THE SIMULATION FOR THE BONE HEALING PROCESS BASED ON MECHANO-REGULATION THEORY CONSIDERED LOADING CONDITION AND COMPOSITE BONE PLATE PROPERTY

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1 Introduction

Human tibia and femur that support the body weights are one of the most frequently injured bones by car accidents or falls. Diaphyseal long bone fractures such as a tibial fracture are usually operated using bone plates (see Fig. 1) with several fastening screws to fix the fracture bone and give the stabilization at the fracture site. Conventional metal bone plates are made of a stainless steel or a titanium alloy which have intrinsic high stiffness relative to the human bones and they usually cause the stress shielding effect. The stress shielding effect induces a stress imbalance between the fractured bones and a bone plate and as a result, the broken bones deliver only small part of the external loads. Under this circumstance, the bone density near the fracture site decreases and this occasionally causes a non-union and bone necrosis. In order to overcome the weak point of the metal bone plates composite bone plates were studied to check the serviceability in view of mechanical function by using finite element analysis and this revealed that the composite bone plates with appropriate Young's modulus produced affirmative mechanical stimulus at the fracture site and relieved stress shielding effect of the fractured bones [1-2]. When bone fracture occurs, the internal fixation devices are applied to the fracture site directly to provide bone stabilization. Among several fixation methods the flexible fixation method allowing a relative movement at the fracture site to some extent is known to promote callus formation when the appropriate mechanical stimulus is provided. The most important thing in this healing method is to control the micro-movement in the appropriate range, therefore the modulus should be carefully controlled considering the fracture status. Fujhara et al. [3-4] fabricated a carbon/PEEK composite bone plate and tested mechanical performances through a 4-point bending test. They provided the appropriate forming condition and the braiding angle. In order to estimate the healing process many related algorithms were proposed; Carter et al. [5], Claes et al. [6] and Lacroix [7] proposed their own mechano-regulation theories with various types of mechanical stimuli such as principal tensile strain, hydrostatic stress, principal strain, hydrostatic pore pressure, deviatoric strain, Fluid flow and so on and they used two parameters to simulate cell differentiations. Perren [8] suggested very simple algorithm to explain the level of healing bone fractures proposing that when the callus has 2~10% interfragmentary gap strains the callus was regarded to be fully cured in a certain healing step. Isaksson et al. [9] tried to summarize all the proposed mechano-regulation theories and compared with each other. Through this research they found that the proposed mechano-regulation theories provided almost the same result on the cell differentiation and its developing pathway. Based on their result, even a mechano-regulation theory with a single parameter such as a deviatoric strain is able to simulate the cell differentiation correctly with almost no differences with the proposed two parameters algorithms. Kim et al. [10] tried to simulate healing process and estimate callus property during healing period when various composite bone plates were applied to the fracture site by using interfragmentary strain theory via finite element analysis. They estimated 4week-interval callus properties by the calculation of gap strains in the previous healing steps and finally proposed the most appropriate stiffness of the bone plate. But this research had a critical limitation; that is, the method was able to estimate average callus property only at 4 week-interval of the healing period because of the lack of information on the standard callus property.

In this paper, our study was focused on the flexible fixation method for inducing micro relative movement at the tibial fracture site which could provide the most appropriate stimulus for bone healing. According to the previous studies on mechano-regulation theories, it was found that mechanical stimulus such as the deviatoric strain at the fracture site has a great influence on bone healing. In our study, as part of applying a mechano-regulation theory to the tibia fracture healing, the finite element analysis was carried out. During performing the finite element analysis (FEA), the analysis of the deviatoric strains as a mechanical stimulus and the corresponding cell phenotype were iteratively estimated by user's subroutine program constructed by Python code which diagnosed the level of the mechanical stimulus and updated cell moduli for the newly developed cell phenotypes automatically at every iterative calculation.

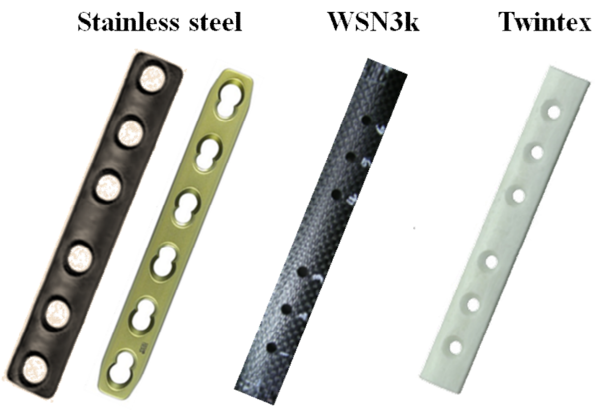

Fig. 1 Several types of bone plates

2 Finite element analysis

2.1 Mechano-regulation theory

A mechano-regulation theory dealing with a deviatoric strain was used to estimate the tissue differentiation and cell phenotype at the fracture site during the healing period. To calculate the deviatoric strains (ε_{ds}) the principal strains $(\varepsilon_{Max}, \varepsilon_{Mid}, \varepsilon_{Min})$ were calculated by FEA in every calculating step (see eg. 1). And the cell phenotypes were classified based on the level of the deviatoric strains generated in the fracture site. The cells was regarded to be developed from a granulation tissue to mature bone via fibrous tissue, cartilage, immature bone, intermediate bone as shown in Fig. 2.

$$\varepsilon_{ds} = \frac{2}{3}\sqrt{\begin{matrix}(\varepsilon_{Max}-\varepsilon_{Mid})^2+(\varepsilon_{Mid}-\varepsilon_{Min})^2 \\ +(\varepsilon_{Min}-\varepsilon_{Max})^2\end{matrix}} \qquad (1)$$

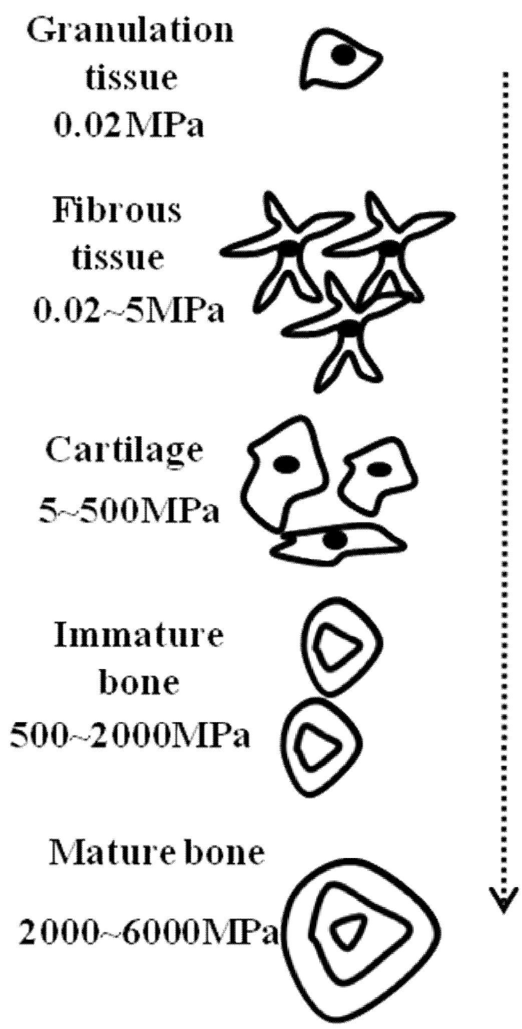

Fig. 2 Process of tissue differentiation

2.2 Iterative calculation for the determination of the cell phenotype

To construct the finite element model of the plate-bone assembly with a fracture gap and calculate the principal strains of the callus elements the commercial finite element code (ABAQUS 6.91) (see Fig. 3) was used. The materials used to design composite bone plates were a carbon/epoxy composites (WSN3k, SK Chemical, Korea) with the stacking sequences of $[0]_{2nT}$, $[\pm 30]_{nT}$, $[\pm 45]_{nT}$ and a glass/polypropylene composite (Twintex, *jb* martin, France) with the stacking sequence of $[0]_{2nT}$ and the material properties were listed in Table 1 including a stainless steel property. The finite element analysis was carried out by the two-step analysis to simulate the actual surgical operation. The first step was screw-fastening process and the second step was load bearing process. The contact element was used in all the contacting surfaces with the friction coefficient of 0.4.

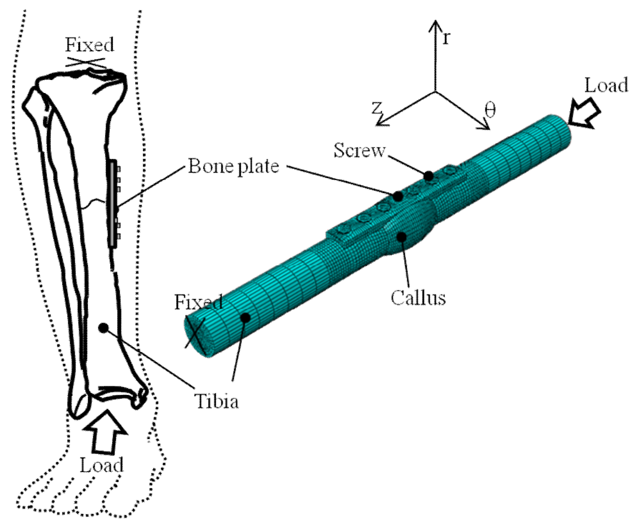

Fig. 3 Finite element model and the loading and boundary conditions.

A user's subroutine for the iterative calculation of gradually healed callus was also constructed by Python code (ver. 3.1). The iterative calculation was carried out for 16 times which represents a single calculation corresponded to the one week of healing period. The cell phenotype was updated by considering the previously calculated deviatoric strains iteratively based on the mechano-regulation theory until the cell phenotype turned into a mature bone considered healing period(see Fig. 4)[11].

Table 1 Material properties of bone plate

Plate type		Young's Modulus(GPa)	Poisson's ratio
Stainless steel		193.0	0.3
WSN3k	$[0]_{2nT}$	E_r=10.0 E_θ=70.0 E_z=70.0	$\nu_{r\theta}$=0.02 ν_{rz}=0.02 $\nu_{\theta z}$=0.13
	$[\pm 30]_{nT}$	E_r=10.0 E_θ=35.8 E_z=35.8	$\nu_{r\theta}$=0.07 ν_{rz}=0.07 $\nu_{\theta z}$=0.55
	$[\pm 45]_{nT}$	E_r=10.0 E_θ=17.9 E_z=17.9	$\nu_{r\theta}$=0.13 ν_{rz}=0.13 $\nu_{\theta z}$=0.78
Twintex $[0]_{2nT}$		E_r=5.30 E_θ=20.0 E_z=20.0	$\nu_{r\theta}$=0.02 ν_{rz}=0.09 $\nu_{\theta z}$=0.78

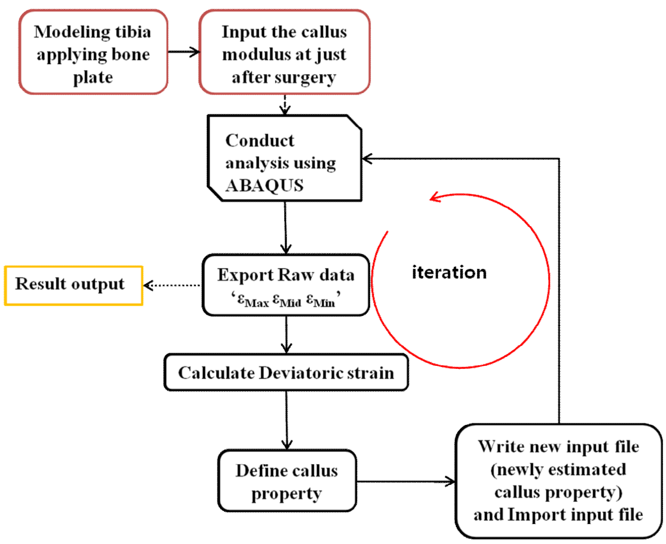

Fig. 4 Iterative calculation process for the determination of cell phenotype according to the healing period..

In order to simulate the patient's walking habit after surgery a 3-step loading condition was introduced. In the first load step (1~8 weeks after surgery) only 10% body weight (10%BW) was imposed on the fracture site considering only the muscle forces. In this step the patient is regarded not to be able to walk properly. In the second step (8~12 weeks after surgery) 200% of body weight (200%BW) was imposed on the fracture site considering some level of mobility of the patient. In this step the patient still have abnormal walking pattern. In the third step (12~16 weeks after surgery) the load increased monotonously from 200% BW to 300% BW which is normal walking pattern.

3 Analysis results

The callus modulus according to the healing period in a week interval when various bone plates were applied to the fracture site was calculated as listed in Table 2.

Table 2 Average modulus of the callus according to the healing period.

Iter. No.	Stainless steel (MPa)	WSN3k			Twintex $[0]_{2nT}$ (MPa)
		$[0]_{2nT}$ (MPa)	$[\pm30]_{nT}$ (MPa)	$[\pm45]_{nT}$ (MPa)	
0	0.02	0.02	0.02	0.02	0.02
1	24	85	380	794	894
2	49	115	926	1161	1261
3	68	264	1209	1464	1584
4	110	467	1312	1664	1744
5	251	768	1412	1764	1850
6	301	858	1452	1874	1905
7	437	942	1492	1884	1911
8	545	964	1522	1894	1927
9	647	967	1532	1904	1943
10	679	968	1543	1904	1949
11	690	980	1549	1904	1954
12	715	988	1555	1904	1970
13	736	996	1562	1904	1976
14	738	1004	1568	1904	1977
15	739	1012	1574	1904	1978
16	740	1020	1581	1904	1978

From the analysis result, it was found that the lower stiffness of the bone plate facilitated well the cell differentiation at the fracture site. But the initial load of 10% of body weight was too low to induce early bone union which means it takes too much time to be healed under the low level of initial loading condition. The stainless steel bone plate was too stiff to stimulate the tissues being differentiated at the fracture site. From the analysis result, the Twintex bone plate provided the best condition for the fracture healing. Based on the finite element analysis, the appropriate plate's property for efficient healing rate during healing period was proposed.

4. Conclusion and discussion

In this study, the finite element analysis for the simulation of the tissue differentiation at the fracture site under the application of various composite bone plates. A mechano-regulation theory dealing with the deviatoric strain was used for the estimation of the cell phenotype developed during the healing process. For the iterative calculation for determining cell phenotype and its material property a user's subroutine programme was prepared using Python code. From the analysis result, it was found that the callus modulus was affected much by the stiffenss of the bone plate. When the initial load is quite low the low level of the bone plate stiffness facilitated the tissue differentiation. But for more precise estimation of the tissue differentiation several things should be refined. First, the loading condition needs to be more realistic considering actual gait cycle of patients. And the material degradation of the composite bone plates when they are applied to the human body environment should be considered because the polymer matrix may be deteriorated when it is exposed to the water enviroment for a long time.

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