A STUDY OF PARAPLEGIC ORTHOSES GAIT TRAINING AND INNOVATION OF ORTHOTIC DESIGN FOR SPINAL CORD INJURED PATIENTS WITH PARAPLEGIA

LI NING

PhD

The Hong Kong Polytechnic University
This programme is jointly offered by The Hong Kong Polytechnic University and Sichuan University
2021

The Hong Kong Polytechnic University

Department of Biomedical Engineering

Sichuan University

Institute for Disaster Management and Reconstruction

A Study of Paraplegic Orthoses Gait Training and Innovation of Orthotic Design for Spinal Cord Injured Patients with Paraplegia

LI NING

August 2020

CERTIFICATE OF ORIGINALITY

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it reproduces no material previously published or written, nor material that has been accepted for the award of any other degree or diploma, except where due acknowledgement has been made in the text.

___________________________________ (Signed)

___Ning LI___________ (Name of student)

Abstract

Spinal cord injury (SCI) induces paralysis of the lower extremities due to the break of connection between the central nervous system and the muscular units of the lower body. Patients with paraplegia usually become very sedentary. Furthermore, the intensity of activities of daily living is not strenuous enough to maintain or elicit improvements in either cardiorespiratory fitness or muscular strength, which could lead to many secondary diseases.

The upright ambulation with orthoses can benefit people with lower-limb paralysis. Consequently, the ability to stand and walk using orthoses is an important goal for patients with paraplegia. However, some adverse events could be caused by inappropriate training. The appropriate orthotic training protocol for paraplegic patients remains unclear. Mechanical limitation of Reciprocating Gait Orthoses (RGOs) with stiff knee joints caused high energy consumption for paraplegic patients. Based on the above issues, this research aims to provide evidence the effectiveness of orthotic training protocol and the feasibility of development design. Therefore, a further clinical trial, a development design, and a gait analysis were conducted as follows.

This study includes three main parts: (1) To conduct a randomized controlled trial (RCT) and evaluate the effectiveness of quantitative intensity orthotic training on patients with paraplegia. (2) To develop a new stance control knee joint combined with reciprocating gait orthoses. (3) To conduct a gait experiment to assess the feasibility of the new stance control RGOs.

The first part: A total of 26 patients finished the RCT including 9 subjects (Age: 38.67±11.00year, 7Male/2Female, Weight: 64.56±11.04Kg, Height: 169.89±8.70m; Lesion lever: 9T) of the control group (CG), 8 subjects (Age: 38.63±8.85year, 5Male/3Female, Weight: 61.75±9.91Kg, Height: 171.25±8.07m; Lesion lever: 8T) of the light-intensity group (LG), and 9 subjects (Age: 36.22±7.68year, 5Male/4Female, Weight: 59.89±15.20Kg, Height: 165.44±5.98m; Lesion lever: 8T/1L) of the moderate intensity group (MG). All patients underwent a 1 session/day, 5 sessions per week orthotic training program using RGOs, the exercise time per session was increased for five minutes every two weeks for a total of eight weeks. The gait efficiency (Physiological Cost Index, PCI), cardiorespiratory fitness (Rating of Perceived Exertion, RPE; 6 Minute Walk Test, 6MWT), and functional ambulation ability (10 Meter Walk Test, 10MWT; Timed Up & Go test, TUG; Walking Index for Spinal Cord Injury

Ⅱ, WISCI Ⅱ) of patients were measured at baseline, four weeks and eight weeks; The quality of life (World Health Organization Quality of Life BREF, WHOQOL-BREF) and activity of daily living (Modified Barthel Index, MBI) were assessed at baseline, eight weeks and three months. Two-way repeated measures analysis of variance (Two-way Repeated ANOVA) was used to analyze the data of each group at the baseline, mid-point, and end-point. The results showed that patients with quantitative intensity orthotic training could significantly promote energy efficiency (MG, $P=0.015$； LG, $P=0.044$), cardiorespiratory fitness (LG, $P=0.003$; MG, $P=0.001$), ambulation ability (10MWT: LG, $P<0.001$，MG, $P=0.011$; TUG: LG, $P=0.008$, MG, $P=0.001$) and ADL (LG, $p'<0.001$; MG, $p'<0.001$); The QoL (CG, $p'=0.031$) and ambulation ability (CG, $p'=0.003$) could significantly decline without regular orthotic training. Patients with moderate intensity orthotic training have better gait efficiency ($p'=0.017$). The conclusion of this part is quantitative intensity orthotic training regularly could benefit paraplegic patients.

The second part: A new purely mechanical stance control knee joint triggered by hip was designed, including the hip trigger module and ratchet and pawl module. The model of newly design knee joint was 3D printed. The rotating hip joint can pull the cable with the reciprocating mechanism. The ratchet and pawl can achieve the lock and free knee joint with the aid of cable and springs. The summary of this part is this newly developed knee joint was designed. This design combines stance control mechanics and reciprocating mechanics.

The third part: A gait analysis experiment was conducted to assess the effectiveness of paraplegic patients with the new stance control RGOs. The included healthy subjects (n=6) completed normal gait (NG), stiff knee RGOs gait (SKG), and stance control RGOs gait (SCG) test by the before-and-after clinical study, set a one-day washout period. A 3D KNEE ANALYSER (KneeKG™, EMOVI INC. Canada) was used to capture the kinematic parameters of participants. These parameters of the range of knee flexion and extension, the degree of knee joint at heel strike, the degree of knee joint at foot flat, and the range of knee movement in stance phase were assessed for three groups. One-way ANOVA was used to analyze the differences in the above gait parameters of the subjects before and after the intervention. The range of knee flexion and extension in the swing phase of the SCG was significantly greater than that in the SKG ($P<0.001$); There was no difference of the range of knee motion in the stance phase between the SKG and SCG. The conclusion of this part is the newly knee joint for purely mechanical stance control combined with the reciprocating gait orthoses could provide motion in the swing phase compared with the traditional RGOs for healthy participants.

The overall conclusion is that the quantitative intensity orthotic training regularly could benefit the paraplegic patients, and the developed orthoses could improve the performance of the gait of users. compared with the traditional RGOs.

Acknowledgements

I gratefully acknowledge the assistance of Prof. Ming ZHANG, Dr. Aaron K.L. LEUNG, and Prof. Chengqi HE for giving useful advice on the research design and revising this article. I would like to give gratitude to the Guangdong Provincial Work Injury Rehabilitation Hospital for strong support in the patients screening and training as well as the Chengdu Sports University for experimental equipment. I am also deeply indebted to all the other teachers in the Department of Biomedical Engineering of The Hong Kong Polytechnic University and Institute for Disaster Management and Reconstruction of Sichuan University. Special thanks should go to The Hong Kong Jockey Club for financial support.

List of Publications

Ning Li, Xiali Xue, Huan Tu, Ming Zhang, Chengqi He. (Published). Anterior cruciate ligament reconstruction with hybrid graft versus autograft A systematic review and meta-analysis. Journal of Healthcare Engineering, 06 October 2021.

Ning Li, Xiali Xue, Zhaojian Meng, Chengfei Gao, Xiaoqian Deng, Aaron K.L. Leung, Ming Zhang, Chengqi He. (in preparation). Effects of moderate-intensity orthotic training on spinal cord injured patients with paraplegia. Plos One.

Ning Li, Zhaojian Men, Xiaoqian Den, Aaron K.L. Leung, Chengqi He. Effects of Moderate Intensity Orthotic Training on Cardiorespiratory Fitness of Paraplegic Patients post Spinal Cord Injury. The 22nd National Conference on Physical Medicine and Rehabilitation of Chinese Medical Association. Guangzhou, August 14-17, 2019.

Ning Li, Aaron K.L. LEUNG. The Training Effects Review of Mechanical Paraplegic Orthoses for Spinal Cord Injury Patients. The 1st International Academic Forum on Sports Medicine and Health 2017. Chengdu, October 25-28, 2017.

Table of Contents

List of Abbreviations

Abbreviated words	Full name
ACSM	American College of Sports Medicine
ADL	Activity of Daily Living
AFOs	Ankle Foot Orthoses
ARGOs	Advanced Reciprocating Gait Orthoses
ASIA	American Spinal Injury Association
BWST	Body Weight Support Training
HGOs	Hip Guide Orthoses
HKAFOs	Hip Knee Ankle Foot Orthoses
HR	Heart Rate
HRmax	Maximal Heart Rate
HRR	Heart Rate Reserve
HRrest	Heart Rate Rest
ICF	International Classification of Functioning, Disability and Health
ICIDH	International Classification of Impairment, Disability and Handicap
IRGOs	Isocentric Reciprocating Gait Orthoses
KAFOs	Knee Ankle Foot Orthoses
LSU-RGO	Louisiana State University Reciprocating Gait Orthosis
MBI	Modified Barthel Index
MET	Metablic Equivalent
MLO	Medial Linkage Orthosis
MSH- KAFO	Medial single hip joint Knee Ankle Foot Orthosis
PCI	Physiological Cost Index
PGOs	Powered Gait Orthoses
QOL	Quality of Life
RCT	Randomized controlled trial
RGOs	Reciprocating Gait Orthoses

RMLOs	Reciprocating Medial Linkage Orthoses
RPE	Rating of Perceived Exertion scale
SCI	Spinal Cord Injury
SCKAFO	Stance Control Knee Ankle Foot Orthosis
SCO	Stance Control Orthosis
SCOKJ	Stance Control Orthotic Knee Joint
THR	Target Heart Rate
TUG	Timed Up & Go Test
WHO	World Health Organization
WHOQOL-BREF	World Health Organization Quality of Life BREF
WISCI Ⅱ	Walking Index for Spinal Cord Injury Ⅱ
WO	Walkabout Orthosis
VO2	Oxygen Consumption
VO2max	Maximal Oxygen Consumption
6MWT	6 Minute Walk Test
10MWT	10 Meter Walk Test

Chapter 1

1. Introduction

1.1 Background

Earthquakes can cause mass casualties, widespread property destruction. Reports of the Lushan earthquakes in 2013 and Wenchuan earthquakes in 2008 show that spinal cord injury (SCI) would be incurred in large numbers of people in such disasters (Shi et al. 2013). This trauma causes paralysis of the lower extremities because of the break of connection between the central nervous central system and the muscular units of the lower body. Patients with paraplegia often become very sedentary, and the intensity of ADL is generally not strenuous enough to maintain or elicit improvements in either cardiorespiratory fitness or muscular strength (Janssen et al. 1994). This leads to low physical fitness and many of the secondary diseases, including obesity, type 2 diabetes, and cardiovascular disease (Myers, Lee, and Kiratli 2007). Since exercise activities possibly reduce the incidence of complications associated with inactivity, patients with paraplegia must participate in structured exercise activities.

Activities have to be well planned and coordinated to allow various therapeutic exercises and purposeful orthotic training. Upright ambulation with orthosis can benefit people with lower-limb paralysis and has been the mainstay treatment method for the physical function and psychological condition of patients with paraplegia (Johnson, Fatone, and Gard 2009b). Consequently, the ability to stand and walk using an orthosis has been stated as an important goal for patients with SCI to achieve (Kobetic et al. 2009).

As for key items of rehabilitation, regaining the upright ambulation ability are including volitional exercise and locomotor exercise, which are used to strengthen activities. There are two different training patterns of volitional exercise for disabled patients, which includes endurance training and resistance training. The primary objective of endurance training is to enhance cardiovascular function and physical fitness, meanwhile resistance training is used to increasing the maximal force output of the muscles.

However, the trauma induced motor deficient caused lower extremities insufficient output; this is why dominant volitional exercises were performed on upper extremities. The exercise modes of endurance training include arm cranking, wheelchair propulsion, swimming, wheelchair sports, circuit resistance training, electrically stimulated cycling, and electrically stimulated walking (Bonder 1998). While, the exercise modes of resistance training include weight stations, free weight, and resistance bands (Myslinski, 2005).

Locomotor exercise is used to strengthen the upright ambulation ability of lower extremities via repetitive and intensive gait practice. It can stimulate neurological response and improve the potential walking function of patients after incomplete SCI (Edgerton and Roy 2009b). Locomotor exercise can be executed by use of the traditional orthosis with lower extremities brace or with the assistance of body weight support using an overhead harness suspended from the ceiling or a frame. Moreover, the body weight support locomotor training can be achieved by manual assistance, functional electrical stimulation, or robot.

These improvements in volitional exercise have less effect on ambulation function for patients with paraplegia. However, locomotor exercise can affect the upright ambulation ability of lower extremities directly. As for the nature of exercise, the body weight support training assisted by power is a passive exercise, whose effects on cardiovascular function can be ignored. Moreover, there is no evidence to uncover the efficiency within different locomotor training (Morawietz and Moffat 2013) (Mehrholz, Kugler, and Pohl 2008). With the advantages of a traditional method, the orthotic training without a driven device can not only provide sufficient exercise intensity but also allow upright ambulation exercise mode.

Although many studies have shown the benefits of regular orthotic training, there are always risks along with the patients during the therapeutic exercises. These include an inadequate rise in the heart rate because of overtraining or fatigue and ineffective training because of lower exercise intensity. These risks are similar to those experienced by persons without paralysis. Special attention is also required when designing and performing an exercise for patients with paraplegia. For example, individuals having SCI at or above the T6 spinal level are prone to episodes of autonomic hyperreflexia when exposed to noxious stimuli (Erickson, 1980). It is thus important to monitor the intensity of the training activity to improve functional recovery and avoid risk. Due to the complexity of SCI with various lesion levels and various severities, a clear consensus on the training protocol is needed to ensure the safety and effectiveness of health-related outcomes (Sisto and Evans 2014b) for clinical practice and as well as study design.

Furthermore, HR is an effective functional outcome parameter about training intensity for healthy people. It is a validated index for measuring VO_2 that doesn't require specialized equipment and linearly correlated with VO_2 during incremental arm ergometry test for patients with SCI levels below T4 (Baron and Nene 1990b). Even though the HR may reflect the orthotic training in the largest degree, however the optimal orthotic training for specific patients remains unclear. Besides, the training standards were set up based on healthy subjects; However, there are not suitable standards for patients with paraplegia. Therefore, the customized intensity of rehabilitation and physiological index monitor is playing a crucial role during the rehabilitation process.

With regarding to the reciprocating gait orthosis (RGO), the most frequently used walking brace for the ambulation needs of the patient with paraplegia. Mechanical limitation of RGO with stiff knee joint caused high energy consumption for paraplegia. However, Stand control orthosis demonstrated that it is a higher energy-efficient method to ambulate than stiff leg (McMillan et al. 2004), because its gait pattern allowed knee flexion during swing (Bernhardt, Irby, and Kaufman 2006). Therefore, we combined with the advantages of flexing during the swing phase and locking during the standing phase into a knee joint structure to reduce the high energy consumption. An improvement of RGOs with a simple and energy-efficient structure may be beneficial to patients with paraplegia. This improved design allows the leg locked and rigid during the stance portion of the gait cycle but allows the limb flex during swing.

Furthermore, a clinical trial should be conducted to explore the effectiveness of orthotic training and find the appropriate training intensity range with safe and effective, a development of the current paraplegic gait orthoses should be performed to help patients improve their gait efficiency, and assess the clinical effect of the new orthoses to verify the feasibility.

1.2 Objectives

The overall objective is to improve the quality of life of patients with paraplegia after spinal cord injury through reasonable orthosis training and orthosis development.

a) To study the functional performance under different orthotic training intensity

b) To improve the design of reciprocating gait orthoses for patients with paraplegia

c) To assess the effect of the improved orthoses on the gait of patients with paraplegia

1.3 Thesis Outline

Chapter 2 describes the randomized controlled trial to investigate the effectiveness of quantitative intensity training with reciprocating gait orthoses (RGOs) of paraplegia patients post SCI.

Chapter 3 describes the design of a new purely mechanical stance control knee joint and development of current RGOs with stance control function.

Chapter 4 describes a gait analysis experiment to investigate the effectiveness of paraplegic patients with the new stance control RGOs.

Chapter 5 of this dissertation provided systematic reviews about the rehabilitation training program and clinical effects for patients with paraplegic post SCI, and a description about the mechanism of the stance control knee joint and development of paraplegic orthoses is in Chapter 5.

Finally, the conclusions and suggestions for future research are in Chapter 6.

Chapter 2

2. Literature Review

2.1 Background

SCI induces paralysis of the lower extremities due to the break of connection between the central nervous system and the muscular units of the lower body. The annual incidence of SCI worldwide was about 39/million (Kumar et al. 2018), and it was about 37/million in China (陈星月 et al. 2018). Patients with paraplegia usually become very sedentary. Furthermore, the intensity of activities of daily living is not strenuous enough to maintain or elicit improvements in either cardiorespiratory fitness or muscular strength. This leads to many secondary diseases, including obesity, type-2 diabetes, and cardiovascular disease, as well as the limitation of the activity of daily living and social participation.

Gait training using orthoses has been considered as an effective exercise therapy method in clinical rehabilitation. The upright ambulation with orthoses can benefit people with lower-limb paralysis, and this is the mainstay treatment method for the physical function of paraplegic patients. Consequently, the ability to stand and walk using orthoses is an important goal for patients with paraplegia. However, some adverse events could be happened caused by inappropriate training, particularly those paraplegic patients who prone to be suffered with the autonomic Nervous System Dysfunction. There is no available evidence concerning the number of repetitions of exercises needed, and the intensity of the exercise and optimal methods for progression. The appropriate orthotic training protocol for paraplegic patients remains unclear.

For the RGOs, the most frequently used walking brace for the ambulation needs of patients with paraplegia. Mechanical limitation of RGOs with stiff knee joint caused high energy consumption for paraplegic patients. However, the stance control knee joint could improve this stiff knee gait. Currently, there isn’t a paraplegic orthosis combined to this mechanism of stance control for patients with paraplegia.

2.2 Functional Training

Remaining seated in a wheelchair has negative effects, so individuals with SCI have a high risk for the development of secondary complications (e.g., shoulder pain, urinary tract infection, skin pressure ulcers, osteopenia, chronic pain, problematic spasticity, depression, CVD, obesity, Type 2 DM). Proper exercise and physical activity reduce the prevalence of secondary complications and improve the quality of life for individuals with SCI (Medicine 2013).

Physical and occupational therapists in rehabilitation help individuals with movement dysfunction improve or adapt their ways of moving, so that they can achieve satisfied function in their activities of daily living and improve their quality of life. Therapists use various types of therapeutic exercise (e.g., strengthening, endurance programs, flexibility, balance activities), as well as functional training (often with assistive devices or ambulatory aids, orthoses, and prostheses), in order to minimize movement dysfunction and remediate or accommodate the underlying impairments. Because the use of therapeutic exercise or functional training can be a means of driving neural plasticity as a mechanism of recovery following nervous system injury. Participating in extended training (i.e., practice, experience) of specific skills and functions enhances performance in areas of the brain associated with those functions; this is the outcome expectation for constraint-induced therapy and task-specific paradigms used in stroke, brain injury, and SCI rehabilitation programs (Behrman, Bowden, and Nair 2006).

2.2.1 Therapeutic Exercise Type

Therapeutic exercise can be utilized in two different strategies: compensatory strategies and functional strategies.

2.2.1.1 Compensatory Strategies

Conventional rehabilitation primarily provides compensatory strategies for accomplishing mobility and strengthening above the level of the lesion. For example, try to substitute upper extremities for dysfunctional lower extremities by the endurance and resistance training of other parts of body. Because the primary pathologic effects are usually limited to paralysis of the lower body, precluding exercise modes such as walking, running, and voluntary leg cycling. Muscle strength training sessions from a seated position in the wheelchair should be complemented with non-wheelchair exercise bouts to involve all trunk stabilizing muscles.

Endurance (Aerobic/Cardiorespiratory) training

The exercise modes of endurance training include arm cranking, wheelchair propulsion, swimming, wheelchair sports, circuit resistance training (Jacobs, Nash, and Rusinowski 2001); electrically stimulated cycling, and electrically stimulated walking.

Resistance training

The exercise modes of resistance training include weight stations, free weight, and resistance bands (Myslinski 2005b). The American College of Sports Medicine (ACSM) divides exercise programming into three categories in 2009: aerobic, strength, and flexibility. In the latest review in 2014, Maremka et al. (Zwinkels et al. 2014) summarized exercise training studies regarding wheelchair propulsion capacity, they divided training into four executed types in practice: interval, endurance (continuous), strength, and mixed training.

The primary objective of endurance training is to enhance the cardiovascular function and physical fitness, meanwhile, resistance training is used to increasing the maximal force output of the muscles. Arm exercise training adaptations are believed to be primarily peripheral (muscular), and may include increased muscular strength and endurance of the arm musculature in the exercise modes used. These may result in 10% to 20% improvements in peak power output and peak oxygen consumption (VO_{2peak}), as well as an enhanced sense of well-being(Medicine 2009). Almost all studies (Bougenot et al. 2003; De Groot et al. 2003; DiCarlo, Supp, and Taylor 1983; Hooker and Wells 1989; Jacobs, Nash, and Rusinowski 2001; Taylor, McDonell, and Brassard 1986) about these training, the training intensity were accurately described in their protocol (Table2), and these patients could get positive results from those interventions. Rimaud et al. (Rimaud, Calmels, and Devillard 2005) recommended interval wheelchair ergometry training at ≥70% HR_{peak} for 30 min/session, 3 sessions/wk.

However, special attention should be given to shoulder muscle imbalance and the prevention of repetitive strain injuries (Medicine 2013). To prevent upper extremity overuse syndromes, such as shoulder impingement syndrome and rotator cuff strain/tear, the first, vary exercise modes from week to week; the second, strengthen muscles of the upper back and posterior shoulder, especially external shoulder rotators; and the last, stretch muscles of anterior shoulder and chest (Medicine 2009). Even though the majority of people with SCI do not recover functional walking, rehabilitative strategies for ambulation beyond the use of orthotic and assistive devices have changed little over the last 20 years (Behrman and Harkema 2000).

2.2.1.2 Functional Strategies (Ambulation Ability)

Functional strategies are used to strengthen the upright ambulation ability of lower extremities via repetitive and intensive gait practice. It can stimulate neurological response and improve the potential walking function of patients after incomplete SCI (Edgerton and Roy 2009). Functional ambulation can be executed by use of the traditional orthosis with lower extremities brace, or with the assistance of body weight support using an overhead harness suspended from the ceiling or a frame.

In the guidelines for exercise testing and prescription in 2013, functional strategies were named functional fitness training that can be corresponded with cardiorespiratory fitness. Functional fitness training involves motor skills such as balance, coordination, gait, and agility, and proprioceptive training and also can be called neuromotor exercise training. Because walking not only involves the ability to move the legs, but also requires the intricate coordination of neural commands to regulate upright balance and posture and the ability to adapt gait to environmental constraints.

Functional or therapeutic ambulation was mentioned in Prosthetics and Orthotics in Clinical Practice in 2011 (May and Lockard 2011), it was described as part-time walking for purpose of exercise and to reduce the health risks of wheelchair sitting. It refers to the use of ambulation as the primary method of mobility during daily functional activity. Appliances used by individuals with paraplegia or paraparesis for functional ambulation include various orthoses combinations of KAFOs and AFOs, bilateral KAFOs, HKAFOs, RGOs, and functional electrical stimulation, used either alone or in conjunction with orthoses. Functional ambulation training is necessary, which includes gait training, as well as training in how to perform other types of functional activities such as step, negotiating all types of indoor and outdoor surfaces, ramps, and getting up and down from the floor.

Orthotic training

Functional ambulation may be defined as the ability to walk, with or without the aid of appropriate assistive devices (such as prostheses, orthoses, canes, or walkers), safely and sufficiently to carry out mobility-related activities of daily living. Orthotic training is a kind of multifaceted physical activity sometimes considered to be neuromotor exercise involve varying combinations of neuromotor exercise, resistance exercise, and flexibility exercise.

The three major approaches to restoring upright mobility receiving the most attention are **mechanical gait orthoses**, **powered gait orthoses,** and **hybrid orthoses** that combine elements of both mechanical and powered or neuroprosthetic interventions. All these various assistive devices have been introduced to aid in improving the walking function of SCI patients.

Mechanical gait orthoses: It currently used to aid walking include hip-knee ankle-foot orthoses (HKAFOs), the Walkabout orthoses (WOs), hip guidance orthoses (HGOs) such as the Parawalker, and examples of reciprocating gait orthoses (RGOs) such as the isocentric reciprocating gait orthosis (IRGOs) and the advanced reciprocating gait orthosis (ARGOs). The mechanical orthotic training without driven devices is the traditional method with a brace that has provided exercise intensity and also upright ambulation exercise mode, and it is widely used in the clinic.

Powered gait orthoses: The development, design, and construction of PGO started in the mid-1970s (Vukobratovic, Hristic, and Stojiljkovic 1974). PGOs have been designed typically to utilize pneumatic actuators, hydraulic actuators, or direct current electric motors to provide external power for the specific joints. The main aim of PGOs is to add power to mechanical joints positioned adjacent to the anatomical hips, knees, or ankles to produce an increase in the speed and the total distance walked (endurance) as well as an improvement in the energy efficiency of such patients during ambulation. But many PGOs are not currently commercially available to the public and therefore would not be able to be used in their home. And so for current PGOs, or robotic rehabilitation devices, the results of majority studies show that there are no abundant evidence to provide the PGOs is better than the other mechanical orthoses in clinical effects (Arazpour, Bani, and Hutchins 2013b).

Hybrid orthoses: It was to combine the different approaches such as mechanical orthosis and FES. The resulting orthosis is called “Hybrid” orthosis and it was proposed as early as 1973 by Tomovic and associates. The orthotic components consist of electromechanical joints that lock and unlock automatically to provide upright stability and free movement powered by FES. Hybrid orthoses may promote more effective neural plasticity than other standard practices like treadmill training, because of the intensive, community based gait practice involved. However, it is not so effective yet in gait recovery, due to muscle fatigue, rapidly induced by FES, leading to interruptions in training.

There is abundant evidence (Harvey, Smith, et al. 1997; Massucci et al. 1998; Abe 2006; Kawashima et al. 2006; Arazpour et al. 2013)using orthotic training that indicates the improvements in walking ability such as proprioception, gait parameters, energy expenditure and reduction in the risk of falls and fear of falling among paraplegic patients. However, there is no available evidence concerning the number of repetitions of exercises needed, the intensity of the exercise, or optimal methods for progression. So mechanical orthosis training still is a crucial role for accomplishing the goal of upright ambulation.

Body weight support training (BWST)

The BWST is a kind of functional ambulation training, also named locomotor training in most literature, that can be achieved by manual assistance, functional electrical stimulation or robot by overhead harness suspending from the ceiling or a frame such as the commercial product Lokomat (Switzerland), Autoambulator (USA) and Lopes (Netherlands). The BWST generally divides into three categories: without and with power-assisted walking performing on a treadmill or overground training which can be performed by manual assistance, functional electrical stimulation (FES), and robotic driven gait training. And different approaches can be combined, for example, the body weight supported treadmill training intervention is a more popular method about two decades. The effectiveness of various forms of locomotor training has been proved for the walking ability in SCI patients (Harkema et al. 2012).

Hisham et al. (Sharif et al. 2014) investigated the effects of 12 weeks of FES-ambulation on overground walking and health-related quality of life (HRQOL) in individuals with SCI and concluded that FES-ambulation was associated with enhanced overground walking in individuals with AIS D SCI, reduced pain, and improved mental health, since functional electrical stimulation engages the leg muscles and has been shown to increase muscle strength and improve muscle morphology after SCI.

Monica et al.(Alcobendas-Maestro et al. 2012) had compared a walking reeducation program using body weight supported training with robotic-assisted (Lokomat) to conventional overground training among individuals with incomplete SCI, and concluded that robotic-assisted training was equivalent to conventional walk training in patients with a variety of nonprogressive spinal cord pathologies for walking speed.

Another study of Edelle et al. (Field-Fote and Roach 2011) published in 2011 compared changes in walking speed and distance associated with 4 locomotor training approaches (treadmill-based training with manual assistance, treadmill-based training with stimulation, overground training with stimulation and treadmill-based training with robotic assistance). Walking parameters of different training approaches indicated that walking speed improved with both overground training and treadmill-based training; however, walking distance improved to a greater extent with over ground training.

In these studies, the training protocol differed each other. There is not a quantitative criterion so that every study has different training prescript. Although BWST is a kind of locomotor training that can improve the potential possible of walking function after SCI by the repetitive and intensive practice of gait. Most of these papers described that the locomotor training is based on neuroplasticity theory. However, the effectiveness of plasticity is related with training time or times of repetition. The different time or frequency of intervention may need to be compared for this training in the future and may need more fundamental animal experiments.

In addition, BWST is passive activity assisted by manual, FES or robot, then actually it can’t provide stimulation to the cardiorespiratory system of paraplegic patients, which maybe is the biggest difference with conventional orthotic training. So in the study of Alexeeva et al. (Alexeeva et al. 2011) indicated that there was no difference between groups in the amount of improvement and no significant training effects on fitness. Some studies showed stronger improvement in functional walking ability following BWS compared to conventional gait training, whereas others did not report the better functional outcomes.

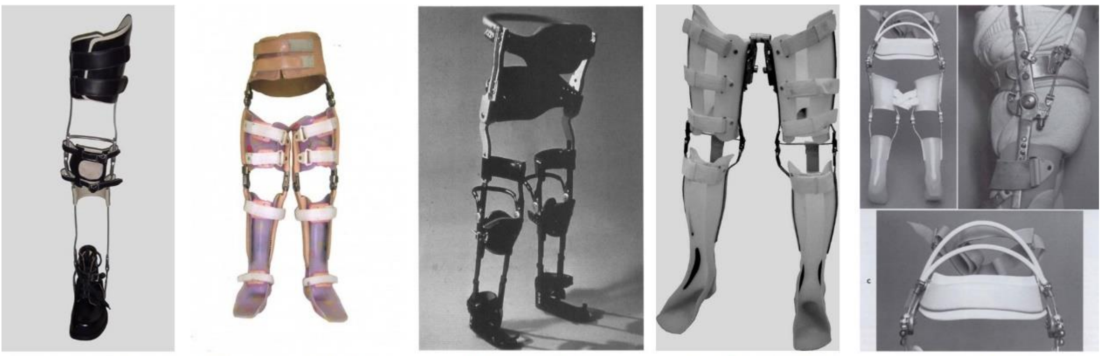
2.2.2 Discussion

As a mechanical device controlled by a program, the PGO and BWST can rigidly execute the mission of repetition in the same activity pattern, but it is not optimal for functional ambulance learning. In contrast, variability and the possibility to make errors are considered as essential components of practice for motor learning. Bernstein’s demand that training should be “repetition without repetition” is considered to be a crucial requirement, and is also supported by recent advances in computational models describing motor learning. And the hybrid or BWST system driven by FES also has problems with exercise efficiency, because this type of training often can’t achieve sufficiently high levels of aerobic work (Berry et al. 2008b). Paraplegic patients engage in passive activity mode. So patient-cooperative control strategies were an active mode that was giving the patient more movement freedom and variability rather than passive repetition and repetition. So, the mechanical orthotic training is a kind of active mode exercise cooperated with orthoses, and it should belong to aerobic activity, because any activity that uses large muscle groups, can be maintained continuously, and is rhythmical in nature can be regarded as an aerobic exercise.

Exercise or training may be a rehabilitation professional’s most potent tool for facilitating neural plasticity. Exercise causes a cascade of events, at both molecular and cellular levels, that support the health and development of neural circuits. While rehabilitation professionals typically endorse aerobic exercise as a means of building functional capacity and activity tolerance. Participation in gait training during rehabilitation after SCI enhances motor learning and neural plasticity in several ways: it is task-specific, provides repetitive practice at high dosage, builds cardiorespiratory fitness, and readies the brain for functional modification of neural circuits. Current evidence about the ability of aerobic exercise to potentiate brain health and function, rehabilitation programs that fail to incorporate a fitness or conditioning component may miss the opportunity to enhance motor learning and recovery of function. This applies to persons with neurological problems, as well as those who may be learning to use an orthosis or prosthesis as a result of neuromuscular and musculoskeletal impairment from trauma, overuse, or disease (Lusardi, Jorge, and Nielsen 2013). However, the neural plasticity theory also challenges us to reevaluate whether our interventions are sufficient, in terms of therapeutic approach, intensity, and duration, to trigger the neuroplasticity changes that will improve function and quality of life.

2.3 Purely Mechanical Paraplegic Orthoses

There are three major approaches to restoring upright mobility, mechanical gait orthoses, powered gait orthoses (PGO), and hybrid orthoses. All these various assistive devices have been introduced to aid SCI patients in improving their walking function. The purely mechanical gait orthoses currently facilitate to aid walking which was used longest and most wildly in the clinic, including the knee-ankle-foot orthoses, hip-knee-ankle-foot orthoses, the hip guidance orthoses such as the Parawalker, the medial linkage orthoses such as the Walkabout orthosis, and the reciprocating gait orthoses such as the isocentric reciprocating gait orthoses and the advanced reciprocating gait orthoses (Figure 2- 1).



Knee-Ankle-Foot Orthosis **Hip-Knee-Ankle-Foot Orthosis** **Hip Guidance Orthosis** **Medial Linkage Orthosis** **Reciprocating Gait Orthosis**

Figure 2-1 Purely Mechanical Paraplegic Gait Orthoses

Upright ambulation with orthosis can benefit people with lower-limb paralysis has been the mainstay treatment method for the physical function (urinary drainage, bowel function, improvement in peripheral circulation, reducing the incidence of pressure sores, reducing osteoporosis) and psychological condition of patients with paraplegia (Johnson, Fatone, and Gard 2009b). Upright ambulation rehabilitation training generally involves performing specific movements to provoke motor plasticity and ultimately improve motor recovery especially for the patients of incomplete SCI. It is crucial for them to improve their musculoskeletal strength and motor control and to minimize functional deficits, because this exercise can stimulate the neurological response of the spinal cord, which mechanisms are neuroplasticity influenced by sensorimotor training (Piazza and Ibáñez 2016). Consequently, the ability to stand and walk using an orthosis has been stated as an important goal for patients with SCI to achieve (Kobetic et al. 2009).

But both of these concepts of energy consumption and energy efficiency are paradoxical in orthosis design and application. Because, in some scenarios, when we expend energy, we gain more of it. And when we save energy, we maybe have an increased risk of complications. That is why this review did not focus on the powered orthoses. If there is the power to help patients, it should assist them and not totally replace their function. And so for current PGO, the results of the majority studies show that there is no abundant evidence to provide the PGO is better than the other mechanical orthoses in clinical effects (Arazpour, Bani, and Hutchins 2013b).

2.3.1 Current Design of Mechanical Orthoses

The orthotic training without a driven device is a traditional method with the brace that has provided exercise intensity and also upright ambulation exercise mode, and it is widely used in the clinic. The design of other mechanical orthoses is almost derived from the KAFO.

Knee Ankle Foot Orthoses and Hip Knee Ankle Foot Orthoses

This device is designed to offer stable support for the paralysis and weak lower limb by a rigid brace from knee to ankle and foot. Most KAFO used for paraplegic patients have knees with locks during standing or walking but could be unlocked when the patients need to sit via a drop lock mechanism. Some KAFOs are extended to hip with pelvic bands in order to help stabilize the hip joint. So theoretically these orthoses are named HKAFO and should not be classed as KAFO. A solid ankle was set in 5-10° dorsiflexion and was reinforced with lateral supports from the stirrups to sole plates. This KAFO is the most commonly prescribed type of orthosis for paraplegic patients. These orthoses provide stabile support while ambulating with knees locked in full extension in a swing phase requires lifting the center of body mass at every step, which increases the energy cost of ambulation at the same time.

Hip Guidance Orthoses

The HGO such as the ParaWalker was developed at the Orthotic Research and Locomotor Assessment Unit (ORLAU) in Oswestry, England.(Rose 1979; Rose, Stallard, and Sankarankutty 1981) The orthosis has two rigid KAFOs and specially designed movable hip joints. The rigid body components help maintain the stability of the lower limb during the stance phase of the gait cycle, and the hip joint with a limited flexion/extension range move forward through pendulum mechanism action causing gravity during the swing phase.

A compared study (Whittle et al. 1991) reported that the most important design aspect of the HGO is its rigidity in single limb support, which enhances the patient’s ability to clear the contralateral limb as it advances in the swing phase. Special joints at the hips allow just enough fore-and-aft movement to permit a stepping pattern. So the functional performance of HGO compared with HKAFO, this orthosis reduces the energy cost of walking because the patient does not have to swing off the lower limb forward, as is necessary with a swing-through gait using conventional HKAFO and crutches. However, a force is still required to lift the center of body mass up provided by the patient, through the same crutch which tilts him sideways.

Medial Linkage Orthoses (MLO) or Medial Single Hip Joint (MSH-KAFO)

This concept of medial linkage orthoses was proposed by Cliquet et al. in 1989 (Cliquet Jr, Baxendale, and Andrews 1989)， and the device of Walkabout (WO) was realized as a device by Kirtley and McKay in 1992 (Kirtley and McKay 1992). These types of orthoses have medially positioned hinged hip joints, which also incorporate a pendulum mechanism to connect two KAFOs for paraplegic patient walking. The WO has a single-axis hinged joint that is positioned at a lower level than the anatomical hip joint. Some researchers have compared the clinical outcome between HKAFO and MSH-KAFO, and they conclude that the MSH-KAFO is a very convenient standing and walking device for paraplegics and is compatible with wheelchair use (Saitoh et al. 1996).

However, the MLO/MSH-KAFO uses a simple hinge mechanism that, being placed below the perineum, is not aligned with the centers of the hip joints, the discrepancy is 100-150 mm. Considering this disadvantage, the orthosis and hip joints rotate on two different axes respectively, the modified device named the Moorong MLO was designed (Middleton et al. 1998). An arcuate sliding link hinge enables the center of rotation of the WO to be raised to match the axis of rotation of the hip joint. Almost at the same time, to overcome the disadvantages of the walkabout orthosis, the Primewalk was developed in 1998 in Japan, with a medial single sliding hip joint linking two KAFOs (Saitoh et al. 1997), which allows the imaginary axis of the hip joint to be positioned 60mm above the real joint. The Moorong MLO and the Primewalk orthoses are both examples of medial linkage orthoses developed from the WO, and share the same mechanism to enable the patients to get an efficient gait. The positive effects of the Primewalk have reported a reduction of gait efficiency for paraplegic subjects compared to when walking with WO (Onogi et al. 2010).

Reciprocating Gait Orthoses

Reciprocal walking for paraplegic patients with complete thoracic lesions has been routinely available since the early 1980s. Douglas et al. (Douglas, Larson, and McCall 1983) introduced the Louisiana State University Reciprocal Gait Orthosis (LSU RGO) in 1983. They described it as a light weight bracing system that gives stabile support to the trunk and lower limbs of the paraplegic patient while allowing, through a cable-coupling system, proper hip joint motion for walking, which is achieved by coupling both hip joints together using two Bowden cables to transmit the necessary forces(Campbell and Moore 1997). This reciprocal coupling has the added benefit of eliminating simultaneous hip flexion, which distinguishes to any variation of KAFO. The locomotion mechanism of RGO is the cable coupling to each extremity. The reciprocal mechanism provides hip joint stability during standing by preventing simultaneous flexion of both hips, but it allows flexion of one hip and simultaneous extension of the other when a step is taken.

Other linked hip-knee-ankle-foot orthoses are the advanced reciprocating gait orthosis (ARGO) and the Isocentric reciprocating gait orthosis (IRGO). Both of these designs can be considered modified versions of the LSU RGO. The ARGO utilizes a single push-pull cable to link the mechanical hip joints (Campbell and Moore 1997). The IRGO, on the other hand, replaces the two Bowden cables with a centrally placed pivoting bar and tie rod arrangement.

2.3.2 The New Design of Mechanical Orthoses

Reciprocating Medial Linkage Orthoses (RMLO)

Reciprocating medial linkage orthoses is a new design concept that combines the medial linkage with reciprocal gait.

With research continuing the effect of clinical of these two kinds of orthoses was compared， people find some disadvantages of MLO. Some studies (Harvey et al. 1998) (Abe 2006)shown that RGOs were superior in static balance, walking velocity, and energy consumption in paraplegic patients compared with the KAFOs and WOs, because the design mechanism of MLO does not provide a reciprocating effect during ambulation.

But the MLO still has its advantages, such as using independence for the SCI patients. Harvey et al. calculated the time taken to don and doff mechanical orthoses and demonstrated that the WO needed significantly less time to undertake these activities than the IRGO (Harvey, Smith, et al. 1997). Their attitude investigation (Harvey, Newton-John, et al. 1997) showed that subjects did not perceive any significant differences between the two orthoses, which means that the RGO is not superior to MLO in clinical application. So either MLO or RGO needs to be improved continually.

Therefore, a new medial linkage system combining the MLO and reciprocal motion was designed by researchers. The Araz MLO (Arazpour et al. 2014) was developed incorporating a medial linkage orthotic system designed to provide reciprocal motion and to improve the walking efficacy of KAFOs or HKAFOs in patients with SCI. The feature of this new device is that a special transmission structure (Figure 2-2 a/b) consisting of four circular gears allows the reciprocal function motion–the extension of one hip and simultaneous of the flexion other. This function facilitates provision of the swing phase of one leg with simultaneous push-off on the contralateral lower limb. After that, this research group from Iran designed another new MLO mechanism (Bani, Arazpour, Farahmand, Sefati, et al. 2015) incorporating a reciprocating motion. This new MLO consists of a gearbox located in the medial, in which two spur gears are arranged on fore and aft (Figure 2-2 c/d). One gear is attached to the right side limb and the other one is attached to the left side. The two gears can move in opposite directions. When the right gear turns backward, it pushes the right gear forward. Each gear's movement is transmitted to the relevant limb through a four-bar mechanism.

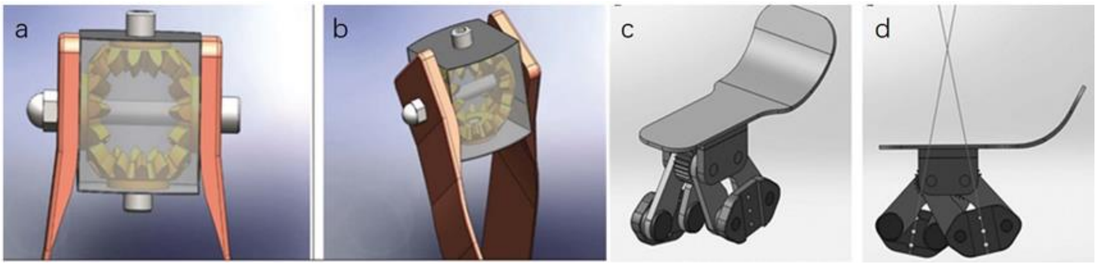


Figure 2-2 (a)(b), Araz MLO; (c)(d), Bani MLO

Reciprocating Gait Mechanism with Stance-control Mechanism

Firm support of lower extremities provides the maximum stability, and then almost paraplegic orthoses are designed with stiff knee joint maintaining weight-bearing stability to ensure safety. Fixed knees are the mechanical structure of all traditional orthoses, including KAFO, HKAFO, MLO/MSH KAFO, RGO, and RMLO, which all could provide stable support for paraplegic patients during the stance phase of gait. However, this gait pattern with the fixed knee can cause an increase in oxygen uptake by as much as 23% per limb (Mattsson and Broström 1989).

The stance control mechanism is theoretically available to avoid this disadvantage, because stance-control is a kind of gait pattern closer to normal – flexing during the swing phase and locking during the stance phase. This stance control mechanism can be realized by different mechanical structures, such as ratchet/pawl design (Van Leederdam and Kunst 1999) from Otto Bock Free Walk and Becker Orthopedic UTX(Figure 2-3-a), clutch and cam design (Hatton, Hatton, and Wallace 2003) from Horton Technology, Inc (Figure 2-3-b), gravity-actuated mechanism (Nijenbanning and Goudsmit 2005) by weighted pawl from Fillauer, LLC., (Figure 2-3-c).

Although this stance-control mechanism demonstrated improved gait kinematics to upright ambulation than stiff leg for KAFO users, this type of orthosis has not demonstrated a significant improvement in producing decreased energy consumption. And the current commercial SCO is not specially designed initially for paraplegic patients of SCI, but for individuals with neuromuscular and/or musculoskeletal disorders exhibit knee instability and weakness because of paresis or paralysis of lower limb muscles. The development of new design of SCO that aims at paraplegic patients and provides them with more efficient gait patterns is required in this field.

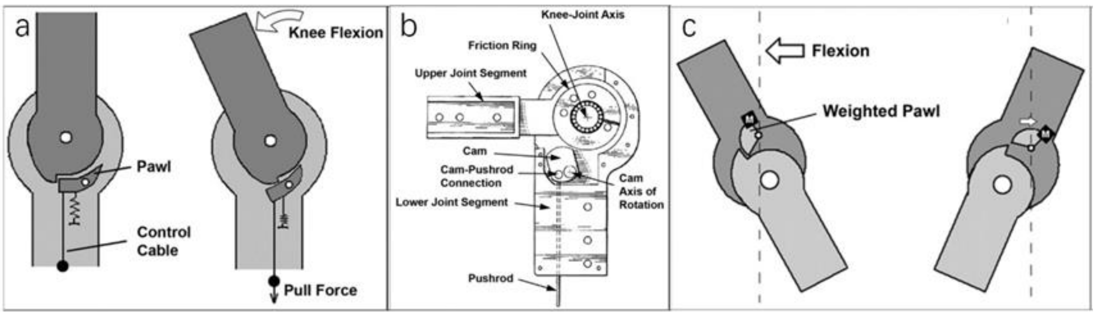


Figure 2- 3 (a) Pawl and ratchet structure of Free Walk; (b) Clutch and cam structure of Horton; (c) Weighted pawl structure of Fillauer

2.4 Clinical Effects of Mechanical Orthoses

2.4.1 Clinical Effects of Current Design of Mechanical Orthoses

2.4.1.1 Friendly Interaction

Various types of paraplegic orthoses have been designed to be used for paraplegic patients to improve their function, and another feature–friendly interaction–also is worth considering. In the survey of Harvey et al (Harvey, Newton-John, et al. 1997), the paraplegic subjects explain that ‘too busy’ is the main reason for not using their orthoses more frequently, which may indicate that their orthoses aren’t convenient. Actually, the primary aim of patients for using orthoses is for therapeutic purposes (Sykes et al. 1995b) including exercise, stretching, or preventing complications by a sedentary lifestyle. So, the independence of orthoses is that the patients can stably and conveniently utilize orthoses to achieve activities of daily living without the assistance of other people, including balance, donning or doffing, sitting or standing, walking up slopes, walking down slopes, or climbing stairs.

Stability

Middletton et al. (Middleton et al. 1997) used a questionnaire to investigate 25 adult subjects with SCI who were fitted and trained in the WO, and included that the standing stability was improved in all subjects. Abe et al. (Abe 2006) quantitative compared the KAFO and WO with RGO about the balance maintenance capability (the total path length of the center of pressure and the area of an ellipse for rejection). In this report, these two incomplete SCI patients (T9, T12) had significantly superior static balance performance when using the RGO than the other two orthoses.

Baardman et al. (Baardman et al. 1997) discussed the 4 kinds of balance outcomes (quiet standing, push and pull balance disturbance test, hand function test) wearing ARGO in 6 paraplegic patients whose spinal cord lesion level were T4-T12 complete paraplegia. This study was to observe the effects of reciprocal linking hinges and no significant differences were found for two structures in different balance conditions. However, the results of the crutch force shown that it is 101.74±21.76 N in the hand function test, more than twice the level in the quiet standing test, which indicated that the crutch force is necessary to maintain balance during functional tasks. A previous study reported that crutch force is an important indicator in functional assessments in the clinic, because the weakness of the upper limb could cause a major threat to the successful and prolonged application of orthoses in paraplegic patients (GELLMAN, SIB, and WATERS 1988).

Another comparison study (Karimi et al. 2013) about quiet stability and functional stability also indicated that the crutch force has a significant difference between the KAFO and ARGO, which means the balance ability of stability in standing with the ARGO is better than that of the KAFO for paraplegic subjects. Therefore, the RGO has more stability than the other mechanical orthoses.

Convenience

Saitoh et al. (Saitoh et al. 1996) reported that the MSH-KAFO has distinguishable real merits compared with HKAFO, which was easier to don and doff by SCI patients. Another compared study from Harvey et al. (Harvey, Smith, et al. 1997) shown that there were no differences between the IRGO and WO in the ability of donning and doffing, up and down stairs or curbs. This study also found that it is significantly easier to walk up slopes when using the IRGO, however, more difficult to change from sitting to standing or standing to sitting using this kind of orthosis. Therefore, it is easier to don and doff with the MSH-KAFO and RGO than the HKAFO, and the MSH-KAFO was more convenient to sit and stand, the IRGO facilitated a more independent gait. But this research indicated that the patients required more orthotic training if they want to gain full independence.

There are few specific studies on the friendly interaction about paraplegic orthoses, and more researchers focus on gait and energy expenditure.

2.4.1.2 Gait parameters

In comparison between the IRGO and KAFO, Leung et al. (Leung et al. 2009b) concluded that paraplegic patients with T12-L1 lesions of complete SCI walk faster when using the IRGO. The velocity of ambulation was 10.46±2.00 m/min using the IRGO, which was significantly faster than 5.51±4.30 m/min using the KAFO, and had a similar velocity 9.6 m/min with a previous study (Massucci et al. 1998). When comparing the IRGO and WO in the study of Harvey et al. (Harvey, Smith, et al. 1997), the patients with complete lesions between T9-T12 walked significantly faster with the IRGO than the WO, which the velocity was 20.4±10.8 m/min and 8.4±7.2 m/min respectively. Another study (Abe 2006) compared three types of orthoses to two incomplete SCI patients with T9 and T12 lesion, there were significant differences between the KAFOs, WOs, and RGOs, which indicated that the RGOs was superior in the gait performance. These studies analyzed the gait performance just from the ambulation velocity and demonstrated that the RGOs was superior to other orthoses, however, there were considerable differences between different studies to the velocity with the RGOs. Therefore, further gait studies in detail are needed whether there is a significant difference.

There were some studies that analyzed the gait parameter in velocity, cadence, and stride length. The mean values of velocity, cadence, and stride length were reported to be 19.8 m/min, 70.02 steps/min, and 0.56 m in SCI patients using the WO (Saitoh et al. 1996). These gait parameters were reported to be 1.44 m/min, 32.0 steps/min, and 0.89 m in SCI patients using the ARGO (IJZERMAN et al. 1997). Onogi et al. (Onogi et al. 2010) compared the different clinical effects of sliding hip joint and simple hinge joint of MLO on temporal gait parameters in 7 SCI patients. The velocity was faster, the cadence was higher, and the stride was longer when using the Primewalk with the sliding hip joint structure than the Walkabout with a simple hinge joint structure, which indicated that the Primawalk improved the gait efficiency by the sliding hip joint mechanism. However, there aren’t significant differences of gait velocity and cadence in a similar study (Winchester et al. 1993b) about the different types of RGOs. But the energy expenditure was significantly lower during ambulation with the IRGOs than the initial RGOs. Therefore, the clinical effects of these orthoses can’t be evaluated only by the gait parameter.

2.4.1.3 Energy expenditure

Arazpour et al. in a review (Arazpour et al. 2015) of the efficacy of orthoses on walking in person with paraplegia reported that the use of mechanical orthoses was reducing because of high rejection rates which caused the high loads on upper limbs and the high rate of energy expenditure experienced.

In Harvey's study (Harvey et al. 1998), there were no significant differences in HR and VO_2 between the WOs and IRGOs, but when the energy expenditure indexes were expressed relative to the velocity, both the physiological cost index (PCI) and O_2 cost were significantly smaller using the IRGOs compared with the WOs. The other previous study (Winchester et al. 1993b) also reported that the PCI was the only significant index when compared to the IRGOs with RGOs. The energy expenditure also was reported in the study of Abe and Leung et al. (Abe 2006; Leung et al. 2009b). The patients walked more efficiently using the IRGOs as compared to using the WOs or KAFOs.

The PCI and O_2 cost were used to evaluate the energy expenditure respectively in these two studies. The energy expenditure of walking is lower using the IRGO compared the KAFO and WO, because this type of orthosis assists hip flexion of patients when they extend another hip joint. In addition, these results also demonstrate that the PCI and O_2 cost are more accurate relative indexes to evaluate the energy expenditure, because the energy expenditure is related to the walking velocity that is a self-selected comfortable speed instructed by researchers.

2.4.2 Clinical Effects of the New Design Mechanical Orthoses

Studies have generally shown that SCO improves knee flexion during the swing phase and increases walking velocity, stride length, and cadence either non-disabled subjects or disabled subjects. The SCO is a mature mechanism that can be available from commercial products. Studies (Zissimopoulos, Fatone, and Gard 2007b) show that the SCO improved the gait parameter and energy expenditure in non-disabled subjects. Davis et al. (Davis, Bach, and Pereira 2010) also proved that the gait parameter performance is superior with stance-control knee joint orthosis than with the locked knee joint in nine disabled subjects who suffered from polio and one from Motor Neuron Disease. But there was no difference in the energy cost of walking or the PCI between these two conditions. For paraplegic subjects, there is only one study (Rasmussen, Smith, and Damiano 2007) that the research subject is a patient with T10 complete SCI. This study compared the temporal-spatial gait data in two conditions of locked knee joints and stance-control joints, and the result indicated that this subject ambulated with a faster and more efficient gait pattern when worn with SCO joint. The above studies all used the Horton Stance-Control Orthotic knee joint.

The RMLO is a new orthosis combining the medial linkage and reciprocal motion. The new Arza MLO was compared with the HKAFO in the gait parameters to an incomplete lesion at T12 level SCI patient. The result of gait analysis demonstrated that this new orthosis could be used to assist paraplegic patients to improve the gait velocity, cadence, and step length, and decreased compensatory motion compared to the HKAFO (Arazpour et al. 2014). The efficacy of another RMLO designed by Bani et al. (Ahmadi Bani et al. 2015) was tested in 4 healthy subjects and the mean of gait velocity and cadence were 5.4±0.42 m/min and 29.54±4.32 steps/min, respectively. The mean of stride length and time were 0.42±0.01 m and 4.89±0.45 s, respectively. However, compared with the gait data of the Arza MLO in paraplegia, the healthy subjects' parameters from Bani were worse, which may be because this kind of new design isn't mature enough and is still experimental. It offers the possibility of improving the clinical performance for paraplegic patients by new mechanical design.

2.4.3 Summary

Only for the mechanical design, the patients' performance with the RGO is superior to other purely mechanical orthoses, because the locomotion mechanism of RGO can provide the gait pattern of extension of one hip and simultaneous of flexion the other when a step is taken. However, considering the difference of patients, it is difficult to evaluate which orthosis is superiors, and it should be to explore which orthosis is more appropriate to a special population.

The reciprocating medial linkage orthoses is a new design concept that combines the medial linkage with reciprocal gait. And the stance-control mechanism also is a better way to save energy. Both these require more experiments to evidence the clinical effects.

Chapter 3

3. The Effectiveness of Quantitative Intensity Orthotic Training on Spinal Cord Injured Patients with Paraplegia

3.1 Introduction

The lifestyle changes in paraplegic patients post SCI. Patients with paraplegia usually become very sedentary. Furthermore, the intensity of activities of daily living is not strenuous enough to maintain or elicit improvements in either cardiorespiratory fitness or muscular strength (Alexander et al. 2009). This leads to low physical fitness and many secondary diseases, including obesity, type-2 diabetes, and cardiovascular disease (Myers and Lee 2007). Besides, patients with SCI induce autonomic nervous system disorders easily, especially cardiovascular dysfunction. Appropriate exercise activities can possibly reduce the incidence of complications associated with inactivity. However, these activities have to be well-planned and coordinated, in order to allow for various therapeutic exercises and purposeful orthotic training to avoid cardiovascular accidents and other sports risks. Therefore, upright ambulation with orthoses can benefit people with lower-limb paralysis, and this is the mainstay treatment method for the physical function of paraplegic patients (Johnson, Fatone, and Gard 2009). Consequently, the ability to stand and walk using orthoses is an important goal for patients with paraplegia (Kobetic et al. 2015).

A systematic review of this study found that the exercise rehabilitation of paraplegic patients can be classified as two different modes: endurance training (Eathorne 1998) and resistance training (Myslinski 2005). Endurance training can improve the cardiopulmonary and physical fitness of patients, while resistance training can enhance muscle strength (王瑞元 and 苏全生 2012). However, due to lower extremity dysfunction, paraplegic patients mainly carry out upper extremity strength and endurance training. The upright ambulation training usually improves the walking ability of the lower extremities by repeated gait exercises, because the potential walking function and neuronal plasticity of patients with incomplete SCI can be improved by stimulation of repeated gait exercises(Edgerton and Roy 2009). There are many ways to achieve the upright ambulation training, including traditional orthoses training and body weight support treadmill training

(BWSTT) using neuromuscular electrical stimulation, robot-assisted or therapist-assisted. However, the BWSTT is a passive exercise mode, and the effect of improving the patient's cardiorespiratory fitness is limited (Alexeeva et al. 2011b; Berry et al. 2008). The use of lower limb orthoses without power devices can not only provide training intensity to the patients, but also realize the gait mode of walking upright(Edgerton and Roy 2009).

The upright ambulation training using orthoses is an important rehabilitation goal for paraplegic patients after SCI(Kobetic et al. 2015). Orthoses currently used to assist paraplegic patients to walk mainly include Hip Knee Ankle Foot Orthoses (HKAFOs), Walkabout Orthoses (WOs), and Hip Guide Orthoses (HGOs), and Reciprocating Gait Orthoses (RGOs). Appropriate orthotic rehabilitation training can reduce the complications caused by inactivity for patients with SCI. Therefore, orthotic training for therapeutic purposes can improve the state of insufficient activities of daily living and can maintain or increase their cardiorespiratory fitness and muscle strength(Johnson, Fatone, and Gard 2009).

Studies found that orthotic training after SCI can achieve the functional walking ability of patients, but also help to improve the patient's condition and reduce complications(Ogilvie, Bowker, and Rowley 1993). However, the training requires an exercise prescription with clear goals and detailed content, in order to reach a better training effect and avoid ineffective training due to insufficient exercise intensity; On the other hand, the well protocol of training can prevent exercise risks, such as cardiac accidents caused by overtraining or fatigue, both of which are related to the exercise intensity during training. The risks caused by improper exercise intensity usually occur in healthy people. Special attention should be paid to patients with SCI who are prone to autonomic dysfunction(Erickson 1980). Therefore, the setting of intensity and monitoring of training is necessary for functional rehabilitation and risk prevention. To carry out clinical rehabilitation training safely and effectively, patients with paraplegia need a clear orthotic training protocol that includes training frequency, intensity, time, type and volume, progression (FITT-VP) (Sisto and Evans 2014).

Exercise intensity refers to the physiological response of the human body during training. It can be measured by oxygen uptake (VO_2), metabolic equivalent (METs), heart rate (HR) (Mehrholz, Kugler, and Pohl

2008b) or Borg Rating of Perceived Exertion scale (RPE) (BORG and A.V. 1982). The maximal oxygen consumption (VO_{2max}) is the most accurate indicator for measuring exercise intensity, but this direct measurement of VO_{2max} requires an incremental load experiment(王瑞元 and 苏全生 2012), which is difficult for paraplegic patients. Neither METs nor RPE is suitable for real-time monitoring during exercise. HR is a simple and reliable indicator of exercise intensity. It has been confirmed in literature that HR is linearly related to VO_2 in the incremental load test of patients with SCI below the Thoracic 4 (T4) level(Baron and Nene 1990). The systematic review of this study found that there was no evidence on the number of repetitions, exercise intensity, and the best training plan in previous studies on orthotic training for paraplegic patients after SCI. Therefore, the appropriate exercise prescription for orthotic training of paraplegic patients remains unclear. The present study aimed to determine the effects of quantitative orthotic training intensity for patients with paraplegia and provide scientific evidence for clinical rehabilitation training for them.

3.2 Methods

3.2.1 Participants

All paraplegic patients were recruited from the Guangdong Provincial Work Injury Rehabilitation Hospital, who had their RGOs fitted and prescribed by experienced orthotists at the Prosthetic and Orthotic Department.

Before recruiting subjects, the research team submitted the research plan and informed consent form to the Chinese Clinical Trial Registry, and the Registration Number is ChiCTR1800016028. Ethics approval (ChiECRCT-20180042) was obtained from the China Ethics Committee of Registering Clinical Trials prior to the screening. When recruiting subjects, the rehabilitation therapists introduced details of the research objective and training program to candidates and their family members. The recruited participants (or family members) provided a written consent prior to participation.

Inclusion criteria

Patients were included when they fulfilled the following criteria: (1) 18-60 years of age; (2) traumatic SCI after two months of injury; (3) ASIA grade A or B of SCI between T6 and L2 (4) willing to attend the training for eight weeks; (5) able to safely walk with the RGOs during clinical consultations.

Exclusion criteria

Patients were excluded when they fulfilled the following criteria: (1) cardiovascular or pulmonary diseases; (2) contractures and severe spasticity; (3) obesity and asymmetric hip positions; (4) osteoporosis with a high risk of pathologic fracture.

Elimination criteria

Patients were excluded when they fulfilled the following criteria: (1) withdrawing by themselves; (2) use other methods of rehabilitation during training; (3) have any serious adverse events and are not suitable to continue training; (4) exercise less than three times a week; (5) fail to complete the training as required.

3.2.2 Sample Size Calculation

Although the heart rate (HR) may reflect the orthotic training in the largest degree,(Karvonen, Kentala, and Mustala 1957) Physiological Cost Index (PCI) was the primary outcome in the present study. According to the previous study on gait performance in patients with SCI conducted by Winchester et al.,(Winchester et al. 1993) the sample size was estimated with a statistical power of 0.8, with the assumption of medium effect size and two-sided significant level of 0.05 by a priori of power analysis with G-power. A sample size of eight per group was calculated through sample size calculation online, based on this reference. It was assumed that there would be 20% drop out cases. Hence, 10 samples per group and a total of 30 patients were needed.

3.2.3 Random and Blind

The candidates were informed about the training program of the present study, and the recruited participants provided a written consent prior to participation. According to the random number (20180525) generator of SPSS 20.0, and based on a 33.3% width for equal percentiles, the recruited participants were randomly assigned into three groups: “1”, Light-intensity Group (LG); “2”, Moderate-intensity Group (MG); “3”, Control Group (CG). The therapist and participants who needed to monitor their real-time exercise HR were not blinded. However, the assessors and researchers for the data analysis were blinded from the present study.

3.2.4 Orthotic Training Protocol

Rehabilitation for patients with paraplegia includes general rehabilitation training and paraplegic orthosis fit and training.

General rehabilitation training

Mainly including the joint range of motion exercises, strength exercises, balance exercises, transfer exercises, standing exercises, and spasm control.

Range of motion exercises: Therapists help patients perform the range of motion exercises for the paralyzed limb such as the hip, knee, and ankle joints. Generally, each joint is 1-2 times per day, and each axial motion of the joint is 20 times.

Strength training: Mainly training the remaining muscle strength and endurance, focusing on the muscles of the shoulder and shoulder girdle. Concentric and eccentric contraction training using dumbbells or sandbags for latissimus dorsi, shoulder girdle muscles, biceps, triceps, brachii, etc.; In addition, it is necessary to train the lower back muscles for patients with low injury levels. At the same time, the coordination and cooperative contraction capabilities between various muscle groups should also be considered.

Transfer training: Transfer and independent transfer skills training for patients with the help of physical therapists, 1-2 times per day, mainly including transfer training between wheelchair and bed, wheelchair and toilet.

Sitting training: With the guidance of the therapist, long sitting and sitting up position training for patients with good spinal stability at an early stage, 2 times per day, 30 minutes-2 hours at a time. And gradually carry out sitting balance training, sitting support training, sitting decompression training, and sitting movement training.

Standing training: Including early tilting-table training and standing training later with the orthoses in parallel bars, which help to increase the cardiopulmonary adaptability and promote the blood circulation of the lower extremities. It can establish a vasomotor compensation mechanism and prevent orthostatic hypotension. The tilting-table starts with a tilt of 20°, 20-30 minutes/time, and gradually increases the angle to 90°; In parallel bars, stand up training with orthoses guided by therapists, 1-2 times per day for 20-30 minutes.

Spasm control: Use the above exercise therapy; and combine with physical agents, such as hyperthermia and functional electrical stimulation; or combine oral antispasmodic drugs, which can effectively inhibit the spasm and abnormal reflex patterns of paraplegic limbs. It is important to patients with paraplegia for standing and walking training with orthoses normally.

Paraplegic Orthosis Assembly and Training

The usual rehabilitation training of patients with RGOs includes orthoses donning and doffing exercises, standing and sitting exercises, parallel bars exercises, indoor flat walking exercises, and outdoor walking exercises.

Orthoses donning and doffing exercises: The main goal is to master donning and doffing orthoses independently and safely, which has high requirements for the patient’s sitting balance, abdominal muscle strength, and coordination of movements. The patients need more practice to orthoses donning, and doffing exercises.

Stand-up and sit-down training: The main goal is that patients can stand up and walk from a bed or wheelchair without assistance and sit back on the bed or wheelchair.

Parallel bars exercises: The patients firstly perform standing exercises in the parallel bars, including head, trunk, and pelvic stabilization, and center of the gravity transfer balance. When they can stand continuously for more than 30 minutes, stride exercises can be tried.

Indoor walking exercises: Transition from walking with a walker to walking with axillary crutches or elbow crutches, from walking with assistance to independent walking, the therapists should explain to the patient the principle of orthoses, and train the patient to transfer the center of gravity with the upper limbs to achieve alternate steps.

Outdoor walking exercises: Including outdoor flat walking, up and down slopes, crossing obstacles, etc. At the beginning of training, the therapists can assist the patients behind them, correct the posture of patients, and improve their walking ability.

3.2.4.1 Paraplegic orthoses fitting and evaluation

The subjects in this study all used RGOs. The treatment team included rehabilitation doctors, prosthetists, and orthotists, Physical therapists. The team evaluated SCI patients and prescribed orthoses. For the prescription of orthoses, the orthotists were responsible for the measurement, casting, and personalized production of RGOs for each patient. In order to ensure the best fit of each orthosis, the alignment evaluation of RGOs was performed after fitting, and then adjustments were made based on the evaluation results.

3.2.4.2 Paraplegic orthosis training intervention

All patients underwent a 1 session/day, 5 sessions per week orthotic training program, for a total of eight weeks, using RGOs after baseline measurements, as a complement to other standard therapies. The training venue was indoor. The training program was that patients conduct standing, sitting, walking, and turn around in parallel bars. When the subjects were familiar with the walking skills inside the bars, they gradually moved to the outside of the bars. Training outside the bars, the patient can use the walker, and gradually walking with elbow crutches or axillary crutches after the patient's balance ability was further improved. Participants in the intervention group were encouraged to walk as much as possible during the training period to maintain a stable intensity, and to allow rest when needed.

This present study used the exercise prescription recommended by the American College of Sports Medicine (ACSM) Ninth Edition Exercise Test and Prescription Guidelines for training intervention. The training intensity (Target Heart Rate, THR) was classified by the intensity of the HR reserve (HRR). The light intensity was 30-40% HRR, and the moderate intensity was 40-60% HRR recommended by the ACSM. (American College of Sports Medicine 2014) HRR was calculated using the Karvonen formula.(Karvonen and Vuorimaa 1988) The maximal heart rate (HR_{max})

was determined according to the age of the patient. Real-time HR was recorded every five seconds using a monitor (Polar) with a chest electrode attached to the patient’s chest region.

HRmax = 220–age

HRR = HRmax - HRrest

THR = (HRR × %intensity) + HRrest

Therefore, the HR range of the light intensity orthotic training was set to 30-40% HRR, and the moderate intensity orthotic training was set to 40-60% HRR. Orthotics training does not include preparation and warm-up time. According to the principle of FITT-VP (Frequency, Intensity, Time, Type of exercise, Volume, Progression, FITT-VP) (American College of Sports Medicine 2014), the exercise time per session was increased for five minutes every two weeks over the eight weeks orthotic training program. After eight weeks of training, a sports bracelet (MAMBO2, Lifesense) will be given to subjects in the experimental group. Continue to carry out the training plan of the original exercise intensity level in the hospital or at home. The subjects were supervised by their smartphone with the clock in method until the end of the 3-month follow-up.

Patients in the intervention groups were encouraged to ambulate as far as possible to maintain a quantitative intensity range during training. Patients in the CG maintain their original orthotic training protocol without the guidance of intensity. All patients were allowed to use handrails, parallel bars, and assistance, when needed, during the training.

3.2.5 Evaluation Indexes

3.2.5.1 Gait efficiency

An HR monitor was used to obtain physical effort data during the test, and the Physiological cost index (PCI) (MacGregor 1981) was calculated to assess the gait efficiency. PCI is a relative index of energy efficiency index that measures energy consumption because energy consumption is related to self-selected comfortable walking speed. This was calculated using the following formula:

$$PCI = (HR_{ss} – HR_{rest}) / V$$

The PCI measurement procedure(Leung et al. 2009) consisted of four phases, which included quiet sitting (five minutes), static standing (five minutes), walking at a speed that was comfortable (six minutes), and final sitting (two minutes). The HR was recorded every five seconds during the entire measurement period. The heart rate at rest (HR_{rest}) was obtained during the last two minutes of the first quiet sitting. The HR at steady state (HRss) was obtained during the last two minutes of the six-minute walk.

3.2.5.2 Cardiorespiratory fitness

Cardiorespiratory Fitness, also known as cardiovascular fitness, is one of the most important components of human fitness. People with good cardiorespiratory fitness usually also have better exercise endurance or aerobic performance. Cardiovascular fitness is sometimes referred to as cardiovascular endurance or aerobic fitness.

Borg's rating of perceived exertion (RPE) scale

The Borg's(Borg 1982) RPE scale measures the perceived exertion. This was used to document the patient's exertion during the test and assess the intensity of the training. The patients in both groups are required to record their feeling of exertion as objectively as possible immediately after the 6MWT.

Six-minute walk test (6MWT)

The 6-minute walk distance provides the integrated global responses of multiple cardiopulmonary and musculoskeletal systems involved in training. (Amatachaya et al. 2014) This test was performed along a 20 m indoor walkway. Patients were instructed to walk from one end of the corridor to the other, and cover as much distance as possible. These patients were allowed to take breaks by standing, or using parallel bars and orthoses, without stopping the timer. The use of any aids and/or physical assistance during the test was recorded. Then, the greatest distance covered was recorded.

3.2.5.3 Functional ambulation ability

Walking index for spinal cord injury II (WISCI II)

The WISCI II is an ordinal scale that captures the extent and nature of assistance (combinations of orthoses, and supporting equipment, such as walkers and human helpers) that a patient with SCI requires to walk. A retrospective study (Ditunno et al. 2013) revealed that the WISCI II was more responsive in detecting changes in locomotor ability in patients with a SCI, when compared to other tests.

Six-minute walk test (6MWT)

During the 6MWT test, the heart rate monitor was used to record the heart rate of the subjects in real-time, and the PCI value of the subject is calculated according to the PCI test steps. And the perceived exertion of subjects was asked immediately after the test and recorded their RPE rating.

10-meter walk test (10MWT)

The 10MWT is the best tool to assess the walking capacity of SCI patients.(Van Hedel, Wirz, and Dietz 2008) The walking time for 10 m was recorded, and the fastest and comfortable speed was chosen by patients with RGOs. The 10-m walk was repeated twice, and the fastest velocity was recorded.

Timed Up and Go (TUG) test

The TUG assessed the time (in seconds) needed to stand up from a chair, walk for 3 m, turn around, walk back and sit down again, as a measure of balance.(Podsiadlo and Richardson 1991) Patients were allowed to use the parallel bars, or have a rest when need.

3.2.5.4 Quality of Life (QOL)

The quality of life (Quality of Life, QOL) evaluation used the World Health Organization Quality of Life BREF (WHOQOL-BREF) to help researchers evaluate the changes in the subjects’ quality of life during treatment. WHOQOL-BREF is a simplified scale for measuring the quality of life developed by the World Health Organization based on the concept of quality of life. There are 26 question items in total, covering four domains of physical health, psychological health, social relationships, and environment.

3.2.5.5 Activity of Daily Living (ADL)

The Modified Barthel Index (MBI) was developed in Australia by Surya Shah, Frank Vanclay, and Betty Cooper. The MBI includes the 10 subtest items, (1) feeding, (2) moving from wheelchair to bed and return, (3) personal grooming, (4) getting on/off the toilet, (5) bathing, (6) walking or propelling a wheelchair, (7) stair climbing, (8) dressing and undressing, (9) bowel and (10) bladder continence, scored on a 5-point ordinal scale which varies from item to item (eg 0, 1, 3, 4, or 5 for personal hygiene; 0, 3, 8, 12 or 15 for ambulation). This scale was developed to enhance the sensitivity of the original scale. The Modified Barthel Index scores the degree of independence of a client from any assistance (regardless of how minor, and for what purpose the assistance is provided). The maximum total score is 100.

3.2.6 Data Collection

All these parameters, including gait efficiency, cardiorespiratory fitness, and functional walking ability, were evaluated at baseline, mid-point (week four), the end of the orthotic training program (week eight), and the 3-month follow-up (month three).

All data of one participant were collected in one day. Thinking about the heart rate could be affected by the physical activity. So, the testing order is as follows, 6MWT, 10MWT, and TUG. The PCI was measured during 6MWT. At the beginning of each walking trial, each subject was instructed to sit for 10 min for calming down to baseline levels before the PCI measurement. The PCI measurement procedure consisted of a 5-min period of quiet rest while sitting, 5 min of static standing, 6 min of walking at a speed that was comfortable to the subject, and a final 2-min period of rest in a sitting position. After 6MWT, the ranking of RPE was recorded. At the same time, the WISCI Ⅱ was evaluated.

3.2.7 Data Analysis

The original data was input in the format of Microsoft Excel, and the statistical analysis of the data was processed by SPSS20.0 (IBM Corporation, USA). One-way analysis of variance (one-way ANOVA) was used to detect insignificant statistical differences of the measurement data of the three groups, and the Cross tabs with Chi-square test were used for level information.

The PCI value, 6-minute walking distance, 10-meter walking time, TUG time, WHOQOL-BREF scale scores in each domain, and MBI total score are all continuous variables, which are consistent with the hypothesis analyzed by studentized residual and Shapiro-Wilk test. Two-way repeated measures analysis of variance (Two-way Repeated ANOVA) was used to analyze the data of each group at the baseline, mid-point, and end-point, to evaluate the interactions time vs. treatment, as well as the main effect of time and treatments. The results against the Mauchly’s sphere hypothesis are conducted with epsilon correction.

When there were interactions of time vs. treatment, it is necessary to analyze the simple effects of time and treatment, respectively; Multivariate analysis of variance was used to discuss the simple effects of the group at three different time points. Welch’s analysis of variance was used for the uneven variance detected by Levene's homogeneity of variance test; The one-way repeated measures analysis of variance (One-way repeated ANOVA) was used to analyze the difference of time factors in different groups for the time simple effect. If a significant difference was detected, multiple comparisons across groups adjusted by the Bonferroni post-hoc tests method were performed. If there were no interactions between the intervention treatments and time, it is necessary to analyze the main effects of time and groups, and further Bonferroni post-hoc tests method.

RPE rating, WISCI Ⅱ rating, and MBI's walking ability evaluation results are rank variables, so the nonparametric test Kruskal-Wallis one-way analysis of variance method was used, and the Bonferroni post-hoc tests method was used for multiple comparisons. The levels of statistical significance were indicated at 0.05 and 0.01.

3.3 Results

3.3.1 Demographic Characteristics

Based on the sample size calculation, this study screened 59 hospitalized patients in the ward, 11 of them refused to participate in this trial study, 18 patients did not meet the inclusion criteria, and 30 subjects were finally included, and 26 subjects completed this intervention experiment and follow-up, 9 in the control group, 8 in the light intensity training group, and 9 in the moderate intensity training group. 4 subjects dropped out this experiment due to various reasons. The dropout situation is as follows: 2 subjects were discharged early and could not complete the eight weeks in-hospital orthotic training; 1 subject was unwilling to continue the experiment due to his reasons; One subject did not complete the experiment due to urinary tract infection requiring treatment (Figure 3-1).

There were no significant differences among the 3 groups in demographic characteristics, baseline age, height, weight, post injury, gender, and lesion level. There were statistical differences in the American Spinal Injury Association (ASIA) rating, which had no effect on the experiments because patients of A or B of ASIA don't have any motor function (Table 3-1).

Table 3-1 Demographic data of the participants

	CG (n=9) Mean±SD	LG (n=8) Mean±SD	MG (n=9) Mean±SD	F	P
Age (Year)	38.67±11.00	38.63±8.85	36.22±7.68	0.2	0.82
Height (cm)	169.89±8.70	171.25±8.07	165.44±5.98	1.366	0.275
Weight (Kg)	64.56±11.035	61.75±9.91	59.89±15.20	0.325	0.726
Post injury (Month)	21.22±17.61	35.13±53.94	9.00±7.05	1.43	0.26
Sex (M/F)	7/2	5/3	5/4		0.599
Lesion Lever (T/L)	9/0	8/0	8/1		0.374
ASIA (A/B)	9/0	8/0	6/3		0.041*

Notes: Differences with statistical significance were marked with superscripts beside the P-values with * by Cross tabs with Chi-square test, p＜0.05.
Abbreviations: ASIA, American Spinal Injury Association

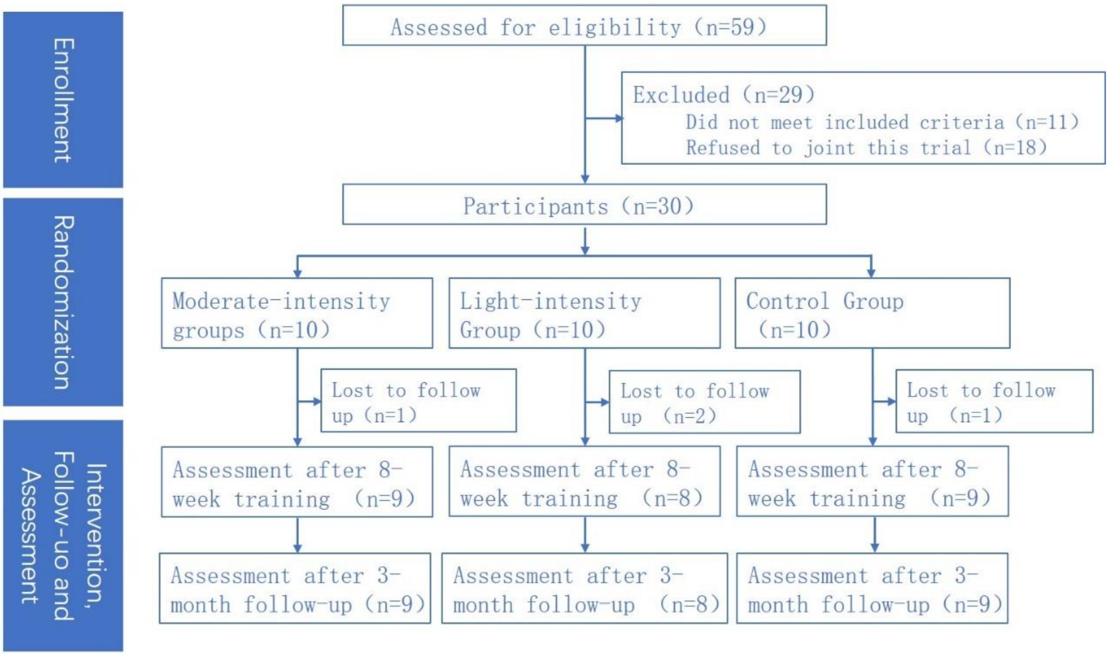


Figure 3-1 Flow chart of the participants

3.3.2 Comparison of the Gait Efficiency

3.3.2.1 Overall Analysis of the PCI Value

The overall analysis of the PCI value of the three groups at three time points was performed by using Two-way repeated ANOVA. After Mauchly's test of sphericity, $p<0.05$, adjusted by Huynh-Feldt method to Epsilon=0.782, the overall analysis found that there were no interactions between intervention treatment and time ($p=0.091$). Therefore, the main effects of the internal factors of the intervention treatment and time were analyzed, and multiple comparisons were adjusted by the Bonferroni post-hoc tests. The main effect difference between groups was not significant ($F=1.087$, $p=0.354$), so the grouping situation had no significant effect on the PCI value; The time factor had statistical significance on the main effects of the PCI value of each group ($F=11.157$, $p<0.001$), so the PCI value of the subjects after eight weeks of orthotic training was significantly lower than that of the baseline ($p<0.01$) (Table 3-2-1).

Due to the statistical significance of the time factor in the PCI value, the post hoc tests exhibited that the statistical differences in the PCI results presented between any two time points, the baseline vs. four weeks (p=0.041), four weeks vs. eight weeks (p=0.018), and the baseline period vs. eight weeks (p=0.002).

3.3.2.2 Intra-group Analysis of the PCI Value

The One-way repeated ANOVA was used to evaluate the effects of eight weeks orthotic training on the gait efficiency of the subjects. For PCI, significant differences were observed with the time effect that consists of these three levels in the intervention groups ($p<0.05$), but no difference in the CG ($p>0.05$). Furthermore, the difference within patients was also statistically significant at week eight vs. baseline ($p'=0.045$) and week eight vs. week four ($p'=0.041$) in MG. While the significant differences of PCI value in the LG at different time points were not obvious (Table 3-2-2, Figure 3-2).

3.3.2.3 Inter-group Analysis of the PCI Value

There were no significant variations for PCI values at the baseline and week four between the three groups (BL: F=0.021, p=0.979; 4w: F=1.928, p=0.168), while the significant group difference for PCI was detected at week eight using Welch analysis of variance, F=4.470, p=0.032. And then the post hoc tests indicated that the difference in the PCI result of MG was significantly lower than that of the control group (p'=0.017) (Table 3-2-3, Figure 3-2).

Table 3-2-1 Overall analysis of the PCI value of the three groups at three time points

	Timepoint	PCI (Mean±SD)	
CG	BL	16.35±13.17	
	4w	16.34±10.47	
	8w	14.91±9.86	
LG	BL	15.16±9.5	
	4w	10.31±6.08	
	8w	8.82±4.41	
MG	BL	15.97±13.16	
	4w	9.6±6.28	
	8w	5.48±3.06	
Overall analysis	Huynh-Feldt	0.782	
Inter-group	F，p	1.087	0.354
Intra-group	F，p	11.157	0.000*
interactions	F，p	2.308	0.091

Note: * indicates a significant difference of time main effect $p<0.05$;
Abbreviations: BL, Baseline; 4w, four weeks; 8w, eight weeks.

Table 3-2-2 Intra-group comparison of the PCI value of the three groups

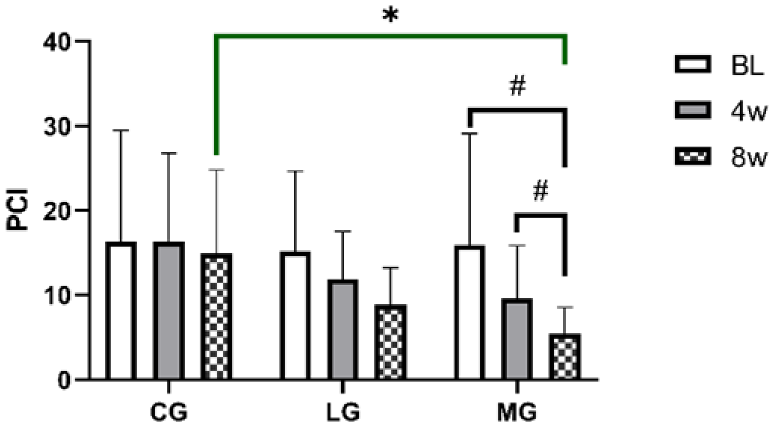
	Overall		4w Vs BL	8w vs BL	8w vs 4w
	F	P	P’	P’	P’
CG	0.349	0.711			
LG	5.419	0.044*	0.232	0.108	0.341
MG	8.088	0.015*	0.144	0.045$^{\#}$	0.041$^{\#}$

Note: * indicates a significant difference of intra-group $p<0.05$, ** indicates $p<0.01$; $^{\#}$ indicates a significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests $p'<0.05$, $P'=pn$, n is the number of comparisons.

Table 3-2-3 Inter-group comparison of the PCI value at three time points

	Overall		CG vs LG	LG vs MG	CG vs MG
	F	p	P’	P’	P’
BL	0.021	0.979			
4w	1.928	0.168			
8w	4.769	0.019*	0.207	0.913	0.017#

Note: * indicates significant difference of inter-group p<0.05, ** indicates p<0.01; # indicates significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons.



Note: * indicates Inter-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons; # indicates Intra-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons.

Abbreviations: PCI, Physiological cost index

Figure 3-2 multiple comparisons of the PCI

3.3.3 Comparison of the Cardiorespiratory Fitness

3.3.3.1 Overall Analysis of RPE and 6MWT

Using the non-parametric test Kruskal-Wallis one-way ANOVA, the RPE scores of three groups were compared at three time points.

The Two-way repeated ANOVA was used to analyze the walking distance of 6MWT of the three groups at three time points. After Mauchly’s test of sphericity, $p<0.05$, adjusted by Huynh-Feldt method to Epsilon=0.885, the overall analysis found that the influence of the time factor was statistically significant for subjects' walking distance of 6MWT ($F=49.283$, $p<0.001$), but the group factors had no significant effect on that ($F=0.391$, $p=0.681$). There were interactions for treatment vs. time ($p<0.001$) (Table 3-3-1). Therefore, it is necessary to analyze the simple effects of time and treatment, respectively.

3.3.3.2 Intra-group Analysis of the RPE and 6MWT

The RPE scores of the three groups were not detected significant differences at different times.

Since the influence of time factor on 6MWT was statistically significant, the One-way repeated ANOVA was further performed on the simple effect of time factor, and the multiple comparisons were made by Bonferroni post-hoc test (Table 3-3-2, Figure 3-3).

In the control group, it did not need to Epsilon correction because of p>0.05 after Mauchly's test of sphericity. The 6MWT walking distance of subjects at baseline, four weeks, and eight weeks were 28.46±25.01m, 33.38±28.62m, and 34.64±29.68m, respectively. The difference of walking distance at three time points was statistically significant (F=4.564, p=0.027). However, no significant difference between the different time points was found with the Bonferroni post-hoc test.

In the LG, it did not need to Epsilon correction because of p>0.05 after Mauchly's sphericity test. The 6MWT walking distances of subjects at baseline, four weeks, and eight weeks were 30.73±15.32m, 37.51±19.11m, and 46.35±17.74m, respectively. The difference of walking distance at three time points was statistically significant (F=17.168, p<0.001). The 6MWT distances of LG subjects at the eight weeks were significantly longer than that at the baseline (p=0.003) and the four weeks (p=0.04) with the Bonferroni post-hoc test.

In the MG, Huynh-Feldt method was used for correction (Epsilon=0.656), because of p<0.05 after Mauchly’s test of sphericity. The 6MWT distances of subjects at baseline, four weeks, and eight weeks were 29.07±18.35m, 39.42±19.57m, and 55.38±24.96m, respectively. And the difference of walking distance at three time points was statistically significant (F=3.766, p<0.001). A significant difference between the different time points was detected with the post hoc test. The 6MWT distance of MG subjects at eight weeks was significantly longer than that at the baseline (p'=0.001) and the eight weeks (p'=0.001). The 6MWT walking distance at four weeks was also significantly longer than that at the baseline (p'=0.015).

3.3.3.3 Inter-group Analysis of the RPE and 6MWT

For RPE scores, significant differences were showed between different groups after eight weeks of training (H=6.657, p=0.036) (Table 3-3-3, Figure 3-3). The median of the RPE score was 15 in the CG, the median of the RPE score was 14 in the LG, and the median of the RPE score was 14 in the MG. However, there was no statistical difference between the baseline and four weeks. Furthermore, the differences were not significant between the three groups with the Bonferroni pos hoc test.

For 6MWT at the baseline, four weeks and eight weeks, the differences of walking distance were not statistically significant between three groups (BL: F=0.029, p=0.972; 4w: F=0.162, p= 0.852; 8w: F=1.571, p=0.229) (Table 3-3-3, Figure 3-3).

Table 3-3-1 Overall analysis of the cardiorespiratory fitness of the three groups at three time points

	Timepoint	6WMT (Mean±SD)	
CG	BL	28.46±25.01	
	4w	33.38±28.62	
	8w	34.64±29.68	
LG	BL	30.73±15.32	
	4w	37.51±19.11	
	8w	46.35±17.74	
MG	BL	29.07±18.35	
	4w	39.42±19.57	
	8w	55.38±24.96	
Overall analysis	Huynh-Feldt	0.885	
Inter-group	F，p	0.391	0.681
Intra-group	F，p	49.283	0.000*
interactions	F，p	7.205	$0.000^{\#}$

Note: * indicates significant difference of time main effect p<0.05;

Abbreviations: 6MWT, 6 Minute Walk Test

Table 3-3-2 Intra-group comparison of the cardiorespiratory fitness of the three groups

		Overall		4w Vs BL	8w vs BL	8w vs 4w
		F	P	P’	P’	P’
RPE		H	P			
	CG	0.989	0.61			
	LG	3.439	0.179			
	MG	2.711	0.258			
6MWT		F	P			
	CG	4.564	0.027*	0.058	0.12	1
	LG	17.168	0.000**	0.081	$0.003^{\#}$	$0.04^{\#}$
	MG	30.766	0.000**	$0.015^{\#}$	$0.001^{\#}$	$0.001^{\#}$

Note: * indicates significant difference of intra-group p<0.05, ** indicates p<0.01; $^{\#}$ indicates significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’=pn, n is the number of comparisons.

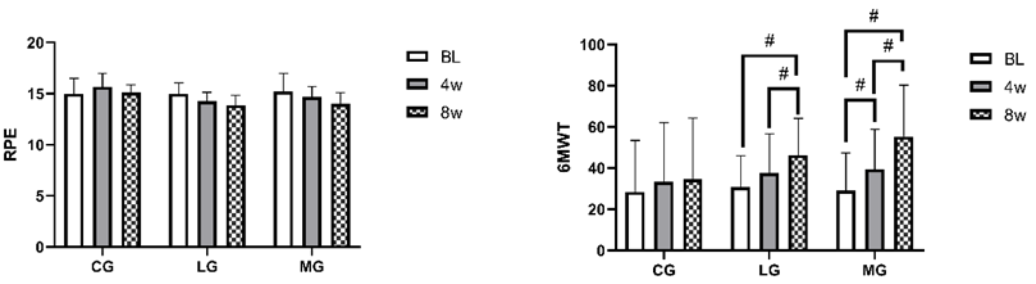
Abbreviations: RPE, Rating of Perceived Exertion; 6MWT, 6 Minute Walk Test

Table 3-3-3 Inter-group comparison of the cardiorespiratory fitness at three time points

		Overall		CG vs LG	LG vs MG	CG vs MG
		F	p	P’	P’	P’
RPE		H	P			
	BL	0.03	0.985			
	4w	5.429	0.066			
	8w	6.957	0.036*	0.083	1	0.074
6MWT		F	p			
	BL	0.028	0.972			
	4w	0.162	0.852			
	8w	1.571	0.229			

Note: * indicates significant difference of inter-group p<0.05, ** indicates p<0.01; $^{\#}$ indicates significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons.

Abbreviations: RPE, Rating of Perceived Exertion; 6MWT, 6 Minute Walk Test



Note: * indicates Intra-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons. # indicates Inter-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons.

Figure 3-3 multiple comparisons of the RPE and 6MWT

3.3.4 Comparison of the Functional Ambulation Ability

3.3.4.1 Overall analysis of 10MWT、TUG、WISC

Two-way repeated ANOVA was applied for the overall analysis of the three groups at three time points for the 10MWT and TGU time. The data of 10MWT assumed Mauchly's sphere hypothesis ($p>0.05$). The data of TUG did not assume the Mauchly's sphere hypothesis ($p<0.05$), it was corrected by the Huynh-Feldt method (Epsilon=0.734). There was no interaction between the treatment and the time ($p=0.493$, $p=0.127$). Therefore, the main effects of the internal factors of time points and groups. The main effects of the groups are not significantly different ($p=0.231$, $p=0.221$). The time factor has statistical significance for the main effects of 10MWT and TUG in each group ($p<0.001$, $P<0.001$). After eight weeks of orthotic training, the subjects' 10MWT and TUG time were significantly lower than those at the baseline ($p<0.001$) (Table 3-4-1).

Due to the statistical significance of the time factor on the 10MWT and TUG time, the post-hoc test shows that the statistical differences between the baseline and the four weeks of 10MWT and TUG time were significant (p=0.004, p<0.001). The differences between the 10MWT and TUG time at the four weeks and eight weeks were very significant (p=0.003, p=0.024); There was a very significant statistical difference between the baseline and the eight weeks in 10MWT and TUG time (p<0.001) (Table 3-4-1).

The WISCI Ⅱ scores of the three groups used the non-parametric test of Kruskal-Wallis one-way analysis of variance to compare the three time points within the group and the different grouping methods.

3.3.4.2 Intra-group analysis of the 10MWT、TUG、WISCI

The effect of eight weeks of orthotic training on the subjects' 10MWT and TUG time was judged by one-way repeated ANOVA. The 10MWT and TUG time of the control group did not change significantly before and after the test (p>0.05). After eight weeks of quantitative exercise intensity paraplegic orthosis training, the 10MWT and TUG time of the LG and MG showed a significant downward trend (10MWT: LG, p =0.000; MG, p=0.011; TUG: LG, p=0.008; MG, p=0.001); It was found that for 10MWT time, LG and MG subjects were significantly lower than the baseline value after eight weeks of training (P'=0.005, p'=0.033) with post-hoc test. At the same time, LG’s 10MWT time was significantly improved at the eight weeks compared with at four weeks (p'=0.013); For TUG time, LG and MG subjects trained after four weeks and eight weeks later were significantly lower than the baseline (LG: 4w vs BL, p'=0.008; 8w vs BL, p'=0.018; MG: 4w Vs BL, p'=0.004; 8w vs BL, p'=0.004). And the TUG time of MG subjects after eight weeks of training was significantly improved compared with that of four weeks (p=0.005) (Table 3-4-2, Figure 3-4).

For the WISCI Ⅱ score, there were statistical differences between the three time points of MG subjects at the baseline, four weeks, and eight weeks after training (H=7.188, p=0.027). The medians of the WISCI Ⅱ scores at the three time points were 5, 6, and 9, respectively; and then the Bonferroni method was used to compare the WISCI Ⅱ scores of MG subjects at different time points. There was a significant difference between the eight weeks and the baseline (p'=0.023 after adjustment), and there was no difference between the other time points. However, the RPE scores of the control group and LG did not show statistical differences between the baseline, four weeks, and eight weeks (Table 3-4-2, Figure 3-4).

3.3.4.3 Inter-group analysis of the 10MWT、TUG、WISCI

There was no statistically significant difference for the 10MWT and TUG time between the three groups at the baseline and the four weeks (10MWT: BL, p=0.678; 4w, p=0.190; TUG: BL, p=0.813; 4w, P=0.257). The main effects of different interventions on 10MWT and TUG time at the 8th week were statistically significant (p=0.034, p=0.009). Furthermore, there was no significant difference between the different interventions for the 10MWT time with the post-hoc test; the TUG time of the MG was significantly lower than the control subjects (p'= 0.008) (Table 3-4-3, Figure 3-4).

The WISCI scores did not show significant differences between the different groups during the baseline, four weeks, and eight weeks of training (Table 3-4-3, Figure 3-4).

Table 3-4-1 Overall analysis of the functional ambulation ability of the three groups at three time points

	Timepoint	10MWT (Mean±SD)		TUG (Mean±SD)	
CG	BL	185.78±96.97		113.78±68.69	
	4w	162±94.56		107.56±68.7	
	8w	142.44±75.38		99.11±51.21	
LG	BL	150±67.78		100.5±48.9	
	4w	123.38±46.19		86.13±47.43	
	8w	80.25±39.5		61.38±26.97	
MG	BL	155.44±101.124		97.78±46.96	
	4w	102.56±48.51		66.56±29.36	
	8w	79.67±37.34		43.44±16.91	
Overall analysis	Huynh-Feldt	-		0.734	
Inter-group	F，p	1.564	0.231	1.612	0.221
Intra-group	F，p	21.183	0.000*	17.923	0.000*
interactions	F，p	0.863	0.493	2.045	0.127

Note: * indicates a significant difference of time main effect p<0.05;

Abbreviations: 10MWT, 10 Meter Walk Test; TUG, Timed Up & Go test

Table 3-4-2 Intra-group comparison of the functional ambulation ability of the three groups

	Overall		4w Vs BL	8w vs BL	8w vs 4w
	F	P	P’	P’	P’
10MWT	F	P			
CG	2.962	0.08			
LG	14.525	0.000**	0.21	0.005#	0.013#
MG	9.262	0.011*	0.083	0.033#	0.06
TUG	F	P			
CG	0.591	0.496			
LG	11.405	0.008**	0.008#	0.018#	0.117
MG	23.41	0.001**	0.004#	0.004#	0.005#
WISCI Ⅱ	H	P			
CG	2.606	0.272			
LG	1.494	0.474			
MG	7.188	0.027*	0.299	0.023#	0.105

Note: * indicates a significant difference of intra-group p<0.05, ** indicates p<0.01; # indicates a significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’=pn, n is the number of comparisons.

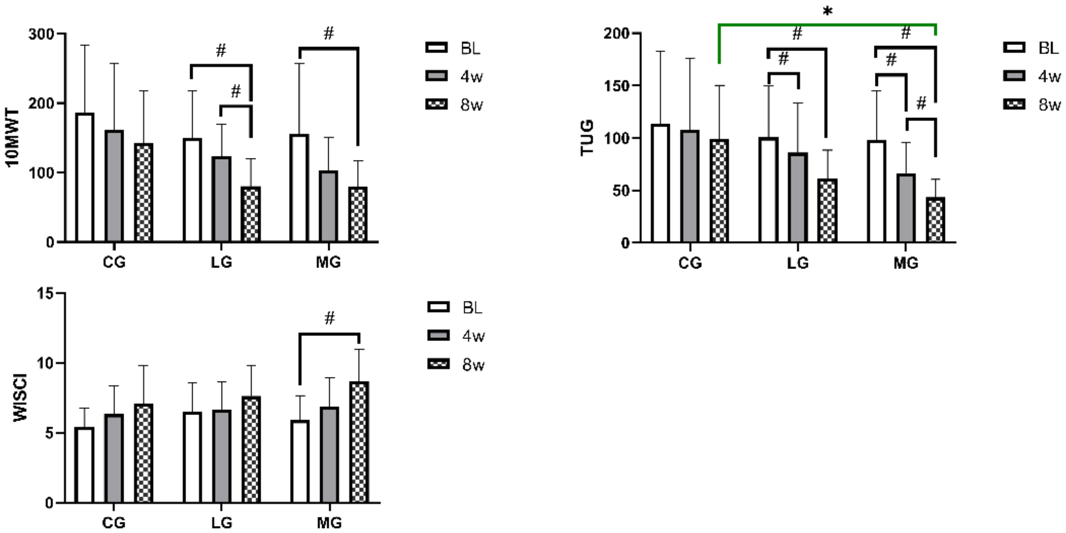
Abbreviations: 10MWT, 10 Meter Walk Test; TUG, Timed Up & Go test; WISCIⅡ, Walking Index for Spinal Cord InjuryⅡ.

Table 3-4-3 Inter-group comparison of the functional ambulation ability at three time points

		Overall		CG vs LG	LG vs MG	CG vs MG
		F	p	P’	P’	P’
10MWT		F	p			
	BL	0.395	0.678			
	4w	1.785	0.190			
	8w	3.915	0.034*	0.081	1	0.066
TUG		F	p			
	BL	0.208	0.813			
	4w	1.441	0.257			
	8w	5.875	0.009**	0.112	0.913	$0.008^{\#}$
WISCI II		H	P			
	BL	1.603	0.449			
	4w	0.599	0.741			
	8w	2.341	0.31			

Note: * indicates a significant difference of intra-group $p<0.05$, ** indicates $p<0.01$; # indicates a significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests $p'<0.05$, P’=pn, n is the number of comparisons.

Abbreviations: 10MWT, 10 Meter Walk Test; TUG, Timed Up & Go test; WISCIⅡ, Walking Index for Spinal Cord InjuryⅡ.



Note: * indicates an Intra-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests $p'<0.05$, P’ = pn, n is the number of comparisons. # indicates Inter-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests $p'<0.05$, P’ = pn, n is the number of comparisons.

Figure 3-4 multiple comparisons of the 10MWT, TUG and WISCI

3.3.5 Comparison of the QOL

3.3.5.1 Overall analysis of physical health, psychological health, social relationships, and environment domains

Two-way repeated ANOVA was applied for the overall analysis of the three groups at three time points for the quality of life. After the Mauchly's test of sphericity and the Huynh-Feldt Epsilon, there was no interaction between the treatment and the time. Therefore, the main effects were analyzed for the internal factors of time points and groups, then the post-hoc test was conducted. There was no significant difference in main effects among groups. The main effect of time factor on the scores of the physiological health and psychological health domains of each group was statistically significant ($p<0.001$, $p<0.001$).

The post-hoc test showed that the scores differences of physiological health and psychological health domains between the eight weeks and the baseline were very significant ($p<0.001$, $p<0.001$). The difference in physical dimension scores between the eight weeks and three months follow-up was statistically significant ($p=0.021$). There was no statistical difference in the psychological dimension scores between the eight weeks and the 3-month follow-up; The scores of the physiological health and psychological health domains between the 3-month follow-up and the baseline were very significant statistical (p<0.001, p<0.001) (Table 3-5-1).

3.3.5.2 Intra-group analysis of physical health, psychological health, social relationships, and environment domains

The scores of physiological health and psychological health domains of the control group, LG and MG before and after training and follow-up have very obvious changes (Physiological health: control group, p=0.001, LG, p<0.001, MG, p=0.001; psychological health: control Group, p<0.001, LG, p<0.001, MG, p=0.003); After the post-hoc test, the physiological health scores of the three groups after eight weeks of orthotic training were significantly higher than the baseline (control group, p'=0.002; LG, p'=0.012; MG, p '=0.010), the psychological health scores of the three groups of subjects after eight weeks of orthotic training were also significantly higher than the baseline data (control group, p'=0.007; LG, p'=0.002; MG, p' =0.011); After three months of follow-up, the scores of physiological health of the three groups decreased compared with those at eight weeks. The decrease of the scores of physiological health of the control group was statistically significant (p'=0.031); The physiological health scores of the LG and MG also decreased during follow-up, but there was no statistical difference (p>0.05); Compared with the physiological health scores of the LG and MG at baseline, significant differences was showed after 3-month follow-up (p=0.006, p=0.002). No statistical difference was found in the control group. After three months of follow-up, the psychological health scores of the three groups were significantly higher than the baseline (control group, p'=0.001; LG, p'=0.003; MG, p'=0.009), but there is no statistically significant difference in the psychological health scores between the 3-month follow-up and eight weeks (Table 3-5-2, Figure 3-5).

There were no significant changes in the social relationships scores of the control group, LG, and MG at the different time point (p>0.05); But the environmental domain scores of the LG showed statistically significant (p=0.017). Afterward, the Post-hoc test found that after three months of follow-up, subjects in LG had significantly higher scores of environmental domains than the baseline (p'=0.027), while no difference was found in the other two groups (Table 3-5-2, Figure 3-5).

3.3.5.3 Inter-group analysis of physical health, psychological health, social relationships, and environment domains

One-way ANOVA was used to analyze the scores differences of the QoL between different groups at three time points. After Levene’s homogeneity test of variance, the Welch was used for uneven variance.

At the baseline and after eight weeks of training, the differences of the physiological health scores were not statistically significant between the groups (BL: F=0.392, p=0.680; 8w: F=0.545, p=0.587); At the 3-month follow-up, the main effect of the physiological health scores between different groups was statistically significant (Welch analysis of variance: F=6.653, p=0.011). Furthermore, the physiological health scores of the control group were significantly lower than those of the MG (p'=0.041); The physiological health scores of the control subjects were also lower than those of the LG subjects, but there was no statistical difference; And there was no statistical difference between LG and MG (Table 3-5-3, Figure 3-5).

At the three time points, the differences in the psychological health, social relationships, and environmental domains scores of the three groups were not statistically significant (p>0.05) (Table 3-5-3, Figure 3-5).

Table 3-5-1 Overall analysis of the WHOQOL-BREF of the three groups at three time points

	Time point	Physical health (Mean±SD)	Psychological health (Mean±SD)	Social relationships (Mean±SD)	Environment (Mean±SD)
CG	BL	29.76±9.78	31.02±11.24	43.52±8.10	39.59±5.63
	8w	41.67±5.65	49.53±10.91	46.30±7.35	43.40±6.89
	3m	34.52±3.57	50.93±4.05	48.15±8.10	42.71±6.81
LG	BL	29.91±6.60	31.77±9.95	45.83±6.30	38.67±4.40
	8w	46.43±11.61	52.08±5.89	41.67±9.96	39.85±8.14
	3m	43.75±8.70	53.65±6.84	42.71±10.39	44.14±6.56
MG	BL	26.98±6.46	33.33±9.99	43.52±5.56	41.32±4.07
	8w	45.24±11.43	54.17±8.07	46.30±7.35	41.32±13.87
	3m	44.45±9.96	52.78±6.59	44.45±7.22	42.71±10.48
Overall analysis	Huynh-Feldt	0.872	0.702	-	0.909
Inter-group	F，p	1.11 0.344	0.561 0.578	0.361 0.701	0.058 0.944
Intra-group	F，p	43.2 0.000*	63.39 0.000*	0.123 0.884	2.342 0.113
interactions	F，p	2.40 0.063	0.154 0.960	1.415 0.244	0.667 0.618

Note: * indicates significant difference of time main effect p<0.05;

Table 3-5-2 Intra-group comparison of the WHOQOL-BREF of the three groups

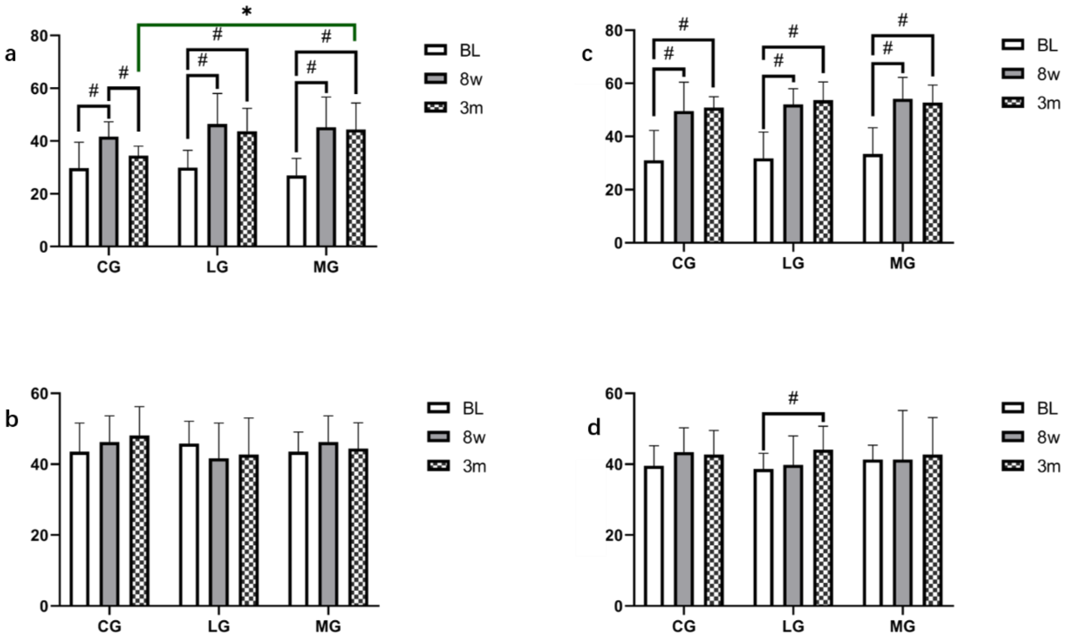
	Overall		8w Vs BL	3m vs BL	3m vs 8w
	F	P	P’	P’	P’
Physical health					
CG	10.482	0.001**	0.002#	0.566	0.031#
LG	16.666	0.000**	0.012#	0.006#	0.732
MG	18.854	0.001**	0.010#	0.002#	1
Psychological health					
CG	21.679	0.000**	0.007#	0.001#	1
LG	29.341	0.000**	0.002#	0.003#	0.854
MG	16.880	0.003**	0.011#	0.009#	0.586
Social relationships					
CG	1.134	0.346			
LG	0.791	0.409			
MG	1.190	0.330			
Environment					
CG	1.884	0.184			
LG	5.566	0.017*	1	0.027#	0.135
MG	0.100	0.905			

Note: * indicates significant difference of intra-group p<0.05, ** indicates p<0.01; # indicates significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’=pn, n is the number of comparisons.

Table 3-5-3 Inter-group comparison of the WHOQOL-BREF at three time points

	Overall		CG vs LG	LG vs MG	CG vs MG
	F	p	P’	P’	P’
Physical health	F	p			
BL	0.392	0.680			
8w	0.545	0.587			
3m	4.389	0.024*	0.073	1	0.041#
Psychological health	F	p			
BL	0.115	0.892			
8w	0.649	0.532			
3m	0.474	0.628			
Social relationships	F	p			
BL	0.325	0.726			
8w	0.876	0.430			
3m	0.902	0.420			
Environment	F	P			
BL	0.685	0.514			
8w	0.264	0.771			
3m	0.084	0.919			

Note: * indicates significant difference of intra-group p<0.05, ** indicates p<0.01; # indicates significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’=pn, n is the number of comparisons.



Note: * indicates Intra-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons. # indicates Inter-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons.

(a) Physical health, (b) Social relationships, (c) Psychological health, (d) Environment

Figure 3-5 multiple comparisons of domains of the WHOQOL-BREF

3.3.6 Comparison of the ADL

3.3.6.1 Overall analysis of the MBI and walking ability

Two-way repeated ANOVA was applied for the overall analysis of the three groups at three time points for the score of the MBI. The time factor has a significant effect on the MBI score of the subjects (F=295.348, p<0.001). The group factor has no significant effect on the MBI score (F=0.377, p=0.690). There was an interaction between the interventions and the time (p<0.001). Therefore, it was necessary to analyze the individual effects of the three groups (Table 3-6-1).

After a 3-month follow-up, it was found that 4 people in the control group abandoned the paraplegic orthoses and switched to a wheelchair. The experimental groups were monitored with the internet, but 1 of the LG and 2 of the MG did not complete the orthotic training and switched to wheelchair exercise too. Therefore, in the MBI table, "wheelchair operation" was chosen for grading. Using the non-parametric test Kruskal-Wallis method to analyze the scores of the three groups.

3.3.6.2 Intra-group analysis of the MBI and walking ability

Perform one-way repeated ANOVA on the effects of the time factor, and the Post-hoc test. The differences of three groups are statistically significant at baseline, eight weeks and three months (Control group, $p<0.001$; LG, $p<0.001$; MG, $p<0.001$) After the Post-hoc test, the difference of the MBI scores between eight weeks and the baseline was very significant (control group, $p'=0.000$; LG, $p'=0.000$; MG, $p'=0.000$). The difference of the MBI scores between three months and baseline was very significant (control group, $p'=0.000$; LG, $p'=0.000$; MG, $p'=0.000$); There were no statistical differences of the MBI score between eight weeks and three months (Table 3-6-2, Figure 3-6).

The walking ability scores of subjects in the control group showed very significant differences between different time points ($H=10.787$, $p=0.005$). The median of the walking ability scores at baseline, eight weeks, and three months follow-up was 8, 15, and 8, respectively; The LG and MG did not show statistical differences at different times. Furthermore, the Bonferroni method was used to compare the control subjects at different times. The walking ability scores were significantly different ($p'=0.003$) between eight weeks and three months (Table 3-6-2, Figure 3-6).

3.3.6.3 Inter-group analysis of the MBI and walking ability

At the baseline, eight weeks, and three months, the differences of the MBI scores of the three groups were not statistically significant (BL: F=0.206, p=0.816; 8W: F=1.167, p= 0.329; 3M: F=2.941, p=0.073) (Table 3-6-3, Figure 3-6).

The walking ability scores showed very significant differences between different groups at the three months (H=10.713, p=0.005). The median of walking ability scores of the three groups were 8, 12, and 12; There was no statistical difference between the groups at the baseline and eight weeks. Furthermore, the Bonferroni method was used for the post-hoc test between different groups at the three months. The walking ability score of the control group was significantly lower than that of the intervention group (p'=0.024, p'=0.009). While the difference between LG and MG was not significant (Table 3-6-3, Figure 3-6).

Table 3-6-1 Overall analysis of the MBI of the three groups at three time points

	Timepoint	MBI (Mean±SD)	
CG	BL	48.11±7.322	
	8w	63.89±6.509	
	3m	59.67±6.461	
LG	BL	48.88±3.796	
	8w	61.38±3.962	
	3m	63.63±3.889	
MG	BL	47.11±5.207	
	8w	65.00±3.873	
	3m	65.44±4.640	
Overall analysis	Huynh-Feldt	-	
Inter-group	F，p	0.377	0.690
Intra-group	F，p	295.348	0.000*
interactions	F，p	6.510	$0.000^{\#}$

Note: * indicates a significant difference of time main effect p<0.05; # indicates a significant difference of interactions

Abbreviations: MBI, Modified Barthel Index

Table 3-6-2 Intra-group comparison of the MBI and walking ability of the three groups

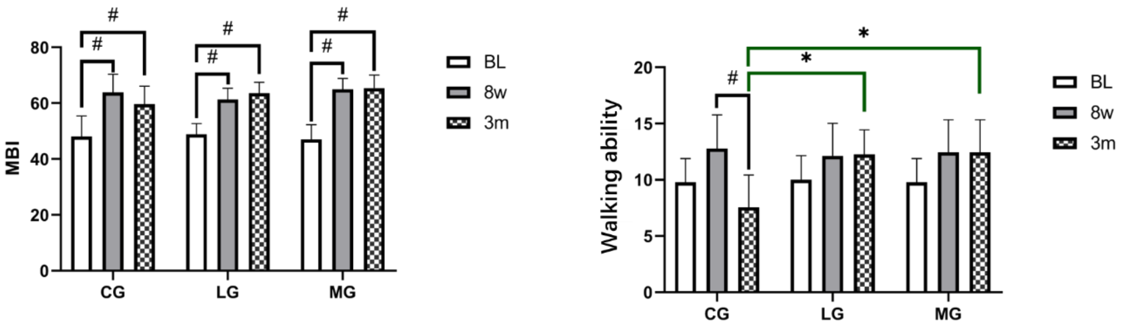
		Overall		8w Vs BL	3m vs BL	3m vs 8w
		F	P	P’	P’	P’
MBI						
	CG	62.474	0.000**	$0.000^{\#}$	$0.000^{\#}$	0.115
	LG	142.396	0.000**	$0.000^{\#}$	$0.000^{\#}$	0.217
	MG	149.963	0.000**	$0.000^{\#}$	$0.000^{\#}$	1
Walking		H	P			
	CG	10.787	0.005**	0.194	0.460	$0.003^{\#}$
	LG	4.007	0.135			
	MG	5.512	0.064			

Note: * indicates a significant difference of intra-group p<0.05, ** indicates p<0.01; # indicates a significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’=pn, n is the number of comparisons.

Table 3-6-3 Inter-group comparison of the MBI and walking ability at three time points

		Overall		CG vs LG	LG vs MG	CG vs MG
		F	p	P’	P’	P’
MBI						
	BL	0.206	0.816			
	8w	1.167	0.329			
	3m	2.941	0.073			
Walking		H	P			
	BL	0.851	0.654			
	8w	0.340	0.844			
	3m	10.713	0.005**	$0.024^{\#}$	1	$0.009^{\#}$

Note: * indicates a significant difference of intra-group p<0.05, ** indicates p<0.01; # indicates a significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’=pn, n is the number of comparisons.



Note: * indicates an Intra-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons. # indicates an Inter-group significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests p’<0.05, P’ = pn, n is the number of comparisons.

Figure 3-6 multiple comparisons of domains of the MBI and Walking ability

3.4 Discussion

Helping paraplegic patients after spinal cord injury regains the ability to walk upright, enhance cardiopulmonary fitness, reduce complications, and improve the quality of life, orthotic training is an important part of the paraplegic patient's rehabilitation. However, in the clinical fitting process, the orthotists require the patient to learn the walking skills of the paraplegic orthoses based on personal experience and clinical observations. Little attention is paid to the intensity of orthotic training, which may cause adverse events by excessive training intensity, or lead to poor training effects by low training intensity. The systematic review has also found that there are few studies systematically to discuss the protocol of orthotic training and rehabilitation effects. There is still a lack of strong evidence on how to use safe and effective exercise intensity for paraplegic orthosis training. In this study, prospective RCT was designed to study the rehabilitation effects of reciprocating paraplegic orthosis training under quantitative exercise intensity on paraplegic patients after SCI to explore safe and effective orthotic exercise rehabilitation programs and provide higher-level evidence for clinical treatments.

This study shows that the light and moderate intensity orthotic training can effectively improve the RGOs walking performance of paraplegic patients compared with the control group. After eight weeks of quantitative exercise intensity orthotic training, it can improve cardiorespiratory fitness and functional walking ability. After eight weeks of orthotic training and three months follow-up, the subjects who adhere to quantitative exercise intensity training can improve their quality of life from the physical and psychological domains. The walking ability in daily activities can also be effectively improved.

3.4.1 Training Intensity and Monitoring

When setting an exercise rehabilitation protocol, in addition to exercise mode, exercise time, and exercise frequency, exercise intensity is the most critical prescription index. In previous studies on paraplegic orthosis training, most researchers only set the duration, frequency, and period in the training plan. However, as the most critical index in the exercise rehabilitation training prescription, exercise intensity is rarely clear. This may be due to the focus of these researches on the feasibility of paraplegic orthoses, which only proves that paraplegic orthoses can help patients with SCI walk again. And the participants using orthoses can have less energy consumption and obtain better gait parameters. At the same time, clinical walking training after fitting paraplegic orthoses also focuses more on enabling patients to master the gait skills of using orthoses. These paraplegic walking devices are used as assistive devices for the disabled. But no attention has been paid to the rehabilitation training with paraplegic walking devices. Therefore, how to scientifically use paraplegic orthoses for rehabilitation training is a gap that has been neglected in the research and clinic.

In this study, quantitative exercise intensity was used to implement paraplegic orthosis gait training on subjects in the experimental group. The definition of exercise intensity was calculated based on each subject’s HRR and ACSM exercise recommendations. Although heart rate is not the most accurate index of exercise intensity, exercise physiology has verified that training monitors can use heart rate to determine training intensity, which is based on the linear relationship between heart rate and maximum oxygen uptake during steady-state sub-extreme intensity exercise(Chen, Fan, and Moe 2002; Mcardle, Katch, and Katch 1991). It is easy to monitor exercise intensity with heart rate. So, subjects have high acceptance and compliance. The heart rate and RPE are the most common methods for monitoring internal load(Halson and L. 2014).

Because each subject’s age and resting heart rate are different, this study uses a heart rate reserve to calculate the target heart rate during exercise to more accurately defines the exercise heart rate range of each subject. Using a chest strap, the heart rate monitor can recode the heart rate more accurately and effectively in real-time. This is also the most common in exercise prescriptions for healthy people (Terbizan, Dolezal, and Albano 2002). According to the latest version of ACSM’s exercise prescription recommendations(Sharp 2014), all patients underwent a quantitative orthotic training for 1 session/day, 5 sessions per week orthotic training program, a total of eight weeks. And the exercise time per session was increased for five minutes every two weeks from 30 minutes/session over the eight weeks orthotic training program. The light intensity is 30-40% HRR, and the moderate intensity is 40-60% HRR. ASCM’s recommendation for the principle of exercise progression for healthy adults is to increase the training time by 5-10 minutes every 1-2 weeks in the first 4-6 weeks to meet the adaptability of the human body. Due to the lack of exercise progression recommendations for people with chronic diseases, this study conservatively adopted the lower limit of this recommendation (To add 5 minutes of training time every 2 weeks).

In the field of sports science, high-intensity interval exercise is also a common training method, but the orthotics training programs with high-intensity is abandoned to ensure the safety of subjects and avoid cardiovascular accidents, because of the exercise prescriptions for chronic patients. Besides, both light intensity and moderate intensity exercise can improve physical condition. However, since moderate intensity exercise stimulates the human cardiovascular system more strongly than light intensity exercise, the effect of moderate intensity exercise training is better than that of light intensity exercise.

This study set up a light intensity group and a moderate intensity group. The results of this study are that the gait performance, cardiorespiratory fitness, functional walking ability, and ADL of the two intervention groups were significantly improved compared with the control group, which also verified previous studies. For walking efficiency and walking ability, the moderate intensity group has more advantages than the light intensity group. This shows that paraplegic orthoses training with quantitative exercise intensity can improve the physical condition of the subjects. If the patients want more efficient gait and walking ability, they need to increase the exercise intensity during orthoses training. In this study, a heart rate monitor was used to monitor the orthotic training process in real-time to ensure that the training was controlled under the quantitative intensity and avoid adverse events caused by inappropriate training. In this study, it is found that the quantitative intensity paraplegic orthoses training customized by heart rate reserve is feasible and effective, and no adverse events occurred during the training.

3.4.2 Gait Efficiency

The energy efficiency research of paraplegic patients using orthoses for gait training has always been a hot issue in this field. Whenever a new orthosis appears, the energy expenditure and gait parameters of this paraplegic orthoses must be tested. Reduced energy consumption and improved gait parameters mean that paraplegic patients can use this orthosis more effectively. High energy consumption is one of the main reasons for paraplegic patients abandon this orthosis(Arazpour, Hutchins, and Ahmadi 2015). However, it is not accurate to judge the mechanical efficiency of paraplegic orthoses only from the energy consumption or gait parameters. For this reason, some researchers chose the PCI to evaluate the gait performance of paraplegic orthoses. PCI value is a relative efficiency index, it is the ratio of the difference between the steady heart rate and the resting heart rate during walking to the walking speed. When calculating PCI, not only the difference in the reserve heart rate of the subjects is considered, but also the heart rate when walking at a certain speed.

This study shows that quantitative intensity paraplegic orthoses training can improve the gait efficiency of the subjects. The PCI value of the MG group was significantly lower at the eight weeks than the baseline and the four weeks. And it was also significantly lower at the eight weeks compared with the control group. There was no difference in the LG group at different time points. It shows that the MG group is better than the LG group in improving gait efficiency. It is worth noting that the 6MWT distance of the control group in this trial has also changed significantly after eight weeks of training. However, there was no difference in the PCI value of the control group before and after training. The inconsistency between the PCI value and the 6MWT result in this experiment has also been reported in the previous literature of Winchester. This study compared the gait parameters and energy consumption of IRGOs and RFOs. It was found that there were no significant differences in the frequency and the rate of stride, and heart rate of the subjects who used these two paraplegic orthoses, but the PCI value of the subjects who used IRGOs was significantly lower. This shows that paraplegic patients with IRGOs could save more energy than those using RFO, even though their gait parameters are the same. This result was also verified in a later comparative study(Harvey et al. 1998b) on using IRGOs and WOs for walk tests in paraplegic patients. This study found that there was no difference in energy expenditure and heart rate during walking between the two groups. The PCI value of the IRGOs group was significantly lower, which means that the gait parameters of the IRGOs group may be better, but the energy consumption is the same. These two studies show that energy expenditure or gait parameters cannot accurately reflect the actual situation of the subject. However, the PCI is a relative value correlated to HR and walking velocity under certain gait parameters. It could provide comprehensive information of the person's heart rate and gait. After comparing the time effect with the Post-hoc, there was a difference between the PCI value between the eight weeks and the baseline for the experimental group, but there was no difference between the four weeks and the baseline. Perhaps it was because for training to improve cardiorespiratory fitness, most of the researchers choose 6 or more weeks of intervention time, and the training time is longer, the effect is better.

3.4.3 Cardiorespiratory Fitness

Cardiorespiratory fitness is the basis for all physical activities, and it is also a prerequisite to improve functions for a virtuous circle. Therefore, it is an important task of sports rehabilitation to improve cardiorespiratory fitness. In this study, it is shown that the 6MWT parameters of the three groups of subjects after eight weeks of moderate intensity orthoses training have been improved, indicating that the paraplegic orthoses training could improve the cardiorespiratory fitness of the patients. Regarding the LG and MG groups, the MG group had higher exercise intensity stimulation than the LG group, so the MG group showed an improvement in cardiorespiratory fitness in the 4th week. However, in the long term, the LG group could be effective too.

The 6MWT is common to evaluate the cardiopulmonary function or the walking ability of elderly patients with cardiopulmonary disease or brain injury. It is also often used in the evaluation of the walking ability of paraplegic orthotics after SCI. However, a systematic review reported that the 6MWT walking distances of different studies are quite different. Perhaps it was caused by different subjects in different studies, such as injury plane range, post-injury time, or the sample size. However, the

RPE ratings of the three groups of subjects did not change during eight weeks of training. This may be due to the adaptive changes in the subjects' cardiorespiratory fitness with the training. Therefore, despite the increase in walking distance and walking speed after training, there was no significant change in scores of the Borg scale. On the contrary, this could indicate the subject's cardiorespiratory ability has improved. Because the scores of RPE refer to the degree of fatigue or subjective exertion when subjects complete a quantitative load. By combining information from muscles, joints (extremities), the cardiovascular system, respiratory system, and central nervous system, it provides an overall subjective perception of effort (Le and Dorstyn). If the subjects could complete the load more easily, this indicates an improvement in cardiorespiratory fitness. Another reason may be that the 6MWT test was completed at a comfortable stride speed selected by the subjects, the degree of fatigue can also be controlled by the subjects, so there is no change before and after the experiment. Therefore, the 6MWT of the three groups improved after eight weeks of training, but the changes before and after the RPE test were not obvious, indicating that the cardiopulmonary ability of the subjects was improved by the gait training. These results suggest that it is necessary to discuss with gait parameters when using RPE to evaluate the cardiopulmonary function of subjects.

Because there is no difference before and after the RPE test, it does not mean that the subject's cardiopulmonary function has not changed. After the experiment, the 6MWT of the cardiorespiratory abilities of the two groups of subjects were improved; In addition, although the 6MWT results of the control group test were statistically significant, the PCI values were not significantly different after eight weeks of training. The 6MWT ability and PCI value of the experimental groups were significantly improved. Moreover, the PCI value in the 8th week was significantly different from that of the control group. This shows that the comprehensive walking efficiency of the experimental group has been improved, and this result also supports previous studies. The PCI value is a relatively accurate indicator of the patient's comprehensive ability.

The focus of this study is that paraplegic orthoses training is a method of sports rehabilitation. This view has been put forward by scholars (Sharp). Paraplegic patients must not only master the skills of using paraplegic orthoses, but also obtain an improvement of cardiopulmonary fitness and functional walking ability with quantitative intensity training. It is the key point to distinguish this study from other paraplegic rehabilitation methods.

3.4.4 Functional Ambulation Ability

The systematic review shows that there are currently two strategies for paraplegia rehabilitation programs. One is compensation strategy, and the other is function strategy. The main purpose of the compensation strategy is to enhance the upper limb strength of paraplegic patients through aerobic endurance training and resistance training. The functional strategy is mainly to achieve the upright walking ability of the lower limbs through repeated gait training with the help of assistive devices. Functional walking ability is another important aspect to evaluate whether paraplegic orthoses are effective, and it is also considered in the design and adaptation of the orthoses. RGOs are a relatively mature product in paraplegic orthoses. It first came from the Louisiana State University Reciprocating Gait Orthosis (LSU-RGO) developed by Louisiana University in 1981 (Douglas et al. 1983). RGOs are currently widely used in the clinic. In this study, RGOs are used to intervene in the gait of patients with paraplegia. The results found that the 10MWT and TUG results of the two experimental groups before and after the test were significantly reduced, indicating that the participants in the experimental groups increased their gait speed and balance after eight weeks of training. And there is a statistical difference between the experimental groups and the control group in the 8th week; The WISCI Ⅱ ratings of the three groups of subjects were significantly improved after the trial, and there was no difference between the groups at the three time points. The 6MWT test results have been discussed in the previous section. It is mentioned here that during the baseline period of the experiment, some subjects can only train and test with the aid of the orthoses in the parallel bars, and the length of the parallel bars is only 5 meters. Therefore, the subjects had more turning movements during the 6MWT test; By the 8th week, most subjects can train and test outside the parallel bars, and the reduction in turning movements may affect the test results. Some studies have suggested that the times the subject turns around during the test, especially the "U" turn, will affect the walking speed and distance. Therefore, the 6MWT distances of the experimental group and the control group have been significantly improved. The 10MWT test is always completed in parallel bars, so the results may be more credible. This can also explain why the 6MWT of the two intervention groups changed significantly over time. However, the 10MWT showed a significant increase from the baseline value only at the 8th week, and the difference between the groups with the control group was also shown at the 8th week. This result also supports the conclusions of previous studies that 10MWT can better reflect the gait improvement of patients with paraplegia in the later stage (three months later) (Hedel, Wirz, and Curt 2006). At the same time, because the subjects trained in the parallel bars and had to practice more turning movements, the TUG results of the two intervention groups were significantly lower than the baseline time after 4 and eight weeks of training. The difference between the groups was shown after eight weeks of training, showing that MG was significantly higher than the control group.

The purpose of this study is to explore the rehabilitation effects of quantitative intensity orthoses training. The influence of differences in walking skills on the results should be eliminated as much as possible. Therefore, the WISCI Ⅱ rating of all subjects in this study starts from level 5. Because the subjects were all rated A or B by the American Spinal Injury Association (ASIA), they did not have any motor function. Therefore, the subjects must use the paraplegic orthoses and master the orthoses walking ability before they conduct gait training. In addition, the items of WISCI Ⅱ have limitations, sometimes the ceiling effect is more obvious. Although the subjects' gait parameters improved, such as stride speed. However, most subjects did not improve their rating after reaching level 9. Because the WISCI Ⅱ item does not include the evaluation of stride speed and walking distance of more than 10 meters. Another reason may be that it is safer for patients to walk with the walker based on clinical experience. But after they are used to walking with a walker, they are no longer willing to use elbow crutches or axillary crutches. A few subjects can reach level 12. But the WISCI Ⅱ rating will not be improved, because the patient has no motor function. Therefore, although the WISCI Ⅱ rating of the MG group at the eight weeks was significantly higher than that of the baseline, there was no difference between the groups after training due to the ceiling effect. There are similar reports in previous literature that the walking distance and speed are accelerated after orthoses exercises, but there is no difference of the WISCI II rating before and after (Wirz et al. 2005). Another reason may be that with the progress of the subjects' training, the patient's course of the disease has exceeded three months. A review study(Hedel, Wirz, and Curt 2006) showed that all walking ability tests are applicable in the first three months after SCI. During 3-6 months, only 10MWT and 6MWT can effectively reflect the improvement of the patient's walking ability, and the WISCI II rating does not seem to be sensitive during this period. This study also suggests that the 10MWT test was not sensitive in the first four weeks of training in the intervention group, and it showed no significant difference until eight weeks later. However, the 6MWT score of the MG group was different in the 4th week. Therefore, combining the two gait parameters can better evaluate the improvement of the subjects' gait in different periods(Alexander et al. 2009; Lam, Noonan, and Eng 2008).

3.4.5 ADL

Paraplegic patients not only lose the ability to stand and walk, but also have many complications due to long term bed rest, sedentary sitting, and injury, such as urinary or fecal incontinence, lung, and urinary system infections, pressure sores, osteoporosis, orthostatic hypotension, obesity, diabetes, etc. (Myers, Lee, and Kiratli 2007b). The use of paraplegic orthoses not only allows patients to regain the function of upright walking, but also can promote nerve regeneration through repeated upright gait exercises (Edgerton and Roy 2009); Enhance cardiopulmonary function and muscle strength to improve the ability of physical activity; Improve bladder control and promote intestinal function, thereby reducing the chance of urinary system infection and better control(Ogilvie, Bowker, and Rowley 1993); Increased standing and walking time can prevent pressure ulcers, deep vein thrombosis and other problems caused by the lifestyle of low physical activity. Thereby improving the ADL ability of paraplegic patients (Post and Noreau 2005), helping patients participate more in daily activities and social activities, overcoming negative emotions from the psychological domain, and ultimately improving the quality of life (Scivoletto et al. 2000).

In this study, the modified Barthel index (MBI) and WHO quality of life was used to evaluate their ADL ability and QOL after eight weeks of orthoses training and three months follow-up. The study found that the ADL ability of the three groups of subjects after eight weeks of training and three months of follow-up were significantly improved compared with the baseline, but there was no change in the MBI score during the follow-up period. It shows that using RGOs paraplegic orthoses for eight weeks of quantitative intensity rehabilitation training could improve the patient's ADL ability. The MBI scale covers ten items, including feeding, moving from wheelchair to bed and return, personal grooming, getting on/off the toilet, bathing, walking or propelling a wheelchair, stair climbing, dressing and undressing, bowel and bladder continence. This study is more concerned about "walking ability", so the rating of this item was analyzed separately. It was found that after eight weeks of training and three months of follow-up, the walking ability scores of the control group showed a tendency to increase first and then decrease.

And the score at the 3-month follow-up was significantly lower than that after the eight weeks of training, indicating that his walking ability dropped significantly during the 3-month follow-up. The reason may be that 4 people in the control group gradually gave up using the paraplegic orthoses after being discharged from the hospital. This item was replaced with a “wheelchair operation” rating, so the score was low. At the same time, the walking ability of the control group was also significantly lower than that of the experimental groups during the three months follow-up. However, there was no difference in walking ability between the two experimental groups before and after training and follow-up. Although some subjects gave up using orthoses, most patients were able to adhere to sports rehabilitation training. Some researchers have used the self-control study to reach similar conclusions (孙嘉利 et al. 2007), RGOs training could help paraplegic patients improve their mobility, and thus improve the activities of daily living, but this study did not carry out long term follow up. All subjects have mastered the skills of RGOs in this RCT, and their walking ability has a high starting point. Therefore, due to the limitation of scoring items, the results are not different before and after eight weeks of training; But this RCT conducted three months of follow-up found that the walking score of the control group decreased, because 4 people in the control group did not adhere to the use and training with the RGOs.

3.4.6 QOL

The purpose of rehabilitation medicine is to improve the quality of life of the sick, injured, and disabled so that they can return to society. Patients with SCI need lifelong rehabilitation training. Correct rehabilitation training is the key to ensuring patients' mental health and quality of life, and can even affect the survival time of paraplegic patients(李淑琴, 唐洁, and 罗兴利 2012). In this study, the World Health Organization WHOQOL-BREF scale was used to assess the QOL of patients with paraplegia in the four domains of physiology, psychology, society, and environment. The study showed that the scores of physiological domains of the three groups increased significantly after eight weeks of orthotics training. The physiological domains of the control group decreased significantly after three months of follow-up, while the two intervention groups did not change. The physiological domains control group was significantly lower than the other two intervention groups during the three months of follow-up, and there was no difference between the two intervention groups. The reason for the decrease was that more patients in the control group abandoned paraplegic orthoses, which resulted in decreased physical activity levels. Due to the SCI, in addition to physical trauma, patients are also accompanied by tremendous psychological pressure. A recent systematic review showed that about 30% of patients with SCI are at risk of depression, and about 19-26% of people with SCI are diagnosed with depression (Williams and Murray 2015). Another survey report shows that the prevalence of anxiety is 15%-32% (Le and Dorstyn 2016). Post-traumatic stress disorder is another common mental illness among people with SCI, and the prevalence is between 7% and 44% (Amatachaya et al.). Therefore, the change of psychological and social adaptability has become an important part of the rehabilitation of paraplegic patients (Dickson et al. 2011; Byrnes et al. 2012). This study did not specifically evaluate the psychology of paraplegic patients. It only made a simple evaluation from the psychological dimension of WHOQOL-BREF. The results found that the three groups of subjects had better psychological status after training and follow-up. But there was no difference before and after follow-up, and there was no difference between the three groups at different time points. It shows that regular rehabilitation training could significantly improve the mental state of the subjects. Some studies also specifically pointed out that customized paraplegic orthoses training has a positive effect on improving patients' ADL ability (刘松怀 et al. 2004); There are also studies using Hamilton anxiety scale and depression scale to assess the impact of personalized paraplegic orthoses training on the mental state of patients with SCI. The results show that the functional recovery and psychological changes of patients after using paraplegic orthoses promote each other (邵秀芹 et al. 2012). Regarding the changes in the social and environmental domains of paraplegic patients, this study did not find any differences before and after the experiment in the overall analysis of the main effects. In the detailed statistical analysis, only the environmental dimension score of the LG was significantly higher than the baseline after three months of follow-up. This may be related to the difference between the subjects' hospital and home environment. In addition, it may also be related to the defects of the scale itself. Studies have pointed out that WHOQOL-BREF is not specifically for SCI patients. Social support may be a long-term problem. Short-term training and follow-up have not found changes. Environmental changes require more support from families and society.

3.4.7 Innovations and limitations

The innovations of this study are as follows: (1) The clinical randomized controlled method was used to systematically explore the rehabilitation effect of RGOs paraplegic orthoses training with quantitative exercise intensity on paraplegic patients. The result of the study is the clinical rehabilitation of paraplegic orthotics after spinal cord injury. The treatment provides a high-level evidence-based basis; (2) According to ACSM's exercise prescription recommendations, this study uses the reserve heart rate method to calculate the exercise target heart rate interval for the first time to set a personalized training intensity and obtain a positive training effect. This provides methods to customize a safe and effective training plan for clinical sports rehabilitation of paraplegic patients.

The limitations of this study are as follows: (1) This study takes PCI as the main outcome indicator and calculates the sample size to include subjects based on previous studies on PCI. However, the sample size is insufficient for secondary outcome indicators, such as 6MWT, which will inevitably affect the experimental results. (2) This study only followed up subjects for three months. Paraplegia after SCI is a sequela of trauma that requires long-term or even lifelong rehabilitation. Although the patient’s function has improved after rehabilitation, the 3-month follow-up time is still insufficient. Especially for the evaluation of patients' ADL and QOL, it may take a longer time for investigation and research. In addition, due to experimental conditions, only questionnaire surveys were conducted on subjects after follow-up without a more comprehensive assessment under laboratory conditions, so the follow-up results were not comprehensive. (3) This study only conducted trials on paraplegic patients who fit RGOs. Although RGOs are widely used in the clinic, WOs are also paraplegic orthoses that are currently used more frequently. Due to the limitation of hospital resources, the comparison test of RGOs and WOs was not carried out, so this study is not comprehensive on the current pure mechanical orthotics.

3.5 Summary

Patients who received quantitative intensity orthotic training could significantly promote the energy efficiency, cardiorespiratory fitness, ambulation ability, and ADL compared with traditional orthotic training without intensity demand; The QoL and ambulation ability could decline without regular orthotic training; Patients with moderate intensity orthotic training have better gait efficiency and ambulation ability than that in light intensity orthotic training; The target heart rate (THR) calculated by heart rate reserve (HRR) could be used to customize the orthotic training intensity for paraplegic patients. Quantitative intensity orthotic training regularly could benefit paraplegic patients, and it could be used in the clinical rehabilitation.

Chapter 4

4. Development of New Stance Control Knee Joint for Reciprocating Gait Orthoses

4.1 Introduction

From purely mechanical paraplegic orthoses to hybrid orthoses, to dynamic gait orthoses, it has a history of nearly one hundred years of development. Paraplegic orthoses have been the most widely used assistive devices for patients with SCI in the clinic. With the development of technology, the Powered Gait Orthoses (PGOs) is the direction of future development, but currently, there are few clinical applications, mainly because this technology is immature and expensive. And some studies have proved that the clinical rehabilitation effect of PGO is not better than purely mechanical orthoses('Gait speed using powered robotic exoskeletons after spinal cord injury: a systematic review and correlational study'; Arazpour, Bani, and Hutchins 2013). For purely mechanical paraplegic orthoses, researchers and clinicians are constantly developing and improving paraplegic orthoses. The purpose is to provide patients with SCI with safer and more effective walking ability, help them recover, and improve their quality of life.

Due to complete spinal cord injury, patients lose motor function of their lower limbs. Therefore, the structure of the orthoses needs to provide firm support for the lower limbs of paraplegics to ensure that patients could stand and walk stably. Almost all knee joints of traditional paraplegic orthoses are designed with locking structures. After manually unlocking, the knee joint can be flexed to facilitate sitting, donning, and doffing, while the locking when standing can maintain stability and safety, including KAFOs, HKAFOs, MLO / MSH-KAFOs, RGOs, and RMLOs. However, studies have shown that this gait pattern with knee stiffness can increase the oxygen uptake of each limb by more than 23% and increase the energy expenditure of patients with paraplegia (Mattsson and Broström 1990). Therefore, how to make paraplegic patients with orthoses get closer to the normal gait, and to ensure their safety, that is a question worthy of consideration by researchers. If there is a joint self-locking structure that can unlock the orthotic knee joint to bend during the swing phase of the patient's walking, and automatically lock the joint to the extended position during the support phase to ensure weight bearing, which can make the paraplegic walk more natural and save energy.

There is currently a new type of orthotic knee joint that moves the knee joint freely during the swing phase and supports the limbs without knee joint flexion during the stance phase. This design is called Stance Control Knee Ankle Foot Orthoses (SCKAFOs), Stance Control Orthotic Knee Joint (SCOKJ), or Stance Control Orthoses (SCOs). This stance control design can avoid the shortcomings of high energy consumption caused by knee joint stiffness because the stance control mechanism can enable the patient to walk closer to normal gait mode. The normal gait mode is that the knee joint is free in the swing phase and locked in the stance phase. This stance control mechanism can be realized by different mechanical structures. This design mainly involves two key structures: trigger and automatic locking. The methods to achieve trigger are mechanical (lower limb swing angle, ankle flexion and extension angle(Van Leederdam and Kunst 1999) (Nijenbanning and Goudsmit 2005), lower limb gravity(Hatton, Hatton, and Wallace 2003), electronic (position or angle sensor); The automatic locking methods are mechanical (ratchet-spring structure or clutch-cam), electronic (electromagnetic control). For example, the ratchet/pawl design from

Otto Bock Free Walk and Becker Orthopedic UTX (Van Leederdam and Kunst 1999), which belongs to the ankle trigger mechanical stance control design. Pull the lever by the change of the ankle dorsiflexion angle, and then the lever pulls the pawl out of the ratchet groove to unlock the knee joint. Therefore, the human knee joint can bend freely during the swing phase. When the heel touches the ground, the human knee joint straightens and the pawl returns to the ratchet groove, thereby automatically locking again; The clutch and cam design from Horton (Rasmussen, Smith, and Damiano) is a mechanical stance control design triggered by human gravity. After the heel touches the ground, the foot of the orthoses bears the weight of the human body and pushes the rod. The rod pushes the pawl in the joint to the ratchet to lock the knee joint. During the swing phase, the sole bears weight, and the push rod is rebounded by the spring to unlock the pawl, which realizes the stance control mechanism; The gravity pawl mechanism developed by the Fillauer(Nijenbanning and Goudsmit 2005) is also a mechanical structure. Its locking function of the knee joint relies on the relative angle changes of the lower limbs during the heel landing phase and the toe off phase. The pawl swings back into the ratchet groove when the heel is initial contact due to its gravity to lock the knee joint. When the toe is off the ground, the ratchet groove swings forward to unlock the knee joint and achieve the stance control mechanism; Otto Bock's E-Mag uses an electromagnetic device controlled by a position sensor to lock and unlock the knee joint (Yakimovich, Lemaire, and Kofman 2009) to achieve the purpose of stance control. However, the above design also has some problems. Research has found that the sensor adaptively control joints is an important direction for the development of lower limb orthoses(Moreno, Fernando, et al. 2008). The new design should reduce accidental triggering of the lock-unlock structure due to factors such as own gravity, lower limb position, or ankle joint instability, which increase the risk of falls in patients with SCI.

In addition, the design of paraplegic orthoses also needs to consider size, weight, and noise to ensure patient acceptance. The ideal orthoses should be quiet and have a very fast reaction time when switching between standing and swinging modes (Yakimovich, Lemaire, and Kofman 2009) (Yakimovich, Kofman, and Lemaire 2006).

At present, studies showed that lower limb orthoses with a stance control can improve gait, increase mobility(Mcmillan et al. 2004b) (Kaufman et al. 1996; Hebert and Liggins 2005; Irby, Kaufman, Mathewson, et al. 1999; Yakimovich, Lemaire, and Kofman 2007) reduce compensatory exercise(Mcmillan et al. 2004b; Hebert and Liggins 2005; Yakimovich, Kofman, and Lemaire 2006), and reduce energy consumption (Kaufman et al. 1996; Lehmann and Stonebridge 1978; Irby, Kaufman, Wirta, et al. 1999). So far, there is only one study on paraplegic patients with a stance control knee joint of Horton(Rasmussen, Smith, and Damiano 2007). The subject of this literature is a paraplegic patient with T10 complete SCI. Compared with the stiff knee joint and stance control knee joint, the kinesiology gait data showed that when using SCOs, subjects can walk with a faster and more effective gait pattern. However, the SCOs used in this study is not specifically for patients with paraplegia, but patients with knee instability or weakness caused by limb muscle paralysis or paralysis. Although the study attempts to apply SCOs combined with RGOs to paraplegic patients, there are currently no SCOs specifically designed for paraplegic patients. Therefore, the advantage of SCOs is that they can realize the stance control gait mode, but there is no product for paraplegic patients; The advantage of RGOs is that it can provide paraplegic patients with a reciprocating gait mode, but the stiff gait with the locked knee joint will increase energy consumption. Currently, there are no reciprocating gait orthoses with the stance control function.

Therefore, the purpose of this research is to design and develop a new Stance Control Orthotic Knee Joint (SCOKJ), which combines the reciprocating motion mechanism and the cable-controlled spring ratchet knee joint locking mechanism triggered by the hip. So that the lower limbs can achieve knee flexion during the swing cycle, and the knee joint is locked during the stance phase to maintain a stable stance control function. To develop the current paraplegic gait orthoses, reduce the gait energy consumption of the orthoses, and improve the gait of paraplegic patients.

4.2 New Purely Mechanical Hip Trigger Stance Control Knee Joint Design

4.2.1 Overall Design

The design purpose of SCOKJ is to meet the stance control function via a special mechanical structure. During the walking cycle, the knee joint can be freely flexed during the swing phase, and the knee joint can be automatically locked when the swing is finished, and the knee joint can be locked during the stance phase and prevent knee flexion. Try to meet the three basic principles of small size, light weight, and low cost (Yakimovich, Lemaire, and Kofman 2009).

According to the above principles and the analysis of the mechanical structure of the current orthoses, the knee joint stance control function can be safely and effectively realized under the premise of ensuring small size, light weight, and low cost. The overall design idea of this study is to use the purely mechanical knee joint structure controlled by cable spring ratchet triggered by the hip joint.

4.2.2 Cable-controlled Hip Trigger Module Design

When paraplegic patients use RGOs for functional walking, the patient has a certain ability to control the hip joint. The reciprocating mechanism of RGOs is realized by the relative movement of the hip joints on both sides. Therefore, this study utilizes the change of the hip joint angle of the RGOs during walking to control the spring ratchet locking structure at the knee joint. The hip joint rotates with the gait cycle, and the rotation would change the length of the steel cable that controlled the knee joint locking device, and the traction of the cable would trigger the locking-unlocking structure.

As shown in Figure 4-1, the cable used to connect the knee joint pawl is fixed at point A on the front side of the hip joint lateral bar. The initial cable length is AB. The lower bar of the hip joint rotates backward “α” degrees around the hip axis, the cable is tightened with this rotation around the fixed point A to pull the pawl, the length of AB' is equal to AB plus BB'. The BB' is the length of the spring deformation when the knee joint spring is pulled by the cable. At this time, the cable pulls the knee joint pawl out of the ratchet groove to achieve the unlocking function of the stance control knee joint.

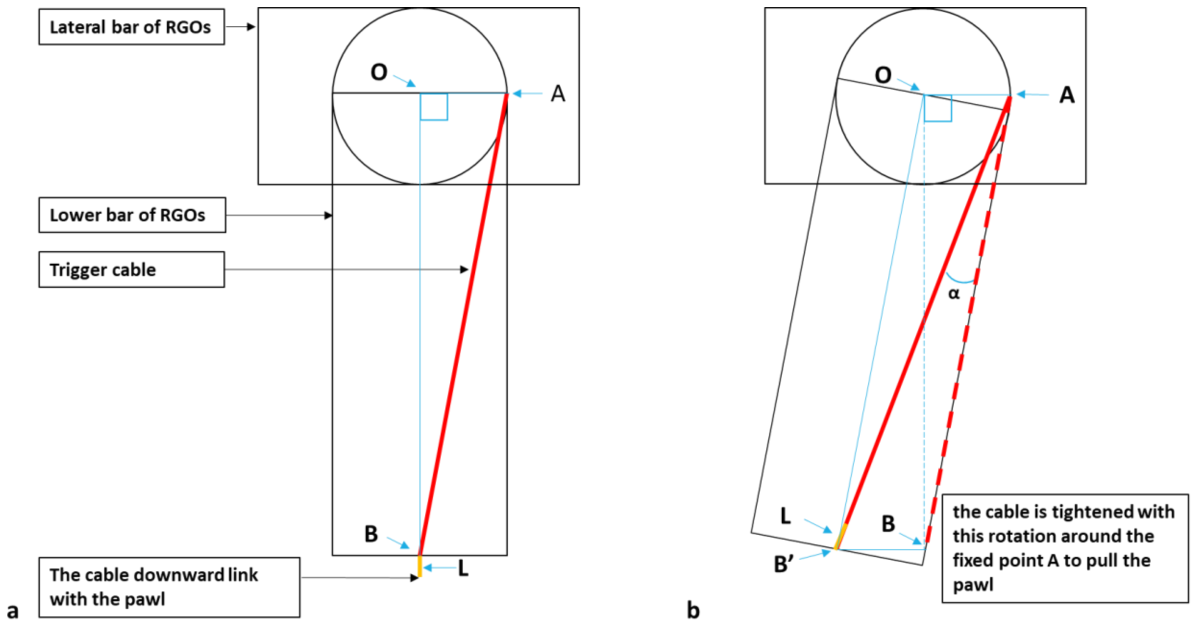


Figure 4-1 Hip trigger cable mechanical transmission mechanism

(a) Before the rotation of the hip of RGOs, (b) Low bar rotates backward “α” degrees around the hip joint axis.

Point A, to fix the cable on the hip lateral bar; Point B and B’, the endpoint of lower bar of RGOs; Point O, hip joint axis; Segment L: a length of spring deformation due to rotation of the lower bar; Angle α, rotation of hip joint of RGOs

4.2.3 Stance Control Module of the Ratchet and Pawl Design

The design with spring and ratchet-pawl is the common method for locking orthotic knee joints. Almost all current paraplegic orthoses adopt this principle. The spring uses elastic force to push the pawl into the ratchet groove to lock the joint. The cable resists the elastic force of the spring and pulls the pawl out of the ratchet groove to unlock the joint. And then the knee joint can rotate around the ratchet. However, the current orthoses lock the knee joint manually. When the paraplegic patient is sitting, the knee joint is manually unlocked to facilitate the flexion of the lower limbs. When the paraplegic patient stands up, the knee joint is passively straightened, and the pawl slides into the ratchet groove as it rotates by the elastic force of spring. Lock the knee joint and maintain a standing posture. This research follows this principle (Figure 4-2).

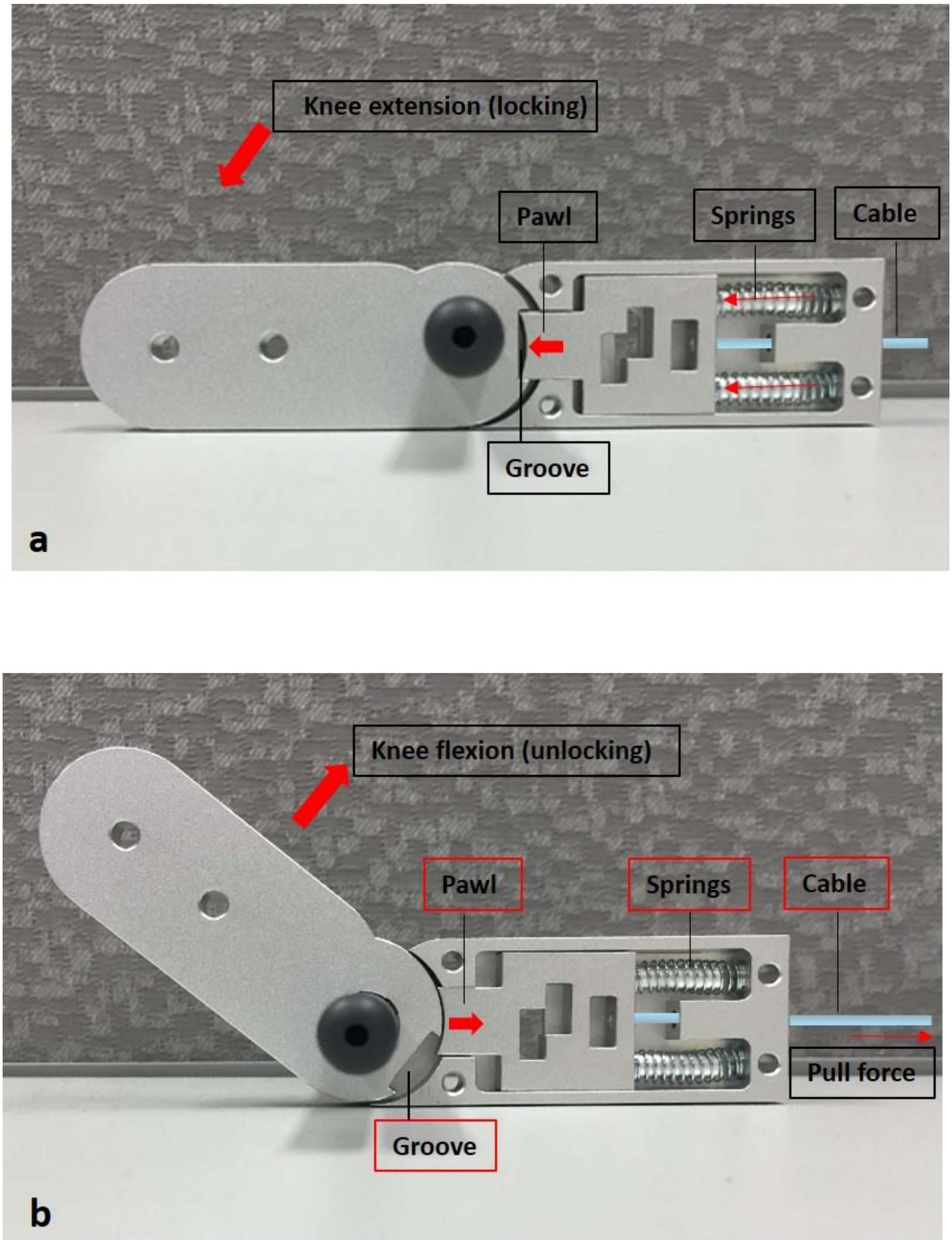


Figure 4-2 cross-sectional view of stance control knee joint locking—unlocking mechanism. (a) locking position; (b) unlocking position

4.2.4 New Purely Mechanical Hip Trigger Stance Control Knee Joint Production

According to the above design ideas, the sketch is drawn by hand (Figure 4-3), the AutoCAD software is used to make plans according to the sketch (Figure 4-4), and the Sketchup software is used to make three-dimensional diagrams (Figure 4-5), Use 3D printing technology to make a polymer model (Figure 4-6) to test the feasibility of the locking mechanism. According to the test results, modify the original design to make CAD plans of each component of the cable-controlled spring ratchet mechanism (Figure 4-7, Appendix D shows the details of other parts). To make the assembly drawing of the component with SolidWorks software (Figure 4-8) and use 6061 aluminum alloy to make the sample (Figure 4-9) and test the locking mechanism in a non-load-bearing environment. The detail of the parameters was shown in the attachments for CAD drawings.

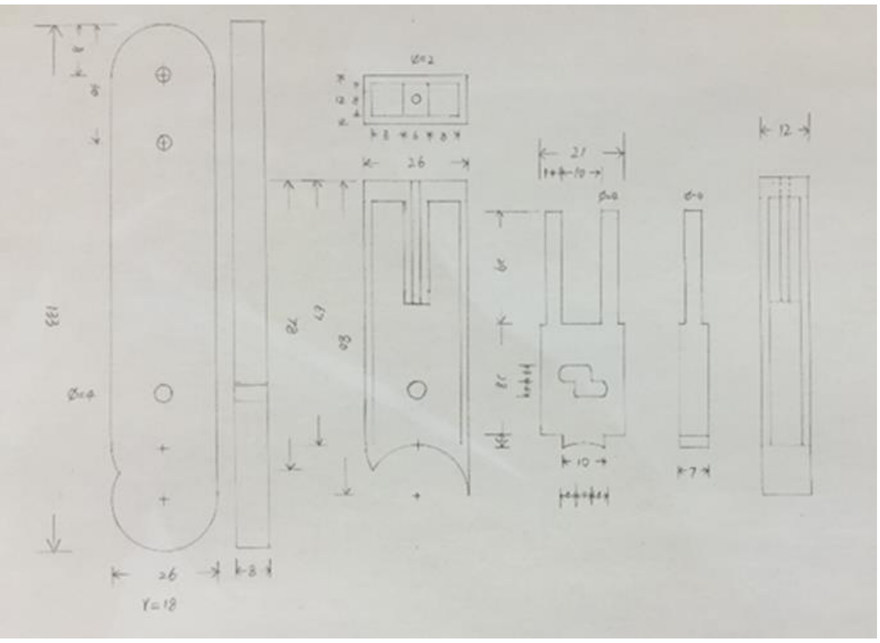


Figure 4-3 Draft

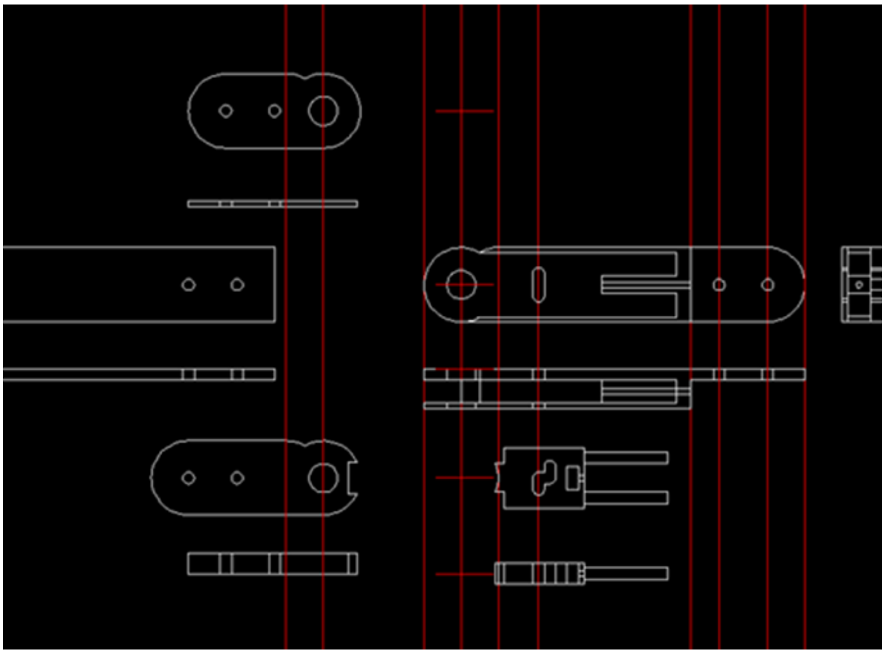


Figure 4-4 Draft by CAD

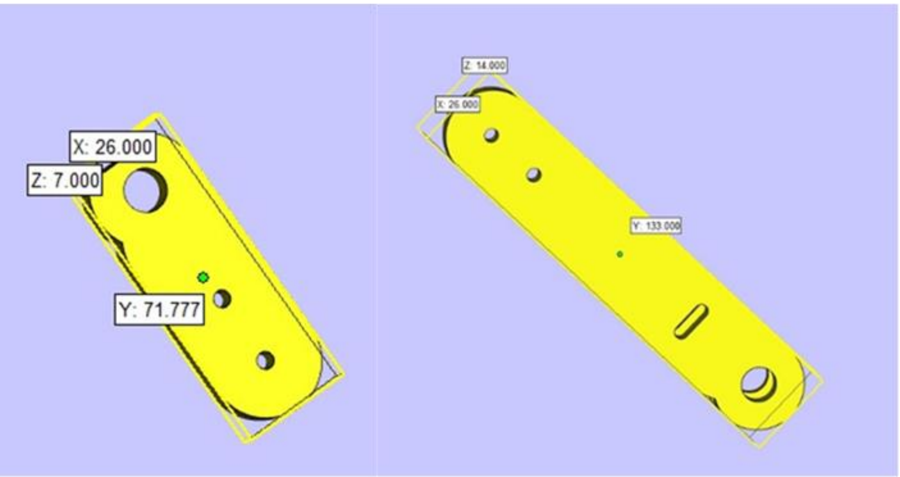


Figure 4-5 Draft by Sketchup

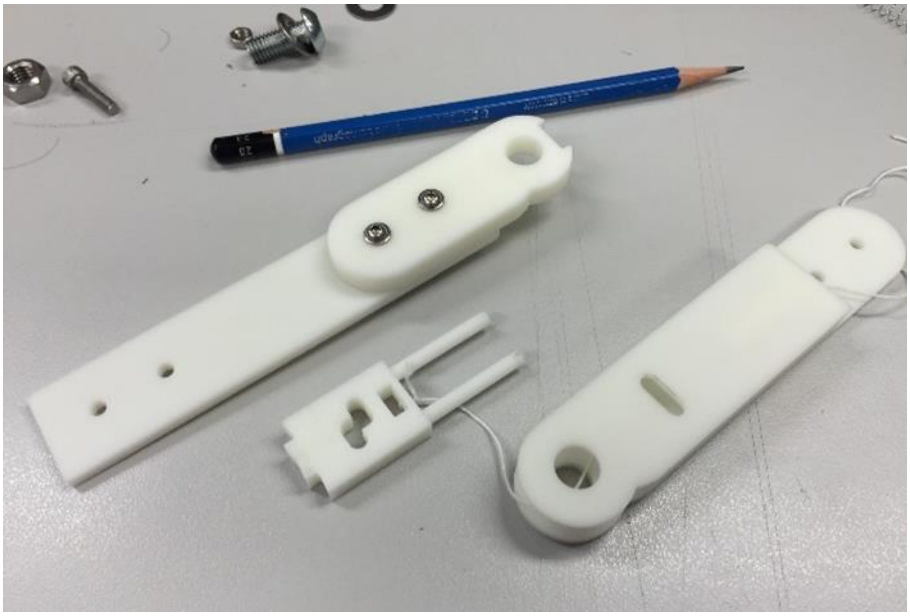


Figure 4-6 Polymer Model

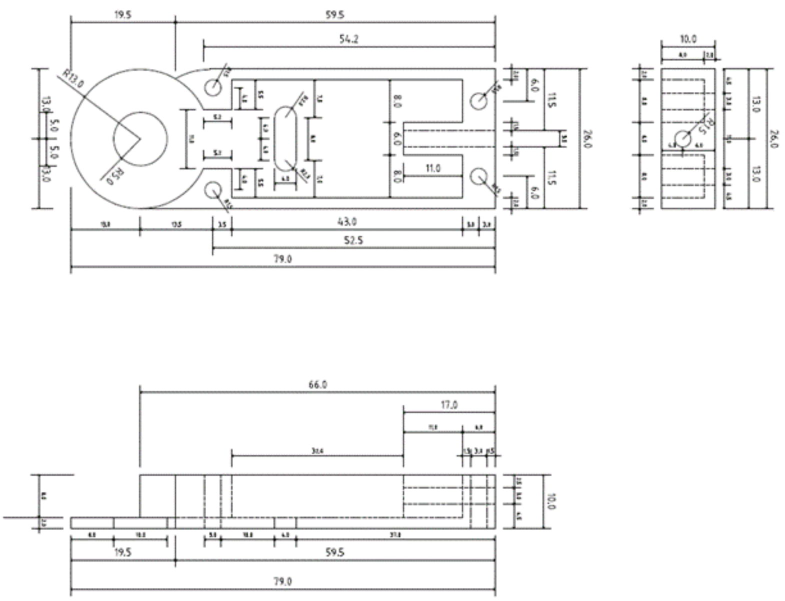


Figure 4-7 Plan by CAD

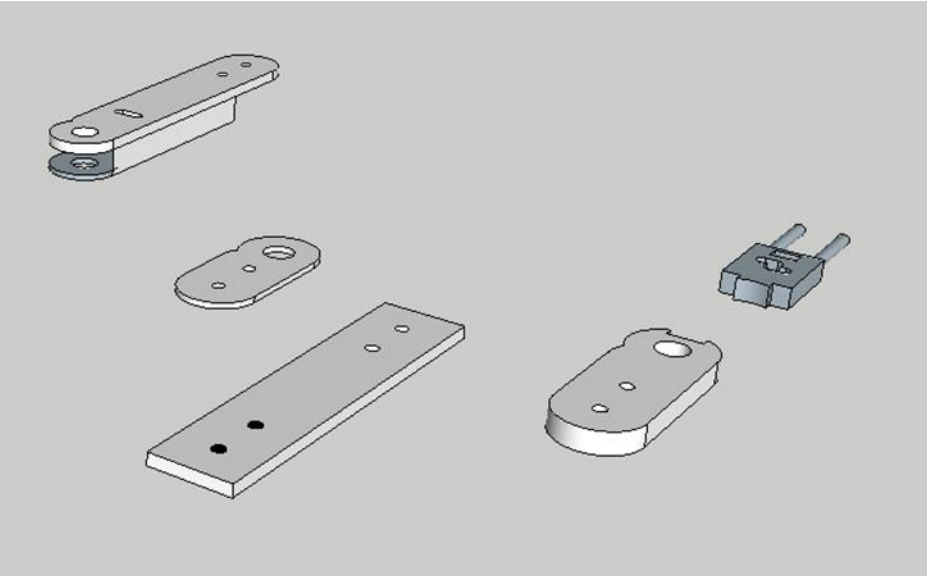


Figure 4-8 Drawing of the Component with SolidWorks

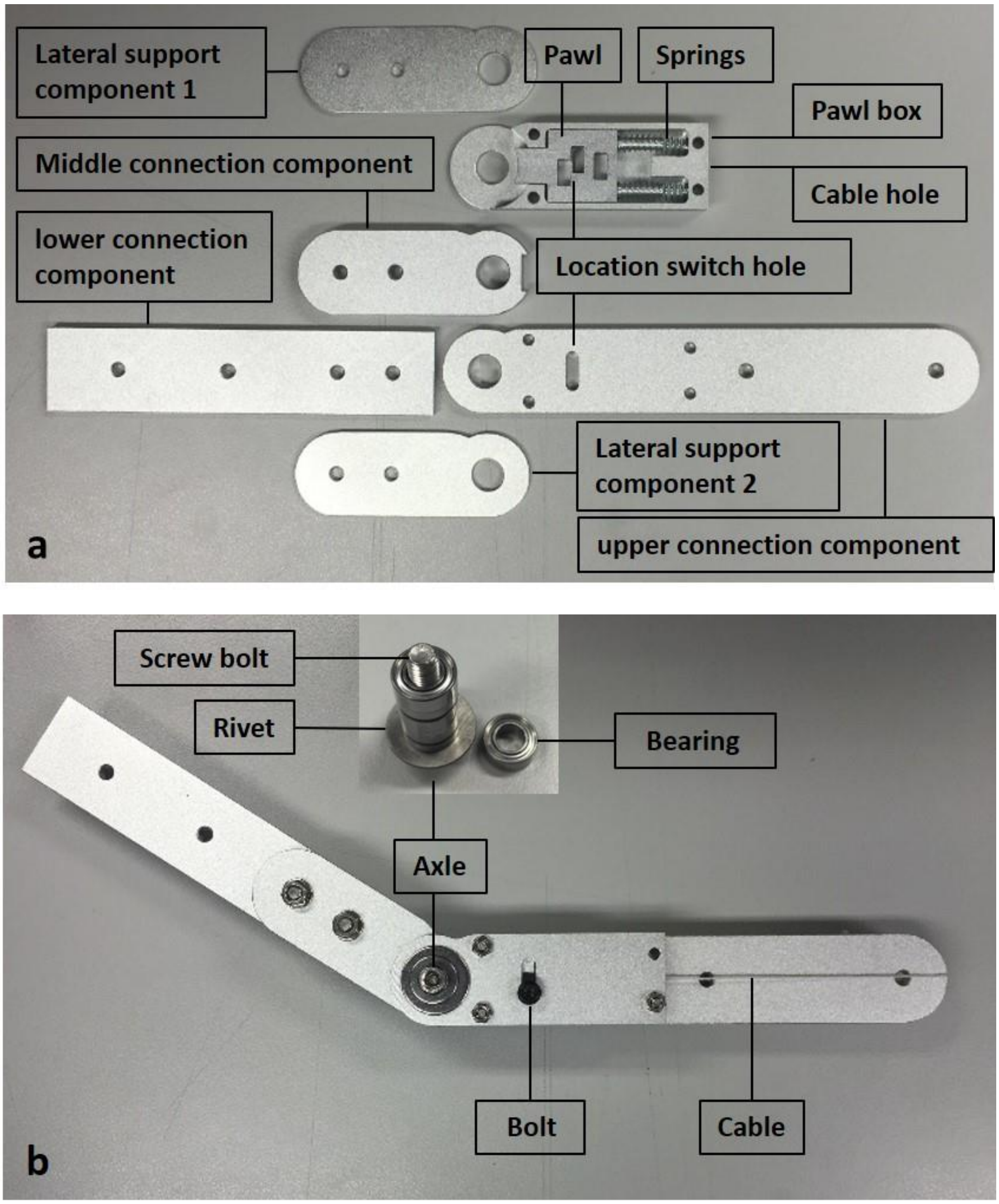


Figure 4-9 Aluminum Alloy Sample

Figure 4-10 The hip trigger stance control knee joint combined with RGOs for gait test

(a) The new stance control knee joint replaces the stiffness joint of RGOs; (b) Locking position of the knee joint; (c) Unlocking position of the knee joint.

(1) Anchor point of cable on the hip joint; (2) Cable; (3) Spring; (4) Pawl; (5) ratchet; (6) axis of knee joint; (7) Upper connection component; (8) lower connection component.

4.5 Improvement of Reciprocating Gait Orthoses

Replace the original knee joint of the RGOs with the new pure mechanical hip trigger stance control knee joint. Fix the cable in the front of the RGOs hip joint lateral bar for the gait test. Because the aluminum structure sample has poor mechanical strength, so the current steel structure joints with spring ratchets are used in the gait test to bear the body weight. The new structure is shown in Figure 3-10-a. In the stance phase, the pawl of the knee joint is located in the ratchet groove, which can lock the knee joint (Figure 4-10-b). When the hip joint of RGOs extends to the end of the stance phase, the cable fixed to the front positioning point of the hip lateral bar is pulled, and then the spring is compressed. The pawl comes out of the ratchet groove, and the knee joint is unlocked (As shown in Figure 4-10-c). The development was completed via a combination of the stance control knee joint with the RGOs.

4.6 Summary

Based on the classification of current SCOKJs and the analysis of their working mechanism, this study summarizes the advantages and disadvantages of different types of SCOKJs, and combined with the functional features post SCI and characteristics of orthotic gait. By mechanical design and development, a new structure of paraplegic orthoses is manufactured.

The design of combining the structure of the stance control knee joint with the reciprocating mechanism was adopted in this study. It is that replacing the stiff knee joint of the current RGOs with a newly designed stance control knee joint. The stance control knee joint is designed with a mechanical ratchet and pawl structure. The alternate swing of the hip joint of the reciprocating gait orthoses is used to design a cable-controlled hip trigger structure. The on-off of the ratchet and pawl are controlled by the rotation of the traction cable of the hip joint to achieve the locking and unlocking of the knee joint. The goal of developing the current RGOs and improving the gait of the paraplegic orthoses is achieved, which is close to the normal gait in which the knee joint remains stable during the stance phase and swings freely during the swing phase. At the same time, it provides a feasible solution for paraplegic patients to achieve more functions at a lower cost. In this study, a new type of stance control knee joint model and improved RGOs were produced via 3D printing.

The innovation of this study is that a new type of purely mechanical stance control knee joint with a cable-controlled hip trigger is designed. This design combined the stance control mechanism with the reciprocating motion mechanism. An aluminum model was printed by 3D to test the feasibility of the device. The limitation of this study is that this design only is a new knee joint stance control structure. Although it overcomes some shortcomings of the current orthoses, it also has some disadvantages. Such as reliability, safety and clinical effects require more comprehensive experiments.

Chapter 5

5. Gait Analysis for Paraplegic Patients with New Stance Control RGOs

5.1 Introduction

Gait is the appearance of the human body during walking by the coordinated movements of the hips, knees, ankles, and feet. Gait analysis refers to the method of detecting abnormal gait during walking, which plays an important role in the fields of rehabilitation engineering, clinical orthopedics, and medical engineering. For people with an abnormal gait, doctors can determine whether to use a prosthesis or orthoses for gait correction and treatment according to the degree of gait abnormality(古恩鹏 et al. 2011).

For patients with lower limb motor dysfunction, gait rehabilitation is an important part of the treatment plan. It can help patients restore function and independence, while improving the overall quality of life. Gait rehabilitation after nerve injury has many therapeutic benefits.

Training and exercise can enhance the motor function of patients with nervous system injuries, such as SCI and stroke. Clinical studies have proved that repetitive exercises can strengthen the neural connections involved in motor tasks, so that patients could relearn to walk faster and better (Arazpour, Bani, and Hutchins 2013).

The phase division of the gait cycle of paraplegic patients using RGOs to walk is similar to the normal gait cycle. During a gait cycle, there are two phases, the support phase, and the swing phase. During walking, the hip joint flexes and extends to complete the reciprocating motion, and the knee and ankle joints always maintain the same angle.

A study shows that, compared with other types of paraplegic orthoses, ARGOs and IRGOs can bring users a higher stride velocity, longer strides length, faster stride frequency, and reduce the energy consumption of paraplegic patients (Bani, Arazpour, Farahmand, Mousavi, et al. 2015). The stride velocity of patients with SCI using RGOs is 0.2-0.3m/s, and the energy expenditure is 1.0mg/kg/m (Bernardi et al. 1995; Hirokawa et al. 1990). However, the average gait speed and oxygen consumption of healthy subjects were 1.28 m/s and 0.176 mL/kg/m, respectively (Castellano, Coratella, and Felici 1999). Although RGOs are easier to walk than other orthoses (such as HKAFO) because it reduces the unnecessary shaking of the center of gravity and a more beautiful gait pattern. But for daily activities, paraplegic patients still choose wheelchairs rather than orthoses (Katz-Leurer et al. 2004; Sykes et al. 1995). The rejection rate is about 46-54% (Franceschini et al.1997). High energy consumption is the main reason for rejection (Franceschini et al.1997). Another study reported that the main reasons for the high energy consumption of RGOs are the excess flexion and extension of the hip joint and the stiff gait of the knee joint (Johnson, Fatone, and Gard 2009).

Therefore, a gait analysis experiment was conducted to assess the effectiveness of paraplegic patients with the new stance control RGOs.

5.2 Methods

5.2.1 Subjects

Healthy adult subjects participated in this study. The exclusion criteria were that the participants had no history of surgery disease or any deformity of the lower limbs. Because the number of paraplegics is small and the condition of the patients varies greatly(Johnson, Fatone, and Gard 2011, 2009), it is difficult to get a consistent result from the verification experiment of the new design on the paraplegic population(Dall et al. 1999). Johnson et al. included healthy adults as subjects when they developed a new orthosis to simulate the paraplegic orthoses gait and evaluate its characteristics (Johnson, Fatone, and Gard 2011). The subjects participating in the trial were given a detailed interpretation of the research purpose and plan, and the subjects who agree to participate in the study need to sign an informed consent form.

This is a before-and-after study. The included subjects completed normal gait (NG), stiff knee RGOs gait (SKG), and stance control RGOs gait (SCG) test, set a one-day washout period, without setting random intervention mode selection.

5.2.2 Materials and Instrumentation

COSMED T170 Sports Treadmill (COSMED, Italy) and 3D KNEE ANALYSER (KneeKG™, EMOVI INC. Canada). The KneeKG system mainly includes the following components: KneeKG.3D-Trackers, Position tracking system based on an infra-red (IR) camera (Spectra) from NDI (60Hz), Knee3D Software (clinical info/Knee3D assessment/Knee3D analysis) (Figure 5-1). The KneeKG is a femoro-tibial dynamic tracking device. The KneeKG system has general applications to measurement, tracking, and recording of 3D knee femoro-tibial position, orientation, and movement. It is appropriate for use in the assessment of the function of the knee, the knee joint condition, and the biomechanical factors that predominate in the development of pathologies and injuries.

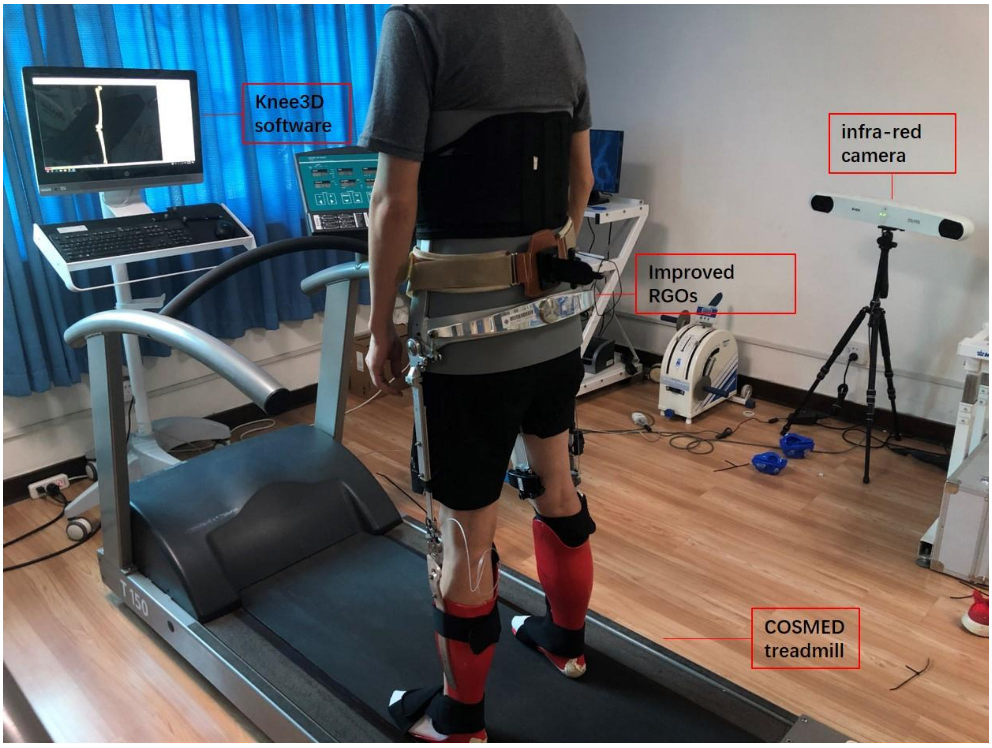


Figure 5-1 Devices for gait test

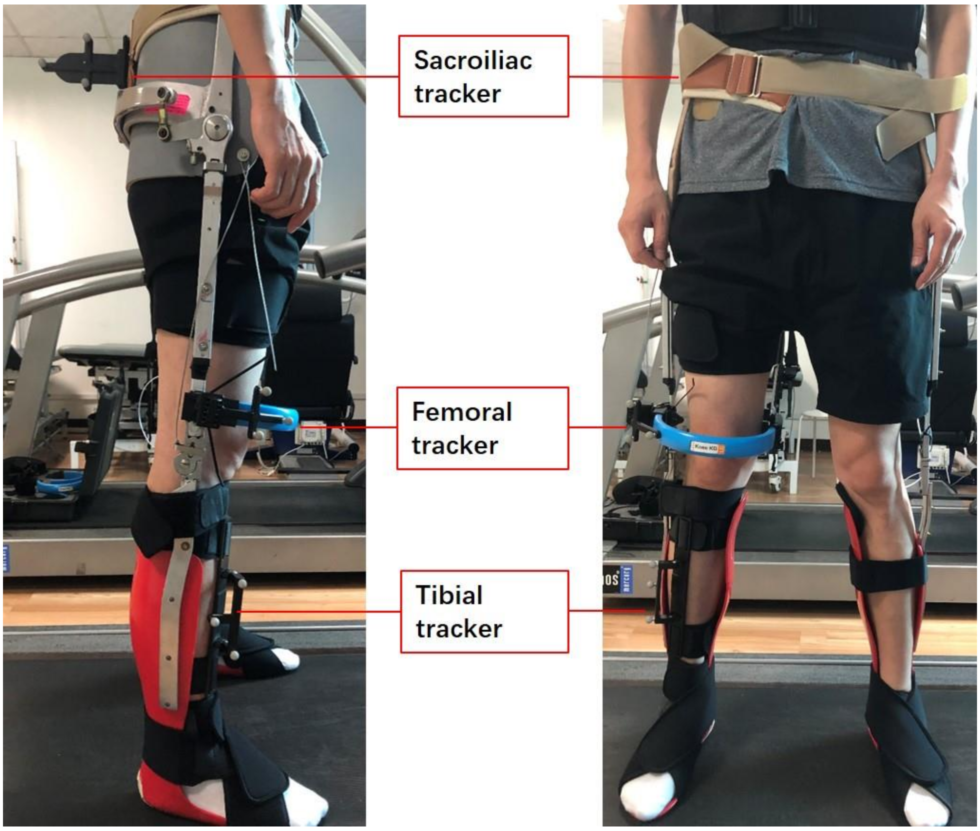


Figure 5-2 Trackers of KneeKG 3D

5.2.3 Gait Experiment

Preparation for the experiment

(1) Basic data test of subjects, including measurement of height, weight, body composition, etc.

(2) Participants must be wearing a pair of shorts to allow the installation of the Knee3D trackers (Figure 5-2), including the femoral part, tibial part, and sacroiliac part. The operator fastens the elastic Velcro bands in order to prevent muscular contraction from interfering with measurements by stretching the elastic Velcro bands.

(3) Open the NDI Track software and set the spatial range to ensure that all trackers (sacroiliac tracker, femoral tracker, tibia tracker, and reference calibration points) can be recorded by Knee3D software. All markers can be recognized by the infrared camera (NDI spectral camera).

(4) The postural-functional calibration procedure can be divided into two sections: first, the ankle, knee, and hip joint centers are defined; secondly, based on a predetermined posture, mediolateral,

anteroposterior, and proximodistal axes are calculated for the femur and the tibia.

(5) Movement acquisition detected by the IR camera will be recorded at a rate of 60 Hz. The subjects walk on the treadmill at a comfortable speed (2km/h), and the walking time is 45s. Participants performed the NG test on KneeKG firstly, and then used RGOs to complete the SKG gait test with the knee joint locked on the second day, and finally used RGOs to complete the SCG gait test with SCOKJ on the third day. An effective test requires at least 15 complete and effective KneeKG gait cycles in 45 seconds. Otherwise, to wear the tracker again, recalibrate, and test again. Collect the parameters of the knee joint in flexion and extension, tibial adduction and abduction, and tibial external rotation and internal rotation in following five key point/phase initial contact (IC), terminal contact (TC), single support (SS), double support (DS) and swing phase (SW). According to the purpose of this experiment, the change of knee flexion and extension angle during the gait cycle is selected for analysis, including the total range of flexion and extension, knee joint angle at the heel strike, knee joint angle at the foot flat, knee joint movement range in the buffer phase and knee joint movement range in the single support phase.

5.2.4 Statistics

The angle parameters of gait are continuous variables, and the data adopts the Shapiro-Wilks test to conform to the normal distribution, and there are no outliers. Therefore, a one-way ANOVA was used to analyze the differences in the above gait parameters of the subjects before and after the intervention, and the Bonferroni method was used for the Post-Hoc test. Using SPSS20.0 software, the levels of statistical significance were indicated at 0.05 and 0.01.

5.3 Results

5.3.1 Demographic Data of Subjects

In order to verify the feasibility of the improved design of the new RGOs, 6 healthy subjects were included in this experiment. The demographic data were shown in Table 5-1.

Table 5-1 Demographic data of the participants (mean±SD)

n	Age (year)	Height (cm)	Weight (Kg)	Fat (%)	Sex (male/female)
6	27.83±6.47	178.67±2.13	68.83±4.06	17.58±3.04	6

5.3.2 Kinematic Characteristics of Knee Joint

The purpose of this study is to verify the range of motion of the knee joint with the developed paraplegic gait orthoses, so it mainly focuses on the kinematic characteristics of the knee joint in gait. Five characteristic parameters are selected for analysis, including the total range of flexion and extension, knee joint angle at the heel strike, knee joint angle at the foot flat, knee joint movement range in the buffer phase, and knee joint movement range in the single support phase.

The knee range of flexion and extension using Welch analysis of variance showed that the angle difference between the three groups of different gait was statistically significant (P<0.001); After the Post-Hoc test, the angle mean value of the SCG has a significant statistical increase of 44.733° compared with the SKG; The angle mean value of the NG has an increase of 56.433° than that of the SKG, and the difference is statistically significant (P<0.001); Compared with the SKG, the angle mean value of the NG increased by 11.700°, and the difference was statistically significant (P<0.001) (Table 5-2).

The overall analysis of the one-way ANOVA of the knee joint angle at the initial contact showed statistical significance (P=0.046), but after the Post-Hoc test, there was no difference between the three groups (Table 5-2).

The overall analysis of the one-way ANOVA of the knee angle at the foot flat showed that the difference between the three groups was statistically significant (P=0.021). The knee hyperextension angle mean value of SKG is 2.617° larger than that of the NG group, which was significantly different (P=0.047); The angle mean value of SCG is 2.683° significantly larger than that of the NG (P=0.041); While there was no statistical difference between SKG and SCG (Table 5-2).

The difference between the knee joint angle at heel strike and foot flat indicates the change of the knee joint movement angle in the buffer phase. The Welch analysis showed that the difference between the three groups was statistically significant (P=0.002); The mean knee cushioning angle of the NG was 2.317° larger than that of the SKG, which was significantly different (P=0.045); The NG has a mean knee cushioning angle of 4.317° that is significantly larger than that of the SCG (P<0.001), But there is no statistical difference between SKG and SCG (Table 5-2).

There was a statistically significant difference between the three groups in the range of motion of the knee joint at the single support phase (P<0.001). It was found that the mean knee range of motion of NG was 7.350° (95%CI: 3.649-11.051) greater than the SKG, which was significantly different (P<0.001); And it was 3.800° significantly larger than that of the SCG (P=0.043); There is no difference between SKG and SCG groups (Table 5-2).

Table 5-2 The statistics results of gait parameters in SKG, SCG and NG

Degree(°)	1: SKG mean±SD	2: SCG mean±SD	3: NG mean±SD	F	P	P’ 1 vs 2	P’ 2 vs 3	P’ 1 vs 3
total range of flexion and extension	3.617 ±0.553	48.350 ±4.105	60.05 ±1.482	3741.980	0.000**	$0.000^{\#}$	$0.000^{\#}$	$0.000^{\#}$
knee joint angle at the heel strike	3.450 ±1.487	1.517 ±1.261	3.150 ±1.143	3.815	0.046	0.064	0.140	1
knee joint angle at the foot flat	3.483 ±1.179	3.550 ±2.560	0.867 ±0.619	5.062	0.021	1	$0.041^{\#}$	$0.047^{\#}$
knee joint motion range in the buffer phase	-0.033 ±0.446	-2.033 ±2.262	2.283 ±1.034	14.629	0.002	0.094	$0.000^{\#}$	$0.045^{\#}$
knee joint motion range in the single support phase	1.767 ±0.927	5.317 ±3.896	9.117 ±0.975	14.314	0.000	0.062	$0.043^{\#}$	$0.000^{\#}$

Note: * indicates a significant difference of intra-group $p<0.05$, ** indicates $p<0.01$; # indicates a significant difference of multiple comparisons adjusted by the Bonferroni post-hoc tests $p'<0.05$, $P'=pn$, n is the number of comparisons.

Abbreviations: NG, normal gait; SKG, stiff knee RGOs gait; SCG, stance control RGOs gait

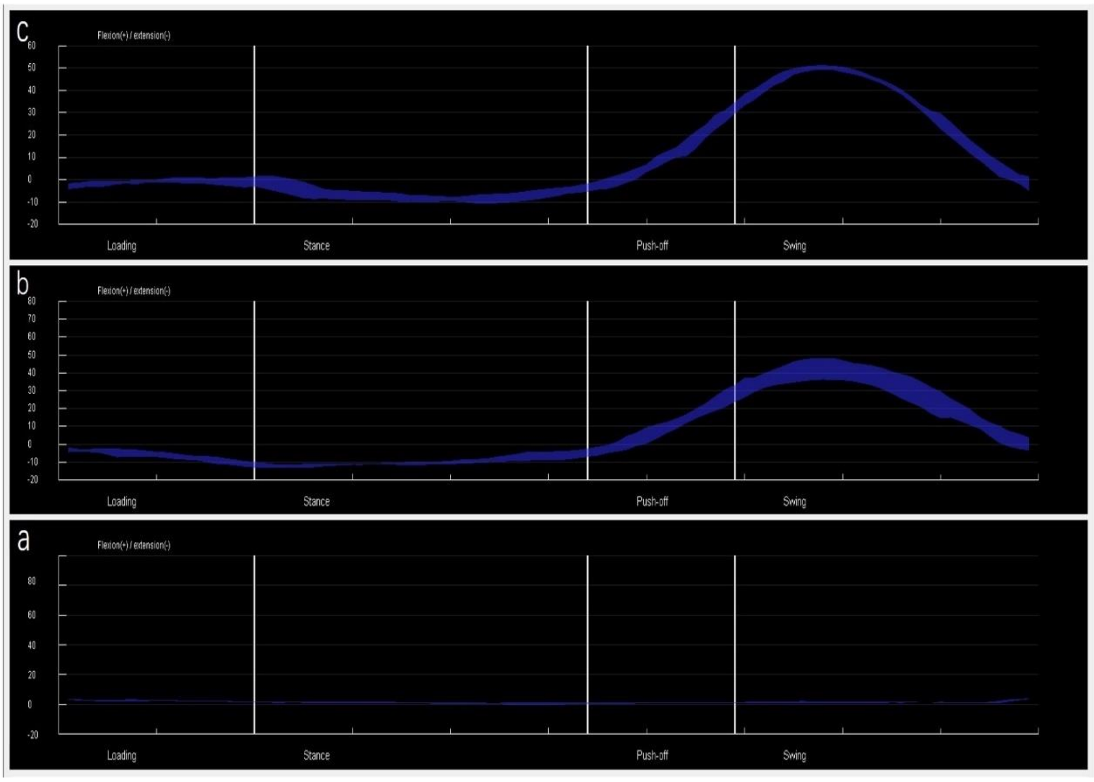


Figure 5-5 (a) Knee joint angle of Subject 1 in the SKG gait cycle; (b) Knee joint angle of Subject 1 in the SCG gait cycle; (c) Knee joint angle of Subject 1 in the NG gait cycle;

5.4 Discussion

Gait analysis is a way to assess the dynamic posture and coordination during movement. This analysis is a means to evaluate, record, and make any necessary corrections for a smooth gait. Identifying hypermobile or hypomobile movements at the joints, whether or not the movement varies from side to side, can help identify proprioceptor and neuromuscular concerns. Assessing any deviations or inconsistencies can be a clue to potential restrictions.

Gait analysis using three dimensional (3D) systems is currently the gold standard for measuring parameters including spatiotemporal variables and joint kinematics. The gait cycle is sometimes called the walking cycle. The gait cycle extends from heel strike to heel strike of one leg and includes the stance and swing phases of both legs. In the basic gait cycle, the movements are divided into the times when the foot is on the ground (the stance phase which takes up 62% of the full gait cycle) and when the foot is off the ground (the swing phase which takes up the remaining 38% of one full gait cycle). During walking, the gravity center of the body shifts up to down and left to right. The movement trajectory is related to the actions of each phase of the gait cycle. When walking at a constant speed, the up and down movement trajectory presents a uniform sine wave. The highest point of upward movement is the mid-stance of the single support phase. The lowest point is in the double support. The legs alternately support, and the gravity center also moves repeatedly in the left and right directions.

This study researched the kinematic characteristics of normal gait, reciprocating paraplegic orthoses gait, and new RGOs with stance control knee joint, and found that the range of knee flexion and extension using the new orthoses in the swing phase can reach 48°, which is significantly improved compared with ordinary orthoses, but it does not achieve the range of motion of knee in normal gait without orthoses. The results of the study show that the newly developed reciprocating paraplegic orthoses with cable-controlled hip trigger stance control knee joint structure can improve the stiffness gait of traditional orthoses knee joint.

The point in the gait cycle when the foot initially makes contact with the ground; represents the end of the swing phase and beginning of the stance phase. At this characteristic moment of the normal gait, the knee joint is straight or hyperextension sometimes. The knee joint angles of subjects in three groups are all hyperextension at this moment. The results of NG subjects were consistent with normal gait characteristics. Since the knee joints of SKG subjects were locked in a state of stiffness, the knee joints were also fully extended at this moment. The knee joints of SCG subjects could bend during the swing phase with the stance control mechanism. The experimental results show that the swing leg could land with the straight knee joint at the end of the swing cycle. The stance control knee joint could lock the knee at this moment to maintain stability during the support period. There is no difference between the SCG and NG at heel strike, indicating that the newly designed orthoses can achieve a walking pattern close to a normal gait.

The gait enters the loading response phase after the heel strike. At this moment, the gravity center of the body gradually moves forward to the supporting leg and reaches the characteristic moment of the foot flat. During this process, the knee joint of the supporting leg correspondingly flexes slightly to absorb the impulse of shock; These experimental results indicate that the gait of the three groups of subjects was significantly different at this moment. The NG subjects had a reduced angle of knee hyperextension at this time with a buffer action. The SKG and SCG subjects did not have buffer flexion at this moment, but the knee joint locking mechanism played a stabilizing effect. Further calculating the angle difference between these two moments, we can know the buffer angle of the knee joint. The experimental results proved that the angle change of the NG subjects in the buffer phase was significantly greater than that of the other two groups, and the NG subjects were in line with a normal gait. At the same time, it also shows that the new orthoses knee joint can be against the buffering and maintain the stability of the knee joint in the patient support phase.

When the gait transitions to the mid stance phase, the knee joint of the normal gait support leg begins to stretch, and then the heel is off the ground and enters the swing phase. At this stance phase, because the knee joints of the two groups wearing orthoses were in a locked state at this phase, there was no movement of the knee joints. When they walk without orthoses, the knee joints in the support phase show a certain range of motion, which is in line with the kinematics law of normal gait. The normal gait has a certain range of motion during the entire support phase due to the buffering phase, it is the same as the typical bimodal curve characteristics of the gait. The experimental results of the angle of motion of the knee joint in the support phase indicate this phenomenon. The motion angle of the knee joint of the NG subjects at this phase is larger than that of the SKG and SCG. Because SKG and SCG subjects wear

RGOs, their knee joints are locked during the entire support phase, so there is no change in joint angle activity during this process.

During the swing phase, the knee joint has maximum flexion. SCOs enable the knee joint to flex freely during the swing phase of the gait cycle. The benefits to orthotics users have been proved (Arazpour et al. 2017; Yakimovich, Lemaire, and Kofman 2007; Davis, Bach, and Pereira 2010b; Zissimopoulos, Fatone, and Gard 2007a; Moreno, Brunetti, et al. 2008; Irby and Bernhardt 2007; Hebert and Liggins 2005). However, the research subjects of the above literature are patients with knee stabilizing muscle weakness, paralysis, or paralysis, such as patients with polio. Combining the knee joint stance control mechanism with the reciprocating motion mechanism, that was applied to paraplegics in a study(Rasmussen et al. 2007). This study developed a device combining IRGOs and SCOKJ (Horton’s Orthotic Lab, Inc., Little Rock, AR): IRGO-SCO. The subject is a patient with complete SCI (T10). The researchers first applied the orthoses to the right side and performed gait training for two months, and then used bilateral SCOKJ. After 1 month of training, the gait test found the total range of knee flexion and extension is 50.0° (left) and 39.2° (right), respectively, indicating that this IRGO-SCO can bring a natural gait pattern to paraplegic patients with complete lower limb dysfunction. However, this study also mentioned that the subject had enough upper limb strength and was able to support himself with the walker to help complete the walking of the lower limbs. Another study (吴强, 马宗浩, and 何成奇) applied the E-Mag active orthoses to a complete SCI paraplegic patient (T10) for gait analysis. And this study found that the total range of knee flexion and extension reached a similar level with the help of E-Mag. The design of newly developed orthoses is same as the above two studies. It also combines a purely mechanical stance control knee joint with the RGOs to explore the feasibility of improving the gait of paraplegic patients. However, the stance control knee joint produced by Horton utilizes body weight to push the pawl into the ratchet with a push rod during the support phase, thereby triggering the knee joint locking mechanism, and the pawl is ejected by a spring to unlock the knee joint during the swing phase. This mechanism using body weight to control the knee joint perhaps result in accidents. For example, if the user swings the center of gravity from side to side, the gravity-free side may be unlocked, resulting in accidents. Although E-Mag is an electromagnetic stance control knee joint orthosis controlled by a smart position sensor, its price is relatively expensive. This stance control knee joint designed in this study is unlocked by the hip trigger cable. when the heel leaves the ground at the terminal contact point, the trigger cable is tightened due to the change of the hip joint angle. The pawl is dragged out from the ratchet groove to unlock the knee joint. This trigger mechanism ensures that the knee joint is unlocked only at the end of the support phase, and then ensures the stability of the knee joint and the safety of the user. Moreover, a simple mechanical structure can effectively reduce costs.

This study mainly verified whether the new hip trigger stance control knee joint can improve the stiffness gait of knee joint with RGOs, so the adduction or abduction of the knee joint and external or internal of tibial rotation are not considered. Another reason is that when subjects wear RGOs for gait exercises, the lower limbs are fixed in the metal bracket of the orthoses. The knee joints of orthoses only have sagittal freedom for flexion and extension movements, so there is no adduction or abduction of the knee joint and external or internal of tibial rotation. According to the results of the KneeKG, the total range of motion of knee flexion and extension has been significantly improved, reaching 48° with the new modified paraplegic orthoses. But it did not reach the knee range of motion (60°) in a normal gait. The results show that the new and improved paraplegic orthoses can effectively improve the gait of the traditional RGOs. The participants have some freedom of motion of the knee joint wearing the new orthoses, but there is still a gap with a normal gait. The possible reason is that the subject has not undergone long-term RGOs gait training and the skill of walking with orthoses is not proficient; The RGOs bracket also restrains the motion of lower limb, so the total range of motion of knee flexion and extension is not as good as the normal gait parameters (Figure 5-5).

The clinical significance of this study is that the new stance control knee joint could achieve the expected effect of improving the stiffness gait of the paraplegic orthoses, and it is feasible to clinical application for the newly developed reciprocation gait orthoses via the gait experiment.

5.5 Limitations

Due to the limitations of patient resources and ethical considerations, the newly designed and improved paraplegic orthoses have not been tested in paraplegic patients and cannot provide direct evidence for its application in the clinic. In addition, due to the limitation of the manufacturing process and research funding, manufacturing process, and research funding constraints, although the aluminum samples were completed, the steel finished products were not produced.

But the gait experiment verified the feasibility of the design principle. The follow-up study will further optimize the design and improvement, gradually iterate the product, and apply it to paraplegic patients.

5.6 Summary

The new design rachet and pawl triggered by hip can work to lock and free knee joint. The new knee joint for purely mechanical stance control combined with the reciprocating gait orthoses could provide some ranges of knee movement in the swing phase compared with the traditional RGOs. This development orthoses could be used in the clinic to improve the gait of paraplegic patients.

Chapter 6

6. Conclusion and Future Work

6.1 Key Finding and Conclusion

Patients who received quantitative intensity orthotic training could significantly promote the energy efficiency, cardiorespiratory fitness, ambulation ability, and ADL compared with traditional orthotic training without intensity demand; The QoL and ambulation ability could decline without regular orthotic training; Patients with moderate intensity orthotic training have better gait efficiency and ambulation ability than that in light intensity orthotic training; The target heart rate calculated by heart rate reserve could be used to customize the orthotic training intensity for paraplegic patients. Quantitative intensity orthotic training regularly could benefit paraplegic patients, and it could be used in clinical rehabilitation.

The new knee joint for purely mechanical stance control triggered by the hip could combine with the reciprocating gait orthosis. The developed orthosis could improve the orthotic gait with the stance control mechanism.

The new design rachet and pawl triggered by hip can work to lock and free knee joint. The new knee joint for purely mechanical stance control combined with the reciprocating gait orthoses could provide some ranges of knee movement in the swing phase and stability in the stance phase compared with the traditional RGOs. This development orthosis could be used in the clinic to improve the gait of paraplegic patients.

6.2 Future Work

Further, optimize the design and improvement would be required in future work. The iteration on the new knee joint for purely mechanical stance control can be made. The steel finished products can be produced with financial support. In the future, we might consider the developed orthoses to apply to paraplegic patients.

References

Abe, Kaoru. 2006. 'Comparison of static balance, walking velocity, and energy consumption with

Ahmadi Bani, M., M. Arazpour, F. Farahmand, S. Sefati, M. Baniasad, S. W. Hutchins, R. Vahab Kashani, and M. E. Mousavi. 2015. 'Design and analysis of a new medial reciprocal linkage using a lower limb paralysis simulator', *Spinal Cord*, 53: 380-6.

Alcobendas-Maestro, Mónica, Ana Esclarín-Ruz, Rosa M Casado-López, Alejandro Muñoz-González, Guillermo Pérez-Mateos, Esteban González-Valdizán, and José Luis R Martín. 2012. 'Lokomat robotic-assisted versus overground training within 3 to 6 months of incomplete spinal cord lesion randomized controlled trial', *Neurorehabilitation and neural repair*, 26: 1058-63.

Alexander, M. S., K. D. Anderson, F Bieringsorensen, A. R. Blight, R Brannon, T. N. Bryce, G Creasey, A Catz, A Curt, and W Donovan. 2009. 'Outcome measures in spinal cord injury: recent assessments and recommendations for future directions', *Spinal Cord*, 47: 582-91.

Alexeeva, Natalia, Carol Sames, Patrick L Jacobs, Lori Hobday, Marcello M DiStasio, Sarah A Mitchell, and Blair Calancie. 2011. 'Comparison of training methods to improve walking in persons with chronic spinal cord injury: a randomized clinical trial', *The journal of spinal cord medicine*, 34: 362-79.

Alexeeva, Natalia, Carol Sames, Patrick L. Jacobs, Lori Hobday, Marcello M. DiStasio, Sarah A. Mitchell, and Blair Calancie. 2011. 'Comparison of training methods to improve walking in persons with chronic spinal cord injury: a randomized clinical trial', *Journal of Spinal Cord Medicine*, 34: 362-79.

Amatachaya, S., S. Naewla, K. Srisim, P. Arrayawichanon, and W. Siritaratiwat. 2014. 'Concurrent validity of the 10-meter walk test as compared with the 6-minute walk test in patients with spinal cord injury at various levels of ability', *Spinal Cord*, 52: 333–6.

American College of Sports Medicine. 2014. *ACSM's Guidelines for Exercise Testing and Prescription* (Wolters Kluwer/Lippincott Williams & Wilkins Health: Philadelphia, PA).

Arazpour, M, Bani M Ahmadi, M Baniasad, M Samadian, and N Golchin. 2017. 'Design, construction, and evaluation of "sensor lock": an electromechanical stance control knee joint', *Disability & Rehabilitation Assistive Technology*, 13: 1.

Arazpour, M, MA Bani, SW Hutchins, and RK Jones. 2013. 'The physiological cost index of walking with mechanical and powered gait orthosis in patients with spinal cord injury', *Spinal cord*, 51: 356-59.

Arazpour, M, MA Bani, SW Hutchins, and M Sayyadfar. 2014. 'The Araz medial linkage orthosis: a new orthosis for walking in patients with spinal cord injury: a single patient study', *Prosthet Orthot Int*, 38: 155.

Arazpour, M, S. W. Hutchins, and Bani M Ahmadi. 2015. 'The efficacy of powered orthoses on walking in persons with paraplegia', *Prosthetics & Orthotics International*, 39: 90.

Arazpour, M, M Samadian, M Bahramizadeh, M Joghtaei, M Maleki, M Ahmadi Bani, and SW Hutchins. 2015. 'The efficiency of orthotic interventions on energy consumption in paraplegic patients: a literature review', *Spinal Cord*, 53: 168-75.

Arazpour, M., M. A. Bani, and S. W. Hutchins. 2013. 'Reciprocal gait orthoses and powered gait orthoses for walking by spinal cord injury patients', *Prosthetics & Orthotics International*, 37: 14-21.

Baardman, G, MJ Ijzerman, HJ Hermen, PH Veltink, HBK Boom, and G Zilvold. 1997. 'The influence of the reciprocal hip joint link in the Advanced Reciprocating Gait Orthosis on standing performance in paraplegia', *Prosthet Orthot Int*, 21: 210-21.

Bani, M Ahmadi, M Arazpour, F Farahmand, S Sefati, M Baniasad, SW Hutchins, R Vahab Kashani, and ME Mousavi. 2015. 'Design and analysis of a new medial reciprocal linkage using a lower limb paralysis simulator', *Spinal Cord*, 53: 380-86.

Bani, Monireh Ahmadi, Mokhtar Arazpour, Farzam Farahmand, Mohmmad Ebrahim Mousavi, and Stephen William Hutchins. 2015. 'The efficiency of mechanical orthoses in affecting parameters associated with daily living in spinal cord injury patients: a literature review', *Disabil Rehabil Assist Technol*, 10: 183-90.

Baron, Z H, and A V Nene. 1990. 'Relationship between heart rate and oxygen uptake in thoracic level paraplegics', *Paraplegia*, 28: 87.

Baron, Z. H., and A. V. Nene. 1990. 'Relationship Between Heart-Rate And Oxygen-Uptake In Thoracic Level Paraplegics', *Paraplegia*, 28: 87-95.

Behrman, Andrea L, Mark G Bowden, and Preeti M Nair. 2006. 'Neuroplasticity after spinal cord injury and training: an emerging paradigm shift in rehabilitation and walking recovery', *Physical therapy*, 86: 1406-25.

Behrman, Andrea L, and Susan J Harkema. 2000. 'Locomotor training after human spinal cord injury: a series of case studies', *Physical therapy*, 80: 688-700.

Bernardi, M, I Canale, V Castellano, Filippo L Di, F Felici, and M Marchetti. 1995. 'The efficiency of walking of paraplegic patients using a reciprocating gait orthosis', *Paraplegia*, 33: 409-15.

Bernhardt, Kathie A, Steven E Irby, and Kenton R Kaufman. 2006. 'Consumer opinions of a stance control knee orthosis', *Prosthetics and orthotics international*, 30: 246-56.

Berry, Helen, Claudio Perret, Benjamin A Saunders, Tanja H Kakebeeke, N Donaldson, D B Allan, and K J Hunt. 2008. 'Cardiorespiratory and power adaptations to stimulated cycle training in paraplegia', *Medicine and Science in Sports and Exercise*, 40: 1573-80.

Berry, Helen Russell, Claudio Perret, Benjamin A Saunders, Tanja H Kakebeeke, Nde N Donaldson, David B Allan, and Kenneth J Hunt. 2008. 'Cardiorespiratory and power adaptations to stimulated cycle training in paraplegia', *Medicine and science in sports and exercise*, 40: 1573-80.

Bonder, B. R. 1998. 'ACSM's exercise management for persons with chronic diseases and disabilities', *Gerontologist*, 38: 757-60.

BORG, and GUNNAR A.V. 1982. 'Psychophysical bases of perceived exertion', *Med Sci Sports Exerc*, 14: 377-81.

Bougenot, MP, N Tordi, Andrew C Betik, X Martin, D Le Foll, B Parratte, J Lonsdorfer, and Jean Denis Rouillon. 2003. 'Effects of a wheelchair ergometer training programme on spinal cord-injured persons', *Spinal cord*, 41: 451-56.

Byrnes, M, J Beilby, P Ray, R Mclennan, J Ker, and S Schug. 2012. 'Patient-focused goal planning process and outcome after spinal cord injury rehabilitation: quantitative and qualitative audit', *Clinical Rehabilitation*, 26: 1141.

Campbell, JH, and TH Moore. 1997. 'Lower extremity orthoses for spinal cord injury', *Atlas of orthoses and assistive devices. 3th ed. St. Louis: Mosby*: 391-400.

Castellano, V., D. Coratella, and F. Felici. 1999. 'Cost of walking and locomotor impairment', *Journal of Electromyography & Kinesiology Official Journal of the International Society of Electrophysiological Kinesiology*, 9: 149.

Chen, M. J., X. Fan, and S. T. Moe. 2002. 'Criterion-related validity of the Borg ratings of perceived exertion scale in healthy individuals: a meta-analysis', *Journal of Sports Sciences*, 20: 873-99.

Cliquet Jr, A, RH Baxendale, and BJ Andrews. 1989. 'Paraplegic locomotion and its metabolic energy expenditure', *Comprehensive neurologic rehabilitation*, 3: 139-46.

Dall, P. M., B Müller, I Stallard, J Edwards, and M. H. Granat. 1999. 'The functional use of the reciprocal hip mechanism during gait for paraplegic patients walking in the Louisiana State University reciprocating gait orthosis', *Prosthetics & Orthotics International*, 23: 152.

Davis, P. C., T. M. Bach, and D. M. Pereira. 2010. 'The effect of stance control orthoses on gait characteristics and energy expenditure in knee-ankle-foot orthosis users', *Prosthet Orthot Int*, 34: 206-15.

De Groot, PCE, N Hjeltnes, AC Heijboer, W Stal, and K Birkeland. 2003. 'Effect of training intensity on physical capacity, lipid profile and insulin sensitivity in early rehabilitation of spinal cord injured individuals', *Spinal cord*, 41: 673-79.

DiCarlo, Stephen E, Michael D Supp, and Holly C Taylor. 1983. 'Effect of arm ergometry training on physical work capacity of individuals with spinal cord injuries', *Physical therapy*, 63: 1104-07.

Dickson, A, R Ward, G O'Brien, D Allan, and R O'Carroll. 2011. 'Difficulties adjusting to post-discharge life following a spinal cord injury: an interpretative phenomenological analysis', *Psychology Health & Medicine*, 16: 463-74.

Ditunno, J. F., Jr., P. L. Ditunno, G. Scivoletto, M. Patrick, M. Dijkers, H. Barbeau, A. S. Burns, R. J. Marino, and M. Schmidt-Read. 2013. 'The walking index for spinal cord injury (WISCI/WISCI II): nature, metric properties, use and misuse', *Spinal Cord*, 51: 346–55.

Douglas, R, P. F. Larson, R D'Ambrosia, and R. E. Mccall. 1983. 'The LSU Reciprocation-Gait Orthosis', *Orthopedics*, 6: 834-39.

Douglas, Roy, Paul F Larson, and Richard E McCall. 1983. 'The LSU reciprocation-gait orthosis', *Orthopedics*, 6: 834-39.

Eathorne, Scott. 1998. 'ACSM's Exercise Management for Persons with Chronic Diseases and Disabilities', *Medicine & Science in Sports & Exercise*, 30: 1461.

Edgerton, V. R., and R. R. Roy. 2009. 'Robotic training and spinal cord plasticity', *Brain Research Bulletin*, 78: 4-12.

Erickson, R P. 1980. 'Autonomic hyperreflexia: pathophysiology and medical management', *Archives of Physical Medicine & Rehabilitation*, 61: 431-40.

Field-Fote, Edelle C, and Kathryn E Roach. 2011. 'Influence of a locomotor training approach on walking speed and distance in people with chronic spinal cord injury: a randomized clinical trial', *Physical therapy*, 91: 48-60.

Franceschini, Marco, Silvano Baratta, Mauro Zampolini, Daniel Loria, and Sergio Lotta. 1997. 'Reciprocating gait orthoses: A multicenter study of their use by spinal cord injured patients', *Arch Phys Med Rehabil,* 78(6):582-586.

'Gait speed using powered robotic exoskeletons after spinal cord injury: a systematic review and correlational study'. *Journal of Neuroengineering & Rehabilitation*, 12: 82.

GELLMAN, HARRIS, IEN SIB, and ROBERT L WATERS. 1988. 'Late complications of the weight-bearing upper extremity in the paraplegic patient', *Clinical Orthopaedics and related research*, 233: 132-35.

Halson, and Shona L. 2014. 'Monitoring Training Load to Understand Fatigue in Athletes', *Sports Medicine*, 44 Suppl 2: S139.

Harkema, Susan J, Jessica Hillyer, Mary Schmidt-Read, Elizabeth Ardolino, Sue Ann Sisto, and Andrea L Behrman. 2012. 'Locomotor training: as a treatment of spinal cord injury and in the progression of neurologic rehabilitation', *Archives of physical medicine and rehabilitation*, 93: 1588-97.

Harvey, Lisa A, Glen M Davis, Merrick B Smith, and Stella Engel. 1998. 'Energy expenditure during gait using the walkabout and isocentric reciprocal gait orthoses in persons with paraplegia', *Archives of physical medicine and rehabilitation*, 79: 945-49.

Harvey, Lisa A, Toby Newton-John, Glen M Davis, Merrick B Smith, and Stella Engel. 1997. 'A comparison of the attitude of paraplegic individuals to the walkabout orthosis and the isocentric reciprocal gait orthosis', *Spinal Cord*, 35: 580-84.

Harvey, Lisa A, Merrick B Smith, Glen M Davis, and Stella Engel. 1997. 'Functional outcomes attained by T9-12 paraplegic patients with the walkabout and the isocentric reciprocal gait orthoses', *Archives of physical medicine and rehabilitation*, 78: 706-11.

Hatton, Bobby Joe, Dale Lynn Hatton, and Zane Grey Wallace. 2003. "Articulating knee supports." In.: Google Patents.

Hebert, J. S., and A. B. Liggins. 2005. 'Gait evaluation of an automatic stance-control knee orthosis in a patient with postpoliomyelitis', *Archives of Physical Medicine & Rehabilitation*, 86: 1676-80.

Hedel, H J A Van, M. Wirz, and A. Curt. 2006. 'Improving walking assessment in subjects with an incomplete spinal cord injury: responsiveness', *Spinal Cord*, 44: 352-56.

Hirokawa, S, M Grimm, T. Le, M Solomonow, R. V. Baratta, H Shoji, and R. D. D'Ambrosia. 1990. 'Energy consumption in paraplegic ambulation using the reciprocating gait orthosis and electric stimulation of the thigh muscles', *Arch Phys Med Rehabil*, 71: 687-94.

Hooker, STEVEN P, and CHRISTINE L Wells. 1989. 'Effects of low-and moderate-intensity training in spinal cord-injured persons', *Medicine and science in sports and exercise*, 21: 18-22.

IJZERMAN, MJ, G BAARDMAN, HJ HERMENS, PH VELTINK, HBK BOOM, and G ZILVOLD. 1997. 'The influence of the reciprocal cable linkage in the advanced reciprocating gait orthosis on paraplegic gait performance', *Prosthet Orthot Int*, 21: 52-61.

Irby, S. E., K. R. Kaufman, J. W. Mathewson, and D. H. Sutherland. 1999. 'Automatic control design for a dynamic knee-brace system', *IEEE Transactions on Rehabilitation Engineering*, 7: 135-39.

Irby, S. E., K. R. Kaufman, R. W. Wirta, and D. H. Sutherland. 1999. 'Optimization and application of a wrap-spring clutch to a dynamic knee-ankle-foot orthosis', *Rehabilitation Engineering IEEE Transactions on*, 7: 130-34.

Irby, Se, and Kakaufman Bernhardt, Kr. 2007. 'Gait changes over time in stance control orthosis users', *Prosthetics & Orthotics International*, 31: 353-61.

Jacobs, Patrick L, MARK S Nash, and JOSEPH W Rusinowski. 2001. 'Circuit training provides cardiorespiratory and strength benefits in persons with paraplegia', *Medicine and science in sports and exercise*, 33: 711-17.

Janssen, TW, CA Van Oers, LH Van der Woude, and A PETER Hollander. 1994. 'Physical strain in daily life of wheelchair users with spinal cord injuries', *Medicine and science in sports and exercise*, 26: 661-70.

Johnson, W. B., S Fatone, and S. A. Gard. 2009. 'Walking mechanics of persons who use reciprocating gait orthoses', *Journal of Rehabilitation Research & Development*, 46: 435-46.

Johnson, William Brett, Stefania Fatone, and Steven A Gard. 2009. 'Walking mechanics of persons who use reciprocating gait orthoses', *J Rehabil Res Dev*, 46: 435-46.

Karimi, Mohammad Taghi, Pouya Amiri, Amir Esrafilian, Jafar Sedigh, and Francis Fatoye. 2013. 'Performance of spinal cord injury individuals while standing with the Mohammad Taghi Karimi reciprocal gait orthosis (MTK-RGO)', *Australasian Physical & Engineering Sciences in Medicine*, 36: 35-42.

Karvonen, J., and T. Vuorimaa. 1988. 'Heart rate and exercise intensity during sports activities. Practical application', *Sports Med*, 5: 303–11.

Karvonen, M.J, E Kentala, and O Mustala. 1957. 'The effects of training on heart rate; a longitudinal study', *Ann Med Exp Biol Fenn*, 35: 307–15.

Katz-Leurer, M, C Weber, J Smerling-Kerem, H Rottem, and S Meyer. 2004. 'Prescribing the reciprocal gait orthosis for myelomeningocele children: a different approach and clinical outcome', *Pediatric Rehabilitation*, 7: 105-09.

Kaufman, R Kenton, Irby, S E, Mathewson, J W, Wirta, R W, Sutherland, and D H. 1996. 'Energy-Efficient Knee-Ankle-Foot Orthosis: A Case Study', *Jpo Journal of Prosthetics & Orthotics*, 8.

Kawashima, N, D Taguchi, K Nakazawa, and M Akai. 2006. 'Effect of lesion level on the orthotic gait performance in individuals with complete paraplegia', *Spinal cord*, 44: 487-94.

Kirtley, C, and SK McKay. 1992. 'Principles and practice of paraplegic locomotion: experience with the walkabout walking system', *Aust Orthot Prosthet Mag*, 7: 4-8.

Kobetic, Rudi, Curtis S To, John R Schnellenberger, Musa L Audu, Thomas C Bulea, Richard Gaudio, Gilles Pinault, Scott Tashman, and Ronald J Triolo. 2009. 'Development of hybrid orthosis for standing, walking, and stair climbing after spinal cord injury', *J Rehabil Res Dev*, 46: 447-62.

Kobetic, Rudi, Curtis S. To, John R. Schnellenberger, Musa L. Audu, Thomas C. Bulea, Richard Gaudio, Gilles Pinault, Scott Tashman, and Ronald J. Triolo. 2015. 'Development of hybrid orthosis for standing, walking, and stair climbing after spinal cord injury', *Journal of Rehabilitation Research & Development*, 46: 447-62.

Kumar, Ramesh, Jaims Lim, Rania A. Mekary, Abbas Rattani, Michael C. Dewan, Salman Y. Sharif, Enrique Osorio-Fonseca, and Kee B. Park. 2018. 'Traumatic spinal injury: global epidemiology and worldwide volume', *World Neurosurgery*: S1878875018303036.

Lam, T. , ., V K Noonan, and J J Eng. 2008. 'A systematic review of functional ambulation outcome measures in spinal cord injury', *Spinal Cord*, 46: 246.

Le, J., and D. Dorstyn. 2016. 'Anxiety prevalence following spinal cord injury: a meta-analysis', *Spinal Cord*, 54: 626-26.

Lehmann, J F, and J B Stonebridge. 1978. 'Knee lock device for knee ankle orthoses for spinal cord injured patients: an evaluation', *Arch Phys Med Rehabil*, 59: 207-11.

Leung, A. K., A. F. Wong, E. C. Wong, and S. W. Hutchins. 2009. 'The physiological cost index of walking with an isocentric reciprocating gait orthosis among patients with T(12) - L(1) spinal cord injury', *Prosthet Orthot Int*, 33: 61–8.

Leung, Aaron KL, Admond FY Wong, Eunice CW Wong, and Stephen W Hutchins. 2009b. 'The physiological cost index of walking with an isocentric reciprocating gait orthosis among patients with T12–L1 spinal cord injury', *Prosthet Orthot Int*, 33: 61-68.

Lusardi, Michelle M, Millee Jorge, and Caroline C Nielsen. 2013. *Orthotics and prosthetics in rehabilitation* (Elsevier Health Sciences).

MacGregor, J. 1981. 'The evaluation of patient performance using long-term ambulatory monitoring technique in the domiciliary environment', *Physiotherapy*, 67: 30–3.

Massucci, Maurizio, G Brunetti, R Piperno, L Betti, and M Franceschini. 1998. 'Walking with the advanced reciprocating gait orthosis (ARGO) in thoracic paraplegic patients: energy expenditure and cardiorespiratory performance', *Spinal cord*, 36: 223-27.

Mattsson, E, and LA Broström. 1989. 'The increase in energy cost of walking with an immobilized knee or an unstable ankle', *Scandinavian journal of rehabilitation medicine*, 22: 51-53.

Mattsson, E., and L A Broström. 1990. 'The increase in energy cost of walking with an immobilized knee or unstable ankle', *Scandinavian Journal of Rehabilitation Medicine*, 22: 51-53.

May, Bella J, and Margery A Lockard. 2011. *Prosthetics & orthotics in clinical practice: a case study approach* (FA Davis).

Mcardle, W. D., F. I. Katch, and V. L. Katch. 1991. 'Exercise Physiology: Energy, Nutrition, and Human Performance, 3rd Edition', *Medicine & Science in Sports & Exercise*, 23: 1403.

McMillan, Amy Gross, Kevin Kendrick, John W Michael, James Aronson, and Gary W Horton. 2004. 'Preliminary evidence for effectiveness of a stance control orthosis', *JPO: Journal of Prosthetics and Orthotics*, 16: 6-13.

Mcmillan, Amy Gross, Kevin Kendrick, John W. Michael, James Aronson, and Gary W. Horton. 2004. 'Preliminary Evidence for Effectiveness of a Stance Control Orthosis', *Jpo Journal of Prosthetics & Orthotics*, 16: 6-13.

Medicine, American College of Sports. 2009. 'ACSM's Exercise Management for Persons with Chronic Diseases and Disabilities-3rd Edition.' in (Human Kinetics; 3 edition (July 6, 2009)).

———. 2013. *ACSM's guidelines for exercise testing and prescription* (Lippincott Williams & Wilkins).

Mehrholz, J., J. Kugler, and M. Pohl. 2008. 'Locomotor training for walking after spinal cord injury', *Spine*, 33:768-77.

Mehrholz, Jan, Joachim Kugler, and Marcus Pohl. 2008. 'Locomotor Training for Walking After Spinal Cord Injury', *Spine*, 33: E768-E77.

Middleton, JW, W Fisher, GM Davis, and RM Smith. 1998. 'A medial linkage orthosis to assist ambulation after spinal cord injury', *Prosthet Orthot Int*, 22: 258-64.

Middleton, JW, JD Yeo, L Blanch, V Vare, K Peterson, and K Brigden. 1997. 'Clinical evaluation of a new orthosis, theWalkabout', for restoration of functional standing and short distance mobility in spinal paralysed individuals', *Spinal Cord*, 35.

Morawietz, C., and F. Moffat. 2013. 'Effects of locomotor training after incomplete spinal cord injury: a systematic review', *Arch Phys Med Rehabil*, 94: 2297-308.

Moreno, Juan C, Brunetti Fernando, Rocon Eduardo, and José L Pons. 2008. 'Immediate effects of a controllable knee ankle foot orthosis for functional compensation of gait in patients with proximal leg weakness', *Medical & Biological Engineering & Computing*, 46: 43-53.

Moreno, Juan C., Fernando Brunetti, Eduardo Rocon, and José L. Pons. 2008. 'Immediate effects of a controllable knee ankle foot orthosis for functional compensation of gait in patients with proximal leg weakness', *Medical & Biological Engineering & Computing*, 46: 43-53.

Myers, J, and Mkiratli Lee, J. 2007. 'Cardiovascular disease in spinal cord injury: an overview of prevalence, risk, evaluation, and management', *American Journal of Physical Medicine & Rehabilitation*, 86: 142-52.

Myers, J., M. Lee, and J. Kiratli. 2007. 'Cardiovascular disease in spinal cord injury: an overview of prevalence, risk, evaluation, and management', *Am J Phys Med Rehabil*, 86: 142-52.

Myers, Jonathan, Matthew Lee, and Jenny Kiratli. 2007. 'Cardiovascular Disease in Spinal Cord Injury: An Overview of Prevalence, Risk, Evaluation, and Management', *American Journal of Physical Medicine & Rehabilitation*, 86: 142-52.

Myslinski, Mary Jane. 2005. 'Evidence-based Exercise Prescription for Individuals with Spinal Cord Injury', *Journal of Neurologic Physical Therapy Jnpt*, 29: 104-06.

Nijenbanning, Gert, and Josephus Anton Goudsmit. 2005. "Gravity operated locking hinge." In.: Google Patents.

Ogilvie, C, P Bowker, and D. I. Rowley. 1993. 'The physiological benefits of paraplegic orthotically aided walking', *Paraplegia*, 31: 111.

Onogi, Keiko, Izumi Kondo, Eiichi Saitoh, Masaki Kato, and Tamaki Oyobe. 2010. 'Comparison of the effects of sliding-type and hinge-type joints of knee-ankle-foot orthoses on temporal gait parameters in patients with paraplegia', *Japanese Journal of Comprehensive Rehabilitation Science*, 1: 1-6.

Piazza, Stefano, and Jaime Ibáñez. 2016. 'Spinal Cord Plasticity and Neuromodulation After SCI.' in, *Emerging Therapies in Neurorehabilitation II* (Springer).

Podsiadlo, D., and S. Richardson. 1991. 'The timed "Up & Go": a test of basic functional mobility for frail elderly persons', *J Am Geriatr Soc*, 39: 142–8.

Post, Marcel, and Luc Noreau. 2005. 'Quality of Life After Spinal Cord Injury', *Journal of Neurologic Physical Therapy*, 29: 139-46.

Rasmussen, A Aaron, Smith, M Keith, Damiano, and L Diane. 2007. 'Biomechanical Evaluation of the Combination of Bilateral Stance-Control Knee-Ankle-Foot Orthoses and a Reciprocating Gait

Orthosis in an Adult With a Spinal Cord Injury', *Jpo Journal of Prosthetics & Orthotics*, 19: 42-47.

Rasmussen, Aaron A, Keith M Smith, and Diane L Damiano. 2007. 'Biomechanical evaluation of the combination of bilateral stance-control knee-ankle-foot orthoses and a reciprocating gait orthosis in an adult with a spinal cord injury', *JPO: Journal of Prosthetics and Orthotics*, 19: 42-47.

Rimaud, D., P. Calmels, and X. Devillard. 2005. 'Training programs in spinal cord injury', *Ann Readapt Med Phys*, 48: 259-69.

Rose, GK. 1979. 'The principles and practice of hip guidance articulations', *Prosthet Orthot Int*, 3: 37-43.

Rose, GK, J Stallard, and M Sankarankutty. 1981. 'Clinical evaluation of spina bifida patients using hip guidance orthosis', *Developmental Medicine & Child Neurology*, 23: 30-40.

Saitoh, E, M Baba, S Sonoda, Y Tomita, M Suzuki, and M Hayashi. 1997. "A new medial single hip joint for paraplegic walkers." In *The 8th World Congress of the International Rehabilitation Medicine Association (IRMA VIII)*, 1299-305.

Saitoh, Eiichi, Toru Suzuki, Shigeru Sonoda, Junko Fujitani, Yutaka Tomita, and Naoichi Chino. 1996. 'Clinical experience with a new hip-knee-ankle-foot orthotic system using a medial single hip joint for paraplegic standing and walking1', *American journal of physical medicine & rehabilitation*, 75: 198-203.

Scivoletto, G, A Petrelli, L Di Lucente, A Giannantoni, U Fuoco, F D"Ambrosio, and V Filippini. 2000. 'One year follow up of spinal cord injury patients using a reciprocating gait orthosis: Preliminary report', *Spinal Cord*, 38: 555-58.

Sharif, Hisham, Kimberley Gammage, Sanghee Chun, and David Ditor. 2014. 'Effects of FES-Ambulation Training on Locomotor Function and Health-Related Quality of Life in Individuals With Spinal Cord Injury', *Topics in spinal cord injury rehabilitation*, 20: 58.

Sharp, N. C. Craig. 2014. *Guidelines for Exercise Testing and Prescription*.

Shi, X. J., G. L. Wang, F. X. Pei, Y. M. Song, T. F. Yang, C. Q. Tu, F. G. Huang, H. Liu, and W. Lin. 2013. '[Comparative analysis of the clinical characteristics of orthopedic inpatients in Lushan and Wenchuan earthquakes]', *Beijing Da Xue Xue Bao*, 45: 688-92.

Sisto, Sue Ann, and Nick Evans. 2014. 'Activity and Fitness in Spinal Cord Injury: Review and Update', *Current Physical Medicine & Rehabilitation Reports*, 2: 147-57.

Sykes, L., J. Edwards, E. S. Powell, and Ers Ross. 1995. 'The reciprocating gait orthosis: long-term usage patterns', *Archives of Physical Medicine & Rehabilitation*, 76: 779.

Sykes, Laura, Jack Edwards, Eric S Powell, and E Raymond S Ross. 1995. 'The reciprocating gait orthosis: long-term usage patterns', *Archives of physical medicine and rehabilitation*, 76: 779-83.

Taylor, AW, E McDonell, and L Brassard. 1986. 'The effects of an arm ergometer training programme on wheelchair subjects', *Spinal cord*, 24: 105-14.

Terbizan, Donna J., Brett A. Dolezal, and Christian Albano. 2002. 'Validity of Seven Commercially Available Heart Rate Monitors', *Measurement in Physical Education & Exercise Science*, 6: 243-47.

Van Hedel, H.J.A, M Wirz, and V Dietz. 2008. 'Standardized assessment of walking capacity after spinal cord injury: the European network approach', *Neurol Res*, 30: 61–73.

Van Leederdam, NG, and EE Kunst. 1999. 'New UTX-swing orthosis: Normal gait and safe standing', *Orthopadie Technik*, 50: 506-15.

Vukobratovic, M, D Hristic, and Z Stojiljkovic. 1974. 'Development of active anthropomorphic exoskeletons', *Medical and Biological Engineering*, 12: 66-80.

Whittle, MW, GM Cochrane, AP Chase, AV Copping, RJ Jefferson, DJ Staples, PT Fenn, and DC Thomas. 1991. 'A comparative trial of two walking systems for paralysed people', *Spinal Cord*, 29: 97-102.

Williams, R, and A Murray. 2015. 'Prevalence of Depression After Spinal Cord Injury: A Meta-Analysis', *Arch Phys Med Rehabil*, 96: 133-40.

Winchester, P.K, J.J Carollo, R.N Parekh, L.M Lutz, and J.W Aston. 1993. 'A comparison of paraplegic gait performance using two types of reciprocating gait orthoses', *Prosthet Orthot Int*, 17: 101–06.

Winchester, PK, JJ Carollo, RN Parekh, LM Lutz, and JW Aston. 1993. 'A comparison of paraplegic gait performance using two types of reciprocating gait orthoses', *Prosthet Orthot Int*, 17: 101-06.

Wirz, Markus, David H. Zemon, Ruediger Rupp, Anke Scheel, Gery Colombo, Volker Dietz, and T. George Hornby. 2005. 'Effectiveness of automated locomotor training in patients with chronic incomplete spinal cord injury: A multicenter trial', *Archives of Physical Medicine & Rehabilitation*, 86: 672-80.

Yakimovich, T, E. D. Lemaire, and J Kofman. 2009. 'Engineering design review of stance-control knee-ankle-foot orthoses', *Journal of Rehabilitation Research & Development*, 46: 257-67.

Yakimovich, T., J. Kofman, and E. D. Lemaire. 2006. 'Design and Evaluation of a Stance-Control Knee-Ankle-Foot Orthosis Knee Joint', *IEEE Transactions on Neural Systems & Rehabilitation Engineering A Publication of the IEEE Engineering in Medicine & Biology Society*, 14: 361.

Yakimovich, Terris, Edward D. Lemaire, and Jonathan Kofman. 2007. 'Preliminary kinematic evaluation of a new stance-control knee–ankle–foot orthosis', *Clinical Biomechanics*, 21: 1081-89.

Zissimopoulos, A, S Fatone, and S. A. Gard. 2007. 'Biomechanical and energetic effects of a stance-control orthotic knee joint', *Journal of Rehabilitation Research & Development*, 44: 503.

Zissimopoulos, Angelika, Stefania Fatone, and Steven A. Gard. 2007. 'Biomechanical and energetic effects of a stance-control orthotic knee joint', *The Journal of Rehabilitation Research and Development*, 44: 503.

Zwinkels, Maremka, Olaf Verschuren, Thomas WJ Janssen, Marjolijn Ketelaar, Tim Takken, FJG Backx, JF de Groot, T Takken, DW Smits, and OW Verschuren. 2014. 'Exercise training programs to improve hand rim wheelchair propulsion capacity: a systematic review', *Clinical rehabilitation*: 0269215514525181.

陈星月, 陈栋, 陈春慧, 王凯, 唐笠, 李宇哲, and 吴爱悯. 2018. '中国创伤性脊髓损伤流行病学和疾病经济负担的系统评价', *中国循证医学杂志*.

古恩鹏, 刘爱峰, 金鸿宾, and 吴思. 2011. '步态分析在临床骨科与康复中的应用', *中国中西医结合外科杂志*, 17: 335-36.

李淑琴, 唐洁, and 罗兴利. 2012. '康复护理干预对脊髓损伤患者心理状态和生存质量的影响', *中国康复医学杂志*, 27: 658-60.

刘松怀, 李建军, 刘根林, and PaulKennedy. 2004. '中英两国四肢瘫患者生活满意度、生活质量及心理状况比较', *中国康复理论与实践*, 10: 604-05.

邵秀芹, 冯珍, 胡伟红, and 尹秀玲. 2012. '个体化截瘫矫形器对脊髓损伤患者心理影响的相关性研究', *中国康复医学杂志*, 27: 356-57.

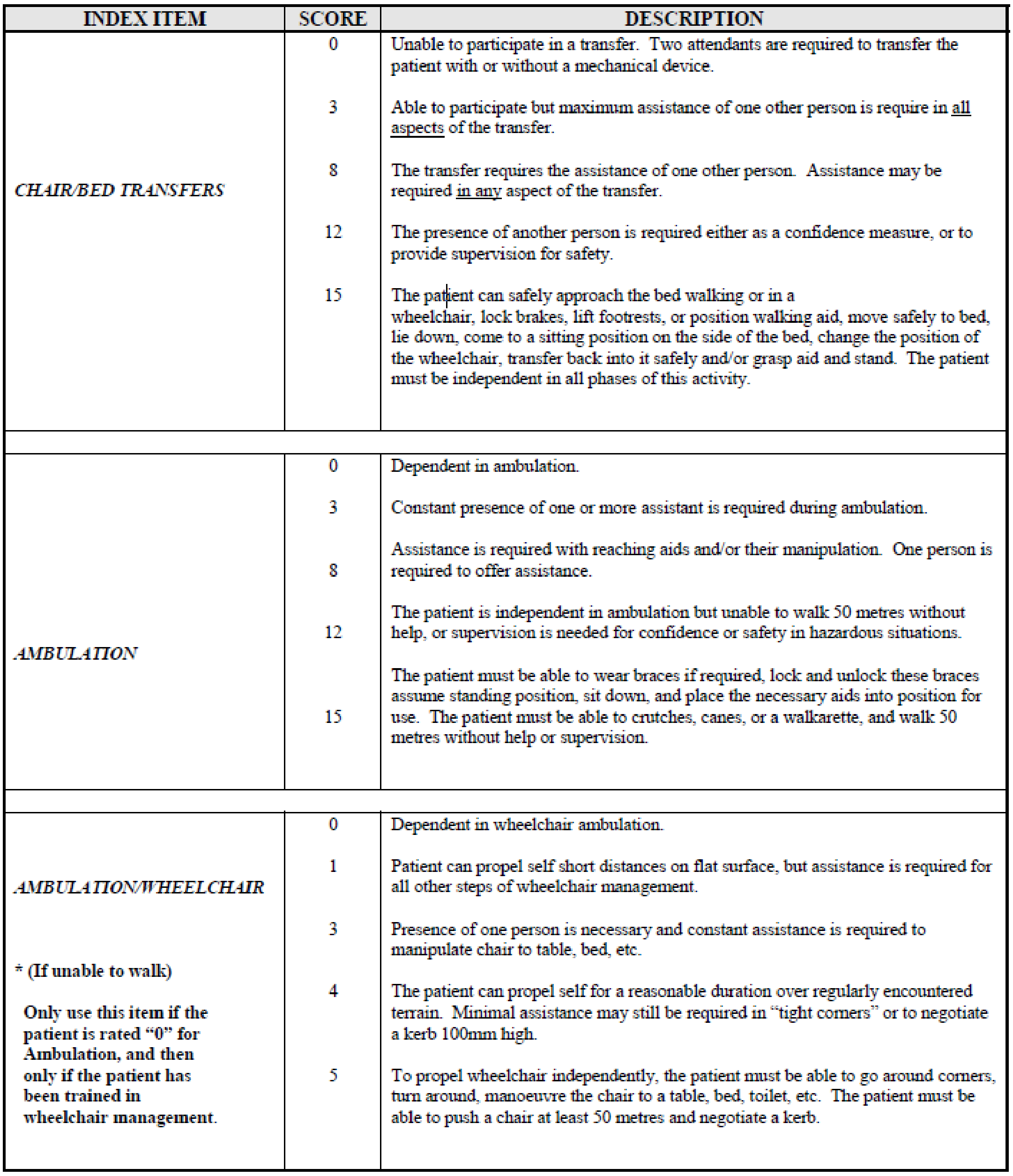
孙嘉利, 欧阳亚涛, 唐丹, and 钟世镇. 2007. '截瘫步行器对截瘫患者日常生活活动能力的影响', *中国康复医学杂志*, 22: 609-11.

王瑞元, and 苏全生. 2012. *运动生理学* (人民体育出版社: 北京).

吴强, 马宗浩, and 何成奇. 2013. 'Comparison of different orthosis for improving gait in patients with spinal cord injury%脊髓损伤患者 E-MAG 和落环锁式膝踝足矫形器的应用对比◆', *中国组织工程研究*, 000: 4152-60.

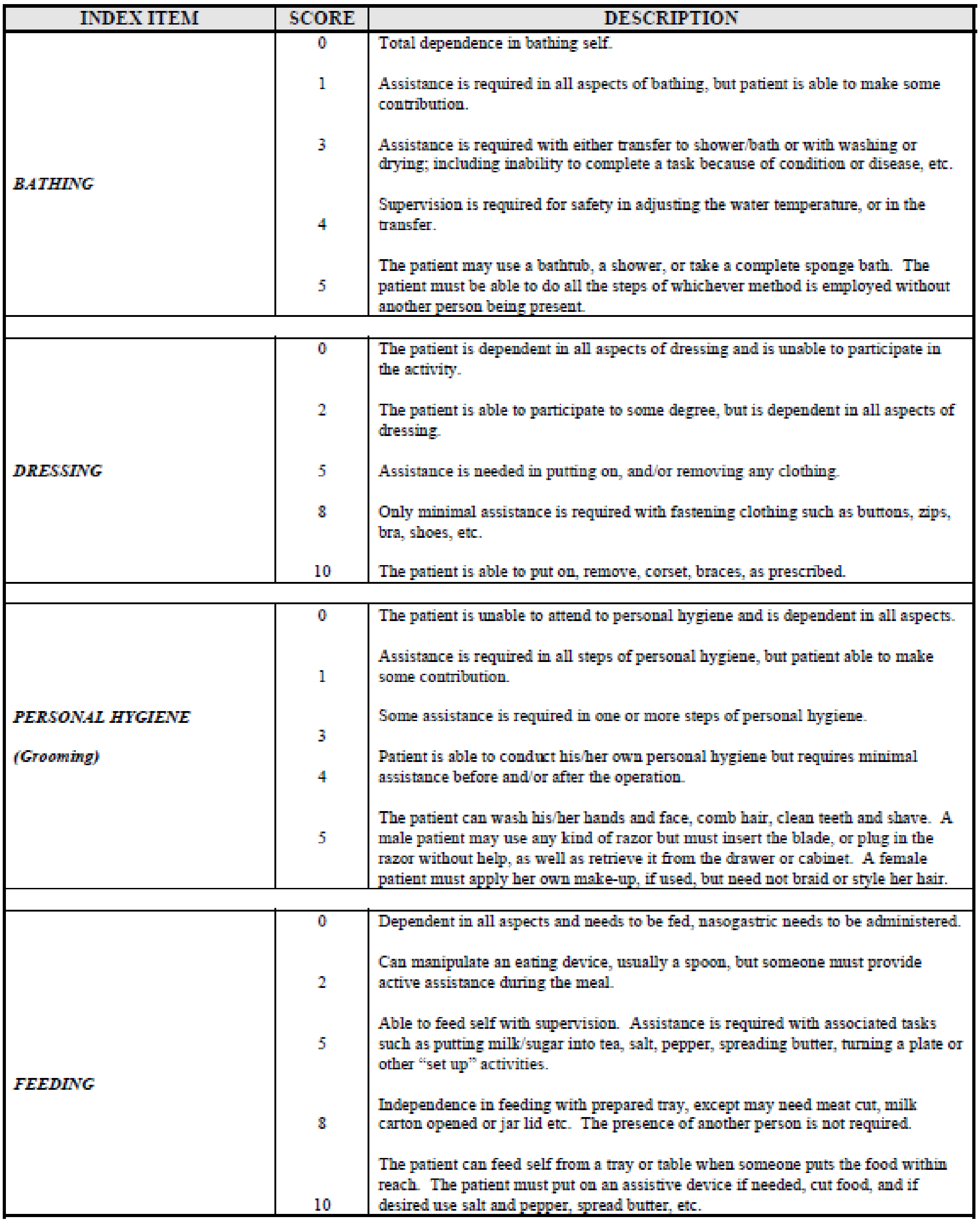
Appendices

Appendix A: Modified Barthel Index (SHAH VERSION) (MBI)



INDEX ITEM	SCORE	DESCRIPTION
CHAIR/BED TRANSFERS	0	Unable to participate in a transfer. Two attendants are required to transfer the patient with or without a mechanical device.
	3	Able to participate but maximum assistance of one other person is require in all aspects of the transfer.
	8	The transfer requires the assistance of one other person. Assistance may be required in any aspect of the transfer.
	12	The presence of another person is required either as a confidence measure, or to provide supervision for safety.
	15	The patient can safely approach the bed walking or in a wheelchair, lock brakes, lift footrests, or position walking aid, move safely to bed, lie down, come to a sitting position on the side of the bed, change the position of the wheelchair, transfer back into it safely and/or grasp aid and stand. The patient must be independent in all phases of this activity.
AMBULATION	0	Dependent in ambulation.
	3	Constant presence of one or more assistant is required during ambulation.
	8	Assistance is required with reaching aids and/or their manipulation. One person is required to offer assistance.
	12	The patient is independent in ambulation but unable to walk 50 metres without help, or supervision is needed for confidence or safety in hazardous situations.
	15	The patient must be able to wear braces if required, lock and unlock these braces assume standing position, sit down, and place the necessary aids into position for use. The patient must be able to crutches, canes, or a walkarette, and walk 50 metres without help or supervision.
AMBULATION/WHEELCHAIR * (If unable to walk) **Only use this item if the patient is rated "0" for Ambulation, and then only if the patient has been trained in wheelchair management.**	0	Dependent in wheelchair ambulation.
	1	Patient can propel self short distances on flat surface, but assistance is required for all other steps of wheelchair management.
	3	Presence of one person is necessary and constant assistance is required to manipulate chair to table, bed, etc.
	4	The patient can propel self for a reasonable duration over regularly encountered terrain. Minimal assistance may still be required in "tight corners" or to negotiate a kerb 100mm high.
	5	To propel wheelchair independently, the patient must be able to go around corners, turn around, manoeuvre the chair to a table, bed, toilet, etc. The patient must be able to push a chair at least 50 metres and negotiate a kerb.

INDEX ITEM	SCORE	DESCRIPTION
STAIR CLIMBING	0	The patient is unable to climb stairs.
	2	Assistance is required in all aspects of chair climbing, including assistance with walking aids.
	5	The patient is able to ascend/descend but is unable to carry walking aids and needs supervision and assistance.
	8	Generally no assistance is required. At times supervision is required for safety due to morning stiffness, shortness of breath, etc.
	10	The patient is able to go up and down a flight of stairs safely without help or supervision. The patient is able to use hand rails, cane or crutches when needed and is able to carry these devices as he/she ascends or descends.
TOILET TRANSFERS	0	Fully dependent in toileting.
	2	Assistance required in all aspects of toileting.
	5	Assistance may be required with management of clothing, transferring, or washing hands.
	8	Supervision may be required for safety with normal toilet. A commode may be used at night but assistance is required for emptying and cleaning.
	10	The patient is able to get on/off the toilet, fasten clothing and use toilet paper without help. If necessary, the patient may use a bed pan or commode or urinal at night, but must be able to empty it and clean it.
BOWEL CONTROL	0	The patient is bowel incontinent.
	2	The patient needs help to assume appropriate position, and with bowel movement facilitatory techniques.
	5	The patient can assume appropriate position, but cannot use facilitatory techniques or clean self without assistance and has frequent accidents. Assistance is required with incontinence aids such as pad, etc.
	8	The patient may require supervision with the use of suppository or enema and has occasional accidents.
	10	The patient can control bowels and has no accidents, can use suppository, or take an enema when necessary.
BLADDER CONTROL	0	The patient is dependent in bladder management, is incontinent, or has indwelling catheter.
	2	The patient is incontinent but is able to assist with the application of an internal or external device.
	5	The patient is generally dry by day, but not at night and needs some assistance with the devices.
	8	The patient is generally dry by day and night, but may have an occasional accident or need minimal assistance with internal or external devices.
	10	The patient is able to control bladder day and night, and/or is independent with internal or external devices.



INDEX ITEM	SCORE	DESCRIPTION
BATHING	0	Total dependence in bathing self.
	1	Assistance is required in all aspects of bathing, but patient is able to make some contribution.
	3	Assistance is required with either transfer to shower/bath or with washing or drying; including inability to complete a task because of condition or disease, etc.
	4	Supervision is required for safety in adjusting the water temperature, or in the transfer.
	5	The patient may use a bathtub, a shower, or take a complete sponge bath. The patient must be able to do all the steps of whichever method is employed without another person being present.
DRESSING	0	The patient is dependent in all aspects of dressing and is unable to participate in the activity.
	2	The patient is able to participate to some degree, but is dependent in all aspects of dressing.
	5	Assistance is needed in putting on, and/or removing any clothing.
	8	Only minimal assistance is required with fastening clothing such as buttons, zips, bra, shoes, etc.
	10	The patient is able to put on, remove, corset, braces, as prescribed.
PERSONAL HYGIENE ***(Grooming)***	0	The patient is unable to attend to personal hygiene and is dependent in all aspects.
	1	Assistance is required in all steps of personal hygiene, but patient able to make some contribution.
	3	Some assistance is required in one or more steps of personal hygiene.
	4	Patient is able to conduct his/her own personal hygiene but requires minimal assistance before and/or after the operation.
	5	The patient can wash his/her hands and face, comb hair, clean teeth and shave. A male patient may use any kind of razor but must insert the blade, or plug in the razor without help, as well as retrieve it from the drawer or cabinet. A female patient must apply her own make-up, if used, but need not braid or style her hair.
FEEDING	0	Dependent in all aspects and needs to be fed, nasogastric needs to be administered.
	2	Can manipulate an eating device, usually a spoon, but someone must provide active assistance during the meal.
	5	Able to feed self with supervision. Assistance is required with associated tasks such as putting milk/sugar into tea, salt, pepper, spreading butter, turning a plate or other "set up" activities.
	8	Independence in feeding with prepared tray, except may need meat cut, milk carton opened or jar lid etc. The presence of another person is not required.
	10	The patient can feed self from a tray or table when someone puts the food within reach. The patient must put on an assistive device if needed, cut food, and if desired use salt and pepper, spread butter, etc.

Downloaded from http://functionalpathways.com/intranet-files/Modifiet_Barthel_Index.pdf

Appendix B: Walking Index for Spinal Cord Injury (WISCI II)

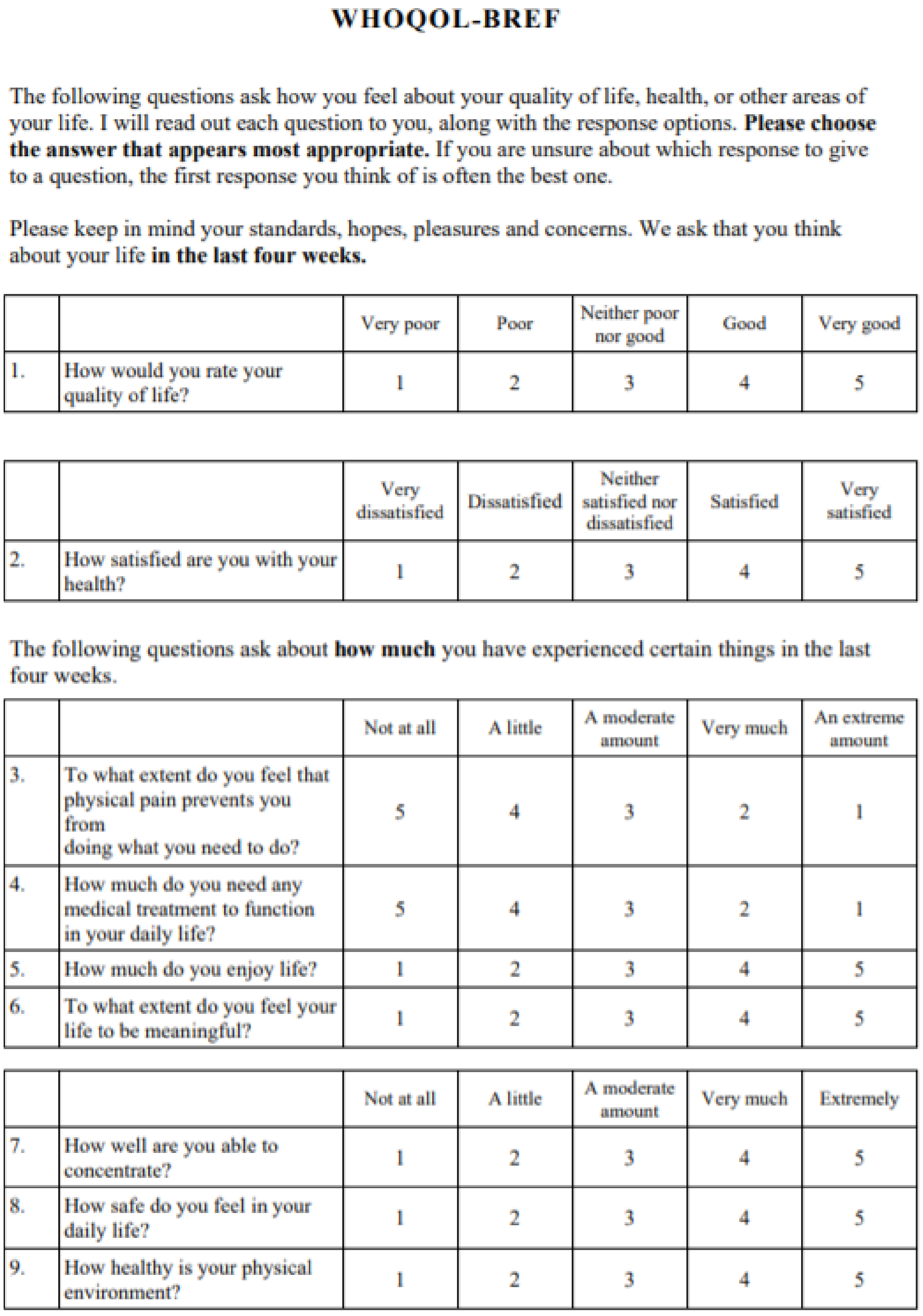
Physical limitation for walking secondary to impairment is defined at the person level and indicates the ability of a person to walk after spinal cord injury. The development of this assessment index required a rank ordering along a dimension of impairment, from the level of most severe impairment (0) to least severe impairment (20) based on the use of devices, braces and physical assistance of one or more persons. The order of the levels suggests each successive level is a less impaired level than the former. The ranking of severity is based on the severity of the impairment and not on functional independence in the environment. The following definitions standardize the terms used in each item:

Physical assistance: ‘Physical assistance of two persons’ is moderate to maximum assistance.
‘Physical assistance of one person’is minimal assistance.
Braces: ‘Braces’ means one or two braces, either short or long leg.
(Splinting of lower extremities for standing is considered long leg bracing).
‘No braces’ means no braces on either leg.
Walker: ‘Walker’ is a conventional rigid walker without wheels.
Crutches: ‘Crutches’ can be Lofstrand (Canadian) or axillary.
Cane: ‘Cane’ is a conventional straight cane.

Level Description
0 Client is unable to stand and/or participate in assisted walking.
1 Ambulates in parallel bars, with braces and physical assistance of two persons, less than 10 meters.
2 Ambulates in parallel bars, with braces and physical assistance of two persons, 10 meters.
3 Ambulates in parallel bars, with braces and physical assistance of one person, 10 meters.
4 Ambulates in parallel bars, no braces and physical assistance of one person, 10 meters.
5 Ambulates in parallel bars, with braces and no physical assistance, 10 meters.
6 Ambulates with walker, with braces and physical assistance of one person, 10 meters.
7 Ambulates with two crutches, with braces and physical assistance of one person, 10 meters.
8 Ambulates with walker, no braces and physical assistance of one person, 10 meters.
9 Ambulates with walker, with braces and no physical assistance, 10 meters.
10 Ambulates with one cane/crutch, with braces and physical assistance of one person, 10 meters.
11 Ambulates with two crutches, no braces and physical assistance of one person, 10 meters.
12 Ambulates with two crutches, with braces and no physical assistance, 10 meters.
13 Ambulates with walker, no braces and no physical assistance, 10 meters.
14 Ambulates with one cane/crutch, no braces and physical assistance of one person, 10 meters.
15 Ambulates with one cane/crutch, with braces and no physical assistance, 10 meters.
16 Ambulates with two crutches, no braces and no physical assistance, 10 meters.
17 Ambulates with no devices, no braces and physical assistance of one person, 10 meters.
18 Ambulates with no devices, with braces and no physical assistance, 10 meters.
19 Ambulates with one cane/crutch, no braces and no physical assistance, 10 meters.
20 Ambulates with no devices, no braces and no physical assistance, 10 meters.

Downloaded from https://www.sralab.org/rehabilitation-measures/walking-index-spinal-cord-injury

Appendix C: WHOQOL-BREF



WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

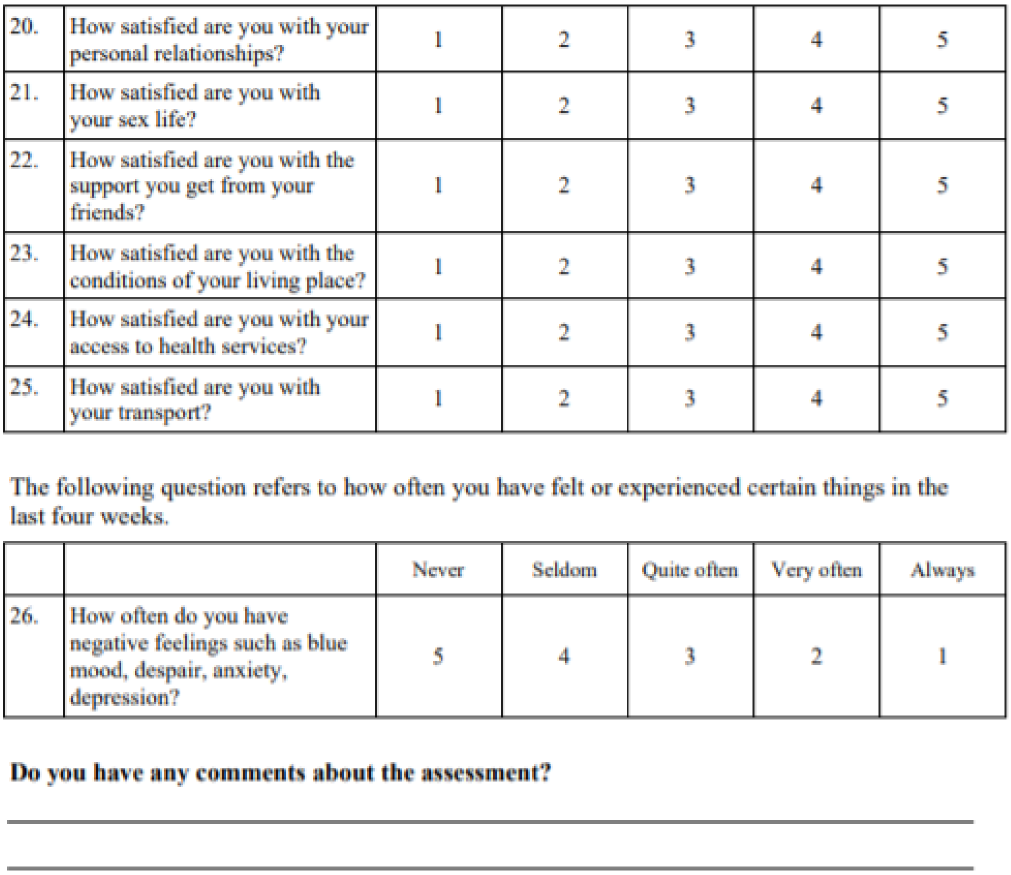
		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5



20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

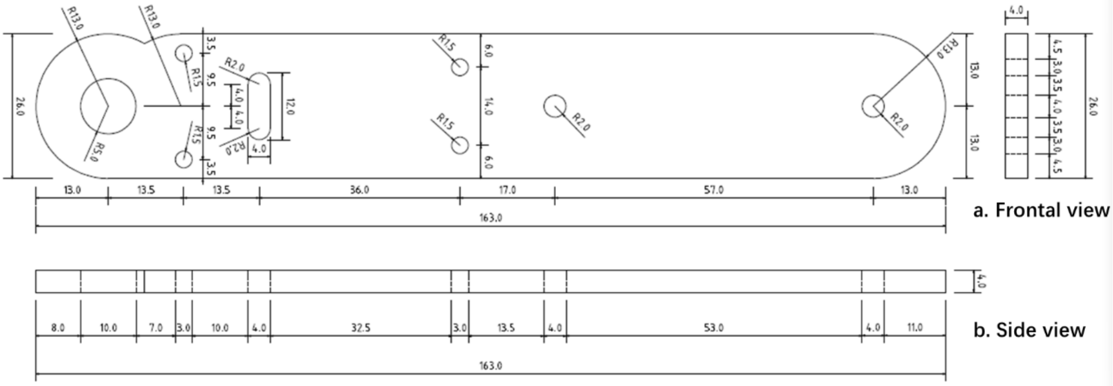
		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

Downloaded from

https://www.who.int/substance_abuse/research_tools/en/english_whoqol.pdf

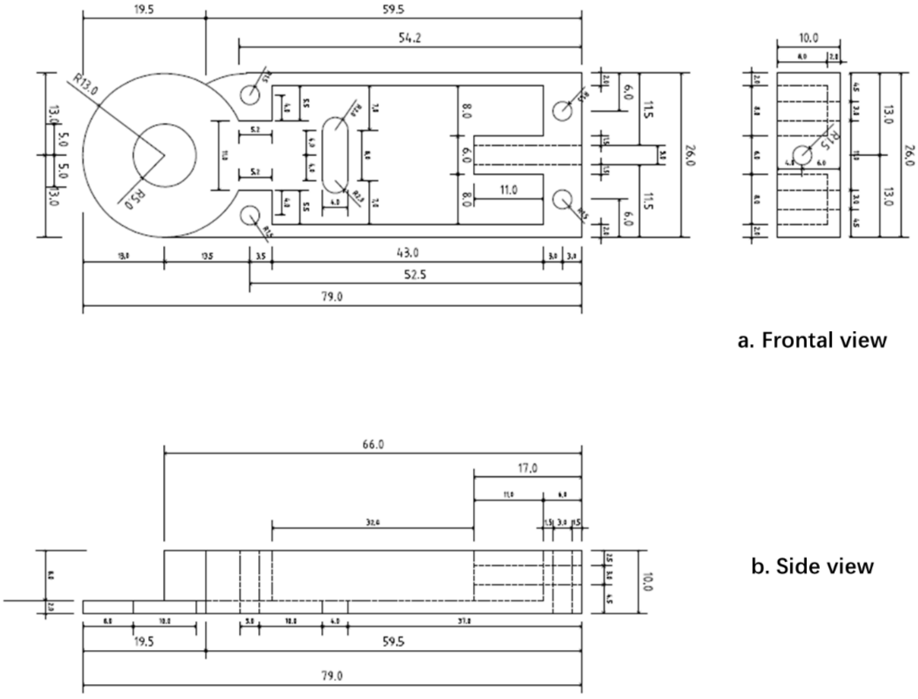
Appendix D: CAD plan of each part of new stance control structure



a. Frontal view

b. Side view

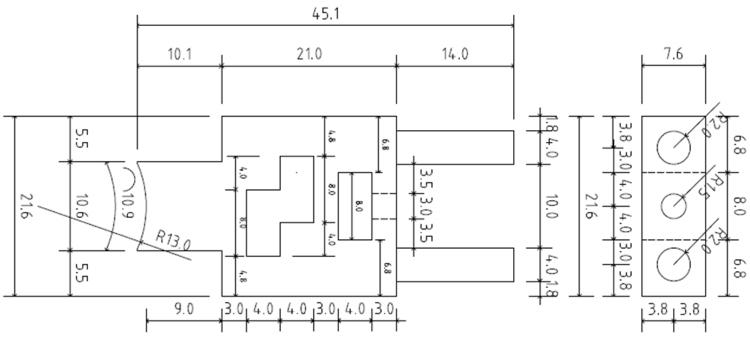
Figure 1 upper connection component（mm）



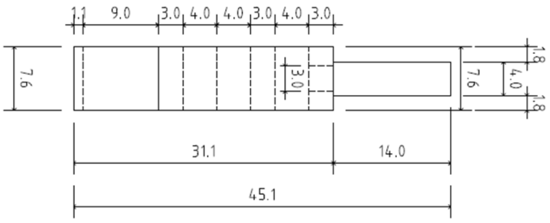
a. Frontal view

b. Side view

Figure 2 Pawl box（mm）

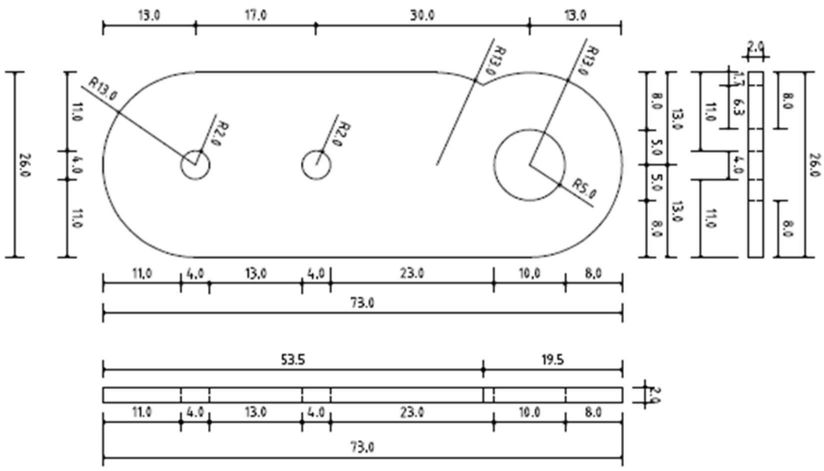


a. Frontal view



b. Side view

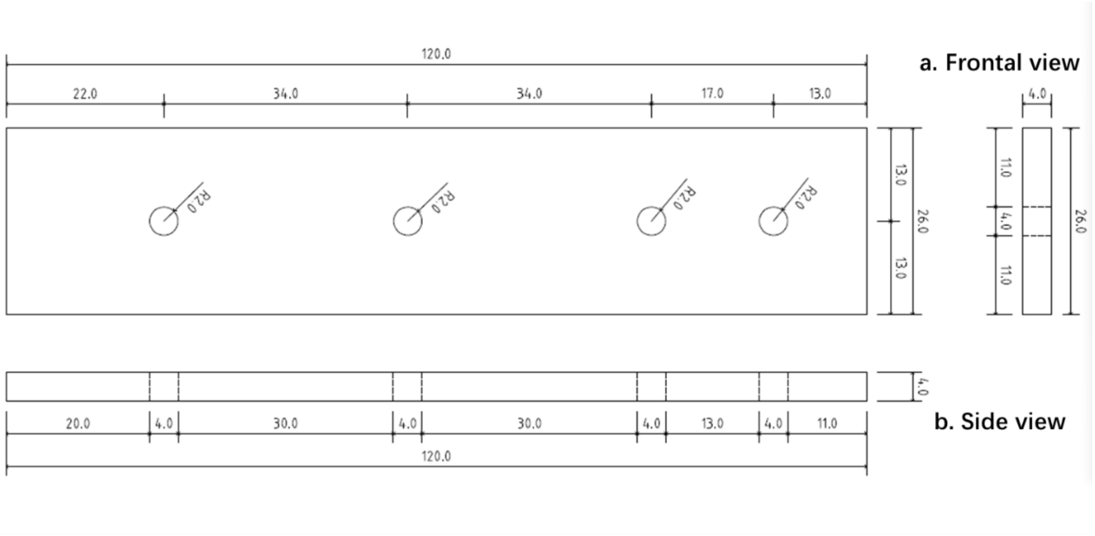
Figure 3 Pawl（mm）



a. Frontal view

b. Side view

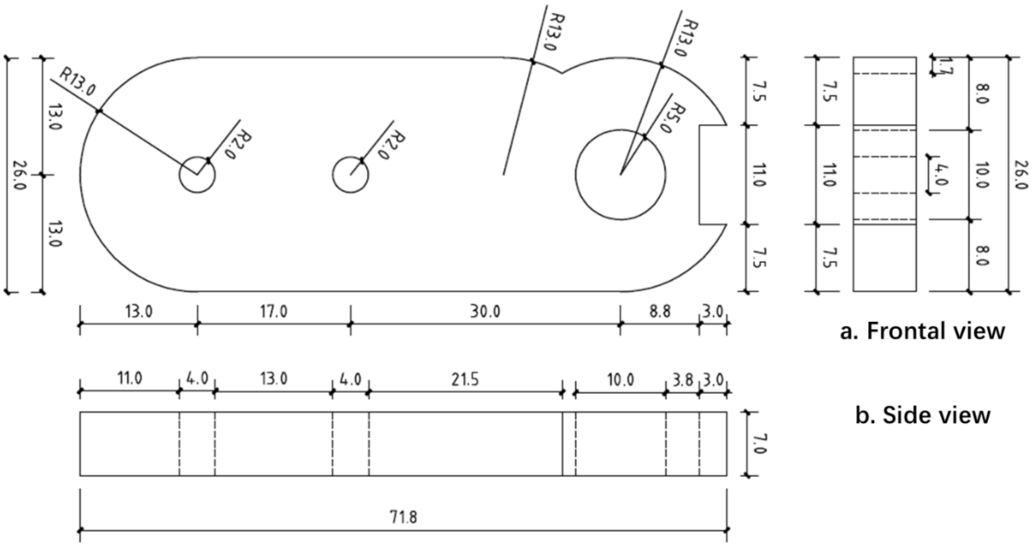
Figure 4 Lateral support component of pawl box（mm）



a. Frontal view

b. Side view

Figure 5 Lower connection component（单位：mm）



a. Frontal view

b. Side view

Figure 6 Ratchet middle connection component（mm）