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Design and Implementation of Novel Elbow Orthosis

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It is popular to use the elongation method with Ilizarov tension stress rule on orthopedic diseases for limb lengthening. But there is no report of Ilizarov tension - stress rule for elbow Orthosis based on relevant literature. The paper designs a new elbow Orthosis by the regenerative principle, tensile stress theory and biomechanical three-point force correction law. Study the effectiveness of elbow Orthosis by static resistance strain measurers and other application. Set up the simulation platform to optimize the design and apply on clinical trials. Record the results of clinical trials to analysis and evaluation and the results show that the novel elbow orthosis is minimally invasive, simple, effective and no complications. On the other words the novel device based on Ilizarov technology can reveals pathological mechanism of patients and the angle regulating controller can be facilely adjusted by doctors and patients.The elbow orthoses meet the requirements of design, mechanical analysis and simulation results confirm its effective mechanical properties. The new structure meet the biological requirements of the human elbow and has the feature of sufficient strength, stiffness necessary, adequate stability ,simple structure, stable, easy to adjust, wear comfortable and safe and reliable. Compared with other methods, the elbow Orthosis provides a new treatment method to restore elbow dysfunction also provides a theoretical basis for the next clinic.

Key words: Elbow, Llizarov, Elbow dysfunction, Orthosis, Mechanics analysis.

With the [1]more and more high-energy injury, the ostoperative stiffness contracture of elbow is more common in clinical practice. From the record, we can see that joint stiffness is caused by fracture on the distal end of humerus and dislocation of elbow. Elbow is very sensitive to trauma in Clinical treatment, but there are not the standardized treatment to the prevention and cure, so it is important to find out the new way to this problem (John, *et al*.,2009;Hong, *et al*.,2011;Eirik, *et al*.,2011).

There are many ways to treat postoperative contracture and stiffness on elbow such as operation and non operation treatment, but all this are difficult to achieve the perfect curative effect. The non operation treatment gradually increase the range of motion and reduce the local inflammatory reaction, but this way has the following questions such as rebound, more serious stiffness, swelling, heterotopic ossification and Iatrogenic fracture. Operation treatment can restore some of the activities of the joint, but this way has the following questions such as extensive destruction on the ligaments and muscles, and instability to the joint for the trauma (Huang, *et al*.,2012; Jiang, *et al*.,2012; Xiao, *et al*.,2011). In addition, all this symptoms will be aggravated by postoperative short-term fixed. Therefore, it is necessary to find out the better treatment to the postoperative contracture and stiffness on elbow. Now days, the study on the orthotic to postoperative contracture and stiffness is currently a hot subject of research in clinical treatment. So

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using the experience from the clinical treatment and the mechanics model design the novel orthosis is significant (Tong, *et al*.,2012; Zhou, *et al*.,2012; Tang, *et al*.,2012).

The paper propose the orthosis, which creeps or stresses relaxation principle to increase joint passive activity, plays an important role in the rehabilitation of the elbow joint dysfunction(Wu *et al*.,2012). In the paper (Zhou, *et al*.,2012), a new type of hallux valgus orthosis which was combined with clinic to the requirements of hallux valgus patients was designed and manufactured.It was tried on a total of 34 Hallux valgus patients,3 of whom were male,31 were female,ages were from 21 to 71,and the average age of them was 42.Hallux valgus angle was from 15.2° to 20.4°,an average of(17.4±2.1)°. After the three month treatment, there were 5 cases getting improvement of pain symptoms, in which a total of 7 cases had pain, accounting for 71.43% of patients who had pain 3 cases had got correction of Hallux valgus,accounting for 8.82% of patients who had hallux valgus. The HVA of 24 Hallux valgus patients did not increase, accounting for 70.59% of patients with Hallux valgus. The new Hallux valgus orthosis has orthopedic features and there is obvious effect on the young patients.

In the paper (LV, *et al*.,2012),the children with spastic cerebral palsy (CP) were divided into observation group(n=20) and control group(n=20) to observe the therapeutic effect of ankle-foot orthosis(AFO) on the children with spastic CP. Both the two groups were trained with Traditional rehabilitation training and the observation group was added with AFO to treat static and dynamic tiptoe. After one course of treatment(3 months), the crus triceps muscular tone in the observation group was much lower than that in the control group($P<0.05$),and the scores of GMFM in the observation group were much higher than those in the control group($P<0.01$) after treatment. So the AFO can decrease the crus triceps muscular tone of the children with spastic CP and improve the gross motor function.

In the paper (Cheng, *et al*.,2012) 40 patients with spastic cerebral palsy were randomly divided into two groups of the control group and the test group. The patients at the control group were treated with the Bobath and Vojta, and the patients at the test group were added to the ankle-foot orthosis (AFO)and low-frequency stimulation. After twelve weeks , there were significant differences of ankle range of motion, modified Ashworth and GMFM scores difference before and after rehabilitation between the test group and control group($P<0.01$).So the AFO combined with low-frequency stimulation is advantageous to rehabilitation of spastic cerebral palsy children.

The stiff adhesion on the elbow is easy to occur after trauma or operation. On the other words, the high energy trauma can cause loss of elbow and knee joint activities and the minor trauma may lead to the elbow and knee joint stiffness. In recent years, fractures around the elbow and soft tissue trauma treatment has made great progress, but the joint adhesion contractures are still quite common (Yao, *et al*.,2012; Zhao, *et al*.,2012).To solve these problems, the elbow orthosis is proposed in clinical treatment(Zhong, *et al*.,2012).Early dynamic orthosis are used to the elbow joint ankylosis by Hepburn in 1991(Hepburn, *et al*.,2012). Hybrid orthosis has also been used in the treatment of forearm rotation contracture, and Lee using dynamic orthosis to the patients has the better results (Lee, *et al*.,2012).But the dynamic orthosis has the disadvantage is that the system cannot get the max tension of the organization to bear. The tissue tearing, bleeding swelling and inflammation may be caused by the continuous large tension. On the other hand, the stress is too small to work. Studies show that it is long to adjust system for patients to use this king of orthosis (Lin, *et al*.,2012).

So, the novel elbow orthosis is first proposed in this paper to solve this problem by tissue regeneration theory and the biomechanics of three point correction rule.

The novel elbow orthosis can improve therapeutic effect, reduce energy consumption. From theoretical analysis and factual examination, we can see that the novel elbow orthosis improve the adjusting speed and precision, and the treatment is compact, and feasible.

Elbow joint orthodontic treatment mechanism

The elbow is a compound hinge joint. The joint capsule, muscular system and numerous ligaments maintain its stability. So the flexion and extension activities depend on the surface angle and the surrounding soft tissue such as joint geometry, bone, joint capsule, ligament and muscle.

Research show that joint capsule has made the phenomenon of contracture and thickening in a few days when the elbow fractures, dislocation or soft tissue injury. And the thickening can reach 3-4 mm. Biological responses come form the elbow on blood chemical irritation and pain be caused by muscle co-contraction may lead to capsular contracture especially in the anterior joint capsule There are many reasons to make the elbow contracture such as the damage of the joint capsule, ligament and muscle. The articular cartilage surface damage, degeneration, malunion, osteophyte, intra-articular loose bodies, long braking and other reasons also bring stiff elbow contracture.

Principle of Ilizarov Biomechanics theory

Biological tissue are slow continue traction and will produces a certain tension, this can stimulate the tissue regeneration and growth. This growth mode are the cell division consistent same as fetal tissue (Qin, *et al.*,2012). With this principle, we can get the model of mechanical principle of elbow in figure1. The F1 is the stress to the forearm, the F2 is the stress to the upper arm and the F3 is the stress to the elbow joint.

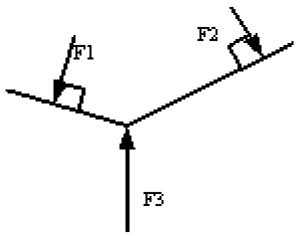

Fig. 1. Mechanical principle of elbow

Structure of elbow orthosis

The novel elbow orthosis is design to overcome the shortcomings of Lizarov elbow fixed drafting device. The Lizarov elbow fixed drafting device fixed the bone by round osseous pin via operation. The patient is unwilling to accept this treatment because that the needle tract is vulnerable to infection and it is not easy to wear. Thinking about all those problems, the elbow orthosis should have some advantages. Firstly, the novel elbow orthosis should have the ability of enough strength. Secondly the novel elbow orthosis should have the ability of necessary safe. Thirdly, the novel elbow orthosis should have the ability of sufficient stability and the lighter weight. Fourthly, the novel elbow orthosis should be comfortable to wear. Finally, the novel elbow orthosis should be easily adjusted by doctors and the patients.

Thinking about those rules and the experience on clinical treatment from doctor, the structure of novel elbow orthsis is shown on the figure2.

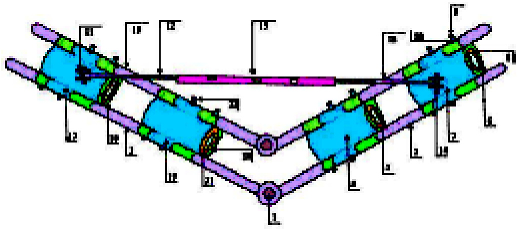

Fig. 2. Structure of the novel elbow orthsis

The orthosis working condition can be easily changed. The figure 3 is the minimum djustment angle (60 degree) and the figure 4 is the maximum adjustment angle(165 degree). The patients and doctors can adjust the adjusting rod (13) at the time of treatment

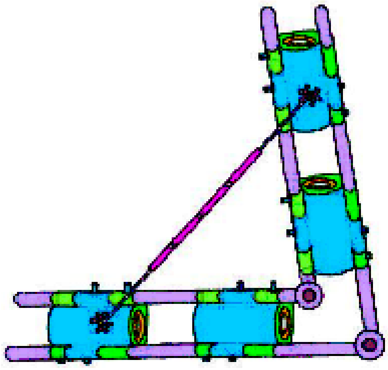

Fig. 3. Minimum djustment angle (60 degree)

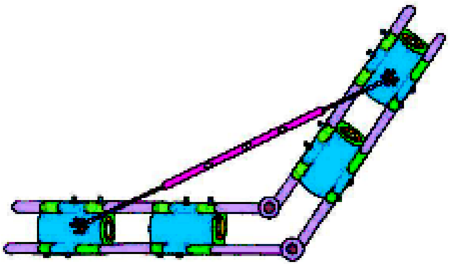

Fig. 4. Minimum djustment angle (60 degree)

Table 1. The message of elbow orthosis

1	connecting bolt
2	upper arm connecting rod A
3	forearm connecting rod A
4	upper arm semicircular fixing plate A-1
5	upper arm semicircular fixing plate A-2
6	upper arm semicircular fixing plate B-1
7	upper arm semicircular fixing plate B-2
8	upper arm pressure pad
9	upper arm screw
10	screw hole
11	forearm connecting bolt
12	dynamic traction screw
13	adjusting rod
14	upper arm bolt
15	forearm arm connecting rod B
16	upper arm connecting rod B
17	forearm arm semicircular fixing plate A-1
18	forearm arm semicircular fixing plate A-2
19	forearm arm semicircular fixing plate B-1
20	forearm arm semicircular fixing plate B-2
21	forearm arm pressure pad
22	forearm arm screw

The upper arm semicircular fixing plate B-1 (6) is fixed by the fixing upper arm screw (9).The upper arm connecting rod A (2) and the forearm connecting rod A(3) are connected by the connecting bolt(1). The dynamic traction screw (12) and the adjusting rod (13) are design to easily adjust parameters of the system. Others units are recorded as the table 1.

The elbow orthsis is make up with many parts and the table 1 is the schedule of the units.

Stress analysis

Using the method at the figure 2, produce the sample and make the experiments in the mechanical laboratory. The static strain gauge is XL2101B6 and the foil resistance strain gauge is BSF120-3AA. The gauges consist of metal foil in the form of a grid. So the sensitive to grid size is 3.1 mm × 1.0 mm and the base size is 6.0mm × 3.0mm.The figure 5 is the strain gauge physical connection

Record the experimental data and simulate on the Matrix Laboratory by the YL-DFNN (Hao, *et al*.,2012). The fuzzy neural network in clinical date analysis has already become is currently a hot subject of research. Applying the neural network in fuzzy systems can solve the fuzzy system knowledge extraction problem. Applying the fuzzy system in neural networks, the neural network is no longer a black box, and humanity's knowledge is very easy to fuse in the neural network. It is apparent that a fuzzy neural networks derives its computing power through, first, massively paralle distributed structure and, second, ability to learn and therefore generalize. Use the YLL-DFNN to identify this experiment, we can get the result as follows.

Fig. 5. Strain gauge

Fig. 6. Static strain gauge

The deformation is non-linear relationship due to the different materials of the orthosis. On the other hand, the stress of forearm connecting rod A is large than forearm semicircular fixing plate A and forearm semicircular fixing plate B for the structure of the orthosis.

The figure 8 is the stress of the forearm rod at the time of experiment. Record the experimental data(x denote the number of rotation, y denote the gage and z denote the stress) and simulate on the Matrix Laboratory. We can get the result as follows. The stress of the connecting rod is increase with the increase of rotations and the different units have the different stress due to the influence of the material and structure, and the maximum is 59.6 Newton.

From the experiment we can see that the novel elbow orthosis is feasible so we let this orthosis to patient in clinical treatment.

Application

Choice the patient in random, in this section, the 5 patients were selected and the table 2 is the schedule of the messages of patients. Let the patients to use this orthosis three months.

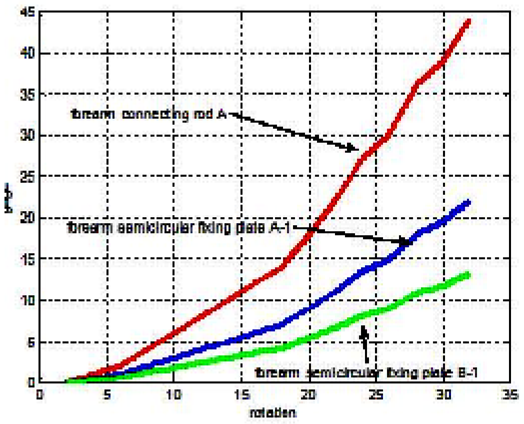

Fig. 7. Stress of forearm

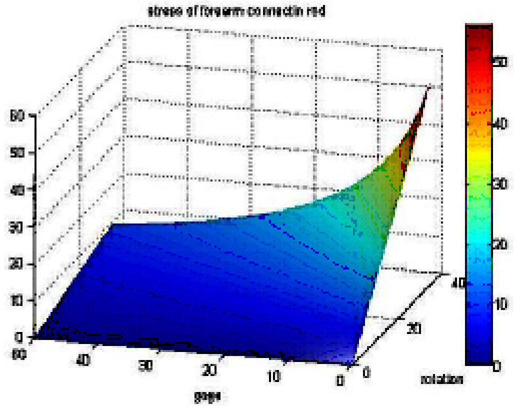

Fig. 8. Stress of forearm connecting rod

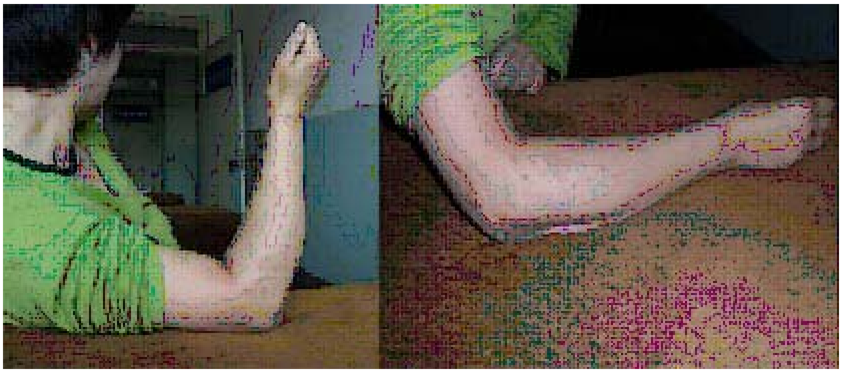

Fig. 9. Range of elbow before treatment

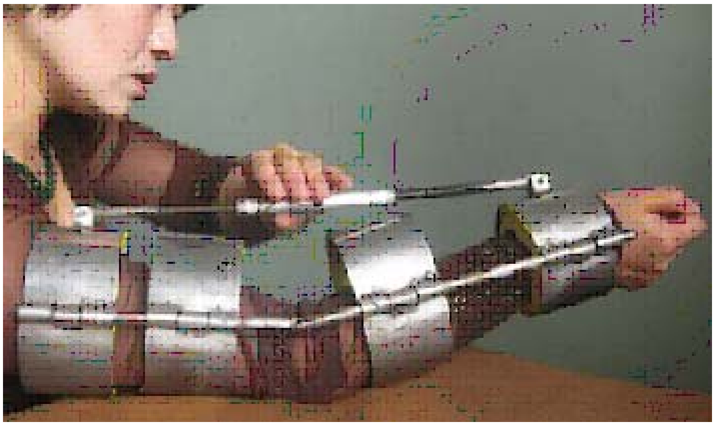

Fig. 10. Range of elbow after treatment

Table 2. The message of patient

Number	1	2	3	4	5
Sex	male	female	male	female	male
Age	26	43	39	41	58
Fracture type	A	D	B	C	D
Wear time(day)	85	91	65	70	89
range of elbow joint after treatment(degree)	25-140	35-130	40-120	40-120	35-125
range of elbow joint before treatment(degree)	65-95	70-90	65-100	80-100	75-95

Let number 2patient use the new elbow orthosis from March 29th, 2012 to July 12th, 2012. The figure 9 is the range of elbow of number 2 patient after operation. The figure 10 is the range of elbow of number 2 patient after treatment. Doctor and patient can easily adjust working condition on orthisis. The change of the range of elbow is almost 40 degree. All this shows that the complications and reoperation can be reduced by elbow orthosis after surgery. The rebound of rehabilitation can be reduced and the rebound of rehabilitation is shorter than other methods. The orthosis is easily wear and the treatment effect is significant.

RESULTS

There is a period of internal fixation or splint and plaster external fixation plaster after elbow fracture. The elbow of patients have varying degrees of dysfunction after removal the external fixation. So the postoperative stiffness and contracture of elbow is more common in clinical practice. In order to find out an effective treatment the novel elbow orthosis is first proposed in this paper.

The novel elbow orthosis is designed by doctors who are working for the long time in clinical care and mechanics researchers who have experience of the mechanical design and the ability of computer simulation. So novel elbow orthosis has the abilities of better biological requirements to the human elbow, sufficient corrective stress, simple structure, comfortable and reliable.

From the experiment and simulation, we can see that orthosis have the enough stress by adjustment the location of dynamic traction screw(12) and adjusting rod(13). The elbow orthosis provides a new treatment method to restore elbow dysfunction and also provides a theoretical basis for the next clinical treatment.

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