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

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**Background:** For correction of cubitus varus deformity resulting from supracondylar fracture of the humerus, we developed an operative method with use of a custom-made surgical guide, designed on the basis of 3-dimensional (3D) computer simulation with computed tomography 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 with use of a custom-made surgical guide. Postoperative computed tomography scan was performed after bone union diagnosis on plain radiographs, and postoperative 3D bone models were compared with preoperative simulation by surface registration technique. In addition, 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, $1.7 \pm 1.8$ mm in anterior-posterior translation, $1.3 \pm 1.8$ mm in lateral-medial translation, and $7.1 \pm 6.3$ mm in proximal-distal translation. The mean humerus-elbow-wrist angle on plain radiographs of the affected side was $15^\circ$ in varus before surgery and improved to $6^\circ$ in valgus after surgery. The mean tilting angle of the affected side was $31^\circ$ before surgery and improved to $40^\circ$ after surgery.

**Conclusion:** The 3D correction of cubitus varus deformity was performed accurately within the allowable error limits.

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

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**Keywords:** Accuracy analysis; three-dimensional; corrective osteotomy; cubitus varus; custom-made guide; computer simulation
Cubitus varus deformity most commonly comes from supracondylar fracture of the humerus and consists of three-dimensional (3D) deformity, which may be associated with varus, extension, and internal rotational deformity. Moderate to severe deformities lead to unsightly appearance, limited range of elbow flexion, joint instability, and tardy nerve palsy. To solve these problems, several methods of corrective osteotomy have been performed. 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. Since 2003, we have been developing an original computer program that employs 3D imaging to simulate anatomic correction of the upper limb deformity based on computed tomography (CT) data. In this system, we used a custom-made osteotomy and reduction guide to reproduce preoperative simulation in the actual surgical treatment of cubitus varus deformities, malunited distal radial fractures, and forearm fractures. Internal fixation of the osteotomy site was performed with 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 with a computer simulation–based custom-made surgical guide and confirmed improved upper limb appearance evaluated by radiographic parameters. 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 with use of preoperative and postoperative 3D CT bone models.

Materials and methods

Subjects

Between 2003 and 2013, 43 consecutive patients with cubitus varus deformity, all resulting from malunion of a distal humerus supracondylar fracture, were treated by 3D corrective osteotomy with a custom-made surgical guide, based on computer simulation derived from preoperative 3D CT models. The 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 I). Part of the clinical results of these patients has already been provided in a previous study (cases 1-10). The mean age of the patients at corrective osteotomy was 17.6 years (range, 8-45 years), and the 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 a 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 maximum forearm supination by a CT scanner (LightSpeed Ultra 16; GE Healthcare, Waukesha, WI, USA) with a low-radiation dose technique. 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 with commercially available software (Bone Viewer and Bone Simulator; Orthree Co, Ltd, Osaka-City, Japan). Deformity of the distal humerus was quantified 3-dimensionally by surface registration technique (Fig. 2). We then simulated closing wedge osteotomy for angular correction, followed by rotational correction on the osteotomy plane with use of 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 to 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 <15° to preserve adequate contact area at the osteotomy site for bone union.

Design and manufacturing of the custom-made surgical guide

To reproduce preoperative simulation in the actual surgery, we developed an operative method that uses a custom-made osteotomy and reduction guides designed on the basis of a preoperative 3D computer simulation and manufactured with medical-grade plastic materials by 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 posterosuperior surface of the distal humerus and fixed with Kirschner wires 1.5 to 2.0 mm in diameter through metal sleeves mounted on the guide after confirmation that all edges of the guide contacted the bone surface exactly. Wedge-shaped osteotomy was performed through the slit with a bone saw (Fig. 4, B and F). Deformity was corrected by bringing the Kirschner wires parallel after removal of the wedge-shaped bone fragment (Fig. 4, C, D, G, and H). While correction was maintained with the reduction guide holding the Kirschner wires in place, bone segments were fixed with 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 to 2 weeks for the plate fixation group and 3 to 4 weeks for the Kirschner wire fixation group, with 90° of elbow flexion. After removal of immobilization, active and passive
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SD, standard deviation; ORIF, open reduction and internal fixation; K, K-wire; TBW, tension band wiring.

* Negative values mean varus deformity.

† Rotation around the x-axis produces varus (+) and valgus (−), rotation around the z-axis produces flexion (+) and extension (−), and rotation around the y-axis produces internal (+) and external (−) rotation.

† Translation along the x-axis produces anterior (+) and posterior (−), translation along the z-axis produces lateral (+) and medial (−), and translation along the y-axis produces proximal (+) and distal (−).

§ Mean and SD of accuracy data were calculated by absolute values of errors.
range of motion exercise was initiated. More details of simulation and surgical techniques are described in previous studies.13,18,19,22,28,34

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 by 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 by 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 by the Euler angle method.20,21,33 The intraobserver and interobserver reliabilities of this evaluation technique were demonstrated to be very high, at 0.90 to 0.98 and 0.92 to 0.96, respectively, in the previous study.33

Statistical analysis

All data were expressed as mean ± standard deviation. Mean and standard deviation of accuracy data were calculated by absolute values of errors. The significance of differences between the preoperative and postoperative radiographic parameters and range of elbow motion were calculated by the Wilcoxon signed rank sum test. A P value of < .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° ± 8.5° in varus and 30.5° ± 12.5°, respectively. These were significantly improved postoperatively to 6.3° ± 5.6° in valgus and 39.6° ± 5.1°, respectively (Table I; \(P < .05\)). The range of elbow motion was 129.4° ± 12.5° in flexion and 9.4° ± 14.1° in extension preoperatively and 139.1° ± 5.9° (\(P < .01\)) in flexion and 3.5° ± 5.2° (\(P = .12\)) in extension postoperatively (Table I). 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° ± 0.7° (range, <0.1°-2.1°) in varus-valgus direction, 0.8° ± 1.3° (range, <0.1°-4.6°) in flexion-extension direction, and 2.9° ± 2.8° (range, <0.1°-9.4°) in internal-external rotational direction (Table I). 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 $\pm$ standard deviation along the y-axis in closed physes cases (cases 2, 4, 8, 9, 10, 11, and 13) was 2.0 $\pm$ 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 that the rate of residual deformity in varus is 5% to 9% in the distal humerus.9,15 Furthermore, the reported residual postoperative difference in the carrying angle between the surgical 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 preoperative and postoperative 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 the normal side, was 0.6° $\pm$ 0.7°, 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 was 9.4°, 6.2 mm, 20.6 mm, and 6.2 mm, respectively, which was 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 by a custom-made guide was performed 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 children and adults, in whom surgical methods were not exactly the same. The custom-made surgical guide may not be suitable in some cases of children with tiny elbows. 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 to 3 hours. The approximate cost for a custom-made guide was considered to be similar.

**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 the origin and the center of the humeral head. The z-axis is the line through the lateral epicondyle on a plane perpendicular to the y-axis. The x-axis is the line perpendicular to the 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 the z-axis produced flexion (+)/extension (−).
to that for total knee arthroplasty, ranging from $650 to $1200 USD. We expect that technologic development will soon reduce the time and cost required. Although the osteotomy guide is available only at our institution at this point, we are now preparing to supply it through a third party.

**Conclusion**

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

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**Disclaimer**

Tsuyoshi Murase MD, PhD owns stock in Orthree Co, Ltd. All the other authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

**References**

Accuracy of three-dimensional humeral corrective osteotomy


