Mechanical Evaluation of Aluminum Alloy Ring Fixator

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Objective: *To test the homemade ring fixator as a tool for correction of bony deformity.*
Material and Method: *The authors developed an aluminum alloy ring fixator and tested it to find out the accuracy of manufacturing and strength of the ring systems under axial load with the Roundness Testing Machine and Lloyd Universal Testing Machine.*
Results: *The mean diameter of the twenty five-drill holes was 6.5843872 ± 0.0521594 mm (mean ± SD). Distance between particular drill holes, which reflected the precision of drilling, had a high accuracy with standard deviation from 0.1138 to 0.1870 mm. The roundness of the rings was 0.2421376 ± 0.12437977 mm (mean ± SD). The system structure had minimal permanent deformity at breaking point, mean yield strength of the system was 4786.9 ± 14.353 N (mean ± SD). This was caused by the failure of the wire. Mean stiffness of the system was 127 N./mm.*
Conclusion: *The aluminum alloy ring fixator was strong enough and well tolerated for clinical usage*

Keywords: *Ring fixator, Ilizarov, Aluminium alloy, Aluminium, External fixator*

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In 1952, Ilizarov invented his ring external fixator and described its construction, usage and applications. The system consisted of four or more rings with two or more cross Kirschner wires under tension per ring. The rings were connected to each other with threaded rod. In 1954, Ilizarov began his apparatus for lengthening extremities. After that, the apparatus was gradually accepted for clinical application and approved by the Food and Drug Administration for fracture fixation, pseudarthrosis of the long bones, limb lengthening by epiphyseal or metaphyseal distraction and correction of bone malformation.

Though the apparatus seemed to be useful, it was continuously improved materially. However, the price of the system is an obstacle for developing countries and low socioeconomic group of patients usually could not afford it. The authors developed a handmade aluminum alloy ring fixator that was used on one patient. Though the authors faced some problems on symmetry of the drill holes, the authors got good clinical results. However, the authors did not have supporting data in perspective of strength of this system.

The objectives of the present study were, first, to study the precision of manufacturing, second, to study the mechanical behavior of the aluminum alloy ring fixator under axial load, and to determine the strength of the system for clinical application.

Material and Method

An aluminum alloy square-end bar, the same dimension as the original one, was bent into a half ring with special bending tools. Mikron computer numerical control drilling tool (Mikron Agie Charmilles Group, Germany) was used to drill into the half rings at precise locations. The half rings were anodized for hardening its surface with a 15% sulphuric acid bath. Five drilled holes (Fig. 1) from five half rings, thus twenty-five holes were chosen for evaluation of the diameter with Optical Video Prob, OMIS 2 (Ram Optical Instrumentation Inc, California). Inner and outer diameter of the five half rings and roundness of the rings was measured

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with Coordinate Measuring System (Microval PFx, Brown & Sharpe, USA). Precision of the drilling sites was evaluated by measuring the distance between the center of the five selected drill holes (Fig. 1) on each of the five rings (variables were named as VAR 00001, VAR 00002, VAR 00003 and VAR 0004) with Co-ordinate Measuring System (Microval PFx, Brown & Sharpe, USA).

The presented ring fixator system was comprised of four full rings with two 1.8 mm Kirschner wires on each full ring. Rings at each end were 2.5 cm apart from each other. All rings were connected to each other with four threaded rods (Fig. 2).

Each Kirschner wire was pre-tensioned at 110 Kg. All of them were secured to the ring with a wire clamp and bolt by using a hand wrench simulating the real situation. For mechanical behavior test, polyvinyl-chloride tubes were used as long bone to ensure uniform and consistent material properties and pin tract responses. Three ring fixator systems were tested with Lloyd Universal Testing Machine (Fig. 3) with continuous load rate at 30 mm/min. Length of outer diameter of each ring and the gap between each pair ended rings were recorded pre-test and post-test for comparison with a digital caliper.

For statistical analysis, descriptive statistics and the paired Student t-test used to determine the deformity of the ring configuration. This was determined at the outer diameter of each ring by measuring the gap between each pair of rings. Kolmogorov - Smirnov test was used to test goodness of fit of data that would further be analyzed with paired Student t-test. A p-value of less than 0.05 with two tailed was considered significance difference between.

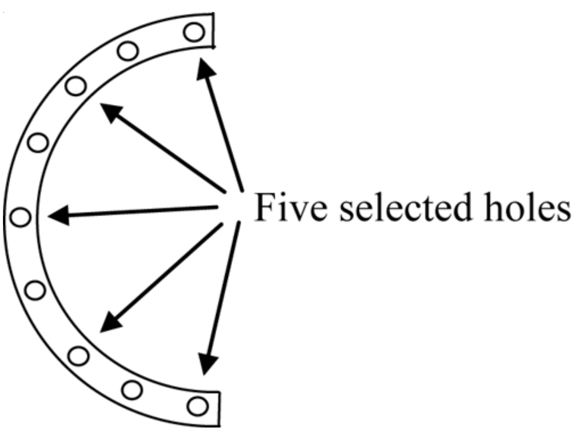

Fig. 1 Five selected holes for evaluation

Fig. 2 System configuration

Fig. 3 The ring fixator system under the testing machine

Results

Mean diameter of the twenty five selected drill holes was 6.5843872 ± 0.0521594 mm (mean ± SD).

The inner diameters of the five half rings were 197.99955 ± 0.81985904 mm (mean ± SD). The outer diameters of the five half rings were 228.24306 ± 0.970154296 mm (mean ± SD).

Mean consecutive distance between the five particular holes (VAR00001 - VAR 00004) on five half rings is demonstrated in Table 1. Standard deviation of the consecutive distances ranged from 0.1135 to 0.1861 mm. The roundness of the rings was 0.2421376 ± 0.12437977 mm (mean ± SD).

The mean yield strength of the three-ring system was 4654.567 ± 229.5704 Newtons with displacement at 57.3067 ± 1.1836 mm (Fig. 4). The overall system still maintained its contour; there was no statistical significance of the ring diameter between pre and post test at 95% confidence (mean difference is -0.0225 ± 2.312818 mm (mean ± SD)) (Table 2). There was no statistical difference of the gap between ended rings pre and post test at 99% confidence (mean difference is 0.027917 ± 0.366226 mm (mean ± SD)) (Table 3). The extension or failure of the system was caused by plastic deformation of Kirschner wire and loosening of the wire clamps (Fig. 5).

Fig. 5 Shows the plastic deformation of K-wire, the ring fixator configuration still maintained (Post-test)

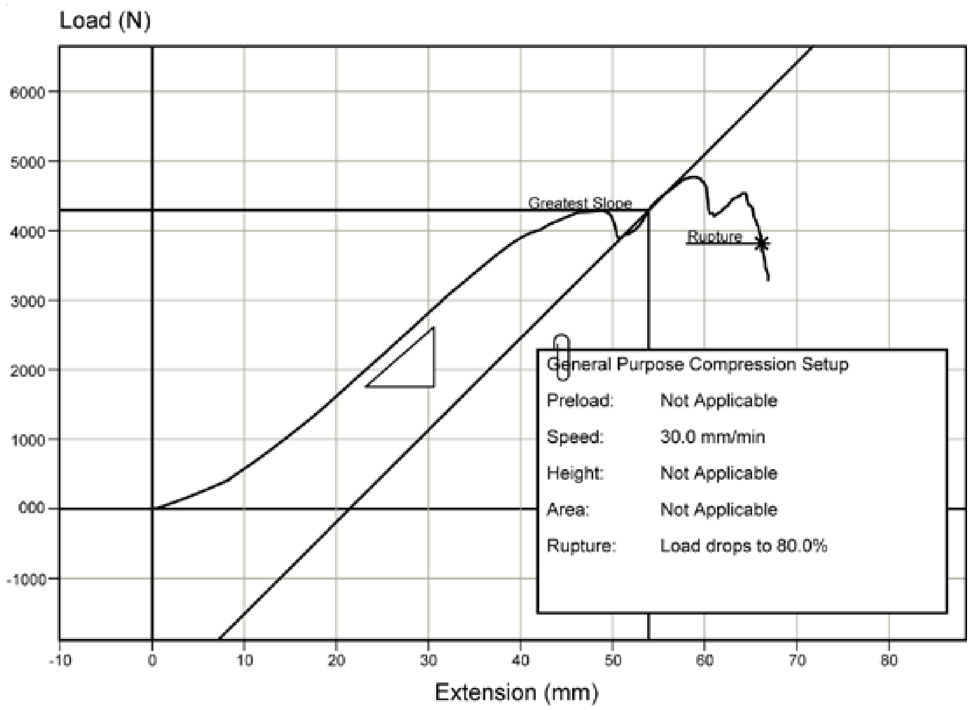

Fig. 4 Load-Displacement (extension) Curve shows yield strength at 4300 N

Table 1. Mean and Standard Deviation of hole and ring diameter, distance between holes

Variable		N	Mean (mm)	Std. Deviation (mm)
Mean diameter of holes		25	6.58438	0.05215942
The inner diameters of the five half rings		5	197.99955	0.81985904
The outer diameters of the five half rings		5	228.24306	0.97015429
Mean consecutive distance				
	VAR00001	5	82.52621	0.131983838
	VAR00002	5	152.10636	0.186136738
	VAR00003	5	198.39314	0.158297135
	VAR00004	5	214.10761	0.113522769

Table 2. Paired samples test 95% (ring diameter pre and post test)

Variable	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pre - Post	-0.0225	2.012818	0.5810506	-1.30138	1.25638391	-0.0387	11	0.969805119

Table 3. Paired samples test 99% confidence interval (Gap between ended rings pre and post test) of the difference

	Paired Differences				t	df	Sig. (2-tailed)
	Mean	Std. Deviation	99% Confidence Interval of the Difference				
			Lower	Upper			
Pre - Post	0.027917	0.36622	-0.181948	0.23778	0.37344	23	0.712241586

Mean load at 2 mm of displacement was 76.667 $\pm$ 8.0829 Newtons. Mean stiffness was 127 N/mm.

Discussion

Ring external fixator is accepted worldwide as a useful tool for orthopedic patients especially in difficult cases[1-5]. The first prototype was stainless steel[6]. Until now, there was evolution in material, from titanium[7] to carbon-fiber composite[8,9].

Aluminum alloy (Sp.gr 2.7) is lightweight material, weighting two to three times less than stainless steel (Sp.gr 7.9). From the authors' limited experience, aluminum alloy ring worked well for clinical usage. Nevertheless, there was scarcely adequate scientific information about the strength of the aluminum alloy system. Pulate et al used an aluminum alloy ring cutting from aluminum tubes cast, but mechanical data is not available[10].

In the present study, the material of the ring was hot treated aluminum alloy. This is stronger than aluminum tube cast. With a hand made bending tool, the mean inner diameter was 197.99 $\pm$ 0.819 mm, the mean outer diameter was 228.243 $\pm$ 0.970 mm. The mean roundness of the rings was 0.2421376 $\pm$ 0.12437977 mm (mean $\pm$ SD). The standard deviation of diameter and roundness was in an acceptable range for general hardware.

To avoid asymmetry of drilled holes on the half ring, a Computerized Control Machine was used to drill the holes at the precise location. From the data standpoint, the distance between drilled holes, which reflected the precision of the drill site, had high accuracy with standard deviation from 0.1138 to 0.1870 mm. The standard deviation of the drilled hole diameter was 0.0521594 mm, which is acceptable for bolt and screw.

The surface of pure aluminum alloy is abrasive and not hard enough. The authors anodized it with a 15% sulphuric acid bath. This would provide corrosive resistance, electrical insulation and abrasive resistance as well as improve paint adhesion. Properties such as porosity, abrasion resistance, color, and flexibility depend on the type, concentration, and temperature of the electrolyte, the strength of the electrical current, the processing time, and the type of metal.

In the present study, the original wire clamp, original Kirschner wire 1.8 mm and original thread rod were used. This eliminated confounding factors. To get results that could be repeated in real situation, all nuts and bolts of the system were tightened manually with maximal force.

Load-displacement behavior of the system under axial load was curvilinear (Fig. 4). Stiffness of the system at various point differed from each other. Overall, the stiffness was initially low and increased later on. Gasser proposed that the remarkable clinical results might come from this specific nonlinear behavior[11]. It seemed that low stiffness at low load may stimulate bone healing, and high stiffness at high load may prevent over tolerance strain at the fracture site.

Comparing with other studies[4,12], stiffness of the presented aluminum alloy ring system (127 N/mm) was not different from the stainless steel ring system (103.91 N/mm) or titanium ring system. It probably meant that load-displacement behavior of the ring was affected from other common factors, Kirschner wire and wire clamp, not from the sort of material used for manufacturing the ring.

The ring fixator system could tolerate the load up to 4654.567 Newtons with displacement at 57.3067 mm. From Table 2 and Table 3, the ring gaps and ring diameters did not differ between pre and post test. This means that the system configuration had not changed after failure. From Fig. 5, the causes of displacement clearly were the elastic elongation of the Kirschner wire, loosening of the wire clamp and the less pretension force. Watson et al commented in his study that though the initial wire tension has an appreciable effect on the wire stiffness; it did not affect the elastic load range of the clamped-wire system[13]. If the authors preferred more stiffness of the system, the authors needed to use a larger Kirschner wire, to apply more pre-tension force and to design a much more securing wire clamp[13,14].

At 2 mm of displacement in the present study, mean load was 76.667 Newtons, which did not differ from other studies[15,16]. In a real situation, because of soft tissue filling the gap between fracture sites, the real load at 2 mm of displacement were usually much more than this figure.

Aluminum alloy ring fixator is strong enough for clinical usage and has a low system weight. This is an advantage over the stainless steel ring type.

Conclusion

Production quality of Aluminum Ring Fixator is acceptable and the fixator is strong enough for clinical application.

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การศึกษาความแข็งแรงของเครื่องยึดกระดูกแบบวงแหวน

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วัตถุประสงค์*: เครื่องยึดกระดูกจากภายนอกแบบวงแหวนเป็นเครื่องมือที่มีประโยชน์ในการรักษาผู้ป่วยทางด้านโรคกระดูกและข้อเป็นอย่างมากคณะผู้วิจัยได้พัฒนาเครื่องยึดกระดูกภายนอกแบบวงแหวนโดยใช้อะลูมิเนียมอัลลอยด์มาทำการขึ้นรูป*

วัสดุและวิธีการ*: ได้ทำการศึกษาถึงคุณภาพการผลิตและความแข็งแรงทางด้านโครงสร้างของเครื่องยึดกระดูกที่ได้ผลิตขึ้น*

ผลการศึกษา*: เส้นผ่าศูนย์กลางของรูที่ทำการเจาะมีค่า 6.5843872 +/- 0.0521594 มม. ระยะระหว่างรูที่กำหนดซึ่งสะท้อนถึงความแม่นยำของการเจาะรูมีค่าความแม่นยำสูงโดยมีค่าความเบี่ยงเบนมาตรฐานระหว่าง 0.1138 มม. ถึง 0.1870 มม. ความโค้งของวงแหวนมีค่า 0.2421376 +/- 0.12437977 มม. ไม่พบความแตกต่างอย่างมีนัยสำคัญของการเปลี่ยนแปลง ขนาดเส้นผ่าศูนย์กลาง ของวงแหวนก่อน และหลังทำการทดสอบที่ระดับความเชื่อมั่น 95% (ค่าเฉลี่ยความแตกต่างก่อนและหลังทำการทดลองคือ -0.3175 +/- 0.9692 มม.) ไม่พบความแตกต่างอย่างมีนัยสำคัญในระยะระหว่างวงแหวนคู่ปลายที่ระดับความเชื่อมั่น 99% (ค่าเฉลี่ยความแตกต่างก่อนและหลังทำการทดลองคือ 0.027917 +/- 0.366226 มม.) โครงสร้างของเครื่องยึดกระดูกมีการผิดรูปน้อยมากที่จุดแตกหัก โดยมีค่าความคลาดเคลื่อนโดยเฉลี่ย 4786.9 +/- 14.353 นิวตัน ซึ่งเกิดจากการยืดตัวของลวดและตัวยึดจับลวด ค่าความตึงมีค่า 127 นิวตัน/มม.*

สรุป*: เครื่องยึดกระดูกภายนอกแบบวงแหวนที่ผลิตโดยใช้อะลูมิเนียมอัลลอยด์มีความแข็งแรงเพียงพอที่จะใช้ในทางคลินิคได้*