Medical Engineering and Physics 56 (2018) 48–53

Contents lists available at ScienceDirect

Medical Engineering and Physics

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

Technical note

Importance of a moderate plate-to-bone distance for the functioning of the far cortical locking system

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ARTICLE INFO

Article history:
Received 4 August 2017
Revised 21 March 2018
Accepted 10 April 2018

Keywords:
Far cortical locking
Interfragmentary movement
Construct stiffness
Biomechanical testing

ABSTRACT

The far cortical locking (FCL) system, a novel bridge-plating technique, aims to deliver controlled and symmetric interfragmentary motion for a potential uniform callus distribution. However, clinical data for the practical use of this system are limited. The current study investigated the biomechanical effect of a locking plate/far cortical locking construct on a simulated comminuted diaphyseal fracture of the synthetic bones at different distance between the plate and the bone. Biomechanical in vitro experiments were performed using composite sawbones as bone models. A 10-mm osteotomy gap was created and bridged with FCL constructs to determine the construct stiffness, strength, and interfragmentary movement under axial compression, which comprised one of three methods: locking plates applied flush to bone, at 2 mm, or at 4 mm from the bone. The plate applied flush to the bone exhibited higher stiffness than those at 2 mm and 4 mm plate elevation. A homogeneous interfragmentary motion at the near and far cortices was observed for the plate at 2 mm, whereas a relatively large movement was observed at the far cortex for the plate applied at 4 mm. A plate-to-bone distance of 2 mm had the advantages of reducing axial stiffness and providing nearly parallel interfragmentary motion. The plate flush to the bone prohibits the dynamic function of the far cortical locking mechanism, and the 4-mm offset was too unstable for fracture healing.

1. Introduction

The main objective of any bone fixation device is to achieve fracture union. Conventional methods that use dynamic compression plates rely on a very rigid construct to allow direct bone healing. In recent decades, the internal fixation of long bone fractures has developed, and now involves biological, rather than mechanical methods; thus, more flexible constructs are favored to induce secondary bone healing by callus formation [1–3]. With the introduction of locking compression plates as a fixed-angle screw locked mechanism, this technique avoids the need for precise reduction and plate compression against the underlying bone while preserving periosteal blood supply [1]. As a less rigid fixation, locking plates allow interfragmentary motion (IFM) to stimulate new bone formation that bridges the fracture site through a process termed biological osteosynthesis [3].

Recent studies have demonstrated that locking plate constructs can be as stiff as the conventional plating constructs [4,5] designed to induce direct bone healing. The relatively high stiffness of locked bridge plating constructs may therefore suppress IFM to an insufficient level, resulting in complications in healing, including delayed union, nonunion, and implant failure [6–8]. Several studies have investigated modulating the stiffness of locked plating constructs by altering the plate length, screw number, and screw position [9–12]. Although these strategies are effective for reducing construct stiffness, the fixed-angle stabilization of locking screws causes an asymmetric motion at the fracture site; that is, an increased movement at the cortex opposite to the plate. By contrast, movement at the near cortex is very limited [13]. This may suppress callus formation, particularly at the near cortex [6,14]. The concept of far cortical locking (FCL) was introduced to provide

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https://doi.org/10.1016/j.medengphy.2018.04.006
1350-4533/

flexible fixation and nearly parallel IFM [13–15], thereby optimizing the mechanical and biological factors of fracture healing.

FCL screws have a reduced midshaft diameter to bypass the near cortex underlying the plate while providing unicortical fixation in the far cortex of the diaphysis. The midshaft of the screw acts as an elastic cantilever beam to enable flexible fixation with locking plates [13–15]. Biomechanical studies using synthetic bone models have demonstrated that FCL fixations generate homogenous fracture movement while preserving fixation stability [13,15,16]. In some cases, the plate was applied at 2-mm elevation from the bone surface [13,16], whereas in other cases the plate was located 1-mm from the bone surface [15]. The farther the fixator is placed from the bone, the less construct stiffness is exhibited. However, the influence of the distance between the plate–FCL system and the bone remains unclear and clinical data are limited [18,19]; therefore, the potential of this system for practical use needs to be determined. The current study aimed to clarify the distance between the plate and bone at which an extramedullary locking plate with FCL screws can be placed such that the IFM is maintained at an appropriate level without considerably weakening its mechanical properties. The specific construct on which this study is based conforms with the typical screw configuration used in the diaphyseal portion of a locked plate construct [15–17]. This was chosen as a typical screw positioning in the diaphyseal portion of a locked plate construct.

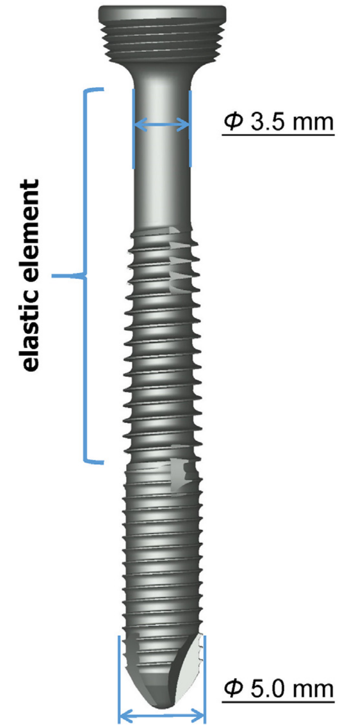

Fig. 1. Far cortical locking (FCL) screw used in the biomechanical test (5.0 mm DDTLS, Dynamic Double-Thread Locking Screw). The screw has a smooth screw neck with a diameter of 3.5 mm to bypass the near cortex.

2. Methods

Normal locking plate constructs (the control) and far cortical locking constructs were tested in femoral diaphysis fracture models with a simulated fracture gap under axial compression loading. Each construct was tested to determine the stiffness, strength, and failure mode. Moreover, cyclic loading tests were performed to determine whether construct failure occurs because of the distance from the implant to the bone surface.

2.1. Implants

Normal locking screws used have a 5.0-mm-diameter thread and a cylindrical profile. The FCL screw employed was the Dynamic Double-Thread Locking (DDTL) screw (A Plus Biotechnology Co., Ltd., New Taipei City, Taiwan) (Fig. 1), which is a dynamic locking-screw design referred to Bottlang et al. [15]. The DDTL screw is slightly tapered in shape. The greater distal body has a 5.0-mm-diameter thread to engage with the far cortex and a 3.5-mm-diameter neck to bypass the near cortex, allowing for elastic bending of the screw shaft. As the axial loading is increased, the contact between the screw shaft and the near cortex can provide additional support and control the elastic motion. 12-hole locking compression plates (ABS Locking Plate, A Plus Biotechnology Co., Ltd., New Taipei City, Taiwan) were used as bridging implants. All plates are 19 mm wide and 212 mm long. All implants were manufactured from titanium alloy (Ti–6Al–4V).

2.2. Specimens

To minimize interspecimen variability, the synthetic bone materials have been widely used as human bone substitutes in many experimental investigations [4,13–16]. In our study, the number of specimens assigned to each mechanical test was five. A total of 40 in vitro experiments were conducted using composite sawbones. The cylinder bone surrogates with a diameter of 30 mm and a wall thickness of 7 mm (Sawbones #3403; Pacific Research Laboratories, Vashon, Washington) were cut in half; plates were then fixed with three screws in both proximal and distal bone surrogates, with a 10-mm osteotomy gap to simulate a comminuted fracture pattern [15]. Using temporary spacers, the plates of FCL system were fixed at three positions: flush to the bone, and at 2 mm and 4 mm elevation from the bone surface (Fig. 2). The screw lengths used for the plate flush to bone at 2 and 4 mm elevation were 40, 42, and 44 mm, respectively. Each screw was tightened to 4 Nm using a torque limiter.

2.3. Loading

All constructs were tested in static and dynamic axial compression by a material test system (HT-2402, Hung-Ta Instrument Co., Taiwan). For the static loading tests, a load was applied proximally through a spherical bearing while the distal end of the specimen was affixed to a platform [15]. The load was increased incrementally until failure occurred at any component of the construct or gap closure of the fracture site. IFM was determined at the near cortex and far cortex with digital calipers at a resolution of 0.01 mm. Axial stiffness was calculated from the applied load and displacement data. Construct strength was determined by progressive increased loading to failure.

To evaluate whether any part of the FCL system would fail during the mechanical stimulus for callus formation, dynamic cyclic loads were applied under force control with a sinusoidal loading between 0 and 200 N at 1 Hz to simulate partial postoperative weight bearing [15,20]. Fatigue failure was defined as a plate or screw breakage or loosening of the screws in the plate or bone. Tests were run for 100,000 cycles if the construct had not already failed. The total number of cycles was chosen to represent 1000 cycles per day for 3 months [21]. Actuator displacement was recorded for comparison.

2.4. Statistical analysis

The stiffness and strength results were compared for different plate-to-bone distances. Analysis of variance was conducted.