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Total hip replacement: the way forward

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There are now estimated to be around 400 000 primary total hip replacements performed in Great Britain each year *(1)* and the number continues to rise. Many of these implants wear out before the patient dies, and some require replacing. In the struggle to produce better joint replacements, there has been a massive proliferation in the number of total hip replacements currently on the market *(2,3)*. This paper looks at the research we have performed to work out the likely demand for primary and revision total hip replacements in the future. It goes on to review the work we have done to validate methods which may be used to predict the longevity of implants, which may then be used to help manufacturers design and test new implants which may give more reliable results in the future.

The need for total hip replacement

Using the Oxford Record Linkage Study (ORLS), a computerised database of all admissions to hospital in the Oxford region, we have been able to make a study of over 10 000 total hip replacements performed between 1975 and 1986 in the Oxford region *(4)*. During that time the chances of an individual in any given district receiving a total hip replacement increased dramatically. However, more importantly, in 1975 the chance of an individual receiving a total hip replacement varied by a factor of seven between districts (from 6 to 45 per 100 000) with a mean rate of 43 per 100 000. By 1985 this variation had narrowed to less than 1.5 to 1 (from 40 to 59 per 100 000) suggesting a much more widespread availability of the operation. The mean had risen to just under 58 per 100 000. One explanation of this finding is that saturation levels were finally being reached and that in the districts with the highest incidence of total hip replacement the service was meeting demands. To test this hypothesis 1000 patients over the age of 60 years in a large general practice in Oxfordshire were identified, and sent a questionnaire asking them if they had symptoms which we had classified as severe enough to warrant total hip replacement *(5)*. We also asked how many had in fact already had a total hip or total knee replacement. Our findings extrapolated up to the total population of the United Kingdom suggests that there may be as many as 400 000 patients alive who have symptoms severe enough to receive a total hip replacement.

In total knee replacement the situation is slightly less advanced in that there are probably only around 200 000 patients who have already received a total knee replacement but nearly 400 000 who need one. These findings have now been corroborated by a much larger study carried out in Leeds which suggests that the unmet demand for total knee replacement is indeed as high as our study had suggested *(6)*. We would therefore conclude that it is unlikely that the present levels of total hip or knee replacement are keeping pace with demand, nor are they catching up with the large backlog of cases already needing a total hip replacement in the community. On top of this the increasing number of patients in the community who have already received total hip replacements means that there is an ever larger pool of patients whose hips are wearing out and may eventually require a revision *(7)*. This operation is complicated, expensive to perform, and does not give results as good as a primary joint replacement *(8)*. The resource implications of this epidemic are even more important when it is realised that they are competing directly with primary joint replacements for resources. On average, each one takes the operating time and bed allocation of between one and two primary joint replacements. In our own unit as many as one in four of the hip replacements coming to the operating table are now revisions rather than primaries *(9)*. One explanation for the dramatic rise in revision operations may be that surgeons are now operating on younger patients than it was previously thought advisable to do in the early days of joint replacement. Once again, using the ORLS data we have tested this hypothesis and found that there is no change in the number of patients under 60 years of age receiving total hip replacement over the 10 years of the study. The main increase in joint replacement has occurred in the older age group. The mean age of total hip replacement has actually risen as a

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result of this. Nevertheless, there is clear evidence that patients are living longer (on average 3% per year). This factor must be contributing to the increase in demand for revision surgery. These figures have subsequently been corroborated by the Trent Hip Register, albeit on lower numbers *(10)*. The indications for hip revision surgery are variable for a number of reasons. These are patient-based, doctor-based and service-based. From the patient-based point of view, the operation is a more severe one than a primary total hip replacement and carries a higher operative risk. On average the patients are older and therefore less healthy when presenting for revision. A significant number of patients may decide to 'soldier on' even though the hip replacement has now, by all objective criteria, failed. Similarly, the surgeon advising the patient on surgery may dissuade the patient from going ahead with the revision because he himself does not wish to perform this rather difficult and unrewarding operation. Finally, the hospital in a bid to satisfy purchasers may decide to concentrate on primary joint replacements which can be done quickly, cheaply and easily. At the end of the day it may be found that revision surgery is much more sensitive to resource availability than to actual demand. Despite the fact that revision is used routinely as an endpoint for measuring success of primary total hip replacement, its sensitivity to resource availability may make time to revision a very unreliable measure of outcome *(11)*.

How long do hip replacements last?

We do not know the answer to this apparently simple question, which is routinely asked by all patients being considered for hip replacement. We know that if revision is used as the endpoint, there are several series reporting survival of more than 90% of total hip replacements for 10 years *(12–14)*. But we know that revision is an unreliable outcome measure, and it is therefore important that we develop and validate a more reproducible and patient-based outcome measure. We have been privileged to be allowed to review the yearly follow-up of over 2000 total hip replacements carried out over a period of more than 20 years by Mr Robin Denham FRCS. This unusual database has allowed us to look at the reliability of the multitude of outcome measure recorded by Mr Denham over the years. If revision is used as the ultimate endpoint, it is found that the onset of moderate pain is the most reliable predictor of the need for the joint to be revised. Deterioration in walking distance and deterioration radiographic appearance are not nearly so reliable. This work suggests that the onset of moderate pain could be used alone as an outcome measure for comparing the longevity of different implants. Indeed, comparing the different designs used by Mr Denham it is found that pain as an outcome allows significant differences between the different implants to be demonstrated when revision alone does not *(11)*. The advantage of the use of pain as a single outcome measure is that it makes follow-up relatively easy, as this can be performed by telephone or by post without the need for an interview or radiographs. A further interesting finding is that if the onset of moderate pain is used as the endpoint (defining failure) rather than revision, a failure rate of around 10% at 10 years rises to nearly 40%, a very different picture of so called success. Even if pain is used as the outcome measure, it requires many hundreds of total hip replacements and follow-up for 10 years or more before significant differences between the best implants can be demonstrated. If the requirements for bringing a new joint replacement on to the open market was that it had to be demonstrated in a clinical trial to be significantly better than the current implants available, it would to all intents and purposes be impossible for a manufacturer to bring a new implant on to the market. Therefore, there is clearly a great need for a reliable and validated technique which will predict the longevity of an implant within 1 or 2 years of its insertion.

Failure prediction

Femoral components of total hip replacements which sink rapidly into the femur after implantation (at rates of more than 1 mm per year) appear to be associated with early failure of the implant in many designs of total hip replacement *(15,16)*. In order to measure sinkage in fractions of a millimetre, it is necessary to implant markers into the bone around the total hip replacement to act as landmarks from which the measurements are taken. If sinkage of the implant in all directions (longitude sinkage, tilt, and rotation) is to be measured, then stereo radiographs must be taken which allow the position of the implant to be calculated in three-dimensional space. This technique stereo radiogrammetry (RSA) was first developed in Sweden *(17)*, and has now been used in our department for several years to study the relationship between migration and failure of implants. We have confirmed, as have several other units, that most implants sink rapidly in the first few months as they bed down in the bone. After that the rate of sinkage is very low indeed in those implants likely to survive for a long period. However, those implants likely to fail early show a more rapid migration rate. This finding has been comparatively easy to demonstrate in cementless hip replacements where the migration rates are high, as are the failure rates. In cemented joint replacements, however, this has been much more difficult to demonstrate, but the use of large numbers of implants and very accurate measuring techniques has at last allowed this to be done *(18)*. It is therefore now fair to say that we have available a validated scientific technique which will enable the likely longevity of an implant design to be calculated within 2 years of implantation. At its present level of accuracy, the system should be able to demonstrate within 2 years that an implant is basically as good as those implants which are currently on the market. What the system cannot do is demonstrate that a new design is better than conventional implants. This would require an order of magnitude, higher accuracy and further validation studies.

The way forward

Currently there are 62 different designs of total hip replacement on the market with further new designs being introduced almost every month *(3)*. None of these implants require any clinical testing before release. Some will, despite excellent theoretical design, turn out to be clinically disastrous (Fig. 1). Under the present circumstances it may be 5 years or even 10 years before a poor design is recognised. By then there can be thousands of hapless patients who have received the implant in the belief that it is one of the best currently available. This is clearly a most unsatisfactory state of affairs, and has already occurred with at least two major designs of implant. One possibility is to introduce a system of categories which would indicate to purchasers, surgeons and patients how much we know about an individual implant, and therefore how safe it is to use. There is nothing new in this concept which was first advocated by the current president of the College nearly 15 years ago *(19)* and was most cogently argued again in 1993 *(20)*. Category A implants would be those designs for which there is more than 10 years follow-up without any change in design. These implants would provide the gold standard against which other implants could be judged.

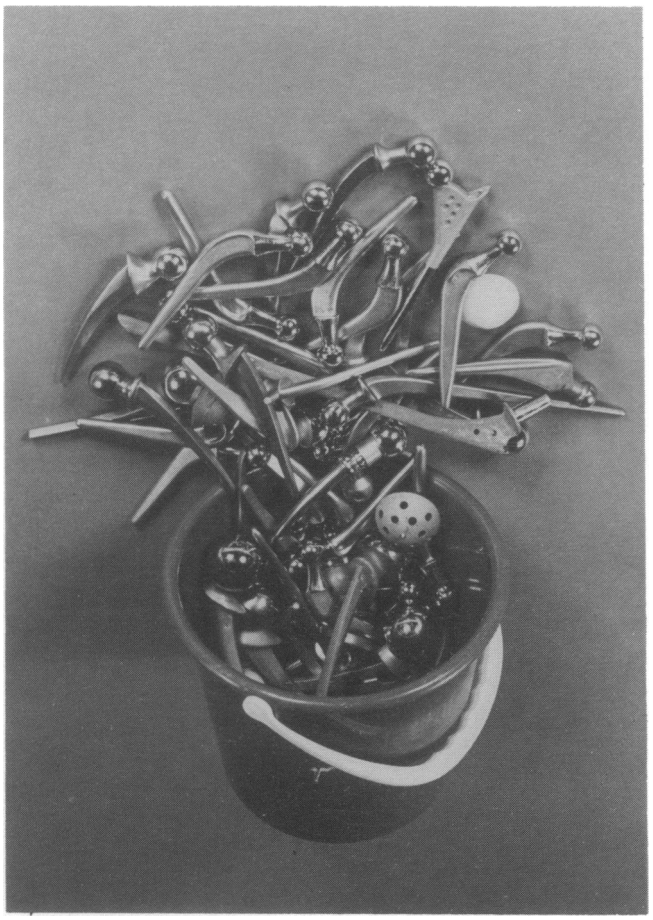

Figure 1. The pile of total hip replacements recently removed at revision surgery from patients in our unit. Each represents a disaster for a patient.

Category B implants would at present consist of those implants which are already on the market but which do not yet have adequate follow-up to be put into Category A. In the first instance Category B would be a 'grandfather clause'. All new designs of implant being brought on to the market would initially go into Category C. These implants could only be used in patients if they were part of a registered clinical trial. This would consist of a minimum of 100 implants followed for at least 2 years clinically and using RSA, to show rates of sinkage. If either the clinical results were unsatisfactory or the migration studies indicated that these implants were likely to fail early, then they would not be allowed to move into Category B. Testing of Category C implants would be carried out at major centres, where properly conducted trials would be performed with independent assessment of the outcome. Category B implants would then become those implants which had performed satisfactorily in Category C. They would be available on general release, but would not be labelled as Category A implants until a properly validated follow-up of 10 years had been performed. During this period some implants would prove to be unsatisfactory clinically. They would be removed from the market. Those which were satisfactory would in the due course of time be moved into Category A. The cost of Category C testing would be met by the manufacturers. The stimulus to perform Category B testing would also lie with the manufacturers, since the marketability of the implant would be enormously enhanced once it moved into Category A. Purchasers would be advised that only Category A implants had a well-proven clinical track record and would be advised to be cautious about buying anything but Category A implants. This system involves no extra cost to the Government, provides reasonable testing requirements for manufacturers, and minimises the chance of a dangerous implant being put into any more patients than absolutely necessary. The development of RSA and its validation as a method of predicting failure, combined with the finding that pain as a single outcome is adequate for predicting failure, has made this simple mechanism of testing possible. All that is required now is the will to introduce the regulations.

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