Original Research

A Biomechanical Study Comparing Different Configurations of the Ilizarov Mini-fixator and Plate Fixation

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Abstract

Objectives: The Ilizarov mini-fixator, an external fixator developed for digits, has a structure different from that of general unilateral external fixators. The purpose of this study was to provide information for clinical external fixator selection by clarifying the biomechanical properties of the Ilizarov mini-fixator.

Methods: Three types of loads were applied to the fracture fixation model using a carbon fiber cylinder as the bone model: axial pressure, 4-point bending, and torsion. Ilizarov mini-fixators with six 1.5 mm pins (6-pin group), four 1.5 mm pins (4-pin group), and four 2.0 mm-threaded-pins (2 mm-pin group) and a group using a 1.5-mm plate (plate group) were set, and the stiffness was compared between these four groups.

Results: Compared to the 6-pin group, which is the basic configuration of the Ilizarov mini-fixator, the 4-pin group had lower stiffness against axial load and bending, and there was no significant difference in stiffness against torsion. The 2 mm-pin group had high stiffness against axial load and bending and low stiffness against torsion. The plate group exhibited high stiffness against axial pressure and low stiffness against bending and torsion.

Conclusions: The Ilizarov mini-fixator is a reasonable option for fixing small phalanges. However, other options should be considered for the fixation of larger bones with higher loads. In particular, a configuration with fewer pins such as the 4-pin model may have insufficient strength during early postoperative exercise, even for fixing the phalanges.

Keywords

biomechanical study, external fixator, hand surgery, Ilizarov

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Introduction

External fixation has become widely used as a treatment for fractures¹⁾. Currently, external fixators are used not only for temporary fixation of fractures but also for final fixation until bone fusion²⁾, bone lengthening³⁾, and release of joint contracture. In the field of hand surgery, various external fixators have been developed, and good results have been reported⁴⁻⁸⁾. On the other hand, the choice of external fixator depends largely on surgeon familiarity and preference⁵⁾.

The Ilizarov mini-fixator is an external fixator developed at the Ilizarov Institute, Russia in the 1990s^{9,10)} and is currently used worldwide¹¹⁻¹⁷⁾. The Ilizarov mini-fixator has been used not only for fracture treatment of the digits¹⁸⁾ but also

for the release of joint contractures¹³⁾, post-traumatic bone lengthening^{17,19)}, lengthening of bones and soft tissue in congenital malformations^{9,14)}, fractures of the foot^{12,15)}, and fixation after forearm osteotomy¹⁶⁾.

It is specialized for digits and is applied using a unique fixation method¹⁹⁾: smooth pins are inserted into the bone fragments from multiple directions, and the pins are bent to bundle them with grooved washers as a fixator-unit. The fixator-units are connected with a threaded rod. The standard configuration of the Ilizarov mini-fixator is three 1.5 mm stainless steel pins fixed with one unit, and the two units are connected with a 3-mm diameter rod. The thickness of the pin and the diameter of the rod can be changed depending on the application. When a heavy load is applied to the ex-

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Figure 1. Fracture model and Ilizarov mini-fixator configuration.

ternal fixator such as for contracture treatment, the Ilizarov mini-fixator with a larger rod (4 mm diameter) is also used^{13,20}. When the bone fragment to be fixed is small, the number of pins may be reduced, and a configuration in which two pins are fixed per unit is also used.

The Ilizarov mini-fixator with thin pins has limited strength. However, this fixator has several advantages including its application in small bones, a high degree of freedom in selecting the pin-insertion point, and the position of the external fixator can be freely adjusted. These characteristics are especially useful for digits, where the load is lighter than that of the lower limbs, the bones are very small, and the position of the external fixator is highly limited to maintain the independent movement of each digit¹⁹.

Similar to the Ilizarov circle-type external fixator, which has different mechanical properties compared to other unilateral external fixators²¹, the Ilizarov mini-fixator may also have its own mechanical characteristics. However, the mechanical properties of the Ilizarov mini-fixator have not been reported. Quantitative expression of the stiffness of the entire structure in which the bone is fixed by the fixing material is important for selecting the fixation method²². The purpose of this study was to provide information for clinical external fixator selection by clarifying the mechanical properties of the Ilizarov mini-fixator.

Methods

Samples

A carbon fiber cylinder (outer diameter, 10 mm; inner diameter, 8 mm) was used as the bone model²³. The outer diameter of the bone model was determined based on the width of the diaphysis of the middle phalanx²⁴. Mechanical tests were performed based on ASTM standards²⁵. Two 10-cm long cylinders were used to simulate a complete transverse fracture with a bone defect. With the 5-mm gap model defined in the ASTM standard, the two units of the Ilizarov mini-fixator come into direct contact without the connecting-

rod interposition. Therefore, the fracture gap was extended to 10 mm in this study. The external fixator pins and screws of the plate were inserted through both walls of the bone model. The distance from the fracture line to the pin/screw insertion point (pin offset) was set to 5 mm, and the distance from the bone model surface to the external fixator frame (frame offset) was set to 10 mm (Figure 1).

Configurations of fixation

In the present study, we compared four fixation methods. In the basic configuration of the Ilizarov mini-fixator, a total of six smooth pins with a 1.5-mm diameter are inserted. The pins were bent and connected with a rod with a 3-mm diameter, to form a pantograph-shaped structure (Figure 2-a, 6-pin group). Because the number of pins may be reduced from this basic configuration, a configuration using a total of four pins, two on each side, was also compared (Figure 2-b, 4-pin group). In other common external fixators used for the hand, threaded pins with a diameter of 2.0 mm or more are usually used, without bending. Therefore, we made a unilateral configuration using four 2.0 mm-threaded-pins. Because the basic Ilizarov mini-fixator cannot grip the 2.0 mm pin, we used the Ilizarov mini-fixator for contracture treatment²⁰, which was enlarged by increasing the rod diameter to 4 mm (Figure 2-c, 2 mm-pin group). As a bridging-plate model, a configuration using a 1.5-mm mini titanium plate (1-mm thick; Keisei Medical Industrial Co., Ltd., Tokyo, Japan) and six screws with a diameter of 2 mm was made (Figure 2-d, plate group). The outer pin span in each configuration was 6 mm for the 6-pin model, 4 mm for the 4-pin model, 6 mm for the 2 mm model, and 11.5 mm for the plate model (Figure 1).

Biomechanical loading

The stiffness was measured in three load modes for each fixation method: axial load, 4-point bending, and torsional loads were applied (Figure 3). Under each condition, three samples were measured five times each. Axial pressure and

Figure 2. Schemas and photographs of the four configurations. (a) Six pins with a 1.5-mm diameter, (b) four pins with a 1.5-mm diameter, (c) four pins with a 2.0-mm diameter, and (d) titanium plate and six screws.

Figure 3. Loading tests. (a) Axial loading, (b) 4-point bending, and (c) torsion.

4-point bending tests were performed using a tensile compression tester (Instron 5966; Instron, Norwood, MA, USA) with a 10-kN load cell (Instron). Custom-made aluminum jigs were used in this study. The load was increased at an axial load of 1 mm/min and a 4-point bending speed of 5 mm/min, and the magnitude of the load and dislocation were recorded at a frequency of 10 Hz. In both tests, the load was stopped before the yield point was reached. In the 2 mm-pin group, in addition to the bending load in the direction that matches the plane of the pins, the load was also applied tilted 45° from the plane of the pins, which is close to the clinical condition (Figure 4).

The torsional load test was performed using a torsion tester (EHF-EV100 kN/TV1 kN-m; Shimazu, Japan) with 1 kN-m (Shimazu). A custom-made aluminum jig was used in this study. The load was increased at a speed of 0.5°/s, and the moments and angles were recorded at a frequency of 3 Hz. The rigidity of the entire bone-fixation device was calculated from the slope of the load-displacement/load-angular

Figure 4. Difference in pin directions.

This figure shows the cross-section of a digit. The pins are inserted at an angle of 45° to avoid interference of the pins with the extensor tendon.

Table 1. Stiffness Under Axial, 4-Point Bending, and Torsional Load.

Configuration	1.5 mm, 6-pin Ilizarov	1.5 mm, 4-pin Ilizarov	2.0 mm, 4-pin Ilizarov (0°)	2.0 mm, 4-pin Ilizarov (45°)	1.5 mm plate
Axial loading (N/mm)	total mean	90.2	50.1	159.8	232.1
	range	(86.5–92.4)	(46.6–53.6)	(157.0–163.3)	(228.2–234.6)
	sample ①	91.9	51.4	159.0	234.0
	sample ②	90.5	51.0	158.9	230.4
	sample ②	88.1	47.8	161.4	231.8
4-point bending (N/mm)	total mean	773.0	155.3	2592.8	1258.4
	range	(764.0–781.0)	(151.6–159.6)	(2412.8–2780.5)	(1010.0–1364.5)
	sample ①	770.0	155.8	2512.6	1247.3
	sample ②	779.0	156.7	2596.7	1257.3
	sample ②	770.5	153.5	2669.0	1270.7
Torsion(Nm/°)	total mean	161.6	154.5	112.6	49.9
	range	(135.1–180.9)	(127.0–182.6)	(92.8–133.6)	(34.1–74.0)
	sample ①	166.0	155.2	111.1	51.1
	sample ②	161.6	158.6	111.0	48.9
	sample ②	157.2	149.5	115.7	49.8

Figure 5. Load–displacement curve under 4-point bending.

These are the load–displacement curves of the three different configurations under 4-point bending. The stiffness of the entire bone-fixing device was calculated from the slope of this curve. When the displacement reached 4 mm, the 6-pin configuration model was loaded with 98.2 N, and the 4-pin configuration model was loaded with 34.9 N. The 2 mm-pin configuration model (without rotation) reached the yield point before it was displaced by 4 mm.

curve of the measurement data. The load was stopped before plastic deformation occurred in all tests. Therefore, the yield points were not measured.

Statistical analysis

For comparison between each condition, the average values of five measurements in the same model (sample mean) were treated as single data (Table 1), and Welch's t-test was performed. Statistical processing was performed using STATA version 13.1 (Stata Corp. College Station, TX, USA). Statistical significance was set at $p < 0.05$.

Results

An example of the load-displacement curve is presented in Figure 5. The measured stiffness data are presented in

Table 1, Figure 6, 7 and 8. Compared to the 6-pin group of the basic configuration, the 4-pin group had lower stiffness under axial load ($p < 0.0001$) and 4-point bending ($p < 0.0001$), and there was no significant difference in the torsional test ($p = 0.12$). In the 2 mm-pin group, when the load was applied tilted 45° from the pin plane during the 4-point bending load, the stiffness was lower than when the load was applied in the pin plane ($p < 0.001$). Compared to the basic 6-pin group, the stiffness of the 2 mm-pin group was higher under axial load ($p < 0.0001$) and 4-point bending (0°: $p < 0.001$, 45°: $p < 0.0001$) and lower under torsional load ($p < 0.001$).

The plate group showed higher stiffness under axial load ($p < 0.0001$) and lower stiffness under 4-point bending ($p < 0.0001$) and torsional load ($p < 0.001$) than the 6-pin group.

Figure 6. Stiffness in axial loading test.

Box plots of the four different configurations under axial loading. In each configuration, three samples are measured five times each. **** indicates statistical significance ($p < 0.0001$). The bottom and top of the box represent the first and third quartiles, the line inside the box is the median, the error bars are the largest and smallest values within a 1.5 interquartile range of the nearer quartile, and any outliers are shown as dots.

Figure 7. Stiffness in 4-point bending test.

Box plots of the five different configurations under 4-point bending. **** indicates statistical significance ($p < 0.0001$). *** indicates statistical significance ($p < 0.001$).

Discussion

Compared to the 6-pin group, the 4-pin group had lower stiffness against axial load and bending, and there was no significant difference in stiffness against torsion. The 2 mm-pin group had high stiffness against axial load and bending and low stiffness against torsion. The plate group exhibited

high stiffness against axial pressure and low stiffness against bending and torsion.

Biomechanical properties of fixation in hand surgery

Many biomechanical studies on hand bone fixation have been reported²⁶⁻³⁴. However, the stiffness required for the external fixator has not been clarified^{26,35}. The stability of ex-

Figure 8. Stiffness in torsion test.

Box plots of the four different configurations under torsion. *** indicates statistical significance ($p < 0.001$). NS indicates no significant difference.

ternal fixators can be investigated experimentally; in contrast, the minimum stability in fracture fixation has been empirically determined³⁵.

When fixing a fracture of digits with an external fixator, the fixator must have sufficient stiffness to heal the fracture without impairing the alignment, even if early exercise rehabilitation is performed³⁵. Currently, the sufficient stiffness of the fixator cannot be determined because the fixation stiffness required to obtain bone fusion and the load applied to each part of the digits during rehabilitation are unclear. It is believed that there is a certain range of fixation stiffness required to obtain bone fusion³⁶. Bone union does not occur if the fixation is too weak or strong³⁷. The fixation stiffness required for bone fusion varies depending on the fracture site, load on the affected limb, fracture type, blood flow around the fracture, and pre-existing disease³⁶. It has also been pointed out that the optimal stiffness for bone fusion may change as the bone fusion process progresses. Further knowledge of the bone fusion mechanism is needed to estimate the sufficient stiffness required for adequate bone fusion processes³⁸.

Although some studies have reported on the load on the fingers during movement, there are no reports on the load distribution during early range of motion exercises. The maximum physiological load on the fingers is reported to be 1.84^{39,40} or 5.6-10.9 Nm⁴¹. The load on the fingers in daily life is reported to be 0.6-0.8⁴² and 0.3-0.6 Nm⁴³. A study is needed to clarify the load generated in each part of the digit during early range of motion exercises.

Interpretation of the results in this study

External fixation is “a method of immobilization that uses percutaneous pins placed in the bone and linked with external connectors”⁴⁰. The basic principle of external fixation is

to bypass the load applied to the fractured part through the frame⁷. In the current study, we adopted a model in which the external fixator bypassed all the loads applied to the fracture site, to compare the properties of the fixation materials. In clinical situations, various factors such as contact between bone fragments, scars, and the callus between the fracture, and the tension of the soft tissue around the fracture site, affect the magnitude of the load through the external fixator^{22,35}.

In the treatment of hand fractures, although it is necessary to perform early active exercise after fixation, rigid fixation that can withstand the gripping action is not required. On the other hand, swelling and scarring after surgery become resistant to movement, and a moment stronger than the physiological value may be required for active motion. Under the 4-point bending condition in this study, a moment of 0.30 Nm is generated under a load of 30 N. Therefore, from **Figure 5**, it is estimated that the 4-pin model is displaced by approximately 4 mm at the lowest value in daily life (0.3 Nm). This estimation indicates that the 4-pin model of the Ilizarov mini-fixator may be at high risk of delayed union or non-union due to insufficient stiffness.

In the 2 mm-pin model, the stiffness changed depending on the direction of the 4-point bending load. In the unilateral configuration of external fixation, where the pins are located on approximately the same plane, the stiffness is high for loads that match the pin plane, and the stiffness is reduced from 1/4 to 1/7 for loads that are perpendicular to the pin plane⁴⁴. Because the pin is rarely inserted in the midline of the dorsal side of the digits, the load from the 45° direction is close to the clinical condition. In addition, the model in which the pins are lined up in one plane becomes extremely weak against the torsional load and becomes stronger when the pin plane opens by 30° or more⁴⁵. In the

present study, the torsional rigidity of the 2 mm-pin and plate groups was low. The basic configuration may be more reliable in situations where a torsional load is applied.

Comparing the 2 mm-pin group and the 6-pin group, the stiffness of the 2 mm-pin group was higher under axial and bending loads. However, highly rigid implants are not always optimal⁴⁶⁾. If the stiffness of the 6-pin model can withstand early active motion, the advantage of having more freedom at the pin-insertion point and distributing the load on the bone should be considered in the selection of the fixation method. The thickness of the pin has the greatest effect on the stiffness of the external fixation⁴⁷⁾. The increase in the pin diameter increases the rigidity by the fourth power. However, the thickness of the pin should be less than 1/3 of the diameter of the bone to which it is inserted^{45,48)}. Pins that are too thick increase stress on the pin-bone interface and are at risk of iatrogenic fractures⁴³⁾. The risk of pin-insertion fracture should be considered, especially in women and children with relatively small bones. There is a report that only women had pin-insertion site fractures in patients with external fixation of the radius⁴⁹⁾. The width of the adult middle phalanx in the coronal plane of the diaphysis is less than 10 mm²⁴⁾, and the width of the sagittal plane of the base of the bone is less than 7 mm⁵⁰⁾. Therefore, the 2.0 mm pin can be too thick for adults with relatively small hands, and children. The Ilizarov mini-fixator may be more suitable for such patients.

Validity of the settings in this study

We measured the stiffness as a measure of stability, which represents the plastic displacement per unit load, rather than the strength, which represents the load that leads to irreversible deformation of the device. Stiffness is an appropriate measure for external fixators because the clinical issue of device stability is the magnitude of displacement rather than the destruction of the device. Since the mechanical data of the Ilizarov mini-fixator have not been previously published, it was expected that the data obtained in this study would be difficult to interpret. Therefore, we used the unilateral configuration and plate models as a comparison, which have been utilized in many previous mechanical experiments.

To measure the stiffness of bone-fixation devices in the hand, mechanical tests using unilateral external fixators^{26,27)}, plates²⁸⁻³³⁾, wires^{28,29,31)}, and intramedullary nails³¹⁾ have been reported. The bending load in these mechanical tests has been widely set from 0.1 to 10.5 Nm. Only Liodaki et al.³³⁾, who used a plate-fixed model with no bone defect, documented a load above 5 Nm, and, in all cases, the bone broke rather than the plate. In addition, Fitoussi et al.²⁷⁾ (dorsal bone defect model, 4-point bending load) and Capo et al.³¹⁾ (PIP joint fixation model, cantilever load) reported using models with bone defects, and the load applied in both studies was only 0.1 Nm. In these previous reports, the inconsistency in loading methods (4-point bending, 3-point bending, and cantilever), bone models, and implant placement makes it difficult to compare data between different studies⁴⁵⁾.

In the present study, ASTM standards were used with the

aim of standardizing the settings. However, when the Ilizarov mini-fixator was placed according to the ASTM settings, the two units of the fixator made direct contact, and the original stiffness of this fixator could not be measured. Therefore, the gap size was widened as a minimum change. As the bending load mode, the moment on the sample becomes non-uniform in the 3-point bending³⁰⁾ and cantilever bending^{29,31,32)}. The 4-point bending was selected in this study because it applies a constant and pure bending moment over the test section³⁴⁾.

Although fresh cadaver³⁰⁻³²⁾ is ideal as the bone material to be fixed in biomechanical studies, animal bones²⁸⁾, artificial bones³³⁾, resins³⁴⁾, embalmed cadaver^{27,29)}, and wood²⁶⁾ have been used as alternatives. Artificial objects have the advantage of being uniform in material and morphology compared to natural bones. In the present study, carbon tubes were selected similar to a previous study on a Hoffman-type external fixator²³⁾.

Limitations

In the current study, a carbon tube was used as a bone model, and the strength of the bone model itself and the strength at the pin-bone interface differed from those of human bones. Therefore, the stiffness of the bone-external fixator complex measured in this study does not directly reflect stiffness during clinical use. Despite such drawback, the stiffness data of each external fixator are clinically important information.

Conclusion

We report the stiffness of the Ilizarov mini external fixator. The basic 6-pin model was less rigid under axial load and 4-point bending than the unilateral model with 2.0 mm pins. The 4-pin model was less rigid under axial load and 4-point bending than the basic 6-pin model. Since the stiffness of fixation required for fixing a fracture of digits has not been determined, it is not clear which method is appropriate. In the future, the selection criteria for each external fixator would be clear, as the bone fusion mechanism and load distribution during early exercise will be elucidated. The Ilizarov mini-fixator is a reasonable option for fixing small phalanges. However, other options should be considered for the fixation of larger bones with higher loads. In particular, a configuration with fewer pins such as the 4-pin model may have insufficient stiffness during early postoperative exercise, even for fixing the phalanges.

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