Does iTero® Help My Invisalign® and Restorative Dentistry? A 3-Phase Clinical Study

by David Galler, DMD

Dr. David Galler is the President of the American Academy of Cosmetic Orthodontics, and has proudly transformed hundreds of smiles with Invisalign® aligners. A featured speaker at numerous study clubs, webinars, national and regional events, Dr. Galler has been featured in educational and marketing materials designed to help practices learn more about Invisalign treatments and clinical techniques. The New York State Dental Journal (Jan. 2009) published his multidisciplinary case incorporating Invisalign, implant, prosthetic, and aesthetic treatment goals. He is the creator of the GST system being utilized by more than 3500 doctors across the country every day.

www.drdavidgaller.com

Dr. Danielle Danzi Goodwin grew up in the suburbs of Washington, D.C., and received her BS in dental hygiene from the University of Maryland School of Dentistry. Her growing love of the profession led her to pursue her DDS from New York University. Dr. Goodwin was a National Health Service Corps scholarship recipient, and fulfilled her postgraduate residency in Rhode Island. Always knowing she was headed back to New York City, she found a job in the financial district as a general and cosmetic dentist. She has been at Premier Dental Associates ever since.

Dr. Goodwin lives in Greenwich, Connecticut, with her husband and two toddler boys.

**Background**

In the current digital age, scanning technology has become ingrained in our culture. Teenagers in malls can now scan a bar code with their phones and comparison shop. Digital x-rays have already been commonplace in most dental offices for the last 10 years. With the advances in scanning technology and the breakthroughs in 3D printing in recent years, the question becomes: How will these influence the dental world?

In 2010, Align Technology purchased a smaller company called Cadent for $190 million. Until this point, the 2 companies had drastically different markets in the dental world and different dental purposes. Align Technology is the maker of Invisalign—invisible braces for adults using Clear Aligner Therapy. Cadent produces the iTero intraoral scanner (Figure 1)—capable of creating a digital model of teeth for restorative purposes by scanning teeth in the mouth without the use of impression material.

Combining the two companies created a major breakthrough in technology, enabling dentists to scan in their patients' dentition for use with Invisalign orthodontics. This could eliminate the use of cumbersome impression materials, create better, more accurate restorations and appliances, and increase the efficiency and quality of the process for creating aligners for orthodontics.

**Study goals**

Dental technology is great and everyone enjoys a new gadget, but unless it really improves a dental practitioner's life, is it worth it? And, in like manner, does it improve a patient's dental experience?

In 2013, Align Technology set out to prove that offices that use the iTero scanner would have higher-quality restorations and increased office efficiency, and asked the author to create and undertake a 3-part independent study to test this assertion.
materials were based on the records of several top Invisalign practitioners.)

**Study parameters**
1. 25 candidates, all Invisalign new case starts, were scanned with iTero
2. All patients were between ages 21 and 40
3. Each patient signed consent form
4. No patients had ever been scanned before
5. Patient dentitions were not screened—random selection
6. 2 different people (1 dentist and 1 assistant) performed scans
7. All scans had less than 3 red marks of incompleteness
8. Study conducted throughout 1 full quarter to correct for sales conditions
9. Continuous scanning mode from the machine
10. Timed from first scan to last scan, recorded by iTero machine
11. Clinicians did not see timer while working
12. Align Technology unaware which patients were in test
13. Saturdays and Sundays excluded from posting ClinChecks
14. No correction for American or Costa Rican holidays when facility was closed
15. Protocols and clinical study submitted to independent review board for approval before study
16. 2011 model of iTero was used throughout the study

**Results**
The results showed that patients scanned with iTero had their ClinChecks posted, on average, in 3 days. The shortest time was 1 day and the longest was 6 days.

With traditional impression materials submitted during the same time period, ClinChecks were posted, on average, in 7 days, with shortest time of 5 days and longest time of 13 days.

**Analysis**
ClinChecks were developed more quickly for Invisalign cases submitted via the iTero scanner. This led to faster treatment, and reduced the amount of time required for patients to receive their appliances by more than 50%.

The study also produced one case that proceeded from patient scan to insertion of Invisalign in 9 days.

**The reduction in production time can be easily understood for 2 reasons:**
First, scanning technology allows the model of the patient to be at the manufacturer’s facility in approximately 15 minutes, versus 3-day shipping via UPS for traditional impressions.
Second, with scanning, Align Technology receives a computer file that is readily handled by its virtual modeling center. With traditional impressions, the impressions must first be scanned manually at the facility and then inverted into detailed virtual images before being processed by the virtual modeling center in Costa Rica.

**Conclusions**

**Efficiency Benefits**
- ClinChecks are posted sooner
- Treatment can begin sooner
- Case submission is cleaner and easier

**Dental Quality Benefits**
- Refinements and midcourse corrections are faster
- Retainers are delivered sooner

---

**Phase II**

**Study question**
Do crowns fabricated with iTero digital scanning technology fit so well that the treatment time required to insert the crown is greatly reduced?

**Study design**
Twenty-five patients who were in need of a single crown underwent preparation by an independent dental office. The prepared teeth were then scanned in with the iTero scanner (Figure 3) and the scans submitted to Digital DC—an iTero-only lab in Belgium—for fabrication of single-unit PFM crowns.

The time required for the practitioner to seat each crown was then recorded. Try-in time was recorded (measured from after removal of the temporary crown to after cementation of the permanent crown). Proper seating of all crowns was evaluated by the practitioner, and x-rays were taken to verify that there were no open margins.

**Study parameters**
1. Each patient signed consent form
2. Ages 21-40
3. All crowns fabricated by Digital DC—an iTero-only lab
4. Same dentist for all 25 crowns
5. Random selection of patient and teeth
6. All teeth were premolars or molars
7. Crown try-in time was recorded
8. Cementation try-in time was recorded
9. Time started when temporary crown was removed
10. Time ended when all cement was removed
11. Time was halted for x-ray to ensure proper seating of crown

---

**Figure 3:** digital scan of prepared tooth.

**Figure 4:** bitewing x-ray verifying proper fit of crown.

**Figure 4a:** bitewing x-ray verifying proper fit of crown.

**Figure 5:** model created by 3D printer.
Appointments for this procedure are commonly scheduled for 30-minute duration.

**Analysis**
The iTero scanner creates a more accurate model, which leads to a better-fitting crown. Common adjustments, such as are necessary because of overly tight contacts and high occlusion, are not needed in crowns fabricated with the iTero scanner. This means that the crowns require fewer manual chairside adjustments by the dentist. The practitioner can then expect to insert the crown with less chair time, in an average of 6 minutes (versus 25 minutes for crowns made using conventional impressions).

The dramatic improvement in fit can perhaps best be understood by the fact that the human element is removed from the equation. In an iTero workflow, minutes after the scan is sent to the lab, the 3D printer is creating the model to the exact specifications of the scan (Figure 5).

Further, traditional impressions usually are not poured up into stone models until they reach the laboratory, typically 2 to 3 days after they’re taken. This opens the possibility of expansion or contraction of the PVS material based on the climate of the surrounding area during the transportation of the material.

Also, the temperature of the stone used to pour up the impression can slightly affect the set of the model and thereby influence the size of the model. This can lead to minute differences in crown size that then need to be manually adjusted by the dentist chairside. This leads to increased chair time.

While scanning in prepared teeth, the dentist is able to visualize the design of crown and occlusal clearance (Figure 6) in real time. The dentist can then make slight adjustments to create a better tooth preparation that can then lead to a better-fitting crown. With traditional impressions, it is harder to analyze the work mid-treatment.

**Conclusions**
Crowns scanned with iTero are inserted 5 times faster than impression-fabricated crowns.

**Efficiency Benefits**
- Fewer adjustments required
- No crown remakes required
- Insertion time faster

**Quality Benefits**
- Better-fitting crowns
- Better dentistry

**Overhead Benefits**
- Less chair time
- Faster appointments

**Results**
The average crown insert time was 6 minutes 2 seconds.
The shortest time was 3:36 and the longest time was 19:29.

There were no remakes required. All crowns fabricated with the iTero scanner were inserted and verified as clinically acceptable with single bitewing x-rays (Figures 4-4a).

Three-month follow-ups showed no problems with any of the crowns, and none had come off.

Dentists commonly report an average try-in and cementation time of 25 minutes for each single-unit crown.
Phase III

Study question
Do iTero-scanned PFM crowns fit better than those made with traditional impression material?

Study design
Twenty-five random patients were prepared for single-unit PFM crowns. These were all done by an independent dental office.

Each of the 25 tooth preparations then had both a traditional impression and an iTero scan taken of the tooth. Each impression was then sent to a specific lab for fabrication of a single-unit PFM. Each iTero scan was sent to a separate lab for fabrication of a single-unit PFM based on the model produced from the scan.

The crowns in each pair were then randomly labeled A and B and placed on the treatment table. The dentist then tried in both crowns, and evaluated which one fit better without any adjustments.

Evaluation consisted of checking contacts, margins, and occlusion. The dentist then picked the crown that fit the best, cemented it in, and recorded it as either A or B.

Independent office personnel then recorded the selection and compared it to the original designation of each crown. The results were then tabulated to determine which type of crown the dentist most often preferred.

Study parameters
1. Each patient signed consent form
2. Ages 21-40
3. All crowns fabricated by Digital DC—an iTero-only lab
4. Same dentist for all 25 crowns
5. Random selection of patient and teeth
6. All teeth were premolars or molars
7. Crown try-in was recorded
8. Cementation try-in was recorded
9. Time started when temporary crown was removed
10. Time ended when all cement was removed
11. Time was halted for x-ray to ensure proper seating of crown

The results seem to point unequivocally to the conclusion that there is greater accuracy and precision in the fabrication of single-unit PFM crowns using digital technology than using human manual labor.

Many factors can cause crowns made by traditional labs to have inaccuracies that necessitate manual adjustments made by the dentist chairside. When the error-prone human fabrication element is removed and replaced with scanning and 3D printing, the end result is superior.

Interestingly, the 3 impression-made crowns that were selected in preference to the iTero fabricated crowns were all preparations that were very subgingival, on molars where moisture control was an issue. A known limitation of the iTero machine manifests in the presence of moisture, where the scan can be difficult to capture. In these limited instances it may still be preferable to use traditional impressions.

Conclusions

Efficiency Benefits
- Fewer adjustments required
- Fewer ill-fitting crowns and remakes

Dental Quality Benefits
- Better-quality crowns
- Better margins, occlusions, and contacts

Overhead Benefits
- Lab fee for iTero crown is $99 vs. $150 for impression crown
- iTero crown requires less chair time

This study was conducted by Dr. David Galter and Dr. Danielle Danzi Goodwin in New York. The iTero lab was used was Digital DC.

For more information about Digital DC, call 888-955-5419 or go to www.digital-dc.com

Study was approved by RCRC Independent Review Board, per approval letter dated January 25, 2013

References


Check it out
To view the entire iTero study, please visit us at http://aaoortho.com/podcasts-webinars