AN INTELLIGENT INTERNAL FIXATOR SYSTEM FOR LONG BONES

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METHODS:
A microcontroller based passive transponder telemetry unit (size 12mm x 12mm, signal transmission range of 7cm) was developed and incorporated in internal fixators (osteosynthesis plates with a locked screw-plate interface, fig.1a). The sensor is a strain gauge bridge placed on the middle of the plate and reacting on plate bending (and to a small degree on axial load). After the functionality of the concept had been demonstrated in vitro (plastic fracture models), the system was prepared for clinical application by biocompatible encapsulation. Biocompatibility and function was then tested in 6 sheep. Up to now, it was applied in 2 patients with distal femoral non unions (fig. 1b). By measurements during fracture healing (fig 1c), evaluation of increasing stiffness of the osteosynthesis under external extremity load as a parameter for consolidation as well as biomechanical investigations under different actions like muscle activation, movements of leg, walking and physical therapy were performed.

RESULTS:
First results showed, that the telemetrically determined values of the plate load showed a good relation to externally applied cyclic axial, varus or valgus loads (fig. 2) and that the amplitudes decreased due to fracture healing. Most interesting results were found under voluntary muscle contraction and therapeutic exercises. As it is difficult to imagine a bending moment in the plate in the clinical situation, values were standardized, setting the plate load under an axial extremity force of 100N (the limit allowed to the patient) as 100%. E.g., contraction of the femoral muscles resulted in plate loads up to 500%, lifting the leg in bed from supine position up to 240%. Peaks up to 150% were observed at the moments when the leg is finally put down by the therapist at the end of an exercise and 320% during exercises which include torsion. Knee flexion on the other hand decreased plate load close to zero. Protective control action of muscle was possible in some slow motions. E.g., when cautiously axially loading the leg, plate load increased before, and then staying constant when the heal is loaded. Sudden movements of the patient, e.g. to position himself however led to peaks up to 480%.

DISCUSSION:
An instrumented “intelligent” internal fixator system was developed and introduced into clinical application. It proved to be useful to give information to the patient about allowed movements and extremity loading, as well as to the physical therapist to avoid exercises possibly harmful in an individual healing situation. Presumably, it will inform the surgeon about possible healing problems. In the view of the authors “intelligent” microelectronically instrumented measuring internal fixators will be routine tools of the orthopedic trauma surgeon in the future.