IMPACT TEST FOR CERAMIC FEMORAL HEADS WITH AND WITHOUT ADAPTER SLEEVE

*Dong, N.G.; *Boucher, F.; *Alexander, T.; *Moindreau, M..; * Wang, A.; **Sharkey, P.F.; *Kester, M.A
*Stryker Orthopaedics, 325 Corporate Drive, Mahwah, NJ 07430 USA
**Thomas Jefferson University, 925 Chestnut St. 5th floor, Philadelphia, PA 19107 USA

Objective:

The micro separation of ceramic bearing couple has been reported in vivo and in vitro studies. However there is no ceramic head strength test established to date to simulate this loading condition. The purpose of this study was to investigate the strength of ceramic femoral heads under simulated static and impact loading conditions with and without adapter sleeve.

Method:

1. (34) 12/14 Titanium alloy taper trunnions were assembled with (9) 28mm-2.5 alumina (Biolox Forte, CeramTec) femoral heads, (9) 28mm-2.5 Delta (Biolox Delta, CeramTec,) ceramic heads and (16) 32mm-2.5 Delta ceramic heads
2. (34) 11/13 Titanium alloy taper trunnions were converted to 12/14 taper by titanium alloy adapter sleeves and then assembled with (9) 28mm-2.5 alumina femoral heads, (9) 28mm-2.5 Delta ceramic heads and (16) 32mm-2.5 Delta ceramic heads.

All test ceramic heads were inspected, cleaned and radiation sterilized. The heads were assembled to corresponding trunnions and were preloaded to 500N by flat APX steel plates at polar. The static failure test of each combination was performed by an MTS test machine at 30kN/min until head broke through the dome point loaded APX steel plates. The maximum breaking forces were recorded and compared for different combinations. The impact test was performed by the Charpy machine with minimum 1° angular interval. The pendulum angle was started at 10° and increased every 10° until the fracture. The end point angle was repeated with 1° increment until fracture or repeated with 1°decrease if head fractured in first hit. The calculated impact energy was recorded. Test was repeated for (5) data points with minimum 2 hits for each head for Delta 32mm-2.5 heads. A new APX steel plate was used for every static and impact test. The statistical analysis was performed by student t test in 95% confidence level.

RESULTS AND DISCUSSION:

There was no statistical difference in all static tests between ceramic heads with direct taper and with adapter sleeve for Forte 28-2.5 heads (Table 1a), Delta 28-2.5 heads (Table 1a), and Delta 32-2.5 heads (Table 2).

With adapter sleeve, there was 85% increase in impact energy resistance for alumina 28-2.5 heads and 28% increase for Delta 28-2.5 heads (N=1) (Table 1b).

With adapter sleeve, there was significant or 20% increase in average impact energy resistance (p= 1.209E-08) for Delta 32-2.5 heads (N=5) (Table 2).

The shortest neck offset was chosen for the minimum polar material thickness, a worst condition for impact. Unlike the ring contact used in current ISO/DIS 7206-10 standard ultimate compression strength (UCS) test, the point contact and impact loading conditions in this study more closely simulated the clinical conditions for the ceramic bearing -especially under micro-separation. The additional interface created by the adapter sleeve theoretically consumes more energy and thus makes less energy available to break the ceramic head. This however has been demonstrated only in the impact load setting which is likely influenced more by the energy level. The energy sharing effect of the adaptor sleeve was diminished when the load level increased in larger 32mm Delta ceramic heads suggesting the more complete seating of sleeve may lead to a less energy consumption. Additionally, the adapter sleeve could also protect the ceramic head from the irregularity of the metal taper, the condition is common for the damaged trunnion in revision.

Table 1a: Static Force (KN) Results of 28mm-2.5 Ceramic Femoral Heads as a Function of Different Test Conditions. N=5

Static Test No.	Alumina 28mm-2.5 / Direct taper	Alumina 28mm-2.5 / Adapter sleeve	Delta 28mm-2.5 / Direct taper	Delta 28mm-2.5 / Adapter sleeve
1	5.01	4.64	11.48	10.99
2	3.98	7.39	11.42	11.92
3	4.83	5.01	11.64	11.99
4	4.87	4.86	10.81	11.41
5	4.53	3.90	10.07	11.88
Mean ± Std. Dev.	4.65± .410	5.16 ± 1.32	11.08 ± .649	11.64 ± .429
	p=0.429		p= 0.148	

Table 1b: Impact Energy (J) Results of 28mm-2.5 Ceramic Femoral Heads as a Function of Different Test Conditions. N=1

	Alumina 28mm-2.5 / Direct taper	Alumina 28mm-2.5 / Adapter sleeve	Delta 28mm-2.5 / Direct taper	Delta 28mm-2.5 / Adapter sleeve
Impact	.492	.912	3.326	4.265

Table 2: Static and Impact Results of 32mm-2.5 Delta Femoral Head as a Function of Different Test Conditions. N=5

	Static (KN)		Impact (J)	
Test No.	Delta 32mm-2.5 / Direct taper	Delta 32mm-2.5 / Adapter sleeve	Delta 32mm-2.5 / Direct taper	Delta 32mm-2.5 / Adapter sleeve
1	22.45	24.93	8.853	10.747
2	23.8	23.3	8.853	10.47
3	24.28	22.19	8.853	10.747
4	23.29	21.26	8.853	10.747
5	24.04	21.1	9.117	10.747
Mean ± Std. Dev.	23.57 ± .726	22.56 ± 1.591	8.91 ± .118	10.69 ± .124
	p=0.230		p= 1.2E-08	

Conclusions:

The adapter sleeve significantly increased the impact resistance of ceramic ball heads.

References:

1.Walter et al:. J Arthroplasty 2004;19:402, 2,Merkert : 9th Biolox symposium. 3.Garino:.10th Biolox symposium. 4.Dong et al:. 50th ORS.