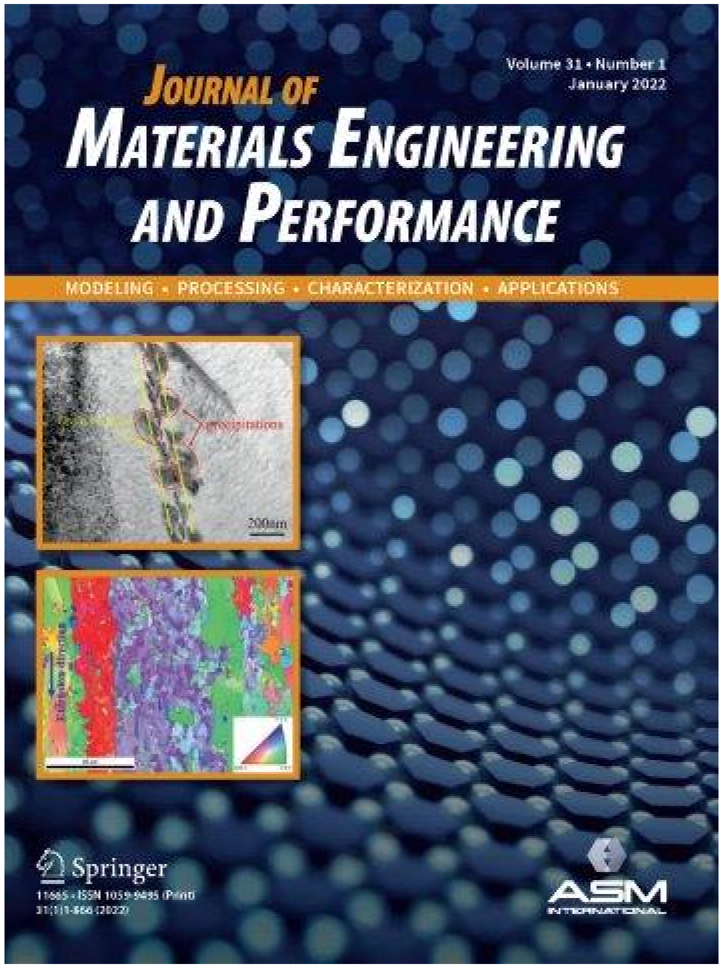


Kinematic Simulation of 6-DOF CTEV (Clubfoot) Corrective Orthosis for its Automation Feasibilities during its Integrated Manufacturing

Journal:	*Journal of Materials Engineering and Performance*
Manuscript ID	JMEP-24-11-39757
Manuscript Type:	Original Research Article
Date Submitted by the Author:	29-Nov-2024
Complete List of Authors:	Mali, Harlal; Malaviya National Institute of Technology Jaipur, Mechanical Engineering Bint, Abhilash; Malaviya National Institute of Technology Jaipur, Mechanical Engineering Singh, Shamsher; Malaviya National Institute of Technology, Mechanical Engineering SUTHAR, SHAILESH; Malaviya National Institute of Technology Jaipur, Mechanical Engineering

Keywords:	Smart orthosis, CTEV, Clubfoot, Trajectory simulation, 6-DOF linkage mechanism, Kinematic simulation

Kinematic Simulation of 6-DOF Clubfoot (CTEV) Corrective Orthosis for its Automation Feasibilities for Integrated Manufacturing.

Harlal Singh Mali[1], Abhilash Bint[1] Shailesh Suthar[1]and Shamsher Singh[1]

[1] Advanced Manufacturing and Mechatronics Lab, Mechanical Engineering Department, Malaviya National Institute of Technology, Jaipur, Rajasthan, 342601, India

Corresponding author: *harlal.singh@gmail.com*

Abstract. Congenital talipes equinovarus (CTEV) is a complicated paediatric foot abnormality that affects 1-8 in 1000 live births. In the last five decades, the non-invasive treatment known as the Ponseti method has been a standard method of treatment that involves serial castings and bilateral braces. The Ponseti approach has a 90% success rate due to its biomechanical understanding and involves correction by serial casting and maintenance by bracing. During the casting phase, patients experience repeated clinic visits, issues related to serial casts and the stigma of bilateral brace for a very long duration of his/her childhood. To overcome the above issues, the research group has developed an innovative unilateral CTEV (clubfoot) Orthosis having six degrees of freedom (DOF). This 6-DOF Orthosis could be an alternative to using the Ponseti method of clubfoot treatment but on the understanding of Ponseti's understanding of Foot Bio-mechanics.

The clinically validated design needs to be automated by incorporation of sensors, actuators, and control units. This paper attempts modelling and simulation for these 6-DOF linkage mechanisms for unilateral clubfoot orthosis so that automation in the orthosis could be achieved. In order to develop a 6-DOF linkage mechanism, initially, 2 and 3-DOF mechanisms were investigated. This allowed to develop an understanding of combining the motion of assembly in forward and inverse kinematics using the angular motion given to each revolute join. The pivot point of a revolute joint is used in the unilateral clubfoot orthosis, and the end-effector's motion on the prescribed trajectory at the given point is traced. The main area of investigation was the trajectory identification, which the child's foot undergoes, and using inverse kinematics to determine the step angle of each joint so that it can be actuated. This will pave the way for integrating hardware for automated and smart CTEV corrective Orthosis manufacturing.

Keywords: Smart orthosis, CTEV, Clubfoot, Trajectory simulation, 6-DOF linkage mechanism, Kinematic simulation.

1 Introduction

With advancements in multidisciplinary medical technologies, there is a growing focus on finding better, more affordable, yet more effective treatments for disease. The leading domains in medical devices are robotics, kinematics simulations, computer-aided design (CAD), computer-aided manufacturing (CAM), and additive manufacturing. This offers new opportunities to develop and improve medical devices such as prosthetics and orthotics, leading to improved treatment of various deformities. One such deformity is Congenital Talipes Equinovarus (CTEV).

CTEV is a serious medical musculoskeletal deformity commonly known as Clubfoot Disease. The affected foot is twisted inward and downward. This affects approximately 1 to 8 in every 1000 babies worldwide at birth, although this rate fluctuates across various nations. This is an idiopathic deformity, and the underlying origins of clubfoot are unknown, numerous studies have found links between genetic and environmental variables and the condition [1]. When CTEV is left untreated, it leads to a complicated and permanent disability of the foot, which makes walking uncomfortable. For untreated CTEV, the calf muscles of the affected leg will be smaller, and the foot will be shorter than a normal foot. The deformation due to clubfoot leads to the disruption of muscles in the lower leg, resulting in the stiffening of joints and ligaments, causing challenges in normal functions [2]. Special medical attention can help treat the condition, but it can only be cured in newborn babies because their soft bones and tendons can be moulded by expert clinicians.

In the last five decades, the non-invasive treatment known as the Ponseti method has been a standard method of treatment that involves serial castings and bilateral braces in correction and maintenance phases respectively. The Ponseti approach has a 90% success rate due to its biomechanical understanding[3] . During the casting phase, patient's experiences various pain points such as repeated clinic visits, un-comforts of castings including pain, skin dehydration, ulcers, thermal injuries, swelling, and more, stigma of bi-lateral brace for very long duration of years to avoid relapse [4]. To overcome the above issues, research group has developed an innovative unilateral CTEV (clubfoot) Orthosis using gear arrangements for not only for motion transfer but also with locking arrangement and having 6-DOF. This 6-DOF Orthosis can be an alternative to using the Ponseti method of clubfoot treatment but on the understanding of Ponseti's understanding of Foot Bio-mechanics upon successful completions of clinical trials [2], [5].

In parallel, advances in kinematic simulation technologies led to the development of virtual CAD models that can simulate human anatomy, consisting of ligament and bone joints and clubfoot deformity. The CAD model can do biomimetics of the biomechanics of clubfoot deformity and the effects of different corrective strategies [6]. These models have, therefore, given insights into the appropriate forces and motions required in correction, which can further be used as a platform for designing automated orthotics devices that can replicate the exact same processes in a clinic. Such devices would improve the accuracy of foot alignment and eliminate human error resulting from manual correction, allowing for scalable solutions to treat clubfoot worldwide. To overcome the challenges associated with CTEV treatment by unilateral orthosis, one of the potential domains is to predict the trajectory of corrective orthotic devices with 6-DOF.

This paper aims to predict the trajectory of corrective orthotic devices with 6-DOF, leading to treat severe clubfoot more conveniently, cost-effectively, and technologically advanced than traditional methods. Initially, the paper attempts to check the feasibility of kinematics links by doing a kinematics simulation of 2-DOF and then 3-DOF with the help of Autodesk Inventor, Onshape, and MATLAB. The feasibility involves the forward and inverse kinematics simulation. Then, this feasibility study paves the way forward and inverse kinematics simulation of 6-DOF to predict the trajectory of 6-DOF Clubfoot orthotic devices[7]. This study is able to provide the impression of functional orthotic medical device in terms of kinematics actuation. Extension of this study to make automated orthotic device by incorporating actuation devices like an electric motor or any other primer movers of primary kinematics link.

2 Methodology

The required softwares are Autodesk Inventor, Onshape and MATLAB. Autodesk Inventor and Onshape are used to build the assembly of unilateral clubfoot orthosis. Onshape is compatible to integrate with MATLAB, while for hardware building, the automation in Clubfoot Treatment has Stepper motors: getting installed on each pivot point of the clubfoot orthosis, Arduino, Jumper wires, Battery, and Breadboard. To develop a 6-DOF linkage mechanism consisting worm and worm gears, first studied a 2 and 3-DOF linkage mechanism to understand how to combine the motion of assembly in forward and inverse kinematics using the angular motion given to each revolute join that was placed on each pivot point of the clubfoot orthosis and the motion of the end-effector on the prescribed trajectory at the given point respectively as shown in Fig. 1. [8]. An automated anthropometric orthosis would be able to accurately predict the trajectory along which the deformed foot would eventually to the correct shape [9]. To do this, a predefined geometry STEP file is used for the MATLAB interface to plot out the predictable path or trajectory that CTEV orthosis should follow.

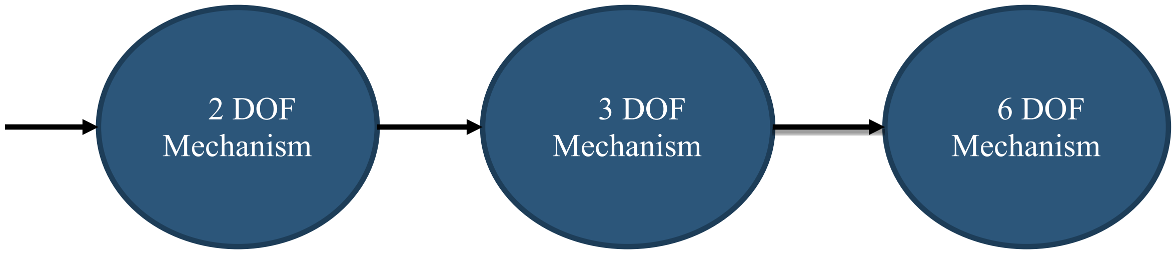


Fig. 1: Development of kinematics of CTEV orthosis

Children between the ages of zero and two who have been fitted with a mechanical worm and worm gear orthosis must be taken to their doctor every 7-10 days to monitor their progress and the deformed foot can be realigned. If the patents were at a faraway place, the process would be excessively laborious, time-consuming, and expensive [10]. In this scenario, CTEV therapy needed to be automated so that time, money, and dependability could all be saved [11]. The clubfoot treatment will be automated through actuators like stepper motors for each joint and mechanisms like worm and worm gear. All the stepper motor control signals could come from a controller like Arduino that was linked to a Simulink model. As soon as the pressure value drops to zero once the muscles have relaxed, the model will restart the actuation of the foot, returning it to the normal shape of the foot. After installing this automation model into this orthosis, parents don't have to take their children to a hospital every week. As a result, time, money, and dependability are reduced [4].

2.1 Two-degrees-of-freedom (2-DOF) linkage mechanism

A 2-DOF connection mechanism is a system of rigid bodies, such as bars, connected by joints or hinges that can move in two different directions simultaneously and can be used to change an input motion or force into a desired output motion or force [12]. This assembly consists of two bars, one end-effector and the base static cylinder. All of them were connected using two revolute joints, which delivered a planner combined motion. As the Fig.2 shows the assembly Creation. This assembly was created using a MATLAB Simulink interface. A predefined cylindrical block was used to create a base link. After running the Simulink model of the 2-DOF Linkage mechanism, the visualisation showed that the 2-DOF linkage mechanism is functioning well. Now, the feasibility analysis by forward and inverse kinematics is done step by step. Forward kinematics is a technique used in robotics and mechanical engineering to calculate the location and orientation of a tool or robot arm from the known locations and orientations of the mechanism's constituent joints and links [8].

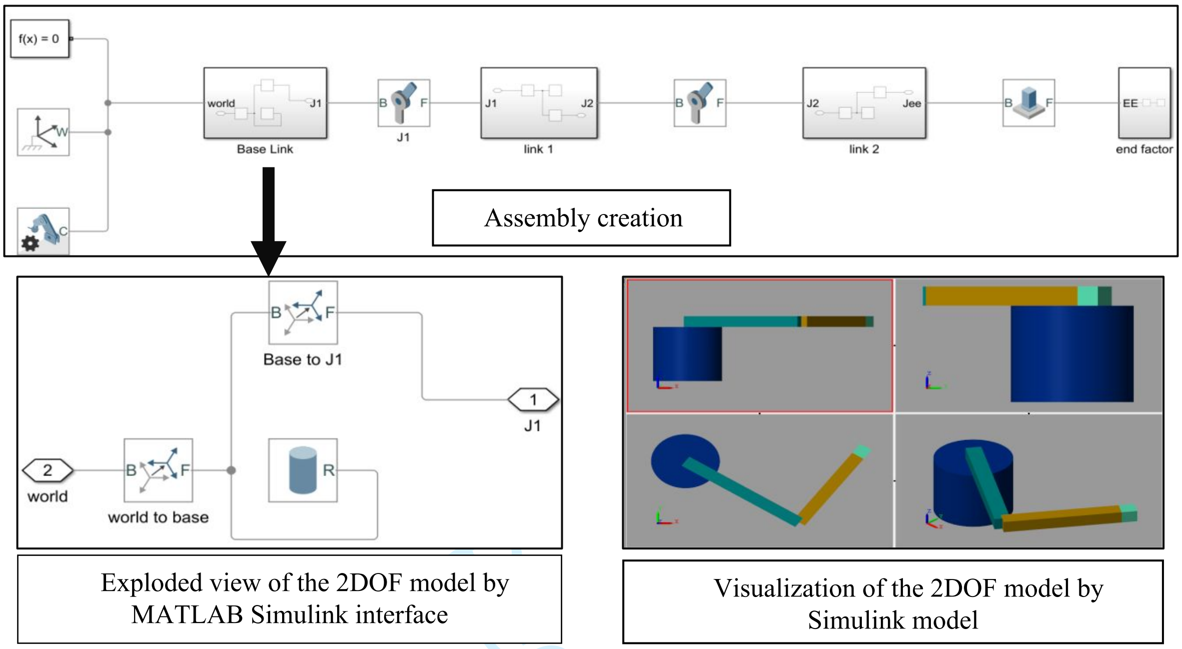


Fig. 2: Assembly creation of the 2-DOF linkage mechanism

Forward kinematics involves defining the position and orientation of each joint in the mechanism in terms of a set of joint angles or joint coordinates and then employing those values to determine the end effector's position and orientation with respect to some fixed reference frame, such as the robot's base as shown in Fig. 3. Here, the sinusoidal wave is inputted to each revolute joint to analyse the behaviour of the end-effector as shown in Fig. 4.

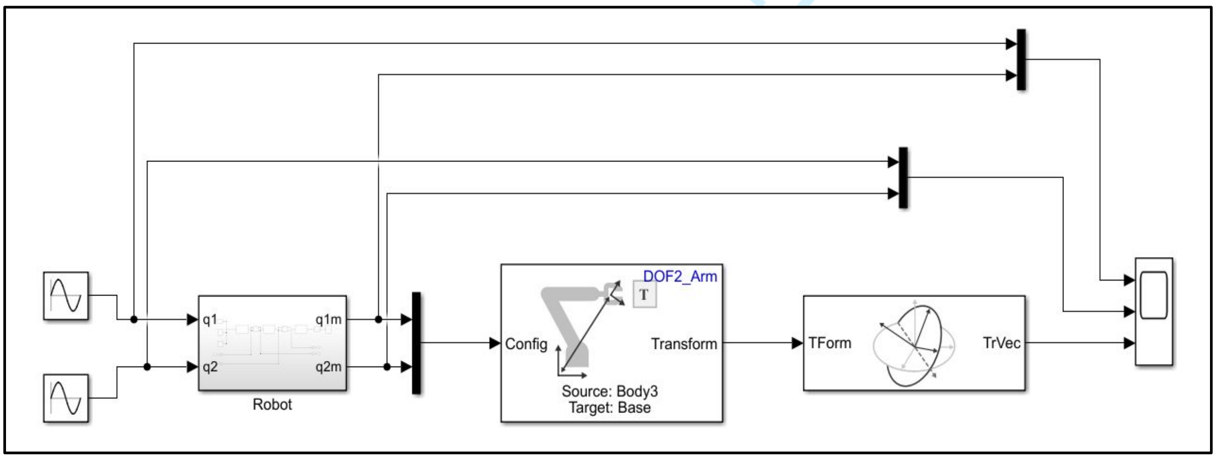


Fig. 3: Forward kinematics of 2-DOF

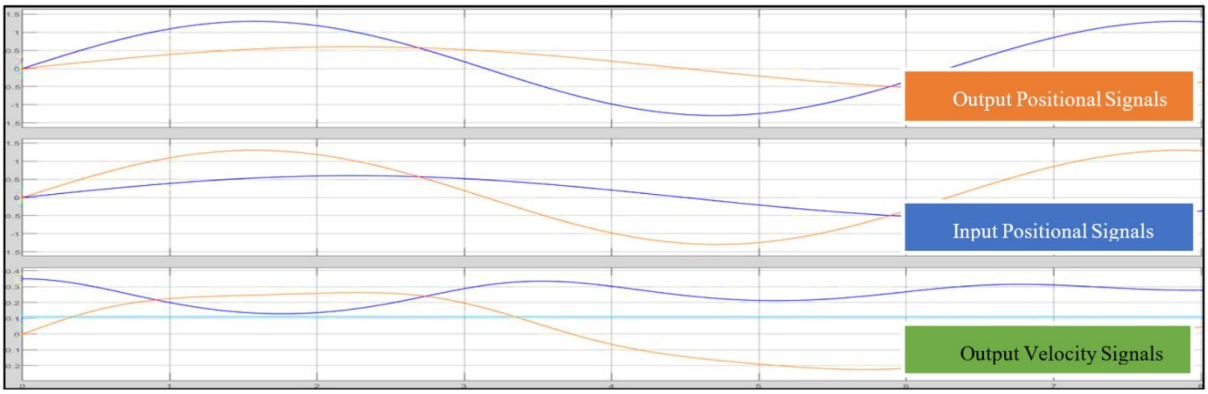


Fig. 4: Behaviour of sinusoidal wave after passing it to the robotic arm.

Inverse kinematics is widely used in robotics, animation, and other industries. Inverse Kinematics of 2- DOF is shown in Fig. 5, including its exploded view. It shows what input the system of moving parts needs to produce a certain result. Here, way-points (wp) were used for analysis purposes. This way-point creates a rectangular geometry on which the end-effector moved [13].

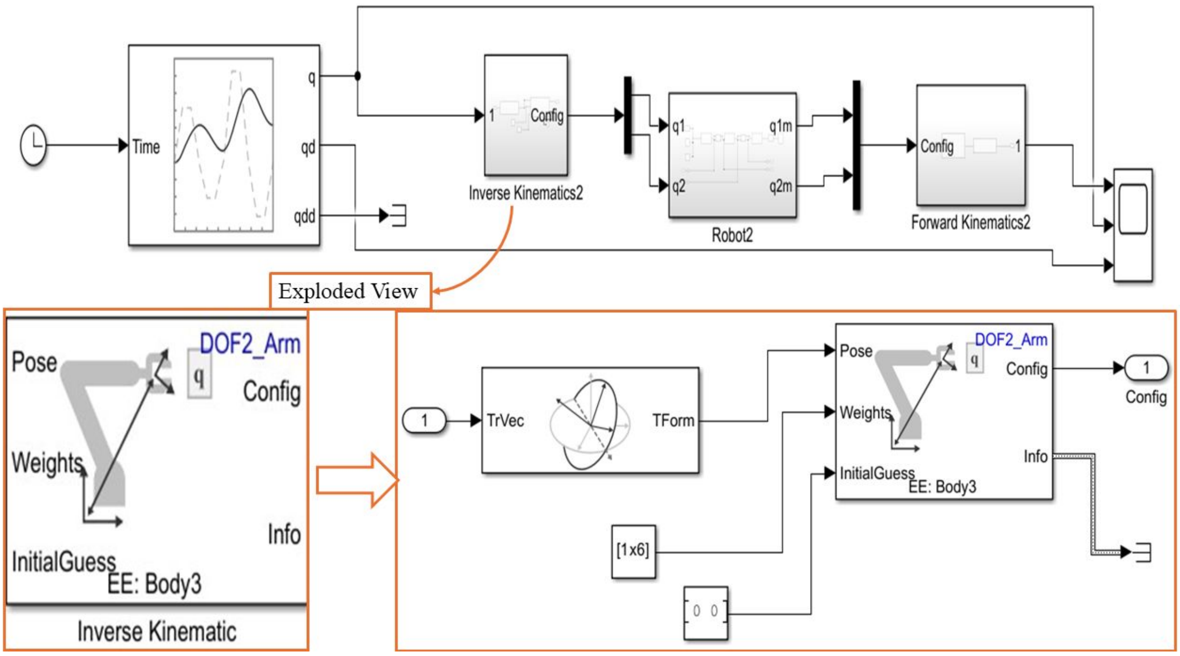


Fig. 5: Inverse kinematics of 2-DOF

The velocity profile of the end-effector is shown in the third section of Fig. 6, along with the end-effector's position in the first section.

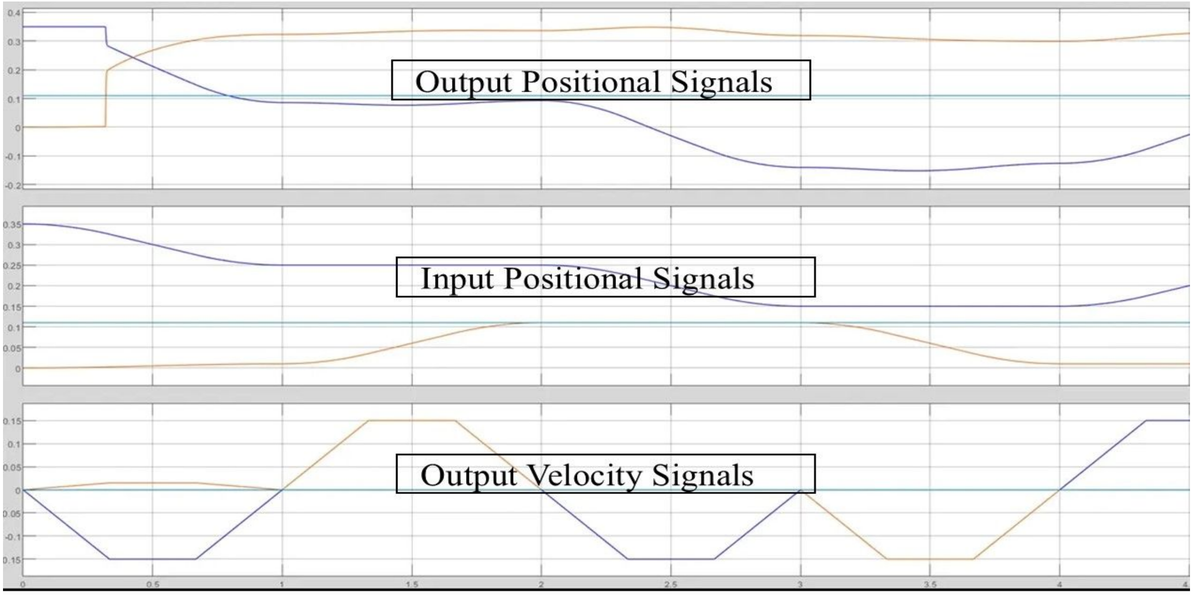


Fig. 6: Position and velocity profile of end-effector

The output velocity profile shows the sinusoidal graphical waveform of the end-effector link in a 2-DOF linkage mechanism. It is plotted as a function of the input link angle or the time elapsed during the motion. It depicts the variation of speed at different points along with linkage movement. Based on the learnings of the 2-DOF linkage mechanism, the next section is developed for 3-DOF kinematic analysis.

2.2 Linkage Mechanism: 3-DOF

This assembly creation was done by using a MATLAB Simulink interface. Here the base Link is a predefined cylindrical block as shown in Fig.7.

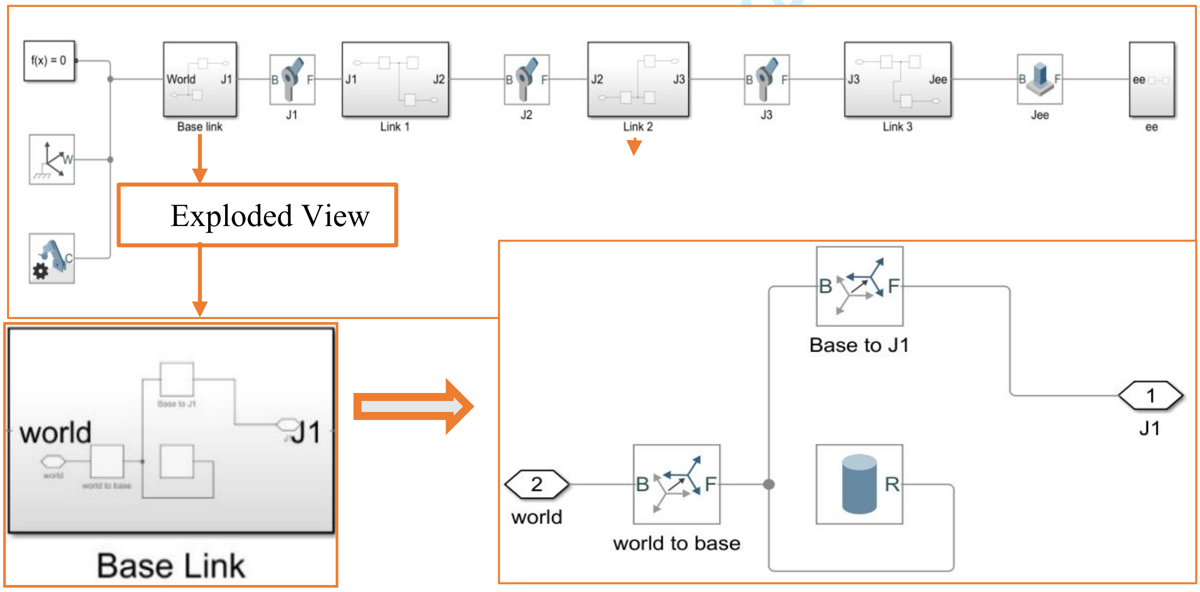


Fig. 7: Assembly creation and exploded view of base link subsystem

After running the Simulink model on MATLAB, the 3-DOF Linkage mechanism visualisation outcome is shown in Fig. 8.

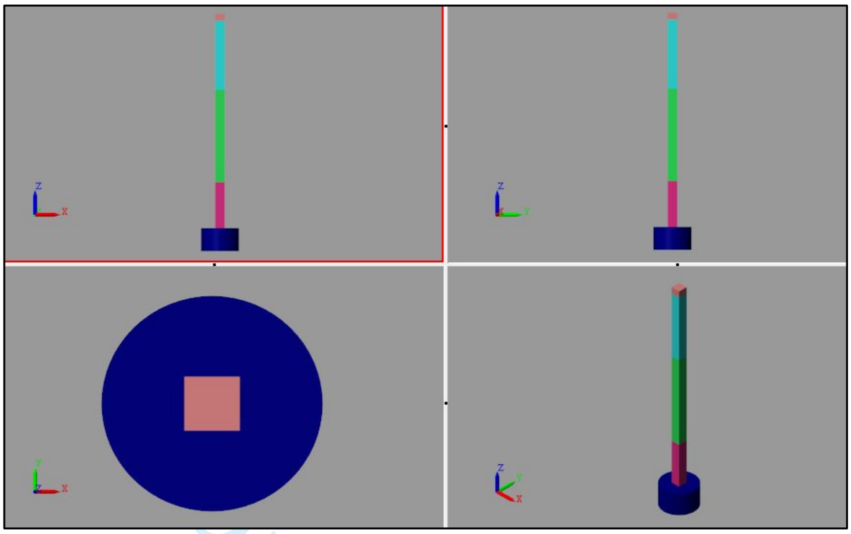


Fig. 8: 3-DOF linkage mechanism.

The 3-DOF linkage mechanism has 4 links, which are shown in different colours to distinguish between links. Forward kinematics of 3-OF are shown in Fig. 9 to analyse the behaviour of this mechanism. The detailed exploded view of the forward kinematics of 3-DOF is also shown in Fig. 9, with detailed link information.

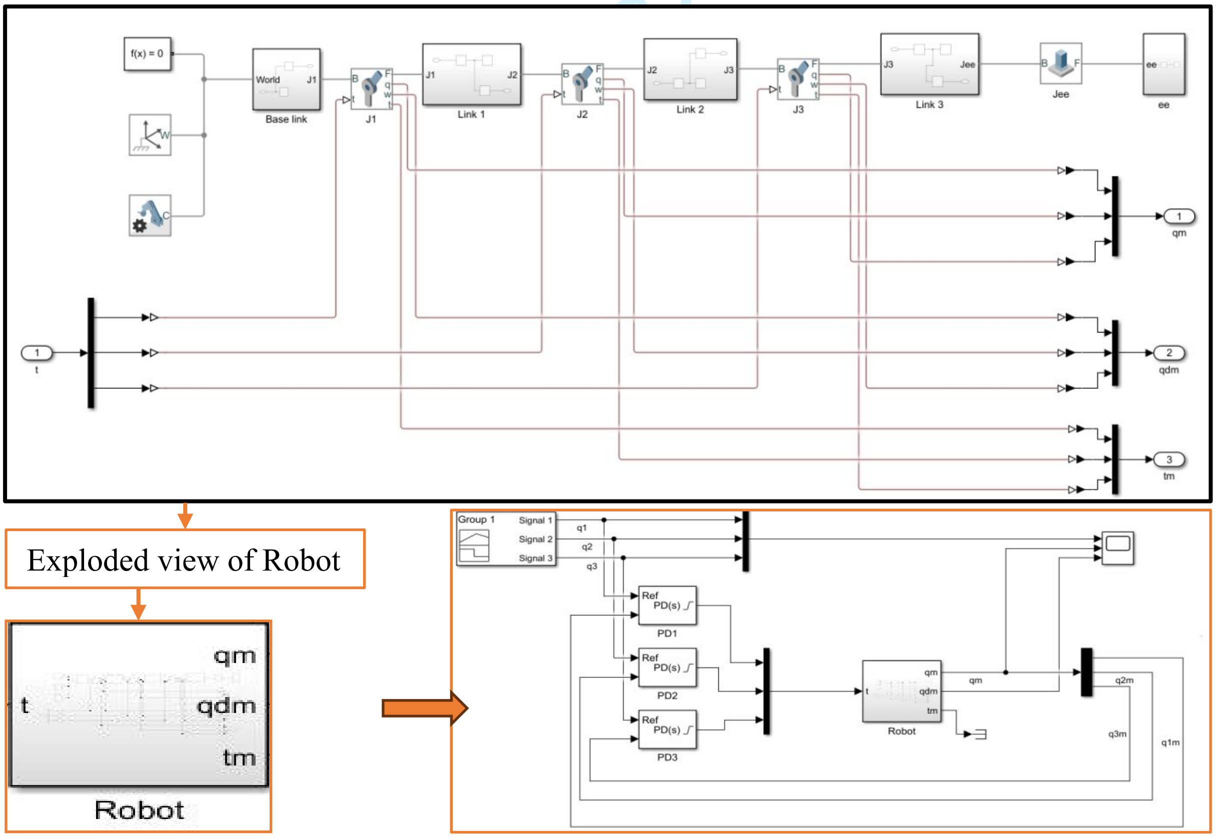


Fig. 9: Forward kinematics of 3-DOF and exploded view of robot subsystem.

The system has an input signal in terms of torque given to all the joints of clubfoot orthosis and corresponding links.

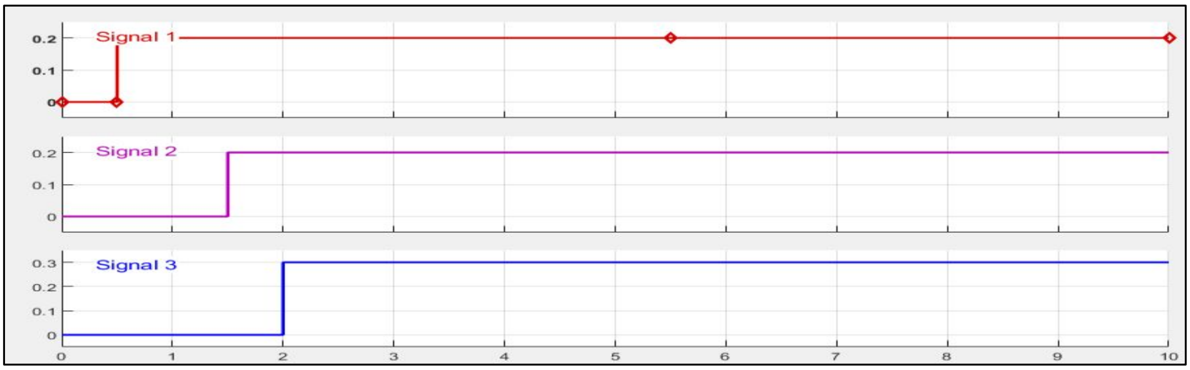


Fig. 10: Input signals for forward kinematics of 3-DOF

It was retrieving the values of position, velocity, and output torque of the end-effector. Fig. 10 depicts the input signals given to each joint of clubfoot orthosis. The Fig. 11 shows the input and output signal of velocity as well as the position of each point.

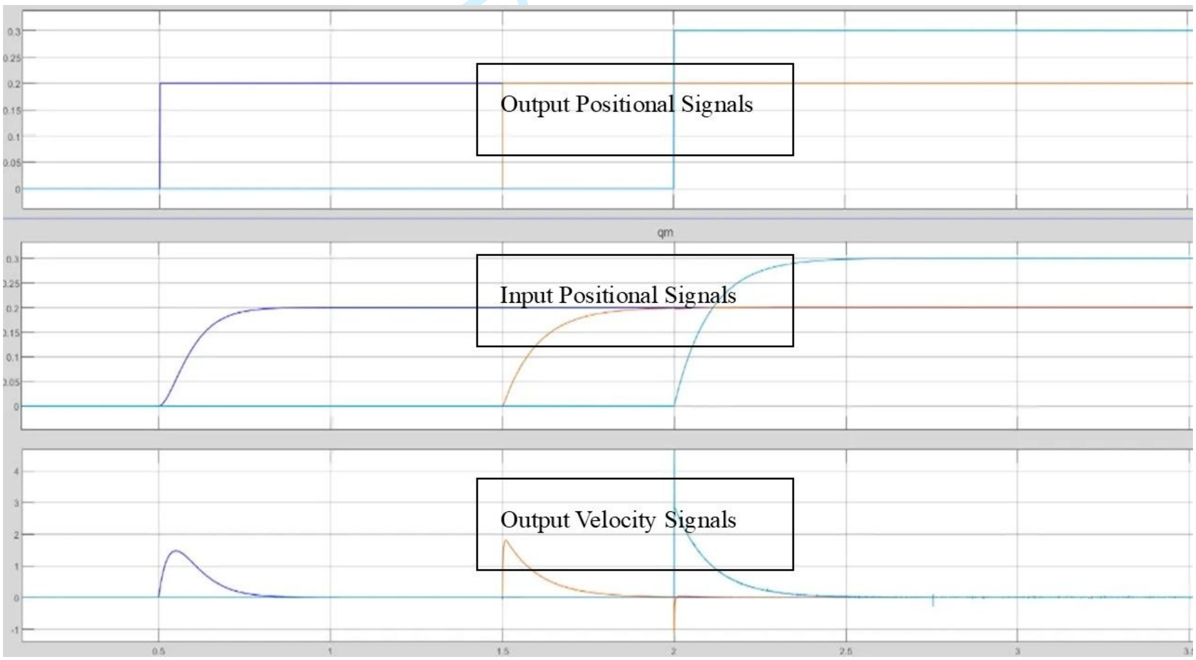


Fig. 11: Input and output signals of velocity and position of each joint.

Inverse kinematics analysis of 3-DOF Here, way-points (wp) are used for analysis purposes. This way-point creates a rectangular geometry on which the end-effector moved. The line diagram of inverse kinematics of 3-DOF is shown in Fig. 12, and the detailed exploded view of the kinematic subsystem is also shown.

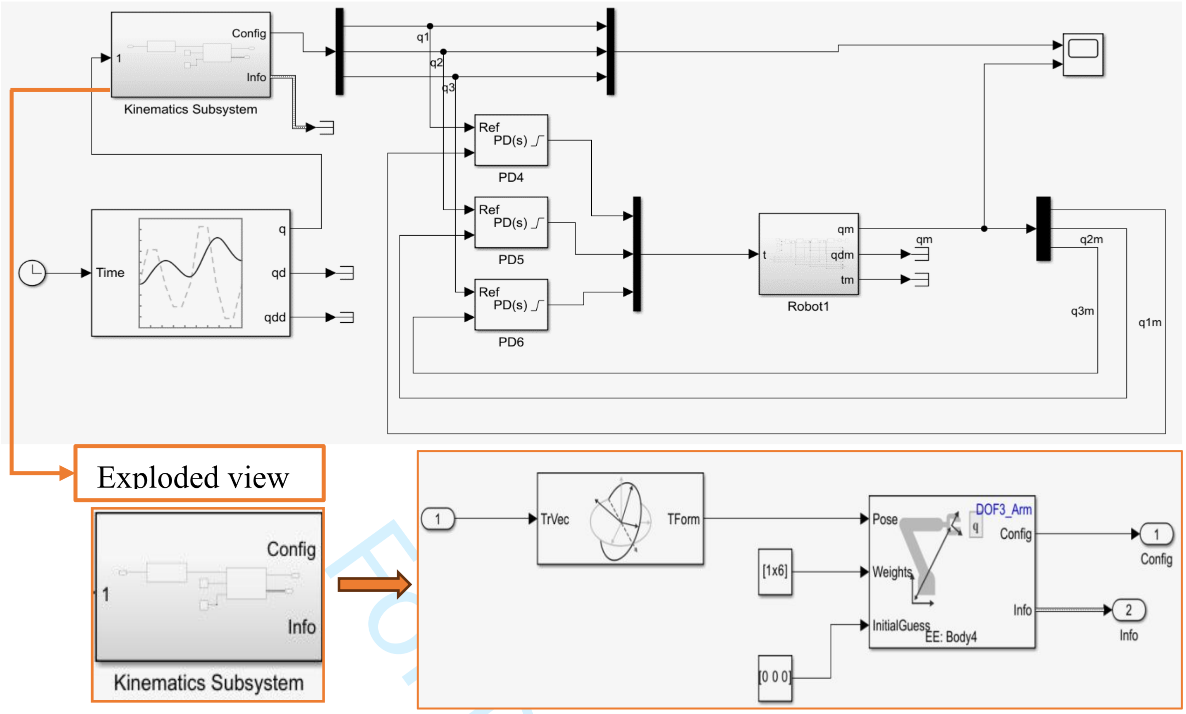


Fig. 12: Inverse kinematics of 3-DOF and exploded view of the kinematic subsystem.

2.3 Linkage Mechanism (Clubfoot Orthosis): 6-DOF

After developing the two and three DOF mechanisms and analysing their kinematics, the 6-DOF mechanism on the CTEV orthosis was analysed. In this CTEV orthosis design, three rotational motions were actuated using the revolute joint. This assembly was created using the Onshape web CAD modelling application and then integrated into the MATLAB Simulink interface, as shown in Fig. 13. Clubfoot orthosis consists of six revolute joints placed on each pivot point to get the desired motion in Yawing, Rolling and Pitching for the forefoot and hindfoot with the help of worm and worm gear mechanism [14]. The complete assembly is shown in Fig. 13.

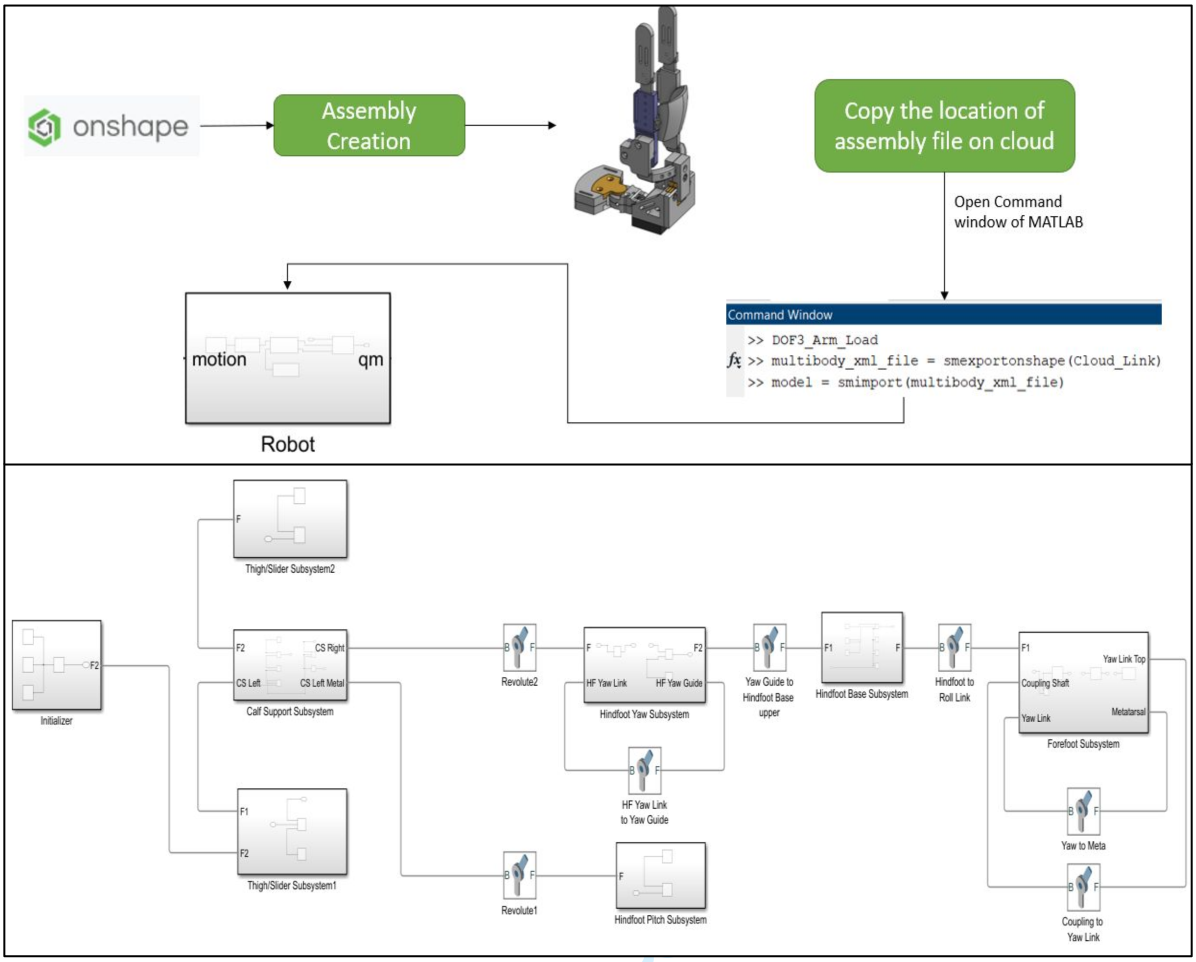
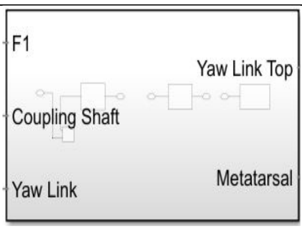
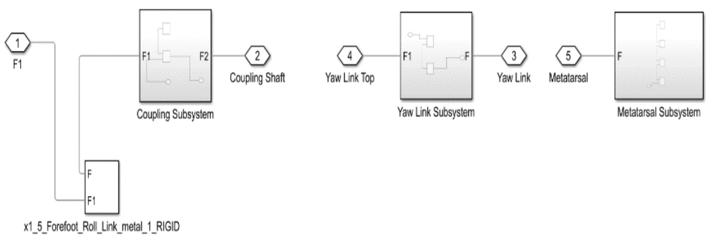
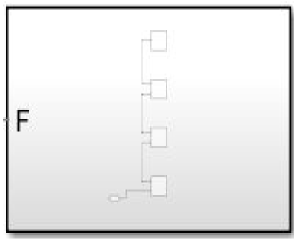
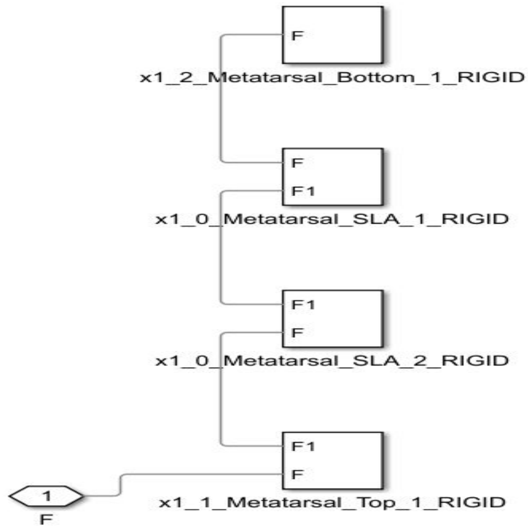
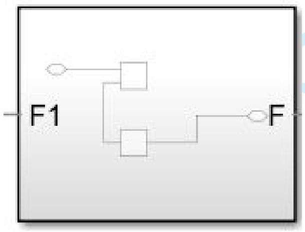
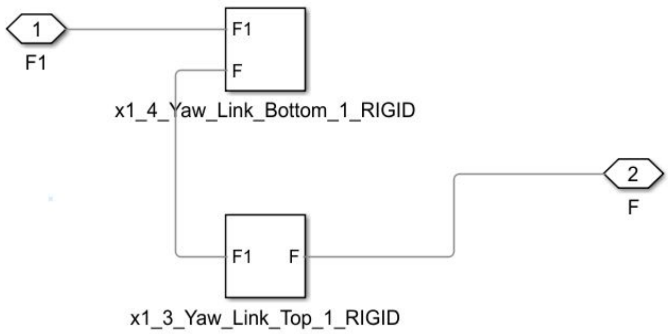
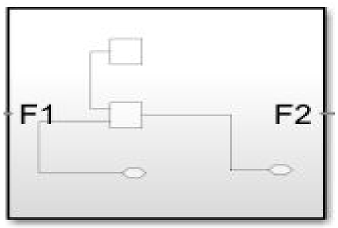
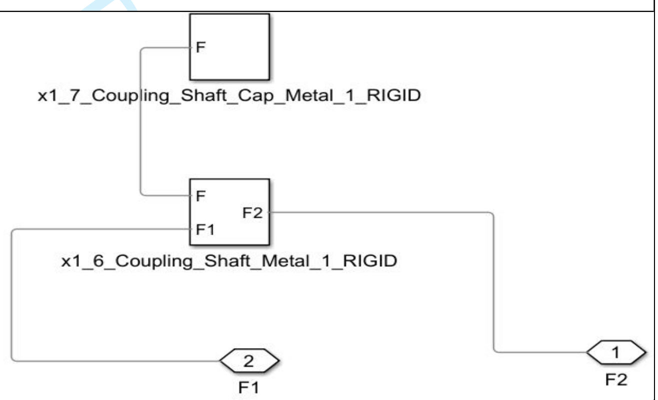
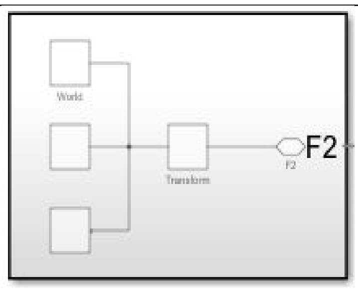
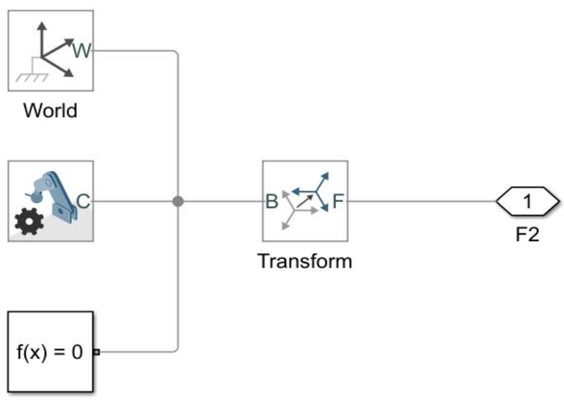


Fig. 13: Clubfoot Assembly and Clubfoot assembly creation on MATLAB environment.

The selected subsystem of the clubfoot orthosis's component parts is exploded and shown in Table 1. below, reveal their precise placement and the precise six motions utilised in its construction. Forefoot subsystem, Metatarsal subsystem, yaw link subsystem, Coupling Subsystem, hindfoot base subsystem, hindfoot yaw subsystem, hindfoot pitch subsystem, thigh/slider subsystem1, thigh/slider subsystem2, calf support subsystem and all these subsystems are assembled to make an initialiser system.

Table 1. Exploded view of all the subsystems used in Clubfoot Orthosis.

Sr.	Subsystem	Exploded View
1	 Forefoot Subsystem	

2	 Metatarsal Subsystem	
3	 Yaw Link Subsystem	
4	 Coupling Subsystem	
11	 Initializer	

The above table discusses the subsystem of CTEV orthosis, and when doing analysis, the forward kinematics of 6-DOF has many external disturbances exerted while running the model on the real condition. A Proportional-Derivative (PD) controller filters all seven signals given to each revolute joint to reduce the external noise. This PD controller was tuned by a MATLAB tuning file. After running the tuning function, the PD controllers were able to predict and control the variation in the system. The detailed forward kinematics of clubfoot is shown in Fig. 14.

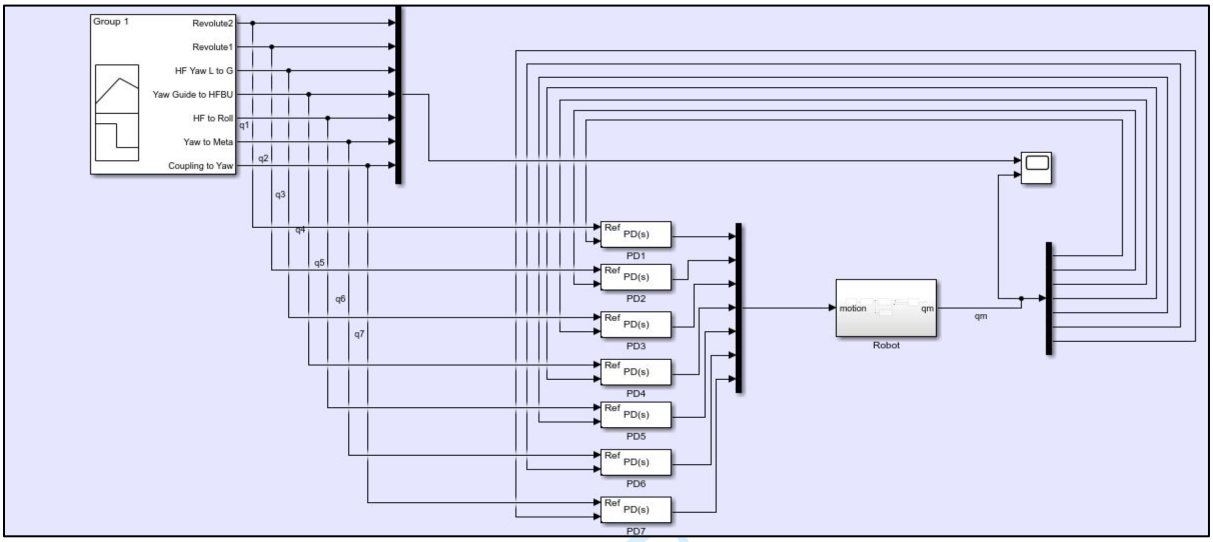


Fig. 14: Forward kinematics of Clubfoot

In forward kinematics, the defined signals are given to the assembly. The outputs in the top section of Fig. 15 show the input signals given to each revolute joint of clubfoot orthosis, and the below section shows the output positional signals, which were controlled by the PD controller to reduce the external environmental variation.

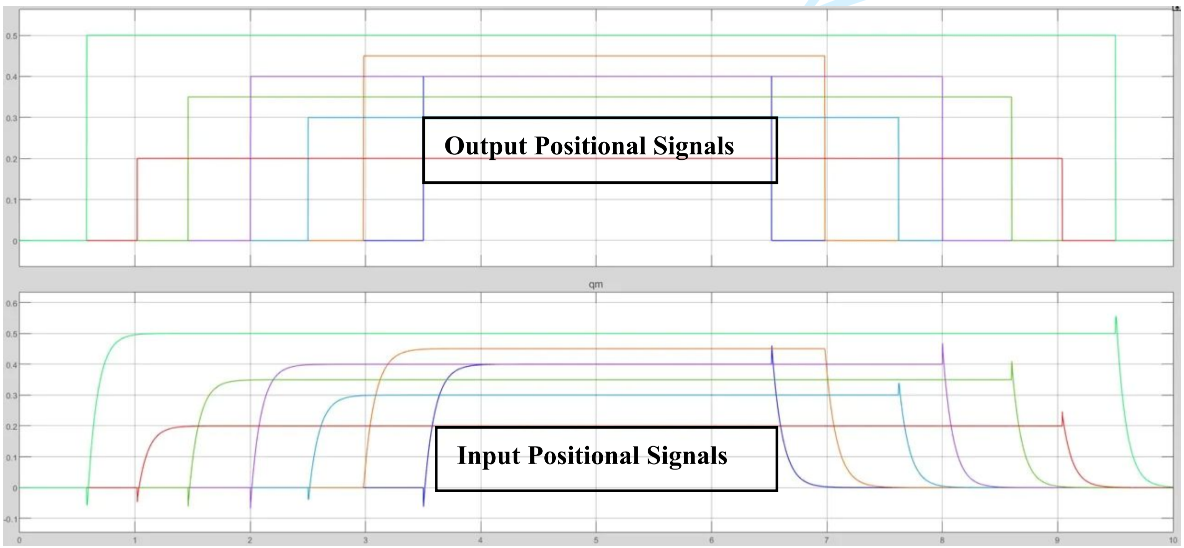


Fig. 15: Input and output signals of each joint

For the inverse kinematics analysis of 6-DOF, there is a way-point (wp1) for the CTEV orthosis movement analysis. The Fig. 16 shows the

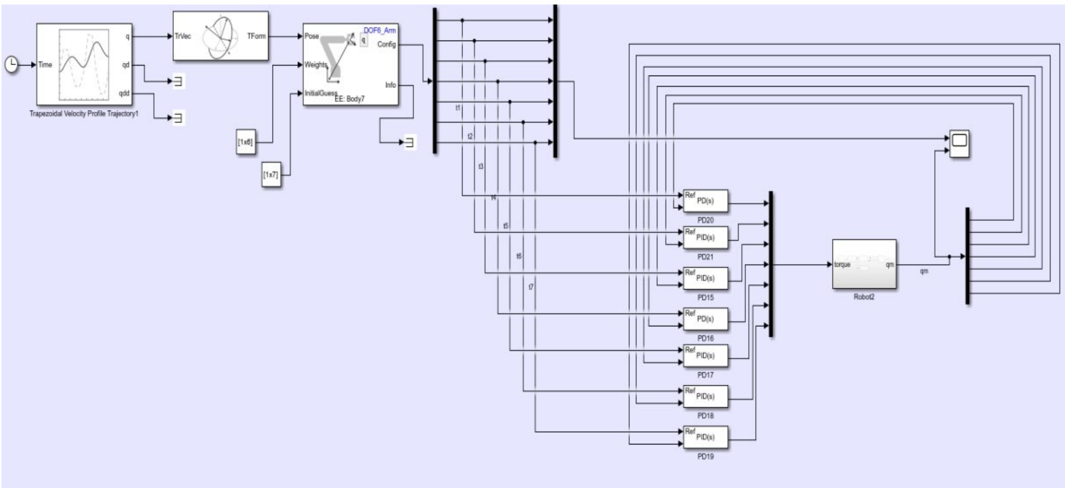


Fig. 16: Inverse kinematics of Clubfoot

This way-point (wp1) creates a path in three-dimensional space in which the end-effector was moving. Here, a trapezoidal profile trajectory is used, followed by an end-effector of the CTEV orthosis. The end effector trajectory analysis follows the gold standard CTEV correction sequence based on understanding Dr Ponseti's biomechanics and treatment method.

3 Results and Discussion

In forward kinematics, the sinusoidal wave is inputted to analyse the behaviour of the end-effector on both revolute joints in the 2-DOF mechanism, but the actual sinusoidal wave behaviour is not obtained while running the 2-DOF model onto the real condition. So, way-points (wp) were used for analysis in the inverse kinematics. This way-point (wp) creates a rectangular geometry on which the end-effector moved. The end-effector's velocity profile shows that the sinusoidal wave is smooth with negligible errors. This expected outcome was applied to 3-DOF linkage mechanisms, and the same forward and inward kinematics motion trajectory analysis was done, as well as the 6-DOF linkage mechanism for unilateral clubfoot orthosis assembly. For the 2 and 3 DOFs, both the forward and inverse kinematics were straightforward problems due to well-defined simple situations for predicting position and angle movement. 6-DOF kinematics for CTEV orthosis had significant challenges due to the intricacies of numerous subsystems. However, the results show accurate trajectory CTEV correction in orthosis movement based on the biomechanics of the Ponseti method. These results underscore the feasibility of using 6 DOF kinematics for advanced CTEV orthotic devices.

4 Conclusions

The study started with a detailed investigation of the CTEV condition, current treatment options, existing CTEV orthosis designs, and the concept behind the orthosis design. Kinematic Simulation of 6-DOF Clubfoot (CTEV) Corrective Orthosis has been carried out in this study for the primary objective to design a highly functional CTEV orthosis addressing the biomechanical understanding of the Ponseti method. The following conclusions are drawn to improve the functionality of the 6-DOF CTEV orthosis mechanism and investigate the scope of implementing automation in it.

- Considering the automation of orthosis the trajectory identification has been carried out, which the child's foot has to take, and inverse kinematics was used to determine the step angle of each joint so that it could be actuated.
- The forward kinematics model was also investigated so that manual override by the doctor is possible.
- This research shown that for developing a proxy of the initial model, which could be working on the principle of accessibility to everyone.
- Based on this study different types of shape and size alterations according to anthropometric studies of Clubfoot can be incorporated into the kinematics mechanism, using both forward and inverse kinematics analysis.
- Design changes may be done to incorporate these sensors and motors in the orthosis.

Funding: This work was supported partially through grant number BIRAC/SIIC0107/BIG-14/19 by the Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT), Government of India and subsequent startup Jaipur Club Foot Pvt. Ltd.

Reference

[1] Riemen, A. H., Lim, J. W., Wong, K. Y., Campbell, D., Pease, F. J., and Barker, S. L., 2022, "Current Understandings in Congenital Talipes Equinovarus," Orthopaedics and Trauma, **36**(6), pp. 295–303. https://doi.org/10.1016/j.mporth.2022.09.001.

[2] Singh, S., and Mali, H. S., 2023, "Foot Abduction Orthosis Compliance in Clubfoot Treatment," *3D Printing in Podiatric Medicine*, Elsevier, pp. 103–121. https://doi.org/10.1016/B978-0-323-91911-1.00012-2.

[3] Ganesan, B., Luximon, A., Al-Jumaily, A., Balasankar, S. K., and Naik, G. R., 2017, "Ponseti Method in the Management of Clubfoot under 2 Years of Age: A Systematic Review," PLOS ONE, **12**(6), p. e0178299. https://doi.org/10.1371/journal.pone.0178299.

[4] Singh, S., and Mali, H. S., 2022, "Clubfoot: Review on Assessment, Treatment, Challenges, and Engineering Aspects," JPO Journal of Prosthetics and Orthotics, **34**(3), pp. e114–e130. https://doi.org/10.1097/JPO.0000000000000431.

[5] Kadhum, M., Lee, M.-H., Czernuszka, J., and Lavy, C., 2019, "An Analysis of the Mechanical Properties of the Ponseti Method in Clubfoot Treatment," Applied Bionics and Biomechanics, **2019**, pp. 1–11. https://doi.org/10.1155/2019/4308462.

[6] Kumar, S., Bongardt, B., Simnofske, M., and Kirchner, F., 2019, "Design and Kinematic Analysis of the Novel Almost Spherical Parallel Mechanism Active Ankle," Journal of Intelligent & Robotic Systems, **94**(2), pp. 303–325. https://doi.org/10.1007/s10846-018-0792-x.

[7] Hroncova, D., Mikova, L., Prada, E., Rakay, R., Jan Sincak, P., and Merva, T., 2022, "Forward and Inverse Robot Model Kinematics and Trajectory Planning," *2022 20th International Conference on Mechatronics - Mechatronika (ME)*, IEEE, pp. 1–9. https://doi.org/10.1109/ME54704.2022.9983355.

[8] Lee, T.-Y., and Shim, J.-K., 2001, "Forward Kinematics of the General 6–6 Stewart Platform Using Algebraic Elimination," Mechanism and Machine Theory, **36**(9), pp. 1073–1085. https://doi.org/10.1016/S0094-114X(01)00034-9.

[9] Yang, G., Mustafa, S. K., Yeo, S. H., Lin, W., and Lim, W. Bin, 2010, "Kinematic Design of an Anthropomimetic 7-DOF Cable-Driven Robotic Arm," Frontiers of Mechanical Engineering in China. https://doi.org/10.1007/s11465-011-0205-3.

[10] Hosseinzadeh, P., and Milbrandt, T. A., 2014, "Congenital Clubfoot," JBJS Reviews, **2**(3). https://doi.org/10.2106/JBJS.RVW.M.00078.

[11] Singh, S., Mali, H. S., and Jain, A. K., 2023, "Contemporary Challenges in Clubfoot Treatment: A Quantitative Study among Indian Parents," Journal of Orthopaedics, **37**, pp. 5–8. https://doi.org/10.1016/j.jor.2023.01.009.

[12] Koraaa, M. M., Ghamry, K. A., Abo-Elnor, M. E., and Elsherif, I. A., 2024, "Inverse Kinematics Analysis of a 2-DOF Stabilized Platform Using Simulink and Simscape," Journal of Physics: Conference Series, **2811**(1), p. 012003. https://doi.org/10.1088/1742-6596/2811/1/012003.

[13] Goldenberg, A., Benhabib, B., and Fenton, R., 1985, "A Complete Generalized Solution to the Inverse Kinematics of Robots," IEEE Journal on Robotics and Automation, **1**(1), pp. 14–20. https://doi.org/10.1109/JRA.1985.1086995.

[14] Singh, S., 2024, "Design Thinking Based Development and Clinical Evaluation of Clubfoot Orthosis," MNIT Jaipur.

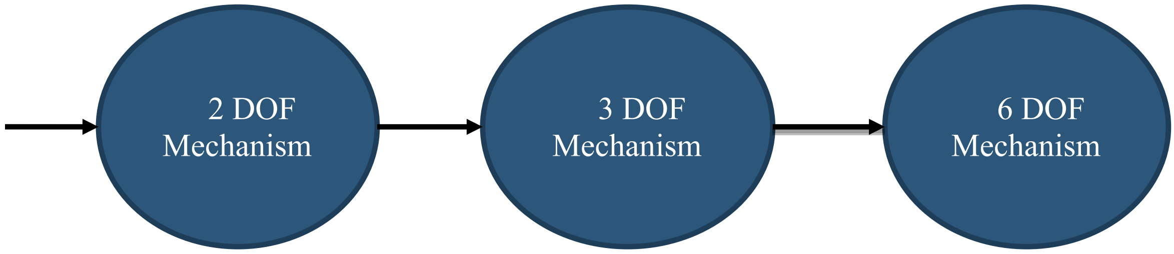


Fig. 1: Development of kinematics of CTEV orthosis

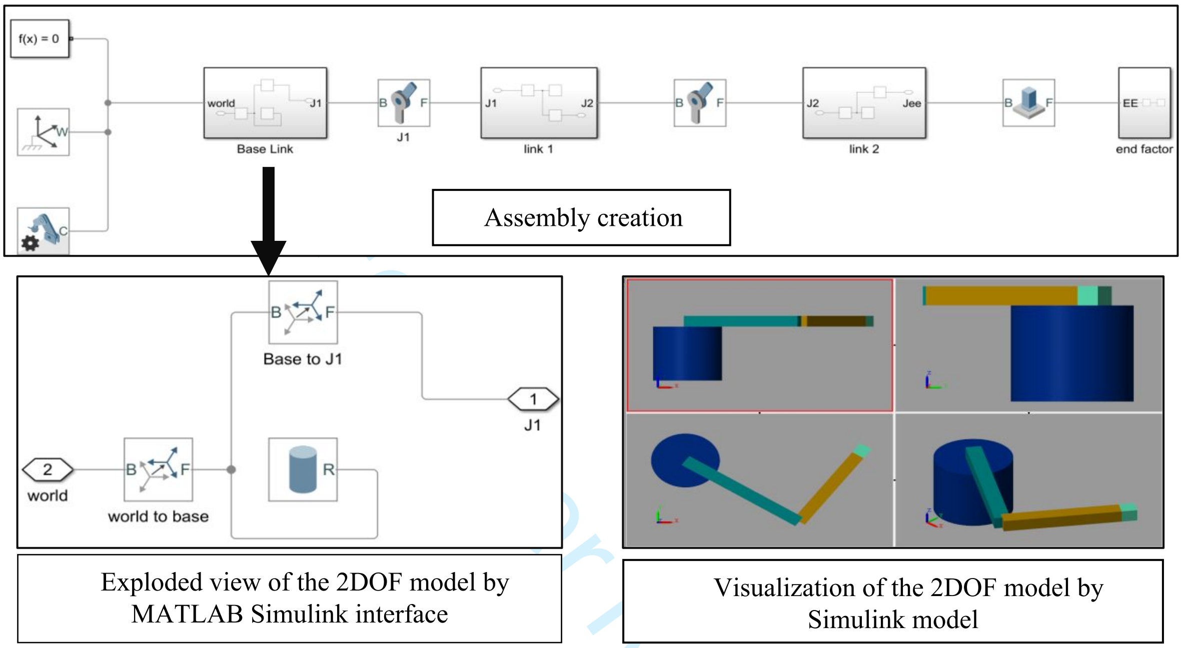


Fig. 2: Assembly creation of the 2-DOF linkage mechanism

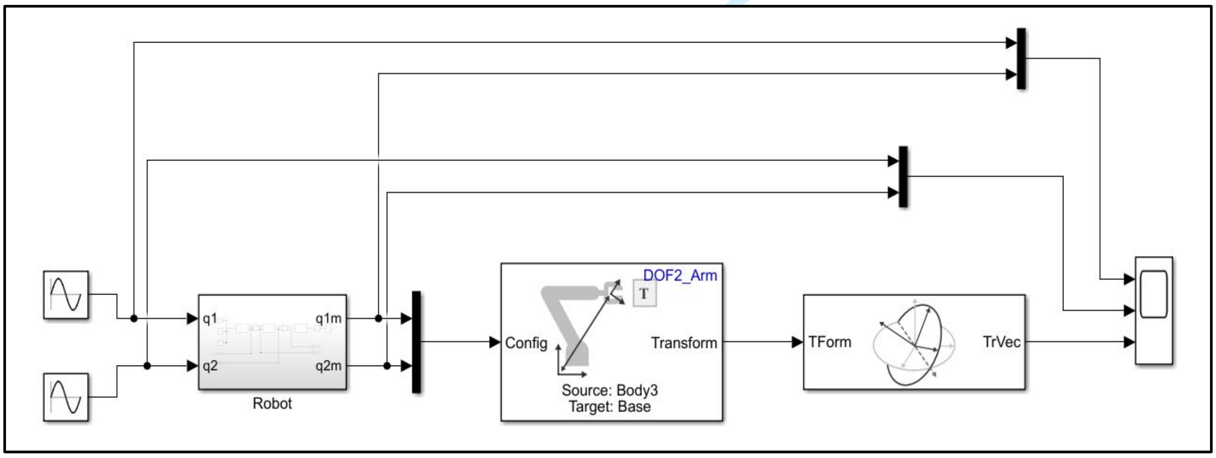


Fig. 3: Forward kinematics of 2-DOF

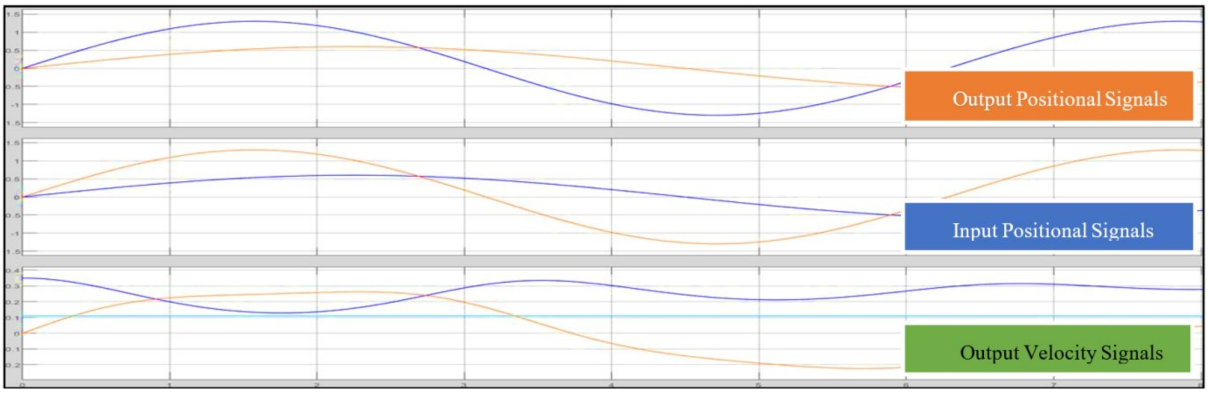


Fig. 4: Behaviour of sinusoidal wave after passing it to the robotic arm.

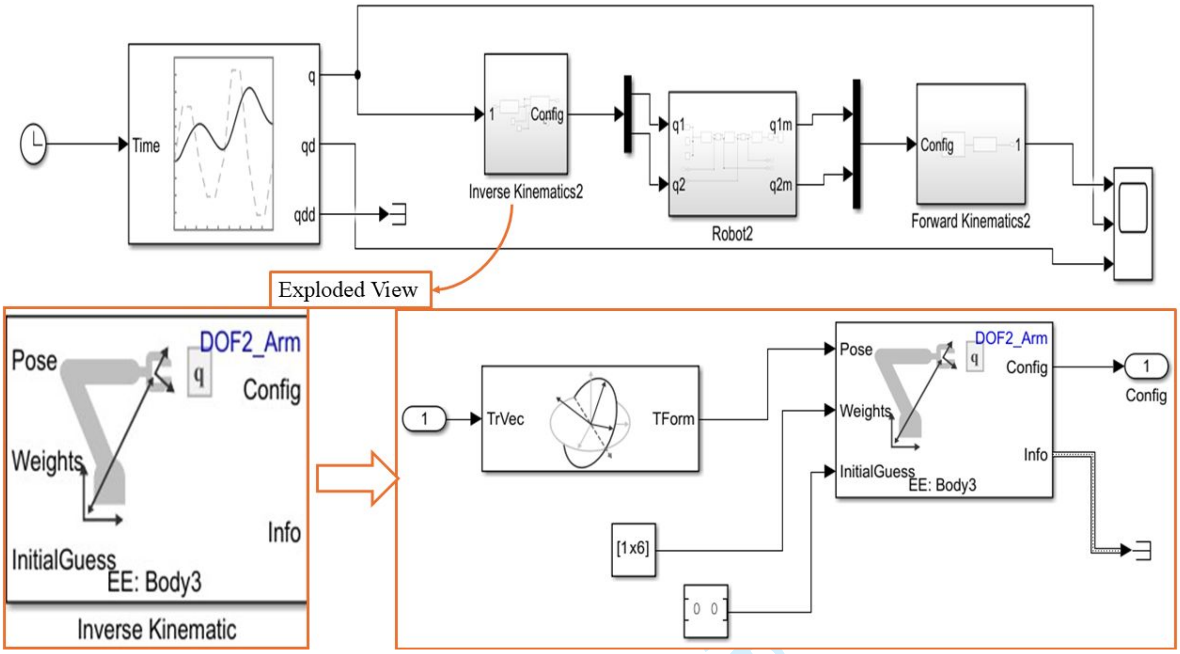


Fig. 5: Inverse kinematics of 2-DOF

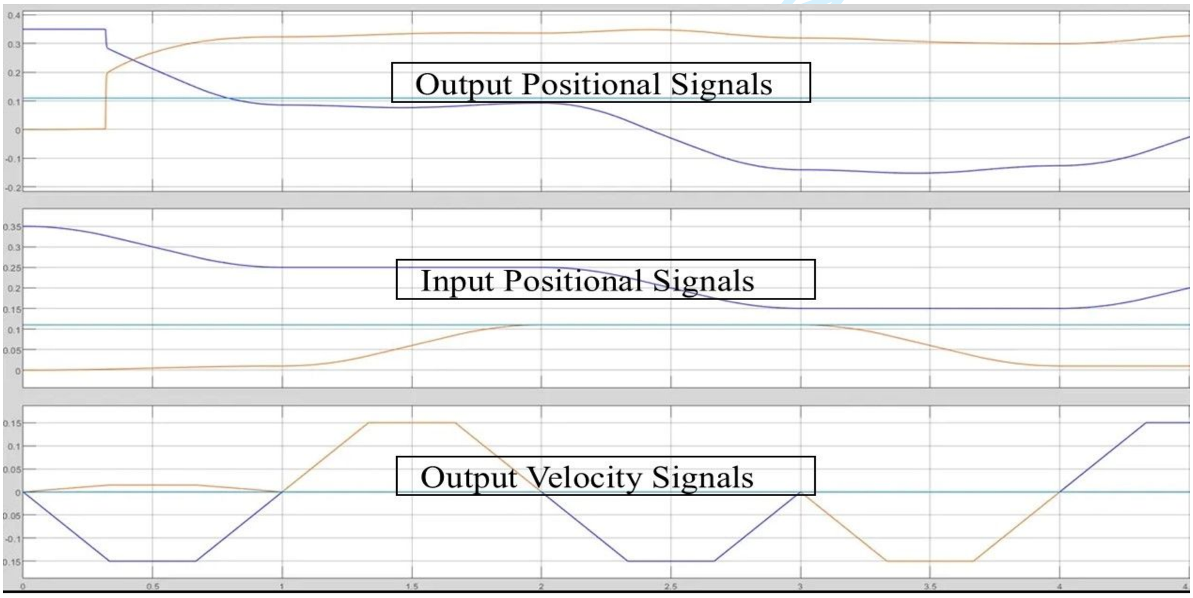


Fig. 6: Position and velocity profile of end-effector

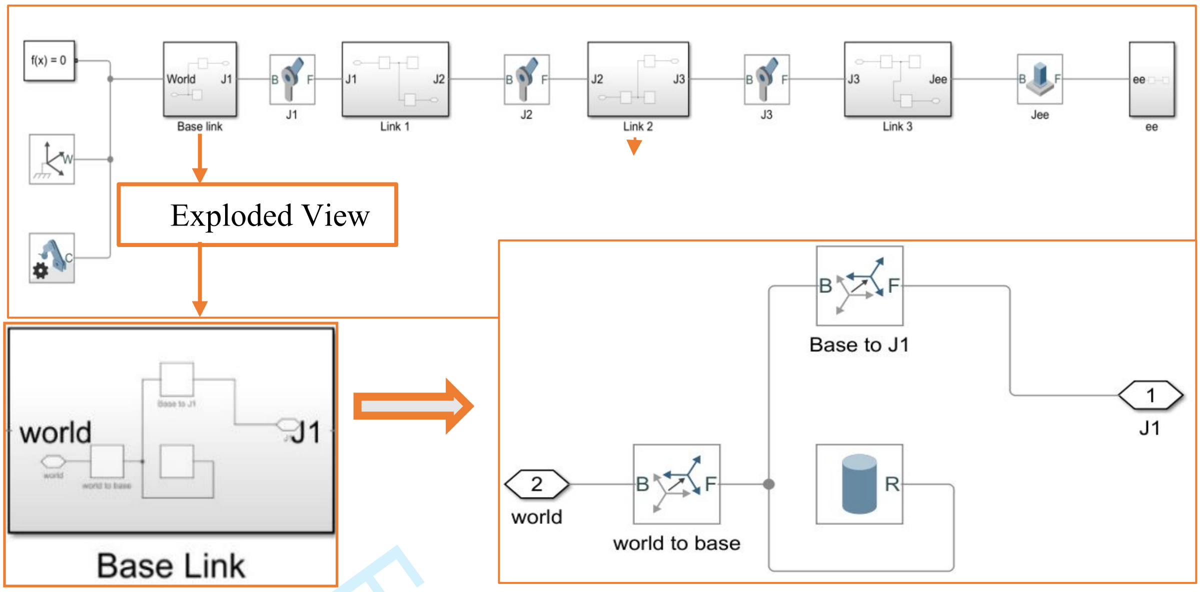


Fig. 7: Assembly creation and exploded view of base link subsystem

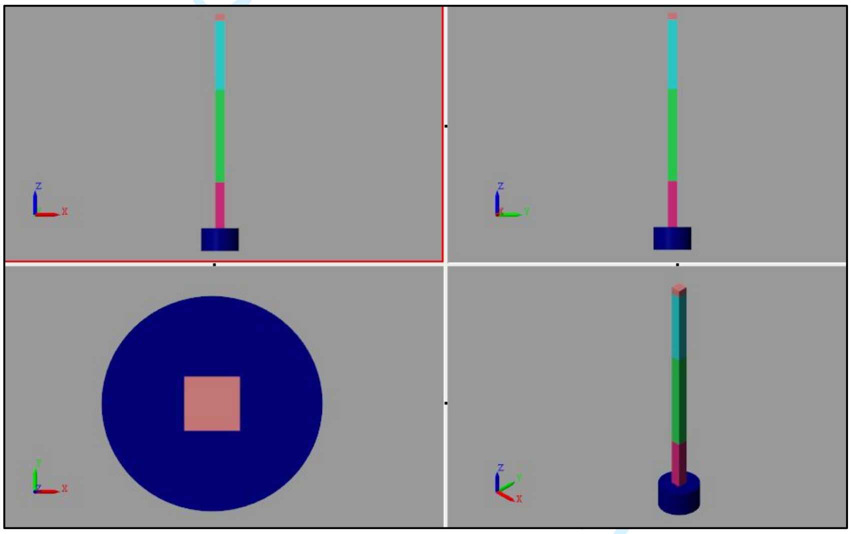


Fig. 8: 3-DOF linkage mechanism.

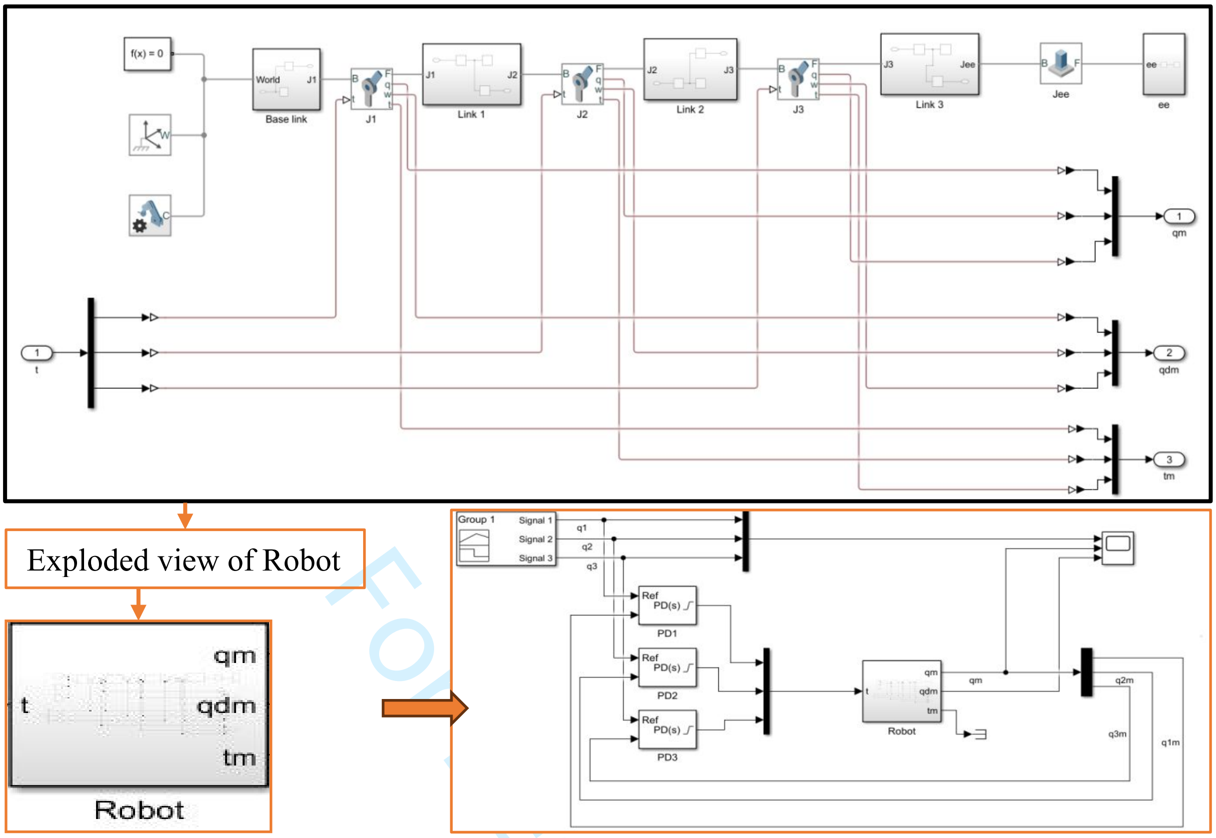


Fig. 9: Forward kinematics of 3-DOF and exploded view of robot subsystem.

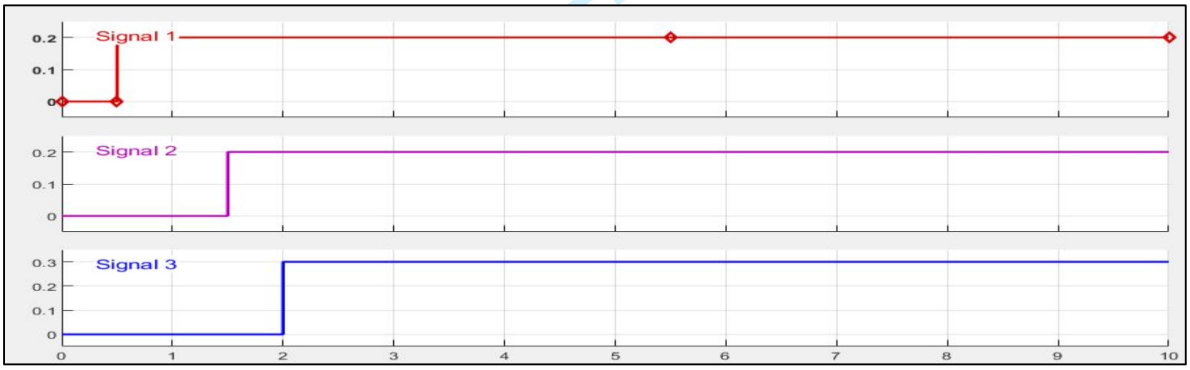


Fig. 10: Input signals for forward kinematics of 3-DOF

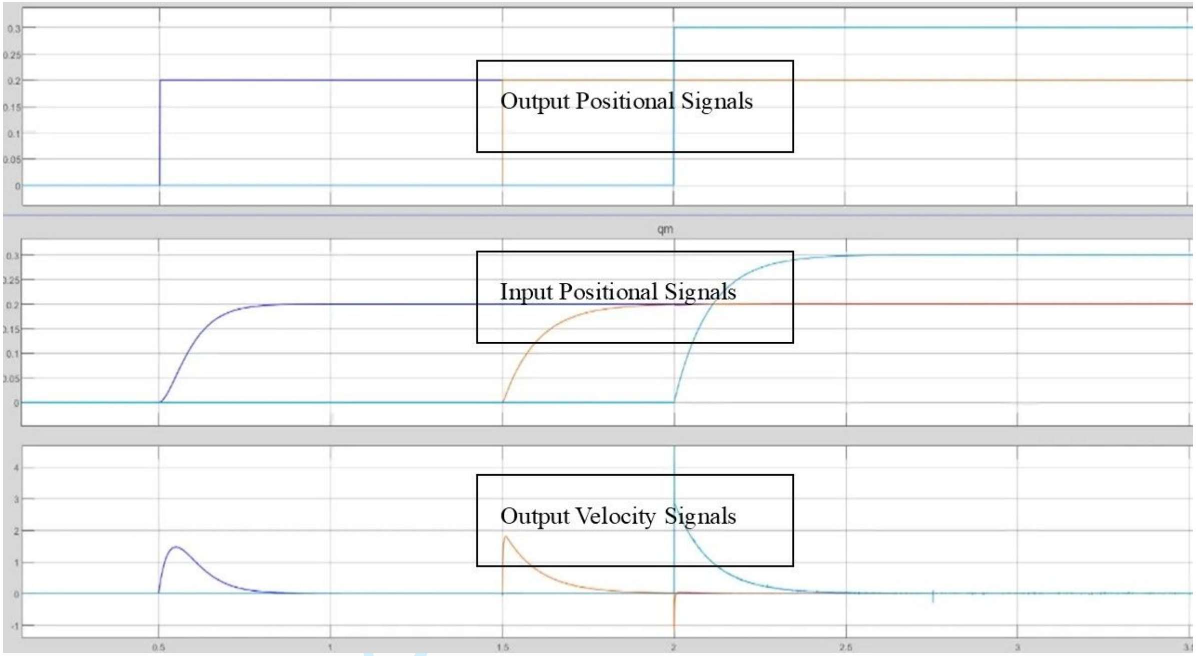


Fig. 11: Input and output signals of velocity and position of each joint.

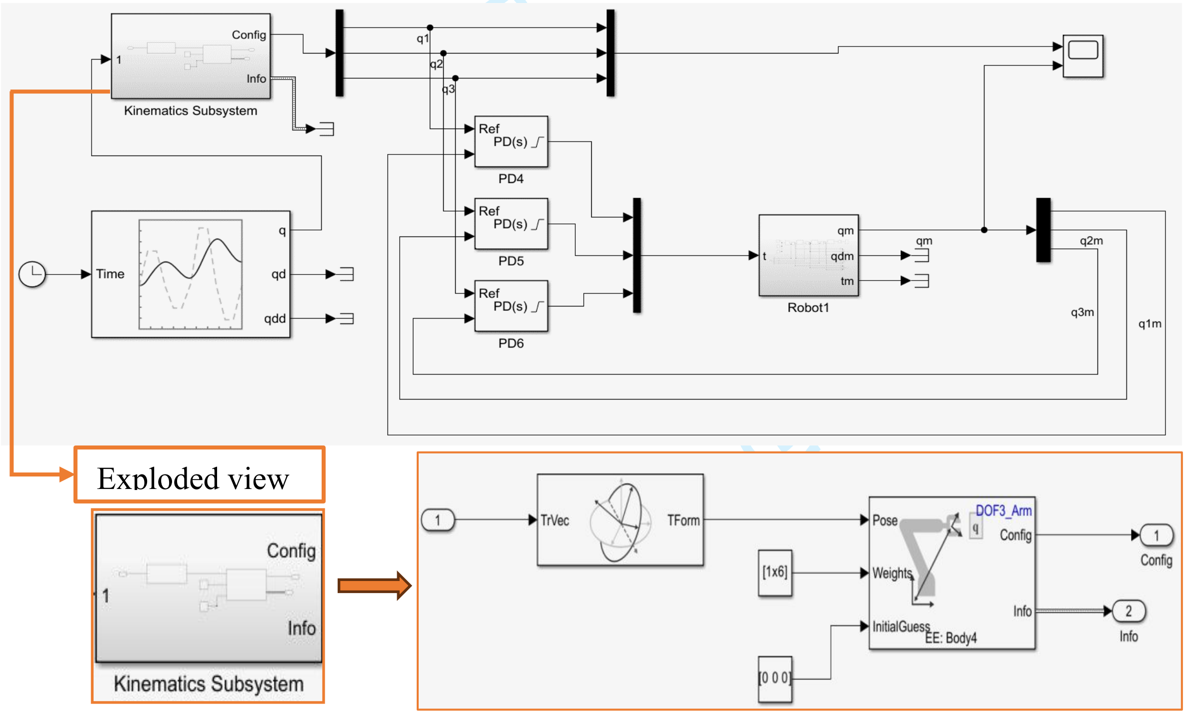


Fig. 12: Inverse kinematics of 3-DOF and exploded view of the kinematic subsystem.

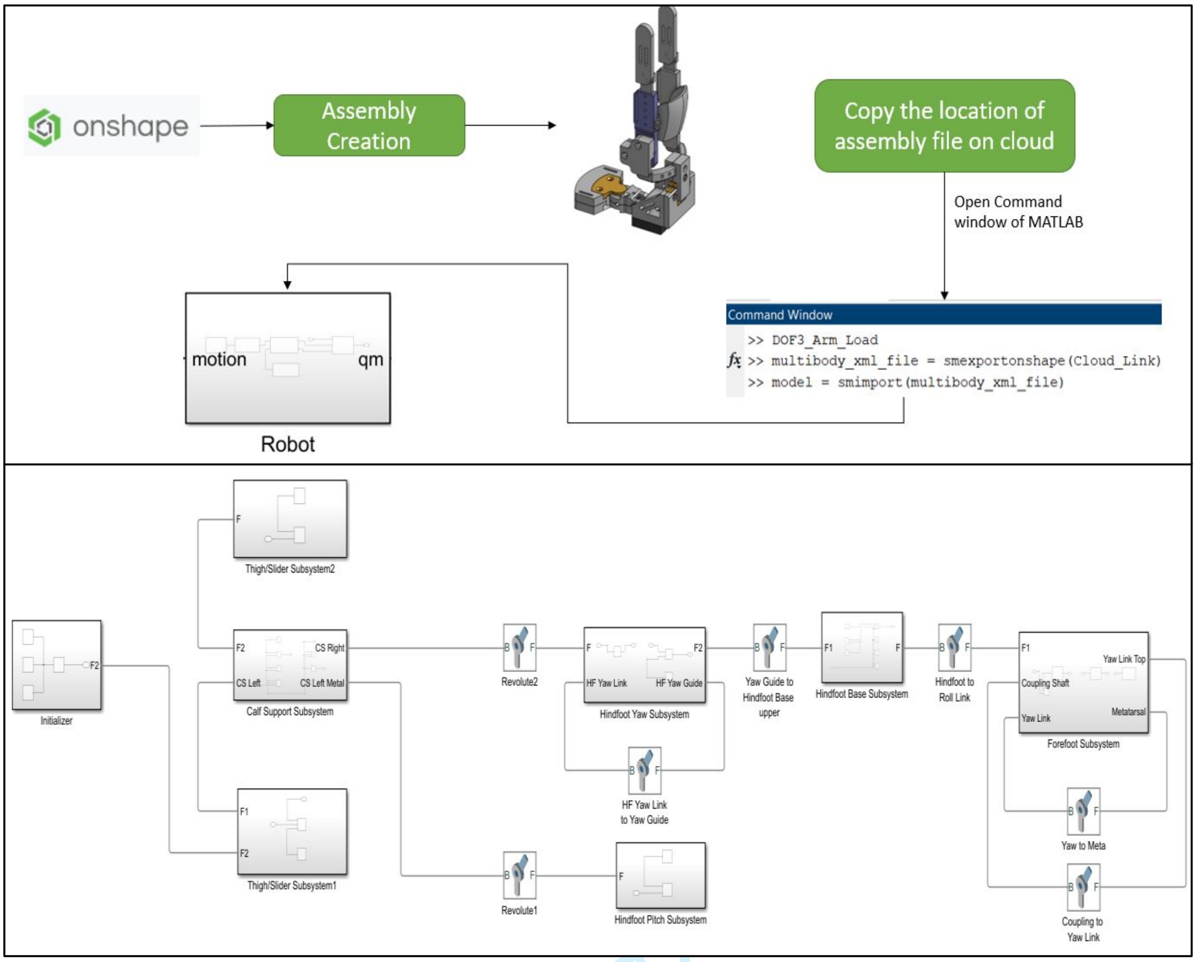


Fig. 13: Clubfoot Assembly and Clubfoot assembly creation on MATLAB environment.

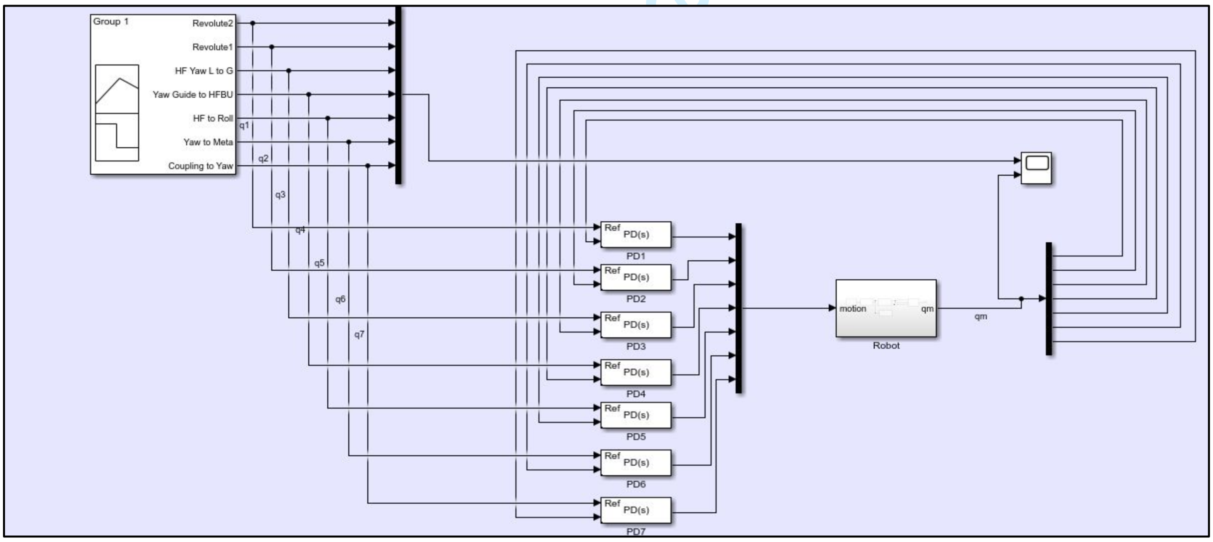


Fig. 14: Forward kinematics of Clubfoot

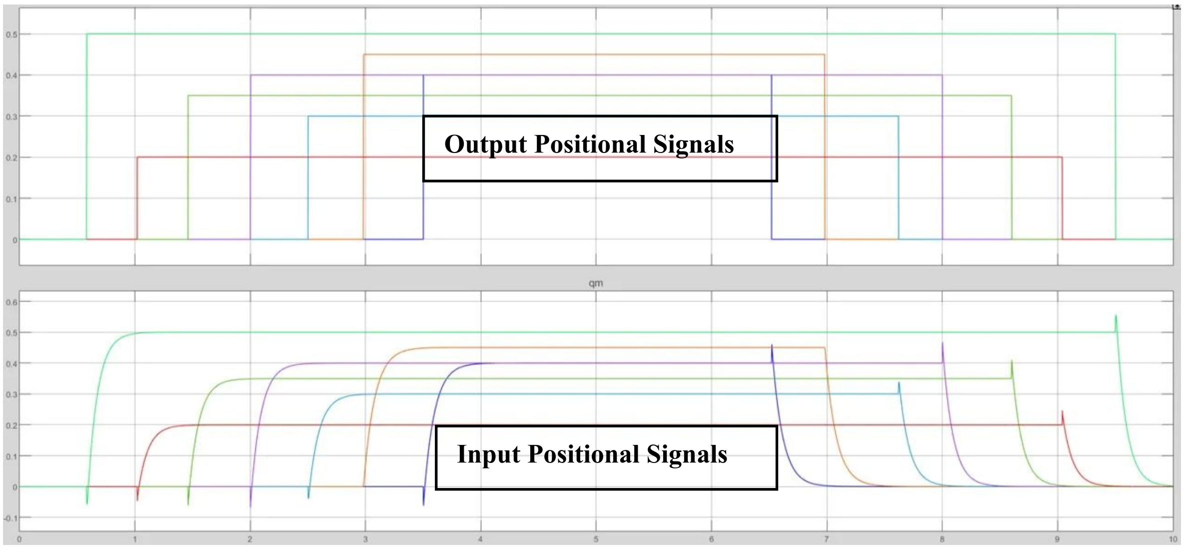


Fig. 15: Input and output signals of each joint

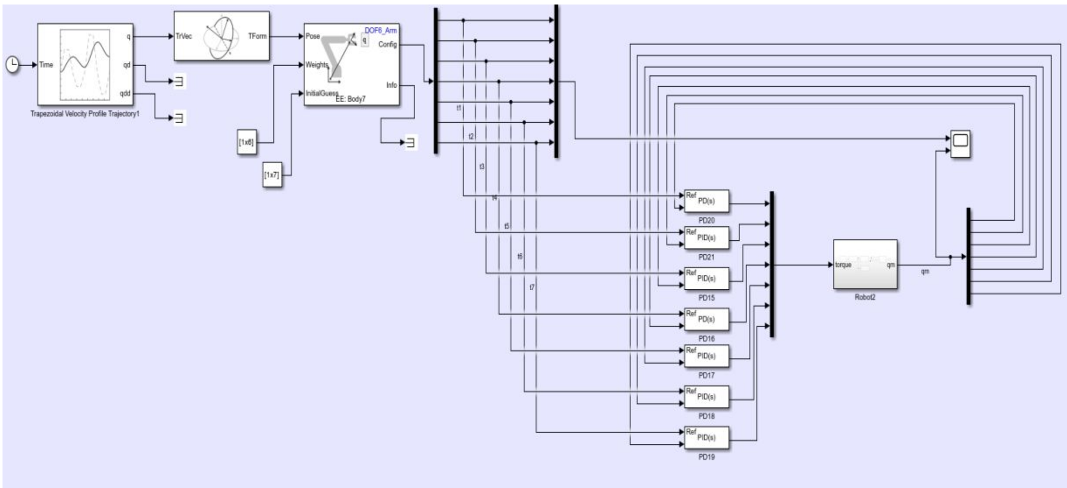
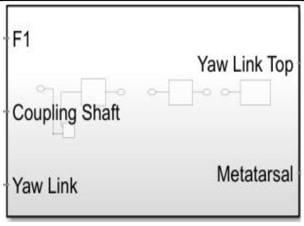
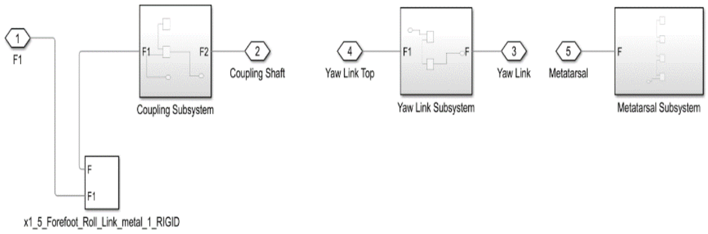
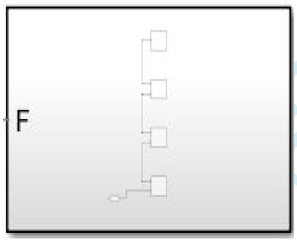
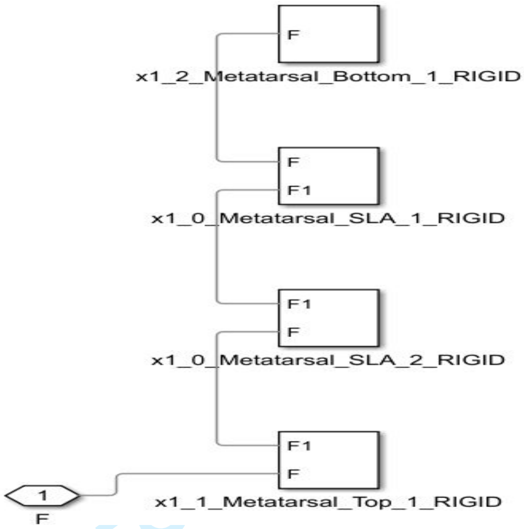
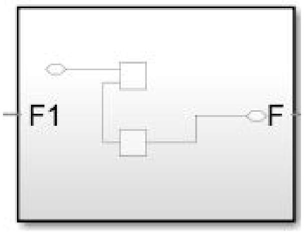
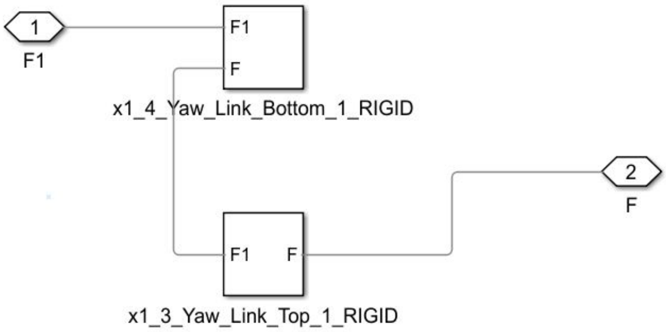
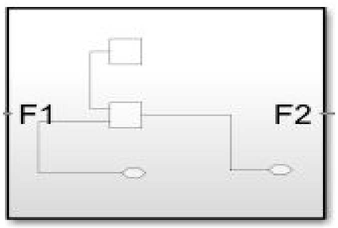
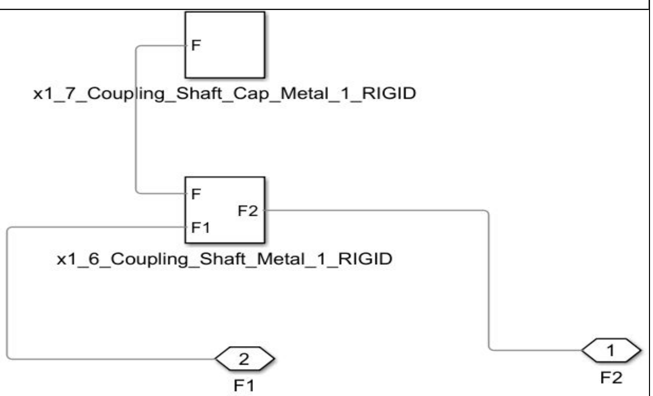
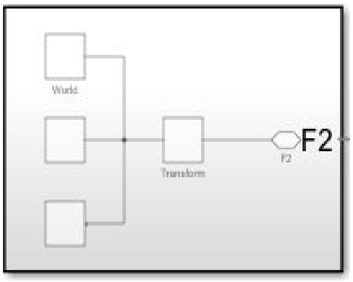


Fig. 16: Inverse kinematics of Clubfoot

Table 1. Exploded view of all the subsystems used in Clubfoot Orthosis.

Sr.	Subsystem	Exploded View
1	 Forefoot Subsystem	
2	 Metatarsal Subsystem	
3	 Yaw Link Subsystem	
4	 Coupling Subsystem	

11	 Initializer