



ORIGINAL ARTICLE

# Development of patient information leaflets for fixed, removable, and functional appliances for Arabic-speaking orthodontic patients



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## KEYWORDS

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Functional appliances

**Abstract Objective:** To develop Orthodontic Patient Information Leaflets (PILs) in Arabic.

**Material & method:** This study included five phases starting with Arabic translation of existing British Orthodontic Society leaflets; initial face validation with three orthodontists; content validation with ten orthodontists; final face validation with ten orthodontists, five postgraduate students, and ten patients; and re-translation to English prior to comparing the new documents with the original PILs to verify that all the necessary information were included. The content validity index (CVI) assessed item level (I-CVI) and scale level (S-CVI).

**Results:** The three Arabic PILs were face validated with inclusion of mini-screws, rapid maxillary expansion, and interproximal reduction. Content validity was perfect with no item I-CVI < 0.80. The S-CVI/Ave for PIL Fixed Appliances = 0.98, PIL Removable Appliances = 0.98 and PIL Functional Appliances = 0.97. In the final face validation, the three leaflets received 100% agreement from all observers for consistency of leaflet format and style, clarity, readability and use of adequate phrases. Finally, the leaflets were re-translated and the information was checked by native English speakers to ensure the completeness of information. There were no discrepancies and face validity was excellent.

**Conclusion:** Valid PILs for Arabic-speaking patients undergoing orthodontic treatment with fixed, removable, and functional appliances have been developed.

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## 1. Introduction

The provision of comprehensive information about treatment procedures is part of routine clinical orthodontic care (Patel et al., 2008). One of the established ways to communicate with patients is by using patient information leaflets (PILs) which

are frequently used during orthodontic consultations. Other methods such as mind maps and acronyms (Thickett and Newton, 2006), and computer-based visual methods (Patel et al., 2008) have also been used.

Lack of adequate information about the nature of treatment was considered as one of the causes of lack of patient cooperation and premature termination of orthodontic treatment (Brattström et al., 1991). Therefore, Mortensen et al. (2003) emphasized improving the method of communication with patients undergoing orthodontic treatment in order to understand the nature of their treatment and improve cooperation.

A Patient Information Leaflet is a document usually enclosed in the outer packaging of medicines or medical devices and is written in the national language(s) of the country where it is sold. PILs are widely used to summarize key information in an easy-to-read format. In orthodontics, PILs are often used to provide information regarding treatment procedures and to reinforce existing knowledge related to treatment choices, benefits, risks, and alternatives. This will in turn improve patient communication and satisfaction (Seehra et al., 2016).

The “Fixed Appliances”, “Removable Appliances”, and “Functional Appliances” PILs, published by the British Orthodontic Society (BOS), provide patients with information related to orthodontic treatment and how to care for orthodontic appliances. This information helps avoid unrealistic expectations of treatment and aims to minimize appliance breakages and iatrogenic effects during orthodontic treatment through increased patient awareness, cooperation and satisfaction (Yassir et al., 2017a).

However, the impact of PILs is unknown with minimal evidence having been published about their effectiveness. Excess information, poor presentation and inclusion of irrelevant data all adversely affect the effectiveness of information leaflets (Rajasundaram et al., 2006). Furthermore, whilst some patients read PILs thoroughly, others do not (Pines, 2015). To be relevant a PIL should therefore aim to align well with the actual experience of the treatment being described.

As these PILs were written in English for British people, using these leaflets in Arabic countries is inappropriate, as English is not the first language and is difficult for many citizens to understand. Therefore, developing PILs in Arabic is very important. Sperber (2004) reported that not only should the information be translated, but the new version should be adapted in a culturally relevant and comprehensible form while maintaining the general meaning and intention of the original item. This is due to trans-cultural differences, some of the contents might not be understandable across cultures and may require alteration (Damato et al., 2005; Howard, 2006). Consequently, the validity of the results could be questionable and need to be reassessed even when the translation process is successfully implemented (Duggal and Bansal, 2010).

Since there are no certified PILs for fixed, removable, and functional appliances in Iraq, this study aimed to develop and validate Arabic version of PILs for these appliances based on the British Orthodontic Society (BOS) PILs to provide patients with adequate information related to orthodontic treatment.

## 2. Materials and methods

This study composed of five phases:

*Phase 1:* Arabic translation of BOS PILs for fixed, removable, and functional appliances by one orthodontist and then revised by two other orthodontists.

*Phase 2:* initial face validation of the Arabic versions of PILs with a panel of three orthodontists

*Phase 3:* content validation of the Arabic versions of PILs with a panel of ten experts (orthodontists).

*Phase 4:* final face validation of the Arabic versions of PILs with ten orthodontists, five postgraduate orthodontic students, and ten orthodontic patients.

*Phase 5:* re-translation of the Arabic version to English language by an independent English linguistic speaker for comparison with the original BOS PILs for each appliance to compare the information between original and new versions.

### 2.1. Phase 1: Arabic translation

The BOS PILs for fixed, removable, and functional appliances were comprehensively read by the principal author (YAY) and then translated to Arabic with some modification in the design by categorizing the information into different headings (Supplementary materials 1). The translated versions were then checked for the adequacy of the language, flow and completeness of the information by two other authors (ASK and HFS). All the three authors speak English and Arabic fluently with Arabic as their first language.

### 2.2. Phase 2: Initial face validation

The three authors (YAY, ASK, and HFS) checked the Arabic draft of the PILs to identify if any other information need to be added, especially for the “PIL Fixed Appliances” as there was no intention to develop as many PILs as those already published by the BOS.

### 2.3. Phase 3: Content validation

After completing all the additions from the initial face validation phase and then organizing the PILs, phase 3 (content validation) started. Invitations were sent to 10 specialist orthodontists (a quota sample of an expert panel) whose first language is Arabic and who practiced both in teaching centers and private clinics. They have different experience level in orthodontics ranging from 9 to 22 years and their age ranged from 37 to 47 years. Each reviewer/expert received a link to the PILs on google forms, along with the invitation letter, instructions, and the constructs that were determined for each PIL. Then, they were asked to review the Arabic versions of PILs and independently determine the relevance of each item in the PIL to the underlying construct by means of a 4-point Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = very relevant). The constructs for each PIL were as follows:

*“PIL Fixed Appliances”:*

“Information leaflet indicated for patients who will wear a fixed orthodontic appliance”

“PIL Removable Appliances”:

“Information leaflet indicated for patients who will wear a removable orthodontic appliance”

“PIL Functional appliances”:

“Information leaflet indicated for patients who will wear a functional orthodontic appliance”

The content validity index (CVI) was used to assess the content validity. It is the proportion of items that are considered relevant to the construct by the content expert raters (Waltz et al., 2005, Polit and Beck, 2006). Lynn’s method (1986) was used to calculate the item-level CVI (I-CVI) and the scale-level CVI (S-CVI).

- *I-CVI = the number of experts who rated each item 3 or 4 (relevant and very relevant)/the total number of experts (i.e. the proportion of experts who rated each item as content valid)*

As there were 10 expert raters in this study, a minimum of eight experts should rate 3 or 4 for each item to consider it as “content valid”, and hence can be retained in the PIL ( $I-CVI \geq 0.80$  at  $P < 0.05$ ).

- *S-CVI (or S-CVI/Ave) = the proportion of total items rated as “content valid”. This can also be obtained by averaging the I-CVIs for all items on the PIL (Polit and Beck, 2006).*

The overall PIL can be considered “valid” when the S-CVI/Ave  $\geq 0.90$  (Waltz et al., 2005).

#### 2.4. Phase 4: Final face validation

Two panels (a professional panel of 10 orthodontists and 5 postgraduate orthodontic students; and a panel of 10 patients) were asked to review the “content valid” PILs in terms of:

- Relevance for orthodontic patients undergoing treatment with fixed, removable, and functional appliances
- Completeness of information
- Clarity of words and overall readability

Each member reviewed the three PILs and a feedback form was used for this assessment with a 4-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree). The patients were volunteers who were selected from different settings using a non-random quota sampling method. Written feedback regarding any further modification was permitted during this phase.

#### 2.5. Phase 5: Re-translation of PILs

In this phase the final Arabic versions of the PILs were re-translated to English by an independent English linguistic speaker and the new English versions were assessed by the authors who are native English speakers (DB and GM). Then, comparison was made with the original BOS PILs to identify if there was any missing information in the newly developed PILs.

### 3. Results

#### 3.1. Phase 1: Arabic translation

The Arabic version of the three PILs were revised and approved by the Arabic-speaking authors in terms of the language content.

#### 3.2. Phase 2: Initial face validation

During this phase, minor modifications, such as changing the photographs and adding some words, like variation in bracket materials, were implemented. It was decided that the “PIL Fixed Appliances” should include as much information regarding treatment with fixed appliances as possible. Therefore, some information from the “PIL Orthodontic Mini-screws”, “PIL Rapid Maxillary Expansion” and “PIL Interproximal Reduction” was included to decrease the number of PILs for the same treatment. The following items were added according to the initial face validation:

“PIL Fixed Appliances”:

1. Difficulty of eating during treatment
2. Difficulty of cleaning teeth and appliances
3. Information to address feelings of embarrassment during treatment
4. The impact of changes in tooth position due to treatment on appearance
5. Arch expansion
6. Interproximal reduction (IPR)
7. Orthodontic mini-screws

“PIL Removable Appliances”:

1. Information to address feelings of embarrassment during treatment
2. The impact of changes in tooth position due to treatment on appearance
3. Information about the stage after finishing active treatment

“PIL Functional Appliances”:

1. Information about the period of age when functional appliances can be used
2. Information about if there is severe pain while wearing the appliance
3. Duration of using the appliance per day
4. Regular visits during active treatment
5. Using the appliance during swimming and playing with musical instrument
6. Information to address feelings of embarrassment during treatment
7. The impact of changes in tooth position due to treatment on appearance
8. Information about the stage after finishing active treatment
9. Adding the reminders at the end of the PIL

### 3.3. Phase 3: Content validation

The three PILs showed perfect content validity with no item receiving I-CVI < 0.80, which meant no item had to be removed. The S-CVI/Ave consequently revealed valid scales (PIL Fixed Appliances S-CVI/Ave = 0.98, PIL Removable Appliances S-CVI/Ave = 0.98, PIL Functional Appliances S-CVI/Ave = 0.97). Therefore, there was no need to perform a second round of content validation.

### 3.4. Phase 4: Final face validation

There was 100% agreement between orthodontists, postgraduate students, and orthodontic patients that the content of these leaflets was appropriate and relevant for orthodontic patients seeking fixed/removable/functional appliance treatment and in terms of consistency of leaflets format and style, clarity, readability, and using of adequate phrases. However, some modifications were suggested as shown in [Table 1](#):

### 3.5. Phase 5: Re-Translation of PILs

The PILs were then re-translated into English and revised by two authors (DB and GM). No discrepancies were found in the information provided within each in terms of either content or appropriateness. No missing information was identified when compared to the original PILs. Excellent face validity was noted for the English versions however some minor linguistic and grammatical modifications were carried out.

## 4. Discussion

This study was designed to develop an Arabic version of orthodontic PILs based on those developed by the BOS for fixed, removable, and functional appliances.

The importance of combining verbal and written information about the nature of orthodontic treatment has been noted to enhance patients' understanding, expectations and compliance with treatment ([Culbertson et al., 1988](#); [Mayeaux et al., 1996](#)), however [Nasr et al. \(2011\)](#) could not find a significant influence of verbal and written information on patients' expectations of orthodontic treatment. But this does not mean that ensuring a complete awareness of the possible challenges patients are likely to experience and the negative impacts of orthodontic appliances especially on eating should be neglected ([Carter et al., 2015](#)) as it has been reported that patients may have unrealistic expectations about the effect of orthodontic appliances on what they eat and drink during treatment ([Sayers and Newton, 2006](#)).

Furthermore, patients may misunderstand or forget some of the verbal information during the consultation appointment ([Ley et al., 1973](#)), therefore a supplementary written/visual information helps to reinforce the verbal information ([Thomson et al., 2001](#)). It has been found that people can retain about 20% of what they hear, but this can be increased up to 50% if it is complemented by written or visual input ([Gauld, 1981](#)). This may explain that the level of satisfaction with treatment was greater for patients who received PIL or those who favored written information ([George et al., 1983](#)).

**Table 1** Modifications that have been carried out for the PILs.

#### PIL Fixed Appliances

**Addition:** pre-treatment and post-treatment photos have been added

**Addition:** the appliance can only be removed by the orthodontist using special instruments at the end of treatment

**Addition:** Interdental brushes and dental superfloss will aid cleaning the area between the teeth and brackets

**Addition:** a picture showing intermaxillary elastics has been added

**Modifying** some words to be easier for native Arabic speakers, such as: irregular teeth and screws

**Modification:** cleaning of teeth after each meal instead of twice daily

**Modification:** use of mouth wash at least once daily instead of after each teeth cleaning

**Addition:** a picture showing retainers after treatment

**Addition:** a note has been added for the patients to declare if they have nickel or latex sensitivity

#### PIL Removable Appliances

**Modifying:** some words to be easier for native Arabic speakers, such as: irregular teeth

**Modification:** your orthodontist may advise you to remove it during eating instead of keeping the removable appliance during eating

**Modification:** cleaning of teeth after each meal instead of twice daily

**Modification:** use of mouth wash at least once daily instead of after each teeth cleaning

**Modification:** the photo showing bad oral hygiene due to improper cleaning has been changed

**Modification:** you should remove the appliance during contact sports, swimming or playing musical instruments instead of you should wear a protective shield during physical exercise

**Deletion:** the item about avoiding hard food was deleted as an option to remove the appliance during eating was added

#### PIL Functional Appliances

**Modification:** cleaning of teeth after each meal instead of twice daily

**Modification:** use of mouth wash at least once daily instead of after each teeth cleaning

**Modification:** the photo showing bad oral hygiene due to improper cleaning has been changed

**Modification:** you should remove the appliance during contact sports, swimming and when playing musical instruments instead of you should wear a protective shield during physical exercise

[Harwood and Harrison \(2004\)](#) recommended that PILs need to be translated to other languages to ensure that patients whose first language is not English are able to provide their informed consent. As there are no Arabic versions of orthodontic PILs, and as patient information is mainly verbally based, introducing PILs in a culturally relevant and comprehensible form for Arabic speakers is needed. The BOS leaflets were selected as they are of higher quality, easier to read, and better designed than those produced by the American Association of Orthodontists (AAO) ([Harwood and Harrison, 2004](#), [Yassir et al., 2017a](#)).

After completing the translation of the BOS PILs, some modifications were required. For the Fixed Appliances PIL, information regarding mini-screws, arch expansion, and interproximal reduction were added to decrease the total number of PILs for fixed appliance treatment, whereas information about the difficulty of eating and cleaning, perception of embarrassment and the impact of treatment on appearance were in agreement with Carter et al. (2015) and were added according to the recommendations from the clinical audit of the BOS PILs (Seehara et al., 2016). This permitted the authors to determine the content of the PIL aligned with patient experience using a questionnaire that has been validated for the evaluation of patient experience during orthodontic treatment (Yassir et al., 2017b). For the removable appliance PIL, minimal information that was added was minimal and related to the feeling of embarrassment, the impact of treatment and subsequent treatment. However, several items were added to the Functional Appliances PIL, and apart from the age of using these appliances, most of the items were similar to those from the Removable Appliances PIL as functional and removable appliances have a great deal in common; the presence of pain information, duration of using appliances per day, regular visits, and other considerations were deemed important for inclusion. An embarrassment item was added to the Removable and Functional PILs, in accordance with the findings of Carter et al. (2015) that all types of appliances may cause anxiety or embarrassment especially when eating or speaking after eating with people who were not familiar, and this feeling may decrease with time.

Regarding content validation of the three leaflets, ten members were included in the expert panel because having more than five reviewers would avoid both inter-rater agreement by chance and artificially inflated CVIs. This in turn helps in identifying and excluding outliers and increases the robustness of the ratings (Lynn, 1986; Haynes et al., 1995). The number of reviewers and the use of a 4-point Likert scale was in accordance with Lynn (1986), Polit and Beck (2006), Polit et al. (2007) and Parsian and Trish Dunning (2009). The selected reviewers had at least nine years of clinical orthodontic experience and of working across different settings (teaching hospitals, general dental centers, and private clinics). Their selection and the clarity of the information provided to them was consistent with the instructions provided by Grant and Davis (1997) and Rubio et al. (2003). The invitation letter, instructions and leaflets were sent electronically (using Google Forms) and independently to the reviewers. All items within these leaflets were rated as relevant to the constructs under investigation, and hence the leaflets as a whole were also content valid. Agreement for the relevant items was in the excellent range for kappa analysis (it was concluded that wherever the I-CVI value is greater than 0.78 it would fall within an excellent range of kappa of 0.75 or higher, regardless of the number of experts) (Polit et al., 2007).

The importance of face validation in this study was noted due to incorporating (1) different review levels; experts, postgraduate students, and patients, and (2) qualitative feedback and suggestions for further modifications. All the reviewers accepted the leaflets and noted their relevance for orthodontic patients for each appliance, however they recommended additional information to be included. For example, modifying existing or adding extra pictures, modifying some words for Arabic speakers, modifying the information relating to cleaning teeth, asking about nickel and latex sensitivity before

treatment, adding an option to remove the removable appliance during eating, and removing removable and functional appliances during contact sport instead of wearing mouthguard.

Adding extra pictures was in accordance with Parker (1996) who reported that the presence of color photos that showed the results of treatment and actual appliances was considered as a positive point for the British Dental Health Foundation leaflets. Modifying information about cleaning teeth from twice daily to after each meal was in order to achieve the maximum oral hygiene level during treatment, whereas reducing the use of mouthwash from “after each teeth cleaning” to “at least once daily” was related to the issue of practicality as most patients will not be able to carry the mouthwash with them during the day. Moreover, adding an option of removing the removable appliances during eating was in agreement with Carter et al. (2015) and due to the fact that some patients may actually become distressed when trying to eat with the appliance in place. Therefore, balancing the maximum wear against the potential upset should be considered when advising patients about wear regimes (Carter et al., 2015).

The final phase was the re-translation of the leaflets and confirming the content by English native speakers to compare if the leaflets aligned with the original versions. This stage found there was adequate content and relevance for orthodontic patients with fixed, removable and functional appliances.

Thickett and Newton (2006) suggested that acronyms and mind map methods could have a slight advantage over written information leaflets especially for short-term recall. Patel et al. (2008) concluded that computer-based visual information was superior to written information in terms of information retention over time. However, as no standard method is available to deliver orthodontic information, producing PILs in Arabic is required, and these can be supplemented by other visual methods in due course.

#### 4.1. Strength of the study

This study provides the first Arabic information leaflets for orthodontic patients and this information was based on a widely used leaflets in the United Kingdom. The leaflets were developed to be easily understood and remembered by patients using clear concise titles, adjunctive questions before the relevant text to attract the reader’s attention, making the sentences active rather than passive, simple, short, and the avoidance of ambiguous medical or technical terms (Alexander, 1999; Kitching, 1990; Parker, 1996; Petterson, 1994; Ong et al., 1996). Moreover, the use of explicit categorization (Kupst et al., 1975) and repetition of the most important information (Ley, 1972) at the end of each leaflet was used to enhance recall. This has been accomplished through different levels of validation (experts, postgraduate students, and patients) in order to make these leaflets culturally adapted and as simple as possible.

#### 4.2. Limitations of the study

Although patient information leaflets are considered as important source of information, they cannot be used as a substitute for verbal information and demonstration for some procedures, such as brushing and flossing during orthodontic treatment (Beaver and Luker, 1997). Therefore, both verbal and written information should be provided to achieve adequate

recall. Although these leaflets were assumed to be understandable by all age groups, a future clinical audit could confirm this and assess the readability for patients with low health literacy.

#### 4.3. Recommendation

Legally and ethically, informed consent should state that the patient has been provided with all the information about treatment and treatment options including risks and benefits. Therefore, these PILs should be carefully read before completing the informed consent process with patients.

Future validation for these leaflets in other Arabic countries may be recommended to make sure that it is understandable in different Arabic-speaking regions.

#### 5. Conclusion

Valid PILs for Arabic speaking orthodontic patients undergoing treatment with fixed, removable, and functional appliances have been developed to provide appropriate written information prior to treatment.

#### 6. Ethical considerations

As the work within this manuscript used the survey method, ethical committee approval was not required.

#### CRediT authorship contribution statement

**Yassir A. Yassir:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Visualization, Writing - original draft, Writing - review & editing. **Ammar S. Kadhum:** Data curation, Formal analysis, Funding acquisition, Investigation, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **Hayder F. Saloom:** Formal analysis, Methodology, Project administration, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **Grant T. McIntyre:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **David R. Bearn:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing.

#### Declaration of Competing Interest

None of the authors have any conflict of interest in respect of this manuscript.

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#### Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sdentj.2019.12.001>.

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