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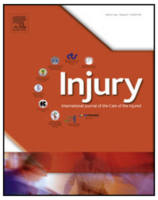

Influence of plate–bone contact on cyclically loaded conically coupled locking plate failure

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ABSTRACT

Introduction: The maintenance of friction between locking plates and bone is not essential, so that they can be applied with a gap between the plate and underlying bone. We hypothesised that the presence of a gap under a locking plate with a conical coupling mechanism would reduce fixation stability or allow uncoupling of the locking screws from the plate.

Materials and methods: Locking plates with two conically coupled locking screws were applied to 6 pairs of adult canine femora. One of each pair had plate to bone contact and the contralateral construct had a 2 mm plate to bone gap. Constructs were cyclically loaded in cantilever bending with 10 percent incremental increases every 1000 cycles at 2 Hz, starting at 250 N. The constructs were fatigued to failure. To evaluate fatigue life of the conical coupling, testing was repeated with aluminium tubing replacing the bone, to eliminate screw–bone cutout failure.

Results: The mean sustained loads and cycles to failure in the contact group (420.80, standard error [SE] 14.97 N; 7612.00, SE 574.70 cycles) were significantly greater than in the gap group (337.50, SE 14.97 N; 4252.00, SE 574.70 cycles), ($p < 0.001$). Failure mode of all bone constructs was via screw cutout from the bone. Aluminium tubing constructs failed via screw or plate fatigue and breaking, with one construct having elevation of the plate over the screw head.

Discussion and conclusions: Elevation of locking plates with a conical coupling system by 2 mm from the bone reduced construct fatigue life but did not result in screw head uncoupling from the plate.

Introduction

Locking plates act as internal fixators with screws perpendicularly engaging the plate holes. The fixed angles of the screws convert the shear stresses placed on the fracture repair sites to compressive forces at the screw–bone interfaces [1,2]. The implants do not rely on friction between the plate and the bone for stability and so do not have to be placed directly against the bone. The application of these plates does not result in the bone stresses that occur with a contact plate [3,4].

To achieve adequate plate–bone contact in traditional plates, exact plate contouring is required as well as extensive soft tissue dissection to expose the bone. This can damage periosteal blood supply [5–7]. As locking plates can be applied without bone contact, a minimally invasive surgical approach can be used, decreasing disruption to the bone blood supply [3,8]. There is also an increase in infection resistance and refracture resistance [7,9]. Overall, improved bone healing has been identified in plate application where there is less bone contact [10].

There are several different types of locking mechanisms employed in locking plate technology. The Less Invasive Stabilisation System (LISS®, Synthes) plate and the Locking Compression Plate (LCP®, Synthes) have round threaded plate holes that lock with the corresponding threads of the locking screw heads [11]. An alternative form of locking mechanism is the Morse cone coupling mechanism, which was a feature of the Point Contact Fixator (PC-Fix) [4]. It had monocortical conically headed screws that locked into the plates and the resistance to torsional and bending forces was comparable with traditional plates [4,12]. The PC-Fix was never commercialised however, because jamming of the screw head to the plate sometimes precluded implant removal from patients following fracture healing. It was suspected that this occurred because excessively high torque was applied when tightening the screws [13,14]. This assumption is supported in

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mechanical studies where plastic deformation of constructs has occurred with high torque application [15].

Another recently developed conical coupling locking plate system is the Fixin® system (Traumavet, Rivoli, Italy). The screw heads also have a Morse cone design that engages with a titanium bushing insert, which in turn screws into a stainless steel plate [16,17].

It could be hypothesised that an increase in the distance of a locking plate from the bone may decrease construct stability. Biomechanical testing has shown that incrementally elevating locking plates with a threaded locking mechanism from the bone, results in progressive compromise of construct stability [1,18]. This has not been evaluated in locking plates with a conical coupling mechanism.

The aim of this study was to evaluate the effect of a 2 mm elevation from the bone of a locking plate with a conical coupling mechanism (Fixin®). Our hypothesis was that the in vitro mechanical stability of a locking plate system that relies on a plate–screw conical coupling may uncouple when the plate is elevated 2 mm from the bone and placed under conditions of cyclic loading.

Materials and methods

Experiment 1: plate–bone constructs

Bone specimen preparation

Six pairs of femora were harvested from healthy, mature Greyhound dogs that were euthanised for reasons unrelated to our study. The bones were stripped of all soft tissue and stored at −80 °C, wrapped in saline moistened cloths and thawed to room temperature prior to testing. They were continuously moistened with saline to limit deterioration. If refreezing was required for short periods, −20 °C was used with the bones again covered in saline moistened cloths to avoid bone dehydration and deterioration [19,20]. Each pair was assessed grossly for any damage that may have occurred with soft tissue stripping. Mediolateral and craniocaudal radiographs (Faxitron XRay Cabinet® Model Number MX20/DX50, Faxitron Bioptics LLC, Tucson, AZ, USA) were taken to ensure that the physes were closed and that there were no signs of pre-existing bone pathology. Dual Energy XRay Absorptiometry (DEXA) scanning was performed (Lunar DPX®, GE Medical Systems, Diegem, Belgium) to quantify the area density of bone mineral at several regions in each bone. The addition of these regions over an entire bone gave the bone mineral content, which could then be normalised to the bone area, providing bone mineral density (BMD) in g/cm^2. The differences in BMD between paired femora were compared using a paired *t*-test and were not significantly different.

Plate–bone construct preparation

The femurs were transected at 75% of their measured diaphyseal length to create a consistent osteotomy site and stainless steel locking plates (AISI 316LVM, Fixin® V3401, 3.5 series, Traumavet, Rivoli, Italy) that were 171 mm long, 3 mm thick, 10 mm wide (8 mm wide between screws) and containing 6 conical coupling holes were cut in half. Each femur had a half-length transected plate applied to the lateral surface with two 3.5 mm self-tapping stainless steel locking screws that engaged both cortices. Paired bones were randomly allocated via a coin toss to one of the two construct groups, either with the plate attached in contact with the bone or the plate attached with a 2 mm plate–bone gap. Two 2 mm diameter Kirschner wires were temporarily placed between the plate and the bone to maintain a consistent 2 mm gap, until screw insertion was complete. The screws were inserted into the matching conically shaped smooth sided titanium alloy (Ti-6A1-4V) bushing inserts, which had external threads that locked into holes in the stainless steel plates (Fig. 1).

The plates were placed with 10 mm overhang from the end of the bone. One screw was placed in the hole adjacent to the osteotomised bone end with the centre of the screw located 7.5 mm from the end and the second screw was placed two screw holes distal to the first, with 25 mm between each screw hole centre. The screws were tightened using a torque-limiting screwdriver (Torqueleader® Model ETW 25 Digital Reader, Torqueleader, Guildford, Surrey, UK) to a torque of 3.0 N m. A minimum of 2.5 N m torque is recommended for the Fixin system [21]. The plate extended 10 mm beyond the end of the bone to allow for testing of the constructs in cantilever bending. Femora were transected 40 mm from the proximal end of the plate so the bone could be potted with the longitudinal axis of the bone perpendicular to the upper surface of the potting mould.

The plate–bone constructs were potted in a fusible alloy (Woods Metal) with a low melting point of 70 °C and then lowered into a 37 °C saline bath for mounting on a servohydraulic materials testing machine (858 Bionix® MTS, Skakopee, MN, USA) fitted with a 2.5 kN load cell. The plate–bone constructs remained immersed in saline throughout testing and each plate was subjected to bidirectional, cyclic bending loads at 2 Hz (Fig. 2). The jig used to apply the bending loads did not induce torsional loading of the plates. Initial bidirectional loads of 250 N were incrementally increased by 10 percent every 1000 cycles until the constructs were fatigued to failure. Pilot testing of a single construct and assessing the load that was tolerated with no visible change to the construct, determined the starting load of 250 N.

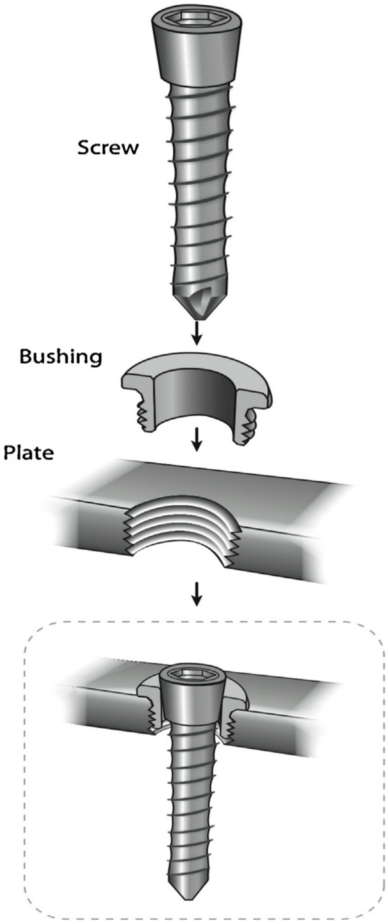

Fig. 1. Components of the conically coupled locking plate.