

4.1 The Concept of CeramTec to Offer Ball Heads Dedicated to Hip Revision Demands

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Aim

Ceramic ball heads are used since 30 years in hip endoprostheses. In the case of a revision where the ball head needs to be exchanged but the stem is fixed, only limited solutions are available on the market. Up to date CeramTec advised not to implant a ceramic ball head on a used stem.

CeramTec has decided to provide a revision solution for this case. This shall give the surgeon the possibility to use a ceramic ball head in a revision case where the stem is fixed in the femur for either a ceramic wear couple solution or a system with a PE insert.

Concept of a Ceramic Revision Ball Head

In revisions where the stem is not exchanged there is always the possibility that the stem is damaged for example by removing the ball head from the stem. A potential damage of the stem will induce a stress concentration when a ceramic ball head is placed directly on the damaged taper which could lead to a breakage of the ceramic ball. Therefore CeramTec has decided to use a system with a metal sleeve (figure 1).

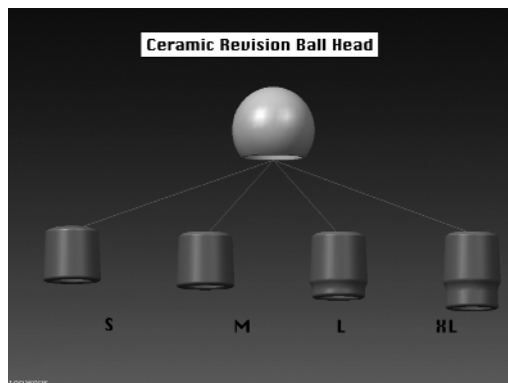


Figure 1:
Concept of ceramic revision ball head with metal sleeve.

The sleeve will be adapted on the taper of the stem which creates a new taper size where the ceramic ball head is put on. The first solution CeramTec wants to place on the market is for 12/14 tapers. Possible neck lengths are S, M, L and also XL which will be realized through different metal sleeves. It is planned to have first two ceramic ball head sizes: 28 mm and 32 mm with one standard taper. Further tapers and other outer diameters (36 mm) will be evaluated.

Ceramic Revision Ball Head with Stem

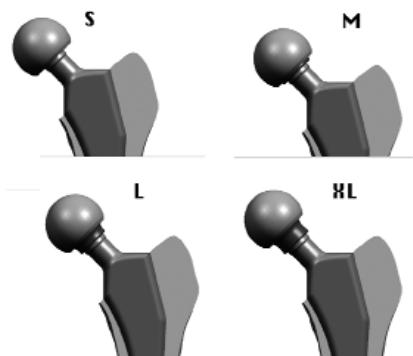


Figure 2:
Combination of ceramic revision ball head
with stem.

Development and Test Concept for the Ceramic Revision Ball Head at CeramTec

The development of a ceramic revision ball head at CeramTec is divided in two major stages. The first stage is dedicated to understand the system of all three components, find limitations to the system and to define the manufacturing standard for the revision ball head. In this phase a large amount of evaluation and validation in production as well as testing in different settings are the major parts. At the end of this stage it should be clear how the ceramic revision ball head is produced and that all necessary processes are validated. The testing involves questions like what is the influence of the metal sleeve or a damage at the taper for the mechanical properties, what are the worst case settings and so on. The answers should provide a detailed overview of the system and how customer projects can be conducted. The second stage will deal with defined customer projects.

Conclusion

During 2004 CeramTec will offer a ceramic revision ball heads system to give the surgeon the opportunity to use ceramic solutions in revisions. The revision system consists of a metal sleeve and a ceramic ball head. The release of the product undergoes two development stages: the first stage to find answers to general question and a second stage where customer projects will be handled.