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Full Length Research Paper

Design and research of a new kind of minimally invasive fixation device in orthopaedics

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A new kind of external fixation for orthopaedics was designed in order to overcome the shortcomings of high weight, difficult operation and high degree of injury for the conventional external fixation. This device uses the so called quick casting method, which can be quickly concreted, to efficiently reduce the injury to patients. It is mainly composed of the macromolecule casting material and the steel stainless nails which fasten the device to the bone. In order to verify the feasibility of the designed structure, FEM (finite element method) was used to simulate the real condition of the load when the device was used after an operation. At the same time, optimum design was also carried out for the number and dimension of the nails in order to obtain the best operation effect. It was concluded from the simulated result that when the real load was applied on the fastened broken bone, the relative displacement of the broken border was just 0.33 mm, which was much lesser than the permitted limit (1 mm). This was in line with the request to cure the patients whose bones are broken and it showed the correctness of the design. Finally, in order to prove the feasibility of the design, ten sheep were used as specimen. It was concluded from X-ray sketches of 2, 4 and 8 weeks that there is no relative displacement between the borders of the broken bone and the bone that was well healed. This indicated that this scheme can be feasibly used to cure the broken bones. However, this design scheme can be used as an effective treatment means.

Key words: External fixation for orthopaedics, quick casting, x-ray image, cure.

INTRODUCTION

As one of the common illnesses for medical science, fracture of the bone can initiate great injury to patients. However, how to quickly and effectively cure this illness became one of the main research directions to osteology. As one of the most effective treatment means, bone-fixation technology (Kapoor et al., 2010; Wähnert et al., 2010; Jupiter and Marent-Huber 2010) is always the main means for the patients. So, many researchers are carrying out their investigations on this research field. Generally, the treating method can be divided into two kinds: Internal fixation method and external method. Internal fixation technology is popularly used by doctors (Südkamp et al., 2010; Rozental et al., 2009), but this kind of method possesses some shortcomings. Firstly, some soft tissue near the broken bone must be cut open during the course of the operation. This may easily cause the infection of the wound. At the same time, the second operation must be carried in order to take out the fixture. This increases the pain of sufferers and the curing time is lengthened correspondingly. In some cases, external fixations are used for some weak people, aged people and some people who are seriously suffering from medical disease (Keeling et al., 2008; Hove et al., 2010; Willie et al., 2009). Comparing this to the former method, this method can effectively decrease the time for treatment, but it still has some shortcomings. Firstly, big bulk and weight for this device can cause severe inconvenience of move-ment to patients and the stainless nail can cause virulent stimulation to patients. At the same time, in order to guarantee the stiffness of the structure, the stainless nail is produced with big radius. This can cause great infection to the wound because of

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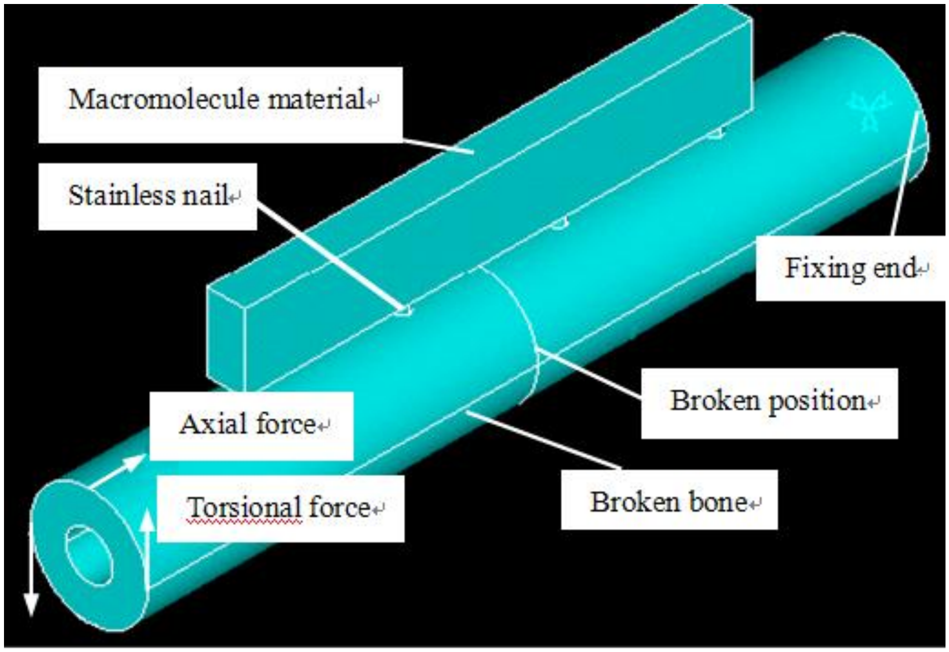

Figure 1. The schematic model of the bone fixation structure.

the operation. How to overcome the shortcomings to both internal and external fixation is of great importance.

This paper introduces a new kind of bone fixation device. It uses the advantages of little weight and bulk for internal fixation. At the same time, like the external fixation device, one operation for the patient is enough. In order to verify the feasibility of the design, Finite Element Method (FEM) software was used to simulate it. Finally, animal experiment was made to prove it and the ideal result was obtained.

MATERIALS AND METHODS

Simple working principle of the fixation is shown in Figure 1. It is mainly composed of the stainless steel nails, the macromolecule supporting structure (polymethyl methacrylate, PMMA) and the broken bone. During the course of the operation, the stainless nails are first installed on the broken bone, before they are fixed by the macromolecule material using the so called quick casting method. So, the broken bone and stainless nail are connected as a whole body by the material. The macromolecule material is used because of its advantages of low concreting temperature and high concreting speed. Additional injuries, except the operations such as the scald (caused by high temperature), split of the bone (caused by the inner stress during the course of the fastening process), etc., are reduced correspondingly. In order to avoid the relative movement (including the rotating and moving) between the nail and macromolecule material, the nail (Figure 2) is produced with a rectangle groove on top of it. Fabricating this device with this method can not only reduce the bulk and weight as compared to the conventional external device, but can also avoid the second-time operation caused by the conventional inner fixation structure. The injury caused by the pre-introduced methods is also decreased. On the other hand, because the structure was cast on the surface of the patient's skin, the possibility of the infection caused by exposure under the air in the external operation was also avoided. In order to increase the stability of the whole structure and decrease the problem of asymmetry distribution of the inner stress, multiple numbers of stainless steel nails were used and symmetrically distributed on the structure.

Figure 2. The stainless steel nail used.

Optimum design and FEM simulation

In order to verify the feasibility of the design, a device was designed and fabricated on the sheep's shinbone before it was used. Before the fabrication, optimum design and FEM simulation was used to increase the reliability of the device. In order to increase the feasibility of the design, some rules must be obeyed as follows:

Table 1. Calculated values of [*F*].

Diameter of the nail (mm)	Ultimate force (N)
2	32.2
3	72.4
4	128.7
5	201.2
6	289.7

Table 2. Shearing force (N) values versus diameter (mm) and number of nails.

Nail diameter (mm)	Shearing force (N)			
	Nails' number			
	2	4	6	8
2	150	75	50	37.5
3	150	75	50	37.5
4	150	75	50	37.5
5	150	75	50	37.5
6	150	75	50	37.5

(1) The radius and number of nails must be few in order to reduce the pain it caused to patients.
(2) The nails must be symmetrically distributed on both sides of the broken bone in order to reduce the possibility of split caused by the asymmetry of stress. As such, it can be selected in even number.
(3) When the operation is finished and the sheep walks, there must not be a split on the position, which means that the concentration of the inner stress must not surpass the ultimate value.
(4) The loaded stress of the nail must not surpass the ultimate value of the stainless steel.
(5) When the sheep is walking after the operation, the maximum gap between the broken bones must not surpass 1 mm.

Number and dimension selection of the nail

According to the aforementioned rule and the real engineering request, the radius of the nail can be in the range of 2 and 6 mm. For the fact that the dimension of the sheep's shinbone is about 50 mm, the length of the nail can be in the range of 50 and 90 mm. The designed weight of the sheep is in the range of 25 and 30 kg. According to material mechanics theory, when the operation is finished, the main load applied on the sheep's leg is axial force. When this force is transformed to the nail, the load applied on it can be the shearing force. The relationship between the load and the shearing stress can be expressed as:

$$\tau = \frac{4F}{\pi d^2} \tag{1}$$

Where, τ is the shearing stress; *F* is the shearing force applied on the nail and *d* is the diameter of the nail (which is equal to the diameter of the hole on the bone).

According to (1), *F* can be expressed as:

$$F = \frac{\pi d^2 \tau}{4} \tag{2}$$

According to the third rule, when the operation was finished, the shearing stress applied on the bone must not surpass the ultimate stress of the bone. Thus, it can be expressed as:

$$F \leq \frac{\pi d^2 [\tau]}{4} \tag{3}$$

Where, $[\tau]$ is the resistance to shear strength of the bone. In most of the design, coefficient of safety *a* must be added in the equation in order to confirm its safety, so (3) can be changed into:

$$F \leq \frac{\pi d^2 [\tau]}{4\alpha} \tag{4}$$

For the fact that this device is going to be used for mankind in the future and the bone is a little brittle, high coefficient of safety must be selected to confirm high reliability. For this design, 8 is selected as the referenced coefficient of safety.

According to pertinent reference, resistance to shear strength of the bone is about 82 MPa. So, the ultimate shearing force applied on the bone can be expressed as:

$$[F] = \frac{\pi d^2 [\tau]}{4\alpha} \tag{5}$$

Combining the range of the nail's dimension from 2 to 6 mm, the calculated [*F*] can be expressed in Table 1.

In this design, the sheep's weight is in the range of 25 to 30 kg. In order to guarantee the reliability of the structure, the load applied on the broken leg is supposed to be 300 N. When the operation ends, the shearing force F_L applied on each nail can be expressed as:

$$F_L = \frac{W}{N} \tag{6}$$

According to (6), for different conditions of the nail's number and diameter, the load applied on the nail can be expressed in Table 2.

Table 3. Pertinent parameters of the simulation.

Bone (mm)			Nail		
Length	**Outer diameter**	**Inner diameter**	**Number**	**Diameter (mm)**	**Length (mm)**
100	30	12	4	4	50

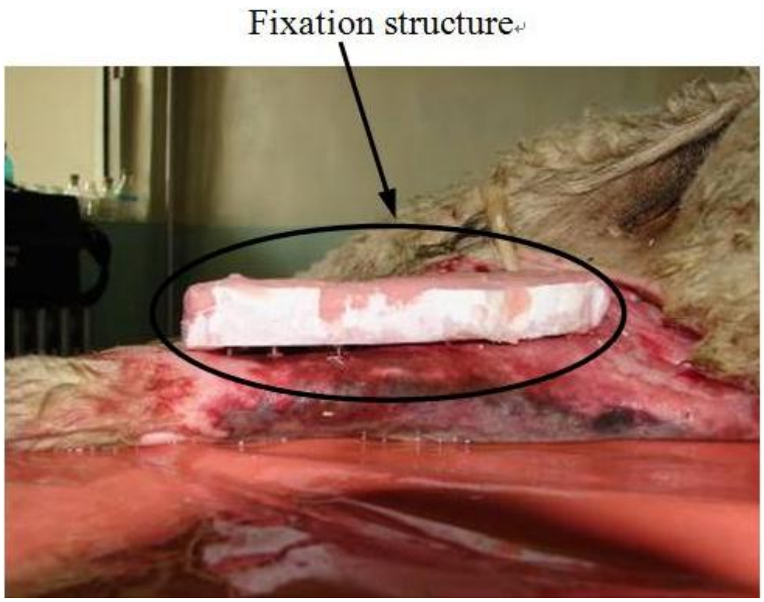

Figure 3. The image of the fixed leg of the sheep.

According to mechanics theory, if one nail on one side is used, the device can be instable; as such, this must be avoided. On the other hand, because the diameter of the sheep's shinbone is just 50 mm, 8 nails are not so necessary. At the same time, because 2 mm is too slim, it is hard to fabricate in bulk. When the diameter is 3 mm, the load close to the ultimate result must also be neglected. So, the fitted combination of the diameter and the number can be (4 mm, 4), (4 mm, 6), (5 mm, 4), (5 mm, 6), (6 mm, 4) and (4 mm, 6). So, according to rule one, (4 mm, 4) can be selected as the best scheme.

FEM simulation

In order to verify the correctness of the design, it is important to calculate the correctness of the whole structure. For the fact that the structure is a little complex, it was difficult for the conventional mechanics theory to obtain the precise result. FEM (Finite Element Method) is one of the effective methods used to solve it. Here, FEM software Ansys was used to prove the feasibility of (4 mm, 4) design. The simulated model is shown in Figure 1, while the detailed dimensions are listed in Table 3. In this model, the elastic modula of the bone, steel nail and macromolecule material were 18, 206 and 30 GPa, respectively, while the possion's ratios were 0.28, 0.3 and 0.2, respectively.

Using the static analysis model of Ansys, when 300 N load was applied on the bone, it was observed that the calculated relative displacement between the broken borders was just 0.33 mm. This was far below the requested value of 1 mm, which was the least distance for the cure. However, this indicated that the design was right.

RESULTS AND DISCUSSION

Animal experiment was carried out in order to verify the validity of the experiment. In this experiment, ten sheep were used as the specimen. Their weights were in the range of 25 and 30 kg. However, the detailed operation steps can be listed as follows: Firstly, the X-ray video fluoroscopy technology was used to carry out the reposition step for the wounded bone until it reached the request for operation. Secondly, the stainless steel nail was used to penetrate the soft organism of the bone. The best distance to the broken end can be 20 mm, and the number of nails can be determined by the real condition. It must be at least two for each end. Thirdly, the exact reposition was further made under the video fluoroscopy, after which the temporary external fixation was made. However, the mould of the self-concreted macromolecule material was placed at the same time. Fourthly, the casting method was used to combine the nail, the broken bone and the macromolecule material, and all the three parts were connected as a whole structure. Fifthly, the temporary external fixation device and the mould were gotten rid of, and this concluded the operation. In order to prove the feasibility of the device, the effect of the operation was observed for 8 weeks until the sheep was recovered.

Figure 3 shows the image of the broken bone for the

Figure 4. The walking picture as soon as the sheep woke up.

sheep during the course of the operation. It was concluded from the sketch that the reposition was very good and no abnormality took place, which indicated that the reliability for this device was perfect. When the sheep woke up, it could stand and walk immediately, which indicated little damnification in the results of the operation. Figure 4 shows the operated sketch of the sheep. Comparing this to the conventional external fixation device, the dimension of the device was greatly reduced. Figure 5 shows the X-ray image of the operated broken leg two weeks after the operation. In this sketch, some bony callus was developed around the broken position. Consequently, no obvious relative movement could be observed between the broken ends of the bone, which indicated that the operation was successful. Four weeks later, bony callus (Figure 6) developed on the wound and obvious remodeling was formed. The fracture line was dim and the position was excellent. Figure 7 shows the X-ray image 8 weeks after the operation. It was concluded from the sketch that the fracture line disappeared, which indicated that the bone healed up and the structure can be taken away now. This process indicates that this is a feasible scheme to cure the broken bone.

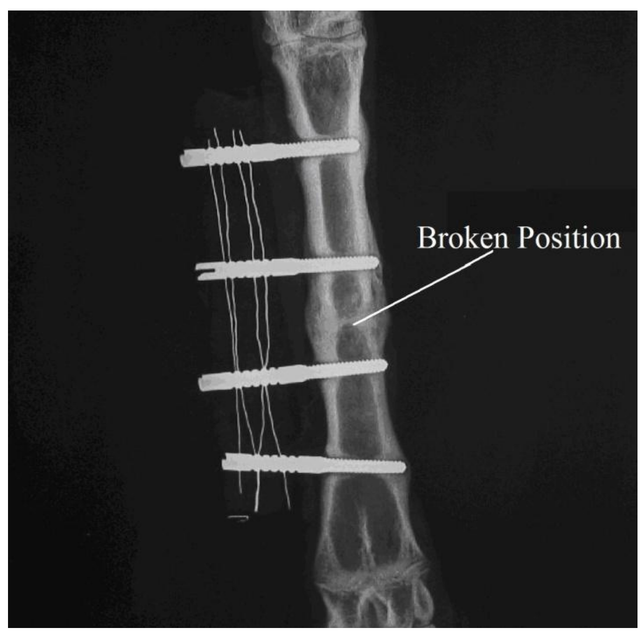

Figure 5. X ray image of the leg two weeks after the operation.

Conclusions

1) A new kind of bone fixation was introduced and designed in order to shorten the healing time and reduce the operation pain of patients whose bones are broken. In this method, the so called quick casting method was used to finish the fabrication.

2) FEM method was used to carry out the optimum design and verify the reliability for the designed structure.

Figure 6. X-ray image of the leg four weeks after the operation.

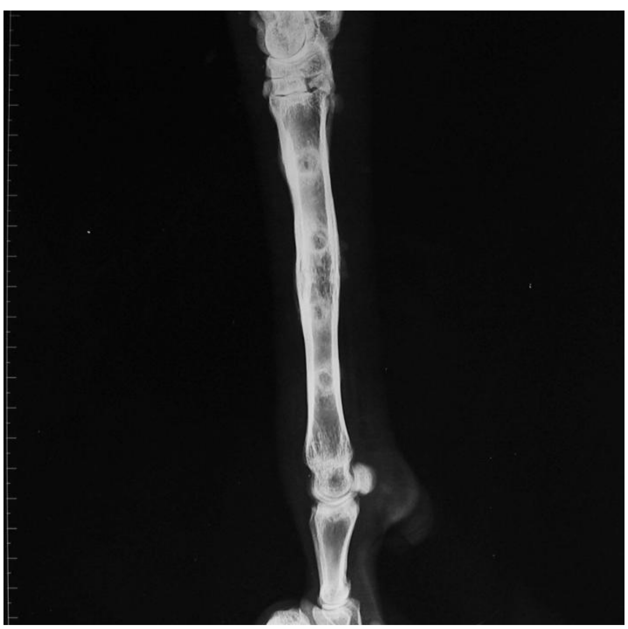

Figure 7. X-ray image of the leg eight weeks after the operation.

It was concluded from the simulated result when the load was applied on the structure that the relative displacement between the broken sides was just 0.33 mm, which was far less than the required value (1 mm). This indicates the correctness of the design.

3) Using the sheep's shinbone as the specimen, animal experiment was made to verify the validity of the device. It was concluded from the experiment that when the operation was finished, no relative displacement took place between the broken sides. This means that the operation was successful and the structure was reliable. From the X-ray images of two, four and eight weeks after operation, we can see that the bone was well healed. This also showed that the structure was well designed.

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