Incomplete seating of the liner with the Trident acetabular system

A CAUSE FOR CONCERN?


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We reviewed the initial post-operative radiographs of the Trident acetabulum and identified a problem with seating of the metal-backed ceramic liner. We identified 117 hips in 113 patients who had undergone primary total hip replacement using the Trident shell with a metal-backed alumina liner. Of these, 19 (16.4%) were noted to have incomplete seating of the liner, as judged by plain anteroposterior and lateral radiographs. One case of complete liner dissociation necessitating early revision was not included in the prevalence figures. One mis-seated liner was revised in the early post-operative period and two that were initially incompletely seated were found on follow-up radiographs to have become correctly seated. There may be technical issues with regard to the implanting of this prosthesis of which surgeons should be aware. However, there is the distinct possibility that the Trident shell deforms upon implantation, thereby preventing complete seating of the liner.

The use of uncemented hip prostheses is increasing in the United Kingdom. In total, 39 000 ‘conventional’ hip replacements (i.e. excluding resurfacing procedures) were performed in 2004.1 Of these, over 15 000 used either fully uncemented or hybrid (uncemented acetabulum with cemented femur) components, representing 38.6% of all ‘conventional’ hip replacements.1 This compares to less than 30% in 2003.1 The potential advantages of uncemented components include reduced operating time, more biological fixation to bone and increased modularity, particularly of the acetabular components. Most modern acetabular shells come with a variety of liner options, including polyethylene (standard or highly cross-linked), metal-on-metal or ceramic, in an attempt to combat the traditional problem of wear of the bearing surface, subsequent osteolysis, and loosening of the implant necessitating revision. Laboratory data cite greatly reduced wear rates for hard-on-hard bearing couples.2 Aseptic loosening secondary to osteolysis from polyethylene wear particles has been shown to be the main cause of implant failure.1 Many surgeons are therefore moving away from traditional metal-on-polyethylene hips in favour of harder bearing couples. Concerns persist with regard to serum cobalt and chromium concentrations from metal-on-metal bearings,3 and despite dramatic improvements in the manufacture and quality of ceramics there is still the potential for the fracture of such bearings.4

There are numerous hip replacement systems available in the United Kingdom. In an attempt to provide quality control, the Orthopaedic Data Evaluation Panel was established in December 2002. The benchmark for approval of the National Institute for Clinical Excellence (NICE) for any prosthesis is ten years of follow-up, with a failure rate of 10% or less on data from more than 500 patients from multiple centres; all product failures must be identified, and there should be an acceptably-sized cohort at ten years for Kaplan-Meier survival analysis.1 Although several femoral components (cemented and uncemented) and seven cemented acetabular components fulfil these criteria, no cementless acetabular systems do so. The availability of multiple bearing inserts compounds this problem, as the Orthopaedic Data Evaluation Panel rating system does not differentiate between the different possible combinations.

The most widely-used uncemented acetabular component is the Trident (Stryker, Mahwah, New Jersey), more than 4 000 of which were implanted in Australia in 2004.5 This implant has the option of either a polyethylene- or a titanium-backed ceramic press-fit liner. This system achieved Federal Drug Administration (FDA) approval in 2003 and has been used in our unit since mid-2004. It
has an Orthopaedic Data Evaluation Panel rating of 3a indicating that the product has a three-year rate of failure of less than 3% with acceptable evidence.1 The metal acetabular shell is titanium alloy with arc deposition of the hydroxyapatite coating. Two varieties exist; one is equatorially expanded (peripheral self-locking) and the other hemispherically expanded. The peripheral self-locking shell is 1.8 mm oversized at the periphery and the hemispherically expanded shell is designed to be inserted into an acetabulum that has been under-reamed by 1 mm to 2 mm, as is standard in uncemented hip arthroplasty (Fig. 1). The ceramic liner is recessed within its titanium backing to prevent impingement of the rim and ceramic chipping. Anti-rotation tabs on the shell ensure correct seating of the liner, which is then impacted to engage as a morse taper within the shell (Fig. 2).

At a recent departmental audit meeting, three cases of improper seating of the metal-backed ceramic liner, visible on routine post-operative radiographs, were identified. As a result, the entire cohort of patients who had undergone hip replacement using the Trident uncemented shell with a ceramic liner was reviewed. This paper describes the prevalence of incomplete seating of the Trident ceramic acetabular liner for our unit and the possible reasons for this.

Patients and Methods
From the theatre logbooks, all patients who had undergone total hip replacement using the Trident acetabular shell with a metal-backed ceramic liner were identified. A total of 117 hips, four of which were staged bilateral, in 113 patients were identified as having undergone primary arthroplasty using the Trident acetabular system with its metal-backed ceramic liner. There were three different femoral/acetabular component combinations using Trident with cemented Exeter (Stryker), uncemented Omnimfit (Stryker) or uncemented Accolade (Stryker) femoral stems. A total of 109 (93.2%) of the Trident shells used were peripheral self-locking. Details of the patients are given in Table I. Of note is the fact that the mean age in this series is younger than usual for hip arthroplasty, reflecting the tendency to use ceramic bearings in younger patients. The earliest available post-operative radiographs, usually taken 24 hours after the operation, were reviewed. We obtain both anteroposterior and lateral radiographs of all hip replacements in the early post-operative period. Three consultant orthopaedic surgeons (AJL, MLG, CMH), each with considerable experience in hip arthroplasty, reviewed the films independently, and a consensus of opinion was reached as to whether or not the liner was correctly seated. If seated correctly, the liner is parallel to the shell (Fig. 3). Mis-seat- ing is identified when there is a gap between the metal back of the liner and the rim of the shell (Fig. 4) with angulation between the liner and shell. The liner was judged to be correctly seated if there was no gap at any point on either anteroposterior or lateral radiographs. For those patients in whom the liner was incorrectly seated, the operative record including the primary diagnosis, the pre-operative presence of abnormal anatomy (for example dysplasia), and details

Table I. Patient demographics, pre-operative diagnosis and surgical approach

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at surgery in yrs (range)</td>
<td>57.9 (24 to 77)</td>
</tr>
<tr>
<td>Men:women</td>
<td>49:64</td>
</tr>
<tr>
<td>Pre-operative diagnosis</td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>85</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>4</td>
</tr>
<tr>
<td>Dysplasia</td>
<td>24</td>
</tr>
<tr>
<td>Previous Perthes' disease</td>
<td>2</td>
</tr>
<tr>
<td>Previous slipped upper femoral epiphysis</td>
<td>1</td>
</tr>
<tr>
<td>Previous fracture</td>
<td>1</td>
</tr>
<tr>
<td>Surgical approach (%)</td>
<td></td>
</tr>
<tr>
<td>Hardinge</td>
<td>63 (53.8)</td>
</tr>
<tr>
<td>Posterior</td>
<td>54 (46.2)</td>
</tr>
</tbody>
</table>

* one patient had undergone previous periacetabular osteotomy for hip dysplasia
of the surgical approach and the surgeon responsible were examined in order to identify whether or not there were technical issues with a particular surgeon or patient subgroup.

**Results**

Within this cohort, a total of 19 liners (16.4%) were judged to be incompletely seated. Details of the pre-operative diagnosis, surgical approach and responsible surgeon for each mis-seated liner are given in Table II. The location of the gap was inferomedially in all cases. When a posterior approach had been used the gap was visible anteriorly on the lateral radiograph, whereas with a Hardinge-type approach the gap tended to be posterior. Figure 4 gives an example of incomplete seating. The surgical technique for the Trident acetabulum advises the surgeon to check that the liner is correctly-seated circumferentially. The least accessible aspect of the acetabulum lies inferomedially in all cases, but the anterior aspect is more difficult to access with the posterior approach. The converse is true for a Hardinge approach. Of 15 surgeons who had used this system, ten had at least one case where the liner was judged to be incompletely seated.

There was one complete dissociation of a liner which was revised uneventfully in the early post-operative period. This was almost certainly due to a technical error on the part of the surgeon involved, and we have excluded this from the reported prevalence of incomplete seating. One further case of slight malpositioning was also revised uneventfully and post-revision films showed the liner to be correctly seated.
Two cases were deemed to have incomplete seating of the liner on post-operative films, but at subsequent review the liner was noted to have spontaneously impacted into the correctly-seated position (Fig. 5).

Discussion
In this study we have shown that the prevalence of incomplete seating of the Trident metal-backed ceramic liner in our unit is 16.4%. The Trident ceramic acetabular system has been in use since 1999, has FDA approval, and has been widely used in the United Kingdom since 2003. We are unaware of any other published series of incomplete seating of ceramic liners using this shell. Previous reports of liner dissociation have involved isolated dislocation of the polyethylene liner or of this occurring in association with wear in the Harris-Galante hip. The only report of dissociation of a ceramic liner followed traumatic dislocation of a hip.

Any newly-introduced arthroplasty system should be easy to use and reliable. The question is whether we have simply found the Trident difficult to use, or if there a design or problem that prevents it from being so. The case of complete dissociation of the liner from the shell was almost certainly a result of surgical error. Several surgeons were responsible for the remaining cases which suggests that surgical technique alone is unlikely to be the cause. All surgeons in our unit were trained in the use of the Trident system before using it, and the Stryker representative attended the first few cases performed by any individual surgeon. Design-related causes are likely therefore to be at least partly responsible for the problem. The pre-operative diagnosis would not appear to be a risk factor for mis-seating of the liner (Tables I and II).

Examination of the Trident shell with its metal-backed aluminium liner ex vivo reveals that the locking mechanism is simple, easy to engage and very strong. Why, therefore, have we identified such a high prevalence of mis-seating? Interposition of soft tissue or bone may be one factor, but a fundamental tenet of hip replacement is adequate visualisation of the acetabulum. Although we cannot completely discount poor visualisation as a possibility, we do not think it is the major reason. The Trident system has a unique design which features a titanium sleeve encapsulating the ceramic that is pre-assembled to the aluminium liner and reportedly increases the material strength of the ceramic insert by 50%. Results at three to five years suggest that the titanium sleeve reduces the incidence of insert chipping on impaction, with no fractures or failures of ceramic bearings. The rim of the titanium sleeve is elevated beyond that of the ceramic in an attempt to prevent impingement between the neck of the femoral prosthesis and the rim of the ceramic, thus avoiding chipping of the ceramic itself (Figs 1 and 2). This elevated rim, because it protrudes beyond the rim of the shell, may prevent inspection of the liner when attempting to assess intra-operative seating. In all cases of incomplete seating, the gap described was evident inferomedially. The current recommendation in hip arthroplasty is to leave the acetabular component slightly ‘closed’ when using ceramic bearings to reduce the potential of point-loading. This is very poorly tolerated by ceramics and can lead to fracture of the bearing or early failure. The combination of a slightly ‘closed’ shell and a liner whose rim protrudes beyond the margins of the impacted shell make it technically difficult to assess complete seating of this liner at its inferomedial aspect.

A secondary explanation is that the shell can deform upon insertion under certain conditions. This phenomenon has recently been reported for the Pinnacle acetabular system (DePuy, Warsaw, Indiana). The Trident shell is one of the thinnest available and is made of titanium, which is a relatively soft metal. The Trident peripheral self-locking liner is equatorially expanded to an oversize of 1.8 mm at the periphery. It is possible that this is excessive, particularly in the dense bone that is found in young patients, who are the group most likely to receive a ceramic bearing couple. Indeed, for this reason, the surgical protocol recommends over-reaming the acetabulum by 1 mm in such circumstances, in order to prevent ‘acetabular fracture, failure to seat the implant fully, or slight deformation of the titanium shell, making seating of the insert more difficult’.

The majority of incompletely seated liners occurred in peripheral self-locking shells, reflecting the predominance of their use, but two cases involved the use of a hemispherically-expanded shell. In both cases the acetabulum was under-reamed by 2 mm. That the shell can deform upon insertion and prevent complete seating of the liner is supported by the observation that two originally mis-seated liners were noted on subsequent radiographs to have become correctly seated spontaneously (Fig. 5). This phenomenon can be explained by the viscoelasticity of bone and elastic recoil of the
shell. Stress relaxation would be expected in the subchondral bone after implantation, and with the normal cyclical loading of the hip during walking and the tendency for all metals to show some elasticity, it is likely that in these cases the shell returns to its normal shape and the liner can therefore seat itself correctly. Conversely, the cases in which the liners remained incompletely seated may be explained if the hoop stresses upon implantation are large enough for plastic deformation of the shell to occur. When this happens, impaction of the liner will lock the morse taper in place. Subsequent reseating will therefore be unlikely, if not impossible. As yet we do not know whether this will lead to adverse consequences, but there is the potential for fretting to occur between the shell and the metal back of the liner as a result of suboptimal engagement of the morse taper. This is of particular concern, bearing in mind the relative youth of the patients in which this system was used. Potential problems include metallosis, implant loosening, and fatigue fracture of either the acetabular shell or the ceramic liner. All patients with persistent mis-seating of the liner are being routinely observed in clinic and will be x-rayed regularly. As there is evidence that other uncemented acetabular shells can deform in hard bone it is likely that most systems are vulnerable to mis-seating of ceramic inserts. The particular design of the Trident metal-backed insert facilitates identification of mis-seating on post-operative radiographs. Ironically, the metal backing may protect the ceramic bearing from point loading within the deformed shell thereby reducing the already small risk of ceramic failure.

We have identified a potential problem with the Trident acetabular shell when used in combination with its metal-backed ceramic liner. We recommend that surgeons should be aware of the difficulties in the seating of this implant, and should take particular care to ensure that the liner is accurately located inferomedially and properly engaged. In addition, we recommend careful review of the post-operative radiographs to look for evidence of incomplete seating of the liner in those patients who have undergone total hip replacement using uncemented acetabular systems.

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References