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Testing the applicability of a conceptual model of oral health in housebound edentulous older people

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Abstract – *Objectives:* The aim of the study was to test prospectively Wilson and Cleary's (1) conceptual model of the direct and mediated pathways between symptom burden, functional status and health perceptions in relation to the oral health of housebound elderly edentulous people. *Methods:* The data were collected as part of a community based randomized control trial of a domiciliary denture service for older people. Measures of self-reported symptoms, functional status and global oral and general health perceptions were collected from 133 participants prior to treatment and at 3-month follow-up. *Results:* The results indicated support for the dominant direct and indirect pathways within the model; worse patient reported symptoms predicted a lower functional status; worse daily functioning predicted lower global oral health perceptions. In addition, the impact of symptom status on oral health perceptions was mediated by patient reported functioning. The treatment (domiciliary denture service) significantly improved functional status and global oral health perceptions. All relationships were significant prospectively that is, from baseline, prior to the intervention, to 3-month follow-up, with the exception of between symptoms functioning. *Conclusion:* The results support Wilson and Cleary's conceptual model of patient outcomes as applied to elderly edentulous people. They highlight the importance of assessing a range of patient-orientated variables in order to help gain a greater understanding of how oral health impacts on individuals' daily lives and well-being. Further conceptual development of the model is discussed, particularly the role of individual difference factors.

Key words: dentures; edentulous; oral health quality of life; structural equation modelling; Wilson and Cleary

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Oral health-related quality of life (OHRQoL) is a multidimensional construct that refers to the extent to which oral disorders disrupt an individual's normal functioning, and is a facet of health-related quality of life (HRQoL). Oral health-related quality of life has, over recent years, become an important focus for assessing the impact of a range of oral conditions on quality of life and well-being (2–4), together with the outcomes of clinical care such as, the effectiveness of treatment interventions (5–7).

However, research to date has been predominately cross-sectional and descriptive. In addition, whilst studies have examined multidimensional aspects of OHRQoL in relation to clinical and other nonclinical variables (3, 8, 9), few have included simultaneously the spectrum of factors that influence HRQoL or attempted to explicitly test the direct and mediated linkages between them within a theoretical model. As such, the utility of the OHRQoL concept has been hampered and, in turn, its usefulness within clinical contexts as part of treatment decisions that will optimize patient as well as clinical outcomes. In order to facilitate effective intervention strategies, it is necessary to

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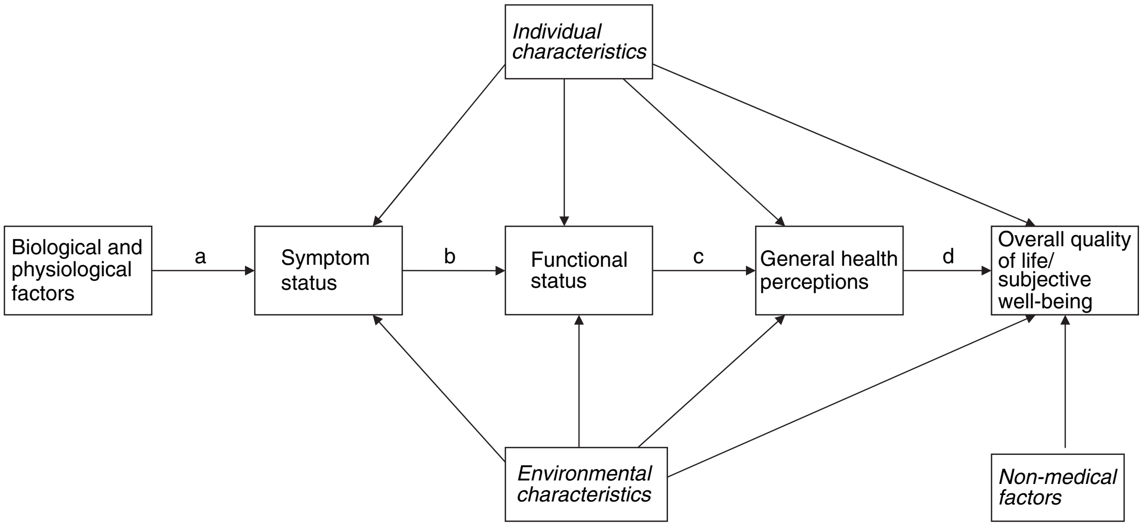

Fig. 1. Conceptual model of patient outcomes in xerostomia adapted from Wilson and Cleary (1 p. 60). Copyright 1995, American Medical Association.

clarify the antecedents and consequents of OHRQoL and the causal processes underlying OHRQoL in specific populations.

One model, which explicitly conceptualizes the relationship between clinical factors and HRQoL and subjective well-being, is that of Wilson and Cleary (1). The model (Fig. 1) is a taxonomy or classification of patient outcomes at five main levels: biological and physiological variables, symptom status, functioning, general health perceptions, and overall quality of life or subjective well-being. Whilst the authors highlight the dominant relationships between the five adjacent levels as depicted in Fig. 1 (i.e. paths a–d), they also clearly state that there are likely to be direct and indirect (mediated) relationships between variables at nonadjacent levels. For example, the impact of clinical variables on everyday functioning is likely to be partially mediated by symptom status (i.e. path a × b).

Empirical studies have used the model in relation to HRQoL for patients with heart disease (10, 11), Hodgkin's lymphoma (12) and HIV/AIDS (13), as well as in an older population sample (14), but only one study has examined the utility of the model for oral health (15). These authors, testing the model in one chronic oral health condition, xerostomia, found support for three of the key direct pathways hypothesized by Wilson and Cleary; biological variables → symptom status, symptom status → functioning and functioning → health perceptions. In addition, there were a number of direct relationships between nonadjacent levels (functioning → well-being; clinical status → well-being), as well as indirect or mediated paths. For example, the impact of clinical variables on daily functional status was mediated by patient's symptoms. These complex interrelationships highlight the importance of testing mediation models; such models are particularly important for theory development and testing, as they help facilitate our understanding of possible causal mechanisms for health, and for identifying important points for clinical intervention (16, 17).

The primary aim of the present research was to examine symptom burden, functioning and health perceptions in relation to OHRQoL of housebound elderly edentulous people in order to further explore the utility of Wilson and Cleary's model to oral health. The objective being to provide a comprehensive *a priori* test of the direct and indirect (mediated) pathways between symptoms, function and health perceptions in order to determine the best model of patient outcomes in this population. Given that OHRQoL is characterized as multidimensional (18), a second aim was to explore the utility of the separate domains of OHRQoL – psychological, social, physical – within the model. Furthermore, unlike previous cross-sectional research (15), we aimed to test the model prospectively, examining lagged relationships between key variables over a 3-month period.

There were a number of reasons for exploring the model in an elderly edentate population. The recent WHO recommendation for improving the health of older people (19), highlights the need for sociobehavioural research examining well-being, oral functioning and quality of life in high risk groups in order to help facilitate treatment planning and the development of effective programmes to improve oral health related quality of life. Indeed, it is known that the dental health and care of older people is often inadequate (20). Although the prevalence of edentulousness is falling, it is still common in the very old with 57% of UK adults aged 75 years or more edentate (21). Functional and social handicaps are frequently reported by edentate people, for example, 41% of complete denture wearers had a dentally related complaint in the recent UK Adult Dental Health Survey (20–22). In addition, ill-fitting dentures can traumatize the oral mucosa, resulting in patient's reporting symptoms of pain and discomfort particularly while eating. This can impact on patient's functioning so they may have difficulty while eating (physical function) which can result in a restriction in their food choice and taking longer to complete their meal. An outcome of this may be that they avoid eating with others (social function) because of their embarrassment (psychological function). Such impacts on functioning may lead to lower oral and general health perceptions. In addition, almost a third of the older population have dry mouth or xerostomia (23). More severe dry mouth can not only indirectly impact on OHRQoL through patient's symptom perceptions but, in addition, directly impacts on a person's overall well-being (15).

Methods

The data were collected as part of a community based randomized control trial of a domiciliary denture service for older people [see Pearson et al. (24) for full description of sample and intervention]. Participants comprised a consecutive sample of older people aged 65 years or over who needed complete dentures ($n = 133$). Patients were accrued by being referred to the Community Dental Service or being identified during a routine screening procedure. Exclusion criteria included never having worn a denture, a record of a chronic confusional state or reduced memory or intellect, being terminally ill or having an urgent need for dentures because of a medical condition.

Participants were visited by the research dentist and a nurse who conducted a clinical examination and obtained a medical history. On a separate visit, a research assistant collected the baseline interview data (see Measures section). Participants were then assigned randomly into either intervention ($n = 65$) or control group ($n = 68$). After randomization, treatment started immediately to provide the intervention group with complete dentures. Treatment for the control group was deferred to the normal waiting list, but in the interim participants received three informal visits from the dentist and nurse to reduce any placebo effect arising from home visits. Three months after completion of treatment of the intervention group, the clinician revisited all participants to repeat the clinical examination. Treatment for the control group was started at this visit. The research assistant subsequently visited all participants to collect follow-up data for the questionnaire measures. Approval was granted from the Research Ethical Committee of King's College Hospital and East London & the City Health Authority Ethics Committee. Written consent was obtained from all participants.

Participant characteristics

Of the 133 participants at baseline (32 men, 101 women), the mean age was 80 years (range = 65–101; SD = 8.4). Ninety-eight participants (73.7%) identified as White, white Irish or White 'other', with 16 (12.0%) describing themselves as Black Somali or Black Caribbean, and 19 (14.3%) identifying as Turkish Cypriot, Greek Cypriot, Jewish or other ethnic group. Forty-four participants were living with their spouse or family member (33%), with 86 living alone (25.6%) or alone with help (39.8%) or 'other' (1.5%). Of the sample, 26 were married (19.5%) and 107 were single, widowed or divorced (81.5%). At 3-month follow-up, there were 127 participants, with four having deceased and two withdrawn from the study.

The majority ($n = 127$) wore a complete denture on both jaws, or on the upper or lower jaw (95.5%). The mean age of the present denture was 17.05 years (range = 1–70; SD = 13.2), and participants had been edentate for a mean of 31.91 years (range = 0.5–70; SD = 16.7). Of the sample, 102 (76.7%) reported never seeing a dentist, 25 (18.8%) when they were having trouble, 2.3% had occasional checkups and 2.3% regular checkups.

Measures

The measures chosen to operationalize symptom status, functioning and health perceptions within Wilson and Cleary's model are described below[1] All measures were collected at both baseline and 3-month follow-up unless indicated otherwise. The

Table 1. Mean and sample ranges of study variables

	Mean (SD)		
	Baseline	3-Month follow-up	Sample range
Symptom status			
Chewing difficulty	12.08 (3.06)	11.15 (3.10)	5–20
Eating impact	10.22 (5.00)	7.99 (4.68)	4–20
Dry mouth	1.07 (0.88)	0.95 (0.76)	0–3
Functioning			
OHIP – total	48.88 (35.17)	26.91 (29.65)	0–180
OHIP – physical	32.95 (20.70)	19.17 (19.18)	0–88
OHIP – psychological	12.07 (11.09)	5.95 (8.73)	0–44
OHIP – social	3.87 (6.26)	1.79 (3.91)	0–32
General health perceptions			
Global oral health	2.68 (1.27)	2.19 (1.22)	1–6
Global general health	2.89 (1.07)	–	1–5
Oral health change	–	3.30 (1.00)	1–5

OHIP, oral health impact profile.

mean, standard deviation and sample range for all measures are given in Table 1.

Symptom status

Symptom status was defined as the patient's ratings of chewing difficulty, eating impact and perceptions of symptoms of dry mouth. Chewing difficulty was assessed by whether participants reported difficulty eating seven indicator foods. Six items were from the Ontario Study of the Oral Health of Older Adults (25), five as per the original (crisp vegetables, boiled vegetables, fresh lettuce, firm meat, fresh apple), one modified (hamburger was replaced by stew/curry), and one additional item (tomatoes). Participants were asked to rate each item from 1 ('could eat easily') to 3 ('could not eat at all'). Scores for each item were summed, with a higher score indicated more difficulty with chewing (range 0–21). Eating impact was measured by three items from Locker's Subjective Oral Health Status Indicators ('taken longer to complete a meal than others', 'enjoyment of food less than used to be', 'prevented from eating foods you would like to eat''), and one additional item ('avoid eating with others'). Each item was rated from 1 ('never') to 5 ('very often'); scores were then summed so that a higher score indicated a greater impact on eating (range 0–20). Dry mouth was assessed by asking participants if they experienced three common symptoms of dry mouth ('daily feeling of dry mouth for more than 3 months', 'frequently drink liquids to help swallowing dry food', 'recurrent or persistently swollen glands as an adult'). Participants responded yes (1) or no (0); items were then summed, with a greater score indicating more symptoms (range 0–3). Cronbach's alpha for the symptom status scale was good (0.79).

Functioning

Functioning was measured by the oral health impact profile (OHIP) (4) which assesses frequency of problems associated with the mouth or dentures on seven dimensions: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability and handicap based on Locker's conceptual model of oral health (18). For this study, a 45-item version was used, with the four items relating to natural teeth deleted. Participants were asked to rate for the last 3 months each of the 45 items on a 5-point scale from 0 ('never') to 4 ('very often'). Three subscales were created representing the three functional domains: physical, social and psychological. Responses to items 16–20 (psychological discomfort) and 29–34 (psychological disability) were summed to represent psychological function (PSY-F; range 0–44); items 1–8 (functional limitation), 9–15 (physical pain), and 21–28 (physical disability) were summed to represent physical function (range 0–92); and items 35–39 (social disability) and 40–45(handicap) were summed to represent social function (range 0–44). Cronbach's alpha for the total scale (.97) and each of the subscales was excellent (.95, .92, .88 for physical, psychological and social dimensions respectively).

[1]The first level of Wilson and Cleary's model (see Fig. 1), biological variables, was not included in this secondary analysis due to clinical status being largely standardized across the sample. Data on overall quality of life was not collected in the original randomized control trial.

General health perceptions
General health perceptions were measured using two single-item ratings of global general health (baseline only) and oral health. Participants were asked to rate their health on scales of 0 ('very poor') to 4 ('very good'). In addition, at follow-up, participants were asked to indicate in the last 3 months any change in oral health on a scale of 0 ('worsened a lot') to 4 ('improved a lot').

Statistical analysis
The analysis followed the recommended two-stage approach to structural equation modelling (SEM) (26). First, we employed confirmatory factor analysis (CFA) to test the hypothesized measurement models. Measurement models specify the relationships between the observed (indicator) variables (e.g. chewing difficulty, eating impact, dry mouth) to the underlying unobserved (latent) constructs (e.g. symptom status). Following specification of the measurement model, we then tested the hypothesized structural equation models which examine the *a priori* direct and indirect relationships between the latent constructs (i.e. symptom status, functioning, health perceptions).

Confirmatory factor analysis

A series of alternative measurement models were tested using CFA[2]. CFA, in contrast to exploratory factor analysis, is used to test whether a data set is consistent with an *a priori* theoretical model. We first tested a 3-factor model in line with Wilson and Cleary's framework (model 1). The three factors (latent variables) were symptom status, functioning and health perceptions. Each factor was allowed to correlate freely with one other. We then tested this model against two simpler models. In model 2 we specified a 2-factor model with two latent variables ('symptom status and functioning', 'health perceptions') which were allowed to co-vary. Model 3 specified a 1-factor unidimensional model with all indicator variables loading on a single factor. This model was used to test the existence of separate factors compared with a general 'psychosocial impact' factor.

The parameters of each model were estimated with maximum likelihood estimation and bootstrapping using AMOS 6.0 (27). The bootstrap framework has been advocated as one approach when sample sizes are small to medium ($n < 200$) (28). Following Shrout and Bolger's (16) techniques, we created 1000 bootstrap samples (re-sampled from the original dataset) in order to derive less biased standard errors and 95% confidence interval (CI) bootstrap percentiles. We report bias-corrected 95% CI (BC 95% CI), as these have been shown to be more accurate with smaller sample sizes (28, 29).

We assessed the adequacy of overall model fit using the chi-square test statistic and the following five supplemental fit indexes: the root-mean-squared error of approximation (RMSEA) with 90% CI, the Goodness of Fit Index (GFI), the Normed Fit Index (NFI), the Incremental Fit Index (IFI) and the comparative fit index (CFI). A nonsignificant chi-square indicates that the model is a plausible representation of the relations among the observed variables. Further, in line with recommendations by Hu and Bentler (30), we take good model fit to be indicated by a RMSEA $\leq$0.06 and NFI, IFI, GFI and CFI values $\geq$0.95.

Structural equation modelling

Following specification of an adequate measurement model, we tested a prospective SEM model in order to estimate the magnitude and direction of the direct and indirect lagged paths between the three latent variables. In line with the hypotheses of Wilson and Cleary (1), we predicted that symptom status at baseline would predict functioning at follow-up (Fig. 1, path b), and functioning at baseline would predict health perceptions at follow-up (path c). In addition, in line with Baker et al. (15) and Sousa and Kwok (13), we predicted that there would be an indirect relationship between symptoms at baseline and health perceptions at follow-up that would be mediated by functioning (paths b $\times$ c). We entered a treatment variable (intervention, control) to control for any effects of the intervention on functioning or health perceptions at follow-up, in addition to a variable representing any change in medical history since the study began. We allowed each of the functioning domain scores (physical, psychological, social) at baseline to be related to the equivalent score at follow-up.

AMOS estimates the total effects, which are made up of both the direct effects (a path direct from one variable to another e.g. functioning to global health perceptions (Fig. 1 path c) and indirect effects [a path mediated through other variables e.g. symptoms to health perceptions

[2]Two measurement models were tested; one for the baseline data and the second for the 3-month follow-up. The results for both models were similar; only those for the baseline data are reported here due to space limitations.

mediated by functioning (paths b × c)]. Total indirect effects represent the sum of one or more specific paths. We assessed whether mediation was present by testing the significance of any indirect effects using the bias-corrected bootstrap CI (16, 17). Within the literature, the bootstrap framework has been advocated as the best approach to test direct and indirect effects in mediation models (16, 17, 31).

Results

Confirmatory factor analysis

The first measurement model to be tested was the 3-factor Wilson and Cleary model. Four of the fit indices (GFI, IFI, NFI and CFI) indicated an acceptable fit (>0.90); however, the RMSEA was below the acceptable level (0.09) and the chi-square significant [χ^2 = 34.67 (17), P < .01]. Inspection of the modification indices indicated that if the error terms for social and psychological function were allowed to co-vary this may improve the fit of the model. Given that conceptually, it is likely that social and psychological functioning are related, and that both domains have common measurement error in that they arise from the same scale, the CFA was re-run to determine whether the modification resulted in an improved fit. The chi-square indicated that the modification significantly improved the fit of the model ($\Delta\chi^2$ = 17.55, Δd.f. = 1, P < 0.001) (see Table 2, model 1 for fit indices).

The 3-factor measurement model can be seen in Fig. 2. Factors (latent variables) are in ellipses, items (indicator variables) are in rectangles and residual error terms in circles. As can be seen from Fig. 2, all item loadings were significant and in the expected direction. The loading for general health, whilst significant was relatively low (0.32). This is perhaps not unexpected given that all remaining indicators were oral health specific. In relation to functioning, the physical domain score had the highest factor loading (0.98), with social having the lowest (0.67). Eating impact had the highest loading for symptom status (0.90) and dry mouth the lowest (0.56). The amount of variance accounted for (R^2) by these indicator variables ranged from 31–97% (excluding general health perceptions, 10%).

As shown in Fig. 2, the correlation between the symptom status and functioning factors was high (0.82) indicating that these may be better represented by a single underlying construct. We tested this with a 2-factor model ('symptom status and functioning', 'health perceptions'). The highly significant chi-square statistic and high RMSEA value indicated that this model did not fit the data well (see model 2, Table 2). Finally, given that the CI around the correlation estimates between symptom status-health perceptions and functioning-health perceptions included 1.0, which may indicate a lack of discriminant validity between these three factors (32), we tested a general unidimensional 1-factor model. In this model, all indicator variables were allowed to load on a general 'psychosocial impact' factor. This model did not fit the data well; indeed, none of the six model fitting criteria were met (see model 3, Table 2).

Finally, in order to test the fit of the 3-factor measurement model relative to the alternative 1- and 2-factor models, we carried out three chi-square difference tests. As can be seen from the model comparison part of Table 2, the difference between both models 1 and 2 and models 1 and 3 were significant. This indicates that model 1

Table 2. Fit indices for the confirmatory factor analysis and number of indices fitting criteria for each of the three models

Model	χ^2 (d.f.) (P)	GFI	IFI	CFI	NFI	RMSEA (90% CI)	Criteria
1.	17.12 (16) (0.**378**)	**0.970**	**0.998**	**0.998**	**0.968**	**0.023** (0.00–0.09)	6
2.	43.53 (18) (0.001)	0.918	**0.950**	0.949	0.918	0.104 (0.07–0.14)	1
3.	47.39 (19) (0.000)	0.911	0.944	0.943	0.910	0.106 (0.07–0.15)	0
Model comparisons							
Model 1 versus 2: $\Delta\chi^2$ (2) = 26.41 P < 0.001							
Model 1 versus 3: $\Delta\chi^2$ (3) = 30.27 P < 0.001							
Model 2 versus 3: $\Delta\chi^2$ (1) = 3.86							

Figures in bold are those in line with the model-fitting criteria. Explanation for each fit index can be found in the statistical analysis section.

Model 1, 3-factor (symptom status, functioning, health perceptions); model 2, 2-factor (symptom status and functioning, health perceptions); model 3, 1-factor ('psychosocial impact'); GFI, Goodness of Fit Index; IFI, Incremental Fit Index; CFI, Comparative Fit Index; NFI, Normed Fit Index; RMSEA, root-mean-square error of approximation; CI, confidence interval.

*P = 0.05; ***P < 0.001.

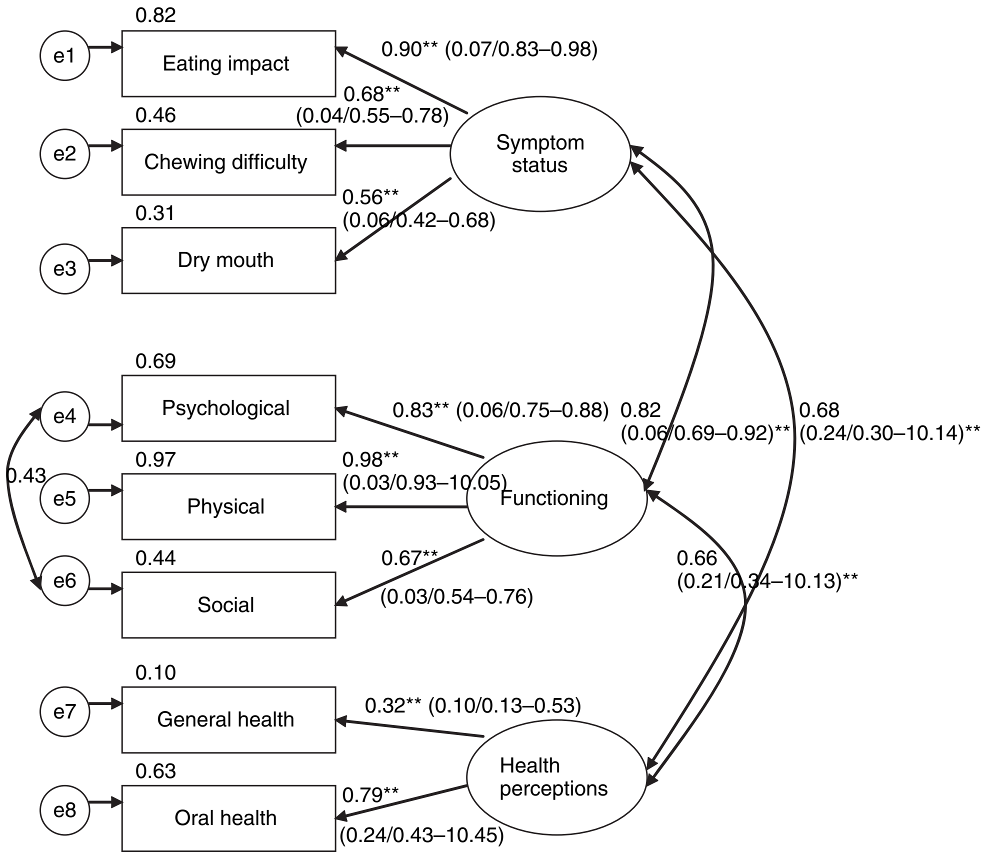

Fig. 2. Bootstrap item loadings (SE/BC 95% CIs), squared multiple correlations and covariances (SE/BC 95% CIs) for the 3-factor measurement model at baseline. $^{**}P < 0.01$.

with three separate factors (symptoms, functioning, health perceptions) better accounted for the data than did either the 2- (symptom/functioning, health perceptions) or 1-factor models (psychosocial impact).

Structural equation modelling

The next step was to test the prospective direct and indirect paths between the three latent variables represented in Wilson and Cleary's model. We did this using a prospective lagged design. It was hypothesized that symptom status at baseline (T1) would predict both functioning at T1 and follow-up (T2), as well as health perceptions at T2. In addition, functioning at T1 and T2 would predict health perceptions at T2. As can be seen in Table 3 (model 1), this model fitted the data well. The model accounted for 67 and 41% of variance in functioning at baseline (SE = 0.10, BC 95% CI = 0.47–0.84, $P < 0.01$) and follow-up respectively (SE = 0.07, BC 95% CI = 0.26–0.52, $P < 0.05$), and 93% of variance in health perceptions at follow-up (SE = 0.07, BC 95% CI = 0.74–1.00, $P < .01$).

Direct effects. The bootstrap standardized estimates, SEs and CI for the direct effects can be seen in Table 4. As can be seen from Table 4, in line with the hypotheses, worse symptom perceptions were

Table 3. Fit indices for the structural equation models

Model	χ^2 (d.f.)	P	GFI	IFI	CFI	NFI	RMSEA (90% CI)	ECVI
1.	48.93 (52)	**0.596**	**0.945**	**1.00**	**1.00**	**0.953**	**0.00** (0.00–0.05)	1.007
2.	53.772 (56)	**0.56**	**0.939**	**1.00**	**1.00**	**0.948**	**0.00** (0.00–0.05)	0.982
Model comparison								
Model 1 versus 2: $\Delta\chi^2$ (4) = 4.84[a]								

Figures in bold are those that meet the model fitting criteria.
Model 1, 3-factor SEM; model 2, more parsimonious 3-factor SEM; ECVI, Expected Cross Validation Index. For all other abbreviations see Table 2.
[a]Nonsignificant

Table 4. Direct effects of the 3-factor prospective structural equation model

Effect	β	Bootstrap SE	Bias-corrected 95% CI
Symptom status (T1)			
Functioning (T1)	0.82	0.06	0.68/0.92**
Functioning (T2)	0.24	0.21	−0.14/0.68
Health perceptions (T2)	−0.06	0.21	−0.55/0.24
Functioning (T1)			
Functioning (T2)	−0.03	0.23	−0.53/0.39
Health perceptions (T2)	0.34	0.21	0.03/0.85*
Functioning (T2)			
Health perceptions (T2)	0.74	0.09	0.59/0.92**
Treatment group			
Functioning (T2)	0.60	0.06	0.49/0.71***
Health perceptions (T2)	0.20	0.09	0.01/0.37*
Change in medical history			
Functioning (T2)	0.03	0.08	−0.13/0.17
Health perceptions (T2)	−0.14	0.06	−0.27/−0.02*

T1, baseline; T2, 3-month follow-up.
*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

associated with poorer functioning at baseline. This relationship was not, however, significant prospectively. In addition, contrary to predictions, there was no prospective relationship between symptom status and health perceptions. Better functioning at baseline did predict better health perceptions at follow-up. Treatment group had an impact on both functioning and health perceptions at 3-month follow-up such that those elderly people who received new dentures through the domiciliary service reported a higher level of functioning and better health perceptions compared to the control group. Finally, change in medical history over the 3-month period was predictive of health perceptions; those elderly people who reported no change reported better health.

Indirect effects. There were two significant total indirect paths in the 3-factor model. Treatment group was indirectly related to health perceptions at follow-up via functional status ($\beta = 0.44$, SE = 0.07, BC 95% CI = 0.32–0.62, $P < 0.001$). Those individuals who received new dentures had better functional status which, in turn, led to higher global oral health ratings. Symptom status was indirectly related to health perceptions at follow-up ($\beta = 0.44$, SE = 0.19, BC 95% CI = 0.18–0.90, $P < 0.01$). This total indirect effect represents all possible paths. Specific indirect effects were calculated by multiplying the estimates of the direct effects of the variables involved in the total pathway with the following results:

1. Symptom status (T1) – functioning (T1) – functioning (T2) – health perceptions (T2) ($\beta = 0.02$)
2. Symptom status (T1) – functioning (T1) – health perceptions (T2) ($\beta = 0.28$)
3. Symptom status (T1) – functioning (T2) – health perceptions (T2) ($\beta = 0.18$)

Examination of these coefficients suggests that the impact of worse symptom status on poorer health perceptions was via lower functional status at baseline and, to a lesser extent, follow-up.

'Final' SEM model (model 2)

In order to create a statistically more parsimonious model, all nonsignificant direct paths were trimmed from model 1. The resulting model was then compared with model 1 using a chi-square difference test (see Table 3, model 2). The nonsignificance of this difference test indicated that the dropped pathways were not important to the model, and that model 2 was a better fit to the data. This model accounted for 67, 36 and 92% of the variance in functioning at T1 and functioning and health perceptions at T2 respectively. The bootstrap standardized estimates, SEs, and BC 95% CIs for the direct and indirect paths for this 'final' model can be seen in Fig. 3.

Discussion

These findings lend support to Wilson and Cleary's conceptual model of patient outcomes (1) as applied to a sample of housebound edentulous older people. As predicted, worse symptom status was associated with lower levels of daily functioning; and lower functioning predicted worse global oral health perceptions. In addition, in line with previous research (13, 15), the relationship between patient reported symptoms and global oral health

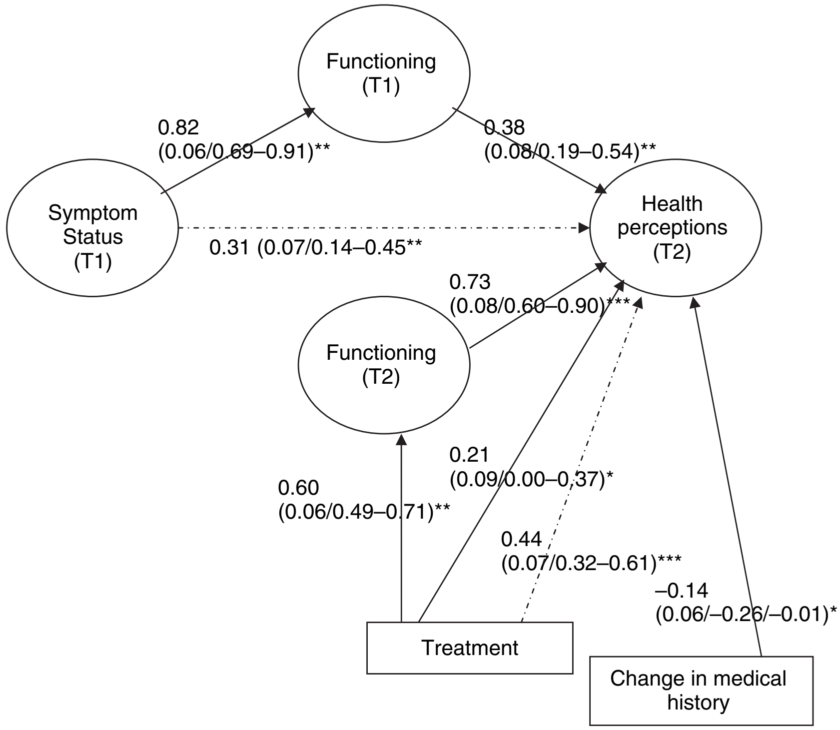

Fig. 3. Bootstrap standardized estimates (SE/BC 95% CIs) for the 'final' more parsimonious prospective 3-factor structural equation model. Indicator variables, and residual error and disturbance terms are omitted to ease interpretation. Solid lines, direct path; dashed line, significant indirect paths. $^{*}P < 0.05$, $^{**}P < 0.01$, $^{***}P < 0.001$.

perceptions was mediated by daily functioning. Those individuals who perceived their symptoms to be worse (greater impact on eating, more difficulty chewing, and more symptoms of dry mouth) reported poorer day-to-day functioning which, in turn, led to lower global oral health ratings. Finally, those older people who received the intervention (domiciliary denture service) reported significantly better daily functioning and global oral health ratings, than did those in the control group.

These relationships were significant prospectively; that is, baseline levels, prior to the intervention, predicted those at 3-month follow-up, with one exception. Participants' baseline symptom status was not predictive of functioning at follow-up. One explanation could be that the highly significant treatment effect negated any lagged analysis. That is, at follow-up, half of the participants had received new dentures during the interim 3-month period. For these, the provision of new dentures greatly enhanced their chewing ability, lessened the impact on eating, and improved daily functioning. As such, there would not be expected to be a relationship between symptom levels prior to the intervention and functioning at follow-up when averaged across all study participants. The finding that symptoms predicted functioning when both were measured cross-sectionally, before the intervention, would support such an interpretation.

A secondary aim of the analysis reported here was to examine separately the psychological, physical and social dimensions of functional status. Unsurprisingly, given the physical limitations experienced by our sample, the greatest impact was on physical functioning, followed by psychological and then social functioning. Given that these were housebound elderly, few social impacts would be expected as measured by OHIP items such as, 'avoid going out', 'unable to enjoy people's company' and 'unable to work'. The results of the confirmatory factor analysis, in which the OHIP social dimension score had the lowest loading on the latent functioning variable and the OHIP physical score the highest, would support the relative importance of these dimensions in this sample. Nevertheless, each of the three-dimension scores were still independent indicators of functioning, albeit significantly interrelated (*covariances* = 0.66–0.82). Data such as these support the importance of distinguishing between the different components of HRQoL when selecting research instruments, and particularly for the analysis of treatment effects (33). This is because when (HR)QoL is used as a clinical outcome measure, some domains might be influenced by treatment whilst others may not (34). Indeed, *post hoc* analysis of the present data indicates that this was the case; for individuals who received treatment, the mean difference in physical functioning (as measured by

OHIP) from baseline to follow-up was 23.19, compared to a difference of 10.45 in psychological and 3.11 in social functioning. This indicates that patients may evaluate the impact of treatment (and oral health) on various aspects of their lives differently. Furthermore, given that the intervention was a physically-orientated treatment, the finding that it led to improved psychological functioning is important. Indeed, it emphasizes the importance of designing clinical interventions that are aimed at minimizing psychological disability and discomfort, and are not solely limited to physical aspects. However, such decisions will depend to a certain extent on the patient population, given that different health conditions are likely to have a differential impact on everyday physical, social and psychological functioning.

The statistical technique utilized here – structural equation modelling – allows us to address complex questions about the interrelationships between clinical and nonclinical variables in oral health through the *a priori* testing of theoretical models. Importantly, such modelling will also allow exploration of the potential role of individual and environmental contextual variables in oral health quality of life. As noted by Wilson and Cleary (1) and others (15), it is likely that a range of contextual factors impact on both the reporting and experience of symptoms, daily functioning, and health perceptions. A host of factors have been identified including coping strategies (35), social support (36), optimism and negative affectivity (37). In relation specifically to Wilson and Cleary's model, sense of coherence (12) and control perceptions (14) have been found to be important individual characteristics in predicting symptom status, functioning and general health perceptions. Such factors were not included in the present study. Yet, in our final model, 67% and 36% of the variance in functioning at T1 and T2 was explained, suggesting that key individual difference and environmental factors may play an important role. For example, it has been found that for older edentulous people, types of coping strategies can impact on OHRQoL (38). Nevertheless, whilst it is important to identify types of contextual factors that might be important, in order to aid further conceptual development of Wilson and Cleary's model, it will also be necessary to examine their exact role in the causal pathways between key variables. For example, such contextual variables may act as moderators, mediators, independent or confounding factors (39). These need to be clarified and operationalized within the Wilson and Cleary's model, whilst recognizing that such factors are likely to play a dynamic role in causal pathways; their effects changing according to time, life circumstance, and/or stage of disease, resulting in what has been termed response shift (40).

Conclusions and implications

This is the first study to systematically model prospectively the pathways hypothesized within Wilson and Cleary's model of patient outcomes in relation to oral health. As such, the findings have a number of implications. To date, much OHRQoL research has been limited by the lack of a systematic application of a theoretical framework. Whilst some previous studies have implicitly used models such as that by Locker (18) or Wilson and Cleary (1), they have not systematically examined proposed relationships contained within them. Our findings support Wilson and Cleary's model as applied to an edentulous elderly population, and further extend the validity of this model within the oral health field (15). Whilst structural equation modelling is a relatively new development in QoL research, the present study has shown that it provides a way of testing hypothetical models and offers wide scope to the theoretical development of the concept of OHRQoL. Further, theoretically-driven research which utilizes such techniques is necessary to aid the development of the field, and to address the many terminological, conceptual and statistical confusions within OHRQoL research.

Finally, our data, together with the report of the original randomized control trial (24), provide evidence for the effectiveness of domiciliary dental care in relieving physical symptoms and improving day-to-day physical, psychological and, to a lesser extent, social functioning.

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