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Biomechanical methods for the assessment of fracture repair

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ABSTRACT

The progress of fracture healing is directly related to an increasing stiffness and strength of the healing fracture. Similarly the weight bearing capacity of a bone directly relates to the mechanical stability of the fracture. Therefore, assessing the progress of fracture repair can be based on the measurement of the mechanical stability of the healing fracture. However, fracture stability is difficult to assess directly due to various obstacles of which shielding of the mechanical properties by the fracture fixation construct is the most relevant one. Several assessment methods have been proposed to overcome these obstacles and to obtain some sort of mechanical surrogate describing the stability of the fracture. The most direct method is the measurement of the flexibility of a fracture under a given external load, which comprises the challenge of accurately measuring the deformation of the bone. Alternative approaches include the measurement of load share between implant and bone by internal or by external sensors. A direct 3 dimensional measurement of bone displacement is provided by radiostereometric analysis which can assess fracture migration and can detect fracture movement under load. More indirect mechanical methods induce cyclic perturbations within the bone and measure the response as a function of healing time. At lower frequencies the perturbations are induced in the form of vibration and at higher frequencies in the form of ultrasonic waves. Both methods provide surrogates for the mechanical properties at the fracture site. Although biomechanical properties of a healing fracture provide a direct and clinically relevant measure for fracture healing, their application will in the near future be limited to clinical studies or research settings.

Introduction

The healing of a bone fracture is a continuous process in which the fracture ends reunite directly under stable mechanical conditions or form a stabilizing extra- and intramedullary callus under flexible mechanical fixation conditions. Typically during the process of healing, the mechanical stability of the healing bone steadily increases – eventually exceeding the mechanical stability of intact bone. The time for union varies anyway between 4 and 40 weeks depending on numerous factors including age, type of bone and of fracture, mode of fracture fixation and most importantly on the definition of fracture union. Currently, there is no such thing as a "Gold Standard" for the definition of when a fracture is healed. Moreover, the different methods available for healing assessment do not correlate very well because they all assess different features of fracture healing.

Particularly in research settings there is the need for objective measures of bone healing to monitor treatment and compare treatment methods. Although there is no consensus when a fracture is actually united, clinical studies as well as individual patient assessment require some sort of definition of a measurable end point of fracture healing. In orthopaedic clinical studies, fracture healing often is one of the most important outcome

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variables and can be described by dichotomous (healed–not healed), multi-level ordinal (scoring system) or continuous variables. Healing is typically assessed at predefined time points at which the completion of the healing process is expected. On the other hand, a reliable indicator for the completion of the healing process (or the lack thereof) can also be of importance for the diagnosis of the individual patient. Such an indicator could guide decisions on cast or implant removal or could determine the need for further treatment or operation to achieve healing.

When is a fracture healed?

The success of fracture repair is defined by the restoration of the bone's biomechanical function [1,2]. However, a definition on when a fractured bone has reached its original biomechanical function is lacking. The biomechanical mechanisms underlying the restoration of the bone's original function are well-known and based upon an increase of stiffness and strength of the fracture callus [2]. The callus raises its stiffness and strength first by enlarging the volume of the newly formed tissue (proliferation) and later on by hardening of the tissue (differentiation and mineralization); changes of the mechanical properties of the callus are non-linear [3]. The fracture callus is a visco-elastic structure, in which the viscous aspect decreases, while the elastic part increases during the course of bone repair [4]. Perren could show that Young's modulus of elasticity rises from 0.5 MPa for granulation tissue to 20,000 MPa for mature bone [5]. It has been further demonstrated that the stiffness of the fracture increases twice as fast as the bending strength. This means that when the stiffness of a healing bone has reached its original amount, the strength will only be half [6]. Therefore, stiffness is a useful mechanical indicator of fracture healing, but limiting measurements to stiffness only might reveal misleading results. Particularly during the early stages of bone repair, plastic deformation of the callus may occur through overloading [7]. Hence, the ability of the callus to resist plastic deformation is another biomechanical indicator of the progress of fracture healing.

Changes of the biomechanical characteristics of the fracture callus can be attributed to the cellular events during the different stages of fracture healing. With decreasing amounts of connective tissue and cartilage and an increasing proportion of mineralized bone, the strength and stiffness of the callus rises [8]. Finally, the viscous environment with only minor mechanical recovery capability is replaced by a solid structure with elastic properties.

For the clinician, monitoring the course of fracture healing, it is difficult to measure the bone's biomechanical function directly. Therefore, he relies on tools reflecting the stiffness and strength of the healing bone indirectly. In the clinical setting, radiographic methods represent the gold standard to evaluate the healing progression of a fractured bone. Animal studies in dogs could show that the cortex to callus ratio of a radiographic evaluation correlates with the stiffness index, as calculated by biomechanical testing, at late stages of bone repair like 24 months post fracture. In contrast, no significant relationship between radiographic and biomechanical findings was evident earlier at 8 and 16 weeks post fracture [9]. This data highlight the limitation of using non-mechanical methods to assess the bone's biomechanical function.

It has been demonstrated that around 25% of the bending stiffness (the ratio of the applied bending moment to the angular displacement) of an intact tibia – when measured in several planes – seem to be sufficient to undergo full weight bearing without significant risk for a re-fracture [10,11]. In tibia fractures fixed by external fixators, this value was reached after approximately 18–51 weeks, depending on the severity of soft tissue injury and fracture pattern (Table 1). Therefore, it has been proposed that a human tibia fracture can be considered healed when the bending stiffness exceeds this threshold of 15 Nm/deg equivalent to 25% of intact bone [4]. It has to be considered that 25% of the stiffness of the intact bone might be not enough for independent weight bearing in all patients. Thus, a higher stiffness might be necessary e.g. in obese patients or patients with osteoporosis. In these patients it might be safer to rely on the patients' subjective self-assessment to start and increase weight bearing. It has been shown that unrestricted weight bearing increases with time after fracture [12,13]. Joslin et al. demonstrated that patients who recovered well reached weight bearing of 90% of normal, while patients with delayed union achieved only 40% of normal at same time [14]. In their study, weight bearing correlated with the bone's stiffness. Obviously, the ability of a patient to bear weight on the fractured limb is controlled by a biofeedback mechanism relating fracture site strain to the stiffness of the fracture [15,16]. These findings suggest that the evaluation of weight bearing (e.g. by measuring ground reaction force) is an easy and useful method to estimate the progress of fracture healing.

Table 1
Median times to independent weight-bearing (clinical healing) related to the severity of the injury [10], 1: classification of Johner and Wrush [17], 2: classification of Gustilo and Anderson [18].

Severity grade	Bone injury [1]	Soft-tissue injury [2]	Time to clinical healing (weeks)
1	A	0	18
2	A	II, III	20
3	B, C	0, I	23
4	B, C	II, III	26
5	Bone loss	II, III	51

Mechanical measurement methods

Direct measurement methods assess a mechanical quality of the bone which changes during the course of the fracture healing process directly. They can be distinguished between methods assessing the structural integrity of the whole bone as compared to methods assessing local tissue properties. The structural integrity of healing bone is typically assessed by measuring the integral stiffness of the extremity by static or dynamic load application. Static loading deforms the extremity in relation to the amount of load applied. In dynamic deformation the vibrational response of the extremity depends on the propagation of the induced oscillations which are primarily determined by the overall mechanical integrity of the bone. Instead of measuring the overall integrity of the healing bone, direct measurements of mechanical properties can also focus on the site of fracture healing. Thus, measurement of local tissue properties at the fracture site directly reflects the mechanical changes of the healing tissue in the fracture gap and in the periosteal fracture callus.

The most frequently assessed mechanical characteristic in fracture healing assessment is the overall stiffness of the fracture. Stiffness measurement requires simultaneous determination of the applied load and the resulting deflection generated by the load. There are various methods to measure the deformation of the limb including goniometers, optical marker tracking, or tracking of the pins in case of external fixation. Alternatively, the deformation can be measured by radiography or fluoroscopic images acquired at the loaded and unloaded situation, respectively. In patients who are treated by external fixators or by cast, the fixation device can be temporarily removed providing direct access to the mechanical integrity of the fractured extremity. In the case of internal fixation with plates or intramedullary nails direct measurement of mechanical integrity of the healing fracture is extremely challenging. The stabilizing effect of the osteosynthesis device completely conceals the instability of the fracture and renders deformation