Clinical Biomechanics 28 (2013) 232–238

Contents lists available at SciVerse ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Biomechanical assessment of a novel bone lengthening plate system — A cadaveric study

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ARTICLE INFO

Article history:
Received 4 July 2012
Accepted 21 November 2012

Keywords:
Femur
Biomechanical stability
Bone lengthening plate
Bone mineral density

ABSTRACT

Background: Although many types of external fixators have been developed for distraction osteogenesis, all have some drawbacks. We recently developed a novel bone lengthening plate to overcome these problems. The purpose of this study is to conduct biomechanical analyses using cadavers to assess the stability of the bone lengthening plate in relation to distraction length and femoral bone mineral density.
Methods: We used human cadaveric femurs (n = 18) to assess the effects of distraction length and bone mineral density on the biomechanical stability of the bone lengthening plate. After establishing control (n = 6, 0 mm lengthening) and experimental groups (n = 12, 30 mm lengthening), we measured biomechanical stability (structural stiffness, ultimate load, and displacement) under a compressive load. The experimental group was subdivided into a group with normal bone mineral density (n = 6) and a group with osteoporosis (n = 6), and the biomechanical stability of these groups was compared.
Finding: Structural stiffness differed significantly between the control (417.6 N/mm) and combined experimental groups (185.6 N/mm, p = 0.002). Ultimate load also differed significantly between the control (1327.8 N) and combined experimental (331.4 N, p = 0.002) groups. Bone mineral density was unrelated to structural stiffness (p = 0.204), ultimate load (0.876), or displacement (0.344). In all cases, failure of the bone lengthening plate occurred at the longitudinal connectors, such as the connecting columns between the upper and lower plates, and the lengthening shaft of the bone lengthening plate.
Interpretation: The biomechanical stability of the bone lengthening plate was affected by the lengthening length but not by bone mineral density. In addition, biomechanical stability during lengthening was most strongly influenced by the longitudinal connectors.

1. Introduction

Distraction osteogenesis was first developed by Ilizarov for treatment of bone infection, leg length discrepancy, and deformities. The procedure involves osteotomy of the long bone, followed by lengthening of the proximal and distal osteotomized bones through periosteal stimulation by using artificial traction of the osteotomized bone (Aldegheri et al., 1989; Brunner et al., 1990; Catagni et al., 2011; Manohar Babu et al., 2012). Ring-type conventional external fixators were developed for distraction osteogenesis, but these devices can damage the muscles, blood vessels, and nerves when the wires inserted for fixation and distraction of the osteotomized bone pass though the structures of the extremities. Furthermore, many patients have difficulty walking due to the bulky size of external fixators (Cavusoglu et al., 2009; Green, 1988; Makarov et al., 1997; Polak et al., 2001). In order to overcome the limitations of conventional external fixators, various modifications, such as the H fixator and the Rancho modification of the Ilizarov frame, have been developed, but these devices have not been able to overcome the limitations of external fixation.

We recently developed a novel bone lengthening plate (BLP) system for bone distraction that overcomes some of the drawbacks of conventional external fixators. In a previous study, finite element analysis of the biomechanical parameters of the BLP was performed to estimate the biomechanical stability of the BLP in clinical applications (under review). Biomechanical analysis of the BLP-attached femur was performed while varying lengthening conditions (from 0 to 50 mm) and for different material properties of the supporting axis. Results demonstrated a 158% decrease in structural stiffness when the lengthening length was increased at 30 mm distraction which is the worst result among the examined variable lengthening

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0268-0033/$ – see front matter
http://dx.doi.org/10.1016/j.clinbiomech.2012.11.011

conditions but still clinically useful. A 128% increase in the structural stiffness was observed with substitution of cobalt-chrome alloys for titanium alloys in the supporting axis. Based on this analysis, the BLP as appears to be a clinically applicable device and this device is the most biomechanically stable when its connecting axis is composed of cobalt-chrome alloys (among the tested, promising materials). These findings indicate that a biomechanical study with cadavers is the next logical step needed to investigate the clinical applicability of the BLP system.

Therefore, the purpose of this study is to investigate the biomechanical stability of the BLP system, including structural stiffness, ultimate displacement, and load, in relation to lengthening length. We also assessed whether bone mineral density (BMD) affects biomechanical stability during lengthening.

2. Methods

2.1. The BLP system

As shown in Fig. 1A, the BLP system is a bone distraction system attached below the skin at the femur, so it does not requires wires to perforate the bone and associated structures. This plate system is covered by the overlying muscle and skin, and there is no need for a bulky device on the outside of the body. This design allows the BLP system to overcome many of the drawbacks of external fixators. As shown in Fig. 1B, the novel BLP system is composed of an upper metal plate attached to the proximal portion of the femur, and a lower metal plate attached to the distal portion of the femur. For bone distraction, the BLP system has a pair of columns that face each other in parallel in the inner space of the upper and lower metal plates. A spring joint is mounted on top of the upper metal plate to transfers rotational motions into straight-line motions, which are eventually conveyed to the lower metal plate through a threaded lengthening shaft. In response to movement of the lengthening shaft and the pair of columns, the lower metal plate moves such that the space between the upper and lower plates increases. The lengthening length (distraction) is 0.7 mm per rotation of the spring joint.

The metal plates and screws are made of titanium alloys, and the lengthening shafts and columns are made of cobalt–chrome alloys. Before selection of these materials, the coupling effects such as galvanic corrosion between cobalt–chrome and titanium was considered. Although there is some disagreement, many clinical and research reports demonstrated the acceptability of using these two alloys together (Cluck and Skaggs, 2006; Kummer and Rose, 1983; Lucas et al., 1981; Rostoker et al., 1974; Venugopalan and Lucas, 1998). On this basis, we chose the material for the lengthening shafts and columns to be cobalt-chrome alloy.

In order to maximize the fixation strength and biomechanical stability of the BLP system, a previously developed design for a locking screws and plate system (LCP) were applied to the BLP and its screws (Fig. 1C). These designs adapted from the LCP are able to minimize motion between the screws and metal plates while the patient walks during lengthening, because the head of the screw and the hole of the metal plate are locked together by their threading, as has been demonstrated in previous studies (Gutwald et al., 2003; Haidukewych and Ricci, 2008; Miller et al., 2008). In addition, this design prevents frictional forces from developing between the bone and the implant, which in turn prevents the development of bone necrosis that can be caused by cortical bone compression (Frigg, 2001; Kaab et al., 2004; Schmal et al., 2011). This is achieved by the lock between the screw and the plate, which prevents purchasing of the screw through the plate. This design is an improvement over conventional plates that provide stable fixation through compression by tightening the screw through the plate (Fig. 1D). Due to this mechanical difference biological fixation, which preserves the tissue surrounding the bone and its blood supply, is made possible by using the LCP system, as has been demonstrated in clinical orthopedic applications (Ronga et al., 2009; Schmal et al., 2011).

2.2. In vitro test of the BLP system with cadaveric femurs

We examined 18 adult cadaveric femurs for exclusion criteria of hematologic, metabolic, metastatic, and other medical diseases and

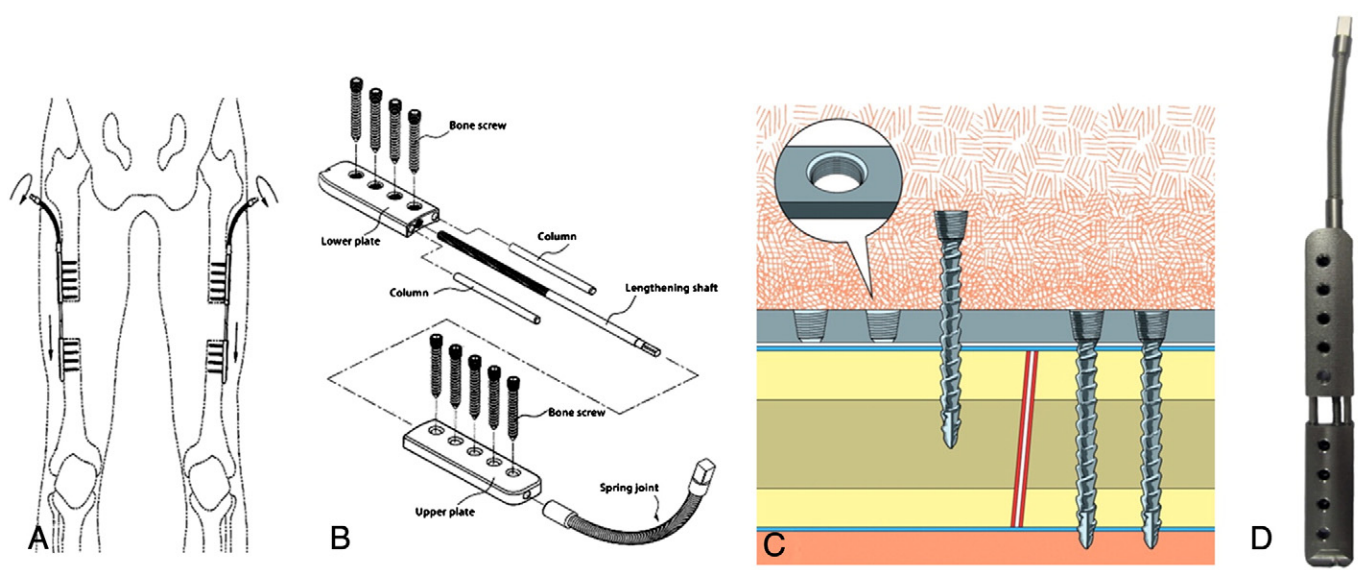

Fig. 1. (A) The metal plates of the novel bone lengthening plate (BLP) system used for bone distraction of the femur, (B) Components of the internal fixation system for bone lengthening. The upper plate is 0.8 mm (thickness) × 20 mm (width) × 70 mm (length) and has 5 holes for screws fixation with 0.8 thread pitch. The lower plate is 0.8 mm (thickness) × 20 mm (width) × 60 mm (length) and has 4 holes for screw fixation with a 0.8 thread pitch. For lengthening, the columns have Ø3.6 (diameter) × 58 mm (length), and the lengthening shaft is Ø4.0 (diameter) × 108 mm (length) (50 mm threaded region with 0.7 thread pitch). The screw has outer diameter Ø4.0, core diameter 2.4 mm, thread pitch 0.8 mm, total length 35 mm, and threaded head 5 mm. (C) The plate hole of the bone lengthening plate (BLP) and the head of the locking screw are threaded as a pair to create a direct lock between the locking screw and the BLP, enabling the BLP to act internally as an external fixator. Additionally, although the plate does not make direct contact with the bone or compress the bone, the BLP with locking screw system provides stability at the fracture site (red line) and since it does not compress the bone with the plate, anatomically important tissue for osteogenesis such as periosteum (blue line) is preserved. (D) Prototype of the novel BLP system.