APPLICATION OF AN ORTHODONTIC AUDITING SYSTEM TO A GRADUATE ORTHODONTIC CLINIC: A PILOT STUDY

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ABSTRACT

Introduction: In the United States, there is currently no universally accepted clinical assessment tool to ensure high quality orthodontic care through routine audit. In this pilot study, I aim to apply the Peer Assessment Rating (PAR) Index to the Temple graduate orthodontic clinic to provide insight on treatment outcomes and distribution of services. To date, this is the first time an established clinically objective measure of malocclusion has been applied to a graduate orthodontic health clinic for routine audit. This audit aims to further investigate: 1. If there are any differences in treatment outcome for patients who had the entirety of their treatment completed with one resident vs patients who were transferred to another resident during their care. 2. If there are any differences in treatment outcome between patients that are paying for their treatment out of pocket vs patients paying through Medicaid insurance programs.

Materials and Methods: A pilot study with a retrospective chart review design that will implement a PAR Index audit to assess treatment outcomes at Temple University Graduate Orthodontic Clinic. 3-dimensional scans before and after treatment were analyzed and measured based upon the PAR index established guidelines. Patient funding and transferal status were extracted from dental EHR software and compared utilizing a difference-in-difference estimation.

Results: 159 patient treatments were evaluated. Transferred patients had a mean PAR score decrease of 71.14%, and non-transferred patients had a mean PAR score decrease of 62.98%. Privately funded patients had a mean PAR score decrease of 61.29%, and insurance funded patients had a mean PAR score decrease of 72.02%. There was a significant difference in pre-treatment PAR score based on patient transfer status ($P = 0.01$)

and funding (P = 0.01) via Students T-test. There was not a significant difference in post-treatment PAR score based on patient transfer status (P = 0.84) and funding (P = 0.70) via Students T-test. There was a significantly different reduction of PAR score by funding status (P = 0.04), but not by transferal status (P = 0.12) based upon the difference-in-difference estimation via negative binomial regression analysis.

Conclusion: Overall, the PAR index can be applied to university orthodontic clinics for routine clinical audit and can provide insight on treatment outcomes and distribution of services. Transferred patient start on average with a significantly more severe malocclusion compared to patients that are not transferred, but their post-treatment PAR scores on average are not significantly different. There was no statistically significant difference treatment outcome between patients who were transferred and those who were not transferred to another resident during treatment. Insurance funded patients start on average with a significantly more severe malocclusion compared to privately funded, but their post-treatment PAR scores on average are not significantly different. There was a significantly greater decrease in PAR score treatment outcome for the insurance funded patients compared to the privately funded patients. Mean PAR score percentage reduction was similar to that of the British regional orthodontic centres in 1995.

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CHAPTER 1

INTRODUCTION

In the United States, there is currently no universally accepted clinical assessment tool to ensure high quality orthodontic care through routine audit. It is vital that orthodontic clinicians have an objective ability to assess their orthodontic treatment outcomes (Richmond et al., 1992). Personal reflection and comparison to one's peers on treatment outcomes could allow practitioners to actively adjust their methodologies to allow for the greatest benefit in their patients care (Richmond et al., 1992; Green J. I., 2016) In the United Kingdom, orthodontists under contract through the National Health Service, are required to submit a percentage of their annual cases to be audited to ensure quality control and fair distribution of services. New contractors are required to submit their first 20 consecutive cases and 10% of their annual cases to a national auditing board. (Burden et al., 1996; British Orthodontic Society, 2009). Established contractors are required to submit 50 cases or 10% of their annual cases to the auditing board (Burden et al., 1996; British Orthodontic Society, 2009). The Index utilized to score these audited cases is the Peer Assessment Index (PAR Index). In 1987, the PAR Index was developed by the British Orthodontic Working Standard Party as a reliable system to assess treatment outcomes (Richmond et al., 1992).

The PAR Index is a quick, reproducible, and effective summary score of dental occlusal abnormalities (Richmond et al., 1992). The higher the PAR score, the greater that individual deviates from ideal occlusion (Richmond et al., 1992). The mean difference in PAR score between pre- and post- treatment allows one to objectively assess the degree of case improvement (Richmond et al., 1992). Based upon the guidelines established by the

British Orthodontic Society, a PAR score reduction of 30% or more is the threshold of being considered an improvement in the individual or groups malocclusion (British Orthodontic Society, 2009). In general, a PAR score reduction of 22 points is considered to be a “great improvement” **(**British Orthodontic Society, 2009). An orthodontic clinician under contract through the National Health Service should aim to have less than 5% of their cases fall below a 30% PAR score reduction and should aim to have a mean PAR reduction greater than 70%. (Burden et al., 1996; British Orthodontic Society, 2009).

CHAPTER 2

REVIEW OF THE LITERATURE

2.1 Orthodontic Indexes

There have been many indexes developed over the years to classify malocclusion. Many of them set out to achieve a method of objectively quantifying treatment need and improvement (Järvinen, 2001). Massler and Frankel in 1951, were one of the first groups to develop a method of quantifying malocclusion. Their goal was to identify the prevalence and degree of malocclusion as it related to the population as a whole (Massler and Frankel, 1951). They initially set the groundwork for future indexes with their index criteria. These criteria, if met, would allow for reliable information about malocclusions to be obtained. The criteria Massler and Frankel developed were as follows:

> 1. It must be simple, accurate, and applicable to large groups of individuals. 2. It must yield quantitative information which will lend itself to statistical analysis. 3. It must be reproducible so that one group can be compared with another. (Massler and Frankel, 1951, p. 753).

While their criteria appear trivial, it allowed Massler and Frankel to be one of the first to quantify the prevalence of malocclusion in a population of 14–18-year-olds (Massler and Frankel, 1951).

Other indices were developed in the 1960s by Summers, Grainger, and Salzmann that utilized parametric scoring scales (Järvinen, 2001). The indexes are the Occlusal Index (OI), Treatment Priority Index (TPI), and Handicapping Malocclusion Assessment Record (HMAR), respectively (Järvinen, 2001). Two new orthodontic treatment need indexes utilizing non-parametric scoring scales were developed in the 1990/ 2000s (Järvinen, 2001). These two new indexes were the Need for Orthodontic Treatment Index (NOTI) and the Index of Orthodontic Treatment Need (IOTN) (Järvinen, 2001). There have been a

variety of orthodontic indices created, but no index has been proven to be as quick, reliable, and reproducible as the peer assessment (PAR) index (Richmond et al., 1992).

2.2 The Peer Assessment Rating Index

In 1987, a group of 10 orthodontists developed the Peer Assessment Rating index (PAR index) in an attempt to standardize treatment assessment in orthodontics (Richmond et al., 1992). At the time, there was no universally accepted objective quantitative measure of malocclusion that orthodontists could reliably use to assess and compare their orthodontic cases (Richmond et al., 1992). The 10 orthodontists examined over two-hundred dental casts, debated, and reached an agreement as to how these cases should be measured in a way that was reliable and reproducible (Richmond et al., 1992). The 10 orthodontists created a system of objective measurements of malocclusion that could be applied both pre-treatment and post-treatment and could also be used to assess an orthodontist's treatment improvement (Richmond et al., 1992). The PAR index has also been found to be reliable with accurate digital 3D models in addition to dental cast measurements (Mayers et. Al, 2005).

The PAR index consists of 11 sections, each of which has scoring based on specific criteria with discrete cutoffs for point values (Richmond et al., 1992). These tables can be found in Richmond et al., 1992 or on the British Orthodontic Societies official website.

The 11 sections of the PAR index are outlined below and taken from Richmond et al., 1992

1. Upper right segment
2. Upper anterior segment
3. Upper left segment
4. Lower right segment

5. Lower anterior segment
6. Lower left segment
7. Right buccal occlusion
8. Overjet
9. Overbite
10. Centerline
11. Left buccal occlusion

(Richmond et al., 1992)

The anatomical zones for the PAR index are as follows; the buccal and anterior segments are divided into 3 sections per arch, the right and left buccal segments and anterior segment (Richmond et al., 1992). The anterior segment consists of the mesial portion of the canine to the mesial portion of the contralateral canine while the buccal segments are each measured from the distal of the canine to their corresponding side to the mesial contact of the first permanent molar (Richmond et al., 1992).

Crowding is measured in the anterior segments as the “shortest distance from the contact points of adjacent teeth parallel to the occlusal plane” (Richmond et al., 1992). The measurement achieved for each contact is then added in the segment to give total discrepancy which is compared to a table outlining the criteria for scoring the segment (Richmond et al., 1992).

If the total added displacement discrepancy falls within the defined range, then the score pertaining to that range is selected for that segment. If a tooth has less than, or equal to 4 mm of space to erupt, then that tooth is counted as impacted in the segment, and a score of 5 is awarded to that segment. If a patient is in the mixed dentition stage, then the mesio-distal widths of the teeth are used to determine the overall discrepancy (Richmond et al., 1992).

Occlusion in the buccal segments is recorded from the canine to the last molar in a segment (Richmond et al., 1992). Occlusion is measured in the antero-posterior, vertical, and transverse planes and scored according to the table below (Richmond et al., 1992). One half unit of discrepancy relates to the tooth as a single unit, i.e. if overall interdigitation in the antero-posterior segment is one half of a tooth discrepancy, then that section would score a 1 (Richmond et al., 1992).

Overbite is recorded based upon the overlap of the anterior teeth, or lack of overlap in an anterior open bite case (Richmond et al., 1992). It is measured from the tooth that has the most overlap in the vertical dimension (Richmond et al., 1992).

Overjet is recorded as the area from lateral incisor to contralateral lateral incisor (Richmond et al., 1992). Measurements are obtained parallel to the occlusal plane and perpendicular to the arch form (Richmond et al., 1992). Anterior crossbites are also recorded in this section as well. Points for this section are awarded based on the degree of crossbite and the amount of teeth in crossbite (Richmond et al., 1992).

The centerline measurement is recorded based on the relation for the maxillary central incisors midline to the mandibular central incisors midline (Richmond et al., 1992). Scoring is based on discrepancies of ¼ of a lower central incisor tooth width (Richmond et al., 1992).

The PAR index overall has great intra- and inter-examiner reliability (Richmond et al., 1992). Richmond et al. found that intra-rater reliability of $R>0.95$ and between examiners of $R=0.91$ indicating excellent intra-rater rand inter-rater reliability (Richmond et al., 1992). This is crucial for an orthodontic index that it to be widely implemented and utilized to accurately and precisely score cases. The PAR index could be utilized in scoring

orthodontic treatment outcomes as well. By scoring the malocclusion before and after treatment, a reduction in PAR score can be calculated and compared (Richmond et al., 1992). Another advantage of the PAR index is that is can also be used to make treatment efficiency and outcome determinations in a group via mean PAR score reductions of the selected group (Richmond et al., 1992). This is the basis for the National Health Services implementation of the PAR score for routine orthodontic auditing (Richmond et al., 1992; British Orthodontic Society, 2022a, British Orthodontic Society, 2022b). To calculate group treatment outcomes the mean PAR Index scores before treatment will be subtracted from the final PAR Index score, and this difference will be defined as a percentage decrease based upon the initial PAR Index score. A mean PAR score reduction post-treatment compared to pre-treatment of 70% is considered to be "a high standard of treatment" (Richmond et al., 1992; British Orthodontic Society, 2022a, British Orthodontic Society, 2022b). A reduction of 50% or less is considered to be, "an overall poor standard of treatment" and a reduction of 30% or less is considered that "the patient's malocclusion has not been improved by orthodontic intervention" (Richmond et al., 1992; British Orthodontic Society, 2022a, British Orthodontic Society, 2022b). The creators of the Peer Assessment Rating Index regard a PAR score of 10 or less to be considered an acceptable occlusion and alignment, and a PAR score of 5 or less to be considered a nearly ideal occlusion (Richmond et al., 1992; British Orthodontic Society, 2022a, British Orthodontic Society, 2022b).

The PAR index has also been found to be reliable with accurate 3D models (Mayers et. al, 2005)

2.3 The PAR Index as an Objective Measure of Orthodontic Treatment Need and Auditing tool

The expert opinion of the orthodontist is still considered to be the gold standard of determining orthodontic treatment need (Firestone et. al, 2002). This expert opinion is subjective in nature and does not allow for defined cut-offs and quantitative assessment of a malocclusion. As stated previously, many indexes have been created to assess and quantify orthodontic treatment need based upon different criteria. One thing that many of orthodontic treatment need indices have in common is their assessments include quantification of occlusal features as a foundational part of their assessment (Firestone et. al, 2002). Therefore, an orthodontic index that has a standardized and systematic measurement of occlusion should be selected to accurately assess orthodontic treatment need. The PAR index has been established as one of the only validated orthodontic occlusal indices that can quantitatively measure patients' deviation from a normal alignment and occlusion (Richmond et al., 1992). The PAR index's reliability and reproducibility both between different raters and at different time points therefore gives it a distinct advantage over other orthodontic indexes and allows the assessors the ability to have accurate and objective numerical cutoffs for treatment need (Richmond et al., 1992). Therefore the National Health Services utilizes the PAR index for its own routine Audit of clinical outcomes in the United Kingdom as it is the only reliable, objective and standardized orthodontic index (Green JI, 2016).

CHAPTER 3

AIMS OF THE INVESTIGATION

This pilot study aims to determine if the United Kingdom's clinical auditing program guidelines can be applied to the Temple Graduate Orthodontic clinic to provide insight on treatment outcomes and distribution of services. The secondary aims for this investigation are as follows: 1. To determine if there is any difference in care between patients who have begun and completed orthodontic treatment with one resident vs patients who have begun orthodontic treatment with one resident and completed orthodontic treatment with another resident. 2. To determine if there is any difference between patients who are paying for their treatment out of pocket vs patients whose treatment is paid for through Medicaid insurance programs.

CHAPTER 4

MATERIALS AND METHODS

4.1 Study Design

A pilot study with a retrospective chart review design that implemented a PAR Index audit to assess treatment outcomes at Temple University Graduate Orthodontic Clinic. The target population were patients at the Temple University Graduate Orthodontic Clinic that: 1. had the entirety of orthodontic treatment completed at the Temple graduate orthodontic clinic and 2. had acceptable, and measurable 3-dimensional iTero scans that were obtained in the months prior to treatment and directly after treatment was completed. 200 patients were initially estimated to be available for measurements at the school.

3-dimensional scans obtained via iTero Scanners, and stored in Dolphin Imaging Software at the Temple University Graduate Orthodontic Clinic before orthodontic treatment and after orthodontic treatment were analyzed and measured in OrthoCad (5.9.1.50) based upon the Peer Assessment Rating Index (PAR Index) guidelines established by the British Orthodontic Working Standard Party (Richmond et al., 1992; British Orthodontic Society 2022). Mean PAR Index scores before treatment were subtracted from the final PAR Index score, and this difference was defined as a percentage decrease based upon the initial PAR Index score. A mean PAR score reduction post-treatment compared to pre-treatment of 70% is considered to be “a high standard of treatment” (Richmond et al., 1992; British Orthodontic Society 2022). A reduction of 50% or less is considered to be, “an overall poor standard of treatment” and a reduction of 30%

or less is considered that “the patient’s malocclusion has not been improved by orthodontic intervention” (Richmond et al., 1992; British Orthodontic Society 2022).

Another comparative grouping was patients who have begun and completed orthodontic treatment with one resident (not transferred) vs patients who have begun orthodontic treatment with one resident and completed orthodontic treatment with another resident (transferred).

A final comparative grouping was patients who are paying for their treatment themselves (private) vs patients would are having their treatment paid for through Medicaid insurance programs (insurance).

4.2 Inclusion and Exclusion Criteria

Inclusion Criteria

- Cases from 1/2017-10/2022 (6 years)
- Measurable pre- and post- treatment 3-Dimensional scans available in iTero MyAligntech™ database
- Patient number data can be extracted from Temple University Kornberg School of Dentistry Department of Orthodontics EHR system (Axium) and internal database
- Patient funding and resident transfer status can be extracted from Temple University Kornberg School of Dentistry Department of Orthodontics EHR system (Axium) and internal database

Exclusion Criteria

- Cases that do not occur during the time interval above
- Limited Orthodontic cases
- Mixed dentition cases

- Extraction cases
- Surgical cases
- Patients that were not compliant with treatment.
- Patients that had treatment terminated early

4.3 Peer Assessment Rating (PAR) Scoring Guidelines

The Peer Assessment Rating index scoring was conducted in accordance with the established guidelines developed and published by the British Orthodontic Working Party (British Orthodontic Society 2022; Richmond et al., 1992).

4.4 Peer Assessment Rating (PAR) Data Collection

Official IRB determination for this project was “Not Human Subject Research Determination” (Appendix A). University approval was obtained to access the EHR of patients with orthodontic codes (D8080, D8080E, D8080M, D8090, D8090E) from 1/2017 to 10/2022. Access to internal patient spreadsheets outlining patient funding and resident transfer status. Access MyCadent iTero™ database to analyze patient 3-dimensional scans to ensure they are adequate for PAR scoring measurements

Search databases above for patients who meet inclusion criteria and do not meet exclusion criteria. Compiled a list of eligible patient names and assigned each of them a de-identified study number in an excel spreadsheet on a HIPAA compliant, password-protected, university computer that can only be accessed by study investigators.

Cases were initially selected and PAR scores calculated with a professor who is calibrated in PAR scoring to ensure proper scoring. This professor was currently utilizing the PAR index for another study at the time of this study. Cases were scored with this professor until scores matched within +/- 2 PAR score points. Consistency of

measurements was evaluated by selecting 5 cases at random at the end of the study to re-score. The scores during the study and after completion of the study were then compared via an intra-class correlation coefficient analysis to determine agreement between the 2 sets of numbers.

A second excel spreadsheet was created on the same computer referenced above that contained the patients de-identified study number, pre-treatment and post-treatment PAR score, patient funding (Medicaid or private funding), and resident transfer (yes or no) as outlined in Appendix B.

PAR index scores were obtained with each patients pre-treatment and post-treatment 3-dimensinoal dental study models according to the guidelines set out by the British Orthodontic Societies standards (British Orthodontic Society 2022; Richmond et al., 1992). Post-treatment PAR scores were not obtained directly after scoring the pre-treatment PAR digital dental study models for the same individual, to attempt to minimize any potential bias or confounding of the results. PAR scores were entered into the second excel sheet. Extraction of patient funding data and resident transfer status from above databases will also be entered into the second excel spreadsheet as outlined in Appendix B.

Compare and analyze data according to statistical data methods outlined below utilizing JMP and “R” Software.

4.5 Statistical Data Collection, Management, and Analysis

Patients' pre-treatment and post treatment PAR scores were obtained according to the standards set by the British Orthodontic Society PAR scoring guidelines (Richmond et. Al., 1992; British Orthodontic Society, 2022; British Orthodontic Society, 2022). Patient

funding, either Medicaid insurance, or private funding was recorded. Patient transfer was also recorded. Data normality was analyzed via visual assessment of data histograms. Mean PAR scores, patient funding, and patient transfer to another resident were compared. Changes in PAR scores pre- and post-treatment were assessed by difference-in-difference estimation. An interaction term between time and patient funding or patient transferal status was included in a negative binomial regression model and the statistical significance was tested. Negative binomial regression analyses were conducted via generalized equation equations with AR(1) working correlation matrix to account for correlation of pre- and post-treatment PAR scores per patient.

A PAR score nomogram was created to show the clinics overall PAR score profile. These nomograms have 2 lines which depict the thresholds for a greatly improved and no difference in PAR score (British Orthodontic Society, 2009). The nomogram has pre-treatment scores on the y-axis, graphed against the Post treatment scores along the x-axis. 2 straight lines are graphed on the nomograms depicting the 2 critical thresholds (British Orthodontic Society, 2009). One line represents the ideal threshold in which a PAR score reduction of 22 points is achieved (British Orthodontic Society, 2009). A case is considered greatly improved if this threshold is reached (British Orthodontic Society, 2009). The second line depicts the lower end threshold of a PAR score reduction of 30% (British Orthodontic Society, 2009). Cases below this 30% threshold are considered to be worse off or no different from the start of the case (British Orthodontic Society, 2009). Mean PAR score reductions for all groups together and separately will be calculated and displayed both quantitatively as a number and qualitatively on nomograms as described above. The number of total cases that fall below the 30% threshold will be given as a

number for the overall cases, and for each group outlined above. 5 cases were utilized for calibration at the start of the study with a professor who is calibrated in PAR scoring to ensure proper scoring. Selection of the 5 cases was randomly selected utilizing a computer randomizer to select the numbers. PAR scores for these 5 cases were then used to compare intra-rater reliability applying an intra-class correlation coefficient with the same 5 cases at the conclusion of the study.

CHAPTER 5

RESULTS

5.1 Description of Pre-treatment and Post-treatment PAR scores

159 patient treatment outcomes were evaluated via the PAR index in total. Of the 159 patients, 79 were transferred to another resident, and 80 were not transferred and completed by the same resident that began the case. Of the 159 patients, 82 funded their orthodontic care privately without the use of Medicaid insurance programs, and 77 had their care paid for by Medicaid insurance programs.

The distribution of pre-treatment and post-treatment PAR scores are outlined in the histograms below (Figure 1, Figure 2).

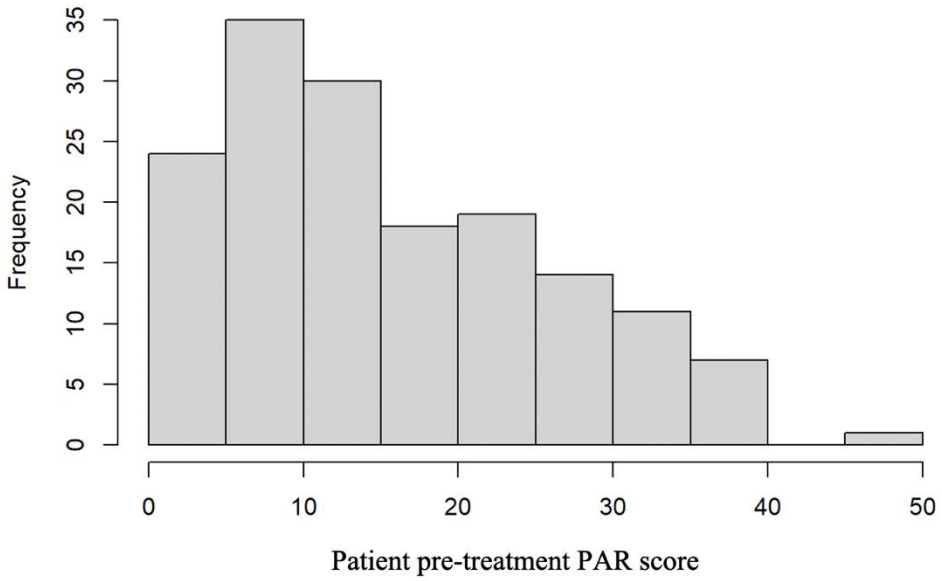

Figure 1. Pre-treatment PAR Score Histogram.

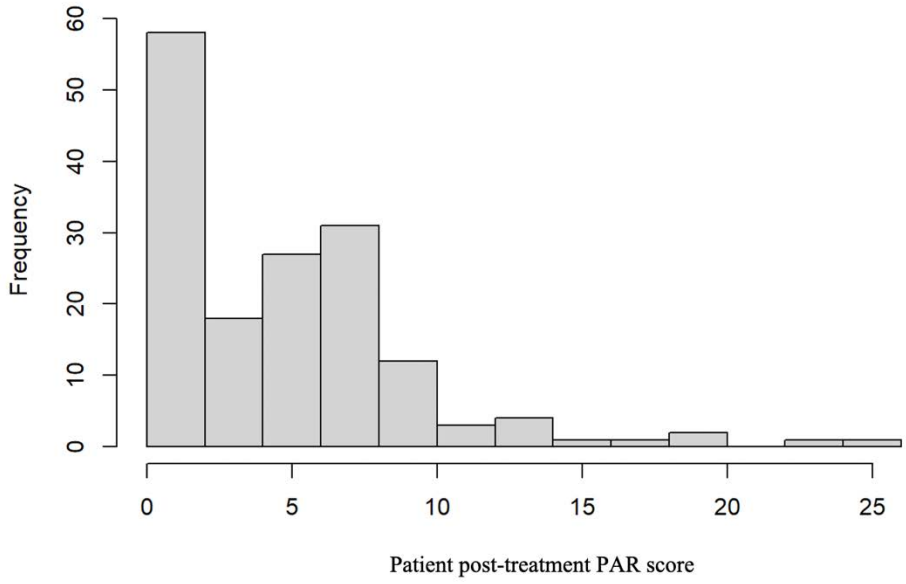

Figure 2. Post-treatment PAR Score Histogram.

The pre-treatment and post-treatment PAR score histograms visually display data that is not normally distributed (Figure 1 and Figure 2). The pre-treatment PAR score histograms show the highest frequency scores in the 5-10 range, with the least frequently occurring scores being in the 45-50 range. The post-treatment PAR score shows the highest frequency in the 0-3 range with the least frequently occurring scores being the 15-17, 23-25 range.

5.2 PAR Nomogram

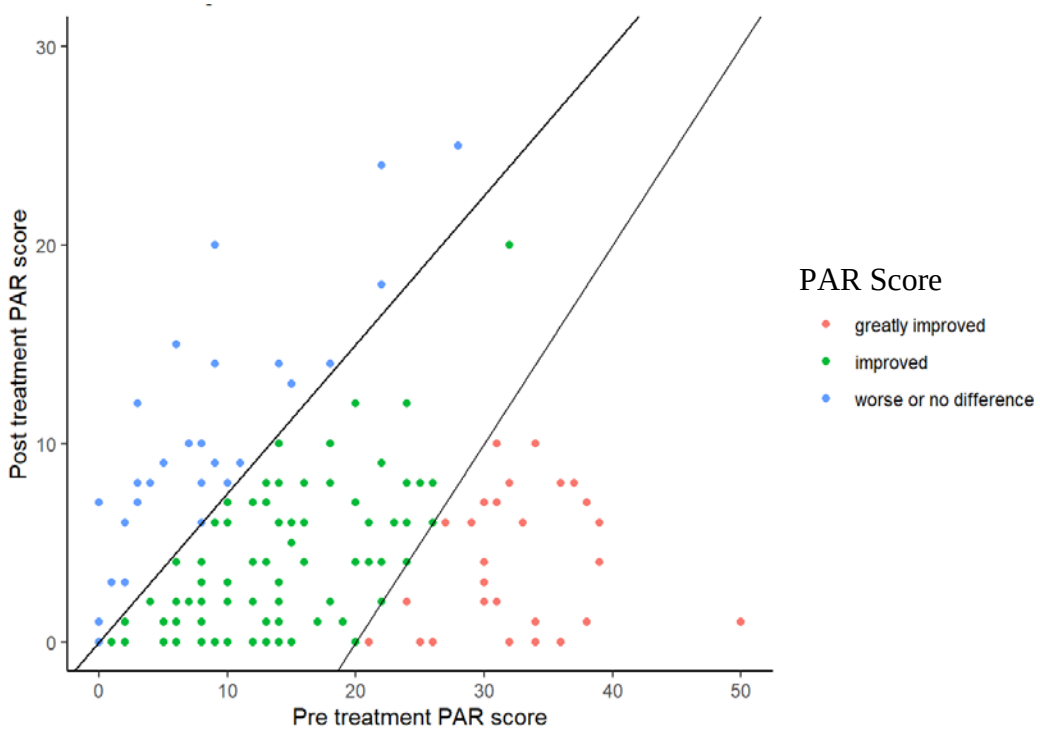

Figure 3. PAR Nomogram. This nomogram depicts the distribution of orthodontic treatment outcomes. PAR score reduction of >70% = Red, 70-30% = Green, <30% = Blue.

A PAR nomogram was created in accordance with the British Orthodontic Societies guidelines and shown in Figure 3 (British Orthodontic Society, 2009). PAR scores that had a greater than 70% reduction are delineated by the right-most line and are outlined with orange dots. PAR scores between 30-70% reduction fall between the lines and are outlined with green dots. PAR scores that had less than 30% reduction are outlined with blue dots and fall to the left of the left-most line in Figure 3. Overall, 30 patients fell into the "greatly improved" category to the far right depicted in orange. 99 patients fell into the "improved" category between the two lines, depicted by the dots in green. 30 patients fell into the "worse or no improvement" category to the far left depicted by the blue dots. 129/159 or

81.1% of patients improved in their malocclusions. 30/159 or 18.9% fell into the worse or no improvement category. Overall, the average pre-treatment PAR score for all 159 patients was 16.2 and the average post-treatment PAR score was 5.3, with an average decrease of 10.9, or 67.5%.

5.3 Treatment Outcomes Based on Patient Transfer

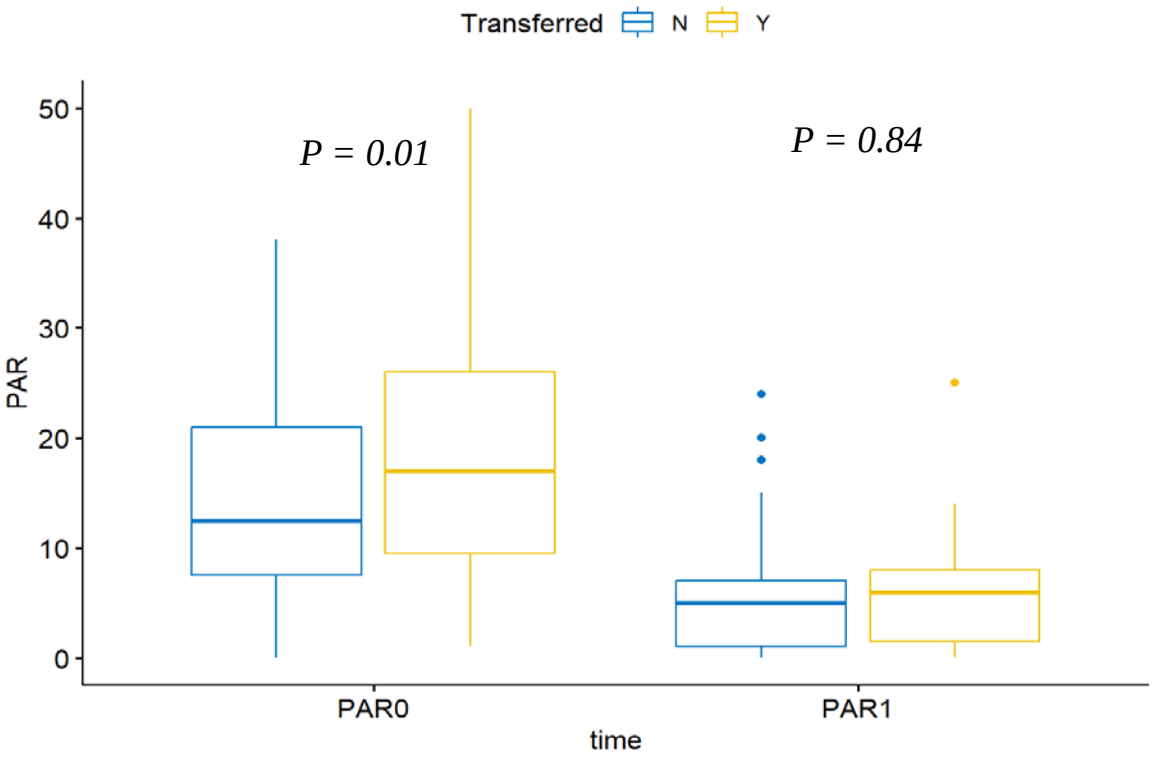

Figure 4. Treatment outcomes based on patient transfer.

The results of comparison between transferred patients vs patients that had the entirety of their treatment completed by one resident are shown in Figure 4, with pre-treatment scores on the left (PAR0) and post-treatment scores on the right (PAR1). Patients that were transferred to another resident are outlined in yellow, and patients that were not transferred are outlined in blue. Of the 159 patient evaluated, there are 80 in the not transferred group, and 79 in the transferred group.

Evaluating the pre-treatment PAR score for each group, it was found that patients who were not transferred had a mean pre-treatment PAR score of 14.0 (standard deviation +/- 9.59) with a median of 12.5. Patients who were transferred had a mean pre-treatment PAR score of 18.5 (standard deviation +/- 10.8) with a median of 17. There was a significant difference ($P = 0.01$) in pre-treatment PAR score based on patient transfer status via Students T-test.

Evaluating the post-treatment PAR score for each group, it was found that patients who were not transferred had a mean post-treatment PAR score of 5.19 (standard deviation +/- 5.08) with a median of 5. Patients who were transferred had a mean post-treatment PAR score of 5.34 (standard deviation +/- 4.38) with a median of 6. There was not a significant difference ($P = 0.84$) in post-treatment PAR score based on patient transfer status via Students T-test.

Comparing the average decrease in PAR score for both groups yields the following: For transferred patients, there was an average decrease of 13.16 points, or a 71.1351% decrease from pre-treatment PAR score. For patients that were not transferred the average decrease in PAR score was 8.81, or a 62.9285% decrease from pre-treatment PAR score.

Table 1. *Transferred and Not-transferred PAR Scores Before and After treatment*

	Pre-treatment PAR score average	Post-treatment PAR score average	Difference in PAR score averages	Mean percent decrease
Not-transferred Mean	14.0 (SD +/- 9.59)	5.19 (SD +/- 5.08)	8.81	62.93%
Transferred Mean	18.5 (SD +/- 10.8)	5.34 (SD +/- 4.38)	13.16	71.14%

Reduction of PAR scores post-treatment was not significantly different by patient transfer status based upon the negative binomial regression analysis ($P = 0.12$).

To further characterize the results, each grouping from the PAR nomogram was applied to the transferred and not-transferred groups. The results are outlined below in Table 2.

Table 2. *PAR Score Nomogram Groupings Based on Transfer*

Category (% PAR Score reduction)	Not-Transferred (# of patients)	Transferred (# of patients)
No improvement (<30%)	21	12
Improved (30-70%)	22	24
Greatly Improved (>70%)	37	43

Overall, 59 out of the 80 (73.75%) total patients in the not-transferred patient group improved in their malocclusion by 30% or more. 21 patients that were not transferred, or 26.25%, either worsened or had no improvement in their malocclusions. In the Not-Transferred patient group, 74 out of the 80 patients (92.50%) completed treatment with a PAR score of less than 10. 67 out of the 79 (84.81%) total patients in the transferred patient group improved in their malocclusion by 30% or more. 12 transferred patients, or 15.19%, either worsened or had no improvement in their malocclusions. In the transferred patient group, 76 out of the 79 patients completed treatment with a PAR score of less than 10 (96.20%).

Further characterizing the 21 patients in the not-transferred patient group that had either worsened or had no improvement in their malocclusion yielded the following. 1 patient started at a PAR score of 0 and finished with PAR score of 0. 14 patients finished at or below a PAR score of 10. 6 patients finished above a PAR score of 10. So overall, 6 patients finished with a less than acceptable PAR score above 10 in the not-transferred patient group out of 80 (7.5%).

Further characterizing the 12 patients in the transferred funded group that had either worsened or had no improvement in their malocclusion yielded the following. 9 patients finished at or below a PAR score of 10. 3 patients improved slightly but had PAR scores greater than 10. So overall, 3 patients finished with a less than acceptable PAR score above 10 in the privately funded group out of 79 (3.80%).

5.4 Treatment Outcomes Based on Patient Funding

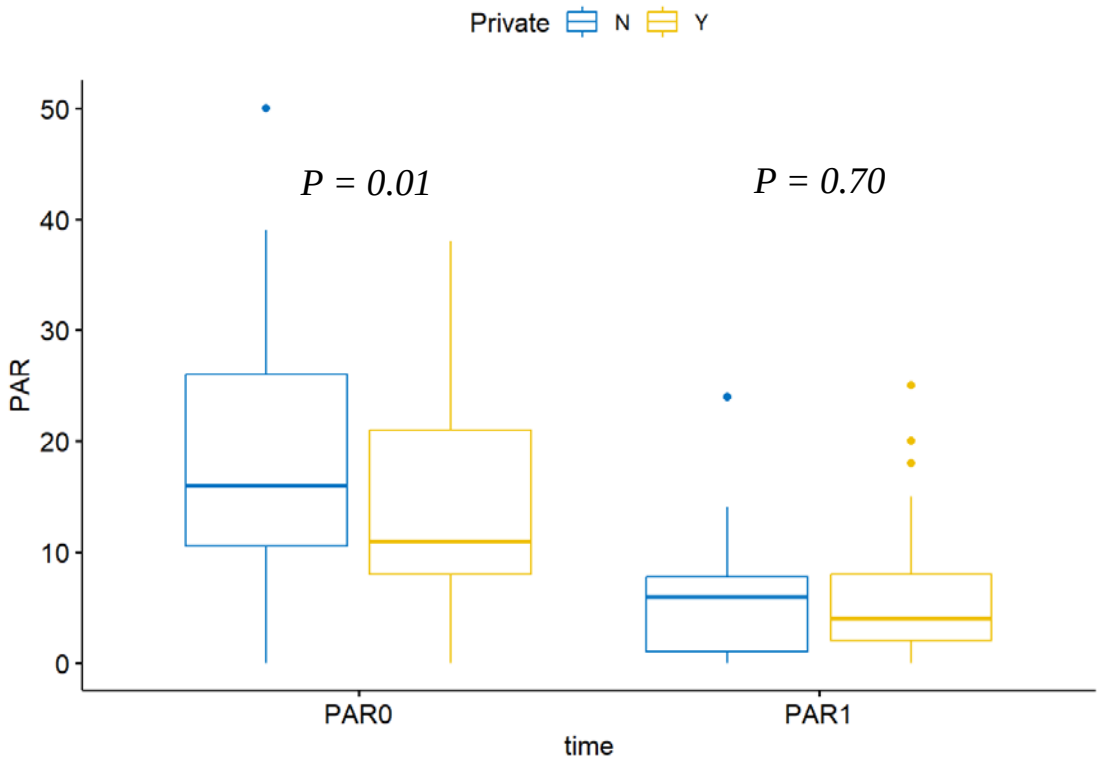

Figure 5. Treatment outcomes based on patient funding.

The results of comparison between patients who are paying for their treatment themselves (private) vs patients that are funded through Medicaid insurance programs (insurance) are shown in Figure 5, with pre-treatment scores on the left (PAR0) and post-treatment scores on the right (PAR1). Patients' treatments that were privately funded are outlined in yellow, and patients that had their treatment paid for by insurance programs

(not private) are outlined in blue. Of the 159 patients evaluated, 82 were in the insurance group and 77 were in the privately funded group.

Evaluating the pre-treatment PAR score for each group, it was found that patients who had their treatment paid for by insurance programs had a mean pre-treatment PAR score of 18.3 (standard deviation +/- 10.9) with a median of 16. Patients that were privately funded had a mean pre-treatment PAR score of 14.0 (standard deviation +/- 9.43) with a median of 11. There was a significant difference ($P = 0.01$) in pre-treatment PAR score based on patient funding status via Students T-test.

Evaluating the post-treatment PAR score for each group, it was found that patients who had their treatment paid for by insurance programs had a mean post-treatment PAR score of 5.12 (standard deviation +/- 4.34) with a median of 6. Patients that were privately funded had a mean post-treatment PAR score of 5.42 (standard deviation +/- 5.15) with a median of 4. There was not a significant difference ($P = 0.70$) in post-treatment PAR score based on patient transfer status via Students T-test.

Comparing the average decrease in PAR score for both groups yields the following: For patients who had their treatment paid for by insurance programs had an average decrease in PAR score of 13.18, or a 72.02% decrease from pre-treatment PAR score. For privately funded patients, there was an average decrease of 8.58 points, or a 61.29% decrease from pre-treatment PAR score.

Table 3. *Private and Insurance Funded PAR Scores Before and After treatment*

	Pre-treatment PAR score average	Post-treatment PAR score average	Difference in PAR score average	Mean percent decrease
Insurance funded	18.3 (SD +/- 10.9)	5.12 (SD +/- 4.34)	13.18	72.02%
Privately funded	14.0 (SD +/- 9.43)	5.42 (SD +/- 5.15)	8.58	61.29%

There was a significantly greater reduction in PAR score post-treatment among insurance funded groups vs privately funding groups (P = 0.04), based upon the negative binomial regression analysis.

To further characterize the results, each grouping from the PAR nomogram was applied to the insurance and privately funded groups. The results are outlined below (Table 4) where the number of patients that fell into each category are shown.

Table 4. *PAR Score Nomogram Groupings for Insurance and Privately Funded Patients*

Category (% PAR Score reduction cutoff)	Insurance (# of patients)	Privately Funded (# of patients)
No improvement (<30%)	14	19
Improved (30-70%)	23	23
Greatly Improved (>70%)	45	35

Overall, 68 out of the 82 (82.93%) total patients in the Insurance funded group improved in their malocclusion by 30% or more. 14 insurance funded patients, or 17.07%, either worsened or had no improvement in their malocclusions. In the insurance funded group, 78 out of the 82 patients (95.12%) completed treatment with a PAR score of less than 10. 58 out of the 77 (75.32%) total patients in the privately funded group improved in their malocclusion by 30% or more. 19 privately funded patients, or 24.66%, either worsened or had no improvement in their malocclusions. In the privately funded group, 73 out of the 77 patients completed treatment with a PAR score of less than 10 (94.80%).

Further characterizing the 14 patients in the insurance funded group that had either worsened or had no improvement in their malocclusion yielded the following. 1 patient started at a PAR score of 0 and finished with PAR score of 0. 8 patients finished at or below a PAR score of 10. 4 patients finished above a PAR score of 10. 1 patient finished at the

same PAR score that they began with between PAR 5-10. So overall, 4 patients finished with a less than acceptable PAR score above 10 in the insurance funded group out of 82 (4.88%).

Further characterizing the 19 patients in the privately funded group that had either worsened or had no improvement in their malocclusion yielded the following. 12 patients finished at or below a PAR score of 10. 2 patients worsened overall and finished above a PAR score of 10. 3 patients finished at the same PAR score that they began with between PAR 5-10. 2 patients improved slightly but had PAR scores greater than 10. So overall, 4 patients finished with a less than acceptable PAR score above 10 in the privately funded group out of 77 (5.19%).

5.5 Visual Representations of PAR Index Results

Figure 6 shows one of the most improved malocclusions. This individual improved from a pre-treatment PAR score of 38 to a post-treatment PAR score of 2. Figure 6 also visually represents a PAR score reduction of greater than 70%. Figure 7 shows the least improved PAR score in this study. This individual's malocclusion worsened from a pre-treatment PAR score of 6 to a post-treatment PAR score of 15. Figure 8 shows a PAR score reduction of about 50% to represent the 30-70% reduction category. This individual improved from a pre-treatment PAR score of 14 to a post-treatment PAR score of 6. Figure 8 also shows what a near 5 PAR score finish looks like visually. Figure 9 represents a less than 30% decrease in PAR score with a below PAR 10 finish. This individual improved from a pre-treatment PAR score of 10 to a post-treatment PAR score of 8.

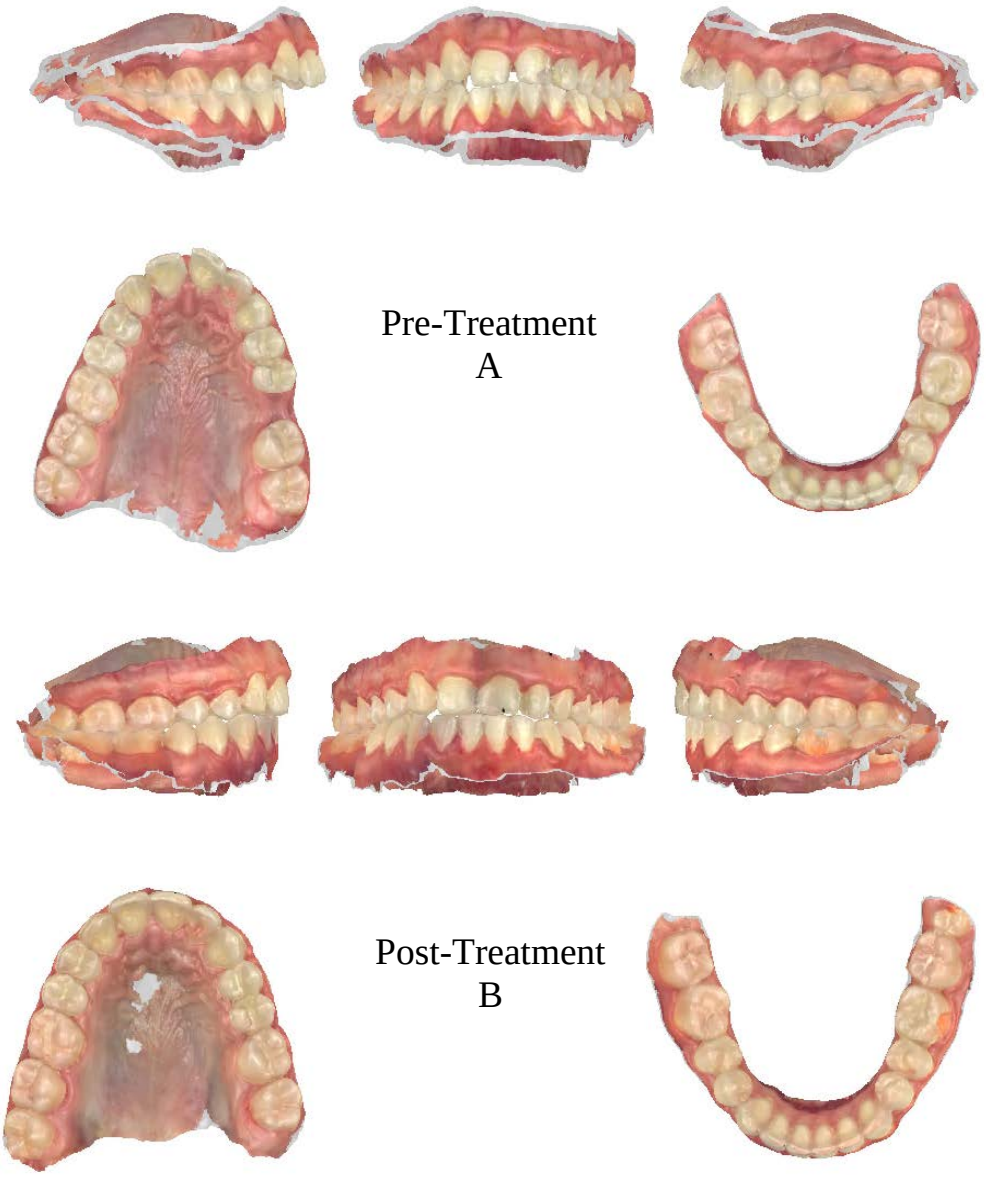

Figure 6. Visual Representation of the Most Improved PAR Score. (A) Pre-treatment photographs PAR score 38 (B) Post-treatment photographs PAR score 2.

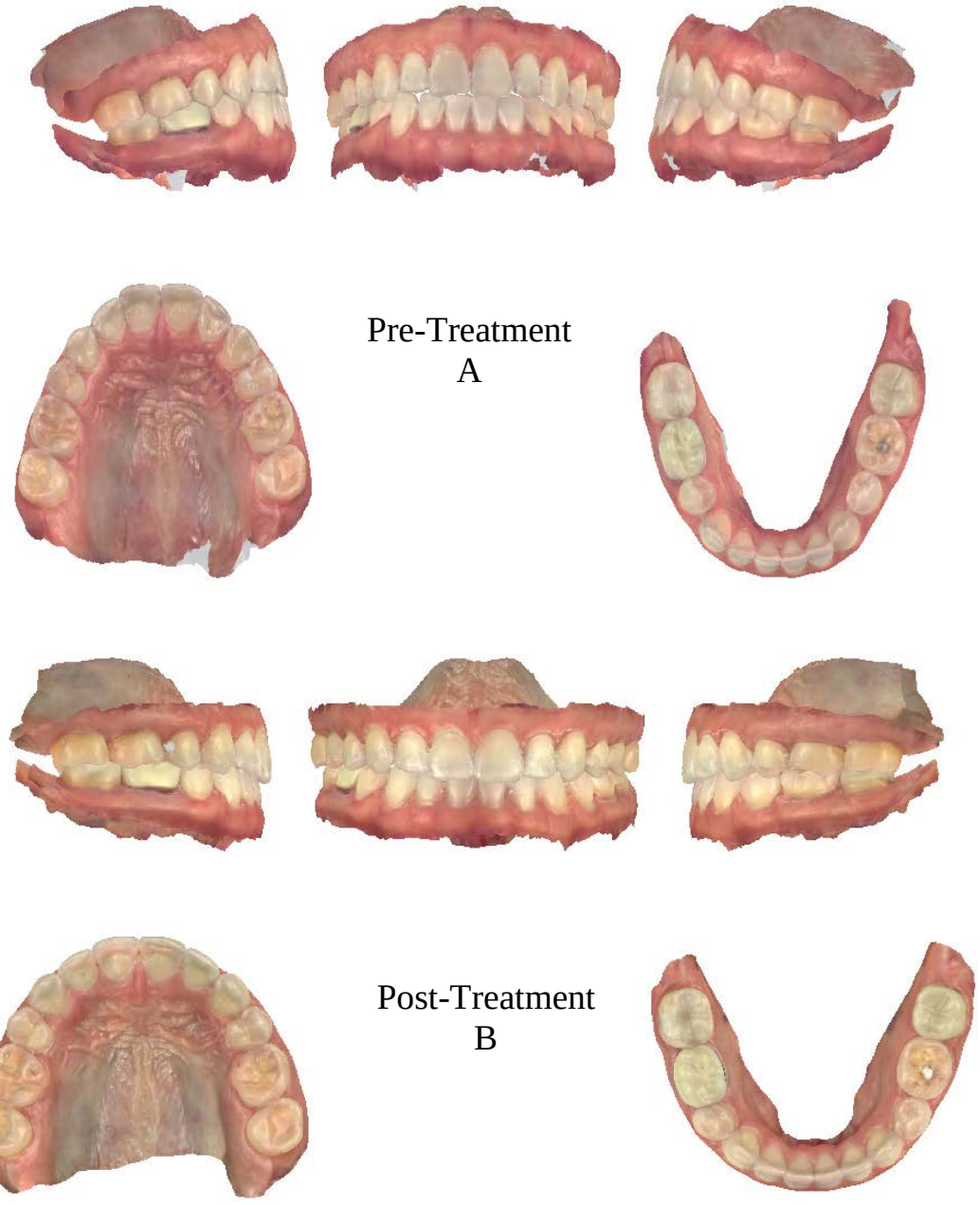

Figure 7. Visual Representation of the Least Improved PAR Score. (A) Pre-treatment photographs PAR score 6 (B) Post-treatment photographs PAR score 15.

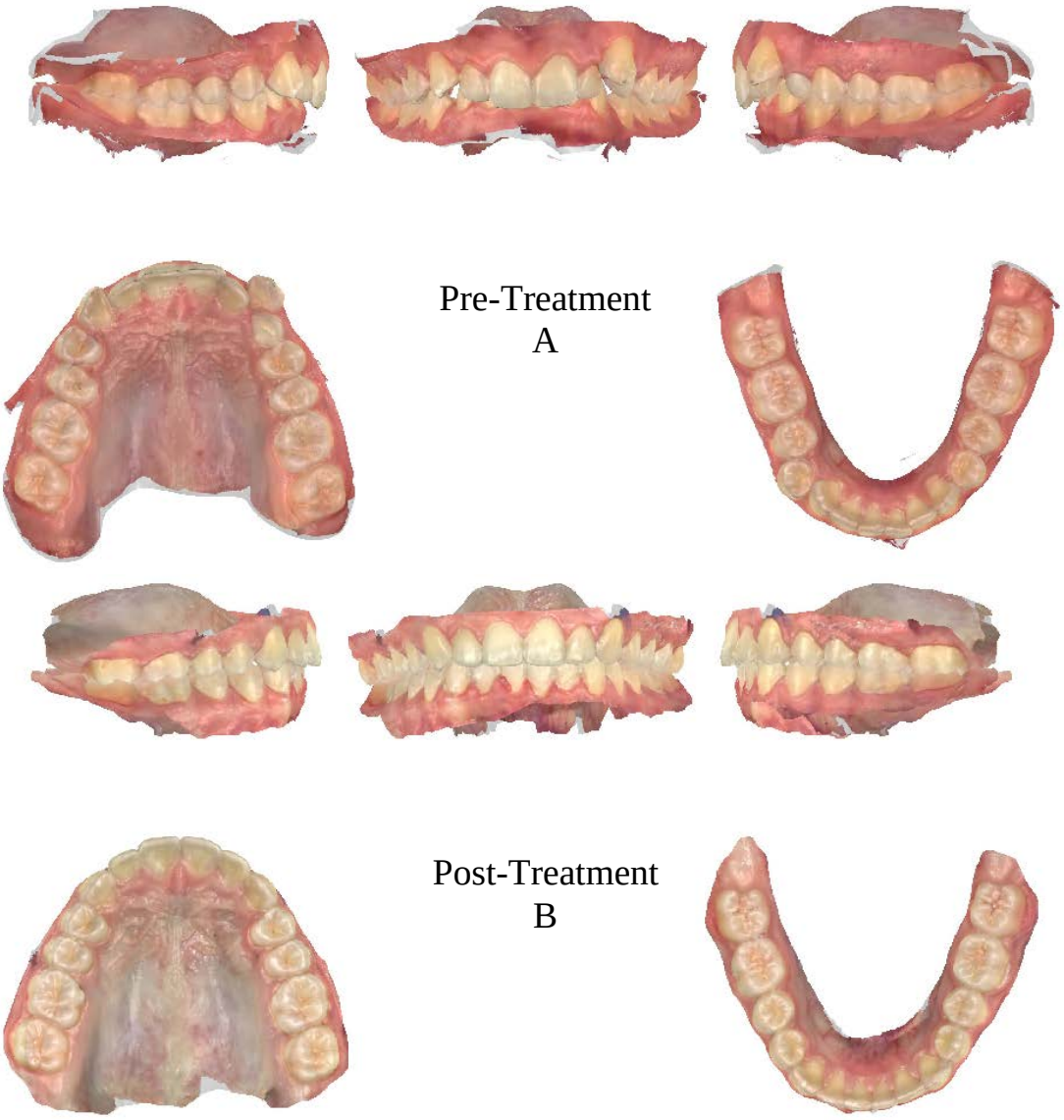

Figure 8. Visual Representation of a PAR Score Reduction Between 30-70%. PAR score reduction between 30-70% with near 5 PAR score finish (A) Pre-treatment photographs PAR score 14 (B) Post-treatment photographs PAR score 6.

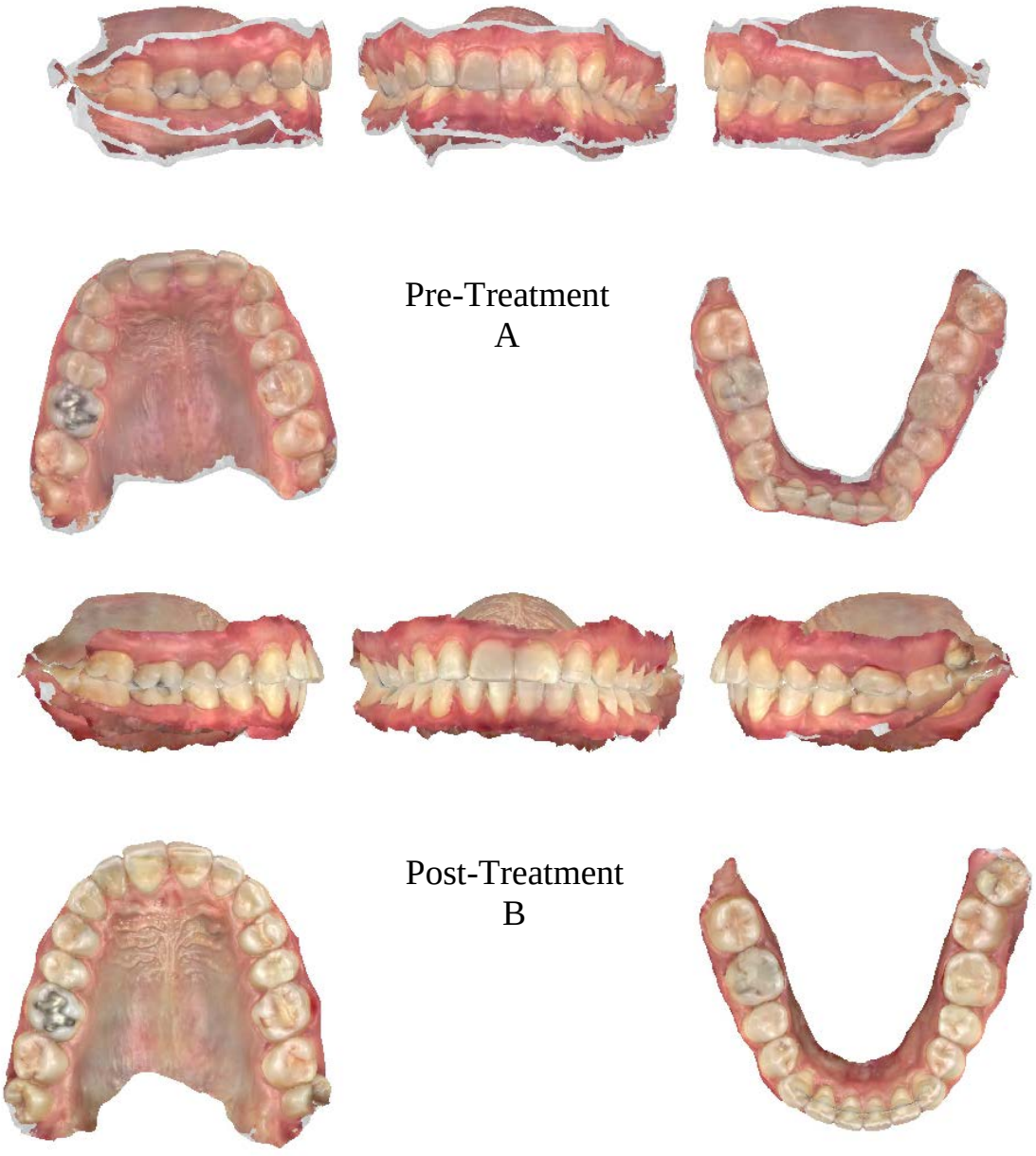

Figure 9. Visual Representation of a PAR Score Reduction of Less Than 30%. (A) Pre-treatment photographs PAR score 10 (B) Post-treatment photographs PAR score 8.

5.6 Evaluation of Scoring Consistency

To evaluate consistency of scoring throughout the project 5 cases were selected at random utilizing computer randomization to select numbers. The 5 cases were then scored again at the end of the study and compared to the initial scoring of the cases using intraclass correlation coefficient (ICC) to assess one-way agreement between the two separate measurement time points. The ICC at the end of the evaluation was 0.979 (95% confidence interval of 0.924<ICC<0.995). The table below shows the initial measurements and rescored measurements at the conclusion of the study.

Table 5. *Consistency of Measurements*

Initial scoring			After study re-scoring		
Study ID	**Pre-treatment PAR score**	**Post-treatment PAR score**	**Study ID**	**Pre-treatment PAR score**	**Post-treatment PAR score**
19	26	6	**19**	27	6
38	8	8	**38**	3	6
75	14	6	**75**	14	7
106	1	3	**106**	1	4
131	25	8	**131**	26	8

CHAPTER 6

DISCUSSION

6.1 Patient Transfer Status Comparisons

Patients that were transferred started with a mean PAR score that was 4.5 points higher than those patients that were not transferred. Transferred patients mean post-treatment PAR scores were slightly higher at 5.34 points than transferred patients at 5.19 points. Transferred patients had a larger mean decrease of 13.16 points and larger percent decrease of 71.14% compared to not transferred patients with a mean decrease of 8.81 points and a percent decrease of 62.93%. From the results found in this study it appears that transferred patients start on average with a more severe malocclusion than those who are not transferred, but their average post-treatment outcome is similar to patients that were not transferred.

To expand on this observation, patients that are transferred in the orthodontic clinic may have treatment plans that are more than 26 months long, thus also indicating a greater severity of malocclusion overall. Generally, more complex or severe malocclusions will require a more sophisticated and lengthy treatment plan/ treatment time. If patients' estimated treatment time is longer than the Orthodontic programs length (26 months), or if the treatment is started at a time where the estimated treatment time is past the graduation date of the treatment initiating resident, then these patients will most likely be transferred to the next resident in their clinical group. One concern that was also raised regards resident hand off and the new operator's effect on the treatment outcome. Atkas et al. found that there was an overall longer treatment time and worse treatment outcomes based upon the American Board of Orthodontist Cast Radiograph Evaluation (ABO-CRE) for patients that

were transferred to another resident (Atkas et al. 2022). Parrish et al. also reports that longer orthodontic treatment times lead to worse treatment outcomes based upon the American Board of Orthodontics Discrepancy Index (Parrish et al. 2011). The results of these studies appear to conflict with the findings of this study as the treatment outcomes were similar between the two groups. A limitation of this study is that the length of time was not evaluated for the transferred patients to determine if the groups were similar between this study, Atkas et al., and Parrish et al. Overall, from the results it appears that transferred patients average improvement in their malocclusion is greater than non-transferred patients and that both groups completed treatment with similar PAR scores at the end of treatment. The findings of this study support that patients who are transferred to another resident at the Temple orthodontic graduate clinic have similar PAR score treatment outcomes to those who have the entirety of treatment completed with one resident.

6.2 Patient Funding Status Comparisons

Patients that were funded by insurance programs started with a mean PAR score that was 4.3 points higher than those patients that were funded privately. Insurance funded patients mean post-treatment PAR scores were slightly lower at 5.12 points than privately funded patients at 5.42 points. Insurance funded patients had a larger mean decrease of 13.18 points and larger percent decrease of 72.02% compared to privately funded patients with a mean decrease of 8.58 points and a percent decrease of 61.29%. From the results found in this study it appears that insurance funded patients start on average with a more severe malocclusion than those who are privately funded, but that their treatment outcome on average is similar at the end of treatment between both groups. It also appears that from

the regression analysis that there is a statistically significant greater decrease in PAR score for the insurance funded patients compared to the privately funded patients.

To further expand on these findings, an investigation on what qualifies a patient for insurance funding must first be established. In Pennsylvania, Medicaid funding for orthodontics is based upon the Salzmann index (Patel et al. 2021). The Salzmann index is an orthodontic treatment need index that evaluates intra-arch deviations and inter-arch deviation and scores a patient's malocclusion based on medical necessity for orthodontic treatment (Patel et al. 2021) A Salzmann score of 25 points or greater is established as one of the main criteria for insurance funding (Patel et al. 2021). Recently, automatic qualifiers have been added and implemented in some state Medicaid programs, which are a checklist of binary indicators of treatment need. If even one of these criteria are met, the patient should be automatically qualified for insurance coverage regardless of the Salzmann score (Patel et al. 2021). Patients who are grouped into the insurance funded category therefore must have had at least one automatic qualifying criteria or a Salzmann score greater than or equal to 25 points. It then also follows that patients who are funded through insurance programs would generally then have a more severe pre-treatment malocclusion to qualify for insurance coverage. The results of this paper appear to support this hypothesis where the pre-treatment PAR score was 18.3 and 14.0 for insurance funded and privately funded patients, respectively. It appears from the results that both groups finish with similar treatment outcomes with PAR scores of 5.12 and 5.42 for insurance funded and privately funded patients, respectively. As stated previously, a PAR score of 10 or less has been established as an acceptable orthodontic treatment outcome, with a PAR score of 5 or less being considered a nearly ideal treatment outcome. The results of this paper support that at

the Temple graduate orthodontic clinic patients finish with nearly ideal treatment outcomes with insurance funded patients having marginally better post-treatment PAR scores than privately funded patients. These results also indicate an excellent distribution of services and equity of care as the insurance patients who start with a more severe malocclusion and require greater care receive it and finish with results similar to those who start with a less severe malocclusion and who have the financial means to correct it.

6.3 PAR Score Reductions Compared to Other Centers

In this study, 18.9% or 30/159 patients fell into the "greatly improved" category. 62.2% or 99/159 patients fell into the "improved" category. 18.9% or 30/159 patients fell into the "worse or no improvement" category according to the PAR nomogram and establish PAR guideline categories. Overall, there was a mean PAR score reduction of 67.5% observed in this study. Shaw, Richmond, and O'Brian published orthodontic treatment outcome findings from the British general dental services, British regional orthodontic clinics, and Norwegian orthodontic specialists in 1995 (Shaw, Richmond, and O'Brian, 1995). For each group, they display how many of the patients studied for each group fall into each of the established PAR index categories. Shaw, Richmond, and O'Brian found that in the General Dental Services in England and Wales there was an overall mean PAR score decrease of 52% (Shaw, Richmond, and O'Brian, 1995). 22% of patients fell into the "greatly improved" category, 57% of patients fell into the "improved" category, and 21% of patients fell into the "worse or no improvement" category (Shaw, Richmond, and O'Brian, 1995). Continuing to the British regional orthodontic centers results Shaw, Richmond, and O'Brian found an overall mean PAR score decrease of 68% (Shaw, Richmond, and O'Brian, 1995). 43% of patients fell into the "greatly improved"

category, 49% of patients fell into the “improved” category, and 8% of patients fell into the “worse or no improvement” category (Shaw, Richmond, and O’Brian, 1995). Moving to The Norwegian orthodontic specialists group Shaw, Richmond, and O’Brian found an overall mean PAR score decrease of 78% (Shaw, Richmond, and O’Brian, 1995). 34% of patients fell into the “greatly improved” category, 61% of patients fell into the “improved” category, and 5% of patients fell into the “worse or no improvement” category (Shaw, Richmond, and O’Brian, 1995). The following information was taken from Shaw, Richmond, and O’Brian, 1995 and adapted with information from this study to compare results in Table 6.

Table 6. *Comparison of Study Treatment Outcome Category Results with Shaw, Richmond, and O’Brian, 1995*

Treatment outcome category (%)	Temple Graduate Orthodontic Clinic	British general dental services	British regional orthodontic centres	Norwegian orthodontic specialists
Greatly Improved	18.9	22	43	34
Improved	62.2	57	49	61
Worse or No Improvement	18.9	21	8	5
Mean Reduction in PAR Score	67.5	52	68	78

Comparing the Temple graduate orthodontic clinic to the British general dental services one can note that the mean reduction in PAR score was greater for the Temple group. There was a greater percentage of patients that fell into both the greatly improved and worse or no improvement categories for the British general dental services group.

There was also a greater percentage of patients that fell into the improved category for the Temple group.

Comparing the Temple graduate orthodontic clinic to the British regional orthodontic centres one can note that the mean reduction in PAR score was about the same for the Temple group. There was a much greater percentage of patients that fell into the greatly improved category for the British regional orthodontic centres with less patients falling into the improved and worse or no improvement category compared to the Temple group.

Comparing the Temple graduate orthodontic clinic to the Norwegian orthodontic specialists one can note that the mean reduction in PAR score was less for the Temple group. There was a similar percentage of patients that fell into the improved category between the two groups. A lower percentage of patients were in the worse or no improvement category for the Norwegian orthodontic specialists and a higher percentage of patients were in the greatly improved category.

6.4 Study Limitations

The inclusion and exclusion criteria for the study will be used to outline the main study limitations. The following were the inclusion and exclusion criteria selected for this study.

Inclusion criteria

- Cases from 1/2017-10/2022 (6 years)
- Measurable pre- and post- treatment 3-Dimensional scans available in iTero MyAligntech™ database
- Patient number data can be extracted from Temple University Kornberg School of Dentistry Department of Orthodontics EHR system (Axium) and internal database

- Patient funding and resident transfer status can be extracted from Temple University Kornberg School of Dentistry Department of Orthodontics EHR system (Axium) and internal database

Exclusion criteria

- Cases that do not occur during the time interval above
- Limited Orthodontic cases
- Mixed dentition cases
- Extraction cases
- Surgical cases
- Patients that were not compliant with treatment.
- Patients that had treatment terminated early

Beginning with the first bullet point of the inclusion criteria and the first bullet point of the exclusion criteria, this study investigated patients who had their treatment completed between the dates of January 2017 and October 2022. All patients that had their treatment completed prior to the start date and after the end date were excluded, therefore only selecting patients that had treatment completed within that 70 month span and within the last 5 years. This date range was selected as it was hypothesized to have the best chances for accurate digital patient records to be present in the Temple university graduate orthodontic clinical databases. Prior to 2017, use of digital scanners in the clinic was not quite as prevalent and thus digital records were not as reliably available for pre-treatment and post-treatment records. This range of about 70 months limits the overall long-term results of the study. In the future, a longer date range could give more insightful data on overall PAR score reductions in the clinic and give a more accurate representation of the

clinics ability to reduce malocclusions. This date range selection also means that patients were generally treated by about 3 years of residents or about 18 different clinicians in total. The limited number of clinicians could also confound the results as some clinicians may be better or worse at improving malocclusions. With so much variability in a clinicians ability, especially during their graduate residency program, some residents may improve the PAR score reductions and other may tend hinder it. Again, a longer date range would allow for more accurate representations of the clinic as a whole in terms of a proper audit. A longer-term audit could also allow each resident to compare their overall clinical ability to reduce malocclusion to a standard which could then help the resident determine where they could improve in the future.

The last 3 bullet points in the inclusion criteria relate to the ability of adequate data collection. In this study, if there were not adequate records, or if the information could not be extracted from the required databases, then those patients were excluded. Patients treatments therefore were excluded if they did not meet this criteria which could have eliminated patients treatments that could have affected the overall PAR score reductions.

The second bullet point of the exclusion criteria relates to limited orthodontic cases. In the Temple graduate orthodontic clinic a limited case is defined as one in which treatment can be completed within 12 months. Patients with limited treatment were excluded so that the data was not confounded with less severe malocclusions and overall simpler treatments that did not require as much complexity to complete. This was thought to confound the overall PAR score reduction by artificially inflating PAR score reductions and lowering the overall mean post-treatment PAR scores. In the future, it would be of interest to examine limited cases only to determine if a high standard of care and greater

PAR score reduction is achieved in these patients. At the conclusion of this study, it appears on occasion that the less severe the malocclusion, the more likely the patient is to end with a higher PAR score that they began with. Further investigation reveals that some patients who start with a low PAR score end treatment with a higher PAR score as some aspects of the PAR score are reduced and a more weighted portion has an increase. For example, if a patient has an initial PAR score of 2 due only to misalignment of upper anterior teeth with no other scoring sections and finishes treatment with well aligned upper anterior teeth and a midline discrepancy of greater than ¼, but less than ½ of a lower central incisor tooth width, then that patient would finish with an overall PAR score of 4. Mean PAR score reduction for this patient would then therefore be an increase of 2. Technically, this patients malocclusion is considered to have worsened even though they finished below an ideal PAR score of 5 and have well aligned teeth.

The following exclusion criteria: mixed dentition cases, extraction cases, and surgical cases were all selected as they were thought to be too difficult to accurately and reproducibly score each case. These patients' malocclusion could all be considered more severe overall and could also give more insight into the magnitude of PAR score reduction. These cases may confound the overall results by increasing the overall mean decrease in PAR score as these patients would most likely have a much higher PAR score overall, and so would have the most room for improvement of their cases. In the future it would be of interest to investigate how each of these excluded criteria factor into and compare to the overall mean PAR decrease.

The last two exclusion criteria categories, patients that were not compliant with treatment and patients that had treatment terminated early, relate to patient compliance. For

this study, we wanted the results to be centered around the clinic as a whole and around the dependent variables selected. These exclusion criteria eliminated patients that most likely finished with compromised treatments that were not due to the clinic or dependent variables. The compromised treatments, if included in this study, may have artificially decreased the total mean PAR score differences and have increased the number of patients that ended above an acceptable PAR score of 10. In the future it would be of interest to see what percentage of patients that fall into this category compromise above a PAR score of 10 mark. It would also be interesting to see at what PAR index score patients and clinicians feel comfortable in terminating treatment when both parties agree to a compromised result due to patient negligence.

Treatment duration was not evaluated in this study and would be beneficial in understanding more about patients' treatments overall. Treatment time could give better insight into treatment effectiveness and efficiency and also highlight some of the more difficult treatments to undertake in a resident clinic. Treatment duration along with patient records could also allow one to better understand if a patient was compliant with treatment or if there were further issues that would confound their PAR score results.

Salzmann index evaluation score were not recorded for the patients that were funded by Medicaid insurances. It would be of interest in the future to determine if there was a correlation between Salzman index scores and PAR scores and if the mean PAR score reduction has any correlation to the treatment outcomes for the insurance funded group.

CHAPTER 7

CONCLUSION

Overall, the PAR index can be applied to university orthodontic clinics for routine clinical audit and can provide insight on treatment outcomes and distribution of services.

1. Transferred patient start on average with a significantly more severe malocclusion compared to patients that are not transferred, but their post-treatment PAR scores on average are not significantly different. There was no statistically significant difference treatment outcome between patients who were transferred and those who were not transferred to another resident during treatment.
2. Insurance funded patients start on average with a significantly more severe malocclusion compared to privately funded, but their post-treatment PAR scores on average are not significantly different. There was a significantly greater decrease in PAR score treatment outcome for the insurance funded patients compared to the privately funded patients.
3. Mean PAR score percentage reduction was similar to that of the British regional orthodontic centres in 1995.

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APPENDIX A

IRB DETERMINATION: NOT HUMAN SUBJECT RESEARCH DETERMINATION

Temple University
Office of the Vice President for Research

Research Integrity & Compliance
Student Faculty Center
3340 N. Broad Street, Suite 304
Philadelphia PA 19140

Institutional Review Board
Phone: (215) 707-3390
Fax: (215) 204-4609
e-mail: irb@temple.edu

Not Human Subject Research Determination

Date: 27-Jan-2023

Protocol Number:	30317
PI:	JAMES J. SCIOTE
Sponsor:	NO EXTERNAL SPONSOR
Project Title:	Application of an orthodontic auditing system to a graduate orthodontic clinic: a pilot study

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On 27-Jan-2023, the IRB reviewed the protocol 30317: Application of an orthodontic auditing system to a graduate orthodontic clinic: a pilot study.

The proposed activity is not research involving human subjects as defined by DHHS or FDA regulations. Consequently, Temple University IRB review and approval is not applicable. You are welcome to pursue the activity, after obtaining any applicable administrative or departmental (non-IRB) approvals.

As this project has not been reviewed or approved by the IRB, please remove all mentions of IRB Approval from the participant-facing study documents (e.g., consent or recruitment material).

This determination applies only to the activities described in this IRB submission and does not apply should any changes be made. Changes could affect this determination, therefore please contact the IRB for guidance.

Please note: A determination of not human subjects research does not mean the project should not be conducted in an ethical manner. As such, this determination is not a prohibition of acquiring consent (in writing or verbal), it is simply a determination that IRB review and approval are not necessary.

DHHS Definitions:
Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

FDA Definitions:
Research - any experiment that involves a test article and one or more human subjects, and that either: a) must meet the requirements for prior submission to the Food and Drug Administration; or b) the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Human subject - an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

For additional information, please see HRP-001 Policy - Definitions and HRP-421 Worksheet - Human Research on the IRB Forms & Standard Operating Procedures page.

APPENDIX B

PAR SCORE RAW DATA COLLECTION

Table 7. *PAR Score Raw Data*

Pt ID	Unweighted pre-treatment	PAR Pretreatment Weighted	Unweighted post-treatment	PAR post-treatment weighted	Transferred Y/N	Private Y/N
1	8	21	1	6	Y	Y
2	2	6	0	0	N	N
3	11	31	2	7	Y	N
4	4	11	3	9	Y	Y
5	10	12	2	7	Y	Y
6	2	8	2	2	N	Y
7	4	10	2	7	N	Y
8	10	30	4	4	Y	N
9	9	32	6	8	Y	N
10	12	31	4	10	Y	N
11	7	26	3	8	Y	N
12	4	12	1	2	Y	Y
13	8	24	4	4	Y	N
14	12	30	2	7	Y	N
16	8	24	3	8	N	Y
17	9	20	0	0	N	N
18	8	21	4	4	Y	Y
19	9	26	1	6	N	N
20	14	29	1	6	Y	N
21	15	36	2	8	N	Y
22	19	50	1	1	Y	N
23	5	15	1	6	N	N
24	6	24	1	6	N	Y
25	7	26	1	6	N	Y
26	4	10	2	3	N	Y
27	8	24	2	12	Y	N
28	9	18	3	14	Y	Y
30	5	15	0	0	Y	N
33	2	5	0	0	Y	Y
34	8	26	1	6	Y	N
35	9	24	2	2	Y	N
36	8	21	1	6	Y	Y
37	8	20	2	7	Y	N
38	2	8	3	8	Y	Y

40	3	9	6	20	N	Y
43	3	10	2	7	N	Y
44	3	8	1	1	N	Y
45	7	14	0	0	N	N
46	4	4	2	2	N	Y
48	2	2	1	6	N	N
49	6	12	0	0	N	N
50	3	9	1	6	N	N
51	0	0	0	0	N	N
52	6	12	0	0	N	Y
53	3	4	1	2	N	N
55	4	5	4	9	N	N
56	8	25	2	8	N	N
57	1	1	0	0	N	N
58	3	12	0	0	N	N
59	14	34	1	1	N	N
60	6	15	4	13	N	N
61	11	32	0	0	Y	Y
62	9	23	1	6	N	N
63	3	8	1	2	N	Y
64	3	14	2	8	N	Y
65	3	16	1	6	N	N
66	12	32	5	20	N	Y
68	0	0	1	1	N	Y
69	3	9	1	6	N	Y
70	11	26	0	0	Y	N
71	4	10	0	0	Y	Y
72	3	7	2	10	Y	Y
74	12	39	1	6	Y	N
75	6	14	1	6	Y	N
76	3	8	1	1	Y	Y
77	4	6	3	4	Y	Y
78	5	14	2	3	N	N
81	9	20	3	12	Y	Y
83	3	13	1	1	Y	Y
85	18	38	2	7	Y	Y
87	2	8	5	6	Y	N
88	3	18	1	2	N	Y
89	10	31	2	2	N	Y
90	9	22	8	18	N	Y
91	6	13	4	4	Y	Y

92	2	5	0	0	Y	N
94	8	22	4	4	N	Y
95	7	30	3	3	Y	N
97	3	10	1	2	Y	Y
98	9	30	2	2	N	Y
100	3	8	0	0	N	Y
101	3	5	1	1	N	N
102	6	20	0	0	N	Y
103	4	15	2	5	Y	N
104	3	8	3	3	N	Y
105	4	4	2	2	Y	Y
106	1	1	2	3	N	Y
107	15	33	1	6	Y	N
108	1	6	1	1	N	Y
109	5	8	7	10	N	N
110	1	2	2	3	N	Y
112	8	20	4	4	Y	Y
115	10	34	0	0	Y	N
117	5	9	4	14	Y	N
118	9	28	8	25	Y	Y
119	4	15	0	0	Y	Y
120	5	19	1	1	N	Y
121	3	14	1	2	N	N
122	3	12	0	0	Y	N
123	0	0	2	7	N	N
124	5	12	4	4	Y	N
125	3	8	0	0	Y	Y
126	9	13	4	7	N	N
127	3	4	3	8	Y	Y
128	4	16	1	6	Y	N
129	9	21	0	0	N	N
131	8	13	3	8	N	N
132	4	15	1	6	N	N
133	8	18	5	10	Y	Y
134	3	7	1	2	Y	Y
135	9	22	8	24	N	N
136	6	21	1	6	N	N
138	5	17	1	1	Y	N
139	2	3	4	12	N	N
140	5	18	4	10	Y	N
141	3	13	2	7	N	Y

142	3	3	2	7	Y	Y
143	7	27	1	6	N	N
144	8	27	1	6	Y	Y
145	9	37	2	8	Y	Y
148	8	36	0	0	N	N
150	1	6	0	0	N	Y
151	3	14	2	8	N	Y
152	3	4	1	2	Y	Y
153	7	18	2	8	Y	N
155	3	9	4	9	Y	Y
156	4	16	2	8	Y	N
158	4	9	0	0	Y	N
159	2	2	1	1	Y	Y
160	2	3	2	7	N	N
161	3	6	2	2	N	Y
162	5	10	3	3	N	N
164	11	29	1	6	N	N
169	4	18	2	8	Y	N
171	3	3	2	8	N	N
173	6	14	1	1	N	N
174	1	6	5	15	N	Y
175	2	8	3	4	N	Y
177	4	14	6	10	Y	Y
179	15	39	3	4	Y	N
180	4	14	3	14	N	N
181	4	10	1	6	N	N
182	11	34	3	10	Y	N
183	1	2	0	0	N	N
184	3	18	4	10	N	Y
185	6	22	4	9	Y	Y
186	13	38	1	1	N	N
187	4	10	3	8	N	N
189	2	8	1	6	N	Y
190	8	22	1	2	N	Y
194	3	8	3	8	Y	Y
195	6	15	1	6	Y	N
197	1	2	1	1	Y	Y
198	6	24	2	8	Y	Y
200	7	32	3	8	Y	N
201	1	1	0	0	Y	Y
202	4	13	0	0	Y	N

203	8	16	2	4	Y	N
204	7	25	0	0	Y	N