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THESIS APPROVAL PAGE FOR MASTER OF SCIENCE IN ORAL BIOLOGY

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Accuracy of an Intraoral Scanner Based on Sleeve Type, Decontamination, and Calibration

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USU Operational Gap: IV, C

The purpose of this study was to evaluate the effect of camera sleeve decontamination protocols and compare their accuracy to single-use alternatives. 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. One hundred sixty optical impressions were completed using a calibrated or uncalibrated intraroral scanner (CEREC PrimeScan, Dentsply Sirona) and a sterilizable, autoclavable with single-use glass or disposable plastic camera sleeve (n=10). Decontamination protocols included dry heat sterilization or high-level disinfection 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 overlayed using 3-dimensional best-fit superimposition. Data were analyzed with Kruskal-Wallis and Mann-Whitney U tests (alpha=0.05). 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. Camera sleeve type, decontamination protocol, and calibration status of the intraoral scanner did not significantly

impact the accuracy of the optical impressions. Any of the currently available camera sleeves can provide similar accuracy in a clinical setting.

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

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 for myriad reasons. Optical impressions are deemed more comfortable for patients, especially vulnerable aging populations, or pediatric patients. (6) They also significantly reduce the cost (about 30% per each crown) and the active working time (90% for final crown) to deliver a final prosthesis. (5, 7) Digital workflow 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) The workflow 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)

Camera mirror sleeves from IOS acquisition units come into contact with mucous membranes but do not pierce any soft tissue or come into contact with bone. Therefore, mirror sleeves can be classified as semi-critical items and according to the Centers for Disease Control (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 proven IOS systems is Primescan AC from Dentsply Sirona (Charlotte, NC). (21) This unit was chosen for the study due to its demonstrated scanning accuracy, but more so due to the availability of single-use disposable and disinfectable sleeves for use during operation. (22-24) Although other IOS systems are comparable in terms of scanning capabilities, no other manufacturer offered an autoclavable and disposable sleeve for comparison at the time of this investigation.

No research has been published evaluating the accuracy of IOS devices 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. Accuracy was determined before and after a decontamination protocol between three groups of scanner sleeves: 1) High-level disinfection (HLD) or dry heat (DH) steel sleeve with sapphire glass viewing window, 2) autoclavable steel sleeve (AS) with single-use viewing window and 3) single-use sleeves (SU) 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. (25) 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.

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

Methods

A custom-made dental stone model (Silky-Rock, Whip Mix, Louisville, KY) with rigidly fixed extracted human teeth was used to make the optical impressions. Teeth were placed in the model as it set and allowed to cure before preparing the teeth for various indirect restorations. 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.

After the teeth were prepared, the model was given four weeks to set to control for any dimensional change in the gypsum that may distort the impressions. The arch was then 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 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 (HLD)
2. HLD sleeve with sapphire window utilizing dry heat sterilization (DH)
3. Autoclavable steel sleeve with single-use viewing window (AS)
4. Single-use sleeves with plastic viewing windows (SU)

   (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 utilized for comparison to baseline and for comparison with the other generated sets. Scanning sets were as follows:

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

(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. Data collection occurred at baseline, with the 25-cycle scans and 50-cycle scans occurring at three and six weeks respectively. Each scanning sleeve 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). (25)

All optical impression data were then superimposed with the reference data set, baseline scan, using a 3-dimensional best-fit alignment method, and 3-dimensional linear differences were calculated for each superimposition (Geomagic 2014, 3D Systems Inc., Rock Hill, SC). The 3-dimensional linear differences were determined by using a pointwise signed distance measurement between the respective surfaces of the superimposed models utilizing the prepared teeth designated

as relevant sites (Geomagic 2014). (Figure 8) At the end, 10 difference maps per optical impression group became available for the calculation of accuracy (n=10). Median positive and absolute value median negative distance measurements were averaged for each impression to generate an average median discrepancy from baseline. 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 (α=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 (23) 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

Statistical analysis determined that there were no differences amongst any of the data sets ($p>0.05$). With this in mind, each data set was able to be compared, thus incorporating more data points. All of the dry-heat sterilized sleeves (DH) and all of the HLD sleeves (HLD) 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. 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, Graphs 1-3)

Discussion

The first null hypothesis was not 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 was not 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 was not 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. (26) 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.

With simplicity in mind, Sirona devoloped 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 appoximately 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. (27) 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 IOS systems and their single-use 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 irrespective of sleeve type, infection control protocol or unit calibratation 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. Given that this was completed on a custom gypsum arch, accuracy differences may become apparent if completed intraorally or on a full arch-sized model. Studies have shown decreased accuracy of all IOS systems in full-arch settings. (1, 28, 29) Concerns for dimensional change of the reference model over time were addressed with a final benchtop scan with the model accomplished a full year after the reference scan. This was compared to the baseline and found to have a mean 3-D linear difference of 3.3 microns. The test groups had a mean linear difference standard deviation of 4.0-4.4 microns. The variance from initiation to completion of data collection of the two benchtop scans seems feasible based on the deviation present within the 160 samples analyzed.

This study did not seek to establish a specific IOS system or sleeve type as superior to other currently available alternatives. The accuracy and precision of numerous multiple-use scanner sleeve IOS set ups has been proven over the years with several systms deemed acceptable for clinical use. This study demonstrated the ability to utilize alternative sleeve types within a single IOS system and achieve equivocal accuracy to the previously proven standard.

Conclusion

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.

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Images and Tables

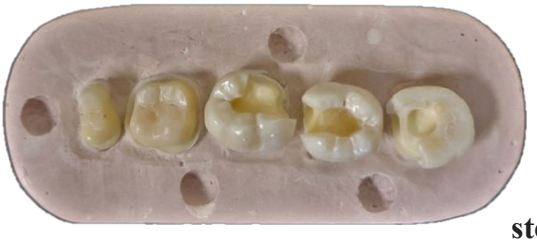


Figure 1 Extracted human teeth set in gypsum stone and prepared for various indirect restorations

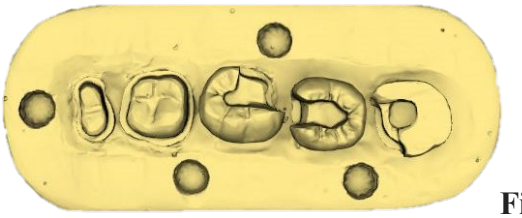


Figure 2 Digitized model generated with bench-top Sirona inEos X5 scanner

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

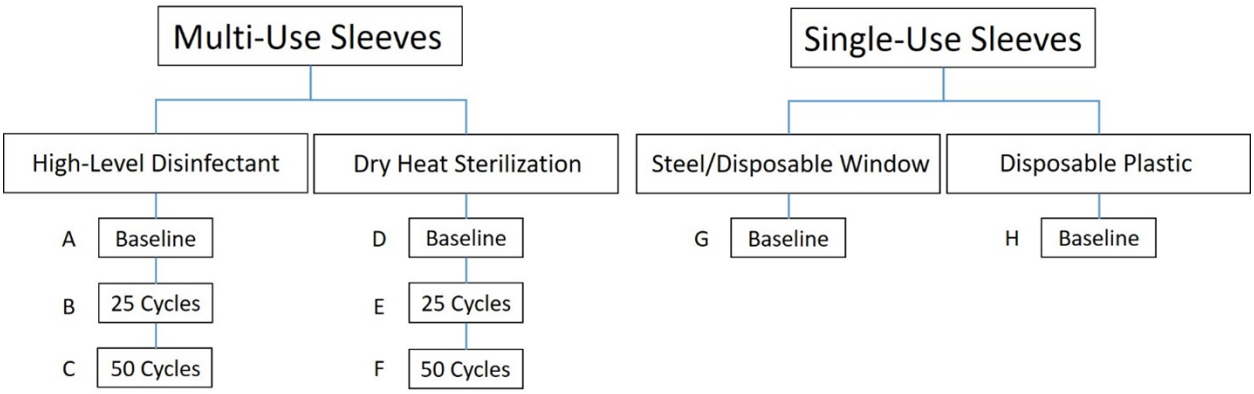


Figure 6 Scanning set groups for data collection and comparison

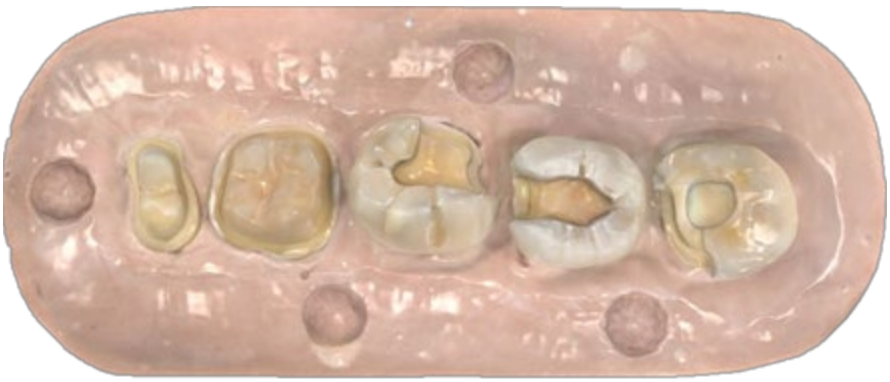


Figure 7 Digitized model using Primescan AC unit

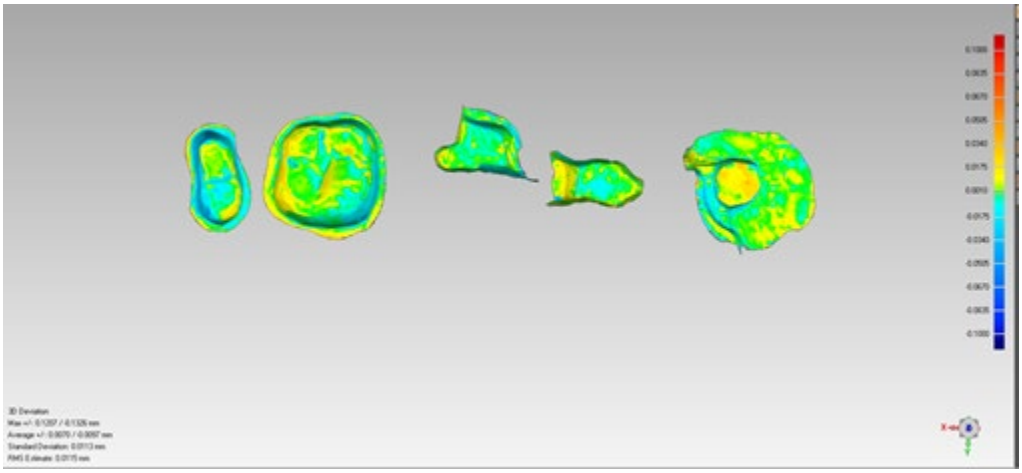
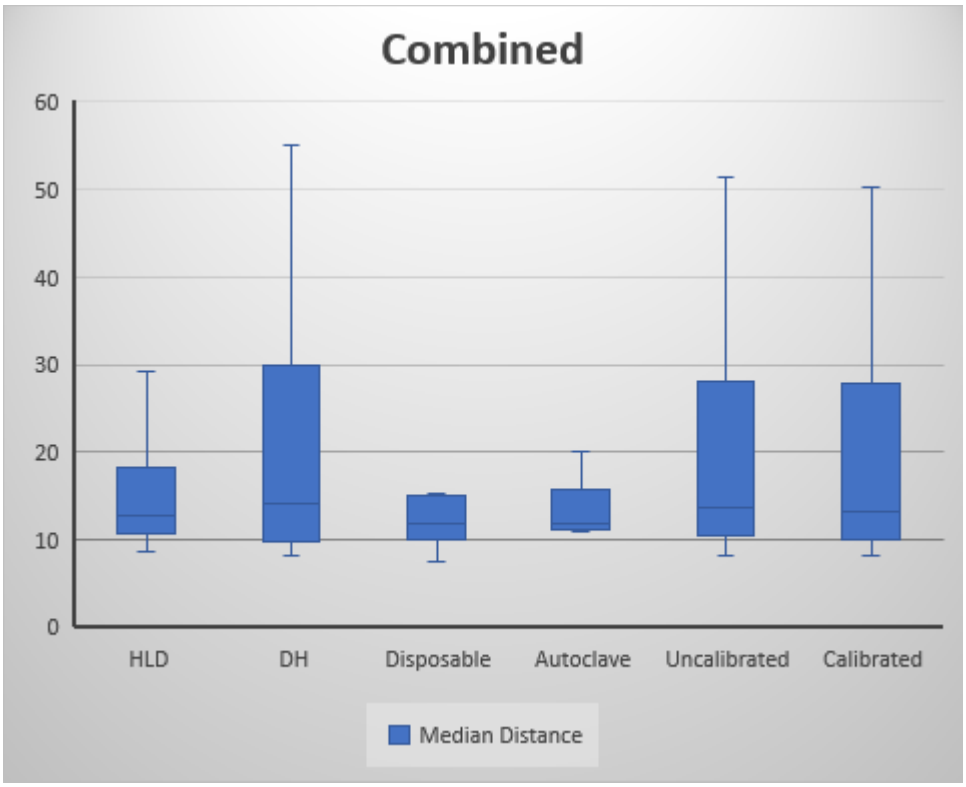


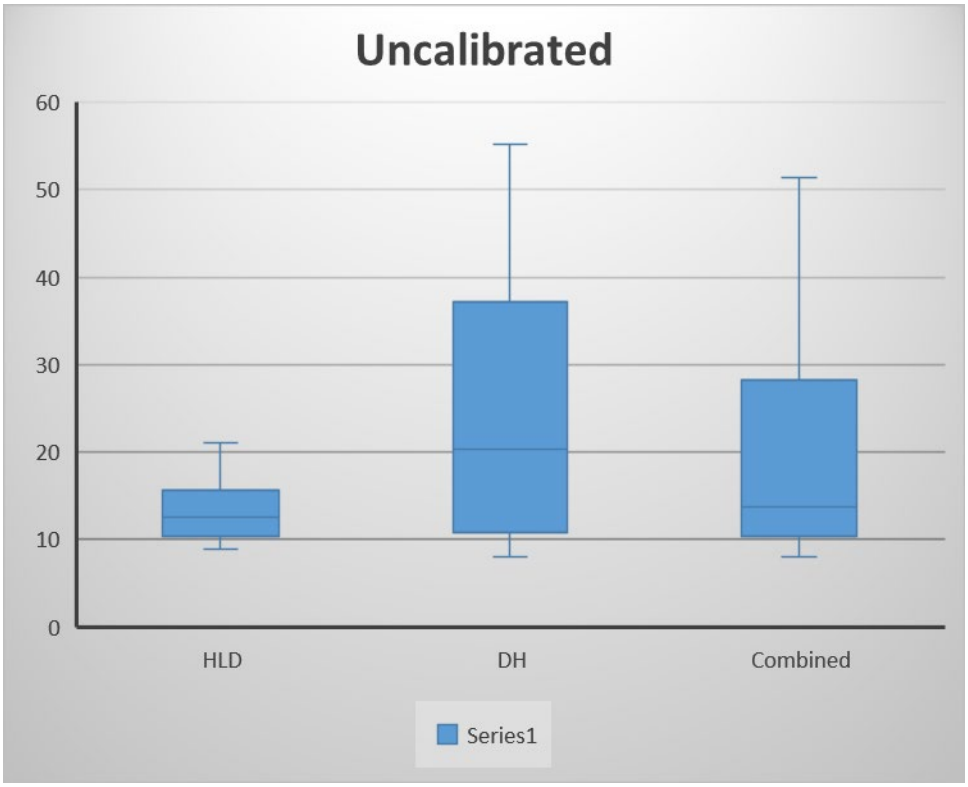
Figure 8 GeoMagic software analysis for 3-dimensional linear discrepancies

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)

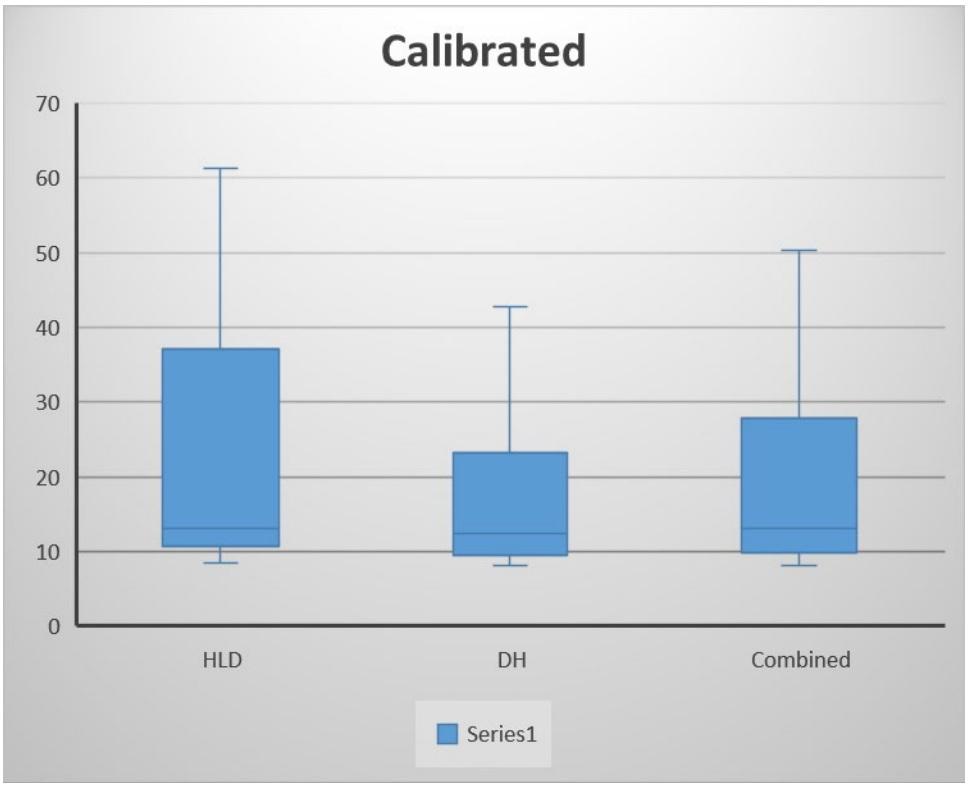
Table 1 Results of statistical analysis demonstrating no appreciable differences between any grouping



Graph 1 Boxplot of combined groups showing accuracy in microns



Graph 2 Boxplot of sleeves utilizing uncalibrated Primescan unit, accuracy in microns



Graph 3 Boxplot of sleeves utilizing calibrated Primescan unit, accuracy in microns