Mode of loosening of matt-finished femoral stems in primary total hip replacement

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ABSTRACT

Objectives: Major advances have occurred in total hip replacement (THR) surgery aiming at minimizing or delaying loosening of the components. Currently, substantial controversy exists regarding the possible role of the surface finish of cemented femoral stems in the loosening process. Several authors have recently suggested that a roughened surface finish of the femoral component in cemented THR can predispose the implant to early loosening and subsequently severe osteolysis. The aim of this study was to evaluate both the incidence of, and the mode of loosening of the cemented femoral components in a large series of primary THR with matt-finished surface followed over a span of 2 decades. The aim was to assess the behavior of bead-blasted chrome-cobalt cemented femoral stems of the computer assisted design (CAD) and Harris Design-2 (HD-2).

Methods: From a prospective study of 161 consecutive hips in 140 patients who underwent primary THR using HD-2 or CAD cemented femoral components performed by a single surgeon between 1976 and 1979, all hips were evaluated with special emphasis on the 73 patients (84 hips) who were followed for an average of 18 years. Among the 161 hips, all femoral stems that became loose were studied in detail. The cement technique used in all cases was the so-called 2nd generation cementing technique. No patient was lost to follow-up. We now report on the subset of 10 hips (6%) (9 patients) among the entire 161 hips that had an aseptic failure of fixation of their femoral components.

Results: Ten of 117 CAD stems (8.5%) and none of 44 HD-2 stems became loose. Five percent (8 of 161) of those (all CAD) were revised due to aseptic loosening. Two of those revisions for aseptic femoral loosening were carried out during the first decade (1.2%). One of these 2 loose stems was converted into a resection arthroplasty at another hospital despite not being loose radiographically and having no osteolysis. The other loose stem was removed at 9 years and 10 months for a fracture secondary to lysis below the tip of the stem. The remaining 8 loose stems were not diagnosed as loose until the 2nd decade following the operation. Six of those 8 stems were revised and 2 have not been revised. The average duration until these 6 were revised was 18 years after the operation (range 14-19). The remaining 2 unrevised stems are debonded (<1mm) but functioning well. No stem showed the early type of rapid lysis reported for the Iowa design. There was no consistent relationship between the development of loosening and osteolysis in the 10 hips that became loose. Among the 5 hips that debonded, the debonding was initially noted at an average of 13 years (range 4-21) but in this group, osteolysis was present in 3 hips and was first noticed at an average of 9 years (range 5-12) after the operation. Of those that developed both osteolysis and radiographic evidence of loosening, the lysis preceded the debonding in 2 of the 3 cases.

Conclusion: There is no evidence in this series of 161 hips that a matt surface finish was associated with either the premature loosening or the marked progressive osteolysis pattern of the type that has been described with the Iowa stem. The evidence in our report does not support the hypothesis that a bead-blasted surface finish in the 2 designs studied here (CAD and HD-2) lead to a high incidence of early loosening and marked progressive lysis. In general, these stems have functioned well in the long term, both clinically and radiologically. This data raises the question that other factors, such as the design, the offset, the high placement of the medial curvature of the stem, and the large body weight in the patients in the Iowa series may have contributed to the early failure of fixation of those hips in that series in conjunction with, or independent of the surface finish of that design of stem.

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Over the last 3 and a half decades, major advances have occurred in total hip replacement (THR) surgery, aiming at achieving an improved combination of implant design and surgical technique in the hope of minimizing and delaying loosening of the components. Since cemented femoral stems are subjected to substantial bending, axial, and torsional forces, changes in design and surface finish have been introduced with the concept of increasing durability of fixation. Improvements in cementing technique such as the use of an intramedullary plug, cement gun, stem centralization, pressurization and porosity reduction have also been introduced.[1-10] Currently, among all these changes, the major controversy regarding cemented femoral stems is that of the rough surface finish.[5,11,12] Evidence from autopsy retrievals of well fixed cemented stems suggests that failure of fixation of cemented stems can be initiated at the prosthesis-cement interface with debonding and subsequent cement fracture.[13-15] In vitro tests show that the bond at this interface can be strengthened by various types of surface macro texturing and by polymethyl methacrylate (PMMA) precoating the stem.[16-18] However, several authors have recently suggested that a roughened surface finish of the femoral component in cemented THR can predispose the implant to early loosening, and if early loosening occurs, it can lead to severe osteolysis.[11] Based on a comparison of their experience with the Iowa stem and the Charnley stem, Mohler et al[11] and Sporer et al[12] suggested that a matt-finish may contribute to premature loosening, and that cemented stems should be smooth or polished. In contrast, others point out that the loosening in any cemented femoral component is multifactorial[5,19] and that the early stem loosening of the Iowa stem may be a reflection of many different factors including component design, offset, torsional stability, as well as the possible influence of surface finish for that specific design. There can be no serious challenge to the concept that loosening of a cemented femoral stem is multifactorial. In addition to the obvious influence of the design of the femoral stem including the offset, body shape, stem shape, section modulus and so forth, there are vital patient factors involved such as age, gender, primary diagnosis (avascular necrosis for example), activity level and others. All of these factors are but part of a matrix that includes the cement used, cementing technique, anatomy of the femur, preparation of the femur, centralization, surgical approach and critically, surgical skill. On this list, surface finish may also be added. Not only is it difficult or even at times impossible to isolate a single factor, such as surface finish, among this constellation of factors, it is also important to appreciate that any one factor may be of greater or lesser import in relationship to a specific design. Thus, for example, the influence of surface finish in the experience of the matt-finish on Iowa designs may or may not be relevant to other femoral designs. To asses the issue of surface finish, we have to reexamined specifically both the incidence of and the mode of loosening of 2 chrome cobalt cemented femoral stems which had matt finished surfaces but with substantially different designs from the Iowa stem, namely the Harris design-2 (HD-2), (Howmedica Inc, Rutherford, New Jersey, United States of America [USA]) and computer assisted design (CAD), (Howmedica Inc, Rutherford, New Jersey, USA). Both the HD-2 and the CAD femoral components had a bead-blasted finish with a RA of approximately 30 micro inches. Our prospective long term follow-up studies on these cemented femoral stems allowed specific reassessment of the incidence of loosening, the duration before revision, the presence or absence of osteolysis in the femur, the timing of the onset of debonding and other evidence of loosening, the timing of the onset and extent of osteolysis, and the relationship between these osteolysis and loosening. Specifically it afforded the opportunity to study the mode of early and late loosening of these matt-finished cemented stems.

The aim of this study was to evaluate both the incidence of, and the mode of loosening of the femoral components in a large series of primary total hip replacements followed over 2 decades to asses the behavior of bead blasted chrome-cobalt cemented femoral stems of the CAD and HD-2 designs. The hypothesis examined was the one suggested by Mohler et al[11] that a bead blasted surface on a cemented femoral stem would lead to early femoral stem loosening, and this would be followed by rapid severe lysis.

Methods. From a prospective study on 161 consecutive hips in 140 patients who underwent primary THR using HD-2 or CAD femoral components by a single surgeon between January 1976 and January 1979 and followed through 1996, those femoral stems that became loose were studied in detail. All hips that were operated on or before January 1978 had an insertion of a CAD stem, while all of those operated after that date had an insertion of a HD-2 component. There were 117 CAD and 44 HD-2 stems. No patient was lost to follow-up. The demographics of the patients, initial diagnosis, inclusions and exclusions from the series and details of the operative techniques were given in the prior report.[9,10] There was no significant demographic difference between those who received CAD and those who received HD-2 stems. The average age of the 140 patients at the time of primary arthroplasty was 61 years (range 21-85). Sixty-seven patients (77 hips) died within 17 years of the index operation. The remaining 73 patients (84 hips) were followed for an average of 18 years (range 17-20). The current report centers on the subset of 10 hips (9 patients) whose femoral components became loose. All stems were bead-blasted and monoblock cobalt chrome femoral components. Details of design of the HD-2 and CAD stems have been previously reported.[6] Simplex-P cement (Howmedica, Rutherford, New Jersey) was used for fixation of the femoral component in all cases. The cement technique used in all cases was the so-called 2nd generation cementing technique, which involved preparing the intramedullary canal by the insertion of a PMMA plug, the use of a cement gun, curettage, irrigation and drying with gauze. Adrenaline-soaked sponges, pulsatile lavage, centralizers for the femoral stem, reduction of the porosity of the cement and a cement-pressurizer were not used. The operations were performed in an operating room with a green house, and the operating team used a body-exhaust system. Among the 161 hips over the 20-year span, 8 (5%) of the femoral components were revised due to aseptic loosening. In 2 additional hips with CAD stems the femoral component were loose according to radiographic criteria but they had not been revised. Both of these stems were diagnosed as being loose based on debonding of the femoral component. The debonding was less than one millimeter thick at the cement-prosthesis interface in zone one and 2 in one stem and in zone 5 in the other. Thus, overall prevalence of aseptic loosening for the entire series was 6% (10 of 161 hips). Among the 8 femoral components revised for aseptic loosening, 7 were revised in conjunction with revision of a loose acetabular component, and one was removed at another institution during a resection arthroplasty procedure performed for pain. No other stems were loose and no femoral revisions were pending at final follow-up. Not included in this analysis are 8 additional well-fixed femoral components that were removed for reasons other than aseptic loosening. One was removed due to late deep sepsis. Another was removed and replaced with a calcar-replacement stem during a reoperation for limited motion from heterotropic ossification, and 6 other solidly fixed stems were removed to gain exposure for revision of loose acetabular components. The clinical data and serial radiographs of the 10 hips with aseptic loosening of the femoral components were meticulously studied. These radiographs included anteroposterior frog lateral, true lateral, and 2 oblique views. The femoral cement mantle was graded on all post-operative radiographs according to criteria initially published by Barrack et al,[1] refined by Mulroy et al[9] and Clohisy and Harris.[4] Definite evidence of loosening of the femoral component required subsidence of either the stem or mantle of cement, bending or breakage of the stem, a fracture in the cement mantle, or debonding of the stem as evidenced by a radiolucent line of any width at the cement-metal interface which was not present on the initial postoperative films. The presence of osteolysis in the femur was defined as any focal area of scalloped, endosteal, intracortical, or cancellous bone resorption that was not linear or if linear had a width greater than 2 mm. Areas of femoral osteolysis were measured and recorded according to location using the zones described by Gruen et al,[20] modified to include a similar set of zones on the lateral films.

Results. The preoperative diagnosis and selected demographic data for the patients with the 10 hips with loose stems is shown in **Table 1**. Selected demographics of the 9 patients are contrasted with the other 131 patients in **Table 2**. There was no statistically significant difference between the 2 groups. Six were females and 3 were males. Two were younger males (45 and 53 years) and each weighed 102 kg. Trochanteric osteotomy was used in 4 of the 10 loose hips, and in 102 of the remaining 151 hips. Concerning the 10 loose stems, all were among the 117 CAD stems (8.5%) and none of 44 HD-2 stems became loose. This difference is not quite significant (p value was 0.06). However, one confounding issue in comparing the experience of the 2 stems was the length of follow-up. The average follow-up period for the CAD stems was 17.8 years and for the HD-2 stems was 16.2 years. Of the 10 loose stems, 7 had a grade C2 femoral cement mantle, compared to 70 hips with C2 in the other 151 hips. This difference is not statistically significant (p=0.26). Five loose hips had radiographic evidence of being loose, all 5 based on debonding and 5 hips did not. Among the 5 stems that were not debonded, 4 were found to be loose at revision surgery despite the absence of radiographic evidence of being loose. The other stem without radiographic evidence of being loose was revised due to a fracture in the femur through an area of osteolysis around the tip of the stem and was loose at surgery. The 5 debonded cases were first diagnosed at a mean interval of 13 years

Table 1 - Diagnosis and population data for sub-set group with loose stems.

Case	Diagnosis	Gender	Weight (kg)	Age at primary THR (years)
1	Post traumatic OA	F	55	62
2	Pistol grip deformity	M	102	53
3	Avascular necrosis	M	102	45
4	Rheumatoid arthritis	F	59	48
5	OA	F	58	60
6	OA	F	58	60
7	OA too advanced	F	66	74
8	OA too advanced	F	72	79
9	Pistol grip deformity	M	84	74
10	Rheumatoid arthritis	F	60	61

Average weight = 72kg and average age = 62 years.
THR - total hip replacement, OA - osteoarthritis, F - female, M - male

Mean	Patients with loose stems (n=9)	Patients with other non-loose stems (n=131)
Mean age	62 yrs (range 45-79)	62 yrs (range 21-85)
Mean weight	73 kg (range 55-102)	71 kg (range 47-109)
Mean height	163 cm (range 155-188)	168 cm (range 135-193)
n - number, yrs - years		

Table 2 - Demographic data for the whole and sub-set groups.

Table 3 - Analysis and findings of x-ray films from 10 patients.

Patient	Femoral cement grade	Earliest femoral lysis	Earliest debonding	Earliest femoral cement Fx	Duration to revision	Comments	Surgery findings
1	C2 in zone 1,5	5 yrs in zone 5, 12, 13, 14	4 yrs in zone 8	None	15 yrs	Slow progression of lysis over 10 yrs No massive proximal or distal lysis No rapid progression of lysis No progression of debonding (continued to be only in zone 8, and did not become wider.	Grossly loose stem at cement-bone interface.
2	B	None	None	None	18 yrs	2 cm calcar resorption at 18 yrs Cyst distal to stem, no lysis on pathology report Revised for acetabular loosening and pain	Stem was loose but not grossly loose. Not debonded. Removed because of osteolytic area antero-medially distal to cement plug, which came back as a cyst not lysis on pathology report.
3	C2 in zone 8, 12	11 yrs in zone 7	15 yrs in zone 8	None	16 yrs	2 cm calcar resorption at 11 yrs No massive loosening No proximal lysis	Grossly loose
4	C2 in zone 2	12 yrs in zone 3, 5	18 yrs in zone 6	18 yrs in zone 3	19 yrs	NA	Grossly loose
5	C2 in zone 8	None	None	None	15 yrs	NA	No lysis Loose femur at PC interface on report from other institute
6	B	None	None	None	14 yrs	NA	Loose at cement bone interface proximally
7	C2 in zone 12	None on last f/u at 7 years at MGH. "Cement disease" diagnosed at other institution 2 years later.	None	None	9 yrs & 6 months	Pathologic fracture through an area of osteolysis distal to tip of prosthesis "Cement disease"	Loose femur
8	B	None	None	None	3 yrs	No evidence of loosening on pre-op x-ray, technic or gallium scans.	Loose femur No lysis Tight cement
9	C2 in zone 3,8	None	8 yrs in zone 1, 2	None	None	Last follow up 1988 Died 1998.	Not revised
10	C2 in	None	21 yrs in zone 5	None	None	NA	Not revised

f/u - follow-up, n - number, pre-op - preoperative, MGH - Massachusetts General Hospital, Fx - fracture, PC - prosthesis-cement

Figure 1 - A radiograph showing **a)** the primary cemented right total hip replacement for post-traumatic arthritis, using a CAD stem of a 62-year-old woman. **b)** Debonding in zone 8 was noticed after 4 years. **c)** Femoral osteolysis was noticed first in zones 8 and 12 at 5 years after total hip replacement. **d)** Before revision surgery at 15 years, showing slow progression of femoral osteolysis over 10 years with no massive proximal or distal lysis and no progression of the debonding. This film shows evidence of the nail track of the internal fixation for the femoral neck fracture. The semicircular contour of the cement within the nail track is a reflection of the surgeon's thumb, which was used to plug the track during cementing. The radiolucency lateral to that does not represent lysis. Slight lysis is present in zones 1, 2, 3 and 5. At revision surgery, the femoral component was grossly loose at the cement-bone interface. The early debonding at 4 years without severe osteolysis required early revision. CAD - computer assisted design

after the primary THR (range 4-21 years). These 5 debonded hips were followed for an additional average period of 2.6 years (range 1-11) after they became debonded and none of them demonstrated progressive debonding. Three of them were revised at 15, 16, and 19 years after primary THR due to symptomatic aseptic loosening. These 3 stems were grossly loose at time of revision (**Figure 1a, 1b, 1c & 1d**). Six of the 10 loose hips did not show femoral osteolysis on radiographs. In the other 4 hips, which have femoral lysis, the osteolysis occurred initially at a mean of 9 years after the primary THR (range 5-12 years) and these 4 hips were followed for a further period average of 6 years (range one-10). One of those 4 hips was revised for a periprosthetic fracture at 9 years and 10 months as mentioned before. His orthopedic surgeon had scheduled him for revision for progressive osteolysis before fractured. The other 3 were revised for symptomatic aseptic femoral loosening at 15, 16, and 19 years after primary THR **(Figure 2a, 2b, 2c & 2d)**. There was no consistent relationship between the development of debonding among 5 that debonded and osteolysis in those 5 hips, nor any consistent relationship between the 4 with osteolysis and debonding in the group with osteolysis. Overall debonding (n=5) was noted initially at an average of 13 years and osteolysis at an average of 9 years after primary THR. In one debonded stem, the debonding was first noted at 4 years and it preceded lysis by one year. In 2 other debonded stems, no osteolysis developed. In the remaining 2 debonded stems, the osteolysis proceeded the debonding by 4 years in one and by 6 years in the other. The 2 debonded stems had no osteolysis. Concerning the 8 femoral stems revised for symptomatic aseptic loosening, the average duration from primary THR to revision was 14 years (range 3-19). Although all 8 were among the 117 CAD stems (6.8%) and none were among the 44 HD-2 stems, this difference was not statistically significant (p=0.17, Yates corrected Chi-square). Six hips had both a loose femoral and acetabular component. One had just a loose femoral component, and the 8 had the periprosthetic fracture through osteolytic area around the tip of a loose femoral component. The 2 stems removed for aseptic loosening prior to 10 years after the primary THR are presented in detail. Both were carried out at other institutions. One was removed at 9 years and 10 months after insertion due to periprosthetic fracture

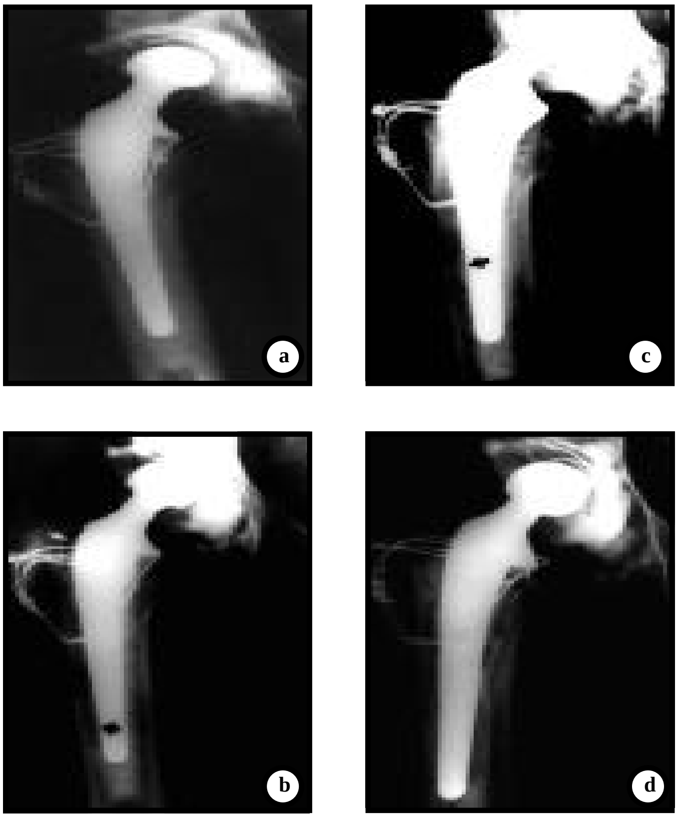

Figure 2 - Radiography of a 48-year-old woman with rheumatoid arthritis **a)** right cemented total hip replacement using a CAD stem. **b)** Femoral osteolysis developed over 12 years following the total hip replacement, in zones 1, 3 and 5. **c)** Debonding was first noticed 18 years after total hip replacement in zone 6. **d)** At 19 years after the total hip replacement and just before revision surgery. The cement had fractured. The stem had subsided in the cement mantle and was grossly loose at surgery. The lysis preceded the debonding. CAD - computer assisted design

through a lytic area around the tip of the prosthesis. The pre-revision radiographs showed an impending fracture of the femur just distal to the prosthesis with major lysis at that level but no evidence of stem loosening. At revision, the stem was loose. The 2nd case was the hip that was converted into a resection arthroplasty 3 years after the primary THR due to persistent pain. Radiographs showed no evidence of loosening or lysis and a preoperative arthrogram was negative for loosening or infection. The gallium scan was negative but the technetium scan was positive around the femoral component. At surgery, the femoral component was loose at the prosthesis-cement interface. A resection arthroplasty was carried out due to a cardiac condition precluding carrying out a full revision operation. The patients with the 2 debonded but unrevised stems did not have important symptoms and were recommended not to have revision surgery. The first of these was 74-year-old at the time of index operation. He had mild and occasionally moderate pain, which was controlled by non-steroidal anti-inflammatory medication. He died 12 years after the operation. The other patient had a Harris hip score of 84 and functioned well on the last follow-up after 18 years of implantation.

Discussion. While emphasis has been placed by some on the adverse features of a matt finish on cemented femoral stems, there is no evidence in this series that bead blasted surface finish was associated with either by premature loosening or the marked progressive osteolysis pattern that has been described with the Iowa stem. The authors of that report acknowledged that other factors might be involved in their experience, such as stem design and patient weight. The evidence in our report shows that in the designs studied here (CAD and HD2), the hypothesis that a bead blasted surface finish leads to a high incidence of early loosening and marked progressive lysis is not supported. The matt-finished HD-2 and CAD femoral stems did well both clinically and radiologically on a long term follow- up.

In addition, in a review of 251 primaries THR with HD-2 stems for an average 5.6 years follow-up, Russoti et al[21] reported the no revisions for aseptic loosening, 1.4% definite radiographic stem loosening and excellent results in 98% of the patients. Bourne et al[2] followed 195 hips (166 patients) with primary THR using HD-2 femoral stems at an average of 12 years. Five stems (3%) required revision for aseptic loosening, at a mean duration of 10.6 years. Another 3 stems (2%) were loose by radiographic criteria, giving an overall rate of 5% (8 of 195) of aseptic loosening of this bead-blasted stem. Thomas et al[22] reviewed the results of 74 primary THR (61 patients) using CAD stems followed for an average of 7 years in a population that was young (mean age 57 years), active, heavy (average weight 79 kilograms) and predominantly male (43 of 61). They reported 6.8% (5 of 74) stem revision rate for aseptic loosening and a radiographic loosening rate of 16% (12 of 74). This revision rate for aseptic loosening at 7 years is similar to our results in the CAD stem in which there was 6.8% (8 of 117) revision rate for aseptic loosening at an average 17.8 years in a slightly older (mean age 62 years) and less heavy (mean 72 kg) population. In a recently published retrospective study, Sporer et al[12] compared the results of 2 surface finishes in primary THR using the Iowa stem, one group (36 hips in 25 patients) had a bead-blasted Iowa stem with an average follow-up of 11.3 years. The 2nd group (45 hips in 37 patients) had a grit-blasted precoated Iowa stem with an average follow-up of 8.2 years. Four bead-blasted components (11%) were either radiographically loose or were revised due to aseptic loosening compared with 11 precoated grit-blasted components (24%). These results led the authors of that report to conclude that a polished surface is superior in cemented femoral stems. The loosening and the revision rate of both these sub-groups of Iowa stems were significantly higher than occurred in a group of HD-2 stems of the similar age and duration.[1] When compared to the report of Barrack et al[1] on 50 hips (44 patients) aged 50 years and under, in which 13 had an HD2 femoral components inserted and studied at 12 years, none of the HD2 stems had a revision for aseptic loosening and only one asymptomatic hip showed debonding in zone one of less than 1 mm. None had lysis. All these stems were bead blasted stems. This stands in contrast the report of Sporer et al.[12] Although the difference between the HD-2 experience and both Iowa groups was not statistically significant (p=0.85 and p=0.35), one compounding factor is the small sample size, which limits the power of the statistical analysis. Several other reports concerning rough finished stems of other designs have demonstrated satisfactory results. Garellick et al[23] reported a prospective randomized study of 410 primary THR using either the Charnley matte-finished stem (206 hips) or the Spectron bead-blasted stem (204 hips). The RA of the Spectron 0.4 microns and the Ra of the Charnley was 0.7 microns. They found 6 Charnley stem revisions for aseptic loosening compared to no Spectron stem revisions for the same reason at 11 years follow-up. At 7 years, the Kaplan-Meier survivorship analysis for aseptic loosening in the Charnley stem was 94.8 ± 5.7, but for the Spectron stem was 100%. A data from the Swedish national hip registry showed 7 years survival rate of Charnley, CAD and Lubinus prosthesis which has a rough surface (RA 1.2 microns) of 93.6, 95.1, and 97.5.[24] It would appear probable that the early loosening failure and the associated lysis in the Iowa stem is multifactorial. The surface finish change from 0.75 microns to 1.2-2.25 microns in the Iowa series may have been adverse for that design but the evidence presented here does not support a general conclusion that in the HD-2 and CAD, a bead-blasted surface finish is adverse. Both the rough surfaced Spectron and Lubinus stems also have excellent results over the first decade.[23,24]

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