

**DEVELOPMENT OF A NEW ORTHOSIS (NEURO-ORTHOSIS) FOR
THE CONTROL OF WRIST MOVEMENTS IN PATIENTS WITH
CARPAL TUNNEL SYNDROME**

by

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ABSTRACT

DEVELOPMENT OF A NEW ORTHOSIS (NEURO-ORTHOSIS) FOR THE CONTROL OF WRIST MOVEMENTS IN PATIENTS WITH CARPAL TUNNEL SYNDROME

Static wrist orthoses (SWOs) are used in carpal tunnel syndrome (CTS) with some drawbacks. As an alternate approach, an active closed-loop wrist control strategy was proposed to limit wrist movements. It was based on the electrical stimulation of antagonistic muscle(s) to prevent motion beyond preset limits. The purposes of the study were to determine whether the proposed “neuro-orthosis” (NeO) system resulted in less restriction in the function and strength of the hand compared to custom-made SWOs and its ability to limit the wrist movements.

A case-control study was designed. 31 right-handed volunteers participated in the study. 12 of them were patients with CTS, and the others were healthy subjects. Function, dexterity, and strengths were measured under three different testing conditions: without orthosis, with a SWO, and with the NeO system. Standardized test instruments and test procedures were used for all measurements. Maximum angles at each direction were recorded while the NeO system was on and off. At the end of the SWO and the NeO test conditions the level of discomfort were questioned by means of 10 cm visual analog scale.

SWOs caused significant decrements in most of the tests with respect to the no-orthosis test condition. The NeO system also led to some limitations in the test scores. However it was found to be less constraining with respect to a SWO. Although the NeO was not able to strictly limit the movements into preset limit, the resulting movement range was still in the safe area. The NeO system resulted in more discomfort in general.

Keywords: Carpal tunnel syndrome, Orthosis, Electrical stimulation

ÖZET

KARPAL TÜNEL SENDROMUNDA EL BİLEĞİ HAREKETLERİNİN KONTROLÜ İÇİN YENİ BİR ORTEZİN (NÖRO-ORTEZ) GELİŞTİRİLMESİ

Statik el bileği ortezleri (SEO) bazı dezavantajlarına rağmen karpal tünel sendromunun (KTS) tedavisinde kullanılmaktadırlar. Alternatif bir yaklaşım olarak el bileği ekleminin hareketlerini kısıtlamak için aktif kapalı-döngü kontrol sistemi kullanılması önerilmiştir. Sistem belirli sınırlar içerisinde el bileği eklemi hareketlerini kısıtlamak için antagonist kasların elektriksel yolla uyarılması prensibine dayanmaktadır. Çalışmanın amacı önerilen “nöro-ortez” (NeO) sisteminin, hastaya özel olarak yapılan SEO’ ne kıyasla elin fonksiyon ve kuvvetinde daha az kısıtlanmaya neden olup olmadığını ve hareketleri kısıtlayabilme becerisini belirlemektir.

Sistemin KTS’lu hastalar üzerinde özel bir etkisi olup olmadığını belirlemek için vaka-kontrol çalışma düzeni tertip edilmiştir. Dominant eli sağ olan 31 gönüllü çalışmaya katılmıştır. Bunların 12’si KTS’u olan hastalar geriye kalanı sağlam deneklerdi. Üç ayrı test koşulunda katılımcıların sağ ellerinin fonksiyon, beceri ve kuvveti ölçülmüştür: ortezsiz, SEO ile ve NeO sistemiyle. El bileği eklemindeki hareketleri ölçmek için özel bir potansiyometrik elektronik açılmaölçer tasarlanmıştır. Tüm test koşullarında standardize edilmiş test cihazları ve yöntemleri kullanılmıştır. Beceri düzeyinin ölçülmesinde kullanılan bir alt testinin uygulanması esnasında NeO sistemi açık ve kapalıyken her yönde ulaşılan en büyük eklem hareket açıları kaydedilmiştir. SEO ve NeO test koşullarının sonunda, rahatsızlık düzeyi 10 cm.lik görsel ağrı ölçeği kullanılarak değerlendirilmiştir.

SEO’leri ortezsiz test koşuluna kıyasla, ölçümlerin birçoğunda kısıtlanmaya neden olmuşlardır. NeO sistemide ölçümlerde bazı kısıtlanmalara neden olmuştur. Bununla birlikte SEO’lerine kıyasla daha az kısıtlayıcı olduğu belirlenmiştir. NeO sistemi el bileği hareketlerini daha önceden belirlenmiş sınırlar içerisinde tam olarak kısıtlayamamasına rağmen, nihai hareket açıklığının hala “güvenli sınırlar” içerisinde olduğu görülmüştür. NeO sistemi genel olarak daha fazla rahatsızlığa neden olmuştur.

Anahtar kelimeler: Karpal tünel sendromu, Ortez, Elektriksel uyarım

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LIST OF SYMBOLS

GF	Gauge factor
ΔR	Change in resistance
R_G	Resistance of the undeformed gauge
ϵ	Strain
V_{OUT}	Output Voltage
V_S	Source voltage
R_L	Load resistance
V_L	Load Voltage
R_P	Potentiometer Resistance

LIST OF ABBREVIATIONS

CTS	Carpal Tunnel Syndrome
CT	Carpal Tunnel
CTP	Carpal Tunnel Pressure
SWO	Static Wrist Orthosis
NeO	“Neuro-Orthosis”
CMC	Carpometacarpal
MC	Midcarpal
MCP	Metacarpophalangeal
PIP	Proximal Interphalangeal
DIP	Distal Interphalangeal
FCR	Flexor Carpi Radialis
FCU	Flexor Carpi Ulnaris
ECRL	Extensor Carpi Radialis Longus
ECRB	Extensor Carpi Radialis Brevis
ECU	Extensor Carpi Ulnaris
TCR	Transverse Carpal Ligament
ICP	Intracarpal Pressure
WHO	Wrist-hand Orthosis
FES	Functional Electrical Stimulation
CNS	Central Nervous System
MS	Medulla Spinalis
ESCM	Electrical Stimulation Controlled Movement
SEG	Strain-gauged Electrogoniometer
PEG	Potentiometric Electrogoniometer
DAQ	Data Acquisition
JHFT	The Jebson Hand Function Test
PPT	The Purdue Pegboard Test
MPPT	Modified Purdue Pegboard Test
JD	Jamar Dynamometer
MS	Modified Sphygmomanometer
mmHg	Millimeters Mercury

1. INTRODUCTION

1.1 Problem Statement

Carpal tunnel syndrome (CTS) is a common, painful condition of the wrist. It is the most commonly seen entrapment neuropathy. CTS is caused by the compression of the median nerve in the carpal tunnel (CT) at the wrist. The compression of the nerve results in symptoms including pain, numbness, and tingling in the involved hand. At severe CTS trophic changes of the skin may accompany these symptoms and pain may radiate up to the elbow and shoulder causing the patient to awaken at night. Due to the involvement of motor and sensory fibers, muscles innervated by the median nerve become atrophied and precision control of the hand is disrupted [1-4]. Treatment is required if the symptoms interfere with the patient's daily life. There are some treatment options. Treatment choices of CTS vary according to the stage of the disease. In general, at patients with mild and moderate CTS, splints immobilizing the wrist in neutral position are the treatment of choice [1, 5-7]. The rationale for using wrist orthoses at the neutral position lies on the relation of the disease with the increased intracarpal pressure. It has been shown that when the wrist is in the neutral position, the intracarpal pressure is minimum. However, the extreme angles of flexion and extension result in dramatic increases in the carpal tunnel pressure CTP [8-12]. When considering the effect of increased CTP on the development of CTS, immobilizing the joint in neutral position or at least restricting the joint in a range of about 10 degrees above and below the neutral position at two planes of motion can alleviate the compressive forces on the median nerve. By means of that, nerve regeneration process can be facilitated. Therefore, orthoses used in the management of CTS are aimed to maintain the neutral position at the wrist joint [10, 12]. It has been demonstrated that orthotic treatment provided improvements in the symptoms of mild and moderate CTS [5, 7, 8, 13]. Custom-made or prefabricated wrist orthoses can be used to maintain the wrist in neutral position. Custom-made static wrist orthoses (SWOs) have an advantage over prefabricated ones in that they can intimately fit to an individual patient and thereby provides better compliance.

In spite of proven therapeutic effects of orthoses in the conservative management of CTS, they have some drawbacks. A SWO which is constructed to fully immobilize the joint is constructed with rigid materials. While they maintain the wrist in neutral position, they may interfere with the accomplishment of daily life activities by disrupting the tenodesis effect. This results in reduced grip and pinch strengths. To fully and forcefully flex the fingers, about 30-40 degrees of wrist extension is required. By this way, extensor tendons of the fingers are loosened to allow the full flexion of the fingers. Another limiting factor is related to the skin area on which the orthosis is applied. A volar SWO occupies at least half of the palmar surface of the hand. However, the palmar surface of the hand provides sensory feedback about an object in contact with the hand. A patient wearing a volar SWO loses significant part of this sensory information. Another problem imposed by the volar wrist orthoses is related to its size. Sometimes they are made up of bulky materials and cover the ulnar side of the hand. Their thickness may interfere with some dexterous activities such as writing and picking up small objects. Another problem is related with the demands of activities on the hand. These demands may change from one person to another. While somebody can accomplish an activity with 25 degrees of extension, another one can perform the same activity with less than 10 degrees of extension. For example, wrist angles during writing activity show variability among people. However, a wrist orthosis with a fixed angle does not consider these personal variabilities. During the orthotic treatment, a change in the fixation angle of the orthosis may be required or it may be broken. In this case, a new orthosis should be constructed. This adds to the cost of the treatment. In addition, long term and/or improper use of an orthosis may result in muscle atrophy.

The effects of wrist orthoses on the function, dexterity and strengths of the hand and upper extremity have been investigated in numerous studies. These researches have been conducted on patients with various rheumatic conditions [14-24]. Although there were controversial results on their effects on the grip strengths, they led to reduction in functional capabilities and dexterity in general. However, at most of these researches, prefabricated wrist orthoses were used in various inflammatory conditions. These diseases and conditions have distinct pathophysiological properties and splinting principles from that of CTS such as the fixation angle and construction materials to be used. Therefore it is

not a convenient way to generalize these results to patients with CTS. There are not any similar studies for patients with CTS in the literature.

1.2 Proposed Control System

An orthosis must be minimally restrictive while it serves to immobilize or support a body part. In this study, a new kind of wrist control strategy called neuro-orthosis (NeO) is proposed. With this control system, electrical stimulation of wrist muscles restricts wrist movements into predetermined ranges of motion. When a movement beyond these ranges is sensed, opposing antagonistic muscles are stimulated through surface electrodes to prevent further motion in the agonistic direction. After the wrist returns to its allowable range, the activation of the muscles ceases. In addition, allowable limits of range can be changed according to the personal preferences or the progression of the disease.

However, there are some practical issues related to surface electrical stimulation of the forearm muscles. There are many muscles controlling the wrist and hand joints in this narrow area. When surface stimulation is used to control these muscles, the stimulation current may spread to neighboring muscles and cause undesirable movements to occur. The other issue is related to the functions of the forearm muscles primarily controlling the wrist movements. They contribute to more than one movement. In addition, surface stimulation may cause discomfort in varying degrees depending on the stimulation characteristics and personnel variabilities.

1.3 Hypothesis and Research Objectives

The principle hypothesis of this study is based on the two facts; (1) there is a relationship between the wrist position and the development of CTS and (2) when the wrist joint is maintained in neutral position, the symptoms of CTS improve.

This study proposes to demonstrate that the application of the new control system is effective in limiting the wrist movements in preset threshold angles while resulting in less restriction in function, dexterity, and strength.

The objectives of this research are summarized as follows;

- (1) To determine whether the proposed control strategy (NeO) has an advantage over a SWO with respect to limitations imposed on the function, dexterity, and strength of the hand.
- (2) To decide the effectiveness of the NeO system on limiting the wrist movements.
- (3) To investigate whether there are CTS specific factors affecting the results of the tests.
- (4) To investigate the effects of SWOs on the function, dexterity, and strength in the hands of patients with CTS and healthy subjects

1.4 Organization of the Thesis

Chapter 2 provides background information for the study. In the first part of this chapter anatomy of hand and wrist, characteristics of CTS, orthoses, the role of the orthotic treatment in CTS, and their effect on the functions and strengths of the hand are discussed. The other part of this chapter deals with neuromuscular electrical stimulation principles, functional electrical stimulation systems, sensors and control methods, experiments with patients, and practical issues related with the stimulation of hand and forearm muscles. Chapter 3 contains information on the experimental design and experimental method of the study including the experiments with strain-gauges, development of the bi-axial potentiometric electrogoniometric sensor and control program, test instruments and test batteries, and circuit design of the muscle stimulator. In Chapter 4, the results from the experiments are presented. The results of the experiments are interpreted and discussed in the Chapter 5. Chapter 6 presents a conclusion. The appendices provide supplemental information. Appendix A contains the evaluation form used in the study, Appendixes B and C include Symptom Severity Scale and Functional Severity Scale respectively.

2. THEORETICAL BACKGROUND

2.1 Anatomy of Hand and Wrist

The wrist joint is not a single joint instead it is a complex set of articulations. When dealing with anatomical structures of the hand, it is necessary to consider wrist and the other joints of the hand together. The normal functioning of the hand depends on the preservation of normal biomechanics and physiology of the joints. Any limitation, contracture, deformity or instability at each of these joints can cause overstresses and excessive forces on the other joints of the hand and lead to compensation at the nearby joints.

2.1.1 Osseous and Joint Structures

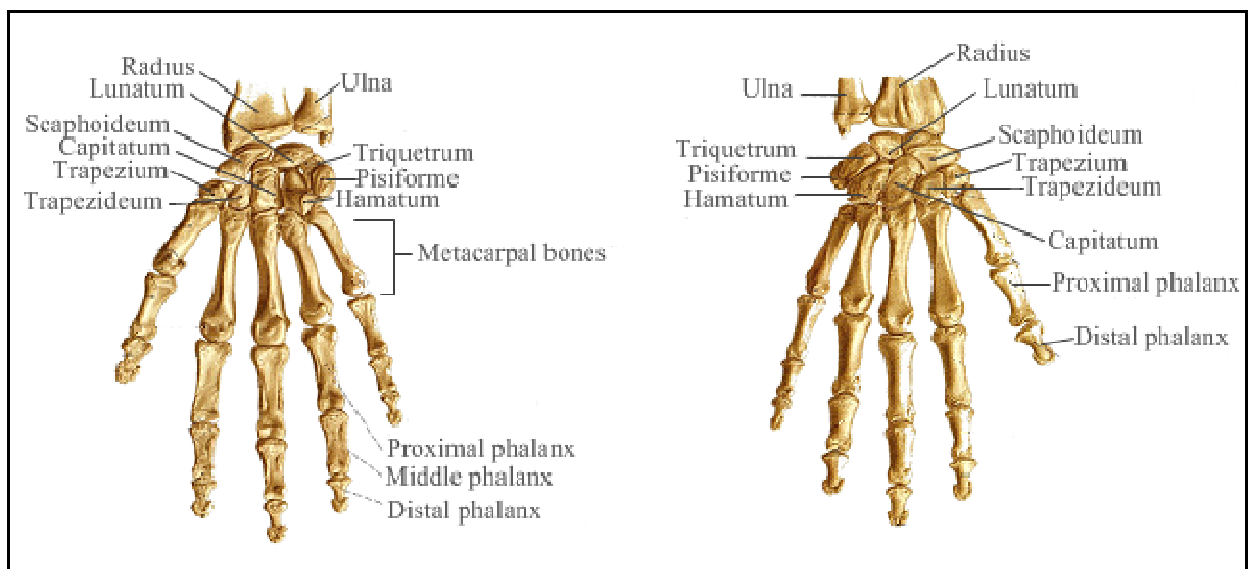


Figure 2.1 The bones and articulations of the hand. Adapted from [25]

There are twenty-seven bones in the hand and wrist (Figure 2.1). Of these bones, 8 carpal bones are parts of the wrist complex. The carpal bones are arranged in two rows. Each of the carpal bones is cuboid in shape. They have six surfaces. Four of them are for articulations with neighboring bones, and the other two are for ligamentous attachments. Distal carpal row is composed of trapezium, trapezoid, capitate, and hamate. They

articulate distally with metacarpal bones to form carpometacarpal (CMC) joints. The CMC articulations between the 2nd and 3rd metacarpals and corresponding carpal bones are more rigid than the other articulations among the other metacarpal and carpal bones. Thereby, 1st, 4th and 5th metacarpal bones can rotate around this rigid structure to allow fingers to be positioned around a circle-shaped object. At the proximal side, the bones of the distal carpal row articulate with those of the proximal carpal row which is composed of scaphoid, lunate and triquetrum. The articulations between the proximal and distal rows of the carpal bones are called midcarpal (MC) joints. Gliding motions occur among the carpal bones during flexion, extension, and radial and ulnar deviation movements. Proximal carpal bones articulate distally with the radius and the triangular cartilage. The distal radius, lunate and triquetrum articulate with the distal ulna through a ligamentous and cartilaginous structure called the ulnocarpal complex (Figure 2.2). The distal ulna does not articulate with any carpal bone. It contributes to the wrist stability through the attachments of the ulnar carpal ligaments [26, 27, 28].

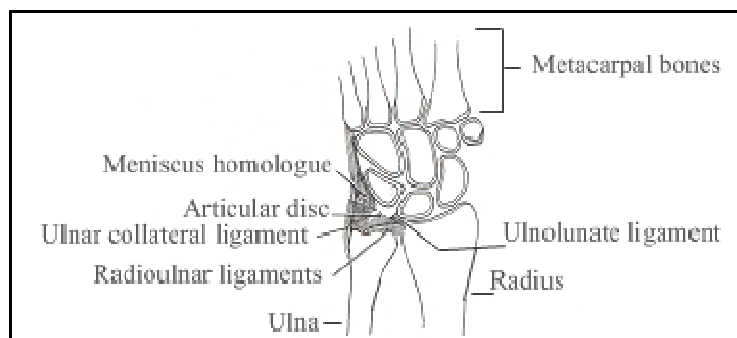


Figure 2.2 The ulnocarpal complex (TP: Trapezioid, TZ: Trapezium, S: Scaphoid, C: Capitate, H: Hamate, L: Lunate, TQ: Triquetrum). Adapted from [26]

The combination of these joints at the wrist allows for a greater range of motion than any other joint. Flexion, extension, radial and ulnar deviation movements are possible at the wrist joint. However, all motions occurring at the wrist joint are not isolated movements. They occur in more than one anatomical plane. Extension occurs with a degree of radial deviation and supination. Flexion involves both ulnar deviation and pronation [26, 27].

The bones of the hand form 2 transverse arches and 1 longitudinal arch. The proximal transverse arch is at the level of distal carpal bones. It is a fixed arch (Figure 2.3).

However the distal transverse arch passing through the metacarpal heads is more mobile and has an oblique shape. This oblique shape is important to adapt the shape of the hand. Two transverse arches are connected by the rigid part of the longitudinal arch. Longitudinal arch is formed of the central carpal bones, 2nd and 3rd metacarpals and index and long fingers. The rotation of 1st, 4th and 5th metacarpal bones around the rigid part of the longitudinal arch enables the palm to flatten or take a concave shape to accommodate to the shapes of the objects in the hand [26, 27].

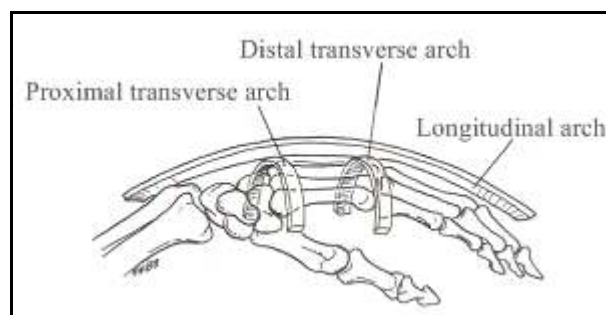


Figure 2.3 The arches of the hand. Adapted from [26]

The distal heads of the metacarpal bones articulate with the proximal phalanges in order to form the metacarpophalangeal (MCP) joints. Flexion, extension, abduction, and adduction movements are possible at these joints. A small degree of rotation is also possible. The motions allow for expansion or spreading of the hand to conform to the object in the hand. The 1st MCP joint differs from the others with respect to its substantial movement capability. This joint is located between the trapezium and the 1st metacarpal bone. In addition to the movements at the other MCP joints, rotation movement is also possible [26].

The interphalangeal joints are located among the phalangeal bones. They are called according to their proximity to the body: proximal and distal interphalangeal (PIP and DIP) joints. They are true hinge joints, therefore allowing motion in only one plane. This provides greater stability in these joints. There is only one interphalangeal joint at the thumb. Thumb is of great importance in hand function. Almost all grasp types require the use of thumb. Thumb must have enough strength and stability to stabilize the objects against the other fingers and palm [26, 27].

2.1.2 Ligaments

Ligaments control the excessive movements of the joints and contribute to the stability of the joints. The complex motions of the wrist and hand are largely dependent on their ligamentous system. The ligamentous system of the wrist and hand (Table 1.1) can be divided into 2 components: extrinsic and intrinsic ligaments [26, 29]. In general, the palmar ligaments are thick and strong. However the dorsal ligaments are much thinner and fewer in number compared to palmar ligaments (Figures 2.4 and 2.5).

Table 1.1
The ligaments of the wrist. Adapted from [26, 27]

Extrinsic ligaments	Proximal extrinsic (radiocarpal) ligaments	Palmar radiocarpal ligament	Superficial ligament	
			Deep ligaments	Radioscaphocapitate (radiocapitate)
				Radioulnate
				Radioscapholunate
			Ulnacarpal complex	Meniscus homologue
Triangular fibrocartilage				
Ulnolunate ligament				
			Ulnar collateral ligament	
		Dorsal radiocarpal ligament		
	Distal extrinsic ligaments			
Intrinsic ligaments	Short ligaments	Palmar ligament		
		Dorsal ligament		
		Interosseous ligament		
	Intermediate ligaments	Lunotriquetral ligament		
		Scapholunate ligament		
		Scaphotrapezium ligament		
	Long ligaments	Palmar intercarpal (V, deltoïd) ligament		
		Dorsal intercarpal ligament		

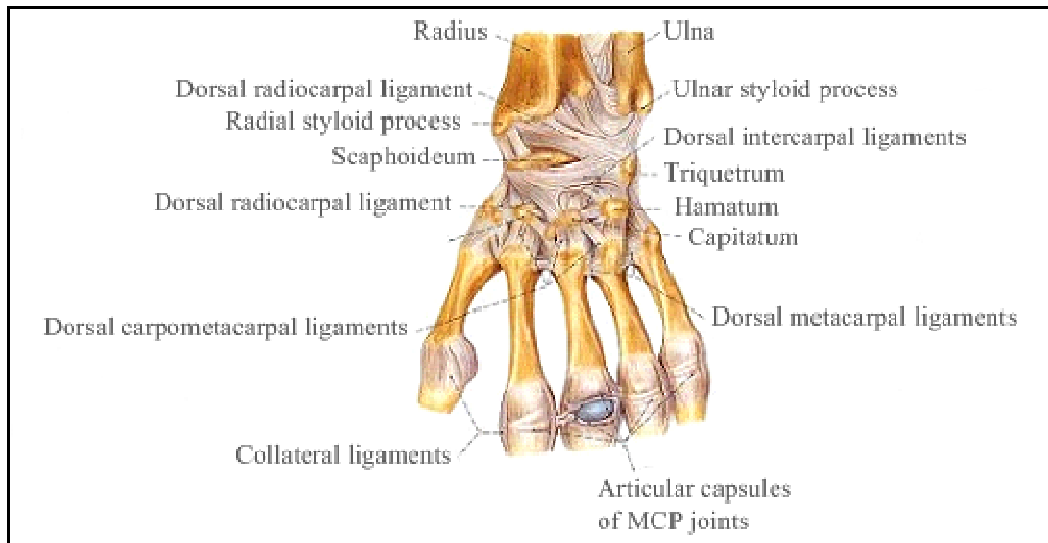


Figure 2.4 Ligaments of the hand (dorsal view). Adapted from [25]

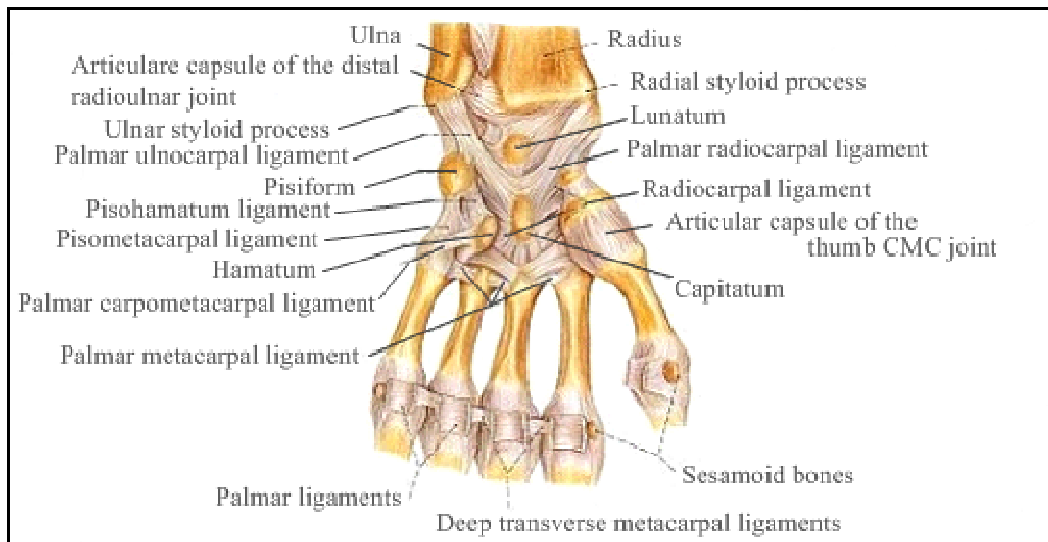


Figure 2.5 Ligaments of the hand (palmar view). Adapted from [25]

The MCP joints consist of joint capsule, collateral ligaments and volar plate. The joint capsule is reinforced by the collateral ligaments. Collateral ligaments allow side-to-side motion when the joint is in extension and tighten as the MCP joints are flexed. The volar plate slides proximally during MCP joint flexion and prevent displacement of MCP joint during extension [26].

The capsular and ligamentous structures in PIP joints allow for motion only in one plane. The collateral ligament and volar plate is tight during extension. Extensor tendons passing through dorsally contribute the stability of the joint. DIP joint has a joint capsule and collateral ligament [26].

2.1.3 Muscles

There are many muscles controlling the wrist and finger movements in the forearm region (Table 2.2). Five muscles directly control the wrist movements. Two of them, m. flexor carpi radialis (FCR) and m. flexor carpi ulnaris (FCU) are responsible for the flexion movement of the wrist. Due to their orientation, they contribute to radial and ulnar deviation movements of the wrist respectively, as their names imply. M. extensor carpi radialis longus (ECRL) and brevis (ECRB) cause wrist extension and radial deviation when they are contracted. The other extensor muscle of the wrist is the m. extensor carpi ulnaris (ECU). Its contribution to wrist extension is small and predominantly elicits ulnar deviation movement together with FCU [27, 29, 30]. Muscles directly controlling the wrist movements lie in the superficial layer of the forearm. All forearm muscles are shown at the Figures 2.6 and 2.7.

Table 2.2
Muscles of the forearm and their motor nerves

Volar forearm muscles	<i>Superficial group</i>	Flexor carpi radialis	Median nerve (C6, 7)		
		Flexor carpi ulnaris	Ulnar nerve (C8, T1)		
		Flexor digiti superficialis	Median nerve (C7, 8, T1)		
		Palmaris longus	Median nerve (C6, 7)		
		Proneus	Median nerve (C6, 7)		
	<i>Deep group</i>	Flexor digiti profundus	Ulnar nerve (C8, T1)		
		Flexor pollicis longus	Median nerve (C8, T1)		
		Proneus quadratus	Median nerve (C8, T1)		
		Dorsal forearm muscles	<i>Superficial group</i>	Anconeus	Radial nerve (C7, 8)
				Brachioradialis	Radial nerve (C5, 6)
Extensor carpi radialis brevis	Radial nerve (C6, 7)				
Extensor carpi radialis longus	Radial nerve (C6, 7)				
Extensor carpi ulnaris	Radial nerve (deep branch) (C6-8)				
Extensor digiti minimi	Radial nerve (deep branch) (C6-8)				
Extensor digitorum communis	Radial nerve (deep branch) (C6-8)				
<i>Deep group</i>	Abductor pollicis longus		Radial nerve (deep branch) (C6, 7)		
	Extensor indicis proprius		Radial nerve (deep branch) (C6-8)		
	Extensor pollicis brevis		Radial nerve (deep branch) (C6, 7)		
	Extensor pollicis longus		Radial nerve (deep branch) (C6-8)		
	Supinator		Radial nerve (deep branch) (C6)		

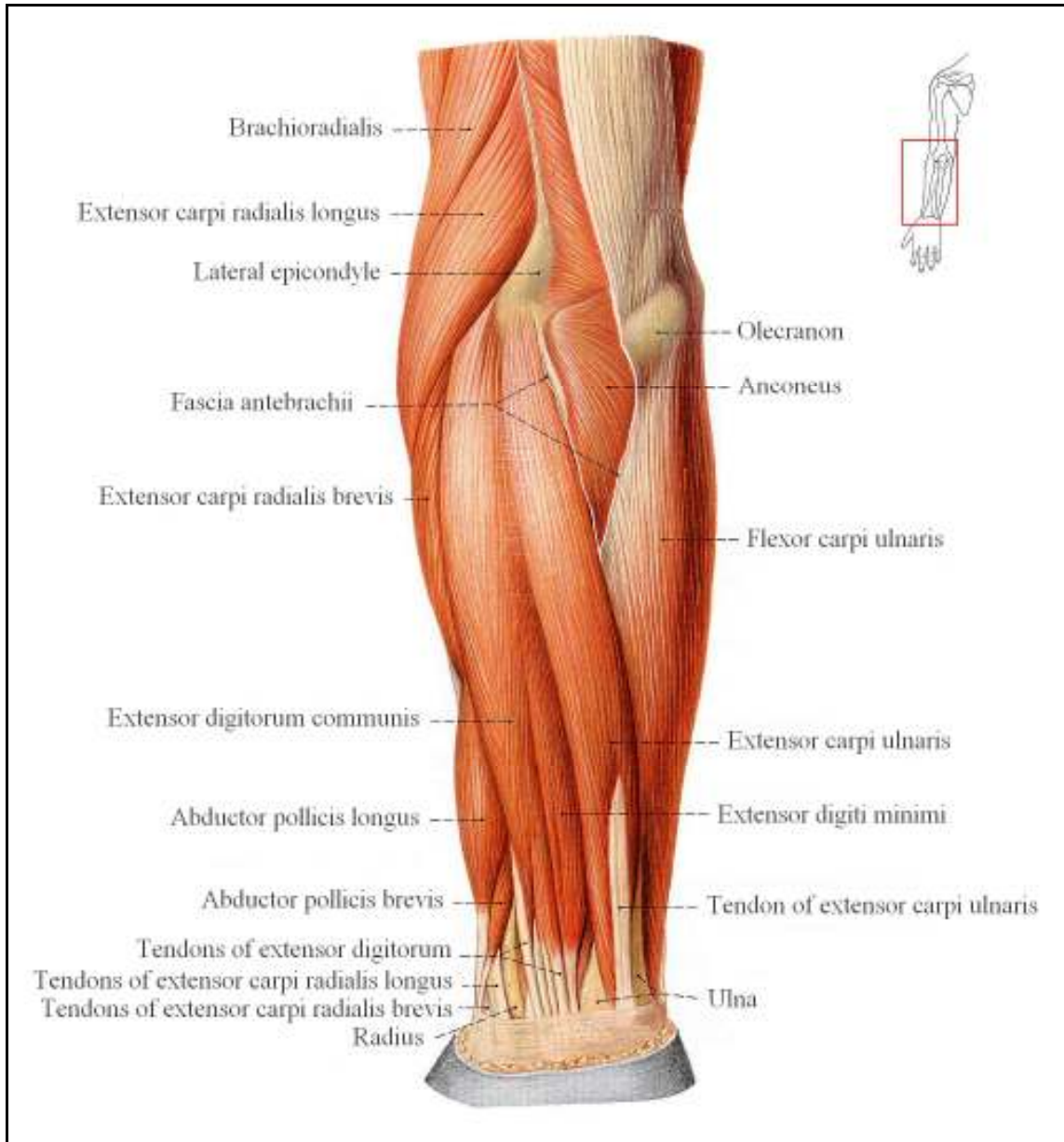


Figure 2.6 Forearm muscles (posterior view). Adapted from [25]

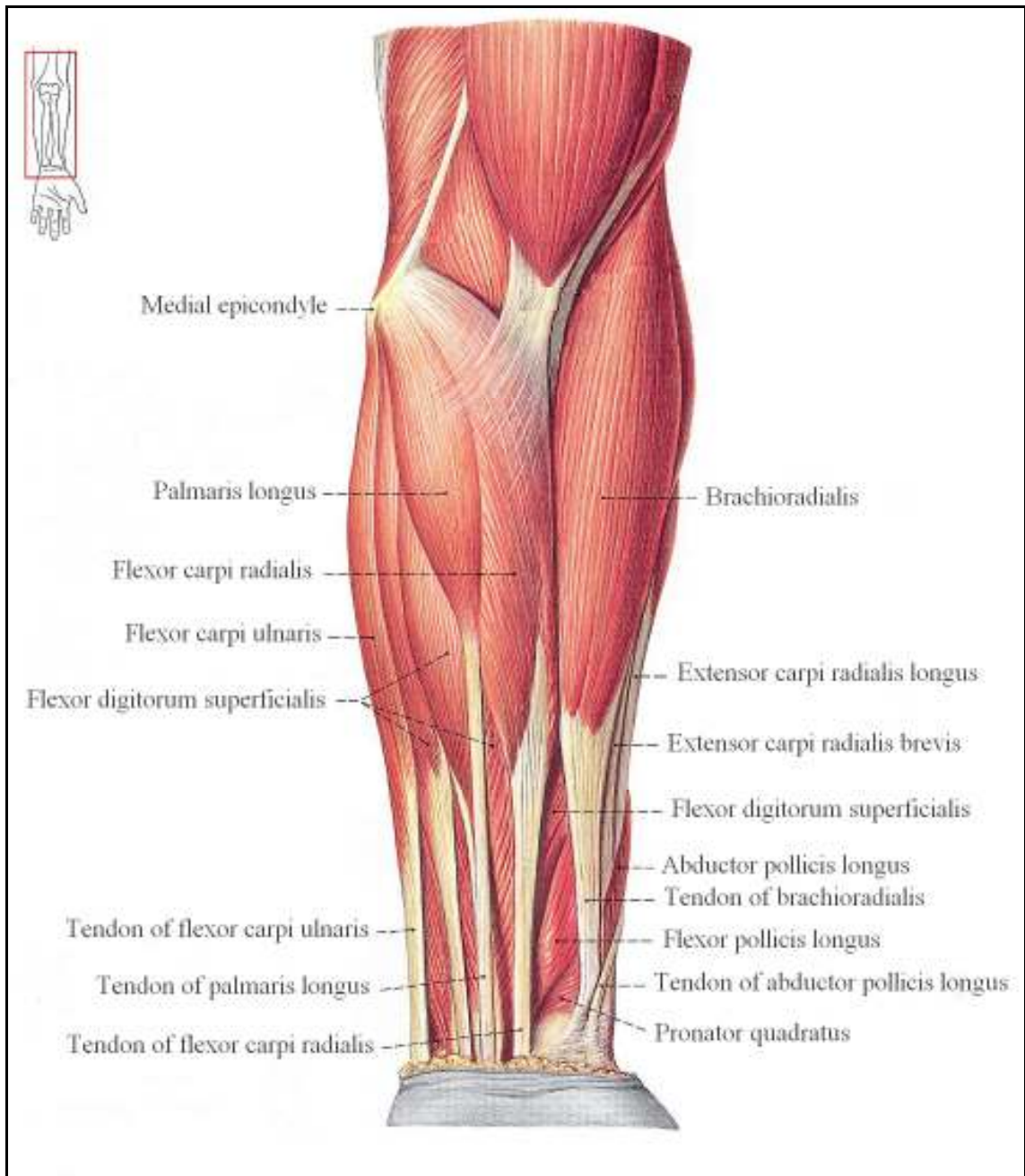


Figure 2.7 Forearm muscles (anterior view). Adapted from [25]

Table 2.3
The origins and insertions of the forearm muscles [29, 30]

Forearm muscles	Origin	Insertion
Flexor carpi radialis	Medial epicondyle of the humerus by common tendon	Volar base of the 2 nd and 3 rd metacarpal bones
Flexor carpi ulnaris	Humeral head: medial epicondyle of the humerus by common tendon Ulnar head: olecranon process and the upper two thirds of dorsal border of the ulna	Pisiform and hamate bone and volar base of the 5 th metacarpal bone
Flexor digitorum superficialis	Humeral head: medial epicondyle of the humerus by common tendon Ulnar head: medial side of coronoid process of ulna Radial head: oblique line of radius	Both sides of the middle phalanges of the 2 nd to 5 th fingers
Palmaris longus	the common forearm flexor origin at the medial epicondyle	The proximal superficial palmar fascia
Pronator teres	Humeral head: medial epicondylar ridge of the humerus and the common forearm flexor tendon Ulnar head: medial side of coronoid process of ulna	Lateral surface of radius at the middle of its body
Flexor digitorum profundus	Volar and medial surfaces of ulna, aponeurosis, and the medial side of coronoid process	Bases of distal phalanges of the 2 nd to 5 th fingers
Flexor pollicis longus	Dorsal surface of the radius, interosseous membrane and the coronoid process of the ulna or medial epicondyle of humerus	Palmar base of the distal phalanx of the thumb
Pronator quadratus	Distal quarter of the palmar surface of the ulna	Distal quarter of palmar surface of the radius.
Anconeus	Lateral epicondyle of the humerus and the posterior capsule of the elbow	Lateral side of olecranon and posterior surface of the ulna
Brachioradialis	Proximal 2/3 of lateral supracondylar ridge of the distal humerus and the lateral intermuscular septum	Lateral side of base of styloid process of the radius
Extensor carpi radialis brevis	Common extensor tendon of the lateral epicondyle and the radial collateral ligament of the elbow	Dorsal base of the 3 rd metacarpal
Extensor carpi radialis longus	Lower 1/3 of lateral supracondylar ridge of the distal humerus and common extensor tendon of lateral epicondyle of humerus	Dorsal base of the 2 nd metacarpal
Extensor carpi ulnaris	Common forearm extensor tendon from the lateral border of the distal humerus, and aponeurosis from dorsal border of ulna	Dorsal base of the 5 th metacarpal
Extensor digiti minimi	Lateral epicondyle of humerus by common extensor tendon	Extensor mechanism and the dorsal base of the proximal phalanx of the 5 th finger
Extensor digitorum communis	Lateral epicondyle of humerus by common extensor tendon	The base of the middle and the proximal phalanges of the 2 nd to 5 th fingers
Abductor pollicis longus	Lateral part of dorsal surface of ulna and the middle third of posterior surface of the radius	The base of the 1 st metacarpal bone
Extensor indicis proprius	Dorsal surface of the ulna and the interosseous membrane	Dorsal base of middle phalanges of the 2 nd finger and the digital extensor mechanism
Extensor pollicis brevis	Dorsal surface of the radius and the radioulnar interosseous membrane	Dorsal base of proximal phalanx of thumb
Extensor pollicis longus	Middle third of the dorsal surface of the ulna and the interosseous membrane	Dorsal base of distal phalanx of thumb
Supinator	Lateral epicondyle of the humerus, the radial collateral ligament of the elbow, and the annular ligament	Lateral and dorsal surface of the proximal third of the radius

Table 2.4
Functions of the forearm muscles [29, 30]

Forearm muscles	Function
Flexor carpi radialis	Flexes and radially deviates the wrist. It weekly contributes to forearm pronation and elbow flexion due to its orientation.
Flexor carpi ulnaris	Flexes and ulnarly deviates the wrist and weekly flexes the elbow
Flexor digitorum superficialis	Flexes the PIP joints of the 2 nd to 5 th fingers.
Palmaris longus	Assists the wrist flexion
Pronator teres	Pronates the forearm, and assists muscles which flex the elbow.
Flexor digitorum profundus	Flexes the DIP joints of the 2 nd to 5 th fingers
Flexor pollicis longus	Flexes the IP and MCP joints of the thumb.
Pronator quadratus	Pronates the forearm.
Anconeus	Assists the elbow extension.
Brachioradialis	Flexes the elbow, along with other flexor muscles of the elbow and assists the forearm supination.
Extensor carpi radialis brevis	Extends and radially deviates the wrist.
Extensor carpi radialis longus	Extends and radially deviates the wrist.
Extensor carpi ulnaris	Extends and ulnarly deviates the wrist and extends the 5 th finger carpometacarpal joint
Extensor digiti minimi	Extends the MCP and PIP joints of the 5 th finger, and extends the CMC joint of this finger when these joints are flexed.
Extensor digitorum communis	Extends the MCP joints of the 2 nd to 5 th fingers.
Abductor pollicis longus	Abducts the CMC joint of the thumb and contribute to the radial deviation movement of the wrist.
Extensor indicis proprius	Extends the MCP and PIP joints of the 2 nd finger.
Extensor pollicis brevis	Extends the MCP joint of the thumb and abducts the CMC joint of the thumb.
Extensor pollicis longus	Extends the IP joint of the thumb.
Supinator	Supinates the forearm.

All muscles controlling the wrist movements take some part of their origins from humerus (Table 2.3). However their moment arms on the elbow joint are small, therefore their contribution to elbow movements is negligible.

Extrinsic hand muscles crossing the wrist joint induces rotational forces on the wrist joint. Especially contraction of finger flexor muscles to grasp an object in the hand results in considerable moments on the wrist joint.

Wrist tenodesis is a basic concept for the hand function. Tenodesis is the reciprocal movement of the wrist and finger joints. The changes in the wrist position affect the ability of the fingers to flex and extend maximally and grasp effectively during prehension. When the wrist is extended, fingers tend to flex and vice versa. Therefore, holding the wrist in flexion causes decrease in grip and pinch strength. This is due to the lack of change in the length of the long finger muscles [26, 27].

The functions of the forearm muscles are shown in Table 2.4.

2.1.4 Nerve Supply

Median, radial, and ulnar nerves provide sensory and motor function to the hand. Radial nerve supply motor branches for mainly extensor and supinator muscles. This nerve also supplies the sensation for the dorsal and radial border of the hand. The median nerve provides motor innervations mainly for flexor and pronator muscles. It also innervates long flexor muscles of the fingers and some intrinsic muscles. Median nerve has sensory branches innervating the palmar surface of the thumb, index and long fingers, and radial side of the ring finger. At the dorsal side, the skin area up to the PIP joint of the index, middle, and radial side of the ring finger is innervated by this nerve. Ulnar nerve supplies motor innervations for interosseal muscles, hypothenar muscles, and some thenar muscles. The sensorial distribution of the ulnar nerve includes the little finger and ulnar side of the ring finger at palmar and dorsal aspects of the hand [26].

2.1.5 Wrist Kinematics

The normal movement range in frontal plane changes from 85 to 90 degrees of flexion to 75 to 80 degrees of extension. However there is a large fluctuation among individuals. Radial and ulnar deviations are about 15 to 20 degrees and 35 to 37 degrees respectively [31, 32]. The flexion and extension movements do not occur only in the radiocarpal joint. Proximal and distal carpal rows contribute to some extent (Figure 2.8). Sarrafian [33] et al. demonstrated that approximately 60% of flexion occurs at the midcarpal joint and 40% occurs at the radiocarpal joint. Similarly during the radial deviation of the hand, the proximal carpal row moves ulnarly while the distal carpal row moves radially. The contribution of the joints to the movements in the sagittal plane is much more complex than in the frontal plane and in similar to the flexion and extension it is a combination of movements at more than one joint (Figure 2.9).

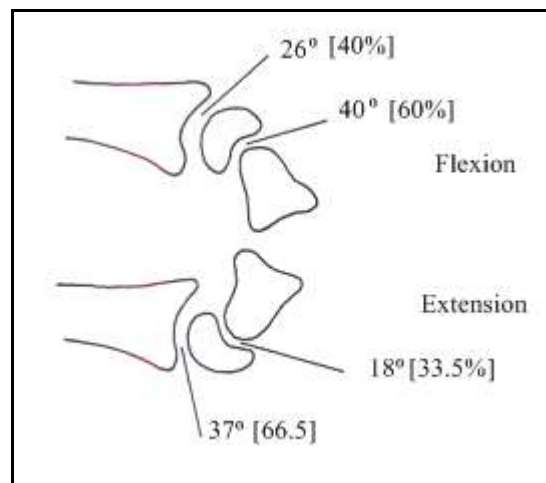


Figure 2.8 Contribution of the midcarpal joint to the total flexion and extension. Adapted from [33]

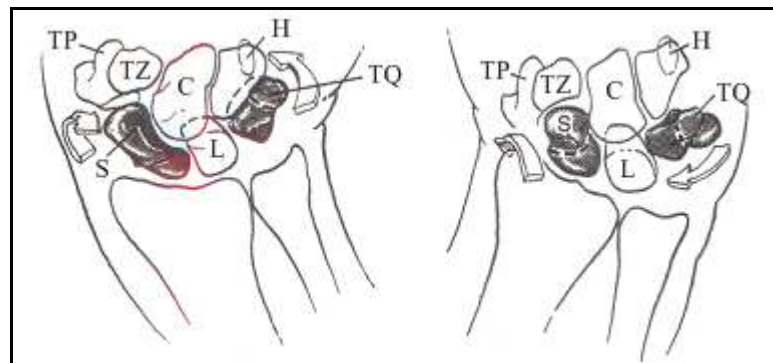


Figure 2.9 Movements of the carpal bones during ulnar (left) and radial (right) deviation (TP: Trapezoidum, TZ: Trapezium, S: Scaphoid, C: Capitulum, H: Hamatum, L: Lunatum, TQ: Triquetrum). Adapted from [27]

2.2 Carpal Tunnel Syndrome

2.2.1 Description

Carpal tunnel syndrome (CTS) is a common, painful condition of the wrist. It is caused by the compression of the median nerve in the CT at the wrist. The carpal tunnel is a closed compartment. The base of the carpal canal is formed with the carpal bones at the dorsal aspect of the hand. Transverse carpal ligament (TCL) covers the tunnel at the palmar aspect. Carpal bones are held together by ligamentous structures. They form a concave surface. This concavity forms the floor and walls of the carpal groove. The fibrous TCL (flexor retinaculum) which is a fibrous and unyielding structure converts this groove into the carpal tunnel (Figure 2.10). CT contains 9 flexor tendons of the fingers as well as the median nerve. The median nerve is superficial to the nine flexor tendons of the fingers.

At this level, the median nerve can be easily compressed by any lesion or pathological condition which increases the volume of the structures [1-3].

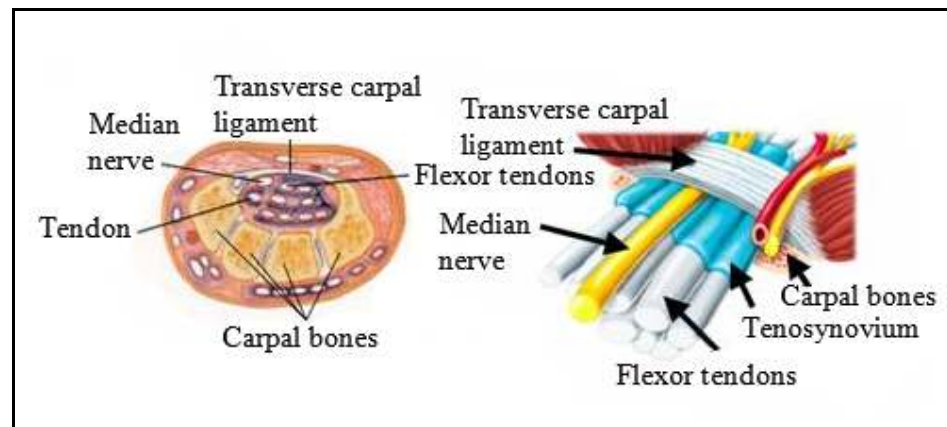


Figure 2.10 The cross-sectional view of the carpal tunnel and the structures passing through it. Adapted from [34]

In general, it is idiopathic. It is the most widely seen entrapment neuropathy and is more common in women. It most commonly occurs in adults over 30 years of age. There is a 10% lifetime risk of developing CTS. The most common form of involvement is bilateral and the severity of the symptoms is generally more prominent in the dominant hand [4, 7]. There are some prevalence and incidence studies. In a study conducted on 715 subjects aged 25 to 74 years in Holland [36], prevalence rates were reported as 5.8% and 0.6% in women and men respectively. At another study based on findings of 2466 subjects in Sweden [37], prevalence rates for women and men and were 3% and 2.1% respectively. These findings were based on the number of clinically and electrophysiologically confirmed CTS patients. The incidences of CTS in women and men were found to be 0.19% and 0.088% respectively in the year 2000 in England [38]. In this study, it was shown that the prevalence of CTS in women tended to increase during the period from 1992 to 2000. According to the age and sex specific rates of new presentations from 1992 to 2000, the CTS was more common in women aged 45-54 years and in men aged 75-84 years. At another study [39] conducted at Mayo Clinic, incidence rate was reported as 0.099 with a female to male ratio of 3:1. The incidence was highest in older men. In women, incidence was higher at the ages between 45 and 54 years.

There are some conditions or diseases which predispose someone to the CTS. The nonspecific tenosynovitis of the flexor tendons in the carpal tunnel is the most common

cause of the CTS [40]. The trauma, dislocation, or arthritic joint changes may lead to alterations in the osseous margins of the carpal bones which may eventually lead to the CTS. The other medical conditions associated with the development of CTS are, inflammatory diseases such as rheumatoid arthritis, and tenosynovitis, hypothyroidism, pregnancy, diabetes mellitus, myxedema, nephrotic syndrome, acromegaly, obesity, amyloidosis, gout, and Paget's disease [1]. In addition to the diseases or conditions mentioned above, some human-related factors may also play a role in the development of CTS. One factor is the diameter of the CT. The diameter of the CT is narrower in female compared to males. This finding supports the higher incidence of CTS in women working in industry [3, 41].

The median nerve contains the nerve fibers of motor, sensory and autonomic nervous systems. It gives motor branches to some thenar and interosseal muscles of the hand after passing through the tunnel. Sensory fibers provide skin sensation of the thumb, index, and middle fingers and the radial side of the ring finger, and the corresponding skin area of the palm at the palmar aspect of the hand. Signs and symptoms of the CTS occur when the median nerve is under pressure in the CT. Sensation area reaches to the distal interphalangeal joint creases of the same fingers at the dorsal side. The usual symptoms of CTS are paresthesias, hypoesthesia, and hypalgesia at the area innervated by the median nerve. At later stages numbness and pain can develop in the median nerve sensory dermatome and may radiate up to the shoulder. Thenar muscle atrophy and trophic changes at the skin can accompany to the other symptoms. The pain is more prominent at night and cause the patient to awaken. During pain attack, patients tend to hold their hands in a characteristic semi-flexed position. All these symptoms results in functional limitations in the daily living activities [1, 42].

The volume of the CT changes with the wrist position. There is an inverse relationship between the intracarpal pressure (ICP) and the volume of the tunnel. When the wrist is in neutral position (0 degrees of extension, and 0 degrees of radial deviation), the volume of the tunnel is at its maximum, thereby minimizing the ICP. In healthy people, the ICP is about 25 mmHg. This pressure value reaches up to about 30mmHg at the extremes of flexion and extension movements. In patients with CTS, ICP can be as high as 110 mmHg in flexion, and 90 mmHg in extension [3]. The effect of increased carpal

tunnel pressure (CTP) on the development of CTS has been shown on several researches [15-18]. It has been demonstrated that the earliest signs of peripheral nerve compression can be shown under the pressure of 20 to 30 mmHg. Axonal transport is impaired at 30 mmHg pressure. The long-term application of pressure at this level causes mild neurophysiologic changes. Gelberman et al. [15] demonstrated that the mean carpal tunnel pressure in patients with characteristic CTS symptoms was found to be about 30 mmHg. The experimental pressures up to 80mmHg result in complete intraneural ischemia. Compression at higher levels leads to intra-neural vascular injury. The degree of injury and edema is related with the magnitude and duration of the compression [47].

2.2.2 Treatment

Treatment is required if the symptoms interfere with the patient's daily life. There is a variety of treatment options. Treatment choices of CTS vary according to the stage of the disease. If there is any underlying disease, the first step should be treatment of it. Treatment of the CTS is divided into two: noninvasive and invasive treatments. Noninvasive treatment is tried first unless there is progressive motor or severe sensory deficit or severe electrodiagnostic abnormality. Treatment may include the use of wrist orthoses, the nonsteroidal, anti-inflammatory drugs, and vitamin B, iontophoresis, and therapeutic ultrasound, diuretics in patients with limb swelling, and avoiding repetitive and forceful activities [5-9, 13, 35, 48, 49]. Invasive treatment will be indicated if noninvasive treatments are not effective or if there is progressive motor deficit, severe sensory deficit, or severe electrodiagnostic abnormality [35]. In general, at patients with mild and moderate CTS, splints immobilizing the wrist in neutral position are the treatment of choice [1, 5-7]. Their use can be combined with local steroid injection. The rationale for using wrist orthoses at the neutral position lies on the relation of the disease with the increased intracarpal pressure. It has been shown that when the wrist is in neutral or near to neutral position, the intracarpal pressure is minimum. The extreme angles of flexion and extension result in dramatic increase in the CTP [8-12]. When considering the effect of increased CTP on the development of CTS, immobilizing the joint in neutral position or at least restricting the joint in a range of about 10 degrees above and below the neutral position at each plane of motion of the wrist can alleviate the compressive forces on the median nerve. By means of that, regeneration process can be facilitated. Therefore wrist splints used in

CTS are aimed maintain neutral position at the wrist [10, 12]. The effect of splinting the wrist in patients with CTS has been studied. Especially in patients with mild and moderate symptoms, it provided improvements in the symptoms of the disease [5, 7, 8, 13]. Deterministic properties for the success of the treatment in these studies were the severity and the duration of the symptoms and electromyographic examinations.

2.3 Orthoses

2.3.1 Description of orthoses

Orthoses are orthopedic devices applied to a body segment. Orthoses are used to rest or immobilize a joint, protect joints by substituting for weak or absent muscle strength, control or assist movement(s), provide feedback, correct deformity and contractures, increase joint stability, provide directional control for coordination problems, and facilitate the recovery of a joint following surgical intervention. Orthoses can also serve as a basis for the attachment of specialized devices that may facilitate function. [51, 51].

Orthoses can be classified according to the body area they cover such as wrist-hand orthoses (WHO) (Figures 2.11 and 2.12) and knee-ankle-foot orthoses. In that classification, there may be several types of orthoses for each body part. Wrist cock-up orthoses and hand resting orthoses are types of WHOs. Hand orthoses are generally called splints [50, 51].



Figure 2.11 Static wrist splint



Figure 2.12 Prefabricated flexible wrist splint

Orthoses are also classified according to whether they have moving parts. Static splints (Figure 2.11) do not have moving parts. They are mainly used to support or rest the body part, prevent motion, correct joint contractures by applying gradual stretch, or align joints. Dynamic splints (Figure 2.13) have moving parts. Movement of the parts is powered by another body part, or electrical stimulation of the muscles, springs, artificial muscles, motors or elastic or pulley traction systems [50- 52].



Figure 2.13 Dynamic ulnar deviation splint

Orthoses are made of various materials. They include the metal plates, low-temperature and high-temperature thermoplastic materials, wires, springs, and elastic textures. The introduction of lightweight, strong, and versatile materials have promoted the production and widespread use of orthoses. Easily-molded thermoplastics materials have enabled the well-fitting of the orthoses to patients. The choice of the suitable material is depend on the type of the orthosis, and the goal of the application. In general, a combination of various materials is used.

Orthoses are used in a variety of diseases and conditions temporarily or continuously. Carpal tunnel syndrome (CTS) is one of these diseases where the wrist orthoses are commonly used.

2.3.2 The effects of wrist orthoses on the hand functions

Orthoses are mainly used to provide rest and stability to the joints and relieve pain in rheumatic conditions. However while they accomplish their jobs, they can limit some functions of the hand. In the literature, there are controversial results on their effects on hand functions. This arises from the use of various kinds of wrist orthoses and subjects having different rheumatic diseases. The orthoses used in these studies can be broadly divided into two groups: prefabricated flexible wrist orthoses and custom-made SWOs. Although there are some structural differences among the prefabricated wrist orthoses they differ from static wrist orthoses with regard to their flexibility. It is possible to move the wrist joint in considerable degrees while wearing these flexible wrist orthoses. However their rigidity can differ from each other depending on the structural properties of their materials. However a custom-made SWO is constructed to fit to an individual and the amount of motion allowed is very small. This difference in flexibility may lead to differences in their effects on hand function. Biddulph [18] studied the effect of one type of prefabricated wrist orthosis (Futuro) in 22 patients with various arthritic conditions. It was found that grip and pinch strengths improved significantly over the study period of 10 days in this study. Kjekken et al. [17] studied the effects of a wrist orthosis on pain, function, and strength in a controlled study. A prefabricated wrist orthosis (Rehband) was used in the study. They found that pain and hand function improved significantly in the group of patients wearing a wrist orthosis. At this study grip pressure and pinch strengths were measured and the level of pain was measured while patients were performing two activities. Anderson and Maas [23] investigated the immediate effects of various wrist orthoses involving prefabricated and custom-made ones. No significant differences among the orthoses and control group were found in the study. Stern [21] studied the grip strength and finger dexterity across five styles of commercial wrist orthoses. Right hand subtest of Purdue Pegboard Test was used to measure finger dexterity and the grip strength was measured with a standard Jamar hand dynamometer. She found that four of the orthoses did not cause significant differences in finger dexterity compared to free hand test

condition. The four of the orthoses used in this study caused reduction in hand strength. At another study by Stern et al [19], it was demonstrated that flexible wrist orthoses reduced grip strength when they were first donned. After a 1-week period, one of these orthoses (Rolyan) afforded the same grip strength as the free hand. The reduction of grip strength was continued with the other two flexible orthoses. There are a few studies investigating the effects of SWOs on hand function in rheumatic conditions. At one of these studies [15], a newly developed custom-made SWO (ThermoLyn) and a flexible wrist orthosis (Futuro) were compared with regard to utility and clinical effectiveness. Although no significant differences were shown on the tested areas, the flexible wrist orthosis tended to be less preferable over the SWO in terms of pain relief and ease of use. Another study with SWOs demonstrated hindrance on the hand dexterity and improved hand strength [24]. However at these studies, the majority of the subjects were patients diagnosed with rheumatoid arthritis (RA). RA is an inflammatory rheumatic disease and the pathophysiology of the disease differs from that of CTS. For this reason the splinting principles and orthotic treatment protocol differ from each other. The wrist orthoses used in RA aim to hold the wrist joint in about 30 to 40 degrees of extension. This amount of extension does not hinder the tenodesis effect (simultaneous wrist extension and finger flexion). Hence less limitation is anticipated with these orthoses. In patients with RA, wrist pain seems to be the most prominent limiting factor for adequate functioning and orthoses serve to alleviate this pain by holding the wrist joint in functional position. However in patients with CTS, wrist orthoses serve to hold the wrist joint in neutral position, thereby it reduces the compressive forces and prevents the increase of intracarpal pressure. Therefore the results obtained from the experiments with other rheumatic conditions can not be generalized to CTS. In the literature, there is no any study investigating the effects of wrist orthoses on the function, dexterity and strengths of the hand in patients with CTS. However it can be anticipated that static orthoses holding the wrist joint in neutral position can lead to more restriction compared to static orthoses holding the wrist joint in functional position due to hindered tenodesis effect.

2.4 Neuromuscular Electrical Stimulation

2.4.1 Basic Principles of Electrical Stimulation

Electrical stimulation is the application of electrical pulses to the body for the purposes of function, treatment, and diagnosis. The use of electrical stimulation for therapeutic or functional purposes covers wide range of conditions including pain relief, muscle strengthening and conditioning [53], facilitation of voluntary motor function, orthotic substitution [54], neural prostheses, muscle reeducation, increasing blood flow, and relaxation of muscle spasms [55, 56].

All therapeutic electrical stimulation generators delivering currents to the electrodes are called transcutaneous electrical stimulators. Transcutaneous electrical nerve stimulators are used to deliver current pulses to peripheral nerves. The terms neuromuscular electrical stimulation and electrical muscle stimulation are used where the muscle is directly stimulated with surface electrodes [57]. Functional electrical stimulation (FES) is used to elicit movements and restore function otherwise impossible. A new kind of electrical stimulation application called threshold electrical stimulation is used to increase blood flow and growth hormone to atrophied muscles.

At the electrode-tissue interface, electronic current passing through the wires converts into ionic current in the tissue. This current leads to depolarization of nerve and muscle cells. In order to cause an action potential in the excitable tissues, the current must have sufficient strength. There are some factors determining the strength of the stimulus: (1) Electrode and tissue impedance. The impedance of the tissues is related with their water and ion content. Additional tissues between the electrode and the excitable tissue reduce the voltage gradient between them. (2) Size of the electrodes and their position. When surface stimulation is used, current intensity diminishes with the increased depth of the tissue and the current intensity is larger under the smaller electrodes. (3) Stimulation parameters such as amplitude and duration of the stimulation pulses.

Electrical stimulation can be delivered using monopolar or bipolar electrode configurations. In the bipolar configuration two electrodes are positioned in the vicinity of the muscle or nerve. In the monopolar configuration active electrodes (cathodes) are positioned in the vicinity of the muscle or nerve, while a single common electrode (anode) is positioned distant to the tissue to be stimulated, somewhere along the neural pathway to the CNS. Stimulation electrodes can be placed in different ways near the nerve within the body or on the skin over the target. Motor nerve stimulation can be achieved by means of electrodes placed on the skin, on the surface of the muscle, in the muscle, on the motor nerve or in the motor nerve. Three types of nerve electrodes are used for this purpose. Surface electrodes are placed on the skin surface. Surface electrodes consist of a metal plate with an electrolytic gel to maintain contact. Stainless-steel, silver-silver chloride, platinum or gold plated surfaces are commonly used materials for surface electrodes. Self-adhesive flexible electrodes made of carbon filled silicon rubber or conductive polymers are also available to use and conforms to various body contours. Surface electrodes are commonly used in rehabilitation, diagnostic, and research purposes [58]. They are easy to use and can be placed noninvasively. However placing them correctly for daily applications can be a problem. The selectivity provided with the surface electrodes are limited and large amount of currents is required to activate muscles. The humidity of the skin and changes in electrode positions can lead to alterations in stimulation characteristics and they can lead to discomfort at intensities sufficient to activate the muscles. All nerves or muscles are not easily accessible for surface stimulation. Some muscles or nerves lie in the deeper layers of the body or they are covered with other excitable tissues not intended to be stimulated. In these cases the electrodes have to be placed in the vicinity of the target excitable tissue. Implanted electrodes are powerful means for reliable and reproducible control of the paralyzed muscles since they offer more selectivity than surface electrodes. Epimysial or intramuscular electrodes are placed on the surface of a muscle or in a muscle respectively. They can be positioned closer to the target motor nerve with respect to the surface electrodes. Epimysial electrodes are sutured to the surface of the muscle or surrounding tissue at the nerve entry point. They have been successfully used to regain the opening and closing of the hand in spinal cord injured patients. Intramuscular electrodes are inserted into the motor end-points of muscles. However, they are more susceptible to breakage. Discomfort due to stimulation of the cutaneous sensory fibers and activation of the non-target muscles can be avoided by these electrodes. Electrodes can also be placed

on or in a nerve. They are called extraneural (cuff) or intraneural electrodes respectively. These kinds of electrodes provide the ability of selectively stimulation of the muscles. Extraneural electrodes encircle the nerve and less invasive. Multipolar nerve cuffs electrodes allow specific portions of the nerve to be independently stimulated and limit the number of implanted components of the system. With these electrodes, threshold of the stimulation currents can be lower, thereby reducing the demand on the power requirement. However invasive methods are required for the placement of this kind of electrodes. The stimulation devices delivering current to the electrodes placed under the skin may either be implanted, or connected the electrode wires via percutaneous wires. Since permanent wounds raise the risk of infection and need elaborate care, implantable stimulators are preferred. Implanted electrodes remain in place permanently, and the stimulation outcome is better defined over longer periods than with surface electrodes [54, 59, 60, 61].

Neuromuscular stimulation can be modeled with a relatively simple electric circuit: generator, electrodes, and tissue. The tissue is an ionic conductor having an impedance of about 10 to 100 Ω . The electrodes are capacitive conductors having impedance from 500 Ω to 5 k Ω . They induce a phase shift of about 10° to 30° . Electrical impedance of the skin has been modeled (Figure 2.14) [62, 63]. The generator can work as a current or voltage regulated device. The amplitude and duration of stimulus pulses, output impedance of the generator, and impedance of electrodes determine the electrical charge that will be delivered to neuromuscular structure. Stimulators are usually referred to as constant-current or constant-voltage devices. Current-regulated stimulators precisely control the charge delivered to the tissue (Figure 2.15). However if the surface of the electrode is too small, they may cause tissue damage [60].

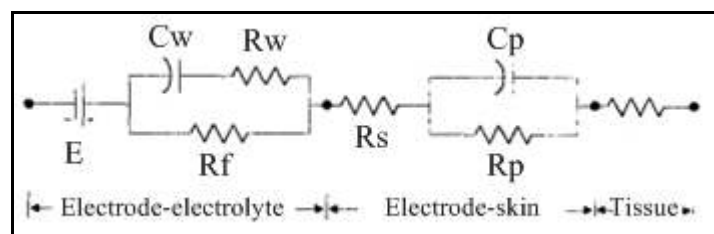


Figure 2.14 The skin-electrode impedance model (E: half-cell potential, R_i : bulk tissue resistance). Adapted from [62]

During the ES, the waveform selected is generally rectangular. A nonrectangular pulse could be utilized, but the rise time must be sufficiently fast so that the nerve

membrane does not accommodate and fails to open its channels. The stimulus waveform may be unidirectional (monophasic) or bidirectional (biphasic). Surface stimulation is more comfortable with biphasic than monophasic stimulation. For implanted electrodes, the potential for damage to the tissue will be lessened with the biphasic stimulus. Tissue damage is significantly related to the pH change at the electrode tissue interface. At the cathode, the pH may increase, while at the anode the environment will become more acidic. While some buffering capacity for pH changes exists in the tissue, the changes with monophasic stimulation are greater than those with biphasic stimulation. Although reactions at the electrodes are not completely reversed with the biphasic stimulation, this stimulus allows significantly greater charge injection before tissue damage is encountered [54, 60].

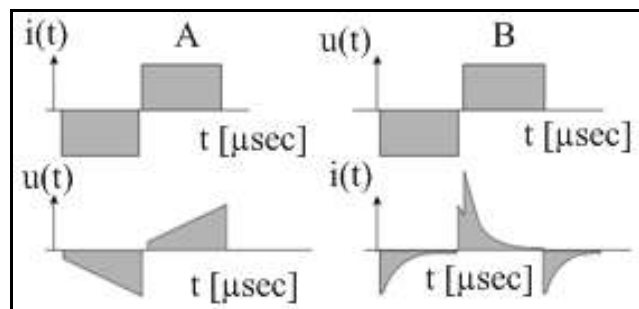


Figure 2.15 The stimulator output shape of pulses. (A) Current-regulated stimulation; (B) voltage-regulated stimulation. The top panels show the output of the stimulator; The bottom shows the current and voltage applied to the tissue. Adapted from [60]

Excitable tissues of the body are nerve, muscle, and sensory cells. ES leads to generation of action potentials in excitable tissues.

2.4.2 Structure of the Nerve

The nerve cell is an electric active cell (Figure 2.16). Nerves transport electrical signals from their source to the target. Nerves carrying control signals from the upper centers to peripheral regions are called efferent nerves. Afferent nerves carry sensory and kinesthetic signals to the upper centers of the central nervous system (CNS). The smallest units of these signals are called action potentials. All electrically excitable cells are able to transport or generate action potentials [59].

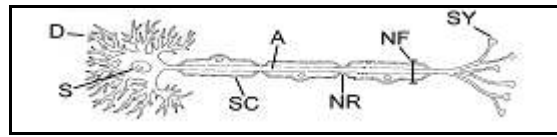


Figure 2.16 Schematic drawing of a motor nerve cell, A: Axon, D: Dendrite, NR: Node of Ranvier, S: Soma, NF: Nerve fiber, S: Synapses. Adapted from [64]

The bodies (soma) of all nerve cells are located in the central nervous system (CNS). The bodies of the 1st (upper) and 2nd (lower) motor neurons are located in the brain and medulla spinalis (MS) respectively. Axons and dendrites are the branches of a nerve cell. The axon of a 1st motor neuron terminates in the anterior horn of the MS. After leaving the soma, the axon of a 2nd motor neuron reaches to its destination in the peripheral regions. The sensory neurons carry information from sensory cells to the CNS. The cell body of a sensory nerve is located in the dorsal horn of the MS. The axons of the myelinated nerve fibers are surrounded with a myelin layer formed by Schwann cells. A nerve is composed of 100 to 2000 single nerve fibers which are organized in bundles within a nerve (Figure 2.17). The diameter of a single nerve fiber is about 12 μ m. The cell membrane of a nerve cell separates the inner compartments of the cell from the environment and allows different substances to pass through it constantly. In its initial stable state there is a potential difference between the inner and outer side of the cell membrane (about -60 mV in nerve cells of humans). Ion pumps force positive ions out of the cell. In this way the voltage of this polarized state is maintained. Ion channels allow selective ions to pass into and out of the cells [59].

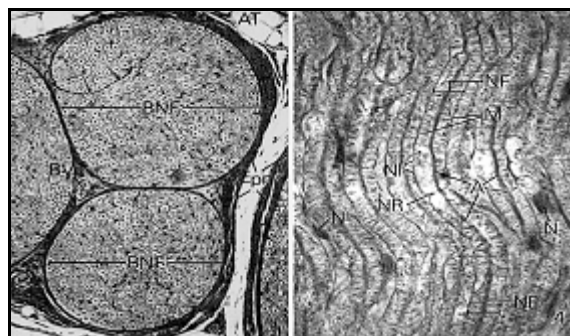


Figure 2.17 Cross section and longitudinal section of the human sciatic nerve. A: Axon, D: Dendrite, NR: Node of Ranvier, AT Fatty Tissue, Epn: Epineurium, S: Soma, BNF: Bundle of nerve fibers, M: Myelin layer, SC: Schwann cell, BV: Blood. Adapted from [65]

The ion channels may either be open or closed depending on electrical voltage, mechanical stress, certain chemical substances, temperature influences or other variables.

Every channel is selective for a specific type of ion. If the electric potential in the cell rises above a threshold value one type of channel opens. That causes positive sodium ions (Na^+) to enter the fiber. This further increases the potential in the cell. This results in an exponential rise of the voltage across the membrane until it reaches its depolarized state. Other ion channels open up to reverse the process and return the fiber into its polarized state. The time course of the voltage across the membrane during the process of excitation to depolarization and back to polarization is called action potential. This process generally lasts some milliseconds. Because of their form action potentials are often referred to as spikes and a sequence of potentials would be a spike train. Action potentials appear in nerve cells as well as in muscle cells. Action potentials in muscle cell initiate contractions [59].

When a single pulse is applied directly to a motor neuron, the corresponding muscle fiber will respond in an all-or-none fashion. Increasing the intensity of the pulse will not increase the magnitude of the fiber's response. When a single adequate pulse is applied to a motor neuron, the muscle innervated by this neuron will respond with a quick contraction. This is immediately followed by relaxation. Such a response is called a twitch. Its magnitude will vary with the number of muscle fibers, which respond to the stimulus, and this will vary directly with the intensity of the pulse up to a finite maximal intensity. A single electrical pulse must have a certain minimal intensity to be effective. The minimal effective intensity is designated as the threshold or minimal stimulus. Subthreshold and subliminal refer to a stimulus of inadequate intensity. As the intensity of the single pulse is increased above the minimum, the contractile force in the muscle increases progressively. This is the result of the activation of more and more muscle fibers. Finally, the intensity that evokes the maximal response of the muscle is reached. At that point all fibers are presumably active. The weakest stimulus intensity that evokes maximal contraction is called the maximal stimulus. A weak but adequate pulse with a rapid rate of rise from zero to its preset intensity will evoke a stronger contraction than a pulse of the same intensity with a slower rise. A minimal rate is required even for an intense stimulus. If intensity rises too gradually, there will be no response at all; the stimulus is then ineffectual [60].

The relationship of intensity and duration of single current pulses in the production of a contraction is shown in the intensity-duration curve (Figure 2.18). The minimal

current required for stimulation is termed the reobasis, and the duration that is required to elicit activation when the stimulation pulse has the intensity twice greater than the reobasis is the chronaxia.

The more abruptly the stimulus is applied, the greater the response of the muscle will be. As the rate decreases, the response will diminish until ultimately, regardless of intensity, the stimulus becomes ineffectual. The decreased effectiveness of a constant intensity at long duration and/or low rate of rise are designated as adaptation or accommodation. If an adequate stimulus is applied to a muscle fiber repeatedly at a rate rapid enough for each succeeding stimulus to reactivate the contractile elements before the previous force has completely subsided, successive responses summate, each building upon the previous one until a maximal level is achieved. If stimulation is continued, the contraction peak is maintained at this level. Such a response is known as tetanus or tetanic contraction. When stimulation ceases, contraction terminates, and the fiber relaxes. However, if the repetitive stimulation is too prolonged, contracture will result, and relaxation will be significantly slowed as compared with normal [60].

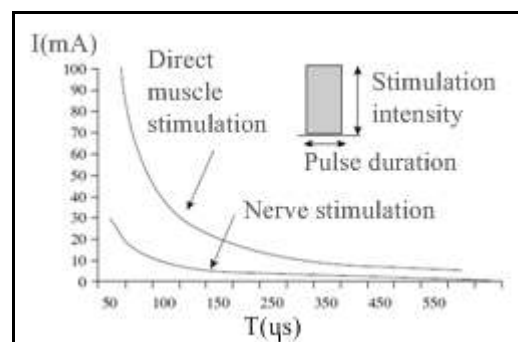


Figure 2.18 The intensity (I)–duration (T) curve. Adapted from [40]

Action potentials are transmitted to the other excitable tissues through synapses (Figure 2.19). Synapses appear in every place of the body where excitable cells interact. When action potentials at the presynaptic terminal enter a synapse, they cause the emission of transmitter substances into the synaptic cleft. These substances travel across the synaptic fault to the postsynaptic terminal and cause selectively opening of ion channels. This leads to a new action potential in the postsynaptic terminal of the synapse. The synapses that form the nerve-muscle interface are also called motor end-plates. Some types of synapses inhibit action potentials [59].

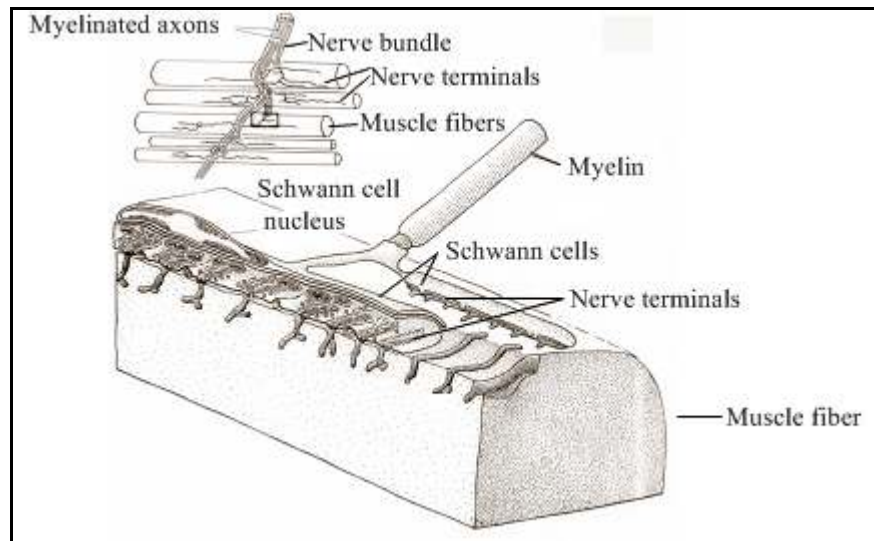


Figure 2.19 The nerve-muscle interface of the frog. Adapted from [66]

Motors axons branch into several smaller segments where they are in contact with the individual muscle cell. Therefore a single action potential traveling on a motor axon induces action potentials on more than one muscle fiber. The collective of muscle cells innervated by a single axon in this way is called a motor unit. The size of motor units ranges from a few up to 1700 muscle fibers depending of the type of muscle and the task it has to perform [39]. Nerve fibers are classified into three major groups, A, B, and C, on the basis of conduction velocities. Group C contains the unmyelinated postganglionic fibers and group B the small myelinated preganglionic fibers of the autonomic nervous system. Group A includes the large, rapidly conducting myelinated somatic fibers. Group A has been further divided into four subgroups: α , β , γ , and δ based on the velocity and diameter [60]. Velocity of conduction depends not only on myelination but also, on the diameter of the fiber. The conduction velocity is proportional to the diameter of the axon, and is in the range of 50 m/sec. The largest motor and sensory nerve fibers (diameters about $20\mu\text{m}$) have conduction velocities up to 120 m/sec. In small unmyelinated fibers, the velocities are from 0.7 to 2 m/sec. Large fibers have lower stimulus thresholds compared with small fibers.

The excitability of nerve fibers changes with the diameter of fibers. Motor unit recruitment order during voluntary effort in humans follows the size principle [67]. According to this principle, the size of the motoneuron determines the order in which

motor neurons are activated. Slow-twitch motor units (with type I skeletal muscle fibers) are recruited first, followed by the fast-twitch motor units (with type II skeletal muscle fibers) as the force demand increases. Recruitment of fast-twitch motor units proceeds from type IIa fibers to type IIb fibers with increasing intensities [68].

During the direct stimulation of nerves, this natural recruitment order reverses. Nerve fibers with larger diameter are more easily excited with respect to those with smaller diameter. This effect is called as reverse recruitment order. However Knaflitz et al. [69] concluded that, motor units are not in general recruited in reverse order of size during electrical stimulation of a muscle motor point. This is contrary to what is observed in direct stimulation of nerves. Geometric factors or a lack of correlation between axonal branch diameter and the diameter of the parent motoneuron axon may lead to this.

2.4.3 Structure of the Muscle

The shortening and broadening of the muscle lead to changes in the joint angle. Muscles consist of various layers of connective tissue. A muscle is composed of thousands of muscle cells called muscle fibers (Figure 2.20). These muscle fibers are covered by the innermost layer of connective tissue, called the endomysium. Muscle fibers are arranged into bundles called fascicle. The next layer of connective tissue called perimysium surrounds each fascicle. A skeletal muscle is composed of many fascicles. The outermost layer of the connective tissue is called epimysium and surrounds the muscle.

The sarcolemma is beneath the endomysium and surrounds each muscle fiber (Figure 2.21). It contains the muscle fiber's cellular contents. The sarcoplasm of the muscle fiber contains the nucleus, myofibrils, enzymes, energy sources, and various specialized cellular structures.

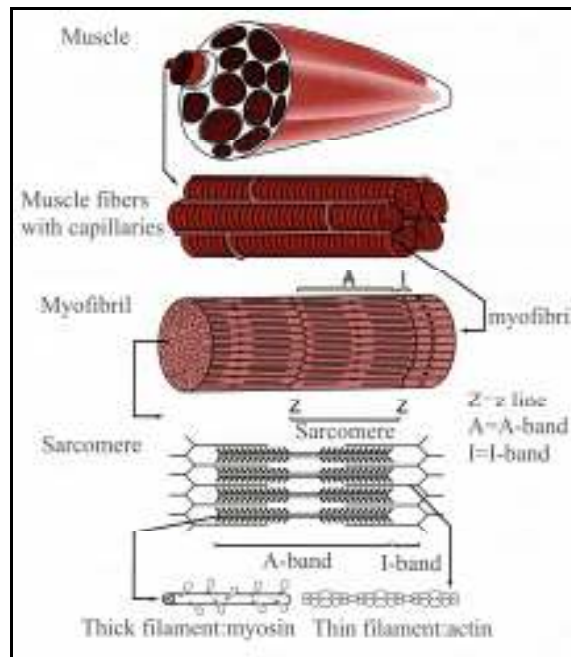


Figure 2.20 The schematic drawing of the skeletal muscle structure. Adapted from [70]

As shown in the Figure 2.20, each muscle fiber is composed of small fibers called myofibrils. Myofibrils are composed of myofilaments. A sarcomere is a functional unit of the muscle fiber. It is also the contractile unit of the entire myofibril. Two zones appear in the sarcomere structure. The I band is the lighter zone and contains some portion of the actin filaments that do not overlap with the thick filaments. The darker zone is called A band. In that region of the sarcomere, actin and myosin myofilaments overlap. The I band is bisected by the Z line. A sarcomere is positioned between two Z lines. [70] In the presence of an action potential, the sarcoplasmic reticulum releases Ca^{2+} ions. The calcium ions bind to troponin. This interaction exposes a myosin binding site on the actin molecule.

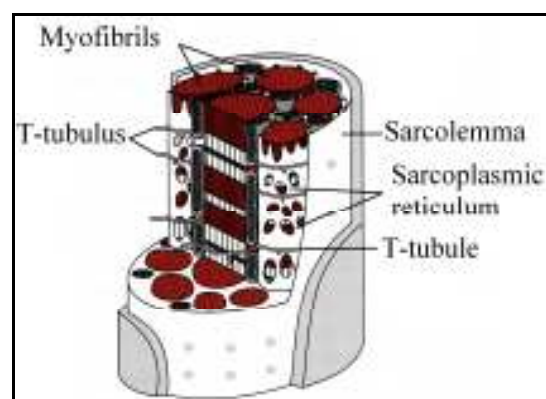


Figure 2.21 The structure of a muscle fiber. Adapted from [70]

In the presence of ATP, the myosin head binds to actin and pulls it along the myosin filament. This causes the sarcomere to shorten. In the presence of Ca_2^+ and ATP, the myosin heads will attach to the actin molecules, pull it, release, and reattach. This process is called cross-bridge cycling [71]. At the Figure 2.22, the actin–myosin orientation within a sarcomere at resting and contracted lengths is shown. Actin has the shape of a double helix (Figure 2.23). The troponin and tropomyosin are important constituents of the actin filament. They regulate the making and breaking of contacts between the actin and myosin filaments during contraction of the muscle.

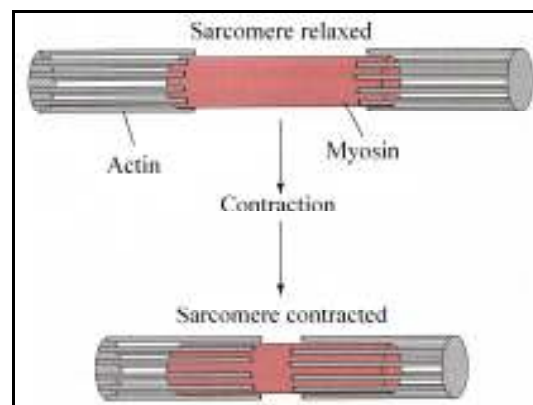


Figure 2.22 Actin and myosin relationships in relaxed and contracted muscles. Adapted from [70]

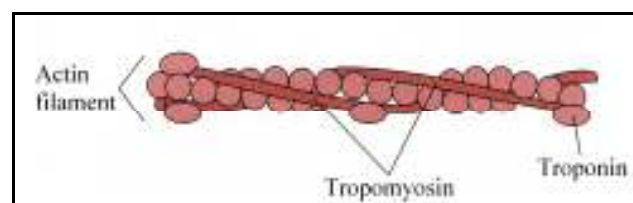


Figure 2.23 The structure of the actin molecule. Adapted from [70]

There are two basic types of skeletal muscle fibers. They are distinguished from each other by their speed of contraction and endurance. Type I fibers are the slow-contraction, high-endurance muscle fibers. They have lower thresholds, tetanize at lower frequencies, fatigue-resistant, and are more sensitive to stretch than the faster fibers. These fibers are aerobic and the major source of energy is fat. The muscles rich in type I fibers are generally the antigravity muscles and appear red. High amounts of myoglobin and a high capillary content result in redness of these muscle fibers. The greater myoglobin and capillary content in red muscles contributes to the greater oxidative capacity of red muscles compared with white muscles. Type II fibers are capable of faster contractions, but more

sensitive to fatigue. This type of fibers is prominent in muscles where maximum force is needed and fatigue is not an issue. Type II fibers have a greater diameter than fibers of type I. This type of muscle fibers is further divided into Type IIa and IIb. Type IIa fibers (fast oxidative glycolytic) are also aerobic and contain some mitochondria. With proper training they will increase the number of mitochondria. The major source of energy is glucose. These fibers come into play when the intensity of our work is between 75% and 85% max heart rate. Type IIb (fast glycolytic) fibers are anaerobic. They contain no mitochondria and do not have the enzymes for the Krebs cycle. Their only source of energy is glucose. They produce an abundance of lactic acid. They come into play when intensity of work is in the anaerobic range. Muscles predominantly composed of fast-fibers are phasic muscles and appear white. They produce quick postural changes and fine skilled movements. Most human striated muscles contain both types of fibers in differing proportions [59, 60, 71].

Natural voluntary contraction with a relatively weak force mainly involves fatigue resistant type I muscle fibers that are innervated by motoneurons with a small diameter. The large, fast nerve fibers that are easier to excite by electrical stimulation, innervate type II muscle fibers. Those muscles have a fast, high twitching force, but are fast fatiguing. For normal grasp tasks type I muscle fibers are used and on demand for faster reaction or a higher force type II fibers are recruited. With lower stimulation intensity first large nerve fibers connected to type II muscles are recruited. Small nerve fibers connected to type I muscle fibers start being recruited with increased stimulus strength [72]. Therefore reverse recruitment order due to ES leads to early muscle fatigue. Fast, fatiguing muscle fibers will be stimulated most of the time, which makes them more prone to fatigue [59]. This fatigue is much more prominent in denervated muscle fibers due to accompanying changes in normal muscle histology. Some special stimulation techniques have been developed to alleviate this problem. A conditioning program before the long-term ES applications such as FES is also used to increase the proportion of fatigue resistant type I muscle fibers.

The length of the muscle at the time of activation affects its ability to develop force. There are three types of muscle contraction: isometric, isotonic, and isokinetic. Isometric contraction refers to the case where no change of length occurs, isotonic to the case where the force is kept constant and isokinetic when the velocity of shortening is kept constant.

2.4.4 Force Development

In a healthy subject, the forces generated by muscles are controlled with the number of activated motor units and firing frequency of the active motor units. When a muscle contraction is produced with stimulation pulses, a number of factors such as the characteristics of the stimulus, the length of the muscle, and the speed at which the muscle is contracting influence the force development in the muscle. The initial length of a muscle influences the magnitude of its contractile response to a given stimulus. A stretched muscle contracts more forcefully than when it is unstretched at the time of activation. This is true whether the contraction is isometric, isotonic, or isokinetic (Figure 2.24) [60].

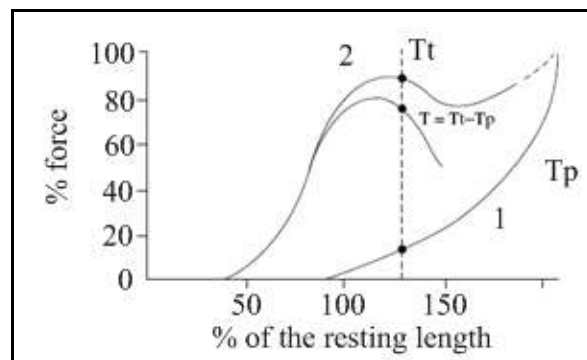


Figure 2.24 Force vs. length curve for an isolated muscle. (1) Passive elastic tension, (2) total force, and (3) force obtained by subtracting of passive force from total force. Adapted from [60]

In electrical stimulation, the number of recruited fibers may be controlled by the strength of the charge. This is a product of the stimulation current and the impulse duration. The relation between one of these two parameters and the muscle force output is frequently termed recruitment curve (Figure 2.25) [59].

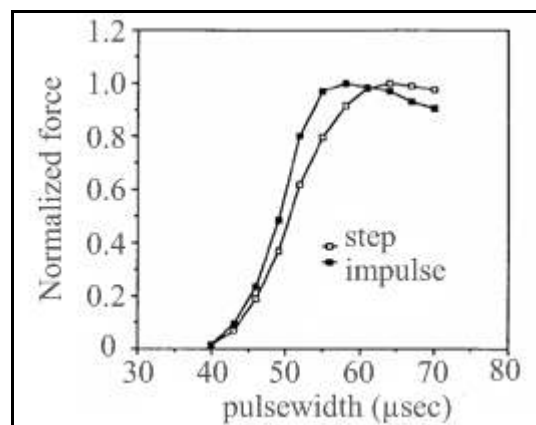


Figure 2.25 The recruitment Curve. Adapted from [73]

To some extent the frequency may also be applied for the force control (frequency modulation). Figure 2.26 demonstrates the increase in muscle force output due to increased stimulation frequency. At frequencies up to 10 Hz the force twitches elicited by the stimulation impulses can be clearly distinguished. At higher frequencies the single twitches overlap to form a smooth contraction. There is no marked increase in force if the stimulation frequency is raised above 30 Hz. Thus the force output for smooth contractions controlled by stimulation frequency is small. The effect of different stimulation frequencies on the development of muscle force at spinal cord injured patients have been investigated [74]. At most ES applications, muscle force is modulated by recruitment process (recruitment modulation). The number of recruited motor units is determined by the stimulation intensity. As the strength of the stimulation increases, more motor units are recruited. Stimulation strength can be altered by changing either the stimulation amplitude or pulse duration [61, 75, 76]. At a recent study [76] combining various combinations of frequency- and pulse-duration- modulations, it is concluded that frequency-modulation showed better performance at peak forces and force-time integrals than pulse-duration-modulation [77].

Although numerous combinations of frequency, amplitude, and duration can be used to generate the required muscle force, most of the clinical electrical stimulation systems [75, 78] use the minimum frequency that can generate a smooth contraction. The intensity of the amplitude is varied to produce the desired force [78]. At FES applications, the targeted muscle force is determined by the task requirements. Therefore, the most suitable combination of parameters will be task dependent.

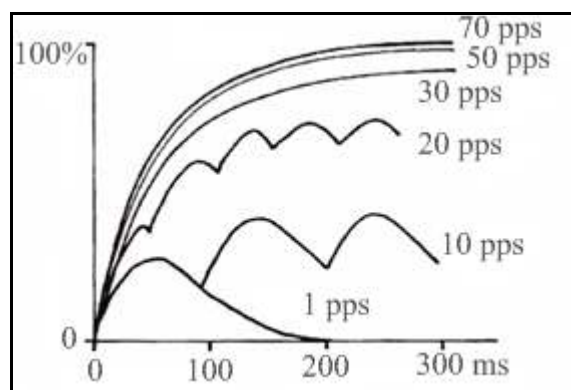


Figure 2.26 Muscle force as a function of stimulus frequency (pps=pulses per second, Hz).
Adapted from [80]

2.4.5 Muscle Fatigue

For effective task performance during electrical stimulation, it is necessary to maintain the level of muscle force. However, during electrical stimulation, skeletal muscles fatigue more rapidly, thereby limiting the clinical use of the electrical stimulation for functional purposes. The differences in motor unit recruitment order, higher activation frequencies and imprecise control of muscle force results in rapid fatigue [78, 79, 80]. Muscle fatigue is much more prominent in paralyzed muscles. In general, early fatigue in FES applications has been linked to the reversal of the size principle, higher stimulation frequencies, and synchronized contraction of muscle fibers. The suggestion that the use of electrical stimulation to obtain muscular contraction results in early fatigue is based on 2 findings: (1) the axons of the larger motor units have a lower resistance to current and conduct action potentials at faster rates than the axons of smaller motor units, and (2) data demonstrate increased fatigue with electrical stimulation versus voluntary contraction [67, 81, 82]. However, at another study it is proposed that electrical stimulation recruits motor units in a non-selective, spatially fixed, and temporarily synchronous pattern. Additionally, the evidence that supports the contention that this recruitment pattern leads to more muscle fatigue compared to voluntary contractions has been shown [81]. At the same study it is proposed that the reversal of recruitment pattern presumed is based on data derived from studies of lower animals and the neurophysiologic principles used these studies cannot be strictly applied during typical electromyostimulation applications to humans. Factors that affect current flow result in a different physiological environment relative to the animal studies. These factors may be skin impedance, subcutaneous fat, and peripheral nerve orientation.

Another factor that leads to early fatigue is that after motor neuron lesions, skeletal muscles undergo marked changes in their morphological, metabolic, and contractile properties. Histo-chemical and metabolic profiles of a muscle change toward Type II fibers after upper motor neuron lesions. Consequently, the heterogeneous human muscle composed of similar amounts of type I and type II fibers shifts towards a homogeneous muscle composed of predominantly type II fibers. Therefore, the activation of a muscle rich in type II fibers results in early fatigue.

Several stimulation techniques and methods have been developed to lessen the fatigue. Some stimulations techniques such as anodic block, subthreshold depolarization prepulse, and single cathode are aimed to reverse the recruitment order. Selective stimulation of muscles by implanted electrodes, improvements in the electrode design, and introduction of some new stimulation waveforms such as “doublets” and “triplets” and asynchronous stimulation with multiple electrodes help to decrease the level of fatigue [61, 83-86].

2.5 The Use of Electrical Stimulation for Function

ES can be used to obtain some functions of the upper and lower extremities. The use of ES for the purpose of function is called FES. In general, FES is used to activate paralyzed muscles caused by 1st motor neuron diseases or injuries where the muscle and its innervating nerve (2nd motor neuron) preserve their integrities. Therefore muscles can take their control signals via their motor points. Motor point is the point on a muscle which enables the greatest motor response with minimal stimulating current. Motor points anatomically correspond to motor end-plates of the muscles. However at the 2nd motor neuron diseases or injuries it cannot be used since motor end-plates are not intact and the normal histology of the muscle is changed. However, at the 2nd motor neuron injuries this condition, contraction of the superficial muscles can be elicited with large amount of currents conducted with superficial electrodes placed on the muscle. However, the quality of the resulting contraction is not good and fatigue can develop easily. Studies on FES systems using surface ES was started with the studies of Liberson and his colleagues [87].

The main problem in the FES applications is to control the movement. The movement elicited by delivering the stimulation pulses to the muscle has complex, non-linear, and time-varying properties. While designing a FES system, these characteristics of the musculoskeletal system should be considered. Some investigators have developed neuromusculoskeletal models under specific conditions to aid the design of FES systems [88, 89].

2.5.1 FES systems for lower limb

Several commercial FES systems have been developed to assist ambulation of paralyzed patients. Most of them have been developed for the management of drop-foot. *WalkAid* [90] was designed for the management of drop-foot. It uses a tilt sensor to turn the stimulation on and off. It uses surface electrodes to deliver the stimulation pulses to the muscles. *The Odstock Dropped Foot Stimulator (ODFS)* [91] has a single or dual channel stimulator for the management of drop-foot. Common peroneal nerve is stimulated via self adhesive surface electrodes. Foot switches trigger the stimulation pulses. Rise and fall stimulation envelope can be adjusted. *MicroFES* [92] is used to correct drop foot in paralyzed subjects. Stimulation impulses are delivered with surface electrodes. *The Hybrid Assist System (HAS)* [93] uses surface stimulation technique with an externally powered brace to assist walking. *The RGO system* [94, 95] contains passive braces together with surface stimulation for the assisted walking. *Parastep* is a multi channel stimulator for assisting standing and walking of spinal cord injured patients. Quadriceps muscle and common peroneal nerve are stimulated. It has four stimulation modalities: sit/stand, stand/sit, right step/left step, left step/right step. Right step and left step functions are used with the help of a walker with finger activated controls. An ankle foot orthosis is usually used.

2.5.2 FES systems for upper limb

Some FES systems to restore some functions of the upper extremity have been developed mainly for spinal cord injured patients. *FESmate* [96] is a portable multi-channel (30 channels) FES system with percutaneous electrodes. It has been used for restoring hand grasp in patients with spinal cord injury. It consists of a system controller and a portable 30-channel stimulator. The stimulation parameters are composed and stored in the system controller. *Handmaster* [97, 98] uses surface stimulation together with a forearm-wrist splint. A push-button switch and a sliding resistor are used to adjust the position of the hand. This system is later improved with the addition of a PC-based system (*Handmaster NESS*) which enables greater flexibility and ease of use. *FreeHand* system [99] is an implanted system. It has 8 output channels. The movements of an externally placed position sensor are used to open or close the fingers. Stimulator is implanted into

the chest. Lateral and palmar prehensions can be provided with this system. *Bionic Glove* [100] is used to improve the grasp with the aid of tenodesis effect. This system can be used in subjects with active control of flexion and extension of the wrist. To sense the wrist movements, a position sensor is mounted on the wrist. Similar device using electromyography (EMG) signals of the wrist extension muscles have also been developed [101]. *The Belgrade Grasping System* [102] was developed to provide hand grasp and reaching function. It has 4 output channels. 3 of them are used to elicit grasping function and the other is used to extend the elbow joint by the stimulation of the triceps muscle. Hand opening and closing are controlled with a push-button switch and the elbow extension is triggered by measuring the subject's shoulder velocity measured with an electrogoniometer. *The system developed by Vidovnik et al.* [103] has three stimulation channels with two stimulation electrodes per channel. Thenar muscles and finger extensor and flexor muscles are stimulated to obtain grasping function. Patients are able to control the stimulation trains. EMG sensor, pressure sensor, or a sliding resistor can be connected to the system.

2.6 Control Systems and Sensors for FES Applications

2.6.1 Control Systems

The use of electrical stimulation to obtain function requires the implementation of various control strategies into the FES system. There are three hierarchical levels in control systems. At the highest control level, actions of the healthy part of the body such as shoulder movements are used to detect the intention of the user to perform a certain movement. Movements of a body part and changes in posture and forces can be measured for this purpose. At the intermediate control level, the sensors are used to provide feedback for the coordination of movements. For example, signals derived from heel switch can be used to detect the phase of the gait. A combination of complex control strategies and sensor systems can be used to obtain functional movements in spinal cord injured (SCI) people. At the lowest control level, continuous feedback control of the electrically stimulated muscles is provided with sensory signals [104].

FES controllers form a set of stimulation parameters to achieve the muscle contraction. There are two basic forms of controllers: open loop and closed loop. *Open-loop control systems* are relatively simple and low-cost. In an open-loop control system, the output from the system has no effect on the input signal and stimulation parameters are predetermined. This approach results in some important limitations. They require manual tuning, produce uneven movements and can lead to over stimulation leading to rapid muscle fatigue. They suffer from lack of the sensitivity to either external disturbances or changes of the system parameters such as fatigue and alterations in the muscle tone and require initial and periodic adjustments which are time-consuming. Open-loop control systems can be divided into the subgroups. *User-controlled open-loop control* is the simplest type. User adjusts the settings or simply turns on or off the system. At *cyclical open-loop control*, the stimulus settings are fixed and every time these settings are repeated without taking any feedback about the effect of the stimulus. *Triggered cycle open-loop control* allows each stimulus train is to be triggered by an action. To overcome the problems imposed by the open-loop control new control strategies have been developed and tested in various FES applications. Figure shows general block diagram for FES control systems [61, 105].

In a *closed-loop control system*, a sensor monitors the effect of the stimulus and the required adjustments are made according to the changes in the answer. A closed-loop system matches the actual values with the required values. By means of that, closed-loop controllers can compensate disturbances and control stabilizations. For example, a closed-loop control strategy used in a FES application for paraplegic standing may detect collapse of the knee while it monitors the knee angle and increase the stimulus strength to the quadriceps muscle. However, closed-control they are more complex and high-cost [61, 105, 106, 107]. There are 5 basic elements of a closed-loop system (Figure 2.27).

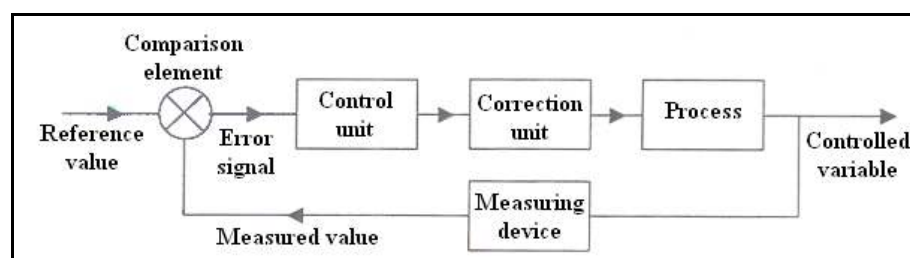


Figure 2.27 The basic elements of a closed-loop system. Adapted from [105]

Comparison element compares the required or reference value of the variable with the measured value of and produces an error signal. It can be regarded as adding the positive reference signal to the measured negative value signal. In a feedback loop, a signal related to the actual condition being achieved is fed back to modify the input signal. If the signal which is fed back subtracts from the input value, it is said to be negative feedback. When the signal fed back adds to the input signal, it is called positive feedback. Control element decides the action to be taken if an error signal is received. Control plans may be fixed or programmable. Correction element produces a change in the process or change the controlled condition. Process element is what is being controlled. Measuring element produces a signal related to a variable condition of the process that is being controlled [105].

In addition to these basic control mechanisms, some control methods based on closed-loop control and a combination of several control methods can be used in FES applications. Feedforward control linearizes the characteristics of the actuator system. Muscle is a nonlinear system, so feedforward is of a great value in muscle control system. It requires the use of an inverse model of the known linearities of the controlled system. When applied, the whole system appears to be linear. Feedforward control does not introduce the delays inherent in closed-loop feedback control. Due to approximations in the model and unpredictable changes in the system, the feedforward inverse model is not perfect. Closed-loop control may be added to increase the system performance. In multistate control, the controller reads the pattern of sensor signals and uses them to interpret the desired state. It uses fixed rules for the transition between one state and the other. Neural net controllers can learn new sensor patterns and associate them with new stimulation patterns. Multilevel control may contain a multilevel organization with elements of open-loop, closed-loop, multistate, and neural net characteristics. However such neuromuscular controllers do not exist at present [107].

Dynamic properties of the muscle contraction should be considered in the design of control systems. There is a time-delay of 50-100 ms between delivering the first stimulation pulse and development of muscle contraction. Contraction force is a dynamic function of the stimulation pulse trains. This dynamic process has been represented in various studies in complexities from a linear first-order model to complex, nonlinear, time

varying higher order models. In order to reduce muscle fatigue, some optimal control algorithms were developed for feedforward FES controllers. Various closed-loop FES controllers have been proposed to avoid the need for extensive tuning. Adaptive feedback control techniques not requiring subject-specific models and are less limited by persistent excitation requirements have been designed and tested [61].

2.6.2 Sensors for FES

Electrical stimulation controlled-movement applications (ESCM) should provide information about the conditions of the system. This is achieved via the use of feedback which can be kinetic or kinematic physical quantities. Kinetic quantities are angles and angular velocities of body segments or joints, and position, velocity and acceleration of specific points of the body. Kinetic quantities are related with the pressure distribution, joint moments and forces [60, 104].

Sensors convert physical quantities into a signal relating to the quantity being measured. Sensors must be cosmetically acceptable and easy to use, have lower consumption, and must provide adequate information about the physical quantity being measured. Sensors used in FES applications are divided into two according to their positions: surface and implanted sensors. Surface sensors are common. They are open to environmental conditions and when they are in operation there may be a lot of cables and other hardware equipment around the body part. In spite of these drawbacks, they can be most suitable solutions for short-term applications. The other alternative to the surface sensors are implanted sensors. These sensors are more suitable for long-term applications in selected subjects like spinal-cord injured patients since they require surgical intervention to be positioned in the body. These sensors communicate with the control box via subcutaneous wires or radio waves. The implantable sensors are located in the skin, muscles, tendons, ligaments, and joint capsule [60].

The sensors used in the ESCM applications can be artificial or natural in structure. In many ESCM applications, the changes in joint angles, joint angular velocities, and contact forces are measured with artificial sensors. Joint angle measurements can be accomplished with various artificial sensors including potentiometers, optocouplers,

optical fibers, strain-gages, hall-effect transducers, and magneto-transistors. Strain-gauged (SEG) and potentiometric electrogoniometers (PEG) are commonly used. Strain-gauge (Figure 2.28) is a device used to measure deformation (strain) of an object. The most common type of strain gauge consists of an insulating flexible backing which supports a metallic foil pattern. The gauge is attached to the object by a suitable adhesive. Deformation of the object leads to deformation in the foil thereby causing changes in electrical resistance. This resistance change is measured with a Wheatstone bridge and is related to the strain by the quantity known as the gauge factor. The gauge factor GF is defined as:

$$GF = (\Delta R / R_G) / \epsilon \quad (2.1)$$

where R_G is the resistance of the undeformed gauge, ΔR is the change in resistance caused by strain, and ϵ is strain. For metallic foil gauges, the gauge factor is usually a little over 2. Foil gauges typically have active areas 2-10 mm in size. Strains up to at least 10% can be measured [108].

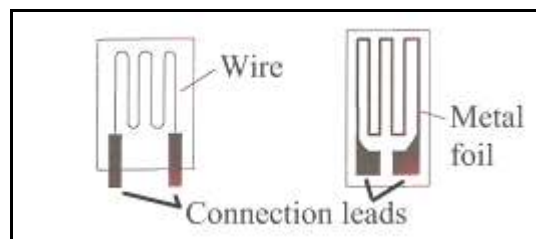


Figure 2.28 Strain-gauges. Adapted from [108]

A SEG (Figure 2.29) is composed of two end blocks and a sensing element between them. Strain gauges are located inside the sensing element. The sensing element houses 0.3 mm diameter flexible steel beam. At the biaxial EG, four small resistive wires are symmetrically mounted along the full length of the beam. Each pair of resistive wires are symmetrically mounted along the full length of the beam. Each pair of opposed resistive wires forms a half-bridge strain gauge transducer. One pair is for extension/flexion and the other pair is for radial/ulnar deviation movements. In a uniaxial strain-gauged electrogoniometer, only a pair of wires is mounted in opposite direction around the flexible wire. Biaxial EGs can take measurements at two planes. However uniaxial EGs can measure at only one plane [104, 109, 110]. SEG have been used in many

movement analysis [111-116], reliability and validity [117-119], and FES control studies [120].



Figure 2.29 Strain-gauged electrogoniometers [109]

Potentiometric goniometers consist of at least one potentiometer, and movable and stationary arms. Stationary arm is fixed to the body of the potentiometer and movable arm is fixed to the rotating or sliding knob of the potentiometer. In general, they are custom-made and take different shapes according to the area on which they are placed. The potentiometric electrogoniometers can take measurements in up to three planes. Some kinds of them can contain 6 potentiometers according to the number of planes to be measured. A potentiometer consists of a resistive element with a moving contact. The moving contact can slide over the whole length of the resistive element. By this way, it is possible to measure linear or rotary displacements. Rotary potentiometers consist of a circular-shaped wire-wound track or a film of conductive plastic over which a rotatable sliding contact can be rotated. The track may be single-turn or helical. With a constant input voltage (V_S) between terminal 1 and terminal 3 (Figure 2.30), the output voltage (V_{OUT}) between terminals 2 and 3 is a fraction of the input voltage.

$$V_{OUT}/V_S = R_{23} / R_{13} \quad (2.2)$$

The fraction depends on the ratio of the resistance R_{23} between terminals 2 and 3 compared with the total resistance R_{13} between terminal 1 and 3.

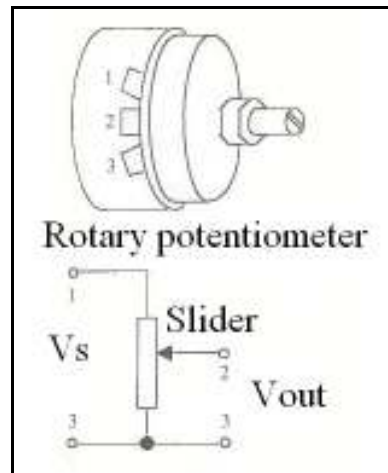


Figure 2.30 A rotary potentiometer [108]

If the track has a constant resistance per unit angle, then the output is proportional to the angle. Hence an angular displacement can be converted into a potential difference. At a potentiometer with a wire-wound track, the slider will change the voltage output in steps. Each step represents a movement of one turn. If the potentiometer has N turns, then the resolution will be $100/N$ (as a percentage). For this reason, the resolution of a wire-wound track is related with the diameter of the wire used. Errors due to non-linearity of the track range from less-than 0.1 % to about 1%. The track resistance range from 20Ω to $200K\Omega$. However a conductive plastic has an infinite resolution. Errors due to non-linearity of the track are in the order of 0.05 %. The conductive plastic has a higher temperature coefficient of resistance. Therefore the effect of the temperature on the accuracy will be larger [108].

Potentiometric electrogoniometers have been used in various studies [121-124]. Tomita et al. [124] developed their custom-made potentiometric electrogoniometer for their studies (Figure 2.31). This electrogoniometer was able to measure movements in two planes of the wrist.

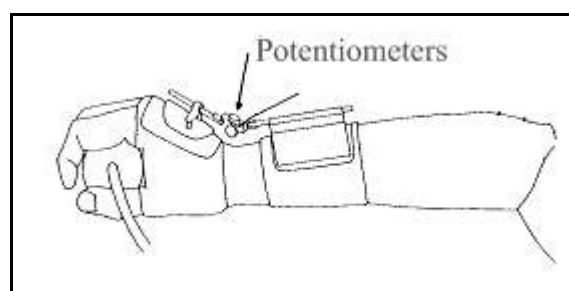


Figure 2.31 The custom-made potentiometric electrogoniometer used in the study by Tomita et al. [124]

Natural sensors of the body can also be used to derive feedback signals. The signals from the skin sensors can be used to obtain pressure distribution at the skin. In addition, signals from the muscles (electromyogram) and nerves (electroneurogram) can be used to control the movements [60, 104].

2.6.3 Limitations of strain-gauged electrogoniometers

In SGE, the flexible steel beam is fixed to the one of the end block. The other end of the beam is allowed to slide within the other end block. But it cannot rotate within this end block. Any rotation between the two end blocks causes measurement errors. Some correction algorithms are used to alleviate this problem. Other source of error at the strain-gauged electrogoniometers is crosstalk. When the crosstalk is present, movement in one anatomical plane causes a false signal in the other anatomical plane even if any motion does not occur in it. Another issue occurs when the sensing part is not located over the centers of movement. However, the center of movement is not a constant point at the wrist joint. Its location changes during movements. This leads to error when taking measurements. In fact, this is a common problem for all kinds of measurement systems for the wrist joint. Measurement errors up to $5^{\circ} \pm 5^{\circ}$ (mean \pm standard deviation) in the frontal plane and $6^{\circ} \pm 5^{\circ}$ in the sagittal plane have been reported [110]

However the other limiting factor related with SE is overlooked when they are used on multi-articulated joints like wrist. Biometrics SG65 or Infotronic XM65 model bi-axial electrogoniometers are commonly used for wrist joint. The length of the distal block is 55mm and 60mm at these models respectively. When the distal block is placed on the 3rd metacarpal bone over the dorsum of the hand, sometimes it covers the whole bone in length and goes beyond the proximal end of the metacarpal bone to include carpal bones in an adult. This is a common situation especially in medium- or small-sized hands. When the proximal end of the distal block goes beyond the midcarpal joint, strain-sensitive part of the electrogoniometer measures the angulations at only radiocarpal joint. However, 60 % of the total flexion and 33.5 % of total extension at the wrist joint occurs at this joint. Also, a similar problem is seen at the radial and ulnar deviation movements [31-33]. At mock-ups used to calibrate the electrogoniometers, the strain-sensitive area covers the whole

single bending area of the experimental joint. The calibration equations are derived from this setup and inserted into the control systems without considering the wrist as a joint complex. In general, some corrections are involved to alleviate the effect of crosstalk which is an inherent characteristic of a strain-gauged electrogoniometer. But the contribution of the intercarpal joints to the total arc of motion is not included into the calibration formulas. In addition, when the sensitive area is bent, the effect of bending will not be homogeneously distributed along the whole length of the sensing element. It will be more prominent in the middle of the sensing element. In this situation, at the area on the sensing element near to the end blocks, the elongation will be less than the one in the middle of the sensing element. So, even the length of the distal end block does not exceed the length of the metacarpal bones, more sensitive area will be more proximal to the joint complex. Other source of error is related with the attachment of the distal end block to the skin. An adhesive double-sided tape is used for this purpose. But skin on the dorsal aspect of the hand is very flexible. So the distal block may lose its alignment with the 3rd metacarpal bones during movements. When the sources of errors are combined, measurement errors up to about 9.7° in extension/flexion and radial/ulnar deviation movements can be observed [110]. This is a high error value and makes it difficult to obtain precise position of the wrist joint.

3. METHOD

3.1 Structure of the system

A closed-loop control strategy was developed. It consists of 3 main modules: 1) sensor, 2) signal processing and waveform generation, and 3) amplification of the generated waveforms (Figure 3.1).

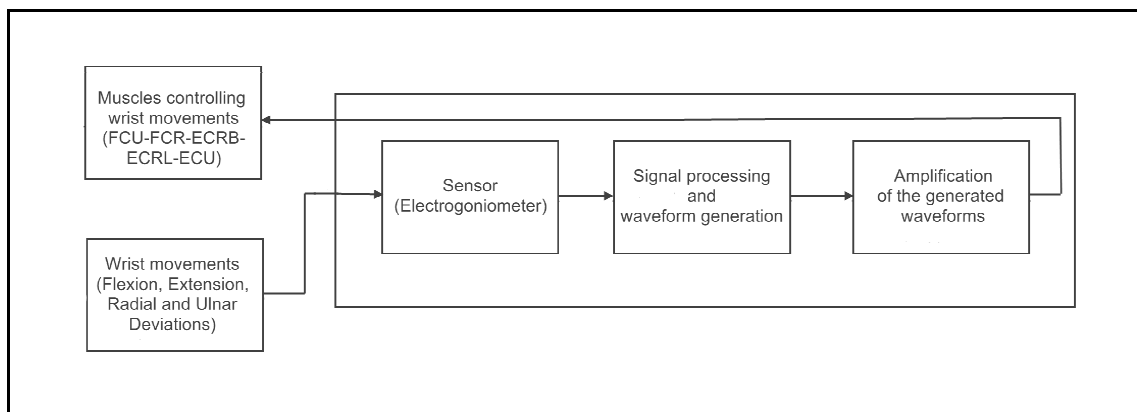


Figure 3.1 The block diagram of the system

3.1.1 Strain-gauged Sensor Experiments

It was decided to develop a sensor to measure the total angulations at the wrist joint. The sensor to be designed must consider the wrist joint as a set of articulations consisting of radiocarpal joint and the articulations among the carpal bones. Wrist joint has a large range of motion especially in the sagittal plane. So the first thing to do was to determine the maximum elongation of the wrist joint when it was moved from neutral to flexion or extension directions and radial or ulnar deviation directions. Extension and flexion movements occurring in the sagittal plane were used for this purpose since the range of motion in this plane is much higher than those in the frontal plane. So maximum elongation in this plane satisfies the elongation in the other plane. A piece of rope was placed on the dorsal aspect of the wrist joint complex while the joint in neutral position. The distal end of the rope was fixed to the middle finger and the proximal end of it was aligned on the mid-dorsal line of the forearm. While keeping this position of the rope, the

wrist joint was flexed to its end limit. This procedure was repeated in the extension direction by using similar arrangements. This test was accomplished on three healthy subjects. It was found that the maximum joint elongation was about 15% of its normal length when it was fully flexed or extended from the neutral position. Therefore elongation capabilities of the strain gauges to be used in the measurement of wrist movements must be at least 15%. So strain gauges (Vishay EP-08-250BG-120) which had an elongation capability of about 20% of its neutral length were chosen to develop the sensor (Figure 3.2).



Figure 3.2 Strain gauges and the adhesive used in the experiments

There were two options for mounting the strain gauges to the backing material (Figure 3.3). One of them was to bind the strain-gauge to the outer surface of a suitable backing material or to place it into a housing material. The next step was to find the suitable backing material on which the strain gauge was bonded. The backing or housing material should be small and light weight, flexible enough to allow full range of motion, and bendable in two axes without significant deformation. For surface application, an adhesive must be able to be used in the surface of the surface material to bond the strain gage. Some materials like silicon do not allow the use of adhesives. It must be durable. Long-term use of the material should not damage its initial characteristics (cracks, loose of regaining its starting position). In case of implanted strain-gage application, the housing material should not provide resistance path between two terminals of the strain gauge. It must oppose axial and transverse forces without damaging the gage inside or on it.

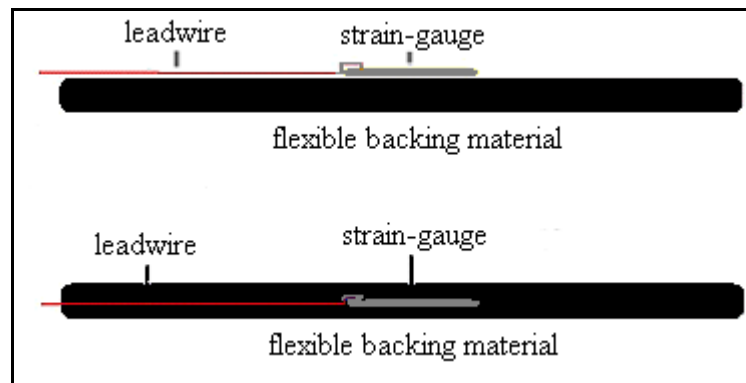


Figure 3.3 Different placements of strain gauges

Synthetic rubber, silicon, thermoplastic materials (Orfit, Aquaplast etc.), Plastrozote, spring, PVC sheets were the candidate materials. At first, the rubber was seen to be a good material for surface and implantation applications. Although it worked well in one direction, it developed folding lines at the bending side when it was bent in transverse direction. This can damage the strain gage and cause measurement errors and resistance to the motion. Thermoplastics are a kind of plastic material. They can be suitable for surface strain-gage applications. When heated to about 60 to 70 centigrade degrees in water or by heating gun, they can be molded into any shape. So they are used in the manufacture of orthoses. Several thermoplastic materials differing in thickness and material properties were tried. Orfit Eco and Aquaplast with a thickness of about 3,2 mm provided a suitable bonding surface and allowed bending in just one plane. However, after some experiments they did not return to their starting position. Orfit Classic with a thickness of about 1.6 mm showed better performance in comparison with the other thermoplastics. It could be more easily folded and preserved its starting position when the bending forces ceased. Since it wasn't bendable in transverse direction, it was molded to accommodate to the turning knob of a miniature rotary potentiometer (Figure 3.4). The combination of the sensors enabled taking measurements in two movement planes. Rotary potentiometer could measure angulations in the radial and ulnar deviation directions and strain-gage bonded thermoplastic could take measurements in the flexion and extension direction.

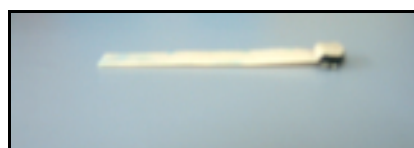


Figure 3.4 The thermoplastic material attached to a miniature a rotary potentiometer

Plastozote provided a suitable surface to bond the gage and did not developed significant deformation when it was cut into the shape of a thin strip. In spite of its resistance free effect on the motions in the two planes, it did not return to its starting neutral position spontaneously. However this disadvantage could be overcome by strictly attaching the gage and Plastozote combination to an elastic glove surrounding the wrist joint. Polyvinyl chloride (PVC) sheet was found to be the most suitable material. It provided additional support when used on or inside the backing or housing material. Strain-gage bonded to the PVC sheet could be placed inside the housing material. In this way the strain gage could be preserved from environmental conditions. This could also allow us to place another strain-gage distally and perpendicularly to the 1st one to measure the angulations at the other plane (Figure 3.5).

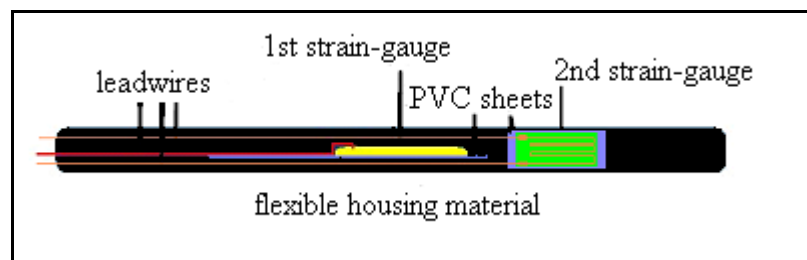


Figure 3.5 The placements of two perpendicular strain gauges with their PVC backings

The placement of the sensors in this way was a challenging work since it required a specially design mold into which liquid silicon was poured and in that mold strain-gauges had to be precisely positioned before pouring liquid silicon. Even if these procedures were completed successfully, the resulting sensor could be larger than the expected since perpendicular placement of the PVC sheets with their strain gauges on them would increase the height of the resulting combination. After some experiments on the materials above, it proved to be more advantages to embed the strain gauge into the silicon. Silicon layer is flexible, can be made in any size, fits easily to the contours of the body part and can be fixed firmly to the elastic glove around the wrist joint. It was decided to start with the experiments with a simple strain-gauged sensor for uniaxial measurements. The liquid silicon (Bayer Ultrasit SK325 with Ultracatalyst 21 and Wacker Elastosil MK512) with its catalyst was used in the manufacture of the housing materials. The PVC sheet with it's strain gauge on it (Figure 3.6) was placed on the first half layer of the liquid silicon poured into the mold (Figure 3.7) together with a piece of fabric woven in crosswise manner to

prevent deformation of the hardened silicon at the longitudinal and transverse directions. This support prevented the excessive elongation of the resulting material at any direction.

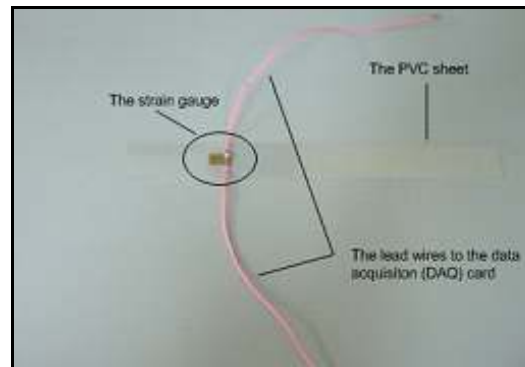


Figure 3.6 The PVC sheet with strain gauge on it



Figure 3.7 The plastic mold used in the construction of the sensor

After the uniaxial sensor (Figure 3.8) became ready for the experiments, a calibration setup to animate the wrist joint movements in one direction was prepared. The proximal end of the sensor was fixed to the board and the distal part was allowed to move in a socket fastened on the distal part of the calibration setup. A linear, rotary potentiometer (10 K Ω) was positioned in line with the joint axis of the calibration setup.



Figure 3.8 The hardened silicon containing PVC sheet with strain-gauge

The angulations between the distal and proximal parts of the calibration setup were measured with a standard mechanical goniometer. Voltage readings corresponding to increments of 10 degrees in upward (extension) and downward (flexion) directions were recorded (Table 3.1).

Table 3.1
The voltage readings corresponding to specific points in flexion and extension directions

Angles (degrees)	Flexion (Volts)	Extension (Volts)
10	- 0.45	1.5
20	- 1	1.7
30	- 1.4	2.18
40	- 2.2	2.34
50	- 2.71	2.63
60	-2. 72	2.83
70	-2. 73	3.10
80	-2.73	3.10
90	-2.73	3.10

To amplify the signals from the strain gauge, a circuitry consisting of a voltage regulator, Wheatstone bridge, operational amplifier, and a multimeter was used. To determine the amount of change in the transducer resistance, deflection-balance method was used (Figure 3.9).

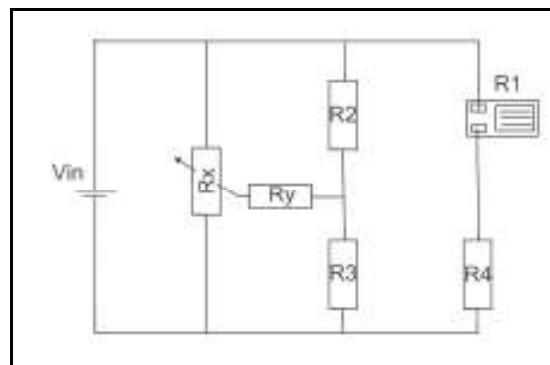


Figure 3.9 Wheatstone bridge used in the experiments (R_1 : Stain-gage (120 ohms), R_2 - R_4 : 120 ohms (1% tolerance), R_x : 1K linear potentiometer, R_y : 3K (1% tolerance), V_{in} : 5 V)

In the beginning, supply voltage of 10 volts caused heating in the strain-gauged sensor. Heating of the strain gauge causes measurement errors. Strain-gage embedded in

the silicon housing may not easily dissipate the heat forming on it. Minimizing the power supply voltage, increasing the resistance values of the each arm, or using half or full bridge configurations may help overcome this problem. However using less supply voltage causes a decrease in V_{out} as well. But it was the most suitable way at that time. Increasing resistance values and/or using the other bridge configurations require the use of many more strain-gages. Strain-gage sensor was used as a quarter-bridge in those experiments. At the beginning, although four arms of the bridge had equal resistances, Wheatstone bridge had a bias voltage. This was related to tolerance (1%) of the resistances. To alleviate this problem, it is advised to use strain-gages at the other 3 arms of the bridge. But the cost and the limited number of the gages did not allow that. A balancing circuit was added to the bridge (R_x and R_y in Figure 3.9). By means of that, when the sensor was in neutral position, it was possible to obtain zero output by making required adjustment via potentiometer.

Strain-gages are very sensitive to strain-related changes. The strain-gages in our experiments had a resistance value of 120 ohms. When it was bent to upward or downward directions until its elongation limits, its resistance changed from 119 to 121 ohms. Even a very small movement of the gage or voltage fluctuations caused abrupt changes in the voltage readings. For example a fluctuation of 1 mV in power supply voltage caused up to 5 degrees measurement error. So, a voltage regulator based on LM7805 and LM7905 (Figure 3.10) was planned to feed the Wheatstone bridge and amplifier circuit. This circuit was able to provide +5.1 and -4.96 Volts continuously until the voltage of the power source went below 8 volts. Hence 2 pieces of 9V batteries could be used for a long time. At the initial tests with power sources, even minute fluctuations of the output from a DC power source led to instability of the readings. So the use of batteries was preferred. 2 pieces of 9 volts batteries were connected in series. The interconnection between the terminals of the batteries was regarded as virtual ground. This power supply was used to feed the Wheatstone bridge and two-stage amplifier circuit (Figure 3.11).

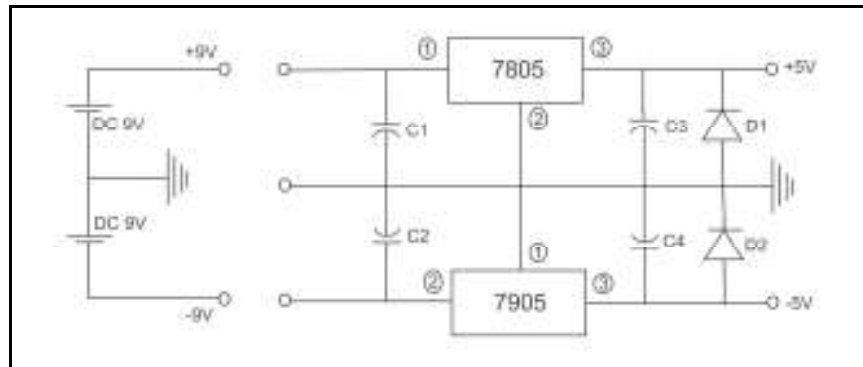


Figure 3.10 Voltage regulator circuit to feed the Wheatstone bridge and amplification circuit (C1: 0.33 μ F, C2: 2.2 μ F, C3=C4: 1 μ F, D1=D2: 1N4001)

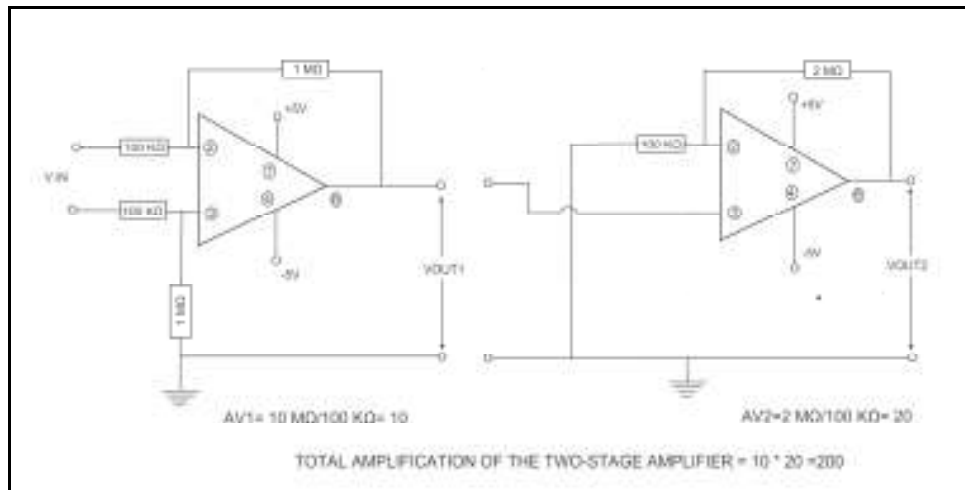


Figure 3.11 The two-stage amplifier circuit

A few OPAMS was tested. It is stated that LM 728 had improved electrical characteristics over LM 721. Although its gain was a little bit more than LM 721, it developed prominent fluctuations at the output. A fluctuation of a few millivolts may be misinterpreted as an angular change and thus activate or modulate the stimulation pulses unnecessarily. LM 324 has advantage over the other two IC's in that it does not require the use of dual polarity power supply and contain four OPAMS in it. That means that it can be powered by a simple battery without additional circuitry and 10^4 times amplification is possible without interconnecting 4 distinct OPAMS. However the experiments with LM 324 failed. The other OPAMS was LM 747. It contains two 741s in it and thus allows 10^2 times amplification. At the Table 3.2, the results of differential input and output relationships from LM 721 and LM 728 IC's were shown.

Table 3.2
The output comparison of LM 721 and LM 728

Input (mV)	LM 721	LM 728
	Output (mV)	Output (mV)
0	0.8	0.5
1	10.4	12-14
2	20	23.5-25
3	30	37-39
4	40.8	48.5-49

The mean frequency of the wrist motions is about 5 Hz in daily use and this does not exceed 10 Hz. most of the time [125]. So a cut-off frequency of about 16 Hz was chosen for low-pass filtering the signals derived from the strain gauge.

$$\omega_0=1/RC=100 \text{ rad/s or } f_0=\omega_0/2\pi =15.9 \quad (3.1)$$

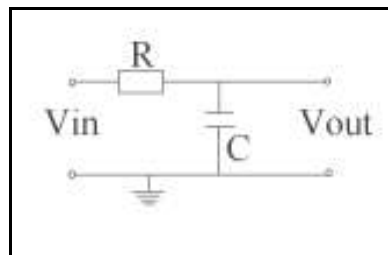


Figure 3.12 The circuit diagram of the low-pass filter ($R=100 \text{ K}\Omega$ and $C=0.1 \mu\text{F}$)

Figure 3.13 and Figure 3.14 demonstrates the output from the amplification circuit without and with low-pass filtering respectively.

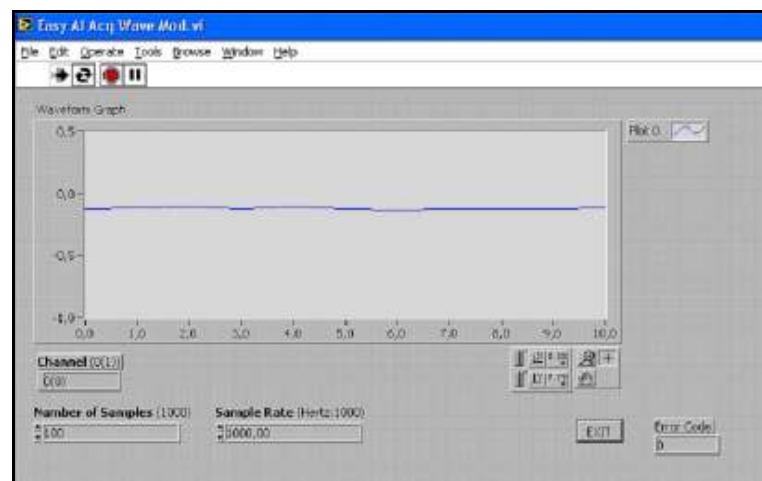


Figure 3.13 The output of the amplification circuit without low-pass filtering

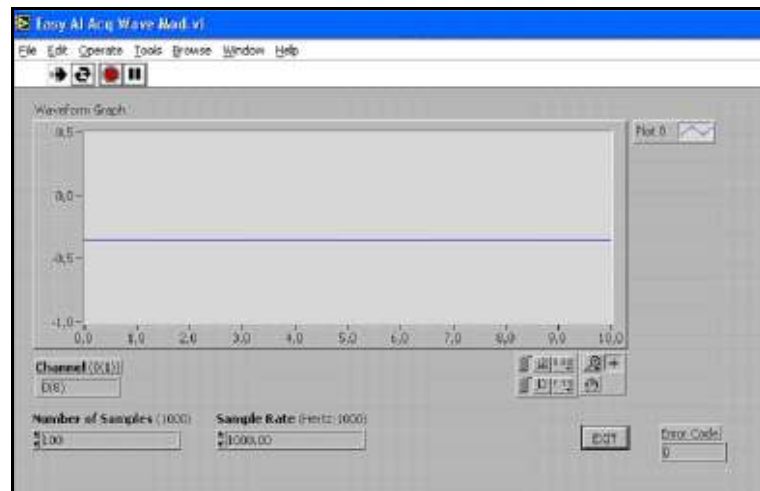


Figure 3.14 The output of the amplification circuit with low-pass filtering

After a lot of experiments, we had decided to end the experiments with strain gauges due to following reasons: Difficulty in finding suitable housing material which allows bending in two perpendicular planes without causing significant deformation on strain gauges, soldering problems, loosening of the connections between the terminals of the gage and lead wires short after soldering, high sensibility of the strain gauge, and calibration problems. Even a minute change (1mm) in the position of the sensor caused large fluctuations in the readings so it was not possible to obtain the same readings after it returned to the starting position.

3.1.2 Development of the Potentiometric Electrogoniometer

3.1.2.1 Construction

After the strain-gauged sensor experiments failed, a biaxial PEG (Figure 3.15) was developed considering the issues related with limitations of the SGE on the wrist joint. Mainly, thermoplastic materials (Orfit eco 3.2mm and Orfit Classic 2mm) were used in the construction of it. It was consisted of 3 parts. The proximal part was formed in the shape of a groove to fit the forearm. The distal part of it was shaped to fit the dorsal aspect of the hand just over the metacarpal bones. The radial sides of these two parts were left open in order to make it to accommodate to hands in various sizes. To fasten the parts on the hand and the forearm Velcro straps were used. In addition, a double-sided adhesive tape was

used to further increase the stability of the distal part. The movements of the distal part are transmitted to the proximal part via two arms. Each arm has a longitudinal groove through which a pin at the distal part passes. Each of the arms is responsible for the motions in one plane and has a hinge just over the radioulnar joint to allow motion at the other plane. Additional contribution of the movements of the carpal bones to the total range is compensated by the elongation of the sliding part of the arms. This elongation is much more prominent in flexion movement. The proximal part houses two precision 10K Ω rotary potentiometers. One of it is located on the dorsal aspect of the proximal part near to the distal rim. It is positioned in a way that it was in line with the 3rd metacarpal bone in an ordinary adult people. This potentiometer was aimed to measure radial and ulnar deviation movements. The other potentiometer was located at the lateral aspect of the proximal part. It is positioned in line with the 5th metacarpal bone and the lateral midline of the forearm. This potentiometer was used to measure flexion and extension movements of the wrist. Interconnecting arms were fixed to the tap of the potentiometers at the proximal part. At the distal part, they were attached to the pins on the dorsal aspect of the distal part. These pins were mounted just on the reference points or lines. They were 3rd metacarpal bone on the dorsal aspect and the 5th metacarpal bone at the lateral aspect.

3.1.2.2 Calibration and validation

Two experiments were conducted to test the performance of the goniometer. For static calibration, thirteen known angles (60, 50, 40, 30, 20, 10, 0, -10, -20, -30, -40, -50, -60) in the sagittal plane (from extension to flexion), and nine known angles (40, 30, 20, 10,

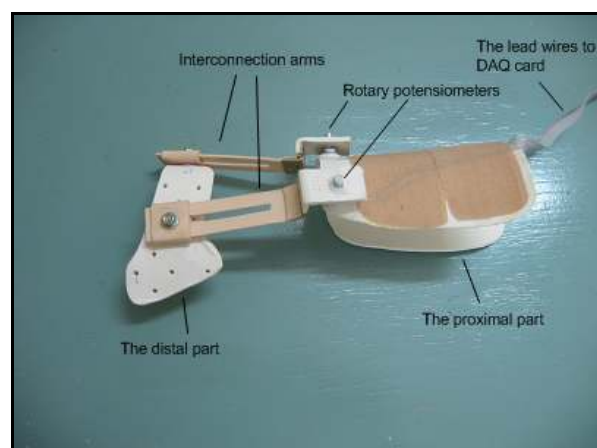


Figure 3.15 The bi-axial potentiometric electrogoniometer

0, -10, -20, -30, -40) in the frontal plane (from radial deviation to ulnar deviation) were measured. A mockup was constructed to animate the wrist joint for the calibration purpose of the new goniometer (Figure 3.16, Figure 3.17). A laser beam in line with the joint axis is placed in front of the distal part of the mold. Real angulations of the joint were measured with a standard mechanical goniometer and projection of the laser beam on to the paper opposite to the mold was marked with increments of 10 degrees in both planes.

Signal processing was done with ADAC 5503 HR_V data acquisition card (Iotech Technology) in a desktop PC (Pentium IV) running under Windows XP. Signals from the sensor were low-pass filtered with a cut-off frequency of 16 Hz. and sampled at 50 Hz. Current source for potentiometers was always provided from the +5V output of the data acquisition (DAQ) board terminal since even minute changes in the voltage due to changes in power supply could cause drifts in measurements. The goniometer was fixed on to the mold by Velcro tapes just as it was on a real hand and forearm. Mold was moved in the two planes while the new goniometer was on it. At first only 4 readings were recorded at each plane and average of them was calculated. It was observed that the voltage change was linear at both planes and linear curve equations were obtained. The angle was found to be equal to $\{205,061 - 66,155 * (\text{voltage})\}$ for sagittal plane and $\{208,450 - 65,954 * (\text{voltage})\}$ for frontal plane. After entering the calibration equations into the program codes (VI's), voltage changes corresponding to each increment at both channels were recorded again. End points were 60 degrees for extension and flexion, and 40 degrees for radial and ulnar deviation. At both planes a total of 10 readings at each increment were recorded. It accounts to 5 readings at one direction at a plane. Mean values of ten measurements at each calibration points for sagittal and frontal planes are shown at Tables 3.3 and 3.4 respectively.

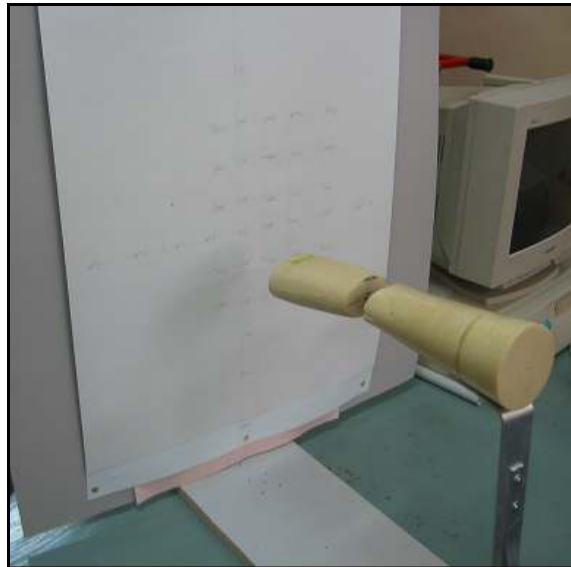


Figure 3.16 The calibration mock-up

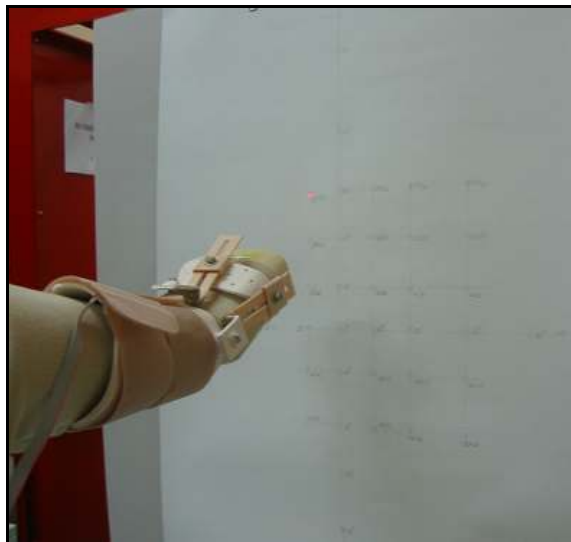


Figure 3.17 The calibration mock-up with the PEG on it

Mean voltages corresponding to each calibration points in the frontal and sagittal plane are graphically shown in the Figures 3.18 and 3.19 respectively.

Table 3.3
The means of measurements in the sagittal plane

Angles	Mean	Minimum	Maximum	SD
E60	2,19200	2,185	2,200	0,005099
E50	2,35100	2,347	2,358	0,003712
E40	2,49400	2,488	2,505	0,005558
E30	2,64000	2,635	2,647	0,003944
E20	2,80800	2,800	2,816	0,005735
E10	2,94600	2,935	2,954	0,005812
N	3,08800	3,083	3,097	0,004472
F10	3,24500	3,235	3,258	0,006683
F20	3,40600	3,398	3,415	0,006218
F30	3,55800	3,550	3,568	0,005676
F40	3,71100	3,700	3,722	0,007102
F50	3,84500	3,840	3,854	0,004619
F60	4,01200	4,005	4,020	0,005735

(SD: Standard deviation, E: Extension, F: Flexion, numbers following the letters E and F imply the angles where the measurements are taken)

Table 3.4
The means of measurements in the frontal plane

Angles	Mean	Minimum	Maximum	SD
RD40	2,55200	2,545	2,561	0,005292
RD30	2,70400	2,690	2,710	0,005657
RD20	2,87000	2,859	2,877	0,005598
RD10	3,00200	2,993	3,010	0,006566
N	3,16000	3,151	3,174	0,007071
UD10	3,30500	3,297	3,315	0,007008
UD20	3,47200	3,460	3,480	0,007118
UD30	3,61200	3,602	3,620	0,005925
UD40	3,76800	3,760	3,777	0,005249

(SD: Standard deviation, N: Neutral position, RD: Radial deviation, UD: Ulnar deviation, numbers following the letters RD and UD imply the angles where the measurements are taken)

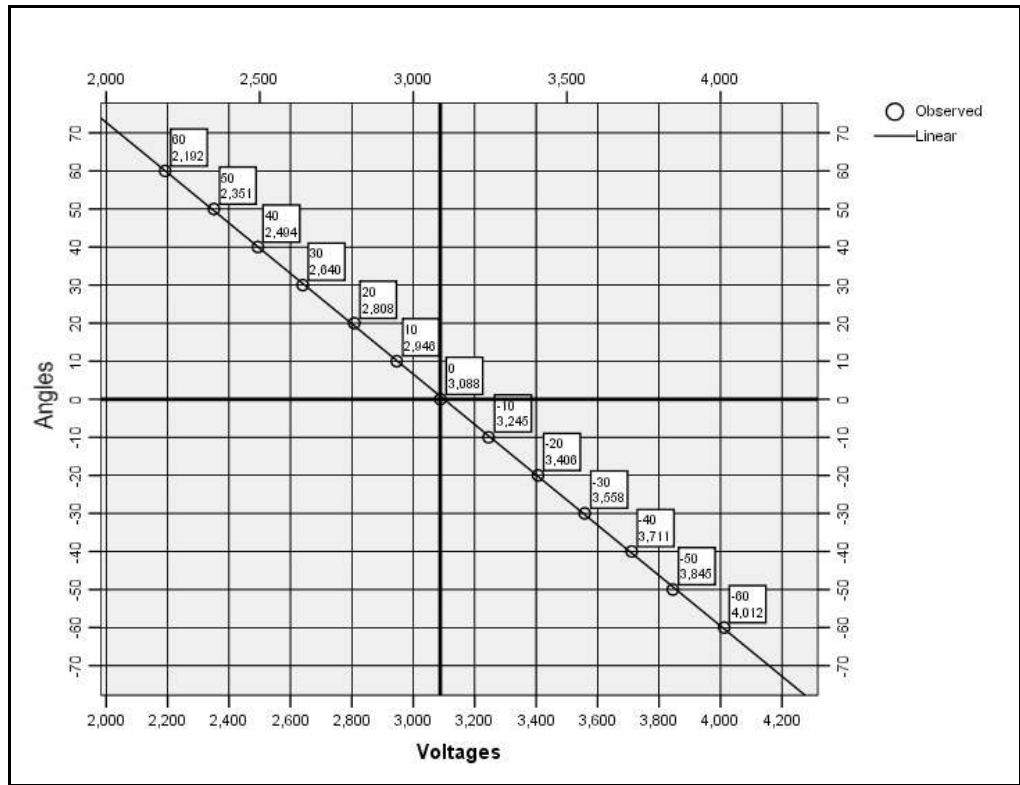


Figure 3.18 Voltage readings corresponding to each calibration points at the sagittal plane

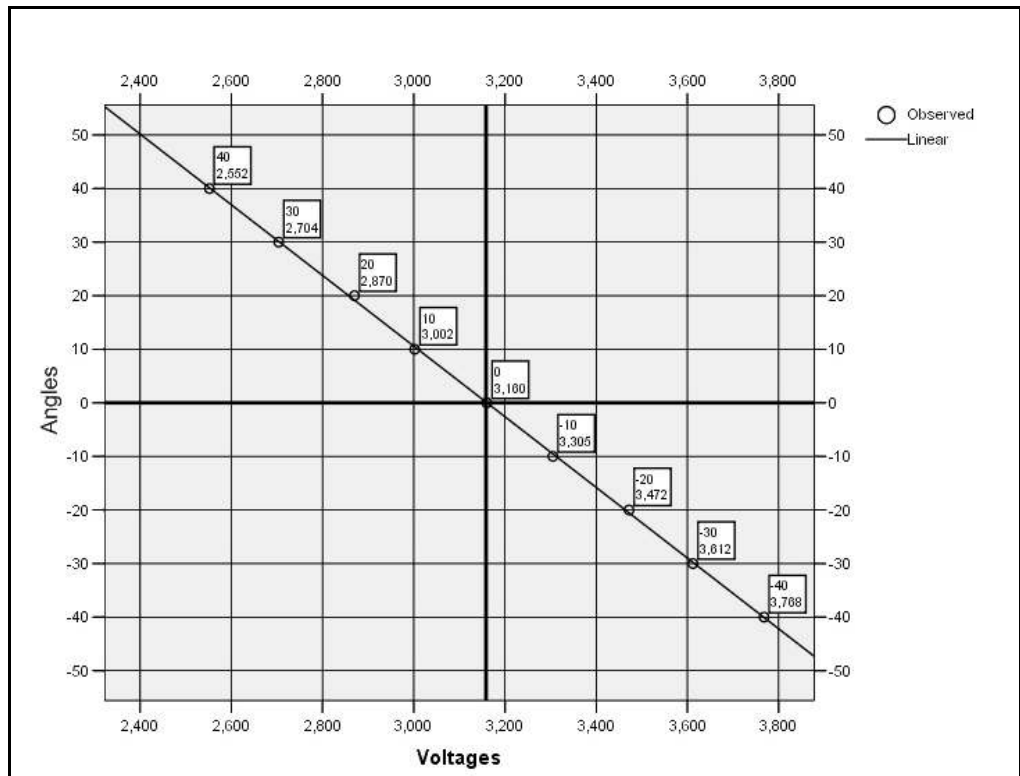


Figure 3.19 Voltage readings corresponding to each calibration point at the frontal plane

To determine the hysteresis, the average of five measurements in one direction at a plane (extension to flexion or radial to ulnar deviation) was compared with the average of the measurements in the opposite direction (flexion to extension or ulnar to radial deviation). Hysteresis graphics are shown at the Figures 3.20 and 3.21 for the sagittal and frontal planes respectively.

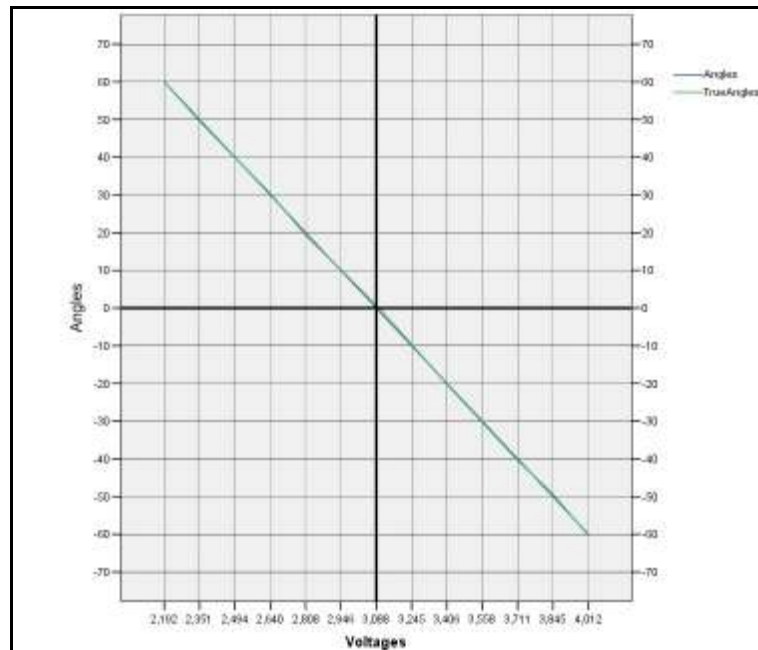


Figure 3.20 The hysteresis graphic for the extension and flexion movements

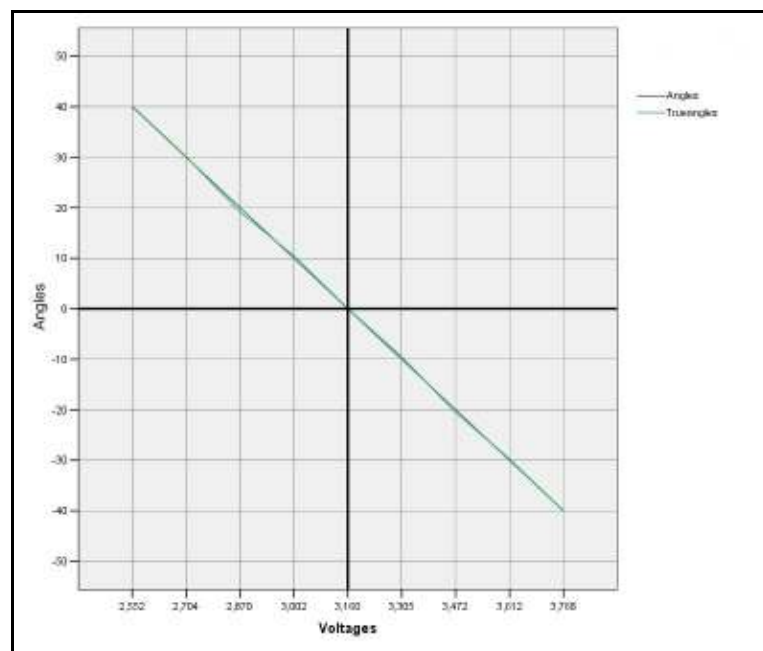


Figure 3.21 The hysteresis graphic for the radial and ulnar deviation movements

Results between the true flexion/extension and radial/ulnar deviation angles, and goniometer measurement angles are shown in Tables 3.5 and 3.6 respectively. The statistical analysis indicated that the true angles and the measured angles have strong relationship across all the range of positions ($p < 0.001$) for flexion/extension and radial/ulnar deviation). The non-repeatability for sagittal and frontal planes was 0.53%, and 0.7%, respectively, and non-linearities were 0.66%, and 1.04%, respectively. The results of non-repeatability and non-linearity of the goniometer in the sagittal and frontal plane are shown in Tables 3.5 and 3.6 respectively. The mean error for extension/flexion was 1.07 and for radial/ulnar deviation it was 1.08 degrees.

Table 3.5
The non-repeatability and non-linearity of the electrogoniometer in the sagittal plane

Angle	Non-repeatability	Non-linearity	
		Measured angle	Input deviation
E60	0,68%	60,20	0,20
E50	0,46%	49,65	0,35
E40	0,67%	40,20	0,20
E30	0,45%	30,50	0,50
E20	0,57%	19,40	0,60
E10	0,64%	10,25	0,25
N	0,45%	0,85	0,85
F10	0,70%	9,54	0,06
F20	0,5%	20,20	0,20
F30	0,5%	30,28	0,28
F40	0,59%	40,40	0,40
F50	0,36%	49,28	0,72
F60	0,37%	60,34	0,66
Average	0,53%	0,7%	

Non-repeatability is defined by the maximum output minus the minimum output divided by the maximum output. Non-linearity is defined by the maximum input deviation divided by the full-scale input. F: flexion, E: extension. The numbers following the letters E and F imply the angles where the measurements were taken.

Table 3.6
The non-repeatability and non-linearity of the electrogoniometer in the frontal plane

Angle	Non-repeatability	Non-linearity	
		Measured angle	Input deviation
RD40	0,62%	40,13	0,13
RD30	0,74%	30,11	0,11
RD20	0,63%	19,16	0,84
RD10	0,56%	10,45	0,55
N	0,73%	0,04	0,04
UD10	0,57%	9,52	0,48
UD20	0,58%	20,54	0,46
UD30	0,50%	29,77	0,23
UD40	0,45%	40,06	0,06
Average	0,66%	1,04%	

Non-repeatability is defined by the maximum output minus the minimum output divided by the maximum output. Non-linearity is defined by the maximum input deviation divided by the full-scale input. RD: radial deviation, UD: ulnar deviation. The numbers following the letters E and F imply the angles where the measurements were taken.

3.1.3 Development of Control Software

The development platform is LabVIEW tool running on a Pentium IV (2.5GHz) desktop PC with Windows XP Professional. LabVIEW is a graphical programming language. Instead of writing program codes line by line, program modules called visual instruments (VIs) representing specific functions are implemented and connected together to form the complete program. By making necessary changes and/or adding control parameters to each VIs, it is possible to control the data acquisition (DAQ) boards and program flow suited to individual needs. LabVIEW in combination with Iotech ADAC 5503 HR_V DAQ boards is used to perform data monitoring, data processing, and generation of stimulation pulses. Windows operating systems do not allow real time operations. However, it is possible to program quasi-real time closed-loop applications by using relatively low loop frequencies of less than 30 Hz. Such a frequency is sufficient to control the stimulus parameters since the response time to a stimulus typically has a delay of 60 to 80 ms. [126]. The DAQ boards used in the study have direct memory access (DMA) feature supported by the LabVIEW and Windows operating systems. LabVIEW

also provides large libraries with all necessary subroutines needed to program such an application.

The program used in the study is able to read 2 input channels and provide various types of waveforms at 4 independent output channels. There are 5 main modules in the program: (1) scanning of input channels, (2) signal processing, (3) waveform generation, (4) amplitude control, and (5) driving output channels. By using controllers on the panel window (Figure 3.22), it is possible to change following parameters: waveforms, amplitude and duration of the waveforms, interpulse intervals, input and output frequency, activation thresholds (angles) for each channel, waiting time to activate the output channels, and the rate at which output channels to reach their maximum amplitude. It is also possible to obtain symmetric, asymmetric, monophasic, and biphasic waveforms.

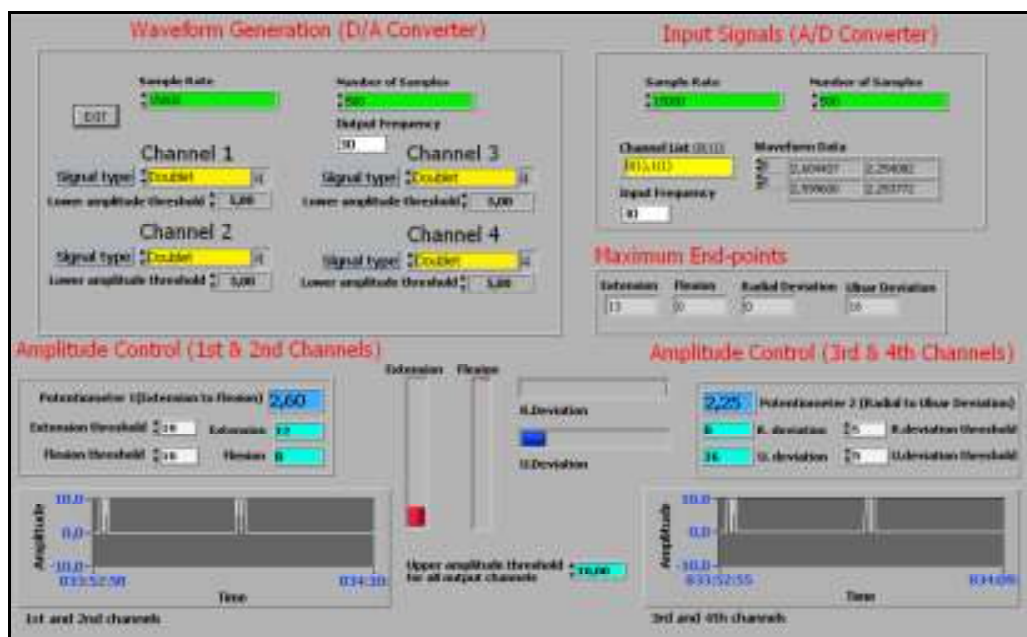


Figure 3.22 Panel window of the control software

Input scanning module enables scanning 2 independent input channels at the same time. The internal clock of the board is used for timing in all sub-modules. The main module is consisted of 6 sub-modules: Analog Input Clear, Initialize Device, Analog Input Configuration, Analog Input Read, Trigger Configuration, and Start Device (Figure 3.23).

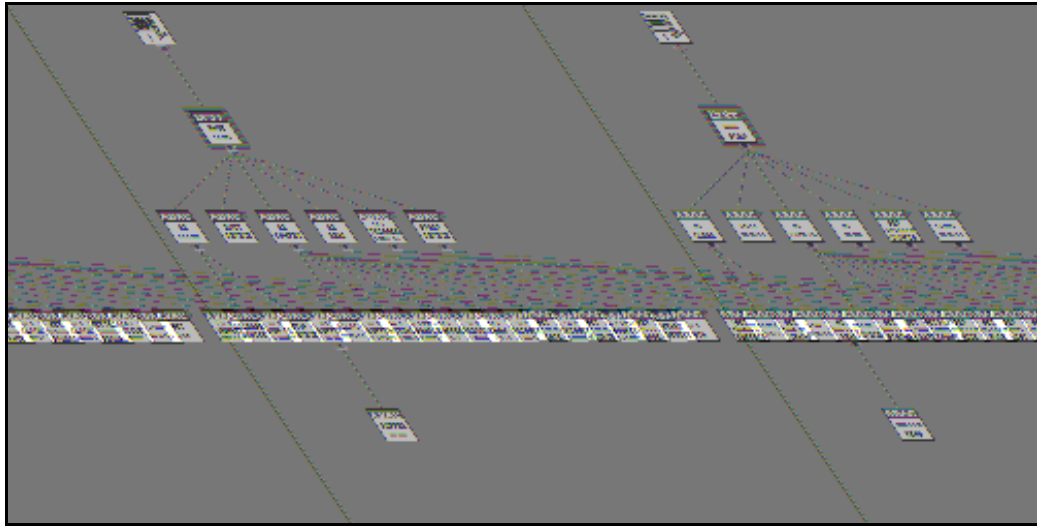


Figure 3.23 The sub-modules of the input scanning module

Two DAQ boards (IoTech ADAC 5503-HRV) are used to obtain the voltage changes across the terminals of the potentiometric sensors and deliver the generated waveforms to the amplification circuit. The outputs of the two potentiometers (10 k Ω each) are low-pass filtered with a cut-off frequency of 16Hz and sampled at 30 Hz. They are delivered to the two input channels of one DAQ board. The two output channels at each DAQ board are used to deliver generated waveforms to the amplification stage of the system.

In the signal processing phase, analog signals are converted into their corresponding angles at both planes by means of their calibration equations. Maximum end-points at each direction are monitored in this phase.

Waveform generation module (Figures 3.24 and 3.25) is able to produce the following waveforms: Square wave, triangular wave, sinusoidal wave, saw-tooth, singlets, doublets, and triplets.

Amplitude control module (Figure 3.26) provides control on the timing and intensity of the generated stimulation pulses. The rate of change of the amplitude is also controlled at this stage. 4 output channels of DAQ boards are driven with the generated waveforms.



Figure 3.24 The panel window of the waveform generation module

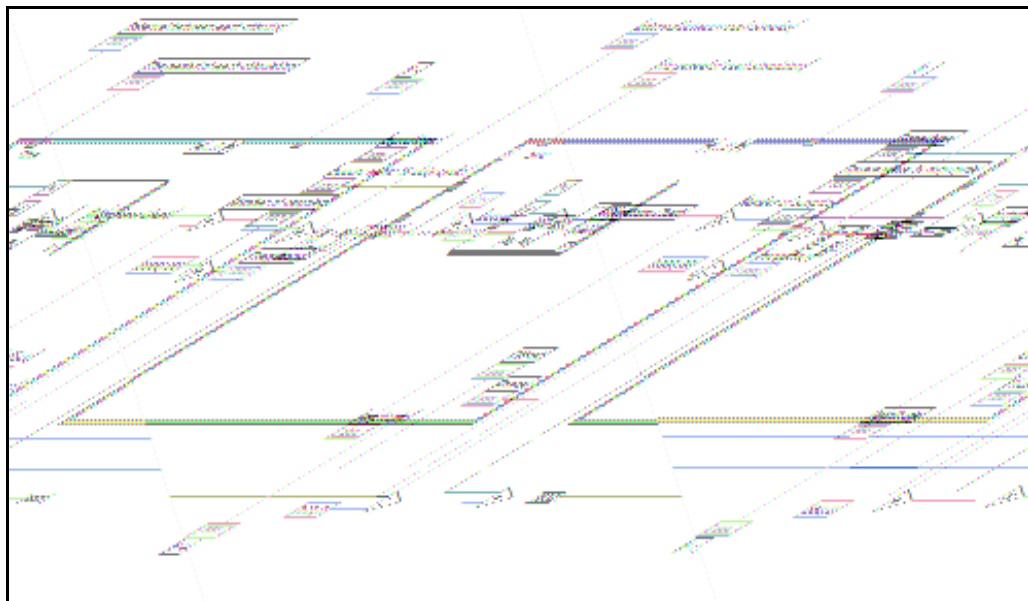


Figure 3.25 The diagram window of the waveform generation module

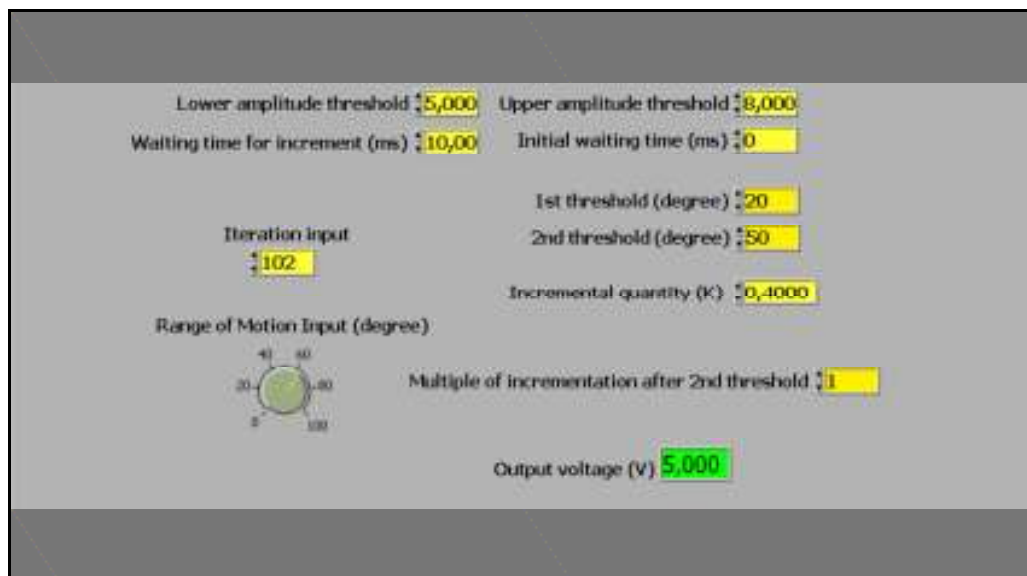


Figure 3.26 The panel window of the amplitude control module

A closed-loop controller (Figure 3.27) using positional feedback to limit the movements of the wrist within the preset interval of range is used. Angular position of the wrist is fed back to the controller. If the wrist rotation exceeds preset threshold(s), the antagonistic muscles predominantly opposing these movements are stimulated. Activation strength is proportional to the integral of the angular error e ($e = \theta_d - \theta$). The stimulation however has an upper and lower limits set on the program. Stimulation signal strength is a function of angular error and integral gain ($S = e \times K_i$). In this way the larger the error between θ_d and θ , the faster the amplitude reaches to its maximum. The integral controller results in a gradual increase of stimulation amplitude which reduces irritation due to sudden stimulation of the muscles.

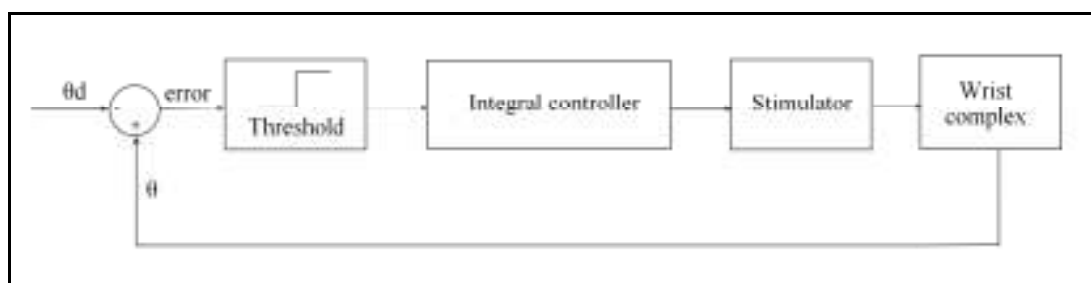


Figure 3.27 The closed-loop controller (θ_d :desired angle, θ :real angle)

3.1.4 Amplification Circuit

Waveforms generated are delivered to the amplification circuit via output terminals of the DAQ cards (Figure 3.28). Amplification circuit can deliver symmetric or asymmetric constant current pulses at approximately 36 mA peak-to-peak. For a square wave output at 20Hz, the peak-to-peak output voltage can reach up to 290 Volts. The patient circuit is isolated from the rest of the system with a photocoupler. This resulting stimulation pulses are delivered to the motor points of the muscles. Circuit design of the amplifier is shown in Figure 3.29. This circuit design was constructed for each output channel and all of them were placed inside an isolated box (Figure 3.30).

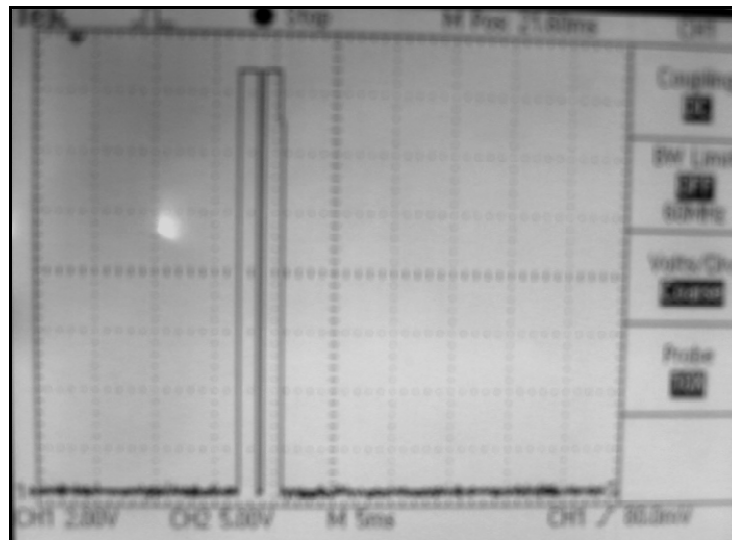


Figure 3.28 The “doublet” stimulation pulses on the oscilloscope screen

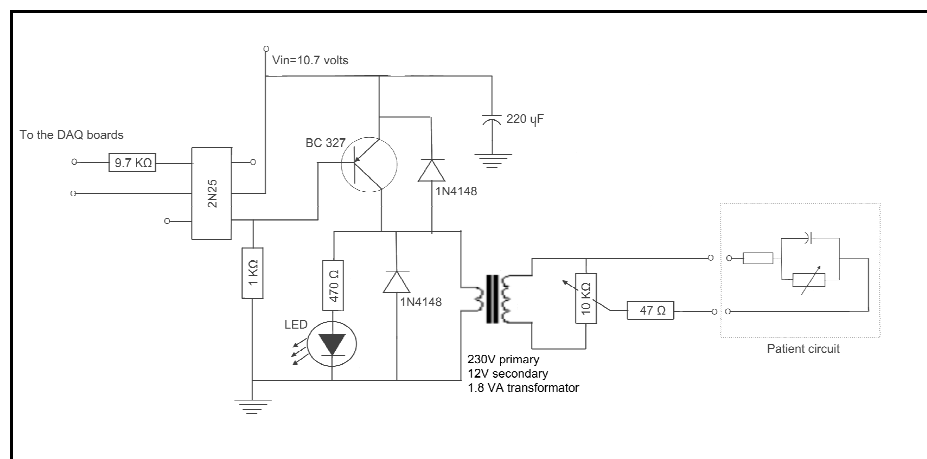


Figure 3.29 The circuit design of the amplifier



Figure 3.30 The plastic box containing the stimulation amplifier

3.2 Experimental Procedure

3.2.1 Subjects

A case-control study design was used to establish whether there were CTS-specific factors affecting the results. The study was conducted in the Rheumatology Department of Cerrahpasa Medical Faculty at Istanbul University under the approval of the Ethics Committee of the same institute. 31 right-handed eligible volunteers in ages between 24 to 64 years participated in the study. 12 of them were patients with CTS and the others were healthy subjects. Characteristics of the subjects at each group are shown in the Table 3.7. Diagnosis of CTS was made by rheumatologists based on both electrophysiological and/or clinical findings. All participants except one at each group completed the study. Patients with CTS and healthy subjects having at least one of the following diseases or conditions were excluded from the study: (1) severe carpal tunnel syndrome based on electrodiagnostic and/or clinical findings, (2) diabetes mellitus, (3) any implantation, open wound, and skin disease in right hand and forearm, (4) cardiac pacemaker and cardiac arrhythmias, (5) restricted range of motion at the wrist joint, (6) fracture history at the hand and forearm, (7) any subluxation or deformity disrupting normal alignment of the wrist, (8) CTS symptoms persisting longer than 12 months, (9) muscle atrophy, deformity and pain in the hand and forearm due to accompanying rheumatic diseases or conditions, and (10) any other polyneuropathies and entrapment neuropathies at the right arm.

Table 3.7
Subject characteristics

Patient no	The order of tests ^a	Patients with CTS					Healthy subjects	
		Age (y)	Duration of the symptoms (m)	Additional diseases or conditions	Symptom Severity Scale Score	Functional Status Scale Score	♀ Age (y)	♂ Age(y)
1	1-2-3	45	9	-	1.8	1.9	36	27
2	1-3-2	38	4	Sjögren syndrome	2.4	1.8	63	24
3	1-2-3	48	3	-	1.5	1.5	37	27
4	1-3-2	41	6	-	2.2	2.8	48	31
5	1-2-3	49	12	Behçet disease	2.3	2	22	39
6	1-3-2	53	4	-	3.4	2.1	48	22
7	1-2-3	37	5	-	2.1	2.3	45	23
8	1-3-2	36	1	Rheumatoid arthritis	2.5	2.1	47	-
9	1-2-3	47	12	-	4	3.8	45	-
10	1-3-2	54	9	-	2.3	2.1	39	-
11	1-2-3	48	6	-	3.3	3	52	-
12	1-3-2	41	5	-	3.6	2.9	48	-
Mean(SD)	-	44.8(6.1)	6.3(3.5)	-	2.6(0.8)	2.4(0.6)	44.2(10)	27.6(5.9)

SD: Standard deviation

^a 1: without a SWO or NeO, 2: with a SWO, and 3: with NeO

3.2.2 Test Instruments and Batteries

A wrist orthosis used to immobilize the wrist joint should minimally restrict the hand function while performing its job. Therefore determining the amount of restrictions imposed on the hand by various control strategies provides an indicator about their limiting effects. For this reason, grip strength, grip pressure, pinch strengths, hand dexterity and function were measured.

3.2.2.1 Hand function

The Jebson Hand Function Test (JHFT) (Figure 3.31) is used to evaluate functional capabilities of the hand and upper extremity. JHFT includes seven subtests: writing a sentence, turning over 3x5 inch cards (simulated page turning), picking up small common objects, stacking checkers, simulated eating, moving empty cans, and moving heavy cans. The test is conducted in comply with the standard procedure described by Jebson et al. [127]. It was demonstrated that the test-retest reliability of subtests ranged from 0.60 to 0.99. This result was based on the 26 patients with stable hand disabilities. The practice effect was not significant on this patient population between two sessions. However, Stern [128] reported significant practice effect for writing and simulated feeding subtests. Norms for JHFT were developed for dominant and nondominant hands [128, 129].



Figure 3.31 The Jebson Hand Function Test used in the experiments

3.2.2.2 Hand dexterity

The Purdue Pegboard Test (PPT) [130] is used to measure gross movements of the upper extremity and finger dexterity. It was originally developed to determine the level of manual skills of the employees. The original test (Figure 3.32) is consisted of a rectangular shaped wooden board. There are 25 small holes in equal sizes around the longitudinal midline of the board. The four cups containing pins, washers, and collars are located at the top of the board. The 25 pins are located at the outer reservoirs at each side. The second cup from the left side contains 40 washers and the other cup houses 20 collars. There are 4 subtests. 3 subtests requiring the subjects to put the pins into the holes on the board as fast as possible is done with right hand, left hand, and both hands. The number of pins inserted in 30 sec. is the score for the right and left hand tests. The number of pairs of pins that are placed during the 30 second period is the score for both hands. In the assembly subtest, a subject is first required to place a pin into the top hole at the same side of the tested hand. After that a washer, a collar, and another washer are placed on the same pin. The test continues with the next hole in the same side. The score is the number of pins assembled in 1 min. And each completed assembly is counted as 4 parts. Test-retest reliability for one trial administration was found to be 0.6 to 0.79. Three trial administrations improved the reliability to the range from 0.82 to 0.91 at the expense of increased administration time [130]. Normative data are present for adults [131] and children [132, 133].



Figure 3.32 The original Purdue Pegboard Test [134]

In the study, a modified version of the PPT (MPPT) was used (Figure 3.33). The dimension of the board is the same as that of the original test. In reply to equal-sized 25 holes in the original test, it has 20 holes arranged in two columns. There are equal number of 4 different sizes of holes (5×4) and corresponding pins and washers. The largest holes are located at the top of the lines. The smallest holes are at the end of the lines. There are four different sizes of washers. They are placed in the cups above the board. Similar to the arrangements of pins in the cups, they are placed from left to right according to their sizes. The larger ones are located at the outer cup at the left side. Each cup contains 10 pins and 10 washers side by side. The sizes of the pins are in comply with the sizes of the washers at each cup. This modified version of the PPT lacks collars. There are 4 subtests in the MPPT. At the right-hand and left-hand tests, subjects are asked to take a pin from the cup and insert it into their corresponding-sized holes at the side of the tested hand. The test is started with the largest dimension of pins and after 5 pins are placed into their holes, it continues with the smaller sized ones until a total of 20 pins are placed into their holes. The time required to complete all the 20 pins is the score of the unilateral test. In the assembly test, the pins are placed in the same way as the unilateral test. But this time after placing a pin into a hole, a washer in the same cup is placed over this pin. The total number of pieces assembled in 30 seconds is the score of this subtest.

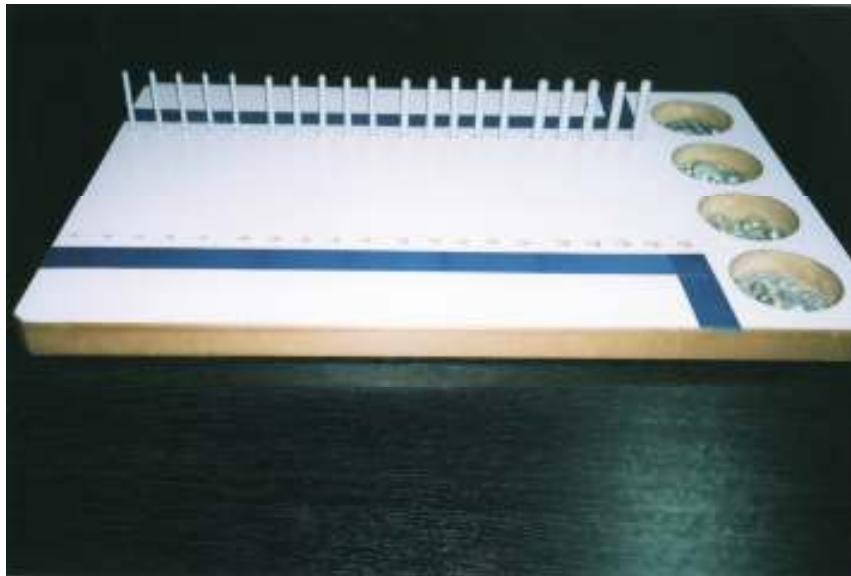


Figure 3.33 The modified Purdue Pegboard Test used in the experiments.

3.2.2.3 Grip strength

To measure grip strength, a calibrated standard Jamar dynamometer (JD) is used (Figure 3.34). Standard JD is a hydraulic instrument and measures static grip strength with handles that can be adjusted to five different positions (2.5, 3.8, 5.1, 6.4 and 7.6 cm apart) [135]. It records the grip strength in kilograms or pounds of force. It is the most widely used and recommended instrument for grip strength [135-137]. The JD is a reliable instrument. Good inter-rater [136-138] and test-retest [136, 139] reliabilities have been demonstrated and adult and children norms have been developed for various populations [140-146]. It was demonstrated that there were variations in the mean grip strength for the same age group among different nations [147] Therefore, when making comparison, it is advised to use specific norms developed in the population where the measurements are taken. It has been demonstrated that the maximal grips are usually achieved at the 2nd or 3rd positions of the JD [148, 149] and the data taken at these positions show more resemblance to normal distribution curve which is an indication of a maximal effort during grasping [150]. In this study, 2nd position of the handle was used.



Figure 3.34 The standard Jamar Dynamometer

3.2.2.4 Grip pressure

Grip pressure is evaluated with a modified sphygmomanometer (MS). MS is a pneumatic instrument (Figure 3.35). It uses the compression of an air-filled bulb or bag to determine grip pressure. It is commonly used with clients who have painful hands and deformities or fragile skin since it is more comfortable to grasp and accommodates to the shape of the hand [151, 152]. It reports pressure in millimeters of mercury (mmHg).



Figure 3.35 The modified sphygmomanometer

It has been used in some researches [153-156], and grip pressure norm has been developed for Turkish population [157]. Grip pressure is different from the grip force. Pressure depends not only on the force applied but also on the area on which it acts. So, two people with the same grip strength can produce two different readings at grip pressure measurements due to the difference in the size of their hands. There are 3 sizes of the bag to accommodate to different-sized hands. Generally, the bag with the diameter of 8 inches (≈ 20.32 cm) is used for people older than 18 years-old. The sphygmomanometer is adapted by rolling up the cuff and securing it at a circumference of 8 inches when inflated to 40 mmHg. After that the securing cuff is placed inside a non-slippery, non-stretch bag. The disadvantage of a classical MS is that it can measure pressures only up to 300 mmHg. Therefore, most of the time, it is impossible to take measurements from healthy subjects whose readings can be much more than 300 mmHg. To overcome this problem in the study, a MS which can measure pressures up to 510 mmHg was designed. To ensure that pressures up to 510 mmHg can be correctly shown by the indicator of an ordinary MS, the air trunk from the bag was divided into two. The one end of the trunk was connected to a

new calibrated pressure indicator (1st indicator) and the other to the sphygmomanometer pressure indicator (2nd indicator). The 1st indicator can measure the pressure in much wider range in millimeters of water (mmH₂O). At the second indicator, a line was drawn on the glass just between the 20 mmHg and 300 mmHg and marked as 320 mmHg. After the indicator completed its first rotation and passed the 320 mmHg, pressure was calculated by adding the readings to the 320 mmHg. For example, if the indicator showed 20 mmHg after completing its first tour, it was accepted as 340 mmHg or 40 mmHg was accepted as 360 mmHg. By this way, 190 mmHg after the 1st rotation of the indicator was read as 510 mmHg. This value was the maximum value shown by the indicator. While two indicators were attached to the same pressure bulb, pressure was increased and readings from both indicators at 11 points were recorded (Table 3.8). A very good correlation ($p < 0.001$) was found between the two indicators. Since the 2nd indicator has greater resolution, it is used in the study.

Table 3.8
The calibration table for the Modified sphygmomanometer

mmH ₂ O	mmHg	Ratio
2500	184	13.58
3000	220	13.63
3500	256	13.67
4000	292	13.70
4500	328	13.72
4700	342	13.74
5000	364	13.73
5500	400	13.75
6000	436	13.76
6500	472	13.77
7000	512	13.67

(1 mmHg = 13.6 mmH₂O)

3.2.2.5 Pinch strengths

For measuring pinch strengths, B&L pinch gauge (Figure 3.36) was used. It has been found to be the most accurate pinchmeter. It has an accuracy of $\pm 1\%$. Inter-rater reliability of the instrument is at least 0.97. Test-retest reliability is about 0.82 for right hand when the mean of three trials are taken [136]. It measures in kilograms (kg) or pounds (lb). Normative data have been established for adults and children by using this gauge in American and Turkish populations [140, 157]. In the study a calibrated, PG-30 model pinch gauge which can able to measure up to 30 lbs in 1lb increments is used.



Figure 3.36 B&L Pinch Gauge

3.2.3 Test Procedure

Before starting the experiments, the eligible volunteers were given information about the test procedures. A training period for all test instruments was allowed and the subjects were familiarized the NeO system for a brief. In addition to the demographic information, the scores of Symptom Severity Scale and Functional Status Scale [158], accompanying diseases and conditions and electrodiagnostic test results were recorded for patients with CTS. The set of tests and measurements were conducted at the right hands of the participants in three different test conditions: (1) with no orthosis (NO), (2) with SWO, and (3) with the NeO. The experiments were started with the 1st test condition to form the baseline measurements and the order of the 2nd and 3rd test conditions were alternated in accordance with the subject number in both groups. At the end of the 2nd and 3rd test conditions the level of discomfort perceived during the experiments were questioned by means of 10 cm visual analog scale (VAS). There were at least 15 minutes of intervals between the test conditions. Before starting experiments, SWOs were constructed and adjustments for the NeO and motor point localizations were done one by one. All the experiments, constructions, and set-up lasted about 2½ to 3 hours for each volunteers.

3.2.3.1 Construction of orthoses

A volar thumbhole SWO (Figure 3.37) holding the wrist in neutral position was designed for each subject. Thermoplastic materials (Orfit Classic or Orfit Eco) with a thickness of 3.2 mm were used for their construction. Orthoses were strictly controlled to

ensure that they did not cause any limitation on the movements of the thumb and MCP joint flexion. Orthoses were fixed to the forearm via Velcro straps.



Figure 3.37 Static thumbhole wrist orthosis

3.2.3.2 Adjustment and adaptation of the NeO control system

During this 30-45 minutes period, motor points and the effective amount of currents were determined for each muscle. Effective amount of current was accepted as the amount of current eliciting the desired movement of the stimulated muscle without spreading or minimally spreading to the neighboring muscles. Right forearm was positioned in the midrange while the shoulder was in 30° flexion and 30° abduction and wrist in neutral position. To precisely locate the motor points of the muscles, an isolated probe with a small-diameter tip and an on-off switch was used. The probe was connected to the cathode of the stimulator output. The software control on the computer was adjusted to give constant amplitude doublet waveforms at 30Hz to the output channel being used. Doublet stimulation pulses were used. The pulse width was 300 microsecond. The pulse interval was 5 milliseconds and N-let period was 40 ms. The intensity of the current was gradually increased until the desired muscle contraction was produced without spreading or minimally spreading to the neighboring muscles while considering the each subject's tolerance of pain and discomfort. It was aimed that at least two-thirds of the normal range of motion of the dominant movement of the stimulated muscle(s) was elicited. When the suitable amount of current was established, it was kept constant at this point for each output channel and the motor points were marked on the skin. This procedure was repeated for all output channels. Following muscles were stimulated to elicit movements: FCR and

FCU for flexion, ECRB for extension, ECU for ulnar deviation, and ECRL for radial deviation.

3.2.3.3 Application of the test instruments and batteries

Each set of tests at two test conditions was conducted in the following order: The MPPT test with 2 subtests, JHFT with all 7 subtests (Figures 3.38 to 3.40), grip pressure, grip strength (Figure 3.41), and pinch strengths measurements. Lateral, palmar, and tip-to-tip pinch strengths were measured respectively.



Figure 3.38 The implementation of the “turning-over cards” subtest of JHFT with the NeO



Figure 3.39 The implementation of the “writing a sentence” subtest of JHFT with the NeO



Figure 3.40 The implementation of the “moving empty cans” subtest of JHFT with a SWO



Figure 3.41 The implementation of the grip strength measurement test with the NeO

Subtests of the modified PPT were applied in the following way. The subject and the test board were positioned in accordance with the original test [130]. At the 1st subtest, subjects were asked to take a pin from the cup starting from the left-hand side with their right hands and insert it into their corresponding-sized holes at the right side of the board. They were instructed to do the test as fast as possible. The test was started with the largest dimension of pins at the left-hand side cup and after 5 pins were placed into their holes, it continued with the smaller sized ones until a total of 20 pins were placed into their holes. The time required to complete all the 20 pins was the score of the unilateral test. In the assembly test, the pins were placed in the same way as the unilateral test. But this time after placing a pin into a hole, a washer in the same cup was placed over this pin. The total number of pieces assembled in 30 seconds was the score of this subtest. JHFT was done according to the standard test procedure [127]. During the strength measurements the

standard protocols described by Mathiowetz et al. [140] was used. The mean of three trials was accepted as the average value for the related test. The strength measurements were done by alternating the hands and allowing at least 15 seconds between each experiment to alleviate the effect of the fatigue.

During the experiments with the NeO system, small-diameter self-adhesive surface electrodes were placed on the motor points and stimulation pulses were delivered via these electrodes. Doublet stimulation pulses were used since it was demonstrated that doublet stimulation pulses were able to produce more force with less fatigue with respect to square wave stimulation pulses [85, 86]. After placing the electrodes, a cover constructed with an elastic fabric was wrapped around the forearm (Figure 3.42). This was done to prevent the loosening and/or movement of the electrodes during experiments. The electrogoniometer was placed on this cover and fastened to the forearm via Velcro straps while considering the alignment of the movable arms and joint axes (Figures 3.43 to 3.45). During the experiments, limits of motion were set to 10 degrees in the sagittal plane and 5 degrees in the frontal plane. All electrode cables were positioned in a way not to cause any limitation to the limb during the experiments.



Figure 3.42 The elastic cover



Figure 3.43 The positioning of the electrogoniometer on the forearm_1



Figure 3.44 The positioning of the electrogoniometer on the forearm_2



Figure 3.45 The positioning of the electrogoniometer on the forearm_3

The experiments with the NeO system started with the MPPT test conducted in two stages. For the 1st stage of the test (OFF stage), the stimulator appeared to be functioning with the lights indicating the presence of the current at each output channel. But the connections from the output terminal of the DAQ card to the amplification circuit were disconnected. So there was actually no current flow to the electrodes. At the 2nd stage (ON), all electrode output channels were re-connected and the subjects were exposed to stimulation pulses. The maximum end points in four movement directions during both OFF and ON stages were recorded.

3.2.3.4 Data analysis

Means and standard deviations for each test condition were calculated. To make comparisons among the three test conditions (NO, NeO, SWO) within the same subject group, relative changes were used instead of absolute values for normalization purposes. The normalization was needed to introduce a relatively patient-independent measurement method since there were significant individual differences in the test results through all the test conditions. The relative change is represented in terms of percentage taking the NO test condition as the basis for each test. Therefore two percent changes, one for the SWO and one for the NeO test conditions were computed to reflect the relative changes. These relative changes were directly used in t-tests by accepting the baseline measurements (NO test condition) as 0. One-sample t test was used to compare these relative changes with the baseline measurements (NO). The comparison between the SWO and NeO test conditions within the same group was done with paired-samples t test. Parametric tests were used since most of the converted data conformed to normal distribution. Secondly, another comparison of the test means was made between the same test conditions of the two subject groups. It was done to determine whether there was any disease specific effect of the each control strategy. This time direct measurement values were compared with independent samples t test. The levels of discomfort with the SWO and the NeO were also compared within and between the subject groups. The maximum angles at ON and OFF stages during the implementation of 1st subtest of the MPPT were also analyzed. SPSS-15 statistical analysis software was used for the calculations.

4. RESULTS

The mean values of the measurements for each test condition (NO, SWO, and NeO) at the groups differentiated by the disease and sex characteristics are shown in Tables 4.1 to 4.4. Due to the sex difference in the healthy subjects group, the data are presented in 3 different tables as healthy (Table 4.2), healthy female (Table 4.3), and healthy male groups (Table 4.4).

Table 4.1
The test means in the group of patients with CTS

Measured variables		Test conditions (Mean(SD) (N=12))		
		NO	SWO	NeO ^a
Jebson-Taylor Hand Function Test^b	<i>J1 (sec)^c</i>	19.35(3.75)	22.97(3.54)	21.61(3.58)
	<i>J2 (sec)</i>	6.71(2.12)	8.33(2.27)	7.93(1.55)
	<i>J3 (sec)</i>	7.25(1.47)	8.22(1.81)	7.48(1.62)
	<i>J4 (sec)</i>	3.1(0.58)	3.43(0.92)	3.18(0.67)
	<i>J5 (sec)</i>	8.54(1.19)	10.11(1.81)	9.26(1.35)
	<i>J6 (sec)</i>	6.14(0.70)	6.42(1.03)	6.04(1.03)
	<i>J7 (sec)</i>	6.02(0.83)	6.76(1.21)	6.3(1.12)
Modified Purdue Pegboard Test^d	<i>MPPT1 (sec)</i>	36.28(5.28)	40.73(5.13)	37.64(5.65)
	<i>MPPT2 (# of pcs.)</i>	16.08(2.10)	14.25(1.76)	15.52(1.80)
Strength Measurements	<i>Grip pressure(mmHg)</i>	177(56)	152(46)	174(54)
	<i>Grip force (kg)</i>	12.63(4.22)	6.48(2.5)	11(3.85)
	<i>Lateral pinch (lbs)</i>	13.97(4.41)	13.13(3.8)	13.68(4.33)
	<i>Palmar pinch(lbs)</i>	12.19(3.45)	10.17(3.24)	11.54(3.11)
	<i>Tip-to-tip pinch (lbs)</i>	10.27(3.01)	9.3(2.84)	10.14(2.95)

^a The number of subjects completing the experiments with NeO were 11.

^b J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^c One patient's score at the 1st subtest of the JHFT was removed because it was out of $\pm 2SD$

^d MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

(NO, SWO, and NeO represent test conditions with no-orthosis, thumbhole static wrist orthosis, and neuro-orthosis test conditions)

SD: Standard deviation

In general, the healthy male subjects performed better at all test conditions with respect to the other subjects. Table 4.5 demonstrates the comparison of means between healthy male and healthy female subjects. Although male subjects' scores at many subtests of function and dexterity were better than those of female healthy subjects, almost all of them did not show significant differences between these two groups. However there were significant differences in strength measurements. It was more prominent under the NeO test condition.

Table 4.2
Test means in the healthy subjects group

Measured variables		Test conditions (Mean(SD) (N=19))		
		NO	SWO	NeO ^a
Jebson-Taylor Hand Function Test^b	<i>J1 (sec)</i>	13.86(2.47)	17.13(3.20)	16.26(2.50)
	<i>J2 (sec)</i>	4.9(0.84)	6.72(1.06)	6.24(1.09)
	<i>J3 (sec)</i>	6.46(0.71)	7.30(0.68)	7.11(0.65)
	<i>J4 (sec)</i>	2.93(0.43)	3.10(0.43)	3.06(0.50)
	<i>J5 (sec)</i>	7.08(0.64)	8.7(2.12)	7.88(1.27)
	<i>J6 (sec)</i>	4.59(0.69)	4.75(0.62)	4.74(0.69)
	<i>J7 (sec)</i>	4.86(0.56)	5.34(0.7)	5.02(0.57)
Modified Purdue Pegboard Test^c	<i>MPPT1 (sec)</i>	31.56(2.34)	35.96(2.43)	34.47(2.29)
	<i>MPPT2 (# of pcs.)</i>	18.10(1.88)	15.21(1.23)	16.72(1.64)
Strength Measurements	<i>Grip pressure (mmHg)</i>	278(40)	253(42)	278(42)
	<i>Grip force (kgs)</i>	22.28(4.08)	11.21(2.53)	21.36(3.86)
	<i>Lateral pinch (lbs)</i>	18.84(3.26)	16.85(3.25)	18.23(3.11)
	<i>Palmar pinch (lbs)</i>	16.66(2.10)	15.92(2.77)	16.58(2.37)
	<i>Tip-to-tip pinch (lbs)</i>	15.68(2.14)	14.02(2.15)	15.44(2.71)

^a The number of subjects completing the experiments with NeO were 18.

^b J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^c MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

NO, SWO, and NeO represent test conditions with no-orthosis, thumbhole static wrist orthosis, and neuro-orthosis test conditions. SD: Standard deviation

Table 4.3
Test means in the healthy female subjects group

Measured variables		Test conditions (Mean(SD) (N=12))		
		NO	SWO	NeO ^a
Jebson-Taylor Hand Function Test^b	<i>J1 (sec)</i>	13.91(2.4)	17.16(2.57)	16.99(2.04)
	<i>J2 (sec)</i>	4.98(0.67)	6.98(1.05)	6.29(0.9)
	<i>J3 (sec)</i>	6.45(0.75)	7.26(0.76)	7(0.6)
	<i>J4 (sec)</i>	2.94(0.31)	3.15(0.33)	3.07(0.33)
	<i>J5 (sec)</i>	7.28(0.64)	8.62(1.64)	7.82(0.49)
	<i>J6 (sec)</i>	4.65(0.58)	4.83(0.38)	4.81(0.44)
	<i>J7 (sec)</i>	4.83(0.57)	5.35(0.68)	5.06(0.49)
Modified Purdue Pegboard Test^c	<i>MPPT1 (sec)</i>	32.47(1.72)	36.48(2.16)	35.25(2.07)
	<i>MPPT2 (# of pcs.)</i>	17.5(1.24)	14.75(0.97)	16.27(0.79)
Strength Measurements	<i>Grip pressure(mmHg)</i>	251(19)	227(23.48)	251(22)
	<i>Grip force (kgs)</i>	20.13(2.66)	10.33(2.07)	19.32(2.45)
	<i>Lateral pinch (lbs)</i>	17(1.61)	14.96(1.23)	16.36(1.05)
	<i>Palmar pinch (lbs)</i>	15.81(1.18)	14.93(1.88)	15.45(1.04)
	<i>Tip-to-tip pinch (lbs)</i>	14.83(1.35)	13.42(1.51)	14.23(1.57)

^a The number of subjects completing the experiments with NeO were 11.

^b J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^c MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

(NO, SWO, and NeO represent test conditions with no-orthosis, thumbhole static wrist orthosis, and neuro-orthosis test conditions). SD: Standard deviation

Table 4.4
Test means in the healthy male subjects group.

Measured variables		Test conditions (Mean(SD) (N=7))		
		NO	SWO	NeO
Jebson-Taylor Hand Function Test^a	<i>J1 (sec)</i>	13.78(2.79)	17.07(4.31)	15.11(2.88)
	<i>J2 (sec)</i>	4.77(1.14)	6.25(0.97)	6.17(1.43)
	<i>J3 (sec)</i>	6.5(0.71)	7.38(0.57)	7.28(0.74)
	<i>J4 (sec)</i>	2.91(0.62)	3.01(0.57)	3.04(0.72)
	<i>J5 (sec)</i>	6.75(0.52)	8.84(2.91)	7.95(2.04)
	<i>J6 (sec)</i>	4.5(0.89)	4.61(0.92)	4.61(1.01)
	<i>J7 (sec)</i>	4.92(0.59)	5.31(0.8)	4.94(0.72)
Modified Purdue Pegboard Test^b	<i>MPPT1 (sec)</i>	30(2.55)	35.05(2.79)	33.24(2.22)
	<i>MPPT2 (# of pcs.)</i>	19.14(2.41)	16(1.29)	17.42(2.37)
Strength Measurements	<i>Grip pressure(mmHg)</i>	325(14)	299(22)	321(25)
	<i>Grip force (kgs)</i>	26(3.41)	12.71(2.69)	24.57(3.55)
	<i>Lateral pinch (lbs)</i>	22(2.97)	20.10(3.09)	21.17(3.01)
	<i>Palmar pinch (lbs)</i>	18.14(2.59)	17.64(3.34)	18.35(2.83)
	<i>Tip-to-tip pinch (lbs)</i>	17.14(2.54)	15.07(2.78)	17.36(3.12)

^a J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^b MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

(NO, SWO, and NeO represent test conditions with no-orthosis, thumbhole static wrist orthosis, and neuro-orthosis test conditions). SD: Standard deviation

Table 4.5
Comparison of the test means between healthy male and female groups.

Measured variables		Test conditions (P value) ^a		
		NO (Female:12, Male:7)	SWO (Female:12, Male:7)	NeO (Female:11, Male:7)
Jebson-Taylor Hand Function Test^b	<i>J1 (sec)</i>	0.921	0.956	0.124
	<i>J2 (sec)</i>	0.678	0.155	0.829
	<i>J3 (sec)</i>	0.888	0.706	0.381
	<i>J4 (sec)</i>	0.917	0.505	0.921
	<i>J5 (sec)</i>	0.086	0.855	0.874
	<i>J6 (sec)</i>	0.662	0.475	0.561
	<i>J7 (sec)</i>	0.733	0.919	0.676
Modified Purdue Pegboard Test^c	<i>MPPT1 (sec)</i>	0.021*	0.232	0.079
	<i>MPPT2 (# of pcs)</i>	0.064	0.028	0.253
Strength Measurements	<i>Grip pressure(mmHg)</i>	0.0001*	0.0001*	0.0001*
	<i>Grip force (kgs)</i>	0.001*	0.045*	0.002*
	<i>Lateral pinch (lbs)</i>	0.0001*	0.004*	0.005*
	<i>Palmar pinch (lbs)</i>	0.057	0.035*	0.035*
	<i>Tip-to-tip pinch (lbs)</i>	0.057	0.107	0.039*

^a Independent samples t-test was used. Significance level was set at p=0.05.

^b J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^c MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

* The tests showing significant differences between the test conditions are signed with an asterisk.

All test means of the healthy female subject group were better than those of patients with CTS. Table 4.6 demonstrates the relative changes of the test scores in patients with CTS with respect to healthy female subjects group. The most prominent deviations were observed in the “writing a sentence” and “moving empty cans” subtests of the JHFT and grip force measurements in all test conditions. Independent t-test results (Table 4.7) showed significant differences at many of the tested areas. The number of tests showing significant difference between the two groups was higher in NO test condition. At NO test condition all tests except the 3rd and 4th subtests of the JHFT and the 2nd subtest of the MPPT test showed significant differences between the two groups. At SWO test condition, the 2nd subtest of the JHFT and the lateral pinch strength test were added to the previous exception list. Although the amount of total deviation was higher in the SWO test condition in comparison to the NeO, the same number of tests demonstrated significant difference in these two test conditions.

Table 4.6
Relative changes of the test scores in patients with CTS compared to healthy female subjects

Measured variables		Test conditions		
		NO (% Difference) ^a	SWO (% Difference)	NeO (% Difference)
Jebson-Taylor Hand Function Test^b	<i>J1 (sec)</i>	-39,11	-33,86	-27,19
	<i>J2 (sec)</i>	-34,74	-19,34	-26,07
	<i>J3 (sec)</i>	-12,40	-13,22	-6,86
	<i>J4 (sec)</i>	-5,44	-8,89	-3,58
	<i>J5 (sec)</i>	-17,31	-17,29	-18,41
	<i>J6 (sec)</i>	-32,04	-32,92	-25,57
	<i>J7 (sec)</i>	-24,64	-26,36	-24,51
Modified Purdue Pegboard Test^c	<i>MPPT1 (sec)</i>	-11,73	-11,65	-6,78
	<i>MPPT2 (# of pcs)</i>	-8,11	-3,39	-4,61
Strength Measurements	<i>Grip pressure(mmHg)</i>	-29,48	-33,04	-30,68
	<i>Grip force (kgs)</i>	-37,26	-37,27	-43,06
	<i>Lateral pinch (lbs)</i>	-17,82	-12,23	-16,38
	<i>Palmar pinch (lbs)</i>	-22,90	-31,88	-25,31
	<i>Tip-to-tip pinch (lbs)</i>	-30,75	-30,70	-28,74
Total deviation		-300,83 %	-280,16 %	-262,44 %

^a Minus sign in front of a percent value implies that the test mean in the CTS group was worse than that of healthy subject group regardless of the test.

^b J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^c MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

The result of the comparisons of relative changes in the group of patients with CTS is shown in the Table 4.8. The sum of the deviations for each test at SWO and NeO test conditions is 210 and 81 respectively. If these total deviations from the baseline

measurements are considered, the limitations caused by the NeO are lower than those of SWO at all tests. In concordant with the amount of these deviations, SWOs led to more limitations than the NeO in terms of significantly different test numbers. These were 11 and 8 for SWO and NeO test conditions respectively. The performance of the subjects in 6 tests was better while they were under the control of the NeO compared to SWO. These tests were strength measurements predominantly.

Table 4.7
Comparison of the test means between healthy females and patients with CTS

Measured variables		Test conditions (P value) ^a		
		NO (Healthy:12, CTS:12)	SWO (Healthy:12, CTS:12)	NeO (Healthy:11, CTS:11)
Jebson-Taylor Hand Function Test^b	<i>J1 (sec)</i>	0.0001*	0.0001*	0.002*
	<i>J2 (sec)</i>	0.018*	0.076	0.006*
	<i>J3 (sec)</i>	0.106	0.112	0.366
	<i>J4 (sec)</i>	0.418	0.337	0.635
	<i>J5 (sec)</i>	0.004*	0.046*	0.003*
	<i>J6 (sec)</i>	0.0001*	0.0001*	0.003*
	<i>J7 (sec)</i>	0.001*	0.003*	0.005*
Modified Purdue Pegboard Test^c	<i>MPPT1 (sec)</i>	0.034*	0.019*	0.211
	<i>MPPT2 (# of pcs)</i>	0.057	0.398	0.218
Strength Measurements	<i>Pressure(mmHg)</i>	0.001*	0.0001*	0.001*
	<i>Force (kgs)</i>	0.0001*	0.0001*	0.0001*
	<i>Lateral (lbs)</i>	0.042*	0.135	0.071
	<i>Palmar (lbs)</i>	0.004*	0.0001*	0.002*
	<i>Tip-to-tip (lbs)</i>	0.0001*	0.0001*	0.001*

^a Independent samples t-test was used. Significance level was set at p=0.05.

^b J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^c MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

* The tests showing significant differences between the test conditions are signed with an asterisk.

Table 4.9 shows the comparison of the test conditions in the healthy subjects group. The sum of the deviations for each test is 231 and 101 for SWO and NeO test conditions respectively. When the baseline measurements are considered, the use of SWO resulted in restriction in all tests. However the NeO did not result in decrease in the performance of 2 tests which were subtests of the strength measurements. In the healthy subjects group, SWO appears to be more restrictive than that of the CTS group in terms of significantly different test numbers (13 vs.11). However in contrary to the results of NO-SWO comparison, NO-NeO comparison in this subject group indicated less restriction than that of CTS group (5 vs. 8). When SWO and the NeO test conditions were compared, 10 tests

showed significant difference in favour of the latter. This was 6 in the group of patients with CTS.

Table 4.10 shows the deviations from the baseline measurements and the comparison of the test conditions in the healthy female subjects group. Due to the dominant number of female subjects in the healthy subjects group, the table characteristics bear resemblance to Table 4.9 in general. However the sum of the deviations in SWO and NeO test conditions was 231 and 106 in this group. The number of tests demonstrating significant difference from the baseline measurements was 12 and 7 for SWO and the NeO respectively. The comparison of SWO and NeO test conditions revealed significant difference in 8 tests. There is an orderly distribution of these tests among the main measured areas in all healthy and healthy female subjects.

The sum of the deviations in the healthy male subjects was 231 and 106 for SWO and NeO test conditions (Table 4.11). When compared to SWO, NeO control system caused less restriction in the tests. In four tests, NO-SWO comparison did not result in significant differences. This was the highest number in all subject groups. However the comparison of the NeO and SWO control systems demonstrated significant difference at only four tests. This number changes from 6 to 10 in the other groups.

Tables 4.12 and 4.13 demonstrate the maximum angulations during the implementation of the 1st subtest of MPPT. The end points are presented for both ON and OFF stages of the experiment. The maximum angular motions in all directions were similar among the subject groups. However, in the group of patients with CTS, the total angulations at the sagittal plane were less than those in the other groups for both test stages. In the sagittal plane, the maximum angulations in the extension movement were higher than flexion. In the frontal plane, the maximum ulnar deviation angle was higher than radial deviation angle. If the amount of angular deviation from the preset activation thresholds (10 and 5 degrees for the sagittal and frontal planes respectively) is taken into consideration, the NeO seems to be more effective in the control of extension and flexion movements compared to radial and ulnar deviation movements. The difference between the maximum angles in OFF and ON stages is very small in the groups of patients with CTS and healthy male subjects.

Table 4.8
The comparison of the test conditions in the group of patients with CTS

Measured variables		Test conditions ^a				P values (t test) ^b		
		SWO		NeO ^c		NO-SWO	NO-NeO	SWO-NeO
		% of the baseline	% change	% of the baseline	% change			
Jebson-Taylor Hand Function Test ^d	<i>J1 (sec)</i>	119	-19	112	-12	0.001*	0.04*	0.062
	<i>J2 (sec)</i>	124	-24	118	-18	0.001*	0.002*	0.545
	<i>J3 (sec)</i>	113	-13	103	-3	0.005*	0.047*	0.046
	<i>J4 (sec)</i>	111	-11	103	-3	0.107	0.306	0.209
	<i>J5 (sec)</i>	118	-18	108	-8	0.011*	0.048*	0.099
	<i>J6 (sec)</i>	105	-5	98	-2	0.006*	0.266	0.021
	<i>J7 (sec)</i>	112	-12	105	-5	0.001*	0.037*	0.022*
Modified Purdue Pegboard Test ^e	<i>MPPT1 (sec)</i>	112	-12	104	-4	0.001*	0.038*	0.007*
	<i>MPPT2 (# of pcs)</i>	89	-11	97	-3	0.001*	0.031*	0.049*
Strength Measurements	<i>Grip pressure(mmHg)</i>	86	-14	98	-2	0.002*	0.313	0.001*
	<i>Grip force (kgs)</i>	51	-49	87	-13	0.0001*	0.006*	0.0001*
	<i>Lateral pinch (lbs)</i>	94	-6	98	-2	0.077	0.750	0.066
	<i>Palmar pinch (lbs)</i>	83	-7	95	-5	0.005*	0.144	0.004*
	<i>Tip-to-tip pinch (lbs)</i>	91	-9	99	-1	0.113	0.815	0.096

^a Minus sign in front of the % values means deterioration with respect to baseline measurements regardless of the test. Plus sign shows improvement.

^b One-sample and paired-samples t-tests were used in the comparisons. Significance level was set at p=0.05.

^c The number of subjects completing the experiments with NeO were 11.

^d J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^e MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

* The tests showing significant differences between the test conditions are shown with an asterisk.

Table 4.9
The comparison of the test conditions in the healthy subjects group

Measured variables		Test conditions ^a				P values (t test) ^b		
		SWO		NeO ^c		NO-SWO	NO-NeO	SWO-NeO
		% of the baseline	% change	% of the baseline	% change			
Jebson-Taylor Hand Function Test ^d	<i>J1 (sec)</i>	124	-24	117	-17	0.0001*	0.014*	0.001*
	<i>J2 (sec)</i>	137	-37	127	-27	0.0001*	0.005*	0.018*
	<i>J3 (sec)</i>	113	-13	110	-10	0.001*	0.034*	0.016*
	<i>J4 (sec)</i>	106	-6	104	-4	0.032*	0.302	0.231
	<i>J5 (sec)</i>	123	-23	111	-11	0.001*	0.099	0.002*
	<i>J6 (sec)</i>	103	-3	103	-3	0.027*	0.806	0.200
	<i>J7 (sec)</i>	110	-10	103	-3	0.0001*	0.657	0.0001*
Modified Purdue Pegboard Test ^e	<i>MPPT1 (sec)</i>	114	-14	109	-9	0.0001*	0.027*	0.0001*
	<i>MPPT2 (# of pcs)</i>	84	-16	92	-8	0.0001*	0.0001*	0.540
Strength Measurements	<i>Grip pressure(mmHg)</i>	91	-9	100	0	0.0001*	0.064	0.0001*
	<i>Grip force (kgs)</i>	50	-50	96	-4	0.0001*	0.012	0.0001*
	<i>Lateral pinch (lbs)</i>	89	-11	97	-3	0.0001*	0.532	0.0001*
	<i>Palmar pinch (lbs)</i>	96	-4	100	0	0.055	0.233	0.074
	<i>Tip-to-tip pinch (lbs)</i>	89	-11	98	-2	0.0001*	0.284	0.001*

^a Minus sign in front of the % values means deterioration with respect to baseline measurements regardless of the test. Plus sign shows improvement.

^b One-sample and paired-samples t-tests were used in the comparisons. Significance level was set at p=0.05.

^c The number of subjects completing the experiments with NeO were 18.

^d J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^e MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

* The tests showing significant differences between the test conditions are shown with an asterisk.

Table 4.10
The comparison of the test conditions in the healthy female subjects group

Measured variables		Test conditions ^a				P values (t test) ^b		
		SWO		NeO ^c		NO-SWO	NO-NeO	SWO-NeO
		% of the baseline	% change	% of the baseline	% change			
Jebson-Taylor Hand Function Test ^d	<i>J1 (sec)</i>	123	-23	122	-22	0.0001*	0.0001*	0.192
	<i>J2 (sec)</i>	140	-40	126	-26	0.005*	0.003*	0.002*
	<i>J3 (sec)</i>	113	-13	109	-9	0.02*	0.03*	0.083
	<i>J4 (sec)</i>	107	-7	104	-4	0.072	0.099	0.258
	<i>J5 (sec)</i>	118	-18	107	-7	0.002*	0.003*	0.034*
	<i>J6 (sec)</i>	104	-4	103	-3	0.105	0.461	0.403
	<i>J7 (sec)</i>	111	-11	105	-5	0.0001*	0.002*	0.004*
Modified Purdue Pegboard Test ^e	<i>MPPT1 (sec)</i>	112	-12	109	-9	0.0001*	0.012*	0.002*
	<i>MPPT2 (# of pcs)</i>	84	-16	93	-7	0.0001*	0.001*	0.002*
Strength Measurements	<i>Grip pressure(mmHg)</i>	90	-10	100	0	0.0001*	0.474	0.0001*
	<i>Grip force (kgs)</i>	51	-49	96	-4	0.034*	0.784	0.021*
	<i>Lateral pinch (lbs)</i>	88	-12	96	-4	0.011*	0.138	0.204
	<i>Palmar pinch (lbs)</i>	94	-6	98	-2	0.0001*	0.560	0.0001*
	<i>Tip-to-tip pinch (lbs)</i>	90	-10	96	-4	0.011*	0.138	0.204

^a Minus sign in front of the % values means deterioration with respect to baseline measurements regardless of the test. Plus sign shows improvement.

^b One-sample and paired-samples t-tests were used in the comparisons. Significance level was set at p=0.05.

^c The number of subjects completing the experiments with NeO were 11.

^d J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^e MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

* The tests showing significant differences between the test conditions are shown with an asterisk.

Table 4.11
The comparison of the test conditions in the healthy male subjects group

Measured variables		Test conditions ^a				P values (t test) ^b		
		SWO		NeO		NO-SWO	NO-NeO	SWO-NeO
		% of the baseline	% change	% of the baseline	% change			
Jebson-Taylor Hand Function Test ^d	<i>J1 (sec)</i>	124	-24	110	-10	0.001*	0.121	0.121
	<i>J2 (sec)</i>	131	-31	129	-29	0.002*	0.017*	0.716
	<i>J3 (sec)</i>	114	-14	112	-12	0.013*	0.012*	0.575
	<i>J4 (sec)</i>	103	-3	104	-4	0.158	0.231	0.951
	<i>J5 (sec)</i>	131	-31	118	-18	0.064	0.088	0.083
	<i>J6 (sec)</i>	102	-2	102	-2	0.165	0.024*	0.326
	<i>J7 (sec)</i>	108	-8	100	0	0.040*	0.955	0.015*
Modified Purdue Pegboard Test ^e	<i>MPPT1 (sec)</i>	117	-17	111	-11	0.0001*	0.018*	0.083
	<i>MPPT2 (# of pcs)</i>	84	-16	91	-9	0.0001*	0.038*	0.072
Strength Measurements	<i>Grip pressure(mmHg)</i>	92	-8	99	-1	0.002*	0.528	0.010*
	<i>Grip force (kgs)</i>	49	-51	95	-5	0.0001*	0.051	0.0001*
	<i>Lateral pinch (lbs)</i>	91	-9	96	-4	0.009*	0.133	0.007*
	<i>Palmar pinch (lbs)</i>	97	-3	101	+1	0.397	0.676	0.270
	<i>Tip-to-tip pinch (lbs)</i>	88	-12	101	+1	0.0001*	0.635	0.0001*

^a Minus sign in front of the % values means deterioration with respect to baseline measurements regardless of the test. Plus sign shows improvement.

^b One-sample and paired-samples t-tests were used in the comparisons. Significance level was set at p=0.05.

^c J1 to J7 represent 1st to 7th subtests of the Jebson Hand Function Test (JHFT) respectively.

^d MPPT1 and MPPT2 represent 1st and 2nd subtests of Modified Purdue Pegboard Test.

* The tests showing significant differences between the test conditions are shown with an asterisk.

Table 4.12
Maximum angulations in the sagittal plane while the NeO was OFF and ON

Subject groups	Test conditions (OFF/ON)	Movements in the sagittal plane in degrees (Mean degree (SD))			
		Extension		Flexion	
		Maximum	Deviation	Maximum	Deviation
Healthy subjects (N=19)	OFF	31.6(7.4)	21.6	26.4(8.7)	16.4
	ON	16.3(4.4)	6.3	14.5(2.8)	4.5
Healthy male subjects (N=7)	OFF	34(8.6)	24	24.9(8.4)	14.9
	ON	14.3(3.9)	4.3	13(3.2)	3
Healthy female subjects (N=12)	OFF	31(6.5)	21	27.4(9.2)	17.4
	ON	17.6(4.3)	7.6	15.5(2.2)	5.5
Patients with CTS (N=11)	OFF	28.3(12.7)	18.3	18.8(10.4)	8.8
	ON	14(2.2)	4	11.3(2.2)	1.3

The term *maximum* implies maximum thresholds reached during the OFF and ON test conditions. *Deviation* is equal to maximum angle minus the preset value to start the activation of stimulation pulses. It was 10 degrees in the sagittal plane measurements.

Table 4.13
Maximum angulations in the frontal plane while the NeO was OFF and ON

Subject groups	Test conditions (OFF/ON)	Movements in the frontal plane in degrees (Mean degree (SD))			
		Radial deviation		Ulnar deviation	
		Maximum	Deviation	Maximum	Deviation
Healthy subjects (N=19)	OFF	11.8(4.2)	6.8	18.5(6.8)	13.5
	ON	8.3(4.2)	2.3	12.6(4.6)	7.6
Healthy male subjects (N=7)	OFF	11(5)	6	15(7.2)	10
	ON	7.1(5.3)	2.1	14.1(6.1)	9.1
Healthy female subjects (N=12)	OFF	12.4(3.6)	7.4	20.6(5.8)	15.6
	ON	9.1(3.3)	4.1	11.6(3.1)	6.6
Patients with CTS (N=11)	OFF	11.2(4.2)	6.2	16.6(6)	11.6
	ON	7.8(3.8)	2.8	13.8(5.3)	8.8

The term *maximum* implies maximum thresholds reached during the OFF and ON test conditions. *Deviation* is equal to maximum angle minus the preset value to start the activation of stimulation pulses. It was 5 degrees in the frontal plane measurements.

The maximum angulations in both OFF and ON stages were compared between various subject groups. There was a significant difference in the radial deviation movement between the groups of patients with CTS and healthy female subjects. This difference was valid for both ON and OFF test stages. However no significant difference was observed between the groups of healthy male and healthy female subjects (Table 4.14). The box plot graphics for the maximum movement threshold angles at each group is presented in the Figures 3.46 to 3.49.

Table 4.14
Comparison of the maximum angular motions between the groups

Movements		Healthy female subjects (G1) vs. Patients with CTS (G2)		Healthy male subjects (G1) vs. Healthy female subjects (G2)	
		P value	G1-G2 (degree)	P value	G1-G2 (degree)
Extension	OFF	0.671	2.7	0.290	3
	ON	0.05	3.6	0.569	-3.3
Flexion	OFF	0.476	8.6	0.516	-2.5
	ON	0.116	4.2	0.093	-2.5
Radial deviation	OFF	0.024*	1.2	0.115	-1.4
	ON	0.009*	1.3	0.067	-2
Ulnar deviation	OFF	0.407	4.6	0.351	-5.6
	ON	0.245	-2.2	0.329	2.5

G1 and G2 represent the mean maximum threshold angles at the same test conditions of the related test groups.

* The tests showing significant differences between the test conditions are shown with an asterisk.

The discomfort levels experienced by the subjects under the SWO and NeO test conditions are presented in Table 4.15. The most of the discomfort associated with the NeO was due to pain from skin irritation. It appears that female subjects suffer more discomfort from both of the control systems in comparison with male subjects. NeO control system led to higher discomfort levels compared to SWO at all subject groups. T test results within each subject group showed significant differences between the discomfort levels experienced with SWO and NeO at all subject groups except healthy male subjects group. When the discomfort levels of the healthy female subjects and patients with CTS were compared, any significant difference was not observed at both of the control strategies. However, a significant difference appeared in the discomfort levels experienced with the NeO when the groups of healthy female and male subjects groups were compared (Table 4.16).

Table 4.15
Discomfort levels during the experiments with SWO and NeO and t-test results

Test Conditions	Subject Groups (Mean (SD))			
	Healthy subjects (N=18) ^a	Healthy male subjects (N=7)	Healthy female subjects (N=11) ^a	Patients with CTS (N=11) ^a
SWO	3.6(1.2)	3.1(1)	3.9(1.2)	3.7 (1.1)
NeO	4.4(1.2)	3.4(1.3)	5(0.9)	4.8(1.6)
P value	0.014*	0.364	0.023*	0.039*

^a Although there were one more subjects at these groups, they did not complete the tests with NeO.

* The tests showing significant differences between the test conditions are shown with an asterisk.

Table 4.16
Comparison of discomfort levels between different subject groups

Test conditions	Healthy females vs. patients with CTS (N=11/11) (P value) ^a	Healthy males vs. healthy females (N=7/11) (P value)
SWO	0.679	0.164
NeO	0.747	0.004*

^a Independent-samples t-test. Significance level was set at $p=0.05$.

The tests showing significant differences between the test conditions are shown with an asterisk.

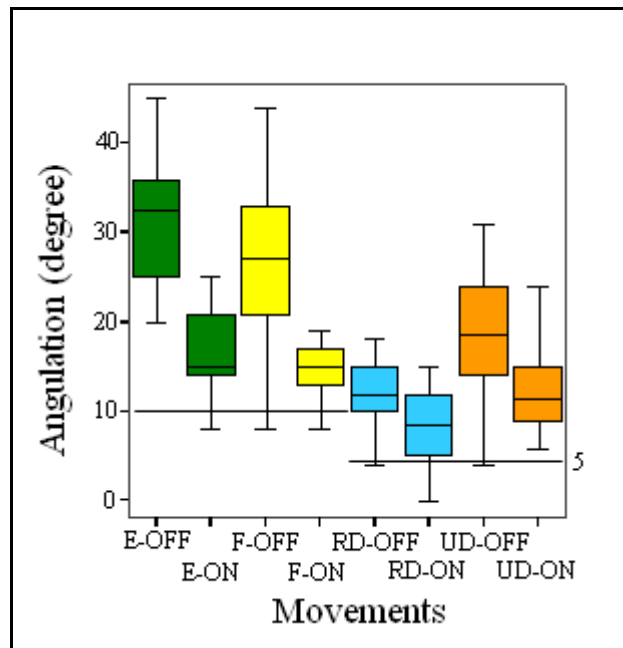


Figure 3.46 Box plot graphics of wrist movements in healthy subjects group. Horizontal lines in line with 10 and 5 degrees represent set values for extension/flexion and radial/ulnar deviation movements respectively.

(E-OFF: Extension in OFF stage, E-ON: Extension in ON stage, F-OFF: Flexion in OFF stage, F-ON: Flexion in ON stage, RD-OFF: Radial deviation in OFF stage, RD-ON: Radial deviation in ON stage)

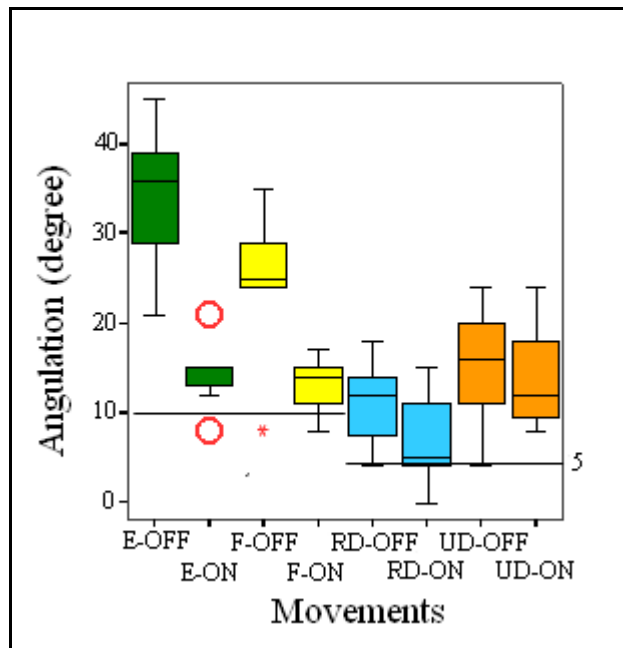


Figure 3.47 Box plot graphics of wrist movements in healthy male subjects group. Horizontal lines in line with 10 and 5 degrees represent set values for extension/flexion and radial/ulnar deviation movements respectively. (E-OFF: Extension in OFF stage, E-ON: Extension in ON stage, F-OFF: Flexion in OFF stage, F-ON: Flexion in ON stage, RD-OFF: Radial deviation in OFF stage, RD-ON: Radial deviation in ON stage)

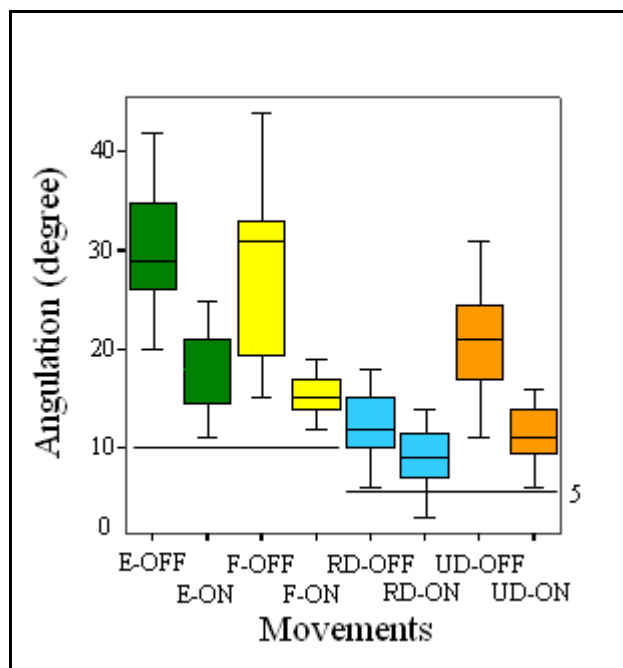


Figure 3.48 Box plot graphics of wrist movements in healthy female subjects group. Horizontal lines in line with 10 and 5 degrees represent set values for extension/flexion and radial/ulnar deviation movements respectively. (E-OFF: Extension in OFF stage, E-ON: Extension in ON stage, F-OFF: Flexion in OFF stage, F-ON: Flexion in ON stage, RD-OFF: Radial deviation in OFF stage, RD-ON: Radial deviation in ON stage)

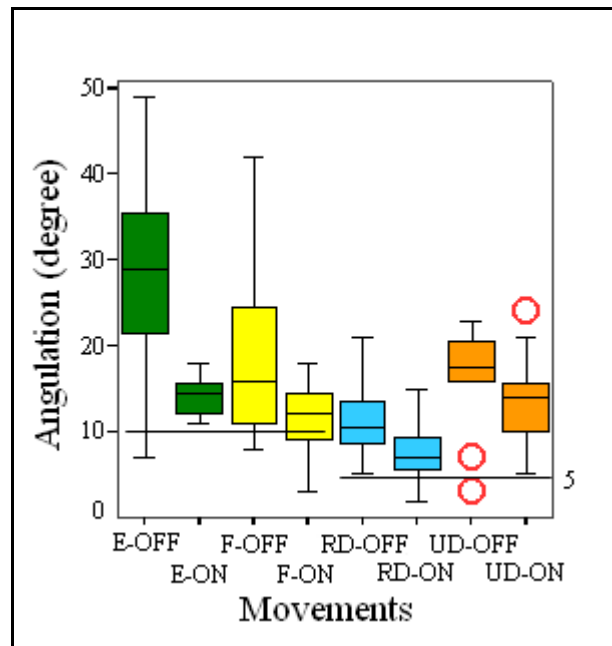


Figure 3.49 Box plot graphics of wrist movements in patients with CTS. Horizontal lines in line with 10 and 5 degrees represent set values for extension/flexion and radial/ulnar deviation movements respectively. (E-OFF: Extension in OFF stage, E-ON: Extension in ON stage, F-OFF: Flexion in OFF stage, F-ON: Flexion in ON stage, RD-OFF: Radial deviation in OFF stage, RD-ON: Radial deviation in ON stage)

5. DISCUSSION AND CONCLUSION

This is the first study in the literature aiming to control wrist movements in four movement directions. A closed-loop control strategy is used. Angular changes in two movement planes are monitored with an electrogoniometer and used as feedback to turn on or off the stimulation pulses to the related muscles. Although there are complex control systems even combining several feedback signals to obtain more precise control over the muscles, we preferred to use only position feedback due to its simplicity. More complex systems to control activation of the muscles are more demanding in terms of hardware and software requirements. Therefore, a complicated system can make the practical use of the resulting controller difficult. If the compliance problems with SWOs [159, 160] and the incidence and prevalence of the CTS [36-39] are taken into account, the simplicity should be a consideration.

The starting point in the study was to develop a control system for patients with CTS. It was aimed to limit the wrist movements into the “safe area” with less restriction compared to a SWO in patients with CTS. Since CTS is not a long-term disease, an invasive system would not be preferred by patients although they provide more precise control over muscles. Therefore, the technique of delivering the stimulation pulses via surface electrodes was chosen. Isolated stimulation of the muscles is difficult in a narrow and “crowded” area. In the literature there are some studies where the controls of the hand and forearm muscles are provided with surface stimulation [97, 98, 161-164]. The common problem in these studies is the difficulty in isolating individual muscles while trying to obtain adequate force. To augment the force produced by muscle contraction, amplitude and/or pulse width modulation are used. However, increased intensity of the stimulation pulses leads to recruitment of the neighboring muscles. This results in unwanted movements. In this study we used the method of Nathan [163]. To alleviate the effect of spreading of the stimulation pulses to other muscles “effective current density” was used. In the adaptation period the current density was increased to elicit at least two-thirds of the movement range in a direction while considering the discomfort due to skin irritation by the stimulation pulses. However during the experiments some current spreading was

observed in 2 patients with CTS and 2 healthy subjects. One of the subjects was female in the healthy group. This spreading occurred in the tests requiring forearm rotation such as “turning over cards” and “picking-up small common objects” and was more prominent in finger and thumb flexors. Some test scores with NeO could have been negatively affected with the current spreading.

During the experiments “doublet” stimulation pulses were used. The reason for using this stimulation waveform depends on their ability to produce more muscle force with less fatigue compared to usual rectangular or square waveforms [85, 86]. Doublet waveforms have some fixed stimulus parameters like pulse width. Therefore the only way to increase the contraction strength was the amplitude modulation. The design of the amplification circuit was adapted to allow production of high voltages. However amplitude modulation caused discomfort due to skin irritation at high voltage levels. Due to this, two female subjects had to leave the experiments. Pulse width modulation can be more suitable for such applications.

A custom-made electrogoniometer was used to monitor angular changes in the wrist joint complex. Wrist joint is composed of many articulations and each of them contributes to total movement in varying degrees. However ordinary bi-axial Sages consider only movements of radiocarpal joint at most of the time. In addition, the distal block of the SGE is fixed to the very mobile dorsal skin of the hand via double-sided self-adhesive tapes. When combined with crosstalk which is an inherent characteristic of the measurements with strain gauges, these drawbacks lead to considerable errors. To control wrist joint movements, position of the joint should be precisely and correctly measured. Due to these reasons, development of a custom-made electrogoniometer was aimed. Firstly, strain gauges were used. However strain gauge experiments failed mainly due to difficulty with finding a suitable housing material and breakdown of the strain gauges short after the experiments started. At the next step, a potentiometric electrogoniometer was developed. It measures the movements of the distal part of the joint complex compared to forearm. The calibration and reliability tests demonstrated that the newly-developed potentiometric electrogoniometer had superior measurement characteristics compared to commonly used SEGs. The non-repeatability for sagittal and frontal planes was 0.53 %, and 0.66 %, respectively, and non-linearities were 0.7 %, and 1.04 %, respectively. Jang

[165] reported that non-repeatability values for a SGE used in his study were 4% for the sagittal plane and 3.3% for the frontal plane. In the same study, the non-linearities were 1.6%, and 0.93%, respectively. With the newly-developed PEG, the mean error for extension/flexion was found to be 1.07 and it was 1.08 degrees for radial/ulnar deviation movements. Different values were reported for SGEs. Jang [166] reported that the mean error was 2.03 and 1.08 degrees for flexion/extension and radial/ulnar deviation respectively. Buchholz and Wellman [167] reported that these values were 7.06 degrees and 5.58 degrees respectively, whereas Marshall et al. [168] reported these values as 9.67 degrees and 9.68 degrees. However the resulting PEG may not be suitable for daily use due to its bulky structure.

Tomita et al. [124] developed a PEG for the measurement of wrist movements in their studies. But they did not report any calibration and reliability data. Although this PEG is similar to our design, the potentiometers were located over the wrist joint. However joint axes of the wrist are not fixed points and their localizations change during the range of movement. Therefore such a design can lead to misleading readings.

Although the PEG used in the study does not have any limiting effect on the wrist joint complex, it can limit pronation and supination movements of the forearm due to the shape of proximal part of it. The proximal part of the sensor was molded in the shape of groove to accommodate the lateral aspect of the forearm. By this way it was aimed to increase the stability of the proximal part during the measurements. A more open design was tested before. However it was observed that it lost its normal alignment in the extremes of pronation and supination movements. The same limiting effect is seen with a SWO since the forearm part of it is molded in the shape of forearm in neutral position. The shape of the forearm changes during the supination and pronation movements. However the rigid proximal part of SWO and the NeO do not accommodate to these changes. This restriction on the forearm rotation can have limiting effects on the function of the arm and hand. Some functional activities require forearm supination. When this is limited, it can somewhat compensated with shoulder rotation when the elbow joint is in extended position. If the elbow joint is flexed, the loss of forearm rotation can not be compensated. During the experiments with SWO and NeO test conditions, this limitation can cause deterioration of the test scores of JHFT and MPPT. This effect could be more prominent in

the “simulated eating”, “turning-over cards, and”picking up small common objects” subtests of JHFT where considerable forearm rotation is required. However this limitation could have limited the spreading of the current to unwanted muscles by limiting the change of the forearm shape.

LabView programming language was chosen for the implementation of the closed-loop controller. Although it seemed somewhat easier to use than the classical programming languages such as C, it imposed some restrictions to the functionality of the control program. To simultaneously control two input channels and four output channels on two DAQ boards under LabView was difficult. There was not any problem in the initial phase of the controller development when less control is required on the DAQ boards. However at later stages when the many components of the controller were combined, the program flow slowed down and sometimes it completely stopped. Hence, we had to remove some components of the controller and limit the input scanning and waveform generation frequencies. Although the controller was able to serve to the aims of this study, it could be more appropriate to use low-level programming languages such as C or Visual Basic in such a control applications. Another problem is that Windows Operating Systems do not allow real time operations. However, since the response time to a stimulus typically has a delay of 60 to 80 ms., it is possible to program quasi-real time closed-loop applications by using relatively low loop frequencies of less than 30 Hz [126].

Wrist movements were tried to be limited into a preset range of motion with the stimulation of antagonist muscles. There is only one study in the literature trying to control the elbow joint with the stimulation of the antagonist muscles. The control of elbow was studied in only one plane of movement. In our study, movement control was tried in four directions at two movement planes. The set values for the activation of the stimulation pulses were 10 degrees in extension and flexion directions and 5 degrees in radial and ulnar deviation movements. The reason for choosing this range interval was related with the relationship between the ICP and the development of CTS. It was shown that ICP is minimum in this movement range [15-18].

The means of the test results are better in male subjects compared to healthy female subjects. If the mean ages are considered, these findings in general conform to the results

of the studies trying to set norms for the related tests [127, 129, 157]. However it is not possible to directly compare the test results with these norms since the groups are composed of people with different ages and the number of subjects is low. Although male subjects performed better in most of the tests, significant difference was only observed in the strength tests. All test means of patients with CTS are worse than those of healthy female subjects. Comparison of the test conditions between the patients with CTS and healthy female subjects showed that the number of test showing significant differences was higher in no-orthosis test condition. This can be explained with the limiting effects of the control systems and the disease itself. CTS led to reduction in strength and functional capabilities of patients in advance. Therefore their test scores are low compared to those of healthy subjects. Addition of another limiting factor may lead to less reduction in the tested areas compared to no previous limitation situation.

Although both control systems resulted in restriction in many of the tests compared to no-orthosis test condition, the test means with NeO control system are better in most of the tests compared to SWO. In the literature there are a few studies investigating the effects of SWOs on the strengths of the hand. At one of these studies [15], a SWO did not significantly change the grip strength. At the other study [168], SWO improved the grip strength while hindering the dexterity. At the later study single-subject design was used and the tests were done with only 3 subjects. SWOs used in these studies were holding the wrist joint in functional position instead of neutral. For these reasons, it can not be appropriate to compare the results of these experiments with this study.

To compare the test results of NO, SWO, and NeO test conditions within the same subject group, normalization was used. The normalization was needed to introduce a relatively patient-independent measurement method since there were significant individual differences in the test results through all the test conditions. If we consider the total relative changes compared to baseline measurements, NeO resulted in less restriction than SWO in the group of patients with CTS. The number of tests showing significant differences from the baseline (NO) measurements is also less than those of SWO. In addition, the comparison of the relative changes between the NeO and SWO test conditions gave significant differences in 8 of the 14 tests. These results support the hypothesis that NeO control system provides less restriction than SWO in patients with CTS.

At the healthy female and male subjects groups, the relative changes from the baseline measurements were lower than those of patients with CTS. Therefore at these groups, the number of tests showing significant differences from NO test condition was less than those of CTS group. So it can be concluded that both control systems resulted in more limitation in patients with CTS compared to NO test condition.

The maximum angles reached during the implementation of the 1st subtest of the MPPT test while the NeO system was OFF and ON conditions demonstrates that the set values are exceeded. Although the comparison of the means between OFF and ON test conditions produced significant differences at all directions except ulnar deviation movement. This means that NeO control system is not able to limit many of the movements in the preset movement interval with the settings used in the experiment. However deviations from the set values in ON stage were much smaller than those when the NeO was is turned OFF. The violation of the preset angular limits can be explained in different ways. First there is a time delay between the application of the stimulation pulses to the muscle and the beginning of the contraction. It can be up to 80 ms. The other point is related with the control strategy of the muscles. To prevent irritation due to stimulation pulses, the intensity of the amplitude starts with half of the set value and reaches to its maximum in a time interval determined by the magnitude of the error. While the intensity of the stimulation reaches to its maximum to resist the movement, the force produced by the agonist muscle cannot overcome the force produced by the antagonist muscle. Although the set limits are exceeded, the mean deviations from the set values are still in the “safe region”. The results of the studies [43-46, 111] investigating the relationship between the ICP and the wrist position and the pathophysiology of the CTS demonstrate that the range of motion limited by the NeO do not cause any significant increase in the ICP.

NeO test condition resulted in more discomfort compared to SWO in all subject groups. The discomfort experienced by the subjects was mainly originating from the application of the stimulation pulses. The comparison of discomfort levels between the SWO and NeO test conditions showed significant differences in all groups except healthy male subjects.

It is the first study trying to limit the wrist movements in four movement directions via electrical stimulation of the muscles. In addition the effects of a SWO holding the wrist joint in neutral position on the functions and strengths of the hand in patients with CTS and healthy subjects were investigated first time. It can be concluded this prototype control system called the NeO can be used in the treatment of CTS with less restriction compared to SWO. This system has flexibility due to its programmable control algorithm. Therefore it can be easily modified for other therapeutic or functional electrical stimulation applications. However this control system must be improved to provide less discomfort and converted into a portable form to be used in daily life.

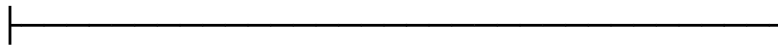
APPENDIX A

EVALUATION FORM

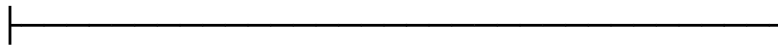
First and surname:		Date:		
Age:		Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female		
Dominant hand:				
<input type="checkbox"/> Clinically and/or <input type="checkbox"/> Electrodiagnostically verified CTS				
<input type="checkbox"/> Bilateral or <input type="checkbox"/> Unilateral				
Duration of the symptoms (months):				
Additional diseases:				
The severity of the CTS: <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe				
Score of the Symptom Severity Scale:				
Score of the Functional Status Scale:				
The order of test conditions:				
Tests and measurements		No orthosis	With orthosis	With control system
		(1)	(2)	(3)
Jebson-Taylor Hand Function Test (in seconds)	<i>Writing a sentence</i>			
	<i>Turning over cards</i>			
	<i>Picking up small objects</i>			
	<i>Stacking checkers</i>			
	<i>Simulated eating</i>			
	<i>Moving empty cans</i>			
	<i>Moving heavy cans</i>			
Modified Purdue-Pegboard	<i>The time required to place 20 pins into holes (sec)</i>			
	<i>Number of pieces collected in 30 sec.</i>			
Strength measurements	<i>Grip pressure (mmHg)</i>			
	<i>Grip strength (kg)</i>			
	<i>Lateral pinch (lb)</i>			
	<i>Palmar pinch (lb)</i>			
	<i>Tip-to-tip pinch (lb)</i>			

The state of the control system	Wrist movements in degrees			
	Extension	Flexion	Radial deviation	Ulnar deviation
OFF				
ON				

The level of discomfort during the experiments with the orthosis



The level of discomfort during the experiments with the control system



APPENDIX B**SYMPTOM SEVERITY SCALE [158]**

The following questions refer to your symptoms within a typical period of 24 hours, during the last two weeks.

Choose one answer in each question.

How strong is the pain on your hand or wrist at night?

- 1- I feel no pain on hand or wrist at night.
- 2- little pain
- 3- moderate pain
- 4- intense pain
- 5- severe pain

How many times did your hand or wrist pain wake you up in a typical night for the last two weeks?

- 1- never
- 2- once
- 3- twice or three times
- 4- four to five times
- 5- more than five times

Do you usually feel hand or wrist pain during the day?

- 1- I never feel pain during the day
- 2- I feel little pain during the day
- 3- I feel moderate pain during the day
- 4- I feel intense pain during the day
- 5- I feel severe pain during the day

How often do you feel hand or wrist pain during the day?

- 1- never
- 2- once or twice a day
- 3- three to five times a day
- 4- more than five times a day
- 5- constant pain

In average, how long do daytime pain episodes last?

- 1- I never feel pain during the day
- 2- less than 10 minutes
- 3- from 10 to 60 minutes
- 4- more than 60 minutes
- 5- I feel constant pain during the day

Do you feel your hand dormant (lost sensitiveness)?

- 1- no
- 2- I feel little dormancy
- 3- I feel moderate dormancy
- 4- I feel intense dormancy
- 5- I feel severe dormancy

Do you feel weakness on your hand or wrist?

- 1- no weakness
- 2- little weakness
- 3- moderate weakness
- 4- intense weakness
- 5- severe weakness

Do you feel a tingling sensation on your hand?

- 1- no tingling sensation
- 2- little tingling sensation
- 3- moderate tingling sensation
- 4- intense tingling sensation
- 5- severe tingling sensation

How strong is dormancy (lost sensitivity) or tingling sensation at night?

- 1- I never feel dormancy or tingling sensation at night
- 2- little
- 3- moderate
- 4- intense
- 5- severe

How often did dormancy or tingling sensation wake you up during a typical night for the last two weeks?

- 1- never
- 2- once
- 3- twice to three times
- 4- four to five times
- 5- more than five times

How difficult do you feel in taking and using small objects, such as keys or pens?

- 1- not difficult
 - 2- a little difficult
 - 3- moderately difficult
 - 4- very difficult
 - 5- severely difficult
-

APPENDIX C
FUNCTIONAL STATUS SCALE [158]

In a typical day for the last two weeks, have your hand or wrist symptoms brought any difficulty in performing the activities listed below?

Please, circle the number that best describes your ability to perform the activity.

<u>ACTIVITY</u>	<u>DEGREE OF DIFFICULTY</u>				
<i>Writing</i>	1	2	3	4	5
<i>Buttoning clothes</i>	1	2	3	4	5
<i>Holding a book while reading</i>	1	2	3	4	5
<i>Holding the telephone hang</i>	1	2	3	4	5
<i>Housekeeping</i>	1	2	3	4	5
<i>Opening a glass vial cap</i>	1	2	3	4	5
<i>Carrying market bags</i>	1	2	3	4	5
<i>Bathing and dressing</i>	1	2	3	4	5

No difficulty (1)

Little difficulty (2)

Moderate difficulty (3)

Intense difficulty (4)

Cannot perform the activity at all due to hands and wrist symptoms (5)

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