Biomechanical Evaluation of a Modified Dorsal Double-plating Fixation with Adjustable Joint and Microthread Designs for Comminuted Extra-articular Distal Radius Fractures

Yu-Hao Lin\textsuperscript{1} Alvin Chao-Yu Chen\textsuperscript{2} Hsien-Nan Kuo\textsuperscript{3}
Tsung-Chih Yu\textsuperscript{3} Ming-Tsung Sun\textsuperscript{1} Chun-Li Lin\textsuperscript{4,*}

\textsuperscript{1}Department of Mechanical Engineering, Chang Gung University, Taoyuan 333, Taiwan, ROC
\textsuperscript{2}Medical Doctor, Department of Orthopaedic Surgery, Chang Gung Memorial Hospital, Taoyuan 333, Taiwan, ROC
\textsuperscript{3}Medical Devices Development Section, Metal Industries Research & Development Centre, Kaohsiung 811, Taiwan, ROC
\textsuperscript{4}Department of Biomedical Engineering, National Yang-Ming University, Taipei 112, Taiwan, ROC

Received 11 Aug 2011; Accepted 24 Nov 2011; doi: 10.5405/jmbe.990

Abstract

This study evaluates the biomechanical strength of a modified dorsal double-plating (MDDP) internal fixation on artificial radius bones using the dynamic fatigue test. The plates are 1.6 mm thick and the upper L plate has an adjustable joint to allow the angular disposition of the bone plate to be changed to secure various bone fracture types. A dual-thread locking screw is used to enhance mechanical retention at the screw/bone interface. A finite element analysis is performed to examine the mechanical bone and fixation system response using a dual-microthread locking screw. An MDDP fixation is made with stainless steel by a manufacturer with ISO13485 quality management systems. Eighteen radius Sawbones were randomly placed into three groups and cut to a standard length of 2.5 cm from the articular surface to form 0\degree, 30\degree, and 60\degree fracture configurations according to the A2 classification in the AO surgery reference. The adjustable joint in the L plates is adjusted and fixed using a fastener connection to have a 0\degree, 30\degree, or 60\degree configuration. Plates and screws are then positioned on the dorso-ulnar side for L plates and the dorso-radial side for I plates to create an angle of 90\degree. The specimens were subjected to oscillating loads of 10 to 150 N at 5 Hz for 20000 cycles. The average stiffness values after 20000 cycles were 425.7, 461.1, and 532.1 N/mm for the 0\degree, 30\degree, and 60\degree constructs, respectively. No difference in stiffness was found for constructs with a given angle throughout the 20000 cycles of testing (p > 0.05). However, significant differences (p < 0.05) in stiffness were found between constructs with different angles at each 500-cycle interval. The lack of gross construct failure during cyclic testing and the reasonable stiffness prove that MDDP internal fixation is sufficiently stable to support restricted postoperative loads.

Keywords: Biomechanics, Distal radius fracture, Dorsal double-plating, Fatigue test, Stiffness

1. Introduction

Fractures of the distal radius are the most common injuries encountered in orthopedics, accounting for approximately 20\% of all fractures. Treatment of these injuries usually depends on the stability of the fracture configuration [1-5]. Unstable displaced distal radius fractures resulting in intra-articular involvement and comminution frequently require surgical fixation [2,3,5]. Many surgical techniques have been developed to restore articular congruity and wrist functions, including external fixation, pinning and plaster casting, and internal fixation. An appropriate method for distal radius fracture needs to restore not only the anatomy, but also biomechanical stability in terms of preventing the re-displacement of the fragments and re-establishing the normal wrist load transmission pattern [6].

Internal fixation with two metal plates, called dorsal double-plating (DDP), has shown promising results [7]. With DDP techniques, a T plate and an I (straight) plate are fixed onto the fractured radius with an angle of 50\degree-70\degree between them. This creates superior stiffness with possible early
mobilization in most cases compared to that of the traditional single T plate and π plate when applied to the unstable distal radius fracture model [8]. Plates with locking screws have recently been developed with greater stiffness and strength than those of standard plates to reduce the possibility of screw loosening and subsequent loss of reduction. Locking plates may also allow for increased periosteal blood supply and eliminate the need for extreme contouring to match the shape of the radius [9,10]. Therefore, current modalities of internal fixation for the distal radius allow the screws to be locked into the plate, which ensures axial as well as angular stability even for low-profile DDP approaches.

Complications with the DDP technique can be addressed surgically and biomechanically. Surgically, a T plate placed on the dorso-ulnar side is associated with an increased risk of extensor tendon irritation or ruptures due to the interactions between the bulky screw heads and the adjacent tendons [11]. Furthermore, because of the limited space of the distal fragment, the fixation screws in the dorso-volar direction of the T plate might interfere with the screw in the radial-ulnar direction of the straight I plate. Biomechanically, distal radius fractures are classified into nine kinds by the AO foundation. The selection of the most appropriate therapy depends on the configuration and sort of fracture [1,12]. Distal bone segment displacement and bone/plate/screw stress are usually major indicators for evaluating the fixation system treatment success rate. However, ideal fixation for the distal radius does not exist and optimal treatment remains a therapeutic challenge [13,14].

To overcome the surgical and biomechanical complications of DDP fixation, the present study proposes the modified dorsal double-plating (MDDP) technique. Compared to the standard DDP technique, MDDP has an angle of 90° instead of 50°-70° between the two buttressing plates to maximize the stability. The profile and structure of the T plate in the MDDP fixation is modified into an L shape. The upper part of the L plate has an adjustable joint to fit various radius fracture configurations. A microthread locking screw is proposed for the cortical bone contact area to improve mechanical retention at the cortical bone/screw interface. The biomechanical strength of MDDP fixed on artificial radius bones is evaluated using the dynamic fatigue test to estimate physiological loads seen over the usual 6-month healing time for this type of injury.

2. Materials and methods

2.1 MDDP

The MDDP technique was proposed by the cooperating research teams at the Computer Aided Engineering in Biomedicine Laboratory at National Yang-Ming University/ Chang Gung University and the Metal Industries Research and Development Center in Taiwan. The MDDP technique uses L and I buttressed plates placed on the dorso-ulnar side (underneath the fourth extensor compartment) and the dorso-radial side (underneath the second extensor compartment), respectively (Fig. 1). The L and I plates have an angle of 90° between them to maximize stability. The plates are 1.6 mm thick and a low profile. The cross-sectional design, undercuts, rounded edges, and tapered tips reduce the potential for soft tissue irritation and ensure optimal blood circulation in the periost, especially when used with locking screws (Fig. 2). An adjustable joint with a male/female fastener connected between the short and long parts of the L plate allows the angular disposition to be adjusted by pivotal movement in 30° increments of a plate member about one axis. The angular disposition may then be fixed (locked). The shape and/or extent of the bone plate can be changed by adjusting the angular disposition of the plate members. Therefore, the plate members may be configured to be secured to different regions of one bone or secured to different bone using fasteners placed in the openings according to the bone fracture configurations (Fig. 1). The microthread locking screw has a 0.35-mm pitch in the upper region (2.5 mm) to provide for cortical bone contact and a 0.6-mm pitch in the lower region for cancellous bone contact. An adjustable joint L plate, an I plate, and a microthread locking screw were made with SUS316LVM stainless steel for testing by a manufacturer with ISO13485 quality management systems (Microwave Precision Co. Ltd., Taichuang, Taiwan) (Figs. 1 and 2).
2.2 Finite element analysis of microthread locking screw

Dual-thread (0.35-mm and 0.6-mm pitches) and single-thread (0.6-mm pitch) locking screw (2.5 mm in diameter) solid models corresponding to the aforementioned defined geometric features (adjustable joint and microthread) were generated using a CAD system (Pro/Engineer; PTC., Waltham, MA, USA) and exported into the finite element (FE) software package (ANSYS, v. 11.0; Swanson Analysis, Inc., Houston, PA., USA) to assemble the bone model (Fig. 3). The bone model was constructed as a 15 mm × 15 mm × 22.5 mm block with a 2-mm-thick shell to simulate cortical bone and with a 3-mm gap to simplify the radius fracture pattern with a metaphyseal wedge according to the 23-A2 classification in the AO surgery reference [15] (Fig. 3). The bone/locking screw system mesh models were generated using a quadratic ten-node tetrahedral structural solid element (204547 elements and 287855 nodes for the dual-thread screw; 199416 elements and 280441 nodes for the single-thread screw). The bonded condition was applied at the locking screw/bone interface to simulate the continuous displacement between the locking screw and bone. Nonlinear contact elements (defined as surface to surface) with 0.3 friction coefficients were used to simulate the interfacial adaptation between the fixation plates and bony surface [16]. Linear-elastic locking screw and bone material properties (elastic modulus for the screw and cortical and cancellous bone were 110, 17, and 1.3 GPa, respectively; Possion’s ratio for all materials was 0.3) were assigned based on the volume definition in the literature [17]. The models were constrained at the proximal end as the boundary condition (Fig. 3). An axial load of 100 N, and bending and torsional moment loads of 1 Nm were applied at the left block end surface to simulate the load conditions [18] (Fig. 3). The magnitudes and directions of the loads were set to simulate the physiological loads experienced with active wrist joint movement during daily activities [18,19]. To investigate the wrist load transmission pattern and check the potential for fracture fragment loosening, the displacements at the fracture gap of the bone block (average in all directions) and the von Mises stresses of the bone block and fixator were recorded to investigate the early motion of the fragments, failure of the plate, and wrist load transmission patterns of the fixation system.

![Figure 3. FE models of dual-thread (0.35-mm and 0.6-mm pitches) and single-thread (0.6-mm pitch) locking screws with 2.5-mm diameter assembled in the bone block model (15 mm × 15 mm × 22.5 mm) with 3-mm gap to simply the radius fracture pattern with a metaphyseal wedge. The von Mises stress distributions of the bone are shown under axial loading conditions.](image)

2.3 Experimental specimen preparation

Eighteen radius Sawbones (Sawbones; Pacific Research Laboratories Inc, Vashon Island, WA, USA) were used as the testing bone to ensure consistent bone shape and size as well as plating conditions throughout biomechanical testing. The bones were randomly placed into three groups (n = 6) and cut to a standard length of 2.5 cm from the articular surface to form 0°, 30°, and 60° fracture configurations according to the A2 classification in the AO surgery reference (Fig. 1) [15]. These fracture configurations describe simple extra-articular fractures with undisplaced fracture but exhibiting no abnormal palmar or dorsal tilt (metaphyseal type). The adjustable joint in the L plates was then adjusted and fixed using the fastener connection between the short and long parts to create 0°, 30°, and 60° constructs. All L plates were then positioned on the dorso-ulnar side (underneath the fourth extensor compartment) and all I plates were positioned on the dorso-radial side (underneath the second extensor compartment) to create an angle of 90°. Two locking screws were fixed on the upper part...
of the L plate (one was inserted into the fastener joint to lock the short and long parts tightly), and two screws were inserted in the bottom of the L plate in the dorso-volar direction. The L plate had three screws inserted in the radial-ulnar direction. Lister’s tubercle was removed with a rongeur from all dorsally platted radii to allow for contoured application (Fig. 4).

2.4 Biomechanical testing

Specimens were vertically embedded in an epoxy resin block and placed within a dynamic test frame (E3000, Instron, Canton, MA, USA). The specimens were subjected to oscillating loads of 10 to 150 N at 5 Hz for 20000 cycles. The maximum load applied represents the upper end of the estimated physiological forces with wrist motion [20-22]. The total load through 20000 cycles represents the upper end of the estimated physiological loads seen over the usual 6-month healing time for this type of injury [8,18,20,23]. The test frame piston was calibrated to measure the axial construct displacement for applied loads. Data for stiffness (N/mm) and fragment displacement (mm) were collected for the first load cycle and at 500-cycle intervals. To determine the significance of variations of stiffness between different angled constructs at each 500-cycle interval and between different cyclic loads in a given construct, measurements were conducted using one-way analysis of variance with MINITAB 14.0 (Minitab, Lebanon, PA, USA).

3. Results

The FE simulation results of the thread type comparison show that the maximum von Mises stress for bone and the fixator and the displacements of dual-thread locking screw were lower than those of the single-thread screw under axial, bending, and torsional loads (Table 1). During cyclic testing, no catastrophic failure occurred for any of the constructs. No gross visible screw loosening or volar cortex displacement was observed. The average stiffness values at 2000 and 20000 cycles were 412.3 and 425.7 N/mm for the 0° constructs, 459.6 and 461.1 N/mm for the 30° constructs, and 509.1 and 532.1 N/mm for the 60° constructs, respectively. From the statistical analysis, no difference in stiffness was found for constructs with a given angle throughout the 20000 cycles of testing (p > 0.05). However, significant differences (p < 0.05) in stiffness were found between constructs with different angles at each 500-cycle interval. Fragment displacement data during cyclic testing revealed no difference for a given construct throughout the entire testing cycle (p > 0.05) (Fig. 5). Displacement that did occur did so within the first 500 cycles of testing. No significant change in fragment displacement occurred from cycle 500 to cycle 20000.

Table 1. Stress values of bone and fixator and fragment displacements of dual-thread and single-thread screws obtained from FE simulations

<table>
<thead>
<tr>
<th>Load</th>
<th>Thread type</th>
<th>Bone stress (MPa)</th>
<th>Fixator stress (MPa)</th>
<th>Fragment displacement (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axial</td>
<td>Dual thread</td>
<td>86.441</td>
<td>723.175</td>
<td>0.984</td>
</tr>
<tr>
<td></td>
<td>Single thread</td>
<td>134.291</td>
<td>812.445</td>
<td>1.126</td>
</tr>
<tr>
<td>Bending</td>
<td>Dual thread</td>
<td>423.634</td>
<td>2019</td>
<td>3.084</td>
</tr>
<tr>
<td></td>
<td>Single thread</td>
<td>644.981</td>
<td>2953</td>
<td>3.719</td>
</tr>
<tr>
<td>Torsional</td>
<td>Dual thread</td>
<td>117.352</td>
<td>490.173</td>
<td>0.421</td>
</tr>
<tr>
<td></td>
<td>Single thread</td>
<td>151.978</td>
<td>682.041</td>
<td>0.524</td>
</tr>
</tbody>
</table>

4. Discussion

Distal radial fractures are often seen in aged and very young populations, with more than two-thirds of them occurred intra-articularly [24]. Because of the high incidence of wrist joint involvement, most studies that have compared the treatment results for this fracture type favored surgical operations [19,24,25]. There are numerous internal fixation techniques implemented by surgeons, each with its advantages and disadvantages according to its original development concept and specific indications. As stated previously, an optimum technique should not only restore wrist alignment biologically but also regain the joint function biomechanically. Dorsal plates have the advantage of acting as a buttress to posterior comminution. Locked plates have greater strength than that of non-locked constructs at the screw/plate junction and may provide a biomechanical advantage by transferring articular loads to this interface [26,27]. Multiple derivations of these constructs are available for treating this type of fracture. However, the effect of plate shape/location and screw type on construct stability remains unclear.

MDDP was designed to eliminate the problems which may be encountered with the DDP technique. With the DDP technique, two screws are inserted on the top of the T plate. However, for cases that have a large fracture degree (usually > 30°) with a small distal fragment or multiple fracture
Biomechanics of Bone Plate for Distal Radius Fractures

Figure 5. Cyclic testing of stiffness of the three construct groups. Differences between construct groups were found to be significant. Displacement occurred early in testing. SE: standard error.

fragments of the distal radius or those with osteoporosis (increased bone porosity), the top screws of the DDP technique would not be able to seize stably for fixation. Furthermore, signs of extensor tendon irritation have been noted following DDP operation. The two screw heads on the T plate may rub on the extensor tendons, causing tendon inflammation [11]. The proposed MDDP technique changes the T shape into an L shape to eliminate the use of the two top screws, which might prevent tendon irritation. Also, an adjustable joint with a fastener connected between the short and long parts of the L plate allows the plate members to be configured to be secured to different regions of one bone or secured to different bone according to the bone fracture configuration. A dual-thread design of an orthodontic screw has been proven to provide better mechanical stability with high removal torque, removal angular momentum, and pull-out force in experimental tests, and is thus used in this study [28]. However, adjustable joint existed in a long plate with about 60, 65, and 70 mm to allow changing its shape and might decrease the stiffness of the plate fixations, dynamic cyclic load was used to test its performance.

To examine the locking screw performance, finite element analysis was performed using a simple bone block with a 3-mm gap assembled with two screw types (dual-thread and single-thread screws) to simulate the radius fracture pattern with a metaphyseal wedge with dorsal plating fixation. The primary stability in a locking screw is related to the tooth-locking mechanism of the thread and the contact area between the microthread and bone surfaces, the mechanical retention between the screw and bone can be augmented. The simulation results show that the dual-thread screw had lower stress values in the bone and fixator and lower displacement. This indicates that a dual-thread locking screw in the cortical bone contact region can provide better primary stability and enhanced mechanical retention than those provided by a single-thread screw and reduce the loosening/failure risk for the fixation screw and plate.

The results of the cyclic testing show significant differences (p < 0.05) in stiffness between constructs with different angles at each 500-cycle interval. The average stiffness values at 2000 and 20000 cycles were 412.3 and 425.7 N/mm for the 0° constructs, 459.6 and 461.1 N/mm for the 30° constructs, and 509.1 and 532.1 N/mm for the 60° constructs. These values are in a reasonable range compared to those given in Gondusky et al.’s study, which analyzed the effect of plate location (volar or dorsal) and screw type (locked or non-locked) on construct stability using a cadaver model and found that the stiffness remained at about 450 N/mm after 5000 cyclic loads for four different constructs [29]. In the present study, there were no gross construct failures during cyclic testing, implying that the final fragment displacement is unlikely to be significantly different from that seen after this period if the construct experiences only postoperative physiological forces within rehabilitation guidelines. From displacements measured at 500-cycle intervals throughout the 20000 cycles of testing, curve patterns were generated. Similar patterns of displacement were found for all construct groups. Fragment displacements of approximately 0.19 to 0.69 mm for 0°, 0.21 to 0.64 mm for 30°, and 0.22 to 0.36 mm for 60° were found during cyclic testing for all construct groups. The displacements occurred early in testing (within the first 500 cycles). Minimal displacement after a period of cyclic loading suggests that final fragment displacement will be unchanged after this period of loading unless the fixture is subjected to supraphysiological loads. The lack of gross construct failures during cyclic testing and the reasonable stiffness indicate that the proposed constructs are sufficiently stable to support restricted postoperative loads.

A limitation of this study is that an artificial bone model was used instead of a fresh frozen cadaver. However, in order to reduce biologic variables, distal radius sawbone models were chosen to control bone density and reduce the large variation in biological/physical cadaver characteristics. The bone model used has also been described in other studies [30,31]. Only six samples in each construct group with differently shaped bone plates might cause large standard deviation. However, reasonable biomechanical equivalence of all constructs supports surgeon discretion in determining operative construct. Otherwise, individual experiments for plate fatigue test and screw torque test followed by ASTM F382/F543 (American Society for Testing and Materials) regulations are needed to
prove the mechanical capability for fitting on FDA (Food and Drug Administration) standard. This study focused on the analysis of the effects of plate design and screw type on construct stability for various fracture models. The cyclic loading data add support to the recommendations that early postoperative restricted motion be allowed [20,32,33]. Fragment displacement during cyclic loading is likely to occur during early motion (first 500 cycles). This may aid surgeons in the timing of postoperative X-ray analysis.

5. Conclusion

These results indicate that the biomechanical strength of MDDP fixed on artificial radius bones under dynamic fatigue tests is sufficient. Further well conducted prospective randomized clinical studies are warranted to enable us to deliver best possible evidence-based treatment for different distal radius fractures.

References