Comparative Study of Micro Motion in Stem Implant and Legacy Stem Implant using FEA

A Dissertation Report
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requirements for the degree of

Master of Engineering

in

CAD / CAM Engineering

by

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DECLARATION

I declare the dissertation work entitled "**Comparative Study Of Micro Motion in Stem Implant and Legacy Stem Implant Using FEA**" represents my ideas in my own words and where other's ideas or words that have been included are adequately cited and referenced the original sources. I also declare that I have adhered to all principles of academic honesty and integrity and I have not misrepresented or fabricated or falsified any idea/data/fact/source in my submission. I understand that any violation of the above will be cause for disciplinary action by the institute and can also evoke penal action from the sources which have thus not been properly cited or from whom proper permission has not been taken when needed.

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CERTIFICATE-I

This is to certify that the dissertation work entitled "**Comparative Study Of Micro Motion in Stem Implant and Legacy Stem Implant Using FEA**" is an authentic record of work carried out by "**Mr. Venus Vermani, R&D Intern – Joint Replacement**", during his engagement as an intern in the Stryker Global Technology Center, Gurgaon from **4th June 2018** to **12th July 2019**. This project work is carried out under our supervision and guidance in partial fulfilment of the requirements for the award of the degree of **Master of Engineering in "CAD/CAM"** at Thapar Institute of Engineering and Technology, Patiala Punjab during the academic year 2018-2019.

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CERTIFICATE-II

This is to certify that the dissertation work entitled **"Comparative Study Of Micro Motion in Stem Implant and Legacy Stem Implant Using FEA"** is an authentic record of work carried out by **"Mr. Venus Vermani, R&D Intern – Joint Replacement"**, during his engagement as an intern in the Stryker Global Technology Center, Gurgaon from **4th June 2018** to **12th July 2019**. This project work is carried out under our supervision and guidance in partial fulfilment of the requirements for the award of the degree of **Master of Engineering in "CAD/CAM"** at Thapar Institute of Engineering and Technology, Patiala Punjab during the academic year 2018-2019.

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ABSTRACT

For the patients having trouble in performing day to today activities like walking, stair climbing, squatting etc., medical companies are providing various solutions like replacement of body's natural joint with the artificial components. These artificial joints mimic the actual working of natural joint by providing real stability and actual range of motion by reconstructing the joint's natural anatomy. One of the components is the stem implant which is inserted inside the Femur bone. This component bears the full body load and transfer it to the knee. This study is regarding the stability of the stem under load conditions. The displacement of the implant is studied with respect to the bone when it is fixed inside the bone during the surgery and when the patient performs stair climbing activity after the surgery. Here various types of implants are studied under the load and their behavior of micro-motion during the activity. FEA methodology is used to setup a method that can provide the results for it. The method is validated using the clinical data of legacy stem called Plasma. To confirm the population compatibility, another study is performed using SOMA (Stryker Orthopedic Modelling And Analysis) by analyzing canal taper angle and implant's sitting position inside the bone. It was observed that there was less amount of micro-motion induced in the conical stem design when compared with legacy Plasma implant.

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LIST OF ABBREVIATIONS

THA	=	Total Hip Arthroplasty
AP	=	Anterior Posterior
ML	=	Medial Lateral
Co	=	Cobalt
Cr	=	Chrome
Ti	=	Titanium
Al	=	Aluminum
V	=	Vanadium
MM	=	Micro-Motion
W1	=	Weight
My	=	Moment
M1	=	Moment 1
M2	=	Moment 2
A	=	Distance from Greater Trochanteral to head center
B	=	Distance from hip center to head center
CAD	=	Computer-Aided Design
SOMA	=	Stryker Orthopedic Modelling And Analysis
FEA	=	Finite Element Analysis
N	=	Newton
GPa	=	Giga Pascal
MPa	=	Mega Pascal
µm	=	Microns
Al	=	Assembly Load
FL	=	Functional Load
HA	=	Hydroxy Apatite

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CHAPTER 1
INTRODUCTION

1.1 Total Hip Replacement System (THR)

When a person's hip has been damaged by arthritis, fracture or wear with age, it becomes difficult for the patient to do every day usual activities. To get rid of the pain, doctor suggests the patient to undergo total hip replacement in which the damaged bone and cartilage is removed and replaced with prosthetic components. It is expected by the patient to have no pain after the surgery and his prosthetic hip joint should work similar to the natural hip. Stryker is in the field of designing such implants for 30 years now with the excellence in terms of orthopedic. With the help of combination of worldwide surgeon panel and engineer expertise of human factor engineer, Stryker is able to provide optimal, intraoperative and efficient Implants to the patient [1].

1.1.1 Implants

Prosthetic components that are used as artificial joints are basically called as Implants. Stryker orthopedic is in business of designing various implants to replicate various body joints. For the patient who undergoes hip replacement expects the functionality of hip similar to natural hip without pain. Accolade II, Trident II, Exeter, Restoration Modular are some of the biggest brands of hip implants offered by Stryker which gives the patient complete satisfaction [2,3]. It is designed in such a way that it works very closely to the natural hip anatomy and that provides the benefit for making patients day to day life activity easy.

1.2 Implant Features

1.2.1 Patient Compatibility

To capture maximum market and to keep business ahead of all the competitor's, company's implant should cover most of the population. As because of diverse population, world has people with different bone size for example on average the size of bone of an American man will be bigger than the bone size of an Asian man. Any person of any ethnic group, age, sex etc. can require total hip replacement so the basic design of implant should not vary and should be of different sizes to make it compatible with most of the population. Stryker has a its own tool called SOMA which stands for

Stryker Orthopedic Modelling And Analysis which can be helpful to predict the patient compatibility of implant [2,3].

1.2.2 Procedure Compatibility

To perform the Total Hip Replacement there are number of ways in which surgeon can do the incision on the Hip. With different incision, technique to perform the surgery changes hence implant and instruments should be compatible with all the approaches to meet every surgeon's need [2].

1.2.3 Material Compatibility

As implant will be implanted inside the body for long period of duration. To prevent any reactions inside the bone, implant material should be bio-compatible. The implant material must be corrosion resistant, it should have high yield strength and fatigue strength to sustain the body load for a period of 10 years. The material should be wear resistant, as it is placed inside the body, debris generation will reduce the life of implant. The selected material should also have modulus of elasticity analogous to bone. If the material is very stronger than the bone, it would lead to thinning of the bone. These qualities are not enough to select the proper material for the implant. Various materials which are used in market these days are

- **Metallic** The popular metallic alloys which are used these days in industry are Gold alloys, Cobalt-Cr alloys. Many industries are using stainless steel to make their implants. Titanium alloys are the most common alloys used for the implant manufacturing these days.
- **Ceramic** This is not given priority against metal but is used when patient is allergic to metals.
- **Polymers** Polyethylene is a material which is used in implants where relative motion is present and wear resistance is required as it's a metal free plastic with high wear resistance.

1.2.4 Ergonomic Design

Ergonomic design which helps surgeon to prepare different bone parts with less instrumentation to minimize overall surgery time.

1.3 Basic Hip Anatomy

A normal hip joint goes through various day to day activities. This joint connects the upper half of the body with lower extremity. Hip joint is one of the largest joint in human body which bears the maximum body weight. It is a ball socket synovial joint. To understand various hip problems, it is important to understand some of the anatomy of body and hip joint. Figure 1.1 below shows the structure of hip joint [1]. Joints - ligaments, bones, tendons, muscles, nerves and blood vessels together form the hip joint. In biological field, different terminology is used to define the orientation, views of the bones. There are three different anatomical planes which are orthogonal to each other and divide body as shown in Figure 1.1 below. Sagittal plane is the plane which divides the body in to left and right, Transverse Plane is the horizontal plane which divides body in to upper and lower half or head and tail, Coronal plane is also called Frontal plane which divides body into front and back.

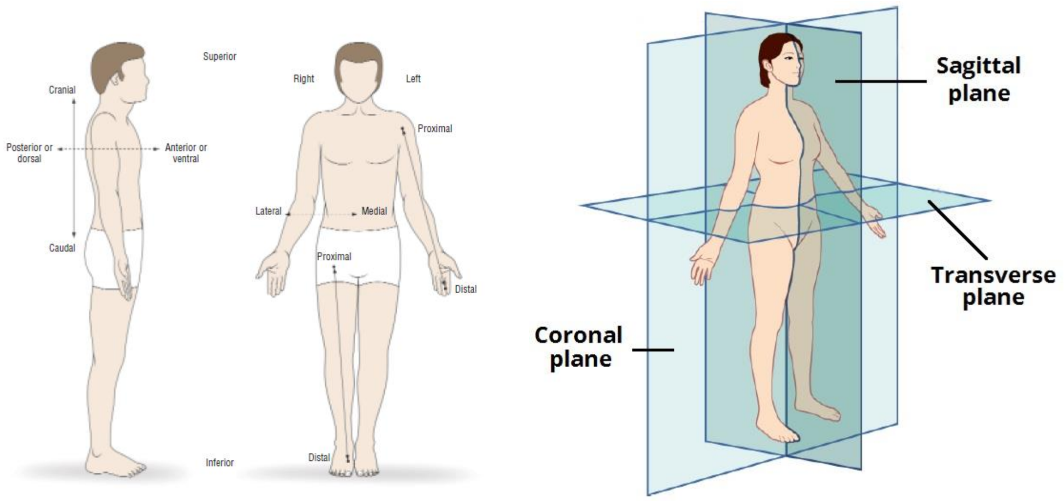


Figure 1.1: Anatomy of human body [1]

To define the part of body with reference to an imaginary line passing through middle of the body, medial is defined as closer to center axis of the body and lateral for relatively away from the center axis. The part which is nearer to head when bisected using Transverse plane is referred as proximal and other as distal. When we talk in reference to Coronal plane the side which is in front is referred as anterior and side which is in the back is referred as posterior. The three main body parts which together forms the hip joint are Acetabulum, Femur and Labrum [1,4].

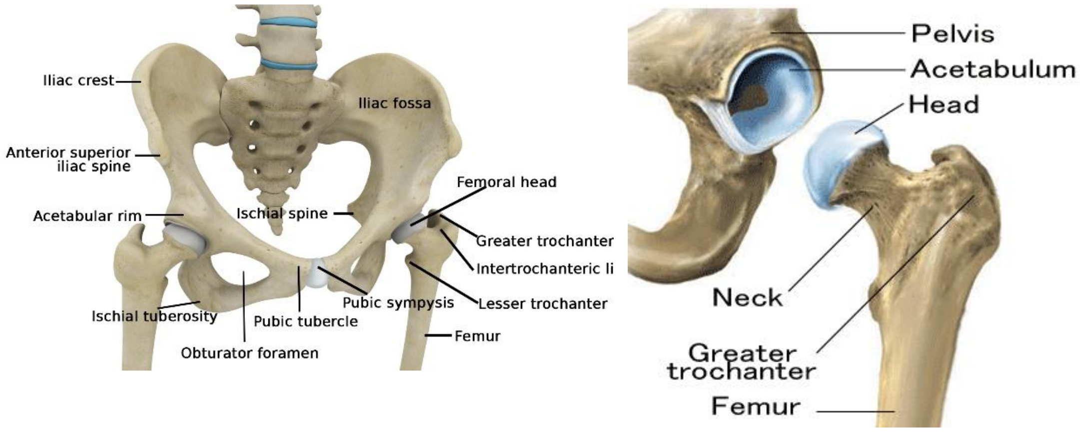


Figure 1.2: View of hip joint [4]

Acetabulum is the socket formed with three bones ilium, ischium and pubic which has the articulating surface over it called acetabulum labrum responsible for providing smooth surface for femoral head to relatively move.

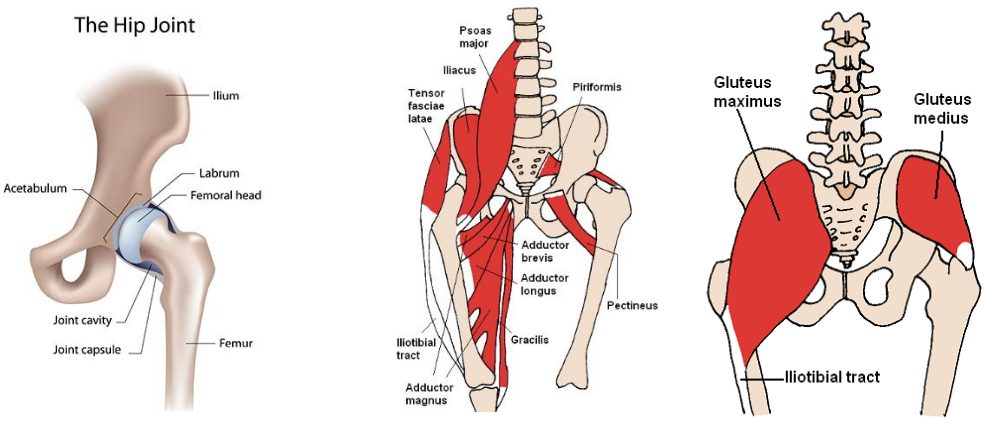


Figure 1.3: Anatomy of Hip Joint [4,5]

Hip joint is covered with many muscles. The major muscles which hides the joint are Gluteus Maximus, Gluteus Medius, Gluteus Minimus and abductor muscles as shown in Figure 1.3.

The nomenclature of main different parts of femur bone are head, neck, trochanter, body of shaft, condyles and patellofemoral groove. The importance and function of each is given below

1.3.1 Femur Head

Femur head is in the proximal side of the Femur. Takes participation in Hip Joint. Transfers the acting load of body to the Hip.

1.3.2 Neck

The neck like structure in Femur supports the femur head. The load from the femur bone gets transfer through neck so bone density in this section is very high

1.3.3 Trochanter

It is powerful protrusion located at proximal and lateral side in Femur.

1.3.4 Shaft

A long and straight part of the Femur bone. The inner side of the shaft has cancellous bone which is also called spongy bone inside which it is hollow, and the bone marrow is present in that hollow space.

1.3.5 Condyle

The portion of femur that contribute to knee joint.

1.3.6 Patellofemoral Groove

Very important part of femur. During the flexion and extension, the patella will follow the path on femur called as patellofemoral groove. Patellofemoral groove also called as patella track.

1.4 Axis of Hip Joint

The femoral head acts as a ball and acetabulum as a socket of ball-socket joint. To understand how hip joint sustains the body load, some of the axis are explained. In human body the axis is divided into two categories based on Load acting criteria/motion criteria and Human anatomy.

1.4.1 Mechanical Axis

Mechanical axis is also called as the axis of alignment or axis of load this is defined as an axis passes through the Centre of hip I.e. Hip Centre to the midpoint of ankle joint which is at second metatarsal. (See Figure 1.4) [6].

1.4.2 Anatomical Axis

Anatomical axis is also called as axis of bone; Anatomical axis is defined as the axis passes through the best fit circle created on shaft of tibial bone.

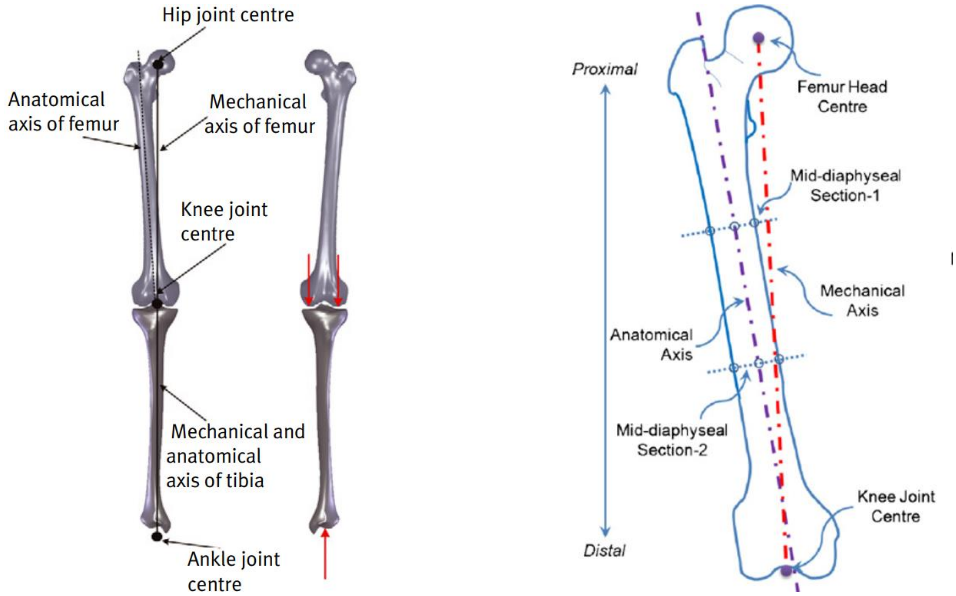


Figure 1.4: Axis of Body [6]

These axes define the Varus and Valgus condition of the body which are the deformities in hips and knees.

1.4.3 Coxa Varus and Coxa Valgus

Valgus in knee is the deviation of bone when the distal portion of bone is medially inclined that is the distal portion of the bone is more towards the mid line of the body. This condition in Knees is called Knock Knees. For Hip Joint, Coxa Valgus is when the angle between the neck line and shaft length is more than 135˚ [7].

Figure 1.5 shows Coxa Varus condition when the angle between femur shaft and femoral neck is less than 120 ˚.

These conditions directly impact on implantation of implant. When surgeon performs the Total Hip Arthroplasty, surgeon’s aim remains to maintain or correct this condition which is to keep the femur head, center of knee and ankle joint center in one single line. These conditions directly impact on implantation of implant. When surgeon performs the Total Hip Arthroplasty, surgeon’s aim remains to maintain or correct this condition which is to keep the femur head, center of knee and ankle joint center in one single line.

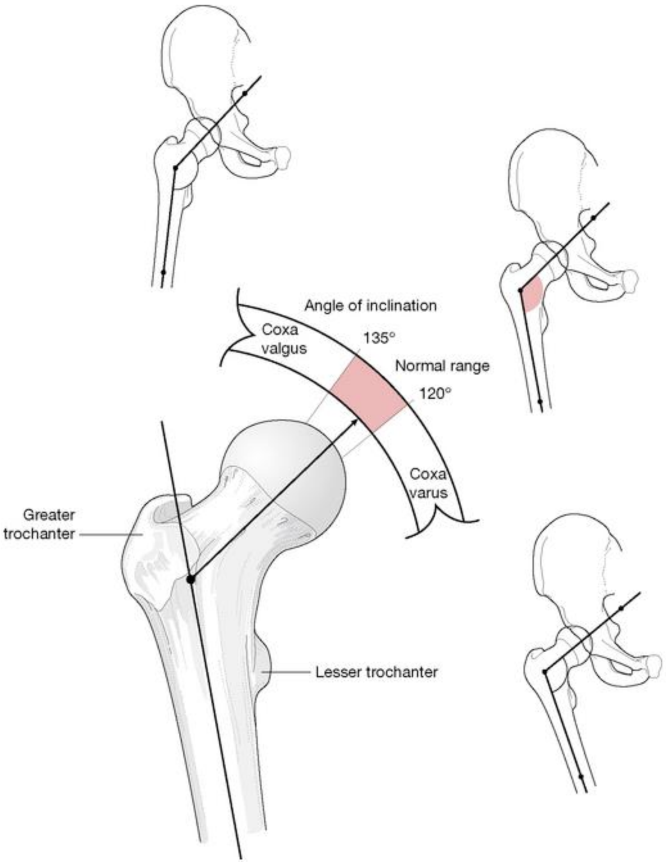


Figure 1.5: Varus and Valgus [7]

CHAPTER 2

TOTAL HIP REPLACEMENT IMPLANTS

When implants are designed, they are designed to keep the natural anatomy of joint unchanged. Patient should not feel any pain and should be able to perform all day to day activities. Figure 21 describes the comparison of normal hip joint with prosthetic hip joint.

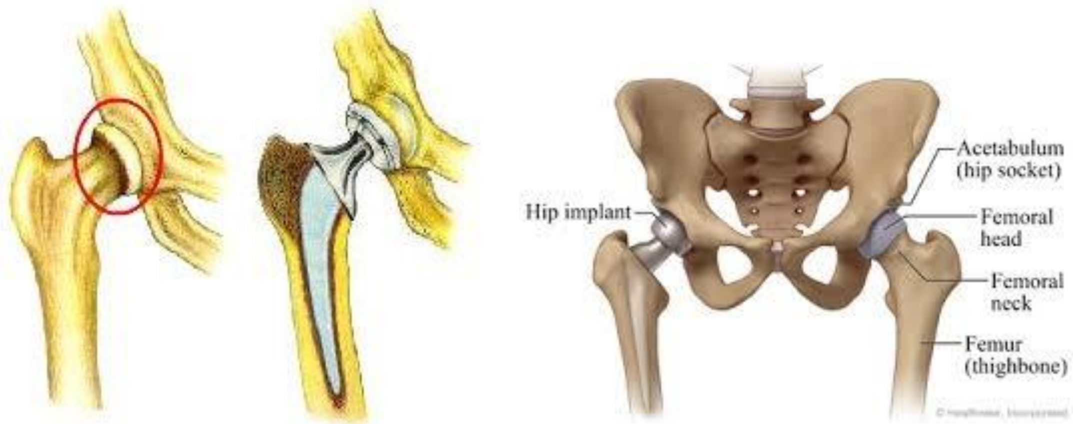


Figure 2.1: Normal Hip joint and THA Joint. [4]

In a THA, the damaged bone is removed and in place of damaged bone prosthetic component is fixed. To make bone compatible with the components various activities are performed like reaming, flattening of bone using various instruments. These activities majorly effect on the fixation of the implant. If surgeon requires more interference between the implant and the bone, he removes less bone than the outer periphery of implant using smaller reamer to get more interference. To replicate the normal hip joint, there are respective prosthetic components for each femoral head, acetabulum, acetabulum labrum and femur body shaft. During the THA the primary focus of surgeon is to get the stability and then range of motion. The most important is to prevent the infection with providing maximum stability, as lack of stability or chances of infection causes the revision surgery in which surgeon has to perform the surgery again where old components of implant system are removed. This section contains some of the components offered by Stryker to the customers and there use location. We have also talked about their importance and types of stem along with the basic idea of micro-motion.

2.1 Implant Components

2.1.1 Shell

Shell is the prosthetic component which goes in to the acetabulum. It acts in a similar way the acetabulum works that is providing the cavity for the femur head. This shell is fixed using tight fit or by using cement to the acetabular cavity after preparing that cavity using various instruments. It is basically a socket in a ball socket joint. See Figure 2.2 where one of the Stryker's famous shell is shown. All the load from the body acts on shell which transfer it to femoral head, femur and transfer it further to the knees.

Figure 2.2: Trident Shell Implant [3]

2.1.2 Femoral Head and Liner

Femoral Head is the artificial component which act as the femur head as the name suggests. This head goes in to the shell and moves inside it. As the head is mostly made up of metal and shell is also a metal and to avoid the metal to metal contact, there is another component made up of plastic and is called Liner. It is the component which imitate the acetabulum labrum and provides the smooth surface and more range of motion. Figure 2.3 shows the liner and femoral head assembly. Liner acts as a separator between metal and metal and prevent the generation of metal ions.

Figure 2.3: Liner and Femoral head [3]

2.1.3 Stem

Stem is the metallic component which goes inside the femur bone shaft and attaches to femoral head with femoral neck. It is responsible for transferring the load from shell to femur bone so that load can be transferred to knees. Stem is the component which gives the strength and fixation to the implant. There are number of designs in stems as it depends on the various parameters that which stem is to be implanted in the bone. Stem along with implant assembly is shown below in Figure 2.4. The design varies on parameters such as patients age, bone quality, type of surgery, how much bone is to be conserved and activity level of the user etc. There are two types of stems in the market

Figure 2.4: Stem and Implant Assembly [3]

- Cemented Stem
- Cement less/Uncemented Type

In Figure 2.5 Stryker's famous stem designs are shown which are Accolade 2, Restoration modular conical stem, Restoration Modular Plasma stem. All these stems are cemented type that means these stems will have tight fit with the bone. Cemented stem are the stems which have some amount of tolerance between the implant and reamed bone. This clearance is given to generate the empty space between the bone and the implant where cement can be poured. This bone cement provides the fixation to the implant. Cement less implants are the implants where the fixation is biological i.e. there is no presence of any fixation material such as bone cement. The bone and implant have direct contact.

Figure 2.5: Accolade II, Conical, Plasma Stem [3]

In our study we have included shorter version of conical stem and Plasma Stem to see the micro-motion of stem inside the bone.

2.2 Micro-Motion in Stems

The stem implant is inserted into the femur bone shaft and is connected to the acetabulum and receives the body load from there. This is the component which provides the stability to the joint. The movement of the implant relative to the surrounding bone which can not been seen with eyes is called the micro-motion. It can be seen at times such as

- During Pre-Surgery Micro-Motion
- After Post-Surgery Micro-Motion

Pre-Surgery micro-motion is during the surgery when implant is implanted inside the bone, Surgeon applies some force to insert stem inside the bone and to check the initial stability of it. During this time, it is possible that implant gets displaced with respect to surrounding bone. This small displacement is one of the types of micro-motion.

Also, some of the stems are not monolithic in design which means surgeon needs to assemble the cone body during the surgery and to assemble this cone body, surgeon may use power tool to do so. Hence stem should have enough stability to overcome this moment force. During this assembly, micro-motion can occur. Post-surgery micro-motion is the type of micro-motion where there is displacement of stem from its initial positions in a long run. This can happen due to the various day today activities performed by the patient.

2.2.1 Direction of Micro-Motion

Micro-motion can be

- Translation along axial direction of stem
- Rotational about the stem axis

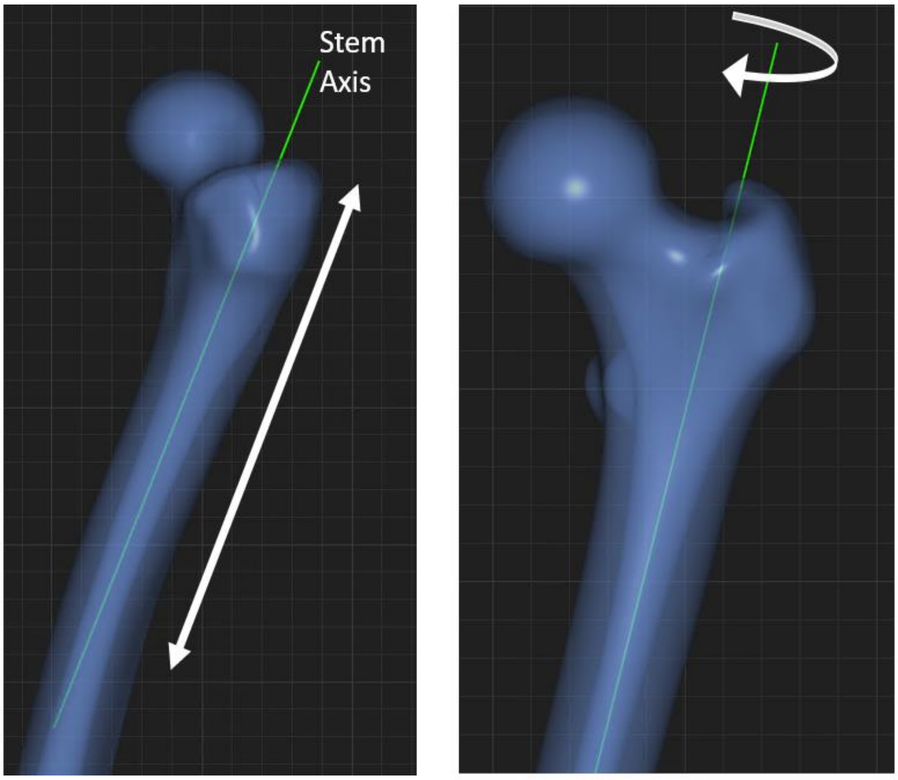


Figure 2.6: Micro-Motion Direction (SOMA)

Figure 2.6 shows the two directions of micro-motion. Here stem axis is the center line of implant which is matched by surgeon with the proximal shaft axis that passes through the isthmus’s central point.

This micro-motion plays a very important role when it comes to the fixation of implant. If the micro-motion is not in desired range various problems arises which are discussed in upcoming content.

2.2.2 Reasons for Micro-Motion

There are various reasons that can cause micro-motion. Some of them are

2.2.2.1 Invalid Design

One of the major reasons for stem micro-motion is the improper design of stem implant. In implants like conical stems, the tapper angle has a great effect on siting of the implant inside the bone. If this angle is wrongly selected, there will be improper fixation inside the bone causing stem to move from its place.

2.2.2.2 Improper Fixation

During the surgery, surgeon tries to achieve three-point fixation inside the bone. It is very difficult for surgeon to check if it is achieved or not. So sometimes it seems to surgeon that he has achieved the required fixation but in real fixation is not as stable as needed hence stem displaces from its position during the surgery or post-surgery.

2.2.2.3 Improper Size Selection

This can occur due error in pre-operative preparations i.e. when wrong size of implant is press fitted inside the bone. If surgeon placed smaller size implant than needed, there won’t be much contact between implant and cortical bone causing it to displace from its position.

2.2.2.4 Improper Type Selection

When best suited implant is not used in the surgery, the chances of micro-motion increases as the design of implant varies as per its user and user’s activity level. For example, when surgeon places cement less stem in older patient where his bone generation ability is not very efficient. In such cases, implant will be more prone to get loosened from its place.

2.2.2.5 Stem Length

This has major effect on the amount of micro-motion that happen, as with the more length contact area increases which reduces the chances of micro-motion.

2.2.2.6 Implant Surface

Implant surface plays a major role in preventing the micro-motion. The surface roughness of the coating of implant can have effect on its movement from its place.

2.2.2.7 Bone Defects

More micro-motion can be seen in bones where bone lack of osteointegration property. This is the ability of bone to grow where it is under more loading/pressure. Once implant is placed inside the bone, long term stability of implant depends upon this property of bone where bone grows and provides more fixation to it.

2.2.3 Effects of Micro-Motion

Excessive micro-motion can have adverse effect such as

2.2.3.1 Revision Surgery

When there is excessive micro-motion it will not allow user to perform day today activity, in which case surgeon asks for revision surgery.

2.2.3.2 Aseptic Loosening

Due to excessive micro-motion implant will displace more from its position which will arise the situation where implant will not have required fixation with the bone.

2.2.3.3 Excessive Wear

More micro-motion can also contribute to debris generation which reduces the implant life and patient needs to go for revision before estimated time.

2.3 Forces on Hip Joint

The load from pelvis comes on hip from where it is transferred to the knee joint. Hip joint is under various types of forces during different activities.

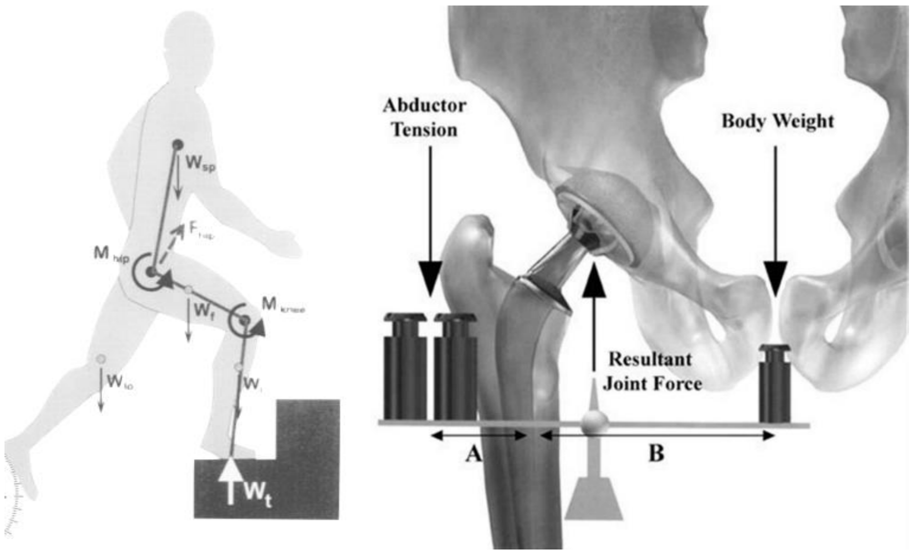


Figure 2.7: Hip Joint Force Balancing [8]

As the pelvis is kept on femur head, there is a force generated by muscle to balance the moment caused by body weight at the junction of femur head and acetabulum. Some of these forces are explained below

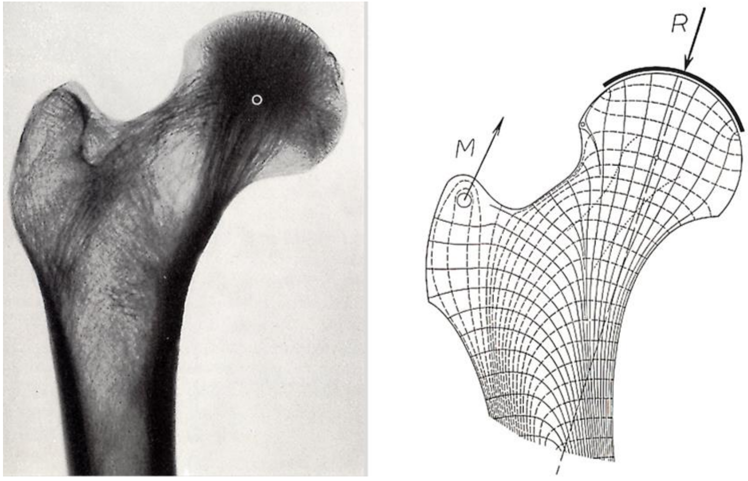


Figure 2.8: Hip Joint Force Distribution [3]

2.3.1 Joint Reaction Force

The force which is generated within the joint to overcome the forces acting on joint. To balance the moment arm generated due to the body weight of patient and abductor tension, a force is generated within the hip joint. It is necessary to maintain pelvis level.

2.3.2 Muscle Force

It is the force generated by the muscle to balance the body weight moment. This force varies as the activity changes. When person is walking this force will be different compared to when person is stair climbing. This is the reason that some activities are more tiring than others.

2.4 FBD of Hip Joint

Body weight is centered along the central axis of the body. This center of gravity weight (W) is far medial from the center of rotation of the hip (COR). To keep the pelvis balanced horizontally during single leg stance or gait, this weight has to be compensated by the gluteal abductor muscles that attach around the greater trochanter at the lateral side of the hip. The distance between this gluteal attachment and COR hip (Distance A) is much smaller than the distance between COR hip and center weight W1 (Distance B). Thus, an unequal balance exists whereby the abductor mechanism has to provide much more power to compensate the forces, the difference being linear with the relative length difference between medial and lateral offset. As this lateral offset (Wb) is usually 2 – 2.5 times smaller than the medial offset (B), the force increase must also be 2 – 2.5 times. This force adds to the body weight already present on top of the hip (total body weight minus single leg weight in single leg stance). The JRF is the sum of all this and thus may amount to 3 – 3.5 times body weight even in rest. With activities this may increase to 7 – 8 times body weight.

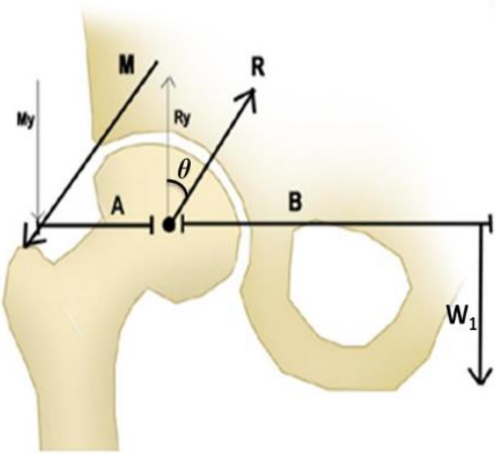


Figure 2.9: FBD of Hip Joint [8]

In Figure 2.9, R is the Joint Reaction Force generated to balance the Moments

Here two moments are generated. One is due to the body weight which is W1. It is equal to half of the upper body weight because pelvis is supported by two such joints. Second due to the Muscle force, M to balance W1. Here A is the distance between head center and B is the distance between head center and center of body/point where body weight is acting.

Table 2.1: Determination of Reaction Forces in Hip Joint

Moment 1, M1 = W1 X B
Moment 2, M2 = My X A
Using Newton Laws,
M1 = M2
W1 X B = My X A
$\frac{W1\,X\,B}{A}$ = My
My = $\frac{W1\,X\,B}{A}$
Ry = My + W1

	=	$\frac{W1 \, X \, B}{A} + \text{W1}$
	=	$\text{W1}(\frac{B}{A} + 1)$
Ry	=	(Variable) times the Half Weight of upper body

W1, A and B are different for different patients. During surgery W1 and B cannot be changed by the surgeon, but distance A can be varied by the surgeon using different cone body sizes to provide some offset. When this distance is increased, the force which muscles needs to exert also decreases, hence muscle has to work less to perform the same activity.

2.5 Stem Fixation

During the stem insertion, the bone is reamed where the cancellous bone is removed until the reamer meets the cortical bone. Before surgeon stops reaming, a very small amount of cortical bone is removed. This technique is used to get a rough estimate of isthmus position as surgeon wants to ream till the isthmus point. For stem to be fixed properly, taper fixation is required when femur is seen in AP view. When the bone is laterally viewed the contact should be at these three positions. These three points are proximally, distally and mid to distally when viewed in AP view.

From Figure 2.10 above, it can be seen that taper angle of the stem plays very important role in the fixation and micro-motion. Incorrect taper angle will lead to less fixation causing more micro-motion. The average taper angle is estimated for majority of population using SOMA (Stryker Orthopedic Modelling And Analysis). To prevent the stem subsidence, it is very important that distal tip of stem is in contact with the cortical bone. This is called as distal fixation and when there is distance between distal tip and cortical bone, stem is more prone to micro-motion that too axially.

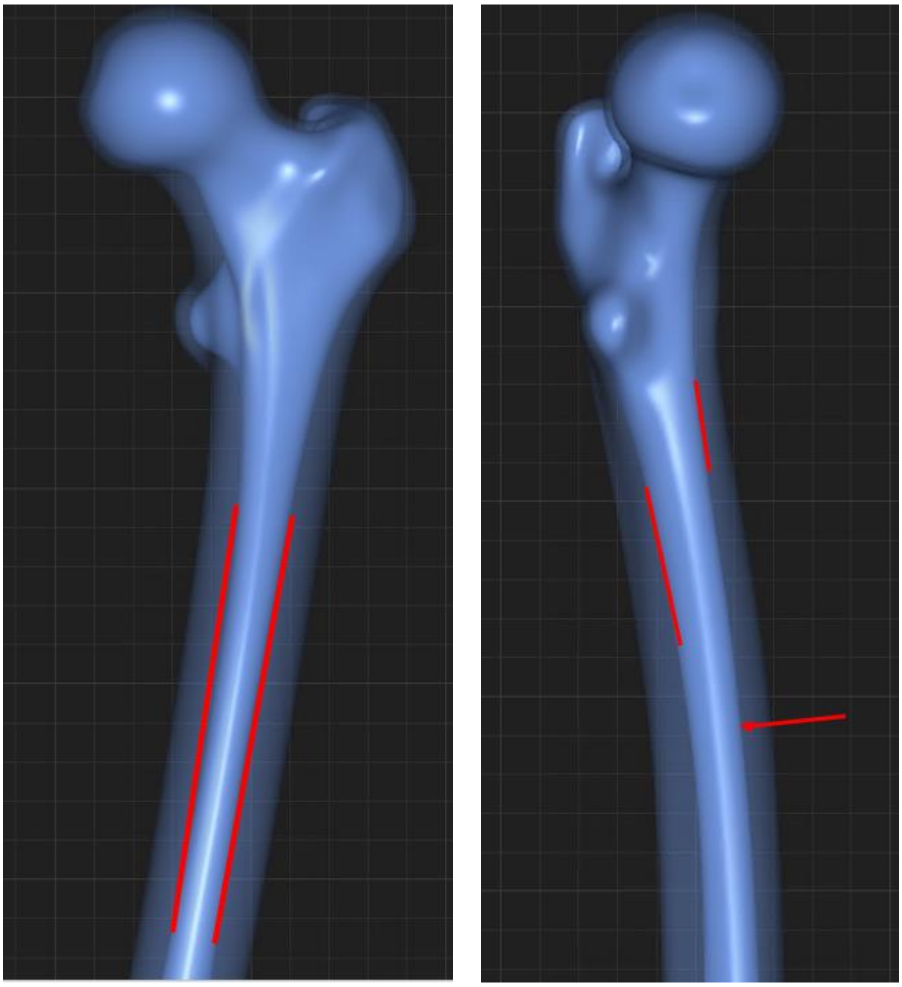


Figure 2.10: AP View (L) MP View (R) of Left Femur (SOMA)

CHAPTER 3
LITERATURE SURVEY

A lot of study has been done on the stem micro-motion because of the criticality of the subject. Different researchers used different approaches to get the result. FDA requires FEA report along with physical testing to launch the implant in to the market. In 2007, Mohammed Rafiq Abdul-Kadir [9] studied the micro-motion in stem for interference fit. He evaluated the FEA model of bone and implant using the approach where he considered only head force unlike another approach where muscle forces are also considered [10]. To make the model more real Florian Boucher [11] used hip Muscles forces in his FEA work to get more realistic results. To get the precise results muscle geometry is required to increase the confidence in the results. Much work has not need done in this field. Studies done by Amtmann and Kummer, 1968; Denham, 1959; Inman, 1947: Jensen, et al., 1971 etc. [12] gave a little idea about the biomechanics geometry.

In the papers M.O. Heller, G. Bergmann [13,14] elaborated the location and amount of hip muscle forces on the femur bone, a method to find the muscle attachments and various muscle forces [15] is explained in the paper. In Figure 3.1 below the coordinate system for bone is shown, in field of bio med, generally this co-ordinate is used.

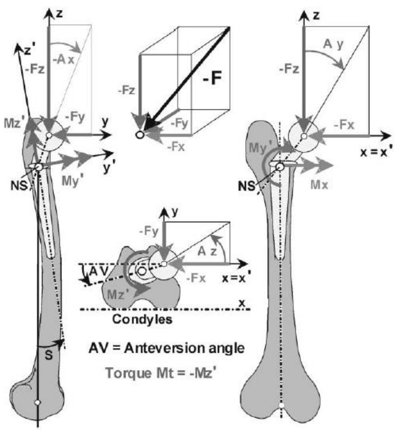


Figure 3.1: Bone Coordinate system [13]

Knowledge regarding the loading condition is provided by the J.P. Kassi in his paper [16]. Rik Huiskes, PhD [17] done preclinical testing on the stems which demonstrated how stresses vary with different stem designs. Sergio Gabarre [18] studied the behavior of two cement-less short stems, this study discussed the friction of coefficient between the bone and implant interface considering the press fit in between. In this study they divided the stem in to 6 parts proximally to distally and simulated for the gait cycle. After the simulation, study discussed regarding the micro-motion rotationally in different levels. Furthermore, how much implant subsidies are also recorded in the results.

In another study, researchers studied how the size of implant effects the mechanical stability of it in relation to the bone quality. They implanted the prostheses in to the femur bone and loaded it cyclically. After loading relative displacement between the bone and prostheses were measured using cameras and reflective marker system. Although they did not consider the muscle forces for the simulation which reduces the bone deformations in actual hence making the case as worst case as required. They clinched the effect of implant at the side of cortical fixation as well as on the cancellous fixation [19].

Westphal et al. discussed regarding the stem design change using FEA. In this study, different designs of stem are compared on the basis of stress shielding and micro-motion. They also did a vitro testing in which implant was potted according to the ISO standards. They also described regarding the non-linearity behavior of the problem and how the analysis is affected with it [20].

Author Abdullah has discussed about the basic arthroplasty and the various types of stem implants [21]. The discussion on the FEA model to check the contact stresses and micro-motion is done in this paper. This paper is about the neck assembled with modular stem. In this study two types of stems are discussed. One which is monolithic and one which is modular. Monolithic are those where body and neck are single component but in modular surgeon has to assemble both giving more flexibility to him/her. Advantages and disadvantages of modular stems are discussed. The surgeon gets to choose various sizes of neck and can offset it from the joint for better fitment and to get more accurate joint line. Modular stems enable designer to mix match the materials for the body of neck and stem. With advantages there are various disadvantages also, such as more fretting due to presence of two mechanically joined parts. There are more chances of implant dissociation and corrosion in case of modular. Various loading conditions are used to get broader aspect of the behavior and results are obtained for various loadings to see the trend and effects of force. Two types of loading are considered in this, Functional loading and assembly loading.

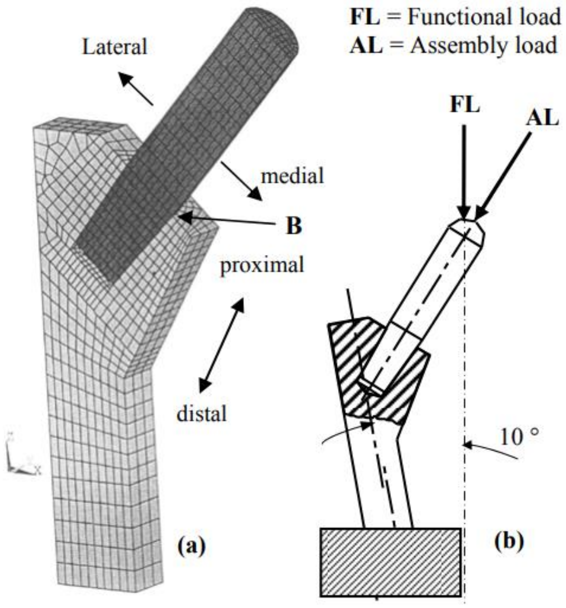


Figure 3.2: Cone Body under FL and AL [21]

The assembly loading is the load applied by the surgeon or power tool when neck is assembled with the body. The functional loading is the load that arises due to various activities. Three models are considered in this study which are when where there is no angle mismatch, when there is positive angle mismatch and when there is negative angle mismatch in taper.

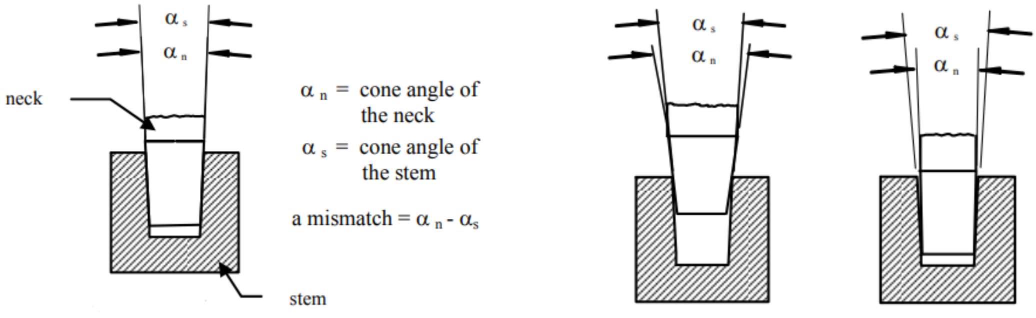


Figure 3.3: Types of Taper Fit [21]

The boundary conditions and meshing of the modelling are also discussed to give the idea of meshing type and contact type. Results are published, and concluded that with high assembly load, better fitment is achieved causing less fretting and less micro-motion at later stages. According to the author surgeon should aim for more than 6000N assembly load. The relation between the stresses, micro-motion and the coefficient of friction is also built. The more friction coefficient means more binding which in turn results to less micro-motion.

A study was performed on dental implants by Gupta and Goyal, this study is important for our study as, FEA model is used to check the amount of micro-motion in dental implants. Here in this study, the two type of implants are taken in to consideration which are meshed with tetrahedron 3D element as shown in Figure 3.4. The implant is placed inside the bone and then various bone properties which are mentioned in paper are then assigned to the part models and then loads are applied to see the micro-motion results using von-mises criteria in both cases and then compared the results. In this study material conditions for cortical bone and cancellous bone are taken exclusively with same poisons ratio for both. The loads are applied perpendicularly to mimic the vitro-study. Here implant, cortical bone and cancellous bone are taken as linearly elastic, homogenous and isotropic. The model is then fixed from below in all three directions which permits the bending of the model [22].

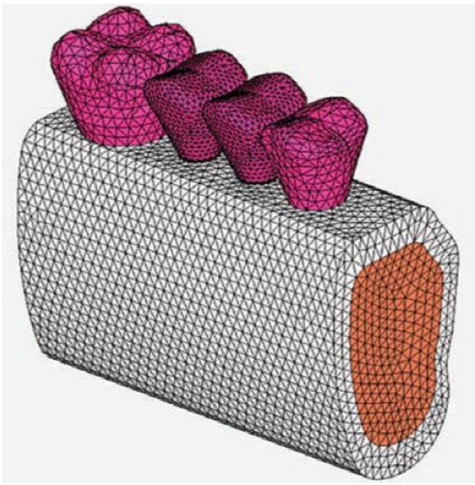
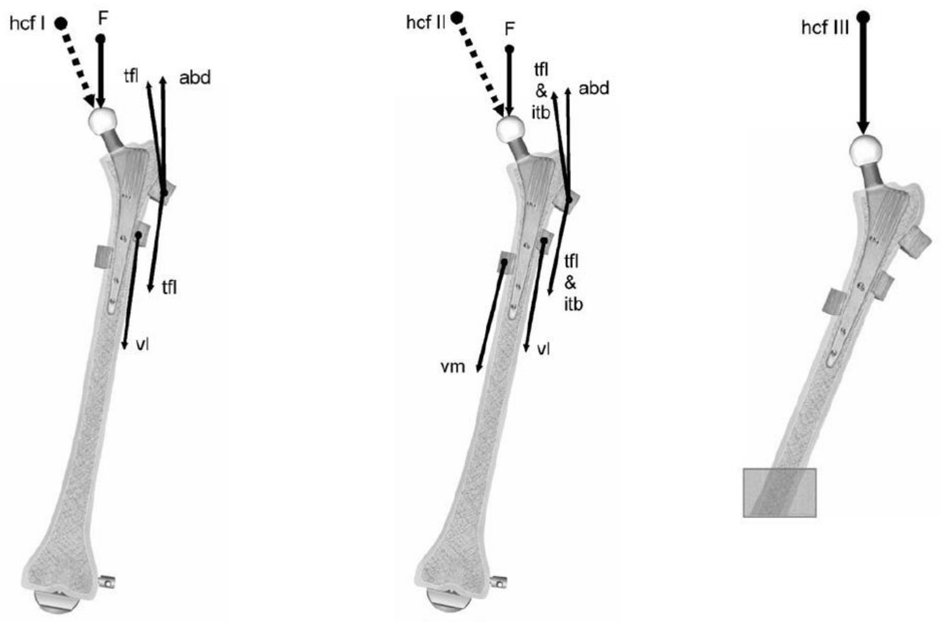


Figure 3.4: FEA Mesh of Dental Implant [22]

Authors Huskies et al. [23] mentioned the importance of pre-clinical testing in hip prosthesis before it is launched in to the market. In this study vitro testing is performed on the stem prosthesis to check the initial stability and post-operative micro-motion under the activity like walking and stair climbing. With this study, results were interpreted that in case of the stair climbing more micro-motion was generated compared to walking. They used 18 femurs and established the setup where muscle forces were simulated along with the hip contact forces. It is suggested that no any other activity has as much extreme instability in stem prosthetic under the simulation of muscle forces as the stair climbing activity. The micro-movement inside the bone seemed to be extremely sensitive to patient activity. In the test setup, LVDT's were used at various locations to check for the micro-motion. For the initial stability, 1000 N is applied axially for the stem insertion. There were three types of loading, first loading had walking force with active muscle force, 2nd loading had stair climbing load with active muscle force while 3rd loading had only the hip contact forces to check for the stability.



Group 1 *Group 2* *Group 3*

Figure 3.5: Grouping as per Load application [23]

Group 1 had the muscle forces like abd: abductor, tfl: tensor fascia Latae, vl: vastus lateralis where in group 2 ther the addition of vm: Vastus Medialis. HCF is the hip contact force. The angles at which activity force is applied is different for both activities. Different abduction and flexion angles were chosen in case of walking when compared to stair climbing. Angles tends to increase for the stair climbing as in that stance the knee moves laterally outward increasing the angles. It was observed that the magnitude and the pattern of micro-motion was more vigorous in case of stairclimbing when compared to walking. Also, it was seen that there was more micro-motion in proximal-distal direction of stem than the posterior lateral direction. Around 30 μm to 250 μm was analyzed in longitudinal direction and 13 μm to 100 μm rotation of the implant within the bone. It was discussed that, cases with stem migration of around 200 μm has the survival rate of 94% after 10 years while in cases where there is higher micro-movement of 800 μm after 1st year has the survival rate of 86% after 6 years. The discussion was done for the inclusion of active muscle force, the bending of implant is more likely to be seen under the testing where only hip contact forces are applied, and no muscle forces are simulated. It is said that there is no exact way to simulate the muscle forces but including these in such tests can give better and more natural results.

3.1 Objectives of Study

3.1.1 Micro Motion study in Short stem

The challenge is to design a bone model setup in which conical stem implant is implanted similarly as surgeon fix it inside the patient's bone during THA using Cad Software. Then the same digital bone model under the real loading condition using Finite Element Analysis is analyzed for validating that the amount of micro motion occur is under required favorable range. The same process is validated for the legacy stem by comparing it with the legacy products for which actual physical testing has been done. The identification of worst case among our day to day life tasks is another challenge and the implementation of same worst-case condition in our analysis makes this Non-linear problem a bit more challenging.

3.1.2 SOMA Study

SOMA is a bone data base owned by Stryker which contains digital bone models of various patients which is used to verify the design by virtual implantation and gives an idea about the product working on more diverse patient population. Using this tool, we gather the information about how much population set will be targeted with the specific size of an implant.

CHAPTER 4

METHODOLOGY

4.1 SOMA Study

4.1.1 Taper Angle Study

To check if the taper angle of stem is really in the optimal range as it is one of the factors affecting the micro-motion SOMA study is performed. If the taper angle of stem is wrongly selected, there would be effects of it on stem sitting. Stryker Orthopedic Modelling and Analysis tool is used to see the optimum range of taper angle which will be compatible with most of the population. Around 1300 bones are studied for this. Using SOMA (Stryker Orthopedic Modelling And Analysis), various planes and various points are projected in to the sample bone and study is performed to check the angle. Below is the detailed explanation of this SOMA Study.

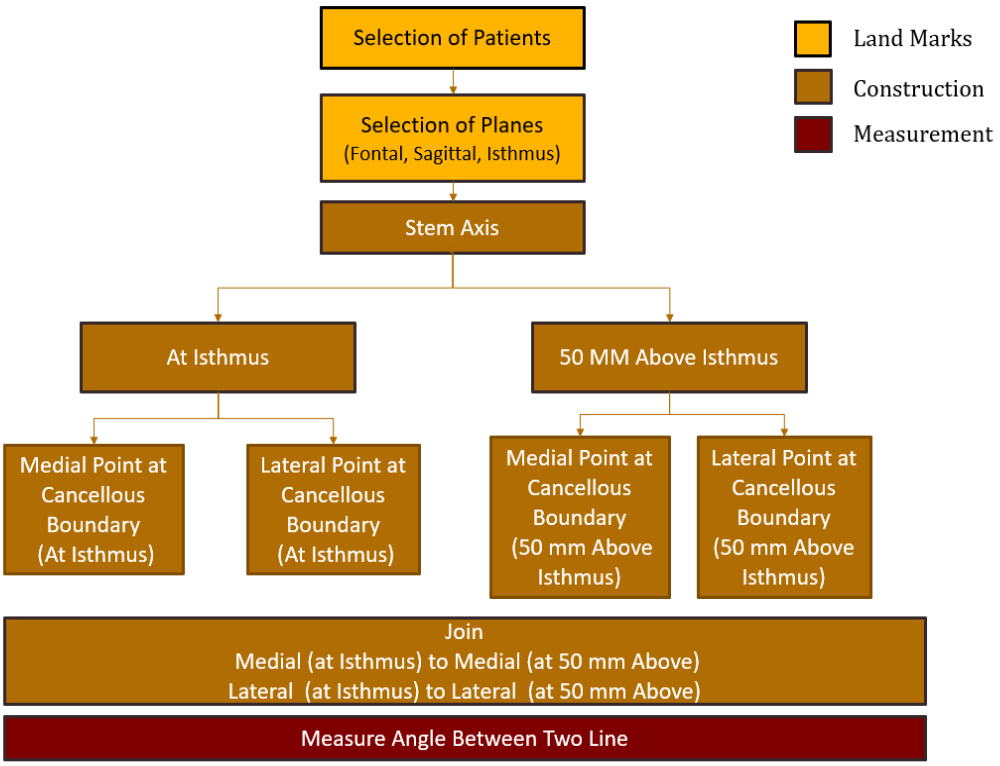


Figure 4.1: Flow to obtain taper angle

To explain the above flow chart, the first thing that is done is to select all patient type in the tool to include all type of patients irrespective of their age, weight and sex.

- To check the taper angle, stem axis is projected using proximal cancellous center points as shown in Figure 4.2.
- Isthmus point is created. Taper angle is measured from Isthmus point to points in proximal side of it (some distance above that it). Isthmus Point is taken as a reference point by surgeon to ream the bone. Till this point cancellous bone is removed. For the proximal points, up to which the slope is measured, the plane created 50 mm above isthmus.

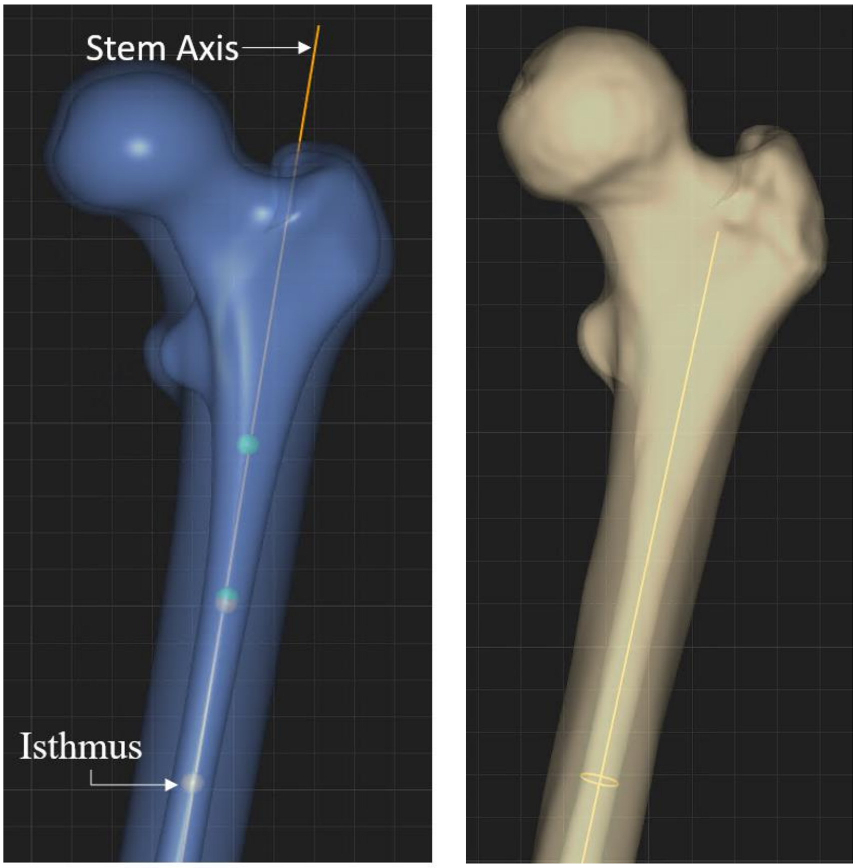


Figure 4.2: Projection of Isthmus and Stem Axis (From SOMA)

- Plane A is generated with isthmus as reference passing from it and orthogonal to the stem axis.
- To generate the AP line from the Isthmus point, intersection of plane A and frontal plane is created through isthmus center point.

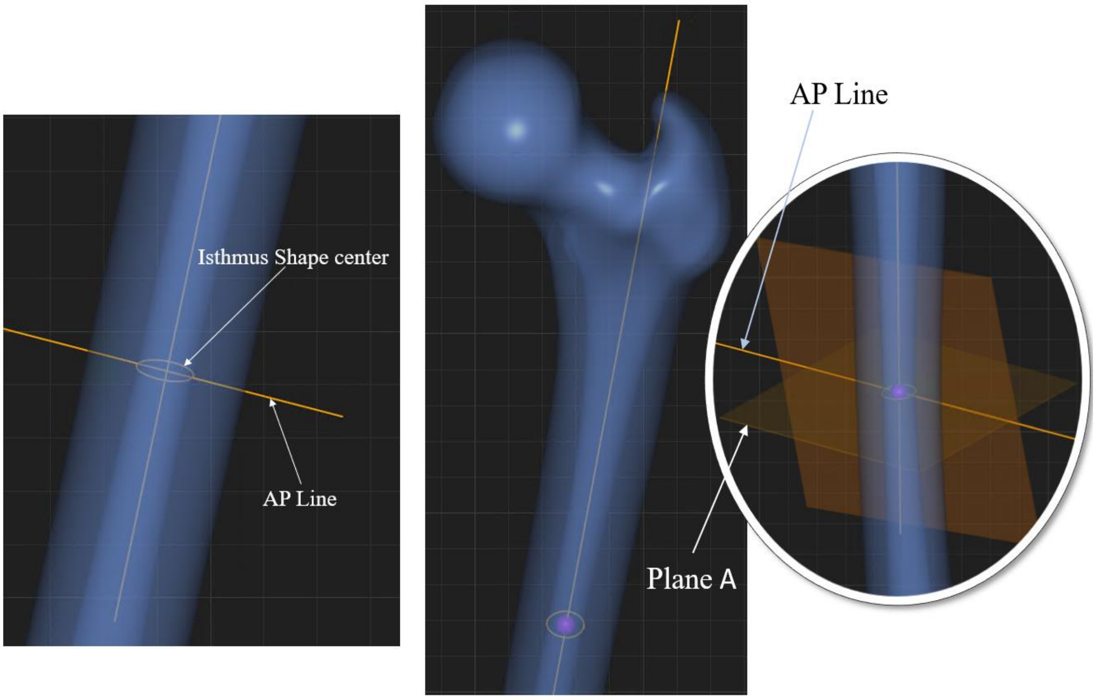


Figure 4.3: AP Line And Isthmus Shape Center (SOMA)

- To generate the ML line at this point, Intersection of plane A which passes through the isthmus and sagittal plane is taken, creating the line.
- Now, Outer shape of cancellous bone at these locations are generated where cancellous bone meets the cortical bone.
- A point is generated where the AP line meets the outer shape boundary of the cancellous bone. This point is named as Medial point.
- To generate the lateral point, the medial point which is created in above steps is translated along the AP line and this point is projected on the cancellous-cortical line where the shape boundary is nearest. This point is named as Lateral Point.

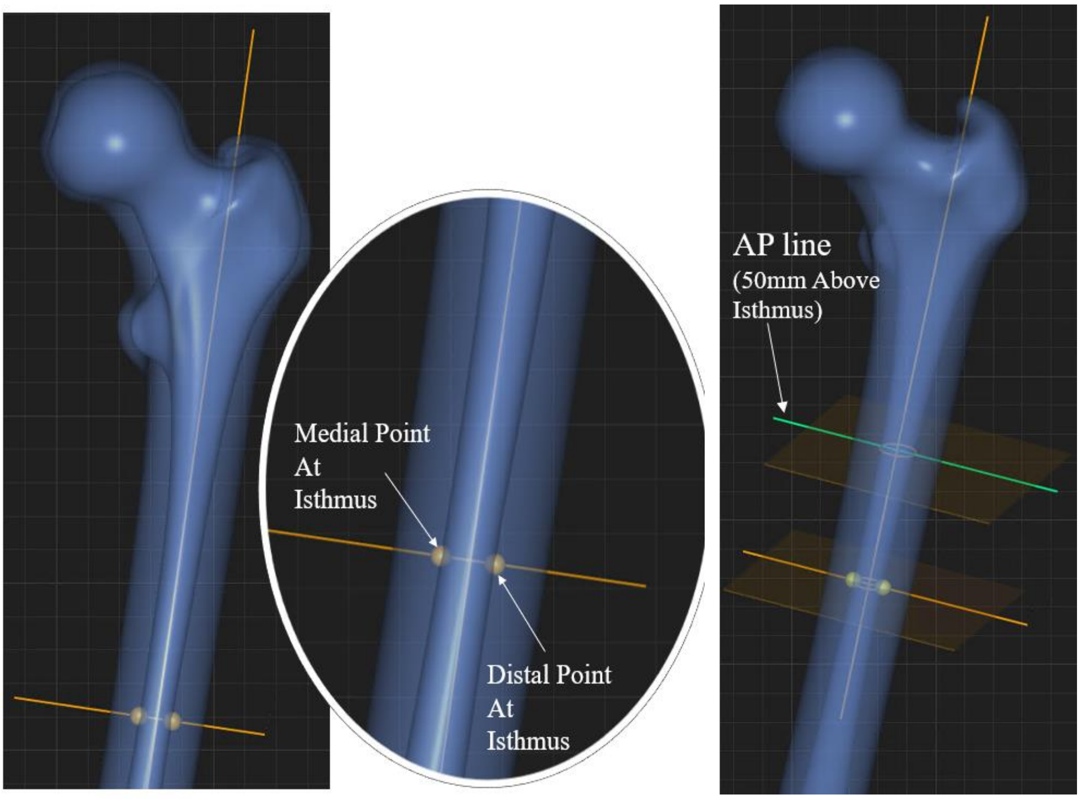


Figure 4.4: Isthmus Medial Point and Lateral Point (SOMA)

- Same way Anterior and Posterior points are generated on the plane 50 mm above isthmus plane in similar way.
- Now these points are joined together to get the taper lines in AP view.
- Angle between these two lines is measured. This measured angle is the taper angle in bone.
- For an implant to be of SOMA design, implant taper angle should lie in the measured range which we obtained from this tool.

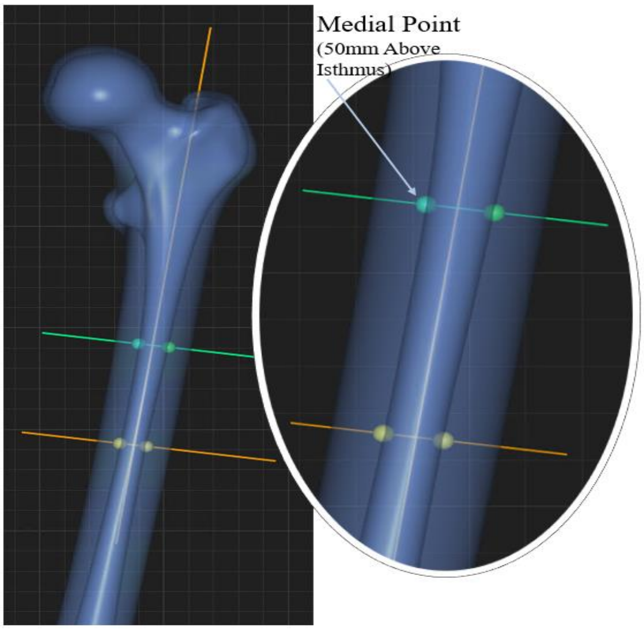


Figure 4.5: 50 mm Above Isthmus Medial and Lateral Points Projection (SOMA)

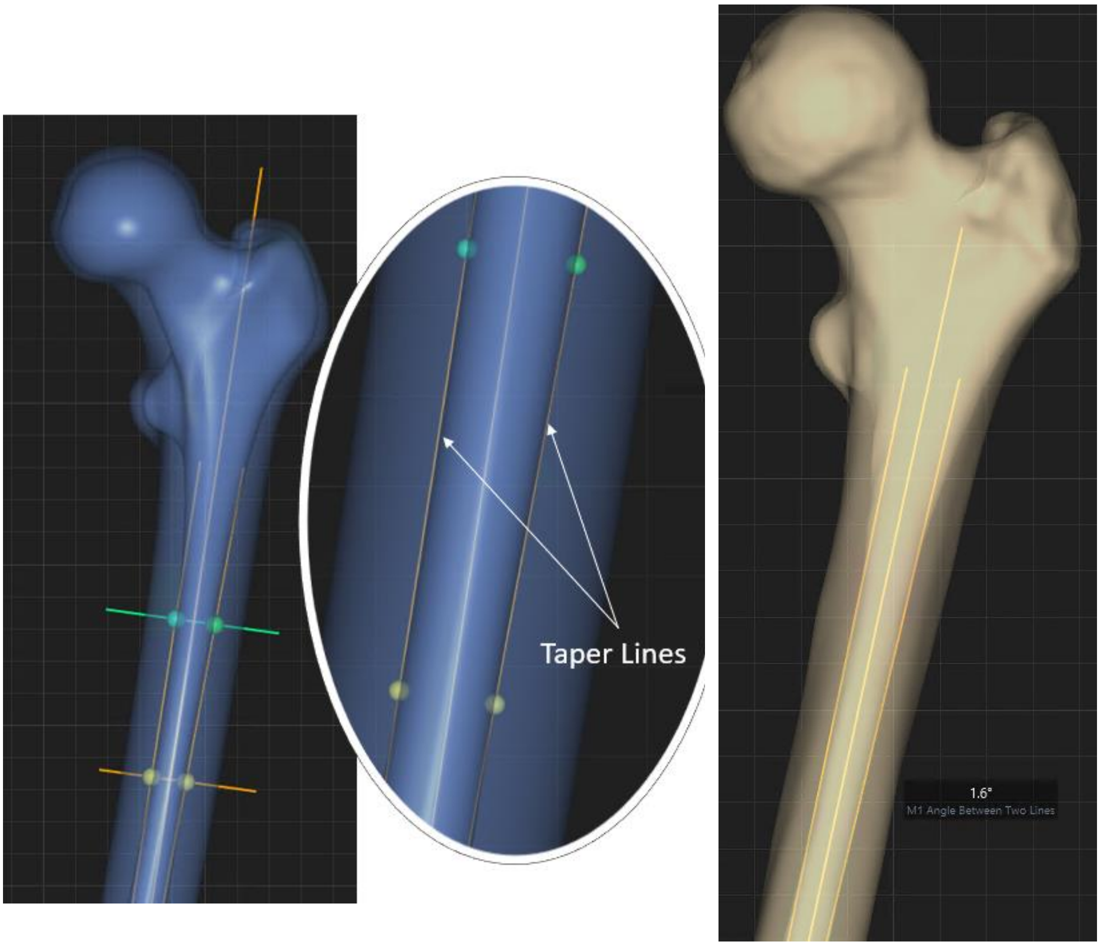


Figure 4.6: Taper Lines Creation and Measurement (SOMA)

4.1.2 Implant Positioning

Placement of implant can be defined using the isthmus point as reference. Implant can either sit above the isthmus or can sit below the isthmus. This is necessary to gather the data to see if the implant is compatible with the bone. The distance between the head center projected on stem axis and isthmus will give the data about the position of the implant. If the distance of isthmus from the head center is less than the implant length, then this will imply that the implant is sited below the isthmus. If this distance is more than the implant length, then that will imply that implant is sitting above the isthmus. To check the compatibility for an implant of particular length, the data can be collected from SOMA for various patients to see the ratio of its compatibility. For Plasma stem having the length of 127 mm making it to 197 mm when attached with 70 mm cone body can be plotted in SOMA to provide the data. A stem axis is plotted using various cancellous center points. Head center is then Projected on to it. Isthmus point is plotted into the bone to measure the distance of isthmus center point from the projected head center. This distance is measured to generate the average data of it. Also, a point is plotted 197mm below the GT point and distance between the isthmus point and this point will provide the position of implant with respect to isthmus. In the similar manner, as per the length of conical stem various such data points are created to get the compatibility data of conical stem.

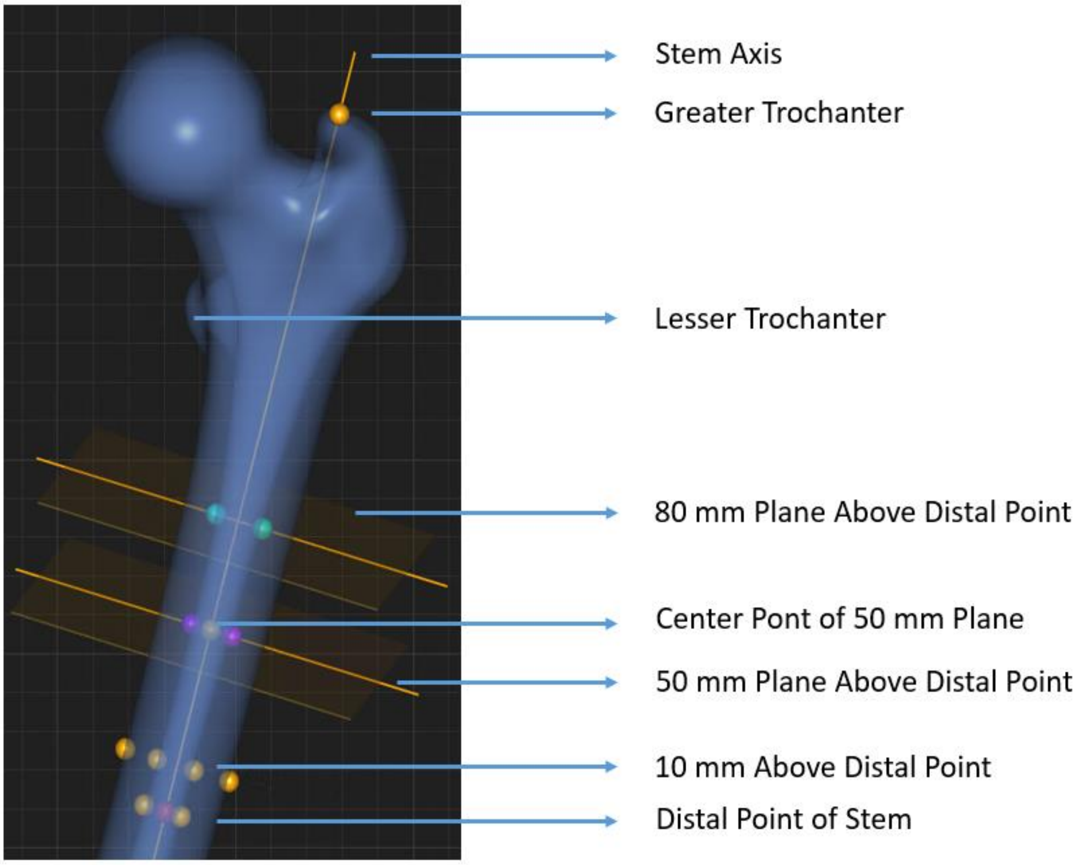


Figure 4.7:Canal Width Measurement at 50 mm and 80 mm Above Isthmus. (SOMA)

4.2 Micro-Motion Study

First, before solving the problem, it is necessary that it should be defined properly. In this study, to evaluate the micro-motion, the knowledge of micro-motion is must. There are two types of micro-motion. This can be understood by the following surgical procedure. When a surgeon inserts the implant and attach the stem with the cone body, he follows a pre-defined process [14]. The steps which affects the methodology are explained below:

1. First surgeon reams the bone and inserts the stem using stem inserter.
2. To seat the implant on its place some defined force is applied on it using a hammer.
3. After impaction some amount of torque is applied on the stem to assemble it with the cone body.

At this step there are chances of an implant to move or displace from its position. Such type of movement of implant from its desired position is called micro-motion. As this motion occurred before the completion of the surgery it can be named as pre-micro motion. if this motion is outside desired range then that leads to improper fitment of implant that causes patient to feel pain and it also leads to decrease in implant life. Surgeon must perform revision surgery in such cases. If Implant sits properly on its position after applying fixation torque. Then patient can do daily tasks. Over a period, with loading there is some displacement of implant with respect to bone. This displacement must be with in desired range else there is loosening of implant which calls for revision surgery. This can be due to improper fitment of implant or bad implant design and such micro-motion is called post-surgery micro-motion. In bio medical field, there is a specific coordinate system for the bone orientation which is widely used and is known as Berghain coordinate system. We have used the same Berghain coordinate system to locate various points. Load is also applied using the same coordinate system.

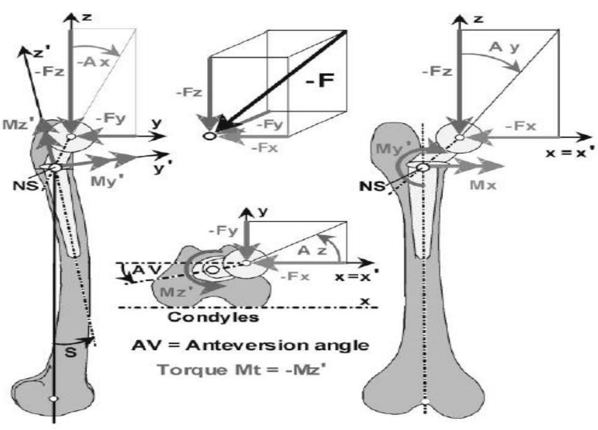


Figure 4.8: Berghain Coordinate System [13]

In our study, we analyze this micro-motion by

- Selecting the best suited CAD model of bone (of suitable size) from SOMA database.
- Preparing the bone model by cutting and reaming the bone virtually in a CAD software similar to the actual bone prepared by the surgeon during surgery to install the required size implant in to the bone using PRO. E.
- Checking whether implant and bone periphery have line to line contact or is it a tight fit. This is necessary for setting FEA set up correctly.
- Checking for best feasible approach for FEA setup from various approaches.
- Setting up FEA for both the stems i.e. for current stem as well as for legacy stem with required boundary conditions.
- Doing SOMA study to generate data related to population usage.
- Comparing the results.

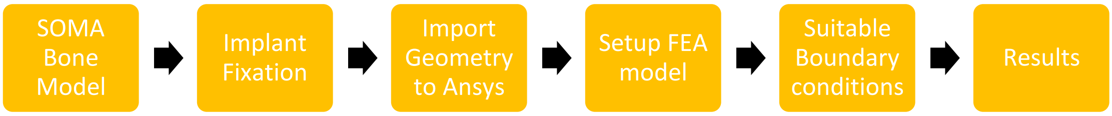


Figure 4.9: Steps Involved in Simulation of Micro-Motion of Stem Implant

One of the approaches during the setup is to consider muscle forces along with head load acting on femur bone while doing stair climbing. In this approach, the challenge which is faced is to find out the angles at which muscles transfer the compressive force on to the femur bone. These angles can be found by knowing where the muscle is attached to the femur. For this study, Stair climbing being the worst case, gluteus Maximus, Medius and Minimus are the three muscles which comes into play when patient climbs the stairs. Weight bearing (head load) and muscle forces are patient weight dependent and are made proportional with a multiplying factor.

In our FEA setup, we will perform analysis in various steps.

- After importing bone in to ANSYS from CAD, it is modified in SPACE CLAIM to cut the bone like the surgery prepared bone.

- Check for interference between Implant and Spongy bone canal.
- Material model is generated for various components such as for:
    - Cortical bone.
    - Cancellous bone/spongy bone
    - Implant.

  Material model for bones varies as per the patient because every patient has different bone density hence a generalized model is modelled to achieve the results.
- Contacts are established in the setup. For this setup there are
    - Frictional contacts
    - Bonded contacts

As due to contact change this problem is treated as NON-LINEAR problem. There are various frictional contacts in our problem such as contact between Implant and spongy bone and contact between Implant and cortical bone. It is very important to have correct contacts in the setup for the solution to converge. Due to improper contacts, Convergence errors are obtained. To get the results close to the reality, these contacts should be real alike i.e. how actually implant behaves inside the bone.

- Body is Meshed with specific Meshing size settings.
  Correct meshing size is required for correct results and for easy convergence. Body mesh is refined to the point where the change in results become negligible.
- Boundary conditions are given as per requirement to the model.
  Here loading is given in various load steps to reduce the error.
  Analysis is run in 4 load Steps
    1. Initial interference is resolved in first step.
    2. Seating load is applied. (Impaction due to handle). This load is the assembly load.
    3. Seating Load is removed.
    4. Apply stairclimbing load at the defined angles on the head center. This load is the functional load.
    5. Functional Load is removed.

- Post-processing is done to obtain the required results.
  To determine pre micro-motion, perform post-processing after step 2. And to determine post-surgery micro-motion, perform post processing activities after step 4.

Below are the elaborated steps performed in simulation of micro-motion of Plasma and Conical stems.

4.2.1 Selection Of Bone

A bone model is designed in SOMA using various landmarks on bone to check if the bone selected has enough distal fixation when viewed in MP view and enough taper fixation in AP view. The compatibility of implant to be used in the selected bone is checked by confirming that the diameter of cancellous bone when measured orthogonally to the stem axis is lesser than the diameter of the implant used. Also, when viewed in Anterior-Posterior view, there is enough penetration of the implant which ensures the distal locking of the stem as shown in figure 4.9.

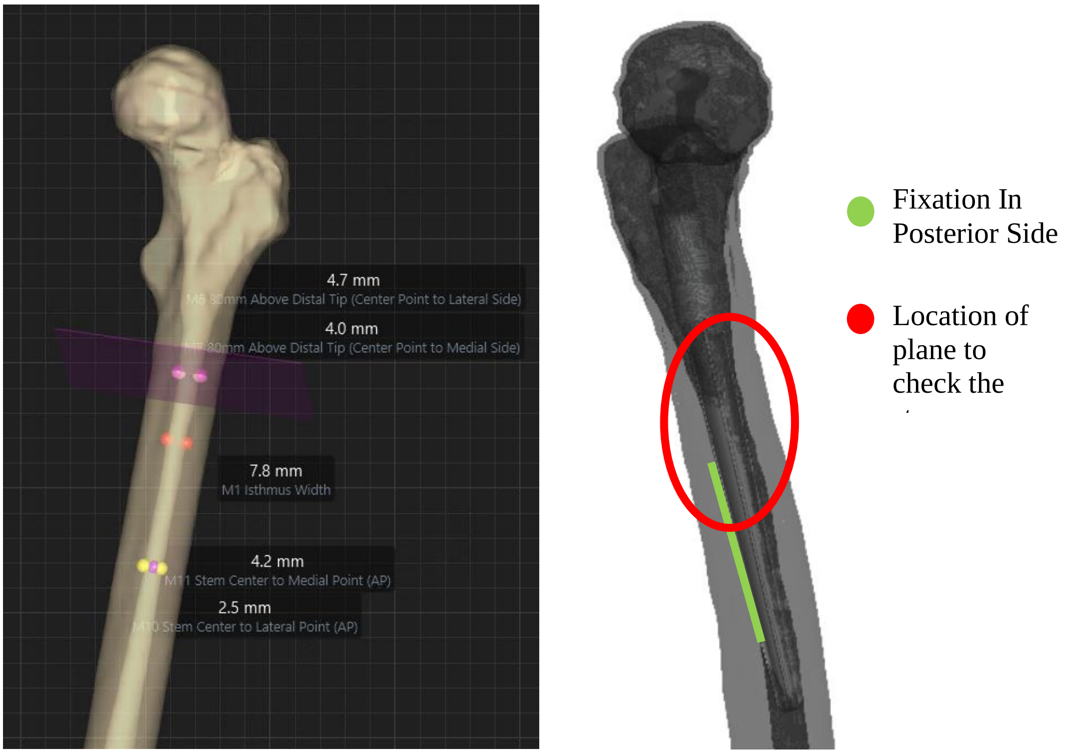


Figure 4.10: Feature Measurement in SOMA. (SOMA(L) and Pro. E (R))

4.2.1.1 Taper Locking

When viewed in AP view, at some distance above the distal end, the distance from the point at central stem axis to Medial point of cancellous bone and the distance from the central axis to Lateral point are measured to get the total canal diameter in AP view. At the same location diameter of stem is obtained to check the difference. If the stem diameter is more than the canal axis it will result in positive distance which implies that there is an interference confirming that it is properly fixed.

Taper Locking for Plasma Stem

Table 4.1: Fixation Engagement for Plasma Stem

S. No	Distance from Center to Medial Point	Distance from Center to Lateral Point	Total Distance (Canal Diameter)	Diameter of Plasma	Difference
1	4.0	4.4	8.4	10.26	1.86

Above it can be seen that the difference is positive which means that the bone has proper fixation because of more stem diameter than the canal diameter.

Taper Locking for Conical Stem

Table 4.2: Fixation Engagement for Conical Stem

S. No	Distance from Center to Medial Point	Distance from Center to Lateral Point	Total Distance (Canal Diameter)	Diameter of Conical	Difference
1	4.7	4.0	8.7	10.8	2.1

Above it can be seen that the difference is positive which means that the bone has proper fixation because of more stem diameter than the canal diameter.

4.2.2 Preparation of Bone

During the surgery, after surgeon make a cut, the bone is prepared where defected and unwanted bone is removed. This removal is not generalized and is very important that it is removed as per some instructions hence by using the Stryker's surgical Protocol [2], which is the literature prescribed by the company to the surgeon's that explains the recommended procedure to perform the surgery while putting the implant inside the body. As every implant has special set of instruments, this manual is very necessary as it gives step by step instructions to prepare the bone, trial the bone etc. As in this study, the analysis is being performed on the Stryker's product, it is compulsory to prepare the bone as per the Stryker's surgical protocol to get more accurate results. So, using

SOMA, the compatible bone is imported in to the CAD and prepared as per the surgical protocol,

- Femur head is removed. In actual surgery, firstly head is removed using the reference instruments. In this case, the removal of the femur head is performed in later stages for the ease.
- Specific size reamer is imported in the CAD in respective of the size of the implant which is to be fixed. It is aligned with the canal axis generated using the points which were imported from the SOMA. After the alignment, given amount of bone is removed.

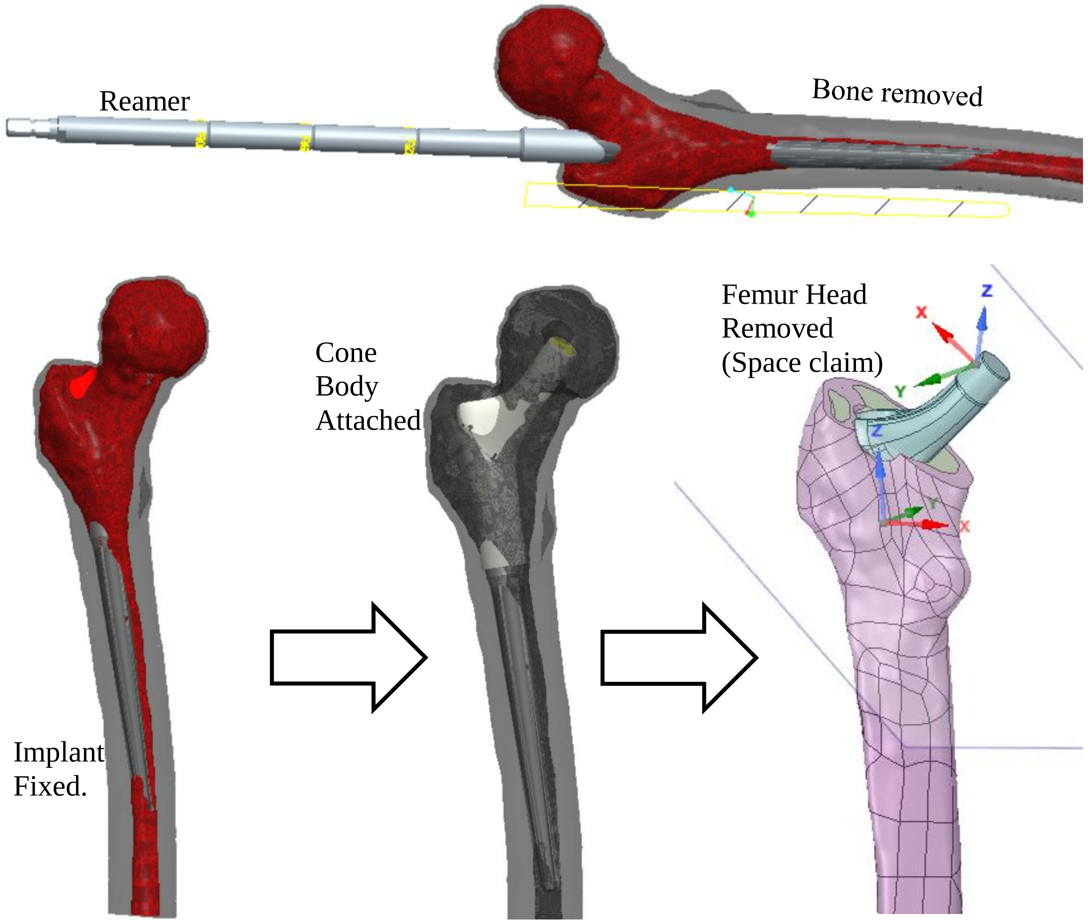


Figure 4.11: Model Setup in CAD (Pro. E)

- Implant of required size imported and constrained inside the bone.
- Cone Body of specific size is fixed on taper head of the implant.
- The co-ordinate system is introduced. This is done with the angles of this coordinate system defined as per the required activity. It is considered that

worst activity is to be simulated hence, the angles chosen are based on the stair climbing activity as functional load.

- This Assembly is converted to .STEP file and imported in to ANSYS Workbench.
- Using the Space-Claim Software, Femur head is removed from the bone as stated earlier.

4.2.3 Materials And Modellings of the Bone

After the bone implant assembly is imported in to the workbench. Geometry is cleaned, repaired and checked for errors. This helps in better meshing. Two coordinate systems are generated

- At head center
- On proximal side at counter bore face, aligned to stem axis

As discussed in earlier section, all the load from acetabulum comes on head center hence this point/coordinate system is used for applying functional load. The other which is aligned to stem axis is for the assembly load.

Materials are assigned for all the components. For the bone, different properties are used for cortical and cancellous bone. As in this study, are of interest is the relative motion of implant with respect to bone. And implant has the contacts with both cortical bone as well as cancellous bone hence it is very important that the proper material conditions are assigned for cortical and cancellous bone. Below is the table with material properties used in the bone. The implant is made up of Ti 6Al 4V. The detailed material properties are mentioned in the below table.

Table 4.3: Material Specifications

Serial Number	Component Name	Material Specification
1	Cortical Bone	Bone Mineral (HA)
2	Cancellous Bone	Bone Mineral (HA)
3	Stem Implant	Ti 6Al 4V
4	Cone Body	Ti 6Al 4V

4.2.3.1 Material Composition

Table 4.4: Material Compositions

Serial Number	Material Specification	Material composition
1	Bone Mineral- Hydroxy Appetite	$Ca_{10}(PO_4)_6(OH)_2$
2	Ti- 6Al- 4V	90% Titanium, 6% Aluminum, 4% Vanadium

4.2.3.2 Input Material Data for Ansys

The required properties for structural analysis are taken from Matweb [25]. The material properties are considered to be isotropic elastic in nature. And derived from Young's Modulus and Poisson's Ratio.

Youngs's Modulus and Poisson's Ratio for each material is shown in below table

Table 4.5: Young's Modulus and Poison's Ratio

Serial Number	Material Properties	Youngs's Modulus	Poisson's Ratio
1	Cortical Bone	160 GPa	0.32
2	Cancellous Bone	136 MPa	0.32
3	Ti 6Al 4V	110 GPa	0.3

4.2.4 Contacts

In a non-linear problem, Contacts have a huge effect on the model convergence and results. For this study, there are two types of contacts present

1. Bonded Contact
   - Cortical bone – Cancellous bone
   - Stem Implant – Cone body
2. Frictional Contact
   - Cortical Bone – Implant
   - Cancellous Bone – Implant

Coefficient of friction which is used is 0.35. One assumption which is taken here is that, same coefficient of friction is used for both of them i.e. when implant is in contact with cortical and when implant is in contact with cancellous bone. This is assumed because most of the cancellous bone is removed during the surgery.

4.2.5 Meshing

The process of dividing the component in to smaller elements is called meshing. This is to distribute the load when applied on component in to smaller elements and then its effect can be analyzed on those small elements. Being the geometry very complex and not symmetric, 3-D Tetrahedral elements and Hexahedron elements are used. The method used is patch-conforming.

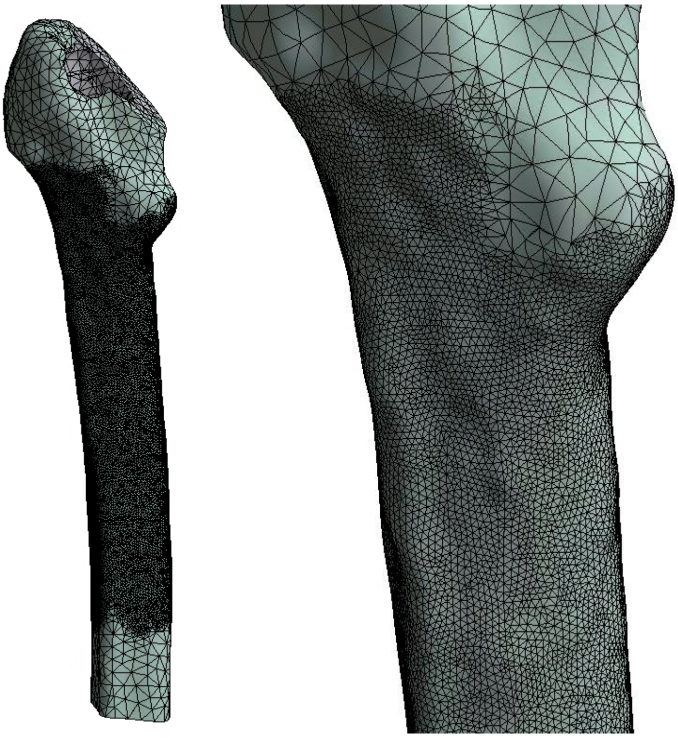


Figure 4.12: Cortical Bone Meshing. (Workbench)

4.2.5.1 Cortical Bone

Cortical Bone is the biggest geometry in the bone-implant assembly. As the interest is in the implant and bone contact hence the cortical body size is kept large which is equals to 4 mm. The global mesh size is kept 2 mm. The Figure 4.11 shows the meshing in cortical bone with adaptive sizing and defeaturing ON. Element used here are Tetrahedral.

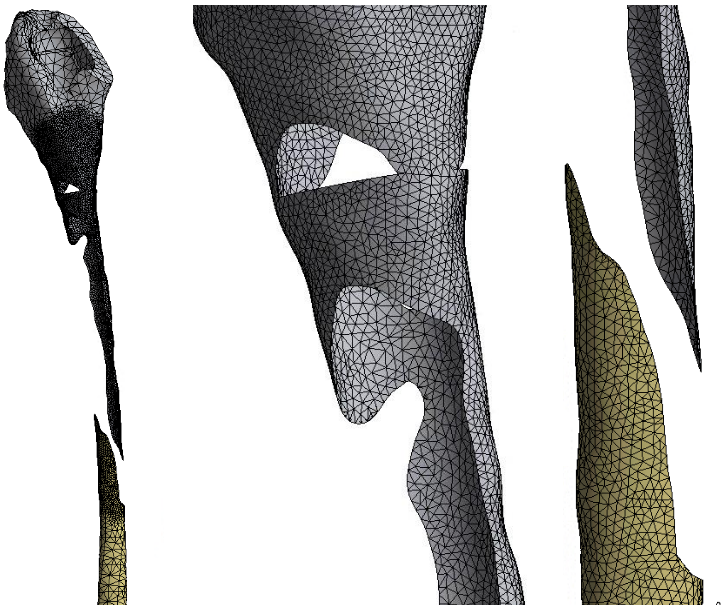


Figure 4.13: Cancellous Bone Meshing. (Workbench)

4.2.5.2 Cancellous Bone

The meshing size for cancellous bone is kept a bit finer than the cortical as it is majorly interacting with the implant. The contact sizing for cancellous bone and implant is considered as 0.8 mm. One of the edges was refined with mesh size of 0.5 mm to improve the mesh quality. The Figure 4.12 shows the meshing in cancellous bone. The global size for it is also taken as 2 mm. The finer elements that are generated is because of the contact sizing.

4.2.5.3 Implant

Implant being the most important component of the assembly hence is meshed with finer mesh elements. The global sizing was kept 2 mm, but the contact sizing is of 0.8 mm. The contact sizing provides the finer element at the location where it is having the contact. The Figure 4.13 below shows the Meshing of both plasma and conical implant.

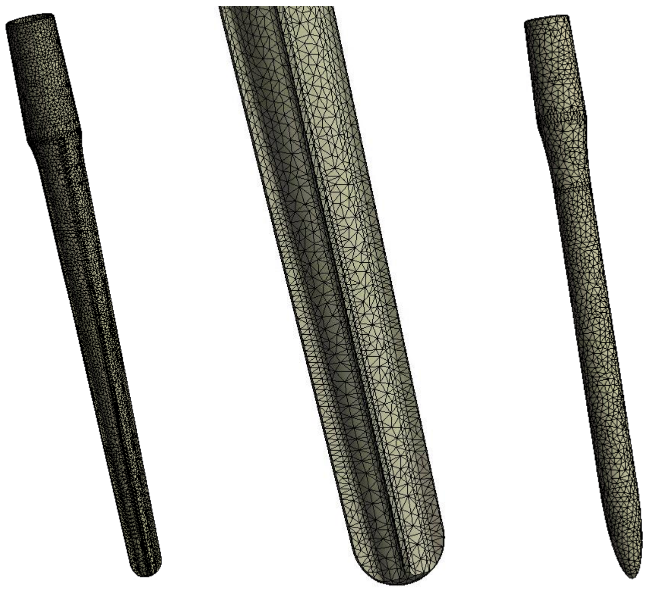


Figure 4.14: Implant Meshing (Workbench)

4.2.6 Boundary Conditions

The bone is fixed from approximately 240 mm from the head center as per the standards. This is done by giving the bone fixed support from the distal end.

Load is applied in different load steps. Assembly load and functional load are applied. Also, Stair climbing effect is taken as the worst case for functional load. Frictionless Support is provided at the implant proximal end as only concerned area is the rotational micro-motion and distal micro-motion in stem axis direction.

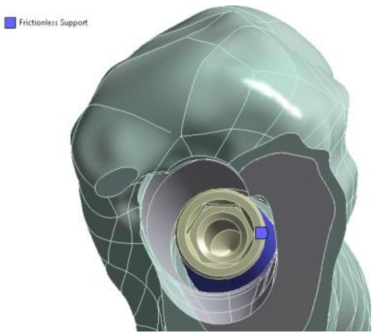


Figure 4.15: Frictional Support (Workbench)

4.2.6.1 Assembly Load

The total amount of impaction force of 2200 N is applied in the z direction. This is the approximate force which a surgeon applies axially on the stem.

4.2.6.2 Functional Load

As explained in above sections functional load is basically the load which acts on the head center while performing the activities. Out of all basic day today activity such as walking, running, chair rise, stair climbing etc. stair climbing has the maximum potential for an implant mechanical failure. Data regarding the various activities is shown in table below. Bone angles varies with various activities. These angles are not exclusive hence there is range of such angles for such activities.

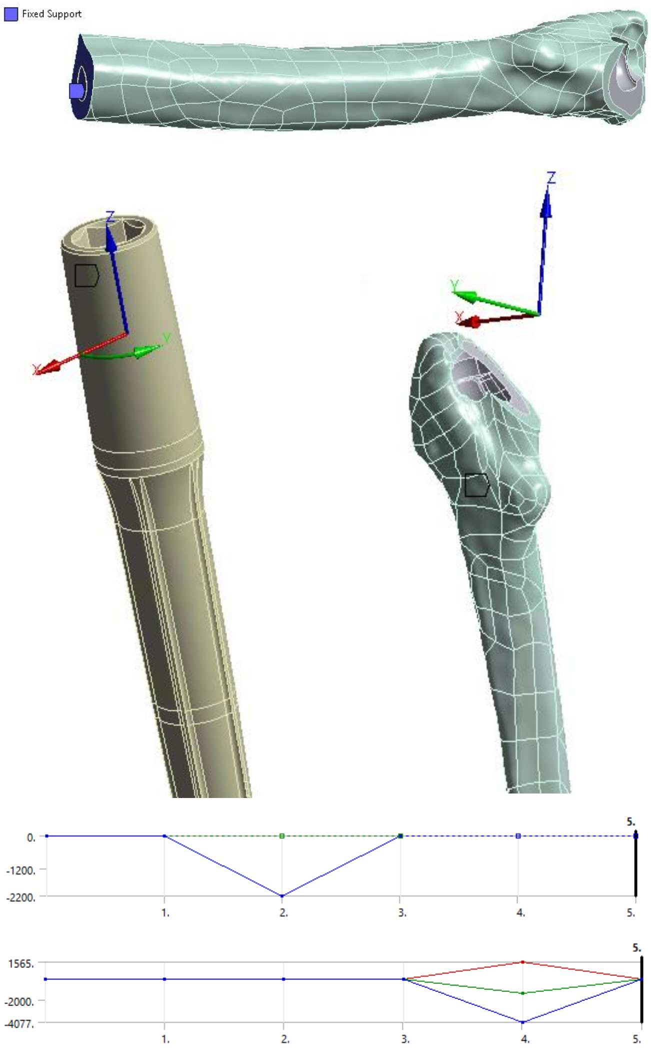


Figure 4.16: Loading Conditions in Ansys (Workbench)

Table 4.6: Activity Load Angles

Activities	Angle In Frontal Plane	Angle in Sagittal Plane
Stair Climbing	18˚	18˚
Walking	17˚	11˚
Stairs Down	16˚	10˚

In Figure 4.16 below, The various data about the forces during various activities is given,

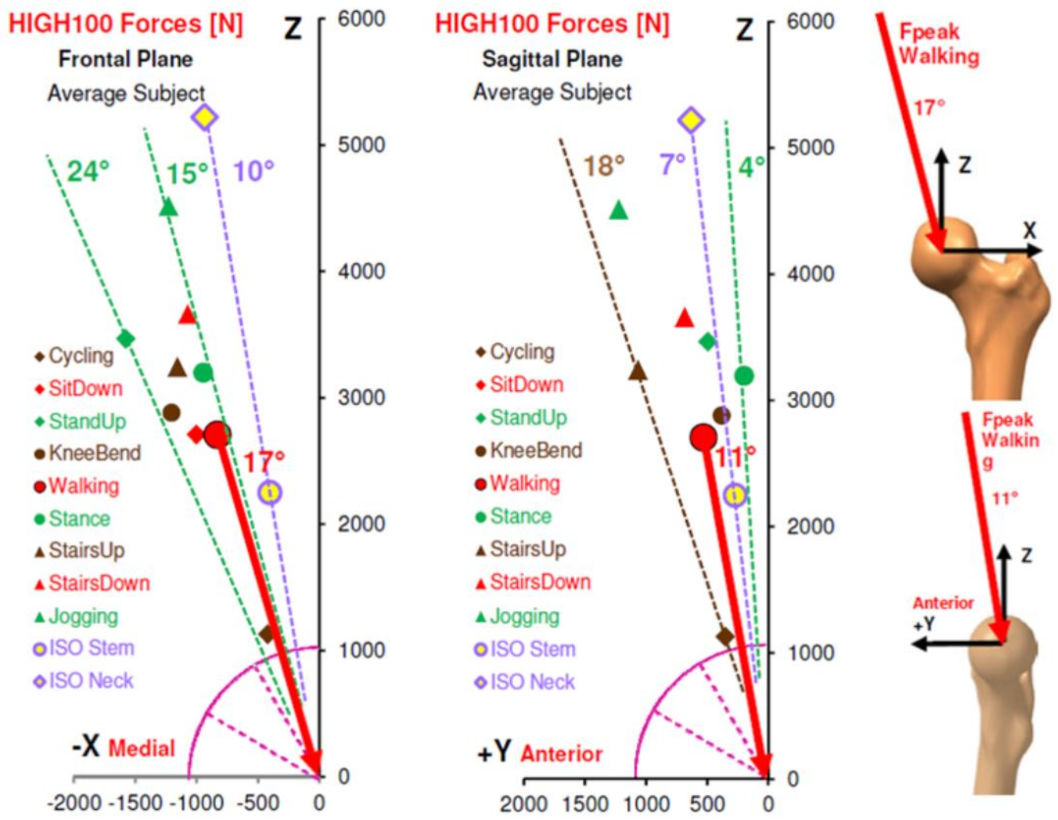
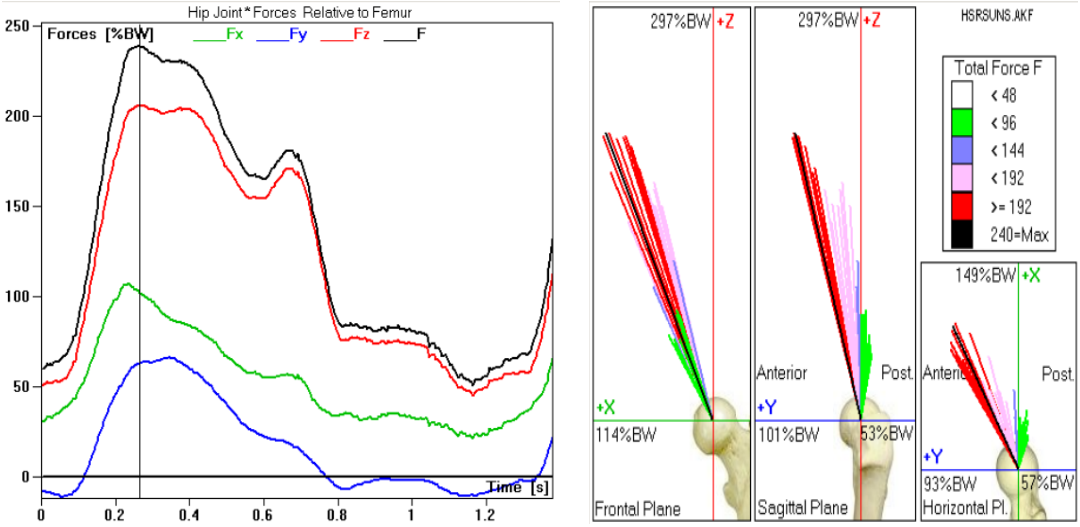


Figure 4.17: Loading Angles for Various Activities [24]

The above graph is showing the various activities and angles at which load on femur comes. To explain above Figure 4.17, in the right side, x, y, z axes are given with the angles at which forces are applied. On the left side detailed data of various activities are mentioned. Such as for activity of sitting down, the force is between medial plane and sagittal plane at an angle of 19 ˚ and angle between anterior plane and sagittal plane is 11 ˚. Similarly, for jogging these two angles are 15 ˚ and 16 ˚ respectively. As from above, the angles for the functional load are considered in both the planes for stair climbing activity which is equals to 18 ˚. The forces which are to be applied during the simulation are obtained using Ortho-load [24]. The Figure 4.17 below shows the forces introduced while stair climbing of one the patient.



Loads (Seconds, %BW, N*m)

	No.	Time	Fx	Fy	Fz	F	Mx	My	Mz	M	Mrk
Min	1	0,0	21	-11	45	51	0	0	0	0	0
Max	306	1,383	108	66	207	240	0	0	0	0	0
Now	58	,26	103	63	207	240	0	0	0	0	0

Figure 4.18: Loading Condition while Stair Climbing Effect [24].

Using the above angles and the forces in the paper. Similar forces are simulated in the Ansys. The co-ordinate system is created and oriented in the angles of required activity, we are considering stair climbing effect hence co-ordinate system is oriented in the angle 18 ˚ for both medially and anteriorly. The forces are calculated using above table by multiplying these with the body weight of the patient. The forces applied in FEA analysis using above data,

Table 4.7: Forces During Stair Climbing Activity

Forces (N)	**FX (N)**	**FY (N)**	**FZ (N)**
Max.	1565	-1386	-4077

Figure 4.15 above shows the graph in Ansys after these conditions are applied. In direction of x around 1500 N is applied. For the Z direction, the amount of load is maximum and is around 4077 N.

CHAPTER 5
RESULTS AND DISCUSSIONS

5.1 SOMA

5.1.1 Taper Angle Study

The setup above is observed for more than 1300 patients. The angle between the two lines is measured when bone is seen in AP view. The data exported is shown in the graph in Figure 5.1. The data shows that most of the population has the taper angle of canal lying in the range of 1˚ to 4˚.

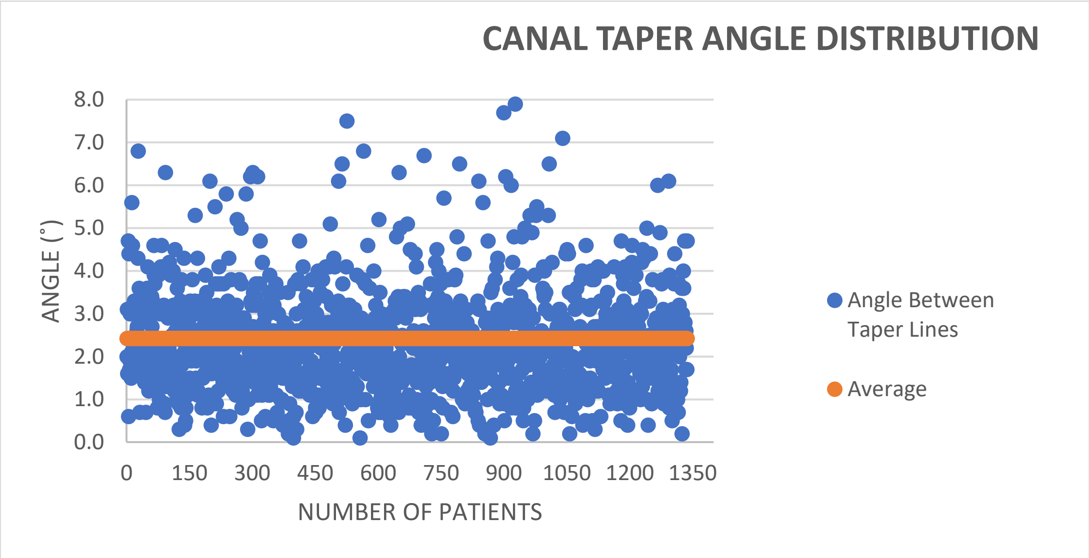


Figure 5.1: Canal Taper Angle Distribution (SOMA)

In above graph, it can be seen that the major of the population has canal taper angle lying In the range of 1˚ to 4˚ angle. The angle that slope makes with respect to stem central axis will be the half of the canal taper angle. If a patient is having 2.4˚ canal taper angle between two slopes, then the angle between stem central axis and the conical taper will be half it i.e. 2.4 ˚. This is the slope with which implant will be designed to cover the maximum population set. From the graph, it is analyzed that some of the patients have angle more than the 4˚ as well. For such cases, the bigger sizes of implants are available in market which can help a company to cover such patients. The custom Implants are also available which are patient specific where the data of patient is recorded and according to that implant is designed. But with the range of 0˚ to 5˚, 95% of the population is covered. Below is the bell curve, plotted using standard deviation for 95 % confidence level. It is clear that with angle 5˚, almost major chunk of population is targeted. As when observed from 0˚ towards the higher angle, the trend is increasing till the angle is 2.4 ˚ this is the point where the maximum density of population lies. This implies that major population is having taper angle of around 2 ˚ to 3 ˚.

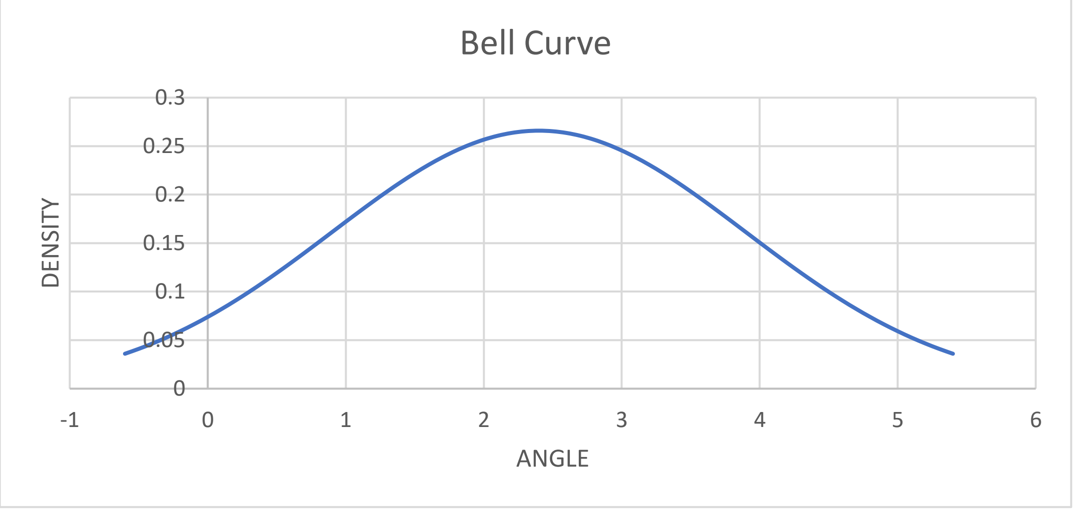


Figure 5.2: Bell Curve representing Population set (SOMA)

5.1.2 Implant Positioning Study

Figure 5.3 below shows the SOMA graph for it. From graph, It is clear that the range of isthmus from the GT lies between the 150 mm to 230 mm. This length is achieved with the addition of cone body to the stem implant. In general, 70 mm of cone body is used. Now, for the Plasma Stem which has the length of 127 mm and is attached with 70 mm cone body providing total length of 197 mm is considered to understand the population compatibility of it. Generally, it is advisable to have the stem implanted below the Isthmus point hence taking this condition as the

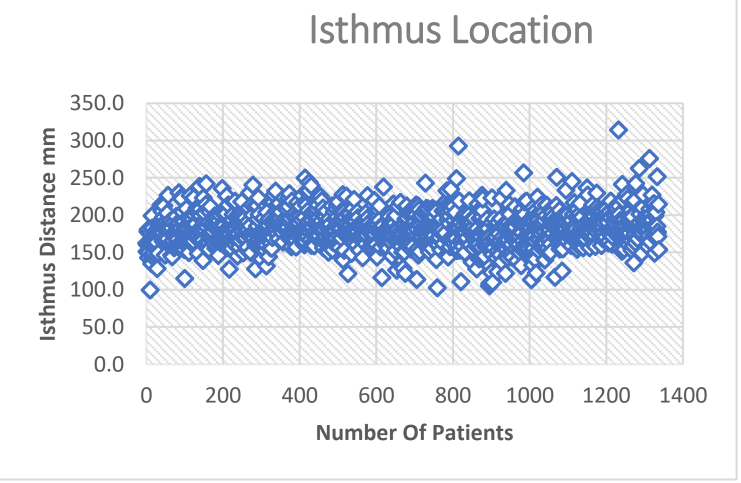
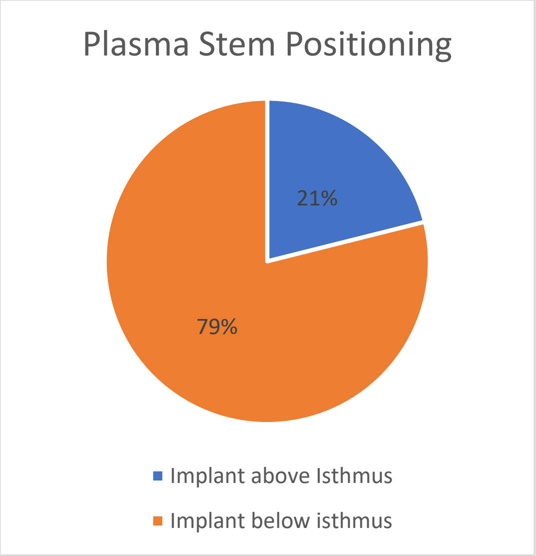


Figure 5.3: Population set for Isthmus Location (SOMA)

consideration for an implant to be compatible. If length is considered as the criterion, it should sit below the isthmus point. As in that case, a better fixation will be achieved. It is also depicted that, there are some patients having isthmus distance of around only 100 mm, such patients require the implant with shorter length. With the custom implant, such patients have always the option where according to the patient specific data, shorter version of implant can be designed. Patients having isthmus distance more than the 230 mm-240 mm, larger size of implants are the option available. The conical stem which is already in the market is having stem length of 155 mm and with 70 mm of cone body, it can provide up to 215 mm length and if surgeon wants higher than that, he can opt for 195 mm with 70 mm cone body making it more than 265 mm. Figure 5.4 below shows the percentage of patients having Plasma Implant and Conical Implant of size A (due to confidentiality, size cannot be disclosed) sitting below the isthmus vs implants sitting above the Isthmus. It shows that around 79% of patients have their implant's distal tip below the isthmus level when they opt for plasma stem Implant. When it comes to Conical stem, around 62% of the patients have their isthmus above the implant's distal tip.



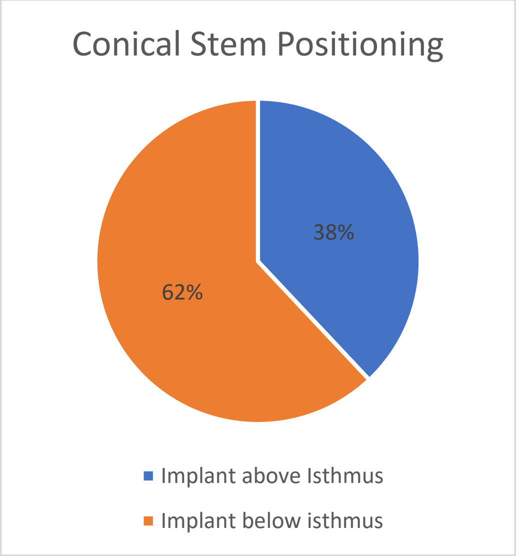


Figure 5.4: Population percentage (SOMA)

5.2 Micro-Motion

5.2.1 Plasma Stem

Micro-motion test was conducted on plasma stem and conical stem for various sizes. For plasma stem two analysis were conducted with various reamer sizes. Analysis 1 was performed where 0.5 mm was under reamed with respect to bone where as in analysis 2, 1 mm under reaming is performed. This is the technique used by the surgeons to get the proper amount of fitment. Figure 5.5 shows the directional and total micro-motion of the Plasma stem with 0.5 under reaming.

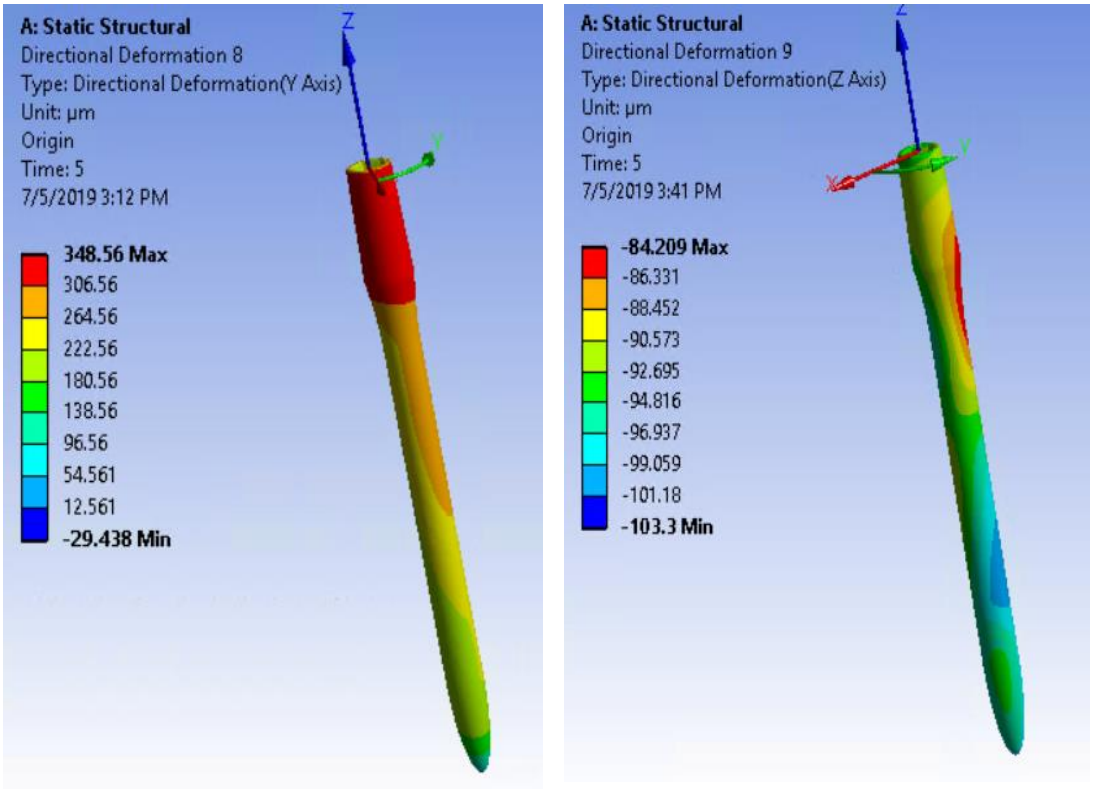


Figure 5.5: Rotational and Axial Deformation in Plasma Stem in AP View. (Workbench)

It can be seen in above results that for rotational micro-motion maximum displacement is in proximal direction, which is around 300 µm and is decreasing as observed towards distal direction. The reason for it is that as the implant gets its maximum fixation distally, the micro-motion should be less in distal portion when compared with proximal direction. As the canal axis increases proximally and plasma implant being the cylindrical, more of cancellous bone is present in proximal direction contacting with the implant. It can be observed that, at the proximal lateral side, implant has displacement in the range of 260 µm -300 µm while when coming towards distally, mid portion of the implant in lateral side has displacement of 180 µm to 260 µm. At extreme distal lateral side, only 50 µm to 150 µm micro-motion is induced. The medial side of the implant which is in contact with the cortical bone has around 150 µm which is important for the osteointegration of bone. This also proves that the main fixation that implant gets is because of its contact with the cortical bone which is in distal portion in this case. From Figure 5.6, it can be realized that there is no cancellous bone in medial mid portion hence there is very less micro-motion in that portion of implant. The property of cancellous bone being spongy and fibrous does not allow implant to have strong stability hence is removed before the implant fixation.

According to the literature survey, for an implant to have long life and no loosening, it should have micro-motion in range of 0 µm to 800 µm and Plasma stem is in market for more than 10 years now with successful clinical history and these results are showing the same thing hence the methodology used to calculate the micro-motion is validated. The micro-motion in axial direction is also evaluated where distal end is having very less micro-motion which is justifiable, as the distal fixation is being achieved from the cortical bone as shown in Figure 5.6. In Figure 5.6, Cancellous bone is present in anterior side of bone (as marked with red) where as in distal portion of it there is no cancellous bone providing a contact between cortical and implant which ensures that stem is constrained in axial direction.

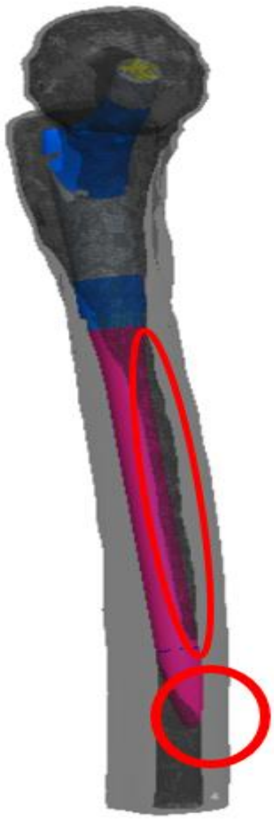


Figure 5.6: Distal Fixation (Workbench)

In below sections, the micro-motion in analyzed for two of the load steps, one when the assembly load is applied and the other when the functional load is applied. This is performed on smallest size of plasma, with 2 cases which are when the bone is 0.5 under reamed with respect to the implant and when the bone is reamed 1 mm under. In case 1, we have the interference fit of 0.5 mm and in case 2 we have the interference fit of 1 mm.

5.2.1.1 Load step 2 (Assembly Load) - 0.5 Under Reaming

Here the results for the axial micro-motion and rotational micro-motion are shown in Figure 5.7. Only ML view is observed for this case. It can be seen that when the assembly load is applied, around 188 µm micro-motion occur in axial direction. Major region in stem has range of 176 µm to 182 µm displacement. Moving towards distal portion, the trend is that the micro-motion is decreasing. The medium region of stem has more axial displacement than the distal portion. For the Rotational micro-motion, due to the assembly load, it has the micro-motion of 108 µm in the posterior side of it. When observed from anterior to posterior side, It reduces from 108 µm to 5 µm. The direction of micro-motion in posterior and anterior side is not in the same direction which implies the stem deformation due to the stiff contact with the bone. These results imply that assembly load does not have any major effect on the rotational micro-motion. It affects the displacement of stem in axial direction. This is because the assembly load is directly applied in the axial direction.

5.2.1.2 Load Step 4 (Functional Load)– 0.5 Under Reaming

Here the results for the axial micro-motion and rotational micro-motion are shown in Figure 5.8. Only ML view is observed for this case. It can be seen that the micro-motion in axial direction is from range 75 µm to 110 µm. There is implant displacement of 79 µm to 90 µm in the distal portion of it. In the proximal side minimum axial micro-motion is observed which is around 75 µm. In posterior side it is around 98 µm where as in anterior side it is around 85 µm. The rotational micro-motion is quite higher for the functional load which is around the 600 µm to 1000 µm. When observed in anterior side the displacement is about 600 µm while in posterior side it is higher and is about 700 µm when compared. These results are for the case when there is interference of 0.5 mm. When there is interference of 1 mm which is always advisable, it is achieved using 1 mm smaller size reamer. The Figure 5.8 shows the results for this case. When the interference of 1 mm is present, the rotational micro-motion is decreased.

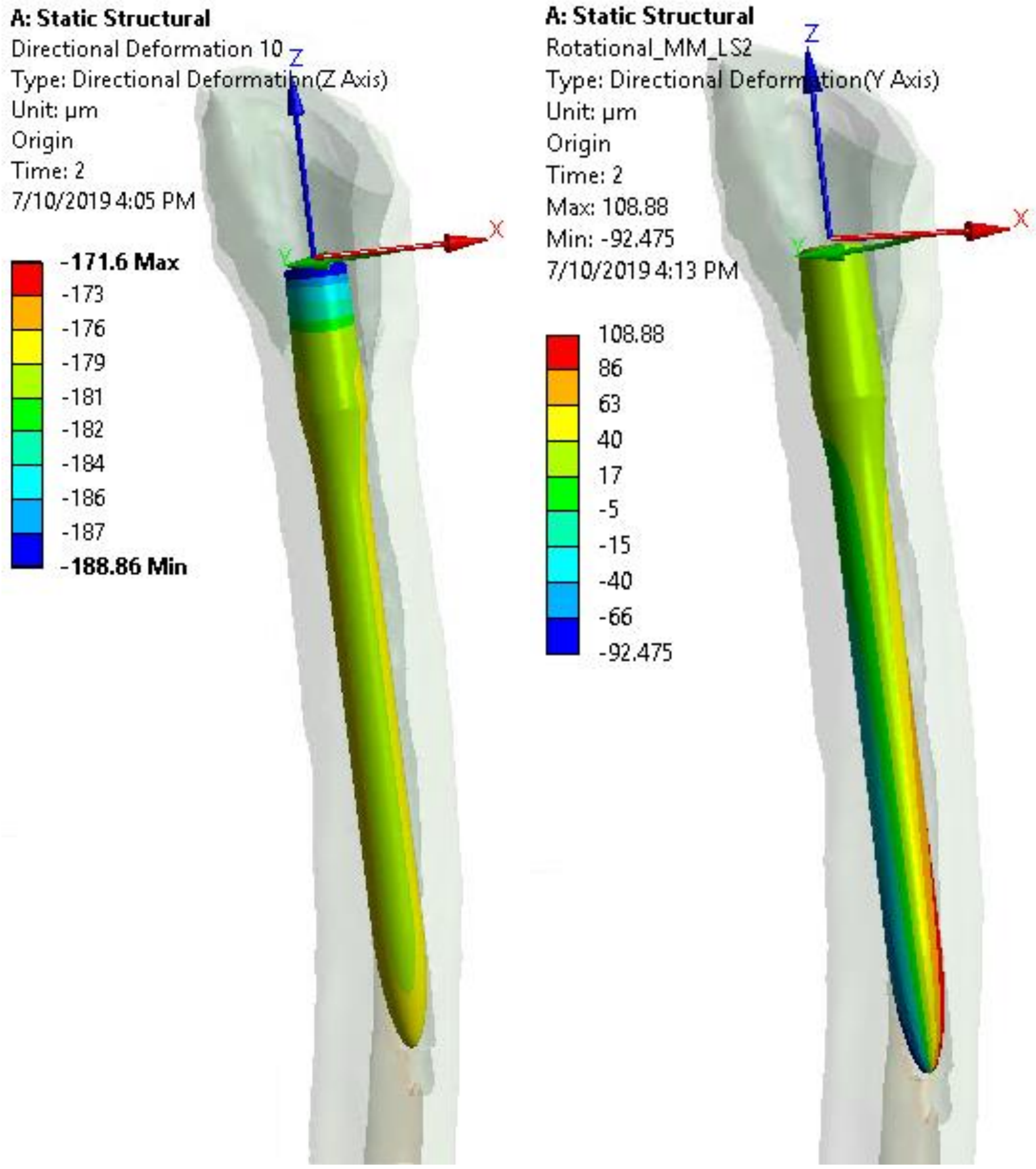


Figure 5.7: Axial Deformation (L) and Rotational Deformation (R) in ML view. (Workbench)

It is clear that maximum rotational micro-motion in case of 1 mm under reaming in proximal cylindrical region is less than 590 µm. If results for 0.5 mm under reamed and 1 mm under reamed are compared for distal micro-motion, it is clear that in case of 1 mm interference the range of micro-motion is from 50 µm to 250 µm which is less than the micro-motion range of 300 µm to 450 µm in 0.5 mm interference. This shows that 1 mm interference fit is reducing the micro-motion hence providing better fixation and working.

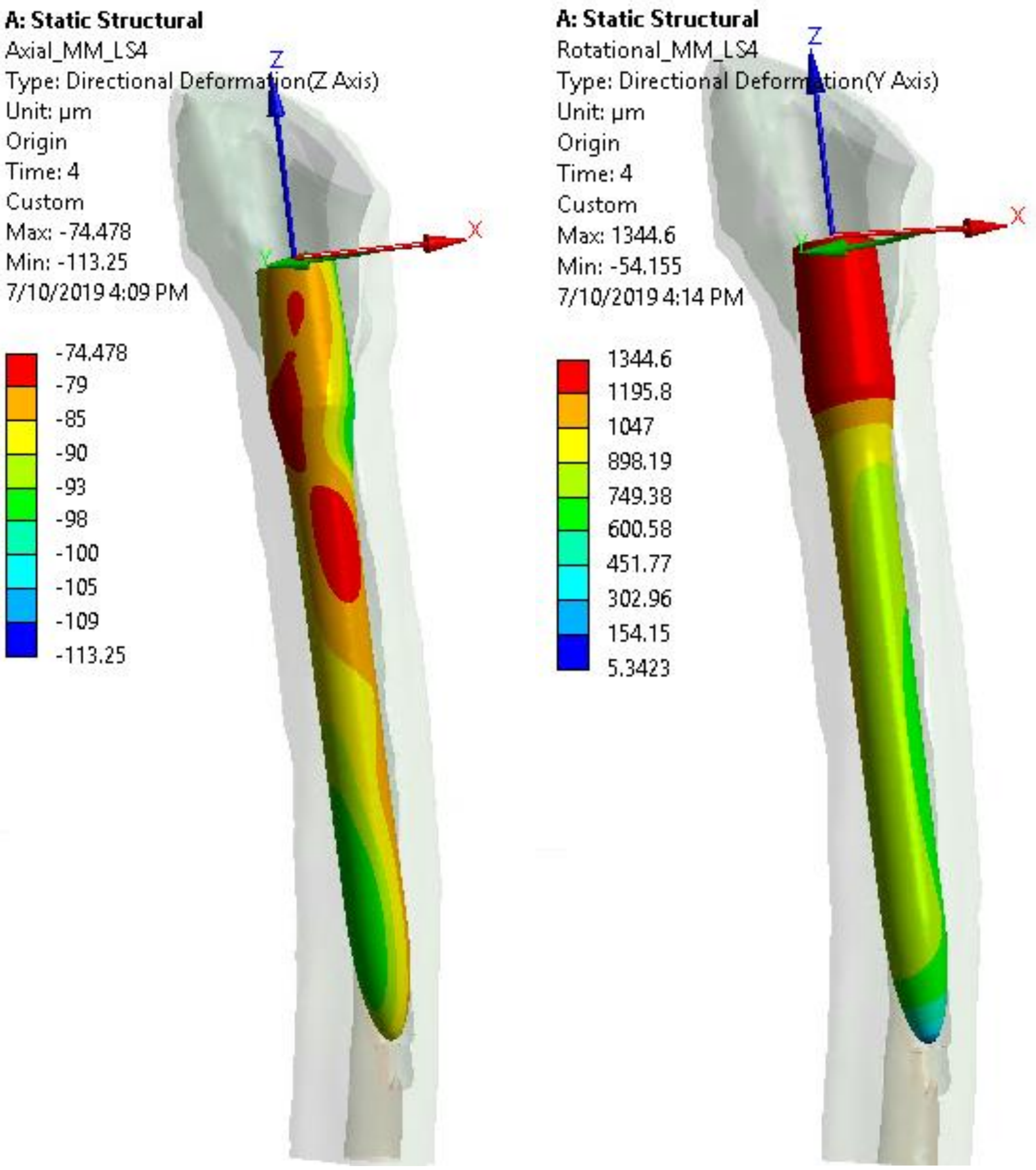


Figure 5.8: Axial Deformation (L) and Rotational Deformation (R) under Functional load. (Workbench)

These results are apt, as the more interference will ensure a better fitment providing more stability to the implant. It can be seen easily in the Figure 5.10. where it is shown in CAD that how much implant is interacting with the cancellous bone. It is seen here that more cancellous bone is removed giving more contact area between implant's distal end and cortical bone in case of 1 mm under reaming when compared to 0.5 mm reaming.

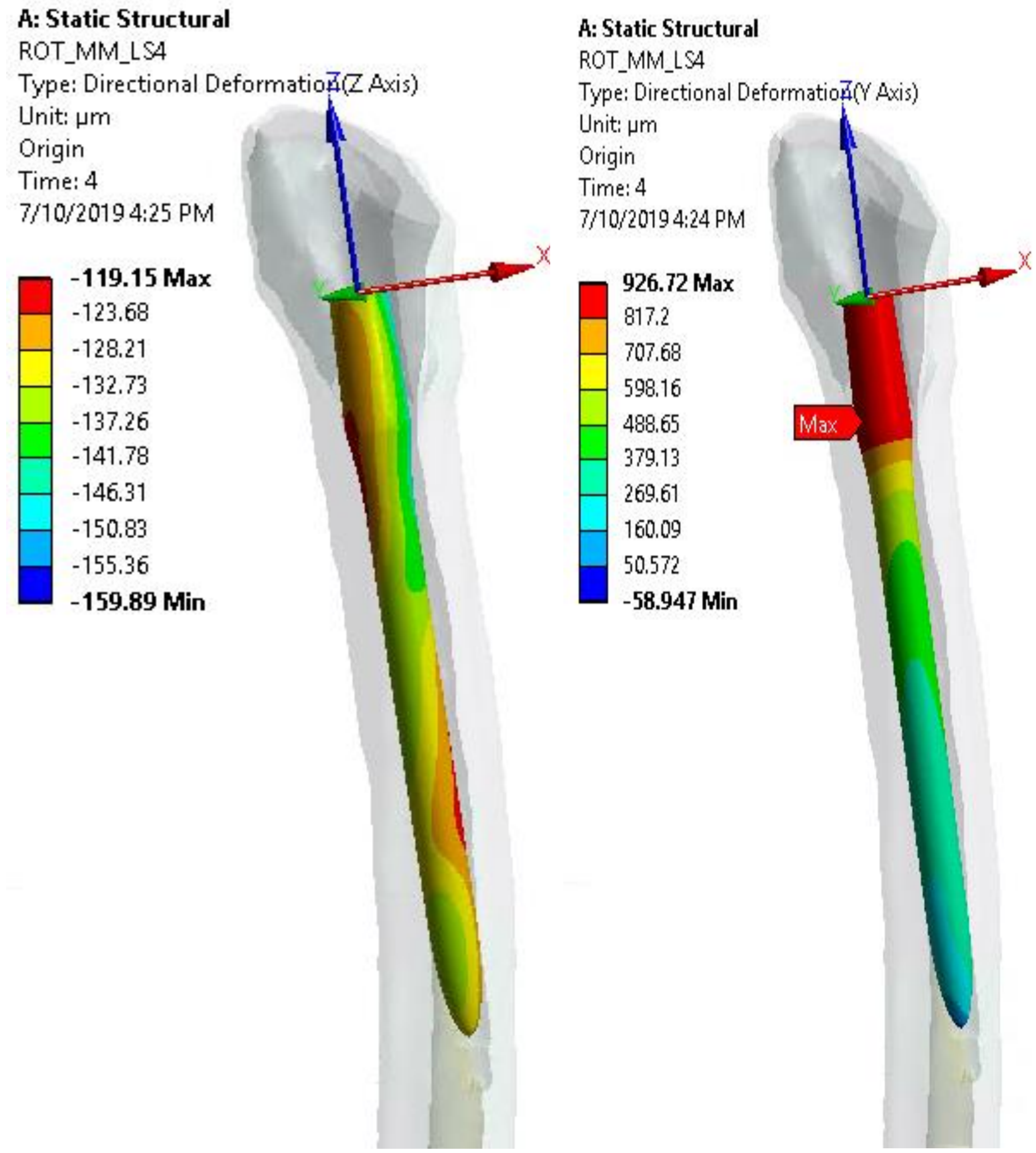


Figure 5.9: Axial Deformation (L) and Rotational Deformation (R) under Functional load. (Workbench)

The results for Plasma stem are under the favorable range of 0 µm to 800 µm as discussed in the literature review. This method is validated as the product Plasma has the clinical history of more than 15 years in the market with a successful success rate. The same methodology is applied to the conical stem to obtain the results. For Conical Stem, the micro-motion is analyzed for two of the sizes, due to the confidentiality and sensitivity of data, these sizes are mentioned as size A and size B and Length L

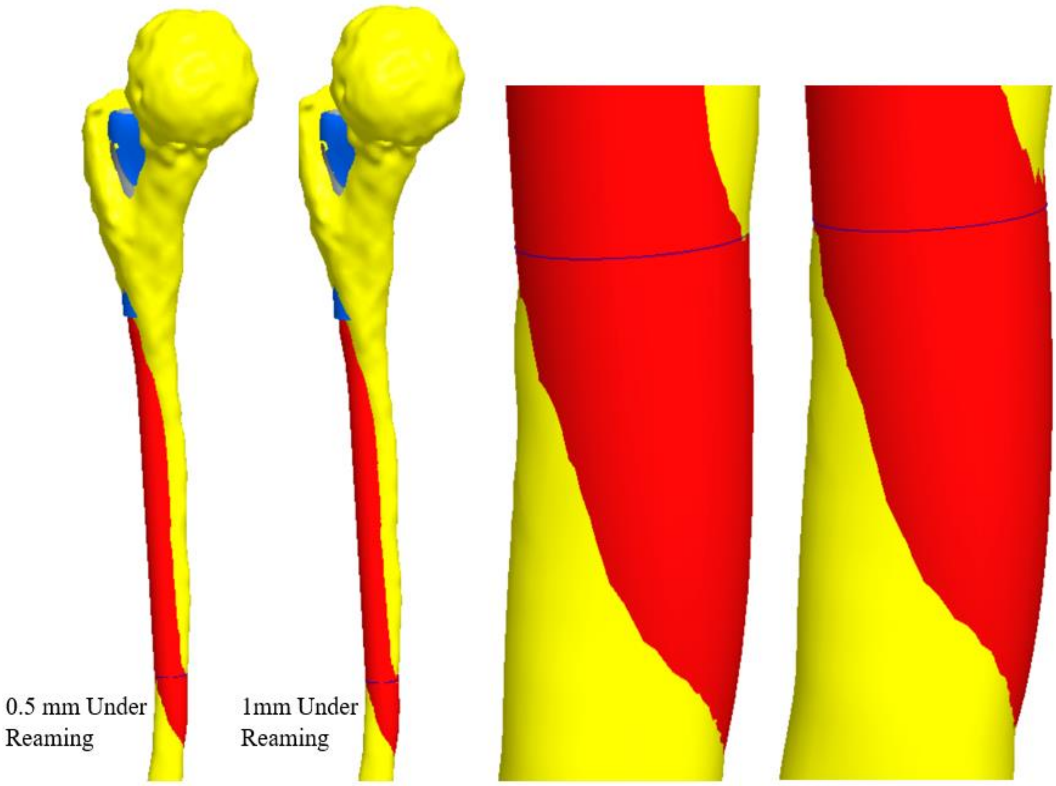


Figure 5.10: 0.5 mm under reaming and 1.0 under reaming (Pro. E)

5.2.2 Conical Stem

5.2.2.1 Stem Size A

The results obtained for size A conical stem are shown below. The results shown were for the micro-motion during load step 2 where the assembly load was maximum and then for the load step 4 where the functional load was maximum. The results were analyzed in two of the view ML view and AP view to see the rotational micro-motion and axial micro-motion. The Figure 5.11 shows the micro-motion in ML and AP view at Load step 2 i.e. under assembly load for the Axial micro-motion. Figure 5.12 show the convergence graph for it.In Figure 5.13, It is clear that when the assembly load of 2200 N is applied in z direction which is axial direction of the stem axis, the maximum micro-motion which is happening in axial direction is around 60 µm and minimum micro-motion around 44 µm. The splineregion has almost similar amount of displacement in between 44 µm to 60 µm. When compared to plasma stem, this design has better performance in respective to micro-motion as stem is displacing very less in axial direction when compared to plasma. It is also clear that in ML view, The anterior region has the trend of decreasing of micro-motion from 61 µm to 44 µm as observed towards distal end from the proximal side. There is around 50 μm in the mid portion of the spline region.

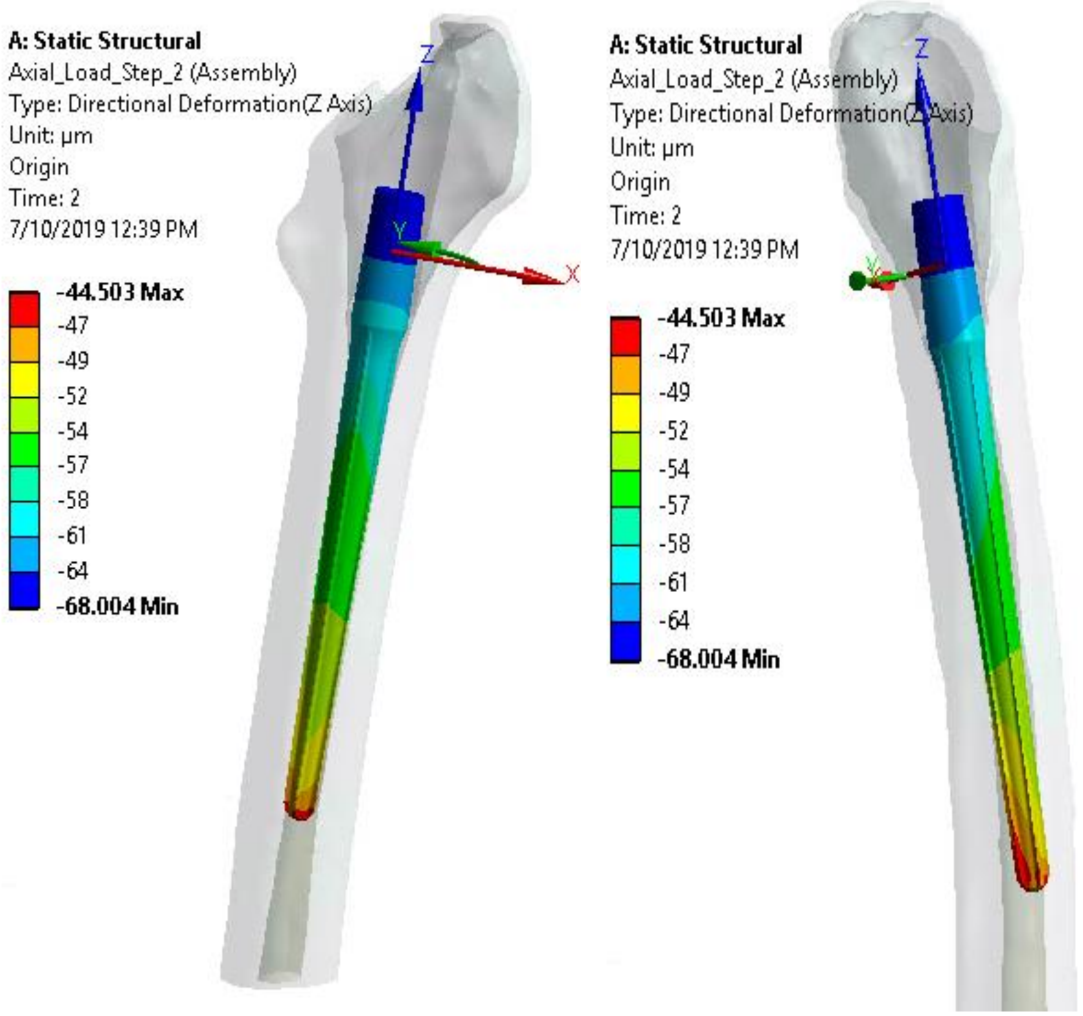


Figure 5.11: Axial Deformation for Assembly Load in AP (L) and ML (R) view. (Workbench)

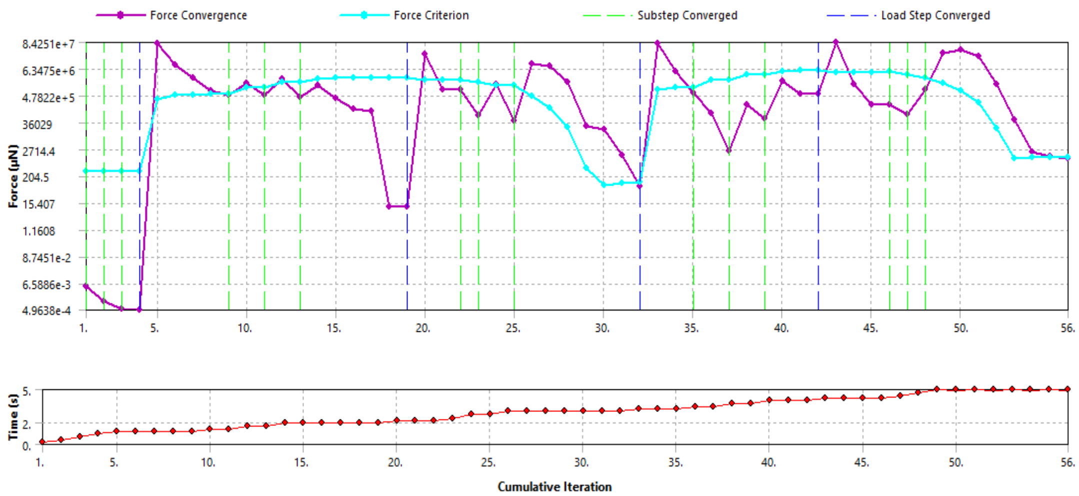


Figure 5.12: Convergence Graph (Workbench)

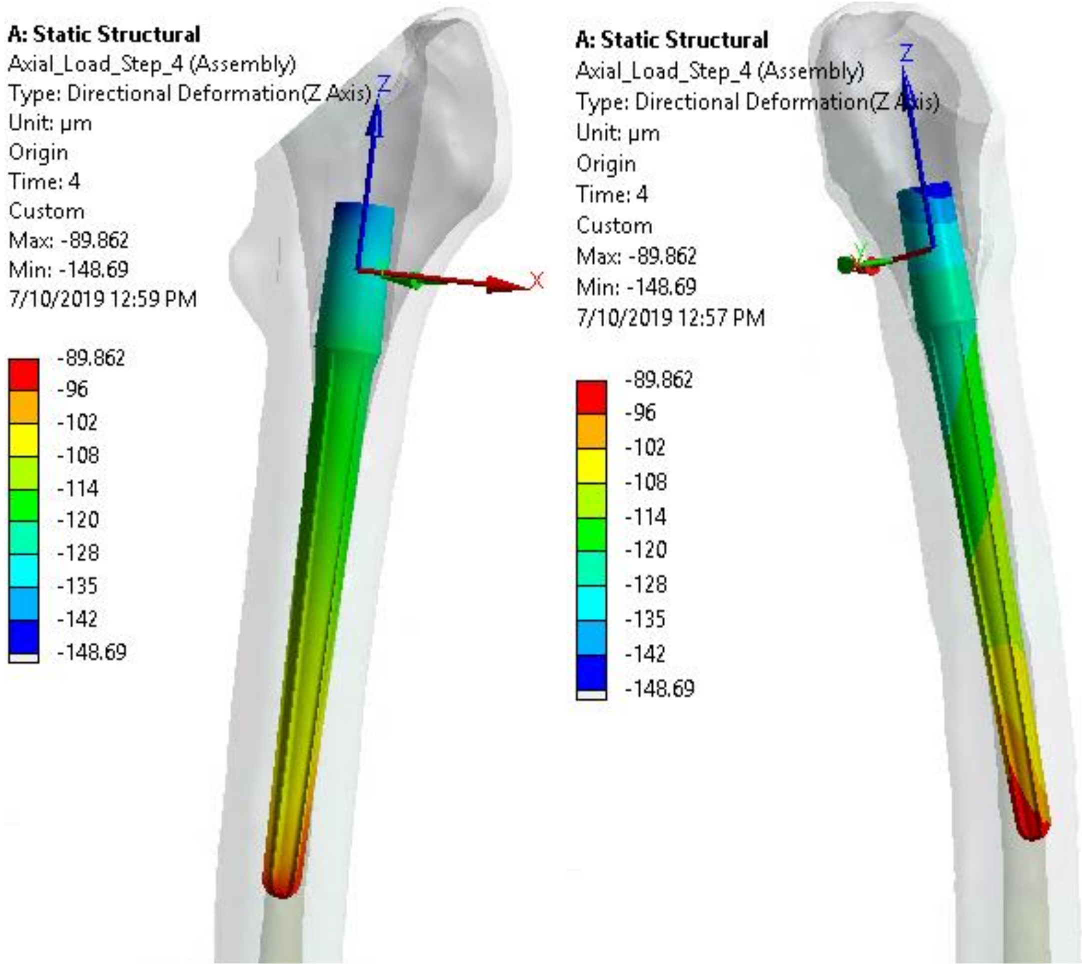


Figure 5.13: Axial Deformation for Functional Load in AP (L) and ML (R) view. (Workbench)

Coming to the load step 4 where the functional load that is forces acting on stem during stair climbing activity is applied, the results are shown in Figure 5.14 in ML view and AP view. Discussing AP view, the trend is decreasing from 128 µm to 90 µm as we move from proximal to distal direction in lateral region. The mid and proximal region of spline has around 120 µm of micro-motion. Distal end has the minimum micro-motion which is around 90 µm. in ML view also, if we analyze results in posterior side of the stem, the trend is same as in proximal side of it there is more of micro-motion compared to distal side.

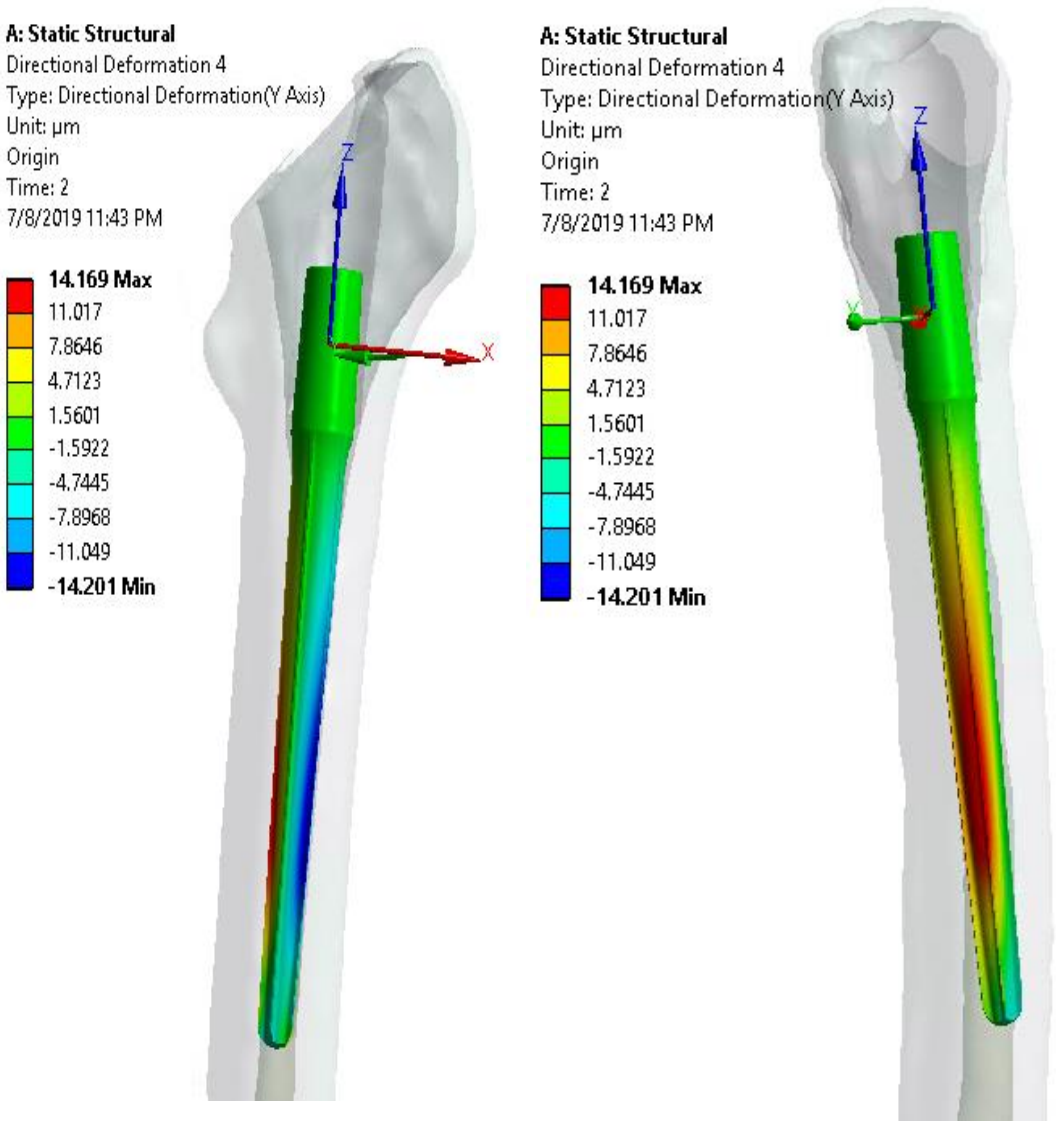


Figure 5.14: Rotational Deformation for Assembly Load in AP (L) and ML (R) view. (Workbench)

For size A, the results for rotational micro-motion when the assembly load of 2200N is applied are shown in Figure 5.15, the range for micro-motion is only till 14 µm. The maximum micro-motion is observed in the mid portion of the stem in posterior side which is ranging from 4 µm to 14 µm when viewed in ML direction.

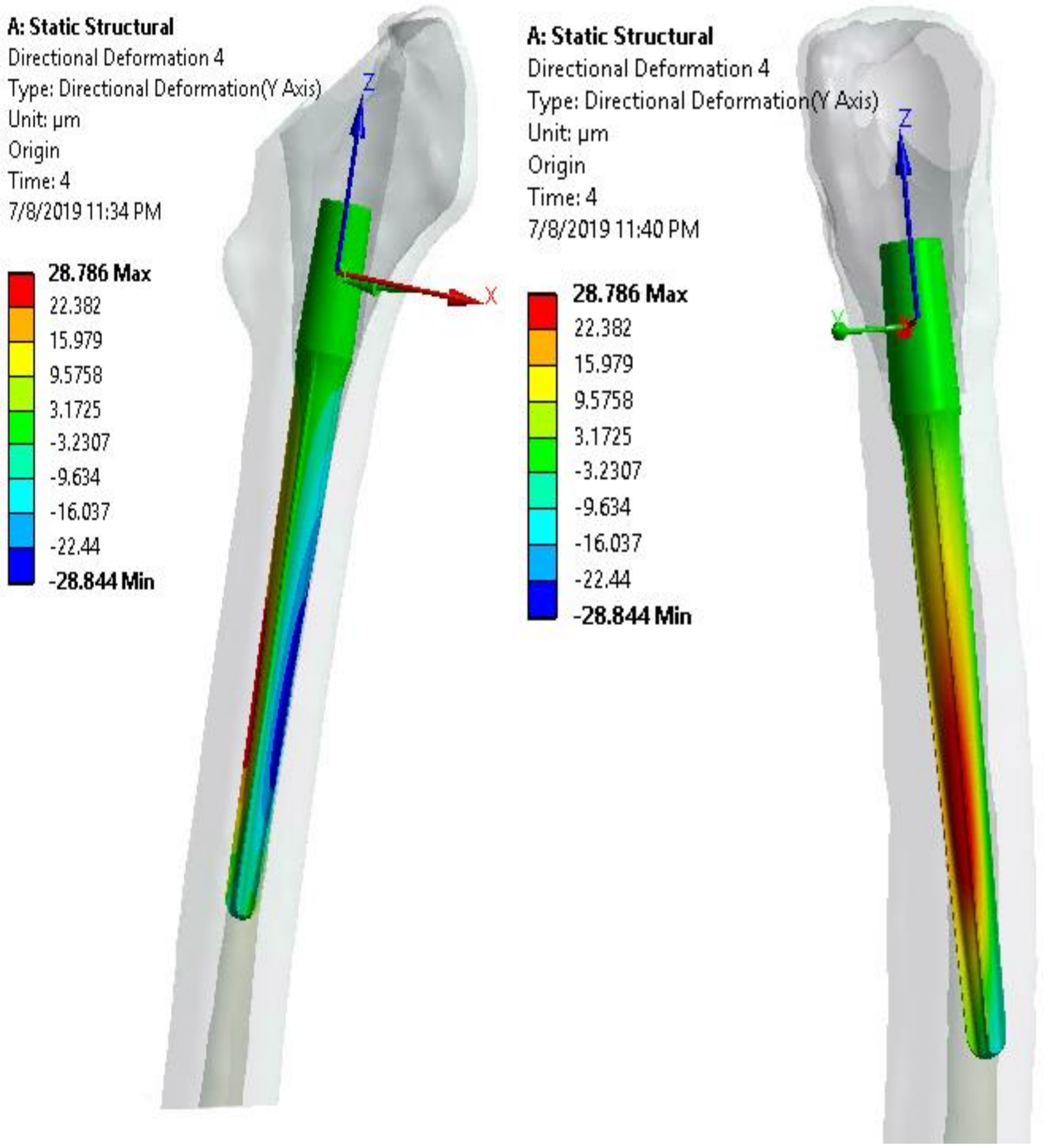


Figure 5.15: Rotational Deformation for Functional Load in AP (L) and ML (R) view. (Workbench)

The distal tip of the implant has negligible movement with respect to bone. In AP view the direction of motion is in opposite direction when compared in lateral and medial region of it. This shows there is a twist kind of motion in stem which cause the loosening of implant if the range increases. Micro-motion from proximal side to the distal end when observed in lateral side tends to increase from 1 µm to 11 µm only. This range of micro-motion is very less and is in the desired range. This ensures that stem does not move rotationally much when assembly load is applied. For the functional load which is load step 4, stem behavior is shown in Figure 5.15 under the stair climbing effect where the maximum range of micro motion is 28 µm. In AP view, the pattern of micro motion in lateral side varies as it decreases from 3 µm to 28 µm as observed towards the distal side of stem. This is the region where the splines are in contact with cancellous as well as cortical making it more prone to the motion. In ML view, anterior side of the implant region has around 3 µm to 10 µm which is in contact with the cancellous bone. The posterior side has the maximum micro-motion of range 9 µm to 28 µm. The distal tip in ML view which is providing the stability has only 3 µm of micro-motion.

5.2.2.2 Stem Size B

For stem size B, results for the micro-motion in stem's axial direction are shown in both views ML and AP in Figure 5.17 for load step 2. In load step 2 where the assembly load is applied, under which the behavior of stem shows that there is maximum of 72 µm. The area of interest is the spline region as the taper body in proximal side will house the cone body hence is not in the scope of study. For the proximal spline region of stem which is in contact with the bone is seen to have the displacement of around 60 µm to 65 µm in AP view and is decreasing to 55 µm - 60 µm as observed towards the distal direction of the stem (the medium portion of spline region) in distal direction at lateral side. In medial side, major region of the stem has micro- motion in range of 52 µm - 58 µm which is less than the range observed in lateral side. When the results are analyzed in ML view, the distal tip of the stem tends to have 50 µm to 55 µm micro-motion which is less than the range of micro-motion in proximal side of it which is around 60 µm and tends the behavior of increasing micro-motion towards proximal direction. When the stem size B is analyzed under the load step 4 for axial displacement, the functional load of stair climbing activity influences the stem as shown in Figure 5.16. In AP view, the results show that in lateral side of stem there is decrease in micro-motion from 65 µm to 47 µm. In distal portion of the tip only 47 µm displacement is occurring. This may be the case because, the distal fixation is achieved from the cortical bone which constraints the implant from displacing deeper. If we compare the load step 2 and load step 4 for axial micro-motion, it can be observed that there is more region with lower amount of micro-motion in load step 4 when compared to load step 2. The reason behind it is because in load step 2, the assembly load of 2200 N is applied in the axial direction of stem which is not the case for functional loading. The angles of application in case of functional loading are different due to the leg position in stair climbing activity.

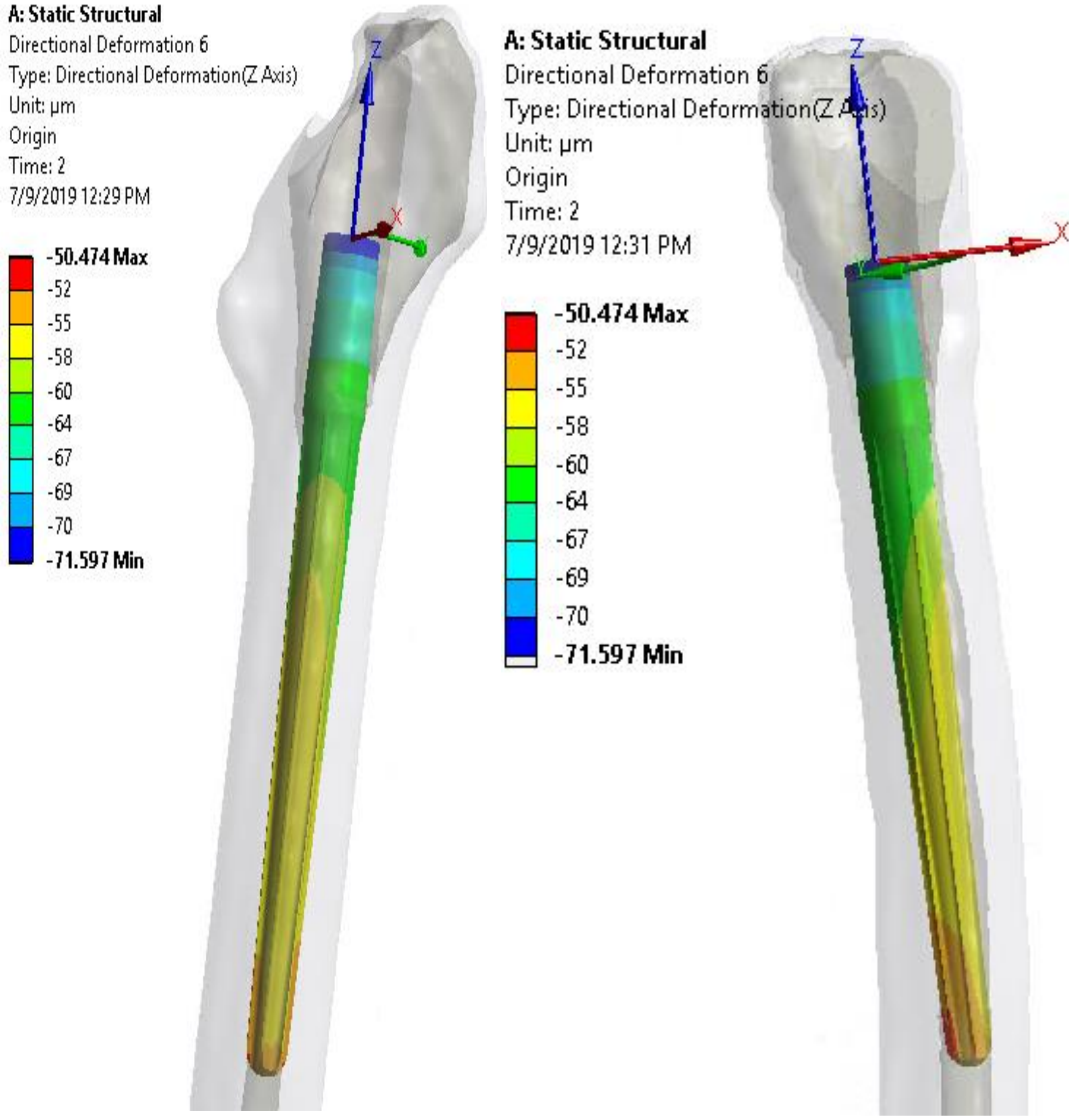


Figure 5.16: Axial Deformation for Assembly Load in AP (L) and ML (R) view for size A. (Workbench)

The rotational displacement is also analyzed for the both cases i.e. load step 2 and load step 4. The Figure 5.18 shows the results of stem when it is under assembly load of 2200 N. When viewed in AP view, the range of motion varies 2 µm to 16 µm.

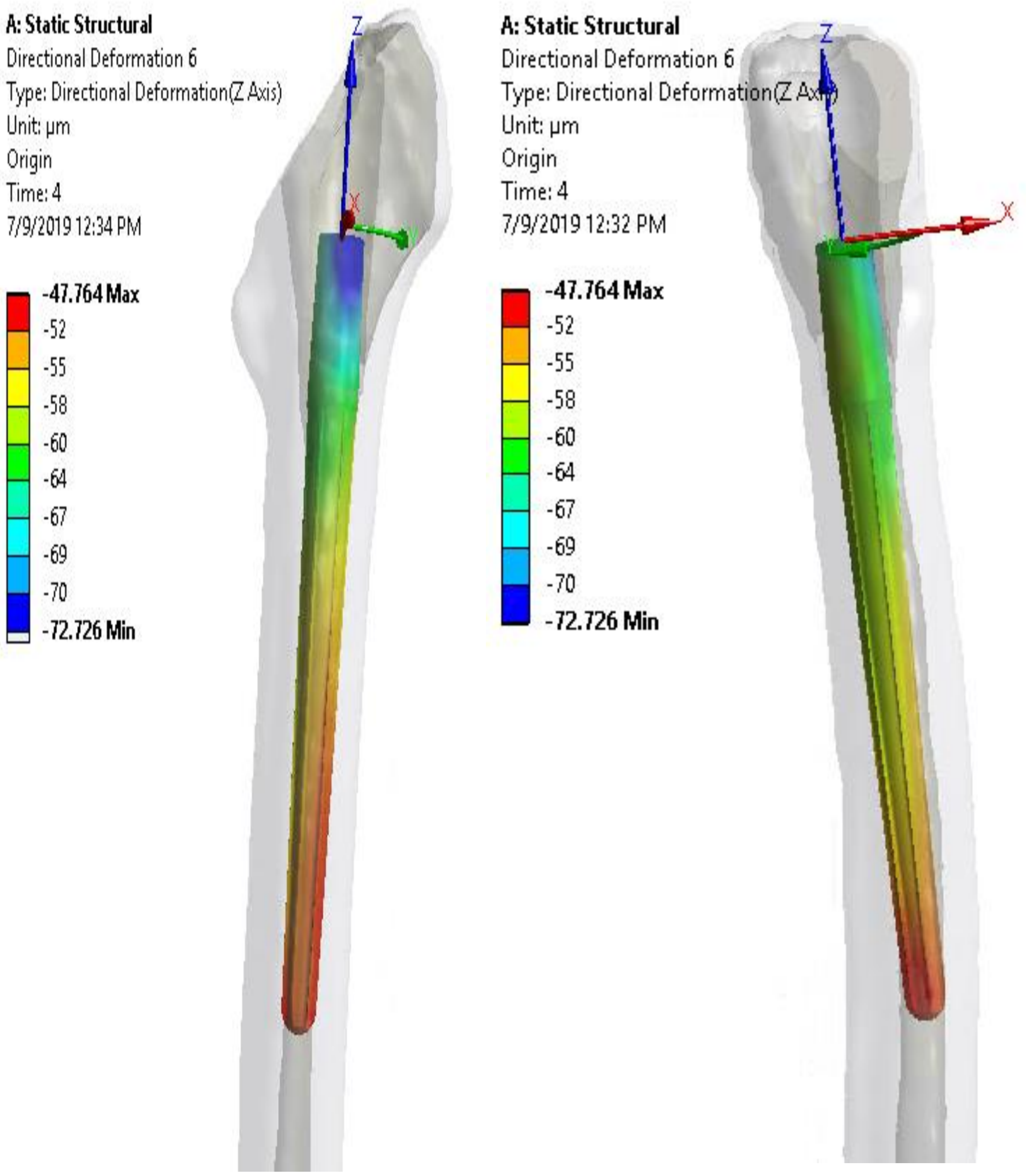


Figure 5.17: Axial Deformation for functional load in AP (L) and ML (R) view. (Workbench)

It is observed that, direction of micro-motion tends to be in opposite direction in mid spline region in lateral and medial direction. The justification for this can be the presence of cortical bone in posterior side while in anterior side there is cancellous bone present. The Assembly load has not much effect on rotational micro-motion because of the assembly load direction, the rotational micro-motion is induced majorly because of the functional load which is applied in load step 4.

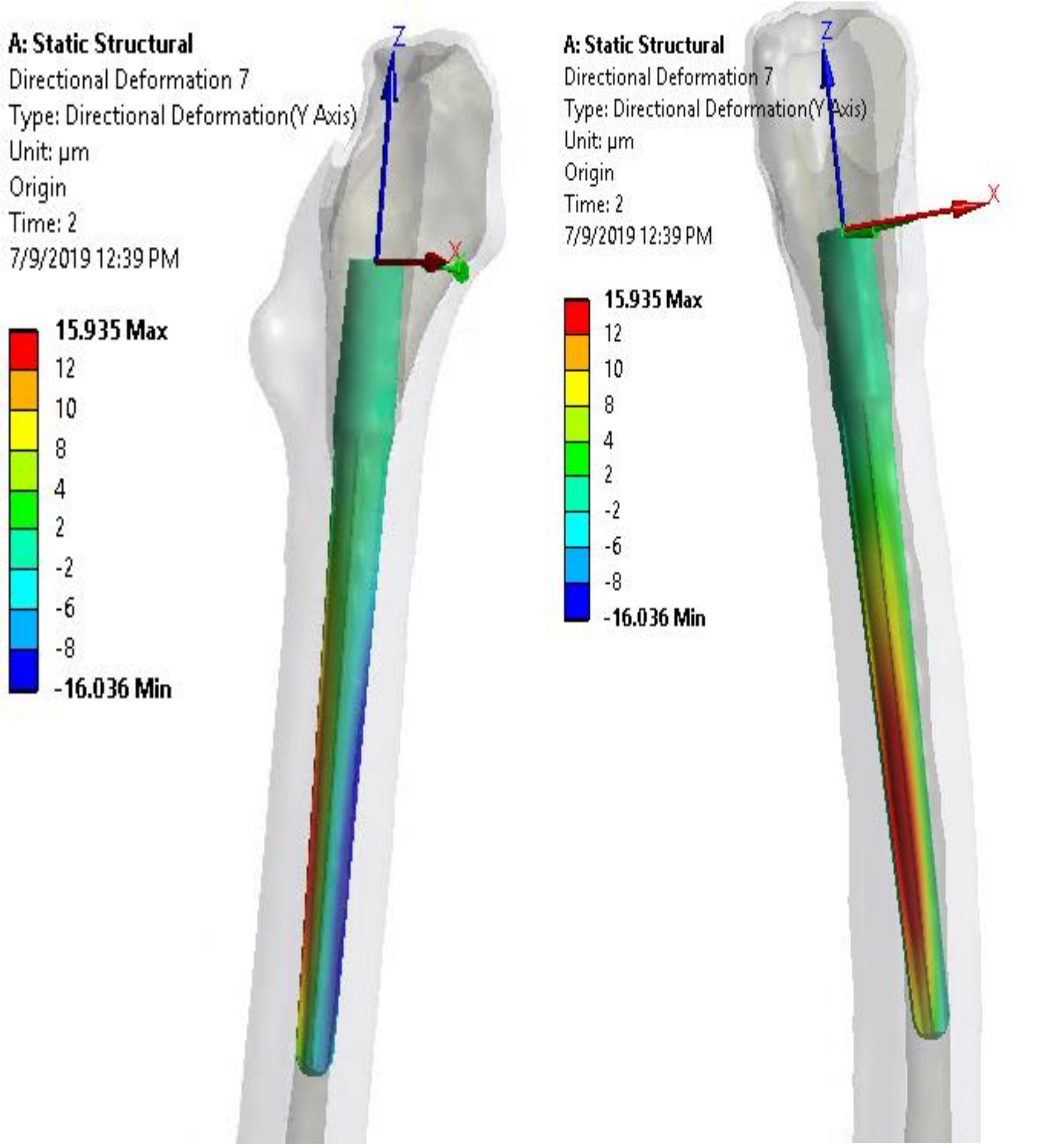


Figure 5.18: Rotational Deformation for Assembly Load in AP (L) and ML (R) view for size B. (Workbench)

The results in rotational direction for the load step 4 are shown in Figure 5.19. The rotational micro-motion majorly has range from 10 µm to 300 µm. The proximal taper feature has around 307 µm but it is the mating feature for the cone body, hence can be excluded from the study perspective. The proximal spline region has micro-motion ranging from 150 µm to 250 µm. The medium region has 50 µm- 150 µm. When viewed in ML view, the distal portion of the stem has negligible micro-motion because of its contact with the cortical bone. The anterior side of stem has slightly more micro-motion than the posterior side.

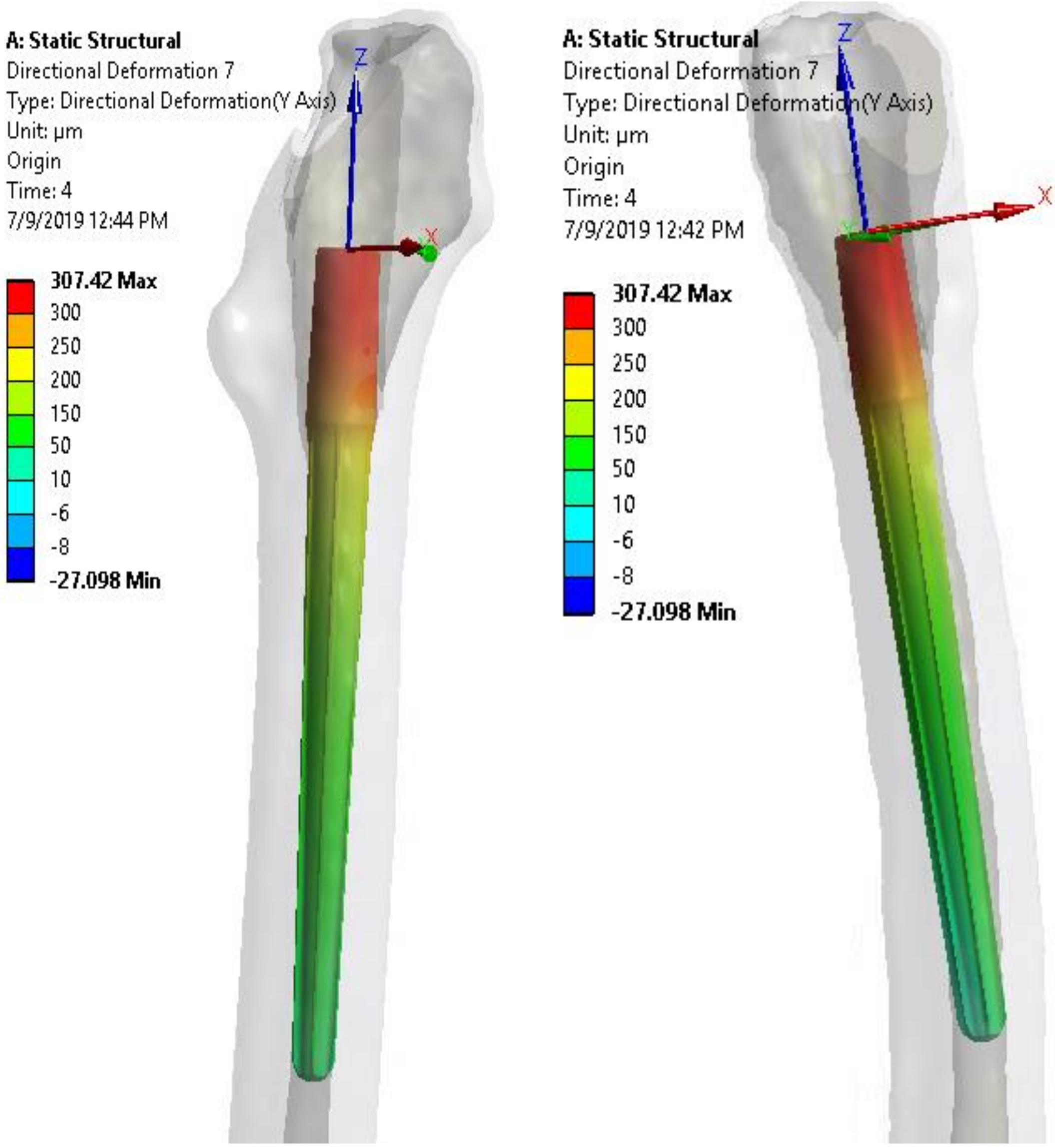


Figure 5.19: Rotational Deformation for Functional Load in AP (L) and ML (R) view for size B. (Workbench)

From above results, it is observed that the rotational micro-motion is more in functional loading compared to assembly loading. This suggests that implant loosing is more due to the functional load whereas the subsidence of the implant is due to the assembly load. Also, the range of micro-motion irrespective of its type i.e. whether its rotational or axial, it is under the desired range.

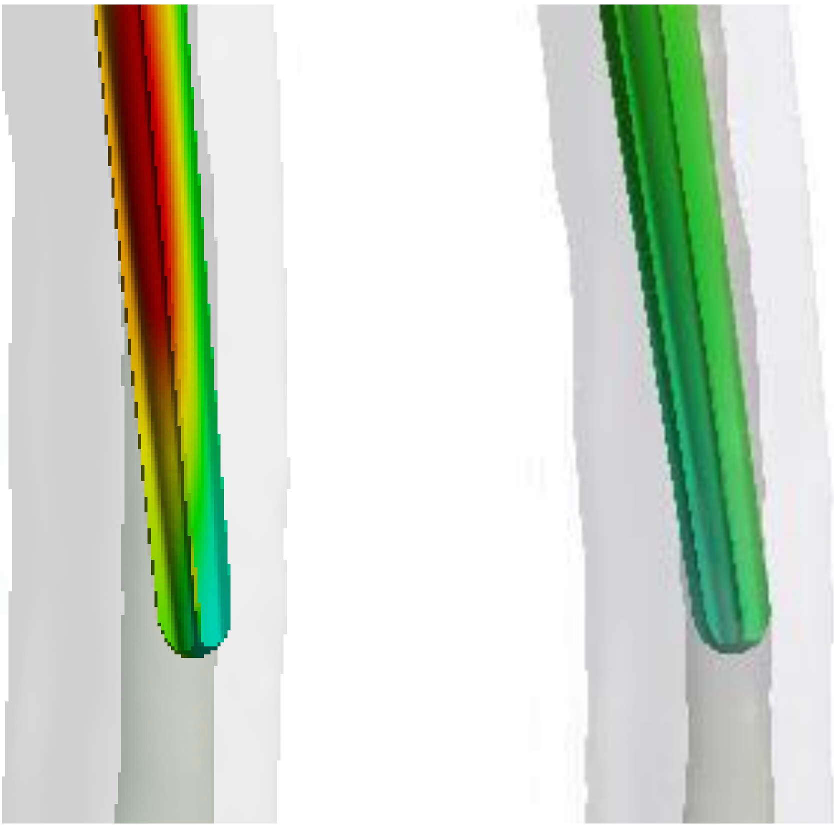


Figure 5.20: Distal Fixation in Size A (L) and Size B(R) (Workbench)

CHAPTER 6
CONCLUSIONS

6.1 Design Aspect

- The fixation is improved by providing more interference between the implant and the bone. This interference provides the stability to the implant by reducing the micro-motion under both assembly loading and functional loading. With increase of 0.5 mm interference, micro-motion is decreased from 450 µm to 300 µm which is around 35% more fixation.
- Conical stem has shown less micro-motion when compared with legacy plasma stem. This was due to the conical shape of splines in conical stem design which makes it SOMA (Stryker Orthopedic Modelling And Analysis) compatible. The slope present in the distal portion of the conical stem provides the more contact area between implant surface and cortical bone as compared to plasma stem. It makes it better than legacy stem in design aspect. Also, the progression of the taper in the conical stem being similar to the cancellous bone canal taper angle. It gives more edge to it as compared to the plasma stem. For rotational micromotion, plasma stem had around 900 µm micro-motion where as it is 300 µm for conical stem. This is around 67% less micro-motion.
- The induced micro-motion in conical stem for both the sizes (size A and size B) is under desired range of 0 µm to 1000 µm which implies that it is fit for use. The trend of micro-motion is that, it tends to decrease in distal direction.
- The assembly loading does not contribute much in rotational micro-motion. It gives the stem axial displacement whereas functional loading contributes to the rotational micro-motion with no major impact on axial micro-motion.

6.1.1 Compatibility Aspect

- From the canal taper angle study, the 20% patient which were not being targeted by the plasma stem were now compatible with this conical stem size. The 40% patient who are incompatible with the conical stems are already targeted by plasma stem. With both of these options in the market, the compatibility of stem with patients have been increased.

- During the fixation of implant, the proper selection of its size is very crucial. From the results it was seen that in case of conical stem size B, the range of micro-motion was more compared to the range of micro-motion in size A. In size A, the range of micro-motion increased from 0 µm - 50 µm to 300 µm when incorrect size B was implanted. This implies that, for the selected type of bone, size A had a better fit compared to size B. The distal fixation has major effect on micro-motion as it can constraint the stem from displacing. The more distal contact of stem with implant surface provides the better the fixation and less micro-motion as shown in Figure 5.20.

6.2 Future Scope

There are a lot of factors affecting the range of micro-motion some of them are design related and some are use environment related. In future, to reduce more of the micro-motion, the coating such as HA, beaded w/appetite etc. which are used on the surface can be considered to refine the results even more. This study is performed only for the stair-climbing activity, same study can be performed for activities like squatting, swimming etc. In future using field of SOMA, the implant can be designed using the trend of cancellous thickness from distal to proximal direction. A study can be performed to check the stress acting on the bone in various implants. Under the stress, bone has tendency to grow such kind of study can help to see where the more stress is generating in the bone and can be differentiated as per required stress and non-required stress which can help in better design of an implant.

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