Novel Micromotion-Balancing Drilling Technology to Increase Proximal Cortical Strain

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Research article

Keywords: Internal fracture fixation, femoral fractures, femur

DOI: https://doi.org/10.21203/rs.3.rs-84456/v1

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Abstract

Background: We aimed to design a micromotion-balancing drilling system on the basis of the existing locking plate to maintain the balance of the micromotion of the cortex on both sides of a fracture region. We tested the system by subjecting it to a few biomechanical tests.

Methods: According to the shape of screw holes on the cortex, the fixed fracture models were divided into a control group (standard screw hole group X126, 6 cases) and an experimental group (elliptical screw hole group N, 36 cases). The experimental group was further divided into 6 subgroups with 6 cases in each (N126, N136, N1256, N1356, N12356, N123456) on the basis of the number and distribution of the screws on the proximal fracture segment. The control, N126, and N136 groups were subjected to 500-N axial load, and other groups were subjected to 1000-N axial load. The displacements of the kinetic head, distal cortex, and proximal cortex were measured. The integral structural stiffness of the model and the proximal cortical strain were calculated. The data of each group were analyzed by paired t-tests.

Results: When the distal cortical strains were 2%, 5%, and 10%, the proximal cortical strains in group N126 were 0.96%, 2.35% and 4.62%, respectively, which were significantly higher than those in the control group (X126) (p<0.05). When the distal cortical strains were 2%, 5% and 10%, the proximal cortical strain in group N126 was significantly higher than that in group N136 (p<0.05). However, there was no significant difference between the proximal cortical strains in the two groups with 4 screws (p>0.05). The proximal cortical strain in the 3-screw groups was significantly higher than that in the 4-screw groups (p<0.05), and there was no significant difference in the proximal cortical strain in the 4-, 5-, and 6-screw groups (p>0.05).

Conclusions: The new drill and the matching sleeves enabled a conventional locking compression plate to be transformed into an internal fixation system and improved the balanced motion of the distal and proximal cortices. Thus, the strain on a fracture site can be controlled by adjusting the drill diameter and sleeve eccentricity.

Background

Distal femoral fractures account for 3–6% of adult femoral fractures and 0.4% of all fractures, and have an extremely high disability and mortality rate [1, 2]. Presently, open reduction and internal fixation surgery are recognized treatment methods for distal femoral fractures [3]. Internal fixation provides the best mechanical stability and accelerates fracture healing, allowing for the early movement of the injured limb [4]. The strain at the fracture site is the key to its healing; however, excessive axial stress and shear force are not conducive to fracture healing. The magnitude of the strain is related to the fracture gap and the relative displacement between the fracture pieces, which largely depends on the stiffness of the fixed structure. Although the ideal stiffness value cannot be determined, overall structural stiffness can be modified by choosing different implants, screw types, and screw or plate positions [5, 6]. When the
stability is too high (in other words, the strain is too low), complications such as nonunion can easily occur [7].

A locking plate is the most commonly used implant in the management of distal femoral fractures as it increases overall stiffness by stabilizing the screw angle [8]. Although the clinical efficacy of a locking plate has shown promise, its related complications, such as delayed healing, implant failure, and nonunion, are common [4].

In response to the high stiffness and small, or uneven, callus formation of a locking plate fixation, Bottlang and Feist proposed the use of Far Cortical Locking (FCL) technology [9]. FCL allows limited axial movement of the cortex (proximal cortex) beneath the plate to promote symmetrical formation of the callus at the distal and proximal cortices. At present, only one company provides a system using FCL technology. The design of the plate and screws varies from the conventional design and its high cost limits its promotion. Analysis of its design and mechanical properties revealed that although the axial activity of the cortex under the plate is increased, it is still limited and insufficient compared to the distal cortex [10]. In addition, the proximal cortical screw hole is round. This can cause additional rotational shear and lateral movement that can impair the formation of the callus between the fracture ends.

The main purpose of our study was to find a solution that would increase the axial movement of the bone cortex on the side of the plate and compensate for the flaws of the FCL design, promote uniform displacement between fracture blocks, and induce symmetrical callus formation without increasing the burden on patients. We designed a micromotion-balancing internal fixation system using the current conventional locking compression plate and screw system. This only required changes to the designs of the drill and sleeve. The diameter of each section of the stepping drill depends on the diameter of the screw to be used. The eccentricity of the sleeve depends on the length of the screws and the gap between the fracture ends. The diameter of the distal cortex hole is the same as the diameter of the locking screw rod in order to interlock the locking screws and the distal cortex. The screw holes of the proximal cortex are oval. Their long diameter increases as the screw length and fracture gap increases. This ensures that the micromotion of the cortex on both sides of the fracture site are always close to balance and promotes the uniform growth of the callus. The other purpose of this study was to perform relevant mechanical tests on this technique to determine whether it could allow the uniform displacement of the distal and proximal cortices under normal physiological load and control the strain at the fracture ends to be between 2% and 10%.

**Methods**

**Experimental materials and equipment**

Stepping drill and matching sleeve: In this study, the fracture gap was set to 2.0 cm (comminuted fracture). In order to achieve secondary healing, the distal and proximal cortical strain needed to be controlled between 2% and 10%. For the convenience of the calculations, we denoted a strain of 5%
(1 mm) as the target value. The length of the proximal cortical oval screw hole was determined to be 6 mm (1 mm plus a screw thread diameter of 5 mm), and the direction was parallel to the long axis of the femur (Fig. 1). The diameter and length of each section of the drill are shown in Fig. 2: d1 is the standard drill diameter, 3.2 mm; d2 is the screw thread diameter, 5.0 mm; and L1 is 2 mm, L2 is 15 mm, and L3 is 100 mm. Figure 3a is a picture of the drill and Fig. 3b shows the stepping design of the drill.

- Sleeves: The two sleeves (Fig. 4) are a set of standard sleeves, the center of which is the same as the center of the hole on the locking plate. The proximal eccentric sleeve has an eccentricity of 1 mm (Fig. 4 shows the 1 mm difference between H1 and H2). Figure 5 shows the side view of the sleeve. The drilling effects of the drill and sleeves are shown in Fig. 1.

- Forty-two left artificial femurs (SAWBONE): Forty-two 6-hole left lateral femoral anatomical locking plates (titanium alloy, combined hole), 66 titanium alloy screws with a diameter of 5.0 mm and length of 40 mm, and 354 titanium alloy locking screws with a diameter of 5.0 mm and length of 55 mm.

- Mechanical test equipment: Instron 5569 mechanical tester (Norwood, MA, USA).

- Data collection: Bluehill 2 (Instron, USA).

- Image acquisition and analysis: VIC-3D (XR-9M, Correlated Solutions Company, Westford, MA, USA).

**Fracture fixation model and group**

- Fracture model: In 42 left artificial femurs, a horizontal osteotomy at a distance of 4.5 cm from the distal articular surface and a fracture model with a gap of 2 cm were established to simulate a comminuted fracture (AO/OTA 33-A3).

- Grouping: The 42 fracture models were divided into a control group and an experimental group. For six cases in the control group (i.e. the standard screw hole group, group X, X126) we used standard sleeves and drill. A 6-hole distal femoral anatomical locking plate was used to fix the fracture. The femoral condyle was drilled with a standard sleeve, and six locking screws with a diameter of 5.0 mm and length of 55 mm were screwed into it. Drill holes were made at positions 1, 2, and 6 at the proximal end of the fracture (1 was closest to the fracture line and 6 was farthest from the fracture line). For position 1, we used a titanium alloy screw with a diameter of 5.0 mm and a length of 40 mm. For positions 5 and 6, we used titanium alloy screws with a diameter of 5.0 mm and a length of 55 mm. The experimental group (i.e. the elliptical screw hole group, group N) was also fixed with the same steel plate. The screws and drilling methods at the part distal to the fracture were the same as that in the control group. For the part proximal to the fracture, the newly designed drill and sleeve were used to form an eccentric screw hole (i.e. eccentric to the proximal end). The locking screws were sequentially screwed in, in accordance with the grouping criterion. According to the number and distribution of screws in the part proximal to the fracture, the experimental group was divided into six subgroups (i.e. N126, N136, N1256, N1356, N12356, N123456) with six cases in each group. The arrangement and grouping of the screws are shown in Table 1 and Fig. 6.
Table 1

| Position | X126 | N126 | N136 | N1256 | N1356 | N12356 | N123456 |
|----------|------|------|------|-------|-------|--------|---------|
| 1        | X    | N    | N    | N     | N     | N      | N       |
| 2        | X    | N    | N    | N     | N     | N      | N       |
| 3        | N    | N    | N    | N     | N     | N      | N       |
| 4        |      |      |      |       |       |        | N       |
| 5        |      | N    | N    | N     | N     | N      | N       |
| 6        | X    | N    | N    | N     | N     | N      | N       |

X indicates standard screw hole, N indicates eccentric screw hole.

Axial compression test of the distal cortex

We put the fracture fixation model in the groove and poured plaster to fix it (Fig. 7). Before loading, we sprayed around the fractured end. Before the test, the overall preload was 10 N. The descending speed of the pressure head of the Instron mechanical tester was 2 mm/min. Axial loads of 500 N were applied to the control, N126, and N136 groups; and 1000 N was applied to the other groups. We used VIC-3D to acquire images (Fig. 8) and calculated the displacement of the proximal cortex and the contralateral cortex (distal cortex) of the proximal end of the fracture. A relation curve between the force value and displacement data collected by the pressure head was created, and the overall stiffness was calculated. The corresponding value of the displacement of the proximal cortex when the distal cortical strains were 2% (0.4 mm), 5% (1.0 mm), and 10% (2.0 mm) was noted, and its ratio to the fracture gap was calculated. This ratio was established as the value of the proximal cortical strain.

Statistical analysis

Paired t-tests, using SPSS 18.0 software, were performed on the load values and proximal cortical displacement values between the groups when the distal cortical strains were 2%, 5%, and 10%. For \( p < 0.05 \), the difference was considered statistically significant.

Results

1. When the distal cortical strains were 2%, 5%, and 10%, the corresponding proximal cortical strains in the group N126 were 0.96%, 2.35%, and 4.62%, respectively; all of which were greater than those in the control group \( p < 0.05 \) (Fig. 9a). The load of group N126 was not different from that of the control group \( p > 0.05 \); however, when the distal cortical strain reached 10%, the load of the experimental group was 759.77 ± 201.64 N, which was 1.46 times greater than that of the control group (Fig. 9b).
2. In the experimental group, when the distal cortical strains were 2%, 5%, and 10%, the proximal cortical strains of the 3-screw groups (N126) were 0.91%, 2.35%, and 4.62%, respectively, which were greater than those of the other subgroups (p < 0.05) (Fig. 10).

3. In the 3-screw groups, the closer the middle screw was to the fracture line, the greater the structural stiffness (p < 0.05, Fig. 11a) with no difference in the proximal cortical strain (p > 0.05, Fig. 11b). The structural rigidity and proximal cortical strain of the 4-screw groups were not affected by the screw distribution (p > 0.05, Figs. 12a and 12b).

4. In the experimental group, when the distal cortical strains were 2% and 5%, there was no difference in the load of each group (p > 0.05); however, when the distal cortical strain was 10%, the loads of the 3- and 4-screw groups were greater than that of the 5- and 6-screw groups (p < 0.05, Fig. 13).

**Discussion**

**Strain and fracture healing**

The strain at the fracture site is the relative variation of the fracture gap in the load direction divided by the initial fracture gap size. Regarding the importance of strain in fracture healing, Perren believed that the strain at the fracture end must be controlled to be between 2% and 10% during secondary healing [11, 12]. Lamellar bone can only withstand a maximum of 2% strain and cartilage can tolerate up to 10% strain. When the strain exceeds 10%, only granulation tissue is generated, and fracture healing does not occur. Simple fractures require anatomical reduction. A strong fixation can reduce the strain at the fracture end, and the fracture can heal by primary healing [4]. Comminuted fractures require a more elastic structure to increase the micromotion between the fracture blocks, keep the fracture ends relatively stable, promote the formation of callus, and achieve secondary healing [13–15]. Comminuted fractures can tolerate more interfragmentary motion than simple fractures because the entire motion in comminuted fractures is shared by multiple smaller fracture spaces [16]. However, excessive interfragmentary motion may lead to hypertrophic nonunion of a fracture, and too little interfragmentary motion may cause bone atrophy [17].

In this study, the fracture model was set as a segmental comminuted fracture. Theoretically, in order to achieve secondary healing, the distal and proximal cortical strain should be controlled to be between 2% and 10% after fixation. However, our experimental results showed that after conventional locking plate fixation, there was an extreme imbalance in distal and proximal cortical strain (control group). Even if the far cortical strain reached 10%, the proximal cortical strain only increased to 3.55%. Our findings align with the clinical research results of Lujan et al., which stated that after locking plate fixation, callus formation is asymmetric and more callus is formed at the distal cortex (opposite to the plate) [10]. Therefore, premature weight-bearing by a heavy-weighted patient (500 N) may lead to inadequate distal cortical callus formation and, eventually, the failure of internal fixation.

**Micromotion-balancing drilling technology**
Inspired by the design concept of FCL technology, we designed a micromotion-balancing drilling technology to further increase the axial displacement of the proximal cortex under the steel plate. Our technology compensates for the aspects lacking in the FCL design, promotes axial displacement, and induces symmetrical formation of callus without increasing the burden of patients. This technology still uses the current standard locking plate system, but with a newly designed drill and sleeve. The drill is designed in a stepping shape. The diameter and length of each segment can be determined according to the screw and femur diameters, and the eccentricity of the sleeve can be determined according to the fracture gap. In this study, screws with a 5.0 mm diameter were used; hence, the diameter of the L2 segment (d1) of the drill was 3.2 mm, and the diameter of the L3 segment (d2) was the same as the screw thread diameter (5.0 mm). In this way, the screws only engaged with the distal cortex and could slide in the proximal cortical hole. The fracture model of this study simulated a segmental comminuted fracture. The fracture gap was set to 2 cm, and the expected strain value was 5%; therefore, we set the eccentricity of the sleeve to 1 mm.

Owing to the loss of cortical support, segmental comminuted fractures require a relatively stable mechanical environment provided by internal fixation in order for the interference caused by bone cortical contact to be ruled out. Our results showed that the strain at the proximal cortex in the experimental group was significantly higher than that in the control group, and that the overall structural stiffness improved at the same time. Thus, our results were similar to the test results of FCL axial stiffness under larger loads (i.e. more than 500 N) reported by Bottlang et al. They stated that extra support provided to the proximal cortex could increase structural rigidity by 6 times [18]. When the distal cortical strains were 2%, 5%, and 10%, the proximal cortical strains of the experimental group were 0.96%, 2.35%, and 4.62%, respectively. There was still a certain gap with the corresponding distal cortical strain that could not achieve complete balance; however, there was a significant improvement compared to the control group. When the far cortical strain reached 10%, the load of the experimental group reached 759.77 ± 201.64 N. Although there was no statistically significant difference compared to the control group, it was seen that the load-bearing capacity has a tendency to increase (i.e. 1.46 times the original load), thus helping patients to perform early weight-bearing exercises.

**Different number and distribution of screws**

Our results showed that the strain of the cortex under the plate of the 3-screw experimental groups was significantly greater than that of other experimental groups, indicating that the micromotion balance in this group was better than that in the other groups. This suggests that for this type of fracture, if only the axial load is considered, fixation with 3 screws at the proximal end of the fracture is sufficient. Three screws not only ensured good micromotion balance, but also reduced the operation time and internal plant costs. In clinical practice, such fractures are often fixed with 3 screws on each side of the fracture gap to achieve good stability [19–22].

When comparing the distance of the 3 screws with different arrangements, our results showed that when the middle screw was far from the fracture line, the overall stiffness and the proximal cortical strain decreased significantly (p < 0.05). These results are similar to the results presented by Bottlang et al. [23].
We also observed that the nearest 1 to 2 screws on both sides of the fracture gap bore most of the load [24].

**Conclusion**

The use of our innovatively designed drill and matching sleeves can transform an ordinary locking plate into an internal fixation system that facilitates distal and proximal cortices to achieve optimal micromotion balance. By adjusting the diameter of the drill and the eccentricity of the sleeve, the strain on the distal and proximal cortices of the fracture can be controlled to promote the balanced formation of the callus. This system is suitable for fractures in which the medial and lateral cortices of the distal femoral metaphysis are severely crushed. Compared with FCL and double plates, it is more conducive to fracture healing and reduced medical costs.

To increase the predictability of the effect of this technology on the human body, studies involving torsional and bending mechanical tests and animal experiments are warranted in the future.

**Declarations**

**Ethics approval and consent to participate:**

In this study, artificial bones were used for relevant tests, and no human or animal experiments were involved.

**Availability of data and materials:**

Not applicable

**Competing interests:**

The authors declare that they have no competing interests.

**Funding:**

The funding source had no role in the design, preparation, or submission of the manuscript. None of the authors received payments or services from a third party for the submitted work.

**Author Contributions Statement:**

Yang Wang and Zhengwei Duan contributed to this article equally in research design, data acquisition and analysis, and paper draft. All authors have read and approved the final submitted manuscript.

**Acknowledgments:**

Not applicable
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**Figures**

![Figure 1](image_url)

**Figure 1**

Comparison of the hole diameters between the standard method and the new drill method; d3 was created by a standard 3.2 mm drill, d4 was created by the new drill with a standard sleeve, and d5 was created by the new drill and 2 sleeves.
Figure 2

Design model of the drill.

Figure 3

3a. The whole drill. 3b. Stepping design of the drill. The steps are indicated with arrows.
Figure 4

Anterior view of a standard sleeve with an eccentricity of 0 mm and an eccentric sleeve with a proximal eccentricity of 1 mm. H1 is the distance from the proximal end of the standard sleeve to the center of the drilling hole. H2 is the distance from the proximal end of the eccentric sleeve to the center of drilling hole.
Figure 5

Lateral view of the sleeve.
Figure 6

Positions of the six drilling holes on the fixation plate.
Figure 7

Anterior view of fixation of the distal femoral fracture model.
Figure 8

Pictures collected and processed by the VIC.

Figure 9

9a. Proximal cortical strain in groups N126 and N136. 9b. Axial load in groups X126 and N126.
Figure 10

Proximal cortical strain for different numbers and distributions of screws at the proximal segment.

Figure 11

11a. Comparison of structure stiffness of groups N126 and N136. 11b. Comparison of proximal cortical strain of groups N126 and N136.
Figure 12

12a. Structural stiffness of groups N1256 and N1356. 12b. Proximal cortical strain of groups N1256 and N1356.

Figure 13

Comparison of axial load for different numbers and distributions of screws at the proximal segment of the fracture.