## Title
Incidence of modern alumina ceramic and alumina matrix composite femoral head failures in nearly 6 million hip implants

## Authors
Gwo-Chin Lee and Raymond H. Kim

## Journal

## Level of Evidence
None given

## Summary
The use of ceramic femoral heads coupled with XPE has been rising steadily in the US. In 2015, 50% of implanted femoral heads were ceramic (American Joint Replacement Registry, Annual Report 2016). Reasons for that were the expectation of decreased wear rates, use of larger heads, and concerns about trunionosis. However, the risk of ceramic fracture still remains a concern. Therefore, the purpose of this study was to evaluate the risk of ceramic femoral head fracture through analysis of the quality control program of CeramTec. Lee and Kim aimed to determine the fracture rate of BIOLOX® forte and BIOLOX® delta heads as well as factors such as time in situ, head size, and taper influence on ceramic head fractures.

Between January 2000 and December 2013, over 3.2 million BIOLOX® forte and 2.78 million BIOLOX® delta heads were sold and implanted worldwide. During this 14 year time interval 672 BIOLOX® forte and 28 BIOLOX® delta head fractures were reported. The fracture rate was 0.020% for BIOLOX® forte and 0.001% for BIOLOX® delta. Most of the fractures (80%) occurred within 48 months. Due to the small number of failures of BIOLOX® delta heads, the data could not be further analyzed. Using available data for analysis, specific events such as trauma, dislocations, or component malposition were associated with fractured heads. Smaller BIOLOX® forte heads (28mm) were also more likely to fracture than larger ones (≥32mm). The same trend was seen for BIOLOX® delta heads, but the sample size was too small for further analysis. The 28mm head with a short neck length (S) was more likely to fracture than other neck lengths. Taper design/mismatch was the principle cause for fracture attributed to the majority of BIOLOX® delta heads and contamination of the stem taper was commonly found in BIOLOX® forte head fractures.

The authors conclude that BIOLOX® delta femoral heads have a significantly lower fracture rate compared to BIOLOX® forte, larger heads (≥32mm) are less likely to fracture, dislocations and taper mismatch and contamination are associated with ceramic head fracture.

## Study Limitations
Actual fracture rates might be higher due to possible underreporting of component failures to CeramTec.

Implant and clinical details for the fractures were often lacking or incomplete, making it difficult to determine the exact circumstances/reasons of the component fractures.

Epidemiology of BIOLOX® delta fractures could not be analyzed in depth due to the small number fractures.

## Key Messages
- BIOLOX® delta femoral heads have a significantly lower fracture rate than BIOLOX® forte heads.
- Smaller femoral heads (≤28mm) are more likely to fracture.
- Important factors for preventing ceramic fractures are appropriate taper design and taper fit (no taper mismatch), proper taper cleansing and impaction of the heads.