EVALUATION - PHILOSOPHY AND PRACTICE

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Introduction

Hopefully the outcome of all our efforts is something practical - an improved piece of clinical hardware or practice and a patient whose lot has been in some way improved. It is necessary at the appropriate stage for an evaluation to be carried out on our work so that judgements can be made about the direction in which we are going and about how our proposals compare with the current solution.

There is always, of course, an element of evaluation in all research. It is part of a continuing process. However the necessity for a more formal process of clinical evaluation will arise and it is the philosophy and practice of this which is discussed here.

Evaluation

It is suggested that all evaluation of prosthetic devices or systems will be conctructed from certain elements - direct comparisons of physical characteristics; subjective assessments by the people concerned such as the prosthetist, patient and surgeon; objective assessments of the extent to which the prosthesis and patient have been integrated and to which the patient's function has been optimised.

The inclusion of any or all of these elements and the emphasis placed upon them will be determined by certain factors. First of these are the aims of the particular evaluation - what is it hoped will be achieved? - and the inter-linked factors of cost and time-scale. The evaluation must be planned on the basis of these factors and all other decisions on the control or elimination of variables etc. made against this background.

A clinical evaluation which has been recently completed illustrates the practice of this philosophy and may help to identify some of the problems.

Aims

At the end of 1970 a number of modular assembly systems

for PTB (patellar tendon bearing) below-knee prostheses were commercially available or at late stages of development. (Modular assembly is the description of systems which are simply assembled from pre-manufactured, standardized components). There was no information which would allow more than superficial comparisons of the systems to be made. To make good this deficit the Scottish Home and Helath Department authorised and funded an evaluation by the Bioengineering Unit of the University of Strathclyde.

This evaluation had two principal aims: to provide design information relating to the clinical and constructional requirement of modular assembly B.K. systems: to provide information so that comparative judgements could be made about different systems with regard to their clinical suitability and physical features. In this case (remembering the three elements - physical characteristics, subjective assessments and objective assessments) the emphasis is inevitably on comparisons of physical characteristics and subjective assessments as modularisation of the PTB is concerned with different systems of achieving the same end. It is only if the system of assembly interferes with the achievement of the satisfactory end that it becomes necessary to identify the reasons. In the particular case of the PTB it is not believed that objective methods of measurement of patient/prosthesis integration are available or perhaps even necessary. The subjective judgements of patient and prosthetist easily reject the unsatisfactory prosthesis and it is likely that to the practised wearer differences in function afforded by those prostheses falling within the acceptable range will be small.

It must be emphasized that the evaluation was planned with these factors in mind and with the intention of providing useful information at an economic cost and within an acceptably short time limit.

Planning

The systems included in the evaluation ranged from those which had been in clinical use for a substantial time to those which were only in the stage of clinical trial. All the principal available systems were included - BRADU (Biomechanical Research and Development Unit, Roehampton, England); Charles A. Blatchford; Otto Bock; J.E. Hanger; United States Manufacturing Co.; Santorium Board of Manitoba - representing all known methods of dynamic alignment.

The number of patients involved initially was 24 which later reduced to 23 as it was not possible to attain a satisfactory fitting on a conventional PTB in time for one of the patients to be included in the modular programme. The total number of fittings resulting in the supply of prostheses was 140. The patient number was selected in consultation with the data analysis group to ensure that adequately representative figures would be obtained. The first patients were seen in December, 1970, and the first conventional prosthesis supplied in February, 1971. The last modular limb was supplied in January, 1972, and the last patient completed a trial period in February, 1972. The evaluation was thus completed within fifteen months.

Pattern

Twenty-four adult male patients were randomly selected. No females were included to avoid undue emphasis on cosmetic problems. All patients were established PTB wearers with mature stumps.

Each patient was fitted firstly with a conventional PTB and then sequentially with each of the six modular systems - the time interval between modular fittings was approximately six weeks. During the week prior to any modular fitting the patient reverted to the conventional PTB to attempt to give him a 'standard' against which to judge each modular limb.

The patients were grouped in threes and the systems fitted in different order to the various groups. This was to ensure that no systems would only be tried on patients whose problems had become familiar to the prosthetist. It was also designed to expose the prosthetist to all systems throughout the programme to assist him in making subjective comparative judgements.

The next stage was to make detailed decisions about the control of variables - for example the use of one prosthetist, the use of identical sockets on each prosthesis for any given patient, the use of identical feet etc.

Decisions were simultaneously being made on the measurements and assessments which would be necessary. These, of course, were dictated by the aims of the evaluation. Such things were measured as the physical properties of the prosthesis - its weight, alignment, position of centre of gravity; the times taken by prosthetist and technician in the various stages of manufacture and assembly.

Subjective assessments were also demanded of all the members of the clinic team including the most important member - the patient.

Results - Statistical Treatment

The treatment of the measured results presented considerable problems. It is possible to make comparisons between one system and the others on individual patients. It is not however possible to correlate these individual comparisons over the whole range of patients and obtain meaningful information. Accordingly it was decided that comparisons should be made from system to system using the information obtained on the same group of patients. In this way the information from one system treated statistically could be compared with the information from another system and the variability due to individual patient differences minimised.

Conclusions

The value of this rational and objective approach to evaluation needs further consideration from those groups who are in the long run concerned with patient care. It has been possible in a relatively short time and inexpensively to make reasoned judgements about the clinical value of several apparently developed pieces of equipment. As a by-product there have also emerged several rather startling and we believe previously undocumented, facts about the PTB prosthesis - notably the wide tolerance in the dynamic alignment apparently acceptable by the patient. The value of all the information obtained to the further development of modular below-knee prosthesis would seem to far outweigh the investment in the evaluation.

In conclusion it is suggested that a formal approach to clinical evaluation with the discipline required would be a worthwhile exercise for those groups concerned with real problems.