excursion of 8˚ for a maximum applied force of 820 N, which was seen for all specimens in the form of posterior tilt. The results were of the same magnitude for the external fixator and buttress plate osteosynthesis, both of which could be recorded up to 440 N. The analysis of beta angle excursions at 300 N (Fig. 9) produced the lowest mean values for the CTN at 0.62˚ anterior alignment (SE 1.33˚; all estimates are back-transformed by power exponentiation). The highest mean value was recorded for the hybrid fixator at 2.91˚ anterior alignment (SE 1.29˚). The values for the other stabilisation procedures lay in the range between the most extreme values. The statistical evaluation of the beta angle excursion values at a force of 300 N yielded a modest effect owing to the implants (Type III effect, p = 0.012). Apparently, this was because of a significant difference between the CTN and the hybrid fixator for which the mean difference was 0.21˚ anterior alignment (95% CI, 0.06 to 0.7).

Relative movements of the fragments in terms of rotation (gamma angle) at 300 N. The mean values for gamma angle excursions showed some implant-related differences (Fig. 10). Initially, the truncated curves once again indicated that
the different specimens were subjected to different maximum loads to yield or until the distance of 9 mm had been completed. The curves for rotation in the horizontal plane are the most uniform compared with the diagram for rotation in the other planes. The most unstable implant by far in terms of torsional deviation was the buttress plate. Here a maximum value of almost 3˚ was recorded as the mean value for angular deviation. The other implants differed relatively little from one another. The analysis of rotational movement at 300 N (Fig. 11) produced the highest mean values for the buttress plate, i.e. 1.66˚ (SE 0.44˚). The other values differed little and lay within the range of 0.31˚ to 0.96˚. Statistical analysis on the basis of the regression model did not reveal a significant variation between the implants.

Discussion
An osteotomy model was chosen for this investigation in order to guarantee a standardised experimental design. The defect simulated a complex fracture pattern without load-carrying support. Nevertheless, this model is a simplification of what is often a complex clinical situation. An attempt was made to create a zone of instability, without any support for the fragments, at the transition of the metaphysis to the diaphysis. Although bone quality is important for the bone-implant construct, our model was designed to investigate the influence of the implant and not the quality of the bone.

Static testing is easier to standardise but only the primary stability of the construct can be investigated. Dynamic testing stimulates the repetitive loads which occur in the post-operative loading phase and would be more representative of a healing fracture. Some parameters cannot be simulated in a biomechanical investigation; for example the changes in bone quality during healing which are caused by the reduced activity of the patient and which lead to osteopenia and consequent reduced fixation of the implants and also the increasing mechanical resistance of the healing fracture.

The results of this study provide an overall view of clear differences between various principles of osteosynthesis.
The highest maximum applied force was recorded for central load carriers (CTN and UTN). Although the recorded values for the other implants are much lower, only the values for the UTN and the hybrid fixator differ significantly as there was a wide scatter of values. The eccentric load carriers, such as the buttress plate (LPO) and the LISS were weak in a varus direction owing to the lateral position of these implants. The eccentric lateral position of the buttress plate and the LISS leads to a greater degree of tilting. Therefore, it is particularly valuable to support the eccentric load carrier temporarily with an external fixator on the medial side when treating unstable fractures.

Sagittal deviation produced values within the same range for all implants. However, the lowest values with the least scatter were recorded for the CTN and the highest values with the greatest scatter for the hybrid fixator. This indicates that no implant offers particular advantages in the sagittal plane.

For rotational deviations, the lateral buttress plate was the weakest. The other implants did not differ from each other significantly. It was notable that the LISS differed significantly from the lateral buttress plate in that significantly smaller rotational deviations were found when compared with the buttress plate which, because it has the same anatomical position on the lateral side of the tibia, behaved similarly to the other implants.

The relevance for clinical practice is that the central load carriers can bear greater loads earlier. No conclusions can be drawn from a quasi-static test on the extent to which stiffer implants (CTN and UTN) effect the biology of fracture healing.

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References


