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The 16-Year Evolution of Proximal Modular Stem Design – Eliminating Failure of Modular Junction

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Abstract

Background: The complexity of hip reconstruction has been and continues to be a perplexing problem with restoring leg length, femoral offset, joint stability and overall hip implant fixation. These were contributing factors that lead to the development of a novel proximal femoral component design "Apex Modular Stem" (Omni, Raynham, MA). The basic stem geometry features a straight stem with a metaphyseal fit and fill cone, a medial triangle and a modular neck junction that allows for version and offset adjustment.

In recent years, there has been great concern with the use of modularity in total hip arthroplasty. The goals of this study are (1) to identify complications with the use of a proximal modular design and (2) demonstrated factors that have eliminated those complications.

Methods: This is a retrospective study of a single surgeon series (Generation I and Generation II) of using the same cementless stem and proximal modular neck body (Apex Modular Stem and Omni Mod Hip Stem) from 2000 to 2016 totaling 2,125 stems (483 Generation I and 1,642 Generation II).

Results: Generation I, 483 stems were implanted between 2000 and 2004 of which 31 alignment pins sheared resulting in a revision rate of 6.4%. Generation II, 1,642 stems have been implanted between 2004 and 2016 all by the same surgeon with no failures of the modular junction.

Conclusion: All implant devices entail a multitude of risks and benefits. The Apex Modular Stem (Generation I), provided excellent fixation, minimal risk of modular junction corrosion, and simple control of anteversion and femoral offset. The limitation was found to be the risk of the alignment pin shearing (6.4%). The pin was enlarged to make it 225% stronger in torsional resistance, and in a subsequent series of over 1,600 femoral stems in a single surgeon series, there were no pin failures over a 12 year duration.

Background

Generation I (Apex Modular Stems) 483 were implanted between 2000 and 2004 on consecutive patients by the senior author. All were performed using the posterior approach. All cases used a mixture of different cementless acetabular components from a variety of manufactures.

Surgical stem and cup preparation and instrumentation has not changed between the two-generation stem designs.

The Dual Press modular junction employs two areas of cylindrical press-fit. To create this 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. Figure 1.

The proximal end of each stem includes an alignment pin that engages with a mating hole on the distal surface of each neck. This pin allows for anteversion position and for de-rotation of the modular neck on the stem. Figure 2.
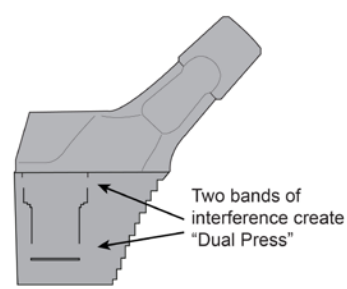
Dual Press™ Technology

Figure 1. Illustration of Press Fit
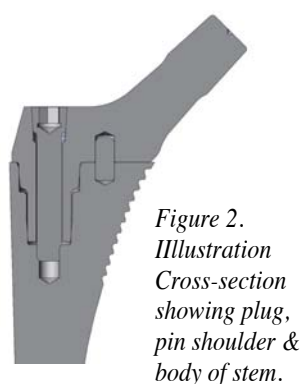
Figure 2. Illlustration Cross-section showing plug, pin shoulder & body of stem.

Methods

Generation I Design "Apex Modular Stem"

The Apex Modular ™ Hip Stem was developed as an evolutionally design based off the successful historical S-Rom® Modular Hip Stem [3,4]. The basic stem geometry was similar to the S-Rom in that both were straight stems with a proximal fit and fill cone and a medial triangle shape. Figure 3A & B.

Figures 3A, and B. A: Apex Modular Stem. Note: Proximal modular shoulder/neck not fully seated (Courtesy George Cipolletti). B: S-Rom® Stem (Courtesy JISRF Archives).

Stem features a novel proximal modular shoulder/neck design that is not a taper junction. This modular junction is a Dual Press. This attachment mechanism is new to orthopaedics but was derived from conventional mechanical tool designs. The entire shoulder of the neck sits flush onto the stem body thus shares load over a larger surface area vs. a taper junction. This provides fatigue values equal to that of a monoblock stem. Figure 4.
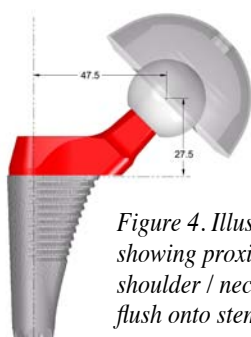

Figure 4. Illustration showing proximal shoulder / neck sitting flush onto stem body.

An alignment pin engages with a mating hole on the distal surface of each modular neck. This provides additional torsional stability, as well as control of version an-

gle. The diameter of the locating pin was 3.175 mm and would engage with one of three holes within the interface of the modular shoulder/neck. This provided 13º of version control. One of three positions could be picked, 13º of anteversion, neutral, or 13º of retroversion. Figure 5A & B.

Figure 5A. Picture of stem body showing location / de-rotational pin. (Courtesy JISRF Archives)

Figure 5B. Underside of neck showing 3 pin holes for version angle. (Courtesy JISRF Archives)

The original design included pre-clinical testing of the following worst-case scenario [5]:
- Six size 2, 9mm stems with medium 42.5 necks, +7 heads (for a total femoral offset of 47.5 mm).
- Assembly forces measured for three stems.
- All six stems fatigued tested as per ISO 7206-4 and 7206-8, under the direction of A. Seth Greenwald, D. Phil (Oxon)
- All six stems survived 5 million cycles at 2300 N.
- Same stems loaded to 81.3 kg of torsion, then axial tension to disassembly, or 1000 lb limit.
- Fretting wear measured.

Additional testing of high cycle fatigue testing was performed [5].
- Size 6, 14.5 mm stem with medium 47.5 neck, + 7 head (for a total femoral offset of 52.5mm).
- Fatigue tested as per ISO 7206-4, with incrementally increased cyclic loads.
- Stem survived 48.5 million cycles, test halted due to failure of embedding material. Maximum load reached 6xBW, for an 81.6 kg individual (492.6 kg).
- Titanium debris average less than 0.001 mm3 per million cycles (less than 0.1 % of wear of MOM hips)

Failure Mode for Generation I "Apex Modular Stem"

The failure of the Apex Modular Junction was primarily limited to the locating/ de-rotational pin. The pin fractured allowing the proximal shoulder/neck piece to rotate back and forth against the proximal portion of the modular stem. This resulted in micro to macro motion, joint instability, pain and excess generation of titanium debris [2,8]. Figure 6.

Patients often heard an initial snapping sound and a

sense of hip instability, progressing to a painful hip. Lateral X-Ray views would demonstrate the implants to be rotated out of position and on rare occasion totally disengage from the Dual Press modular junction. Revision of the failed implant is not overly difficult. The proximal neck can be removed by hand providing direct access to the stem body. Retrieval instruments allowed for firm attachment and with the help of flexible ostetomes or a small high-speed burr you can break the bony attachment with minimal bone destruction. Often femoral replacement can be done with a primary length stem. Figures 7A, B, & C.
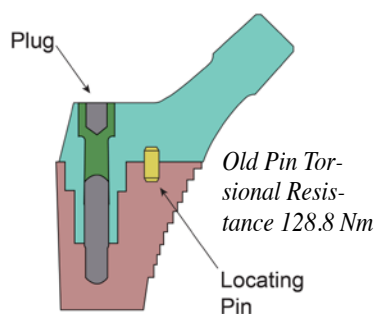

Figure 6. Illustration showing cross-section of Generation I and locating pin that was the point of failure. Pin diameter 3.175 mm. (Courtesy Anna Farad)

Since the two modular pieces are titanium there often would be considerable black debris and staining of the tissues making one think of corrosion. This was not the case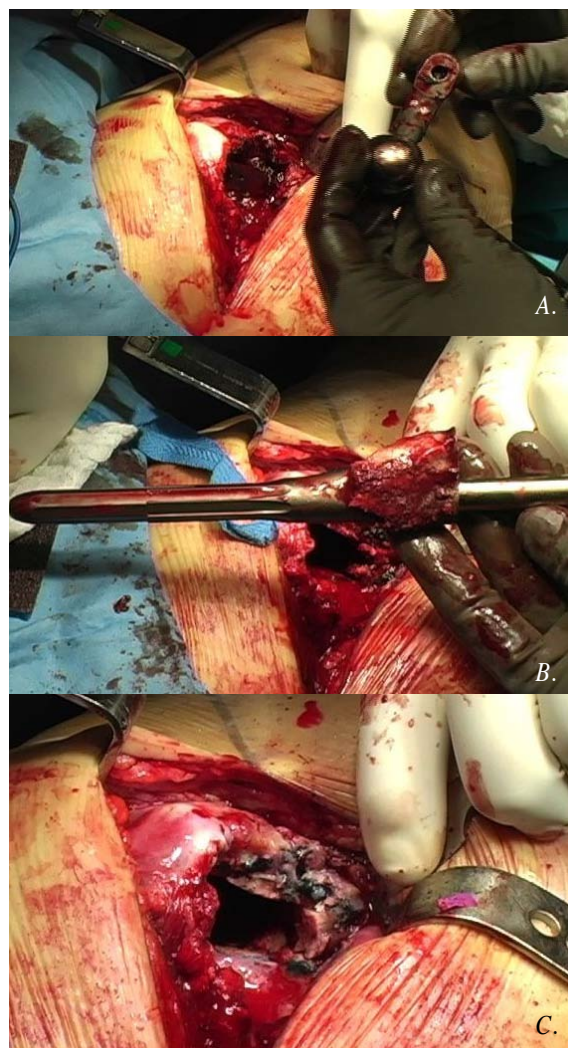. Titanium is a relatively soft material and abrasion debris is easily generated. You might also think the fractured location/ de-rotation pin was a fatigue failure problem. This was also not the case. Figures 8, 9A, B, & C.

Figure 8. Retrieved Apex Modular Stem showing broken locating pin with no other apparent damage to Dual Press Modular Junction. Note: Good bone attachment to porous surface. (Courtesy JISRF Archives)

Figures 7A, B, and C. A: Post-op A/P X-ray of a fractured locating/ de-rotational pin. Note: is difficult to appreciate the pin has been broken on this view. B: Lateral X-Ray demonstrating modular should/ neck component has rotated out of position of function. C: A/P x-ray showing bi-lateral hips with Apex Modular stem on the left side, and a S-Rom (primary stem-length) that replaced the fractured locating/ de-rotational pin on the right. (Courtesy T. Tkach)

Figures 9A, B, and C. A: Picture showing proximal modular shoulder/neck with femoral head attached. B: Showing stem removed with significant bone attached to proximal porous area with retrieval instrument attached C: Showing stem removed with black titanium debris. Note: this is not corrosion (Courtesy JISRF Archives).

Metallic fatigue failures clearly demonstrate upon examination a surface fingerprint. There will be a fatigue source or crack initiation then a crack propagation resulting in fatigue failure. Although fatigue has been thought of as a function of time it has been shown that it is the number of repetitions of stress rather than mere duration of time.

So it is important to realize that fatigue cycles are accumulative and this has been the historical failure mode of fractured total hip stems [9,10] (Figure 10).
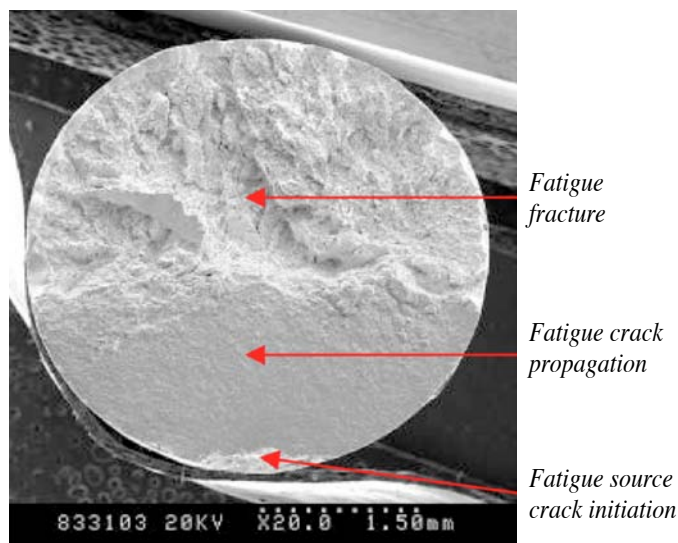

Figure 10. Typical cross-sectional image of a metal fatigued failure showing source, propagation and fracture. (Courtesy JISRF Archives source unknown.)

Upon inspection of the retrieved fractured pins (c.c.) there was no evidence of a fatigue failure [11]. So what was the cause of the fracture? The hypothesis is a dynamic high impact torsional shear failure marked by a vigorous physical force applying a load well beyond the shear strength of the material. Another way of expressing this would be a moment of momentum that produces a load beyond the shear strength of the material. Example jumping off the bed of a pick-up truck landing with your foot internally rotated or possibly stumbling could generate a high dynamic impact torsional load resulting in a shear failure of the locating/de-rotational pin.

It was further thought that the Dual Press plug would have additional property values that would contribute to the overall integrity of the composite design, which in hindsight had little torsional resistance value.

Results for Generation I "Apex Modular Stem"

Generation I, 483 stems were implanted between 2000 and 2004. 31 alignment pins sheared resulting in a revision rate 6.4%.

The stem system was voluntary withdrawn from the market and redesigned to a more robust design.

Table 1: Generation I Results

Total Implants from 2000 - 2004		483
Revisions	Pin Shear	31
	Infection	2
	Dislocation	1
	Total	34
% Revisions	Pin Shear	6.4%
	Infection	0.4%
	Dislocation	0.2%
	Periprosthetic Fracture	0.0%
	Total	7.0%

Generation II Design "Omni Mod Stem"

The Omni Mod Stem design is the exact same features of the proximal shoulder / neck and the stem body from Gen I with changes to the structures within the Dual Modular junction (plug to bolt and diameter of locating pin from 3.175 mm to 4.775 mm). The dimensions for the two bands of interference fit remained the same.
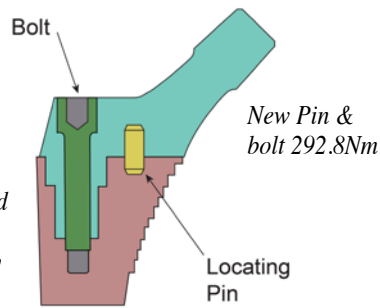
The increase in pin diameter resulted in creating two different shoulder / neck configurations. One style has a single engagement hole for neutral version and a second style that has two holes for selection of anteversion or retroversion at 13°. (Figure 11A, B, & C)

Figures 11A, B & C. A: Larger diameter pin (c.c. 4.775 mm) within the stem body of the Dual Press Modular junction. B: A single engagement hole that provides a neutral neck position. C: Two holes that provide 13º of version angle. (anteversion or retroversion)

This corrective action resulted in 225% increase in torsional strength. It serves as an example that changes and improvements are possible once there is a full understanding of the problem. There have been no reported mechanical failures of its modular junction since 2004 with the improved design "Omni MOD Stem" (Figure 12). [13]

Figure 12. Illustration cross-section of improved Dual Press on Omni Modular Generation II Design increased pin diameter to 3.175 mm increased torsional strength by 225%. (Courtesy Anna Farad)

Bolt

New Pin & bolt 292.8Nm

Locating Pin

Table 2: Generation II Results

Total Implants from 2004 - 2016		1642
Revisions	Pin Shear	0
	Infection	4
	Dislocation	1
	Periprosthetic Fracture	1
	Total	6
% Revisions	Pin Shear	0.0%
	Infection	0.2%
	Dislocation	0.1%
	Periprosthetic Fracture	0.1%
	Total	0.4%

Results for Generation II "Omni Mod Stem"

1,642 stems have been implanted since

2004 and 2016 utilizing the same stem surgical technique. There have been no pin shear failures since this more robust design has been introduced.

There have been no reported complications with the improved "Dual Press" Modular Junction.

Note: There have been two reported fractured necks from Australia, not the modular junction, as with conventional monoblock stem designs.

Discussion

The knowledge of implant failure and implant testing is continuing to grow but often as we solve one mode of failure we create another failure that has not been anticipated. Historical review and preclinical testing might meet the required standards set by regulatory bodies to achieve market release, but often these standards do not consider the ever-increasing physical activity and loads that these devices are encountering [10].

It was further thought that the Dual Press plug would have additional property values that would contribute to the overall integrity of the composite design, which in hindsight had little torsional resistance value.

Historical torque levels in our opinion have been underestimated in today's patient life styles that demonstrate increased physical activity. Previous studies have demonstrated torque values ranging between 15 Nm (11 ft-lbs) and 37 Nm (27 ft-lbs) depending on the physical activity (rising from chair to single-limb stance) [5].

The trends over the past ten years have been the use of large femoral heads, increased femoral offset, metal on metal bearings along with increased patient activity. All of these factors increase torque [8]. On average, a 1-mm true lateral increase to the ball center offset will increase torque values by 8%. A 1-mm increase in vertical height (leg length) will increase torque by 6% [8]. Torque is a force applied over a distance (lever arm) that causes rotation about a fulcrum (axis of rotation) (Torque=Force

(Fm) x Moment Arm). The greater the torque a muscle can produce, the greater the movement it will produce on the body's levers.

We now know by experience that the hip sees torque values over (128.8 Nm), as demonstrated in our mechanical failures of the Apex Modular hip stems [10,12] (Figure 13).

This paper follows on previous publications of this unique modular junction and demonstrates that design and materials can be improved upon once there is clear understanding of the failure mode. It is important to remember all devices are subject to failure. It is also necessary to recognize design and material limits and not to over-indicate in high-risk patients. Patient activities are higher and generate higher mechanical loads than historical references.

A number of modular junctions have come and gone from clinical use. Nevertheless, the endeavor to improve clinical outcomes should be continued.

Modularity can be designed and fabricated to provide safe, reliable, and reproducible clinical results. Because there are no laboratory tests allowing accurate prediction of the service life and performance of implant parts, clinical experience with a large number of cases over a period of several years is the only reliable indicator. However, clinical evaluations should only begin after conducting aggressive basic science material and mechanical testing to anticipate potential failure modes. Individual patient physical activities should be considered when deciding on stem modularity features. Since there are no standards established for modular junctions the overall performance of modular junctions are not equal. Careful review of basic engineering principles is necessary and recognizing design limits will reduce the indication of overuse [2,4,8,9,10].

We encourage early publication of all devices (good, bad & ugly) and continuation of those publications as clinical experience and outcomes become available.
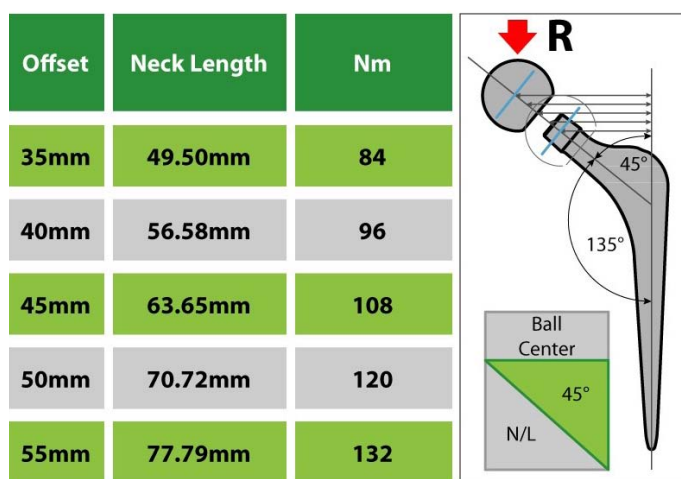
Offset	Neck Length	Nm
35mm	49.50mm	84
40mm	56.58mm	96
45mm	63.65mm	108
50mm	70.72mm	120
55mm	77.79mm	132

Figure 13. Chart Showing Torque Loads Generated by Femoral Offset and Neck Length

Conclusion

All implant devices entail a multitude of risks and benefits. The Apex Modular Stem (Generation I), provided excellent fixation, minimal risk of modular junction corrosion, and simple control of anteversion and femoral offset. The limitation was found to be the risk of the alignment pin shearing (6.4%). The pin was enlarged to make it 225% stronger in torsional resistance, and in a subsequent series of over 1,600 femoral stems in a single surgeon series, there were no pin failures over a 12 year duration.

Improvements in this modular junction design have eliminated the mechanical failures of the first Generation design.

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AUTHOR DISCLOSURES

Tkach royalty and equity (Omni); McTighe equity (Omni)