CHAPTER 4

DESIGN OF A BIOMIMETIC FOUR-BAR LINKAGE KNEE JOINT FOR A KAFO

4.1 Introduction

In some types of lower limb impairments, a KAFO may be used as a supportive device without the knee being locked for ambulation. Such a KAFO, which allows knee flexion-extension while maintaining medio-lateral stability, is prescribed for long term usage for people with mild to moderate knee varus/valgus or knee hyperextension, along with the need for ankle or foot control (Hsu *et al.*, 2008). Patients undergoing knee surgery due to sports/traumatic injury also use a similar KAFO during the post-surgery recovery period. Such a KAFO helps the user recover from temporary muscle power loss, controls posture and helps in weight bearing as well. A single-axis knee joint without a lock is commonly used in such orthoses.

The anatomical knee joint is assumed to be a hinge joint for the sake of simplicity in the design of a single-axis knee joint. However, it is a well known fact that human knee joint motion is polycentric in nature as a result of rolling and sliding of the femur on the tibial plateau (Masouros *et al.*, 2010). The human knee joint may appear as a simple hinge joint, but functions like a polycentric joint - a joint with a moving IC. Bracing a single-axis orthotic joint on the multi-axial human knee joint creates a relative sliding motion (called pistoning) between the orthosis and the limb. Pistoning causes slippage and exerts unwanted forces on the limb. (A model for pistoning in a KAFO is presented in Chapter 6). Orthosis users experience discomfort due to the sliding motion and pain due to the binding forces exerted by straps that oppose the sliding motion (Lew *et al.*, 1982). The pistoning problem can be mitigated by designing a knee joint that mimics the motion of the anatomical knee center. Polycentric knee joints with gears or cam-follower type mechanisms are commonly used to trace the knee centrode (the locus of the IC as the knee flexes) (Hsu *et al.*, 2008; Foster and Milani, 1979; Walker *et al.*, 1985). However, these mechanisms are complex and costly to manufacture and difficult to customize based on user needs. Knee braces available in the market, which are sleeves worn intimately to support and stabilize painful or injured knees, may make use of a four-bar mechanism (4BM), which closely mimics assumed anatomical knee motion (Bertomeu *et al.*, 2007; Townsend and Williams, 1994; Lusardi *et al.*, 2013). A 4BM is the simplest movable closed chain linkage, the motion of which can be completely defined in an analytical way. Being a planar mechanism with four links pivoted to one another, a 4BM is easy to manufacture as well. These benefits of a 4BM make it a good choice to use in the design of assistive devices.

Since a KAFO extends from the thigh to the foot with supporting metallic uprights for load-bearing, the location of the orthotic knee is shifted mediolaterally. The objective of this chapter is to present an improved and computationally efficient method for four-bar linkage synthesis, which accounts for the medio-lateral position of the orthotic knee and reproduces human knee motion more accurately. The optimization algorithm used to find the best suitable 4BM is an evolutionary algorithm known as Genetic Algorithm (GA). GA mimics the process of biological evolution to obtain the optimal solution. A method for alignment of the new biomimetic knee joint is also proposed, since that is an important component for effective functioning of the KAFO. It is hypothesized that the optimally synthesized four-bar knee joint will help in reducing pistoning motion between the orthosis and the limb of a KAFO user. Thus, the biomimetic design, in turn, will improve comfort for the orthosis user while performing various ADLs. The design requirements are identified based on the user feedback survey. Figure 4.1 shows the design specifications that serve as a guideline to design the biomimetic four-bar orthotic knee joint. The framework for research presented in Chapter 1, Figure 1.11 will be used to design and test the new orthotic knee joint.

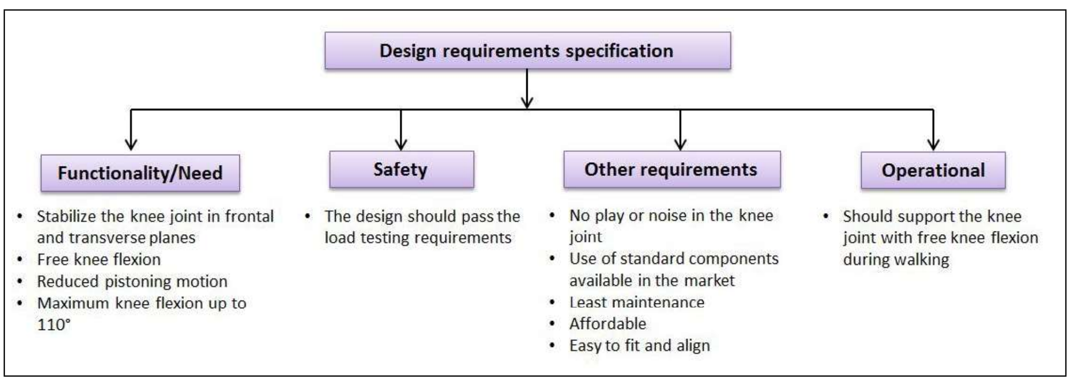


Figure 4.1: Design requirements specifications for the biomimetic knee joint design

4.2 Methods

4.2.1 Method for finding the reference centrode:

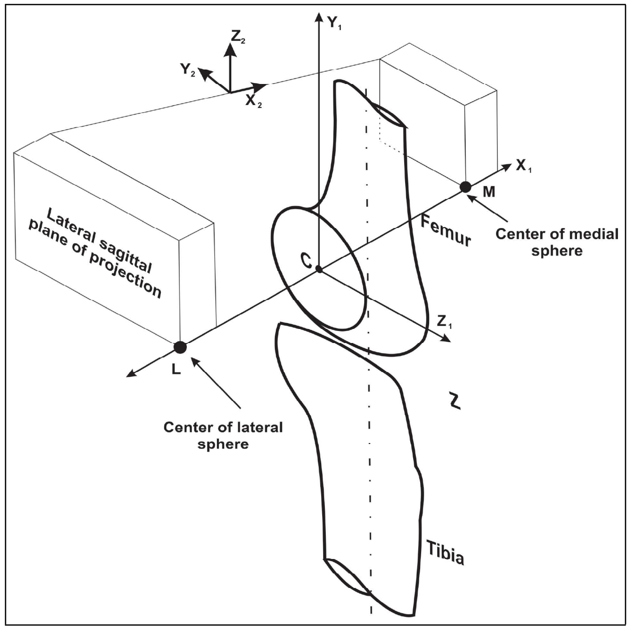


Figure 4.2: A model to generate the reference knee centrode (Adapted from Walker *et al.* (1985))

It is important to understand and quantify the motion of the human knee joint before proceeding to design an artificial one that mimics it. There have been multiple attempts to find the human knee center motion as reported in the literature. The simplest approach considers the human knee joint as mono-centric, while other studies (Frankel *et al.*, 1971; Walker *et al.*, 1972; Lewis and Lew, 1978; Kurosawa *et al.*, 1985) have attempted to find a moving center of rotation (IC) of the knee joint. Walker *et al.* (1985) studied the geometry and motion of the normal human knee of 14 cadavers and 8 volunteers. It was found that the posterior femoral condyles can be modeled as spherical surfaces. Using this approach, three-dimensional motion of the femur on the tibia was defined. Previous studies (Frankel *et al.*, 1971; Smidt, 1973) have described knee motion using IC of the femur on the tibia in the sagittal plane only, which has been found to suffer from various inaccuracies (Soudan *et al.*, 1979). Despite an extensive search, the author was unable to find any recent development/model with regard to the anatomical knee centrode. However, the findings from Walker *et al.* (1988) related to the overall knee motion are in agreement with latest research based on fluoroscopy (Komistek *et al.*, 2003). The current developments are directed towards finding three dimensional overall knee motion during various ADLs and not the knee centrode. Hence, the knee centrode data from Walker *et al.* (1988) was used.

The equations describing knee motion presented by Walker *et al.* (1988) consider the effect of varus and internal rotation on the tibio-femoral joint motion in the sagittal plane. The planar knee centrode is obtained by projecting 3D femoral axis motion on the sagittal plane. Best-fit quadratic equations (Eq.4.1 to 4.4) used to calculate motion parameters for varus rotation (Varus), internal rotation (IntRot), anterior-posterior translation (zdist) and proximal-distal translation (ydist) as a function of knee flexion angle (β) are given by Walker *et al.* (1988).

$$Varus = (0.0791\times\beta) - (5.733\times10^{-4}\times\beta^2) - (7.682\times10^{-6}\times\beta^3) + (5.759\times10^{-8}\times\beta^4) \tag{4.1}$$

$$IntRot = (0.3695\times\beta) - (2.958\times10^{-3}\times\beta^2) + (7.666\times10^{-6}\times\beta^3) \tag{4.2}$$

$$ydist = (-0.0683\times\beta) + (8.804\times10^{-4}\times\beta^2) - (3.750\times10^{-6}\times\beta^3) \tag{4.3}$$

and,

$$zdist = (-0.1283\times\beta) + (4.796\times10^{-4}\times\beta^2), \tag{4.4}$$

where, the knee flexion angle is measured in degrees and displacements are in millimeters. These equations are used to determine the coordinates of a knee center of rotation in the sagittal plane at a lateral distance equal to the value of X_1 coordinate. The maximum medio-lateral width of the average knee was found to be 80 mm (Walker *et al.*, 1985). Hence, it was assumed that the 4BM is placed at 60 mm (to account for skin and orthosis spacing) from the origin of the knee coordinate system in the medial (+ve side) and lateral (-ve side) planes as shown in Figure 4.2. At a flexion angle ranging from $0^\circ - 120^\circ$, equations from Walker *et al.* (1988) are used to obtain transformed coordinates of the point on the femoral axis in Y_1-Z_1 system. The coordinates of the IC at an interval of 5° knee flexion angle are generated.

$$X_1 = -60$$

$$Y_1 = -\sin(Varus)\times X_1 + ydist$$

$$Z_1 = \cos(Varus)\times\sin(IntRot)\times X_1 + zdist$$

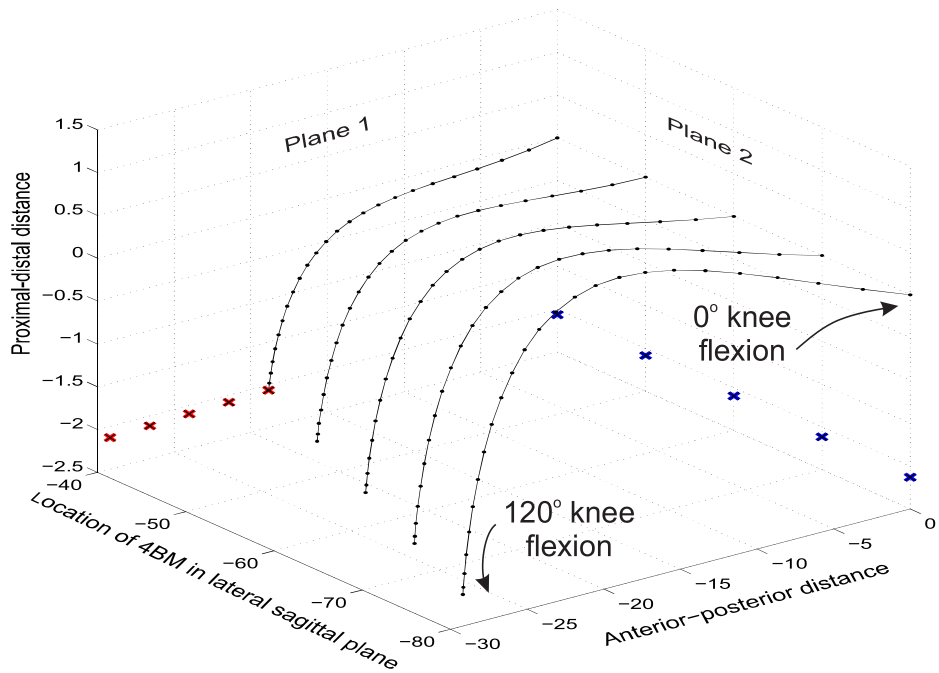


Figure 4.3: Variation in the reference knee centrode projected on the lateral plane located at the distance where 4BM is placed. Synthesized 4BM should trace the knee centrode in that plane.

The only variable parameter in the calculation of the reference centrode is the location of the plane of projection on which the three-dimensional femoral axis is projected. Figure 4.3 shows the variation in reference centrode when projected on planes placed at a lateral distance ranging from 40 to 80 mm from the origin. Red cross marks in plane 1 show that the variation of IC along the Z_1 axis (in Figure 4.2) corresponding to 120° knee flexion is significant and ranges from 19 to 29 mm in the posterior direction. Similarly, blue cross marks in plane 2 show the proximal-distal variation of IC (i.e. along the Y_1 axis in Figure 4.2) corresponding to 120° knee flexion is almost negligible. However, for the purpose of optimization, the reference centrode considered is the one projected on a lateral plane placed at 60 mm.

4.2.2 Four-bar linkage position analysis: Vector loop closure method

Figure 4.4 shows the reference 4BM configuration considered in the design. In this approach (Norton, 1998), a vector loop is created around the linkage for position analysis of the four-bar mechanism. Links are represented as position vectors for which the sum of the vectors around the loop is zero. The magnitudes of the position vectors are the link lengths of the four-bar mechanism to be synthesized. In this case, θ_3 is the input angle because the coupler link will be actuated by the hip during walking. Furthermore,

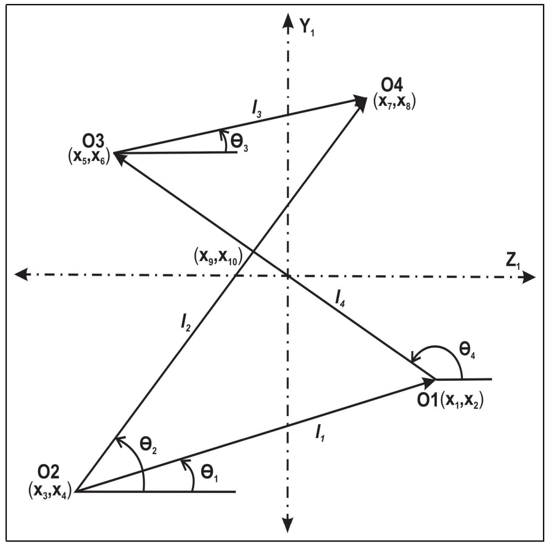


Figure 4.4: Configuration of a four-bar linkage

the inclination of link 1 (θ_1) is known from the initial configuration. The relation between angle θ_4 and other 4BM parameters to define the complete configuration of the 4BM at any instant of time is found.

$$l_1 \cos\theta_1 + l_4 \cos\theta_4 + l_3 \cos\theta_3 - l_2 \cos\theta_2 = 0 \tag{4.5}$$

$$l_1 \sin\theta_1 + l_4 \sin\theta_4 + l_3 \sin\theta_3 - l_2 \sin\theta_2 = 0 \tag{4.6}$$

Squaring and adding Eq. 4.5 and Eq. 4.6

$$l_2^2 = (l_1 \cos\theta_1 + l_3 \cos\theta_3 + l_4 \cos\theta_4)^2 + (l_1 \sin\theta_1 + l_3 \sin\theta_3 + l_4 \sin\theta_4)^2. \tag{4.7}$$

Simplifying and rearranging terms

$$\begin{aligned}(\frac{l_1^2 + l_3^2 + l_4^2 - l_2^2}{2}) + l_1 l_4 \cos\theta_1 \cos\theta_4 + l_1 l_3 \cos\theta_1 \cos\theta_3 + l_3 l_4 \cos\theta_3 \cos\theta_4 + \\ l_1 l_4 \sin\theta_1 \sin\theta_4 + l_1 l_3 \sin\theta_1 \sin\theta_3 + l_3 l_4 \sin\theta_3 \sin\theta_4 = 0.\end{aligned} \tag{4.8}$$

Substitute

$$\sin\theta_4 = (\frac{2\tan\theta_4/2}{1+\tan^2\theta_4/2}), \qquad \cos\theta_4 = (\frac{1-\tan^2\theta_4/2}{1+\tan^2\theta_4/2}), and \qquad K = \frac{(l_1^2 + l_3^2 + l_4^2 - l_2^2)}{2}.$$

Simplifying

$$\mathbf{A}\tan^2\theta_4/2 + \mathbf{B}\tan\theta_4/2 + \mathbf{C} = 0 \tag{4.9}$$

Eq. 4.9 is quadratic in $\tan\theta_4/2$, where

$$\mathbf{A} = (K - l_1 l_4 \cos\theta_1 - l_3 l_4 \cos\theta_3 + l_1 l_3 \cos(\theta_1 - \theta_3))$$

$$\mathbf{B} = 2(l_1 l_4 \sin\theta_1 + l_3 l_4 \sin\theta_3)$$

$$\mathbf{C} = (K + l_1 l_4 \cos\theta_1 + l_3 l_4 \cos\theta_3 + l_1 l_3 \cos(\theta_1 - \theta_3))$$

From Eq. 4.9, one can obtain the value of the angle θ_4 as a function of θ_3 as the angle θ_1 is fixed for a given configuration.

$$\theta_4 = 2\arctan\left(\frac{-B \pm \sqrt{B^2 - 4AC}}{2A}\right) \tag{4.10}$$

Eq. 4.10 gives two values of θ_4, which correspond to two different configurations of a 4BM. Appropriate value of θ_4 is chosen for the analysis.

4.2.3 Locating the IC of a crossed four-bar linkage

The aim is study the relative motion between the shank and thigh. At any instant, the thigh rotates over the shank about the knee center, which is the IC of link 3 with respect to link 1. By the Aronhold-Kennedy theorem (Norton, 1998), the IC of the two links is located by intersection of two straight lines: the first line passes through pivot points O1 and O3 and the second line passes through pivot points O2 and O4 of the 4BM as shown in Figure 4.4. The equations of the two straight lines are written using two-point form as shown below:

$$x_9(x_8 - x_4) + x_{10}(x_3 - x_7) = x_3 x_8 - x_4 x_7 \tag{4.11}$$

$$x_9(x_6 - x_2) + x_{10}(x_1 - x_5) = x_1 x_6 - x_2 x_5 \tag{4.12}$$

Representing the above algebraic equations 4.11 and 4.12 in matrix form,

$$\begin{bmatrix} (x_8 - x_4) & (x_3 - x_7) \\ (x_6 - x_2) & (x_1 - x_5) \end{bmatrix} \begin{Bmatrix} x_9 \\ x_{10} \end{Bmatrix} = \begin{bmatrix} x_3 x_8 - x_4 x_7 \\ x_1 x_6 - x_2 x_5 \end{bmatrix} \tag{4.13}$$

$$\begin{Bmatrix} x_9 \\ x_{10} \end{Bmatrix} = \begin{bmatrix} (x_8 - x_4) & (x_3 - x_7) \\ (x_6 - x_2) & (x_1 - x_5) \end{bmatrix}^{-1} \begin{bmatrix} x_3 x_8 - x_4 x_7 \\ x_1 x_6 - x_2 x_5 \end{bmatrix}. \tag{4.14}$$

Here, x_9 and x_{10} are the x and y coordinates of the IC respectively. The literature (Hobson and Torfason, 1974; Sancisi *et al.*, 2009; Poliakov *et al.*, 2012; Xie *et al.*, 2014) presents various methods to calculate the coordinates of the IC based on algebraic equations. The basic building block of numerical computational softwares such as MATLAB$^{\text{TM}}$ or SCILAB is the matrix and the fundamental data type is an array (Chapman, 2008). Vectorized commands or codes run faster in such software environments (Pratap, 2015). The matrix formulation approach presented here for calculation of an IC of a 4BM allows for faster processing in computational software. The apparent benefits are reduction in simulation time and increased computational efficiency.

4.2.4 Objective function and constraints

The goal of the optimization is to find a 4BM, which mimics the anatomical knee motion (based on a reference centrode) as closely as possible while satisfying the specified constraints. This goal can be accomplished by minimizing the distance between the reference centrode and the centrode of a synthesized 4BM. Thus, the objective function is to minimize the sum of the Euclidean norm (l_2 norm) of a vector directed from the i$^{\text{th}}$ point on a reference knee centrode $(P(i)_{ref})$ to the i$^{\text{th}}$ point on a synthesized 4BM centrode$(P(i)_{syn})$.

$$\bar{N}_i = \bar{P}(i)_{ref} - \bar{P}(i)_{syn} \tag{4.15}$$

The only constraint used for the optimization is the size constraint on the synthesized links. Link lengths (l_1, l_2, l_3, l_4 in mm) are judicially constrained to avoid bulky 4BM solutions. The optimization problem, in its general form, can be stated as:

$$\textit{Minimize:} \quad obj = \sum_{i=1}^{n} \|\bar{N}_i\|_2 \tag{4.16}$$

$$\textit{subject to:} \quad 20 \leq l_1, l_2, l_3, l_4 \leq 60 \tag{4.17}$$

4.2.5 Optimization method: Genetic Algorithm approach

Traditional derivative-based optimization techniques fail to find global optima when an intricate and discontinuous multi-variable objective function is encountered. Hence, a GA with elitist strategy available in MATLAB$^{\text{TM}}$ (R2014a, The Math Works Inc., USA) software is used for optimal synthesis of the 4BM. GAs are non-traditional optimization techniques, which simulate the process of biological evolution. The central theme of GA is based on Darwin's theory of survival of the fittest, which explains the natural selection process. The fitness function is the objective function specified in Eq.4.16. Eight variables (planar coordinates of four pivots of the 4BM) are required to evaluate the fitness function. The GA generates a random initial population (here, a set of 300 vectors with eight variables each), which is used for reproduction, crossover and mutation operations to produce the next better generation. This process of evolution continues until the GA meets the stopping criteria, namely, the average change in the fitness function value over the number of generations is of the order of 10^{-6} or lower.

4.2.6 Choice of parameters for the GA

The population type specified in the GA is of the double vector type. This generates a random population of data type *double*. The population size is set to 300 as the number of variables are more in this case (i.e., 8). With a large population size, the GA searches the solution space more thoroughly, thereby increasing a chance of converging to the global optima. However, a large population size also increases the computing time. Both the creation function and mutation function are set to *constraint dependent*. The fitness scaling function, *rank* scales the raw scores based on the rank of each individual, rather than its score. Rank fitness scaling function removes the effect of the spread of the raw scores. A *Stochastic uniform* selection function is used to choose parents for the next generation. Reproduction operation in the GA creates children at each new generation based on the elite count and crossover fraction. Elite count specifies the number of individuals that are guaranteed to survive to the next generation, which in this case is 15 ($default = 0.05\times$ population size). Crossover operation is set to produce 80% individuals of the next generation while 20% are produced by mutation. Constraint parameters for the non-linear constraint solver and stopping criteria are set to *default* options in the GA. The GA code was run at least five times in a loop to check whether the GA has converged to a global minima and the best solution (the one with the least value of the objective function) amongst the set of closely spaced optimal solutions was selected. A set of closely spaced optimal solutions in Table 4.1 imply the robustness of the GA.

Table 4.1: Objective function values after five runs of Genetic algorithm. The value shown in boldface letters is taken as the optimal solution.

Iteration No	**Objective Function Value**
1	4.61
2	4.64
3	4.14
4	**4.10**
5	4.40

4.3 Results and discussion

The synthesized mechanism that mimics the reference knee centrode is a crossed 4BM as shown in Figure 4.5. It is a Grashof class-II linkage in which the sum of the lengths of the longest and shortest links is greater than the sum of the lengths of other two links. In such a mechanism, fixing of any of the links always results in a triple rocker

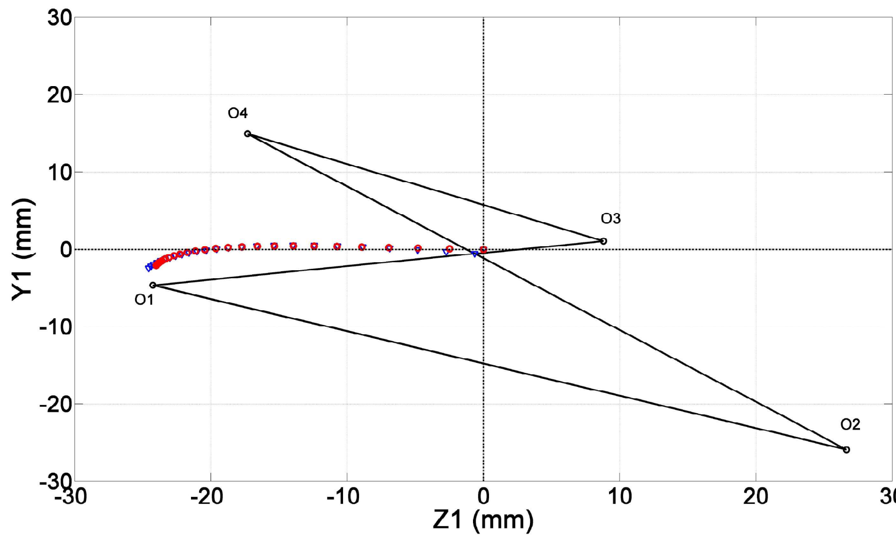


Figure 4.5: Optimal four-bar linkage with anatomical reference (Red circles) and synthesized centrodes (Blue triangles)

mechanism. However, it is ensured during optimization that the coupler of any synthesized mechanism is capable of rotating at least 110° to allow for a comfortable sitting posture. Here the knee flexion range is restricted to 110°, as deep knee flexion is not recommended for the target user group of this knee joint.

Table 4.2: Mean error between the motion of different knee joints and human polycentric knee motion

Sr.No	**Type of knee joint**	**Mean error (mm)**
1	Single axis knee joint	16.9
2	OCFL knee joint (Bertomeu *et al.*, 2007)	1.3
3	Synthesized 4BM	0.2

The application of an optimization approach is shown for the case where the 4BM is placed at 60 mm on the lateral side. Table 4.2 shows the mean error between the motion of different orthotic knee joints compared with human polycentric knee motion based on a reference knee centrode. In this work, the average distance between a point on the reference centrode and the corresponding point on the synthesized 4BM centrode is 0.2 mm. The average error between the motion of a single axis knee joint and anatomical motion of the human knee is 16.9 mm, which is quite high. This nonconformity with the human knee motion leads to pistoning in an orthosis causing discomfort and pain to the user. The average error between the reference centrode and the centrode of the synthesized four-bar knee in this work is 0.2 mm as compared to 1.3 mm in a previous study by Bertomeu *et al.* (2007). The low error implies that an improved solution is obtained using the presented 4BM formulation and optimization approach.

4.3.1 Computer Aided Design (CAD) model

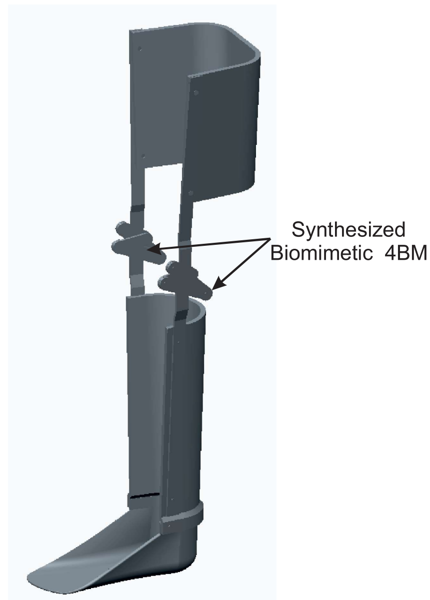


Figure 4.6: CAD model of the synthesized biomimetic 4BM knee joint assembled in a KAFO

A CAD model of the synthesized 4BM is prepared and assembled in a KAFO using Creo Parametric^{TM} software. Figure 4.6 shows that the 4BM knee joint is compact and being a planar linkage, it is easy to fabricate using modern manufacturing techniques such as laser cutting, 3D printing etc.

4.3.2 Alignment guidelines

Alignment of the designed 4BM with respect to the anatomical knee center is important to achieve the best performance from the orthotic knee during walking. An optimally-synthesized biomimetic orthotic four-bar knee joint can still create a pistoning motion if not aligned properly with the anatomical knee. For the purpose of alignment, the greater trochanter and lateral malleolus are chosen as bony prominences for locating the hip and the ankle joint respectively. A hip-ankle line known as alignment reference line (ARL) is defined. Uprights are metal bars, which attach the orthotic knee joint to the thigh shell of an orthosis. Uprights connected to link 1 and link 3 are held vertically and shifted such that the intersection point of link 2 and link 4 is 10 mm behind the ARL and 19 mm above the medial tibial plateau (MTP) as shown in Figure. 4.7. Functional performance of an orthotic knee joint varies with a misalignment of the anatomical and

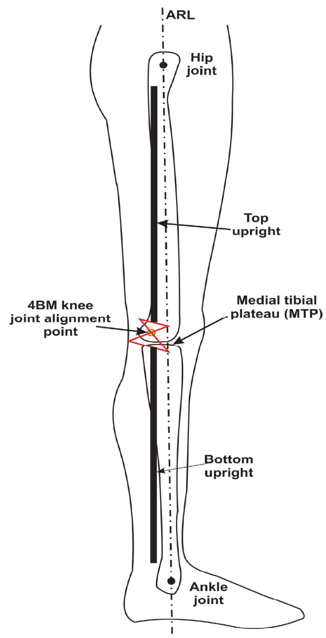


Figure 4.7: Schematic diagram for knee alignment of the biomimetic four-bar orthotic knee

orthotic knee joint. The sensitivity of orthotic knee joints to correct alignment and the resulting pistoning effects will be explored in more detail in the Chapter 6.

The X_1 coordinate (along the medio-lateral axis, as shown in Figure 4.2) in the calculation of a reference knee centrode indicates the position of the four-bar knee joint in the sagittal plane. For more accurate results, variation in the medio-lateral distance among the population can be measured and then used in the equation for calculation of a reference knee centrode, as shown in Figure 4.3. Accounting for the medio-lateral location of the orthosis facilitates the design of customized orthotic knee joints using the method presented here. Thus, the method will be useful to design knee joints for the pediatric population as well, where the variation in knee centrode is likely to be more significant.

The performance of the synthesized 4BM is subject to the accuracy of the anatomical knee center data obtained from the literature. The method for generating the reference knee centrode in this study is chosen based on the experimental validation (Walker *et al.*, 1988) and consideration of the 3D nature of the human knee centrode. However, with the advent of technology, newer data sets predicting anatomical knee centrode motion more accurately might appear. The optimization approach presented here is robust enough to mimic the knee motion for any such futuristic data sets.

The underlying assumption in the design approach presented here is that the knee joint has single movement pattern in all human beings, which is captured by the mathematical model used from the literature. However, in reality anatomical variability between the motion of knee joints of different people exists and in the presence of disability it is further enhanced. Thus, designing an orthotic knee joint with the consideration of knee joint deformity and subsequent variation in the motion pattern is part of the future work.

4.4 Closure

A generalized optimization technique for synthesis of a 4BM to trace a specified centrode is presented in this chapter. The new method is applied to design an orthotic knee joint for a KAFO for use in braces where a locked knee is unnecessary and mimicking the anatomical knee center is required. GA used for the optimization proves to be a suitable and robust tool for the optimal synthesis of a 4BM. The method outlined here can be used to synthesize a 4BM for other applications as well. A similar method (with a different objective) is used in the next chapter for the synthesis of an assistive four-bar mechanism (non-biomimetic) for a KAFO, as an alternative to a SCKAFO. Analysis of the reduction in pistoning, when a single axis orthotic knee joint is replaced by a 4BM mimicking the anatomical knee motion, can be performed using the pistoning simulation model presented in Chapter 6. The biomimetic four-bar orthotic knee joint needs to be manufactured and clinically evaluated with the target user group. Clinical trials need ethics committee and IRB approval, which made clinical evaluation of the proposed joint challenging within the scope and timeline of this work. Future work, outside the scope of this thesis, includes design and fabrication of the 4BM and clinical trials to obtain feedback about the performance of the new biomimetic orthotic knee joint.

CHAPTER 5

DESIGN AND FEASIBILITY STUDY OF AN ASSISTIVE FOUR-BAR LINKAGE KNEE JOINT FOR A KAFO

5.1 Introduction

In the preceding chapter, the use of a crossed four-bar mechanism to mimic the anatomical knee center to reduce the pistoning motion between the limb and the orthosis was shown. Patients undergoing knee surgery due to sports/traumatic injury use a KAFO with a polycentric knee joint during the post-surgery recovery period. Such post-operative immobilization brace assists the user to recover from temporary muscle power loss, controls posture and helps in weight bearing as well. However, such crossed four-bar knee joints are not good from a stability point of view if they are to be prescribed for KAFO users with quadriceps muscle weakness and have problems with sagittal plane instability because of limitations in the hip muscles. Such users need support to stabilize the knee during stance and hence a locked knee joint is generally given to them. Some users, however, may have sufficient hip musculature to exercise a certain amount of (though less-than-normal) knee control. Such users are also candidates for SCKAFOs and may benefit from an alternative joint that provides more user control.

In prosthetics, Radcliffe (2003) proposed use of suitably designed non-biomimetic 4BMs that could provide a prosthesis user with limited musculature better voluntary control to stabilize the knee. The characteristics offered by a four-bar mechanism to assist voluntary control are well-known and usually utilized in the design of prosthetic knee joints available in the market. Now, the question that arises is, can a non-biomimetic four-bar orthotic knee joint be designed to assist a KAFO user to have better control over stance stability and swing flexion during walking? The 4BM knees conventionally used in orthotics are biomimetic ones (crossed 4BM) and the characteristic anatomical knee centrode they mimic is not useful from the stability point of view. The use of an open 4BM configuration generates a characteristic centrode to provide stability during stance and ease of knee flexion during swing. Thus it can provide voluntary control to a KAFO user during walking. This idea considers kinetics and is more sophisticated and appropriate than the traditional design thinking that the knee joint kinematics needs to be mimicked in orthotic knee joint. The literature review shows that the use of the polycentric nature of a 4BM in a KAFO has not been explored much.

Vishnu Vardhan Reddy and Sujatha (2009) proposed a four-bar knee joint for a KAFO, which provides increased stance phase stability while allowing swing flexion thereby making the locking feature in the knee joint unnecessary. However, the method used for the design of an optimized 4BM is based on an assumed centrode, which is not robust as there is no single centrode applicable to all KAFO users. Recently Kim and JinBock (2011) developed a four-bar linkage orthotic knee joint, which provides stance stability and swing phase knee flexion and functions like a SCKAFO. Further, they conducted clinical trials to compare the gait of users walking with a drop-lock type KAFO and the four-bar linkage KAFO and reported that the four-bar knee improved spatiotemporal parameters, gait symmetry and energy consumption in level surface and stairs walking (Kim *et al.*, 2013). The four-bar knee designed by Kim and JinBock (2011) aimed at stance stability only and did not consider reducing the hip flexion moment required to initiate the swing. Drawing inspiration from prosthetic knees, the use of an assistive 4-bar knee for KAFO users that could serve as an alternative to SCKAFOs is proposed. The objective of this work is to design an assistive orthotic 4-bar knee joint that can provide stance stability and free knee flexion during swing and thus improve the gait of a KAFO user. This chapter discusses the biomechanical benefits offered by an orthotic 4BM knee joint and a method for its optimal synthesis. Further challenges involved in practical implementation of the 4BM knee joint in a KAFO are discussed at the end of the chapter. The design requirements are identified based on the user feedback survey presented in Chapter 2. Figure 5.1 shows the design specifications that serve as a guideline to design the assistive four-bar orthotic knee joint. The framework for research presented in Chapter 1, Figure 1.11 will be used to design and test the new orthotic knee joint.

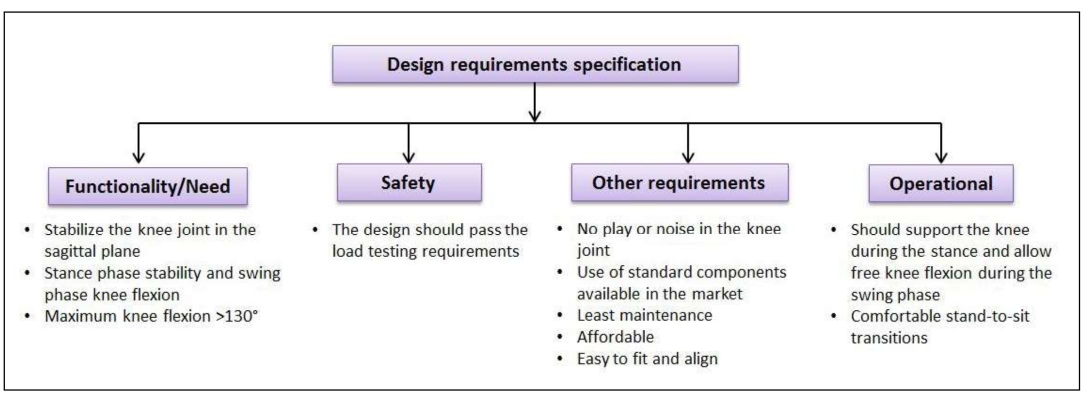
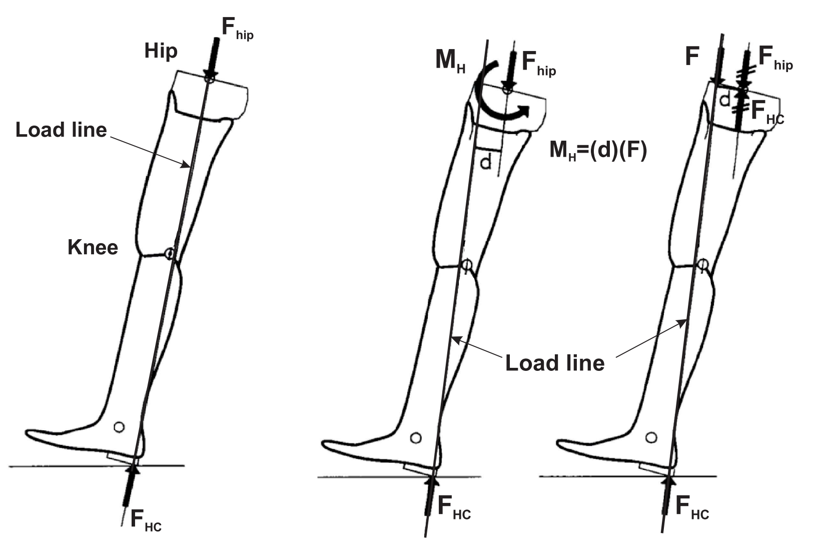


Figure 5.1: Design requirements specifications for the assistive four-bar orthotic knee joint design

5.2 Biomechanics of four-bar knee control

The anatomical knee joint is polycentric in nature due to the rolling and gliding motion of the femoral condyles on the tibial plateau (Masouros *et al.*, 2010). The human knee structure is complex and the knee motion is activated and controlled by different muscle groups and restricted by the ligaments. In case of post-operative knee braces or fracture braces the goal is to provide support to the knee and immobilize the knee for recovery. All other musculature being intact to stabilize the knee, mimicking the human knee kinematics makes sense in such case to prevent pistoning of a brace on the leg. In the absence of the required musculature and the physiological knee structure, mimicking the human knee motion is impractical as in the case of a person with a transfemoral (above-knee or A/K) amputation. In such cases, prosthetic knee joints are designed wisely to compensate for the lack of muscle strength and still allow the user to walk comfortably. Radcliffe (1977) first proposed the concept of knee stability using a 4BM in his pioneering work on polycentric knee mechanisms for prostheses. A mathematical relation between the IC of a 4BM, the load line and the stabilizing hip moment was proposed and these concepts were used to design a polycentric knee joint for a transfemoral prosthesis user. Here, the line of action of the resultant GRF originating from the CoP is known as the load line.



(a) Unstable knee at the heel contact in absence of stabilizing hip moment

(b) Stabilized knee at the heel contact using the hip musculature

Figure 5.2: Mechanics of voluntary stability at heel contact using the hip musculature. (Adapted from: Radcliffe (1994))

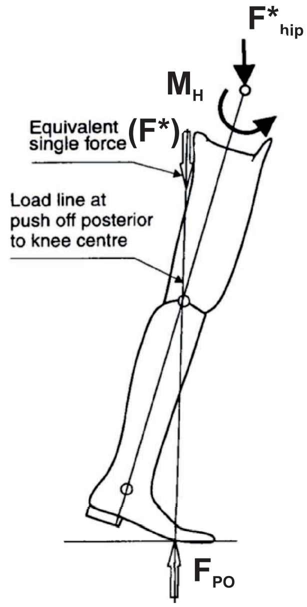


Figure 5.3: Mechanics of voluntary stability at push off using the hip musculature (Adapted from: Radcliffe (1994)

Figure 5.2(a) shows the load line at heel contact for a typical A/K prosthesis. In Figures 5.2 and 5.3, F_{HC} and F_{PO} represent the GRF at heel contact and push off, while F^* represents equivalent single force acting at the hip. It can be seen that, at the instant of heel contact, the load line passes behind the knee center, causing the knee to flex and creating a situation of instability. However, that does not happen in reality. This is due to the fact that most A/K prosthesis users make use of their residual hip musculature on the amputated side to apply a hip extension moment (M_H) and shift the load line in front of the knee, thereby achieving stability during stance as shown in Figure 5.2(b). Similarly, during push off, the user exerts a hip flexion moment to shift the load line in front of the knee center to initiate the swing phase as shown in Figure 5.3. Thus, the knee stability of a prosthetic knee joint is primarily controlled by the residual hip musculature of an amputee and the location of the knee joint center with respect to the load line. Polycentric mechanisms such as a 4BM have an IC that moves with the flexion of the knee. The IC of a 4BM can be aligned to provide voluntary knee stability, which makes such a knee a suitable candidate for the prosthetic knee joint. If we superimpose the stability diagrams during heel contact and push off, we get the zone of voluntary stability (as shown in Figure 5.4) in which the IC remains behind the load line during the stance phase to provide stability and moves ahead of the load line during push off to reduce the effort required to initiate the swing flexion. A 4BM can be designed such that the IC remains in the zone of voluntary stability.

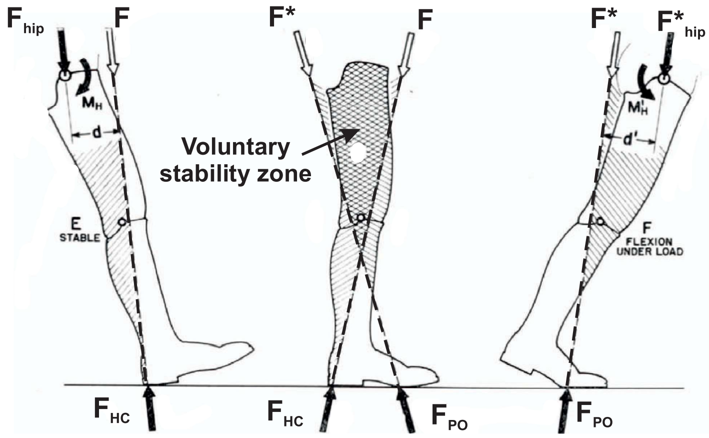


Figure 5.4: Zone of voluntary stability (Adapted from: Radcliffe (1977))

Further, Radcliffe (2003) in his seminal work showed that, though different four-bar prosthetic knee joints have varying centrode shapes, their functional characteristics are quite similar. Based on this, he concluded that the performance of a four-bar knee joint during the stance and the swing phase depends on a non-dimensional number called the "flexion factor". The flexion factor is defined as a ratio of normal distance of the IC from the load line to the height of the IC from the CoP along the load line. In short, the movement of the IC with respect to the load line is an important characteristic. To locate the orientation of the load line during walking, it is assumed that, in the absence of an active hip moment, the load line originating from the CoP passes through the hip joint center (Radcliffe, 2003). It essentially means that the user has no hip muscle strength. This assumption also allows taking into consideration stability requirements of the weakest subjects. However, in reality users will have some residual hip muscle strength, which will serve as an additional benefit to effectively control the designed four-bar knee joint.

5.3 Optimal synthesis of a four-bar mechanism

5.3.1 Four-bar linkage position analysis: Vector loop closure method

Figure 5.5 shows the reference 4BM configuration considered in the design. In this approach (Norton, 1998), (which was also utilized in the previous chapter and is repeated here because there is a slight change in the formulation as the configuration of a 4BM is different in this case), a vector loop is created around the linkage for position analysis of the four-bar mechanism. Links are represented as position vectors for which the sum of the vectors around the loop is zero. The magnitudes of the position vectors are the link lengths of the four-bar mechanism to be synthesized. In this case, θ_3 is the input angle

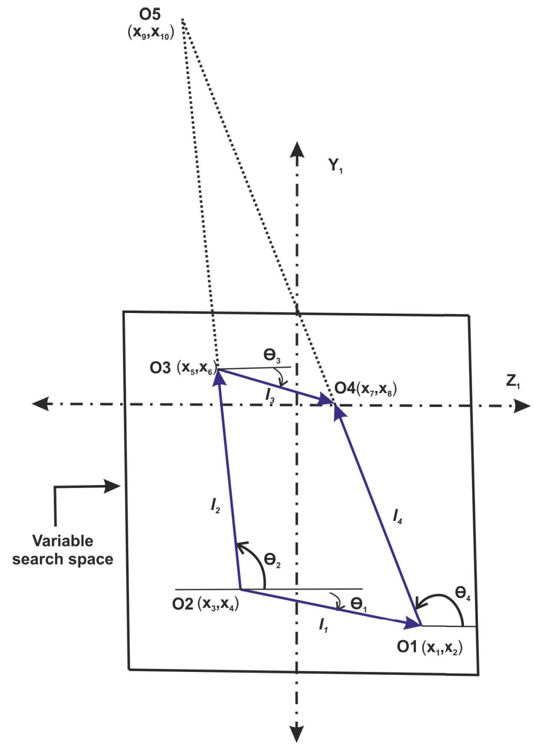


Figure 5.5: Configuration of a four-bar linkage

because the coupler link will be actuated by the hip during walking. Furthermore, the inclination of link 1 (θ_1) is known from the initial configuration. The relation between angle θ_2 and other 4BM parameters to define the complete configuration of the 4BM at any instant of time is found.

$$l_2 \cos\theta_2 + l_3 \cos\theta_3 - l_4 \cos\theta_4 - l_1 \cos\theta_1 = 0 \tag{5.1}$$

$$l_2 \sin\theta_2 + l_3 \sin\theta_3 - l_4 \sin\theta_4 - l1 \sin\theta_1 = 0 \tag{5.2}$$

Squaring and adding Eq. 5.1 and Eq. 5.2

$$l_4^2 = (l_2 \cos\theta_2 + l_3 \cos\theta_3 - l_1 \cos\theta_1)^2 + (l_2 \sin\theta_2 + l_3 \sin\theta_3 - l_1 \sin\theta_1)^2 \tag{5.3}$$

Simplifying and rearranging terms

$$\begin{aligned}(\frac{(l_1^2 + l_2^2 + l_3^2 - l_4^2)}{2}) + l_2 l_3 \cos\theta_2 \cos\theta_3 - l_1 l_3 \cos\theta_1 \cos\theta_3 - l_1 l_2 \cos\theta_1 \cos\theta_2 + \\ l_2 l_3 \sin\theta_2 \sin\theta_3 - l_1 l_3 \sin\theta_1 \sin\theta_3 - l_1 l_2 \sin\theta_1 \sin\theta_2 = 0\end{aligned} \tag{5.4}$$

Substitute

$$\sin\theta_2 = (\frac{2\tan(\theta_2/2)}{1+\tan^2(\theta_2/2)}), \quad \cos\theta_2 = (\frac{1-\tan^2(\theta_2/2)}{1+\tan^2(\theta_2/2)}), and \quad K = \frac{(l_1^2 + l_2^2 + l_3^2 - l_4^2)}{2}$$

Simplifying above equation

$$\mathbf{A}\tan^2(\theta_2/2)+\mathbf{B}\tan(\theta_2/2)+\mathbf{C}=0 \tag{5.5}$$

Eq. 5.5 is quadratic in $\tan\theta_2/2$, where

$$\mathbf{A}=(K-l_2l_3\cos\theta_3+l_1l_2\cos\theta_1-l_1l_3\cos(\theta_1-\theta_3))$$

$$\mathbf{B}=2(l_2l_3\sin\theta_3-l_1l_2\sin\theta_1)$$

$$\mathbf{C}=(K+l_2l_3\cos\theta_3-l_1l_2\cos\theta_1-l_1l_3\cos(\theta_1-\theta_3))$$

From Eq. 5.5, the value of the angle θ_2 as a function of θ_3 can be obtained as the angle θ_1 is fixed for a given configuration.

$$\theta_2=2\arctan\left(\frac{-B\pm\sqrt{B^2-4AC}}{2A}\right) \tag{5.6}$$

Eq. 5.6 gives two values of θ_2, which correspond to two different configurations of a 4BM. Appropriate value of θ_2 is chosen for the analysis.

5.3.2 Locating the IC of a four-bar linkage

The matrix formulation approach presented in the previous chapter is used for calculation of the IC of a 4BM. The new method allows for faster processing in computational software. The aim is to study the relative motion between the shank and thigh. At any instant, the thigh rotates with respect to the shank about the knee center, which is the IC of link 3 with respect to link 1. The IC of the two links is located by the intersection of two straight lines: the first line passes through pivot points O2 and O3 and the second line passes through pivot points O1 and O4 of the 4BM as shown in Figure 5.5. The equations of the two straight lines are written using two-point form as shown below:

$$x_9(x_6-x_4)+x_{10}(x_3-x_5)=x_3(x_6-x_4)-x_4(x_5-x_3) \tag{5.7}$$

$$x_9(x_8-x_2)+x_{10}(x_1-x_7)=x_1(x_8-x_2)-x_2(x_7-x_1) \tag{5.8}$$

Representing the above algebraic equations 5.7 and 5.8 in matrix form

$$\begin{bmatrix}(x_6-x_4) & (x_3-x_5)\\(x_8-x_2) & (x_1-x_7)\end{bmatrix}\begin{Bmatrix}x_9\\x_{10}\end{Bmatrix}=\begin{bmatrix}(x_3x_6-x_4x_5)\\(x_1x_8-x_2x_7)\end{bmatrix}$$

$$\begin{Bmatrix}x_9\\x_{10}\end{Bmatrix}=\begin{bmatrix}(x_6-x_4) & (x_3-x_5)\\(x_8-x_2) & (x_1-x_7)\end{bmatrix}^{-1}\begin{bmatrix}(x_3x_6-x_4x_5)\\(x_1x_8-x_2x_7)\end{bmatrix}$$

Here, x_9 and x_{10} are the x and y coordinates of the IC respectively.

5.3.3 Calculation of the flexion factor during the stance and the swing phase

Using an approach similar to (Radcliffe, 2003), the hip moment is expressed as follows:

$$M_H = FL(p/q) \tag{5.9}$$

where, M_H is the required hip moment, F is the axial force along the load line, L is the distance from the hip joint to the CoP along the load line, p is the normal distance of the IC from the load line, and q is the height of the IC from the CoP along the load line. The hip moment is the product of the load factor and the flexion factor. The load factor (FL) is user specific, but remains constant for a particular user. The flexion factor varies as the knee flexes and the required stabilizing hip moment is directly proportional to this factor considering the load factor as constant for a specific user. Hence, the flexion factor (p/q), which is the varying parameter, decides the stability during the heel contact and ease of flexion during push off.

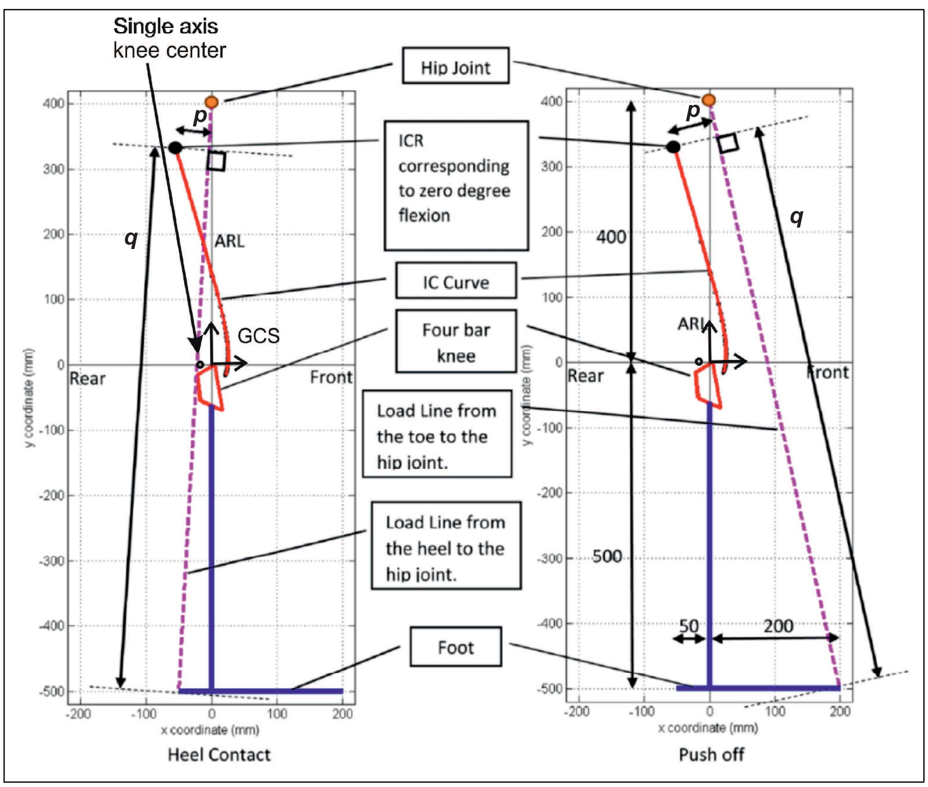


Figure 5.6: Configuration diagram for calculation of flexion factor (*p/q*) for a typical four-bar knee (Adapted from:Anand and Sujatha (2016))

The dimensions used for the lower limb model are shown in Figure 5.6. This configuration is similar to the one used by Radcliffe (2003). The alignment reference line (ARL) is the line joining the hip and the ankle joint centers (shown with dotted magenta line in Figure 5.6). The X-axis of the global coordinate system (GCS) is located at the level of the knee center and the Y-axis along the ARL. The single axis knee center is located at a height of 500 mm from the ground and 10 mm behind the ARL in. The hip joint is located at a height of 400 mm above the knee center along the ARL. This means the effective leg length (L) is 900 mm. The heel is 50 mm behind the ARL and toe lies 200 mm in front of the ARL. The 4BM is positioned such that the top front pivot of the 4BM is located at the level of anatomical knee center. This reduces the optimization variables (i.e coordinates of a 4BM) to seven as the Y coordinate of fourth pivot is now set to zero. A sample 4BM with its IC curve (shown with red line in Figure 5.6) is chosen for illustration purpose.

For the purpose of stability analysis at heel contact and push off, the CoP location is assumed to be fixed at the heel (50 mm behind the ARL) and at the ball of the foot (100 mm in front of the ARL), respectively. This is a valid assumption since the heel and the forefoot function as pivots during the initial and the terminal stance, respectively, according to the theory of three rockers proposed by Perry (1992). A single-axis orthotic knee joint with a free knee (the knee center located 10 mm behind the ARL) and an offset knee (the knee center located 20 mm behind the ARL) were analyzed and compared with the synthesized 4BM.

5.3.4 Formulation of the optimization problem

Based on the theory proposed by Radcliffe (2003), a set of parameters to optimally design a four-bar prosthetic knee joint are suggested by Anand and Sujatha (2016). Some of those parameters relevant to the design of a four-bar orthotic knee joint are used as optimality criteria. These parameters are explained below:

1. **Heel contact flexion factor:** A negative value of the heel contact flexion factor is desirable. It implies that the knee is stable at initial contact without the user exerting any stabilizing hip moment.

2. **Stable stance flexion angle:** This parameter is derived from the heel contact flexion factor. It is the knee flexion angle up to which the heel contact flexion factor is negative. Even if a KAFO user lands on a slightly flexed knee, the knee will not buckle as long as the flexion factor is negative. In countries like India, where uneven terrain is frequently encountered, stable stance flexion angle is of significant importance for stability during ambulation.

3. **Push off flexion factor:** In order to initiate the swing, the knee has to flex during

the push off phase. However, the knee is always extended during push off due to the anterior positioning of the load line. Hence, the user has to exert a flexion moment at the hip to shift the load line behind the knee center to initiate the knee flexion. The smaller the required flexion moment, the easier the push off to swing transition. This requirement means that a push off flexion factor should be close to zero.

4. **Measure of the stabilizing hip moment (in stance) or flexion initiation moment (during swing):** A positive value of the flexion factor implies that a user has to exert a proportional extension moment to stabilize the knee during stance. After a few degrees of initial stable stance flexion range, the user has to apply a stabilizing hip moment to shift the load line behind the knee center. However, it should be remembered that this required hip moment must be within the ability of KAFO users owing to the weak musculature on the braced limb side. The same measure is applicable to the hip flexion moment required to initiate the swing during push off phase. Though this criterion was not explicitly used in the objective function, it was used to select the four-bar linkage from the set of closely spaced optimal solutions.

5. **Maximum overall knee flexion angle:** This parameter is of utmost importance for user comfort while sitting, squatting and kneeling activities, which are basic ADLs for a user in India as discussed in Chapter 2. For a comfortable squatting posture, knee flexion more than 130° is required (Hemmerich *et al.*, 2006). The 4BM is synthesized using Grashof criterion with a coupler being the shortest link, which allows for the maximum overall knee flexion angle.

Individuals with weak quadriceps muscles are unable to control the flexion of the knee under the action of the GRF during the stance phase of walking. Thus, to improve the gait of people with quadriceps weakness, maximum stability during stance and reduced effort during initiation of swing is required. From the above-mentioned criteria, it can be understood that the flexion factor at stance and swing are important parameters governing the biomechanics of the four-bar knee joint. Thus, the goal is to minimize the flexion factor at stance and maximize the flexion factor during swing, which are proportional to the hip moments that the user has to apply to control the knee. Then, the optimal assistive 4BM will require lower-than-normal hip moments to control stability at stance and ease initiation of swing than biomimetic or single-axis knees. Flexion factor is calculated for the initial 10° of stance and swing flexion. The combined objective function is expressed such that the weighted combination of the flexion factor at stance and swing is minimized. The optimization problem in its general form, can be stated as:

$$\textit{Minimize:} \quad \textit{function} = \alpha\Big[\sum_{\theta=0}^{10}\Big(\frac{p}{q}\Big)\Big]_{Stance} - \beta\Big[\sum_{\theta=0}^{10}\Big(\frac{p}{q}\Big)\Big]_{Swing} \tag{5.10}$$

Subject to:

1. *Grashof criterion for a 4BM:* which states that a 4BM has at least one revolving link if the sum of the lengths of the longest and shortest links is less than the sum of lengths of other two links. This criterion ensures the rotatability of a coupler (link attached to top upright), thus allowing for the maximum overall knee flexion angle.
   $(l_3 + l_4) - (l_1 + l_2) \leq 0$

2. *Size constraints on the link lengths*: Link lengths are judiciously constrained to avoid bulky 4BM solutions and to ensure that the coupler is the shortest link.
   $20 \leq l_1, l_2, l_4 \leq 60$ and $20 \leq l_3 \leq 30$

3. *Constraints to maintain proportionality of the assistive 4BM for the purpose of alignment and feasibility of the synthesized 4BM. Here the angle of a line joining the midpoints of top and bottom link is constrained.*
   $70^\circ \leq \gamma \leq 110^\circ$

where, θ is the knee flexion angle. Additionally, upper and lower bounds on the design variables were provided considering the shape and the cosmetic appearance of a 4BM.
The weighting factors ($\alpha = 0.4$) and ($\beta = 0.6$) were judicially decided based on what an actual fabricated prototype would look like. The weighting factor combination of ($\alpha = 1$and $\beta = 0$) will produce a hyper-stance-stable 4BM knee joint that will be locked throughout the gait cycle and the combination of ($\alpha = 0$ and $\beta = 1$) will produce a freely flexing 4BM knee with the least stance stability.

5.3.5 Optimization method: GA approach

MATLAB$^{\text{TM}}$ (R2014a, The Math Works Inc., USA) software is used for optimal synthesis of the assistive 4BM. To search for the global optimum of an intricate objective function and nonlinear constraints, powerful non-traditional optimization technique such as genetic algorithms was employed. GA with elitist strategy was used for the optimization.

GAs are powerful non-traditional optimization techniques, which mimic the process of evolution. Hence, they are also called as evolutionary optimization techniques. Darwin's theory of natural selection is the central theme based on which GAs function. Only the fittest survive and reproduce such that successive generations are improved. GAs work on the functional values and do not use auxiliary information such as function derivatives as used in calculus based optimization techniques. Basic building blocks of GA are initial population, reproduction, crossover and mutation. GA generates a random initial population (here each vector with seven variables), which is used for reproduction, crossover and mutation operations to produce the next better generation. This process of evolution continues until the GA meets the stopping criteria, namely, the average change in the fitness function value over the number of generations is of the order of 10^{-6} or lower.

5.3.6 Choice of parameters for the GA

The population type specified in the GA is of the double vector type. This generates a random population of data type *double*. The population size is set to 300 as the number of variables are more in this case (i.e. 7). With a large population size, the GA searches the solution space more thoroughly, thereby increasing a chance of converging to the global optima. However, a large population size also increases the computing time. Both the creation function and mutation function are set to *constraint dependent*. The fitness scaling function, *rank* scales the raw scores based on the rank of each individual, rather than its score. Rank fitness scaling function removes the effect of the spread of the raw scores. A *Stochastic uniform* selection function is used to choose parents for the next generation. Reproduction operation in the GA creates children at each new generation based on the elite count and crossover fraction. Elite count specifies the number of individuals that are guaranteed to survive to the next generation, which in this case is 15 (default= 5%of the population size). Crossover operation is set to produce 80% individuals of the next generation while 20% are produced by mutation. Constraint parameters for the nonlinear constraint solver and stopping criteria are set to *default* options in the GA. The GA code was run at least five times in a loop to check whether the GA has converged to a global minima and the best solution amongst the set of closely spaced optimal solutions is handpicked considering the cosmetic appearance.

5.4 Results and discussion

5.4.1 Optimization results

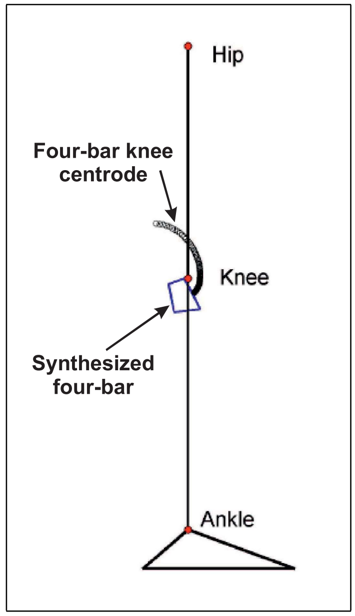


Figure 5.7: Synthesized four-bar linkage with centrode

The synthesized assistive 4BM is a Grashof class-I double rocker mechanism, in which the sum of the lengths of the longest and shortest links is less than the sum of the lengths of other two links. The synthesized 4BM with a characteristic centrode is shown in Figure 5.7. The assistive 4BM provides user-controlled geometric locking as compared to the mechanical locking systems present in existing KAFOs such as drop lock, bail lock etc. Absence of a mechanical locking system, which allows for an easy stand-to-sit and sit-to-stand transition, is another benefit of the new design.

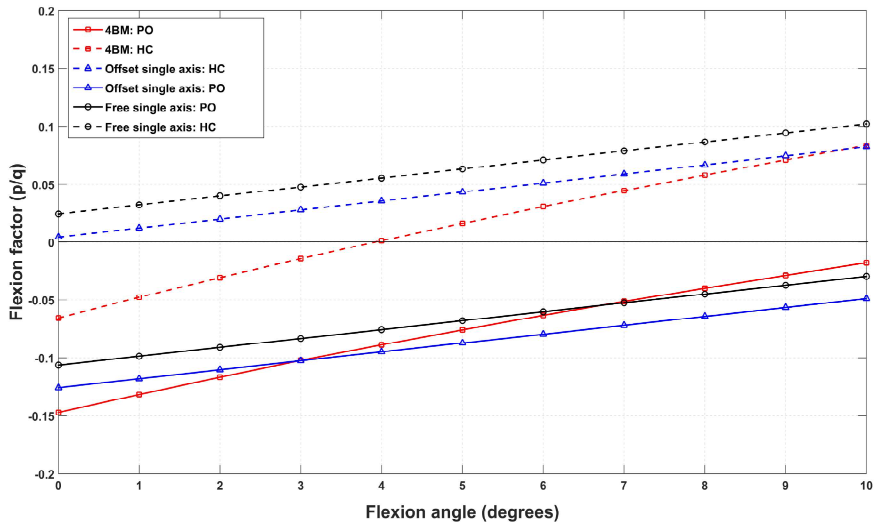


Figure 5.8: Comparison of the heel contact (HC) and the push off (PO) flexion factors for the single-axis free knee, single-axis offset knee and the synthesized assistive 4BM over 10° of the knee flexion.

Figure 5.8 shows the variation of the flexion factor against the knee flexion angle for the synthesized assistive 4BM, free single-axis knee and offset single-axis knee. Flexion factor is proportional to the hip moment required at heel contact and push off. A negative flexion factor implies that an extension moment acts at the knee and the knee is stable at heel contact without requiring any stabilizing hip moment.

At heel contact, for both the free and offset single-axis knees, the flexion factor is positive, which means that a flexion moment acts at the knee and the knee joint is unstable. The user must exert a small hip extension moment to shift the load line behind the knee center to actively gain the stability. The new assistive four-bar design provides 4° of stable stance phase knee flexion up to which case a user need not exert any stabilizing moment. Further, a user can voluntarily control the stance stability for an additional 4°-5° of knee flexion, assuming that the user is capable of generating the required hip moment. The stabilizing hip moment required with the synthesized assistive four-bar knee is less than that for the offset single-axis knee joint until 10° of knee flexion. With such reduced requirements of the hip strength, users can control the knee stability by applying a small hip extension moment, even when they land on a flexed knee, a likelihood on uneven terrain. Thus, stability issues arising during community ambulation with an offset single-axis knee joint can be overcome with such an assistive four-bar orthotic knee joint.

During the push off phase, the flexion factor for all three knee joints are negative, indicating the necessity of a hip flexion moment to initiate swing flexion. The four-bar knee is difficult to flex as compared to the single-axis knees as the IC is designed to remain behind the load line for the initial few degrees of knee flexion. Thus, an increase in the stance stability demands a greater effort to flex the knee during push-off. However, the requirement of the flexion moment reduces with the assistive four-bar knee and it is lower than that for the single-axis knee after 7° of the knee flexion as shown in Figure 5.8. In the absence of required musculature to flex the knee, the user has to adapt the circumduction strategy for ground clearance during the swing phase.

For a user who can control the stability of the knee during stance and initiate swing flexion using available hip muscle strength, the assistive 4-bar design can serve as a cost-effective, mechanically operated stance control KAFO.

5.4.2 Computer aided design (CAD) model

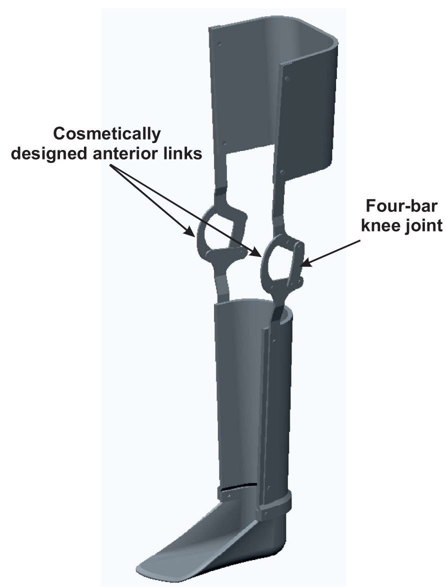


Figure 5.9: CAD model of the synthesized 4BM knee joint assembled in a KAFO

A CAD model of the synthesized assistive 4BM is constructed and assembled in a KAFO using Creo Parametric^{TM} software. The maximum flexion provided by the 4BM is 130° after which the thigh and shank portions of the KAFO interfere with each other. Anterior links are modeled such that the knee joint matches the cosmetic appearance of the anatomical knee in the sitting posture. Figure 5.9 shows that the 4BM knee joint is compact and being a planar linkage, it is easy to manufacture using techniques such as laser cutting or CNC milling. The CAD model presented here is for illustration purpose. In practice, the 4BM will be aligned such that the top right pivot (in the configuration diagram Figure 5.5) matches the optimal anatomical knee center location as described in the 4BM configuration used for optimal synthesis. However, this method of alignment needs to be further evaluated for resulting pistoning effects. It is considered as a part of the future work and is mentioned in the Section 5.4.3. In addition, parallel alignment of the four-bar linkages on both sides needs to be done carefully.

5.4.3 Challenges and future scope

Various challenges identified to guide the future design of assistive 4BM orthotic knee joints are listed below:

1. KAFO users generally have weaker musculature when compared to transfemoral amputees because in the case of an A/K amputation the hip musculature is likely functional in the majority of users. Thus a KAFO user has a lower ability to voluntarily stabilize the knee joint during stance as compared to an A/K prosthesis user, which means that the zone of voluntary stability (shown in Figure 5.4) is further shrunk for a typical KAFO user. The shrunk zone of voluntary stability control presents a design challenge.

2. The characteristic knee centrode required for the orthotic assistive 4BM is different from the anatomical knee centrode. Thus, the motion of a 4BM orthotic knee and the anatomical knee differs. The relative motion between the limb and the orthosis may exert unwanted constraint forces and pistoning forces on the limb (Lew *et al.*, 1982). This is a major concern and needs to be addressed by minimizing the pistoning effect using some mechanical arrangement. A pistoning simulation model proposed in the next chapter can be used to study the pistoning effect. Based on this consideration, alignment of the assistive four-bar orthotic knee with respect to the anatomical knee center needs to be worked out.

3. The apparent shank shortening provided by a 4BM in a prosthesis helps to clear the ground (Gard *et al.*, 1996), but likely exerts a longitudinal force in the case of an orthosis due to the presence of the limb. This effect may need to be mitigated.

5.5 Closure

The concept of an assistive four-bar orthotic knee joint is novel and more sophisticated than the various existing orthotic knee joint designs. Hence, it needs to be thoroughly evaluated and analyzed before testing on the users. In this work a method for optimal synthesis of a 4BM, which can provide stability during stance and free knee flexion during swing for a typical KAFO user is proposed. Further evaluation of the synthesized 4BM with regard to the pistoning motion is required, which will also help to decide the proper alignment of the 4BM with respect to the anatomical knee. The design must be tested for strength before conducting user feedback trials. The clinical trials need ethics committee and IRB approval, which made clinical evaluation of the proposed joint challenging within the scope and timeline of this work.