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Analysis and prediction of total hip replacement performance

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The survival of total hip replacement in patients operated on at the Royal National Orthopaedic Hospital was analysed for two types of Stanmore prostheses: (a) metal-on-metal prostheses of various development designs inserted between 1963–72 (173), and (b) metal-on-plastic prostheses of one design inserted between 1969–72 (248). The survival criterion was taken to be non-removal of the prosthesis and all cases not removed were regarded as survivors. The results indicated that for metal-on-metal prostheses the overall probability of survival was only 53% after 11 years and the average annual probability of removal irrespective of cause was 5.5%. As expected, for metal-on-plastic prostheses the results were considerably better, the figures being 88% after eight years and 1.5% respectively. For both prosthesis types the predominant failure mode was loosening and for this failure mode the annual rate of removal increased as the follow-up time increased, suggesting that loosening is a wearing-out process. Femoral component fracture occurred less frequently, but also appeared to be a wearing-out process. Finally, it is demonstrated how the analysis can be used to predict the probability of survival at some time in the future.

1. Introduction

Follow-up studies on patients with total hip replacements appear regularly in the literature. Typically these studies are concerned with the causes of failure, the types of complication and the effects of various factors on the outcome. These factors may be surgical, clinical or pathological, or they may relate to the design or manufacture of the prosthesis. The outcome may be assessed in terms of function, movement and relief of pain. Usually these studies include statistics, but sometimes these statistics are not as meaningful as they might be, and cannot readily be compared with statistics presented in other studies. Thus, for example, in determining the incidence of some failure mode or other only the overall incidence may be given, i.e., the number of failures within a certain time period divided by the number in the study. But how is a two-year follow-up to be compared with a four-year follow-up? Moreover, sometimes the study is concerned with a group of patients with varying follow-up periods, in which case the significance of the overall incidence becomes even less clear.

Fortunately actuarial methods exist for constructing life tables which enable both the annual and overall failure (or survival) rates to be determined as a function of time for a group of patients with varying follow-up periods. These methods are used in other branches of medical research, for example in studies concerning the survival of patients suffering from a particular disease. In these studies survival may be measured from a particular stage in the disease, or from the time when a particular operation took place. The end point may be the death of the patient, or the reappearance of symptoms. Similar methods are used in engineering applications to study the reliability of components. Fig. 1 shows the time dependence of the conditional failure rate for a typical engineering component. This curve, called the "bathtub" curve because of its shape, is composed of three distinct regions. It can be seen that a failure rate decreasing with time is charac-

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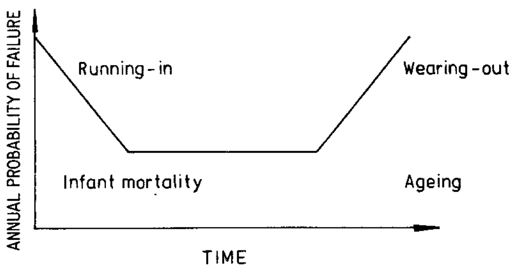

Figure 1 Bath-tub curve: annual probability of failure plotted against time.

teristic of a running-in process, whereas one increasing with time is characteristic of a wearing-out process [1].

When considering total hip replacements it is the survival of the prosthesis *in situ* which matters and for the purposes of the present study the survival criterion was taken to be non-removal. Survival was measured from the date of insertion to the date of removal and a removal was considered to have occurred when all or part of the component was removed regardless of whether the component was subsequently reinserted. The chosen end point, namely removal, was perhaps not sufficiently severe, but it was relatively unambiguous and provided a conservative estimate of the chances of obtaining an unsatisfactory result. In principle any end point is possible and a more severe but subjective one such as the onset of pain could have been chosen instead.

Using these methods the survival of more than 400 total hip replacements inserted at the Royal National Orthopaedic Hospital over the period 1963 to 1972 was studied. The annual removal rate as well as the overall survival rate were determined as a function of time. Similarly the annual removal rate was determined for different failure modes, and the time dependence of removals due to loosening and fracture was determined. The behaviour of the earlier metal-on-metal (m/m) prostheses was compared with that of the more recent metal-on-plastic (m/p) ones. Finally, the likelihood of any given total hip replacement being satisfactory at some time in the future was determined.

TABLE I Insertion details

	Metal-on-metal	Metal-on-plastic
Number of insertions	173	248
Type of component	Various designs	One design
Insertion date	1963–1972	1969–1972

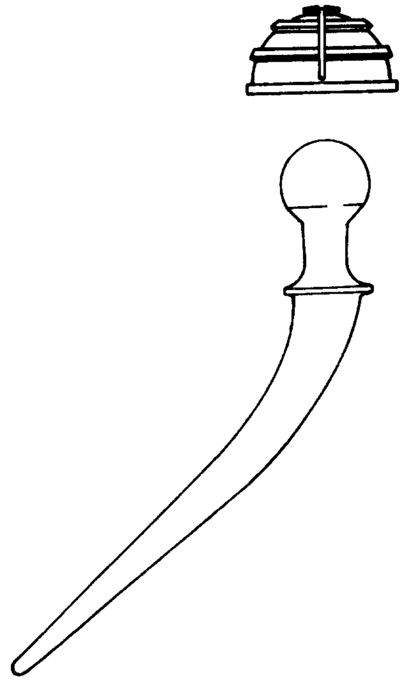

Figure 2 Diagram of Stanmore metal-on-plastic total hip replacement.

2. Materials and methods

Between April 1963 and August 1972, 173 total hip replacements using Stanmore m/m components were carried out. In most cases the trochanter was detached, although in a few cases the posterior approach was used, in which case the trochanter was not detached. All but one of the femoral components and all but 15 of the cups were inserted using acrylic bone cement. Between June 1969 and April 1972, 248 total hip replacements using Stanmore m/p components were carried out. The surgical and clinical details were similar to those for the former group, although in this group a larger percentage of the operations were done using the posterior approach. Table I summarizes the insertion details for the two groups.

The m/m components were of various developmental designs. The m/p components were of one

TABLE II Number of insertions on an annual basis

Interval (Jan–Dec)	Number of m/m	Number of m/p
1963–1964	3	–
1965–1966	17	–
1967–1968	103	–
1969–1970	35	73
1971–1972	15	175

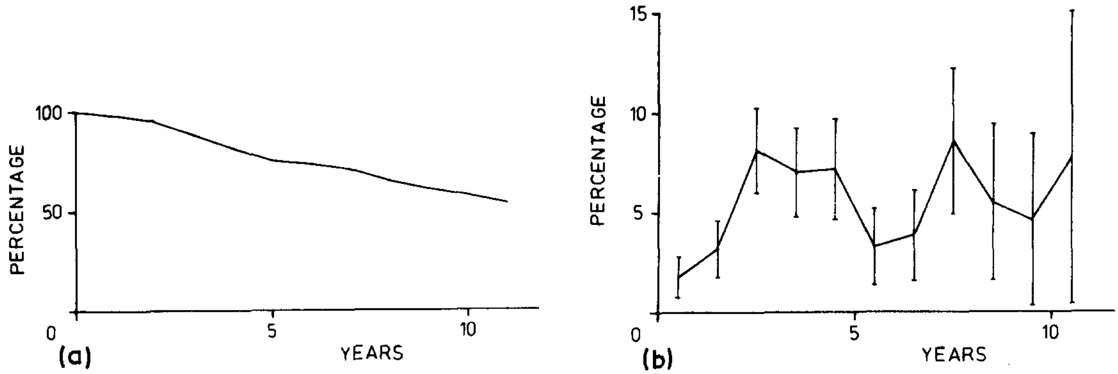

Figure 3 Survival of metal-on-metal total hip replacements. (a) Overall probability of survival as percentage versus time since operation in years; (b) annual probability of removal as percentage versus time since operation in years.

design, the cup being of high-density polyethylene (Fig. 2). All the metal components were manufactured by one manufacturer using air-melt, air-cast cobalt–chrome–molybdenum alloy. Table II gives the number of insertions on an annual basis. Previous publications give additional information including the sex, age and weight of the patients, the design of the components, the number of surgeons involved and the type of antibiotic cover used [2, 3].

For each patient the length of the follow-up was determined either from the notes or from a questionnaire. Similarly the condition of the patient at the last follow-up was determined. Survival tables (modified life tables) were constructed using the method described by Armitage [4]. A brief account of the method has been given in previous articles [2, 3].

3. Results

3.1. Removals irrespective of cause

Figs 3 and 4 show the overall probability of survival and the annual probability of removal for two prosthesis types. It can be seen that for m/m prostheses the overall probability of survival was 53% after 11 years. The average annual probability of removal was 5.5%. For m/p prostheses the figures were 88% after eight years and 1.5% respectively.

It can be seen from Figs 3 and 4 that for both m/m and m/p prostheses the annual failure rate was approximately constant (independent of time) and this observation was confirmed by more detailed statistical analysis. For the m/m case however the evidence for a constant failure rate was stronger if the first two post-operative years were omitted. Thus there was a suggestion that the failure rate increased over the first two years and then reached a constant value of 6% thereafter. There was also a suggestion that for both cases the failure rate increased after very long follow-up times as the consequence of a wearing-out process, but the evidence was insufficient to be sure about this.

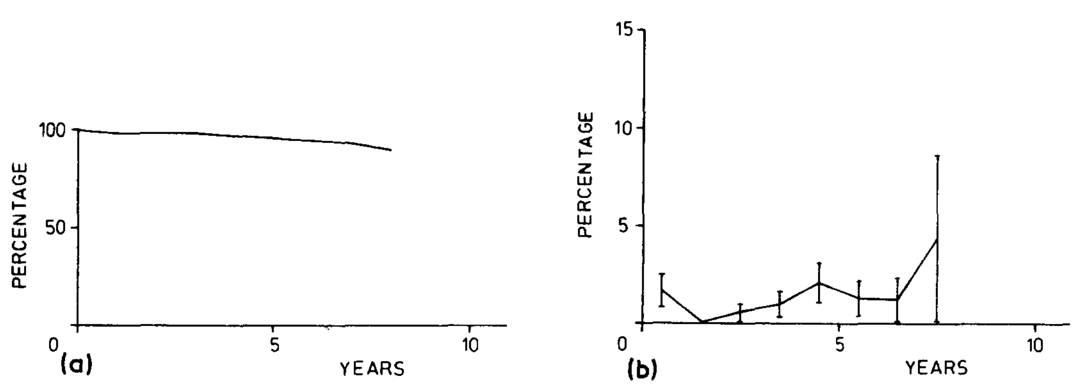

Figure 4 Survival of metal-on-plastic total hip replacements. (a) Overall probability of survival as percentage versus time since operation in years; (b) annual probability of removal as percentage versus time since operation in years.

TABLE III Cause and number of removals

Cause	Metal-on-metal	Metal-on-plastic
Loose	42	9
Dislocated	2	3
Infected	4	–
Broken stem	3	2
Other	3	1
Total	54	15

3.2. Removal according to cause

Table III shows the cause of removals for both m/m and m/p removals. It can be seen from the table that the majority of components were removed for looseness, i.e. fixation failure. Because looseness was the predominant failure mode it was investigated in further detail [2]. It was noted that for the m/m failures it was the cup which was loose in the majority of cases, presumably due both to the method of fixation and to high frictional torque, whereas for the m/p failures it was the stem. The time dependence of loosening was studied by constructing life tables as before. Fig. 5 shows the behaviour of the annual failure rate, in this case using a two-year time interval. There was a suggestion for both types of prostheses that the rate increased with time. This result is consistent with the view that loosening is related to the mechanical breakdown of interdigitations between acrylic cement and bone [5, 6].

As regards other failure modes little can be said on account of the relatively small numbers involved. It was evident however that removals due to dislocations and infections tended to occur early on. The time dependence of the fracture rate for broken stems was determined as shown in Fig. 6 by combining the data for the two groups giving a total of five fractures. Although the data is too scanty to permit any firm conclusions to be drawn, the trend suggests a wearing-out process consistent with the view that the components fail by metal fatigue [7–9].

4. Discussion

The validity of the chosen survival criterion, the validity of the survival method given its underlying assumptions, and the advantages of the survival method compared with other methods have been discussed in earlier publications [2, 3]. The statistical comparison of survival data is discussed elsewhere [10]. To predict the survival probability at some future time, say after a twenty-year period, the curves in Figs 3 and 4 can be extrapolated. In this manner the median survival time can be obtained from the intercept at the 50% level:

Metal-on-metal: median = 11.8 years

Metal-on-plastic: median = 34.5 years.

Alternatively, since the observed annual failure rate is approximately constant, and since a constant failure rate implies an exponential distribution of failure times, an exponential model can be used instead, i.e.

$$P = 1 - e^{-\lambda t}$$

where P is the overall probability of failure, t is the time after which the failure probability is to be predicted and λ is the value of the constant failure

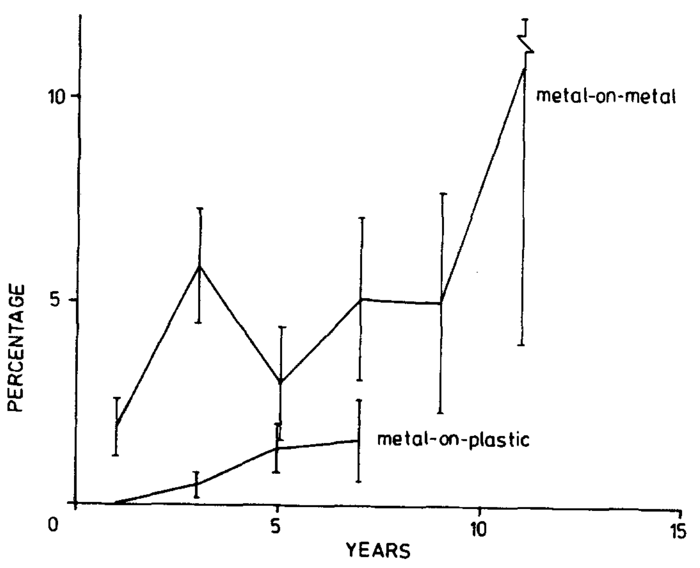

Figure 5 Annual probability of removal for loosening as percentage versus time since operation in years.

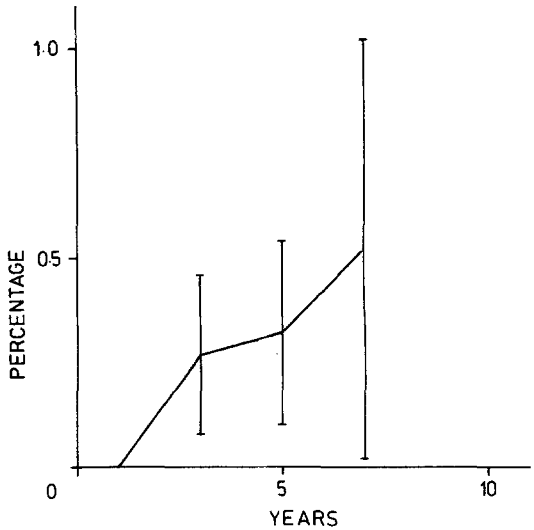

Figure 6 Annual probability of femoral component fracture as a percentage versus time since operation in years: metal-on-metal and metal-on-plastic combined.

rate, determined from the data. For this model it is easy to show that the mean lifetime is $1/\lambda$, and the probability of survival after any time period can be obtained using the above formula. Thus, using the values of λ obtained previously, namely 5.5% and 1.5%, the following values were obtained for the probability of survival after twenty years:

Metal-on-metal: probability = 33%

Metal-on-plastic: probability = 74%.

Both these methods of predicting future trends have the same disadvantage, namely they presuppose that past behaviour will be manifest in the future. Thus neither method allows sufficiently for ageing or wearing-out processes and both fail to take into account the possibility that failures due to loosening and fracture may occur with even greater frequency after longer follow-up times. Consequently, although both methods demonstrate the type of prediction that can be made, these particular predictions must be treated with caution.

Finally, it need hardly be mentioned that the methods used in this analysis of total hip replacement survival are equally applicable to studies of other implants, for example cardio-vascular and dental, and can also be used in the evaluation of clinical trials [10].

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References

1. D. R. COX, "Renewal Theory: Monograph on Applied Probability" (Methuen, London, 1962).
2. H. S. DOBBS, *J. Bone and Joint Surg.* **62B** (1980) 168.
3. *Idem,* Proceedings of the Conference on Implant Retrieval, 1980 (National Bureau of Standards, Washington, D.C., 1981).
4. P. ARMITAGE, "Statistical Methods in Medical Research" (Blackwell, Oxford, 1971) pp. 408–14.
5. C. A. HOMSY, The Hip, Proceedings of the First Open Scientific Meeting of the Hip Society (C. V. Mosby, St. Louis, 1973) 156–163.
6. E. M. EVANS, M. A. R. FREEMAN, A. J. MILLER and B. VERNON-ROBERTS, *J. Bone and Joint Surg.* **56B** (1974) 626.
7. H. S. DOBBS, *J. Bioeng.* **1** (1977) 189.
8. *Idem, Engineering in Medicine* 7 (1978) 107.
9. *Idem, ibid.* 8 (1979) 237.
10. R. PETO *et al, Brit. J. Cancer* **35** (1979) 1.

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