Clinical Biomechanics 51 (2018) 67–75

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Development of an orthosis for simultaneous three-dimensional correction of clubfoot deformity

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A R T I C L E I N F O

Keywords:
Clubfoot
CTEV
Orthosis
Treatment
Deformity

A B S T R A C T

Background: Clubfoot is a three-dimensional deformity of the foot in which the foot is twisted in three mutually perpendicular planes from the normal shape of the foot. Of the various treatment methods that are available to manage clubfoot, non-operative approaches are preferred. The conventional non-operative method of treatment is to apply a series of casts to the infant's clubfoot to gradually manipulate its position. However, prolonged use of casts can result in skin rash, skin dehydration and ulcers on the soft skin of an infant. Treatment using orthosis represents an alternative non-operative and convenient technique because an orthosis can be put on and taken off at any time.

Methods: In the present study, an orthosis was developed according to the rotation of three mutually perpendicular planes and was subsequently tested on five patients over the duration of one week.

Findings: In all five cases, the desired incremental correction to the clubfoot was achieved through the one week intervention with the orthosis. No form of rash, dehydration, ulcers, and so on were observed on the skin of any baby involved in the study during or following application of the orthosis.

Interpretation: By using the developed orthosis, partial correction of the clubfoot deformity was achieved over a short period of time. However the widespread use of this device for extended durations and with a larger number of patients will generate further evidence of the extent to which this orthosis can reliably treat clubfoot.

1. Introduction

Clubfoot, which is technically referred to as *congenital talipes equinovarus*, is a complex musculoskeletal deformity in which the foot is three-dimensionally twisted from the normal shape of the foot (Yapp et al., 2012; Penny, 2005; Ballantyne and Macnicol, 2002; Wainwright et al., 2002: Pekindil et al., 2001). Worldwide, clubfeet affects 1–7 newborns per 1000 births (Barry, 2005; Kerat et al., 2002). Clubfoot is twice as common in boys as it is in girls. In 50% of the cases of clubfoot, the deformity is bilateral (Bass, 2012; Gibbons and Montgomery, 2003). Various surgical (Fig. 1a) and non-surgical (Fig. 1b) methods have traditionally been used to correct clubfoot deformities. The condition of clubfoot further deteriorates if it is neglected during infancy (Pandey, 2002).

In terms of the biomechanics of the clubfoot, the motion of the foot occurs in three mutually perpendicular orthogonal planes known as the coronal plane, sagittal plane, and transverse plane (Abboud, 2002). The origin of this coordinate system lies at the ankle of the foot (Fig. 2a). Inversion-eversion, extension-flexion, and adduction-abduction are motions of the foot that occur as the foot is rotated about axes that are perpendicular to the coronal, sagittal and transverse planes respectively.

The treatments that are most commonly employed to treat the condition of clubfoot in infants have changed dramatically over the last decade as non-operative treatments have become more popular (Bass, 2012; Karol and Jeans, 2011). Conventional non-surgical treatments typically involve a gradual correction of the deformity through physical manipulations followed by the application of a cast to maintain the correction achieved through each manipulation (Hulme, 2005; Wedge et al., 2001). However, prolonged use of casts results in skin dehydration and ulcers (Villeda et al., 2008). Swelling of the toes can also occur if the cast is too tight (Staheli, 2009). Wearing a cast for a prolonged period of time can also be a frustrating and painful experience for the patient (William, 2010). Furthermore, Halanski et al. (Halanski et al., 2007) reported the possibility of thermal injuries on the skin due to the rise in temperature of the skin below the plaster.

Approximately 80% of children born with a clubfoot deformity are born in the developing world, and the large majority of such patients do

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https://doi.org/10.1016/j.clinbiomech.2017.12.002
Received 28 May 2017; Accepted 3 December 2017

Fig. 1. Treatment of clubfoot (a) surgical (Mowafi et al., 2009) (b) conventional non-surgical.

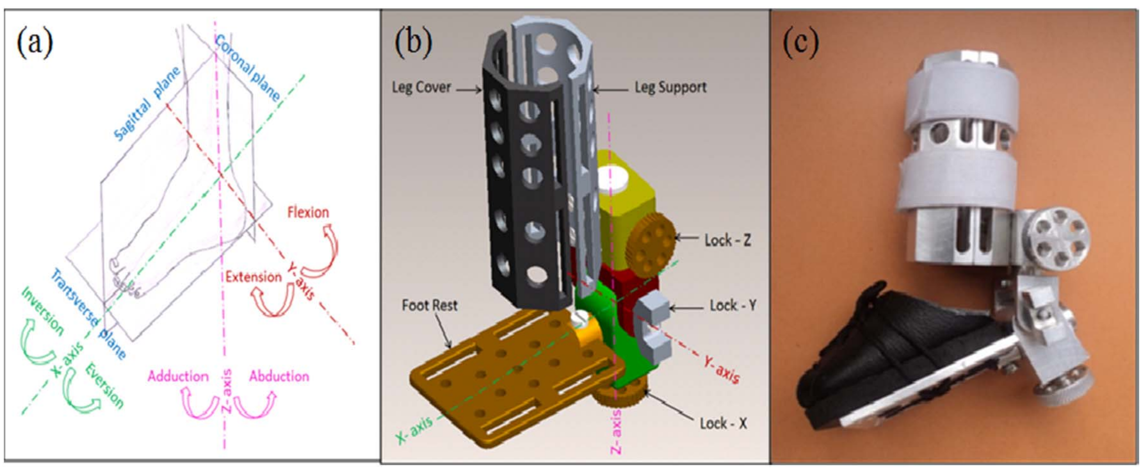

Fig. 2. (a) Movement of foot in about three axes (lateral view, left foot) (b) motion of orthosis about three axes (CAD model) (c) fabricated clubfoot orthosis.

not have access to appropriate medical care. In developing nations, clubfoot may go untreated due to a lack of funding. Alternatively, patients may be required to travel long distances to access treatment due to the lack of appropriate medical resources in accessible locations (Kazibwe and Struthers, 2009; Penny, 2005). People who live in developing areas of the world may encounter a lot of difficulties attending weekly sessions for the application of casts for the treatment of clubfoot; in such cases, the use of orthosis for the treatment of clubfoot may be exceedingly advantageous.

To overcome such problems, there is a need for a simple, lightweight, human-friendly and user-operated device that can be systematically adjusted in accordance with the requirements of the treatment. Thus, following due consultation with an orthopaedist, this study proposes an alternative non-surgical biomechanical method for treating clubfoot in infants. An orthosis has been developed in this work to simultaneously correct three-dimensional clubfoot deformity.

2. Materials and methods

2.1. Fabrication of the orthosis

A clubfoot is twisted about three axes, X, Y, and Z, which are perpendicular to the coronal, sagittal, and transverse planes respectively. The orthosis employed in this study was designed on the basis of these three mutually perpendicular planes. These planes were controlled by three axes to pass through three mutually perpendicular planes. Inversion-eversion motion was controlled by the X-axis, extension-flexion motion was controlled by the Y-axis, and adduction-abduction motion was controlled by the Z-axis.

The CAD software pro/ENGINEER (Wildfire 4.0) was used to model the proposed orthosis (Fig. 2b). The rotation of the X-, Y-, and Z-axis could be locked and unlocked using Lock-X, Lock-Y, and Lock-Z respectively. The leg support was designed to support the leg of the baby up to the knee. A leg cover was fastened to the leg support to ensure a good grip between the support and the leg of the baby.

The orthosis was fabricated (Fig. 2c) as per a 3D model that was created using CAD software. Velcro and adhesive tape were used to hold the leg between the leg support and the leg cover. The shoe, which was designed to hold the clubfoot in place, was fixed on a footrest and could be changed according to treatment requirements. Multiple holes were incorporated into the leg support and the leg cover to provide ventilation. Moreover, these holes also reduced the weight of the orthosis. Aluminium was used to fabricate the orthosis because it is both lightweight and waterproof.

The shoe, which was fixed to the footrest, was constructed of a combination of two materials. The inner layer of the shoe was made of cotton, which was designed to increase the comfort of the wearer due to its malleable nature. The outer layer of the shoe was constructed of leather, which helped to mould the foot.

2.2. Operation of clubfoot orthosis

2.2.1. Control of inversion-eversion

The motion of inversion-eversion was controlled by rotating the X-axis using Lock-X (Fig. 3a, b). The footrest could be rotated in a clockwise or anticlockwise direction about the X-axis. The footrest was