Development of a Functional Fixator System for Bone Deformity Near Joints

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A functional external fixator system for bone deformity near the joints using worm gear was developed for curing the angle difference in fracture bones while the lengthening bar was developed for curing the differences in length, also in fracture bones. Both experiments and FE analysis were performed to compare the elastic stiffness in several loading modes and to improve the functional external fixator system for bone deformity near joints. The FE model using compressive and bending FE analysis was applied due to the angle differentiations. The results indicate that compressive stiffness value in the experiment was 175.43 N/mm, bending stiffness value in the experiment was 259.74 N/mm, compressive stiffness value in the FEA was 188.67 N/mm, and bending stiffness value in the FEA was 285.71 N/mm. Errors between experiments and FEA were less than 10% in both the compressive stiffness and the bending stiffness. The maximum stress (157 MPa) applied to the angle of the clamp was lower than the yield stress (176.4 MPa) of SUS316L. The degree of stiffness in both axial compression and bending of the new fixator are about 2 times greater than other products, with the exception of EBI (2003).

Key Words : Angle, Bending Stiffness, Bone Fracture, Compressive Stiffness, Finite Element Analysis, Functional, Maximum Stress, Union, Worm Gear

1. Introduction

External fixation, one of the healing methods used to cure bone fractures caused by external physical impact, uses an array of externally connected pins fixed to fractured bones through the skin. Since its introduction in 1853, the method has improved continuously. In particular, a unilateral external fixation device has been reported to be the most suitable on the grounds that it is small and simple ; its pins and supporting bars can be firmly secured ; dynamic axial compressive load can be applied ; and a half pin with strong resistance to lateral bending and torsional forces can be used (Behrens, 1989 ; Sisk, 1983).

There are two types of bone union that take place during the fracture healing process : primary bone union (Perren, 1979) that occurs after anatomical reposition of the fractured area followed by stable internal fixation and secondary bone union that enables callus formation by allowing slight movement while the fracture area is set. Many authors point out that the axial stiffness of the fixator has great influence on the axial load and motion at the fracture area due to the importance of rigid internal fixation during the primary bone union process (Oh et al., 1998 ; Kempson et al., 1981 ; Kristiansen et al., 1987 ; Paley et al., 1990 ; Lee et al., 2002). For this reason, a study has been made for comparison between axial displacement stiffness of the fixator system and that of commercialized products (Kempson et al., 1981).

From cases of surgical operations utilizing the fixator system, cracks and subsequent replacement

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of fixator components were reported to be problematic. Thus, the need for further improvement of the fixator system function to adjust the height of the fixator and the length of the bar was raised in order to accommodate complex fractures (Kim et al., 2000).

In this study, we developed an improved external fixator system, which has a high degree of mechanical stiffness and can be used for fracture treatment without limitation to the location and form of the fracture. In order to understand the function of the previously developed multi-purpose external fixator system, the axial compressive stiffness and bending stiffness obtained from the experiment performed in accordance with the ASTM standard were compared to those obtained from the finite element analysis model. Stress analysis was performed for the external fixator system based on axial compression, bending and angle under identical force in order to locate the sites for potential fissures.

2. Manufacture

Figure 1 presents the developed functional external fixator system, which consists of three parts: lengthening bar, worm-geared free style fixture and free style fixture.

The free style fixture in the right circle in Fig. 1 consists of a three-pin clamp body, fixture body and serration body with fine grooves for complete connection disallowing rotation and displacement between the free style fixture and the fixture body.

As depicted in Fig. 2, the lengthening bar consists of an internal bar and an external bar. It can be lengthened by up to 40 mm using a length adjusting bolt.

As shown in Fig. 3, the worm-geared free style fixture is comprised of a three-pin clamp body, rotating body and fixture body. The three-pin clamp body is composed of the three-pin clamp that fixes the pin screw, three-pin cover and the cover bolts for the three-pin cover. It can rotate around the Y-axis. The rotating body connects the three-pin clamp body and the fixture body, and it can rotate around the Z-axis. It can revolve within the range of ± 40. The fixture body has a structure that can be connected to the lengthening bar, and it can rotate around the X-axis.

The length and angle of the functional external fixator system configured in this way can be adjusted according to the location and form of the fracture. By way of such functions of the external fixator system, the treatment of open fracture of the long bone and the humerus, especially humeral fracture accompanied with blood vessel damage, can be facilitated via the acceleration of the bone union and effective position adjustment of the fractured bones according to the progress

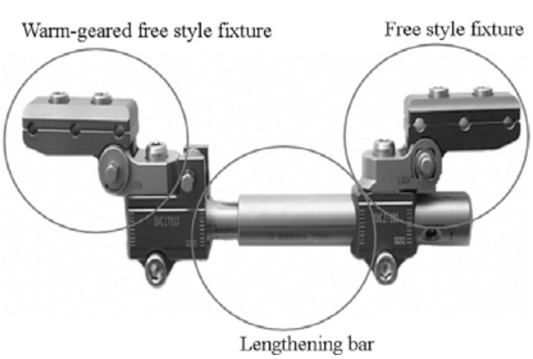

Fig. 1 Functional external fixator system

Fig. 2 Lengthening bar

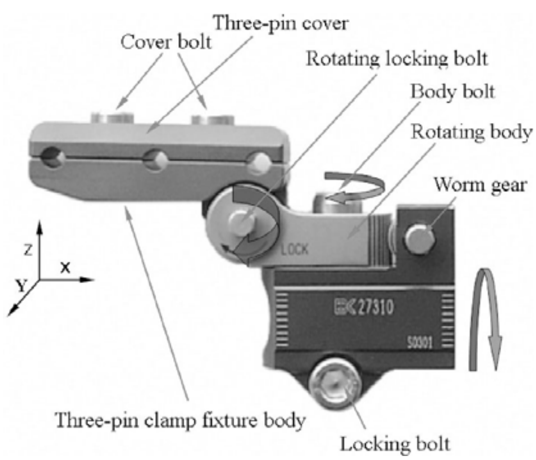

Fig. 3 Clamp using worm gear

of the treatment.

In order to alleviate inconvenience to the patient having to constantly transport this external fixator, it is essential that it be light. To achieve this, Al2024-T4 (aluminum alloy) is utilized for the fixture and fixture body, SUS316L for the pin screw that is inserted into the human body, and SUS316 for lengthening of the bar and other part.

3. Experiment and Results

3.1 Conditions for experiment

The experiment was conducted in accordance with the relevant provision of the ASTM F1541-01 A7. Each structure was firmly fastened.

For both the axial compressive stiffness test and bending stiffness test, axial compression and bending were applied on the acryl rods by increasing it from 0N to 250N to obtain the 'Load-Displacement' curve. This curve was employed to calculate the stiffness.

For the axial compressive stiffness test, the external fixator system mounted on the acryl rods was fixed on the jig and then mounted on the universal tester. Next, the axial compression (0N～250N) was applied on the acryl rods at the worm-geared free style fixture as shown in Fig. 4 with the acryl rods at the free style fixture being firmly fastened.

Following the same procedure as above, the bending stiffness test was performed by applying bending force (0N～250N) at the middle of the acryl rods of the worm-geared free style fixture and free style fixture as shown in Fig. 5. The roller supports were placed in the center of the distance between the pin screws and the free style fixture. The distance of the roller supports was 130 mm.

3.2 Experiment results

Results of the experiments using the universal tester are indicated with dots as presented in Figs. 6 and 7. In order to compare these results with those by the linear finite element analysis, the experiment data were linearized by using the least square curve fitting method in the MATLAB methods (Mathwork Inc., V 6.0). The results of the linearization are shown in Figs. 6 and 7 in full line.

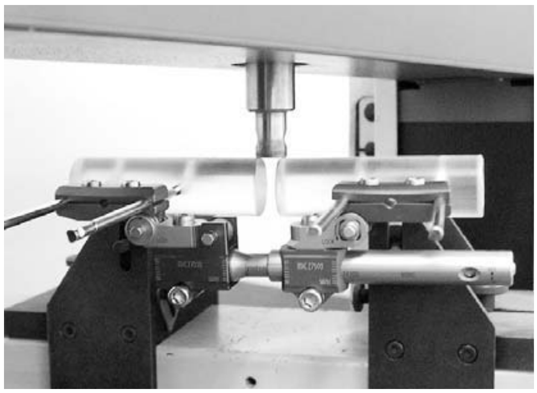

Fig. 5 Bending test configuration

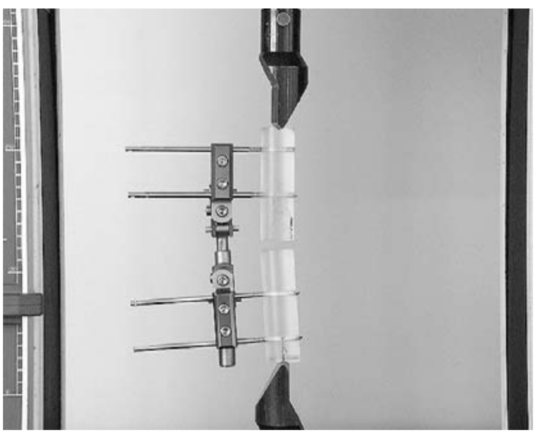

Fig. 4 Axial compression test configuration

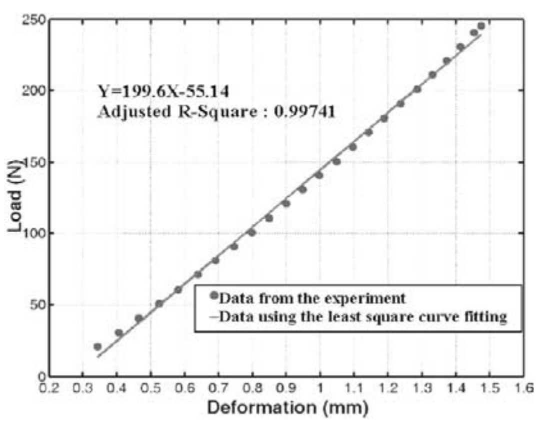

Fig. 6 Axial Compression experiment result

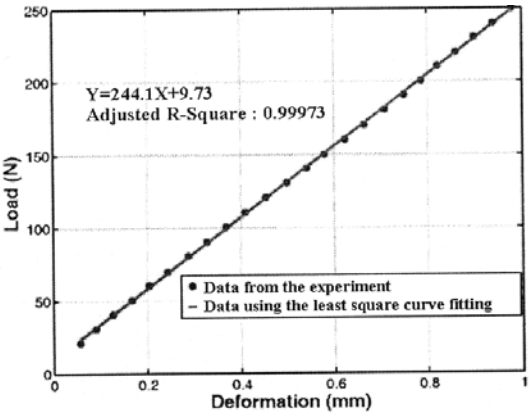

Fig. 7 Bending experiment result

Results of the axial compression and bending stiffness tests indicated as 'Load-Displacement' curves indicate that the axial compression stiffness is 175.43 N/mm and the bending stiffness is 259.74 N/mm as illustrated in Figs. 6 and 7, respectively.

4. Finite Element Analysis and Result

4.1 Analysis method

In order to analyze the external fixator system used for the experiment, three dimensional modeling of each part was carried out based on the 2D CAD drawings using CATIA (Dassault Systems, Ver. 5.8). A total of 22 parts were designed and used for system assembly. A three dimensional image was created by assembling these parts.

After converting the surface information of the model into IGES file, the meshing of the finite element model was performed using HyperMesh (Altair Engineering, Ver. 5), a pre-/post-processing program. A total of 29650 elements were employed in the finite element analysis including 28680 CHEXA type solid elements and 970 CPENTA type solid elements with the exception of the CTETRA elements. The number of nodes was 36425 in total.

4.2 Condition for analysis

In the axial compression analysis, since the linear result by linear analysis was expected for the acryl rod at the worm-geared free style fixture, Y and Z axes were fixed while the X-axis remained free for displacement under the compressive force of 200N. Thus, only axial displacement was made possible. In addition, the acryl rod at the bottom section was fixed at the middle of the rod for all X, Y and Z-axes. The material properties used for the analysis were as shown in Table 1.

Table 1 Material property

Material	Property	Value
AL2024	E	73 KN/mm^2
	υ	0.33
SUS316L	E	210 KN/mm^2
	υ	0.28
ACRYL	E	2.4 KN/mm^2
	υ	0.35
SUS316	E	200 KN/mm^2
	υ	0.26

In the bending analysis, as in the case of the support test, four elements at the upper part of the acryl rod end were placed under compression force so that the compression force was applied to the acryl rod in the bending test. According to the ASTM requirements, the supports were fixed with rollers in order to set the Y and Z-axes while leaving the X-axis free. The distance between supports is 130 mm.

In treating the bone fracture without limitation to the location and type of the fracture, which is one of the main purposes of the functional external fixator system, the possibility of crack development for each part shall be checked through the proper experiment according to the angle formed by the anatomy axis (reference axis) and the varus (or valgus) due to injury. However, since there was no test standard in accordance with the ASTM, the analysis according to the angle was performed using the mesh model that is within the predictive error range in the axial compression test and bending test.

In the analysis of compression according to the angle, 200N was vertically applied to the acryl rod that is connected to the rotating body.

The support parts were completely fixed to disallow movement in the X, Y and Z directions. Although the worm-geared free style fixture permits ±40° movement, since the angle is adjusted within ±15° clinically in many cases, finite element analysis was performed in order to understand the stress distribution of the external fixator system at 5, 10 and 15 according to the external force applied to the worm-geared free style fixture. The predictive error range through the analysis results was limited within 10% due to the errors resulting from the complex structure, clearance between worm and gear, experimental errors, and incorrect modulus of elasticity of the acryl rod composed of synthetic resin.

4.3 Results of compression and bending analysis

The linear analysis program, MSC/NASTRAN for Windows 4.0 (MSC, Ver. 4) was used. According to the axial compression and bending analysis, the stiffness of the external fixator system was compared to the results of the experiment, and analysis was performed in order to identify the stress distribution at each part.

Table 2 presents the analysis results. The axial compression stiffness from the load- displacement curve was 188.67 N/mm, which deviates from the test result by approximately 7.06%. In addition, the bending stiffness in the bending test analysis was 285.71 N/mm, which strays from the test result by approximately 9.09%. Since the errors of the analysis results were within the predictive error range, it was understood that the analysis was performed smoothly.

The stress distribution through analysis is as indicated in Figs. 9 and 10 (enlarged views of the area are indicated by "A" in the above Fig. 8). In the compression analysis, the maximum stress was concentrated on the internal pin screw that was fixed with a three-pin clamp body of the free style fixture and three-pin cover, and it was 103 MPa. In the bending analysis, the maximum stress was concentrated on the external pin screw that

Table 2 Comparing stiffness results

Classification	Result	Value	Error
Axial compressive stiffness	Experiment	175.43 N/mm	7.06%
	Analysis	188.67 N/mm	
Bending stiffness	Experiment	259.74 N/mm	9.09%
	Analysis	285.71 N/mm	

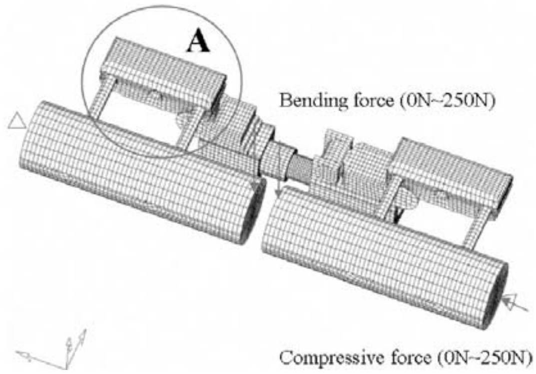

Fig. 8 Analysis model

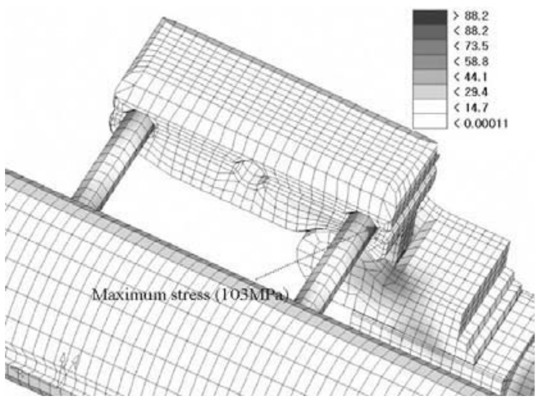

Fig. 9 Axial compression analysis result

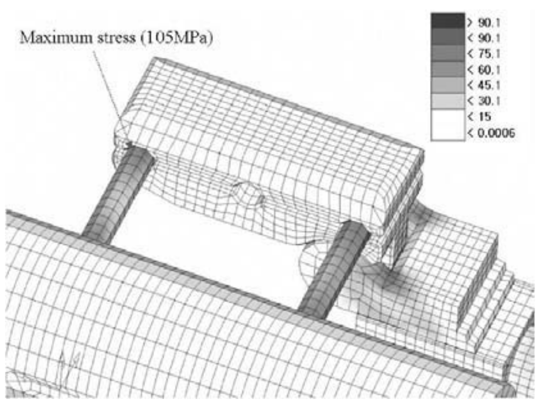

Fig. 10 Bending analysis result

was fixed with a three-pin clamp body of the free style fixture and three-pin cover, and it was 105 MPa.

In the axial compression analysis and bending analysis, the errors of the analysis results were within the predictive error range (10%) presented in the conditions for analysis, and the maximum stress was found at the pin screw, which was lower than 205.8 MPa, the yield stress of the SUS316L. Therefore, analysis according to the angle was performed.

In order to compare the performance of this external fixator system with that of existing products, the axial compression stiffness and bending stiffness of the external fixator system was contrasted with those of other commercialized products as shown in Figs. 11 and 12. The axial compression stiffness of the external fixator system (BK) used in this experiment was 71.2% that of EBI (2003), while bending stiffness was 94.1% that of EBI (2003). However, through the comparison with other products, it was found that the axial compression stiffness and bending stiffness were higher by more than two times those of the previous products (Koo et al., 2003).

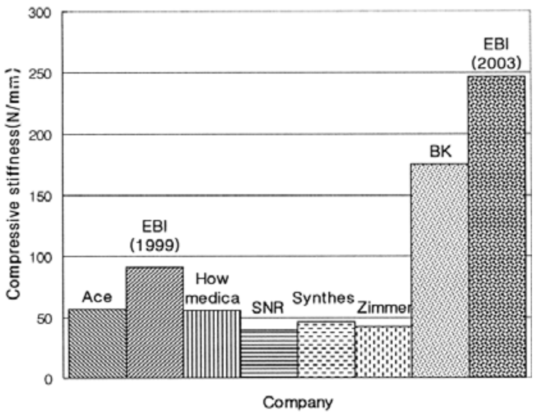

Fig. 11 Comparing axial compressive stiffness in products

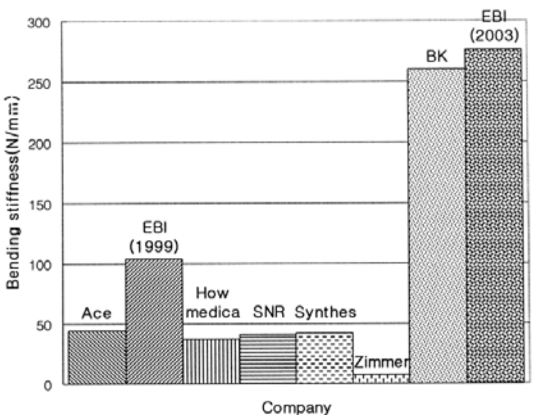

Fig. 12 Comparing Bending stiffness in products

4.4 Analysis results according to angle

Assuming that the stress in the analysis according to the angle would concentrate on the same area where stress was concentrated in the axial compression and bending analysis, three stress concentrating parts were selected to compare the analysis result according to the angle. View_Point _A indicates the area where the concentrated stress changes in the internal rod of the lengthening bar; View_Point _B indicates the serration body showing the phenomenon of stress concentration in the axial compression and bending analysis; and View_Point _C demonstrates the internal pin screw that was expected to have great stress according to the angle.

With the analysis model in Fig. 13, analysis was performed using worm gear with the angles (θ) which were fixed at 5, 10 and 15.

From the analysis results in the above Figs. 14∼16, it was established that the concentrated stress increased at each part as the angle increased. The maximum stress was discovered on the same internal pin screw, which was fixed with a three-pin clamp body of the free style fixture and a three-pin cover, where the maximum stress existed in the axial compression analysis. Table 3

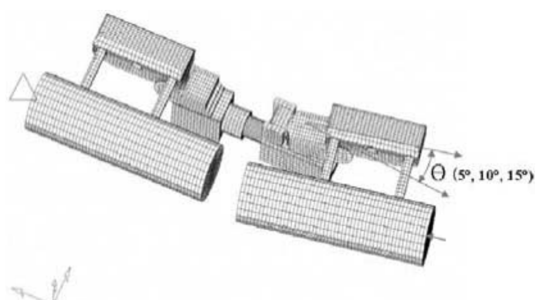

Fig. 13 Analysis model

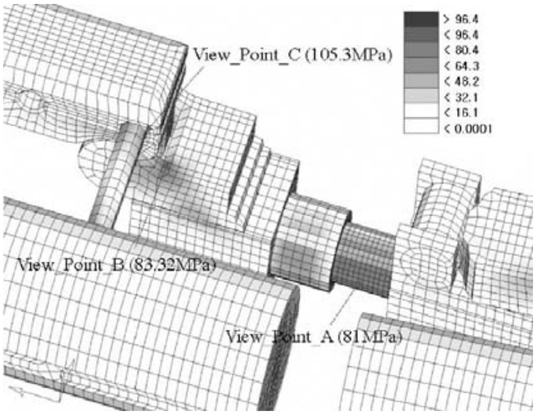

Fig. 14 Analysis result (θ=5 degree)

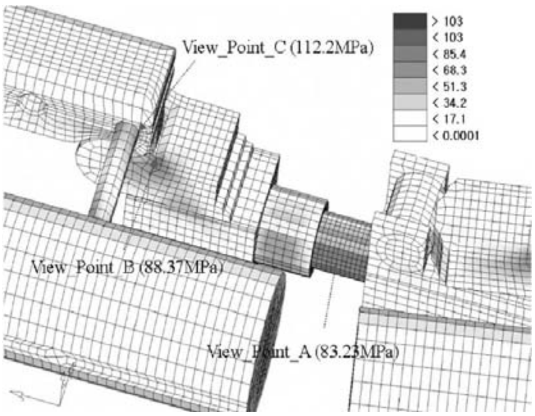

Fig. 15 Analysis result (θ=10 degree)

indicates the stress results at the selected stress concentrating areas.

5. Discussion and Conclusion

This study performed the comparison of axial compression stiffness and bending stiffness of the developed external fixator system with that obtained from the analysis. With the analysis model used for the comparison, the stress change rate at the stress concentrating area according to the angle was measured.

Furthermore, through this study, areas where stress was concentrated were observed and it was discovered that the stress was intensified on the internal and external pin screws fixed with a three-pin clamp body and three-pin cover of the free style fixture. Moreover, from the results of the

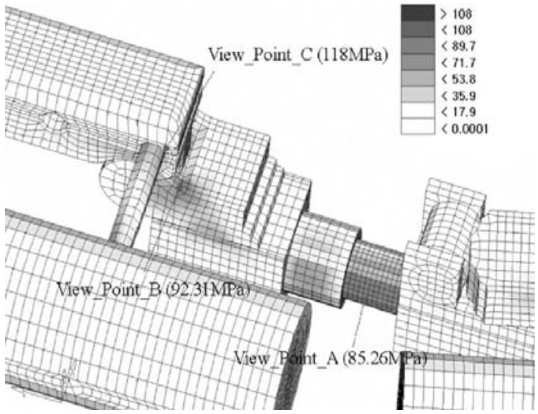

Fig. 16 Analysis result (θ=15 degree)

Table 3 Angle results

	5°	10°	15°
View_Point _A	81.00 MPa	83.23 MPa	85.26 MPa
View_Point _B	83.32 MPa	88.37 MPa	92.31 MPa
View_Point _C	105.30 MPa	112.20 MPa	118.00 MPa
Maximum Stress	113.00 MPa	120.00 MPa	126.00 MPa

analysis according to the angle, it could be seen that under constant load (200N) the stress applied to the external fixator system increased as the angle increased. However, it was determined that the stress increase rate with the increase of the angle was dissimilar between the parts, with the stress increase rate of each part being as follows: approximately 0.42 MPa per degree at the internal rod of the lengthening bar; approximately 0.89 MPa per degree at the serration body; and approximately 1.27 MPa per degree at the pin screw. The stress increase rate at the area of maximum stress was 1.30 MPa per degree. From the above findings concerning the stress increase rate, it was known that when the above angle was 40 under 200N external force during the course of clinical treatment of a patient, the maximum stress was 157.0 MPa, which is lower than the yield strength (176.4 MPa for SUS316L and 205.8 MPa for SUS316) of the material used for this experiment. From this it can be said that crack problems will be nonexistent in each part of the functional external fixator system.

The developed functional external fixator system can be applied to fit the bone union status of a patient for correct reduction during the clinical period through the fine adjustment of the angle using not only the general lengthening function but also the characteristics of the functional worm gear. In addition, it is thought to contribute to the increase in the convenience of fine correction and operation of bone fracture.

References

Behrens, F., 1989, "General Theory and Principles of External Fixation," *Clin Orthop*, Vol. 241, pp. 15～23.

Kempson, G. E. and Campbell, D., 1981, "The Comparative Stiffness of External Fixation Frames," *Injury*, Vol. 12-4, pp. 297～304.

Kim, H. T., Lee S. H., 2000, "Clinical Application of Domestic External Fixator System (Dyna-Extor)," *Korean Orthopaedic Association Journal*, Vol. 35, pp. 845～849.

Koo, T. K. K., Kim, Y. H., Choi, D. B., Jua, K. G., Lim, J., Inoue, N. and Chao, E. Y. S., 2003, "Stiffness Analysis of Dynafix External Fixator System," *2003 Summer Bioengineering Confercnce*, pp. 1227～1228.

Kristiansen, T., Fleming, B., Reinecke, S. and Pope, M. H., 1987, "Comparative Study of Fracture Gap Motion in External Fixation," *Clinical Biomechanics*, Vol. 2-4, pp. 191～195.

Lee, M. K., Choi, K. and Choi, I, H., 2002, "The Effect of Mechanical Dynamization on Regenerative Bone Healing," *Porceedings of the Korean Society of Precision Engineering Conference*, pp. 158～161.

Oh, J. K. and Park, J. H, 1998, "Axial Stiffness of the Ilizarov External Fixator System Using Rancho Method," *Korean Orthopaedic Association Journal*, Vol. 33, No. 7, pp. 1928～1932.

Paley, D., Flemming, B., Catagni, M., Kristiansen, T. and Pope, M., 1990, "Mechanical Evaluation of External Fixators Used Limb Lengthening," *Clin Orthop*, Vol. 250, pp. 50～57.

Perren, S. M., 1979, "Physical and Biological Aspects of Fracture Healing with Special Reference to Internal Fixation," *Clin Orthop*, Vol. 138, pp. 175～196.

Sisk, T. D., 1983, "External Fixation, Historic Review, Advantage, Complications, and Indications," *Clin Orthop*, Vol. 180, pp. 15～22.