DEVELOPMENT OF A MARKER-LESS RADIOSTEREOMETRIC ANALYSIS (RSA) METHOD FOR USE IN MEASURING POLYETHYLENE WEAR: A COMPARATIVE STUDY
+Brägdon, C R; +*Börbin, N; +Greene, M E; +Freiberg, A; +Jasty, M; +Rubash, H E; +Harris, W H, +Malchau, H

+Orthopaedic Biomechanics and Biomaterials Laboratory, Massachusetts General Hospital, Boston, MA 02114 617-726-3869 fax: 617-726-3883 cbragdon@partners.org

Introduction: The most accurate method of measuring wear of polyethylene in total hip replacement patients is by using radiostereometric analysis (RSA), a two plane radiographic technique that reproduces three dimensional geometry. However, this technique requires that a number of tantalum beads be placed into the acetabular implant. The need for these added markers limits the number of patients that can be enrolled in a clinical study. In addition, some implants, such as those made of cobalt chrome or tantalum metal, are too radio-dense to allow visualization of the tantalum markers. A new technique has been developed that can locate the acetabular component by utilizing image analysis of the implant projection in order to determine its three dimensional position. The purpose of this study is two-fold: the first is to use the standard RSA technique to assess the rate of penetration of the femoral head in two groups of total hip replacement (THR) patients who have received a form of highly cross-linked polyethylene that has markedly improved wear resistance with one group having a standard 28mm diameter femoral and the second group having a larger 36mm diameter femoral head. It is hypothesized that the penetration of the femoral head into the polyethylene will be significantly less using the cross linked polyethylene than the conventional polyethylene and that there will be no increase in wear when a larger diameter femoral head is used in conjunction with a highly cross-linked polyethylene. The second purpose is to perform a comparative study of the results of a new marker-free RSA method with that of the standard RSA method utilizes markers placed in the polyethylene acetabular component using the same set of radiographic films. It is hypothesized that the results will be similar using the two techniques.

Methods: Institutional IRB approval was obtained for this clinical study. A group of 29 patients in need of total hip replacement were enrolled in this RSA hip study. Sixteen patients received cementless Trilogy Acetabular components with 28 millimeter diameter femoral heads and thirteen patients received the same type of components with a 36 millimeter femoral head diameter. Depending on the outer diameter of the polyethylene insert, up to eighteen Tantalum beads, 1.0 millimeter in diameter, were press fit into the peripheral flange of the polyethylene liner prior to insertion into the metal shell using a custom made alignment jig. Initial standing RSA radiographs were taken at the time of the first postoperative office visit, within six weeks following surgery. Bi-planar standing radiographs of each patient were obtained in conjunction with the RSA calibration cage 43 (RSA Biomedical, Umeå, Sweden). Subsequent radiographs were scheduled for six months postoperatively, at one year postoperatively and yearly thereafter.

Femoral head penetration measurements were performed using the latest UnRSA software package version 6.0 (RSA Biomedical, Umeå, Sweden). This version can either use the three-dimensional position of the tantalum markers to locate the acetabular component or use an edge detection algorithm to determine the three dimensional center and alignment of the acetabular component based on the outside curvature of the shell and the rim of the component. The 6 week films were used as the reference films and the total superior penetration values were calculated at each radiographic follow-up. Statistical comparison of the results obtained by the two methods was performed using a paired t-test.

Results: The average and standard error of the femoral head penetration for each group of patients receiving 28mm and 36mm femoral heads over the first three year period using the standard RSA method are shown in Figure 1. At one year follow-up the mean femoral head penetration of the 28mm femoral head group was 0.07±0.01 millimeters. At three years follow-up, there was no significant increase in femoral head penetration, 0.16±0.02 millimeters (p=0.65). At one year follow-up the average femoral head penetration of the 36 millimeter femoral head group was lower than that measured for the 28 millimeter diameter group, 0.05±0.02 millimeters, although not significantly different (p=0.73). At three years follow-up, this value increased to 0.11±0.01 millimeters, again not significantly (p=0.74). Therefore, no significant increase in femoral head penetration can be measured after the initial bedding-in period. Importantly, the penetration values measured so far at three years follow-up are similar for the two head sizes (p=0.53).

Figure 2 displays the average penetration results using the marker-less RSA method. The overall results are similar to those of Figure 1 and described above for the standard RSA method. There was no significant difference in the results using the marker-less method compared to the results of the standard RSA method for either head size group.

Conclusion: In this preliminary report, using the most precise method of radiographic measurement to evaluate the use of a 36 millimeter diameter femoral head against highly cross-linked polyethylene, there was no difference in the superior penetration of the femoral head at three years compared to the use of a 28 millimeter femoral head. The measurements presented are based on the initial follow-up radiographs and therefore include the early bedding in of the femoral head due to plastic deformation of the polyethylene insert as well as true wear. The magnitude of bedding in that occurs in the first year with this highly cross-linked material has been measured under in vitro loading conditions to be about 0.1 millimeters. This suggests that very little wear has occurred in either group, regardless of head size.

The results obtained using the marker-free version of the RSA software from the same set of radiographs show good agreement with the standard RSA method which employs tantalum beads attached to the implants. An RSA system that does not rely on additional implant markers would facilitate future clinical studies of implant wear as well as implant stability. It also allows inclusion of images in which a sufficient number of markers are not visible for conventional RSA evaluation. Finally, it would be of special utility when the radio-density of the implant material interferes with the visualization of the implant markers.

AFFILIATED INSTITUTIONS FOR CO-AUTHORS:
*Department of Computing Science, Umeå University, Umeå, Sweden

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