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Post sterilization of intraoral scan body and the effect it has on the axes and distances between three adjacent implants: in-vitro study

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Abstract

Background The purpose of this pilot in-vitro study was to assess the effect of sterilization on the intra-implant axis, inter-implant axis, intra-implant distance and inter-implant distance of three implants in a straight line by using laboratory scanner (LBS) versus intra-oral scanner (IOS) with intra-oral scan bodies (ISB). Methods: A printed 3D model with three internal hex analogs in the positions 15#,16#,17# was used. Zirkonzhan (ZZ) intra-oral scan body (ISB), two-piece titanium was used. The ZZ ISBs were scanned by 7 Series dental wings (LBS) and 30 times by Primescan (IOS) pre sterilization and 30 times post sterilization. For each scan (pre and post) stereolithography (STL) file was created and a comparison between all the scans pre sterilization and post sterilization were superimposed on the laboratory scan by using a 3D analyzing software. A Kolmogorov-Smirnov test performed followed by Wilcoxon Signed Ranks tests. ($p < 0.05$) Results: Post sterilization of the ZZ ISB, the mean errors were significantly increased for the inter-implant distances ($p < 0.0005$), intra-implant distances 1,2,3 ($p < 0.0005$), intra-implant axis 1,3 ($p < 0.0005$) and inter-implant axes 13,23 ($p < 0.05$). In contrast, the mean errors for intra-implant axis 2 ($p < 0.0005$) and inter-implant axis 12 ($p < 0.0005$) were significantly reduced. Conclusions: ZZ ISB showed changes in all four parameters after sterilization. The middle ISB had the largest changes in mean error regarding all four parameters. Sterilization process may affect the three-dimensional (3D) structure of the ZZ ISB after three cycles. There is a lack in the literature in this field and there is a need for further studies to explore the effect of sterilization (multiple cycles) on different ISBs and for creating an approved guidelines regarding the amount of sterilization for each ISB in the industry.

Keywords CAD-CAM, Scan abutment, Intraoral scan body, Sterilization, Autoclave, Implant axis, Titanium, Primescan, Dental implants, Oral rehabilitation

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Introduction

Compared to conventional impressions for teeth and implants applied by many dentists, intra-oral digital impressions have some advantages as reduced distortion of impression materials, less chair time, obtaining digital file, more patient comfort, etc. These advantages contribute to the raising popularity of intra-oral digital impressions among dentists [1–4].

Intraoral scanners (IOSs) are being used in everyday dentistry for implant prosthodontics [5], by using intra-oral scan bodies (ISBs) IOSs can capture the position and orientation of the implant and conveying it into a computer aided design (CAD) mesh [6, 7].

ISBs are varying in geometry and have three main areas: base, body and scan region at the top. These three regions can be from different materials and the two most common materials are titanium (Ti) type 5 and polyetheretherketone (PEEK) [8, 9].

Recent studies demonstrated that under thermal process PEEK may undergo three dimensional changes [10, 11] and high tightening torque over 5Ncm may affect the accuracy of the PEEK ISB due to a displacement of the base [12].

Ti is a metallic element common for different uses in dentistry [13]. Ti sterilization may affect its mechanical properties depending on the sterilization method and the number of cycles, possible results are Ti dissolution, change in retention force values, surface morphology, roughness, hydrophobicity, etc. [14]. Burkhardt et al. found that contamination of Ti-base abutments followed by cleaning (different protocols were tested) can degrade the bonding properties to titanium and only the protocol with alcohol after contamination showed bond failure (in thermo-mechanical aging tests) and hence lower retention force value [15].

As mentioned, ISBs are intended to capture the location, angulation, and connection orientation of the dental implant in the patient's mouth during the scanning. Therefore, prior to each placement of the ISB into the patient mouth it must be cleaned and sterilized to eliminate bacteria, fungi, spore contamination and to avoid any harm to the patient. Sterilization can be achieved by different cleaning treatments; the most common one is Autoclave (hydrothermal treatment) which is widely used to sterilize medical and surgical instruments by subjecting them to the high-pressure saturated steam at 121 °C for over 15–20 min [16].

In addition to the guarantee of biocompatible decontaminated ISB, adherence to the ISB sterilization protocol suggested by the company is also essential lest causing damage to the scan body leading to inaccurate scanning data. In general, Sterilization factors; amount of heat and pressure applied, chemical used, number of cycles, etc. can alter mechanical properties of materials which in

turn, regarding ISB specifically, may negatively influence the accuracy of the scanning data, for example, as a result the thermal expansion caused to the scan body by the autoclave [17]. Therefore, it should not be used immediately right after sterilization. According to the protocol of ISO 17665 (Appendix 1) scan body steam sterilization is the recommended method.

Clinically, the design of the restoration (passive fit, contact areas, occlusal contacts, etc.) is influenced by the implant axis captured. This fact emphasizes the importance of capturing the implant axis accurately and if the sterilization process affects the three dimensional structure of the ISB and causes a deformation it has a clinical relevance as the restoration is not accurate and this is an important factor for everyday dentistry.

As there are not many studies in this field exploring the effect of sterilization on the accuracy of ISBs more research is needed. The purpose of this pilot in-vitro study was to evaluate the influence of the sterilization process by autoclave on the changes of several parameters (intra-implant distance, inter-implant distance, intra-implant axis and inter-implant axis) of three implants in a straight line (positions #15, #16, #17) by comparing laboratory scanning (LBS, gold standard) versus intra-oral scanning (IOS) with Zirkonzahn (ZZ) ISB before and after sterilization. Our null hypothesis was that no difference will be found before and after sterilization regarding all four parameters (intra-implant distance, inter-implant distance, intra-implant axis and inter-implant axis).

Materials and methods

A resin V-Print model was used in this study, it was printed by a SolFlex 650*350 3D printer (VOCO GmbH, Heidelberg, Germany). In the location of teeth #15 (1), #16 (2), #17 (3) we inserted to the model a MIS standard internal hexagon implant analog, at the diameter 3.75 mm and length 11.5 mm. Zirkonzahn (ZZ, Titanium, two piece) intra-oral scan body (ISB) was used, it has a cylindrical/asymmetric geometry, internal hex connection (Fig. 1).

By using electronic implant prosthetic screw driver iSD900 (NSK®, Osaka, Japan) at 15 N.cm. both ISB were screwed to the implant analog. By using a 7 Series dental wings (Dental wings®, Montreal QC, Canada) laboratory desktop scanner both ISB were scanned (reference model) and a QR file was created and then converted to STL file. We used Primescan (CEREC® Primescan; Dentsply Sirona, Milford, DE, USA) which is based on a confocal technology for the intra-oral scans (In-vitro) and we followed the scanning protocol which is suggested by Sirona. ZZ ISBs were scanned 30 times, and for each scan we produced a STL file. A comparison between the laboratory scan (reference model) and 30 scans from the IOS was done by digital software (PolyWorks® 2020;

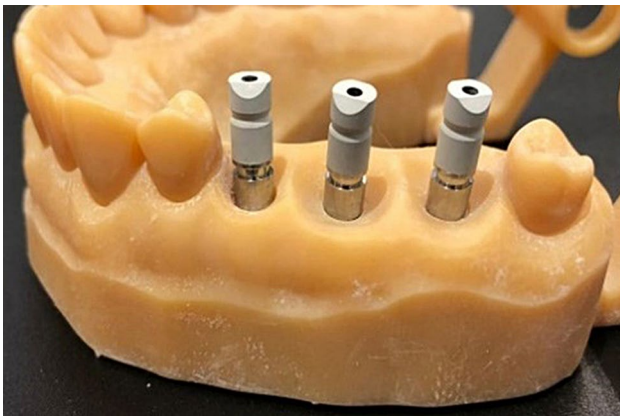


Fig. 1 Three ZZ ISB in place of teeth 15, 16, 17

InnovMetric, Québec QC, CANADA) using the best-fit method.

After finishing the pre-sterilization comparison, we used an autoclave (IOVU-752 S, Tuttnauer, Bet-shemesh, Israel), three successive cycles of sterilization were made for each one of the ZZ ISB (alone) with the following protocol: temperature 134 C, exposure time of three minutes and twenty minutes of dry time under pressure of 15 psi and following by twenty minutes air-dry as recommended by the manufacture.

We repeated the same comparison as we did with the pre-sterilization group by superimpose the post-sterilization ZZ ISB to the LBS (reference model) which was done by digital software (PolyWorks® 2020; InnovMetric, Québec QC, CANADA) using the best-fit method (15 points were chosen manually each time).

ZZ ISB has a geometry with a flat surface pointed to the buccal (Fig. 1). Number 1 was defined for the mesial abutment (#15), number 2 for the medial (#16) and number 3 for the distal (#17). We used PolyWorks 2020 | Inspector™ Software Verification and Measurement, and a superimposition (best-fit algorithm) was done for the laboratory scan (reference model) with each one of the

intra-oral scans (thirty times for each one of the ZZ ISB), also based on the adjacent teeth of the model. By doing superimposition process we can measure all the data which we seek. We used several definitions: (Fig. 2)

- Upper plane** (blue plane)- is defined as the best-fitted associated top surface of the ZZ ISB.
- Cylinder** (green)- is defined as the best-fitted associated with the outer cylinder of ZZ ISB (plane).
- Axis** (purple line)- is defined by the longitudinal axis of the associated best-fitted cylinder to the ZZ ISB.
- Central point** (Black dot)- is defined by the point of intersection between the cylinder and the upper plane of the ZZ ISB.
- Side plane** (red plane)- is defined as the best-fitted associated side plane of the ZZ ISB.
- Sideline** (grey line)- is defined by the line of intersection between the upper plane and the side plane, used for defining the system of axes of each ZZ ISB.
- Inter-implant distance** (white intermitted line) - is defined as the distance between two central points: distance 1–2, distance 2–3 and distance 1–3. The deviation of each distance from the reference was calculated by subtraction.
- Inter-implant angle** (intermitted brown arch)- The angle formed between the axes 148 of each two ISBs: Inter-implant angle 1-2, Inter-implant angle 2-3, Inter-implant 149 angle 1-3.
- System of Axes** - For each ZZ ISB of the reference model, we defined a system of axes that originates in the central point. The X-axis (red) represents the buccal–lingual plane, positive direction is towards the buccal. The Y-axis (green) represents the mesial–distal plane, positive direction is towards to the distal. The Z-axis (blue) represents the

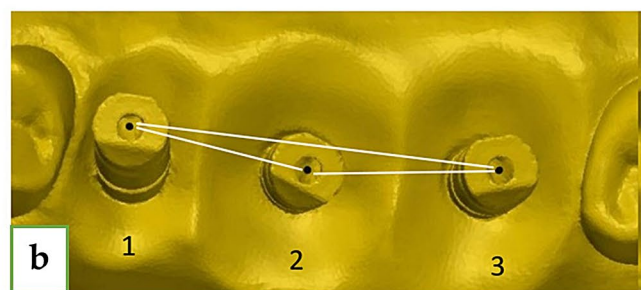
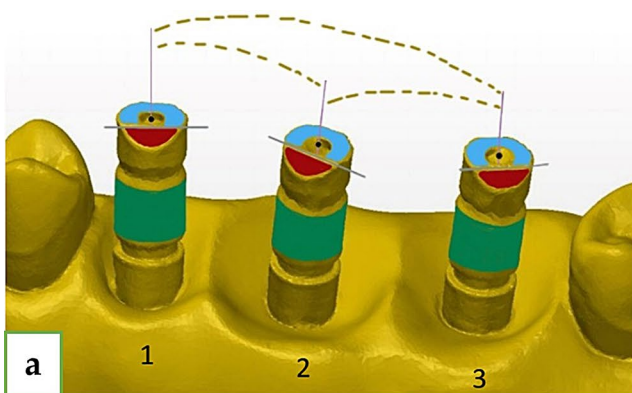


Fig. 2 (a) ZZ upper plane (blue), cylinder (green), axis (purple), central point (black), side plane (red), sideline (grey), inter-implant angle (brown). (b) ZZ inter-implant distance (white)

occlusal–gingival plane, positive direction is towards to the occlusal (Fig. 3).

For calculating the deviation from the reference model (laboratory scan) for the following parameters (intra-implant distance; intra-implant angle; inter-implant distance; inter-implant angle) we used two methods:

First one is superimposition by using PolyWorks | Inspector™ Software Verification and Measurement, we superimposed (best-fit algorithm) the STL files (Laboratory scan versus thirty pre sterilization scans and another thirty post sterilization scans) for receiving the following parameters:

1. Intra-implant distance_{1,2,3} (mm) – the distance between each single central point of the laboratory scan and its counterpart central point of the intra-oral scan was defined as the shift of the scan axes in the intra-oral scan (x, y, z) with respect to the indirect scan (X, Y, Z). This was calculated as the following: Intra-implant distance $1, 2, 3 = \sqrt{(X - x)^2 + (Y - y)^2 + (Z - z)^2}$, ($X, Y, Z = 0$)
2. Intra-implant angle_{1,2,3} (angle) – calculated as the three-dimensional angle between each single longitudinal axis of the laboratory scan and its counterpart longitudinal axis of the intra-oral scan.

Second one is subtraction for receiving the following parameters:

3. Inter-implant distance_{1-2, 2-3, 1-3} (mm) – the deviation of each Inter-implant distance from the reference was calculated by simply subtracting the values. Superimposition was not needed.
4. Inter-implant angle_{1-2, 2-3, 1-3} (angle) – the deviation of each Inter-implant angle from the reference model

was calculated by simply subtracting the values. Superimposition was not needed.

Statistical analysis was performed using the Statistical Package for Social Sciences for Windows Release 23.0 (SPSS Inc., Chicago, IL, USA). We used a Kolmogorov-Smirnov test which showed no normal distribution ($p < 0.05$). Wilcoxon Signed Ranks tests were used to evaluate the differences before and after sterilization of the experiment variables (ZZ ISB). The statistical significance level for this work was $p < 0.05$.

Results

A Kolmogorov-Smirnov test performed on the study variables indicated a no normal distribution ($p < 0.05$) and therefore, Wilcoxon Signed Ranks tests were used to evaluate the differences before and after sterilization of the experiment variables.

Table 1 shows the mean error, standard deviation (SD), range and percentiles (P25, P50, P75) of inter-implant distances 12,23,13, intra-implant distance 1,2,3, intra-implant axis 1,2,3 and inter-implant axes 12,23,13 of ZZ ISB, before and after sterilization.

After sterilization of the ZZ ISB, the mean errors were significantly increased (less accuracy) for the inter-implant distance 12 ($p = 0.0005$), inter-implant distance 23 ($p = 0.0005$), inter-implant distance 13 ($p = 0.0005$) (Fig. 4), intra-implant distance 1 ($p = 0.0005$), intra-implant distance 2 ($p = 0.004$), intra-implant distance 3 ($p = 0.0005$) (Fig. 5), intra-implant axis 1 ($p = 0.0005$), intra-implant axis 3 ($p = 0.0005$) (Fig. 6), inter-implant axis 23 ($p = 0.009$) and inter-implant axis 13 ($p = 0.0005$) (Fig. 7). In contrast, the mean errors for intra-implant axis 2 ($p = 0.0005$) and inter-implant axis 12 ($p = 0.0005$) were significantly reduced.

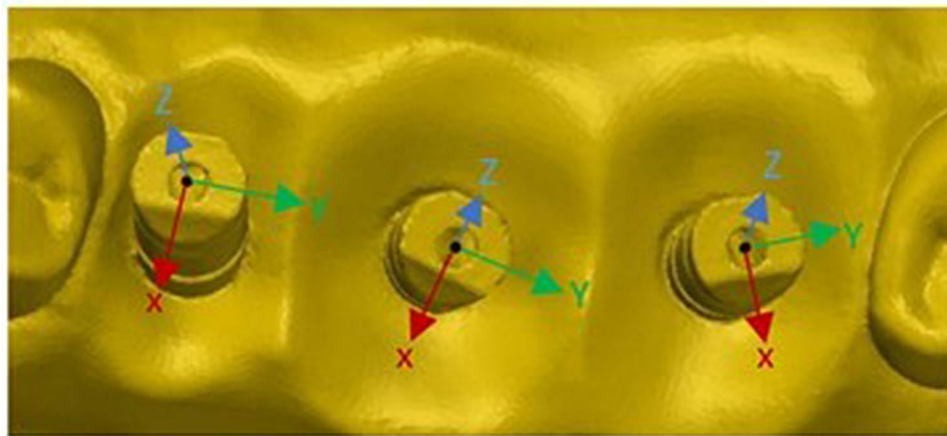


Fig. 3 (a) ZZ X, Y, Z axes

Table 1 Mean error, $\pm$ SD, Range, P25 (25 percentile), P50 (50 percentile) and P75 (75 percentile) of inter-implant distance 12,23,13, intra-implant distance 1,2,3, intra-implant axis 1,2,3 and inter-implant axes 12,23,13 of ZZ ISB before and after sterilization

	ZZ ISB pre sterilization				ZZ ISB post sterilization			
	Mean ($\pm$ SD) Range	P25	P50	P75	Mean ($\pm$ SD) Range	P25	P50	P75
Inter-implant Distance 12 (mm)	0.081 ($\pm$ 0.014) 0.074	0.072	0.081	0.086	0.108 ($\pm$ 0.019) 0.102	0.102	0.113	0.119
Inter-implant Distance 23 (mm)	-0.131 ($\pm$ 0.010) 0.044	-0.138	-0.133	-0.124	-0.190 ($\pm$ 0.033) 0.195	-0.205	-0.192	-0.187
Inter-implant Distance 13 (mm)	-0.045 ($\pm$ 0.011) 0.045	-0.052	-0.046	-0.038	-0.061 ($\pm$ 0.011) 0.054	-0.071	-0.062	-0.055
Intra-implant distance (Central point 1) (mm)	0.057 ($\pm$ 0.007) 0.023	0.049	0.057	0.064	0.080 ($\pm$ 0.010) 0.035	0.074	0.077	0.090
Intra-implant distance (Central point 2) (mm)	0.135 ($\pm$ 0.007) 0.032	0.132	0.135	0.140	0.149 ($\pm$ 0.029) 0.125	0.135	0.143	0.151
Intra-implant distance (Central point 3) (mm)	0.021 ($\pm$ 0.007) 0.030	0.016	0.021	0.027	0.073 ($\pm$ 0.011) 0.051	0.064	0.073	0.078
Intra-implant axis Delta axis 1 (angle)	0.294 ($\pm$ 0.084) 0.457	0.244	0.311	0.344	0.746 ($\pm$ 0.107) 0.433	0.664	0.748	0.815
Intra-implant axis Delta axis 2 (angle)	1.457 ($\pm$ 0.077) 0.335	1.140	1.463	1.498	1.087 ($\pm$ 0.233) 1.465	1.015	1.069	1.173
Intra-implant axis Delta axis 3 (angle)	0.139 ($\pm$ 0.059) 0.243	0.094	0.142	0.189	0.288 ($\pm$ 0.089) 0.367	0.242	0.297	0.342
Inter-implant axis Delta axis 12 (angle)	0.392 ($\pm$ 0.113) 0.551	0.300	0.407	0.469	-0.390 ($\pm$ 0.388) 1.944	-0.614	-0.456	-0.324
Inter-implant axis Delta axis 23 (angle)	-1.001 ($\pm$ 0.082) 0.331	-1.067	-0.955	-0.947	-1.035 ($\pm$ 0.413) 2.368	-1.188	-1.103	-1.048
Inter-implant axis Delta axis 13 (angle)	-0.209 ($\pm$ 0.089) 0.399	-0.266	-0.217	-0.157	-0.449 ($\pm$ 0.155) 0.782	-0.520	-0.463	-0.382

Discussion

In this In-vitro study, we used a previous method [18] which we already suggested for evaluating the differences of several parameters (inter-implant distance, intra-implant distance, inter-implant angle and intra-implant angle) between LBS scans (gold standard) versus IOS scans by using ZZ ISB before and after sterilization.

The results of the study show that all parameters (intra-implant distance, inter-implant distance, intra-implant axis, and inter-implant axis) are significantly different between pre sterilization and post sterilization. These results indicate that we need to reject our null hypothesis as there are significant differences between pre-sterilization and post-sterilization for the ZZ ISB.

It is very interesting to see that for all parameters except two (intra-implant axis 2 and inter-implant axis 12) the post sterilization mean errors were significantly higher compared to the pre sterilization mean errors. For the other two parameters (intra-implant axis 2 and inter-implant axis 12) the post sterilization mean errors were significantly lower compared to the pre sterilization mean errors.

The middle implant (2) has the highest mean errors for all four parameters (inter-implant distance, intra-implant distance, inter-implant axis, and intra-implant axis). intra-implant axis 2 has the highest mean error for both pre sterilization and post sterilization, we received a lower mean error post sterilization which can be explained by the fact that when scanning an edentulous area which do not have landmarks like teeth it may affects

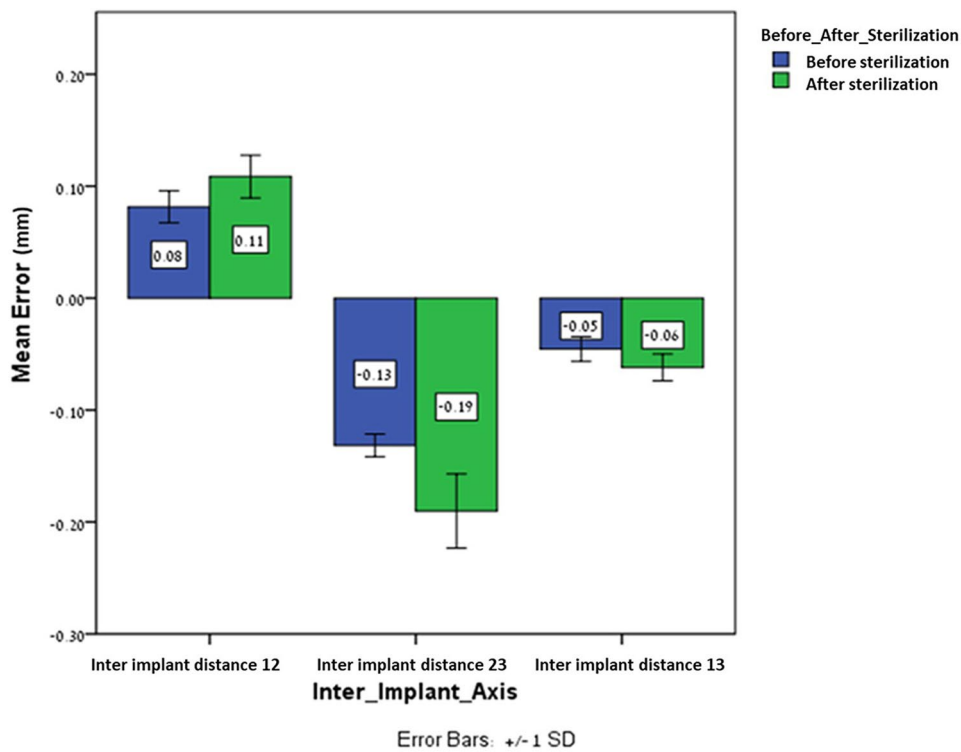


Fig. 4 The mean error and $\pm$ SD of inter-implant distance 12,23,13 of ZZ ISB before and after sterilization

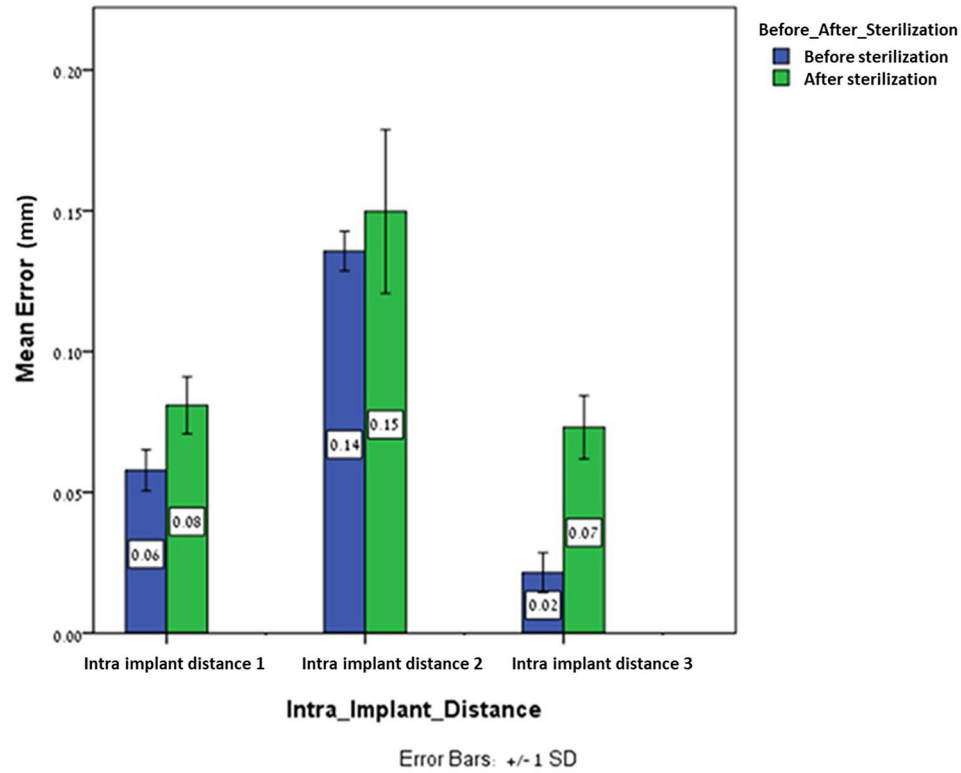


Fig. 5 The mean error and $\pm$ SD of intra-implant distance of ZZ ISB before and after sterilization

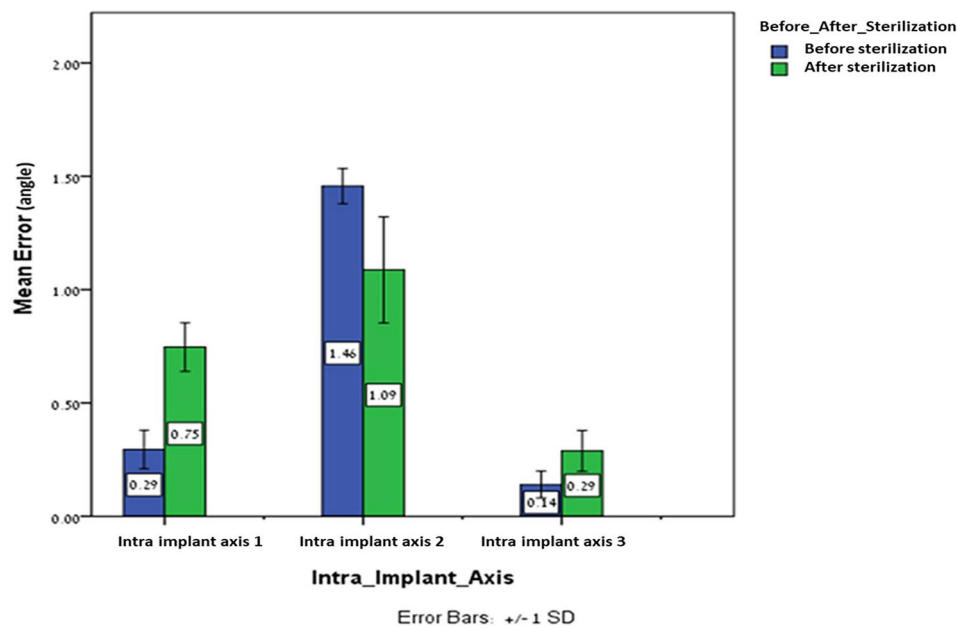


Fig. 6 The mean error and $\pm$ SD of intra-implant axis 1,2,3 of ZZ ISB before and after sterilization

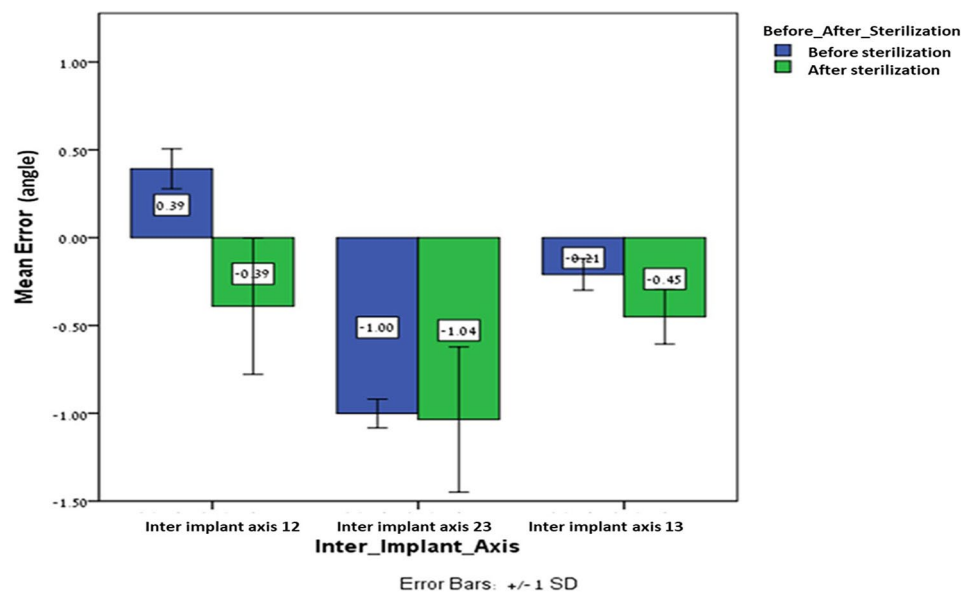


Fig. 7 mean error and $\pm$ SD of intra-implant axis 12,23,13 of ZZ ISB before and after sterilization

the distortion and increases it [19, 20]. Therefore, when we received such a large distortion with the pre sterilization scan we assumed that the effect of the sterilization (only three cycles) in this area is eligible in relation to the distortion of the scan and this can explain why we received lower mean error for the post sterilization (for the middle implant (2)). It is worth mentioning that we could not find in the current literature experiments that focus on the effect of post sterilization in a wide edentulous area but only with two implants [17, 21].

In this research we used ZZ ISB abutment which is made only from titanium with white plasma coating on the upper half. In the industry there are also ISBs from poly-ether-ether-ketone (PEEK) but we decided not to use them as in recent studies it was shown that PEEK has more deformations than titanium both because of sterilization process and multiple use [10, 22].

Diker et al. used both PEEK and titanium ISBs with different torques (5,10,15 Ncm), successive 25 cycles of sterilization and measured the changes in three axes (x, y,z). They showed that for titanium ISB at torque of 10 Ncm

there was a higher displacement for the pre sterilization compared to post sterilization. In our study we used a torque of 15 Ncm, same protocol of sterilization but we did only 3 cycles and we also received a higher displacement in the pre sterilization compared to the post sterilization for intra implant axis 2 [17].

Kato et al. used a stone model with two implants, PEEK ISBs and measured the inter-implant distance and inter-implant angle pre sterilization and post sterilization. The PEEK ISBs were sterilized with ten cycles and were super imposed before and after sterilization. In this study they showed significant changes in both inter-implant distance and inter-implant angles regarding sterilization. The changes after sterilization were inconsistent, sometimes higher than baseline and sometimes lower than baseline. In our study we used a similar method and software as Kato et al. did, we used titanium ISB and not PEEK and we did only three cycles of sterilization at the same protocol as Kato et al. did. When comparing pre sterilization to post sterilization we also received changes in the mean errors and inconsistency results regarding inter-implant distance which we already explained before [21].

Andriessen et al. demonstrated that when using an implant at a length of 14.8 mm the deviation of the intra-implant angle must be at maximum of 0.194 degrees which may lead to a difference of 50 μ m at the apex of the implant. However, we know from the literature that a misfit of 22 to 100 μ m can be tolerate, so the number of 100 μ m or less is not a strict for passive fit [23–25]. In our study the change between pre sterilization and post sterilization regarding inter-implant distance did not exceed 60 μ m (inter-implant distance 23), but we only performed three cycles of sterilization and it would be very interesting to investigate in the future if more cycles will exceed the limit of 100 μ m because than the effect on passive fit will be higher and this is an important factor in the clinic for everyday dentistry when dealing with implants prosthodontics.

As there is a lack both in the current literature and guidelines from the manufactures regarding the effect of sterilization on ISBs we decided to perform this pilot study for measuring the inter-implant distance, intra-implant distance, inter-implant angle and intra-implant angle between LBS and IOS by using titanium ZZ ISB for three implants in a straight line at two stages: pre sterilization and post sterilization. As this is only a pilot study, we now realize due to the results that future research in this field should be done by using higher number of sterilization cycles, more ISBs from different materials, metal model and not resin, other types of IOSs, coordinating measuring machine (CMM) as a gold standard instead of LBS and a complete edentulous arch. It is worth mentioning the limitations of this in-vitro design: only one

intra-oral scanner, only one laboratory scanner, only one ISB, only three cycles of sterilization, in-vitro study which does not resemble the oral environment.

Conclusions

1. ZZ ISB showed significant changes in all four parameters (inter-implant distance, intra-implant distance, inter-implant axis and intra-implant axis) comparing pre sterilization to post sterilization.
2. The middle ISB had the largest changes in mean error regarding all parameters.
3. Sterilization process may affects the three-dimensional (3D) structure of the ZZ ISB after three cycles.
4. There is a lack in the literature in this field and there is a need for further studies to explore the effect of sterilization (multiple cycles) on ISB.
5. There is a need for approved guidelines regarding the amount of sterilization for each ISB in the industry (ISB maximum number of reuse).

Appendix 1

Parameters (acc. to ISO 17665, EN 13060, EN 285 and AAMI TIR12)

Method	Steam (EU**)	Steam	Steam
Cycle Type	Dynamic air removal (prevacuum)	Dynamic air removal	Gravity displacement
Temperature	134°C	132°C (270°F)	135°C (275°F)
Exposure Time*	3 minutes	4 minutes	10 minutes
Dry Time	20 minutes	20 minutes	30 minutes

* Minimum exposure times, the operating times are longer and may vary depending on the device. ** EU customers are required to use these steam sterilization parameters

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Author contributions

Conceptualization, G.B.I. and A.S.; methodology, A.S. and G.B.I.; software, N.U.; validation, S.R. and O.R.; formal analysis, D.L.; investigation, A.S.; resources, D.L.; data curation, D.L. and Y.K.; writing—original draft preparation, G.B.I. and A.S.; writing—review and editing, J.N. and Y.K.; visualization, G.B.I.; supervision, A.S.; project administration, G.B.I.; funding acquisition, G.B.I. All authors have read and agreed to the published version of the manuscript.

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Data availability

All data supporting the findings of this study are available within the paper and its Supplementary Information.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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