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Application of magnetic rods for fixation in orthopedic treatments

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ABSTRACT

Achieving an efficient fixation for complicated fractures and scaffold application treatments is a challenging surgery problem. Although many fixation approaches have been advanced and actively pursued, the optimal solution for long bone defects has not yet been defined. This paper promotes an innovative fixation method based on application of magnetic forces.

The efficiency of this approach was investigated on the basis of finite element modeling for scaffold application and analytical calculations for diaphyseal fractures. Three different configurations have been analyzed including combinations of small cylindrical permanent magnets or stainless steel rods, inserted rigidly in the bone intramedullary canals and in the scaffold. It was shown that attractive forces as high as 75 N can be achieved. While these forces do not reach the strength of mechanical forces in traditional fixators, the employment of magnetic rods is expected to be beneficial by reducing considerably the interface micromotions. It can additionally support magneto-mechanical stimulations as well as enabling a magnetically assisted targeted delivery of drugs and other bio-agents.

1. Introduction

Bone fractures are among the most common orthopedic injures and extremity fractures represent most frequent of them. The healing of such injures represents a complex regenerative process initiating in response to fracture or to scaffold implantation.

To achieve a complete regeneration and a fully functional bone, many interrelated anatomical, biomechanical and biochemical processes must occur in adequate sequence and mode [1]. Particularly, bone healing typically requires a correct anatomical reduction of the fracture ends, a stable primary fixation and prevention of micromotions at interfaces. While various methods are already utilized for long bone fixation [2–6], an impeccable fixation approach guaranteeing the most efficient healing process has not yet been determined. Noteworthy, existing fixation methods, even the most successful ones, are quite invasive and may induce complications causing long healing times.

The idea of the current study is to propose an innovative method for long bone fixation by incorporating intramedullary magnetic rods. We have previously demonstrated the possibility to apply magnetic forces to osteochondral scaffold fixation [7–9]. Those encouraging results have stimulated current investigation in an attempt to promote the magnetic fixation to the more complicated case of long bone defects.

Intramedullary rods, also known as intramedullary nails, are widely used independently or additionally to other fixation systems like external fixators or orthopedic plates. Fixation of the injured bone without opening of the fracture site reduces the surgical trauma of the periosteum, which has a key role in the fracture healing [4–6]. On the other hand, when fracture site must be opened, for example, to apply a scaffold or an internal orthopedic plate, the implantation of small magnetic rods directly in the fracture site would not require additional cuts, hence in these cases it can be considered as little invasive. We analyze various magnetic configurations and show that the application of magnetic rods can provide advantages with respect to standard intramedullary rods.

The matter was approached theoretically on the basis of detailed calculations and simulations within a finite element method (FEM). The simulations have involved parameters and values as close as possible to real *in vivo* cases. This allowed to reveal correct data for attractive forces, resulting in numbers that are promising and interesting for real medical applications. This work will be useful to agree on the choice of the magnetic devices

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and their arrangement in further *in vivo* experiments, whose realization before similar estimations would have been ethically incorrect.

2. Materials and methods

2.1. Software

The forces between two permanent magnets adopted for fracture treatment were calculated analytically in Matlab 7.6 (Matlab R2008b, The MathWorks Inc., Natick, MA, USA) *via* programs developed by authors on the basis of formulas from [10].

For scaffold application computer modeling with COMSOL 3.5 (Comsol Inc., Stockholm, Sweden) was employed to calculate magnetic forces between different magnetic rods *via* Maxwell Stress Tensor. The cylindrical symmetry of the studied configurations (see below) permitted to use Multiphysics–*Magnetostatics–2D axial symmetry* application mode, significantly decreasing the computational time. Nevertheless, the investigation of the lateral displacement between objects required the application of 3D approaches: the AC/DC *Module-3D Magnetostatics—No Currents* mode was used in this case. Utilizing only half of the studied configurations allowed to refine the mesh as well as to reduce the calculation time.

Due to finite element analysis, the choice of the object mesh is crucial for obtaining correct solutions. The most adequate mesh was specifically identified for all the considered objects choosing appropriate subdomain mesh parameters such as maximum element size and/or element growth rate and using a refine mesh method. For a correct comparison of different magnetic materials the same mesh was utilized for the same geometric configurations. Finally, the modeling involved a sufficiently large air sphere (R=333 mm) surrounding the magnetic objects and having magnetic insulation boundary condition.

2.2. Magnetic materials and configurations

The use of intramedullary rods spreads from fractures treatment to critical long bone defects, where the latter is often based on scaffold utilization to replace lost/sick bone. Fig. 1 visualizes two magnetic fixation cases investigated in our study. For fracture treatment we considered two equal cylindrical permanent magnets firmly fixed inside the bones (Fig. 1a). Whereas for scaffold assisted application the considered configuration included one central 30 mm long magnetic rod firmly incorporated into the scaffold and two 20 mm long magnetic rods fitted into adjacent medullary bone cavities (Fig. 1b).

Although a magnet implantation technique is similar to common intramedullary nailing, the short magnet size (10–20 mm) enables its easy insertion directly through the opened injured site without additional osteotomy. A sufficiently rigid fixation of magnetic rods into the bone can be ensured embedding the devices into drilled intramedullary canal of required diameter. After the healing the rods remaining in the bone can be treated similarly to common intramedullary nailing devices.

In order to cover the widest possible range of applications we calculated the fixation forces for three magnetic rod diameters: 4, 8 and 14 mm were chosen as applicable to either small arm bones or to big leg bones.

Two magnetic materials were employed in our simulations and calculations: NdFeB permanent magnet with residual magnetization B_r=1.2 T and stainless steel with saturation magnetization M_s=1.4 T. For permanent magnets the magnetic field can be

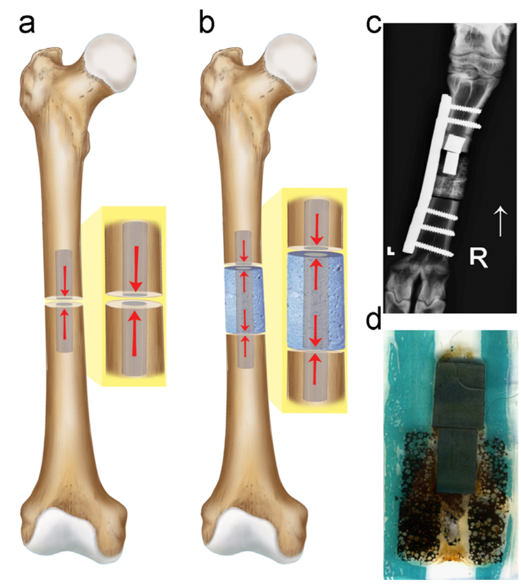

Fig. 1. Magnetic fixation: schematic set up of fracture case (a) and scaffold application (b); postoperative radiographic assessment (c); histological test (d).

described *via* the relation

$$\boldsymbol{B} = \mu_0 \boldsymbol{H} + \boldsymbol{B}_r, \quad (1)$$

where μ_0 is the free space permeability, $\boldsymbol{H}$ is the applied magnetic field and $\boldsymbol{B}_r$ is the residual magnet magnetization. The magnetic forces are directly proportional to the square of $\boldsymbol{B}_r$. The chosen stainless steel represents a magnetically soft material and its magnetic characteristics can be accurately expressed by

$$\boldsymbol{B} = \mu_0 (\boldsymbol{H} + \boldsymbol{M}), \quad (2)$$

where $\boldsymbol{M}$ is the material magnetization. In our simulations we have used experimentally obtained magnetization curve $M(H)$ for stainless steel AISI 410L powder (Institut Hochfeld-Magnetlabor, Helmholtz-Zentrum Dresden-Rossendorf (HZDR), Germany).

In vivo experiments are beyond the scope of this paper. The paper presents the estimation of the magnetic fixation capability, mandatory before any *in vivo* experiment. Nevertheless, we show as example data dealing with *in vivo* investigation of the magnetic scaffold fixation (Fig. 1c) similar to the first of the three considered configurations (Fig. 4a, MAG). In experiment the scaffold was fixed by internal metal plate. Magnetic fixation was added only to one scaffold end to evidence the interfacial magnetic effect on tissue regeneration with respect to purely mechanical fixation at another interface. While these data are not sufficient to be considered as a prove of the above described theoretical achievements, the used image (Fig. 1d, histological test) clearly demonstrates the appeal of such *in vivo* experiments, indicating good bone regeneration inside the scaffold especially near the magnets.

Moreover, recent publication showed a very good biocompatibility of titanium-coated NdFeB magnets in *in vivo* experiments. No sites of necrosis or inflammation due to corrosion products or iron toxicity were detected in the bone tissue surrounding magnets at 4 weeks after surgery [8].

It is important to mention, that the magnetic flux density used in our calculations never exceeded the value of the safety strength of 400 mT at the body tissue established by ICNIRP (International Commission on Non Ionizing Radiation Protection). This value is given by the “Guidelines on Limits of Exposure to Static Magnetic Fields” (2009) and holds for any part of the body, while the exposure limit of limbs is set at 8 T. It has to be mentioned nevertheless that in spite of such limitations it was showed that strong static magnetic field (8 T) not only reduce cell proliferation,