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Design of anatomically locked plate for posterior malleolus by computer aided technique

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Abstract
Objective: To use computer aided technology to design anatomic plate for the posterior ankle by software Mimics, CT and 3D printing.
Methods: The CT data of 20 normal ankles were imported into software Mimics in dicom format for three dimensional reconstruction of the ankle joint. The within the inside of the turn angle and the after the lateral varus angle of the posterior ankle, the twist height in the sagittal plane and the height of security zone for screw insertion in the posterior ankle cross—section were measured. The anatomic plate for the posterior ankle designed on the basis of 3 D reconstruction of the ankle joint using the software Mimics, CT and 3D printing The 3D printing was used to manufacture models of the anatomic plate which were tested and evaluated on the 15 fresh cadaver specimen.
Results: The measurements showed that the within the inside of the turn angle and the after the lateral varus angle of the posterior ankle increased gradually from the central axis of posterior ankle, while the twist height reduce from the external to the internal. The Computer aided technology design of the plate was achieved on the basis of the measurement data. The anatomic models of the plate fit the 15 fresh cadaver specimen of posterior ankle very well.
Conclusions: Design of anatomic plate can be carried out using CT data, software Mimics and 3D printing. This study provides some references and methods for Computer aided technology design of or internal fixation devices

Keywords: Ankle joint, computer aided design, 3D printing, bone plates, internal fixation of fracture

1. Introduction
Ankle joint is one of the three joints of human lower limb, and it is the key joint of human body movement. Its stability and flexibility are the basic guarantee for the human body to complete standing, walking and jumping. Because the ankle joint bearing the largest, so the ankle fracture is one of the most common types of fractures, the most common intra-articular fractures, young adults most likely to occur, mostly revolving violence or indirect violence caused by about 4% of body fractures [1], which involves the ankle about 7% -44% [2], for the most complex, treatment is relatively difficult. Such as improper early treatment, easily lead to instability of the ankle, pain and late traumatic ankle arthritis, how effective anatomical reduction of fractures, stable fracture of the ankle joint stability is particularly important [3], and in this Based on early functional exercise to restore the normal physiological function of the ankle joint [4]. Currently used to treat posterior malleolar fracture fixation devices are hollow tension screws, absorbable screws, support plate, anti-skate plate, metacarpal plate, oblique T-shaped plate, external fixator [5-7], a variety of fixed devices are There are certain advantages, but there are still some limitations. This group summarizes the advantages of existing fixed devices, combined with the anatomy of the posterior malleolus physiology characteristics, research and design of an anatomical locking plate in line with the ankle. In recent years, with the rapid development of orthopedic techniques and theories, the configuration of internal fixation devices in fracture patients has undergone tremendous changes. Most of the traditional steel plate designs are designed with cadaver specimens and a single plane imaging. Nowadays, with the rapid development and application of digital orthopedic and 3D printing technology, using 3D reconstruction technology of CT, computer technology and 3D printing technology, it can be divided into different anatomical parts

according to different patients, different parts, different fracture characteristics and bone matching. Fixed plate, and even some special needs of patients with anatomical design of anatomical plate [8-10].The purpose of this study in the initial use of existing ankle CT data using Mimics 10.01 software and Ungraphics NX5.0 software to design the ankle Anatomically locking the plate.

2. Materials and Methods

2.1 data acquisition and statistics

Twenty cases of ankle joint tomography were recorded and statistically analyzed by CT in our hospital from June, 2015 to June, 2016, and the data were recorded on DVD disc. 12 males, 28-52 years old, average 40.0 years old, female 8 cases; aged 25 to 47 years, mean 31.0 years. Spiral CT original data scanning conditions: the use of spiral CT on the ankle key to continuous tomography. Scanning parameters: voltage 120 kV, current 94 mA, layer thickness 0.5 mm, 512 × 512 from the array.

2.2 Data processing and three-dimensional reconstruction

CT scan data will be. Dicom format Mimicsl0.0l software, the first gray-scale extraction of ankle bone border after the contour information area, and then use the regional segmentation to extract the ankle joint information area of each bone, each bone block into a single independent entity and The best model was used to reconstruct the three-dimensional model of the ankle joint. Stl format output saved [10].

2.3 Measurement and analysis of three - dimensional data

Refer to Hong Jianyuan, Ding Zhenqi, Kang two period [11] and other measurement indicators and methods.

A. The posterolateral medial inversion angle, lateral varus angle measurement: in the sagittal plane Mimicsl0.0l software in the posterior malleolus axis and the posterior malleolus measurement, lateral rotation between the tangent angle. Respectively, from the central axis inward and outward equally divided into 6 segments, respectively, recorded within each measured varus angle, lateral varus measured data, were recorded as al, a2, a3, a4, a5, a6, b1, B2, b3, b4, b5, b6.

B. Measurements of the height of the implant safety zone: The vertical height of the midline of the tibiofibular joint to the midpoint of the tangency of the posterior malleolus is shown on the coronal plane of the ankle. The measurement method is as follows: first determine the joint of the tibiofibular coronal plane, and then determine the posterior malleolus coronal layer, the number of layers between the recorded as n, according to the CT scan layer from 0.5mm, calculate the height c, Consider the diameter of the screw 3.5 mm (mostly 3.5mm), it should be included in the data processing, that is, c = (0.5 xn +3.5) mm, set the nail safe area in the plane Determined as plane B.

C. Measurement of the height of the twist: The vertical distance, in mm, from the point on the sagittal plane of the ankle that begins to twist from the plane of the implanted screw. The measurement method is: according to the height of the implanted screw safety area, the safe area of the implant screw is drawn horizontally in the sagittal plane. In the measurement of the posterolateral medial varus and lateral varus, Angle, lateral varus angle were the most point A, B to the implantation screw safety area horizontal plane, measured its height d, f, is measured, the lateral torsion height, And d1, d2, d3, d4, d5, and d6, respectively. F1, f2, f3, f4, f5, f6 to obtain the average of all the specimens measured as an important indicator of drawing and design of steel (Figure 1-1).

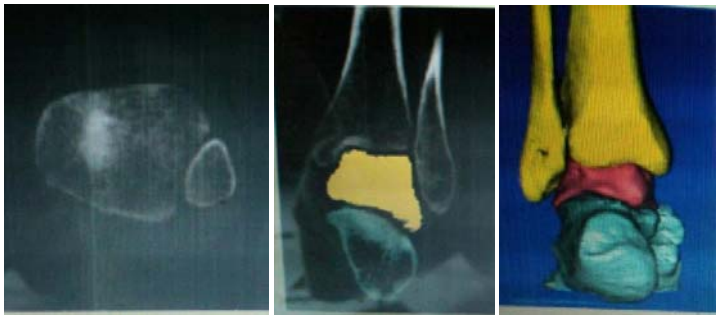

Fig 1-1

D. Measurement of posterior malleolar width: After the ankle on the coronal plane after the ankle after the lips tangential start from the distal to the proximal every 5mm measured width (unit: mm), to 30mm away from the distal ankle, were recorded as h1, h2, H3, h4, h5.

E. Plate design and 3D printing: using computer-aided design software Unigraphics NX 5.0 according to the relevant measurement data and angle, the width of the design of the anatomical locking plate to calculate the screw hole spacing, Stl file (Figure 1-2). Anatomical locking plate designed according to (Figure 1-2) was matched, fitted and verified in the posterior malleolus three-dimensional space using computer three-dimensional imaging technique (Fig.1-3), showing good fit, And finally with the combination of polyethylene materials, 3D printing technology, the steel plate template ratio (1; 1) print out (Figure 1-4).

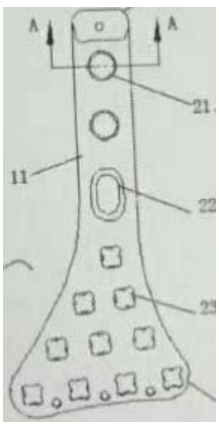

Fig 1-2 **Fig 1-4**

Fig 1-3

F. Steel plate template to verify the experiment: The posterior malleolus of the posterior malleolus was dissected and the posterior malleolus was completely exposed to the posterior malleolus. The posterior malleolus of the posterior malleolus was removed and the posterior malleolus was completely exposed to the ankle. Bone structure) of the plate model validation, found that the steel plate in the posterior malleolus degree of fit, placement and angle of the ideal, in line with the ankle anatomical locking plate design requirements. (Figures 1-5)

Fig 1-5

3. Results

The implantation screw safety area height c = (30.35 ± 0.65) mm, internal measurement varus angle: al = (43.280 ° ± 0.38 °), a2 = (46.320 ° ± 0.24 °), A3 = (49.260 ° ± 0.32 °), and a4 = (52.22 ° ± 0.18 °). A5 = (56.20 ° ± 0.36 °), a6 = (59.34 ° ± 0.27 °) B2 = (26.18 ° ± 0.27 °), b3 = (29.36 ° ± 0.12 °), b4 = (34.26 ° ± 0.29 °), b5 = (36.38) ° ± 0.26 °), b6 = (39.29 ° ± 0.32 °). D2 = (24.26 ± 0.27) mm, d3 = (27.32 ± 0.24) mm, d4 = (28.31) ± 0.32) mm, d5 = (29.42 ± 0.21) mm, d6 = (30.38 ± 0.15) mm.

F1 = (14.24 ± 0.25) mm, f2 = (18.32 ± 0.31) mm, f3 = (21.36 ± 0.18) mm, f4 = (23.26 ± 0.25) mm, f5 = (26.39 ± 0.15) mm, f6 = (27.35 ± 0.20) mm.

H2 = (27.32 ± 0.34) mm, h3 = (17.64 ± 0.18) mm, h4 = (12.53 ± 0.12) mm, h2 = (32.40 ± 0.11) 0.27) mm, h5 = (11.37 ± 0.39) mm. From the above data shows the posterior malleolus, lateral varus angle by the ankle axis inward, lateral gradually increased, and the height of the twist reduced from the inside out, ankle width from top to bottom gradually widened, implantation of screw safety zone and Height is proportional.

Through ankle CT scan and three-dimensional reconstruction, and by MimicslO. 01 and Unigraphics5.0 software and 3D printing technology to print the ankle anatomical locking plate template. The plate was modeled on the ankle bone of the adult cadavers. The plate was well fitted to the posterior malleolus. The position and angle of the ankle were in agreement with the design of the posterior malleolus locking plate.

4. Discuss

At this stage of whether the use of posterior malleolar fracture fixation has been controversial [12]. At present, the ankle joint involving the ankle of the clinical ankle fractures often use hollow tension screws, absorbable screws, support plate, anti-skate plate, metacarpal plate, oblique T-shaped plate, external fixator to replace the fixed ankle fracture. But clinically has not yet seen a special ankle anatomical locking plate. Because after the fracture of the ankle, posterior malleolus posterior lip curvature is more special, the shape of the plate to be similar with the posterior malleolus anatomy, a good fit in order to achieve anatomical reduction of fractures, thereby reducing the local soft tissue injury and reduce nonunion Probability. Now the domestic involved in the posterior malleolar fracture surgery commonly used hollow tension screw, absorbable screws, support plate, anti-skate plate, metacarpal plate, oblique T-shaped plate, external fixator and other shortcomings: 1, 2, plate shape, size, width of the posterior malleolus anatomy is not suitable for the characteristics of the posterior malleolus plate, the need to shape, thereby increasing the fatigue stress of the plate, intraoperative or postoperative rehabilitation of steel easy to break the sub-risk, can not achieve effective stability of internal fixation; Posterior tibial muscle tendon may have an impact. 3, the hollow nail is only suitable for large ankle fractures and the operation of the block, if the crush of bone, osteoporosis patients, prone to screw loosening occurred [13]. Therefore, orthopedic surgeons in clinical work will be envisaged to improve the original fixation or design a new fixation.

With the development of CT imaging technology, the three-dimensional tomographic images of relevant parts of patients can be obtained, and the digital technology based on it has been widely used in orthopedics [14-17]. Anatomical locking steel plate needs to achieve anatomical shape and bone to achieve the key is to reverse the surface through the precise measurement of data, internal fixation design must meet ergonomic, biomechanical requirements [10]. The design of internal fixation requires the repeated operation of the computer-aided design software and repeated simulation of the design to modify the design to design the most reasonable and most matching internal fixation.

The research of this subject combines the computer-aided technique and 3D printing technology to provide the anatomical basis for the design and application of the anatomical locking plate of the ankle through the three-dimensional reconstruction of the ankle and the anatomical data. In this study, the posterior malleolus of the patient's CT scan to the relevant data using three-dimensional image reconstruction software and engineering software design of the ankle of the anatomical plate. The initial anatomical data used normal unbleached patient data, eliminating the need for a simulated reset procedure, a relatively reduced workload, and more accurate measurement data. The steel plate model was made by the polyethylene plate and the ankle bone of the adult cadaver. The plate model was verified by the plate model (Fig. 1-5). Thus simplifying the use of mechanical processing of steel plate manufacturing complex and cumbersome, and to produce more accurate than the traditional steel plate, while easier to improve the steel plate to shorten the time of steel production. And even the traditional can not be processed to produce complex multi-angle high-buckling surface of the steel.

Compared with the traditional design of steel need to test, in clinical validation process, anatomical parts of the mismatch will lead to the production of steel plate design several times to change. In this study, CT scan, Mimics and UnigraphicsNX5.0 software were used to complete the whole process, and the design of internal fixation was shortened from conceptual design to simulation verification. Compared with the traditional autopsy studies, it has the advantages of high accuracy, good matching, high repeatable rate, small soft tissue destruction and saving medical resources. In addition to considering biomechanical stability during the design of internal fixation, The intensity of fracture, etc., but also taking into account the reduction of fractures, internal fixation,

surgical incision revealed, fracture site exposure, and intraoperative fracture anatomical reductions and many other factors such as restrictions on the design of the impact [10]. At the same time, the data of length, angle and curvature of the fixation were obtained by the software, which reduced the systematic error of manual measurement by cadaver specimen, and improved the accuracy, reliability and practicability of the result.

The appearance of the anatomical locking plate design in accordance with the curve of the ankle joint edge surface design, in line with the anatomical anatomy of the anatomy, intraoperative plasticity that can not close fit with the cortical bone. Plate by the body, ankle 2 parts. Body for the straight plate, proximal ramp design, easy to insert the steel plate, reducing the damage of soft tissue, to achieve the purpose of minimally invasive. The proximal suture hole (2mm), can be applied to temporary Fix, pressure or traction. 2 holes in the middle of the plate can be used to lock nails or ordinary nails for pressure or lock. The middle part of the sliding hole, can be used for steel plate up and down adjustment, select the appropriate placement. Ankle from both sides of the body to the curved curved expansion of the steel plate for the lateral multi-nail arrangement, every 5mm for a row from the proximal to distal in order to 1, 2, 3, 4 nail hole, Can be screwed from different angles and multi-plane fixed at the same time make the fracture block fixation more reliable. Conventional screws and locking screws can be used to provide angular stability and increase the fixation of complex bone. (2mm), can be used for temporary reduction or fixed, after the ankle lips arc design, in order to restore the ankle after the fracture surface, stabilize the ankle after the lips, the ankle lips, Provides anatomic reset conditions. Especially more suitable for the posterior malleolus of crushed bone, osteoporosis patients. Above the nail hole according to AO standard design. (Figure 1-6)

(Right) (Left)

Fig 1-6

Bone thickness in the ankle joint thinning, reduce the posterior tibialis tendon friction, plate thickness changes, so that it can automatically and posterior ankle bone surface attachment, can reduce the damage to soft tissue. Because the ankle for the anatomical design and ankle more matching, no longer need to be shaping, can reduce the operation time and blood loss; due to the plate with a special point of contact design [18-19], to ensure that the steel plate and bone surface with 1mm spacing, Minimizing the contact area between the plate and the bone surface, to protect the blood supply to the cortical bone plate [20], at the same time with locking and pressure function, the transformation between the steel plate and bone surface force for the plate and And to provide adequate healing biomechanical environment for fracture healing [21], reducing local blood flow obstruction, causing local bone necrosis and bone resorption induced [22]. Reducing bone nonunion occurred. When the intraoperative fracture, can not be satisfied with the reduction can also be used when the anatomical plate as a reset reference, easy to shorten the operation time and postoperative fracture infection. At the same time, the anatomical design of the plate ankle play a kind of pressure plate effect, which can be used in mechanics because of the action area [7], to prevent rotation or shear displacement of the fracture block, in line with biomechanical principles. Plate-screw-bone structure, which can resist the stress above the talus and the tension stress of the posterior tibiofibular ligament, restore the normal anatomical structure of the ankle hole and prevent the dislocation of the talus and keep the ankle joint stable. Titanium alloy material and bone elastic modulus similar to good tissue compatibility. 23 rehabilitation exercises in the postoperative weight-bearing process will save a good location to stimulate the fracture, causing bone callus formation [24] so that the Patients with early ankle exercise, passive exercise, not only help restore ankle function, can reduce ankle stiffness, lower extremity venous thrombosis, pressure sores, pulmonary infection, osteoporosis, and even reduce the ankle degeneration Risk [25].

This study provides a good post-ankle anatomical plate design process and philosophy. The posterior malleolus anatomical internal fixation plate was made by cT scanning, Mimics and Unigraphics NX 5.0 software and 3D printing technology [26-

[28]. It was found that the plate fit well in the posterior malleolus, and the position and angle of the plate were appropriate. The plate was designed according to the anatomical anatomical locking plate. However, the following problems were found: Steel plate verification As a result of using 3D printing polyethylene stencil, only subjective observation, Measurement, the lack of relatively objective observation and evaluation of indicators (for example, can not use x-ray film to the scientific evaluation of the plate and the ankle fit situation). Because of the small amount of data, we need to increase the sample size in later clinical validation, increase the samples of different age groups, make the database data more sufficient, reduce the statistical analysis error and improve the accuracy rate. (Finite element analysis), posterior malleolus anatomy and clinical biomechanics of the late posterior malleolus plate to provide a certain method and reference.

At present, there are domestic use of computer-aided technology and 3D printing technology in a short time customization of fixed equipment case reports [29]. With the rapid development of digital orthopedic and 3D printing technology and the surgeon's clinical experience and the level of medical equipment companies increased substantially, plate, internal fixation of manufacturing technology and design concepts, may be widely used in clinical, to address the patient's Pain and postoperative complications, for the majority of patients with the Gospel.

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