Study of Biomechanical Properties and Behavior of Bone Regeneration using Nano Distraction Methods.

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Abstract

Elongation of long bones is currently the most often performed by distraction osteogenesis method. After osteotomy of the diaphysis and bone fragments stabilization by external fixator the formed callus in interfragmental gap is sequentially stretching during the treatment process of gradual extension. Continuous optimization of the treatment plan during active elongation and neutral fixation can make a key contribution to the quality of bone tissue formation and consolidation, the appearance of a full bone, and significantly treatment time reduction. To optimize the treatment plan parameters the biomechanical study of bone regenerate behavior was prepared according to various criteria in characteristic stages of its consolidation and ossification.

Keywords: elongation, distraction osteogenesis, biomechanical processes, bone regenerate ossification, interfragmental tissue

1. INTRODUCTION

Presented study involves the partial results of biomechanical analysis of the genesis, consolidation and ossification processes of interfragmental tissue according to several criteria in case of long bones lengthening by distraction osteogenesis method. Extension of the diaphyses in children and adolescents is achieved by planar osteotomy followed by gradual mutual distraction of the opposite vital bone fragments. Controlled stress and strain changes initiated by external effects, which very effectively regulate the rate of healing and formation of new bone tissue support structures simultaneously with adequate development of elastic and viscoelastic properties, are very important for the development of quality interfragmental tissue [1]. Within presented study an evaluation of detailed radiographic analysis of the bone regenerate development is performed in a group of patients during periods of active elongation and neutral fixation. Interim results are combined with theoretical numerical simulations of homogeneous and inhomogeneous volume development of callus in various stages of new bone tissue formation process.

2. RADIOGRAPHIC ANALYSIS OF BONE REGENERATE

Radiographic analysis of the bone regenerate development during the elongation and consolidation process evaluates a total of 26 tibia and 11 femurs of 14 elongated patients with achondroplasia (the age range 6-16 years, 10 men and 4 women) and total of 14 tibia and 3 femurs of 12 elongated patients with unilateral hypoplasia (the age range 2-23 years, 4 men and 8 women) [2].

2.1 EVALUATION OF DATA SET

The average final prolongation in patients with achondroplasia was 72.8 mm on tibia and 78.7 mm on femur and in patients with unilateral hypoplasia 62.5 mm on tibia and 68.0 mm on femur. A comprehensive assessment involves determining of the callus geometric criteria CDR (Callus Diameter Ratio), i.e. the criterion of the mutual proportion of the narrowest part of callus to the osteotomy level on the tibia or femur in radiographic 2D projection, with regard to the prediction of the bone regenerate collapse possibility after fixation extraction based on extensive statistical evaluation of data sets [3]. Cases of the average CDR criteria achieved values of less than 85% mostly lead to the deformation or collapse of the bone regenerate. In evaluating set the deformation or collapse of the callus was detected in all cases at 5 tibia and 2 femurs with CDR < 85% in patiens with achondroplasia (19% of all patients), and at 6 tibia and 2 femurs with CDR < 85% of patients with unilateral hypoplasia the callus collapse occurred in cases of 5 tibia and 1 femur (total of 35% of patients). In other cases, with CDR criteria values > 85%, there has been a successful genesis of new bone tissue without any complications.

2.2 ANALYSIS OF CALLUS DEVELOPMENT DURING TREATMENT

Specific case of successful extension of the left tibia in the patient without achondroplasia (woman, 6 years) with a total treatment time of 200 days was chosen for detailed radiographic analysis of the running of interfragmental tissue formation and ossification during the active elongation and neutral fixation period (Figure1). Radiographic evaluation of the callus development process from the elongation beginning is carried out by the treatment program analysis with corresponding detailed review of 2D projection images at different stages of treatment (Figure2, 3) [4]. The evaluation includes the monitoring of overall regenerate shape, detailed morphology and structure at characteristic stages of regeneration.

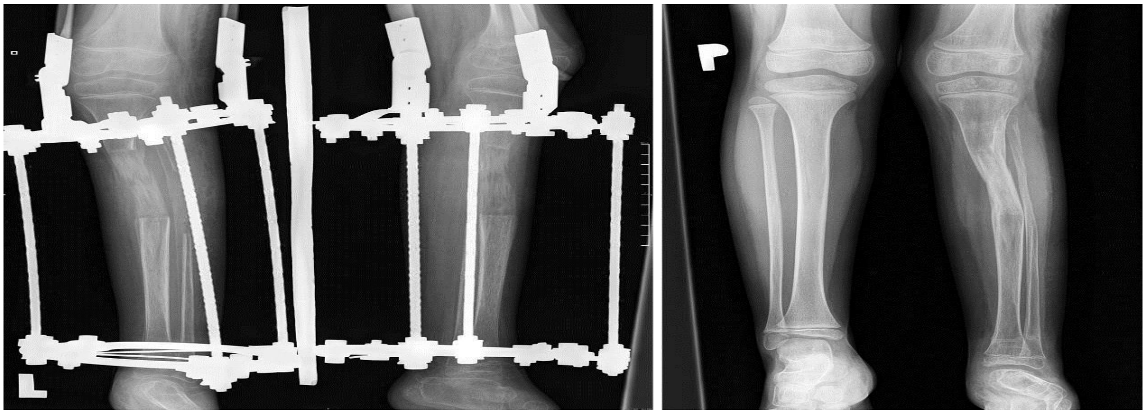

Figure 1. 65 mm extension of the left tibia using the Ilizarov apparatus, left: tibia 3 months after osteotomy, 1 month after the end of elongation, left limb, A/P and L projection, right: tibia 6 months after osteotomy, 1 month after extraction of external fixation, both limbs, A/P projection

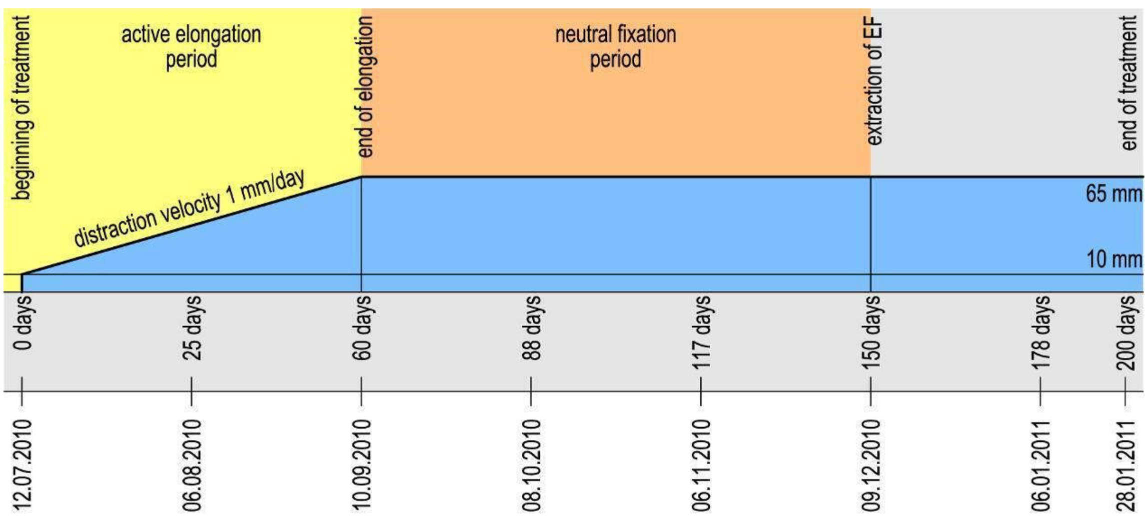

Figure2. Analysis of the treatment program

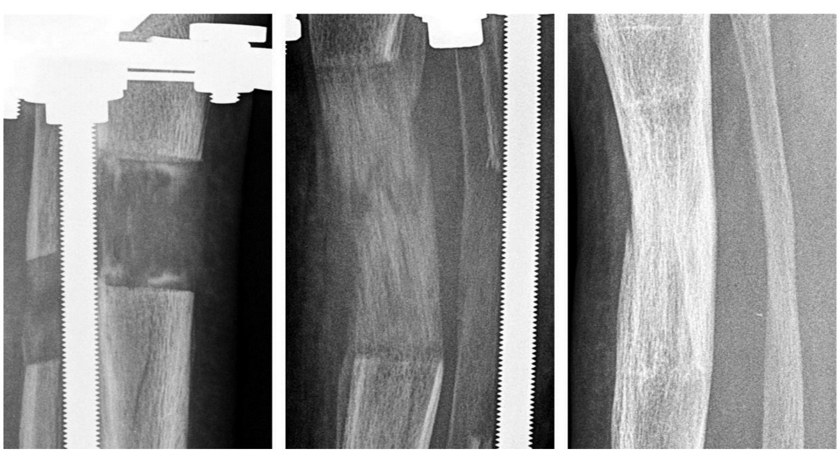

Figure 3. Detail of interfragmental tissue formation, from left side: callus after 25 days, 88 days and 200 days from the beginning of treatment

3. NUMERICAL VERIFICATION OF INTERFRAGMENTAL TISSUE FORMATION

Numerical part of biomechanical study of bone callus genesis includes the simulation of new bone tissue formation in interfragmental space at individual stages of treatment program. The analysis is prepared in relation with the part of radiographic evaluation of a 65 mm tibia extension particular case for a detailed 3D analysis of individual characteristic bone tissue formation sub-stages during healing process, especially in the period of active elongation.

Computational process is executed using a 3D FEM model in ANSYS APDL environment. In this work, an alternative solution is made by a single iteration step, which corresponds approximately to the time around 30-th day of treatment process (active elongation period). Distribution of hydrostatic and deviatoric components of stress fields in the sagittal section under the tensile deformation load of vital bone fragments (represented by 10 mm value of the mutual movement) is the basis for the evaluation of volume and internal callus tissue structure temporal changes (Figure4).

The secondary objective of the numerical verifications is analysis of the bone regenerate behavior and redistribution of stress and strain states according to the change of external interfragmental tissue borders. The study takes into account the initial shape of the callus formed immediately after osteotomy and without depending on external biomechanical influences, and the shape changes initiated by biomechanical processes during extension, consolidation and ossification processes

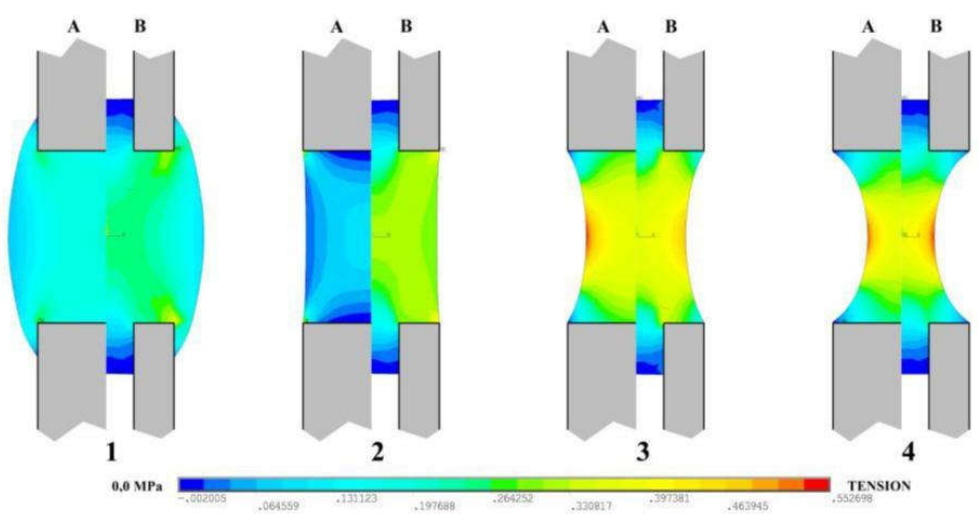

Figure 4. Sagittal section of callus, distribution of principal stress σ_1 (MPa), fragments without (A) and with (B) intramedullar canal, with characteristic (1) hypertrophic, (2) cylindrical, (3) concave, hypotrophic, (4) central, very hypotrophic shape of callus

4. CONCLUSION

The results of performed analyzes can be recapitulated into the following interim conclusions, which will be, in solving of other phases of prediction problem of bone regenerate biomechanical properties during long bones elongation, the subject of further detailed verifications:

(1) The radiographic and numerical analyzes of the development of the bone regenerate external geometry shows that the shape changes of borders occurs as a result of temporal changes of stress-strain states and material properties of intefragmental tissue throughout the treatment period. While immediately after osteotomy the callus can be generally characterized mostly as a hypertrophic, during the following phases in medial zone the loss of incurred granulated tissue occurs. The relatively rapid volume reduction is also evident in periosteal localities of callus near the bone shaft fragments.

Simultaneously we can say that the interfragmental tissue can be approximately till 30-th day of treatment characterized as a homogeneous and isotropic (with elasticity modulus of approximately E = 1,0 MPa), corresponding to the advanced stage of granulation tissue with the beginning of fibrotisation (phase 1 of the active elongation period). The second phase of active extension period is typical by an inhomogeneous development of highly oriented fibrous tissue with the early local consolidation (ossification). In the neutral fixation period the volume re-expansion can conversely occurs, especially in medial zone of regenerate, as a result of very intensive consolidation and ossification of interfragmental tissue (due to increase of stress values and decrement of deformations). Within inhomogeneous development of callus tissue is in volume also apparent the regulation of tissue structure organization to genetically predetermined shape of diaphysis, including the restoration of intramedullary canal. Radiographic evaluation of entire data set also confirmed that the improving of the bone regenerate geometry occurs in the following approximately 6 months after external fixator extraction, this phenomenon is called the peripheral lateral drift corticalis.

(2) Decrease of callus tissue toward the longitudinal axis of the diaphysis is characterized as **Hypotrophic drift (HD)**. Loss of the granulated tissue in the medial zone of callus is a consequence of the dominant tensile stress effect during extension process (Figure5).

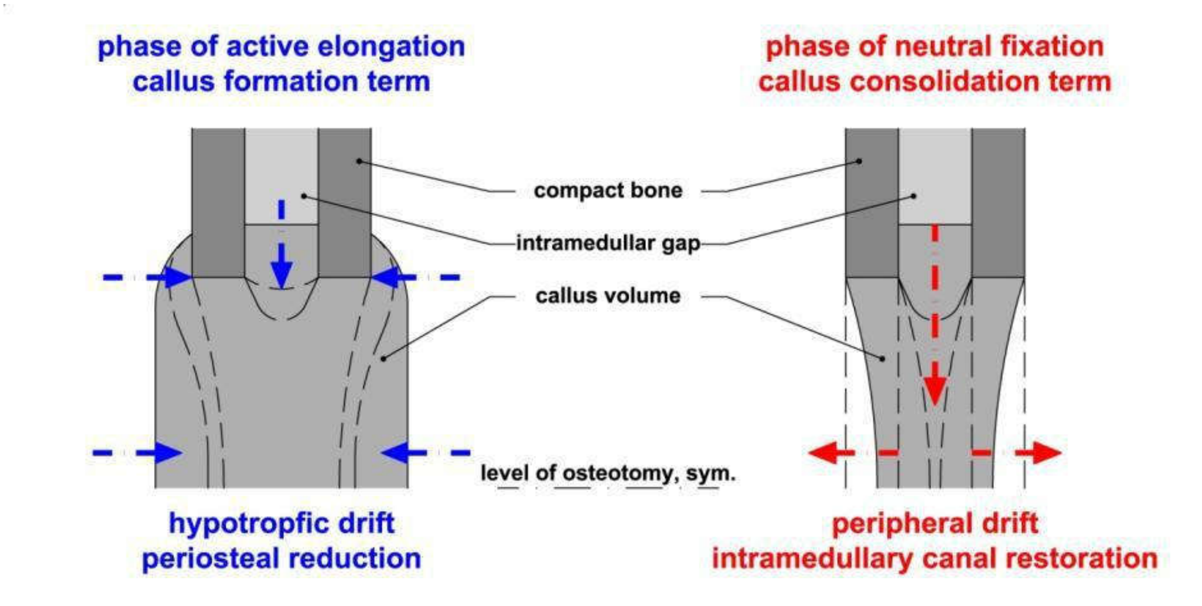

Figure 5. Schematic sagittal section of the proximal half of the callus, the consequences of hypotrophic and peripheral drift on bone regenerate

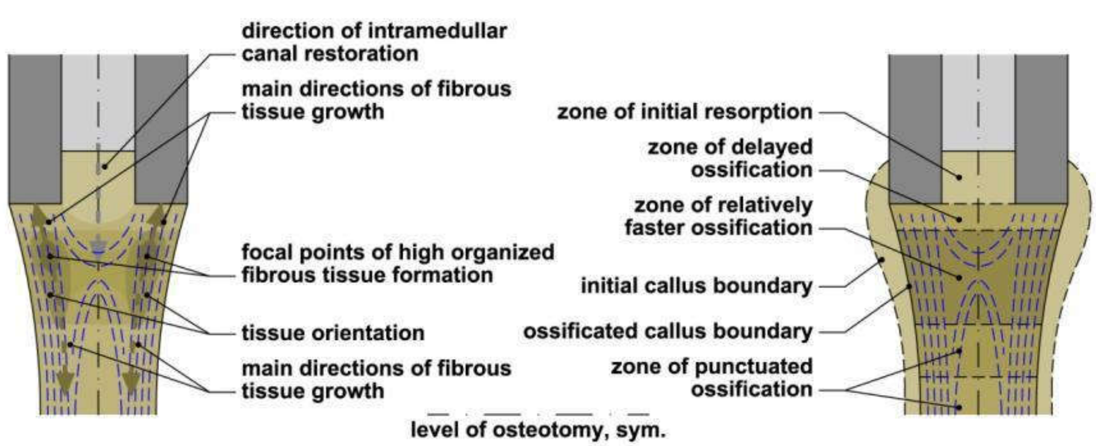

Figure 6. Schematic sagittal section of the proximal half of the callus, left: kinetics of fibrous tissue formation, right: division of the section into the zones of inhomogeneous ossification

(3) The increase of the ossified tissue volume in the medial zone of callus away from the longitudinal axis of the diaphysis is called **Peripheral drift (PD)**. Positive hypertrophy of the bone regenerate takes place only in case of hypotrophic callus during consolidation and ossification processes (Figure5).

(4) Depending on the stress-strain states analysis and radiographic classification the proximal half of the callus can be divided into zones with different development of interfragmental tissue, sites with dominant production of organized tissue structures and with prediction of their expansion directions (Figure6). During the gradual elongation of the diaphysis, respectively, in the course of the mutual distraction of bone fragments the characteristic phenotypes of tissue structures, i.e. the sites with dominant representation of mutually different cell populations and of the various degrees of intramembranous ossification are formed in the regenerated space of callus. These in-time metabolic (biochemical) different zones are continuously interconnected. With regard to the production of tissue phenotypes in different parts of the bone regenerate volume the proximal half (at 4-th up to 6-th week after osteotomy) can be horizontally divided into three main zones:

- **Zone of punctuated ossification (ZPO)**, mostly represented by the highly organized fibrous structure. The locality is from the biomechanical point of view characterized by greatest changes of the strain in axial direction of the diaphysis, especially in the surface layers of the callus medial zone.
- **Zone of delayed ossification (ZDO)**, i.e. the locality of callus with less advanced osteogenesis due to the greatest changes of the stress state during the running of consolidation processes. The zone is in the immediate vicinity of the bone fragment surface of the diaphysis and is characterized by a vast presence of fibroblast and osteoblast populations, but without the production of osteoid.
- **Zone of relatively faster ossification (ZFO)** is locality of the most advanced osteogenesis, which is caused by comparatively time-stable distribution of stress and strain throughout the cross-section creating suitable conditions for the acceleration of intramembranous ossification and osteoid formation.

(5) The foregoing evaluation and assessment of the callus development running within the bones lengthening process forms the basis for preparing the detailed analysis of the bone regenerate behavior (formation, consolidation and ossification) throughout the treatment period and subsequently for creating an effective tool for classification and coordinated optimization of treatment program in connection with the application of new, electronically controlled, extension apparatus [5].

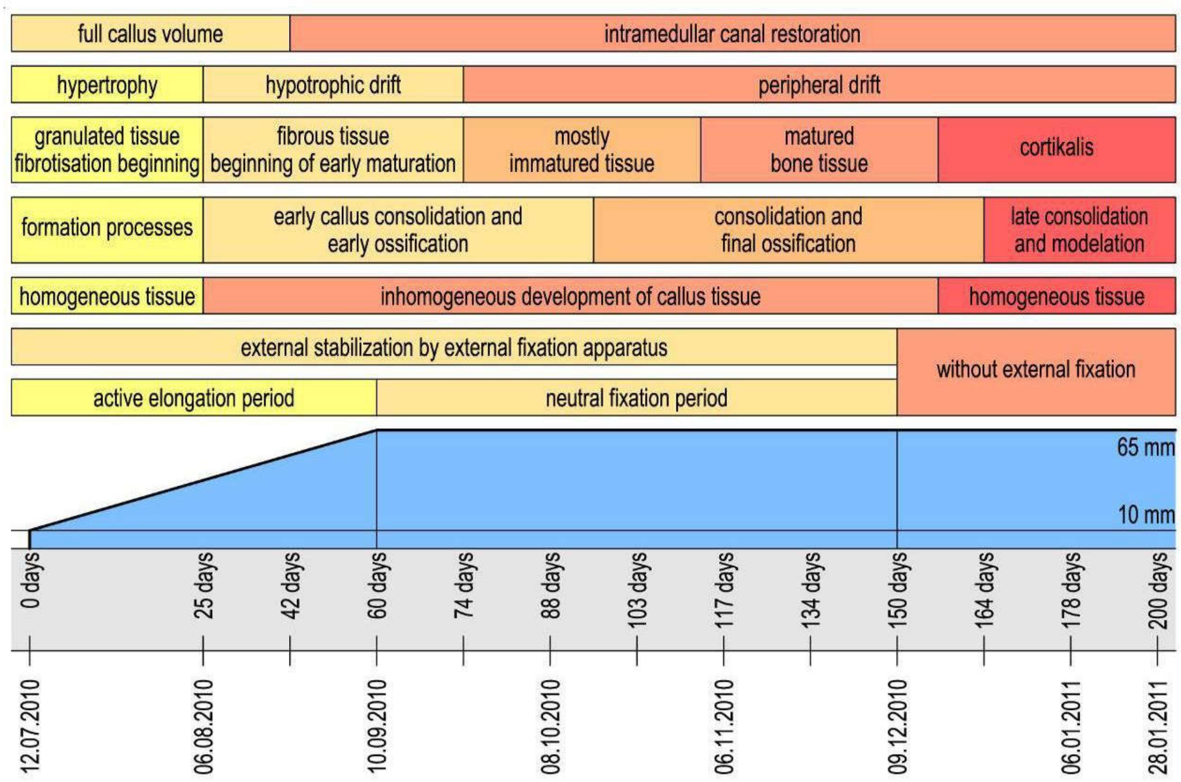

Figure7. Detailed analysis of the bone regenerate development during treatment period according to various criteria

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