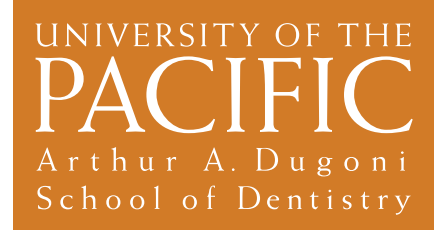




# The Inter-clinician Variability of Invisalign Treatment Objectives



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## Abstract

**Objective:** The purpose of this study is to see how different experienced clinicians evaluate alternative ClinCheck treatment plans prepared for the same cases by other experienced clinicians.

**Methods:** To investigate the preferences of experienced clinicians among these approaches when treating with the Invisalign appliance, a panel of twelve clinical orthodontists was randomly chosen from among the 200 clinicians most experienced with Invisalign treatment. Twelve representative cases treated earlier using the appliance were identified and their pre-treatment records were duplicated electronically. The records for each case were re-evaluated independently by each of six blinded randomly assigned members of the panel, each of whom re-planned treatment for six cases. The matrix of cases by clinicians was designed to maximize the number of cases in which any two clinicians re-planned treatment for the same case. The clinicians evaluated all the ClinChecks and ranked the "Most Desirable" and "Least Desirable" ClinChecks and wrote comments supporting their decisions on a supplied form. **Results:** A very small number of ClinChecks had complete agreement in rankings among clinicians while most other ClinChecks had some level of disagreement. Anterior Occlusion (26%), Staging (17%), and Attachments (13%) had the highest number of clinician comments and accounted for 52% of all comments. **Conclusions:** The rankings of various solutions differed markedly among clinicians and across cases. The frequencies of some comments categories shed some light on important factors experienced clinicians take into consideration when evaluating ClinChecks.

## Introduction

**Background**  
For many years orthodontic research has examined differences in clinicians' treatment objectives. For example, studies have examined extraction versus non-extraction therapy while others have evaluated expansion preferences. Invisalign, a relatively new method for treatment malocclusion, uses a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position (Figure 1). At this point in time, there has been little examination of among clinicians' Invisalign treatment objectives.

What has not been prior possible and is now available to clinicians is the ability to visually observe a treatment plan from beginning to end in 3D and view all the tooth movement stages in between (Figure 2). The ability to view the treatment plan from beginning to and allows the doctor to make judgments on the success or failure of their treatment plan and the outcome of their finished cases.

Providing sample cases to different clinicians for diagnosis and treatment planning may illuminate similarities or differences in Invisalign treatment objectives. The purpose of this study is to see how different experienced clinicians evaluate alternative ClinCheck treatment plans prepared for the same cases by other experienced clinicians.

## Hypotheses

Null hypothesis: If clinicians with similar advanced experience levels evaluate each others Invisalign ClinChecks of the same cases, then there will be no significant differences in their ranking and/or reasons for their ranking decisions.

## Significance

As of January 1, 2005, there were over 30,000 orthodontists and general practitioner dentists worldwide who have been trained and certified to administer treatment using Invisalign. Additionally, there are over 250,000 patients in treatment in over 30 countries. Understanding the treatment planning decisions made by experienced Invisalign clinicians can give other clinicians insights on how to better treatment plan their own cases.

## Materials & Methods

**Overview:** Data was gathered from the University of the Pacific ClinCheck Study. Analysis was focused on the Phase II of the ClinCheck study known as "First Comparison of Alternative ClinChecks." In this phase experienced clinicians evaluated each others ClinChecks in a blinded fashion.

**Sample of Judges:** Twelve experienced Invisalign clinicians participated in the study. Experienced clinicians were defined as orthodontists who had been certified in the Invisalign technique for 3 years or more and had started at least 150 cases. The sample of twelve clinicians was chosen randomly from a list over of over 200 doctors meeting these requirements at the start of the study.

**Sample of Cases:** The cases used in this study were selected non-randomly from among completed cases entered in the Align Technology's "State-Your-Case" contests of 2001-2003. The cases were reviewed and selected retrospectively in such a way as to purposefully represent the specific types of malocclusion most frequently treated using the Invisalign appliance.

**Distribution of Cases:** Each case was assigned randomly to six clinicians according to a matrix designed to maximize the number of cases in which any two clinicians re-planned treatment for the same case (Table 1).

## Study Phases

**1. Phase I: Diagnosis and Treatment Planning Using ClinCheck:**  
Participating clinicians evaluated cases selected for the study electronically. A CD-ROM disk containing the pre-treatment records (photographs, radiographs, and 3D ClinCheck study models in maximum intercuspation) were sent by mail (Figure 3 & 4). Each of the twelve clinicians diagnosed and planned treatment for selected cases using Align's Prescription and Diagnosis Form. The completed forms were sent to Align for the creation of a ClinCheck which was reviewed and modified until approved. These final ClinChecks were used for next two phases to follow.

**2. Phase II: First Comparison of Alternative ClinChecks:**  
In this phase of the study, each clinician evaluated six cases. Each case had the six other doctors ClinChecks and the actual treated ClinCheck that was previously used in the actual treatment of the patient. The seven ClinChecks for each case were sorted in random order and all identifying markers were removed to blind the clinicians. A CD-ROM disk containing these ClinChecks was sent by mail to the clinicians. The clinicians evaluated all the ClinChecks and ranked the "Most Desirable" and "Least Desirable" ClinChecks and wrote comments supporting their decisions on a supplied form (Figure 5).

**3. Phase III: Second Comparison of Alternative ClinChecks:**  
In the final phase, their ClinCheck and the actual course of treatment of each of the six cases was revealed along with the actual treated ClinCheck. A CD-ROM disk containing these ClinChecks was sent by mail to the clinicians. With this information, the clinicians were asked to re-evaluate their own ClinCheck and the actual treatment performed.

## Data Collection & Analysis

This research project focuses on Phase II acquired variables as follows:

- Cases identified as Most Desirable
- Cases identified as Least Desirable
- Cases identified as neither Most Desirable nor Least Desirable
- Written comments were later categorized by study administrators into two general categories "Favorable" and "Unfavorable."
  - Cases ranked as Most Desirable had their comments classified as Favorable.
  - Cases ranked as Least Desirable had their comments classified as Unfavorable.

- Additionally, study administrators further classified written comments into ClinCheck categories as follows: "Anterior Occlusion;" "Staging;" "Attachments;" "Posterior Occlusion;" "Arch Form;" "IPR;" "Extraction Pattern;" "Predictability;" "Limited Treatment;" "Other;" "Ambiguous."

## Results

Rankings of the Most Desirable and Least Desirable show that for some ClinChecks there is considerable agreements among clinicians (Figure 6&7). However, the same case with the ClinCheck treatment planned differently may have disagreement among clinicians (Figure 8&9). However, the distribution of clinician reasons why they found the ClinChecks Most Desirable and Least Desirable showed definitive trends. The twelve clinicians made a total of 716 comments. Approximately 90% of the written comments were unambiguous and could be classified into definitive ClinCheck categories selected by study administrators (Table 2). The top three areas that these clinicians commented on accounted for 52% of all comments were Anterior Occlusion (26%), Staging (17%), and Attachments (13%) (Graph 1).

## Discussion

Interesting treatment preferences and patterns were observed. A very small number of ClinChecks had complete agreement in rankings among clinicians while most others ClinChecks had some level of disagreement. Additionally specific comments, such as Limited Treatment, were used to describe Most Desirable for some clinicians and Least Desirable to other clinicians. Despite some irregularities among ranking of the ClinChecks, overall comment results indicate that there are a few key areas of focus for which experienced clinicians commented on the most. For example, the categories of Anterior Occlusion and Staging accounted for over 1/3 of the total comments alone. It is important for novice Invisalign users to understand the ClinCheck categories which experienced clinicians use to define a ClinCheck as Most Desirable or Least Desirable and be sure to evaluate those key categories. Making these ClinChecks available online (along with their comments and rankings) may help novice clinicians can further accelerate their learning curve of ClinCheck review.

## Conclusion

It is evident that the null hypothesis must be rejected. When clinicians with similar advanced experience levels evaluate each others Invisalign ClinChecks of the same cases, there are differences in their ranking and/or reasons for their ranking decisions. Considerable variability among experienced clinicians was found when they must decide which ClinCheck are "Most Desirable" and "Least Desirable." However, it is important to recognize that there were a few reasons (Anterior Occlusion, Staging, and Attachments) which accounted for the majority of the clinicians' comments. Understanding the reasons which made these ClinChecks "Most Desirable" and "Least Desirable" may help doctors to understand their own preferences. In summary, frequencies of some comments categories shed some light on important factors experienced clinicians take into consideration when evaluating ClinChecks. Future areas of study will be focused on understanding individual clinician comments patterns to understand trends among individual clinicians and individual case types.

The study was supported in part by Align Technology, Inc.

Cases	Clinicians											
	1	2	3	4	5	6	7	8	9	10	11	12
1	•					•	•	•			•	•
2			•				•	•	•			
3	•	•		•				•		•	•	
4	•		•		•		•			•	•	
5					•		•	•		•	•	
6	•	•	•	•			•	•		•	•	•
7		•	•	•	•					•	•	•
8											•	
9	•			•	•	•	•					•
10		•						•		•		
11		•	•	•	•				•	•		
12		•	•	•	•				•	•		

Table 1: Demonstrates the method by which cases were randomly and systematically assigned to experienced clinicians.

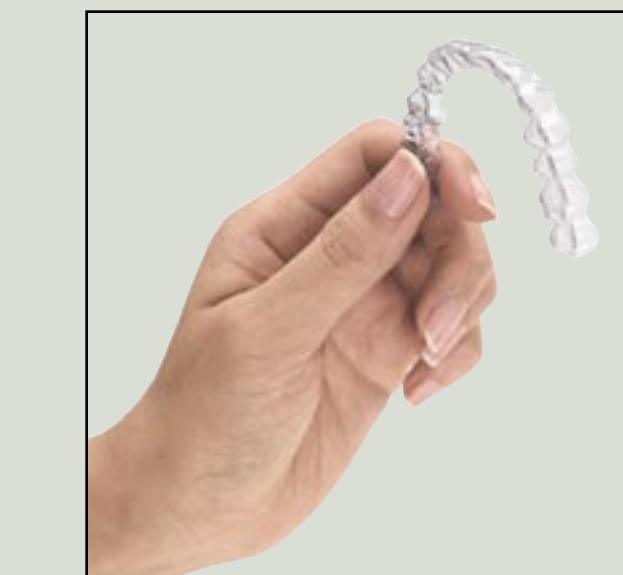


Figure 1: Aligner used as a part of the Invisalign System



Figure 2: ClinCheck software used by clinicians to make treatment plans and evaluate treatment outcomes.



Figure 3: Example Case (Rebecca Hart). Initial Records (Photos and Radiographs) shown. Age: 34yrs; Gender: Female; Case Description: Mild Class II right, Class II tendency left, open bite.



Figure 4: Example Case (Rebecca Hart). Initial Records (Study Models)

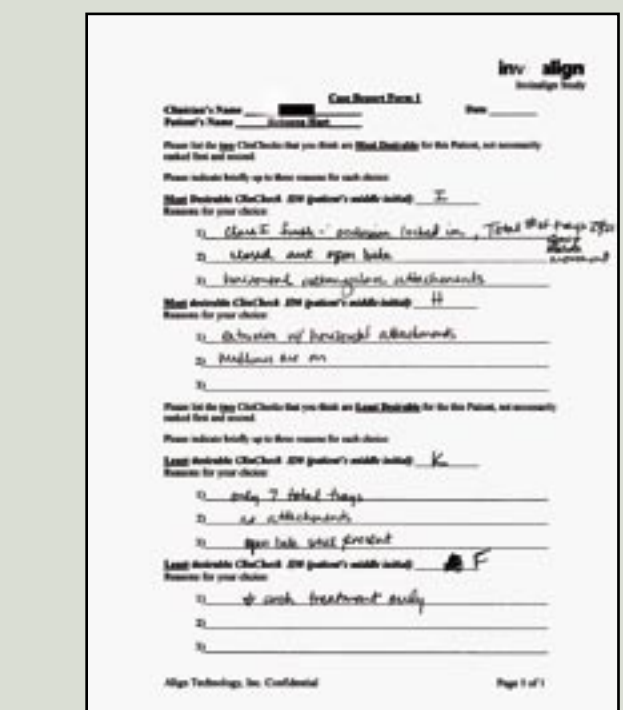


Figure 5: Example Case (Rebecca Hart). Final stage of ClinCheck Version H.



Figure 6: Example Case (Rebecca Hart). Case Report Form (Clinician H)

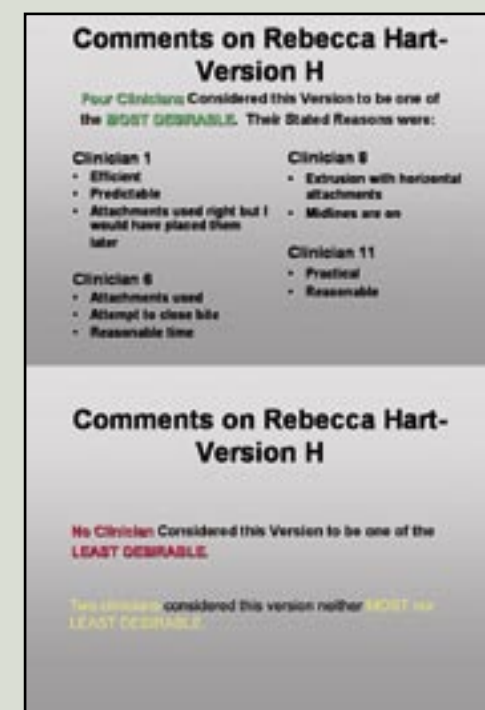


Figure 7: Example Case (Rebecca Hart). ClinCheck Version H Comments from of all clinicians who ranked the case and wrote comments are shown.



Figure 8: Example Case (Rebecca Hart). Final stage of ClinCheck Version F

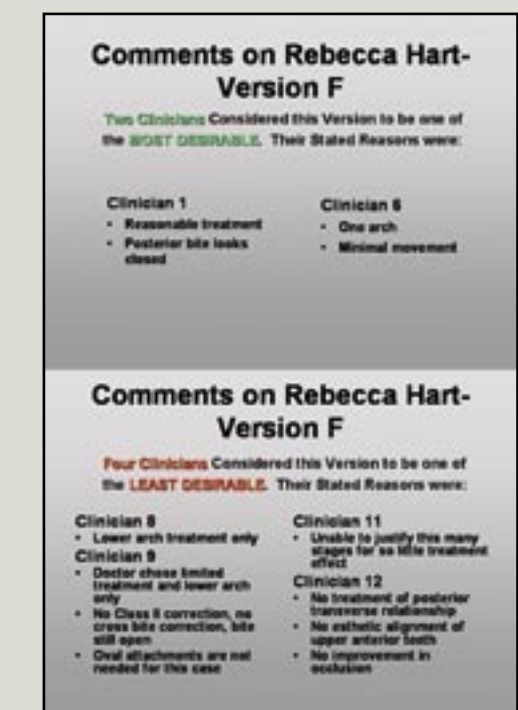
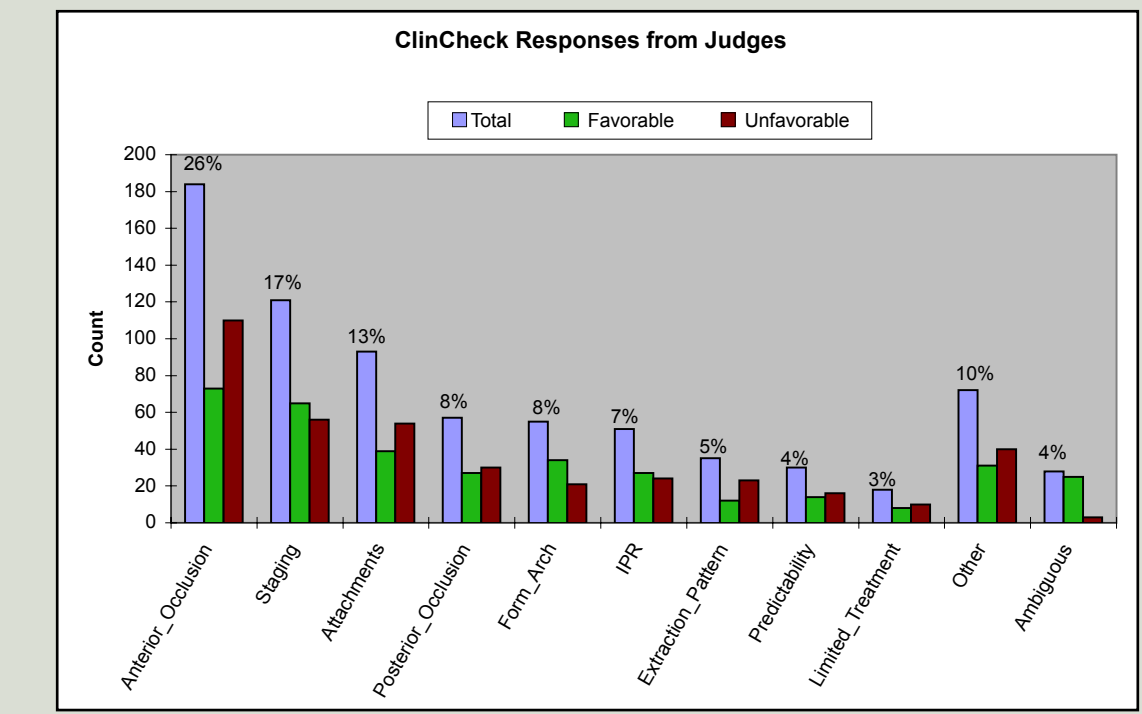


Figure 9: Example Case (Rebecca Hart). ClinCheck Version F Comments from of all clinicians who ranked the case and wrote comments are shown.

Category	Total	% of Total	Favorable	Unfavorable
Anterior Occlusion	184	26%	73	110
Staging	121	17%	65	56
Attachments	93	13%	39	54
Posterior Occlusion	57	8%	27	30
Arch Form	55	8%	34	21
IPR	51	7%	27	24
Extraction Pattern	35	5%	12	23
Predictability	30	4%	14	16
Limited treatment	18	3%	8	10
Other	72	10%	31	40
Ambiguous	28	4%	25	3
Sum	716	1	330	384

Table 2: Summary of experienced clinician comment data. Comments were classified as favorable when the case was ranked as most desirable. Comments were classified as unfavorable when the case was ranked as least desirable



Graph 1: Illustrates distribution of all comments by experienced clinicians.