Poster Exhibit
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“Within Any Important Issue, There Are Always Aspects No One Wishes To Discuss” – Femoral Component Failure

- G. Orwell

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Introduction And Aims

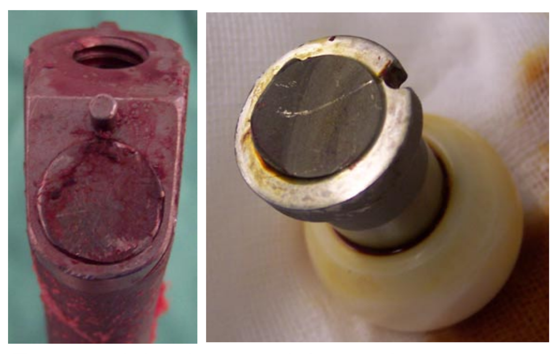
Complications still occur in THA. One of these complications continues to be femoral component failure.

This subject needs more open discussion. The literature documents examples that unsupported stems will fail regardless of fixation, material, and design but has not recently addressed the risk due to increased patient activity.

Metal fatigue is caused by repeated cycling of the load. It is a progressive localized damage due to fluctuating stresses and strains on the material.


Fatigue failure c.c. modular neck.

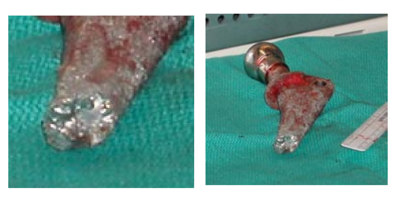
Metal fatigue cracks initiate and propagate in regions where the strain is most severe.


Fractured titanium modular neck.

The process of fatigue consists of three stages:

- Initial crack initiation
- Progressive crack growth across the part
- Final sudden fracture of the remaining cross section

All devices are subject to fatigue failure especially with the increased patient activity we are seeing today. There are reports of device failure regardless of material, and regardless of design style (monoblock, modular).


Fractured chrome cobalt AML® monoblock stem.

Recent reports of failures of modular revision stems have led to more vigorous testing and the development of implants with stronger modular junctions. In addition stems have been designed with greater ability for bony fixation above the modular junction. It is anticipated that modular stems which allow for fixation above and below the modular junction should be less susceptible to late failure of those junctions. Recognizing design and material limits is part of the surgeon's responsibility in choosing the appropriate implant.


Fractured titanium SROM® stem.


Fx. c.c. cemented | Fx. Bridge™ Titanium Cemented | Fx. c.c. cementless

Reducing Fatigue Failure

The most effective method of reducing fatigue failure is to make improvements in design:

- Eliminate or reduce stress raisers by streamlining the part;
- Avoid sharp surface tears resulting from punching, stamping, shearing, or other processes;
- Prevent the development of surface discontinuities during processing;
- Reduce or eliminate tensile residual stresses caused by manufacturing;
- Improve the details of fabrication and fastening procedures.

There are a number of methods available to a manufacturer to increase fatigue strength and reduce fretting wear. However, no individual design, material, or process offers absolute guarantees with regard to mechanical failure given the increased popularity of high-impact activities in today's lifestyles.

Methods

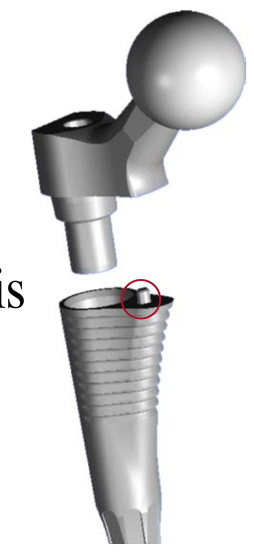
1,568 cementless stems were implanted since June 2000 for primary THA featuring a proximal modular neck design. All were implanted in six separate centers by eight surgeons. Twenty-two femoral component failures (locking pins) occurred between 13 to 50 months post-operatively. Each center used a different surgical approach (posterior, anterior muscle sparing, modified direct lateral) and a variety of cups and bearing surfaces.

All cases were reviewed as to surgical technique; implant size, patient activity and examination of retrieved device.

Material

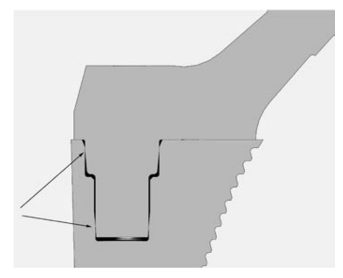
Apex Modular™ Stem Design

- Modular necks for optimized lateral offset, leg length, and anteversion
- Key-hole proximal geometry with steps for good fill and initial stability
- Circumferential plasma sprayed CP titanium coating
- Distal slot(s) for reduced end stem stiffness
- No skirted heads
- Modular design allows for large selection of necks, to achieve proper combination of lateral offset, leg length, and anteversion
- Dual Press™ connection is simple, robust, and stable
- Indexing pin permits selection of neutral, and 16º anteversion position

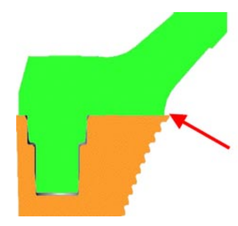


Dual Press™

The Dual Press modular junction employs two areas of cylindrical press-fit.



To create a mechanical lock, the proximal and distal diameters of the peg are slightly larger than the corresponding holes in the stem, creating two bands of interference, or “press-fit”.


Apex's Dual Press™ connection allows neck to fully seat. Stem provides medial support, which increases strength and allows higher lateral offsets.

Results

Twenty-two locking pins were sheared resulting in torsional instability of the proximal modular junction. Patient's complaint of an initial popping sound associated with a sense of hip instability was consistent in all. Pain was mild to moderate with initial x-ray appearance normal.

Surgical intervention found locking pin to be sheared with rotational instability of the proximal neck and black staining of tissue due to metal debris. Twenty-one stems have been revised with standard length cementless stems of a variety of designs. All have gone on to full recovery. One patient is not a surgical candidate and is not experiencing any significant pain.

No material or fabrication defects were found. No surgical errors were found. Mechanical testing demonstrated safety levels to be beyond published activity loads. The culprit (in most cases) appears to be patient activity.

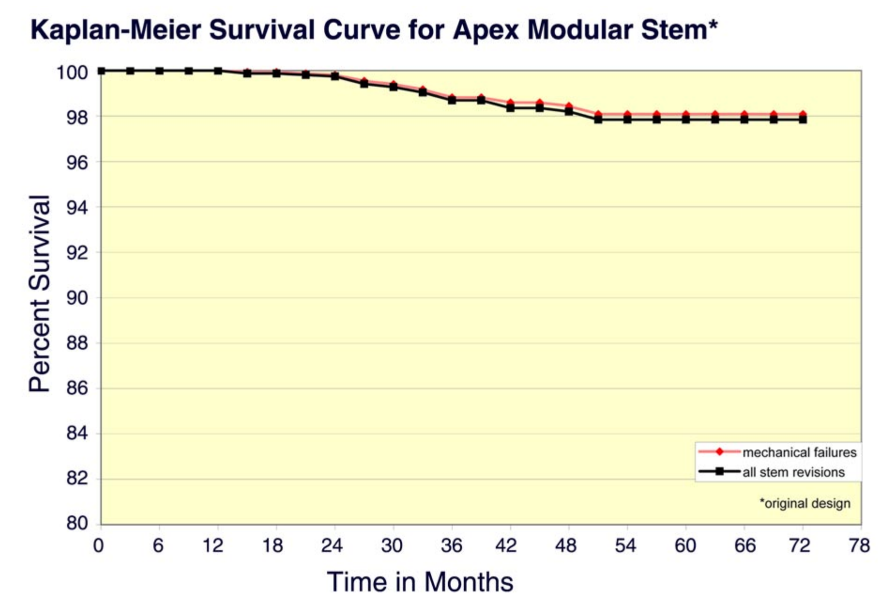
Stem Removal

Components are designed with an axial extraction feature that facilitates removal. This allows preservation of proximal bone stock for re-implantation.


Retrieved stem.

Apex Neck Retrievals

All retrieved stems that we have been examined suggest quasi-static shear failure of the alignment pin – a single high load (high torsion) event. There is no evidence of fatigue failure as described earlier.

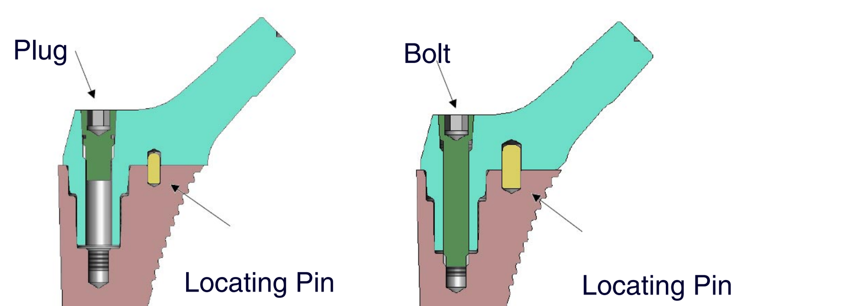


Kaplan-Meier survival analysis indicates a 98% survival at six years, including these mechanical failures.

Apex Improvements

Pin strength:

Old- 95 ft-lbs New- 216 ft-lbs



Pin diameter has been increased from .125” to .188” along with added feature of a bolt that engages the stem. This has resulted in +225% increase in torsional strength.

Conclusions

Historical published reports on torsion loading along with BMI have been underestimated. Increased patient activities are subjecting devices to unprecedented load levels.

Current patient activities generate excess of 95 ft pounds of torque. This review should be helpful in stem selection and increased warning guidelines as to patient activities.

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