Foot Orthoses Based on Bombyx Silk Fiber Polymer Composite in the Treatment of Flexible Flat Feet Children

Suwicha Techapoowapat

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Author Miss Suwicha Techapoowapat

Major Program Biomedical Engineering

Major Advisor :

…………………………………

(Dr.Jirut Meesane)

Examining Committee :

…………………………………..Chairperson

(Assist.Prof.Navaporn Chadchavalpanichaya, M.D.)

………………………………………….....

(Dr.Jirut Meesane)

……………………………………………

(Assist.Prof.Wipawan Leelasamran, M.D.)

……………………………………………..

(Dr.Ponusa Jitputhi)

The Graduate School, Prince of Songkla University, has approved this thesis as fulfillment of the requirements for the Master of Science Degree in Biomedical Engineering

…………………………………………

(Assoc.Prof.Dr.Teerapol Srichana)

Dean of Graduate School

This is to certify that the work here submitted is the result of the candidate’s own investigations. Due acknowledgement has been made of any assistance received.

____________________Signature

(Dr.Jirut Meesane)

Major Advisor

____________________Signature

(Suwicha Techapoowapat)

Candidate

I hereby certify that this work has not been accepted in substance for any degree, and is not being currently submitted in candidature for any degree.

____________________Signature

(Suwicha Techapoowapat)

Candidate

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ABSTRACT

The natural Bombyx Silk fibers polymer composites materials for fabricating the foot orthoses instead of carbon fibers polymer composites to treat the flexible flat feet children had been studied. The research provided the information to support that silk fibers polymer composites foot orthoses can provide good characteristics and positive effects in the flat feet treatment. The Natural Bombyx Silk Fibers were fabricated as silk fibers polymer composites using the matrix of acrylic resin by lamination thermoforming technique. The materials were tested physical and mechanical properties for investigation compared to the synthetic carbon fibers polymer composites. The results found that synthetic carbon fiber polymer composites provided higher a performance of mechanical testing, including tensile and flexural strength than natural Bombyx silk fibers polymer composites. However, the silk fiber polymer composites had the increasing in percent of elongation before breaking. Furthermore, the silk fiber polymer composites had a good tendency to increase flexural strength and less fatigue failure while providing a lower weight ratio and thickness ratio compared to the carbon fiber polymer composites. That is the suitable properties of the foot orthoses that should be light weight and thickness while providing good strength and absorbing torque. Morphology of both polymers composite was analyzed by Scanning Electron Microscope (SEM). The results showed that the adhesion between fiber and matrix for silk fiber polymer composite is better than carbon fiber polymer composite. The foot orthoses from Bombyx silk fibers polymer composites and carbon fiber polymer composites were fabricated to the children flat feet participants. The Staheli Arch Index (SAI), the Naturalized Navicular Height Truncated (NNHT) measurement and the Resting Calcaneal Stance Position (RCSP) had been assessed before and after wearing the foot orthoses within group and between groups. The statistical analysis showed the improvement within group of the two in each parameter. However, the improvement different between two groups were not statistical significant. The clinical results stated that silk fibers polymer composites foot orthoses can be used to treat the flexible flat feet children. It indicated that silk fiber polymer composite had no different from the carbon fibers polymer composites foot orthoses with the statistical significant. Moreover, the positive feedback responses from the wearers and the economical prices efficiency can be gained.

Keywords: Flexible flat feet, Natural Bombyx silk fibers polymer composite, Lamination compression techniques

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Suwicha Techapoowapat

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Chapter 1

Introduction

1.1 Background

The custom-made foot orthoses have been used in clinical treatment for many years. There are many available technologies in manufacturing foot orthoses with variety of material using in different functions. So it can be classified into three categories according to the physical rigidity following the review by Clark et al.; soft, semi-rigid and rigid. They also indicated that rigid orthoses can decrease forefoot and rearfoot pain and also decrease the stage of foot deformities. The common belief is exposed to the public that a correctly fitting rigid device can correct biomechanical alignment of the skeletal structure. To obtain the functional foot orthotic devices following the prescription, the material choosing is needed to be take into consideration.

Nowadays, there are varieties of foot orthotic material choices. The important physical characteristics are the key point to examine the proper indication for the foot orthotic using which are temperature, elasticity, hardness, density, durability, flexibility, compressibility and resilience (Caselli MA et al.) However, the distinguish points that seem to influence the decisions are density and hardness. The high density will provide little cushioning and has the ability to show the rigid characteristic which are essential for correcting foot structure such as flat feet symptom.

1.1.1 Fiber-reinforced Polymer Composites for Foot Orthoses

The required properties for the reinforcing material would be:

- Lightweight
- Strong under tension
- Strong under compression
- Flexible enough to absorb torque
- Stiff to resist bending and shear stress

- Durable to resist fracture under impact
- Capable to resisting stress in all planes
- Cost effective
- Easy to apply

(Dale A. Berry, 43)

1.1.2 Manufacture of a Carbon Fiber Orthotic

Pre-impregnated (prepreg) composite materials are used for the fabrication of the insoles.

Pre-preg is a term for "pre-impregnated" composite fibres where a material, such as epoxy is already present. These usually take the form of a weave or are uni-directional. They already contain an amount of the matrix material used to bond them together and to other components during manufacture. The pre-preg are mostly stored in cooled areas since activation is most commonly done by heat. Hence, composite structures built of pre-pregs will mostly require an oven or autoclave to cure out.

There are several advantages and disadvantages of the pre-preg process in comparison to the hot injection process. Pre-preg allows one to impregnate the fibers on a flat workable surface, or rather in an industrial process, and then later form the impregnated fibers to a shape which could prove to be problematic for the hot injection process. Prepreg also allows one to impregnate a bulk amount of fiber and then store it in a cooled area for an extended period of time to cure later. Unfortunately the process can also be time consuming in comparison to the hot injection process.

Figure 1-1 Pre-preg Material

http://en.wikipedia.org/wiki/Pre-preg (Accessed August 7, 2012)

P. Crabtree et al. [36] had shown the way to fabricate the insole by using Pre-impregnated (prepreg) composite materials. The processes ran by two steps of hand lay-up and vacuum thermoforming. Lamination was done by laying up the plantar surface of the positive cast mold in order to produce thin and stiff light-weight insole. Reinforcing areas were added to ensure the specific area's stiffness. The following construction process was then placed under the vacuum thermoforming for the bonding of all layers. The final device was then ground off to finish the orthotic shape and to finish fitting within the desired shoes.

Figure 1-2 Laying up Process [36]

1.1.3 Bombyx Mori Silk Fiber

Fibers produced by silk worn are natural composite. The unique mechanical properties of these fibers provided important clinical repair options for many applications. The tests of mechanical properties suggest that they provide the remarkable combination of strength and toughness. However, these silk fibers demonstrate not so good resistance in compression that is different them from other synthetic fibers like Kevlar. (Perez-Rigueriro et al. 2000)

Table 1-1 Properties of Bombyx mori plain woven natural silk fabric [48]

Properties of Bombyx mori plain woven natural silk fabric	
Elongation	9%
Modulus of elasticity	22 GNm
Thickness	0.42 mm
Ultimate strength	11 GNm

The silk fibers are special more than other fibers because a study had showed that the silk fibers had less failure to strain and stiffness in a high performance condition when compare to other natural fibers for example Spider Silk.

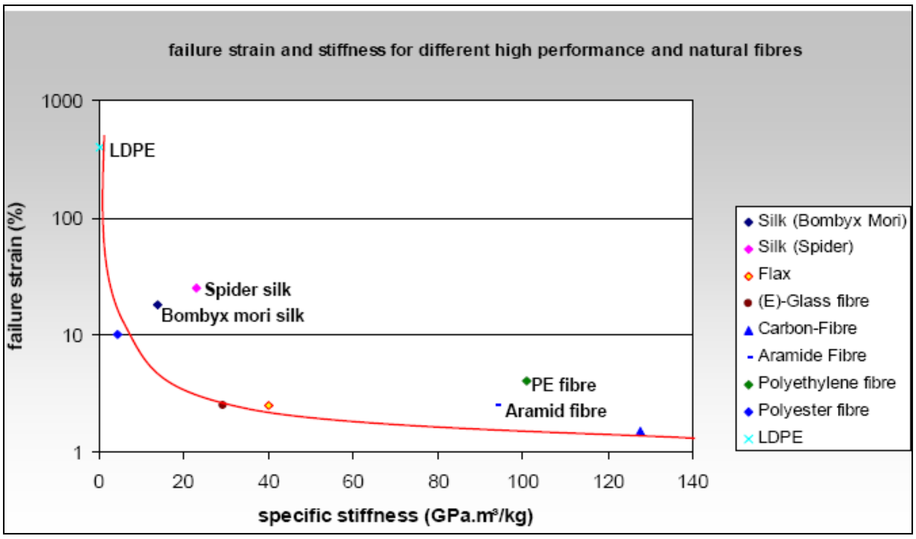


Figure 1-3 Failure Strain and Stiffness of fibers [58]

Table 1-2 Comparison of mechanical properties [52]

Types of Fibre	Material	Density (g/cm3)	Tensile Strength (MPa)	Young's Modulus (GPa)	Elongation at Failure (%)
Natural Fibres	Spider Silk	1.3	1300-2000	30	19-30
	Enhanced *B.Mori* Silk	1.3-1.38	600-700	12.2	30-35
	B. Mori Silk	1.3-1.38	500	8.5-8.6	15
	Flax	1.45	500-900	50-70	1.5-4.0
	Hemp	1.48	350-800	30-60	1.6-4.0
Synthetic Fibres	Kevlar 49	1.44	3600-4100	130	2.8
	Carbon	1.4	4000	235	2
	E-glass	2.5	3100-3800	76-79	4.8
	Dyneema	0.97	2300-3500	550	2.7-4.5
	High Grade Steel	7.8	1000	200	30

1.1.4 Natural Bombyx Mori Silk Fibers Polymer Composites

Silk fibers are natural fibers that influence the way of human living. The variety advantages come from the multifunction, strength and biodegradable characteristic.

- Environmental reasons: renewable resources, thermally recyclable,biodegradable,CO2 Neutral, and low energy consumption
- Cost effective: potentially low cost
- Health and safety: less abrasion for skin irritation, more pleasant to handle
- Good specific mechanical properties: high stiffness, low density
- not suspected of causing lung cancer

(Mohanty et al. 2005; Frederick and Norman 2004; Joseph et al. 2002; Bos 2004)

There was one research that studied about Bombyx mori woven natural silk (WNS) as a reinforcement which considered about its environmental and mechanical properties. The study showed that silk was among the strongest fibers produced in nature with high specific-strength and high specific-stiffness, extremely elastic and resilient. The previous studies by Bledzki et al. (1999), Craven et al. (2000), and Perez-Rigueriro et al. (2000) had informed that Bombyx mori silk was better than Kevlar or steel in term of elongation at failure. Moreover, it had a good capacity to absorb energy because of their structural advantages; silk could provide the improvement for impact resistance.

The polymer matrix could be applied for its structural usage in the fabrication of light weight bodies and other composite structures where energy absorption is a key design factor.

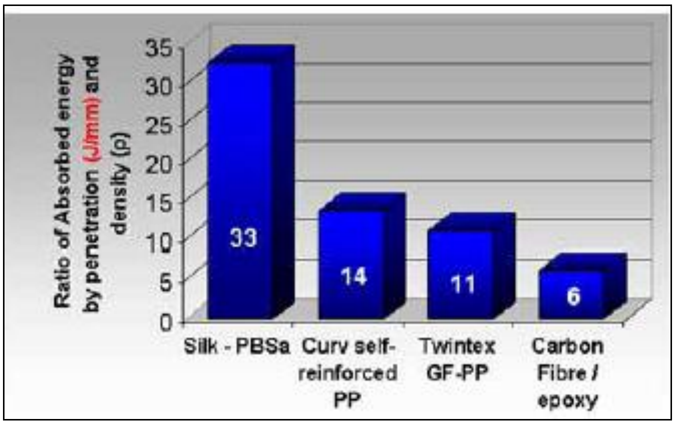


Figure 1-4 Ratio of energy absorption of fibers [58]

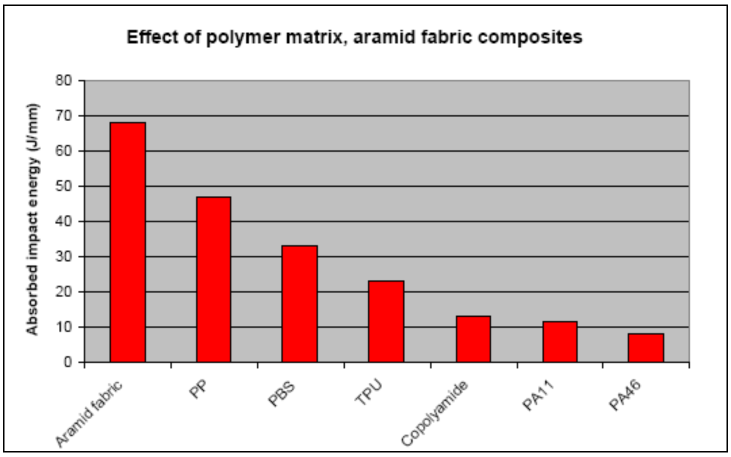


Figure 1-5 Effect of Polymer Matrix on impact energy absorption [58]

1.1.5 Pes Planus

Children's flat feet or another name **'Pes planus'** is a common concern for the child's growth as it can develop to be abnormal feet and lead to have abnormal walking or pain for the child. Since, there were a lot of treatment for this disease, the multidisciplinary team including physicians, podiatrist, and prosthetist & orthotist(P&O) have tried to find the better way to deal with this problem but there still has no definitive treatment way and has to cope with each patient differently. The treatments consist of conservative and non-conservative (surgery) ways depending on doctors and team decision; however, the former one is more possible to deal with. The conservative treatment is whatever methods that can change the foot muscles and skeletal function to alleviate flat foot indications and from that, the methods should depend on rehabilitation treatment including both physiotherapy exercises and foot orthotic devices.

Prosthetist and Orthotist (P&O), one of the rehabilitation team, is a healthcare profession who manages comprehensive device for patient care that suits for patient's pathology. The main knowledge that serves for the treatment of P&O includes Anatomy and Physiology, Biomechanics that have to understand the fundamental concept to adjust it according to the patients, and the Material Subjects that need to know in choosing the best option for both patient and treatment guidelines. In the duty of P&O after the physician's prescription, foot orthoses (conservative treatment) play for the major role part to treat with pediatric flat feet. P&O specialists will prescribe and fabricate the foot orthotic device to align the proper foot biomechanics and position with the materials available in the market nowadays that have the efficient properties to correct foot alignment and can be easily put inside shoes. Nowadays, many volumes of P&O journals and papers have stated about foot orthotic devices and their manufacturing, so they classified two differently types named as the cryogenic machining of soft foam polymers and the autoclaving of a carbon fiber composite material.

However, there was the same no definite guideline to prescribe and fabricate the most suitable choices of foot orthoses which have a variety in material and designs come up with vary properties and the high prices that cannot support by the government hospital or parents. In Thailand and in other developing countries where economical status is still poor will lead to gain low standard of orthotic treatment options and some patients can't afford such over price so it will lead to quit the treatment. Due to global competition and the popular of economic sustainable concept began in the mid 20th century; the researchers are lead to explore the development of highly resource-efficient products to compensate the use of synthetic fiber materials. The main point is from trying to use the natural textile from Thailand environment that can present for its low material and production costs. These will lead to new production technology and will make the economical product which can be used in real. This study aims to analyze the use of Bombyx silk textile which is biodegradable material and has high performance of physical property as the reinforcement material for the foot orthotic that suits for children with flexible flatfeet.

In the present study**,** the researcher had found out the new material option based from nature for flexible flat feet treatment that is suitable for an economic condition and to find out the effect of foot orthotic intervention in treating the pediatric flat feet that should end up with the most suitable solutions and satisfactions of all doctors, parents and children. Furthermore, the researcher expects that silk fibers polymer composites can gain equal standard of good foot orthotic material properties compare to available materials in the markets at the same time and can also be used in real clinical situations.

1.2 Objectives of Research

1.2.1 Scientific

To find out the new material options of foot orthotic devices by using Bombyx silk textile as reinforcement material in treating flexible flat feet pediatric patients in the parts of material, design and its applications that will provide good physical properties and mechanical properties when compare to carbon fiber reinforcing foot orthotic devices.

1.2.2 Clinic

To discuss about the effect of silk fibers polymer composite foot orthotic interventions after using the devices to treat children with flexible flat feet and to prove that they will provide positive effect that can be used in real clinical situation.

1.2.3 Economic

To make a new choice of foot orthotic material option that suits with country's economy condition and can be used in Thailand's clinical treatment.

1.3 Literature Review

In this study, there have been reviewed the involving literatures following these:

1.3.1 Flat Feet Prevalence

Pfeiffer et al. [5] had done the research to see the prevalence of flat foot 5 years ago in 835 flexible flat feet children aged 3 to 6 years old and the results showed that flat foot has a relationship with the children's age, sex and the body weight. The more ages the children were, the less prevalence of flat feet occured (54% at 3 years, 24% at 6 years). From this result, it can be explained that newborn child has a lot of adipose tissue under plantar area and that will make the foot tending to be flat. This type of feet is named as floppy feet but it is not true flat feet. When the muscles grow up with enough strength and good re-alignment of soft tissues and bone, then the foot arch of the floppy feet will be formed-up later. The best treatment of this floppy feet child is to let the child walking bare feet but not foot orthoses. Sex was another one which showed inverse relationship. The results showed higher rate of flat feet in boys (52%) more than girls (36%). The last option that played the direct results was the body weight. Over-weight children (51%) and obese children (62%) were the major group that experienced flat feet. The best way to deal form this problem was to control the child's weight. From this study, the podiatric physicians and the P&O can separate the true flat feet child whether conservative (non-surgical) or non-conservative (surgical) care will do.

1.3.2 Pediatric Flat Feet Non-surgical Management

(Wenger et al. 1989, 3) Pediatricians in Texas Scottish Rite Hospital had done the prospective study in children with flexible flat feet in the age of 1 to 6 years old to verify the result of cosmetic appearance of foot and their functional symptoms. The researchers provided the children with corrective orthopedic shoes, heel cup, custom-made foot orthoses and the others were set for the control group. They assessed the results by radiographic pictures and the improvement was shown in all four groups with no significant difference.

(Whitford et al. 2007, 2) 160 of Australian children with flexible Calcaneovalgus and low medial arch in the age of 7 to 11 years old are done by the small randomized controlled trial research. The researcher investigated gross motor proficiency; self-perception, exercise efficiency and pain in a year time in three groups (no treatment, non custom-made foot orthoses and custom-made foot orthoses) No Significant difference among groups was found in all measurements.

1.3.3 Foot Orthotic Intervention

Figure 1-6 Many kinds of foot orthoses available in the market today

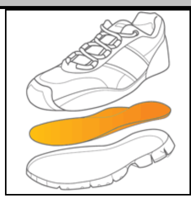
http://orthese.wordpress.com/2011/04/11/what-is-foot-orthotics/ (Accessed August 7, 2012)

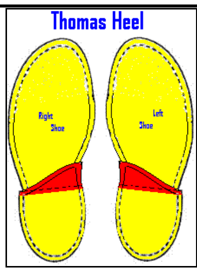
Foot orthoses (FO) are the well known devices that physicians, podiatrists and P&O use to correct abnormal foot posture and gait pattern of the patients nowadays.(Collins et al.

2007 ; Landorf and Keenans 2007 ; McMillan and Payne 2008) There are many advantages of foot orthoses not only correcting and compensating foot pressure, but also providing comfort for the patients. In functional flat feet children, foot orthoses are the tools for the specialists to treat the patient as conservative treatment (non-surgery technique) (Landorf and Keenan 2000). As there are many options in choosing materials and designs, the effect and quality that occurs in the result of treatment may differ depending on the type of orthotic chosen. Actually, foot orthoses need specialist and dexterity of fabrication (custom-made FO); however, they are so popular and easily to find in the market (prefabricated – off the shelf FO). (Landorf et al. 2001)

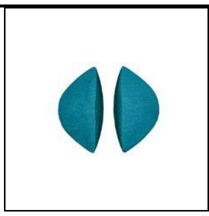
Here are the summary of the foot orthoses descriptions that have been using in treating pediatric flatfeet patients which are vary in designs and terminology use. The types of devices are included of accommodative, functional, over-the-counter, pre-fabricated and custom-made foot orthoses.

Table 1-3 The foot orthoses description that have been using in treating pediatric flatfeet patients which are vary in designs and terminology use.

Authors	**Foot orthoses terminology**	**Picture of foot orthoses**	**Orthotic Details**
Whitford [2], Penneau [12]	Over-the-counter	 http://gear.runnersworld.com/2011/01/orthotics-friend-or-foe.html (Accessed July 15, 2012)	A device fabricated from a generic foot cast

Whitford [2], Selby-Silverstein [16], Jay [11], Penneau [12], Bordelon[13]	Custom made foot orthosis	 http://www.frankstonorthopaedicservices.com.au/custom_made_foot_orthotics.htm (Accessed July 15, 2012)	A device fabricated from measurements and casts of individuals patients Feet.
Leung [1], Wenger [3], Penneau [12], Scharer [20]	UCBL (Universal California Biomechanics Laboratory)	 http://www.coxorthotics.com/pediatricODs.htm (Accessed July 15, 2012)	A maximum control foot orthoses with a molded heel cup which holds the heel in a vertical position. The UCBL also the controls the medial arch and the lateral boarder of the rearfoot.
Capasso [15]	Dynamic Heel Cup	 http://www.dynamic-living.com/product/silicone-gelsmart-heel-cups/# (Accessed July 15, 2012)	A customized heel cup with a medial wedge positioning the heel 5 degree inverted. An insole within the heel cup further inverted the heel, but pronated the forefoot.
Gould [4]	Thomas Heel	 http://www.bellsouthpwp2.net/A/_/A_PROSTH/Home	Fixed to the sole of the shoe and comprises an anterior-medial extension to the normal shoe heel to provide additional longitudinal arch support. This extension may be variable length, depending on the extent of the support required,

		/Services/Pedorthics/Shoe %20Modifications/HTML %20Shoe%20Modification s/Thomas%20Heel.htm (Accessed July 15, 2012)	and its effect may be augmented further by a medial wedge.
Gould [4], Valmessy [32], Penneau [12]	Medial Heel Wedge	 http://www.feetrelief.com/feetrelief/Lynco_L420.htm (Accessed July 15, 2012)	A medial heel wedge is posted within the shoe to stabilize the rear foot. Various forms are used.
Wenger [3], Scharer [20]	Helfet heel cups	 http://www.orthobullets.com/pediatrics/4069/flexible-flatfoot (Accessed July 15, 2012)	A heel cup that extends from the heel to metatarsal heads. Stabilizes the heel, subtalar and mid-tarsal joints.
Capasso [15]	Simple Insole	 http://langergrp.com/index.php?main_page=document_general_info&products_id=1168&language=en (Accessed July 15, 2012)	Constructed with a flat base material to which various pads may be added. The pads apply corrective or supportive forces to the plantar surface of the foot.

Gould [4]	longitudinal arch support	 http://www.allegromedical.com/orthopedics-orthotics-c528/longitudinal-arch-support-p557265.html (Accessed July 15, 2012)	Moulded devices which follow the plantar contours of the foot. These supports reduce increased plantar pressures by spreading the load across a larger area of the plantar surface. Bespoke devices which are fabricated from a cast of the foot.
Jay [11]	DSIS (Dynamic stabilizing insole system)	 http://www.ortho4peds.com/orthotics_day.asp (Accessed July 15, 2012)	'Dynamic stabilizing innersole system' that inverts the calcaneus.

1.4 Scope of Study

In this study, there have been set the scope of this study following these:

1.4.1 To compare the silk fibers polymer composite to carbon fiber polymer composite in the parts of physical and mechanical properties in order to gain quality in foot orthoses fabrication.

1.4.2 To investigate the insole prescription principles in the treatment of flexible flat feet that will provide the positive effects in real clinical situation. To design and fabricate silk fiber polymer composite foot orthoses for flexible flat feet children and compare the clinical results to carbon fiber polymer composite foot orthoses.

1.4.3 To find out available materials and options in the market in terms of prices and usage and then compare to the material in the study research.

1.5 Research Hypothesis Results

1.5.1 Bombyx silk textile as reinforcement material in the polymer composites will provide good physical and mechanical properties when compare to carbon fiber polymer composites.

1.5.2 The positive effect of orthotic intervention will show out after using Bombyx silk fiber polymer composite foot orthotic devices for children with flexible flat feet and can be used in real clinical situation.

1.5.3 The Bombyx silk fiber polymer composite foot orthoses will show less price when compare to available foot orthoses in the market.

1.6 Research Outcome Benefits

1.6.1 The knowledge for the improvement of Bombyx Silk Textile as foot orthotic reinforcement material in flat feet pediatric patient.

1.6.2 Patients' good optimistic and encouragement in treating the flexible flat feet by using the silk fiber polymer composite foot orthoses.

1.6.3 The new choice of foot orthotic material option for Thailand's clinical using.

Chapter 2

Review of Literature

2.1 Foot Orthotic Material Choices and Manufacturing

Foot orthoses are the devices that use in treating foot pathologies. The prescription principles for choosing the proper foot orthoses that suit the foot pathologies are the type of foot orthoses, the modification within the device and the materials that will be used for fabrication. The material chosen is one of the essential and interesting points to be concerned as they influenced the strength and the functional of the foot orthoses.

These are the types of foot orthotic material chosen:

2.1.1 Plastics

The popular type is polypropylene group. The semi-rigid and rigid foot orthoses stand in this group. Because of its physical characteristic by being above glass transition temperature, it presents the low-specific gravity and high stiffness. The thermoplastic is one of the outstanding characteristic as it can soften when heated and hardened when cooled so the reshape of the orthotic device can be obtained easily. Plastic can be provided in many different thicknesses, strength and color according to the proper use of the specialists. However, the disadvantage is the presentation of notch or groove can result in stress point that may eventually crack that leads to short lifespan of the device. For the reason that the strength and rigid of the device has to gain from the thickness of plastic, so the patients who has too much excess of body weight have the only choice to wear the thicker device leads to the difficulty to slip inside shoes.

2.1.2 Foam Materials

The EVA (ethyl-vinyl-acetate), polyethylene and polyurethane are the examples of foam materials. They can be either open cell foams or close cell foams. Open cell foam is a polymer that have the space that allow the interaction between the pockets of air, in contrast the close cell foam present differently and it outstanding by its water-tight material. Polyurethane is one that is popular to be top cover insole for its durability and ease of manufacture and provide greater comfort. There are available in market's name for example, Cross-linked polyethylenes (CL-PE) include the trade names Plastazote®, Pelite, Aliplast®, Dermaplast®, XPE, and Nickelplast™. It is widespread use for total-contact, pressure reducing orthotic, accommodative foot-mold and providing good absorption and durable. It shows water repellent resistant but the strong detergent can damage the material. Temperature is one of the weak points because hot climate can change the physical property of the foam. Besides these in the normal temperature, the foam can be resist to crack and odor and not aggressive to sensitive skin. Anyway, this kind of material is proper and widespread use for cushioning and comfortable and there are available in many colors.

2.1.3 Carbon Fiber-reinforced Polymer Composite

CFRP is the composite material that combines acrylic plastic with carbon fibers reinforcement. The polymer is usually an epoxy, vinyl ester or polyester thermosetting plastic, and phenol formaldehyde resins. The outstanding characteristic is the extremely high stiffness compare to weight ratio and its rigidity. So the device will appear with the light-weight and the space-saving. However, the disadvantage appears for its difficult to work with as it requires a higher softening temperature, a faster vacuuming and require a complete accuracy during the "pull," as it does not re-work easily because of its thermosetting property.

From the materials above, it can be seen that each material have both benefits and disadvantages. So the specialists need to look over some disadvantage points and choose the proper material that suit for pathology solving and function. The market's price is also one of the main different things as the more rigid and complex of fabricating will lead to high price of foot orthotic.

2.2 Fiber-reinforced Polymer Composites

Composites are mixing of two materials in which one of the materials, called the reinforcing phase, is in the form of fibers, sheets, or particles, and are embedded in the other materials called the matrix phase. The advantages of the composites to be selected for certain applications:

- High strength to weight ratio (low density high tensile strength)

- High creep resistance
- High tensile strength at elevated temperatures
- High toughness

A composite include the core or middle material which is acrylic group such as polypropylene and the outside layers of a fabric made from carbon fibers, glass fibers, aramid fibers or combinations. The outstanding features of the final device for its benefits are:

- The relatively thin
- Lightweight
- Strong and not brittle
- Easily fabricated into the complex shape
- Adjustment can be made at a later time.

The fabric layers can be made by many ways; woven fibers, unidirectional fibers, chopped fibers, continuous random strand mats or combinations. The directions of the fabric layers can be varied depending on the physical characteristic of the composites.

2.2.1 Polymer Matrix

2.2.1.1 Thermoset Polymer Matrix

Thermoset Polymer Matrices are synthetic polymer reinforcements that are the most widely used in composite materials. The thermoset polymer matrices used in composites can be related to their individual composition, properties and applications. The different types of thermoset polymer matrices used in composites are: Bis-Maleimids (BMI), Epoxy (Epoxide), Phenolic (PF), Polyester (UP), Polyimide, Polyurethane (PUR), Silicone.

Thermoset materials are usually liquid or malleable prior to curing, and designed to be molded into their final form. Has the property of undergoing a chemical reaction by the action of heat, catalyst, ultraviolet light, etc., to become a relatively insoluble and infusible substance. They develop a well-bonded three-dimensional structure upon curing. Once hardened or cross-linked, they will decompose rather than melt. Thermoset materials are generally stronger than thermoplastic materials due to this 3-D network of bonds, and are also better suited to high-temperature applications up to the decomposition temperature of the material.

Thermosets are made by mixing two components (a resin and a hardener) which react and harden, either at room temperature or on heating. The resulting polymer is usually heavily cross-linked, so thermosets are also called as network polymers. The cross-links form during the polymerization of the liquid resin and hardener, so the structure is almost always amorphous. On reheating the crosslink prevent true melting or viscous flow so the polymer cannot be hot-worked. Further heating just causes it to decompose.

Types of Thermosetting polymers

- Epoxy: Epoxy is a polymer that contains an epoxide group in its chemical structure. Example: DGEBA (Diglcidyl Ether of Bisphenol A) Charecteristics of Epoxy: Better Moisture, Resistance, Low shrinkage, Good adhesion with Reinforcement
- Polyester: A condensation reaction between a glycol and an unsaturated dibasic acid result in polyester. This contains a double bond C=C between its carbon atoms. Example: poly ethylene terephthalate (PET). Characteristics of Polyester: Cheap, Resistance to variety of chemicals, Adequate moisture resistance

Advantages of thermoset composites are:

- Well established processing and application history
- Overall, better economics than thermoplastic (T.P.) polymers
- Better high temperature (H/T) properties
- Good wetting and adhesion to reinforcement

Disadvantages of thermoset composites are:

- Resins and composite materials must be refrigerated
- Long process cycles
- Reduced impact –toughness
- Poor recycling capabilities
- More difficult repair ability

http://en.wikipedia.org/wiki/Thermoset_polymer_matrices (Accessed July 15, 2012)

2.2.1.2 Thermoplastic Polymer Matrix

TPMC are based on the use of thermoplastic polymer as matrix of the composites. Thermoplastic individual molecules are linear in structure with no chemical linking between them.

They are held in place by weak secondary bond (intermolecular force), such as van der Walls bonds and hydrogen. It is related to the reversibility of thermal actions on the material during fabrication of the final element so the devices can be possible to pre-fabricate semi-finished items and later take them to final shape and dimensions with no time limit for that.Presently the most interesting for actual applications are PEI (Polyethyleneimine), PPS (Polyphenylene Sulfide), PEEK (Polyetheretherketone) and PEKK (Polyetherketoneketone).

Advantages of thermoplastic composites are:

- Low production cycle time
- High toughness and impact resistance
- Reforming possibility
- High reparability
- Joining and assembly by local fusion bonding
- Uncontrolled shelf life
- Recyclability and environmental protection
- Good chemical resistance

Disadvantages of thermoplastic composites are:

- High processing temperatures
- High processing pressures
- Draping difficulties

http://www.scitopics.com/thermoplastic_matrix_composites.html (Accessed July 15, 2012)

2.2.2 Reinforcement Fiber

Fiber-Reinforced Polymer is a composite material made of a polymer matrix reinforced with fibers. This things use fibrous materials to gain the mechanically enhancement of strength and elasticity of plastics. That means fibers can increase the modulus of the matrix material. The reason why fiber-reinforced composites are relatively expensive is fibers are difficult to process into composites. How much the strength and elasticity be performed will result from

- the kind of fiber using

- the type of the matrix using
- the volume relative to one another
- the fiber length and orientation

2.2.2.1 The Fiber Process Manufacturing

Nowadays, there are two kinds of reinforcing fiber according to its orientation and dimension.

- Two dimensional fiber-reinforced polymer

The fibers are aligned in the plane of X-direction and Y-direction without the through thickness (Z-direction)

- Three dimensional fiber-reinforced polymer

The fibers structures are included all three planes, X-direction, Y-direction and Z-direction. This type of composite polymer performs the increasing of through-thickness mechanical property and the improvement of the impact damage tolerance that can be found in two dimension fiber-reinforced polymer.

The manufacture of fiber's forming

A very important consideration when working with composites is one of the principles of the fiber—all the available strength and characteristics of a composite fiber are displayed and produced only along the length of the fiber. There are four different ways to form the thread strand fiber through the textile processing techniques: weaving, braiding, knitting, and stitching.

- Weaving is the conventional technique to fabricate the two dimensional fiber-reinforcing fiber and in the multilayer weaving, the three dimensional fibers can be performed as well. The difficulty in forming this process is to waste the time for setting up the warp yarns on the loom. In weaves, the fiber direction is run in the direction of 0 degree and 90 degree so it is called the standard weaving process. So it can be used according to the device that impacts the progression of forces.
- Braiding is the process to produce the alignment of fabric fibers that are interwoven with each other in the direction of 45 degrees angles to one another. Like a weaving form, the braiding

fabric can be proper for the progressive force device. Moreover, it can increase the torsion stiffness of the device.

- Knitting fibers can be still done by traditional methods of warp and weft knitting. But nowadays, there is the improvement of the machine control for needle knitting and it can obtain the three dimension fiber. Knitting fibers are sometimes suitable for device layer spacing or to make a finishing device.
- Stitching is the simple pattern of the fiber forming technique. It provides a greater degree of flexibility in the fabric lay-up of the component than is possible with the other textile processes, which have restrictions on the fiber orientations that can be produced.

Bonded fabrics can be classified as unidirectional, bidirectional and multidirectional surface constructions:

- Unidirectional bonded fabrics demonstrate the all parallel fibers to each other and are held in position using suitable measures so that it can create a strong anisotropic material. The high bending strength in the fibre direction (0 degree) can be achieved and at the same time it can provide medium torsion strength.
- Bidirectional bonded fabrics have the two directions of the fiber running. The most easily seen is the fiber at the angle of 0 degree/90 degree. A woven cloth stands in this type of fabric. It is good for localized strength, but is capable of providing singles composite properties in one direction alone. And the plain to be effective is that the fibers should run in the perpendicular position of the stress. So the fiber can provide both medium bending strength in 0 degree and 90 degree direction and medium torsion strength for the use of the device.
- Multidirectional bonded fabrics consist of two bidirectional bonded fabric layers offset at 45 degree on top of each other. This type of fabrics performs quasi-isotropic characteristics at the fabric level. This type can achieve uniform strength with equal resistance to fracture in all directions and the pattern form of fabric to be success in this criterion should be in a mat or knit form. That means the low bending strength in the 90 degree direction will occur but the high torsion strength will create at the same time.

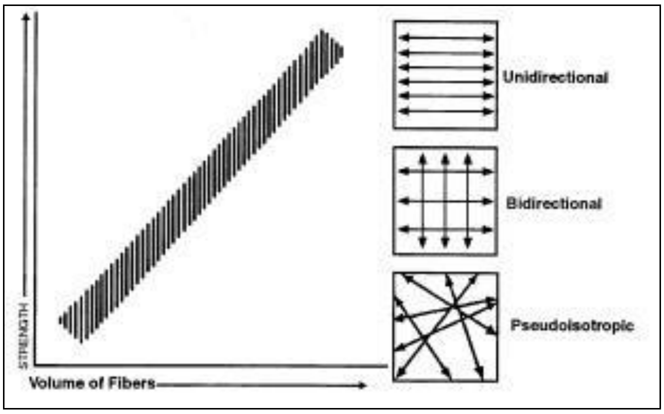


Figure 2-1 Strength Relation to fiber orientation [Schwarz, 1992]

2.2.2.2 Moulding Process

There are two types of moulding process that seem to be different: Composite moulding process and wet moulding. Composite moulding uses Prepreg FRP (pre-fabricated), meaning the plastics are fibre reinforced before being put through further moulding processes. Sheets of Prepreg FRP are heated and then continue to the compress process in different ways to get geometric shapes of the device. In contrast, wet moulding still combines the fiber reinforcement and the matrix preparation and resist during the moulding process.

2.2.2.3 Fabrication of Fiber-reinforced Polymer Composite

The FRP process needs the matrix that meets the certain requirement to ensure a successful of the reinforcement of itself. The properly saturation of the matrix is one of the key point for the success, and should bond with the fibers within a suitable curing period. The matrix should preferably bond chemically with the fiber reinforcement for maximum adhesion and should also able to complete enveloping fibers to protect them from cuts and notches that would reduce their strength, and to transfer forces to the fibers. Finally the matrix should be of a plastic that remains chemically and physically stable during and after reinforcement and moulding processes. To be suitable for reinforcement material fiber additives must increase the tensile strength and modulus of elasticity of the matrix and meet the following conditions; fibers must exceed critical fiber content; the strength and rigidity of fibers itself must exceed the strength and rigidity of the matrix alone; and there must be optimum bonding between fibers and matrix.

2.2.2.4 Development of Fiber Reinforcement

Early in the development of the fiber-reinforcement were come from the tradition textile and fabrics. The chemical surface treatment is special requirement to bond these fabrics for the good adhesion of composites polymer to the fiber surface. Techniques to remove these materials were developed, primarily by continuous or batch heat cleaning. It was then necessary to apply new “coupling agents” (also known as finishes or surface treatments), an important ingredient in sizing systems, to facilitate adhesion of polymers to fibers, particularly under wet conditions and fiber processing. Most reinforcements for either thermosetting or thermoplastic resins receive some form of surface treatments, either during fiber manufacture or as a subsequent treatment. Other materials applied to fibers as they are produced include resinous binders to hold fibers together in bundles and lubricants to protect fibers from degradation caused by process abrasion.

2.2.3 Composite Fabrication Technique

There are varieties of polymer processing forming processes available.

2.2.3.1 Thermoplastic Thermoforming Technique

Plastic material sheet is desired to perform the complex shape of the foot mold by vacuum forming. The thermoforming process needs heat and pressure to make the plastic to get shape. Foot orthotic shoe inserts are usually make by acrylic such as polyethylene and polypropylene. The advantage is the ease of making adjustment to the foot orthoses by using localized heating to make changes in the specific areas with destroying the structure and the integrity of the shoes insert according to its thermoplastic property. However, a lot of difficulties occur for many reasons:

- In order to gain the proper rigidity, the final device is quite thick and heavy.
- It’s hard to don and doff in shoes so the wearer needs to buy shoes which size are much bigger to have the space for the accommodation.
- It’s is not durable and easily for breaking for its brittle.

2.2.3.2 Thermosetting Lamination Technique

The shoe insert can obtain from the numbers of techniques of laying upon a positive foot mold layers by layers by layers with various material including piece of felt cloth, thermoset resin and layers of carbon fiber reinforcement. The disadvantage of this technique are the difficulty of the fabricating process as mentioned above and the unable to adjust shape with heat since it has been setting from its thermosetting property. Although, the disadvantages appear, the benefits come out in many ways:

- The final device is very thin.
- It's hard to be brittle.
- It provides high strength of the device.

2.2.3.3 Thermoplastic Thermoformable Composite Material

Form the Thermoplastic Thermoforming Technique and Thermosetting Lamination Techniques, Both have the difficulties encountered. Nowadays, the researchers have tried to studies and present the material that can be overcome the problems facing. They found the new technique by using the thermoplastic thermoformable composite material which is provided by thermoplastic construction.

2.3 Fiber-reinforced Polymer Composites for Foot Orthoses

Since 1981, the researchers have tried to study the proper use of high technology of synthetic material, especially Kevlar, Carbon Fiber and Fiber Glass. Then the specialists have tried to use or adapt these new technologies in P&O use. They started to fabricate the prostheses or orthoses by lamination techniques mixing these composites and stockinet with a lot of kinds of resin. After that, they brought the device to study about its physical properties including the tension testing and compression. The secondary outcome could also demonstrate about strain and the fatigue characteristic of the device.

The benefits of fabricating by laminating technique are its lightness, durability, and ability to be stiff and reinforced in any area desired. The disadvantages are that it is time-consuming and expensive when compared to vacuum forming technique. There had been the study identified that for laminating shoe inserts, arch supports, and UCBL inserts, two layers of carbon-fiber stockinette would provided very good results.

2.3.1 Synthetic Carbon Fiber

Carbon fiber is created using polyacrylonitrile (PAN), pitch or rayon fiber precursors. Carbon Fibers were first produced in the 19th Century and in the 1975, it was produced to the market in the form of textile reinforcing materials. The Carbon Fiber composites are really interesting as they can provide light weight and very stiff. Moreover, it is able to hold its shape under stress due to its impressive strength under both tension and compression. The structural compromise of the carbon fibers is that the stiffness creates brittleness and a poor resistance to impact.

The carbon fiber-reinforced composites are composed of carbon fiber embedded in a synthetic material matrix. However, the main factor to assess the mechanical properties is from carbon fiber. With predetermined orientation of the fibers, stability and stiffness can be substantially increased. Resins such as epoxy or phenolic resins and foams such as polyurethane and polystyrene, which provide good fiber cohesion and resistance to weathering, are used as matrix material.

Carbon Fibers have high versatile characteristics. They have a low specific gravity but a high level of strength and stiffness. Moreover, they are chemically inert to a specific large extent, electrically conductive, thermal stable, infusible, biocompatible and permeable to X-rays. However, any damage to the filaments would be the result of breaking points. Carbon fiber composites are more brittle (less strain at break) than glass or aramid. Carbon fibers can cause galvanic corrosion when used next to metals. A barrier material such as glass and resin is used to prevent this occurrence.

Foot orthotic thermoplastic composite

The US Patent No.4,778,717 Oct.18,1988 has shown the new generation of thermoplastic thermoformable composite material which overcomes many of the problems occur from both thermoplastic instructions and thermoset laminate instruction. The advantages points are the relatively thin and light weight, yet are strong and not brittle. Moreover, it is easy to fabricate into the complex shape and the post formable by heat adjusting.

A composite includes a core of a thermoplastic material such as acrylic and together with the outside material layers of fabric reinforcements.

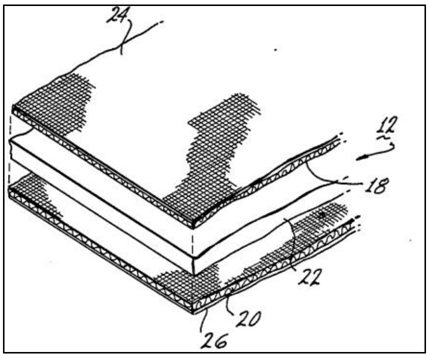


Figure 2-2 a form of a number layers (US Patent No.4,778,717 1988)

2.4 Bombyx Mori Silk Fiber

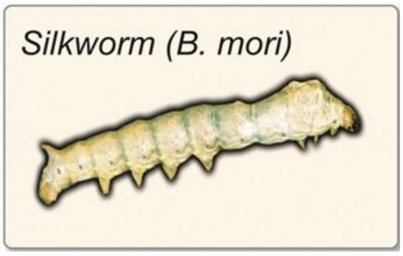


Figure 2-3 Photograph of a Bombyx mori silkworm (J.G. Hardy et.al 2010)

Silk fibers are produced from the silk worn that feast on Mulberry leaves from the moment they are born until they are ready to spin their cocoons, which is about 35 days. This fiber, known as raw silk, is then spun into silk yarn and threads. Bombyx Mori is chosen in this research. This kind of natural silk presents a lot in the south of Thailand especially Narathiwath Province where Queen Sirikit has set up “Queen Sirikit Sericulture Center” here and tried to lead the people in Thailand to realize the beautiful, important and economical suitable for the country. Moreover, Queen Sirikit and the Center are support about the research academic for silk adaptation benefits and use.

B. mori Silk Fibers which each thread consists of the varying in size and structure have been studies for many years and use in many industries for their remarkable of mechanical properties of the characteristic strength. The studies found that silk fibers is a highly breathable fabric that seems to appropriate for all climates that means it has high moisture absorbance. Silk that is collected from farms has very smooth skin and a bright sheen and smooth color and luster; yet the natural fibers have shortcomings as they are prone to photo yellowing, and have poor rub resistance and wrinkle recovery.

Bombyx Mori silk structure composes of two main chains of fibroins protein made up of parallel bundles of nanofibrils. Fibroin is coated with the gummy sericin protein. The chemical composition of fibroin consists of the amino acids glycine, alanine and serine present in the form of beta sheets. High tensile strength of silkworm silk is attributed to two main reasons. Firstly, the large amount of small sized glycine molecule produces a tightly and efficiently packed structure. Secondly, the extensive network of strong hydrogen bonds within the fibroins chains renders the silk fibers high strength and elongation. The gummy sericin is responsible for conferring the properties of anti-oxidation, antibacterial, UV resistance and hydrophilicity (Zhang *et al.* 2002, Hakimi 2006).

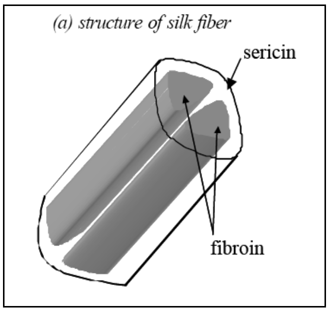


Figure 2-4 Structure of silk fiber [50]

2.5 Bombyx Mori Silk Fibers Polymer Composites

The silk natural fibers have been used in many industries and in the different forms. Recently, there have been happened the interesting field of using natural fibers composite for making the strength structures depending on the way they are forming, woven or braid composites, that have used to increase the stiffness etc. and the techniques they will use.

2.5.1 Silk Process Form of Reinforcement

There are various process of weaving pattern such as weaving, braiding or knitting, form reinforcement to this composite because the fiber are important to embed with the matrix material to gain proper strength and tolerance as the synthetic fiber reinforcement thread has to be considered and align in the design orientation.

In two dimensional woven fabrics composite for example plain weave, a “warp” or longitudinal fiber tow are interlaced with every second “fill” or width fiber tow. The orientation of only two axes demonstrates the great strength and stiffness (Rajiv.A.Nalik et al. 1995) Plain weaving pattern is typically used for weaving reinforcement fabrics due to its balanced structure. Tensile properties of differently woven silk fabric can be determined by ASTM D5035 (Standard Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method).

Another form to improve mechanical properties of weaved fabrics is stitching. When multiple layers of weaved fabrics are incorporated into composites, the through thickness properties are weak. Stitching of multiple layers of woven fabrics together can interlocking the space and improve the interlaminar fracture toughness. Plain woven Kevlar fabrics rubber composite were demonstrated to have higher ballistic performance than that of unstitched fabrics, due to diamond stitching of the Kevlar fabrics, (Ahmad 2007).

2.6 The Flat-footed Child

The foot is one of the important parts of children’s life and is one of the magic organs of the body. The foot can be clarified into parts to be easily seen in its major functions that are the foot bones and the foot arch. The major foot bone to bear weight is the Calcaneous bone (heel bone) and the arch for providing good shock absorption and propulsion like a spring is the medial longitudinal arch. The children who concern to have flat feet are identified to have both of two things abnormal which are a valgus heel position and a flattened of the medial longitudinal arch. Not only two main key points for flat feet are identified, but the secondary signs can also be seen.

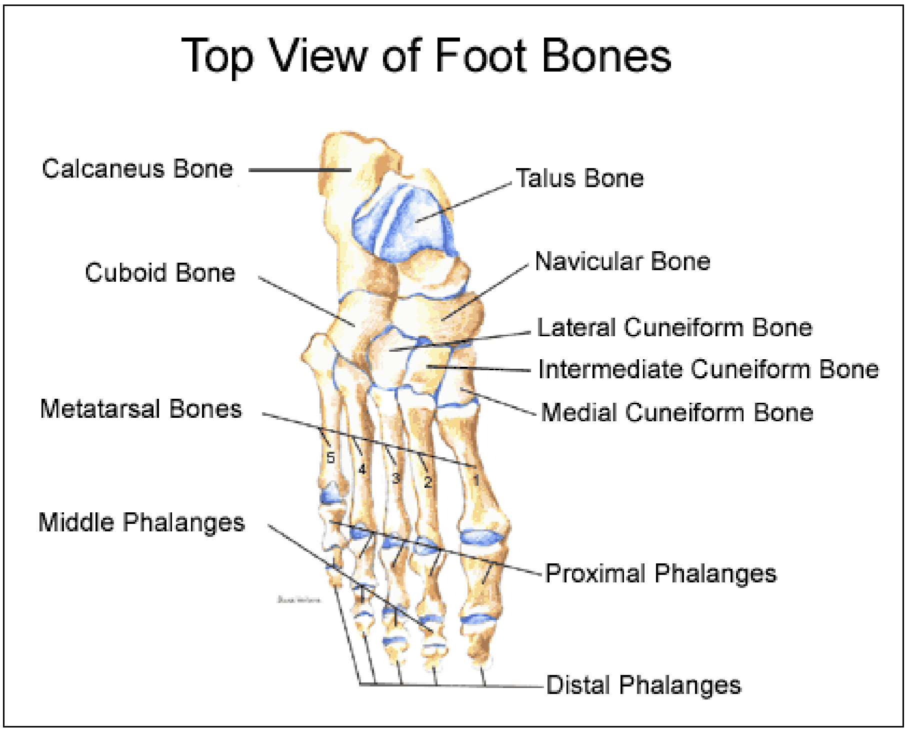


Figure 2-5 Child's foot bone anatomy

http://footclinic.wordpress.com/2009/09/11/anatomy-human-foot/ (Accessed June 8, 2012)

From the figure.2-1 are all the names of the foot's bone to easily understand the child's foot anatomy. Navicular Bone is the most important bone that bulges outward to show the clue of flat foot and may lead to pain after. The human foot has two longitudinal arches. Firstly, transverse arch which are maintained by the interlocking shapes of the foot bones, strong ligaments, and have the duty to pulling muscles during activity. When the weight bearing and no weight of foot were done, little mobility of these arches occur which makes walking and running more economical in terms of energy. Another one that can be examined from a footprint is called the medial longitudinal arch which stayed like curves above the ground. From the two kinds of arch, the arch that collapses in the child's foot seeing from the ground is the medial longitudinal arch. Normally the foot should have the proper arch height. This arch extends under the plantar area. From the research survey in 1957 of Morley about flat feet in London school, the results exhibit that the child under 5 years of age tends to have flat feet due to the fat under the plantar area. However; from the radiological study, the results give another explanation. The pictures express that the low calcaneal inclination angle is the variable induces to depress medial longitudinal arch. About the fat under the foot, it could be retained in a short time as the foot is immature, after that, when the foot is get in shape estimate for a year, the fat tends to be disappeared. However, another reason that will make the arch to be collapsed comes from too much strain on the tendon and ligaments of the feet. Thus, we should find out the scene of flat feet that occur in the children whether they comes from what reason and whether it is still flexible and correctable or not.

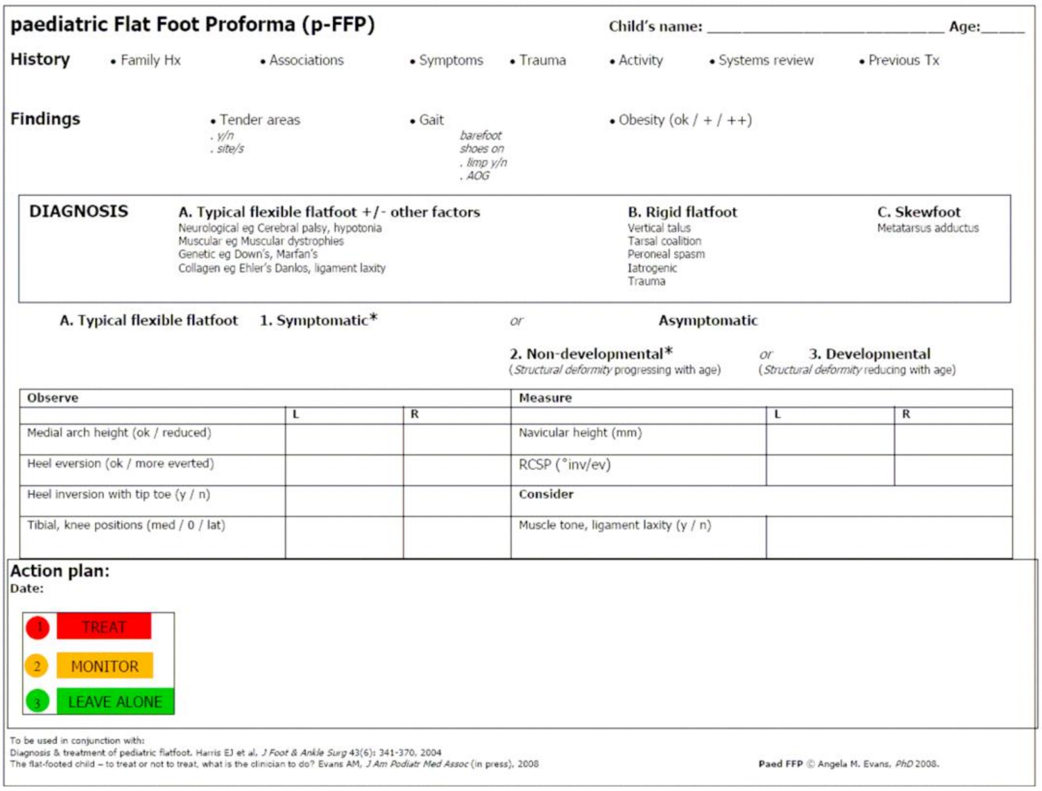
The calcaneal eversion or the eversion of the heel (valgus heel) is one of the symbols of flat foot but not every child who experience of it has foot flat. The child's calcaneus may be normally everted from 5-10 degrees at the onset of ambulation. During normal development, the eversion angles should be reduced approximately 1 degree per year. The heel should be in perpendicular position in 7 years of the child's age. So it means that the child can have everted heel but the degree of it should be in range of normal development; otherwise, it can be diagnosis to have flat feet. The conclusions of the clinical signs to diagnosis flat footed child are:

1. The medial longitudinal arch collapse.
2. The heel eversion
3. The Navicular bulge edge
4. The forefoot abduction

2.7 Flat Feet Identification

The flat foot can be divided into categories up to the goal of treatment. The first group depends on foot pain of the children in the painful or not painful. The second depends on strategy of the foot as it is flexible or rigid. And the last one depends on the physiology of the foot whether it still has the potential to function or not. In the view point of podiatrist and P&O, the painful flat feet that can be flexible and still be functional are the major group to challenge them to treat by prescribing good foot orthoses. The problem is "child always has flat feet from their born" so it is one point of the podiatrist and P&O to classified whether the foot have symptom that is necessary to treat or not.

There is a set planning guideline to treat or not to treat for flat feet named "Pediatric Flat Feet Proforma (p-FFP)" which are widely used. That will make the physicians and the specialists have more exactly decision to identified type of flat feet and from this assessment, the survey for prevalence of flatfeet had been studied.



paediatric Flat Foot Proforma (p-FFP) Child's name: ____________ Age:_____

History • Family Hx • Associations • Symptoms • Trauma • Activity • Systems review • Previous Tx

Findings • Tender areas . y/n . site/s • Gait barefoot shoes on . limp y/n . AOG • Obesity (ok / + / ++)

DIAGNOSIS

A. Typical flexible flatfoot +/- other factors
Neurological eg Cerebral palsy, hypotonia
Muscular eg Muscular dystrophies
Genetic eg Down's, Marfan's
Collagen eg Ehler's Danlos, ligament laxity

B. Rigid flatfoot
Vertical talus
Tarsal coalition
Peroneal spasm
Iatrogenic
Trauma

C. Skewfoot
Metatarsus adductus

A. Typical flexible flatfoot **1. Symptomatic*** *or* **Asymptomatic**

2. Non-developmental* (*Structural deformity* progressing with age) *or* **3. Developmental** (*Structural deformity* reducing with age)

Observe	L	R	Measure	L	R
Medial arch height (ok / reduced)			Navicular height (mm)		
Heel eversion (ok / more everted)			RCSP (°inv/ev)		
Heel inversion with tip toe (y / n)			**Consider**		
Tibial, knee positions (med / 0 / lat)			Muscle tone, ligament laxity (y / n)		

Action plan:
Date:

1 TREAT
2 MONITOR
3 LEAVE ALONE

To be used in conjunction with:
Diagnosis & treatment of pediatric flatfoot. Harris EJ et al, *J Foot & Ankle Surg* 43(6): 341-370. 2004
The flat-footed child – to treat or not to treat, what is the clinician to do? Evans AM, *J Am Podiatr Med Assoc* (in press), 2008

Paed FFP © Angela M. Evans, *PhD* 2008.

Figure 2-6 Pediatric Flat Feet Proforma (p-FFP) [18]

2.8 Foot Testing and Measuring Instruments

The flat feet evaluation can be done by means of the footprint. For obtaining footprints, the tool we selected was a pedigraphy instrument (foot pressure graph), which is usually be the clinical foot assessment tools for both physicians and P&O. The easily process could be done by letting the child seated on the chair, placed the foot on the rubber layer, with contralateral side out of the platform and told the child to stand up. The examiner controlled foot position on the platform to get a natural foot and a clear footprint.

Figure 2-7 Rubber layer and plastic base impregnated with regular stamp ink for capturing footprints

Other methodologies to do the foot assessment that can increase the measurement accuracy are:

- strength platforms, graded scales
- “moirè” photopodometry
- Digiped

2.9 Foot Outcome Measures

The flat feet testing parameters are the key main points that used to diagnosis and determine the type and weight bearing of the foot. The parameters composed of:

2.9.1 Clinical Examination

In clinical situations, there have been many ways to prove and diagnosis the foot pathology and also the flat feet condition by using the scientific methods and theories available.

2.9.1.1 Observation, Palpation

The first assessment in clinical situation to diagnosis the appearance of the foot and pathology, observation and palpation are being in the process. The flat feet can be seen by the medial longitudinal arch collapsed, the heel eversion, the Navicular bulge edge and the forefoot abduction.

2.9.1.2 Foot Flexibility

Jack's great toe extension test is the way to test flat foot flexibility. The method can be done by placing the foot on the floor and flex the hullux. The ability of the foot to flex and form the arch is called flexibility of the foot. In contrast, although flexing the hullux is done, the arch can't be formed so that mean the tested foot is rigid.

Figure 2-8 Jack's great toe extension test

http://www.bloggang.com/viewblog.php?id=dr-kong&date=29-09-2010&group=2&gblog=9

(Accessed November 11, 2012)

2.9.1.3 Heel Angle

The calcaneal eversion or the eversion of the heel (valgus heel) is one of the symbols of flat foot but not every child who experience of it has foot flat. The child's calcaneus may be normally everted from 5-10 degrees at the onset of ambulation. During normal development, the eversion angles should be reduced approximately 1 degree per year. The heel should be in perpendicular position in 7 years of the child's age. So it means that the child can have everted heel but the degree of it should be in range of normal development; otherwise, it can be diagnosis to have flat feet.

The resting calcaneal stance position (RSCP)

The resting calcaneal stance position (RSCP) is one of the angle-related indices to screen the abnormal foot position that lead to have flat feet. It is also the clinical assessment of the static foot posture.

Practical Calcaneal Stance Position= Child's age – 7

2.9.2 Footprints Diagnosis

Medial longitudinal arch is the arch that is focused to explain the characteristic of foot posture. It can be obtained to assess by bringing out from footprints, radiographic or pedography and then making it into quantitative by calculating from clinical or anthropometric measurements.

2.9.2.1 The Staheli Arch Index (SAI)

The Staheli arch index is the footprint parameter that will demonstrate the ratio between central and posterior regions of this footprint, determining a mean SAI and a limit to the flat-foot. This instrument is important to measure the static-postural changes of the feet.

The Staheli arch index can be calculated by following: Draw a tangent line to the medial forefoot edge and at the heel region then find the mean point of these lines. From this point, draw a perpendicular line across the footprint and do the same procedure at the heel tangency point. The Final Step is to measure the support width of the central region to the foot (A) and of the heel region (B) in millimeters. The Staheli arch index (SAI) can be calculated by this formulation by dividing the A value by B value.

$$SAI = A/B$$

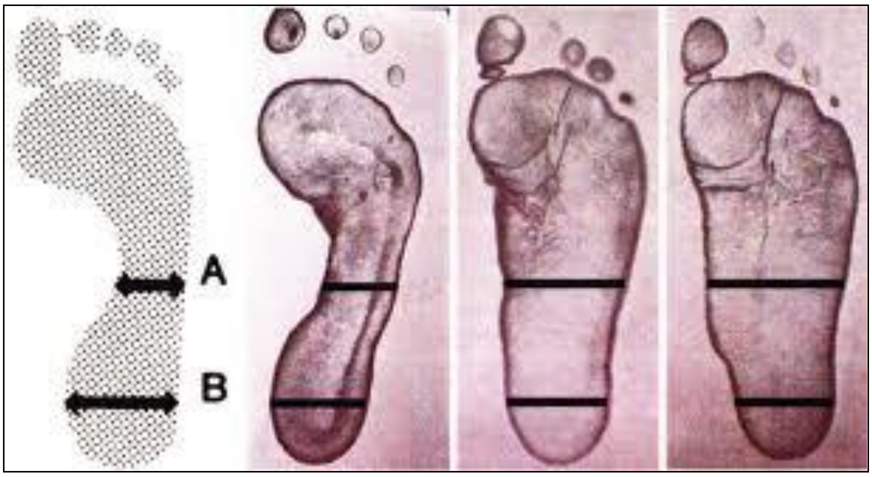


Figure 2-9 Measurement of the width of the central region
(A) and heel region (B) of the foot, in millimeters, on a footprint.
http://www.springerimages.com/Images/RSS/1-10.1007_s12306-009-0037-z-3
(Accessed November 11, 2012)

-An arch index of less than 0.21 has been said to be indicative of a cavus foot [59]
-An arch index of greater than 0.26 is indicative of planus foot [59]
-An arch index between 0.21~0.26 corroborates normal arch height [59]

2.9.2.2 The Normalized Navicular Height Truncated Measurement (NNHT)

The normalized navicular height truncated measurement is one of the key main points that show the dimension-related indices. These measurements will provide in the 'ratio' that seem to have moderate to high correlations with angular measurements when compared with the radiographs, which provide the most valid representation of skeletal foot alignment.

Normalised navicular height truncated is the ratio of navicular height relative to the truncated length of the foot. Navicular height is the distance measured from the most medial prominence of the navicular tuberosity to the supporting surface. Foot length is truncated by measuring the perpendicular distance from the first metatarsophalangeal joint to the most posterior aspect of the heel, with a lower normalised navicular height ratio indicating a flatter foot

Normalized navicular height truncated is calculated by finding the ratio when dividing the height of the navicular tuberosity perpendicular to the ground (H) by the truncated foot length (L). The value of NNHT less than 0.26 is indicated to have flat feet.

Normalized Navicular Height Truncated = H/L

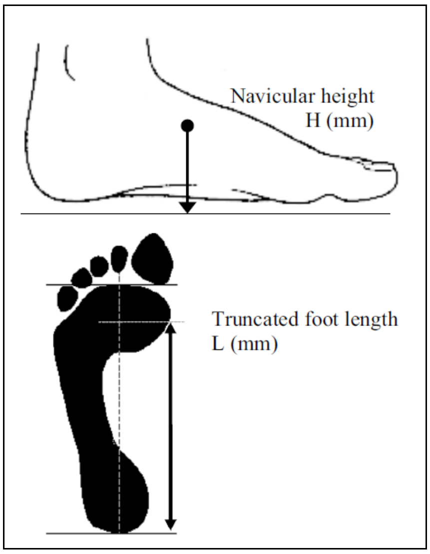


Figure 2-10 The navicular height and the truncated foot length to calculate for the normalized navicular truncated measurement [59]

2.10 Pediatric Flat Feet Non-Surgical Management

Conservative or non-surgical management is one of the ways to cure for flat feet in children after the physicians had exam the type of flat as symptomatic flexible flat feet. There are many programs set up for the patients including of physical therapy (exercising and necessary activities prescribing), proper shoes and insole (foot orthoses). The major expectations are the ability to strengthen foot muscles, align good posture of the foot skeletal (increase foot arch) and avoid pain for children's feet. However, how much the importance of non-surgical technique will be still remaining unclear.

There are many studies about non-surgical technique of flexible flat feet children to address its efficacy. The management from the first time seeing the children will use the pediatric flexible flat foot Performa as an evidence-based [18]. All studies provides the subjects with foot orthoses (vary in the studies) and footwear (with or without modification) for the intervention groups.

2.11 Foot Orthotic Intervention

From all identifications, it helps podiatric physicians and also P&O to have careful diagnosis and examination of flat footed child as there are many types of what we call flat foot. However, not all the types of flat foot need for the treatment because of the pathology. Most children who experienced flat feet don't have pain in their feet so it's no need to have a tough treatment as its unnecessary just only activities teaching and physical therapy and exercises guideline are enough. But for symptomatic flat feet, rigid flat feet, and flat feet that we can see its progression or the pattern of walking or other signs need for the special treatment – surgical technique and non-surgical technique and also physical therapy and proper exercise programs.

In this research report, as the report composer is in the duty of P&O, the non-surgical technique is going to be a key point consideration. The non-surgical technique is the way to deal with shoes and in-shoes system that try to correct and compensate foot posture for the flat foot child. The major goal is to bring their foot back into neutral position and to increase for the arch height to gain proper weight bearing and mobility of the child's foot. Moreover, the research found that foot orthoses can enthusiasm clinical effect for good muscles activities. Nowadays, there are lot kinds of foot orthoses available for flat feet children; however, the proper design one and its effect still remains controversial.

2.6.1 Foot Orthoses

Foot orthoses are widely used in non-surgical management of pediatric flexible flat feet for initial treatment; however, there are no definitive patterns of foot orthoses using and their effects of intervention. There are many studies about these that the researchers tried to find the answers that foot orthoses are necessary and be helpful for the children's feet or not. All studies show the immediate foot-wear and foot orthoses found an improvement in foot posture. There are just two studies that investigate the effect of foot-wear with foot orthoses. And the two both showed the reduction in foot abduction significantly. Although, not every studies show the improvement or the good outcomes with statistical significant, but the effects of the foot orthotic in flexible flat feet children show the good development of the children's feet and haven't shown the adverse effect to get rid of from using it.

Moreover, the design and material of foot orthoses are very difficult to choose. Foot orthoses can be categorized as soft, rigid and semi-rigid which are vary in quantitative motion control and depends on the patients. The most cost-effective choices would be take into considerations. Many low-cost, generic foot orthoses can provide good positional support of the child's foot and relief of presenting symptoms. From the studies we can see that UCBL design or the design that have rigid, semi-rigid shell or property to correct the Calcaneus angle of the children's feet showed the positive effect and were popular in application. The UCBL usually makes up from thin, light weight, semi-rigid polypropylene; however, its design looks bulky and makes difficulty utilizing in most shoes. Nowadays, there are many UCBL modification and design that increase both function and cosmesis of the orthoses. The fabric or very thin foam will be use for the liner to create comfort and increase friction of the orthoses.

There are other designs that tried to combine or create the new pattern and function of foot orthoses for example the foot orthoses should tried to contour the foot shape of the children as much as possible with arch cookies or medial heel wedge to optimize correcting the Calcaneal angle and have proper Resting Calcaneal Stance Position (RCSP). The foam is the popular material using. The material and designs are varying in the market nowadays but the custom-made foot orthoses casting from individual foot give positive feedback for the children feet.

Not only foot orthotic that we have to pay attention, but also the children's shoes. Prescription of proper shoes to the children with flat feet will be the other good point for rapidly correcting the symptom. Sometimes shoe modification is necessary as the studied had informed that shoes with counter, shank, Thomas heel and wedges can also correct in Calcaneal angle and improvement of the foot arch. However, there has no study to see the effect when combining the foot orthosis and shoe modification together for the treatment of flexible flat feet yet.

Although, the foot orthotic intervention in treating pediatric flexible flat foot provides the positive effect, the follow up process after the treatment is still essential. As the children grow up quickly, the change of foot orthotic size and material sometimes are necessary.

The successful use of functional foot orthoses, of any material, is based upon the shared responsibility of the prescribing clinician and the orthotic laboratory.

The main consideration in the orthosis of treatment of children's flatfoot

1 The shape of the foot orthosis relative to the geometry of the plantar foot and,

2 The ability of the orthosis to resist deformation inside the shoe in response to loads from the foot.

In children's flat foot, the medial longitudinal arch should be supported firmly and the medial heel wedge needs to be given extra varus support. In this way, both the medial heel wedge and medial longitudinal arch of the foot will receive increased magnitudes of reaction force from the orthosis which will, in turn,

- Increase the external subtalar joint supination moment and
- Increase the external forefoot plantarflexion moment (i.e. medial arch raising moment)

Chapter 3

Research Methodology

This research is an "Applied Research" to seek for the optional choice for foot orthotic in the treating physiologic flat feet children by using available material in the country while gaining the utilities and physical properties. And this research also is an "Experimental Research" to find out the outcome after using the foot orthotic device for patient with flat feet.

Research Method: Pilot Study Experimental Design: Pretest-Posttest Design

This research includes the 2 important parts.

1. Study of the silk fibers polymer composites in the parts of physical and mechanical properties in order to gain quality in fabricating foot orthoses when compared to carbon fibers polymer composites.

2. Design and Fabricate silk fibers polymer composite foot orthoses for physiologic flat feet children and compare the clinical results with carbon fiber polymer composite foot orthoses.

In the first part, the research has sought the results that Bombyx silk fibers have good and enough quality for making the foot orthoses when comparing with carbon fiber. And in the second part after fabricating the Bombyx silk fiber as composite foot orthoses, the clinical results when using by participants' subjects will provide positive effect both function and satisfaction. Each part has the following details:

3.1 Study of the Silk Fibers Polymer Composites

The parts of physical and mechanical properties testing will be studied and compared to carbon fibers polymer composite. Moreover, the process of scanning electron microscopy (SEM) had been done to emphasize the results.

3.1.1 Materials

- Silk Textile from Mulberry Silkworm Fiber - Bombyx silk textile is woven from "Queen Sirikiit Seri Culture Center" in Narathiwat. After Mulberry worms had fed for 45-52 days.

They will provide the fibers for 6-7 days for us for collecting. The handicraft will keep all the fibers together and start to weave for the silk cloth. That means we can get silk cloth from Mulberry worms in the raw and pure condition with its true color.

- Carbon Fiber Cloth (0/90 Degree)

Name of product: 616B1 - Carbon Fiber Webbing

Use of the substance / preparation: carbon-fibres for reinforcing

Company name: Otto Bock HealthCare Deutschland GmbH & Co. KG

- Stockinette Cloth

- Acrylic Resin

Name of product: 617H55 - C-ORTHOCRYL Resin

Use of the substance / preparation: Lamination Resin for orthopaedic procedures

Company name: Otto Bock HealthCare Deutschland GmbH & Co. KG

Chemical characterization: Solution of acrylic polymers in methylmethacrylate, containing softener.

- Hardening Powder

Name of product: 617P37 – for Orthocryl Resin

Company name: Otto Bock HealthCare Deutschland GmbH & Co. KG

Use of the substance / preparation: mix with the resin

3.1.2 Fabrication methods

3.1.2.1 Silk Preparation

Control of fiber length and orientation -Since the studies have proved that the Bombyx Mori Woven Natural Silk has the interlacing of fiber bundles which can prevent the growth of damage and increase the impact of toughness. So the pattern of forming is very crucial that have to be thought about. To compare with the carbon synthetic fiber and the orientation needed for the foot orthoses, the plain weave bi-directional alignment of silk cloth has be chosen for this study in the direction of 0 degree “fill” width fiber tow and 90 degree “warp”. From the fiber length and the orientation control, the optimization of medium bending strength in 0 degree and 90 degree direction and medium torsion strength that appropriate for the foot to function biomechanically can be achieved.

3.1.2.2 Composite Fabrication Process

Prepare the chemical agents for lamination by weighing the C-ORTHOCRYL Resin and the hardening powder in the mixing ratio of 100 parts resin to 2-3 parts Hardener.

Figure 3-1 Chemical agents for lamination

Place the mold plate on the vacuum machine and cover it with the PVA bag to make the composite not stick to the plate and easily take out.

Three layers of cloths and fibers in the sandwich style:

1. Stockinet – Bombyx Silk Textile – Stockinet
2. Stockinet – Carbon Fiber Webbing – Stockinet

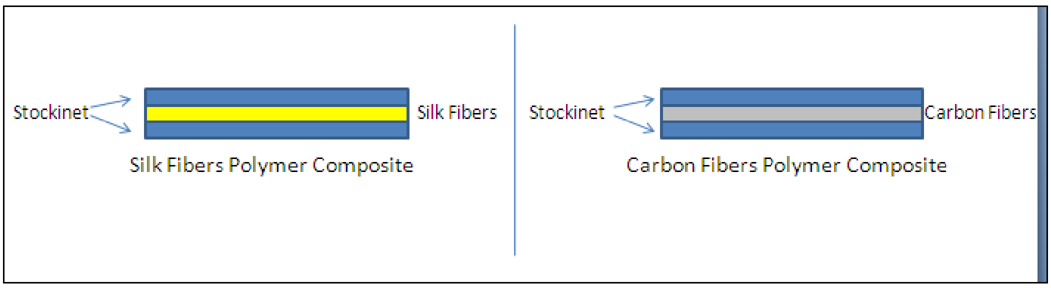


Figure 3-2 Layers of the composites

The all prepared layers are set on the mold plate. Pour the mixing of chemical agents on the top of the plate gradually until the liquid suck and widespread into the cloths and fibers. Cover the top of the surface again with PVA bag and try to leave air bubbles as less as possible. Open the vacuum machine to let the air come out and make the chemical liquid agents spread and attach all over the mold plate. Wait for the chemical action sets and becomes dry and hard.

Figure 3-3 Vacuum machine (left)

and the chemical action of composite making on vacuum machine (right)

After that, the composite flat sheet can be achieved which can be used to form the foot orthoses in the future. But at this stage, the composite sheets will be brought and cut into indentified pieces for laboratory testing in the next step.

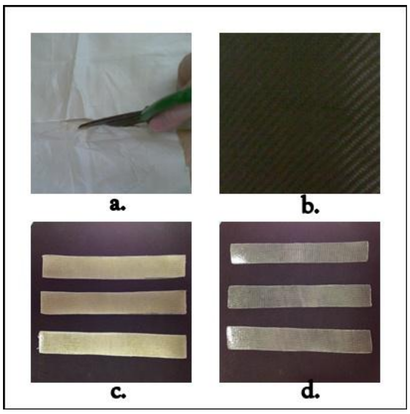


Figure 3-4 a) Silk Fiber b) Carbon Fiber

c) Silk Fiber Polymer Composites d) Carbon Fiber Polymer Composites

3.1.3 Testing and Characterizations

3.1.3.1 Physical Properties Test

Weight ratio and thickness ratio are two parameters that will compare for the two composites physical properties. The research had used 10 samples for testing. The instrument using for finding the weight of the composites is the "Precision Balance" with its repeatability of 0.001 g. And the thickness of the composites was found by using the thickness gauge called "Goniometer". To find the average thickness within the rectangular piece of the composite, the five reference points were used to measure including the four borders of the composites and the middle area of the composites. From the all data, both weights and thicknesses of the composites can be achieved and the mean values are calculated for the weight ratio and thickness ratio.

Figure 3-5 The "Precision Balance"

with its repeatability of 0.001 g.

3.1.3.2 Mechanical Properties Test

In this study, we use the Universal Testing Machine (Zwick/Roell) in the edition of Proline 20 kn for ASTM tester of D638 standard.

Figure 3-6 Universal Testing Machine (Zwick/Roell) Proline 20 kn

Table 3-1 Universal Testing Machine (Zwick/Roell) Specification

Machine Name:	Universal Testing Machine
Manufacturer:	Zwick/Roell
Specifications:	Model Proline 20 kn series • Tension, compression, and 3- and 4-point bending loading available • 1 kN and 20 kN load cells • Displacement rates: .005 - 500 mm/min • Computer control and data collection • Automated data analysis capabilities • ASTM standard and custom test methods available

3.1.3.2.1 Tensile Strength Test

A tensile test is a mechanical test that the machine will deform or break the specimen or sampling under gradually increasing tension load [55]. And from this test, it can be used to plot a stress-strain curve and also other mechanical properties can be obtained from the graph. Some of the most important mechanical properties that can be obtained from the stress-strain curve include yield strength, modulus of elasticity (Young's modulus), Ultimate tensile strength, ductility, and toughness.

Tensile test will perform on the two different types of foot orthotic composite samples under study of both control group and experimental group, which were acrylic resin with carbon fiber and acrylic resin with silk cloth.

The tensile strength tests of both synthetic and natural fibers were investigated by using the universal testing machine with the ASTM standard of D638 (Type IV), according to the plastic property using the Universal Testing Machine. All specimens were prepared in a rectangular shape of 13x2cm before being cut in the dumbbell shape for testing. The test speed was 10 mm/min and a minimum of five specimens were tested in each case to obtain the average values.

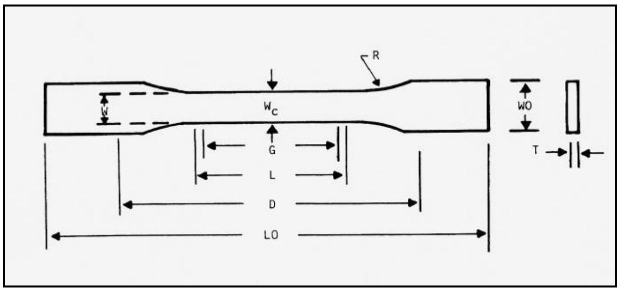


Figure 3-7 ASTM D638 Tensile Properties of Plastics –dumbbell specimen [55]

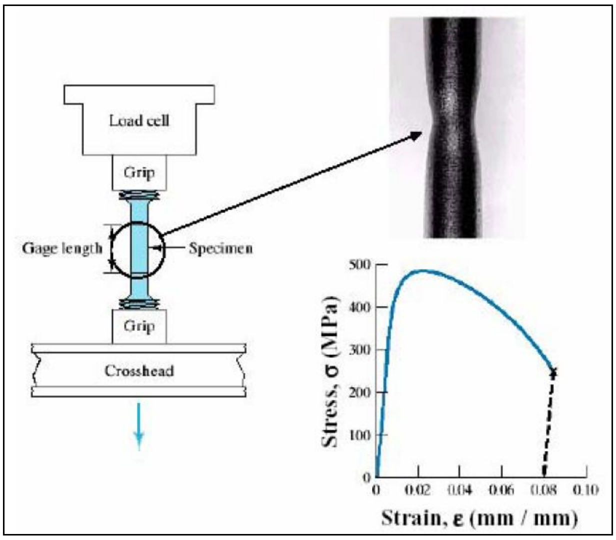


Figure 3-8 Tensile strength test characteristics and stress-strain curve obtaining from the test [55]

The measured data from the tests are used to calculate ultimate tensile strength and the longitudinal modulus of elasticity using the following equations (Masters and Portanova, 1996)

Table 3-2 Formulas in tensile strength test

Data	Formula
Ultimate tensile strength (UTS)	$\sigma_Y = P/(bD)$
Longitudinal modulus of elasticity	$E_Y = \Delta\sigma/\Delta\varepsilon$

In these equations, P is the maximum load, b is the specimen's width, D is the specimen's thickness, $\Delta\sigma / \Delta\varepsilon$ is the slope of the linear region of the stress-strain curve.

3.1.3.2.2 Hardness Test

Hardness is the ability of a material to resist plastic deformation and fracture [55]. The Rockwell hardness tester is the test using an indenter to press against the surface of the material under study. Hardness Rockwell Testing determines the strength of a material by measuring the depth of penetration an indenter makes on the prepared surface and a specified load. Hardness Rockwell values can be measured utilizing loads of 15-150 kg.

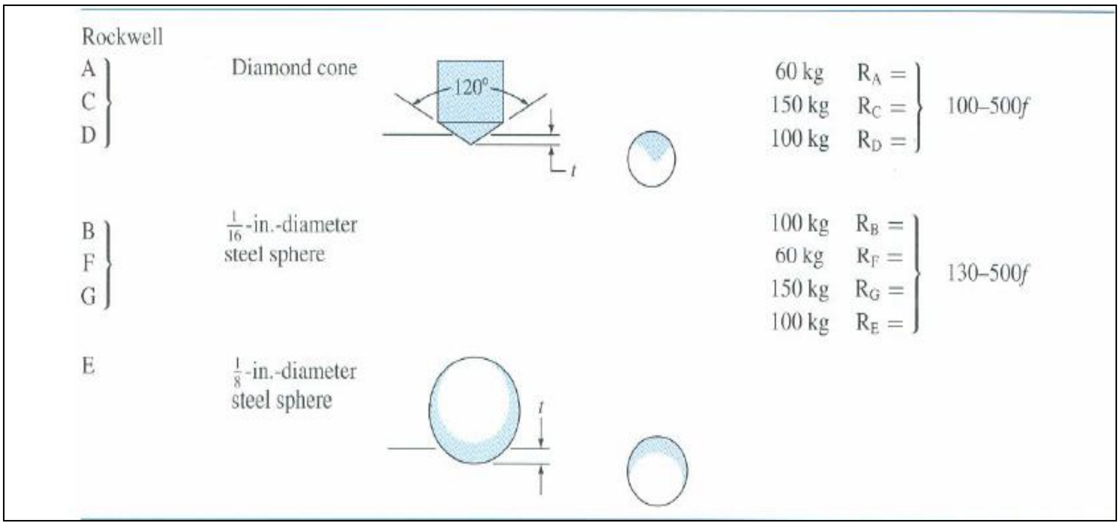


Figure 3-9 The Rockwell hardness test concept

http://www.instron.co.th/wa/applications/test_types/hardness/rockwell.aspx

(Accessed November 18, 2012)

A steel ball under a minor load is applied to the surface of the specimen. This indents slightly and assures good contact. The gauge is then set to zero. The major load is applied for 15 seconds and removed, leaving the minor load still applied. The indentation remaining after 15 seconds is read directly off the dial. There is a minor load (10 grams) which constantly presses on the indenter; a major load will be applied to the material gradually until equilibrium point has been reached. Then the major load will be removed and some of the penetration it caused will recover. At this point the residual penetration is measured and that is the hardness of that material. The two sample types of the study will perform on this test including five samples of carbon fibers polymer composites and five samples of silk fibers polymer composites.

The ASTM D2240 Rockwell hardness tester is the test for Shore Durometer of the material under study in being resisted in penetration under load. The five specimens of two groups of fibers were measured and the mean values were calculated and presented.

3.1.3.2.3 Flexural Test (Bend Test)

The test measures the stiffness and strength of a material as it is being deformed in three-point flexural bending. In flexure tests, the modulus of elasticity, thickness shear modulus, strength with respect to normal stress sYB, and interlaminar shear strength can be translated. The elementary theory of bending that have to be considered is the material of a bar is assumed to be isotropic, homogeneous, and of equal tensile and compression strengths. (Zweben et al. 1979)

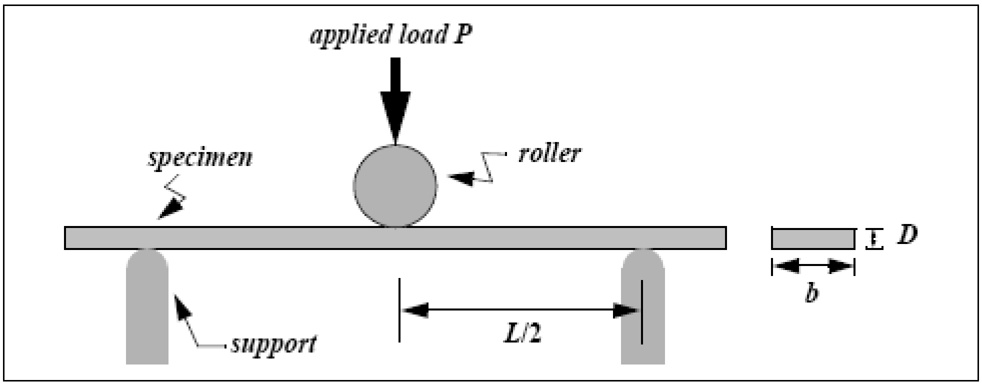


Figure 3-10 Three-point loading flexural test (Zweben et al., 1979)

In a flexure test, the specimen can fail in tension in the bottom face, compression on the top face, by shear, or by some interaction of these stresses. The mode of failure is strongly dependent on span-to-thickness ratio (sometimes called aspect ratio) L/D

The five specimens are cut to test at two different span-to-thickness (L/D) ratios to determine the flexural properties of the material, following Test Method I of the ASTM D790. All tests were conducted using the Universal Testing Machine (All Around 10kN, Zwick//Roell. The average dimensional measurements of the flexural test specimens are listed. The three point flexural bend test was done in the standard ASTM D790. The flexural strength and modulus were obtained from this test.

Table 3-3 Formulas in flexural strength test

Data	Formula
The flexural modulus	$E_Y^B = L^3m/(4bD^3)$
The flexural strength	$\sigma_Y^B = 3PL/(2bD^2)$

In these equations, P is the maximum load, b is the specimen's width and L/D is the span-to-thickness ratio of the specimens.

3.1.3.2.4 Fatigue Test

Material fatigue test

The test applies to a cyclical load or strain to the sample and determines the resiliency or durability of the material by measuring the number of cycles to failure (W. Van Paepegem et. al). Fatigue experiments are performed to examine the behavior of both the grips and the material under fatigue loading conditions. With respect to the material under study, the displacement during a load controlled fatigue test between 0 and 45 MPa shear stress at 2 Hz. In general, the material behavior has an increase in permanent deformation and a decrease in shear stiffness until a certain point in time, after which a drastic increase in deformation and temperature occurs. The latter exceeds the softening temperature of the matrix. Also, the maximum value of the shear stress amplitude for fatigue with R = 0 as well as the loading frequency have a large influence on the fatigue lifetime. The five specimens from each group are test for finding out the material fatigue.

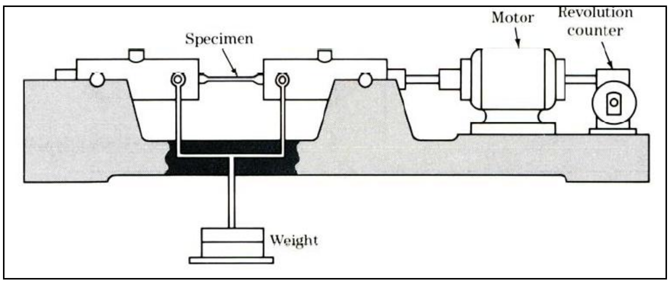


Figure 3-11 Fatigue test (R.R. Moor)

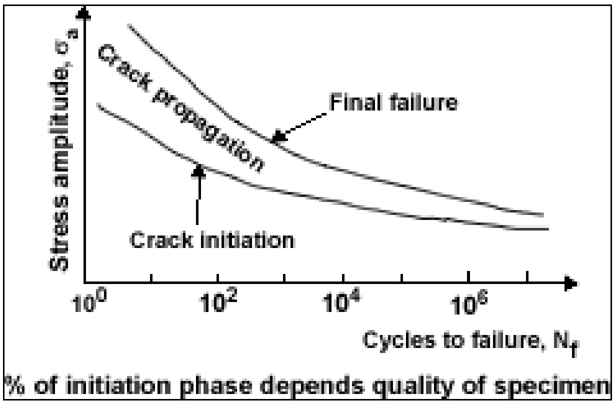


Figure 3-12 Graph of stress and number of cycles (SN Curve)
in fatigue test (Zweben et al., 1979)

Table 3-4 Formula in fatigue test

Data	Formula
Stress Amplitude	$\sigma_a = \frac{\sigma_{\max} - \sigma_{\min}}{2}$

In these equations, σ is the stress load.

Device fatigue test

After the forming of composite sheets to composite foot orthoses, the fatigue test of the device had been done in order to prove the durability for using of the device. The five foot orthoses from two composites group are test to find out the device fatigue. The modify gauge for testing fatigue for composite foot orthoses had been done by assuming the walking gait pattern of the human per round when applying force to the composite foot orthoses in the same speed and Hz. of the device. This modified gauge used 2 Hz speed for testing [ISPO 1977]. The shank and the prosthetic feet are fixed to the gauge. The composite foot orthoses are attached under the prosthetic feet and then run the machine.

Figure 3-13 The modified gauge machine for device fatigue test

3.1.3.3 SEM Analysis

A scanning electron microscopy (SEM) is a type of electron microscope that analysis on morphology and topography of samples. It is an important tool for material to analyze morphology of metals, ceramics and plastic materials. In this study, SEM was used to analyze morphology of fracture area of samples. Furthermore, adhesion between fibers and matrix was also analyzed and considered by SEM. To prepare sample for analyze, the samples were placed in a low vacuum, slightly humid environment inside the SEM which stay on the metal sheet and coated with gold. The fractured area was at the (0, 0) co-ordinates of the mount so as to focus on the crack area. There were two conditions of composites that need to take into considerations for SEM to compare the cross section and attaching different:

- The composites under cutting by saw condition
- The composites under passing the tensile strength test

Figure 3-14 SEM Machnine JSM 5800 LV

Figure 3-15 Composite preparation and gold coated for SEM analysis

3.2 Study of Effect of Silk Fibers Polymer Composites Foot Orthoses on Flexible Flat Feet Children

The research is aimed to find the effect of silk fiber polymer composite foot orthoses when using to treat the physiologic flat feet children by comparing before and after wearing foot orthoses for a given period of 14 weeks.

The silk fiber polymer composite foot orthoses and the carbon fiber ones are prescribed for the participants on the design of ¾ foot orthoses with individual foot shape and correction that need to take consideration in each case because of different problems encounter. The fabrication processes are:

3.2.1 Foot Orthotic Fabrication Process

There are 3 major steps in the fabrication process:

1. Patient Casting to get the "Positive Foot Mold" by prosthetist and orthotist (P&O)

Patients & tools preparation

- Let the patient sit on the chair with foot attach floor.
- Use "Pedilen Foam Impression Tray"—Otto Bock Company.

Casting

- Put the foam tray under the patient's foot with foot in the neutral position (Subtalar joint neutral).
- Do the partial weight compression

After Casting

- Get the real model shape of the patient's foot(negative cast)
- Mix the plaster powder with water in the ration of 60:40, pour into the "negative cast"

- Pill out the excess pieces of foam and get the "positive foot mold".

Figure 3-16 Participant's feet cast in "Pedilin Foam Impression Tray"

Figure 3-17 Positive Foot Mold

2. Positive Cast Modification Process

When the positive mold of foot is prepared, the next step is to plan what area need to do the modification in order to correct patient's flat feet following the P&O knowledge. The major goals are the area of arch support that have to be increased and area of Navicular bone that have to be raised up by making "the supinator posterior wedge".

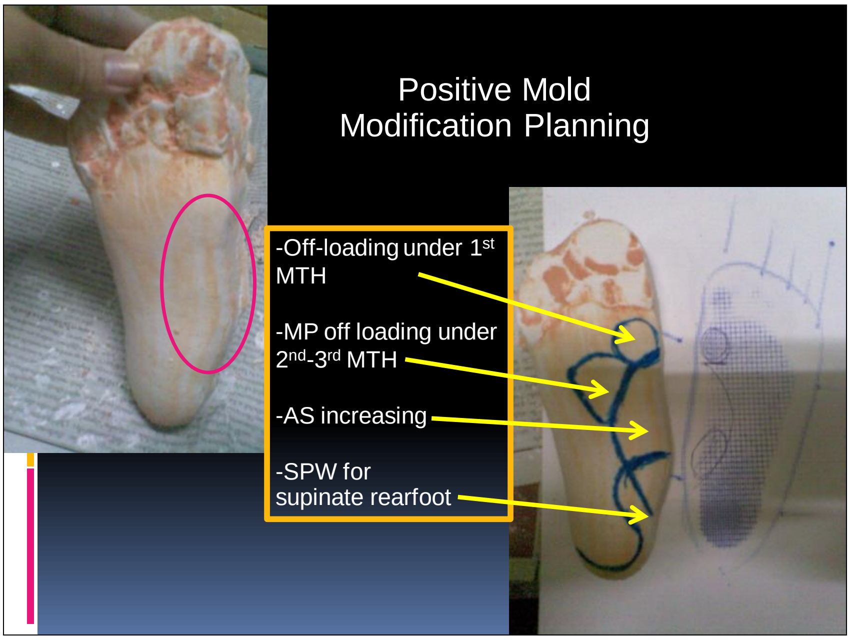


Figure 3-18 Positive Mold Modification Planning

Then P&O will remove plaster out from the mold by using padding and wedging technique to correct the patient's foot biomechanics.

Figure 3-19 Positive Modification Process

Figure 3-20 Finishing Positive Foot Mold

3. Insole Fabrication Process

Material Preparation

For silk fiber polymer composite group

- Polyethylene Foam 3mm thickness
- Acrylic Resin 80:20
- Stockinette Cloth 2 layers
- Silk weave cloth 1 layers

For carbon fiber polymer composite group

- Polyethylene Foam 3mm thickness
- Acrylic Resin 80:20
- Stockinette Cloth 2 layers
- Carbon Fiber webbing 1 layers

The process of making the composite plate is the same as above by mixing chemical agents together, pouring on the material prepared and using vacuum machine to suck the air out and waiting for it to set and dry.

Figure 3-21 Bombyx silk fiber polymer composite sheets

Fabrication process

To fabricate the custom made foot orthoses for correcting physiologic flat feet children, the fabrication details should go following these:

- Put the positive mold on the vacuum thermoforming press

Figure 3-22 Positive mold on the vacuum press

- Prepare for the first comfortable insole layer with polyethylene foam 3 mm thickness materials. Glue one side of the material, put it in the heating oven 200ºc for 1 minute, bring them out and put on the positive mold. Open the vacuum machine to suck the air out and make the polyethylene foam material attaching and form with the mold.

Figure 3-23 The first comfortable insole layer

- Preparing the composite plate by cutting them into the "U" shape for insole. Glue the one side of composite with adhesive bonding glue.

Figure 3-24 Preparing the composite

- Put the composite plate in the electronic heating oven with temperature 200 ºc for 5 minutes to make it deform the hard itself to become softer before attaching to the mold shape.

Figure 3-25 The composite in the heat oven

- Put the hot and soft composite plate on the positive mold with the glue part attach with the first comfortable layer. Open the vacuum press machine to suck the air out and make the composite to attach and form with the positive mold to get into the insole shape.

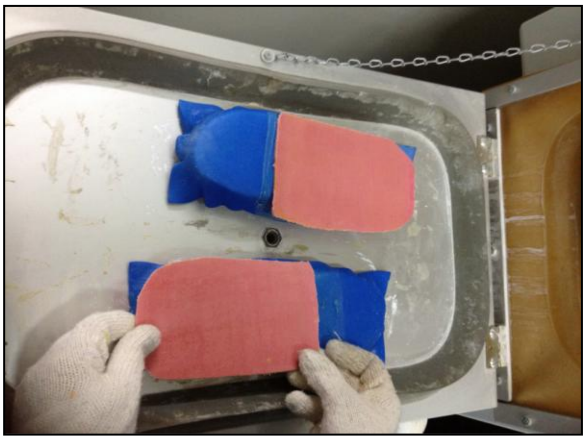


Figure 3-26 The soft composite plate on the positive mold

Figure 3-27 The vacuum press machine suck the air out to attach the positive mold

- When the composites are formed into the mold and the temperature is cool down. Open the vacuum press machine and release the air pump. The composite will get into the shape of insole without changing their form again.

Figure 3-28 The setting in the form of foot orthoses of composites

- Prepare for the insole last in the aim of providing stability and not rotating inside shoes with microcellular rubber (MCR) material 10 mm thickness. Cut the material in to the square shape of as long as the calcaneus bones covering. Glue the material, put it in the heating oven 200ºc for 2 minutes, take it out and put on top of the composite layer. Open the vacuum press machine again to suck the air out and make the material attach with the mold.

Figure 3-29 The microcellular rubber on top of the composite layer

- Finally, the composite foot orthoses with excessive trimlines have to bring to the next step for cutting off and grinding into the shoes.

Figure 3-30 Composite foot orthoses with excessive trimlines

Grinding and finishing process

After getting the foot orthotic from the foot positive, the next process is grinding the foot orthoses with the sandpaper router grinding machine to gain the proper trimline and cosmetic of the device before donning to the shoes.

Figure 3-31 Cut the trimlines

Figure 3-32 The final product of composite foot orthoses

3.2.2 Foot Orthoses Clinical Testing

3.2.2.1Research Participants

The research participants are the pediatric patients who come to Songklanagarind Hospital with the chief complain of flat feet. After the doctor has diagnosis for physiologic flatfeet condition and plan to use the foot orthotic intervention for the treatment, then the patients will come to the prosthetic and orthotic unit and enter to the research. However, parents of all participate pediatric patients will sign for the inform consent before entering to the research study. Numbers of participants in this research are 13 people which are divided into the group of silk polymer composite foot orthoses for 7 people and the rest were the carbon fiber polymer composite group.

3.2.2.2 Inclusion Criteria

- Pediatric flexible flatfeet patient
- Age 7-18 years old
- Body Mass Index (BMI) 18.5-23 kg/m^2
- Never experience the foot orthotic history before
- Never experience the foot pain from flat feet before

Exclusion Criteria

- Pediatric Flatfeet Patient with pathologic type
- Age less than 7 years old or over 18 years old
- Body Mass Index (BMI) under 18.5 kg/m^2 or over 23 kg/m^2

- Experience foot orthotic history

- Painful flatfeet condition

3.2.2.3 Research Instruments

- Foot Pressure Graph (Tread Marker article number 743P2 – Otto BocK)

- Weighing apparatus

- Height apparatus

- Goniometer Tool

- Ruler

3.2.2.4 Collection of Data

a) Pediatric patient interview and inform consent after doctor diagnosis as having physiologic flat feet.

b) Measure weight and height of the participants to calculate for the body mass index (BMI) of the participants.

c) Measure static foot pressure to find “Staheli arch index (SAI)” with the foot pressure graph.

d) Measure the normalized Navicular height to calculate for the “Normalized Navicular Height Truncated (NNHT)” measurement.

e) Find out “Resting Calcaneal Stance Position (RCSP)” Measurement with Goniometer.

Data Collection Method

a) Participants will be explained about the research method, research benefits, risks that may happen and the way for solving from the researcher.

b) Participants will measure the weight and height on the day entering the research to find out the BMI.

c) Participants will have to measure the static foot pressure to find "Staheli arch index (SAI)" with foot pressure graph, measure the natural Navicular height to find out the "Normalized Navicular Height Truncated (NNHT)", and measure the "Resting Calcaneal Stance Position (RCSP)" with Goniometer.

d) Each participant has to do the foot casting in order to make custom-made foot orthotic device by prosthetist and orthotist (P&O). The P&O who measure and fabricate the orthotic device is the same person for all participants in order to get rid of error from dexterity.

e) Each participant will get one pair of custom-made composite foot orthotic device to don inside the own patient's shoes. The participants have to wear the composite foot orthotic device in everyday for 3 months (14 weeks) before having the follow-up appointment from P&O.

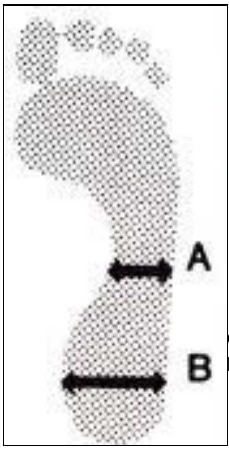
f) After wearing for 3 months (14 weeks), the patient will have to do the foot measurement with foot pressure graph to find out the SAI, NNHT and RCSP again.

Data Required

- Body mass index from weight and height measurement can be calculated by the formula:

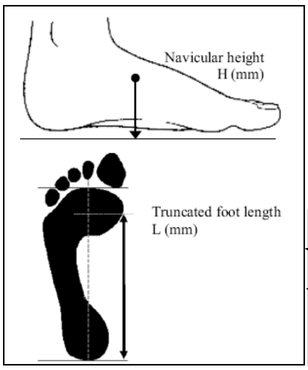
$$\text{BMI} = \frac{\text{mass(kg)}}{(\text{height(m)})^2}$$

- Foot Pressure from Foot pressure Graph to investigate the changes of "Staheli arch index (SAI)" data before and after wearing foot orthosis.



Staheli Arch Index (SAI)
= A / B

- Natural Navicular Height to calculate for "Normalized Navicular Truncated (NNHT)" before and after wearing foot orthoses.



Normalized Navicular Height Truncated (NNHT)
= H / L

- "Resting Calcaneal Stance Position (RCSP)" value before and after wearing foot orthoses.

Figure 3-33 Measuring for RCSP

3.2.2.4 Statistical Analysis

The statistical analysis was using the Statistical Package for the Social Sciences (SPSS) version 18. The research used the descriptive analysis to find the mean value.

In material testing, to compare the efficiency between silk fiber polymer composites (SFC) and carbon fiber polymer composites (CFC), the research used "Paired Sample T- test" with the 95% confident interval of P value < 0.05 can be interpreted to be significant. The graphs were plot by using the Graphpad Program Prism 6.

In clinical testing, to compare the improvement before wearing and after wearing the foot orthotic device within group, the research used "Paired Sample T test" with the significant in the P value < 0.05. To compare the improvement between two groups in before and after wearing the foot orthotic device, the research used "Independent Sample T-Test" with the significant in the P-value<0.05. The graphs were plot by using the Graphpad Program Prism 6.

3.2.2.5 Assessment of Composites Foot Orthoses Functional Using from Participants

Participants' satisfaction questionnaire is used to assess the attitude of using towards the composite foot orthoses of the participants. The questionnaire will ask about the the quality and probability of composite foot orthoses that influence their using and the attitude of functional using and economic efficiency will be performed.

Chapter 4

Results

This research includes the 2 important parts which are the material testing part and the clinical testing part. And the results go following these:

4.1 The material testing results

This research aims to study of the silk fiber polymer composite in the parts of physical and mechanical properties in order to gain quality in fabricating foot orthoses when compared to carbon fiber polymer composite. Moreover, the research had gone through the SEM analysis to see more details of material morphology.

4.1.1 General Information of Samples Testing

We have two groups of sample testing which are 5 samples of silk fiber polymer composite (SFC) group and 5 samples of carbon fiber polymer composite (CFC) group. They are all produced for the composites in the same size preparing for the tests. The physical and mechanical tests of the two composites groups were done to compare and discuss. In each test, specimens were tested and calculated for the mean values.

4.1.2 The Physical Properties Test Results

The specimens had prepared in the same size of 13cm x 2cm. The physical properties results in weight ratio and thickness were performed.

The Bombyx Mori silk fiber polymer composites showed a lower weight ratio and lower thickness ratio when compared to the synthetic fiber polymer composites. The different values demonstrated the significance. The weight ratio of SFC is 1.508 less than the CFC. The thicknesses of the materials also show the different up to 0.4 mm although this research had been used the total plies of fabrication process as silk fiber cloth is thinner than carbon fiber cloth.

These results supported the facts that Bombyx Mori silk is a natural fiber that has low density (1.3-1.38 g/cm³) when compared with any other synthetic fibers.

Table 4-1 The physical properties test results

Composite Type	Physical Properties of Composites		
	Size	Weight (g/cm²)	Thickness (mm)
Bombyx Silk Fiber Polymer Composites	13 cm x 2 cm	4.600±0.370	1.8±0.2
Carbon Fiber Polymer Composites	13 cm x 2 cm	6.108±0.245	2.2±0.4

4.1.3 The Mechanical Properties Test Results

4.1.3.1 Hardness Test Results

The Rockwell Hardness test was done following ASTM D 2240 showed the results in hardness shore D of the composites. The results showed that Bombyx silk fiber polymer composites had the potential of Hardness Shore D to 63.6±4.8 while the carbon fiber polymer composites had shown nearly the same values of 63.7±7.2. The results identified that both silk fiber polymer composites and carbon fiber polymer composites had quite nearly the same hardness, although they had provided different ratios of weight and thickness.

Table 4-2 The hardness test results

Composite Type	Mechanical Properties of Composites
	Hardness Shore D
Bombyx Silk Fiber Polymer Composites	63.6±4.8
Carbon Fiber Polymer Composites	63.7±7.2

4.1.3.2 Tensile Strength Test Results

The tensile strength tests were used to investigate the deformation or breakage of the specimens under a gradually increasing tension load. The results show that the synthetic carbon fiber polymer composites had a high average value of tension load (93.1±19.6 MPa) when compared to the Bombyx Mori silk fiber polymer composites (27.3±2.22 MPa). The difference values of the tensile strength of the two composites are statistical significant for P-value <0.05 (P-value = 0.017)

Table 4-3 The tensile strength test results of the two composites
(Mean significant difference at the P<0.05 level with an asterisk (*))

Composite Type	Mechanical Properties of Composites	
	Tensile Strength (MPa)	Tensile Strength / Weight (MPa/g)
Bombyx Silk Fiber Polymer Composites	27.3±2.22	5.935±0.004
Carbon Fiber Polymer Composites	93.1±19.6	15.078±2.661
P-Value	0.017*	-

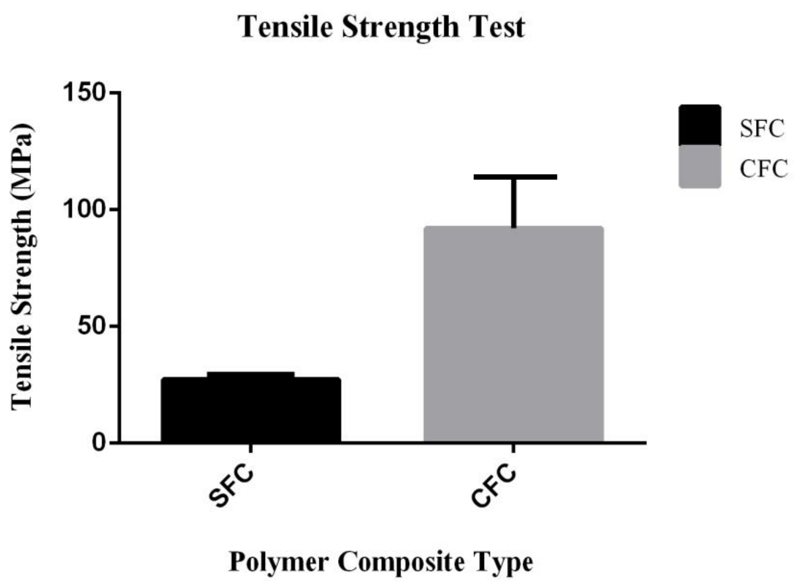


Figure 4-1 Tensile strength of the two composites

Percent of elongation at break

In the tensile strength test, the percent value of elongation of material before breakage had been shown. Interestingly, the elongation percentage (6.9%±2.3%) of silk fiber polymer composite had shown higher value than the carbon fiber composite (2.8%±1.6%). The percentage values were quite different and show the significant value (P-value = 0.012)

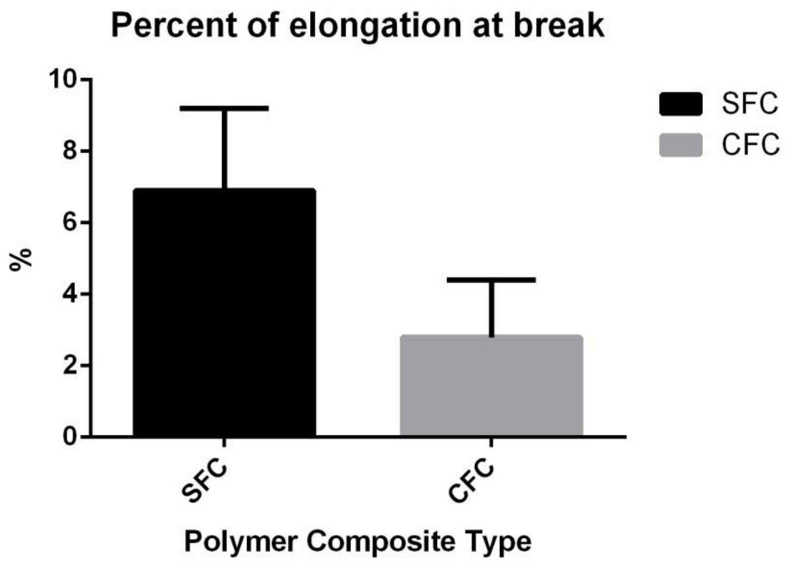


Figure 4-2 Percent of elongation at break of the two composites

Young's Modulus

In the tensile strength test, the Modulus of elasticity values were obtained under the stress-strain curves to show the tendency to be deformed elastically. The modulus of elasticity 498.25±79.74 MPa, silk fiber polymer composite, has less value than carbon fiber polymer composite 1,294±500.59 MPa; however, the different values were not shown the statistical significant (P-value = 0.072).

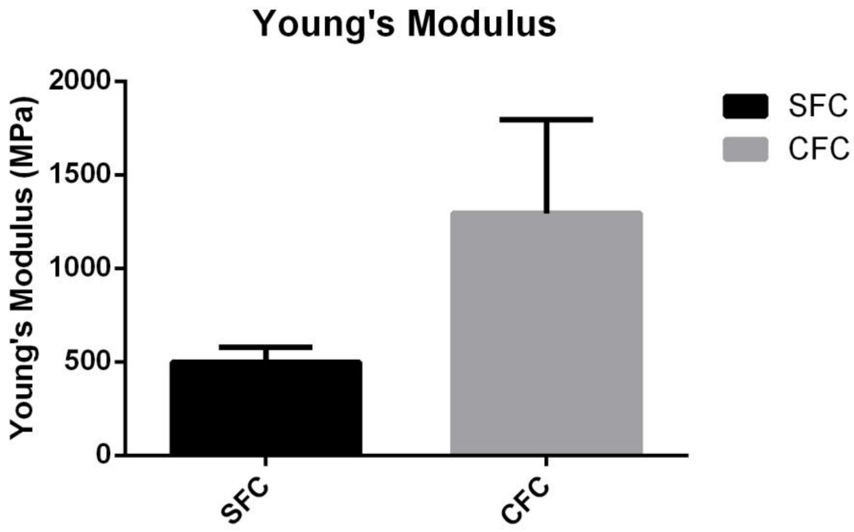


Figure 4-3 Young's Modulus of the two composites

4.1.3.3 Flexural Strength Test Results

Flexural bend test was done under the standard of ASTM D 790 for three points of the composites. This test will provide the values from the calculation of flexural strength that can predict the ability of deforming resistance under the load of the composites. The results showed that the natural Bombyx silk composites had the flexural strength of 41.4±2.34 MPa which was less than the synthetic carbon fibers group with the values of 81.3±6.42 MPa. The different values showed the statistical significant (P-value = 0.000).

Table 4-4 The flexural strength test results

(Mean significant difference at the $P<0.05$ level with an asterisk (*))

Composite Type	Mechanical Properties of Composites	
	Flexural Strength (MPa)	Flexural Strength / Weight (MPa/g)
Bombyx Silk Fiber Polymer Composites	41.4±2.34	8.935±0.002
Carbon Fiber Polymer Composites	81.3±6.42	13.310±0.427
P-Value	0.000*	-

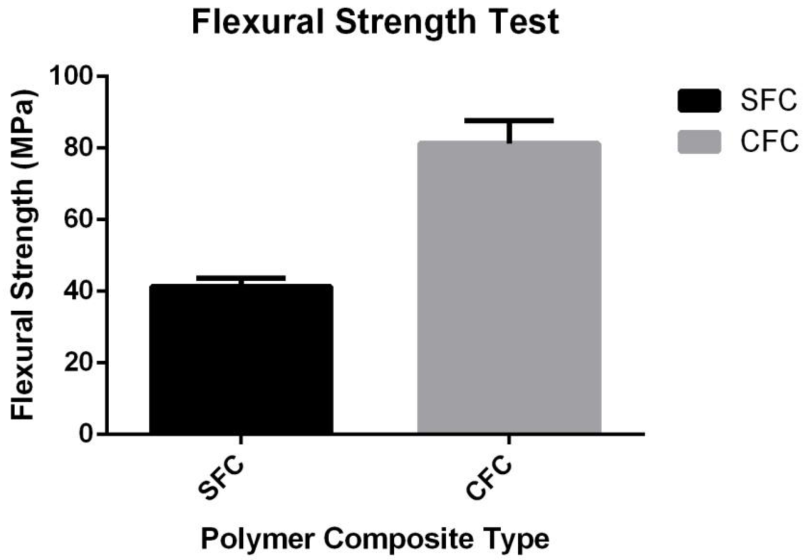


Figure 4-4 Flexural strength of the two composites

Flexural Modulus

The flexural modulus shows the tendency of the materials to bend before deformation. The results showed that the bombyx silk fiber polymer composites had less values of 1,601±150 MPa than the carbon fiber polymer composites of 3,000±109 MPa and the different values between the two composites showed the statistical significant (P-value=0.000).

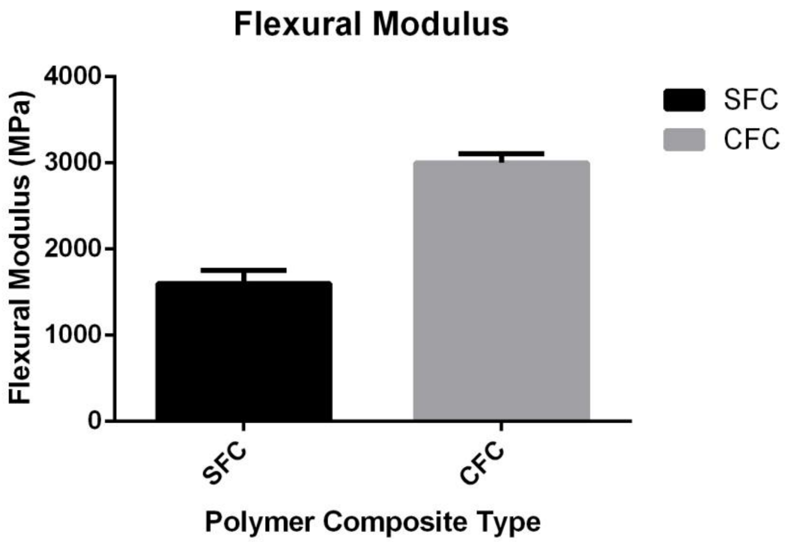


Figure 4-5 Flexural Modulus of the two composites

4.1.3.3 Fatigue Test Results

The material fatigue test had been done using the Instron machine and provided cycle loading to the materials. The results showed that silk fibers polymer composites given higher numbers of rounds (24,860±1,688) that the carbon fibers polymers composites (19,468±652.92) with statistically significant.

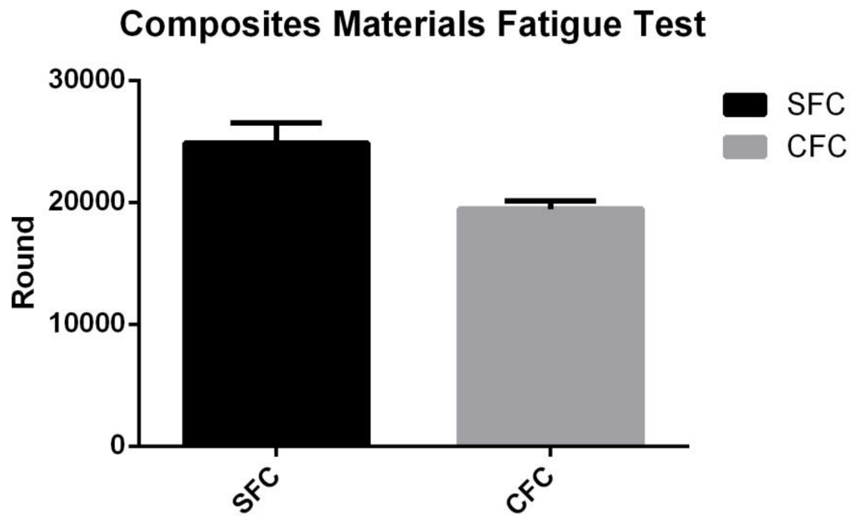


Figure 4-6 Comparison of composites materials fatigue test

4.1.3.4 Device Fatigue Test Results

The device fatigue test had been done by using modified gauge device. This modified gauge used 2 Hz speed for testing. The results showed the satisfied round numbers that silk fibers polymer composites had higher round numbers (90,246±3,116.53) than the round numbers (73,706.67±6,136.548) of carbon fiber polymer composites.

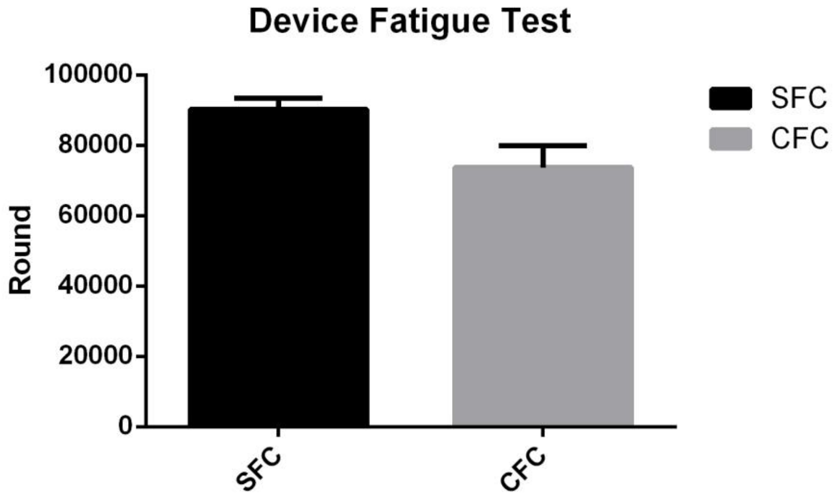


Figure 4-7 Device Fatigue of the two composites

4.1.3 The Scanning Electron Microscopy (SEM) Analysis

The SEM analysis in this research was done to analyze the surface morphology of the materials to see how good materials surfaces were attached before and after tensile strength testing. The two conditions of composites were done to compare the cross section and attaching different under cutting by saw condition and under passing the tensile strength test.

In 30 percent magnification under the saw cutting condition, the surface of silk fiber polymer composites had better attachment with the matrix with no space between layers while the carbon fiber polymer composites had shown the little space between layers. In the matrix area for both two fibers group, the holes had appeared because of the air inside the composites as in figure 4-9. In 200 percent magnification, the space between the layers can be clearly seen in the carbon fiber polymer composites while the silk fibers composites had quite small spaces between the fiber and the matrix as in figure 4-10.

Under passing the tensile strength test, the fibers had been pulled and tore following the test that lead to split the layers between the fibers and the matrix. In 30 percent magnification, the silk fibers composites were still shown better attachment between the layers while the carbon fiber composites shown the straight stripe of carbon fibers and spaces can be seen. In 200 percent magnification, the silk fibers had torn from the matrix surface as the carbon fibers; however, the spaces between layers were not quite wide.

a

b

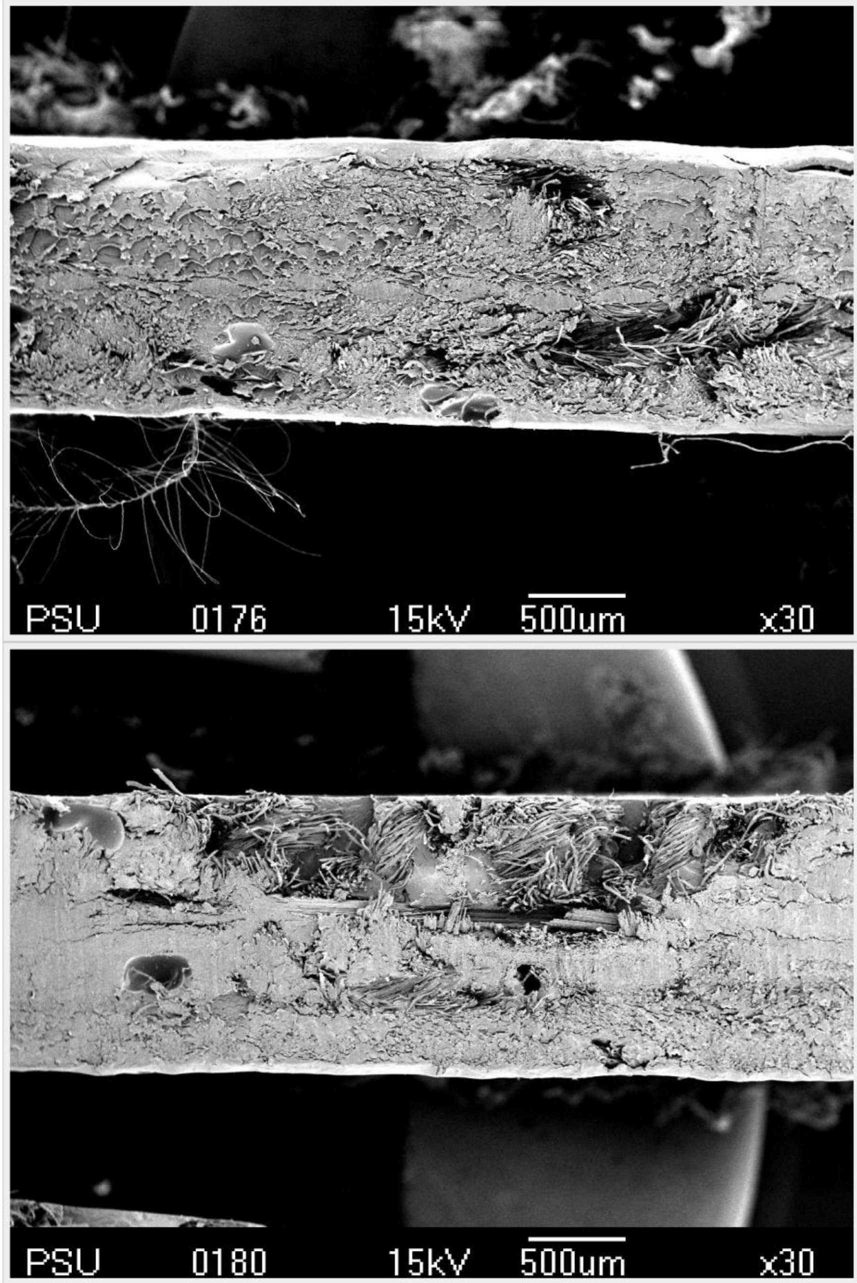


Figure 4-8 SEM Analysis with 30 percent magnification under cutting condition

a) silk fiber polymer composite b) carbon fiber polymer composite

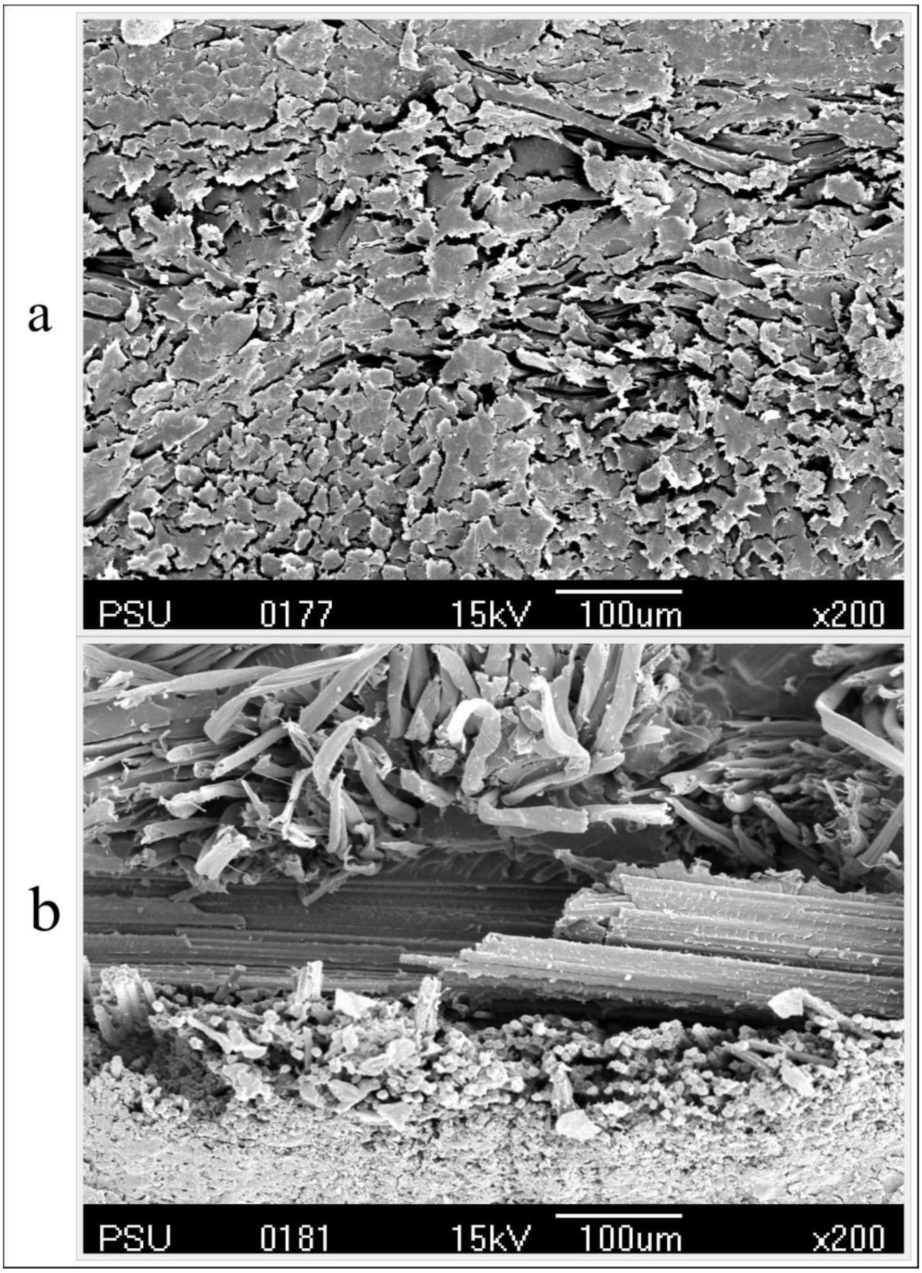


Figure 4-9 SEM Analysis with 200 percent magnification under cutting condition a) silk fiber polymer composite b) carbon fiber polymer composite

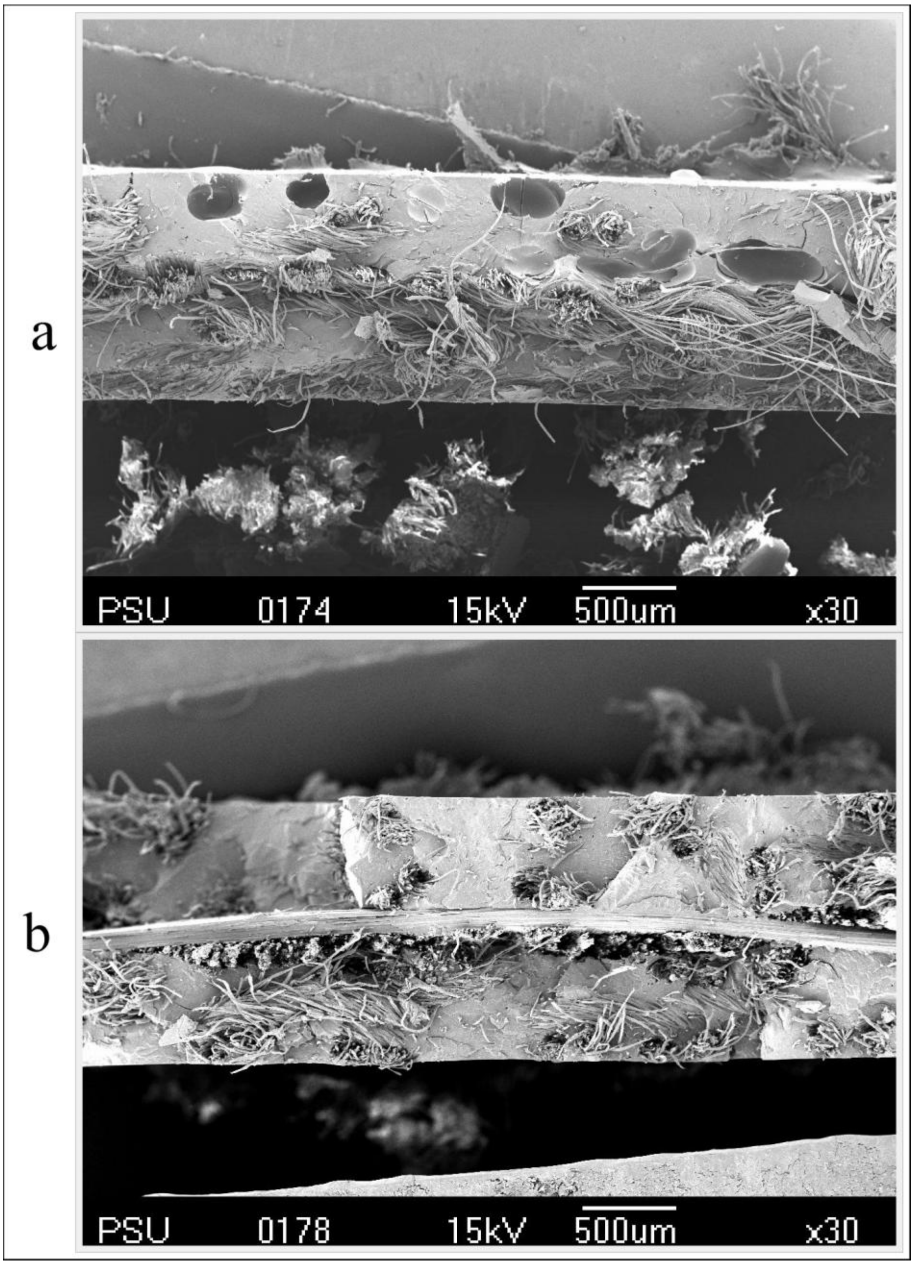


Figure 4-10 SEM Analysis with 30 percent magnification under passing tensile strength test a) silk fiber polymer composite b) carbon fiber polymer composite

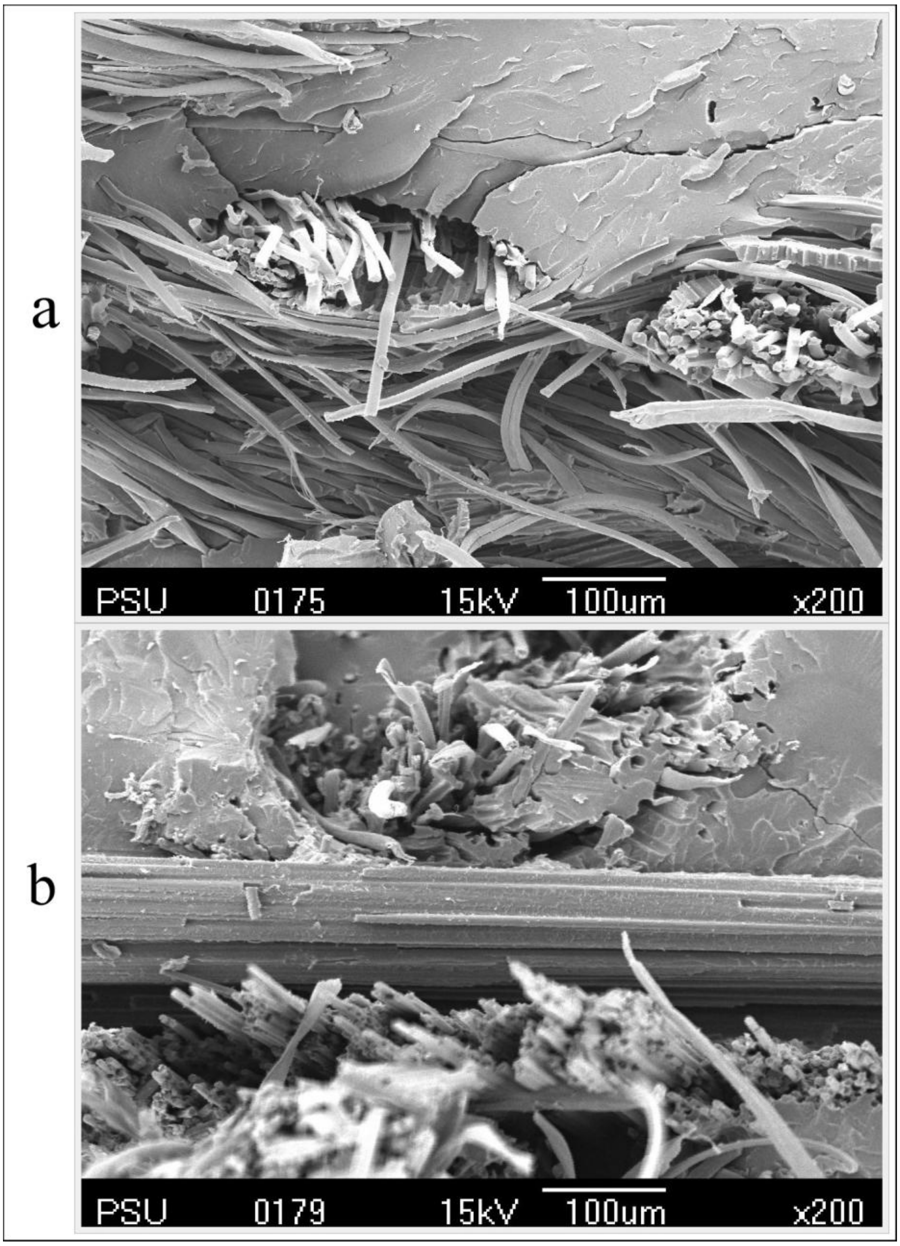


Figure 4-11 SEM Analysis with 200 percent magnification under passing tensile strength test a) silk fiber polymer composite b) carbon fiber polymer composite

4.2 Clinical Testing Results

This research will design and fabricate silk fiber polymer composite foot orthoses for physiologic flat feet children and compare the clinical results with carbon fiber polymer composite foot orthoses.

4.2.1 Participants Characteristics

For all participants of 14, the research had been separated into two groups which are the silk fiber polymer composites (SFC) group for 7 and carbon fiber polymer composites (CFC) group for 6 by randomization. One participant in CFC group was excluded because of the follow-up absent. There are one boy and 6 girls in SFC group and 2 boys and 4 girls in CFC group. In the mean ages in the SFC group were 11.43±2.45 years old and in the CFC group were 10.00±3.49 years old. The weight and height of all participants were collected and calculated for body mass index (BMI). The SFC group had the mean BMI of 23.18±2.82 and CFC group of 21.74±0.97. Every participant had bilateral flat feet and never experienced foot orthoses before.

Table 4-5 Participants Characteristics

	SFC Participants	CFC Participants
Numbers (people)	7	6
Age (years)	11.43±2.45	10.00±3.49
Weight (kg)	52.57±16.05	37.08±19.56
Height (cm)	151.14±19.33	128±31.05
BMI (kg/m²)	23.18±2.82	21.74±0.97

4.2.2 The Studies of Foot Pressure Graph

The Foot pressure graph is the instrument to investigate the foot pressure distribution. The foot pressure graph of all the participants were done and shown that all participants had flat feet both sides. The foot pressure graph was obtained before and after wearing foot orthoses to see the changes.

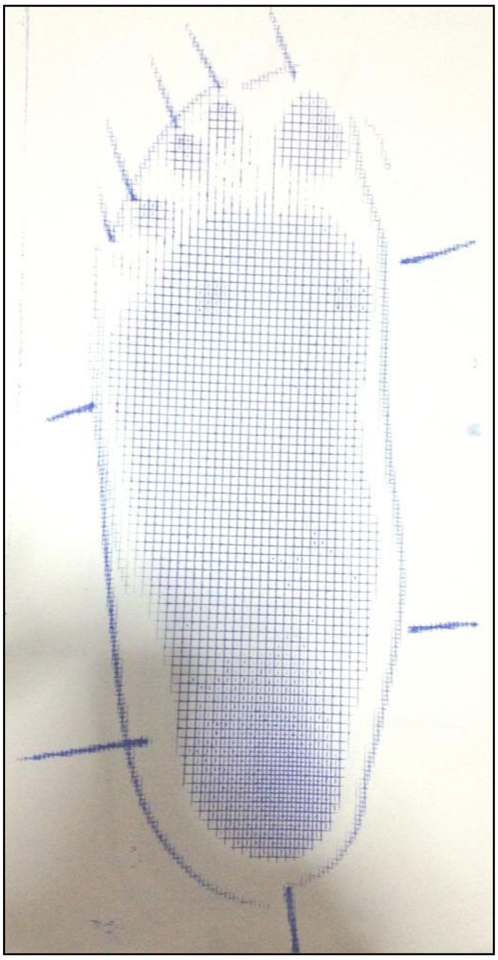


Figure 4-12 Flat feet shown in foot pressure graph

4.2.2 The Studies of Staheli Arch Index (SAI)

The Staheli arch index (SAI) is the parameter that used to measure the static-postural changes of the feet. The SAI can be calculated the value from the foot pressure graph obtained from the participants. An arch index of greater than 0.26 is indicative to have a planus foot. The SAI was done in both feet before and after wearing the foot orthoses. Before wearing the orthoses, all participants in both two groups were shown the SAI value more than 0.26. After wearing the foot orthoses, both two groups showed the improvement of flat feet condition as the values of SAI became less. From the SAI data of participants in both two groups, the arch index before wearing and after wearing the foot orthoses showed the value more than 0.26, however, after wearing the foot orthoses, the arch index seem to get lower than before.

Table 4-6 SAI Characteristic before and after wearing
silk fiber polymer composite foot orthoses

SFC Characteristic	Mean	SD	Range
SAI left foot before wearing FO	1.2271	0.27041	0.73-1.50
SAI right foot before wearing FO	1.1071	0.24824	0.77-1.33
SAI left foot after wearing FO	1.0757	0.28815	0.71-1.48
SAI right foot after wearing FO	0.9629	0.30247	0.59-1.37

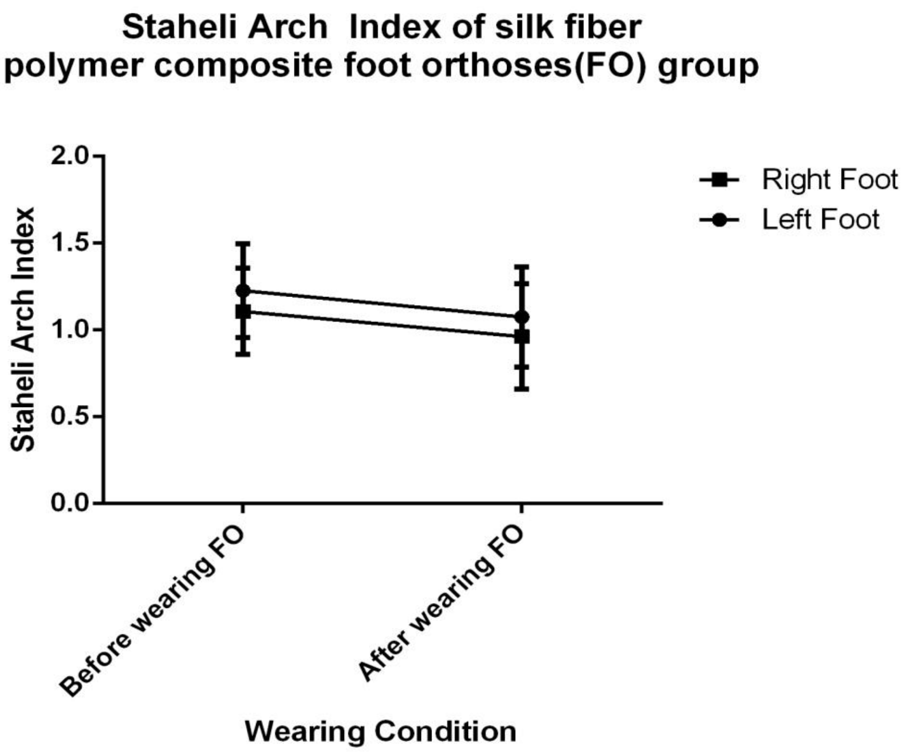


Figure 4-13 Staheli Arch Index of silk fiber polymer composite group

Table 4-7 SAI Characteristic before and after wearing

carbon fiber polymer composite foot orthoses

CFC Characteristic	Mean	SD	Range
SAI left foot before wearing FO	1.1233	0.27682	0.77-1.52
SAI right foot before wearing FO	1.0983	0.28089	0.74-1.42
SAI left foot after wearing FO	1.0983	0.28632	0.75-1.50
SAI right foot after wearing FO	1.0917	0.28875	0.66-1.42

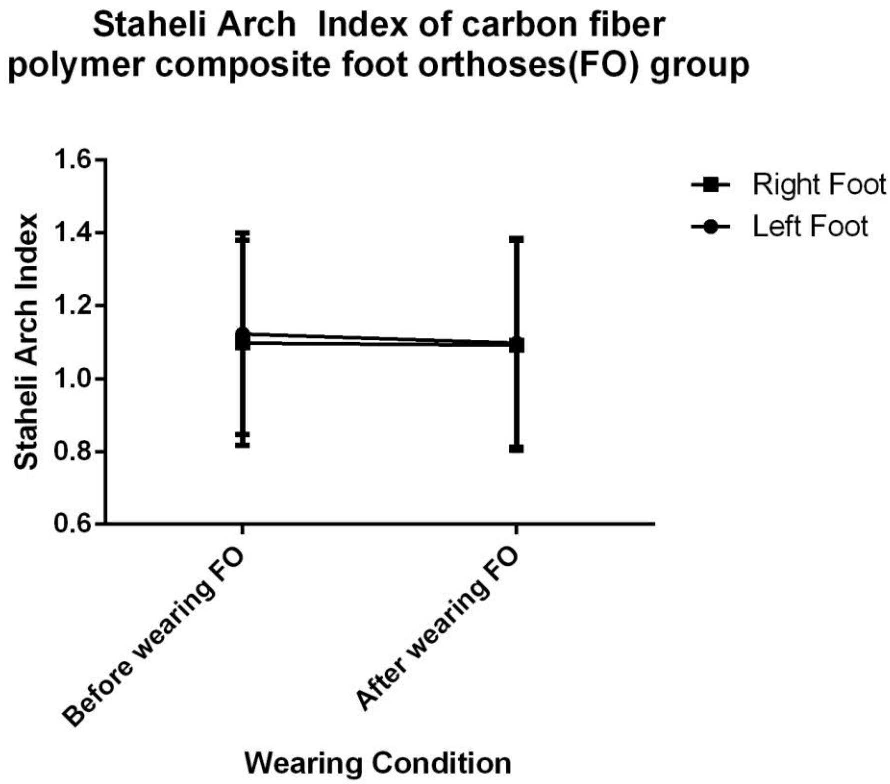


Figure 4-14 Staheli Arch Index of carbon fiber polymer composite group

In the silk fiber polymer composites group, the results showed that there are the SAI value became getting lower in every participants. The difference between before and after wearing the foot orthoses was statistically significant of P-value < 0.05 in both left foot (P-value=0.035) and right foot (P-value=0.019). Within the carbon fiber polymer composites group, the SAI value also showed the lower value than before but the significant difference did not show. When compare between two groups in before and after wearing the foot orthoses, the changes did not show the different and the significant value.

Table 4-8 Comparison of SAI in Silk Fiber Polymer Composite Group between before and after wearing the foot orthoses (Mean significant difference at the P<0.05 level with an asterisk (*))

SFC Characteristics	Mean (SD)	P-Value
SAI left side	0.15143 (0.14173)	0.035*
SAI right side	0.14429 (0.12026)	0.019*

Table 4-9 Comparison of SAI in Carbon Fiber Polymer Composite Group between before and after wearing the foot orthoses (Mean significant difference at the P<0.05 level with an asterisk (*))

CFC Characteristics	Mean (SD)	P-Value
SAI left side	0.02500 (0.02510)	0.059
SAI right side	0.00667 (0.12258)	0.899

Table 4-10 Comparison of SAI between silk fiber composite group and carbon fiber polymer composite group in before and after wearing the foot orthoses
(Mean significant difference at the P<0.05 level with an asterisk (*))

Characteristics	Before Wearing FO		After Wearing FO	
	Mean Difference	P-Value	Mean Difference	P-Value
SAI left side	0.10381	0.510	-0.02262	0.890
SAI right side	0.00881	0.954	-0.12881	0.450

4.2.3 The Studies of Normalized Navicular Height Truncated (NNHT) Measurement

The Normalized Navicular Height Truncated (NNHT) Measurement is another parameter to assess the symptom of flatfeet. The value of less than 0.24 is indicated to have flat feet. From the NNHT data of participants in both two groups, the NNHT before wearing and after wearing the foot orthoses showed the value less than 0.24, however, after wearing the foot orthoses, the NNHT seem to get higher than before.

Table 4-11 NNHT Characteristic before and after wearing silk fiber polymer composite foot orthoses

SFC Characteristic	Mean	SD	Range
NNHT left foot before wearing FO	0.2129	0.03729	0.17-0.28
NNHT right foot before wearing FO	0.2200	0.02944	0.19-0.28
NNHT left foot after wearing FO	0.2300	0.04000	0.20-0.31
NNHT right foot after wearing FO	0.2329	0.03450	0.20-0.30

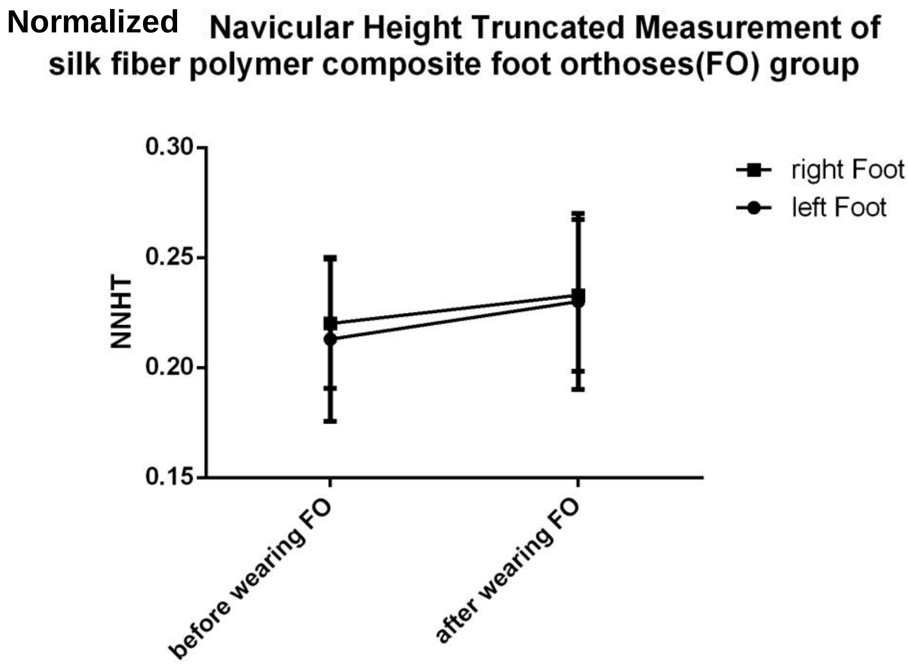


Figure 4-15 Normalized Navicular Height Truncated (NNHT) Measurement of silk fiber polymer composite group

Table 4-12 NNHT Characteristic before and after wearing carbon fiber polymer composite foot orthoses

CFC Characteristic	Mean	SD	Range
NNHT left foot before wearing FO	0.1967	0.04082	0.12-0.23
NNHT right foot before wearing FO	0.1950	0.03564	0.13-0.23
NNHT left foot after wearing FO	0.2117	0.04167	0.13-0.24
NNHT right foot after wearing FO	0.2100	0.03225	0.15-0.24

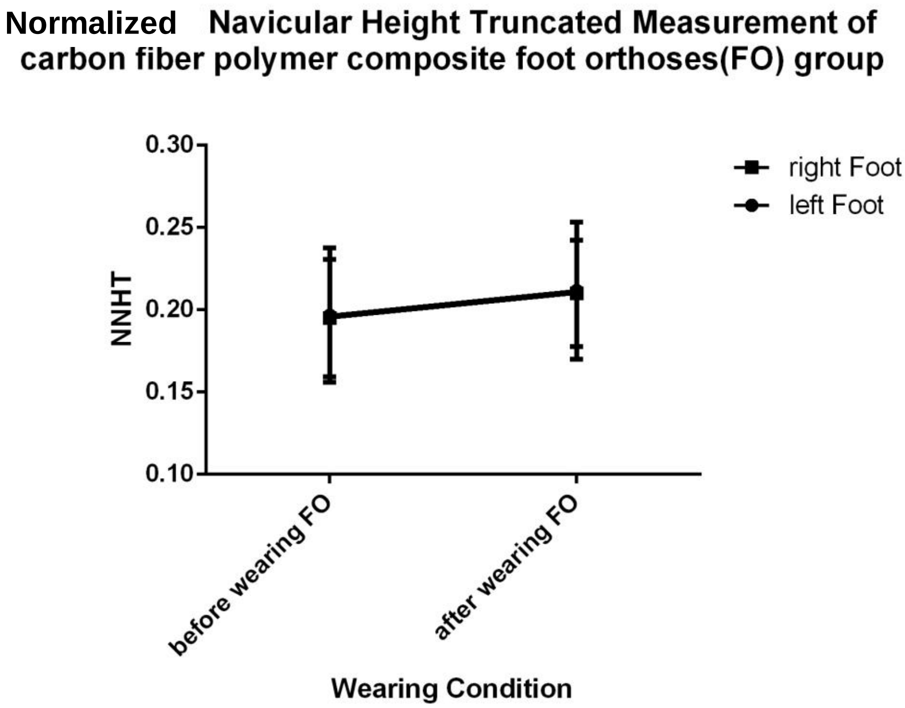


Figure 4-16 Normalized Navicular Height Truncated (NNHT) Measurement of carbon fiber polymer composite group

The results showed that there are the higher NNHT values in participants in the silk fiber polymer composites group. The difference between before and after wearing the foot orthoses was statistically significant of P-value < 0.05 in both left foot (P-value=0.017) and right foot (P-value=0.004). In the carbon fiber polymer composites group, the NNHT values also became higher than before with the significant difference can be seen. However, when the research compared the results between two groups of device in before and after wearing the foot orthoses, the changes did not show the different and the significant value.

Table 4-13 Comparison of NNHT in Silk Fiber Polymer Composite Group between before and after wearing the foot orthoses (Mean significant difference at the P<0.05 level with an asterisk (*))

NNHT Characteristics	Mean (SD)	P-Value
NNHT left side	-0.01714 (0.01380)	0.017*
NNHT right side	-0.01286 (0.00756)	0.004*

Table 4-14 Comparison of NNHT in Carbon Fiber Polymer Composite Group between before and after wearing the foot orthoses (Mean significant difference at the P<0.05 level with an asterisk (*))

NNHT Characteristics	Mean (SD)	P-Value
NNHT left side	-0.01500 (0.01049)	0.017*
NNHT right side	-0.01500 (0.01049)	0.017*

Table 4-15 Comparison of NNHT between silk fiber composite group and carbon fiber polymer composite group in before and after wearing the foot orthoses (Mean significant difference at the P<0.05 level with an asterisk (*))

Characteristics	Before Wearing FO		After Wearing FO	
	Mean Difference	P-Value	Mean Difference	P-Value
NNHT left side	0.01619	0.475	0.01833	0.438
NNHT right side	0.02500	0.203	0.02286	0.243

4.2.4 The Studies of Resting Calcaneal Stance Position (RCSP)

The Resting Calcaneal Stance Position (RCSP) measures the degree of the calcaneus valgus from flat feet. The valgus of more than 0 degree seems to experience flat feet. From the RCSP data of participants in both two groups, the RCSP before wearing and after wearing the foot orthoses showed the degree value more than 0 degree; however, after wearing the foot orthoses, every participant seem to have the same or less degree value than before.

Table 4-16 RCSP Characteristic before and after wearing silk fiber polymer composite foot orthoses

SFC Characteristic	Mean	SD	Range
RCSP left foot before wearing FO	7.57	2.699	5-13
RCSP right foot before wearing FO	7.86	1.069	7-10
RCSP left foot after wearing FO	6.43	2.992	5-13
RCSP right foot after wearing FO	6.71	0.951	5-8

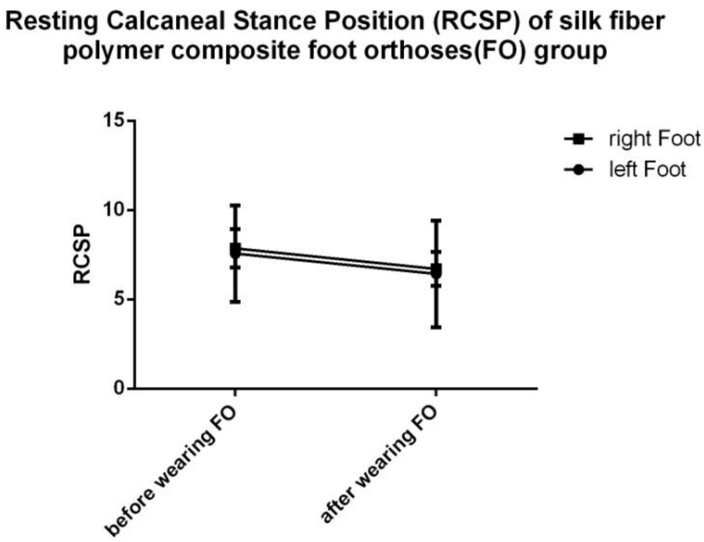


Figure 4-17 Resting Calcaneal Stance Position (RCSP) of silk fiber polymer composite group

Table 4-17 RCSP Characteristic before and after wearing

carbon fiber polymer composite foot orthoses

CFC Characteristic	Mean	SD	Range
RCSP left foot before wearing FO	8.00	2.530	5-12
RCSP right foot before wearing FO	7.83	1.941	5-10
RCSP left foot after wearing FO	7.00	1.897	5-10
RCSP right foot after wearing FO	6.67	2.066	5-10

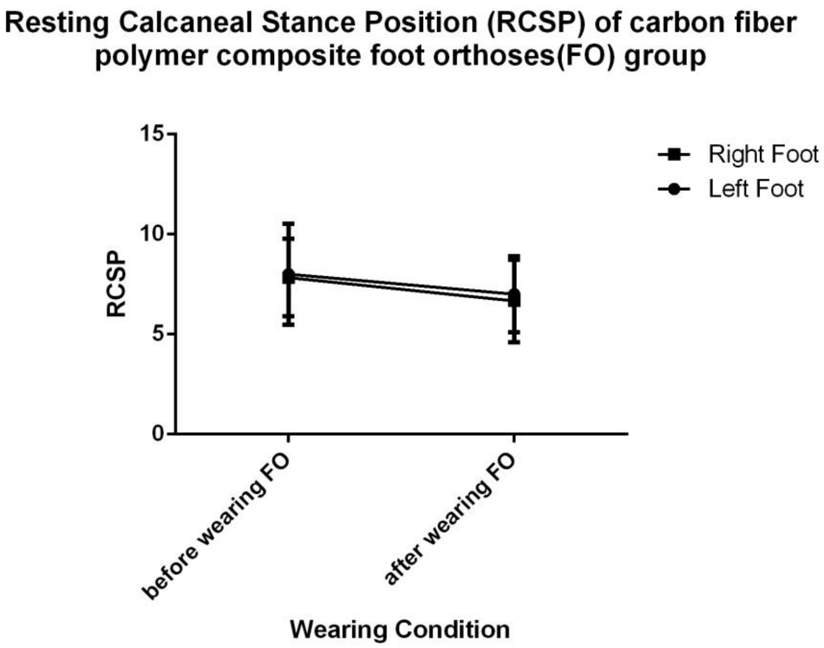


Figure 4-18 Resting Calcaneal Stance Position (RCSP) of

carbon fiber polymer composite group

The results showed that there are the decreases in degrees in participants in the silk fiber polymer composites group. The difference between before and after wearing the foot orthoses was statistically significant of P-value < 0.05 in both left foot (P-value=0.047) and right foot (P-value=0.047). In the carbon fiber polymer composites group, the RCSP values also decrease in degrees than before with the significant difference of the left foot (P-value=0.076) and the right foot (P-value=0.034). However, when the research compared the results between two groups of device in before and after wearing the foot orthoses, the changes did not show the different and the significant value.

Table 4-18 Comparison of RCSP in Silk Fiber Polymer Composite Group between before and after wearing the foot orthoses (Mean significant difference at the P<0.05 level with an asterisk (*))

RCSP Characteristics	Mean (SD)	P-Value
RCSP left side	1.143 (1.215)	0.047*
RCSP right side	1.143 (1.215)	0.047*

Table 4-19 Comparison of RCSP in Carbon Fiber Polymer Composite Group between before and after wearing the foot orthoses (Mean significant difference at the P<0.05 level with an asterisk (*))

RCSP Characteristics	Mean (SD)	P-Value
RCSP left side	1.000 (1.095)	0.076*
RCSP right side	1.167 (0.983)	0.034*

Table 4-20 Comparison of RCSP between silk fiber composite group and carbon fiber polymer composite group in before and after wearing the foot orthoses

(Mean significant difference at the P<0.05 level with an asterisk (*))

Characteristics	Before Wearing FO		After Wearing FO	
	Mean Difference	P-Value	Mean Difference	P-Value
RCSP left side	-0.429	0.773	-0.571	0.685
RCSP right side	0.979	0.024	0.048	0.960

4.2.5 The Assessment from Participant's Satisfaction Questionnaires

After wearing the foot orthoses, the participants in both two groups had filled out the satisfaction questionnaires. The silk fibers polymer composites group had the number of 7 participants with 7 questionnaires and the carbon fibers polymer composites group had the number of 6 participants with 6 questionnaires.

The participants in silk fibers polymer composites groups stated that they all totally agree (100%) that the foot orthoses could help to treat their flat feet pathology. While they were using, they feel safe and ensure with the foot orthotic device. It is easy to use and don inside the shoes. In the point of waking gait characteristics, 6 participants (85.71%) out of 7 were satisfied with the foot characteristics and walking pattern; however, the one participant left was stated that they felt and noticed that the feet still looked abnormal and waling with the valgus pattern as before. About the price of the silk fibers polymer composites foot orthotic device, 5 participants (71.43%) out of 7 were satisfied with the price and can be affordable if they were needed to wear next time of treatment but the 2 said that the prices were quite high if they thought that it is the foot orthoses for the children. For additional comments from the participants, one participant stated that he didn't like the color of the foot orthoses as he preferred to have plain color for example brown or black of the foot orthoses and one participant stated that she felt very glad to know that the clinics nowadays have a device to treat the foot pathology.

In the carbon fibers polymer composites group, the all participants (100%) stated that the wearing foot orthoses can help the flat feet pathology. The foot orthoses were safe and easy to use. 4 participants (66.67%) out of 6 participants stated that it could help their foot alignment and walking characteristics but the two left claimed that they were hard to be seen the differences within eyes sights. The 3 participants (50%) could be afforded with the price of the foot orthoses while the 3 left (50%) stated that the foot orthoses were very expensive. For additional comments, 2 participants (33.33%) stated that the foot orthoses are too hard and not flexible for running.

Chapter 5

Discussions and Conclusion

The 3 important parts which are the scientific part, the clinical part and the economical part are brought to be discussed following these:

5.1 Scientific - The materials testing results

The two composites material testing which are silk fibers polymer composites and carbon fibers polymer composites had been done in the physical properties test and mechanical properties test. Moreover, the materials had been studies through the morphology by using Scanning Electron Microscope (SEM) analysis. The objectives are to find out the differences, the advantages of silk fiber polymer composites to be used for foot orthoses as medical devices to treat the flat feet pathology instead of carbon fiber foot orthoses.

Silk fibers and carbon fibers were produced as the composites in the same size preparing for the tests. The physical properties of the composites can be achieved from the base materials that affected the characteristics of the composites. The physical properties that need to take into consideration are weight ratio and thickness of the composites. The two composites groups were performed and find the mean value. The Bombyx Mori silk fiber polymer composites showed a lower weight ratio and lower thickness ratio when compared to the synthetic fiber polymer composites. These results supported the facts that Bombyx Mori silk is a natural fiber that has low density (1.3-1.38 g/cm^3) when compared to any other synthetic fibers. Although the two composites were produced in the same size and equal plies of fabrication, the weight ratio and thickness ratio of the natural composites still be less than the synthetic one. From this results, it can be referred that silk fiber polymer composite has the feasibility to be produced as materials for medical devices that need special properties of light weight and not cumbersome.

The mechanical testing that were done for this research were the hardness test, the tensile strength test, the flexural strength test and the fatigue test. The same as physical properties testing, the two composites groups were produced for the same size for the test.

The hardness test by finding "Hardness Shore D" demonstrated that the Bombyx silk fibers polymer composites had shown nearly the same values of hardness as carbon fiber polymer composites, although they had provided different ratios of density according to weight and thickness. Concerning this result, it showed that silk fibers polymer composites might be used as materials for medical devices that need scratch resistance that can be bearable with the breakage.

The tensile strength tests were used to investigate the deformation or breakage of the specimens under a gradually increasing tension load. The results showed that the synthetic carbon fiber polymer composites had a high average value of tension load with the statistical significance values shown when compared to the Bombyx Mori silk fiber polymer composites. For modulus of elasticity, silk fiber polymer composite has also fewer values than carbon fiber polymer composites significantly. Interestingly, the elongation percentage of silk composite is higher than the carbon fiber composite with statistical significant. According to this result, it showed that silk fibers polymer composite was more ductile than carbon fibers polymer composite, due to its toughness, and has the feasibility to be used as a material for medical devices. Such material might be a good choice for foot orthoses.

The flexural strength tests from the three point flexural bend test of the composites were done. This test will provide the calculations values of flexural strength and flexural modulus that can predict the ability of deforming resistance under the load of the composites. The results showed that the natural bombyx silk fibers polymer composites had the less flexural strength than the synthetic carbon fibers polymer composites group with statistical significant.

From the test results, the strength per weight of the composites can be calculated and discussed on the point of strength per weight of tensile and flexural test. The results displayed that the carbon fiber polymer composites had both a higher value of the tensile strength and the tensile strength per weight than the natural fibers polymer composites. And the flexural strength and flexural strength per weight of the synthetic fibers had performed the same tendency.

Interestingly, comparison of the tensile strength and flexural strength of the composites was expressed that the natural bombyx silk fibers polymer composites had high flexural strength and low tensile strength; that means that they had good resistance under bending and torque. Conversely, although the carbon fiber polymer composites had shown the high value of tensile strength, the ability of resisting in bending and torque was low. Concerning the above results, it might be deduced that the silk fiber polymer composites had the good properties of medical applications that required flexible strength. Such flexural strength of silk fibers polymer composites might be a good choice for foot orthoses.

The fatigue tests of the two composites were done to determine the resiliency or durability of the material by measuring the number of cycles to failure. The results showed that silk fibers polymer composites had the higher numbers of cycles loading than the carbon fibers polymer composites. The carbon fibers polymer composites were destroyed from using more than the silk fibers polymer composites. However, the effects of destruction that leads to fatigue failure may come from the stress concentration, the size and surface defect of composites. From the results, the silk fibers polymer composites can be used as medical devices that can bear with the fatigue using more than the carbon fibers polymer composites. Significantly, because of good fatigue testing results for silk fibers polymer composites, it promises to use as materials for foot orthoses.

The device fatigue tests also showed the same tendency as the composite material fatigue test. From the composite foot orthoses that test with the gauge attached with prosthetic foot and shank, the numbers of the rounds like gait cycle can be counted. The results showed that the silk fibers polymer composites foot orthoses can bear with the fatigue test with the more number of gait cycles than the carbon fiber polymer composites. Moreover, the positions of the destroyed area before stopped were the trim of the foot orthoses not the plantar part that needs to bear weight of the wearers. From the results, the silk fibers polymer composites can be prolonged using of the wearers much more than the carbon fibers ones. Importantly, such device as good results of fatigue testing, the results indicate that device made by silk fibers polymer composite might be a suitable choice for foot orthoses.

To prove all the physical and mechanical testing, the SEM analysis was done to see the attachment and the destruction areas and overall morphology of the two composites. The cutting surface and the surface after tensile testing done were shown the same tendency that silk fibers polymer composites can attach with the matrix which is acrylic resin very well as the photos showed very narrow spaces between the plies of the matrix while the carbon fibers polymer composites still provided the gap between the plies that can be easily seen. The SEM analysis can be confirmed that the silk fibers polymer composites have good morphology and less weak points that lead to the destruction of the composites than carbon fibers polymer composites. As the results, such morphology of fibers polymer composite indicate that silk fiber has good adhesion with matrix. Such good adhesion might be the cause of good fatigue results of silk fiber composite.

In the part of material testing, it can be concluded that the silk fibers polymer composites are the natural composites that are very crucial and can be the alternative choice for the medical devices. Because of their own physical characteristics of light weight, strongly packed structure and good mechanical characteristics of strength and toughness and deforming resistance, the Bombyx Mori silk polymer composites can become the new trend of the material that has good properties for working, like the synthetic carbon fiber polymer composites; moreover, the low price and fact that they are not harmful to patients. Therefore, Bombyx Mori silk fibers polymer composite is promising material for medical applications.

5.2 Clinic - The clinical testing results

Foot orthoses are widely used in non-surgical management of pediatric flexible flat feet for initial treatment; however, there are no definitive patterns of foot orthoses using and their effects of intervention. There are many studies about these that the researchers tried to find the answers that foot orthoses are necessary and be helpful for the children’s feet or not. All studies show the immediate foot-wear and foot orthoses found an improvement in foot posture. The studied showed the reduction in foot abduction significantly. Although, not every studies show the improvement or the good outcomes with statistical significant, but the effects of the foot orthotic in flexible flat feet children show the good development of the children’s feet and haven’t shown the adverse effect to get rid of from using it.

Moreover, the design and material of foot orthoses are very difficult to choose. Foot orthoses can be categorized as soft, rigid and semi-rigid which are vary in quantitative motion control and depends on the patients. The most cost-effective choices would be take into considerations. Many low-cost, generic foot orthoses can provide good positional support of the child’s foot and relief of presenting symptoms. UCBL design or the design that have rigid, semi-rigid shell have property to correct the Calcaneus angle of the children's feet showed the positive effect and were popular in application. The UCBL usually makes up from thin, light weight, semi-rigid polypropylene; however, its design looks bulky and makes difficulty utilizing in most shoes. Nowadays, there are many UCBL modification and design that increase both function and cosmesis of the orthoses. The fabric or very thin foam will be use for the liner to create comfort and increase friction of the orthoses.

From the studies review before, this research had conquered the weak points of using in clinic by choosing the UCBL design of the foot orthoses to treat the flexible flat feet children by using the silk fiber polymer composite that is rigid enough to control the foot arch and alignment and less bulky and to substitute the rigid synthetic carbon fiber foot orthoses.

The two group participants were set in the group of 7. The BMI of the participants had controlled in range of normal in order to cut out any other variance. The ages of the participants were chosen in the range of 7 to 18 years old which were the children that can be progress in bony alignment and pathology. The participants had never been experienced to used to foot orthoses before in order to see the progression and efficacy of the foot orthoses to treat symptoms and to alleviate the acclimatization of the users. The participants were blind to choose the foot orthoses group but the examiner was not blind. In carbon fibers polymer composites foot orthoses group, 1 participant was excluded because of lost follow-up. The research had used 3 parameters that identified the flat feet conditions to assess the improvement of the pathology after wearing the foot orthoses which are Staheli Arch Index (SAI), Normalized Navicular Height Truncated (NNHT) measurement, and the Resting Calcaneal Stance Position (RCSP). To compare the improvement, all measurements were done before and after wearing the foot orthoses. All participants got the custom-made foot orthoses that made by the researcher who is the prosthetist and orthotist. The participants must wear the foot orthoses with their comfortable shoes in daily living to acclimatize with the shoes and need to wear the foot orthoses for 14 weeks before coming to the follow-up. The statistical using in the research was the SPSS version 18 to calculate the mean value and the significant level at $P\text{-value}<0.05$. And the graphs were plot by using the Graphpad Program Prism 6.

From the results within the silk fibers polymer composites foot orthoses group, the SAI both left and right foot of the participants had come down in ratio with statistical significant that means the proportional between the midfoot area and the rearfoot area shows the proper foot weight bearing and becomes less flat that before. These changes are inferred through the evaluation of footprints as the medial longitudinal arch has been found to correlate with footprint measurements. The tendency of the SAI results in carbon fiber polymer composites foot orthoses group was the same that wearing the foot orthoses can lead to have less flat of feet; however the different before and after wearing the foot orthoses was not statistical significant. And when compare between two groups, the improvement could be seen but there are no statistical different. The results of SAI can show that wearing the foot orthoses from both two kinds of composites can provided positive effect of foot that bear proper weight and less flat than before.

The NNHT is the ratio of the Height of Navicular bone which is the land mark bone that will collapse to the ground or be misalignment to the truncated foot length. This value is another one parameter to identify the flat feet because of the dimension of the foot alignment to the ground. In silk fibers polymer composites group, the NNHT had become higher in ratio than before in both left and right foot with statistically significant that means the arch dimensions had become higher and the flat of the arch is less than before. In carbon fiber polymer composites, the NNHT had the tendency to be the same as the natural composites device; however, when compare the efficacy of the two materials device group, the improvement occurred but the statistical significant different cannot be seen. The results of NNHT informed that silk fibers polymer composites foot orthoses can be alternative choice to choose for making the foot orthoses that provide positive effect of NNHT for having less flat of feet.

The RCSP is the subjective data collecting from the examiner to see the improvement of the foot alignment that showed the flat feet condition because of the valgus heel position. All participants in both two groups showed the RCSP more than 5 degree in the first time. After wearing the foot orthoses, silk fibers polymer composites foot orthoses participants showed less degree values than before with statistical significant the same as the participants in carbon fibers polymer composites foot orthoses group; however, some participants still showed the same degree of value than before. When compare the improvement of the two groups, the decreasing of the degree value can be seen but they had provided no statistical significant. The results of RCSP can be interpreted that the silk fiber polymer composites devices had the same efficacy as carbon fiber polymer composites to control and correct the foot alignment that are abnormal concerns of flat feet.

From the point of views from the participants' questionnaires, the silk fiber polymer composites foot orthoses had the good responses from the wearer that it can treat the pathology, comfortable, easy to wear, satisfied with the gait characteristic and also affordable with price while the participants from the carbon fibers polymer composites group give more additional comments that the carbon fiber foot orthoses prices seem to be expensive and moreover, it is hard and not flexible for the sport plays.

For the clinical testing results, it can be proved that silk fibers polymer composites foot orthoses can provide positive effects to treat flat feet symptoms in the term of improving of the three parameters which are SAI, NNHT and RCSP and not different from carbon fibers polymer composites foot orthoses. Moreover, the silk fibers polymers composites had good feedback respond from participants' using much more than the synthetic one. They can be used for the alternative choices for fabricating foot orthoses instead of carbon fibers polymer composites.

5.3 Economic Justification

Foot orthsoes are well known for the treatment device of foot pathology. The efficacies of the foot orthoses are from the dexterity and knowledge of the prosthetists and orthotists and the manufacturers; moreover, the strength and the utility of the foot orthoses should be gain from the material used. There are many private companies that supply the raw material for foot orthoses fabricating and the hospitals or clinics or insole manufacturing places can choose what type of materials will be used. The more quality and suitable with the pathology materials, the more expensive they will be. Nowadays, the carbon fibers foot orthoses play the role part of the device trends because of not only its physic cal properties that will make the insoles not to be thick inside shoes and but also the strength characteristics. However, the prices of the insoles are very high and unaffordable in some patients. The hospitals and the manufacturing companies have tried to decrease these high fixed costs, so they tried to use low quality of material instead for example the polypropylene sheet. Although the plastics are cheaper than the carbon fibers composites, the strength and mechanical properties of the materials are very low. The more strength needed, the more thickness of the materials should be gained. So this research tried to find out the new materials from natural sources that can correct the weak points of the carbon fiber composites insoles and substituted using with the economy efficiency.

Table 5-1 Comparison of prices between
FO Composites in the markets and silk fibers polymer composite foot orthoses

FO Composites Market Available Options		Silk Fibers Polymer Composites Foot Orthoses	
● Poly C Carbonet Sheet 4800 baht /m²	**2,440 baht**	● **Acrylic Resin 11,560 baht/carton (4.6 kg)**	**800 baht**
● Thermo formable composite insole	**3,574 baht**	● **Hardener 400 baht/pack(150g)**	**15 baht**
● Springlite carbon foot plate	**3,292 baht**	● **Stockinette cloth (13 cm * 20 cm) 2 pieces**	**45 baht**
● Carbon reinforcing insole	**4,548 baht**	● **Silk Textile (13 cm * 20 cm) 2 pieces**	**100 baht**
		Total	**960 baht**

From the materials testing and clinical testing results, they can be insist that silk fibers polymer composites can be used as foot orthoses devices to correct the flat feet pathology as good as carbon fibers polymer composites. However, the prices from the fix costs were very low. The fix costs of the natural devices were only 960 baht per one pair of insole when compare to the carbon fibers insole prices which were around 2,000 baht up to 5,000 baht. Theses lead to save cost of money for the hospitals, patients and companies up to 40%-80% and can gain quality of the materials at the same time.

5.4 Limitations and Recommendations for Future Studies Plans

5.4.1 Material Part

- The matrix of the composites could be change to other matrix, for example, epoxy resin, PU to find out the different in the physical and mechanical properties of the materials that will influence in the quality of the foot orthoses.

- The natural fiber using in this study is the bombyx silk fibers but other kinds of silk fibers haven't taken a test yet. The results of the physical and mechanical properties can be changed if the kind of the silk fibers changes.

- The material testing should involve the compression testing to see the variable of the materials under the compress loading.

5.4.1 Clinical Part

- The instrument to assess foot pressure is the footprint from the foot pressure graph. There is more reliable foot assessments available that use the computer to identified and interpret for example, FSA systems.

-The parameters to prove the improvement of the pathology should be more than SAI, NNHT and RCSP that assess the static alignment of foot. X-rays and gait lab should be used to assess in terms of dynamic alignment.

-This research is a pilot study research. The results may vary according to the researcher or examiners. It should be change to other study types in order to emphasize the reliability of the clinical results.

- The foot pathology should be change to other foot pathology types to see the efficacies of the foot orthoses to treat the symptoms.

REFERENCES

1. Leung AK, Cheng JC, Mak AF. Orthotic design and foot impression procedures to control foot alignment. Prosthet Orthot Int 2004; 28(3):254–62.

2. Whitford D, Esterman A. A randomized controlled trial of two types of in-shoe orthoses in children with flexible excess pronation of the feet. Foot Ankle Int 2007; 28(6):715–23.

3. Wenger DR, Mauldin D, Speck G, et al. Corrective shoes and inserts as treatment for flexible flatfoot in infants and children. J Bone Joint Surg Am 1989; 71(6):800–10.

4. Gould N, Moreland M, Alvarez R, et al. Development of the child's arch. Foot Ankle 1989; 9(5):241–5.

5. Pfeiffer M, Kotz R, Ledl T, et al. Prevalence of flat foot in preschool-aged children. Pediatrics 2006; 118(2):634–9.

6. Evans AM. The flat-footed child—to treat or not to treat: what is the clinician to do? J Am Podiatric Med Assoc 2008; 98(5):386–93.

7. Bordelon RL: Hypermobile flatfoot in children. Comprehension, evaluation, and treatment. Clinical Orthopaedics & Related Research 1983; 181:7-14.

8. Whitford D, Esterman A: A randomized controlled trial of two types of in-shoe orthoses in children with flexible excess pronation of the feet. Foot and Ankle International 2007; 28:715-723.

9. Evans AM, Scutter SD, Iasiello H: Measuring the pediatric foot – a criterion validity and reliability study of navicular height in 4-year-old children. The Foot 2003; 13:76-82.

10. Powell M, Seid M, Szer IS: Efficacy of custom foot orthoses in improving pain and functional status in children with juvenile idiopathic arthritis: a randomized trial. J Rheumatol 2005; 32: 943.

11. Jay RM, Schoenhaus HD, Seymour C, et al.: The Dynamic Stabilizing Innersole System (DSIS): the management of hyperpronation in children. J Foot Ankle Surg 1995; 34: 124.

12. Penneauk, Lutter LD, Winter RB: Pes planus: radiographic changes with foot orthoses and shoes. Foot Ankle 1982; 2: 299.

13. Bordelon RL: Correction of hyper mobile flatfoot in children by molded insert. Foot Ankle 1980; 1: 143.

14. Cappello T, Song KM. Determining treatment of flatfeet in children. Curr Opin Pediatr. 1998; 10(1):77-81.

15. Capasso G. Dynamic varus heel cup: a new orthosis for treating pes planovalgus. Ital J Orthop Traumatol. 1993; 19:113-123.

16. Shelby-Silverstein, L, Hillstrom, H, Palisano, R. The effect of foot orthoses on standing foot posture and gait of young children with Down syndrome. Neurorehabilitation 2001; 16:183.

17. Bleck, E, Berzins, U: Conservative management of pes valgus with plantarflexed talus, flexible. Clinical Orthopedics 1977; 122:85.

18. A.M. Evans, K. Rome, A Cochrane review of the evidence for non-surgical interventions for flexible pediatric flat feet. European Journal of Physical and Rehabilitation Medicine 2011; 47:69-89.

19. Madeline Vanstory, How should you treat a child with flat feet?. The Journal of Family Practise 2010; 59(6)

20. Paul R. Scherer, Treatment of Pediatric Flexible Flatfoot with Functional Orthoses, Podiatry Management 2008

21. George S. Murley, Do foot orthoses change lower limb muscle activity in flat-arched feet towards a pattern observed in normal-arched feet?. Clinical Biomechanics 2010; 25:728-736.

22. Lockard MA. Foot orthoses. Physical Therapy. 1988; 68(12):1866-73.

23. Hunter S, Dolan MG, Davis JM. Foot Orthotics in Therapy and Sport. Human Kinetics.1995.

24. Nigg BM, Nurse MA, Stefanyshyn DJ. Shoe inserts and orthotics for sport and physical applications. Medicine and Science in Sports and Exercise. 1999; 21(7): 421-8.

25. Smith LS, Clarke TE, Hamill CL, Santopietro F. The effects of soft and semi-rigid orthoses upon rearfoot movement in running. Journal of the American Podiatric

Medical Association.1986; 76(4): 227-33.

26. Padhiar N. Foot orthoses and their role in injury management. SportEX medicine. 2001; (8):6-8.

27. Razeghi M, Batt ME. Biomechanical analysis of the effect of orthotic shoe inserts - A review of the literature. Sports Medicine. 2000; 29(6): 425-38.

28. Nigg B, Khan A, Fisher V, Stefanyshyn D. Effect of shoe insert construction on foot and leg movement. Medicine and Science in Sports and Exercise 1998; 30(4): 550-5.

29. MacLean C, Davis I, Hamill J. Influence of a custom foot orthotic intervention on lower extremity dynamics in healthy runners. Clinical Biomechanics 2006; 21(6): 623-30.

30. Verdejo R, Mills N. Performance of EVA foam in running shoes. in The Engineering of Sport 4, Ujihashi S, Haake SJ, Editors. Blackwell Science. 2002; 580-7.

31. Millet G, Perrey S, Divert C, Foissac M. The role of engineering in fatigue reduction during human locomotion –a review. Sports Engineering. 2006; 9: 209-20.

32. Valmassy RL. Clinical biomechanics of the lower extremities. St Louis, Missouri: Mosby, Inc. 1996.

33. Paton J, Jones RB, Stenhouse E, Bruce G. The physical characteristics of materials used in the manufacture of orthoses for patients with diabetes. Foot and Ankle International. 2007; 28: 1057-63.

34. Nicolopoulos CS, Black J, Anderson EG. Foot orthoses materials. The Foot. 2000; 10: 1-3.

35. Klasson BL. Carbon-fiber and fiber lamination in prosthetics and orthotics - some basic theory and practical advice for the practitioner Prosthetics and Orthotics International. 1995; 19(2): 74-91.

36. Crabtree P, Dhokia V, Ansell M, Newman S. Design and manufacture of customised orthotics for sporting applications. Engineering of Sport 7, 2008; (1): 309-17.

37. Arnaldo J.Calculation of Staheli's Plantar Arch index and Prevalence of Flat Feet: a Study with 100Children Aged 5-9 Years. ACTA ORTOP BRAS 15. 2007; (2): 68-71.

38. Smallman, R. E., and R.J. Bishop. Modern Physical Metallurgy and Materials Engineering. 6th ed. Oxford: Butterworth-Heinemann, 1999.

39. Synthetic Resin - Use in Aircraft Construction, The Times, London England, Monday 1936; 47497: 14.

40. Moulded glass Fiber Sandwich Fuselages for BT-15 Airplane, Army Air Force Technical 1944; 5159.

41. Donald V. Rosato, Dominick V. Rosato, and John Murphy. Reinforced plastics handbook; Elsevier; 2004; 586.

42. Tong, L, A.P. Mouritz, and M.k. Bannister. 3D Fibre Reinforced Polymer Composites. Oxford: Elsevier, 2002.

43. Dale A. Berry, C.P.(C).Composite Materials for Orthotics and Prosthetics. Orthotics and Prosthetics, 40(4): 34-43.

44. Carbon fiber, http://www.thefullwiki.org/Carbon_fiber

45. Properties of Silk Fabric, Properties of Silk Fabric eHow_com.mht

46. C. Vepari, D.L. Kaplan, Silk as a biomaterial/ Prog. Polym. Sci. 32. 2007; 991–1007.

47. G.H. Altman et al. Silk-based biomaterials / Biomaterials 24. 2003; 401–416.

48. Ude et al . The impact damage response of plain woven natural silk/epoxy laminated composite plates/ International Journal of Engineering, Science and Technology, 2010; 2(5): 128-140.

49. A.Alavudeen,M. Thiruchitrambalam, N.Venkateshwaran and A.Athijayamanil. Review of natural fiber reinforced woven composite.Rev.Adv.Mater.Sci.27. 2011;146-150

50. Teruo Kimura. Application of Silk Fabrics to Biodegradable Artistic Composite

51. D. Chadramohan et al. / (IJAEST). Tensile and hardness tests on natural fiber reinforced composite material. International Journal of Advanced Engineering Sciences and Technologies. 6(1): 097 – 104.

52. K.M. Kelvin Loh and C.K. Willy Tan. Natural Silkworm Silk-Epoxy Resin Composite for High Performance Application. Metal, Ceramic and Polymeric Composites for Various Uses, the writer's handbook, School of Applied Science, Republic Polytechnic Singapore. 325-340.

53. S. Padma Priya and S. K. Rai. Studies on the mechanical performance of PMMA

and PC toughened epoxy–silk composites. Journal of reinforced plastics and composites, 2005; 0(0)

54. Piggot, M.R., & Harris B. (1980). Compression strength of carbon, glass and Kevlar-49 fiber reinforced polyester resins. Journal of material Science, 15, 2523-2538

55. Bhavana Shekhar, "Mechanical properties of carbon hybrid braided structure for lower limb prostheses", The Undersigned Project Committee Approves the Master's Project Titled, The Faculty of the Department of General Engineering San José State University, 2009.

56. A.W. van Vuure. Natural Fiber Composites: Tough (silk) and stromg (bamboo). Katholieke Universiteit Leuven

57. Zulkifli R., Azhari C.H., Ghazali M.J., Ismail A.R., Sulong A.B. Interlaminar FractureToughness of Multi-Layer Woven Silk/EpoxyComposites Treated with Coupling Agent.European. Journal of Scientific Research. 2009; 27(3) : 454-462.

58. Muhammad Jannah bin Jusoh. Studies on the properties of woven natural fibers reinforced unsaturated polyester composites. University Sains Malaysia. The master degree thesis,September2008

59. George S Murley., Hylton B Menz., and Karl B Landorf. A protocol for classifying normal- and flat-arched foot posture for research studies using clinical and radiographic measurements. Journal of Foot and Ankle Research, 2009; 2(22): 1-13.

Appendix

Appendix A

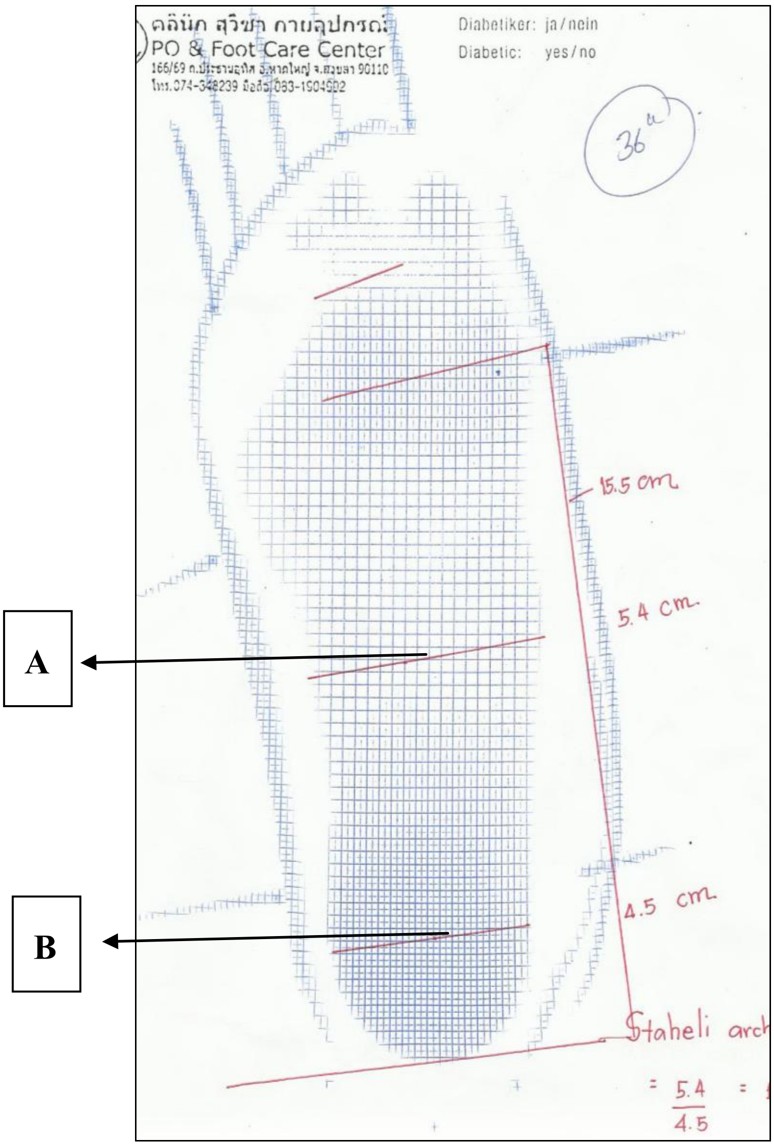
The methods for finding parameter values from foot pressure graph

The methods for finding Staheli Arch Index (SAI) from foot pressure graph

1. From the foot pressure graph, find the foot length excluding the toes and divide by 2 then the mid foot point will get. From the mid foot point, draw the horizontal line and measure the foot width and label to be A.

2. Find the center of the heel, draw the horizontal line and measure the length. Then Label to be B

Staheli Arch Index (SAI)
= A / B

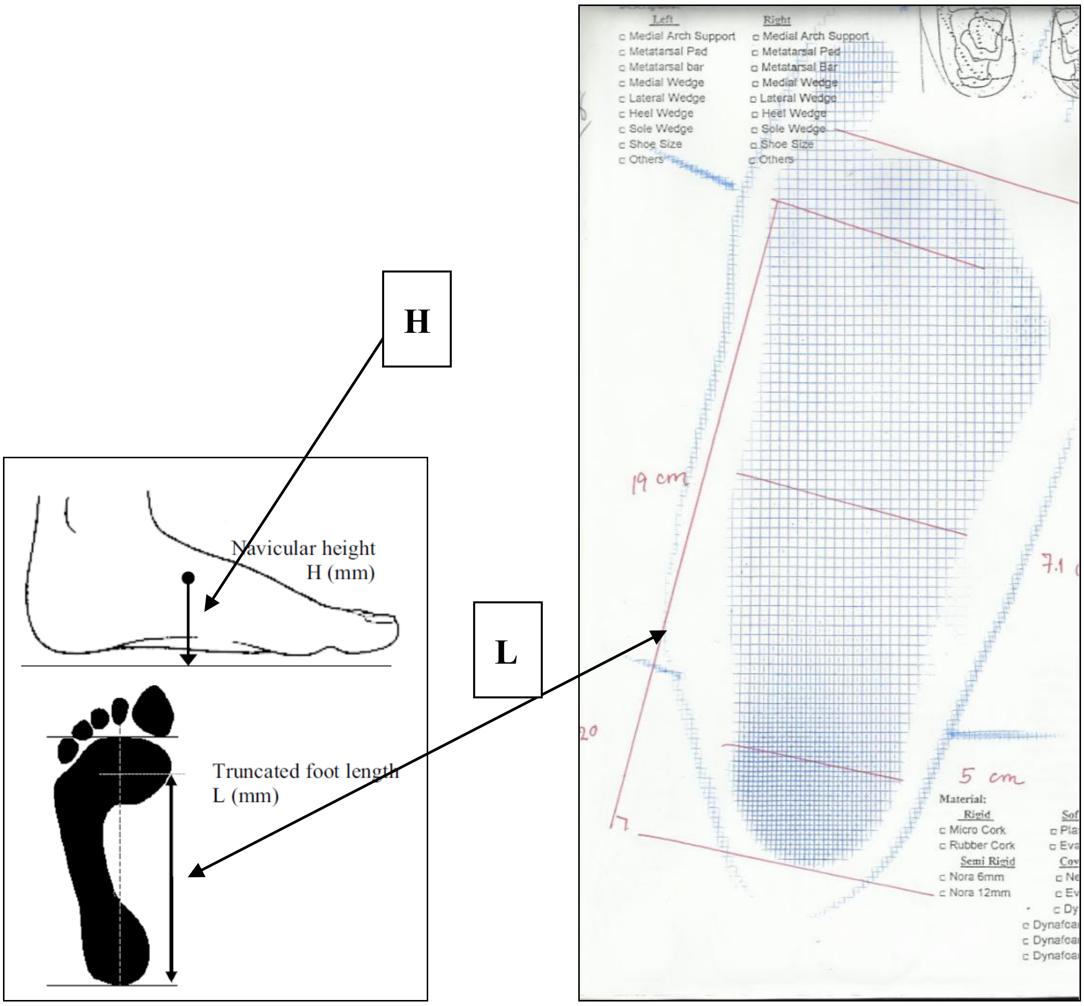


The methods for finding Normalized Navicular Height Truncated (NNHT)

Measurement from foot pressure graph

1. Find the Navicular Height, Navicular height is the distance measured from the most medial prominence of the navicular tuberosity to the supporting surface. Then label to be H.

2. Find the foot pressure graph, measuring the perpendicular distance from the first metatarsophalangeal joint to the most posterior aspect of the heel. Then Label to be L.



Normalized Navicular Height Truncated (NNHT)

= H / L

Appendix B

The Research Invitation for Attending Form

ใบเชิญชวนเข้าร่วมโครงการศึกษาวิจัย

ชื่อโครงการ แผ่นรองในรองเท้าหล่อพิเศษเฉพาะรายแบบใช้ไยไหมเสริมความแข็งแรงสามารถใช้ในการรักษาผู้ป่วยเด็กโรคเท้าแบนได้

ปัจจุบันโรคเท้าแบนเป็นโรคที่สามารถพบได้บ่อยในเด็ก อายุไม่เกิน 7 ปี แต่หากอายุเกิน 7 ปีแล้วแต่ยังคงมีลักษณะโครงสร้างเท้าเป็นโรคเท้าแบนอยู่ จะทำให้เกิดปัญหาเกี่ยวกับการทำงานของกล้ามเนื้อและโรคอื่นๆที่เกี่ยวข้องตามมาได้ในภายหลัง ดังนั้นการให้การรักษาโรคเท้าแบนจึงมีความสำคัญเพื่อป้องกันไม่ให้ลักษณะโครงสร้างเท้าผิดปกติและรบกวนระบบการทำงานของกล้ามเนื้ออื่นๆ

การรักษาที่เป็นที่นิยมได้แก่ การใช้แผ่นรองในรองเท้า เพื่อช่วยดัดแก้ลักษณะโครงสร้างเท้าและให้เท้าและกล้ามเนื้อเท้ารวมถึงกล้ามเนื้ออื่นๆที่เกี่ยวข้องสามารถทำงานได้อย่างปกติ แต่ปัจจุบันวัสดุที่สามารถนำมาใช้ในการทำแผ่นรองเท้า มักทำจากวัสดุสังเคราะห์ มีราคาแพง และ ต้องนำเข้าจากต่างประเทศ ทำให้ผู้ป่วยสามารถเข้าถึงการรักษาที่มีคุณภาพได้ลดลง จึงได้มีการวิจัยเพื่อใช้วัสดุธรรมชาติในการนำมาทำแผ่นรองในรองเท้าเพื่อที่มีประสิทธิภาพเทียบเท่ากับวัสดุสังเคราะห์และสามารถใช้ในการรักษาโรคเท้าแบนในเด็กได้

จึงเป็นโอกาสอันดี ขอเรียนเชิญผู้ป่วยเด็กที่มีอุ้งเท้าแบน ได้เข้าร่วมโครงการศึกษาในครั้งนี้ เพื่อศึกษาผลของวัสดุที่สามารถนำมาใช้ทำแผ่นรองในรองเท้าและแก้ไขปัญหาเท้าแบนในเด็กได้

ผู้ป่วยที่เข้าร่วมการวิจัย จะได้รับการสัมภาษณ์จากผู้ทำวิจัย และ ได้รับแผ่นรองในรองเท้าเพื่อรักษาโรคเท้าแบนคนละ 1 คู่ และให้กลับไปใส่ที่บ้านเป็นเวลา 4 สัปดาห์ และจึงกลับมาเพื่อเก็บข้อมูลอีกครั้งหนึ่ง โดยใช้เวลาในการเก็บข้อมูลคนละ 1 ชั่วโมง

หมายเหตุ หากท่านมีข้อสงสัยหรือซักถามใดๆ สามารถสอบถามเพิ่มเติมได้ที่ โทร 074-45160-, 074-451743 หรือ 083-1904992 ติดต่อ นางสาว สุวิชา เตชะภูวภัทร ในวันและเวลาราชการ

ขอขอบพระคุณเป็นอย่างสูง

(นางสาว สุวิชา เตชะภูวภัทร)

Appendix C

The Research Inform Consent Form

แบบฟอร์ม

ใบยินยอมเข้าร่วมการโครงการ / ใบยินยอมรับการรักษา

ชื่อโครงการ อุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในการรักษาโรคเท้าแบนยืดหยุ่นในเด็ก

ข้าพเจ้า(นาย,นาง,นางสาว)..(นามสกุล)... ผู้ปกครองของ (ด.ช.,ด.ญ.)..(นามสกุล)...ยินยอมรับการตรวจวัดตามวิธีที่ นางสาว สุวิชา เตชะภูวภัทร นักกายอุปกรณ์ และ นักศึกษาหลักสูตรปริญญาโท สาขา วิศวกรรมชีวการแพทย์ คณะแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ได้อธิบายให้ข้าพเจ้าทราบ (ดังใบเชิญชวนให้ร่วมโครงการวิจัยที่แนบมานี้)

หากมีข้อสงสัยเกี่ยวกับการตรวจวัด ข้าพเจ้ามีสิทธิ์ซักถามได้ในระหว่างการตรวจวัด หากการกระทำและคำชี้แจงของผู้รักษายังไม่เป็นที่พอใจ ข้าพเจ้ามีสิทธิ์แจ้งต่อประธารกรรมการพิจารณาจริยธรรมการวิจัยในคน (คณบดีคณะแพทยศาสตร์ โทร 074-451100) หรือ ผู้อำนวยการโรงพยาบาลสงขลานครินทร์ (โทร 074-451010) ได้ และหากไม่พอใจในการรักษ า ข้าพเจ้ามีสิทธิ์ปฏิเสธการรักษาการตรวจวัดวิธีนี้ได้ทันทีโดยไม่เสียสิทธิในการรับการรักษาในโรงพยาบาลสงขลานครินทร์ต่อไป

ข้าพเจ้าได้อ่านและเข้าใจเกี่ยวกับการตรวจวัดทั้งหมดตามคำอธิบายข้างต้นแล้ว ข้าพเจ้ายินยอมรับการตรวจวัดตามวิธีดังกล่าว

…………………………………………..	....
(………………………………………….)	(วัน/เดือน/ปี)
(ลายเซ็นต์ผู้ปกครองผู้ป่วย / อาสาสมัคร)	
…………………………………………..	....
(………………………………………….)	(วัน/เดือน/ปี)
(ลายเซ็นต์นักวิจัย)	
…………………………………………..	....
(………………………………………….)	(วัน/เดือน/ปี)
(ลายเซ็นต์พยาน)	

แบบฟอร์ม

ใบยินยอมเข้าร่วมการโครงการ / ใบยินยอมรับการรักษา

ชื่อโครงการ อุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนใน การรักษาโรคเท้าแบนยืดหยุ่นในเด็ก

ข้าพเจ้า(นาย,นาง,นางสาว)..(นามสกุล).. ยินยอมรับการตรวจวัดตามวิธีที่ นางสาว สุวิชา เตชะภูวภัทร นักกายอุปกรณ์ และ นักศึกษาหลักสูตรปริญญาโท สาขาวิศวกรรมชีวการแพทย์ คณะแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ได้อธิบายให้ข้าพเจ้าทราบ (ดังใบเชิญชวนให้ร่วมโครงการวิจัยที่แนบมานี้)

หากมีข้อสงสัยเกี่ยวกับการตรวจวัด ข้าพเจ้ามีสิทธิ์ซักถามได้ในระหว่างการตรวจวัด หากการกระทำและคำชี้แจงของผู้รักษายังไม่เป็นที่พอใจ ข้าพเจ้ามีสิทธิ์แจ้งต่อประธารกรรมการพิจารณาจริยธรรมการวิจัยในคน (คณบดีคณะแพทยศาสตร์ โทร 074-451100) หรือ ผู้อำนวยการโรงพยาบาลสงขลานครินทร์ (โทร 074-451010) ได้ และหากไม่พอใจในการรักษ า ข้าพเจ้ามีสิทธิ์ปฏิเสธการรักษาการตรวจวัดวิธีนี้ได้ทันทีโดยไม่เสียสิทธิในการรับการรักษาในโรงพยาบาลสงขลานครินทร์ต่อไป

ข้าพเจ้าได้อ่านและเข้าใจเกี่ยวกับการตรวจวัดทั้งหมดตามคำอธิบายข้างต้นแล้ว ข้าพเจ้ายินยอมรับการตรวจวัดตามวิธีดังกล่าว

………………………………………….. ....

(………………………………………….) (วัน/เดือน/ปี)

(ลายเซ็นต์ผู้ปกครองผู้ป่วย / อาสาสมัคร)

………………………………………….. ....

(………………………………………….) (วัน/เดือน/ปี)

(ลายเซ็นต์นักวิจัย)

………………………………………….. ....

(………………………………………….) (วัน/เดือน/ปี)

(ลายเซ็นต์พยาน)

Appendix D

The Research Collecting Clinical Data

แบบฟอร์มการเก็บข้อมูล

แผ่นรองในรองเท้าหล่อพิเศษเฉพาะรายแบบใช้ใยไหมเสริมความแข็งแรงสามารถ

ใช้ในการรักษาผู้ป่วยเด็กโรคเท้าแบนได้

ส่วนที่ 1 ข้อมูลทั่วไป

เพศ ชาย ☐ หญิง ☐

อายุ ☐ 1-7 ☐ 7-15 ☐ 16-18 น้ำหนัก........kg ส่วนสูง........cm

BMI …………………………….

อาชีพ .... ศึกษาที่ ....

โรค เท้าแบน ข้างที่เป็น ซ้าย ☐ ขวา ☐

ระยะเวลาของโรคที่สังเกตพบ ....

ระยะเวลาในการบำบัดด้วยวิธีทางออร์โธปิดิกส์และเวชศาสตร์ฟื้นฟู......................................

ส่วนที่ 2 Assessment and Measurement

ระยะเวลาการใส่ ....

ก่อนใส่ Foot Orthoses

Ix	Left	Right	Comment
Foot Print			
Arch Index			
NNHT			
RCSP			

หลังใส่ Foot Orthoses 4 สัปดาห์

Ix	Left	Right	Comment
Foot Print			
Arch Index			
NNHT			
RCSP			

นางสาว สุวิชา เตชะภูวภัทร

สถาบันวิศวกรรมชีวการแพทย์ คณะแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

Appendix E

The Part of Result Collecting Clinical Data

แบบฟอร์มการเก็บข้อมูล

แผ่นรองในรองเท้าหล่อพิเศษเฉพาะรายแบบใช้ใยไหมเสริมความแข็งแรงสามารถ

ใช้ในการรักษาผู้ป่วยเด็กโรคเท้าแบนได้

ส่วนที่ 1 ข้อมูลทั่วไป

ชื่อ ด.ญ. ศรีตระกูล คุณธรรม

เพศ ☐ ชาย ☑ หญิง

อายุ ☐ 1-7 ☑ 7-15 (12) ☐ 16-18 น้ำหนัก 44 kg ส่วนสูง 145 cm

อาชีพ นักเรียน ศึกษาที่ รร. ศรีสว่างวงศ์

โรค ☑ เท้าแบน ข้างที่เป็น ☑ ✓ ซ้าย ✓ ขวา

ระยะเวลาของโรคที่สังเกตพบ 1 ปี BMI 20.93

ระยะเวลาในการบำบัดด้วยวิธีทางออร์โธปิดิกส์และเวชศาสตร์ฟื้นฟู -

ส่วนที่ 2 Assessment and Measurement

ระยะเวลาการใส่ 5 ก.ค. 55 - 11 ต.ค. 55

ก่อนใส่ Foot Orthoses

Ix	Left	Right	Comment
Foot Print	✓	✓	
Arch Index	1.2	1.30	> 0.26
NNHT	0.22	0.21	< 0.24
RCSP	13°	8°	

หลังใส่ Foot Orthoses 4 สัปดาห์

Ix	Left	Right	Comment
Foot Print	✓	✓	
Arch Index	1	1.11	
NNHT	0.22	0.29	
RCSP	13°	8°	

นางสาว สุวิชา เดชะภูวภัทร สถาบันวิศวกรรมชีวการแพทย์ คณะแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

Appendix F

The Research Satisfaction Questionnaire

แบบสอบถามความพึงพอใจต่ออุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสม
ของเส้นใยไหมหม่อนในการรักษาโรคเท้าแบนยืดหยุ่นในเด็ก

แบบสอบถามนี้จัดทำขึ้นเพื่อสอบถามความพึงพอใจของผู้ป่วยที่มีต่ออุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในการรักษาโรคเท้าแบนแบบยืดหยุ่นในเด็ก เพื่อนำไปใช้ในการพัฒนาอุปกรณ์ที่ใช้เพื่อการรักษาผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น

คำชี้แจง แบบสอบถามแบ่งออกเป็น 3 ส่วน คือ

ส่วนที่ 1 แบบสอบถามเกี่ยวกับข้อมูลทั่วไป

ส่วนที่ 2 แบบสอบถามเกี่ยวกับความพึงพอใจของ ผู้ป่วย / ผู้ปกครองของผู้ป่วย ที่มีต่ออุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น

ส่วนที่ 3 ข้อเสนอแนะและความคิดเห็นเพิ่มเติม

<u>คำชี้แจง</u> โปรดทำเครื่องหมาย / ลงใน ☐ ที่ตรงกับความเป็นจริงของท่านมากที่สุด

<u>ส่วนที่ 1</u> ข้อมูลทั่วไป

เพศ ชาย ☐ หญิง ☐

อายุ ☐ 1-7 ☐ 7-15 ☐ 16-18

อาชีพ ....ศึกษาที่ ....

โรค เท้าแบน ☐

ข้างที่เป็น ซ้าย ☐ ขวา ☐

ระยะเวลาของโรคที่สังเกตพบ ....

ระยะเวลาในการบำบัดด้วยวิธีทางออร์โธปิดิกส์และเวชศาสตร์ฟื้นฟู ....

<u>ส่วนที่ 2</u> แบบสอบถามเกี่ยวกับความพึงพอใจของผู้ปกครองของผู้ป่วย /ผู้ป่วย ที่มีต่ออุปกรณ์พยุงส้นเท้า และฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น

1. ท่านคิดว่าอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น มีประโยชน์ สามารถนำไปใช้ในการรักษาโรคเท้าแบนแบบยืดหยุ่นได้หรือไม่

....

....

....

2. เมื่อสวมใส่และใช้งานอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น ท่าน/บุตรหลานของท่านรู้สึกสบายและปลอดภัยในการใช้งานหรือไม่ อย่างไร

………

………

………

3. การใช้งานอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่นสามารถใช้งานได้ง่ายหรือไม่ อย่างไร

……

……

……

4. ลักษณะเท้าและท่าทางการเดินเป็นที่น่าพอใจหรือไม่ อย่างไร

……

……

……....

5. ท่านคิดว่าราคาของอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่นมีความเหมาะสมหรือไม่ อย่างไร

……

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<u>ส่วนที่ 2</u> ข้อเสนอแนะ / ความคิดเห็นเพิ่มเติม

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ขอขอบพระคุณท่านที่สละเวลาตอบแบบสอบถามในครั้งนี้

นางสาว สุวิชา เตชะภูวภัทร

Appendix G

The Part of Result Satisfaction Questionnaire

ด.ญ. ภัทรศยา ศิริภักดี
12 ปี 159 cm. 55kg

แบบสอบถามความพึงพอใจต่ออุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสม ของเส้นใยไหมในการรักษาโรคเท้าแบนยืดหยุ่นในเด็ก

แบบสอบถามนี้จัดทำขึ้นเพื่อสอบถามความพึงพอใจของผู้ป่วยที่มีต่ออุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมในการรักษาโรคเท้าแบนแบบยืดหยุ่นในเด็กเพื่อนำไปใช้ในการพัฒนาอุปกรณ์ที่ใช้เพื่อการรักษาผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น

คำชี้แจง แบบสอบถามแบ่งออกเป็น 3 ส่วน คือ

ส่วนที่ 1 แบบสอบถามเกี่ยวกับข้อมูลทั่วไป

ส่วนที่ 2 แบบสอบถามเกี่ยวกับความพึงพอใจของ ผู้ป่วย / ผู้ปกครองของผู้ป่วย ที่มีต่ออุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมหม่อนในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น

ส่วนที่ 3 ข้อเสนอแนะและความคิดเห็นเพิ่มเติม

<u>คำชี้แจง</u> โปรดทำเครื่องหมาย / ลงใน ☐ ที่ตรงกับความเป็นจริงของท่านมากที่สุด

<u>ส่วนที่ 1</u> ข้อมูลทั่วไป

เพศ ☐ ชาย ☑ หญิง

อายุ ☐ 1-7 ☑ 7-15 ☐ 16-18

อาชีพ ....นักเรียน.... ศึกษาที่ ....ม.1. 2....

โรค เท้าแบน

ข้างที่เป็น ☑ ซ้าย ☑ ขวา

ระยะเวลาของโรคที่สังเกตพบ ....1 เดือน....

ระยะเวลาในการบำบัดด้วยวิธีทางออร์โธปิดิกส์และเวชศาสตร์ฟื้นฟู ....—....

<u>ส่วนที่ 2</u> แบบสอบถามเกี่ยวกับความพึงพอใจของผู้ปกครองของผู้ป่วย/ผู้ป่วย ที่มีต่ออุปกรณ์พยุงส้นเท้า และฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น

1. ท่านคิดว่าอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น มีประโยชน์ สามารถนำไปใช้ในการรักษาโรคเท้าแบนแบบยืดหยุ่นได้หรือไม่

   ได้

2. เมื่อสวมใส่และใช้งานอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่น ท่าน/บุตรหลานของท่านรู้สึกสบายและปลอดภัยในการใช้งานหรือไม่ อย่างไร

   รู้สึก ใส่สบาย ไม่แข็งมากเกินไป

3. การใช้งานอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่นสามารถใช้งานได้ง่ายหรือไม่ อย่างไร

   การใช้งาน สามารถใช้ได้ง่าย ดี ไม่ลำบากมาก

4. ลักษณะเท้าและท่าทางการเดินเป็นที่น่าพอใจหรือไม่ อย่างไร

   พอใจ

5. ท่านคิดว่าราคาของอุปกรณ์พยุงส้นเท้าและฝ่าเท้าผลิตจากวัสดุผสมของเส้นใยไหมในผู้ป่วยเด็กโรคเท้าแบนแบบยืดหยุ่นมีความเหมาะสมหรือไม่ อย่างไร

   ราคา มีความเหมาะสม

<u>ส่วนที่ 2</u> ข้อเสนอแนะ / ความคิดเห็นเพิ่มเติม

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ขอขอบพระคุณท่านที่สละเวลาตอบแบบสอบถามในครั้งนี้

นางสาว สุวิชา เตชะภูวภัทร

ผู้จัดทำโครงการวิจัย

Appendix H

The Thesis Knowledge Proceeding

In the title of “Comparison on the Physical and Mechanical Properties of Natural Bombyx Silk Fiber Polymer Composite and Carbon Fiber Polymer Composite”

Name of Conference: Biomedical Engineering International Conference (BMEiCON-2012)

5-7 December 2012 at Sunee Grand Hotel in Ubonratchathani

Feasibility of Bombyx Silk Fiber Polymer Composite as materials for medical applications: Preparation, Physical and Mechanical properties

Suwicha Techapoowapat
Institute of Biomedical Engineering
Faculty of Medicine, Prince of Songkla University
Songkla, Thailand
mukky_13@hotmail.com

Jirut Meesane
Institute of Biomedical Engineering
Faculty of Medicine, Prince of Songkla University
Songkla, Thailand
jirutmeesane999@yahoo.co.uk

***Abstract*—Natural Bombyx Silk Fibers were fabricated as silk fiber polymer composites using acrylic resin by lamination thermoforming technique. The physical and mechanical properties of the composites were investigated and the test results were compared to the synthetic carbon fiber polymer composites. The results found that although synthetic carbon fiber polymer composites provided as high a performance of mechanical testing, including tensile strength test, hardness test and flexural test as natural Bombyx silk fiber polymer composites; however, the natural fiber composites had a lower weight ratio and thickness ratio compared to the synthetic polymer composites.**

***Keywords*—Natural Bombyx Silk Fiber Polymer Composite, Carbon Fiber Polymer Composite, acrylic resin, lamination compression techniques, Mechanical test**

INTRODUCTION

Nowadays, the natural fiber has become an attractive alternative for research (Corrales et al., 2007; Herrera and Valadez, 2005) [11]. Bombyx Mori silk fibers are natural fibers produced from the silk worm that feast on Mulberry leaves [3]. Each thread consists of varying sizes and structures that have been studied for many years and used in many industries for their remarkable mechanical properties and characteristic strength [3]. The unique property provides the outstanding characteristics of strength and it is more ductile when compared with synthetic fibers [3]. Furthermore, Bombyx Mori silk fibers provides low cost fabrication when compared to other synthetic fibers, for instance, carbon fibers and aramid fibers (Mohanty et al., 2005; Frederick and Norman, 2004; Joseph et al., 2002) [10]. In this research, Bombyx Mori silk fibers were fabricated into polymer composite materials for medical applications.

FIBER REINFORCEMENCED POLYMER COMPOSITE

Composites are the blending of two materials between the reinforcing materials that used to be in the kind of fiber and the matrix phase that the fiber will be placed in. The fiber can be both synthetic fibers and natural fibers that can be made in many patterns (Strike & Hillery, 2000) [7]. The polymer matrix can be from any of the following: thermosetting polymer matrix, which is usually made from Bis-Maleimids (BMI), Epoxy (Epoxide), Phenolic (PF), Polyester (UP), Polyimide, Polyurethane (PUR), Silicone ma etc. or thermoplastic polymer matrix, which is usually made from acrylic group etc. (Ramakrishna et al., 2001) [7]. The disadvantages of the thermosetting polymer composites are their difficulty to repair and poor recycling ability (Evans, & Gregson, 1998) [7] while thermoplastic polymer composites are heat adjustable and recyclable. The benefits that can be gained from the composites are their low density and high tensile strength compared to the weight ratio, and some of the composites can provide high toughness (Varadarajulu et al.) [4]. For these reasons, the outstanding features of the final products fabricated from the composites can be relatively thin, light weight, strong and easily fabricated at the same time and so on the medical devices will use these profits to fulfill the utilities (Ramakrishna et al., 2001)[7].

POLYMER COMPOSITE FABRICATION TECHNIQUE

There are a variety of composite fabrication techniques available depending on the material using appropriation. The fabrications include the lamination techniques [2] which are suitable for the thermosetting composites that need to mix the chemical agents together so it takes times for fabrication, and the thermoforming(vacuum) techniques [2] that need a vacuum air pump to suck the air out and attach with the mold but isn't suitable for thermosetting composites. The lamination technique usually makes for thermosetting composites and the thermoforming techniques (vacuum) usually makes for thermoplastic composites. Both techniques depend on the matrix composites being used. From the difficulties encountered in thermosetting composites and thermoplastic composites, the market nowadays has presented the Pre-preg material which injects the chemical agents to the hot plate and cools it down and then uses heat or an oven to thermoform it with the mold [11]. Our research used the technique of fabrication that is called thermoplastic composite lamination thermoforming, which can use the chemical agents that aid thermoplastic properties to do the lamination and make it contour with the mold shape by vacuum techniques at the same time.

In our research, intensively, to consider feasibility to promise such composite as materials for medical applications, has been emphasized in this research. The physical properties include the weight ratio, thickness ratio, and hardness. The mechanical properties test will be interested in the tensile strength and flexural strength test. All testing results between bombyx silk and carbon fiber polymer composite will be compared. Moreover, the fabrication of bombyx silk fiber polymer composites by using lamination thermoforming techniques will be demonstrated.

MATERIAL AND METHODS

Material used

The polymer composite material using

The Acrylic resin (617H55 - C-ORTHOCRYL Resin) from Otto Bock Company was used for the polymer matrix in this study in order to do the lamination process and gain the thermoplastic property. The Hardening Powder (617P37 – for Orthocryl Resin) from Otto Bock Company also was used to mix with the resin.

- *The natural fiber using*

  Bombyx Mori silk textile is woven from " Queen Sirikit Sericulture Center Narathiwat". The handicraft will keep all the fibers together and start to weave for the silk cloth. We can get silk cloth from Mulberry worms in the raw and pure condition with its true color.
- *The synthetic fiber using*

  Carbon fiber cloth (616B1 - Carbon Fiber Webbing) from Otto Bock Company was used in the study in the weaving pattern of 0/90 degree.

Lamination Thermoforming Composite Fabrication Technique

This research will use this technique to make medical device materials from the process. They will combine the process of lamination and thermoforming that will be done at the same time. Here are the fabrication processes:

Prepare the chemical agents for lamination by weighing the C-ORTHOCRYL Resin and the hardening powder in the mixing ratio of 100 parts resin to 2-3 parts Hardener

Place the mold plate on the vacuum machine (fig.1) and cover it with the PVA bag to make the composite not stick to the plate and ensure that it is easily to remove.

Three layers of cloths and fibers in the sandwich style:

Stockinette – Bombyx Silk Textile – Stockinette

Stockinette – Carbon Fiber Webbing – Stockinette

They are all set on the mold plate.

Pour the mix of chemical agents on the top of the plate gradually until the liquid is sucked and spread widely into the cloths and fibers.

Cover the top of the surface again with PVA bag and try to leave as few air bubbles as possible.

Open the vacuum machine to let the air come out and make the chemical liquid agents spread and attach all over the mold plate. (fig.1) Wait for the chemical action to set and become dry and hard.

The picture of vacuum machine (left) and the chemical action of composite making on vacuum machine (right)

Physical Properties Test

The mean weight ratio and the mean thickness ratio of the two groups of fibers were calculated. The weights were measured by the "Precision Balance" with the repeatability of 0.001 g. The thickness was measured by the thickness gauge called "Goniometer".

Mechanical Properties Test

Tensile Strength Test

The tensile strength tests of both synthetic and natural fibers were investigated by using the universal testing machine with the ASTM standard of D638 (Type IV), according to the plastic property using the Universal Testing Machine. All specimens were prepared in a rectangular shape of 13x2cm before being cut in the dumbbell shape for testing. The test speed was 10 mm/min and a minimum of eight specimens were tested in each case to obtain the average values.

Hardness Test

The ASTM D2240 Rockwell hardness tester is the test for Shore Durometer of the material under study in being resisted in penetration under load. The specimens of two groups of fibers were measured and the mean values were calculated and presented.

Flexural Test

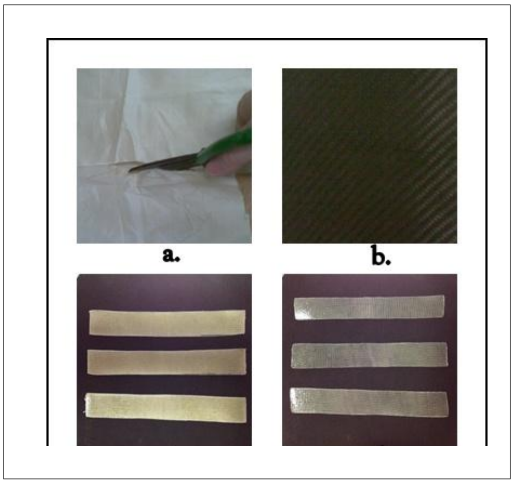
The three point flexural bend test was done in the standard ASTM D790. The flexural strength and modulus were obtained from this test.

RESULTS AND DISCUSSION

Silk fiber and carbon fiber are shown in fig.2, and used to produce for the composites in the same size preparing for the tests. The physical properties can be gained from the base materials that influenced the performance of the composites.

The physical and mechanical tests of the two composites groups were done to compare and discuss. In each test, eight specimens were tested and calculated for the mean values. From Table I, the physical properties results in weight ratio and thickness were performed. The Bombyx Mori silk fiber polymer composites showed a lower weight ratio and lower thickness ratio when compared to the synthetic fiber polymer composites. The different values demonstrated the significance. These results supported the facts that Bombyx Mori silk is a natural fiber that has low density (1.3-1.38 g/cm³) [3] when compared with any other synthetic fibers.

From this result, it can be deduced that silk fiber polymer composite has the feasibility to be used as materials for medical devices that need to be light weight and comfortable for patients to use.



The pictures of a) Silk Fiber b) Carbon Fiber c) Silk Fiber Polymer Composites d) Carbon Fiber Polymer Composites

Tensile Strength Test Results

The tensile strength tests were used to investigate the deformation or breakage of the specimens under a gradually increasing tension load. The results in Table II show that the synthetic carbon fiber polymer composites had a high average value of tension load (92.1 MPa) when compared to the Bombyx Mori silk fiber polymer composites (27.3 MPa). For modulus of elasticity 449 MPa, silk fiber polymer composite has less value than carbon fiber polymer composite 2760 MPa as shown in table II.

Interestingly, the elongation percentage (6.9%) of silk composite is higher than the carbon fiber composite (2.8%). According to this result, it showed that silk fiber composite was more ductile than carbon fiber composite, due to its toughness, has the feasibility to be used as a material for medical devices.

Hardness Test Results

From Table I, the Rockwell Hardness test following ASTM D 2240 demonstrated that the Bombyx silk fiber polymer composites had the potential of Hardness Shore D to 63.6 while the carbon fiber polymer composites had shown nearly the same values of 63.7. The results indicate that both silk fiber polymer composites and carbon fiber polymer composites had the same hardness, although they had provided different ratios of density.

Concerning this result, it showed that silk fiber composites might be used as materials for medical devices that need scratch resistance.

Flexural Test Results

The ASTM D 790 for three point flexural bend test of the composites was done. This test will provide the values from the calculation of flexural strength and flexural modulus that can predict the ability of deforming resistance under the load of the composites. The results from Table II show that the natural bombyx silk composites had the flexural strength of 41.4 MPa which was less than the synthetic carbon fibers group with the values of 81.3 MPa. From the test results, the specific strength of the composites can be calculated and is discussed in Table III on the point of specific tensile strength and specific flexural strength. The results displayed that the carbon fiber polymer composites had both a higher value of the tensile strength and the specific tensile strength than the natural fibers polymer composites. And the flexural strength and specific flexural strength of the synthetic fibers had performed the same tendency.

Interestingly, from Fig.3, the graph compares the tensile strength and flexural strength of the composites. The figure was expressed that the natural bombyx silk fiber polymer composites had high strength flexural and low tensile strength; that means that they had good resistance under bending and torque. Conversely, although the synthetic carbon fiber polymer composites had shown the high value of tensile strength, the ability of resisting in bending and torque was low.

Concerning the above results, it can be deduced that the Bombyx silk fiber polymer composites had the required flexible strength necessary for materials used with medical applications.

PHYSICAL PROPERTIES TEST RESULTS OF COMPOSITES

Composite Type	Physical Properties of Composites			
	size	*Weight (g /cm³)*	*Thickness (mm)*	*Hardness Shore D*
Bombyx Silk Fiber Polymer Composites	13cm x 2 cm	4.600	1.8	63.6
Carbon Fiber Polymer Composites	13cm x 2 cm	6.108	2.2	63.7

MECHANICAL PROPERTIES TEST RESULTS OF COMPOSITES

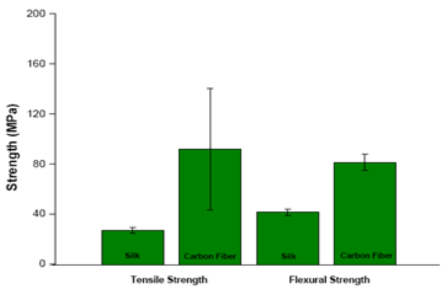
Composite Type	Specific Strength of Composites				
	Weight (g /cm³)	*Tensile Strength (MPa)*	*Specific Tensile Strength (MPa)*	*Flexural Strength (MPa)*	*Specific Flexural Strength (MPa)*
Bombyx Silk Fiber Polymer Composite	4.600	27.3	5.935	41.4	8.935
Carbon Fiber Polymer Composite	6.108	92.1	15.078	81.3	13.310

MECHANICAL PROPERTIES TEST RESULTS OF COMPOSITES

Composite Type	Mechanical Properties of Composites				
	Tensile Strength (MPa)	*% Elonga -tion at break*	*Young's Modulus (MPa)*	*Flexural Strength (MPa)*	*Flexural Modulus (MPa)*
Bombyx Silk Fiber Polymer Composites	27.3	6.9%	449	41.4	1,601
Standard Deviation (SD)	2.22	2.3	131	2.34	150
Carbon Fiber Polymer Composites	92.1	2.8%	2,760	81.3	3,000
Standard Deviation (SD)	48.4	1.6	2,490	6.42	109

Comparison of Tensile Strength and Flexural Strength of Two Composites

Composite Type	Tensile Strength and Flexural Strength Comparison		
	Tensile Strength (MPa)	Flexural Strength (MPa)	Percentage Comparison
Bombyx Silk Fiber Polymer Composite	27.3	41.4	+51.6%
Carbon Fiber Polymer Composite	92.1	81.3	-11.7%



CONCLUSIONS

The lamination thermoforming technique is one of the successful composite fabrication methods that is suitable for both thermoplastic and thermosetting material property. The processes are not too difficult and do not take too much time.

The Bombyx Mori silk polymer composites are the natural composites that are very crucial and can be the alternative choice for studying in the medical fields. Because of their own physical characteristics of light weight, strongly packed structure and good mechanical characteristics of strength and toughness and deforming resistance, the Bombyx Mori silk polymer composites can become the new trend of the material that has good properties for working, like the synthetic carbon fiber polymer composites; moreover, the low price and fact that they are not harmful to patients. Therefore, Bombyx Mori silk fiber polymer composite is promising material for medical applications.

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REFERENCES

D. Chadramohan et al. / (IJAEST). Tensile and hardness tests on natural fiber reinforced composite material. International Journal of Advanced Engineering Sciences and Technologies. Vol No. 6, Issue No. 1, pp.097 – 104.

Klasson BL. Carbon-fiber and fiber lamination in prosthetics and orthotics - some basic theory and practical advice for the practitioner Prosthetics and Orthotics International. 1995. 19(2): pp. 74-91.

K.M. Kelvin Loh and C.K. Willy Tan. Natural Silkworm Silk-Epoxy Resin Composite for High Performance Application. Metal, Ceramic and Polymeric Composites for Various Uses, the writer's handbook, School of Applied Science, Republic Polytechnic Singapore, pp.325-340.

S. PADMA PRIYA AND S. K. RAI. Studies on the mechanical performance of PMMA and PC toughened epoxy–silk composites. Journal of reinforced plastics and composites, Vol. 00, No. 00/2005.

Berry, D.A. (1987), Composite materials for orthotics and prosthetics. Orthot Prosthet , 40,35–43.

Piggot, M.R., & Harris B. (1980). Compression strength of carbon, glass and Kevlar-49 fiber reinforced polyester resins. Journal of material Science, 15, 2523-2538

Bhavana Shekhar, "Mechanical properties of carbon hybrid braided structure for lower limb prostheses", The Undersigned Project Committee Approves the Master's Project Titled, The Faculty of the Department of General Engineering San José State University, December 2009

A.W. van Vuure. Natural Fiber Composites: Tough (silk) and stromg (bamboo). Katholieke Universiteit Leuven

Zulkifli R., Azhari C.H., Ghazali M.J., Ismail A.R., Sulong A.B. (2009). Interlaminar FractureToughness of Multi-Layer Woven Silk/EpoxyComposites Treated with Coupling Agent.European Journal of Scientific Research Vol.27No.3, pp. 454-462.

Muhammad Jannah bin Jusoh. Studies on the properties of woven natural fibers reinforced unsaturated polyester composites. University Sains Malaysia. The master degree thesis,September2008

Crabtree, P., Dhokia, V., Newman, S. and Ansell, M., 2009. Manufacturing methodology for personalised symptom-specific sports insoles. Robotics and Computer-Integrated Manufacturing, 25 (6), pp. 972-977

VITAE

Name Suwicha Techapoowapat

Student ID 5410320005

Educational Attainment

Degree	Name of Institution	Year of Graduation
Bachelor Degree of Science (Prosthetics and Orthotics)	Mahidol University	2006

Work – Position and Address

- Certified Prosthetist and Orthotist (CPO), Songklanagarind Hospital,
  5 Karnjanavanich Road, Hatyai, Songkhla 90110
  Thailand
  Tel +6674-451-609
- Managing director of PO & Foot Care Center
  166/69 Pratanutid Road, Hatyai, Songkhla 90110
  Thailand
  Tel +6674-348-239

List of Publication and Proceedings

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