UnB – UNIVERSIDADE DE BRASÍLIA

FGA – FACULDADE GAMA

BIOMEDICAL ENGINEERING POSTGRADUATE PROGRAM

DIABETIC HAND SYNDROME: MODELING AND SIMULATION

YESENIA MARIA SIERRA ORTEGA

ADVISOR: Dra. Suélia de Siqueira Rodrigues Fleury Rosa
CO-ADVISOR: Ms. Mário Fabricio Fleury Rosa

MASTER DISSERTATION ON BIOMEDICAL ENGINEERING

BRASÍLIA/DF : JULY – 2016

UnB - UNIVERSIDADE DE BRASÍLIA

FGA - FACULDADE GAMA

BIOMEDICAL ENGINEERING POSTGRADUATE PROGRAM

Diabetic Hand Syndrome: Modeling and Simulation

YESENIA MARIA SIERRA ORTEGA

MASTER DISSERTATION SUBMITTED TO THE BIOMEDICAL ENGINEERING POSTGRADUATE PROGRAM OF *FACULDADE GAMA* OF *UNIVERSIDADE DE BRASÍLIA*, AS PART OF THE REQUIREMENTS FOR OBTAINING THE MASTER IN BIOMEDICAL ENGINEERING DEGREE.

APPROVED BY:

SUÉLIA DE SIQUEIRA RODRIGUES FLEURY ROSA, Dra. - FGA / UNB

(Advisor)

MÁRIO FÁBRICIO FLEURY ROSA, Ms. - FCE / UNB

(Co-advisor)

CRISTIANO JACQUES MIOSSO RODRIGUES MENDES, Dr. - FGA / UNB

(Internal Reviewer)

CICÍLIA RAQUEL MAIA LEITE, Dra. – UERN

(External Reviewer)

BRASÍLIA/DF, 04 / 07 / 2016.

FICHA CATALOGRÁFICA

YESENIA MARIA SIERRA ORTEGA
DIABETIC HAND SYNDROME: MODELING AND SIMULATION, [Distrito Federal] 2016.
051A/2016. 55 p., 210 x 297 mm (FGA/UnB Gama, Mestre, Engenharia Biomédica, 2016).
Dissertação de Mestrado - Universidade de Brasília. Faculdade Gama. Programa de Pós-Graduação em Engenharia Biomédica.
1. Síndrome da mão diabética. 2. Grafos de Ligação.
3. Análise Dinâmica 4. Tecnologia Assistiva
I. FGA UnB Gama/ UnB. II.DIABETIC HAND SYNDROME: MODELING AND SIMULATION

REFERÊNCIA BIBLIOGRÁFICA

SIERRA, Y.M.O. (2016). DIABETIC HAND SYNDROME: MODELING AND SIMULATION. Dissertação de Mestrado em engenharia biomédica, Publicação 051A/2016. Programa de Pós-graduação em Engenharia Biomédica, Faculdade Gama, Universidade de Brasília, Brasília, DF, 55 p

CESSÃO DE DIREITOS

2016.
Qd 32, Lote 42, Casa 02, Gama Leste .
CEP: 72460-320, Brasília, DF – Brasil

ACKNOWLEDGEMENTS

I would like to thank all the people who supported me in achieving this goal, from those who supported me with their good feelings to those who gave me a little of your time to help me develop this work.

My most sincere gratitude to my advisor Professor Dr. Suélia Rodrigues Fleury Rosa, because she is a professional with an incredible dedication to the field of science and research, being a respectable and kind human, able to understand and help in difficult times.

I thank my colleagues for always give me a little of their time.

Finally, I thank my close friends and my partner, who were always listening to my problems, for their wise counselling and words of encouragement.

ABSTRACT

DIABETIC HAND SYNDROME: MODELING AND SIMULATION

Author: YESENIA MARIA SIERRA ORTEGA
Advisor: Profª. Dra. Suélia de Siqueira Rodrigues Fleury Rosa
Co-advisor: Prof. Ms. Mário Fabricio Fleury Rosa
Postgraduate Program in Biomedical Engineering
Brasília, July 2016.

Diabetes mellitus (DM) is a chronic disease that can affect any individual, regardless of age or sex, provoking alterations in the body's normal functioning. A severe complication associated to DM called diabetic hand syndrome (DHS). This syndrome causes loss in the hand strength and movement control, and comes accompanied by three diseases: trigger finger, Dupuytren contracture and limited joint mobility. Objective: perform an exploratory research on DHS. Obtain a mathematical model that represents the dynamics of a hand affected by DHS, to propose a device able to aid in the treatment of this disease and establish a control theory that describes the dynamic behavior of the hand using the device designed. Methodology: three healthy individuals participated voluntarily in the evaluation of the functionality of the device. In order to do this they performed handling tests with different objects to observe the changes in the basic movements of the hand. I measured the strength of the subjects' hands using an e-clear dynamometer and applied a structured quiz to know the appreciation of the individuals to the device. Results: I developed a mathematical model of the DHS using BG. The biomedical assistive device designed consist in a glove with dampers made of latex. After analyzing the tests and exercises that the individuals made I observed that they could handle objects up to 30% faster, however they underperformed the writing tests, both on paper and on a cellphone. The individuals had a higher angle of opening in the hand with the device. Conclusion: this work reached its objectives; the mathematical model and the device were developed. By the obtained results, the device does not interfere with the sensibility of the hand, allows performing better the movements of the hand and gives a passive extension to the hand due to the latex layers. I suggest that handling tests be made with diabetic patients with DHS in order to evaluate the dynamic response of these patients and generate a commercial orthotic for the DHS patients to use.

Key-words: Diabetic Hand Syndrome, Dynamic Analysis, Bond Graph, Assistive Technology

RESUMO

SÍNDROME DA MÃO DIABÉTICA: MODELAGEM E SIMULAÇÃO

Autor: YESENIA MARIA SIERRA ORTEGA
Orientadora: Profª. Dra. Suélia de Siqueira Rodrigues Fleury Rosa
Co-orientador: Prof. Ms. Mário Fabricio Fleury Rosa
Programa de Pós-Graduação em Engenharia Biomédica
Brasília, July 2016

Diabetes Mellitus (DM) é uma doença crônica que pode afetar qualquer indivíduo, podendo provocar alterações e disfunções no portador da doença, ou seja, no diabético. Uma complicação severa associada é chamada síndrome da mão diabética (SMD). Esta doença pode provocar a perda de força e controle dos movimentos da mão, caracterizada por três disfunções: dedo do gatilho, contratura do Dupuytren e a limitação da mobilidade articular. Objetivo: Realizar uma pesquisa do tipo exploratória sobre o SMD. Obter um modelo matemático que represente a dinâmica da mão com SMD, propor o desenho de um dispositivo capaz de auxiliar no tratamento desta doença e estabelecer uma teoria de controle que descreva o comportamento dinâmico da mão, usando o dispositivo apresentado. Materiais e métodos: três indivíduos saudáveis, voluntários, para participar na avaliação da funcionalidade do dispositivo proposto. Para isso foram realizadas provas de manipulação com diferentes objetos para observar as possíveis alterações nos movimentos básicos da mão. Foi avaliada a força da mão por médio de um dinamômetro da marca e•clear. Foi aplicado um questionário estruturado para averiguar a familiaridade dos indivíduos em relação ao dispositivo. Resultados: foi obtido o modelo matemático da SDM utilizando a ferramenta BG. O dispositivo bioassistência desenhado consiste em uma luva com amortecedores feita à base de látex natural. Foi observado mediante os testes realizados que os indivíduos conseguiram manipular os objetos até 30% mais rápido, no entanto foi observado que os indivíduos tiveram dificuldade para escrever com a luva, reportando até o dobro do tempo em relação ao não uso da luva. Observou-se que quanto mais camadas de látex adicionadas à luva, maior será o grau de abertura da mão. Conclusão: o objetivo do trabalho foi contemplado no que diz respeito a propor um modelo matemático e a proposta de um possível tratamento para a SMD. A partir dos resultados obtidos o dispositivo proposto não interfere na sensibilidade da mão e permite realizar os movimentos naturais da mão com maior destreza, permite a extensão passiva dos dedos devido as diversas camadas de látex. É sugerida a realização das provas de manipulação com a luva com pacientes com DM e SMD para avaliar as resposta dinâmica destes pacientes e assim gerar uma órteses comercial destinado para pacientes com DM e SMD.

Palavras-chaves: Síndrome da mão diabética, Grafos de Ligação, Análise Dinâmica, Tecnologia Assistiva.

CONTENTS

1 INTRODUCTION 1
1.1 PRESENTATION 1
1.2 MOTIVATION 2
1.3 PROBLEM STATEMENT 2
1.4 OBJECTIVES 4
2 MECHANICAL SYSTEM ANALYSIS - DHS 5
2.1 INTRODUCTION 5
2.2 MORPHOLOGICAL AND FUNCTIONAL ASPECTS OF THE UPPER LIMB - HAND 5
2.3 BIOMECHANICAL ANALYSIS OF A HEALTHY HAND 6
2.4 BIOMECHANICAL ANALYSIS OF A HAND WITH DHS 8
2.5 MECHANICAL MODEL OF THE LOSS OF STRENGHT IN THE HAND OF PATIENT WITH DHS 11
2.6 CONCLUSION 14
3 DYNAMIC MODEL OF THE DHS 15
3.1 INTRODUCTION 15
3.2 BOND GRAPH METHOD 15
3.3 SOFTWARE 20-SIM 16
3.4 MATHEMATICAL MODEL 17
3.5 DETERMINATION OF VARIABLES AND SIMULATIONS 19
3.6 CONCLUSION 21
4 BIOMEDICAL ASSISTIVE DEVICE 22
4.1 INTRODUCTION 22
4.2 PROTOTYPE DESIGN 22
4.2.1 Mold and cast making 23
4.2.2 Dampers design 26
4.2.3 Damper insertion 27
4.2.4 Prototype making 30
4.3 ORGANIC CONTROL 32
4.4 RECOMMENDATIONS 33
4.5 CONCLUSIONS 33
5 EXPERIMENTAL VALIDATION OF THE BIOMEDICAL ASSISTIVE DEVICE 34
5.1 INTRODUCTION 34
5.2 CONSTRUCTION FEATURES 34
5.3 DEXTERITY TESTS 36

5.4 STRENGTH TESTS 37
5.5 QUESTIONNAIRE 38
5.6 COST 38
5.7 MATHEMATICAL ANALYSIS OF THE SYSTEM 41
5.8 TECHNICAL DATA SHEET OF THE PROTOTYPE 41
5.9 CONCLUSION 42
6 CONCLUSIONS AND FUTURE WORK 44
6.1 CONCLUSION 44
6.2 CONSIDERATIONS ABOUT THE RESEARCH 45
6.3 FUTURE WORKS 45
7 REFERENCES 46
8 GLOSSARY 49

APPENDIX A CONTAINER LAYOUT 50
APPENDIX B ASYMMETRICAL BLOCK LAYOUT 51
APPENDIX C QUESTIONNAIRE 52
APPENDIX D TEST 53

LIST OF TABLES

Table 1 – Degree of mobility that represent the major joints of the hand. 8
Table 2 – System constants. 18
Table 3 – State space model's variables. 19
Table 4 – Values of system constants. 19
Table 5 – Average size of the cushions, obtained by measuring ten cushions made of plaster using a digital vernier. 27
Table 6 – Average measurements of the hand 28
Table 7 – General information of the subjects 34
Table 8 – Amount of material and time necessary for the manufacture of each mold. . . 35
Table 9 – Latex amount used for making each layer and recording of the time that was established for each application Latex. 35
Table 10 – Record of weight in grams of each of the gloves proposed. 36
Table 11 – Record of weight in grams of each of the gloves proposed. 37
Table 12 – Record of the opening angle of the hand without glove, with the six layers glove and with the seven layers glove. 37
Table 13 – Record of the opening angle of the hand without glove, with the six layers glove and with the seven layers glove. 38
Table 14 – Development costs of the biomedical assistive device proposed. 40
Table 15 – Minimum amount of materials needed for the manufacture of a glove made of latex withdampers to correct and contribute to the rehabilitation of patients with DHS. 40
Table 16 – Values of the constants with and without glove for simulation and experimental validation of the proposed mathematical model. 41

LIST OF FIGURES

Figure 1 – Anatomy of the hand: Arrangement of joints and phalanges of the hand, source:(Shumay-Cook & Woollacott, 2010). 7
Figure 2 – Biomechanical hand movements and degrees of freedom provided by the fingers. 9
Figure 3 – Movements of the hand grip. (A) Cylindrical (B) point (C) hook (D) palm (E) spherical (F) lateral, source (DRFOP, 2016). 9
Figure 4 – Set of DHS characteristics diseases: (a) Dupuytren's contracture (b) Trigger finger (c) Limited joint mobility, source (FSS, 2016) 10
Figure 5 – (A) Hand with neuropathy, waxy skin; (B) analogue model with five inverted pendulums representing fingers; (C) two inverted pendulum model representing the fourth and fifth fingers, source (COG, 2016). 12
Figure 6 – Physical diagrammed model of the right hand, in which the elements are subject to mechanical relations, which are standards of balance in an optimum state to obtain the mechanical equations. 13
Figure 7 – Link elements of a Bond Graph. 16
Figure 8 – The program interface 20 SIM and mechanical system design using DHS elements for obtaining BG causality system. 17
Figure 9 – BG model for a hand with DHS. 17
Figure 10 – (a) System answer to a unit step excitation; (b) Answer to the system step with a 50% reduced resistance R1; (c) Answer to unit step with a 100% increment of the capacitive element C1; (d) Answer to unit step with a 100% increment in the resistive and capacitive elements. 20
Figure 11 – a) System's answer to an impulse; (b) System's answer to an impulse with a damper coefficient of 0.01. 20
Figure 12 – Geometric place of the system roots. 21
Figure 13 – Design Basis. a) Latex insole for diabetic feet treatment, b) Finger extending active ferule, y c) Saebo® metacarpal orthosis, sources: (Reis, 2013),(Ortoiberica, 2016),(Saebo, 2016). 23
Figure 14 – Mold and cast making. (a) Hand immersion in the alginate mix (b) Mold (c) Filing the mold with plaster (d) Plaster cast 25
Figure 15 – Selected reference points for measuring the dimensions of width and length of the hand intended to design the container where it will be obtained alginate and plaster molds. 25

Figure 16 – Containers for making the alginate mold and plaster cast. a) The container used for the production of molds during this work, its dimensions are height: 21 cm and base: 20.5 x 8.5 cm. b) Proposed design for future making of molds and casts, its dimensions are: height 28 cm and base 14 x 26 cm. (see Appendix A for more details). 26
Figure 17 – Manufacture of dampers from a commercial Lego block, using latex and dental plaster to copy the format of discs. a) Thin latex layer over the block. b) Remove the template once the latex is dry. c) Obtainingthe dampers using dental plaster template latex. 27
Figure 18 – Allocation of the dampers with an asymmetrical hexagonal arrangement according to the size of the phalange. a) Lineal distribution for small phalanges, under the average. b) Pyramidal distribution for medium phalanges, average measures. c) Hexagonal distribution for average phalanges. d) Double hexagonal distribution for large phalanges, above the average. 28
Figure 19 – Dampers blocks with asymmetric distribution for a standard damper distribution in the casts. a) Asymmetric block of plaster dampers on a plastic lid. b) SolidWorks design (for more details see Appendix B). 29
Figure 20 – Proposals for the bio-inspired device. a) 5 layers latex glove without dampers on the thumb. b) 6 layers latex glove without dampers on the thumb. c) 7 layers latex glove with dampers on the thumb and at the bottom of the palm. . . 31
Figure 21 – Record of changes in the gloves when used for four hours. a) Glove with fivelayers has multiple tears on the back and palm. b) The six layers glove present two breaks in the opening region of the fifth finger. c) Aging of latex when in constant contact with the environment. 36
Figure 22 – Bar chart of the responses given by the subjects to the questionnaire. 39
Figure 23 – Simulations of system behavior with and without gloves. a) On the left, the graph in response to a unit step without gloves system is shown. b) On the right, the graph shows in response to a unit step system with the seven layers glove. 42
Figure 24 – Detailed design of the container used for making the alginate mold and plaster cast. 50
Figure 25 – Detailed design of asymmetric block. 51
Figure 26 – Lego test. 53
Figure 27 – Writing test. 53
Figure 28 – Mini-Balls test. 54
Figure 29 – Turn the pages of a book. 54
Figure 30 – Open a Bottle. 54
Figure 31 – Squeeze ball. 55
Figure 32 – Compress spring. 55

LIST OF ABBREVIATIONS AND ACRONYMS

20-sim	Twenty-sim
AT	Assistive Technology
BG	Bond Graph
CAT	Committee of Assistive Technology
DD	Dupuytrern's Disease
DHS	Diabetic Hand Syndrome
DM	Diabetes Mellitus
FTS	Trigger Finger
GDL	Freedom Degrees
IDF	International Diabetes Federation
LJM	Limited Joint Mobility
SBD	Sociedad Brasilera de Diabetes
WHO	World Health Organization

LIST OF SYMBOLS

M	Mass (Kg)
K	Elasticity Coefficient (N/m)
B	Damping Coefficient (N.s/m)
α	Geometric Angle (^{o})
β	Geometric Angle (^{o})
R	Resistive Element
F	Force (N)
I	Inertia
C	Capacitive Element

1 INTRODUCTION

1.1 PRESENTATION

Diabetes mellitus (DM) is a set of metabolic disorders with chronic or permanently high concentrations of glucose (hyperglycemia) in the blood. Hyperglycemia is a result of when the pancreas stops producing enough insulin or when the body fails to effectively use the insulin it produces (Dullius, 2007).

The World Health Organization (WHO) estimated that in 2014 there were 422 million adults with diabetes worldwide, a figure that according to the International Diabetes Federation (FID, 2013) could reach, according to statistics, 591.9 million by 2035. DM represents the fourth leading cause of death by disease, with a mortality rate of over one million cases annually. In 2012, 1.5 million people died as a direct result of diabetes worldwide (WHO, 2016).

Different causes have been associated with increased prevalence of DM, such as the general growth and aging of the population, a sedentary lifestyle, obesity and genetics. This metabolic disease is more prevalent in developed or developing countries, like the United States (US), United Kingdom (UK), Mexico, China and Brazil. According to the Brazilian Society of Diabetes (SBD, for its initials in Portuguese), Brazil ranks fourth among countries with the highest rate of people with diabetes with more than 13 million diabetics (Haffner, 2002) (SBD S. B., 2016).

The treatment of complications, which include temporary and permanent disability and premature mortality caused by diabetes represent a growing economic and social burden not only for the affected individuals and their families but also to the health system. Treatments cost up to 1.5 - 2.5% of the budget costs of a country. According to the Brazilian Society of Diabetes, Brazil presented a total expenditure of 3.9 billion US dollars in expenses for diagnostic and treatment of diabetic patients in 2012 (SBD, 2014). Diabetes is mainly characterized by complications at vascular and musculoskeletal levels. However, studies and currently available treatments only focus on treating diabetic foot and diabetic retinopathies, ignoring diabetic neuropathies that are causing musculoskeletal complications in the upper limbs, specifically in the hands (Jeong & Chang, 2014) (Lebiedz-Odrobina D, 2010). This is worrying since there are diseases in the upper limbs as Diabetic Hand Syndrome (DHS) that cause great impact on the patient's life, and in many cases has been ignored by both patient and routine physician (Al-Matubsi, Hamdan, AlHanbali, Oriquat, & Salim, 2011) (Larkin & Barnie, 2014).

1.2 MOTIVATION

The human being is physically and mentally designed to move and interact with its surrounding environment. The feedback between the environment and the human being is possible because the human body is physiologically composed by a series of joints, tissues and muscles that keep the body in balance by a set of structures, forces, and fittings.

The hand is an organ that belongs to the upper extremities and allows us to interact with the environment around us. Among the features that can be highlighted is the manipulation of objects, which is necessary to fulfil most mundane daily activities. To carry out this function, a simultaneous feedback of nerve receptors in the fingers that transfer information such as temperature and strength to the muscles of the forearm to hold objects is necessary. In the case of a patient with DHS this feedback is interrupted because this disease affects sensitivity, strength, precision and hand control (Shumay-Cook & Woollacott, 2010).

This research is considered of the exploratory, because it involves a rigorous literature review, analysis of systems that encourage understanding of the problem. In addition, with the aim of contributing to the study of DHS, this research proposes a quantitative analysis of this disease by designing a similar system model using mechanical elements. After, this model will serve as a basis for the development of a mathematical model of the system, which in turn, will contribute to the design of a control system for the describes of the dynamics of hand affected by DHS, using a biomedical assistive device designed. In parallel, a device that meets the needs of a diabetic patient with DHS is proposed. The designed glove's mission is to allow the creation of a barrier between the environment and hand, moisturize the skin of the hand, increasing the force the patient may exercise, and to improve the sensitivity of the hand. These three contributions are considered original and are intended to stimulate the study of DHS.

1.3 PROBLEM STATEMENT

Three diseases characterize DHS: trigger finger, Dupuytren's contracture and joint mobility limitation, and can affect patients with type I and II diabetes and its symptoms can appear after 10 to 20 years with DM. Among the complications of diabetic hand syndrome, motor and neurological disorders are exhibited (Chiu, Hsu, Kuo, & Su, 2014) (Larkin & Barnie, 2014). Some of the consequences of this disease: lack of sensitivity, slow healing, loss of control and precision of movement, which greatly increases the chances of accidents which can cause serious injury, amputation or even death (Silva, Jakimiu, & Skare, 2014) (Yang Chien-Ju, 2015).

Currently, there is insufficient information in the literature on the DHS to present a treatment that corrects it permanently, nor is the relationship between the skeletal-muscle and neural loss of hand function known (Jeong & Chang, 2014) (E. Centinus, 2005). This is due to the little amount of interest in this disease in the fields of science and medicine. Some research shows that DHS symptoms may begin to appear after 10 to 20 years with DM (Chiu, Hsu, Kuo,

& Su, 2014) (Larkin & Barnie, 2014). The time of onset and diagnosis of DHS would depend on several aspects such as poor metabolic control, the presence of micro-vascular problems or lack of diagnostic tests in upper extremities diseases. Researchers verify the importance of regular application of physical and neurological tests diagnostics in patients with DM, since most of the patients had two or more diseases in their hands. They have also shown that patients with DHS not become aware of the changes in hand function in their daily routine. This happens in many cases, as the patient adjusts to the changes that occur gradually in their hands, hereby is the importance of controlling the DM and of the physical examination (Al-Matubsi, Hamdan, AlHanbali, Oriquat, & Salim, 2011) (Larkin & Barnie, 2014).

Considering that, there is little information in the literature about DHS, that it affects an organ that is essential to the daily activities of the human, and that I found no evidences of a developed treatment for this disease. This research proposes new study methods for this disease through tree tools used today to alleviate the problems of individuals with some kind of diseases.

One of the tools currently used for the representation of complex systems is the Bond Graph tool, which allows a graphical representation of the flow of energy of a given system that can integrate systems from different domains of energy into one through a series of established relationships (Rosa & Altoé, 2013). Many scientific studies have proven the ability of this modeling method and simulation of physiological systems, this due to the easy development of models obtained and easy understanding of the relationship between system variables. Bond Graph has been used for the dynamic modeling and monitoring of the path of a healthy hand (Qian & Rahmani, 2013), to mathematically model the cutting process of the human tibia by an automatic saw (Rosa & Souza, 2013) and a mathematical representation of the human esophagus (Rosa & Altoé, 2013).

The biomaterial latex is employed, highly used in medical devices, and can be used to substitute a part of a living system, as reflected in the work done by Mrué in 1996 that analyses the replacement of the cervical esophagus by a biosynthetic Latex prosthesis in dogs. This scientist also studied natural latex bio-membranes as a means to repair partial lesions in the esophagus (Mrué, 1996). Latex can also assist in the improvement of the function of organs and damaged tissues. Such results can be appraised in the works of (Reis, 2013), where she developed a system, which allows regeneration and scarring of wounds present in patients with diabetic foot through a latex sheet and a LED light emitting circuit. And in the work made by Ribeiro and Rodrigues, which developed a mathematical model and a latex lens for the amblyopic eye treatment (Ribeiro A. R. & Rodrigues, 2014).

I will also employ the bases of Assistive Technology, which is an interdisciplinary knowledge area, that includes products, resources, methodologies and strategies in order to promote an attend the lives of people with reduced mobility, aiming to their autonomy, independence, better living standard and social inclusion. Some categories in this area are daily life enhancers, vehicular adaptations, orthotics and prostheses. Assistive Technology is a conception that was included in the research area of Brazil since November 2006, when the Committee of Assistive Technology (CAT), through its decree number 142, proposed its inclusion as a concept.

1.4 OBJECTIVES

This work has as a main objective to obtain a mathematical model of the hand with DHS, for the study and analysis of the dynamic behavior of it. To do this, I used the Bond Graph modeling method that evaluates the energy flow of the system. After the construction of the mathematical model, I develop a prototype glove using natural latex, which will contribute to the treatment of DHS. Finally, I implement an organic control system, which, together with the glove to obtain data on the behavior of a hand, with and without the glove, to validate the mathematical model of the system.

The specific objectives are:

1. Recollect relevant and consistent information on DHS, in order to build an analogue model through mechanical elements.

2. Develop a mathematical model for DHS using the analogue model and BG theory.

3. Make the prototype of the device with latex, considering the characteristics of a hand affected by DHS and with the AT approach.

4. Perform dexterity and strength test with three healthy subjects, to analyze how the use of the device interferes in the hands dynamic.

5. Evaluate the response of the mathematical model, using the literature values and the tests performed with the device. The exit value of the simulations represents the actual strength the hand exerts.

6. Develop a control system that allows analyzing the hand dynamic when the subject uses the device. This using a new control theory called Organic Control.

2 MECHANICAL SYSTEM ANALYSIS - DHS

2.1 INTRODUCTION

This chapter presents the overall analysis of the human hand and gives a detailed study of DHS using mechanical elements. First, the physiology and functionality of a healthy hand will be analyzed. Then, a biomechanical analysis of the main features of the hand with DHS will be presented. Finally, the simplifications obtained and the mechanical model resulting of a thorough analysis of the system will be presented

2.2 MORPHOLOGICAL AND FUNCTIONAL ASPECTS OF THE UPPER LIMB - HAND

The study of the upper limb focused on the morphology and functionality of the hand, allows an overview of the elements that compose it, specifically, the understanding of the functional processes of the hand and all its elements. Subsequently, this study will extract the most relevant aspects of the hand, for the preparation of its analogue model and mathematical representation.

The upper limb is composed of the shoulder, arm, forearm, wrist and hand. Being the first three responsible for placing the hand and wrist in space, while the latter two are responsible for performing fine movements. Fine motor hand skills allow daily activities such as dressing, eating, brushing teeth and combing. The upper limb function also plays an important role in gross motor skills such as walking, regaining balance, and the protection of the body from injury. For example, when a person stumbles while walking, the whole of the upper limb is positioned to avoid falling. The arms seek to restore the balance while the hands attempt to isolate the body from surfaces to avoid injury (Shumay-Cook & Woollacott, 2010).

The upper limb has greater mobility than the lower limb, even when they have structural similarities (Hamilll & Knutzen, 2008). The lower member is composed of several segments: thigh, kneecap, leg, ankle and foot. This is relevant since most studies and treatments for the upper limb are placed in the background when compared to the lower limb (Larkin & Barnie, 2014).

The hand is one of the most delicate and most skilled human body organs. Allowing activities with lots of pressure and force. In addition to the motor skills of the hand, it is also able to receive and transmit useful information about the external environment. Its mobility is due largely to the fact that its movements are controlled by muscles found in the forearm. Forearm muscles attach to the bones of the fingers by long tendons that pass through the wrist. These muscles endow fingers mobility and strength that would not be possible if all the muscles had to be connected directly (Da Costa et al., 2005).

The ability to perceive and transmit information to the brain about the characteristics of an object is due to the hand being equipped with four kinds of skin receptors which respond to light, deep pressure, pain and temperature. Providing two essential functions: the grip and touch. The sense of touch fully develops the capacity of the hand, without it, it would be impossible for humans to measure the gripping force. Nails also play a crucial role. If no rigid structure existed to press against, judging how tightly objects should be grabbed would be impossible (Shumay-Cook & Woollacott, 2010).

The skeleton of the hand is made up of 27 bones, which for the purposes of this work can be classified into two large groups: metacarpals and phalanges. Thus it can be concluded that the hand has basically two types of joints: metacarpophalangeal and interphalangeal. Where the first are unique to each finger and the latter exist in duos in all fingers but the thumb, in which there is only one. Additionally hand consists of about 40 muscles, and a large amount of ligaments, tendons and nerve endings. The anatomy of the human hand is shown in Figure 1 (Hamilll & Knutzen, 2008).

2.3 BIOMECHANICAL ANALYSIS OF A HEALTHY HAND

The application of concepts and biomechanical principles in this research are based on its multidisciplinary nature, which involve the knowledge of functional anatomy, physics, mathematics, biology and physiology and allow an objective analysis of the structure and movement of the human hand. The study of Biomechanics seek to objectively analyze and understand the performance of the human body linking the structure of the human body and its movement in order to understand (Da Costa et al., 2005):

- How the movement of the human system is generated.
- How the environment influences and modifies movement.
- The factors that determine the loads on the system.
- How the execution of a movement influences other bodily structures.

These parameters will be used for the conclusive analysis of the changes occurring in a hand with DHS, thus distinguish the main parameters to be considered in the construction of the model analogue to the system.

For the hand movement to be effective, and in addition to the correct state of the structures that make up the hand, the proper functioning of the organs of the eye (sight), arm, forearm and wrist as well as a good posture are necessary. That is, when there is an abnormality in the operation of any of the organs of the human body, this will adversely affect their motor ability. For example, if a person wants to move a cylindrical object of which its material and content is unknown, the feedback of the information received between the skin receptors of the hand with

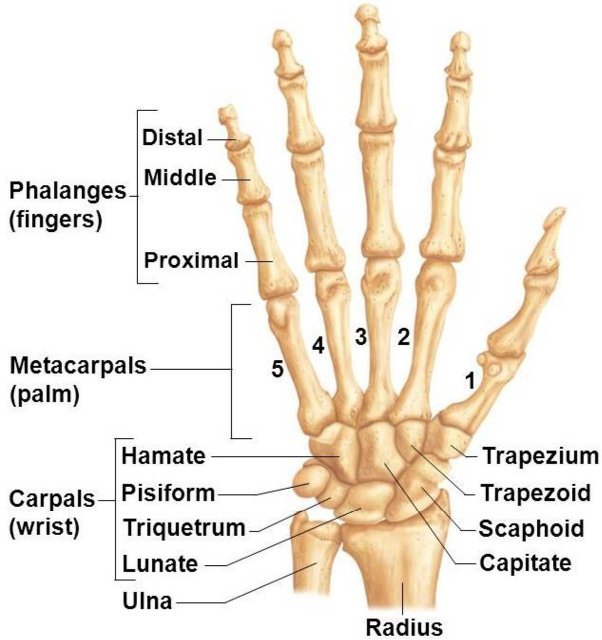


Figure 1 – Anatomy of the hand: Arrangement of joints and phalanges of the hand, source:(Shumay-Cook & Woollacott, 2010).

information coming from the eye to optimally adjust what is the best grip strength necessary to achieve lift and move the desired object, as well as the spine and arms to position the hand in space is necessary. Which is why it is concluded that the achievement of natural hand movements require the hand to be healthy, environmental control and feedback between the stimulus received by hand receptors with internal signals, commonly controlled by the cerebellum to position and keep the rest of the body in a particular position (Shumay-Cook & Woollacott, 2010).

Furthermore, the proper functioning of the organs that position the hand, require the good performance of muscle and bone structures of the hand. The hand is one of the most complex organs in the human body, consisting of 27 bones and more than 40 muscles, as described in the previous section. Focusing on the bone structure of the hand, we have that it is mainly composed of the metacarpal bones and phalanges. Consequently, it is known that the joints that provide greater mobility to hand are the metacarpophalangeal and interphalangeal joints. Leaving in the background the radioulnar, intercarpal and mediocarpales joints, due to low mobility that these give the hand. The biomechanical properties of these joints are shown in Table 1 (Da Costa et al., 2005).

Finally, the most relevant factors of the system in mechanical terms are determined, which will be essential to obtain the analogue and mathematical model of the system. After analysing the data in Table 1, it is observed that fingers 2,3,4 and 5 have two degrees of freedom that allow the performance of the movements of abduction, adduction, flexion and extension. Meanwhile, the thumb is the finger with the greatest functionality in the hand. Representing 40% of its functions, it possesses five degrees of freedom that allow movements of opposi-

Table 1 – Degree of mobility that represent the major joints of the hand.

Joints	Finger 1	Finger 2	Finger 3	Finger 4	Finger 5
Carpometacarpal	Flexion and extension $50^o - 80^o$ Abduction and Adduction $40^o - 80^o$	Limited movement	Limited movement	Increase flexion $10^o - 30^o$	Increase flexion $10^o - 30^o$
Metacarpophalangeal	Flexion $30^o - 90^o$ Extension 15^o	Flexion $70^o - 90^o$. Allows more flexion to the 5th finger and less flexion to the finger 2nd. Abduction and Adduction 20^o			
Distal Interphalangeal	Extension $0^o - 5^o$ and Flexion 90^o				
Proximal Interphalangeal	Extension 0^o and Flexion 90^o , except the 5th finger flexion 135^o				

tion, pre-emption, flexion, extension, supination and pronation. To get a better understanding and standardization of terminologies in areas of health and engineering, the Figure 2 which represents the movements of the hand was developed.

The rich mechanical functionality of the hand is largely due to the movements that it can perform. Combining two or more of the movements presented in Figure 2, six forms of hand grip are obtained: Cylindrical Grasp, Tip, Hook or Snap, Palmar, Spherical Grasp and Lateral (Figure 3).

2.4 BIOMECHANICAL ANALYSIS OF A HAND WITH DHS

Previously, biomechanical characteristics of a healthy hand were detailed. This section features a hand with DHS obtained from the limited and valuable information found in the literature. Using the principles of biomechanics outlined in the previous section, the changes that significantly affect the functionality of the hand will be determined. Such alterations will be translated into a mechanical language for the construction of a model analogue to the system.

In some cases, it can occur that the broad mobility of the hand is significantly reduced, as it is in the case of musculoskeletal diseases such as: limited joint mobility, Dupuytren's contracture and trigger finger (Figure 4). These diseases can occur in individuals with heavy manual labor or exercising considerable and / or constant forces on the hand, as well as in patients with diabetes type I and II, being the incidence in diabetic patients up to four times higher. In diabetic patients this series of anomalies are defined as Diabetic Hand Syndrome (Rosenbloom, 2014). Some of the symptoms associated with DHS are: chronic pain, numbness, loss of strength, loss of sensation and loss of control (Yang Chien-Ju, 2015). The most obvious morphological alterations are hardened and stiff skin with waxy appearance, thermal alterations and appearance of nodules in the palm of the hand. The nodules usually appear first in the palmar region of the fourth finger and then emerge in the 5th and 3rd finger. Over time these become fibrosis, which may lead the patient to functional disability (Silva MBG, 2012)(HG,

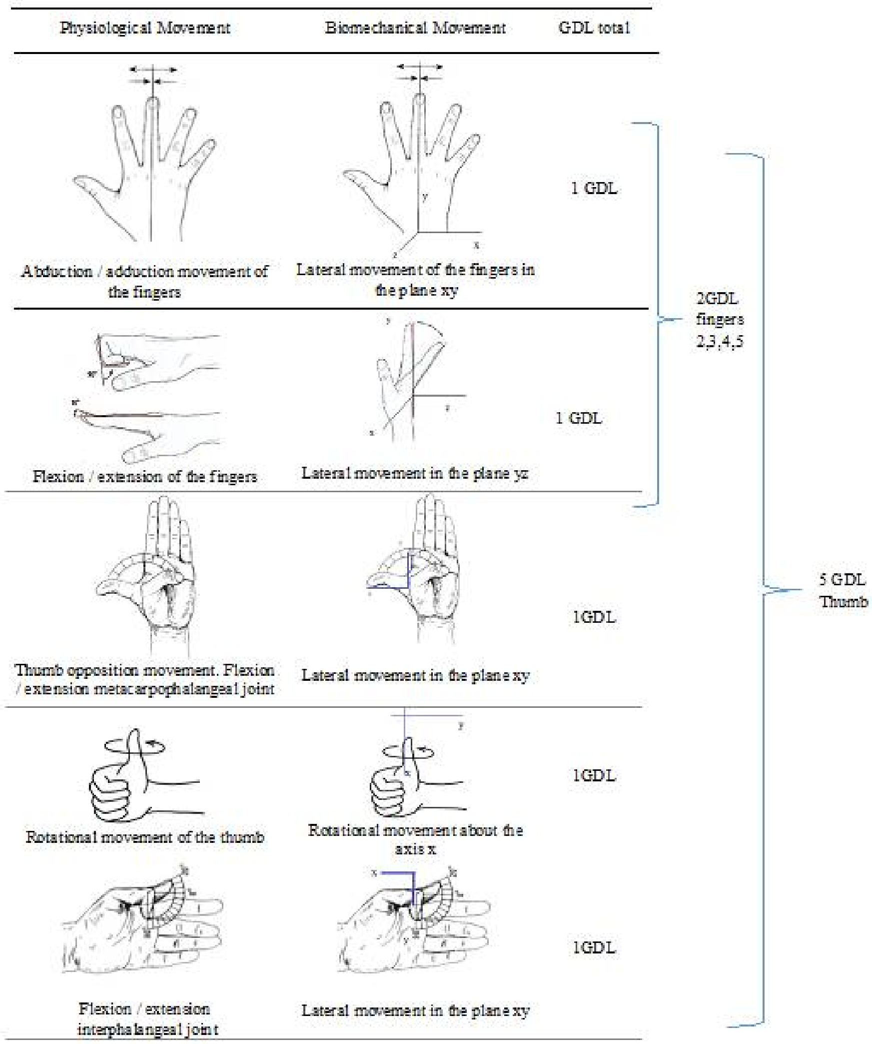


Figure 2 – Biomechanical hand movements and degrees of freedom provided by the fingers.

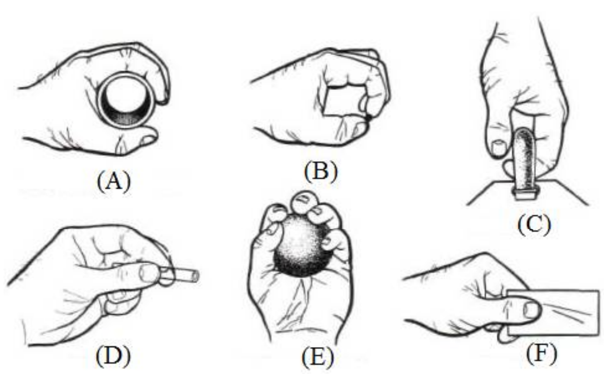


Figure 3 – Movements of the hand grip. (A) Cylindrical (B) point (C) hook (D) palm (E) spherical (F) lateral, source (DRFOP, 2016).

VI, D, & Veltin, 2014). Commonly, these characteristics begin to appear after 10 years with diabetes mellitus and can affect both children and adults. Its incidence depends largely on the precautions that the patient has had in their diet, blood glucose control, physical activity and regular medical checks (Larkin & Barnie, 2014).

The disruptions caused by the DHS affect different natural hand movements such as abduction and adduction movements that are significantly limited by permanently flexed fingers because in this position the collateral ligaments are very stressed, limiting lateral movements of the fingers. The unwanted bending of the fourth finger will also subsequently affect the flex of the 3rd and 5th finger. This occurs because the flexor tendons have the same muscle and tendon origin, which concludes in these three fingers not being able to flex independently (Shumay-Cook & Woollacott, 2010).

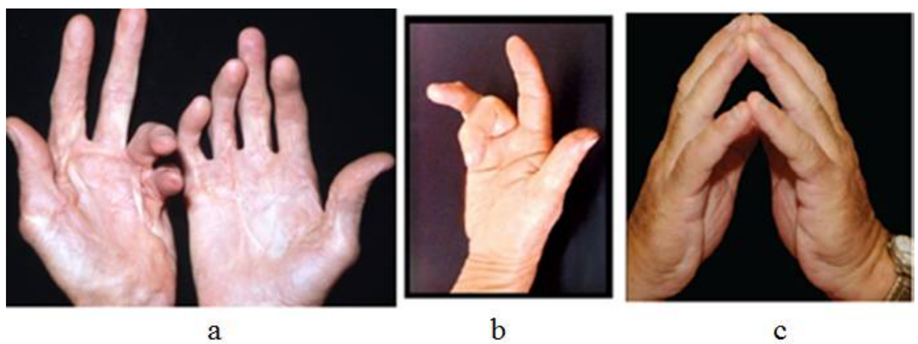


Figure 4 – Set of DHS characteristics diseases: (a) Dupuytren's contracture (b) Trigger finger (c) Limited joint mobility, source (FSS, 2016)

Commonly, hand strength is associated with grip strength, where the extensor muscles give the maximum force and fine movements are performed by the intrinsic muscles (Hamilll & Knutzen, 2008). In the case of diabetic patients, cells constituting the musculoskeletal system exhibit various complications, amongst which atrophy in muscle fibers stands out (E. Centinus, 2005). This atrophy produce a decrease in the rate of muscle contraction, which implies loss of muscle strength (Silva, Jakimiu, & Skare, 2014). The hand is also a sensitive organ because the skin of the hand, particularly the palms of hands and fingers, are endowed with nerve receptors and a large area of the somatosensory cortex, which occupies 30% of the primary motor area, which represents an area five times greater than the foot portion. All activities involving gripping and grappling involve the continuous monitoring of the activity of touch receptors and hand pressing. The answer of the hand receptors is important to protect it from possible injury. This feedback system between the brain and the hand is altered in patients with DHS, since this disease affects sensitivity, scarring, loss of control, loss of strength and precision in the movements of the hand, which interfere with the normal hand functions, which are (Hamilll & Knutzen, 2008)(Da Costa et al., 2005):

- Performing delicate movements.

- Grasp of objects and tools.
- Communication and expression of emotions.
- Appreciation of external environment and object characteristics.

DHS affects the quality of life of patients and increases the likelihood of accidents causing injuries, amputations or death cases. Despite this, it has not attracted the attention of scientists and physicians, to the point of not knowing the relationship between skeletal and neural muscle disorders with loss of hand function or a treatment designed to correct and address the needs of diabetic patients with DHS (Jeong & Chang, 2014)(Yang Chien-Ju, 2015).

Considering Figure 2 and the different skeletal muscle and neuronal alterations caused by the DHS, the important points to note about the DHS are summarized:

- No information is available on the relationship between the motor and neuronal damage.
- The damage done is proportionally related to the time the patient has had DM and DHS.
- The thumb is the finger least affected by DHS.
- The fingers most affected by the disease are fingers 4 and 5.
- It is impossible to perform the movement of abduction and adduction in the 2nd, 3rd, 4th and 5th finger.
- The moment of flexion and extension of the fingers is restricted and in some cases, impossible to perform.
- Currently there is no treatment for DHS.
- DHS significantly reduces the performance of grip movements.

With the information obtained through the exploratory research of DHS, the design based on the aspects mentioned in the previous paragraph, the analogue model of a hand and consequently the mathematical model of the system would be performed. These contribute to the study of the dynamic behavior of the system.

2.5 MECHANICAL MODEL OF THE LOSS OF STRENGHT IN THE HAND OF PATIENT WITH DHS

Due to the characteristics of the DHS, the first procedure was to create a similar mechanical model that represents its behaviour closer to reality way, i.e. translate the physiological system into mechanical terms. Figure 5 shows a diabetic hand with tendon deformities and reduced angles between the fingers. Thus, the most important parameter to be analyzed is the amplitude of out of hand and precision of movement.

The following considerations were made in modeling the system to maintain the simplicity thereof:

I The model developed is only an approximate representation; this means that there is not only one model of the system, but a family of models with different features and performances.

II Ideal Elements.

III Only fingers that look most affected by DHS were modelled: fifth and the fourth.

IV The influence of muscles, tendons, phalanges and blood tissue were ignored.

V The influence of other fingers were not considered.

VI The finger was considered as a homogeneous bar.

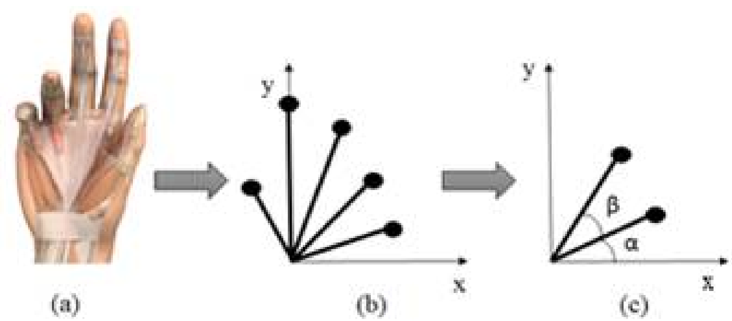


Figure 5 – (A) Hand with neuropathy, waxy skin; (B) analogue model with five inverted pendulums representing fingers; (C) two inverted pendulum model representing the fourth and fifth fingers, source (COG, 2016).

According to the simplifications described above, in this study only the lateral movement of the fingers was analyzed. We infer that the inverted pendulum is the closest approximation to the fingers affected by DHS. Figure 5 shows the mechanical simplification for diabetic hand, where α and β represent the aperture angle between the fingers and considering the third finger as fixed on the y-axis, the angle β represents the separation between the fingers and the angle α the maximum separation between the x-axis and the fifth finger.

In the set of phenomena that deform and reduce the flexibility in the hand, it is understood that an alteration in the trajectory would happen. The patient has an intention of movement that due to the characteristics of their condition will be altered. This research aimed to specify such a path alteration as a result of the loss of muscle strength, thus reaffirming that it occurs due to mechanical factors and thus reducing the complexity of the approach. Based on the analogy of the inverted pendulum with lateral movement of the fingers, an analogue mechanical model of the system with the main features of DHS would be created. This analogue model represents in detail the elements that interfere with the natural movement of the hand through a mass-spring-damper system. Figure 6 shows the analogue model of DHS.

In addition to the considerations made for the model of the inverted pendulum, some other deliberations were made in the analogue mass-spring-damper model:

I The geometric characteristics of the fingers were ignored.

II The masses were studied as point masses.

III The movement between the fingers was analyzed from the palmar region.

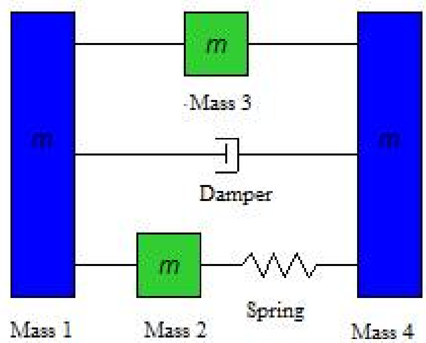


Figure 6 – Physical diagrammed model of the right hand, in which the elements are subject to mechanical relations, which are standards of balance in an optimum state to obtain the mechanical equations.

Analysing Figure 6, we can see that the mass (according to Newton's second law) is the cause of the acceleration of the mass of the hand, providing information about the loss of acceleration compared to the really exerted by the hand. The damper represents the delay in muscle activation. To represent the propulsion movement, a spring in series with a mass representing the resistance to the deformation of the movement is used.

Interestingly, the physical limits of the system should be clearly specified at this moment in time. In the case of mechanical systems, a free body diagram is created by the established balance relationship. In the methodology of BG, the same principle is applied, being that in BG, a nodal relationship is acquired by the variables, which are flow (f) and effort (e) that need to make an effort or connectivity with the way. In the case of the mechanical elements, the speed is a source of stress and force is the flow source. The spring is an accumulator of effort, the mass a flow accumulator and the damper a dissipating element.

Even in relation to the model shown in Figure 6, some items can be included to simulate the muscle weakness inherent in DHS. Thus, in this system, the forces are applied while the spring and damper suffer compression and extension. A careful analysis will be performed on these variables when they are in the state-space form.

2.6 CONCLUSION

This chapter presented an overview of the hand system and the biomechanical alterations resulting from DHS. I summarized the main features of DHS to establish the mechanical considerations in a modeling of the system.

In order to develop the mechanical system I needed to have knowledge of the workings of the human hand and mechanical engineering. Finally, through a series of simplifications, we obtained the model for the system behavior under the influence of DHS. To the best of my knowledge, such model did not exist in the scientific literature and, it can help to understand better this condition.

3 DYNAMIC MODEL OF THE DHS

3.1 INTRODUCTION

The aim of this chapter is to present the mathematical model that describes the behavior of DHS in function of the time, for this purpose, the methodology and software used will be briefly explained. In the first section the BG methodology will be studied, explaining the basic concepts used to reach the construction of the final model. In the second section we will explain why the 20-sim software was selected. Finally, the mathematical model obtained will be described.

3.2 BOND GRAPH METHOD

Most commonly, the mathematical representation of systems is obtained through three methods: Newton-Euler method, the LaGrange equation and dynamic equation of Kane. These mathematical models are difficult to develop and it is even more difficult to understand the relationship between their variables. Furthermore, these methodologies generate specific mathematical models and do not allow the insertion of new elements to those systems. Considering that, this work aims to develop a mathematical model of the hand's functioning with DHS, which represents a challenge because of its great structural complexity. It was determined that the BG methodology is the most appropriate one for this study.

The BG theory, graphics ligation, was created by Professor H. M. Paynter, at the Massachusetts Institute of Technology in 1959. This theory allows the representation of the exchange of energy between each of the system components, its methodology is widely explained in (Filho, 2003)(Karnopp, Margolis, & Rosenberg, 2000).

This study focuses on the analysis of the gripping ability and mobility of a hand with DHS, for which deep analysis were made in order to obtain a mechanical and simplified model of the studied system. The analog model was presented in the previous chapter; this is indispensable for the representation of the system in a model Bond Graph.

It will be used the procedure given by (Gmiterko, Hroncová, & Sarga, Setember, 2011), to transform the analog system of a hand with DHS, shown in Figure 6 in a system BG, performing the following steps:

1. Identification of the physical domain of the system and identification of the capacitive elements (C), resistive (R), inertial (I), power flow (SF) or effort (BE) in the system.
2. Identification of other energy variables such as the speed of mass elements, and any existing type 1 links.

3. Identifying efforts difference and identifying the type 0 links.
4. Connection between the elements found in step 1 with their efforts or with the efforts difference represented by type 1 link.
5. Assigning causalities automatically made by the simulation software 20-Sim.

3.3 SOFTWARE 20-SIM

The 20-SIM software allows analysis through BG model system. One of the most important properties of this program is causality determination on each link. The process of determining the causality of each link requires rigorous element knowledge and a systematic approach on how the connection between ports, having into account the effort and the direction of energy flow, besides of having a clear idea of what is happening in each port. Due to great effort, time and knowledge involved in this process, the software will be used for automatic production of causality, as well as design and system analysis.

Causality is one of the elements of a BG diagram; it establishes cause and effect relationships between variables and flow stress. The Figure 7 shows an example of causality, in which the vertical bar at the beginning or end of the bond indicates that has been attributed causality to it, meaning that there are two variables, the effort and flow, only one of them can be controlled, and the supplement variable is the answer to the imposed control on that link.

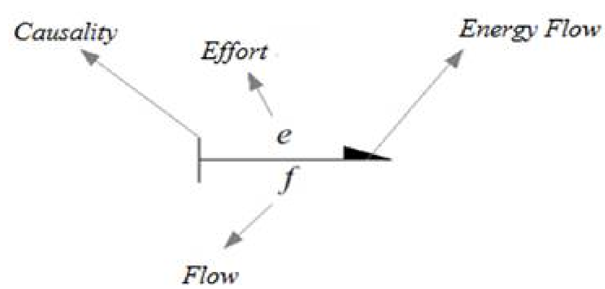


Figure 7 – Link elements of a Bond Graph.

To obtain causality in 20-SIM, I must first build the model with the elements that conform it, in this case mechanical elements. Once you obtained the model, I proceed to start the analysis of causality and obtain state-space equations. As the equations do not come in the form of matrices, the user must build them. In this study the state-space equations were obtained through manual calculations and verified with those obtained in 20-SIM.

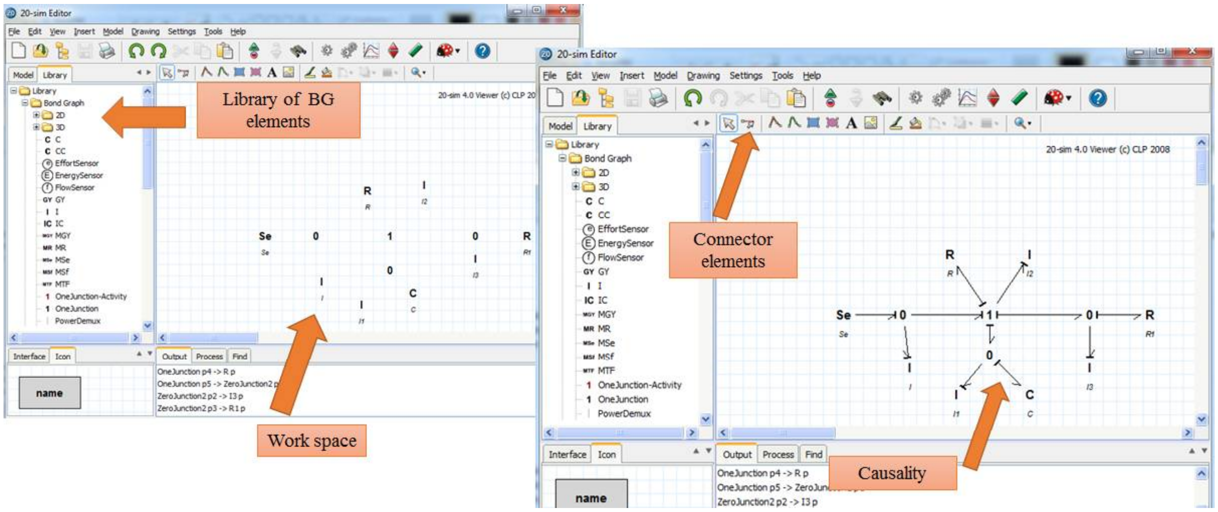


Figure 8 – The program interface 20 SIM and mechanical system design using DHS elements for obtaining BG causality system.

3.4 MATHEMATICAL MODEL

The mathematical representation of DHS was obtained through the sequential application of changes of a physical model to an analog model, first the inverted pendulum, then a model of mass-spring-damper and finally a BG model, from which the mathematical equations which were obtained. BG is a system composed of four basic group elements: one port passive, one port active, two ports, and two junctions, as illustrated in Figure 3. System constants are shown in Table 2. In the analog model of DHS we will be using the elements of a port. These elements only have variable effort (e) and flow (f).

The BG model shows the difference between the strength that the patient wishes to exercise and the one actually exercised. Figure 9 shows all the forces that interact in the system. Se represents the signal of the intended movement, sent from the brain to finger to exert a force of magnitude F_i. Parallel to the strength F_i is the finger's mass $(I1)$. In series with $I1$, we find the mechanical elements $R_1, C_1, I2$ and $I3$.

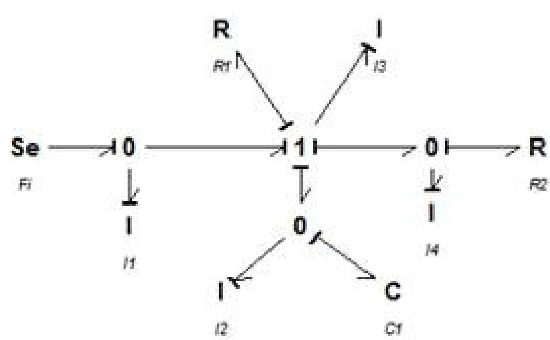


Figure 9 – BG model for a hand with DHS.

Connected in parallel with these elements is the mass M_4 the fourth finger $(I4)$ and R_2 friction. It must be remembered that the fourth finger is the first to be affected by the DHS, and therefore, the finger with the biggest influence in the response time and flexibility. The R_2 element represents the delay in the elastic response of the fourth finger.

To obtain the system equations we will use the representation in state space form mainly because three important aspects are contributing to this work. Those are:

- The state space representation is not unique, making it possible to represent the same system over state space model.
- They can be represented variables that could not be measured or analyzed.
- Exposes the possibility of working with the concept of transfer function in conjunction with a variety of graphic techniques such as the place of the Nyquist roots. It is this type of methodology presents the most appropriate method for the computational analysis system.

In the system presented in this study, there is no derivative fortuity, which means that the state equation of that system will have the form $\dot{x} = Ax + Bu$. The system equation is given by:

$$\begin{bmatrix} \dot{x_1} \\ \dot{x_2} \\ \dot{x_3} \\ \dot{x_4} \\ \dot{x_5} \end{bmatrix} = \begin{bmatrix} 0 & 0 & 0 & 0 & 0 \\ 0 & \frac{-R_1-R_2}{I_3} & 0 & \frac{-1}{C_1} & \frac{R_2}{I_4} \\ 0 & 0 & 0 & \frac{1}{C_1} & 0 \\ 0 & \frac{1}{I_3} & \frac{-1}{I_2} & 0 & 0 \\ 0 & \frac{R_3}{I_3} & 0 & 0 & \frac{-R_2}{I_4} \end{bmatrix} \begin{bmatrix} x_1 \\ x_2 \\ x_3 \\ x_4 \\ x_5 \end{bmatrix} + \begin{bmatrix} 1 \\ 1 \\ 0 \\ 0 \\ 0 \end{bmatrix} \begin{bmatrix} S_e \end{bmatrix}$$

The outputs of the systems are obtained by:

$$[y] = [C][x] + [D]u$$

Table 2 – System constants.

CONSTANTS	**REAL SYSTEM DESCRIPTION**	**ANALOG SYSTEM DESCRIPTION**	**BG**	**STATE**
F_i	MOVEMENT OF INTENT	INPUT FORCE		–
M_1	LITTLE FINGER MASS	INERTIA	$I1$	x_1
M_2/C_1	ELASTIC DELAYED RESPONSE	INERTIA I2 /SPRING IN PARALLEL	I2/C_1	x_2
M_3	CAUSE OF HAND ACCELERATION	INERTIA I3	I3	x_3
M_4	RING FINGER MASS	INERTIA I4	I4	x_4
B_1	DELAY OF MUSCLE ACTIVATION	VISCOUS DAMPER	R_1	x_5
$K2$	RING FINGER FLEXIBILITY LOST	LINEAR FRICTION	R_2	–

Table 3 – State space model's variables.

System	Model	Classification
State Vector	$[x_1, x_2, x_3, x_4, x_5]$	
Input Vector	SE (Desired Strength)	Order $x \in R^5$
Matrix A	Dimension 5x5	SISO System
Matrix B	Dimension 1x5	Linear System
Output matrix	Dimension 5x1	Implicit System
Matrix C	Dimension 1x5	Continuous
Output Vector	Exerted Force	

3.5 DETERMINATION OF VARIABLES AND SIMULATIONS

Simulations were run in order to verify the validity of the previously presented mathematical model. For the running of the simulation, values of the system variables where estimated, based on information extracted from the literature and some other considerations. Such considerations were necessary, since in the studied literature there are no explicit values for the variables we are studying.

For the elasticity and damping coefficients, we established a range between 3-6 N/m and 6-10 N.s/m for each (Lindhard & Moller., 1927). Any value in that range was considered a healthy hand. Due to the lack of explicit values in the literature about the geometrical and physical characteristics of the human hand, several considerations were made to estimate the weight of the fingers. First, the fingers were considered as solid cylinders, whose measurements were approximated according to a study performed on Chilean individuals (Binvignat, Lizana, & Olave, 2012). Afterwards, the maximum weight that a hand prosthesis can have was found; it cannot be greater than 0.500 Kg (Díaz Montes & Dorador González, 2010). Finally, we concluded that a human finger must weigh between 0.010-0.050 Kg. Based in the data obtained from the literature and some other considerations, we obtained the values of the row Simulation 1 (Table 4) and with those values we decided to make a variation in them in order to verify their influence on the dynamic of the system. The state space matrix was simulated using Matlab, with the values presented in Table 4.

Table 4 – Values of system constants.

System Constants	Simulation 1	Simulation 2	Simulation 3	Simulation 4
M_1	0.030 kg	0.030 kg	0.030 kg	0.030 kg
M_2	0.010 kg	0.010 kg	0.010 kg	0.010 kg
M_3	0.020 kg	0.020 kg	0.020 kg	0.020 kg
M_4	0.050 kg	0.050 kg	0.050 kg	0.050 kg
K_1	3 N/m	1,5 N/m	6 N/m	6 N/m
K_2	6 N/m	6 N/m	6 N/m	12 N/m
B_1	12 N.s/m	12 N.s/m	12 N.s/m	24 N.s/m

Figure 10 shows the results of the simulations of the state space system, for the values in Table 4. It was obtained a response to the system step from the perspective that the primary state is x_5, that is, the vector $C = [00001]$. In order to observe the damper behavior better, we obtained the graphs in Figure 11, where the response to the impulse was obtained.

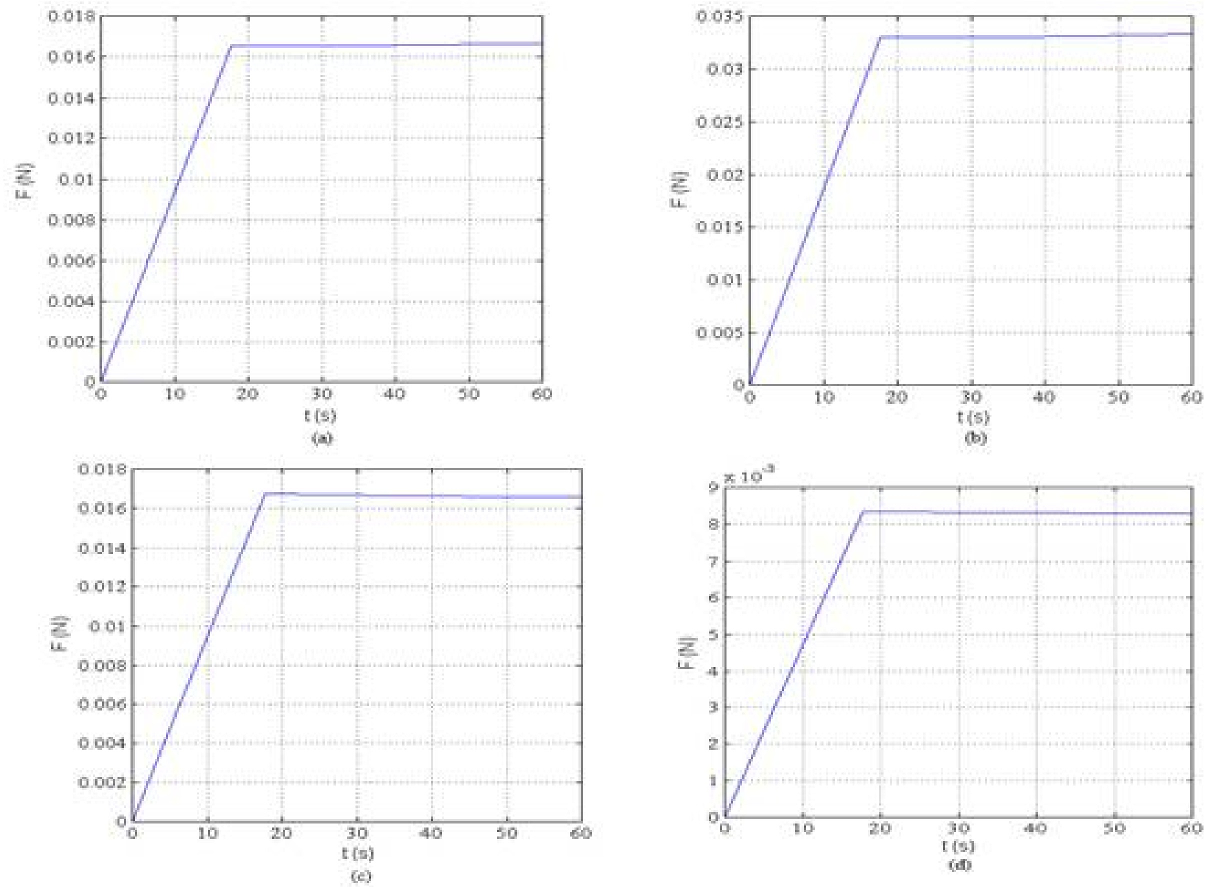


Figure 10 – (a) System answer to a unit step excitation; (b) Answer to the system step with a 50% reduced resistance R1; (c) Answer to unit step with a 100% increment of the capacitive element C1; (d) Answer to unit step with a 100% increment in the resistive and capacitive elements.

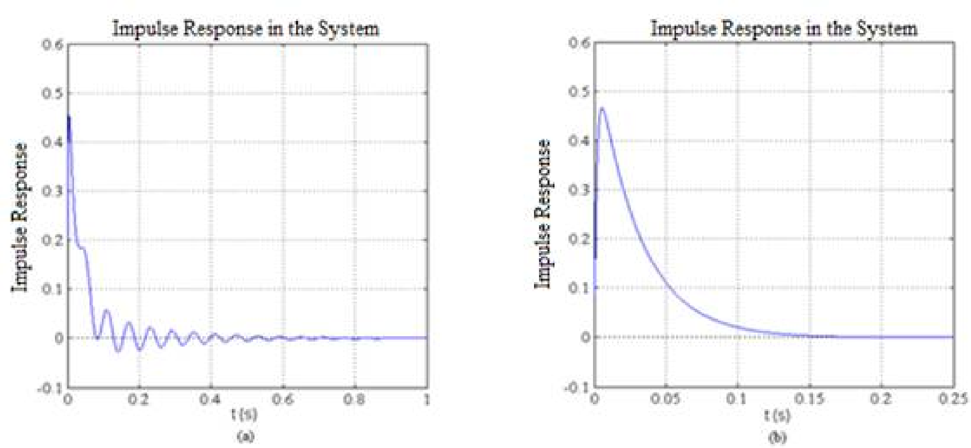


Figure 11 – a) System's answer to an impulse; (b) System's answer to an impulse with a damper coefficient of 0.01.

In order to make an evaluation of the system stability, we traced curves with the geometrical place of system roots, shown in Figure 12.

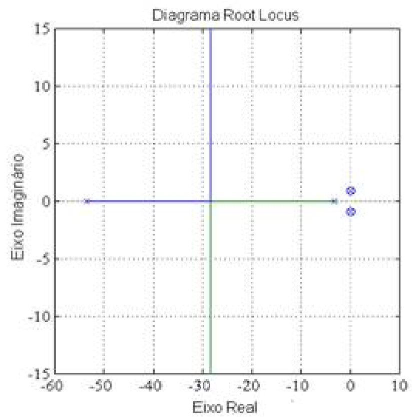


Figure 12 – Geometric place of the system roots.

3.6 CONCLUSION

This chapter produced the flux diagram or BG model of DHS, which facilitates the understanding of the relation between each of the system variables. From this diagram, I developed the DHS mathematical model, that express the delay in the muscles activation and the strength loss in a DHS affected hand.

For the development of the mathematical model, it was necessary to study the basics of BG methodology in order to establish properly the flow of energy between each of the system components. This process required basic knowledge of physics, mechanics and even intuition. I evaluated the model using the values found in the literature, and obtained graphics that shows that the higher the damping coefficient, higher will be the muscles activation time and the higher the elasticity coefficient the higher the strength that the hand exerts. It is recommended deeper studies about the mechanical properties of muscles and tendons of the hand in order to approximate the mathematical model to the reality of a human hand.

Finally, I conclude that the results obtained in this chapter are a contribution to the field of science and medicine, and that the mathematical model will be the basis for proposing a device succor to the treatment of this disease and a control law organic thereof.

4 BIOMEDICAL ASSISTIVE DEVICE

4.1 INTRODUCTION

This chapter will present a detailed outline of the materials and methods used for the design and manufacture of a biomedical assistive device, which has the objective of restoring power, control, sensitivity and texture of the hands of patients with DHS.

For the development of this product were adopted parameters established by Assistive Technology. The AT is an interdisciplinary area of knowledge encompassing products, methodologies, strategies, practices and services in order to provide an improved quality of life, independence and social inclusion in people with some type of deficiency, and facilitates the life of people without deficiencies (MACHADO & SOBRAL, 2015). It was determined, applying the parameters set up by this area of knowledge, to create an original device focused on diabetic patients.

The parameters that must be met for the device to be considered an AT are:

- Determine which are the needs of the patient that must be attended, and the impact this technology will have for the patient and their environment.
- Determine how the product will be available for the patients. This includes studying aspects such as costs, adaptation, implementation, maintenance, repair and replacement of AT resources.
- Analysis of possible therapies, interventions and services needed for rehabilitation. And if necessary to guide and train the patient, family or health professionals for the realization of such rehabilitation.
- Establish what the adequate use of the proposed technology is.
- Inclusion and consideration of methods to spread information on this technology.

The design of the device is intended to meet the above parameters and at the same time present characteristics that stand out and validate their relevance in the field of medicine. All of this work is done in order for this glove to be considered an initial proposal for making an orthotic device that helps the restoration of the dynamics of hand.

4.2 PROTOTYPE DESIGN

The prototype was designed having three things into consideration (Figure 13):

- There are no treatments that correct or prevent the consequences of DHS. However, there are commercial orthoses that help dealing with skeletal muscle disorders in the hands of patients with carpal tunnel syndrome, arthritis, Parkinson’s disease, among others.

- Tissues, insoles, and even organs’ sections with the latex biomaterial. Where it has proven to be a biomaterial that works for the reconstruction and refurbishment of dead tissue, as is the case of the insoles made of latex, which have contributed to healing and preventing dryness present in the feet of diabetic patients (Reis, 2013).

- The fundamentals of AT allow to unify the ideas and hypotheses for correctly delineating and framing the device and the target audience. It will be made a device for diabetic patients afflicted by DHS, using a soft-hard technology.(MACHADO & SOBRAL, 2015).

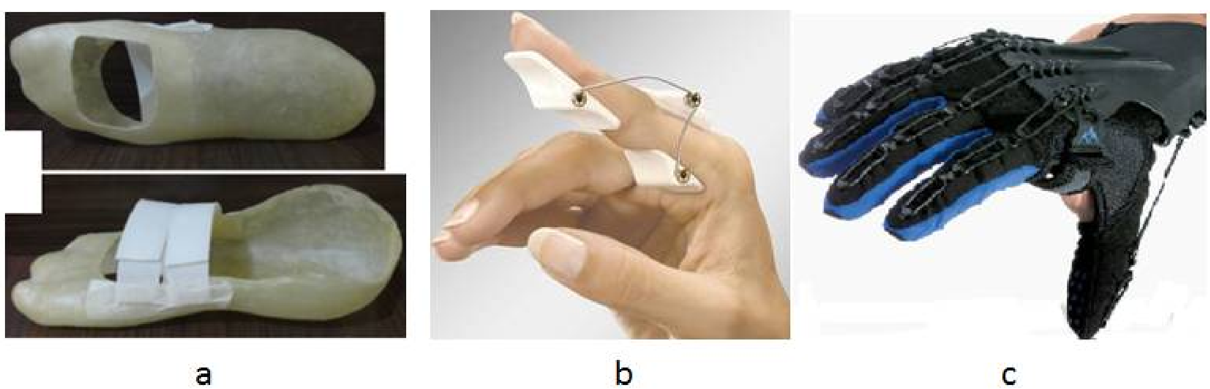


Figure 13 – Design Basis. a) Latex insole for diabetic feet treatment, b) Finger extending active ferule, y c) Saebo® metacarpal orthosis, sources: (Reis, 2013),(Ortoiberica, 2016),(Saebo, 2016).

The device will be designed based on the format of a glove. Selected for the manufacture of bio-inspired glove, the elements were based on the complexity of the geometry of the hand and the aspects that they should contribute. These are:

- The dental plaster and alginate to obtain a mold with similar feature to those of the actual hand.

- Damping elements that increase the sensitivity and dynamic response of the hand.

- The latex material to recover the appearance and texture of the skin.

4.2.1 Mold and cast making

Because latex is a viscous and liquid substance that easily acquires the characteristics of the surface on which it is placed. It takes making a mold that can replicate as many characteristics of the patient’s hands. For fabrication of the hand mold alginic acid is used, which is obtained from brown algae and is widely used in industry and in dentistry for dental impressions. This substance was also considered due to its high percentage of humidity, which can be used in sensitive places such as the mouth, and allows you to copy large amount of information of the desired surface.

For the preparation of the mold, the following procedure which is illustrated in Figure 14 was performed:

- The mixture was prepared. Dencril® type II dental set alginate was used, mixed with drinking water in a plastic container for five minutes until having a homogenous mix. The proportions are half measure of water for a measure of alginate.
- After the mixture is obtained the patient's hand is immersed in the mixture for a period of 10 to 15 minutes, and then carefully removed from it. The mixture should adopt a gelatinous pink (Figure 14.a).
- From the mold is obtained the cast. The plaster used is Coltene® type IV pink plaster (Figure 14.b). The proportions are half measure of drinking water for a measure of mold.
- The plaster is let to dry for 40 minutes (Figure 14.c) and the plaster cast is carefully extracted from the alginate as shown in Figure 14.d.
- Finally, the piece is sanded with smooth sandpaper to remove any plaster cast reliefs.

Some additional considerations to keep in mind when making the mold of the hand are:

- It is important vigorously and rapidly mixing the alginate and water mixture to prevent it from clotting and clumping. If this happens, the resulting mixture is unusable and must be discarded.
- It is recommended to first pour the necessary amount of alginate in the container and then go slowly and steadily adding drinking water. This process avoids the formation of lumps in the mixture.
- It is recommended to follow the instructions of each brand, even when among different brands there is little difference between the proportions. Since it could take longer for the alginate to dry or turn out that the plaster cast is very fragile and brittle, and we would need to make it again.
- It´s recommended using plastic containers which edges that are smooth as well as considering the use tissues or soft brackets on the edges of the container, since patients tend to rest the forearm on these.

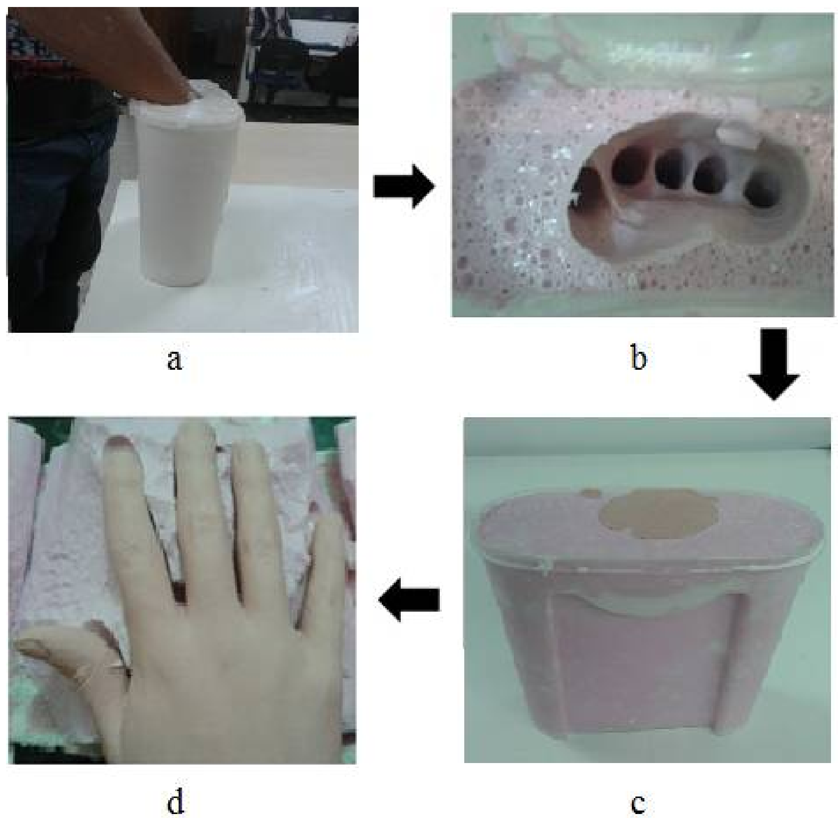


Figure 14 – Mold and cast making. (a) Hand immersion in the alginate mix (b) Mold (c) Filing the mold with plaster (d) Plaster cast

Having established the protocol for making the plaster cast of the hand, was considered necessary to establish the minimum measures that the container should have. This in order to minimize the amount of material used, to get the impression of the open hand and up to the wrist hand and save time searching for containers with the specifications on the market, valuable time that could be used in conducting and analyzing experiments. The size of an adult's hand was obtained from the literature. The measures are: large 18.5 - 16.8 cm and width: 8 – 9.6 cm. Width and large are measured as shown in Figure 15 (Binvignat, Almagià, Lizana, & Olave, 2012).

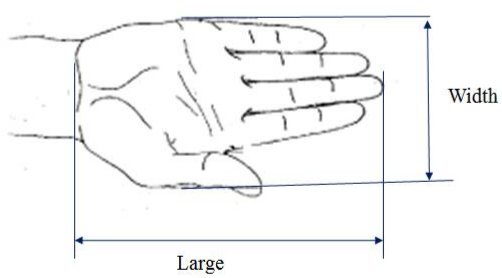


Figure 15 – Selected reference points for measuring the dimensions of width and length of the hand intended to design the container where it will be obtained alginate and plaster molds.

Considering the hand's dimensions the established measures should be the minimum required for the container. Figure 16 shows the used container and the proposed one. Appendix A shows the design plan for the proposed container. It was considered that the nylon would be an ideal material for making it since it has an affordable price, it is easy to clean, durable and provides good finish. For reasons of time and objectives outside of this research that model was not made.

a b

Figure 16 – Containers for making the alginate mold and plaster cast. a) The container used for the production of molds during this work, its dimensions are height: 21 cm and base: 20.5 x 8.5 cm. b) Proposed design for future making of molds and casts, its dimensions are: height 28 cm and base 14 x 26 cm. (see Appendix A for more details).

4.2.2 Dampers design

To determine the geometry of the cushions was used the equation $Pressure = \frac{Force}{Area}$. After analyzing the mathematical relationships in the area of: a circle, a square, a rectangle, it was concluded that the area of a circle is the larger one and therefore has less pressure. In addition, it has a geometry that minimizes the occurrence of stress concentration points and is easy to replicate.

Procedure to analyze what is the most appropriate distribution of cushions in hand:

I It was considered placing cushions on the areas of greatest hand contact, which would be the tips of fingers, palmar region under the toes, and phalanges of each finger.

II It was determined not to place cushions in the area where the phalanges come together to avoiding further limitations in the patient movement.

III Hexagonal and asymmetrical distribution of dampers in the phalanges was considered to provide a better grip (Figure 18.c).

IV The amount of damping in the palmar region and the fingertips depend on the size of the hand. Considering that the allocation should be oval in the tips of the fingers and linear in the lower region of the palmar fingers. These distributions are best adapted to the shape of the surfaces.

Initially, I worked with different commercial molds that allow replicating the geometry of small disks, and their adjustment to the size of the fingers, where it was found that the size and height of the circles of a block of Lego brand conformed to the desired dimensions. The dimensions of the dampers (disks) are shown in Table 5. The procedure to make molds of said geometry as illustrated in Figure 17.

Table 5 – Average size of the cushions, obtained by measuring ten cushions made of plaster using a digital vernier.

Dimension	**Average**
Diameter	4.76 ± 0.05 mm
Height	1.8 ± 0.2 mm

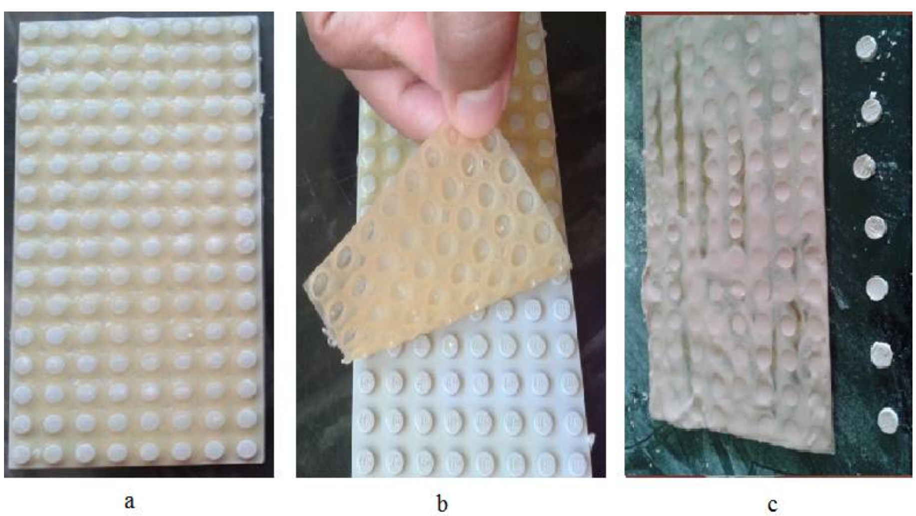


Figure 17 – Manufacture of dampers from a commercial Lego block, using latex and dental plaster to copy the format of discs. a) Thin latex layer over the block. b) Remove the template once the latex is dry. c) Obtainingthe dampers using dental plaster template latex.

4.2.3 Damper insertion

Once designed and obtained the dampers, I evaluated what would be the best procedure to fix them to the plaster caster. First, I tested with commercial fast drying glue and distributed according to the considerations listed above. This process managed to effectively set the dampers on the cast in the desired locations. However, I observed that this procedure demands great precision and time. Therefore I considered necessary to design a board based on the established distribution for the dampers, as shown in Figure 19, which serve to make templates made of latex to help the location of the dampers. This plate was made with Plaster disks on a rectangular plastic surface with edges, to obtain latex templates with uniform thickness. The distribution of the discs was obtained after being considered several parameters including: the average size of the phalanges, and the size and distribution of the dampers. The dimensions of the asymmetric bloc of dampers made with SolidWorks is shown in Appendix B.

The phalanges' average measurements were obtained from the literature, and are shown in Table 6 (Binvignat, Almagià, Lizana, & Olave, 2012). Considering that the dimensions of the phalanges differ depending on the individual and the parameters established for the distribution of dampers, exposed in the previous section. Four damper distributions were established and are shown in Figure 18. The selection of these must be based on the appreciation of impressions observed in the plaster mold and the size of the phalange.

Table 6 – Average measurements of the hand

Finger/Phalange	**I**	**II**	**III**	**IV**	**V**
Distal	32 mm	26 mm	32 mm	30 mm	23 mm
Medial	–	30 mm	35 mm	35 mm	25 mm
Proximal	38 mm	45 mm	50 mm	40 mm	35 mm

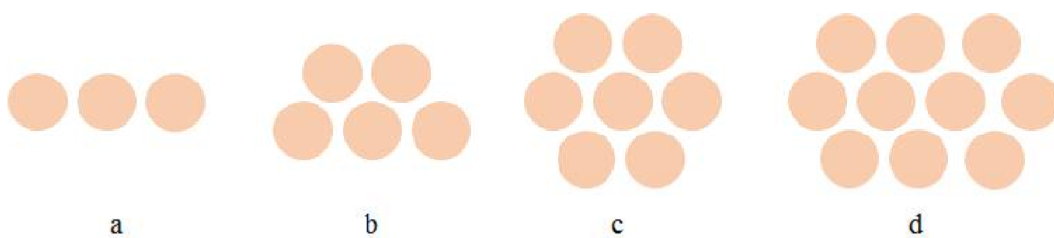
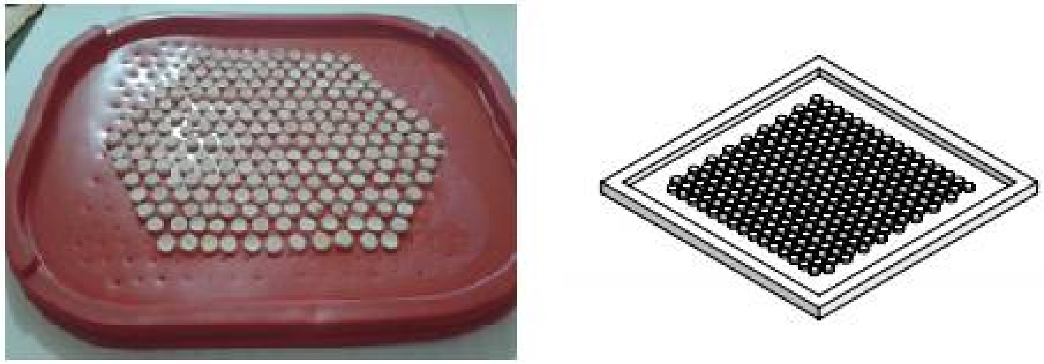


Figure 18 – Allocation of the dampers with an asymmetrical hexagonal arrangement according to the size of the phalange. a) Lineal distribution for small phalanges, under the average. b) Pyramidal distribution for medium phalanges, average measures. c) Hexagonal distribution for average phalanges. d) Double hexagonal distribution for large phalanges, above the average.

Afterwards, two methods were developed to insert the dampers to the plaster cast, where the choice will depend on the skills of the professional performing the experiments, how much the DHS has affected the patient's hand and location of the parameters discussed above. Such methods are defined below:

METHOD I

1. Perform plaster cast of the hand, following the steps outlined above.



a b

Figure 19 – Dampers blocks with asymmetric distribution for a standard damper distribution in the casts. a) Asymmetric block of plaster dampers on a plastic lid. b) SolidWorks design (for more details see Appendix B).

2. Applying latex in the plate in Figure 19, to the level of the shock absorbers, careful not to cover them completely.
3. Allow to dry for 30 min at room temperature.
4. Carefully remove latex obtained template. It should be as in Figure 17.b.
5. Place on a clean surface and cut small templates with proper distribution. (Figure 18)
6. Locate each template obtained in the phalanges of the hand of ready-made plaster. Secure these by a sewing thread or nylon.
7. Perform plaster mix and fill each hole in the template.
8. Allow to dry for 30 min and carefully remove the templates within latex.
9. Sand excesses and round the edges of the dampers Plaster.

METHOD II

1. Applying latex in the plate in Figure 19, to the level of the dampers, caring to cover the entire surface with latex.
2. Allow to dry for 30 minutes at room temperature.
3. Carefully grab the latex glove and pull it inside out to reveal the holes, fill the holes with latex.
4. Allow to dry for 30 more minutes at room temperature.
5. Put on a clean Surface and cut small templates with permanent distribution. (Figure 18)

6. Seek and secure each template with gauze or microporous tape on the patient's fingers.
7. Make the plaster mold, as detailed in section mold making.
8. Remove the gauze with the latex templates and lean the patient's hand.
9. Sand the plaster mold.

Finally, the procedure shown in Figure 17, will be carried away using asymmetric block shown in Figure 19. With the integration of this new block to the glove manufacturing process, it has been achieved a standardization in the preparation and insertion of the dampers. Consequently, the dampers on the tip of the fingers and the palmar region below the fingers are placed manually using the dampers obtained from the process illustrated in Figure 17 which will be replacing the Lego block by the asymmetric shown in Figure 19 . These will be attached to the plaster using commercial fast drying glue. These should be positioned according to the parameters set out in section dampers design. The dampers are fixed in the phalanges using the method I or II.

4.2.4 Prototype making

A biomaterial is any natural or synthetic substance that can be used to replace part of a living system or to function in close contact with living tissue. There are many studies that consider applying latex or living tissue implant material. Showing satisfactory results, as (Ribeiro A. R. & Rodrigues, 2014), (Brandão et al., 2007) and some others already set out in the introduction to this work.

The latex used is extracted from Brazilian tree *Hevea brasiliensis*, it is a thick and viscous fluid with whitish appearance extracted from the inner layer of the stem of this tree. According to (Alves, 2004), Natural latex is composed of 36% de rubber particles, 1,4% protein, 1,6% carbohydrate, 1% lipids, 0.6% of glycolipids and phospholipids, 0.5% of inorganic components, 58.5% water and 0.4% of other substances. Constituents that are not rubber particles are biologically important for the metabolism of Latex and affect their physical and chemical properties is this fluid (Paula et al., 2010). In order to the solid particles be removed, the latex must to be centrifuged, with the objective of conferring elasticity to the final compound, strength and biocompatibility necessary for making the proposed device.In this work it was used latex brand DU LATEX, which was acquired in the national market.

To manipulating the natural latex commercial latex gloves were used, a glass container to store it, plastic wrap to avoid direct contact of the environment with the glove made, foil to protect from light and aging, sponge and cloth for cleaning, and the use of masks to prevent aspiration of ammonia which can lead to allergies and headaches.

The experiments were done at the Laboratory of BioEngLab, FGA, Brasilia, with an average ambient temperature of 30^o C. The method of applying latex was through brushstrokes, performed with a fine bristle paintbrush to prevent unwanted reliefs. The number of layers was determined from two parameters: no ruptures in the film when removed from the mold and covering the entirety of the worked area. After application of the latex, the glove was allowed to dry at room temperature.

Care of peeled off latex must be taken which in case of occurrence must be corrected before the first minute with a paintbrush or cotton swab to avoid unwanted reliefs on the glove. The glove must be allowed to dry at least 15 to 30 minutes between layer and layer. Finally the glove is removed from the mold at least 12 hours after the last latex application. We should wait for the latex to fully vulcanize because the geometry of the hand mold with dampers makes the removal of the glove process fairly rigorous. Then the glove is placed in plastic wrap and foil to stop the vulcanization process due to contact with the ambient air.

The three models of gloves were proposed to be studied, are shown in Figure 20. These are:

1. Five layer latex glove with dampers on the finger, except on the thumb. There is no evidence in the literature that DHS affects the mobility of the thumb. The absence of dampers on the thumb could facilitate the adaptation of the patient.

2. Six layer latex glove with dampers, except the thumb.

3. Seven layer latex glove with dampers in all fingers and the palm of the hand to protect the palm of hand in the high contact areas. The dampers on the bottom of the palm were inserted manually using a hexagonal distribution.

a b c

Figure 20 – Proposals for the bio-inspired device. a) 5 layers latex glove without dampers on the thumb. b) 6 layers latex glove without dampers on the thumb. c) 7 layers latex glove with dampers on the thumb and at the bottom of the palm.

4.3 ORGANIC CONTROL

Representation of the behavior of biological system has been a big challenge for the scientists. It has been found possible to represent such systems through dynamical systems. In previous chapters it has been shown how it is possible to model a complex biological system as in the case of the human hand, in order to get answers from the system, presenting consistent values according to the specifications given.

When a system that uses dynamic control theory is modeled, we obtain a mathematical model whose main function is to associate the variables involved and deliver an output response that is consistent with the desired response. This model should be designed so that the response can be constantly monitored and changed via a feedback to the system itself, so that it can be corrected by acting on the dynamics of the system, provided there is no significant discrepancy between the results to be obtained.

In the case of this work it was exhibited a mathematical model representing the movement of a hand with delayed activation of muscles and loss of strength. It emerged the need to create a device that alters the dynamic response of the system, therefore a device capable of accelerating and activating the system is proposed.

Organic control theory arises in this context, which aims to build architectures or devices that can change the behavior of complex systems. The intervention of an organic controller aims to control the system behavior through a biomaterial (natural latex), which directly interfere in system performance. This will work in conjunction with devices and software to generate a controller capable of raising an intelligent system interference.

Organic control basically consists of manufacturing, a controller from a biomaterial, which can act on the dynamics of a biological system. The main objective of organic controller is to obtain an output response, according to the performance specifications of an operating system within acceptable specifications and standards. The importance of the concept of organic control justifies the need for a new approach to control biological systems, which are often complex systems with nonlinear dynamic and high dimensionalities (Ribeiro A. R. and Rodrigues, 2014).

Keeping in mind the definitions presented, it is proposed inserting a glove made from latex, which function as a controller, changing the output response, by activating the dynamics of hand with DHS. This activation is obtained when a new mass system is introduced (glove with shock absorbers), which will work in conjunction with the mathematical model obtained, to monitor the system, and that in turn may lead to new treatments or data to help learn more DHS.

Considering that DHS interferes in the natural movements of the hand, which can cause serious accidents and decreasing the quality of life of the patient, it is concluded that the exposed prototype is an innovative contribution which will help and restore hand movement.

4.4 RECOMMENDATIONS

- Explain to the patient the right way to reach into the Alginate, to avoid repetition in this process. It is necessary that the patient enter the hand as extended as possible with the half-open fingers and without contact with the container walls.
- Both methods proposed for inserting the dampers provide the desired result. However, it is considered that in the case of patients with very little strength and mobility in the hands use Method 2 in conjunction with a 3D printer. It was found in the tests that taking the hand out of the Alginate mixture once it has already hardened may be difficult or stressful for people with poor mobility or in patients with a very pronounced curvature.
- Making molds nylon designed to standardize the manufacturing process is highly recommended.

4.5 CONCLUSIONS

The design of the proposed gloves are considered versatile because of its easy adaptation to different sizes of hands and fingers, meets the needs of a patient with DHS, and is made of a biomaterial that does not cause allergies, helps transpiration skin and creates a barrier between the hand and the environment.

The validation of these is considered necessary to determine what the final prototype, which is necessary to perform cost analysis, maintenance, among other aspects that need to be evaluated for the final product is considered as an A.T.

The study details of the three proposed gloves will be presented in the next chapter to select the glove that offers more benefits for the treatment of DHS.

5 EXPERIMENTAL VALIDATION OF THE BIOMEDICAL ASSISTIVE DEVICE

5.1 INTRODUCTION

This chapter will evaluate the proposals for the design of the glove, presented in the previous chapter. The gloves used in the tests were made tailored to the dominant hand of each individual, because it is the most used during the execution of everyday tasks which will help to have a clearer idea about the comfort, strength and grip of the glove. The tests to be performed were selected based on the basic movements and gripping shown in Figures 2 and 3.

First will be evaluated the construction characteristics of each glove. Subsequently will be made handling and strength tests with gloves that have presented positive results in the above assessment, followed by the application of a questionnaire that will showcase the qualitative impressions of individuals using the glove.

Finally, it will be made the analysis of results obtained in the experiments, to select which of the proposals meet the objectives. From that final model will be calculated the costs for development and production, and presented its technical data sheet. It is important to remember that the proposed design seeks to not be a universal design, but a customized and interactive process that involves a series of procedures, considerations and methodologies, that sometimes are strenuous, in order to reach a final design that meets all or most desired requirements.

Each of the tests was made with the consent of three healthy individuals and do not compromise the welfare and health of the patient. Due to the little number of subjects, that they are healthy, that the test are not invasive nor do they represent any risk to the subjects' health, the evaluation and approbation of an ethics committee was not necessary. The general characteristics of the subjects are in the next table:

Table 7 – General information of the subjects

Subject	Sex	Age	Occupation
1	Man	22	Administrative Auxiliary
2	Woman	59	Housewife
3	Man	26	Student

5.2 CONSTRUCTION FEATURES

It was measured and recorded how much material was used to make each mold and the time to make each. These are shown in the following table:

Table 8 – Amount of material and time necessary for the manufacture of each mold.

	Hand size	Mold			Cast			Total time
Subject	(mm)	Alginate (gr)	Water (ml)	t (min)	Alginate (gr)	Water (ml)	t (min)	(min)
1	a=9.5 b=18.4	300	1600	15	600	250	60	75
2	a= 11,5 b= 17,3	325	1700	10	550	200	60	70
3	a= 11,02 b= 18,7	400	1600	15	650	300	60	75

First, it was conducted a visual inspection to determine how many latex layers are necessary for the glove to not present tears when removed from the plaster cast. Gloves with five layers presented little or no tearing. Gloves with six and seven layers showed no tears. Subsequently, it was reported the amount of latex applied in each layer and drying time between layers. This is shown in the following table:

Table 9 – Latex amount used for making each layer and recording of the time that was established for each application Latex.

Subject	Layers (ml) / Drying time (min)							ml total
	I	II	III	IV	V)	VI	VII	t total
1	20 ml 40 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	80 ml 220 min
2	20 ml 40 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	80 ml 220 min
3	20 ml 40 min	15 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	10 ml 30 min	85 ml 220 min

Then I evaluated the resistance of the glove, I asked individuals to use each glove for four of their workdays. From this experience, I observed that the glove with five layers presented a lot of tearing in all cases, the sixlayers one presented tearing in two individuals and two tears in the thumb on one of the individuals, and the glove with seven layers presented no tearing in neither of the gloves delivered. Was also noted that even when individuals report having not exposed the glove to direct sunlight, the gloves changed their color from yellow to dark yellow, which shows the aging of latex in direct contact to the environment. All observed changes are shown in Figure 21.

I asked directly and openly to the individuals to narrate their experience using the gloves. From the answers obtained I concluded that none of them experienced discomfort perform their daily tasks, one reported having difficulty writing with pen and cellphone, and then commented that his hands were sweating after an hour using the glove.

Finally were registered the weight of each glove. These are shown in Table 10.

After analyzing the results, it was decided to discard the fivelayers glovebecause it hadvery little resistance to use. Dexterity tests will be performed on the six and seven layers gloves, which reported almost or no damage during construction tests.

a b c

Figure 21 – Record of changes in the gloves when used for four hours. a) Glove with fivelayers has multiple tears on the back and palm. b) The six layers glove present two breaks in the opening region of the fifth finger. c) Aging of latex when in constant contact with the environment.

Table 10 – Record of weight in grams of each of the gloves proposed.

Subject	**Weight (gr)**		
	5 Layers	**6 Layers**	**7 Layers**
1	14.82	17.07	20.89
2	15.03	18.37	19.55
3	20.28	23.11	28.29

5.3 DEXTERITY TESTS

I designed and prepared eight tests to evaluate the abilities of the hand with and without glove. In order to analyze with more accuracy the obtained results, the times of execution of each test were registered. In addition, the tests were recorded for performing an observational analysis of the behavior of individuals. The detailed description of each of the tests are shown in Appendix D. The values obtained from the tests are reported in Table 11.

For testing the glove, the following steps are executed:

- Explain to the individual what each test is and how to do it.
- It is recorded the video of the individual performing the tests and simultaneously measured the duration of performing each of the tests.
- Once the individual finished making the eight tests, he rest for five minutes and three measurements will be made with the dynamometer. Then they are asked to put on the glove and use it for 15 minutes to become familiar with it. This process is done 3 times,

the first without glove, the second with the six layers glove and the third with the seven layers glove.

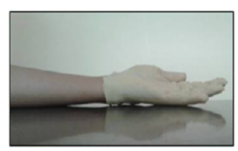
Table 11 – Record of weight in grams of each of the gloves proposed.

Testing time	Subject 1			Subject 2			Subject 3		
t (seg)	**Without Glove**	**6 Layers**	**7 Layers**	**Without Glove**	**6 Layers**	**7 Layers**	**Without Glove**	**6 Layers**	**7 Layers**
Legos	36.41	37.38	31.17	45.35	36.06	36.36	40.60	28.40	31.62
Write in Paper	37.99	48.34	50.84	47.4	38.60	38.20	48.13	40.15	37.62
Mini Balls	18.30	18.05	15.54	19.68	13.93	12.93	26.91	26.72	26.14
Turn Pages	15.34	15.50	12.72	12.3	10.95	11.98	12.40	13.09	8.70
Grab Bottle	9.19	8.37	7.49	6.12	6.60	6.81	13.33	11.11	10.06
Squeeze Ball	5.54	4.58	3.91	3.36	2.59	2.95	5.21	3.86	3.78
Compress Spring	30.82	22.34	18.87	18.53	19.36	17.33	21.95	20.29	17.64

Observing the results from the writing on paper and writing on mobile tests is concluded that the presence of the glove lowers the performance these tasks, the results agree with the opinions reported by individuals during the endurance test. However, the rest of the evidence report that the presence of the glove gives more grip to the hand.

After the dexterity tests, it was considered pertinent to observe and study the opening of the hand with and without glove. This considering that the atrophy in the flexor and extensor muscles and tendons causes the hand to flex, impeding the natural and voluntary finger extension. The angles were measured using free software GIMP 2.8

Table 12 – Record of the opening angle of the hand without glove, with the six layers glove and with the seven layers glove.

Subject	 **Whitout Glove**	 **Glove with 6 layer**	 **Glov with 7 layer**
1	67.54^o	10.60^o	9.46^o
2	41.55^o	3.25^o	6.93^o
3	31.10^o	22.15^o	19.23^o

The measured angles record how the presence of the glove and increased layers latex allow a wider opening of the hand. Subject 2 gave inconsistent data compared with the other two subjects, this can be due to errors using the program or wrong positioning of the hand when capturing the image of the experiment.

5.4 STRENGTH TESTS

For the measuring of the gripping strength exerted by each individual, was used a commercial Dynamometer e-clear. Three measurements were conducted in each stage, as mentioned in the previous section. The measured values are shown in the table 13

Table 13 – Record of the opening angle of the hand without glove, with the six layers glove and with the seven layers glove.

Subject	Tests	1	Strength (Kgf) 2	3	Average (Kgf)
	Without Glove	22.8	23.3	25.1	24 ± 1
1	6 Layers	23.8	22.3	22.6	22.9 ± 0.6
	7 Layers	23.3	20.1	21.7	22 ± 1
	Without Glove	20.9	24.2	25.3	23 ± 2
2	6 Layers	20.7	18.5	16.7	19 ± 2
	7 Layers	20.1	18.3	19.3	19.23 ± 0.7
	Without Glove	51.9	53.3	57.3	54 ± 2
3	6 Layers	53.3	53.3	49.7	52 ± 2
	7 Layers	47.7	49.1	52.4	50 ± 2

By studying the above table it is obtained that the six layers glove offers a reduced strength of 4.58%, 17.40% and 3.70% respectively. While the glove of seven layers offers a reduced strength of 9.60%, 16.40% and 04.07% respectively for each individual. The strength reduction tests the functionality of the buffers, which store energy and prevent the hand of being affected by external forces while providing more grip.

5.5 QUESTIONNAIRE

I performed a questionnaire of nine closed questions in order to know and report the experience and perception of the glove by individuals. The questionnaire is in Appendix C and the responses of it were plotted in Figure 22. I asked questions about comfort, quality, aesthetics and grip to analyze which aspects should be modified or included in the design of the prototype. There was no criticism in terms of aesthetics and quality (Question 8).

Individuals felt no discomfort or difficulty in manipulating objects using the glove. However, they did not like the feeling that they could not exert the same force without the glove (Question 5). Therefore, I concluded that should include talks that guide patients on the use, care and purpose of the glove to cause a better reception and understanding of it.

Considering the results of the strength and dexterity tests and the questionnaire, is determined that the proposed device for treating DHS will be the glove with seven layers of latex because it offers good grip, endurance and provides greater opening hand.

5.6 COST

Considering the need of incorporating new technologies to deliver health care and the need to adapt national budgets to build and spread them. It was considered appropriate to con-

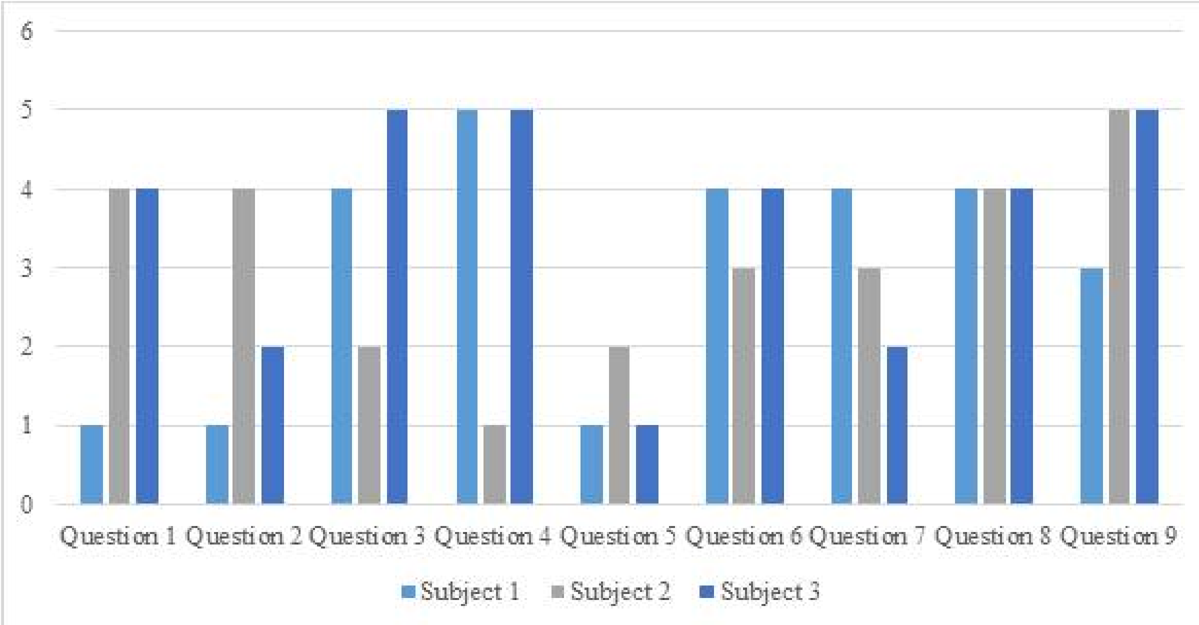


Figure 22 – Bar chart of the responses given by the subjects to the questionnaire.

duct a brief analysis of the development and production costs of the proposed biomedical assistive device, considering some parameters set out in Budget Impact Analysis (MS, 2012).

Among the most important aspects to note are the cost-effectiveness and budget impact. First, was selected the audience which is intended to use the glove designed in this case was specially designed for patients with DHS. However, due to the versatility of the design and the results of tests it is considered that this device could also help in the treatment of other musculoskeletal diseases of the hand.

Secondly, there are costs to develop and produce the proposed device. Raw material costs for the production of a seven layers latex glove are shown in Table 14.

Several considerations for calculating costs were necessary, these are:

1. The salary of skilled labor will equal the value of a master's scholarship, since a researcher and student of Biomedical Engineering area developed this work. The value of the scholarship is equal to R$ 1,500.00per month.

2. Some cost are difficult to calculate such as water, transportation and light, so these were grouped into the category miscellaneous expenses.

3. For the production of the glove we considered that a health technician is able to understand and correctly perform the selected device manufacturing, for this reason the labor cost of production was based on the salary of this professional. A health technician receives approximately R$ 1,100.00 per month, i.e. R$ 6.88 per hour, this considering working eight hours a day for 20 days a month

Table 14 – Development costs of the biomedical assistive device proposed.

Supplies	Quantity	Cost per glove(R$)	Total cost (R$)
Alginate	6	23	138
Plaster	6	36	216
Latex	2	70	140
Glue	1	12	12
Beaker 20ml	1	5	5
Beaker 800ml	1	18	18
Digital Vernier scale	1	90	90
Legos	10	5	50
Plastic containers	3	20	60
Whisk	1	20	20
Paintbrush	2	12	24
Latex Gloves (box)	1	15	15
Face masks (box)	1	20	20
Plastic wrap (roll 30m)	1	15	15
Foil (roll 30m)	1	15	15
Digital Dynamometer	1	250	250
Books, magazines, Internet (hours)	40	3.5	140
Sandpaper	6	1	6
Skilled labor (months)	12	1500	18000
Other expenses		300	300
Total			19534

4. The amount of materials and time used for calculating of production are obtained through tables 8 and 9.

Table 15 – Minimum amount of materials needed for the manufacture of a glove made of latex withdampers to correct and contribute to the rehabilitation of patients with DHS.

Supplies	Quantity	Total cost (R$)
Alginate	331,67 gr	18,61
Plaster	600 gr	21,6
Latex	81,67 ml	4
Glue	2 gr	1,2
Latex Gloves (box)	1	1
Face masks (box)	1	1
Plastic wrap	1 m	0,5
Foil	1 m	0,5
Sandpaper	1	1
Skilled labor	6 hr	41,25
Others expenses		30
Total (R$)		120,66

5.7 MATHEMATICAL ANALYSIS OF THE SYSTEM

In chapters Mechanical Analysis and Dynamic Model was proposed and analyzed a mathematical system that represents a hand with DHS. The simulations were previously obtained from data extracted from the literature. This section will consider those values and those obtained from experimental tests in order to compare and validate the proposed mathematical system.

Some considerations were taken to validate the mathematical model through the experimental data. These are:

- The analogue system was analyzed. The variables are altered by the presence of the glove. These are: the resistive coefficient R_1, capacitive coefficient C_1, and inertia M_2. The values used for the simulations are recorded in Table 13, where values are without gloves:F_i, R_1, C_1 , M_2, and values with glove: F_i', R_1', C_1' , M_2'.
- The mathematical model uses as variables the ones from the seven layer latex glove.

Table 16 – Values of the constants with and without glove for simulation and experimental validation of the proposed mathematical model.

F_i F_i'	R_1 R_1'	C_1 C_1'	M_2 M_2'	F_s F_s'	**% strength reduction**
1 N	3 N/m	12 N.s/m	0	0.016 N	98.4%
1 N	4.5 N/m	10.8 N.s/m	0.02089 gr	0.011 N	98.9%

When observing Figure 23 and the results reported in the above table, I concluded that there is a decrease in the applied force because the dampers inserted in the glove store energy thereby protecting the hand of forces and external impacts. With it I can validate the mathematical model.In addition, the functionality of the seven layers glove is proven.

5.8 TECHNICAL DATA SHEET OF THE PROTOTYPE

The glove made in this paper was designed specifically considering the needs and characteristics of diabetic patients with DHS. The glove is made from latex to ensure the welfare and health of the patient. This material provides comfort and allows perspiration of the patient's hand for recovery of skin texture and dynamics of hand.

- Biodegradable and disposable gloves.
- Made of 100% natural latex.
- Lightweight, approximate weight 23 gr.

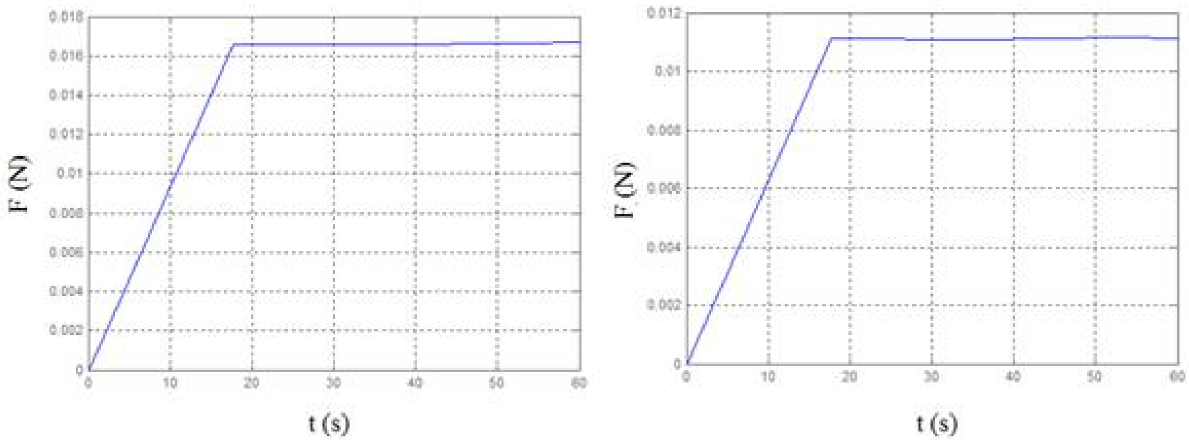


Figure 23 – Simulations of system behavior with and without gloves. a) On the left, the graph in response to a unit step without gloves system is shown. b) On the right, the graph shows in response to a unit step system with the seven layers glove.

- Color: light yellow.
- The size and design is personalized and individualized.
- It is not sterilized and is lightly powdered with cornstarch to prevent sticking of the inner walls of the glove when the product reaches temperatures above 25^o C.
- Provide excellent finger sensitivity.
- Smooth surface on the back of the hand and with the presence of pellets that dampers impacts on the areas of greatest hand contact.
- The thickness of the back of the hand is approximately 0.50 mm and the palm of 0.95 mm.
- Full design covers from the fingers to the wrist and has reinforcement to give more resistance.

Some recommendations on the use and care of the glove:

- Store in a cool place.
- Do not expose to direct sunlight.
- Avoid direct contact with ovens or aggressive cleaning products.

5.9 CONCLUSION

The subjects reported that their hands perspired after an hour using the glove, which indicates that latex does not provokes sin dryness in their hands, which is positive for the patients with DHS. Because they have sin dryness in their hands, rough skin, nodules and lack of perspiring.

Through the calculation of the hand opening angle with and without the glove, I observed that the glove allows for a wider angle. The subjects also performed in less time the movement of abduction and adduction with the glove than without it. From these results, I consider that the device could help to decrease the tension over the collateral ligaments, making easier for the subject to perform the movements of abduction and adduction of the fingers, movements that are severely damaged in the DHS patients.

From analyzing the mathematical model, I conclude that the experimental results are coherent with the mathematical model, namely a decrease in the strength exerted by the hand. However, there are few studies that show values for the elasticity and damping coefficients, which would contribute to this mathematical model to be closer to reality.

For lack of time, I did not establish the duration of the glove. However, I observed that latex ages quickly when directly exposed to light, and the seven layer latex glove can endure half a day of work without tearing.

The oval arrangement allowed the dampers to create a uniform surface on the fingertip that facilitates gripping and handling any object regardless of size.

It is determined that the asymmetrical distribution, based on the geometry of a hexagon, provides a versatile design that can easily fit different sizes of the phalanges, provide a better grip and do not interfere with the natural movements of the hand. Moreover, the minimum amount of layers that a glove should have is seven. Applying more layers is left to the considerations that may provide a health care professional, because the glove with seven layers opposes enough resistance to close the hand, and a stiffer glove could cause discomfort or fatigue to a patient with little time with DHS.

It is considered that the glove would reach affordable costs once the manufacturing procedure is standardized and streamlined.

6 CONCLUSIONS AND FUTURE WORK

Since the hands are the main organ used to interact with our environment, it is considered important the development of care and treatment that ensure its normal operation. And so came the need to study new treatment methods for DHS.

This final chapter will present how this work's objectives were achieved, the final considerations, contributions and proposals for future work on this research.

6.1 CONCLUSION

The aims of this work were accomplished satisfactorily. For I managed to lift and summarize the sparse but valuable information that about the DHS. With this information, I were able to study the functioning and morphology of a healthy hand, thereby performing a biomechanical analysis of the alterations on the patients' hands product of the DHS.

By analyzing the system from the perspective of biomechanics it was possible to understand which are the areas most affected by the DHS, which led to the design of a system analogue to the hand with DHS, using mechanical elements to represent the loss of strength and delay activation of the muscles of the hand. Using the BG methodology to reach a mathematical representation of the lateral movement of the fingers, methodology that has been widely used in modeling biological systems.

Once obtained the mathematical model of the system, simulations were performed using values from the literature, to verify that the proposed model throw results in accordance with the performance of a hand with DHS.

Subsequently I designed a glove made of natural latex and insert shock absorbers on it, to minimize impacts on the hand and improve grip that could contribute to the treatment of DHS.

After tests with the glove, I concluded that this prototype presents an attractive proposal for the fields of science and medicine, offering results that demonstrate its functionality. From the results obtained in chapter 5, the glove could help to refurbish the skin because it allows the hand to perspire. It could also help to prevent the apparition of nodules and facilitate the hand's movements because it allows the opening of the hand.

I consider that the results obtained in this work open the possibility of obtaining a product that have potential for treating people with DHS and with the ability to adapt to the treatment of other musculoskeletal hands as arthritis, De Quervain tenosynovitis, carpal tunnel among many other diseases that seriously affect quality and patient survival. However, the application of tests is necessary for reaching a final model and to make clear which are the advantages and disadvantages that this device offers to DHS patients

6.2 CONSIDERATIONS ABOUT THE RESEARCH

This research produced groundbreaking results for the analysis and treatment of DHS. During lifting on information about the DHS, hypothesis that led to obtaining an analogue system and mathematical model were generated, as well as designing a glove made from natural latex for the treatment and prevention of DHS. It was also noted that there is little information and interest in the study and treatment of this disease. And, lack of information, publicity and programs focused on spreading as preventing, treating and help fight diabetes and its consequences, which presents alarming statistics.

6.3 FUTURE WORKS

From the results obtained in testing, validation of the functional model and the constraints encountered when developing the concept, we highlight some aspects to expand with base on this project. These are:

- Determine the therapeutic methods that best serve to achieve improving and resetting the dynamics of hand.
- Determine the length and shape appropriate to motivate, guide and develop strategies for patient recovery.
- Study the combination of latex with other materials to enhance strength and durability, such as soot, which is applied to increase resistance in rubbers.
- Conduct studies with diabetic patients in order to complete the design process of the proposed glove.
- Explore new methodologies allows to manufacture gloves in large quantities and in less time. This would help to reduce production costs, and consequently will reduce the final cost per glove. Some methodologies that can be considered are applying the layers by direct immersion in latex and immediately after immersed in room temperature water as it was observed that latex hardens when exposed to water, however it takes longer to dry. It could also be designed a method to accelerate the drying time by placing the gloves in axis rotating at high speed, while steam is applied at high temperatures similar to the process used to manufacture the commercial latex gloves.

7 REFERENCES

Al-Matubsi, H. Y., Hamdan, F., AlHanbali, O. A., Oriquat, G. A., & Salim, M. (2011). Diabetic hand syndromes as a clinical and diagnostic tool for. ELSEVIER, 225-229.

Alves, M. (2004). Estudo da borracha natural para utilizacao em periodos de entressafra mun composto. Campinas: Faculdade de Engenharia Química, Universidade Estadual de Campinas.

Binvignat, O. A., Lizana, P., & Olave, E. (2012). Aspectos Biométricos de la Mano de Individuos Chilenos. International Journal of Morphology, 30(2), 599-606.

Binvignat, O., Almagià, A., Lizana, P., & Olave, E. (2012). Aspectos Biométricos de la Mano de Individuos Chilenos. Int. J. Morphol.,, 30(2), 599-606.

Brandao, M., Netto, J., Thomazini, J., J.J., L., Muglia, V., & Piccinato, C. (2007). Prótese vascular derivada do látex. Jornal Vascular Brasileiro, págs. 130-141.

Chiu, H.-Y., Hsu, H.-Y., Kuo, L.-C., & Su, F.-C. (2014). How the Impact of Median Neuropathy on Sensorimotor Control Capability of Hands for Diabetes: An Achievable. PLoS ONE, 9(4), 9.

Da Costa, P., Martinello-Rosa, S., Batista, L., Viotto, M. J., Salvini, T., & Novak, E. (2005). Movimento Articular. Aspectos Morfólogicos e Funcionais. Sao Paulo: Manole.

Díaz Montes, J. C., & Dorador González, J. (2010). El Futuro en las Protesis de mano. XVI CONGRESO INTERNACIONAL ANUAL DE LA SOMIM. Monterrey.

Dullius, J. (2007). Diabetes Mellitus saúde, educacao, atividades físicas. Editora UnB.

E. Centinus, M. B. (2005). Hand grip strenght in patients with type 2 diabetes mellitus. Elsevier, 70(Diab. Res. Clin. Pract. (3)), 278-286.

FID, F. I. (2013). Atlas de la Diabetes de la FID. FID.

Filho, A. A. (2003). Análise de Sistemas Dinâmicos. São José dos Campos: CTA/ITA.

FSS. (20 de 03 de 2016). La enfermedad de Dupuytren . Obtenido de Fissioterapia Blogspot : http://fissioterapia.blogspot.com.br/2012/03/la-enfermedad-de-dupuytren.html

Gmiterko, A., Hroncová, D., & Sarga. (Setember, 2011). Modeling Mechanical Systems Using Bond Graphs. Modeling of Mechanical and Mechatronic Systems. Slovak Republic: Her'any.

Haffner, S. (2002). Type 2 diabetes: Unravelling its causes and consequences.

Hamilll, J., & Knutzen, K. (2008). Bases Biomecanicas do Movimento Humano. Sao Paulo: Manole.

HG, K., VI, S., D, R., & Veltin. (2014). Assenment of Hand Kinematics using and magnetic sensors . Journal of NeuroEngineering and Reabilitation, 70, 11.

Jeong, D. H., & C. H. (2014). The Quantitative Relationship Between Physical Examinations and the Nerve Conduction of the Carpal Tunnel Syndrome in Patients With and Without a Diabetic Polyneuropathy. Annals of Rehabilitation Medicine, 38(1), 57-63.

Karnopp, D., Margolis, D., & Rosenberg, R. (2000). System Dynamics: Modeling and Simulation of Mechatronic Systems, 3rd ed. . New York: Horizon.

Larkin, M. E., & Barnie, A. (2014). Musculoskeletal Complications in. Diabetes Care, 37, 1863-1869.

Lebiedz-Odrobina D, K. J. (2010). Rheumatic manifestation of diabetes mellitus. Rheumatic Disease Clinics of North America, 36(ScienceDirect (4)), 681–699.

Lindhard, J., & Moller., J. P. (1927). On the Elasticity of Skeletal Muscles. Copenhagen: Laboratory for the Physiology of Gymnastics, University of Copenhagen.

MACHADO, G. J., & SOBRAL, M. N. (10 de 11 de 2015). www.galvaofilho.net. Obtenido de TECNOLOGIA ASSISTIVA E EDUCAÇÃO INCLUSIVA : ⟨http://www.galvaofilho.net/TA_dequesetrata.htm⟩

Ministerio da Saúde, D. d. (2012). Diretrizes Metodológicas - Análise De Impacto Orçamentário. Brasilia, Brasil: Ministerio da Saúde, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Departamento de Ciencia e Tecnologia.

Mrué, F. (1996). Substituição do Esôfago Cervical de por Prótese Biossintética de látex: estudo experimental em cães. Dissertação de mestrado. Universidade de São Paulo.: Faculdade de Medicina.

Ortoiberica. (January 2016). Férula extensora dedos. Obtenido de Ortoibérica : http://www.ortoiberica.com/(protesica-exogena-ortesica/ortesis-rigidas/ferula-extensora-dedos$_{7}84_{8}2_{7}105_{01p}ro.html$

Qian, Y., & Rahmani, A. (2013). Bond Graph Modeling and Simulation of a Dexterous Hand. Proceedings of the 1st International and 16th National Conference on Machines and Mechanisms, 55-61.

Reis, M. (2013). Sistema Indutor de Neoformação Tecidual para Pé Diabético com Circuito Emissor de Luz de LEDs e Utilização do Látex Natural [Tese]. Brasília: Universidade de Brasília.

Ribeiro A. R. and Rodrigues, S. S. (2014). Modelagem Matemática do Olho Ambliope para Tratamento com Oclusor Derivado de Latex. Uberlândia, MG, Brasil.: VIII Congresso Nacional de Engenharia Mecânica.

Rosa, & Souza, Ê. (2013). Modelagem matemática da tíbia humana usando Bond Graph., 29, págs. 329-342.

Rosa, S. S., & Altoé, M. (2013). Modelagem vínculo Gráfico do esôfago humano e análise, considerando a interferência na plenitude de um indivíduo, reduzindo o fluxo de esôfago mecânica.

Revista Brasilera Eng. Biomédica, 29(3).

Rosenbloom, A. L. (2014). PERIARTICULAR HAND JOINT LIMITATION SYNDROMES IN DIABETES. ENDOCRINE PRACTICE, 20(8), 4.

Saebo. (May 16 2016). Obtenido de MedicalExpo: http://www.medicalexpo.com/prod/saebo/product-80464-675086.html

SBD. (2014). Diretrizes da Sociedade Brasilera de Diabetes 2013-2014. Brasil: Grupo Editorial Nacional, GEN.

SBD, S. B. (April 10 2016). Obtenido de SBD, Sociedad Brasilera de Diabetes: ⟨http://www.diabetes.org.br/⟩ Shumay-Cook, A., & Woollacott, M. (2010). Controle Motor . Sao Paulo: Manole.

Silva MBG, S. T. (2012). Manifestações musculoesqueléticas em diabetes mellitus. Revista Brasileira Reumatologia, 52(4), 594-609.

Silva, F. d., Jakimiu, F. O., & Skare, T. L. (2014). Diabetic hands: A study on strength and function. Elsevier , 162-165.

WHO, W. H. (2016). Diabetes. Recuperado el 18 de April de 2016, de ⟨http://www.who.int/es/⟩

Yang Chien-Ju, H. H.-Y.-H.-L.-Y.-c. (2015). The associations among hand dexterity, funtional performance, and quality of life in diabetic patients with neuropathic hand from objetive and patient perceived measurements. Springer, 24(Qual Life Res), 213-221.

8 GLOSSARY

DAMPER: It is defined as the ability of a system or body to dissipate energy, or do something less intense or violent.

DEGREE FREEDOM: engineering term used to refer to the minimum number of parameters required to specify and completely determine the motion of a body.

MORPHOLOGY: study of the external shape and structure of organs or organisms.

ORTHESIS: external device or apparatus used to support, align, or prevent deformity, or improve the function of movable body parts.

SENSITIVITY LOSS: It is characterized by alterations in sensation or natural perception of the senses. The continuous loss of sensitivity translates appearance: tingling, numbness, dryness, etc., usually produced by a pathology in any sector of the structures of the central or peripheral nervous system

HARD TECHNOLOGY : They are represented by equipment, machines and knowledge well-structured and ready for use.

SOFT TECHNOLOGY: are all those strategies used to produce a permanent commitment to the work of hosting, resolve and autonomise. That is, it is knowledge and commitment provided by the medical staff.

HARD-SOFT TECHNOLOGY: They are those related to knowledge capable of addressing a job, and capable of producing new knowledge standards and protocols to open the possibility to produce new innovations.

APPENDIX A – CONTAINER LAYOUT

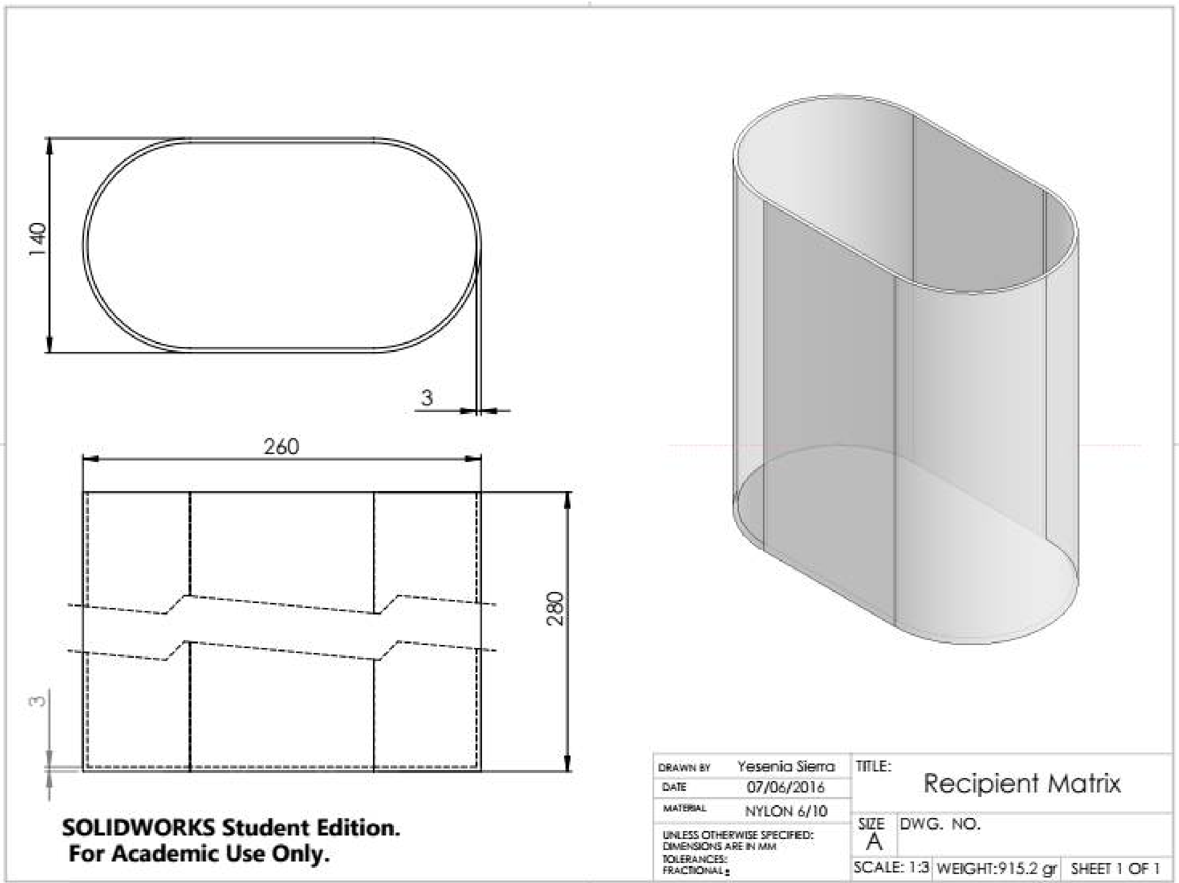


Figure 24 – Detailed design of the container used for making the alginate mold and plaster cast.

APPENDIX B – ASYMMETRICAL BLOCK LAYOUT

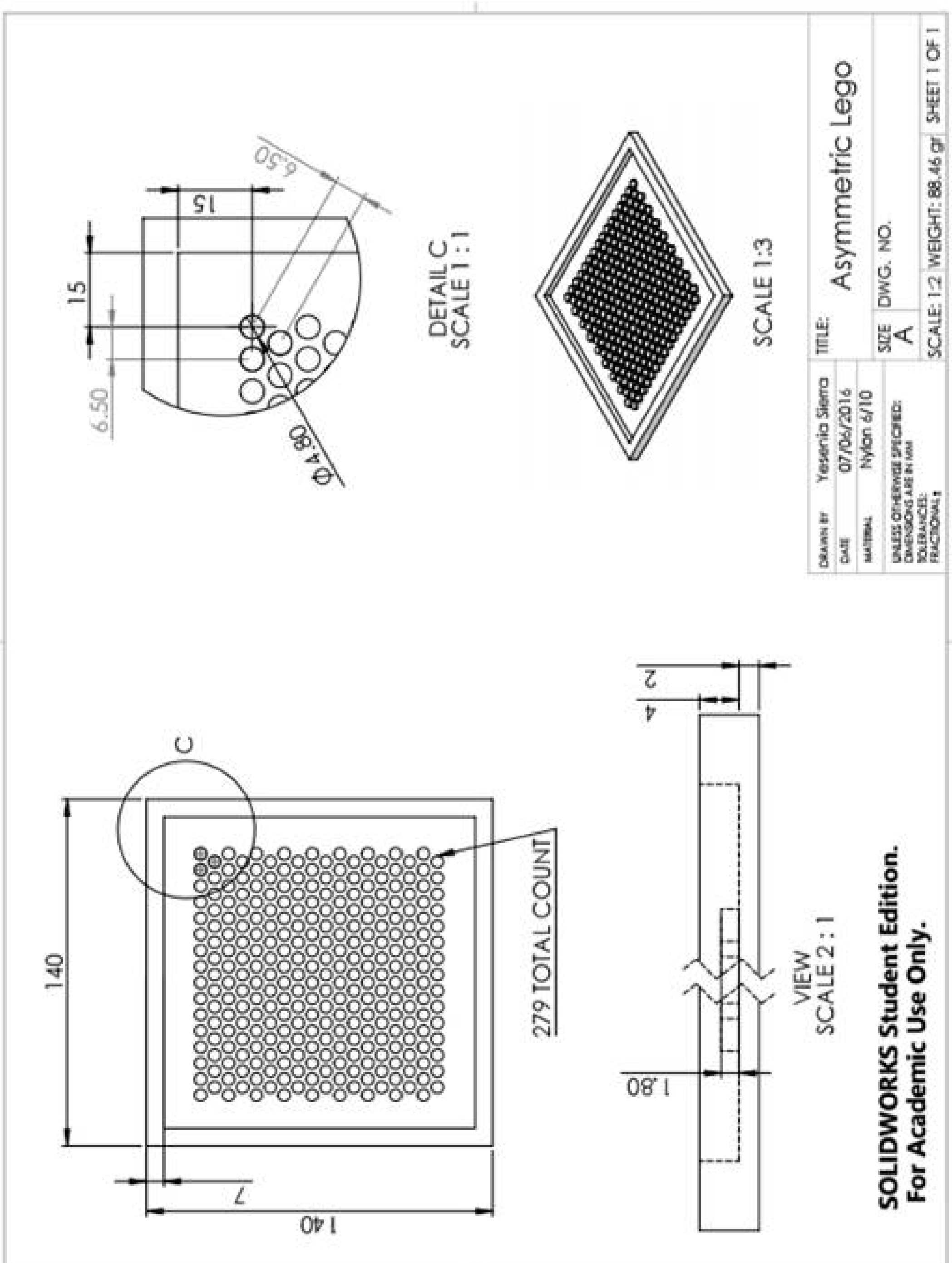


Figure 25 – Detailed design of asymmetric block.

APPENDIX C – QUESTIONNAIRE

According to your experience with the glove, give a score of 1-5 to the following aspects. Being 5 the best score and the 1 worst.

1. Did you feel any difference grabbing objects using the glove?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

2. Do you feel uncomfortable when using the glove?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

3. Do you believe that regular use of this glove can fix the mobility and dexterity problems in the hands of diabetic patients?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

4. Do you feel confidence grabbing objects?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

5. Do you believe that you exerted more force with the glove?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

6. How to qualify aesthetics of the glove?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

7. How to qualify the comfort when wearing the glove?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

8. How do you qualify the experience of wearing the glove?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

9. How do you qualify the quality of the glove?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5

APPENDIX D – TEST

The tests were conducted on a table with smooth surface to avoid interference from external elements in the manipulation of objects.

1. Join four Lego blocks and then separate them. Holding in descending order each of the blocks from the start point marked on the table and are piled and joined in the center of the table, and then separated and placed back at the starting point.

Figure 26 – Lego test.

2. Write on a piece of white paper and pen the following personal information: full name, address and cellphone number. Then rewrite the same information on the smart phone, with the dictionary deactivated.

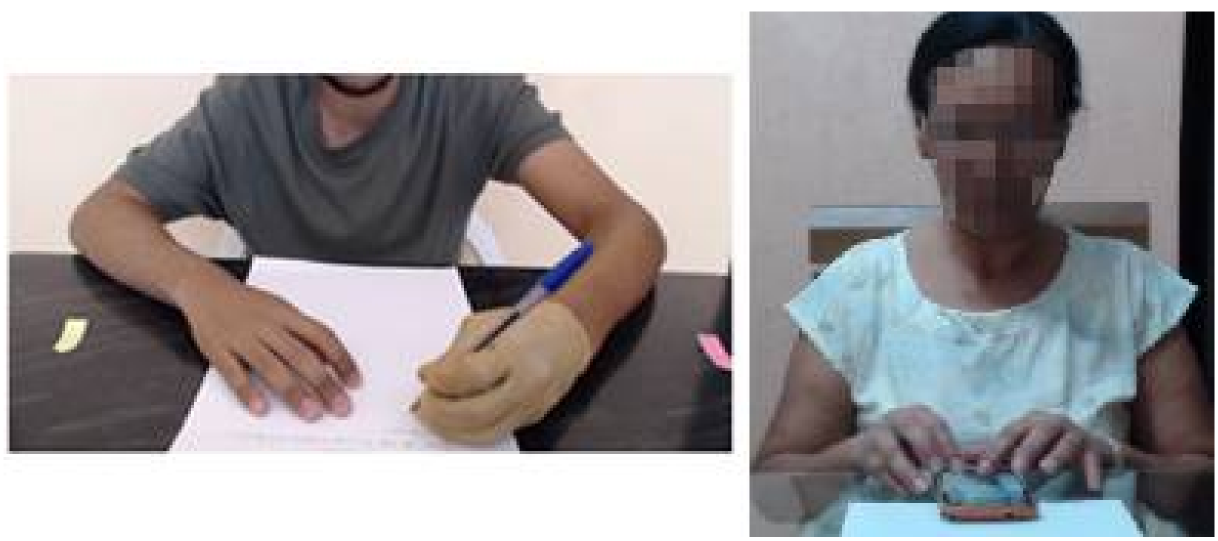


Figure 27 – Writing test.

3. Holding three small objects. They were selected three objects 3mm, 5mm and 7mm long with an approximate thickness of 1 mm, to check how the glove alters the grip and sensitivity of the hand.

4. Turn 5 pages of a book, to study friction offered by the glove.

Figure 28 – Mini-Balls test.

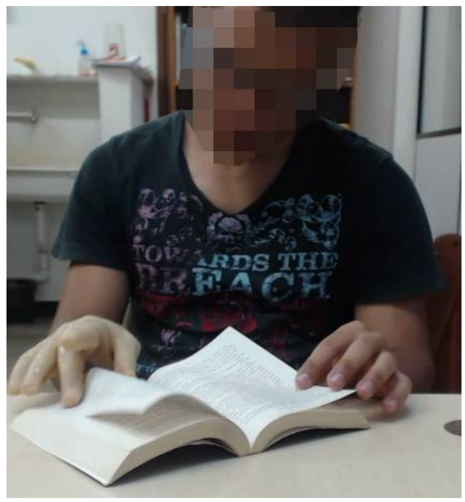


Figure 29 – Turn the pages of a book.

5. Test with a cylindrical container. Is used a bottle of water of 600 ml, to analyze the grip and hand grip.

Figure 30 – Open a Bottle.

6. Squeeze rubber ball to observe the grip of the hand.

7. Lateral movement of the fingers. We asked the patient to perform abduction and adduction movement with a spring between the fingers, and repeat these movements three times each as shown in the figure below.

Figure 31 – Squeeze ball.

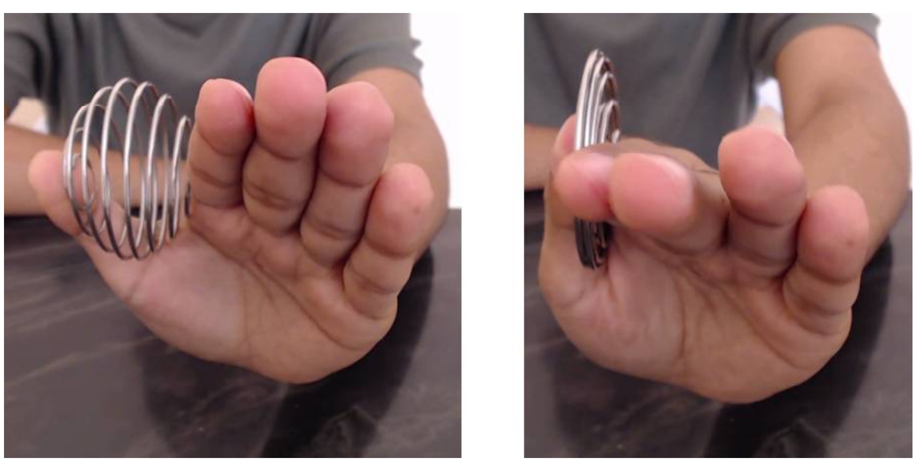


Figure 32 – Compress spring.