The Lysis Threshold Concept and Reasons To Reject It

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INTRODUCTION

A widely held concept suggests that there is an acceptable threshold, or lower limit, of particle generation at the articulation in total hip arthroplasty (THA) below which periprosthetic osteolysis following total hip replacement surgery is minimal or does not occur, the so-called "lysis threshold". Such a concept might provide guidance in assessing to what extent improvement needs to be made in reducing the adhesive/abrasive wear of ultra high molecular weight polyethylene for total hip arthroplasty. The corollary of this idea is that the aim of improving the wear resistance of ultra high molecular weight polyethylene for total hip arthroplasty simply should try to maintain the particle generation below this threshold. Studies from Wroblewski and Siney (1), Sochart (2), Dowd et al. (3), and Mckellop (4) appear to support this concept. Dumbleton and coauthors (5) conclude "for practical purposes, we suggest that a hip bearing wear rate of 0.1mm per year can be taken as a wear threshold for polyethylene: below this level, osteolysis is rare and above this level, the risk of osteolysis increases substantially."

For example, Wroblewski's data from 1342 hips show that at an average 10.3 year follow-up, those patients whose calculated average annual "wear" rate was 0.1mm per year or less had a 3.9% incidence of acetabular migration. If the annual femoral head penetration rate was between 0.1 and 0.2mm per year, the incidence of acetabular migration was 16.7%. This study, as well as in Sochart's report (2) of patients under the age of 40 at the time of their total hip replacement, showed that more wear is worse. Other data also show that more wear is worse but that may not be the issue. The lysis threshold concept examines a different issue. It examines the low wear end of the spectrum, not the high end.

Further analysis of this apparently appealing concept, however, raises 5 serious concerns about the validity of the concept. The first issue is that many of the studies that appear to support this concept have a duration of follow-up that is too short. The studies reported by Wroblewski and Siney (1) and by Dowd et al. (3) cover only 10 years. It is well known that the incidence of lysis increases with increasing time. Ten years is too short. To make a decision on the basis of 10-years of follow-up ignores the important facts that most patients undergoing total hip replacement have life expectancies much longer than 10 years and that lysis increases with time.

Secondly, lysis does occur patients whose penetration rate was 0.1mm per year or less. Sochart (2) found at 19.5 years of follow-up, of his cases with the lowest wear (100 microns or less per year), 9% of the patients had lysis. In the report by Wroblewski's group (1) only one group was free of socket migration, the group with "no measurable wear", not the group with wear of 0.1 mm/year.

Thirdly, some reports used a limited definition of periprosthetic osteolysis. They did not include the type of lysis shown by our finding (6) that periprosthetic osteolysis is the cause of radiolucent zones at the interface between cement and the acetabular bone. This linear form of periprosthetic osteolysis leads loosening of cemented acetabular components. If cases such as these with loss of fixation because of retroacetabular linear lysis are not included in the definition of lysis, the data are misleading and erroneous.

Fourthly, plain radiography has serious limitations as the diagnostic endpoint to define lysis, as recently shown by Puri et al. (8). Helical computer tomography for the assessment of acetabular osteolysis following total hip replacement was compared to plain radiography in a group of patients who had well-fixed, cementless total hip replacements. Plain radiography detected lysis in 32% of the hips, but 52% showed evidence of osteolysis on the helical computerized tomography. Plain films grossly underestimate the true incidence of lysis.

Our fifth concern regarding the concept of a "lysis threshold" is the important observation that factors other than wear can play a major role in the incidence of osteolysis. The strong role of other factors was clear from the matched pair series report by Goetz et al. (12). In that study the prevalence of femoral osteolysis in hips with the Harris-Galante (HG, Zimmer, Warsaw, IN) cementless femoral components was compared to those with cemented femoral components. The patients were matched by age, sex, weight, duration of follow-up head size, polyethylene thickness and diagnosis. The acetabular component and the polyethylene were the same for both groups. All of the arthroplasties were performed by the same surgeon and were followed for a mean period of 6 years (minimum 4 years).

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Femoral osteolysis developed in 29% of the hips with an HG femoral component compared with none that had the Precoat cemented femoral component, a highly statistically significance difference.

These data demonstrate the importance of other factors on the incidence of osteolysis - not just the amount of particle generation. These findings show the influence of the concept of the effective joint space (10) and the adverse effect of cementless femoral components which have a patched proximal porous-coated design. This finding was confirmed also by Dorr et al. (11) and was shown experimentally by Bobyn et al. (12). While the issue of patched porous surfaces on the HG femoral component was a major contributor to periprosthetic osteolysis in that study, this is but one major manifestation of a general observation, namely that the specific features of individual designs play very important roles in the incidence of periprosthetic osteolysis. Such a high incidence of periprosthetic osteolysis (60% at 10-years) has been reported also by several other groups. For example, Hellman's group (13) reported in the Omniflex (Stryker Howmedica Osteonics, Mahwah, NJ) series and in another report a 18% pelvic lysis plus 32% femoral lysis at 8.8 years in a subset of patients with cementless Anatomic Medullary Locking (AML, Depuy Orthopaedics, Warsaw, IN) total hip prosthesis (14,17). These studies support the idea that specifies design features in total hip replacement may strongly influence the incidence of osteolysis.

Also, included in the "other factors" may be individual susceptibility for osteolysis, as exemplified by cases such as this patient, who at 24 years had extensive wear with marked penetration of the femoral head into the polyethylene but no radiographic evidence of osteolysis (Figure 1).

The article by Dumbleton and coauthors (5) was thorough, thoughtful, and carefully considered. It presented many of the inherent limitations of the lysis threshold concept along with the database supporting it. In fact, in the text of the article the authors suggest that for cementless total hip arthroplasty, perhaps the threshold might be better set at 50 micra per year.

Figure 1

However, in the conclusion, they suggest penetration of the femoral head into the polyethylene of 100 micra per year as an acceptable "lysis threshold."

In summary, five serious reservations challenge the utility of the concept of a "lysis threshold" at commonly proposed 100μm of femoral head penetration into polyethylene per year. They are, first, the duration of some studies used to support this concept is too short. Lysis, in many series, progressively increases with time and especially after 10 years. Secondly, in several series used in supporting this threshold level, lysis does occur. And with longer time the incidence of lysis in these groups is likely to increase. Thirdly, some of the reports supporting this concept use unacceptably limited definitions of osteolysis. Fourthly, all these reports rely on a diagnostic endpoint that has limited accuracy, namely plain radiographs. And finally, factors other than wear itself, especially design features of the total hip implants, can play a major role in the incidence of lysis independent of the rate of wear.

We conclude that for the optimum, long-term reduction in the incidence of periprosthetic osteolysis in total hip replacements using metal-on-polyethylene articulations, wear reduction should be maximized to the fullest extent possible.

References

1. **Wroblewski BM, Siney PD.** Charnley Low-Friction Arthroplasty in the Young Patient. Clin Orthop 1992;285:45-47.
2. **Sochart D.** Relationship of Acetabular Wear ton Osteolysis and Loosening in Total Hip Arthroplasty. Clin Orthop, 1999;363:135-150.
3. **Dowd J, Sychterz CJ, Young AM, Engh C.** Characterization of Long-Term Femoral-Head-Penetration Rates: Association with and Prediciton of Osteolysis. J Bone Joint Surg Am 2000;82A:1102-1107.
4. **McKellop HA.** What evidence is there for using alternative bearing materials? In: Implant Wear in Total Joint Replacent. Timothy M. Wright and Stuart B. Goodman, Rosemont, IL: American Academy of Orthopaedic Surgeons, 2001, pp 206-215.
5. **Dumbleton JH, Manley MT, Edidin AA.** A Literature Review of the Association Between Wear Rate and Osteolysis in Total Hip Arthroplasty. J Arthroplasty 2002;15:649-661.
6. **Schmalzried, T, Kwong L, Jasty M, Sedlacek R, Haire T, O'Connor D, Bragdon C, Kabo J, Malcolm A, Harris W.** "The mechanism of loosening of cemented acetabular components in total hip arthroplasty. Analysis of specimens retrieved at autopsy." Clin Orthop 1992;274: 60-78.
7. **Charnley J.** Low friction arthroplasty of the hip. Berlin: Springer Verlag, 1979, pp 75-85.
8. **Puri L, Wixson RL, Stern SH, Kohli J, Hendrix RW, Stulberg D.** Use of Helical Computed Tomography for the Assessment of Acetabular Osteolysis After Total Hip Arthroplasty. J Bone Joint Surg Am 2002;84A:609-614.
9. **Goetz DD, Smith EJ, Harris WH.** The Prevalence of Femoral Osteolysis Associated with Components Inserted with or without Cement in Total Hip Replacements: A Retrospective Matched-Pair Series. J Bone Joint Surg Am 1994;76A:1121-1129.
10. **Schmalzried TP, Jasy M, Harris WH.** Periprosthetic bone loss in total hip arthroplasty. Polyethylene wear debris and the concept of the effective joint space. J Bone Joint Surg 1992;76A:849-63.
11. **Dorr LD, Lewonowski K, Lucero M, Harris M, Wan Z..** Failure mechanisms of anatomic porous replacement in cementless total hip replacement. Clin Orthop 1997;334: 157-67.
12. **Bobyn, J, Jacobs J, Tanzer M, Urban R, Aribindi R, Sumner D, Turner T, Brooks C.** The susceptibility of smooth implant surfaces to periimplant fibrosis and migration of polyethylene wear debris. Clin Orthop 1995;311:21-39.
13. **Hellman EJ, Capello WN, Feinberg JR.** Omnifit cementless total hip arthroplasty. A 10-year average followup. Clin Orthop 1999;364:164-74.
14. **Zicat B, Engh CA, Gokcen E.** Patterns of Osteolysis around Total Hip Components Inserted with and without Cement. J Bone Joint Surg Am 1995;77A:432-439.