PERFORMANCE EVALUATION OF KINECTIV® TECHNOLOGY

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Background: Recent advances in modularity of total hip replacement offer the surgeon greater intraoperative flexibility to accurately reconstruct the hip joint. However, modularity raises concerns regarding fretting debris and potential fracture. The *Zimmer*® M/L Taper Hip Prosthesis with *Kinectiv*® Technology is an implant that uses modular neck and stem components to allow greater intraoperative freedom in the selection of leg length, offset and version than typical implants and to facilitate implantation with minimally invasive techniques. The purpose of this paper is to report on the testing that was conducted on the modular neck taper junction and stem including wear debris, strength and stability evaluations to assess its performance characteristics in various *in vivo* conditions.

Methods: Using finite element analysis, the worst case stem and neck constructs were identified. Bench testing was performed on fifty stems using anteverted, retroverted and straight neck configurations for ten million cycles using test methods and performance requirements previously used for the clinically successful *VerSys*® Primary Hip Stems. For fretting wear debris evaluation, quantitative accelerated corrosion fatigue testing was conducted on traditional stem/head and *Kinectiv* Stem/Neck/Head constructs. Junction stability associated with initial assembly was also evaluated. Following preliminary investigation, development of CoCr neck components was discontinued due to a five-fold increase in wear debris of the CoCr neck/Ti-6Al-4V stem construct compared to the +10.5mm head/stem construct.

Results: Fifty *Kinectiv* hip stem and neck constructs representing straight, anteverted and retroverted conditions successfully passed ten million cycles of fatigue testing without fracture. The combined mass loss of the *Kinectiv* stem and neck and the +0mm femoral head components was less than that observed with a conventional +10.5mm head/stem construct. The *Kinectiv* neck/stem junction demonstrated distraction forces in excess of those required to separate a 12/14 head/neck taper.

Conclusions: The *Zimmer* M/L Taper with *Kinectiv* Technology successfully meets Zimmer's performance strength requirements that have proven successful for many years. The *Zimmer* M/L Taper with *Kinectiv* Technology demonstrates less fretting corrosion than a clinically successful standard 12/14 taper with a long offset femoral head. The *Zimmer* M/L Taper with *Kinectiv* Technology provides a secure fit of the modular components.

Introduction

A primary goal of a successful total hip replacement is to reestablish correct hip biomechanics. Three important factors for biomechanical reconstruction of the hip are leg length, offset and avoidance of impingement. During the earlier days of total hip replacement, surgeons used monolithic stem-head implants which made head center restoration challenging. The introduction of modular heads in the early 1980s was an important advance in prosthetic design. The added versatility to the surgical procedure facilitated a more accurate and stable biomechanical reconstruction. Initial concerns about adding an additional source of particulate debris and ultimately failure were debated.[1] But these initial concerns about strength and particulate debris abated with the ensuing clinical success of these constructs and the modular head-stem prosthetic design has become the standard. Although these modular designs offer enhanced versatility, intraoperative adjustment usually affects multiple variables. For example, an increase in head length to improve muscle tension not only changes femoral offset but also increases leg length which may not be desirable. Further, modular head designs do not enable changes in femoral version which is an important consideration in regard to implant-implant impingement.

Figure 1 — *Zimmer* M/L Taper with *Kinectiv* Technology.

The *Zimmer* M/L Taper with *Kinectiv* Technology (Figure 1) is a prosthetic design that employs modular stem and neck components to allow for greater intraoperative freedom in selection of leg length, offset and version. Numerous neck options allow the surgeon to independently control leg length, femoral offset, version and proximal stem fit. This simple intraoperative flexibility in adjusting head center location and optimizing hip kinematics is particularly important during minimally invasive hip procedures. The low profile modular neck design also eases insertion to minimize soft tissue obstruction and trauma. *Kinectiv* Technology was developed giving careful consideration to the important factors of total hip replacement including leg length, offset, impingement avoidance, broad range of patient anatomies, and minimally invasive surgery to facilitate optimal restoration of hip biomechanics and patient function.[2-7]

As was the case two decades ago, concerns regarding an additional potential site of stem fracture and particulate debris generation need to be addressed. Years of extensive engineering design, laboratory testing, and clinical consultation have been devoted to optimizing the structural integrity and junction debris characteristics of the *Kinectiv* implants. The development and testing of this system not only addressed typical implant performance requirements but criteria exclusive to modular junctions as well. Specifically, these requirements included:

1. Proximal Implant Strength,
2. Fretting/Corrosion,
3. Junction Stability.

The *Zimmer* M/L Taper with *Kinectiv* Technology, after five years of extensive research and development, is a modular neck implant design that:

- meets Zimmer's performance fatigue strength requirements that have proven successful for many years;
- demonstrates less fretting/corrosion wear debris than a clinically successful standard 12/14 neck taper with a long offset femoral head;
- provides a secure fit of the modular components that exceeds that which has been demonstrated by conventional head/neck taper assemblies.

The following provides a brief historical summary of the performance of clinically successful Zimmer hip implants and the pre-clinical testing conducted that ensured success. This, in turn, provided a framework for the *Zimmer* M/L Taper with *Kinectiv* Technology testing.

Proximal Implant Strength

Design of femoral hip implants is a balance between desired features, geometry envelope, and limitations of material properties. For example, a common constraint is the shape of the proximal femoral neck and its relationship to maximum range of motion, since the design must also have adequate fatigue strength to survive *in vivo* loading conditions.

Zimmer implants are designed to rigorous internal strength requirements and published standards, which are based upon the clinical performance of both Zimmer implants and predicate non-Zimmer implants. In a recent review of over 300,000 primary *VerSys* prostheses implanted since 2000, Zimmer's reported fracture rate is less than 0.0018%. This is an outstanding statistic considering the wide range of patients and *in vivo* conditions to which these implants are subjected.[8] A review of the 2005 Annual Report of the Swedish Hip Arthroplasty Register of femoral hip stems from many manufacturers indicated 306 primary hip stem fractures out of 256,298 implantations; a fracture rate of 0.12%.[9]

Finite Element Analysis

Many iterations of design, analysis and testing were performed in the development of the final design of the *Kinectiv* stem and neck components. Prior to testing, extensive finite element analysis was conducted considering neck offset, leg length, version and stem size to identify the worst case implant combinations. For the modular design, it was important to consider the stress state as well as other factors that influence the fretting fatigue strength performance of the device, such as contact pressure (Figure 2).

The introduction of modular necks with version to allow for fine-tuning of the head center location presents a new consideration in performance strength evaluation. The anteverted and retroverted necks significantly alter the spatial relationship between the joint reaction force and the modular junction. The finite element analysis and testing of these necks involved modification of the stem orientation according to the angle of version introduced by the neck component to simulate the expected clinical situation (Figure 3).

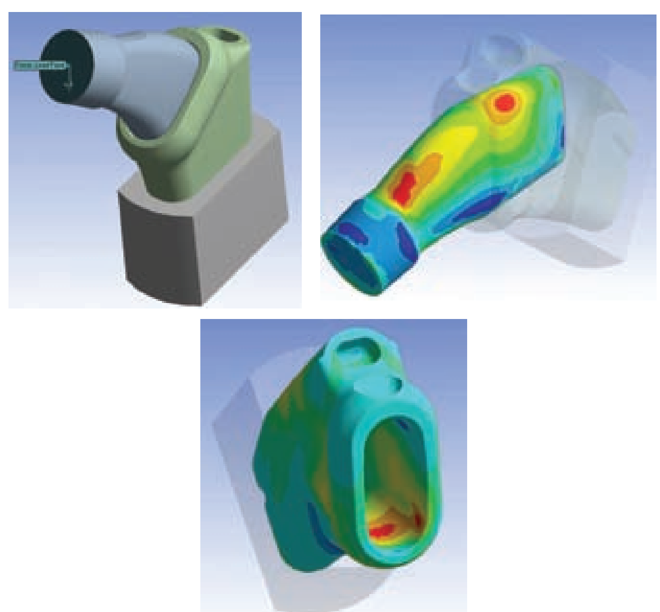


Figure 2 — Typical FEA setup and resulting stress distibutions.

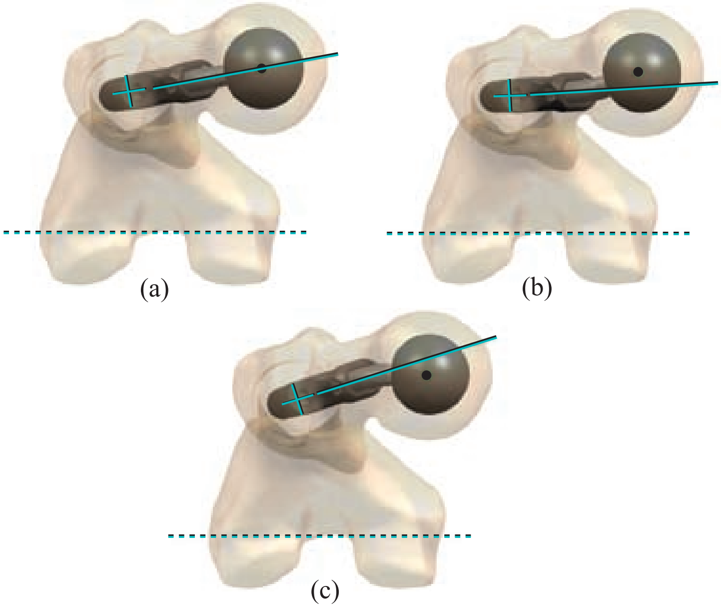


Figure 3 — Approach utilized for finite element analysis and testing of stems with a) straight, b) anteverted and c) retroverted neck components.

Testing Methodology

The strength requirements imposed on the *Kinectiv* Technology implants were the same as those for the *VerSys* Primary Hip Stems. ISO 7206 and ASTM F 1612 describe the test methodologies for cyclic fatigue performance evaluation of the proximal, unsupported region of the femoral hip stems. The strength performance requirements for the *Kinectiv* Technology implants, which includes loading, orientation, cycles and number of test samples, is more stringent than those detailed by ISO or ASTM.[10-14] Zimmer's test orientation is slightly different than the ISO orientation. When the actual peak test load is adjusted to compensate for the difference in orientation, Zimmer's load is higher than those recommended by ISO or ASTM (Figure 4). Further, Zimmer required 10 samples of each worst case configuration to complete 10 million cycles without fracture.

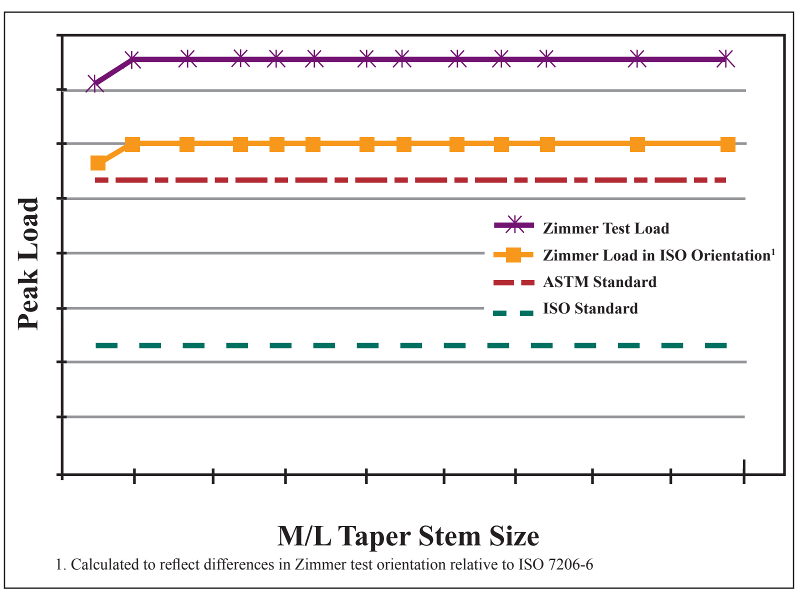


Figure 4 — Zimmer fatigue strength performance test loads.[30]

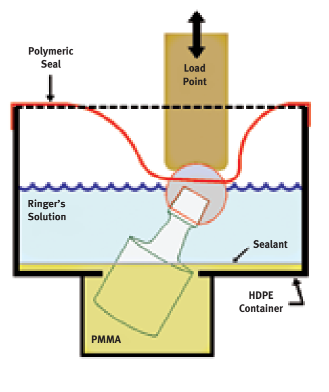
For the final design, 50 small and mid-sized *Zimmer* M/L Taper with *Kinectiv* Technology hip stems were successfully fatigue tested with straight, anteverted and retroverted necks per the loading requirements described above for 10 million cycles without fracture of the stem or neck components.

Fretting/Corrosion

Numerous design and clinical factors are associated with the fretting and corrosion performance of implant modularity.[15-20] To predict the clinical performance of modular implant designs, it is necessary to accelerate the test using load and environmental parameters. Through retrieval analysis and testing, Zimmer has been able to refine the test parameters to match the clinical observations of Zimmer's original 6 degree and newer 12/14 head/stem taper designs (Figure 5). Specifically, a set of tests was conducted varying load, number of cycles, environment, temperature, and acidity (pH) of the environment. Testing was conducted utilizing the configuration illustrated in Figure 6 for *Tivanium*® Ti-6Al-4V alloy 6 degree and 12/14 neck tapers in combination with long offset *Zimaloy*® CoCr alloy femoral heads.[21,22] The polymeric load point, high density polyethylene (HDPE) container, and polymeric seal helped maintain the environmental conditions and isolated the modularity of interest.

Through qualitative examination, the final combination of test parameters that most resembled the clinical head/stem taper results was selected. These test parameters that were subsequently used for evaluation of the *Kinectiv* Technology design were observed to be more aggressive than those previously published for evaluation of other modular neck implants.[15]

Figure 5 — Laboratory taper observations (a,b) representing accelerated corrosion fatigue test that most closely replicated the upper bound of clinical observations (c,d) of the Ti-6A1-4V 6 degree and 12/14 head/stem tapers.



Loading	Sinusoidal waveform R = 0.1 (max/min ratio)
Environment	Ringer's Solution Acidic pH Increased Temperature
Frequency	5 Hz
Orientation	(M/L angle, A/P angle) Straight (10°/9°)[10,11]
Equipment	Closed Loop Servo-hydraulic test machines in Load control
Cycles	10,000,000

Figure 6 — Head/stem taper accelerated corrosion fatigue test setup and final test parameters. Testing was conducted utilizing *Zimaloy* CoCr femoral heads and *Tivanium* stem tapers.

Quantitative Assessment

Following determination of the final test parameters (Figure 6), testing was conducted to quantify the fretting corrosion response of the head/stem and *Kinectiv* Taper Systems. Implants manufactured per normal processes that met the design specifications were utilized for testing. Porous coatings were removed to prevent undue influence of the coating on the mass loss measurement. The accelerated corrosion fatigue test with mass loss quantification consisted of the following steps:

1. Precleaning and initial mass determination – consisted of sonication, multiple cycles of manufacturing grade cleaning and analytical balance mass measurement.

2. Sample preparation – consisted of potting sample, assembling the head, neck and stem components via a low magnitude impact, and creation of the testing chamber. The test chamber was filled with Ringer's solution at the prescribed pH, being certain that the fluid level was above the entire modular junction being evaluated.

3. Corrosion fatigue testing (Figure 7) – The sample/test chamber was placed in a secondary, heated bath on the test machine. Each sample was tested according to the parameters previously outlined. The pH and temperature of the Ringer's solution were monitored and adjusted as necessary throughout the test.

4. Post-test and final mass determination – consisted of sonication, multiple cycles of manufacturing grade cleaning and analytical balance mass measurement.

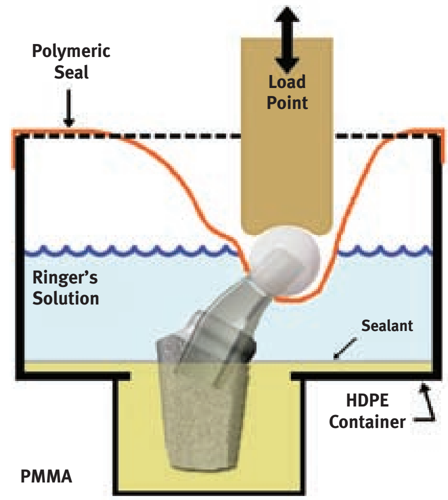


Figure 7 — Accelerated corrosion fatigue test setup of modular neck/stem isolating the neck/stem modularity.

Materials

Accelerated corrosion fatigue testing with mass loss assessment was conducted on the predicate 12/14 *Tivanium* Ti-6Al-4V hip stem taper with *Zimaloy* CoCr femoral heads of +0 mm and +10.5mm lengths.[21,22] In addition, the *Zimmer* M/L Taper with *Kinectiv* Technology in combination with an extra-extended offset modular neck was evaluated. To isolate the mass loss associated with the fretting corrosion performance of the neck/stem modularity, a +0mm alumina ceramic femoral head was utilized.[18,23] In each case, the modular junction of interest was in solution.

Results and Discussion

The quantitative results of the accelerated corrosion fatigue testing are shown in Figure 8.

- These results demonstrate that the offset of the femoral head plays a significant role in the fretting corrosion performance. The +10.5mm CoCr femoral head/*Tivanium* stem construct (gray bar) observed significantly greater mass loss than the +0mm CoCr femoral head/*Tivanium* stem construct (blue bar). Previous studies have also suggested that longer offset femoral heads observe greater degrees of fretting corrosion.[24,25]

- The collective mass loss of the *Tivanium Kinectiv* neck and stem components (pink bar) was also less than that of the +10.5mm CoCr head on a *Tivanium* stem. All of the mass loss of the neck was considered to be from the neck/stem modularity, although there was likely some material loss associated with fretting at the ceramic head/neck taper junction.

- The combined mass loss of the +0mm CoCr femoral head/*Tivanium* stem with the *Kinectiv* neck and stem (blue+pink bars) was less than that of the +10.5mm length femoral head/stem taper (gray bar).

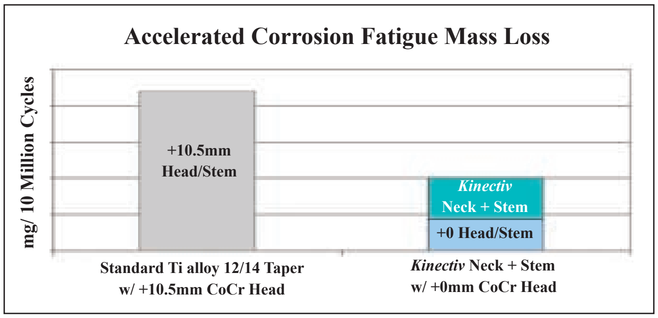


Figure 8 — Accelerated corrosion fatigue mass loss results of +10.5mm (gray) and +0mm (blue) CoCr femoral heads on *Tivanium* stems and mass loss of the *Kinectiv* extra-extended neck and stem components (teal).

Junction Stability

The distraction forces required to separate the *Kinectiv* Technology neck/stem coupling following initial assembly were also evaluated. The *Kinectiv* neck was assembled to the stem using a controlled compressive load as suggested by ASTM F 2009.[26] The force required to distract the neck from the stem was then measured. The *Kinectiv* neck/stem junction demonstrated distraction forces that exceeded those required to separate a typical 12/14 head/neck taper (Figure 9).

As suggested by research conducted by other institutions, the *Kinectiv* neck/stem junction is expected to be even more stable after initial cyclic loading via patient activities.[27] Nevertheless, initial stability of the modularity is still important to ensure that the modularity does not disassociate or allow bone chips and other debris to enter into the modularity prior to first loading by the implant recipient.

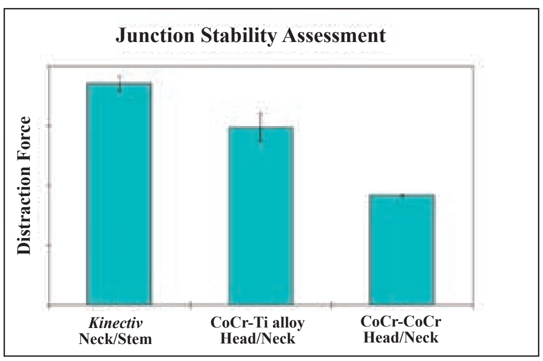


Figure 9 — Distraction force measurements for *Kinectiv* implant modularity compared to standard head/neck distraction forces of different material combinations.

Design Considerations

As previously mentioned, Zimmer research and development engineers went through many iterations prior to establishing the final design. Throughout this process, it was observed that the performance of a modular neck implant is very sensitive to subtle design changes. This resulted in modifications to the neck and stem components with respect to material selection, junction size and version offering to meet the requirements of fretting/corrosion and strength performance.

Mixed-Alloy Performance

Early designs incorporating CoCr alloy modular necks paired with Ti-6Al-4V stem components demonstrated the ability to meet the fatigue strength performance requirements. However, the fretting/corrosion debris performance of the CoCr neck/Ti-6Al-4V stem construct in accelerated corrosion fatigue testing was not acceptable (Figures 10,11). Fretting corrosion tests indicated a five-fold increase in mass loss of the preliminary CoCr neck/Ti-6Al-4V stem design relative to the benchmark head/stem modularity. Therefore, CoCr neck/Ti-6Al-4V stem modularity was not pursued in the final design. Increased frequency of fretting/corrosion of mixed-alloy head/neck taper systems has previously been reported.[28, 29]

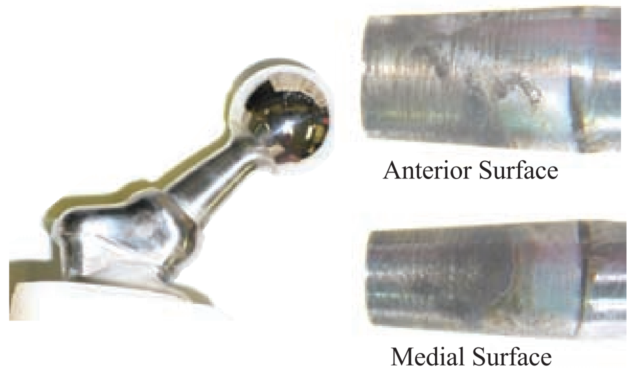


Figure 10 — Preliminary modular neck design with CoCr monoblock head/neck and Ti-6Al-4V stem and post-accelerated corrosion fatigue test surface condition of the CoCr neck taper.

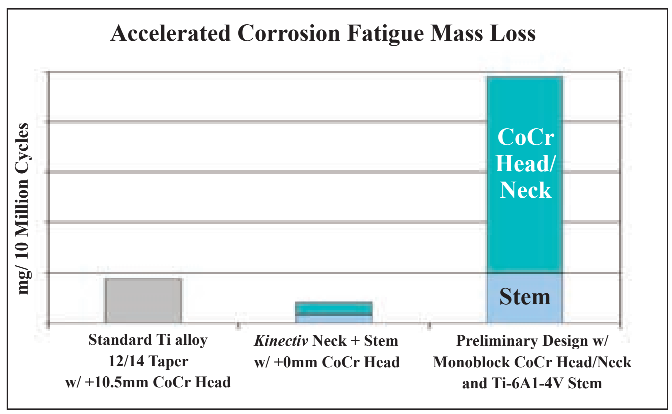


Figure 11 — Mass loss results comparing the final Ti-6Al-4V/Ti-6Al-4V *Kinectiv* Technology design with a preliminary design incorporating a CoCr neck/ Ti-6Al-4V stem.

Strength

The following are a few of the considerations employed in the *Kinectiv* Technology design to meet the performance strength requirements.

- *Junction Geometry* – There are many factors involved in modular junction design that have direct and indirect influences on the strength performance of the implant. These factors affect local reaction forces, stress states, contact pressures, and fretting motion that significantly affect the strength of the construct. One aspect of this is junction length. The simplified illustration of Figure 12 shows the relationship of the forces acting on the neck component. As the length of the neck/stem taper (L_{Taper}) decreases, the reaction forces at the proximal (F_O) and distal (F_R) regions of the taper increase for a given head center location (L_{Neck}). The design features embodied in the *Kinectiv* Technology design, including shape, size and surface finish, have been carefully engineered to meet Zimmer's rigorous strength requirements while maintaining minimal fretting motion.

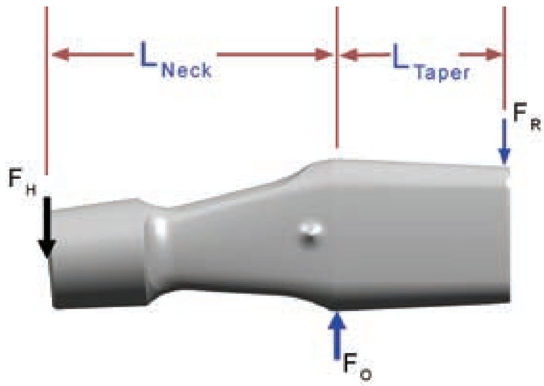


Figure 12 — Simplified model of forces acting on a modular neck.

- *Amount of version* (Figure 13)– The amount of version provided by the modular neck has a strong influence on the strength of the modular construct. *Kinectiv* Technology offers the amount of version that successfully meets Zimmer's stringent strength requirements. While meeting the strength requirements, the version provided by the anteverted and retroverted necks was optimized to address a wide range of patient anatomies.[3,5,7] For a given head center location, *Kinectiv* Technology offers the same amount of version regardless of neck shaft angle.

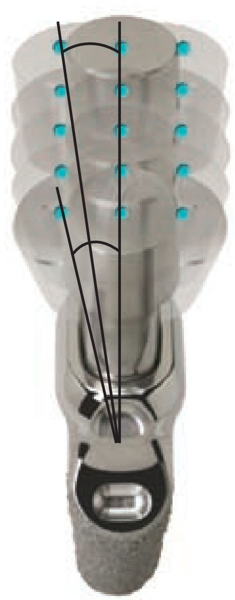


Figure 13 — Version provided by *Kinectiv* Technology.

With Zimmer's innovative, exclusive use of the +0mm femoral head, *Kinectiv* Technology is able to meet the critical requirements of clinical need and implant strength without skirted femoral heads that can reduce range of motion.

Conclusions

Many factors must be considered in the development of a modular neck implant. Small changes in the design, such as material selection, version, and junction length can profoundly influence the performance of the modular implant. The result of over five years of development of *Kinectiv* Technology is a modular neck femoral design that:

1. meets Zimmer's performance fatigue strength requirements that have proven successful for many years;

2. demonstrates less fretting/corrosion wear debris than a clinically successful standard 12/14 neck taper with a long offset femoral head;

3. provides a secure fit of the modular components that exceeds that which has been demonstrated by conventional head/neck taper assemblies;

4. addresses a wide range of patient femoral morphologies.

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