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Research Article

An Investigation on the Evaluation and Improvement of Existing Features of Foot Exercise Apparatus Designed for Use in Evertor and Invertor Muscle Dysfunction

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ABSTRACT

Clubfoot deformity is one of the most important congenital anomalies of paediatric orthopaedics and characterised by equinus, supination and inversion of the foot muscles. Although treatment of this pathology, which presents as a gait disorder in the early stages of development, is currently attempted with exercise, physiotherapy and/or surgical approaches, the success rates of these treatments are low and/or lateral compression recurs. This situation confronts many children and their families with the difficulties and costs of the treatment process. The aim of this study is to produce and develop an apparatus for the treatment of this dysfunction with today's engineering approaches. For this purpose, in this study, a prototype was designed and manufactured using three-dimensional (3D) printing method with tough polylactic acid (PLA). The prototype can support both the right and left foot and enables to exercise up to angles of 31.8° for both evertor and invertor muscle.

Keywords: *Clubfoot deformity, Evertor muscle, Design and fabrication, 3D printer*

Evertör ve Invertör Kas Disfonksiyonları için Ayak Egzersiz Aletinin Kavramsal Tasarımı ve 3D Yazıcı ile Üretimi

ÖZET

Çarpık ayak deformitesi pediatrik ortopedinin en önemli konjenital anomalilerinden biridir ve ayak kaslarının ekinus, supinasyon ve inversiyonu ile karakterizedir. Gelişimin erken dönemlerinde yürüme bozukluğu olarak ortaya çıkan bu patolojinin tedavisi için günümüzde egzersiz, fizyoterapi ve/veya cerrahi yaklaşımlarla yapılmaya çalışılsa da bu tedavilerin başarı oranları düşüktür ve/veya yan basma sorunu yeniden tekrarlamaktadır. Bu durum birçok çocuk ve ailesini tedavi sürecinin zorlukları ve maliyetleri ile karşı karşıya bırakmaktadır. Bu çalışmanın amacı, günümüz mühendislik yaklaşımları ile bu fonksiyon bozukluğunun tedavisine yönelik bir aparat üretmek ve geliştirmektir. Bu amaçla, bu

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çalışmada sert polilaktik asit (PLA) ile üç boyutlu (3D) baskı yöntemi kullanılarak bir prototip tasarlanmış ve üretilmiştir. Prototip hem sağ hem de sol ayağı destekleyebilmekte ve hem evertor hem de invertor kasları için 31,8°'lik açılara kadar egzersiz yapmaya olanak sağlamaktadır.

Anahtar Kelimeler: *Çarpık ayak deformitesi, Evertor kası, Tasarım ve fabrikasyon, 3D yazıcı*

I. INTRODUCTION

Clubfoot is one of the major and common congenital anomalies in paediatric orthopaedics in the world and it is characterized by equinus, supination, and inversion of the foot. This defect is a dysfunction of the evertor and inverter muscles that causes impairments, limitations, and disabilities in the gait of children and adults besides painful and uncomfortable situations for the patient (Figure 1) [1, 2]. Treatment of this case includes serial casting and, rarely, surgery [1-5]. Children are also followed through their growing years and frequently require secondary procedures. Long-term follow-up is crucial for evaluating different treatments such as surgery vs. casting [2, 3]. The goal in the correction of congenital clubfoot is to obtain a painless, straight, plantigrade, mobile foot with reestablishment of anatomic bony relationships, normal radiographic appearance, and which allows the development of a normal gait pattern [5].

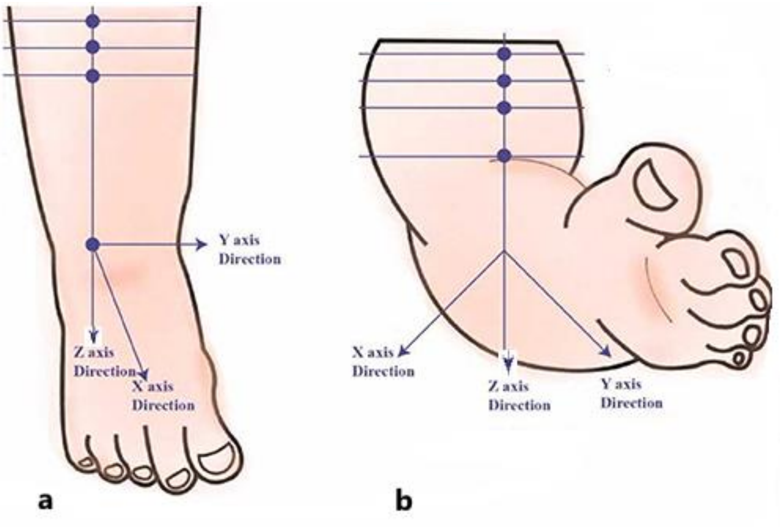

Figure 1. (a) *Normal foot and* ***(b)*** *Clubfoot anomaly appearance according to X, Y and Z directions [6]*

It is known that the treatment of clubfoot has been known since ancient times and various approaches have been applied for treatment since these times [1, 7, 8]. Today, it is tried to be treated with exercises, physical therapy and/or surgical approaches and to facilitate the daily life of individuals; however, these treatments have low success rates and/or relapse of side pressure. Today, it is tried to be treated with exercises, physical therapy and/or surgical approaches and to facilitate the daily life of individuals; however, these treatments have low success rates and/or relapse of side pressure. Ponseti Method is the gold standard protocol for the treatment of clubfoot and enables successive serial manipulations and plastering to achieve successful results. But although it is the gold standard, recurrences can be seen in clubfoot treatment up to 50%, regardless of the successful initial treatment process and the satisfactory results obtained. This is a situation encountered with non-compliance with the Ponseti brace protocol. Repeated manual applications or surgical interventions may be required in curing the pathology for recurrence of the deformity [9-11]. Each patient may need a personalized but also a cheaper treatment because this lifelong treatment has high costs for the families [11, 12]. On the other hand, consisting of treatments, especially for patients older than 4-5 years old, are boring, time wasting and sometimes torture for them and hard to control for parents. More research is needed to determine whether a specific treatment approach is beneficial for children [13] and there is a great expectation for new different approaches. At this very moment, designing technological developments for the health sector has been a key element in biomedical engineering education. As Petroski [14, 15] has stated, design is the "soul of engineering". The incredible contributions of today's technology and engineering approaches in medicine have laid the groundwork for the production and development of an apparatus for curing this dysfunction. Today, personalised designs are customized to various parts of the human body in accordance with the geometric specifications with an increasing attention. Three-dimensional design technologies take attention and are utilised for the needs of human body which is an organic object and show free-form properties [16]. In our study, for children, we re-designed and fabricated a foot exercise apparatus, using the principles of basic biomechatronics and biomedical devices, and printed an apparatus using a 3D printer for use in evertor and inverter muscle dysfunction. There is a lack of personalised devices clubfoot deformity especially for children older than 24 months and for the first time in this study, a novel and functional device is presented.

II. MATERIALS AND METHODS

In this study we evaluated a prototype apparatus called as $Pedped_1$ that was conceptualised as a mobile application mediated exercise device for children who were diagnosed with clubfoot. Although this device was useful, it was a *prototype* and has some limitations. To overcome the limitations such as movement restrictions and limited usability for both right and left foot, we re-designed and then fabricated the new version of $Pedped_2$, the device. The design, 3D printer-supported studies were carried out within the scope of this study and the tough PLA used in this study were carried out by using the facilities of Mechatronics Engineering Department and Life Sciences and Biomedical Engineering Application and Research Centre at Istanbul Gelişim University. Electronic components were obtained from Dr. Özyalvaç.

A. DIGITAL EVALUATION

$Pedped_1$ was digitized using a computer aided design (CAD) software SolidWorks© which is a 3D solid modeling program for designing and assembling parts [17, 18]. 3D properties of the apparatus were transferred to the solid modeling program to generate schemes and tailored via its tools. Technical and clinical expectations were discussed by our team and re-digitized according to orthopedic treatment requirements and biomedical device design fundamentals [14].

B. DESIGN PROCESS

The design process is an important period of biomedical device development and needs sufficient attention to be given as it affects the long-term outcome of the devices. In this study, design fundamentals and engineering cares were both handled to content the basic expectations for users (doctors, nurses, practitioners, patients etc.) [19]. For these purposes, the finite element analysis (FEA) can be appropriate. In biomechatronics, FEA is applied to living systems, especially the human body, is an important tool for simulating human body studies and conducting comparative studies [20]. The FEA has become increasingly popular among researchers in the field of computational biomechanics as it allows us to understand the detailed biomechanical responses of load-bearing biological systems [20]. In order to perform FEA, ANSYS software was used to provide numerical analyses of structural affects to the pedal directly [21]. Considering the apparatus and the lower part of the leg (crus) where the apparatus will be mounted and the amount of force that will be applied to the pedal part of the apparatus with a child's foot was analysed. During the force loading analyses, it was assumed that no other force would be applied to any part of the apparatus other than the pedal part. On the other hand, tough PLA material, which we will print with a 3D printer, was considered in the analysis studies and the forces to be applied to the pedal part of the apparatus produced with this material were evaluated. The maximum angle that can occur during the maximum stress was calculated. Several different schemes that have a lightweight, space-saving and pleasing to the eye models were designed using SolidWorks© 2022 software for rendering and assembling three-dimensional models (Figure 2).

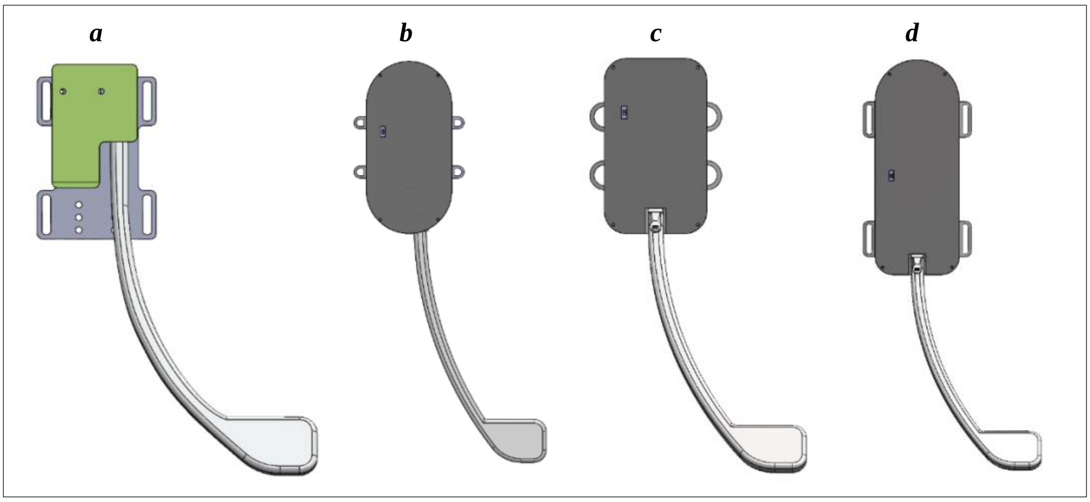

Figure 2. (a) *The first (Pedped1) and* ***(b, c, d)*** *the other new ideas of samples designs [22].*

C. MATERIAL SELECTION AND FABRICATION (3D PRINTING)

Another important step for biomedical device design is material selection. Choice of materials will impact virtually all aspects of the device's use: the dimensions, lifespan, and capabilities of the device; the cost and complexity of validation, manufacture, and application [23]. In other words, *design process* is linked to the material choice and *material selection process* is linked to *the fabrication process*. Thus a well-known material needs to be evaluated considering both the design and fabrication. According to physical features of the designed apparatus we searched the literature and decided to fabricate it via 3D printing. *Tough PLA* was appeared as a reasonable material for our 3D printing procedures. Tough PLA is a design material that combines the stiffness of PLA with the impact resistance and strength of ABS, has high surface quality and can be printed very easily [24, 25]. Properties by manufacturer of tough PLA (BCN3D, Barcelona, Spain) are like as 1,21 g/mL specific gravity with a tensile strength at yield and break 46 and 19 MPa, respectively. Also, the elongation strain at yield is 2% while elongation at break is 27%. Vicat Softening point is 57 ºC.

Fabrication of the apparatus was provided with 3D printing method that is an additive manufacturing. This method enables the cost-effective, sensitive and faster synthesis of complex 3D structures such as human body parts and is increasingly replacing many traditional methods [26]. In this process, a tough PLA filament with a tolerance of ± 0.10 mm Ø and ≥ 95% roundness and a size of 2.85 mm was used for the Epsilon W50 (BCN3D, Barcelona, Spain) 3D printer. The printing parameters were layer thickness 0.05 - 0.5 mm, nozzle diameter 0.4 mm, layer height 0.1 mm, fill 80%, fill overlap 15% and wall thickness 0.8 mm. The specimens were produced horizontally.

On the other hand, the analysis of *Pedped*$_2$ was carried out with the finite element model method using ANSYS program. The SOLID187 element was used in the finite element model. SOLID187 is a 3D element with 10 nodes and has quadratic displacement behavior and is suitable for modeling irregular structures (e.g. those produced by CAD/CAM systems). On the other hand, the SOLID187 element defines 10 nodes (Figure 3) with 3 degrees of freedom at each node. This element, with its plasticity, hyperelasticity, creep, strain hardening, strain hardening, high deformation and high tensile capacity [27, 28], was used for the analysis of *Pedped*$_2$.

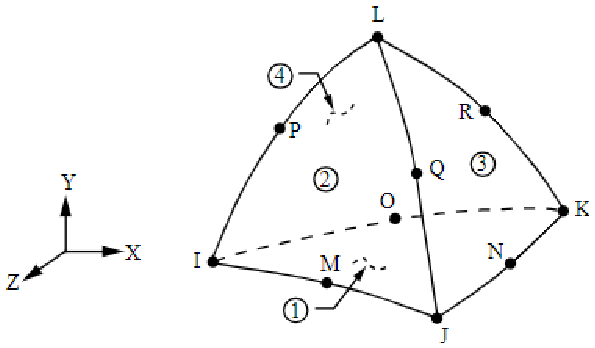

Figure 3. *Solid187 element of 10 nodes with X, Y and Z axis (ANSYS Manual) [28].*

III. RESULTS AND DISCUSSION

A. RESULTS

The final design and fabricated prototype of device (*Pedped*$_2$) is shown in Figure 2. Different from the first version, *Pedped*$_2$ includes two parts: the *main body* and the *pedal* part that are connected to each other with female and male joints (Figure 4). The main body of the design is used to fix the apparatus to the tibia of the children with the help of a bandage. The pedal, which is connected to the main body, forms the moving mechanism of the apparatus with its golf club-shaped design. The pedal part is ergonomic and provides convenience for both right and left feet to perform both evertor and inverter muscle movements.

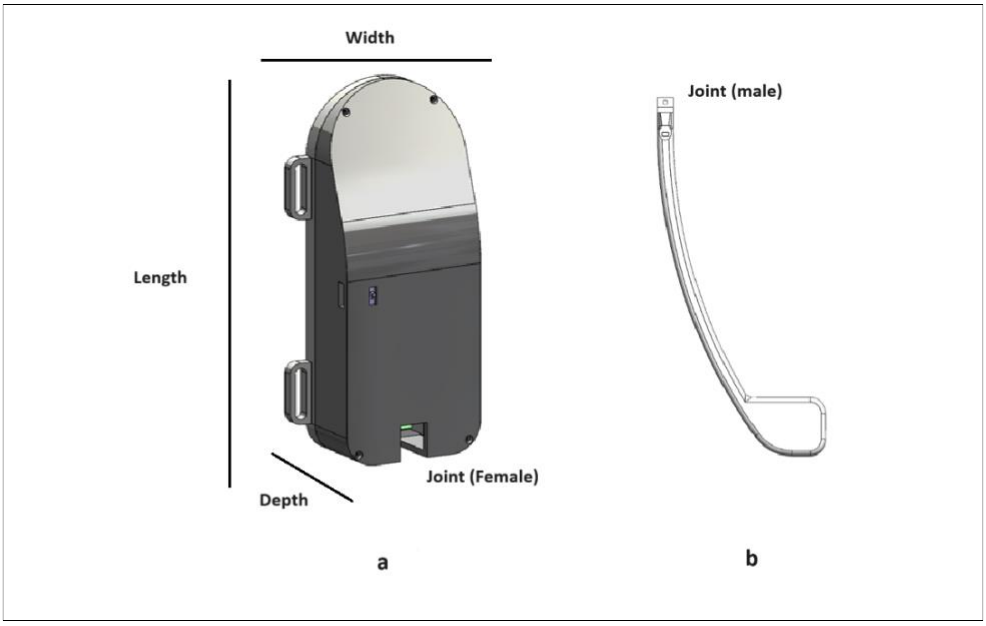

Figure 4. *The parts of 3D printed prototype of Pedped*$_2$ ***(a)*** *The main body; and* ***(b)*** *pedal [22].*

First version could be used just for one foot and just left or right movement. That was the major limitation of *Pedped*$_1$. On the other hand, as seen on Table 1, *Pedped*$_1$ has 3 separate parts and total weight of these parts were heavier, and release degree of the pedal was lower. *Pedped*$_2$ had advantages with its lighter, free movement support and two-sided feet that helps to work out both right and left feet for evertor and invertor muscles' movements. This version of the apparatus' pedal enables to exercise up to angles of 31.8° for both evertor and invertor muscle. Total length of *Pedped*$_2$ is longer that helps to allows the weight of the device to be distributed over the surface of the tibia.

Table 1. *Comparison of the measurements of Pedped$_1$ and Pedped$_2$. Measurements were obtained from Atesoglu, 2023 [22].*

	Part of the device	**Width** (mm)	**Length** (mm)	**Dept** (mm)	**Weight** (g)	**Release degree**
Pedped$_1$	*Main body*	47.3	68.5	42	179	-
	Pedal	155.5	273	Top 48 Buttom 52	239	27.4
	Joint	66	90	6 - 10	31	-
Pedped$_2$	*Main body*	90	180	Top 8 Buttom 39	197	-
	Pedal	10	199	10	21	31.8

The apparatus in consideration is designed for the treatment of clubfoot as a completely different product that has no counterpart, especially for children to make their exercises enjoyable without difficulty (Figure 5).

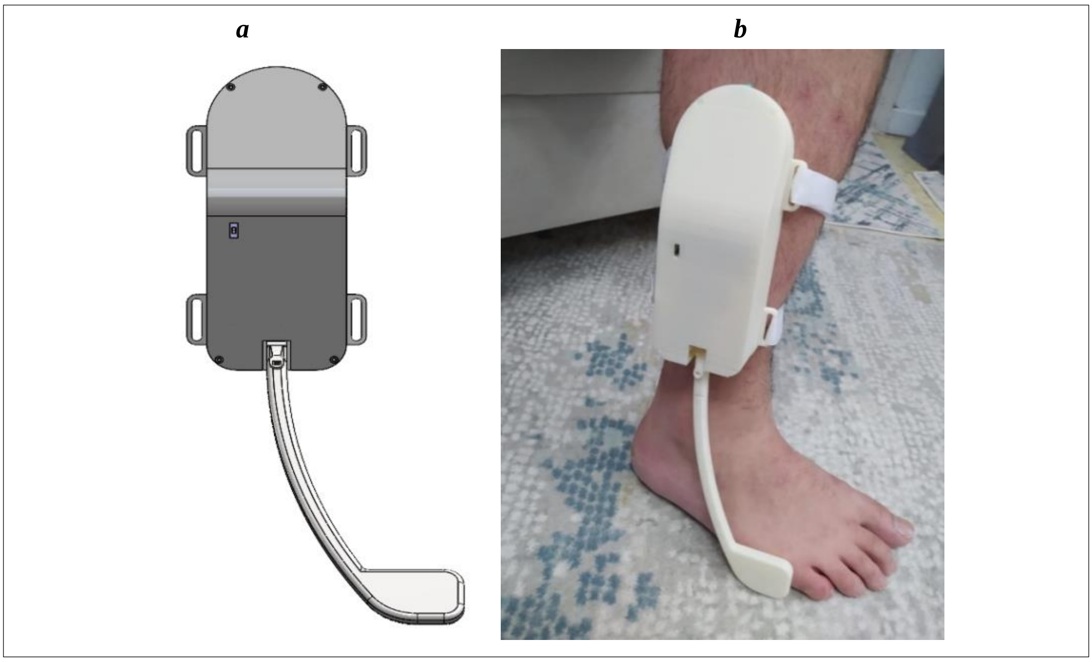

Figure 4. *Final design of Pedped$_2$* ***(a)*** *illustration,* ***(b)*** *fabricated prototype on the foot [22].*

We also evaluated the meshing process of the apparatus and obtained the two-sided isometric view (Figure 6a and 6b). Figure 7a and 7b shows the boundary conditions of *Pedped$_2$*. After the boundary conditions were determined, total deformation (Figure 7c and 7d), stress and strain analyses were performed for F=0.5 N and F=1 N according to our experiments (Data not shown).

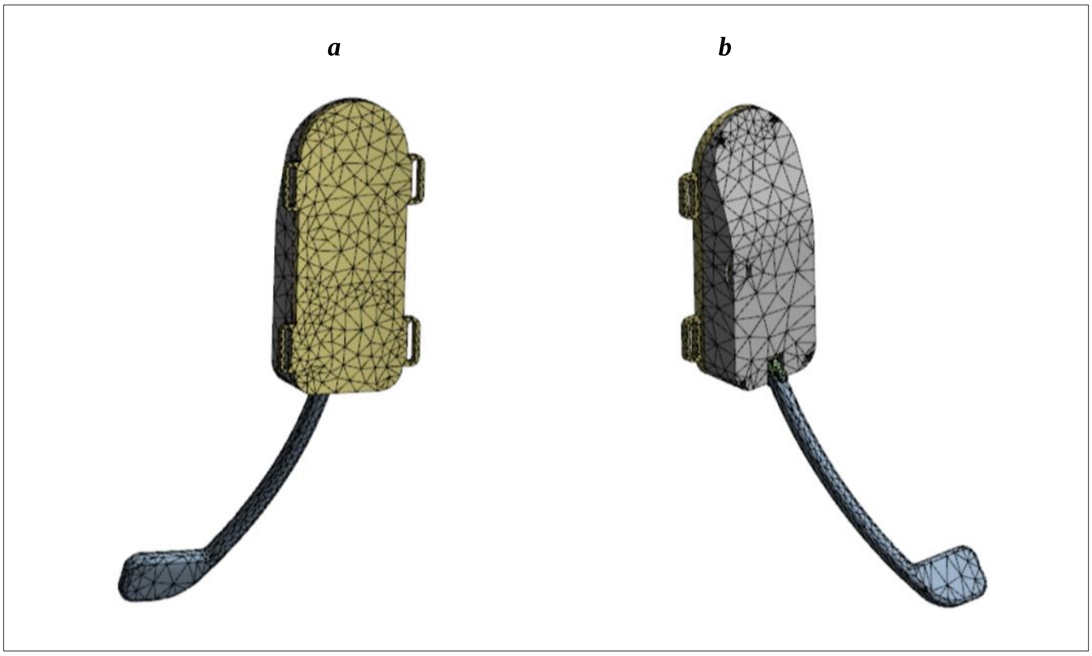

Figure 6. *Isometric view of the mesh of Pedped$_2$* ***(a)*** *back side* ***(b)*** *front side*

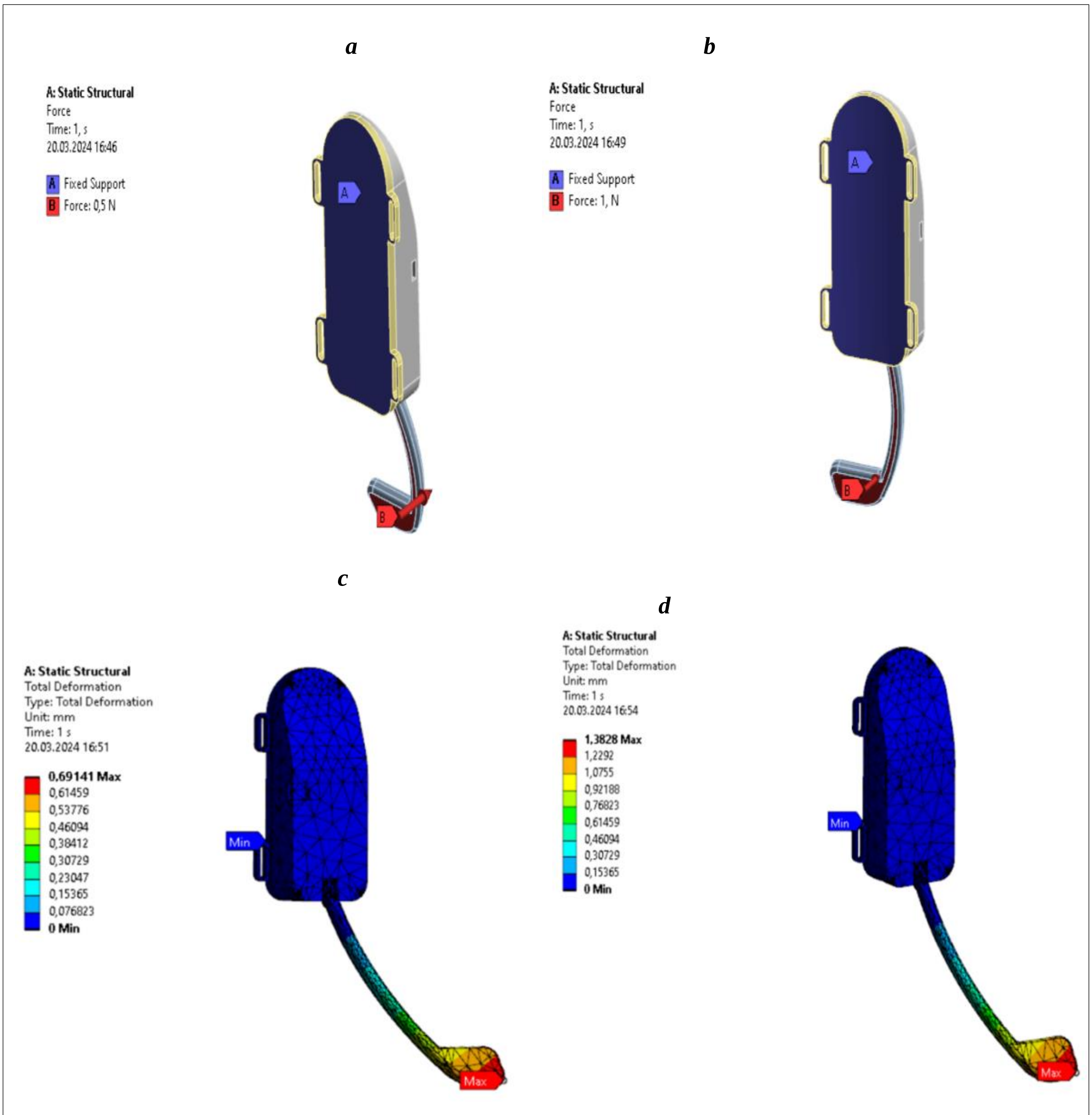

Figure 7. *Boundary conditions for Pedped$_2$ simulations when* ***(a)*** *F=0,5 N* ***(b)*** *F=1 N; and total deformation when* ***(c)*** *F=0,5 N* ***(d)*** *F=1 N*

The aim of the new version is to be user-friendly in design, to be advantageous in terms of price/performance in production, to have a post-modern design and to fully serve its orthopaedic clinical purpose. Total deformation, stress and strain analyses results showed that *Pedped$_2$* is a suitable apparatus to handle the exercises for evertor and invertor muscles. The apparatus also has the necessary mechanical and electronic parts to ensure its operation. These mechanical parts are discs and springs; the electronic parts are potentiometer; PCB card and battery A potentiometer is basically a type of adjustable resistor. However, since it has a rotatable structure, it can also be used for position detection. It was also used for our purpose in this study. Finally, there is an application interface that allows the device to be connected to the phone. The electrical parts of the device were not evaluated in this study; thus, they were placed into the main body. The whole mechanic and electric systems worked correctly.

B. DISCUSSION

In recent years, engineering studies in the field of health have developed rapidly and thousands of products that can be used for diagnosis and treatment have begun to be offered to humanity. It is expected that the number of medical devices to be made in this area will increase even more. On the other hand, for low- and middle-income countries, the design of medical devices is of vital importance. Both the development of the country and the opportunity to access technology at a more affordable price should be provided [29].

There is a very important need in the field of orthopaedics for engineering supported devices. Based on these purposes and needs, we used mechatronics engineering approaches together with biomedical device designs, and with the studies carried out, its effectiveness was increased, and it became a user-friendly apparatus. It helps to work out both right and left feet for evertor and invertor muscles' movements. The pedal helps to exercise up to angles of 31.8° for both evertor and invertor muscle. The apparatus in question can be used to effectively improve congenital clubfoot deformity, and a similar product is not available in the field of health. While many rehabilitation interventions involve the foot and ankle, the contributions of the foot and ankle to normal gait are not well understood. More specifically, understanding the effects of congenital defects, injuries, or other alterations in the lower limb and particularly the foot and ankle on mobility is a continuing challenge to medical rehabilitation researchers. Especially mobility in children is a very important title of the field, and there is limited apparatus and studies in literature. For this purpose, Savonen et al (2020) reported a study about a 3D printed brace (*RepRaps*) that can be used for babies using open-source CAD software (FreeCAD) for design, polylactic acid (PLA) as the material for 3D printing. Similar to our study they used printing fabrication method and but different from our study, *RepRaps* is for children, and it needs re-arrangements on the brace while the child grows. On the other hand, it has multiple exercises advantages for the rotations of the movements such as angle brackets with angles of 90°, 95°, 100°, 105°, and 110°[12]. Recent years, apart from traditional techniques, engineering technologies are stated such as developing new procedures for older children according to their needs [30-32].

IV. CONCLUSION

The aim of this study was to design a mobile application game-supported device that can be used by children with clubfoot aged 4-5 years and older. The prototype was fabricated using a 3D printer and the main material used is Tough PLA, a common textile product as a belt, electronic part inserted into the main body. As conclusion, in this study, it is aimed to make the exercises in the treatment process fun, affordable and not exhausting for children with clubfoot deformity who have undergone surgical intervention. In addition, an innovative approach that may delay or may not require no more surgical intervention in the treatment process is presented. However, further mechanical and electronically improvements and clinical investigation need to be conducted since the device has not been tested with real patients.

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The authors declare that there is no conflict of interest regarding the publication of this article.

AUTHOR’S CONTRUBUTION:

In this study, we evaluated an apparatus (Pedped$_1$) that was conceptualised by O.N.Ö., S.Y.B. has conceptualised the re-design of the study, wrote the article. U.A. has used the software for designing *PedPed$_2$* and printed it using 3D printer.

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