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Original article

Three valid questionnaires for patient perception of fixed appliance orthodontic treatment

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Summary

Background/objective: To assess the validity and reliability of a series of three questionnaires for the quantification of patient perception of fixed appliance orthodontic treatment.

Subjects and methods: The study was carried out at the University of Dundee with content and face validity being assessed using proformas. Initially ten experts (Orthodontic Specialists) assessed content validity with 11 professionals (seven Orthodontic Specialists and four Postgraduates) and 20 patients assessing face validity. Content validity was determined according to the values of item-level content validity index (I-CVI) and scale-level CVI (S-CVI/Ave), while specially designed feedback forms were used for face validation. Internal consistency determined the reliability of the questionnaires according to the value of Cronbach alpha correlation coefficient test. The three questionnaires were then modified according to the recommendations of professionals and patients with seven experts reassessing content validity and ten newly selected patients assessing face validity.

Results: The first round of content validity revealed that around half of the items in the questionnaires were not valid. Therefore, the questionnaires were not valid as a whole (S-CVI/Ave = 0.60). After modifying the questionnaires and removing the non-valid items, the new versions of the Pre-treatment, Orthodontic Experience, and Post-treatment Questionnaires showed high levels of face validity, content validity (S-CVI/Ave: 0.99, 0.97, and 0.99, respectively) and good levels of internal consistency ($\alpha = 0.86, 0.78, \text{ and } 0.88$, respectively).

Limitation: The patient sample was collected from a single university clinic and from one city within the UK and this could affect the generalizability of the results.

Conclusion: Three content valid and reliable questionnaires have been developed and validated for the evaluation of patient perception of fixed appliance orthodontic treatment.

Implications: Unlike other tools that assess oral health quality of life, this series of three questionnaires assess the perception of fixed appliance orthodontic treatment before, during and after treatment.

Introduction

Questionnaire validity is the ability of a questionnaire to address its objectives (i.e. whether or not it measures what it is intended to

measure) (1,2). Content validity is ‘the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose’ (3). This can

- also be defined as 'the degree to which an instrument has an appropriate sample of items for the construct being measured' (4). Content validity is undertaken by experts to ascertain whether the content of the questionnaire is appropriate and relevant to the purpose of the study or if particular items should be omitted or if additional items and statements are required (1,4,5). A panel of at least three experts is required, but a larger number is advisable to determine the relevance of the individual items and the scale as a whole to the underlying construct (what the questionnaire intends to measure). This is done both qualitatively and quantitatively using the content validity index (5). Alternatively, face validity is considered as the simplest as well as the weakest form of validity and is sometimes confused with content validity. However, it is more superficial and does not require any quantitative methods. It measures the appropriateness of the content of the questionnaire, which can be regarded as 'on the face of it', by evaluating its appearance in terms of relevance to the construct, clarity of the language and readability, style and formatting consistency and feasibility. It can be evaluated by experts and respondents as well (2,5-9).
- Questionnaire reliability is a process in which the questionnaire is reviewed to determine reproducibility or stability (repeatability) and internal consistency (to ensure that the items of the questionnaire are well fitted conceptually) (2,6).
- Most of the published studies in the literature have used questionnaires designed for children (with or without help from their parents) using generic oral health-related quality of life (OHRQoL) questionnaires or modified versions of these. These include the 14-item Oral Health Impact Profile (OHIP and OHIP-14), the Child Perception Questionnaire (CPQ and CPQ11-14), the United Kingdom Oral Health-Related Quality of Life (OHQoL-UK), the Oral Impacts on Daily Performance (OIDP), the Short-Form 36-Item Health Survey (SF-36), Oral Aesthetic Subjective Impact Scale (OASIS), Malocclusion Impact Questionnaire (MIQ), and the Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ). Other specific questionnaires evaluate aesthetics (e.g. the Dental Aesthetic Index) or pain during treatment. These instruments were not originally developed for patients undergoing fixed appliance orthodontic treatment but for the impact of malocclusion or other health issues on quality of life and they may not be directly applicable in orthodontics (10-12), and so may not address certain aspects of fixed appliance orthodontic treatment. Currently, the impact of orthodontic treatment is usually measured in terms of the improvement of the oral health-related quality of life with little attention to the impact of appliances on treatment. Therefore, this study aimed to develop a set of validated questionnaires to assess patient perception throughout orthodontic treatment with fixed appliances.
- The questionnaires used in this study were produced by O'Brien *et al.* (13) for the evaluation of patient perception and experience with functional appliances and since fixed and functional appliance orthodontic treatment share many aspects it was decided to modify and validate these questionnaires for fixed appliances rather than starting afresh.
- The null hypothesis was that the series of three questionnaires are not valid indices for measuring patient expectation, experience and satisfaction with fixed appliance orthodontic treatment.
- ## Subjects and methods
- Content and face validity were undertaken to assess the validity of the three questionnaires through two rounds.
- ### Content validity
- A quota sample of ten Specialist Orthodontists were invited to participate in an expert panel for content validity. They were international, practiced in a variety of geographical regions and settings with different levels of experience. Each expert/reviewer received copies of the three questionnaires along with instructions, the three constructs and their domains. The experts were asked to independently determine the relevance of each questionnaire item to the relevant underlying construct using a 4-point Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = relevant, 4 = very relevant). The constructs were created after a comprehensive review of the literature and expert consultation as suggested by Lynn (5) and Mastaglia *et al.* (14).
- The Constructs*
- Pre-treatment Questionnaire:
 'Patient expectations of treatment with fixed orthodontic appliances'
- Smiles-Better Questionnaire:
 'Patient experience during active treatment with fixed orthodontic appliances'
- Post-treatment Questionnaire:
 'Having undergone orthodontic treatment with fixed orthodontic appliances, this will have had an impact on the patient's dental health status and lifestyle'
- Content validity was assessed using the content validity index (CVI), which is the proportion of items in the questionnaire considered relevant to the construct by the content expert raters (15,16). Both the item-level CVI (I-CVI) and the content validity of the overall scale or the scale-level CVI (S-CVI) were calculated according to Lynn's method (1986) (5,12,13). The item-level CVI (I-CVI) was calculated as the number of content experts who rated each item 3 or 4 (relevant and very relevant) divided by the total number of experts (the proportion of experts who rated each item as content valid). Therefore, the 4-point ordinal scale was dichotomised into a 2-point nominal scale of 'relevant' and 'not relevant'. Since the number of expert raters in this study was 10, a minimum of eight experts rating 3 or 4 were needed to determine the item to be content valid and therefore retained in the questionnaire (I-CVI \geq 0.80 at $P < 0.05$). The S-CVI (or S-CVI/Ave) was calculated as the proportion of total items rated as 'content valid'. This was also obtained by averaging the I-CVIs for all items on the scale (16). For the overall questionnaire to be valid a minimum accepted level of S-CVI/Ave was 0.90 as recommended by Waltz *et al.* (15).
- ### Face validity
- The professional panel consisted of eleven members (seven Specialist Orthodontists and four orthodontic postgraduate students) of varying nationality and experience. Each member of the panel was asked to review the questionnaires to assess the appropriateness for patients treated with fixed orthodontic appliances as well as the clarity of the phrases, consistency of the style and formatting, completeness, and order of the questions. The professional panel recorded their data on feedback forms created for this purpose using a 4-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree). The same procedure was followed with a group of 20 patients, who consented to participate and were provided with a copy of each questionnaire and the respective feedback form. They were selected using a non-random quota sampling method from

patients scheduled for fixed appliance treatment from a variety of age groups with no need for adjunctive treatment. The feedback proformas followed a systematic layout and were designed by the authors and then by an independent reviewer before use.

Questionnaire modification

The questionnaires were then modified by excluding the non-valid items (those with I-CVI < 0.8) from content validity with other items modified and additional items included according to the feedback from the face validity panels (two items for the Pre-treatment and three items for the Post-treatment Questionnaires).

Revalidation

The same procedures were performed in the second round of validation. A panel of seven experts (six of whom participated in the first round) and a further non-random quota sample of ten patients were involved.

Reliability

The validated versions of the Smiles-Better (Orthodontic Experience Questionnaire), Pre-treatment and Post-treatment Questionnaires were assessed for internal consistency reliability to determine the strength of inter-item correlations. Due to the change in the environment/situation of patients because of treatment, it was not possible to test the questionnaires for repeatability (test-retest). In order to identify the number of subscales with items that were primarily related to each other within the Orthodontic Experience Questionnaire, a factor analysis using principal components analysis with varimax rotation was undertaken.

Statistical analyses

Content validity was determined according to the values of I-CVI and S-CVI/Ave using a spreadsheet (Excel, Microsoft, Washington, USA).

Regarding face validity, a questionnaire is only assessed as valid when it 'looks like' a valid measure of the construct with adequate percentage of each parameter in the feedback form (>70 per cent was used in the absence of a published threshold as this is generally accepted as being adequate in agreement tests). The Cronbach alpha correlation coefficient was used for assessing internal consistency reliability (9). The acceptable value was considered as ≥ 0.70 (17,18). Factor analysis using principal components analysis with varimax rotation was undertaken to identify the number of underlying subscales. Statistical Package for Social Sciences for Windows, version 22.0 (SPSS Inc, Chicago, IL, USA) was used for Cronbach alpha and factor analysis.

Results

Pre-treatment questionnaire

First round of validation

For content validity, 12 items were relevant to the construct under investigation (I-CVI ≥ 0.80), while 11 items were non-valid (I-CVI < 0.80). The CVI for the overall questionnaire (S-CVI/Ave) was 0.60, which is below the threshold for questionnaire validity (0.90; Table 1). The non-valid items were therefore removed.

The questionnaire had near perfect agreement with both professionals and patients for face validity (overall agreement = 97.52 per cent and 100.00 per cent, respectively). Following this round, the questionnaire was modified according to the recommendations of the professionals and patients by merging six items to become three items, whilst two items were added: 'To make it easier to brush my teeth' and 'To stop/prevent pain in my jaws/joints' (Supplementary Tables 1 and 2). The total number of items therefore became 11.

Revalidation

Only one of the additional items (related to pain) was not content valid (I-CVI = 0.57). However, the overall questionnaire had almost perfect content validity (S-CVI/Ave = 0.95), and after removing the

Table 1. Content validity results for each item in the Pre- and Post-treatment Questionnaires (first round)

| Validity | No. | Pre-treatment Questionnaire Items | I-CVI | Post-treatment Questionnaire Items | I-CVI |
|-----------------|-----|--|-------|--|-------|
| Valid items | 1 | To make my smile nicer | 1.00 | It has made my teeth look nicer | 1.00 |
| | 2 | To make my teeth look nicer | 1.00 | It has made my face look better | 0.90 |
| | 3 | To make my face look better | 0.80 | It has made me look better | 1.00 |
| | 4 | To make me look better | 1.00 | It has made me more confident | 1.00 |
| | 5 | To feel more confident | 0.90 | It has made me feel better about myself | 1.00 |
| | 6 | To make me feel better about myself | 1.00 | It has made me feel better about going out | 1.00 |
| | 7 | To make me feel better about going out | 0.80 | It has made it easier to get on with people | 0.80 |
| | 8 | To help my top and bottom teeth fit together | 0.80 | It has helped my top and bottom teeth fit together | 1.00 |
| | 9 | To help my front teeth fit together | 0.90 | It has helped my front teeth fit together | 1.00 |
| | 10 | To help my back teeth fit together | 0.80 | It has helped my back teeth fit together | 0.80 |
| | 11 | To help me chew food better | 0.80 | It has made it easier to chew my food | 0.80 |
| | 12 | To make it easier to bite into food | 0.80 | It has made it easier to bite into food | 0.90 |
| Non-valid items | 1 | To make my family happy | 0.40 | It has made my family happier | 0.30 |
| | 2 | To help me with my school work | 0.00 | It has helped me with my schoolwork | 0.20 |
| | 3 | To help my breathing | 0.10 | It has helped my breathing | 0.10 |
| | 4 | To help me speak more clearly | 0.40 | It has helped me speak more clearly | 0.40 |
| | 5 | To keep my gums healthy | 0.60 | It has made my gums healthier | 0.60 |
| | 6 | To make me healthier | 0.20 | It has made me healthier | 0.10 |
| | 7 | To keep me from losing teeth in the future | 0.40 | It will stop me losing teeth in the future | 0.10 |
| | 8 | To help me make friends | 0.30 | It is easier to make friends | 0.70 |
| | 9 | To keep my jaw joints healthy | 0.20 | It has helped to keep my jaw joints healthy | 0.10 |
| | 10 | To help keep my jaw joint from clicking | 0.30 | It keeps my jaw joint from clicking | 0.20 |
| | 11 | To make it easier to get on with people | 0.40 | | |
| | | S-CVI/Ave | 0.60 | S-CVI/Ave | 0.64 |

non-valid item, the S-CVI/Ave increased to 0.99. Only one item had I-CVI = 0.86, while nine items had I-CVI = 1 (Table 2). The feedback from the experts in this round recommended re-including the non-valid item 'To make it easier to get on with people' and to merge it with 'To make me feel better about going out' in order to match the same item in the Post-treatment Questionnaire.

The 10 patients indicated that the questionnaire was clear, understandable, easy to follow and had a consistent format and layout. No further recommendations were provided.

The new version of the Pre-treatment Questionnaire comprising ten items and was therefore found to be almost perfect in terms of content and face validity (Supplementary Questionnaire 1).

Post-treatment questionnaire

First round of validation.

Only 12 items were content valid and relevant to the construct under investigation (I-CVI ≥ 0.80), while 10 items were non-valid (I-CVI < 0.80). The CVI for the overall questionnaire (S-CVI/Ave) was 0.64, which was below the threshold for questionnaire validity (0.90; Table 1). The non-valid items were therefore deleted.

The professional and patient groups considered the questionnaire as having appropriate face validity to be used as a 'Post-treatment Questionnaire for Orthodontic Patients' (overall agreement = 98.35 per cent and 100.00 per cent, respectively). Following this round, the questionnaire was modified according to the recommendations of the professionals and patients by merging eight items to become four items, whilst three items were added: 'It has made my smile better', 'It is easier to brush my teeth' and 'My jaw/joint pain is better' (Supplementary Tables 1 and 2). The total number of items therefore became 11.

Revalidation

The results revealed that only one of the additional items (related to pain) was not valid (I-CVI = 0.57). However, the overall questionnaire had almost perfect content validity (S-CVI/Ave = 0.94) prior to removing the non-valid item which increased to 0.97 when removed. Eight items received a total agreement (I-CVI = 1.00), while two items had I-CVI = 0.86 (Table 2).

The questionnaire retained face validity as all of the patients reported that the questionnaire was clear, understandable, easy to follow and had a consistent format and layout. No additional recommendations were required.

The new version of the Post-treatment Questionnaire consisted of 10 items and was therefore found to have high levels of both content and face validity (Supplementary Questionnaire 2).

Smiles-better questionnaire

First round of validation

Only 21 items were content valid and relevant to the construct under investigation (I-CVI ≥ 0.80), while 38 items were non-valid (I-CVI < 0.80). The overall questionnaire was also non-valid (S-CVI/Ave = 0.60; Table 3).

Both the professional and patient groups had near perfect agreement that the questionnaire had face validity as a 'Questionnaire for Orthodontic Patients during Treatment' (overall agreement = 97.73 per cent and 98.75 per cent, respectively). Since the valid items for the friendship and family relationship categories were the same, the professionals recommended merging them together with one heading 'Getting on with Friends and Family' (four items merged to two). Therefore, the total number of items became 19 (Supplementary Table 1).

Revalidation

All the items were content valid and the questionnaire as a whole was also content valid (S-CVI/Ave = 0.97). Fifteen items received total agreement (I-CVI = 1.00) and four items had I-CVI = 0.86 (Table 4). The panel recommended moving the item 'Keeping the brace clean is a nuisance' to the first section of the experience of wearing a brace and to change the word 'visits' to 'appointments'.

The modified questionnaire was considered as having appropriate face validity because all 10 patients confirmed that it was clear, understandable, easy to follow and had a consistent format and layout. There were no further recommendations.

The new version of the Orthodontic Experience Questionnaire consisted of 19 items and was found to have adequate content and face validity (Supplementary Questionnaire 3).

Reliability

The Cronbach alpha coefficient for the retained items in the Pre- and Post-treatment Questionnaires demonstrated that both the Pre- and Post-treatment Questionnaires have good internal consistency reliability (α = 0.86 and 0.88, respectively). The same test was used to assess internal consistency for the whole Orthodontic Experience Questionnaire. Three items were not included in the final model: two because of their nominal nature (unlike the rest that were ordinal), namely 'Is wearing a brace what you expected?' and 'Have you had any extra appointments to the hospital because your brace has broken?' and the third excluded item was the effect on hobbies/interest because it was a separate

Table 2. Content validity results for each item in the Pre- and Post-treatment Questionnaires (second round)

| Pre-treatment Questionnaire | I-CVI | Post-treatment Questionnaire | I-CVI |
|--|-------|---|-------|
| To make my teeth look better | 1.00 | It has made my teeth look better | 1.00 |
| To make my smile better | 1.00 | It has made my smile better | 1.00 |
| To make my face look better | 1.00 | It has made my face look better | 1.00 |
| To make me more confident and feel better about myself | 1.00 | It has made me more confident and I feel better about myself | 1.00 |
| To make me feel better about going out | 1.00 | It has made me feel better about going out and easier to get on with people | 0.86 |
| To help my top and bottom teeth fit together | 1.00 | It has helped my top and bottom teeth fit together | 1.00 |
| To help my front teeth fit together | 1.00 | It has helped my front teeth fit together | 1.00 |
| To help my back teeth fit together | 0.86 | It has helped my back teeth fit together | 0.86 |
| To help me chew food more easily | 1.00 | It has made it easier to chew my food | 1.00 |
| To make it easier to brush my teeth | 1.00 | It is easier to brush my teeth | 1.00 |
| To stop / prevent pain in my jaws / joints | 0.57 | My jaw / joint pain is better | 0.57 |
| S-CVI/Ave | 0.95 | S-CVI/Ave | 0.94 |

4.5

4.10

4.15

4.20

4.25

4.30

4.35

4.40

4.45

4.65

4.70

4.75

4.80

4.85

4.90

4.95

4.100

4.105

4.110

4.115

4.120

Table 3. Content validity results for each item in the Smiles-Better Questionnaire (first round)

| Category | Item | I-CVI | | |
|----------|---------------------------------------|--|------|-------|
| 5.5 | Changes because of wearing your brace | Speech | 0.70 | 5.65 |
| | | Eating | 0.80 | |
| | | Drinking | 0.70 | |
| | | Sleeping | 0.50 | |
| | | Appearance | 1.00 | |
| 5.10 | How have the followings affected you? | I am teased | 1.00 | 5.70 |
| | | Sore teeth | 1.00 | |
| | | Soreness in your mouth | 1.00 | |
| | | Soreness from rubbing | 0.90 | |
| | | Feeling embarrassed | 0.80 | |
| 5.15 | Schoolwork | Dribbling | 0.60 | 5.75 |
| | | Keeping the brace clean is a nuisance | 1.00 | |
| | | How have any changes in your speech affected your schoolwork? | 0.50 | |
| | | How have any changes in your eating affected your schoolwork? | 0.20 | |
| | | How have any changes in how you drink affected your schoolwork? | 0.00 | |
| 5.20 | | How have any changes in your sleep patterns affected your schoolwork? | 0.20 | 5.80 |
| | | How have any changes in your appearance affected your schoolwork? | 0.60 | |
| | | If you have experienced teasing how has it affected your schoolwork? | 0.80 | |
| | | Sore teeth | 0.80 | |
| | | Soreness in your mouth | 0.80 | |
| 5.25 | Getting on with friends | Soreness from rubbing | 0.70 | 5.85 |
| | | Feeling embarrassed | 0.70 | |
| | | Dribbling | 0.20 | |
| | | Keeping the brace clean | 0.50 | |
| | | How have any changes in your speech affected your friendship? | 0.50 | |
| 5.30 | | How have any changes in your eating affected your friendship? | 0.30 | 5.90 |
| | | How have any changes in how you drink affected your friendship? | 0.10 | |
| | | How have any changes in your sleep patterns affected your friendship? | 0.10 | |
| | | How have any changes in your appearance affected your friendship? | 0.90 | |
| | | If you have experienced teasing how has it affected your friendship? | 0.90 | |
| 5.35 | Family relationships | Sore teeth | 0.10 | 5.95 |
| | | Soreness in your mouth | 0.10 | |
| | | Soreness from rubbing | 0.10 | |
| | | Feeling embarrassed | 0.70 | |
| | | Dribbling | 0.40 | |
| 5.40 | | Keeping the brace clean | 0.40 | 5.100 |
| | | How have any changes in your speech affected your relationship with your family? | 0.50 | |
| | | How have any changes in your eating affected your relationship with your family? | 0.50 | |
| | | How have any changes in how you drink affected your relationship with your family? | 0.10 | |
| | | How have any changes in your sleep patterns affected your relationship with your family? | 0.50 | |
| 5.45 | | How have any changes in your appearance affected your relationship with your family? | 0.80 | 5.105 |
| | | If you have experienced teasing how has it affected your relationship with your family? | 0.90 | |
| | | Sore teeth | 0.50 | |
| | | Soreness in your mouth | 0.50 | |
| | | Soreness from rubbing | 0.50 | |
| 5.50 | Hobbies/interests | Feeling embarrassed | 0.70 | 5.110 |
| | | Dribbling | 0.40 | |
| | | Keeping the brace clean | 0.60 | |
| | | Music | 0.80 | |
| | | Sport | 0.60 | |
| 5.55 | Tooth movement | Drama | 0.60 | 5.115 |
| | | Singing | 0.60 | |
| | | Going to clubs e.g. scouts or guides | 0.40 | |
| | | Now that you are wearing a brace, do you feel that your teeth are moving? | 0.90 | |
| | | Is it important to you whether or not your teeth are moving? | 0.70 | |
| 5.60 | Your experience of wearing a brace | Is wearing a brace what you expected? | 1.00 | 5.120 |
| | | Have you had any extra visits to the hospital because your brace has broken? | 0.80 | |
| | | If you have had to make extra visits because your brace has broken, has this bothered you? | 0.90 | |
| 5.60 | Your advice to other patients | Based upon YOUR experience of wearing a brace, what would YOU say to someone who was about to have a brace fitted? | 1.00 | 5.120 |
| | | S-CVI/Ave | 0.60 | |

item. The final model therefore consisted of 18 valid items and the result was acceptable ($\alpha = 0.78$). An attempt was then made to cluster items using principal components factor analysis and consequently two main groups or domains were developed (Table 5). These explained 41.5 per cent of variance. The first group included 10 items measuring function, self-concept and interpersonal relations, which involved 26.5 per cent of variance (eigen value = 4.78) and had appropriate internal consistency ($\alpha = 0.82$). The second group included six items measuring pain and experience with fixed appliances. It comprised 14.9 per cent of variance (eigen value = 2.70) and had an acceptable Cronbach alpha value ($\alpha = 0.71$). Two items, related to tooth movement and cleaning of a brace were not included in the above groups due to the low factor loading.

Discussion

This study was designed to assess the validity of three questionnaires for the evaluation of patient perception with fixed appliance orthodontic treatment. As the modified questionnaires demonstrated high levels of validity and good reliability, the null hypothesis was rejected. The questionnaires were initially developed for the evaluation of patient perception and experience with functional appliances, so it is reasonable that some items in the original versions were not relevant to fixed appliance treatment. Content validity is important for every scale/questionnaire, because it ensures that the contents are relevant and representative of the targeted construct and respondents. Otherwise, the data might not fully represent some important aspects of the construct or alternatively could measure variables

Table 4. Content validity results for each item in the Smiles-Better Questionnaire/Orthodontic Experience Questionnaire (second round)

| Category | Item | I-CVI |
|---------------------------------------|--|-------|
| Your experience of wearing a brace | Is wearing a brace what you expected? | 1.00 |
| | Have you had any extra visits to the hospital because your brace has broken? | 1.00 |
| | If you have had to make extra visits because your brace has broken, has this bothered you? | 1.00 |
| | Now that you are wearing a brace do you feel that your teeth are moving? | 0.86 |
| Changes due to wearing your brace | Keeping the brace clean is a nuisance | 1.00 |
| | Eating | 1.00 |
| | Appearance | 1.00 |
| How have the followings affected you? | If you were called names or bullied about your teeth before you started treatment, has this changed? | 1.00 |
| | Sore teeth | 1.00 |
| | Soreness in your mouth | 1.00 |
| | Soreness from rubbing | 1.00 |
| School or work | Feeling embarrassed | 1.00 |
| | Sore teeth | 0.86 |
| | Soreness in your mouth | 0.86 |
| Getting on with friends and family | Called names or bullied due to your brace | 1.00 |
| | Changes in your appearance | 0.86 |
| | Called names or bullied | 1.00 |
| Hobbies/interests | e.g. Music | 1.00 |
| Your advice to other patients | Based upon YOUR experience of wearing a brace, what would YOU say to someone who was about to have a brace fitted? | 1.00 |
| S-CVI/Ave | | 0.97 |

Table 5. Cronbach alpha for the two groups emerged from the Orthodontic Experience Questionnaire using principal components factor analysis (No. of valid cases = 33)

| Domain | Cronbach alpha | Factor loading |
|--|----------------|----------------|
| Group 1: function, self-concept and interpersonal relation | 0.82 | |
| Appearance | | 0.62 |
| If you were called names or bullied about your teeth before you started treatment, has this changed? | | 0.75 |
| Feeling embarrassed | | 0.50 |
| Being called names or bullied due to your brace (school or work) | | 0.74 |
| Appearance (friendship) | | 0.89 |
| Being called names or bullied due to your brace (friendship) | | 0.62 |
| Appearance (family) | | 0.64 |
| Being called names or bullied due to your brace (family) | | 0.64 |
| Eating | | 0.62 |
| Soreness from rubbing | | 0.49 |
| Group 2: pain and experience of wearing a brace | 0.71 | |
| If you have had to make extra appointments because your brace has broken, has this bothered you? | | 0.33 |
| Overall experience | | 0.23 |
| Sore teeth | | 0.73 |
| Soreness in your mouth | | 0.80 |
| Sore teeth (school or work) | | 0.70 |
| Soreness in your mouth (school or work) | | 0.80 |

7.5 from outside the construct domains and consequently the clinical implications derived from that scale would be misleading (3,19). It has also been pointed out that content validity is an essential and primary test for any new or revised scale. It cannot be preceded or substituted by other tests but can be followed by reliability tests or other types of validity such as construct validity or criterion-related validity (20–22).

7.10 **Content validity**

7.10 The quality of content validity of a questionnaire is based on the collective opinion and rating by experts. This depends on their level of experience in the content area and can be considerably compromised by one or more poor content experts (8,19). The expert judges were selected from university dental hospitals and district general hospitals with both adequate clinical and teaching experience in the content field under investigation. The criteria for the selection of the content experts as well as the clear information provided to them about the content construct and domains and the design of the invitation letter were all in accordance with the instructions provided by Grant and Davis (23) and Rubio *et al.* (20). It has also been mentioned that increasing the number of content reviewers to greater than five can account for artificially inflated CVIs or inter-rater agreement occurring by chance, and aids in identifying and excluding outliers, as well as increasing the robustness of the ratings (3,5).
 7.15 The number of the expert reviewers and the use of the 4-point Likert scale were consistent with the recommendations of Lynn (5), Polit and Beck (16), Polit *et al.* (24) and Parsian and Trish Dunning (7).

7.20 Although one round can be acceptable for validation, all the questionnaires in the current study were assessed using two validation rounds in order to allow the questionnaires to be modified and to improve their robustness. Lynn (5), Haynes *et al.* (3), Rubio *et al.* (20) and Polit *et al.* (24) recommended using two rounds of validation or multiple revisions for further refinement, unless only minor and insignificant modifications are required. Moreover, Polit *et al.* (24) suggested inviting a larger expert panel in the first round (about 8 to 12 experts) and a smaller panel in the second round (about 3 to 5 experts). For this study, 10 experts participated in the first round and seven in the second round. In the first round, content validation revealed that 11 out of 23 items were not valid for the Pre-treatment Questionnaire, 38 out of 59 items were not valid for the Smiles-Better, and 10 out of 22 items were not valid for the Post-treatment Questionnaire. These items were subsequently removed from the questionnaires. The original forms of the three questionnaires were also not valid as a whole as they had a S-CVI/Ave value of 0.60 which is below the acceptable threshold of validity. The high number of non-valid items in the Smiles-Better Questionnaire could also be explained because it was relatively long with a lot of repetitive items. For that reason, both experts and respondents recommended the number of items to be reduced. The relevant items in the current study had received percentages of agreement in accordance with both Lynn (5) and Polit *et al.* (24) (it would fall within an excellent range of Kappa analysis of 0.75 or higher).

7.40 Questions about tooth brushing were added both to the Pre- and Post-treatment Questionnaires as they were considered by experts as one of the important missing aspects. Similarly, the ‘smile’ question was added to the Post-treatment Questionnaire due to the importance of smiling for overall facial aesthetics and the close relation of this to orthodontic treatment, as well as to match the Pre-treatment Questionnaire which includes a similar item. On the other hand, two patients in the first round felt that adding questions about dental and jaw pain would be beneficial for both the Pre- and Post-treatment

Questionnaires. However, these items were removed in the second round (Supplementary Table 1). This was because the experts reported that pain is not one of the reasons for seeking orthodontic treatment. This conflict between patients and experts was interesting. The added item (pain in jaws) was recommended by a minority of respondents (2 of 20 patients), whilst the majority of the experts believed that it was not content relevant. In this situation, a balance should be made between the weakest form of validity (face validity by patients) and the more robust form (content validity by experts). Consequently, the finding of content validity is more robust and resulted in the retention of only the most relevant items, such as the pain questions in the Orthodontic Experience Questionnaire because pain is experienced during fixed appliance orthodontic treatment.

7.65 The redundancy of items that mapped to similar aspects of the construct, such as ‘To make my face look better’ and ‘To make me look better’ as indicated by some assessors, allowed these to be merged so that the questionnaires were shorter and easier to answer (Supplementary Table 2).

7.70 Some modifications were found to be useful for the Smiles-Better Questionnaire. The title was changed to the ‘Orthodontic Experience Questionnaire’ to reduce the influence on patients’ answers about smile and appearance. The word ‘Teasing’ was vague and confusing for many patients, therefore it was modified to ‘Called names or bullied’. Similarly, the item ‘I am teased’ was modified to ‘If you were called names or bullied about your teeth before you started treatment, has this changed?’ in an attempt to decrease ambiguity for patients who have not been teased previously as well as to eliminate any confusion about whether teasing was due to the pre-treatment malocclusion or due to appliances. One of the most important modifications related to the ‘Schoolwork’ items because this questionnaire was originally intended to be used by a school age group who can be treated with functional appliances. As a result, it was modified to ‘School or Work’ to be more broadly applicable to all age groups.

7.75 In order to balance the rating options (Improved; No change; Worse/Slightly worse; and Much worse), the ‘Much worse’ category was removed with ‘Slightly worse’ changed to ‘Worse’. It was also suggested that the items relating to the experience of wearing an appliance and tooth movement would be more logical at the beginning of the questionnaire before asking more sensitive questions such as those related to appearance, name-calling, bullying and embarrassment.

7.80 **Face validity**

7.85 For face validity, there was no specific method to be followed. It was therefore decided to evaluate this by achieving an adequate percentage of agreement for each parameter and for the overall questionnaire in the feedback form for professionals and patients. The face validity form was designed in a systematic approach in order to improve the quality of face validity assessment per Trochim *et al.* (9). It was surprising to find that the three questionnaires had adequate face validity even in the first round of validation when they were not content valid. This supports the claim that face validity is the weakest form of validation and using it alone unaided by other types of validation might lead to spurious results. Waltz *et al.* (19) mentioned that face validity does not represent validity in its true sense where there is evidence that the questionnaire is measuring what it was intended to measure, but it only indicates that the scale or questionnaire is apparently measuring what it was claimed to measure (upon review by laypersons). This would in turn encourage respondents and could increase the response rate. However, in this study both content and face validation complemented each other

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because the qualitative feedback was incorporated with the face validation, which was important for adding and modifying some items and this can also be considered as a part of content or pre-content validation. Moreover, both professionals and patients were included in this face validation. This was in line with Lynn (5) who emphasized the importance of asking experts to identify if any important aspects have been omitted, and whether they have recommendations or modifications to improve the items.

Reliability

Reliability of the three questionnaires was measured using the Cronbach alpha test for internal consistency. Test–retest reliability was not evaluated due to the change in respondents' situations. This was in accordance with DeVon *et al.* (6) who stated that test–retest reliability is not suitable for scales or conditions that are changeable over time such as mood, attitude or knowledge especially when there is an intervention. The whole Orthodontic Experience Questionnaire and two domains emerging from it measuring appearance and pain (mainly) had adequate internal consistency ($\alpha = 0.78, 0.82, \text{ and } 0.71$, respectively) (17,18,25,26) and these explained 41.5 per cent of the variance. These two domains included only 16 items, while the non-included items were considered either as individual items testing different aspects of the same construct so they may not be highly correlated with each other or with the total score, or they had low factors loading (<0.2) and consequently these were removed by the analysis. The Pre- and Post-treatment Questionnaires also demonstrated good internal consistency ($\alpha = 0.86$ and 0.88 , respectively).

Comparison with other questionnaires

Modifying a questionnaire is not an uncommon procedure. Bos *et al.* (27) used a questionnaire designed for patients undergoing orthognathic surgery and modified it in order to be used for orthodontic patients. Several modifications to OHRQoL questionnaires for orthodontic patients have been described. However, authors have modified generic OHRQoL questionnaires that were originally developed to measure the impact of malocclusion on quality of life, (28) orthodontic-specific aspects on quality of life (e.g. psychosocial impact of dental aesthetics), (29) or the impact of pain during treatment on quality of life. (30) Moreover, previously published valid and reliable questionnaires have limitations, for example some of these questionnaires are age specific (28–36). Other limitations are related to the aims of existing questionnaires developed for cross-sectional use to measure either motivation, expectations, experiences, or satisfaction (28–37). However, including multiple aspects such as expectations and experience (35) or expectations and satisfaction (37) in the same questionnaire may cause a problem of difficulty in implementing the questionnaire at different time periods. The set of questionnaires presented here were designed to assess patient expectations, experiences, and satisfaction throughout a course of treatment at the appropriate time. Although, these questionnaires were originally designed for orthodontic patients with different appliances, they were comprehensive in their contents, so they were regarded as a good baseline to start with and to be refined and modified in order to be used for orthodontic patients with fixed appliances. This could allow them to be used in clinical trials with fixed appliances.

When comparing the Pre-treatment Questionnaire with a previously developed questionnaire by Sayers and Newton (34), the latter mainly focused on the measurement of patient and parent expectations of orthodontic treatment. The Pre-treatment Questionnaire in this study measures patient expectations and their motivation for seeking treatment, which could be beneficial in identifying patient

needs during treatment and also aligns to the Post-treatment Questionnaire presented here.

With regard to the validation methods, some studies have depended solely on face validity (31,32,34,35,37), which may not be robust enough to fully assess the validity of questionnaires when compared to the content validity process. Mandall *et al.* (33) assumed their questionnaire measuring the impact of fixed appliance on daily life as having face and content validity; however, this was based only on the method of development without using any formal validity assessment.

The patient sample for this study was collected from a single university clinic and from one city within the UK and this could potentially affect the generalizability of the results. However, the impact of this work is that a series of three valid and reliable questionnaires have been developed that are concise and suitable for assessing patient perception at different stages of treatment by all age groups. Future work could investigate if modifications of the questionnaires are required to be valid for other ethnic groups and to convert them to other languages.

Conclusions

1. Three content valid and reliable (internally consistent) questionnaires have been developed for the evaluation of patient expectations, experience, and the impact of treatment with fixed orthodontic appliances.
2. Based on the results of face and content validity undertaken in this study, face validity alone is not robust enough to demonstrate validity of questionnaire for use in this area.
3. This study has demonstrated the importance of both quantitative and qualitative methods in the assessment of validity.

Supplementary material

Supplementary material is available at the *European Journal of Orthodontics* online.

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Ethical approval

The study was conducted in Scotland, United Kingdom. It was sponsored by the University of Dundee, while ethical approval was obtained from the NHS Tayside Committee on Medical Research Ethics (East of Scotland Ethics Service) in October 2009. Research and Development (R&D) approval was obtained from the NHS Tayside Research and Development in November 2009.

Conflict of interest

None to declare

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