

2.1 Ceramic Ball Head Retrieval Data

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Since the 1970's when first it was realized that the properties of alumina ceramics could be exploited to provide better implants for orthopedic applications, the field has expanded enormously. Applications depend on the fact that alumina ceramics are corrosion resistant, offer an excellent biocompatibility, are synoviaphil, are extremely hard and scratch resistant, and provide wear characteristics suitable for bearing surfaces in total hip replacement (1). Resultant orthopedic use has enjoyed more than 20 years' clinical success. Up to the present more than 2.5 million alumina femoral heads have been implanted. Their popularity is based on two facts: extremely low wear rate and reliability.

It is a fact that materials scientists have substantially improved the properties of wear resistant alumina, e. g. mechanical strength which is correlated to reliability, i.e. fracture in vivo. There are three generation of medical-grade alumina. The latest one is an alumina that is hot isostatic pressed (HIP), laser marked and proof-tested (2, 3). Some important properties are listed in table 1.

Table 1 Some characteristics of BIOLOX® forte ceramics (Typical values)

Property	1st generation	2nd generation	3rd generation
Bending strength (MPa)	> 450	> 500	> 550
Density (g /cm ³)	3.94	3.96	3.98
Grain size (µm)	≤ 4.5	≤ 3.2	≤ 1.8
HIP	no	no	yes
Laser Marking	no	no	yes
100% control	yes	yes	yes
Proof-test	no	no	yes

In 1995 Toni (4) published a review reporting a list of fracture rates which ranged between 0% for today's ceramics and up more than 10% for ceramics manufactured before 1980. It is important to note that these high fracture rates were caused by

materials manufactured by companies that are not on the market anymore. These old aluminas had a low density, a very coarse microstructures, and are not in compliance with specifications valid today, e.g. ISO 6474 and ASTM F 603. The in vivo fracture rates of the most commonly used ceramic BIOLOX® forte have been analyzed by various groups, e.g. Semlitsch of Sulzer medica published reports based on more than half a million heads (5, 6). CeramTec's reports are based on more than 1.5 million heads (7–9). The fracture rate of ceramic femoral BIOLOX® forte heads are listed in table 2.

Table 2 Fracture rate of BIOLOX® forte ceramics

1st generation	2nd generation	3rd generation
0.026%	0.014%	0.004%
26 : 100,000	14 : 100,000	4 : 100,000

Analyzing the clinical experience of 25 years it can be concluded that the technical improvements are offering reliability (3, 4–6, 8, 9).

Results of wear tests with a hip simulator and investigations of retrievals prove that the wear rate of the wear couple BIOLOX® forte-on-BIOLOX® forte is extremely low (10–12).

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