IN BRIEF

- This paper highlights the problems of conducting a clinical trial in general practice.
- It shows that dentists use clinical judgements rather than the trial protocol for seeing patients and cavities for use in such a trial.
- There is a tendency among practitioners not to follow 'directions for use' when finishing materials.
- There is a need for the profession to set up a way of conducting clinical trials in general practices.

The advantages and disadvantages of running a clinical trial in general practices

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This paper reviews the experiences encountered in running a clinical trial on the use of a metal reinforced glass-ionomer cement in general dental practices. The practitioners were asked to place both the test material and amalgam in the same patient and to take impressions both at placement and at three recall intervals. Subsequently plaster casts were produced from these impressions. These were then assessed by three independent observers to provide evaluation of the relative wear of the two restoratives under evaluation. A commercial laboratory manufactured the models on which the three independent observers carried out the assessment of wear. Although the practitioners indicated they would be able to provide the number of restorations required in a relatively short period these expected numbers were never achieved. Despite recruitment of additional participants the trial never did achieve the number of restorations required. The performance of the metal reinforced glass ionomer appeared to vary dependent on the practitioner placing the filling. Questioning of the participants found that some participants were finishing the material using a method specifically contraindicated in the protocol for the trial, the directions supplied with the product, and in briefing sessions held prior to the trial. This implies that there can be major problems in undertaking clinical trials of this nature in the general dental service and has serious clinical implications for those contemplating this type of evaluation and for manufacturers introducing new products.

The study attempted to assess the relative wear rate of amalgam and a metal reinforced glass-ionomer cement (MRGIC) in similar sites in the mouth. The MRGIC had previously only been recommended for selected use in the posterior section of the mouth. The experimental material was being evaluated as an alternative to amalgam.

The rationale for carrying out this clinical study was based on the following facts:

- Compared with early MRGICs, the experimental material used in the trial was reportedly significantly stronger in compression, flexure, and tension.[1,2]
- *In vitro* wear tests used by ACTA[3] have been found to correlate well with *in vivo* wear[4,5] for direct filling materials of various generic types.

The test material when evaluated this way showed lower wear rates than earlier materials, such as conventional and resin modified glass-ionomers.[6]

The level reported for wear of fully matured material was similar to posterior composite resin[6] that had received provisional approval for use in posterior sections of the mouth by the ADA.

- Further anecdotal evidence from use of this material by a number of selected clinicians indicated that it could be used in occlusal cavities.[7]

A further advantage of the material was that it had a packable consistency similar to amalgam. To ensure that this consistency was achieved in clinical use it was provided in an encapsulated form, since a previous study (reported in this journal) showed that practitioners frequently did not use the correct powder liquid ratios.[8]

As a large proportion (~65%) of occlusal restorations in adults involves the replacement of existing fillings[9] any replacement material should have handling and consistency properties that are similar to dental amalgam.

The object of this study was to compare the wear rates of amalgam and the experimental material randomly in the general dental services.

TRIAL DESIGN

The following factors were taken into

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account in the trial design:

a) Since wear rates of individual restorations are reported to be very variable,[10] a large number of restorations would be required.
b) To prevent operator bias practitioners were requested to use amalgam and MRGIC alternately in every cavity regarded as suitable for amalgam. This was also to ensure that the material under evaluation was compared with amalgam in all load-bearing restorations where amalgam may be used. (Originally the intention was that this was to be carried out when the patient presented with two suitable cavities. This was very quickly found impractical and removed as a requirement).
c) The only grounds for patient exclusion were for specific medical conditions, patent non-availability for follow up or failure to provide informed consent.
The selection criteria were as follows:

i) Teeth
Premolars and permanent molars, in occlusal contact, not showing severe wear, and not showing severe loss of periodontal support.
ii) Cavity requirements
Class I and II cavities including MODs that have interproximal contacts. Restorations must not be in contact with ceramic restorative materials. The average bucco-lingual width of each cavity must be at least 1/3 the distance between cusp tips. The average cavity depth must be at least 1.5 mm.

d) The practitioners were expected to follow the directions for use for both restorative products. In an attempt to achieve this, a detailed protocol and training sessions were instituted.
e) The sample size of the general dental practitioners was selected to ensure that the requisite restorations were placed in as small time span as possible. This was based on discussions with the practitioners who confirmed that they could complete the required restorations in the time span and follow the protocol instructions.
f) The impressions were taken in an addition cured silicone material. To ensure consistent model production and reduce the risk of dimensional change the impressions were cast in stone by a commercial dental laboratory.
g) The resulting stone models of the restorations produced at placement were scored for clinical acceptability when examined by the three experienced clinical assessors.

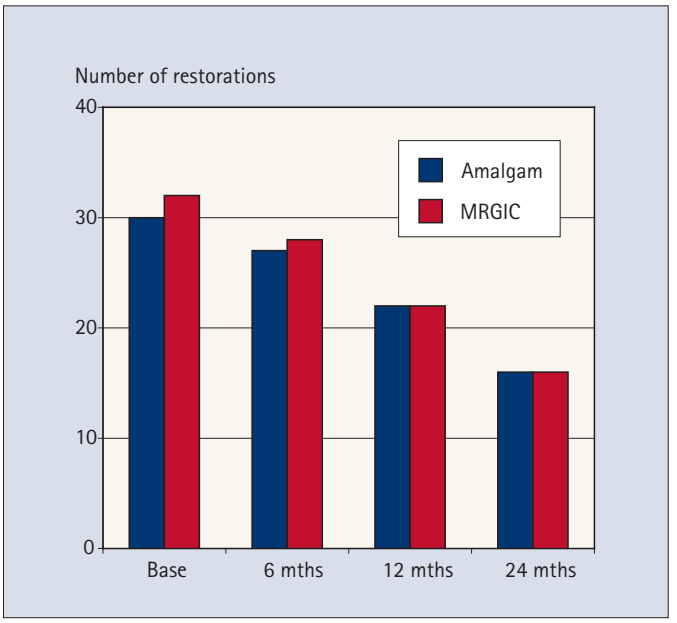

Fig. 1 Figure showing recall figures for both materials

RATIONALE FOR CONDUCTING THE TRIAL IN GENERAL PRACTICES

It was felt that the advantages of conducting the trial in general practices rather than in a hospital environment were as follows:

- Of the 31,500 practitioners on the dental register in June 2001[11] there were 18,995 working in the NHS, of which the majority would be placing restorations. There was a total of 7.4 million one and two surface amalgam restorations placed in England and Wales in 2001 under NHS contract.[12] As most dentists working in the NHS are in the GDS rather than the hospital service or the community of the above numbers most of the restorations placed must be in the general dental services. Using these figures these GDPs are producing at least one amalgam restoration per day. This would mean that each practitioner could easily place the required number of restorations within the period of the trial.
- These restorations will be placed in a clinical environment where time and expertise would be representative of the majority of practitioners.
- General practice should produce sufficient restorations for a study.
- The general dental practice has an efficient recall system for the monitoring of the restorations.

The protocol for the trial received ethical approval from the ethics committee of the Eastman Dental Institute.

The initial protocol required that pairs of restorations were to be selected and by the toss of a coin, one restored with amalgam and the other with the experimental material. Post placement impressions were then to be taken. Impressions were to be repeated at 6, 12, 24 and 36 months. These impressions were cast by the commercial laboratory and subsequently scored for wear using the Vivadent modified Leinfelder optical standard method.[13]

PRACTITIONER INVOLVEMENT

A number of general practitioners from South East England were identified and an initial briefing as to the trial requirements given. Of these, ten agreed to participate and confirmed they would have no problems in producing the number of restorations within the 10-week inclusive period. A number declined because of time constraints.

The group of ten were given a second briefing session. In this they were shown the experimental material and its method of use. They were further briefed on the protocol they were to adopt, including tooth selection, and detailed instructions on the finishing of the MRGIC. Information sheets were provided for their patients and the trial assessment forms explained. Provision was made to reimburse them for the extra time and for the posting of the impressions to the laboratory. The participating practitioners were supplied with all materials; this included radiographic film, finishing materials and impression materials.

OUTCOME

It was expected that using the relatively loose inclusion criteria set out above, the requisite number of 200 restorations would be completed within a period of at the most 10 weeks.

It soon became apparent that six of the original ten participants were unlikely to produce any restorations. The remaining four practitioners produced only eight pairs of restorations over 18 months.

Since it was apparent that in the London area paired restorations could be a problem; the protocol was modified so that patients with single restorations could be used with the type of restoration placed alternating between the two materials. A further eight practitioners were recruited in Western Scotland where there is a higher caries rate. They underwent similar briefing to the London practitioners. Two of these practitioners completed their ten pairs of restorations within the 10-week period. The remainder either produced none or a very limited number, one taking 2 years to produce four restorations. A further eight practitioners in the Bristol area were subsequently recruited. Even after the briefing few restorations were obtained. The total number produced by all the participants after 2 years was 30 amalgams and 32 MRGIC. All the practitioners were visited and given detailed instructions on the materials, their handling and finishing. In addition they were given details as to who they should contact if they required help or advice throughout the trial period.

It was clear almost from the outset that the majority of the participating practitioners were exercising exclusion criteria that did not match the protocol. They were not selecting the restorations randomly but using their clinical judgement as to which cases were suitable. One of the participants subsequently confirmed using clinical judgement on placement of the MRGIC.

It was noted that the wear rates from the experimental material differed from one practitioner to another. In order to investigate this all the practitioners were visited and asked to describe in detail their handling and finishing procedures for the experimental material. This immediately highlighted the fact that the majority of participating practitioners finished their restorations in different ways ignoring both the directions for use and the finishing instructions provided.

Comparing the trial design with the trial outcome the following points came to light:

- The number of restorations placed were much lower than the potential numbers available, as deduced from the Dental Practice Board figures. On these figures all the restorations could have been placed in 2 weeks.
- Of those obtained, the restorations did appear to have been placed alternately as the impressions received from each practitioner were alternately of amalgam and MRGIC.
- Only two practitioners did not appear to exercise their own clinical exclusion criteria. It was apparent that the practitioners were selective in both patients and placement sites for MRGIC. This implied that they did not have confidence in the laboratory evidence and limited clinical information available for the experimental material. However none of the participants expressed any such concern either at the initial briefings or when subsequently contacted or visited.
- The subsequent finishing of the experimental material was done in a variety of ways. Some trimmed excess material dry and others used high-speed diamonds with water spray although this was contraindicated in the protocol and the directions for use. However it was clear from discussions that the materials were mixed according to the manufacturers instructions.
- The number of restorations was insufficient for any statistical analysis to be carried out.
- The recall of the patients was acceptable. Figure 1 shows the recall figures. It should be noted that as some participants did not submit their restorations until the trial had been underway for almost 2 years and that after 3.5 years the trial was terminated.
- The impressions from which the casts were produced were of a high quality permitting effective assessment by the independent evaluators.
- At placement the quality of the restorations was satisfactory.

In view of these findings we feel attempting a clinical trial using general practitioners is extremely difficult. There are many problems associated with the general dental services. Dentists in general practice adopt their own individual working methods. They are quite rightly protective of their patients who provide their income and it may be that they are concerned in using their patients for experimental work in determining the extended suitability of materials beyond their previous use. This suggests that they have a preconceived idea for the use of generic types of material and this leads them to use their clinical judgement when selecting suitable sites for different materials. In selecting materials it would appear to be essential, in retrospect, for the practitioners to be in closer contact with the organisers of the trial. This could be accomplished both by more information on the materials, more visits and contact through electronic mail.

It is possible that the ideal solution would be a centre with a ready source of patients where the already selected patients were treated by a general practitioner attending for a day. The restorations would then automatically be done alternately. Either the practitioner or another person would do the impressions and the recall impressions. This would achieve the numbers rapidly and avoid clinical judgement. This procedure is in some way similar to the general dental practice research network reported on by Kay *et al.*[14]

In addition, the failure of the practitioners to adhere to the protocol of this study has implications for manufacturers when introducing new products to the profession. They should ensure that the method of use of the material matches or is similar to current materials to reduce the risks of mishandling and influencing performance.

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