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Original Article

Biomechanical research on an elastic internal fixation bolt for treating distal lower extremity syndesmosis injury

Lian Wang[1], Dongzhu Liang[2], Weidong Zhao[2], Peidong Sun[2], Zongbao Wang[3,1]

[1]School of Kinesiology, Shanghai University of Sport, Shanghai, China; [2]Guangdong Provincial Key Laboratory of Medical Biomechanics, Southern Medical University, Guangzhou, Guangdong Province, China; [3]Anhui Provincial Hospital of Integrated Chinese and Western Medicine (The Third Clinical Medicine School of Anhui University of Chinese Medicine), Hefei, Anhui Province, China

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Abstract: Purpose: The goal of this study was to explore the effect of biomechanical property on an elastic internal fixation bolt fixing for distal lower extremity syndesmosis injury and to understand the superiority of this internal fixation bolt. Methods: A total of 12 frozen calves from 6 male cadavers were cut anteroinferior tibiofibular ligament, posteroinferior tibiofibular ligament, transverse tibiofibular ligament, interosseous tibiofibular ligament and deltoid ligament to make syndesmosis injury models, and were randomly divided into two groups: the elastic bolt group and the conventional screw group. Separation displacement, foot and ankle's axial stiffness and inferior tibiofibular intra-articular pressure distribution of baseline, model, elastic bolt group and conventional screw group were measured by biomechanical testing methods, optical non-contact measurement system and stress measurement system. Results: Both elastic bolt and conventional screw could preferably control the separation displacement of syndesmosis injury but conventional screw was stronger than bolt. The axial stiffness of foot and ankle after bolt and screw fixation showed a strong resistance ability to deformation, for which bolt was weaker than screw fixation. Additionally, pressure concentration distribution had some lateral shift for both elastic bolt and conventional screw group, and the former one had less shift which was similar to the intra-articular pressure concentration distribution of a healthy tibiofibular joint. Conclusion: The elastic fixation bolt device for the treatment of syndesmosis injury can maintain the inferior tibiofibular joint micromotion, achieve normal biomechanical characteristics of tibiofibular joint and promote the rehabilitation of syndesmosis injuries.

Keywords: Biomechanics, elastic bolt, internal fixation, syndesmosis injury, tibiofibular joint, treatment

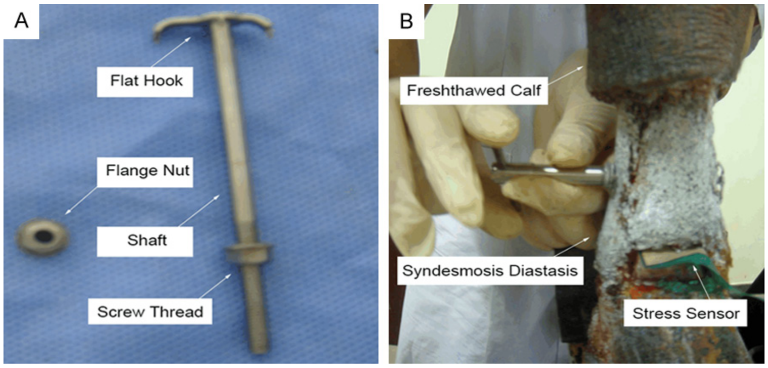
Introduction

Distal lower extremity syndesmosis (DLES) injury has a certain incidence in the sports involving lower extremity primarily. Previous reports indicated that DLES damages contribute to 1-11% of all ankle injuries, while present epidemiology research has reported that it is 17-74% in ankle injuries of young athletes, especially in football, skiing and hockey [1, 2]. Without proper treatment, prognosis of ankle would be seriously affected by wider space of DLES and chronic instability [3, 4]. Thus, even a small displacement of ankle mortise can reduce joint contact area and enhance the in teraction force of tibial astragaloid joint, leading to persistent pain and osteoarthritis [5-7]. At the present time, the most common surgical treatment of DLES injury is elastic internal fixation [8, 9]. In this study, an elastic fixation bolt equipment was designed (**Figure 1**) that has been issued a patent (China Invention Patent #: 201210170403.1) [10] to compare with conventional cortical bone screw for fixing DLES separation using biomechanical test to determine their advantages in sustaining the microinching of distal tibiofibular joint.

Materials and methods

Subjects

A total of 12 frozen calves from 6 male cadavers of 30 to 56 years old were measured exclud-



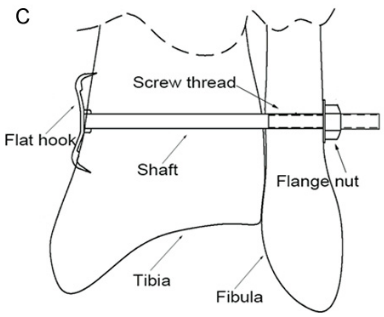


Figure 1. A. Elastic bolt and flange nut. B. A socket wrench for Allen screw was used to fix the syndesmosis diastasis with a flange nut. Speckles on the surface of bone were made with black and white paints. The top end of this sample was fixed to the BOSE equipment. C. Schematic diagram of the elastic fixation bolt when it passed from tibia to fibula by drilled tunnel.

ing foot malformation and trauma by X-ray images. Fresh sample calves were frozen and stored at -20°C for 7 days to 8 months before the measurement. The study was conducted according to the Helsinki Declaration and approved by the Medical Ethics Committee of Nanfang Hospital, Southern Medical University.

Experimental equipment

BOSE Electro Force ®3510 high precision biomaterials experimental system (Bose Corp., Shanghai, China) (Force Value: 15 ± 7.5 KN; Dynamic Strain: ± 25 mm; Frequency: 100 Hz), polymethylmethacrylate (type I), polymethylmethacrylate (type II), liquid formulation, electric drill, bone saw, operation blade holder, blade, black spray painting, white spray painting, custom-made foot fixed metal plate, 3.5 mm cortical full-thread screw, 3.5 mm half-thread elastic fixation bolt suits for DLES injuries including a socket wrench for Allen screws, hexagon flange nuts, stainless steel hooked bolt (**Figure 1A**, **1B**) (Dragon Crown Medical Co. Ltd., Jinan, China) and ARAMIS Optical Non-contact Measurement System (GOM GmbH, Braunschweig, Germany). The stress measurement system includes stress collector and stress sensor connected by a computer and its software.

Design idea of the elastic fixation bolt (**Figure 1C**)-one end of screw shaft is a flat hook and two hooks appearing arc shaped to maintain certain micromotion. There is a convex platform to confine hook into more tibia bone. The height of the convex platform is approximately 1.5 mm. The bolts are fixed to pass from tibia to fibula by drilled tunnel. The bolt of half screw thread may be used to fix the syndesmosis diastasis with a flange nut.

Experimental site: Guangdong Provincial Key Laboratory of Medical Biomechanics.

Methods

Sample preparation: Soft tissues of 4.5 cm region around the ankle joint were sectioned, including skin, subcutaneous tissue and partial ligament, retaining anteroinferior tibiofibular ligament (AITFL), posteroinferior tibiofibular ligament (PITFL), transverse tibiofibular ligament (TTL), interosseous tibiofibular ligament (ITL), deltoid ligament (DL) and interosseous membrane to test. Next, soft tissues of the top end 2.5 cm region of calves were removed and only the proximal lower extremity syndesmosis was kept. The aim was to mimic the practical human injury models. Another advantage was to banish the previous single intact DLES. These injury models were divided into two groups: elastic bolt and conventional screw (four cortical bone), each group with six samples.

Experimental machine operation: Fixed block at the top end of calves was made for fixing it on the BOSE equipment. The fixed block was made by mixing polymethylmethacrylate of type I and II. Lastly, the surface of exposed tibia and fibular bone was cleaned with dry cloth to make speckles for accurate localization with the optical non-contact measurement system. Top ends of calves were embedded into the groove of BOSE equipment and screwed tightly. Different ankle flexion-extension angles were set to mimic in vivo condition. The samples were slowly loaded with axial force to 750 N at neutral position, dorsal extension (10°), plantar flexion (20°), inversion (15°), eversion (10°), internal rotation (5°) and external rota-

Table 1. Separation displacement of DLES diastasis on the coronal plane using different methods

Separation displacement (mm)	Neutral position	Dorsal extension	Plantar flexion	External rotation	Internal rotation	Eversion	Inversion
Model (N = 12)	-0.85 ± 0.92	-0.69 ± 0.50	0.22 ± 0.36	1.86 ± 1.57	0.49 ± 0.45	1.80 ± 1.62	0.22 ± 0.24
Elastic bolt (n = 6)	-0.21 ± 0.23	0.26 ± 0.34	-0.24 ± 0.31	0.26 ± 0.45**	0.16 ± 0.14	0.21 ± 0.24*	0.19 ± 0.29
Conventional screw (n = 6)	-0.17 ± 0.25*	0.23 ± 0.31	-0.21 ± 0.35	0.18 ± 0.20**	0.12 ± 0.14	0.12 ± 0.19**	0.14 ± 0.26

Abbreviations: DLES, distal lower extremity syndesmosis. *$p < 0.05$ and **$p < 0.01$, compared with model.

Table 2. Axial stiffness of ankle and foot using different methods

Axial stiffness (N/mm)	Baseline (N = 12)	Model (N = 12)	Elastic bolt (n = 6)	Conventional screw (n = 6)
Foot	1195.45 ± 59.64*	1032.21 ± 43.69	1228.67 ± 65.79*	1323.91 ± 994.72**
Ankle	152.59 ± 49.22*	138.83 ± 59.54	157.36 ± 62.55*	171.52 ± 61.28**

*$p < 0.05$ and **$p < 0.01$, compared with model.

tion (15°) position. Before experiment, samples were pre-loaded to eliminate creep by human bone demands.

Assessment Index: The separation displacement of DLES on the coronal plane in different positions, axial stiffness of foot and ankle and pressure distribution in the tibiotalar joint of baseline, model, elastic bolt group and conventional screw group were measured by biomechanical testing methods, optical non-contact measurement system and stress measurement system.

Statistical analysis

Statistical analysis was processed by software SPSS, version 20.0. Data are presented from each group with six or twelve calves. All values are expressed as means ± standard deviation in the tables. Statistical analysis of the results was performed by t test for comparing the significance between groups and time points. A two-way unpaired t test with a Welch's correction was used to compare the difference between elastic bolt group and conventional screw group. The paired Student's t test was applied to compare the data before and after making models and doing mechanical test. *P* value less than 0.05 was considered statistically significant and *P* value less than 0.01 was considered very statistically significant.

Results

The separation displacement of DLES diastasis on the coronal plane using different methods.

As shown in **Table 1**, by comparing conventional screw group and elastic bolt group with model, separation displacement of DLES diastasis using both methods was significantly reduced at the external rotation ($p < 0.01$; $p < 0.01$) and eversion position($p < 0.01$; $p < 0.05$) on the coronal plane. This indicated that the two fixation methods were effective at some positions. Between conventional screw group and elastic bolt group, the separation displacement of the former one was shorter. This indicated that elastic bolt fixation had a certain elastic property.

The axial stiffness of ankle and foot using different methods

As shown in **Table 2**, axial stiffness of foot and ankle of baseline, elastic bolt and conventional screw group were significantly higher than that of model by up to 15.8% (foot) ($p < 0.05$) and 19.0% (ankle) ($p < 0.05$), 28.3% (foot) ($p < 0.05$) and 9.9% (ankle) ($p < 0.05$), 13.3% (foot) ($p < 0.01$) and 23.5% (ankle) ($p < 0.01$), respectively. The axial stiffness of conventional screw group was the highest. The elastic bolt group was slightly higher than baseline. Therefore, elastic fixation bolt had biomechanical superiority.

The pressure distribution of different fixation methods at neutral position

Explanation: The darker the yellow color, the higher the pressure and vice versa.

As shown in **Figure 2** for the contour plot of pressure distribution, the biomechanical property of elastic bolt group approached to baseline level, yet the pressure concentration region of conventional screw group had more evident lateral shift.

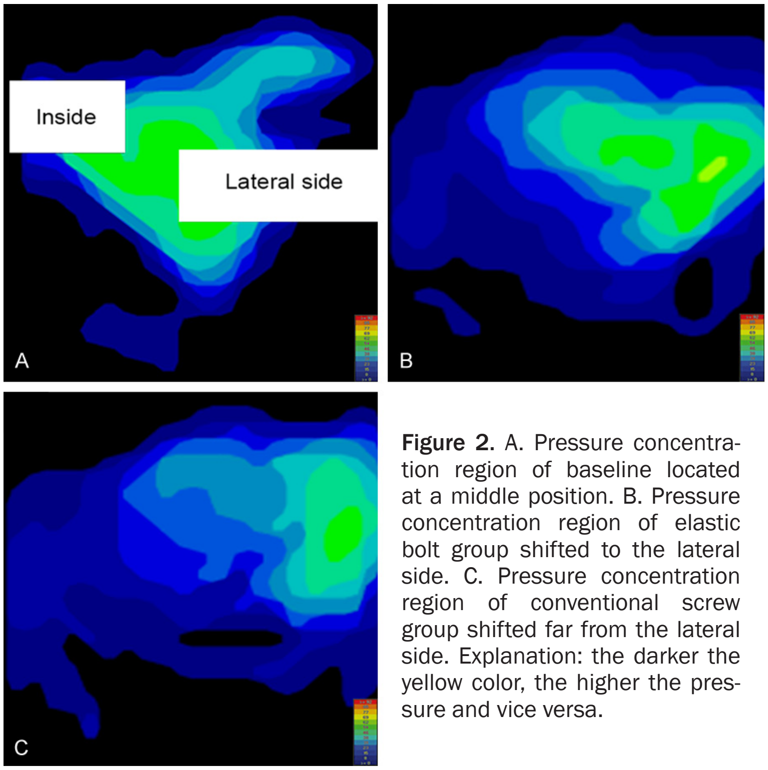


Figure 2. A. Pressure concentration region of baseline located at a middle position. B. Pressure concentration region of elastic bolt group shifted to the lateral side. C. Pressure concentration region of conventional screw group shifted far from the lateral side. Explanation: the darker the yellow color, the higher the pressure and vice versa.

Discussion

Although DLES injury is rare in the general population, it is common in lower-extremity-related athletes. Treating it properly is important to improve rehabilitation and performance of the patients. DLES consists of AITFL, PITFL, TTL, ITL, and interosseous membrane [11, 12].

To date, the most popular method is strong internal fixation, and cortical bone screw is the most common one due to its simplicity of operation. However, this treatment limits the normal physiological movement of distal tibiofibular joint and has the risk of loosening, release and breakage [13]. Moreover, DLES may turn from fiber connection to synostosis or ossification [6]. As a result, better treatment has been explored. Walsh [14] reported that complete immobilization of ligament has done no good to its healing and mechanical property. For the ankle mortise unstability caused by ligament injury, non-rigid internal fixation is conducive to the recovery of the structure and strength of ligament, maintenance of the micromotion of DLES, promotion of generating fibrous tissues and healing of ligament [15, 16]. It was reported that the Suture-Button flexible installation, which was used in the clinic recently, could promote healing [17-19]. Suture-Button is a button device connecting both side bone surfaces with high strength suture that passes through the bone tunnel as conventional screw horizontally thrilled through tibiofibular and distal tibiofibular joint [20-23]. In contrast, some studies indicated that flexible installation might result in loss of reduction, higher price and complicated operation [24-26]. Therefore, investigation of elastic fixation, which was easier to operate, was the focal issue attracting more and more attention for the treatment of DLES injury [27].

The results of the present study indicate that the elastic bolt was better for limiting the separation in coronal section after DLES injury. In addition, it could keep the micromotion of DLES with certain elastic space, which might develop construction and strength restoration of normal ligament tissue. Although the elastic bolt has less rigidity than conventional screw, it is closer to the normal tissue of DLES [28]. Therefore, it has better ability to resist distortion. The pressure distribution map indicated that pressure distribution area of baseline located in the central section, while after fixing with conventional screw, pressure distribution located in the lateral (fibular). However, the lateral shift of pressure distribution of elastic bolt group was mild, and it was more medial than conventional screw group. Compared with baseline, pressure distribution of conventional screw fixation had more lateral shift. Therefore, conventional screw might not have positive physical effect in the long term. In contrast, elastic bolt may have more persistent positive effect because of its less lateral shift. According to the features of pressure concentration distribution, the tibiofibular separation was improved significantly after internal fixation. However, the common ground of pressure distribution concentrated area was lateral shift in varying degrees. A previous study, which compared 1.5 mm double Kirschner wire with 3.5 mm screw on pressure distribution, indicated that both of these methods had lateral shift compared with baseline [29, 30]. In future study, it will be important to determine whether this phenomenon is typical or not. The uniqueness of our present study was the application of optical non-contact measurement system to record the displacement and maintaining the integrity of supra-tibiofibular joint at the same time. Certainly, it still has limitations when applying on smaller sample.

In conclusion, the elastic bolt has certain elastic property and biomechanical superiority for improving the recovery of ligament. Therefore, patients could stand up earlier and treatment for DLES would be promoted in the near future. Moreover, it is more affordable and easier to apply it in clinical practice.

Disclosure of conflict of interest

None.

Address correspondence to: Zongbao Wang, Anhui Provincial Hospital of Integrated Chinese and Western Medicine (The Third Clinical Medicine School of Anhui University of Chinese Medicine), No. 45, Shihe Road, Wulidun Subdistrict, Shushan District, Hefei 230061, Anhui Province, China. Tel: +86 18156005640/+86 0551-62736630; E-mail: wang673099692@hotmail.com

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