

Insertion of tantalum beads in RSA of the hip

Variations in incidence of extra-osseous beads with insertion site

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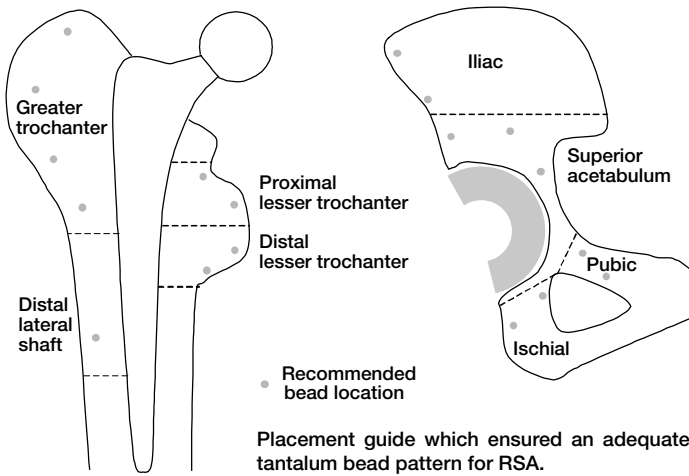
ABSTRACT Radiostereometric analysis (RSA) is a technique that can be used to measure the in-vivo micro-motion of the components of hip arthroplasty. It requires the insertion of tantalum beads into the bone permitting analysis of the radiographs. Extra-osseous beads reduce the usable bead pattern and previous studies have reported their incidence in the proximal femur as between 11% and 13% of all inserted beads. We reviewed the relative incidence of extra-osseous beads by examining 1038 radiographs of 97 patients who were part of an ongoing RSA hip study. Extra-osseous beads were seen in 44% of our patients with most having a single extra-osseous bead. The relative incidence of extra-osseous beads was 2% and 6% in the femur and pelvis, respectively. We observed a reduction in the incidence of the femoral beads with time, but not of the pelvis, which suggests that experience in the insertion technique improves the insertion rates at least of the femur. Our findings indicate that the incidence of extra-osseous beads is lower than previously reported. However, care should be taken in the design of studies to ensure that an adequate number of beads are placed in locations which are both surgically achievable and technically useful.

The use of radiostereometric analysis (RSA) in the assessment of total hip arthroplasty is well-recognized as an accurate technique in the measurement of small movements of implants (Chafetz et al. 1985, Mjöberg et al. 1986, Nistor et al. 1991, Søballe et al. 1993, Kiss et al. 1995, 1996). This technique requires the insertion of tantalum beads into a stable location in the bone during surgery (Kärrholm et al. 1997). Tantalum has been used

in surgical procedures for more than 25 years and is histologically biocompatible (Alberius 1983, Aronson et al. 1985). However, due to difficulties in insertion at surgery, beads may fail to be successfully implanted in the bone and consequently appear to be extra-osseous on the follow-up radiographs. In a recent study, Eldridge et al. (1998) found that 40% of their patients who had tantalum beads inserted into the proximal femur had one or more extra-osseous beads, which means that 13% of the beads are extra-osseous. Moreover, they felt that on two occasions an extra-osseous bead had migrated towards the joint space, although none had entered it. Such reports have raised concern about the potential risk of third-body wear caused by the RSA procedure. A further review of 13 RSA studies of the femur (Biedermann et al. 2001) found an average of 11% of inserted beads in an extra-osseous position. Although there has not been a documented case of an extra-osseous bead causing complications, the movement of the bead with the soft tissues makes it unsuitable for the RSA analysis (Kärrholm et al. 1997).

The accuracy of an RSA study depends on careful planning of the positions and the number of beads inserted. Many factors must be considered. Beads should be placed around the implant in positions that can be reliably achieved surgically, give a good spread of the bead pattern and are visible in both radiographic views of the stereo pair. We therefore developed a bead placement protocol based on the previous experience of established centers (Kärrholm et al. 1997), the participating surgeons and research scientists.

In order to evaluate the success of our protocol, we examined all available radiographs of the



patients in our study to determine the presence of extra-osseous beads and ascertain whether insertion into any particular area resulted in a greater relative incidence.

Method

Our center has inserted tantalum beads into 97 patients in order to analyze the migration of various designs of total hip prostheses, using RSA, based on the technique described by Selvik (1989). Informed consent was obtained from all patients. The tantalum beads were inserted during total hip replacement. Following reaming of the acetabulum, pelvic beads were inserted into the ilium, superior acetabulum, pubic ramus and ischium. The femoral beads were inserted into the greater trochanter, proximal and distal lesser trochanter and the lateral shaft of the femur after its preparation. The beads were inserted directly into the cancellous bone, except for those in the ilium and the lateral shaft of the femur, which were inserted through the cortical surface of the bone. A placement guide was provided for the surgeons as a reference for bead insertion (Figure). 10 tantalum beads were also embedded in the polyethylene of the acetabular component during the manufacturing process. 5 surgeons inserted the beads. A specialized insertion tool was used that incorporates a spring-loaded piston (RSA Biomedical Innovations AB, Sweden). The patients had RSA examinations at 7 days, 6, 12, 18 and

24 months after the procedure. Moreover, standard follow-up radiographs were taken as follows: an AP pelvis at 7 days; AP hip at 7 days, then at 6, 12 and 24 months; and lateral obliques at 6 weeks and 24 months. The first 33 patients in the study had terminated their 2-year follow-up and had a complete set of films, as above. Since the study is still in progress, the last 20 patients had only their postoperative films available for analysis. The other subjects were in various stages of follow-up.

All the films available for each patient were studied. The number of beads in bone, and those that were extra-osseous were recorded by region, as indicated on the placement guide. We calculated the relative incidence of a bead that was extra-osseous as the ratio of a region's extra-osseous beads to the total number of beads inserted in that region. In order to determine evidence of a change in the relative incidence with time, which may occur as the amount of experience in the insertion technique increases, these figures were further broken down into sequential groups of 20 patients from the start of the study.

Results

We reviewed 1038 radiographs with a median of 11 (2–17) films per patient. Excluding the acetabular beads, 1485 beads were inserted into the 97 patients, which resulted in a median of 16 (5–20) beads inserted into each patient. This corresponds to a median of 8 (1–11) osseous beads in the femur and 8 (2–10) in the pelvis.

The RSA technique requires at least 3 osseous beads in the pelvic or femoral regions to permit an accurate analysis. Only 4 cases could not be analyzed because of an inadequate number of beads (3 femoral and 1 pelvic).

We found that 57 beads were extra-osseous on one or more films taken during the study (Table 1). Extra-osseous beads were found in 43 patients, 34 of these had an extra-osseous pelvic bead while

Table 1. Number of osseous and extra-osseous beads inserted into the regions around the hip prosthesis, showing the incidence of extra-osseous beads

Region	Osseous n	Extra-osseous n	(%)
Pelvic			
Iliac	109	21	16
Superior acetabulum	309	9	3
Pubic	164	10	6
Ischial	136	3	2
Total	718	43	6
Femoral			
Greater trochanter	344	9	3
Proximal lesser trochanter	160	1	1
Distal lesser trochanter	147	1	1
Lateral shaft	59	3	5
Total	710	14	2

only 12 of them had an extra-osseous femoral bead.

The relative incidence of extra-osseous beads in the femur was 2% and in the pelvis was 6%. It can be seen that the relative incidence varies markedly according to the region of insertion (Table 1), and that, in general, the pelvic regions had a higher incidence than the femoral.

We found some evidence of a reduction in the incidence in the femur after the first 20 patients, but not in the pelvis (Table 2).

Discussion

Eldridge et al. (1998) studied 64 total hip replacement patients who had roentgen monophotogrammetric analysis (RMA). They reported that 40% of their patients had an extra-osseous bead. Although this appears to be comparable to the 44% of patients in our study, they inserted fewer beads with a median of only 4 (2–8) beads inserted per patient, and beads were inserted only into the proximal femur. In their review of bead position, they divided the beads into peri-osseous and extra-osseous. Of 274 beads inserted, 36 were found to be in the soft tissue (21 peri-osseous and 15 extra-osseous). We classified all peri-osseous and extra-osseous beads as extra-osseous.

A comparison of the relative incidence of extra-osseous beads in the femur shows that Eldridge et al. (1998) reported 13% and Biedermann et al.

Table 2. Relative incidence (%) of pelvic and femoral extra-osseous beads by sequential groups of 20 patients as surgeon-experience increases

Regional relative incidence	Patient group				
	1–20	21–40	41–60	61–80	81–97
Pelvic	8	6	4	4	7
Femoral	6	1	1	1	2

(2001) 11%. In contrast, our observed relative incidence was only 2%. We feel that different insertion devices and techniques may account for some of the variation in the incidence of extra-osseous beads.

Our results show a higher incidence of femoral extra-osseous beads in earlier cases (Table 2). In these cases, the insertion of the proximal femoral beads was attempted through both the cortical and internal surfaces of the femoral shaft. As experience was gained, insertion directly into the cancellous bone from inside the reamed femoral shaft was felt to be more reliable. In consequence, the incidence of extra-osseous beads will be influenced by the fact that misplaced beads inserted from the internal surface are likely to fall into the femoral shaft and be washed out by the irrigation, while those inserted from the external surface will remain in the extra-osseous tissues, if misplaced.

Previously published studies have not reported an incidence of extra-osseous beads in the pelvis. Compared to the femur, a higher relative incidence was observed in the pelvis. This was consistent with the experience of the surgeons, who found insertion of tantalum beads into the pelvis technically more challenging. This difference is most probably due to the fact that during the procedure the proximal femur is centered in the wound, thus allowing bead insertion under direct visualization, whereas in the pelvis, there is often a poor field of view.

It can be seen that insertion of beads into the anterior superior iliac spine and the lateral shaft of the femur produce the highest incidence of extra-osseous beads in their respective regions (Table 1). In both these areas the beads were inserted directly through the cortical bone, in contrast to the other bead sites, which were inserted directly into the cancellous bone after reaming. A possible reason

for this could be that the insertion through cortical bone is more likely to dislodge the bead from the introducer and as a result, lie in an extra-osseous position. It may be that in designing future studies the route through which the bead is passed during insertion may need to be considered in order to try and improve the number of osseous beads, and therefore accuracy.

In some cases, fewer osseous beads were inserted than had been planned. This may be due to the bead being inadequately loaded into the introducer or that the bead was dislodged from the bone during pulsed lavage of the bone before cementing. While care in loading the bead introducer should improve this problem, the more beads which one attempts to insert should improve the chances of an adequate number in a stable osseous position on analysis.

It should also be considered that not all the extra-osseous beads would have been picked up in our study. This may be the case particularly in patients recruited to the study later, who have fewer films for analysis. However, all patients had radiographs reviewed from several different angles, but this is unlikely to invalidate the overall results.

During the design of an RSA study, care should be taken to ensure the intended areas of bead insertion are easily accessible during surgery. On the other hand, beads must be implanted in positions that are visible on both radiographs and that produce a well conditioned bead pattern (Kärrholm et al. 1997).

The higher relative incidence of femoral extra-osseous beads in early cases shows the importance of early feedback to the operating surgeons as to insertion techniques that may be responsible for unsatisfactory bead insertion rates. Where sites with a high relative incidence of extra-osseous beads are noted, the surgical technique or site should be changed.

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