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Feasibility of magnetic activation of a maxillofacial distraction osteogenesis, design of a new device[☆]



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ABSTRACT

Purpose: Distraction osteogenesis is a technique of bone lengthening which uses the bone's natural healing process. Current devices for craniofacial distraction require a transmucosal or transcutaneous activator and are associated with numerous complications. The aim of this study was to evaluate the feasibility of a rodless magnetic activation device that could be used in craniofacial distraction.

Methods: The method is based on the torque applied between two unaligned permanent magnets. This torque depends on magnet size, shape, composition, magnetization and distance between the two magnets. Using a configuration close to that which would be applied in actual distraction osteogenesis (in terms of the distance between the two magnets), we performed an analytical study and evaluated the results.

Results: We observed good agreement between the model and the experimental results, finding that the transmitted force value is comparable to the force required in mandibular distraction. Thus, we proposed a design of a new distracting device consisting of a cylindrical permanent magnet diametrically magnetized and fixed to an endless screw along its main axis. Activation of the distraction motion is achieved through interaction of the first magnet with a second cylindrical magnet whose magnetization is orthogonal to its main axis and to the device's endless screw.

Conclusion: This preliminary study demonstrates that magnetic activation for mandibular osteogenic distraction is feasible and that device size is not a constraint. We propose a prototypic device.

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1. Introduction

Distraction osteogenesis (DOG) has become an important part of the craniofacial surgeon's armarium (Winters and Tatum, 2014; Nada et al., 2010; Adolphs et al., 2014). With this technique, de novo bone lengthening occurs gradually. It is an essential procedure in children with craniofacial deformities, and is applied in a large number of malformations (e.g. congenital, acquired) and localizations (e.g. lower/upper face) (Yu et al., 2004; McCarthy et al., 1995; Meazzini et al., 2012). Distraction osteogenesis involves an initial

injury, recruitment of mesenchymal stem cells, mechanical linear forces, and callus consolidation. Accordingly, the distraction protocol consists of a surgical osteotomy followed by a latency period in which mesenchymal stem cells are recruited, then activation and finally consolidation (Bouletreau et al., 2002).

The first report of craniofacial DOG was by Snyder in 1973 (Snyder et al., 1973), but it was not until 1992 that craniofacial DOG was used on children with congenital mandibular anomalies. Initially, McCarthy and colleagues developed extra-oral distraction devices (McCarthy et al., 2001). These devices were fixed to the bone by transcutaneous pins (McCarthy et al., 1995). However, psychological problems and facial scarring associated with the use of those extra-oral devices led to the emergence of intraoral devices. The first intraoral distractor consisted of a miniaturized extra-oral device (McCarthy et al., 1995), but then through the work of Diner and colleagues, craniofacial bone distraction devices were

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developed based on clinical and anatomical indications (Diner et al., 1996, 1997; Ansari et al., 2015). Since McCarthy's first description, DOG devices have been miniaturized and improved, but can still be discomforting to the patient. Moreover, craniofacial DOG needs to be done through a transmucosal or transcutaneous activator, leading to multiple potential problems such as bacterial infection, activator rod discomfort (the rod prevents dental occlusion), screw-tool fear, chronic wounding, rod covered up ... (Verlinden et al., 2015; Saulacic et al., 2009).

The limitations of the current techniques motivated researchers to develop third-generation DOG devices. Two types of third-generation distractors exist or are under development: continuous automatic distraction and discontinuous activated distraction (Goldwasser et al., 2012). In the past few years, various mechanisms have been proposed to achieve automated distraction: electric motors, spring-assisted devices, hydraulic systems. In all these devices, the distraction progress could not be measured without radiographic imaging (Goldwasser et al., 2012; Saman et al., 2013). Moreover, these solutions raised problems of miniaturization (Goldwasser et al., 2012; Saman et al., 2013).

Another approach to improve the DOG device is to achieve distraction through distant activation. For example, Soubeiran (WO-A-0178614) (Soubeiran, 2001) described a DOG device activated through a magnetic field. His device consisted of a centromedullar distractor and an external magnet. Rotation of the distractor is performed by rotation of another magnet around the distractor device. However, for many reasons this technique is not applicable in maxillofacial surgery: it is not possible to use a centromedullar device, it is not possible to turn around craniofacial bone, large magnetic fields are required, and there is a risk of displacement of materials and screws.

Recently, our team developed a prototypic DOG device activated by a static magnetic field. The aim of the present work is to introduce this magnetically activated distraction device. First, we present the physics underlying the magnetic interaction, we then describe the device, and finally we examine the feasibility and propose a size for the prototype.

2. Materials and methods

2.1. Physical basis

First, we detail the basic principles of the physical model describing the interaction between two magnets. A permanent magnet is composed of material, which maintains an intrinsic magnetization \vec{M} after having been submitted to an external magnetic excitation. Thereby, it produces a static magnetic field \vec{B} that can attract or repel other magnets. The magnetic field configuration depends on the shape of the magnet and the position of the north and south poles. As a first approximation, whatever its form, we can model a magnet by a magnetic dipole $\vec{m}_i = \vec{M}_i V_i$ (where V_i is the volume of the magnet), oriented in the same direction as the magnetization vector, and which generates a dipolar magnetic field:

$$\vec{B}(\vec{r}) = \frac{\mu_0}{4\pi} \left(\frac{3\vec{r}(\vec{m} \cdot \vec{r})}{r^5} - \frac{\vec{m}}{r^3} \right) \quad (1)$$

where μ_0 is the permeability of free space, and \vec{r} the vector designating the position of the considered magnetic field with respect to the position of the magnetic dipole. According to Equation (1), the magnetic field is lower the greater the distance to the magnet. Force is mass times acceleration, which corresponds to the sum of influences that changes the velocity of an object. In the International System of Units this measure in the Newton (N),

which corresponds to the force that when applied to a 1 kg mass gives an acceleration of 1 meter per second or approximately to the weight induced by a mass of 0.1 kg. Torque is a vector that measures the tendency of a force to rotate an object about some axis. As it depends on the distance between the point of application of the force and the rotation axis, it is measured in Newton meters. In the case of two magnets (C_1) and (C_2) interacting, the torque applied from (C_2) on (C_1) is $\vec{\Gamma} = \vec{m}_1 \times \vec{B}_2$, where $\vec{m}_1 = \vec{M}_1 V_1$ is the magnetic moment of (C_1) and \vec{B}_2 is the magnetic field generated by (C_2) at the (C_1) position. We constrain the model to two cylindrical magnets diametrically magnetized and oriented along their main axis as illustrated in Fig. 1. The torque along this axis is:

$$\vec{\Gamma} \cdot \vec{u}_z = \frac{M_1 V_1 \cdot M_2 V_2 \mu_0}{2\pi r^3} \sin \alpha \quad (2)$$

which depends on (i) the cube of the distance between the magnets, r^3 ; (ii) the volumes V_1 and V_2 of the two magnets; (iii) their magnetization \vec{M}_1 and \vec{M}_2 ; and (iv) α , the angle between \vec{M}_1 and \vec{M}_2 . Note that the maximum torque is applied for $\alpha = 90^\circ$, and this torque is zero when the two magnetizations are aligned. Here, our aim was to study the transmitted torque from one magnet to another to confirm that this method could be used to activate the mandibular distraction.

2.2. Description of a new distraction device

The new distraction device is based on the same geometry we described in Fig. 2, with two cylindrical magnets diametrically magnetized and oriented along their main axis. In the distraction device, the internal magnet (C_1) is fixed to the endless screw by one of its two circular faces. When the external magnet (C_2) rotates around the z-axis, the change in magnetic field induces a torque Γ on magnet (C_1), which is directly transmitted to the endless screw without any loss, causing the two plates attached to the mandible to diverge. The magnets are composed of Neodymium alloy (Nd-Fe-B), which creates a large magnetization.

2.3. Experiments

To study the feasibility of the device and determine the sizing of the internal magnet, which must be the smallest possible to reduce the volume of the device, we performed the following experiment (described in Fig. 3) to measure the transmitted torque between a large and a small magnet separated by different distances, r . We clamped a cubic magnet (C_2) of length and width 30 mm and with a thickness of 15 mm to a rotating platform. A cylindrical magnet (C_1) with a diameter of 10 mm and a height of 10 mm was clamped to a second rotating platform. Both platforms rotated on the same axis and the distance r between the two magnets could be varied from 0 to 20 mm. The cylindrical magnet (C_1) was fixed to a cogwheel attached by a nontensile string to a vertical load. The weight of the load was measured with a precision scale, and the reduction in weight depends linearly on the torque transmitted to magnet (C_1). The experiments were performed as follows: for a given distance r we rotated magnet (C_2), which applied a torque on magnet (C_1), which in turn applied a force opposite to gravity to the counterweight. The device was designed and constructed in the Institute of Mechanical Science and Industrial Applications of ENSTA Paris-Tech.

3. Results

The first step was to determine the magnetization of each magnet we used in the experiments, because the properties stated

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