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Changes in parent-assessed oral health-related quality of life among young children following dental treatment under general anaesthetic

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Abstract – *Objective:* To estimate the nature and magnitude of changes in oral health-related quality of life (OHRQoL) among children having dental treatment under general anaesthetic (GA) and to examine the evaluative properties of the Child Oral Health-related Quality of Life Questionnaire (COHQOL©). *Methods:* Data from a consecutive clinical sample of the parents/caregivers of children receiving dental treatment under GA at Wellington and Kenepuru Hospitals were collected from parents using the Parental-Caregivers Perception Questionnaire (P-CPQ) and the Family Impact Scale (FIS), which both form part of the COHQOL© Questionnaire. The first questionnaire was completed before treatment or while the participant's child was undergoing treatment. The follow-up questionnaire was completed 1–4 weeks afterward. Treatment-associated changes in OHRQoL were determined by comparing baseline and follow-up data for the mean scores and the prevalence of impacts. The discriminative properties of the instrument were confirmed and then its evaluative properties were assessed (by examining its test–retest reliability, responsiveness and longitudinal construct validity). The minimally important difference was determined for the overall scale and subscales. *Results:* Complete baseline and follow-up data were obtained for 202 and 130 participants, respectively (64.4% follow-up rate). The evaluative properties of the P-CPQ and FIS were acceptable. There were substantial and highly statistically significant reductions in mean P-CPQ and FIS scores after treatment, with effect sizes ranging from moderate to large, depending on the subscale being examined. The minimally important difference was shown by almost two-thirds of the children treated. *Conclusion:* The provision of dental treatment under GA for young children with severe dental caries experience is associated with substantial and highly significant improvements in both their OHRQoL and in the impact on their families. The P-CPQ and the FIS show promise as evaluative measures for use in dental health services research.

Key words: children; HRQoL; general anaesthetic; quality of life

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The concept of oral health-related quality of life (OHRQoL) relates to the impact which oral health or disease has on the individual's daily functioning, well-being or life quality. It has been described as a multidimensional construct comprised of domains such as the impact of disease on physical oral functions associated with chewing, swallowing and speaking; the absence of discomfort and pain; psychosocial issues such as social discomfort in conversation, or concerns about appearance and

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social functioning associated with performance of normal roles; self-perceived oral health status and treatment needs; and the survival of the individual. The development of instruments for assessing OHRQoL in children has occurred only recently, with early attention having focused on their validation and discriminative properties. Their use as evaluative measures has yet to be examined, yet it is their potential as outcome measures which makes them so interesting for those involved in health services research (1).

Measures for children's OHRQoL have undergone considerable development in recent years, with the Child Oral Health Quality of Life Questionnaire (COHQOL©) the first to be described and validated (2). The COHQOL© consists of two age-specific Child Perception Questionnaires (the CPQ_{8-10} and the CPQ_{11-14}; aimed at 8- to 10-year olds and 11- to 14-year olds, respectively), a Parental-Caregivers Perceptions Questionnaire (P-CPQ) and a Family Impact Scale (FIS). The FIS enables determination of the effect of a child's condition on his/her family; the psychometric properties of the FIS are acceptable, with excellent reliability and good construct validity being reported (3), but its use and performance in larger population samples or clinical studies remain unreported to date. The COHQOL© was developed with the intention of being applicable to children with a wide range of dental, oral and orofacial disorders, and that its various component scales be of use not just as discriminative measures, but also as evaluative tools in assessing oral health outcomes (2–4).

While most children are able to undergo dental treatment in the conventional setting, some child patients are too young or fail to respond to the usual behaviour management techniques (5, 6). Recourse to dental treatment under general anaesthesia (GA) is common in those situations. It has been reported that 3% of children in one part of New Zealand have had such treatment by the time they are 5 years old (7). It is somewhat surprising that, despite its longstanding acceptance as an appropriate part of the paediatric dentistry repertoire, there has been surprisingly little examination of the outcomes of treatment under GA. One important reason for this has been the lack of a validated measure. Nevertheless, justifying the allocation of scarce health service resources to such a resource-intensive intervention requires irrefutable information on its benefits for children and their families.

To date, there have been seven reports on OHRQoL-related outcomes of dental treatment for children under general anaesthetic (6). None has used a validated, multi-item scale: all have used batteries of questions which have differed in their length, exact content and administration methods. The number of items used has ranged from 5 (8, 9) to 41 (10). All have focused on oral or dental pain, eating and chewing habits or difficulty, sleeping habits, and social or behavioural factors. Some have also explored aspects of parental satisfaction with the child's treatment. The findings of these studies were broadly similar: all reported improvements in children's quality of life, with fewer children experiencing symptoms (such as dental/oral pain, eating problems, interrupted sleep, or irritability) or behavioural problems following dental treatment.

The emergence of a measure such as the COHQOL© offers the opportunity to build upon that earlier work by using a validated OHRQoL scale to assess outcomes among children having dental treatment under GA. Accordingly, the aims of this study were: (a) to estimate the nature and magnitude of changes in OHRQoL among children having dental treatment under GA; and (b) to examine the evaluative properties of the COHQOL©.

Methods

Participants

Ethical approval for the study was obtained from the Central Regional Ethics Committee in February 2005. The participants were a consecutive clinical convenience sample of the parents/caregivers of children who were receiving dental treatment under GA at Wellington and Kenepuru hospitals at any time during the 5-month period of March–July 2005. Children receiving dental treatment at these hospitals reside in the greater Wellington region, which includes Wellington, Porirua, the Hutt Valley, the Kapiti Coast and Wairarapa. All of the parents/caregivers of children receiving dental treatment under GA were invited to participate in the study, but those who could not speak or read English fluently were included only if a suitable interpreter was present. Information regarding the study was given to potential participants in the form of a written covering letter/information sheet, with further verbal information being provided by the hospital dentist if necessary. Consent was obtained in writing.

Study procedures

Self-administered questionnaires were used to collect the data. The first was completed by the parent/caregiver while the child was undergoing the operation. The follow-up questionnaire was given to parents/caregivers to complete at the child's postoperative review appointment; this typically occurred 1–3 weeks after the operation. If the family failed to attend the postoperative review appointment (or if one had not been required), the questionnaire was mailed to them 1–3 weeks afterward (with a self-addressed and postage-paid envelope). If this had not been returned within 1 month, a second copy was then mailed, and a reminder telephone call made. No questionnaires were administered by telephone interview.

Measures

Standard sociodemographic data on the participants and their children were collected, including the child's gender, age and ethnicity. The ethnicity data were recoded into the five groups of European, Māori, Samoan, Other Pacific Islanders and Other. Data on child age were collected in months and recoded into the three groups of 'Preschool' (<5 years old), 'Early school' (5 and 6 years old), and 'Older' (7 years old and older). Families were categorized using an area-based socioeconomic status (SES) measure, the NZDep2001 (11), which assigns deprivation scores to small geographical areas called meshblocks, which are the smallest geographic area used by Statistics New Zealand in the collection and analysis of data. The median number of individuals per meshblock during the 2001 Census was 87. The index combines nine variables from the 2001 Census which reflect aspects of both material and social deprivation. An individual's SES is then determined by geocoding the residential address, with the assigned SES being the score for the meshblock in which they live. The data were recoded into the three groups of 'High deprivation' (scores 1 to 3), 'Medium deprivation' (scores 4 to 7)' and 'Low deprivation' (scores 8 to 10).

Information on the dental treatment received by each child was collected directly from the operation record when possible, or abstracted from the dental file retrospectively. The treatment data collected consisted of the number, surfaces and materials of restorations placed, and the number of extractions undertaken. The DMFS/dmfs index was not used, as it was anticipated that many of the children would be in the mixed dentition, complicating its use in this age group.

Oral health-related quality of life

The OHRQoL instrument used in this study was a 49-item questionnaire which combined the P-CPQ and the FIS components of the COHQOL© questionnaire (3, 4). The questionnaires were obtained in November 2004 from The University of Toronto. The items sought information on the frequency of impacts. For example, the baseline questionnaire asked 'In the past 3 months, how often has your child had…pain in the teeth, lips, jaws or mouth?', while the follow-up questionnaire asked 'Since the operation to fix their teeth…how often has your child had pain in the teeth, lips, jaws or mouth?' These were scored using a five-point Likert scale (response options: 0, 'Never'; 1, 'Once or twice'; 2, 'Sometimes'; 3, 'Often'; 4, 'Every day or almost every day'). A 'Don't know' response option was also provided, and scored as 0; this has been reported previously not to significantly alter overall findings, and prevents the loss of valuable information which would occur if complete data from participants with nonresponse to some items were deleted. The following subscale scores were created by summing the responses to conceptually based, discrete subsets of items: *oral symptoms*, comprising six items; *functional limitations* (seven items); *emotional well-being* (eight items); and *social well-being* (10 items). In addition, scores from 14 items on the impacts of the child's oral condition on parents and other family members were summed to create a *family impact* score (FIS).

Global change ratings and oral health measures

A global transition rating pertaining to perceptions in change in the child's quality of life since having dental treatment completed was included in the follow-up questionnaire. This asked 'Since the operation to fix their teeth, is your child's overall quality of life… much improved/a little improved/the same/a little worse/much worse'. Included in both baseline and follow-up questionnaires were the global rating questions 'How would you rate the health of your child's teeth, lips, jaws and mouth?' and 'How much is your child's overall well-being affected by the condition of his/her teeth, lips, jaws or mouth?', each scored on a five-point scale ranging from 'Excellent' to 'Poor'.

Statistical analyses

Cross-sectional construct validity and internal consistency

These were both examined using pretreatment scores. Cross-sectional construct validity was evaluated by examining the association between the rating of how much the child's oral condition affected his/her overall well-being and the mean values for pretreatment scores. The Kruskal–Wallis test was used to test the statistical significance of the observed associations. Internal consistency was assessed using Cronbach's alpha.

Responsiveness

The mean scores for the overall P-CPQ and subscales and the FIS, before and after treatment, and the mean change in scores were calculated. Change scores were computed by subtracting post-treatment scores from pretreatment scores. Thus, a positive change score indicates an improvement in OHRQoL, and a negative change scores indicates a deterioration. Paired *t*-tests were used to test the statistical significance of the changes, and the clinical significance or meaningful magnitude of change was determined by the calculation of effect sizes. Effect-size statistics were calculated by dividing the mean of change scores by the standard deviation of the pretreatment scores, in order to give a dimensionless measure of effect. Effect-size statistics of <0.2 indicate a small clinically meaningful magnitude of change, 0.2–0.7 a moderate change and >0.7 a large change.

Longitudinal construct validity

This was evaluated in a number of ways, but first by scrutinizing the association between change scores and the post-treatment global transition judgements (using one-way analysis of variance). As used previously (1), acceptable longitudinal construct validity is apparent where: individuals reporting deterioration have negative mean change scores; those reporting stability have change scores of approximately zero; and those reporting improvement have positive change scores. Secondly, paired *t*-tests were used to examine the significance of the within-individual change of those who changed and those for whom stability was reported. If the former is significant and the latter nonsignificant, there is support for the assertion that the measure is responsive. Independent-sample *t*-tests were used to compare the pooled mean change scores of those who improved and those who were stable. Thirdly, the mean change scores of those for whom 'a little' improvement was reported were used to determine the minimally important difference for the P-CPQ and its four subscales.

Results

Sample characteristics and follow-up rate

The parents/caregivers of 214 children were recruited during the study period (204 from Kenepuru Hospital and 10 from Wellington Hospital). Of those, six were excluded: four questionnaires contained many incomplete items; one was removed because the child received only an oral examination under GA and did not require any dental treatment; and one child experienced an adverse anaesthetic incident. This left a total of 208 for whom baseline data were collected, and complete data (i.e. without any item nonresponse) were available for 202 (97.1%) of those. Follow-up questionnaires were obtained for 138 (66.3%) of the baseline respondents. Complete baseline and follow-up data were available for 130 (94.2%) of these, which represents 64.4% of the sample for whom complete baseline data were available. The age of those children ranged from 30 to 181 months (2.5–15.1 years) and 60.0% were <6 years old. A high proportion of the questionnaires were completed by mothers of the children. Mothers completed some 167 (83.8%) and 108 (83.1%) of the baseline questionnaires and follow-up questionnaires, while fathers completed 29 (13.8%) and 17 (13.1%) respectively. Family members other than parents completed eight (3.8%) and four (3.1%) of questionnaires, while other informants completed two (1.0%) and one (0.8%), respectively; data on the informant were missing for two children. For 103 children (79.2% of those followed up), both questionnaires were completed by the mother, while both were completed by the father for 12 children (9.2%). For 12 children (9.2%), different individuals completed the baseline and follow-up questionnaires (and there were no significant differences between them and the remainder of the sample with respect to either baseline or follow-up scale scores).

The sociodemographic characteristics of the sample at baseline and those for whom follow-up questionnaires were completed are compared in Table 1. Males slightly outnumbered females at both baseline and follow up, while Māori or Pacific Island children accounted for approximately half of

Table 1. Baseline sociodemographic characteristics of children by follow-up status (brackets contain percentages unless otherwise specified)

	Baseline sample	Followed up	Lost to follow-up
Gender			
Female	95 (47.0)	63 (48.5)	32 (44.4)
Male	107 (53.0)	67 (51.5)	40 (55.6)
Ethnicity			
European	78 (38.6)	54 (41.5)	24 (33.3)
Māori	55 (27.2)	37 (28.5)	18 (25.0)
Samoan	36 (17.8)	18 (13.8)	18 (25.0)
Other Pacific Island	16 (7.9)	9 (6.9)	7 (9.7)
Other	17 (8.4)	12 (9.2)	5 (6.9)
Deprivation category[a]			
High	81 (40.3)	47 (36.2)	34 (47.9)
Medium	68 (33.8)	44 (33.8)	24 (33.8)
Low	52 (25.9)	39 (30.0)	13 (18.3)
Age group (months)			
Preschool (0–4 years)	80 (39.6)	49 (37.7)	31 (43.1)
Early school (5–6 years)	77 (38.1)	50 (38.5)	27 (37.5)
Older (7 years and older)	45 (22.3)	31 (23.8)	14 (19.4)
Mean age in months (SD)	70.2 (25.4)	71.6 (26.2)	67.7 (22.5)
Total	202 (100.0)	130 (64.4)	72 (35.6)

[a] Data missing for one individual.

the sample. More Samoan and Other Pacific Island children were lost to follow up than from the other ethnic groups, but this difference was not statistically significant.

Cross-sectional construct validity and internal consistency reliability

Data on pretreatment P-CPQ scale (and subscale) and FIS scale scores by parent-rated child well-being and Cronbach's alpha are presented in Table 2. There was a highly significant association between parent-rated child oral health and the scale and subscale scores, with all observed gradients as expected. With the exception of those for the *oral symptoms* and *functional limitations* subscales, Cronbach's alpha scores were all in the acceptable range of 0.70–0.90.

Longitudinal construct validity

Data on the mean change scores for the scales are presented by global transition judgement category in Table 3. Change scores for the P-CPQ were progressively smaller across the global transition categories from 'Much improved' to 'Worse/A little worse' (the latter two categories were combined because of small numbers), with the poorest outcome category experiencing negative changes (representing a deterioration in OHRQoL). Similar patterns were observed for the FIS and the P-CPQ subscale scores, with the exception of the *social well-being* subscale, where the change experienced by those who had not changed was greater than that for those who had improved a little. With the exception of the *social well-being* subscale, all

Table 2. Pretreatment P-CPQ scale (and subscale) and FIS scores by parent-rated well-being and Cronbach's alpha (brackets contain standard deviations unless otherwise indicated)

	How much is the child's overall well-being affected by his/her mouth?				
	Not at all/very little	Some	A lot/very much	*P*-value	Cronbach's alpha
Number of children (%)	51 (39.2)	47 (36.2)	32 (24.6)		
Overall P-CPQ score	16.7 (10.9)	28.0 (11.0)	37.5 (20.4)	<0.001	0.90
P-CPQ subscale					
Oral symptoms	5.1 (2.8)	7.4 (3.1)	8.6 (4.1)	<0.001	0.59
Functional limitations	6.0 (4.3)	9.4 (4.2)	11.8 (6.8)	<0.001	0.66
Emotional well-being	3.6 (3.9)	7.1 (4.2)	10.4 (6.4)	<0.001	0.78
Social well-being	2.0 (3.0)	4.0 (3.8)	6.7 (6.8)	<0.001	0.84
Family impact score	7.7 (7.0)	10.1 (5.9)	14.0 (10.6)	<0.001	0.88

Table 3. Mean P-CPQ and FIS scale change scores, by global transition judgement item

	Child's overall OHRQoL since the operation			
	Much improved	A little improved	The same	Worse/a little worse
Number of participants[a] (%)	89 (69.0)	20 (15.5)	18 (14.0)	2 (1.6)
Change in overall P-CPQ	17.9	7.8	5.6[b]	−7.5
Change in P-CPQ subscale				
Oral symptoms	5.1	4.0	2.8[b]	−0.5
Functional limitations	4.9	1.5	0.9[b]	−2.0
Emotional well-being	5.4	2.0	0.3[b]	−2.0
Social well-being	2.5	0.4	1.4	−3.0
Change in FIS	7.7	3.2	2.5[b]	2.0

[a] Data missing for one participant.
[b] $P < 0.05$; ANOVA, omitting the Worse group because of small numbers.

differences were statistically significant. Oneway ANOVA showed that, for the P-CPQ score, the 'Much improved' group differed from the other three, but the other groups did not differ.

Responsiveness

Data on the preoperative and postoperative scale and subscale scores are presented (with effect-size statistics) in Table 4. The large reductions in scores were associated with effect sizes showing moderate to large clinically meaningful changes in all scales and subscales. By subscale, the mean follow-up score for *functional limitations* was twice that of the others, while the largest change score was observed for *oral symptoms*. Prior to treatment, the most apparent floor effect was seen in the *social well-being* domain, with almost one-quarter scoring 0, while 45% of children scored 0 in the *emotional well-being* domain after treatment. No ceiling effects were observed in any scale.

Further data on effect sizes are presented in Table 5, this time by global transition judgement category. Effect sizes for the P-CPQ were progressively smaller across the global transition categories

Table 4. Mean overall and domain scores at baseline and follow up, with effect sizes

	Baseline		Follow up				
	Mean score (SD)	Range (no. scoring 0)	Mean score (SD)	Range (no. scoring 0)	Change in score (SD)	Effect size	Effect-size description
Overall P-CPQ score	25.9 (16.1)	2–85 (0)	11.8 (11.5)[a]	1–58 (0)	14.1 (15.4)	0.9	Large
P-CPQ subscale							
Oral symptoms	6.8 (3.6)	0–18 (1)	2.3 (2.2)[a]	0–11 (22)	4.8 (3.6)	1.3	Large
Functional limitations	8.7 (5.5)	0–25 (4)	5.0 (4.8)[a]	0–20 (19)	3.7 (5.4)	0.7	Moderate
Emotional well-being	6.6 (5.4)	0–27 (14)	2.5 (3.9)[a]	0–22 (58)	3.7 (5.4)	0.8	Large
Social well-being	3.9 (4.8)	0–24 (30)	2.0 (3.1)[a]	0–16 (52)	1.9 (4.6)	0.4	Moderate
Family impact scale	10.1 (8.1)	0–41 (8)	4.0 (4.4)[a]	0–20 (33)	6.2 (7.5)	0.8	Large

[a] $P < 0.0001$; paired *t*-test.

Table 5. Effect sizes for the P-CPQ and the FIS, by global transition judgement item

	Child's overall OHRQoL since the operation			
	Much improved	A little improved	The same	Worse/a little worse
Number of participants[a] (%)	89 (69.0)	20 (15.5)	18 (14.0)	2 (1.6)
Overall P-CPQ	1.1	0.5	0.4	−0.5
P-CPQ subscale				
Oral symptoms	1.4	1.1	0.8	−0.1
Functional limitations	0.9	0.3	0.2	−0.4
Emotional well-being	1.3	0.4	0.1	−0.4
Social well-being	0.5	0.1	0.3	−0.6
Family impact scale	1.0	0.4	0.3	0.3

[a] Data missing for one participant.

from 'Much improved' to 'Worse/A little worse'. Similar patterns were observed for the FIS and the P-CPQ subscale scores, with the exception of the *social well-being* subscale, where the effect size for those who had not changed was greater than that for those who had improved a little.

Among those who remained stable, the differences between the pre- and post-treatment scores for the P-CPQ and FIS scales were not significantly different (determined by paired *t*-tests), with the exception of the *oral symptoms* subscale scores. In all cases, the post-treatment score was lower than the pretreatment score. Among those who improved a little, pre- and post-treatment scores differed significantly ($P < 0.05$) for all except the *functional limitations*, *emotional well-being* and *social well-being* subscales; again, the post-treatment score was lower than the pretreatment score in all cases. For those who improved a lot, pre- and post-treatment scores differed significantly for all at the $P < 0.0001$ level. Because deterioration was reported for only two individuals, their scores were not considered. The mean change score among those who improved was 16.0 (sd, 15.2), while that for those who remained the same was 5.6 (SD, 12.6; $P = 0.005$; Mann–Whitney *U*-test).

The minimal important difference (equivalent to the mean change score of those for whom a little improvement was reported) was 8 for the P-CPQ, and 3 for the FIS. For the P-CPQ subscales, it was 4 for *oral symptoms*, 2 for *functional limitations*, 2 for *emotional well-being*, and 1 for *social well-being* (rounding to the nearest digit, and rounding up where rounding would have meant a change of 0).

Having determined the minimal important difference, we then computed the percentage of individuals showing or exceeding the minimal important difference by each of the scales and subscales, and then examined their sociodemographic and treatment characteristics (Table 6). Overall, nearly two-thirds of participants showed or exceeded the minimal important difference for the P-CPQ, while only about 40% did so for the FIS. A higher proportion of males than females experienced that level of improvement, but the difference failed to reach statistical significance ($P = 0.09$). The only statistically significant difference observed was that over three-quarters of Māori children (but only half of the European children) manifested that level of improvement with respect to the *oral symptoms* subscale. Where the FIS is concerned, two observations are worthy of note, despite their lack of statistical significance: first, there was a gradient apparent across the ascending categories of deprivation, whereby a higher proportion of families in low-deprivation areas showed or exceeded the minimal important difference; second, a lower proportion of families where older children had been treated showed or exceeded the minimal important difference.

Among the 130 children who were followed up, 106 (81.5%) received one or more restorative

Table 6. Number of participants showing or exceeding the minimal important difference, by sociodemographic characteristics

	P-CPQ scale and subscales					
	Overall	Oral symptoms	Functional limitations	Emotional well-being	Social well-being	FIS
Gender						
Female	35 (55.6)	35 (55.6)	40 (63.5)	38 (60.3)	34 (54.0)	23 (37.1)
Male	47 (70.1)	44 (65.7)	47 (70.1)	45 (67.2)	38 (56.7)	28 (42.4)
Ethnicity						
European	30 (55.6)	27 (50.0)[a]	34 (63.0)	34 (63.0)	30 (55.6)	20 (38.5)
Māori	28 (75.7)	29 (78.4)	25 (67.6)	24 (64.9)	20 (54.1)	14 (37.8)
Pacific Is./Other	24 (61.5)	23 (59.0)	28 (71.8)	25 (64.1)	22 (56.4)	17 (43.6)
Deprivation category						
High	32 (68.1)	30 (63.8)	33 (70.2)	29 (61.7)	26 (55.3)	15 (31.9)
Medium	27 (61.4)	29 (65.9)	29 (65.9)	31 (70.5)	21 (47.7)	18 (42.9)
Low	23 (59.0)	20 (51.3)	25 (64.1)	23 (59.0)	25 (64.1)	18 (46.2)
Agegroup (months)						
Preschool (0–4 years)	33 (67.3)	30 (61.2)	33 (67.3)	31 (63.3)	23 (46.9)	21 (43.8)
Early-school (5–6 years)	31 (62.0)	32 (64.0)	33 (66.0)	35 (70.0)	32 (64.0)	23 (46.9)
Older (7+ years)	18 (58.1)	17 (54.8)	21 (67.7)	17 (54.8)	17 (54.8)	7 (22.6)
All combined	82 (63.1)	79 (60.8)	87 (66.9)	83 (63.8)	72 (55.4)	51 (39.8)

[a] $P < 0.05$; chi-square test.

procedures (overall mean 3.8, SD 2.9, median 4), while 122 (93.8%) received one or more extractions (overall mean 3.3, SD 2.4, median 3). The mean total number of restorative or exodontic procedures was 7.1 (SD 3.9, median 7). When the latter was categorised (first by using a median split and then by dividing into quartiles), there were no statistically significant differences or consistent gradients in baseline P-CPQ (whether total or subscale) or FIS scores across either. Similarly, change scores showed no clear pattern either (data available on request).

Discussion

This study aimed to document changes in OHRQoL among children having dental treatment under GA, and, in doing so, to examine the evaluative properties of the COHQOL©. It describes the use of the P-CPQ and FIS to assess the quality of life of children from the greater Wellington region receiving dental treatment under general anaesthetic at Wellington and Kenepuru hospitals. The majority of children requiring dental treatment under GA had severe dental caries, often involving many teeth, and the provision of treatment was associated with substantial and highly statistically significant improvements in their OHRQoL, irrespective of how much actual treatment they had received. The COHQOL© was found to have acceptable properties as an evaluative measure.

Before discussion of the findings, it is appropriate to consider the size, representativeness and retention of the sample. Determining the necessary sample size for a study such as this was difficult, as few similar studies had been undertaken, and we opted to take a consecutive sample of cases presenting for treatment under GA over a set period. Fortuitously, this resulted in the number of participants at baseline ($n = 208$) being substantially greater than almost all of the previous studies in this field (6), and the number assessed at follow-up ($n = 130$) is also higher. While far short of the desired 100%, the 64% follow-up rate is satisfactory and compares favourably with previous studies. The consecutive nature of the sample and the fact that there were no significant differences between those who were followed up and the others suggest that the group for whom there are complete data should be representative of children who undergo dental treatment under GA in the greater Wellington area.

The instrument

Responsiveness is an important characteristic of OHRQoL instruments which are to be used as evaluative measures. Because they are expected to represent change over time, longitudinal validity, reproducibility and the ability to detect minimally important clinical changes are key properties, over and above those of cross-sectional validity and test–retest reliability (1). All of these aspects were examined in the current study, and, while almost all were observed to be acceptable for both the P-CPQ and the FIS, there were some minor concerns with some aspects of the subscales. For example, the internal consistency reliability of the *functional limitations* and *oral symptoms* subscales was not as high as would be desired. The relatively low Cronbach's alpha for the latter most likely reflects the fact that it is not really a scale representing a single construct; rather, it is a check-list of what can be independent events (such as 'pain' and 'bleeding gums'). Longitudinal construct validity was acceptable for both the P-CPQ and the FIS, and the responsiveness of both was satisfactory. Finally, it should be pointed out that the P-CPQ was developed for use with children aged between 6 and 14 years; that a high proportion (60%) of the children in the current study were younger than 6 years old means that there may have been content validity problems with the scale, and this may have affected its performance.

Does the OHRQoL of children undergoing treatment under GA actually improve?

Having considered the sample and the properties of the instrument which was used to make the pre- and post-treatment measurements, attention can now turn to the issue of whether there are positive OHRQoL outcomes from treating those children under GA. The data in Tables 4 and 6 provide evidence that this is the case, with both a substantial decrease in overall mean scores and the fact that more than six of 10 children showed the minimal important difference in the change in overall P-CPQ score. There were minor differences by subscale, with two-thirds of patients showing (or exceeding) the minimal important difference in score on the *functional limitations* subscale, but only 55% doing so on the *social well-being* subscale. The larger proportion of Māori children (relative to the other two ethnic categories) showing or exceeding the minimally important difference on the *oral symptoms* subscale is also reflected in their overall P-CPQ, and suggests that the benefits of the treatment under GA for those children are important, particularly in light of New Zealand's commitment to reducing ethnic inequalities in oral health (12). Where the FIS is concerned, the minimal important difference was shown or exceeded with only about 40% of children, despite the 'large' effect size calculated for the change in mean FIS score. This suggests that the magnitude of the change in score was great among the 40% who did show or exceed the minimal important difference. The data in Table 6 suggest that a slightly higher proportion of those families were from areas of low socioeconomic deprivation (although the difference did not reach statistical significance).

With any examination of change scores, it is always possible that a proportion of the observed change is attributable to a phenomenon known as 'regression to the mean (RTM)' (13), whereby those with more extreme baseline scores tend to have less extreme scores at follow up, regardless of any real change in the characteristic being measured. An indication of the RTM effect can be gauged from the data in Table 3, where the mean change in score among children for whom OHRQoL since the operation was judged using the global measure to be 'the same' was 5.6 for the overall P-CPQ. If it is assumed that this is indeed the amount of change which was due to RTM, it is possible then to adjust the effect sizes presented in Table 4 for that by correcting the mean baseline scores by that amount and then recalculating the effect sizes. This results in the following effect sizes and descriptors: overall P-CPQ 0.53 (moderate); *oral symptoms* 0.47 (moderate); *functional limitations* 0.51 (moderate); *emotional well-being* 0.70 (large); *social well-being* 0.10 (small); and FIS 0.44 (moderate). Other than for the *social well-being* subscale, the observed changes were at least 'moderate', and support the assertion that the OHRQoL of children undergoing treatment under GA does improve measurably.

Statistical manipulations notwithstanding, the ideal design for this study would have been to also have a comparison group which did not receive treatment. This would have allowed comparison of changes in scores over time between a treated group and one who had not received treatment. It is unfortunate that practical constraints precluded this. The conflict between methodological rigour and the practical constraints of working within the health system is one of the challenges of health services research. In this study, we did not set out to compare the nature and magnitude of changes in OHRQoL in children who were or were not being treated. That remains a very interesting research question which needs to be answered. However, before this can be done, the researchers would need to be very confident of the instrument's evaluative properties; it is no coincidence that our second aim was to examine those. Having shown that the measure 'works' in this respect (and having estimated the minimal important difference), we now advocate its use in carefully designed comparative studies.

In summary, the findings of this study indicate that the dental treatment of young children under GA is associated with considerable improvement in their oral-health-related quality of life (on average), with almost two-thirds showing improvements that their parents perceive as beneficial. Both the P-CPQ and the FIS were designed to be used ultimately as evaluative tools, and have been shown here to have satisfactory discriminative and evaluative properties. Our findings indicate that they are able to detect oral health impacts in children with extensive dental caries, and that they are responsive to the changes in OHRQoL associated with the provision of treatment. Of course, the children in this study are among those with the worst oral health in their age group, with many experiencing long-term dental pain and difficulty eating and sleeping prior to receiving dental treatment. This means that the sensitivity of the instruments to more subtle differences and changes in child oral health requires further investigation. However, the P-CPQ and FIS appear to be sound measures to use in oral health outcomes research among families with young children. Future work with those measures should determine whether there are differences in OHRQoL outcomes associated with different intervention strategies (e.g. multiple extractions versus full-mouth rehabilitation).

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