

Accuracy of Intraoral Camera Sleeves Based on Decontamination and Calibration

Abstract

Aim: The purpose of this study was to evaluate the effect of camera sleeve decontamination protocols and compare their accuracy to single-use alternatives. This was accomplished utilizing controls for unit calibration.

Materials and Methods: Five extracted human teeth were set into a gypsum stone model and prepared for various indirect restorations. A baseline optical impression was completed with a bench-top scanner (X5, Dentsply/Sirona) and exported for reference. One hundred forty optical impressions were completed using a calibrated or uncalibrated PrimeScan unit and a sterilizable, autoclavable with single-use glass or disposable plastic camera sleeve (n=10). Decontamination protocols included dry heat sterilization (Cox RapidHeat/CPAC) or high-level disinfection (Cidex OPA/Johnson & Johnson) with scans at baseline, and after 25 and 50 cycles. Individual optical impressions were compared to baseline using the prepared teeth surfaces as references and overlaid using 3-dimensional best-fit superimposition. PrimeScan impressions were compared to the baseline model and evaluated for 3-dimensional linear disparity (GeoMagic). Data were analyzed with Kruskal-Wallis and Mann-Whitney U tests ($\alpha=0.05$).

Results: No significant differences in median linear distance were found regardless of sleeve type, decontamination protocol, or calibration status ($p>0.05$). All groups demonstrated statistically similar linear disparities ranging from 11.78-14.00 microns. The most precise sleeves were single-use, although not statistically different than the multi-use sleeve.

Conclusions: Camera sleeve type, decontamination protocol, and calibration status of the PrimeScan unit did not significantly impact the accuracy of the optical impressions. Any of the currently available camera sleeves used according to manufacturer's recommendations can provide similar accuracy in a clinical setting.

Keywords: accuracy, CAD/CAM, mirror sleeves, decontamination, calibration

Disclosure: Funding for the present study was provided by the 59th Clinical Investigations and Research Support, Joint Base San Antonio, Lackland, Texas.

Conflict of interest statement: The views expressed are those of the authors and do not reflect the official views or policy of the Uniformed Services University, Department of Defense, or its Components. The authors do not have any financial interest in the companies whose materials are discussed in this abstract. The views of Dentsply/Sirona, Cox, Johnson and Johnson, or Geomagic are not necessarily the official views of, or endorsed by, the U.S. Government, the Department of Defense, or the Department of the Air Force. No Federal endorsement of Dentsply/Sirona, Cox, Johnson and Johnson, or Geomagic is intended.

Introduction

Digital dentistry has become a mainstay of clinical practice over the past several decades. With the advent of new technologies, comes the opportunity to incorporate new tools and hardware into the clinical workflow. Intraoral scanners (IOS) have become increasingly more prevalent in modern dental practices with their ability to save time and money while increasing patient satisfaction. (1) Repeated studies have demonstrated the capabilities of IOS to achieve optical impressions equal to, if not superior, to those made through traditional methods. (2-5)

Computer Aided Design/Computer Aided Manufacture (CAD/CAM) use is increasing in dentistry across clinics targeted at all socioeconomic levels. Surveys and research have shown a digital workflow is desirable because optical impressions are deemed more comfortable for patients (mainly vulnerable aging populations or pediatric patients) (6) and it significantly reduces the costs (about 30% per each crown) and the active working time (90% for final crown) to deliver a final prosthesis. (5, 7) Also, it allows the exclusive use of esthetic and more biocompatible materials (e.g., zirconium oxide, lithium disilicate) (8, 9) and the flexibility to manufacture from simple crown to complex dental implant supported restorations and orthodontic appliances. (4, 10) This provides the appeal of virtual technology to promote business while delivering a product which is superior in terms of fit, impression time and frequency of adjustment (11). (12)

With new clinical armamentaria comes a need for understanding the proper utilization for safe patient use. This includes more than the direct patient contact - specifically sterilization and cross-contamination control. Cross infection remains one of the major challenges of the dental profession. (13) The risk of spreading disease can be significantly reduced with adherence to recommended infection control practices that include proper cleaning and disinfection or sterilization of instruments and devices used in the procedure. In November 2008, to assist in ensuring proper processing of contaminated instruments used during procedures, the Centers for Disease Control and Prevention (CDC) published their *Guideline for Disinfection and Sterilization in Healthcare Facilities* that “presents a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes; that approach is based on well-designed studies assessing the efficacy (through laboratory investigations) and effectiveness (through clinical studies) of disinfection and sterilization procedures.” (14)

Included in the CDC guidelines are recommendations for various instrument and patient care paraphernalia decontamination protocols based upon appropriate classification. The classification of patient care items recommending disinfection and sterilization was first codified by Spaulding in 1968. (15) This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization. (16-18) Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semi-critical, or noncritical according to the degree of risk for infection involved in use of the items. (19)

Critical items are those that penetrate soft tissue or bone or enter into or make contact with the bloodstream or other normally sterile tissue. Critical items that have the highest risk of transmitting infection should always be decontaminated via sterilization. (20) Semi-critical items are those instruments that do not penetrate soft tissue or bone but contact mucous membranes or non-intact skin such as mirrors, reusable impression trays and amalgam condensers. These items present with a moderate to low risk for disease transmission and the method of decontamination can be sterilization or high-level disinfection (HLD). (21) Finally, noncritical items are those that make contact with intact skin, which typically provides an excellent barrier for most microorganisms. These noncritical items are classified as least risk to no risk of potential disease transmission and the method of decontamination is intermediate to low-level disinfection such as surface disinfection. (14)

Camera mirror sleeves from IOS acquisition units are one particular item that comes into contact with mucous membranes but does not pierce any soft tissue or come into contact with bone. Therefore, mirror sleeves can be classified as semi-critical items and according to CDC recommendations should be sterilized after each use if possible. (20) Although this is not yet an absolute standard of care, disregarding CDC guidelines for lower decontamination options can be a serious risk for patient cross contamination.

Many varieties of IOS exist on the open market from numerous manufacturers across the globe. Accuracy and ease of use studies have been performed under both laboratory and clinical settings to differentiate amongst the available products. One of the consistently high-ranking products is the Primescan AC from Dentsply Sirona (Charlotte, NC). (22) This particular unit was chosen for this study due to its reportedly unparalleled scanning accuracy, as well as the availability of single-use disposable and disinfected sleeves for use during operation. (23-25) The continued market-leading accuracy paired with the capability to utilize various camera sleeves made the PrimeScan AC IOS unit the ideal choice for this study.

With the widespread dissemination of the SARS-CoV-2 virus, infection control has come to the forefront of the medical community and for the populace as a whole. No research has been published evaluating the accuracy of IOS devices, namely Primescan AC, under various decontamination protocols of the scanner sleeve. The aim of this study was to determine any changes in the accuracy of the Primescan AC IOS attributable to differing decontamination techniques of the scanner sleeve. This was accomplished by comparing accuracy before and after a decontamination protocol between three groups of scanner sleeves: 1) HLD or dry heat steel sleeve with sapphire glass viewing window, 2) autoclavable steel sleeve with single-use viewing window and 3) single-use sleeves with plastic viewing windows. Based on aforementioned guidelines for classification, the scanner sleeves are semi-critical and can be either sterilized, as recommended, or merely treated with HLD and placed back into clinical use. Due to multiple methods for allowable decontamination, this study sought to determine statistically and clinically significant differences in scanning accuracy between the various protocols and sleeve types.

Along with the variance in decontamination protocol and associated hardware, this study sought to control for the calibration status of the underlying scanning device. Per manufacturer's instructions, PrimeScan AC units are to be calibrated monthly or when moved, whichever comes first. (26) Although yet unproven, this mandate leads to the assumption of quality degradation over time and with extended use as the delicate optical components lose their trueness and precision. There has been no research published to date which evaluates the accuracy of the PrimeScan AC IOS system with regards to the currently available sleeves, the recommended decontamination protocols or the frequency of calibration of the unit.

The following null hypotheses were tested in this study: 1) There would be no difference in scanning accuracy between sleeve groups prior to decontamination protocol; 2) there would be no difference in scanning accuracy between sleeves following multiple rounds of high-level disinfection or sterilization; and 3) there would be no difference in scanning accuracy between separate scanning units based on calibration status.

Methods:

A custom-made dental stone model with rigidly fixed extracted human teeth was used to make the optical impressions. The reference model contained four different types of single-tooth preparations. The extracted teeth were labeled A-E; teeth A and B were prepared for full contour crowns, tooth C for a disto-occlusolingual onlay, tooth D for a mesio-occlusal inlay and tooth E for a chamber retained endodontic crown. Figure 1 shows the reference model with the respective tooth preparations. The teeth were prepared and then the arch was scanned using a bench-top scanner (InEos X5, Dentsply Sirona). This served as the baseline reference to which each generated optical impression was compared. The custom arch was then scanned with a PrimeScan AC unit utilizing one of a variety of scanning sleeves under various decontamination conditions. The optical impressions were then converted into a standard tessellation language (STL) file for 3-dimensional analysis. (Figures 1 and 2)

Scanning sleeves were separated into four distinct groups:

1. HLD sleeve with sapphire window utilizing HLD
2. HLD sleeve with sapphire window utilizing dry heat sterilization
3. Autoclavable steel sleeve with single-use viewing window
4. Single-use sleeves with plastic viewing windows

(Figures 3-5)

Groups 1 and 2 were sterilized using HLD and dry heat, respectively. Groups 3 and 4 were not sterilized as the viewing window in both groups are single-use. However, groups 3 and 4 were utilized as benchmarks to compare with the first two groups.

Ten HLD sleeves were allocated to groups 1 and 2. Group 3 utilized ten distinct viewing windows in the same autoclavable sleeve. Group 4 consisted of 10 single-use sleeves. All of the sleeves were sourced directly from the manufacturer utilizing traditional purchasing channels. Each sleeve and viewing window were randomly assigned a number 1-10 to maintain consistency throughout the study. An optical impression was made with each sleeve or window and was used as the data point for that data set. Optical impressions were completed by the same provider to minimize discrepancies in the scanning process. Manufacturer's recommended scanning strategies were used and all scan data was exported as binary STL files for further processing (CEREC software 5.1, Dentsply Sirona). Each set of sleeves and windows were used to produce optical impressions as a unit in the same chronological order before moving on to the next set. Sleeves in groups 1 and 2 were utilized before any decontamination protocol for baseline and after 25 and 50 decontamination cycles for comparison. Single-use viewing windows, groups 3 and 4, were used without any decontamination protocol and generated a comparison reference. Groups 1 and 2 produced three data sets each: baseline, 25 decontamination cycles and 50 decontamination cycles. Groups 3 and 4 each produced a single baseline data set. Each set of 10 sleeves was averaged for comparison to baseline and for comparison with the other generated sets. Scanning sets were as follows:

- A. HLD sleeve without decontamination
- B. HLD sleeve after 25 cycles of HLD decontamination
- C. HLD sleeve after 50 cycles of HLD decontamination
- D. HLD sleeve without decontamination
- E. HLD sleeve with 25 cycles of dry heat sterilization
- F. HLD sleeve with 50 cycles of dry heat sterilization
- G. Autoclavable sleeve without decontamination
- H. Single-use sleeve without decontamination

(Figure 6)

One Primescan AC unit was utilized which was calibrated prior to each data set collection and one Primescan AC unit was utilized which was not calibrated at all during the length of the data collection. This allowed control for unit calibration as a variable in the data sets. The uncalibrated unit was moved around the treatment facility approximately one-quarter of a mile and over numerous doorways and thresholds to simulate excessive movement within a real-world scenario. This was completed once after the baseline scan sets and again following the 25-cycle scan sets. Each scanning set was utilized on both Primescan AC units to generate optical impressions. This generated 16 total data sets for comparison, 8 on a calibrated unit and 8 on a non-calibrated unit with the scanning sets (A-H) as listed above. (Figure 7)

The decontamination protocol included two standards: high-level disinfection and dry heat sterilization. Both methods followed the manufacturer's recommendations explicitly. Preliminary cleaning for both groups was the same: cleansing of the sleeve with disinfectant wipes (CaviWipe, Kerr Corporation, Brea, CA), wiping the sleeve with absorbent cotton gauze

dipped in sterilized drinking water and drying of the sleeve with a lint-free cloth. Cold sterilization was carried out with the Dentsply Sirona HLD set using the recommended high-level disinfectant (CIDEX OPA, Johnson & Johnson, New Brunswick, NJ) for 12 minutes. Prior to each cycle, the CIDEX OPA solution was verified for effectiveness using CIDEX OPA solution test strips (Johnson & Johnson) according to manufacturer's instructions. Dry heat sterilization was performed unwrapped at 190° C for six minutes using a dry heat sterilizer unit (Cox RapidHeat, CPAC Equipment Inc., Leicester, NY). (26)

The data sets were used for comparison and analyzed for any linear 3-dimensional changes. STL files generated from each optical impression were overlaid with the baseline benchtop scan and median 3-dimensional linear differences were compared to one another and analyzed for any statistical differences. Optical impressions were compared utilizing 3-dimensional superimposition and 3-dimensional difference analysis method (Geomagic 2014, 3D Systems Inc., Rock Hill, SC). We determined the 3-dimensional linear differences by using a pointwise signed distance measurement between the respective surfaces of the superimposed models utilizing the prepared teeth as relevant sites (Geomagic 2014). (Figure 8)

Before superimposition, the preparations were selected in all data sets as relevant matching regions. All optical impression data was then superimposed with the reference data set, baseline scans, using a 3-dimensional best-fit alignment method, and 3-dimensional linear differences were calculated for each superimposition (Geomagic 2014). At the end, 10 difference maps per optical impression group became available for the calculation of accuracy (n=10). Normal distribution and equality of variances were tested with Shapiro-Wilk and Levene tests and found not to be normally distributed. Subsequent statistical analysis was performed using Kruskal-Wallis and Mann-Whitney U tests ($\alpha=0.05$) with adapted significance levels using statistical analysis software (SPSS, Version 26, IBM, Chicago, IL). Differences with $p < 0.05$ were deemed statistically significant.

The power analysis was performed assuming a large effect size ($f = 0.70$) based on the previous study (24) for a 2-sided test with a significance level α of 0.05. The sample size of 10 sleeves per group achieved 95% power. For this reason, we assigned 10 sleeves or viewing windows per data set test group.

Results:

After completing all 160 individual optical impressions, the STL files were overlaid on the reference model generated from the bench-top scanner for comparison. Individual sleeves were utilized in the same order throughout the data collection for each data set. At the initiation of each new data set generated on the calibrated PrimeScan AC unit, it was calibrated afresh according to manufacturer's instructions. All optical impressions were individually compared to the bench-top reference and 3-dimensional linear variance was calibrated. Median positive and absolute value median negative distance measurements were averaged for each impression to

generate an average median discrepancy from baseline. Each measurement was then analyzed for statistical difference between each data set. Statistical analysis determined that there were no differences amongst any of the data sets ($p > 0.05$). With this in mind, we were able to compare each data set incorporating more data points. All of the dry-heat sterilized sleeves and all of the HLD sleeves were able to be combined regardless of number of decontamination cycles. Once again, there was no statistical difference between any of the decontamination protocols, any of the sleeve types or either calibration status. Table 1 demonstrates the analysis and shows the median linear distance and interquartile range for each respective grouping. Median distance ranged from 11.78-14.00 microns amongst the various data groupings. When comparing the interquartile ranges of the groups, the single-use sleeves were significantly smaller than the groupings with multi-use sleeves, albeit with many fewer sleeves as data points. (Table 1)

Discussion:

The first null hypothesis failed to be rejected as no differences in accuracy were found between any of the sleeve types before decontamination protocols were initiated. This shows factory-direct sleeves are all capable of delivering similar quality results straight out of their respective packaging. The second null hypothesis failed to be rejected as no differences in accuracy were found between any of the sleeve types after decontamination protocols were completed at 25 and 50 cycles. This shows any sleeve type may be used irrespective to its type or repeated use, up to 50 cycles. The third null hypothesis failed to be rejected as no differences in accuracy were found between any of the optical impressions when comparing the same sleeve on a calibrated unit with an uncalibrated unit. This shows a stability of precision and trueness of the camera components over the duration of our data collection.

Digital dentistry continues to push forward and become increasingly more ubiquitous throughout modern clinics. The ease of use, cost savings and patient perception drive its adoption as the upcoming standard of care. Understanding the limitations and shortcomings of the hardware and software components enables clinicians to make informed decisions with regards to adoption and implementation. Appropriate case selection continues to play a role with regards to capabilities of the CAD/CAM process and the available materials with which to generate the final prostheses. When considering the use of an IOS unit, clinicians must be able to trust the accuracy of the optical impression in order to generate a well-fitting restoration. (27) Adoption of proper decontamination and sterilization protocol should not require a sacrifice in quality. As demonstrated in this study, there was no appreciable change which would affect clinical performance when following manufacturer's instructions for multi-use sleeves.

Clinical practices and manufacturer's recommendations have not always aligned due to non-compliance from practitioners. (12, 28) Studies have specifically targeted the rationale for and against adoption of infection control protocol in clinical settings. In a 2012 study, 3042 responding United States based dentists were surveyed about implementation of the latest CDC guidelines for in-office infection control protocol. Researchers found the attitude of the provider was the most important factor in proper employment of infection control protocol. (29) This

finding is consistent with other researchers who determined that personal attitudes are associated most strongly with guideline implementation. (30) Investigators in several systematic reviews found that younger health care professionals with less experience were more inclined to implement clinical practice guidelines than were older professionals with more experience. (31-33) The adoption of new technology and implementation of recommended guidelines trends towards the rising generation of health care providers. It was pertinent to determine if stringent adherence to currently proposed infection control guidelines have a meaningful effect on workflow and accuracy in the digital realm.

With simplicity in mind, Sirona developed the single-use plastic sleeve which demonstrated the most accurate impression of any group. With low cost and no necessity to sterilize equipment, this may prove to be a strong contender for clinical adoption. The autoclavable sleeve, although not currently available in all markets, also bears consideration. It is priced roughly half the cost of the standard sleeve with an additional per-impression cost approximately equal to the disposable sleeve price for its single-use plastic window. Any of the three sleeves can produce an impression that is simple to obtain efficiently and accurately. This bodes well for this particular digital workflow and for digital dentistry in general. As increasingly more clinicians adopt technology into their office, patients will continue to advocate for treatment modalities that are safe and effective. A recent systematic review with meta-analysis confirmed intraoral scanning is a suitable alternative to conventional impression procedures, promoting less discomfort for patients sensitive to taste, nausea, and breathing difficulty than when conventional impression making techniques are used. (34) Having these options at the disposal enables a choice that best reflects clinical preference.

As of now, there are no other studies evaluating the accuracy between the currently available PrimeScan IOS sleeves. There are also no current published studies with respect to any available IOS system and their accuracy relative to calibration status. This is the first study to demonstrate constant accuracy irregardless of sleeve, infection control protocol or unit calibration status. Although the results are promising, continued decontamination cycles of the multi-use sleeves may demonstrate sleeve, and ultimately accuracy degradation. The calibration comparison also alleviates some concern for practitioners who do not reliably maintain their units. The data collection period exceeded the one month recommended timeframe and the amount of movement the uncalibrated unit was subjected to should far outpace anything found under typical clinical scenarios; however, the recommendation remains to follow the manufacturer's instructions for prompt and proper camera calibration. As this was a table-top study, several patient-related factors may compromise our generated results. There was no consideration for moisture contamination or ease of use intraorally. When we attempted to calibrate the unit with a disposable sleeve, it was discovered that the sleeve is slightly larger than the steel sleeves and calibration cannot be completed while a disposable sleeve is being utilized.

Conclusions:

Sirona digital workflow remains one of the most utilized systems in digital dentistry. Their latest IOS unit, PrimeScan AC, builds upon previous iterations with increased clinical applicability. (35) The introduction of various camera sleeves affords the opportunity to determine if there exist

differences amongst them in ease of use, cost or quality. Based on the results of this study, the single-use camera sleeve should receive strong consideration for adoption as it eliminates a significant portion of the infection prevention protocol, maintains the highest accuracy and has a remarkably low per-case cost. Camera sleeve type, decontamination protocol, and calibration status of the PrimeScan unit did not significantly impact the accuracy of the optical impressions. Any of the currently available camera sleeves used according to manufacturer's recommendations can provide similar accuracy in a clinical setting.

References:

1. Abduo J, Elseyoufi M. Accuracy of Intraoral Scanners: A Systematic Review of Influencing Factors. *Eur J Prosthodont Restor Dent*. 2018;26(3):101-21.
2. Goujat A, Abouelleil H, Colon P, Jeannin C, Pradelle N, Seux D, et al. Marginal and internal fit of CAD-CAM inlay/onlay restorations: A systematic review of in vitro studies. *J Prosthet Dent*. 2019;121(4):590-7 e3.
3. Boeddinghaus M, Breloer ES, Rehmann P, Wostmann B. Accuracy of single-tooth restorations based on intraoral digital and conventional impressions in patients. *Clin Oral Investig*. 2015;19(8):2027-34.
4. Abduo J, Lyons K, Bennamoun M. Trends in computer-aided manufacturing in prosthodontics: a review of the available streams. *Int J Dent*. 2014;2014:783948.
5. Mangano F, Shibli JA, Fortin T. Digital Dentistry: New Materials and Techniques. *Int J Dent*. 2016;2016:5261247.
6. Gallardo YR, Bohner L, Tortamano P, Pigozzo MN, Lagana DC, Sesma N. Patient outcomes and procedure working time for digital versus conventional impressions: A systematic review. *J Prosthet Dent*. 2018;119(2):214-9.
7. Flugge TV, Schlager S, Nelson K, Nahles S, Metzger MC. Precision of intraoral digital dental impressions with iTero and extraoral digitization with the iTero and a model scanner. *Am J Orthod Dentofacial Orthop*. 2013;144(3):471-8.
8. Miyazaki T, Hotta Y, Kunii J, Kuriyama S, Tamaki Y. A review of dental CAD/CAM: current status and future perspectives from 20 years of experience. *Dent Mater J*. 2009;28(1):44-56.
9. Zarone F, Ferrari M, Mangano FG, Leone R, Sorrentino R. "Digitally Oriented Materials": Focus on Lithium Disilicate Ceramics. *Int J Dent*. 2016;2016:9840594.
10. Tordiglione L, De Franco M, Bosetti G. The Prosthetic Workflow in the Digital Era. *Int J Dent*. 2016;2016:9823025.
11. Koulivand S, Ghodsi S, Siadat H, Alikhasi M. A clinical comparison of digital and conventional impression techniques regarding finish line locations and impression time. *J Esthet Restor Dent*. 2020;32(2):236-43.
12. Barengi L, Barengi A, Cadeo C, Di Blasio A. Innovation by Computer-Aided Design/Computer-Aided Manufacturing Technology: A Look at Infection Prevention in Dental Settings. *Biomed Res Int*. 2019;2019:6092018.
13. Ganavadiya R, Gupta R, Khandelwal G, Saxena V, Tomar P, Chandra Shekar B. Disinfecting efficacy of three chemical disinfectants on contaminated diagnostic instruments: A randomized trial. *Journal of Basic and Clinical Pharmacy*. 2014;5(4):98.
14. Rutala WA, Weber DJ. Guideline for Disinfection and Sterilization in Healthcare Facilities: Centers For Disease Control; 2008 [updated May 2019. 2008:[Available from: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>].

15. Spaulding E. Chemical disinfection of medical and surgical materials. In: Lawrence C BS, editor. Disinfection, sterilization, and preservation. Philadelphia: Lea & Febiger; 1958. p. 517-31.
16. Favero M, Bond W. Chemical disinfection of medical and surgical materials. In: Block S, editor. Disinfection, sterilization, and preservation. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 881-917.
17. Simmons BP. CDC guidelines for the prevention and control of nosocomial infections. Guideline for prevention of intravascular infections. *Am J Infect Control*. 1983;11(5):183-99.
18. Block S. Disinfection, sterilization, and preservation. Philadelphia: Lippincott Williams & Wilkins; 2001.
19. Kruze JP, Henrichs LE, Mack K, Vandewalle KS. Effectiveness of various decontamination methods on CAD/CAM camera mirror sleeves. *Int J Comput Dent*. 2019;22(2):177-85.
20. Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care. In: Prevention CfDca, editor. Atlanta, GA: US Dept of Health and Human Services; 2016.
21. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. In: Administration USDoHaHSFaD, editor. <https://www.fda.gov/media/80265/download2015>.
22. Kim RJY, Benic GI, Park JM. Trueness of ten intraoral scanners in determining the positions of simulated implant scan bodies. *Sci Rep*. 2021;11(1):2606.
23. Skramstad MJ. Welcome to Cerec Primescan AC. *Int J Comput Dent*. 2019;22(1):69-78.
24. Zimmermann M, Ender A, Mehl A. Local accuracy of actual intraoral scanning systems for single-tooth preparations in vitro. *J Am Dent Assoc*. 2020;151(2):127-35.
25. Gurpinar B, Tak O. Effect of pulp chamber depth on the accuracy of endocrown scans made with different intraoral scanners versus an industrial scanner: An in vitro study. *J Prosthet Dent*. 2020.
26. GmbH SDS. Sirona Dental CAD/CAM System CEREC Primescan AC Operating Instructions. 2020.
27. Nulty AB. A Comparison of Full Arch Trueness and Precision of Nine Intra-Oral Digital Scanners and Four Lab Digital Scanners. *Dent J (Basel)*. 2021;9(7).
28. Beauchemin M, Cohn E, Shelton RC. Implementation of Clinical Practice Guidelines in the Health Care Setting: A Concept Analysis. *ANS Adv Nurs Sci*. 2019;42(4):307-24.
29. Cleveland JL, Bonito AJ, Corley TJ, Foster M, Barker L, Gordon Brown G, et al. Advancing infection control in dental care settings: factors associated with dentists' implementation of guidelines from the Centers for Disease Control and Prevention. *J Am Dent Assoc*. 2012;143(10):1127-38.
30. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*. 2004;8(6):iii-iv, 1-72.
31. Francke AL, Smit MC, de Veer AJ, Mistiaen P. Factors influencing the implementation of clinical guidelines for health care professionals: a systematic meta-review. *BMC Med Inform Decis Mak*. 2008;8:38.
32. Simpson SH, Marrie TJ, Majumdar SR. Do guidelines guide pneumonia practice? A systematic review of interventions and barriers to best practice in the management of community-acquired pneumonia. *Respir Care Clin N Am*. 2005;11(1):1-13.
33. Davis DA, Taylor-Vaisey A. Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. *Cmaj*. 1997;157(4):408-16.
34. de Paris Matos T, Wambier LM, Favoreto MW, Rezende CEE, Reis A, Loguercio AD, et al. Patient-related outcomes of conventional impression making versus intraoral scanning for prosthetic rehabilitation: A systematic review and meta-analysis. *J Prosthet Dent*. 2021.
35. Dupagne L, Tapie L, Lebon N, Mawussi B. Comparison of the acquisition accuracy and digitizing noise of 9 intraoral and extraoral scanners: An objective method. *J Prosthet Dent*. 2021.

Images and Tables



Figure 1 Extracted human teeth set in gypsum stone and prepared for various indirect restorations

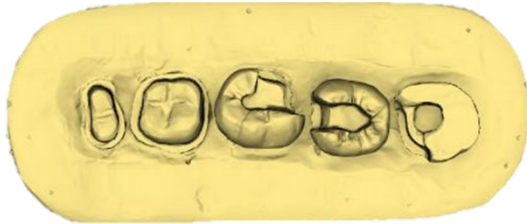


Figure 2 Digitized model generated with bench-top Sirona inEos X5 scanner



Figure 3 Sterilizable stainless steel sleeve with sapphire glass viewing window

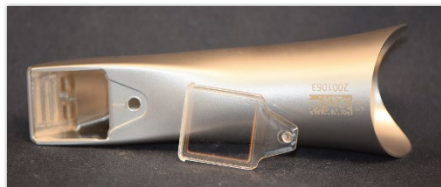


Figure 4 Autoclavable steel sleeve with single-use plastic viewing window



Figure 5 Single-use plastic sleeve with plastic viewing window

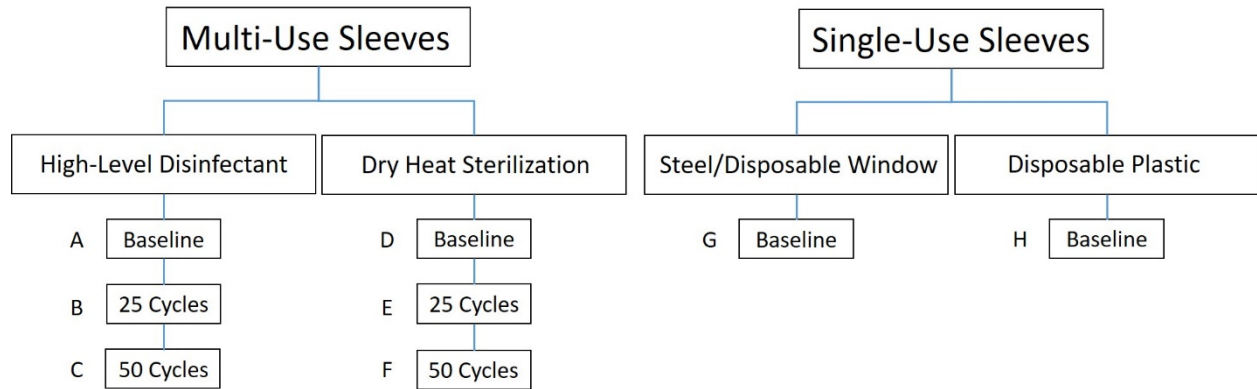


Figure 6 Scanning set groups for data collection and comparison



Figure 7 Digitized model using PrimeScan AC unit

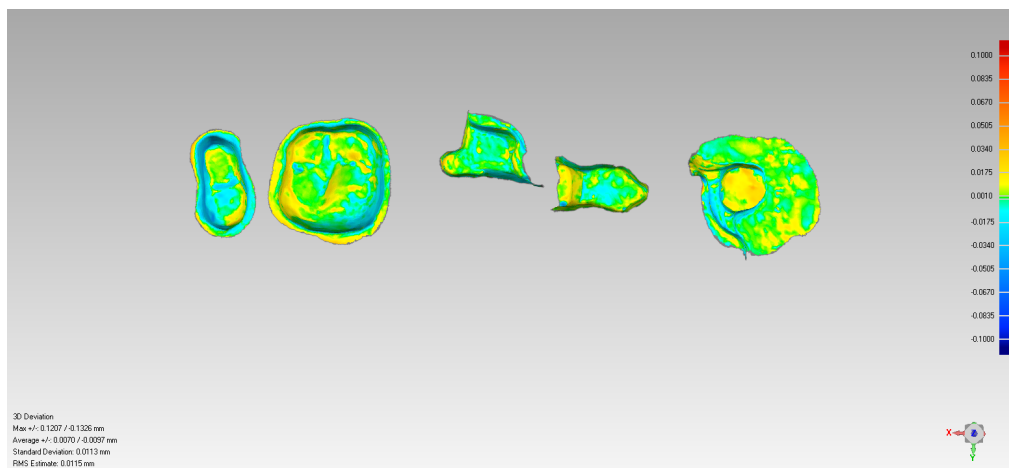


Figure 8 GeoMagic software analysis for 3-dimensional linear discrepancies

Group	Distance (microns) Median (IQR)
Stainless Steel	13.43 (17.80)
Dry Heat	14.00 (21.13)
High-Level Disinfectant	12.65 (7.66)
Calibrated	13.10 (17.89)
Uncalibrated	13.73 (17.78)
Autoclavable	11.90 (4.58)
Single-Use	11.78 (4.99)

Table 1 Results of statistical analysis demonstrating no significant differences between any grouping