A study of the Elite Plus femoral component using radiostereometric analysis

Sir,

I read with interest the article by Derbyshire and Porter in the June 2007 issue entitled, “A study of the Elite Plus femoral component using radiostereometric analysis.” I would like to raise a few points regarding the use of the radiostereometric analysis (RSA) technique in their assessment of the motion of the Elite Plus femoral component.

There are a number of points in the paper which could make the conclusions drawn not entirely reliable. Radiostereometric analysis has been recognised as a surrogate marker for final outcome with relatively small numbers of patients over a relatively short period of follow-up. There have been recent attempts to standardise the techniques used in RSA and the presentation of results in order to allow meaningful comparisons of studies. In terms of the methods used, the authors have not stated a number of important variables. The size of the markers used has not been expressed, which can influence the accuracy of the results. In the case of the four patients excluded from the study because of insufficient scatter or number of markers visible, these variables are not stated. The authors also do not state if a calibration cage was used and whether this was validated.

My final concern regards the authors’ use of “double examinations” in the study. It is stated that the double examinations were only performed on five subjects. Ideally, all patients should have double examinations performed. It is also stated that the patients with the lowest number of repeat examinations had double examinations performed in order to reduce the risk of exposure to radiation. This raises two points; it is hard to see how the patients with the lowest number of repeat exposures could be identified in a prospective study when the number of exposures that would be required by subsequent subjects is not known. It is also likely that the patients that required the least number of exposures in order to obtain adequate radiographs are those least likely to suffer from inaccuracies during repeat examination. This data could therefore prove falsely reassuring.

The authors state that their results differ from those of a previous RSA study and that there have been a number of conflicting clinical studies. The data presented does add to what is already known regarding the Elite Plus stem but it is possible that small errors or inconsistencies introduced by the use of the RSA technique could be important in determining the long-term results of this stem when using a surrogate marker such as RSA.

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Author’s reply:

Sir,

We thank Mr Whitehouse for his comments on our paper. He raised a number of points which he suggested might render our conclusions unreliable.

He questioned if we had used a calibration cage and whether this had been validated. He also asked what size of markers we had used because he believed this might have influenced the accuracy of our measurements. As mentioned in our paper, we used the Swedish UmRSA system. This is probably the most well known of RSA systems and numerous papers have been published on its accuracy and clinical use. The system comprises software, a validated calibration cage, a marker head injector and tantalum marker beads (available in diameters of 0.5 mm, 0.8 mm and 1.0 mm). The software included automatic detection of each marker head image centre. The two marker heads fixed to each femoral component had diameters of 0.8 mm. We used 1.0 mm diameter beads in the proximal femur. This size is amongst the three “standardised calibration cages” in the RSA technique.
Condition Number. The paper cited by Mr Whitehouse\textsuperscript{1} describes the standard bead sizes described by Valstar et al\textsuperscript{1} in reference 3 of Mr Whitehouse’s letter. Indeed, 1.0 mm diameter beads are used by Valstar’s group.\textsuperscript{2}

Although we had decided upon a sample size of 25, we eventually inserted a total of 29 RSA femoral stems (29 patients). This was because the radiographs of four of our early patients had an insufficient number of visible marker beads or the marker bead scatter was insufficient. A minimum of three bone marker beads must be visible in order to determine the three-dimensional position of the bone segment. If the bone markers are too close to one another (low scatter), the accuracy of the measurement - particularly rotations - is reduced. The UmRSA software displays a measure of the marker bead scatter, referred to as the Condition Number. In general, the accuracy deteriorates with increasing Condition Number. The paper cited by Mr Whitehouse\textsuperscript{1} describes the recommended limit for the Condition Number. The four patients were rejected during the first few months of the project and had no bearing on the project or on our conclusions.

We agree that double examinations should ideally have been performed on all patients. However, there were ethical considerations relating to the total X-ray exposure over the three-year course of the project. This was particularly true for patients who had one or more repeated X-rays (because of inadequate radiographs) at one or more of the examination appointments. Although the overall X-ray exposure for an RSA examination is much less than for a standard anteroposterior (AP) pelvic X-ray examination, the total exposure, including repeats, over a three-year period (seven appointments) can add up, and we took due consideration of this. Radiosterometric analysis requires special radiological set-up and not because of a specific property of the patient (e.g. size or obesity). We do not agree, therefore, that our choice of patients partaking in the double examinations had any bearing on the precision of the measurements. As we pointed out in our paper, our double examination results compare favourably with those from other studies in which the UmRSA system has been employed. The number of patients subjected to double examinations (five) in our study compares with the number used (seven) in an RSA study of the Elite Plus by the Oxford group.\textsuperscript{3}

There was another consideration with regard to double examinations. We did not feel that it would be fair to the patient to carry out double examinations before six months while healing was still taking place. In carrying out a double examination, we rearranged the X-ray equipment and asked the patient to leave the room before re-setting the equipment and taking the second set of radiographs. It was not necessary to put the patient through this during one of the first few RSA appointments. We therefore carried out double examinations during the middle stages of the project - at which time we had sufficient records of the cumulative X-ray exposure for each patient. Of course, patients might have accrued more exposure at the subsequent examination appointment, but the numbers were sufficient for us to make a judgement about this.

The main conclusion of our study was that only one femoral component was migrating excessively at three years. We were able to attribute this excessive migration to high patient demand. Even if our defence of the accuracy of the RSA technique is disregarded, it is clear that there was just one outlier in our results. That stem was continuing to migrate at three years and the magnitude of its migration was several times that of the other stems. The most inaccurate of techniques would have identified this.

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