

An Alternative Conservative Approach to Hip Reconstruction

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Abstract

Primary Total Hip Arthroplasty (THA) has been a very effective surgical procedure, with improvements in design and clinical outcomes since the days of Sir John Charnley. [1-4] However, many implant femoral hip designs and surgical approaches have not been considered conservative for bone preservation.

Insertion of a femoral stem in THA does alter the physiological loading of the femur. Often these altered loading conditions can and do lead to bone reaction (stress shielding) and loss of proximal bone. Proximal stress shielding occurs regardless of fixation method (cement, cementless). [5,6]

This stress shielding and bone loss can lead to implant loosening and or breakage of the implant. In an attempt to reduce these boney changes some designers have advocated the conservative concept of "Neck Replacement" THA. [7-9]

This paper is a review of past, present and future development within this narrow classification of Neck Replacement Arthroplasty with highlighted focus on the Silent[™] Implant.

Key Words: total hip arthroplasty, tissue-sparing, neck-preserving, and conservative approach.

Introduction

There has been significant focus on the development of short stems over the past twenty years with most implant companies now offering a selection of designs. Many of these designs range from just shorter versions of current conventional length stems to a broad range of novel new design concepts including neck replacement only designs.

The Joint Implant Surgery and Research Foundation (JISRF) has developed and advocated for a femoral implant classification system based on primary fixation (stabilization) contact region. This classification system has been presented at a number of continuing medical educational (CME) seminars and has been well received. The basic categories of classification include the following: head stabilized, neck stabilized, metaphyseal stabilized, and conventional metaphyseal/diaphyseal stabilized. This classification system should help clarify the design principles inherent with each type and provide some guidance when researchers and other investigators are reporting on the outcomes of the various implant styles.

The structurer of the Classification System is as

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www.jisrf.org Founded in 1971 (Non-Profit)

follows:

- 1. Head Stabilized
 - A. Hip Resurfacing
 - B. Mid-Head Stem
- 2. Neck Stabilized
 - A. Short Curved Stems
 - B. Short Lateral Engaging Stem
 - C. Neck Plugs or Neck Only
- 3. Metaphyseal Stabilized
 - A. Taper Stems
 - B. Bulky/Fit and Fill Stems
- 4. Conventional Metaphyseal/Diaphyseal Stabilized This paper will only review 2 C. Neck Only Replacements.

Review (JISRF Classification 2 c.)

This is a narrow classification of devices with just a limited quantity of implants in the market. However, interest appears to be increasing, in part, with the significant decline of hip resurfacing (HR).

Models of neck plugs in development or currently on the market include the Silent Hip from DePuy, launched in 2009; the Primoris Neck Replacement from Biomet; the Spiron[™] Hip by ARGE Medical Technics; the CUT[™] Stem by Orthodynamics; and the TSI[™] Hip by Concept Design & Development, LLC. All of these devices have a common theme: engagement in the femoral neck and a 12/14 modular head neck taper. As many of these models are still in development, details on precise specifications and early clinical results are available for only three models of neck replacements: the Spiron[™] Hip, the CUT[™] Stem, and the Silent[™] Hip.

The Spiron[™] Hip

This hip has a conical, self-cutting screw that is inserted without cement into the prepared subcapital femoral neck.

The CUT[™] Stem

The implant is made from a cobalt-chromium-molybdenum (CoCrMo) alloy and has a macroporous structure. The stem is curved at the distal tip designed to rest against the lateral cortex of the femur.



ARGE Medical Technics, Hannover, Germany



The TSI™ Neck Implant

Designed to load the medial calcar with a novel conical flare with a multiplanar implant body for enhanced rotational stability and surface area for fixation.

The Primoris[™] Neck Replacement

It has a collared lip for abutment on the resected femoral neck and may reduce the risk of subsidence. Cross section is trapezoidal for rotational stability and optimizes fit and fill of the neck.

The Silent[™] Hip

Optimizes soft-tissue preservation that may enable earlier recovery and rehabilitation. The original design concept was by Dr. Mathhius Honl in Germany 1997.

Three reviews will be discussed on this device the first is short to mid-term results from two clinical studies across eight centers and was presented as a poster at the British Orthopaedic Association Annual Meeting in 2009 and the senior author"s personal series with a 6-7 year follow-up. In addition, we are reviewing the Australian experience of three surgeons.

Methods for BOA Poster [11]

A pilot clinical study used Radiostereometric Analysis (RSA) to demonstrate the implant stability. Following satisfactory results over the early post operative period, a larger, second phase study was initiated with a wider group of surgeons, to demonstrate the transferability of the surgical technique in a larger group of patients. No design changes were made to the SilentTM Hip throughout the clinical evaluation period.

41 hips were recruited in two centers (Australia, Germany) throughout 2003 in the RSA pilot study. 100 hips were recruited in second phase clinical study by eight surgeons in seven centers (Australia, France, Germany, Italy, UK) between May 2005 and



Concept, Design & Development, LLC (CDD™) Chagrin Falls, Ohio

Biomet, Warsaw Indiana



DePuy International Leeds, England

October 2008. Surgical approaches including posterior, direct anterior and anterolateral were used across the two studies according to each surgeon's standard practice.

Methods for Waller Series [12]

15 Hips in 14 patients (13 males, 1 female), average age 56 (49-66). BMI range 23-35 (mean 27.4) all bone stock Dorr type A, with OA in all cases. ASR cementess cup and XL metal heads used in all cases with a 6-7 year follow up.

Implant

A neck only replacement that features a taper style shape of titanium alloy with a fully DuoFix[™] cementless coating for



long-term fixation. It features a 12/14 head neck modular taper. The hip is available in five cross-sectional sizes at 2 mm increments measured at 3 mm below the shoulder of the implant. A variety of implant lengths are available depending on stem cross sectional size.

Finite Element Analysis



FEA shows that the Silent Hip loads the bone in a more physiological manner transfers load, via the neck, to the femoral shaft.

Surgical Technique [13]

The Silent Hip lends itself to implantation with any surgical approach, however, is very user friendly in smaller tissue sparring approach including the direct anterior approach. Powered reaming of the femoral neck, as opposed to broaching, ensures precise cavity preparation, optimizing positioning and press fit for optimum in-growth and fixation.

A void is created



at the tip of the prosthesis, which allows the sides of Silent[™] Hip to lock in place and prevents contact with the lateral cortex. This prevents contact with the lateral cortex which could cause the taper to disengage.



Results of RSA Studies [11]

Results show that the Silent[™] Hip achieves stability and does not exhibit continuing patterns of

X-Rays of 54 year old female pilot study patient, operated for osteoarthritis.





Immediate Post-Operative

5 Year X-Ray

movement over time.

Only one hip in the RSA pilot study exhibited movement of more than 1mm in any direction, which can be explained by proximal bone resorption following a deep infection. Despite this loss of bone, this subject remains unrevised at five years and is clinically asymptomatic, with maximum reported values for HHS and OHS.

In a total of 141 hips, four revisions of the Silent[™] Hip have been necessary. Three were following periprosthetic femoral neck fractures in the first month post-operatively. An independent review of the fracture cases concluded that these failures were further to a combination of sub-optimal patient selection and surgical technique, and none were directly related to the SilentTM Hip. The fourth patient had their Silent[™] Hip revised following an early postoperative deep infection.

The combined Kaplan-Meier survivorship of the Silent[™] Hip based on revision of the stem for both studies is 97% (95% CI of 94–100%) at three years.



Results for Senior Author's Series











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Complications

Stem revisions = 0 ASR cup revisions for metallosis = 6 Note: All Silent Stems were solidly fixed at revision. 3 of the 6 stems scored lower after revision. Thigh pain = 0 DVT non-occlusive = 1

Radiographic Review

5 years n=15

- Loosening = 0
- Subsidence = 0
- Migration = 0
- Radiolucent lines = 0

Angle of Implantation

- Mean CCD angle 138°
- CCD range 125-155°
- All within 9° of native

The angle of implantation did not appear to have any effect on range of motion, thigh pain, hip scores or implant migration.





Preliminary FEA showed high Von Mises stresses in zones 2 & 5 if the implant made no contact with the lateral cortex.

Lateral Cortex Contact

Other than distal pedestal formation lateral cortex contact did not appear to have any effect on range of motion, hip scores, thigh pain or implant migration.



The Combined Australian Experience

Forty cases from three surgeons (J. Sullivan, R. Verhuel and C. Waller.

- 1 death from pancreatic cancer
- 1 early fracture due to technical error (short neck cut)
- Harris Hip Scores 52 pre to 97 post-op
- Oxford hip scores 23 pre to 46 post
- UCLA rating 5.2 pre to 7.8 post-op

• No other complications at 2-4 years Observations on the Forty Australian Cases

Silent Stem provides stable initial fixation capable of immediate full weight bearing. Osteintegration remains stable at 6-7 years and short neck cut with a long implant is a risky combination.



One fracture.

Overall Conclusions

The Silent[™] Hip successfully achieves the desired aims of a safe and effective femoral implant for use in primary hip replacement with the alleviation of pain, restoration of function, marked improvements in patient outcomes and a stable X-Ray appearance, whilst conserving bone stock. The majority of problems have been associated with the ASR[™] metal on metal bearing system for metallosis. We no



longer recommend or use metal on metal bearings with the Silent Neck Replacement or for that matter any total hip replacement.

Initial and mid-term fixation has held up well even in the face of metallosis. Radiographic appearance demonstrates the calcar bone becomes stronger over time.

The Silent Hip has been used exclusively in Dorr type A bone, however, it would seem appropriate in selective type B bone in middle-aged males.

There is no question that this is a bone preserving surgical approach to hip arthroplasty and may be a reasonable surgical alternative to hip resurfacing and to conventional cementless stems for the younger more active patient.

The JISRF Stem Classification System should provide clarification and guidance when reporting on new novel femoral stem designs.



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