Original Research Article

Role of length of locking screws & surgeon strength in precision of placing locking screws in In-vitro osteoporotic saw bone model

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ABSTRACT

Locking compression plate technology needs perfect seating of the locking screw head in the corresponding recess in the plate hole for a stable construct. The purpose of this study is to quantify screw-plate angle. In this study, a total of 750 locking screws of different lengths were placed by six residents. The measured angles were compared with Repeated Measures ANOVA method. Significant differences were seen for 40mm, 50mm, 70mm and 80mm screw length (p < 0.05) to assess the deviation of angle in pre-training, post-training and final experiment. The placement of locking screws precisely can help avoid an easily preventable surgical risk factor for fixation failure.

Background:
The evolution of Locking Compression Plate (LCP) technology has radically changed the practice of fracture fixation. This technology mandates meticulous detail in surgical technique in placing the locking screw. It demands perfect seating of the locking screw head in the corresponding recess in the plate hole. The purpose of this study is to quantify screw-plate angle i.e., off-axis screw trajectory and its change with an increase in the length of screw and strength of the surgeons.

Materials and Methods:
Six orthopaedic residents were selected. The surgeons were familiarized with the instrumentation. A total of 750 locking screws of different lengths were placed in a locking plate in osteoporotic saw bone models using a torque measuring screw driver. The deviation was assessed for 150 screws inserted in pre-training, post-training and the final test under the supervision of the senior author. Immediate feedback on the performance and objective proof of precision was given within an hour by measuring the angle of deviation on X-ray using InstaPACS.

Collected data was entered in MS Excel sheet. Descriptive statistics were presented in mean ±SD for continuous variables and count with percentage for Categorical variables. Repeated Measures ANOVA was used to assess the difference in deviation of angle pre-training, post-training and final experiment with the length of the screw. IBM SPSS 25.0 software was used for data analysis.

Results:
Surgeon grip strength and torque applied had no significant association with the angle of deviation. The surgeons exceeded 10 Newton meter torque in pretraining. This applied torque decreased after training in the post-training and final experiments. The length of the screw and angle of deviation were found to positively correlate in pre-training and final experiment. In this study, 40 out of 150 (26%) studied screw insertions were off-axis. Most of the deviations (29) were only one degree (19.33%). The remaining 11 were more than 2 degrees (6.67%). The maximum off-axis was 4.3 degrees. Significant differences were seen for 40mm, 50mm, 70mm and 80mm screw length (p < 0.05) in pre-training, post-training and the final experiment.

Conclusions:
This study signifies that practice under supervision with immediate and objective feedback is a valuable learning tool. Real time feedback definitely improves the surgical confidence that will result in better patient outcome in placing locking screws. The placement of locking screws precisely can help avoid an easily preventable surgical risk factor for fixation failure.

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1. Introduction

The basic principles of internal fixation using a conventional plate and screw system are direct anatomical reduction and stable internal fixation of the fracture. This procedure requires contouring of the plate to perfectly match the anatomy of the broken bone. The screws are then tightened to compress the plate onto the bone. The actual stability of the fixation construct relies on friction between the plate and the bone. This technique of fixation risks increases in vascular damage to the broken bone by blocking the periosteal blood supply under the plate.

The Locked Compression Plating (LCP) concept evolved over time to address this concern. The locking plate ideally must not touch the bone. It functions mechanically like an external fixator placed within the body. The plate is surgically placed under the muscle along the length of the bone and often alluded to as an ‘internal fixator.’ This system too consists of a plate and screws but the screws are locked in the plate. This technique almost eliminates the need for plate contact with bone reducing the risk of further biological damage to the broken bone.

The LCP can be used depending on the fracture situation, in the conventional technique (compression principle), bridging technique (internal fixator principle) or a combination of both.

The LCP was developed primarily for the treatment of osteoporotic bone fractures. Mobilization of the injured limb after fracture fixation reduces the risk of fracture disease –but imposes stresses on the fixation construct. These stresses (loading forces) directly transfer from bone to plate in locking plate constructs (Figure 1). The fixation construct functions like a fixed angle beam reducing the dependency on the quality of bone for stability. This necessitates perfect seating of the locking screw in the locking hole of the plate. Any deviation in trajectory may weaken the construct stiffness. The threaded screw hole in the locking plate provides for co-axial insertion and full engagement of the screw head. This prevents toggling (micro-motion) of the screw. The demand for accuracy is unforgiving and despite the necessary tools provided, precise insertion of the screw is challenging and may not always be possible. This mismatch has been implicated in early construct failure by reducing the screw-plate interface strength.

2. Materials and Methods

This prospective experimental study was carried out in the biomechanical laboratory at Indian Spinal Injuries Centre, Vasant Kunj, New Delhi from March 2019 to December 2020. The compilation and analysis of the data were done from November 2020 to December 2020. The study was approved by the research review committee of the institute. In this study participant surgeons were fully informed in detail about the study and all records maintained.

The sample specimens were osteoporotic Bone Models of BMD - 2.5 with block of size 18 x 9 cm (Figure 2). A total of 24 blocks were used for the purpose of the study. One block served as a template for three to six plate fixations.

A standard Dynamometer (Constant model: 14192-709E, China) was used to measure grip strength and the unit was set to pounds (lbs). A torque measuring screw driver (Tonichi Mfg. Co. Ltd., Tokyo, Japan) was used to measure the torque in Newton-meter (Nm) with a maximum of 10 Nm and least count of 0.2 Nm.

ORTHOCARE (Indian company) LCP plates and screws were used for the purpose of training of the surgeons. AO Synthes LCP plates and locking screws were used for the purpose of final testing. Variable angle technology instruments were not used.

2.1. Methodology

4.5 mm nine-hole narrow LCP was used for training and final testing.

2.2. The sequence of screw insertion was

1. Fifth hole for screw length 40mm
2. Third hole for screw length 50mm
3. Seventh hole for screw length 60mm
4. Ninth hole for screw length 70mm
5. First hole for screw length 80mm
The first trial was performed by a supervisor in the biomechanical laboratory using standard technique of the locking screw insertion.

2.3. Steps followed for screw placement

1. Grip strength of the surgeon was measured three times giving a gap of 30 seconds between two trials.
2. 9-hole narrow LCP was fixed to the bone block with paper clips
3. The Bone block was kept parallel to the ground for the experiment
4. The locking sleeve was tightened to the plate hole number 5
5. Drilling was done using a drill bit of 4.3 mm diameter
6. Locking sleeve removed
7. The length of drilled hole was measured with the help of depth gauge
8. Locking screw inserted into the drilled hole and tightened with torque measuring screw driver
9. Final torque was noted
10. Paper clips were removed
11. Block was taken for x-ray

Steps from 4 to 9 were used for further screw placement in the decided order.

Initially X-rays were taken in three planes (Antero-Posterior, Axial and Lateral). In Antero-Posterior plane, the angle could not be measured because of the superimposition of the plate image over screws (Figure 3). In the axial plane too, axial deviation of the individual screw was not possible because of overlapping screw images (Figure 4). In lateral plane, the angle of screw to the plate for the individual screw was possible to measure. Hence it was decided to take only lateral plane X-rays of the block to measure the angle of the locking screw to the plate.

Fig. 3: X-ray image of the block taken in Antero-posterior plane

2.4. Method of angle measurement

Considering the outer border of plate as flat, a line drawn over the outer surface of the plate connecting proximal and distal outer surface of the plate in a magnified view of X-ray in instaPACS. Angle of screw to the plate was measured by connecting lines drawn over outer or inner borders of the screw and outer border of the plate (Fig. 5). These measurements were done in magnified view to avoid error of angle measurement.

Fig. 4: X-ray image of the block taken in Axial plane

Fig. 5: Image showing angle measurement in magnified view

The assessment of the screw placement was done by the senior author who judged and taught the placement of screws as per standard methods. This assessment was made under the following criteria:

1. Placement of Sleeve
2. Use of adequate drill bit size
3. Drilling methods
4. Instrument handling
5. Use of depth gauge to measure the drilled depth
6. Screws placement using torque limiting screw driver

Each criterion was given a score of two.

Scoring done
Proper – 2
Improper - 1

The score of the experts was also correlated using Spearman rank correlation (r value).

The training was provided to the selected residents by making them insert 100 locking screws in bone models using standard methods.

After completion of training, each trained resident was made to place one locking screw of different length in cancellous saw bone models (40, 50, 60, 70, 80 mm) using torque measuring screw driver in the same sequence as was done in pre-training period and X-rays were taken to measure angles.

Final experiment was done using Synthes locking plate construct. At this stage each resident was made to place screws of varying length (each three in number) as per standard methods with the same sequence in the locking plate. Radiographs were taken in lateral view and angle measured.

All the relevant data, scoring and comments by the expert was noted in a separate notebook.

2.5. Data management

Collected data were recorded and was entered in MS Excel in the following format:

Data table for screws placement and their measured angles (Table 1):

Variables were correlated in the following manner:

1. Grip strength versus torque applied for tightening of the screw.
2. Strength versus angular deviation of different surgeons with constant screw length.
3. Screw length versus angular deviation per surgeon.

2.5.1. Statistical analysis

Descriptive statistics were presented in mean± standard deviation (SD) for continuous variables and count with percentage for categorical variables. Test-retest reliability (test consistency) were checked using intra-class correlation coefficient (ICC) with mixed-way model – Absolute agreement type and interpretations were done.

Repeated Measures ANOVA was used to assess the difference in deviation of angle pre-training, post-training and final experiment with length of the screw. Multiple-comparison test was performed with the least significant difference (LSD) correction criteria. The P-value less than 0.05 was considered as statistically significant. IBM SPSS 25.0 software was used for data analysis.

3. Results

Variables used in the experiment were grip strength (GS), length of the locking screw, torque used for tightening of the screw and deviation in the insertion of the locking screw with the plate.

Five screws were inserted by each surgeon (i.e., 30) in pre- and post-training and 15 screws were inserted by each surgeon (i.e., 90) in the final experiment.

3.1. Correlation: Grip strength and torque of different surgeons

In the pre-training experiment, there no significant correlation found of torque applied in screw tightening with grip strength however in the post-training (r = -0.556; p=0.001) and final experiment (r = -0.422; p=0.020), correlations of torque applied to grip strength were significantly negatively correlated.

3.2. Correlation: Grip strength versus angular deviation of different surgeons with constant screw length

There was no significant association observed between GS and angular deviation during pre-training and final experiment (r<0.2) while the correlation for post-training experiment was 0.288 however not statistically significant.

3.3. Correlation: Screw length versus angular deviation

The deviation was assessed for 150 screws inserted in pre-training, post-training and the final test. In the study, 40 out of 150 (26.67%) studied screw insertions were off-axis. Most of the deviations (29) were only one degree (19.33%). The remaining eleven were more than 2 degrees (7.33%). The maximum off-axis was 4.32 degrees.

In the pre-training experiment, there was a significant positive correlation of the length of the screw inserted with the deviation (r= 0.412; p=0.024) suggesting that with the increase in the length of screw, there is an increased deviation of angle.

In the post-training experiment, there was a non-significant negative correlation (r= -0.257; p=0.170) found between deviation and length of the screw which indicates with there is a decrease in deviation with the increase in the length of screw.

In the final experiment, there was a non-significant positive correlation (r = 0.239; p=0.204) observed between deviation and length of the screw.

3.4. Repeated measures ANOVA test (Table 2)

For the 40mm length screw, mean deviation of angle differed significantly (p=0.024) across three time points i.e., pre-training (Mean±SD: 0.77± 0.39), post-training (1.19 ± 0.81) and final experiment (0.19±0.08).

A post-hoc pairwise comparison was done and the mean difference was found to be significant for pre-training & final experiment (p=0.013) and for post-training & final
Table 1: Data table for screws placement and their measured angles:

<table>
<thead>
<tr>
<th>Screw Length (mm)</th>
<th>Surgeon</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>O1</td>
</tr>
<tr>
<td>PRE</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>90.53</td>
</tr>
<tr>
<td>50</td>
<td>91.64</td>
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<td>60</td>
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<tr>
<td>70</td>
<td>91.89</td>
</tr>
<tr>
<td>80</td>
<td>92.52</td>
</tr>
<tr>
<td>POST</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>92.08</td>
</tr>
<tr>
<td>50</td>
<td>89.47</td>
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<tr>
<td>60</td>
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<tr>
<td>70</td>
<td>91.63</td>
</tr>
<tr>
<td>80</td>
<td>89.01</td>
</tr>
<tr>
<td>Final (average)</td>
<td></td>
</tr>
<tr>
<td>40</td>
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<td>50</td>
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<tr>
<td>70</td>
<td>89.34</td>
</tr>
<tr>
<td>80</td>
<td>89.70</td>
</tr>
</tbody>
</table>

Fig. 6: Angle of deviation with length of screw in pre-training, post-training and final experiment

Table 2: Correlations of all the variables used in the experiment

<table>
<thead>
<tr>
<th>Length</th>
<th>Dev_post</th>
<th>GS</th>
<th>Dev_FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.412*</td>
<td>0.037</td>
<td>0.085</td>
<td>0.233</td>
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<tr>
<td>0.024</td>
<td>0.846</td>
<td>0.654</td>
<td>0.215</td>
</tr>
</tbody>
</table>

r: Pearson Correlation Coefficient; Sig.: p-value
* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

For the 50mm length screw, mean deviation of angle differed significantly (p=0.028) across three time points i.e., pre-training (Mean±SD: 1.43±0.80), post-training (0.53±0.25) and final experiment (0.54±0.34). A post-hoc pairwise comparison revealed that the mean difference was significant for pre-training & post-training experiment (p=0.017). For the 60mm length screw, mean deviation of angle did not differed significantly (p=0.175) across three time points i.e. pre-training (Mean±SD: 1.67±1.15), post-training (0.91±0.69) and final experiment (0.60±0.44).

3.5. Post-hoc pairwise comparison showed insignificant mean difference for all combinations

For the 70mm length screw, mean deviation of angle differed significantly (p=0.028) across three time points i.e., pre-training (Mean±SD: 2.23±1.91), post-training (0.96±1.23) and final experiment (0.45±0.20). When the pairwise comparison was done of pre, post and experiment data for the screw length of 80 mm, the mean difference was found to be significant for pre-training and final experiment with p-value of 0.007.

4. Discussion

The evolution of LCP technology has drastically changed the practice of fracture fixation. The philosophy, however, remains the same, i.e., appropriate stability with early return to function and bone union. This technology demands a special surgical technique in placing the locking screw. Surgical outcomes have changed for the good but newer failure mechanisms have emerged. These failures have been variously attributed to surgeon error, instrumentation error and technical errors. The known errors reported due to the technique are failure of reduction, an inappropriate working
length of plates, high screw density with rigid fixation, off-axis insertion of the locking screw, over-tightening of the screw head and screw mismatch in hybrid fixation constructs.\(^1,3\)

Literature suggests that the implant failure risk increases with off-axis insertion of the screw.\(^4,6,7\) Kaab et al performed a biomechanical study to check off-axis insertion and failure. They inserted locking screws at 0, 5 and 10 degrees off-axis which subsequently were loaded until failure. They found that with the increase in off-axis of locking screw insertion (>5 degrees), there is a significant decrease in construct stability.\(^6\) In 2014, Cartner et al performed a study using foam blocks by inserting locking screws at various angles in a 3.5 mm LCP. They proved in their biomechanical study that locking screws inserted more than 3 degrees eccentric failed primarily by locking mechanism disengagement. Screws inserted at less than 3 degrees failed primarily via screw deformation at the narrowest dimension below the head.\(^9\) In 2015, Schneider et al. conducted a biomechanical study over foam block models replicating unstable intertrochanteric fracture by the placement of screws at 2 degrees off-axis. They found that deviation as less as 2 degrees resulted in the loosening of the screws due to disengagement of the screw head from the plate.\(^10\)

In the present study, 40 out of 150 (26.67%) studied screw insertions were off-axis. The surgical error had halved in the final exercise. When the longer screws are considered, the error rate dropped to a third. The persistence of an off-axis insertion suggests that human error is inevitable.

A positive correlation was seen between the length of the screw and its deviation in the pre-training experiment. This was statistically significant. This suggests that the hypothesis of the risk of wobbling of the screw increasing with longer screw insertion is correct. Osteoporotic bone is softer bone and provides less resistance while drilling and inserting the screws. It was observed that surgeons tended to push instead of turn the screwdriver during placement of longer screws. This element of push could be a reason for trajectory change and off-axis deviation of the locking screw. Insertion by hand compared to use of power instrument consumes more time and is fatiguing. Almost 120 semi-supinations of the forearm were observed during the insertion of a 70 mm screw.

In the post-training experiment, a negative correlation was seen between the length of the screw and its deviation. Precision improved with the length of the screw inserted. This indicates that surgeons were now more aware and more cautious during longer screw insertion. Training was provided for over 100 screw insertion in bone blocks under guidance and also during live surgeries. With immediate and positive feedback of good performance surgeon confidence improved. However, the deviation persisted in the insertion of shorter length screws which may reflect over-confidence in shorter screw insertion. This suggests that despite the awareness of the need for precision in screw insertion, humans will make errors.

In the final experiment using Synthes implants (Titanium plate) and instruments, a positive correlation of length and deviation of the screws was observed. The performance of the surgeons had improved. The error in the deviation persisted but was much less than the previous testing and was not statistically significant. This could be due to the enhanced surgical awareness and confidence supported by a more precise instrumentation system. The tactile skills gained during the training period too may have contributed to more precise screw placements. Despite the awareness and the availability of precise tools, the placement of locking screws remains challenging. The persistence of error in the controlled setting of the laboratory suggests that the margins for mistakes could be higher in live patients.

Variation in the insertional torque was hypothesized to vary with surgeon grip strength. We did not find any correlation between grip strength and the variation in the angle of the screw inserted. However, there was a negative correlation between grip strength and insertional torque. This suggests that before training the surgeons were not sure or aware of the amount of torque needed to lock the screw heads. Every surgeon tightened the locking screw to the best of their ability touching as high as 10Nm (which was the maximum reading of the torque measuring screwdriver). After immediate and real-time feedback on the importance of torque and the desired level of 4 Nm for the 5.0 mm locking screws, surgeons became conscious of this requirement. Those with higher grip strength, aware of their ability tightened screws to significantly lower torque than their inherent ability. On the other hand, surgeons with weaker grip strength probably underestimated their ability and ended up tightening screws to just under their maximum potential that was much higher than the desired 4 Nm.

Overtightening of the screws leads to cross-threading of the screw head. It was observed that there was a tendency to compensate off-axis insertion of the screw by increasing the insertion torque. This happens subconsciously as the thread mismatch is visible to the naked eye and the mind tries to compensate by overtightening. However, it has been reported that this overtightening does not counterbalance the cross-threading of the screw onto the plate hole leaving the fracture fixation construct weaker.\(^8,9,11\)

Out of 150 screw insertion torques measured, 97% were 4 Nm and above. Odds favour overtightening of screw heads. The feel of good resistance in conventional plating technique provides the reassurance of a secure hold. The subconscious mind retains this inherent bias while placing locking screws and this has been frequently observed. This is an unavoidable error of technique. Familiarity with the implant and its instrumentation can help mitigate this avoidable error that can compromise fracture fixation.
Repetition of the surgical technique develops psychomotor skill and enhances tactile biofeedback to improve the perfection of surgical technique. Unfortunately, in most training programs in our country, the trainee learns on the live patient or in conferences via hands-on workshops. Surgical confidence in most post-graduates is low and the chances of error in live surgery multiply with the added responsibility of multitasking during surgery.

In the pre-training experiment, the surgeons were not aware of the orientation of locking and non-locking holes in the plate. This confusion arises from the eight shaped screw hole, a feature unique to the Synthes implants. Other standard implants have distinct and separate plate holes for locking and non-locking screws. Synthes implants are the gold standard and most frequently mimicked system. The pre-test plate was made of titanium and the drill sleeve and other instrumentations are made up of stainless steel. The plate is of softer material compared to the drill sleeve. The harder material may cut its thread in the softer material plate. One surgeon inadvertently locked the drill sleeve into the non-locking hole of the plate. This suggests the potential for error in cross-threading the guiding drill sleeve and compromising subsequent screw insertion. On many occasions, surgeons had not locked the drill sleeve securely into the locking hole which loosened and backed out while drilling the hole or during the removal of the drill bit.

When all the data was compared with repeated ANOVA measure for the length of the screw and deviation of insertion, significance was found for 40mm, 50mm, 70mm and 80mm length screw with a p-value of less than 0.005. This suggests that with training the surgeon’s performance improved in the post-training and final experiments. It is a known fact that practice improves performance. Practice under supervision with immediate feedback on the performance is far more superior in enhancing surgical skill.

This study demonstrates that along with the awareness, practice improved the precision of screw placement. Such training programs with the establishment of a biomechanical laboratory for the young surgeons will improve their confidence, skill and precision.

5. Conclusion

This study suggests that practice under supervision with repetition of surgical technique and immediate objective feedback are valuable learning methods. Real-time feedback definitely improves the surgical confidence that will result in better patient outcomes. The placement of locking screws precisely can help avoid an easily preventable surgical risk factor of failure.

6. Source of Funding

None.

7. Conflict of Interest

None.

8. Acknowledgement

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