Patient Experiences and Emergency Appointments Associated with Orthodontic Appliance Treatment

By

Ashley Cassandra Phuong

A thesis submitted in partial fulfillment of the requirements for the degree of

Master of Science

Medical Sciences - Orthodontics

University of Alberta

ABSTRACT

OBJECTIVE: To investigate patient experience and emergency visits during treatment with the Xbow appliance compared to the Forsus Fatigue Resistant Device (FFRD) used concomitant to full fixed appliances using an existing questionnaire from the literature, and to use the information gained to begin to develop the questionnaire into a common valid and reliable instrument to capture patients' experiences with orthodontic appliances.

METHODS:

First study: Paper questionnaires were administered to 48 adolescent patients with mild-moderate Class II malocclusion randomly allocated into 2 treatment groups: Xbow and FFRD. Patients were instructed to complete the questionnaires at 1 week after insertion of the appliance, and 2 months after insertion of the appliance. Amount of time required to become accustomed to the appliance, side effects experienced, breakage occurrence, as well as the sources of discomfort were explored.

Second study: Modifications were made to the original questionnaire based on findings from the first study. The modified instrument was used in think-aloud cognitive interviews with 9 patients (pre-adolescent, adolescent and adult) currently in treatment with any orthodontic appliance other than full fixed braces for at least 1 month to test the understandability and interpretability of the questions.

RESULTS:

First study: The overall experience with the appliance was similar between the Xbow group and the FFRD group. The majority of the FFRD group felt that insertion of the appliance was quick and easy, compared to the Xbow group which tended to disagree with that statement. The

Xbow group reported the appliance was noticeable, and also some difficulty to open wide/yawn compared the FFRD group. The majority of patients were accustomed to the appliances within 2 months, with the reported mean time to "get used to" the Xbow being 3.95 weeks, and 2.25 weeks for the FFRD. Within the first 2 months, 50% of Xbow patients and 31.57% of FFRD patients reported experiencing a breakage that required an additional appointment. There was no difference in questionnaire responses after 1 week or 2 months.

Second study: Reading comprehension was difficult for younger patients (age 12 and under). Several participants failed to follow written instructions within the questionnaire resulting in response error. Questions regarding eating or drinking with the appliance should be modified for patients treated with removable appliances. Wording of some questions needed improvement to make the questions more understandable, and wording of some response options/Likert scales needed improvement to better match the question. Valuable information elucidating patient experiences was gained from open-ended questions.

CONCLUSIONS: The Xbow and the FFRD are similar in terms of additional appointments and overall patient experiences. Any differences are likely due to the fact that the FFRD is inserted after patients have already become accustomed to full fixed braces. Patients' experiences do not change significantly between 1 week and 2 months. Questionnaires can provide valuable information to orthodontic clinicians and researchers regarding patient experiences associated with orthodontic appliances. This study has begun the process of establishing validity evidence using response processes for a common instrument to capture patient experiences with orthodontic appliances. A rough second draft of the instrument has been developed. Further

testing of the second draft of the instrument is recommended before large-scale administration of the instrument is done.

Preface

This thesis is an original work by Ashley Phuong. The research project, of which this thesis is a part of, received research ethics approval from the University of Alberta Research Ethics Board, Project Name “Crossbow vs Forsus RCT”, No. Pro00021423, March 2012, and “Development of an Improved Patient Experience Questionnaire”, No. Pro00077738, November 2017.

Acknowledgements

I would like to thank my supervisor, Dr. Carlos Flores Mir, for his support, guidance and mentorship over the past 3 years. Additionally, I am grateful to the members of my committee, Dr. Mary Roduta Roberts and Dr. Paul Major for their insight, support and encouragement throughout the development and writing of my thesis.

Special thanks go to Nikki McGill, Helena Gartner and Susan Helwig at the University of Alberta Graduate Orthodontic Clinic for their help and support throughout the data collection process.

I would also like to thank my classmates, Dr. Cecilia Ponce Garcia, Dr. Sahar Abtahi and Dr. Alycia Sam for taking this journey with me.

And lastly, thank you to my husband, Ryan, for his for all of his patience, love and support that have made the past 3 years possible.

Table of Contents

List of Tables

List of Figures

Chapter 1: INTRODUCTION

1.1 Statement of the Problem

A Class II malocclusion is one of the most common clinical problems faced by orthodontists with an estimated one-third of all orthodontic patients treated for this condition.[1] There are many different treatment modalities for correcting Class II malocclusions, including non-extraction, non-surgical treatment involving fixed or removable Class II corrector appliances. These appliances are commonly used for correction of mild to moderate Class II malocclusion cases where dental camouflage of an underlying skeletal problem appears to be a reasonable option. Previous studies have demonstrated that patients have higher cooperation and completion rates with fixed versus removable Class II appliances[2] and thus non-compliance fixed Class II corrector therapy has become increasingly popular.

There are many fixed Class II correctors available for use today, each associated with its own advantages and disadvantages. The Forsus Fatigue Resistant Device (FFRD) (3M Unitek, Monrovia, Calif), consists of a spring that is used concomitant with full fixed appliances to correct Class II dental malocclusion (Figure 1.1). The FFRD is inserted after levelling and aligning of the teeth is completed and a full dimensional archwire is passively in place, which is typically at least 6-8 months into orthodontic treatment. The Xbow appliance (pronounced “crossbow”) is a fixed Class II corrector which consists of 3 main components: a maxillary Hyrax expander, a modified lower holding arch, and interarch springs (FFRD springs) (Figure 1.2). The Xbow is designed to obtain a rapid overcorrection of Class II dental malocclusions in children and adolescents before full fixed appliances are inserted.

A previous study has shown that total treatment length with the Xbow was on average 6 months less than the FFRD, and the total time spent in full fixed appliances was 10 months less than the FFRD[3]. Reduced treatment length is appealing to both patients and clinicians, and reduced time spent in full fixed appliances reduces risk of complications associated with extended time in full fixed appliances such as caries and orthodontically induced external apical root resorption[4].

If treatment effects with both appliances are similar, another differentiating factor clinicians may consider when choosing an appliance may be patient experience and potential comfort. It is important to consider these aspects when selecting a fixed Class II corrector as it will be in place for several months and cannot be removed by the patients themselves to temporarily relieve any level of soft tissue or functional discomfort. Due to their bulky nature they are usually associated with a certain degree of intraoral discomfort and potential appliance breakage.[2]

1.2 Significance of Study

Breakages, and in certain cases discomfort, can result in significant distress for the patient and require "emergency" visits to the orthodontic office, which can ultimately extend the patient's total treatment time and also increase office overhead. These emergency appointments can quickly become a burden on the practitioner, the patient, and their family. Discomfort and extended length of treatment can result in reduced satisfaction with orthodontic treatment.[5] With the wide variety of fixed Class II correctors available for use, it would be beneficial for clinicians to understand the most common sources of discomfort or effects on daily activities associated with specific appliances when considering their use. Clinicians may find this

information useful to educate patients as well as potentially reduce anxiety and motivate patients treated with fixed Class II correctors. Complications resulting in emergency appointments can range from being resolved quickly with minor adjustment to remake of the appliance requiring impressions, additional laboratory costs, and further appointments for insertion. Thus, knowledge about type and frequency of complications associated with specific appliances will also be useful to clinicians.

Questionnaires can be used to gather information from patients regarding their experiences with such appliances. A previous study from the University of Buffalo by Bowman et al[6] used a non-validated questionnaire to investigate patient experiences during treatment with the FFRD in 2012. This questionnaire was developed based on two existing questionnaires: 1. The ''Smiles Better'' survey that was used in the research of O'Brien et al[2] comparing the Herbst and Twin Block appliances, and 2. A survey developed by Lisa Alvetro and David Solid[6] where current and former FFRD patients were questioned about their experiences. Although Bowman et al did find some valuable information about patient experiences with the FFRD, they also reported that the questionnaire may have been confusing or burdensome for some respondents and thus should be shortened and simplified. They also recommended that the questionnaire should have been tested for validity and reliability in order to better support their conclusions.

Since then, modified versions of this questionnaire have been used in several other published articles in an attempt to capture and compare patient experiences with Class II corrector appliances. Elkordy et al[7] compared patient experiences with the FFRD with and without mini-implant anchorage. Hamilton et al[8] compared patient experiences with the FFRD

to the Carriere Motion Class II Correction appliance. Gandhi et al[9] compared patient experiences with the FFRD to the mandibular protraction appliance. These modified versions were shortened and simplified from the original, but were still not tested for validity or reliability. All of the above studies showed signs that respondents may have misinterpreted some of the items. We cannot be certain that any of the questionnaires used above truly captured "patient experience" as defined by the questionnaires themselves. It would be useful for clinicians and for future studies to be able to use a common valid and reliable questionnaire to capture patient experiences with different appliances.

Before validity and reliability of an instrument can be tested, the instrument should first demonstrate that it captures what the researchers intend. Pre-testing questions in their questionnaire context enables researchers to establish whether: 1. Respondents can understand the question concept or task, 2. They do so in a consistent way, and 3. In a way the researcher intended[10]. The cognitive interview method has come to be viewed as an important means to ensure the quality and accuracy of questionnaires and is used to identify and analyze sources of response error in questionnaires[11].

1.3 Objectives

A first study was executed using the existing questionnaire from Bowman et al[6] to investigate patients' comfort levels and overall experience during treatment with the Xbow appliance compared to the FFRD used concomitant to full fixed appliances, as well as quantify the emergency appointments associated with the aforementioned appliances. This data was collected from participants in a randomized clinical trial that involved the assessment of the

efficacy of full orthodontic treatment with either one of those two approaches. The primary focus of that RCT was not to measure patient's experience.

The following goal was to systematically assess what is known so far about patients' experiences or emergency appointments when using fixed Class II correctors and to identify the existing questionnaires used to capture patients' experiences in the literature. A systematic review was completed in this regard.

Finally, a second study was executed for the first steps of the development of a new questionnaire instrument to capture orthodontic patient experiences. A first draft of a new instrument was developed based on the strengths and limitations of current questionnaires and the feedback and experiences noted from the first study. A think-aloud cognitive interview approach was used to gain additional feedback on this draft of the new instrument.

1.4 Research Questions

1. How does patient experience or frequency of emergency visits compare for patients treated with the FFRD vs. Xbow Class II correction appliances among participants of a previously completed RCT?
2. What do we know so far in regards to patients' experiences or emergency appointments when using fixed Class II correctors? What existing questionnaires have been used to capture patients' experiences during Class II malocclusion orthodontic treatment?
3. To what extent is a modified draft instrument understandable and interpretable by orthodontic patients? How can this draft instrument be improved in the future?

1.5 Null Hypothesis

H_{o1}: There are no differences in patient experience or emergency visits for patients treated with the FFRD vs. Xbow Class II correction appliances.

H_{o2}: There are no differences in patient experience or emergency visits for patients treated with the FFRD vs. Xbow Class II correction appliances between 1 week and 2 months post-insertion.

1.6 References

1. Burkhardt, Donald R., McNamara, James A., and Baccetti T. Maxillary molar distalization or mandibular enhancement: A cephalometric comparison of comprehensive orthodontic treatment including the pendulum and the Herbst appliances. *Am. J. Orthod. Dentofac. Orthop.* 2003;123(2):108–16.

2. O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or Twin-block. 2003;5406(August 2002):128–37.

3. Miller RA, Tieu L, Flores-mir C. Incisor inclination changes produced by two compliance-free Class II correction protocols for the treatment of mild to moderate Class II malocclusions. 2013;83(3).

4. Proffit WR. *Contemporary Orthodontics*. 5th Editio. (Elsevier, ed.). St. Louis, Missouri

5. Pachêco-Pereira C, Pereira JR, Dick BD, Perez A, Flores-Mir C. Factors associated with patient and parent satisfaction after orthodontic treatment: A systematic review. *Am. J. Orthod. Dentofacial Orthop.* 2015;148(4):652–9. Available at: http://www.ajodo.org/article/S0889540615007751/fulltext.

6. Bowman AC, Saltaji H, Flores-mir C, Preston B, Tabbaa S. Patient experiences with the Forsus

Fatigue Resistant Device. *Angle Orthod.* 2013;83(3):437–46.

7. Elkordy SA, Fayed MMS, Abouelezz AM, Attia KH. Comparison of patient acceptance of the Forsus Fatigue Resistant Device with and without miniimplant anchorage: A randomized controlled trial. *Am. J. Orthod. Dentofac. Orthop.* 2015;148(5):755–64. Available at: http://dx.doi.org/10.1016/j.ajodo.2015.06.015.

8. Hamilton, CF; Saltaji, H; Preston, CB; Flores-Mir, C; Tabbaa S. Adolescent patients ' experience with the Carriere distalizer appliance. *Eur. J. Paediatr. Dent.* 2013;14(3):219–24.

9. Gandhi P, Goel M, Batra P. Relative comparison and assessment of patient ' s attitude and discomfort between two different types of fixed functional appliances : A comprehensive survey. *J. Orthod. Res.* 2013;1(3):83–8.

10. Collins D. Pretesting survey instruments : An overview of cognitive methods. *Qual. Life Res.* 2003;12:229–38.

11. Willis GB. *Cognitive Interviewing: A Tool for Improving Questionnaire Design*. Thousand Oaks, CA: SAGE Publications; 2005.

1.7 Figures

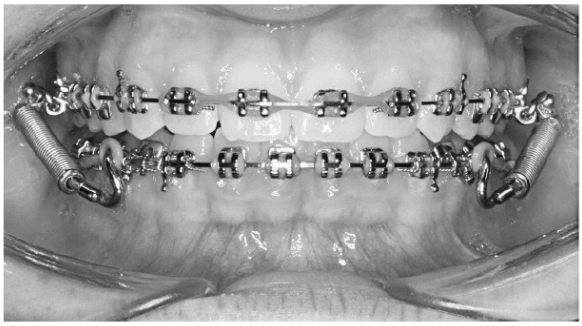

Figure 1.1. *FFRD used concurrent with full-fixed appliances*

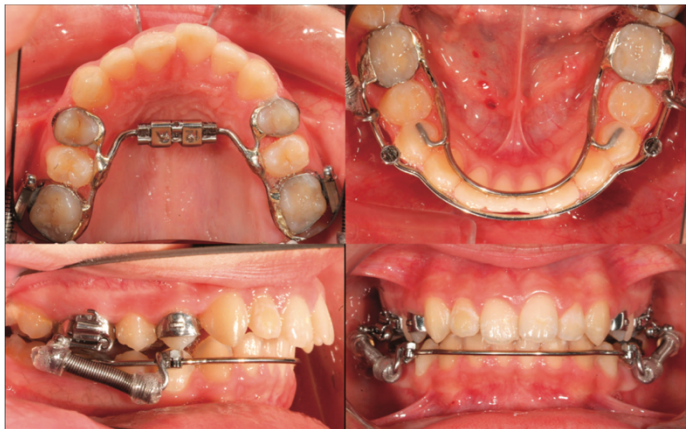

Figure 1.2. *Xbow appliance*

CHAPTER 2: PATIENT EXPERIENCES WITH THE XBOW APPLIANCE COMPARED TO THE CONVENTIONAL USE OF THE FORSUS FATIGUE RESISTANT DEVICE: A RANDOMIZED CLINICAL TRIAL

2.1 Introduction

Class II malocclusions are among the most common clinical problems faced by orthodontists[1]. Many different treatment modalities for correcting Class II malocclusions exist, including non-extraction, non-surgical treatment involving fixed or removable Class II corrector appliances. There are an abundance of studies in orthodontic literature comparing the efficiency and efficacy of these different appliances. Previous studies have suggested that patients have higher cooperation and completion rates with fixed versus removable Class II appliances[2] and thus compliance-free fixed Class II corrector therapy has become increasingly popular.

However, due to their bulky nature compliance-free fixed Class II correctors are usually associated with a certain degree of intraoral discomfort and potential appliance breakage[2]. Breakages, and in certain cases discomfort, can result in significant distress for the patient and could require "emergency" visits to the orthodontic office, which can ultimately extend the patient's total treatment time and also increase office overhead. These emergency appointments can quickly become a burden on the practitioner, the patient, and their family. Discomfort and extended length of treatment can result in reduced satisfaction with orthodontic treatment[3].

A previous study from the University of Buffalo[4] used a non-validated questionnaire to investigate patient experiences during treatment with the Forsus Fatique Resistant Device (FFRD) (3M Unitek, Monrovia, Calif), commonly referred to as Forsus. The FFRD consists of a spring that is used concomitant with full fixed appliances (braces) to correct Class II dental malocclusion

(Figure 2.1). The FFRD is inserted after levelling and aligning of the teeth is completed and a full dimensional archwire is passively in place which is typically at least 6 months into orthodontic treatment. This previous study found that after 2 months of FFRD use, the side effect that most bothered patients was soreness in the lips/cheeks from rubbing. They also found that 37.3% of patients experienced a "breakage" of the FFRD requiring an extra visit to the office.

The Xbow appliance (www.crossboworthodontic.com) is a fixed Class II corrector which consists of 3 main components: a maxillary Hyrax expander, a modified lower holding arch, and interarch springs (FFRD springs) (Figure 2.2). The Xbow is designed to obtain a rapid overcorrection of Class II dental malocclusions in children and adolescents before full fixed appliances are inserted. A previous study has shown that total treatment length with the Xbow was on average 6 months less than the FFRD, and the total time spent in full fixed appliances was 10 months less than the FFRD[5]. Reduced treatment length is appealing to both patients and clinicians, and reduced time spent in full fixed appliances reduces risk of complications associated with extended time in full fixed appliances such as caries and orthodontically induced external apical root resorption[6].

To our knowledge, there have been no studies done to investigate patients' experiences during treatment with the Xbow appliance. The research questions of this study are: How does patient experience or frequency of emergency visits compare for patients treated with the FFRD vs. Xbow Class II correction appliances?

H_{o1}: There are no differences in patient experience or emergency visits for patients treated with the FFRD vs. Xbow Class II correction appliances.

H_{o2}: There are no differences in response to questions regarding their experience or emergency visits for patients treated with the FFRD vs. Xbow Class II correction appliances between 1 week and 2 months post-insertion.

2.2 Materials and Methods

2.2.1 Trial design

This parallel-group randomized trial had a 1:1 allocation ratio.

2.2.2 Participants

The Human Ethics Research Office at the University of Alberta granted authorization for this study. Patients were treated in the University of Alberta Graduate Orthodontic Clinic. The data collected from this study was part of a broader randomized clinical trial measuring treatment outcome from the same sample. Inclusion criteria were as follows: 1. At least ½ cusp Class II dental malocclusion bilaterally; 2. Age between 11-17 years; 3. First premolars fully erupted; 4. Second premolars expected to be erupting within the next 6 months if not already fully erupted. Patients who were deemed on clinical assessment to be undoubtedly surgical cases were excluded. All were diagnosed and planned for treatment by the same experienced orthodontist.

2.2.3 Interventions

The 2 treatment groups were: 1. Xbow followed by full fixed appliances, and 2. FFRD used in combination with full fixed appliances. In the FFRD group, a trans-palatal arch was fabricated using bands (3M Unitek) on the maxillary first molars and cemented using Band-Lok (Reliance Orthodontic). 0.022-in slot MBT prescription brackets were bonded to both arches and leveling and alignment progressed until reaching 0.018x0.025-in stainless steel or TMA archwires. The proper size of the FFRD was selected based on manufacturer's instructions and was inserted bilaterally into the mesial aspect of the maxillary molar band headgear tube using

either an L-pin or EZ-module, and the push rod inserted onto the mandibular archwire distal to the mandibular canine. Either cinching back of the mandibular archwires or placement of tie-back modules through the push-rod loop to the mandibular first molar were added for mandibular anchorage.

In the Xbow group, either a trans-palatal arch or Hyrax expander was fabricated using bands (either GAC or 3M Unitek) on the maxillary first molars, and cemented using Band-Lok (Reliance Orthodontic). A modified lower holding arch was fabricated using bands (either GAC or 3M Unitek) on the maxillary first molars, and cemented using Band-Lok (Reliance Orthodontic). The proper size of the FFRD was selected based on manufacturer's instructions and was inserted bilaterally into the mesial aspect of the maxillary molar band headgear tube using either an L-pin or EZ-module, and the push rod inserted onto the lower triple arch and secured with a Guerin lock adjacent to the mandibular first bicuspid.

2.2.4 Outcomes

The day the Xbow or FFRD was inserted patients were given a set of 3 paper questionnaires to take home and be completed at 1 week, 1 month, and 2 months post-insertion. Due to some confusion between the clinical staff and the patients regarding the timing of questionnaire completion, the 1-month questionnaire was eventually eliminated from this study. Patients returned each completed questionnaire to the clinic at their closest corresponding scheduled appointment.

The questionnaire used in this study was a non-validated questionnaire developed at the University of Buffalo. The questionnaire was unaltered from its original form and the term "Forsus" was left on the questionnaire for both the Xbow and FFRD groups (Appendix I). Questions 1-9 asked patients how they felt when they "first got the Forsus appliance". Questions

10-18 asked patients how they felt “right now”. For questions 1-17, 5-point Likert-scales (“Strongly agree” to “Strongly disagree”), 3-point Likert scales (“Not at all” to “A lot”) and yes/no questions were used. Question 16a asked patients to place an “X” along a horizontal line ranging from 0 weeks 8 weeks indicating how long it took to get used to the appliance. Question 18 was an open-ended question where patients were asked to give advice to future patients.

Additional analysis of treatment notes was done to confirm and categorize the number of emergency appointments during the full duration of Xbow and Forsus treatment as this information may be useful for clinicians.

2.2.5 Sample Size

Sample size was calculated based on previous studies assessing amount of mandibular incisor proclination during Class II malocclusion treatment with fixed Class II correctors. A total of 20 participants per group were needed. Considering a potential 20% loss to follow-up, a sample size of 50 patients was desired.

2.2.6 Randomization

Randomization was done by a blinded statistician who generated codes representing each treatment group and placing the codes in sealed numbered envelopes. After patients and their parents consented to take part in the study, the treatment coordinator uninvolved directly with the study opened the consecutive envelope and assigned the patient to that treatment group.

2.2.7 Blinding

Blinding of patients and clinicians was impossible.

2.3 Statistical Analysis

At the end of the data collection period, responses were collected and subjected to statistical analysis. Analyses were performed using IBM SPSS Statistics for Macintosh, Version 24.0 (IBM Corp., Armonk, NY, USA).

To investigate the equivalence of the two treatment groups the following statistical analyses were performed. An independent Student's t-test was used to determine if patient age at appliance insertion was different based on treatment groups. A Chi-squared test was applied to determine if sex distribution was even among treatment groups. MANOVA was applied to determine if there was a relationship between age, sex, and questionnaire responses.

Descriptive statistics were performed for responses to questions of interest. Due to the ordinal nature of the Likert-scale data and violations of normality, non-parametric methods were used. Separate Mann-Whitney U tests were used to determine the differences in Likert scale response to each question between treatment groups at both T1 and T2. Chi-squared tests were used to determine if there were differences in yes/no responses. An independent t-test was performed on log transformed data to compare the mean time in weeks reported in question 16a to "get used" to the appliance between Xbow and FFRD. The data was log transformed to obtain data normality and to utilize the multiplicative effect. Separate Mann-Whitney U tests were used to determine differences in responses to questions between T1 and T2 from each treatment group.

Any responses to closed-ended questions left blank were excluded from the analyses by pairwise deletion in order to retain as much information as possible. A list of questions excluded from statistical analysis with reasons for exclusion can be found in Appendix II. For all statistical analyses performed a significance level of $\alpha = 0.05$ was used.

2.4 Results

Participant flow is illustrated in Figure 2.3.

A few patients did not complete treatment as assigned: One patient discontinued Xbow treatment shortly after insertion due to claimed "allergy" to the appliance. This was followed up

with visits to an allergist with inconclusive results. This patient started treatment later. Another Xbow patient completed the Xbow portion of treatment but moved away while completing the level and alignment phase. Two patients allocated to the FFRD group were not given the intervention because after initial leveling and aligning with full fixed appliances their malocclusion was not considered severe enough to require treatment with the FFRD. A total of 48 patients completed the questionnaires from the 51 that started the RCT (data from the patient that moved away was considered valid for this study as questionnaires were completed when needed). Four patients from the FFRD group and three patients from the Xbow group were later excluded from analysis due to completing the questionnaires at incorrect time points, thus reducing the total sample size in this study to 41, with 19 (12 female, 7 male) FFRD patients and 22 (12 female, 10 male) Xbow patients.

There was a difference in age at appliance insertion date based on treatment group ($P<0.001$), with the mean age of FFRD patients being 14.84 (14.16, 15.53) years of age and the mean age of Xbow treated patients being 13.36 (12.79, 13.94) years of age. There were no sex differences in patient groups ($P=0.577$). There was no relationship between age ($P=0.409$) or sex ($P=0.958$) on questionnaire response. Thirteen of forty-one (31.7%) of analyzed subjects had at least 1 response left blank on a questionnaire at either T1 (8/41, 19.5%) or T2 (6/41, 14.6%), with 1 subject with at least 1 response left blank at both T1 and T2.

Regarding the first objective, for most questions there was no evidence of a difference in response between Xbow and FFRD groups ($P>0.05$) (Tables 2.1-2.4). For the following questions there was evidence of a difference in response: Question 3 (“The appointment to place Forsus was quick and easy”) with the Xbow group reporting more disagreement ($P=0.020$), Question 5

("How noticeable was the Forsus to friends and family?") with the Xbow group reporting more noticeability (P=0.016), and Question 11f ("Right now, how much has the following affected you?: Difficult to open wide/yawn") with the Xbow group reporting more difficulty (P=0.016). Although median values are recognized as the most appropriate method of reporting ordinal data, mean values were also calculated and reported in our study as we found for some questions they were useful in illustrating trends.

Regarding the second objective, for all questions there was no evidence of a difference in response to questions at 1 week compared to 2 months (P>0.05) for either of the Xbow or FFRD groups.

Fifty percent (50%) of Xbow patients and 31.57% of FFRD patients reported experiencing a "breakage" that required an additional appointment within the first 2 months of insertion; however, there is no evidence of a difference between these rates (P=0.327) (Figure 2.4). A bar graph representing crosstabulation of responses to Question 14 ("Have you had any extra visits to the orthodontist because the Forsus was broken?") vs. Question 4 ("I was given instructions for wear and care of the Forsus") suggests no association between responses to these questions (Figure 2.5).

A summary of data retrieved from each patient's treatment notes can be viewed in Tables 2.6 and 2.7. This data revealed a mean of 1.3 emergency visits per FFRD patient with 65.22% of FFRD treated patients experiencing at least 1 visit, and a mean of 2.2 emergency visits per Xbow patient with 76% of Xbow treated patients experiencing at least 1 visit throughout the duration of treatment with the respective appliance. The mean treatment duration for each group was not analyzed for this study.

For patients who answered “yes” to Question 16 (“At this time, do you feel like you have gotten used to the Forsus?”), there is suggestive but inconclusive evidence (P=0.090) that there is a difference in the mean number of weeks it takes to “get used” to the Xbow or FFRD, with Xbow reporting 3.95 weeks and FFRD reporting 2.25 weeks. Using the multiplicative effect of log transformation, the FFRD group “got used” to the appliance 1.45 times quicker than the Xbow group, although again, the evidence is inconclusive (P=0.090). There is no evidence of a difference between Xbow and FFRD treated patients in proportion of patients who reported being “used to” the appliance at 2 months (P=0.249), with 84.21% of FFRD patients and 95.45% of Xbow patients reporting being used to the appliance (Figure 2.6).

2.5 Discussion

When the treatment effects are considered equal or clinically relatively similar, patient comfort and breakage of appliances may become a key factor for orthodontists selecting a specific fixed Class II corrector. This study looked at two treatment methods with the common variable of the FFRD bite jumping spring as the device of force application. Due to the intermaxillary position of the spring, it may be prone to dislodgement or breakage during normal functional activities such as eating. Also, due to the attachment site of the spring lateral to the maxillary first molars in both appliances, it is prone to causing sores in the cheeks around the molar tubes. Thus, the evidence that there was no difference between the Xbow (50%) and FFRD (31.57%) groups in reported incidence of “breakage” or reported soreness in the lips/cheeks from rubbing is reasonable. The results were also similar to those reported by Bowman (37.3%). Elkordy et al[7] distinguished between true “breakages” and “separation of parts” of the FFRD where they found 19% of patients experienced breakages and 25% of

patients experienced separation of parts for a total of 43.7% of patients, which is also similar to the results of our questionnaire. Our questionnaire did not distinguish between true breakages and dislodgements because from the patient's perspective it makes no difference whether the appliance was truly broken or merely dislodged as both situations impose the same inconvenience to patients and parents having to come in for an additional appointment.

As treatment notes were examined for the full duration of Xbow or FFRD treatment rather than the 2 month time point from the questionnaires, the results for percentage of patients experiencing emergency appointments from the notes are different than the numbers reported from the questionnaires (Treatment notes: Xbow 76%, FFRD 65.22% vs. Questionnaires: Xbow 50%, FFRD 31.57%). Part of this difference may be attributed to the fact that treatment note analysis included all 48 patients who received the interventions versus 41 patients who completed the questionnaires. This difference may also suggest that a number of emergencies can occur beyond 2 months after insertion. Based on the treatment notes, 48% (12/25) of Xbow treated patients and 17.39% (4/23) of FFRD treated patients experienced band breakage. In addition to the inconvenience for the patient, band breakage is a significant complication for clinicians as it usually requires significant clinical chair time, laboratory costs, as well as a further additional appointment to re-insert the repaired appliance. The Xbow group likely experienced a higher incidence of band breakage due to a manufacturing flaw in the specific batch of bands that were used for this group of patients, thus 48% is likely an inflated number.

Compared to FFRD treated patients, Xbow treated patients found the placement of the appliance somewhat less quick and easy than FFRD patients, with the FFRD group reporting

median score of “Agree” and the Xbow group reporting a median score of “Neutral”. This difference was expected, since the initial appointment to place the Xbow does require cementing the Hyrax and lingual arch in addition to the FFRD springs alone. A way for clinicians to make the insertion process “easier” for patients would be to cement the Hyrax and lingual arch at a separate appointment before insertion of the springs.

When asked “How noticeable was the Forsus to friends and family?”, the Xbow group reported a median response of “A Little”, whereas the FFRD group reported a median score of “Neutral”. This response was also anticipated as FFRD patients had already been in treatment with full fixed appliances for 6-12 months prior to the insertion of the FFRD springs, during which time friends and family have already noticed the braces and the springs were a minor addition which was likely unnoticeable.

The Xbow group also reported more difficulty opening wide/yawning than FFRD patients, with the FFRD group reporting a median response of “Not at all” and Xbow group reporting a median response of “A little”. A possible explanation for this was described by a patient from the Xbow group in Question 18 (“Your advice to other patients: Based on your experience of wearing the Forsus, what would you say to someone who was about to start wearing the Forsus?”): *“Don’t open your mouth too wide, your cheeks will get pinched”*. This “pinching” may be due to the design of the Xbow push rod having more distance to slide and rotate pinching the cheeks on the lower holding arch, versus sliding on a relatively short distance of orthodontic archwire between 2 teeth used with the FFRD.

For all questions there were no differences in responses between 1 week and 2 months for each of the treatment groups. This may be explained by Stewart et al[8], who found that most

problems relating to discomfort and pain from appliances were resolved within 4-7 days. They also found that responses to questionnaire items did not change significantly between 7, 14, or 90 days. A study regarding palatal expanders by De Fillipe et al[9] also reported that problems with oral discomfort, speech and mastication were resolved within the first 7 days of treatment. Our results suggest that after the initial period of discomfort, responses may be more dependent on the patients themselves than changing over time. For example, if a particular patient is bothered "A little" by sores in the cheek at 1 week, they will still be bothered "A little" by sores in the cheek after 2 months. As seen with Question 16 (Figure 2.5), there are some patients do not report to be completely used to the appliance even after 2 months.

Regarding the amount of time in weeks reported to "get used" to the appliance, there is some inconclusive evidence that patients who were used to the appliance after 2 months in the FFRD group got used to the appliance approximately 1.3 weeks quicker than the Xbow group. As discussed above, this is likely due to patients treated with FFRD already wearing full fixed appliances for 6-12 months prior to FFRD spring insertion. Thus these patients are already acclimated to having orthodontic appliances in the mouth as well as to any tenderness of the teeth caused by orthodontic force. Adding the FFRD springs to full fixed appliances is a relatively minor addition compared to the Xbow group who had the springs inserted at the beginning of treatment before experiencing the force of full fixed appliances. As discussed earlier, if the springs were inserted at a separate appointment after the insertion of the Hyrax and lingual arch, patients would likely "get used" to the springs quicker since they have already become acclimated to the Hyrax and lingual arch being in the mouth. However, despite the apparent increased acclimation period for Xbow patients, at 2 months there was no difference between

FFRD and Xbow groups in proportion of patients who reported they have gotten used to the appliance. This 2-4 week acclimation period for both appliances is also similar to the results reported in the literature for the FFRD[4] and Carriere[10] appliances.

The responses to Question 18 "Your advice to other patients: Based on your experience of wearing the Forsus, what would you say to someone who was about to start wearing the Forsus?" also provided rich information regarding patient's overall experiences. Common themes from both groups included initial discomfort which would eventually "go away", and also food getting caught in the appliances. However, it is interesting that 4 comments from the Xbow group specifically referenced sores or pinching of the cheeks, whereas none of the comments from the FFRD group specifically mentioned the cheeks.

FFRD treated patients were an average of 1.48 years older at appliance insertion than the Xbow treated patients. This is partly due to the FFRD requiring a period of 6-12 months of leveling and alignment with fixed braces prior to insertion. However, there was no evidence of age influencing questionnaire response.

2.6.1 Limitations

The subjects from this clinical trial were all patients of the University of Alberta graduate orthodontic clinic. The subjects were all treated by the same experienced orthodontist; however, the university setting may have impacted the results. University patients tend to have lower dental IQ, poorer compliance with instructions, and poorer compliance with appointments than private orthodontic practice patients[2], and thus the results may not be extrapolated to the general population.

In retrospect, some flaws in study design had a negative effect on the outcome of this study. Patients were given the paper questionnaires at appliance insertion and were told to complete them at specific time points – however there was no way to ensure they were truly completed at those time points. The 7 patients who were excluded from the study had completed the questionnaires at grossly incorrect time points, as reported by themselves, but it is highly likely that other included patients had also completed the questionnaires at incorrect time points, but simply did not report it. Also, 31.7% of analyzed patients had at least 1 response left blank on a questionnaire at either T1 or T2, including 2 patients who left at least 1 entire page blank. Lastly, due to a printing error, sixteen sets of questionnaires were distributed missing the final page and thus those 16 patients were missing responses to Questions 17 and 18. Having an online questionnaire with a time deadline would aid in eliminating these pitfalls.

Another limitation was the use of this particular non-validated questionnaire. Since the questionnaire was not validated, we do not truly know if any of the questions truly captured the specific patient experience. Also, the questionnaire was long and unmodified from its original form for this study. Its length and wordiness may have contributed to incomplete responses or may have led to inappropriate responses to some questions. Attempts should be made to modify and validate the questionnaire.

Any data retrieved from treatment notes is limited by the accuracy of the data entered manually into the notes. Since the clinical staff at the University of Alberta orthodontic graduate clinic knew that these patients were part of a randomized clinical trial, note charting may be likely more accurate and detailed than for non-trial patients.

Sample size was not calculated for this specific question.

2.7 Conclusions

The Xbow and the FFRD are similar in terms of complications (50% of Xbow patients and 32% of FFRD patients) and additional appointments (2.2 for Xbow patients and 1.3 for FFRD patients)) and overall patient experiences. The majority of patients were accustomed to the appliances within 2 months and no significant changes were noted in patients' responses to questionnaire items between 1 week and 2 months. Some slight differences were noted such as the fact that the FFRD group felt that insertion of the appliance was quick and easy, compared to the Xbow group who had a neutral response to this statement and that the Xbow group reported the appliance was slightly more noticeable, and a little more difficulty to open wide/yawn compared the FFRD group.

2.8 References

1. Burkhardt, Donald R., McNamara, James A., and Baccetti T. Maxillary molar distalization or mandibular enhancement: A cephalometric comparison of comprehensive orthodontic treatment including the pendulum and the Herbst appliances. *Am. J. Orthod. Dentofac. Orthop.* 2003;123(2):108–16.

2. O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or Twin-block. 2003;5406(August 2002):128–37.

3. Pachêco-Pereira C, Pereira JR, Dick BD, Perez A, Flores-Mir C. Factors associated with patient and parent satisfaction after orthodontic treatment: A systematic review. *Am. J. Orthod. Dentofacial Orthop.* 2015;148(4):652–9. Available at: http://www.ajodo.org/article/S0889540615007751/fulltext.

4. Bowman AC, Saltaji H, Flores-mir C, Preston B, Tabbaa S. Patient experiences with the Forsus Fatigue Resistant Device. *Angle Orthod.* 2013;83(3):437–46.

5. Miller RA, Tieu L, Flores-mir C. Incisor inclination changes produced by two compliance-free Class II correction protocols for the treatment of mild to moderate Class II malocclusions. 2013;83(3).

6. Proffit WR. *Contemporary Orthodontics*. 5th Editio. (Elsevier, ed.). St. Louis, Missouri

7. Elkordy SA, Fayed MMS, Abouelezz AM, Attia KH. Comparison of patient acceptance of the Forsus Fatigue Resistant Device with and without miniimplant anchorage: A randomized controlled trial. *Am. J. Orthod. Dentofac. Orthop.* 2015;148(5):755–64. Available at: http://dx.doi.org/10.1016/j.ajodo.2015.06.015.

8. Stewart FN, Kerr WJS, Taylor PJS. Appliance wear : the patient's point of view. 1997;19(October):377–82.

9. De Felippe NLO De, Silveira AC Da, Viana G, Smith B. Influence of palatal expanders on oral comfort, speech, and mastication. *Am. J. Orthod. Dentofac. Orthop.* 2010;137(1):48–53. Available at: http://dx.doi.org/10.1016/j.ajodo.2008.01.023.

10. Hamilton, CF; Saltaji, H; Preston, CB; Flores-Mir, C; Tabbaa S. Adolescent patients ' experience with the Carriere distalizer appliance. *Eur. J. Paediatr. Dent.* 2013;14(3):219–24.

2.9 Figures

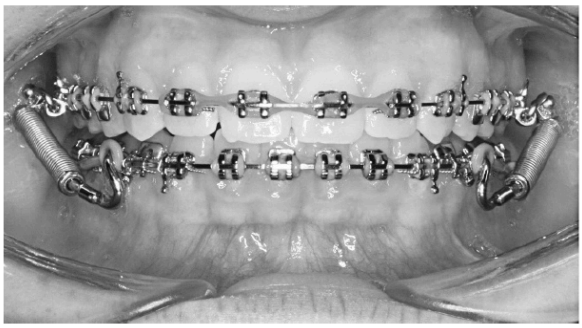

Figure 2.1. *FFRD used concurrent with full-fixed appliances*

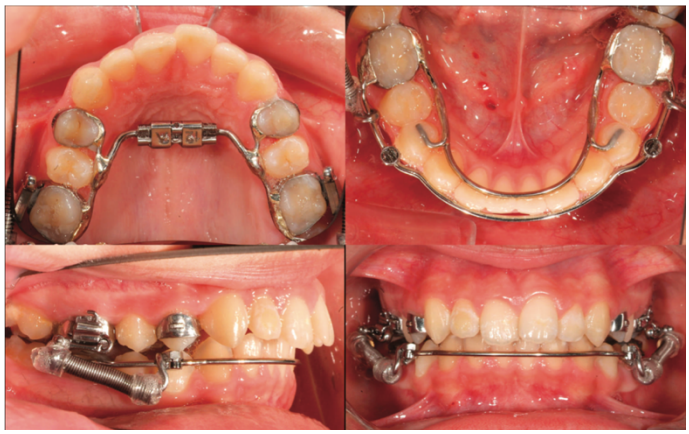

Figure 2.2. *Xbow appliance*

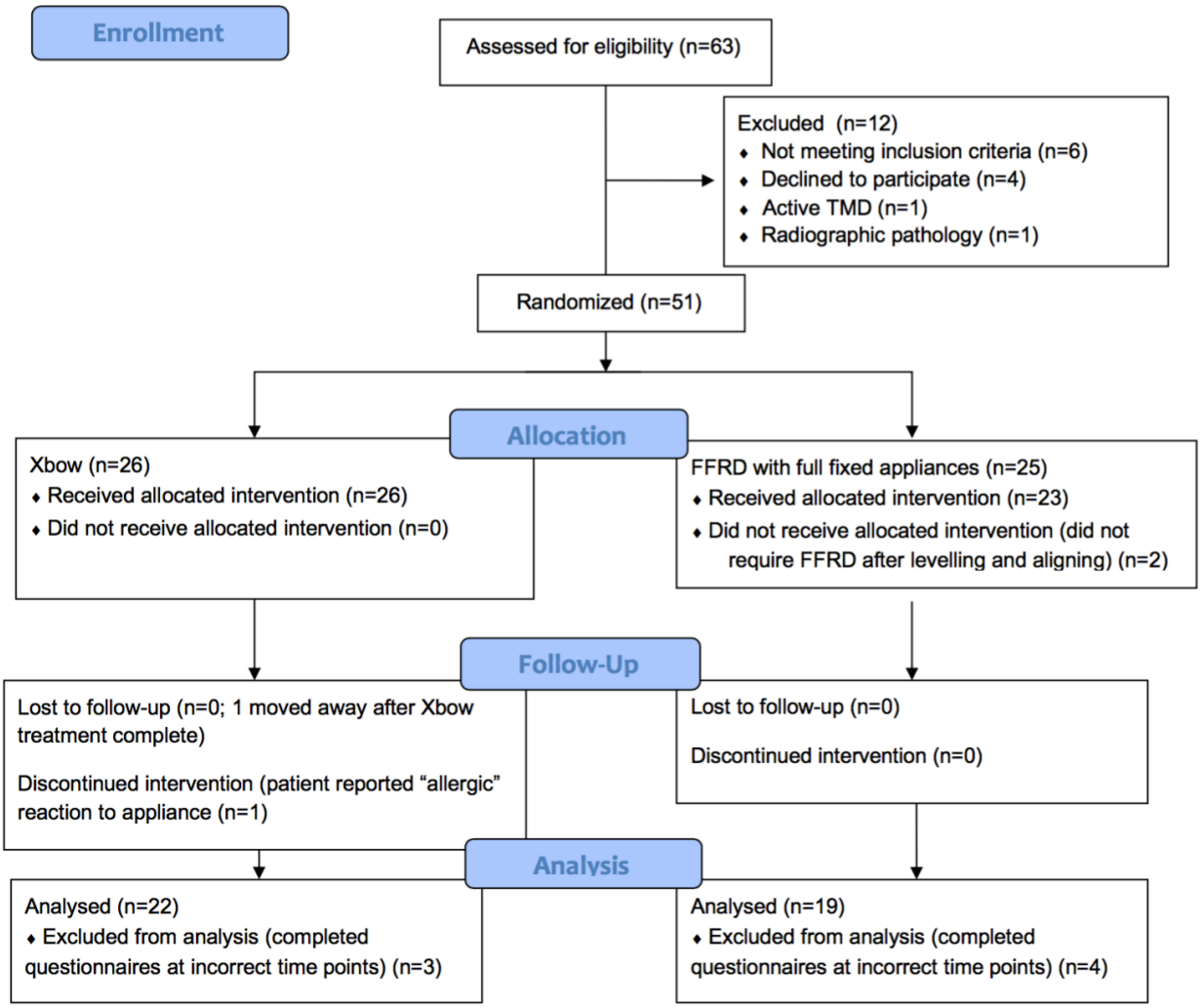

Figure 2.3. *CONSORT flow diagram on enrolment of patients into the study*

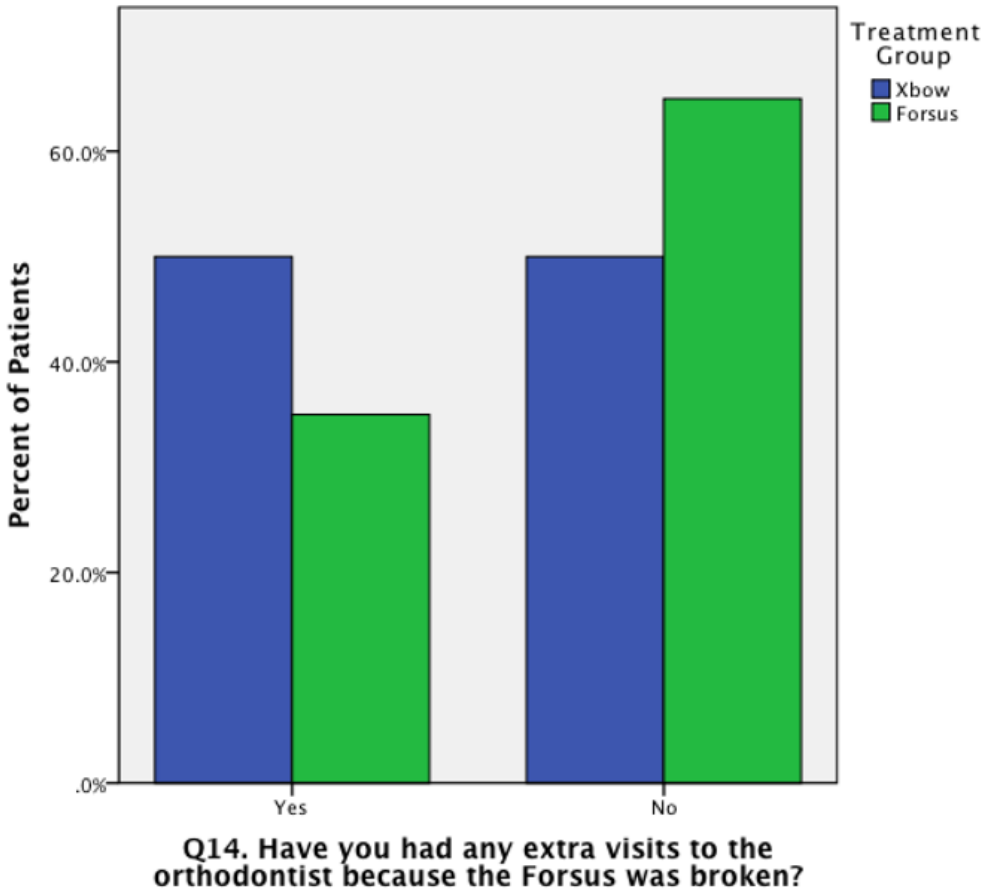

Figure 2.4. *Bar graph representing responses from Xbow and FFRD treated patients at 2 months for Question 14 "Have you had any extra visits to the orthodontist because the Forsus was broken?"*

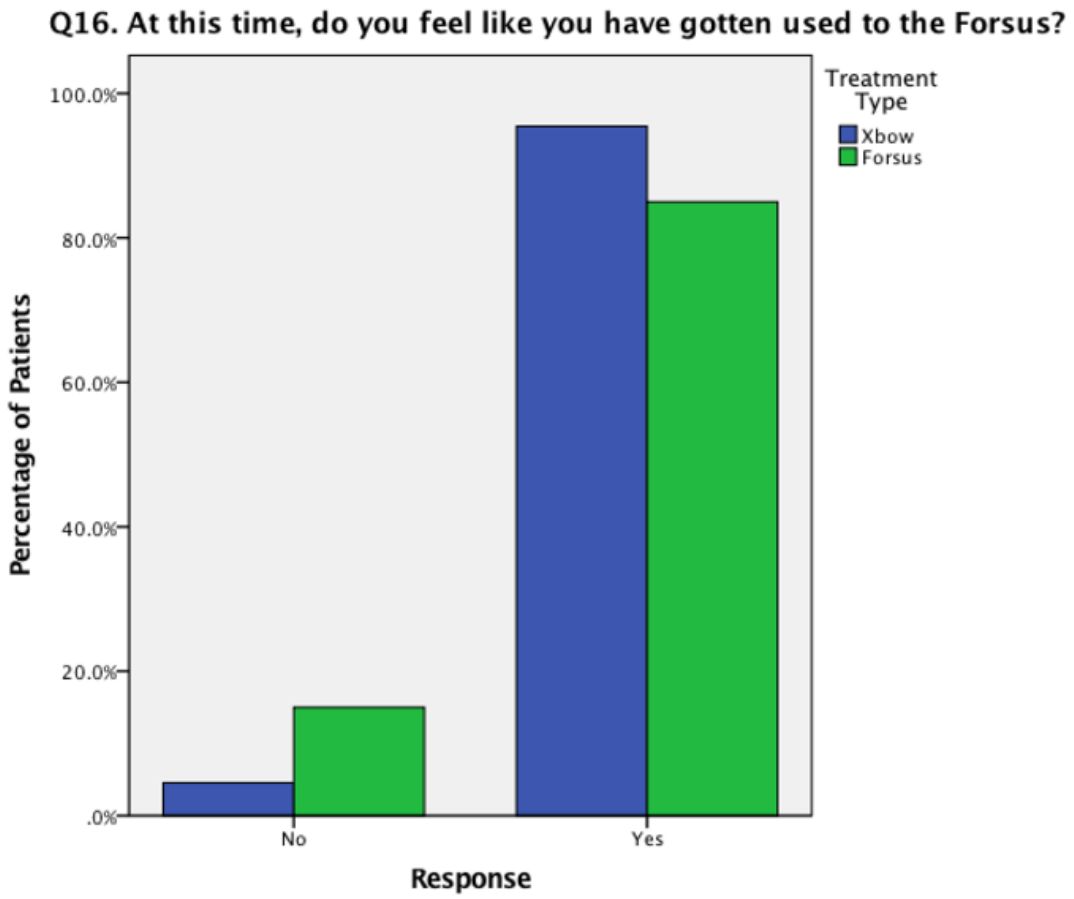

Figure 2.5 *Bar graph representing responses from Xbow and FFRD treated patients at 2 months for Question 16 "At this time, do you feel like you have gotten used to the Forsus?"*

2.10 Tables

Table 2.1 *Mean and median responses to questionnaire items from FFRD and Xbow treated patients (Scale: 1=Strongly agree, 2=Agree, 3=Neutral, 4=Disagree, 5=Strongly Disagree), α = 0.05*

Question	FFRD Mean (Median)	Xbow Mean (Median)	Mann-Whitney U-test P-Value
1. I was given a complete description of the Forsus before wearing it	2.08 (2.00)	2.02 (2.00)	0.773
2. When I first saw it, the Forsus appliance looked scary/overwhelming	3.16 (3.00)	2.93 (3.00)	0.311
3. The appointment to place the Forsus was quick and easy	2.16 (2.00)	2.58 (3.00)	0.020*
4. I was given instructions for wear and care of the Forsus	2.21 (2.00)	2.21 (2.00)	0.668

Table 2.2 *Mean and median responses to questionnaire items from FFRD and Xbow treated patients (Scale: 1=Very Noticeable, 2=Somewhat, 3=Neutral, 4=A little, 5=Not Noticeable), α = 0.05*

Question	FFRD Mean (Median)	Xbow Mean (Median)	Mann-Whitney U-test P-Value
5. How noticeable was the Forsus to friends and family?	3.61 (4.00)	2.91 (3.00)[b]	0.016*

NOTE: b: Note that for this question, a **lower** score corresponds with **more** noticeability

Table 2.3 *Mean and median responses to questionnaire items from FFRD and Xbow treated patients (Scale: 1=Much Improved, 2=Improved, 3=Neutral, 4=Slightly Worse, 5=Much Worse), α = 0.05*

Question	FFRD Mean (Median)	Xbow Mean (Median)	Mann-Whitney U-test P-Value
10a. Right now, while you are wearing the Forsus, how much have the following things changed: Speech?	3.11 (3.00)	3.07 (3.00)	0.928
10b. Right now, while you are wearing the Forsus, how much have the following things changed: Eating?	3.06 (3.00)	3.26 (3.00)	0.459
10c. Right now, while you are wearing the Forsus, how much have the following things changed: Drinking?	2.91 (3.00)	3.00 (3.00)	0.728
10d. Right now, while you are wearing the Forsus, how much have the following things changed: Sleeping?	3.00 (3.00)	3.02 (3.00)	0.754
10e. Right now, while you are wearing the Forsus, how much have the following things changed: Appearance?	2.89 (3.00)	3.05 (3.00)	0.635
10f. Right now, while you are wearing the Forsus, how much have the following things changed: I am teased?	2.89 (3.00)	2.98 (3.00)	0.842

Table 2.4 *Mean and median responses to questionnaire items from FFRD and Xbow treated patients (Scale: 1=Not at all, 2=A little, 3=A lot), α = 0.05*

Question	FFRD Mean (Median)	Xbow Mean (Median)	Mann-Whitney U-test P-Value
11a. Right now, while you are wearing the Forsus, how much has the following affected you: Sore teeth?	1.58 (1.00)	1.84 (2.00)	0.084
11b. Right now, while you are wearing the Forsus, how much has the following affected you: Sore jaw?	1.56 (1.00)	1.82 (2.00)	0.119
11c. Right now, while you are wearing the Forsus, how much has the following affected you: Soreness on the lip/cheek from rubbing?	1.83 (2.00)	1.90 (2.00)	0.692
11d. Right now, while you are wearing the Forsus, how much has the following affected you: Feeling embarrassed?	1.14 (1.00)	1.20 (1.00)	0.743
11e. Right now, while you are wearing the Forsus, how much has the following affected you: Drooling?	1.67 (2.00)	1.77 (2.00)	0.480
11f. Right now, while you are wearing the Forsus, how much has the following affected you: Difficult to open wide/yawn?	1.36 (1.00)	1.72 (2.00)	0.016*
11g. Right now, while you are wearing the Forsus, how much has the following affected you: Keeping Forsus clean is a pain	1.64 (1.50)	1.84 (2.00)	0.188

Table 2.5 *Descriptive statistics for responses from Xbow and FFRD treated patients at 2 months post-insertion for Question 16a "How long did it take you to get used to the Forsus?"*

Treatment group	N	Mean (weeks)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower bound	Upper bound		
Xbow	21	3.95	2.729	0.596	2.71	5.19	0	8
FFRD	17	2.65	1.693	0.411	1.78	3.52	1	8

Table 2.6 *Reason and number of emergency visits for FFRD and Xbow treated patients*

Reason for Emergency Visit	Number of emergency visits for FFRD patients	Number of emergency visits for XBow patients
Broken Band	4	16
Loose Band	2	7
Detached or loose spring components requiring minor adjustment	5	13
Broken or lost spring components requiring replacement	6	10
Soft-tissue sores	2	9
Lost tie-back modules	5	n/a
Bracket off due to FFRD	3	n/a
Broken AW due to FFRD	2	n/a
Total Emergency Visits	**29**	**55**
Mean emergency visits per patient	**1.3**	**2.2**

Table 2.7 *Prevalence of emergency visits for FFRD and Xbow treated patients*

	Number of Patients	
Number of Emergency Visits	**FFRD**	**Xbow**
None	8/23	6/25
	34.78%	24%
At least 1	15/23	19/25
	65.22%	76%

2.11 APPENDIX

2.11.1 APPENDIX I: Questionnaire

Experience with the Forsus Appliance

First, please tell us about yourself.

Age: _____ years old

Sex: Male Female (circle one)

These questions are about when you FIRST got the Forsus appliance. Please circle only one answer.

1. I was given a complete description of the Forsus appliance before wearing it.
Strongly Agree Agree Neutral Disagree Strongly Disagree

2. When I first saw it, the Forsus appliance looked scary/overwhelming.
Strongly Agree Agree Neutral Disagree Strongly Disagree

3. The appointment the Forsus was placed was quick and easy.
Strongly Agree Agree Neutral Disagree Strongly Disagree

4. I was given instructions for wear and care of the Forsus.
Strongly Agree Agree Neutral Disagree Strongly Disagree

5. How noticeable was the Forsus (not just your braces) to friends and family?
Very Noticeable Somewhat Neutral A little Not Noticeable

6. Did you wear elastics or rubber bands before you had the Forsus? **Yes No**
***If you answered YES, please answer question 6a, below. If you answered NO, go to question 7.*

6a. Fill in the blank: Wearing the Forsus is _____ than wearing rubber bands/elastics.
Way easier Somewhat easier No Different Somewhat Harder Way Harder

These questions are about WHEN YOU FIRST GOT THE FORSUS APPLIANCE. Please circle only one answer.

7. WHEN YOU FIRST GOT THE FORSUS, how much did the following things change?

Speech	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Eating	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Drinking	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Sleeping	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Appearance	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
I am teased	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**

8. WHEN YOU FIRST GOT THE FORSUS, how much did the following affect you?

Sore teeth	**Not at all**	**A little**	**A lot**
Sore jaw	**Not at all**	**A little**	**A lot**
Soreness on lip/cheek from rubbing	**Not at all**	**A little**	**A lot**
Feeling embarrassed	**Not at all**	**A little**	**A lot**
Drooling	**Not at all**	**A little**	**A lot**
Difficult to open wide/yawn	**Not at all**	**A little**	**A lot**
Keeping Forsus clean is a pain	**Not at all**	**A little**	**A lot**

9. WHEN YOU FIRST GOT THE FORSUS, how did wearing the Forsus affect
Your school work?

Much improved Improved Same Slightly worse Much worse

Getting along with your friends?

Much improved Improved Same Slightly worse Much worse

Getting along with your family?

Much improved Improved Same Slightly worse Much worse

Participation in music? What type of music? _____ OR I don't participate in music. _____

Much improved Improved Same Slightly worse Much worse

Participation in sports? What type of sports? _____OR I don't participate in sports. _____

Much improved Improved Same Slightly worse Much worse

These questions are about how you feel about the Forsus appliance RIGHT NOW. Please circle only one answer.

10. RIGHT NOW, while you are wearing the Forsus, how much have the following things changed?

Speech	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Eating	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Drinking	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Sleeping	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Appearance	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
I am teased	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**

11. RIGHT NOW, while you are wearing the Forsus, how much has the following affected you?

Sore teeth	**Not at all**	**A little**	**A lot**
Sore jaw	**Not at all**	**A little**	**A lot**
Soreness on lip/cheek from rubbing	**Not at all**	**A little**	**A lot**
Feeling embarrassed	**Not at all**	**A little**	**A lot**
Drooling	**Not at all**	**A little**	**A lot**
Difficult to open wide/yawn	**Not at all**	**A little**	**A lot**
Keeping Forsus clean is a pain	**Not at all**	**A little**	**A lot**

12. RIGHT NOW, while you are wearing the Forsus, how has wearing the Forsus affected
Your schoolwork?

Much improved Improved Same Slightly worse Much worse

Getting along with friends?

Much improved Improved Same Slightly worse Much worse

Getting along with your family?

Much improved Improved Same Slightly worse Much worse

Participation in music? What type of music? _____ OR I don't participate in music. _____

Much improved Improved Same Slightly worse Much worse

Participation in sports? What type of sports? _____ OR I don't participate in sports. _____

Much improved Improved Same Slightly worse Much worse

These questions are about how you feel about the Forsus RIGHT NOW. Please circle only one answer.

13. I enjoy seeing the difference the Forsus appliance is making in my facial appearance.
Strongly Agree Agree Neutral Disagree Strongly Disagree

14.Have you had any extra visits to the orthodontist because the Forsus was broken?
Yes No

15. If you had to make extra visits to the orthodontist because the Forsus was broken, has this bothered you?
Not at All A little A lot It did not break

16. At this time, do you feel like you have gotten used to the Forsus? **Yes No**
***If you answered YES, please answer question 16a, below. If you answered NO, go to question* 17.

16a. How long did it take to get used to the Forsus?
Please place an "X" anywhere on the horizontal line that corresponds to your answer.

0 weeks 4 weeks 8 weeks

17. Overall, how do you feel about your experience with the Forsus appliance?
Really Good Good Neutral Bad Really bad

18. Your advice to other patients: Based on your experience of wearing the Forsus, what would you say to someone who was about to start wearing the Forsus? (Use back of sheet if necessary.)

Thank you. Please seal survey in envelope and return to your orthodontist or staff member.

2.11.2 Appendix II: Summary of questions excluded from statistical analysis

Question excluded from statistical analysis	Reason
6. Did you wear elastics or rubber bands before you had the Forsus?	Study participants did not wear rubber bands before appliance treatment
6a. Fill in the blank: Wearing the Forsus is _____ than wearing rubber bands/elastics	Study participants did not wear rubber bands before appliance treatment
7. WHEN YOU FIRST GOT THE FORSUS, how much did the following things change? • **Speech** • **Eating** • **Drinking** • **Sleeping** • **Appearance** • **I am teased**	Not interested in data from participants attempting to recall previous experiences
8. WHEN YOU FIRST GOT THE FORSUS, how much did the following affect you? • **Sore teeth** • **Sore jaw** • **Soreness on the lip/cheek from running** • **Feeling embarrassed** • **Drooling** • **Difficult to open wide/yawn** • **Keeping Forsus clean is a pain**	Not interested in data from participants attempting to recall previous experiences
9. WHEN YOU FIRST GOT THE FORSUS, how did wearing the Forsus affect: • **Your school work** • **Getting along with friends** • **Getting along with family** • **Participation in music? What type of music?** • **Participation in sports? What type or sports?**	Not interested in data from participants attempting to recall previous experiences
12. RIGHT NOW, how has wearing the Forsus affected: • **Participation in music? What type of music?** • **Participation in sports? What type or sports?**	Sample size too small: Music: Left blank by 25/41 participants Sports: Left blank by 14/41 participants
17. Overall, how do you feel about your experience with the Forsus appliance?	Misprinted on questionnaire given to 16/41 participants

CHAPTER 3: ADDITIONAL APPOINTMENTS AND DISCOMFORT ASSOCIATED WITH COMPLIANCE-FREE FIXED CLASS II CORRECTOR TREATMENT: A SYSTEMATIC REVIEW

3.1 INTRODUCTION

A Class II malocclusion is one of the most common problems faced by orthodontists, with an estimated one-third of all orthodontic patients treated for this condition[1]. There are many different treatment modalities for correcting Class II malocclusions including non-extraction non-surgical approaches involving fixed or removable Class II corrector appliances[2]. These appliances are commonly used for correction of mild to moderate Class II malocclusion cases where dental camouflage of an underlying skeletal problem appears to be a reasonable option. Previous studies have suggested that patients have higher cooperation and completion rates with fixed versus removable Class II appliances[3] and thus non-compliance fixed Class II corrector therapy has become increasingly popular.

There are a number of fixed Class II correctors available for use today, each associated with their own advantages and disadvantages. There are intra-maxillary appliances (Distal Jet, Pendulum) which are typically used to treat patients with maxillary dentoalveolar protrusion, and inter-maxillary appliances (Herbst Appliance, Jasper Jumper, Mandibular Anterior Repositioning Appliance (MARA), Forsus Fatigue Resistant Device, Xbow) which are typically used to treat patients with mild mandibular skeletal retrusion associated with Class II occlusion[1]. Both treatment approaches typically produce some level of maxillary molar distal movement and upper or lower incisor buccal inclination, depending on the appliance and time of use[4,5]. Overall their effects seem to be mainly dentoalveolar rather than skeletal[6].

It is also important to consider the patient's potential comfort when selecting a fixed Class II corrector as it will be in place for several months and cannot be temporarily removed by the patients themselves to relieve any level of soft tissue or functional discomfort. Due to their bulky nature they can be associated with a certain degree of patient discomfort and potential appliance breakage[3]. Breakages and, in certain cases discomfort, can result in a significant distress for the patient and will require emergency visits to the orthodontic office, which can ultimately extend the patient's total treatment time and also increase any office's overhead. These emergency appointments can quickly become a burden on the practitioner, the patient, and their family. Discomfort and extended length of treatment can result in reduced satisfaction with orthodontic treatment[7].

Some publications had qualified and/or quantified emergencies and discomfort levels associated with specific fixed Class II correctors. From them it appears that the pattern of complications depends on the type and design of the appliance used. To our knowledge, there have been no systematic attempts to summarize the available related information. Therefore, we undertook a critical analysis of the literature to determine the frequency and type of emergency, and discomfort levels associated with fixed Class II correctors. Clinicians may find this information useful when considering the selection of fixed Class II correctors for specific patients.

3.2 MATERIALS AND METHODS

3.2.1 Protocol Registration

The study protocol was not registered.

3.2.2 Eligibility Criteria

Studies examining patient's sources of discomfort or emergency appointments associated with compliance-free Class II correctors were included. Studies containing only identical samples from previously published studies were excluded to avoid duplication of results. In this event, the earlier published study was included. No restrictions were placed on country or original language, although articles not available in English were excluded. A PICOS (population, intervention, comparison, outcome, study design) format, according to PRISMA guidelines[8], was used to support the inclusion-exclusion criteria:

Population: Orthodontic patients with Class II malocclusion. No restrictions applied regarding age and sex.

Intervention: A non-surgical, non-extraction orthodontic treatment involving a compliance-free fixed Class II corrector (e.g., Herbst, Jasper Jumper, Mandibular Anterior Repositioning Appliance (MARA), Forsus, Xbow, Distal Jet, Pendulum).

Comparison: A non-surgical, non-extraction orthodontic treatment involving another compliance-free fixed Class II corrector or a compliance-dependent removable Class II corrector, or no comparison.

Outcome: Patient's sources of discomfort, number and type of emergency appointments during active fixed Class II corrector therapy.

Study Design: Cross-sectional, retrospective and prospective clinical studies, and randomized clinical studies. Case reports and series of cases were excluded.

3.2.3 Information Sources

Comprehensive searches up to July 2018 were conducted using the following electronic

bibliographic databases: MEDLINE (OvidSP), PubMed, Web of Science, and Embase. A partial grey literature search was taken using Google Scholar and OpenGrey.

3.2.4 Search Strategy

Details of the terms and how they were combined per database can be found in Appendix I. No restrictions were applied to the electronic search. Duplicate results were removed upon identification with the help of a reference management software (RefWorks-COS, ProQuest, Bethesda, Md).

3.2.5 Study Selection

Two reviewers (orthodontic graduate students) independently performed eligibility assessment of the initial database searches results. The reviewers initially determined articles' eligibility by reading the title and abstracts, if available, of each article identified by the initial electronic search. All articles that appear to meet the inclusion criteria passed the initial screening, and the reviewers acquired the full text articles for the next phase. In the second screening phase, the same reviewers independently re-evaluated the selected full articles in terms of the eligibility criteria.

During the final selection, the reviewers also hand searched the reference lists of the articles accepted in the second screening to identify any additional resources that may have been overlooked in the electronic database search. Disagreements between them were solved by consensus. When additional information was needed, efforts were made to contact the authors.

3.2.6 Data Collection Process

One reviewer did data extraction, and the other crosschecked all collected information. Once again, disagreements were solved by consensus.

3.2.7 Data Extraction

When available data was extracted for each of the selected studies based on the following outcomes: study design, sample size, age at start of treatment, type of fixed Class II corrector used, frequency of emergency visits expressed as a percentage of all treated patients or frequency of events per patient, type of emergency visit, the chief complaint during emergency visit, and potential sources of discomfort. If the study did not report the incidence of emergency visits as a percentage of all treated patients or frequency of events per patient, percentage or frequency of events per patient was calculated based on the data provided in the study if possible. Study demographics including publication year and country where study was conducted were also collected.

3.2.8 Risk of bias in individual studies

We appraised selected studies according to the Cochrane Collaboration's tool for assessing Risk of Bias tool for randomized controlled trials[9], the ROBINS-I (Risk of Bias in Non-randomized Studies-of Interventions) tool for non-randomized studies[10], and the Newcastle-Ottawa Scale for cross-sectional studies[11].

3.2.9 Synthesis of results and risk of bias across studies

Meta-analysis was planned if there was adequate data homogeneity. After the initial search, it became apparent that a meta-analysis was not justified because of data heterogeneity (different appliances, different data recollection processes).

3.2.10 Level of evidence

A summary of the overall strength of evidence was presented using "Grading of recommendations, assessment, development and evaluation" (GRADE) tool[12]. The included studies were evaluated according to their design, study quality, consistency, and directness. The inconsistency was not assessed in the included studies.

3.3 RESULTS

3.3.1 Study Selection

Searches of electronic databases and other sources yielded 308 articles (Figure 3.1). Once duplicates were removed only 171 remained. Initial screening, which was based on title and available abstract, reduced the 171 articles to 15. The second screening phase involved examining the full articles and hand-search of their reference lists which led to the addition of 2 articles[13,14]. After the second screening, 1 article[15] was eliminated due to our inability to locate a translated version or access to a translator, and 1 article[16] was eliminated due to having the same study sample as an already included article[17]. In the end, the selection process yielded 15 articles that satisfied our search criteria for inclusion in the systematic review.

3.3.2 Study Characteristics

Selected articles were separated by study type. Two studies were randomized controlled trials[3,18], ten studies were prospective or retrospective non-randomized clinical trials[13,14,19–26], and three studies were cross-sectional studies[17,27,28]. Tables 3.1-3.3 provide a summary of important methodological data and study results.

The appliance types studied were mostly variations of the Forsus spring and Herbst appliance. Eleven[3,13,28,19–26]of the fifteen studies we included compared emergencies while using different styles of Herbst appliances. Sanden's study[21] and Schioth's study[22] used the same sample of full mandibular cast-splint Herbst subjects to compare with their own respective groups, thus the data for the mandibular cast-splint Herbst subjects is summarized twice in the tables.

The selected studies were published between 2002 and 2018, and the number of patients per studied group ranged from 8 to 182. 1542 patients were evaluated in total. The patients' mean age at start of treatment ranged from 10 to 16.9 years and the fixed Class II corrector treatment duration ranged from 4 to 12 months.

The incidence of emergency visits ranged from 22% to 88% in patients treated with the stainless-steel crown Herbst and the removable mandibular acrylic splint Herbst, respectively. The majority of the studies reported incidences greater than 60%. Patients often experienced more than one complication; however, investigators did not consistently report the number of events. Those who did report frequency of events ranged from an average of 0.42 events per patient for patients treated with the Manni Telescopic Herbst to an average of 4.29 events per patient for patients treated with the cast cobalt chromium Herbst. Chief complaint during

emergency visits was not reported consistently in all studies. Regarding the studies that examined discomfort, the main area of discomfort from all examined appliances was soreness or ulcerations in the cheek.

3.3.3 Risk of Bias

For the two randomized clinical trials included[3,18], the quality of reported methodology was mostly good but still with high risk of bias due to the impossibility to blind participants and personnel in studies using orthodontic appliances, and due to clinical patient drop-out resulting in increased risk of attrition bias (Figure 3.2).

For the non-randomized studies, the quality of reported methodology was also mostly good with moderate risk of bias due to inherent problems of non-randomized trials (Table 3.4) and cross-sectional studies (Table 3.5) such as lack of blind evaluation and small sample size.

3.3.4 Synthesis of Results and Risk of Bias Across Studies

The results from the included studies in this systematic review were too heterogeneous (different appliances, different data recollection processes) to justify a meta-analysis.

3.3.5 Level of Evidence

A moderate level of evidence was observed among the two randomized trials (114 patients) on the evaluation of emergencies. Among non-randomized/cross-sectional studies a low level of evidence was observed (Table 3.6).

3.4 DISCUSSION

Our goal in this systematic review was to analyze the available literature to determine the frequency, type of emergency, and comfort levels associated with fixed Class II correctors. We attempted to highlight patterns for clinicians to consider before making fixed Class II appliance selection decisions. The results suggest that the incidence of complications with all reported fixed Class II correctors is relatively high and may be related to the anchorage design of the appliances. Caution should be exercised when extrapolating these findings to non-evaluated fixed Class II designs. For some relatively similar designs it may be intuitive to extrapolate the findings but for others it may not be the case.

3.4.1 Summary of Evidence

Most studies found no statistically significant differences in the incidence of emergency appointments between the examined fixed Class II correctors; however, some patterns were noted.

Hagg et al.[19] compared two different anchorage designs of the Herbst appliance: banded and cast-splinted. They found that although both designs experienced similar incidences of complications requiring emergency appointments, the banded style experienced significantly more fractures, while the cast splint style experienced more dislodgment of the cast splint. Fracture of the Herbst usually requires fabrication of a new appliance, which requires further clinical and laboratory time as well as an additional appointment to cement the new appliance. Thus, they concluded that although the banded Herbst was more retentive, the cast splint style ultimately resulted in less clinical chair time and laboratory time required to service the

appliance.

Sanden et al.[21] also examined banded vs. cast-splinted Herbst with a much larger sample size. They found that the most common complication for both groups was band or cast-splint loosening, but that in addition the banded appliances were more likely to fracture. The higher rate of band vs. cast-splint fracture is likely because bands are much thinner than cast-splints, and that bands are further weakened when soldering axles to the bands. This study also found that due to the forces on the anchorage teeth, the most common areas for banded Herbst fracture were mesiobuccally at the maxillary first molar bands and distobuccally at the mandibular first premolar bands. This is likely due to the point of force application and related force stress levels. Telescope breakage was equally common between banded and splinted groups.

Silva et al.[23] compared the removable mandibular acrylic splint Herbst (RMS) to the cantilever Herbst (HC) also found no significant difference in the incidence of emergency appointments associated with the appliance type or the fixation mode. However, they did find a significant difference associated with the telescoping system used. Patients treated with the Dentaurum Type 1 telescope were 2.9 times more susceptible to complications than the PMA telescope system, regardless of the Herbst type. The investigators also categorized complications as “relatively easy” or “relatively complex”. The RMS group experienced significantly less “relatively complex” complications than the HC group. They also supported their conclusions using evidence from four studies[13,19,21,22] which are also included in our review. By comparing their results with the results from these studies, Silva et al.[23] concluded that most patients have a maximum of three complications during Herbst treatment with the evaluated designs. The

investigators also reported an average of 2.5 complications per patient. This is less than the 4.29 complications per patient reported by O'Brien et al. [3] and this may be at least partially due to the fact that O'Brien's study sample was not financially responsible for their treatment and may have been less compliant with instructions regarding avoiding certain foods or activities[3].

Kanuru et al.[25] compared a removable mandibular acrylic splint Herbst with a cantilever Herbst. Additionally, the groups the further subdivided by telescopic system, either PMA or Dentaurum, and also by fixation mode, either by crown or band. They found that the differences in complication rate between the type of Herbst and fixation mode were insignificant. However, they did find that the Dentaurum telescope (65.6%) had a higher complication rate than the PMA telescope (48%).

Some studies did find statistically significant differences between groups. Moro et al.[13] found that patients treated with a cantilever bite jumper style Herbst exhibited a significantly fewer complications requiring emergency appointments than patients treated with the removable mandibular acrylic splint Herbst. Similarly, Manni and Cozzani[26] found that the Hanks Telescoping Herbst (HTH) had significantly fewer emergencies than the removable mandibular acrylic splint Herbst. Conversely, they also found that the HTH had a significantly higher rate of failure to complete treatment than the removable mandibular acrylic splint Herbst (RMS). They suspected this was due to lesions in the oral cavity caused by the HTH, which forced the patient to discontinue treatment. Manni and Mutinelli[24] found that that Manni Telescopic Herbst (MTH) group had significantly fewer total complications and significantly fewer reversible complications (complications that did not require appliance removal) than the RMS group (25.9% vs 51.2%, and 20.2% vs 51.1%, respectively). The authors contributed this difference to the new telescopic

system with the MTH that allows lateral excursions up to 12°, as well as the use of a Rollo band which is sandblasted and thicker than a conventional band.

Wiechmann et al.[28] compared a novel WIN Herbst (WIN, DW LingualSystems) used in combination with a lingual full fixed appliance (Incognito, 3M Unitek) to complication rates found in the literature, all of which are included in this systematic review. The telescopes are inserted into Herbst attachments that are bonded with adhesive attachment shells on the buccal surfaces of the maxillary first molars and canines, concomitant with treatment with full lingual braces. Wiechmann found that only 28.57% of patients experienced 1 or more complications, the most common being Herbst attachment loosening/bond failure. Since there is no laboratory cost associated with this complication and the attachments can rebonded easily chairside, Wiechmann proposed the WIN Herbst to be superior to comparable vestibular Herbst appliances as well as banded Herbst appliances designed for use with lingual systems.

In terms of discomfort, Moro et al.[13] and Silva et al.[23] found that the cantilever Herbst tended to hurt the patient's cheek during the first week of use. Latkauskiene et al.[20] found that most patients got used to the stainless steel crown Herbst appliance within the first week of use. These results suggest that after an adjustment period of 1 week with these designs of Herbst appliances patients may not experience significant discomfort. Manni and Mutinelli[24] also concluded that the 12° of lateral excursion allowed by the MTH is also the likely reason that mild ulcerative lesions in the cheeks were significantly more likely in the MTH group (6.7%) compared to the RMS group (0%).

Heinig et al.[27] found that 38% of patients reported pain inside the cheek from the Forsus Nitinol Flat Spring. Similarly, and to a greater extent, Bowman et al.[17] also found that cheek

irritation was the most common source of discomfort for patients treated with the Forsus Fatique Resistant Device (FFRD). Although cheek irritation and other side effects generally decreased over time, the investigators found that some patients did experience a worsening in cheek irritation between 2 and 4 months, likely due to development of ulcers. Gandhi et al.[14] compared the FFRD with the Mandibular Protraction Appliance IV and also concluded that discomfort-related side effects diminished over 30 days for both appliances.

Elkordy et al.[18] compared the FFRD with a mini-implant anchored FFRD and found no significant differences in any of the assessed outcomes between groups. They also reported the same breakage rate of 19% for both groups. This is less than the 37.3% breakage rate reported by Bowman et al.[17]; however, the investigators also reported "separation of parts" separately from "breakage", and the exact definitions of each one were not well defined. Separation of parts was reported at 25%, thus the total emergency visit rate was actually 43.7%. Elkordy also differed from Bowman[17] in that they found that most patients did not report any significant pain in the cheeks.

One excluded study[16] examined the patients' experience with the Carriere distalizer (CDA) compared to the FFRD group from Bowman[17]. As the CDA is not compliance-free we could not include this study in our review; however, the article reports only 14.3% of patients treated with the CDA having a breakage resulting in an extra appointment. This incidence was significantly lower than the FFRD group, and is the lowest of any study included in our review. The investigators also concluded that soreness from the CDA rubbing the cheek or lip was significantly less than the FFRD. These results suggest that a less bulky appliance design such as the CDA may be related to fewer emergency appointments and increased patient comfort. The overall buccal

protrusion of the spring mechanisms around the upper first molars in fixed Class II correctors is likely the main cause of the cheek irritation.

Experienced clinicians often make modifications to fixed Class II correctors to improve patient comfort and to prevent emergencies. For example, spring caps are available to cover the anterior or posterior portion of the spring that may pinch the lower lip or cheek, and comfort caps are also available for the Herbst appliance for the same purpose. A mesial insertion of the FFRD into the maxillary molar tube instead of the traditional distal insertion is another popular modification that reduces sores in the cheek adjacent to the maxillary molars. Location of where the FFRD is attached on the lower archwire can also vary between practitioner, which also has an impact on patient comfort and dislodgement of the device. Ceka bond is an adhesive often added to secure hex screws on a Herbst to prevent dislodgement of the rods. The use of these techniques and others could have a great impact on patient comfort levels and the frequency of emergency appointments, and it is unknown which, if any, modifications were applied in the included studies.

A low to moderate level of evidence was verified among the included studies, with a moderate to high risk of bias. The small sample size and dropout rate of the included studies suggests the need of more well-designed studies to a more reliable answer to the question investigated in this review.

Although not all the available fixed Class II correctors were considered in this review some potentially useful information was synthesized. For Herbst variations, there is a certain level of consistency between the different reports regarding the most common expected type of emergency being dislodgment or fracture of the tooth-borne anchorage device, and that after a

one-week adaptation period most of the discomfort associated with these types of appliances is minimized. Finally, clinicians should be aware that it appears that an average of 1-4 complications per patient are to be expected. For Forsus-type appliances, the emergency visit rate ranging from 37.3-43.7% of treated patients, with the most common source of discomfort being sores or ulceration in the cheek. Any discomfort associated with Forsus-type appliances also diminishes with time. This information is useful to clinicians when considering use of different Class II correctors as it gives greater insight into how much office chair time is required to manage that specific Class II corrector.

3.4.2 Limitations

Despite the many types of fixed Class II correctors on the market, the studies we identified mostly involved variations of only two appliances: the Herbst appliance and the Forsus Fatigue Resistance Device springs. This is likely due to the fact that these appliances are the most widely used fixed Class II correctors and have the most published data surrounding them. Additional research is needed to examine other compliance-free Class II correctors beyond Herbst and Forsus. There were no studies identified investigating complications or discomfort using other compliance-free intra-maxillary appliances.

The methodologies the investigators used to record and evaluate the incidence and type of emergencies were not standardized, so a meta-analysis was not justified. The lack of standardized methodology makes it difficult to compare different fixed Class II correctors. Not all investigators reported the type of emergency or the treatment required to resolve the emergency at the appointment.

The samples from the included studies came from varied settings with practitioners of with varied experience levels and varied clinical protocols, including multi-operator university clinics, single-operator university clinics, single-practitioner private orthodontic clinics, multiple private orthodontic clinics, hospital-based clinics, or a mixed sample from university and private clinics. This also likely has a large impact on wide range of incidence of emergency visits associated with the appliances.

For the included studies the sample size/power calculation was not based on the frequency and type of emergency, and discomfort levels in patients undergoing Class II fixed corrector therapy. Usually, these outcomes are assessed as secondary outcomes in the primary study and hence the results/conclusions reported by this SR were likely based on underpowered studies which did not have a sufficiently large sample size to detect differences between intervention groups.

3.5 CONCLUSIONS

- The main source of discomfort from Forsus-type appliances for most evaluated patients appears to be soreness in the cheeks (low level of evidence with a weak recommendation strength).
- Most evaluated patients treated with a Herbst appliance, regardless of design, will experience complications (fractures and/or dislodging) requiring emergency appointments (moderate level of evidence with a weak recommendation strength).
- A standardized method for reporting orthodontic emergencies to compare different appliance designs is suggested.

3.6 REFERENCES

1. Burkhardt DR, McNamara Jr. JA, Baccetti T. Maxillary molar distalization or mandibular

enhancement: a cephalometric comparison of comprehensive orthodontic treatment including the pendulum and the Herbst appliances. *Am J Orthod Dentofac. Orthop* 2003;123(2):108–16.

2. Pacha MM, Fleming PS, Johal A. A comparison of the efficacy of fixed versus removable functional appliances in children with Class II malocclusion: A systematic review. *Eur. J. Orthod.* 2016;38(6):621–30.

3. O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or twin-block appliances: a randomized, controlled trial. *Am. J. Orthod. Dentofacial Orthop.* 2003;124(2):128–37.

4. Antonarakis GS, Kiliaridis S. Treating Class II malocclusion in children. Vertical skeletal effects of high-pull or low-pull headgear during comprehensive orthodontic treatment and retention. *Orthod Craniofac Res* 2015;18(2):86–95.

5. Shen, G; Hagg, U; Darendeliler M. Skeletal effects of bite jumping therapy on the mandible – removable vs . fixed functional appliances. *Orthod. Craniofacial Res.* 2005;8:2–10.

6. Zymperdikas VF, Koretsi V, Papageorgiou SN, Papadopoulos MA. Treatment effects of fixed functional appliances in patients with Class II malocclusion: a systematic review and meta-analysis. *Eur. J. Orthod.* 2016;38(2):113–26.

7. Pachêco-Pereira C, Pereira JR, Dick BD, Perez A, Flores-Mir C. Factors associated with patient and parent satisfaction after orthodontic treatment: A systematic review. *Am. J. Orthod. Dentofacial Orthop.* 2015;148(4):652–9. Available at: http://www.ajodo.org/article/S0889540615007751/fulltext.

8. Moher D, Liberati A, Tetzlaff J, et al. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med.* 2009;6(7):e1000097.

9. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;343:d5928.

10. Sterne JA, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* 2016;355.

11. Wells G, Shea B, O'Connell D, et al. *The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses*. Ottawa Hosp. Univ. Ottawa.; 2013.

12. Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J. Clin. Epidemiol.* 2011;64(4):401–6.

13. Moro A, Janson G, Moresca R, Freitas MR de, Henriques JFC. Estudo comparativo de complicações durante o uso do aparelho de Herbst com cantiléver e com splint inferior de acrílico removível. *Dental Press J. Orthod.* 2011;16(1):e1–7.

14. Gandhi P, Goel M, Batra P. Relative comparison and assessment of patient ' s attitude and discomfort between two different types of fixed functional appliances : A comprehensive survey. 2013;1(3).

15. Tian X, Wu Z, Zhang S, Zhang M, Lin X. Patients' experiences with the Forsus appliance]. *Shanghai Kou Qiang Yi Xue* 2014;23(2):209–13.

16. Hamilton, CF; Saltaji, H; Preston, CB; Flores-Mir, C; Tabbaa S. Adolescent patients ' experience with the Carriere distalizer appliance. *Eur. J. Paediatr. Dent.* 2013;14(3):219–24.

17. Bowman AC, Saltaji H, Flores-mir C, Preston B, Tabbaa S. Patient experiences with the Forsus Fatigue Resistant Device. *Angle Orthod.* 2013;83(3):437–46.

18. Elkordy SA, Fayed MMS, Abouelezz AM, Attia KH. Comparison of patient acceptance of the Forsus Fatigue Resistant Device with and without miniimplant anchorage: A randomized

controlled trial. *Am. J. Orthod. Dentofac. Orthop.* 2015;148(5):755–64. Available at: http://dx.doi.org/10.1016/j.ajodo.2015.06.015.

19. Hagg, Urban; Tse, Edmond; Rabie, A, Robinson W. A comparison of splinted and banded Herbst appliances: treatment changes and complications. *Aust. Orthod. J.* 2002;18(2):76–81.

20. Latkauskiene D, Jakobsone G, McNamara JA. A prospective study on the clinical effectiveness of the stainless steel crown Herbst appliance. *Prog. Orthod.* 2012;13(2):100–8.

21. Sanden E, Pancherz H, Hansen K. Complications during Herbst appliance treatment. *J. Clin. Orthod.* 2004;38(3):130–3.

22. Schiöth T, von Bremen J, Pancherz H, Ruf S. Complications during Herbst appliance treatment with reduced mandibular cast splints : a prospective, clinical multicenter study. *J. Orofac. Orthop.* 2007;68(4):321–7.

23. Silva JFE, Gerszewski C, Moresca RC, Correr GM, Flores-Mir C, Moro A. Retrospective study of clinical complications during orthodontic treatment with either a removable mandibular acrylic splint Herbst or with a cantilever Herbst. *Angle Orthod.* 2015;85(1):64–71.

24. Manni A, Mutinelli S, Cerruto C, Giraudo P, Romano R, Cozzani M. Comparison of complications in the conventional telescopic Herbst rod and tube and Manni telescopic Herbst: A retrospective clinical study. *Angle Orthod.* 2018;88(4):377–83. Available at: http://www.angle.org/doi/10.2319/082317-569.1.

25. Kanuru R, Bhasin V, Khatri A, Dodda K, Singh E, Grover S. Comparison of Complications in Removable Mandibular Acrylic Splint and Cantilever Herbst for Management of Class II Malocclusion : A Retrospective Study. *J. Contemp. Dent. Pract.* 2017;18(May):363–5.

26. Manni A, Cozzani M, Mazzotta L, Fiore VP, Mutinelli S. Acrylic splint Herbst and Hanks

telescoping Herbst : A retrospective study of emergencies , retreatments , treatment times. *Int. Orthod.* 2014;12(1):100–10. Available at: http://dx.doi.org/10.1016/j.ortho.2013.12.015.

27. Heinig N, Göz G. Clinical application and effects of the Forsus spring. A study of a new Herbst hybrid. *J. Orofac. Orthop.* 2001;62(6):436–50.

28. Wiechmann D, Vu J, Schwestka-polly R, Helms H, Knösel M. Clinical complications during treatment with a modified Herbst appliance in combination with a lingual appliance. *Head Face Med.* 2015;11(31):1–10.

3.7 FIGURES

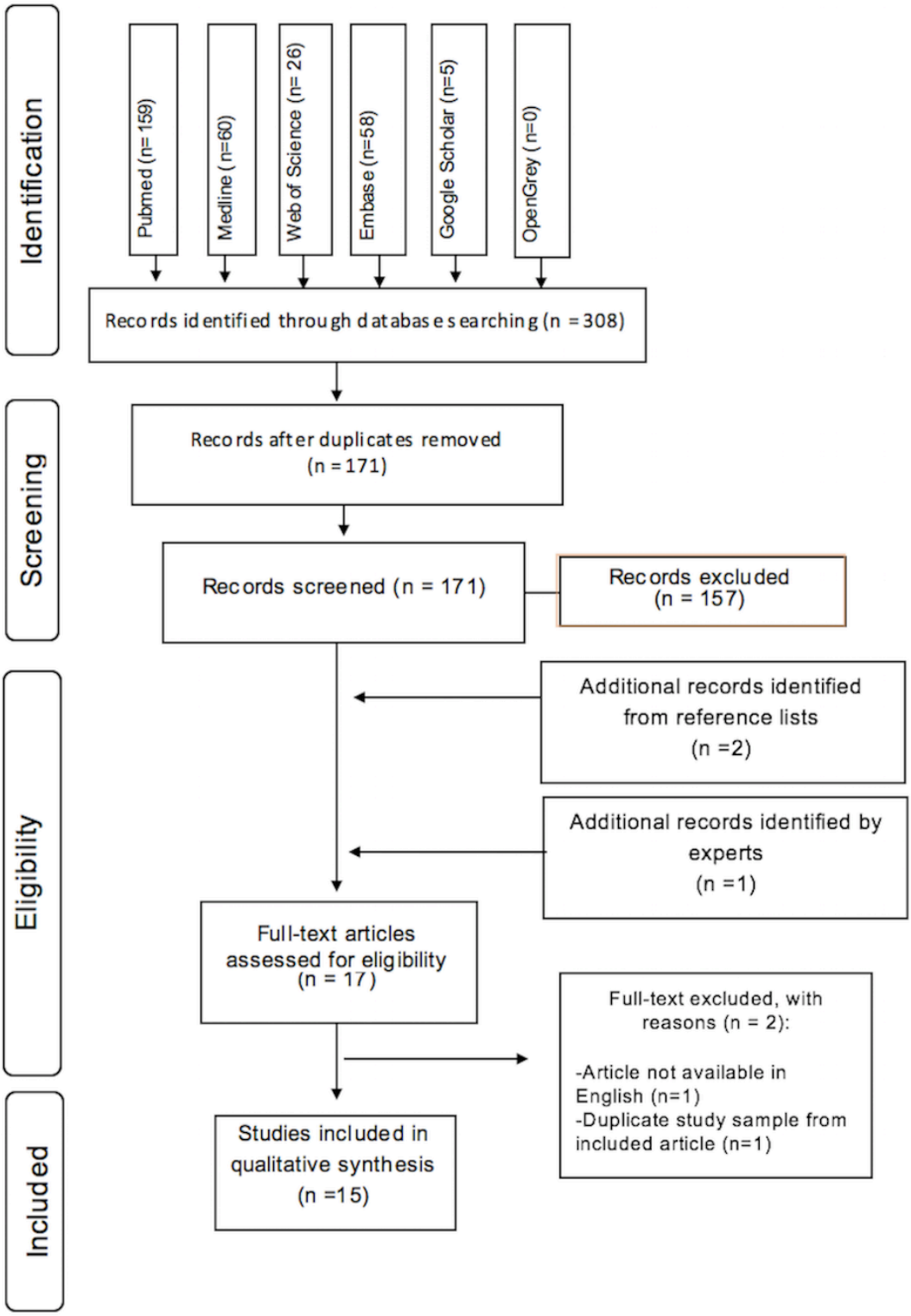

Figure 3.1. *Flow chart with number of records identified and removed at each stage of the review according to PRISMA statement*

Figure 3.2 *Risk of Bias (RoB) of the randomized studies, The Cochrane Collaboration's tool for assessing risk of bias.*

3.8 TABLES

Table 3.1. *Summary of randomized clinical trials (n=2).*

	Country	Appliance Type(s)	Sample Size for each appliance type	Treatment Duration	Age at start (years)	Percentage of treated patients with 1 or more complications or Frequency of Emergencies	Reported types of Emergencies
Elkordy and Fayed 2015[18]	Egypt	Forsus Fatigue Resistant Device (FFRD)	16 (0 male, 16 female)	3.8-8	13.25 (SD 1.12)	19% breakage 25% separation of parts	Breakage Separation of parts
		FFRD with mini-implant anchorage	16 (0 male, 16 female)	3.8-8	13.07 (SD 1.41)	19% breakage 31% separation of parts	

O'Brien and Wright 2003[3]	United Kingdom	Cast Cobalt Chromium Herbst	105 (50 male, 55 female) 82 completed treatment n=70 in results	5.81 (95% CI 5.13-6.48)	12.74 (95% CI 12.48-12.99)	4.29 events/patient (95% CI 3.51-5.06)	Debonding and fractured components

***Table 3.2**. Summary of non-randomized clinical trials (n=10).*

	Country	**Study Type**	**Appliance Type(s)**	**Sample Size for each appliance type**	**Treatment Duration (months)**	**Age at start (years)**	**Percentage of treated patients with 1 or more complications**	**Reported types of Emergencies (N of events or % of patients)**
Gandhi and Goel 2013[14]	India	Prospective	FFRD	8 (sex not specified)	At least 2 months	14.5	n/a	Day 1: sore teeth (100%), sore jaws (87.5%), sore muscles (62.5%), headache (50%) Day 30: none
			Mandibular Protraction Appliance IV (MPA-IV)	8 (sex not specified)		14.5		Day 1: sore teeth (87.5%), sore jaws (50%), sore muscles (87.5%), headache (50%) Day 30: none

Hagg and Tse 2002[19]	China	Prospective	Banded Herbst	14 (8 male, 6 female)	6.4 (SD 0.7)	13.4 (SD 1.9)	85.71% 3.8 events/patient	Herbst fractured (40), Herbst dislodged (1)
			Cast splint Herbst (canine to 1st molar)	14 (6 male, 8 female)	7.1 (SD 0.8)	13.0 (SD 1.1)	78.57% 2.9 events/patient	Herbst fractured (6), Herbst dislodged (47)
Kanuru and Bhasin 2017[25]	India	Retrospective	Removable mandibular acrylic splint Herbst	72 (40 male, 32 female)	Not reported	Not reported	69.44%	screw loosening (12), crown debond (8), distortion of rod (5), fracture of crown (9), breakage of lower splint (7), breakage of pivot (10), transpalatal arch breakage (6), cantilever inducing gingival lesion (9), cantilever inducing palatal lesion (2), lesion on cheek due to long rod (4)
			Cantilever Herbst	42 (21 male, 21 female)	Not reported	Not reported	71.43%	screw loosening (8), crown debond (4), distortion of rod (3), fracture of

								crown (5), breakage of lower splint (2), breakage of pivot (8), transpalatal arch breakage (5), cantilever inducing gingival lesion (2), cantilever inducing palatal lesion (4), lesion on cheek due to long rod (1)
Latkauskiene and Jakobsone 2011[20]	Lithuania	Prospective	Stainless steel crown Herbst (SSCs on maxillary 1st molars and mandibular 1st premolars)	175	12	n/a	22.28%	19 patients (10.9%) unscrewing screws, 2 patients (1.1%) broke the lingual arch between premolars, 15 patients (8.6%) broke the occlusal rests, 2 patients (1.1%) damaged the upper first molars attachment, 3 patients (1.7%) experienced loosening of the upper first molar crowns, 5 patients

								(2.9%) bent the rods
Manni and Cozzani 2014[26]	Italy	Retrospective	Removable mandibular acrylic splint Herbst	155 (74 male, 81 female)	12	9.99 (SD 3.5)	48%	Detached Herbst, Breakage with ability to repair Herbst, Breakage requiring remake of Herbst
			Hanks Telescoping Herbst	53 (20 male, 33 female)	12	11.3 (SD 4.2)	26.42%	
Manni and Mutinelli[24]	Italy		Removable mandibular acrylic splint Herbst	90 (48 male, 42 female)	7.8	Males: 11.2 (SD 1.4) Females: 10.8 (SD 1.4)	51.2% 0.95 events/patient	Reversible complications (51.1%), Irreversible complications following reversible complications (6.7%)
			Manni telescopic Herbst	89 (48 male, 41 female)	9.8	Males: 11.3 (SD 1.5) Females: 11.0 (SD 1.4)	25.9% 0.42 events/patient	Reversible complications (20.2%), Irreversible complications following reversible complications (2.2%), Irreversible complications not following reversible complications (5.6%), Mild ulcerative lesions (6.7%)

Moro and Janson 2008[13]	Brazil	Prospective	Herbst Cantilever Bite Jumper (crowns on all 1st molars)	21 (15 male, 6 female)	12	12.25	66.67% 1.14 events/patient	Crown debond (6), screw loosening (6), lesion in palate due to TPA (5), lesion in cheek due to cantilever screw (2), rod distortion (2), lesion in cheek due to too long rod (1), crown fracture (1), lesion in gingiva due to cantilever (1)
			Removable mandibular acrylic splint Herbst	21 (11 male, 10 female)	12	11.25	85.71% 2.52 events/patient	Crown debond (1), screw loosening (24), lesion in palate due to TPA (6), rod distortion (3), lesion in cheek due to too long rod (1), crown fracture (1), lower splint breakage (13), poor use of splint (lack of use) (2), pivot breakage (1),

								breakage of TPA (1)
Sanden and Pancherz 2004[23]	Germany	Prospective	Banded Herbst	134 (82 male, 52 female)	7	n/a	67%	17.4% Maxillary band breakages, 12.4% mandibular band breakages, 5.8% telescope breakages, 42.4% maxillary band loosening, 22.2% mandibular band loosening
			Cast splint Herbst (canine to 1st molar)	182 (89 male, 93 female)	7	n/a	60%	0.8% maxillary splint breakages, 1.3% mandibular splint breakages, 4.3% telescope breakages, 66.9% maxillary splint loosening, 26.8% mandibular splint loosening

Schioth and von Bremen 2007[24]	Germany and Switzerland	Prospective	Reduced cast splint Herbst (canine to second premolar)	50 (27 male, 23 female)	8	15	58%	56.3% Maxillary splint loosening, 32.5% mandibular splint loosening, 8.8% telescope breakage, 2.5% mandibular splint breakage
			Cast splint Herbst (canine to molar) **same as Sanden	182 (89 male, 93 female)	7	n/a	60%	66.9% maxillary splint loosening, 26.8% mandibular splint loosening, 4.3% telescope breakage, 0.8% maxillary splint breakage, 1.3% mandibular splint breakage
Silva and Gerszewski 2015[25]	Brazil	Retrospective	Cantilever Herbst	34 (17 male, 17 female)	12 (SD 2.15)	11.7 (SD 2.4)	85.29%	Lesion in palate caused by transpalatal arch, lesion in cheek caused by long rod,

			Removable mandibular acrylic splint Herbst	125 (65 male, 60 female)	12 (SD 2.15)	11.3 (SD 2.3)	88%	screw loosening, crown debonding, rod distortion, crown fracture, mucosal injury caused by lingual arch, lesion in cheek caused by cantilever screw, rod loosening, lower splint breakage, poor use of splint (lack of use), pivot breakage, and transpalatal arch breakage

Table 3.3. *Summary of cross-sectional studies (n=3).*

	Country	Appliance Type(s)	Sample Size for each appliance type	Treatment Duration (months)	Age (years)	Incidence of Emergencies (% of patients)	Reported types of Emergencies	Patient discomfort reported (% of patients or N of events)
Bowman and Saltaji 2013[17]	US	FFRD	70 (29 male, 40 female, 1 unknown)	At least 2 months	14.5 (SD 1.5)	37.3%	Breakage	When first inserted: sore teeth, soreness on lip/cheek from rubbing, sore jaw At least 2 months after insertion: soreness on the lip/cheek from rubbing
Heinig and Goz 2001[26]	Germany	Forsus Nitinol Flat Spring Device (FNFD)	13 (8 male, 5 female)	4	14.2	n/a	n/a	Pain inside cheek (38%)
Wiechmann and Vu 2015[28]	Germany	WIN-Herbst used with a lingual appliance	35 (12 male, 23 female)	6.3	16.9	28.57%	Debonding of attachments	Herbst attachment loosening (8), L-pin fractures (5)

Table 3.4. *Risk of Bias (RoB) of the non-randomized studies, according to the ROBINS-I Tool.*

Domains		Gandhi and Goel [14]	Hagg and Tse [19]	Kanuru and Bhasin [25]	Latkauskiene and Jakobsone [20]	Manni and Cozzani [26]	Manni and Mutinelli[24]	Moro and Janson [13]	Sanden and Pancherz [21]	Schiöth and von Bremen [22]	Silva and Gerszewski [23]
Preintervention	Bias due to Confounding	Low	Low	Low	Low	Low	Low	NI	Moderate	Low	Low
	Bias in Selecting Participants for the Study	Low	Low	Low	Moderate	Low	Low	Low	Low	Low	Moderate
At intervention	Bias in Classifying Interventions	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Postintervention	Bias due to Deviations From Intended Intervention	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
	Bias due to Missing Data	Low	Low	Moderate	Low	Low	Low	Low	Low	Low	Low
	Bias in Measuring Outcomes	Low	Low	NI	Low	Low	Low	Low	Low	Low	Low
	Bias in Selecting Reported Result	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
	Overall RoB Judgment	Low	Low	NI	Moderate	Low	Low	NI	Moderate	Low	Moderate

NI: No Information; NA: Not Applicable.

Table 3.5. *Risk of Bias (RoB) of the cross-sectional studies, according to the Newcastle-Ottawa Scale adapted for cross-sectional studies.*

	Bowman and Saltaji[17]	Heinig and Goz[26]	Wiechmann and Vu[28]
Selection (maximum 5 stars)	3	2	2
Comparability (maximum 2 stars)	1	1	1
Outcome (maximum 3 stars)	3	2	3
Total Score (maximum 10)	7	5	6

Table 3.6. Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) instrument.

Compliance-free fixed Class II corrector compared to [comparison] for [health problem and/or population]

Bibliography:

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with [comparison]	Risk difference with compliance-free fixed Class II corrector
Emergencies assessed with: number of events follow up: range 4.5 months to 5 months	114 (2 RCTs)	⨁⨁⨁◯ MODERATE [a,b]	-	not pooled	not pooled
Emergencies assessed with: number of events follow up: range 1 months to 15 months	1461 (13 observational studies)	⨁⨁◯◯ LOW [a]	not pooled	not pooled	not pooled

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. The included studies presented differences in outcomes measure.
b. Selection bias were identified in both studies. The blinding process presented pitfalls in Elkordy et al. (2007). Attrition bias were present in O'Brien et al. (2003).

3.9 Appendix

3.9.1 Appendix I. Databases and search strategies

Database	Search Strategy	Results
Medline: 1948 to present	orthodont* AND (emergenc* OR breakage* OR failure* OR complication* OR experience*) AND (fixed class II corrector OR forsus OR xbow OR herbst OR twin force OR esprit OR jasper jumper OR MARA OR distal jet OR pendulum)	60
Web of Science: 1899 to present	TS=(orthodont* AND (emergenc* OR breakage* OR failure* OR complication* OR experience*) AND (fixed class II corrector OR forsus OR xbow OR herbst OR twin force OR esprit OR jasper jumper OR MARA OR distal jet OR pendulum))	26
PubMed: 1950 to present	Same as Medline	159
Embase: 1980 to present	Same as Medline	58

CHAPTER 4: PATIENT EXPERIENCES DURING ORTHODONTIC TREATMENT: INITIAL STEPS FOR THE DEVELOPMENT OF A CLINICAL QUESTIONNAIRE USING PATIENT INTERVIEWS

4.1 Introduction

In orthodontics there are a number of different treatment modalities that can be used to achieve a similar result. When the end result is relatively equal an attentive orthodontist may consider other factors such as a patient's potential experience with an appliance when selecting their preferred treatment method. However, it can be difficult to capture what a patient's experience with an appliance truly is. Questionnaires have been used to gather information from patients regarding their experiences with orthodontic appliances. A previous study from the University of Buffalo by Bowman et al[1] used a non-validated questionnaire to investigate patient experiences during treatment with the Forsus Fatigue Resistant Device (FFRD) in 2012. This questionnaire was developed based on two existing questionnaires: 1. The ''Smiles Better'' survey that was used in the research of O'Brien et al[2] comparing the Herbst and Twin Block appliances, and 2. A survey developed by Lisa Alvetro and David Solid where current and former FFRD patients were questioned about their experiences with the appliance. Although Bowman did find some valuable information about patient experiences with the FFRD, they also found evidence that suggested the questionnaire was confusing or burdensome for some respondents and thus should be shortened and simplified.

Since Bowman's study, modified versions of this questionnaire have been used in several other published articles in an attempt to capture and compare patient experiences with

Class II corrector appliances. Elkordy et al[3] compared patient experiences with the FFRD with and without mini-implant anchorage. Hamilton et al[4] compared patient experiences with the FFRD to the Carriere Motion Class II Correction appliance. Gandhi et al[5] compared patient experiences with the FFRD to the mandibular protraction appliance. These modified versions were shortened and simplified from the original but continued to show signs that respondents may have misinterpreted some of the items. We cannot be certain that any of the questionnaires used above truly captured "patient experience" as they were not properly validated. It would be useful for clinicians and for future research studies to be able to use a common, valid and reliable instrument to capture patient experiences with different orthodontic appliances. A common instrument with established validity and reliability may allow for direct comparison of patient experiences with different appliances which may assist clinicians when selecting their appliance of choice.

Before large scale administration of an instrument, it should first demonstrate validity evidence that it captures what the researchers intend. Pre-testing questions in a questionnaire context enables researchers to establish whether: 1. Respondents can understand the question, concept, or task, 2. They do so in a consistent way, and 3. In a way the researcher intended[6]. The cognitive interview method has come to be viewed as an important means to ensure the quality and accuracy of questionnaires and is used to identify and analyze sources of response error in questionnaires[7]. Cognitive interviewing to improve questionnaire design involves testing a range of target questions that may pose difficulties originating in the cognitive processing of those questions. A researcher may intend one interpretation of a question, yet find that individuals presented with the question interpret it in an alternate way that might also

seem reasonable in retrospect. Cognitive interviews can expose these alternate interpretations and guide us to modify our questionnaire wording to enhance the clarity. Through cognitive interviews, we can also generate validity evidence by looking at response processes[8] and the evidence collected can tell us the extent by which respondents answer the questions as intended.

Ideally, questionnaire items should first be developed based on data from a focus groups of experts, in this case likely clinical orthodontists and researchers. These items could then be modified in focus groups of orthodontic patients before a draft instrument is formed to establish content validity. At that point, think-aloud cognitive interviews with a small sample of participants can be done to establish face validity. Since Bowman's questionnaire was used in our Xbow vs Forsus study in Chapter 3, it seems reasonable to attempt to improve the existing questionnaire rather than start from scratch.

To our knowledge, there have been no attempts to develop an instrument to capture patient experiences with orthodontic appliances in a systematic way. Therefore, the purpose of this study is to improve upon the existing questionnaire to develop it into a valid instrument to capture patients' experiences with orthodontic appliances. The objective of this study is to investigate the extent by which the questions are understandable and capture patients' experiences with their appliances using the cognitive interview method.

4.1.1 Research Questions

1. To what extent is the modified instrument understandable and interpretable by orthodontic patients?

2. Based on Research Question #1, how can the modified instrument continue to be improved?

4.2 Materials and Methods

4.2.1 Development of the Draft Instrument

The original questionnaire from the University of Buffalo (Appendix I), which was also used unaltered in our Xbow vs. Forsus study in Chapter 3, formed the basis of the draft instrument. The original questionnaire was used by Bowman to compare changes over time by asking patients to recall how they felt "When you first got the Forsus" and "Right now". Due to recall bias, this was not likely an accurate way to assess changes in response over time. Furthermore, the primary aim of our instrument is not to evaluate changes in response over time, but to capture patient experiences. Thus the "When you first got the Forsus" questions were removed from our draft instrument. The removal of these questions significantly shortened the length of the instrument. Questions deemed to provide unimportant information to clinicians, which in most cases were questions also excluded from previous modified versions of the questionnaire[3,5], were also eliminated to further reduce length. Questions that were considered poorly worded by the investigators were edited for clarity. The term "Forsus" was replaced by "appliance" in order to generalize the instrument for use with other orthodontic appliances, not specifically fixed Class II correctors. Questions comparing the appliance to Class II elastics were also eliminated for this reason.

Five-point Likert-scale format was kept for most questions as 5-point scales give sufficient discrimination for most purposes and are easily understood by respondents[9]. Three-point Likert

scale format was kept for questions that had used this format in Bowman's questionnaire. Likert scales were changed to reflect the convention of lower values on the left-hand side of the page consistently for each question, unlike the Bowman's questionnaire which had lower values on the right-hand side of the page for most but not all questions. A question from Bowman's questionnaire had used a visual analog scale asking patients to place an "X" along a horizontal line from 0-8 weeks to correspond with the number of weeks it took them to get used to the Forsus. Most respondents from the Xbow vs. Forsus study placed the "X" somewhere between 1-4 weeks, thus the visual analog scale was replaced with the options "Less than 1 week", "1-2 weeks", "2-3 weeks", "3-4 weeks", and "More than 4 weeks" in the draft instrument.

The open-ended question at the end of Bowman's questionnaire *("Your advice to other patients: Based on your experience of wearing the Forsus, what would you say to someone who was about to start wearing the Forsus?")* provided rich information regarding patient experiences with the Xbow and Forsus appliances, thus this question and additional new open-ended questions were included in the draft instrument.

Questions were grouped into thematic categories: initial impressions, instructions/information, aesthetics, impact on daily life, maintenance, and overall experience. The final draft instrument consisted of 10 5-point Likert-scale questions, 6 3-point Likert-scale questions, 3 "Yes" or "No" questions, and 4 open-ended questions. An additional open-ended question was included asking participants if there were any aspects of their experience with their appliance they thought should be added to the questionnaire.

4.2.2 Participants and Interview Protocol

The Human Ethics Research Office at the University of Alberta granted authorization for this study. Participants were recruited from the University of Alberta Graduate Orthodontic Clinic. Inclusion criteria were as follows: 1. Undergoing orthodontic treatment with a fixed or removable orthodontic appliance other than only full fixed braces for at least 4 weeks, 2. Ability to read and write in English. There were no age restrictions. Patients being treated directly by the principal investigators (AP and CF) were excluded from recruitment to avoid coercion. Patients treated with only full fixed braces without auxiliary appliances were excluded from this stage in the study as the aim of this study was to modify the questionnaire targeted specifically for auxiliary appliances.

The interview format was a combination of the think-aloud and probing methods of cognitive interviewing[6]. The interviewer (AP) used a script to begin the interaction with the participant (Appendix II). Participants were instructed to complete the paper draft instrument and read each question and their answer aloud. Participant were asked to explain their interpretation of each question and why they selected their answer to the interviewer. Participants were encouraged to think aloud as they answered each question and advise the interviewer if there were any issues with comprehension. The interviewer actively assisted the participant with comprehension as needed. The interviewer used probes such as "Tell me what you're thinking" if there was a pause of more than 15 seconds during the interview. The interviewer took written notes during the interview regarding the understandability and interpretation of questions. Response errors, such as circling one response while thinking aloud another, were noted by the interviewer.

4.2.3 Data Analysis

The interviews were audio recorded using QuickTime software on the interviewer's MacBook computer. The files were encrypted before saving. The interviewer/principal investigator referenced the notes taken during the live interview as well as made additional notes while reviewing the audio files regarding the understandability and interpretation of the questions. The interviewer/principal investigator found that there were relatively few sources of error during the interviews, thus it was decided by the interviewer/principal investigator that data analysis would be conducted using informal analysis of the think-aloud protocol as described by Willis[7]. No formal coding scheme was used during analysis as informal analysis without coding is normally used for think-alouds[7]. The final draft of the instrument used and observations from the informal analysis can be viewed in Appendix III.

4.3 Results

Participants consented and participated in the think-aloud interview on the same day with the interviewer conducting no more than 3 interviews per day. As this was the first round of interviewing with a goal to pretest the questionnaire to a broad audience, there were no restrictions on age or sex and thus the first eligible participants to consent to the study were included. After the third day of interviewing it became apparent to the interviewer/principal investigator that the sample size was sufficient for this round of interviews since modest sample sizes of between 5-15 individuals are normally tested in a cognitive interviewing round[7] and there were apparent patterns in interviews thus far. A total of 9 participants were recruited and participated in the think-aloud interviews. The participant ages ranged from 11-49 years old, consisting of 4 pre-adolescent patients (age 12 and under), 3 adolescent patients (age 13-

17), and 2 adult patients (age 18 and over) treated with fixed or removable appliances (Table 4.1).

The first type of error to emerge from analysis of the interviews was with pre-adolescent participants having difficulty with reading comprehension. One 11 year-old participant could not read aloud or understand the word "insight" from the preamble. Two 11 year-old participants could not comprehend the preamble and were unfamiliar with the term "aspect" in the open-ended questions. One pre-adolescent participant could not read the word "noticeable", although they did understand the meaning of the word when it was read aloud by the interviewer.

The second type of error was regarding applicability of a question to a specific participant. Two participants were unsure how to respond to *"How has the appliance affected your speech?"* because their speech was not affected and they were not aware that speech could be affected by an appliance. A similar problem arose for *"How has the appliance affected eating and/or drinking?"* for participants using removable appliances. Three of four participants using removable appliances interpreted that since their appliance is removed during eating and drinking, "Same" was the most appropriate response. One of four participants interpreted that since it is an inconvenience to remove the appliance during eating and drinking, "Slightly worse" was the most appropriate response.

A third source of error was due to not following instructions. Question 12 asked *"Have you had any extra visits to the orthodontist because the appliance was broken? **If you answered YES, please answer question 12b. If NO, skip to question 13"*. Four of eight participants continued to answer question 12b although they had answered "No" to question

12. Question 12b asked *"If you had to make extra visits to the orthodontist because the appliance was broken, was this inconvenient for you?"*. One participant interpreted 12b as a hypothetical question and responded "Yes" because *if* they had to make an extra visit, it would be inconvenient. The other participants responded "No" simply because they did not have any extra visits to the orthodontist.

It became apparent during data analysis that there was an error in the response options listed for Question 10b "*Since the appointment you received the appliance, how long did it take you to get used to it?"* with response options being "Less than 1 week", "1-2 weeks", "2-3 weeks", and "More than 4 weeks". The range of 3-4 weeks was missing. However, none of the participants noticed this error as 9 of 9 participants had selected either "Less than 1 week", "1-2 weeks", or "2-3 weeks". Interestingly, one pre-adolescent participant did ask, "What should I choose if it was exactly 1 week?".

Regarding the open-ended questions, one adolescent participant asked for clarification on what type of response we were looking for with question 14, *"In your own words, what is the WORST aspect of wearing the appliance?"*. The participant was not sure if we were looking for features of the appliance itself or experiences. Regarding question 15, *"In your own words, what is the BEST aspect of wearing the appliance?"*, 6 of 9 participants mentioned the improvement in the bite or teeth without prompting. One participant was unsure of what to say until prompted that they could mention teeth. Eight of nine participants had advice for other patients. No participants had anything to add about their experience that was not already asked. Only 1 of 9 participants had a suggestion for a question that should be added to the questionnaire and suggested we ask "Is there any part of the braces that made your mouth

hurt?". Although evaluating *responses* to questions was not the primary objective of this study, some responses to open-ended questions did provide rich information elucidating how these questions were interpreted. A summary of the responses to the open-ended questions can be found in Table 4.2.

4.4 Discussion

Based on the results of these initial exploratory interviews, it is apparent that an adequate level of reading comprehension is required for responding to a written instrument. We should not assume that every patient undergoing orthodontic treatment is at the level of reading comprehension required for a specific probing instrument. Regrettably, a reading comprehension level tool was not used on the instrument before the study was administered. A Flesch-Kincaid Grade Level Test (*Microsoft Word Version 16.13.1*) was applied to the instrument after analysis revealing a score of 7.3, which corresponds to a 7th grade reading level. This agrees with our findings that preadolescent patients had more difficulty understanding the wording of the instrument than adolescent and adult patients. It appeared that preadolescents had difficulty understanding the preamble that explained the purpose of the questionnaire. When asked what they thought the purpose of the questionnaire was in their own words, they could not. However, this task could be considered paraphrasing, and De Leeuw found that children aged 7-12 are good at thinking aloud but are not adept at paraphrasing orally due to the cognitive demands of the task[10]. Perhaps the preamble was understood but they simply could not express this to the interviewer.

Other questionnaires in the literature focused mainly on adolescents as they are the main population for treatment with fixed Class II correctors. However, pre-adolescents are

often treated with expansion appliances and removable appliances, and capturing their experiences is also, if not more, valuable to clinicians. Poor experiences with Phase 1 pre-adolescent treatment can lead to patient burnout during Phase 2 adolescent treatment[11]. Perhaps a separate instrument should be developed for pre-adolescent patients, at a 4^{th} – 5^{th} grade reading level. Alternatively, perhaps a common instrument at a 6th grade reading level (intended for adolescents and adults) could be administered to pre-adolescent participants verbally by an adult to bypass any reading component.

The results also suggest that some questions should be reworded for clarity. It is evident that the terms "best aspect" and "worst aspect" were difficult for some younger participants to comprehend and also could be interpreted in different ways by older participants. Perhaps rewording to "What do most enjoy about wearing your appliance?" and "What do you least enjoy about wearing your appliance?" would result in more consistent responses regarding experiences with the appliance which would be valuable to clinicians.

Regarding the question *"How has the appliance affected your speech?"*, oral feedback from a participant suggests that the response scale of "Much worse" to "Much Improved" does not match the question since it seems unlikely that speech could be improved by an appliance alone. In the Xbow vs. Forsus study, most participants selected a response ranging between "Much worse" to "Same" for this question. A question regarding effect on speech could be added to the existing multi-part question *"Since you started wearing the appliance, how much has the following affected you?"*. Adding the line "Speech is worse" with the existing response options of "Not at all", "A little" and "A lot" may more appropriately represent experience with speech.

Regarding the problems with *"How has the appliance affected eating and/or drinking?"*, oral feedback from the participants indicated that perhaps the response scale could be modified to reflect difficulty rather than improvement. Rather than "Much worse" to "Much Improved", changing the scale to "Much Harder" to "Much Easier" may help elucidate this question to the participants. Confusion surrounding this question also suggests that removable appliances should be assessed separately from fixed appliances. Having a different version of the instrument, or perhaps a designated set of questions, focused towards removable appliances would help eliminate this confusion. The question targeted to removable appliances could be worded as, *"It is inconvenient for me to remove my appliance during eating and/or drinking"* with a response scale from "Strongly Disagree" to "Strongly Agree". This format matches the format of some of the other questions, however it may also lead to response error if "inconvenient" is read or interpreted as "convenient". Further testing will be necessary. As clear aligner therapy is ever increasing in popularity with adults as well as adolescents, development of a separate instrument for patients wearing removable appliances may be worthwhile.

One pre-adolescent participant had an interesting issue with Question 10b "*Since the appointment you received the appliance, how long did it take you to get used to it?"* with response options being "Less than 1 week", "1-2 weeks", "2-3 weeks", and "More than 4 weeks". The participant asked "What should I choose if it was exactly 1 week?". Bowman's questionnaire had asked participants to respond to a version of this question using a visual analog scale by placing an "X" along a horizontal line from 0-8 weeks, which may have avoided this problem. However, it can be difficult to analyze the exact placement of an "X" which is why

we chose not to include a visual analog scale in our instrument. Still, surprisingly all participants from the Xbow vs. Forsus study placed the "X" in a position corresponding to a discrete number of weeks which allowed us to calculate and compare means, which cannot be done with the current format of responses representing ranges. Conversely, Bowman's format did not provide the range of "Less than 1 week", which 3 of 9 participants selected during our think aloud study. This leads us to believe that perhaps the mean number of weeks to "get used to the appliance" calculated in the Xbow vs. Forsus study is flawed since participants were unable to select an option of less than 1 week. If we are looking for a more precise response, perhaps a visual analog scale using dashed lines representing days rather than weeks could be used, however it is unlikely that participants would be able to pinpoint exactly how many days it took them to get used to the appliance. A range is likely most valuable to clinicians, whereas a precise number of days might be valuable for researchers who intend to use statistics to compare different appliances. Eight of nine participants in the think aloud study had no issue selecting a range.

Gower[12] suggested that think aloud interviews can lead the participant to read less and cause them to miss or skip instructions. This may be the case of one adult participant who selected "Strongly disagree" while reading aloud "Strongly agree" to question 11 *"The appliance is easy to keep clean"*. This participant reported that they were unsure why they made the error, and that they thought it may have been due to the placement of the option on the left-hand side of page. However, all the questions consistently had the response "Strongly disagree" on the left side of the page and only the response to question 11 was circled incorrectly. In retrospect, to make the instrument appear more consistent fluid for readers, all

questions should have been reworded to be asked in a common way with a common 5-point Likert response scale. Reading less and missing/skipping instructions may also be the case with questions 12 and 12b, where half of the participants failed to follow the written instructions. This question could be reverted back to its original wording from Bowman's questionnaire: *"Have you had any extra visits to the orthodontist because the appliance was broken?"* with response choices of "Yes" or "No" and *"If you had to make extra visits to the orthodontist because the appliance was broken, has this bothered you?"* with response options "Not at all", "A little", "A lot", and "It did not break". However, our results from these questions in the Xbow vs. Forsus study also revealed response errors, with 4 of 41 participants responding with something other than "It did not break" even though they had responded "No" to the previous question. This is may be due to participants responding to the follow-up question hypothetically as some did in the think aloud study. Answering the question hypothetically is not necessarily a negative error as this information would be useful for clinicians.

It is apparent that there are likely 2 different applications for the instrument: one for clinicians to gain insight on their patient's experiences with their appliances, and one for researchers to have an objective way to compare patient experiences with different appliances to each other. A statistician will need to be consulted in order to advise researchers the most appropriate method to compare 5-point Likert scale responses between treatment groups.

Participants were asked in an opened-ended question if there were any aspects of their experience that they wished to express that were not already asked in the questionnaire. For the purposes of this study, "patient experience" is defined by the items in the questionnaire itself, but further aspects of experience could be considered in further iterations of this

questionnaire or a completely new one. Since a patient's individual experience can be highly subjective and might be influenced by an individual's pain tolerance, a question regarding pain tolerance or experiences during previous medical and dental procedures could be added to the questionnaire in an attempt to gauge pain tolerance between subjects. However, the wording of this type of question may be difficult for a pre-adolescent patient to comprehend, and pre-adolescents may not have had many previous experiences with medical or dental pain.

After analysis of the interview data a rough second draft of the instrument was developed by simplifying the preamble, rewording questions that were misinterpreted (specifically questions 8, 9, 14, 15), changing all multiple choice questions to 5-point Likert format with similar response options, highlighting instructions, and correcting the error to question 10b. The second draft can be viewed in Appendix IV. This second draft of the instrument should be pilot tested in subsequent interviews.

Recommendations future testing are:

- Verbally administer the instrument to pre-adolescent patients to avoid problems with reading comprehension, or consider developing a separate instrument for pre-adolescent patients with simpler wording
- Administer separate versions or sets of questions for removable and fixed appliances

Once the second draft been pilot tested in a further round of interviews for comprehension and sources of response error, further tests can be done to establish reliability.

4.5 Limitations

The information gained from these interviews is limited by the interviewing protocol, the truthfulness of the participants, and the consistency of the interviewer. Due to the nature of human interaction during the interviews there may have been inconsistencies between interviews that may have affected the results.

4.6 Conclusions and Next Steps

Overall, these initial exploratory interviews provided some valuable feedback to continue to develop the instrument. Conclusions drawn from the initial round of interviews are:

- Reading comprehension was difficult for younger patients (age 12 and under)
- Several participants failed to follow written instructions within the questionnaire
- Valuable information elucidating patient experiences can be obtained from open-ended questions
- Questions regarding eating or drinking with the appliance require modification for patients treated with removable appliances
- Wording of some questions require modification to make the questions more understandable
- Wording of some response options/Likert scales require modification to better match the question

4.7 References

1. Bowman AC, Saltaji H, Flores-mir C, Preston B, Tabbaa S. Patient experiences with the Forsus Fatigue Resistant Device. *Angle Orthod.* 2013;83(3):437–46.

2. O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or Twin-block. 2003;5406(August 2002):128–37.

3. Elkordy SA, Fayed MMS, Abouelezz AM, Attia KH. Comparison of patient acceptance of the Forsus Fatigue Resistant Device with and without miniimplant anchorage: A randomized controlled trial. *Am. J. Orthod. Dentofac. Orthop.* 2015;148(5):755–64. Available at: http://dx.doi.org/10.1016/j.ajodo.2015.06.015.

4. Hamilton, CF; Saltaji, H; Preston, CB; Flores-Mir, C; Tabbaa S. Adolescent patients ' experience with the Carriere distalizer appliance. *Eur. J. Paediatr. Dent.* 2013;14(3):219–24.

5. Gandhi P, Goel M, Batra P. Relative comparison and assessment of patient ' s attitude and discomfort between two different types of fixed functional appliances : A comprehensive survey. *J. Orthod. Res.* 2013;1(3):83–8.

6. Collins D. Pretesting survey instruments : An overview of cognitive methods. *Qual. Life Res.* 2003;12:229–38.

7. Willis GB. *Cognitive Interviewing: A Tool for Improving Questionnaire Design*. Thousand Oaks, CA: SAGE Publications; 2005.

8. American Educational Research Association issuing body. *Standards for educational and psychological testing*. Washington, DC: American Educational Research Association; 2014.

9. Brace I. *Questionnaire Design: How to Plan, Structure, and Write Survey Material for Effective Market Research*. 3rd ed. Kogan Page; 2013.

10. de Leeuw E, Borgers N, Smits A. Pretesting questionnaires for children and adolescents. In: Presser, S., Rothgeb, J.M., Couper, M.P., Lessler, J.T., Martin, E., Martin, J., Singer E, ed. *Methods for testing and evaluating questionnaires* Wiley; 2004:409–29.

11. Hsieh TJ, Pinskaya Y, Roberts WE. Assessment of orthodontic treatment outcomes: early treatment versus late treatment. *Angle Orthod.* 2005;75(2):162–70.

12. Gower A, Dibbs R. Cognitive Research: Designing a "respondent friendly" questionnaire for the 1991 Census. In: *Proceedings of the US Bureau of the Census Annual Research Conference*; 1989:257–66.

4.8 Tables

Table 4.1. *Participant information*

Participant	Appliance	Age
1	Hyrax	11
2	Finger Spring Appliance	11
3	W-arch	12
4	Wilson Bimetric Distalizing Arch	12
5	Carriere	13
6	Hyrax and Lower Holding Arch	14
7	Forsus	15
8	Carriere	42
9	Invisalign	49

Table 4.2 *Responses to open-ended questions*

Participant	In your own words, what is the WORST aspect of wearing the appliance?	In your own words, what is the BEST aspect of wearing the appliance?	Your advice to other patients: Based on your experience, what would you say to someone who was about	Is there anything else you want to tell us about your experience	Are there any aspects of your experience with your appliance you think we need

			to start wearing the appliance?	**with the appliance that has not been already asked?**	**to add to this questionnaire?**
1	Getting food stuck on it	Speaking	You drool a lot	No	No
2	That I have to take it out to eat	It moves my teeth very fast	I would say that it goes by fast as long as you wear it	No	No
3	The pain	Getting good teeth	Be ready for pain	No	No
4	There is a lot of cleaning	It will pay off in the future	You can still eat all the food you want, just be careful	No	Is there any part of the braces that made your mouth hurt?
5	Food getting stuck in my teeth (Rubber) bands breaking Cuts inside my mouth/gums	Seeing change in my teeth	Keep your (rubber) bands in a bag Always have extra (rubber) bands Pain is normal Brushing the metal parts	No	No
6	Getting food stuck on the lower part	The difference it was making in my upper jaw	Keep it clean	No	No
7	It rubs against your gums	The change it does	*None*	No	No
8	Elastics very noticeable	Very small No pain	Do it	No	No
9	The worst thing for me is my speech is not the same	The best aspect is straighter teeth	First day is easy, second and third day you have sore lips where the trays rub, then it gets easier	No	No

4.8 APPENDIX

4.8.1 Appendix I: Original questionnaire: Experience with the Forsus Appliance, Bowman et al

Experience with the Forsus Appliance

First, please tell us about yourself.

Age: _____ years old

Sex: Male Female (circle one)

These questions are about when you FIRST got the Forsus appliance. Please circle only one answer.

1. I was given a complete description of the Forsus appliance before wearing it.
Strongly Agree Agree Neutral Disagree Strongly Disagree

2. When I first saw it, the Forsus appliance looked scary/overwhelming.
Strongly Agree Agree Neutral Disagree Strongly Disagree

3. The appointment the Forsus was placed was quick and easy.
Strongly Agree Agree Neutral Disagree Strongly Disagree

4. I was given instructions for wear and care of the Forsus.
Strongly Agree Agree Neutral Disagree Strongly Disagree

5. How noticeable was the Forsus (not just your braces) to friends and family?
Very Noticeable Somewhat Neutral A little Not Noticeable

6. Did you wear elastics or rubber bands before you had the Forsus? **Yes No**
***If you answered YES, please answer question 6a, below. If you answered NO, go to question 7.*

6a. Fill in the blank: Wearing the Forsus is _____ than wearing rubber bands/elastics.
Way easier Somewhat easier No Different Somewhat Harder Way Harder

These questions are about WHEN YOU FIRST GOT THE FORSUS APPLIANCE. Please circle only one answer.

7. WHEN YOU FIRST GOT THE FORSUS, how much did the following things change?

Speech	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Eating	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Drinking	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Sleeping	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Appearance	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**

I am teased **Much improved Improved Same Slightly worse Much worse**

8. WHEN YOU FIRST GOT THE FORSUS, how much did the following affect you?

Sore teeth	**Not at all**	**A little**	**A lot**
Sore jaw	**Not at all**	**A little**	**A lot**
Soreness on lip/cheek from rubbing	**Not at all**	**A little**	**A lot**
Feeling embarrassed	**Not at all**	**A little**	**A lot**
Drooling	**Not at all**	**A little**	**A lot**
Difficult to open wide/yawn	**Not at all**	**A little**	**A lot**
Keeping Forsus clean is a pain	**Not at all**	**A little**	**A lot**

9. WHEN YOU FIRST GOT THE FORSUS, how did wearing the Forsus affect
Your school work?
Much improved Improved Same Slightly worse Much worse
Getting along with your friends?
Much improved Improved Same Slightly worse Much worse
Getting along with your family?
Much improved Improved Same Slightly worse Much worse
Participation in music? What type of music? _____ OR I don't participate in music. _____
Much improved Improved Same Slightly worse Much worse
Participation in sports? What type of sports? _____OR I don't participate in sports. _____
Much improved Improved Same Slightly worse Much worse

These questions are about how you feel about the Forsus appliance RIGHT NOW. Please circle only one answer.

10. RIGHT NOW, while you are wearing the Forsus, how much have the following things changed?

Speech	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Eating	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Drinking	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Sleeping	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Appearance	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**
I am teased	**Much improved**	**Improved**	**Same**	**Slightly worse**	**Much worse**

11. RIGHT NOW, while you are wearing the Forsus, how much has the following affected you?

Sore teeth	**Not at all**	**A little**	**A lot**
Sore jaw	**Not at all**	**A little**	**A lot**
Soreness on lip/cheek from rubbing	**Not at all**	**A little**	**A lot**
Feeling embarrassed	**Not at all**	**A little**	**A lot**
Drooling	**Not at all**	**A little**	**A lot**
Difficult to open wide/yawn	**Not at all**	**A little**	**A lot**
Keeping Forsus clean is a pain	**Not at all**	**A little**	**A lot**

12. RIGHT NOW, while you are wearing the Forsus, how has wearing the Forsus affected Your schoolwork?

Much improved Improved Same Slightly worse Much worse

Getting along with friends?

Much improved Improved Same Slightly worse Much worse

Getting along with your family?

Much improved Improved Same Slightly worse Much worse

Participation in music? What type of music? _____ OR I don't participate in music. _____

Much improved Improved Same Slightly worse Much worse

Participation in sports? What type of sports? _____ OR I don't participate in sports. _____

Much improved Improved Same Slightly worse Much worse

These questions are about how you feel about the Forsus RIGHT NOW. Please circle only one answer.

13. I enjoy seeing the difference the Forsus appliance is making in my facial appearance.

Strongly Agree Agree Neutral Disagree Strongly Disagree

14.Have you had any extra visits to the orthodontist because the Forsus was broken?

Yes No

15. If you had to make extra visits to the orthodontist because the Forsus was broken, has this bothered you?

Not at All A little A lot It did not break

16. At this time, do you feel like you have gotten used to the Forsus? **Yes No**

***If you answered YES, please answer question 16a, below. If you answered NO, go to question* 17.

16a. How long did it take to get used to the Forsus?

Please place an "X" anywhere on the horizontal line that corresponds to your answer.

0 weeks 4 weeks 8 weeks

17. Overall, how do you feel about your experience with the Forsus appliance?

Really Good Good Neutral Bad Really bad

18. Your advice to other patients: Based on your experience of wearing the Forsus, what would you say to someone who was about to start wearing the Forsus? (Use back of sheet if necessary.)

Thank you. Please seal survey in envelope and return to your orthodontist or staff member.

4.8.2 Appendix II: Interviewer Script

Interviewer Script for Think-Aloud Survey
My name is _____ and I am helping the orthodontists at the University of Alberta with this project. We are interested in how our patients interpret a new survey about orthodontic appliances. Our goal here is to get a better understanding of how effective our survey questions are. To do this, I am going to ask you to fill out this paper survey as if you were filling it out by yourself at home for your orthodontist.

As you are filling out the survey, I will ask you to tell me everything you are thinking for each question on the survey. Please explain, out loud in your own words, what you think each question is asking and why you are selecting the answer you choose. Don't hesitate to speak up whenever something seems unclear, is hard to answer, or doesn't apply to you. We can also skip questions and come back to them later, if that is what you want to do. I'll also take notes. Do you have any questions, or is anything not clear?

I will record our session because I want to get an accurate record of what you say. All the information you share with me today will be kept anonymous. No one will be able to identify you. Do you have any questions or concerns?

****

At this time provide the participant with the "Patients' Experiences with Orthodontic Appliances Survey". Start recording and ask the participant to first read the preamble at the beginning of the survey and to let you know if they have any questions. Next, ask them to take their time to fill out the paper survey with pen/pencil as if they were filling it out alone at home for their orthodontist, but thinking aloud. Use the probes below as necessary. Probes to use if the participant is silent for more than 20 seconds during the think-aloud session:

- Tell me what you are thinking.
- How did you arrive at your answer?
- In your own words, what is this question asking?
- Tell me more about that. Why do you say _____ ?

4.8.3 Appendix III: Administered draft instrument used in the think aloud study with observations by the interviewer: Experiences with your Orthodontic Appliance

Survey: Experiences with your Orthodontic Appliance

Purpose: This survey has been developed to gather feedback regarding your experience with your specific appliance. This information will give your orthodontist insight from your point of view. The information you provide will remain private and confidential outside of our research.

OBSERVATIONS: Two 11-year old participants did not understand the preamble. Reading comprehension was the main issue. Both could not read the word "insight".

First, please tell us about yourself.

Age: _____ years old

Sex: Male Female (circle one)

Please circle only one answer.

Initial Impressions

1. When I first saw the appliance, it looked scary/overwhelming.

Strongly Disagree Disagree Neutral Agree Strongly Agree

OBSERVATIONS: The question was interpreted as intended. Respondents mentioned that they thought the appliance "looked like it would hurt" or "looked painful".

2. The appointment when the appliance was placed was quick and easy.

Strongly Disagree Disagree Neutral Agree Strongly Agree

OBSERVATIONS: One participant was unsure how to answer because "It was not quick and easy". Several respondents selected neutral, describing that the procedure was not quick, but took as long as expected. This is likely due to their expectations based on previous medical/dental appointments.

Instructions/Information

3. I was given a description of the appliance before wearing it.

Strongly Disagree Disagree Neutral Agree Strongly Agree

OBSERVATIONS: The question was interpreted as intended.

4. I was given instructions on wear and care of the appliance.

Strongly Disagree Disagree Neutral Agree Strongly Agree

OBSERVATIONS: The question was interpreted as intended.

Aesthetics

5. The appliance is noticeable to friends and family.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

OBSERVATIONS: The question was generally interpreted as intended. One 11-year old participant could not read the word "noticeable" but understood the question when it was read aloud by the interviewer.

6. I enjoy seeing the difference the appliance is making in my bite.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

OBSERVATIONS: The question was interpreted as intended. All participants had positive responses.

Impact on Daily Life

7. Since you started wearing the appliance, how much has the following affected you?

Sore teeth	**Not at all**	**A little**	**A lot**
Sore jaw	**Not at all**	**A little**	**A lot**
Soreness on lip/cheek from rubbing	**Not at all**	**A little**	**A lot**
Feeling embarrassed	**Not at all**	**A little**	**A lot**
Drooling	**Not at all**	**A little**	**A lot**
Difficult to open wide/yawn	**Not at all**	**A little**	**A lot**

OBSERVATIONS: The questions were interpreted as intended.

8. How has the appliance affected your speech?

Much worse **Slightly Worse** **Same** **Improved** **Much Improved**

OBSERVATIONS: Two participants were unsure of how to answer this question because they were unsure how the appliance could affect speech. Perhaps the question should ask, "If at all, how has the appliance affected your speech?"

9. How has the appliance affected eating and/or drinking?

Much worse **Slightly Worse** **Same** **Improved** **Much Improved**

OBSERVATIONS: The question was interpreted as intended although participants using removable appliances were unsure how to respond since the appliances are removed during eating and drinking. One responded "Slightly worse" since it is an inconvenience to remove the appliance when eating and drinking. Two responded "Same" since eating and drinking is the same once the appliance is removed.

10. At this time, do you feel like you have gotten used to the appliance?

Yes **No**

***If you answered YES, please answer question 10b. If NO, skip to question 11.*

OBSERVATIONS: The question was interpreted as intended.

10b. Since the appointment you received the appliance, how long did it take you to get used to it?

Less than 1 week **1-2 weeks** **2-3 weeks** **More than 4 weeks**

OBSERVATIONS: The question was interpreted as intended. One participant was unsure which answer to choose as he wanted to tell us "1 week" precisely rather than a range.

Maintenance

11. The appliance is easy to keep clean.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

OBSERVATIONS: The question was interpreted as intended. One adult patient accidentally circled "Strongly Disagree" while reading aloud "Strongly Agree" and reported that it was due to the placement of the responses on the page.

12. Have you had any extra visits to the orthodontist because the appliance was broken?

Yes **No**

***If you answered YES, please answer question 12b. If NO, skip to question 13.*

OBSERVATIONS: Four participants did not read the asterisked instructions. They continued to answer 12b even if they selected "No" for question 12.

12b. If you had to make extra visits to the orthodontist because the appliance was broken, was this inconvenient for you?

Yes **No**

OBSERVATIONS: The question was interpreted as intended by those who followed the asterisked instructions. Those who answered "No" to question 12 either answered hypothetically or continued to answer "No" because they did not have to make extra visits.

Overall

13. Overall, how do you feel about your experience with the appliance?

Really Bad **Bad** **Neutral** **Good** **Really Good**

OBSERVATIONS: The question was interpreted as intended and overall the responses were positive.

Please write your responses in the space below.

14. In your own words, what is the WORST aspect of wearing the appliance?

OBSERVATIONS: Two pre-adolescent participants did not comprehend the word "aspect". One adolescent participant was unsure what was being asked – specifically what was meant by "worst aspect".

15. In your own words, what is the BEST aspect of wearing the appliance?
COMMENT: One participant could not think of an answer until prompted that they could talk about teeth. Most participants mentioned that they enjoyed changes in teeth/bite without prompting.

16. Your advice to other patients: Based on your experience, what would you say to someone who was about to start wearing the appliance?

OBSERVATIONS: The question was interpreted as intended and 8 of 9 participants had advice to give.

17. Is there anything else you want to tell us about your experience with the appliance that has not been already asked?

OBSERVATIONS: The question was interpreted as intended however none of the participants had anything to say.

18. Are there any aspects of your experience with your appliance you think we need to add to this questionnaire?

OBSERVATIONS: The question was interpreted as intended however only 1 adolescent participant had a suggestion for a future question. They suggested to ask "Is there any part of the braces that made your mouth hurt?" and to be an open-ended question so future respondents could specify which parts of the appliance "hurt". This may be a useful tool as sometimes we incorrectly assume which parts of an appliance are uncomfortable.

Thank you!

4.8.4 Appendix IV: Second draft of the instrument to be tested in a second round of interviews

Survey: Experiences with your Orthodontic Appliance

Purpose: This survey has been developed to gather feedback regarding your experience with your specific appliance. This information will help your orthodontist understand your point of view. The information you provide will remain private and confidential outside of our research.

First, please tell us about yourself.

Age: _____ years old

Sex: Male Female (circle one)

Please circle only one answer.

Initial Impressions

1. When I first saw the appliance, it looked scary/overwhelming.

Strongly Disagree Disagree Neutral Agree Strongly Agree

2. The appointment when the appliance was placed was quick and easy.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Instructions/Information

3. I was given a description of the appliance before wearing it.

Strongly Disagree Disagree Neutral Agree Strongly Agree

4. I was given instructions on wear and care of the appliance.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Aesthetics

5. The appliance is noticeable to friends and family.

Strongly Disagree Disagree Neutral Agree Strongly Agree

6. I enjoy seeing the difference the appliance is making in my bite.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Impact on Daily Life

7. The appliance makes my teeth sore

Strongly Disagree Disagree Neutral Agree Strongly Agree

8. The appliance makes my jaw sore

Strongly Disagree Disagree Neutral Agree Strongly Agree

9. The appliance gives me sores on the lip/cheek from rubbing

Strongly Disagree Disagree Neutral Agree Strongly Agree

10. The appliance makes me feel embarrassed

Strongly Disagree Disagree Neutral Agree Strongly Agree

11. The appliance makes me drool

Strongly Disagree Disagree Neutral Agree Strongly Agree

12. The appliance makes it difficult to open wide/yawn

Strongly Disagree Disagree Neutral Agree Strongly Agree

13. The appliance makes my speech worse

Strongly Disagree Disagree Neutral Agree Strongly Agree

14. Please respond to only 1 question below according to the type of appliance you are wearing (FIXED=glued in the mouth, REMOVABLE=you can remove it yourself to eat and brush):
a. FIXED APPLIANCES: How has the appliance affected eating and/or drinking?
Much Harder **Slightly Harder** **Same** **Easier** **Much Easier**

b. REMOVABLE APPLIANCES: It is inconvenient for me to remove my appliance during eating and/or drinking
Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

15. At this time, do you feel like you have gotten used to the appliance?
Yes **No**

If you answered YES, please answer question 15b. If NO, skip to question 16*

15b. Since the appointment you received the appliance, how long did it take you to get used to it?
Less than 1 week **1-2 weeks** **2-3 weeks** **3-4 weeks** **More than 4 weeks**

Maintenance
16. The appliance is easy to keep clean.
Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

17. Have you had any extra visits to the orthodontist because the appliance was broken?
Yes **No**

If you answered YES, please answer question 17b. If NO, skip to question 12*

17b. If you had to make extra visits to the orthodontist because the appliance was broken, was this inconvenient for you?
Yes **No**

Overall
18. Overall, how do you feel about your experience with the appliance?
Really Bad **Bad** **Neutral** **Good** **Really Good**

Please write your responses in the space below.
19. In your own words, what do MOST enjoy about wearing your appliance?

20. In your own words, what do LEAST enjoy about wearing your appliance?

21. Your advice to other patients: Based on your experience, what would you say to someone who was about to start wearing the appliance?

22. Is there anything else you want to tell us about your experience with the appliance that has not been already asked?

23. Are there any aspects of your experience with your appliance you think we need to add to this questionnaire?

Thank you!

CHAPTER 5: GENERAL DISCUSSION

5.1 Introduction

Compliance-free fixed Class II corrector appliances have become increasingly popular in the current orthodontic landscape. Most orthodontic companies have a version of a fixed Class II corrector that all provide similar treatment results. With so many options available to the orthodontist, factors such as frequency of emergency visits associated with the appliance as well as patient experience with the appliance become more important than ever.

The purpose of this thesis was to investigate patient experience and emergency visits during treatment with the Xbow appliance compared to the Forsus Fatigue Resistant Device (FFRD) used concomitant to full fixed appliances using an existing questionnaire from the literature[1], and to use the information gained to begin to develop the questionnaire into a common valid and reliable instrument to capture patients' experiences with orthodontic appliances.

The research questions of this thesis were:

1. How does patient experience or frequency of emergency visits compare for patients treated with the FFRD vs. Xbow Class II correction appliances among participants of a previously completed RCT?
2. What do we know so far in regards to patients' experiences or emergency appointments when using fixed Class II correctors? What existing questionnaires have been used to capture patients' experiences during Class II malocclusion orthodontic treatment?

3. To what extent is a modified draft instrument understandable and interpretable by orthodontic patients? How can this draft instrument be improved in the future?

5.2 Summary of Results

5.2.1 Chapter 2 Results

Regarding the first research question, findings collected from study patients treated with the Xbow or FFRD using the original questionnaire were as follows:

- The Xbow and the FFRD are similar in terms of complications requiring additional appointments and overall patient experiences with evidence of some slight differences:
    - The FFRD group felt that insertion of the appliance was quick and easy, compared to the Xbow group who had a neutral response to this statement
    - The Xbow group reported the appliance was slightly more noticeable, and a little more difficulty to open wide/yawn compared the FFRD group
- Differences are likely due to the fact that the FFRD is inserted after patients have already become accustomed to full fixed braces
- The majority of patients were accustomed to the appliances within 2 months, and those who were accustomed reported the mean time to "get used to" the Xbow go be 3.95 weeks, and 2.25 weeks for the FFRD
- Patients' responses to questionnaire items did not change significantly between 1 week and 2 months
- 50% of Xbow treated patients and 31.57% of FFRD treated patients reported experiencing a "breakage" that required an additional appointment within the first 2 months of insertion

- Based on treatment notes, 76% of Xbow treated patients and 65.22% of FFRD treated patients experienced at least 1 emergency visit during the course of the appliance treatment (most longer than the 2 months assessed above)
- Based on treatment notes, 48% of Xbow treated patients and 17.39% of FFRD treated patients experienced band breakage

5.2.2 Chapter 3 Results

Our systematic review of the literature revealed the following:

- The main source of discomfort from Forsus-type appliances for most evaluated patients appears to be soreness in the cheeks
- Most evaluated patients treated with a Herbst appliance, regardless of design, will experience complications (fractures and/or dislodging) requiring emergency appointments
- A standardized method for reporting orthodontic emergencies to compare different appliance designs is needed
- A common and valid instrument to capture patient's experiences with different appliance designs is needed

5.2.3 Chapter 4 Results

Regarding the second and third research questions, findings from the think aloud interviews with patients currently in treatment with orthodontic appliances were as follows:

- Reading comprehension was difficult for younger patients (age 12 and under)
- Several participants failed to follow written instructions within the questionnaire

- Valuable information elucidating patient experiences was gained from open-ended questions
- Questions regarding eating or drinking with the appliance needed to be modified for patients treated with removable appliances
- Wording of some questions required modification to make the questions more understandable
- Wording of some response options/Likert scales required modification to better match the question

5.3 Limitations

In retrospect, some flaws in the design of the Xbow vs FFRD study had a negative effect on the quality of the results. Patients were given the paper questionnaires at appliance insertion and were told to complete them at specific time points – however there was no way to ensure they were truly completed at those time points. Seven patients were excluded from the study due to completing the questionnaires at grossly incorrect time points, as reported by themselves, but it is highly likely that other included patients had also completed the questionnaires at incorrect time points. Also, 31.7% of analyzed patients had at least 1 response left blank on a questionnaire at either T1 or T2, including 2 patients who left at least 1 entire page blank. Lastly, due to a printing error, 16 sets of questionnaires were distributed missing the final page and thus those 16 patients were missing responses to Questions 17 and 18.

Another limitation was the use of this particular non-validated questionnaire. Since the questionnaire was not validated, we do not truly know if any of the questions truly captured the specific patient experience. Also, the questionnaire was long and unmodified from its original

form for this study. Its length and wordiness may have contributed to incomplete responses or may have led to inappropriate responses to some questions.

Any data retrieved from treatment notes was limited by the accuracy of the data entered manually into the notes.

This thesis did not follow the traditional sequence for questionnaire development and validation. Ideally, a questionnaire items should have been first developed based on data from focus groups of experts, in this case likely clinical orthodontists and researchers. These items could then be modified in focus groups of orthodontic patients before a draft instrument is formed to establish content validity. At that point, the think-aloud interviews with a small sample of participants could be done to establish face validity. Once the questionnaire has been validated in several rounds of interviewing, the valid questionnaire could then have been used in the FFRD vs Xbow study as part of a reliability test for internal consistency. Ideally, a sample size for reliability test should be about 20 subjects per questionnaire item[2]. Thus, the sample size for a reliability study using our draft instrument thus far should be approximately 400 subjects. Unfortunately, due to the timing of this thesis and the timing of the orthodontic treatment of the subjects randomized clinical trial from the graduate orthodontic clinic, the ideal sequence of questionnaire development was not possible. A summary of the sequence of events from this thesis and future steps can be viewed in Figure 5.1.

5.4 Future Studies

Overall, the findings from the clinical trial and these initial exploratory interviews provided some valuable feedback to continue to develop the instrument. The second draft of

the instrument should be pilot tested in subsequent interviews. Recommendations future testing are:

- Verbally administer the instrument to pre-adolescent patients to avoid problems with reading comprehension, or consider developing a separate instrument for pre-adolescent patients with simpler wording
- Administer separate versions or sets of questions for removable and fixed appliances

Once the second draft been pilot tested for comprehension and sources of response error, further tests can be done to establish reliability.

Once reliability has been established, the questionnaire can be used by orthodontic clinicians and researchers to capture patient's experiences with different orthodontic appliances. If another study comparing 2 similar but different appliances is to be conducted, recommendations for study design are as follows:

- Online administration of the questionnaire to avoid responses being left blank
- If different time points are to be investigated, open the questionnaire completion window for a set period of time (ie. a few days) to ensure timely completion

5.6 Conclusions and Final Thoughts

In summary, this thesis first compared patient's experiences with the Xbow compared to the conventional use of the FFRD in a randomized clinical trial. It became apparent from the results of that study that there were limitations with the instrument and that a systematic review of the literature was necessary. Based on the findings from the systematic review and from the clinical trial, a second study was conducted to begin the process of validating a common instrument to capture patient's experiences with orthodontic appliances. This thesis

has begun the process of establishing validity evidence using response processes[4] for a new instrument. A rough second draft of the instrument has been developed. Further testing of the second draft of the instrument is recommended before reliability testing and large-scale administration of the instrument is done.

In conclusion, patients to be treated with the Xbow or FFRD should be advised that they will experience some level of functional limitation and discomfort, but that this will diminish within a few weeks. It is apparent from the results of the thesis that questionnaires can provide valuable information to orthodontic clinicians and researchers regarding patient experiences associated with orthodontic appliances. One interesting finding that has not yet been addressed is that information collected from patients from the Xbow vs FFRD study as well as from the think aloud study support that most patients enjoy seeing the difference in their teeth and/or bite regardless of any pain or discomfort caused by the appliance. For instance, one adolescent participant from the think aloud study reported that the worst aspect of wearing the appliance was "It rubs against your gums", the best aspect of wearing the appliance was "The change it does", and when asked *"Overall, how do you feel about your appliance?"* they selected the most positive response of "Really Good". A study regarding patient satisfaction with orthodontic treatment[3] found that pain or discomfort associated with appliance treatment did not affect satisfaction because discomfort was accepted as part of the treatment process. Perhaps treatment result or perceived treatment result has a strong influence on patient experience as well.

5.7 References

1. Bowman AC, Saltaji H, Flores-mir C, Preston B, Tabbaa S. Patient experiences with the Forsus

Fatigue Resistant Device. *Angle Orthod.* 2013;83(3):437–46.

2. Anthoine E, Moret L, Regnault A, Sbille V, Hardouin JB. Sample size used to validate a scale: A review of publications on newly-developed patient reported outcomes measures. *Health Qual. Life Outcomes* 2014;12(1):1–10.

3. Wong L, Ryan FS, Christensen LR, Cunningham SJ. Factors influencing satisfaction with the process of orthodontic treatment in adult patients. *Am. J. Orthod. Dentofac. Orthop.* 2018;153(3):362–70. Available at: https://doi.org/10.1016/j.ajodo.2017.07.017.

4. American Educational Research Association issuing body. *Standards for educational and psychological testing*. Washington, DC: American Educational Research Association; 2014.

5.8 Figures

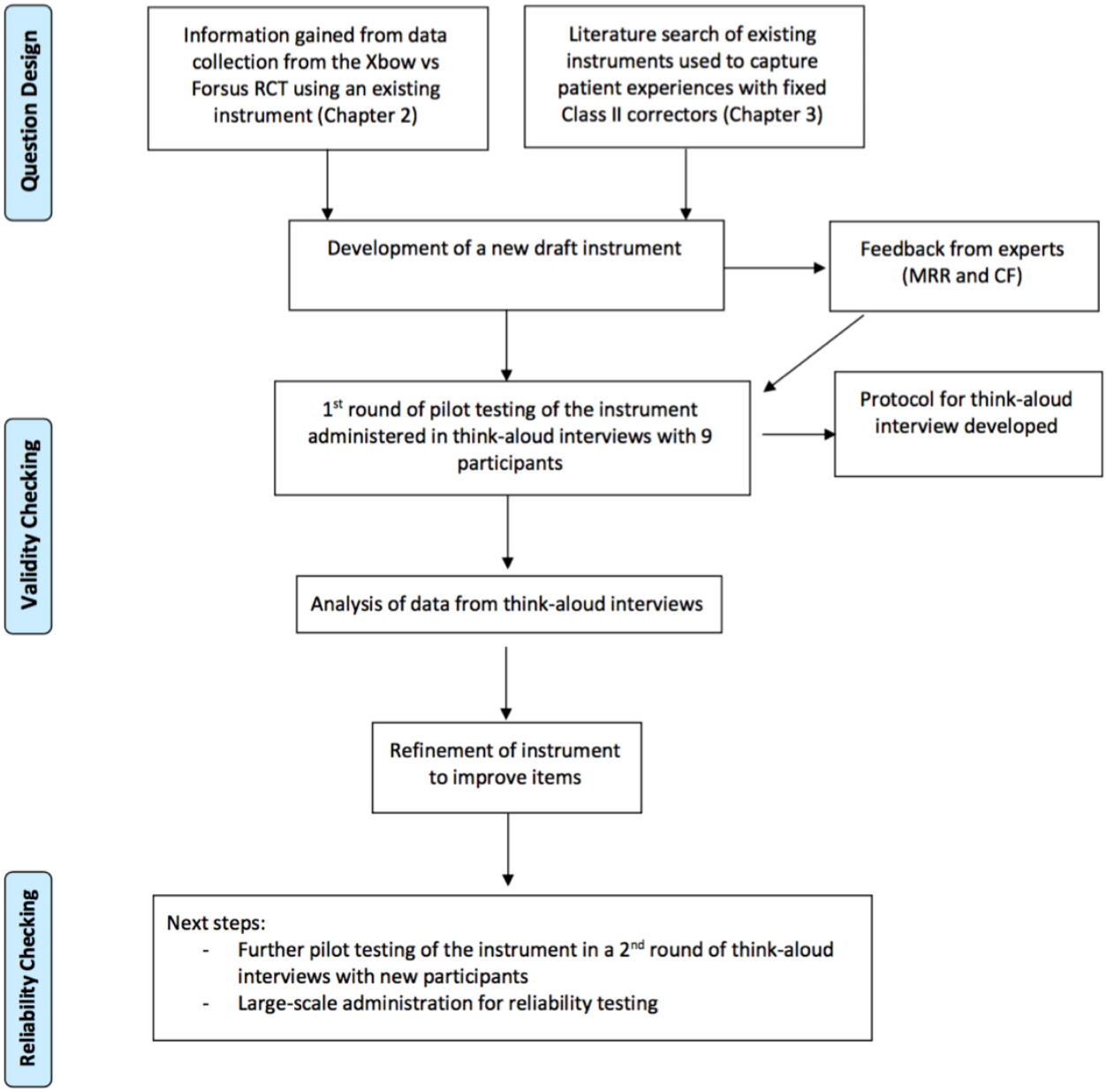

Figure 5.1 *Summary of steps completed during this thesis and next steps*

Bibliography

1. Burkhardt, Donald R., McNamara, James A., and Baccetti T. Maxillary molar distalization or mandibular enhancement: A cephalometric comparison of comprehensive orthodontic treatment including the pendulum and the Herbst appliances. *Am. J. Orthod. Dentofac. Orthop.* 2003;123(2):108–16.

2. O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or Twin-block. 2003;5406(August 2002):128–37.

3. Miller RA, Tieu L, Flores-mir C. Incisor inclination changes produced by two compliance-free Class II correction protocols for the treatment of mild to moderate Class II malocclusions. 2013;83(3).

4. Proffit WR. *Contemporary Orthodontics*. 5th Editio. (Elsevier, ed.). St. Louis, Missouri

5. Pachêco-Pereira C, Pereira JR, Dick BD, Perez A, Flores-Mir C. Factors associated with patient and parent satisfaction after orthodontic treatment: A systematic review. *Am. J. Orthod. Dentofacial Orthop.* 2015;148(4):652–9. Available at: http://www.ajodo.org/article/S0889540615007751/fulltext.

6. Bowman AC, Saltaji H, Flores-mir C, Preston B, Tabbaa S. Patient experiences with the Forsus Fatigue Resistant Device. *Angle Orthod.* 2013;83(3):437–46.

7. Elkordy SA, Fayed MMS, Abouelezz AM, Attia KH. Comparison of patient acceptance of the Forsus Fatigue Resistant Device with and without miniimplant anchorage: A randomized controlled trial. *Am. J. Orthod. Dentofac. Orthop.* 2015;148(5):755–64. Available at: http://dx.doi.org/10.1016/j.ajodo.2015.06.015.

8. Hamilton, CF; Saltaji, H; Preston, CB; Flores-Mir, C; Tabbaa S. Adolescent patients ' experience with the Carriere distalizer appliance. *Eur. J. Paediatr. Dent.* 2013;14(3):219–24.

9. Gandhi P, Goel M, Batra P. Relative comparison and assessment of patient ' s attitude and discomfort between two different types of fixed functional appliances : A comprehensive survey. *J. Orthod. Res.* 2013;1(3):83–8.

10. Collins D. Pretesting survey instruments : An overview of cognitive methods. *Qual. Life Res.* 2003;12:229–38.

11. Willis GB. *Cognitive Interviewing: A Tool for Improving Questionnaire Design*. Thousand Oaks, CA: SAGE Publications; 2005.

12. Stewart FN, Kerr WJS, Taylor PJS. Appliance wear : the patient's point of view. 1997;19(October):377–82.

13. De Felippe NLO De, Silveira AC Da, Viana G, Smith B. Influence of palatal expanders on oral comfort, speech, and mastication. *Am. J. Orthod. Dentofac. Orthop.* 2010;137(1):48–53.

Available at: http://dx.doi.org/10.1016/j.ajodo.2008.01.023.

14. Burkhardt DR, McNamara Jr. JA, Baccetti T. Maxillary molar distalization or mandibular enhancement: a cephalometric comparison of comprehensive orthodontic treatment including the pendulum and the Herbst appliances. *Am J Orthod Dentofac. Orthop* 2003;123(2):108–16.

15. Pacha MM, Fleming PS, Johal A. A comparison of the efficacy of fixed versus removable functional appliances in children with Class II malocclusion: A systematic review. *Eur. J. Orthod.* 2016;38(6):621–30.

16. O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or twin-block appliances: a randomized, controlled trial. *Am. J. Orthod. Dentofacial Orthop.* 2003;124(2):128–37.

17. Antonarakis GS, Kiliaridis S. Treating Class II malocclusion in children. Vertical skeletal effects of high-pull or low-pull headgear during comprehensive orthodontic treatment and retention. *Orthod Craniofac Res* 2015;18(2):86–95.

18. Shen, G; Hagg, U; Darendeliler M. Skeletal effects of bite jumping therapy on the mandible – removable vs . fixed functional appliances. *Orthod. Craniofacial Res.* 2005;8:2–10.

19. Zymperdikas VF, Koretsi V, Papageorgiou SN, Papadopoulos MA. Treatment effects of fixed functional appliances in patients with Class II malocclusion: a systematic review and meta-

analysis. *Eur. J. Orthod.* 2016;38(2):113–26.

20. Moher D, Liberati A, Tetzlaff J, et al. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med.* 2009;6(7):e1000097.

21. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;343:d5928.

22. Sterne JA, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* 2016;355.

23. Wells G, Shea B, O'Connell D, et al. *The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses*. Ottawa Hosp. Univ. Ottawa.; 2013.

24. Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J. Clin. Epidemiol.* 2011;64(4):401–6.

25. Moro A, Janson G, Moresca R, Freitas MR de, Henriques JFC. Estudo comparativo de complicações durante o uso do aparelho de Herbst com cantiléver e com splint inferior de acrílico removível. *Dental Press J. Orthod.* 2011;16(1):e1–7.

26. Gandhi P, Goel M, Batra P. Relative comparison and assessment of patient ' s attitude and discomfort between two different types of fixed functional appliances : A comprehensive survey.

2013;1(3).

27. Tian X, Wu Z, Zhang S, Zhang M, Lin X. [Patients' experiences with the Forsus appliance]. *Shanghai Kou Qiang Yi Xue* 2014;23(2):209–13.

28. Hagg, Urban; Tse, Edmond; Rabie, A, Robinson W. A comparison of splinted and banded Herbst appliances: treatment changes and complications. *Aust. Orthod. J.* 2002;18(2):76–81.

29. Latkauskiene D, Jakobsone G, McNamara JA. A prospective study on the clinical effectiveness of the stainless steel crown Herbst appliance. *Prog. Orthod.* 2012;13(2):100–8.

30. Sanden E, Pancherz H, Hansen K. Complications during Herbst appliance treatment. *J. Clin. Orthod.* 2004;38(3):130–3.

31. Schiöth T, von Bremen J, Pancherz H, Ruf S. Complications during Herbst appliance treatment with reduced mandibular cast splints : a prospective, clinical multicenter study. *J. Orofac. Orthop.* 2007;68(4):321–7.

32. Silva JFE, Gerszewski C, Moresca RC, Correr GM, Flores-Mir C, Moro A. Retrospective study of clinical complications during orthodontic treatment with either a removable mandibular acrylic splint Herbst or with a cantilever Herbst. *Angle Orthod.* 2015;85(1):64–71.

33. Manni A, Mutinelli S, Cerruto C, Giraudo P, Romano R, Cozzani M. Comparison of

complications in the conventional telescopic Herbst rod and tube and Manni telescopic Herbst: A retrospective clinical study. *Angle Orthod.* 2018;88(4):377–83. Available at: http://www.angle.org/doi/10.2319/082317-569.1.

34. Kanuru R, Bhasin V, Khatri A, Dodda K, Singh E, Grover S. Comparison of Complications in Removable Mandibular Acrylic Splint and Cantilever Herbst for Management of Class II Malocclusion : A Retrospective Study. *J. Contemp. Dent. Pract.* 2017;18(May):363–5.

35. Manni A, Cozzani M, Mazzotta L, Fiore VP, Mutinelli S. Acrylic splint Herbst and Hanks telescoping Herbst : A retrospective study of emergencies , retreatments , treatment times. *Int. Orthod.* 2014;12(1):100–10. Available at: http://dx.doi.org/10.1016/j.ortho.2013.12.015.

36. Heinig N, Göz G. Clinical application and effects of the Forsus spring. A study of a new Herbst hybrid. *J. Orofac. Orthop.* 2001;62(6):436–50.

37. Wiechmann D, Vu J, Schwestka-polly R, Helms H, Knösel M. Clinical complications during treatment with a modified Herbst appliance in combination with a lingual appliance. *Head Face Med.* 2015;11(31):1–10.

38. American Educational Research Association issuing body. *Standards for educational and psychological testing*. Washington, DC: American Educational Research Association; 2014.

39. Brace I. *Questionnaire Design: How to Plan, Structure, and Write Survey Material for Effective*

Market Research. 3rd ed. Kogan Page; 2013.

40. de Leeuw E, Borgers N, Smits A. Pretesting questionnaires for children and adolescents. In: Presser, S., Rothgeb, J.M., Couper, M.P., Lessler, J.T., Martin, E., Martin, J., Singer E, ed. *Methods for testing and evaluating questionnaires* Wiley; 2004:409–29.

41. Hsieh TJ, Pinskaya Y, Roberts WE. Assessment of orthodontic treatment outcomes: early treatment versus late treatment. *Angle Orthod.* 2005;75(2):162–70.

42. Gower A, Dibbs R. Cognitive Research: Designing a "respondent friendly" questionnaire for the 1991 Census. In: *Proceedings of the US Bureau of the Census Annual Research Conference*; 1989:257–66.

43. Anthoine E, Moret L, Regnault A, Sbille V, Hardouin JB. Sample size used to validate a scale: A review of publications on newly-developed patient reported outcomes measures. *Health Qual. Life Outcomes* 2014;12(1):1–10.

44. Wong L, Ryan FS, Christensen LR, Cunningham SJ. Factors influencing satisfaction with the process of orthodontic treatment in adult patients. *Am. J. Orthod. Dentofac. Orthop.* 2018;153(3):362–70. Available at: https://doi.org/10.1016/j.ajodo.2017.07.017.