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ABSTRACTS

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TITLE

DESIGN RATIONALE FOR THE STABILITY™ CEMENTESS TOTAL HIP SYSTEM

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Optimization of fit and fill has taken several approaches: off the shelf one piece; off the shelf modular pieces; ore-operative customs; intra-op customs. The growing concern of osteolysis has led to the development of the Stability hip system- This system offers the versatility of modular components, however, it reduces the potential sites that can generate particulate debris.

There are many design features available on cementless total hips today- However, we are still very limited in our selection of materials. We now know modularity is a site for generation of particulate debris. We must be careful in our selection of modularity to insure that we do not extend the risk benefit ratio beyond reasonable approaches. In a revision situation it is desirable to have many intra-operative options. However, routine primary surgery particularly in a patient with a life expectancy over 20 years may be a different situation. Do we really need to consider using excessive modular sites that can generate increased particulate debris for these routine cases, or can we accomplish the reconstruction with a more conventional one-piece stem?

Utilization of proven design concepts and proven fabrication techniques have now made it possible to generate increased sizes for an off the shelf one-piece, cementless primary total hip stem.

The short term clinical results of the intra-operative custom technique of Identifit™ has had-mixed results in the United States. However, the learning experience has demonstrated a number of factors. Initial focus was on fit and fill. Then the importance of shape was introduced, and recently the advent of macrotexturing and flutes.

Fit and fill, shape, and surface geometry are all important ingredients to achieve axial and torsional stability. However, fit and fill is difficult to achieve due to the varying geometry of the proximal femur. A question is how can we improve our ability to fit and fill varying geometries. One answer is to have a large quantity of sizes, the second is- customs, and the third is modular designs. All three of these answers must address the geometry considerations of proximal size and shape, distal size and shape, and stem length.

Although the cost of customs has been coming down, it still is not equivalent to standard cementless, off the shelf devices. In addition, pre-operative customs limit the intra-operative options that one is faced with and requires considerable pre-operative precision in working with the devise manufacturer.

On the other hand, in the past, a large quantity of sizes has been prohibitive because of cost involvement in standard manufacturing procedures. However, Orthogenesis technology of surface milling now makes this option cost effective. A large quantity of sizes offers many intraoperative options and reduces pre-operative precision planning. However, it still requires understanding all options (sizes) and requirements for surgical technique.

Modularity has been cost effective, offers many intra-operative options, generally has a high demanding surgical technique, also a high learning curve in understanding of intraoperative options and has been shown to be a site for generation of particulate debris, which can lead to osteolysis.

Overview - Stability Components

A. Initial sizes, four diameters (12, 14, 16, 18 mm)

   Standard Stem Length (150,155, 160,165 mm)

   The tapered neck permits the use of a variety of head diameters, neck lengths, and C.C. or ceramic material.

B. Graduated Proximal Design

   There are two cone bodies for each diameter stem. Also, two triangle sizes for each cone size. A total of four different proximal sizes are available for each stem diameter.

C. Design Features Stem

   A material: titanium alloy.

1. Taper neck - allows for modular heads.
2. Conical proximal body with medial triangles - allows for better fit and fill.
3. A circular, distal diameter stem - allows for easy, precise preparation by reaming.
4. Longitudinal flutes on distal stem - increased torsional resistance.
5. Non-bead blasted surface (chem-mill) - reduces surface particulate debris.
6. Forged titanium alloy - excel lent fatigue strength, low bending modulus.
7. HA coated - increased bony response.
8. Proximal body - approximates the shape of the prepared endosteal cortex.
9. Proximal body - five degree taper proximal to distal.
10. Proximal steps - transfer hoop tension into compression. Helps reduce subsidence. Also helps to increase shear resistance of proximal coatings.
11. Two triangle sizes per cone - allows for better fit and fill.
12. Distal coronal slot - reduces distal bending stiffness.
13. Offers versatility of many sizes for routine primary indication while reducing the need for modular sites now known to produce particulate debris.

Summary

The fabrication process of surface milling now allows for increasing off the shelf size offerings reducing the need for modularity and customization; and, more importantly, lends itself to design evolution in a cost effective manner.