Design and Development of Universal Counter Wrench and Poly Sleeve/Filler Bushing Removal Tool for Triathlon Limb Salvage Program

A Thesis submitted in the fulfillment of the requirement for the award of the degree of

Master of Engineering

in

CAD/CAM Engineering

Submitted by

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PATIALA
(July 2019)

DECLARATION

I declare the dissertation work entitled **"Design and Development of Universal Counter Wrench and Poly Sleeve/Filler Bushing Removal Tool for Triathlon Limb Salvage Program"** 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.

Nikhil Sharma
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CERTIFICATE

This is to certify that the dissertation work entitled **"Design and Development of Universal Counter Wrench and Poly Sleeve/Filler. Bushing Removal Tool for Triathlon Limb Salvage Program"** is an authentic record of work carried out by **"Mr. Nikhil Sharma, 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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Nikhil Sharma

ABSTRACT

The objective of the project **"Design and Development of Universal Counter Wrench and Poly Sleeve/Filler Bushing Removal Tool for Triathlon Limb Salvage Program"** is to make a hinge portfolio which combines the design analogies of global modular replacement system, Modular Rotating Hinge System, Massive Endoprosthesis Tumor System, Stanmore Modular Individualized Lower Extremity System. The work presented in this thesis for "New Product Development Process" of two instruments: Universal Counter Wrench and Poly Sleeve/Filler Bushing Removal Tool. The primary objective of the work is to conceptualize a design which can fulfill the needs and requirements from the surgeon such as functionality, marketing with regards to cost, sterility, cleaning, packaging and manufacturing perspective. And then to check that the design concept is stable and robust. Firstly, literature survey was performed to gain knowledge in the knee surgery portfolio. The hinge is basically third stage and the most complex stage of implantation. The study was divided into two parts. The first part deals with the survivorship aspects of the primary and revision surgeries from around the globe and the second part of the study focused on the comparative study of the implants and the instruments failure of competitors and the major causes of the failure of the hinge construct to have in depth knowledge of the key design concepts of the medical implants and instruments. The process is divided into three phases. In the first phase, the material is finalized depending upon the standards of medical industry and compatibility with the engaging instruments/implants. For this, different available materials are compared based on the desired properties. And then, the documentation was done based on the design inputs from surgeons, cleaning, sterility and marketing. In the second phase, the design conceptualization is carried out. It includes design calculation with regards to engagement with mating component, and then analysis of different concepts is performed. The selected concept is then verified by tolerance analysis with assembly, finite element method, benchtop testing to see how the instrument behaves in surgical environment and to verify the theoretical results. The finalized concept is then prototyped to have a real look and feel of the final product. Finally, the conclusions, learnings and scope for future work is presented.

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LIST OF ABBREVIATIONS

GMRS	=	global modular replacement system
MRH	=	Modular Rotating Hinge System
METS	=	Massive Endoprosthesis Tumor System
SMILES	=	Stanmore Modular Individualized Lower Extremity System
TKA	=	Total Knee Arthroplasty
MCL	=	Medial collateral ligament
LCL	=	Lateral collateral ligament
ROM	=	Range of motion
VP	=	Vertical position
LL	=	Length of the patella ligament
CP	=	Femoral condylar plane
PA	=	Articulating surface of patella length
JL	=	Joint line
ME	=	Medial femoral epicondyle
TT	=	Tibial tubercle
IPP	=	Inferior pole of the patella
FH	=	Fibular head
MBT	=	Metal backed tibia
APT	=	All polyethylene tibia
SOMA	=	Stryker orthopedics modelling and analytics
TS	=	Total Stabilizer
DIOVV	=	Design input output verification validation
DFMECA	=	Design failure modes effects and criticality analysis
SS	=	Stainless steel
ASME	=	American society of mechanical engineers
RTKA	=	Revision of total knee arthroplasty
RTHA	=	Revision of total hip arthroplasty

Chapter 1
Introduction

1.1 Background and Scope of Triathlon Limb Salvage

The Triathlon Limb Salvage is integration of portfolios like global modular replacement system (GMRS), Modular Rotating Hinge System (MRH), Massive Endoprosthesis Tumor System (METS) and Stanmore Modular Individualized Lower Extremity System (SMILES). The Triathlon Limb Salvage System is designed to meet patient's expectations for Lifestyle Recovery [1]. The Triathlon Limb Salvage deals with the "Hinge" case of the knee. Since there is a large part of population which is in range of 45-80 years of ages, there are large numbers of cases with osteoarthritis patients, the number of revision cases are increasing [2]. In most of the revision cases of knee surgery the conventional designs of implant are used [3-4]. The criteria are when a surgeon decides then the case will be treated with revision scenario are defined [5]. Table 1.1 shows the different comorbidities in patients of different age groups who went through the knee surgery with hinged implants. It can be depicted from the data that Dyslipidemia is common diseases in females while Hyperextension is common in both genders. From Table 1.1 it is also evident that most of the infected population lies between 50-75 years.

Table 1.1: Data indicating implantation of Hinge assembly [6].

PATIENTS	AGE	GENDER	MULTIPLE DISEASES
1	69	F	Hypertension, Dyslipidemia
2	55	F	Rheumatoid arthritis
3	72	F	Hypertension, Dyslipidemia
4	60	M	Hypertension, Gouty arthritis
5	68	M	No comorbidities
6	55	F	Hypertension

Hinge case, in many a times is a result of primary case failure, there can be various cases in which a total knee arthroplasty (TKA) results in revision. Figure 1.1 shows specifically the reasons which can cause TKA failure and it can be concluded that “Infection” is one of the most common reason which can cause the patient to go for a revision surgery.

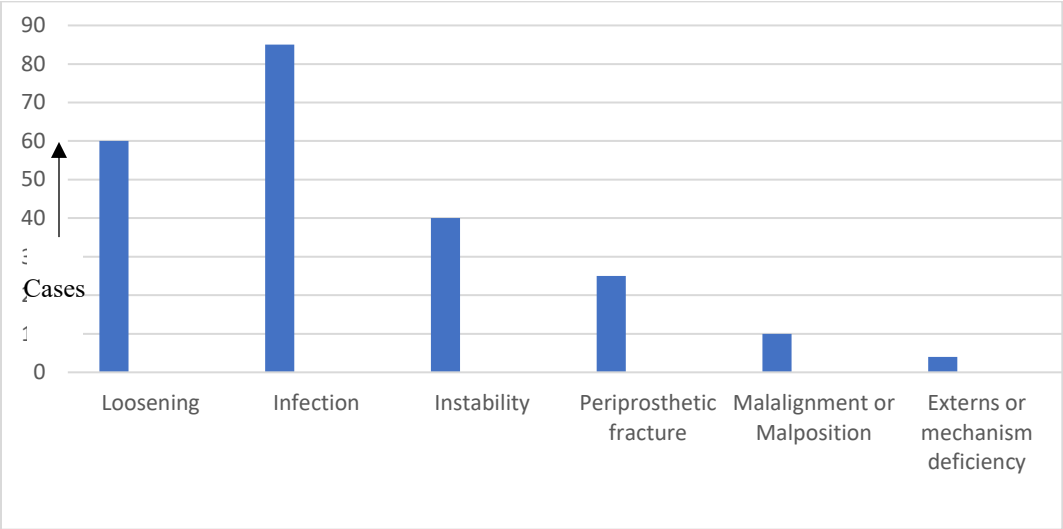


Figure 1.1: Leading Causes (Early) of TKA failure [1]

Following can be some of the common symptoms of infection after TKA:

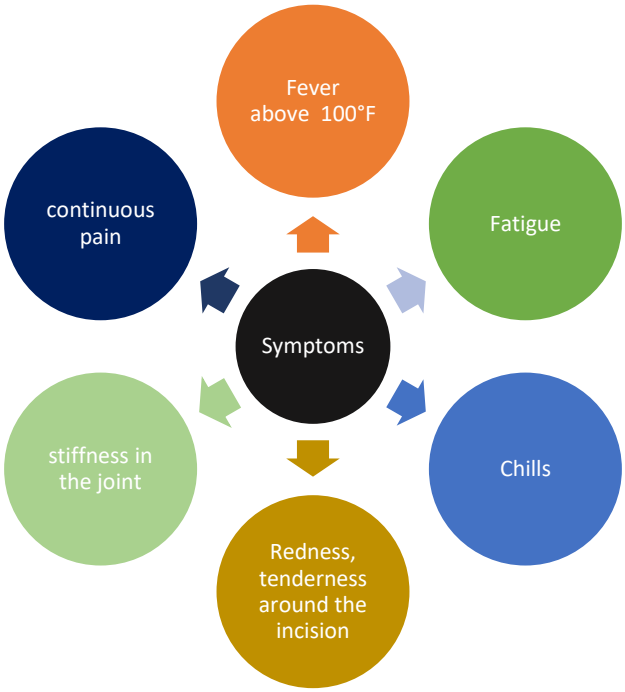


Figure 1.2: Common symptoms of infection after TKA

Some of the other reasons which could led to Revision or core hinge case can be

- *Medial and lateral collateral ligaments insufficiency (figure 1.3)*: The collateral ligaments are the one which supports knee joint on the sides, therefore on the medial science it called medial collateral ligament (MCL) while on the lateral side it is referred to as lateral collateral ligament (LCL). If one of the collateral ligaments becomes loose or tight it will not be able to perform its function properly and hence there will be constraints in range of motion (ROM)

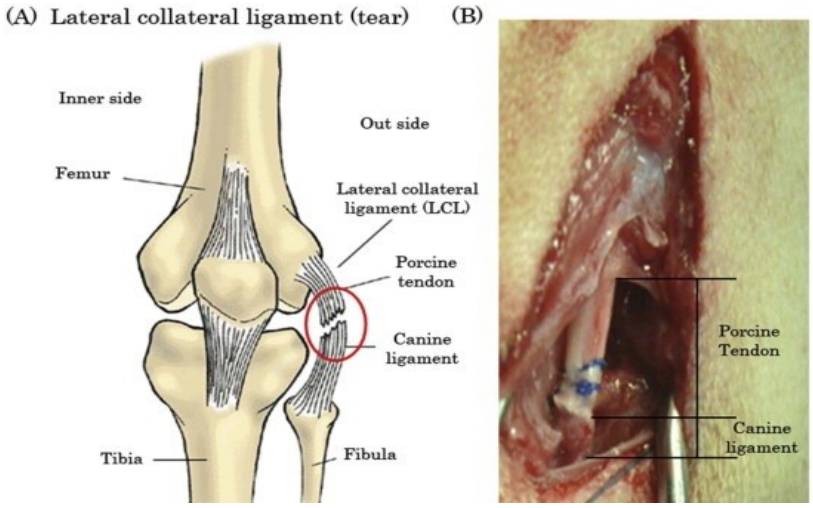


Figure 1.3: Medial and lateral collateral ligaments insufficiency

- *Bone loss in the femur along with loss of medial and lateral collaterals (figure 1.4)*

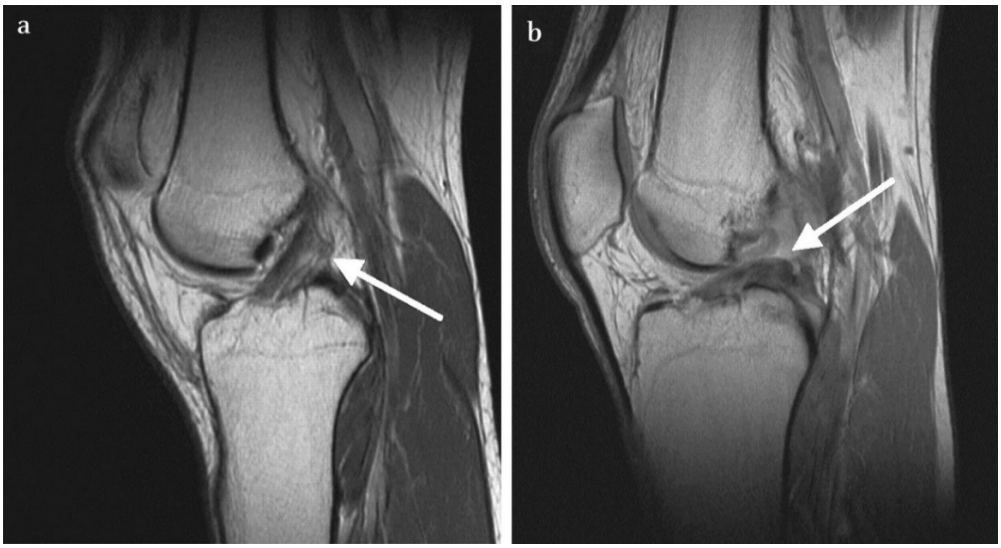


Figure 1.4: Bone destruction of femoral condyles

- *Loosening of medial and lateral collateral ligament (figure 1.5)*: During the surgery if the surgeon makes ineffective cuts on the bone or if the joint line is not restored correctly there can be gaps while extending and flexing knee which can cause pain, loosening of implant, patient is not able to walk properly. This is illustrated in Fig. 1.5.

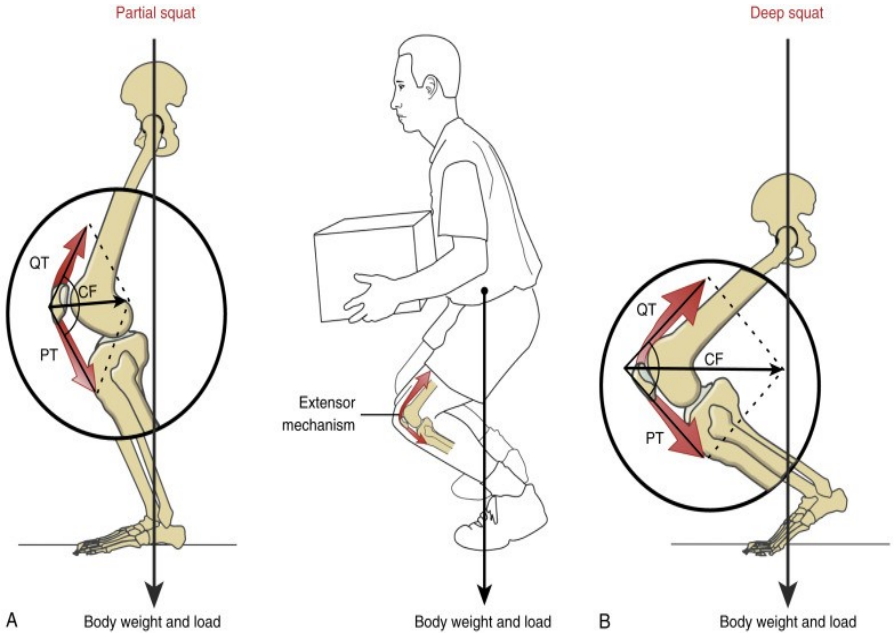


Figure 1.5: Gaps in different standing positions

- *Fixed Varus or valgus deformity greater than 20^0 (figure 1.6)* : Varus-vulgus ranging from five degrees to seven degrees is acceptable, but any value besides that is a deformity. Figure 1.6 illustrates this type of deformity.

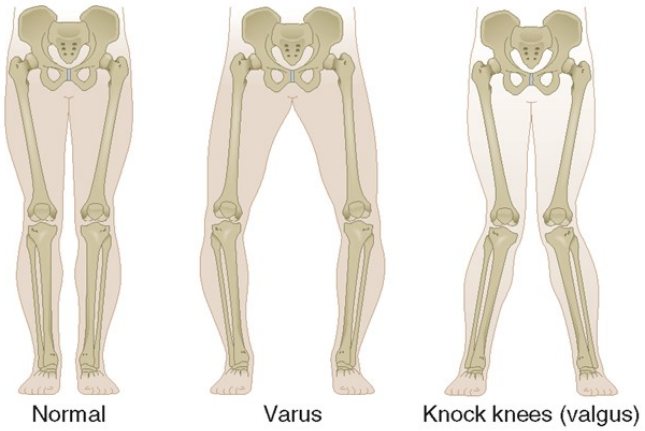


Figure 1.6: Varus and Vulgus Deformity

- *Severe rheumatoid arthritis (figure 1.7)*: Rheumatoid arthritis is an autoimmune disorder which is affects the joints primarily.

Figure 1.7: Rheumatoid Arthritis

- *Neuromuscular diseases that occur with excessive knee hyperextension*: Figure 1.8 explains neuromuscular diseases that occur with excessive knee hyperextension. It can result in Anterior pelvic tilt, posterior pelvic tilt or in many cases it results in shift of pelvis.

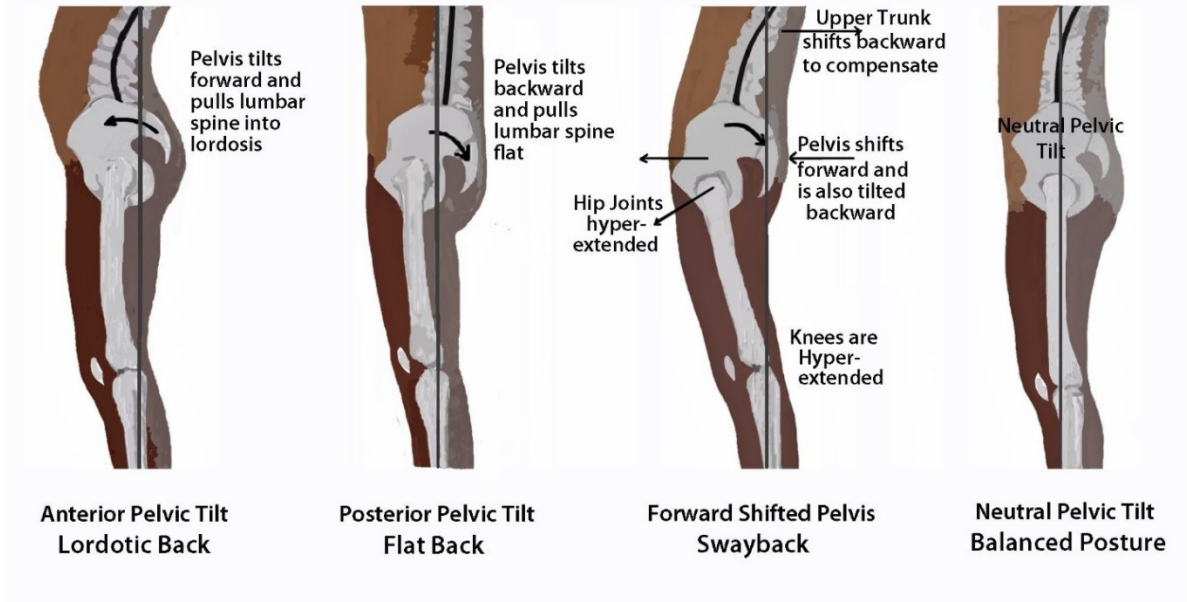


Figure 1.8: Effect of Pelvic Tilt and Hip/Knee Hyperextension on Lower Body Posture

- *Total Knee Arthroplasty infection (figure 1.9)*: In many cases during the TKA the soft tissues get infected due to surgery environment, instruments being used are not properly sterilized, etc. Hence there is a high probability of infection. Also, if the implant is not seated properly the bone can get infected. Figure 1.9 shows how the knee joint get infected with inaccurate placement of implant.

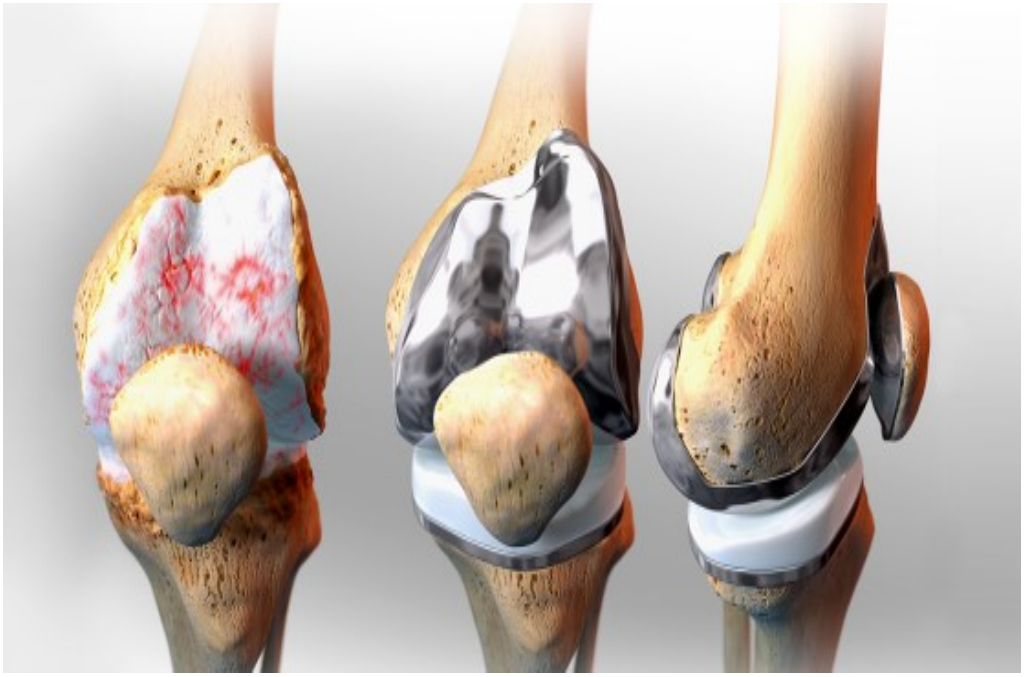


Figure 1.9: Post TKA Infection

Stryker's moto is "together with our customers we make healthcare better". Stryker believes in making implants design which is approximately resembles the natural anatomy of the body that's one of the key factors of being a giant in the medical industry. The knee implants are designed with the help of Stryker orthopedic modelling and analytic software (SOMA), which is the largest database any medical company ever had. The implants have been designed with the support from engineering and medical experts and Stryker holds a successful clinical history of most of its implants and instruments. Figure 1.10 shows how the TLS project is getting integrated from four different projects.

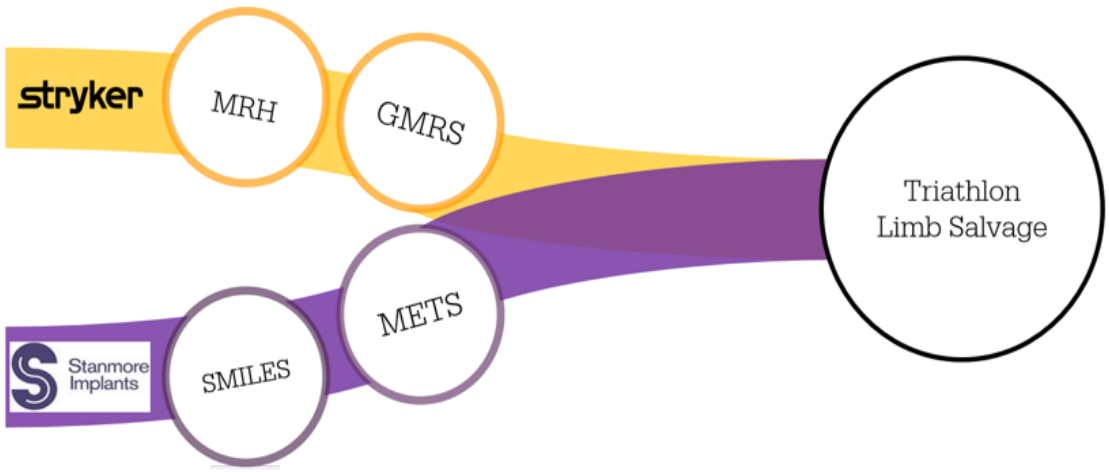


Figure 1.10: TLS Scope [Stryker Medical Devices and Equipment Manufacturing Company (www.stryker.com) Retrieved on May 14, 2019.]

1.2 Stryker Orthopedic modelling and analysis (SOMA)

Stryker orthopedic modelling and analysis is Stryker's database of computed tomography scans. Figure 1.11 shows an interface of SOMA. As there are differences in bone morphology from region to region, age and sex, so there was a need for a tool which can store large number of patient data including bone dimensions in medial-lateral, anterior-posterior aspects, bone landmarks, bone density etc. The SOMA helps for calculating the dimensions of the landmarks which helps in design conceptualization of the implant taking into consideration all the stored population data. SOMA helps in defining the major dimensions of the implant both on the femur and the tibial side. Figure 1.12 below shows how the SOMA anatomical tool can help in defining distance between the femoral head and the anatomical axis

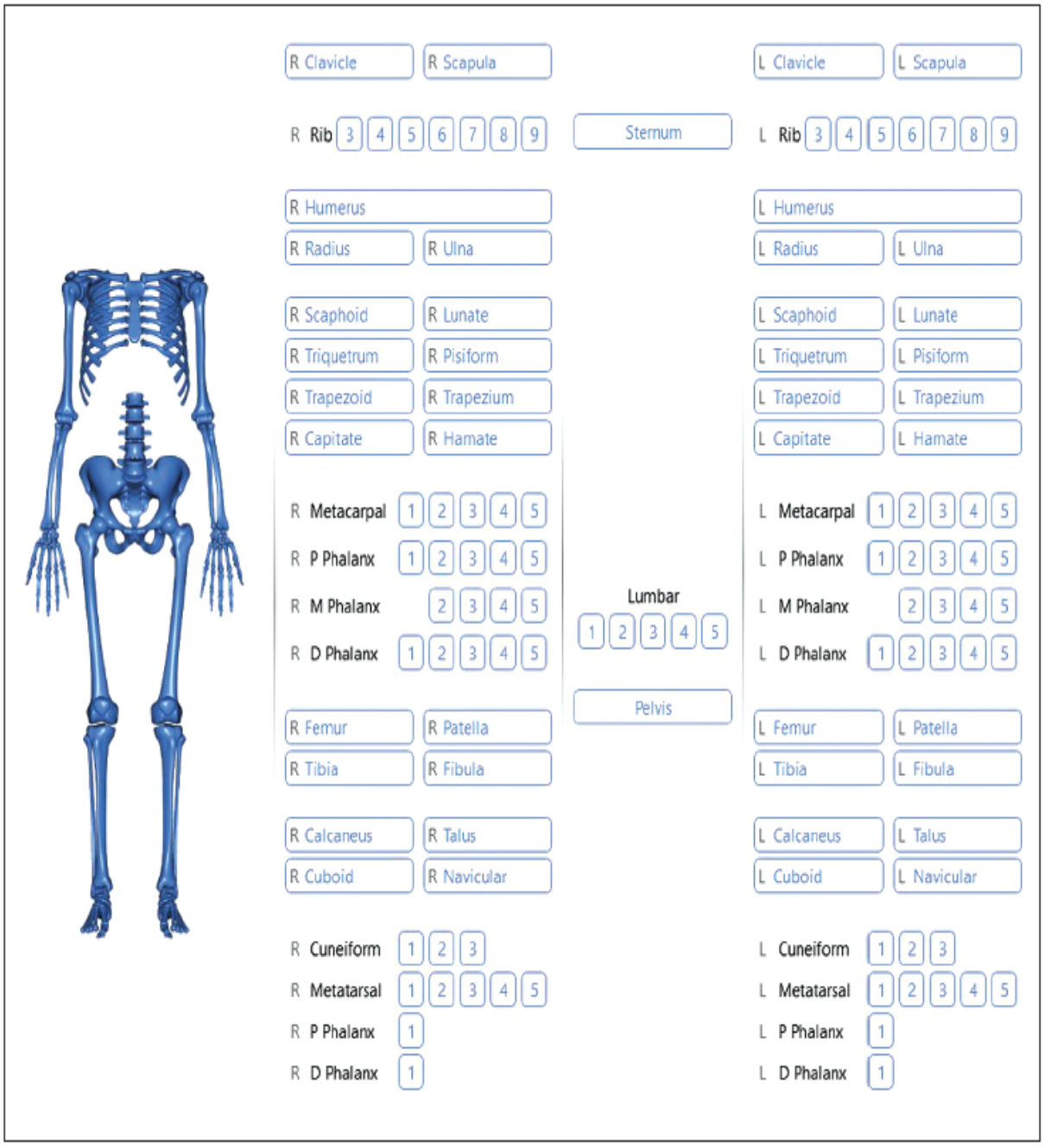


Figure 1.11: SOMA Interface

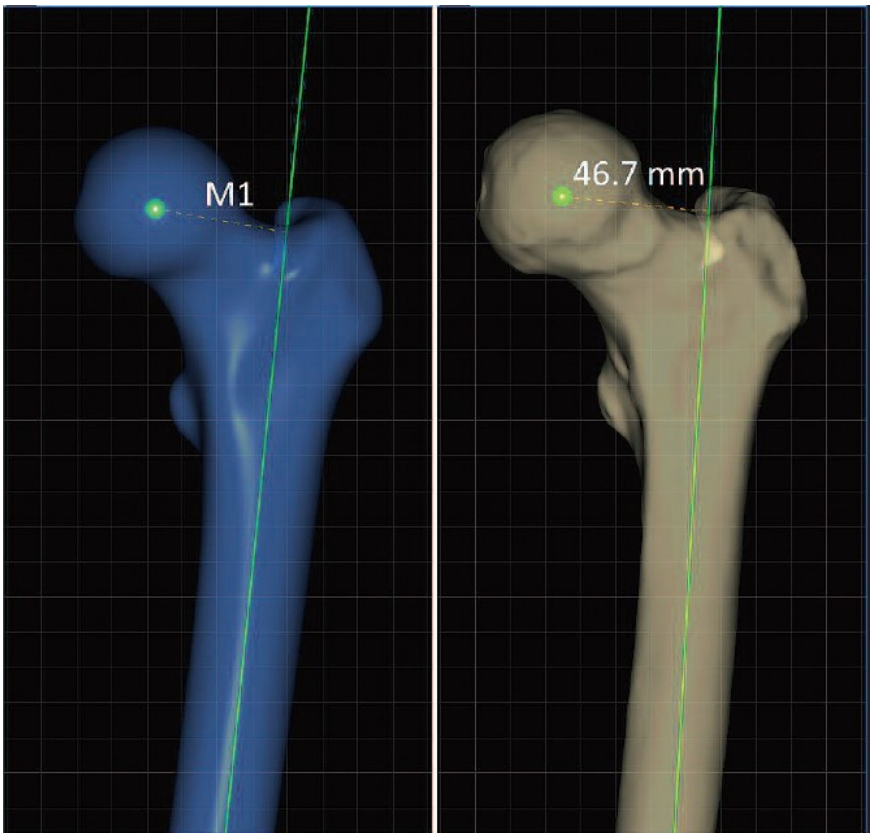


Figure 1.12: SOMA anatomical tool showing measurement of length from femoral head to anatomical axis

Chapter 2
Literature Review

2.1 Literature Review

The literature review on the various revisions and hinge strategies has been carried out and briefly discussed in this chapter.

2.1.1 Literature Review on Survivorship

Atul F. Kamath et al. (2017) [7] performed their investigation on the major cause behind the revision after the total knee arthroplasty (TKA). The total sample size for this study was divided into two groups *viz.* revision of total knee arthroplasty (RTKA) and revision of total hip arthroplasty (RTHA) respectively. The sample sizes taken for RTKA and RTHA was 73,878 and 33,289, respectively. The age group of patients varied from <45 to 85+ years, the study showed that for population less than the age of 45 years the rate of revision for hip and knee is 6.9% and 3.2% respectively, for age group between 45-54 the rate revision for knee and hip is between 15.7% and 13.4% respectively. For age group between 55-64 the rate of revision for hip and knee is 23.1% and 28.8% respectively. And for age group above 84 years the rate of revision for hip and knee is 7.3% and 4%, respectively. The study specified that the revision rate with respect to female was 51.5% for RTHA and 50.1% for RTKA, while if men population is considered, it varies as 48.5% for RTHA and 49.95 for RTKA. The study was also specified as per the ethnicity as the white population's share for RTHA is 83.9% and for RTKA is 83.4% while the black has 9.4% for RTHA and 9.7% for RTKA. The Asian population contributes to 1.2% in RTHA and 1.1% in RTKA. The Study also diversified the cost of surgery as Medicare cost share is 62% in RTHA and 59.8% in RTKA. Private hospitals charges 27.2% for RTHA and 29.9% for RTKA. Also, if the hospital type is Rural, then the cost share for RTHA is 6.6% and for RTKA is 9.2%, while the Urban hospital cost share is 36% in case of RTHA and 39.4% for RTKA. The study concluded that the major reason behind the revision comprises of dislocation of the implant from the primary surgery which causes

periprosthetic infection, mechanical loosening, implant failure, surface wear along with some of the other causes behind the revision case as can be seen from figure 2.1.

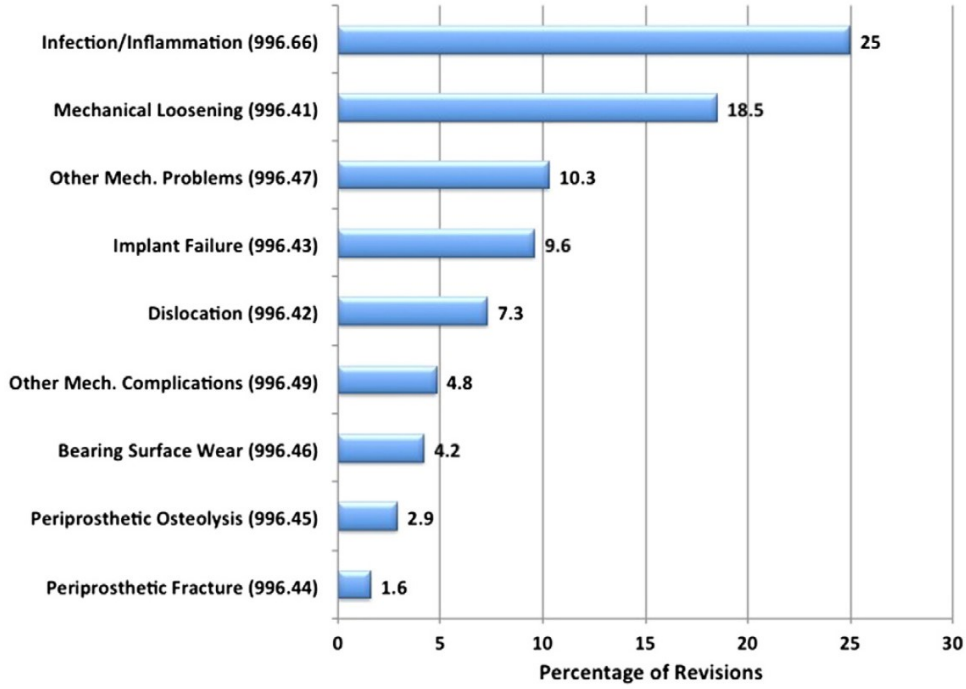
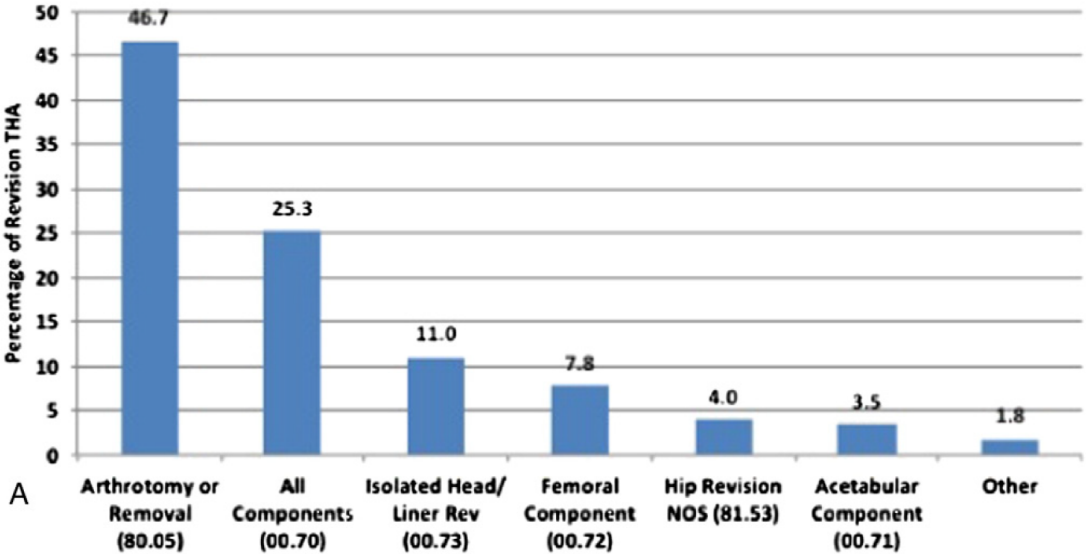


Figure 2.1: Causes of revision [7].

The study was further extended to find the procedure being carried out for replacement after the infection damaged it. Figure 2.2 describes the different component being affected due to periprosthetic infection for TKA and THA.



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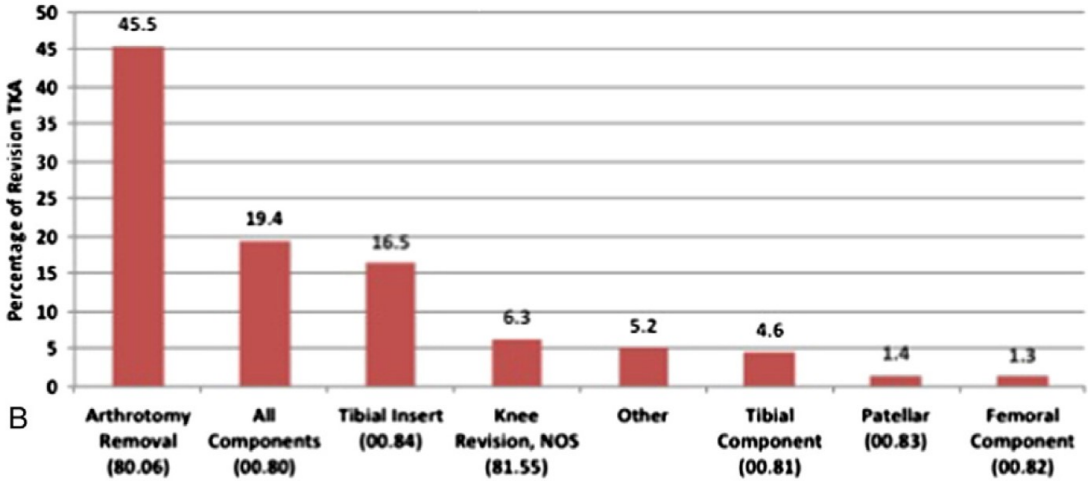


Figure 2.2: (A) Revision THA procedures for PJI. (B) Revision TKA procedures for PJI [7].

Joshua K. L. et al. (2013) [8] investigated a special case where the hinge mechanism failure (Zimmer) was registered. The case study included 72 years old patient (male) who underwent multiple knee surgeries due to implant loosening, fracture and significant rate of osteolysis. From another study carried out by Ayers et al. [9] X-ray can be seen in Fig. 2.3 showing recurvatum deformity, an imbalance due to soft tissue damage.

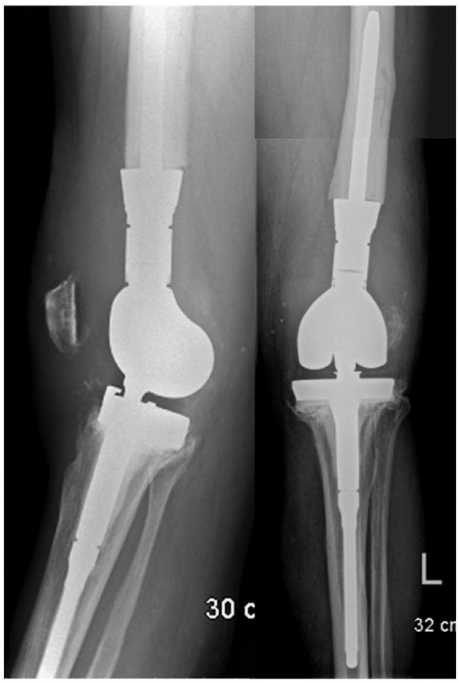


Figure 2.3: X-rays reflecting the recurvatum deformity [8].

The problem identified in this case study was that the polyethylene inserts which is placed in between the metallic femoral component and the post is not strong enough to defend the forces across it which leads to the deformation. Label A in figure 2.4 shows the picture of the knee in extension where the engagement of post with roof of the notch can be seen from the highlighted circles, while label B shows retrieved poly inserts.

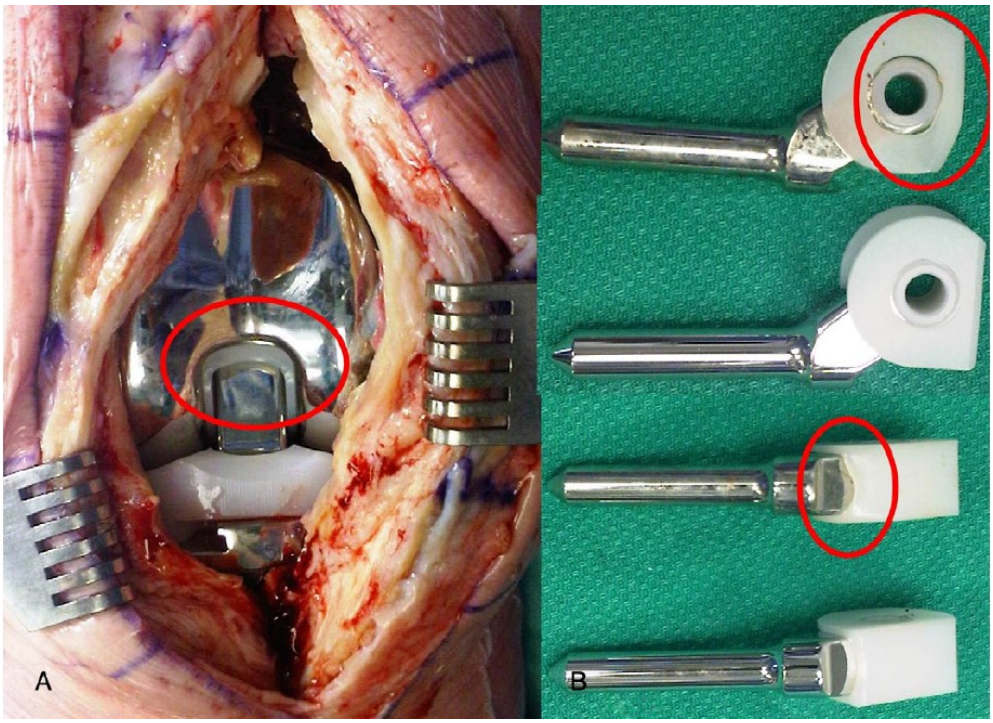


Figure 2.4: (A) Intraoperative photograph of the knee in extension. Red circle demonstrates metal post engaging the roof of the notch where the poly insert is being deformed. (B) Retrieved poly insert and hinge showing deformation of poly (red circles)[8].

Daniel R.P. Neumann et al. (2012) [10] performed a study which aimed at outcomes of salvage knee revision (figure 2.5 and table 2.2). The sample size taken was 24 and the time considered for follow-up was taken as 36 months. The evaluation criteria for the study were knee score and functional score. The study first identified the reason which could lead to an unsuccessful revision which came out to be collateral ligaments instability, loosening and infection [11-13].

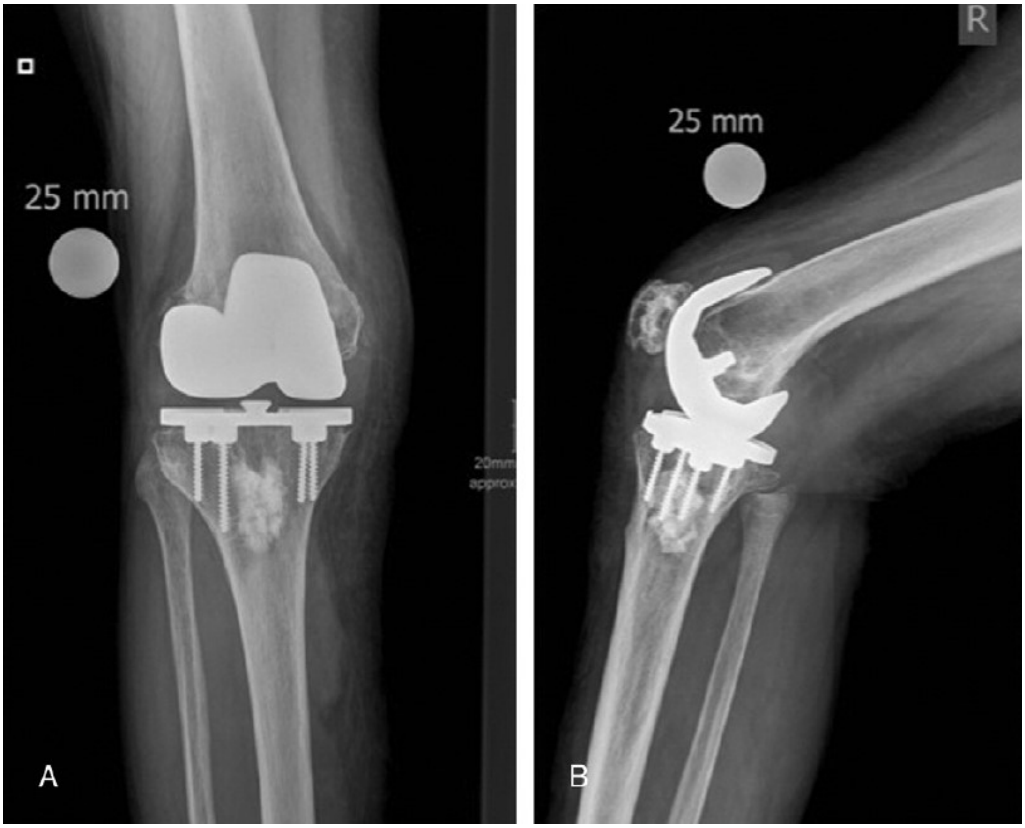


Figure 2.5: A and B, Anterior posterior and lateral radiographs of the right knee [10].

Table 2.1: Overall Total Knee Revisions [10].

Constraint	Cases	Percentage	Tibial Stem	Femoral Stem
Rotating hinge knee	24	19.5%	100%	100%
Posterior stabilized	99	80.5%	100%	55%

The study concluded that in overall the revision knee surgery improved the functioning of knee (functional arc) and the knee score went up from 25 points to 91 while the functional scores varied from 35 to 85.

E. R. Ahlmann et al. (2006) [15] investigated the survivorship of the limb i.e. femur, tibia after 5 years and 10 years. The study was first conducted for neoplastic disease and it included 211 patients (Table 2.2). The total percentage for the implant survivorship is 78 % after 5 years and 60% after 10 years of implantation and survivorship of the limb was found to be 97.6% (Fig. 2.6).

The study founded that the total population for the metastatic disease is 86 in number out of which 12 were alive and 74 cases were dead, and the diagnosis included 72 patients for the proximal femur and 10 patients for distal femur, while there was none for the proximal tibia, approximately 4 patients was there for total femur diagnosis. The case for isteosarcoma included 42 patients, out of which 35 were alive and 7 are dead, the cases for proximal femur included 6 patients and distal femur was 29. While the cases for proximal tibia was 6, and for total femur is 1. The category of giant cell tumor included 31 patients out of which 30 were alive and 1 case was dead, it included 3 proximal femur cases and 17 distal femur cases, while there was no case with total femur and in case of proximal tibia there was 11 patients. In Chondrosarcoma the total number of patients was 14 out of which 8 were alive and 6 were already dead, the cases for proximal femur, distal femur was 5 and 6 respectively while there was no case for total femur and proximal tibia included 3 patients. The hemangiopericytoma category included a total of 7 patients out of which 5 were alive and 2 were dead, the cases for proximal femur included 5 patients while for distal femur the total number of patients was 4 and for total femur it was none. The cases for proximal tibia included 1 patient. The category of malignant fibrous histiocytoma included a total of 6 patients out of which 5 were alive while 1 was dead, and the cases for proximal femur included none of the patient while for distal femur the total number of patients was 3 and none patient for the total femur. The total number of patients for proximal tibia was 3. The category for multiple myeloma included 6 patients out of which 1 was alive and rest of 5 were dead, the cases for proximal femur and distal femur included 4 and 1 patient respectively, while there was 1 patient for total femur. There was no patient in case of the proximal tibia. Figure 2.6 explains the relationship of survivorship with respect to time in months, and it can be depicted from the figure that the implants success rate decreases for the older age patients with multiple diseases, and with time the implant also wears out.

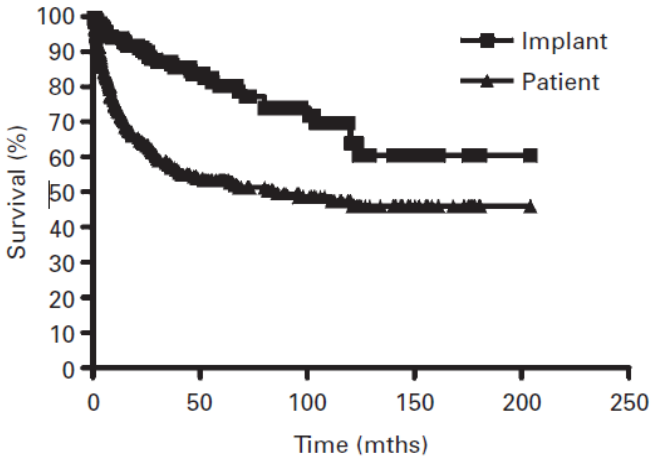


Figure 2.6: Survivorship Curve for the lower limb [15].

Michael Mason et al. (2006) [16] studied the effect of the joint line (JL) on the post-operative condition of the patient. The study firstly decided four primary landmarks from where the displacement of the joint line was taken namely medial femoral epicondyle (ME), fibular head (FH), tibial tubercle (TT) and the inferior pole of the patella (IPP). The motivation behind starting this study was the previous study results and cadaver studies carried out by Cummings et al. [17] which suggested an increase in the patellofemoral forces leading to deformation and displacement [18,19] and loosening of the collaterals [20]. The instrument used for measurement was femoral cutting guide for ME to JL and Joint line scale for TT and IPP (see Fig. 2.7). Figure 2.8 shows the respective instruments while taking the measurement.

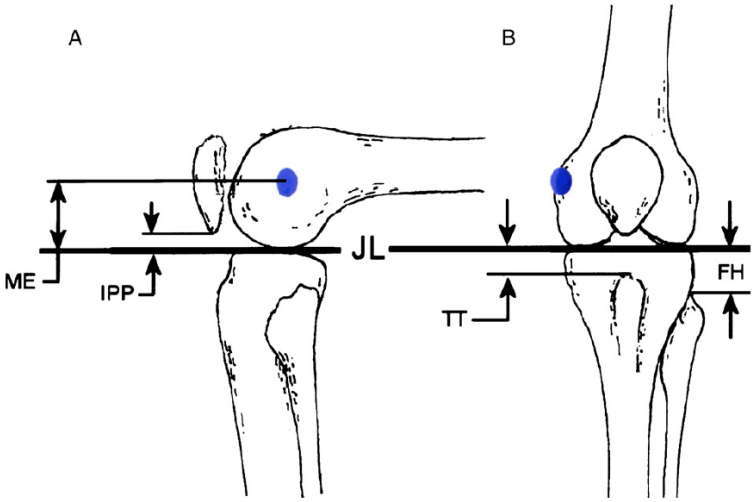


Figure 2.7: The cadaver knee in (A) 908 of flexion when measuring the distances of the ME and IPP to the JL, and (B) full extension when measuring the distance of the TT and FH to the JL [16].

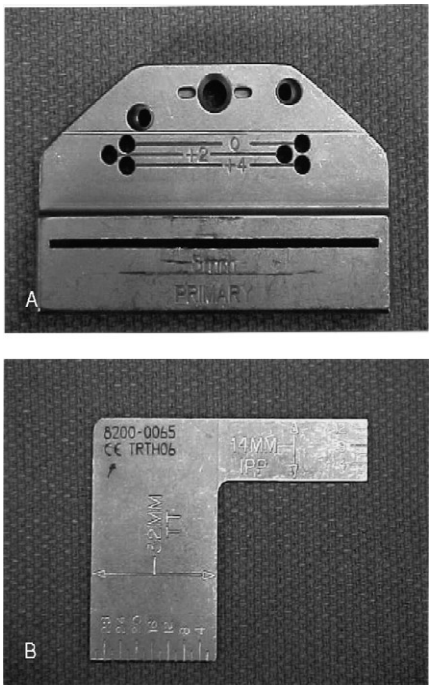


Figure 2.8: (A) Modified distal femoral cutting guide. (B) JL scale [16].

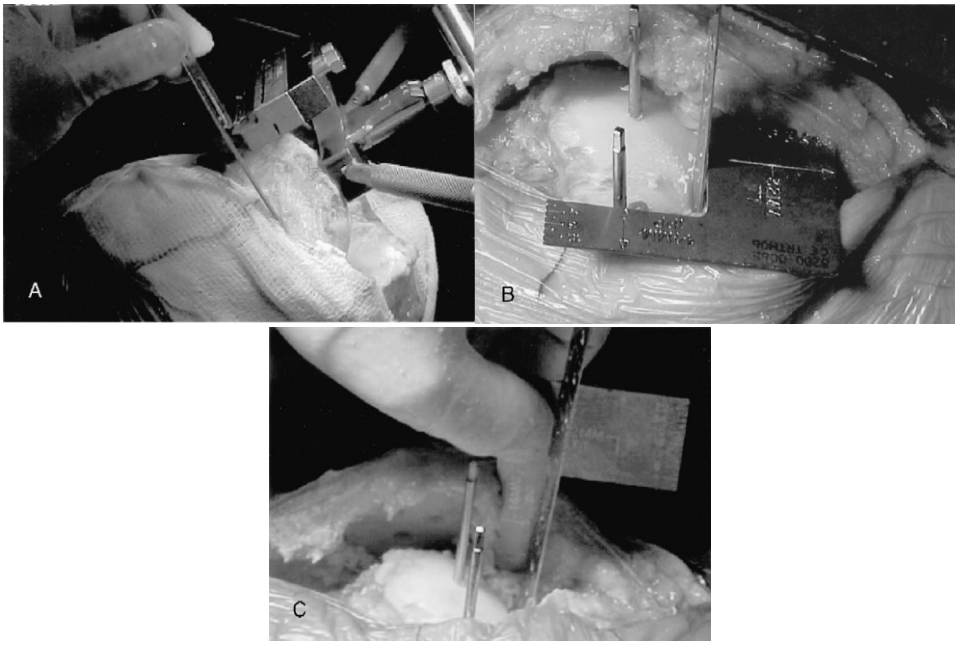


Figure 2.9: (A) Positioning the JL instruments during the validation study. Note that the distance between the scribe line and the resection slot takes the thickness of the implant into account for (B) TT, and (C) IPP [16].

The results are represented in the Table 2.3 from all the references to the joint line. It can be concluded from the tabular data and Fig. 2.10 that the best reference from the selected references to measure the joint line is Medial Epicondylar and it's coincident

with the trans epicondylar axis (TEA) [21] so it's more accurate and precise to take measurements from ME.

Table 2.2: Estimated variation of each JL method [16].

Parameter	Mean (mm)	CV Cadaver (%)	CV Surgeon (%)	CV Error within surgery (%)	CV Total (%)
IPP to JL	13.71	18.80	26.14	12.21	34.43
ME to JL	28.37	0	12.21	6.33	13.75
TT to JL (TT)	32.36	19.29	15.53	4.30	25.14
FH to JL	27.36	11.19	23.52	6.40	26.82

The figure 2.10 below shows the relationship of population with respect to the implant size, as it can be depicted from the figure that the implant size above 5 is the most widely used one while the sizes between 4 and 5 are least common. the ME, IPP and TT represents the medial femoral epicondyle, inferior pole of the patella and tibial tubercle respectively.

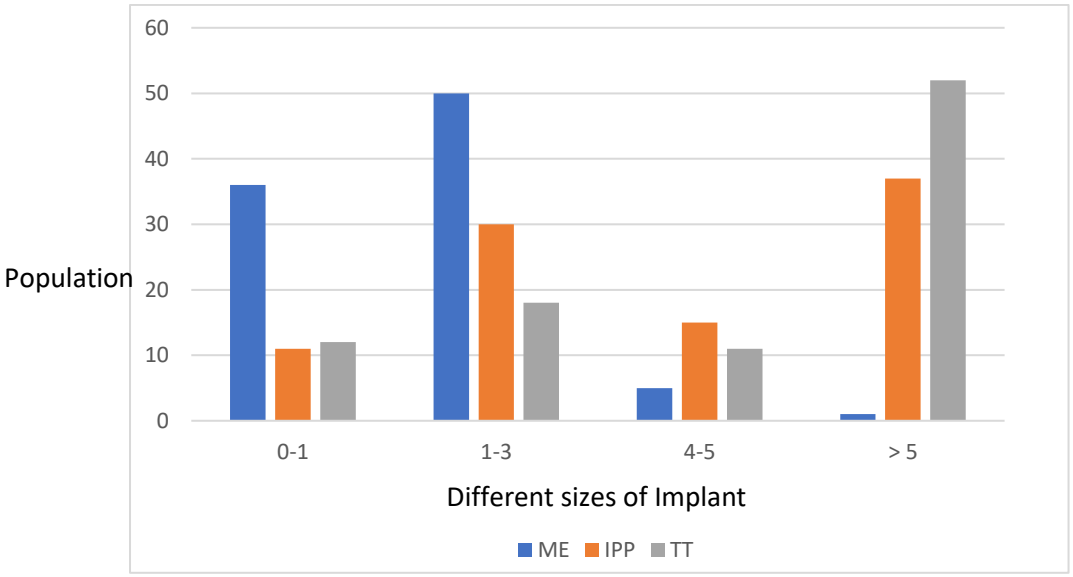


Figure 2.10: Range of accuracy for locating joint line [16].

2.1.2 Literature Review on Implant and Instrument Design

Joerg Friesenbichler et al. (2013) [22] investigated the stability of the hinge construct with respect to different components. Limb salvage surgery is complicated as compared to primary surgery. Also, the soft tissues are infected and do not play any role in stabilizing the knee [23-25]. The appropriate size of the implant required which can restrict bone loss [26-30].

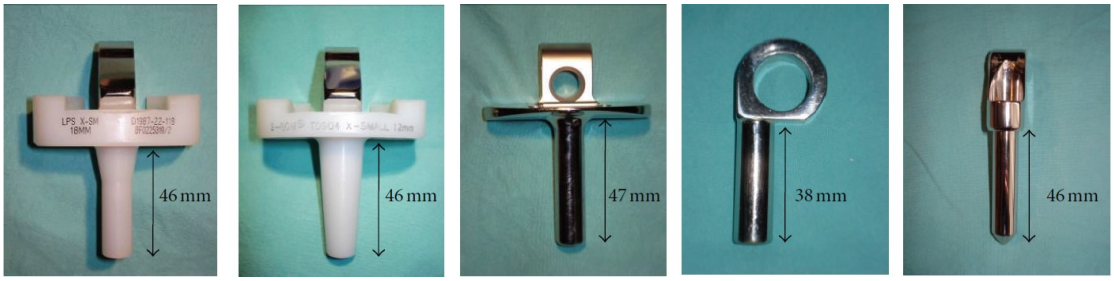


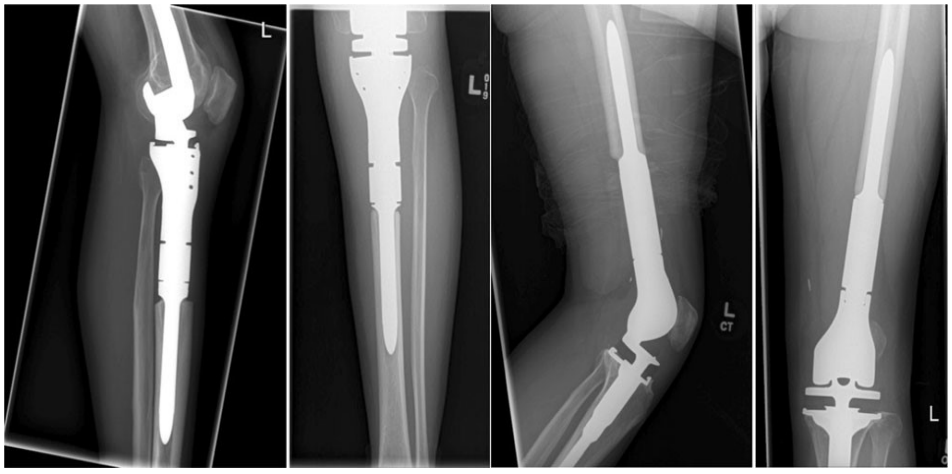
Figure 2.11: The length and the shape of the tested polyethylene rotational stems of five rotating hinge prostheses used for the biomechanical analysis: LPS/M.B.T., S-ROM Noiles, GMRS, RT-Plus, and NexGen [22]

Table 2.3: Specifications of the polyethylene inlay of six tested rotating hinge knee devices [22].

Manufacturer	Stem length (mm)	Stem taper (deg)	Polyethylene inlay (mm)
Stryker-GMRS	47	0	10
DuPuy-LPS/M.B.T	46	0	-
Dupuy-S.ROM Noiles	46	5	-
PLUS, Orthopedics-RT-Plus	38	0	8
Zimmer-NexGen	46	0	12
Zimmer-NexGen	60	0	26

The rotational stability is the most important concern for a hinge construct and for stability soft tissues play very important role. This is also explained by Kabo et al. [31] and Harrison Jr. et al. [32]. The conclusion is that with shorter and tapered pegs the rotating hinge construct have more stability, while the long and cylindrical pegs can be helpful for patients having higher percentage of bone loss. Table 2.4 shows the comparative study of Stryker's stem length, stem taper and polyethylene inlay with competitors like Dupuy, Zimmer.

Patrick W.O' Donnell et al. (2013) [33] carried out the study which aimed at to inspect the functioning of the GMRS non-fluted diaphyseal press fit stem for tumor cases. The study involved 53 patients and the number of implants used were 54. In present scenario the oncology cases are operative with the help of chemotherapy and limb salvage surgery [34, 35]. A comparative study was carried out in which the patients were divided in two groups (Fig. 2.12). Group A patients were operated using the Stryker restoration stem while group B patients were operated using GMRS non-fluted stem.



A **B**

Figure 2.12: Radiographs of the inserted stem as part of knee reconstruction (A) the non-fluted stem inserted after proximal tibial resection, (B) the custom non-fluted stem inserted after distal femoral resection [33].

The follow-up period for evaluation of both stems was 22 months. The results obtained from both the groups was that many of Stryker restoration stems were found to be fractured while there was no mechanical fractured registered with GMRS non-fluted stems. The study included history of implants for tibial and femoral components. The number of proximal tibial implants were 13 while for proximal femur the number of implants were 6 in number and for distal femur the implanted number is 35 which is the highest of all three.

Samuel N. Crosby et al. (2011) [36] did a comparative study between metal backed and all poly tibia in the case of mega-prostheses. The earlier trend was to use metal backed tibia (MBT) and not All-poly tibia (APT). The common reason for the failure of the implant failure includes loosening, infection [37-39]. The study included 72 sample size out of which MBT was 42 and APT was 30 (Table 2.7). The study included a minimum

follow-up of 23 months and regular X-rays were recorded for both the categories. Of the MBT, there were three fractured registered while with respect to APT two fractures were registered. Average time for the failure was recorded as 4.3 months.

The study included survey for the APT and MBT cases. The sample size for men and women in case of APT was 15 each and in case of the MBT the number of women is 26 while number of men was 16. The population selected consist of varying diversity with 25 white, 4 African and 1 Hispanic in case of APT, while MBT included 36 white and 6 African-American. The population was further subdivided in terms of average age, as in APT case it came out to be 49.4 while for MBT it was 49.7. The average weight is also considered to be one of criteria for subdivision of the population, in case of APT it was 77.7 while for MBT it was 84.7. The BMI was also calculated for both the categories. For APT case the BMI came out to be 26.3 for the age group 17-38, while for MBT the BMI comes out to be 30.2 for the age group 14-54. Figure 2.13 shows the radiograph of the fractured tibial bone which was operated 2 months ago.

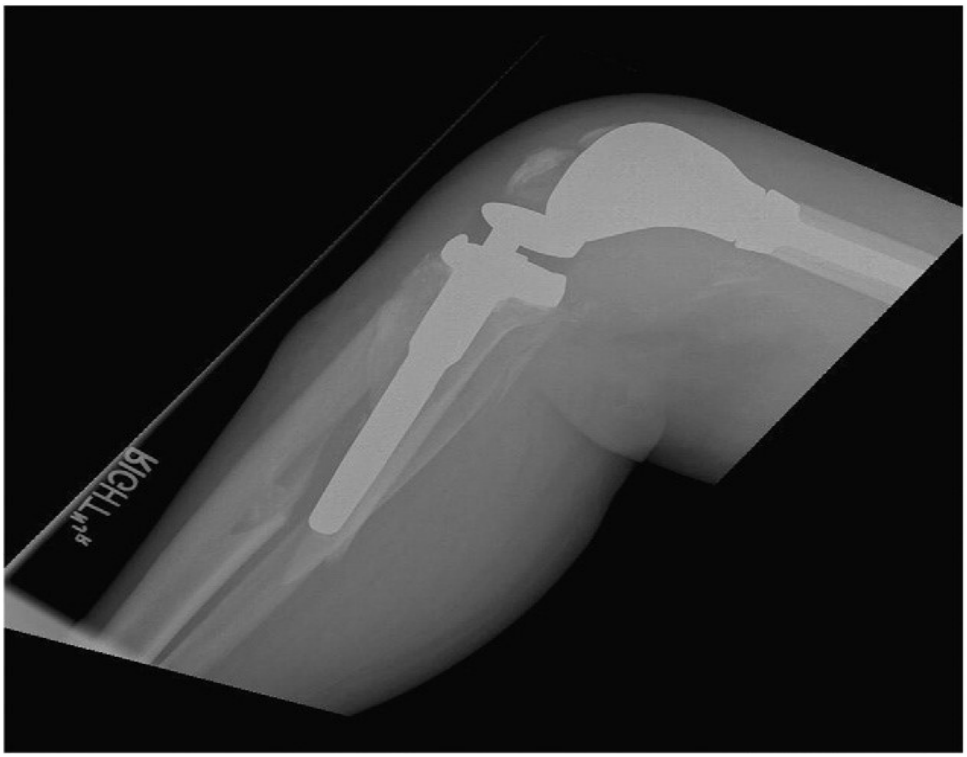


Figure 2.13: Radiograph of periprosthetic tibia fracture that occurred 2 months after implantation [36].

The main cause behind the failure of the tibia was found to be rotating tibial component (Fig. 2.13). This study concluded that there was no technical advantage of one over another (APT and MBT). Hence the choice really depends upon the cost offering benefits.

Ran Schwarzkopf et al. (2011) [40] investigated that in the recent years there has been an increase in the number of the failure post revision surgeries [41]. So, they conducted an experiment with the hinge construct.

Case 1(Fig. 2.14)**:** The case study involved 58-year-old male. The subject has undergone TKA. After some time, he felt decrease/inefficient in the range of motion, so some X-rays are performed and the reason behind the decrease range of motion came out to be infection. So, the subject needed to undergo revision. After couple of months hinge construct failure was registered and the reason found to be failure of the insert.

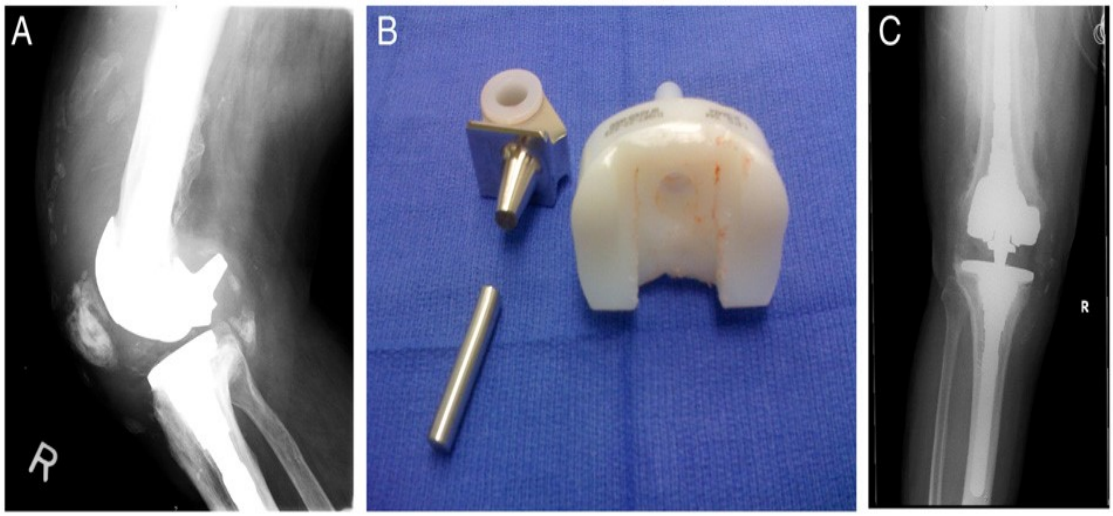


Figure 2.14: (A) a lateral radiograph of the right knee shows a fractured rotating hinge TKA. (B) Explanted broken prosthesis showing a fractured stem of the tibial insert. (C) an anteroposterior radiograph of the right knee status post revision TKA with a rotating hinge prosthesis [40].

Case 2 (Fig. 2.15)**:** The case study involved 65-year-old female. The patient experienced instability in the collateral ligaments while walking after 2-3 years from TKA. The revision of the subject was done, and it was registered that the joint line was elevated 9 mm, the hinge inserts failed and the component which fractured was found to be hinge insert.

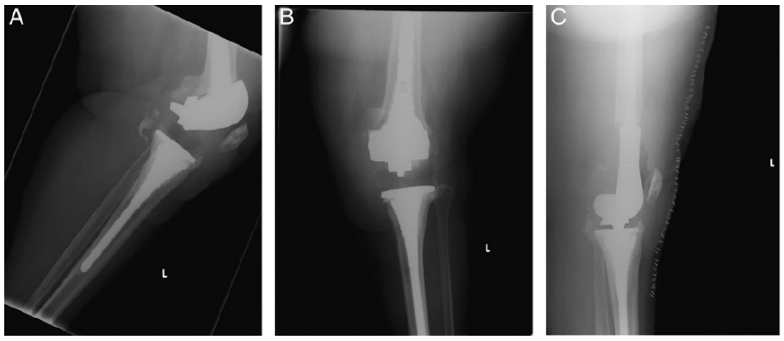


Figure 2.15: (A) Lateral radiograph of the left knee shows a fractured rotating hinge TKA. (B) Anteroposterior radiograph of the left knee shows a fractured rotating hinge TKA. (C) Lateral radiograph of the left knee status post-revision TKA with a distal femoral–replacing implant [40].

Both the cases were studied closely, and it was concluded that the main cause behind failure of the hinge insert was due to excessive cantilever bending.

William G. Ward et al. (2003) [42] studied how length and taper of knee implant stem can affect the dislocation of the whole construct. The reason behind loosing stability of the construct can be due to tumor resection, multiple knee replacement, trauma, deformity or surgical reconstruction [43-47]. So, the samples size taken for the study was two and seven manufacturers were asked to make them and the maximum dislocation was measured by considering the degree of rotation of stem, as shown in Fig. 2.16. Fig 2.16 illustrates the minimal varus-valgus toggle or tilt associated with a long stem with a minimal taper compared with the increased varus-valgus toggle or tilt associated with a short, more tapered stem under similar conditions (25 mm) of joint distraction.

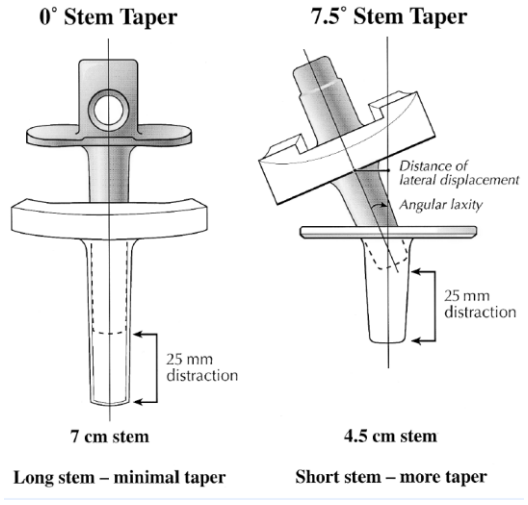


Figure 2.16: Varus-valgus toggle or tilt associated with stem under similar conditions of joint distraction [42].

Table 2.4: Degree of tilt according to the amount of distraction [42].

	Tilt (deg)						
Distraction (mm)	**Howmedica**	**Intermedics/ Sulzer Medica**	**Techmedica**	**Wright Medical Technology**	**Biomet (12 mm Polyethylene Tray)**	**Biomet (22 mm Polyethylene Tray)**	**S-ROM**
5	0.8	0.9	1.1	0	0.6	1.2	1.5
10	0.9	1.9	2.1	0.5	1.0	0.7	3.2
15	1.3	2.8	2.8	0.5	1.1	1.0	5.5
20	1.8	4.3	4.0	0.5	1.1	1.2	8.6
25	2.1	5.7	5.3	0.5	1.1	1.9	14.3
30	3.3	8.2	7.1	0.7	1.1	2.9	
35	3.8	11.1	9.9	1.5	1.4		
40	5.0	16.1	14.4	4.0	2.1		
45	7.4						
50	14.0						

Based on these results and considering the tilt measured from different manufacturer's the new design parameter included taper and length of the stem to primary focus. Table above explains the variation in degree of tilt respective to products offered by the competitors, it can be depicted that for distraction 5 mm the highest tilt occurred in S-ROM and for 40 mm distraction the biggest contributor is intermedics. While howmedica is the only one to have a tilt of 50 mm.

O. Norman et al. (1983) [48] investigated the vertical position (VP) of patella, the constituting factors in the research are length of the patella ligament (LL) and geometry of patella, femoral condylar plane (CP), body-height, articulating surface of patella length (PA). The study included 91 patients out of which 57 were males and 34 were females.

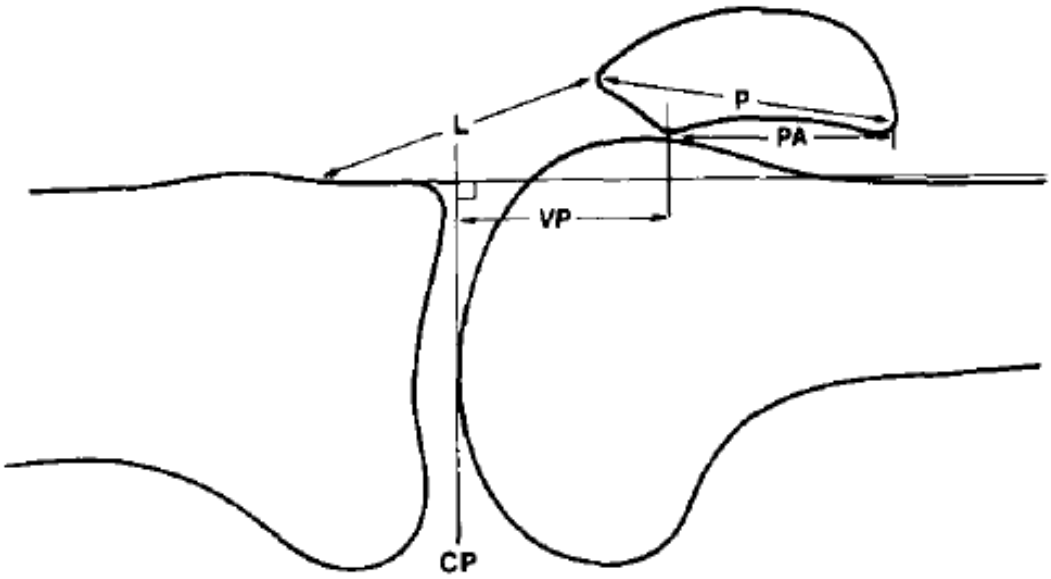


Figure 2.17: Studied parameters affecting the vertical position of the patella [48].

The Measured parameters were formulated from the derived formula:

$$\frac{\text{Measured length (cm)}}{\text{Body Height}} \times 10 = \text{Relative length}$$

Table 2.5 below represents the survey for 34 females and 34 males with respect to different parameters calculation using above formula, the parameters included vertical position of patella, ligament deviation from mean, patella and articular surface of patella. It was concluded that the difference in standard deviation for male and female population in case of vertical position of patella and ligament is not significant.

Table 2.5: Studied parameter in relation to the body length (males n=57, females n=34) [48].

Parameters	Sex	mean	Range	± Standard deviation	Difference
Vertical position of patella	M F	0.21 0.21	0.17-0.26 0.17-0.26	0.02 0.02	Not Significant
Ligament	M F	0.28 0.28	0.23-0.34 0.24-0.34	0.03 0.03	Not Significant
Patella	M F	0.29 0.26	0.25-0.33 0.23-0.30	0.02 0.02	***
Articular surface of patella	M F	0.21 0.20	0.17-0.24 0.17-0.23	0.02 0.01	*

Blacburn and Peel (1980) [49] in their study shows that there was no difference between different sexes as far as the length of the articulating surface and patella height was taken into consideration. Outer bridge [50] concluded that there is no relation between patella ligament and body height. This Study confirmed the results obtained by Insall and Salvati [51], Lancourt and Cristini [52], Marks and Bentley [53]. That the stable knee joints the ratio of length of patella ligament and length of patella is approximately one.

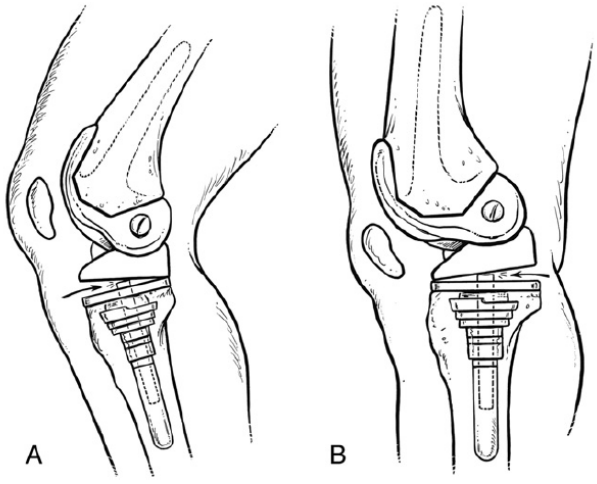


Figure 2.18: (A) and (B), Diagram showing the non-rotatory motion and the cantilever effect that are predisposed to the prosthesis failure [49].

The hinge insert design was studied in detail and it was concluded that the first generation insert [54] included metal to metal movement which constrained the motion in single plane which resulted in early failure of the hinge construct. The second generation of hinge inserts [55] gives the rotating degree of freedom. The third-generation hinge inserts provide the torsional stability along with greater range of motion by having diaphyseal engagement.

2.2 Summary of the Literature Review:

From the literature review presented above it has been found that

- Some of the authors worked in identifying the cause behind the failure of the hinge construct, considering various aspects such as the material, the geometry, stem geometry, etc. Different approaches have been opted to evaluate the result such as comparative study between two products from different companies. **(Atul F. Kamath et al. (2017), Joerg friesenbichler et al. (2013), E. R. Ahlmann et al. (2006), Samuel N. Crosby et al. (2011), Joshua k. L. et al. (2013)).**
- Some of the authors have investigated the reason behind the early failure of the construct impacting the survivorship of the limb. The study used regular follow-up with the sample population for enough period and made use of the statistical tools to evaluate the data. (**E. R. Ahlmann et al. (2006), Michael Mason et al. (2006), William G. Ward et al. (2003)).**
- On the other hand, some of the authors did investigation with regards to the design of various components of the implants used in the revision surgeries and evaluated that the previous trends should be changed, many of the findings helped in changing the design of stem, taper in the bearing post, slope in the bumper etc**. (Patrick W.O' Donnell et al. (2013), Ran Schwarzkopf et al. (2011), Daniel R.P. Neumann et al. (2012)).**

Chapter 3

Research Gaps, Problem Formulation and Work Plan

This chapter highlights the various gaps in the existing literature work. Taking into consideration these gaps and the shortcomings in the existing system, problem formulation is established.

3.1 Gaps in Literature

As the Triathlon Limb Salvage program is an integration of four programs, so the objective is to fulfill the lacking needs in the integrating projects. Following gaps are identified from the literature

- MRH does not have a good history with regards to the patella tracking, there have been many complaints registered from patients as they feel “jerk” while sitting down and standing up or flexion and extension. This is one of the major drawbacks.
- Also, the design was having multiple radii i.e. having multiple center of rotation, which is why there is no smooth motion in the functional arc, because the range for one radius is covered the center of rotation changes and there is sudden shift which results in jerk.
- One of the major drawbacks in the previously existing projects is they are designed such that higher percentage of bone is removed from the patient since the sizes available for respective implant construct does not cover the entire population around the globe.
- One of the major drawbacks in the previous design also covers the inefficient keel profile, which is responsible for the loosening of the tibial component and hence disturbing the positioning of the whole hinge construct. This has been one of the major causes for failure post revision or hinge cases.
- The sizes which MRH is having are extra small, small, medium, large, and extra-large and there have been many complaints registered that these sizes do not cover the entire population.

3.2 Problem Formulation

Triathlon Limb Salvage project under consideration aims at improving the patella tracking and for doing so we are leveraging our legacy product Triathlon which has a long successful clinical history. The design will consist of single radius, i.e. the implant is going to have a single radius in the functional arc. Therefore, in TLS attempt will be made to come up with seven sizes which will be covering the entire population based on the systematic analysis using SOMA (Stryker orthopedics modelling and analytic). Utilizing the Stryker's SOMA database, attempt will be made to reduce the bone lose as compared to the previous systems.

3.3 Objectives

Based on the problem formulation efforts are made to satisfy the following mentioned objectives:

3.3.1 Design of TLS Universal Counter Wrench (Fig. 3.1): The challenge is to design an instrument which can hold triathlon baseplate (all sizes), TLS baseplate (all sizes), triathlon femoral component (all sizes), and can apply counter torque while final tightening of stem. The instrument should also have a feature which can unlock the offset adapter trial.

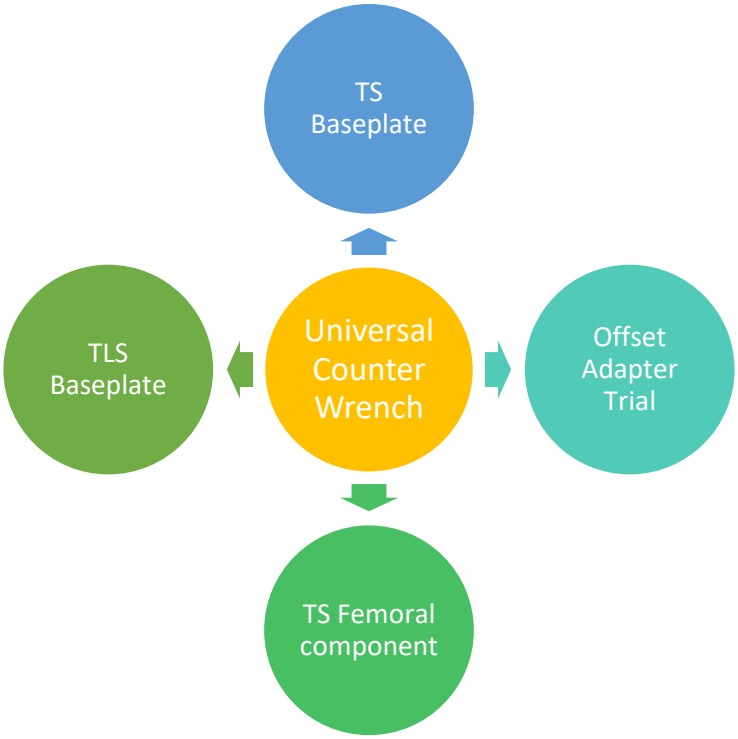


Figure 3.1: Universal Counter Wrench Compatibility

3.3.2 Design of Poly Sleeve/Filler Bushing Removal Tool (Fig. 3.2): The challenge is to design an instrument (metal) which can engage and pull out the poly-sleeve (plastic) in hinge case and filler bushing (metal) in intraoperative case. Poly Sleeve and filler bushing serve as the linkages between the baseplates and the femoral component.

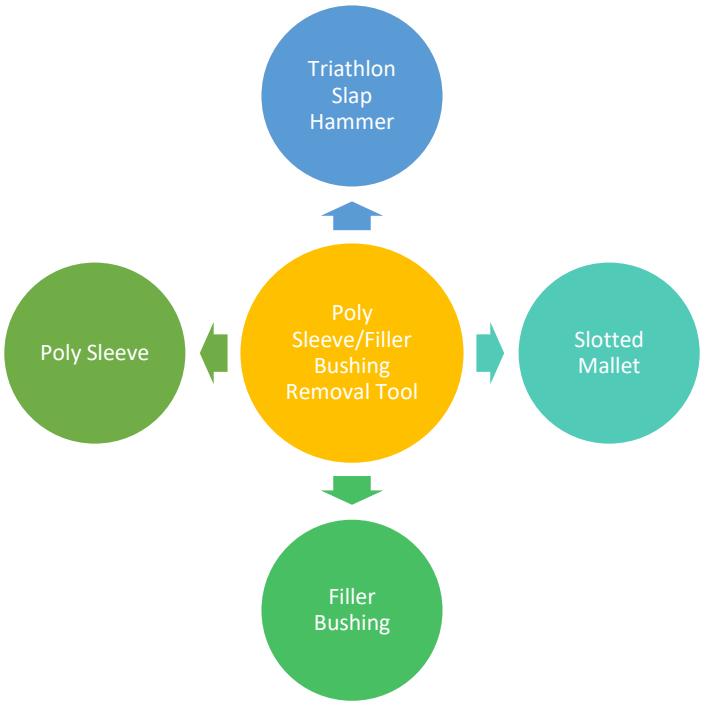


Figure 3.2: Poly Sleeve/ Filler Bushing Removal Tool Compatibility

3.4 Work Plan

To carry out the objectives of the project, work is carried out in following phases:

Phase 1: Selection of material for the instrument, Documenting the design need from surgeon and marketing

Phase 2: Design conceptualization, Design Analysis (Tolerance analysis/Testing)

Phase 3: Finalizing the Design Concept, Results and discussions

The flowchart below (Figure 3.3) describes in detail about the task to be performed in each phase.

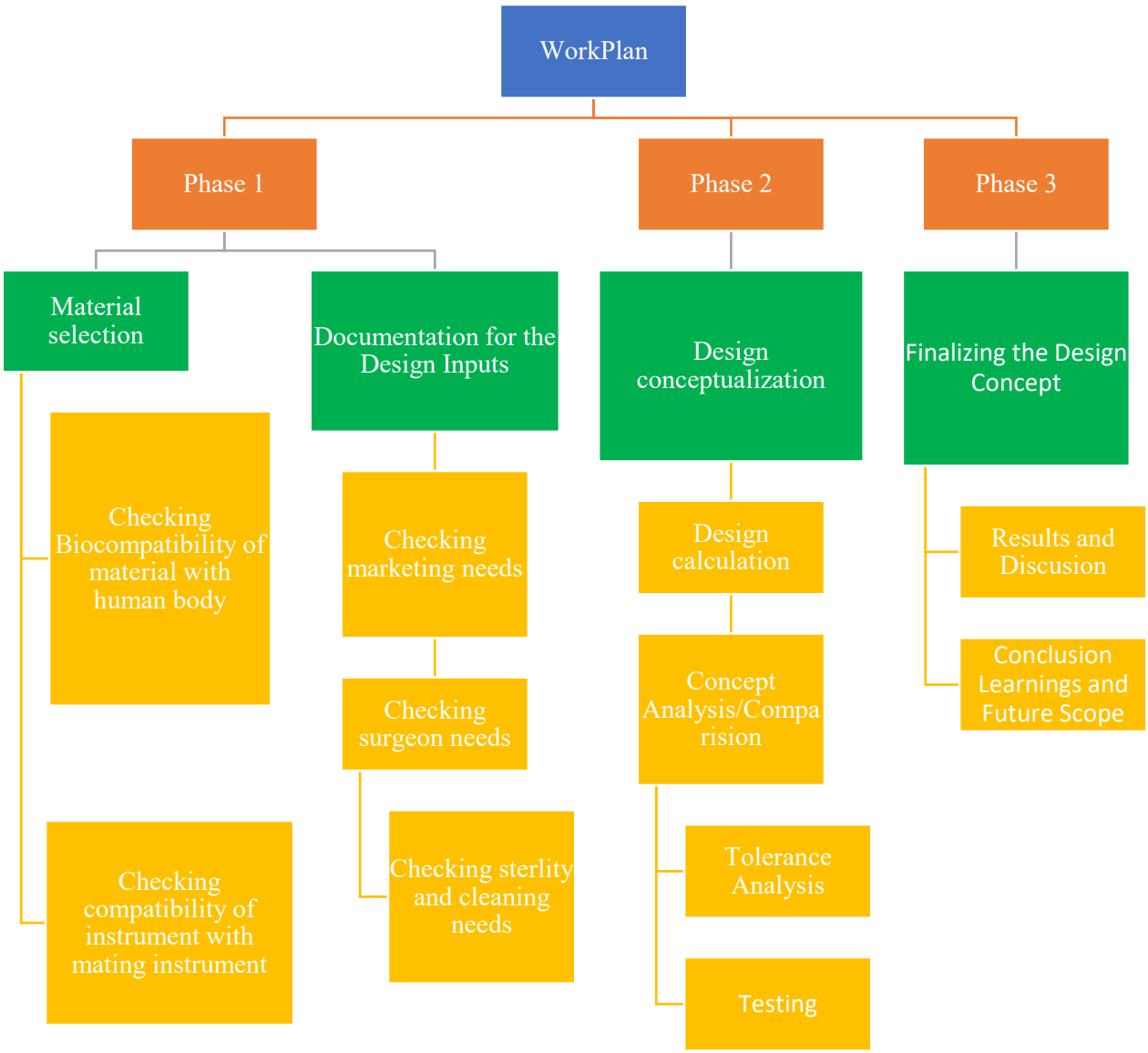


Figure 3.3: Flowchart of work plan

Chapter 4

Material Selection

4.1 Introduction

The selection of material plays very important role for the instrument, doesn't matter how good the design is, if the material is not up to the mark the design will fail. In the medical industry one of the most crucial factor while selecting the material is "biocompatibility", i.e. is the material compatible with the body or not. And if the material is biocompatible, the secondary check will be whether the instrument is compatible with the mating/engaging instrument and implants.

4.2 Selection of material

The selection of material requires a review of the material that are biocompatible with the human body. Such a combination of material system for orthopedics application is shown in Fig. 4.1.

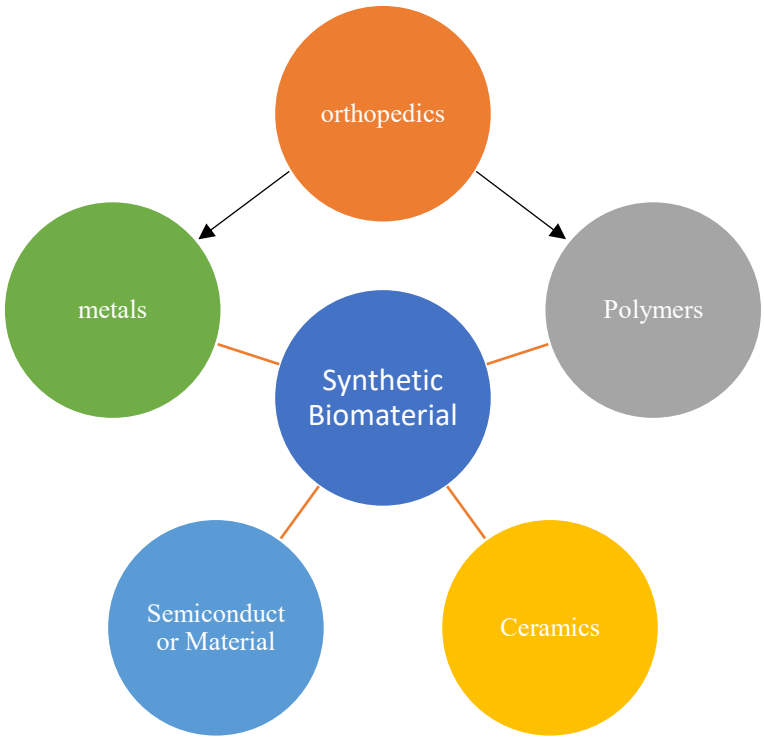


Figure 4.1: Types of biomaterial

The materials most often used in the orthopedics are metals and polymers. The notable characteristics of the material used with the human body are as follows:

- A chemical composition that should not have adverse reaction with the tissues. With respect to metals the required property is resistance against corrosion and with respect to polymers the required property is resistance to biological degradation.
- The material should have adequate strength to sustain the loads implied by the body on the implant.
- Material should have resistance against wear as it leads to debris generation.

The flowchart below (Fig. 4.2) explains in detail the properties that are required for the material to be used with the instruments and implants. Table 4.1 and 4.2 presents some of the widely used material systems for the application in the material industry.

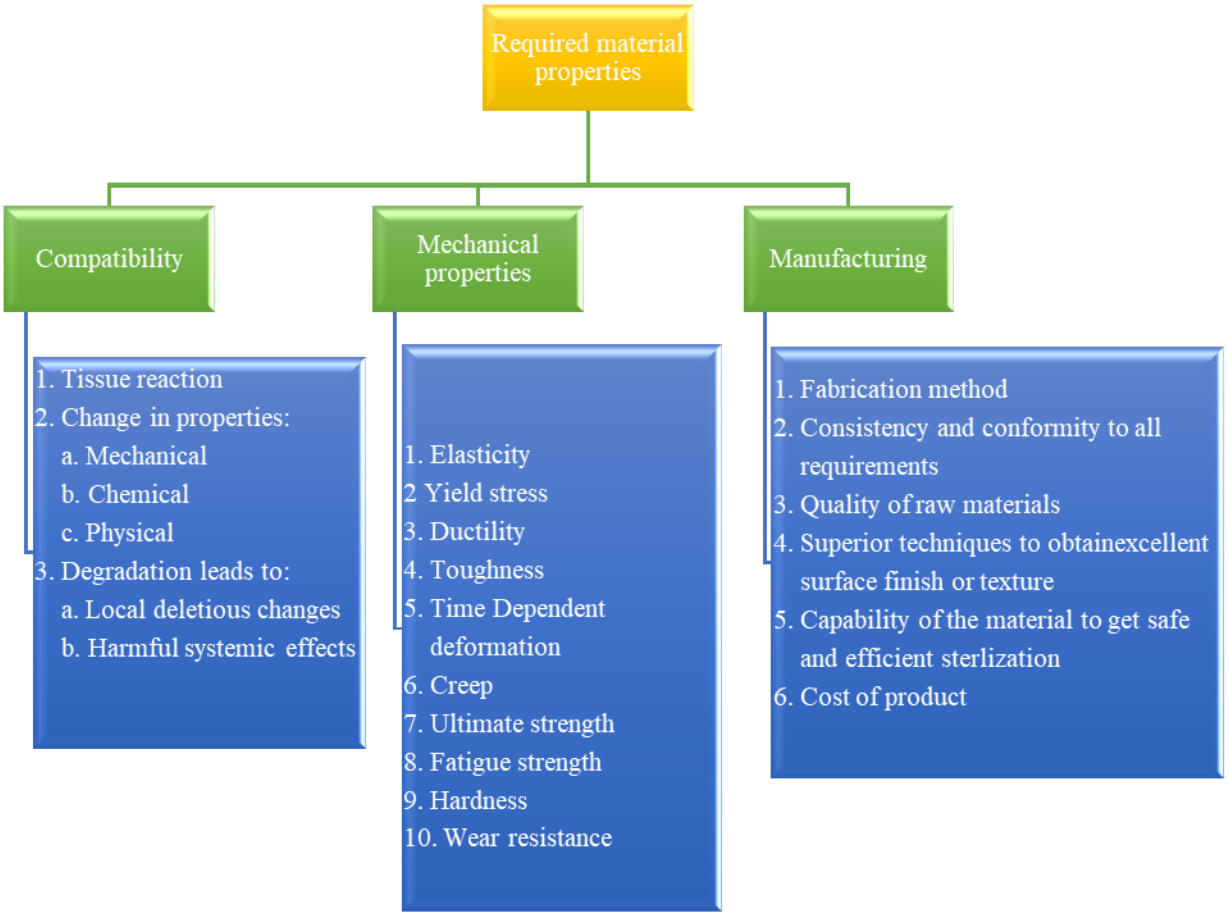


Figure 4.2: Flowchart of material properties [56]

Table 4.1: Examples of Metals and alloys used in medical industry [56].

Metal and alloys	Application
Stainless steel	Fracture fixation, stents, surgical instruments
CP-Ti, Ti-Al-V, Ti-Al-Nb, Ti-13Nb-13Zr, Ti-Mo-Zr, Ti-Mo-Zr-Fe	Bone and joint replacement, fracture fixation, dental implants, pacemaker encapsulation
CoCr-Mo, Cr-Ni-Cr-Mo	Bone and joint replacement, dental restorations, heart valves
Ni-Ti	Bone plates, stents, orthodontic wires
Gold Alloy	Dental restorations
Silver products	Antibacterial agents
Platinum and Pt-Ir	Electrodes
Hg-Ag-Sn amalgam	Dental restorations

Table 4.2: Examples of Polymers used in medical industry [56].

Polymers	Application
Polyethylene	Joint replacement
Polypropylene	Sutures
PET	Sutures, vascular prosthesis
Polyamides	Sutures
PTFE	Soft-tissue augmentation, vascular prostheses
Polyester	Vascular prostheses, drug delivery systems
Polyurethanes	Blood-contacting devices
PVC	Tubing
PMMA	Dental restorations, intraocular lenses, joint replacement (bone cements)
Silicones	Soft-tissue replacement, ophthalmology
Hydrogels	Ophthalmology, drug-delivery systems

4.3 Material for instrument 1: TLS Universal Counter Wrench

The TLS Universal counter wrench is required to hold and apply counter torque for TS baseplates, TLS baseplates and TS femoral component while tightening of the stem and should also contains a feature which can unlock the offset adapter trail. So, the material for the mating/ engaging instruments/implants are as follows (Fig.4.3):

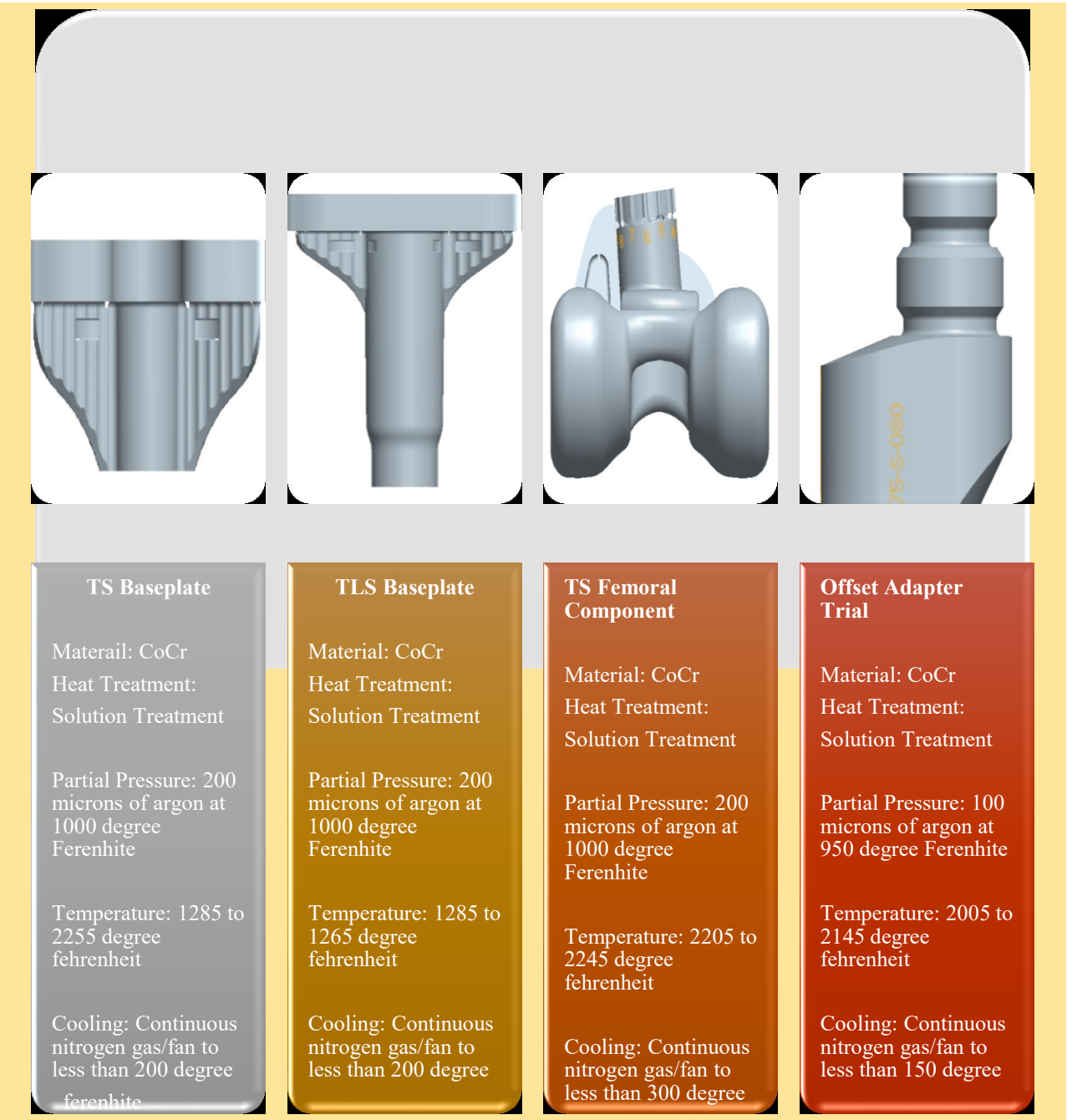


Figure 4.3: Material and heat treatment for mating/engaging components with TLS universal counter wrench

As the mating/engaging material is CoCr, the table below (Table 4.3) defines the required properties to be considered while selection of material for TLS universal counter wrench.

Table 4.3: CoCr mechanical property requirements [1].

Condition	Diameter or Thickness Inches [in] (mm)	Ultimate Tensile Strength min psi Min (MPa)	Yield Strength 0.2% offset min psi Min (MPa)	Elongation 2 in 2" or 4D or 4W Min (%)	Reduction of Area Min (%)	Typical Hardness HRC3
Annealed	All	130,000 (896)	75,000 (517)	20	20	25
Hot Worked	From 0.250 in to 4.00 in (6.35 to 101.6mm)	145,000 (1,000)	101,000 (696)	12	12	28
Warm Worked	From 0.250 in to 2.50 in (6.35 to 63.5 mm)	170,000 (1,172)	120,000 (827)	12	12	35

The material selection criteria for the TLS universal counter wrench is 17-4 PH Stainless Steel (SS) taken from the Predicate total stabilizer (TS) universal counter wrench, as the TS universal counter wrench has a successful clinical history and there are no major complaints registered to the present day as per design input output verification validation (DIOVV) – A00X3XX, design failure modes effects and criticality analysis (DFMECA) – A004XX, Risk I.D – A006XX.

Table 4.4: 17-4 SS mechanical property requirements [1].

Condition	Diameter or Thickness Inches [in] (mm)	Ultimate Tensile Strength min psi Min (Psi)	Yield Strength 0.2% offset min psi Min (Psi)	Elongation 2 in 2" or 4D or 4W Min (%)	Reduction of Area Min (%)	Typical Hardness HRC3
Annealed	All	190,000	170,000	5	25	40

4.4 Material for instrument 2: Poly Sleeve/Filler Bushing Removal Tool:

The Poly Sleeve/Filler Bushing Removal Tool is required to extract the filler bushing in the intraoperative case and poly sleeve in the hinge case. The instruments which are going to assist in the extraction of the implants are slotted mallet and triathlon slap hammer.

Figure 4.4: Material and heat treatment for mating/engaging components with poly sleeve/filler bushing removal tool.

The properties of CoCr and 17-4 SS can be taken from above Table 4.4. The material selected for the poly sleeve/filler bushing removal tool is more critical as in one case the instrument (metal) is going to extract the poly sleeve which is made up of plastic (polyethylene) while in another case the instrument (metal) have to extract filler bushing which is made up of CoCr, and on the other hand the extraction instruments which are going to assist in the extraction are slotted mallet which is made up of CoCr and triathlon slap hammer which is made up of 17-4 SS. Therefore, selection of material for the instrument becomes critical. The material taken into consideration for the implants and extraction instruments is 455 SS (Table 4.5) and its verification will be done by testing.

Table 4.5: 455 SS mechanical property requirements [1].

Condition	**Diameter or Thickness Inches [in] (mm)**	**Ultimate Tensile Strength Min (Psi)**	**Yield Strength 0.2% offset Min (Psi)**	**Elongation 2 in 2" or 4D or 4W Min (%)**	**Reduction of Area Min (%)**	**Typical Hardness HRC3**
Annealed	All	235,000	220,000	8	30	47

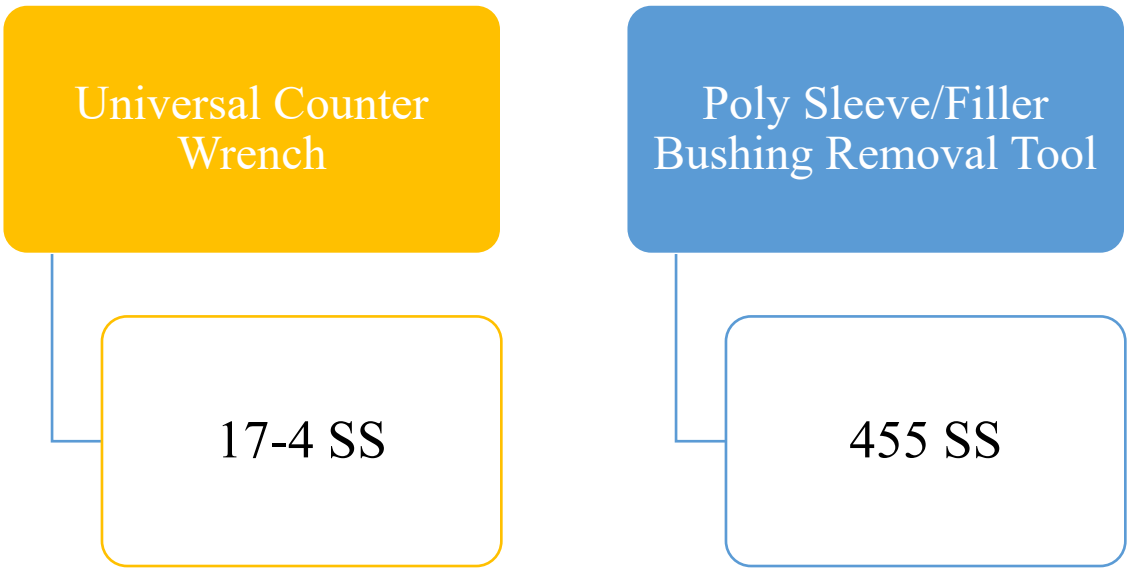


Figure 4.5: Final material selection for both the instruments

4.5 Chemical composition for the selected material

After the selection of material, the chemical composition is decided based on the desired mechanical properties. For selecting the appropriate combination, the standard charts as per the organization are followed. For 17-4 SS the selected chemical composition is as per HMS31XXX (Table 4.6) and for 455 SS the chemical composition is as per H455XX (Table 4.7).

Table 4.6: Chemical composition requirement for 17-4 SS [1]

Element	**Composition Range (Wt. %)**	**Product Analysis Tolerances (Tolerance over the maximum limit or under the minimum)**
Carbon (C)	0.07 max	+ 0.01
Manganese (Mn)	1 max	+ 0.03
Phosphorus (P)	0.040 max	+ 0.005
Sulfur (S)	0.030 max	+ 0.005
Silicon (Si)	1 max	+ 0.05
Chromium (Cr)	15 – 17.50	± 0.20
Nickel (Ni)	3 – 5	± 0.07
Copper (Cu)	3 – 5	± 0.15
Molybdenum (Mo)	0.50 max	---
Columbium (Cb) & Tantalum (Ta)	0.15 – 0.45	± 0.05
Iron (Fe)	Balance	---

Table 4.7: Chemical composition requirement for 455 SS [1].

Element	**Composition Range (Wt. %)**	**Product Analysis Tolerances (Tolerance over the maximum limit or under the minimum)**
Carbon (C)	0.07 max	+ 0.01
Manganese (Mn)	1 max	+ 0.03
Phosphorus (P)	0.040 max	+ 0.005
Sulfur (S)	0.030 max	+ 0.005
Silicon (Si)	1 max	+ 0.05
Chromium (Cr)	15 – 17.50	± 0.20
Nickel (Ni)	3 – 5	± 0.07
Copper (Cu)	3 – 5	± 0.15
Titanium (Ti)	0.8 – 1.40	1.50 – 1.80
Columbium (Cb) + Tantalum (Ta)	0.10 – 0.50	-
Molybdenum (Mo)	0.50	0.75 – 1.25
Nitrogen (N)	-	0.01
Iron (Fe)	Balance	Balance

Chapter 5

Documentation for design inputs

5.1 Introduction

This chapter demonstrates the various design inputs which are requested by the marketing department depending upon the market condition and competitor's product, the needs or requirements of surgeon for the required instruments in the current scenario, and the constraints from the sterility department as the design should not contain features which could not be sterilized.

5.2 Instrument 1: Universal Counter Wrench

Table 5.1: User needs, design inputs and details for universal counter wrench.

User Need	Design Input	Detail
Marketing	The instrument must be compatible with the legacy implants	Business need
	Control cost of the instrument	Cost targets shall be consistent with financial plan
	Product labeling must be consistent with other Stryker products.	Business need
	The instrument must be provided with understandable and complete Instructions for Use.	Written instructions for selecting and using the instrument must be provided.
	The instrument, package, and labeling must comply with environmental regulations.	Product and labeling must meet criteria outlined in DXXXX.
Sterility and Cleaning	Instrument must be clean	Prior to distribution into the field, the levels of any manufacturing agent

		detected on a new instrument must not exceed the limits set forth in DXXXX, "Biological and Chemical Testing of Implants and Instruments Procedure".
	Instruments must be sterile	When cleaned in worst case conditions, the instrument must meet acceptance criteria of 6.4µg/cm^2 for protein and 2.4µg/cm^2 for hemoglobin and visually clean devices as per DXXXXX.
		There shall be no evidence of packaging material transfer to the instrument throughout physical stress testing of the packaged product according to DXXXXX, "Shipping Test Procedure for Sterile Product."
Surgeon	Instrument must be able to function as intended throughout its life.	XXX surgeries represent 5 years of use at high volume surgical centers. See memo AXXXXXX for calculations of instrument use.
	Metallic instrument(s) must be corrosion resistant.	The corrosion resistance is deemed to be visually acceptable by Marketing after being conditioned/subjected to any of the test methods defined in DXXXXX, ASTM FXXXXX, or ISO XXXXX
	Instrument must transmit counter torque to TS baseplate, TS femoral implant, and TLS baseplate without implant plastic deformation and or loss of function.	The Instrument design must be robust to counter the torque while final tightening of the stem.
	Instrument must be designed for	Device design to allow for use by either

	use by a single surgeon.	right- or left-handed surgeons during implant to stem final tightening.
	Instrument must not impinge the user's hand.	Refer to "AAMI XXXX Section XX.XX.X Subsection X"
	Instrument must contain a feature which can disassemble the Offset Adapter Trial.	Instrument must have a feature to engage and unlock Offset Adapter Trial
	Instrument must sustain counter torque for final tightening of the implant stem.	Instrument must sustain equivalent or greater counter torque for final tightening of the implant stem without fracture and or plastic deformation

5.3 Instrument 2: Poly Sleeve/Filler Bushing Removal Tool

Table 5.2: User needs, design inputs and details for poly sleeve/filler bushing removal tool.

User Need	Design Input	Detail
Marketing	The instrument must be compatible with the legacy implants	Business need
	Control cost of the instrument	Cost targets shall be consistent with financial plan
	Product labeling must be consistent with other Stryker products.	Business need
	The instrument must be provided with understandable and complete Instructions for Use.	Written instructions for selecting and using the instrument must be provided.
	The instrument, package, and labeling must comply with environmental regulations.	Product and labeling must meet criteria outlined in DXXXX.

Sterility and Cleaning	Instrument must be clean	Prior to distribution into the field, the levels of any manufacturing agent detected on a new instrument must not exceed the limits set forth in DXXXX, "Biological and Chemical Testing of Implants and Instruments Procedure".
	Debris that may arise from use of the instrument must not be excessive.	Debris that may be generated from the use of the instrument or in conjunction with mating device(s) must be less than or equivalent to (within a practical lower limit) that produced by Trident Polyethylene Removal Tool
	Instruments must be sterile	When cleaned in worst case conditions, the instrument must meet acceptance criteria of 6.4µg/cm2 for protein and 2.4µg/cm2 for hemoglobin and visually clean devices as per DXXXXX.
		There shall be no evidence of packaging material transfer to the instrument throughout physical stress testing of the packaged product according to DXXXXX, "Shipping Test Procedure for Sterile Product."
Surgeon	Instrument must be able to function as intended throughout its life.	XXX surgeries represent 5 years of use at high volume surgical centers. See memo AXXXXXX for calculations of instrument use.
	Metallic instrument(s) must be corrosion resistant.	The corrosion resistance is deemed to be visually acceptable by Marketing after being conditioned/subjected to any of the

		test methods defined in DXXXXX, ASTM FXXXXX, or ISO XXXXX
	Instrument must sustain enough impaction energy, without involuntary disassembly of the tibial sleeve or filler bushing from the inner diameter of the boss on the TLS baseplates	Poly Sleeve/Filler Bushing removal tool design must include an impaction surface equivalent or larger in size (diameter and thickness) for removal of the tibial sleeve and filler bushing insitu same as the predicate Scorpio Keel Punches
		Poly Sleeve/Filler Bushing removal tool must be compatible relative to min/max clearances and minimum length of mallet extraction throw/travel within the envelope of fit of the predicate combination of Slotted Mallet 1120-1000 with the Scorpio Keel Punches
		Poly Sleeve/Filler Bushing removal tool must be compatible relative to min/max clearances with the Triathlon Slap Hammer (p/n 6541-4-803) same as predicate Triathlon All - Poly Tibia Keel Punch
	Poly Sleeve/Filler Bushing Removal Tool must withstand 4.4J, 15 cycles of impact in single surgery without fracture, plastic deformation and/or disassembly from the implant.	Impaction load and cycles utilized in this study are reflective of the maximum calculated energy applied to a tibial implant and the average number of impacts as documented in RD-XX-X-XX

	Instrument must be designed for use by a single surgeon.	Device design to allow for use by either right- or left-handed surgeons during implant to stem final tightening.
	Instrument must not impinge the user's hand.	Refer to "AAMI XXXX Section XX.XX.X Subsection X"
	Poly Sleeve/Filler Bushing Removal Tool must be compatible with TLS Tibial Sleeve	Poly Sleeve/Filler Bushing Removal Tool must contain a feature which allows for secure engagement of the inner diameter of the Tibial Sleeve Implant
	Poly Sleeve/Filler Bushing Removal Tool must be compatible with Filler Bushing	Poly Sleeve/Filler Bushing Removal Tool must contain external threads which securely maximize engagement with the XXX-XX threads of the Filler Bushing implant

Chapter 6

Design Conceptualization

6.1 Introduction

This chapter demonstrates the process of design conceptualization for all the instruments. There are various steps involved in design conceptualization such as design calculation, tolerance analysis, FEA, testing, etc. It all depends upon the design inputs and outputs parameters. Many of the references in the design calculation are obtained with the help of Stryker orthopedic modelling and analysis (SOMA).

6.2 Design development for instrument 1: Universal Counter Wrench

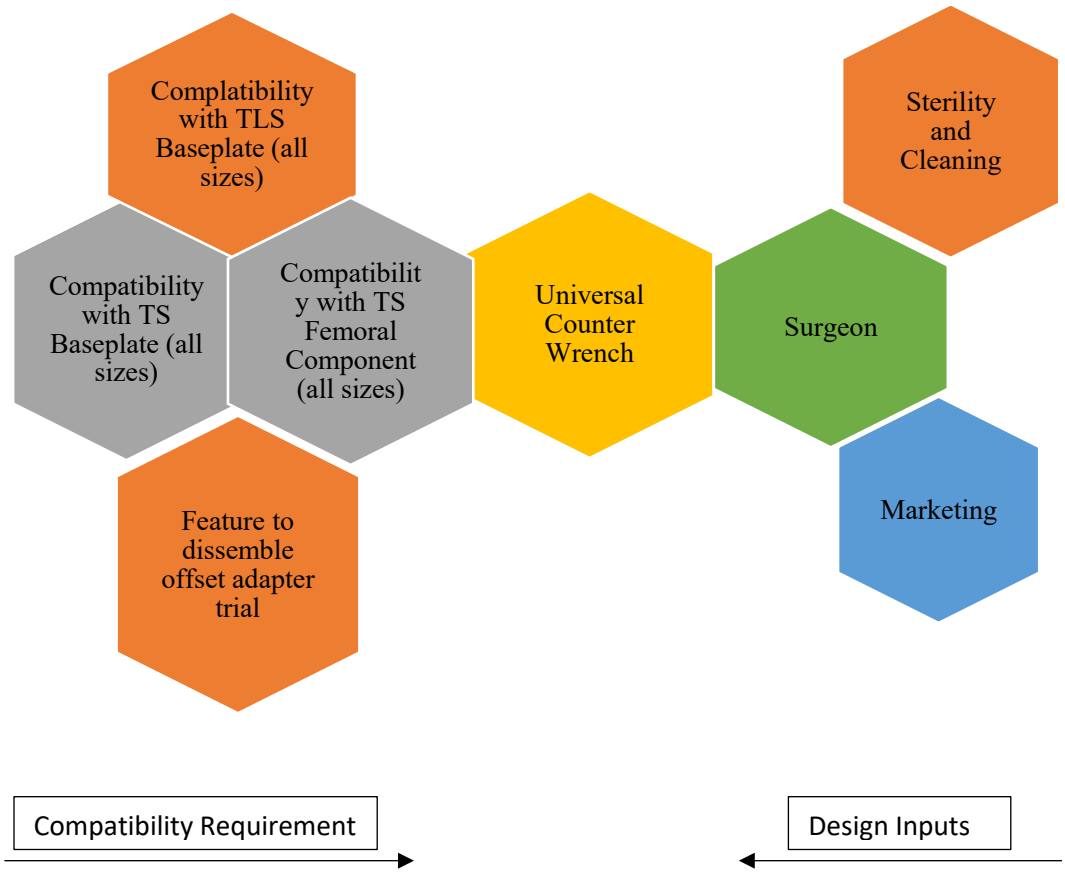


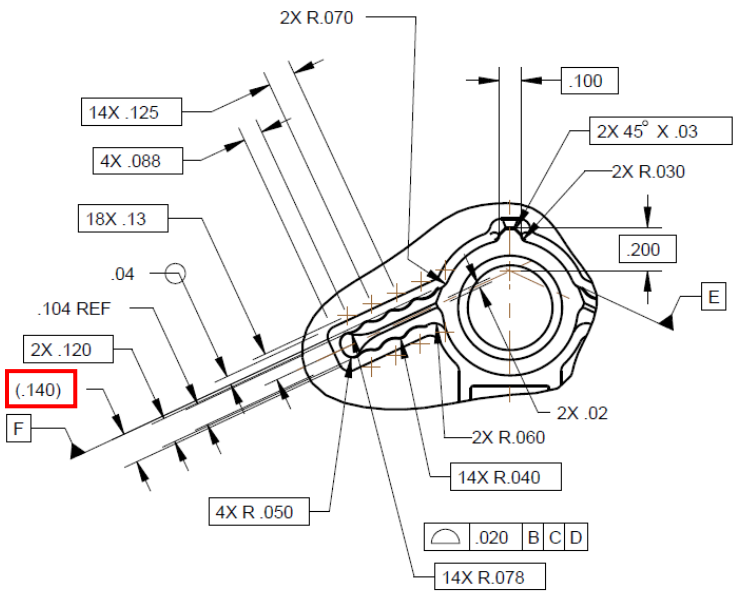
Figure 6.1: Universal counter wrench compatibility requirements and design inputs

The requirements from cleanability and sterility department, marketing and surgeon have been discussed in chapter 5 and taken into consideration for the design and development of instrument (Fig. 6.1). The design challenges include compatibility with the TS and TLS baseplates (all sizes), TS femoral component (all sizes) and feature to unlock the offset adapter trial. The TS baseplates (all sizes), TS femoral component (all sizes) are already launched in the market and hence there engineering drawing data is presented in table 6.1, while TLS baseplate (all sizes) and offset adapter trial is not yet released in the market and hence the dimensions are hided as per the company's policy. The various steps involved in the design and analysis of the Universal Counter Wrench is detailed in the subsequent sections.

6.2.1 Analyzing TS baseplate (Size 1 and Size 8), TLS baseplate (Size 1 & Size 7), TS femoral component, Triathlon handle, Offset adapter trial.

Table 6.1-6.8 and Figs. 6.2-6.28 shows the technical drawings and essential dimensions of various parts of Universal counter wrench viz., TS baseplate, TLS baseplate, femoral component, triathlon handle and offset adapter trial.

Table 6.1: TS Baseplate Size 1 (Drawing: 5521-B-100-1).

Drawing	Remarks
 Figure 6.2: TS baseplate size 1- Keel Profile Width	Keel Profile Width = 0.140 Inches

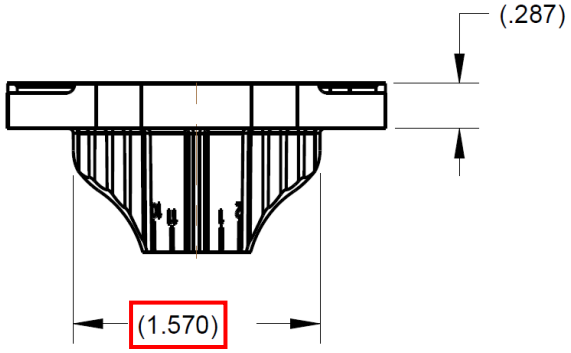
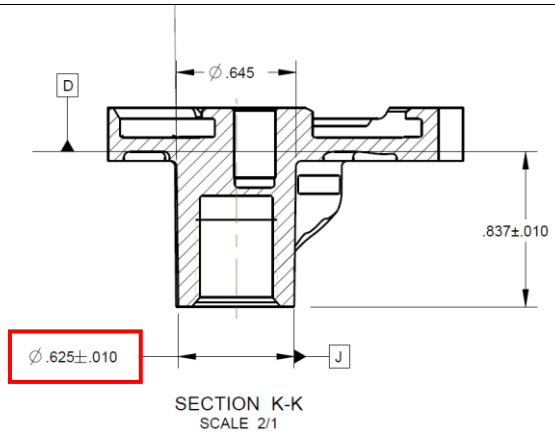
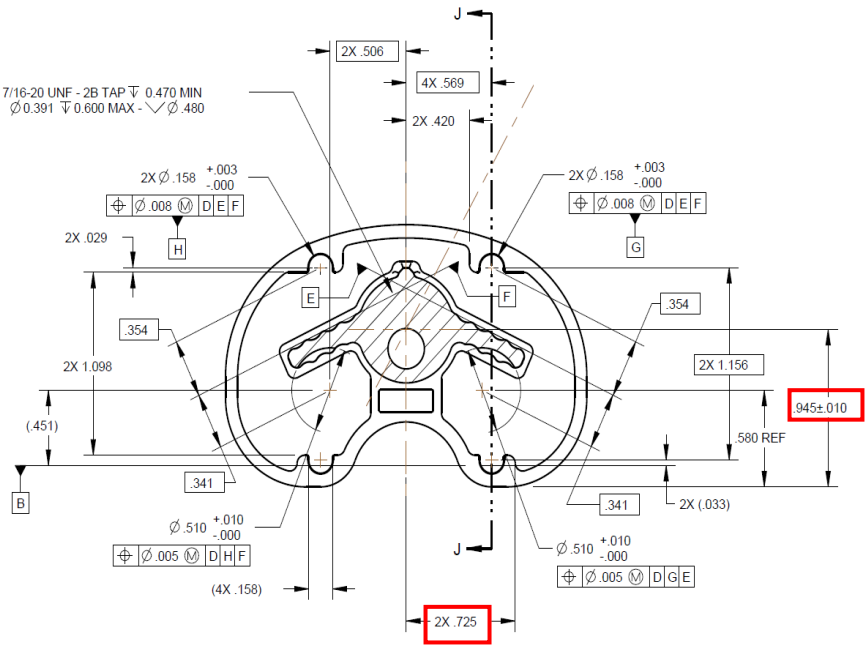
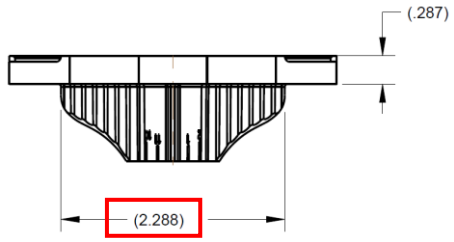
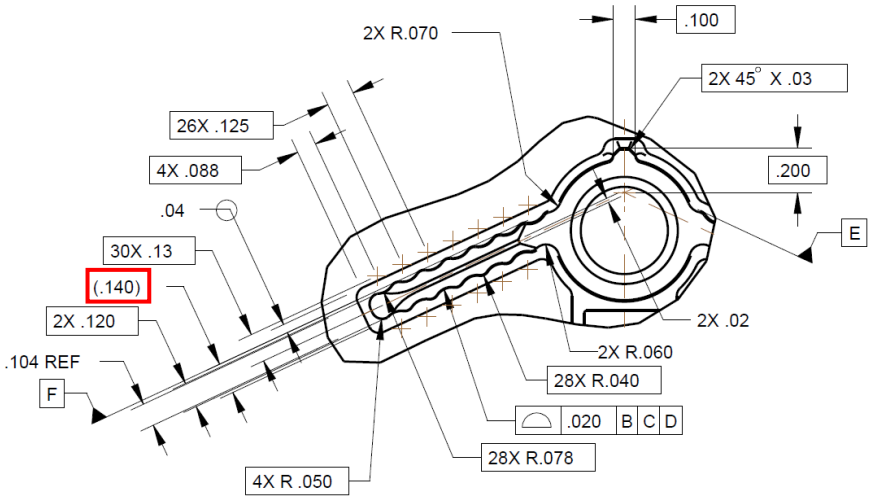
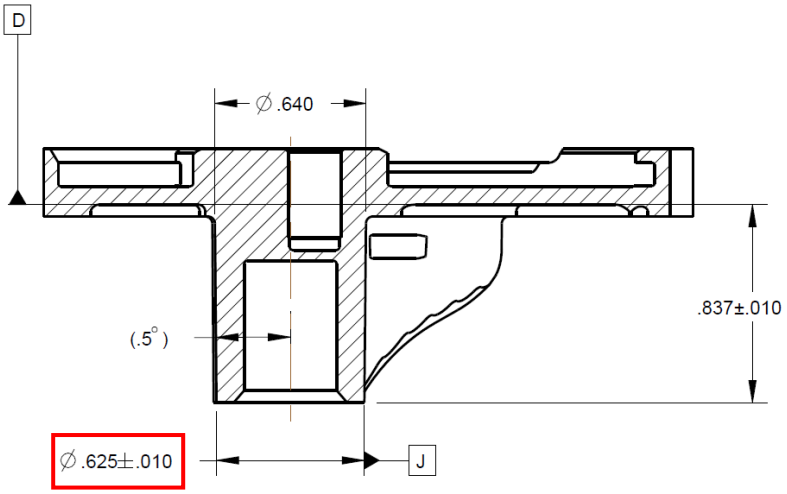
 Figure 6.3: TS baseplate size 1- Keel Width	Keel Width = 1.570 Inches
 Figure 6.4: TS baseplate size 1- Baseplate boss diameter	Baseplate Boss Diameter = Ø.615 to Ø.635 Inches
 Figure 6.5: TS baseplate size 1- Distance from Boss Centre and Baseplate Posterior end	Distance from Boss Centre and Baseplate Posterior end = .935 to .955 Inches Baseplate Slot Width = .725 Inches

Table 6.2: TS Baseplate Size 8 (Drawing: 5521-B-800-1).

Drawing	Remarks
 Figure 6.6: TS baseplate size 8 - Keel width	Keel Width = 2.288 Inches
 Figure 6.7: TS baseplate size 8 - Keel Profile Width	Keel Profile Width = .140 Inches
 Figure 6.8: TS baseplate size 8 - Baseplate Boss Diameter	Baseplate Boss Diameter = Ø.615 to Ø.635 Inches

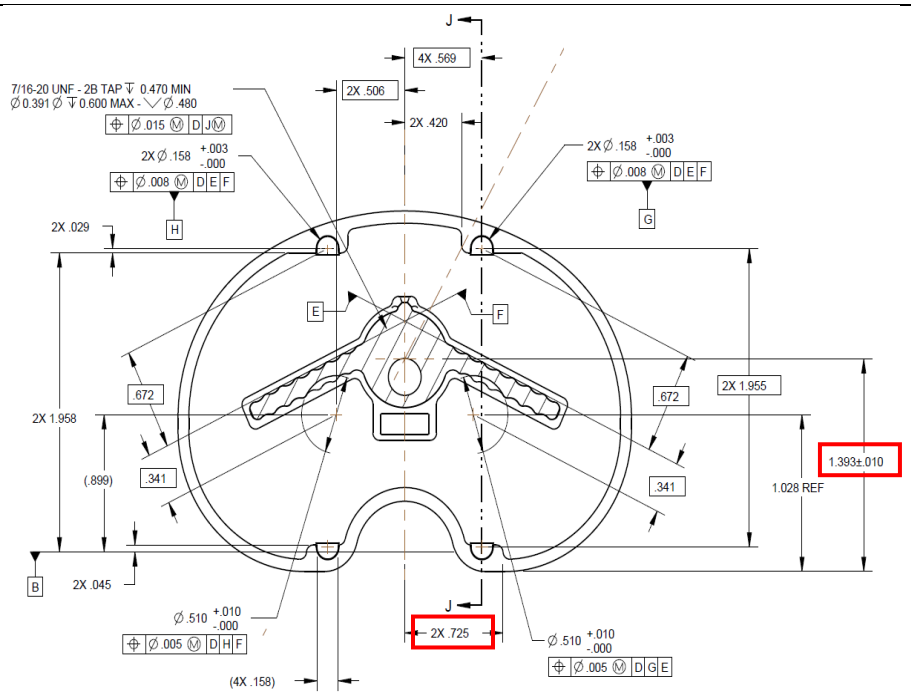
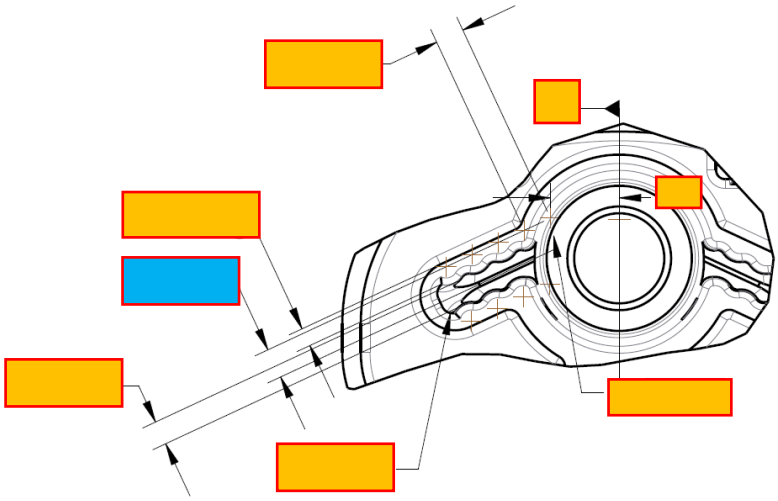
 Figure 6.9: TS baseplate size 8 - Distance from Boss Centre and Baseplate Posterior end	Distance from Boss Centre and Baseplate Posterior end = 1.283 to 1.403 Inches Baseplate Slot Width = .725 Inches

Table 6.3: TLS Baseplate Size 1 (Drawing: 6543-6-XXX).

Drawing	Remarks
 Figure 6.10: TLS baseplate size 1 - Keel Profile Width. Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Keel Profile Width = 0.140 + X1

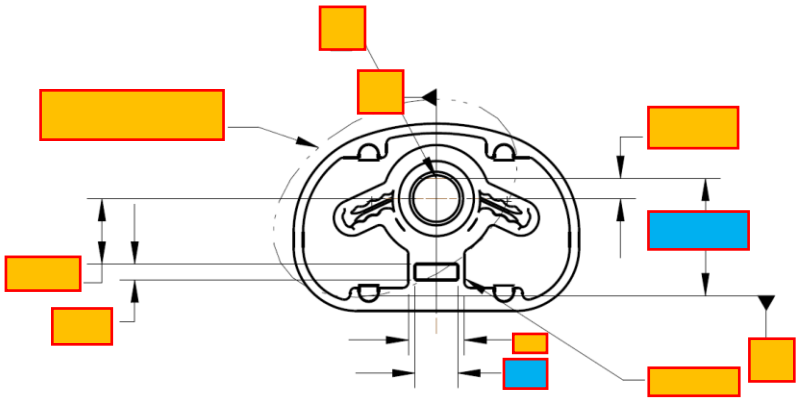


Figure 6.11: TLS baseplate size 1 - Distance from Boss Centre and Baseplate Posterior end.
Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.

Distance from Boss Centre and Baseplate Posterior end = Same as TS

Baseplate Slot Width = .725 – Z1

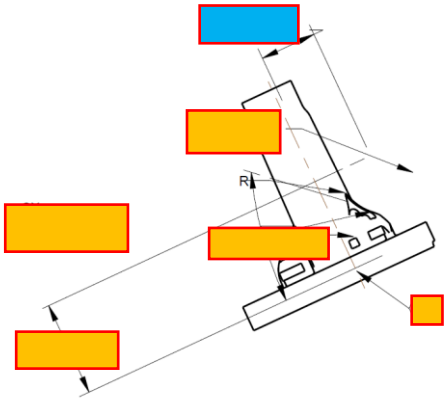


Figure 6.12: TLS baseplate size 1 - Keel Width.

Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.

Keel Width = 1.570 + X2

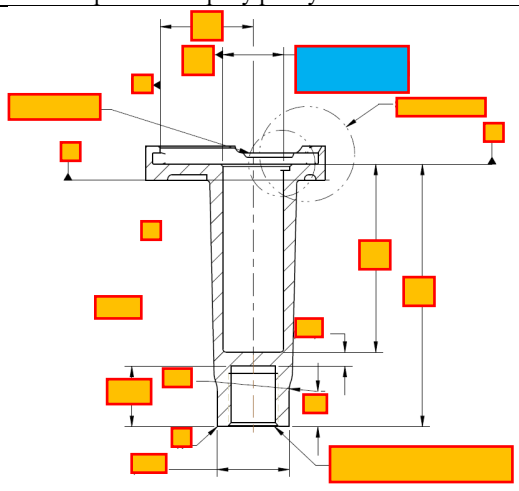
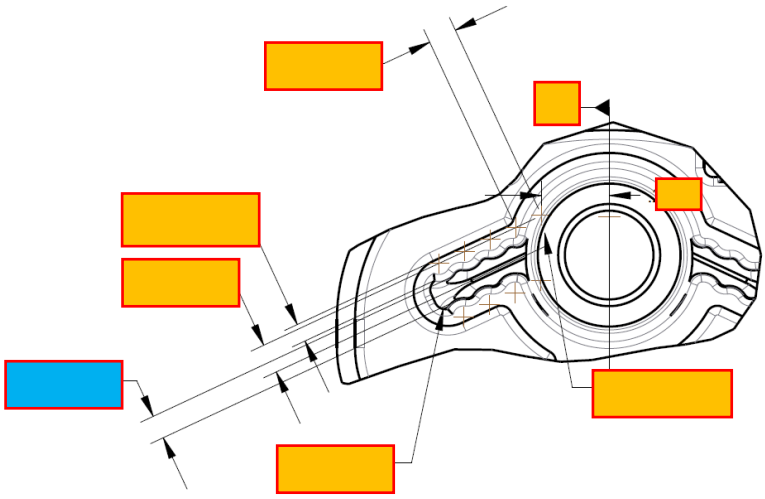
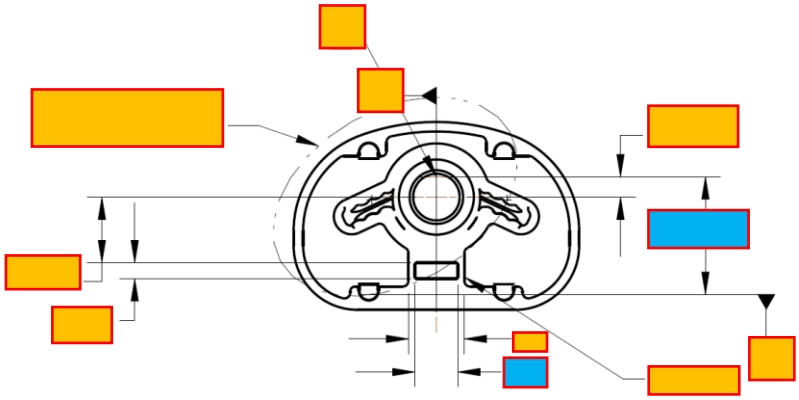


Figure 6.13: TLS baseplate size 1 - Baseplate Boss Diameter
Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.

Baseplate Boss Diameter = Ø.625 + X3

Table 6.4: TLS Baseplate Size 7 (Drawing: 6543-4-XXX).

Drawing	Remarks
 Figure 6.14: TLS baseplate size 7 - Keel Profile Width. Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Keel Profile Width = 1.570 + X1
 Figure 6.15: TLS baseplate size 7 - Distance from Boss Centre and Baseplate Posterior end. Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Distance from Boss Centre and Baseplate Posterior end = Same as TS Baseplate Slot Width = .725 – Z2

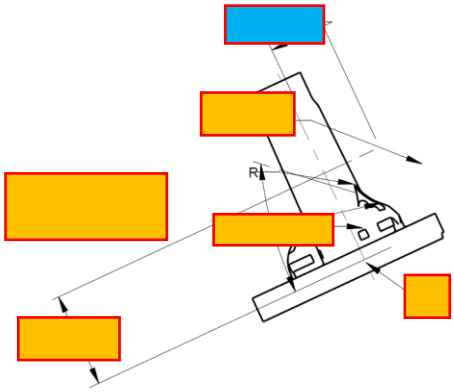
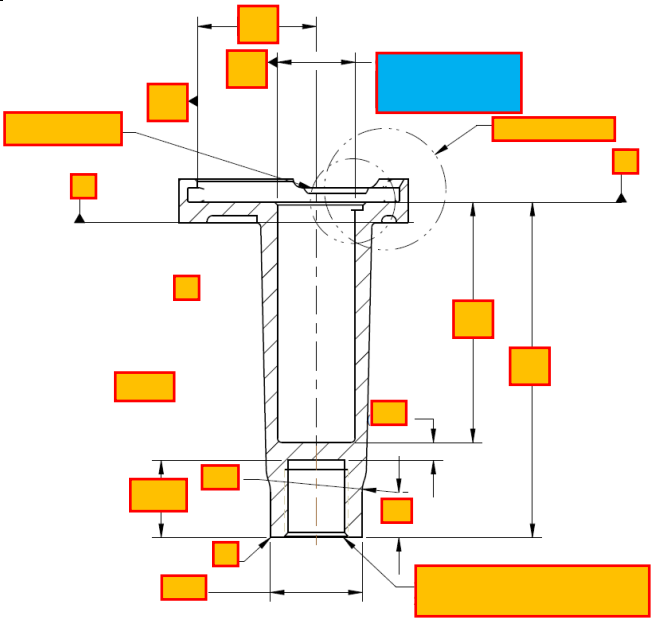
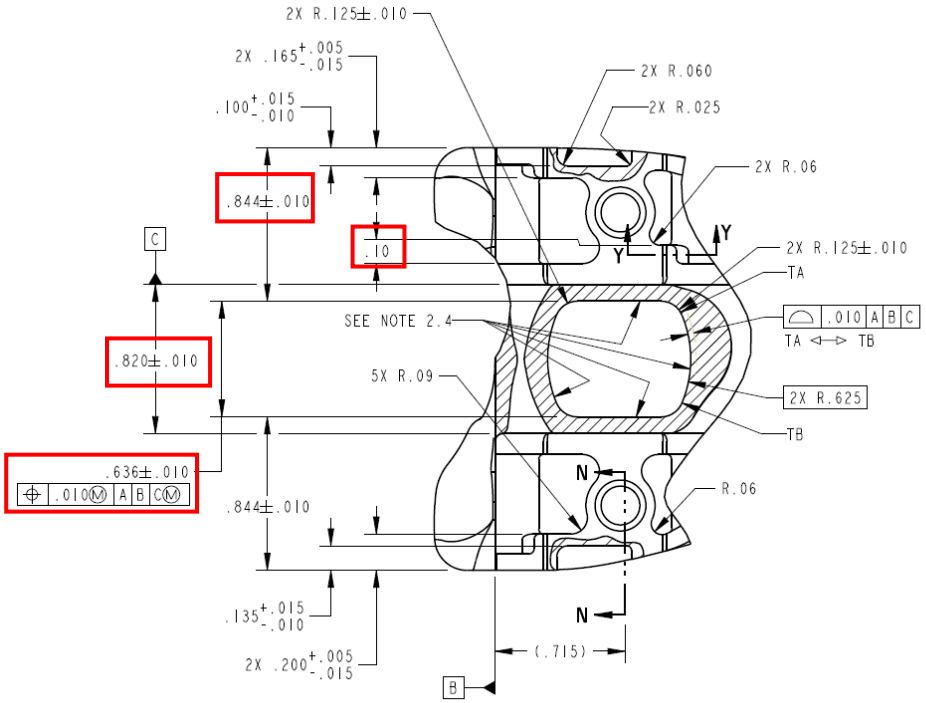
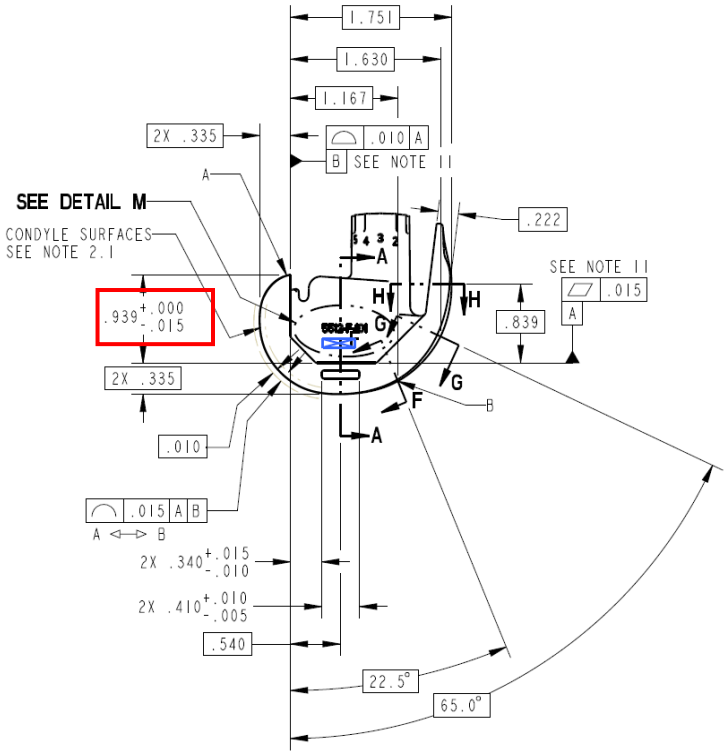
 Figure 6.16: TLS baseplate size 7 - Keel Width Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Keel Width = 2.288 + Y1
 Figure 6.17: TLS baseplate size 7 - Baseplate Boss Diameter Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Baseplate Boss Diameter = Ø.625 + X3

Table 6.5: TS Femoral Component Size 1 (Drawing: 5512-F-101).

Drawing	Remarks
 Figure 6.18: TS Femoral Component Size 1 – Condyle width	Condyle Slot Width = .810 to .830 Inches Condyle Width = .834 to .854 Inches Internal thicness of the slot = .626 to .646 Inches
 Figure 6.19: TS Femoral Component Size 1 - Femoral Tab Posterior suface height	Femoral Tab Posterior suface height = .939 to .924 Inches Distance from boss center to posterior end: 1.167 Inches

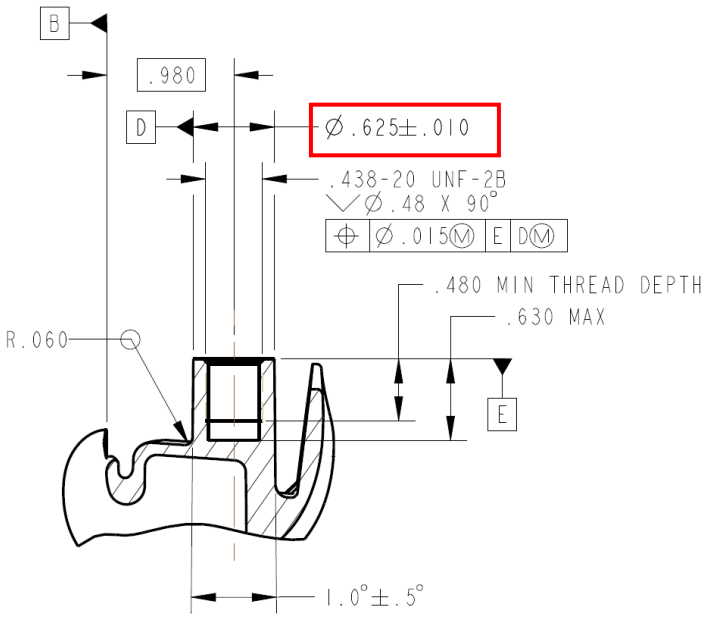
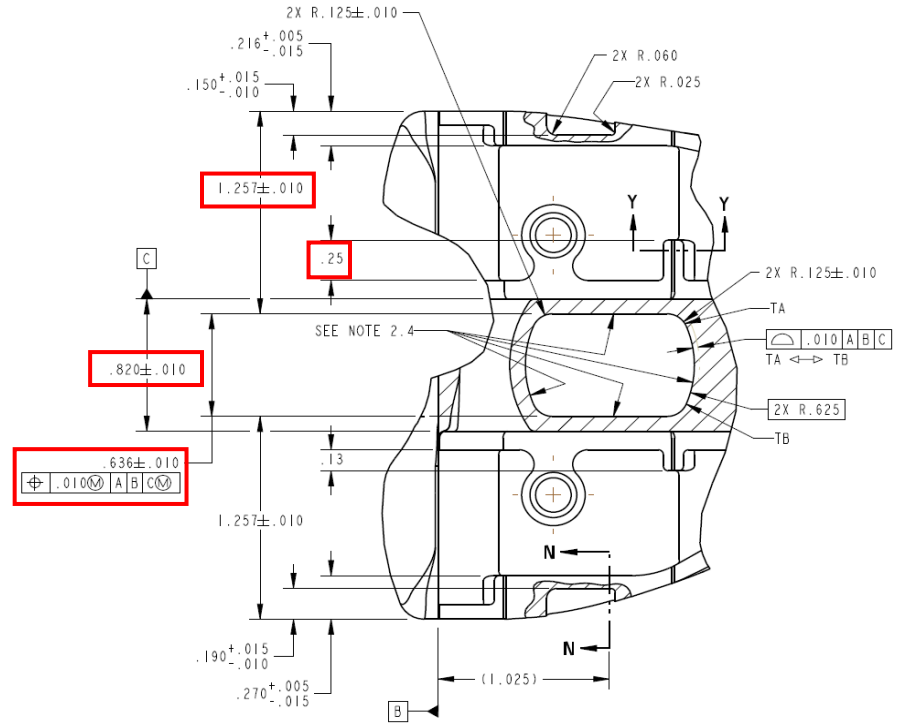
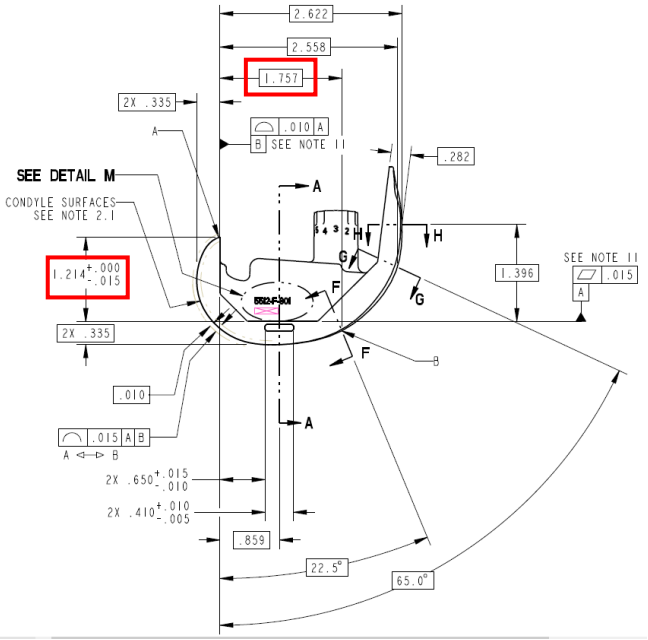


Figure 6.20: TS Femoral Component Size 1 - Femoral Component Boss Diameter

Femoral Component Boss Diameter = Ø.615 to Ø.635 Inches

Table 6.6: TS Femoral Component Size 8 (Drawing: 5512-F-801).

Drawing	Remarks
 Figure 6.21: TS Femoral Component Size 8 – Condyle width	Condyle Slot Width = .810 to .830 Inches Condyle Width = 1.247 to 1.267 Inches Internal thicness of the slot = .626 to .646 Inches
 Figure 6.22: TS Femoral Component Size 8 - Femoral Tab Posterior suface height	Femoral Tab Posterior suface height = 1.214 to 1.199 Inches Distance from Boss center to posterior end: 1.757 Inches

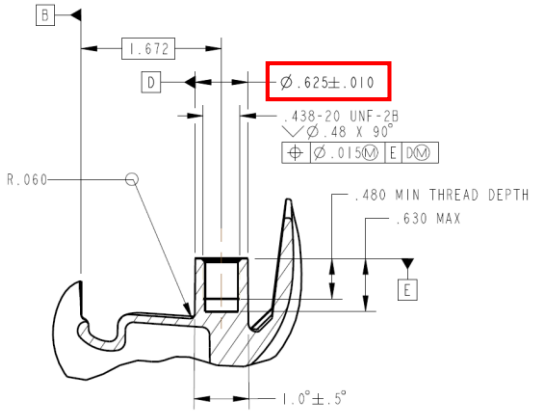
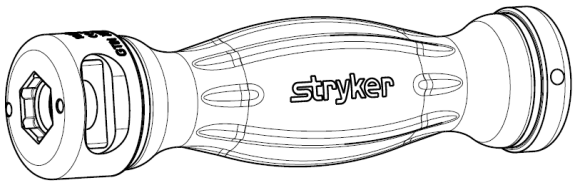
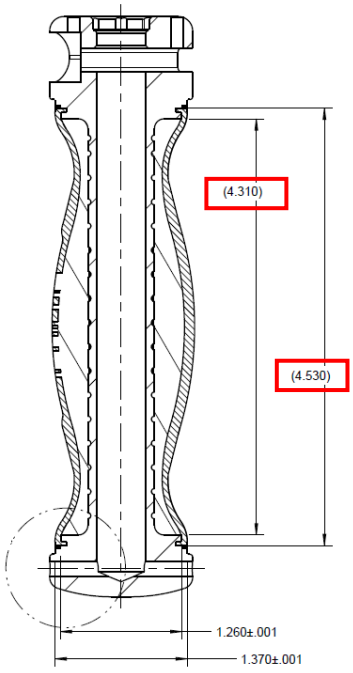
 Figure 6.23: TS Femoral Component Size 8 - Femoral Component Boss Diameter	Femoral Component Boss Diameter = Ø.615 to Ø.635 Inches

Table 6.7: Triathlon Handle (Drawing: 9000-8-XXX).

Drawing	Remarks
 Figure 6.24: Triathlon Handle	
 Figure 6.25: Triathlon Handle - Overall Length of slot	Overall Length of slot = 4.310 Inches

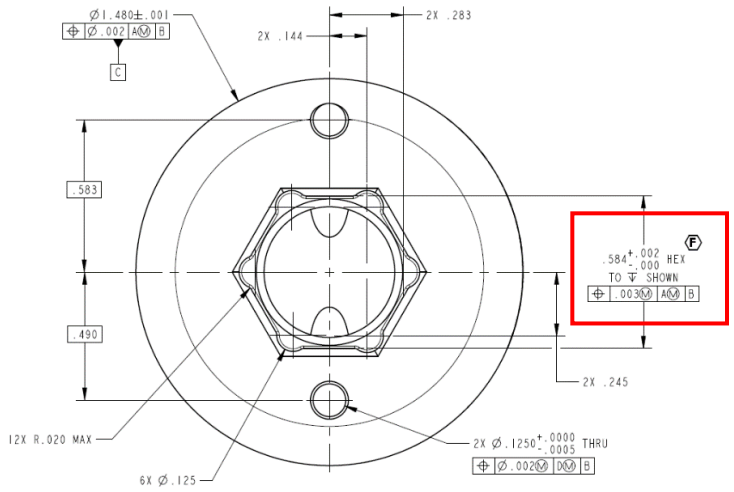
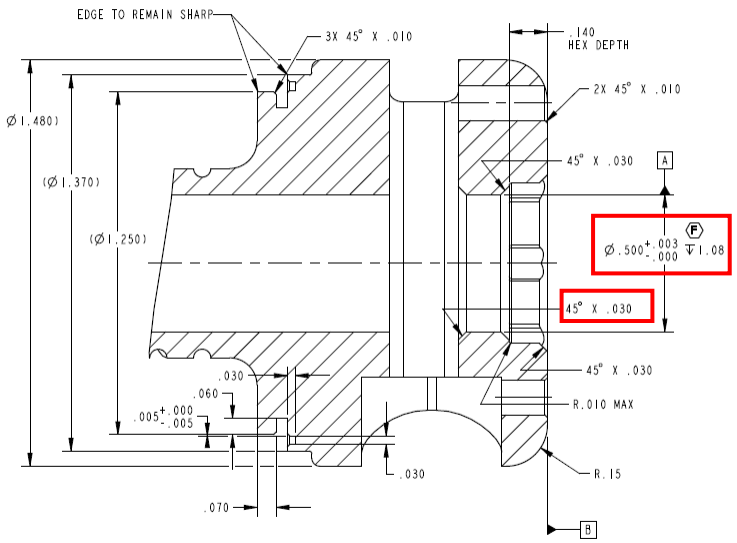
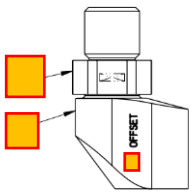
 Figure 6.26: Triathlon Handle - Length of Hexagonal slot	Length of Hexagonal slot = .586 to .584 Inches
 Figure 6.27: Triathlon Handle - Angle of Hexagonal slot	Angle of Hexagonal slot = 45° Diameter of hole = Ø.503 to Ø.500 Inches

Table 6.8: Offset Adapter (5570-S-020-1).

Drawing	Remarks
 Figure 6.28: offset adapter trial slot geometry Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Length of slot = .45” Width of slot = .255”

6.2.2 Summary of dimensional constraints for design of profile for holding TS baseplate, TLS baseplate, TS femoral component (*Note : All the linear dimensions are in Inches)

- TS Baseplate Keel Profile Width (size 1 & size 8) = .140 (1)
- TS Baseplate Keel Width: Size 1 = 1.570 (2)

  Size 8 = 2.288 (3)
- TS Baseplate boss diameter (size 1 & size 8) = Ø.625 ± .010 (4)
- TS Baseplate slot width: Size 1 = .945 ± .010 (5)

  Size 8 = 1.393 ± .010 (6)
- Distance from Boss Centre and TS Baseplate Posterior end: Size 1 = .935 to .955 (6.1)

  Size 8 = 1.283 to 1.403 (6.2)
- TLS Baseplate Keel Profile Width (size 1 & size 7) = 1.570 + X1 (7)
- TLS Baseplate Keel Width: Size 1 = 1.570 + X2 (8)

  Size 7 = 1.570 + Y1 (9)
- TLS Baseplate boss diameter (size 1 & size 7) = Ø.625 + X3 (10)
- TLS Baseplate slot width: Size 1 = .725 – Z1 (11)

  Size 7 = .725 – Z2 (12)
- Distance of Boss Centre and TLS Baseplate Posterior end: Size 1 = Same as TS (12.1)
- Distance of Boss Centre and TLS Baseplate Posterior end: Size 1 = Same as TS (12.2)
- TS Femoral Component Condyle Slot Width: Size 1 = .810 to .830 (13)

  Size 8 = .810 to .830 (14)
- TS Femoral Component Condyle Width: Size 1 = .834 to .854 (15)

  Size 8 = 1.247 to 1.267 (16)
- TS Femoral Component Internal thickness of the slot: Size 1 = .626 to .646 (17)

  Size 8 = .626 to .646 (18)
- TS Femoral Component Tabs Posterior suface height: Size 1 = 1.214 to 1.199 (19)

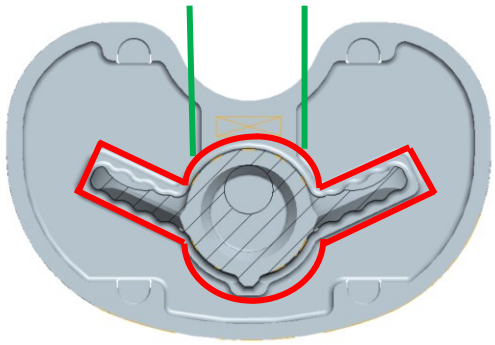
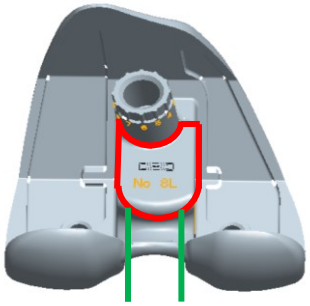
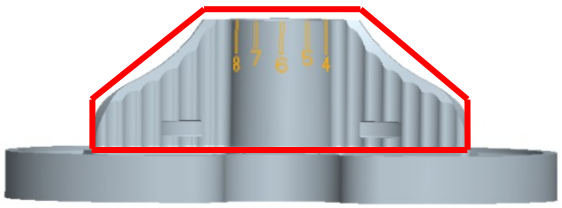
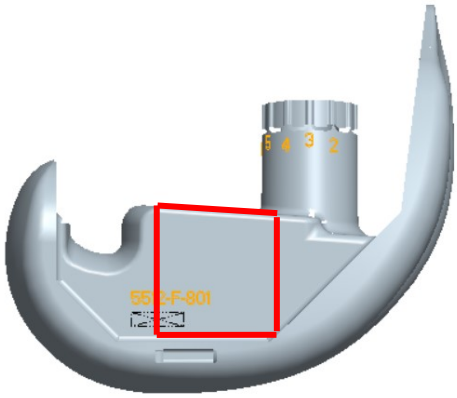
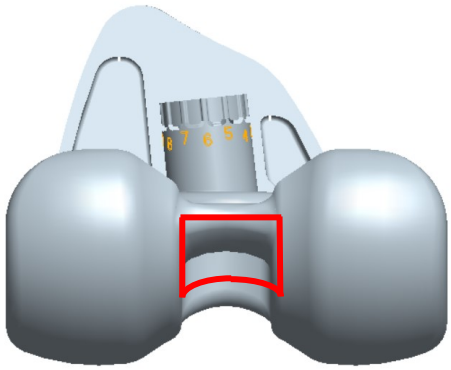
  Size 8 = 1.214 to 1.199 (20)
- TS Femoral Component Boss Diameter: Size1 = Ø.615 to Ø.635 (21)

  Size 8 = Ø.615 to Ø.635 (22)

- TS Femoral Component Distance of boss center to posterior end: Size1 = 1.167 (22.1)

  Size 8 = 1.757 (22.2)

Table 6.9: Profile requirement for baseplate and femoral component.

Baseplate	TS Femoral Component
	
	
	

6.2.3 Calculation for design of shaft

- Shaft subjected to combination of torque and bending moment:

$$\tau = \frac{(16 \times T)}{\pi \times D^3} \tag{23}$$

$$\sigma_b = \frac{32 \times M}{\pi \times D^3} \tag{24}$$

- Shaft subjected to axial loads:

$$\sigma_t = \frac{P}{A} \tag{25}$$

Where P = Axial load acting on shaft

A = Cross-sectional Area of shaft

- According to American society of mechanical engineers (ASME) code, the bending and twisting moment are multiplied by K_b and K_t, respectively to account for shock and fatigue in operating condition (Table 6.10)

$$T_e = \sqrt{(K_b \times M^2) + (K_t \times T^2)} \tag{26}$$

$$M_e = (K_b \times M) + \sqrt{(K_b \times M^2) + (K_t \times T^2)} \tag{27}$$

Table 6.10: Load relationship with K_b and K_t

Type of Load	K_b	K_t
Gradually applied load	1.5	1
Suddenly applied load (minor shock)	1.5-2	1-1.5
Suddenly applied load	2-3	1.5-3

- Taking into consideration the case of gradually applied load as the surgeon will not apply sudden load or impact load, from HE752018 (Human factor engineering standards)

T = 4.43 lbf (a)

M = 1.77 lbf (b)

τ = 558.18 psi (c)

σ_b = 69.88 psi (d)

- From equations (23) and (26)

$$558.18 = \frac{\left(16 \times \sqrt{(1.5 \times (0.2)^2) + (1 \times (0.6)^2)}\right)}{\pi \times D1^3} \quad (28)$$

D1 = 0.180 Inches (29)

- From equation (24) and (27)

$$69.88 = \frac{32 \times (1.5 \times 0.2) + \sqrt{(1.5 \times (0.2)^2) + (1 \times (0.6)^2)}}{\pi \times D2^3} \quad (30)$$

D2 = 0.375 Inches (31)

- From (29) and (31),

D = 0.375 Inches (32)

6.2.4 Dimensional constraints for Design of triathlon handle:

- Overall Length of slot = 4.310 Inches (Table 6.7) (33)
- Length of Hexagonal slot = .586 to .584 Inches (Table 6.7) (34)
- Angle of Hexagonal slot = 45˚ (Table 6.7) (35)
- Diameter of hole = Ø.503 to Ø.500 (Table 6.7) (36)
- Profile requirement for Triathlon Handle

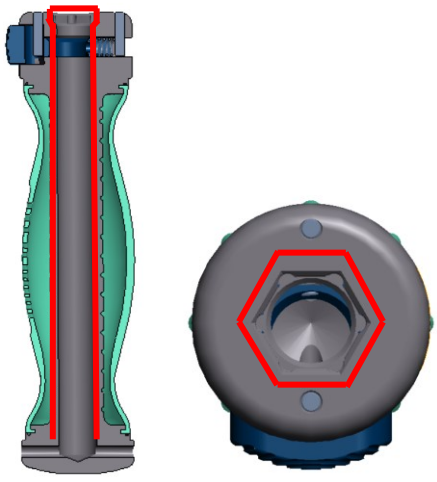


Figure 6.29: Triathlon handle fitting

6.2.5 Dimensional constraints for Design of Offset adapter trial unlocking profile:

- Length of slot = .45 Inches (Table 6.8) (37)
- Width of slot = .255 Inches (Table 6.8) (38)

6.2.6 Worst Case Analysis for the profile for holding TS baseplate, TLS baseplate, TS femoral component:

Since the maximum and minimum dimensions vary for TS Baseplate and TLS baseplate, the limits need to be calculated for all the dimension of the profile to accommodate for both the baseplates.

- Keel profile width: a" (From equations 1 and 7) (39)
- Keel width: b" (From equations 2, 3, 8 and 9) (40)
- Boss diameter clearance: c" (From equations 4, 10, 21 and 22) (41)
- Slot width: d" (From equations 5, 6, 11, 12, 13 and 14) (42)
- Tabs height: e" (From equations 19, 20) (43)
- Tabs Width: f" (Free Dimension) (44)
  (Note: For finalizing the free/floating dimension, referring legacy instrumentation 6541-X-XXX, for a minimum width) (45)
- Overall length of the profile: z" (From equations 6.1, 6.2, 12.1, 12.2, 22.1 and 22.2) (46)
- Diameter of the shaft: ØN" (From equation 32) (47)
- Length of hexagonal slot: g" (Taking clearance into consideration) (From 34) (48)
- Angle of hexagonal slot: h" (From equation 35) (49)
- Triathlon handle fitting length: i" (Triathlon fitting) + j" (Offset adapter slot length) = r" (From equations 33, 34 and 37) (50)
- Triathlon handle fitting Diameter: k" (Triathlon fitting) + q" (Offset adapter slot width) (From equations 36, 38) (51)
- Offset adapter trial unlocks profile length: j" (From equation 37) (52)
- Offset adapter trial unlocks profile width: q" (From equation 38) (53)
- Overall Length of universal counter wrench: g" + r" = s" (54)

6.2.7 CAD model of universal counter wrench based on worst case analysis calculation

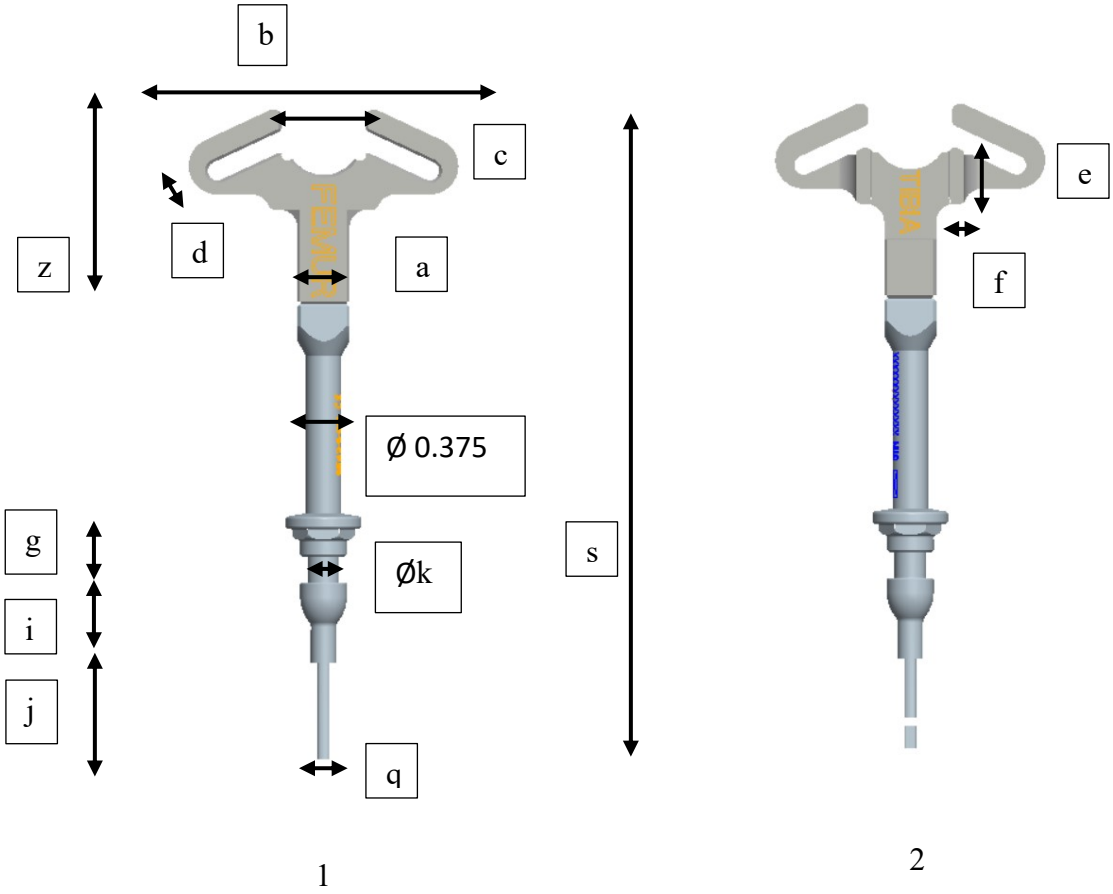


Figure 7.1: Front view of universal counter wrench, 2. Back view of universal counter wrench

6.3 Design development for instrument 2: Poly Sleeve/Filler Bushing Removal Tool

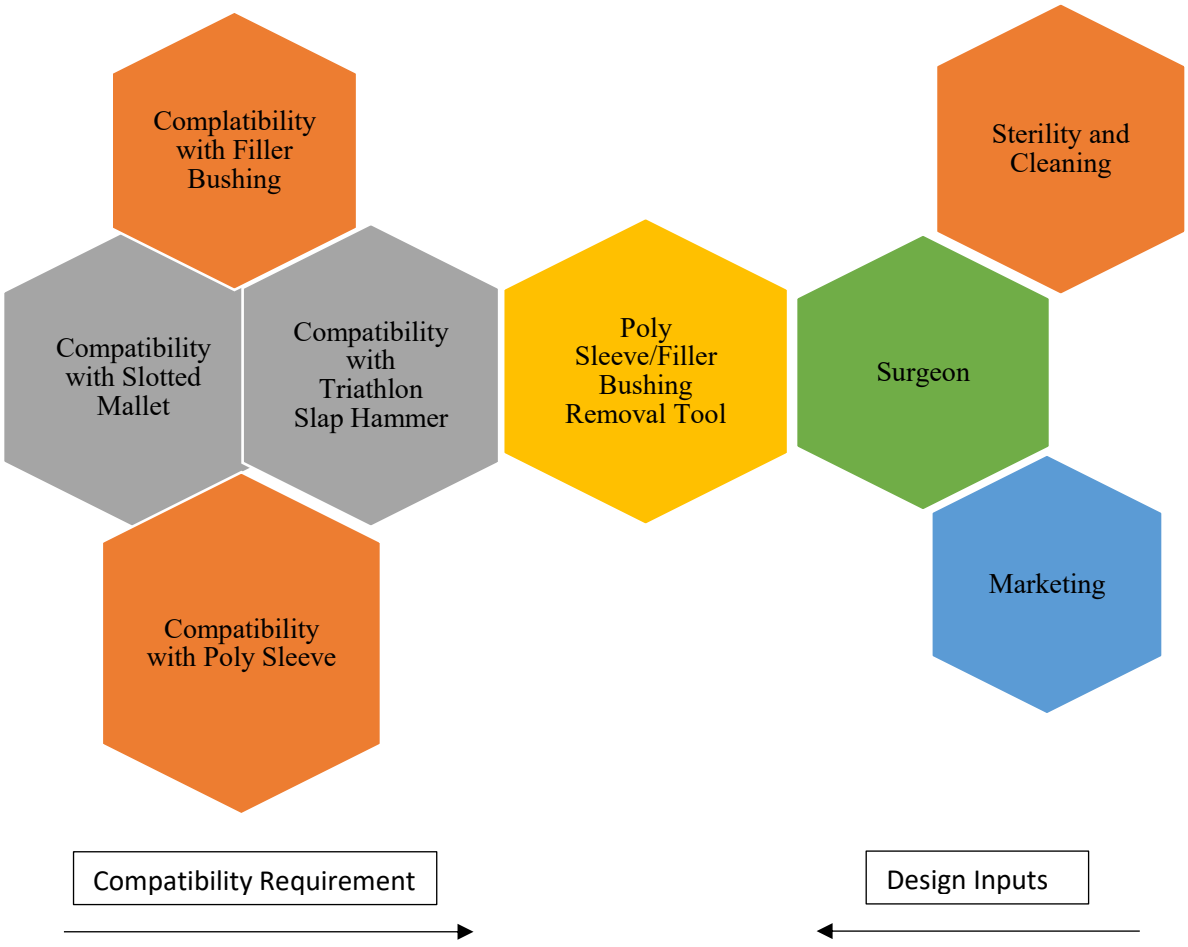


Figure 6.30: Poly Sleeve/Filler Bushing Removal Tool compatibility requirements and design inputs

The requirements from cleanability and sterility department, marketing and surgeon have been taken into consideration as discussed in chapter 5. The design challenges include compatibility with the filler bushing, poly – sleeve, triathlon slap hammer, and slotted mallet. The various steps involved in the design and analysis of the said tool is detailed in the subsequent sections.

6.3.1 Analyzing filler bushing and poly sleeve

Table 6.11: Filler Bushing (Drawing: 5612-X-XXX-XX).

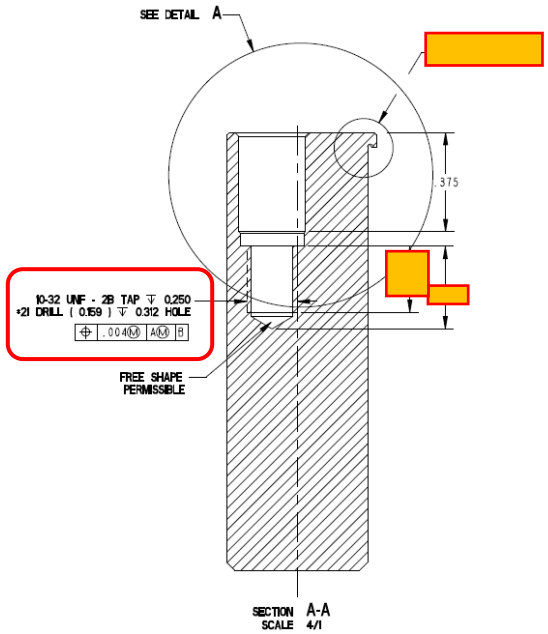
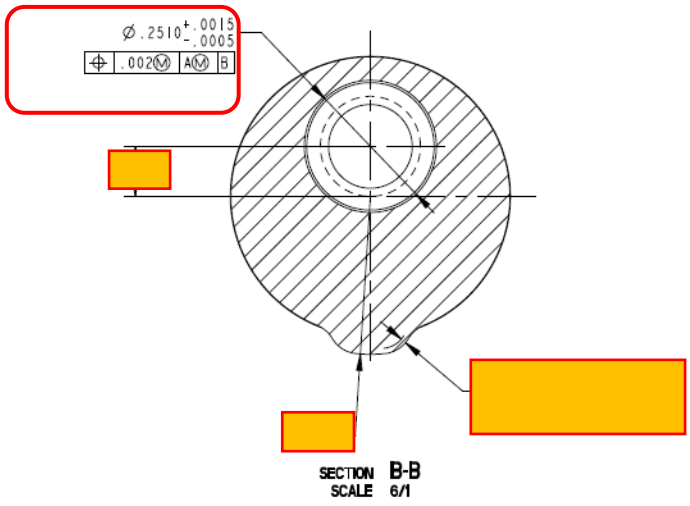
Drawing	Remarks
 Figure 6.31: Filler Bushing Thread specification for proximal hole Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Thread specification for proximal hole: 10-32, UNF – 2B, TAP .250, 21 Drill .159, Hole 0.312 Height of the distal hole = .375 Inches
 Figure 6.32 - Filler Bushing - Diameter of the distal hole Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Diameter of the distal hole = .2525 to .2505 Inches

Table 6.12: Poly Sleeve (Drawing 6481-X-XXX).

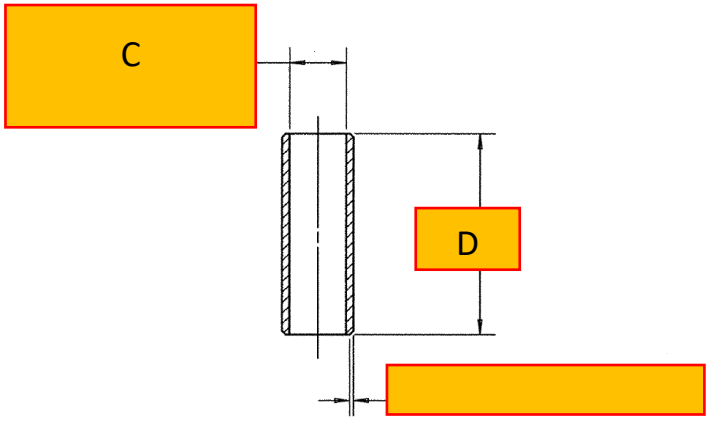
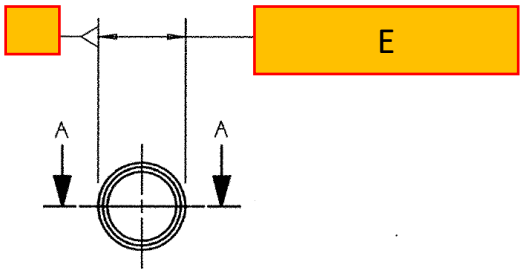
Drawing	Output
 Figure 6.33: Poly Sleeve Internal diameter Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Internal diameter of sleeve = C Height of the sleeve = D
 Figure 6.34: Poly Sleeve - Outer diameter of sleeve Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Outer diameter of sleeve = E

Table 6.13: Slotted Mallet (Drawing: 1120-XXXX).

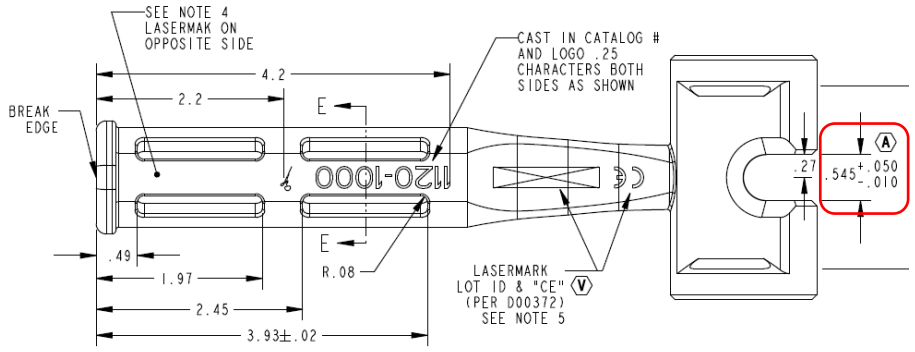
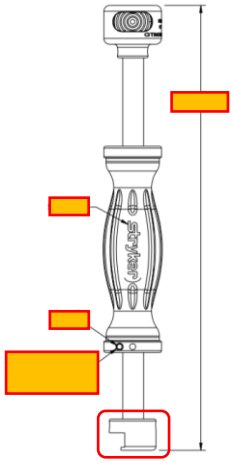
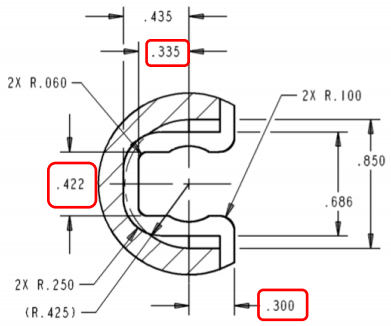
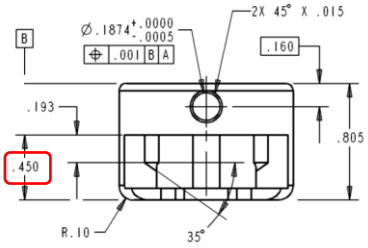
Drawing	Output
 Figure 6.35: Slotted Mallet - Width of slot	Width of slot = .550 to .535 Inches

Table 6.14: Triathlon slap hammer (Drawing: 6541-4-XXX).

Drawing	Output
 Figure 6.36: Triathlon slap hammer - Critical features Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.	Critical feature highlighted
 Figure 6.37: Triathlon slap hammer – Slot geometry	Length of the slot = .335” + .300” = .635” Width of the slot = .422”
 Figure 6.38: Triathlon slap hammer - Height of the slot	Height of the slot = .450”

6.3.2 Calculation for design of compatible filler bushing threads:

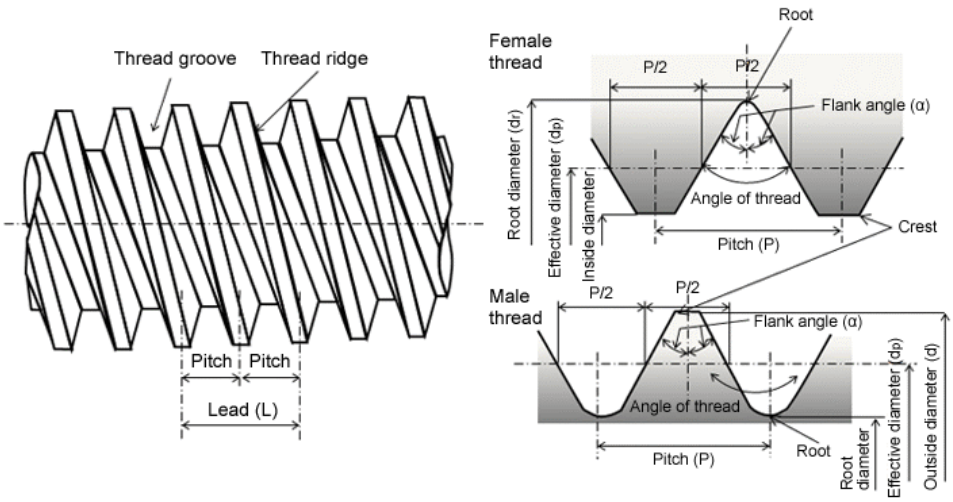


Figure 6.39: Thread Terminology and specification [57]

- Thread specification for proximal hole: 10-32, UNF – 2B, TAP .250, 21 Drill .159, Hole 0.312 are provided below (1')
  - Threads per inch = 32 [58] (2')
  - Basic major diameter = .1900" [58] (3')
  - Basic effective diameter = .1697" [58] (4')
  - Basic minor diameter of internal threads = .1562" [58] (5')
- Height of the distal hole = .375 Inches (6')
- Diameter of the distal hole = .2525 to .2505 Inches (7')
- From equation (3') we can conclude the pitch [57] (8')

$$p = \frac{1}{\text{Number of pitch per thread}}$$

$$p = \frac{1}{32}$$

$$p = .03125 \quad (9')$$

- Tensile stress area = A_t inch^2 (10')

$$A_{t=}\ 0.25 \times \pi \left(\frac{d_{p+}\, d_r}{2}\right)^2$$

$$A_{t=}\ .02 \text{ inch}^2 \quad (11')$$

6.3.3 Calculation for design of compatible poly-sleeve threads:

The requirement in case of poly sleeve is that the instrument should engage its threads with plastic body by tapping action and then the surgeon will pull out the instrument along with the sleeve. To serve this purpose the required type of thread is ‘self-tapping threads. These threads will enter the poly sleeve with the help of tapping action and they should be such that the cutting can be initiated easily. Another required feature is something which can go against the plastic burr, since metal is going to cut through the plastic so there will be generation of plastic debris, which will stop any further engagement of instrument with sleeve.

The figure below shows the different types of Self tapping screws, to show the type of thread forms.

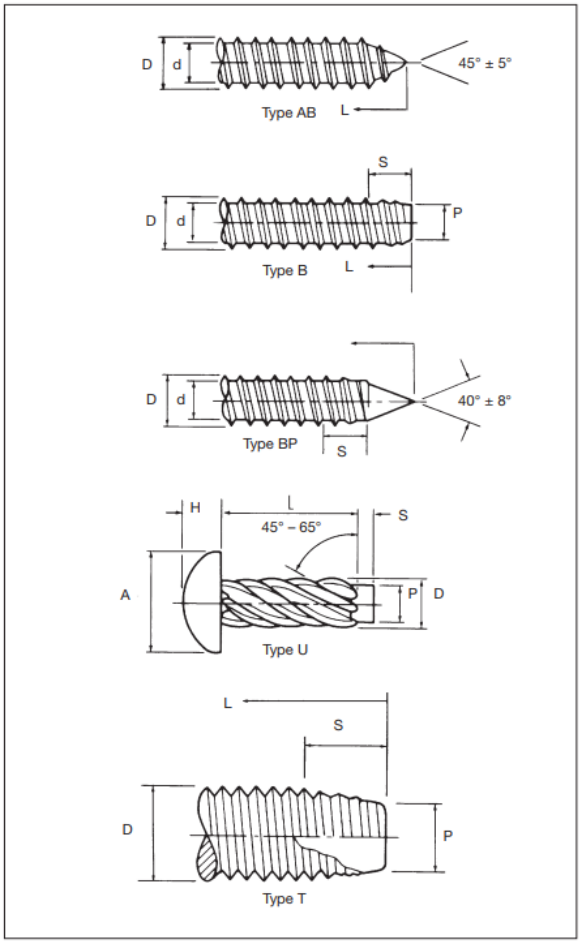


Figure 6.40: Types of self-tapping screws [59]

In the conditions described above with regards to required threads, type AB and type BP can be good at initiating the cutting and entering the sleeve, but both will

be unable to go through the plastic burr, on the other side Type T cutting threads fulfills all the condition. Hence type T cutting threads are finalized.

Self-tapping screw pull out force 'F' can be calculated as

$F = S_s \times A$

$F = S_s \times \pi \times D_p \times L$ (12')

Where:

S_s = Shear stress = $\frac{S_t}{\sqrt{3}}$ (13')

A = Shear area = $\pi \times D_p \times L$

D_p = Pitch Diameter

L = Axial length of full thread engagement

From HE752018 (Human factor engineering standards) axially applied load can be estimated as

(F) = 3.6 Pounds (14')

S_t = 30.2688 psi (15')

Shear stress can be determined using the following equation:

$S_s = \frac{30.2688}{\sqrt{3}}$

S_s = 17.4757 psi (16')

Required length of the thread, L:

$3.6 = Ss \times \pi \times .1697 \times L$, (D = .1697 From 4')

L = 0.3867" (17')

Pitch from stripping torque 'T' can be determined as

$$T = F_r \frac{(p + 2\pi f r)}{(2\pi r - fp)} \quad (18')$$

Where:

r = Pitch radius

p = pitch

f = coefficient of friction

From HE752018 (Human factor engineering standards)

T = 11.855 lbf

f = 0.2 [59]

Therefore,

$$11.855 = 56\frac{(p + 2\pi(0.2 \times 0.8485)}{(2\pi(0.8485) - 0.2p)}$$

$$p = 0.06 \qquad (19')$$

From (8'), Threads per Inch:

$$\text{Threads per inch} = \frac{1}{0.06}$$

$$\text{Threads per inch} = 16.66$$

$$\text{Threads per inch} = 17 \qquad (20')$$

6.3.4 Calculation for design of Shaft

Shaft subjected to combination of torque and bending moment:

$$\tau = \frac{(16 \times T)}{\pi \times D^3} \qquad \text{From equation (23)}$$

$$\sigma_b = \frac{32 \times M}{\pi \times D^3} \qquad \text{From equation (24)}$$

$$T_e = \sqrt{(K_b \times M^2) + (K_t \times T^2)} \qquad \text{From equation (26)}$$

$$M_e = (K_b \times M) + \sqrt{(K_b \times M^2) + (K_t \times T^2)} \qquad \text{From equation (27)}$$

From HE752018 (Human factor engineering standards)

$T = 4.43$ lbf (a')

$M = 1.77$ lbf (b')

$\tau = 22.059$ psi (c')

$\sigma_b = 50.98$ psi (d')

$K_b = 1.5$ From Table 6.10

$K_t = 1$ From Table 6.10

From Equation (23) and (26)

$$22.059 = \frac{\left(16 \times \sqrt{(1.5 \times (0.2)^2) + (1 \times (0.6)^2)}\right)}{\pi \times D1'^3}$$

D1' = 0.531 Inches (21')

From equation (24) and (27)

$$50.98 = \frac{32 \times (1.5 \times 0.2) + \sqrt{(1.5 \times (0.2)^2) + (1 \times (0.6)^2)}}{\pi \times D2'^3}$$

D2’ = 0.4 Inches (22’)

From (21’) and (22’)

D = 0.531 Inches (D<.545” or slotted mallet width) (23’)

6.3.5 Calculation for design of Impaction Plate (for slotted mallet)

The impaction plate design is taken from predicate device i.e. Scorpio keel punch and it can withstand 4.4J, 15 cycles of impact in single surgery without fracture, plastic deformation and/or disassembly from the implant.

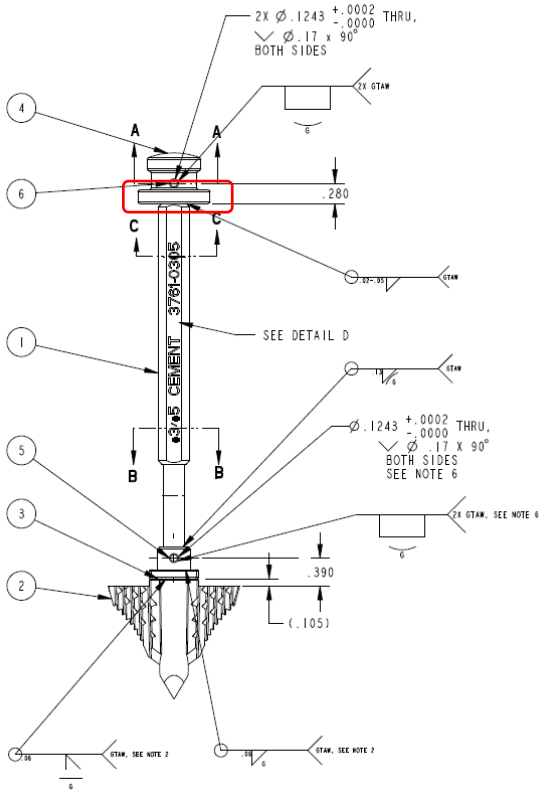


Figure 6.41: Scorpio keel punch

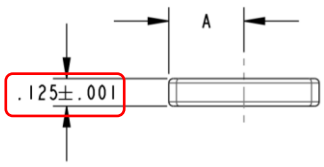


Figure 6.42: Stop plate

Diameter of plate = .126 to .124 Inches

6.3.6 Calculation for design of triathlon slap hammer fitting

- Length of the slot = .635” – Stryker standard tolerances
- Width of the slot = .422” – Stryker standard tolerances
- Height of the slot = .450” – Stryker standard tolerances

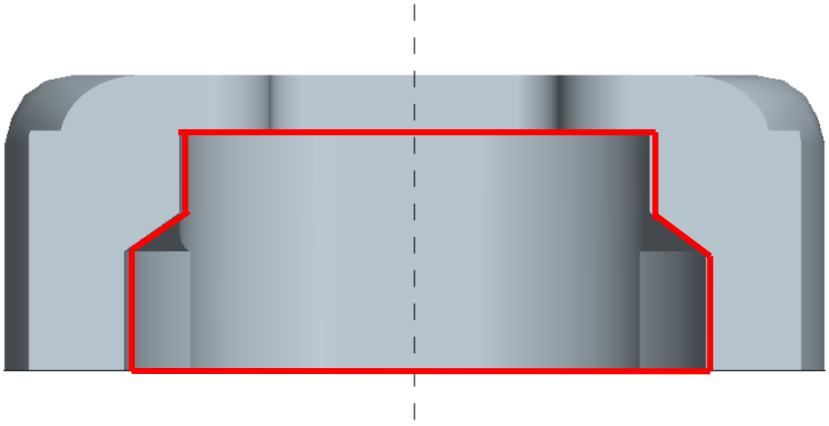


Figure 6.43: Front profile requirement for Triathlon Handle

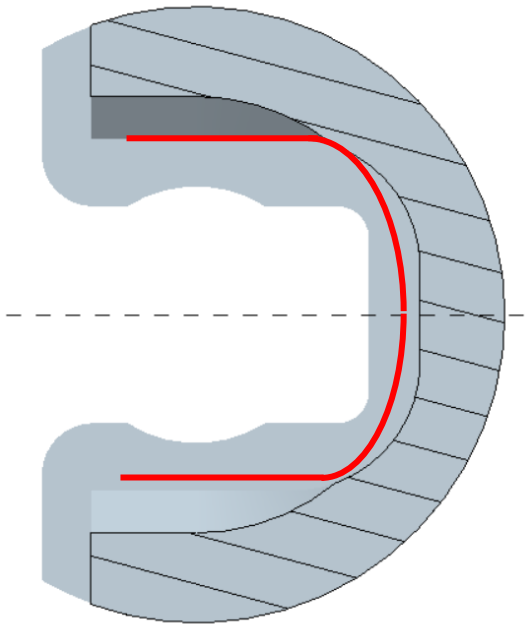


Figure 6.44: Top profile requirement for Triathlon Handle

6.3.7 Concept Selection Based on Stress Analysis

Based on the above calculations, there are some possible designs which can be proposed. In concept selection process, these designs will be compared based on poly sleeve threads failure with the help of finite element method, using the Ansys software. The final design

selection will be based on Ergonomics, manufacturability, and stress analysis. After the single concept is finalized, benchtop testing will be done to test the failure of filler bushing removal threads.

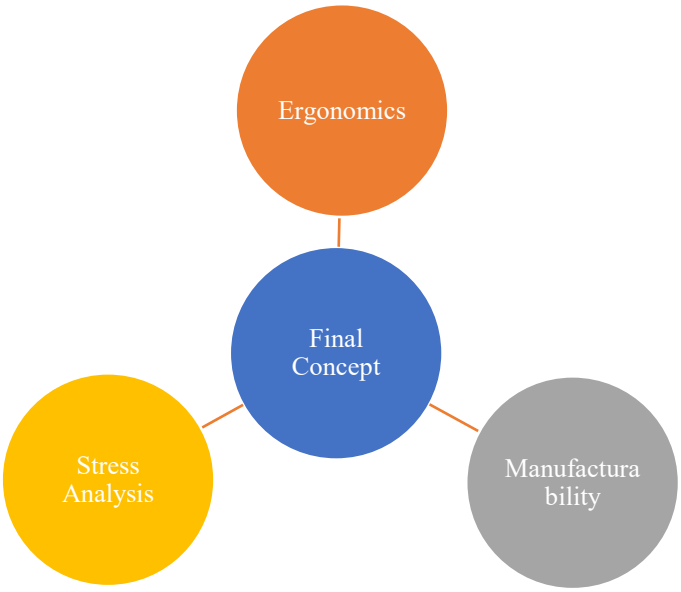


Figure 6.45: Final concept selection criteria

6.3.7.1 Design Concepts

Design Concept 1: The design 1 contains threads for pulling filler bushing and poly sleeve on the same side of the shaft and on the other end impaction plate with triathlon slap hammer fitting on top of it is attached as shown in the figure 6.46 below.

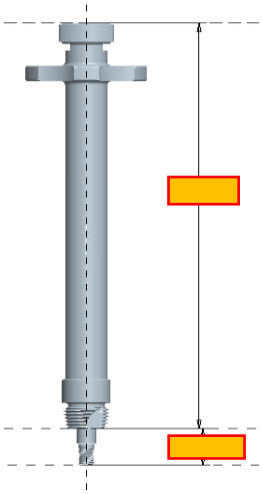


Figure 6.46: Design Concept 1

Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.

Design Concept 2: The design 2 contains threads for pulling filler bushing and poly sleeve on opposite side of the shaft and the impaction plate is kept in the middle as shown in the figure 6.47 below. Design concept 2 is rejected before the simulation as it does not have any compatible feature for the triathlon slap hammer attachment, it's not ergonomically stable to handle and it does not give enough room for the mallet to travel.

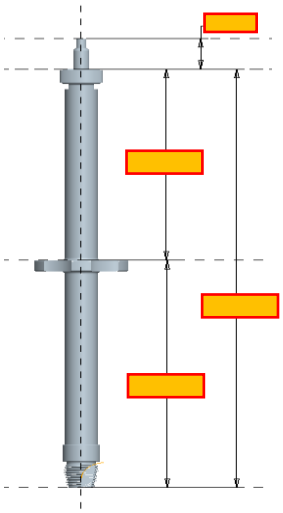


Figure 6.47: Design Concept 2

Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.

Design Concept 3: The design contains threads for pulling filler bushing and poly sleeve on opposite side of the shaft and the impaction plate is kept on both sides, and there is a shaft attached in the middle to assist in pulling out the respective implants as shown in the figure below.

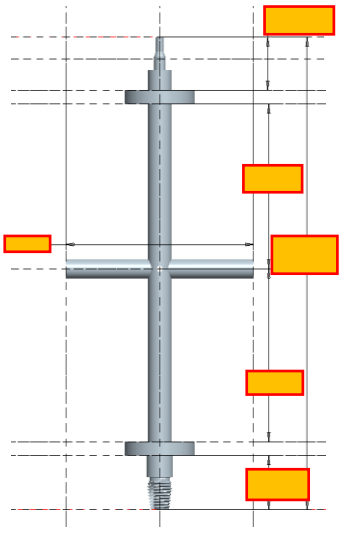


Figure 6.48: Design Concept 3

Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.

6.3.7.2 Comparative study: Comparative study for design concept 1 and 3 is done using Ansys workbench 19.1: The Sleeve can be pulled by the instrument with the help of triathlon slap hammer as well as slotted mallet depending on their availability. The Analysis is done considering the worst case i.e. with mallet as it will be impacted on the stop plate, while the slap hammer will pull gradually, so there are higher chances of failure with slotted mallet.

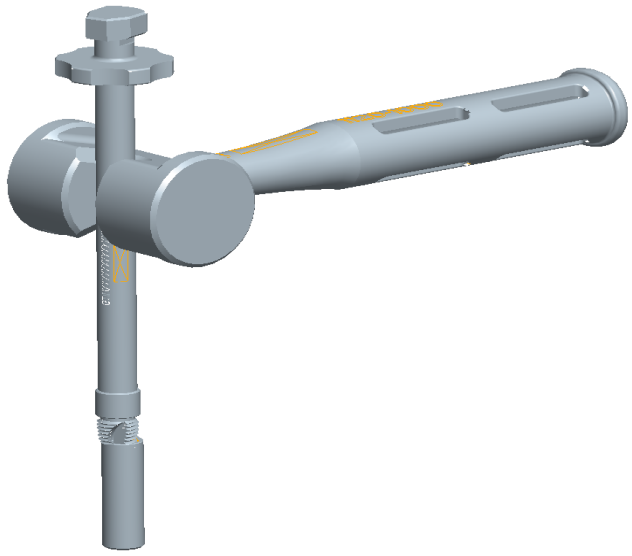


Figure 6.49: Assembly of Design concept 1 with slotted mallet (worst case)

A. Material Properties:

Table 6.15: 455 Material Properties.

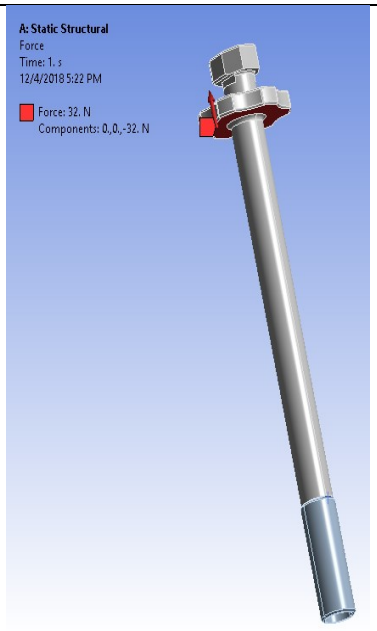
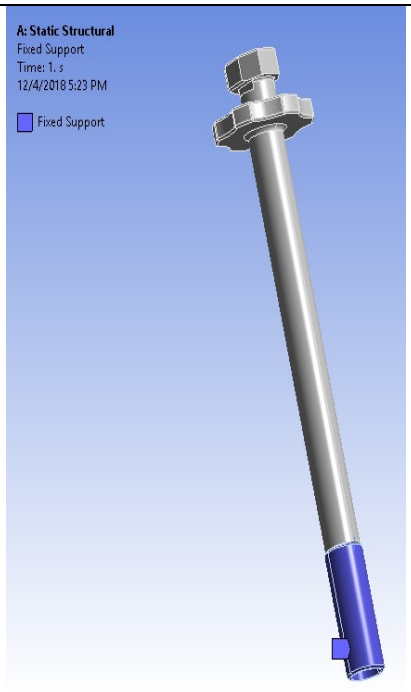
Sr.No.	Material	Density	Young's Modulus	Poisson's Ratio
1	455 SS	0.28 $lbin^{(-3)}$	2.901e7 psi	0.3
2	Poly sleeve	0.034 $lbin^{(-3)}$	1.2966e7 psi	0.46

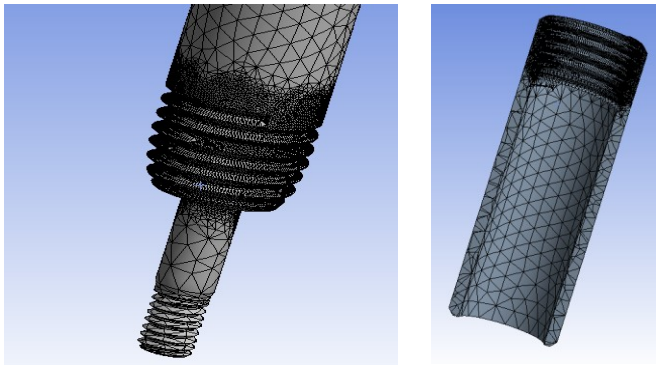
B. Boundary Conditions

For simulating the exact surgical environment, the Poly sleeve is fixed, and the force is applied on the stop plate. Contacts are defined in the simulation to make sure of proper engagement between the mating components. Bonded contacts are used due to its ability to converge the solution within the given domain. Patch conforming algorithm is used as it in

this technique all faces and edges along with their boundaries (patches) are taken into consideration and there are less chances of error.

Table 6.16: Boundary conditions for simulation.

Force Applied	32 N
FOS	2
Application Point	 Figure 6.50: Point of application of force
Fixed Support	 Figure 6.51: Fixed support

Mesh size	0.25 mm  Figure 6.53: Meshing
Mesh Method	Tetrahedron
Algorithm	Patch Conforming
Type of Contact	Bonded

C. Results:

- Design Concept 1:

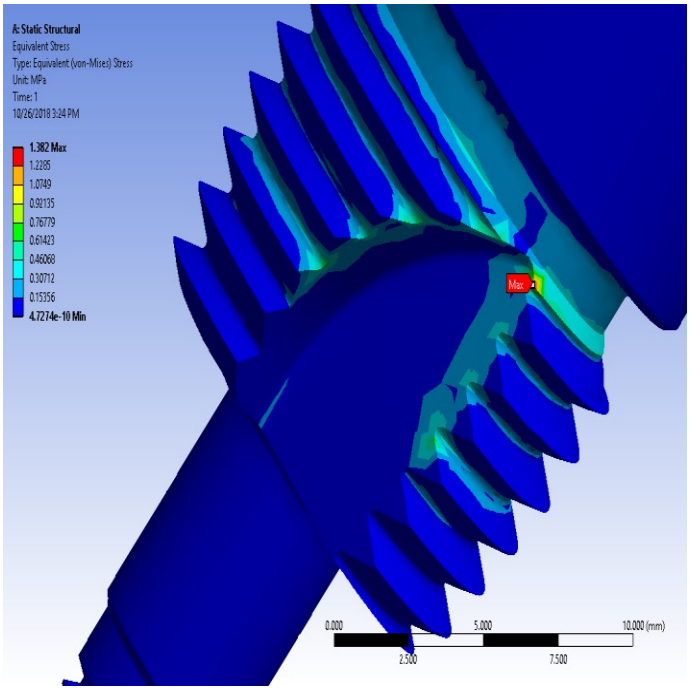


Figure 6.54: Equivalent stress – Design Concept 1

- Design Concept 3:

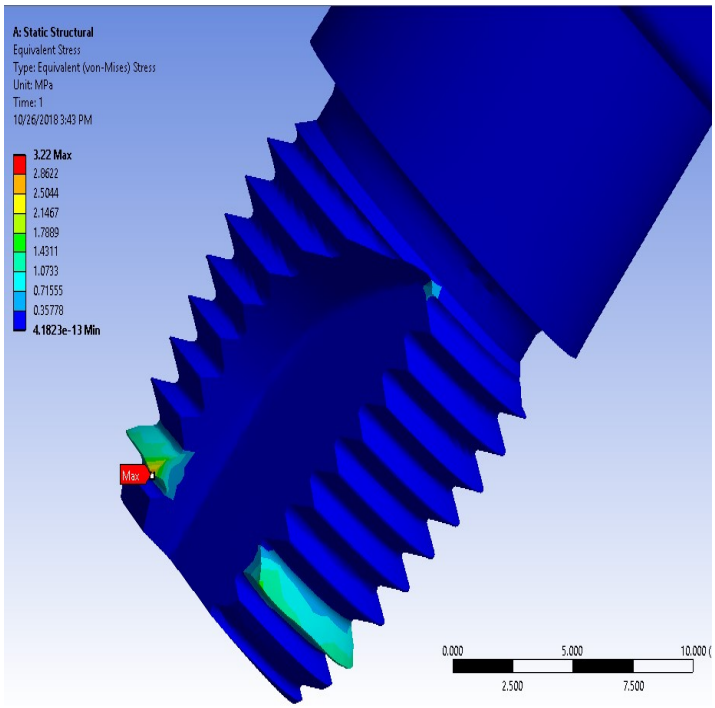


Figure 6.55: Equivalent stress – Design Concept 3

From figure 6.54 and figure 6.55 it can be noted that the maximum stress for design concept 1 is 1.3 MPa while maximum stress for design concept 3 is 3.2 MPa keeping all the boundary conditions same, hence design concept 1 was selected to undergo the benchtop testing, to check failure load in case of filler bushing.

6.3.7.3 CAD model of Poly sleeve/filler bushing removal tool

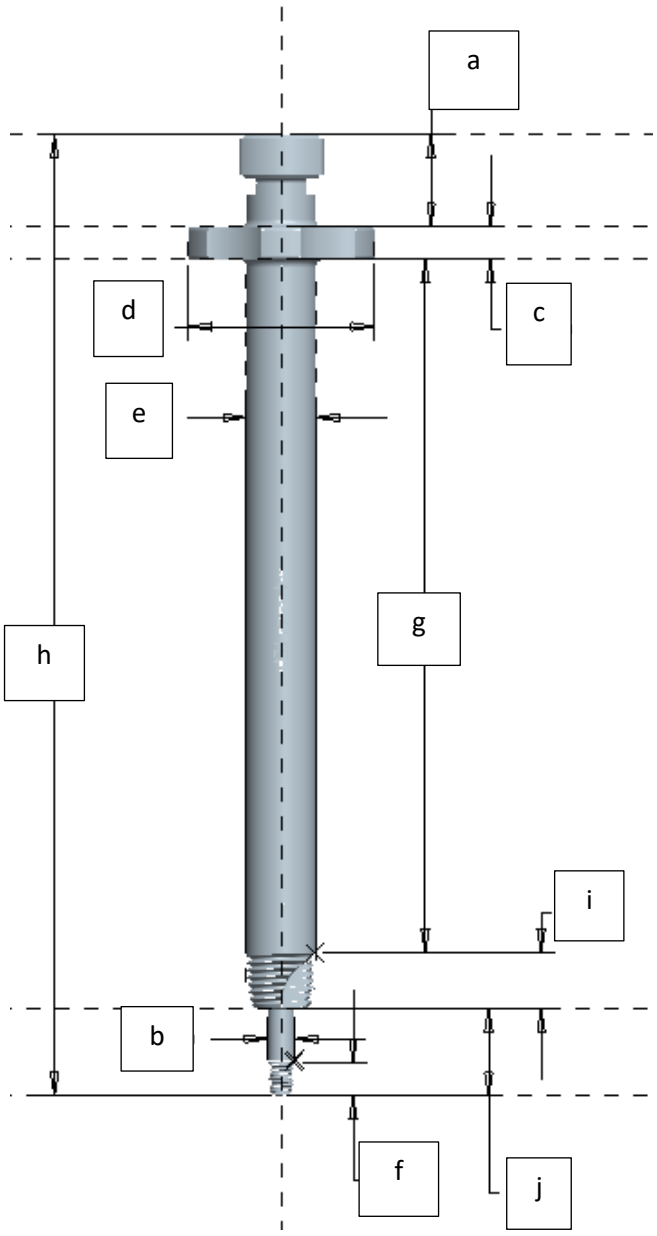


Figure 7.10: Front view of poly sleeve/filler bushing removal tool

6.3.8 Experimental setup:

6.3.8.1 Aim of experiment: The purpose of this Poly Sleeve/Filler Bushing Removal Tool bench test was to evaluate the structural integrity of the tool's 10-32 UNF 2A thread in the axial loading and cantilever loading (alternative use/involuntary loading) conditions. In addition, the test was used to evaluate the tool's Type T cutting thread profile for use in removing the tibial sleeve from the ID of the baseplate boss. Both the axial and cantilever tests will be performed to failure of the device to assess the limits of the design, as well as to confirm that said loads will be well passed any clinically relevant axial/cantilever load that may be applied by the surgeon during clinical use.

6.3.8.2 Methodology: For testing purpose the sample size was kept 3, the instruments was fixed in the fixture which resembles the baseplate, and a pulling force is applied in the upward direction, and the failure load is noted.

*Note : Fixture clamp was exchanged for each evaluation in attempt to minimize tilt of the test platform during testing due to load axial load.

Figure 6.56: Experimental setup

Chapter 7

Results and discussion

7.1 Introduction

In the present work, two instruments are designed as per the compatibility requirement and user need. The designed concept then underwent the analysis – Tolerance analysis, FEM, Benchtop testing. The following chapter the results of the design verification and developed prototypes (Metal/Plastic).

7.2 Instrument 1: Universal Counter Wrench

The Results obtained from the theoretical calculations are verified by doing finite element analysis for instrument 1. Figure 7.1 describes the cases which will be verified through FEA.

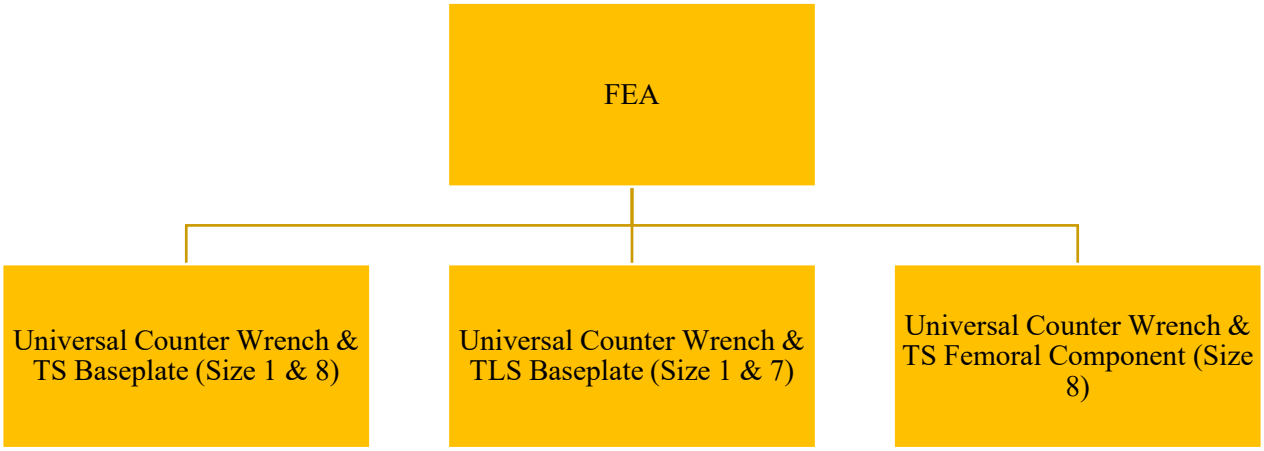


Figure 7.1: FEA process flow for universal counter wrench

7.2.1 Boundary Conditions

Table 7.1 presents the selected parameters for boundary condition which are utilized to perform the analysis.

Table 7.1: FEA boundary conditions

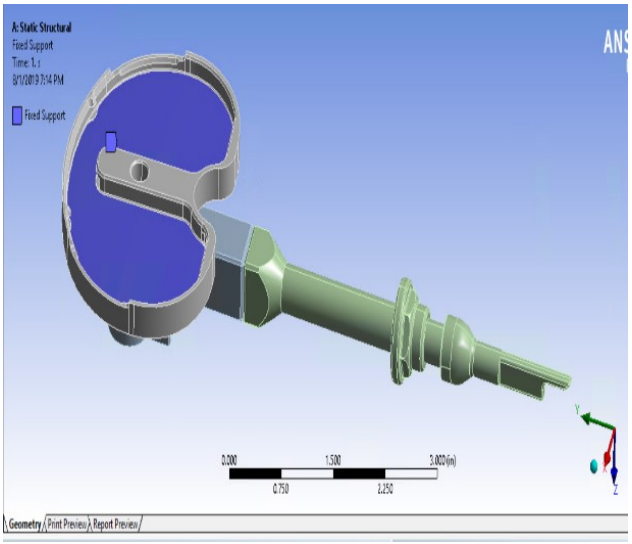
Parameters	Details
Mesh Size	0.13 mm
Mesh Method	Tetrahedron
Algorithm	Patch Conforming
Type of Contact	Bonded
Fixed Support	

Figure 7.2: Fixed support - Baseplate

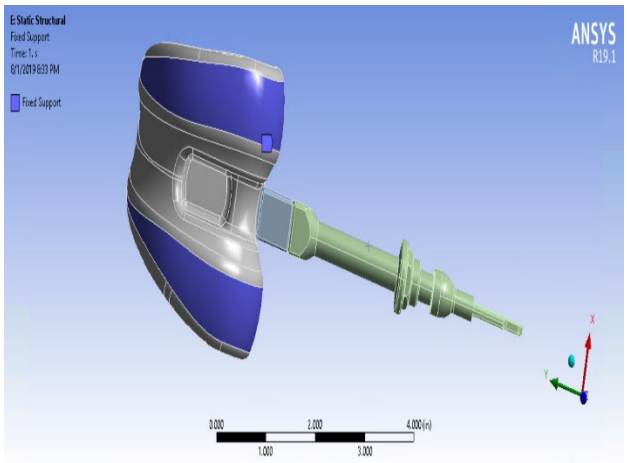


Figure 7.3: Fixed support – Femoral component

Point of application of moment and torque

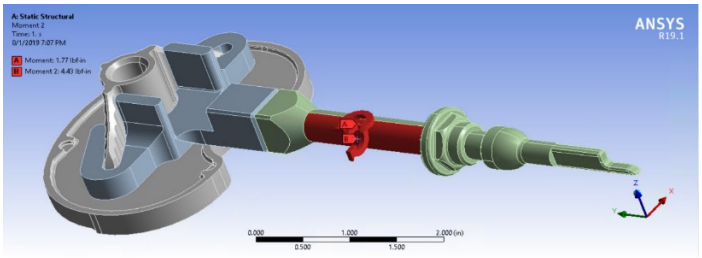


Figure 7.4: Application of moment and torque

7.2.2 Results

- **Case 1: Universal counter wrench and TS baseplate (size 1)**

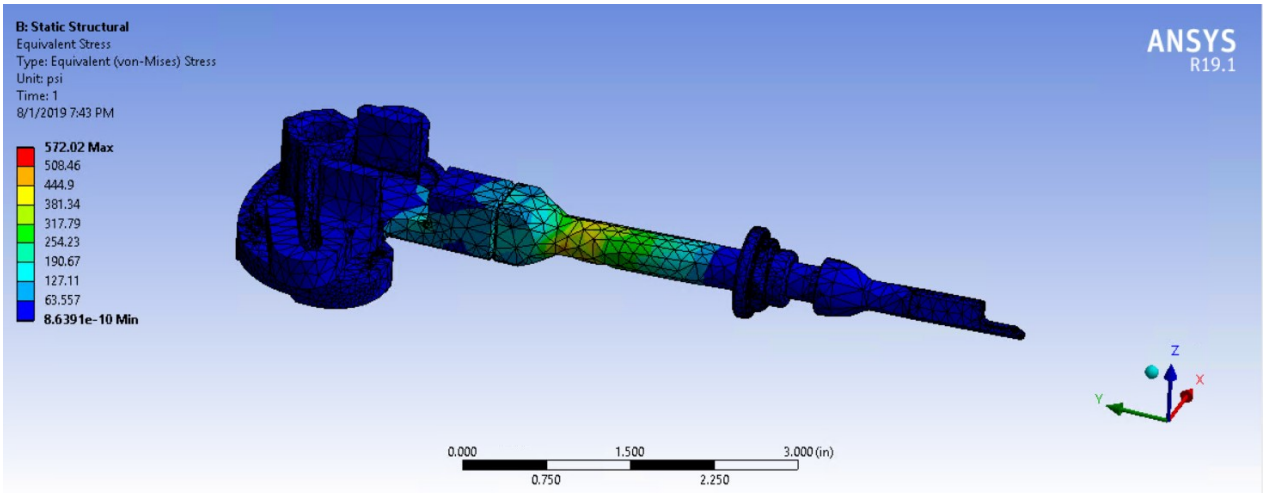


Figure 7.5: FEA universal counter wrench and TS baseplate size 1

- **Case 2: Universal counter wrench and TS baseplate (size 8)**

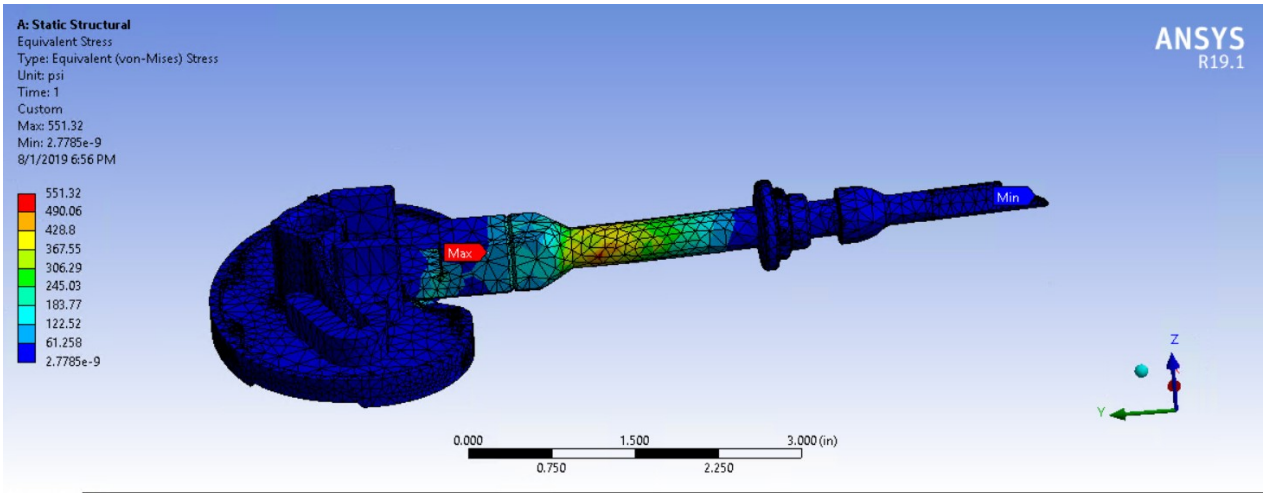


Figure 7.6: FEA universal counter wrench and TS baseplate size 8

- **Case 3: Universal counter wrench and TLS baseplate (size 1)**

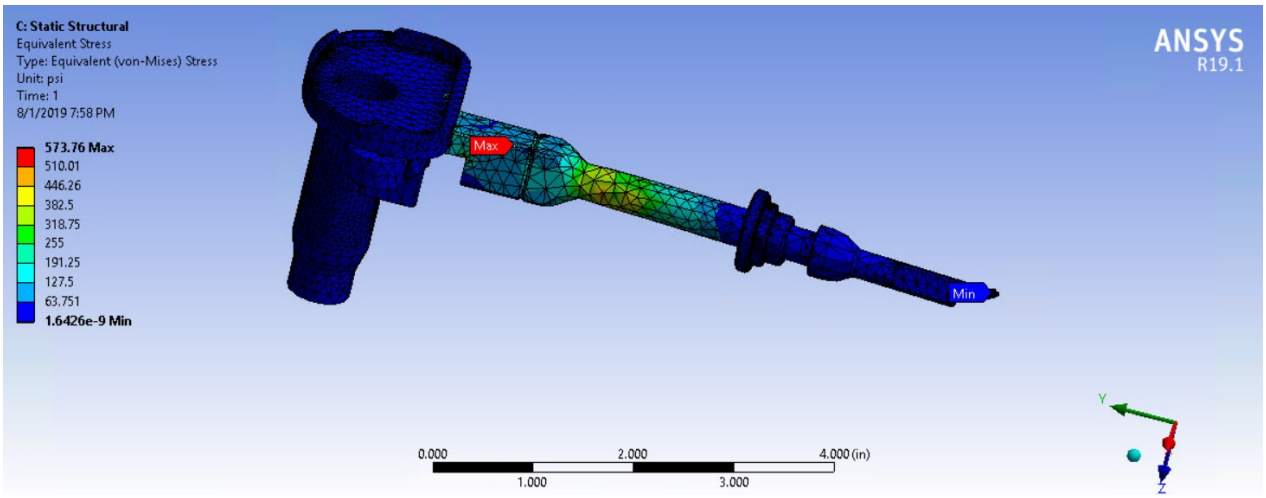


Figure 7.7: FEA universal counter wrench and TLS baseplate size 1

- **Case 4: Universal counter wrench and TLS baseplate (size 7)**

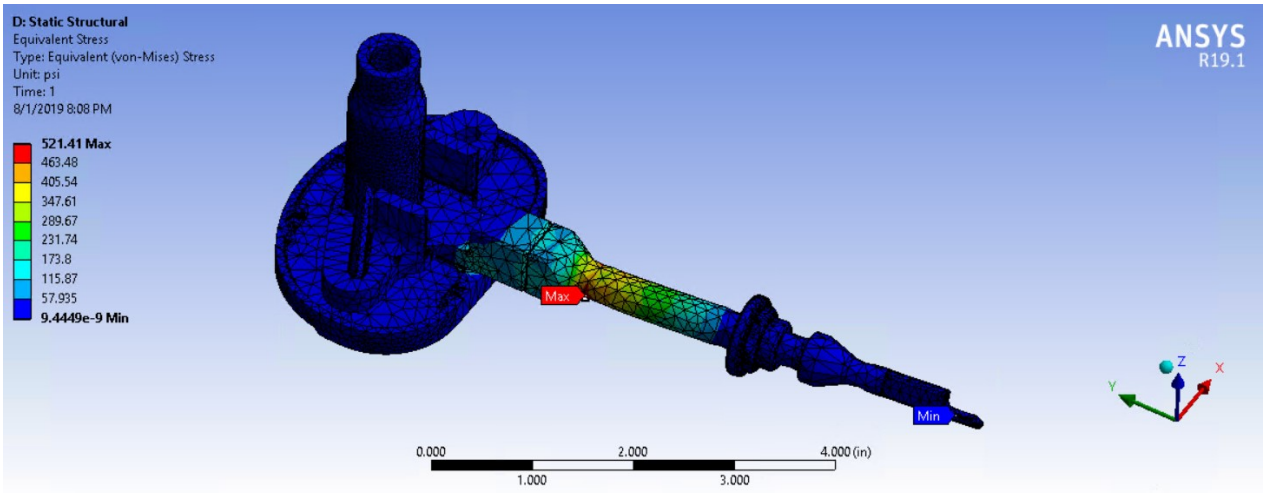


Figure 7.8: FEA universal counter wrench and TLS baseplate size 7

- **Case 5: Universal counter wrench and TS femoral component (size 8)**

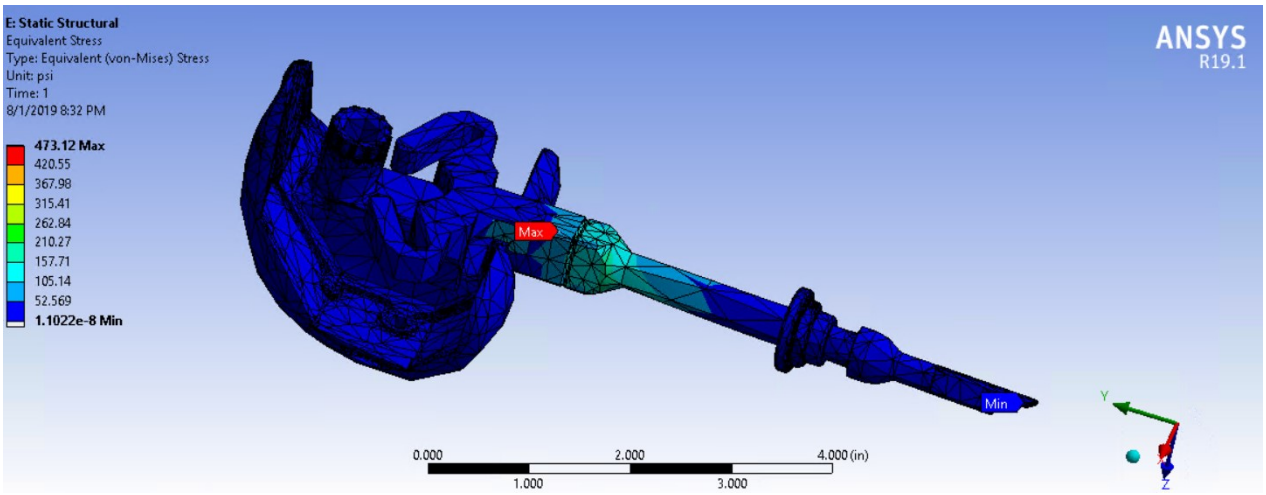


Figure 7.9: FEA universal counter wrench and TS femoral component size 8

- **Summary of results**

  Table 7.2 presents the result of all the cases of engagement of universal counter wrench with TS baseplate (size 1 & 8), TLS baseplate (size 1 & 7), TS femoral component (size 8).

Table 7.2: FEA results summary

Parameter	TS Baseplate Size 1	TS Baseplate Size 8	TLS Baseplate Size 1	TLS Baseplate Size 7	TS Femoral (Size 8)
Stress	572.02 psi	551.32 psi	573.76 psi	521.41 psi	473.12 psi

7.2.3 Tolerance analysis

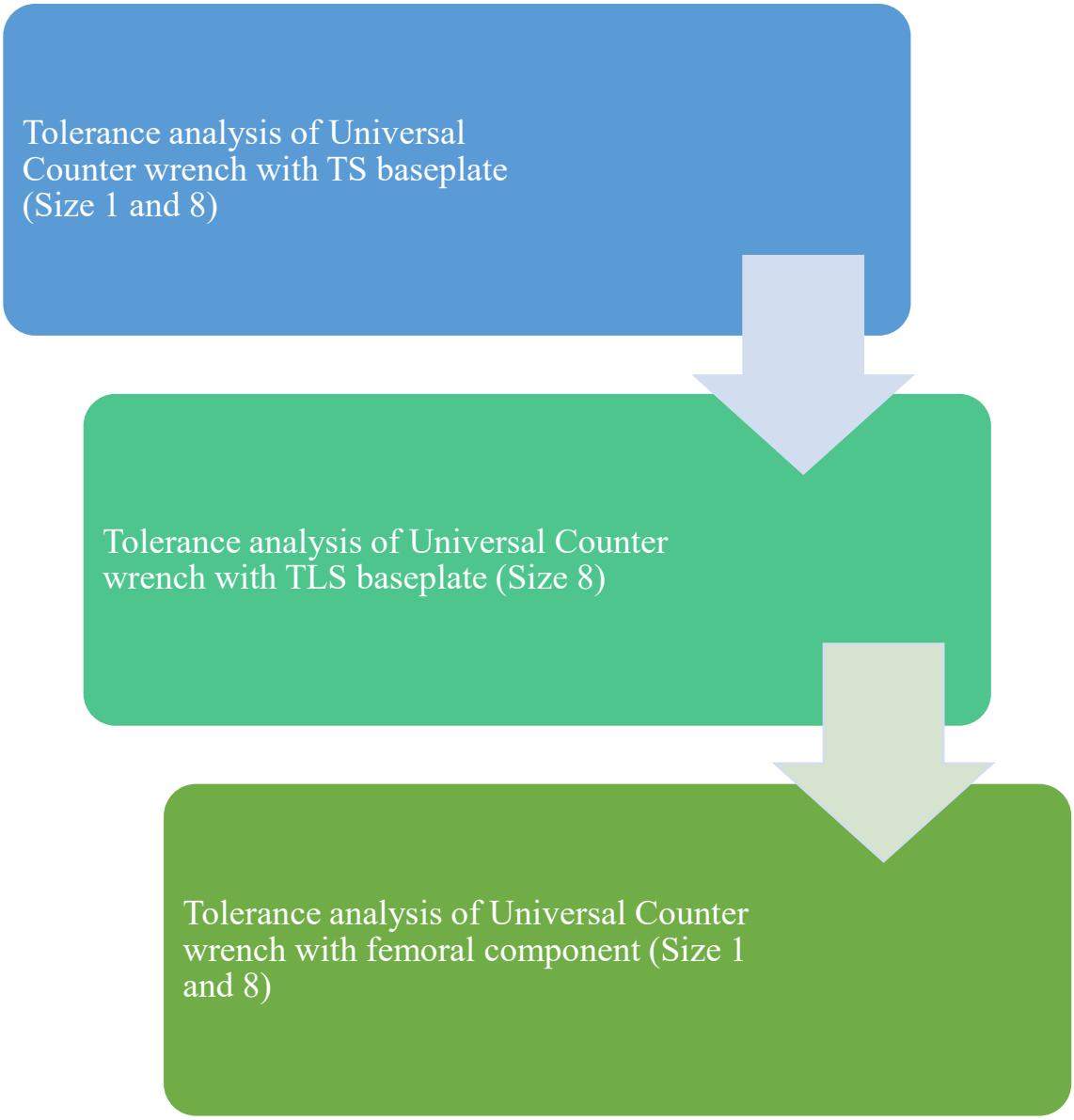


Figure 7.10: Universal counter wrench tolerance analysis workflow

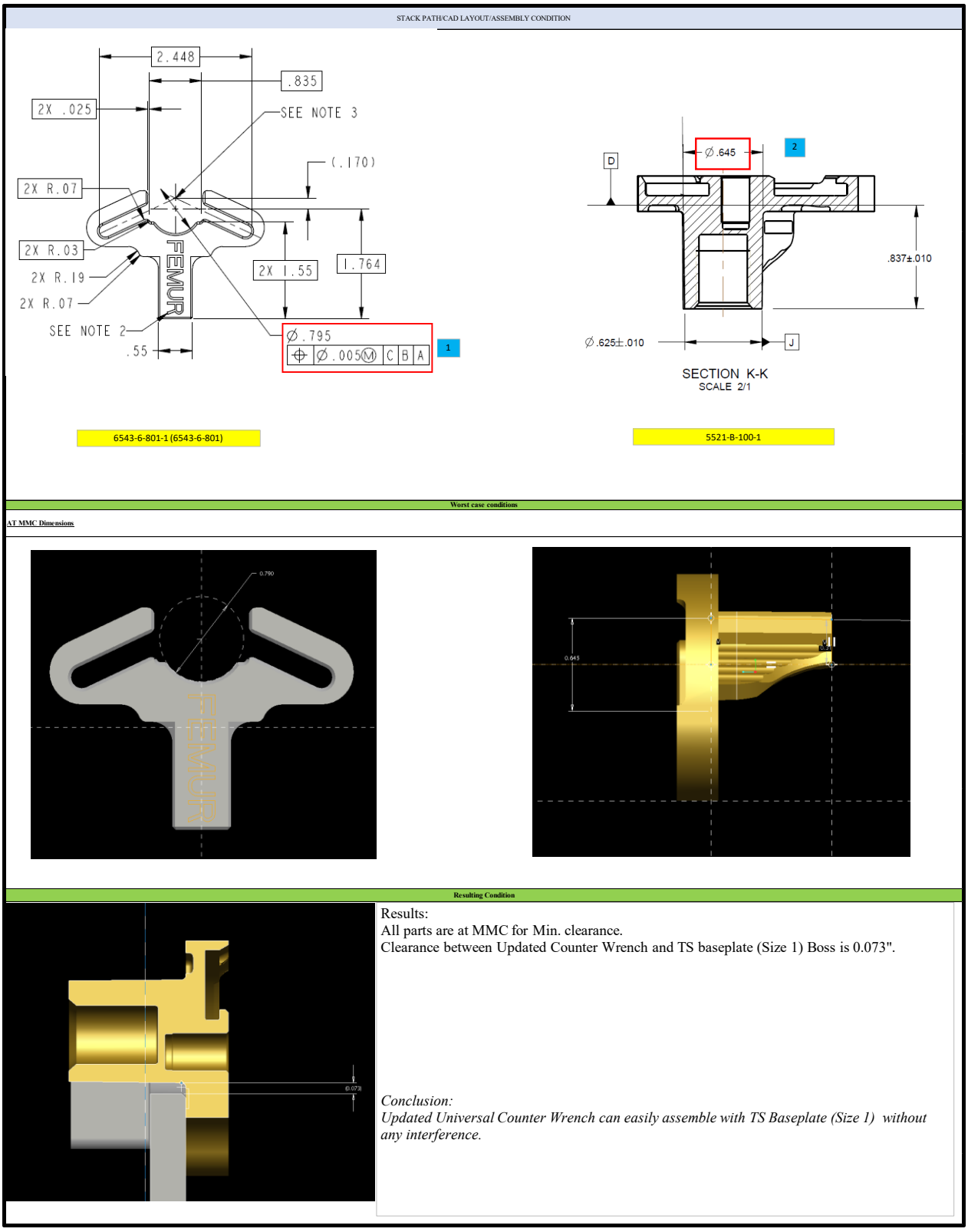


Figure 7.11: Assembly of Universal Counter Wrench with TS Baseplate Size 1 (Tolerance report T01XXX)

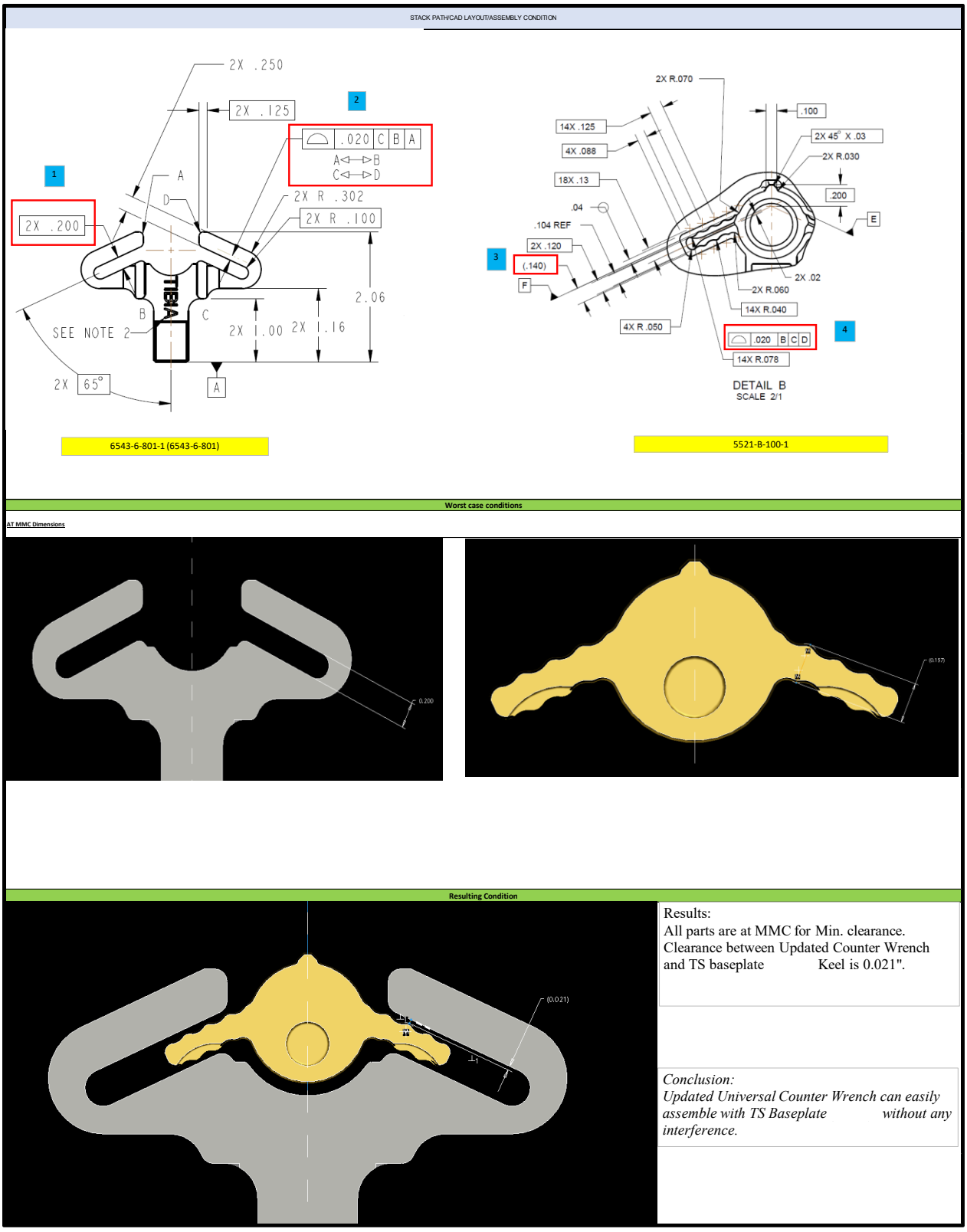


Figure 7.12: Assembly of Universal Counter Wrench with TS Baseplate size 8 (Tolerance report T02XXX)

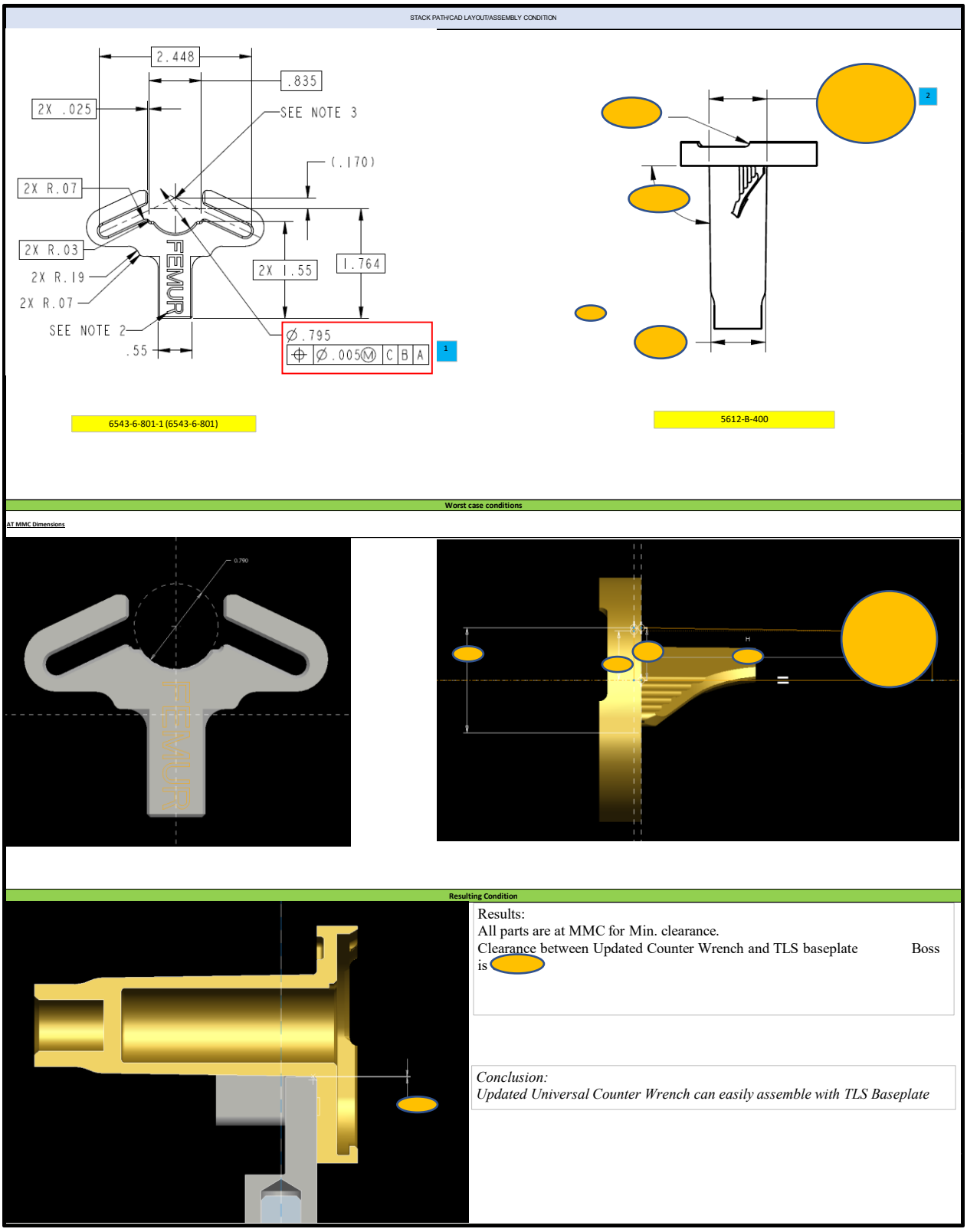


Figure 7.13: Assembly of Universal Counter Wrench with TLS Baseplate size 8 (Tolerance report T03XXX)

Note: Since the product is not launched yet in the market, some of the dimensions are hided as per the company policy.

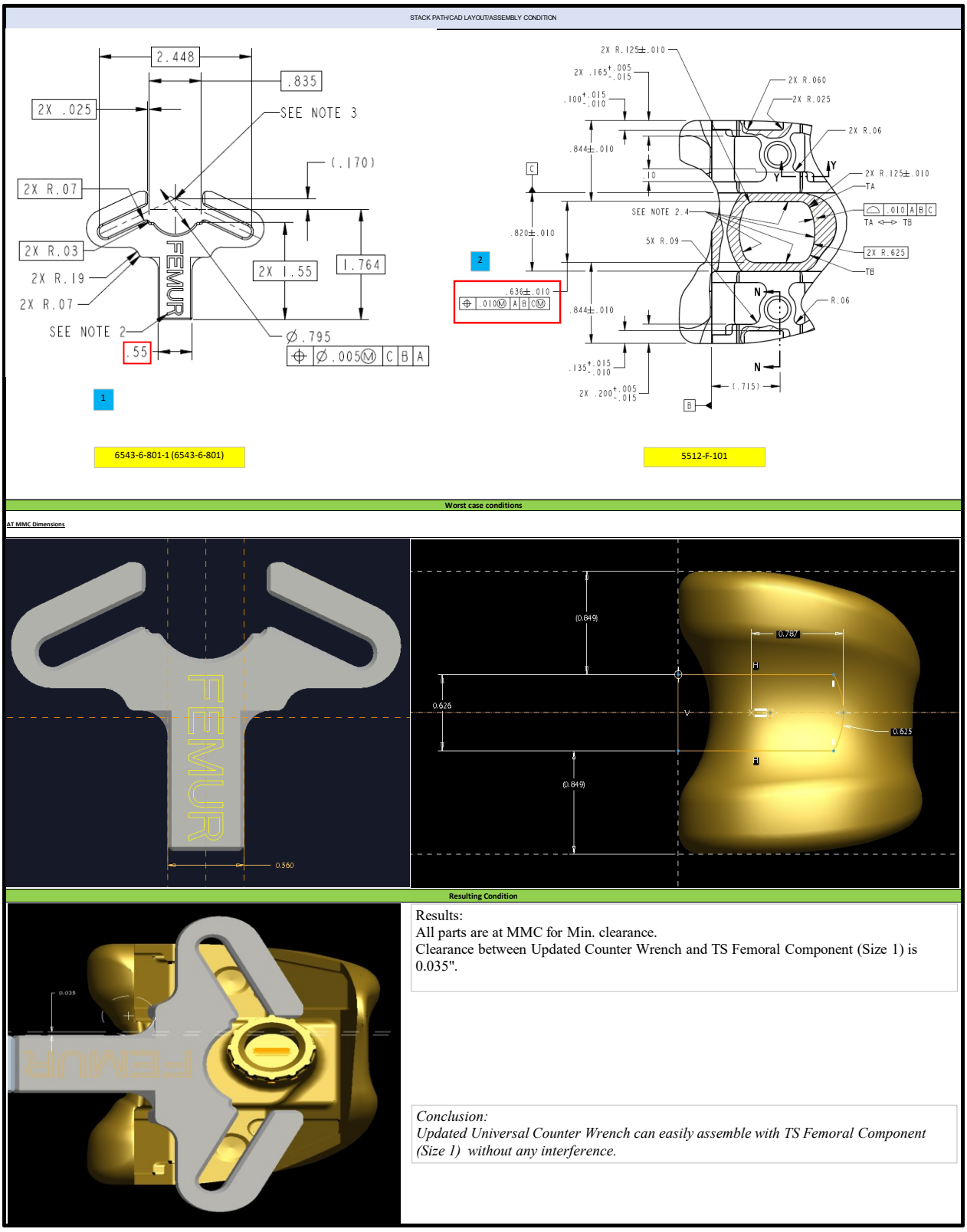


Figure 7.14: Assembly of Universal Counter Wrench with TS Femoral Component size 1 (Tolerance report T04XXX)

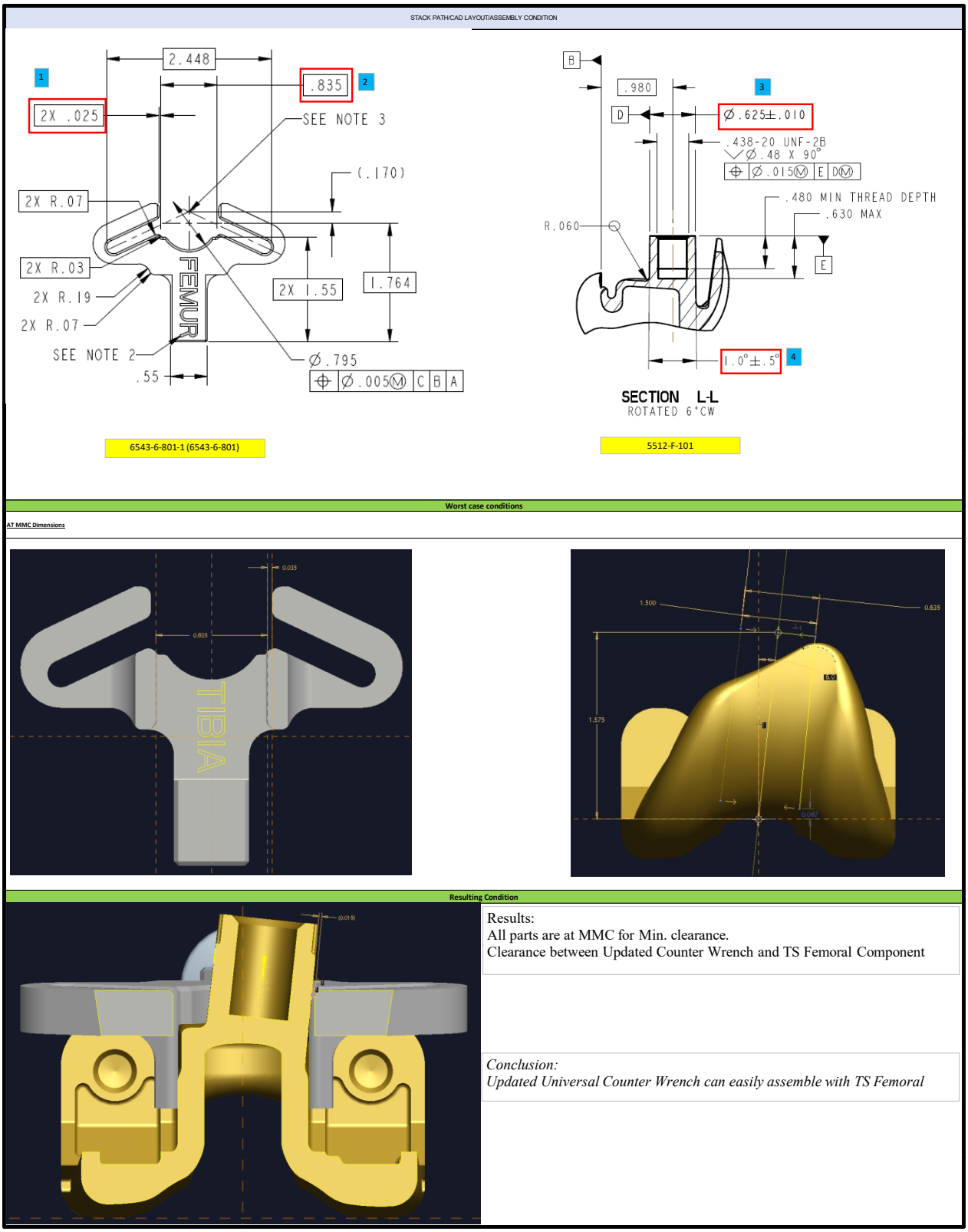


Figure 7.15: Assembly of Universal Counter Wrench with TS Femoral Component size 8 (Tolerance report T05XXX)

7.2.4 Development of Prototypes

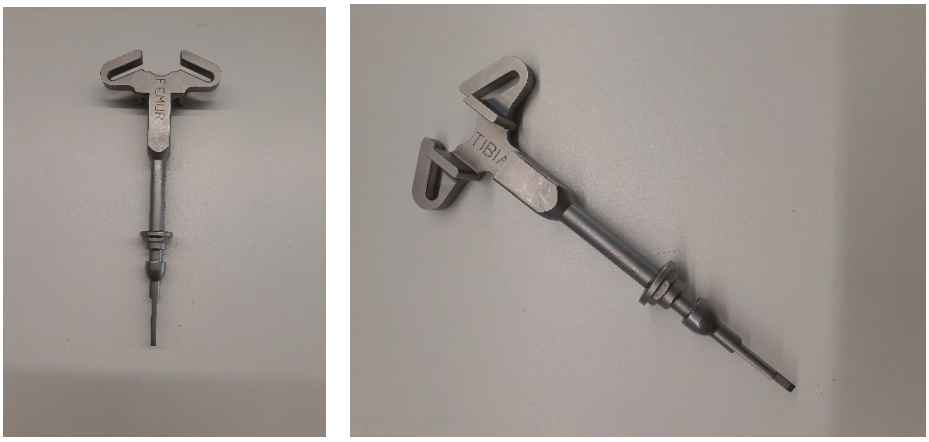


Figure 7.16: Universal counter wrench prototype (Metal)

7.3 Instrument 2: Poly Sleeve/Filler Bushing Removal Tool

7.3.1 Finite Element Analysis

Based on the design calculation two design concepts were possible, and to narrow down to one finite element analysis was done considering the poly sleeve removal case, the conditions regarding the material, mesh, method is discussed in chapter 6. The results obtained from finite element analysis are discussed in table below. The design concept one experiences less stress as compared to design concept 3, but location of failure is also important, design concept 1fails at the grooves which are provided in the threads for debris removal while the design concept 3 fails on the threads which starts cutting of threads.

Table 7.3: Failure mode and stress for design concept 1 and 3.

Design Concept	Stress (MPa)	Location of Max stress
1	1.3	Groove
3	3.2	Starting threads

7.3.2 Ergonomics and functionality perspective:

The two concepts are than checked in the engineering lab (Report R01XXX) with surgeons to check them in terms of functionality and ergonomics, and their feedback was recorded, in terms of functionality both concepts were able pull out poly sleeve, in terms of ease of handling design concept 3 was found to be complicated. Also, the surgical instruments are

transferred in trays for surgeries and design concept 3 will occupy larger space due to horizontal shaft in the middle.

7.3.3 Manufacturing Perspective:

The two design concepts sent to the vendor to check that which design is easy to manufacture and cheaper as far as cost is concerned. Design concept 1 can be manufactured as a monolithic component, i.e. no additional operation such as drilling, welding is required on it whereas design concept 3 has shaft in the middle for which first a hole must be drilled in the shaft and then the two shafts must be welded together. Therefore, two additional processes will be additionally be required for manufacturing design concept 3. Therefore, it is going to cost more as compared to design concept 1. Based on the FEM, ergonomics, and manufacturability analysis design concept 1 is finalized and it will now undergo benchtop testing to verify pulling off filler bushing

7.3.4 Benchtop Testing Results

7.3.4.1 Axial pull test

Table 7.4: Experimental results for axial load.

	Specimen	**Maximum load (N)**	**Extension at Maximum load (mm)**
1	Part 1	15168.48	8.76
2	Part 2	11011.58	4.55
3	Part 3	21243.79	5.77
Mean		15807.95	6.36
Standard Deviation		5145.99	2.16

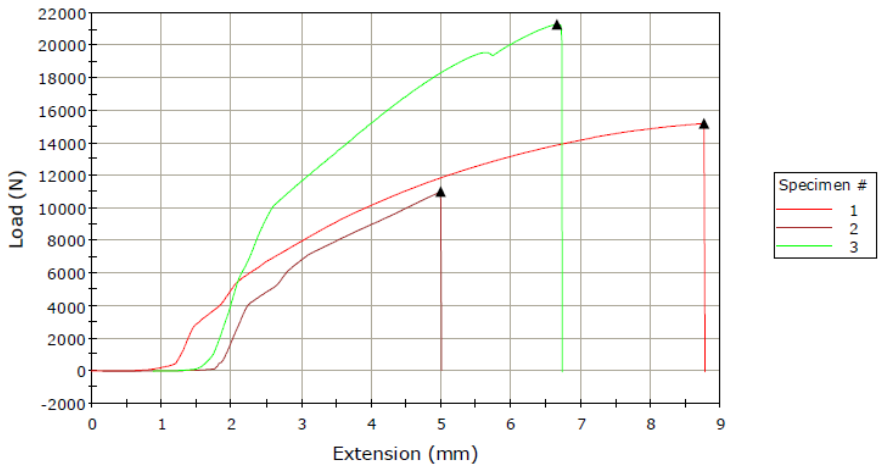


Figure 7.17: Axial failure load for all 3 specimens

- Failure mode for axial load is found to be by fracture at shaft above threads

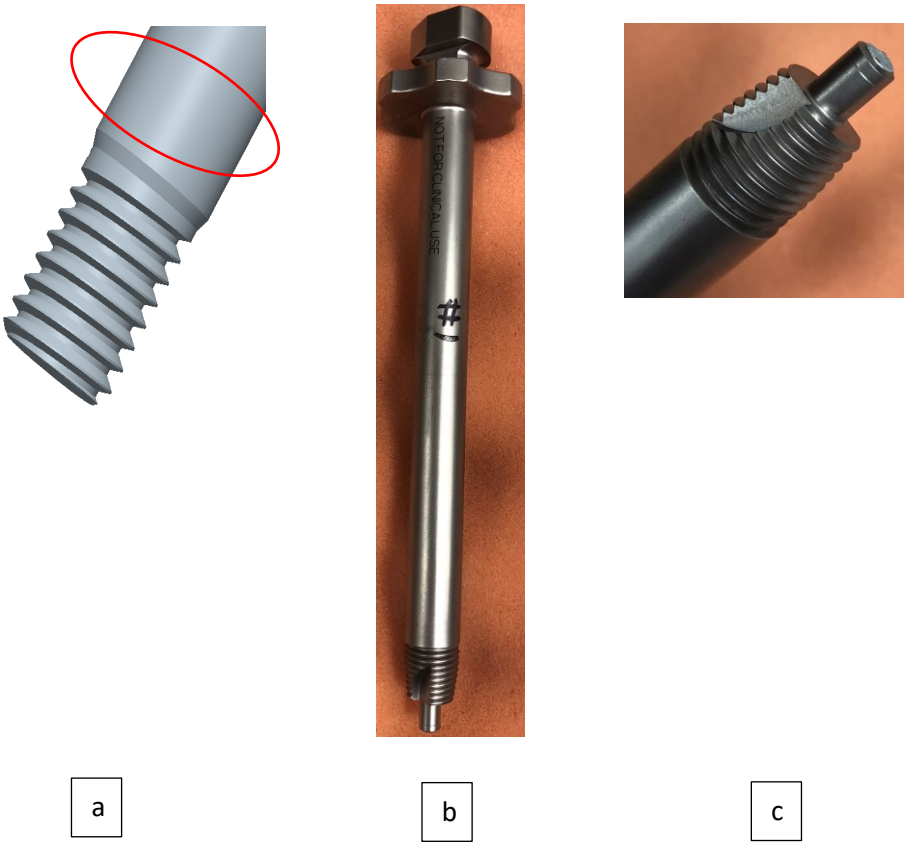


Figure 7.18: Failure location: Axial pull test

7.3.4.2 Cantilever Test:

Table 7.5: Experimental results for cantilever load.

	Specimen	Maximum load (N)	Extension at Maximum load (mm)
1	Part 1	1410.64	5.04
2	Part 2	880.55	5.92
3	Part 3	1379.21	5.05
Mean		1223.47	5.34
Standard Deviation		297.38899	0.50379

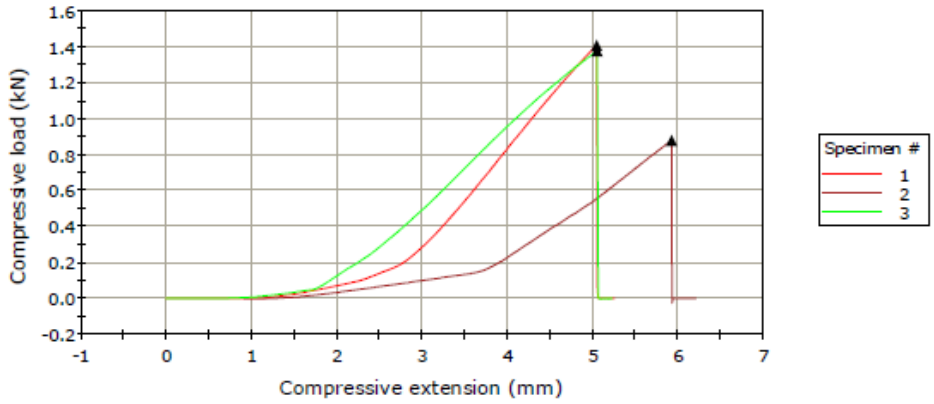


Figure 7.19: Cantilever failure load for all 3 specimens

- Failure mode for cantilever load is found to by fracture at threads runout

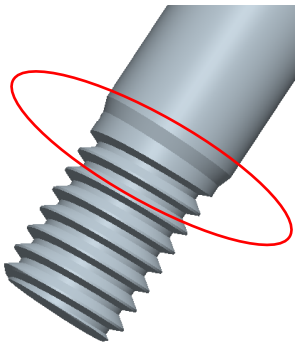


Figure 7.20: Failure location: Cantilever test

7.3.5 **Tibial sleeve removal evaluation**:

The key finding from this evaluation is listed below.

- Some downward pressure required while turning to engage sleeve.
- Two turns enough for sleeve engagement.
- OD of sleeve expands when tool engaged resulting in slightly more effort to remove.
- No mallet required for sleeve removal.
- No Damage to baseplate or tool because of evaluation.

Figure 7.21: Removal tool engaged with poly sleeve

Chapter 8

Conclusions, learnings and future scope

8.1 Conclusion

The present work focuses on the design and development of two instruments i.e. universal counter wrench and poly sleeve/filler bushing removal tool under the umbrella of Triathlon Limb Salvage Program. The purpose of counter wrench is to hold the TS and TLS baseplate and TS femoral component and to apply counter torque while final tightening of the stem as well as unlock the offset adapter trial while the removal tool is supposed to pull out the filler bushing and poly sleeve in intraoperative and hinge case, respectively. The design calculation is performed taking into consideration the compatibility of the mating instruments and functionality of the instruments. The design is made such that it fulfills the requirement from cleanability and sterility. The material selected is biocompatible with the human body and ensures no harm to the patient. The design concepts are verified with methods like tolerance analysis, finite element analysis and benchtop testing to ensure the correctness of theoretical results. The prototypes for the finalized design concepts are made in the manufacturing facility and inspected by the vendor to ensure the dimensions and tolerances are as per the requirement.

The work presented here is summarized as follows:

- Multiple concepts are developed for single design requirement and then optimized according to the loading conditions and intent of use.
- The design concept was verified using different methods like tolerance analysis, finite element analysis to verify the theoretical calculations.
- The design concepts were verified with benchtop testing which proved the robustness of the design in terms of strength and fulfilled the criteria of functionality.
- The presented work is a testimonial of development of “New Product Development” in the industrial environment and comprises of various stages such as developing a concept from scratch and then optimizing it as per the dimensional constraints, and after the design gets matured enough it is tested and verified for the intended use.

8.2 Learnings

The triathlon limb salvage projects deal with hinge case of the knee and therefore the instrumentation and implant design become complex. The design concept development process was challenging as well as a good learning experience. The industrial exposure helped in applying the theoretical concepts in practical environment and to learn the various aspects of design. The present study also helped in understanding the manufacturing aspects of the design, as anything can be created in the software but not everything is manufacturable; there are limits to design and to understand that was a big learning.

The major learning involves the following:

- **Concept development:** In the concept development phase the learning included implementing different ideas to fulfill the needs of surgeons, marketing, cleaning and sterility departments as well as how the product can be better than the competitors.
- **Engineering analysis:** In engineering analysis the key learning included verification of the design concept, comparison of engineering drawings.
- **Design Verification:** Design verification means to confirm that the design inputs are completely satisfied. It is a theoretical exercise designer to make sure that no requirements are missed in the design. In this work the tolerance analysis is done for the universal counter wrench, while bench top testing and FEM is performed for the poly sleeve/filler bushing removal tool.
- **Manufacturing aspects of design:** The manufacturing aspects of design is one of the most important aspect of design as any concept can be modelled in the software, but the role of the design engineer is to understand how the design product will be manufactured, i.e. by which processes the product will be manufactured and how the cost can be reduced.
- **Design Validation:** Design validation is a practical exercise that ensures that the product, as built, will function to meet the requirements. In this work the validation is done with surgeon's presence in the benchtop testing and validation by design engineers in engineering labs.

8.3 Future Scope

The triathlon limb salvage is a huge project and includes large number of instrumentation and implants. The present work is performed under defined constraints such as limitation to material and its composition, limitation with biocompatibility, limitation with size and weight of the instrument, challenges with respect to cleanability and sterility of the instrument. More research can be performed with respect to material technology which can aim towards a biocompatible material which can offer less wear, light weight, and anti-corrosion properties.

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