DEVELOPING A THREE-DIMENSIONAL (3D) ASSESSMENT METHOD FOR CLUBFOOT

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Developing A Three-Dimensional (3D) Assessment Method for Clubfoot

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CERTIFICATE OF ORIGINALITY

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ABSTRACT

Congenital talipes equinovarus (CTEV) is one of the most common complex orthopedic deformities in newborn babies which is more in males than females (3:1). The condition is characterized by four components of foot deformities: cavus, adductus, varus and equinus (CAVE). The rate of prevalence of CTEV is 1 in per 1000 live births. The etiology, classification, assessment, and management of clubfoot remain controversial. There is no standardized assessment for clubfoot deformity. An accurate evaluation of clubfoot is very essential for quantifying the initial severity of the deformity and determining the treatment options, as well as predicting the prognosis and treatment outcomes. Although there are a number of evaluation methods have been proposed to assess the severity of clubfoot, most of the assessment methods are too subjective. These assessment systems will not provide strongly objective measured clinical evidence. Imaging modalities such as magnetic resonance imaging (MRI), and computerized tomography (CT) scanning can be used to evaluate the initial severity of the clubfoot, but these techniques are too expensive for repeated use at each weekly casting session. Reliable, valid and accurate assessments would help to reducing relapses and the burden to the children and their family in terms of hospital expenses, and other long term complications to children with clubfoot. There is a necessity to develop a valid, reliable and objective tool to evaluate clubfoot. Thus, this study has developed an effective 3D assessment system, based on 3D scanning, to measure clubfoot severity and response to casting intervention. As a secondary aim, the thermo-physiological changes in the clubfoot was observed and correlated with the response to the casting intervention. This study is an explorative study and the study design has been approved by the Human Research Ethics Committees (HREC); registration number HREC/16/SCHN/163. The study was reviewed and approved on 17 August 2016 by the Sydney Children's Hospitals Network Human Research Ethics Committee in Sydney, Australia.
To develop the 3D assessment system for clubfoot, two experiments were conducted in this study. Five samples (N=5) were used in the experiments. Two rubber clubfoot models (N=2) were ordered online from Massons Healthcare, a private limited company that imports and distributes orthotics in Australia. One child with clubfoot was selected to develop the 3D scanned clubfoot model with pre and post intervention scans (N=2). In addition, one normal foot 3D scan (N=1) was collected to compare the difference between normal foot and clubfoot. A Kinect XBOX was used as a 3D scanner to obtain the scanned images from the child with unilateral clubfoot, normal foot, and the two rubber models. The scanned 3D images were processed by using Artec 9 Studio (3D scanner software) and CATIA V5 software (3D modeling software). Based on the 3D modelling, the 3D scanned images of the clubfoot were sectioned into five anatomical areas. Then, 5 cross sections were created from 5 anatomical surface lines. From the 5 surface lines, 5 cross section areas were developed: cross section angles of the center point, maximum lateral border, maximum medial border, maximum dorsal side, and maximum plantar side of the foot. The final step in developing the new 3D measurement scale was the development of 3 angles under the components of 5 cross section areas:

A. Center of cross section angle

1. Ankle-Heel-Midfoot-Area cross section angle (AHMA Angle)

2. Heel-midfoot-metatarsal phalangeal joint area cross section angle (HMMA Angle).

3. Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area cross section angle (MMPAA)

B. Maximum lateral border cross section angle

1. Lateral border of Ankle-Heel-Midfoot-Area cross section angle (LBAHMA Angle)
2. Lateral border of Heel-midfoot-metatarsal phalangeal joint area cross section angle (LBHMMA).

3. Lateral border of Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area cross section angle (LBMMMPA)

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3. Medial border of midfoot- metatarsal phalangeal joint -proximal phalangeal joint area cross section angle (MBMMPA)

D. Maximum dorsal side cross section angle

1. Dorsal side of Ankle-Heel-Midfoot-Area cross section angle (DS-AHMA Angle)

2. Dorsal side of Heel-midfoot-metatarsal phalangeal joint area cross section angle (DS-HMMA).

3. Dorsal side of Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area (DS MMPA) center of cross section angle

E. Maximum planter side cross section angle

1. Plantar side of Ankle-Heel-Midfoot-Area cross section angle (PSAHMA Angle)

2. Plantar side Heel-midfoot-metatarsal phalangeal joint area cross section angle (PSHMMA).

3. Plantar side Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area cross section angle (PSMMPA)

The measurement of pre and post casting intervention were compared and the results showed the differences between pre and post intervention. In addition, the severe and corrected clubfoot were compared with normal foot and the results showed the all the angles of sixth
week correction is closely reached to the range of normal foot cross section angles. The results of this study show that these measurements can be used to predict the four components of the clubfoot deformities.

In this study, infrared (IR) thermography is used to collect thermal images of the children with clubfoot (N=4) before and after casting. The study explored the thermophysiological changes between the casting interventions. In total, 120 thermal images were collected from the dorsal, plantar, medial, lateral and heel sides of the foot. FLIR and MATLAB software were used to obtain ten cutoff mean temperatures. The results showed reduced temperature after the first casting and temperature difference between the weekly castings. This novel method can be used to observe thermal changes in the clubfoot between castings to avoid complications such as pressure ulcers, swelling, pressure sores and related complications and relapses. Furthermore, this research study finding shows that IR thermography can be used as an additional diagnostic tool to evaluate and observe the thermophysiological changes in the clubfoot.

In this study, a new 3D objective analysis (objective assessment) method has been developed for analyzing clubfoot deformity. This 3D method is developed from 2D images of severe clubfoot, which was obtained from computed tomography. This method provides a new way to create a 3D model of the bones of a severe clubfoot from 2D slices as well as helps to analyze the relative position of the foot bones and objectively quantify the severity of the clubfoot.

Furthermore, a systematic review study was conducted to examine how the technical protocols in the Ponseti treatment followed in the selected 12 studies could achieve the initial correction, and better understand the outcomes of the study, including success rate, number of castings and percentage of surgical recommendations, as well as review the rate of relapse and relapse patterns of the causative factors of clubfoot for relapses. It is found that the
Ponseti method requires fewer castings and shorter duration to achieve correction, and has a lower relapse rate in comparison to other methods. However, few studies have focused and described the relapse pattern, and causes of relapse. There is still lack of information regarding the causes of relapse or recurrences of clubfoot. In addition, this study found that variations in the bracing protocol schedule.

As described above, this study results provide useful information and new objective assessment methods to quantify the severities of the clubfoot. In addition, this study used infrared imaging method and the results provided a useful information about skin temperature distribution between the castings and this infrared imaging can be used to prevent the complications from casting and relapses. The output of this research project can be extended to develop objective assessment methods for quantifying the initial severities of the clubfoot and provide new knowledge on developing 3D based objective assessment methods.
LIST OF PUBLICATIONS

Manuscripts under preparation

1. Ganesan Balasankar, Joanne Yip, Adel Al-Jumaily, Luximon Ameersing, Ey Batlle, Anna. A new method of computed tomography based three-dimensional evaluation for bone to bone alignment analysis in clubfoot. *In submission to Plos one*

2. Ganesan Balasankar, Joanne Yip, Adel Al-Jumaily, Luximon Ameersing, Paul Gibbons & Alison Chivers. Thermographic evaluation of clubfoot casting intervention. *In submission to Nature Scientific Reports*


Peer-reviewed Journal Papers


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**Conference papers**


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CHAPTER 1 INTRODUCTION

1.1 Background

Congenital talipes equinovarus or clubfoot is a common pediatric congenital foot deformity that occurs in about 0.9 to 7 children in 1000 live births (Smith et al. 2014; Wynne-Davies, 1972; Hussain et al. 2014; Shiels, Coley, Kean & Adler, 2007). The condition is characterized by four types of foot deformities: hindfoot equinus, midfoot cavus, forefoot adductus and hindfoot varus (Meena, Sharma, Gangary & Lohia, 2014) (Figure 1.1). Clubfoot can be either idiopathic or associated with neurological or orthopedic conditions. The causes are still not clearly known. Children with untreated clubfoot suffer from physical, social and psychological issues. They may find it difficult to walk, and changes in gait pattern and challenges in their daily life activities. They may also suffer socially because of the stigma. However, there are various conservative methods as well as surgical treatment proposed to treat the clubfoot. Among these treatment methods, the Ponseti method is considered to be an effective treatment method that corrects the clubfoot deformity with very few complications, and nowadays, this treatment is accepted as the gold standard in the treatment of clubfoot. The Ponseti method consists of 2 phases. The first phase of treatment involves manipulation, serial casting, percutaneous tendo Achilles tenotomy, and the second phase involves bracing. Although the Ponseti method is accepted as a successful conservative treatment method for treating clubfoot, relapses (approximately 10% to 30 %) and other complications such as pressure ulceration from casting, and partial correction; that is, a rocker bottom foot, are unavoidable (Balasankar et al., 2017; Bhaskar & Piyush Patni, 2013; Chu & Lehman, 2012).
To evaluate the severity of clubfoot, there are many classifications and assessment techniques proposed that assess severity and relapse, including clinical, functional, radiological and imaging methods. In clinical settings, assessments need to be accurate, reliable and valid to predict the prognosis of diseases, select the most appropriate type of treatment and monitor the intervention to ensure its success. However, there is no universal standard assessment method available to quantify the initial severity of clubfoot. Nowadays, the Pirani scoring system and Dimeglio assessment scoring system are commonly used in clinical settings to evaluate the outcome of clubfoot intervention. The four components of clubfoot deformities and treatment outcomes are measured based on the physical aspects of the clubfoot in these two scales (Chu, Labar, Sala, van Bosse & Lehman, 2010; Bergerault et al., 2013). However, these studies have reported that these two scales are subjective and cannot objectively quantify the initial severity. In addition, a previous study by Jain, Mehtani, Goel, Jain, Sood & Jain, (2012), stated that the interobserver and intraobserver variabilities of these scales are not entirely satisfied. Although the Pirani score is useful for effectively assessing the clubfoot
severity, sometimes it is not reduced to 0, even if the foot has been fully corrected with fifteen degrees of dorsiflexion and seventy degrees of abduction of the foot (Khan et al., 2017). In terms of radiological evaluation methods for clubfoot, previous studies (Hutchins et al. 1985; Ramanathan & Abboud, 2010) claim that the repeatability and accuracy are questionable. Radiological evaluation methods cannot provide reliable information due to the lack of ossified bones in newborn babies. Furthermore, accurately positioning the feet of a newborn baby is difficult during radiological examinations. Other imaging modalities such as magnetic resonance imaging (MRI), and computed tomography (CT) are expensive procedures for evaluation of weekly serial casting. Therefore, the main purpose of this study is to systematically review the effectiveness of clubfoot intervention, and develop an objective assessment method to obtain a better understanding as well as in-depth knowledge of the structural changes in clubfoot patients after casting intervention. This study also explores the relationship between the changes in the surface skin temperature of the affected feet and casting intervention.

1.2 Problem statement

The Ponseti method of treatment has been widely accepted by orthopedic surgeons worldwide to correct clubfoot because of its success rate. This treatment method has been accepted worldwide as ‘Gold Standard’ to correct clubfoot deformity of children who are younger than 2 years old. This treatment can also be extended to those who are over the age of two years and children with neglected clubfoot, but not accepted in general practice. Early treatment of children with clubfoot is recommended for successful treatment outcomes. However, relapses are very common which affect the long term success of treatment.
Therefore, there is a need to review systematically to find the effectiveness of the Ponseti method as a treatment option for children under 2 years old to evaluate adherence to treatment protocols and the outcome measures.

Another issue with clubfoot intervention is accurate evaluation of the treatment method because there is no universal standardized assessment method developed to date for evaluating the severity of clubfoot. An accurate evaluation of clubfoot, with an objective method of evaluation, would be useful to measure the severity of clubfoot, progress of the treatment, and number of castings still required for a plantigrade foot. The scoring systems that are used now in clinical settings to predict the progress of clubfoot intervention are subjective in nature. For example, the literature states that sometimes clinicians achieve full correction of clubfoot, however, the Pirani score is still not reduced to score of 0, and it leads the orthopaedic practitioners continue to perform casting until get the Pirani score 0. Also, this score does not reflect the accurate evaluation of dorsiflexion and abduction of the foot in all patients. Objective measures such as CT and MRI can be used as objective measurement methods; however, they are expensive to carry out for every casting, and parents worry about radiation exposure of their newborn babies, and most rural or remote areas will not have facilities with these equipment. Therefore, there is a need to develop an assessment method to simply, quantitatively and objectively assess clubfoot.

Generally, the temperature will be higher in the muscle contracture side of the body parts due to increased blood flow to the area. In clubfoot deformity, most of the ligaments, joints, muscles and other soft tissues are contracted toward the medial side of the foot. The Ponseti method of clubfoot intervention involves different types of interventions: manipulation,
casting, Achilles tenotomy and bracing. However, there is no evidence on whether the thermal distribution pattern during casting intervention is increasing or decreasing. Also, the feet might increase in temperature and pressure ulcers or swelling due to casting might happen due to improperly applied castings or casting slippage during treatment or improper fit of foot abduction orthosis in the maintenance phase of the Ponseti method.

Therefore, an in-depth understanding of the thermal distribution in clubfoot is necessary to increase treatment success rate and reduce complications. Few in the literature have used CT scanning to evaluate the torsion angle of the ankle mortise, calcaneocuboid angle, talus declination angle of the talus neck, morphological features of the talus and calcaneus, and the relationship between the shape of the bones and joints of the hindfoot. Although different types of deformities and positions of the forefoot have been discussed for clubfoot in the literature, there is no evidence of the relationship between the angle of the hindfoot bones (calcaneus and talus) and metatarsal bones and other forefoot bones such as the proximal, middle and distal phalanges of the clubfoot due to the complexity of the three-dimensional deformity of clubfoot.

1.3 Aims of this study

This is an exploratory study that aims to develop an effective three-dimensional (3D) assessment system, based on 3D scanning, to evaluate the severity of clubfoot and response to casting intervention. The secondary aim is to explore the thermo-physiological changes in the clubfoot in response to casting intervention.

1.4 Objectives of this study

The research objectives of this study are as follows:
1. To establish a thorough scientific understanding of the anatomical, physiological, and shape of the clubfoot, and quantify the structural changes of the clubfoot in response to the Ponseti method of manipulation and serial casting intervention.

2. To develop an objective measurement system based on 3D technology to accurately assess the initial severity of the clubfoot deformity and select appropriate intervention options, and predict the prognosis of casting intervention, relapse of clubfoot, and to predict the number of castings required to obtain the full correction of clubfoot.

3. To develop a 3D objective measurement system that assesses the severity of clubfoot based on CT images, and scientifically analyze and quantify the anatomical structural changes of the clubfoot by calculating the angles of the foot in order to improve the accuracy of CT scanning.

4. To evaluate the thermophysiological changes and patterns of skin temperature distribution in the clubfoot, and establish a thermophysiological relationship between clubfoot severity and response to manipulation and serial casting with the Ponseti method, and explore the feasibility of developing a method for thermography evaluation of clubfoot to objectively assess the progress of the intervention.

5. To systematically review the effectiveness of Ponseti intervention for children with less than two years, and to review how the Ponseti techniques regime strictly followed in their study to achieve the initial correction, and to find the outcome of the study, including success rate, number of casts, and to review the relapses and relapse pattern of the clubfoot and causative factors for relapses.
1.5 Project Originality and Significance

Clubfoot is one of the most common and complex 3D deformity that occurs in newborn babies. Accurate assessment is essential for developing an effective treatment for any medical condition, including clubfoot deformity. There are many classification and assessment methods (clinical, radiological, biomechanical, imaging, and functional) which have been used to evaluate the progress of clubfoot casting intervention and predict the relapse of the clubfoot. However, a standardized assessment method for evaluating, quantifying, and grading the severity of the clubfoot is still controversial and lacking. Most of the existing assessments are either subjective or expensive, allows radiation exposure, or not applicable to newborn babies such as pressure measurements. Therefore, the originality of this project is to address the knowledge gap with current assessment methods, and develop effective and objective assessment methods to quantify severity as well as visualize the abnormal arrangement of the bones of the foot and ankle that occurs with this deformity for subjective observations.

This project proposes to use a portable, low cost, and non-radiation 3D scanner (Kinect Xbox) to obtain 3D images of clubfoot and develop a new assessment system based on calculating the cross-section angles from 3D clubfoot images. This cross-section angle from the new assessment system would be useful for monitoring and predicting the prognosis and structural changes of the clubfoot at each casting in the clubfoot intervention, and suitable treatment options. This low-cost imaging method could also be used to predict the number of castings required to accurately normalize the foot, and for telemedicine in remote areas. This
3D modelling technology for clubfoot could also be used to develop customized clubfoot braces and castings.

This study also proposes to use an infrared camera to obtain thermal images of the clubfoot, which can be used to measure the surface skin temperature of the foot at each stage of the casting intervention. Also, this information is useful for observing the thermal physiological patterns of the clubfoot to avoid further complications such as pressure ulcers due to more casting pressure resultant of slippage and brace discomfort. It could be adapted as a supportive diagnosis method to prevent complications and improve compliance to treatment.

Another significance of this project is the development of a 3D model of severe clubfoot bones from the 2D slices of scanned CT images. The semi-automatic assessment method ability of CT provides useful information on the abnormality of the tarsal, metatarsal and phalangeal bones of the severe clubfoot, and allows analysis of the relationships among the hindfoot, midfoot and forefoot and their alignment. Moreover, these three objective assessment methods are useful for improving the effectiveness of clubfoot intervention in a cost-effective manner, and reduce the burden on parents and children. The output of the semi-automatic objective assessment methods can extend into other orthopedic deformities of the foot, and especially advance our knowledge and provide new direction towards 3D based cost effective assessments of foot deformities.

1.6 Outline of the thesis

This thesis is organized into the following 8 chapters as shown in the flow diagram (Figure 1.2).
Figure 1.2 Flow diagram of research methodology
Chapter 1 provides an introduction on the background of the research, the aims and objectives of this research study, and the significance and contribution of this study.

Chapter 2 provides an introduction on previous research and discusses them, as well as the general anatomy of the foot and ankle, clubfoot deformity, causes of clubfoot, prevalence of clubfoot, different assessment methods and medical imaging techniques, and rationale of this research study. Chapter 3 offers a systematic review on the effectiveness of the Ponseti method for clubfoot intervention of children under the age of two years old, which includes the method of data collection and the procedures, current assessment systems that are used to assess severity, and relapse patterns of those with clubfoot, causes of relapses, bracing protocols, and adherence and variations of the Ponseti method protocols that are followed by Ponseti practitioners.

Chapter 4 provides an introduction on a protocol study and proposes a new method of evaluation by using a Kinect scanner and infrared thermography. Also, ethics and proposed method of data analysis for developing a classification system for clubfoot deformity are also discussed.

Chapter 5 provides an introduction on a clinical study and discusses the observed progress of clubfoot intervention by recording a photo based evaluation for each week of casting and the complications of clubfoot casting. In addition, this chapter offers a new method for developing 3D clubfoot bone models, and a novel measurement system for clubfoot based on 3D clubfoot bone modelling. The bone model was developed from the reconstruction of 2D slices of scanned CT images into 3D images by using MATLAB. The angles between each bone of the foot are calculated based on the talus, calcaneus, fibula and tibia of the ankle joint.
to observe the abnormal position of the feet. It would be useful to understand the alignment of the ankle and foot bones clearly and see the relationship and arrangement between the bones.

Chapter 6 provides an introduction and discussion on the development of a new 3D assessment method, study design, subject requirements, ethics approval, algorithm and procedures for developing a 3D clubfoot assessment method, and the results and discussion. Three-dimensional surface modeling of the clubfoot was collected before and after the casting intervention by using a portable scanner and processed by using Artec Studio 9 and CATIA software. CATIA V5 Software was used to develop the cross section based a 3D measurement scale. This findings of the cross section angle is useful for predicting the prognosis of the clubfoot treatment.

Chapter 7 is an introduction and discussion of a novel approach for assessing clubfoot by using an infrared thermography imaging method. Details on the study design, subject requirements, ethics approval, data collection and data analysis procedures are outlined. The data are collected from weekly Ponseti castings for clubfoot. The collected infrared images of the clubfoot were processed by using FLIR and MATLAB software to obtain the distribution of the skin temperature.

Finally, Chapter 8 discusses the overall main findings and outcome of the thesis, strengths and limitations of this project study, and recommendations for future research work.
CHAPTER 2 LITERATURE REVIEW

2.1 Anatomy of the foot

2.1.1 Bones of the foot

The human foot is one of the most complex structures, and consists of twenty-six bones, thirty-three joints, hundreds of ligaments, tendons, intrinsic and extrinsic muscles, nerves, arteries, and veins. It helps to support the human body with the ground during walking, standing, and performing daily activities. The tarsus is located on the posterior side of the foot, and metatarsals and phalanges on the anterior side of the foot. Foot bones can be grouped into three different categories: there are 7 tarsal bones (calcaneus, talus, medial cuneiform, intermediate cuneiform, lateral cuneiform, cuboid and navicular), 5 metatarsal bones, and 14 phalangeal bones (proximal, middle and distal phalanges). Also, two sesamoid bones are located under the first metatarsal head of the foot (Ma & Luximon, 2014). Figures 2.1, 2.2, and 2.3 show the superior and medial, dorsal, plantar, medial and lateral views of the foot and bones respectively. In addition, the foot can be divided into three categories based on its functions; that is, the hindfoot, midfoot, and forefoot. The hindfoot consists of the calcaneus and talus, and midfoot consists of the navicular, cuboid, and medial, intermediate and lateral cuneiform, and the forefoot is formed by the metatarsals and phalanges (Nurzynska et al. 2012). Seven tarsus bones or articulating bones are found under the tibia and fibula and also anteriorly articulate with the metatarsal bones. The talus head is situated about 12 mm above the ground (Nurzynska et al. 2012). Generally, three points of the foot come into contact with the ground: the calcaneal tuberosity on the medial side, first metatarsal head on the
anterior-medial side, and fifth metatarsal head. The muscles, joints, ligaments, and soft tissue structures of the foot together form a ‘functional unit’. This unit helps to bear the body weight (static foot), and support walking, running, and jumping (Ridalo & Palm, 2001).

Figure 2.1 Anatomy of the foot – superior and medial views (Hawass et al., 2011; adapted and modified)

Figure 2.2 Medial view of the human foot
(http://www.corpshumain.ca/en/Os_jambe_en.php)
2.1.2 Arches of the foot

The arches of the foot are made up of bones, short and longer ligaments, tendons, and plantar aponeurosis. They act like a shock absorber and weight bearer during standing, walking, and running. The shape of the foot bones, such as the tarsal and metatarsals are interlocked together, forming the foot arches: the medial longitudinal, lateral longitudinal, and transverse arches (Figure 2.4). These arches are strengthened by the vault which is located just posterior to the 1st - 5th metatarsal heads (Riegger, 1988). It is mainly supported by the short and long plantar ligaments, ligaments at the dorsal side, plantar aponeurosis, calcaneonavicular ligament, and extrinsic muscles such as the tibialis anterior and posterior, flexor hallucis brevis and longus, peroneus longus, and intrinsic muscles of the foot (Nurzynska et al. 2012). The medial longitudinal arch is the most concave shaped, formed by the following bones: talus, calcaneus, navicular, medial, intermediate and lateral cuneiform, and first, second, and third metatarsal bones (Stolwijk, 2014; Huson, 1991; Lieberman, 2012; Lieberman et al.)

Figure 2.3 Lateral view of the foot (http://www.healthcommunities.com/)
The stability of the medial longitudinal arch is strengthened by the plantar aponeurosis or plantar fascia, which is located from the calcaneal posterior tuberosity to the head of the metatarsal bones, spring ligament (calcaneonavicular), and flexor hallucis longus, tibialis anterior, and flexor digitorum longus of the second and third toes (Ma & Luximon, 2014). The lateral longitudinal arch is formed by the calcaneus, cuboid, and fourth and fifth metatarsal bones of the foot (Lieberman, 2012; Lieberman et al. 2010; Huson, 1991). It is a more flat shape and supports the body weight. Muscles and ligaments are more important for supporting the lateral longitudinal arch just like the bones of the foot such as plantar aponeurosis, short and long planter ligaments, flexor digitorum longus tendon for 4th and 5th toes, peroneus longus tendons, and short muscles of the sole on the lateral side of the foot (Ridola & Palma, 2001). Another arch of the foot is called as transverse arch, which consists of the bases of the 1st – 5th metatarsal bones, medial, intermediate and lateral cuneiforms, and cuboid bones. The transverse arch is supported by various ligaments (dorsal and plantar ligaments), transverse ligaments, interosseous muscles, transverse head of the adductor hallucis muscle in the first and fifth toes, tibialis posterior, and peroneus longus muscle (Nurzynska et al., 2012). The medial cuneiform and base of the first metatarsal bone act as the medial pillar of the transverse arch, and third, fourth, fifth metatarsals, lateral cuneiform and cuboid act as the lateral pillar of the transverse arch (Moore et al., 2010).
2.1.3 Ankle and foot joints

The ankle part of the lower extremities consists of the distal end of the tibia and fibula, and talus bones to form the ankle joint (Figure 2.5). It is also called the talocrural joint. The ankle is a hinge type of joint so it will allow one degree of freedom of movement, such as plantar flexion and dorsiflexion. However, the ankle joint will also move with the subtalar joints (talocalcaneonavicular (TCN) and talocalcaneal joints) of the foot. Also, the tibia and fibula are articulated with the upper part of the trochlear surface of the talus bone (Palastanga, 2011; Logan & Ralph, 2012; Ma et al., 2012). The medial and lateral malleolus act as the stabilizers of the ankle joint. The articular surface of the ankle joint consists of the inferior surface of the tibia, fibula, medial side of the lateral malleolus, and lateral side of the medial malleolus, and covered by the articular cartilage. There are two types of ligaments that support and stabilize the ankle joints: the deltoid and lateral collateral ligaments. Generally, the lateral collateral ligaments are considered to be weaker ligaments than the deltoid ligaments of the ankle (Ma
et al., 2012). The lateral collateral ligaments are composed of three ligaments: the anterior talofibular ligaments (ATFL), calcaneofibular ligaments (CFL), and posterior talofibular ligaments (PTFL) (Figure 2.6). The medial collateral ligaments are triangular in shape and covers the inner part of the talus, calcaneus, and distal end of the tibia (Figure 2.7). The triangular shaped medial ligaments can be differentiated at the insertion part of the distal end. There are two types: the superficial deltoid ligaments and the deep ligaments. The apex parts of the superficial bands are attached to the anterior and medial parts of the medial malleolus of the tibia, and the deepest parts of the ligaments are anteriorly attached from the navicular to the body of the talus (Palastanga, 2011). The primary function of the ankle ligaments is to maintain the stability of the joints and control their movement. Therefore, the lateral ligaments are responsible for controlling dorsiflexion movements. Also, they will increase the internal rotation of the talus while performing planter flexion movements. However, the lateral ligaments will not support plantar flexion. The dorsiflexion of the ankle joint is supported by the medial, calcaneofibular, and posterior talofibular ligaments. At the same time, the plantar flexion movements involve the anterior part of the medial and anterior talofibular ligaments (Palastanga, 2011).
Figure 2.5 Anterior and lateral views of ankle joint (Source: Southern California Orthopedic Institute, 2015)

Figure 2.6. Lateral view of ankle joint and lateral ligaments (stemcelldoc.wordpress.com)
2.1.4 Joints of the foot

The joints of the human foot can be classified into several different types including: the subtalar joint, TCN, calcaneocuboid, midtarsal, tarsometatarsal, metatarsophalangeal (MTP), and interphalangeal joints.

2.1.5 Subtalar joint

The subtalar joint is a synovial type joint, and also called a talocalcaneal joint, which is formed by the posterior concave surface of the talus bone, and the convex surface of the upper surface of the heel bone (calcaneus) (Moore & Agur, 2007). Generally, the capsule around the joint will be thick enough to form the ligaments especially on the anterior part of the synovial joint. The posterior and anterior bands of the interosseous TCN ligaments are
situated between the superior surface of the calcaneus and inferior surface of the talus bone. The subtalar joint is responsible for the inversion and eversion motions of the foot (Figure 2.8). In addition, it is also responsible for the supination and pronation of the foot together with the articulation of the TCN joint (Won, 2005). Figure 2.9 shows the inversion and eversion movements of a normal foot.

Figure 2.8 Subtalar joint (slideshare.net)

Figure 2.9 Inversion and eversion of foot (slideshare.net)
2.1.6 Talocalcaneonavicular joint

The TCN joint is a ball and socket synovial type joint, which is made up of convex part of the talus, upper surface of the sustentaculum tali (medial articular surface), anterior surface of the calcaneus body, and concave side of the posterior surface of the navicular bone of the foot. In addition, it posteriorly articulated with the plantar calcaneonavicular and talonavicular ligaments (Palastanga, 2011). The TCN joint supports the inversion and eversion movement of the foot. Figure 2.10 shows the talocalcaneonavicular joint.

![Figure 2.10 Talocalcaneonavicular joint (slide share.net)](image)

2.1.7 Calcaneo-cuboid joint

The calcaneo-cuboid joint is a synovial type joint, which consists of the anterior surface of the calcaneus and posterior surface of the cuboid (Platzer, 2011). This joint is mainly supported by the following ligaments: dorsal calcaneocuboid, bifurcate, plantar calcaneocuboid and plantar calcaneocuboid ligaments, and this joint bears the body weight with the lateral longitudinal arch of the foot. Also, the calcaneo-cuboid joint supports the pronation and supination motions of the foot (Palastanga, 2011; Drake et al., 2012).
2.1.8 Transverse, Tarsometatarsal, Metatarsophalangeal and Interphalangeal Joints

The midtarsal or transverse joint is associated with the talocalcaneonavicular and calcaneocuboid joints, and also referred to as Chopart’s joint, which is always associated with the ankle joint while performing foot motions, especially inversion and eversion motions. The inversion of the forefoot is achieved by supination at the midtarsal joint and adduction of the subtalar joint, while the eversion of the foot is achieved by pronation at the midtarsal joint and abduction at the subtalar joint (Palastanga, 2011). The tarsometatarsal joints are formed by five, three cuneiform (medial, lateral, intermediate) and the cuboid bones. The MTP joints are made up of the head of the metatarsal bones and base of the proximal phalanges of the foot. These MTP joints are supported by the medial and lateral collateral ligaments, and inferiorly supported by the plantar ligament. In addition, all five plantar ligaments are connected to the deep transverse ligaments to keep the toes normally aligned without spreading apart (Clipping, 2007).

2.1.9 Muscles of the foot

The muscles of the ankle and foot can be classified into two groups of muscles: the 12 tendons of the extrinsic muscles of the foot and the intrinsic muscles of the foot. The tendons of the muscles that originate from the lower leg are called the extrinsic muscles of the foot. At the same time, the twelve intrinsic muscles arise from within the foot and insert on the foot (Clipping, 2007). The tendons of the tibialis anterior, extensor digitorum longus, extensor hallucis longus, and peroneus tertius insert into the dorsum of the foot. The dorsum of the foot has only one muscle, which is the extensor digitorum brevis (Figure. 20). The sole
of the foot has four layers of muscles. The first layer of muscle of the plantar aspect consists of the abductor hallucis, flexor digitorum brevis, and abductor digiti minimi. The second layer of the foot muscles consists of the lumbricals and flexor accessorius. The third layer of foot muscles are the adductor hallucis (transverse and oblique heads), flexor digiti minimi brevis, flexor hallucis brevis. Finally, the fourth layer of the foot muscles consists of the dorsal and plantar interosseous, and the tendons of the tibialis posterior and peroneus longus (Figures 2.11, 2.12, 2.13, and 2.14).

Figure 2.11  Muscles on the dorsum of the foot (http://anatomyproartifex.blogspot.hk/)
Figure 2.12 First layer of muscles on the sole of the foot (Marieb & Hoehn, 2006)

Figure 2.13 Second layer of muscles on the sole of the foot (Marieb & Hoehn, 2006)

Figure 2.14 Third and fourth layers of muscles on the sole of the foot (Marieb & Hoehn, 2006)
2.2. Clubfoot

2.2.1 Introduction

Clubfoot is one of the most complex foot deformities in newborn babies. It occurs in one in 1000 live births, and approximately 200,000 babies are born with congenital clubfoot annually worldwide (Global Clubfoot Initiative, 2017). There is a high percentage of clubfoot babies born in the developing countries, which is about 80% (Global Clubfoot Initiative, 2017). Clubfoot deformity is characterized by four types of deformities: hindfoot equinus, hindfoot varus, forefoot adductus and midfoot cavus (Ramanathan & Abboud, 2010). There are also evident structural changes of the foot, which include contracture of the peroneus and calf muscles, soft tissues on the medial side of the foot, subluxation of the TCN joint, dislocated talus, and contractured ligaments (Seravalli et al. 2014; Herring, 2013).

2.2.2 Prevalence of clubfoot

Clubfoot has been documented since 1000 B.C., for instance, the 1300 B.C. Egyptian tomb paintings showed that the 19th dynasty Pharaoh had clubfoot (Figure 2.15) (http://soignerunpiedbot.com), and treatment for clubfoot was found at around 1000 B.C. in India (Dobbs, Morcuende, Gurnett & Ponseti, 2000). A painting in 1642 by Jusepe de Ribera, a Spanish painter, showed a clubfoot beggar (Figure 2.16). However, concrete statistics on the prevalence of clubfoot have only been recently available in the literatures, in which the incidence rate of clubfoot is 0.9 to 7 children in 1000 live births (Beals, 1978; Shiels et al., 2007; Hussain et al., 2014; Bhargava, Prakash, Tandon, Arora, Bhatt & Bhargava, 2013). The
highest prevalence of clubfoot is found in the Polynesian population and the lowest in the Chinese population (Dobbs & Gurnett, 2012; Chung et al., 1969; Beals, 1978). According to the Global Clubfoot Initiative (2017), the highest prevalence of clubfoot in in Hawaii (0.68) and the lowest in the Philippines (0.76); see Table 2.1. In terms of gender, clubfoot is commonly found in the male population at a ratio of than female (2:1), which is consistently similar in all ethnic groups worldwide (Gadhok et al. 2012; Alberman, 1965; Cartlidge, 1984; Wynne-Davies, 1964; Lochmiller, 1998; Foster & Davis, 2006; Dobbs & Gurnett, 2009). In addition, 50% of the cases are bilateral clubfoot and unilateral clubfoot is commonly found on the right foot in children (Wynne-Davies, 1964).
Table 2.1 Prevalence of clubfoot (Source from Global Clubfoot Initiative, 2017)

<table>
<thead>
<tr>
<th>Source</th>
<th>Country</th>
<th>Incidence/Live births</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carey et al. 2003</td>
<td>Australia: Aboriginal</td>
<td>3.49</td>
</tr>
<tr>
<td>Carey et al. 2003</td>
<td>Australia: Caucasian</td>
<td>1.11</td>
</tr>
<tr>
<td>Paton et al. 2010</td>
<td>Belgium</td>
<td>1.6</td>
</tr>
<tr>
<td>Krogsgaard et al. (2006)</td>
<td>Denmark</td>
<td>1.2</td>
</tr>
<tr>
<td>Dietz (2002)</td>
<td>Hawaii</td>
<td>6.8</td>
</tr>
<tr>
<td>Mittal et al. 1993</td>
<td>India</td>
<td>0.9</td>
</tr>
<tr>
<td>Yamamoto (1979)</td>
<td>Japan</td>
<td>0.87</td>
</tr>
<tr>
<td>Aguilar (2010)</td>
<td>Philippines</td>
<td>0.76</td>
</tr>
<tr>
<td>Wallander et al. (2006)</td>
<td>Sweden</td>
<td>1.4</td>
</tr>
<tr>
<td>Pirani (2009)</td>
<td>Uganda</td>
<td>1.2</td>
</tr>
<tr>
<td>Dietz (2002)</td>
<td>USA</td>
<td>1</td>
</tr>
</tbody>
</table>

2.2.3 Etiology

There have been many theories proposed that attempt to explain for the causes for the occurrence of clubfoot in new born babies. However, the cause of clubfoot is still remaining controversial. In particular, three theories are more popular: first theory is the Hippocrates theory, in which clubfoot is said to be caused by external pressure on the foot, and then the second theory claimed that causes of neurogenic pathogenesis and finally, abnormality of the
bones of the feet (Bass, 2011). Some studies claimed that the genetic factors cause of clubfoot (Dobbs & Gurnett, 2012; Andriesse, 2007), and more prevalent in monozygotic twins (Engell, Dambiorg, Andersen, Kyvik & Thomsen, 2006), and other factors such as vascular abnormalities, abnormal position in the uterus, environmental causes, anatomical factors (Dietz, 1985; Siapkara & Duncan, 2007; Dobbs & Gurnett, 2009), and resultant of an enterovirus intrauterine infection, seasonal variations in month of birth (Barker & Macnicol, 2002), an abnormal intracellular structure of the muscles of foot (Gray & Katz, 1981; Herceg et al., 2006), and increased maternal homocysteine levels (Karakurt et al., 2003). However, Carney and Coburn, (2005) found no relationship between seasonal variations in month of birth and clubfoot. In addition, around 20% of the clubfoot cases are associated with other birth defect malformations such as arthrogryposis, myelodysplasia, Down’s syndrome, Larson’s syndrome, Freeman-Sheldon syndrome, and multiple congenital abnormalities (Gibbons & Gray, 2013; Siapkara & Duncan, 2007; Wynne-Davies, 1964; Foster & Davis, 2006), of which, distal arthrogryposis and meningomyelocele are considered to be the main etiological factors among the different nervous system disorders (Gordon, 1998). Furthermore, clubfoot is associated with various risk factors such as male gender, smoking during pregnancy period, gestational diabetes mellitus, maternal age, marital status, and parity (Nguyen et al. 2012). Literature review, this study finds a number of theories that contemplate on the causes of clubfoot but the exact cause is still unknown.
2.2.4 Pathoanatomy and Biomechanics of Clubfoot

The pathoanatomy and biomechanics of clubfoot are essential to gain an in-depth understanding of clubfoot. In 1800, the anatomy of clubfoot was described by Antonio Scarpa who claimed that clubfoot is caused by the dislocation of the TCN joints (Anand & Sala, 2008). Goldstein claimed that the outward rotation of the talus in the ankle mortise is the primary cause of clubfoot (Anand & Sala, 2008).

In newborn babies, biomechanical and functional restrictions are absent in the normal foot but will appear in the plantigrade position when children start to stand and walk. The ossification center of the navicular and three cuneiforms are not present at birth. At the same time, the hindfoot bones (calcaneus and talus) are ossified at birth (Wallander, 2010). The clubfoot is characterized with a firm equinus position of the hindfoot, retraction of the gastrosoleus muscles, and calcaneus in the varus position (inverted position). In varus deformity, the hindfoot is rotated inwards, especially at the TCN joint (Anand & Sala, 2008).

At the same time, adductus deformity occurs at the subtalar and talonavicular joints. The medial side of the forefoot faces in an upward direction in relation to the hindfoot. The cavus deformity is involved with forefoot plantar flexion along with contribution to equinus position (Anand & Sala, 2008). The medial displacement and inverted position in relation to the talus can be seen in the clubfoot due to misalignment of the calcaneus, cuboid, and navicular bone (Jeevan et al., 2011). Sometimes, the neck of the talus bone is shorter or absent. With palpation examination, the talus bone is found to be near the medial malleolus (Ponseti, 1992). The other hindfoot bone, the calcaneus, is rotated medially (horizontal plane), inverted and adducted under the talar head in the equinus (Ponseti & Campos, 1972;
The calcaneal and talus bone are in a planter flexed position, which causes the varus deformity in the hindfoot. The navicular bone is displaced towards the head of the talus in severe cases of clubfoot as shown in Figure 2.17 (Pirani et al., 2001; Riegger, 1988; Maranho & Volpon, 2011). One of the tarsal bones, the cuboid, moves towards the direction of the medial side of the foot and in relation to the calcaneus. The adduction of the forefoot is caused by the medial displacement of the tarsometatarsal joints and metatarsal diaphysis (Maranho & Volpon, 2011). In addition, the tarsometatarsal joints and metatarsal diaphysis are medialized and pronated in relation to the hindfoot. The hindfoot is more supinated than the forefoot, thus causing cavus deformity and posterior skin creases (Ponseti, 1992).

Additionally, there are a number of abnormalities that can be seen in clubfoot patients, such as atrophy of the muscles (tibialis posterior and soleus muscles), abnormalities of the tarsal bones, shortening and thickening of the ligaments (medial, posterior, and plantar regions), fibrotic changes in the tendons, tendon sheaths, muscles and ligaments (Ippolito & Ponseti, 1980; Maranho & Volpon, 2011; Pous & Diméglio, 1978; Da Paz & de Souza, 1978), subluxation of the talocalcaneocuboid joints (Nordin et al., 2002), and shortness of the foot (Siapkara & Duncan, 2007). Increased levels of type I fibre can be found in the soleus, tibialis posterior, long toe flexors, and peroneal muscles of the affected leg as opposed to the unaffected leg (Gray & Katz, 1981). However, some studies have reported that increased levels of type I fibre are caused by neurogenic issues (Isaacs et al., 1977). On the other hand, a recent study by Herceg et al. (2006) examined types I and type II fibres in 431 muscle specimens, which were collected during the period of posteriomedial release surgery, and the
results showed that there is an equal level of types I and type II fibre in 99% of the muscle specimens. Furthermore, one of the research groups (Merrill, Gurnett, Siegel, Sonavane & Dobbs, 2011) found the deficiency or absence of an arterial supply especially the anterior tibial and dorsalis pedis arteries, and diminished size of peroneal artery in the clubfoot.

![Figure 2.17 Clubfoot- Displacement of bones](image)

**2.2.5 Management of clubfoot**

The treatment for clubfoot has a long history and was initially described by Hippocrates in 400 B.C. He recommended manipulation techniques and using bandages to treat the clubfoot. These techniques have been transformed but now, similar techniques are used in the conservative management of clubfoot today (Global Clubfoot Initiative, 2017). In earlier periods, children with clubfoot were treated with different techniques, as shown in Figure 2.18.
Clubfoot treatment in 1806 (Global Clubfoot Initiative, 2017)

Thomas Wrench (Global Clubfoot Initiative, 2017)

Surgical treatment of clubfoot in 1800 (Global Clubfoot Initiative, 2017)

Figure 2.18 Clubfoot management in earlier periods of time (Global Clubfoot Initiative, 2017)

Based on the principles of Hippocrates’s techniques, there are a number of conservative methods proposed to correct clubfoot deformity such as the Ponseti method, (manipulation, casting, Achilles tendon tenotomy, foot abduction brace), French functional method/French physiotherapy method, physical procedures such as heat therapy, movement or kinesthesio-
therapy, electro therapy, footwear or shoe modifications, and splints and orthotics (Utrilla-Rodriguez et al., 2012). After observing many complications that arise from surgical procedures, Kite (1972) introduced casting techniques to treat clubfoot. Whether clubfoot is better treated through surgical or other less invasive methods has been debated for centuries (Carroll, 2012; Singh, Roshan & Ram, 2013). However, the Ponseti method has become very popular and found to be an effective treatment method in the last few decades. In addition, another conservative method, French taping is starting to be more prevalent in many parts of the world. The advantages of the Ponseti method is that it is non-invasive and alleviates the stiffness of joints, as well as pain from surgical management (Laaveg, 1980). In the following section, the conservative methods to treat clubfoot will be discussed in detail.

2.2.5.1 Ponseti method

The Ponseti method consists of weekly gentle manipulation, serial long leg casting, Achilles tendon percutaneous tenotomy, and bracing techniques. The main purpose of the Ponseti method is to achieve full correction of clubfoot deformities such as forefoot adductus and midfoot cavus, hindfoot varus, and ankle equinus (Ponseti, 1992). As shown in Figure 2.19, the midfoot cavus is corrected by the supination of the forefoot along with pressure applied onto the first metatarsal head of the foot. The deformity is mostly corrected after the first week of casting (Radler, 2013). Equinus deformity resultant of forefoot adductus and hindfoot varus can be corrected in the following 2-5 castings by applying counter pressure onto the head of the talus with the foot in the abducted position and externally rotated (Bergerault et al., 2013; Ganesan et al., 2016). The casting should be changed on a weekly
basis (Figure 2.20). In addition to manipulation, percutaneous tenotomy, in which the tendon is divided and lengthened, is carried out if equinus deformity persists (Figure 2.21). Subsequently, the corrected foot will be immobilized for three weeks with maximum dorsiflexion and sixty degrees of abduction (Lara et al., 2013). The second phase of treatment in the Ponseti method is bracing, and the child has to wear a foot abduction brace for 23 hours a day and a period of 3 months (Figure 2.22). After twelve weeks, the brace is recommended during the night and nap time up to 4 years of age (Wallander, 2010). Previous studies have reported that the success of this technique is about 78% (Cooper & Dietz, 1995; Pulak & Swamy, 2012). Ponseti (1994) indicated that 89% of the cases are treated successfully without open surgical treatment through conservative techniques in the Ponseti method. However, in a study by Singh et al. (2013), 85% of the cases still require Achilles tenotomy to correct the equinus deformity.

Figure 2.19 Manipulation of clubfoot with Ponseti technique (Mosca, 2016)
Figure 2.20 Casting in Ponseti method

Figure 2.21 Percutaneous Achilles tenotomy

Figure 2.22 Dobbs clubfoot bar (author’s photo)
2.2.5.2 French functional method

The French functional or physiotherapy method is one of the more popular methods of non-invasive management. The principle behind the French functional method is that clubfoot is caused by contracture of the medial side of the foot, such as the soft tissues which are not only contracted but also fibrotic, and involves the posterior tibialis tendons and muscles. In addition, clubfoot is also due to weakness of the lateral side of the foot structures, such peroneus longus and peroneus brevis muscles, and deviation of the mid-tarsal joints. When compared to the Ponseti method, the French functional method requires daily manipulation and stretching (Singh et al., 2013). The correction must be maintained with elastic taping and splints until the next day (Steinman et al. 2009) (Figures 2.23 and 2.24). The treatment needs to be continued for 2-3 months, followed by stretching and manipulation for another 6 months. During the first phase of the treatment, the heel needs to be massaged, stretched, distracted, stimulated, and everted. In the second phase, splints are worn for 2-3 years during the night when the child is sleeping (Wallander, 2010)

![Figure 2.23 French taping method](image)
2.2.5.3 Copenhagen Method

The Copenhagen method for correcting clubfoot has been the least discussed in the literature. This method was developed at a Danish orthopedic hospital in 1976. The treatment involves flexion and manipulation, muscle stimulation of the foot, and plaster casting (Utrilla-Rodríguez et al., 2012). These need to be carried out daily to achieve a plantigrade foot and will take up to 6 weeks (Ward & Shelton, 2015). This method is very similar to the French functional method, but has a different way of placing the dressing and implementing splinting (Reimann, 1967). The bandage is used to correct the foot as alternative to the braces, and needs to be monitored until the patient’s feet reach skeletal maturity. There is also the modified Copenhagen method in which the adducted deformity is corrected first, and then corrections to the cavus, varus, and equinus deformities will be made (Utrilla-Rodríguez et al., 2012). The practitioner needs to use one hand to hold the hindfoot, cuboid bone, and tibial epiphysis, while other hand applies distraction on the first metatarsophangeal joint as shown in Figure 2.25A. In Figure 2.25B, the cavus is corrected by supination of the forefoot, and at
the same time, the first metatarsal area of the foot is dorsiflexed. In correcting the varus deformity, the heel of the foot is held by one hand while providing pressure onto the head of the talus to move it inside and at the same time, providing pressure onto the calcaneal bone to move it outwards. The other hand induces pressure onto the metatarsal head as shown in Figure 2.25C. The equinus deformity is corrected by applying gentle traction on the tendons of the heel and performing dorsiflexion on the forefoot (Figure 2.25D). In addition, muscles stimulation is applied onto the lateral side of the foot (Aurell, Johansson, Hansson & Jonsson, 2002; Utrilla-Rodríguez et al., 2012). In the final stage, a Larsen Active T splint is used for 7 to 8 months to avoid relapse and then a splint is used at night when the child is sleeping. Utrilla-Rodriguez et al. (2012) reported that 55% of the cases need not involve surgery and only 2% required an Achilles tenotomy.

A. Correction of adducted deformity

B. Correction of cavus deformity
2.3 Assessment of clubfoot

2.3.1 Development of clubfoot assessment

The assessment of clubfoot deformity is necessary for evaluating the severity of the condition, deciding on the treatment options, evaluating the treatment outcomes as well as predicting the prognosis (Herd et al., 2004). Although the pathological anatomy of clubfoot was first described by Hippocrates around 400 BC, there is still no universal assessment method to assess the initial severity of clubfoot deformity (Chu et al., 2010; Yeung et al., 2005; Gigante et al., 2004; Catterall, 1991; Catterall, 1994, Dimeglio et al., 1995). However, a number of researchers have proposed both subjective and objective methods for clubfoot assessment, including clinical, functional and radiological methods. Herd et al. (2004) stated that most of the assessment techniques in the literature have a mix of both subjective and objective methods. Generally, subjective assessment is less reproducible, and inaccurate to predict the prognosis. However, most clubfoot classifications are based on “subjective” clinical assessment methods. According to the subjective classification systems, the...
quantification of clubfoot severity is “mild”, “moderate”, “severe”, or “very severe”, but these classification systems will not provide accurate enough, and the scoring will vary from clinicians to clinician (Cosma & Vasilescu, 2015; Pandey & Pandey, 2003). In the literature review, assessment scales and imaging modalities are described in detail.

2.3.2 Pirani scoring system for clubfoot assessment

The Pirani scoring system is one of the most commonly used systems in clubfoot clinical settings, and provides a simple system clubfoot by examining the physical appearance of the foot (Bergerault et al. 2013; Dyer & Davis, 2006; Bor et al., 2009). The scale consists of two components (hindfoot score- HFS and midfoot score-MFS) with 6 clinical scoring items, including three morphological signs of changes in the hindfoot and three in the midfoot (Figure 2.26). The HFS items are: posterior crease (PC), empty heel (EH), rigid equinus (RE), and the MFS items are: curvature of the lateral foot (LCF), medial crease (MC), and position of the lateral head of the talus (LHT). Each is scored into one of three situations: 0 - no abnormality; 0.5 - moderate abnormality; and 1 - severe abnormality. The total score is 6, which denotes severe deformity and 0 is a normal foot (Pirani, Outerbridge, Sawatzky & Stothers, 1999). The inter-observer reliability for the Pirani scoring system shows a higher Kappa score (0.92) when compared to other scoring system (Halanski et al., 2010; Wainwright et al., 2002; Pirani et al., 1999). In terms of predicting the number of castings required to correct the clubfoot and possibility of tenotomy, higher Pirani score at the baseline means increased chances of casting and tenotomy (Singh, 2008; Mejabiet et al., 2016). For instance, there is a 72% chance that the foot requires tenotomy if the initial HFS is
about 2.5 or 3, and the Spearman’s rank correlation coefficient shows a highly significant positive correlation between the number of castings and baseline Pirani score \( (r = 0.72, p < 0.0005) \) (Dyer & Davis, 2006). However, a fairly high correlation was observed by Dyer and Davis (2006) when analyzing the Achilles tenotomy and non-tenotomy groups, which is 0.66 and 0.79 respectively. Despite the subjectivity of this scoring system, there is good inter- and intra-observer variabilities. The interobserver variability was tested with 5 different orthopedic surgeons and the total kappa score is - 0.71 (Jain, Ajmera, Solanki, Verma, 2017). The intra-rater and inter-rater reliabilities of physiotherapists were examined by using the Pirani score from digital photographs of clubfoot, on which they indicated the six clinical signs of clubfoot, and the results showed excellent intra-rater and fair inter-rater reliabilities (Harvey, Daley, Mudge, Sims, Adams, Gray & Kumar, 2012). In contrast, although this scale is commonly used on children with neonatal clubfoot to monitor their clubfoot severity and its prognostic value, and better in predicting the outcomes as discussed earlier, some studies have reported that some of the measurements in this scale are not perfect, such as for the cavus and medial crease in the midfoot and posterior crease and emptiness of the heel in the hindfoot (Chu et al., 2010; Bergerault, Fournier & Bonnard, 2013). Furthermore, some researchers claim that the Pirani score cannot well predict the number of castings required to correct the clubfoot condition (0.34 and 0.33) (Chu et al., 2010) or cannot do so at all \( (r=0.12) \) (Gao, Tomlinson & Walker, 2014). In summary, this study has found several studies that question the validity of the current classification systems and suggest the use of objective standarized assessment methods to evaluate the treatment or determine the prognostic significance (Chu et al., 2010; Ramanathan & Abboud, 2010; Singh, 2008; Jain et al., 2009;
In the following section, the Dimeglio classification for clubfoot which is another commonly used assessment method will be described in detail.

**Midfoot score**

- **CLB**
- **MC**
- **LHT**
Hindfoot score

PC

RE

EH

Figure 2.26 Pirani scoring system
2.3.3 Dimeglio classification for clubfoot

In 1995, the Dimeglio scoring system for the classification of clubfoot was provided by Dimeglio and his colleagues (Dimeglio et al., 1995). This scoring system contains four anatomical parameters of measurement, that is, a) sagittal plane equinus, b) frontal plane varus deviation, c) ‘derotation’ around the talus of the calcaneo-forefoot block, and d) adduction of the forefoot on the hindfoot in the horizontal plane, and each parameter has a minimum score of 0 to a maximum of score of 4 points (16 points), and an additional 4 points are added for posterior and medial creases, poor calf fibrous musculature and cavus (Cosma & Vasilescu, 2015; Wainwright, et.al., 2002) (Figure 2.27). The total score that can obtained from the Dimeglio system is 20, which includes the four additional points as discussed above. Clubfoot can be classified into 4 types based on the total score, including: benign for a score that is less than 4, moderate for a score of 5 to 10, severe for a score of 10 to 15, and very severe for 15 to 20 (see Table 2.2). Several studies have reported that this classification system is useful for predicting the number of castings required for correction, possibility of Achilles tenotomy, and clubfoot relapses (Dimeglio et al., 1995; Sinha et al., 2016; Thacker et al., 2004). At the same time, Sinha et al. (2016) reported that the Dimeglio score has a moderate correlation (0.439) in predicting the number of castings. Wainwright et al. (2002) examined the reliability of four classification systems (Dimeglio classification, that of Ponseti and Smoley, Harrold and Walker, and Catterall) and found that the Dimeglio classification system has moderate to substantial reliability as opposed to other systems. Cosma and Vasilescu (2015) assessed the reliability and reproducibility of the Dimeglio and Pirani
scoring systems and found that the Dimeglio system has a coefficient of 0.85 and showed that the learning curve is relatively short with very good interobserver reliability (0.83; \( p = 0.0001 \)) (Flynn et al., 1998). In contrast, in another study, the Dimeglio score has poor correlation with number of castings required for correction (\( r_s = 0.34 \) vs. 0.33) but the highest correlation with equinus (\( r_s = 0.39 \)) and forefoot adduction (\( r_s = 0.35 \)) (Chu et al., 2010).

The literature review showed that there are number of classifications described in detail. However, there does not appear to be a standardized and objective assessment tool for clubfoot until now to accurately assess clubfoot severity, and monitor and predict the prognosis of clubfoot casting or surgical intervention.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Type /Features</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>Benign: Reducible without any resistance</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Grade II</td>
<td>Moderate: Reducible with certain degree of resistance</td>
<td>5-10</td>
</tr>
<tr>
<td>Grade III</td>
<td>Severe : Reducible against strong resistance</td>
<td>10-15</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Very severe : Not reducible</td>
<td>15-20</td>
</tr>
</tbody>
</table>
Figure 2.27 Dimeglio scale for clubfoot classification (Source: Wainwright et al., 2002)

2.3.4 Disease specific index (DSI) scale

In 2001, the disease specific index (DSI) was developed by Roye et al. (2001) to assess the outcome of clubfoot treatment (Table 2.3). There are a number of studies that have used the “disease specific index (DSI) scale” as a measure of function in patients and their satisfaction (Dietz et al., 2009; Roye, Vitale, Gelijns & Roye, 2001; Symeonidis et al., 2016; Graf, et al., 2010; Church et al. 2016; Gray, Burns & Bellemore, 2014). This scale consists of 10 items
and the score for each item ranges from one to four. A lower DSI score (10 points) indicates the best outcome and a higher score (40 points) represents the worst outcome. Roye et al. (2001) tested the reliability of the DSI with Cronbach’s alpha, and found that a satisfactory internal consistency alpha score for satisfaction - 0.72, function subscale - 0.68, and total score - 0.76. In addition, the DSI score has a positive linear relationship with the Pediatric Quality of Life Inventory TM (PedsQLTM 4.0) (for total score: p=0.00). Dietz et al. (2009) assessed the DSI scores in clubfoot patients (mean age 8.6 years, ranged from 5 to 12 years), those who were treated with joint-sparing techniques such as the Ponseti method or joint-invasive surgery, and the study results showed that the DSI scores are higher in joint-sparing techniques than joint-invasive surgery. On other hand, the total score (p = 0.040) and functional subscale of the DSI (p = 0.040) received a higher score but the satisfaction subscale of DSI is not significant (p = 0.100). Gray et al. (2014) used the DSI as one of the outcome measures of function in patients and the satisfaction of 20 children with clubfoot (age range: 53 ± 10 months) , those who were referred for tibialis anterior tendon transfer surgery. Their results indicated that higher scores at the base line than the group who were referred for non-tibialis anterior tendon transfer surgery (mean difference, 5; 95% CI, 1–8; p = 0.008). However, there is no significant relationship between the two groups at the 3 (p = 0.099), 6 (p = 0.055), and 12 month (p = 0.076) follow-up. In 2013, Radler, Mindler, Riedl, Lipkowski, & Kranzl (2013) found a total score of 85.3 in the DSI (± 13.01 SD) out of 100 points in 65 clubfoot patients and this scale was administered for those between the age range of 3.3 to 8.9 years old. Some studies use the DSI evaluation score as an outcome measure for the surgical release of adult clubfoot patients but Graf et al. (2010) did not provide findings
on function and satisfaction except for pain with the DSI. Furthermore, previous studies, such as Dietz et al. (2009), recommended that the DSI scale should be used with other validated outcome measurement scales, test-retest reliability studies, and studies with different age groups to validate DSI scores as an outcome measure. The literature review on the DSI questionnaire showed that most of the studies use the questionnaire to measure surgically treated clubfoot (long term results), and for follow up to assess the quality of life in the different age groups of children. However, Roye et al. (2001) reported that this scale is not responsive enough to measure the initial severity of the clubfoot before (preoperative) and after treatment (postoperative). Also, the questionnaire is not reliable because it can also be administered through the parents or guardians, or young children who are not capable of reporting on their health status in a reliable manner.
### Table 2.3 Disease-specific instrument scale (Source: Symeonidis et al., 2016)

<table>
<thead>
<tr>
<th>A. Disease-specific score questionnaire</th>
<th>Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1. How satisfied are you with your foot?</td>
<td>very satisfied</td>
</tr>
<tr>
<td>2. How satisfied are you with your feet appearance?</td>
<td>very satisfied</td>
</tr>
<tr>
<td>3. How often are you teased because of your clubfoot?</td>
<td>never</td>
</tr>
<tr>
<td>4. How often do you have problems finding shoes that fit?</td>
<td>never</td>
</tr>
<tr>
<td>5. How often do you have problems finding shoes that you like?</td>
<td>never</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Function</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you ever complain of pain in your [affected] foot?</td>
<td>no</td>
<td>yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How limited is your ability to walk?</td>
<td>not at all limited</td>
<td>somewhat limited</td>
<td>moderately limited</td>
<td>very limited</td>
</tr>
<tr>
<td>to run?</td>
<td>not at all limited</td>
<td>somewhat limited</td>
<td>moderately limited</td>
<td>very limited</td>
</tr>
<tr>
<td>How often do you complain of pain during heavy exercise?</td>
<td>never</td>
<td>sometimes</td>
<td>usually</td>
<td>always</td>
</tr>
<tr>
<td>How often do you complain of pain during moderate exercise?</td>
<td>never</td>
<td>sometimes</td>
<td>usually</td>
<td>always</td>
</tr>
</tbody>
</table>

#### 2.3.5 Carroll clubfoot severity

Most clubfoot deformities can be corrected by using the Ponseti method. A small percentage of those with clubfoot cannot be easily treated because of the severity of the deformity, which can be classified as very severe, teratogenic, or stiff-stiff (Goldner & Fitch.; Dimeglio, 1995; Pandey & Pandey, 1994). One of the studies (Horn et al., 2013) compared the rate of radiological surgery following the implementation of the Ponseti and Kite methods of
clubfoot treatment. Also, this study used the Carroll approach to assess and quantify the pre-operative severity of the clubfoot. The scale used consists of 10 components: calf atrophy, posterior displacement of the lateral malleolus, medial or posterior creases, curved lateral border, cavus deformity, in equinus, navicular fixed to medial malleolus, os calcis fixed to the fibula, no mid-tarsal mobility, fixed forefoot supination and the score ranges from 0 to 10. Horn et al. (2013) used the Carroll approach to evaluate the clubfoot severity before performing posteromedial release (PMR) or Posterior release (PR) operation, in that the average pre-operative scores of the posteromedial release (PMR) (40%) is 8, and 2.8 in the posterior release (PR) in the pre-Ponseti group. However, this scale has been used in very few studies and therefore provides little evidence of its validity (Horn et al., 2013).

2.3.6 Biomechanical assessment methods for evaluating clubfoot

The assessment of clubfoot is essential for predicting the prognosis of the treatment. Generally, the clinical evaluations, and radiological and functional assessments have been used as conventional methods to predict the prognosis of clubfoot intervention. Several researchers have described biomechanical-foot pressure assessment in their studies (Herd et al., 2004, 2008) and bimalleolar angular measurements for clubfoot (Jain et al., 2001, Dube et al., 2015; Ramanathan & Abboud, 2010; Singh, 2008; Jain, 2009; Ramanathan et al. 2009; Trivedi et al. 2017, Anshuman et al., 2016), Pedobarography (Gray et al., 2014).

The bimalleolar angular measurements are carried out as follows: the child’s feet will be maintained in the plantigrade or weight bearing position on a paper sheet followed by foot tracing. At the same time, the prominent or mid points of the medial and lateral malleoli are
marked on both sides of the foot prints with a pencil and ruler. Thereafter, a line will be
drawn on the foot print (long axis of the foot) from the second toe to the most prominent or
convex part of the heel. On the same footprint, another line (bimalleolar axis line) is drawn
between the medial and lateral malleoli. The anteromedial foot bimalleolar angle (FBM)
angle is calculated at the intersecting point of two lines (Jain et al., 2001; Singh, 2008;
Anshuman et al., 2016; Obeidat, Mustafa & Darwish, 2011)

In 1979, Kumar proposed a foot tracing method (inked foot print) to assess the severity of
clubfoot and grade the severity after correction. In this assessment method, the foot is grasped
by both hands of the examiner and then the foot is placed onto a rubber stamp. Thereafter,
foot prints were collected by standing with the feet on a white sheet which is placed on an
even surface (Figure 2.28). In the foot print assessment method, the severity and progression
of the clubfoot are determined by the shape and pattern of the inked foot print. However,
previous studies have reported that there is no correlation found clubfoot severity and grading
the severity after the correction of the clubfoot. Subsequently, McKay (1982 and 1983)
examined the “calcaneal bimalleolar angle”, which is measured between the bimalleolar
plane and long axis of the foot. However, the calcaneal bimalleolar angle is not related to the
severity of clubfoot deformity.
Later, Jain et al. (2001) assessed the anteromedial FBM on the clubfoot footprint and normal infant foot (Indian population) to establish a normal FBM among normal children and assess clubfoot severity and progress of treatment. The FBM angle was collected from 91 normal infants (182 feet) and 51 clubfoot children (84 clubfeet). The FBM angle was classified into Grades I, II and III deformities. Among the 51 clubfoot children, five feet were a Grade I deformity (mean of FBM angle of 73.2°), twenty-one feet were a Grade II deformity (mean of 66.6°), and fifty-eight feet were a Grade III deformity (mean of 54.7°). The results reported that the average FBM angle is 82.5° in normal infants. Moreover, more than half or 56% with a Grade III deformity required surgical intervention (circumferential subtalar release (CSTR)). Jain et al. (2001) also reported that the FBM angle increases from 47 degrees to 83 degrees on the right foot (after CSTR), and from 45 degrees to 78 degrees on the left foot (after CSTR). At the same time, the FBM angle is increased from 61 degrees to 84 degrees on the right foot, and 60 to 70 degrees on the left foot with non-operative treatment. Only a few researchers have investigated the correlation between foot bimalleolar angle and Pirani score on clubfoot severity in managing clubfoot with the Ponseti method, including Singh (2008);
Dube et al. (2015); Anshuman et al. (2016); and Jain et al. (2012). All reported that the correlation between the FBM angle and Pirani score is statistically significant.

Recently, Anshuman et al. (2016) examined the correlation between the FBM angle and Pirani score on the Ponseti management of the clubfoot at baseline, for every week of the treatment, as well as for the follow up. For example, the Figure 2.29 shows the results of the severity of the clubfoot at the baseline (FBM of 66° and Pirani score of 5) and Ponseti treatment in the successive week which is evaluated by FBM and Pirani score. In the first week, the FBM is 70° and Pirani score is 4; second week, the FBM is 74° and Pirani score is 3; third week, FBM -78° and Pirani score 1.5; fourth week, FBM 84° and Pirani score is 0.5; and fifth week, FBM is 84° and Pirani score is 0. The results indicated that the FBM angle is well correlated with the Pirani score at every stage of the management of idiopathic clubfoot. The FBM angle can also be used as an objective means to assess the severity, progression, and deterioration of the clubfoot. However, this angle measurement for quantifying the severity of clubfoot is determined by position of the forefoot and shape of the heel. Moreover, this parameter helps to indirectly predict the forefoot adduction and varus of the hindfoot, but not to measure the equinus (Jain, Zulfikar, Kumar, & Dhammi, 2001; Anshuman et al., 2016).
In 2014, Gray et al. study used pedobarography and other biomechanical assessment methods such as muscle strength, plantar loading to evaluate the effectiveness of tibialis anterior tendon transfer in twenty recurrent clubfoot patients. The results were compared with twelve...
age matched control group those who were treated with Ponseti method. The outcome of their study reported that eversion-to-inversion strength (mean difference: 8% body weight; 95% CI, 26% - 11%; p = 0.412) and plantar loading (p >0.251) improved and maintained at time 12 month follow-up.

2.3.7 Radiological evaluation methods of clubfoot

Several researchers have stated that the application of radiography as an evaluation method is useful for objectively assessing clubfoot severity (see for e.g., Radler et al. 2007; Zimmerman et al. 2015; Katz et al. 1997; Vanderwilde et al. 1988; Simons, 1978). Generally, radiological evaluation methods were widely used by orthopedic practitioners to assess clubfoot deformity and determine the treatment options until the development of the Ponseti method. The radiological procedure is performed at two different views to obtain the angles in a stressed (weight bearing foot) dorsiflexion position (Anand & Sala, 2008). The first view is the antero-posterior (AP) view (talocalcaneal angle or Kite’s angle and talo first metatarsal angle) (Figure 2.30). The second view is the lateral view (talocalcaneal and tibiocalcaneal angles) (Figures 2.31 and 2.32). According to Zimmerman et al. (2015), hindfoot equinus, varus and restricted dorsiflexion can be assessed by examining the talocalcaneal angle.

After the Ponseti method gained popularity for treating clubfoot, the use of radiographic methods has become less prevalent. In clinical practices, the use of radiologic measurements for evaluating clubfoot might be useful to obtain objective parameters that predict the recurrence of clubfoot (Zimmerman et al. 2015; Radler et al. 2007; de Gheldere & Docquier, 2008). However, they are not normally recommended at the early stages of infancy, due to incomplete ossified bones in the feet and also concerns about the accuracy and repeatability
of the assessment tool because it is difficult to maintain the feet accurately in an inherent position (Ramanathan & Abboud, 2007; Foster & Davis, 2007; Cummings et al. 2002; Macnicol et al. 2000; Hak & Gautsch, 1995; Hutchins et al. 1985; Noh & Park, 2013; Radler et al. 2007; Simons, 1978), and the repeatability is questionable and ambiguous (Yapp et al. 2012).

Figure 2.30 Talocalcaneal angle or Kite’s angle

- Talo-calcaneal angle = 30° - 45°
2.3.8 Ultrasound for clubfoot evaluation

The role of ultrasound in clubfoot assessment is discussed in this section. A large number of studies have been conducted with ultrasound (US) as an assessment means of clubfoot severity (Desai, Aroojis & Mehta, 2008; Aurell et al. 2002; Nasr, Berman & Rehm, 2014; Agarwal, Qureshi, Kumar, Garg & Gupta, 2012; El-Adwar & Kotb, 2010; Bhargava et al., 2013; Bhargava, Tandon, Prakash, Arora, Bhatt & Bhargava, 2012; Pinto, Blumetti, Iha, Terasaka, Sodré & Ishida, 2008; Gupta, Sudesh, Prakash, Tripathy & Dhillon, 2012; Marleixa et al., 2012).

Previous studies claim that ultrasound, which is a non-invasive radiation-free imaging method, can be used to assess the non-ossified components of clubfoot, (Siapkara & Duncan, 2007), grade clubfoot severity following correction made by the Ponseti method (Desai et al., 2008; El-Adwar & Kotb, 2010), evaluate the posterior and anterior tibial arteries (Pinto et al.,
evaluate the talonavicular angle (Gupta, Sudesh, Prakash, Tripathy & Dhillon, 2012), assess the healing of the Achilles tendon after percutaneous tenotomy including parameters such as size (Agarwal et al., 2012; Marleix a et al., 2012; Nasr et al., 2014), assess the clubfoot anatomy such as measuring the distance between the medial malleolus and navicular bone (Aurell et al., 2002; Desai et al., 2008) and the talo-cuneiform angle (Desai et al., 2008). Furthermore, a study by Aurell et al. (2002) recommended the use of ultrasound to examine the various parameters of the clubfoot and assess severity such as distance between the medial malleolus navicular (MMN), medial deviation of the neck of the talus (MNT), length of the talus, medial side tissue thickness (MSTT), distance between the calcaneus and cuboid (CC-calcaneocuboid distance), and subjective grading on the medial displacement of the navicular in relation to the head of the talus (score of 0 - no displacement, score of 1 - less than 50% medial navicular displacement, score of 2 - greater than 50% displacement, and score of 3 - complete navicular subluxation). For example, Desai et al. (2008) conducted a study with 26 patients and 32 clubfeet by using sonography and revealed that the distance between the MMN and the talo-cuneiform angle is significantly increased at the end of the clubfoot intervention process (P< 0.001). They also claimed that ultrasound is a valuable assessment tool with an accuracy of 0.1 mm and one degree of angle measurement. In view of the intraobserver reliability of ultrasound measurements, the pre-treatment group had an intraobserver correlation coefficient of 0.94 k, and the intraobserver correlation coefficient of the post-treatment group who underwent manipulation is 0.86 (k value). Recently, some studies have been performed with dynamic sonography on the congenital clubfoot, followed by correction of the clubfoot, in which the distance between the malleolus and navicular
tuberosities was examined in three dynamic stress positions (neutral, abduction and adduction) (Shiels et al., 2007; Bhargava et al., 2013), and the results showed a significant difference (P<0.001) between the normal foot and clubfoot in all three positions (clubfoot: neutral-3.47 mm, adduction- 1.85 mm, abduction-5.39 mm; normal feet (mean): neutral-8.78 mm, adduction-6.19 mm, abduction-11.90 mm) (Shiels et al., 2007). Although a number of researchers have adopted ultrasonic measurement methods, there is no consistency with the use of standardized measured variables to quantify the severity of the clubfoot. Moreover, some studies have found that there is no correlation between clinical grading such as the Dimeglio classification and Pirani scoring with ultrasonic measurement variables (Desai et al., 2008; Suda, Suda & Grill, 2006; Aurell et al., 2002).

2.3.9 Role of CT and MRI analysis in clubfoot severity

The previous literature indicates that CT and MRI are important in assessing clubfoot severity, which will be discussed in this section. However, few studies report the use of MRI and CT for visualizing the interosseous relationship between the individual bones of a newborn with clubfoot and the overall morphology (Kamageya, Shinohara, Kuniyoshi & Moriya, 2001; Johnston, Hobatho, Baker & Baunin, 1995, Wang, Petursdottir, Leifsdottir, Rehnberg & Ahlstrom, 1999). A study by, Reikerås, Kristiansen, Gunderson and Steen (2001) conducted CT scanning to compare the tibial torsion between children with clubfoot (n=24) and healthy patients (n=24), and the results showed that the external torsion of the leg is lower (21º) than that of the healthy subjects (30º) (p = 0.002). Some studies use CT scanning to develop a 3D model of the clubfoot to design the orthosis (Vijayaragavan,
Kurian, Sulayman & Gopal, 2014), and for teaching materials (Windisch et al., 2007). In terms of assessing the anteroposterior talocalcaneal angle (Kite’s angle) in treated clubfoot (48 clubfeet and 28 normal feet), Ippolito, Fraracci, Farsetti and De Maio (2004) found that there is a statistical difference of about 15° (mean) between the radiographic and CT measurements in 36 clubfeet (p < 0.0001). On the other hand, there is no statistical difference between the measurements of the declination angle of the neck of the talus and the posterior calcaneal facet angle. Furthermore, they reported misleading radiographic measurements of the anteroposterior talocalcaneal angle in the 75% of treated clubfoot patients. Based on the results of their study, the use of radiographic measurements of the anteroposterior talocalcaneal angle is not a valid method to assess the severity of clubfoot.

In terms of using MRI, there are also very few in the extant literature who have demonstrate the role of MRI in clubfoot assessment. Cahuzac, Baunin, Luu, Estivalezes, Gauzy and Hobatho (1999) used MRI to determine the volume and principal axes of the inertia of the bone as well as the cartilaginous structure of the hindfoot, and found a lower volume of 20% in the bones and hindfoot as opposed to the normal foot. The volume of the talus and calcaneal bone is reduced 40% and 20 % respectively in clubfeet. Therefore, talus bone growth will be affected more than that of the calcaneus in clubfoot patients. The evaluation of the interosseous relationship (cartilaginous structure and long axis of the osseous) is however, not statistically significant (p > 0.05); that is, the osseous nucleus of the talus is medially rotated more in the clubfoot (14.5 ± 5°) than the normal talus (10 ± 4.5°). Itohara et al. (2005) found that reduction in the volume of the talus bone is 20.1% and that of the calcaneus is
15.7%, while the talar and calcaneus ossific nucleus are reduced 42.6% and 12.1%, respectively. The length of the talus is shorter in the clubfoot (8.2%) than the normal foot. Figure 2.33 shows the relationship between the principal axis of inertia ossific nuclei and the cartilaginous structure (Itohara et al., 2005). Duce et al. (2013) conducted an MRI study which combines a multiple regression analysis (MRA). They found that the volume of the tibia, fibula, and lower leg muscles is smaller in unilateral clubfoot than the unaffected foot. Other studies suggest that MRI could be used to objectively quantify the severity of clubfoot by assessing the inertia ossific nuclei of the talus and calcaneus relative to their cartilaginous angle (Cahuzac et al., 1999; Itohara et al., 2005), inter-cartilaginous relationship with the calcaneus and bimalleolar axes, volume of the bone and cartilaginous structures (Cahuzac et al., 1999). A study by Cahuzac et al. (1999), an MRI evaluation is performed after the casting treatment which could be influenced by the volume of the bone and cartilaginous structures due to the continuous casting pressure placed onto the clubfoot. Above all, the triclofos sodium (100 mg/kg) was given as a sedative for each child before performing the MRI, and also their feet were positioned by using a carbon fiber splint. However, this study has found that the use of MRI or CT for children with neonatal clubfoot is not prevalent in the everyday clinical settings and assessment of clubfoot and questionable in very rural and remote health settings. These imaging techniques are challenging as an assessment tool to predict, evaluate, and quantify the severity of clubfoot for weekly serial castings (Kamegaya et al., 2001; Wang et al., 1999; Zeznik & Hodges, 2001). There are also other issues with the use of CT for children with neonatal clubfoot. They are exposed to radiation, and expensive, and time consuming. Finally, CT provides a poor resolution in comparison to MRI. In the following
section, commonly used scales for clubfoot in everyday settings of clinics for serial casting will be discussed.

![Diagram of normal and clubfoot foot structures with principal axes of inertia ossific nuclei and cartilaginous structure shown by MRI.](Source: Itohara et al., 2005).

**Figure 2.33** Principal axis of inertia ossific nuclei and the cartilaginous structure shown by MRI (Source: Itohara et al., 2005).

### 2.3.10 Role of three dimensional scanning for normal feet and medical applications

Three dimensional (3D) scanning has been used to generate 3D images of normal feet and evaluate or quantify the shape and structure of feet (Ma and Luximon, 2014). Taha et al. (2014) used the Kinect Xbox as a 3D scanner to accurately measure the anthropometry of normal feet, including the length and width, heel width, lateral malleolus height, foot width...
circumference, and lateral malleolus height (Figure 2.34). In addition, they concluded that measurement of the anthropometry of normal feet with 3D scanning is more accurate than manual measurements, because it reduces variability and increases repeatability. However, few studies have used 3D scanning to quantify the deformities of abnormal feet. De Mits et al. (2012) used noninvasive 3D scanning to quantify the severity and structure of the feet of rheumatoid arthritis patients (Figure 2.35). They used green velvet markers to determine the parameters of the feet structure (height of top of ball girth, instep length, height of sphyron fibulare, and height of toes 1 and 5). The collected parameters of the rheumatoid arthritis feet by the 3D scanner were compared with the radiographic features of the same feet. The results of the 3D evaluation study showed significant differences between normal and abnormal feet.

Gutekunst et al. (2012) predicted that future research that uses non-irradiating 3D dimensional modalities, such as MRI and CT, with a land-marking method would be useful for determining the severity of deformities, such as the clubfoot. However, both are expensive procedures for quantifying and evaluating the severity of clubfoot at each stage of clubfoot casting. Therefore, the use of the Kinect 3D scanner to explore the structural changes in clubfoot and quantify the severity of clubfoot is proposed in this study.
2.3.11 Infrared thermography

Infrared thermography has been considered as an additional tool for diagnosing and monitoring different pathological conditions, such as osteoarthritis, femoral artery thrombosis and cervical spondylosis (Bardhan et al. 2015; Saxena & Willital, 2008) (Figure 2.36). The technique can show abnormalities in skin temperature on the affected areas of the body, and
is also useful on areas of inflammation by calculating the thermal distribution on the skin. To
best of my knowledge, very few studies has been conducted to quantify the distribution of
skin temperature of normal feet (Vardasca et al., 2012; Uematsu et al., 1998; Zaproudina et
al., 2008; Niu et al., 2001; Sun et al., 2005). However, no studies have been conducted on the
skin temperature distribution of clubfoot. Oliveira et al. (2016) proposed a grading and
diagnostic system for ankle sprains by using thermography (Figure 2.37). Therefore, this
study will use infrared thermography to explore the temperature distribution changes in
response to Ponseti casting and manipulation techniques.

a. Osteoarthritis (Bardhan et al. 2015)
b. Cervical spondylosis (Bardhan et al. 2015)
C. Left femoral artery thrombosis in 10-year-old child before and after treatment (Saxena & Willital, 2008)

Figures 2.36 Thermography images of various medical conditions

Figure 2.37 Examples of lateral views of 3 grades of ankle sprains. Top- Grade I, middle: Grade
II and bottom: Grade III) with ROI marked and thermal symmetry value provided (Source: Oliveira et al. 2016)

2.4 Summary

A structured evaluation of clubfoot is necessary to accurately quantify clubfoot severity before and after treatment and evaluate the progress of treatment (Siapkara & Duncan, 2007). The Pirani scoring system and Dimeglio classification are widely used to measure the severity of clubfoot (Flynn et al. 1999). However, some aspects of the prognostic measurements, such as medial and posterior creases, cavus deformity, and heel emptiness are considered to affect both measurement systems (Bergerault et al. 2013; Chu et al. 2010). In terms of 3D assessment, MRI can be used to visualize soft tissue structures, bone ossification, and cartilage of the clubfoot foot (Richards & Dempsey, 2007) and assess the misalignment of talonavicular joint; therefore, a useful way to assess the severity of clubfoot deformity (Kamegaya et al., 2001). However, MRI is an expensive procedure to perform after each casting and may require sedation or the use of general anaesthesia in infants. Therefore, his is a “proof of concept” study that seeks to determine the feasibility of a 3D assessment method to evaluate a) the initial severity of the clubfoot and b) its response to the Ponseti method of manipulation and casting. Clubfoot is a globally prevalent condition which, in developing countries and rural areas, is often managed by non-medically trained personnel. A reliable, non-invasive 3D assessment method to evaluate clubfoot severity and its response to treatment could be used in telemedicine, for example, to advise such personnel on the progress of treatment of the clubfoot. A secondary aim of this study is to explore the
relationship, if any, between the thermophysiological changes in the clubfoot at each stage of casting.
CHAPTER 3 A SYSTEMATIC REVIEW ON PONSETI METHOD IN THE MANAGEMENT OF CLUBFOOT UNDER 2 YEARS OF AGE

3.1 Introduction

The aims of this systematic review study are to review how the Ponseti treatment protocol strictly followed in their studies to achieve the initial clubfoot correction, and to find out the success rate of clubfoot intervention, including casting, bracing, and percentages of surgical recommendations, and to review the causes and percentages of the relapses.

A systematic literature search was conducted for articles published between from January 2000 to September 2015 using the following electronic databases: Cumulative Index to Nursing and Allied Health Literature (CINHAL), PubMed, Medline, Scopus for relevant articles to identify the Ponseti method of intervention to correct the clubfoot deformity. Figure 3.1 shows the process of articles search and articles were selected for this study (Ganesan et. al.2017).

The following flow chart (Figure 3.1) describes the method of the articles search, inclusion and exclusion criteria for selecting articles, method of extraction of the articles, outcome of the articles, and results.
Figure 3.1. Flow chart of literature search and recruitment process (Ganesan et. al. 2017)
3.2 Study selection

The title and abstract of articles were screened thoroughly to select the relevant articles that related to the using of Ponseti method of intervention for clubfoot. The articles were reviewed and extracted according to the inclusion criteria and exclusion criteria of this systematic study.

3.2.1 Inclusion criteria

Articles were selected based on the following inclusion criteria: Only full length, available studies with using the Ponseti method as an intervention for clubfoot deformities, and articles published in English were only considered, and children with clubfoot < 2 years old of age. According to the Ponseti classification, the clubfoot with < 2 years old are considered as untreated clubfoot.

3.2.2 Exclusion criteria

Articles published in other languages will be excluded from this study. The studies with neglected clubfoot, associated deformities, short-term outcome, survey type of studies, and surgical treatment for clubfoot correction, and the only purpose of testing the different casting materials were excluded in this systematic review.

3.2.3 Data Extraction

As first step, a characteristic of clubfoot patients were extracted from the selected articles and it was documented into the data extraction sheet. Then the extracted data was reviewed thoroughly for the purpose of accuracy of data. The following information (characteristics of clubfoot patients) was extracted from the selected articles and it was included into the data
3.3 Results

The summary of all selected articles is described in Table 3.1. A total of 852 children with clubfoot and 1206 clubfeet were included in this systematic review study. Of these 12 studies, a total of 293 bilateral clubfoot were identified. The study characteristics such as number of castings, treatment duration, and the follow-up period was differed from one article to another. The average of earlier casting presentation would be helpful determine the effectiveness of the treatment. Therefore, the clubfoot treatment should be started as early as possible to correct the clubfoot deformity. Most of the studies reported that the Ponseti method of intervention was started after immediate birth.
<table>
<thead>
<tr>
<th>References</th>
<th>Study design/ number of children/feet</th>
<th>Types of Intervention/ groups/gender</th>
<th>Side of clubfoot (Bilateral &amp; unilateral clubfoot)</th>
<th>Age at Initial casting/ Number of casting</th>
<th>Bracing protocol</th>
<th>PAT/Surgery/ Outcome measurement/ Results (mean)</th>
<th>Relapse/follow up period (Mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elgohary &amp; Abulsaad, 2015</td>
<td>Prospective study/ 41 Children /66 CF</td>
<td>Traditional Ponseti method</td>
<td>TPM: 14 children with BCF and 6 children with UCF. APM: 11 BCF and 10 UCF</td>
<td>TPM Group: 10.7 ± 6.28 weeks. APM Group: 11.57 ± 6.9 weeks (from two to twenty six weeks). TPM: One casting per week (4.88 ± 0.88 casting for full correction). APM: Casting twice per week (5.16 ± 0.72 casting for full correction)</td>
<td>Modified Denis–Browne orthosis (70 degree of external rotation on affected foot and 40 degree of external rotation on normal side).</td>
<td>TPM: 91.2 % (31 feet of 34) APM: 93.8 % (30 feet of 32)</td>
<td>Pirani score: clubfoot with &lt; 4 of Pirani score was included. After the intervention, TPM: 5.17 ± 0.62 (range 4–6) to 0.49 ± 0.42 (0.0–1). APM: 5.13 ± 0.61 (range 4–6) to 0.52 ± 0.38 (0.0–1).</td>
</tr>
<tr>
<td>Colburn &amp; Williams, 2003</td>
<td>34 children (B=28;G=6) /57 CF</td>
<td>Ponseti method</td>
<td>Children with clubfoot were included from first day to 6 months. Average of 4.8 casting (ranges from 3–7); Average of 4.8 casting (from 3 to 14) for those previously treated with other treatments.</td>
<td>Straight-last shoes with a foot abduction bar with 60° - 70° external rotation of the corrected foot/23 hrs per day/3months. Then, 12 hrs/day until 2 years</td>
<td>Dimeglio score was 11.2 average; Range from 7-15) for those who are not received any previous clubfoot treatment. The results of the average score was 11.2 (range: 7-17) in patient received some other treatments previously.</td>
<td>34 children (54 feet out of 57 feet) were corrected without PMR (95 %). Serial casting, Manipulation, PAT: 38 feet (77%). Manipulation and casting: 28% (16)</td>
<td>Relapses: 6 children. Regained successful correction with manipulation, serial casting and straight-last shoe with foot abduction bar</td>
</tr>
</tbody>
</table>

Table 3.1. Characteristics of the studies (Ganesan et al., 2017)
Mohammad Hallaj-Moghaddam et al. 2015

| Prospective study / N=85 | Ponseti method (M= 69%, F-31%) | Bilateral: 61.2%. Eighteen percentages- LCF, and 21 percentages of the clubfoot – RCF. 5.7 castings (4 to 8 casting). One casting/wk. Mean age: 8 days at the time of first casting. It ranges from (1-60 days). Average number of casting: 4-8. | Full time Dennis-Browne splint protocol - 6 months. Then, Part time Dennis-Browne splint protocol for 3 years | PAT: Tenotomy was performed in 76 patients (89.4 %). Successful results with plantigrade foot. The child started to walk at the mean age of 12th months. Complications: Pain, tenderness after tenotomy for 3 children, one patient had minor infection after tenotomy. BCF had lower outcome than UCF(2.1 ± Dimeglio score: Baseline: 16 ± 3.4; after casting - 1.6 ± 6.2. | Relapse rate was 27.1% (follow-up period: 5-72 months)/ Follow - up: Every 3-4 months/1-2 years; After that, 6-12 months follow-up was done. |
### Pulak & Swamy, 2015
**Study Design:** Prospective study/N=40/53
**Methods:** Ponseti method
**Results:**
- BCF: 14 Children; UCF: 25 children
- Initial presentation 6 weeks/35 cases. Average casts for full correction: 4.9. Average duration of casting < 7 wks in > 85% of the patients. Some cases, it increased up to 10 weeks of casting.
- Orthosis: 23hrs/first 3 months. After that, night time only for 2-4 yrs.
- Tenotomy was done in 94.3 % of the patients.
- Tenotomy was done in 94.3 % of the patients.

### Sud et al. 2008
**Study Design:** Prospective randomized study (N=45/67 CF)
**Methods:** Ponseti method (N=36) Kite’s Method (N=31)
**Results:**
- < 3 months of age (5-90 days). Ponseti method : 5 to 90 days Kite’s Method: 5 to 90 days. Casting: Ponseti method: 3 to 12 casting. Kite’s Method 3 to 23 casting
- Foot abduction bar: 2-3 months (full time). Then, 2-4 years (night only)
- Ponseti method: 2 patients Kite’s Method :10 patients

### Sætersdal et al. 2012
**Study Design:** Multicenter clinical study/ (N=116/162 CF)
**Methods:** Ponseti method
**Results:**
- Boys : 72% Girls: 28%
- BCF: 46 UCF: 70
- First cast: with second day and Ranged from 0-9 days of life. 4 patients (First casting): 18, 37, 58, and 60 days of life.
- Standard bilateral foot abduction brace : 63 %, Unilateral above-the-knee brace-32%
- PAT: 79% Soft tissue release : 3%
- Pirani Score : 4.8 (2.5–6) ROM of foot and ankle
- Relapse: 27 feet Second time casting: 15 feet; Second time tenotomy- 18 PMR: 3 feet; Posterior release: 2. One TA tendon transfer.
### Selmani, 2012

<table>
<thead>
<tr>
<th>Method</th>
<th>N = 100 /150</th>
<th>Ponseti method (N=76); B: 38; G: 20</th>
<th>Kite’s Method (N=74); B:28 G: 20</th>
<th>Average casting: 7.2 (3–13).</th>
<th>Bilateral FAB with soft cast: 3%. No brace: one child</th>
<th>PMG: Dennis - Browne bar splints with open-toe tarsopronator shoes (70° of external Rotation. Protocol: Full time- Until walking age.</th>
<th>PAT</th>
<th>Pirani Score: PMG - 5.2±0.8. Correction: Achieved 96 % (73 Feet (96ft). KMG: Pirani score: ROM : 8.21° - dorsiflexion to 13.32° - plantar flexion.</th>
<th>Relapses: 10 feet (13.7%)/36.2 months in Ponseti group (First year follow-up) Follow-up : Ponseti - 36.2 months ± SD 3.2; Final follow-up: No relapses. Kite group: 35.1 months ± SD 2.5 (33 to 38 months) and 100 feet.</th>
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<tr>
<td>PMG:</td>
<td>26- BCF</td>
<td>PMG: 2–90 KMG: 2–90. Since Birth/ Average casting: PMG - 4 to 12 (7.1±1.8) ; KMG: 4 to 22 (11.34±6.3). Casting 7 to 10 days.</td>
<td>PMG:</td>
<td>PAT</td>
<td>Only</td>
<td>Extensive</td>
<td>Walking : age of 13</td>
<td>Relapses: 17 (10%)</td>
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<tr>
<td>Source</td>
<td>Study Type</td>
<td>Patient Group</td>
<td>Details</td>
<td>Results</td>
<td>Complications</td>
<td>Follow-Up</td>
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<tr>
<td>Pavone et al. 2013</td>
<td>Case series (N= 157/ 256 CF)</td>
<td>(N =76); B: 107 (68%); G: 50</td>
<td>months. Lesser than 5 casting (90% of the patients). Full correction: 20 days (range: 14-24 days). bracelet: 2 to 3 months (full-time). Naptime and night for 3 to 4 years. corrective surgery - 4 (2.5%); PAT- 86% months Complications: 12 patients (8%) - erythema, slight swelling on toes. ROM: Aorsiflexion posttenotomy was 20° (Range 0 – 35 degrees).</td>
<td>/26 months (6 months - 8 years)</td>
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<td>Ponseti method</td>
<td>N= 82/114 CF</td>
<td>Ponseti method N= B: 56(68.29%); BCF: 32 (39%) UCF: 50 (60.9%) – RCF: 28 (56%) in the UCF and 22 had LCF Age: 0-36 weeks. Initial casting: 14 days (3-81 days)/ 76 (92.68%) Patients: range 0 – 12 wks; 4 patients: range from 13-24 wks; 2 patients: 25-36 wks. /6.6 casting (Average) Denis Browne splint: 24/day for 3 months. Night time: 3 years. PAT: 82.93% (68 patients) – 28 BCF; 40 UCF. Pirani score: 5.56 points/ range 4.3 to 6 points. i.e 53 children: 6 points of pirani score; 22 children - Functional Ponseti Scores: 96. 34 % (79 patients) – Good or excellent. Complications: phlebostatic Syndrome (2 children). Plaster sore on the talar head side. 2 children: minor heel sores due to D-B.</td>
<td>/ 6.6 casting (Average)</td>
<td>Relapse: 3 (5 feet) patients (3.7%): one adductus and varus, one equinus, all deormities in one. Follow-up: 4 years (13 – 83 months)</td>
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<td>Rijal et al. 2010</td>
<td>Case series (N= 38/60 CF)</td>
<td>N= 38/60 CF Ponseti method (N = 30); Kite Method (N=30)</td>
<td>BCF: 22 UCF:16 Less than 2 years of age Abduction splint with shoes- 3 months; 23 hours/day; then, night time: 2-4 PAT: 29 (96%) out of 30 patients. Hindfoot, mid foot and total Pirani scores (1-10 weeks). Pirani score improved faster in 12 bilateral clubfeet (P&lt;0.05).</td>
<td>Weekly follow-up/10 weeks</td>
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<td>Study</td>
<td>Type</td>
<td>Intervention 1</td>
<td>Intervention 2</td>
<td>Duration</td>
<td>Number of Casting</td>
<td>Duration of Treatment</td>
<td>Number of Patients</td>
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<td>Sanghvi &amp; Mittal, 2009</td>
<td>Randomized study</td>
<td>Ponseti method</td>
<td>Kite method</td>
<td>0-36 weeks</td>
<td>13 BCF, 6 RCF, 6 LCF</td>
<td>PMG: full-time splinting; After walking age: night time only splint and daytime – shoes (4-5 years) with an open toe box, lateral flaring of the sole, straight medial border, and reverse Thomas heels shoes. PMG: open-toe</td>
<td>KMG: 13 Patients in KMG</td>
<td>3 years</td>
<td>3 Relapses in KMG. One bilateral relapses in PMG.</td>
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<tr>
<td>Segev et al. 2005</td>
<td>Cohort study/72 infants</td>
<td>Ponseti method (N=32); 48 CF, B:20, G:12. Traditional method (Modified Kite and Lovell technique): N=40 (61 feet)/B:31;G:9</td>
<td>PMG: 50% BCF and left are more involved. TM: 21 BCF</td>
<td>Above knee casting. PMG: 96% patients were treated from the birth. One patient: 3 wks and another patient: 6 wks. TM: duration of casting: 4.0 months (Average).</td>
<td>PMG: Dennis Brown splint for 3 months/24hrs, then night time only until 2 years. TM: 29 PMR and 6 PR.</td>
<td>PAT: 47 CF in PMG (Average 2.4 age months); TM: 29 PMR and 6 PR.</td>
<td>Dimeglio-Bensahel scoring. Before the treatment of PMG: 11.9 and after 3.2 (average). 94% achieved in PMG.</td>
<td>Follow-up: 54.9 months (44-68 months) in TM; PMG – 29.2 months. 3 residual deformities. 44% residual deformity at TM</td>
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PMR, Posteromedial release; CF, clubfoot; TPM, Traditional Ponseti method; TM, Traditional method; PMG, Ponseti method group; KMG, Kite method group, UCF, Unilateral clubfoot; BCF, Bilateral clubfoot; RCF, Right side clubfoot; LCF, Left side clubfoot; ROM, Range of motion; wks, weeks; PAT, Percutaneous Achilles tenotomy. (Ganesan et al., 2017)
3.4 Discussion

In the selected 12 studies, most of the studies have compared the effectiveness of the Ponseti casting intervention with the Kite method. Elgohary & Abulsaad (2015) study used accelerated Ponseti method to compare with currently available method of clubfoot treatment, and the results of this study found that the accelerated Ponseti method is safe and similar to the commonly used Ponseti method for clubfoot correction.

3.4.1 Casting techniques and numbers of casts

As described in the earlier paragraph, 12 studies were identified for this review to systematically address the effectiveness of the Ponseti method and number of casting required to achieve the full correction of clubfoot. Based on the review of selected studies, all studies (12 studies) reported that the number of casting used to achieve the normal grade foot (as shown in Table 3.1). Among the 12 studies, 5 (Sud, Tiwari, Sharma & Kapoor, 2008; Sanghavi & Mittal, 2009; Rijal et al. 2010; Segev et al., 2005; Selmani, 2012) studies used Kite techniques to compare with the Ponseti casting method for correcting the clubfoot. All of these studies reported that Ponseti method required the less duration and fewer casting than Kite method to achieve achieved the initial correction of the clubfoot. The success rate of Ponseti method’s correction was 96 % and the follow-up time was 36.2 months. However, success rate of the Kite’s method for full correction of the clubfoot was 74.3 %, and it was achieved in an average of 35.1 months (Selmani, 2012). A study by Sud et al. (2008) reported that the success rate was 91.7% in Ponseti method and the correction was achieved in the average of 27.2 months follow-up, but the success rate of Kite method was 67.7% at time of 24.8 months follow-up. In contract, the achievement of correction rate was nearly similar (Ponseti-87% & Kite method-79%), but the average of casting was low in Ponseti group (7 casts) that Kite (10 casts) and the duration of treatment took only 10
and 13 weeks in the Ponseti method and Kite method respectively (Sanghavi and Mittal, 2009). In Elgohary and Abulsaad study found that the average casting was $4.88 \pm 0.88$ (4-7 casts) in the traditional Ponseti method and the accelerated Ponseti group took about $5.16 \pm 0.72$ casts (4-7 casts), and less than five casts in both groups in this study (84.8%). Selmani reported that full correction of clubfoot was achieved in an average 4-12 casting in Ponseti and the average of 4-20 castings in the kite method. Also this review noted that duration of casting periods was 7 to 10 days for each casting. In addition, the accelerated group achieved the full correction in 11 to 12 days (two times casting/week) and it was 21–42 days in the traditional Ponseti method. Also, there was much difference between accelerated and tradition group in terms period of time (Elgohary & Abulsaad, 2015). Previously, Morcuende et al. 2005 study found that the success rate of accelerated Ponseti techniques (Casting/5 days once) was similar to the traditional method. Another study by Xu (2011) studied with casting twice a week, and the results was same as traditional method. Pulak &Swamy (2012) study achieved the full correction with less than 5 casts and the average casting was 4.9 casts in 75% of the children. Of these 12 studies, one study reported that the time duration for casting performances and it took five to nine minutes for each casting and the time for procedures and Achilles tenotomy with casting took from six to eleven minutes (Hallaj-Moghaddam et al., 2015). In Morcuende & Abbasi (2005) study, the following guidelines were practiced: As a first step, casting was done from the toe to lower knee area and in the following step of casting was done from the knee to thigh area. About ninety percentages of patients were achieved the full correction of the foot with less than five casts. Of these of 12 selected studies, one of the study (Sud at al., 2008) defined that the casting management is considered as failure if not achieved the correction of foot within the year, and these patients is recommended for surgery after obtaining the consent from the participants. In
this study, Ponseti management was required less casting (3-12 casting) when compared with Kite method, for achieving full correction of the clubfoot. In contrast, three to twenty three casting was used in the Kite method to achieve full correction of the clubfoot. One of study Pavone et al., (2013) reported that severe initial deformity or the earlier treatment started after fifteen weeks of birth is required high number of casting. However, there are number of controversy is existing in the effect of late presentation of clubfoot treatment and the results of intervention. Some studies stated that late presentation of clubfoot management does not impact on the results of outcome (Morcuende et al., 2004). On the other hand, a study by Abdelgawad et al. (2007) found that there was 6.6% failure rate due to the late presentation of Ponseti treatment. But, among the twelve studies, one of the selected study (Pavone et al., 2013) reported that there is no correlation between age of treatment presentation and final results of the range of motion (ROM) of the foot. But sometimes it’s taking more casts, and the full correction of the foot was achieved with the average of five to ten casts in their study. Two of the studies from the selected articles for the review (Sanghvi & Mittal 2009; Selmani, 2012), conducted the complications of castings such as margin of the cast, assessment of neurovascular details, swelling, changes of the skin discoloration in toes of the feet and baby’s excessive crying. Of these twelve studies, only one study (Sætersdal et al., 2012) used the two different types of casting materials to treat children with clubfoot, which are semi-rigid fibreglass, and plaster of Paris. About 78% clubfoot children with clubfoot was treated semi-rigid fibreglass, and plaster of Paris was used in 22% of the children with clubfoot. However, the outcomes of these casting materials are still controversial based on the report of Sætersdal et al., 2012 study. In addition, the average of 7.2 casts was used for the total of 162 clubfoot to attain the full initial correction including the last casting after Achilles tenotomy. At the sametime, there was only the average of 3-5 casts used
for four patients those had a mild clubfoot. Among 162 clubfoot treated in this study, 10 children used bilateral brace and 5 children used unilateral brace. These children were treated again with recasting. In addition, this study found that those who are managed by unilateral brace had received more casting management. To achieve the success of casting treatment, the corrected clubfoot should also be maintained by braces to prevent the recurrences of clubfoot deformity.

3.4.2 Bracing

In the maintenance phase of Ponseti method, foot abduction braces (FAB) has been used to maintain the fully corrected clubfoot and to avoid the relapses or recurrences of clubfoot. In these 12 studies, this review found that variations in the schedule of bracing protocol and it ranges from 23 hours per day or two to six months for full time, and the night time braces ranged from 2-5 years (Sud et al., 2008; Hallaj-Moghaddam et al., 2015; Sætersdal et al., 2012; Elgohary & Abulsaad, 2015; Sanghvi & Mitta, 2009; Segev et al., 2005; Colburn & Williams, 2003; Selmani, 2012; Morcuende et al., 2004; Pavone et al., 2013; Pulak & Swamy 2012; Rijal et al., 2010). This study found that few studies used the braces for full time or 24 hours per day and need to wear for two to three months (Morcuende et al., 2004; Pavone et al., 2013; Hallaj-Moghaddam et al., 2015). Among these studies, Hallaj-Moghaddam and Moradi (2015) stated that they used full time brace for 6 months to maintain correction of the foot. On the other hand, 3 studies used the full time abduction braces for 23 hours per day up to two to three months (Colburn & Williams, 2003; Pulak & Swamy 2012; Rijal et al., 2010). Two of the studies from this selected articles stated that the children with corrected foot used the splint up to the age of walking, and then, they recommended for using the night time braces for up to 4 years of age (Selmani, 2012; Sanghvi & Mitta, 2009). However, originally the Ponseti method recommended wearing the full time brace up to 2 to 3 months and night time for up to 3 to 4
years. Sætersdal et al., (2012) study used different types of foot abduction braces and they changed into different types of braces in their bracing protocol. For example, FAB was used among 62% of children, and then 30% of children were moved from Mitchell from Markell, and 12% of the children used from bilateral FAB into flexible custom-made unilateral above-the-knee brace, and 3% of children were changed into a softcast or scotchcast removable brace. This review noticed that the position of correcting foot in the bracing varies in their bracing treatment. For instance, Selmani, (2012) study prescribed the foot external rotation in 70 degrees; another study recommended keeping the external rotation of the feet in 60 - 70 degrees. In the Ponseti treatment protocol, bracing has essential role for achieving the successful rate of clubfoot correction (Zhao et al., 2014).

3.4.3 Relapses and its characteristics

Most of the studies stated that Ponseti method is a successful treatment method to correct the clubfoot (Segev et al., 2005; Ponseti, 2002; Owen & Kembhavi, 2012). But, previous literatures stated that that 10-30 percentages of the relapses rate are very common (Chu & Lehman, 2012; Masrouha & Morcuende, 2012). In this review, of the 12 studies, noticed that relapses of clubfoot in 9 studies (Colburn & Williams, 2003; Morcuende et al., 2004; Segev et al., 2005; Sud et al., 2008; Pulak & Swamy 2012; Selmani, 2012; Pavone et al., 2013; Elghohary & Abulsaad, 2015; Hallaj-Moghaddam, et al., 2015). The highest rate of relapse was 27.1% (Hallaj-Moghaddam et al., 2015) and the lowest relapse rate was two clubfoot and it was reported in Pulak and Swamy (2012) study. Of these 12 selected articles, one of the study (Hallaj-Moghaddam et al., 2015), reported that maximum relapses rate was recorded at the end of the follow-up, that is average of 5-72 months and the relapses rate was 27.1, and also a total of 89.4% of patients (76) was recommended for the tenotomy. Few studies described about the
occurrence of pattern of the clubfoot relapses after the initial correction (Segev et al., 2005; Selmani, 2012; Elgohary & Abulsaad, 2015; Hallaj-Moghaddam et al., 2015). For instance, Pavone et al. (2013) study found that 3% of relapses rate in their study, and the relapse pattern was noticed as adductus and varus in one foot, relapse of equinus in another foot, and an another child’s foot was totally relapsed with all components of clubfoot deformity. Pavone et al., (2013) study reported that these relapses occur due to the reason of non-compliance of braces, and disturbed braced protocol because poor education and socioeconomic status of parents of children with clubfoot. But, some studies did not describe about the relapse pattern (Colburn & Williams, 2003; Sætersdal et al., 2012). One study in 12, Morcuende et al. (2004) study reported that, about 11% of the children with clubfoot had relapses, and it was corrected by manipulation, re-casting, and Achilles tenotomy. However, in this study, 2.5% of the relapses were recommended for transfer of tibialis tendon and Achilles tendon lengthening. In Elgohary and Abulsaad (2015) study found that 14.7% of children had relapsed due to the reason of non-compliance bracing and 90% of relapses had initial high Pirani score. But, Dobbs et al. reported that initial severity is not impact on the relapses. Relapses in Other studies: six cases (Colburn & Williams, 2003), 27 feet (Sætersdal et al., 2012), 13.2% (Selmani, 2012), and two cases (Pulak & Swamy 2012), 27.1% (Hallaj-Moghaddam et al., 2015), 21.7% (Sud et al., 2008).

3.4.4 Relapsing Factors

Most of the studies recommended that earlier treatment helps to avoid the relapses and to achieve the full correction of clubfoot (Herzenberg et al., 2002; Nather & Bose, 1987; Selmani, 2012; Ponseti, 1992). Especially, the bracing compliance is playing a role to obtain the success of the Ponseti treatment, and to avoid the relapses (Dobbs et al., 2004; Morcuende et al., 2004). The relapses can be assessed by Dimeglio score or Pirani scoring system (Ponseti, 2002; Owen &
Kembhavi, 2012). It can also be evaluated based on the requirement of surgical procedures and it can be classified as minor or major relapses (Haft et al., 2007).

Ponseti (2002), study reported that 78% of the clubfoot relapses is occurring by non-compliance of braces, and this study also reported that the relapse rate in compliance of foot abduction braces is low (7%). Bracing with non-compliance is having a tendency to develop the occurrence of clubfoot relapses (Dobbs et al., 2004; Morcuende et al., 2004). But, the relapses are not associated at age of initial presentation, casting numbers, and previous history of treatment failure. It is also noticed that the noncompliance bracing is the main cause for the clubfoot and not adherence of bracing protocol followed by caregivers or parents of the children (Zionts et al., 2012). Even though, the non-adherence of bracing is considered as a causes of relapse, there are number studies suggested other different opinion for causative or risk factors for relapses of clubfoot: low educational status of parents, low income parents (< US $20,000), and ethnicity (Native American ethnicity) (Zhao et al., 2014). On the other hand, Morcuende et al. (2004) study reported that noncompliance of bracing will induce the relapses 17 times greater than compliance with the braces and in their study about average of 2.5 patients were recommended for tibialis anterior tendon transfer (those children with non-compliance) to the surgery of third cuneiform to avoid further relapses of the clubfoot. Three studies did not describe the reason for the relapses of the clubfoot (Pulak & Swamy 2012; Sanghvi & Mitta, 2009; Rijal et al., 2010). Three studies described the reason for the relapses of the clubfoot (Colburn & Williams, 2003; Selmani, 2012; Pavone, Testa, Costarella, Pavone & Sessa, 2013). Some authors reported that poor experience in casting procedures and tenotomy surgeries, uncomfortable braces, poor education and socioeconomic status (Morcuende et al., 2004; Pavone, 2002; Goksan, 2002), less follow-up period (Segev et al., 2005). Selmani, (2012) study reported that mostly the relapses
noticed in the first year of follow up period and the range of relapse in this period was 13.7 percentages and therefore they concluded that the relapses is not related to the initial severity or age of the child with clubfoot (Sud et al., 2012). Of these 12 studies, one of the study by Hallaj-Moghaddam et al., (2015) tried to explore that causes of different factor for clubfoot relapses such as gender, age, age at initial presentation of casting, other associated deformities, walking age, castings numbers, tenotomy, initial severity score (Dimeglio score), and satisfaction. This study found that the compliance of bracing was 97%, however the relapse rate was in 27% of the patients, and this study also reported that noncompliance of braces, and other factors (initial severity, below knee casting, and low education status) would be causes for relapse rate. Previous studies are mainly reported about the relationship between the bracing compliance and relapses. According to the Morcuende et al. (2004) stated that “non-compliance” is considered that those children not wearing the FAB for a period of 10 hours per day. At the same time Dobbs et al. (2004) defined as “complete discontinuation of foot abduction braces” is considered as non-compliance. Also, of these selected studies, there was no pervious literature described about the grading for compliance of braces in details excluding Sætersdal et al. (2012) study. The Sætersdal et al. (2012) study reported the grading system for the compliance of brace (Excellent: Using the braces continuously until the follow up period (4 years of age) or at least 10 hours/day/night time; Good: Using the braces continuously until the follow up (2 years of age) or at least 6 to 8 hours/day/night time; Fair: < 2 years of age or <6 hours; Non-compliant: discontinued the braces before the age of 1). To achieve the successful clubfoot correction, and without relapses, the in-depth knowledge of detailed manipulation techniques, proper identification of pattern of relapses, and adherence to the original protocol of the Ponseti
treatment of casting, and bracing is necessary to prevent the relapses (Cooper & Dietz, 1995; Ponseti, 1996; Zhao et al., 2014).

3.4.5. Evaluation of treatment outcome and surgical recommendations

The Pirani scoring system or Dimeglio scoring system has been widely used as a outcome measurement scale for evaluating the severity of the clubfoot, and to monitor the progress of clubfoot treatment (Ponseti method). These outcome measurement scales were also used to predict the necessity of Achilles tenotomy surgery to correct the equinus (Dyer & Davis, 2006; Janicki et al., 2009). Janicki et al., (2009) study suggested that Achilles tenotomy surgery is required to correct the equinus deformity for those children with clubfoot having the initial Pirani score > 5, At the same time, Achilles tenotomy surgery is not required if the initial Pirani score is < 3. However, one of the studies used the outcome rate of extensive corrective surgery, relapses rate, initial correction of the clubfoot as an outcome measures for the clubfoot treatment (Morcuende et al. (2004). In addition, this study reported that the average achievement of dorsiflexion at ankle is 20 degrees, and initial correction rate was 20 days, and 10 % of relapses rate was noticed after the initial treatment. Other outcome measures such as goniometry, was used to find out the effectiveness of clubfoot treatment by evaluating the range of motion (ROM) for ankle (dorsiflexion and planter flexion) (Pulak & Swamy 2012). The results of outcome measures for clubfoot intervention are described in the Table 1 (the selected 12 studies). In that, the Dimeglio score was decreased at the end of the follow-up and it was 16 ± 3.4 to 1.6 ± 6.2 (Hallaj-Moghaddam et al., 2015); and the average score was 11.2 before the casting (Colburn & Williams, 2003). However, this study did not described in details about the Dimeglio score reduction after casting and follow-up period. Also, this study reported that three children were treated with posteromedial release surgery (received previous intervention population) (Colburn
& Williams, 2003). Some of the studies used Pirani score for assessing the outcome; however, they did not reported clearly about the pre and post or follow-up score (Selmani, 2012). In Pavone et al. study (2013), the initial Pirani score was an average of 5.56, and after the casting, the results found that percutaneous tenotomy was for 82.93% patients. As some of the previous studies, this author also not explained the details of post intervention, however, they reported follow-up (mean of 4 years), 98.78% of the patients had attained normal passive ROM, 96.34% of patients received good to excellent results based on the functional Ponseti scoring system. Some studies (Pulak & Swamy 2012) reported the all components of the Pirani score including total score (5.6) and the hindfoot score (2.9) and midfoot score (2.8) and 94.3% had tenotomy. Another study (Rijal et al., 2010) reported that the hindfoot score was decreased (2.62 to 0.7) in Ponseti method and Kite's method (2.79 to 1.31) at the follow-up (weeks of 10). Also, the midfoot score was reduced from 2.62 to 0.5 in Ponseti method and 2.7 and 1.04 in Kite, and 96% had tenotomy in the Ponseti method. Sætersdal et al., (2012) used the range of motion and Pirani score as outcome measure, and the mean initial Pirani score was 4.8. After the casting intervention, 78% of the patients had 0 or 0.5 Pirani score, 22% of the patients had 1 or 1.5, and one child had 3.5 Pirani score. In addition, this review noticed that 92% of the corrected foot achieved more than 15° of dorsiflexion, 84% of children freed from adducted deformities, and 40° degrees of external rotation achieved in 93% patients, and adducted deformity in 4%. Sanghvi & Mittal, (2009) study used the following outcome measurements method to assess the severity: a) Clinical assessments such as relapses, muscle power, calf muscle atrophy, passive ROM, appearance of the foot, size of foot, and other complications; b) Functional assessments - Gait pattern, functional limitation, pain, satisfaction and shoe comfort wear; c) Radiological assessments- talo-calcaneal angle, talo-first-metatarsal angle, and talo-calcaneal index. These
three components of this outcome measures together graded as excellent (85 to 100 points); good (70 to 84 points); fair (60 to 69 points); poor (less than 60 points). The overall results of this study reported that the success rate of Ponseti method was 87% and Kite method was 79%. In Segev study, this review found that the success rate of Ponseti method 94% (the Dimeglio score was decreased from 11.9 to 3.2), and 47 feet was performed with tenotomy, however, 6% of the foot had residual deformity (Segev et al., 2005).

3.5 Summary
The main strength of this study is that the study thoroughly followed a systematic approach to find out the relevant studies on clubfoot with the Ponseti method. In conclusion, this review study concluded that the Ponseti method required fewer casts than other methods to correct the clubfoot deformity. In addition, this study found that Ponseti method has some advantages such as less relapses rate, shorter treatment duration to achieve the full correction. On the other hand, very few studies only reported the relapse pattern, and causes for the relapses. There is still limited information on the causes of relapse or recurrences of the clubfoot. Few studies stated that poor socioeconomic status and bracing non-compliance for causes of relapse. However, the duration of discontinuity of braces or pattern of relapses, or any grading system for compliance was not reported in these studies. Also, it is noticed that two or three studies described the relapse pattern, bracing regime and discussion parts, in which the authors followed the previous articles without modification of any sentences or paragraph. Therefore, this review suggested that there is a need for number of systematic studies in this area for evaluation of clubfoot treatment and to evaluate and review the causes or pattern of relapse, adherence of foot orthosis and long term follow-up, and also to avoid the duplication of the existing publications. This systematic review study has also some limitations such as this study only included child with less
than less than two years old. Therefore, this study is not focused that more than two years old children with clubfoot, neglected clubfoot. In the future study, this study suggested that to do through literature search on databases with including neglected clubfoot, and study design with including associated abnormalities, and more RCTs with using Ponseti method and other clubfoot intervention to see the outcome differences.
CHAPTER 4 RESEARCH METHODS AND STUDY PROTOCOL

4.1 Introduction

The aim of this chapter is to develop a reliable, non-invasive 3D assessment method to evaluate clubfoot severity and its response to treatment. The relationship, if any, between the thermophysiological changes in the normal foot and the clubfoot at each stage of casting and develop an image classification system of clubfoot is explored. The thermal changes between stages of casting are evaluated and monitored for clubfoot pathological conditions. The abnormality of the thermal distribution from clubfoot patient could provide insightful data for researchers or clinicians.

A study protocol is proposed and several research questions of 3D scanning and infrared imaging are addressed (i) the accuracy and reproducibility of 3D scanning method for quantifying the severity of clubfoot, (ii) the reliability and reproducibility of 3D scanning method for detection and quantification of the structural changes in clubfoot in response to manipulation and casting intervention, (iii) the possibility of infrared imaging method to identify the predictable patterns of thermophysiological changes in the clubfoot, and (iv) the changes between the normal foot and the clubfoot in relation to thermophysiological functions.

4.2 Exploratory study design

This study uses a Kinect 3D scanner to explore the changes in the clubfoot structure after each casting stage of Ponseti method. Also, an infrared camera will be used to explore the thermophysiological changes at each casting stage of the clubfoot intervention. The study has been reviewed and approved on 17 August 2016 by the Sydney Children's Hospitals Network Human
Research Ethics Committee, Sydney, Australia, and the registration number is HREC/16/SCHN/163.

4.2.1 Participants/ Study population
A total of 20 clubfoot children who are less than 2 years old will be recruited from The Children's Hospital at Westmead. Data will also be collected from a total of 10 unaffected feet, from children with unilateral clubfoot to obtain the normal foot reference. Inclusion criteria includes: a) Idiopathic congenital clubfoot b) both gender c) bilateral and unilateral clubfoot d) Children less than 2 years old with untreated clubfoot. Exclusion criteria includes: a) A treated congenital clubfoot b) Clubfoot associated with other neurological conditions c) Child with untreated clubfoot above the age of 2.

4.2.2 Procedures (Recruitment, Consent, and Data collection)
A total of twenty children with untreated clubfoot (N=20; 10 clubfoot; 10 normal feet) will be recruited for this study. In addition, a total of 10 normal feet data will be collected from those children with unilateral clubfoot to obtain the normal foot reference. An invitation letter and copy of information sheet will be sent to the parents of the children with clubfoot prior to their clinical visit, in order to allow them to make an informed decision on the participation of their child in this study. The aims and objectives of this study, procedures, and the equipment details (risk and any harmful effects) will be explained to parents. If the participant’s parents agree to allow their child to participate in this research, a consent form will be provided at their first clinical visit. After the signing of the consent form from the participants, demographic details will be collected such as age, gender, types of clubfoot whether is unilateral or bilateral. The following flow chart illustrates the method of this study (Figure 4.1).
Figure 4.1 Flowchart of study method (Ganesan et al., 2017)
4.2.3 Equipment/Measurement tools

In this study, a Kinect 3D scanner and infrared camera will be used as assessment tools. The 3D images and infrared images will be taken at a distance of approximately 30-50 cm from the foot of the child. The Kinect and infrared camera does not make any contact with the foot during the scanning procedures. Moreover, the both equipment does not emit radiation, and there are no harm or risks to children or parents or practitioners.

4.3 Data collection procedures

After obtaining informed consent form the children with clubfoot, the following procedures will be followed:

4.3.1 Assessment 1

The child with clubfoot will be positioned in a small “V” shape baby bed, and this bed helps to maintain the child in a supine position with approximately 20-30° flexion of the hip and 30-45° flexion of the knee. The shape of bed provides comfort and support to the baby in the lying position. This V shape bed will be kept in the adjustable height of hospital bed before positioning the child. After positioning the baby, a small black-colour sticker will be used to identify the following anatomical landmarks: medial malleolus, lateral malleolus, 1st and 5th metatarsal-heads, head of the talus, and heel bone. The parents will be requested to hold the below knee of their children for 30 seconds to maintain the position of the foot. Then, the Kinect scanner will be used to move around the foot to obtain the 3D images. The 3D scanner will be moved from the medial side of the foot in a clockwise direction to obtain the right side foot 3D images. For obtaining the left side foot 3D images, 3D scanner will be moved from the medial border of the foot in a counter-clockwise direction. The process of obtaining 3D clubfoot images from children with clubfoot requires thirty to sixty seconds, and the marking process of anatomical landmark
with color sticker requires one to two minutes. A total of 3 trials of scanning will be carried out to establish the reliability and validity of this scanner. One minute of interval will be given to child between each trial. The 3D scanning will be performed before each casting intervention (once a week). A total of 6-8 scanning will be obtained from the each participant, and the scanning will be collected up to the last casting, that is before and after the tenotomy. The same procedures will be followed for normal foot of the children, but the scanning will be done once only for the normal foot during their first clinical visit.

4.3.2 Assessment 2

The child with clubfoot will be positioned in a small baby bed with supine position. Then, the examiner will use the infrared camera to obtain the infrared images from the following regions of the clubfoot and normal foot: dorsal, plantar, medial, lateral, and heel. In this proposed study protocol, the following guidelines will be used to collect the infrared images. The experiment room temperature will be maintained 22 - 26º. The infrared images will be collected after 15 minutes of removal of casting to avoid the casting - temperature effect. The capturing of the infrared images requires 1-2 minutes. Moreover, the infrared images will be obtained at each week of before the casting intervention (once a week). Three trials will be done to establish the reliability and validity of the equipment. The same procedures will be done for collecting infrared images from the normal foot. However, the infrared images will be collected only once for the unaffected foot with three trials at the time of first week of their hospital visit.

4.4 Data analysis

4.4.1 Method of 3D image analysis

The collected 3D images of the clubfoot and normal foot will be stored in the computer as obj. or stl. files format. The images will be processed by using Artec software to develop the 3D images
of the foot. After that, the processed data will be analysed in the following methods of data analysis to quantify the severity of the clubfoot, and to predict the progress of the clubfoot casting treatment. The methods of data analysis includes 3D foot alignment in the x, y, z coordinates system, cross-sections, parameter estimations, and curvature analysis will be performed in the clubfoot and normal foot (Figure 4.2). The analysed parameters of the clubfoot (cross-sections, parameter estimations, and curvature analysis) will be compared to the parameters of the 3D normal foot. The z-axis is located on the center of the ankle region. After the alignment of the foot, the cross sections will be done in the lower leg at 5 mm distance (or the distance can be adjusted). The center of the points will be calculated for the each cross section of foot (3D scanned data). Based on the center of the cross section points, a linear regression will be plotted to make the lower center as the “z-axis direction”. The “X-axis direction” will be based towards the direction of patella of the knee. The “Y-axis direction” will be based on the direction medial side of the foot. The center point (zero point) is estimated at the position of ankle joint.

Figure 4.2 Foot alignment (Images are adapted from Texas Foot & Ankle Group – Keller with permission and alignment was done by Ganesan et al., 2017).
4.4.2 Methods of Cross-sections, parameters estimation and curvature analysis

The cross sections will be created at every 5mm distance (or the distance can be adjusted) along the Z-Axis in the foot. These every 5 mm distance cross sections will be used to find out the differences after correction of the clubfoot and see the differences between clubfoot and from the normal feet. The each cross-section parameters (length, width, and the radial distance) from the center to the cross-section edge for specific angles (15°, 30°, 45°, 60°…. ) will also be calculated as shown in Figure 4.3. Similarly, the cross sections will be computed along the Y-Axis and X-Axis. These cross-sections parameters will be compared to estimate the different levels of deviation in the clubfoot.

Figure 4.3. Cross sections (Images are adapted from Texas Foot & Ankle Group – Keller with permission and cross sections are created by Ganesan et al., 2017)
The parameters and curvatures analysis will be used to evaluate the severity of the clubfoot, and to compare the differences between normal foot and clubfoot. Moreover, the position the marked anatomical landmarks such as 1\textsuperscript{st} metatarsal head, 5\textsuperscript{th} metatarsal-head, head of the talus, medial malleolus, lateral malleolus, and heel bone with respect to the coordinate system will also be highlighting the differences between the clubfoot with respect to unaffected foot.

4.4.3 Statistics for 3D images

The demographic data such as age, gender, and type of clubfoot will be analysed by using descriptive statistics and the mean and standard deviation will be calculated. One way repeated measure ANOVA will be used to evaluate the effectives of different levels (weekly) of casting intervention. To achieve the aims of this study, the parameters includes, angles, and the cross section parameters such as length, width, and the radial distance will be calculated from the 3D clubfoot images. In addition, the parameters of distance between the anatomical landmarks (the distance between the head of the talus and medial malleolus, medial border and lateral border of the foot) will also be calculated (Table 4.1).
Table 4.1 Parameters from 3D imaging analysis and Infrared imaging

<table>
<thead>
<tr>
<th>S.No</th>
<th>Parameters from 3D and thermography assessment method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parameters from 3D images</td>
</tr>
<tr>
<td>1</td>
<td>Angles</td>
</tr>
<tr>
<td>2</td>
<td>Length</td>
</tr>
<tr>
<td>3</td>
<td>Width</td>
</tr>
<tr>
<td>4</td>
<td>Radial distance</td>
</tr>
<tr>
<td></td>
<td>Distance between the anatomical landmarks</td>
</tr>
<tr>
<td>5</td>
<td>Medial border of the foot</td>
</tr>
<tr>
<td>6</td>
<td>Lateral border of the foot</td>
</tr>
<tr>
<td>7</td>
<td>Distance between the talar head and medial malleolus</td>
</tr>
<tr>
<td></td>
<td>Parameters from Infrared image</td>
</tr>
<tr>
<td>8</td>
<td>Foot skin temperature</td>
</tr>
</tbody>
</table>

As described in the “Method for 3D image analysis”, the parameters of 3D images such as length, width, and the radial distance from the center to the cross section edge for specific angles such as 15°, 30°, 45°, 60°…., will be calculated, and then linear regression will be plotted. After that, the Statistical Package for the Social Sciences (SPSS) will be used to calculate the mean and standard deviation from the method of descriptive statistics. The mean and standard deviations will be calculated for the parameters from 3D images. The results of the parameters from 3D images (length, width, radial distance) will be used to evaluate the structural changes of clubfoot after the Ponseti casting. Moreover, the mean and standard deviation will also be analysed for the additional parameters – parameters for the distance between anatomical
landmarks (the distance between the talus head, lateral malleolus and medial malleolus; medial border: medial malleolus (MM) to the first MTP joint; lateral border: lateral malleolus (LM) to the fifth MTP joint). To predict the number of casting required for correcting the full correction of clubfoot, the average differences of pre and post intervention parameters (length, width, and radial distance) will be calculated. In addition, these average parameters will be used to evaluate the different levels of severity of the clubfoot. The foot shape can also be sampled and curvatures will be analysed in this study. For example, as shown in Figure 4.4, When the angle is $\alpha$ for Section I and the cross section will be in the z-axis, the radial length is $zRi\alpha$. The curvature can be estimated by using various values for various angles. In addition, an automatic classification method will be developed for evaluation the clubfoot severity from the clubfoot 3D and it can be done by using feature extraction and support vector machine (SVM) classifier model in MATLAB.

![Parameter estimation and curvature](example, Section i) (Ganesan et al., 2017)
4.4.4 Infrared image analysis and statistics

**Parameters:** The skin temperature of the clubfoot after each casting intervention will be analysed based on the selected region of interest (ROI): forefoot, mid foot and hindfoot skin temperature. The skin temperature of the club foot between the each casting can be used to explore the thermophysiological changes. In addition, the skin temperature of the normal foot and the skin temperature of the selected region of the clubfoot will be compared. The Statistical Package for the Social Sciences (SPSS) will be used to conduct the descriptive statistics. In the descriptive statistics, an independent T-test will be conducted to see the differences in skin temperature between the clubfoot and normal foot. In MATLAB, the image processing approach and machine learning techniques will be selected and processed to develop an automatic classification system for clubfoot.

The following steps will be used to analyze the thermal images in MATLAB. At first, the Kruskal-Wallis test or Shapiro-Wilk test will be conducted to analyze the normal distribution of the collected thermal image data of clubfoot and normal foot. In the next stage of image analysis, an algorithm will be developed to automatically find the selected areas (ROI) of the foot (forefoot, mid-foot, hindfoot). To segment the selected areas of the foot (forefoot, mid-foot, and hind-foot), a Canny edge detection operator and gradient operator will be conducted by using MATLAB. After that, the image segmentation process will be conducted for the 3 selected (ROI) areas of the clubfoot. Then, the feature extraction of thermal images of the clubfoot will be done as a final step of this process. Statistically, feature extraction will be performed by using higher order statistical features; and the cross section and histogram generation will be conducted for the selected region of the foot. Other statistics such as descriptive statistics, kurtosis, skewness, and entropy statistical tests will be used to see the thermophysiological changes of selected areas.
of the foot. Mean and standard deviation will be conducted in SPSS with descriptive statistics to find out the normal distribution of the skin temperature of the foot. The analysis of entropy statistical features will be used to find out the abnormalities of the segmented thermal images. It can be used to classify the clubfoot based on the severity. In the method of developing automatic classification system for clubfoot, a SVM classifier model will be used to classify the severity of the clubfoot into different types such as mild, moderate, or severe. For accuracy, the sensitivity and specificity will be conducted by receiver operating characteristic (ROC) analysis.

4.5 Summary

The management of clubfoot is still challenging in terms of its evaluation and treatment methods. The accurate evaluation of clubfoot is necessary for assessing the initial severity, selecting the method of intervention, monitoring and predicting the progress of the casting intervention, and predicting the relapses of the club foot (Wainwright et al., 2002; Herd et al., 2004; Siapkara and Duncan, 2007, Ramanathan and Abboud, 2010; Jain et al., 2012; Fan et al., 2017; Jain et al., 2017). Nowadays, there are several assessment methods or scoring systems that have been used as assessment tools to evaluate the initial severity of clubfoot. However there is no universal standard assessment methods available to assess the initial severity of this deformity (Yapp et al., 2012; Ramanathan and Abboud, 2010; Ramanathan et al., 2009; Dyer and Davis, 2006; Gigante et al., 2004; Jain et al., 2001).

This is the first study attempts to assess the initial severity of the clubfoot by using a low cost 3D scanner and thermal imaging methods. The main aims and objectives of this study is to develop an automatic classification system to assess the severity of the clubfoot. The collected 3D parameters data (Angles, cross section parameters such as length, width, radial distance, distance between the anatomical landmarks, and temperature of the foot skin) will be used to evaluate the
initial severity of the clubfoot. The proposed novel 3D assessment system can be used as an objective assessment method for quantifying the severity of clubfoot after each stage of weekly casting (treatment phase) and bracing techniques (maintenance phase) of Ponseti methods. The primary advantages of using Kinect 3D scanning is low cost, no harm or risks, non-radiating equipment, high efficiency and reliability. It can also be used in both rural areas as well as hospital settings due to the advantage of this equipment such as portable and low-cost. Another advantage of this method is that it can be used without sedation of child during the scanning. However, this study has some limitations. Acquisition of 3D images from the babies’ feet is very difficult than collecting data from the adult feet. Moreover, collecting the data from the feet is harder than other body parts. Because the obtaining 3D images from the plantar view of foot is quite difficult in the standing position of children or adults. Similarly, the 3D image of heel and ankle areas of foot cannot be visible in the lying position of the new born child. Therefore, a “v” shape bed is selected for positioning the baby and to obtain the full 3D view of the foot. Another limitation of this study is that manpower, and 2 trained persons are required to collect the 3D images of clubfoot successfully because one person requires handling the 3D scanner. At the same time, other person is needed to operate the computer and Artec studio 3D software. In addition, a constant distance is about approximately 50 cm between the 3D scanner and foot should be maintained while performing the scanning to acquire the high quality 3D images of the foot. The 3D scanning software will interfere and create noisy 3D images if the scanner is too far or too close to feet. Another limitation of this study is that this study is used only one hospital site/ Ponseti clinic for data collection. Therefore, the data collection for this study is time consuming. Also, further ethical approval is required to extend the work to another clubfoot clinic.
The significance of this study is to develop a 3D automatic assessment method to evaluate the initial severity of the clubfoot, and to monitor and predict the progress of the clubfoot intervention. It can be used to predict the number of castings required to achieve the full correction of clubfoot. It would also be useful to assess the severity of clubfoot in rural/remote areas where medical specialist is unavailable. In addition, the outcomes of this novel assessment approach will also be useful to do further research to develop the comfortable and customized braces to avoid the relapse of the clubfoot.
CHAPTER 5 THREE-DIMENSIONAL EVALUATION MODEL FOR BONE TO BONE RELATIONSHIPS AND CLUBFOOT

5.1 Introduction

This chapter provides the details of new three dimensional assessment methods for clubfoot deformity. The objectives of this chapter is to develop a three dimensional CT evaluation bone model to measure the relationship between the foot bones. A severe clubfoot CT scan of four-year-old boy was used to develop the 3D bone model and to find the bone to bone relationships in the foot.

Very few studies in the extant literature have reported on the use of CT scanning in for assessing the progress of clubfoot intervention. The treatment progress of clubfoot can be objectively measured by calculating different angles such as the anteroposterior talocalcaneal and calcaneocuboid angles, based on 2D images of "slices" of scanned areas. Also, CT images provide a better understanding of the abnormalities in the size and shape of the talus, calcaneus, and other tarsal bones and their relationships. However, there are no studies that have analysed the bone to bone relationships in clubfoot deformities in relation to the hindfoot, midfoot, and forefoot bones especially in terms of the ankle region bones (tibia and fibula) relationships with other bones: talus and calcaneus metatarsals, proximal and distal phalanges, and cuboid bone.

The aim of this chapter is to therefore demonstrate and evaluate the "abnormal" arrangement of the bones of the ankle and foot in clubfoot by evaluating the bone to bone relationships, and develop a 3D model for clubfoot. Therefore, a new method for assessing severe clubfoot is proposed in this chapter by measuring bone to bone relationships. The 3D model is used to evaluate the angle of each bone in the foot such as the first to the fifth metatarsals, five proximal
phalanges, four middle phalanges, and five distal phalanges, calcaneus, talus and cuboid bones in relation to the alignment of ankle bones of tibia and fibula.

This chapter consists of the following sections. Section 5.2 describes the method, acquiring 2D CT slices from images, and aligning and removing noise from the 2D CT slices. Section 5.3 describes the 3D modelling of the clubfoot, adapting software for 3D modelling of the clubfoot, and processing and analysing the data. Section 5.4 provides a discussion on the results, aligning and measuring the angles of the calcaneus and talus cuboid, metatarsal, proximal phalangeal, and middle and distal phalangeal bones in relation to the tibia bones in the ankle, and finally, Section 5.5 provides the chapter summary

5.2 Method

5.2.1 Acquisition of 2D CT slice images

A CT scan was performed on a four-year-old boy with a severe clubfoot. The helical CT scans were obtained by using a Lightspeed 8 Ultra CT scanner (GE Healthcare Technologies, Waukesha, Wisconsin, USA) to develop the 3D model of the clubfoot bones. Before performing the scanning, written informed consent was obtained from the parent of the child. The obtained CT scanning parameters are: CT dose (CTD) volume -1.71 mGy, tube voltage 100 KV, tube current – 23 mA and section thickness – 2.5 mm. The following steps were done for the post processing of the 2D images as shown in Figure 5.1: acquiring the 2D slices, aligning and removing the noise from the 2D slices, processing the images with MATLAB, developing a 3D model for the clubfoot bones and analysing the alignment of bones at foot and ankle.
Figure 5.1 Framework for developing 3D model of clubfoot bones and analysing severe clubfoot

5.2.2 Aligning and removing noise from 2D slices

The first step for developing the 3D model was to align the 2D slices. Image noises such as patient information, the information of CTD volume, tube voltage, tube current and section thickness, and lines between and under images were manually removed from the CT scanned images on a Microsoft Windows 10 operated PC., and then the centre of the bone was marked by applying a red dot in each 2D slice of the images. The processing of the 2D slices are shown in Figure 5.2.
Figure 5.2 Process of removing noise from images and marking severe clubfoot (axial view)
5.2.3 Three-dimensional modelling of clubfoot

5.2.3.1 Software adapted for 3D modelling of clubfoot and data analysis

In this study, MATLAB R2017a, (The MathWorks, Inc., 2017) is used to develop the 3D model of clubfoot and analyse the bone to bone relationships. This is a computing programming language software that is commonly used in the research environment for developing algorithms, visualising data, processing image data, carrying out mathematical computations and plotting functions (The MathWorks, Inc., 2017; Gonzalez & Woods, 2004).

5.3 Data processing and analysis

The 2D slices of the CT images were aligned as described in the previous section. The aligned 2D slices were imported into MATLAB R2017a (The MathWorks, Inc., 2017). The red dots in the aligned 2D slices helped to identify each of the bones of the ankle and foot complex, and the red dots of every slice were merged together into red-dotted lines for each bone of the foot (Figure 5.3). The MATLAB program was tailored to select the landmarks in the x, y, and z coordinate system (xyz vectors) and automatically create 3D models of the foot (Stereolithography (STL)) based on the position of the landmarks of the lower end of tibia of the ankle region and the interested bones of the foot. To develop the STL file (3D format) of the 3D model of the clubfoot bones, 5 points or landmarks (green color) are selected, see Figure 5.4. The first point represents the lower end of tibia. The second and third points represent the lower end of the fibula and lower part of the tibia respectively. The fourth and fifth points were selected at the proximal and distal end of the bones of interest (that is, the anterior and posterior side of calcaneus, talus, cuboid, the tarsal, metatarsals, proximal and distal phalanges of the foot) to examine the relationship between the bones of interest and the tibia (Figure 5.4). In the next
step, the 3D model of the bones of the clubfoot was created in STL format as shown in Figures 5.5 (YZ view (90,0), 5.6 (XY view (0,90)), and 5.7 (XZ view). The STL format allows the model of the bones to be viewed or rotated for different 3D views, such as the tibia, fibula and metatarsal can be seen in the same plane of the XZ view (0, 0), as shown in Figures 5.5, 5.6 and 5.7 shows the relationship between the ankle (especially tibial bone) and first metatarsal.

The relationships among the orientations of interested bones and the tibia and fibula bones were described by using x, y, and z Cardan angles. In this study, the Cardan angles for the tibia-first, tibia-second, tibia-third, tibia-fourth, and tibia-fifth metatarsals, tibia- proximal, tibia - middle, and tibia - distal phalangeal bones, and calcaneus- tibia, tibia – cuboid, talus -tibia, calcaneus-middle, and calcaneus- distal phalangeal bones were calculated for severe clubfoot.
A. XYZ coordinate and alignment at ankle region

B. First metatarsal bone relationship to the ankle

Figure 5.5 Position and alignment of first metatarsal in relative to the tibia (YZ view (90,0))

Figure 5.6 Position and alignment of first metatarsal in relative to the tibia XY view (0,90)
5.4 Results and discussion

In this study, a semi-automated assessment method was developed to create a 3D model of the bones of a severe clubfoot and analyse the bone to bone relationships of severe clubfoot. The lower end of tibial bone of ankle of the foot was used as the centre of the axis landmark (X axis), to objectively and quantitatively determine the orientation between each bone of the foot and ankle. The results of the x, y, z angles of each bone of the foot (calcaneus, talus, cuboid, metatarsal, tarsal, proximal and distal phalangeal bones) were calculated in relation to the ankle bone of tibia (Table 5.1-5.5).

Clubfoot is a complex three-dimensional congenital deformity with abnormalities of the bones, joints, ligaments, muscles, and other soft tissue structures of the foot. Specifically, this deformity involves four characteristics of abnormalities in the foot including equinus, varus, adductus, and
cavus deformities (Mejabi et al., 2016; Miedzybrodzka, 2003). Many studies have used three-dimensional MRI to determine the volume of the talus and calcaneus and compared them with those of the normal foot of individuals with unilateral clubfoot (Cahuzac et al., 1999; Itohara et al., 2005), and Kamegaya et al. (2000) examined the following angles such as calcaneus adduction, the navicular bone angle, and talar neck angles, and calcaneus shift index. Kamegaya et al. (2001) also examined the talo-navicular (head of the talus and navicular) relationship. Itohara et al. (2005a) assessed the talar head and neck deviation, and the ossific nucleus of the talus and calcaneus. In addition, Itohara et al. (2005b) investigated the length of the talus and calcaneus. One of the previous study assessed the talocalcaneal angle in the sagittal plane, talar head and neck-axis-internal rotation, calcaneal-axis-internal rotation, transverse talar neck and head, posterior side calcaneus external rotation, and calcaneus angle (Pekindi et al., 2001). On the other hand, a few studies have used CT scanning to assess the changes in the shape and size of the tarsal bones in the clubfoot, such as the subtalar, talonavicular and calcaneocuboid joints, and the torsion angle of the ankle mortice, declination angle of the neck of the talus (Farsetti et al., 2009), subtalar, talonavicular , and calcaneocuboid angle (Ippolito et al., 2004), to develop a 3D model to better understand the complexities of the clubfoot (Windisch et al., 2007), and understanding of deformation of the talus and calcaneus (Epeldegui, 2012). The complexity of the anatomical structure and shape of the clubfoot means that it is difficult to describe them objectively. Therefore, a semi-automated 3D model for clubfoot is developed in this study to objectively and mathematically describe the clubfoot by calculating the angles and to find out the bone to bone relationships. The differences in the x, y, and z angles of each bone of the foot are discussed in the following sections.
5.4.1 Measuring the alignment of calcaneus, talus, cuboid bones relative to lower end of tibia

In clubfoot, all of the tarsus bones (calcaneus, cuboid, navicular, and the first, second, and third cuneiforms) are rotated into inward direction in relation to the lower end of tibia and fibula. The calcaneus is involved with all four components of clubfoot deformities including equinus, varus, adductus and cavus. In clubfoot deformity, the cuboid bone shifts medially along with the anterior end of the calcaneus (Anand & Sala, 2008). The results of x, y, and z coordinate angles of the calcaneus, talus, and cuboid bone describes a rotation in relative to the tibial bone of the ankle region. The table 5.1 shows the results of calcaneus, talus, cuboid bones alignment in relation to the lower end of tibia of the ankle region in the severe clubfoot. In addition, the calcaneus, talus, cuboid bones position are shown in figures 5.8, 5.9 and 5.10 respectively in the x, y,z direction. Among all axis of calcaneus, talus, and cuboid bone, the z axis represents as smallest inertia of moment. Therefore, the results of z axis showed that the relative angle of calcaneus, talus, and cuboid bone were 24.51 °, 09.32°, 9.41 ° (z axis angle) respectively in relation to ankle region (lower end of tibia).

Table 5.1. Calculation of angles of calcaneus, talus, cuboid bones in severe clubfoot

<table>
<thead>
<tr>
<th>Bone relationship</th>
<th>Angle X</th>
<th>Angle Y</th>
<th>Angle Z</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcaneus relative to</td>
<td>84.5308</td>
<td>113.8218</td>
<td>24.5185</td>
</tr>
<tr>
<td>lower end of Tibia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talus relative to</td>
<td>89.1044</td>
<td>99.2805</td>
<td>9.3244</td>
</tr>
<tr>
<td>lower end of Tibia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cuboid relative to</td>
<td>98.8301</td>
<td>93.2369</td>
<td>9.4137</td>
</tr>
<tr>
<td>lower end of tibia</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 5.8 Calcaneus bone position in relative to the lower end of tibia (ankle region)

Figure 5.9 Measurement of talus angles and its position in relative to the lower end of tibia (ankle region) (YZ view)
5.4.2 Measuring the alignment of metatarsal bones relative to lower end of tibia

The results of orientation between the talus and ankle area showed that the x-axis angle of the first metatarsal bone to fifth metatarsal has higher values than other metatarsal bones (Table 5.2). This is due to the mal-alignment of the two osseous columns (medial osseous columns - talus, navicular, lateral, middle, and medial cuneiforms, and first three metatarsal bones; lateral osseous columns - calcaneus, cuboids, and the fourth – fifth metatarsals (Epeldegui, 2012). This study found that the x axis directed medially, y axis directed towards inferiorly and anteriorly, and the z axis was in the vertical direction in the metatarsal bone, and this study also found that the x axis directed medially, y axis directed towards inferiorly, and the z axis is vertical axis in
the ankle region of the foot (Figure 5.7). The lowest value of z axis was observed in the fifth metatarsal bone (30.37º). These differences in the x, y, z angles of the metatarsal bones can be used for comparison purposes with normal foot angles to evaluate the severity (midfoot area) of the clubfoot.

**Table 5.2. Angles at metatarsal bones in relation to the tibial bone**

<table>
<thead>
<tr>
<th>Axis</th>
<th>First MT</th>
<th>Second MT</th>
<th>Third MT</th>
<th>Fourth MT</th>
<th>Fifth MT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angle X</td>
<td>74.7724</td>
<td>73.8849</td>
<td>68.3948</td>
<td>67.5999</td>
<td>68.3120</td>
</tr>
<tr>
<td>Angle Y</td>
<td>46.3456</td>
<td>45.7610</td>
<td>48.7914</td>
<td>56.6890</td>
<td>69.8154</td>
</tr>
<tr>
<td>Angle Z</td>
<td>47.6112</td>
<td>48.6634</td>
<td>49.0007</td>
<td>41.9471</td>
<td>30.3708</td>
</tr>
</tbody>
</table>

5.4.3 Measuring the alignment of proximal, middle, and distal phalangeal bones relative to the lower end of tibia

When the proximal phalangeal bones relative to tibia were objectively measured, the angle of the y-axis has a higher value than that of the angle of the x and z axes, and among x, y, z angles axis, the fifth proximal phalangeal bone has a greater y axis angle (91.02º), followed by 80.07º and 86.35º for the third and second proximal phalanges respectively (Table 5.3). On other hand, the proximal phalanges have the lowest z-axis angle in comparison to the other axis of the proximal phalangeal bones. The decreased z axis angle indicates that the proximal phalangeal bones are higher planter flexed, and adducted in relative to the ankle of the foot. The figure 5.11 shows the
x, y, z direction of first proximal phalanx of the severe clubfoot in relation to the lower end of tibia of ankle region.

Table 5.3 Angles at proximal phalanges in relation to ankle region of tibia

<table>
<thead>
<tr>
<th>Angles</th>
<th>First PP</th>
<th>Second PP</th>
<th>Third PP</th>
<th>Fourth PP</th>
<th>Fifth PP</th>
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<tr>
<td>Angle X</td>
<td>62.5339</td>
<td>56.5441</td>
<td>55.6095</td>
<td>64.2867</td>
<td>50.8717</td>
</tr>
<tr>
<td>Angle Y</td>
<td>68.7169</td>
<td>86.3594</td>
<td>80.0784</td>
<td>75.3336</td>
<td>91.02</td>
</tr>
<tr>
<td>Angle Z</td>
<td>35.9390</td>
<td>33.7066</td>
<td>36.1943</td>
<td>30.1551</td>
<td>39.1469</td>
</tr>
</tbody>
</table>
The Table 5.4 shows the results of measurement of angles at middle phalanges of the foot in relation to the ankle. The second to fifth toes (second MP- middle phalanx of second toe, third MP- middle phalanx of third toe, fourth MP- middle phalanx of fourth toe, fifth MP- middle phalanx of fifth toe of the foot) are only having middle phalanges. In the measurements of the orientation of the middle phalangeal bones in relation to the ankle region, the x- axis angle of the fifth middle phalanx was the largest angle 98.05º, followed by the fifth middle phalanx at 87.18 in y-axis, and the second and third middle phalanx were 70.91º and 72.74 respectively in the x-axis . The smallest angle was 8.53º at the fifth middle phalanx of the severe clubfoot. In view of the y-axis angle, the third (41.08º ) and fourth (47.19º) middle phalangeal bones had the smallest angle of in relation to the ankle, and in the z-axis, the fifth middle phalanx had lowest angle (8.53º) and it was more deviated than the other proximal phalanges.

The Table 5.5 shows the results of measurement of angles at distal phalanges of the foot in relation to the ankle. In the measurements of the orientation of the distal phalangeal bones in relation to the ankle region, the x- axis of third and fourth distal phalangeal bones had largest angle, such as 112.86º and 106º respectively. The following figure 5.12 shows the orientation of first distal phalanx in relation to the ankle of tibia. These results indicate that the third and fourth distal phalangeal bones moved more medially than other distal phalanges. In the x-axis orientation, the lowest x-axis angle (65.47º) was noticed in the fifth distal phalanx bone. The z-axis is long axis in the distal phalangeal bones, and the smallest moment of inertia than x and y axis. The angle of third and fourth distal phalangeal bones of z axis were lower than other distal phalanges of the z axis, and lower angles when compared to other axis (x,y) of the distal phalangeal bones.
Figure 5.12 The relationship between ankle (lower end of tibia) and first distal phalanx

Table 5.4 Angles at middle phalanges in relation to ankle

<table>
<thead>
<tr>
<th>Axis</th>
<th>Second MP</th>
<th>Third MP</th>
<th>Fourth MP</th>
<th>Fifth MP</th>
</tr>
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<tr>
<td>Angle X</td>
<td>56.32</td>
<td>70.91</td>
<td>72.74</td>
<td>98.05</td>
</tr>
<tr>
<td>Angle Y</td>
<td>67.38</td>
<td>41.08</td>
<td>47.19</td>
<td>87.18</td>
</tr>
<tr>
<td>Angle Z</td>
<td>42.44</td>
<td>55.24</td>
<td>47.85</td>
<td>8.53</td>
</tr>
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</table>
Table 5.5 Angles at distal phalanges in relation to ankle

<table>
<thead>
<tr>
<th>Axis</th>
<th>First</th>
<th>Second DP</th>
<th>Third DP</th>
<th>Fourth DP</th>
<th>Fifth DP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angle X</td>
<td>68.9534</td>
<td>112.8662</td>
<td>106.0701</td>
<td>89.5617</td>
<td>65.4726</td>
</tr>
<tr>
<td>Angle Y</td>
<td>90.6062</td>
<td>48.6924</td>
<td>96.1530</td>
<td>73.6605</td>
<td>76.6475</td>
</tr>
</tbody>
</table>

The complex three-dimensional deformity of the clubfoot is involved with malalignments of medial and lateral osseous columns. The adductus, cavus, and varus deformities of the clubfoot is mainly caused by the involved of talus, calcaneus, navicular, and cuboid bones (Epeldegui, 2012). The equinus deformity occurs at the ankle joint, talocalcaneonavicular joint and the forefoot. Furthermore, all the tarsus bones (calcaneus, cuboid, navicular, and the first, second, and third cuneiforms except talus) are rotated into inward direction in relation to the lower part of the leg, that is, in relation to the lower end of tibia and fibula (Anand and Sala, 2008). Therefore, it is necessary to assess the medial and lateral osseous columns and their relationship with the lower leg for a better understanding of the relationship of each bone in foot and ankle. However, the use of conventional radiographic or CT images is not the best way to examine clubfoot deformity. These images are only useful for examining the pathological anatomy of the clubfoot in a 2D plane. Therefore, it is difficult to completely assess the morphology, alignment of the bones of the foot and all of the hindfoot joints (Johnston et al., 1995; Ippolito et al., 2004). Another issue with 2D images is that they cannot provide fully reliable information to assess the
alignment and morphology of the tarsal bones as they have not been ossified in newborn babies or infants (Itohara, 2004; Herzenberg, 1988). In this study, the CT images are reconstructed into 3D images to examine the alignment of the bones of the foot, and relationship between the ankle and other bones of the foot. The differences from the objective angular measurements in this study can be used for comparison purposes of a normal foot as well as clubfoot to quantity the deformation of the clubfoot. Generally, three planes (sagittal, frontal or coronal, and the transverse planes are used to assess joint motion, such as plantar flexion and dorsiflexion (sagittal plane), abduction and adduction (coronal or frontal plane), and inversion and eversion (transverse plane) movements. However, the planes used differ depending on the bone to bone relationship (Ledoux et al., 2006). In this study, it is found that there are differences in bone rotation and angular deviation relative to ankle of the foot. This proposed method still has a number of limitations, such as small sample size and lack of CT images of the normal foot for comparing the bone angles between the clubfoot and a normal foot. This novel assessment-angular measurement can also be used to assess the other pathological anatomy of the foot such as pes cavus, pes planus.

5.5 Summary
In this chapter, a 3D model for severe clubfoot has been discussed, which is developed from 2D images obtained from CT scanning. MATLAB, a computer software program, is also used to automatically execute functions that calculate the angle of each bone of the foot. As a result, the x,y, and z coordinate angles are determined for each bone of the foot (calcaneus, talus, and cuboid bones, the metatarsals, and the proximal, middle and distal phalanges ) from the CT images. Although this is a novel method for obtaining 3D angular measurements from CT
images for severe clubfoot, it is still an expensive and time-consuming process in which data for each stage of the clubfoot treatment need to be collected. In chapter 6, a study proposes a protocol for developing a low cost new 3D assessment method for clubfoot in the next chapter.
CHAPTER 6 DEVELOPING A 3D ASSESSMENT METHOD FOR CLUBFOOT

6.1 Introduction

This chapter outlines the method used in this research study. In recent decades, advanced developments in medical imaging and 3D technology have allowed researchers and health care practitioners to gain a more in-depth understanding of the human anatomy and physiology as well as diseases, and provide accurate diagnoses and personalized treatment especially those that consider the different anatomical and physiological conditions of the human body. This chapter also discusses the process of obtaining ethical approval and recruiting participants for this study, and the equipment and techniques adopted to obtain the 3D data. In addition, this chapter will provide details of the protocols that are used in this research work. The chapter consists of the following sections. Chapter 6.2 outlines the study design and details of obtaining ethical approval for the work. Chapter 6.3 discusses the process of subject recruitment and details of the study population. Chapter 6.4 provides details on the equipment used for this study. Chapter 6.5 concerns the data collection.

6.2 Study design

This is an exploratory study that uses a Kinect XBOX as a 3D scanner/infrared camera (Chapter 4) to the changes in clubfoot structure and thermophysiological changes at each casting stage of the clubfoot intervention. The study has been reviewed and approved by the Sydney Children's Hospitals Network Human Research Ethics Committee, Sydney, Australia. The HREC is accredited by the New South Wales (NSW) Department of Health (Australia) as a leading HREC under the model for single ethical and scientific reviews, and by the
National Health and Medical Research Council (NHMRC) as a certified committee for reviewing multi-centre clinical research projects.

6.3 Participants/ Study population

A total of four children with clubfoot (2 males and 2 females) were recruited from the Children's Hospital at Westmead, Sydney, Australia to develop the 3D assessment method. In this study, among the four children with clubfoot, one pre and one post intervention sample (n=2) was selected to develop a 3D scanned model of the clubfoot for this study. A normal foot (n=1) sample was also collected to compare the normal and clubfoot. In addition, 2 rubber clubfoot models (MD orthopedics) (partially corrected and severe clubfoot) were obtained from Massons Healthcare, a private limited company that imports and distributes orthotics in Australia. Prior to the experiment, an invitation letter with a copy of the participation information sheet was sent to the parents of children with clubfoot (Figure 6.1). The inclusion and exclusion criteria for this study are as follows.

6.3.1 Inclusion criteria

a) Idiopathic congenital clubfoot
b) Both gender
c) Bilateral and unilateral clubfoot
d) Children less than 2 years old with untreated clubfoot.

6.3.2 Exclusion criteria

a) A treated congenital clubfoot
b) Clubfoot associated with other neurological conditions
c) Child with untreated clubfoot above the age of 2.
Figure 6.1 Flowchart of study design

1. Orthopedic surgeon determines eligibility of child for study
2. Invitation letter and copy of participation information sheet sent to parents/caregivers
3. Informed signed consent form received from parents who are willing to participate in study

Subject recruitment

Rubber clubfoot model samples (N=2)
- Severe clubfoot
- Partially corrected clubfoot

3D modeling of rubber clubfoot model

Clubfoot samples (N=2)/Normal foot (N=1)
- Before casting intervention
- At 6th week of casting intervention
- Normal foot (n=1)
- 30-60 sec per 3D scan

3D modeling of severe clubfoot, normal foot, and rubber model

New 3D assessment method
6.4 Kinect XBOX as scanner/camera

6.4.1 3D scanner

In this research work, a Kinect XBOX 360 is used as a scanner/camera to collect 3D images or obtain the 3D shape of the clubfoot and normal foot. Therefore, the scanning system consists of a Kinect XBOX 360, an MSI laptop and Artec 9 Studio (3D scanner software). The Kinect XBOX has an RGB camera, infrared camera, multi-microphone array, a camera tilt bar and other components (Figure 6.2). The specifications of the Kinect XBOX is provided in Table 6.1. The RGB camera can capture three different colors of images, which have a resolution of 1280 x 960 at 15 frames per second, or 640 × 480 at 30 frames per second (Matthew, 2012). It also has an infrared (IR) emitter, which emits the IR signals, and a depth sensor which reads these signals that are reflected back to the sensor. Then, the reflected signals are converted into depth information. The sensor on the Kinect XBOX has a 57° horizontal field of view and a 43° vertical field of view. It cannot capture images in certain situations, such as when the object and Kinect XBOX are placed very close together, or too far away from each other, or when there is poor reflection (such as when there is sunlight).

A number of previous studies have reported that the Kinect XBOX is a reliable and valid measurement tool for clinical research applications. Huber et al. (2015) showed that the Kinect XBOX is a highly reliable (ICC0.76–0.98) and valid measurement tool for measuring the angles of the shoulder joints. They showed that the concurrent validity of the Kinect is ± 5° in comparison to other measurement tools at a 95 % limit of agreement. Another study by Mentiplay et al. (2013) examined the reliability and validity of the Kinect for measuring the static foot posture and the results showed moderate to good intra-rater reliability ($\rho = 0.62$ to 0.78) with the Foot Posture Index test and moderate to good correlations ($\rho = 0.51$ to 0.85)
with a 3D motion analysis (3DMA) system. The Kinect is a more reliable measurement tool in the majority of foot posture measurements as opposed to traditional methods. Furthermore, it can be used as an accurate automated anthropometric measurement tool to assess the body composition, shape, surface area and volume (Soileau et al. 2016). In terms of cost, many 3D acquisition equipment and 3D scanners have been developed throughout the past few decades; however, the Kinect has a low cost (approximately HK$1899) (Microsoft Kinect, 2017). In addition, it has several advantages such as accurate depth information and real time use (Wu & Bainbridge-Smith, 2011) Therefore, the Kinect is adopted in this study because it is accurate, small, portable and inexpensive.

### Table 6.1 Microsoft Kinect specifications

<table>
<thead>
<tr>
<th>Kinect</th>
<th>Array Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viewing angle</td>
<td>43° vertical by 57° horizontal field of view</td>
</tr>
<tr>
<td>Vertical tilt range</td>
<td>±27°</td>
</tr>
<tr>
<td>Frame rate (depth and color stream)</td>
<td>30 frames per second (FPS)</td>
</tr>
<tr>
<td>Audio format</td>
<td>16-kHz, 24-bit mono pulse code modulation (PCM)</td>
</tr>
<tr>
<td>Audio input characteristics</td>
<td>A four-microphone array with 24-bit analog-to-digital converter (ADC) and Kinect-resident signal processing including acoustic echo cancellation and noise suppression</td>
</tr>
<tr>
<td>Accelerometer characteristics</td>
<td>A 2G/4G/8G accelerometer configured for the 2G range, with a 1° accuracy upper limit</td>
</tr>
</tbody>
</table>
6.4.2 Hardware Specifications of Kinect

A high configuration computer is essential for acquiring and rendering 3D images from the Kinect XBOX. Technically, a computer with a RAM greater than 4 GB, and a dual-core or multicore CPU will have the capability to acquire and manage the 3D data (Das, Murmann, Cohrn & Raskar, 2017). Therefore, in this study, an MSI laptop is used with the following specifications: CPU-Intel Core i7-4700MQ, RAM-16 GB, DDR3L memory, NVIDIA GeForce GTX 765M/GDDR5 2 GB).

6.4.3 Artec software

Artec studio 9 software was installed into the MSI laptop to acquire the 3D images of the foot. Like other related types of software, Artec has an accuracy of 1~2 mm and powerful post processing features in automatic global registration, rough and fine registration, smoothening, noise removing, filling in the holes, and importing and exporting options with the following formats: obj, ply, stl, and wrl, and many more other 3D formats.
Infrared- 3D depth cameras (Infrared projector and sensor); 2. CMOS color sensor/RGB camera for RGB imaging; 3 and 4. Microphone array

**Figure 6.2 Kinect and its components (Microsoft)**

### 6.5 Data collection process

The process of data collection commenced with an invitation letter sent to the parents of the children with clubfoot as illustrated in the flow chart in Figure 6.1. Informed consent (see Appendix A for form) was obtained from the parents of the children with clubfoot, that is, those who were interested in participating in the study. After obtaining consent from the participants, the demographics of each child were collected. In addition, information about the experiments and the procedures were provided to the parents or caregiver of the child on an information sheet.

#### 6.5.1. Experiment I

Before starting, a Kinect XBOX 360 (Microsoft, USA) was connected to the MSI laptop, and Artec studio 9 software was used to capture the 3D images on the computer (Figure 6.3). A
small baby bed was positioned at a height of 120 cm which is the level of a hospital bed (Figure 6.4). In addition, the bed was kept in the middle of the room for ease of 3D scanning at 360 degrees without any interruption. After the child was received by the orthopedic surgeon, the scanning procedures were then explained to the parent(s). First, the child was positioned on the small bed as shown in Figure 6.4. Then, the parent was instructed to hold the knee or contralateral foot gently for 30 seconds of scanning, as shown in Figure 6.5. The operation of Artec on the laptop was carried out by a trained volunteer while the camera on the Kinect XBOX was operated by another individual who moved around the foot to capture the 3D images. To capture 3D images of the right side of the foot, the Kinect was moved from the medial border of the clubfoot in a clockwise direction. The final step consisted of saving the scanned 3D images onto the MSI laptop. The total time for scanning, positioning the child and marking (anatomical landmarks) the foot took 3-5 minutes. The scanning was performed at the first week of before casting intervention and at the 6 week of casting intervention. Therefore, two 3D foot scans (N=2) were collected from the affected foot at the beginning and post intervention before the second phase of the Ponseti intervention. In addition, a 3D foot scan (N=1) was collected from the normal foot and the procedures were followed as clubfoot 3D scanning.

Figure 6.3 Equipment for experiment
6.5.2. Experiment II

In first part of the second experiment, rubber clubfoot models (partially corrected clubfoot and severe clubfoot) were used to develop the 3D models (Figures 6.6 and 6.7 respectively).
The rubber clubfoot models (MD Orthopaedics) were ordered online from Massons Healthcare, a private limited company that imports and distributes orthotics in Australia. The rubber clubfoot model was positioned on the table in the medial view and then, 3D scanning was performed by using the Kinect XBOX 360. The second step involved the capturing of a 3D image of the same rubber model but the heel part of the foot. The procedure described above for the partially corrected clubfoot model was also carried out for the severe clubfoot model. The captured 3D images were saved on the MSI laptop with Artec.

Figure 6.6 Rubber model of partially corrected clubfoot
6.5.3 Acquisition of 3D clubfoot model

Acquiring a 3D clubfoot model is a challenging step with newborn babies in the Ponseti method of casting and serial manipulation, since a newborn baby who is just a few weeks old cannot sit or stand to obtain the 3D clubfoot model. In this study, there are a number of steps that have been carefully followed to obtain the 3D clubfoot model by using the Kinect as a scanner and Artec software. Therefore, the following are important factors for obtaining a valid and reliable clubfoot model.

1. The bed on which the child is placed, and its position are very essential for performing 3D scanning without interruption. In this study, the hospital bed is placed about 130 – 150 cm above the ground.

2. Positioning the baby is important. In this study, a small baby bathing bed is used, as shown in Figure 6.4. This small baby bathing bed has a “V shape” and perpendicular at the end of the bed. The “V shape” is useful for keeping the baby in a supine position with approximately 20-30º hip flexion and 30-45º knee flexion, and sometimes, this position is useful for obtaining the 3D image without the need for the parent to hold the knee of the child.
3. Human resources is important because to perform the scanning, at least three persons are needed; that is, one person for scanning, one person to operate Artec on the laptop, and one person to stand closely to the child as a safety precaution.

![Algorithm for developing 3D clubfoot model and developing a new Assessment method](image)

Figure 6.8 Algorithm for developing 3D clubfoot model and developing a new Assessment method

In the previous sections, the method for positioning the child and ways that the experiments were carried out has been explained in detail. Therefore, the following sections will provide the rest of the details on 3D image processing with Artec and alignment of the clubfoot model and developing a new method for evaluating clubfoot with CATIA 3D modeling.
software. The flowchart in Figure 6.8 shows the algorithm for developing a 3D clubfoot model and a new assessment method. In addition, the results and discussion of this new 3D evaluation method will be provided.

6.5.4 Methods of 3D image processing with Artec studio 9 and RGB D mapping

In this section, the collected 3D scanned images of the rubber clubfoot models (partially corrected and severe clubfoot) and the clubfoot of the child before the casting intervention (one clubfeet scan) and after the casting intervention (at the week of 6 – post intervention), and a normal foot 3D scan were processed with Artec (www.artec3d.com). The first step was to clean the data by using editing tools (such as the eraser). Then, 3 steps were carried out to develop the clubfoot 3D model, including registration, fusion and post-processing of the data. Registration of the data includes rough serial, fine serial, and global serial registrations. Global serial registration is used in this study. The region of interest (ROI) was selected and areas that were not of interest were removed by using the editing tools of Artec. Then, smooth fusion was used by selecting the real time fusion option, and the holes in the scans were filled for the top view of the foot and smoothening was done with the post processing step in Artec. Figure 6.9 shows the process of creating the 3D rubber model of a severe clubfoot; Figure 6.10 the 3D model (surface) of a severe clubfoot of a child.
Figure 6.9 Creating rubber clubfoot model with Artec (severe clubfoot before intervention)

Figure 6.10: Creating 3D clubfoot model with Artec (severe clubfoot from child with unilateral clubfoot at baseline)
6.6 Developing new assessment method for clubfoot

In this section, the process for developing a new clubfoot evaluation method by using CATIA 5, a 3D modeling software (CATIA V5: Dassault Systemes Inc) will be discussed, including alignment, cross sectioning the foot, and measuring the different angles.

6.6.1 Step 1. Alignment of 3D model clubfoot

One normal 3D foot image, and four 3D clubfoot images (2 from rubber models, and 2 from children participants) were processed with Artec and the processed files were exported in the STL file format. Then, all of the collected STL files were aligned by using CATIA 5, a 3D modeling software, in the x, y, and z coordinate planes. The x,y plane in the coordinate system represents the orientation of the clubfoot model and a positive direction. The foot was aligned in different planes such as the heel pointing towards the toes of the forefoot (y axis) and from the direction of lateral border of the foot to the medial side of the foot. Figure 6.11 shows the yz plane view of the 3D model of a severe clubfoot, which was collected from the rubber clubfoot model. The same procedures were carried out for the rubber clubfoot model, model of the clubfoot of the children and normal foot.
6.6.2 Step 2: Sectioning scanned 3D clubfoot model

In sectioning the 3D clubfoot model, five lines were drawn on the foot to cross section the foot. These lines are drawn as shown in Figure 6.12 and the selected anatomical areas are as follows.

1. **First cross section line:** The first line was marked on the ankle and the line was drawn between just above the tip of the heel to the anterior side of the foot and ankle.

2. **Second cross section line:** The second line was drawn in the heel area of the foot, that is, from the tip of the heel area to the anterior or dorsal side of the ankle.

3. **Third cross section line:** The third line was drawn on the midfoot area of the foot, and this line was drawn on the medial to lateral or lateral to medial side of the foot.

4. **Fourth cross section line:** The fourth line was drawn on the metatarsal phalangeal (MTP) joint area of the foot; this line was drawn on medial to lateral or lateral to medial side of the foot.
5. **Fifth cross section line:** The fifth line was drawn on the proximal phalangeal joint of the toes and the line was drawn on the medial to lateral or lateral to medial side of the foot.

![Figure 6.12 Sectioning foot with five surface lines](image)

(1) Ankle area (2) heel area (3) midfoot area (4) metatarsal phalangeal joint, and (5) proximal phalangeal joint of toes.

After making the five surface lines, five cross sections (ankle: cross section, cross section at the heel; cross section of the midfoot area; cross section at the MTP, cross section at proximal interphalangeal (PIP) joint area) based on the surface lines were created on the scanned 3D model of a child with a clubfoot and rubber model and then, cross sectioning was performed on the maximum medial side to the maximum lateral side, and from the maximum dorsal side to the plantar side, as shown in figure. 6.13 and 6.14.
Figure 6.13 Cross section of 3D clubfoot of newborn child with severe unilateral Clubfoot
6.6.3 Step 3: Methods for calculating angles between center of cross sections

In Step 3 of developing a new clubfoot assessment method, a line was drawn between the first center of the cross section of a clubfoot (cross section of the ankle) to the center of the second cross section of the clubfoot (cross section of the heel), and then a second line was drawn from the center of the second cross section to the center point of the third cross section (cross section of midfoot). These three cross section centers form the first angle, which is called the angle of the center of the cross section of the ankle-heel-midfoot-area (AHMA angle). Likewise, the first cross section angles are calculated, and lines from the center of the second cross section to the centers of the third and fourth cross sections together form an
angle at the center point of the third cross section area, which is called the heel-midfoot-metatarsal phalangeal joint area (HMMA). Then, the third angle was determined among the lines of the center points of the third, fourth and fifth cross sections and a point was formed at the center point of the fourth cross section. This third angle is the midfoot-metatarsal phalangeal joint - proximal phalangeal joint area (MMPA) - center of cross section angle (Figure 6.15). The same procedures were followed for the maximum medial side of the foot angle, maximum lateral side of the foot angle, maximum plantar side of the foot angle and maximum of dorsal side of the foot angle from the center of the five cross sections of the foot (ankle, heel, midfoot, metatarsal phalangeal (MTP) joint, and proximal phalangeal joint area of the toes).

Table 6.2 shows the development of the new 3D assessment method for clubfoot (3DAMC). The following angles were calculated on for the maximum angles at the medial and lateral borders, and the plantar and dorsal sides of the foot from the center point of the five cross sections, and the angles between the center of the cross sections are as follows.

A. Center of cross section angle
1. Ankle-Heel-Midfoot-Area - center of cross section angle (AHMA Angle)
2. Heel-midfoot-metatarsal phalangeal joint area- center of cross section angle (HMMA angle).
3. Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area - center of cross section angle (MMPAA angle)

B. Maximum lateral border cross section angle
1. Lateral border of Ankle-Heel-Midfoot-Area cross section angle (LBAHMA Angle)
2. Lateral border of Heel-midfoot-metatarsal phalangeal joint area (LBHMMA Angle).
3. Lateral border of Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area of cross section angle (LBMMMPA angle)
C. Maximum medial border cross section angle

1. Medial border of Ankle-Heel-Midfoot-Area cross section angle (MBAHMA Angle)
2. Medial border of heel-midfoot-metatarsal phalangeal joint area (MBHMMA).
3. Medial border of midfoot- metatarsal phalangeal joint -proximal phalangeal joint area (MBMMPA) center of cross section angle

D. Maximum dorsal side cross section angle

1. Dorsal side of Ankle-Heel-Midfoot-Area cross section angle (DS-AHMA Angle)
2. Dorsal side of Heel-midfoot-metatarsal phalangeal joint area (DS-HMMA).
3. Dorsal side of Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area of cross section angle (DS MMPA angle)

E. Maximum planter side cross section angle

1. Plantar side of Ankle-Heel-Midfoot-Area cross section angle (PSAHMA Angle)
2. Plantar side Heel-midfoot-metatarsal phalangeal joint area of cross section angle (PSHMMA).
3. Plantar side Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area of cross section angle (PSMMPA).
Figure 6.15 Alignment of center of cross sections and three centers of cross sections angles
Table 6.2 Development of new 3D assessment method for clubfoot (3DAMC)

<table>
<thead>
<tr>
<th>3D Parameters</th>
<th>Baseline score</th>
<th>1 wk of casting</th>
<th>2 wks of casting</th>
<th>3 wks of casting</th>
<th>4 wks of casting</th>
<th>5 wks of casting</th>
<th>6 wks of casting</th>
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<tbody>
<tr>
<td><strong>A. Center of the cross sections angle</strong></td>
<td></td>
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<tr>
<td>1. Ankle-Heel-Midfoot-Area cross section angle (AHMA Angle)</td>
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<tr>
<td>2. Heel-midfoot-metatarsal phalangeal joint area (HMMA angle)</td>
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<tr>
<td>3. Midfoot-metatarsal phalangeal joint - proximal phalangeal joint area of cross section angle (MMPA angle)</td>
<td></td>
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<tr>
<td><strong>B. Maximum lateral border cross section angle</strong></td>
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<td></td>
</tr>
<tr>
<td>1. Lateral border of Ankle-Heel-Midfoot-Area cross section angle (LBAHMA Angle)</td>
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</tr>
<tr>
<td>2. Lateral border of Heel-midfoot-metatarsal phalangeal joint area (LBHMMMA)</td>
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<tr>
<td>3. Lateral border of</td>
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<tr>
<td>C. Maximum medial border cross section angle</td>
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<tr>
<td>1. Medial border of Ankle-Heel-Midfoot-Area cross section angle (MBAHMA Angle)</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>3. Medial border of Midfoot-metatarsal phalangeal joint-proximal phalangeal joint area cross section angle (MBMMPA)</td>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D. Maximum dorsal side cross section angle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Dorsal side of Ankle-Heel-Midfoot-Area cross section angle (DS-AHMA Angle)</td>
</tr>
<tr>
<td>2. Dorsal side of</td>
</tr>
<tr>
<td>Heel-midfoot-metatarsal phalangeal joint area cross section angle (DS-HMMA angle)</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>3. Dorsal side of Midfoot- metatarsal phalangeal joint-proximal phalangeal joint area of cross section angle (DS MMPA angle)</td>
</tr>
</tbody>
</table>

**E. Maximum planter side cross section angle**

<table>
<thead>
<tr>
<th>1. Plantar side of Ankle-Heel-Midfoot-Area cross section angle (PSAHMA Angle)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Plantar side Heel-midfoot-metatarsal phalangeal joint area (PSHMMA Angle)</td>
</tr>
<tr>
<td>3. Plantar side Midfoot- metatarsal phalangeal joint - proximal phalangeal joint area cross section angle (PSMMPA)</td>
</tr>
</tbody>
</table>
6.6.4 Results and discussion

A new inexpensive 3D assessment method called 3DAMC and its assessment parameters have been developed in this study to objectively evaluate clubfoot deformity. This evaluation system consists of 5 components including center of the cross sections angle, Maximum lateral border cross section angle, Maximum medial border cross section angle, Maximum dorsal side cross section angle, and Maximum planter side cross section angle. A total of 2 samples of the rubber clubfoot model (one severe clubfoot and one partially corrected clubfoot) were processed with Artec and CATIA 5 and further evaluated with 3DAMC. In terms of data collection from the participants, data were collected from a 2 week old child with severe clubfoot by using the Kinect as a 3D scanner at baseline, and sixth weeks of casting. In addition, a normal 3D foot scan was also collected. After processing the data, the results of the pre- and post- intervention (one week before and after) were compared, and it also compared with normal foot (see Table 6.3).

The method of calculating the angles and determining the results is provided in Figures 6.16 - 6.24. Figure 6.16 shows the results for the angle of the center of the cross sections (AHMA, HMMA and MMPA Angles) of the rubber clubfoot model. The method and results for other angles of the cross section of the 3DAMC for the rubber model are also shown in Figures 6.17 to 6.20: maximum lateral border cross section angle (Figure 6.17), maximum medial border cross section angle (Figure 6.18), maximum dorsal side cross section angle (Figure 6.19), and maximum planter side cross section angle (Figure 6.20). The angles of the cross section of the foot of the child with clubfoot were calculated before casting and at 6 weeks after casting, and the calculation of the various cross section angles is shown in Figures 6.21-6.25. The results of the 3DAMC showed a difference between all of the cross-section angles of the child with clubfoot and the rubber model as shown in Tables 6.3 and 6.4, respectively.
Figure 6.16 Center of the cross section angles on rubber model of severe clubfoot

AHMA Angle

HMMA Angle

MMPA Angle

Figure 6.17 Maximum lateral border cross section angle

Figure 6.18 Maximum medial border cross section angle
Figure 6.19 Maximum dorsal side cross section angle

Figure 6.20 Maximum planter side cross section angle

Figure 6.21 Center of the angle of the cross section - child with severe clubfoot deformity
Figure 6.22 Maximum angle of the cross section at lateral border - child with severe clubfoot deformity

Figure 6.23 Maximum angle of the cross section at medial border - child with severe clubfoot
Figure 6.24 Maximum angle of the cross section of dorsal side - child with severe clubfoot deformity

Figure 6.25 Maximum cross section angle of plantar side - child with severe clubfoot deformity
Table 6.3 Results of pre and post casting (6 weeks) as intervention, and comparison with normal foot

<table>
<thead>
<tr>
<th>3D Parameters</th>
<th>Baseline score of severe clubfoot (degrees in 360º)</th>
<th>6th wk casting score of clubfoot (degrees in 360º)</th>
<th>Normal foot (Left side) (degrees in 360º)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Center of the cross sections angle</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 AHMA Angle</td>
<td>205</td>
<td>215.8</td>
<td>225.0</td>
</tr>
<tr>
<td>2 HMMA Angle</td>
<td>215.7</td>
<td>192</td>
<td>161.0</td>
</tr>
<tr>
<td>3 MMPA Angle</td>
<td>207.7</td>
<td>153.4(206.6º/360º)</td>
<td>155.0</td>
</tr>
<tr>
<td><strong>B. Maximum lateral border cross section angle</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 LBAHMA Angle</td>
<td>143.9</td>
<td>167.1</td>
<td>231.5 (128.5)</td>
</tr>
<tr>
<td>2 LBHMMA Angle</td>
<td>164</td>
<td>118.2(241.1/360º)</td>
<td>157.6</td>
</tr>
<tr>
<td>3 LBMMMPA Angle</td>
<td>157.6</td>
<td>167.4</td>
<td>155.3</td>
</tr>
<tr>
<td><strong>C. Maximum medial border cross section angle</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 MBAHMA Angle</td>
<td>194.3</td>
<td>170.1</td>
<td>143.9</td>
</tr>
<tr>
<td>2 MBHMMA Angle</td>
<td>143.9</td>
<td>220.3</td>
<td>160.4/199.6</td>
</tr>
<tr>
<td>3 MBMMPA Angle</td>
<td>122.4</td>
<td>193.7</td>
<td>211.2(148.8)</td>
</tr>
<tr>
<td><strong>D. Maximum dorsal side cross section angle</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 DSAHMA Angle</td>
<td>147.1</td>
<td>213.2</td>
<td>142.9/217.1</td>
</tr>
<tr>
<td>2 DSHMMA Angle</td>
<td>206.6</td>
<td>198.8</td>
<td>158.4</td>
</tr>
<tr>
<td>3 DSMMPA Angle</td>
<td>200.7</td>
<td>166.3</td>
<td>142.1</td>
</tr>
<tr>
<td><strong>E. Maximum planter side cross section angle</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 PSAHMA Angle</td>
<td>250.4</td>
<td>232.6</td>
<td>114.7(245.3)</td>
</tr>
<tr>
<td>2 PSHMMA Angle</td>
<td>145.8</td>
<td>162.2</td>
<td>169.3</td>
</tr>
<tr>
<td>3 PSMMPA Angle</td>
<td>147.2</td>
<td>167.4</td>
<td>196.9</td>
</tr>
</tbody>
</table>
Table 6.4 Results of rubber clubfoot model (severe and partially corrected)

<table>
<thead>
<tr>
<th>3D clubfoot assessment parameters</th>
<th>Baseline score</th>
<th>Partially corrected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Center of the cross section angle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AHMA Angle</td>
<td>220.6</td>
<td>261</td>
</tr>
<tr>
<td>HMMA</td>
<td>199.3</td>
<td>150.7</td>
</tr>
<tr>
<td>MMPA</td>
<td>199.2</td>
<td>160.2</td>
</tr>
<tr>
<td><strong>B. Maximum lateral border cross section angle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBAHMA Angle</td>
<td>229.3</td>
<td>236</td>
</tr>
<tr>
<td>LBHMMA Angle</td>
<td>224.5</td>
<td>197.4</td>
</tr>
<tr>
<td>LBMMMPA</td>
<td>223</td>
<td>199.6</td>
</tr>
<tr>
<td><strong>C. Maximum medial border cross section angle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBAHMA Angle</td>
<td>157.4</td>
<td>266.6</td>
</tr>
<tr>
<td>Medial border of MBHMMA</td>
<td>230.2</td>
<td>213.9</td>
</tr>
<tr>
<td>MBMMPA</td>
<td>152.5</td>
<td>151.8</td>
</tr>
<tr>
<td><strong>D. Maximum dorsal side cross section angle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DS-AHMA Angle</td>
<td>227.5</td>
<td>202.7</td>
</tr>
<tr>
<td>DS-HMMA</td>
<td>230.5</td>
<td>145.5</td>
</tr>
<tr>
<td>DS MMPA</td>
<td>187.8</td>
<td>208.3</td>
</tr>
<tr>
<td><strong>E. Maximum planter side cross section angle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSAHMA Angle</td>
<td>246</td>
<td>257.9</td>
</tr>
<tr>
<td>PSHMMA Angle</td>
<td>190.4</td>
<td>120.1</td>
</tr>
<tr>
<td>PSMMPA angle</td>
<td>155.1</td>
<td>214.2</td>
</tr>
</tbody>
</table>
The baseline score (out of 360 degrees) of the AHMA Angle is increased from 205° to 215.8°. This angle is measured on the hindfoot part of the cross section of the foot. The results of this score show that 10.8° increased laterally from the baseline and can be used to assess the degree of hindfoot varus of the clubfoot and the alignment of hindfoot and midfoot areas. The differences between pre and post treatment for the five cross sections of the clubfoot and rubber clubfoot model are shown in Figures 6.26 – 6.30. The HMMA Angle is reduced from 215.7° to 192° which suggests that the relationship between the heel and midfoot and forefoot adduction could be measured with the HMMA Angle in the 3DAMC. The MMPA Angle is reduced from 207.7° to 153.4°. There is an increased LBAHMA Angle post evaluation, and decreased angle of the cross section of the LBHMMA, and increased angle at the LBMMMP at 6 weeks post evaluation. Therefore, the correction of the midfoot and hindfoot can be evaluated at the lateral side of the cross sections of the clubfoot. The scanned angles from the rubber models showed the same results obtained from the child with clubfoot. However, the LBAHMA Angle is larger in the rubber model. The results from the maximum angle of the cross section at the medial border showed an increase from the baseline, which means that the varus, cavus, and adducted deformities are reduced. At the maximum of dorsal side cross section angle, the dorsal side of Ankle-Heel-Midfoot-Area cross section angle (DS-AHMA Angle) is increased from 147.1° to 213.2°. This means that the heel is moving in an upwards direction and there is more dorsiflexion. It is also possible to determine equinus deformity by measuring the PSAHMA Angle at the maximum angle of the cross section of the plantar side. The 3DAMC can be therefore used to measure all of the components of the clubfoot for objective measurements. The method is a reliable and objective means to quantify the severity of clubfoot accurately and can be used to predict the prognosis and select the appropriate intervention for clubfoot.

The following 3D images of a clubfoot shows the progress of clubfoot casting intervention in different views including the dorsal or superior, planter or inferior, medial and lateral views.
(Figures 6.31A-6.31E). The pre-and post-casting 3D clubfoot models were aligned at the center of the ankle. The position of the uncorrected clubfoot was medially rotated, adducted and inverted position at the time of the first casting. After 5 weeks of casting of correction, the corrected feet is turned into abducted and everted position as shown in Figure 6.31 A-E.

![Graph 1](image1.png)  
2 week child with right clubfoot before and after casting

![Graph 2](image2.png)  
Rubber clubfoot model before and after partial correction

**Figure 6.26 Results of 3D imaging of centre of the cross-section angle**

![Graph 3](image3.png)  
2 week child with right clubfoot before and after casting

![Graph 4](image4.png)  
Rubber clubfoot model before and partial correction

**Figure 6.27 Results of maximum lateral border cross section angle**
2 week child with right clubfoot before and after casting

Rubber clubfoot model (severe and partial correction)

**Figure 6.28** Results of 3D imaging of maximum medial border cross section angle

2 week child with right clubfoot before and after casting

Rubber clubfoot model severe and partial correction

**Figure 6.29** Results of 3D imaging of maximum dorsal side cross section angle
2 week child with right clubfoot before and after casting

Rubber clubfoot model (severe and partial correction)

Figure 6.30. Results of 3D imaging of maximum planter side cross section angle
Figure 6.31 Different views of 3D clubfoot model after casting intervention (Pre-casting and at 6th week of casting)

E. View of cross sectional changes between corrected clubfoot and severe clubfoot
6.6.4.1 Results of pre and post casting (6 weeks) intervention, and comparison with normal foot

Most of the current classification systems are subjective in nature and evaluations are based on physical appearance or reducibility. Sometimes, subjective types of classification scoring systems, such as the Pirani scoring system, may or may not reach a score of 0 even if the foot has been fully corrected (Khan et al., 2017). Another study by Wainwright et al. (2002) suggested that a reliable and valid assessment scale should be used to assess the clubfoot, which needs to separately consider the information of all the areas of the clubfoot, such as the midfoot, hindfoot, and forefoot. That is because clubfoot severity differs in these areas. Therefore, the initial severity and progress of the casting treatment for clubfoot are evaluated in these three different areas of the foot in this study. Two cross section lines on the hindfoot, one on the midfoot, and two on the forefoot were drawn, from which, three cross section angles were calculated on the dorsal, medial and lateral sides, as well as the lateral and centre, of the foot. These cross section angles were compared with those of a normal foot (Figure 6.32). Clubfoot is a three dimensional deformity. Therefore, each cross section angle could be used to evaluate the initial severity, and monitor and predict the structural changes in the clubfoot at all different levels of the foot.
To measure the severity in all levels or areas of the clubfoot, the five components of 3D cross section angle of the 3DAMC- clubfoot evaluation system was divided into three parts: Hindfoot- 3DAMC (Table 6.5), Midfoot- 3DAMC(Table 6.6), and Forefoot-3DAMC (Table 6.7 ). In the hindfoot, the centre of the cross section angle in a severe clubfoot is 205º, which is less than 20º in comparison with a normal foot. The cross section angle of the medial border decreased laterally at the sixth weeks of casting treatment (from 194.3º to 170.1º), which means that there is correction of the hindfoot varus deformity. A normal angle of the 3D cross section on the medial side is 143.9º. The 3D cross section angle of the lateral side increased after correction of the varus and cavus deformities. At the same time, the 3D cross section angle of the lateral side of the normal foot is 231.5º. The cross section angles of the medial and lateral sides could be used to predict the correction of varus and adductus deformities of the clubfoot. The cross section angle of the dorsal side (DS-AHMA Angle) of the hindfoot (severe clubfoot- 147.1º, corrected clubfoot – 213.2º) is greater than that of the

Figure 6.32 Three-Dimensional (3D) angle measurements of normal foot
normal foot (142.9°). The 3D cross section angle of the plantar side (PSAHMA Angle) is reduced from 250.4° to 232.6° at the 6th week of casting. Both of these angles could be used to predict the hindfoot equinus and varus positions of the foot. In the Pirani scoring system, the hindfoot score consists of three items: the posterior heel crease, empty heel, and rigidity of equinus. The palpation of the emptiness of the heel differs depending on the experience of the Ponseti practitioner.

Table 6.5 Hindfoot measurement in 3DAMC

<table>
<thead>
<tr>
<th>Hindfoot Measurement</th>
<th>3D cross section angle of severe clubfoot</th>
<th>3D cross section angle of corrected clubfoot</th>
<th>3D cross section angle of normal foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHMA Angle</td>
<td>205</td>
<td>215.8</td>
<td>225.0</td>
</tr>
<tr>
<td>LBAHMA Angle</td>
<td>143.9</td>
<td>167.1</td>
<td>231.5 (128.5)</td>
</tr>
<tr>
<td>MBAHMA Angle</td>
<td>194.3</td>
<td>170.1</td>
<td>143.9</td>
</tr>
<tr>
<td>DS-AHMA Angle</td>
<td>147.1</td>
<td>213.2</td>
<td>217.1 (142.9)</td>
</tr>
<tr>
<td>PSAHMA Angle</td>
<td>250.4</td>
<td>232.6</td>
<td>245.3 (114.7)</td>
</tr>
</tbody>
</table>

Figure 6.33 Results of hindfoot severity of the clubfoot before and after casting and comparison with normal foot
In this study, the structural changes of the midfoot deformities were measured by the HMMA, LBHMMA, MBHMMA, DSHMMA, and PSHMMA angles. The centre of the HMMA angle is laterally reduced from 215.7° to 192° at the sixth week of casting due to the correction of the cavus and adductus deformities. Adductus deformity is found at the talonavicular and the anterior-subtalar joints. The forefoot faces in an upward direction because of hindfoot alignment with forefoot. As the deformity is three dimensional, the equinus deformity involves the ankle joint, TCN joint and the forefoot, and there is varus deformity in the TCN joint. Likewise, the hindfoot equinus involves forefoot plantar flexion (Anand & Sala, 2008). The cross section angle of the lateral border is laterally reduced (from 164° to 118.2° (241.1° /360°), and the medial border is medially increased (143.9° to 220.3°) at the sixth weeks of casting. When the adducted and cavus foot is corrected, the DS-HMMA angle is (206.6° to 198.8°) is decreased anteriorly and the PSHMMA angle of the plantar side is increased (145.8° to 162.2°) anteriorly. The medial, lateral, and the center of cross section angles could be used to measure the severity of the adductus and varus deformities of the clubfoot. In addition, the medial border of the cross section angle can be used to measure the cavus of the midfoot. The dorsal and planter side of the cross section angles could be used to evaluate the equinus deformities of clubfoot and the alignment of hindfoot, forefoot and midfoot. This present study found that all cross section angles are closely reached to the range of normal foot- cross sections angle.

At the 6 week of evaluation in the forefoot, the centre of the cross section - MMPA Angle is laterally reduced from 207.7° to 153.4°. The laterally decreased angle shows the correction of forefoot adduction. The medial border of the clubfoot is generally adducted, plantar flexed and facing in an upward direction. After the 5 castings, the cross section angle of the medial border is increased (122.4° to 193.7°) due to the abduction of the corrected feet. The DS-
MMPA angle is reduced from 200.7° to 166.3° dorsally; this shows abduction and improvement of dorsiflexion in the corrected feet, and the PSMMPA Angle is increased from 147.2° to 167.4° after the 5th casting in the clubfoot treatment.

<table>
<thead>
<tr>
<th>Table 6.6 Results of midfoot measurement in 3DAMC</th>
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<tbody>
<tr>
<td><strong>Midfoot Measurement</strong></td>
</tr>
<tr>
<td>3D Midfoot Parameter- cross section angle</td>
</tr>
<tr>
<td>3D cross section angle of severe clubfoot (360°)</td>
</tr>
<tr>
<td>HMMA Angle</td>
</tr>
<tr>
<td>LBHMMA Angle</td>
</tr>
<tr>
<td>MBHMMA Angle</td>
</tr>
<tr>
<td>DS-HMMA Angle</td>
</tr>
<tr>
<td>PSHMMA Angle</td>
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</tbody>
</table>

Figure 6.34 Results of midfoot severity of the clubfoot before and after casting, and comparison with normal foot
Table 6.7 Results of forefoot measurement in 3DAMC

<table>
<thead>
<tr>
<th>Forefoot Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3D Forefoot Parameter- cross section angle</strong></td>
</tr>
<tr>
<td>MMPA Angle</td>
</tr>
<tr>
<td>LBMMMPA Angle</td>
</tr>
<tr>
<td>MBMMMPA Angle</td>
</tr>
<tr>
<td>DS MMMPA Angle</td>
</tr>
<tr>
<td>PSMMPA Angle</td>
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</tbody>
</table>

Figure 6.35 Results of forefoot severity of the clubfoot before and after casting and comparison with normal foot.

Many previous studies have indicated that an objective method is important for accurately assessing clubfoot (Ramanathana, Herda, Macnicolb & Abboud, 2009; Ramanathan & Abboud, 2010). A valid and reliable assessment means is necessary for prescribing the appropriate treatment, predicting the prognosis and determining the success of treatment as
well as classifying or grading the severity of the clubfoot. Reliable and objective techniques such as MRI or CT are expensive to carry out, would not be available in rural settings and increase the cost of treatment. Although CT or MRI is available in urban settings, it is still challenging to prescribe these techniques for evaluating serial casting due to cost, and practical issues, such as the need to give a sedative to the child. In previous studies, a number of evaluation methods have been proposed to evaluate clubfoot severity, such as the Pirani scoring system, Dimeglio scale, and that of Harrold and Walker classification. However, these scoring systems do not have optimum interobserver and intraobserver variability. In addition, they are subjective in nature and do not provide objective evidence (Jain, Mehtani, Goel, Jain, Sood & Jain, 2012). Furthermore, some studies have reported on objective assessment methods to quantify the severity of the clubfoot such as using the F-scan in-shoe analysis system, pedographs, and foot tracing of the foot bimalleolar angle (Herd, Ramanathan, Cochrane, Macnicol & Abboud, 2008; Jain, Mehtani, Goel, Jain, Sood & Jain, 2012). However, these evaluating systems can be reliable and valid tool for assessing the clubfoot severity successfully in the walking age. For instance, with foot tracing, the leg needs to be held and the foot placed firmly onto the paper to trace the foot, and sometimes it is improperly traced which might be caused by external pressure induced onto the leg and foot by the practitioner. Therefore, it is recommended here that the proposed 3DAMC can be used as a means of measurement to assess the initial clubfoot severity and for telemedicine practices in rural settings. The initial severity can be evaluated weekly at a low cost, and objectively and subjectively determine the properties of the foot.

The proposed 3DAMC uses a 3D scanner which has a very low cost and is a portable device. That is, the Kinect is a very inexpensive 3D scanner when compared to other scanners, such as the Metris ModelMaker1 ($88,444), VIVID-9i (Konica Minolta; Nikon; $55,000), or the Breuckmann Smart Scan 3D-HE (Kaiwei, 2016). Another advantage is that the Kinect can be
used for clinical assessment and observation in rural settings and underdeveloped countries. In addition, most 3D foot scanners require a standing position to obtain the 3D image, which is difficult for newborn babies. However, the Kinect is portable and the proposed method here for positioning the baby is convenient to perform 3D scanning.

6.7 Summary

This chapter has provided an introduction and discussion of the objectives and methods, study design, ethical approval details, two types of experiments, and processing of 3D images with different software, such as Artec and CATIA 5. Rubber models of a severe clubfoot as well as a partially corrected clubfoot, and 3D data collected from two children with unilateral clubfoot have been analyzed, and then 3D modeling of the clubfoot has been carried out. A new 3D assessment method called 3DAMC is subsequently developed and compared with the 3D imaging results of pre-and post-intervention of clubfoot. However, this study had some limitations such as sample size and no normative reference values. In this research study, one pre and post 3D images of clubfoot were only used to develop the 3D assessment system. In addition, this study recruited four subjects but only one parent accepted to participate in this study for 3D scanning.

A new evaluation method for clubfoot will be provided in Chapter 7 with the use of IR thermography to evaluate the thermophysiological changes in the clubfoot before and after casting. Four clubfoot participants are recruited to carry out the evaluation, and thermal images are collected. The IR images are then processed by using FLIR and MATLAB (Maths Works, USA). The results will also be provided in Chapter 7.
CHAPTER 7 THERMOGRAPHIC EVALUATION OF CLUBFOOT

7.1 Introduction

This chapter outlines an evaluation method which involves infrared imaging of the clubfoot. Recently, advanced developments in computer hardware and software technologies mean that infrared thermal applications are becoming very widespread in the medical field. They have been used by doctors and other health care professionals to diagnose and determine the appropriate treatment, and provide a more in-depth understanding of the thermo-physiological changes and diseases in the human body.

This chapter discusses the process of ethical approval and subject recruitment of those with clubfoot, and the techniques adopted to obtain the thermal image data of the clubfoot. In addition, this chapter will provide details on the protocols that are used in this research work.

7.2 Study design

This is an exploratory study design that uses an infrared thermography (IRT) camera to explore the clubfoot thermophysiological changes at each stage of the casting intervention. The study has been reviewed and approved by the Sydney Children's Hospitals Network Human Research Ethics Committee, Sydney, Australia and the Human Research Ethics Committee (HREC) reference number is HREC/16/SCHN/163. The total time for approving this study was approximately 8 - 10 months including clearance for radiation free equipment, health examination of the investigators, police clearance checks for working with children and site-specific approval, and meetings with research ethics officers for discussion and presentation about the thermal imaging component of the study. The ethics application was then assessed and found to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) on 17 August 2016 and site-specific approval was obtained on 21 November 2016.
7.3 Participants/ Study population

A total of 4 children with clubfoot (2 males and 2 females) less than 2 years old were recruited from the Children's Hospital in Westmead, Sydney, Australia. However, the parents of one of the children withdrew from the study before the commencement of the thermal imaging as they transferred to another hospital facility that was closer to their home. Among the 4 remaining children, 2 have a bilateral clubfoot and 2 have a unilateral clubfoot. The all unilateral clubfoot had a right clubfoot deformity. The demographics of the participants are provided in Table 7.1. Prior to the experiment, an invitation letter with a copy of the participation information sheet was sent to the parents of children with clubfoot. The inclusion and exclusion criteria for this study are as follows.

7.3.1. Inclusion criteria

a) Idiopathic congenital clubfoot

b) Both gender

c) Bilateral and unilateral clubfoot

d) Children less than 2 years old with untreated clubfoot

7.3.2 Exclusion criteria

a) A treated congenital clubfoot

b) Clubfoot associated with other neurological conditions

c) Child with untreated clubfoot above the age of 2
Table 7.1 Demographics of study participants

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age</th>
<th>Type of Clubfoot</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>2 weeks old</td>
<td>Unilateral</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>2 weeks old</td>
<td>Bilateral</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>1.5 weeks old</td>
<td>Bilateral</td>
</tr>
<tr>
<td>4</td>
<td>Female</td>
<td>1.5 weeks old</td>
<td>Unilateral</td>
</tr>
</tbody>
</table>

7.4 Infrared Camera

Infrared cameras have been widely used as an IRT diagnostic tool in the medical field, especially for dermatological problems, orthopedic and neurological disorders, vascular problems, urological disorders, fever, and breast cancer (Hildebrandt, Raschner, & Ammer, 2009; Ishigaki et al., 1989; Gulevich et al., 1997; Ng & Acharya, 2009). Since 1987, the American Medical Association Council has recognized IRT as a diagnostic technique (Hildebrandt, Raschner, & Ammer, 2009). In this research work, an infrared camera (model E33, FLIR Systems) is used to collect thermal images of the skin of both the clubfoot and normal foot (Figure 7.1). Table 7.2 lists the specifications of the camera: the infrared resolution is 160×120 pixels (19,200 pixels for a thermal image) with a minimum focus distance of about 25° x 19° /0.2 m (0.66 ft.). The measurement of the object temperature ranges from -20°C to +120°C (-4°F to +248°F), and 0°C to +650°C (+32°F to +1202°F). The thermal sensitivity/ noise equivalent temperature difference (NETD) of the infrared camera is <0.07°C @ +30°C (+86°F) / 70 mK and the accuracy is ±2°C (±3.6°F) or ±2% of the readings. Infrared radiation is defined as —All objects whose temperature is above absolute zero emit EM radiation over a particular wavelength range (Jones, 1998; Maldagu, 2001) and the infrared wave length is between 0.75–1000 μm (Lahiri, Bagavathiappan, Jayakumar & Philip, 2012). In human skin, the wavelength range of emitted infrared radiation is between 2–20 μm (Steketee, 1973). Figure 7.2 shows the wave length of different imaging modalities.
along with their functions. When an object has a high temperature, it produces more infrared radiation. This invisible radiation can be detected by infrared cameras, which will then be converted into thermal images. Infrared radiation is not visible to the human eye (Vollmer & Mollmann, 2011). This process is called IRT, which has many advantages, such as implementation in real time, no physical contact required, radiation free, and the ROIs of two dimensional images can be selected for examination (Usamentiaga, Venegas, Guerediaga, Vega, Molleda & Bulnes, 2014).

Previous studies have reported that IRT is a reliable and valid measurement technique to assess thermophysiological changes for various diseases. The validity of IRT is demonstrated well in diagnosing reflex sympathetic dystrophy, various injuries, many pathological problems (Bruehl et al. 1996), dermatological issues (George et al. 2008), and diabetes mellitus (Sivanandam et al. 2012). For example, Burnham et al. (2006) reported that infrared thermometers demonstrate good validity (intraclass correlation coefficient (ICC) =0.92), are somewhat more responsive, quicker and transportable in comparison to conventional thermistors. Moreover, the reliability of IRT has been demonstrated in several studies, such as a study by Oerlemans (1999) on reflex sympathetic dystrophy (RSD) (ICC =0.94); Spalding (2008) on arthritis of the wrist (ICC =0.94), and McCoy (2011) on the spine (ICC = 0.95– 0.97). The major advantage of using an infrared camera is that it does not emit radiation. In addition, the camera is very safe to use without posing any risks to patients, parents/caregiver, or clinicians. Based on the consideration of all of these factors, a FLIR infrared camera is therefore used in this study as a reliable measurement tool for measuring the surface skin temperature of the foot.
Table 7.2 Specifications of infrared camera (Source: Peiport Scientific Limited, FLIR)

<table>
<thead>
<tr>
<th>Imaging and optical data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Field of view (FOV) / Minimum focus distance</td>
<td>25° x 19° / 0.2m (0.66 ft.)</td>
</tr>
<tr>
<td>Spatial resolution (FOV)</td>
<td>2.7 mrad</td>
</tr>
<tr>
<td>Thermal sensitivity / NETD</td>
<td>&lt;0.07°C @ +30°C (+86°F) / 70mK</td>
</tr>
<tr>
<td>Image frequency</td>
<td>60 Hz</td>
</tr>
<tr>
<td>Focus</td>
<td>Manual</td>
</tr>
<tr>
<td>Zoom</td>
<td>1-4x continuous, digital zoom, including panning</td>
</tr>
<tr>
<td>Focal Plane Array (FPA) / Spectral range</td>
<td>Uncooled microbolometer / 7.5-13 μm</td>
</tr>
<tr>
<td>IR resolution</td>
<td>160 x 120 pixels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Image presentation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Display</td>
<td>Touchscreen, 3.5 in. wide screen LCD, 320 x 240 pixels</td>
</tr>
<tr>
<td>Image modes</td>
<td>IR image, visual image, thermal fusion, Picture-in-Picture, thumbnail gallery</td>
</tr>
<tr>
<td>Thermal fusion</td>
<td>IR image shown above, below or within temp interval on visual image</td>
</tr>
<tr>
<td>Picture-in-Picture</td>
<td>Resizable and movable IR area on visual image</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measurement</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Object temperature range</td>
<td>-20°C to +120°C (-4°F to +248°F), 0°C to +650°C (+32°F to +1202°F)</td>
</tr>
<tr>
<td>Accuracy</td>
<td>±2°C (±3.6°F) or ±2% of reading</td>
</tr>
</tbody>
</table>

Figure 7.1 FLIR Camera
<table>
<thead>
<tr>
<th>Radiation / Wavelength</th>
<th>Modality</th>
<th>Medical information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio Wave</td>
<td>MRI image</td>
<td>Anatomy</td>
</tr>
<tr>
<td>10^{-3}</td>
<td></td>
<td>Edema, flow</td>
</tr>
<tr>
<td>Microwave</td>
<td>Ultrasound</td>
<td>Anatomy and Physiology</td>
</tr>
<tr>
<td>10^{-2}</td>
<td></td>
<td>Tissue structure characteristics, flow</td>
</tr>
<tr>
<td>Infrared</td>
<td>Infrared Imaging</td>
<td></td>
</tr>
<tr>
<td>10^{-5}</td>
<td></td>
<td>Anatomy Intraarticular structure, inflammation</td>
</tr>
<tr>
<td>Visible Light</td>
<td>Arthroscopy</td>
<td>Healing/Therapy</td>
</tr>
<tr>
<td>10^{-8}</td>
<td></td>
<td>Skin, chronic</td>
</tr>
<tr>
<td>Ultraviolet</td>
<td>UV-radiation</td>
<td>Inflammation</td>
</tr>
<tr>
<td>10^{-8}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>X-Ray</td>
<td>X-Ray</td>
<td>Anatomy</td>
</tr>
<tr>
<td>10^{-10}</td>
<td></td>
<td>Bone injuries</td>
</tr>
<tr>
<td>Gamma ray</td>
<td>Scintigraphy</td>
<td>Physiology</td>
</tr>
<tr>
<td>10^{-12}</td>
<td></td>
<td>Inflammation, metabolism of the bone</td>
</tr>
</tbody>
</table>

Figure 7.2 Different types of medical imaging modalities (Hildebrandt et al., 2010)
7.4.1 FLIR Software

FLIR Tools Software for PC was used to generate a report from the infrared images. This software is easy to use and has several key features such as measurement tools (measurement tools-spots, area boxes, circles, lines, and Delta T); options for importing the data search and filtering the infrared images from the FLIR camera directly; and options for measuring the ROI areas and then importing the data as a CSV file for analysis. In addition, headers, footers, and logos can be added by using this software.

7.5 Data collection procedures

The process of data collection commenced with an invitation letter sent to the parents of the children with clubfoot as illustrated in the flow chart in Figure 7.3. Informed consent (see Appendix A for form) was obtained from the parents of the children with clubfoot, that is, those who were interested in participating in the study. After obtaining consent from the participants, the demographics of each child were collected. In addition, information about the experiments and the procedures were provided to the parents or caregiver of the child on an information sheet.

Details of the experiment procedures, including positioning the bed and child, obtaining the ROI of selected areas of the foot, duration of the experiment procedures, and the period of data collection are discussed in the next section.
Figure 7.3 Flowchart of subject recruitment and study design for thermal imaging

As indicated earlier in this chapter and Chapter 4, informed consent was obtained, and in this part of the study, to take infrared images. The protocols of the University of Glamorgan were followed to obtain the thermal images, including the exporting of the images from the IR camera (Hildebrandt, Raschner & Ammer, 2010). The room temperature was maintained at about 22-26ºC during the experiment. In addition, the feet of the children were washed with tap water after removing the casting to prevent the casting effect of temperature and then they were asked to wait for 10 -15 minutes at a normal room temperature for acclimation. Then,
the child was positioned in a supine position in a small bed (Figure 7.4). The small bed was positioned at a height of 120 cm on a hospital bed. Then, the parent of the child was instructed to hold the leg of the child as shown in Figure 7.5. The FLIR camera was then used to collect infrared images from the following areas of the foot: dorsal, plantar, medial, and lateral sides. To take an infrared image of the heel of the foot, the parent held the child closely to his/her body or chest. In the heel position, a square shaped sheet was placed behind the leg of the child to prevent noisy images. The entire process of capturing the infrared images required about 3-5 minutes including positioning the child. In this experiment, infrared images are collected from all of the participants from the first casting to the 6 week of casting. The details of the clinical observations from the infrared images are provided in the results section.

Figure 7.4 Positioning of baby with clubfoot on bed for 3D and infrared imaging
7.6 Data processing and analysis

An outline of the method for analyzing the data is shown in Figure 7.6. The infrared images that were taken before and after the weekly castings were edited by using Microsoft Paint. The cleaned images versus uncleaned images are shown in Figure 7.7. The collected images (dorsal, medial, plantar, heel and lateral sides of the foot) were processed by using MATLAB 2017a (Mathworks Inc, MA, USA). With the help of MALAB programming, the mean, maximum, minimum and standard deviation of skin temperature distribution data were collected in the selection region of interested areas of the foot. These collected data (mean temperature of foot) were analyzed by using SPSS software (Statistical Package for the Social Sciences, 1968).
Figure 7.6 Flow chart- Algorithms for processing of clubfoot thermal image data
Figure 7.7 Example of different views of original clubfoot infrared images vs. digitally cleaned thermal images of clubfoot (Subject 1)
7.7 Results and discussion

7.7.1 Demographics

Four patients with clubfoot between 0 to 2 weeks old (2 females and 2 males) (N=4) were recruited from the Children’s Hospital at Westmead in Sydney. The significance of the difference in temperature in the weekly serial castings was tested with a general linear model. A total of 120 thermal images of the children were collected from the dorsal, plantar, medial, heel, and lateral sides of the foot. For example, the collected infrared images from the dorsal side of the foot before and after casting intervention are shown in Figure 7.8.

A. Thermal image of clubfoot before casting  B. Thermal image of clubfoot after first casting
C. Thermal image of clubfoot after second casting
D. Thermal image of clubfoot after third casting
E. Thermal image of clubfoot after fourth casting
F. Thermal image of clubfoot after fifth casting (Week 6)

Figure 7.8 Thermography images of Ponseti serial casting (1-6 weeks)

(Red - high temperature area; Blue and Green – low temperature area)
7.7.2 Skin temperature distribution on foot

For all of the participants, 10 cut off scores related to temperature (minimum, maximum, range, standard deviation, and mean temperature) were obtained from each infrared image of the clubfoot. For example, MATLAB processed clubfoot images with 10 cutoff ranges as shown in Figures 7.9 and 7.10. The figure shows the mean temperature of the plantar side of the foot before the casting intervention (Subject 1). The maximum mean temperature is 33.8°C±0.20°C at the heel of the plantar side of the foot, and the minimum mean temperature is 31.7°C±1.84°C at the plantar side of the foot. After 5 weeks of casting, no changes were found in the maximum mean temperature at the plantar side of the foot (33.8°C±0.20°C). Achilles tendon tightness could be the cause for the increased temperature on the heel region of the plantar side of the foot. However, the minimum mean temperature is decreased to 30.8°C±3.03°C on the plantar side of the foot. At times, temperature or pathophysiological changes can be subjectively visualized from the thermal images of human body parts. Observation of the thermal images is standardized by the International Organization for Standardization and it is recommended that the red and blue colors in the images represent high and low temperatures respectively (Hildebrandt et al., 2012). For example, Figures 7.8A to 7.8 F show the infrared images of the dorsal side of the foot before and after casting. A subjective observation of the thermal images leads to the conclusion that the surface skin temperature is reduced weekly in the forefoot area when compared with the baseline thermal images. The reduced skin temperature on the forefoot might be due to the correction of forefoot adduction. Chapter 7.7.3 discusses in detail the statistical analysis of the thermophysiological changes in the clubfoot before and after the casting intervention.
Figure 7.9 Mean temperature of clubfoot before intervention (plantar side of the foot)
7.7.3 Results of statistical analysis of thermal changes on the clubfoot

In this study, a univariate analysis is used to analyze and to describe the relationship between the weekly casting interventions and thermal changes in the skin of the clubfoot. The thermal images were collected at pre-intervention (first week), and the second, third, fourth, fifth, and sixth weeks. Also, thermal images of five different areas of the clubfoot were collected and analyzed: the medial, lateral, dorsal, and plantar sides as well as the heel of the clubfoot. When performing the univariate analysis, the threshold level for statistical significance was set at $p < 0.05$. The temperature was computed as a dependent variable with SPSS (mean value for each cut off score), and the fixed factors were the temperature cut off and weekly casting intervention. In addition, a post hoc analysis was performed with Tukey’s honest significant difference (HSD) and least significance difference (LSD) tests at a 95% confidence interval. The results of the analysed mean temperature will be discussed in the following sections.

7.7.3.1 Thermal changes on the dorsal side of foot after weekly casting

The results of the mean temperature analysis are shown in Table 7.3. A higher maximum mean temperature ($T_{mean}$) ($M=32.26°C$, $SD = .93$, 95% CI: 31.8 - 32.6) was noticed in the first week (pre - intervention) of casting. However, the temperature declined on the 6th week.
The differences between the minimum and maximum means of the temperatures are shown in Table 7.3. According to the results from the post hoc analysis, significant results are found at the 6th week as opposed to all of the other weeks (p=.000) among the participants (F=6.122). The plot in Figures 7.11 and 7.12 shows the thermal changes in skin on the dorsal side of the foot for participants 1 and 2, respectively. The baseline mean temperature on the dorsal side of the clubfoot is slightly increased until the 4th week and then gradually decreases at the 6th week (Figure 7.11). However, there is no difference in the maximum mean temperature at the heel at the 6th week. In contrast, the skin temperature of the dorsal side of the foot of in Subject 2 steadily decreases at baseline to the 5th week (Figure 7.12). However, the temperature is increased on the 6th week. The clinical thermal images show a reduced temperature at the forefoot and midfoot area. Mostly, the skin temperature of the foot remains constant or increases at the dorsum of the foot near the heel (Figure 7.13). Overall, the skin temperature on the dorsal side of the foot slightly is decreased at the week of six in all participants in the 6 weeks of casting (M=31.1, SD=1.6, 95% CI: 30.1-31.1, p=0.00).

Table 7.3 Results of thermal changes on the dorsal side of foot

<table>
<thead>
<tr>
<th>Week/Casting</th>
<th>Mean (°C)</th>
<th>Std</th>
<th>95% Confidence Interval Lower Bound</th>
<th>95% Confidence Interval Upper Bound</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Pre-Intervention)</td>
<td>32.26</td>
<td>.936</td>
<td>31.85</td>
<td>32.678</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>31.88</td>
<td>.862</td>
<td>31.4</td>
<td>32.301</td>
<td>0.153</td>
</tr>
<tr>
<td>3</td>
<td>31.78</td>
<td>1.13</td>
<td>31.36</td>
<td>32.195</td>
<td>0.067</td>
</tr>
<tr>
<td>4</td>
<td>32.21</td>
<td>1.21</td>
<td>31.80</td>
<td>32.632</td>
<td>0.862</td>
</tr>
<tr>
<td>5</td>
<td>31.71</td>
<td>2.08</td>
<td>31.238</td>
<td>32.195</td>
<td>0.055</td>
</tr>
<tr>
<td>6</td>
<td>30.67</td>
<td>1.67</td>
<td>30.197</td>
<td>31.153</td>
<td>0.000</td>
</tr>
</tbody>
</table>
Figure 7.11 Thermal changes on dorsal side of foot after weekly casting (Subject 1)

Figure 7.12 Thermal changes on the dorsal side of foot after weekly casting (Subject 2)
7.7.3.2 Thermal changes in skin of heel of clubfoot before and after casting intervention

In contrast to the dorsal side of the foot, the mean temperature of the foot was not maintained between pre-and post-intervention, and the mean temperature slightly increased at the 6th week in comparison to pre-intervention (M=31.59°, SD=1.13, 95% CI:31.2-31.9, p=0.49). The test of between subjects showed a significant effect of the casting (F=23.09; p=0.00). However, the pre-intervention had no difference in temperature changes between the baseline and at the 6th week (p=.99) based on the post hoc testing (Tukey’s HSD test) and LSD test (p=0.49). In contrast, the second (M=30.899°, SD=0.82, 95% CI: 30.60 - 31.195, p=0.01), fourth (M=30.72, SD=0.81, 95% CI: 30.43- 31.02, p=.001), fifth week (M=32.93, SD: 1.09, CI: 32.59-33.27, p=0.00) had significant temperature changes after the casting intervention.

The descriptive statistics of the skin temperature of the heel are provided in Table 7.4. The plot in Figures 7.14 and 7.15 shows that at the 2nd, 4th and 6th weeks, temperature changes are reduced in Subject 1. In addition, the skin temperature of the heel fluctuated throughout the casting period (Figure 7.15). This study also finds that the mean temperature is high at the 5th week, and overall, the skin temperature is slightly less than baseline at the 6th week.
Table 7.4 Thermal changes in skin of heel of clubfoot

<table>
<thead>
<tr>
<th>Week/Casting</th>
<th>Mean (°C)</th>
<th>Std</th>
<th>95% Confidence Interval Lower Bound</th>
<th>95% Confidence Interval Upper Bound</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Pre-Intervention)</td>
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<td>1.64</td>
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<td>31.734</td>
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</tr>
<tr>
<td>2</td>
<td>30.899</td>
<td>0.82</td>
<td>30.603</td>
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<td>1.17</td>
<td>31.492</td>
<td>32.083</td>
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<tr>
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<td>30.431</td>
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<td>1.09</td>
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<td>33.274</td>
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<td>1.13</td>
<td>31.254</td>
<td>31.937</td>
<td>0.49</td>
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</table>

Figure 7.14 Thermal changes of heel after weekly casting (Subject 1)
7.7.3.3 Thermal changes in skin of lateral side of clubfoot

The highest mean temperature on the lateral side of the foot is evident at the 5\textsuperscript{th} week (M=32.66°C, SD=1.04, 95% CI: 32.26 -33.06, p=0.17); see Table 7.5. The post hoc analysis results (LSD test) showed that the baseline score is significantly different at the 2\textsuperscript{nd} (M=32.05°C, SD=0.77, 95% CI: 31.70-32.39, p=0.05), 3\textsuperscript{rd} (M=31.61, SD=1.11, 95% CI: 31.27-31.96, p=0.00), and 6\textsuperscript{th} weeks (M=31.15°C, SD=1.59, 95% CI: 30.75-31.54, p=.000). In addition, a significant temperature difference is found at 6 weeks in comparison to the 4\textsuperscript{th} (p= .002) and 5\textsuperscript{th} (p=0.00) weeks. Figure 7.16 shows that skin temperature of the lateral side of the foot is slightly reduced at the 2\textsuperscript{nd} week, then slightly increases up to the 5\textsuperscript{th} week, and then decreases on the 6\textsuperscript{th} week. Figure 7.17 shows the estimated marginal means of the skin temperature on the lateral side of the foot for all participants. It shows a reduced temperature at the 6\textsuperscript{th} week, during which the foot achieved enough of a range of motion for abduction (60–70°) (Radler, 2013). Therefore, the temperature might be decreasing at the forefoot and midfoot area rather than the baseline for all of the participants.
Figure 7.16 Thermal changes in skin of lateral side of foot after weekly casting (Subject 1)

Figure 7.17 Estimated marginal means of skin temperature of lateral side of foot
Table 7.5 Thermal changes in skin of lateral side of clubfoot

<table>
<thead>
<tr>
<th>Week/Casting</th>
<th>Mean (°C)</th>
<th>Std</th>
<th>95% Confidence Interval Lower Bound</th>
<th>95% Confidence Interval Upper Bound</th>
<th>P value</th>
</tr>
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<td>1.01</td>
<td>32.054</td>
<td>32.74</td>
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<td>31.709</td>
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<td>31.6195</td>
<td>1.11</td>
<td>31.274</td>
<td>31.96</td>
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<td>4</td>
<td>32.1995</td>
<td>1.07</td>
<td>31.854</td>
<td>32.54</td>
<td>0.269</td>
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<td>32.6650</td>
<td>1.04</td>
<td>32.267</td>
<td>33.06</td>
<td>0.172</td>
</tr>
<tr>
<td>6</td>
<td>31.1500</td>
<td>1.59</td>
<td>30.752</td>
<td>31.54</td>
<td>0.000</td>
</tr>
</tbody>
</table>

7.7.3.4 Thermal changes in skin of medial side of foot

The test of between subjects showed no difference in the temperature between the pre and post-tests (F= 2.0; P=.067). The mean and standard deviation for the medial side of the clubfoot are provided in Table 7.6 and an example of the thermal changes in the skin of the medial side of the clubfoot of Subject 1 is plotted in Figure 7.18. There was no difference between pre and post intervention (M=31.90, SD=1.27, 95% CI: 31.36-32.43, p= 0.56). At the same time, the Fisher's least significant difference (LSD) test showed that the 2\textsuperscript{nd} (p= .044) and 3\textsuperscript{rd} weeks (p=0.25) have a significant difference in comparison to the 6\textsuperscript{th} week. At the first casting, the clinicians try to align the forefoot with the midfoot and hindfoot to correct the cavus (Global Help, 2011; Radler, 2013). However, based on the analysis results of the upper and lower limits generated by the 95% confidence interval, there is a reduced temperature after the first casting on the medial side of the foot. For instance, Figure 7.18
shows a reduced temperature (maximum and minimum mean) on the medial side of the foot, followed by a significant reduction at the 5th week for the first subject. However, for the second subject, the temperature slightly increases at the 5th week, and is reduced at the 2nd, 3rd and 6th weeks (Figure 7.19). Overall, the temperature changes in which there is a temperature decrease are found at the medial side of the foot. After manipulation and correcting the cavus by first casting and then followed by the correction of the forefoot adduction and varus, the temperature of the skin becomes constant (Table 7.6)

<table>
<thead>
<tr>
<th>Week/Casting</th>
<th>Mean (°C)</th>
<th>Std</th>
<th>95% Confidence Interval Lower Bound</th>
<th>95% Confidence Interval Upper Bound</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Baseline)</td>
<td>31.7</td>
<td>1.26</td>
<td>31.236</td>
<td>32.166</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>31.08</td>
<td>1.11</td>
<td>30.624</td>
<td>31.553</td>
<td>0.59</td>
</tr>
<tr>
<td>3</td>
<td>31.17</td>
<td>0.943</td>
<td>30.707</td>
<td>31.637</td>
<td>0.10</td>
</tr>
<tr>
<td>4</td>
<td>31.82</td>
<td>0.71</td>
<td>31.362</td>
<td>32.291</td>
<td>0.69</td>
</tr>
<tr>
<td>5</td>
<td>31.27</td>
<td>2.93</td>
<td>30.734</td>
<td>31.808</td>
<td>0.21</td>
</tr>
<tr>
<td>6</td>
<td>31.90</td>
<td>1.27</td>
<td>31.365</td>
<td>32.439</td>
<td>0.56</td>
</tr>
</tbody>
</table>

Table 7.6 Thermal changes in skin of medial side of clubfoot
7.7.3.5 Thermal changes in skin of plantar side of foot

As shown in Table 7.7, a high mean value of the skin temperature can be observed for the plantar side of the foot on the 5th week (M=32.59°C; SD=1.62, 95% CI: 32.17 – 33.01, p=0.00). In addition, there is no difference between pre-intervention and the 6th week (M=31.28, SD=1.12, 95% CI: 30.86-31.70, p=0.68). However, the 4th (M=31.98°C, SD=0.84,
95% CI: 31.61-32.34, p=0.02) and 5th weeks (p=0.00) had significant temperature changes after casting intervention. The changes in the skin temperature between the pre and post casting weeks are plotted for Subject 1; see Figures 7.20 and 7.21. The estimated marginal means of the skin temperature of the plantar side of the foot for both participants show that the temperature is reduced after cavus correction at the 1st casting. During the following castings to simultaneously correct the forefoot abduction and varus, the skin temperature was slightly increased at the 4th 5th and 6th weeks (Table 7.7). On the other hand, a high skin temperature was found at the 5th week in comparison to the other castings (Figure 7.21).

<table>
<thead>
<tr>
<th>Week/Casting</th>
<th>Mean (°C)</th>
<th>Std</th>
<th>95% Confidence Interval Lower Bound</th>
<th>95% Confidence Interval Upper Bound</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Baseline)</td>
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<td>1.27</td>
<td>31.00</td>
<td>31.73</td>
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<tr>
<td>2</td>
<td>31.12</td>
<td>1.22</td>
<td>30.75</td>
<td>31.48</td>
<td>0.20</td>
</tr>
<tr>
<td>3</td>
<td>31.08</td>
<td>0.86</td>
<td>30.71</td>
<td>31.44</td>
<td>0.20</td>
</tr>
<tr>
<td>4</td>
<td>31.98</td>
<td>0.84</td>
<td>31.61</td>
<td>32.34</td>
<td>0.02</td>
</tr>
<tr>
<td>5</td>
<td>32.59</td>
<td>1.62</td>
<td>32.17</td>
<td>33.01</td>
<td>0.00</td>
</tr>
<tr>
<td>6</td>
<td>31.28</td>
<td>1.12</td>
<td>30.86</td>
<td>31.70</td>
<td>0.68</td>
</tr>
</tbody>
</table>

Table 7.7 Descriptive statistics of mean temperature of plantar side of foot
7.8 Role of infrared thermography evaluation for clubfoot

Recently, infrared thermography evaluation is being used as a diagnostic tool to assess thermophysiological changes related to musculoskeletal disorders, such as sports injuries (Bruckner & Khan, 2006), muscle spasms and injuries, soft tissue rheumatism (Ring & Ammer, 2012; Fischer & Chang, 1986), juvenile idiopathic arthritis (Lerkvaleekul et al., ...)
scoliosis (Kwok et al., 2017), osteoarthritis (Varju, Pieper, Renner & Kraus, 2004), and traumatic injuries (Flørenes, Bere, Nordsletten, Heir, & Bahr, 2009). Infrared thermography is also used for evaluating the progress of manual therapy and thermophysiological changes afterwards (Wu, Yu, Chuang, Huang, Chen & Chen, 2009). In clubfoot, infrared thermography can be used as an additional tool to assess thermophysiological changes after casting, manipulation, and bracing are carried out in the Ponseti method. An understanding of the temperature changes in the skin of the clubfoot during the period of casting is useful for avoiding complications such as infections, necrosis and other musculoskeletal deformations, and contributes to progressing the treatment. For example, a study by Chotigavanichaya, Eamsobhana, Ariyawatkul, Saelim and Kaewpornsawan (2016) reported that 5.48% of the children experience skin irritation during serial casting. Another study reported that two children with clubfoot experienced pain and tenderness, and one had Achilles tendon tenotomy. These could be avoided with the use of infrared thermography. In our experience in clinical visit, there were few cases observed with infections after the casting (Figure 7.22). There are a number of studies reported that infrared imaging could be used to diagnosis the musculoskeletal and neurological problems. For example, the inflammation, skin irritation or infections on diabetic feet could be diagnosed by monitoring the skin temperature with the use infrared imaging (van Netten, Prijs, Baal, Heijden & Bus, 2014).

Infrared thermography uses portable, non-radiative and noninvasive equipment. Therefore, the technique can be used in both rural and hospital settings, and the infrared images are useful for examining the thermophysiological changes after casting and manipulation, detecting complications as well as understanding the physiological changes of the clubfoot. In addition, the changes in the physiology of the clubfoot during casting and bracing can be observed and monitored, especially pressure induced swelling, infection or ulceration, and
progress of the treatment. An in-depth understanding of the thermal distribution in the skin of
the clubfoot before and after casting is therefore useful for increasing the success of
intervention, and to reduce complications and rate of relapse due to improper bracing and
casting. In this study, the samples used for analysis is very less. A research with large sample
size can be useful to develop the thermophysiological model and temperature distribution of
the clubfoot to find out the progress of the treatment followed by casting intervention

![Image](image_url)

A. Pressure sores after casting  
B. Casting removed by caregiver

Figure 7.22 Complications of improper casting - pressure sores and infection in clubfoot

7.9 Summary

In this chapter, the mean temperature changes of the clubfoot before and after casting are
examined and the thermophysiological changes of the clubfoot after casting are observed.
The process of obtaining ethics approval, method of positioning the child for imaging,
experimental process and data collection procedures, cleaning of noisy images, algorithm for
analyzing thermal images, statistical methods for analysis of infrared images and the role of
thermography as an evaluation method for clubfoot have been discussed. In the next chapter,
the advantages of 3D measurements and a thermophysiological study of the clubfoot, and
their strengths and limitations will be discussed in detail, along with recommendations for future work.
CHAPTER 8 CONCLUSIONS AND SUGGESTIONS FOR FUTURE RESEARCH WORK

8.1 Introduction

This research work has developed a new and objective 3D assessment method (3DAMC) to quantify the severity of clubfoot. Details on the thermophysiological changes of the clubfoot after serial weekly castings carried out with the use of Ponseti techniques have also been elaborated. To achieve both objective measurement methods, a number of steps are followed and the details are provided in the following sections of this chapter. The application of 3D technology in the medical field is becoming more popular in the development of medical devices such as orthotics and prostheses. The literature review study found that general standardized assessment scale for clubfoot is still lacking. To the best of the author’s knowledge, this is the first study that uses an inexpensive form of 3D technology along with thermography to measure and quantify the severity of clubfoot deformity. Generally, the Kinect XBOX is used for playing video games, but with the development of advanced computer software technology, the Kinect XBOX is now adapted as a scanner to create 3D models of the human body including 3D total body scans, as well as 3D hand and foot scans. Sometimes, the Kinect is used in rehabilitation training especially stroke rehabilitation. In this study, the Kinect XBOX is adopted as a 3D scanner to develop a 3D model of the clubfoot. From the 3D modeling of the clubfoot and with the advanced development of computer technology, this study has established a new objective assessment method for clubfoot. The method can be useful for quantifying the severity of clubfoot, predict relapses, and monitor the treatment progress. However, the reliability and validity of this method need to be verified. The outcomes and achievement of the research work are discussed in the following sections.
8.2 Three-dimensional modelling of clubfoot and development of 3D assessment method

In this research work, a new assessment model is developed and proposed by using a low-cost scanner based on 3D technology. Standard 3D acquisition protocols are designed and implemented to collect data on the clubfoot. The collected data are then processed and assessed. The findings lead to recommendations for future work. A number of steps have been carried out to acquire the clubfoot model including ethics approval, subject recruitment, and 3D image processing of the acquired scanned images to obtain the 3D model of the clubfoot. Three-dimensional modeling of the clubfoot has been performed on 4 sample: one pre-intervention (severe clubfoot) and one post intervention (corrected clubfoot) scans are collected from a child with a unilateral clubfoot, as well as rubber models of severe and partially corrected clubfoot. In addition, one normal 3D foot was collected to compare the difference between normal and clubfoot 3D parameters. The commercially available Artec 9 studio software is used to process the collected 3D scanned images and develop 3D modelling of the surface of the clubfoot. One normal foot and four 3D models of the surface of the clubfoot are consequently developed in this study. Then, CATIA 5 software is used to examine the cross section of the 3D clubfoot. From the cross sections, five clinical parameters (angles) are established: Center of the cross sections angle, maximum lateral border cross section angle, maximum medial border cross section angle, maximum dorsal side cross section angle, maximum planter side cross section angle) were established as discussed in the chapter 3. These five parameters were subdivided into 3 cross sections angle such as Ankle-Heel-Midfoot-Area cross section angle (AHMA Angle), Heel-midfoot-metatarsal phalangeal joint area (HMMA), Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area (MMPA) center of cross section angle, Lateral border of Ankle-Heel-Midfoot-Area cross section angle (LBAHMA Angle), Lateral border of Heel-midfoot-metatarsal phalangeal joint area (LBHMMMA), Lateral border of Midfoot- metatarsal
phalangeal joint -proximal phalangeal joint area (LBMMPA) of cross section angle, Medial border of Ankle-Heel-Midfoot-Area cross section angle (MBAHMA Angle), Medial border of Heel-midfoot-metatarsal phalangeal joint area (Medial border of MBHMMA), Medial border of Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area (MBMMPA) of cross section angle, Dorsal side of Ankle-Heel-Midfoot-Area cross section angle (DS-AHMA Angle), Dorsal side of Heel-midfoot-metatarsal phalangeal joint area (DS-HMMA), Dorsal side of Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area (DS MMPA) of cross section angle, Plantar side of Ankle-Heel-Midfoot-Area cross section angle (PSAHMA Angle), Plantar side Heel-midfoot-metatarsal phalangeal joint area (PSHMMA), Plantar side Midfoot- metatarsal phalangeal joint -proximal phalangeal joint area (PSMMPA) of cross section angle.

Based on this new 3D measurement method, the baseline of a severe clubfoot and at the 6th week of casting (before the casting is performed) are compared and it is found that there is a difference between pre and post intervention, which validates the method for quantifying the severity of clubfoot deformities such as cavus, adductus, varus, and equinus. According to the observations made, the AHMA Angle is useful for identifying varus deformity, and the HMMA angle to predict forefoot abduction, and the relationship of the hindfoot with the forefoot. However, there is little difference in some of the angles especially in the toe areas. For example, there is very little difference between the pre and post intervention carried out on the clubfoot on the center of the angle of the cross section of the MMPA. The angle of the cross section at the LBHMMA is reduced in the evaluation at post casting which indicates that the forefoot and midfoot deformities of the clubfoot have been reduced. For instance, the DS-AHMA Angle is found to have increased from 147.1° to 213.2°, which confirms that the forefoot, midfoot and hindfoot show improvement in alignment. This larger DS-AHMA Angle means that the heel is moving in an upwards direction and there is more dorsiflexion or range of motion at the ankle. Likewise, the PSAHMA Angle can be used to assess the
equinus deformity of the clubfoot. The 3DAMC can be therefore used to measure all of the parts of the clubfoot for objective measurements. The proposed 3DAMC has been therefore designed and implemented, and used to assess the severity of the clubfoot deformity prior and after casting. However, one of the limitations of this study is a very small sample size. Therefore, the study results cannot be generalized and a correlation analysis with existing clubfoot grading systems cannot be carried out. In terms of capturing 3D images by using Kinect, the task requires a well-trained person to capture the images, process and analyze the 3D images, and quantify the severity of the clubfoot.

In this study, the hindfoot, midfoot, and forefoot measurements are used to predict the four components of clubfoot deformity. This measurement scale can also be used to predict information separately for all components of the foot. One of the limitations of this low cost 3D measurement system is that it does not allow the measurement of soft tissue abnormalities. Another difficulty of 3D scanning by using the xBox Kinect is acquiring clear 3D images of the foot. If the scanning is carried out too far or too close to the feet, this will create distorted images. Three dimensional scans can be obtained of adult feet in 30-60 seconds. However, obtaining 3D images from a baby is a very difficult process as she/he moves his/her feet very frequently. Sometimes, scanning had to be carried out two or three times in order to obtain noise-free 3D clubfoot images.

The findings of this 3DAMC provide a platform for the development of a 3D assessment method for quantifying the severity of clubfoot and could initiate further research that can carry out objective assessments with an automatic method. Therefore, this study recommends that further research work needs to be carried out with a larger sample size to validate the method. In addition, the angles obtained by the 3DAMC need to be compared with those of other clubfoot assessment methods.
8.3 Infrared thermography evaluation of clubfoot

In Chapter 7, an IR thermography evaluation was introduced to evaluate the skin temperature distribution changes in the clubfoot before and after casting, and thermal images were taken from five regions of the foot: the medial, dorsal, lateral, and plantar sides, and the heel of the foot. Noise was removed from the collected images and then, an average of 10 cut off temperatures was taken from each side of the thermal images of the clubfoot by using MATLAB. It is found that there is a significant difference in the skin temperature between pre-and post-intervention. In addition, it is also subjectively (visually) observed that there are color changes in the IR images of the clubfoot. Red denotes a high temperature in the IR images, and blue, a low temperature. Based on the observed color, the skin temperature is found to be reduced in the forefoot and midfoot areas after 3rd and 4th weeks. Therefore, this study has established a standard reference evaluation for analyzing the thermal distribution on the clubfoot in the different anatomical regions of the foot.

Several studies have reported that skin temperature changes can be measured in the following musculoskeletal conditions: pain, swelling, muscle contractures or spasms, and muscular or other types of soft tissue injuries (Schmitt & Guillot, 1984; Ring and Ammer, 2012). In clubfoot deformity, the contractures of muscle, tendon and tendon sheaths, ligaments, joint capsules and other soft tissue contractures are found in the ankle and talocalcaneonavicular joint locations, especially posterior, medial plantar, subtalar and plantar side contractures (Anand and Sala, 2008). Sometimes, there is a reduced temperature detected by the palmar side of the thumb after manipulation of the cervical regions (Sterling et al., 2001). Likewise, the Ponseti method involves different techniques such as manipulation, casting, and Achilles tenotomy in the clubfoot treatment phase and bracing techniques in the maintenance phase of corrected clubfoot (Anand and Sala, 2008). There is the possibility of temperature changes in the clubfoot after manipulation, casting, Achilles tenotomy, or bracing. In addition, some
studies have reported that the complications of the Ponseti method: forefoot and toes swelling, hyper abducted position of the midfoot or rocker-bottom foot, and casting slippage (Ponseti et al., 2006), pain, infection, and tenderness in the foot after tenotomy procedures (Hallaj-Moghaddam et al., 2015), pseudo-aneurysms (Burghardt et al., 2008), erythema and mild swelling (Burghardt et al., 2008; Morcuende et al. 2004), Phlebostatic Syndrome, talar head side sore, and heel side sore due to D-B (Pavone et al. 2013). These above mentioned complications occurs due to the pressure of casting, incorrect applications or slipped casts, improper fit or uncomfortable of foot abduction bracing. These complications can be monitored or detected by the evaluation of thermal changes on the foot. For instance, the skin temperature will be high in the inflammatory and injured conditions (Hildebrandt et al., 2010). Therefore, an in-depth understanding of temperature distribution for clubfoot casting intervention is needed in the assessment of clubfoot to avoid complications such as pressure ulcers, swelling, pressure sores and related complications and relapses, and increase the success rate of intervention. This research study shows that IR thermography evaluation can be adopted as an additional diagnostic tool to observe the thermophysiological changes of the clubfoot.

8.4 Three-dimensional analysis of clubfoot based on CT scanning

In Chapter 5, a new 3D analysis (objective assessment) method for analyzing clubfoot deformity was developed from 2D images of CT scans. The method can be used to quantify the relative position of the foot bones of the clubfoot. To develop the 3D objective assessment method, 3D modelling of the bones of a severe clubfoot was carried out by using MATLAB. In the first step, a 3D model of the bones of a severe clubfoot was created in the STL format. Following that, the MATLAB program was also used to automatically execute functions that calculate the angle of each bone of the foot. The novel method provides a platform for developing a 3D model of the bones from 2D images obtained through CT, and
quantify the severity, align the foot bones, and show the relationship between the foot bones. This new way of calculating the angles between each bone of the foot is useful for determining the severity and structural alignment of the individual bones, and observing the relative changes in position between the bones after casting. Furthermore, the method provides a new way to create a 3D model of the bones of a severe clubfoot from 2D slices. In this study, the relative position of the foot bones is analyzed only from the CT images of the severe clubfoot. Further research would therefore be useful for comparing the relative orientation of the foot bones between a normal foot and a clubfoot as well as between castings.

8.5 A systematic review on Ponseti method intervention under two years of age

In Chapter 3, a systematic study was carried out to determine the effectiveness of the Ponseti method as a form of intervention for those less than two years of age with clubfoot. Initially, the Ponseti method was proposed for children with clubfoot less than two years of age. Nowadays, this method is extended to treat children with clubfoot who are over the age of two years but generally, Ponseti practitioners recommend that earlier treatment is crucial for successful outcomes. Although conservative treatment methods are considered to be effective for correcting the clubfoot, relapses are not uncommon. In addition, very few have conducted systematic studies to determine the effectiveness of clubfoot intervention. Therefore, a literature search was performed between, 2000 to 2015, from the following databases: Medline, Cumulative Index to Nursing and Allied Health Literature (CINHAL), PubMed, and Scopus to review. The articles were only published in English, and using Ponseti method for children with clubfoot with less than two years were considered for this systematic literature search. The results of literature search found that 1095 articles from four electronic databases, and finally twelve articles were included in this review based on the inclusion and exclusion criteria. This research study found that treating clubfoot children with Ponseti
method required very less casting, time, and had less relapse rate than other methods (Balasankar et al., 2017). On the other hand, this study found that nine articles reported about the relapses of clubfoot in out of 12 studies. The relapse pattern of the clubfoot and its causes were described in only few studies. Few studies reported that the following factor for causes of relapses of the clubfoot: poor socioeconomic status and bracing compliance. However, there was no detailed explanation in the previous studies such as duration of noncompliance braces, grading for bracing compliance or relapses pattern as well as exact causes for clubfoot relapse (Balasankar et al., 2017). Also, this study found that adherence of Ponseti treatment protocols by practitioners are varied by researchers to researchers. This study also had several limitations: a) this study had included only one group of review and did not compare with age group more than two years or Ponseti for neglected children with clubfoot and or children with clubfoot with other associated abnormalities (Balasankar et al., 2017). Therefore, this research study suggested for further research with more systematic and meta-analysis studies, Cochrane reviews studies on children with more than two years old, neglected clubfoot and or clubfoot with other associated abnormalities are needed to find out the adherence of Ponseti treatment protocol by practitioners.

8.6 Proposed study protocol on clubfoot for further research

In chapter 4, a protocol study with methodology was designed to develop a three-dimensional assessment method and thermographic evaluation of clubfoot. In this protocol study method, current issues of grading or assessment system for clubfoot were discussed and recommended the future research to fill the gap of current issues in the quantifying severities of the clubfoot. In addition, positioning a new born baby is very difficult for performing radiological evaluation, or with other imaging modalities and 3D scanning procedures. It is difficult to obtain the shape of the planter side of the foot for new born babies from the commercially available 3D scanners. Therefore, this study adapted a “V” shape bed to solve
this issue and the aim was achieved successfully and obtained the 3D shape of the foot in all sides (plantar, heel, dorsal, medial, and lateral side of foot) for developing clubfoot surface modelling.

In the new proposed method, the scanner (Kinetic) is relatively inexpensive, radiation free and easy to use in hospital or rural hospital settings. Also, it is portable and can be easily carried anywhere to carry out 3D scanning. The severity of clubfoot can be accurately assessed, and all four components of clubfoot deformities (cavus, adductus, varus, and equinus) can be predicted. In addition, the new method can be used for telemedicine practices due to the advanced technology. Three-dimensional images can be sent to doctors from rural areas, and doctors can visually assess the 3D images of the clubfoot and suggest the appropriate intervention. In addition, this study has also proposed an IR thermography method to evaluate clubfoot which can be used to assess the thermophysiological changes in the skin of the clubfoot between castings and bracings.

8.7 Limitations and Suggestions for future work

A 3D quantitative assessment of the clubfoot has been proposed and demonstrated in this study. Based on the work, much further research work can be carried out. The modelling of the clubfoot and the 3D assessment method, and IR thermography assessment are discussed in Chapters 4, 6, and 7 respectively. There are some limitations in this research study, such as sample size and methodological issues. In Chapters 6 and 7, the sample size is very small for comparing the differences between pre-and post-intervention for both the 3DAMC and IR thermography evaluation of the clubfoot. Initially, the plan for this study was to recruit 20 subjects from the Children’s Hospital at Westmead in Sydney, Australia. However, the ethics approval process in Australia took much longer than anticipated and so there was not enough time to collect a larger sample of data for this study. Therefore, this study developed a 3D
based clubfoot modelling and 3D clubfoot assessment system from a small sample size of clubfoot. In the future, more work is needed to apply the system to a larger sample size to establish the reliability and validity of this 3D clubfoot assessment system and a comparison with other existing grading systems for clubfoot deformity. Therefore, to validate the 3DAMC, further research work is suggested with a larger sample size.

In this study, only the 1st and 6th weeks of casting are compared by using the 3D evaluation system. To determine the severity of the clubfoot, 3D cross section angles should be collected at the weekly casting, bracing and follow-up sessions. Also, the research work can be carried out with normal feet for comparison purposes, establish the reliability and validity, and correlate the system with other assessment systems for clubfoot deformity.

A number of imaging technologies have been proposed to improve the assessment of clubfoot deformities such as MRI and CT. However, these procedures are time consuming and expensive, and involve other ethical issues with newborn babies. On the other hand, 3D surface imaging is cost effective, portable and easy to use in all types of clinical settings. Another advantage of 3D measurement is that it can be done automatically by using computer aided technology. In addition, foot measurements from 3D scanning could be less human errors than manual measurements (Taha et al., 2014)

There are number of studies that have reported on clubfoot relapse, which is about 10-30% of the cases, which occurs due to non-compliance with bracing (Chu & Lehman, 2012; Masrouha & Morcuende, 2012; Morcuende et al., 2004). Therefore, the accuracy of the cross section angles measured with a 3D system could be useful in evaluating, designing, and supporting bracing compliance in children with clubfoot. However, the scope of this study does not include the evaluation of accuracy of the measurement scale of clubfoot before and after the bracing schedule. In addition, the child with clubfoot is referred for tenotomy procedures to correct their equinus deformity. However, this study could not collect the 3D
measurements after the equinus correction of the clubfoot due to time limitations and practical difficulties in the hospital. Therefore, the future study should be carried out with large sample size with better statistical analysis for 3D measurement of dorsal and plantar cross-section angles to establish the reliability and validity. It could be helpful for researchers to understand in-depth understanding to determine the necessity of tenotomy. These new novel measurement methods could be more supportive to existing imaging assessment methods and further research can be done on cross sectional angles along with soft tissue abnormalities especially in muscle and bones in MRI imaging methods to find out the correlation of this assessment method.

The method for the IR thermography evaluation of the clubfoot can also be done during the maintenance phase of the Ponseti technique. According to the literature review, noncompliance with casting is one of the reasons for clubfoot relapses. Therefore, IR images can be used as an additional diagnostic tool if there are any abnormalities in the skin of the foot to avoid complications and improve bracing compliance. Also, IR image based automatic classification can be used to classify the severity, and also applied as a telemedicine technique. The same principle, a machine learning approach, can be applied to develop an automatic classification system based on the Kinect 3D images of the clubfoot. As discussed earlier, this is pioneering work on 3D based objective measurements of clubfoot deformity and other researchers may find it helpful to develop a quantitative measurement method to further facilitate the success of clubfoot intervention.
STANDARD CONSENT FORM

Developing a three-dimensional (3D) assessment method for clubfoot

**Title**
Developing a three-dimensional (3D) assessment method for clubfoot

**Short Title**
3D assessment for clubfoot

**HREC Number**
HREC/16/SCHN/163

**Project Sponsor**
University of Technology Sydney & The Hong Kong Polytechnic University

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I have read and understand the Information Sheet, and give my consent for my child to participate in
this research study, which has been explained to me by Ms Alison Chivers, Physiotherapist, The
Children’s Hospital at Westmead, Sydney and or Balasankar Ganesan, PhD Student, University of
Technology Sydney, Australia.

________________________________________________________________________

I understand that I am free to withdraw from the study at any time and this decision will not
otherwise affect my child’s treatment at the Hospital.

NAME OF CHILD: _________________________________________ (Please print)

NAME OF PARENT OR GUARDIAN: ____________________________ (Please print)

SIGNATURE OF PARENT OR GUARDIAN: ______________________ Date: ______

NAME OF WITNESS: ________________________________________ (Please print)

SIGNATURE OF WITNESS: _________________________________ Date: ______

NAME OF INTERPRETER: ____________________________________ (Please print)

SIGNATURE OF INTERPRETER: ____________________________ Date: ______
Appendix B

Invitation Letter

Dear Sir/Madam,

You are invited to participate in the research study, —"Developing a three-dimensional (3D) assessment method for clubfoot”, conducted by the Department of Orthopaedics at The Children’s Hospital Westmead in conjunction with the Faculty of Engineering & IT, University of Technology Sydney, Australia.

Attached to this letter of invitation is a Participant Information Sheet about what you would be asked to do if you agree to participate in the study.

We will be happy to answer any questions you have about the study. You may contact the Principal Investigator Balasankar Ganesan at Balasankar.Ganesan@student.uts.edu.au or 0415417948 or any of the project team listed in the below email.

Participation in this project is voluntary and you can decide not to take part. You can also withdraw at any time and this will not affect your child’s regular treatment at the Hospital.

If you would like to participate in this study, please contact Balasankar Ganesan at Balasankar.Ganesan@student.uts.edu.au or 0415417948.

Project team information:

| Dr Paul Gibbons,  |
| Department Head, General Orthopaedics, Orthopaedic Surgeon, The Children's Hospital at Westmead, Sydney |
| Email: paul.gibbons@sydney.edu.au |

| Ms Alison Chivers,  |
| Physiotherapist, The Children’s Hospital at Westmead, Sydney |
| Email: alison.chivers@health.nsw.gov.au |

| Dr. Luximon Ameersing  |
| Associate Professor of Design, The Hong Kong Polytechnic University |
| Hung Hom, Hong Kong |
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| Associate Professor, Faculty of Engineering and IT, (CHT - Centre for Health Technologies), University of Technology Sydney, Australia. |
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| Phone: +61 2 9514 7939 |

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| PhD Student, (Occupational Therapist), Faculty of Engineering and IT, University of Technology Sydney, Australia. |
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Thank you for your consideration.
APPENDIX - C

RESEARCH ARTICLE

Ponseti method in the management of clubfoot under 2 years of age: A systematic review

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Abstract

Background

Congenital talipes equinovarus (CTEV), also known as clubfoot, is common congenital orthopedic foot deformity in children characterized by four components of foot deformities: hindfoot equinus, hindfoot varus, midfoot cavus, and forefoot adduction. Although a number of conservative and surgical methods have been proposed to correct the clubfoot deformity, the relapses of the clubfoot are not uncommon. Several previous literatures discussed about the technical details of Ponseti method, adherence of Ponseti protocol among walking age or older children. However there is a necessity to investigate the relapse pattern, compliance of bracing, number of casts used in treatment and the percentages of surgical referral under two years of age for clear understanding and better practice to achieve successful outcome without or reduce relapse. Therefore this study aims to review the current evidence of Ponseti method (manipulation, casting, percutaneous Achilles tenotomy, and bracing) in the management of clubfoot under two years of age.

Materials and methods

Articles were searched from 2000 to 2015, in the following databases to identify the effectiveness of Ponseti method treatment for clubfoot: Medline, Cumulative Index to Nursing and Allied Health Literature (CINHAL), PubMed, and Scopus. The database searches were limited to articles published in English, and articles were focused on the effectiveness of Ponseti method on children with less than 2 years of age.

Results

Of the outcome of 1095 articles from four electronic databases, twelve articles were included in the review. Pirani scoring system, Dimegio scoring system, measuring the range of motion and rate of relapses were used as outcome measures.
Conclusions
In conclusion, all reviewed, 12 articles reported that Ponseti method is a very effective method to correct the clubfoot deformities. However, we noticed that relapses occur in nine studies, which is due to the non-adherence of bracing regime and other factors such as low income and social economic status.

Introduction
Congenital talipes equinovarus (CTEV) or clubfoot is one of the most common pediatric foot deformity occurs at 1 in 1000 live births [1, 2]. It consists of four components: Ankle equinus, hindfoot varus, forefoot adductus, and midfoot cavus [3–6]. Although, there are a number of conservative or non-conservative treatments have been used to correct the clubfoot, it is still challenging to treat the most severe cases of clubfoot. For the last 150 years, the treatment methods used for clubfoot are still controversial [7]. Because, the extensive surgical procedures (repeated soft tissue releases) on the clubfoot lead to induce some complications such as stiffness of foot, arthritic problems and poor quality of life [8]. After that, a number of conservative methods are proposed to correct the clubfoot deformity with the following techniques such as different methods of manipulations, orthosis or splinting or bracing, casting, and strapping [9–12]. Historically, conservative management was introduced by Hippocrates in around 400 BC [13, 14]. Later, in 1939, Kite introduced his method [15], referred as kite method, which is including manipulation and casting technique, but the success rate of this method was poor [2, 11, 16]. Subsequently, in 1963, Ponseti developed a conservative method, called as Ponseti method, with manipulation, casting, Achilles tenotomy and bracing, and it takes about four to five weeks to achieve the full correction of all four components of the clubfoot deformity [17, 18]. In this method, Achilles tenotomy is used to release the equinus deformity and bracing for maintaining the corrected clubfoot [19, 20], and it helps to obtain the plantigrade, functional, pain-free foot [21]. Although orthopedic surgeons agreed that initial treatment for clubfoot should be a conservative method to correct the clubfoot successfully [17, 22–27], the relapses, partial correction of clubfoot- rocker bottom foot is still not avoidable [28, 29]. Based on the literature search, in the past five decades, a number of studies have reviewed and published which include the history of development of conservative method and its management in the clubfoot [30, 31], controversies in the clubfoot management [32], current updates of clubfoot treatment and effectiveness of Ponseti method [1, 33, 34], different types of conservative methods (Ponseti techniques, Kite’s method, and French physical therapy method) and results of Ponseti methods [35], using sonography for the evaluation of clubfoot treatment outcome [36]. For a period of century, to the best of our knowledge, there were only 5 systematic review articles published on the clubfoot with related Ponseti management [37–41] and one as Cochrane review [42], in which Smythe, Kuper (41), study discussed about the birth prevalence of clubfoot in the group of low- and middle-income countries. Although other studies reviewed the relapses, bracing protocol, and percutaneous tenotomy, there were no studies systematically reviewed specifically in a particular age population especially children under the age of two years. Despite several studies reported that initial presentation, Ponseti techniques provide more successful results [17, 43, 44], the clubfoot relapses or recurrences of the clubfoot can be still seen in the children with less than 2 years of age followed by the Ponseti method of treatment. Adherence of Ponseti and his colleagues protocol is necessary to achieve full successful clubfoot treatment without relapses or any deformities. Several literatures review articles
reported the technical details and adherence of Ponseti protocol among walking age or older children. Initially, Ponseti developed his method and its protocol for children with clubfoot below the age of two years. However, most of the clubfoot based review studies focused either the group of children with walking age or over the age of 10 years [45], and hence the future studies should be focused with number of casts, percentages of surgical procedures, frequency and management of clubfoot relapses [46]. Therefore, this systematic review study aims to investigate the following details in the children with less than 2 years treated with Ponseti method: A) to review how the Ponseti treatment technical regime strictly followed in their study to achieve the initial correction B) to find the outcome of the study, including success rate, number of casts and percentages of surgical recommendations, and to review the relapses and relapse pattern of the clubfoot causative factors for relapses.

**Materials and methods**

**Search strategy**

A systematic literature search was performed by three authors (BG, GRN, and SB) for articles published between from January 2000 to September 2015 in the following electronic databases: Medline, Cumulative Index to Nursing and Allied Health Literature (CINHAL), PubMed, Scopus for relevant articles to identify the Ponseti method of treatment to treat clubfoot. The process of literature search and articles selected for this study is illustrated in Fig. 1. The flow chart summarizes the method of the literature search, inclusion and exclusion criteria for selecting articles, method of extraction of the articles, outcome of the articles, and results. The following key words were used in the electronic databases: “Clubfoot or CTEV or congenital talipes equinovarus”, “Ponseti method or Ponseti treatment”, “clubfoot treatment or clubfoot management” (“S1 File”). The articles published in the English language were only considered for this review. In addition, we followed the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) in this systematic review study (“S2 File”).

**Study selection**

The title and abstract of the Ponseti method for clubfoot related articles were reviewed and extracted by investigators (BG, AL, AA, and GRN) based on the inclusion criteria and exclusion criteria of this study. The following information was examined in the abstract and title for selecting the articles: **Inclusion criteria:** Articles were selected based on the following inclusion criteria: Studies with using the Ponseti method as an intervention for clubfoot deformities, articles restricted into the language of English with full text, clubfoot children with less than 2 years. According to the Ponseti classification, children with less than 2 years are considered as untreated clubfoot [47, 48]. **Exclusion criteria:** Articles published in other languages, neglected clubfoot, associated with other problems, survey studies, short-term outcome, surgical management of clubfoot and Ponseti method of intervention for testing the effectiveness of different casting materials were excluded in this systematic review.

**Data extraction**

Two authors extracted data on characteristics of clubfoot patients from the selected articles and recorded into the data extraction sheet, followed by the extracted data was reviewed by two authors for accuracy. The following characteristics of clubfoot patients and selected articles were included into the data extraction sheet: study design, sample size and number of children, number of feet, types of intervention, intervention groups, gender, affected side of the clubfoot (bilateral & unilateral clubfoot), age at initial casting, number of casting, schedule of
bracing protocol, details of PAT, outcome measurement scale, results (mean), and the details of relapses rate and follow-up.

Results

Outcome of study articles

In the initial literature search, from January 2000 to November 2015, 1095 articles were identified from the four databases: Medline (n = 260), Cumulative Index to Nursing and Allied Health Literature (CINHAL) (n = 80), PubMed (n = 346), Scopus (n = 408). In the first stages of the screening, 1050 articles were excluded through screening the title and abstract based on inclusion and exclusion criteria and we included 45 articles for further screening. At the second stages of screening...
process, we excluded 33 articles due to the following main reasons: full text was not available, full text articles was not in English, conference proceedings, duplication of articles, children over than 2 years of age, neglected clubfoot, clubfoot associated with other problems, survey studies, short-term outcome, other treatments such as operative treatment, Ponseti method with different casting materials, different purpose of the studies other than finding effectiveness of Ponseti method among children with clubfoot. As a result, 12 studies were satisfied our selection criteria for the systematic review study after application of all inclusion and exclusion criteria in 45 articles [49–60]. Among the twelve studies, there were four prospective studies [49–52], one multicenter clinical study [53], one consecutive clinical series [54], two randomized controlled study [55, 56], one cohort study [57] and other three clinical studies [58–60].

Patient characteristics
The summary of all articles is described in Table 1. There is a total of 852 clubfoot children with 1206 clubfoot were included in this review. In the 12 studies, a total of 293 bilateral clubfoot children are identified [49, 50, 52, 53, 55, 56, 58–60]. Few studies reported that the affected side of the foot is either right side or left side of the foot, [50, 51, 55, 60]. One of the study [54] did not mention the type of clubfoot (affected side). The number of castings, duration of treatment, follow-up is varied from one study to another study. The average initial presentation of casting would determine the effectiveness of the treatment. Therefore, the clubfoot intervention should be started as early as possible [3]. In most of the studies, Ponseti method of treatment was started after immediate birth.

Discussion
In the selected twelve studies, most of the studies have compared the effectiveness of the Ponseti method with the Kite method. There are five studies used Kite method among the twelve selected studies [50, 55–57, 59]. One of the study used accelerated Ponseti method to compare the current existing method of intervention for the clubfoot deformity, and the results of this study stated that the accelerated Ponseti method is safe as a traditional Ponseti method of treatment for clubfoot intervention [49]. The Ponseti treatment regime included manipulation, serial casting, Achilles tendon tenotomy and Bracing—Foot abduction brace [7, 19, 20].

Casting techniques and numbers of casts
In this review, we assessed the number of castings used in the studies, and all of the selected 12 studies reported the number of casts used to achieve the full correction of clubfoot (35–46). Five studies [58, 55–57, 59] used Kite method techniques to compare with the Ponseti method in the correction of clubfoot. These studies reported that Ponseti method achieved the initial correction in shorter time and used fewer casts than the Kite method. The percentages of Ponseti method’s correction success rate was 96% (follow-up time- 36.2 months) and the Kite’s method full correction success rate was 74.3% at the time of an average of 35.1 months [59]; Another study by Sud et al. 2008, achieved 91.7% in Ponseti method (Average of 27.24 follow-up) and Kite method 67.7% at time of 24.8 months follow-up [50]. Although the achievement of correction rate was similar in each group (Ponseti-87% & Kite method-79%), the average of casting was less in Ponseti group (7 casts in Ponseti and 10 casts in Kite’s method) and the duration of treatment took only 10 weeks in the Ponseti method and 13 weeks for Kite method [55]. In Elghory and Abulsaad (49) study, an average of 4.88 ± 0.88 castings (4–7 casts) were used to achieve the full correction of the clubfoot for traditional Ponseti method group and the average of 5.16 ± 0.72 cast (4–7 casts) in the accelerated Ponseti group, in which 84.8% feet required less than 3 casts in both groups. Another study [59] reported that an average 4–12 casting was only used to get the full correction
<table>
<thead>
<tr>
<th>References</th>
<th>Study design/number of children/feet</th>
<th>Types of Intervention (Bilateral &amp; Unilateral clubfoot)</th>
<th>Side of clubfoot (Bilateral &amp; Unilateral clubfoot)</th>
<th>Age at Initial casting/Number of casting</th>
<th>Bracing protocol</th>
<th>PAT /Surgery/Outcome measurement/Results (mean)</th>
<th>Relapse/follow up (mean)</th>
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<tr>
<td>Elghoray &amp; Abulaaad, 2015</td>
<td>Prospective study/41 Children 46 CF</td>
<td>Traditional Ponseti method (20 Children/34 feet/B = 14; G = 6). Accelerated Ponseti method (21 children/32 feet/B = 12; G = 9). TFM: 14 children with BCF and 6 children with UCF. APM: 11 BCF and 10 UCF.</td>
<td>TFM Group: 10.7 ± 6.28 weeks. APM Group: 11.57 ± 6.9 weeks (from two to twenty six weeks). TFM: One casting per week (4.88 ± 0.88 casting for full correction). APM: Casting twice per week (5.16 ± 0.72 casting for full correction). Modified Denis-Browne orthosis (70 degrees of external rotation on affected foot and 40 degrees of external rotation on normal side). TFM: 91.2% (31 feet of 34) APM: 93.8% (30 feet of 32)</td>
<td>Pirani score: clubfoot with &lt; 4 of Pirani score was included. After the intervention, TFM: 5.17 ± 0.62 (range 4–6) to 0.49 ± 0.42 (0.0–1). APM: 5.13 ± 0.61 (range 4–6) to 0.52 ± 0.36 (0.0–1).</td>
<td>Pirani score: clubfoot with &lt; 4 of Pirani score was included. After the intervention, TFM: 5.17 ± 0.62 (range 4–6) to 0.49 ± 0.42 (0.0–1). APM: 5.13 ± 0.61 (range 4–6) to 0.52 ± 0.36 (0.0–1).</td>
<td>TFM: 14.7% (equinus, heel varus and/or forefoot adduction); APM: 15.6%</td>
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<td>Colburn &amp; Williams, 2003</td>
<td>34 children (B = 28, G = 6) (37 CF)</td>
<td>Ponseti method</td>
<td>BCF – 23 infants; UCF – 11 infants. Children with clubfoot were included from first day to 6 months. Average of 4.8 casting (ranges from 3–7). Average of 4.8 casting (from 3 to 14) for those previously treated with other treatments. Straight-last shoes with a foot abduction bar with 60 - 70° external rotation of the corrected foot 3-6 months. Then, 12 hrs/day until 2 years.</td>
<td>34 children (64 feet out of 57 feet) were corrected without PMR (95%). Serial casting. Manipulation. PAT: 36 feet (77%). Manipulation and casting: 28% (16 clubfoot) corrected with manipulation and casting only. 0% only was done by PMR.</td>
<td>Dimiego score was 11.2 average. Range from 7–15 for those who are not received any previous clubfoot treatment. The results of the average score was 11.2 (range: 7–17) in patient received some other treatments previously.</td>
<td>Relapses: 6 children. Required successful connection with manipulation, serial casting and straight-last shoe with foot abduction bar</td>
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<td>Mohammed et al. 2015</td>
<td>Prospective study/N = 86</td>
<td>Ponseti method (M = 69%, F = 31%)</td>
<td>Bilateral: 61.2%, Eighteen percentages LCF, and 21 percentages of the clubfoot-RCF. 5.7 castings (4 to 8 casting). One casting wk. Mean age: 8 days at the time of first casting. It ranges from (1–40 days). Average number of casting: 4–8. Full time Dennis-Browne splint protocol —6 months. Then, Part time Dennis-Browne splint protocol for 3 years.</td>
<td>PAT: Tenotomy was performed in 76 patients (89.4%). Successful results with plantigrade foot. The child started to walk at the mean age of 12th months. Complications: Pain, tenderness after tenotomy for 3 children, one patient had minor infection after tenotomy. BCF had lower outcome than UCF(2.1 ± 1.0 versus 0.63 ± 3.0)</td>
<td>Dimiego score: Baseline: 16 ± 3.4; after casting—16 ± 6.2.</td>
<td>Relapse rate was 27.1% (follow-up period: 5–72 months). Follow—up: Every 3-4 months/1-2 years. After that, 6-12 months follow-up was done.</td>
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<td>Pulak &amp; Swamy, 2015</td>
<td>Prospective study/N = 40/53 feet</td>
<td>Ponseti method</td>
<td>BCF: 14 Children; UCF: 25 children Initial presentation 6 weeks/36 cases. Average casts for full correction: 4.9. Average duration of casting = 7 wks in &gt; 85% of the patients. Some cases, it increased up to 10 weeks of casting.</td>
<td>Orthosis: 23hrs/first 3 months. After that, time only for 2–4 yrs. Tenotomy was done in 94.3% of the patients.</td>
<td>1. Pirani score. 2. Goniometry (Initial score): 48 / good results (90.6%). 3: Acceptable &amp; 2 child got unsuccessful correction.</td>
<td>19.5 months (6–12 months). 2 relapses</td>
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<tr>
<th>References</th>
<th>Study design/ number of children/feet</th>
<th>Types of Intervention/ groups/sex</th>
<th>Side of clubfoot (Bilateral &amp; unilateral clubfoot)</th>
<th>Age at initial casting/ Number of casting</th>
<th>Bracing protocol</th>
<th>PAT /Surgery/</th>
<th>Outcome measurement/ Results (mean)</th>
<th>Relapse/follow up period (Mean)</th>
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<tbody>
<tr>
<td>Salimani, 2012</td>
<td>N = 100/150 CF</td>
<td>Ponseti method: (N = 75); B: 38; G: 20 Kite’s Method: (N = 74); B: 28; G: 20</td>
<td>PMG: 20-BCF KMG: 24 BCF</td>
<td>after birth PMG: 2-90 KMG: 2-90. Since Birth/ Average casting: PMG—4 to 12 (7.1 ±1.6); KMG: 4 to 22 (11.34±6.3). Casting 7 to 10 days.</td>
<td>PMG: Dennis—Browne bar Dennis Browne bar splints with open toe tarsopronator shoes (70°) of external Rotation. Protocol: Full time—Until walking age. KMG: Full time right spirt, right time only spirt. For 4 years—open toe box shoes, straight medial border, lateral flaring of the sole, and reverse Thomas heels.</td>
<td>PAT</td>
<td>Pirani Score: PMG—5.32±0.8 Correction: Achieved 96% (73 Feet (96%)). KMG: Pirani score: ROM: 8.21°— dorsiflexion to 13.32°— plantar flexion.</td>
<td>Relapses: 10 feet (13.7%)/36.2 months in Ponseti group. First follow-up: Follow-up: Ponseti - 36.2 months ± SD 3.2; Final follow-up: No relapses. Kite group: 36.1 months ± SD 2.5 (33 to 38 months) and 100 feet.</td>
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<td>Morcuende et al. 2004</td>
<td>Consecutive case series (N = 157/256 CF)</td>
<td>Ponseti method: (N = 76); B: 107 (68%); G: 50</td>
<td>NA</td>
<td>188 (81%) &lt; 6 months. Lesser than 5 casting (80% of the patients). Full correction: 20 days (range: 14–24 days).</td>
<td>Foot-abduction brace: 2 to 3 months (full-time). Naiture and night for 3 to 4 years</td>
<td>Extensive corrective surgery—4 (2.5%). PAT: 86%</td>
<td>Walking: age of 13 months Complications: 12 patients (8%)— erythema, slight swelling on toes. ROM: Aorsi/Flexion posteriorotomy was 20° (Range 0–35 degrees).</td>
<td>Relapses: 17 (10%) / 26 months (6-8 years)</td>
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<td>References</td>
<td>Study design/ number of children/feet</td>
<td>Types of Intervention/ groups/ gender</td>
<td>Side of clubfoot (Bilateral &amp; unilateral clubfoot)</td>
<td>Age at Initial casting/ Number of casting</td>
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<td>Pavone et al. 2013</td>
<td>N = 82/114 CF  N = B: 56 (68.29%);</td>
<td>Ponseti method (N = 30);</td>
<td>BCF: 32 (39%), UCF: 50 (60.9%); RCF: 28 (33%) in the UCF and 22 had LCF</td>
<td>Age: 0-26 weeks. Initial casting: 14 days (3-31 days); 76 (92.68%) Patients: range 0-12 wks; 4 patients: range from 13-24 wks; 2 patients: 25-36 wks.</td>
<td>Denis Browne splint: 24/day for 3 months. Night time: 3 years.</td>
<td>PAT: 82.93% (68 patients) - 28 BCF, 40 UCF.</td>
<td>Pirani score: 5.66 points. Range 4.3 to 6 points.</td>
<td>Relapse: 2 (5 feet) patients (3.7%): one adductus and varus, one equinus, all deformities in one. Follow-up: 4 years (13-83 months)</td>
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<td>Rijal et al. 2010</td>
<td>N = 38/60 CF  N = Kite Method (N = 30)</td>
<td>Ponseti method (N = 30); Kite Method (N = 30)</td>
<td>BCF: 22 UCF:16</td>
<td>Less than 2 years of age</td>
<td>Abduction splint with shoes: 3 months: 23 hours/day; then, night time: 3-4 years. Walking: Custom made clubfoot shoes.</td>
<td>PAT: 89% (16 out of 30 patients).</td>
<td>Hindfoot, midfoot and total Pirani scores (1-10 weeks). Pirani score improved faster in 12 bilateral clubfeet (p=.05). BCF (12 Bilateral clubfoot). Hind foot score: more fastly in PMG (0.7) than KMG (1.31) at 10th weeks. Midfoot score: more fastly in PMG (0.5) than KMG (1.04) at 10th weeks. Total score: more fastly in PMG (1.2) than KMG (2.36) at 10th weeks. UCF (12 Patients): PMG had significant improvement at 8th week.</td>
<td>Weekly follow-up/10 weeks</td>
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<td>Sanghvi &amp; Mittal, 2009</td>
<td>Randomized study/ N = 42 /64 CF</td>
<td>Ponseti method (N = 21); B:13; G:8, 30 clubfeet Kite Method: N = 21; B:14; G:7 (34 clubfoot)</td>
<td>KMG: 13 BCF, RCF: 5, LCF: 3 PMG: 9 BCF, 6 RCF, 6 LCF</td>
<td>0-36 weeks. Number of casting: PMG: 10 wks; KMG:13 wks</td>
<td>KMG: full-time splinting. After walking age: night time only and daytime-shoes (4-6 years) with an open toe box, lateral fusing of the sole, straight medial border, and reverse Thomas heels shoes. PMG: open toe bankanator with D-B bar (70° of external rotation); UCF: 40° to 45° of external rotation of normal foot. Full time and then night time only and shoes for 4-5 years.</td>
<td>PMR: 3 Patients in KMG</td>
<td>Kite method: 79%; Ponseti method: 87%. ROM: 12 degrees of dorsiflexion at PMG and 6° at KMG.</td>
<td>Follow-up: 3 years. 3 Relapses in KMG. One bilateral relapses in PMG.</td>
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<tr>
<td>References</td>
<td>Study design/ number of children/feet</td>
<td>Types of Intervention/ gender</td>
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<td>Segev et al. 2005</td>
<td>Cohort study/ 72 infants</td>
<td>Ponseti method (N = 32); B: 20, G: 12; Traditional method (Modified Kite and Lovell technique); N = 40 (61 feet); B: 31, G: 9</td>
<td>PMG: 60% BCF and left are more involved. TMT: 21 BCF</td>
<td>Above knee casting. PMG: 96% patients were treated from the birth. One patient: 3 wks and another patient: 5 wks. TM: duration of casting: 4.0 months (Average)</td>
<td>PMG: Dennis Brown splint for 3 months/ 24hrs, then night time only until 2 years.</td>
<td>PAT: 47 CF in PMG (Average 2.4 age months); TM: 29 PMG and 6 RR.</td>
<td>Dimaggio-Bonahfere scoring. Before the treatment of PMG: 11.9 and after 3.3 (average). 94% achieved in PMG.</td>
<td>Follow-up: 54.9 months (44–68 months) in TM; PMG—29.2 months. 3 residual deformities, 44% residual deformity at TM</td>
</tr>
</tbody>
</table>

PMR, Posteromedial release; CF, clubfoot; TPM, Traditional Ponseti method; TM, Traditional method; PMG, Ponseti method group; KMG, Kite method group; UCF, Unilateral clubfoot; BCF, Bilateral clubfoot; RCF, Right side clubfoot; LCF, Left side clubfoot; ROM, Range of motion; wks, weeks; PAT, Percutaneous Achilles tenotomy.

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of clubfoot, but, in the Kite method took an average of 4–20 castings and also between the casting duration periods varied in their study (7 to 10 days per casting).

On the other hand, the accelerated group achieved full correction of clubfoot from 11 to 12 days (castings twice per week) and for the traditional Ponseti method group was 21–42 days. Also, the accelerated group achieved nearly same as a traditional Ponseti group in a short period of time [49]. However, in the accelerated Ponseti technique, the casting was performed two times a week. Previously, Morcuende et al. 2005 studies tried the accelerated Ponseti techniques with every 5 days casting instead of 7 days once, and Xu [61] studied with casting twice a week, and the results of both studies showed successful correction as same as traditional method and also the duration of the treatment period was less than the original method. Of these 12 selected studies, one study achieved the full clubfoot correction with less than 5 casts (average of 4.9 casts) in 75% of the cases [52]. Only one study described about the casting procedure time, and it took 5 to 9 minutes for each casting (Average 4–8 casting) and for Achilles tenotomy with last casting ranged from 6 to 11 minutes [51]. In Morcuende, Abbasi (18) study, the following steps of casting procedures were performed to maintain the correction of clubfoot: in the first step casting was performed from toe to lower knee and in the second step casting was performed from the knee to thigh area, and 90% of patients were treated with less than 5 casts. Among the selected studies, one of the study [59] stated that the casting treatment is considered as failure if not achieved full correction within a year, and these patients referred to surgery after obtaining the consent from the patient. In this study, Ponseti method was compared with Kite method, in which the Ponseti method took less casting ranged from 3–12 for achieving full correction of the clubfoot. At the same time, 3–23 casts were used in the Kite method. According to the Pavone, Testa (60) more casting is required if the initial deformity is severe or initial treatment is started after 15 weeks of birth. However, there is a still controversy in the impact of late presentation of treatment and outcome of the results. Some authors reported that late presentation of treatment does not affect the outcome of the results [54, 62–65]. At the same time, the study of Abdelgawad et al. stated that 6.6% failure rate of Ponseti treatment due to the late presentation of the treatment. But one of the selected studies for this review, Pavone, Testa (60) reported that there is no correlation between age of presentation and final outcome of range of motion of the feet even though taking more casts, and the clubfoot was corrected with the range of 5–10 casts in their study. Only two of the studies [56, 59] from this review conducted post casting checking such as margin of the cast, neurovascular assessments, as well as the patients were instructed to see other complications: swelling, discoloration of the skin of the toes and baby’s excessive crying. Out of 12 selected studies, only one study [53] treated the clubfoot children with two different types of casting materials, in which 78% clubfoot children were treated with semi-rigid fiberglass cast and 22% of them were plaster of Paris. However, the results of these casting materials are still controversial based on the report of [53]. In addition, the average of 7.2 casts (total of 162 feet) was used in this study to achieve full initial correction including the final cast after tenotomy. Only 3–3 casts were used for 4 children those had a mild foot deformity. Among 162 feet treated in this study, 15 feet (10 bilateral brace & 5 unilateral brace) were treated with recasting and also this study reported that those who are treated with unilateral brace had more casts than bilateral brace. At the same time, the corrected clubfoot should be maintained by foot abduction braces to prevent the relapses or recurrences of clubfoot [30, 64, 66–70].

**Bracing**

Foot abduction braces (FAB) of the Ponseti method protocol are essential to maintain the corrected clubfoot and to avoid the relapses. In these 12 studies, we noticed variations in the
bracing protocol schedule and it ranges from 2–6 months for full time or 23 hours, and then followed by 2–5 years in night time [49–50]. Several studies reported that braces need to wear for full time or 24 hours per day up to 2–3 months [51, 54, 60]. All these moreover, Haji-Moghaddam, Moradi (51) study reported that they used full time abduction brace up to 6 months. Three studies stated that full time abduction braces need to wear 23 hours per day up to 2–3 months [52, 56, 58]. Two of the authors from this review reported that the children (clubfoot) used the splint up to the walking age, and then worn the braces night time for up to four years [55, 59]. However, originally the Ponseti method suggested wearing the full time brace up to two to three months and thereafter at night time for up to 3–4 years. One study [53] used different types of braces and changed their brace type in the bracing protocol: 62% of children were used FAB, then 30% user changed into Mitchell from Markell, and 12% user changed into flexible custom-made unilateral above-the-knee brace from bilateral FAB, and 3% are changed into a softcast or scotchcast removable brace/cast. Moreover, we observed that a change in the position of correcting foot varies in the bracing regime. For example, one of the study used 70 degrees of external rotation of clubfoot [49]; another study positioned the feet in a 60–70 degrees of external rotation in their bracing protocol. Non-compliance brace causes the relapse of correcting clubfoot, which affects the success of the Ponseti treatment [71].

Relapses and its characteristics

Several studies reported that Ponseti method is a successful conservative method to correct the clubfoot deformity [57, 52, 73]. However, previous literatures reported that 10–30 percentages of the relapses are very common [24, 75]. In this review, of the 12 studies, we found that relapses in nine studies [49–52, 54, 57–60, 62]. The maximum of relapse rate was 27.1% [51] and the lowest relapse rate (two relapses) was observed in Pulak and Swamy [52] study. From the selected 12 articles, one of the study [51], stated that maximum relapses rate (27.1%) at the end of the follow-up (average of 5–72 months) period. Total of 76 patients (89.4%) underwent the tenotomy surgical procedures in this study. Few studies reported the relapse pattern of the clubfoot after the initial correction such as forefoot adductus, hindfoot varus, midfoot cavus and ankle equinus [49, 51, 57, 59]. For example, Pavone et al. [60] reported in their study about 3% of relapses rate, one foot was relapsed by adductus and varus relapse pattern, another foot was affected by equinus, and one foot was totally relapsed with all four components of clubfoot. These relapses occur due to non-compliance with Denis browne splint, and infrequently use of splint because of lack of education and socioeconomic status of parents of clubfoot children [50]. But, in few studies, clubfoot relapse pattern is not clearly described [53, 58]. We observed in Morcuende et al. study, 11% of the clubfoot children had relapses, and relapses are corrected by manipulation, re-casting, and tendoachilles tenotomy. However, 2.5% of the relapses patients were treated by tibialis tendon transfer and lengthening of Achilles tendon. In Elgohary and Abulsaid (49) study, 14.7% of clubfeet had relapsed due to non-compliance of brace, with 90% of relapses cases had initial high Pirani score (90%). At the same time, Dobbs et al. reported that relapses are not dependent on the initial severity of the clubfoot. Other studies, relapses: 6 cases [58], 27.1% [51], 21.7%[50], 27 feet [53], 13.2% [59], and 2 cases [52] were noticed in the selected articles for our review.

Relapsing factors

Ponseti practitioners recommended that clubfoot should be treated as early as possible after birth to avoid the relapses and to achieve the full correction of clubfoot [7,16, 26, 28, 59]. Especially, to avoid the recurrence or relapse pattern of the clubfoot, compliance of foot abduction braces is necessary in the Ponseti treatment [30, 54]. The relapses of clubfoot are evaluated by
either foot morphology or Dimelgio score or Pirani scoring system [72–75]. It can also be evaluated or classified as minor or major relapses based on how much necessity of surgical release requirement [67]. Approximately 78% of the clubfoot relapses occur due to the reason of non-compliance foot abduction braces, and 7% of relapses occur with compliance of foot abduction braces [72]. Non-compliance of foot abduction braces is having a tendency to induce the relapse of the patient [30, 54]. Relapses are not associated at age of presentation, numbers of casting, and previous history of unsuccessful treatment. It is observed that the noncompliance bracing is being the main issue for relapses for the clubfoot and bracing protocol was not strictly followed by caregivers or family members [70]. Although non adherence of bracing is the leading cause of relapse, number of researches suggested other different causative or risk factors for relapses of correcting clubfoot such as low educational level of parents, low income (< US $20,000), and Native American ethnicity [71]. In our selected review articles, Morcuende et al. study [54] states that noncompliance is 17 times greater than compliance of braces for occurrence of relapses and their study referred 2.5 patients (Children with non-compliance of FAB) for anterior tibial tendon transfer to the third cuneiform surgery to avoid additional relapses. Poor socio-economic status and lack of understanding causes relapses in two patients [60]. Three studies [52, 55–56] do not describe the causes of relapses in their studies. Three studies were only described the compliance of braces [58–60]. Some authors suggested that poor experience in casting techniques, improper tenotomy surgeries, ill-fitting of FAB as well as poor education and socioeconomic status of parents for the reason of recurrence [54, 66, 76], short term follow-up [57]. One selected article in our study reported that 13.7 percentages of relapses occurred in the first year of age in follow-up [59] and so that they are drawn a conclusion relapses is not related to age factor or severity of the foot [50, 59]. Of twelve study, only one study [51] was tried to analyze the relapsing related to different factors such as gender, age, age at first casting, clubfoot with other deformities, walking age, number of castings, initial severity score (Dimelgio score), tenotomy, and satisfaction. However, the brace compliance was 97 percentages but the relapse occurred in 27% of the patients and this study suggested that relapse rate might be due to noncompliance of braces, initial severity, below knee casting, and low education level of level of parent’s. Previous literatures have only been discussed about the relationship between the compliance of braces and relapses. According to the Morcuende et al. “Compliance” defined as the children not wearing the foot abduction orthosis for a period of 10 hours per day consider as compliance [54] and Dobbs et al. defined as “complete discontinuation of FAB” [30]. However, there were no studies described about the grade of compliance of braces in details in our selected studies except Setersdahl et al. study [53]. In our selected study for this review [53] graded the compliance of brace as Excellent: use the braces continually until the follow up (4 years of age) or at least 10 hours every day for night time regime; Good: use the braces continually until the follow up (2 years of age) or at least 6 to 8 hours every day for night time regime; Fair: If the braces used less than 2 years of age or less than 6 hours; Non-compliant: If the braces discounted before the age of one year. However, there is no studies described the any grade of compliance for relapses in our selected studies. Identification of relapse pattern, and adherence to the original protocol of the Ponseti method with understanding of detailed manipulation, casting, bracing is necessary to prevent the relapses [3, 19, 38].

Evaluation of treatment outcome and surgical recommendations

In the evaluation or outcome of the clubfoot treatment by Ponseti method, most of the studies, using Pirani scoring system or Dimelgio scoring system as outcome measurement scale for assessing the clubfoot deformity. In addition, these measurement scales are also helps to
predict whether the percutaneous Achilles tenotomy is needed or not to correct the equinus [72–76]. If the initial score of Pirani is greater than 5, then it should be corrected with Achilles tenotomy to correct the equinus but the score is less than 3, there is no requirement of this surgery [78]. On the other hand, Morcuende et al.[34], used initial correction of the clubfoot, the rate of extensive corrective surgery, and relapses rate as an outcome measures to evaluate the effectiveness of intervention. The results of Morcuende et al. study [54] showed are: Average achievement of dorsiflexion at ankle is 20 degrees, and initial correction was achieved in 20 days, and relapses were noticed about 10% followed by initial treatment. Some studies, used goniometry to assess the ankle range of motion (ROM) such as dorsiflexion and planter flexion to find out the effectiveness [52] of clubfoot deformities. The results and measurement outcomes of the selected 12 studies are described in the Table 1. The Dimégio score was reduced from 16 ± 3.4 to 1.6 ± 6.2 at the end of the follow-up [51]; and was an average of 11.2 (received no previous treatment and received previous treatment) before the casting at Colburn & Williams study. However, the Colburn & Williams study does not explain how much the Dimégio score reduced after casting and follow-up, and this study stated that performed posteromedial release surgery for 3 children (received previous treatment group) [58]. Some of the studies used Pirani scoring system for evaluation but in the outcome evaluation the study did not clearly described the pre and post or follow-up of Pirani scoring outcome [59]. In Pavone et al. study [60], the Pirani score was an average of 5.56 before the casting treatment, and thereafter the results suggested that 82.93% for percutaneous tenotomy after the casting. However, this study also not described about the post Pirani scores but in the follow-up (mean of 4 years follow-up), 98.78% patients had normal passive range of motion, achieved good to excellent results (96.34%) in the functional Ponseti scoring system score [60]. Some studies reported the all parts of the Pirani score including total score (5.6) and the hindfoot score and midfoot score was at 2.9 and 2.8 respectively, and 94.3% of the cases were referred to tenotomy [52], and in another study the hindfoot Pirani score reduced from 2.62 to 0.7 in Ponseti method and 2.79 to 1.31 Kite’s method at the 10th weeks of follow-up. Also, the midfoot score of Ponseti method and Kite method’s decreased from 2.62 and 2.7 to 0.5 and 1.04 respectively, and 96% went for tenotomy surgery in the Ponseti method [56]. One study [53] reported the range of motion as well as Pirani score, the mean Pirani score was 4.8 before the treatment. Thereafter, Pirani score of 0 or 0.5 in 78% of the patients, 1 or 1.5 in 22% of the patients, 3.5 score was noted only one patients. In addition, we observed in their study is about 92% achieved more than 15 degrees of dorsiflexion, 84% of feet freed from adduction deformities, and 93% had more than 40 degrees of external rotation, and 4% feet had adducted deformity. Only one study [55] used the following measurements method to assess the outcome: a) Clinical assessments (relapses, passive ROM, appearance of the foot, muscle power; calf muscle atrophy, size of the foot size, and other complications); b) Functional assessments (Gait pattern, functional limitation, pain, satisfaction of the patients and shoe comfort wear); c) Radiological assessments- talocalcanean angle, talo first metatarsal angle, and talocalcanean index. All these three components together graded as excellent-85 to 100 points; good -70 to 84 points; fair—60 to 69 points; poor <60 points. The overall results of this study showed 87% success rate in Ponseti method and 79% in Kite method. In Segev study, 94% of the feet corrected successfully in the Ponseti method (the average of Dimégio score reduced from 11.9 to 3.2), and tenotomy was performed in 47 feet. At the same time, 6% had residual deformity [57].

Strength and limitations of this systematic review

The main strength of this review is that it thoroughly followed a systematic method and analysis method than previous published few systematic review articles and several reviews on
clubfoot with Ponseti method. Also, this review study found that 2 or 3 articles selected in this review, even though they compared the Ponseti method with Kite method and showed that Ponseti techniques are superior to the Kite method, the publications were same as other ones without changing the written script (protocol, some of the results and discussion parts of the articles), and other details.

Conclusion
In conclusion, this study reviewed all aspects of Ponseti techniques, comparison of the Ponseti method with the Kite method, and the outcome of the results. Number of casts used in clubfoot intervention, number of patients underwent for surgical procedures, and the relapses pattern of clubfoot followed by correction of clubfoot. Overall, this review found that the Ponseti method required fewer casts, shorter duration to achieve the correction, less relapses rate than other methods. On the other hand, few studies were only described the relapse pattern, and causes of relapse. There is still lack of information regarding the causes of relapse or recurrences of clubfoot. Some of the studies reported that poor socioeconomic status and bracing compliance. However, the authors did not describe the duration of discontinuity of braces or relapses pattern, or any grading for bracing compliance in their outcome. Also, we noticed that two or three studies described the relapse pattern, bracing protocol and discussion of the results, in which they followed previous articles without changing any sentences or paragraph of the previous articles. It seems that there is a need for more systematic or Cochrane review in this area for doing careful evaluation of clubfoot intervention and also to avoid the duplication of the previous articles, and to evaluate and review the relapse pattern, adherence of bracing protocol and long term follow-up. This systematic review study has some limitations such as this study reviewed only children with less than two years old. Therefore, this study does not include clubfoot children with more than two years old, neglected clubfoot with using the Ponseti method. In the future study, it is recommended that to do more literature search on databases to review the neglected clubfoot, clubfoot with other abnormalities, more randomized control studies with using Ponseti method and other interventions.

Supporting information
S1 File. Electronic search strategy.
(PDF)

S2 File. The PRISMA checklist.
(DOC)

Author Contributions
Conceptualization: BG.
Data curation: BG GRN SB.
Formal analysis: BG SB GRN.
Funding acquisition: AL BG.
Investigation: BG AL AA GRN.
Methodology: BG AL AA GRN.
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Software: BG AL AA.
Supervision: AL AA.
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Visualization: BG SB.
Writing – original draft: BG AL AA GRN SB.
Writing – review & editing: BG AL AA GRN.

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