

Study Protocol

THREE DIMENSIONAL (3D) ASSESMENT OF CLUBFOOT

Abstract

Background: The congenital talipes equinovarus (CTEV) or clubfoot is one of the most common and complex congenital deformities and is a completely reversible condition with timely and appropriate treatment. The aim of this study is to perform three dimensional assessments for clubfoot to evaluate the initial severity of the clubfoot and to monitor the structural changes in clubfoot after each casting intervention.

Methods: A Comparative Experimental Prospective Study conducted from October 2019 to October 2021 for a period of 2 year in the Department of Orthopaedics, JNMC & AVBRH. With institutional ethics committee approval, children with unilateral clubfoot are recruited consecutively by convenient sampling till the sample size is reached. The 3D scanning using Kinect 3D scanner is performed weekly before each casting. Pirani Score and 3D assessment at different time periods are considered as primary outcome variables.

Results: In this study we will get to know the severity of club foot after each casting interval and the structural changes can be evaluated in foot of patient to quantify the extent of disease and the improvement after treatment protocol

Conclusion: Our study primarily tries to evaluate clubfoot by using 3D scanner and get the quantification of the disease

Keywords: Congenital talipes equinovarus, CTEV, clubfoot, Pirani score, Kinect 3D scanner, cross section angle.

INTRODUCTION:

One of the most frequent and difficult congenital malformations is congenital talipes equinovarus (CTEV), sometimes known as clubfoot. Idiopathic clubfoot is predicted to affect 1 to 2 out of every 1,000 live births.¹ Ankle equinus, hindfoot varus, forefoot adductus, and midfoot cavus are the four components of the deformity.² Although clubfoot is frequently mistaken for an equinovarus deformity, other deformities such as calcaneovalgus, equinovalgus, and calcaneovarus can also be involved.³ There are two types of equinovarus deformities: congenital and acquired. Equinus, varus, adductus, and cavus are all characteristics of a real clubfoot. The equinus deformity affects the ankle, talocalcaneonavicular (TCN), and forefoot joints. The hind foot is rotated inwards in the varus component, which occurs largely at the TCN joint. Except for the talus, the entire tarsus is turned inward in relation to the lower leg. The medial edge of the forefoot faces upward because it follows the hind foot. The talonavicular and anterior subtalar joints are involved in the adductus deformity. The forefoot plantar flexion component of the cavus contributes to the composite equinus.⁴ The goal of any therapy to correct CTEV is to at least minimize the all aspects involved in causing the clubfoot deformity, if not completely remove, such that the treatment results in a functional, pain-free foot that is normal-looking plantigrade with mobility and free of calluses and be able to be accommodated in a shoe.⁵

Clubfoot is the fifth most common congenital birth abnormality and the most frequent in the musculoskeletal system, affecting around 150,000 babies worldwide each year.^{6 7 8} Epidemiological studies published in the previous 55 years suggest a birth prevalence of 0.5 to 2.0 cases per 1000 live births, resulting in 7–43 clubfoot cases per million per year, depending on the birth rate.⁹ Clubfoot is expected to affect 1.2 out of every 1000 live births in India.⁹

Treatment usually consists of foot manipulation, serial casting, bracing, and, on rare occasions, Achilles tenotomies and surgery; nevertheless, surgical methods were more popular in the past.¹⁰ It's critical to be able to explain the treatment and likely outcome to the parents of a CTEV infant. Because the condition's clinical course and severity are unpredictable, it's impossible to determine the severity at first presentation or compare treatment outcomes. To overcome this issue, a variety of classification schemes have been developed.¹¹ The most widely used clinical grading systems are Harrold and Walker¹², Catterall¹³, Diméglio et al¹⁴, and the Pirani scoring system¹⁵. However, because there is no direct evaluation of anatomical links, clinical assessment remains subjective and incorrect.¹⁶

Imaging modalities provide objective details of the severities of CTEV but there are some disadvantages with them. Radiographs can be used to confirm a clinical diagnosis and rule out associated abnormalities, but they have some limitations like inability to see cartilaginous tarsal bones, delayed appearance and eccentric location of ossification centres resulting in inaccurate angular measurements on radiographs, and the dangers of radiation exposure.¹⁷ The pliability of distinct compartments of the clubfoot and their correctability on manipulation can be determined using sonography.¹¹ With no threat of radiation exposure, sonography can be used repeatedly to monitor treatment response. Any erroneous corrections or non-responding feet can be detected early and treated surgically.¹⁸ but ultrasound is limited by intra observer and inter-observer variability.¹⁹ The CT procedure emits radioactive waves, which may have adverse effects on humans.²⁰ Volumetric magnetic resonance imaging revealed variations in the volume and length of three muscle compartments in the lower limb with a clubfoot deformity (anterior, lateral, and postero-medial muscular compartments).²¹ In patients with clubfoot, a noninvasive noncontrast-enhanced 3-D MRA and MRI can be used to identify soft tissue and vascular irregularities.²² MRI and CT are expensive procedures to be repeatedly undertaken to assess the progress of casting and infants require sedation to make them calm or relax during the MRI procedures. Commercially available 3D scanners are being used to evaluate the structure and shapes of the normal foot in foot orthosis industry and shoe industry. The length and width of the foot, the width of the heel, the height of the lateral malleolus, the circumference of the foot, the arch height index, and the height of the lateral malleolus are all taken into account.^{23 24} Burhan et al reported that the Kinect® XBOX 360 gaming sensor is capable of producing 3D reconstructed geometry in designing orthotic with good functionality.²⁵ Only one study investigated changes in clubfoot structure and thermo-physiological functioning status during each casting step of clubfoot treatments using a Kinect 3D scanner and an infrared camera.²⁶ The purpose of this study is to employ a Kinect 3D scanner to do a three-dimensional assessment of clubfoot in order to establish the severity of the problem at the outset and to track structural changes in the clubfoot after each casting intervention.

Need of the study

Clubfoot, also known as Congenital Talipes Equinovarus (CTEV), is a complex, congenital deformity of the foot with inward and downward rotation of the foot. It is one of the most common pediatric foot deformity that is completely treatable with early intervention. The first mode of treatment is a non-surgical one with casting of the foot periodically, monitoring the progress. It is necessary to ascertain the severity of the deformities associated with clubfoot for appropriate treatment. Radiographs of the foot are ineffective during the first few months after birth because many of the tarsal bones have not yet begun to ossify. As CTEV is a three-dimensional deformity, it benefits to have 3D images of the foot. Kinect 3D scanner is a cost-effective means for monitoring clubfoot deformity, which can be used even at remote places where appropriate radiographic equipment is not available. There is also no hazard of radiation to the newborn. There are no studies except for one in this context. The current study is carried out to validate the efficacy of Kinect 3D scanner in measuring clubfoot deformity by correlating it with Pirani scoring system.

AIM

To perform and develop three-dimensional assessment method for clubfoot.

Objectives:

- 1) we will measure the severity of clubfoot
- 2) To evaluate the three-dimensional changes in clubfoot after every casting

Methodology:

A combined total of 30 feet in clubfoot patients having age less than 2 years old coming to the out patients department of AVBRH would be taken in this study. So, that the parents should take wise decision about their child, an invitation letter from the department of orthopaedic would be given. An Enrollement form would be filled by the parents in local language. In short, they will be explained about the complications of participating in the study. If the parents are ready to take part consents will be taken and basic details will be collected

The child will be held in whichever position the child in comfortable. The 3D Kinect camera will be taken to click 3 dimensional images of the foot starting from medial malleolus to lateral malleolus or vice versa and the collected images will be then taken for analysis

Inclusion criteria:

- (a) congenital club foot without cause
- (b) both male and female
- (c) bilateral clubfoot
- (d) less than two years clubfoot without treatment

Exclusion criteria:

- a) already treated clubfoot
- (b) clubfoot in association with other disorders
- (c) children more than 2 years of age

Sample size:

After the approval from the institutional ethics committee, the study will be conducted on 30 recruited clubfeet subjects, who are less than 2 years old, visiting the out-patient's department of AVBRH.

Expected Outcomes/Results:

In this study we will get to know the severity of club foot after each casting interval and the structural changes can be evaluated in foot of patient to quantify the extent of disease and the improvement after treatment protocol

Discussion: Clubfoot treatment can be challenging at times so we need a set device or treatment protocol which can be followed. Our study aims at using 3D scanner to assess the severity of this disease without any trouble to the child which can be experienced in several imaging studies (14). Our treatment and diagnostic tool can be used as an ideal way to treat this deformity in children

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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UNDER PEER REVIEW