**Postoperative accuracy analysis of three-dimensional corrective osteotomy for cubitus
varus deformity using a custom-made surgical guide based on computer simulation**

Running title: Accuracy of three-dimensional humeral corrective osteotomy

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Disclaimer

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28

Running Title: Accuracy of three-dimensional humeral corrective osteotomy

Abstract

Background

For correcting cubitus varus deformity resulting from supracondylar fracture of the humerus, we developed an operative method using a custom-made surgical guide, designed on the basis of three-dimensional (3D) computer simulation with computed tomography (CT) data. The purpose of this study was to investigate the postoperative accuracy of this system in clinical cases.

Methods

Subjects included 17 consecutive patients (13 males and 4 females) with cubitus varus deformity after supracondylar fracture. Patients underwent 3D corrective osteotomy using a custom-made surgical guide. Postoperative CT scan was performed after bone union diagnosis on plain radiographs, and postoperative 3D bone models were compared with preoperative simulation using surface registration technique. Additionally, we evaluated radiographic parameters (humerus-elbow-wrist angle and tilting angle) and range of elbow motion at the most recent follow-up.

Results

Mean errors in 3D corrective osteotomy were $0.6^{\circ} \pm 0.7^{\circ}$ in varus–valgus rotation, $0.8^{\circ} \pm 1.3^{\circ}$ in flexion–extension rotation, $2.9^{\circ} \pm 2.8^{\circ}$ in internal–external rotation, 1.7 ± 1.8 mm in anterior–posterior translation, 1.3 ± 1.8 mm in lateral–medial translation, and 7.1 ± 6.3 mm in proximal–distal translation. Mean humerus-elbow-wrist angle on plain radiographs of the affected side were 15° in varus before surgery and improved to 6° in valgus after surgery. Mean tilting angle of the affected side were 31° before surgery and improved 40° after surgery.

54 **Conclusion**

55 3D correction of cubitus varus deformity was performed accurately within the allowable error
56 limits.

57 **Level of evidence:** Level IV, Case Series, Treatment Study

58 **Keywords:** Accuracy analysis; three-dimensional; corrective osteotomy; cubitus varus;
59 custom-made guide; computer simulation

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Introduction

Cubitus varus deformity most commonly comes from supracondylar fracture of the humerus,^{7,26,39} and consists of three-dimensional (3D) deformity, which may be associated with varus, extension and internal rotational deformity.³³ Moderate to severe deformities lead to unsightly appearance, limited range of elbow flexion, joint instability, and tardy nerve palsy.^{1,11,16,17,24,25} To solve these problems, several methods of corrective osteotomy have been performed.^{3,4,5,6,7,8,9,14,15,32,37} However, conventional corrective osteotomy can leave a certain degree of deformity, because it is not always easy to correct complex 3D bone deformities with preoperative planning based on plain radiographs and free-hand operation.^{9,10,15,30,38} Since 2003, we have been developing an original computer program that employs 3D imaging to simulate anatomical correction of the upper limb deformity based on computed tomography (CT) data.^{18,21,22,34} In this system, we used a custom-made osteotomy and reduction guides to reproduce preoperative simulation in the actual surgical treatment of cubitus varus deformities, malunited distal radial fractures and forearm fractures.^{18,21,22} Internal fixation of the osteotomy site was performed using Kirschner wires or bone plates while the correction was being temporarily maintained.

In a previous retrospective case series, we reported on the clinical results of 30 patients who underwent 3D corrective osteotomy using a computer simulation-based custom-made surgical guide and confirmed improved upper limb appearance evaluated by radiographic parameters.³⁴ However, detailed 3D accuracy of the osteotomy, measured with CT data, remains to be determined. The purpose of this study was to determine the accuracy of this system in clinical cases using pre- and postoperative 3D CT bone models.

Materials and Methods

Subjects

Our institutional review board approved this study. Between 2003 and 2013, 43 consecutive patients with cubitus varus deformity, all resulting from malunion of the distal humerus supracondylar fracture were treated with 3D corrective osteotomy using a custom-made surgical guide, based on computer simulation, derived from pre-operative 3D CT models. Mean age at the initial injuries was 6.4 years (range, 3-11 years). Seventeen of these patients (13 males and 4 females) underwent postoperative CT scan, and they were reviewed retrospectively with a mean follow-up period of 24.0 months (range, 8–43 months) (Table 1). Part of clinical results of these patients was already provided in a previous study (case 1-10).³⁴ Mean patient age at corrective osteotomy was 17.6 years (range, 8–45 years) and mean duration from initial injury to surgery was 135 months (range, 12–480 months). Of the 17 patients, 13 had been treated with cast immobilization for the initial fracture, 3 had undergone percutaneous pinning and 1 had undergone open reduction and internal fixation with Kirschner wire. All patients had unilateral deformity of the elbow and complained of an unsightly physical appearance (Fig. 1). In addition to appearance, 4 patients (cases 1, 7, 12, and 15) complained of restricted elbow flexion. Two patients (cases 1 and 7) complained of hyperextension of the elbow greater than 20° compared with the unaffected side. One case with long duration of deformity (case 4) was associated with varus instability of the elbow joint.

Image acquisition and preoperative simulation

Bilateral upper limbs were scanned in the maximum forearm supination using a CT scanner (LightSpeed Ultra 16; GE Healthcare, Waukesha, WI, USA) with a low-radiation dose technique.^{18,27,33} Slice thickness was 1.25 mm. We created 3D bone surface models of the bilateral humerus, radius, and ulna from digital data and evaluated the deformity and simulated preoperative planning using commercially available software (Bone Viewer® and Bone Simulator®, Orthree Co., Ltd, Osaka-City, Japan). Deformity of the distal humerus was quantified three-dimensionally using surface registration technique (Fig. 2).^{2,12} We then simulated closing wedge osteotomy for angular correction, followed by rotational correction on the osteotomy plane using mirror images of the contralateral unaffected bone as the template based on the deformity evaluation (Fig. 3). The distal segment of the humerus was repositioned medially on the osteotomy plane to align the lateral cortical bone line and minimize prominence of the lateral condyle (Fig. 3, D). For case 6 with gross internal rotation deformity, we decreased rotational correction leaving a residual rotational deformity less than 15° to preserve adequate contact area at the osteotomy site for bony union.³⁴

Design and manufacturing of the custom-made surgical guide

To reproduce preoperative simulation in the actual surgery, we developed an operative method using a custom-made osteotomy and reduction guides that was designed on the basis of a preoperative 3D computer simulation^{13,18,21,22,28,34} and manufactured with medical grade plastic materials using rapid prototype technology.

Surgical methods

Through a lateral approach in 7 cases or posterior approach in 10 cases, we exposed the distal humerus. The custom-made osteotomy guide was placed on the posterolateral

surface of the distal humerus and fixed with Kirschner wires 1.5–2.0 mm in diameter through metal sleeves mounted on the guide after confirming all edges of the guide contacted the bone surface exactly. Wedge-shaped osteotomy was performed through the slit using a bone saw (Fig. 4, B and F). Deformity was corrected by bringing the Kirschner wires parallel after removing the wedge-shaped bone fragment (Fig. 4, C, D, G, and H). While maintaining correction with the reduction guide holding the Kirschner wires in place, bone segments were fixed using additional Kirschner wires placed across the osteotomy (4 cases), additional tension-band wiring (6 cases) for patients with open physes, or bone plates for those with closed physes (7 cases). After surgery, a long arm splint was applied for 1–2 weeks for the plate fixation group and 3–4 weeks for the Kirschner wire fixation group, with 90° elbow flexion. After removal of immobilization, active and passive range of motion exercise was initiated. More details of simulation and surgical techniques are described in previous studies.^{13,18,21,22,28,34}

Radiographic and clinical evaluation

All patients underwent radiographic and clinical evaluations before surgery and at the most recent follow-up examination. Bone union was considered to be achieved when the osteotomy gap had disappeared and trabecular bone continuity was confirmed on plain radiographs. We measured the humerus-elbow-wrist angle, which is defined by the longitudinal axis of the humerus and a line passing through the proximal and distal midpoints of the radius and ulna on anteroposterior radiographs.^{31,33,34} We also measured the tilting angle, which is defined as the anterior tilt of the articular condyles with respect to the long axis of the humerus on the lateral radiographs.^{33,34} For clinical evaluation, we measured the range of elbow flexion–extension using a goniometer, with the forearm in neutral position.

Accuracy evaluation

Postoperative CT scan of the affected upper extremity was performed after bone union was confirmed on plain radiographs. The postoperative 3D bone model was compared with the preoperative simulated goal model. Error in the corrective surgery was calculated by superimposing the CT bone model proximally and distally using surface registration technique (Fig. 5, A and B).^{2,12} To quantify the 3D error, the modified orthogonal reference system of the humerus that was originally advocated by the International Society of Biomechanics was used (Fig. 5, C).^{29,40} The difference between the preoperative computer simulation and the postoperative result was calculated with 6 degrees of freedom based on the local coordinate system using the Euler angle method.^{19,20,33} The intra- and inter-observer reliabilities of this evaluation technique were demonstrated to be very high, at 0.90–0.98 and 0.92–0.96, respectively, in the previous study.³³

Statistical analysis

All data were expressed as mean $\pm$ standard deviation (SD). Mean and SD of accuracy data were calculated using absolute values of errors. The significance of differences between the preoperative and postoperative radiographic parameters and range of elbow motion were calculated using the Wilcoxon signed-rank sum test. A p value of less than 0.05 was considered significant.

Results

Radiographic and clinical outcomes

In all patients, the custom-made osteotomy guides closely fitted the preplanned bone surface, and surgery was performed as preoperatively simulated (Fig. 6). Bone union was completed at a mean of 4.7 months postoperatively (range, 2–12 months). The mean preoperative humerus-elbow-wrist angle and tilting angle of the affected side were $15.4^{\circ} \pm 8.5^{\circ}$ in varus and $30.5^{\circ} \pm 12.5^{\circ}$, respectively. These were significantly improved postoperatively to $6.3^{\circ} \pm 5.6^{\circ}$ in valgus and $39.6^{\circ} \pm 5.1^{\circ}$, respectively (Table 1, $p < 0.05$). The range of elbow motion was $129.4^{\circ} \pm 12.5^{\circ}$ in flexion and $9.4^{\circ} \pm 14.1^{\circ}$ in extension preoperatively, and $139.1^{\circ} \pm 5.9^{\circ}$ ($p < 0.01$) in flexion and $3.5^{\circ} \pm 5.2^{\circ}$ ($p = 0.12$) in extension postoperatively (Table 1). Hyperextension of the elbow was observed in 2 cases (case 1, 40° and case 7, 30°) preoperatively and was normalized postoperatively.

Accuracy data

Postoperative CT assessment was performed at a mean of 6.3 months (range, 2–9 months). The mean angular and rotational errors were $0.6^{\circ} \pm 0.7^{\circ}$ (range, $<0.1^{\circ}$ – 2.1°) in varus–valgus direction, $0.8^{\circ} \pm 1.3^{\circ}$ (range, $<0.1^{\circ}$ – 4.6°) in flexion–extension direction, and $2.9^{\circ} \pm 2.8^{\circ}$ (range, $<0.1^{\circ}$ – 9.4°) in internal–external rotational direction (Table 1). The mean translational errors were 1.7 ± 1.8 mm (range, <0.1 – 6.2 mm) in anterior–posterior direction, 1.3 ± 1.8 mm (range, 0.1 – 6.2 mm) in lateral–medial direction, and 7.1 ± 6.3 mm (range, <0.1 – 20.6 mm) in proximal–distal direction. Translation in the distal direction (a negative translation y value) greater than 10 mm was observed in cases 5, 6, 14, and 15 with open physes, which may include longitudinal humerus growth. Mean translation and SD along y-axis in closed physes cases (cases 2, 4, 8, 9, 10, 11, and 13) was 2.0 ± 3.0 mm.

Discussion

Previous studies investigating corrective osteotomy for cubitus varus deformity, based on 2D preoperative planning, in which the amount of correction is determined by the preoperative radiographs and rotational range of shoulder motion, demonstrate the rate of residual deformity in varus is 5%–9% in the distal humerus.^{9,15} Furthermore, the reported residual postoperative difference in the carrying angle between the operated and normal sides is up to 30°.^{3,31} To improve surgical accuracy of deformity correction for this condition, a surgical method using a computer simulation-based custom-made surgical guide, has been developed with improved radiographic and clinical outcomes.^{34,36,41} However, in these reports the 3D accuracy of the osteotomy is not clear.

In the current study using both pre-operative and post-operative 3D CT data, the mean rotational error in varus–valgus rotation, corresponding to the difference in the carrying angle between the postoperative affected side and normal side, was $0.6^{\circ} \pm 0.7^{\circ}$, which was considerably small compared with previous studies.^{3,8,15} However, the maximum value of error for internal–external rotation, anterior–posterior translation, proximal–distal translation, and lateral–medial translation, were 9.4°, 6.2 mm, 20.6 mm, and 6.2 mm, respectively, which were relatively large. In closing wedge osteotomy, correction of angular deformity, in terms of varus–valgus and flexion–extension, is mostly determined by wedge osteotomy. However, rotation and translation can suffer from loss of correction during internal fixation. Errors in distal directional translation in open physes may reflect bone growth. Thus, in the current study, relatively large errors in internal–external rotation and anterior–posterior and lateral–medial directional translation may result from loss of correction during internal fixation. On the other hand, maximum errors in varus–valgus and flexion–extension were 2.1° and 4.6°, respectively, indicating that the osteotomy using a custom-made guide was performed quite accurately for angular correction. Recently, we have developed a custom-made bone plate in

combination with a custom-made osteotomy guide that exactly fits the bone surface after correction and enables simultaneous accurate reduction and fixation.²⁹ This could be a future solution to improve rotational and translational correction in adult cases.

The current study has several limitations. The number of cases was small. We did not perform a controlled study to compare our 3D method with the conventional 2D method. Furthermore, duration between surgery and CT scanning varied among cases, ranging from 2 to 9 months. Therefore, postoperative bone remodeling and bone growth influenced the measurements. The study included both child and adult cases, in which surgical methods were not exactly same. The custom-made surgical guide may not be suitable in some children cases with tiny elbow. Although many of the patients underwent surgery for cosmetic purposes, patient satisfaction was not included in this study. Shortcomings of our method include the need for specialized computer software, the time and cost of simulation, and the design and manufacturing of the custom-made guides. We used commercially available computer software and preoperative simulation requires 2–3 h. The approximate cost for a custom-made guide was considered to be similar to that for total knee arthroplasty,^{23,35} ranging from \$650 to \$1200 U.S.D. We expect that technological development will soon reduce the time and cost required. Although the osteotomy guide is only available at our institution at this point, we are now preparing to supply it through a third party.

240 **Conclusion**

241 In the current study, to determine accuracy analysis of our system, correction of
242 varus–valgus and flexion–extension deformity was performed accurately within the allowable
243 error limits. Although correction of internal–external rotation and translation deformity has
244 room for improvement, we believe this system has advantages and will be one of the standard
245 treatment options for corrective osteotomy of cubitus varus deformity.

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Figure and Table Legends

Figure 1 Preoperative photos and radiographs of case 16. A 9-year-old boy presented with a left cubitus varus deformity (A). Humerus-elbow-wrist angle and tilting angle were 15° in varus (B) and 25° (C), respectively.

Figure 2 3D bone models of a left cubitus varus deformity constructed from CT data. Deformity was evaluated by superimposing the proximal segment of the affected humerus onto the contralateral unaffected humerus and quantified three-dimensionally; varus (A), extension (B), and internal rotation (C).

Figure 3 Process of preoperative computer simulation. Anterior view of the left elbow. The distal and proximal osteotomy plane defined by the correction amount was set (A). The wedge-shaped bone was cut and removed (B). 3D deformity was corrected (C) and the distal segment was repositioned medially to prevent lateral condyle prominence (D).

Figure 4 Process of surgery using the custom-made surgical guide. Posterolateral view (A-D) and lateral view (E-H). The custom-made osteotomy guide was secured on the posterolateral surface of the distal humerus with Kirschner wires and wedge-shaped osteotomy was performed through the slits (B and F). The wedge bone (blue fragment) was removed (C and G). Deformity was corrected by making the Kirschner wires parallel with the custom-made reduction guide (D and H).

Figure 5 Accuracy evaluation. Superimposing the bone models proximally (A) and distally

(B). The orthogonal reference system of the right humerus was set according to the International Society of Biomechanics reference system³³ (C). The origin is the midpoint of the line connecting the lateral and medial epicondyle tips of the humerus. The y-axis is the line connecting origin and center of humeral head. The z-axis is the line through lateral epicondyle on plane perpendicular to the y-axis. The x-axis is the line perpendicular to yz plane. Clockwise rotation was defined as a positive angle. Rotation around the x-axis produced varus (+)/valgus (-), rotation around the y-axis produced internal rotation (+)/external rotation (-), and rotation around z-axis produced flexion (+)/extension (-).

Figure 6. Postoperative photos and radiographs of Case 16. The varus deformity has been corrected (A). The osteotomy site was fixed using tension-band wiring (B and C). Humerus-elbow-wrist angle and tilting angle improved to 6° in valgus (B) and 35° (C), respectively, after surgery.

Table 1 SD, standard deviation. *Negative values means varus deformity. †Rotation around the x-axis produces varus (+) and valgus (-), rotation around z-axis produces flexion (+) and extension (-), and rotation around y-axis produces internal (+) and external rotation (-). ‡Translation along the x-axis produces anterior (+) and posterior (-), translation along z-axis produces lateral (+) and medial (-), and translation along y-axis produces proximal (+) and distal (-). §Mean and SD of accuracy data were calculated using absolute values of errors.

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Table 1. Patient data, postoperative results, and accuracy analysis

Patient Data									Clinical Findings			Radiological Findings									Accuracy Data					
Case	Age at Surgery (y)	Gender	Side	Initial Treatment	Duration of Deformity (mo)	Internal Fixation	Time from Surgery to CT (mo)	Follow-up period (mo)	Range of Elbow Motion (Flexion/Extension) (degrees)			Time to Bone Union (mo)	Humerus-Elbow-Wrist Angle (degrees)*			Tilting Angle (degrees)			Errors							
									Preoperative	Postoperative	Unaffected Side		Preoperative	Postoperative	Unaffected Side	Rotaion (degrees)†			Translation (mm)‡							
																X (varus-valgus)	Z (flexion-extension)	Y (internal-external rotation)	X (anterior-posterior)	Z (lateral-medial)	Y (proximal-distal)					
1	8	M	L	Cast	54	K	5	28	100/40	145/10	145/10	3	-18	7	7	13	35	40	-0.8	1.6	3.4	2.3	1.2	-9.2		
2	13	M	R	Cast	96	Plate	7	22	140/0	140/0	145/0	4	-20	8	8	41	40	45	-0.1	0.1	-0.6	0.9	0.7	-8.0		
3	9	M	R	Cast	72	K+TBW	6	34	140/20	150/10	150/10	3	-12	7	5	28	38	42	2.1	-0.1	-1.4	0.8	3.8	-8.6		
4	45	M	L	Cast	480	Plate	2	43	135/-5	130/5	140/5	6	-20	6	9	35	44	45	-0.2	-0.1	-1.0	-2.1	0.3	-3.8		
5	9	M	R	Cast	72	K	6	15	135/5	135/5	140/5	2	-40	-10	0	28	33	40	0.4	0.8	1.5	5.4	-6.2	-18.6		
6	10	F	L	Cast	84	K+TBW	9	36	140/15	150/15	150/15	3	-20	5	5	20	37	40	0.3	0.1	0.4	0.2	-1.0	-13.4		
7	8	M	L	Cast	12	K	7	26	110/30	140/0	140/10	3	-15	6	8	0	30	35	-0.4	0.2	1.8	0.0	0.1	9.9		
8	17	F	R	Cast	144	Plate	9	28	125/20	140/10	140/10	6	-10	5	8	40	45	47	0.0	0.0	0.0	0.0	0.1	0.0		
9	33	M	L	Cast	336	Plate	6	17	130/15	140/5	140/5	9	-8	10	13	40	45	48	0.0	0.2	9.4	0.1	-0.1	-0.2		
10	24	F	L	Cast	192	Plate	7	28	140/5	140/0	145/10	7	-15	12	13	37	45	43	0.0	2.7	3.6	-6.2	-0.5	-0.1		
11	34	M	L	Pinning	348	Plate	9	28	130/-5	130/0	140/0	7	-6	9	10	45	45	45	1.1	0.3	0.3	1.2	4.7	1.1		
12	11	F	L	Cast	12	K	4	27	120/10	140/0	145/0	3	-7	12	12	41	42	43	0.0	0.2	0.9	0.5	0.1	5.3		
13	33	M	L	Cast	300	Plate	6	26	135/0	130/0	135/0	12	-25	4	5	46	46	42	0.8	-2.2	2.2	-3.7	0.8	0.7		
14	12	M	R	Pinning	12	K+TBW	8	19	130/-15	135/-5	140/5	3	-10	10	15	17	37	42	1.3	-0.1	7.5	0.8	-1.0	-11.0		
15	12	M	L	ORIF (K)	12	K+TBW	8	15	110/20	140/5	140/15	2	-5	-3	-3	30	43	42	-0.5	0.2	3.7	-1.2	-1.6	-20.6		
16	9	M	L	Cast	40	K+TBW	4	8	140/10	140/0	140/15	3	-15	6	7	25	35	30	2.0	4.6	3.8	1.4	-0.4	-5.4		
17	13	M	L	Pinning	36	K+TBW	4	8	140/-5	140/0	145/5	4	-15	13	15	32	34	35	0.2	-0.2	7.5	1.4	-0.1	-4.0		
Mean	17.6				135.4		6.3	24.0	129.4/9.4	139.1/3.5	142.4/7.1	4.7	-15.4	6.3	8.1	30.5	39.6	41.4	0.6§	0.8§	2.9§	1.7§	1.3§	7.1§		
SD	11.6				144.3		2.0	9.5	12.5/14.1	5.9/5.2	4.0/5.3	2.8	8.5	5.6	4.9	12.5	5.1	4.6	0.7§	1.3§	2.8§	1.8§	1.8§	6.3§		