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Paper #16

## Reliability of Ceramic Heads in over 5.7 Million Hip Replacements

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**Introduction:** Because of improvements in ceramic materials and manufacturing the incidence of ceramic failures has decreased over time. Recent concerns with corrosion have contributed to an increase in ceramic ball head utilization. The purpose of this study is to report the incidence of modern alumina bearing failures from a single major ceramic manufacturer in over 5.7 million hip implants and to identify trends in the modes of failure of these implants.

**Methods:** Beginning in the year 2000, CeramTec AG (Plochingen, Germany) began a comprehensive program for reporting and gathering failure data on its products. From January 1, 2000 to December 31, 2013 3.2 million pure alumina and 2.52 million alumina matrix composite ceramic balls heads were implanted worldwide. During this period, there were 672 pure alumina and 26 alumina matrix composite femoral head fractures. The fractures were analyzed with respect to time to failure, head size, and implant factors.

**Results:** The incidence of clinical fractures of modern pure alumina femoral heads and alumina matrix composite femoral heads was 1 in 5000 (0.021%) and 1 in 100,000 (0.001%) respectively ( $p < 0.0001$ ). The majority of implant failures (80%) occurred within 48 months following surgery ( $p < 0.01$ ). Fractures were usually associated with specific events such as trauma, mismatched components, and dislocations. Large diameter heads were associated with a lower rate of fracture compared to smaller diameter femoral heads (0.030% for 28 mm heads vs 0.008% for heads 32mm or greater ( $p < 0.01$ ) for modern pure alumina and 0.004% for 28mm heads vs. 0.0004% for 32mm alumina matrix composite heads ( $p < 0.001$ ). The neck lengths of the femoral ball heads were also a factor: a short taper 28mm ball head was more likely to fracture compared to other neck lengths ( $p < 0.01$ ).

**Conclusion:** Modern alumina ceramic heads are reliable with extremely low risk of fracture. The reliability is even better with alumina matrix composite heads.

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