Acquisition of iTero Element® Intraoral Scanners:

Three-Year Examination of Practice Volume Changes and Economic Impact

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Abstract

Digital intraoral scanning can support practice growth and profitability by giving the dental patient and the practitioner the ability to visualize Invisalign® treatment outcomes together. Analyses were undertaken to evaluate the economic impact of digital scanning on Invisalign practice receipts to determine the percent increase in gross receipts for Invisalign that were associated with the introduction of an iTero Element® intraoral scanner (i.e., the case lift). An interrupted time series analysis was applied to 72 months (36 months prior to, and 36 months following, scanner introduction) of Invisalign receipt data from 616 orthodontic practices worldwide. Similarly, the trending of monthly Invisalign receipts after scanner introduction (i.e., pre-post slope change) and the projected impact of scanner introduction were also examined for specific practices that represented general practices (GPs; n = 1,115) worldwide with low volumes (i.e., 5 or fewer Invisalign receipts in the 12 months prior to acquiring the iTero Element intraoral scanner) and low-volume orthodontic practices worldwide (n = 1,076). This secondary analysis was extended to worldwide GPs across 24 months (n = 363) and 36 months (n = 135) post-scanner introduction, and for worldwide orthodontists at 24 months (n = 421) and 36 months (n = 141) as well. The analyses showed that acquisition of an iTero Element intraoral scanner was associated with a statistically significant increase in Invisalign practice receipts at the time of scanner introduction. When projected across the first 36 months after scanner acquisition, this increase amounted to an average of an additional 59.23 receipts for the sample of 616 orthodontic practices worldwide, and an additional 28.61 and 80.27 receipts, respectively, for the low-volume general practitioners and orthodontists.

Key Words

Lift, iTero, iTero Element, intraoral scanning, Invisalign, scanner, slope, simulator, regression

Digital scanning is a gateway to efficiency within today's dental practice, enabling practitioners to fulfill important clinical and patient objectives with accuracy and predictability.[1,2] For the clinician, it provides vital information that includes three-dimensional visualization of the patient's anatomy and the display of intraoral structures in the detail necessary for accurate diagnosis and treatment.[3] Digital scanning with iTero scanners (Align Technology, Inc., San Jose, CA) enables the practitioner to leverage efficiencies throughout a digital restorative or orthodontic workflow, with a broad range of applications that include Invisalign® treatment, custom-milled models, custom implant abutments, and chairside milling connections. For these reasons, iTero scans have been used in more than 2.6 million restorative crown, bridge, and implant cases,[4] and in 7.6 million orthodontic scans.[4]

Historically, treatment has been accomplished with the use of traditional (analog) impressions

Table 1. Challenges of Traditional Impression Taking
• Inconsistent mixing of impression material
• Improper tray filling
• Insufficient setting time
• Internal voids
• Tray separation
• Inadequate marginal detail
• Marginal tears, drags, or pulls
• Surface contamination
• Voids/defects in poured models

and two-dimensional imaging (e.g., radiographs and photographs). However, a number of challenges can impact the reliable and accurate capture of the patient's intraoral anatomy using traditional elastomeric impressions (Table 1).[1-3,5] With digital scans, there are fewer opportunities for errors during impression taking, with errors occurring related to an incorrect scanning technique and failure to verify scans before releasing them. Both digital and traditional impressions require proper soft tissue management and adequate isolation. Further, the opportunity to use virtual/milled/printed models removes sources of errors observed with poured models. Digital (scanned) impressions have been found to be at least as, or more, accurate compared to traditional impressions. Additionally, patient difficulty in breathing or gagging can be encountered during traditional impression taking.[6] The ability of digital scanning to provide a superior chairside experience has been observed, as well as greater efficiency and reduced chairside time compared to traditional impression taking,[7-9] with one study finding that digital impressions were 59% faster.[10]

Whereas elastomeric impression materials have remained relatively constant in material composition and clinical application over recent years, digital scanning experiences continued innovation and development. Recent advances for iTero Element scanners include processors that enable high-definition color scanning of the patient's arch, which can be completed in as little as 60 seconds,[11] and that integrate applications such as iTero TimeLapse visualization and the Invisalign Outcome Simulator technology. Each supports the diagnostic and communication capabilities of the practitioner—the iTero TimeLapse tool with its ability to display and quantify changes to intraoral structures over time, and the Invisalign Outcome Simulator with its capacity to help patients visualize potential Invisalign treatment outcomes. "We use the Invisalign Outcome Simulator for all of our Invisalign patients and for all types of appliances that the laboratory makes for us," states Dr. Cayetana Manglano, an orthodontist in Valencia, Spain. "We use it for all applications, and for every single patient." To this point, in a recent study it was found that 60% of patients who were shown Invisalign Outcome Simulator results with the iTero Element scanner started Invisalign treatment.[12] In examining practice volume changes associated with acquisition of a digital scanner, the principal author observed, "A strong hypothesis is that the increase [i.e., in practice receipts] 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."[13]

In a recent study, it was found that 60% of patients who were shown Invisalign Outcome Simulator results with the iTero Element scanner started Invisalign treatment.

The aforementioned 2017 study principally explored the connection between iTero scanner introduction and increases in Invisalign treatment starts. The study used data collected from 1,871 general practices (GPs)

and orthodontic practices worldwide over a 48-month period, of which 24 months were prior to, and 24 months following, scanner introduction. The results from the interrupted time series analyses showed that acquisition of an iTero scanner was associated with a significant increase in practice receipts of 5.92 and 11.85 Invisalign cases in the first 12 and 24 months, respectively, following scanner introduction.[13] Noted the authors, "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 introduction trends."[13]

The results of a 2017 study showed that acquisition of an iTero scanner was associated with a significant increase in practice receipts in the first 12 and 24 months following scanner introduction.

The following analysis, conducted 12 months following completion of the previous publication, examines this additional time period (i.e., the data examined was for 36 months pre- and post-scanner introduction), using the methodology consistent with the initial study.

Materials and Methods

Dataset Description and Model Identification

As previously,[13] global data from practices in North America, Europe, Middle East, and Asia were extracted. This included data from Invisalign orthodontists and general practitioners (GPs) who integrated an iTero Element scanner into their practices during the study period. Invisalign practice receipt data were collected objectively via instrument-driven electronic reporting, consequently ensuring the validity and reliability of the data.

Data were structured according to the number of Invisalign receipts each month prior to iTero Element scanner introduction (i.e., from 36 months prior to 1 month prior) and post-introduction (i.e., from 1 month post to 36 months post). Sample sizes were determined based on the available amount of data, and analyses were conducted for practices with sufficient data available for inclusion at pre- and post-12, 24, or 36 months. As practices acquired the scanner at any time during the year, the data time points were not connected to any specific month. Thus, any seasonal effects that may affect Invisalign practice receipts could not be estimated in these analyses, and potential history or cohort confounding effects were unlikely due to the varying month of scanner introduction.

As in the 2017 study, these data were used to determine the "case lift," i.e., the percent increase in gross receipts for Invisalign treatment following the introduction of the iTero Element intraoral scanner. Practice data were analyzed using a segmented regression approach in which an abrupt change in practice receipts was hypothesized at the month of the scanner introduction, which, depending on the analysis, was at month 13, 25, or 37. Pre-scanner introduction time series data were evaluated before model identification to ensure normality and homoscedasticity.[14]

The initial model included the following terms:

$Y_1 = b_0 + b_1$ (time) + b_2 (intervention) + b_3 (time_after_intervention) + e, whereby

b_0 represented the constant (i.e., initial level of receipts) for the pre-scanner-introduction data;

b_1 represented the slope of the pre-scanner-introduction time series;

b_2 represented the change in receipts at the introduction of the scanner;

b_3 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_2 term assessed the presence of an abrupt increase in Invisalign practice receipts during the month of iTero Element scanner introduction, and the significance of the b_3 term assessed the presence of a longer shift in the trend of Invisalign receipts from pre- to post-scanner introduction. 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.[14,15]

For the analyses relating to the 616 orthodontic practices worldwide, autocorrelation revealed a slow decay in autocorrelation, with significant autocorrelation at the first, and possibly second and third lags. A Prais-Winsten regression was conducted, and the Durbin-Watson statistic showed a change from 1.06 ($p < .01$) to 2.36 (p = n.s.), showing that no lingering autocorrelation was present.[16] Visual inspection of autocorrelation regression residuals confirmed this as well.

The same procedure was used for the secondary analyses, which were applied to the low-volume GP and orthodontic practices (low volume equating to 5 or fewer receipts in the 12 months prior to acquiring the iTero Element scanner). For these six analyses (i.e., 12-, 24-, and 36-month segments for the GPs and 12-, 24-, and 36-month segments for the orthodontic practices), four revealed significant autocorrelations, resulting in subsequent Prais-Winsten regressions. The other two analyses revealed no initial autocorrelations; thus, traditional regression analyses were performed to estimate the impact of scanner introduction.

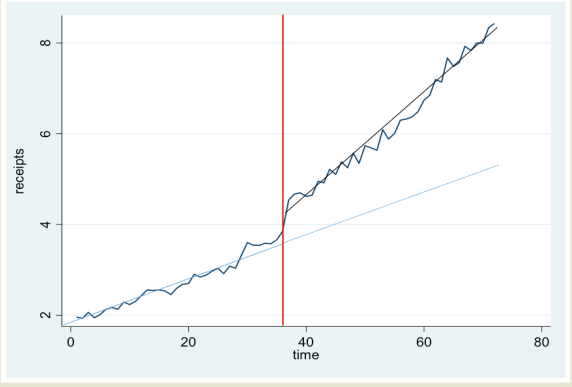

Figure 1. Time series plot of worldwide orthodontic practices (n = 616) showing Invisalign receipt increase at month 37. Note change in pre- and post-slope values indicating a higher number of monthly receipts than before scanner introduction.

Table 2. Results of Analysis of 36 Months of iTero Element Scanner and Invisalign Practice Receipts – Orthodontists Globally (n = 616)

receipts	B Coefficient	Std. Err.	t	p	[95% Conf. Interval]	
time	0.0517654	0.0038311	13.51	< .001	0.0441206	0.0594102
intervention	0.5617913	0.1045294	5.37	< .001	0.3532061	0.7703765
timeafterint	0.0619129	0.0056956	10.87	< .001	0.0505475	0.0732783
constant	1.78025	0.0833086	21.37	< .001	1.614011	1.94649
rho	0.4706682					
Durbin-Watson statistic (original)	1.064981					
Durbin-Watson statistic (transformed)	2.357657					

Results

Impact of Scanner Introduction on Practice Receipts

As demonstrated in Table 2, in the analysis examining all orthodontic practices (n = 616), all predictors were significant at $p < 0.001$. As Figure 1 shows, the number of receipts increased through month 37—the month of scanner introduction—at which point there occurred an abrupt increase in Invisalign receipts. To assess the extent of the increase, actual receipts reported were compared to the expected receipts had the scanner not been introduced (i.e., the receipts estimated via a counterfactual regression line using only pre-scanner data). The number of Invisalign receipts as predicted by the counterfactual regression line at time (month) 37 was: Y' = 1.78 + .052(37) = 3.69. The number of practice receipts at time 37 as predicted by the full model was: Y' = 1.78 + .052(37) + .56(1) + .062(0) = 4.26. This signifies a 15.2% increase in practice receipts at the month of the introduction of the scanner.

Pre- and Post-Scanner Trends on Invisalign Practice Receipts

Among the 616 orthodontic practices, changes were evident in the monthly trends for Invisalign practice receipts following introduction of an iTero Element scanner. In the regression model, parameter b_3 represented the change in slope between pre- and post-scanner introduction and was significantly higher than the pre-scanner slope. When projected across the first 36 months after scanner acquisition, this amounted to 59.23 more practice receipts, a 35.76% increase over the expected volume projected via the counterfactual line (i.e., without the scanner).

Impact on Practice Receipts – Low-volume GP and Low-volume Orthodontic Practices

Tables 3 - 5 present the results of the regression analyses for the worldwide low-volume GP practices, and Tables 6 - 8 for the low-volume orthodontic practices. Findings from the analyses show that scanner introduction produced a positive lift for the low-volume GPs in all three analyses (i.e., using 12, 24, and 36 months of pre-post data). Utilizing a sample size of 1,115 GPs across 12 months of post-scanner data, the case lift amounted to 7.19, representing a 326.07% increase in gross receipts for Invisalign treatment. Across 24 months of post-scanner data, a 470.47% increase in gross receipts (case lift = 16.47) was observed for 363 GPs, while 135 GPs experienced a 716.89% increase in gross receipts (case lift = 28.61) over 36 months of post-scanner

Table 3. Results of Analysis at 12 Months – Low-Volume GPs Globally (n = 1,115)

receipts	B Coefficient	Std. Err.	t	p	[95% Conf. Interval]	
time	0.0099365	0.0038526	2.58	0.018	0.0019001	0.017973
intervention	0.7270763	0.0316672	22.96	< .001	0.6610196	0.793133
timeafterint	-0.0232154	0.0060162	-3.86	0.001	-0.035765	-0.0106659
constant	0.0579162	0.0299218	1.94	0.067	-0.0044995	0.1203318
rho	0.5024574					
Durbin-Watson statistic (original)	0.998584					
Durbin-Watson statistic (transformed)	1.753669					

data, when compared to the volume projected by the counterfactual regression line (i.e., estimated trend without the scanner).

This trend was also evident in low-volume orthodontic practices, with an 286.56% increase in gross practice receipts (case lift of 10.68) across the first 12 months after scanner introduction based on a sample size of 1,076 orthodontists. Across 24 months of post-scanner data, gross practice receipts increased by 1,467.83% (case lift = 37.64), given 421 orthodontists, and across 36 months of post-scanner data an increase of 1,684.45% was observed for gross practice receipts (case lift = 80.27; n = 141).

Discussion

The results of the analyses of orthodontic practices (n = 616) show that there was a statistically significant growth in practice receipts (b = 0.5618; p < 0.001) at the time of scanner introduction. The post-introduction slope was significantly higher than the pre-slope, suggesting an increase in monthly practice receipts. When projected across 36 months, adoption of the iTero Element scanner was associated with an increase of 59.23 receipts (a 35.76% lift). This increase suggested that adoption of the iTero Element scanner translated to an economic benefit for orthodontists. Assuming an average patient fee of $5,500 for an Invisalign case,[17] this translates to a total increase in gross receipts of $325,765 over 3 years.

The findings of this study, using 6 years of data, further suggest that an orthodontist's investment in the iTero Element scanner (MSRP = $29,999) would lead to returns in less than one year or sooner. Practice benefits are observed by Dr. Joshua Epstein of Manalapan, NJ: "We do nearly 400 Invisalign cases annually now, which is perhaps a two-fold increase in our production compared to before purchasing an iTero scanner." Similar observations are noted in GP practices, which showed almost the same results in these analyses (discussed below). "Our practices did approximately 25 Invisalign cases yearly prior to incorporating digital scanning," says Dr. Robin Bethell of Austin, TX, "and by the end of our first year with iTero scanners we had finished 80 cases. This year we're targeted to do 400+ cases among our three practices."

A related goal of the study was to explore the projected impact of the iTero Element scanner on monthly Invisalign receipts for low-volume GP and low-volume orthodontic practices across three different pre-post time spans. For all six analyses (i.e., 12-, 24-, and 36-month spans for GPs and 12-, 24-, and 36-month spans for orthodontic practices), the results revealed a significant increase in receipts at the month of the scanner introduction. With regard to the pre-post slope change, three analyses revealed no change in slope, two revealed an increase in slope, and one a slight significant slope decrease. That said, in all analyses the end

Table 4. Results of Analysis at 24 Months – Low-Volume GPs Globally (n = 363)

receipts	B Coefficient	Std. Err.	t	p	[95% Conf. Interval]	
time	-0.0019589	0.0019794	-0.99	0.328	-0.0059481	0.0020304
intervention	0.6862995	0.0379789	18.07	< .001	0.609758	0.762841
timeafterint	0.0045114	0.0028504	1.58	0.121	-0.0012332	0.010256
constant	0.145883	0.0284937	5.12	< .001	0.0884577	0.2033082
rho	0.2143314					
Durbin-Watson statistic (original)	1.574922					
Durbin-Watson statistic (transformed)	1.861479					

Table 5. Results of Analysis at 36 Months – Low-Volume GPs Globally (*n* = 135)					
receipts	**B Coefficient**	**Std. Err.**	***t***	***p***	**[95% Conf. Interval]**
time	0.0001697	0.0013888	0.12	0.903	-0.0026016 0.002941
intervention	0.7946918	0.0408298	19.46	< .001	0.7132173 0.8761664
timeafterint	0.0039049	0.001964	1.99	0.051	-0.0000143 0.007824
constant	0.1108524	0.0294661	3.76	< .001	0.0520537 0.1696512

Table 6. Results of Analysis at 12 Months – Low-Volume Orthodontists Globally (*n* = 1,076)					
receipts	**B Coefficient**	**Std. Err.**	***t***	***p***	**[95% Conf. Interval]**
time	0.0167864	0.0051617	3.25	0.004	0.0060192 0.0275536
intervention	0.8899069	0.0459657	19.36	< .001	0.7940242 0.9857897
timeafterint	0.0119672	0.0077954	1.54	0.14	-0.0042938 0.0282282
constant	0.0168346	0.0392134	0.43	0.672	-0.0649632 0.0986324
rho	0.3769086				
Durbin-Watson statistic (original)	1.390837				
Durbin-Watson statistic (transformed)	1.753230				

Table 7. Results of Analysis at 24 Months – Low-Volume Orthodontists Globally (*n* = 421)					
receipts	**B Coefficient**	**Std. Err.**	***t***	***p***	**[95% Conf. Interval]**
time	0.0012195	0.0018818	0.65	0.52	-0.0025729 0.005012
intervention	0.9576806	0.0366611	26.12	< .001	0.8837949 1.031566
timeafterint	0.0531134	0.0026769	19.84	< .001	0.0477185 0.0585082
constant	0.1068572	0.0269463	3.97	< .001	0.0525505 0.161164
rho	0.0874432				
Durbin-Watson statistic (original)	1.826035				
Durbin-Watson statistic (transformed)	2.003047				

Table 8. Results of Analysis at 36 Months – Low-Volume Orthodontists Globally (*n* = 141)					
receipts	**B Coefficient**	**Std. Err.**	***t***	***p***	**[95% Conf. Interval]**
time	-0.0002656	0.0017253	-0.15	0.878	-0.0037085 0.0031772
intervention	0.8980144	0.0507239	17.7	< .001	0.7967964 0.9992325
timeafterint	0.0761029	0.00244	31.19	< .001	0.0712339 0.0809718
constant	0.1323764	0.0366066	3.62	0.001	0.0593292 0.2054237

result was an increase in lift (i.e., more receipts submitted over time) with percentage increases in receipts ranging from 286% to 1684%. Thus, in all analyses, practitioners experienced a net financial gain as a result of acquiring the scanner. For example, for the 36-month analyses, low-volume GP practices saw an increase of $157,355 over three years, and low-volume orthodontic practices saw an increase of $441,458 over the same time period.

It is worthwhile to note that the above estimate is only accurate if the iTero Element scanner is used solely for Invisalign treatments. Of importance, and as discussed in the previous study,[13] the iTero scanner has applications in numerous restorative procedures, such as veneers, full-coverage crowns, fixed partial dentures, bleaching trays, mouth guards, and for various implant procedures in both the diagnostic and restorative phases of treatment. This suggests that GPs would see a quicker return on investment if the scanner were to be used for multiple purposes and, therefore, that the present study's results underestimate the potential overall economic benefit of adopting an iTero scanner. Longer-term studies, as well as analyses on the economic benefit of the iTero Element scanner for non-orthodontic procedures, remain areas for future exploration and research.

Conclusion

Consistent with the study reported in 2017, the current study's results demonstrate that the adoption of an iTero Element intraoral scanner is associated with a statistically significant increase in Invisalign-related practice receipts in the month directly following scanner introduction for all three sets of analyses. When projected across the first 36 months after the introduction of the scanner to an orthodontic practice, this amounts to a volume lift of 59.23 receipts and translates to an estimated $325,765 increase in gross receipts over 3 years. Similarly, when the analysis is conducted using only low-volume GP practices and low-volume orthodontic practices, there is a pronounced increase of 28.61 and 80.27 receipts, respectively, over the first 36 months. Overall, the findings suggest practitioners stand to see their initial financial investment in the scanner lead to a return on investment within the first year of use following acquisition of the scanner.

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Note: Doctor practices in this analysis were located in the following countries: AU, AT, BE, BM, CA, CH, CY, CZ, DE, DK, ES, FI, FR, GB, GR, HK, IE, IN, IT, JP, KR, LI, LT, LU, NL, NZ, PL, PR, PT, RE, RU, SE, SG, SK, TH, TW, US, VN.

References

1. Seelbach P, Brueckel C, Wostmann B. Accuracy of digital and conventional impression techniques and workflow. *Clin Oral Invest* 2012;17:1759-64.

2. Kim SY, Kim MJ, Kwon HB. Accuracy of dies captured by an intraoral digital impression system using parallel confocal imaging. *Int J Prosthodont* 2013;26:161-3.

3. Shillingburg HT, et al., eds. *Fundamentals of Fixed Prosthodontics. Quintessence Publishing,* Carol Stream, IL, 1997.

4. Data on file, Align Technology, as of April 1, 2018.

5. Kamimura E, Tanaka S, Takaba M, et al. In vivo evaluation of inter-operator reproducibility of digital dental and conventional impression techniques. *PLOS ONE* 2017;12(6):e0179188. Available at: https://doi.org/10.1371/journal.pone.0179188.

6. Farrier S, Pretty IA, Lynch CD, Addy LD. Gagging during impression making: Techniques for reduction. *Dent Update* 2011;38(3):171-2, 174-6.

7. Lee SJ, Gallucci GO. Digital vs. conventional implant impressions: efficiency outcomes. *Clin Oral Implants Res* 2013;24:111-5.

8. Joda T, Bragger U. Patient-centered outcomes comparing digital and conventional implant impression procedures: a randomized crossover trial. *Clin Oral Implants* Res 2018;27(12:e185-9. [Epub ahead of print]

9. Gjelvold B, Chrcanovic BR, Korduner E-K, Collin-Bagewitz I, Kisch J. Intraoral digital impression technique compared to conventional impression technique. A randomized clinical trial. *J Prosthod* 2015;00:1-6.

10. Yuzbasioglu E, Kurt H, Turunc R, Bilir H. Comparison of digital and conventional impression techniques: Evaluation of patients' perception, treatment comfort, effectiveness and clinical outcomes. *BMC Oral Healt*h 2014;14:10. doi: 10.1186/1472-6831-14-10.

11. Data on file at Align Technology. Scan times vary and depend on individual experience.

12. Based on a survey of n=101 orthodontists and general dentists (from U.S., Canada and U.K, in July 2018; GP=60, ortho=41) who used the Invisalign Outcome Simulator in the past year and were asked, "For the patients who were presented the option of Invisalign treatment in the past 12 months, and for whom you have used the Invisalign Outcome Simulator, what percentage of these patients started Invisalign treatment?"

13. Mackay MM, Fallah M, Danyal T. Acquisition of a digital intraoral scanning device: An examination of practice volume changes and the economic impact via an interrupted time series analysis. *J Clin Dent* 2017;28(Suppl):S1-S5.

14. Tabachnick BG, Fidell LS, eds. *Using Multivariate Statistics* (6th ed.). Pearson/Allyn & Bacon, Boston, MA, 2007.

15. McDowall D, McCleary R, Meidinger EE, Hay RA, eds. Interrupted Time Series Analysis. Sage Publications, Newbury Park, CA, 1980.

16. Savin NA, White KJ. The Durbin-Watson test for serial correlation with extreme sample sizes or many regressors. *Econometrica* 1977;45(8):1989-96.

17. Invisible orthodontic aligners. www.webMD.com. Accessed November 9, 2018. Available at: http://www.webmd.com/oral-health/guide/invisible-orthodontic-aligners#2.