Clinical experience with gamma irradiation-crosslinked polyethylene – A 14 to 20 year follow-up report

Abstract:
In an attempt to reduce polyethylene wear and subsequent osteolysis, the Pretoria (Grobelaar) prosthesis was designed in 1976. Due to a high rate of linear wear and post-operative dislocation previously experienced with the 22mm head, a 30 mm head size was selected, at the expense of an expected increase in volumetric wear. In an effort to offset this anticipated problem, the first and fourth authors have embarked upon a programme to improve polyethylene by means of gamma crosslinking. The finished cups were subjected to gamma rays in an acetylene crosslinking medium, thereby eliminating the need for high irradiation dosages to achieve crosslinking. As a result undue brittleness was prevented. At 100kG mainly the superficial 300-micron was crosslinked, creating a “case-hardening” effect. The femoral component was a modified stainless steel Charly design with a u-bolt attachment for trochanter re-fixation.

From 1977 to 1983 over 1000 of these implants were used by the first and second authors in Pretoria and Johannesburg respectively. Our follow-up of 100+ survivors ranged between 14 to 21 years, averaging 16.5 years. The Pretoria series showed complete lack of measurable wear in 56 out of 64 cases, and which lead to only two revisions due to granulomatous osteolytic loosening. In the Johannesburg series there were two cases with wear-related loosening out of 39 survivors, leading to revisions.

Introduction
In the quest for perfection, the ultimate permanent implant seems to be forever evasive. Almost every single aspect of joint replacement has already been implicated. Many modifications were implemented, but the further we stray from Sir John Charnley’s original concept, the more we seem to falter. Metals have been refined and strengthened, and acrylic cement was unfairly blamed, leading to the cementless era with its many pitfalls and disappointments. In the words of Mike Freeman, “Implants seldom failed because of cement, but rather in spite of cement.”

In the mid-seventies the first author became convinced that polyethylene particles were the main reason for destructive sub-interface osteolysis. He subsequently presented clinical evidence, at the low friction society at Midhurst (1983), of many cases of polyethylene granuloma due to wear of the Charnley cup. The response was severe and unanimous criticism and non-belief, except by Prof. Maurice Muller, who was in the audience and has seen this phenomenon many times before in Bern. Earlier reports had already been published independently by Mike Freeman and by Hans Willert. Since then many efforts have been made to reduce particle production in total joint replacement, notably material changes (ceramics, chrome cobalt, nitriding, carbon impregnation) and design changes (larger heads, larger and smaller tolerances, smaller diameter necks). None of these measures proved perfect.

In 1978 the first and fourth authors embarked upon a polyethylene improvement programme, subjecting polyethylene to gamma rays in the presence of a crosslinking gas. This was therefore a combination of irradiation-crosslinking and chemical-crosslinking. These cups were implanted by the 1st and 2nd authors.
in Pretoria and Johannesburg in over 1000 cases, shortly before the ceramic era.

This article deals with the long-term follow-up of these cases, demonstrating almost complete lack of wear, the sustaining of the interface and an extremely low incidence of polyethylene granuloma-induced implant loosening. It also demonstrated that although UHMW polyethylene remains the weak link in joint replacement, it nevertheless also remains the gold standard of joint replacement, provided that certain requirements are met.

Material and methods

RAM extruded rectangular bars (RCH 1000) were supplied by Hoechst. Acetabular cups were machined to their final dimensions and then gamma irradiated in stainless steel containers filled with acetylene gas. 300-microns surface crosslinking was achieved at 100Kg (Fig 9). Sterilisation took place afterwards in plastic bags in air.

From 1977 to 1982, 650 cases were operated in Pretoria by the first author using these cups. The femoral component was a modified Charnley stainless steel monoblock device with a large 30 mm head diameter, and a u-bolt for trochanteric re-fixation (Fig 1). All patients routinely received this implant and then were followed up after six months and bi-annually. Only 64 cases eventually qualified in the Pretoria series. Exclusion criteria were strict and included any follow-up less than 14 years, sepsis, dislocation, stem fractures, and other rare non-wear related causes of failure. Follow-up was by personal consultation, examination, and x-ray review. Only AP-views were examined - all cases magnified to 18% as per our specific instruction to the radiology departments. Follow-up was 14 to 22 years with an average of 15.5 years. Linear wear was measured according to our own version of a combination of the Griffith's and Livermore's methods (Fig 2). Retrieval specimens were anxiously sought, but were rarely available since explanation due to polyethylene wear was extremely rare.

Two years later (1979), Dr. FA Weber commenced his series with this implant, both in his private practice and his state appointment practice. A total of 409 cases were completed over the next five years. Of the 263 private patients, 263 were detailed, 144 answers received, 33 died, 111 positive and two negative answers.

Results: y - project

<table>
<thead>
<tr>
<th>Case</th>
<th>16 yrs</th>
<th>3.0 mm</th>
<th>(0.19 mm/yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 2</td>
<td>14 yrs</td>
<td>2.0 mm</td>
<td>(0.14 mm/yr)</td>
</tr>
<tr>
<td>Case 3</td>
<td>14 yrs</td>
<td>1.0 mm</td>
<td>(0.07 mm/yr)</td>
</tr>
<tr>
<td>Case 4</td>
<td>13 yrs</td>
<td>1.0 mm</td>
<td>(0.08 mm/yr)</td>
</tr>
<tr>
<td>Case 5</td>
<td>16 yrs</td>
<td>1.0 mm</td>
<td>(0.06 mm/yr)</td>
</tr>
<tr>
<td>Case 6</td>
<td>15 yrs</td>
<td>1.0 mm</td>
<td>(0.07 mm/yr)</td>
</tr>
<tr>
<td>Case 7</td>
<td>17 yrs</td>
<td>1.0 mm</td>
<td>(0.06 mm/yr)</td>
</tr>
<tr>
<td>Case 8</td>
<td>18 yrs</td>
<td>1.0 mm</td>
<td>(0.05 mm/yr)</td>
</tr>
<tr>
<td>Average wear in these 8 cases:</td>
<td></td>
<td></td>
<td>0.09 mm/yr</td>
</tr>
<tr>
<td>Average wear rate for the 64 cases:</td>
<td></td>
<td></td>
<td>0.011 mm/yr</td>
</tr>
</tbody>
</table>

For this particular study, 39 hips from the Johannesburg series in 33 patients have qualified in terms of the inclusion criteria specified in the protocol. These were radiologically and clinically followed up in Johannesburg.

Results

The Pretoria Series:

In 64 hips performed in 62 patients, 56 cases had no measurable wear at all. Therefore only eight cases had wear ranging from 1.0 to 4.0 mm total wear.

Since 56 hips showed no measurable wear at all, the total annual wear extrapolated to the entire series was an extremely low 0.011 mm linear wear per annum.
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Since a high premium is placed on the all-important integrity of the interface, individual cases of cup wear were analysed in terms of the degree of osteolysis in the respective Charnley and Gruen zones. The two cases displaying major wear in all acetabular zones obviously had loose implants, and were both revised, leading to a 3% revision rate due to wear.

### Results: y - project

<table>
<thead>
<tr>
<th>Changes: 8 cases</th>
<th>Charnley Zones</th>
<th>Gruen Zones</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cup wear</td>
<td>(Acet.Lysis)</td>
<td>(Fem.Lysis)</td>
<td></td>
</tr>
<tr>
<td>Case 1</td>
<td>3.0 mm</td>
<td>2-5 mm</td>
<td>0-4 mm</td>
</tr>
<tr>
<td>Case 2</td>
<td>2.0 mm</td>
<td>1-6 mm</td>
<td>0-6 mm</td>
</tr>
<tr>
<td>Case 3</td>
<td>1.0 mm</td>
<td>0-3 mm</td>
<td>0-2 mm</td>
</tr>
<tr>
<td>Case 4</td>
<td>1.0 mm</td>
<td>0-3 mm</td>
<td>0-3 mm</td>
</tr>
<tr>
<td>Case 5</td>
<td>1.0 mm</td>
<td>0-4 mm</td>
<td>0-3 mm</td>
</tr>
<tr>
<td>Case 6</td>
<td>1.0 mm</td>
<td>0-2 mm</td>
<td>0-2 mm</td>
</tr>
<tr>
<td>Case 7</td>
<td>1.0 mm</td>
<td>0-0 mm</td>
<td>0-3 mm</td>
</tr>
<tr>
<td>Case 8</td>
<td>1.0 mm</td>
<td>0-0 mm</td>
<td>0-1 mm</td>
</tr>
</tbody>
</table>

Although it was found that cup wear was generally associated with osteolysis and thus gradual interface destruction, interface changes also appeared in the cases where no wear was present. However, in these cases interface changes were of a stable nature and did not increase with time. We have objectively studied interface changes in the entire series, and found that important changes were present in all three acetabular zones, but mainly in femoral zones 1, 6, and 7.

### Case Examples:

![Fig 4: An x-ray of the worst case of wear in this study. Picture taken at 15 years when wear was measured at 2.5mm with severe granuloma and loosening - leading to revision surgery later on.](image1)

**The Johannesburg series**

Results were remarkably similar to that of the Pretoria series. A total of 39 cases were followed between 13 to 22 years with an average of 15.5 years. Thirty of these cases showed no measurable wear at all. The other nine cases showed wear ranging from 0.7mm to 1.5mm wear only.

Two of these nine cases were revised, which means that only 5% of these 39 cases, after 15.5 years were re-operated due to wear-related looseness.
Larger heads undoubtedly have certain advantages. They are more stable in bigger patients, and exhibits less linear wear. Our series was performed with large 30mm head size, and we believe that crosslinking in this particular size helped us to overcome the degrees of volumetric wear described for larger heads in the literature.\(^1\)

In a controversial article by Wroblewski\(^1\) as late as 1985, he showed little concern about polyethylene particles as a cause of osteolytic failure, but considered linear wear as a major cause of mechanical impingement failure in 22mm heads. His 15 to 20 year wear rate was 0.096mm per year, compared to our 30mm crosslinked cups of 0.011mm - almost ten times less than the Wrightington experience. Even after introducing ceramics and crosslinking later on, in 1996 Wroblewski reported a high rate of 1st year wear, 0.29 mm per year. He described this as "settling in", but we believe this high degree of initial wear is highly unacceptable. It may be due to surface oxidation after their method of crosslinking, combined with the very high linear forces associated with the 22mm head size.

Finally, what makes the South-African experience truly spectacular is the fact that this particular series was performed 23 years ago in a very small Pretoria factory, assisted by the Atomic Energy Board. Very little sophistication existed in those days in terms of manufacturing process and material choices. Ordinary carbon stainless steel, femoral components with a large head size were manually polished and these results are a tribute to the quality standards achieved.

Furthermore, polyethylene RAM extruded material was the only polyethylene type available to us, and possessed questionable material consolidation, if compared to modern alternatives.

No annealing was done to eradicate free radicals and thus reduce oxidation. Packaging was in air, and should ideally be in inert medium to prevent oxidation.

Nevertheless, recently at the Effort meeting in Brussels, May 1999, the first author challenged an audience of 500 surgeons to match these results, even if only in a single case experience, as demonstrated in Fig 7 and Fig 8. Instead, there was an unusual degree of appreciation from the audience, who acknowledged the fact that these results were truly spectacular, surpassing even the good results of super materials such as ceramics.

We believe that the low wear rates reported in these two independent South African series were undoubtedly the result of gamma crosslinking of the polyethylene. Perhaps the method that we employed added to the good results - a combination of chemical (acetylene) and radiation (gamma) crosslinking applied post-manufacture to the implants. This reduces the need for gamma irradiation dosages and consequently prevents brittleness.

What then about the future?

We have to improve on our 10% follow-up figure, and are actively sourcing the remainder of the 15 to 20 year follow-up cases at present. Superior quality UHMW polyethylene and HEAD materials (notably ceramics) and finishing processes may be beneficial. Head sizes are less important than before, but cup wall thickness is of great importance. I believe that we have now reached a stage where wear prediction in vivo can honestly be set at 25 to 30 years at least.

References