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Evaluation of the compatibility of ceramic ball head and femoral stem taper on the new type THR

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ABSTRACT

Purpose: of this paper was follow up of compatibility of femoral component taper from TiAl6V4 ELI acc. ISO5832-3 and ceramic head of the new type of total hip join replacement THR - ZRM® in vitro.

Design/methodology/approach: from december 2006 to august 2007 we have tested THR taper component and ball ceramic head. On the base of our patents (SK, CZ, EU, USA) from 1999 to 2006 we have designed and developed the new type of cementlesss THR - ZRM®. These total hip replacements were tested in our prospective study. We have evaluated compatibility and loading resistance of taper of THR ZRM® made from TiAl6V4alloy ELI and ceramic ball head Biolox® forte (28-12/14L) by tests of burst strength, pull out, rotational stability, fatigue and post-fatigue. Tests were monitored independent observer.

Findings: in the burst test were tested 7 parts and average loading was 54 kN. The reached values comply with the requirements according to CeramTec procedure VA 02 04 4129 and the FDA Guidance document for the preparation of premarket notifications for ceramic ball hip systems. In the fatigue test all specimens test at a maximum load of 14 kN reached 10 million cycles without mechanical failure. The post fatigue test was performed with load of 46 kN and no failure of head and taper system was observed. The pull-off tests were made with pull out strength of 1439 N has been used on 5 parts and no pullout of ceramic ball head of taper femoral component was observed. Last was the test of rotational stability, where ball head was rotational stable under strength of 1254 Ncm.

Research limitations/implications: this study was performed on the small group of spices but enough relevant according FDA and international ISO prescriptions.

Originality/value: this study is original by publishing first results of the new cementless THR- ZRM® tests of compatibility and fatigue of metal taper and ceramic ball head. Value of this paper is in vitro testing and prepares ZRM® cementless THR for clinical use in human.

Keywords: THR; Compatibility; Fatigue; Pull out; Burst; Rotational stability

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MATERIALS MANUFACTURING AND PROCESSING

1. Introduction

Total hip replacement THR is one of the best surgical treatments of damaged hip joint by dysplasia, osteoarthritis, inflammation, tumor, avascular necrosis and trauma. These help to give patients a new dimension of mobility with freedom from pain even at an advanced age and upgraded and extended orthopedic surgery in an unheard-of manner. From 1999 to 2006 we have designed and developed the new prototype of cementless total hip replacement- THR ZRM® made from TiAl6V4 ELI alloy (according to ISO 5832-3). Purpose of our previous study was developed new desing of femoral component with vertical and horizontal anchorage ribs, press fit technique of implantation of femoral component and acetabular cup component. Acetabular cup component is shaped sphere-conical with special self tapered thread on the surface and ceramic camp liner. When we have finished development of this new ZRM® prototype, we have decided to test compatibility of ceramic ball head and femoral component metal taper.

2. Material and methods

Purpose of this study was to assess if Biolox® forte ball heads 28-12/14L on tested tapers of the new ZRM® THR from TiAl6V4-ELI alloy (Fig. 1) according (ISO 5832-3) comply with the requirements for component testing according CeramTec procedure VA02044129 and the FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems. This ceramic ball head and metal taper compatibility was tested by burst test, fatigue and post-fatigue test, pull-out test and test of rotational stability. Before tests samples- ball heads Biolox® forte and metal tapers have been dimensionally inspected according CeramTec connection measuring and differences in the dimensions against connection were detected.

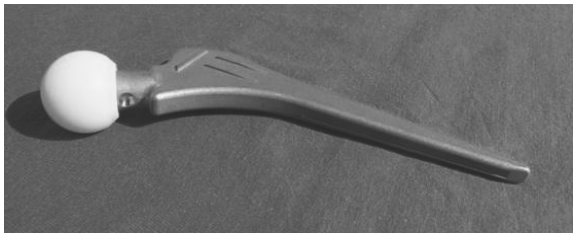

Fig. 1. Femoral stem taper with put on ceramic ball head Biolox® forte

Burst tests were made as compression test of femoral head on 7 tested parts in dry air under the average loading 54 kN with minimum value of 45 kN.

Fatigue tests have been performed in Ringers solution and 3 samples. All specimens were tested at a maximum load of 14 kN reached in10 million cycles. On the (Fig. 3) is very interesting from the experimental point of view that on the internal surface of con of ceramic head was an excellent quality pushed the peripheral surface of con femoral part.

Post fatigue tests reached values were with minimum of 1343 N strength on 3 samples (Fig. 3).

Pull off tests have been performed with minimum value of 1343 N (Fig. 2 and Fig. 3).

Rotational stability test have been made with minimum value 1132 Ncm. *Post fatigue* tests were made with 3 samples and minimum value of strength was 42 kN with an average 46 kN and standard deviation was 6 kN. The reached values comply with the requirements according to CeramTec procedure Va 02 04 4129 and the FDA Guidance.

Pull-off tests were made on 5 test specimens with minimum value of pull of strength 1343 N and average 1439 N with standard deviation 85 N.

Rotational stability has been tested on 3 samples with minimum of 1132 Ncm rotational strength and average 1252 Ncm with standard deviation of 191 Ncm.

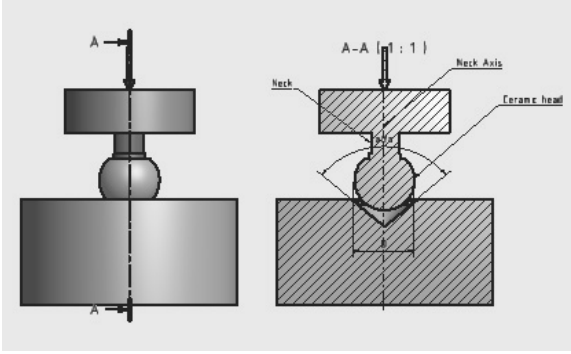

Fig. 2. Set - up used for fatigue and post-fatigue testing according to ISO 7260-10

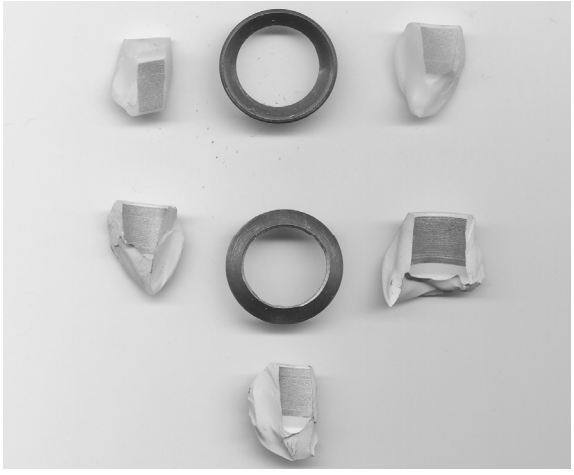

Fig. 3. The ceramic ball head Biolox® forte after the test Pull off

Figures 4 and 5 show ceramic ball head Biolox® forte before total destruction and Figure 6 show new prototype of cementless total hip replacement THR - ZRM®.

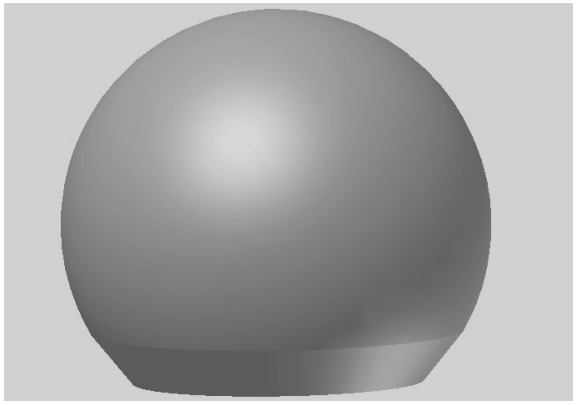

Fig. 4. The ceramic ball head Biolox® forte (28-12/14L) before total destruction

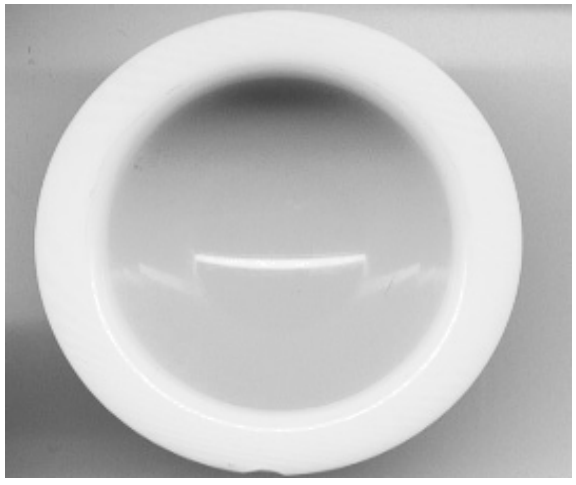

Fig. 5. The ceramic ball head Biolox® forte (28-12/14L) before total destruction

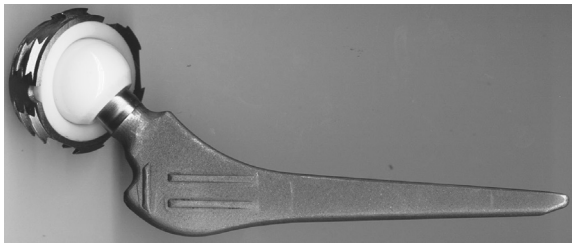

Fig. 6. Complete of the new prototype of cementless total hip replacement THR - ZRM®

3. Results

Our study had been performed by tests of compatibility and resistance of TiAl6V4-ELI alloy femoral component taper THR ZRM® and ceramic ball head Biolox® forte. When we have started this study we have excluded one taper after dimensional inspection of samples of tapers, because this taper have showed a deviation regarding its angle. The five types of tests were made with follow results.

Burst tests have been performed on 7 test parts with minimum value of compression 45 kN and average 54 kN with standard deviation 6 kN.

Fatigue tests have been made with 3 samples and all tested specimens at a maximum load of 14 kN reached in 10 million cycles without mechanical failure.

4. Conclusions

1. The results of our test study were aimed to compatibility and loading resistance of ceramic ball head Biolox® forte and femoral component taper of ZRM® cementless THR.
2. The TEP ZRM was compiled with the requirements according to CeramTec procedure VA 02 04 4129.
3. It was tested by regarding burst strength.
4. It was tested by fatigue test.
5. It was tested by post-fatigue burst strength.
6. It was tested by pull-off.
7. It was tested by rotational stability.
8. These results also comply with the requirements according to the FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems regarding burst strength, fatigue test, post-fatigue burst strength and pull-off tests.

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