Patient and Parent Opinion of the Use of Recycled Orthodontic Brackets: An International Comparison

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Abstract. The aim of this study was to determine the opinion of patients and parents to the use of recycled orthodontic brackets. The design consisted of a questionnaire survey, which took place in the orthodontic departments of two teaching hospitals (Cardiff, Wales, and Dunedin, New Zealand). The subjects were patients (and parents of those under 18 years) undergoing active fixed appliance treatment and similar groups of those on the waiting list for fixed appliance treatment.

There were no significant differences of opinion between gender, patient, parent, or centre. There were significant differences of opinion between those under treatment and those on the waiting list; those under treatment were less concerned about wearing recycled brackets than those waiting for treatment.

All respondents felt that they should be told if recycled brackets were to be used, and any savings arising from their use passed on to the consumer.

Index words: Lay Opinion, Questionnaire Survey, Recycled Brackets.

Refereed Paper

Introduction

Recycling of orthodontic brackets is in widespread use (Postlethwaite, 1992). Her extensive literature review reports that the recycling process has little effect on the bracket slot dimensions or bond strength, but there may be structural changes in the metal of the bracket which may promote corrosion.

A recent United Kingdom survey (Coley-Smith and Rock, 1997) has shown that a quarter of consultants and 60 per cent of specialist practitioners recycle brackets. Fortyeight per cent of consultants who recycle brackets did so once only, and 13 per cent recycled more than three times or did not know how many times they recycled the brackets. Twenty per cent of specialist practitioners who recycle brackets recycled them once, and 64 per cent recycled more than three times or did not know how many times they recycled. Ninety-six per cent of consultants, and 92 per cent of specialist practitioners did not inform their patients that they used recycled brackets. The ethical issues related to the use of recycled brackets without informing the patient were briefly discussed and the feeling of the University Teachers Group of the British Orthodontic Society that this practice is unethical was recorded.

In the United States, attention has turned to the ethical and medico-legal aspects of using reconditioned brackets (Unkel, 1987; Matasa, 1989; DiPasquale 1992a,b; Bowers, 1993; Machen, 1993). The ethical considerations seem mainly to revolve around the use of recycled brackets without the patient's knowledge and without a commensu-

rate reduction in fee. The medico-legal aspects are mainly concerned with the re-use of a piece of medical equipment which is marketed as 'single use only'. DiPasquale (1992a,b) represented the bracket manufacturer's view which, for obvious reasons, was not supportive of the recycling of brackets. Bowers (1993) represented the orthodontist's viewpoint, stating that no legal acts were being transgressed, and recycled brackets were safe and effective. Machen (1993), who is both an orthodontist and an attorney, reviewed the legal position and concluded that provided informed consent is obtained, the use of recycled brackets is defensible in American law. Appliances which have been labelled as single use, but which are subsequently reused, may lead to liability if some damage occurs as a result of the use of the recycled appliance. Liability will probably rest with the company which offers the recycling process. At the time of publication, no test cases had been found.

In the United Kingdom and in New Zealand there has been remarkably little debate on these issues. The British Orthodontic Society recently advised that brackets should be autoclaved before being sent for recycling and autoclaved again on their return (BOS News, Winter 96/97). Forthcoming European legislation signified by the CE mark (Conformité Européene) is likely to have an impact on the UK market in a similar manner to the Medical Device Amendments, the Safe Medical Device Act and the Federal Food, Drug and Cosmetic Act in the United States (DiPasquale, 1992a). Legislation relating to the U.K. is mediated by the Medical Devices Agency (MDA), which is

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an executive agency of the Department of Health. The MDA has issued two bulletins relevant to this issue entitled 'The Reuse of Medical Devices Supplied for Single Use Only' (1995), and 'The Application of the EC Medical Devices Directive to Dentists' (1995). Both of these are obtainable from the Medical Devices Agency, Department of Health, Room 621, 14 Russell Square, London WC1B 5EP, U.K.

All member countries of the European Community (EC) must begin applying the Medical Device Directive (93/42/EEC) by January 1995, with a three-and-a-half year transition period. Thus, by June 1998, all medical devices governed by the Directive, and marketed within the EC must conform to certain minimum standards before they may carry the CE mark. The MDA advises that dental materials, appliances, instruments and equipment will be regarded as medical devices, and be covered by the new regulations. Orthodontic appliances fall into the above categories and will, therefore, be subject to the legislation.

The medicolegal issues of using recycled brackets may well have to be tested in a court of law before advice may be confidently given. The ethical aspects which may influence a jury's decision may be anticipated by taking lay opinion on the subject. This project was designed to seek interested lay opinion on the use of recycled brackets within four groups of individuals in two different countries which, although enjoying some common links, have slightly different methods of delivery of orthodontic care.

Materials and Methods

The four groups of individuals polled comprised:

- (1) patients undergoing active orthodontic treatment with fixed appliances;
- (2) parents of children under the age of 18 years who were receiving active fixed appliance orthodontic treatment:
- (3) patients who were on the waiting list for provision of a fixed appliance;
- (4) parents of children under the age of 18 years who were on the waiting list for provision of a fixed appliance.

The patients were under treatment or waiting for treatment, in the Orthodontic Department of the Dental Schools in Cardiff (University of Wales, United Kingdom), or Dunedin (University of Otago, New Zealand).

Opinion was sought by means of a questionnaire. For those under active treatment, the questionnaire was presented to the patient (and their parent where appropriate) during one of their routine visits, with a request to complete the form and place it in a box situated on clinic. This took place over a 6-week period during October and November 1994. Patients/parents were requested not to complete a second questionnaire if they returned for treatment during the 6-week period.

Questionnaires were posted to those on the waiting list and a reply paid envelope was included. All questionnaires were anonymous and no follow-up of non-responders to the postal questionnaire was attempted. With the exception of minor alterations to the wording, all questions to the four different groups were similar. Where appropriate, chi-square tests were applied to the numbers of responses obtained to test for significance of difference between gender, groups, or country.

Results

Three-hundred-and-sixty-five responses were received in total (Table 1). There were no statistically significant differences between gender, or between patients and their parents, or between the Cardiff and Dunedin groups, and consequently these are considered together.

Those waiting for treatment were much less willing to accept second-hand brackets than were those under treatment (Table 2) and this difference reached statistical significance (P<0.01). The reasons given for not wanting recycled brackets between any groups were not significantly different and, consequently, were pooled across all respondents and are presented in ranked order in Table 3.

A clear majority of patients and their parents want to be told if their brackets have been recycled and believe that this should be a legal requirement. When the groups under treatment are compared with the groups on the waiting list, a statistically significant difference emerges, with those already under treatment being less concerned about this than those waiting for treatment (Table 4).

When asked about the financial aspects, a majority of respondents (60 per cent) did not feel they should pay more to have new brackets and a greater majority (85 per cent) felt that there should be a reduction in fees for those who are provided with recycled brackets. Of those who felt

TABLE 1 Number of responses

	Cardiff	Dunedin
Patients	45	85
Parents	34	32
Waiting list patients	75	35
Waiting list parents	35	24
Total	189	176

Table 2 If you were about to start orthodontic treatment now, would you mind wearing second hand brackets? (%)

	Yes	No
Patients undergoing treatment	40	60
Parents of patients undergoing treatment	33	67
Waiting list patients	53	47
Waiting list parents	57	43

Difference between patients + parents under treatment and patients + parents on waiting list: chi square = 9.83, df 1, P < 0.01.

TABLE 3 Reasons for not wanting second-hand brackets rank order (number of responses)

Don't like the thought of them having been in another mouth	1 (64)
Cross-infection risk	2 (28)
Unhygienic/unhealthy	3 (27)
Prefer new brackets	4 (23)
No response	5 (22)
Unconvinced that bracket function would remain unaltered	6 (18)

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TABLE 4 Percentage of respondents saying Yes to wanting to be told if the brackets were second-hand, and thinking that they should have a legal right to be told if brackes are second-hand,

	Patients v Want to be told	Patients under treatment told Legally have to be told	Patien Want to be told	Patients on waiting list Want to be told Legally have to be told	Parents un Want to be told	Parents under treatment Parents on waiting list be told Legally have to be told Want to be told Legally have to be told	Parents Want to be told	Parents on waiting list be told Legally have to be told
Cardiff	09	19	8	28	65	76	82	88
Dunedin	70	74	74	91	81	78	26	88
Total	<i>L</i> 9	72	83	98	73	77	98	88

Chi-square for difference between patients + parents under treatment v. patients + parents on waiting list for feeling they should have a legal right to be told if brackets are second-hand 10-25 (df.1), Chi-square for difference between patients + parents under treatment v. patients + parents on waiting list for wanting to be told if brackets are second-hand = 10-42 (df 1), P<001.

that there should be a fee adjustment, 39 per cent felt it should be in the order of £5·00 (or NZ\$10·00 estimated to be approximately equivalent to 10 per cent of the cost of brackets for treatment of upper and lower arches), 31 per cent around £12·00 (NZ\$25·00; 25 per cent of cost of brackets), and 29 per cent around £25·00 (NZ\$50·00; 50 per cent of cost of brackets).

The final question asked which they would personally prefer to wear on their teeth. Sixty-five per cent wanted new brackets and 35 per cent 'Didn't mind' (one individual expressed a preference for second-hand brackets).

Discussion

It is difficult to decide why there should be a difference in perception of the acceptability of recycled brackets between those undergoing treatment and those awaiting treatment. The second and third reasons given in Table 3 are related to concerns over cross-infection, but even combining these two together, they fail to reach the number who just do not like the idea. Very few are concerned about the function of the recycled bracket. The preamble to the questionnaire stated clearly that the brackets would be cleaned and sterilized prior to re-use, and that their function would only be altered in very minor ways. Given this information, one could have expected greater concern about function (which may influence the eventual outcome of treatment) than about cross-infection.

The majority of respondents wanted to be told if they were to have recycled brackets and felt even more strongly that it should be a legal requirement that they are told. This provides a valuable indicator for those tempted to test the withholding of such information in a court of law. On the basis of the results of this survey, a jury is unlikely to be sympathetic to the practitioner who uses recycled brackets without informing the patient. It is known that recycled brackets are more prone to corrosion (Maijer and Smith, 1982) and it is also known that the corrosion products are more likely to lead to indelible staining of the enamel (Ceen and Gwinnett, 1980). At present, it is up to individual practitioners to decide the magnitude of this risk.

It is also clear that patients expect any savings which accrue from the use of recycled brackets to be passed on to them in the form of reduced fees. Under private contract, the cost of brackets compared with the global treatment sum is small, and the saving, once the cost of recycling is taken into account, when using recycled brackets will be an even smaller proportion of the overall cost. Nevertheless, it would seem prudent to incorporate this information into a consent form or to have patient information leaflets clearly stating the practice policy on this issue, and on the use of recycled brackets in the event of accidental debonds.

Another area which needs further discussion and clarification is that of the evidence on which manufacturers base their view that brackets are only suitable for single use. In fact, it could be argued that the manufacturers are aiding and abetting recycling of brackets by the incorporation of permanent identification marking on their brackets. The evidence thus far would suggest that brackets will suffer little or no reduction in performance following one

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recycling process, provided that strict quality controls are in place to identify and eliminate distorted brackets.

Some may take issue with the terminology used in the questionnaire. It was felt that people would understand the term 'second hand', which was less likely to lead to confusion than 'recycled' with its connotations of melting down and recasting of used brackets. 'Reconditioned' would be another alternative, but this is a more complex concept which some of the younger patients may have had difficulty in understanding.

Conclusions

This survey shows that interested lay opinion is not totally opposed to the use of recycled brackets, but patients would expect to be told if those brackets had been recycled and they would expect any savings to be passed on to them.

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