นิพนธ์ต้นฉบับ • Original Article

การศึกษาความแข็งแรงในโครงสร้างของเครื่องยึดตรึงกระดูกนิ้วมือภายนอกที่สามารถปรับความยาวได้แบบใหม่ โดยเปรียบเทียบกับเครื่องยึดตรึงกระดูกนิ้วมือแบบอื่น

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Biomechanical Evaluation of Disposable Digital External Fixators (DDEFs) : A Comparative Study with New Design.

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หลักการและเหตุผล: ปัจจุบันกระดูกหักที่บริเวณนิ้วมือหลายรูปแบบ มีความจำเป็นต้องใช้เครื่องยึดตรึงกระดูกนิ้วมือทั้งชนิดที่ผลิตเพื่อการค้าและชนิดที่ใช้แล้วทิ้ง ซึ่งปัจจุบันมีราคาแพงมาก และยังไม่มีการศึกษาเปรียบเทียบความแข็งแรงของเครื่องยึดตรึงกระดูกนิ้วมือชนิดต่าง ๆ โดยเฉพาะชนิดที่ใช้แล้วทิ้ง ซึ่งทางคณะผู้วิจัยจึงได้คิดเครื่องยึดตรึงกระดูกนิ้วมือภายนอกชนิดใหม่ที่สามารถปรับความยาวได้ และมีราคาถูกกว่าชนิดอื่นที่มีใช้ในปัจจุบัน

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบความแข็งแรงในโครงสร้างของเครื่องยึดตรึงกระดูกนิ้วมือภายนอกชนิดใช้แล้วทิ้งรูปแบบต่างๆ

รูปแบบการศึกษา: การวิจัยเชิงทดลอง

สถานที่ทำการศึกษา: ภาควิชาออร์โธปิดิกส์ คณะแพทยศาสตร์ และคณะทันตแพทยศาสตร์ มหาวิทยาลัยขอนแก่น

วัสดุและวิธีการ: เครื่องยึดตรึงกระดูกนิ้วมือภายนอกชนิดใช้แล้วทิ้งทั้ง 3 ชนิดคือ Poorman, Godwin และ ALDiEs ถูกเตรียมไว้ 3 รูปแบบคือ ชนิดที่มีโครงด้านเดียวขนาดเล็ก ชนิดที่มีโครงด้านเดียวขนาดใหญ่ และชนิดที่มีโครง 2 ด้าน ชนิดละ 10 ตัวอย่าง แล้วยึดติดกับกระดูกเทียมจากนั้นจึงเข้าเครื่องทดสอบความแข็งแรงของวัสดุ(Loyed instrument) โดยจะเก็บข้อมูลเกี่ยวกับความแข็งแรงในโครงสร้าง, yield stress(YS) และ ultimate stress(US) จากโปรแกรมคอมพิวเตอร์ จากนั้นจึงนำข้อมูลมาวิเคราะห์โดยสถิติที่ใช้คือ ANOVA และ Post hoc LSD

ผลการศึกษา: ความแข็งแรงในโครงสร้างของเครื่องยึดตรึงกระดูกนิ้วมือแบบมีโครงด้านเดียวรูปแบบของ Poorman, Godwin

Background: There are many conditions of phalangeal fractures require digital external fixators both commercial and disposable. The biomechanical comparative studies of these fixators have not been reported especially for disposable digital external fixators (DDEFs). The new design, adjustable length digital external fixator (ALDiEs) was innovated

Purpose: To compare the biomechanical properties of various DDEFs.

Materials and Methods: Synbone; Swiss made, Model 4060 900285 were used to be the phalangeal model for the biomechanical testing. Three types of DDEs and their applications were tested. Ten samples of each type were fixed into phalangeal models. Biomechanical analyses were performed by material testing machine, Loyed Instrument interfaced with Windap data analysis software. The structural stiffness (SS), Yield stress (YS) and ultimate stress (US) both in compression and distraction forces were recorded. Statistical analysis was performed using ANOVA and a *post hoc* LSD.

Study design: Experimental study

Setting: Orthopedics department, Faculty of Medicine, Khon Kaen University

Results: The SS of one frame Poorman DDEFs, Godwin DDEFs and ALDiEs were 14.54, 14.83 and 12.43 N/mm. in orderly. The Godwin DDEFs had the highest SS

และ ALDiEs คือ 14.54, 14.83 และ 12.43 นิวตัน/มม. ตามลำดับ ซึ่งรูปแบบของ Godwin มีความแข็งแรงที่สุด (P<0.05) แต่เมื่อเปรียบเทียบ yield stress และ Ultimate stress ระหว่างเครื่องยึดตรึงชนิดโครงด้านเดียวพบว่าไม่มีความแตกต่างกันทางสถิติ ส่วนความแข็งแรงของเครื่องยึดตรึงฯที่มีโครง 2 ด้านชนิดของ Poorman, Godwin และ ALDiEs คือ 25.09, 35.23 และ 35.09 นิวตัน/มม.ตามลำดับ ซึ่งพบว่ารูปแบบของ Godwin มีความแข็งแรงมากที่สุดอย่างมีนัยสำคัญทางสถิติ ส่วนชนิดของ ALDiEs มี YS และ US สูงที่สุดอย่างมีนัยสำคัญทางสถิติ

วิจารณ์และสรุปผล: จากการศึกษาที่ผ่านมาพบว่า[4] เครื่องยึดตรึงกระดูกนิ้วมือชนิดที่ใช้แล้วทิ้งที่มีโครงด้านเดียวสามารถทนแรงได้เฉพาะเมื่อนิ้วอยู่เฉย ๆ โดยไม่ได้ใช้งาน ส่วนรูปแบบที่มีโครง 2 ด้านชนิดของ Godwin และ ALDiEs สามารถรับแรงขนาดที่มีการจับวัตถุเบา ๆ ได้ และจากการศึกษาไม่แนะนำให้ใช้รูปแบบของ Poorman ชนิดที่มีโครงด้านเดียวในการยึดตรึงกระดูกนิ้วมือเนื่องจากความแข็งแรงไม่เพียงพอ

(P<0.05). No statistical different in YS and US between the various one frame DDEFs. The SS of the two-frame group, the Poorman DDEFs, Godwin DDEFs and ALDiEs are 25.09, 35.23 and 35.09 N/mm in orderly. Godwin DDEFs had the highest SS (P<0.05). The two-frame of the ALDiEs have the highest YS and US (P<0.05). All ALDiEs were failed by deformation. All the Poorman DDEFs were failed by cemented fractures. The Godwin DDEFs were failed by pin-rod displacement.

Discussion and conclusions: According to the previous study[4]. All one frame DDEFs can resist only physiologic load but can't resist the load during pinching or light grip. From this study, we found that only two-frame of the ALDiEs and Godwin DDEFs could resist to loading force during pinching and light grip but couldn't resist to the force grip. Because of the low stiffness, one- frame of the Poorman DDEFs may not be appropriate fixation method for proximal phalangeal fractures.

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Introduction

Metacarpal and phalangeal fractures are the most common fracture of upper extremities[6]. Many types of fractures require external fixator such as severe comminuted fracture, bone loss and infected open fracture[1,8]. The commercial digital external fixators are expensive and not available in almost hospital in Thailand. Therefore, various types of disposable digital external fixators have been invented and applied to these situations. However, some of them are still expensive and not effective, for example, the Poorman type[4], which is expensive, because it use bone cement filled in plastic tube as a rod (Figure1-C) or Godwin type[2], using 2 ml. syringe as a rod, which is too bulky and no mechanical locking between the pin and the rod (Figure1-D). Moreover, the structural stiffness of these two types of DDEFs have not been reported. Therefore we innovated the new design of the external fixator using available instruments which are inexpensive and widely applicable. We called it çAdjustable Length Digital External Fixatoré or ALDiEs. This study aimed to evaluate the biomechanical properties of various types of disposable digital external fixators compared with our new design.

Materials and methods

Materials and equipment for making ALDiEs

For making ALDiEs, two K-wires, wires, pinnose pliers and wire cutter were required, The first step of the constitution was started by the two k-wires were drilled into the bone. The interpin distance(IPD) was measured (Figure 2-A). One k-wire was called static pin. The other one was called translating pin. The length of static pin was two times of IPD plus the length of measurement bar that you needed to compose. By using pin nose pliers, the static pin was bent as a hook at the end of k-wire (Figure2-B) then the second and third bending static pin were done in the sagittal plane as picture2-C. For the translating pin, the length of k-wire was two times of IPD and there were 3 steps of the bending. The first step was bending the K-wire in coronal plane (Figure2-D). The second step, the k-wire was bend at the distal end as a hook. The third step, to create the pin-rod junction, the pin was bend as figure 2-F. Finally, two k-wire were composed together by side to side pushing.

There were three wirings control in ALDiEs. The first one was the bending wire control, the second one was the compression-wire control and the third one was the

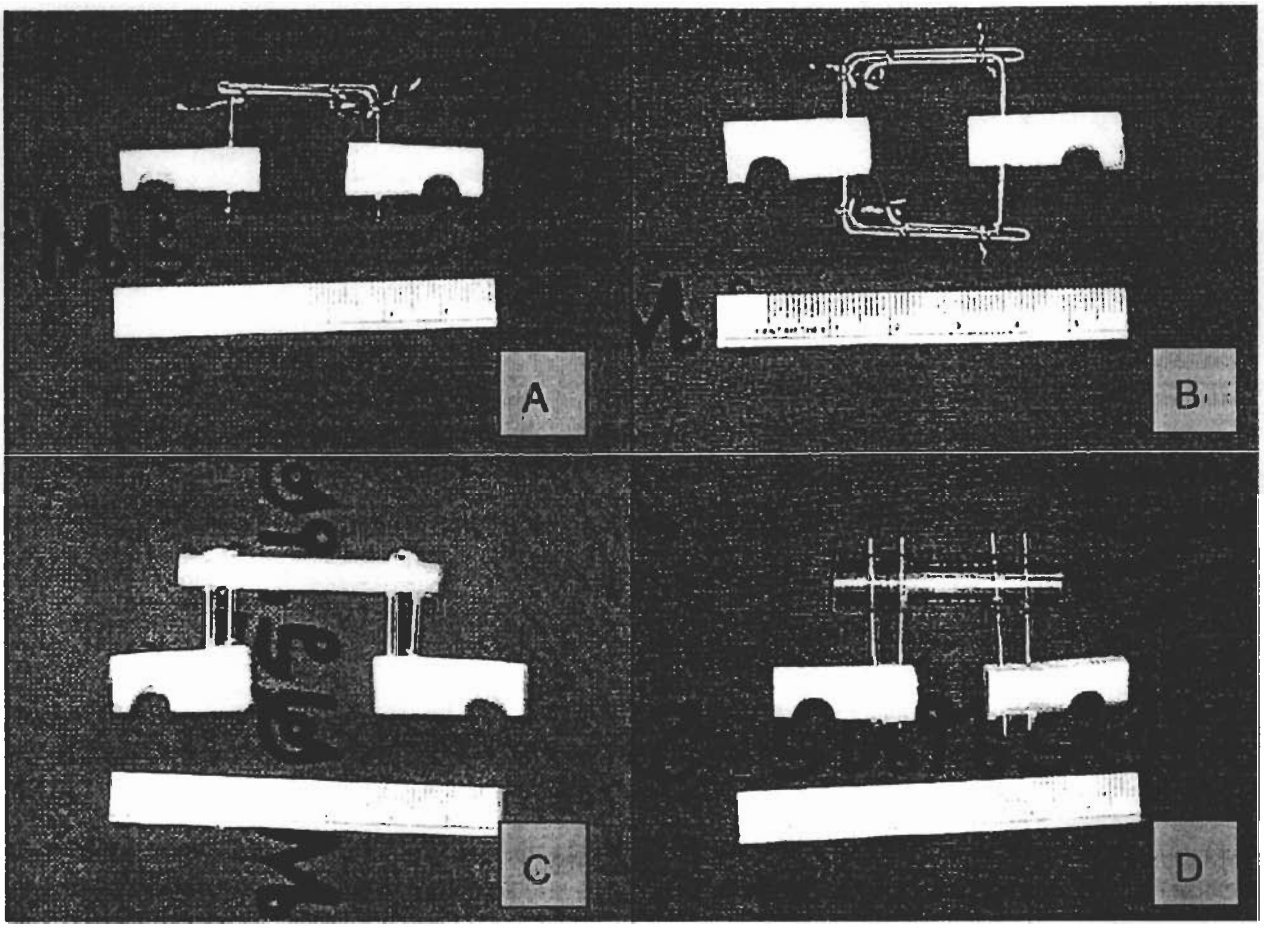

Figure 1: Various types of disposable digital external fixators were fixed with Synbone: A = small size-ALDiEs, B = 2frame-ALDiEs, C = large size-Poorman, D = Godwin

distraction-wire control (as picture 3). The compression and distraction-wire control could be applied base on the concept that if the wire loop provided the hook A moved to rod B, the compression effect of the system would be produced. On the other hand, if the wire loop provided the hook A moved to the hook C, the distraction effect of the system would be produced.

Preparation for biomechanical testing

Three types of disposable digital external fixators were prepared into 3 forms. The first one was the one-frame-small size group, which using the K-wire No. 1.25 and 25 mm. long. This model was for the middle phalangeal fixation. The second one was the one-frame-large size group, which using K-wire No. 1.6 and 40mm. long. This model was for the proximal phalangeal fixation. The last one was the two-frame-small size group, which using K-wire No. 1.25 and 25 mm. long. This model was for the unstable middle phalangeal fixation.

Ten samples were prepared for each form of each type. All of samples were fixed to phalangeal models, Synbone model 4060 900285. The distance between the rod and the phalangeal model was 10 mm.

The preliminary testing was performed. One sample of each type and their form were tested by the material testing machine, Loyed instrument, interfaced with Windap data analysis software. The load deformation curve were used for defining the elastic limit of each type of fixators.

After we known about the elastic limit of each sample. We performed the second testing by using ten samples of each types. By windap data analysis software, the structural stiffness of each forms and types were recorded and calculated by defining their range between 25-50% of elastic limit with five times repititive testing of each sample. Yield stress was defined at 0.02 elastic index or 2% strain[9] and the ultimate stress was recorded at the final testing for the system failure. The failure mode of each sample was recorded.

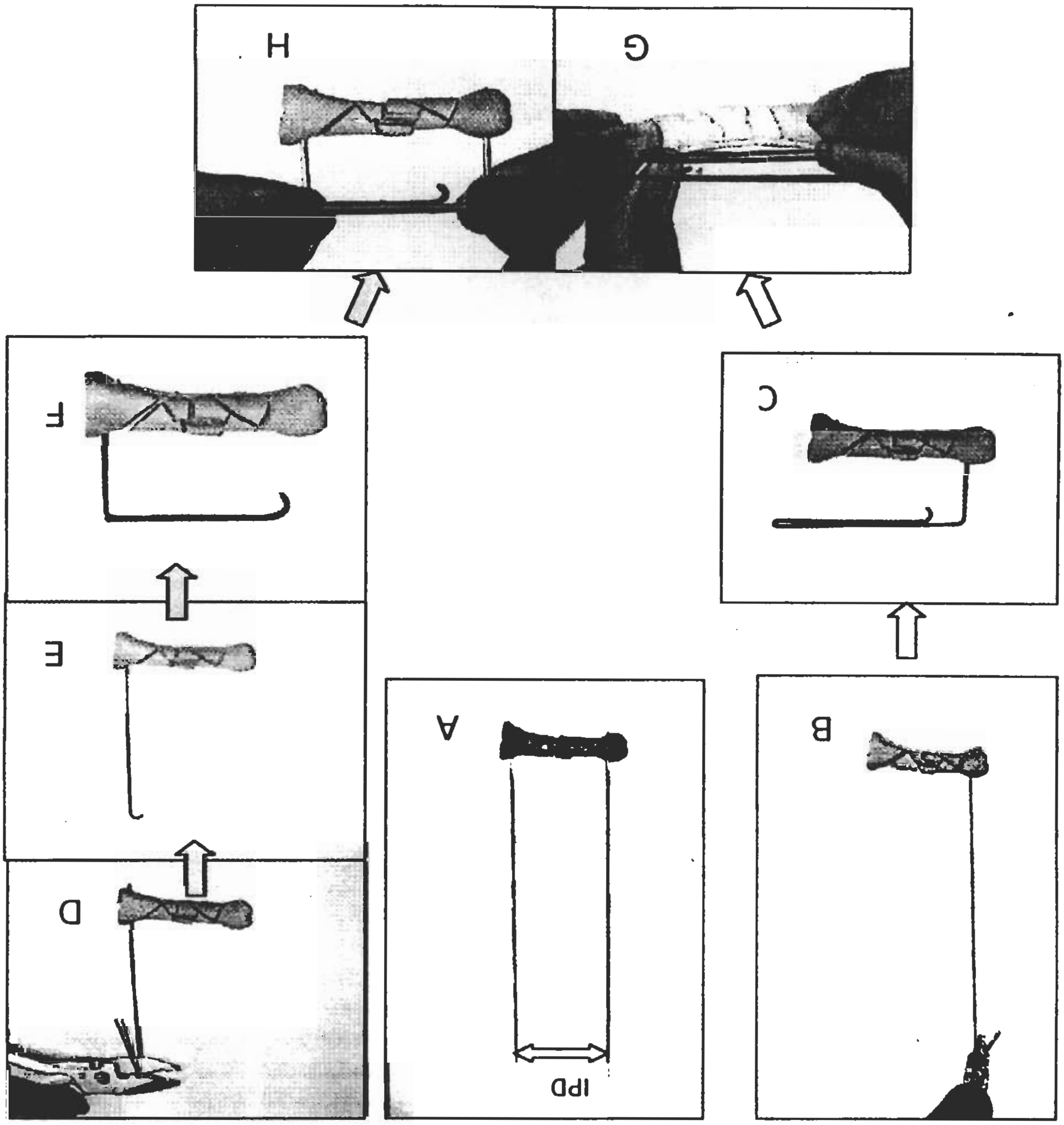

Figure 2: A = 2 K-wire were insret into bone and interpin distance was measured(IPD), Left pin is static pin, Right pin is translational pin, B = 1st step bending for static pin in sagittal plane, C = 2nd and 3rd step bending for static pin, D = 1st step bending of translating pin in coronal plane, E = 2nd step bending at the distal end as a hook and E = 3rd step bend at the pin rod junction, G,H = compose together

Statistical analysis

Sample sizes were calculated from the data of the preliminary testing by determining type I error 5%, type II error 20% and magnitude of difference 2 mm.. There were 7.34 samples for each groups.

The SPSS software were used for the statistical analysis. The significant difference was determine at $P<0.05$ level. Analysis of varience were used for comparing the structural stiffness, the yield stress and the ultimate stress within each groups. Post hoc multiple comparison Least Significant Different (LSD) were used to determine the pair difference.

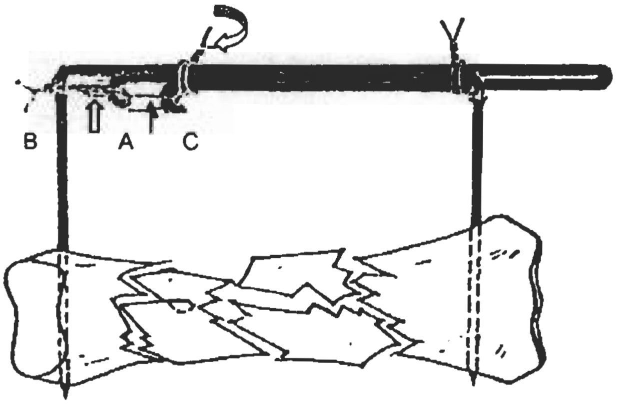

Figure 3: Picture show wiring control, rod B, hook A, hook C. Block arrow show compression wire, line arrow show distraction wire and curve arrow show bending wire control.

Results

In the one-frame-small size group, the structural stiffness of compression of the Poorman type, the Godwin type and ALDiEs were 14.54, 14.31 and 12.63 N/mm.(Table 1) in orderly, For the destructive testing, the structural stiffness of the Poorman type, the Godwin type and ALDiEs were 14.53, 12.24 and 15.31 N/mm respectively. The statistical analysis showed that the one frame-small size group, the Godwin type had the highest structural stiffness in distraction significantly ($P<0.05$) and the other pairs were not significance. ALDiEs had the highest yield and ultimate stress both in compression and distraction which were significant difference from the Poorman type ($P<0.05$) but not different from the Godwin type (as table 1).

In the two-frame group, the structural stiffness of distraction of the Poorman type, the Godwin type and ALDiEs were 25.56, 35.03 and 33.29 N/mm. The Godwin type had highest structural stiffness in distraction, which was significant difference from the other types, ALDiEs had the highest yield and ultimate stress, which is significant difference from the other types (Table 1)

In the model for the proximal phalangeal fixation, the one-frame-large size group, the structural stiffness of distraction of Poorman type and ALDiEs were 8.08 and 16.41 N/mm., which were significant difference ($P<0.05$). The yield and ultimate stress of ALDiEs were significantly higher than the Poorman type ($P<0.05$).

Mode of failures

All one frame ALDiEs in both sizes were failed by deformation. Both form of Poormans type, the one-frame and two-frames groups were failed by cemented fracture. The one-frame group of the Godwin type was failed by deformation in 6 samples and 4 samples were failed by the pin-rod displacement (as table 2). The most common of failures for the two-frames group of the Godwin type was the pin-rod displacement. Others were failed at bone-pin junction and bone-machine junctions.

Discussion

In this study, we classified disposable digital external fixator into two models. The first one was the model for middle phalangeal fixation, which were the one-frame-small size and two- frames groups. All types of disposable digital external fixators can be applied into these forms. The second one was the model for proximal phalangeal fixation, which was the one-frame-large size group. The Godwin

Table 1 Biomechanical properties of disposable digital external fixators

TYPES	STIFFNESS(N.)		YIELD (N./mm.)		ULTIMATE LOAD (N.)	
	Compression	Distraction	Compression	Distraction	Compression	Distraction
Model for Middle Phalangeal fixations						
1. Poorman : S	14.54 ±0.87	14.53±0.65	25.13±1.03	17.80±1.28	33.04 ±3.88	25.23 ±6.35
2. ALDiEs : S	12.63±0.87	12.24±1.34	25.56±5.79	24.12±3.94 U	31.99±7.9U	32.19 ±5.59U
3. Godwin	14.31±0.98	15.31±0.89*	25.42±3.73	22.78±2.51	25.42±3.78	28.61±8.18
4. Poorman : 2frame	25.09±0.99	25.56±1.32	59.30±2.80	50.38±3.41	88.25±4.88	67.98 ±6.95
5. ALDiEs : 2frame	35.09±2.51	33.29±2.40	80.04±4.61*	88.58±4.08*	126.64±12.04*	131.36 ±8.85*
6. Godwin : 2frame	35.23±1.42	35.03±1.05*	69.38±4.14	82.54±6.30	123.64±18.04	131.36±8.42
Model for Proximal Phalangeal fixations						
1. Poorman : L	8.54±0.98	8.08±1.25	26.03±1.51	26.03±1.29	38.81±3.32	30.84±8.01
2. ALDiEs : L	15.46±1.35	16.41±1.73*	34.17±2.89	25.53±2.19	41.19±2.94	38.50±6.04

S = small size, L=large size

** = significance different from other types, † = significant difference from Poorman type but not from Godwin type*

Table 2 Mode of failures

Types	Deformation	Cement fractures	Pin-Rod displacement	Bone-Pin junction	Bone-Machine junction
Model for Middle Phalangeal fixations					
1. Poorman : S	-	10	-	-	-
2. ALDiEs : S	10	-	-	-	-
3. Godwin	6	-	4	-	-
4. Poorman : 2frames	-	10	-	-	-
5. ALDiEs : 2frames	7	-	-	1	2
6. Godwin : 2frames	2	-	4	3	1
Model for Proximal Phalangeal fixations					
1. Poorman : L	-	10	-	-	-
2. ALDiEs : L	10	-	-	-	-

S = small size, L=large size

type could not be modified into this group because it uses 2 ml. syringe as a rod and the length of the syringe is 3 cm. Therefore, in these model we could not modifed into the two-frame group. However, in clinical practice, the two-frame digital external fixator could not be used in this area because there are no enough space.

According to the Ann'study, all one frame disposable digital external fixator have adequate stability for the middle phalangeal fracture fixation. Because it can resist physiologic load and provide early motion of the finger joints but it can not allow for the light grip. From our study, all two-frame disposable digital external fixators had adequate stability for the middle phalangeal fixation. For the biomechanical stand point, the two-frame disposable digital external fixators could provide early motion of the finger joints and light grip of the hand but not for the force grip. For the proximal phalangeal fixation model, we found that only ALDiEs had adequate stability.

In the cost-consideration AlDiEs was the cheapest DDEFs, it was 50 times cheaper than commercial type and 10 time cheaper than Poorman type. It is a dynamic fixator, which can adjust the length postoperatively and can be produced the compression and distraction force to the fracture site.

The proposed clinical applications of the ALDiEs when compared with other devices' applications[3,5,7]. The application of the two-frame fixation can be used to adjust the angulation and the length simultaneously by compress one side and distract another side. The distraction effect of the ALDiEs may be used for distraction soft tissue after osteotomy, in case of malunion, to keep the length of the digit. There may have some roles in simple fracture, because it may not produce the cortical necrosis at the fracture site like cross k-wire or interosseous wiring and may produce the compression force at the fracture site. So it may enhance the bone healing particularly in the case of delayed union, however, these applications require further clinical studies.

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