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A controllable thoracolumbar external fixation brace

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Abstract: Based on the theoretical basis of "dynamic and static combination" in traditional Chinese medicine, a controllable thoracolumbar external fixation brace was developed. Using new photosensitive resin materials, combined with three-dimensional modeling technology and 3D printing technology, a controllable thoracolumbar external fixation brace was designed and developed. In this study, the new adjustable thoracolumbar spine brace can fix and support the body to assist in restoring the biomechanical stability of the spine, and has a better therapeutic effect on shortening the bed treatment time of patients with thoracic and lumbar compression fractures.

1. Introduction

Vertebral compression fracture (VCF) is currently the most common spinal fracture, while simple thoracic and lumbar compression fracture is a vertebral stability fracture that occurs in the thoracic and lumbar segment, and there is no fracture of the vertebral body appendage of the vertebral body and no nerve damage [1]. The main cause of thoracic and lumbar compression fractures is the longitudinal violence of the spine, resulting in longitudinal compression deformation of the vertebral body, which affects function [2]. Therefore, in the conservative treatment of simple thoracic and lumbar fractures, in addition to ensuring the stability of the spine, it is also necessary to give the patient an appropriate size of longitudinal support according to the segment of the fracture. In the existing conservative treatment, traction therapy and pillow cushioning require long-term bed rest, which is prone to various complications. Compared with other conservative treatments, brace therapy can make patients get out of bed early, which can effectively avoid the complications caused by long-term bed rest.

At present, thoracic and lumbar external braces are mainly divided into soft, rigid, and semi-rigid braces. The soft brace is mainly supported by longitudinally filled rigid sheets such as metal or plastic, and the rest fits the body like a tight. Hard braces primarily maintain spinal stability by restricting movement in any direction of the spine [3], such as Boston overlapbraces (BO). Semi-rigid braces or dynamic braces are between rigid and flexible braces, represented by Spinomed braces [4], which mainly fix the spine by a flexible support backplate and a leather belt, none of which can provide longitudinal support for the thoracolumbar spine. For the treatment of thoracic and lumbar fractures, the Jewett hyperextension brace and the TLSO thoraco-lumbar sacral orthosis (TLSO) [5], which

provide longitudinal support but do not regulate its size.

The theory of "dynamic and static combination" is the most important of the four major treatment principles of traditional Chinese medicine for the recovery of fracture function [2], ensuring effective fixation and appropriate exercise are more conducive to the recovery of fracture. Therefore, based on the theory of dynamic and static combination of traditional Chinese medicine, this study is designed to change and regulate the longitudinal support force as the movement, and the inherent characteristics of the brace itself to provide sufficient continuous support force and stability as static, dynamic, and static combination and mutual coordination. Development of external fixation braces to achieve ideal therapeutic results.

2. Materials and Methods

2.1. Materials

Because each patient has a different size and spinal injury, the brace needs to be tailored to the patient's condition. In this study, a photosensitive resin material was used as the main material of the brace, which has a high degree of curing, which can reduce the shrinkage of the post-curing molding model, thereby reducing the post-curing deformation.

2.2. Production Method

The patient's supine thoracolumbar spine was scanned by Philips 1.5T magnetic resonance imaging machine and Philips 64 rows of 128-slice high-grade spiral CT, and saved in DI-COM format. The CT data were extracted by MIMICS 20.0 and a three-dimensional model of the spine was constructed, and the NMR data was extracted using 3-matic solid-work to form a soft tissue structure model. Then import the reference data model into POR-E, and use POR-E to design the wearable brace model. The brace is generated by 3D printing technology and spliced to complete the brace. The design diagram is shown in Figure 1.

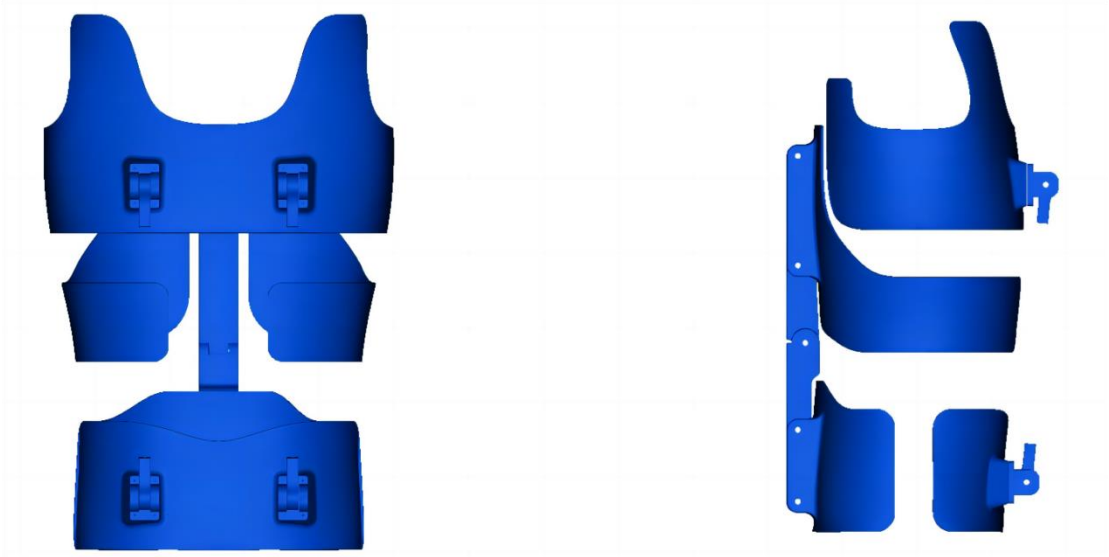

Figure 1: Front and side view of computer brace design

3. Design

3.1. Functional Design

In this study, the brace design was divided into two parts: the external fixed bone part and the adjustable support part. Multiple adjustment designs increase post-wear comfort, strengthen the connection between upper and lower, dynamic, and braking, and provide continuous and stable support while combining safe movement restriction devices with a 10-degree range at the rear of the brace to create space for thoracic and lumbar movement. This not only keeps the geometric position of the fracture after the fracture is reduced, but also provides a dynamic space for the patient's physiological activities, so that the paravertebral muscles of the affected area can be restored and exercised while having fixed support, to avoid spinal instability and low back pain caused by muscle atrophy, reflecting the theory of "dynamic and static combination" of orthopedic injury science in traditional Chinese medicine [2]. The coordination and unity of movement and static also promotes the smooth flow of meridians, the normal operation of qi and blood, leads to "neutralization", promotes fracture healing, and enables VCF patients to achieve the effects of braking and fixation in the standing position of the spine after injury, correcting and restoring the normal physiological curvature of the spine, and adjusting the angle of spinal flexion and extension, as Wang Fuzhi pointed out in "The Theory of Internal Strength Diagram" [2], "movement and static, qi and blood are harmonious, and if the disease is not born, it is necessary to make the best of its life". In the process of wearing the brace, the doctor can continuously adjust the support strength by rotating the spiral sleeve, plus various functional exercises, enhance the strength of the lower back muscles, promote fracture healing, and prevent the recurrence of fractures.

3.2. Adjustable Structure Design

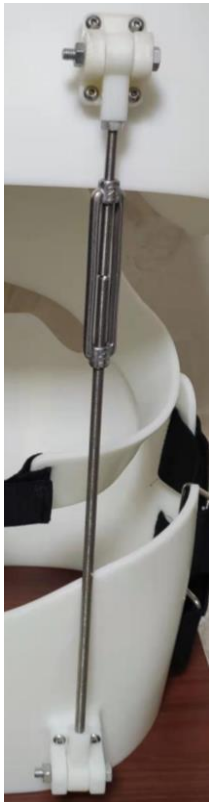

Figure 2: Adjustable support structure

The front-mounted controllable support structure provides longitudinal continuous and stable support stress, and the bracing device achieves the effect of two-way extension of the screw through the movement of the rotating sleeve, disperses the stress load of the paravertebral muscles, stabilizes the biomechanical stability of the spine after injury from multiple stress points, controls the size of the support force, adjusts the overall stability of the spine after injury, prevents further collapse of the injured vertebral body, and corrects the kyphotic deformity with obvious effect, see Figure 2. The back is designed with a dynamic safety restriction structure, which is combined with the support structure to form a dynamic and stable whole, and the concept of combining dynamic and static in the field of orthopedic injury science of traditional Chinese medicine is used to enable the patient to wear a brace to move to the ground while maintaining the biomechanical stability of the spine to achieve spinal forward flexion within the safety range, see Figure 3. It is guaranteed to complete simple daily life actions, help VCF patients get out of bed as soon as possible, improve the quality of life of conservative treatment, and reduce the incidence of kyphosis in VCF patients during conservative treatment.

Figure 3: Adjustable precursor micro-motion structure

4. How to Use

When used, the patient is seated, and the assistant assists the patient to put on the brace through the velcro at the connection. After the wear is attached, the doctor rotates the brace device to the length of the best effect of the adjuvant treatment. It reduces the longitudinal force of the fractured vertebral body when standing, distributes the stress of the vertebral body to multiple joints outside the spine, and achieves mechanical stability in the coronal and sagittal planes. It plays the role of assisting patients to get out of bed as soon as possible, reducing the complications of long-term bed rest, improving the quality of life of conservative treatment under the condition of relieving pain, and adjusting the length of chest stretch by doctors according to the progress of the patient's condition during the treatment process, to achieve the role of real-time adjustment of treatment height for the condition.

5. Conclusions

Thoracic and lumbar compression fractures are usually caused by high-energy injuries and are mostly not accompanied by nerve damage. Therefore, we treat these patients conservatively. Non-surgical treatment of premature movement in patients with thoracic and lumbar compression fractures can lead to complications such as loss of thoracic and lumbar vertebral height, worsening correction angle, and refracture. However, long-term low back pain and movement restrictions after injury may cause patients to develop irrational stress, depression, and anxiety, which seriously affect the quality of life.

The brace designed in this study combines the theory of "dynamic and static combination" of

traditional Chinese medicine orthopedic injury science with modern 3D printing technology, which solves the current clinical problem of conservative treatment of simple thoracic and lumbar compression fractures. Realize the advantages of medical-engineering cooperation, simulate the mechanical analysis in clinical practice through computer, and solve the problem of dispersion of force load in the injured spine more accurately and visually. 3D printing uses MRI or CT thin-layer scanning to obtain images, and generates 3D models through computer modelling software to complete the design of customized braces, and uses liquid photosensitive resin as raw material through light-curing three-dimensional molding technology, and cures liquid photosensitive resin layer by layer by controlling laser irradiation, and finally obtains a complete product. 3D printed thoracolumbar braces have many advantages, including overall lightweight, high degree of precision customization, high comfort and do not affect the patient's daily life movements. In addition, the brace also has the characteristics of multi-point and multi-regulation, which prevents long-term low back pain and spinal instability caused by paravertebral muscle atrophy, shortens bed rest time, and improves the prognosis and quality of life of patients. In summary, this study provides a new and effective method for the conservative treatment of simple thoracic and lumbar compression fractures.

In summary, the adjustable thoracolumbar external fixation brace designed in this study can fix and support the body, help restore the biomechanical stability of the spine, shorten the bed treatment time of patients with thoracic and lumbar compression fractures, and is an effective new type of thoracolumbar external fixation brace. Due to funding and time constraints, this study failed to conduct clinical trial observation and corresponding index detection. Our research group will improve relevant clinical observations and index detection in future experiments.

Acknowledgement

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