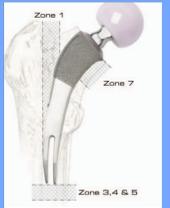




“Design Rationale And Early Clinical/Surgical Observations With A Tissue Sparing Stem For THA In Osteoarthritis”

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Purpose:

Total hip arthroplasty is one of the most effective orthopaedic procedures with a very high success rate as measured by pain relief, improved function and patient satisfaction. However, since the introduction of total hip arthroplasty in the 1940s, a range of design philosophies for femoral components have demonstrated variable clinical results. Aseptic loosening, joint dislocation, thigh pain, bone resorption and femoral component failure have been some of the complications that plague this procedure.^{1,2} The past few years has seen an influx of so-called short stems with very little clarification as to design features, required surgical technique and long-term clinical outcomes. Most devices, meet with some level of learning curve and most systems do little in the way of warning new surgeons as to the perils and pitfalls during the initial surgical phase. This paper is designed to review the lessons learned during the first year of surgical experience with a new neck stabilized implant stem.^{1,2,3,4.}

Why the need for a new design concept?

• Concerns with survivorship of young active patients

(Kaplan-Meier 72% to 86% in patients <60 yrs. old)⁵

Hips fail for a number of reasons:^{6,7,8,9}

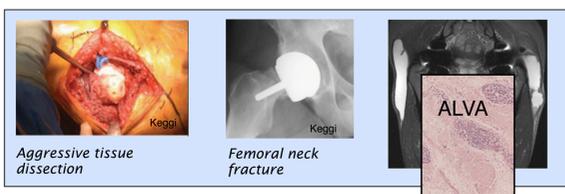
- Loosening of the hip replacement
- Infection of the hip replacement
- Dislocation of the hip
- Breakage or wearing out of the implant
- Damage to the surrounding bone (periprosthetic fracture)

Examples of failures of conventional THA



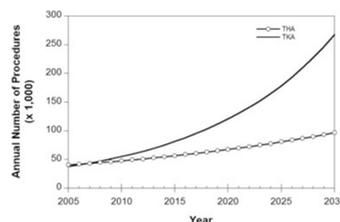
• Concerns with Hip Resurfacing^{10,11} (Decreasing indications)

- Broader indications
- Broader selection of bearing material (MoM biological concerns: Aseptic, Lymphocytic Vasculitis and Associated Lesions)
- More conservative approach (Tissue sparing both hard and soft tissue)



• Concerns with Rising Health Care Cost

- Hip replacements are expected to increase 174% in the next 20 years¹²
- The number of patients waiting more than nine months for hip and knee replacements in North Wales has increased by 11,700%.
- Less inventory requirements
- Less instruments



• Concerns with Retrieval and Conversion for Revisions

- More hard & soft tissue to work with for revision surgery



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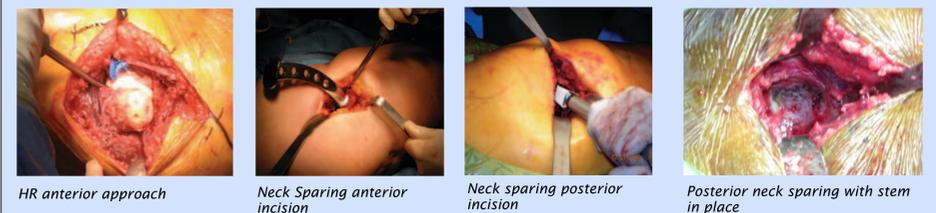
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Methods:

1,225 ARCTM Tissue Sparing Stems implanted since April 2010 by 25 TSI™ Surgeon Members with direct follow up with the lead clinical / surgical team. Typical patient profile showed two-thirds being female with an age range being between 17 to early 90s. 90% were treated for OA.



Example: anterior approach for HR vs. single incision anterior approach for neck sparing stem. Posterior approach for neck sparing good exposure on socket with retention of femoral neck.



All were implanted with cementless acetabular components of four different designs and four different bearing surfaces. Intraoperative x-rays were taken on all patients undergoing the posterior approach and half of all anterior approach patients had intraoperative fluoroscopy or plain x-rays taken.

FEA studies were evaluated to determine best stem orientation and instrumentation designed and developed for surgical preparation of femoral stem.

Results:

Anterior Approach

Dislocations = 2
Stem Revisions = 3
Aseptic Loosening = 1
Superficial Infection = 2
Septic Loosening = 0
Leg length discrepancy +/- 7mm = 9
Occult Fx distal end of the stem = 1
Calcar Fxs. wired = 2
Calcar Fxs. not wired = 3
Hip Pain = 2
Subsidence >5mm = 3
Intra-op femoral perforations = 3
Mismatch heads = 2

Posterior Approach

Dislocations = 2
Stem Revisions = 2
Aseptic Loosening = 0
Superficial Infection = 0
Leg length discrepancy +/- 7mm = 7
Fractures distal = 0
Calcar Cracks wired = 1
Calcar Cracks not wired = 2
Hip Pain = 1 (being watch)
Subsidence > 5mm = 0
Intra-op calcar fractures resulting in stem bailout = 2
Head / neck disassociation = 1

Discussion:

There is a short learning curve for the surgeon (2-3 cases) and an easy transition for the O.R. surgical team with only one pan of instruments. Survey of our TSI members clearly demonstrates that the majority of surgeons feel that there is reduced surgical time resulting in less blood loss, shorter hospital stay and quicker rehab back to full weight bearing and return to full active life style than compared to their standard conventional cementless THA. A few surgeons feel the short neck sparing stem is equivalent to their conventional stems however no one feels that this approach is less than equivalent to conventional cementless THA.

Observations:

The initial year (April 2010 to April 2011) results of a novel modular neck stabilized curved stem design clearly demonstrates that this approach can be used as a main stream treatment for the osteoarthritic patient.

The advantage of neck sparing stabilized stems saves tissue, both hard (bone) and soft tissue as compared to conventional

cementless total hip stem designs. This new approach has the potential benefit of less blood loss, quicker rehabilitation and if necessary easier removal and conversion of revision surgery. We are encouraged with our initial clinical / surgical impression and believe the potential advantages warrant further evaluation of this new approach to THA.

