Development of Site-specific Locking Plates for Acetabular Fractures

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abstract

Site-specific locking plates have gained popularity for the treatment of fractures. However, the clinical use of a site-specific locking plate for acetabular fractures remains untested due to production limits. To design a universal site-specific locking plate for acetabular fractures, the 3-dimensional (3D) photographic records of 171 pelvises were retrospectively studied to generate a universal posterior innominate bone surface. Using 3D photographic processing software, the 3D coordinate system was reset according to bony landmarks and was scaled based on the acetabular diameter to allow a direct comparison between surfaces. The measured surface was separated into measurement units. At each measurement unit, the authors calculated the average z-axis values in all samples and obtained the 3D coordinate values of the point cloud that could be reconstructed into the universal surface. A plate was subsequently designed in 3D photographic processing software, and the orientation and distribution of locking screws was included. To manufacture a plate, the data were entered into Unigraphics NX version 6.0 software (Siemens PLM Software, Co, Ltd, Plano, Texas) and a CNC digital milling machine (FANUC Co, Ltd, Yamanashi, Japan). The resulting locking plate fit excellently with the reduced bone surface intraoperatively. Plate contouring was avoided intraoperatively. Universal 3.5-mm locking screws locked successfully into the plate, and their orientations were consistent with the design. No screw yielded to acetabular penetration. This method of designing a site-specific acetabular locking plate is practical, and the plates are suitable for clinical use. These site-specific locking plates may be an option for the treatment of acetabular fractures, particularly in elderly patients.

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Figure: Deviation color map showing a sphere created that closely matched the acetabular interface. When the sphere was attached to the acetabular interface as accurately as possible, its diameter was noted.
The surgical treatment of acetabular fractures is among the most challenging orthopedic procedures. With aging populations, acetabular fractures in elderly patients have become common.1-3 Comminution is often severe and bone quality is often poor; therefore, conventional fixation techniques are subject to failure.4,5 A novel method for internal fracture fixation has been developed that uses locking plates and screws. This new plate technology provides more secure fixation in osteoporotic bones than conventional plates and prevents screw backout or toggle, thereby reducing the fixation failure risk.6-8 Similarly, the use of site-specific locking plates to treat periarticular fractures has resulted in excellent clinical outcomes, a lower articular penetration risk, less plate contouring time during osteosynthesis surgery, and a lower failure rate.8-10 A site-specific locking plate could be a useful and novel solution for acetabular fractures, particularly in elderly patients.

However, production limits restrict their clinical implementation. To the authors’ knowledge, 1 study has reported the clinical use of a conventional locking plate for the treatment of a posterior wall fracture of the acetabulum.11 Regarding site-specific locking plates for the treatment of acetabular fractures, the field remains unexplored. The innominate bone, in which the acetabulum resides, is one of the most complicated parts of the human skeleton and can hinder the design of a site-specific plate for this location. Furthermore, a universal database of the innominate bone surface is essential for the design and development of a site-specific anatomical implant that could be attached accurately. To the authors’ knowledge, no practical and reproducible methods have been published that describe the irregular, curved, and 3-dimensional (3D) innominate bone surface. Hence, it is important to investigate optimal methods to detail the surface of this irregular bone and compare the results with different individuals and groups to build a universal database.

The surface of the innominate bone is irregular and curved. In the engineering field, these types of surfaces are typically described as point clouds.12-15 The aim of this study was to describe the surface of the innominate bone as a point cloud and to build a universal database for the design of a site-specific anatomical locking plate for the treatment of acetabular fractures. The hypothesis was that using method, the innominate bone surface could be divided into quantifiable units to enable comparison between individuals. By statistically analyzing sets of these point clouds in large sample populations, a universal database of innominate bone surfaces could be developed. Furthermore, using this database, the design of site-specific locking plates for the treatment of acetabular fractures could become practical and enable the clinical use of acetabular site-specific locking plates.

**Materials and Methods**

**Samples**

The authors retrospectively studied pelvic computed tomography (CT) data in Chinese patients. Inclusion criteria were pelvic CT data obtained from adults (age range, 18-60 years) who were scanned during routine physical examinations or if diseases were suspected that did not affect the bony structure of the pelvis. Exclusion criteria were patients with detectable pelvic abnormalities, bone destruction of the pelvis due to preexisting disease, and...
severe osteoporosis and osteophytes that could affect 3D imaging.

Two hundred pelvises were examined, and 171 pelvises met the inclusion criteria. One hundred men and 71 women with a mean age of 47.2±5.7 years (range, 22-60 years) and 43.5±6.2 years (range 18-57 years), respectively, were included. Thirty-five pelvises were examined due to gynecological disorders, 118 due to the suspicion of a pelvic cavity or hypogastric disease, 14 during routine postoperative follow-up, and 4 during annual physicals.

**Image Data Acquisition and Image Processing**

Pelvic imaging data were obtained using a 64-slice spiral CT (Siemens, Munich, Germany) scanner. The CT settings were as follows: voltage, 120 kV; current, 165 mA; scanning frame inclination angle, 0°; 512×512 matrix; the scanner table proceeded 1.5 mm (pitch value) when the radiograph tube underwent 1 rotation; slice thickness, 1 mm; reconstruction interval, 1 mm.

The DICOM file format was introduced into Materialise’s interactive medical image control system (MIMICS) version 10.0 software (Materialise Co, Ltd, Leuven, Belgium) for 3D reconstruction and editing to remove noise and to image the femur part. The results were saved as STL files and transferred into the Imageware version 12.1 software (EDS Co, Ltd, Plano, Texas).

**Coordinate Modification and Point Cloud Acquisition**

In Imageware, plane S was constructed based on the anteroinferior iliac spine (point A), the ischiadic spine (point B), and the ischiadic crest (point O). A line was then drawn from point O to A in plane S. Point O was defined as the origin, line OA was the x-axis, and OT was a line perpendicular to OA that served as the y-axis of a rectangular coordinated system in plane S. Line OZ was perpendicular to plane S and denoted the z-axis (Figure 1).

The surface of a bone can vary widely based on its size. Because the innominate bone was magnified similarly to the acetabulum, one-tenth of the diameter (D) of the acetabulum (D/10) was chosen as the measurement unit of the new coordinate system. This relative unit was used for each measured innominate bone. A mark was entered at every distance D/10 in the x- and y-axes, thereby generating a grid of coordinates in plane S. Each intersection of the grid of coordinates was defined as a measurement point. From each measurement point, lines perpendicular to plane S were created, and the crossing points between the lines and the measured surface (reflection points) were later obtained using z-axis values in the Imageware software (Figure 1). All reflection points of the surface being measured comprised the point cloud for that surface. Finally, the coordinates of all points were obtained for further editing and statistical analysis.

**Measurement of Acetabular Diameter and Data Analysis**

To measure the acetabular diameter, a sphere was constructed that matched the interface of the acetabulum as accurately as possible. When the sphere was attached to the interface of acetabulum, the diameter was noted (Figure 2). The samples were divided into 2 subgroups based on sex. Tests of normality of distribution and t tests were used to analyze the data and to investigate whether differences existed between the subgroups. The range in acetabular diameters was used to further determine the size of the anatomical plate that was designed. The results were used to divide the finalized plates into subtypes.

**Analysis of the Z Value and Establishment of the Surface Database**

All Z values from each patient can be regarded as a set. Mean values were calculated for each set at every measurement point (x, y). Although the measured surfaces were scaled based on the acetabular diameter, individual differences may exist and may lead to the loss of reflection points. In those instances, the averages were calculated based on the values of the remaining reflection points to address anatomical variations to the greatest extent possible. These calculations enabled the 3D coordinates of all measurement points—x, y, z (x,y)—to be obtained. These point clouds generated the database of the posterior surface of the innominate bone. Using this database, a surface can be reconstructed, and when multiplied by one-tenth of the diameter of a particular acetabulum, a universal surface may be obtained that is consistent with most posterior surfaces of innominate bones of that particular acetabular diameter. To validate this consistency of the universal surface, the authors fitted it to every sample. The largest deviation for each fitting was noted.

**Design and Manufacture of the Anatomical Locking Plate**

First, a suitable attachment site was determined, and the plate shape was de-
signed based on the most common surgical approach, the fixation requirements, and the surgeon’s preferences. The screw orientation and distribution was then adjusted to achieve secure fracture fixation while avoiding articular penetration (Figure 3). The designed 3D photographic image of the plate was aligned with the posterior surface of the innominate bone of each sample to validate its consistency with the bone surface and to determine whether the designed orientation of the screws avoided articulation. Data on the plate containing the screws, which included screw orientation and distribution, were saved using IGES formats and were entered into Unigraphics NX version 6.0 software (Siemens PLM Software Co, Ltd, Plano, Texas). The Unigraphics software was used to encode the plate design, and the generated code was entered into a Computerized Numerical Control (CNC) digital milling machine (FANUC Co, Ltd, Yamanashi, Japan) to manufacture the locking plate and drill the locking holes. ASTM F136 Ti-6Al-4V ELI medical titanium (Baoji Unique Titanium Industry Co, Ltd, Hunan, China) was used to manufacture the plate because it is used widely in the medical field and is biocompatible, strong, lightweight, and corrosionresistant. Following fabrication, the plates were trimmed to remove excess metal and were cleaned, polished, and anodized. Finally, the plates were tested by fitting it to the patients’ pelvic rapid-prototyping model and were implemented intraoperatively.

Statistical Analysis

Tests of normality of distribution and t tests were performed using Prizm version 5.0 software (GraphPad Software, Inc, La Jolla, California). Using Matlab software R2010a (MathWorks, Inc, Natick, Massachusetts), spatial statistics was used to remove noise and calculate an optimal surface. The surface was reconstructed based on the 3D coordinates of the point cloud, which minimized variance and systematic errors, thereby resulting in a surface that was smoother and more consistent with the actual innominate bones.

RESULTS

Acetabular Diameter

In the 171 pelvises, the acetabular diameters were 57.6±2.9 and 52.6±2.6 mm for men and women, respectively (P<.05). However, the majority of the acetabular diameters ranged from 48 to 62 mm regardless of sex (Figure 2). Therefore, the authors divided the innominate bones into 3 groups based on acetabular diameter: 47.5 to 52.5 mm; 52.5 to 57.5 mm; and 57.5 to 62.5 mm. Because the authors’ database uses magnifications based on acetabular diameter, the designed plates based on this database were also divided into 3 sizes obtained by magnifying the database values based on D: small (D=50 mm [D range, 47.5-52.5 mm]); medium (D=55 mm [D range, 52.5-
57.5 mm); and large (D=60 mm [D range, 52.5-57.5 mm]).

**Z Value Analysis and the Posterior Innominate Bone Surfaces Database**

The mean number of measurement points in each sample was 427 (range, 379-466 points), in which 335 (75.2%) measurement points had reflection points in all samples (loss rate, 0%). One hundred thirty-one measurement points showed a loss of reflection points (loss rate range, 1%-99%). Mean Z values of all measurement points ranged from 0 to 8.78±6.42 D/10 and, with X and Y values, comprised a 3D point cloud of coordinates. These data were entered into Matlab, and spatial statistics analysis was performed to calculate the nearest curved surface based on this point cloud (Figure 4). A set of 3D coordinates were used to develop a database of the posterior surface of the innominate bone, and on transferring these data to Imageware, a universal surface was reconstructed. Because magnification was tethered to any acetabular diameter (multiplied by D/10), a universal innominate bone posterior surface was obtained. To test the extent to which the derived surface was consistent with the bone surface, it was compared virtually with posterior acetabular surfaces isolated from all samples. Mean deviations between the universal surface and the random bone surfaces were 2.8±1.5 and 2.7±1.6 mm on and beneath the surface, respectively (Figure 5). The designed plates were also placed virtually against all of the samples, and the mean deviation of the plate from the bone surface was 3.2±1.0 mm.

**Clinical Use of a Derived Anatomic Locking Plate for Acetabular Fractures**

The derived locking plate fit excellently onto the pelvic Rapid-Prototyping model preoperatively and the reduced bone surface intraoperatively. Plate contouring was avoided intraoperatively. Universal 3.5-mm locking screws locked successfully to the plate, and their orien-

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**Figure 4:** The 3-dimensional coordinates, using mean Z values, were entered into Matlab R2010a software (MathWorks, Inc, Natick, Massachusetts), and spatial statistics was used to calculate and reconstruct the closest-matching curved surface (A) based on the point cloud (B). The point cloud (C) was then transferred into Imageware software to construct the universal surface (D).

**Figure 5:** The derived surface was compared virtually with posterior acetabular surfaces isolated from all samples to test for consistency with the bone surface (A). Mean deviations between the universal surface and the random bone surfaces were 2.8±1.5 and 2.7±1.6 mm on and beneath the surface, respectively (B). The plates were positioned virtually on all of the samples (C, D), and mean deviation of the plate from the bone surface was 3.2±1.0 mm (E).
tations were consistent with the design and avoided hip articulation. The screws avoided acetabular penetration, which was validated with intraoperative fluoroscopy and postoperative CT scans. Due to the tilt angle, the screws were inserted to 3.5- to 5.0-mm depths in their bone tunnel, thereby providing more secure fixation compared with conventional reconstruction locking plates that have limited screw-insertion angles while facilitating insertion in a limited operating space.

This procedure was repeated in a series of patients with various fracture types, including simple and associated types (eg, transverse fractures and fractures of both columns [unpublished data]), and good outcomes were achieved during follow-up (Figure 6).

**DISCUSSION**

Following the introduction of biological and modern osteosynthesis surgery and the wide use of minimally invasive techniques and personalized management strategies, the use of site-specific locking plates has increased. Several site-specific locking plates have been developed for specific fracture sites, particularly periartricular fractures (eg, LPHP plates [Synthes, Inc, Solothurn, Switzerland] for proximal humeral fractures and the DVR plates [DePuy Orthopaedics, Inc, Warsaw, Indiana] for distal radial fractures). Excellent clinical results have been reported for these plates; however, site-specific locking plates

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**Figure 6:** A 52-year-old woman had associated acetabular transverse and posterior wall fractures. After studying radiographs including anteroposterior, lateral, obturator oblique, and iliac oblique view (A, anteroposterior view) and a reconstruction of computed tomography photography (B), a K-L approach and a medium-sized site-specific locking plate (C) were chosen. The locking plate fit excellently on the reduced bone surface intraoperatively (D). Plate contouring was avoided. The universal 3.5-mm locking screws locked successfully with the plate, and their orientation was consistent with the design and avoided hip articulation which was confirmed in postoperative radiographs (E, anteroposterior view) and reconstruction of computed tomography photography (F, posterior view; G, lateral view). At 18-month follow-up, the fractures had healed without complications due to implant failure in radiographs (H, anteroposterior view; I, iliac oblique view). The hip joint had no limitation to range of motion (J) and returned to normal function (K) without pain while walking.
have not been adequately developed for the treatment of acetabular fractures.

While obtaining the anatomical shape of the plate’s interface, it is essential to obtain a universal innominate bone surface that matches most innominate bone surfaces in size and shape. Therefore, the site-specific plates designed based on this surface will be suitable for the majority of patients. To investigate the morphology of the innominate bone in large-scale samples, 3D image processing techniques should be used. In the past 2 decades, 3D anatomical images reconstructed using CT data have often been used for diagnosis and therapy. Measuring bone morphology from 3D photography in image-processing software has also been an accurate, noninvasive, and feasible method for analyzing several samples.

However, the complicated nature of the anatomical shape of the innominate bone poses other difficulties for the development of site-specific plates for acetabular fractures. As an important hip joint component, the innominate bone is more complex than its femur with regard to measurement and individual differences. Individual differences in the innominate bone’s size, location, position, and shape make it difficult to quantitatively analyze similarities and differences between individuals. To address these issues, it is necessary to position the measured surfaces and to scale their sizes to enable comparisons.

In the current study, the anteroinferior iliac spine, ischiadic spine, and ischiadic crest were used to build a reference surface that adjusts the posterior surface of the innominate bone into a fixed position because these 3 bony landmarks are easily found. The plane closest to the measured surface is based on these landmarks; thus, a Z value on the measured surface could be a positive number. This design protocol reduced systematic error. The surface was then scaled in reference to the acetabular diameter, thereby minimizing the differences due to the size of the acetabulum.

Although all measured surfaces are oriented and scaled appropriately, a degree of difficulty remains in determining the differences between surfaces and obtaining a nearest surface. In addition, few publications have reported successful and universal methods for describing these surfaces to enable comparisons. In the field of engineering, point clouds have been used to describe the shell or interface of a 3D object. By adapting this system and resetting the measurement unit of the 3D coordinates based on the acetabular diameter (D/10), a set of measurement points was obtained to enable the generation of a reference surface. For every measurement point, the Z value of the measured surface remained the only variable. By analyzing and calculating the mean value of all corresponding Z values for all measurement points in all samples, the 3D coordinates of a set of points can be obtained, and these points generate a point cloud that can be reconstructed as a surface.

The point cloud can contain a significant level of noise, which would lead to a relatively rough surface. Therefore, the challenge lies in reconstructing a smooth surface. The average smoothing function in Matlab reduces noise using neighboring points and corresponding planes, thereby allowing the generation of a constructed surface that represents a true mean of all surfaces. This method risks ignoring variations in the posterior surface of the innominate bone of certain individuals. For example, it has been reported that women have wider, greater sciatic notches than men. However, this variation has little effect on the design of acetabular site-specific plates because the plate rarely extends into this area. In addition, few reports have focused on the surface anatomy of the innominate bone. Currently, unknown minimal variations exist; however, in the authors’ clinical experience of using site-specific plates designed based on this surface, these suspected differences have given no cause for concern.

When designing the plate, its shape and attachment location should be determined based on the most frequent surgical exposure site, fracture type, and surgeons’ preferences. The distribution and orientation of the screws should avoid articular penetration. In addition, the orientation of the screws should use diverging angulation to ensure stability. Once designed, the plate could enter production using modern engineering techniques.

Using this plate intraoperatively is not technically demanding. Anatomical reduction is the key to enabling surgical procedures to achieve positive clinical outcomes. Surgeons would need to study radiographs preoperatively to determine the optimal plate size. The interface of the plate is sufficiently consistent with the irregular surfaces of the innominate bone to prevent misaligned attachment immediately after reduction. When a fracture is overly comminuted and perfect reduction cannot be achieved, intraoperative photography or CT scans could help determine where to place the plate.

CONCLUSION
In the current study, the locking plate’s excellent fit, lack of contouring, screw orientation consistency with design, lack of acetabular penetration, and secure and stable fixation that is conducive to rehabilitation indicate that this method is practical and suitable for clinical use. With cooperation between the fields of engineering and medicine, site-specific locking plates similar to that described in this article may become a novel and viable option for the treatment of acetabular fractures, particularly in elderly patients with osteoporosis.

REFERENCES


