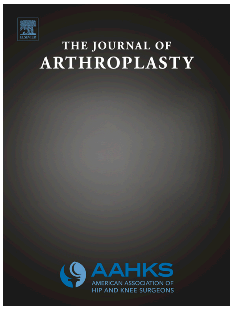

Development and Verification of Novel Porous Titanium Metaphyseal Cones for Revision Total Knee Arthroplasty

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Development and Verification of Novel Porous Titanium Metaphyseal Cones for Revision Total Knee Arthroplasty

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Development and Verification of Novel Porous Titanium Metaphyseal Cones for Revision Total Knee Arthroplasty

Abstract

Background: Porous metaphyseal cones are widely used in revision knee arthroplasty. A new system of porous titanium metaphyseal cones has been designed based on the femoral and tibial morphology derived from a CT based anatomical database. The purpose of this study is to evaluate the initial mechanical stability of the new porous titanium revision cone system by measuring the micromotion under physiologic loading compared to a widely-used existing porous tantalum metaphyseal cone system.

Methods: The new cones were designed to precisely fit the femoral and tibial anatomy, and 3D printing technology was used to manufacture these porous titanium cones. The stability of the new titanium cones and the widely used tantalum cones were compared under physiologic loading conditions in bench top test model.

Results: The stability of the new titanium cones was either equivalent or better than the tantalum cones. The new titanium femoral cone construct had significantly less micromotion compared to the traditional femoral cone construct in 5 of the 12 directions measured ($p<0.05$) while no statistical difference was found in 7 directions. The new porous titanium metaphyseal tibial cones demonstrated less micromotion in medial varus/valgus ($p=0.004$) and posterior compressive micromotion ($p=0.002$) compared to the traditional porous tantalum system.

Conclusion: The findings of this biomechanical study demonstrate satisfactory mechanical stability of an anatomical-based porous titanium metaphyseal cone system for femoral and tibial bone loss as measured by micromotion under physiologic loading. The new cone design, in combination with instrumentation that facilitates surgical efficiency, is encouraging. Long term clinical follow up is warranted.

Keywords: Knee revision cones, 3D printing, porous titanium, micromotion

Background

Revision total knee arthroplasty (TKA) is a growing procedure with varying case complexity. It is estimated that the number of revision TKAs performed in the United States is projected to grow from 38,000 in 2005 to 268,200 by the year 2030 placing a large burden on health care costs [1, 2]. Complex revision cases often present with significant metaphyseal bone loss, which may be due to infection, osteolysis, loosening of the primary implant or iatrogenic loss with implant resection. Larger bone defects require more extensive reconstructive efforts and have been traditionally managed with the use of large structural allografts [3-12], impaction bone grafting techniques with or without mesh augmentation [13-16], fabrication of custom prosthetic components [17], or the use of specialized hinged knee components [18]. In the past decade, large metaphyseal defects have been effectively managed with partially porous metal stepped “sleeves” or porous tantalum metaphyseal cones, both of which have excellent early term results [19-27]. Addressing the bone loss can be challenging and the optimal reconstruction method is often debated and remains unknown.

While porous metaphyseal cones have shown high success rates in the short and mid-term [19, 22, 23, 25, 26], the existing cones have demonstrated some limitations regarding geometry and size in comparison to the bony anatomy and defects encountered in revision knee arthroplasty. This creates an intraoperative challenge for the surgeon to reproducibly and accurately contour the bone to accurately match the implant chosen. The process of machining the bone accurately may be technically challenging.

A new system of porous titanium metaphyseal cones have been designed based on the femoral and tibial morphology derived from a CT based anatomical database. The purpose of this study is to evaluate the initial mechanical stability of the new porous titanium revision cone system by measuring the micromotion under physiologic loading compared to a widely-used existing porous tantalum metaphyseal cone system.

Materials and Methods

The new porous titanium metaphyseal cone implants were designed to be used with an accompanying instrumentation system to accurately and precisely fit the anatomy of the proximal tibia and distal femur. These revision cone geometries are manufactured from porous titanium (Tritanium, Stryker, Mahwah, NJ) using state of the art additive manufacturing techniques. The anatomy-based fit was achieved by using an extensive database of CT scans (SOMA, Stryker, Mahwah, NJ), which creates 3D models of the proximal tibia and distal femur and delineates the cortical boundaries of the bone. A more detailed description of SOMA and its application in implant design can be found elsewhere [28-31]. A virtual revision TKA algorithm was established on 478 tibias (mean age 58 and 40% male) and 921 femurs (mean age 58 and 56% male). The virtual intramedullary (IM) canal was identified and used to determine alignment and the bone resection plane. Revision resections of 13mm on the tibia and 11mm on the femur were performed to approximate additional bone loss inherent with implant removal during a revision procedure. Tibial baseplate sizing was determined based on rotation oriented to the medial third of the tubercle and tibial plateau coverage with less than 1mm of overhang. Femoral component rotation and sizing was based on approximating the posterior condyles to restore the posterior condylar offset and anterior cortical run-out to avoid notching and maximize anterior cortical contact. The femoral component rotation was aligned with the epicondylar axis.

A series of conical cuts were modeled in SOMA representing the shape of metaphyseal cones in three distinct geometries, (Figure 1). Figure 2 illustrates these geometries assembled to bone models with compatible revision knee components. Measurements were taken from the simulated reamer axes to the outer shell of the cortical bone to characterize acceptable cone size, as illustrated in Figures 3. Appropriate sizing and “fit” was identified by the scenario that maximized host bone contact but within the cortical boundaries of the CT scan model for a given implant. Final cone designs are illustrated in Figure 4.

Femoral micromotion

Seventeen composite femurs (Sawbones; Pacific Research, Vashon, WA) with a cancellous analog of 20 pound per cubic foot (pcf) density were used for this study. The composite femurs were prepared according to the surgical protocols of the new porous titanium design (Triathlon Tritanium Cone Augments System, Stryker, Mahwah, NJ) and the traditional porous tantalum design (Trabecular Metal Revision Knee System, Zimmer, Warsaw, IN). An experienced revision arthroplasty surgeon was enlisted to prepare the composite femurs for the traditional porous tantalum cone system in order to more accurately simulate the in vivo technique and preparation with a high-speed burr. The new porous titanium cones were prepared with a reamer-based system designed to provide an intimate fit with the bone per the surgical protocol. A series of conical reamers prepared the central base with adjacent medial and lateral “lobed” portions via controlled and guided instrumentation, Figure 5. Ten of the new porous titanium cones and seven of the traditional porous tantalum cones were implanted. Medium size femoral components from both systems were used for this test. The new cone system utilized a

50mm stem. Since the traditional system has a taller boss, a 30mm stem was used. The total boss/stem length for both systems was 75mm.

The cemented femur/cones constructs were spray painted with a black and white speckle pattern on the lateral side as per protocol for the optical micromotion measurements and then mounted to a six-station knee joint wear simulator. A line of sight optical measurement system was used to track the speckle pattern to measure micromotion between the implant construct and femur. Loading which replicated a level walking activity was simulated for 154,000 cycles. The cycle count represents the number of walking steps taken during the time for biological fixation to occur, typically a 6-week time period [32, 33]. Micromotion was measured in the x, y, and z directions at the midpoints of the anterior flange, anterior chamfer, posterior chamfer and posterior condyles between the composite femurs and the femoral components, (Figure 6).

Tibial micromotion

Mechanical testing of the new porous titanium tibial cone system (Triathlon Tritanium Cone Augments System, Stryker, Mahwah, NJ) and traditional porous tantalum cones (Trabecular Metal Revision Knee System, Zimmer, Warsaw, IN) was performed using linear variable displacement transducers (LVDT). Similar to the femoral specimens, tibial composite specimens were prepared by an experienced revision arthroplasty surgeon with the manufacturer-recommended surgical technique. The traditional porous tantalum cones were prepared with a high-speed burr to shape the proximal tibial in the approximate geometry to accept the implant in order to maximize composite bone contact. Similarly the new porous titanium tibial cones were prepared with a reamer-based system designed to provide a more intimate fit with the bone per the surgical protocol. A central conical reamer was utilized to a particular depth and a medial lobed shape prepared with a smaller conical reamer via controlled and guided instrumentation, (Figure 7). Micromotion of the cemented baseplate/cone construct with respect to the tibia was measured in 10 test models during a stair descent loading profile (Figure 8) for 10,000 cycles. The number of cycles represents 6-8 weeks of stair descent activity, again the approximate length of time for initiation of bone ingrowth to occur according to published literature [32, 33]. Six LVDTs were placed on anterior, posterior, medial and lateral aspects of the construct to measure varus/valgus displacement, internal/external rotation, compression and lift off. The test setup is shown in Figure 9.

Statistical Analysis

Unpaired T-tests and one-sided T-tests were used to evaluate statistical comparison of peak-to-peak micromotion, compression, and lift off between groups.

Results

Computer simulation using CT Database (SOMA)

The three types of cone designs shown in Figure 1 were evaluated in the CT scans available in the SOMA database. The fit results of these cone designs under various resection scenarios are presented in Tables 1 through 3. When the femoral cone geometry was paired with its optimal femoral component size, the average fit was seen to be 92% at the resection level and 60% when buried 5mm deeper into the bone (Table 3).

The analysis demonstrated that the symmetric porous titanium tibial cone geometry fit an average of 98% at the identified original resection level and 96% at the additional 5mm resection level (5mm more distal on the tibia) of all bones when used with the optimally compatible tibial baseplate (Table 1). When analyzing the fit of the asymmetric tibial cone geometry, up to 10° of rotation around the tibial axis (internal/external rotation) with respect to the tibial baseplate was allowed. This rotational freedom is desirable in a surgical application where bone void size and location is not totally aligned with the optimal tibial component rotation approximately at the level of the medial one-third of tibial tubercle width. At neutral rotation to the tibial implant, the asymmetric tibial cone geometry fit an average of 87% of bones at the resection level and 38% of bones when 5mm below the original resection level. When 10° of internal rotation was utilized, the asymmetric tibial cone fit increased to 97% of bones at the resection level and 78% of bones when 5mm sub-flush (Table 2).

Femoral Micromotion

The micromotion results for the new porous titanium and traditional porous tantalum femoral cone designs are presented in Table 4. The new titanium femoral cone construct had significantly less micromotion compared to the traditional femoral cone construct in 5 of the 12 directions measured ($p<0.05$, Table 4). These results were noted at the posterior condyle, anterior flange and anterior chamfer locations. Results in other directions of motion were comparable between devices (Table 4).

Tibial Micromotion

The tibial micromotion test results are presented in Table 5. The new porous titanium tibial metaphyseal cone system demonstrated similar micromotion values under loading compared to traditional porous tantalum cone system with the numbers available ($p \geq 0.05$) in internal external rotation, varus/valgus and lift off during a simulated stair descent activity. The new porous titanium metaphyseal tibial cones demonstrated less micromotion in medial varus/valgus (p=0.004) and posterior compressive micromotion (p=0.002) compared to the traditional porous tantalum system.

Discussion

Porous metaphyseal cones and sleeves have emerged as a useful method to accomplish the goal of providing structural support for tibial and femoral implants as well as filling larger bone voids in revision TKA [19-27]. Short and medium term evidence on tantalum cones now exists that supports the use of these implants in the reconstruction of large tibial defects in revision TKA [19, 21-26]. Despite these clinical results, the surgical preparation for these devices remains technically challenging. This prompted the innovation of a new porous titanium metaphyseal cone system with an anatomically based shape from three-dimensional modeling of an extensive CT database. The main objective of the accompanying instrumentation was to facilitate efficient bone preparation with an intimate press-fit and cortical contact for maximal stability. Implant mechanical stability is essential for these cementless devices to successfully osseointegrate and reconstitute the femoral or tibial metaphysis providing mechanical support for the implant and associated cement mantle. The assumption in this study that the traditional porous tantalum metaphyseal cones are an appropriate comparison for what constitutes adequate mechanical stability is supported by the successful clinical results of these devices. Early outcomes with highly porous metaphyseal tantalum cones utilized in large tibial defects for revision total knee arthroplasty have been reported by multiple authors [25, 26]. Meneghini et al reported a series of fifteen revision knee arthroplasties that were performed with a porous tantalum metaphyseal tibial cone and were followed for a minimum of two years. All tibial cones were found to be osseointegrated radiographically and clinically at final follow up with no reported failures [25]. In a series of sixteen revision total knee arthroplasties with severe tibial defects, Long and Scuderi reported good results with osseointegration of the porous tantalum cone 14/16 cases at a minimum 2-year follow up [26]. Similar results have been reported in the femoral version of the porous tantalum metaphyseal cones [21-23]. Howard et al. reported on twenty-four femoral porous tantalum cones in complex revision total knee arthroplasty and found no radiographic failure or loosening at a minimum two years follow up [23].

Longer-term results are also available with highly porous tantalum metaphyseal tibial cones, and have demonstrated continued good results [19]. Kamath et al. recently reported on 66 highly porous tibial metaphyseal cones used in Type 2 and 3 AORI tibial defects. At a minimum 5-year follow-up, the authors report one revision for aseptic loosening and one radiograph with progressive radiolucencies concerning for fibrous ingrowth with a greater than 95% revision-free survivorship at latest follow up[19].

The results of this study demonstrate the relative equivalency, and in some specific locations superiority, of the new porous titanium cones to the clinically successful traditional porous tantalum cones with respect to mechanical stability as measured by micromotion under physiologic loading. By virtue of the successful clinical results of the porous tantalum cones in multiple series, and similarities between the porous structure of porous tantalum and titanium, the porous titanium cones are expected to perform well in theory. This methodology of demonstrating mechanical stability of an innovative design compared to a successful predicate is accepted in the peer-reviewed literature [34-37].

In addition to the top priority of clinical success, surgical efficiency is a very important consideration for patients, surgeons and the healthcare system. With the ever growing burden of revision knee arthroplasty and the projections of increasing demand for these procedures, it is essential that arthroplasty surgeons maximize their surgical efficiency in these lengthy and complex procedures. These new porous titanium metaphyseal cones were designed to maximize surgical efficiency in several ways, including through a geometric implant fit derived from an anatomical CT database and a streamlined reamer-based instrumentation that eliminates non-instrumented manual high-speed burring.

Our study does have limitations. First, the mechanical testing performed in this study was performed on sawbones composite replicate femoral and tibial specimens, which may not accurately represent the in vivo scenario of revision bone. However, we believe the mechanical stability of devices is appropriately compared in these specimens due to their homogeneity, which minimizes confounding variables associated with cadaveric specimens. Further, this testing methodology has been accepted in the hip and knee arthroplasty peer-reviewed literature [34-37]. Second, although the biologic fixation potential of highly porous titanium has been studied and supported [38], equivalency in osseointegration and subsequent interfacial strength of porous titanium compared to the clinically successful porous tantalum has not been fully elucidated. This underscores the need for close clinical follow up of these devices in the short and long term in order to corroborate these biomechanical findings.

In summary, the findings of this biomechanical study demonstrate satisfactory mechanical stability of an anatomical-based porous titanium metaphyseal cone system for femoral and tibial bone loss as measured by micromotion under physiologic loading. The findings of optimized mechanical stability of these new titanium cones compared to the clinically successful porous tantalum cones, in combination with instrumentation that facilitates surgical efficiency, is encouraging. However, close clinical follow up is warranted and should include radiographic and clinical outcomes in the early and longer term.

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Figure Legends

Fig 1: Modeling of three distinct conical geometries

Fig 2: Cone geometries assembled to bone models

Fig 3: Illustrates of measurements from simulated reamer axes to cortical bone that was used to determine cone fit

Fig 4: Illustration of the design of the symmetric, asymmetric and the femoral cones manufactured by additive manufacturing using porous titanium

Fig 5: Illustration of femoral preparation using central and medial/lateral lobe reamers

Fig 6: Micromotion measurement locations and direction

Fig 7: Illustration of tibial preparation using central and medial/lateral lobe reamers

Fig 8: Loading profile used in the study

Fig 9: Test set up for tibial micromotion test

Table 1: Simulated average fit results of the symmetric tibial cones for various orientations

Orientation	**Average percentage of fit**
Resection level, neutral rotation	98%
5mm below resection, neutral rotation	96%

Table 2: Simulated average fit results of the asymmetric tibial cones for various orientations

Orientation		**Average percentage of fit**
Resection level	Neutral rotation	87%
	10° Internal rotation	97%
5 mm below resection	Neutral rotation	38%
	10° Internal rotation	78%

Table 3: Simulated average fit results of the femoral cones for various orientations

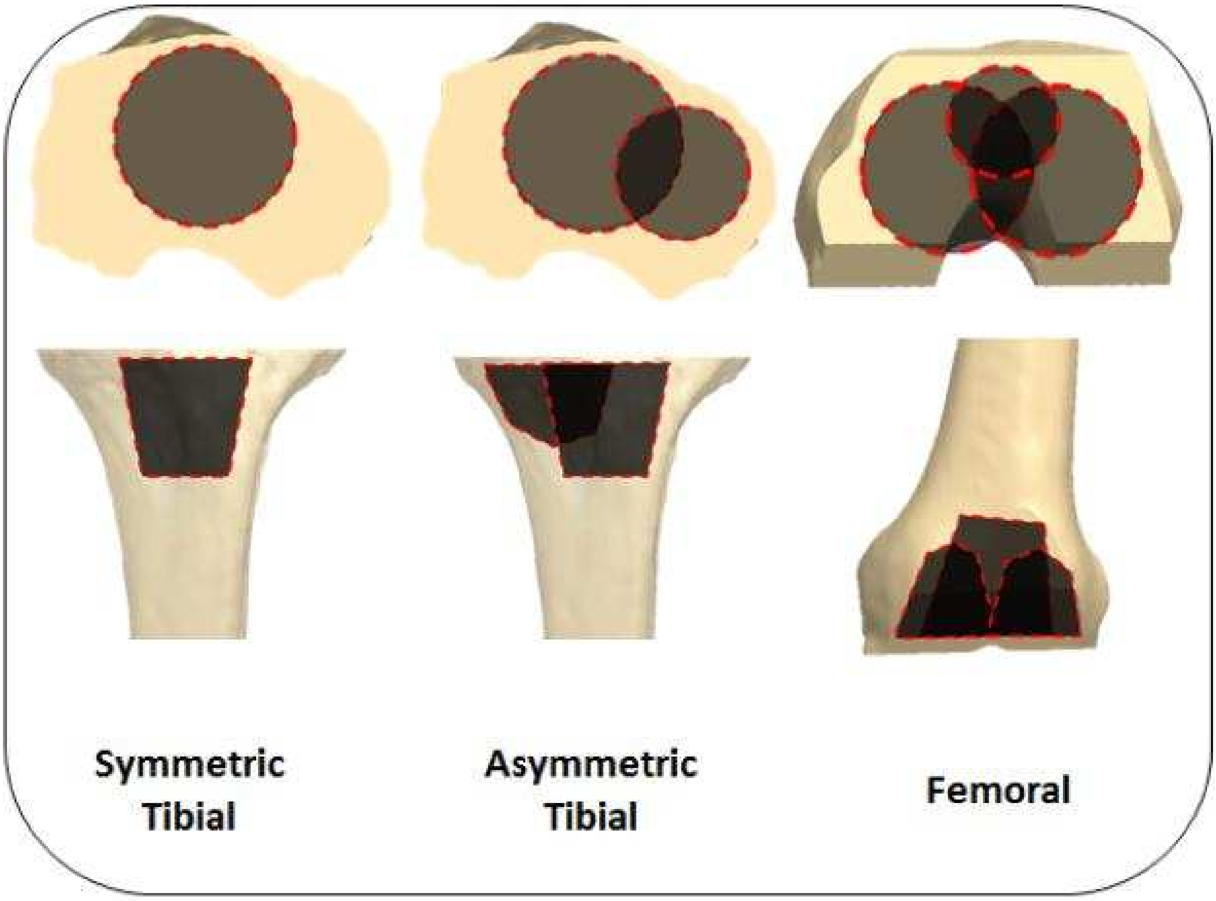
Orientation	**Average percentage of fit**
Resection level, neutral rotation	92%
5mm below resection, neutral rotation	60%

Table 4: Femoral micromotion results for the two cone systems. Bolded values indicate significant difference between New and Traditional Systems (p<0.05).

Design		**Posterior condyle**			**Anterior flange**			**Anterior Chamfer**			**Posterior Chamfer**		
		x	y	z	x	y	z	x	y	z	x	y	z
New cone system	Average	12.31	11.95	34.1	14.4	14.38	24.79	13.1	16.6	34.8	13.6	13.57	27.2
	SD	5.57	6.51	18.6	10.3	3.97	4.96	7.24	6.05	9.24	4.58	4.58	9.53
	N	10	10	10	10	10	10	10	10	10	10	10	10
Traditional cone system	Average	24.9	14.89	35.92	33.4	20.3	26.4	32.2	27.4	27.6	31.3	31.3	28.95
	SD	6.24	3.4	14.7	17.7	14.7	11.9	13.3	15.3	10.4	22.2	8.64	5.38
	N	7	7	7	7	7	7	7	7	7	7	7	7
t- test	p- value	**0.001**	0.122	0.388	**0.007**	0.169	0.374	**0.004**	0.61	0.917	**0.04**	**0.039**	0.319

Table 5: Tibial micromotion results for the two cone systems. Bolded values indicate significant difference between New and Traditional Systems (p<0.05).

Design		**Varus/Valgus motion**		**Internal/external rotation**		**Compression and lift off**	
		Medial S/I (mm)	Lateral S/I (mm)	Medial A/P (mm)	Lateral A/P (mm)	Posterior S/I (mm)	Anterior S/I (mm)
New cone system	Average	0.029	0.05	0.021	0.011	0.036	0.013
	SD	0.012	0.009	0.008	0.012	0.007	0.003
	N	10	10	10	10	10	10
Traditional cone system	Average	0.064	0.055	0.023	0.008	0.069	0.033
	SD	0.025	0.009	0.005	0.003	0.02	0.029
	N	10	10	10	10	10	10
t- test	p- value	**0.004**	0.105	0.247	0.363	**0.002**	0.064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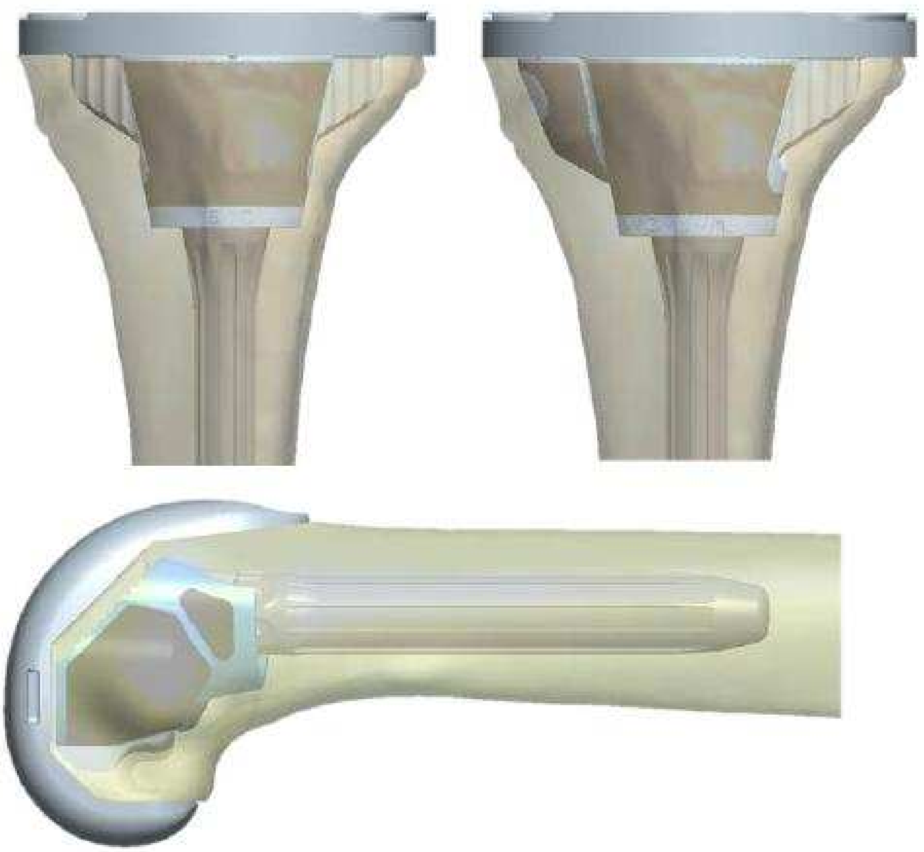
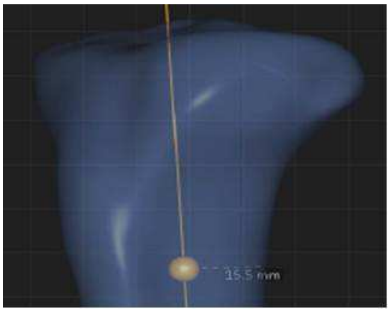
Asymmetric Tibial
Femoral

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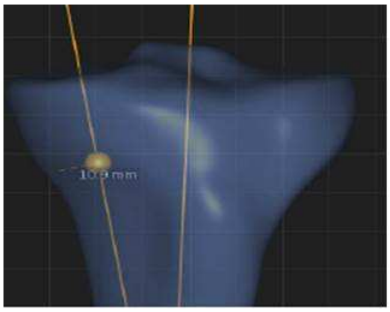
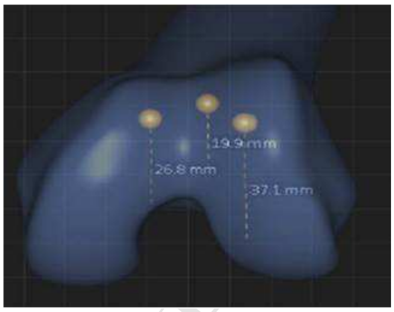
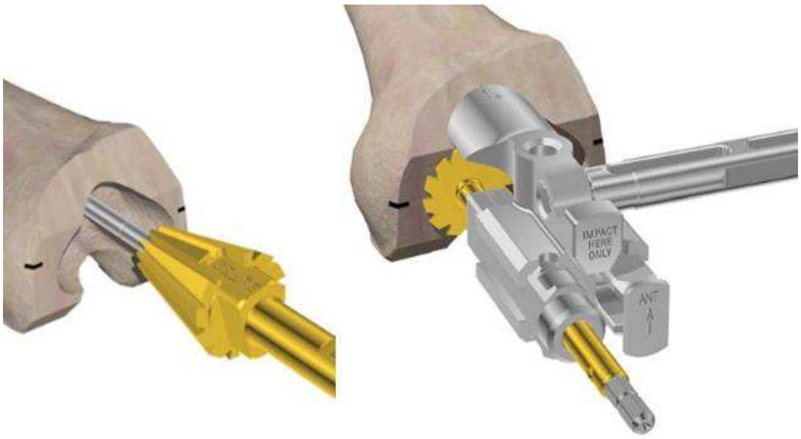
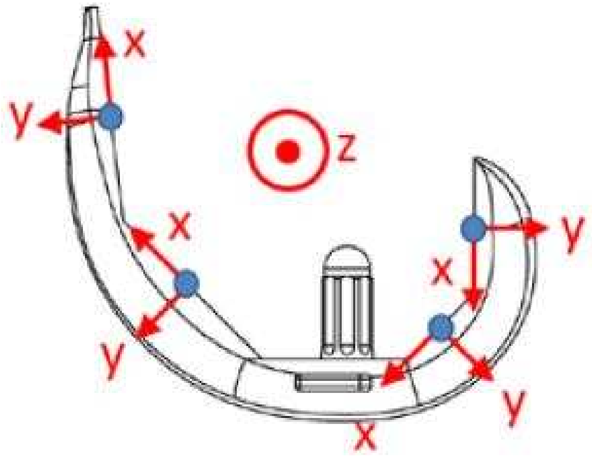
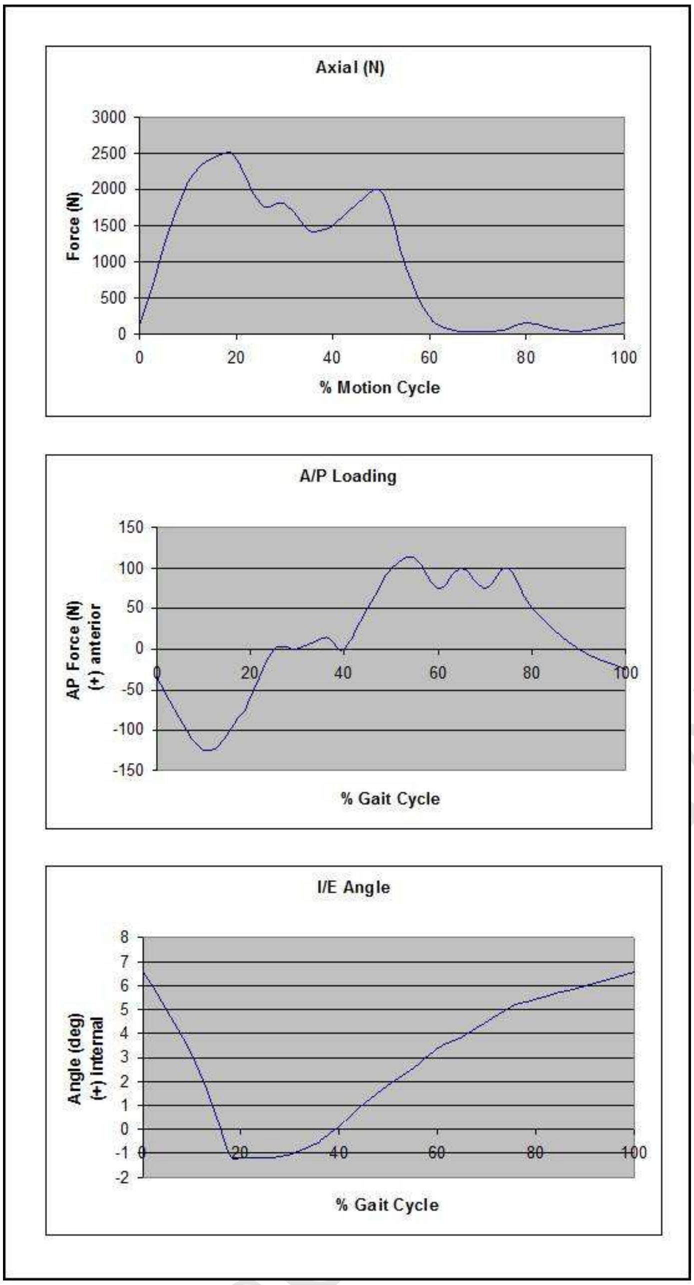

10.9 mm


19.9 mm
26.8 mm
37.1 mm


IMPACT
HERE
ONLY
ANT


x
y
z
x
y
y
x
x
y


Axial (N)
Force (N)
3000
2500
2000
1500
1000
500
0
0
20
40
60
80
100
% Motion Cycle
A/P Loading
AP Force (N)
(+) anterior
150
100
50
0
-50
-100
-150
0
20
40
60
80
100
% Gait Cycle
I/E Angle
Angle (deg)
(+) Internal
8
7
6
5
4
3
2
1
0
-1
-2
0
20
40
60
80
100
% Gait Cycle