A three-dimensional reconstruction plate for displaced midshaft fractures of the clavicle

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This randomised study compared outcomes in patients with displaced fractures of the clavicle treated by open reduction and fixation by a reconstruction plate which was placed either superiorly or three-dimensionally. Between 2003 and 2006, 133 consecutive patients with a mean age of 44.2 years (18 to 60) with displaced midshaft fractures of the clavicle were allocated randomly to a three-dimensional (3D) (67 patients) or superior group (66). Outcome measures included the peri-operative outcome index, delayed union, revision surgery and symptoms beyond 16 weeks. CT was used to reconstruct an image of each affected clavicle and Photoshop 7.0 software employed to calculate the percentage of the clavicular cortical area in the sagittal plane. The patients were reviewed clinically and radiographically at four and 12 months after the operation. The superior plate group had a higher rate of delayed union and had more symptomatic patients than the 3D group (p < 0.05). The percentage comparisons of cortical bone area showed that cortical bone in the superior distal segment is thicker than in the inferior segment, it is also thicker in the anterior mid-section than in the posterior (p < 0.05).

If fixation of midshaft fractures of the clavicle with a plate is indicated, a 3D reconstruction plate is better than one placed superiorly, because it is consistent with the stress distribution and shape of the clavicle.

Fractures of the midshaft of the clavicle usually unite when treated non-operatively.1,2 However, displaced or comminuted fractures carry a risk of malunion with cosmetic deformity and recent studies have reported a rate of nonunion of more than 15%.3

The operative treatment of displaced comminuted mid-clavicular fractures is by open reduction and stabilisation with wires, pins, or plates with screws. Whereas plating may be the logical choice to deal comprehensively with such fractures, including complicated injuries or nonunions,4 the plate may be difficult to secure because of the complex threedimensional (3D) shape of the clavicle. Therefore, a correctly-shaped plate would be required to reduce the risk of complications.5,6 Such a design would need to withstand the natural stresses within the bone. This study was undertaken to measure the shape of the cortical bone of the clavicle by CT and to assess the influence of the position of the plate on outcome.

Patients and Methods
Between 2003 and 2006, 133 consecutive patients were included in the study. All had a completely displaced fracture of the mid-third of the clavicle, amenable to plate fixation with a minimum of three screws in both fragments. The exclusion criteria were open fractures, age under 18 years or over 60, fracture in the proximal or distal clavicle, associated nerve or tendon injuries, multiple injuries, additional fractures in the same or contralateral limb, previous fracture in the injured clavicle, abnormal function in the uninjured side, inflammatory joint disease, cerebrovascular disease or other severe medical illness and the inability to give informed consent or to complete questionnaires. All patients gave informed consent and the study was approved by the Institutional Review Board of our hospital. The patients gave permission for exposure to additional radiation. The operation was usually performed within two days of admission, in most cases by the first author (J-WS), an experienced orthopaedic surgeon. In the operating theatre, the patients were allocated to one of two treatment groups according to sequentially-opened sealed envelopes based on a computer-generated randomisation list.
Of the 150 patients with displaced midshaft fractures of the clavicle who were identified, 133 met the criteria for enrolment (Table I). There were 58 women and 75 men with a mean age at operation of 44.2 years (18 to 60). The mechanism of injury included a road traffic accident, mostly low-energy, in 48 cases and a fall in 85. There were 56 left-sided injuries and 77 right. The fractures were spiral in 37 cases and comminuted in 96. A total of 67 fractures were fixed with a 3D contoured cortical reconstruction plate and 66 with a superior reconstruction plate (Table I).

The affected clavicles were scanned by spiral CT (Somatom sensation 4, Siemens Medical Solutions, Erlangen, Germany) and the data processed by a Leonardo work station (Siemens Medical Solutions) and a Kodak Dry view 8700 (Kodak Company Ltd, Tokyo, Japan) digital camera. CT scans of both clavicles were performed with the patient supine and then continuous volume scans of the affected clavicle were carried out. The scanning layer width was 0.5 mm to 5 mm and distance was 1 mm to 2 mm. Reconstructions were carried out in a layer width of 0.5 mm to 2 mm. The images were sent to the work station and underwent multi-plane reconstruction in a layer width of 0.5 mm to 2 mm by Syngo 3D software (Siemens Medical Solutions Inc., Malvern, Pennsylvania). When measuring an image, each clavicle was divided into distal, middle and proximal parts. Taking the centre point of each section, all images were sent to the computer and processed by Photoshop 7.0 (Adobe Systems, San Jose, California) (Fig. 1). The position and percentage area of cortex was obtained for different anatomical sites by calculating the pixels of the images (Table II).

### Table I. Clinical data of the 133 patients

<table>
<thead>
<tr>
<th></th>
<th>3D plate group (n = 67)</th>
<th>Superior plate group (n = 66)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Mean age in years (range)</td>
<td>43.8 (26 to 60)</td>
<td>44.7 (18 to 51)</td>
<td>0.631*</td>
</tr>
<tr>
<td>Women (%)</td>
<td>28 (41.8)</td>
<td>30 (45.5)</td>
<td>0.452†</td>
</tr>
<tr>
<td>Men (%)</td>
<td>39 (58.2)</td>
<td>36 (54.5)</td>
<td>0.394†</td>
</tr>
<tr>
<td>Fracture type (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comminuted</td>
<td>51 (76.1)</td>
<td>45 (68.2)</td>
<td>0.582²</td>
</tr>
<tr>
<td>Spiral</td>
<td>16 (23.9)</td>
<td>21 (31.8)</td>
<td>0.116⁷</td>
</tr>
</tbody>
</table>

* student *t*-test  
† chi-squared test

Operative technique. Under general anaesthetic and with the patient in a semi-sitting position, the fracture was approached through an oblique incision. The larger branches of the supraclavicular nerves were identified and protected. Comminuted fragments were secured with lag screws if possible or loosely sutured, and then positioned under the plate. In each case a 3.5 mm reconstruction plate was contoured according to the shape decided by randomisation. An aluminium template was bent to a smooth, continuous contour, avoiding bends through screw holes. In the 3D group the plate was fixed on the superior distal and proximal anterior fragments (Fig. 2). In the superior group the plate was S shaped and fixed on the superior surface.

When drilling, attention was focused on preventing injury to the subclavian vessels and pleura. Fluoroscopy was used intra-operatively and plain anteroposterior radiographs obtained the following day.

The patients underwent clinical and radiological assessment at four and 12 months after operation by independent surgeons (W-XD, XL, C-LW).

All patients had sufficient records, were interviewed according to the protocol and examined by the non-participating surgeons (HJ, MZ-C). The cases were randomised after initial assessment, so that the examiner was blinded to the group allocation. All images of the cortex area were measured independently three times (by JY, ZH) and the mean recorded by the three authors.

Statistical analysis. Statistical analysis was by SPSS 11.5 for Windows (SPSS Inc., Chicago, Illinois). The Student’s *t*-test was used for the comparison of means for parametric scale variables in independent groups. Each complication was denoted as an absolute value with chi-squared tests. Odds ratios and means were compared between the groups with 95% confidence intervals (CI) excluding the value of one.
and zero respectively being considered as statistically significant differences. All tests were two-sided and the level of significance was set at p < 0.05.

Results
At four months after operation all wounds had healed and the radiographs showed healing of the fractures in 63 patients (94%) fixed with a 3D plate and in 43 (65.2%) with a superior plate. In these patients the movements and strength of the shoulder showed no difference from the uninjured side (independent-samples t-test; p = 0.036). There were 15 symptomatic patients (22.7%) in the superior and three (4.5%) in the 3D group. There was delayed union in nine patients (6.8%), eight of whom were in the superior group (chi-squared test; p = 0.018). These required revision and were excluded from the 12-month review along with seven others, including four in the superior plate group, who did not attend for examination. The revision procedure used a 3D plate with bone grafting and solid union was achieved in all cases. There were no significant differences in operation time (independent-samples t-test; p = 0.334) or hospital stay (p = 0.361). The incidence of delayed union was 1.5% in the 3D plate group, and 12.1% in the superior plate group (Fisher’s exact test; p = 0.018, OR 8.702, 95% CI 1.055 to 71.755). The frequency of symptoms in the superior plate group was significantly higher than in 3D plate group both in four months (22.7% vs 4.5%, p = 0.002, OR 6.25, 95% CI 1.709 to 22.805) and 12 months (18.5% vs 3.2%, Pearson’s chi-squared test; p = 0.015, OR 5.755, 95% CI 1.207 to 27.445) after surgery. Measurements of clavicular cortical bone in the sagittal plane by CT showed that the superior part of distal segment and anterior cortical bone of the mid-section were thicker (paired samples t-test; p < 0.05; Table II).

Discussion
The clavicle stabilises the glenohumeral joint in the sagittal plane, providing a centre of rotation for the shoulder joint. During elevation of the arm, the glenohumeral joint moves twice as much as the scapulothoracic joint and the clavicle rotates, relatively lengthens, and moves through an arc of 60°. The junction of the outer and middle third is the thinnest part of the bone and the only area not protected by or reinforced with muscle and ligamentous attachments. It is also the area subjected to the greatest bending and torsional stresses. Its anatomical features make it prone to fracture, particularly with a fall on the point of the shoulder, resulting in an axial load to the clavicle. Adult mid-clavicular fractures often present a foreshortened spiral oblique configuration with upward displacement of the proximal fragment as a result of the pull of the sternocleidomastoid muscle, while the distal fragment is displaced and rotated anteriorly and downward as a result of the pull of the deltoid muscle and the weight of the upper limb. The mid-clavicle consists mainly of tubular cortical bone with limited contact area for fracture healing and there is no specific nutrient artery. However, the suprascapular, thoraco-acromial and internal thoracic arteries, along with the musculoskeletal envelope provide a rich blood supply. The complex morphology and functional anatomy of the clavicle place considerable demands on any plate, wherever placed. Most surgeons prefer a contoured two dimensional plate on the superior surface. However, with respect to 3D morphology, functional anatomy and multidirectional forces, a superior plate cannot completely limit displacement. New designs such as the low contact dynamic compression and the locking clavicle plate, have better biomechanical stabilis-

Table II. A percentage (mean (sd)) comparison of the cortical bone area of the clavicle

<table>
<thead>
<tr>
<th>Cortical bone of clavicle</th>
<th>Distal section of cortical bone area</th>
<th>Mid-section of cortical bone area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>54 (6)</td>
<td>65 (7)†</td>
</tr>
<tr>
<td>Posterior</td>
<td>46 (7)</td>
<td>35 (6)</td>
</tr>
<tr>
<td>Superior</td>
<td>55 (5)†</td>
<td>50 (4)</td>
</tr>
<tr>
<td>Inferior</td>
<td>45 (6)</td>
<td>50 (3)</td>
</tr>
</tbody>
</table>

* the anteroposterior area comparison, paired samples t-test; t = 4.912, p = 0.000
† the superoinferior area comparison, paired samples t-test; t = 3.124, p = 0.003
ity than the reconstruction plate, but are still prone to this weakness.6,11 3D fixation better addresses the functional anatomy, as confirmed by this study.

With regard to the formation of cortical bone and fracture healing, thicker bone grows on the compression side than on the tension side.12 Also cortical bone becomes thicker with increasing compression stress.13 As our CT scans showed that thicker cortical bone lay anteriorly in the mid section and superiorly in the distal segment, it is logical to contour a 3D plate to exploit the compression characteristics of these areas. Unlike a superior two-dimensional plate it can better adapt to natural stresses in the bone. There was no significant statistical difference in the perioperative progress of both groups. We believe that, if internal fixation of a midshaft fracture of the clavicle is indicated, a 3D reconstruction plate is better than one placed superiorly.

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References