

# Orthodontic Treatment Outcomes in the Long Term: Findings From a Longitudinal Study of New Zealanders

W. M. Thomson, BDS, MA, MComDent, PhD<sup>a</sup>

**Abstract:** The aim of this study was to use a health services research (HSR) approach to examine the longer-term outcomes of orthodontic treatment. Participants in a longstanding population-based New Zealand cohort study (the Dunedin Multidisciplinary Health and Development Study) were allocated to one of four malocclusion severity categories on the basis of orthodontic data collected at age 12. The outcome of that care by age 26 was evaluated using the key indicators of equity (was it fair?); efficacy (did it work?); effectiveness (did it work in the longer term?); and safety (was it associated with a greater subsequent experience of caries, periodontal disease, or tooth loss?). Data were available for 452 Study members, of whom 56.2% were in the minor/none category, 29.0% were in the definite category, 10.2% were in the severe category, and 4.6% were in the handicapping treatment-need category. No clear differences in treatment uptake by socioeconomic status were apparent, and the proportion treated increased across the malocclusion severity categories, as did the proportion that showed an improvement following treatment. By age 26 a difference between those who had and those who had not been treated was evident, with the percentage of those rating their dental appearance as above average increasing with increasing severity of the age-12 orthodontic treatment need. This was also true for the percentage that considered their orthodontic treatment to have been successful. There were no significant differences in caries experience, periodontal disease occurrence, or tooth loss between those who had and had not been treated by age 26. This study has found the equity, efficacy, effectiveness, and safety of orthodontic treatment in the Dunedin cohort to be acceptable. (*Angle Orthod* 2002;72:449–455.)

**Key Words:** Orthodontic treatment; Longitudinal study; Evaluation; Health services research

## INTRODUCTION

The concept of evidence-based dental care has become prevalent in recent years, due in no small part to the increasing emphasis on accountability and quality in health care.<sup>1</sup> Increasingly severe constraints and demands on oral health resources, together with a rise in consumer participation at all levels of the health system, have led to a greater scrutiny of all types of oral health care. Consumers and policy makers alike seek quality, value for money, and measurable benefits from oral health care, and orthodontic care is no exception. In the late 1980s, the poor quality of the knowledge base in orthodontics was highlighted,<sup>2</sup> with clinical decisions based upon low-level information from case reports, case series, cross-sectional studies, and anecdotal

reports. Although there have been improvements since that time, there is still a shortage of evidence from studies that have evaluated orthodontic treatment. In particular, there have been no reports from population-based prospective longitudinal studies on the long-term outcome of orthodontic treatment.

A combination of health services research and an epidemiological approach is appropriate for examining the longer-term outcomes of orthodontic treatment in a population. Although dental epidemiological techniques provide the data with which the task can be achieved, the interdisciplinary field of dental health services research provides the framework with which those outcomes can be evaluated.<sup>3</sup> That framework specifies systematic examination of the characteristics of equity, efficacy, effectiveness, efficiency, and safety.

With equity, the issue to be considered is whether the allocation of orthodontic treatment was fair and rational;<sup>4</sup> ie, was treatment uptake greater among those with greater malocclusion severity without systematic differences by socioeconomic status (SES) or other important characteristics?

Efficacy has been defined as the level of benefit that an

<sup>a</sup> Associate Professor in Dental Public Health, School of Dentistry, The University of Otago, Dunedin, New Zealand.

Corresponding author: Dr W.M. Thomson, Department of Oral Sciences and Orthodontics, School of Dentistry, PO Box 647, Dunedin, New Zealand  
(e-mail: mthomson@gandalf.otago.ac.nz).

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intervention or treatment gives when used under the best possible circumstances.<sup>1</sup> Another approach to considering efficacy is to ask, does the treatment actually work?

Effectiveness is achieved when persons who receive the treatment experience a significantly better overall clinical outcome than those who do not.<sup>5</sup> In other words, does the treatment actually work in the real world?

Examining efficiency broadens the analysis to include consideration of the costs of providing the service, but the requisite collection of treatment-cost data from a variety of sources is not usually undertaken in a dental epidemiological study.

Investigating the safety of orthodontic treatment should involve determining the nature and extent of any short- or long-term adverse oral health outcomes of having it. In theory, there are a number of potential adverse consequences of orthodontic treatment.<sup>6</sup> These include root resorption, which, if severe enough, may result in the loss of teeth; smooth-surface caries resulting either from the appliance preventing adequate plaque control or through the sequelae to debonding events; or periodontal effects due to either direct appliance impingement or its preventing adequate plaque control.

Access to a population-based longitudinal study with data both on malocclusion at an early age and orthodontic treatment history and treatment outcomes by adulthood would enable examination of the longer-term outcomes of orthodontic treatment in a manner that has not hitherto been possible. The aim of this study was to examine the longer-term outcomes of orthodontic treatment among participants in a longstanding cohort study of young New Zealanders.

## MATERIALS AND METHODS

### Sample

The Dunedin Multidisciplinary Health and Development Study<sup>7</sup> (DMHDS) is a longitudinal study of a birth cohort of children who were born at the Queen Mary Hospital in Dunedin, New Zealand, between April 1, 1972, and March 31, 1973. The sample that formed the basis for the longitudinal study was 1037 children, and they were assessed within a month of their third birthdays. Periodic collections of health and developmental data (including dental examinations) have been undertaken since then, and the current study uses data collected at age 26. Ethical approval for the dental section of the study was obtained from the Ethics Committee of the Southern Regional Health Authority. All participants signed an informed consent statement approved by that committee.

### Measures

At age 12, only those Study members who were residing in the greater Dunedin area were dentally examined. The data used in the current investigation come from data col-

**TABLE 1.** Self-reported Sociodemographic and Clinical Measures Used in the Current Investigation

	Age(s) When Measure Used
Self-reported and sociodemographic measures	
Self-rated dental appearance relative to peers	26
Have you had (or are you currently having) orthodontic treatment?	15, 18, 26
Type of orthodontic treatment	15, 18
Rating of orthodontic treatment outcome	26
Socioeconomic status	5
Clinical measures	
Ad hoc clinical orthodontic characteristics	12
Dental Aesthetic Index	15, 18
Dental caries status (by surface)	18, 26
Tooth loss experience	18, 26
Periodontal attachment loss	26

**TABLE 2.** Items Used in the Dental Aesthetic Index and Age-12 Mini-DAI

Item	Weight	Collected at Age 12?
Visibly missing incisor, canine, or premolar	6	Yes
Crowding in the incisor segments	1	Yes
Spacing in the incisor segments	1	Yes
Diastema (mm)	3	No
Largest maxillary anterior irregularity (mm)	1	No
Largest mandibular anterior irregularity (mm)	1	No
Anterior maxillary overjet (mm)	2	Yes
Anterior mandibular overjet (mm)	4	No
Vertical anterior open bite (mm)	4	Yes
Anteroposterior molar relation	4	Yes

lection phases at ages 12, 15, 18, and 26 in the Dunedin study and comprise both self-report measures and clinical orthodontic data (Table 1). Study members were asked to rate their dental appearance at each of ages 15, 18, and 26. At ages 15 and 18, they were asked if they had had orthodontic treatment, and whether that had been with fixed or removable appliance therapy (braces or a plate). At age 26, the subjects were asked to rate the outcome of their orthodontic treatment (if they had had such treatment). Orthodontic clinical data were collected at ages 12, 15, and 18, but no malocclusion information was collected at age 26.

The Dental Aesthetic Index<sup>8</sup> (DAI) was used to capture the clinical information at ages 15 and 18, but not at age 12, because the age-12 data collection took place in 1984 and 1985, and the DAI was not published until 1986. Nevertheless, all but four of the clinical characteristics that comprise the DAI items had actually been recorded at age 12 (Table 2). Only two of those items had weights greater than 1.0 in computing the DAI scale score, and one of them (the diastema) is relatively common, whereas the other (the anterior mandibular overjet) is not. Calculation of a mini-DAI score for each participant at age 12 was possible, and

**TABLE 3.** Categorization of Treatment Need Using the Mini-Dental Aesthetic Index (DAI) and DAI Scales

Mini-DAI Score Range	Description of Severity Level <sup>a</sup>	DAI Score Range Equivalent
<11	Minor or no anomaly; no treatment indicated	<26
11–15	Definite malocclusion; treatment elective	26–31
16–18	Severe malocclusion; treatment highly desirable	32–35
19+	Handicapping malocclusion; treatment mandatory	36+

<sup>a</sup> After Estioko et al.<sup>13</sup>

the validity of this approach was examined by comparing the age-12 mini-DAI and age-15 DAI scale scores of those Study members who had not yet received orthodontic treatment by age 15. Once the validity of that approach was determined, the mini-DAI score was used to allocate each Study member to a treatment-need category using the same category descriptions as those used with the DAI (Table 3). The cut-off scores for each treatment-need category at age 12 were determined by observing the distribution of scale scores among those untreated by age 15.

Dental examinations at ages 18 and 26 were conducted using calibrated dental examiners, and DMFT and DMFS scores were calculated for each age. Dental caries increment was computed by comparing caries status at 18 and 26 years for each surface. The net increment was computed by subtracting the number of reversals from the gross increment. The tooth-loss increment due to caries between ages 18 and 26 was obtained by observing—for each tooth that had been present at 18—its presence or absence at 26, and ascertaining the reason for its absence at that age. Periodontal measurements were made at age 26 in two quadrants (quadrants 1 and 3 for Study members whose DMHDS identification number is odd, and quadrants 2 and 4 for those with an even identification number; the mix of odd and even ID numbers was approximately 50:50). Those measurements were made in only two quadrants because of time constraints. Three sites (mesiobuccal, buccal, and distolingual) per tooth were examined, and gingival recession (the distance in millimeters from the cemento-enamel junction to the gingival margin) and probing depth (the distance from the tip of the probe to the gingival margin) were recorded using an NIDR probe. Midbuccal measurements for molars were made at the midpoint of the mesial root. All measurements were rounded down to the nearest whole millimeter at the time of recording. Where the gingival margin was situated more than 1 mm coronally to the cemento-enamel junction, a negative value for gingival recession was recorded. Gingival bleeding was assessed for each tooth by recording the presence or absence of blood at any of the three probing sites 10 seconds after probing and was

recorded as present or absent. Periodontal measurements were not conducted on Study members who reported a history of cardiac valvular anomalies or rheumatic fever. At the analysis stage, summing the measurements for gingival recession and probing depth computed the loss of periodontal attachment for each site. Third molars were not included in the analysis of the periodontal data.

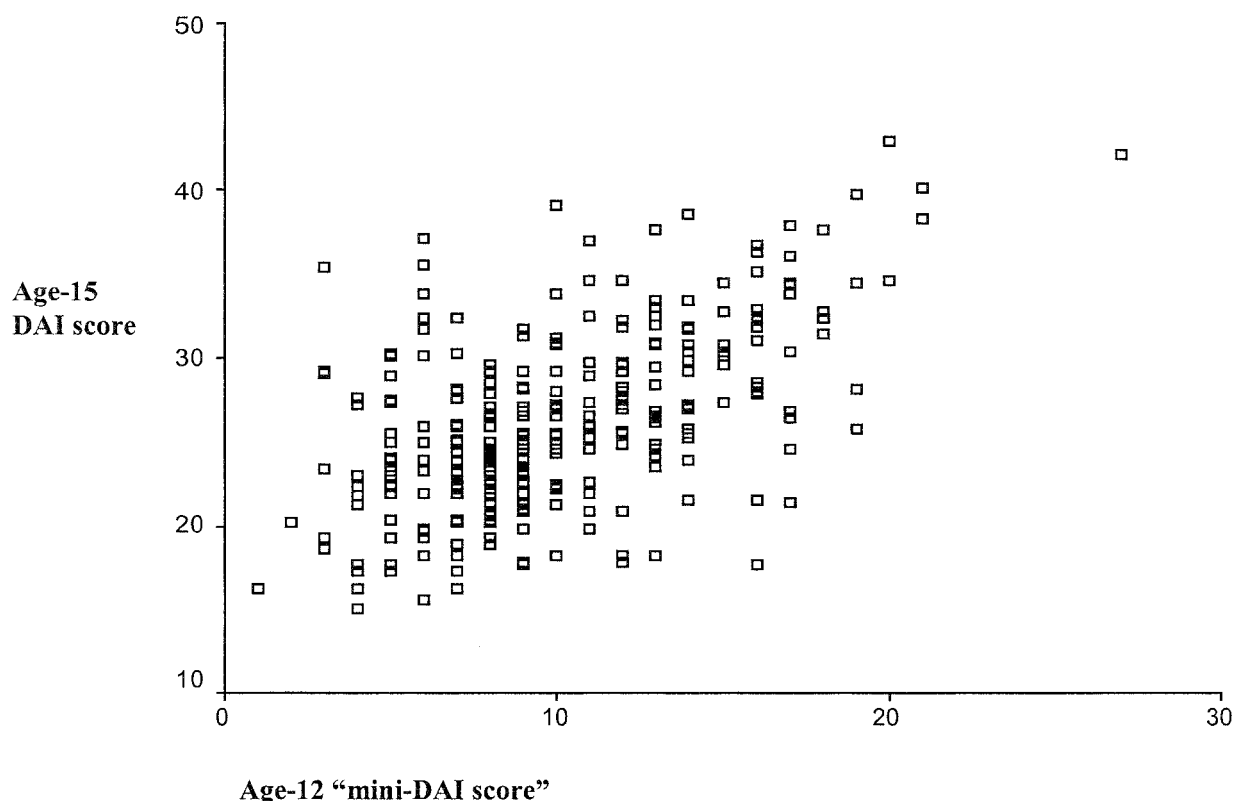
An estimate of social class was obtained for each participant by using information collected at age 5 regarding parental occupation. This data was subsequently categorized into SES using standard New Zealand occupationally based indices,<sup>9,10</sup> which employ a six-interval classification (where, for example, a doctor scores 1 and a laborer scores 6). The estimate for the male parent was used where possible, and participants with a score of 1 or 2 were allocated to the high SES class group, those with a score of 3 or 4 were allocated to the medium SES group, and those remaining were allocated to the low SES group. Students and homemakers were unable to be categorized and were allocated to the latter group.

Although basic dental care for New Zealand children is funded by the State until they reach 18 years of age, almost all orthodontic treatment is provided through the private sector. The bulk of that treatment is carried out by specialist orthodontists, although it has been estimated that general dentists treat up to 25% of all orthodontic patients.<sup>11</sup> However, this analysis did not distinguish between individuals treated by orthodontists and those treated by dentists.

### Key indicators

The equity of orthodontic treatment was examined using two key indicators: (1) the receipt of treatment by treatment-need category, and (2) the receipt of treatment by SES group. For the efficacy of orthodontic treatment, the key indicator used was the proportion of Study members who moved to a less severe treatment-need category following treatment. The definition of effectiveness of treatment was altered somewhat from that described above and was used here to refer to the longer-term success (or otherwise) of treatment. It was measured using Study members' (1) rating of the success of their orthodontic treatment, and (2) self-rated dental appearance (at age 26) relative to their peers. Investigating the efficiency of orthodontic treatment was beyond the scope of the current study. The safety of orthodontic treatment was examined using the following clinical indicators: (1) cumulative dental caries experience by age 26; (2) dental caries increment from ages 18 to 26; (3) gingival recession and periodontal loss of attachment by age 26; and (4) tooth loss by age 26.

The statistical analysis of the data commenced with the generation of descriptive statistics, followed by the examination and testing of bivariate associations using chi-square tests for categorical dependent variables and independent sample *t*-tests for continuous dependent variables.



**FIGURE 1.** Age-15 DAI scores plotted against age-12 “mini-DAI” scores for Study members who had not been treated by age 15.

## RESULTS

Five hundred Study members resided in the greater Dunedin area and were dentally examined at age 12. Malocclusion data were available for 478, of whom 477 were dentally examined at age 26. Of these, 452 could be categorized by parental SES at age 5 and had an age-12 mini-DAI score computed. All subsequent analyses in this investigation are based on those 452 individuals.

At age 26, a total of 930 Study members were dentally examined, and the 478 who were not included in the current investigation did not differ from those who were by sex or their dental caries experience by age 26. However, there were proportionately fewer individuals of low SES (and correspondingly fewer episodic users of dentistry) among those who were included in this study.

Figure 1 presents a scatter plot of the mini-DAI scores and age-15 DAI scores for those who had not received treatment by age 15. The correlation between the two scores was moderate ( $r = 0.6$ ;  $P < .01$ ).

### Equity of orthodontic treatment allocation

The distribution of Study members across the orthodontic treatment-need categories is presented in Table 4 along with the percentage in each SES group who had been treated by ages 18 and 26. The proportion treated by age 18 increased across the categories of increasing severity of orthodontic

treatment need. When treatment by age 26 was included, the proportion treated increased in each category, with two-thirds of those in the handicapping category having been treated by age 26. No clear SES differences were apparent. Some 26.1%, 27.0%, and 20.8% of the high, medium, and low SES groups, respectively, had obtained treatment by age 18 ( $P > .05$ ), and this small gradient had all but disappeared by age 26.

One-third of those with a handicapping malocclusion and more than half of those with a severe malocclusion had not been treated by age 26. This meant that 42% of those with a severe or worse malocclusion had obtained orthodontic treatment by age 18, with that increasing to approximately half (49%) by age 26.

### Efficacy of orthodontic treatment

This issue can only be examined with respect to orthodontic treatment by the age of 18, as that was the last age at which the DAI was used (permitting allocation of each Study member to a treatment-need category using the score ranges in Table 2). Of the 115 Study members treated by age 18, 40 (34.8%) improved; ie, they moved from a more severe treatment-need category to a less severe one following treatment. Similarly, 40 (34.8%) stayed in the same category, and 35 (30.4%) had moved to a more severe category by age 18. When the 50 Study members in the minor



**TABLE 4.** Number of Study Members Treated by Age 18 According to Mode of Treatment and Socioeconomic Status (Percentages in Parentheses)

	Age-12 Orthodontic Treatment Need Category				All Combined
	Minor/None	Definite	Severe	Handicapping	
Total number	254 (56.2)	131 (29.0)	46 (10.2)	21 (4.6)	452 (100.0)
Number treated by age 18 <sup>a</sup>	50 (19.7)	37 (28.2)	15 (32.6)	13 (61.9)*	115 (25.5)
Number treated by age 26 <sup>a</sup>	59 (23.2)	48 (36.6)	19 (41.3)	14 (66.7)*	140 (31.0)
Socioeconomic status group					
High					
Number in category	49	34	4	5	92
Number treated by 18	7 (14.3)	14 (41.2)	1 (25.0)	2 (40.0)**	24 (26.1)
Number treated by 26	9 (18.4)	16 (47.1)	1 (25.0)	3 (60.0)**	29 (31.5)
Medium					
Number in category	147	69	32	11	259
Number treated by 18	33 (22.4)	17 (24.6)	13 (40.6)	7 (63.6)*	70 (27.0)
Number treated by 26	35 (23.8)	23 (33.3)	15 (46.9)	7 (63.6)*	80 (30.9)
Low					
Number in category	58	28	10	5	101
Number treated by 18	10 (17.2)	6 (21.4)	1 (10.0)	4 (80.0)*	21 (20.8)
Number treated by 26	15 (25.9)	9 (32.1)	3 (30.0)	4 (80.0)	31 (30.7)

\*  $P < .01$ .\*\*  $P < .05$ .**TABLE 5.** Rating of Orthodontic Treatment and Age-26 Dental Appearance (Relative to Peers) by Receipt of Treatment by Age 26 and Age-12 Treatment Need Category (Percentages in Parentheses)<sup>a</sup>

	Age-12 Orthodontic Treatment Need Category				All Combined
	Minor/None	Definite	Severe	Handicapping	
Treatment rated positively	42 (71.2)	32 (66.7)	15 (78.9)	11 (76.6)	100 (71.4)
Self-rated dental appearance above average <sup>b</sup>					
Not treated by age 26	121 (62.4)	43 (51.8)	10 (37.0)	2 (28.6)*	176 (56.6)
Treated by age 26	36 (61.0)	33 (68.8)	12 (63.2)	10 (71.4)	91 (65.0)

<sup>a</sup> Each percentage given here is the proportion of Study members in that cell of the table; for example, 37.0% of those in the "severe" group who had not been treated rated their dental appearance above average, and the remaining 73.0% of that group rated their appearance as worse.

<sup>b</sup> Data missing for one Study member.

\*  $P < .05$ .

category were omitted from this analysis (because they could only stay in the same category or move to a worse one), 40 (61.5%) of the remainder improved, 13 (20.0%) stayed the same, and 12 (18.5%) moved to a worse category. The percentage improving in each of the treatment-need categories was 51.4% for the definite, 73.3% for the severe, and 76.9% for the handicapping category.

### Effectiveness of orthodontic treatment

The percentage of Study members who considered their orthodontic treatment successful increased across the increasing age-12 treatment-need categories (Table 5). The difference between Study members who had been treated and those who had not been treated by age 26 in the proportion rating their dental appearance as above average increased with increasing severity of age-12 orthodontic treatment need. In the severe category, for example, 37.0% of those who had not been treated rated themselves above av-

erage, compared with 63.2% of those who had received orthodontic treatment.

### Safety of orthodontic treatment

Data on clinical characteristics by age 26 and history of orthodontic treatment are presented in Table 6. There were no significant differences between those who had been treated by age 26 and those who had not in their caries experience, periodontal disease occurrence, or tooth loss, and this null finding held when fixed appliance treatment only was examined.

## DISCUSSION

This investigation used epidemiological data from a longstanding prospective observational study to systematically evaluate the equity, efficacy, effectiveness, and safety of orthodontic treatment using a health services research

**TABLE 6.** Clinical Characteristics at Age 26 by History of Orthodontic Treatment

	Fixed Appliance Treatment by Age 18		Any Orthodontic Treatment by Age 26	
	Not Treated	Treated	Not Treated	Treated
Dental caries				
DMFS by age 26 (sd)	12.3 (11.4)	10.3 (10.0)	12.0 (10.7)	12.0 (12.3)
DFS increment 18–26 (sd)	4.9 (5.6)	4.1 (4.8)	4.7 (5.6)	4.8 (5.2)
Periodontal attachment loss 4+ mm				
Prevalence <sup>a</sup> (%)	58 (15.8)	16 (18.8)	46 (14.7)	28 (20.0)
Extent <sup>b</sup> (sd)	0.8 (2.4)	0.8 (2.0)	0.7 (2.4)	0.9 (2.0)
Gingival recession 1+ mm				
Prevalence <sup>a</sup> (%)	254 (69.2)	57 (67.1)	219 (70.2)	92 (65.7)
Extent <sup>b</sup> (sd)	6.0 (7.0)	6.2 (6.9)	6.1 (7.0)	6.0 (6.9)
Tooth loss				
One or more teeth missing by age 26 (%)	35 (9.5)	7 (8.2)	30 (9.6)	12 (8.6)
One or more third molars extracted by age 26 (%)	149 (40.6)	31 (36.5)	122 (39.1)	58 (41.4)

<sup>a</sup> Number (and percentage) of Study members meeting the case definition.

<sup>b</sup> Mean percentage of teeth meeting the criterion.

(HSR) approach. The investigation differs from previous approaches in the use of data from a population-based longitudinal study and in the emphasis on HSR criteria, rather than orthodontic clinical indicators. Before discussion of the findings, however, it is appropriate to discuss two key areas of concern. The first is the representativeness of the sample (and, by inference, the generalizability of the findings), and the second is the validity of the age-12 mini-DAI measure of malocclusion severity.

The Dunedin cohort members have been shown to be largely representative of their age-group peers in the New Zealand population on all characteristics except ethnicity, where the proportion of Maori is lower than that in the wider population.<sup>7</sup> However, the age-12 dental assessments were only conducted on those Study members who were residing in the greater Dunedin area (those who were living elsewhere were not included, contrary to the normal procedure for DMHDS assessments), with the result that those of lower SES were underrepresented in the sample that took part in the current investigation. Although it is unclear how this underrepresentation would have affected the study outcome, generalizing from those findings should be done with caution.

It is unfortunate that the age-12 assessments were conducted a year or two before Cons et al<sup>8</sup> published their work on the DAI, because one of the most important issues in assessing the current investigation is the validity of the malocclusion measure (the mini-DAI), which was used to allocate Study members to the four treatment-need categories. Although most components of the DAI were able to be retrieved from the malocclusion data, which had been recorded at age 12, two of the four that were not collected had weights greater than 1.0. One of them (the anterior mandibular overjet) is relatively uncommon, and its absence is unlikely to have had much effect. The other (the diastema) is relatively common, and its not being used is likely to have resulted in some Study members being al-

located to a lower malocclusion severity category than otherwise might have occurred. The fact that the correlation between the age-12 mini-DAI scores and the age-15 DAI scores among those who had not received treatment by age 15 was only moderate tends to support this assertion. The overall effect on the current investigation is unknown and can really only be determined by conducting a separate validation study (which is beyond the scope of this investigation).

### Equity of orthodontic treatment

Was the uptake of orthodontic treatment by Study members fair? From the treatment-need perspective, it certainly appeared to be so, with the treated percentage increasing across the categories of increasing malocclusion severity. Moreover, there were no apparent SES differences, which runs counter to expectations, particularly in view of a recent report<sup>12</sup> of profound SES differences in caries-associated tooth loss in the same cohort. The most likely explanation for the absence of SES differences is that, unlike elsewhere in New Zealand, Dunedin residents have access to considerably cheaper orthodontic treatment through the University of Otago School of Dentistry, and that would have reduced the financial barrier to treatment uptake among those of lower SES.

The fact that only about half of those with a severe or handicapping malocclusion had been treated by age 26 is of unclear significance in the absence of information on the desire (or lack thereof) for treatment among those who had not been treated by that age. Whether the situation is satisfactory clearly depends on a value judgment by the observer: is the glass half-full or half-empty?

### Efficacy of orthodontic treatment

The current study's data suggest that orthodontic treatment is efficacious for most of those who undergo it, with

almost two-thirds of those treated moving to a less severe malocclusion category. However, in examining the efficacy of treatment for those who had received it, it would have been ideal to have full DAI scores at age 12. This would have allowed the use of the DAI in an evaluative manner. That is, the change in DAI score for each orthodontically treated Study member could have been monitored assuming that the DAI would indeed have been sensitive enough to have reflected relatively minor, but still clinically and socially significant, changes in malocclusion. Unfortunately, that was not possible, and the categorical approach, which had to be used, was a compromise that may have had some bearing on the findings. For example, it is possible that some of those who were on the borderline between two categories may have actually moved to the more severe category (or vice versa) without having had much of a change to their malocclusion, whereas others may have undergone considerable change but remained in the same category. Nevertheless, there is sufficient evidence in the current study's data to support the assertion that orthodontic treatment is efficacious.

### Longer-term effectiveness of orthodontic treatment

Together with the Study members' ratings of their orthodontic treatment, the self-ratings of dental appearance by age 26 offered compelling evidence of the longer-term effectiveness of treatment, with the differential between those who had and had not been treated increasing steadily across the categories of malocclusion severity. This was perhaps the most convincing of the findings from this study and suggests that orthodontic treatment may have psychosocial benefits for those who undergo it, particularly among those with a severe or handicapping malocclusion. The ultimate judge of the success of treatment is not the clinician, but the individual who has been treated. Any clinical indicators that are used must be considered secondary to the personal and social outcomes of treatment.

### Safety of orthodontic treatment

This study provides no population-level evidence that orthodontic treatment is harmful to oral health with, on average, no differences in a range of important clinical parameters between those who had or had not been treated. It should be emphasized that this finding applies at the group level only. The possibility of greater caries and periodontal disease experience should be acknowledged for each individual who is treated, and thus the appropriate preventive measures should continue to be emphasized. The loss of one or more third molars was included as an indicator because it was hypothesized that, by virtue of having undergone diagnostic radiography for orthodontic purposes, orthodontic patients would be more likely to have had the presence of impacted third molars noted and, therefore, be

more likely to have been referred for their extraction. This was not supported possibly, because of the age at which most of the treated Study members would have received their care.

In summary, this study examined the equity, efficacy, effectiveness, and safety of orthodontic treatment among participants in a longstanding cohort study. The equity of care was found to be acceptable given that there were no clear SES differences in uptake (although this may be due to a local dental school reducing financial barriers to treatment). The treatment was found to be efficacious for most of those who underwent it, and the longer-term effectiveness of treatment was convincingly demonstrated. The safety of treatment was demonstrated by the absence of differences (in a number of clinical indicators) between those who were and who were not treated.

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