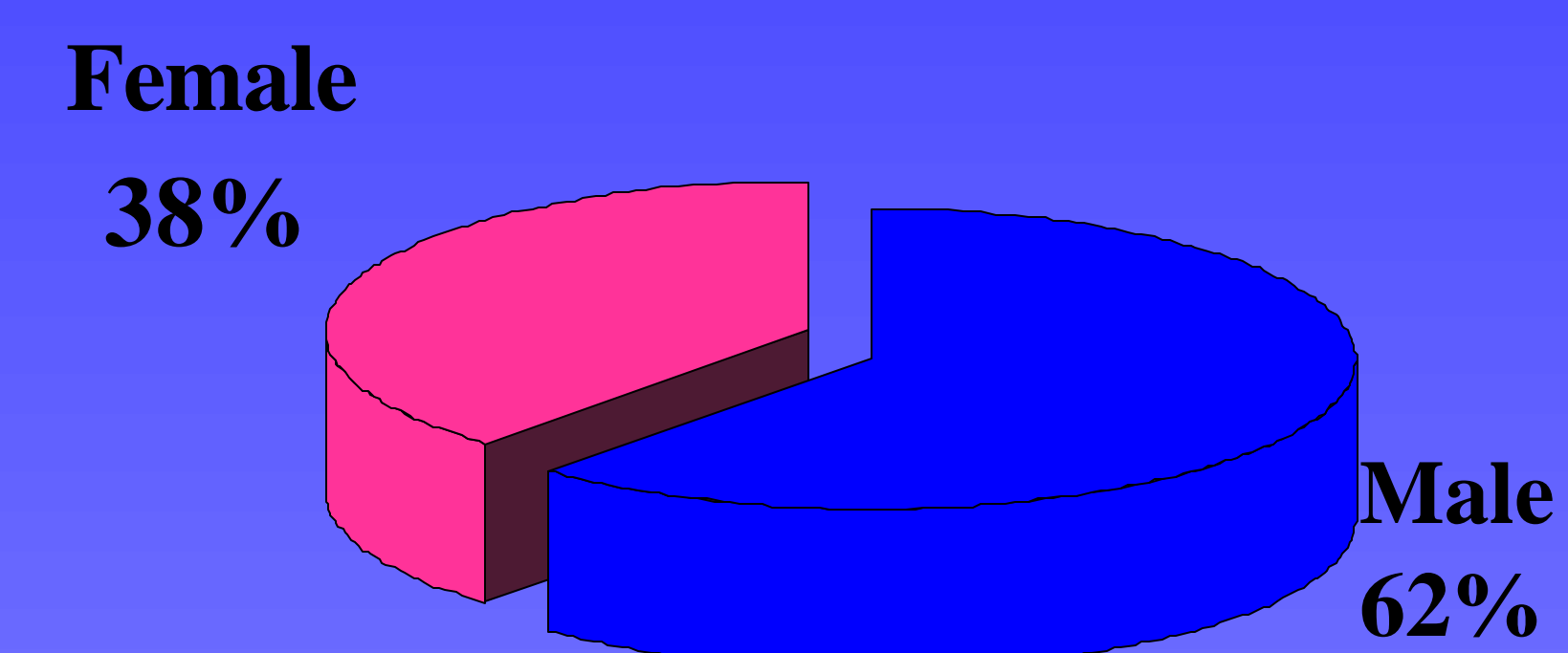


US Experience with Alumina Ceramic-Ceramic THA

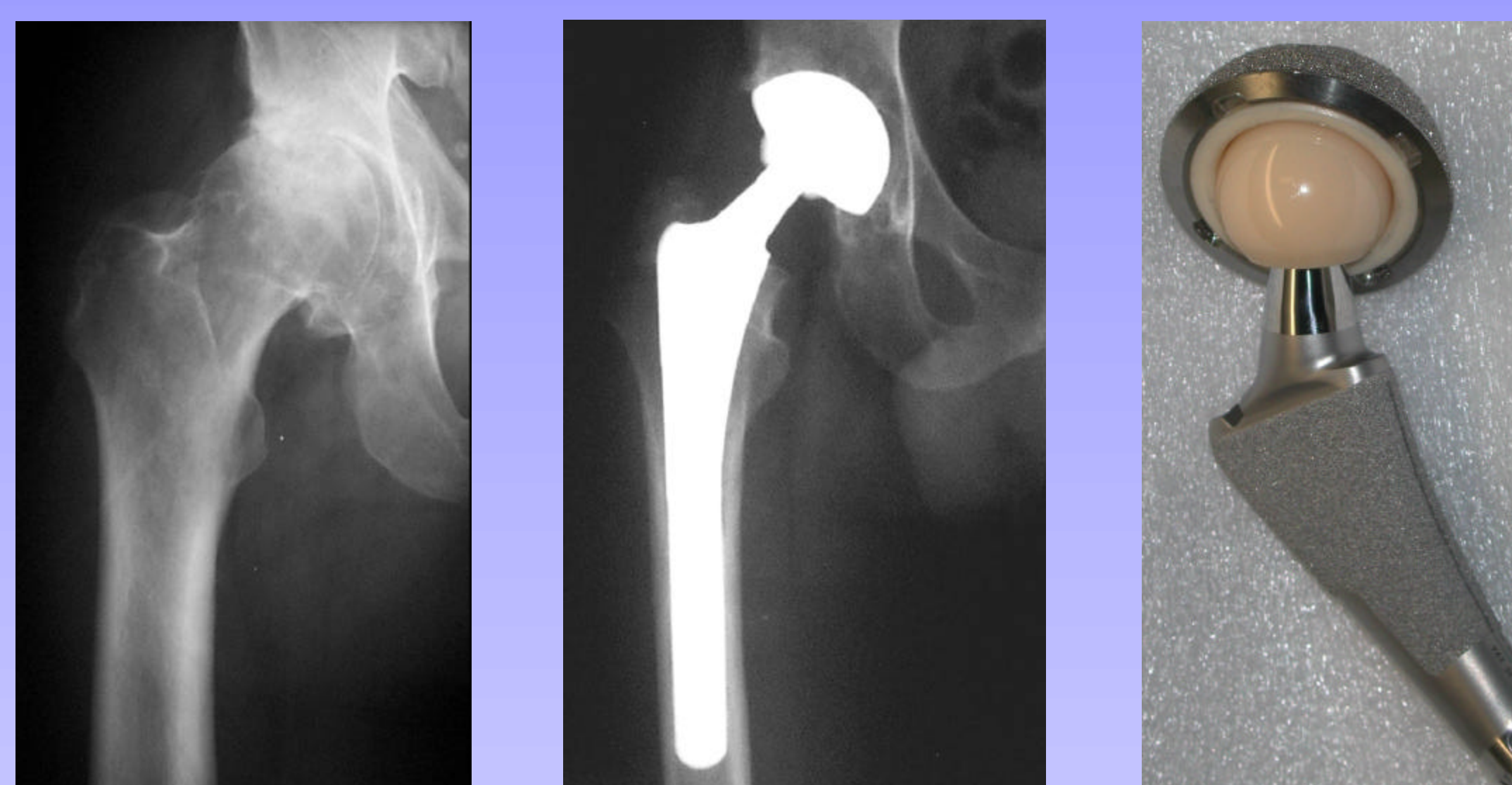
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INTRODUCTION:

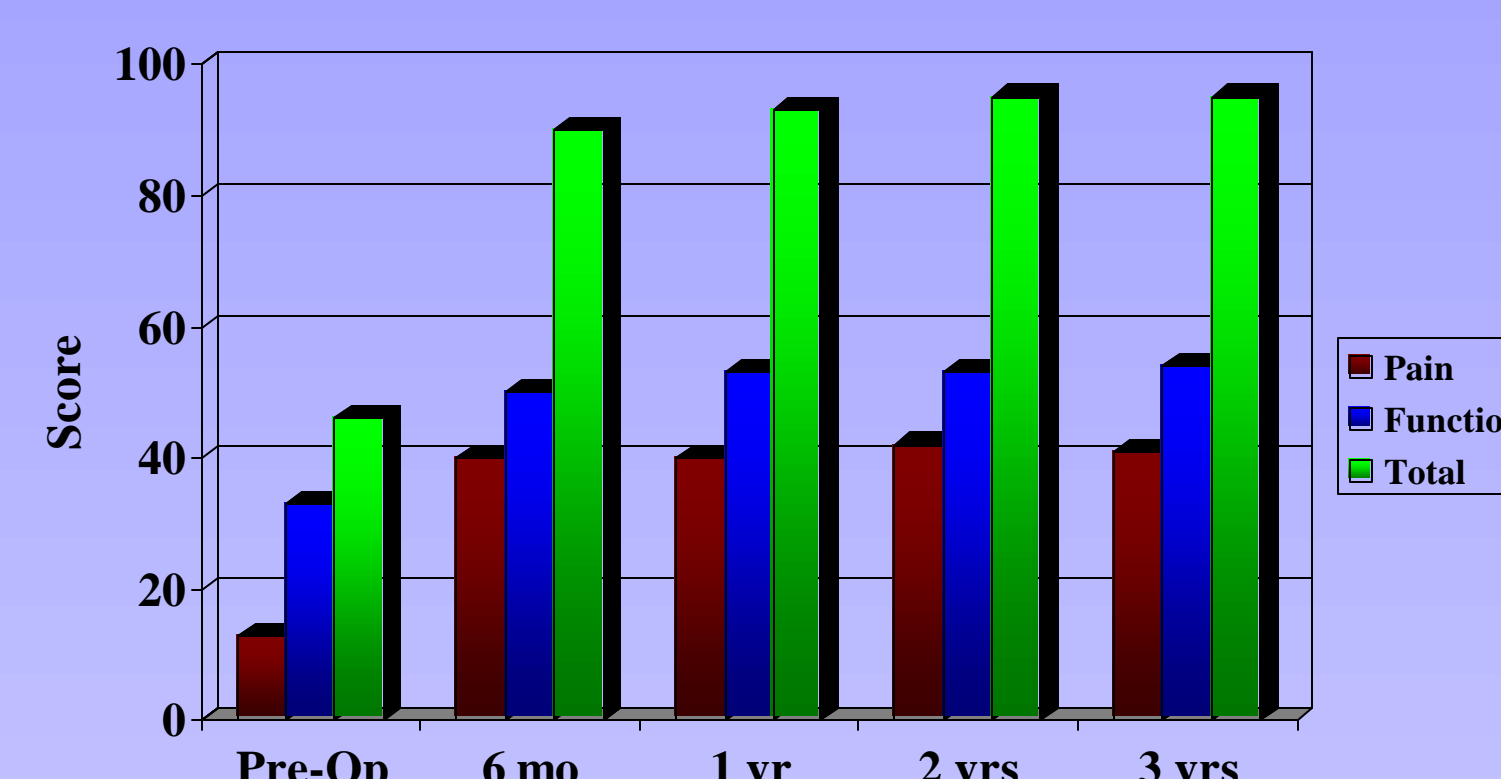
UHMWPE-debris induced osteolysis is the most common long-term problem in THA. The scientific basis for cross-linked PE (XL-PE) is purely based on idealized laboratory wear studies without published clinical results. Further, third body wear and femoral head scratches have been shown to accelerate XL-PE wear rates to 2,000 to 750,000 times higher than Alumina Ceramic-Ceramic bearings. By contrast, Alumina Ceramic-Ceramic THA has both laboratory and clinical data supporting its use. Clinical data on the current alumina bearings exceeds 10 years overall and exceeds 4 years in the US. Further, Alumina ceramics eliminate polyethylene wear debris and greatly reduce debris generation overall. The current study reviews an American experience with second generation Ceramic-Ceramic THA.



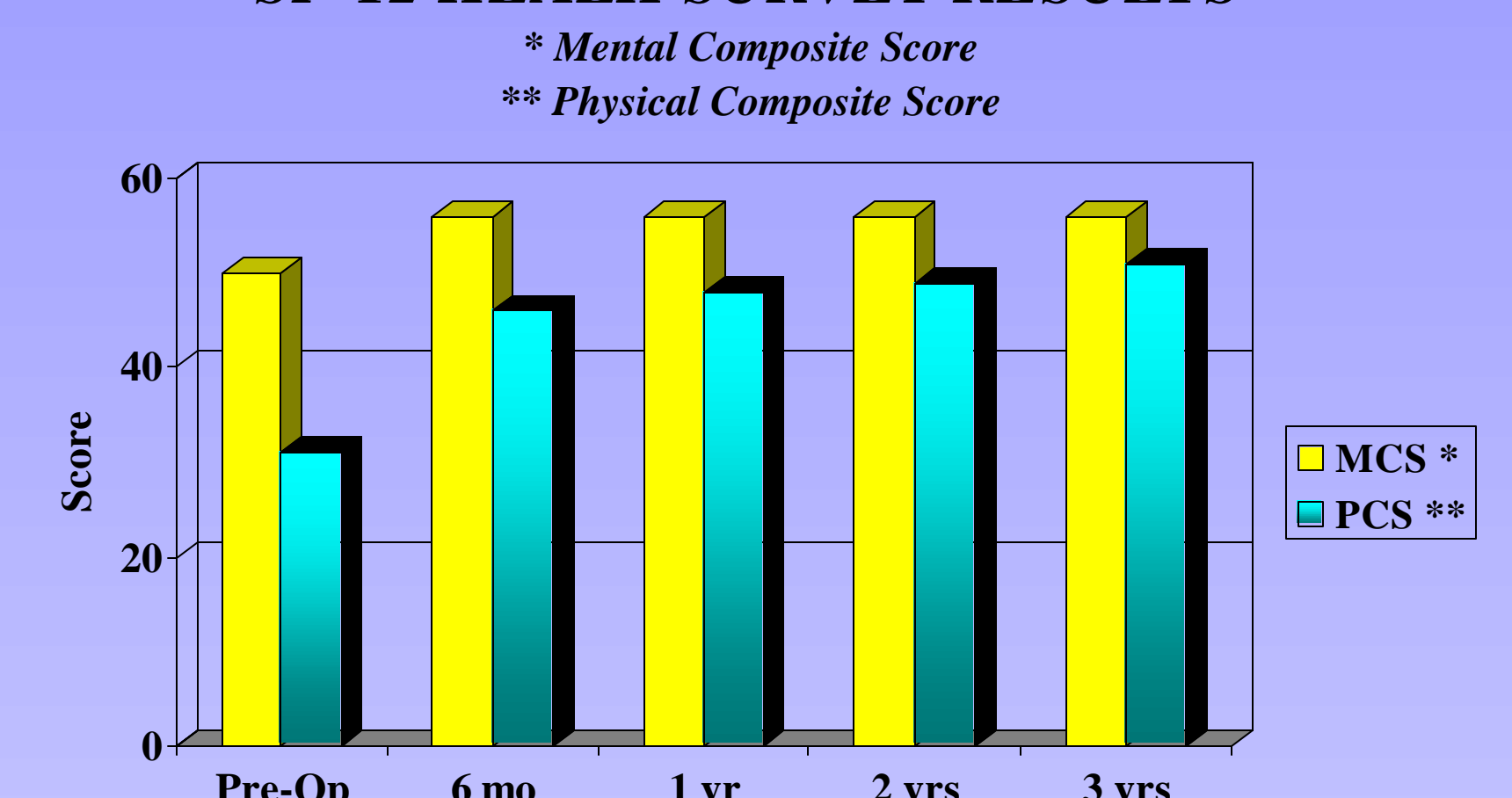
DEMOGRAPHICS	
Mean Age (years) (sd; range)	52 (11; 20-80)
Mean Weight (pounds) (sd; range)	190 (44; 90-355)
Body Mass Index (sd; range)	30 (6; 17-68)



HARRIS HIP SCORES



SF-12 HEALTH SURVEY RESULTS



METHODS:

1,116 alumina ceramic-ceramic hips (Ceramic TRANSCEND® Hip System, Wright Medical Technology, Inc.) were implanted at 12 centers in the US from April, 1997 to December, 2001 in a prospective FDA/IDE study. Mechanical testing showed that fracture strength of the acetabular liner exceeded 17,000 lbs. Clinical data is available on 1078 procedures. Patients averaged 52 years of age (range: 20-80). 62% of the patients were male, 38% were female. Diagnoses by incidence included OA, AVN, DDH, and traumatic arthritis.

Of 1,116 THAs, 147 had a minimum follow-up of 3 years with a mean follow-up time of 3.3 years. The average Harris Hip Score was 44.0 preoperatively and 93.6 at the last follow-up in the 3 year follow-up group. Of the 1,116 THAs, there have been 12 revisions (Table 1). These included 3 for instability, 2 for inadvertent implantation of incorrect components, 2 for failure of osseointegration, 1 for cemented femoral loosening, 1 for a mal-assembled component, 1 for deep infection, 1 for wear from recurrent subluxation, and 1 for chronic pain without discernable evidence of problems. Subsidence was reported for the population for 0.4% of the femoral stems and migration of the acetabular cups for 0.1% of the population. There have been no cases of osteolysis around either the femoral or acetabular component and no cases of post-operative ceramic fracture.

DISCUSSION AND CONCLUSION:

Both laboratory and clinical data demonstrate the reliability of Alumina Ceramic-Ceramic Bearings. There are no published comparable clinical studies supporting the use of XLPE. These results clearly demonstrate that Alumina Ceramic-Ceramic THA is extremely reliable without evidence of fracture or osteolysis at up to 4 ½ years after surgery.

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