Current Status Of Electron Beam Highly Crosslinked Polyethylene

William H. Harris, MD, DSc
Massachusetts General Hospital

INTRODUCTION

New evidence augments the strong support for the use of electron beam highly crosslinked, subsequently melted ultra high molecular weight polyethylene in total hip replacement arthroplasty. Three new studies involving three different demographic groups and two different measurement techniques have found that the wear rate after bedding in has finished taking place is about 8 microns per year. This is similar to the wear rate of hard on hard bearings. Retrieval specimens obtained up to 3 years after insertion confirm the minimal wear, by exhibiting persisting machine marks throughout the inside diameter of the liner. Also retrieval specimens confirm that the material does not oxidize.

No evidence exists of fatigue failure except three cases out of 150,000, in which malposition of the acetabular component produced abnormally high contact stresses on the unsupported polyethylene of an extended lip.

The *in vivo* wear, oxidation resistance, and mechanical properties this material have been excellent, with *in vivo* durations now exceeding 5 years. The other major compelling advantages over hard on hard bearings include familiarity, adaptability, forgiveness and cost.

Electron beam irradiated, highly crosslinked, subsequently melted ultra high molecular weight polyethylene as an alternate bearing surface has several advantages. These include

1) An extremely low wear rate
2) The absence of oxidation
3) The ability to use larger heads
4) Familiarity
5) Adaptability
6) Forgiveness
7) The absence of the specific disadvantages of metal on metal.
8) The absence of the specific disadvantage of ceramic on ceramic and
9) Low cost

Three contemporary *in vivo* studies of electron beam irradiated, subsequently melted, highly crosslinked UHMPE confirm the high wear resistance that this crosslinking produces. In a radiostereometric analysis (RSA) study[7] , 32 patients (54 hips) receiving bilateral simultaneous total hip replacements using a modular, cementless socket were studied with RSA contrasting polyethylene which was gamma sterilized in nitrogen versus electron beam irradiated, subsequently melted, highly crosslinked polyethylene (10 Mrad e-beam irradiation). These patients were followed for 2 years. At 2 years the mean total proximal penetration was 210 microns in the control group in contrast with 80 microns in the highly crosslinked group ($p<0.005$). After the first year, i.e., after the bedding in and creep had subsided, there was no detectable further penetration of the femoral head into the highly cross-linked polyethylene.

In the second RSA study[7], 61 hips in 60 patients were randomized to receive either electron beam irradiated, subsequently melted, highly crosslinked UHMPE (9.5 Mrad) or conventional polyethylene which had been gamma sterilized in nitrogen. All polyethylene cups were cemented into the pelvis. At three years the penetration of the femoral head into the highly crosslinked polyethylene was significantly less than in the conventional material. In the supine examinations, the mean proximal total penetration in the control group was 250 microns whereas the penetration in the highly crosslinked group was 130 microns ($p=0.002$). Furthermore, after the first year there was no measurable further penetration into the highly crosslinked material.

In the third study[9], the Martell system[10] was used to measure wear in two cohorts: 243 acceptable radiographs pairs taken from 109 hips in which e-beam irradiated, post irradiation melted, highly crosslinked polyethylene was used, over durations of up to 44 months, and 238 acceptable radiographic pairs from an age-matched population of patients who had traditional polyethylene (gamma sterilized in air), with durations up to 48 months. For both materials the steady state wear rate was determined after the bedding in process had been completed.

For the highly crosslinked polyethylene, the average steady

William H. Harris, MD, DSc, is Alan Gerry Clinical Professor of Orthopaedic Surgery and Director of Orthopaedic Biomechanics and Biomaterials Laboratory, Department of Orthopaedic Surgery,

Supported by a grant from The William H. Harris, MD Foundation

Please address correspondence to:

William H. Harris, M.D.
Director, Orthopaedic Biomechanics and Biomaterials Laboratory
Massachusetts General Hospital
55 Fruit Street, GRB 1126
Boston, MA 02114
(617) 724-0526 (voice)
(617) 726-3883 (fax)
wharris.obbl@partners.org

state wear rate was 8 microns per year, in contrast to the average penetration rate of 135 microns per year for traditional polyethylene. This 94% reduction in polyethylene wear *in vivo* was highly statistically significant (p= 0.003).

Martell's study[9] reported that traditional wear factors that influence the wear of conventional UHMPE, including head size, gender, age, activity level or BMI, did not increase the wear rate of e-beam irradiated, post irradiation melted, highly crosslinked polyethylenes.

Selected new UHMPE materials have such a high resistance to wear during *in vitro* hip simulator testing that wear in these studies was independent of head diameter, testing head diameters from 22 to 46mm in size[11]. If these data were confirmed *in vivo*, surgeons would no longer need to use small heads, which would be a major advantage in terms of increased stability and range of motion[3-5].

Head sizes larger than 32 mm eliminate component-to-component impingement, which is the most common mode of impingement[4]. Larger heads can reduce the dislocation risks and increase range of motion--a powerful set of advantages not possible previously with traditional polyethylene[3,4]. Not only are these larger heads likely to reduce both the risk of and incidence of dislocation, they would also be excellent tools for treating recurrent dislocation. This includes a new design of constrained sockets that uses a simpler construct, highly crosslinked polyethylene, large diameter heads and nearly full range of motion[5].

Since these features of very low wear rates and the lack of oxidation are shared in common with the hard on hard articulations, other factors will dictate the choice of the preferred alternate bearing surface for total hip arthroplasty. These other considerations for using highly crosslinked polyethylene center on familiarity, adaptability, forgiveness, the absence of specific disadvantages of metal on metal, the absence of specific disadvantages of ceramic on ceramic, and cost.

With polyethylene there is no learning curve. There are no limitations unique to the crosslinked polyethylene that have not already been well established over the past forty years of the use of polyethylene. The material looks, feels and behaves exactly like "old" polyethylene, except for the low wear rates and the absence of oxidation. Since over half of all total hip replacements in the United States are done by surgeons who do fewer than one a month[8], this is a strong advantage. Adaptability is an outstanding advantage of highly crosslinked polyethylene. In the hard on hard couples it is not possible to have extended lip liners, offset liners or constrained liners.

In terms of forgiveness, polyethylene has major advantages. Impingement with polyethylene is relatively benign. Impingement with metal on metal produces metallosis and damages the shell or the femoral neck. Impingement with ceramic on ceramic can lead to chipping and creation of abrasive third body debris[1,2].

Another important aspect of forgiveness is the issue of minor degrees of malposition of the acetabular components. In both types of hard on hard bearings, if the degree of abduction of the acetabular component is higher than the desired range, stripe wear[1,2,12,13], accelerated wear and progressive damage to the articular surface of the femoral head and the acetabulum can occur. Both the metal on metal and ceramic on ceramic articulations are subject to accelerated wear associated with microseparation[6,12-14]. Microseparation in a metal on polyethylene articulations does not accelerate wear[15]; in fact wear is less.

The specific disadvantages of metal on metal include the issues of metallic debris and its third body effect on the articulating surface, the resulting metallosis and its effect in accelerating macrophage responses, remote metal deposits, and elevated metal ion levels. In addition, there is the issue of hypersensitivity[16].

The specific disadvantages in terms of ceramic on ceramic include the limited number of head-neck sizes, the risk of fracture of the femoral head, the risk of fracture of the acetabular component, chipping if impingement occurs, stripped wear, and the accelerated wear that can occur with higher degrees of abduction of the acetabular component[1,2,13]. In one recent report stripped wear was present in about half of the retrieved specimens at about 3 years post insertion.

Finally, the issue of cost is very important. Hard on hard articulations are more expensive than the highly crosslinked polyethylene.

Thus a strong case can be made for the use of electron beam irradiated highly crosslinked, subsequently, melted polyethylene in total hip arthroplasty.

References

1. **Bierbaum BE, Kuesis D, Morrison JC, Ward D, Nairus J.** Ceramic on ceramic total hip arthroplasty. Seminars in Arthroplasty. 2001; 16:31-36.
2. **Bierbaum BE, Nairus J, Kuesis D, Morrison JC and Ward D:** Ceramic-on-ceramic bearings in total hip arthroplasty. Clinical Orthop. 2002; 158-163.
3. **Burroughs BR, Rubash HE and Harris WH:** Femoral head sizes larger than 32 mm against highly cross-linked polyethylene. Clinical Orthop. 2002; 150-157.
4. **Burroughs BR, Hallstrom B, Golladay GJ, Hoeffel D and Harris WH:** Range of motion and stability in total hip arthroplasty with femoral head sizes 28, 32, 38 and 44 mm: an in-vitro study. Accepted for Publication in J. Arthroplasty. 2003.
5. **Burroughs BR, Golladay GJ, Hallstrom B and Harris WH:** A novel constrained acetabular liner design with increased range of motion. J Arthro. 2001; 16, Suppl. 1: 31-36.
6. **Butterfield M, Stewart TWS, Ingham E, Stone M and Fisher J:** Wear of metal-metal and ceramic-ceramic hip prostheses with swing phase microseparation. 48th Annual Meeting of the Orthopaedic Research Society. Paper: 0128, 2002.
7. **Digas G, Karrholm J, Thanner J, Malchau H and Herberts P:** Highly cross-linked polyethylene in hip arthroplasty. Randomized study using radiostereometry. Presented at the EFORT meeting, Helsinki, Finland, May 8, 2004.
8. **Katz JN, Losina E, Barrett H, Phillips CB, Mahamed, NN, et al.:** Association between hospital and surgeon procedure volume and outcomes of total hip replacement in the US Medicare population. J. Bone Joint Surg. 83(A). 2001; 1622-1629.
9. **Manning DW, Chiang PP, Martell MM, Galante JO and Harris WH:** *In vivo* wear of traditional versus highly crosslinked polyethylene. Presented at the AAHKS Meeting. Dallas, TX, November 2, 2003.
10. **Martell JM, Berkson E, Berger R, Jacobs J:** Comparison of two and three-dimensional computerized polyethylene wear analysis after total hip arthroplasty. J Bone Joint Surg, 85(A). 2003; 1111-1117.
11. **Muratoglu OK, Bragdon CR, O'Connor D, Perinchief RS, Estok DM 2nd, Jasty M, Harris WH.** Larger diameter femoral heads used in conjunction with a highly cross-linked ultra-high molecular weight polyethylene: a new concept. J Arthro. 2001; 16: 24-30.
12. **Nevelos J, Ingham E, Doyle C, Streicher RM, Nevelos A, Walter W, Fisher J, Eng D.** Microseparation of the centers of alumina artificial hip joints during simulator testing produces clinically relevant wear rates and patterns. J. Arthro. 2000; 15: 793-795.
13. **Nevelos J, Ingham E, Doyle C, Streicher R, Nevelos A, et al.** Microseparation of the centers of alumina-alumina artificial hip joints during simulator testing produces clinically relevant wear rates and patterns. J Arthro. 2000; 15(6): 793-795.
14. **Stewart TD, Tipper JL, Insley G, Streicher RM, Ingham E, Fisher J.** Longterm wear of ceramic matrix composite materials for hip prostheses under severe swing phase microseparation. Wiley InterScience, Inc. 2001; 569-573.
15. **Williams S, Butterfield M, Stewart T, Ingham E, Stone M, Fisher J.** Wear and deformation of ceramic-on-polyethylene total hip replacements with joint laxity and swing phase microseparation. Proc Inst. Mech. Eng. Part H – J of Eng Med. 2003; 217(2):147-53.
16. **Willert HG, Buchhorn GH, Fayyazi A, Lohmann CH.** Histopathological changes in tissue surrounding metal/metal joints - signs of delayed type hypersensitivity? (DTH). World Tribology Forum in Arthroplasty. 2001; 147-166.