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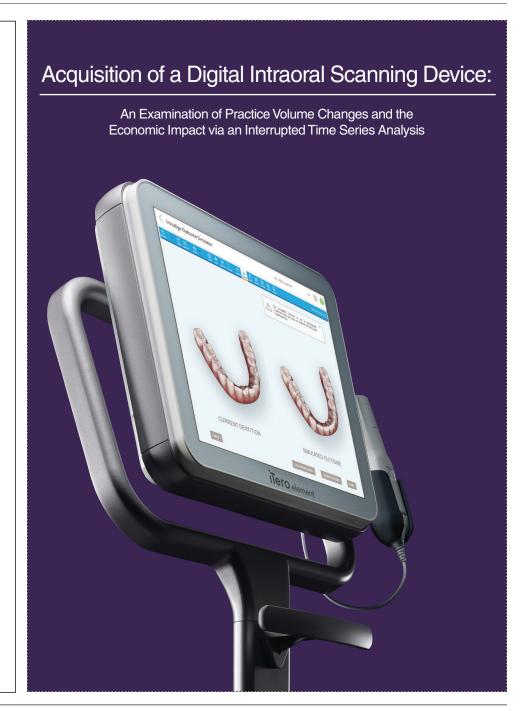
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## Acquisition of a Digital Intraoral Scanning Device: An Examination of Practice Volume Changes and the Economic Impact via an Interrupted Time Series Analysis Michael M. Mackay, PhD Statistical and Methodological Consultant The University of Memphis College of Education Memphis, TN, USA Mohammad Fallah, BSD, MSD **Associate Clinical Professor of Orthodontics** University of the Pacific Arthur A. Dugoni School of Dentistry San Francisco, CA, USA Tiffany Danyal, DDS **General Practice** Clarkston, MI, USA

### Acquisition of a Digital Intraoral Scanning Device: An Examination of Practice Volume Changes and the Economic Impact via an Interrupted Time Series Analysis

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#### Abstract

- **Objective:** To evaluate the impact of digital scanning in general dental practices and orthodontic practices to determine the percentage of lift, *i.e.*, the percent increase in gross receipts, of Invisalign® treatment starts following the introduction of an iTero® intraoral scanner.
- Methods: An interrupted time series analysis was conducted on 48 months (24 pre- and 24 post-scanner introduction) of Invisalign receipt data from 1,871 general practitioner (GP) and orthodontic practices located worldwide. Analyses also explored the presence of a longer shift in the trend of monthly Invisalign receipts after scanner introduction (*i.e.*, pre-post slope change), and projected the impact of the introduction of the scanner within a specific subset of practices (n = 319) that represented North American GPs with low initial practice volumes (*i.e.*, 5 or fewer receipts in the 12 months prior to acquiring the scanner).
- Results: For the entire sample, introduction of the iTero intraoral scanner at month 25 showed a significant and abrupt increase in receipts for Invisalign therapy (b = 0.49; p < 0.001). When compared to the counterfactual regression line prediction without the scanner, in month 25 Invisalign practice receipts increased from the predicted value of 2.38 to 2.88, an increase of 20.71%. When the analysis was conducted using only low-volume GP practices in North America, the introduction of the scanner at month 25 also led to a significant and abrupt increase in practice receipts (b = 0.28; p < 0.001), and this increase was still evident 24 months after scanner introduction.
- Conclusion: The results show that acquiring an iTero intraoral scanner as a precursor to Invisalign therapy is associated with a significant increase in Invisalign practice receipts. When projected across the first 12 months, this increase amounts to an additional 5.92 receipts for the entire sample (*i.e.*, 1,871 GP and orthodontic practices worldwide) and an additional 3.41 receipts for the subset of 319 low-volume, North American GPs.

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#### Introduction

Orthodontic treatment and prosthodontic care depend on successful completion of an intermediate step, whereby the clinician must accurately capture and replicate the intraoral structures of the patient. <sup>1,2</sup> The involved process, however, is complex and multifactorial. Elastomeric materials such as polyvinylsiloxane (PVS) or polyether have traditionally been used to accomplish the impression process at the center of this indirect technique, yet have been superseded by digital intraoral scans (*e.g.*, iTero® intraoral scanners, Align Technology, Inc., San Jose, CA, USA) for a variety of reasons that include their accuracy, the efficiencies provided to the members of the restorative team, and their utility throughout a digital workflow. <sup>3,4</sup>

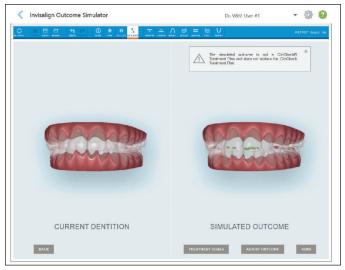
This growing adoption of iTero digital scanning by dental professionals worldwide has already produced more than 1.2 million restorative scans over 2.7 million orthodontic scans (Internal data; Align Technology, Inc.), and promises to increase as the technology

is integrated within workflows that support restorative dentistry, implant diagnostics, treatment planning, and Invisalign® therapy (Align Technology, Inc., San Jose, CA). The interoperability of iTero scanners, yielding an "open system" stereolithographic file, enables the scans to be integrated within numerous third-party providers and practice management solutions. Additionally, new generations of dental practitioners have shown a bias toward dental technologies such as iTero that are intuitive to their experiences as users of digital solutions for their lives as consumers.<sup>5,6</sup>

Expediency is a fundamental advantage of the digital impression process. From the procedural standpoint, digital scanning affords a simple solution for chairside technical challenges such as voids, tears, gaps, distortions, and the like that are often associated with PVS or polyether analog impressions. As a result, digital impressions have demonstrated excellent accuracy (*i.e.*, as measured by internal fit and

accessible marginal inaccuracy) that results in fewer rejections in Invisalign scans and greater efficiency in the cementation appointment, with fewer remakes for the dental laboratory and faster seating for the practitioner.<sup>3,4,8</sup>

Digital intraoral scanners afford a superior patient chairside experience as well, eliminating discomfort to the patient, difficulty breathing, gagging, and similar concerns inherent to a conventional dental impression. The digital capture of the intraoral environment also enables the clinician to present during patient consultation a simulation of the projected outcome of Invisalign therapy (*i.e.*, Invisalign® Outcome Simulator, Align Technology, Inc., San Jose, CA) and thereby serve as a catalyst for patient acceptance of proposed orthodontic treatment (Figure 1). This is critical in the contemporary



**Figure 1.** Simulated treatment outcome achieved through Invisalign therapy (Invisalign Outcome Simulator, iTero Element, Align Technology, Inc., San Jose, CA).

practice, where the patient is an informed consumer with access to resources regarding the expense, duration, and steps involved in a successful treatment outcome. By displaying chairside for the patient how his or her dentition will appear following treatment, the clinician is able to conduct patient education in real time, motivate the patient to consider treatment, and to adjust the treatment plan "live" and incorporate the patient's feedback in the treatment plan sent to Align Technology, Inc. Thus, iTero scanners have assumed a larger role in the contemporary dental practice, and their impact in driving Invisalign case acceptance is similarly increasing in a quantifiable manner.

Based on these trends, the following analyses were undertaken to evaluate the impact of digital scanning on Invisalign therapy starts in the general dental practice (GP) and orthodontic practice (Ortho) to determine the "lift," *i.e.*, the percent increase in gross receipts, witnessed in Invisalign treatment, following the introduction of the iTero intraoral scanner. The analyses assessed three research questions:

- 1) Does the introduction of the iTero scanner lead to an abrupt increase in Invisalign practice receipts at the time of scanner introduction?
- 2) Is there a change in the monthly trend of Invisalign practice receipts from pre- to post-scanner introduction?
- 3) When examining only North American GPs with low initial volume of practice receipts (*i.e.*, 5 or fewer in the 12 months prior to scanner introduction), does the acquisition of the iTero scanner lead to an abrupt increase in practice receipts?

#### **Materials and Methods**

#### **Dataset Description**

Global data were mined and included all Invisalign customers who purchased an iTero scanner. This dataset represented 1,871 GP and orthodontic practices worldwide (31% GP, 69% orthodontic; 84.40% North America, 11.11% Europe/Middle East, 4.22% Asia Pacific, 0.27% Latin America). Practice receipt data for Invisalign were collected objectively via instrument-driven electronic reporting; thus, the validity and reliability of the data were assured. Practices acquired the iTero intraoral scanner at any point in time between January 2013 and April 2015.

Data were structured to represent the number of Invisalign receipts each month prior to iTero scanner introduction (*i.e.*, from 24 months prior to 1 month prior) and post-introduction (*i.e.*, from 1 month post to 24 months post). Due to the fact that practices acquired the scanner at any time during the year, the data time points are not connected to any specific month. In other words, the actual calendar month representing scanner introduction differs across the practices, and the data time points are not associated with specific calendar months. Thus, any seasonal effects that may affect Invisalign practice receipts could not be estimated in the current analyses, and potential history or cohort confounding effects were unlikely due to the varying month of scanner introduction.

#### Identification of Model

Data were analyzed using a segmented regression approach in which an abrupt change in practice receipts was hypothesized at month 25, the month representing scanner introduction. The hypothesis was made *a priori* (*i.e.*, before analysis) to avoid capitalizing on chance relationships in the data. <sup>10</sup> Before model identification, the pre-scanner introduction time series data were evaluated to ensure normality and homoscedasticity. <sup>11</sup>

The initial model included the following terms:

 $Y_t = b_0 + b_1$  (time) +  $b_2$  (intervention) +  $b_3$  (time\_after\_intervention) + e

whereby

b<sub>0</sub> represented the constant (*i.e.*, initial level of receipts) for the pre-scanner-introduction data;

b<sub>1</sub> represented the slope of the pre-scanner-introduction time series; b<sub>2</sub> represented the change in receipts at the introduction of the scanner:

b<sub>3</sub> represented the change in slope between pre- and post-scanner introduction; and

e represented the estimate of error (i.e., residual).

In this model, the significance of the b<sub>2</sub> term assessed the presence of an abrupt increase in Invisalign practice receipts at the time of iTero scanner introduction, and the significance of the b<sub>3</sub> term assessed the presence of a longer shift in the trend of Invisalign receipts from pre- to post-scanner introduction.

Time series data may exhibit autocorrelations that can downwardbias regression standard errors and result in a Type I error or exaggerated significance. <sup>12,13</sup> Thus, before parameter estimates were made with the model, an iterative model identification process was employed whereby 1) autocorrelation and partial autocorrelation plots of pre-scanner data were visually examined; 2) if autocorrelation was found, the model was adjusted for autocorrelation by conducting a Prais-Winsten AR(1) GLS regression; 3) the results of the Prais-Winsten regression, specifically the produced Durbin-Watson statistics, were examined to determine if the autocorrelation was adequately accounted for; and 4) autocorrelation and partial autocorrelation plots of regression residuals were examined one final time to assess any lingering autocorrelation.<sup>11,14</sup>

For the analysis relating to Research Question 1, which used the entire sample of 1,871 GP and orthodontic practices, autocorrelation and partial autocorrelation plots revealed a slow decay in autocorrelation, with significant autocorrelation at one, and possibly two lags. A Prais-Winsten regression was conducted, and the Durbin-Watson statistic showed a decrease from 1.11 (p < 0.01) to 2.09 (p = n.s.), signifying that no remaining autocorrelation was present. A visual inspection of autocorrelation and partial autocorrelation plots of regression residuals confirmed this as well.

For the analysis relating to Research Question 2, which used the subsample of 319 North American GPs with low initial volume of practice receipts (*i.e.*, 5 or fewer in the 12 months prior to scanner introduction), autocorrelation and partial autocorrelation plots revealed no significant lags and the pre-intervention slope was not significantly different from zero, indicating a flat regression line (see Table II and Figure 3). As a result, a traditional linear regression analysis was conducted on this subsample.

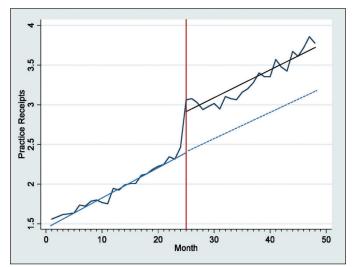
#### Results

Research Question 1: Does the Introduction of the iTero Scanner Lead to an Abrupt Increase in Invisalign Practice Receipts at the Time of Scanner Introduction?

As Table I shows, in this analysis all predictors were significant at p < 0.001 except for time after intervention (timeafterint), which was non-significant at (p = 0.832). As a result, the model was reduced to the following parameters: Y' = 1.4839 + .0360 (time) + .4936 (intervention).

As Figure 2 shows, at month 1, the number of Invisalign practice receipts was 1.48 and the number of receipts increased through month 25, the month of the scanner introduction, at which point there occurred an abrupt increase in Invisalign receipts. To assess the extent of the increase, receipt estimates were calculated at month 25 using the counterfactual regression line (*i.e.*, the regression line

before the introduction of the scanner, expressed as the dotted blue line in Figure 2) and compared to the receipts estimated by the entire regression equation (*i.e.*, the equation that included post-scanner introduction data, expressed as the solid black line in Figure 3). The number of Invisalign receipts as predicted by the counterfactual regression line at time 25 is: Y' = 1.4839 + .0360 (25) = 2.3839. The number of practice receipts at time 25 as predicted by the full model is: Y' = 1.4839 + .0360 (25) + .4936 (1) = 2.8775, signifying a 20.71% increase in practice receipts at the time of the introduction of the scanner.



**Figure 2.** Time series plot showing receipt increase at month 25. Red line denotes introduction of the iTero intraoral scanner.

### Research Question 2: Is There a Change in the Monthly Trend of Invisalign Practice Receipts from Pre- to Post-scanner Introduction?

In the regression model, parameter  $b_3$  represents the change in slope between pre- and post-scanner introduction. This parameter was estimated at 0.001 (p = 0.832), indicating that the pre- and post-scanner slopes do not differ significantly from each other. A visual inspection of the time series data (Figure 3) confirms that the two slopes are essentially identical. Thus, the results show that the initial increase of 0.49 practice receipts at the time of scanner introduction is maintained

**Table I**Results of Analysis of 48 Months of iTero Intraoral Scanner and Invisalign Practice Receipts

	•				
AlliTeroData	Coef.	Std. Err.	t	р	95% Conf. Interval
time	0.36033	0.0033818	10.66	0.000	0.0292174 0.0428485
intervention	0.04936223	0.0602825	8.19	0.000	0.3721308
timeafterint	0.0010874	0.005088	0.21	0.832	-0.0091668 0.0113417
_cons	1.483883	0.0498177	29.79	0.000	1.383482 1.584284

time = slope pre-scanner intervention; intervention = introduction of the intraoral scanner at month 25; timeafterint = change in slope pre- and post-scanner introduction; \_cons = regression constant.

**Table II**Results of Analysis on Low-Volume North American GPs

NASVGPsOnly	Coef.	Std. Err.	t	p	95% Conf. Interval
time	-0.0006474	0.0013491	-0.48	0.634	-0.0033664 0.0020716
intervention	0.2838344	0.0264486	10.73	0.000	0.2305309
timeafterint	0.0013848	0.0019079	0.73	0.472	-0.0024604 0.0052299
_cons	0.1121939	0.019277	5.82	0.000	0.0733436 0.1510442

time = slope pre-scanner intervention; intervention = introduction of the intraoral scanner at month 25; timeafterint = change in slope pre- and post-scanner introduction; \_cons = regression constant.

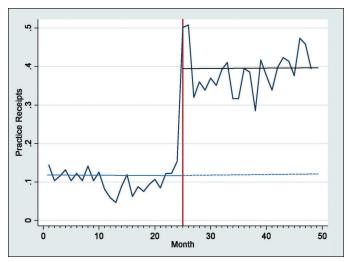


Figure 3. Time series plot showing receipt increase for low-volume, North American GPs. Red line denotes introduction of the iTero intraoral scanner.

across time. When projected across the first 12 months after scanner acquisition, this amounts to 5.92 more practice receipts, a 19.11% increase over the expected volume projected via the counterfactual line.

Research Question 3: When Examining Only North American GPs with Low Initial Volume of Practice Receipts (i.e., 5 or Fewer in the 12 Months Prior to Scanner Introduction), Does the Introduction of the iTero Scanner Lead to an Abrupt Increase in Practice Receipts?

Table II presents the results of the regression analysis for this subset of GPs. In this model, the only significant parameters were the constant ( $b_0 = 0.1122$ ; p < 0.001) and intervention ( $b_2 = 0.2838$ ; p < 0.001); thus, the regression model was reduced to: Y' = 0.1122 + 0.2838 (*intervention*).

As Figure 3 shows, the number of estimated receipts for any month prior to scanner introduction was 0.11 (p < 0.001) and the introduction of the scanner was associated with a significant increase in receipts (b = 0.28; p < 0.001). The pre-scanner slope was not significant (p = 0.634) and neither was the change in the slopes from pre- to post-scanner introduction (p = 0.472). Similar to the results of Research Question 2, the findings suggest that scanner introduction is associated with an increase of 0.28 practice receipts, which remains steady across time and amounts to 3.41 more receipts annually when compared to the volume projected by the counterfactual line.

#### Discussion

The results of Research Question 1 show that at the time of scanner introduction there was a statistically significant growth in practice receipts (b = 0.4936; p < 0.001), representing a 20.71% increase. This increase remained steady across time (*i.e.*, there is no pre-post slope change), suggesting that the adoption of the iTero scanner translates to an economic benefit for practitioners: when projected across the first 12 months, it is associated with an increase of 5.92 receipts and, assuming a \$5,500 average cost of an Invisalign case (internal data, Align Technology, Inc.), <sup>16</sup> amounts to an annual increase of \$32,560.

The findings further suggest that a practitioner's initial monetary investment in the iTero scanner (MSRP = \$29,999) would lead to returns within about a year if a practitioner used the scanner to only perform Invisalign procedures. In reality, the iTero scanner has applications in numerous restorative procedures, such as veneers, full-

coverage crowns, fixed partial dentures, trays, mouth guards, and for various implant procedures in both the diagnostic and execution phases of treatment. The present study's results, therefore, provide an underestimate of the true overall economic benefit of adopting an iTero scanner, and future research should examine the economic benefit of the scanner with respect to additional procedures.

The present study also explored whether there was a change in the monthly trend (i.e., slope) of Invisalign practice receipts from pre-to post-scanner introduction. The results reveal no significant change in slope between pre- and post-scanner introduction (b = 0.0011; p = 0.832); the post-scanner trend, shown in black in Figure 2, is not different from the trend prior to scanner introduction, shown in blue. Both slopes show a steady increase, indicating that the number of practice receipts is increasing throughout the entire 48 months represented in the data set, and that practitioners will see an 11.85 (17.64%) increase in volume receipts over the 24 months after acquiring the scanner. We urge readers to use caution when interpreting this finding because the amount of volume increase is moderated by initial practice volume. As discussed below, results relating to Research Question 3 show that North American GP practices with low initial volume (< 5 annually) do not exhibit the steadily increasing slope, and therefore have a different projected volume change.

The third goal of the present study was to explore the projected impact of the iTero scanner on monthly Invisalign receipts for low-volume GP practices in North America. Consistent with Research Question 1, the results show a significant abrupt increase in practice receipts at the time of scanner introduction (b = 0.2838; p < 0.001) that remains non-changing across time (*i.e.*, flat slope). When projected to 12 months post-scanner introduction, this increase represents a change of 3.41 additional receipts, representing an annual increase of \$18,755, and suggesting that the initial financial investment in the scanner would lead to a return on investment in the second year of using the scanner. It is worthwhile to mention that this estimate is only accurate if the scanner is solely used for Invisalign treatments. As discussed above, iTero scanners have numerous applications beyond Invisalign treatments, suggesting that practitioners would see a quicker return on investment if the scanner was used for multiple purposes.

#### **Limitations and Future Directions**

One avenue for future research has been identified above: studies should explore the economic benefits of the adoption of iTero scanners with respect to additional applications of the scanner, such as veneers, crowns, and dentures. A comprehensive evaluation of the lift across all procedures performed with the scanner would provide a much more accurate estimate of the true economic impact of purchasing an iTero scanner.

As more data become available over time, it will be worthwhile to re-conduct these analyses. Additional time periods will serve to provide more accurate parameter estimates, in particular the pre- and post-scanner trends. The analysis using all iTero users showed an increasing trend in receipts across all 48 months of data, whereas the analysis using only small volume North American GPs showed a stationary trend across the same time period. It is possible that this difference is a statistical anomaly that will disappear if more time points are included in the analysis.

Future research should also examine the specific reasons the introduction of the iTero scanner leads to an abrupt increase in practice

receipts. A strong hypothesis is that the increase is due to the scanner's capacity to preview the potential outcome of Invisalign therapy to a patient during the consultation phase by use of the Invisalign Outcome Simulator. If this is true, then a similar increase in receipts would be evident with other virtual simulations that are not specific to the iTero scanner. Alternatively, the increase could be due to reasons that are specific to the iTero scanner, such as clinicians' satisfaction with the precision-fit of aligners generated by the scan, or scanner efficiency and ease-of-use. Knowing which of these factors is the primary driver of the increase in Invisalign practice receipts would provide valuable insights for dental professionals contemplating the incorporation of iTero within their practices.

Another possible reason for the increase in practice receipts may be attributable to a self-selection effect. The initial purchase of the iTero scanner signals motivation in the practitioner to use the scanner. Practitioners who bought the scanner had the intention to perform more procedures and, as a result, the exhibited increase in practice receipts may be partly due to practitioners simply scheduling more Invisalign consults. If this is the case, then the receipt increase determined in the present study is not solely a function of the scanner but also likely a byproduct of practitioners having more consults in the first place. The dataset used in this study did not contain data about the number of consults each practitioner performed per month, making it impossible to determine the strength of the self-selection effect. It is our hope that future studies examine the effect of acquiring an iTero scanner while adjusting for increases in consults and practitioner motivation. Alternatively, future studies could employ a control group of practitioners who perform Invisalign procedures without the use of an iTero scanner.

#### Conclusion

This study's results demonstrate that the adoption of an iTero intraoral scanner is associated with a statistically significant increase in Invisalign-related practice receipts in the month directly following scanner introduction. When projected across the first 12 months after the introduction of the scanner, this amounts to an annual volume lift of 5.92 receipts and translates to an estimated \$32,560. Similarly, when the analysis is conducted using only low-volume North American GPs, there is a significant increase of 3.41 receipts over the first 12 months that amounts to \$18,755. Overall, the findings suggest practitioners stand to see their initial financial investment in the scanner lead to a return on investment in either the first or second year of using the scanner.

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**Conflict of Interest:** The authors declare no financial or non-financial interest in the company or the materials cited herein, and acknowledge receipt of an expense stipend for composition of this analysis.

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