BIOMECHANICAL EVALUATION OF HYBRID LOCKED PLATING FOR HUMERAL SHAFT FRACTURE FIXATION

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ABSTRACT

Bone plate and screws are commonly used for fixation of humeral shaft fractures. A hybrid construct with unlocked screws and locked screws has gained popularity for fixation of comminuted fractures. Unlocked screws are used to reduce fracture gap while locked screws with better fixation strength helps maintain and protect the fixation. It is currently unclear if configurations with different number of unlocked and locked screws would perform the same biomechanically. The purpose of this study was to carry out biomechanical tests to elucidate if performance of a hybrid construct was dependent on screw pattern.

A total of 18 humeral shaft fracture models divided into 3 groups were plated with a 6-hole straight shaft plate under 3 different screw configurations. Comparisons were made between 1 unlocked and 2 locked screw (Technique A) and 2 unlocked and 1 locked screw (Technique B) against the Control which is an all locked construct. All fracture models were first tested dynamically under 4-point bending to fluctuate between bending moments of 1.2Nm and 12Nm. Tests were carried out at 1Hz for 10,000 cycles. Fracture gap and plate stiffness monitored during tests were used for comparison between the 3 configurations. Static failure tests were subsequently carried out to measure the construct stiffness, yield and failure strengths. Failure test was carried out in displacement control at the rate of 0.5 mm/sec.
The control and the hybrid constructs demonstrated similar behavior for both
dynamic tests and static failure tests. There were no significant difference between the
configurations in stiffness (p = 0.153) and fracture gap micromotion (p = 0.563) in
dynamic tests. There were also no significant differences between 3 configurations in
yield strength (p = 0.854), failure strength (p = 0.076) and stiffness (p = 0.409) in static
failure tests.

The current study showed no significant difference between all-locking, double
locking and single locking configurations of screw-plate constructs used in fixation of
humeral shaft fractures. The results of this study provided biomechanical evidence to
orthopedic surgeons in using hybrid plated constructs.
I would like to express my deepest gratitude to both my advisors, Dr. Juay Seng Tan and Dr. Glen Njus (Late) for their continuous encouragement, support and invaluable guidance throughout the course of this research. This project would not have been successful without valuable suggestions from Dr. Tan. I would like to appreciate my committee members, Dr. Daniel Sheffer and Dr. Narender Reddy for their enthusiastic involvement and being on my committee. I am also thankful to Rick Nemer for his generous help during the whole masters program. He is a great support for every student in Biomedical Engineering department throughout the program.

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TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIST OF TABLES</td>
<td>ix</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>xi</td>
</tr>
<tr>
<td>CHAPTER</td>
<td></td>
</tr>
<tr>
<td>I. INTRODUCTION</td>
<td></td>
</tr>
<tr>
<td>1.1. Background</td>
<td>1</td>
</tr>
<tr>
<td>1.2. Purpose</td>
<td>8</td>
</tr>
<tr>
<td>1.3. Justification</td>
<td>10</td>
</tr>
<tr>
<td>II. LITERATURE</td>
<td>13</td>
</tr>
<tr>
<td>2.1. Bone</td>
<td></td>
</tr>
<tr>
<td>2.1.1. Composition of Bone</td>
<td>13</td>
</tr>
<tr>
<td>2.1.2. Structure of Long Bones</td>
<td>15</td>
</tr>
<tr>
<td>2.1.3. Properties of Cortical Bone</td>
<td>16</td>
</tr>
<tr>
<td>2.1.4. Modeling and Remodeling of Bone</td>
<td>17</td>
</tr>
<tr>
<td>2.2. Bone Fractures</td>
<td></td>
</tr>
<tr>
<td>2.2.1. Types of Fracture</td>
<td>19</td>
</tr>
<tr>
<td>2.2.2. AO Classification of Humeral Shaft Fractures</td>
<td>20</td>
</tr>
<tr>
<td>2.3. Fracture Fixation</td>
<td>22</td>
</tr>
<tr>
<td>2.3.1. Fracture Treatment Without Surgical Intervention</td>
<td>22</td>
</tr>
</tbody>
</table>
2.3.2. Fracture Stabilization Using Rigid Surgical Fixation ................................. 23

2.4. Fracture Healing ............................................................................................ 23

2.4.1. Primary Bone Healing ................................................................................ 24

2.4.2. Secondary Bone Healing .......................................................................... 26

2.4.3. Vascularity of Fracture Healing ................................................................. 29

2.5. Locking Compression Plate ........................................................................... 31

2.5.1. Concerns with Locking Compression Plate ............................................... 33

2.5.2. Working Length ....................................................................................... 33

2.5.3. Unicortical Locked Screws and Bicortical Non-Locking Lag Screws ......... 34

2.5.4. Insertion of Locking Screws ..................................................................... 34

III. MATERIALS AND METHODS ..................................................................... 36

3.1 Study Design ................................................................................................. 36

3.1.1. Determination of Sample Size ................................................................. 37

3.2. Specimen Preparation .................................................................................. 38

3.2.1. Synthetic Bone Specimens ..................................................................... 38

3.2.2. Specimen Potting Procedure ................................................................. 39

3.2.3. Bone Plate and Screws .......................................................................... 42

3.2.4. Fracture Model ...................................................................................... 44

3.2.5. Liquid Metal Strain Gage (LMSG) ......................................................... 45

3.3. Dynamic Test ............................................................................................ 47

3.3.1. Test Protocol ......................................................................................... 48

3.3.2. Data Analysis ....................................................................................... 51

3.4. Static Failure Test Protocol ......................................................................... 51
3.4.1. Optoelectronic Camera .................................................................................... 52
3.4.2. Data Analysis ................................................................................................... 56
3.5. Statistical Analysis ................................................................................................. 57
IV. RESULTS ................................................................................................................... 59
4.1 Overview ................................................................................................................. 59
4.2. Construct Stiffness in Dynamic Tests ................................................................. 59
4.3. Fracture Gap in Dynamic Tests ............................................................................ 64
4.4. Yield in Static Failure Tests .................................................................................. 68
4.5. Failure Load in Static Failure Analysis ................................................................. 70
4.6. Construct Bending Stiffness in Static Failure Tests ............................................ 72
4.7. Failure Region ....................................................................................................... 73
V. DISCUSSION AND CONCLUSION .......................................................................... 78
5.1. Overview ................................................................................................................. 78
5.2. Clinical Relevance ............................................................................................... 78
5.3. Selection of Test Parameters ............................................................................... 81
5.4. Analysis of Results .............................................................................................. 82
5.5. Limitation .............................................................................................................. 84
5.6. Conclusion ........................................................................................................... 87
REFERENCES ................................................................................................................. 88
APPENDICES ............................................................................................................... 91
APPENDIX A. CALCULATION OF FORCES .......................................................... 92
APPENDIX B. TESTING MACHINE SPECIFICATIONS ........................................ 93
APPENDIX C. SAS PROGRAMS FOR ANOVA TEST RESULTS ..................... 94
APPENDIX D. STATIC FAILURE ANALYSIS PLOTS FOR ALL 18 INDIVIDUAL SPECIMENS ...................................................................................... 102

APPENDIX E. COPYRIGHT NOTICE .............................................................................. 114
LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1. Mechanical Properties of the Synthetic Bone Material</td>
<td>39</td>
</tr>
<tr>
<td>4.1. Average Stiffness (N/mm) at Specific Cyclic Intervals</td>
<td>64</td>
</tr>
<tr>
<td>4.2. Average Fracture Gaps (mm) at Specific Cyclic Intervals</td>
<td>68</td>
</tr>
<tr>
<td>4.3. Elastic Stiffness, Failure Load and Failure Regions of the 3 Different Configurations Measured During the Static Failure Tests</td>
<td>74</td>
</tr>
<tr>
<td>4.4. Expected Failure Patterns for the Three Different Types of Configurations Based on Null Hypothesis of No Significant Difference</td>
<td>76</td>
</tr>
<tr>
<td>4.5. Observed Failure Patterns for the Three Different Types of Configurations</td>
<td>77</td>
</tr>
</tbody>
</table>


**LIST OF FIGURES**

<table>
<thead>
<tr>
<th>Figure</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1. Fracture fixation of the humerus with multiple bone fragments using a long bone plate and screws</td>
<td>2</td>
</tr>
<tr>
<td>1.2. A compression plate compressed to bone using lag screws. The lag screws are used to bring the 2 bone fragments together and cause the plate to compress against the bone. The fixation strength between the bone plate and bone depends on compression forces generated by the lag screws. This in turn is dependent on the fixation strength of the screw threads onto the bone</td>
<td>3</td>
</tr>
<tr>
<td>1.3. Ellipsoidal slotted holes in compression plates are designed to match the hemispherical under surface of the screw head. The holes are also ramped to assist in achieving fracture reduction</td>
<td>4</td>
</tr>
<tr>
<td>1.4. Locked plate system features screw threads on the length of the screw that engage bone and with screw threads on the screw head that engages the bone plate. The screws and plate moves as a single rigid construct and loosening of individual screws are prevented</td>
<td>5</td>
</tr>
<tr>
<td>1.5. The locking compression plate uses the combination of both compression lag screws and locking screws. This is possible with a unique hole in the bone plate that could accommodate either screw</td>
<td>7</td>
</tr>
<tr>
<td>1.6. Graph from Gardner’s study illustrating the change in stiffness relative to the initial stiffness during cyclic torsion testing in the three groups. The unlocked group was significantly less stiff than the locked and hybrid groups throughout the experiment. There were no differences in the measurements between the locked and hybrid constructs at any cyclic interval</td>
<td>8</td>
</tr>
<tr>
<td>1.7. Configuration of screws used in the current study included a control group with 6 locking screws (Control group), a first study group with 4 locking and 2 non-locking screws (Technique A) and a second study group with 2 locking and 4 non-locking screws (Technique B)</td>
<td>9</td>
</tr>
</tbody>
</table>
1.8. The use of locked screws near the fracture gap is associated with more uniform stress pattern across the fracture gap and is recommended by the manufacturer ................................................................. 11

2.1. Bone composition consists of organic and inorganic matrix and bone cells including osteocytes, osteoblasts and osteoclasts ..................................................................................................... 14

2.2. The diaphysis is primarily made up of cortical bone while the epiphysis are made up of trabecular bone surrounded by a thin shell of cortical bone ......................... 16

2.3. Cortical bone is linear elastic initially with a stiffness of about 17GPa and has a small plastic region. Bone is brittle and a small strain would result in fracture ..... 17

2.4. Different types of fractures. Less severe are the simple, transverse and greenstick fractures while the most severe are the comminuted and spiral fractures...... 20

2.5. Type 12-A fractures are simple fractures without additional fragments. Type 12-B fractures are fractures with a wedge fragment. Type 12-C fractures are complex fractures with multiple fragments ............................................................... 21

2.6. Direct bone healing where the fracture fragments are held in close opposition by interfragmentary compression. Even though the interfragmentary compression appears to have no gaps, the perfect apposition on a microscopic level is not possible and there exists a series of small gaps (#1) and contact points (#2) ................... 24

2.7. Cutting cone tunneling from left to right. The leading edge of the cutting cone on right has multinucleated osteoclasts to resorb the dead bone and the trailing edge has a conical surface which is lined with osteoblasts that lay down new bone. Direct bone formation takes place without an intermediary cartilaginous phase ............................................................................................................ 25

2.8. Inflammatory phase with torn periosteum, hematoma, necrotic marrow and dead cells ........................................................................................................................... 27

2.9. Reparative phase with callus formation ................................................................. 28

2.10. Remodeling phase with bone remodeling ........................................................................ 29

2.11. Locking compression plate with combi-holes that allow the fixation of both locking and non-locking screws to the same construct ......................................................... 32

2.12. An alignment tool is attached to the bone plate to guide the drill bit so as to attain precise centering and orientation of the screw......................................................... 35

xii
3.1. Pictorial representation of the fracture model with 3 different screw configurations used in the study. Control group consisted of all locking screws. Technique A had 2 locking screws near to the fracture site and 1 non-locking screw on each end. Technique B had 1 locking screw near to the fracture site and 2 non-locking screws on each end. A sample size of 6 was used in each configuration with a total of 18 specimens. The same samples were tested non-destructively on the dynamic tests followed by destructive static failure tests.

3.2. Cross section of sawbone with bi-homogeneous composite cylinders consists of a glass fiber reinforced epoxy shell (to represent cortical bone) and a core with closed cell polyurethane foam (to represent trabecular bone).

3.3. Square blocks used for attachment on both sides for preventing the rotation of the specimen during tests.

3.4. Bone Potting Assembly (A) Bone center alignment blocks were used to center the synthetic bone within the square blocks. (B) Square block alignment frame was used to align the square blocks in the same plane. (C) Assembled alignment jig. Synthetic bone was capped with bone center alignment blocks and square aluminum blocks on each end.

3.5. PMMA cement was used to pot synthetic bone into aluminum square blocks.

3.6. 8-Hole stainless steel locking compression plate used for the study.

3.7. Diameter 4.0 mm and length 22 mm stainless steel locking screw with threaded screw head (left arrow), and diameter 4.5 mm and length 38 mm stainless steel cortical screw with smooth hemi-spherical screw head (right arrow).

3.8. The three different configurations after complete specimen preparation. Same type of plate was used in all the different configurations and all plates were applied flush to the synthetic bones by first inserting the non-locking screws followed by the locking screws.

3.9. The 5 mm fracture gap at the midpoint of the synthetic bone to simulate the worst case fracture gap within a comminuted unstable fracture.

3.10. Ramp function was applied to tension the liquid metal strain gage (LMSG) to 0.00508 m (0.2 inch). From the total displacement of LMSG and voltage variation, a calibration constant was determined in mm/V for each LMSG.

3.11. LMSG applied to the opening of the gap for determination of fracture gap micromotion.
3.12. Schematic of the 4-Point Bending test system, where displacement and gap
micro-motion were measured for an applied 4-point bending load.......................... 48

3.13. The whole 4 Point Bending test system with the specimen placed in
between bending jigs......................................................................................................... 48

3.14. The above figure shows the maximum and minimum load applied which
becomes the bending moment........................................................................................... 49

3.15. 3D Model of the servo-hydraulic materials testing system used to conduct
4-point bending in the specimens with the 4-point bending jigs attached....................... 50

3.16. Test was carried out in displacement control at a test speed of 0.5 mm/sec
up to a crosshead displacement of 10 mm. The load response was non-linear ............... 52

3.17. An optoelectronic camera system with an accuracy of ±0.1 mm and
±0.13 degrees used to capture the rotation of the specimen during static failure tests.... 53

3.18. A “marker array” consisted of 4 IRLEDs attached onto a plexi-glass. Each
rigid body whose 3D motion is of interest is rigidly attached with a marker array.
The optotrak camera tracks motion of each IRLED, and as an array of at least
3 non-collinear markers the 3D motion is defined............................................................ 53

3.19. Specimen was loaded in a testing machine with marker array attached to
both square blocks and also on the top loading assembly. These marker arrays
acted as rigid bodies for measurement of the translation and rotation under a
4-point bending load ......................................................................................................... 54

3.20. Optotrak camera system positioned 2.25 meters in front of the test specimen
to capture motion during a 4-point bending test ............................................................... 55

3.21. 2 marker arrays with 4 IRLEDs each were attached to each square block.
Forces acting downwards (F) were applied by the actuator on the aluminum
blocks. Forces acting upwards were the reaction forces from the bottom jig.
A custom coordinate system was set up with the bottom left marker of the right
array as the origin, line joining the bottom markers of the right array as X-axis
and the line joining the origin marker and the marker above it as Y-axis. The
parameters measured were the moment applied and total angular displacement
Θ (Θ₁ + Θ₂) .................................................................................................................................. 56

4.1. A typical force versus displacement curve obtained at intervals. Twenty
cycles analyzed at each interval. The increasing slope was defined as the stiffness
of the construct .................................................................................................................. 60
4.2. Stiffness variation of the 6 test specimens in the Control Group over the 10,000 cycles fatigue tests ................................................................. 61

4.3. Stiffness variation of 6 test specimens in Technique A (double locking screws) over the 10,000 cycles of fatigue tests ................................................................. 61

4.4. Stiffness variation of 6 test specimens in Technique B (single locking screws) over the 10,000 cycles of fatigue tests ................................................................. 62

4.5. Mean construct stiffness for the 3 configurations at 10,000 cycles were not significantly different (p = 0.153). There was a trend of higher stiffness after 10,000 cycles of loading ................................................................. 63

4.6. A typical 20 cycle sample of force versus fracture gap curve. Total fracture gap was calculated as the difference between maximum and minimum gap opening .... 65

4.7. Total fracture gap of the 6 test specimens in the Control Group over the 10,000 cycles fatigue tests ................................................................. 65

4.8. Total fracture gap of the 6 test specimens in Technique A (double locking screws) over 10,000 cycles fatigue tests ................................................................. 66

4.9. Total fracture gap of the 6 test specimens in Technique B (single locking screws) over 10,000 cycles fatigue tests ................................................................. 66

4.10. Mean fracture gap for the 3 configurations at 10,000 cycle were not significantly different (p = 0.563) ................................................................. 67

4.11. Typical moment versus angular displacement curve with an elastic and a plastic zone for specimens tested under 4-point bending ......................................... 69

4.12. Mean yield moment for the 3 constructs (p = 0.854). Error bars denote standard deviation ................................................................. 70

4.13. Typical moment versus angular displacement curve with a linear elastic region, a non-linear plastic region and a failure. Failure was defined as a 10° permanent plastic deformation ................................................................. 71

4.14. Typical moment versus angular displacement curve with a linear elastic region, a non-linear plastic region and a failure. Failure in this case was observed as a sudden drop in the moment value causing a negative slope ................................................................. 71

4.15. Mean failure moments for the 3 constructs (p = 0.076). Error bars denote standard deviation ................................................................. 72
4.16. Mean elastic stiffness for the 3 different constructs (p = 0.409). Error bars denote standard deviations .......................................................... 73

4.17. Example of failure at the screw bone interface (F1) for the first locking screws near to fracture gap (shown by the circles). Five specimens in the Control Group, two specimens of Technique A (Double Locking) and one specimen in Technique B (Single Locking) failed by this mode ........................................ 75

4.18. Example of failure of bone at the far bicortical screw (F2) (shown by the circle). Three specimens in Technique B (Single Locking) and two specimens in Technique A (Double Locking) failed by this mode .................................................... 75

4.19. Example of failure at the plate (F3) (shown by the arrow). Two specimens of Technique A (Double Locking), one specimen of Technique B (Single Locking) and one specimen of Control Group failed by this mode ..................................................... 76
CHAPTER I

INTRODUCTION

1.1. Background

Humeral shaft fracture has been shown in epidemiology studies to occur most commonly in females above 60 years old and in males between 21 to 30 years old [Tytherleigh-Strong et al, 1998]. The incidence of humeral shaft fracture per 100,000 people averages about 30 cases a year for population aged between 16 to 50 but increases up to 80-100 cases for ages 60 and above [Tytherleigh-Strong et al., 1998; Ekholm et al., 2006]. With estimated increase in aging population from 39 million to 94 million from 2000 to 2050 in United States, the number of humeral shaft fracture cases can be projected to increase to 90,000 cases a year by 2050.

Humeral shaft fracture in aged people commonly occurs from low energy trauma such as fall from a standing height while in the younger population they tend to be caused by high energy trauma resulting from motor vehicle accidents, fall from greater heights, sports injuries or industrial accidents [Ekholm et al., 2006]. About 40% to 60% of humeral fractures occur in the mid shaft while 30% to 40% occur in the proximal and 10% to 20% occur in the distal humerus. Among these fractures, simple fractures account for two thirds while more complex fractures involving spiral or multiple
fragments account for the rest of all humeral fractures. [Tytherleigh-Strong et al., 1998; Ekholm et al., 2006].

Bone plate and screws are commonly used for the fixation of bone fractures (Figure 1.1). Bone plates are available in different lengths, various number of holes and with a variety of holes or slot designs to accommodate different screws. Plate and screw systems can be used to fix simple as well as complex fractures with multiple bone fragments.

![Image](www.medscape.com)

Figure 1.1. Fracture fixation of the humerus with multiple bone fragments using a long bone plate and screws [www.medscape.com].

Conventional fracture fixation plates are commonly referred to as compression plates. Compression plates as the name implies are pressed against the surface of the bone. The success of compression plates depends on adequate purchase of the screws in the bone to create compression of the plate against the bone surface (Figure 1.2). In
patients with compromised bone quality, especially among the elderly patients, loosening of the screws at the screw-bone interface may result in retropulsion of individual screw, or worse, loosening of the entire fracture fixation construct. With over three quarters of all humeral shaft fractures occurring in the elderly patients, both screw retropulsion and plate loosening are regular concerns for orthopaedic surgeons.

Lag screws are commonly used with compression plates to achieve fracture reduction (closure of fracture gaps). To further utilize the advantage of lag screws when used with compression plates, they may be angled to be perpendicular to the fracture surface (Figure 1.2).

Figure 1.2. A compression plate compressed to bone using lag screws. The lag screws are used to bring the 2 bone fragments together and cause the plate to compress against the bone. The fixation strength between the bone plate and bone depends on compression forces generated by the lag screws. This in turn is dependent on the fixation strength of the screw threads onto the bone [www.synthes.com].

To allow for screw angulations, compression plates commonly have ellipsoidal slotted holes designed to match the hemispherical under surface of the screw head and have ramped holes to assist in achieving fracture reduction (Figure 1.3). These features in compression plates allow the surgeon to achieve better fracture reduction.
Figure 1.3. Ellipsoidal slotted holes in compression plates are designed to match the hemispherical under surface of the screw head. The holes are also ramped to assist in achieving fracture reduction [http://emedicine.medscape.com].

Additional stand-alone lag screws may also be inserted across fracture fragments from different directions without engaging the bone plate to achieve fracture reduction of loose bone fragments in comminuted fractures. With adequate fracture reduction and stability across the fracture gap with compression plate fixation, primary fracture healing may take place without callus formation. Studies suggest recovery duration is shorter in primary healing without callus formation [Stevens et al., 2008].

Compression plates are however unsuitable for use in patients with poor bone quality as loosening of screws could occur at the screw-bone interface. A loosened screw would subsequently result in screw retropulsion, plate loosening and loss of stability across the fracture gap. Compression plates are thus unsuitable for most elderly patients. With increasing number of fractures in the elderly, new fracture fixation techniques have been developed.

The locked plate technique is an alternative procedure to compression plate and is intended for use in patients with poor bone quality. Threads on the screw head in the
locked plate technique secure directly onto the threaded bone plates (Figure 1.4). The screws and plate thus act as a single rigid construct.

![Locked plate system features](image)

Figure 1.4. Locked plate system features screw threads on the length of the screw that engage bone and with screw threads on the screw head that engages the bone plate. The screws and plate moves as a single rigid construct and loosening of individual screws are prevented [www.synthes.com, http://emedicine.medscape.com].

Individual screws in a locked plate are prevented from loosening when used in weaker bone, and consequently the bone plates are prevented from loosening from the bone. In locked plates, the threaded screw heads engage threads on corresponding holes of the bone plate. Thus the screw engages both bone and bone plate for anchoring. In patients with weak bone quality, even when the bone-implant interface along the screw length is compromised, the screw will still remain in place with fixation strength derived from the threaded screw head against the threaded holes in the plate. Thus screws in locked plates are prevented from toggling, loosening and retropulsion. This locked plate technique is popular for fracture fixation in patients with compromised bone quality [Gardner et al., 2006; Stoffel et al., 2003].

The locked plate technique when used on its own however have certain disadvantages. Firstly, the threads on the plate restrict the insertion angle of the screws to a fixed axis. Without allowing for angulations, the screws cannot be inserted effectively across two fracture fragments. Secondly, unlike lag screws, the locked screws are not
capable of closing the gaps between bone fragments to achieve fracture reduction. The locked plate technique is thus associated with larger fracture gaps and secondary fracture healing. One feature of secondary fracture healing between fracture fragments is the formation of fracture callus. This fracture callus later becomes the scaffold for new bone growth across the fracture gap. In essence, the locked plate technique results in longer recovery time. These primary disadvantages make the locked plate technique inferior to compression plate technique.

Although the fracture healing time is longer, the locked plate technique has one advantage over the compression plate technique. The locked plate technique is suitable for use in the elderly and osteoporotic patients with compromised bone quality. This is mainly because the locked plate technique could alleviate the issues of screw loosening associated with insertion into poor quality bone.

With recent innovation, the locking compression plate (LCP), combines both features of compression and locked plate techniques in a single fracture plate (Figure 1.5). In the locking compression plate, compression lag screws are first used to achieve reduction of the fracture fragments. Subsequently, locked screws are inserted to secure the fixation and prevent loosening. Mechanical locking against bone fragments may be achieved with multiple screws that are locked onto the bone plate.
Figure 1.5. The locking compression plate uses the combination of both compression lag screws and locking screws. This is possible with a unique hole in the bone plate that could accommodate either screw [www.aofoundation.org].

Locking compression plates achieve adequate reduction through the lag screws and prevent implant loosening through the locked screws. This new hybrid technique with both non-locking and locking screws used with a locking compression plate has recently become the de facto treatment technique for fracture fixation in osteoporotic bones [Gardner et al., 2006].

Using a mechanical testing setup, Gardner et. al. (2006) found that a combination of four locking screws and two non-locking screws resulted in construct strength more similar to an all locking construct than an all non-locking compression screws construct (Figure 1.6).
Figure 1.6. Graph from Gardner's study illustrating the change in stiffness relative to the initial stiffness during cyclic torsion testing in the three groups. The unlocked group was significantly less stiff than the locked and hybrid groups throughout the experiment. There were no differences in the measurements between the locked and hybrid constructs at any cyclic interval [Gardner et al., 2006].

To date, no other studies have tested the behavior of other combinations of locking and non-locking screws on fixation strength. The effects of other combinations of unlocked and locked screw types on fixation strength are yet to be fully understood. The current study is designed to address this clinically relevant research problem.

1.2. Purpose

This project is designed to quantify the difference in mechanical performance under pure bending between (Figure 1.7):
1. Control group (All locking): 6 locking screws

2. Technique A (Double locking): 4 locking and 2 non-locking screws

3. Technique B (Single locking): 2 locking and 4 non-locking screws

Figure 1.7. Configuration of screws used in the current study included a control group with 6 locking screws (Control group), a first study group with 4 locking and 2 non-locking screws (Technique A) and a second study group with 2 locking and 4 non-locking screws (Technique B).

The control group with 6 locking screws is equivalent to the locked plate technique. Technique A is a LCP configuration with a combination of 4 locking screws and 2 non-locking screws and is similar to the combination in Gardner et al. (2006) except in the placement location of the 2 non-locking screws. Technique B with a combination of 2 locking screws and 4 non-locking screws is a new LCP configuration under investigation in the current study.

Fracture reduction is initially achieved by insertion of 2 or 4 compression lag screws. The plate should be prevented from loosening by further insertion of 2 or 4
locking screws subsequently. However, it is unclear presently if Techniques A and B would provide the same fixation strength across the fracture gap.

Null Hypotheses:

1. There is no difference between 3 types of configurations in terms of stiffness, gap – micromotion, yield strength, and failure strength
2. There are no failure patterns associated with the configurations in the static failure tests

Alternate Hypotheses

1. There is a difference between 3 types of configurations in at least one of the measured parameter, which include stiffness, gap – micromotion, yield strength and failure strength
2. Failure patterns are associated with one or more configurations in the static failure tests

The use of compression screws would help to achieve better fracture reduction especially in complex fractures with multiple bone fragments while the use of locked screws would help to prevent construct loosening in the weak bone. The purpose of the current study is to provide orthopaedic and trauma surgeons with supporting biomechanical data regarding the use of Technique A and Technique B.

1.3. Justification

In the current study Technique A consisted of 4 locking screws and 2 non-locking screws, with the non-locking screws placed farthest away from the fracture gap. Locking screws placed nearer to the fracture site created a more uniform stress distribution in the
surrounding bone and fracture gap (Figure 1.8) and is recommended by the manufacturer.

Stress pattern across the fracture site could affect the fracture healing process across the fracture gap. The effects of stress pattern on fracture healing was however not part of the scope of current study. In the earlier study by Gardner et al., the non-locking screws were placed close to the fracture gap instead. In the current study Technique A was configured according to the manufacturer’s recommendation.

Figure 1.8. The use of locked screws near the fracture gap is associated with more uniform stress pattern across the fracture gap and is recommended by the manufacturer [www.synthes.com].

In Technique B, the hybrid model consisted of 2 locking screws and 4 non-locking screws. The use of 4 instead of 2 non-locking screws might result in better fracture reduction across various fracture surfaces especially when multiple fracture fragments are present. The compromise in 2 instead of 4 locking screws might be the reduction fixation strength in osteoporotic bones. It is currently not known if this configuration of 2 locking and 4 non-locking screws is superior, inferior or similar to Technique A in terms of strength of the fracture fixation construct. Technique B was
thus configured for direct comparison against Technique A. With the same number of locking and non-locking screws as Technique A, Gardner et al. found the construct strength to be no different than an all-locking screw configuration.

In the current study, synthetic bones were used to represent adult humerus. Synthetic bones have uniform material properties and provided a uniform platform for comparison between different fracture fixation constructs.

The synthetic bone specimens were prepared with a 5 mm fracture gap. This fracture gap size was chosen to simulate the worst-case scenario of a large fracture gap in a complex comminuted fracture and to simulate an unstable fracture model. The 5 mm fracture gap acted as a region in the fracture that does not transmit load in a complex comminuted fracture. The fixation strength in Techniques A and B were compared under this idealized fracture model.

A minimum of 3 screws on each side of the fracture plate had been found to attain sufficient construct stiffness and the use of more than 3 screws did not significantly increase its stability in any method of loading [Stoffel et al., 2003]. The current study thus utilized 3 screws on each side of the fracture gap. The use of longer plates with more screws would require larger incision and more muscle stripping clinically.

Bicortical lag screws and unicortical locked screws were used in this study. Locked screws are usually used clinically with unicortical purchase while lag screws are usually used with bicortical purchase. Thus the screw length used in the current study followed closely to actual clinical situation.
CHAPTER II

LITERATURE

2.1. Bone

Bone acts as a framework for our body. Its major functions are protection of soft structures and mechanical load bearing opposing external forces [Rüedi et al. 2007]. Based on load experienced, bone would eventually adapt to the increased or decreased mechanical demand by altering its mechanical and structural properties as well as geometry [Jones et al. 1977, Thompson et al. 1992, Woo et al. 1981]. For example, heavy exercise increases bone density whereas prolonged bed rest, disuse and zero gravity environment reduces bone density. Bone geometry could change during aging and also as a result of fracture healing or fixation. These adaptive phenomena are directed towards restoring and maintaining the overall structural integrity of the skeleton despite localized changes in mechanical environment.

2.1.1. Composition of Bone

Bone is a connective tissue that consists of organic cells embedded among a matrix made up of organic and inorganic constituents. The organic cells include osteoclasts, osteoblasts and osteocytes. Osteoclasts are the cells that resorb bone by
eroding their way through by first demineralizing the adjacent bone with acids and then dissolving its collagen with enzymes. This occurs at a rate of tens of micrometers per day. Osteoblasts are mononuclear cells that produce osteoid, the organic portion of bone matrix. Osteoblasts regenerate or cause bone apposition at the rate of 1μm/day [Martin et al. 1998]. Osteocytes play an important role in sensing mechanical stress in bone and in activating osteoblasts and osteoclasts to resorb or grow bone accordingly.

Bone cells are responsible for the formation and maintenance of the extracellular matrix (Figure 2.1). This extracellular matrix consists of 90% collagen and 10% amorphous ground substances made up of glycosaminoglycans and proteoglycans [Mow and Hayes 1997, Martin et al. 1998].

![Figure 2.1. Bone composition consists of organic and inorganic matrix and bone cells including osteocytes, osteoblasts and osteoclasts. [www.wikipedia.com].](image-url)
Collagen found in the bone are Type I collagen that are also found in dermis, tendons and ligaments. Presence of stable intermolecular cross-links in collagen gives bone its flexibility as well as its rigidity and strength in tension and compression.

Bone matrix also contains inorganic mineral components such as calcium phosphate and calcium carbonate in the form of hydroxyapatite crystals and amorphous calcium phosphate. Some lesser quantities of sodium magnesium and fluoride are also present. These mineral salts that permeate the organic matrix attribute to the strength and rigidity of the bone. Even though the function of noncollagenous proteins is unclear, the most abundant non-collagenous protein osteocalcin, which is secreted by osteoblasts, appears to be important in the mineralization of new bone.

2.1.2. Structure of Long Bones

The shaft of a long bone, the diaphysis, is primarily made up of cortical bone while the proximal and distal regions of a long bone, the epiphysis, consists of trabecular bone surrounded by a thin shell of cortical bone (Figure 2.2). Bone can be classified as cortical or trabecular based on its relative density. Trabecular bone in the epiphyses is continuous with the inner surface of the cortical shell and exists as a three dimensional interconnected network [Mow and Hayes, 1997]. Trabecular bone has plate and rod structures. The structure and mechanical properties of trabecular bone is remarkably similar to that of porous engineering foams. It has been widely assumed that the morphology and density of trabecular bone are related to stresses imposed during daily activities and the direction of these imposed maximum and minimum stresses determine direction of the trabecular orientation [Mow and Hayes, 1997]. Thus in regions with low
loading condition trabeculae tend to form rod like structures, whereas in regions of high load, the cell wall thicken and spread and would resemble perforated plate [Mow and Hayes, 1997].

Figure 2.2. The diaphysis is primarily made up of cortical bone while the epiphysis are made up of trabecular bone surrounded by a thin shell of cortical bone. [www.oetc.kctcs.edu].

2.1.3. Properties of Cortical Bone

Cortical bone has a longitudinal modulus of elasticity of 17 GPa [Mow and Hayes 1997]. While bone is strong with failure strength of 53-135 MPa in tension and 131-205 MPa in compression, it has a small failure strain of about 0.007-0.031 in tension and 0.019-0.087 in compression. Its high stiffness and small plastic region makes bone a brittle material (Figure 2.3).
Figure 2.3. Cortical bone is linear elastic initially with a stiffness of about 17GPa and has a small plastic region. Bone is brittle and a small strain would result in fracture. [www.asbweb.org].

2.1.4. Modeling and Remodeling of Bone

Bone development is characterized by growth in diameter as well as length. Growth in length is achieved through endochondral ossification in the growth plate; whereas growth in diameter is accomplished by periosteal intramembranous ossification [Martin et al. 1998]. Bone development includes both bone formation and resorption taking place continuously through a highly regulated process that occurs during growth and throughout life. The process of bone formation and resorption is governed by Wolff’s law which describes the formation of bone at higher loaded regions and resorption of bone at under loaded regions.

During growth, bone is removed from some sites while being added at some other sites. This constant sculpting process of bone formation at some places and bone resorption at some other places is known as modeling [Martin et al., 1998]. As each
growing child loads his or her skeleton in somewhat different ways during growth, each bone shapes up according to the loading environment experienced.

Throughout a person’s life the internal architecture of bone continuously changes with bone modeling and remodeling. Localized fatigue damage occurs in trabecular bone routinely. The accumulation of such fatigue damages, in engineering materials, would eventually lead to fatigue fracture. Bone as a living tissue is however able to repair and remodel. Bone remodeling occurs with the constant removal of material by osteoclasts and new bone formation by osteoblasts. Remodeling can be considered as the mechanical fine tuning of the skeleton to increase its mechanical efficiency. Osteoclasts and osteoblasts engage in both modeling and remodeling by reshaping and replacing portions of the skeleton [Martin et al., 1998].

The distinct differences between bone modeling and remodeling can be summarized as follows:

1. In bone modeling, osteoclasts and osteoblasts act independent of each other. In bone remodeling they act sequentially by coupled actions of the two types of cells.

2. Bone modeling result in the change of bone size, shape or both, while bone remodeling usually does not involve the change in bone size or shape.

3. The rate of bone modeling is drastically reduced once skeletal maturity is reached. Bone remodeling occurs throughout one’s life. Bone remodeling is substantially reduced after growth stops.

4. Bone modeling at a particular site is a continuous process which occurs till skeletal maturity. Bone remodeling takes place in episodes with definite beginning and ending whose main purpose is repair.
2.2. Bone Fractures

Bone fracture often takes place as a result of single or multiple overloads. It results in a loss of bony continuity and consequently a loss in mobility, support function and load bearing, and is painful. Besides failure of the hard tissue (bone), fracture also results in damage to soft tissues across the fractured surfaces. Further, discontinuity across the bone sometimes also results in rupture of blood vessels.

2.2.1. Types of Fracture

There are different classifications of fracture of the long bone. Fracture classification can be used to assist with the prognosis of the fracture and as a guide for surgeons in determining treatment method. These different types of fractures could also help radiologists, clinicians, surgeons, other medical staff and even engineers to speak a common language with each other.

Anatomic description of the fracture and extent of the fracture are usually used for classification (Figure 2.4). Less severe fractures include simple, transverse and incomplete fractures. At the intermediate level of severity are the oblique and compound fracture. The most severe fractures are comminuted and spiral fractures.
Figure 2.4. Different types of fractures. Less severe are the simple, transverse and greenstick fractures while the most severe are the comminuted and spiral fractures. [www.mdconsult.com].

In addition, a closed fracture does not have bone exposed outside the skin whereas an open fracture involves penetration of bone through the skin. Less severe fractures tend to be close fracture whereas more severe fractures can be either open or close fractures. Open fractures add to the severity of the fracture with the presence of more soft tissue damage and possible infection.

2.2.2. AO Classification of Humeral Shaft Fractures

The AO classification has been established to describe fractures of almost every bone in the human body. In the AO classification of humeral shaft fractures, simple fractures are classified as 12-A fractures (Figure 2.5). Typically, these fractures are located in the middle third of the humeral shaft. Wedge fractures of the humeral shaft with a wedge fragment are classified as 12-B fractures. Complex fractures of the humeral shaft with multiple fragments are classified as 12-C fractures. These fractures
may extend into either or both the proximal and the distal metaphysis. Complex fractures are caused by high energy impacts.

Figure 2.5. Type 12-A fractures are simple fractures without additional fragments. Type 12-B fractures are fractures with a wedge fragment. Type 12-C fractures are complex fractures with multiple fragments. [www.aona.com].
2.3. Fracture Fixation

Fracture fixation varies from simple cast and splint techniques to surgical intervention with internal or external devices. The choice of treatment technique is dependent on severity of the fracture, open or closed fracture, fracture classification and location of fracture.

2.3.1. Fracture Treatment Without Surgical Intervention

Stable fractures are treated without surgical intervention. Simple fractures with non-displaced fragments and intact periosteum are relatively stable fractures which require minimal treatment. Simple fractures are usually closed fractures, and in bones with low load bearing roles, could be treated without surgical intervention. One example is fracture of the ribs or the ulna. The body naturally would produce a temporary stabilizing effect to the mobile fragments by pain-induced contraction of the surrounding muscles. At the same time hematoma and swelling increase the hydraulic-pressure and further stabilize the fractured region.

Fractured bone fragments often are required to be set in the right alignment. Proper alignment would prevent subsequent deformity and possible impairment of function. Traction along the long axis is a method to restore bone alignment [Ruedi et al., 2000]. This is followed by external splinting with plastic or plaster cast. Splints and casts serve to maintain gross alignment and fracture reduction [Ruedi et al., 2000]. They also help to stabilize the fracture and reduce the mobility of the fragments during fracture healing. Due to the poor coupling between cast and the bone with surrounding interposed
soft tissue, mobility of fracture fragments are not totally eliminated and secondary bone healing takes place.

2.3.2. Fracture Stabilization Using Rigid Surgical Fixation

Rigid surgical fixations are commonly used in complex fractures and when the affected bone is required to bear load. One example is fracture of the tibia or femur. The intention of surgical intervention is to get the patient back to normal daily activity such as walking, as soon as possible. With unstable fractures, the role of rigid surgical fixation is to restore stability and function immediately.

With rigid surgical fixation, stability of the fracture fragments can be achieved and load bearing could be introduced right after surgery. Another role of the surgical devices is to eliminate motion across the fracture site, by interfragmentary compression (compression between fracture fragments), so as to promote rapid fracture healing. Interfragmentary compression at the fracture site maintains contact between the fracture fragments and to load the fragments. With sufficient stability and load, primary bone healing could occur across the fracture site.

2.4. Fracture Healing

Fracture healing can be broadly classified as primary and secondary bone healing. The main differences are in the fracture gap size, healing duration and the formation of fibrous tissues and bone calluses.
2.4.1. Primary Bone Healing

Primary bone healing occurs in conditions where the fracture gap size is small and there is stability across the fracture surface. Primary bone healing occurs over a shorter healing duration and usually occurs when rigid fixation is used to provide necessary stability.

With adequate rigid fracture fixation, fracture fragments are held in close apposition with minimal interfragmentary displacement. Perfect apposition of the fracture fragments on a microscopic level is impossible to obtain during an interfragmentary compression which results in a series of small gaps and contact points (Figure 2.6).

![Figure 2.6. Direct bone healing where the fracture fragments are held in close opposition by interfragmentary compression. Even though the interfragmentary compression appears to have no gaps, the perfect apposition on a microscopic level is not possible and there exists a series of small gaps (#1) and contact points (#2) [McKinley, 2003].](image)

In primary bone healing, there is minimal activity of bone near the fracture site in the first few days. This state of minimal activity is followed by resorption of hematoma which reduces swelling. The wound healing process is triggered by the formation of
repair tissue. In the sequential healing process, gap healing occurs first followed by contact healing.

In gap healing, small gaps of the size of 200μm or less (width of an osteon) get filled rapidly by mature lamellar bone as a result of the direct bone formation [McKinley, 2003]. Larger gaps are slowly filled by primitive woven bone [McKinley, 2003]. In contact healing, as primitive woven bone formed during initial gap healing stage is not strong enough, it undergoes remodeling to achieve pre-fracture strength during contact healing [McKinley, 2003]. This remodeling process occurs in a series of events controlled by the basic multicellular units which are activated by the fracture.

Figure 2.7. Cutting cone tunneling from left to right. The leading edge of the cutting cone on right has multinucleated osteoclasts to resorb the dead bone and the trailing edge has a conical surface which is lined with osteoblasts that lay down new bone. Direct bone formation takes place without an intermediary cartilaginous phase. [Wraighte et al., 2006].

These basic multicellular units form a cutting cone (Figure 2.7) with osteoclasts on the leading surface of the cone followed by osteoblasts lining the trailing edge.
[McKinley, 2003]. The cutting cones burrow through the fracture cortices and across the fracture plane, creating a void which is gradually filled in by new bone matrix [McKinley, 2003]. The osteoclasts in the leading edge of the cutting cone advances approximately 50 μm/day whereas the osteoblasts produce bone matrix at approximately 1 μm/day, filling the void carved out by the osteoclasts [McKinley, 2003]. Full recovery takes approximately 3 to 6 months [McKinley, 2003].

2.4.2. Secondary Bone Healing

Secondary bone healing occurs in conditions where the fracture gap size is larger and there is lesser stability across the fracture surface. Secondary bone healing takes place with an inflammatory phase, a reparative phase and a remodeling phase. The entire process occurs over a longer duration than primary bone healing and is usually associated with external casts or splints and with insufficiently rigid surgical fixation.

Fracture hematoma that occurs with injury triggers the initial inflammatory stage (Figure 2.8). Ends of the fractured bone develop ischemia because of the avascular nature of the bone after injury [McKinley, 2003]. The necrotic cells thus formed along with the cells within fracture hematoma release chemotactic molecules that initiate the inflammatory response, mainly by recruiting inflammatory cells. The inflammatory cells rapidly enter the fracture hematoma and promote a full inflammatory response which causes pain and swelling [McKinley, 2003].
In the inflammatory phase pain and swelling results in a natural hydraulic splinting that voluntarily immobilizes the limb and creates a mechanical environment that facilitates fracture healing by minimizing interfragmentary motion. Inflammatory response is self-limiting and subsides after several days. The inflammatory cells reabsorb necrotic ends of the fractured bone and produce molecular signals that recruit cells to initiate fracture repair [McKinley, 2003].

The reparative phase occurs through all possible pathways including the marrow cavity, periosteum and surrounding soft tissues [McKinley, 2003]. In the reparative phase, there is a cascade of cellular and chemical events which result in the formation of new blood vessel and bone callus. The bone callus is made up of fibrous tissue, granulation tissue and cartilage (Figure 2.9). While material property of bone callus is relatively weaker than bone, with a larger outer diameter the fractured bone with callus have the same structural property as normal bone.
Figure 2.9. Reparative phase with callus formation [www.boneandspine.com].

In the final remodeling phase, the bone callus is gradually remodeled into new bone (Figure 2.10). Union between the distal and proximal bone fragments occurs in this remodeling phase. It takes several years before the fracture could be considered to be fully healed.
2.4.3. Vascularity of Fracture Healing

Ruptured blood vessels at a fracture site trigger important biological reactions that activate bone resorption in the inflammatory phase. In subsequent reparative and remodeling phases vascular presence is necessary so as to initiate the chemical agents that help in inducing bone formation [Rüedi et al., 2007]. Bone healing takes place when the disrupted vascular supply at the fracture site gets re-established during the reparative and remodeling phase.

The vascular supply in an intact adult long bone can be derived from 3 sources. The first vascular source is the nutrient artery which enters the bone through the cortical diaphysis and divides proximally and distally within the endosteal canal. The second type of vascular supply consists of the arteries that supply the metaphyseal region and branch
with the endosteal supply from the nutrient artery. The third category of blood vessels rises from the periosteum and which perfuses the outer surface of the bone. Other supplies include the vessels entering the bone at the epiphyseal region. In a normal, uninjured bone, the endosteal supply accounts for the perfusion of inner two thirds of the cortex in the diaphysis region. The remaining outer one-third of the cortex is perfused by the periosteal vasculature, whereas in the metaphyseal region the endosteal supply from the metaphyseal arteries accounts for most of the perfusion [McKinley, 2003].

Long bone fracture completely disrupts endosteal blood supply whereas periosteal blood supply is disrupted locally around the fracture site. The amount of damage is directly related to the severity of the disruption of the periosteal blood supply. This disruption causes ischemia that eventually leads to necrosis of the fractured ends [McKinley, 2003]. The necrosis and inflammation of the fracture site send signals to initiate revascularization of the fractured bone and surrounding callus, which results in endosteal revascularization followed by reconstitution of the periosteal circulation. Periosteal revascularization process is sensitive to local mechanical environment, whereby the density of new blood vessels is reduced if excessive interfragmentary motion is detected [McKinley, 2003].

The stability achieved with rigid surgical fixation, which results in primary healing, has been found to have more positive effects on the blood supply as the stable conditions promote easier repair of blood vessels across the fracture site [Ruedi et al., 2000]. Surgical intervention using intramedullary fixation devices or bone plates on the other hand could significantly reduce the endosteal and periosteal revascularization at regions of bone-implant contact. With compression plate for instance, a force of 2000-
3000 N is pressed against the bone which disrupts bone supply from the periosteum [Perren, 2003]. The locked plate technique however results in gaps between the plate and the bone thus could facilitate vascularization from the periosteum [Perren, 2003].

2.5. Locking Compression Plate

The locking compression plate (LCP) is an extramedullary type of implant system that can work on the biomechanical principles of both the compression plate technique as well as the locked plate technique at the same time [Sommer et al., 2003; Hasenboehler et al., 2007]. A uniquely designed combination hole (combi-hole) allows for the insertion of either a locking screw or a non-locking screw into it depending on the type of biomechanical principle required to fix the fracture (Figure 2.11). This offers the surgeon greater flexibility in choosing the combination of screws needed, depending on the nature of fracture, quality of the bone, access to the fracture, condition of the patient etc. [Robert, 2003, Sommer et al., 2003].
In addition, other than the intended use of the locking compression plate as a combination of compression and locked plate technique, the locking compression plate could also be utilized solely as a compression plate or as a locked plate.

The compression plate technique is mainly used in joint fractures and simple metaphyseal and diaphyseal fracture patterns whereas the locked plate technique is mostly used in multi-fragmentary metaphyseal and diaphyseal fractures. A combination of both the plating techniques is used primarily with multi-fragmentary metaphyseal and diaphyseal fractures. These different principles of application give surgeons the freedom to select the most suitable treatment method for a fracture when needed [Sommer et al., 2003; Ahmad et al., 2007, Frigg, 2001].

Figure 2.11. Locking compression plate with combi-holes that allow the fixation of both locking and non-locking screws to the same construct [www.synthes.com].
With the combined biomechanical advantages of the compression plate and locked plate technique the combination technique does not depend solely on screw purchase in the bone to maintain construct strength. The locking compression plate can thus be utilized in osteoporotic bones [Miller, 2007].

2.5.1. Concerns with Locking Compression Plate

With the locking compression plate, it should be ensured beforehand that the compression screws and the locked screws should not interfere with each other and produce a delayed union or non union [Sommer et al., 2003]. One of the basic principles that should be taken into account with the locking compression plate is the order of inserting the locking and the non-locking screws. Locking screws do not pull in the bone towards the plate and when inserted first result in a gap between the plate and the bone. Subsequently if a lag screw is tightened it will attempt to close that gap and thus work against the locking screw. The strength of the construct could be adversely affected if the screws are inserted in the wrong order [Perren, 2003].

On the other hand, with the lag screws inserted first followed by the locking screws, there is no gap between the bone and the plate. This would result in reduced periosteal vascular supply and is detrimental to bone healing [Perren, 2003].

2.5.2. Working Length

The mechanical stability of the locking compression plate construct is influenced to a great extent by its working length. Working length is the distance between the 2 nearest screws straddling across the fracture site. Working length could be increased by
simply not inserting a screw near to the fracture site. With a smaller working length, there would be higher stress concentration in the plate within the working length. An increase in working length results in lower stresses in the plate due to stress distribution over this larger working length. On the other hand, a larger working length might result in reduced fatigue lifespan of the plate [Stoffel et al., 2003]. A larger working length would also result in higher interfragmentary motion.

2.5.3. Unicortical Locked Screws and Bicortical Non-Locking Lag Screws

Locked screws and lag screws in a locking compression plate have different length. Locked screws in the locking compression plate are usually inserted only through the proximal cortex in the diaphyseal segment of the bone [Perren, 2003]. It is found that unicortical screws result in providing sufficient stability to the locking compression plate construct [Roberts et al., 2007, Frigg et al., 2001]. As the distal cortex plays a major part in the angular stability rather than the resistance to pull out, the unicortical locked screws which already have an angular stability is enough to replace the non-locking bicortical lag screws [Perren, 2003]. An advantage with unicortical screws is less bone invasion and periosteal stripping, which is less disruptive to surrounding tissue [Sommer et al., 2003].

2.5.4. Insertion of Locking Screws

One important consideration during insertion of the locking screw is its centering with respect to the screw hole in the plate. A pilot hole needs to be drilled into the underlying bone first before screw insertion. This process should be carried out with the help of proper centering tools to attain accurate orientation and positioning of each screw
(Figure 2.12) [Sommer et al., 2003]. Without proper pre-drilling and alignment the bone screw will cause undesirable wear of the threads on the plate and the screw [Sommer et al., 2003].

Figure 2.12. An alignment tool is attached to the bone plate to guide the drill bit so as to attain precise centering and orientation of the screw[www.synthes.com].
3.1 Study Design

This study was designed to evaluate the difference in stiffness and fixation strength between various screw plate configurations using a dynamic 4-point bend test and the difference in yield, failure and elastic stiffness using a static failure 4-point bend test. The following 3 different symmetrical configurations were used for this study (Figure 3.1):

![Figure 3.1](image_url)

Figure 3.1. Pictorial representation of the fracture model with 3 different screw configurations used in the study. Control group consisted of all locking screws. Technique A had 2 locking screws near to the fracture site and 1 non-locking screw on each end. Technique B had 1 locking screw near to the fracture site and 2 non-locking screws on each end. A sample size of 6 was used in each configuration with a total of 18 specimens. The same samples were tested non-destructively on the dynamic tests followed by destructive static failure tests.
1) Control – All locking construct (only locking screws)

2) Technique A – 2 locking screws and 1 non-locking bicortical screw

3) Technique B – 1 locking screw and 2 non-locking bicortical screws

The control group represented the all locking screw assembly to which each new configuration was compared. Identical bone plates were used with three different configurations of screws to determine if there were any significant differences between these configurations. Synthetic bone specimens with uniform properties along its length were used for consistent comparisons between these proposed configurations.

3.1.1. Determination of Sample Size

Power analysis was conducted for determination of the sample size by using the equation,

\[ n \geq \frac{2(\sigma/\delta)^2 \times (t_{\alpha,\nu} + t_{2(1-P),\nu})^2}{\sigma^2} \]

Where, \( n \): sample size

\( \sigma \): True standard deviation

\( \delta \): Smallest true difference to be detected

\( \nu \): Degrees of freedom

\( \alpha \): Significance level

\( P \): power of the test

\( t \): two tailed t-table value.

In this study, a true standard deviation of 10% was assumed. The smallest true difference to be detected was set to 25%, the power of the test 95%, and a significance
level of 0.05. The number of samples required for each group was determined to be 6, yielding a total of 18 samples in the whole study.

3.2. Specimen Preparation

Specimens were prepared prior to the mechanical testing based on the preparation methodology followed in similar studies. The major components used in the specimen preparation were synthetic bone, bone cement, aluminum blocks, bone plates, and screws.

3.2.1. Synthetic Bone Specimens

Sawbones® (Pacific Research Laboratories, Vashon Island, WA) were used to represent bone in this study. Sawbones® used in this study were synthetic rods having bi-homogeneous composite cylinders with a glass fiber reinforced epoxy shell to represent cortical bone and a core with closed cell polyurethane foam to represent trabecular bone (Figures 3.2). Rods having length of 323.9 mm, diameter of 20 mm and a cortical thickness of 2 mm were used.

Figure 3.2. Cross section of sawbone with bi-homogeneous composite cylinders consists of a glass fiber reinforced epoxy shell (to represent cortical bone) and a core with closed cell polyurethane foam (to represent trabecular bone).
It has been suggested in the literature that synthetic bones mimic mechanical properties of actual human bone [Ahmad et al., 2006]. To avoid the variable material properties associated with use of cadaveric specimens, synthetic bones with consistent material properties between specimens and along their lengths were chosen as a substitute for cadaveric specimens. Synthetic samples provided the advantage of inter-specimen consistency which was helpful in analyzing the results of this comparative study. Moreover, actual human cadaveric specimens have variable geometry which could add as a compounding factor to the study’s variables. Synthetic bones used in this study have structural properties that represent the adult human humerus (Table 3.1).

Table 3.1. Mechanical Properties of the Synthetic Bone Material (Courtesy – Pacific Research Laboratories Inc.)

<table>
<thead>
<tr>
<th>Bone Type</th>
<th>Density (pcf)</th>
<th>Compressive</th>
<th>Tensile</th>
<th>Shear</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(g/cc)</td>
<td>Stren. (MPa)</td>
<td>Mod. (MPa)</td>
<td>Stren. (MPa)</td>
</tr>
<tr>
<td>Inner Core</td>
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<td>0.24</td>
<td>5.2</td>
<td>156</td>
</tr>
<tr>
<td>Outer Shell</td>
<td>102</td>
<td>1.64</td>
<td>157</td>
<td>16700</td>
</tr>
</tbody>
</table>


3.2.2. Specimen Potting Procedure

Both ends of each sawbone were first mounted in aluminum square blocks having a thickness of 5mm, width of 25mm and a height of 75mm respectively (Figure 3.3). These aluminum square blocks attached on both sides of the synthetic bone were used for
load application during the 4 – point bending tests. The square blocks also prevented rotation of the specimen during testing.

Figure 3.3. Square blocks used for attachment on both sides for preventing the rotation of the specimen during tests.

To align the synthetic bone within the aluminum blocks a custom made potting alignment jig was used (Figure 3.4). A bone center alignment block aligned the synthetic bone to each square block. A square block alignment frame aligned the 2 square blocks at either ends in the same plane. The assembly was made with tight tolerances so that it had an interference fit. Poor alignment of square blocks would result in undesirable secondary loads.
Figure 3.4. Bone Potting Assembly (A) Bone center alignment blocks were used to center the synthetic bone within the square blocks. (B) Square block alignment frame was used to align the square blocks in the same plane. (C) Assembled alignment jig. Synthetic bone was capped with bone center alignment blocks and square aluminum blocks on each end.

To secure the synthetic bone within the aluminum square blocks, polymethyl methacrylate (PMMA) cement (Coralite Duz All, Bosworth, Skokie, IL) was used as the potting material (Fig 3.5). The prepared mixture of cement, initially in the liquid state, was poured into the aluminum square blocks. The cement in the potting assembly jig was allowed to set for 20 minutes. To further secure the specimen to the square blocks, 2 orthogonal through holes were drilled through square blocks, synthetic bone and PMMA
on adjacent sides of each square block and 2 steinman pins (ø = 5 mm) were inserted through them.

Figure 3.5. PMMA cement was used to pot synthetic bone into aluminum square blocks [www.bosworth.com].

3.2.3. Bone Plate and Screws

All 18 specimens were installed with a new clinically used 8-hole stainless steel humeral shaft fracture fixation locking compression plate (LCP, Synthes Inc., West Chester, PA) (Figure 3.6). The combination screw holes of the LCP are capable of receiving either a threaded screw head (locking screw) or a smooth hemi-spherical screw head (lag screw).

Figure 3.6. 8-Hole stainless steel locking compression plate used for the study.
Two different types of screws employed in this study were Ø 4.0 mm self-tapping locking screws having a length of 22 mm and Ø 4.5 mm self-tapping cortex lag screws having a length of 38 mm (Figure 3.7). A total of six screws were applied onto each specimen with 3 screws placed symmetrically on either side of a fracture gap.

Figure 3.7. Diameter 4.0 mm and length 22 mm stainless steel locking screw with threaded screw head (left arrow), and diameter 4.5 mm and length 38 mm stainless steel cortical screw with smooth hemi-spherical screw head (right arrow).

All screws and plates were implanted by a surgeon in accordance with the manufacturer’s recommended technique. In hybrid configurations with both types of screws, the non-locking lag screws were applied first followed by locking screws. Fixation of non-locking screws compressed the bone plates against the sawbone. This procedure is practiced clinically.

Standard Synthes drill guides, drill bits and screw drivers were used for application of screws on plates. The torque applied to tighten the screws was determined by the surgeon. All plates were fixed by the same surgeon to achieve inter-specimen consistency. The plate was aligned against the flat surface of the square blocks (Figure 3.8).
Figure 3.8. The three different configurations after complete specimen preparation. Same type of plate was used in all the different configurations and all plates were applied flush to the synthetic bones by first inserting the non-locking screws followed by the locking screws.

3.2.4. Fracture Model

The fracture model consisted of a fracture gap of 5 mm at the mid span of the construct to simulate the worst case gap size in a comminuted fracture (Figure 3.9). This
45

The fracture mode has also been used in other studies [Gardner et al., 2006; Ahmad et al., 2006]. The fracture gap was created using a ø 5mm end mill on a milling machine. Extreme care was taken to prevent contact of the end mill with the bone plate. Hand files were used to cut the final sawbone material in the gap. Special care was taken not to apply any load that might bend the specimen while creating the fracture gap.

Figure 3.9. The 5 mm fracture gap at the midpoint of the synthetic bone to simulate the worst case fracture gap within a comminuted unstable fracture.

3.2.5. Liquid Metal Strain Gage (LMSG)

Liquid metal strain gages (LMSG) (Parks Medical Electronics Inc., Aloha, OR) were used for measuring the fracture gap micromotion for every specimen. A change in length due to the axial stresses would result in proportional resistance change in the LMSG. These resistance changes were converted to voltage by wiring the LMSG in parallel with one arm of a wheatstone circuit inside a bridge amplifier (Gould, T&M, Valley View, OH). During testing, a new LMSG was attached to each specimen prior to loading.

All LMSGs had a 10 mm long silastic tube filled with mercury. The LMSG’s were calibrated both prior to the attachment to synthetic bone as well as after the test to
make sure the calibration constants has not changed during the course of the test. Calibration was done by mounting LMSG on the material testing system and tensioning it under displacement control by a distance of 2.0 mm (20% strain). During displacement the LMSG voltage from the amplifier was recorded. The linear variable differential transformer (LVDT) displacement data from the testing machine were recorded at the same rate. The slope of LVDT displacement versus LMSG voltage gave the mm/V value for each LMSG which was used as the calibration factor for voltage to displacement conversion (Figure 3.10).

![Figure 3.10. Ramp function was applied to tension the liquid metal strain gage (LMSG) to 0.00508 m (0.2 inch). From the total displacement of LMSG and voltage variation, a calibration constant was determined in mm/V for each LMSG.](image)

Dynamic response to sinusoidal strain inputs of the LMSG is frequency-independent up to 50 Hz without phase shift. The LMSG is also velocity-independent over the range of nominal strain rates from 20/s to 0.02/s. LMSG is capable of
maintaining stable outputs when held stretched at fixed lengths, immediately following stepwise displacement inputs. Thermal artifacts are modest (0.185% apparent strain per degree C), and there was no appreciable sensitivity to non-axial strains. LMSG used for the current study had an accuracy of .01 mm as stated by the manufacturer.

The calibrated LMSG was fastened to the synthetic bone on the opposite side from the bone plate (Figure 3.11). Following the manufacturer’s instruction each LMSG was stretched to 1.5 mm and held in the stretched position using cyanoacrylate glue while attaching the LMSG to the synthetic bone. This was to ensure that the gage was in the linear range for both elongation and contraction.

![Figure 3.11. LMSG applied to the opening of the gap for determination of fracture gap micromotion.](image)

3.3. Dynamic Test

Dynamic tests were conducted to simulate the healing period. The tests measured the stiffness of the construct as well as the fracture gap micro-motion.
3.3.1. Test Protocol

All 18 specimens were tested non-destructively in 4-point bending. Specimens from the 3 configurations were tested in random order. Each specimen was aligned with the bone plate on the top (Figure 3.12, 3.13). The stiffness of the construct from the actuator displacement and the fracture gap micro-motion were measured.

Figure 3.12. Schematic of the 4-Point Bending test system, where displacement and gap micro-motion were measured for an applied 4-point bending load.

Figure 3.13. The whole 4 Point Bending test system with the specimen placed in between bending jigs.
Cyclic loads were applied under load control with maximum moment of 12 Nm and a minimum moment of 1.2 Nm at a rate of 1 Hz (Figure 3.14). Cyclic tests were conducted for 10,000 cycles to simulate a healing period of 3 months. Assuming a person applies bending force 100 times a day for 3 months will result in almost 10,000 cycles of this motion. If a healing period of 6 months is assumed the 10,000 cycles is a good estimation for a condition half way through healing. The stiffness and fracture gap micro-motion during this time frame gave a reasonable comparison between 3 different configurations. The tests were terminated at 10,000 cycles if the construct had not failed.

Figure 3.14. The above figure shows the maximum and minimum load applied which becomes the bending moment.

A servo-hydraulic materials testing system (Shore Western Manufacturing Company, Monrovia, CA) with a capacity of up to 20,000 N, was used to conduct the 4-point bending tests. The system consisted of three major elements; a 20,000 N load frame (Model No. 301.2), a hydraulic power supply system (Model No. 110.01) and a control console housing the Shore Western servo controller and a signal generation equipment.
Actuator force was measured using a 9000 N load cell (Model 3132 –2K, Eaton Corporation, Troy, MI). A linear variable differential transformer (LVDT) (internal to the load frame) was used to record actuator displacement during testing.

![3D Model of the servo-hydraulic materials testing system used to conduct 4-point bending in the specimens with the 4-point bending jigs attached.](image)

Applied load, actuator displacement and change in fracture gap were measured and recorded during dynamic testing. Load, LVDT displacement and LMSG displacements were amplified and sampled at a rate of 40 Hz on an analog to digital (A/D) system (Kiethley Metrabyte, Tauton, MA) and stored on a PC. The amplifier system (Gould, T&M, Valley View, OH) has a signal conditioner with bridge excitation, rejection of electrical noise and calibrated zero suppression. This direct coupled, plug-in
dc bridge amplifier was used to process voltage signals from Load, LVDT and LMSG data.

3.3.2. Data Analysis

Data were sampled for duration of 20 seconds (20 cycles) at 0, 100, 250, 500, 1000, 1500, 2000, 2500, 3000, 4000, 5000, 6000, 7000, 8000, 9000, 10000 cycles respectively. From each of these collection points 20 cycles were analyzed. These data were used to generate force-displacement (LVDT) and force-fracture gap (LMSG) curves at cycles 0, 100, 250, 500, 1000, 1500, 2000, 2500, 3000, 4000, 5000, 6000, 7000, 8000, 9000, 10000. The stiffness of the assembly at each of these intervals was calculated from the force-displacement curve. The increasing load was considered for the stiffness calculation. The fracture gap micro-motion values were obtained using the difference between the maximum fracture gap opening and minimum fracture gap opening. These fracture gap sizes corresponded to the maximum and minimum applied moments of 12 Nm and 1.2 Nm. Construct stiffness and fracture gap size were compared statistically between configurations.

3.4. Static Failure Test Protocol

Next, static 4-point bending failure tests were conducted to determine the construct stiffness, yield moment and failure moment. These 4-point bending tests were carried out in displacement control up to a displacement of 10 mm. The applied displacement was ramped linearly to 10 mm at a rate of 0.5 mm/s over a total time period of 20 seconds. Both the load cell and linear variable differential transformer (LVDT)
were externally calibrated before and after each test to ensure that calibration did not change over the duration of the test.

![Graph](image)

Figure 3.16. Test was carried out in displacement control at a test speed of 0.5 mm/sec up to a crosshead displacement of 10 mm. The load response was non-linear.

3.4.1. Optoelectronic Camera

An optoelectronic camera system (Optotrak Certus, Northern Digital Inc., Waterloo, ON) (Figure 3.16) was used to measure the angular displacement of the specimens during 4-point bending tests. The camera system tracked the three dimensional (3D) positions of infra-red light emitting diodes (IRLED) within its field of view. With a minimum of 3 non-collinear IRLEDs attached to each rigid body, the camera system was used to track 3D motion of rigid bodies. The optotrak had an accuracy of ±0.1 mm and ±0.13 degrees in measuring 3D rigid body motion, as stated by the manufacturer.
Figure 3.17. An optoelectronic camera system with an accuracy of ±0.1 mm and ±0.13 degrees used to capture the rotation of the specimen during static failure tests.

Attached to each aluminum square block was a set of marker arrays with 4 infra-red light emitting diodes (IRLED) (Figure 3.18). The marker arrays were attached to the side of each square block and faced towards the optotrak system (Figure 3.19).

Figure 3.18. A “marker array” consisted of 4 IRLEDs attached onto a plexi-glass. Each rigid body whose 3D motion is of interest is rigidly attached with a marker array. The optotrak camera tracks motion of each IRLED, and as an array of at least 3 non-collinear markers the 3D motion is defined.
Marker arrays were tightly attached to the specimens using small screws in order to prevent the vibration of arrays during the application of load. The 2 marker arrays on the specimens act as 2 different rigid bodies and their motion can be examined under a 4-point bending to obtain the angles made by the system during loading. The marker arrays were attached to the aluminum blocks; since the aluminum blocks being farthest away from the center of the specimen deform least during the application of a load.

Figure 3.19. Specimen was loaded in a testing machine with marker array attached to both square blocks and also on the top loading assembly. These marker arrays acted as rigid bodies for measurement of the translation and rotation under a 4-point bending load.
The camera system was positioned 2.25 meters in front of the test specimen (Figure 3.20). The path between the camera and the testing system was cleared of any obstructions during the measurement.

Figure 3.20. Optotrak camera system positioned 2.25 meters in front of the test specimen to capture motion during a 4-point bending test.

A local co-ordinate system was created to measure the main rotation during testing (Figure 3.21). The bottom left marker of the right marker array (right rigid body) was considered as the origin (Figure 3.21). The XY axes were in the plane of the square block that faced the camera. The Z-axis thus pointed perpendicularly towards the camera. During 4-point bending tests, Z rotation was the main axis of motion. Rigid body rotation
was independent of location of measurement. The rotations were measured with respect to the origin. Total rotations of both left and right marker arrays $\Theta_1$ and $\Theta_2$ were added up and used for subsequent analysis.

Figure 3.21. 2 marker arrays with 4 IREDs each were attached to each square block. Forces acting downwards (F) were applied by the actuator on the aluminum blocks. Forces acting upwards were the reaction forces from the bottom jig. A custom coordinate system was set up with the bottom left marker of the right array as the origin, line joining the bottom markers of the right array as X-axis and the line joining the origin marker and the marker above it as Y-axis. The parameters measured were the moment applied and total angular displacement $\Theta$ ($\Theta_1 + \Theta_2$).

3.4.2. Data Analysis

The sampling rate for load, LVDT displacement and optotrak 3D kinematics data were at 100 Hz. These data obtained from two different machines were synchronized, and analyzed for the yield moment, failure moment and stiffness. As these tests were carried out under displacement control, rotation was the abscissa of the plot and the moment (in Newton meters) was the ordinate. The yield and failure moments were determined as the
moments that caused 2° permanent deformation and 10° permanent deformation respectively. This definition is based on the ASTM test method for metallic medical bone screws [ASTM F 543-02, Annual Book of ASTM Standards 2003]. Slope of the linear region of the moment – angular displacement (Θ) curve gave the elastic stiffness of the construct. The failure site within the different constructs was recorded after each failure test. Failure mode of each specimen was also documented by visual analysis to check for any common pattern in failure of different configurations.

3.5. Statistical Analysis

Single factor analysis of variance (ANOVA) was carried out to compare between different configurations. For dynamic tests, stiffness and fracture gap micromotion were compared between control group, Technique A and Technique B. For static failure tests, construct stiffness, yield moment and failure moment were compared between different configurations. Statistical analysis was performed using SAS software package (SAS Institute, Cary, NC). A p-value of less than 0.05 was considered as statistically significant. If there were any significant differences in the results, post hoc Student-Newman Keuls (SNK) tests were performed. Chi-square tests were carried out on the failure pattern to determine the differences between configurations.
CHAPTER IV
RESULTS

4.1 Overview

In dynamic tests, there were no significant differences between various configurations for 1) stiffness, calculated as the ratio of applied load to LVDT displacement, and 2) fracture gap size. Similarly in the static failure tests there were no significant differences between configurations for, 3) yield moments, 4) failure moments and 5) elastic stiffness.

4.2. Construct Stiffness in Dynamic Tests

Load and displacement data were analyzed at specific intervals to determine the stiffness of the constructs. The load-displacement graphs plotted for 20 cycles at these intervals yielded a curve with a hysteresis loop (Figure 4.1). The stiffness of the construct at each of these intervals was calculated from the slope of the force displacement curve. The increasing slope was defined as the stiffness of the construct whereas area enclosed between the hysteresis loop represented the energy lost during each cycle.
Figure 4.1. A typical force versus displacement curve obtained at intervals. Twenty cycles analyzed at each interval. The increasing slope was defined as the stiffness of the construct.

Construct stiffness was plotted against loading cycles for all specimens from Control Group (Figure 4.2), Technique A (Figure 4.3) and Technique B (Figure 4.4). Construct stiffness generally remained constant at around 300 N/mm up to 10,000 cycles. These results indicated that the constructs were stable in a test environment which simulated fracture healing duration of 3 months.
Figure 4.2. Stiffness variation of the 6 test specimens in the Control Group over the 10,000 cycles fatigue tests.

Figure 4.3. Stiffness variation of 6 test specimens in Technique A (double locking screws) over the 10,000 cycles of fatigue tests.
In Techniques A and B there was one specimen with higher and fluctuating stiffness from the start to the end of the fatigue tests. During post tests inspection, it was discovered that for these two specimens only, there were permanent indentation marks on the aluminum square blocks, which indicated application of higher loads than intended. This could have been caused by a bad electrical connection for the load cell signal, leading to erroneous data during the load controlled cyclic tests. Due to aforementioned technical error, data for these 2 specimens in their respective groups were not included for further analysis. Thus there were 6 test specimens in the Control Group, 5 test specimens in Technique A and 5 in Technique B. A total of 16 specimens were included in the statistical analysis instead of the intended 18 specimens.

Mean stiffnesses were compared between the three configurations (Figure 4.5). There was a trend of increased mean stiffness with increased number of cyclic loading. Technique A (double locking screw) and Technique B (single locking screw) had similar
mean stiffness values throughout, which were higher than the control group with all locking screws (Table 4.1). Mean stiffness at 10,000 cycles between the 3 configurations were not significantly different (p = 0.153).

![Graph showing stiffness over fatigue cycles for different configurations](image)

Figure 4.5. Mean construct stiffness for the 3 configurations at 10,000 cycles were not significantly different (p = 0.153). There was a trend of higher stiffness after 10,000 cycles of loading.
Table 4.1. Average Stiffness (N/mm) at Specific Cyclic Intervals.

<table>
<thead>
<tr>
<th>Cycles</th>
<th>Control (n=6)</th>
<th>Technique A (n=5)</th>
<th>Technique B (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stiffness (N/mm)</td>
<td>Standard Deviation</td>
<td>Stiffness (N/mm)</td>
</tr>
<tr>
<td>10</td>
<td>303.70</td>
<td>36.93</td>
<td>335.66</td>
</tr>
<tr>
<td>110</td>
<td>304.39</td>
<td>35.92</td>
<td>335.92</td>
</tr>
<tr>
<td>260</td>
<td>305.37</td>
<td>34.54</td>
<td>336.30</td>
</tr>
<tr>
<td>510</td>
<td>306.88</td>
<td>32.52</td>
<td>336.94</td>
</tr>
<tr>
<td>1010</td>
<td>309.49</td>
<td>29.51</td>
<td>338.17</td>
</tr>
<tr>
<td>1510</td>
<td>311.58</td>
<td>27.65</td>
<td>339.38</td>
</tr>
<tr>
<td>2010</td>
<td>313.21</td>
<td>26.72</td>
<td>340.55</td>
</tr>
<tr>
<td>2510</td>
<td>314.42</td>
<td>26.49</td>
<td>341.69</td>
</tr>
<tr>
<td>3010</td>
<td>315.27</td>
<td>26.82</td>
<td>342.80</td>
</tr>
<tr>
<td>4010</td>
<td>316.10</td>
<td>28.71</td>
<td>344.91</td>
</tr>
<tr>
<td>5010</td>
<td>316.11</td>
<td>31.82</td>
<td>346.90</td>
</tr>
<tr>
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<td>315.71</td>
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</tr>
<tr>
<td>7010</td>
<td>315.32</td>
<td>39.09</td>
<td>350.47</td>
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<td>315.34</td>
<td>41.54</td>
<td>352.05</td>
</tr>
<tr>
<td>9010</td>
<td>316.21</td>
<td>41.87</td>
<td>353.51</td>
</tr>
<tr>
<td>10010</td>
<td>318.31</td>
<td>39.13</td>
<td>354.86</td>
</tr>
</tbody>
</table>

4.3. Fracture Gap in Dynamic Tests

Fracture gap measured at definite intervals, yielded a curve with a hysteresis loop (Figure 4.6). Total fracture gap was calculated as the difference between maximum and minimum gap opening. Fracture gap was plotted against loading cycles for each specimen for the Control Group (Figure 4.7), Technique A (Figure 4.8) and Technique B (Figure 4.9). For each specimen, this gap generally remained constant at around 2 mm up to 10,000 cycles. These fracture gap results, in agreement with stiffness results, indicated that all fixation constructs were stable during this simulated fracture healing duration.
Figure 4.6. A typical 20 cycle sample of force versus fracture gap curve. Total fracture gap was calculated as the difference between maximum and minimum gap opening.

Figure 4.7. Total fracture gap of the 6 test specimens in the Control Group over the 10,000 cycles fatigue tests.
In addition to observations made for stiffness results for the two excluded specimens, their corresponding fracture gaps were also irregular and fluctuating. The
higher applied load resulted in larger minimum gap opening and a smaller increase in gap opening at the maximum applied load. Fracture gap data for these same 2 specimens were excluded from further analysis. Mean fracture gap from remaining specimens were compared between the 3 configurations and were not statistically significant (p = 0.563) (Figure 4.10, Table 4.2).

![Fracture gap data for the 3 configurations at 10,000 cycle were not significantly different (p = 0.563).](image)

Figure 4.10. Mean fracture gap for the 3 configurations at 10,000 cycle were not significantly different (p = 0.563).

There was a trend of smaller fracture gap with higher loading cycles. Fracture gap was linearly related to loading cycles in all remaining specimens except for one case in Technique B (Figure 4.9). If this sample was excluded from mean fracture gap plot, Technique B would also be linearly related to loading cycles. In that case mean fracture gap would remain statistically not significant between the 3 configurations.
Table 4.2. Average Fracture Gaps (mm) at Specific Cyclic Intervals

<table>
<thead>
<tr>
<th>Cycles</th>
<th>Control (n=6)</th>
<th>Technique A (n=5)</th>
<th>Technique B (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gap (mm)</td>
<td>Standard Deviation</td>
<td>Gap (mm)</td>
</tr>
<tr>
<td>10</td>
<td>2.08</td>
<td>0.22</td>
<td>2.07</td>
</tr>
<tr>
<td>110</td>
<td>2.08</td>
<td>0.22</td>
<td>2.07</td>
</tr>
<tr>
<td>260</td>
<td>2.08</td>
<td>0.22</td>
<td>2.06</td>
</tr>
<tr>
<td>510</td>
<td>2.08</td>
<td>0.22</td>
<td>2.06</td>
</tr>
<tr>
<td>1010</td>
<td>2.08</td>
<td>0.22</td>
<td>2.05</td>
</tr>
<tr>
<td>1510</td>
<td>2.07</td>
<td>0.22</td>
<td>2.05</td>
</tr>
<tr>
<td>2010</td>
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<td>0.22</td>
<td>2.04</td>
</tr>
<tr>
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<td>0.22</td>
<td>2.03</td>
</tr>
<tr>
<td>3010</td>
<td>2.07</td>
<td>0.22</td>
<td>2.03</td>
</tr>
<tr>
<td>4010</td>
<td>2.06</td>
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<tr>
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<td>0.24</td>
<td>1.99</td>
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<td>0.24</td>
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<td>0.25</td>
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</tr>
<tr>
<td>10010</td>
<td>2.03</td>
<td>0.26</td>
<td>1.94</td>
</tr>
</tbody>
</table>

4.4. Yield in Static Failure Tests

Static 4-point bending failure tests resulted in load (moment) versus displacement (angular rotation) curves which were expected of a hookean material. A linear elastic region was typically observed, followed by a plastic region and finally failure (Figure 4.11) for all specimens. Yielding of the specimen construct was defined as the applied moment necessary to create a 2° plastic deformation in the construct.
Failure of the construct was defined as the applied moment that caused 10° plastic deformation in the constructs. Stiffness for each specimen was defined as the slope of the load-displacement curve in the elastic region.

Yield moment for the Control Group had a mean of $27.82 \pm 1.11$ Nm and for Technique A and B had $28.06 \pm 0.27$ Nm and $27.70 \pm 1.38$ Nm respectively. Mean yield moment for the 3 configurations were not significantly different ($p = 0.854$) (Figure 4.12).
4.5. Failure Load in Static Failure Analysis

Failures of the constructs were found to occur with 2 modes. In the first mode, failure occurred with 10° permanent plastic deformation (Figure 4.13). In the second mode of failure a sudden drop in the moment was observed before 10° permanent deformation (Figure 4.14). One specimen in Technique B group was discarded from failure analysis since it neither reached the 10° permanent deformation nor had any failure pattern.
Figure 4.13. Typical moment versus angular displacement curve with a linear elastic region, a non-linear plastic region and a failure. Failure was defined as a 10° permanent plastic deformation.

Figure 4.14. Typical moment versus angular displacement curve with a linear elastic region, a non-linear plastic region and a failure. Failure in this case was observed as a sudden drop in the moment value causing a negative slope.
Out of 18 specimens, 10 specimens recorded a failure before the 10° permanent deformation. Mean failure moments for Technique A (38.03 ± 2.32 Nm) and Technique B (37.61 ± 3.98 Nm) tend to be higher than for the Control Group (32.98 ± 4.15 Nm). There was however no statistical significance between the 3 configurations (p = 0.076).

![Failure Moment Chart]

Figure 4.15. Mean failure moments for the 3 constructs (p = 0.076). Error bars denote standard deviation.

4.6. Construct Bending Stiffness in Static Failure Tests

Construct bending stiffness for the Control Group had a mean of 1.77 ± 0.03 Nm/deg and for Techniques A and B the stiffness were 1.83 ± 0.05 and 1.80 ± 0.07 Nm/deg respectively (Figure 4.16). There was no significant difference in the stiffnesses between the 3 different constructs (p = 0.409).
Figure 4.16. Mean elastic stiffness for the 3 different constructs (p = 0.409). Error bars denote standard deviations.

4.7. Failure Region

Several regions of failure on the specimen were observed (Table 4.3). Failure of 5 specimens in the Control group was observed as pull out of the locking screws (F1) near the fracture gap (Figure 4.17). This mode of failure was also observed in 2 specimens from Technique A and one specimen from Technique B. Two specimens in Technique A and 3 in Technique B failed across the synthetic bone at the farthest bi-cortical screw hole (F2) (Figure 4.18) on either one side or both sides. Other specimens failed with permanent deformation of the plate (F3), with one instance in Control Group, two in Technique A and one in Technique B respectively.
Table 4.3. Elastic Stiffness, Failure Load and Failure Regions of the 3 Different Configurations Measured During the Static Failure Tests

<table>
<thead>
<tr>
<th></th>
<th>Stiffness (Nm/deg)</th>
<th>Yield Moment (Nm)</th>
<th>Failure Moment (Nm)</th>
<th>Failure Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1.80</td>
<td>28.92</td>
<td>34.23</td>
<td>F1: Failure at the plate and screw bone interface *</td>
</tr>
<tr>
<td></td>
<td>1.80</td>
<td>27.62</td>
<td>35.90</td>
<td>F1: Failure at the plate and screw bone interface *</td>
</tr>
<tr>
<td></td>
<td>1.78</td>
<td>28.94</td>
<td>39.21</td>
<td>F3: Failure at the plate</td>
</tr>
<tr>
<td></td>
<td>1.77</td>
<td>26.67</td>
<td>29.63</td>
<td>F1: Failure at the plate and screw bone interface *</td>
</tr>
<tr>
<td></td>
<td>1.75</td>
<td>26.12</td>
<td>26.50</td>
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</tr>
<tr>
<td></td>
<td>1.72</td>
<td>28.64</td>
<td>31.91</td>
<td>F1: Failure at the plate and screw bone interface *</td>
</tr>
<tr>
<td>Double Locking Technique A</td>
<td>1.88</td>
<td>27.72</td>
<td>38.01</td>
<td>F2: Failure at the plate followed by far bicortical screw</td>
</tr>
<tr>
<td></td>
<td>1.85</td>
<td>28.07</td>
<td>35.61</td>
<td>F2: Failure at the far bicortical screw*</td>
</tr>
<tr>
<td></td>
<td>1.76</td>
<td>27.98</td>
<td>37.03</td>
<td>F3: Failure at the plate</td>
</tr>
<tr>
<td></td>
<td>1.75</td>
<td>27.83</td>
<td>35.62</td>
<td>F1: Failure at the plate and screw bone interface *</td>
</tr>
<tr>
<td></td>
<td>1.79</td>
<td>28.21</td>
<td>39.85</td>
<td>F1: Failure at the plate and screw bone interface *</td>
</tr>
<tr>
<td>Single Locking Technique B</td>
<td>1.71</td>
<td>29.33</td>
<td>-</td>
<td>No Failure</td>
</tr>
<tr>
<td></td>
<td>1.88</td>
<td>27.09</td>
<td>40.93</td>
<td>F3: Failure at the plate</td>
</tr>
<tr>
<td></td>
<td>1.84</td>
<td>27.60</td>
<td>41.05</td>
<td>F2: Failure at the far bicortical screw*</td>
</tr>
<tr>
<td></td>
<td>1.74</td>
<td>26.75</td>
<td>30.24</td>
<td>F1: Failure at the plate and screw bone interface *</td>
</tr>
<tr>
<td></td>
<td>1.74</td>
<td>29.63</td>
<td>38.89</td>
<td>F2: Failure at the far bicortical screw*</td>
</tr>
<tr>
<td></td>
<td>1.89</td>
<td>25.77</td>
<td>36.96</td>
<td>F2: Failure at the far bicortical screw</td>
</tr>
</tbody>
</table>

*: denote plates that failed before 10° permanent deformation
Figure 4.17. Example of failure at the screw bone interface (F1) for the first locking screws near to fracture gap (shown by the circles). Five specimens in the Control Group, two specimens of Technique A (Double Locking) and one specimen in Technique B (Single Locking) failed by this mode.

Figure 4.18. Example of failure of bone at the far bicortical screw (F2) (shown by the circle). Three specimens in Technique B (Single Locking) and two specimens in Technique A (Double Locking) failed by this mode.
Failure modes of different configurations were compared using a chi-square test to check for any possible patterns. Chi-square test was conducted by comparing the expected values based on null hypotheses (Table 4.4) versus the results (Table 4.5). The comparison showed a significant failure pattern for the control group ($p = 0.030$), whereas failure patterns were not observed for Technique A and Technique B.

Table 4.4. Expected Failure Patterns for the Three Different Types of Configurations Based on Null Hypothesis of No Significant Difference.

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Technique A</th>
<th>Technique B</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>2</td>
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<tr>
<td>F2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>F3</td>
<td>2</td>
<td>2</td>
<td>2</td>
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</tbody>
</table>
Table 4.5. Observed Failure Patterns for The Three Different Types of Configurations.

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Technique A</th>
<th>Technique B</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>5</td>
<td>2</td>
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</tr>
<tr>
<td>F2</td>
<td>0</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>F3</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
CHAPTER V
DISCUSSION AND CONCLUSION

5.1. Overview

Comparison between three different screw-plate configurations evaluated in this study indicated no statistical differences in dynamic tests as well as static failure tests. Test analysis showed that Technique A (Double locking screw configuration) and Technique B (Single locking screw configuration) behaved similar to the control group (All locking screw configuration) in terms of construct stiffness (in both static and dynamic tests), fracture gap micro-motion (in dynamic test), yield moment (in static test) and failure moment (in static test) respectively.

5.2. Clinical Relevance

In clinical situations, various factors such as fracture location, type, severity, vascularity, bone quality, selected fixation device and type of technique used greatly influence fracture healing. Hence comprehensive knowledge of different fracture fixation systems and their effects on fracture healing process is necessary for trauma surgeons to achieve the best outcome. Relevant concerns associated with these fixation systems and techniques include micro motion across fracture site and construct stiffness. Clinical
studies have shown that the amount of displacement across fracture fragments is directly related to the type of fracture healing such as primary healing, secondary healing or non-union of the associated fragments. Non-union can lead to limited activity, further complications, revision surgeries and unnecessary suffering of the patient. Further, physiologic loads often involve a combination of axial, bending and torsional loads, which have a detrimental effect on fixation strength of the device used. Therefore it is important to evaluate fracture fixation systems and techniques in terms of advantages, reliability and consequences of their use. An all locking screw-plate system, which is assumed to have advantages over other screw-plate systems, was chosen as the control for the current study. Two new configurations were compared with a commonly used all locking screw configuration. Dynamic tests were used to measure construct stiffness and micro motion at the fracture site. During dynamic testing, a bending moment of 12 Nm was applied to bend the construct within its elastic region for 10,000 cycles so as to simulate the application of bending forces that might be encountered during fracture healing process. Strength of each construct following 10,000 cycles of dynamic testing was evaluated through a static failure test in which construct stiffness, yield moment, failure moment and failure pattern were measured. No significant differences were observed between configurations for these parameters in both dynamic and static tests.

Individuals with comminuted fractures of the humeral diaphysis are mostly at a risk of delayed union or non-union in [Gardner et al., 2006]. Such fractures with fixation using non-locking screws alone are prone to screw loosening and prolonged healing duration. In contrast, use of locking plate system which has the screw head screwed into the threaded plate results in a more stable system for a longer healing period. The plate
and the screw acts as a single unit and thereby loosening and subsequent toggling of the screws are prevented. Gardner et al. [2006] showed that a hybrid configuration with one set of non-locking screws and 2 sets of locking screws behaved similar to an all locking screw construct. These results gave clinicians support in using a hybrid construct and allow clinicians to make use of the advantages offered by both type of constructs. The set of non-locking screws act as lag screws for compressing fracture fragments whereas locking screws might provide further stability with a lower potential of loosening. It is often observed that while treating complex comminuted fractures more non-locking screws may have to be utilized to compress multiple fracture fragments. The current study expanded upon Gardner’s results and showed that the usage of 1 or 2 sets of non-locking screws (4 non-locking screws and 2 locking screws) maintained the stiffness and gap micromotion similar to that of all locking screw configuration during the simulated fracture healing period. The results of the current study indicate that the use of one or two sets of non-locking lag screws could be used to achieve reduction of fracture fragments, and yet achieve similar construct strength as all locking screws. These multiple options provide flexibility to surgeons during fixation of diaphyseal comminuted fractures. The current results were also in concurrence with Gardner’s results in that no difference were found between constructs with one set of non-locking screws and constructs with all locking screws.

For long bones, an average diaphyseal cortical thickness of 4.4 mm has been recorded by Tingart et al. [2003]. Specimens 70 years of age or younger had a combined mean cortical thickness of 4.8 ± 1.0 mm while those older than 70 years were 3.8 ± 0.9 mm [Tingart et al., 2003]. The thickness of the synthetic specimen used in the current
study was 4 mm. Synthetic bone specimens used have a density of 1.64 g/cm³. This is close to the apparent density of human cortical bone (1.80 g/cm³) [An, 2002]. The mean ultimate strength of femoral cortical bone in longitudinal tension and compression for a population between 19-80 years of age have been found to be 133 MPa and 193 MPa respectively [Hayes and Gerhart, 1985; Reilly and Burstein, 1975]. In comparison, the tensile and compressive strength of the synthetic bone specimens were 106 MPa and 157 MPa respectively.

5.3. Selection of Test Parameters

When a person picks up a weight in his hand with elbow bent, the forces applied to the humerus are predominantly bending forces. The 4-point bending force used in the current study simulated such loading condition on a humerus bone. It can be estimated that lifting 25 N in the hand with elbow bent at a certain angle would result in a bending moment of 12 Nm applied to the mid shaft of his humerus. Cyclic frequencies up to 5 Hz are typically used to test orthopedic implants in the ASTM standards. A lower cyclic loading rate of 1 Hz was utilized in the current study to represent the maximum rate in normal human arm motion.

In static failure analysis, the actuator was moved under displacement control at a constant speed up to a displacement of 10 mm. It was observed that actuator displacement greater than 10 mm would result in specimen touching the bottom of the test jig. There is no ASTM test standard currently that is similar to the present study. The parameters used in the ASTM test for evaluation of metallic medical bone screws (ASTM F 543-02) which compared torque versus angular displacement of screws was
comparable to those used in the current study. In the ASTM F 543-02 a 2° deformation was considered as yield whereas a 10° permanent deformation was considered as failure. These same definitions were applied onto the static failure test results in the current study to define the yield and permanent deformation.

5.4. Analysis of Results

Results of the dynamic analysis showed that Technique A (double locking screws) and Technique B (single locking screw) were very similar to each other in construct stiffness and both showed stiffness values higher than the control group (all locking screws). Even though the fracture gap values for all three groups were very close to each other, a small divergence of mean values for technique B was noticed towards 10,000 cycles. This was mainly due to result of one specimen which affected the overall mean data. Results from this one specimen might have been a rogue data as all other data sets were mostly linear. In order to analyze if this trend indicated any differences between the stiffness and fracture gap values an ANOVA was performed on the test data. The analysis showed no differences between the maximum diverged values though there were some ambiguities about why fracture gap decreased while stiffness increased over time. Stiffness from the static failure test results might be a better indicator of construct stiffness in the elastic region of these specimens.

Although the stiffness of the constructs was expected to decrease with time during dynamic testing [Gardner et al., 2006] the current study showed contrary results. Slight increase in the stiffness of the constructs and a slight reduction in fracture gap were observed. A probable reason could be that frictional forces developed between the load
applicators and aluminum blocks caused a rough surface that hindered spring back over time and thereby increased the stiffness and reduced the fracture gap micro-motion. The static failure test that followed the dynamic test gave a more accurate and comparable value of elastic stiffness of the constructs as the frictional forces played a less significant role in the absence of repetitive load application.

During static failure tests, the position was held constant at 10 mm when this maximum displacement was reached on the testing machine. It was noted that at this constant displacement, reaction load was not maintained at the peak value; instead stress relaxation occurred. This behavior might have been due to stress relaxation at the screw bone interface in the synthetic material. Data during stress relaxation were not considered for analysis.

Several failure mode patterns were observed in each of the different configurations analyzed in this study. Even though the all-locking control group had a very consistent failure pattern, it showed the highest standard deviation and the lowest failure moment. Lower failure loads obtained for the control group was due to pull out of the screws near the fracture gap. It can be estimated that stress concentration in these screws resulted from the stiff all-locking screw construct. This mode of screw pull out was also observed in two specimens from technique A and one specimen from technique B. However such occurrence was less noticed in technique B (Single locking screw construct) because there were 2 non-locking screws with wider cutting flutes that might have prevented the pull out of locking screws near them. Also, some of the specimens from technique A and technique B had total failures in which the specimen broke into two pieces at the farthest non-locking screw holes on either one or both sides of the
construct. Wider cutting flutes of the non-locking screws acted as crack propagation points that initiated total failure of these specimens. The failure pattern observed in the control group led to the rejection of the second null hypothesis.

5.5. Limitation

Although the results of this study showed important findings regarding currently used screw-plate fixation techniques during fracture treatment, there were certain inherent limitations. The effect of frictional forces between the rollers and the aluminum blocks played a significant role during dynamic testing. Even though oil was applied to the surfaces at constant intervals, it was assumed that frictional force increased with increasing load cycles and gradually created a rough surface on which load was applied. In retrospect the cylinders should have been replaced with rollers as per ASTM standard for 4-point bending. One specimen from Technique A (double locking screw group) and another specimen from Technique B (single locking screw group) were discarded because of the uneven application of load due to aforementioned increased frictional forces.

Further, synthetic bones were used instead of actual cadaveric bones to reduce inter-specimen variability and allow the test to detect difference between constructs using minimum sample size. However, the results obtained from in-vitro testing of these bi-homogenous cylinders cannot be directly extrapolated to clinical settings as actual human bones and in-vivo physiologic conditions are far more complicated [Ahmed et al., 2006]. The variation in geometry and anisotropic material properties of real bones were not taken into consideration. Also, actual in-vivo loading of human bones is a complex
phenomenon which involves a combination of several types of loads such as torsional, axial, bending, shear etc [Ahmed et al., 2006]. Therefore, 4-point bending load applied in this study does not accurately replicate complex loading of bones as in their in-vivo conditions.

Although the apparent density of synthetic bones was similar to osteoporotic bones, synthetic bones did not have bone mineral densities (BMD). As the bone mineral density plays an important role in determining bone quality and in turn affects the fixation device used, applicability of the current results to osteoporotic patients is still unclear.

Gardner’s study which emphasized on the behavior of screw-plate configurations under torsional load, concluded that the torsional stiffness of a hybrid configuration was similar to the all locking screw configuration in an induced osteoporotic condition for 1000 cycles. Even though the current study neither used an osteoporotic model nor an induced osteoporotic condition, both hybrid models (Technique A and Technique B) behaved similar to the all locking construct (Control group) in terms of aforementioned test parameters during dynamic mechanical tests as well as static failure tests. Thus a limitation of this study is that present results might not be applicable in treating fractures of osteoporotic or poor quality bones.

This study utilized a 4-point bending test protocol to determine difference between the behavior of constructs in various configurations. However, in other long bones such as femur and tibia the diaphyseal region experiences multidirectional loads such as axial and torsional forces in addition to bending. Hence, results of this study might not be directly extrapolated to screw-plate systems applied on such long bones.
Future studies could address the effects of axial and torsional loads to determine if hybrid constructs can be similarly applied to other long bones in an instance of diaphyseal comminuted fracture.

It is known that an eight hole straight plate is also commonly used for the treatment of mid shaft fractures. A longer plate has to be applied for a more extensive comminuted fracture. Other combinations of screw types, number of screws and empty screw holes may behave differently in longer fixation plates [Gardner et al., 2006]. These variables were not included in the current study.

Clinical studies showed that the type of fracture plating used would determine the method of bone healing. However, biological effects associated with fracture healing were not accounted in the current study even though it plays a significant role in the whole fracture fixation procedure.

During post testing analysis, specimens discarded due to technical errors reduced the sample size used for statistical analysis. Fewer number of specimens used as compared to that determined during power analysis might have resulted in non-significant difference between the configurations. Availability of higher number of specimens might have led to different results than those obtained in this study.

It should also be considered that the apparatus used for the current study was an old analog testing machine without complete control. The system had certain limitations when compared to contemporary testing machines with inbuilt software for better control, accuracy, repeatability, signal conditioning and data acquisition.
During data collection from the testing and motion capture systems, synchronization of load data from testing machine with the rotation data from motion analysis system were carried out manually. Even though care was taken to keep the margin of error small, there could still be some error involved due to the absence of automated synchronization.

5.6. Conclusion

This study found no difference between all-locking, double locking and single locking configurations of screw-plate constructs used for the fixation of humeral shaft fractures. Findings from the current study provides further support towards the use of up to four non-locking and two locking screws for the fixation of comminuted humeral shaft fractures.
REFERENCES


APPENDICES
APPENDIX A

CALCULATION OF FORCES

Figure A.1. The equivalent 4-point bending system where forces are applied on either side of the construct to simulate bending of the bone in-vivo. The dimensions of the 4-point bending jig where the distance between the top and bottom rollers are shown.

\[ M = -(F)(P/2) + (F)(L/2) = (F)(a) \]

\[ M = -(F)(98.425) + (F)(136.525) = (F)(136.525 - 98.425) = (F)(38.1) \text{ Nmm} \]

\[ M = 12 \text{ Nm} \]

\[ 2F = 630 \text{ N} \]

The force that has to be applied by the 4-point bending jig
APPENDIX B

TESTING MACHINE SPECIFICATIONS

Frequency:

Accuracy: +/- .25%

Stability: +/- .1% of setting for 24 hours

Main Output:

Maximum load: 1000 ohm

Amplitude: 20 V P-P 1000 ohm

Stability: +/-2mV for 24 hours

Sine Wave:

Distortion :< .2%

Frequency Response: +/- .1dB

Sample Points: 8192 at X1 to X.000001 range

2048 at X10 range
APPENDIX C

SAS PROGRAMS FOR ANOVA TEST RESULTS

C.1. SAS Program and Output for Test 1: LVDT Stiffness at 10000 cycles

data;
input category $ n @@;
do observation = 1 to n;
input strength @@;
output;
end;
datalines;
control  6  244.7786  363.4330  327.3038  323.3001  324.611  302.5056
single  5  394.4424  340.4186  364.7503  342.7231  325.2051
double  5  442.4113  349.623  331.877  335.765  332.7069
;
proc print;
proc glm;
class category;
model strength=category;
means category/snk;
run;

OUTPUT:

The GLM Procedure

Dependent Variable: strength

Source                   DF     Sum of     Mean Square   F Value   Pr > F
                        Squares
Model                     2     6573.25849     3286.62925       2.17    0.1532
Error                    13     19644.36710     1511.10516
Corrected Total         15     26217.62559

R-Square   Coeff Var   Root MSE   strength Mean
0.250719   11.42092   38.87294   340.3659

Source     DF     Type I SS     Mean Square   F Value   Pr > F
category   2     6573.258491     3286.629246       2.17    0.1532
The GLM Procedure

Student-Newman-Keuls Test for strength

NOTE: This test controls the Type I experimentwise error rate under the complete null hypothesis but not under partial null hypotheses.

Alpha                           0.05
Error Degrees of Freedom        13
Error Mean Square              1511.105
Harmonic Mean of Cell Sizes    5.294118

NOTE: Cell sizes are not equal.

Number of Means              2     3
Critical Range               51.618255  63.08722

Means with the same letter are not significantly different.

SNK Grouping          Mean      N    category
A        358.48      5    double
A        353.51      5    single
A        314.32      6    control

C.2. SAS Program and Output for Test 2: LMSG Displacement at 10000 cycles

data;
input category $ n @;
do observation =1 to n;
input strength @@;
output;
end;
datalines;
control 6 2.5454 1.9113 1.9525 1.8954 1.8466 2.1848
single 5 2.0734 1.9906 1.8723 1.8103 2.0235
double 5 1.9805 1.6345 1.9088 1.9750 2.1492
;
proc print;
proc glm;
class category;
model strength=category;
means category/snk;
run;
OUTPUT:

The GLM Procedure

Dependent Variable: strength

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<tr>
<th>Source</th>
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<th>Sum of Squares</th>
<th>Mean Square</th>
<th>F Value</th>
<th>Pr &gt; F</th>
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<tr>
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<td>0.05038843</td>
<td>0.02519421</td>
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<td>0.5631</td>
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<td>Error</td>
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<td>0.54553639</td>
<td>0.04196434</td>
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<td></td>
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<tr>
<td>Corrected Total</td>
<td>15</td>
<td>0.59592481</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

R-Square     Coeff Var      Root MSE    strength Mean
0.084555      10.32192      0.204852         1.984631

Source          DF       Type I SS     Mean Square | F Value | Pr > F |
category         2      0.05038843 | 0.02519421 | 0.60    | 0.5631 |

Source          DF     Type III SS     Mean Square | F Value | Pr > F |
category         2      0.05038843 | 0.02519421 | 0.60    | 0.5631 |

The GLM Procedure

Student-Newman-Keuls Test for strength

NOTE: This test controls the Type I experimentwise error rate under the complete null hypothesis but not under partial null hypotheses.

Alpha                           0.05
Error Degrees of Freedom          13
Error Mean Square           0.041964
Harmonic Mean of Cell Sizes 5.294118

NOTE: Cell sizes are not equal.

Number of Means              2              3
Critical Range       0.2720171       0.332456

Means with the same letter are not significantly different.

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<tr>
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<th>category</th>
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<td>control</td>
</tr>
<tr>
<td>A</td>
<td>1.9540</td>
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<td>single</td>
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<tr>
<td>A</td>
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<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

96
C.3. SAS Program and Output for Test 3: Yield moment of the static failure test

data;
input category $ n @;
do observation =1 to n;
input strength @@;
output;
end;
datalines;
single 6 27.7229 28.5403 28.0668 27.9780 27.8347 28.2046
double 6 29.3335 27.0930 27.5956 26.7495 29.6334 25.7671
;
proc print;
proc glm;
class category;
model strength=category;
means category/snk;
run;

OUTPUT:

The GLM Procedure

Dependent Variable: strength

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>Sum of Squares</th>
<th>Mean Square</th>
<th>F Value</th>
<th>Pr &gt; F</th>
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<tbody>
<tr>
<td>Model</td>
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<td>0.40764691</td>
<td>0.20382345</td>
<td>0.16</td>
<td>0.8544</td>
</tr>
<tr>
<td>Error</td>
<td>15</td>
<td>19.23017458</td>
<td>1.28201164</td>
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</tr>
<tr>
<td>Corrected Total</td>
<td>17</td>
<td>19.63782148</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

R-Square        | Coeff Var | Root MSE | strength Mean
<table>
<thead>
<tr>
<th></th>
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</tr>
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<tbody>
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<td>0.020758</td>
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Source          | DF | Type I SS | Mean Square | F Value | Pr > F |
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<td>0.8544</td>
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Source          | DF | Type III SS | Mean Square | F Value | Pr > F |
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<td>0.40764691</td>
<td>0.20382345</td>
<td>0.16</td>
<td>0.8544</td>
</tr>
</tbody>
</table>
Student-Newman-Keuls Test for strength

NOTE: This test controls the Type I experimentwise error rate under the complete null hypothesis but not under partial null hypotheses.

Alpha                        0.05
Error Degrees of Freedom       15
Error Mean Square        1.282012

Number of Means              2              3
Critical Range       1.3933507      1.6979933

Means with the same letter are not significantly different.

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<th>Mean</th>
<th>N</th>
<th>category</th>
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<tr>
<td>A</td>
<td>28.0579</td>
<td>6</td>
<td>single</td>
</tr>
<tr>
<td>A</td>
<td>27.8188</td>
<td>6</td>
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<tr>
<td>A</td>
<td>27.6954</td>
<td>6</td>
<td>double</td>
</tr>
</tbody>
</table>

C.4. SAS Program and Output for Test 4: Failure moment of the static failure test

data;
input category $ n @;
do observation =1 to n;
input strength @@;
output;
end;
datalines;
control 6 34.2279 35.8968 39.2055 29.6302 26.4968 31.9120
    39.2055 29.6302 26.4968 31.9120
single 6 38.0078 42.0618 35.6130 37.0291 35.6243 39.8506
    35.6130 37.0291 35.6243 39.8506
double 5 40.9294 41.0454 30.2432 38.8898 36.9588 38.8898
    30.2432 38.8898 36.9588 38.8898
;
proc print;
proc glm;
class category;
model strength=category;
means category/snk;
run;
OUTPUT:

The GLM Procedure

Dependent Variable: strength

<table>
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<tr>
<th>Source</th>
<th>DF</th>
<th>Sum of Squares</th>
<th>Mean Square</th>
<th>F Value</th>
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<td>95.4624943</td>
<td>47.7312471</td>
<td>3.11</td>
<td>0.0760</td>
</tr>
<tr>
<td>Error</td>
<td>14</td>
<td>214.5255967</td>
<td>15.3232569</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrected Total</td>
<td>16</td>
<td>309.9880909</td>
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</tr>
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R-Square     Coeff Var      Root MSE    strength Mean
0.307955      10.84484      3.914493         36.09544

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<th>Source</th>
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<th>Type I SS</th>
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<td>47.73124713</td>
<td>3.11</td>
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<td>47.73124713</td>
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<td>0.0760</td>
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</tbody>
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Student-Newman-Keuls Test for strength

NOTE: This test controls the Type I experimentwise error rate under the complete null hypothesis but not under partial null hypotheses.

Alpha                          0.05
Error Degrees of Freedom       14
Error Mean Square               15.32326
Harmonic Mean of Cell Sizes     5.625

NOTE: Cell sizes are not equal.

Number of Means                2   3
Critical Range                 5.0062590   6.1091328

Means with the same letter are not significantly different.

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<tr>
<td>A</td>
<td>37.613</td>
<td>5</td>
<td>double</td>
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<tr>
<td>A</td>
<td>32.895</td>
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<td>control</td>
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C.5. SAS Program and Output for Test 5: Stiffness of the static failure test

```sas
data;
input category $ n @;
do observation =1 to n;
input strength @@;
output;
end;
datalines;
control 6 1.8010 1.8022 1.7792 1.7659 1.7499 1.7170
single 6 1.8751 1.8835 1.8458 1.7574 1.7499 1.7881
double 6 1.7091 1.8760 1.8352 1.7443 1.7384 1.8931
;
proc print;
proc glm;
class category;
model strength=category;
means category/snk;
run;
```

OUTPUT:

The GLM Procedure

Dependent Variable: strength

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<th>Mean Square</th>
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<td>0.00345766</td>
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<td>Corrected Total</td>
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R-Square       Coeff Var     Root MSE     strength Mean
0.114152       3.332111      0.059813     1.795061

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<td>0.4029</td>
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<td>0.00691531</td>
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<td>0.97</td>
<td>0.4029</td>
</tr>
</tbody>
</table>

Student-Newman-Keuls Test for strength
NOTE: This test controls the Type I experimentwise error rate under the complete null hypothesis but
not under partial null hypotheses.

Alpha                        0.05
Error Degrees of Freedom       15
Error Mean Square        0.003578

Number of Means              2              3
Critical Range        0.073606      0.0896992

Means with the same letter are not significantly different.

SNK Grouping          Mean      N    category
A       1.81663      6    single
A       1.79935      6    double
A       1.76920
APPENDIX D

STATIC FAILURE ANALYSIS PLOTS FOR ALL 18 INDIVIDUAL SPECIMENS

The moment versus angular displacement of the control group specimens during the static failure analysis are shown below. The moment at which straight line from the $2^\circ$ permanent deformation intersected with the moment versus displacement curve was considered as the yield. Similarly the moment at which the straight line from the $10^\circ$ permanent deformation intersected with the moment versus angular displacement curve was considered as failure if prior failure did not happen.

Figure D.1. Moment versus angular displacement of a control group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.2. Moment versus angular displacement of a control group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.

Figure D.3. Moment versus angular displacement of a control group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.4. Moment versus angular displacement of a control group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.

Figure D.5. Moment versus angular displacement of a control group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.6. Moment versus angular displacement of a control group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
The moment versus angular displacement of the Technique A group specimens during the static failure analysis are shown below. The cross sign indicate the yield point and the triangular sign show the failure point. The moment at which straight line from the 2° permanent deformation intersected with the moment versus displacement curve was considered as the yield. Similarly the moment at which the straight line from the 10° permanent deformation intersected with the moment versus angular displacement curve was considered as failure if prior failure did not happen.

![Graph](image)

Figure D.7. Moment versus angular displacement of a Technique A group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.8. Moment versus angular displacement of a Technique A group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.

Figure D.9. Moment versus angular displacement of a Technique A group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.10. Moment versus angular displacement of a Technique A group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.

Figure D.11. Moment versus angular displacement of a Technique A group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.12. Moment versus angular displacement of a Technique A group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
The moment versus angular displacement of the Technique B group specimens during the static failure analysis are shown below. The cross sign indicate the yield point and the triangular sign show the failure point. The moment at which straight line from the 2° permanent deformation intersected with the moment versus displacement curve was considered as the yield. Similarly the moment at which the straight line from the 10° permanent deformation intersected with the moment versus angular displacement curve was considered as failure if prior failure did not happen.

Figure D.13. Moment versus angular displacement of a Technique B group specimen. The cross sign indicate the yield point and the triangular sign show the failure point. This specimen couldn’t reach failure as lesser force was applied to it. Therefore the failure moment as well as the mode of failure was not obtained from this specimen.
Figure D.14. Moment versus angular displacement of a Technique B group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.

Figure D.15. Moment versus angular displacement of a Technique B group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.16. Moment versus angular displacement of a Technique B group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.

Figure D.17. Moment versus angular displacement of a Technique B group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
Figure D.18. Moment versus angular displacement of a Technique B group specimen. The cross sign indicate the yield point and the triangular sign show the failure point.
APPENDIX E

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