Design and Application of Ankle Foot Orthosis with Intelligent Load Control in the Treatment of Lower Limb Fracture*[1]

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Abstract: Purpose. Through the design and construction of a kind of intelligent control knee fracture load of ankle foot orthoses (AFO), accurately deal with knee fracture due to the large weight of the load more slow walk on training time and cause illnesses out many problems, for knee fracture under precise control load early rehabilitation training to provide a new type of rehabilitation ankle foot orthoses. Method. The design is based on different in patients with fracture of knee gait training when the load reaches the limit set, using the knee patellar ligament bearing to reduce the load of knee fractures, femoral condyle inside and outside the stand along the suspension mechanism to prevent the AFO walking slippage, make the patient's body was no longer under the knee or part to bear the extra load according to the assessment, its core technology is to drop the displacement and the load regulation of organic combine, and then a real-time observation adjustment for below the knee fracture rehabilitation training in the role of body weight. Conclusion. Through the clinical experiment proved that the intelligent AFO can meet the knee fracture patients in stand up to different requirements of training period of body weight.

Introduction

The fracture of knee joint mainly includes the fracture of lower limb and ankle, which accounts for more than 20% of the total fracture. The tibiofibula double fracture, tibial fracture and fibula fracture of the lower limb are usually open or comminuted, which accounts for about 13% of total fracture[1], while ankle fracture is 7.19%[2]. Early postoperative rehabilitation is considered important, but till now, there are only a few bases to follow for the standard of complete postoperative weight bearing time[3-4]. It is found that because of the limitation of load-bearing exercise in the early postoperative period, bed rest time is prolonged, complications are increased, and functional recovery is affected[5]. At present, more and more scholars conduct the concept of accelerated rehabilitation surgery, which means to reduce the perioperative harm of patients through multidisciplinary cooperation. It includes preoperative advance analgesia, psychological care, minimizing physical discomfort such as postoperative pain, early rehabilitation exercise and so on[6]. At present, the concept of accelerated rehabilitation surgery is gradually emerging in orthopedic surgery. Studies have shown that the application of this concept in orthopedics can

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improve patients' psychological stress response, improve postoperative physical condition, and reduce postoperative pain[7] . With the development of rehabilitation medicine, assistive devices and orthosis have gradually replaced gypsum as a means of conservative treatment in orthopaedic surgery[8]. For example, the patellar ligament bearing orthosis in the lower limb orthosis (also known as PTB ankle orthosis) is a load-free orthosis. It is divided into partial load-freed and full load-free according to its function, and it is suitable for early load-free training of various diseases below the lower limb. When there is no possibility of re-operation for tibiofibular fracture and tibial pseudarthrosis after repeated surgical treatment failure, ankle foot orthosis (AFO) bearing patellar ligament should be worn. Besides, there is no possibility of further surgical improvement of foot or ankle fractures and injuries caused by any reasons. AFO patients wearing patellar ligament and completely free of load do not need any assistive devices to stand and walk well. Using patellar ligament load-bearing fis can provide early rehabilitation training, improve local blood perfusion, and promote fracture healing. In the treatment of limb fracture, AFO can prevent problems of possible joint deformity, force line or stability. To conduct rehabilitation training safely and timely, shorten the course of the patients, and promote the patients with tibiofibular fracture to return to normal life as soon as possible, the suitable AFO is quite important. Most of the partial and full load-free adaptations of conventional patellar ligament load-bearing orthosis cannot be accurately quantified and adjusted based on the experience of orthosis technicians. The basic elements of the AFO system should include the coordination among patients, AFO and rehabilitation training. The main goal is to optimize the efficiency of patients - AFO - rehabilitation training. In the design of intelligent AFO, we should scientifically consider the factors of patients' pathology, rehabilitation psychology and the interaction of patients, AFO and rehabilitation training, so as to ensure the safety, comfort and high efficiency of rehabilitation when using AFO. The adding of intelligent load collection and regulation is the basis for clinicians to solve the safety of rehabilitation prescriptions, and is the theoretical support of the "patient-centered" concept. Based on these questions, we have developed a light, durable, accurate AFO for postoperative limb fractures, which aims to provide help for the early rehabilitation of such patients.

1. Design Concept of Intelligent AFO for Lower Limb Fracture

1.1 Research of Intelligent AFO for Lower Limb Fracture

One of the most important rehabilitation steps of lower limb fracture is the training of standing and walking with partial or full load-free intelligent AFO. Patients often think that rehabilitation does not start until the fracture has healed, and orthopedists are used to fully entrusting rehabilitation to physicians in physiotherapy and rehabilitation. These concepts are incorrect. In fact, fracture rehabilitation is an important part of the medical process, and it should start as soon as the patients enter the hospital[9]. Postoperative rehabilitation should follow the three principles of individuation, gradualness and comprehensiveness. Scientific rehabilitation guidance can improve the surgery effect and restore the limb function to the maximum extent. In some cases, assistive devices are even the only means of rehabilitation for some people with physical dysfunction[10]. In recent years, rehabilitation robot-assisted neurorehabilitation and motion training control have become the main development direction and research focus of rehabilitation worldwide[11]. American "Delisa's Physical Medicine and Rehabilitation" divides rehabilitation robots into four major mechatronic products: robotic assistive devices, prosthetics, orthosis, and rehabilitation robots[12-15]. Zhang Xiaoyu, Ping Wei et al, divide personal care robots into three common types: mobile service robots, assisted robots, and manned robots. Each of them can be divided into sub-categories: mobile service robot, assisted robot and manned robot. This fully shows that rehabilitation robot research has become the focus for assistive devices, but it will take time to interface with clinical applications. Hai Zhifan et al, have developed a knee joint exerciser, and applied the exerciser when 72 patients with tibia fractures can get out of bed to move. The results show that this device can promote the extension and flexion of knee joint. The lower limb rehabilitation aid mechanism designed by Harbin Institute of Technology mainly includes walking aid and lifting mechanisms. With these two devices, patients can perform functional exercises to restore health without the help of others.

1.2 R & D of Intelligent AFO of Intelligent Lower Limb Fracture

As we all know, the rehabilitation of patients with fracture requires that the injury or the surgical site is relatively fixed, while the normal part of the joint maintains the motor function. In this way, proper muscle strength training can be performed to promote blood circulation, enhance the function of dynamic and static structural stability, and prevent complications. The basic goal of rehabilitation is to maintain muscle strength and endurance. The existing AFOs in the medical market have the disadvantages that they cannot accurately control the fracture endurance, are expensive, and have poor patient compliance. At present, in the domestic and international medical markets, there is no intelligent control load AFO for lower limb fracture that can fix, correct, free from load, and that can accurately control displacement and load. Concerning the needs of clinical patients, we have cooperated with Harbin University of Science and Technology, Chengdu University of Electronic Science and Technology, and Affiliated Sichuan Provincial Rehabilitation Hospital of Chengdu University of TCM. The expert team of Dalian Port Hospital and Affiliated Sichuan Provincial Rehabilitation Hospital of Chengdu University of TCM led by the author put forward the design ideas and specific requirements of the orthosis. Moreover, it is specifically implemented by Harbin University of Science and Technology and Chengdu University of Electronic Science and Technology. We have jointly developed an "intelligent AFO that precisely controls the load" with adjustable range.

1.3 Problems to be Solved in the R & D of Intelligent AFO

The core idea is to solve the problem of load-free quantification of the injured limb after landing and the adjustment of load-free in the rehabilitation training. In other words, the early rehabilitation training can be realized after the descending displacement or becoming intelligent and controllable. According to our continuous observation and research, we believe that load-free AFO and load-regulating device of the patellar ligament can limit the lower limb's downward displacement space of 2-3 cm when walking. Besides, when the injured part is designed to bear 10 kg(tentatively, the displacement and bearing range can be set and adjusted by the clinician based on the recovery of the injured limb), it automatically changes to the patellar ligament. Within this displacement, the load adjustment device keeps the controllable state of the force and displacement of the lower limb.

2. Material Selection and Manufacture of Intelligent AFO

2.1 Material Selection of Intelligent AFO

The intelligent AFO is made of high-strength 5mm high-temperature polypropylene board, which is manufactured according to the high-temperature molding of patients' limb shape. The material has good fatigue and bending resistance. Intelligent AFO reduces the load of lower limb fracture with the load bearing of the patellar ligament. The suspension mechanism of the supracondyle of the femur can prevent AFO from slipping when standing and walking, and can stabilize, support, protect and fix the fracture end, prevent deformity and secondary injury. Patients with closed fracture can get training by wearing intelligent AFO 20-25 days after intramedullary nailing. And patients with open type B fracture after 4 to 6 weeks can wear lower limb intelligent AFO to walk.

2.2 Pressure Sensing System

The device consists of three parts:

(1) Pressure sensor and data acquisition circuit installed on the intelligent AFO of the experimental lower limb fracture (as shown in Fig.1); During the wearing of the intelligent AFO, the test subjects collect pressure parameters of the internal and external condyles of femur and patellar ligaments;

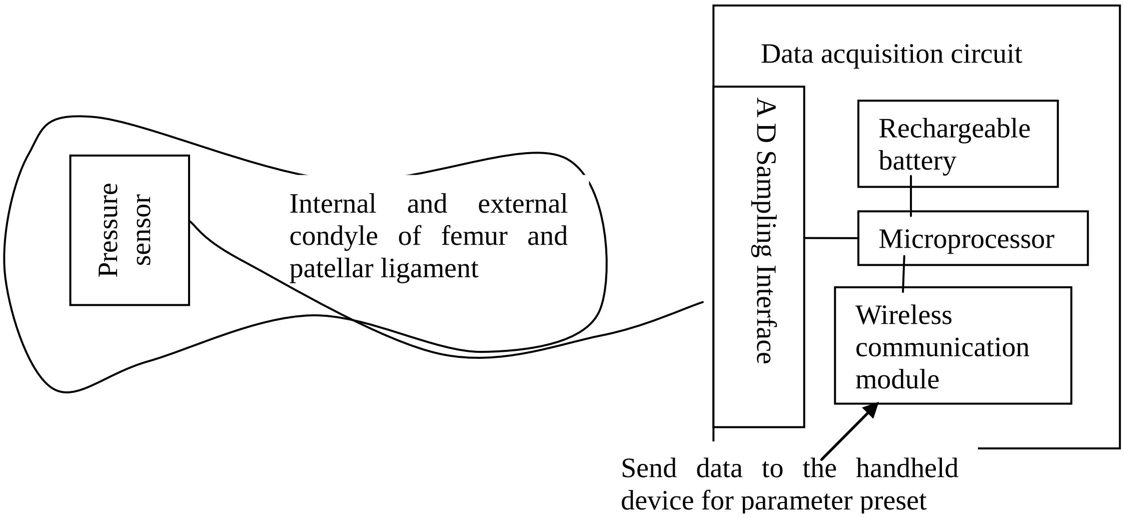
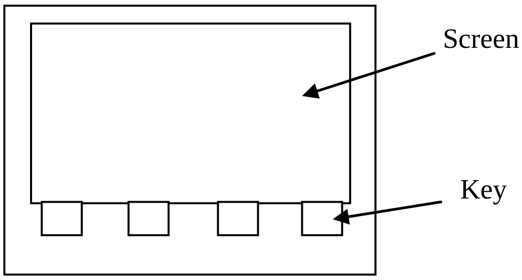
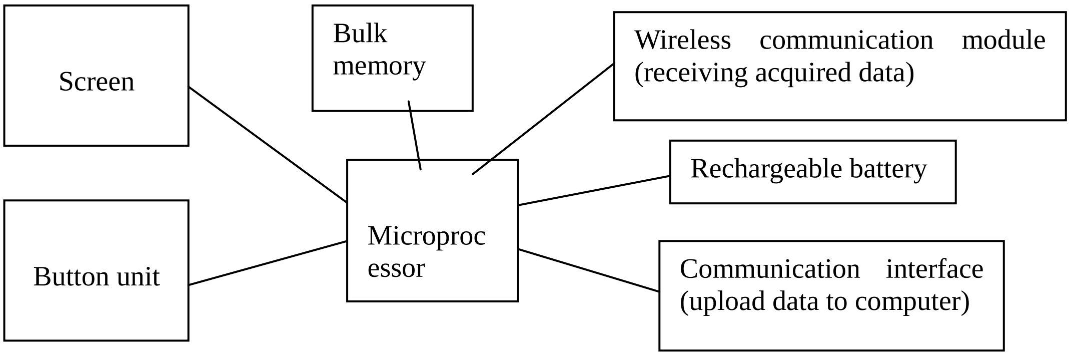


Fig. 1 Diagram of pressure sensor and data acquisition circuit

(2) The handled display and recording device for users is used to display and record the pressure data of the internal and external condyles of femur and patellar ligament of the subjects (as shown in Fig. 2);



(a) Outline Diagram of Handled Device



（**b**）Circuit Diagram of Handled Device

Fig. 2 Diagram of Handled Device

(3) Computer equipment for data analysis and processing;

When the intelligent control load AFO of the lower limb fracture is connected to the PC, the pressure sensor can upload the detected data. The pressure sensing rehabilitation evaluation training system receives data from sensors through a data link, records pressure data, displays timely, and saves relevant data according to the set time. By analyzing the historical evaluation data and training data of patients, the treatment plan can be adjusted in time.

The intelligent control load AFO of lower limb fracture has 3 modules including real-time monitoring, data management and data display. The main task of real-time monitoring is to collect pressure data; data management is to process the acquired data; and data display is to display data in the form of text and graphics.

3. Structural Features of Intelligent Rehabilitation Assistive Device for Lower Limb Fracture

To meet the needs of clinical patients (Fig. 3-6), the core idea is that when the injured limb is landing, this load-free AFO and load-regulating device of the patellar ligament can limit the lower limb's downward displacement space of 2-3 cm as walking. When designing to 10 kg(tentatively, the displacement and bearing range can be set and adjusted by the clinician based on the recovery of the injured limb), it automatically changes to the patellar ligament. Within this displacement, the load adjustment device keeps the controllable state of the force and displacement of the lower limb.

Fig. 3 Front of Intelligent Control Load Intelligent AFO of Lower Limb Fracture Limb Fracture

Fig. 4 Lateral face of Control Load AFO of Lower

Fig. 5 Tibial Trochanter Device (force displacement Device for of lower limbs can be withstood) of Lower Limb Fracture

Fig. 6 Displacement and Load-free Intelligent Control Load AFO

3.1 Functions of Rehabilitation Brace after the Operation of Lower Limb

The functions of the rehabilitation brace after the operation of lower limb is quite many. On the one hand, AFO can effectively protect the initially healed fractures from re-fractures during rehabilitation; On the other hand, on the premise of ensuring safety and comfort, patients can be assisted in early rehabilitation as soon as possible. (Please add reference information) For example: ① Performing walking training in advance. Walking can accelerate the whole blood circulation of patients, make more blood perfusion to tibiofibular, and then promote its healing; ② Yu Chunmei et al, show that accurate load-bearing is to prevent swelling of tibiofibular or muscle atrophy; ③ Preventing osteoporosis; ④ Preventing ankylosis. Furthermore, it can accelerate rehabilitation, shorten the rehabilitation cycle, improve the living standard of patients and return to society as soon as possible.

3.2 Advantages of Rehabilitation Brace after the Operation of Lower Limb

This product is a kind of post-operative rehabilitation brace which can adjust the load range of fracture. It meets the different requirements of patients after fracture surgery in different rehabilitation periods, and has the following advantages:

1) It can precisely adjust the load range of the lower limbs of patients with fracture. For example, the initial setting is 4 cm down, which represents a load of 10 kg; the adjustable range is 0-30 kg, and the accuracy is 10 g. When the load reaches the set limit, the limb force device can use the force of the proximal part of the AFO acting on the internal and external femoral condyle and the patellar ligament. In this way, the patients' tibiofibular no longer bear unsafe load, and play a protective role.
2) The AFO is small in size, light in weight, and convenient to carry and use. It is suitable for use in hospitals, homes and any other rehabilitation training places.
3) The device designed in this study has no data processing module, no power supply, simple structure, high accuracy and wide adjustable range. It has the advantages of low manufacturing cost, convenient maintenance, economic applicability, comfort, stable function and popularity. Orthopedic doctors can use it after simple training.
4) Because of its large number of patients in clinical orthopedic diagnosis and treatment, it has strong clinical practicability and wide market application prospect.

3.3 Limitations of Intelligent Control Load AFO of Lower Limb Fracture

Though the AFO has strong clinical practicability, it also has some limitations, like:

1) AFO is only suitable for patients with good knee joints and intact skin, otherwise it cannot be used.

2) This AFO is not suitable for mass production in advance. This is because the AFO needs to be tailored to the specific situation of patients with tibiofibular fracture in order to maximize its accurate rehabilitation function and comfort.
3) The AFO needs to continuously adjust displacement and load values based on the degree of healing of patients with tibiofibular fracture. In this way, AFO can reduce the pressure and limit the displacement accurately, and promote the postoperative rehabilitation of patients with tibiofibular fracture.
4) The bottom of this AFO has a certain thickness, so it needs a part of the filler under the foot of patients' healthy side to keep the same length of both legs.
5) When the force device under the knee starts to work, its compression around the knee joint of the tibiofibular fracture patients will cause them certain discomfort, which requires a break-in period.

4. Conclusion

In order to improve the adaptability and wearability of intelligent control load AFO for the patients with lower limb fracture, the universal design is performed on patients and AFO. Meanwhile, the intelligent and lightweight design is conducted to ensure the wearing comfort and the safety of patients during standing and walking training.

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