Electronic Distraction Force Measurements to Optimize Segmental Transport in an Ilizarov Fixator

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Introduction:  Callus distraction is a procedure to generate bone by an osteotomy followed by a slow distraction of the osteotomy gap. It is applied either to perform bone lengthening or to fill a defect by transport of a bone segment through the defect. Application of the latter is typically done in cases of osteomyelitis with substantial bone loss, being complex clinical situations. Several parameters have been investigated to optimize the procedure, such as the speed of distraction, a delay between surgery and beginning of distraction or the technique of the osteotomy to best preserve perfusion. There are cases of more than 30cm tubular femur bone (with approx. 3cm diameter) generated. So, distraction osteogenesis can be considered an effective means of tissue engineering of large amount of bone. However, individual assessment of the bone formation in patients is not possible yet. Assessment is done by radiographs, where calcification in many cases may occur not before later stages of treatment. A possible solution for this problem can be the continuous measurement of distraction forces, related to the stiffness of the emerging callus. So, an electronic distraction force measurement system was developed to be mounted into an external fixator and applied clinically. In the performed preliminary study the questions to be answered were which magnitude of forces and increase rates of the forces are created in humans and which force parameters can be related with clinical observations such as the quality of the formed bone or emerging complications.

Methods:  In a first setup, 2 strain gauge based force sensors were inserted in the medial and lateral cable of a cable distraction system in an Ilizarov external ring fixator. Measurements were taken with a measuring amplifier in intervals of 2 to 4 weeks postoperatively over the distraction period. Distraction was started between 3 and 12 days postoperatively with a rate of 0.25mm every 6 hours (1mm/day). The second, currently used microelectronic system consists of two force sensors and a small control unit including a microprocessor to automatically control the timing of the measurements and store the data on an SD-card. Measurements were performed every 5 seconds. Reading out the data and storing measurement timetables into the control unit was performed via Bluetooth by a personal Computer (fig.1). Additionally, an app is under development, which enables the patient to see the course of force on a smartphone and the doctor to additionally access the system for programming from a tablet Computer (fig.2).

Evaluated were distraction forces at day 15, i.e., after initially stretching of the system, and in the middle of the distraction period, as well as the corresponding rates of increase of the force and the form of the measurement curves.
Figure 1: System to measure forces acting on a transport segment during callus distraction, mounted on a left lower leg. The two distraction cables with inserted sensors, connected with the control unit are shown.

Figure 2: Actual system consisting of two force sensors, the small control unit and a tablet pc. The tablet pc reads out the course of the force over time and sends programming information to the control unit connected via Bluetooth.
**Results:** 22 Patients were investigated with the first setup (mean age 44 years, standard deviation 16.3 years, 4 female, 18 male). The defect length was in the mean 9 cm (standard deviation 3.3cm). In all cases the filling of the defect with bone of good quality was successful.

The distraction forces 15 days after beginning of the distraction was in the mean 63 N (standard deviation 30 N) in 16 cases without complications and 109 N (standard deviation 61 N) in 6 cases with complications as premature consolidation or rupture of a cable. In the middle of the distraction period the values were 155 N (standard deviation 72 N) and 274 N (standard deviation 102 N), respectively. Complications were even more distinct different, when evaluating the increase of the force per day. If calculated in the middle of the distraction period or (when complications occurred early) just before the complication, values were 3.4 N/day (standard deviation 2.0 N/day) in uneventful and 7.3 N/day (standard deviation 4.9 N/day) in the complication group. Age, body weight and defect length showed no significant (p>0.05) correlation with the distraction forces in the investigated patients.

Continuous measurements (fig.3) with the current system (6 patients) additionally allowed to evaluate variations during the day. There were found relevant standard deviations of up to 30% of the absolute force values over the day. These were due to random patient activity rather than being related to expectable temporal increases after the 4 adjustments of the distraction per day, which could not be distinguished.

Additional theoretical analysis revealed that the force in the cables is influenced by the stiffness of the newly formed bone, the tissue to be compressed in the defect region, stretching of attached soft tissues, geometry of the directions of the cables and friction in the roller bearing redirecting the cables.

![Figure 3: Example case. 50yr. old patient with a 12cm segmental defect of the distal tibia because of a posttraumatic osteomyelitis. Shown are anteroposterior and lateral radiographs after resection of the infected bone and inserting antibiotic chains (right), anteroposterior radiographs during the distraction period (top), radiographs at end of treatment (right) and a graph showing the measured distraction forces over time (mean values per day). Red arrow shows timepoint of the rupture of a transport cable, followed by the restauration of force after repair. Final decrease of the force is related to the stationary...](image-url)
phase without further transport after docking. In this patient high forces were measured, leading to a rupture of the cable as a complication, however forming a bone in good density and good tubular shape.

**Discussion:** Measuring the distraction forces during segment transport can be performed with relatively small effort and a system readily to be built of state of the art electronic parts found in digital cameras or smartphones. It could be demonstrated, that the measurement help to detect complications. Currently, radiographs are evaluated in relation to the force measurements. The aim is to develop the system into a treatment option with individually controlling the distraction speed depending on the elasticity of the emerging callus. It will be possible to control the treatment continuously and with less radiation and even to avoid visits by telemetric transmission of the measured data via the smartphone of the patient. In further clinical studies on optimizing in vivo distraction tissue engineering, the distraction force will be an important objective parameter.

**Significance:** Segmental transport to fill large bone defects is still a very important treatment option. Applying modern microelectronics in the external fixator is a promising development to improve its outcome by individual distraction force measurements.

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