"Design Considerations for Modular Taper Junctions"

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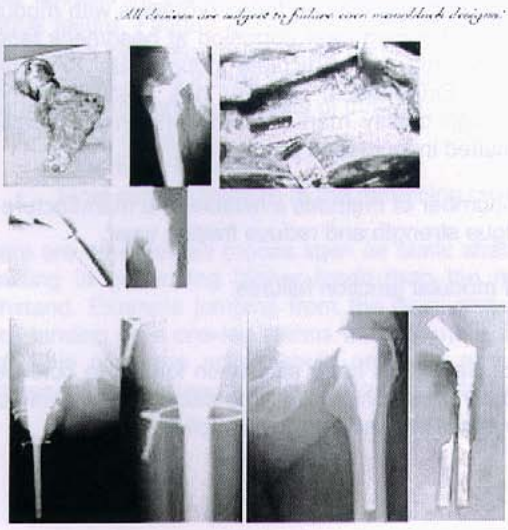

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Modular hips mean modular junctions and there is concern with the overall integrity of modular connections. The issues of fatigue, fretting and corrosion are areas that we are all concerned with and need to know how our individual modular devices stack up. It is not possible for community based orthopaedic surgeons to know or be familiar with all the current standards for material testing but we do have a responsibility to demand and review from device manufactures appropriate material test on the devices we are using especially new materials and designs.

Patient activity is placing higher demands than ever before on total joint reconstruction and revision surgery is often the reality especially when one does not understand or appreciate the limits of design and / or material of the device that is selected.

It was not that long ago that we faced problems with modular acetabular cups, concern over corrosion at head/neck tapers and lysis generated by particulate debris due to fretting abrasion wear. Orthopaedic industry has made significant advances in high quality manufacturing and implant design that have resulted in increased product offerings.

There are a number of methods available to a manufacture to increase fatigue strength and reduce fretting wear.

Examples of modular junction failures:
Modular Necks

Titanium modular necks have also been known to cold-weld into the modular taper junction making disengagement difficult and in some cases impossible to accomplish.

Even chrome cobalt modular necks have shown fatigue failure in specific modular designs.
Most devices including modular junctions fail as a result of fatigue failure. Fatigue is caused by repeated cycling of the load. It is a progressive localized damage due to strains on the material. Cracks initiate where the strain is most severe.
The progress of fatigue consists of three stages:

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

There are other failure modes such as static shear: an event resulting in generating higher loads than the material can withstand. Example jumping from the back end of a pickup truck landing on a one-leg stance with internal rotation of the foot. This one time action could generate enough load to surpass the yield strength of the implanted material.

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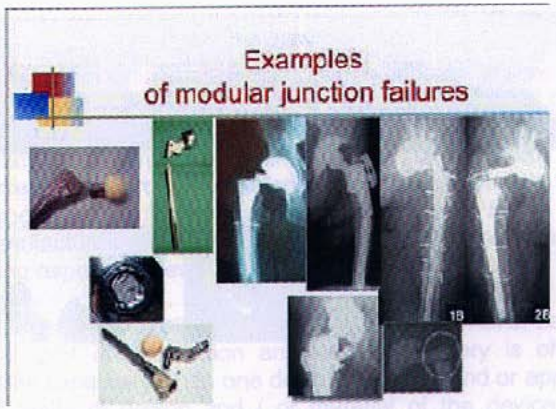
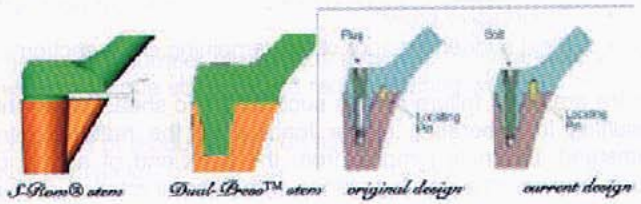
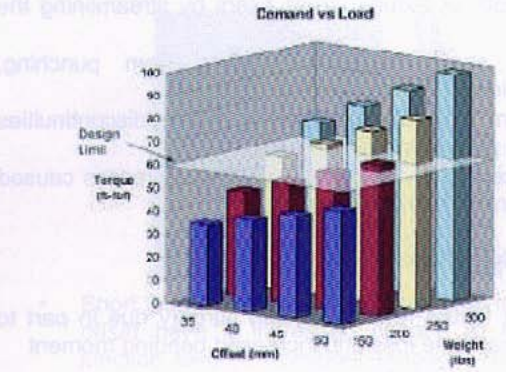


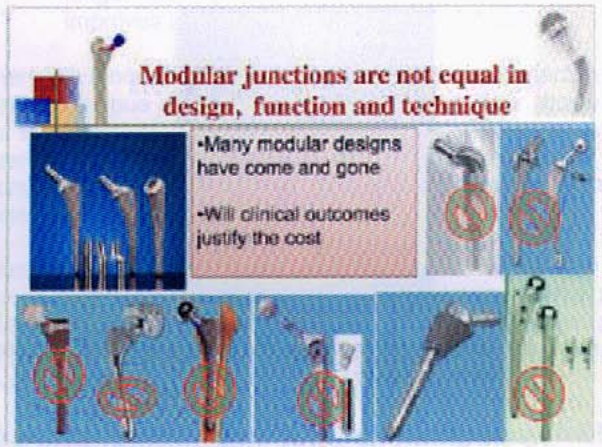
Dual Press™ First Generation Modular Junction (note: has never been sold in Australia)

This device has a different failure mode "Static-Shear" not a typical fatigue problem!



- Historical torsional loads in the hip 200 in-lbs /16 ft-lbs
- S-Rom taper 400 in-lbs /33-lbs.
- Original Dual Press™ stem 95 ft.-lbs. current at 216 ft.-lbs.





Reducing modular junction failures:
There are two specific actions that can reduce device failures.
1. Limit your indications to patients that have low to moderate BMI and /or limit their activity
2. Improve device properties by design and material.

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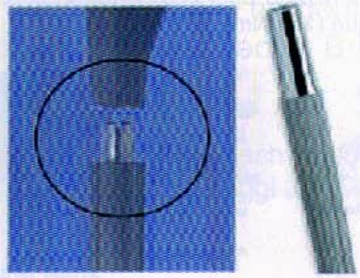
- Eliminate or reduce stress risers by streamlining the part;
- Avoid sharp surfaces resulting from punching, stamping, shearing or other processes;
- Prevent the development of surface discontinuities during processing;
- Reduce or eliminate tensile residual stresses caused by manufacturing

Mid-Stem Modular Taper Junctions:

- Higher failure rate in revision surgery due in part to proximal bone loss and increased bending moment

- Both fatigue and torsional strength are directly related to surface contact



- Short mid-stem tapers used with a longer femoral offset have a increased chance to have modular junction failures (torsional slippage, fatigue etc.)The longer taper provides greater surfaces contact and improves both torsional and fatigue strength.

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 failures given the increased popularity of high-impact activities in today's lifestyles.

Summary

Not all modular junctions are equal. Recognizing design and material limits are important and part of the manufacture and surgeons responsibility in advocating and selection for any given patient.

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

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Current patient related activities generate in-excess of 95 ft. pounds of torque (128 Nm).

Torsional Loads

>Stumbling 30-40 Nm it only takes 30 Nm of torque to put implant stability at risk

It is recommended to use devices that take retrievability into consideration.