"COMPARATIVE EVALUATION OF MARGINAL AND INTERNAL FIT OF SINGLE POSTERIOR IMPLANT RETAINED CROWN FABRICATED USING CONVENTIONAL AND DIGITAL IMPRESSION WORKFLOW- AN IN VIVO STUDY"

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REG. NO- IM0222002

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Head of Department

Dr. RAMESH NAYAKAR M.D.S.
Professor & Head,
Department of Prosthodontics
and Crown & Bridge,
KAHER'S Vishwanath Katti Institute
of Dental Sciences, Belagavi.

Date: 17/04/2025

Place: Belagavi

Professor and Head
Department of Prosthodontics
KLE V. K. Institute of Dental Sciences,
Belagavi

Principal

Dr. ALKA D. KALE M.D.S. PhD
Principal,
KAHER'S Vishwanath Katti Institute
of Dental Sciences,
Belagavi.

PRINCIPAL
KLE V.K. Institute of Dental Sciences
Nehru Nagar BELAGAVI-590010

Date: 17/4/25

Place: Belagavi

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Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

A Constituent Unit of KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State

Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)

☎: 0831-2470362 Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 E-mail:principal@kledental-bgm.edu.in

Date : 18/4/2025 Serial No. : 428

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UG / PG / Ph.D / Staff : PG
Batch & Year : 2022-2025
Department : Department of Prosthodontics and crown & bridge

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A Constituent college of

K.L.E. Academy of Higher Education and Research

J.N.M.C. Campus, Nehru Nagar Belagavi -590010 Karnataka.

Department of Prosthodontics and crown & Bridge

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This is to certify that the Biostatistics art of Dissertation/ Research work of **REG. NO- IM0222002** t under the guidance of Professor, Department of Prosthodontics and Crown and Bridge entitle **"COMPARATIVE EVALUATION OF MARGINAL AND INTERNAL FIT OF SINGLE POSTERIOR IMPLANT RETAINED CROWN FABRICATED USING CONVENTIONAL AND DIGITAL IMPRESSION WORKFLOW- AN IN VIVO STUDY"** has been done under my guidance and considered satisfactory.

Place: Belagavi

Date: 27/03/2025

Name and signature of Biostatistician

Dr. S. B. Javali, Ph.D.
Professor In Statistics
Department of Community Medicine
USM KLE International Medical Programme
BELAGAVI-590010

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LIST OF ABBREVIATIONS USED IN THE STUDY

ANOVA	ANALYSIS OF VARIANCE
Ti	TITANIUM
CAD CAM	COMPUTED AIDED DESIGN / COMPUTER AIDED MANUFACTURING
DMLS	DIRECT METAL LASER SINTERING
IOS	INTRA ORAL SCANNER
PVS	POLY VINYL SILOXANE
PFM	PORCELAIN FUSED TO METAL
FPD	FIXED PARTIAL DENTURE
FDP	FIXED DENTAL PROSTHESIS
RVG	RADIOVISOGRAPHY
µm	MICRO METER
MO	MESIO-OCCLUSAL
DO	DISTO- OCCLUSAL
MM	MESIO-MIDDLE
DM	DISTO- MIDDLE
DC	DISTO-CERVICAL
MC	MESIO-CERVICAL
AM	ADDITIVE MANUFACTURING
IOS	INTRA ORAL SCANNER
ISB	INRA ORAL SCAN BODY
Co-Cr	COBALT CHROMIUM
STL	STANDARD TESSELLATION LANGUAGE
Na: YAG	NEODYMIUM-DOPED YTTRIUM ALUMINUM GARNET
EBM	ELECTRON BEAM MELTING
SLM	SELECTIVE LASER MELTING
SLS	SELECTIVE LASER SINTERING

ABSTRACT

STATEMENT OF PROBLEM

The introduction of digital impression technology has greatly changed the accuracy of prosthesis, while traditional/conventional impression techniques, still in use have also shown to produce acceptable prosthesis with regards to fit of the prosthesis. The latest technology in prosthetic dentistry for fabrication of crown is CAD/CAM technology and Direct Metal Laser-sintering (DMLS). Implant-supported ceramic fused to metal crowns are commonly utilized. As a result, numerous researchers have assessed the fit accuracy between metal copings and abutments, and they have come to the conclusion that the production techniques, metal alloys, as well as impression technique used may all have an impact on the fit of the restoration even in digital technology. Hence, the adaptation and accuracy of implant crowns depending upon the fabrication as well as impression technique still remains unclear.

PURPOSE

To evaluate marginal & internal fit of single posterior implant retained crowns fabricated using conventional and digital impression workflow.

METHODOLOGY

A total of 15 patients who have completed stage I of implant placement in upper or lower posterior (molar) region were considered for stage II of implant prostheses. These 15 patients undergone both conventional impression workflow (GROUP A) and digital impression workflow (GROUP B) for the fabrication of two different types of crowns for a single posterior implant supported restoration. 15 PFM crowns were fabricated from conventional impression workflow (GROUP A) using lost wax technique while, other 15 PFM crowns were fabricated from digital impression workflow (GROUP B) using DMLS technology. After the fabrication of crowns, marginal and internal fit was evaluated using silicon replica technique.

RESULTS

The study's findings were examined and statistical analysis was performed. Tukey's multiple posthoc methods and the t test were used to compare the marginal & internal fit between study groups A and B. The interior fit of the crowns made using the digital impression workflow differed statistically significantly from that of the crowns made using the conventional impression technique (p=0.0001).

CONCLUSION

The study concluded that the restorations fabricated by digital impression workflow exhibited superior marginal as well as internal adaptation as compared with the restorations fabricated by conventional impression workflow. There was statistically significant difference seen regarding internal fit of the implant retained crowns fabricated by both the workflows. The crowns fabricated from digital impression workflow showed statistically significant difference and more accurate internal fit as compared to the crowns fabricated by conventional impression workflow. Though the marginal fit of the implant retained crowns fabricated by digital impression workflow was superior than the crowns fabricated by conventional impression workflow, there was lack of significance seen in the marginal fit between the two workflows.

KEYWORDS : Dental implants, marginal fit, internal fit, DMLS, lost wax technique, open tray impression, scan body, intraoral scanning

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INTRODUCTION

A smile is a window into one's personality. Having teeth is essential for maintaining mastication, speech and a positive self-image. Tooth loss might severely interfere with mastication, speech and social interactions. Losing a tooth is an extremely painful and stressful experience that is considered a major life event. Due to this a major social and psychological readjustment is required. In the past, removable complete dentures and partial dentures either fixed or removable have been used to replace a few missing teeth in patients who are partially edentulous. Rapid research and development in the field of dental implants, particularly in advanced nations, has been supported by the need to replace lost teeth with a natural-looking replacement.[1]

Dental implants may be taken into consideration as a new method of tooth replacement as compared with bridges which were utilized traditionally. The primary advantage of dental implants as compared with bridges is they no longer require the destruction of the tooth shape adjoining to the edentulous area.[2]

The success of implant supported or tooth supported restoration depends upon accuracy of impression. Making an impression is an essential clinical step for precisely and suitably documenting the 3-D intraoral interactions between teeth, implants, and surrounding structures. Errors during the impression-making process inevitably led to laboratory errors, which impair precision and cause prostheses to not fit properly.[3]

Many factors have direct influence on implant impression accuracy, such as the technique of impression making, the materials used for impression making, the number of implants, in addition to the parallelism of the implants or abutments used.[4]

In conventional implant impression technique, we have to transfer position of dental implants from patients' mouth to a functional cast. In order to do this transfer, conventional workflow require screw-retained impression copings. After attaching these screw-retained impression copings to the implant, the impression material is loaded into the impression trays. There are two methods, in the first method the impression copings are picked up in the set impression material which in other terms called as pick-up method while, in the second method impression copings are attached to implant fixture and impression is made. After this the impression copings are removed from the fixture and placed in the intended area of the impression with the lab analog, this method is called as transfer method.

For these above-mentioned conventional impression workflows either open tray or closed tray impression can be done.[5]

Open impression trays are used for the pick-up impression method. The screw of the impression copings needs to be released in order to remove the impression along with the copings and to access this screw, impression tray over the impression copings is drilled. [5]

While closed impression trays are used for transfer method, as no access to the screw- retained copings is required. Whenever there are multiple pick-up impression copings, then splinting of these multiple copings with the help of acrylic resin or other materials is done before adding impression material. This splinting is done to prevent impression copings from moving within the elastomeric impression. Earlier studies reported that the accuracy of splinted impression copings is higher as compared to non-splinted copings.[5]

These impressions are then transferred to dental laboratory. So, during the transportation of these impression there might be significant variation in temperature movement, time lag between impression making & cast preparing. The surface wettability of the gypsum product, the ambient temperature, and the disinfectant used to disinfect impression may result in additional dimensional variation of these conventional impressions.[6]

After taking conventional impression, fabrication of prosthesis is done by lost wax technique of casting method. After that wax pattern is fabricated and invested in a suitable investment material and a mould is prepared. This mold is then put in a burnout furnace for burnout procedure. A hollow created by this burnout process is used to pour more molten metal during the casting process. After casting, the obtained prosthesis is checked for fitting on the working cast. [7]

Marginal fit & internal fit is considered very crucial for the long-term success of the prosthesis. The appropriate seating of implant prosthesis on abutments is very critical to achieve the excellent prognosis of the treatment. The accurate fit of the prosthesis is affected by impression material and technique, master cast production, accuracy of impression transfer onto the cast, wax used for wax pattern fabrication, investment material used for casting, alloy used for coping fabrication, alloy properties, thickness of the coping, type and brand used for ceramic buildup, shrinkage, and various ceramic properties. These all can impact the marginal fit & internal fit of the implant-supported fixed prosthesis.[7]

Due to all these inaccuracies, the final fabricated prosthesis will be of altered axial contours, surface texture, marginal placement and marginal defects. This inaccurately fabricated crown leads to gingivitis and other periodontal problem.[8]

In order to reduce these inaccuracies in dental prosthesis, the digital method to fabricate the crown came into existence. By using these digitized implant impressions and CAD/CAM technology, fabrications of implant-supported prostheses can be done.[9]

In dentistry, CAD/CAM technology was first used in 1970. These days, it is used in almost every laboratory and, for a few ambitious clinicians, at the chairside. Three main pillars support the development of CAD/CAM: (1) data processing, (2) data collecting, and (3) production. The CAD/CAM system has advanced from a closed to an open access system. Prior to this advancement, the processes of designing, producing, and digitizing were all closed systems. Now after ages it has become an open access so it is possible for us to collect information from a wide range of sources and at the same time it also gives access to a wide range of fabrication technique along with variety of materials to fabricate prosthesis.[10]

Due to the development in CAD CAM generation, it is feasible to deliver cost effective treatment with minimal errors. Other advantages of technology are that there is increase in the quality of restoration, and increase in precision, accuracy of the prosthesis. After the development of CAD CAM technology occurred, the usage of intra oral digital scanners came into existence to capture virtual impression of hard and soft intraoral tissues. Due to the usage of intra oral scanners, use of impression trays and materials were excluded from treatment procedure. [11]

Digital imaging, digital design, and digitally controlled machining could all be combined after the Sirona CEREC1 system became available in 1985. Clinicians started using Sirona CEREC1 system to capture digital image of hard and soft intraoral tissues and restorations. After capturing this digital impression then they were further used to digitally design the restorations, then the further ceramic milling was carried out to fabricate ceramic inlay restorations .[12]

To use an intraoral scanner to capture the correct intraoral implant position, a specific transfer post called an intra-oral scan body (ISB) is essential.[13]

Due to the advancement in this digital technology, there is no need to do land transportation, production of a gypsum cast and eventually articulation of that cast and several other laboratorial steps. Thus, the possible errors that may arise during prosthesis fabrication are excluded. In order to fabricate a prosthesis digitally, a picture of an implant abutment and neighbouring and opposing teeth must be obtained. Following this, a 3-D file is produced, which is subsequently utilized to fabricate a crown.[14]

In conventional workflow, the lost wax technique & casting method is used to fabricate prosthesis. This process involves a significant number of laboratory stages and a higher risk of laboratory errors. The problems associated with the lost wax technique are now resolved by digital methods and CAD/CAM technologies.[15]

Digital method of fabricating prosthesis can be of 2 types i.e. it can either additive or subtractive. Technologies for additive manufacturing (AM) provide an alternative to subtractive fabrication and conventional casting procedures. When compared to conventional technology, additive manufacturing (AM) offers many advantages, such as the ability to fabricate in a freeform manner, reduced waste from material, and lighter design. But in addition to its many benefits, this cutting-edge technology has its own drawbacks, like a small building platform and slow speed of fabrication. Powder bed fusion technology is the most widely used AM type for producing Co-Cr along with the Ti alloy metals for implant dentistry. This PBF technology includes the processes of selective laser sintering and electron beam melting (EBM).[16]

With SLS technology, metal powder is selectively melted into a thin, solid layer that is 20–100 micro meter thick using a powerful laser beam (Na: YAG laser). This one-by-one sliced metal object is then fused with the first layer after another coating of metal powder has been applied. Until the metal structure is produced, this process is repeated.[10, 13] Instead of melting away, the metal powder is sintered because the temperature employed in the production process is too low to achieve the metal's melting point. Despite being one of the most effective 3D printing methods, Selective Laser Sintering have some restrictions & drawbacks such as post process cooling can cause shrinkage, parts have rough surfaces and a separate cleaning chamber is required. [17]

SLM technology uses premium lasers such as CO2 or Na: YAG lasers that enable the metal powder to melt completely in an inert chamber filled with nitrogen or argon that has been cleaned.[13, 18] The temperature of the completely build platform is often raised to 200 °C. The powder's particle size falls between 20 and 60 µm. Studies have shown that DMLS technologies have reduced manufacturing costs & time, while also minimizing human errors such as wax pattern distortion & casting irregularities, leading to improved accuracy compared to traditional casting techniques.[18]

A proper and clinically acceptable fit between the prosthesis and the abutment is essential for the long-term prognosis of implant prostheses.

Internal fit of prosthesis is defined as "The perpendicular distance between the intaglio surface of the restoration and the external wall of the abutment". A uniform internal gap between the abutment and the restoration's intaglio surface offers the necessary room for cementation. The likelihood of the prosthetic restoration failing, decreases with decreasing disparity. Due to the increase in the marginal discrepancy the peri-implant region experiences bacterial growth and ensuing inflammatory responses which leads to the resorption of surrounding bone structure. [19]

Different studies have different ranges for the clinically acceptable marginal discrepancy value. Marginal discrepancy values exceeding 120 mm have been found to be clinically unacceptable. The literature has described a number of techniques for measuring marginal discrepancy, the most popular of which are the replica, sectioning, and direct microscopy methods.[20]

It's important to distinguish between methods for determining the marginal fit that can be applied in vivo and those that are limited to in vitro use. Under in vivo conditions internal fit of the prosthesis is measured between intaglio surface of crown and abutment. The silicon replica technique has been commonly used technique to evaluate marginal & internal fit of prosthesis. This technique is non-destructive and suitable for in vivo studies .[21]

Under in vitro conditions the internal fit is checked on the model and the intaglio surface of prosthesis under preset conditions. Since it is simpler to achieve a tiny gap between the restoration and the tooth in a lab setting than in clinical dentistry, several in vitro investigations have been carried out to assess the internal & marginal fit of implant-supported restorations, very few in vivo studies have been carried out to evaluate the same. Comparing and evaluating the internal and marginal fit of implant-retained prosthesis made with conventional and digital process is the aim of this in vivo study.

NEED FOR THE STUDY

For patients who are partially edentulous, implant-supported FDP's have emerged as a popular treatment option with respectable success rates. The long-term survival of any dental restoration depends on the implant-supported restoration fitting precisely. If there is ill fitting due to discrepancy in the marginal & internal fit between the restoration and the implant abutment it will lead to biologic complications of the peri implant tissue & an inflammatory response in the soft tissues surrounding the implant.[1]

The fit of this restoration not only depends on precision of the fabrication method but also the impression technique utilized to record the tissues.[2]

At present there are various impression techniques available for manufacturing of implant crowns. The introduction of digital impression technology has greatly changed the accuracy of prosthesis, while traditional/conventional impression techniques, still in use have also shown to produce acceptable prosthesis with regards to fit. The latest technology in prosthetic dentistry for fabrication of crown is CAD/CAM technology & Direct Metal Laser-sintering (DMLS). These are specially used for fabrication of metal restorations / metal framework and full ceramic restoration.[10]

Implant-supported metal-ceramic crowns are commonly utilized. As a result, numerous researchers have assessed the fit accuracy between metal copings and abutments, and they have come to the conclusion that the production techniques, metal alloys, as well as impression technique might have an impact on the fit accuracy of the restoration even in digital technology.[13]

In the fabrication procedure of implant crowns, traditional/conventional fixture-level implant impression techniques combined with master casts and restoration with PFM crowns continue to be the gold standard. However, this conventional workflow is frequently linked to lengthy appointments, multiple clinical and laboratorial steps, intricate fabrication processes that require sensitive techniques as well as patient-related complications like suffocation hazards, gagging, and taste irritation during the impression-taking processes.[14]

An alternative to the well-established conventional impression workflow is the next gen digital workflow. The clinical patient situation is virtually registered with a contact-free transfer using an intraoral optical scanner (IOS) system.[13]

When comparing digital impression workflow with traditional impression workflow for tooth-supported fixed partial dentures, clinical and in vitro studies have found inconsistent accuracy. Furthermore, it has been noted that the scanning protocol, operator training and experience, arch scan type, and reflective agent use, all can affect the accuracy of the digital workflow.[5]

As compared to numerous in vitro studies, very few in vivo studies have been performed to assess marginal & internal fit of implant crowns So, this in vivo study's goal is to assess and compare the internal and marginal fit of implant-retained crowns made with conventional and digital workflows.

HYPOTHESIS

NULL HYPOTHESIS

There is no difference between marginal & internal fit of single posterior implant retained crowns fabricated using conventional and digital impression workflow.

RESEARCH HYPOTHESIS

There is difference between marginal and internal fit of single posterior implant retained crowns fabricated using conventional and digital impression workflow.

AIMS AND OBJECTIVES

AIM:

Evaluating and comparing marginal and internal fit of single posterior implant retained crowns fabricated using conventional and digital impression workflow.

OBJECTIVE:

To evaluate marginal and internal fit of single posterior implant retained crowns fabricated using conventional and digital impression workflow.

To compare marginal and internal fit of single posterior implant retained crowns fabricated using conventional and digital impression workflow.

REVIEW OF LITERATURE

1. Holmes et al in1989 described the terminology "fit". He found that the methods used for measuring the adaptation of the restoration differ considerably in the available literature. Holmes et al have co-related measurements of discrepancy at different points as they would be geometrically associated to each other. He concluded that "internal gap is the distance perpendicular from axial wall of tooth to the intaglio surface of the coping, whereas the similar measurement at the finish line is the marginal gap". Additionally, he said that the "horizontal marginal gap is measured 90 degrees from the path of coping removal, and the vertical marginal gap is the vertical misfit calculated along the path of coping removal". [22]
2. Samet et al in 1995 described the "computer-aided design and manufacture" system used in the fabrication of metal substructure required for layering of ceramic over metal prosthesis. In this article he explained the different stages of production: digitizing stage, processing stage, and milling stage, with focus on the system's ability to produce metal substructure for single-unit as well as multiple-unit prosthesis. To assess marginal fit he conducted a pilot study of metal copings produced by the Titan system. However, in this pilot study marginal fit ranged from 111 to 270 µm, the clinical accepted marginal fit of conventional cast crowns ranges from 28 to 120 µm. He inferred that the main plus points of this system are its simplicity and reproducibility.[23]
3. To determine how change in the temperature impacted the dimensional stability of PVS and polyether materials, Marco Corso et al. (1998) conducted a study. He came to the conclusion that while the overall dimensional changes were

minuscule, the dimensional stability of the horizontal as well as vertical lines was statistically significantly impacted by variations in storage temperature.[24]

4. In 2008, M. Laurent et al. carried out a study to assess the accuracy of the silicone replica approach in determining adaptation of crown under clinical conditions. He verified the accuracy of the technique at 3 different locations i.e. middle third, cervical, and occlusal third. According to the study, comparison of adaptation is possible regardless of the silicone employed by measuring a silicone replica that replicates the cement space between the abutment and restoration. When combined with the right materials, this method enables accurate estimation of the actual cement thickness in vivo condition following cementation. Any position (occlusal, axial, or cervical) might be measured using this technique. [25]

5. The shear bond strength of ceramics & base metal dental alloys was assessed by Akova et al. in 2008. The experimental groups were cast Co-Cr & laser-sintered alloys, while the control group was cast Ni-Cr alloy. A comparison of binding strength was conducted using ten study samples specimens from each group. The shear bond strength was measured using a specially designed stainless-steel instrument, and the results indicated that there were lack of significance between the group of base metal alloys that were sintered with a laser and the group that was cast conventionally. The study concluded that the new laser-sintering method for Co-Cr alloy thus seems promising for dental applications.[26]

6. A study by P. Bouchard et al. (2009) assessed the financial viability of dental implants and fixed partial dentures as initial treatments for individuals with a single missing tooth. He came to the conclusion that, because the bridge method has a greater mean cost-effectiveness than the implant, implants can be regarded as a first-line strategy because of their success rate and cost-effectiveness.[27]

7. Andreas Syrek et al. (2010) used the active wavefront sampling method in an in vivo investigation to assess all-ceramic crowns fabricated using digital impression technique. The investigation discovered that both groups' marginal differences fell within acceptable therapeutic bounds. Compared to crowns constructed from silicone impressions, those made utilizing intraoral scans demonstrated superior marginal adaptation. Furthermore, the interproximal contact area quality of intraoral scan-fabricated crowns was superior, and the occlusion performance of both groups was comparable.[28]

8. Ten cobalt chromium copings were made using DMLS, printable pattern resin, and conventional wax pattern; Bhaskaran et al. (2013) measured the internal and marginal gaps in these copings. The pressure indicator paste was used to fix each sample onto a model. Eight distinct locations were used to assess the vertical marginal gap. Then, along the midline, the copings were divided and sectioned. The same master model was used to cement this sectioned coping once more, and it was assessed for internal gaps at four predefined locations. A video measuring device was used to record both measures. The copings produced by DMLS method showed statistically significant minimal value followed by 3D Printing. The measurements for internal gap were maximum and statistically significant for inlay casting wax. [29]

9. For implants angled at a 15-degree angle, Balouch F et al. (2013) evaluated two different impression methods (open tray & closed tray). According to the study, angulated implants put additional strain on the materials used to make impressions, which resulted in deformations that persisted after the molds were taken out. The closed tray approach, on the other hand, considerably decreased dimensional changes on tilted implants. The closed tray method was the suggested approach because it was also quicker and simpler to utilize.[30]

10. Tamac et al in 2014 compared the internal & marginal adaptation of PFM crowns manufactured using 3 different techniques: DMLS, CAD/CAM milling, & conventional casting. 20 crowns were fabricated in each group for 42 patients. The method used to record “marginal gap and internal adaptation” was silicone replica technique. It was measured at 3 regions: occlusal surface, axial wall, and occluso-axial angle surface before luting the crowns. For all three groups the difference in values at margin, axial wall region measurements were statistically insignificant. However, at the occluso-axial region and the occlusal surface values for DMLS group were higher in comparison with groups CAD/CAM milling and conventional casting.[31]

11. For implant-supported single-unit reconstructions, Tim Joda et al. (2014) compared the time and cost effectiveness of digital processes to traditional techniques. The outcomes demonstrated that the digital process outperformed the traditional method, resulting in quicker and more effective prosthesis treatments. According to the study's findings, the digital workflow might speed up the procedure and provide excellent single-unit restorations supported by implants at a competitive cost-benefit ratio.[32]

12. To compare patient outcomes during digital and analog implant impressions, Tim et al. (2014) conducted a randomized controlled experiment. In terms of patient perception and happiness, his study found that the digital workflow was widely acknowledged as the most favoured and efficient implant impression approach when compared to the traditional technique. When a skilled team of dentists and dental assistants conducted the digital impression procedure with IOS, it was significantly patient-friendly than the standard approach in terms of treatment comfort. [33]

13. Harald Nesse et al. (2015) carried out an in vitro investigation to compare internal & marginal fit for FDP's made using three distinct techniques: SLM, conventional casting & milling. He concluded that SLM restorations had the lowest internal & marginal fit, whereas the milling technique yielded the best results. Furthermore, clinically acceptable internal fit values were not produced by the SLM technique.[34]

14. Using a fixed zirconia dental prosthesis with four pieces, Jazmin Hidalgo et al. (2015) conducted an in vitro study to evaluate the accuracy of the impression replica technique. His research indicates that the silicon replica method is a useful method for evaluating the internal and external fit of artificial crowns, but it produces slight variations.[35]

15. Moritz Boeddinghaus et al. (2015) conducted a clinical trial to investigate the marginal fit of crowns based on 3 different intraoral digital scanning techniques and one conventional impression method. He came to the conclusion that, in terms of marginal fit, zirconia copings showed better results which were fabricated using intraoral scans. However, laboratory scans of a traditional model were similar. Additionally, he came to the conclusion that when the finish lines were visible and kept dry, the digital intraoral scanning can be considered as a substitute for a traditional impression.[36]

16. In 2015, Jong-Kyoung Park et al. compared the internal & marginal fit of metal copings made using three distinct manufacturing techniques: DMLS systems, computer-aided milling, & casting. The study found that the internal & marginal gap of copings fabricated using DMLS & CAD-CAM milling came within the clinical acceptable (<120µm), despite the fact that the discrepancy varied with fabrication methods. Although the study demonstrated that digital systems were

superior to the conventional casting approach, there is still room for advancement in digital systems. [37]

17. In an in vivo study, Zhuoli Huang et al. (2015) compared the internal & marginal fittings of two metal ceramic restorations made by lost-wax casting with those of SLM (Selective Laser Sintering) metal ceramic restorations. Additionally, he also evaluated the impact of tooth type on these crowns' internal & marginal fit.

    A total 330 castings were made in this investigation using SLM Co-Cr (n=110), cast Co-Cr alloy & cast Co-Cr alloy. The "replica technique" was used to capture the "marginal and internal gaps" of copings. The replicas were divided into sections, and each cross section's "marginal and internal gap" width was measured using a stereomicroscope. The results of the study showed that the marginal fit of SLM Co-Cr restorations was equivalent to that of cast Au-Pt ceramo-metal restorations and superior to that of cast Co-Cr metal ceramic restorations. The SLM Co-Cr restoration's occlusal fit was less accurate than that of the two cast metal ceramic restorations. Both internal and marginal fit were unaffected by the type of tooth. [38]

18. In order to investigate three distinct manufacturing techniques with respect to retention, marginal & internal fit of Co-Cr copings, Lövgren et al. carried out an in vitro study in 2016. Three different fabrication techniques, i.e. laser-sintering, milling, and lost wax, were used to produce 12 cobalt-chromium alloy copings for each group. Using interferometry, the surface topography of 2 copings from each group was examined. 10 copings from each group were utilized in the replication procedure to assess internal & marginal fit. The uniaxial tensile force pull-off test was used to assess the retention of the copings. When compared to copings made by milling or the milled wax/lost

wax process, Co-Cr copings made with laser-sintering technology demonstrated better internal & marginal adaptation.[39]

19. Using pre-sintered metal blocks, Barıs Pas¸alı et al. (2017) conducted an in vitro study to investigate the marginal fit of PFM crowns supported by a single implant. He disclosed that, though the restorations made using the milling-sintering method produced outcomes that were clinically satisfactory, the new technique was not as accurate as the milling method in terms of marginal fit.[40]

20. A study comparing the outcomes of digital and analog methods for single implant restoration was carried out by Francesco Mangano et al. (2018). This randomized controlled trial demonstrated low complication rates (8%), and excellent success rates (92%) for both workflows. There were no appreciable variations in PIMBL between the two groups a year following the delivery of the final crown. The study found that patients were more satisfied and preferred digital treatments because digital impressions required less time than traditional ones. [41]

21. Motaz S. Osman et al. (2019) conducted an in vitro study to assess the impact of impression accuracy for parallel as well as angled implants using open & closed tray approaches. Despite the fact that the open tray method frequently produced better results, the study showed no discernible differences between the two approaches. However, the open tray method outperformed the closed tray method for non-parallel implant.[42]

22. Son et al in 2019 compared five techniques used for assessment marginal as well as internal adaptation of fixed prostheses. The five types of methods used for assessment were TSM- triple scan method, silicone replica technique, cross-sectional method, optical coherence tomography and micro-computed tomography. In this study author observed that in silicone replica technique and

cross-sectional method groups “marginal and internal fit” was similar, whereas for micro-computed tomography and optical coherence tomography groups marginal & internal fit was similar. Overall, values for all the five methods were within the clinical permissible range. Hence author inferred that the inexpensive and comparatively easy to use SRT method can be used an alternative for CSM method. [43]

23. In 2019, Bengisu Yildirim et al. carried out an in vitro investigation to assess the internal and marginal fit of implant-supported metal copings made using 3 distinct fabrication techniques. Straight titanium abutments were fitted onto implant analog at the tissue level. He immersed 36 specimens in acrylic resin and divided them into 3 groupings at based on fabrication technique: DMLS, CAD/CAM, & Lost Wax (LW). A total of 36 metal copings supported by Co-Cr implants were made i.e. 12 for each group. The silicone replica method was used to measure coping's marginal, axial, and occlusal fits. According to the study's findings, copings manufactured using the LW process & DMLS had an internal and marginal fit that was within a range that was clinically acceptable. Copings made using CAD/CAM technology, however, revealed marginal misfit that was marginally greater than the values that are clinically acceptable. [44]

24. Zuskova et al in 2019 investigated and compared the influence of CAD/CAM milling technology on the overall adaptation of metal copings. For scanning and designing the restoration identical CAD technology was used. Total 20 frameworks were prepared with two different manufacturing techniques (“computer numerical control milling” [CNCM] and “direct metal laser sintering” [DMLS]) - ten specimens in each group. All specimens were scanned and digitized by the laboratory scanner. The adaptation discrepancies for the restorations were analysed in three dimensions by Geometric Modelling Library

(GML). The DMLS group showed less variation from the average than milled group. A minute variation of 0.04 µm was detected between the two groups. The author concluded that, given the limitations of this investigation, there was lack of difference in the overall fit between CNCM and DMLS restorations. [45]

25. In 2020, Gholamrezaei et al. used a profilometer to assess the marginal & internal fit of Co-Cr copings made by traditional casting & selective laser melting (SLM). The copings that were fabricated with both methods were seated on the model, and vertical marginal misfit was measured using a profilometer. In contrast, silicone was applied inside the copings and placed on the model, which stands in for the luting cement, for the internal fit evaluation of the light body addition. Silicone material was separated after polymerization from coping carefully and its weight was measured. The study concluded that the copings produced by SLM technique exhibited a lower vertical marginal discrepancy in comparison with the casting group. Nonetheless, in terms of internal fit there was lack of significance between the two groups. [46]

26. In order to assess the marginal fit of PFM crown supported by a single implant and fabricated using the lost wax process and DMLS, Harshita Narang et al. (2021) carried out in vitro research. According to the study, crowns created with the DMLS process had a somewhat better fit than those created with the lost wax approach.[7]

27. Using replica weighing, triple scanning, and SEM, Sina Mohammadi Sadr et al. (2022) examined the internal adaptation of PFM crowns made using CAD/CAM & lost-wax techniques at every stage of fabrication. According to the study, there were no appreciable variations in the internal adaptation of the crowns between the CAD/CAM & lost-wax groups during any stage of manufacture. After porcelain application, the CAD/CAM group's internal fit was much better,

however the replica weighting approach revealed no difference between study groups in the framework stage (p >.05). Following cementation, there was no difference between the CAD/CAM & lost wax study groups according to electron microscopy data. He also found that the triple scanning, replica weighing techniques did not significantly correlate.[15]

28. In 2022, Haghi et al. carried out a RCT to assess chairside adjustment time and clinical fit for implant-supported crowns made using fully and partially digital procedures. Twenty-eight people who had two consecutive posterior implants were enrolled by him. A splinted zirconia restoration was placed over two bespoke titanium abutments for each of these patients. A cast-free digital procedure and a digital scan were used to build prostheses for the control group (n=14). However, the test group's (n=14) prosthesis was made using a partially digital approach and a traditional impression. This implant prosthesis was delivered by a blinded researcher. Using a digital chronograph, the amount of time needed for clinical adjustment was noted. According to the results, the control group's (full digital workflow) total mean adjustment time was noticeably longer than the test group's (partial digital process). The crowns made using a full digital workflow required less time for occlusal modifications than crowns made using a partial digital technology.[47]

29. In 2024, Worapat Jarangkul et al. carried out RCT to evaluate the amount of time needed for single-implant crowns in digital and traditional workflows. He also assessed the prosthesis composed of lithium disilicate and ceramic networks infiltrated with polymers. Forty patients who required a single-implant crown in the posterior regions were enrolled by him. He split these 40 patients into two groups at random. He employed an intraoral scanner for the digital workflows group and polyether impression material for the conventional

workflows in order to capture the intraoral position of the implant fixture. According to the study's findings, the computerized workflows for the single-implant crown procedure saved 39.2% of the time than the traditional procedure (P <.0001). Even though he came to the conclusion that both digital and traditional workflow protocols could successfully complete single-implant monolithic crowns with posterior regions, the digital approach saved more time than the traditional method in terms of data collection and laboratory steps, while clinical try-in and delivery times were comparable.[48]

30. Manuel António Sampaio-Fernandes et al. (2024) conducted an in vitro study comparing 3 digital impression methods: digitization using an IOS, digitization of the traditional impression (without dental casts), & digitization of the die stone cast. The purpose of the study was to compare the time and cost implications for implant-supported prostheses. Three models were made using 1, 2, and 6 implants to evaluate the time required for extraoral operations and intraoral scanning were reviewed in order to determine the cost and duration of digital impression technique on implants. Material consumption, time investment, and operator-related costs were taken into consideration while evaluating costs. Three phases of time were tracked: (1) taking impressions, (2) creating models, and (3) finishing the entire process. According to the findings, intraoral scanning is quicker and less expensive option than traditional imprint techniques, with benefits like less material consumption and shorter procedure times.[49]

31. In order to assess patient-reported results and document time efficiency for intraoral digital scanning and analogue implant impressions made in Kennedy's class I cases with three units implant assisted restorations, Wafaa Youssef Elashry et al. carried out an in vivo study in 2024. Eight patients in a crossover

study underwent both a digital impression using a TRIOS 3Shape intraoral scanner (IOS) and a traditional polyvinyl-siloxane impression material (PVS) for bilateral distal extension cases with three screw-retained implant-supported restorations on each side of the oral cavity. Surveys using the visual analogue scale were employed to gauge patient satisfaction and the extent of convenience-related factors. Additionally, separate documentation of the working time for each and every impression method was made. Based on the findings, the study came to the conclusion that both imprint methods adequately documented each participant's 3D implant placement. However, in terms of clinical working time and patient outcomes, the intraoral scanning impression outperformed the conventional impression.[50]

32. Ioana Cristea et al. carried out a retrospective analysis in 2022 to ascertain the success & survival rates of implant supported PFM FPD’s and those that were supported by teeth. In order to assess 74 implant-supported FPD and 52 tooth-supported PFM FPD’s, he split the patients into two groups. The study's findings demonstrated that while prosthetic success was greater for implant-supported FPD, there were substantial and non-significant statistical variations in the survival rates of both FPD categories.[51]

33. In 2024, Rafal Riyadh Rajab et al. employed 45 prefabricated titanium abutments in an in vitro investigation. Based on the use of scanning assistance agents, he separated the samples into three groups (n = 15 each). As the scanning aid agent, he employed a scan body for Group 1 (G1: control); liquid paint for Group 2; and powder spray for Group 3. To scan as well as to mill the crown, an imaging scanning assistance agent was given to each abutment. The same intraoral scanner was used for all scans, and Geomagic Control X software

and digital silicone replica techniques were used to analyse the internal fit digitally. There was lack of significance seen in all the study group.[52]

34. In 2024, Massimo Corsalini et al. carried out a three-arm structured clinical RCT in which they examined three distinct workflows: entirely analog, fully digital, and a combination of digital and analog. Comparing each workflow's clinical characteristics in terms of interproximal and occlusal contact (IC and OC), marginal adaptation, impression time (IT), and how satisfied patients were using a VAS scale was the main goal of the study. The study involved seventy-two patients in all. The study's findings demonstrated that the digital workflow's Interproximal and Occlusal Contacts were noticeably superior to the others. There was lack of significance between the fit of the abutment and the implant. Making an impact required less time in the digital workflow. When comparing the digital process to the traditional workflow, patient satisfaction was shown to be greater. Despite the study's limitations, these findings demonstrated that digital workflows were more accurate and patient-tolerant than traditional methods. Therefore, the author proposed that, when carried out by skilled practitioners, digital dentistry is a good substitute for the traditional workflow.[53]

35. The possible consequences of several porcelain firings cycles and pattern fabrication techniques (traditional lost wax technique, milling, & 3D printing) on the marginal fit of three-unit implant-retained PFM FPD’s were assessed in a study by Rashin Giti et al. (2024). Using three methods 3 above mentioned methods he fabricated thirty Co-Cr alloy frameworks (ten per group). He used a direct microscopic approach at a magnification of ×80 to measure the marginal gap. According to the study's findings, the 3D printing group's marginal gap values were noticeably lower than those of the other two groups. After three firing cycles, the milling group's vertical gap increased significantly, but the

other two groups showed no discernible change. Therefore, the study came to the conclusion that 3D printing offers a better marginal fit than traditional hand-wax pattern creation techniques and CAD-CAM milling.[54]

MATERIALS AND METHODOLOGY

SOURCE OF DATA/ LABORATORY DETAILS:

- KAHER's KLE VKIDS Department of Prosthodontics and Crown & Bridge.
- DMLS crowns and conventionally fabricated PFM crowns were procured from Precision Dental Studio, Kolhapur.
- Measurements were performed at Praj Metallurgical Laboratory, Pune.

DATA COLLECTION

SAMPLE SIZE

According to the sample size estimation done, a total of 30 crowns were fabricated. Out of the 30 crowns, 15 crowns were fabricated by conventional impression workflow (GROUP A) and 15 crowns were fabricated by digital impression workflow (GROUP B).

INCLUSION CRITERIA:

- Patient age between 21-60 years.
- A patient who has successfully finished stage I of implant treatment and requires an implant-supported crown in the posterior region
- Absence of any medical condition.
- Absence of any periodontal disease.
- The Opposing arch should have fixed permanent restoration or natural teeth
- At least one fixed permanent restoration on a tooth or implant, or an intact neighbouring tooth, must be present.
- Patients who agree to complete the informed consent form and are ready to take part in the current trial.

EXCLUSION CRITERIA:

- Participants having inadequate oral hygiene.
- Implants showing signs of peri-implantitis.
- Presence of periapical radiolucency at adjacent teeth.
- Periodontitis or persistent intraoral infections.
- Absence of adjacent teeth.
- Untreated mucosal diseases.
- Presence of parafunctional habits.

Table 1: List of materials used for the research (Fig. 1)

Sr No.	MATERIAL	MANUFACTURER
1.	Light Body Polyvinyl Siloxane Impression Material	3M ESPE, Seefeld, Germany
2.	Putty Polyvinyl Siloxane Impression Material	3M ESPE, Seefeld, Germany
3.	Tray Adhesive	3M ESPE, USA
4.	Pick up impression Coping	Osstem, Busan, Korea
5.	Co-Cr Metal Alloy Pellets	Girobond NBS, Amann Girrbach, Germany
6.	Veneering Ceramics	VITA VMK 95
7.	Inlay Wax	Bego, Germany
8.	Die Stone	Pearstone Die Stone
9.	Die Lubricant	Picosilk-Renfert, Germany
10.	Die Spacer	Die Master, Renfert
11.	Phosphate Bonded Investment Material	Bego, Germany
12.	Bp Blade	Hindustan Surgicals, India
13.	Scan Body	Osstem, Busan, Korea
14.	Digital Analog	Osstem, Busan, Korea
15.	Pick up Impression Coping	Osstem, Busan, Korea
16.	Implant Analog	Osstem, Busan, Korea

Table 2: Armamentarium and equipment used in the study (Fig. 2)

Sr No.	MATERIAL	MANUFACTURER
1.	Mouth Mirror, Probe, Explorer, Tweezer, Kidney tray	G.D.C, India
2.	PKT Instrument set	Visa Stainless Steel, Germany
3.	Metal Casting Ring	Keystone Industries, Germany
4.	Induction Casting Machine	Fornax, Bego
5.	Phosphate Bonded Investment Material	Bego Miditherm-26150
6.	Automatic Mixer	Easy Mix-26090
7.	Sandblasting Unit	Bego Duostar Z2-26115
8.	Ceramic Furnace	Vita vacumat
9.	Direct metal laser sintering	EOSINT M270
10.	Digital Stereomicroscope	XTL 3400E, wuzhou New Found Co. Ltd, China
11.	Die Lubricant	Picosilk-Renfert, Germany
12.	Die Spacer	Die Master, Renfert
13.	Phosphate Bonded Investment Material	Bego, Germany
14.	Bp Blade	Hindustan Surgicals, India
15.	Sprue Wax	Renfert Germany
16.	Introral Scanner	MEDIT i500, Meridius Medical Europe Limited

Methodology

Steps in Conventional impression workflow (GROUP A)

- 15 crowns were fabricated using conventional impression workflow using lost wax technique and casting method (GROUP A) and remaining 15 crowns were fabricated using the digital impression workflow and direct metal laser sintering method (GROUP B).
- For the conventional impression technique, a stock tray was used with an open window over the designated implant to unscrew the open tray impression coping screw (Osstem, Busan, Korea). The tray was coated with a tray adhesive (3M ESPE, USA).
- Then the healing abutment (Osstem, Busan, Korea) was removed and the pickup impression coping was secured over the implant fixture. (Figure 2,3)
- Radiograph was taken to verify the proper seating of open tray impression coping over the fixture. (Figure 4)
- Open tray was loaded with polyvinylsiloxane impression material (3M ESPETM, Seefeld, Germany). Once the material was polymerized, the open tray impression coping screw was uncrewed through the prepared window and the impression was retrieved and checked for accuracy and detailed reproduction. (Figure 5)
- Healing abutment was then re-inserted into the implant.
- Implant lab analog (Osstem, Busan, Korea) was attached to the picked-up impression coping in the impression and the impression was poured using Type IV gypsum (Pearstone Die Stone Class IV) and a working model was obtained.

- Alginate impression was made of the opposing arch, poured with Type IV gypsum material and interocclusal bite records was made.
- Then these models were sent to the laboratory for crown fabrication by lost wax technique of conventional workflow.

Steps in crown fabrication by conventional laboratory workflow.

- For conventional casting, a die spacer of thickness 25 μm was applied to the selected transfer abutment of appropriate size maintaining clearance of 0.5 mm above the margins.
- A wax pattern was then made of uniform thickness over the abutment and measured using dental callipers to control coping thickness.
- The pattern was then be sprued onto the crucible former, invested using phosphate bonded investment material and coping was fabricated using conventional lost wax technique. (Figure 6)
- Once the copings were fabricated, finishing and polishing of the coping was done.
- Try in of the metal copings was done and then ceramic layering was carried out.
- VITA VMK® 95 veneering ceramics were used for both the study groups. (Figure 7)
- First oxidization process was done, after which opaque porcelain was applied to metal coping and left to dry. First firing cycle temperature was 500°C to 960°C for 20 minutes (Figure 8). It was followed by veneering of dentin porcelain and enamel porcelain materials and firing for 25 minutes at 500°C to 930°C in a ceramic furnace (Vita Vacumat 40 T). Diamond rotary instrument with water coolant was used to remove surface irregularities, and in the end glaze porcelain

material was applied and fired once for 12 minutes at 500°C to 920°C. (Figure 9)

Steps in digital impression workflow (GROUP B)

- Once conventional impression was completed, digital impression workflow was carried out.
- This digital impression workflow was performed with a Medit i-500 intra oral scanner (Figure 18) to capture implant scan body which was attached onto the implant. Radiograph was taken to verify the proper seating of open tray impression coping over the fixture.
- Before scanning, the healing abutment was removed and a scan body (Osstem, Busan, Korea) of appropriate size was selected and torqued upto 15Ncm onto the implant. (Figure 16)
- Radiograph was taken to verify the proper seating of open tray impression coping over the fixture. (Figure 17)
- Upon radiographic confirmation of proper fit of the scan body, intra oral scanning was performed to record implant scan body position.
- Scanning was limited to the posterior segment of the interest involving one tooth on either side of the implant, including the antagonist arch and a bite registration scan.
- On confirmation of proper details of the scan, all these reports of the scan were sent to the dental laboratory in a (.STL) file format along with the details of scan body used and a digital lab analog for virtual designing and fabrication of the PFM crown using DMLS technology. (Figure 19)

Steps in crown fabrication by digital laboratory workflow.

- Once all the details of the intra oral scanning were obtained CAD software program was used for designing of the metal copings.
- The data was saved as a STL format.
- The STL file format along with the digital lab analog were used for the fabrication of copings with the help of EOSINT M270 DMLS machine. (Figure 20)
- Once the coping was fabricated, finishing and polishing of the coping was carried out and the try in of the coping was carried out on the model.
- Then the ceramic layering was done using the same technique mentioned previously for Group A. (Figure 21)

Silicone replica fabrication

- Once the crowns were fabricated from both study groups, then these crowns were intra orally subjected to silicon replica technique to evaluate the internal & marginal fit of the restoration.
- For silicon replica fabrication, the healing abutment were removed first from patients' mouth and it was then replaced by transfer abutment received from the lab along with the fabricated crown. (Figure 10)
- Once we placed transfer abutment on the fixture, light body PVS material was mixed and injected into the intaglio surface of PFM crown (Figure 11) from study Group A and was placed over the abutment using controlled finger pressure for 3 minutes until the margins of the restoration and abutment were closely seated together. (Figure 12)
- Same procedure was followed for crowns from study Group B

- So, once the injected material polymerized, crown was removed from implant abutment and from patients' mouth
- On the removed crown's intaglio surface putty impression material was pressed into the intaglio surface of the crown which was already lined by light body impression material.
- After setting of the putty, silicone replica was gently removed from the crown.
- The silicon replica obtained from Group A were all labelled from all the sides as B (buccal), L(lingual), M(mesial), D(distal) with a red coloured marker (Figure 13), while Group B replicas were also labelled similarly from all the sides with a black coloured marker. (Figure 22).

Measurement of marginal and internal fit using digital stereomicroscope:

- The obtained silicon replica was then sent to the Praj metallurgy lab for measuring the marginal & internal gap of the crown.
- In the laboratory, collected silicone replica was sectioned in two planes along Bucco-lingual and Mesio-distal directions with the help of a BP blade.
- Measurements were recorded at 10 predefined points for each silicone replica sample out of which, marginal fit was measured at 4 points (buccal, lingual, mesial, distal) and internal fit at 6 points (mesio-occlusal, mesio-middle, mesio-cervical, disto-occlusal, disto-middle, disto-cervical) and the n measurement point was determined followed by statistical analysis for the values obtained was performed. (Figure 1)
- Each section was examined under Stereo microscope (XTL 3400E, wuzhou New Found Co. Ltd., China) at 10X magnification. (Figure 14)

- All measurements were made for each crown by the same observer and were noted in a tabular form.
- Digital images were captured and examined by image analysis system (MVIG 2005, Chroma systems Pvt. Ltd., India). (Figure 15)

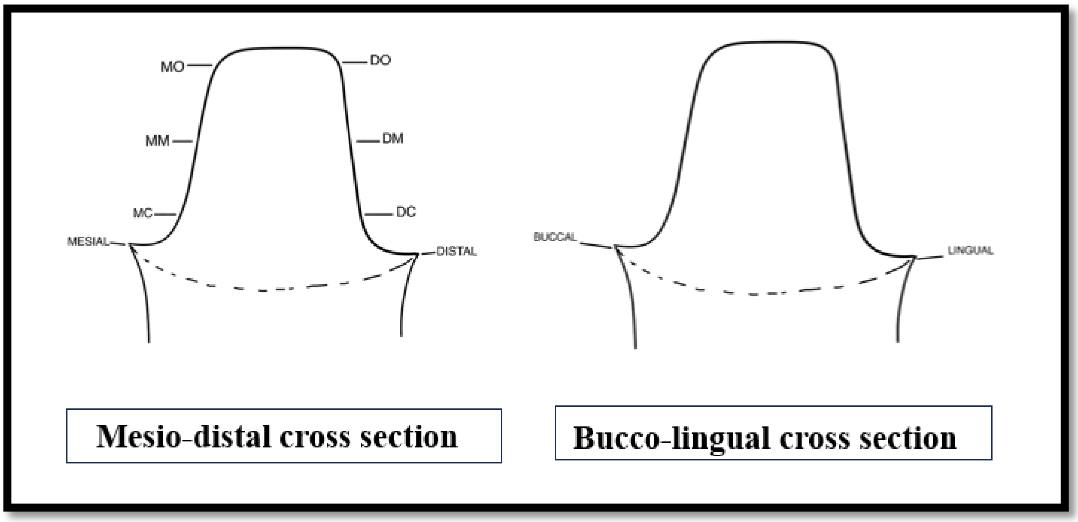


Fig 1: Schematic representation of silica replica sectioning

Fig 2: Healing Abutment Placed On Fixture

Fig 3: Open tray impression coping placed on fixture after removal of healing abutment

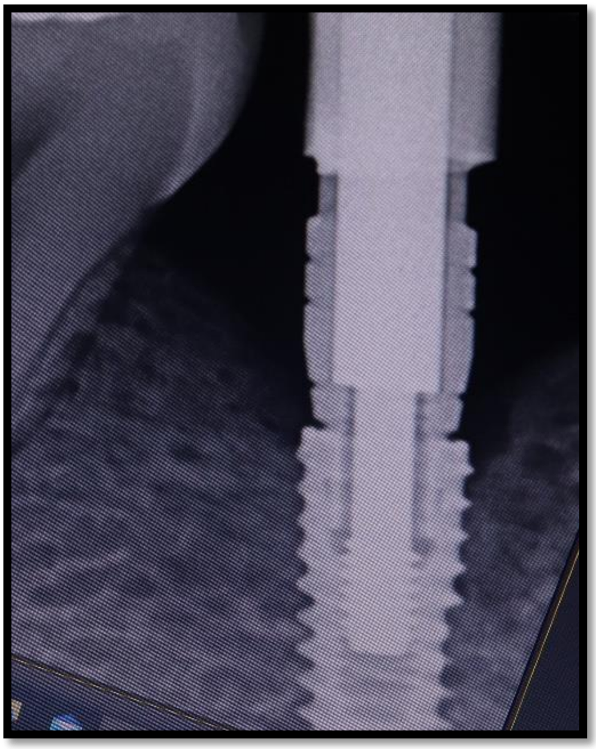


Fig 4: RVG taken to verify proper seating of open tray impression coping on fixture

Fig 5: Conventional open tray impression

Fig 6: Casting Machine (Begofornax T-26300)

Fig 7: Vita Vmk® 95 Veneering Ceramic Powder

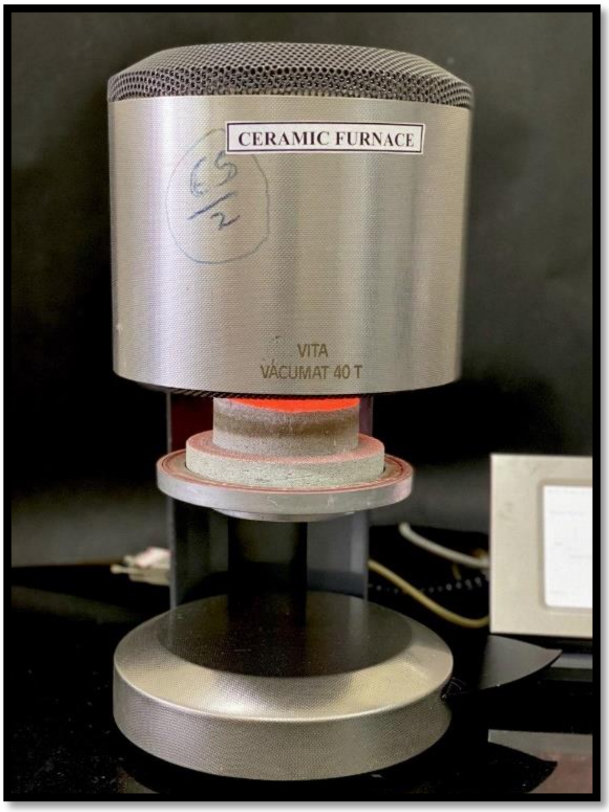


Fig 8: Ceramic Furnace (Vita Vacumat 40 T)

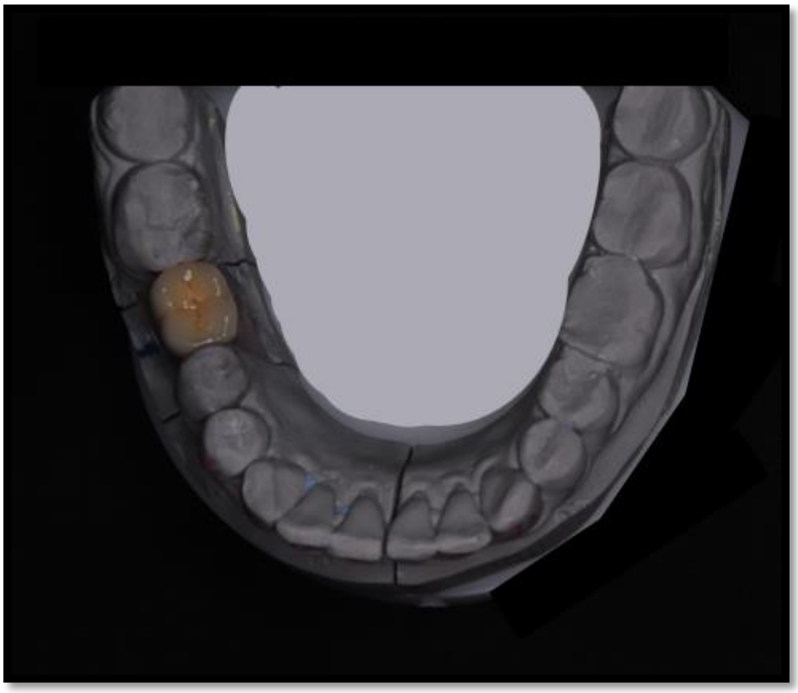


Fig 9: PFM crown fabricated with lost wax technique

Fig 10: Transfer abutment fixed onto the fixture after removal of healing abutment

Fig 11: Light body injected in the intaglio surface of crown

Fig 12: Crown placed on the abutment with finger pressure

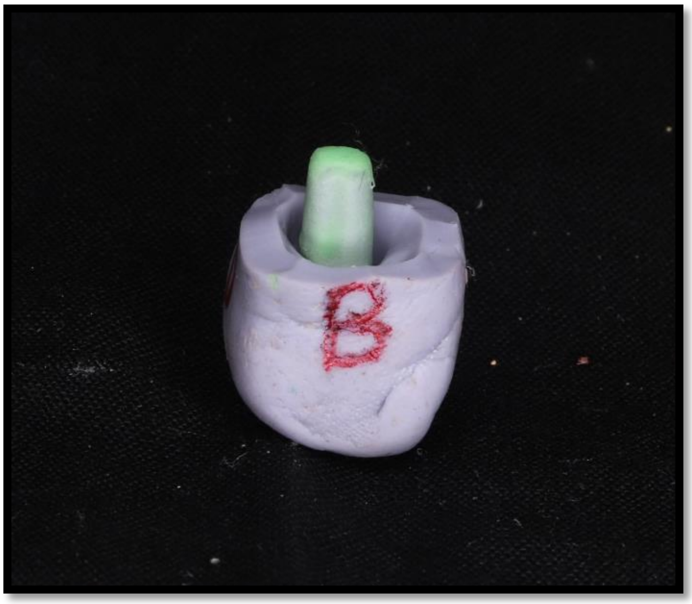


Fig 13: Red colored markings on silicon replica of crown fabricated with conventional impression workflow

Fig 14: Digital stereomicroscope (Xtl 3400e, Wuzhou New found co. Ltd., china

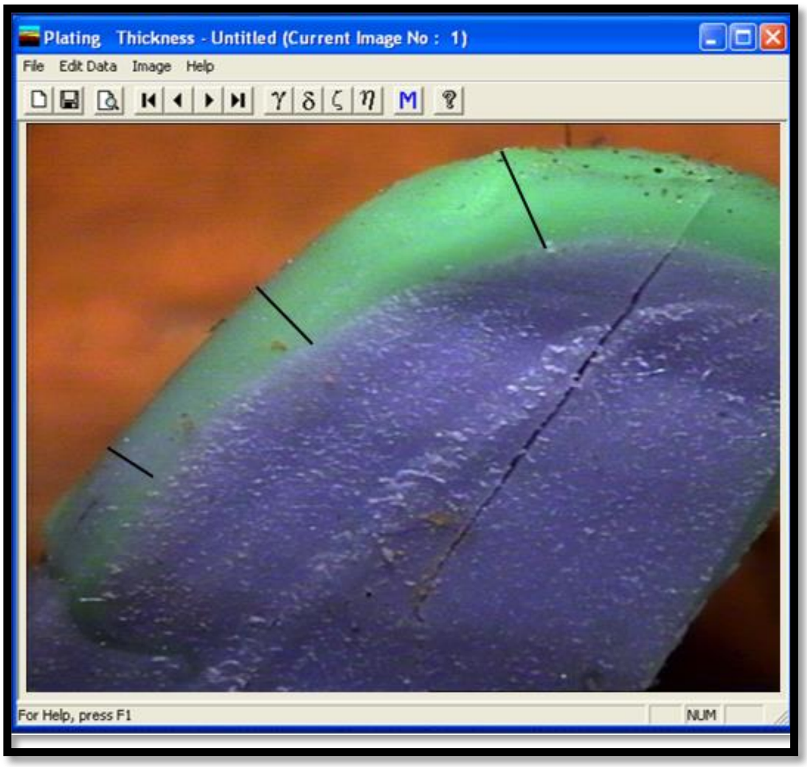


Fig 15: Measurements of marginal and internal gap recorded using image analysis system (MVIG 2005, chroma systems PVT. Ltd., India)

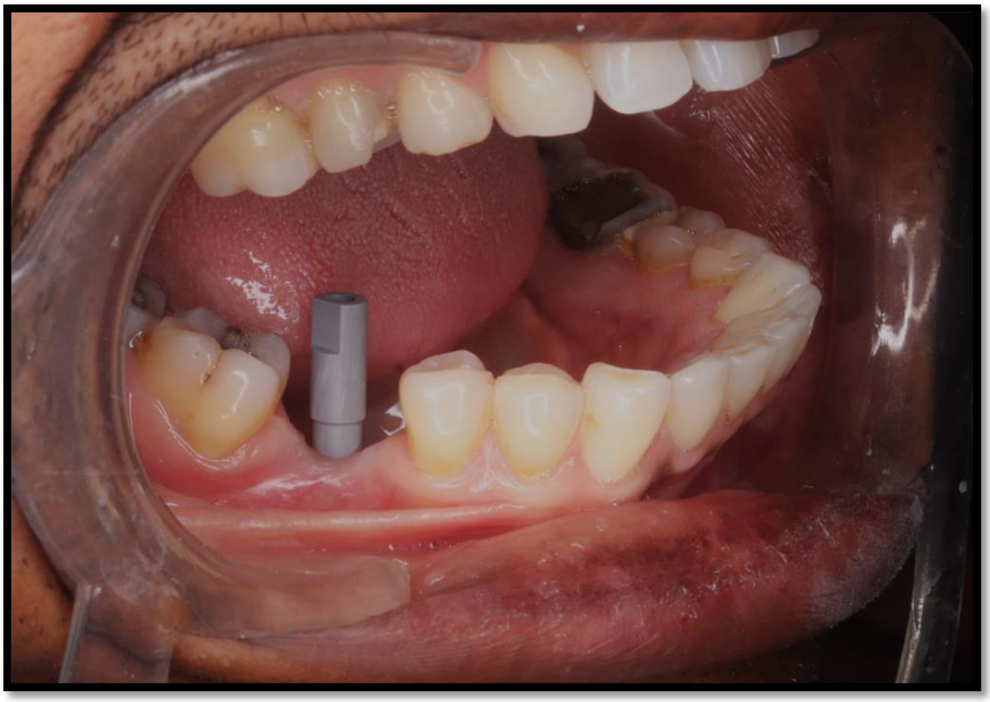


Fig 16: Scan body placed on fixture after removal of healing abutment

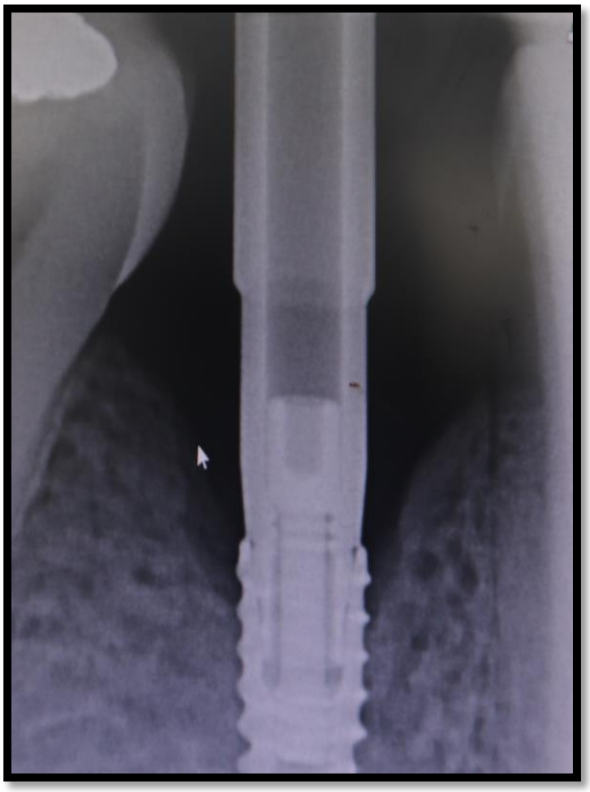


Fig 17: RVG taken to verify proper seating of scan body on fixture

Fig 18: Medit I500, Meridius Medical Europe Limited

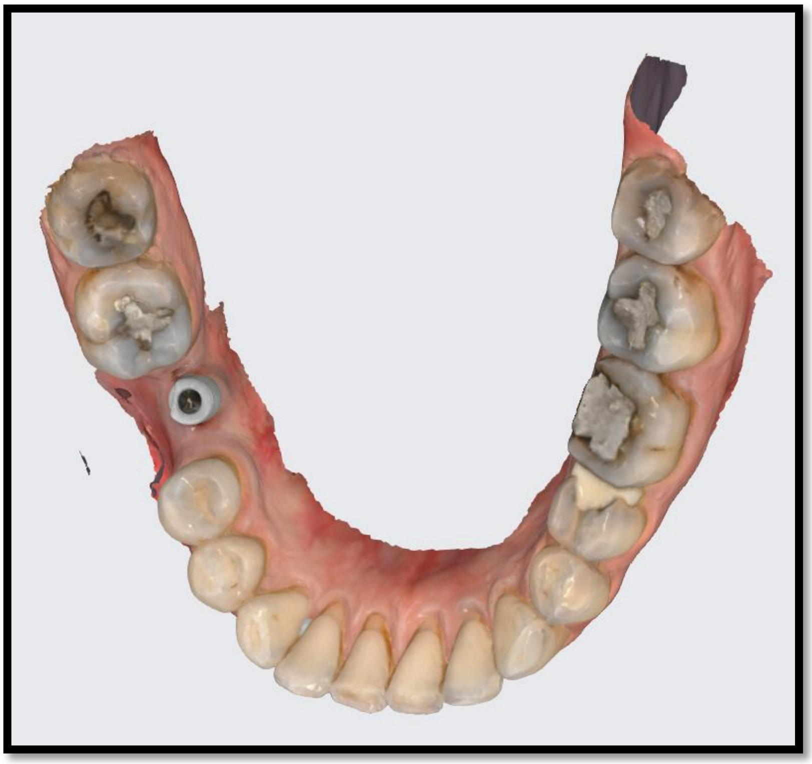


Fig 19: .STL file of a mandibular arch along with a scan body

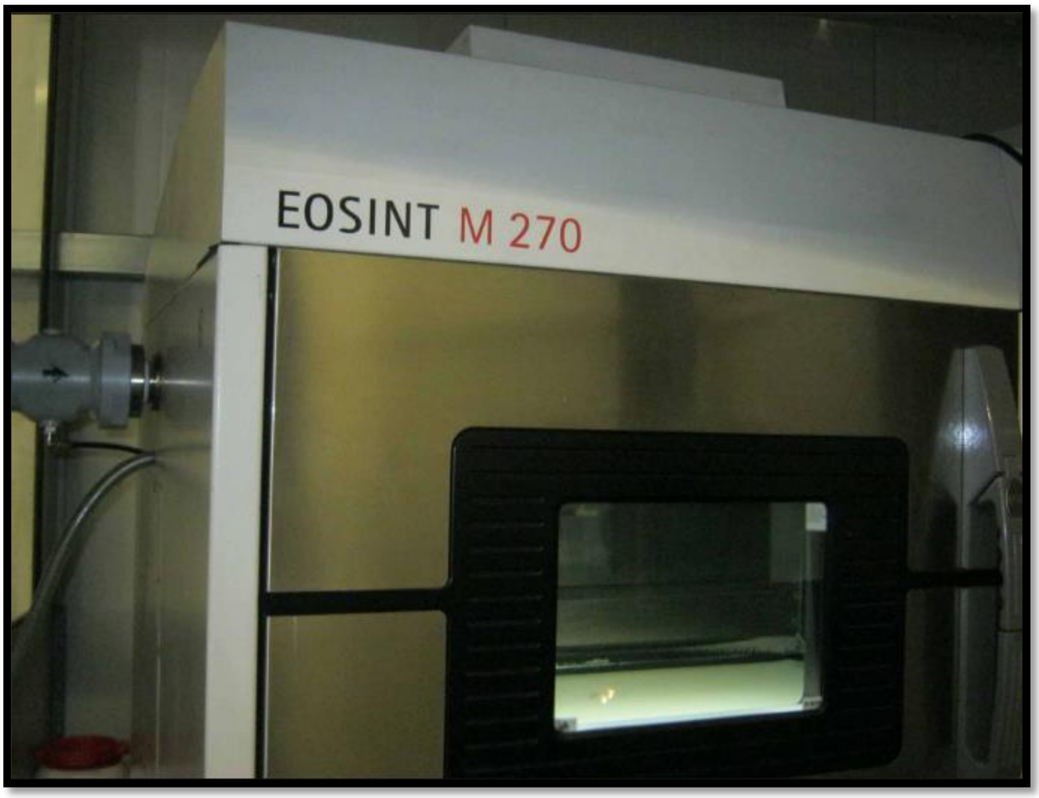


Fig 20: EOSINT M270 DMLS Machine

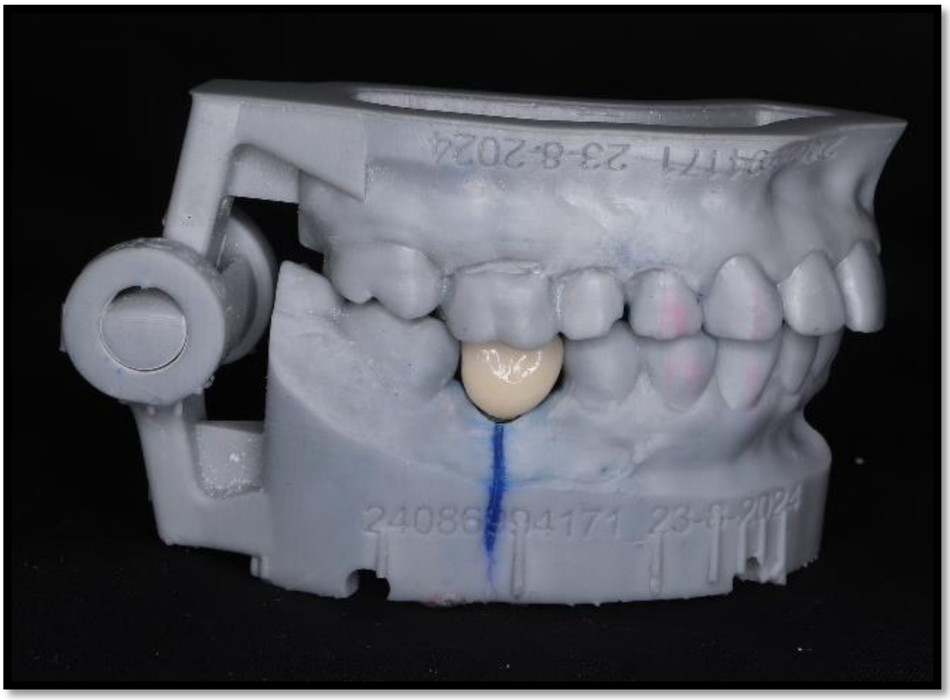


Fig 21: Crown fabricated with DMLS technique

Fig 22: Black coloured markings on silicon replica of crown fabricated with digital impression workflow

Fig 23: Crown cemented over the abutment

RESULTS

In order to draw conclusions from the experimental data, the measurements from this in-vivo investigation were assessed and compared, and the effects of traditional & digital workflow on the internal gap and marginal gap of a single implant supported PFM crown were statistically analysed.

The samples were grouped as follows:

GROUP A: Posterior implant supported crowns fabricated by Conventional workflow

GROUP B: Posterior implant supported crowns fabricated by Digital workflow

Two-way ANOVA was used to compare the marginal difference in between 2 groups and four sections in micrometres (μm).

Tukey's multiple posthoc methods were used to compare the mean & standard deviation of the marginal gap in micrometres (μm) between Group A& Group B samples pairwise.

Tukey's multiple posthoc techniques were used to compare the marginal gaps of four distinct sections taken from the Group A and B samples pairwise.

While to compare the internal gap between Group A and B at 6 points was done by using t test.

For both study groups, descriptive statistical metrics like mean, standard deviation, percentage of change, and standard error of means were calculated and quantified. The independent t test was used to compare the means of the internal & marginal gaps between the two research groups.

Table 3: Summary of marginal gap in micro meter (µm) in 2 groups and 4 sections

Factor	Levels of Factor	n	Mean	SD	SE	95% CI for mean	
						Lower	Upper
Groups	Group A	60	104.58	10.44	1.35	101.89	107.28
	Group B	60	102.95	10.44	1.35	100.25	105.65
Sections	Buccal	30	102.53	10.63	1.94	98.56	106.50
	Lingual	30	101.80	10.92	1.99	97.72	105.88
	Mesial	30	105.97	10.76	1.96	101.95	109.98
	Distal	30	104.77	9.31	1.70	101.29	108.24
Interaction	Group A with Buccal	15	102.27	9.38	2.42	97.07	107.46
	Group A with Lingual	15	101.93	11.11	2.87	95.78	108.08
	Group A with Mesial	15	108.27	11.04	2.85	102.15	114.38
	Group A with Distal	15	105.87	9.80	2.53	100.44	111.30
	Group B with Buccal	15	102.80	12.07	3.12	96.11	109.49
	Group B with Lingual	15	101.67	11.12	2.87	95.51	107.83
	Group B with Mesial	15	103.67	10.31	2.66	97.95	109.38
	Group B with Distal	15	103.67	8.98	2.32	98.69	108.64

The mean marginal gap along with the standard deviation in micrometres for two groups and four sections are summarized in the above table. The 2 study groups were Group A and B. while the four sections evaluated for marginal gap were buccal, lingual, mesial, distal.

Table 4: Comparison of 2 groups and 4 sections with marginal gap in micro meter (μm) by Two-way ANOVA

Sources of variation	Sum of squares	Degrees of freedom	Mean sum of squares	F-value	p-value
Main effects					
Group	80.03	1	80.03	0.7227	0.3971
Sections	336.87	3	112.29	1.0140	0.3894
2-way interaction effects					
Group*Sections	117.63	3	39.21	0.3541	0.7863
Error	12402.93	112	110.74		
Total	12937.47	119			

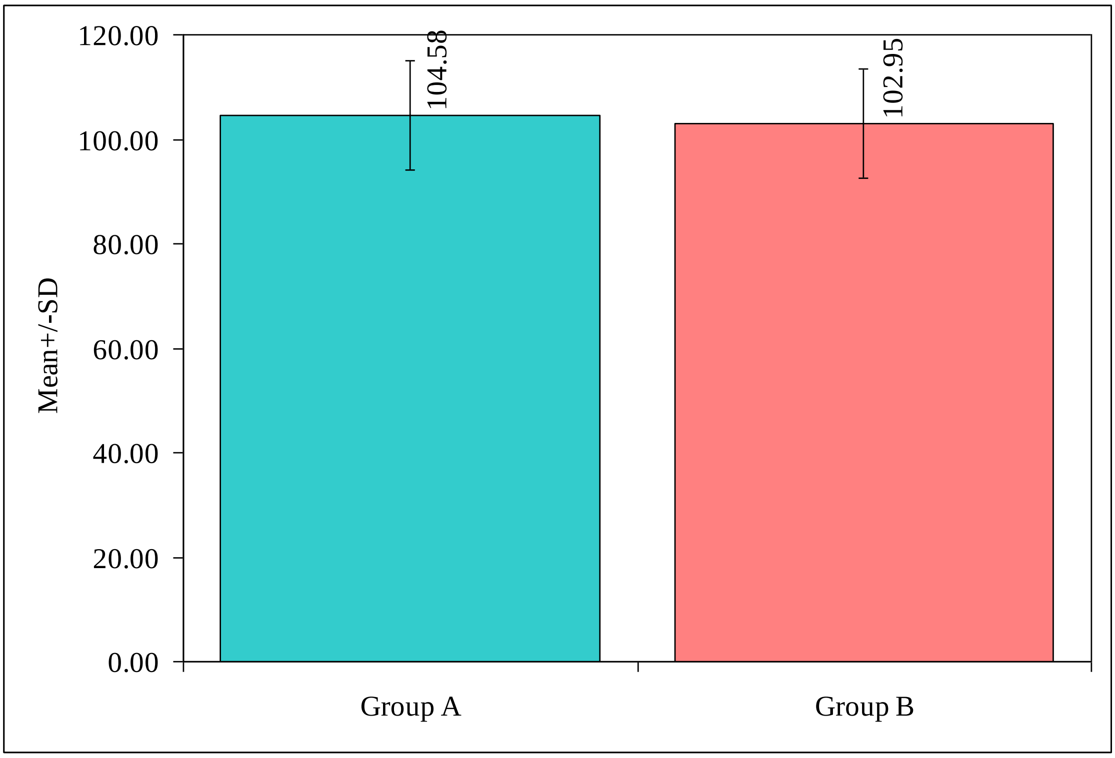
The mean marginal gap values of the four different sections (lingual, mesial, distal, buccal) and two study groups (Group A and Group B) in micrometres (μm) are compared in the above table using two-way ANOVA. The marginal gap of the posterior implant-supported prosthesis did not differ significantly between the two research groups or the four parts.

Table 5: Pair wise comparison of group A and B with marginal gap in micro meter (µm) using Tukeys multiple posthoc procedures

Groups	Group A	Group B
Mean	104.58	102.95
SD	10.44	10.44
Group A	-	P=0.3972
Group B	P=0.3972	-

The above table represents pair wise comparison of two groups with Marginal gap in micro meter (µm). Comparison between two groups was done using Tukeys multiple posthoc procedures. Though the mean marginal gap value for Group A was 104.58 µm and for Group B it was 102.95 µm, there was lack of statistical significance difference seen among the 2 study groups regarding the marginal gap of a implant supported crown.

<u>Graph 1: Comparison of two groups with marginal gap in micro meter (µm)</u>



The mean marginal gap values for the 2 research groups are compared in the above graph. Group B (Digital technique) has the lowest mean marginal gap (µm) with a mean value of 102.95 µm, whereas Group A (Conventional method) has the greatest mean value of 104.58 µm.

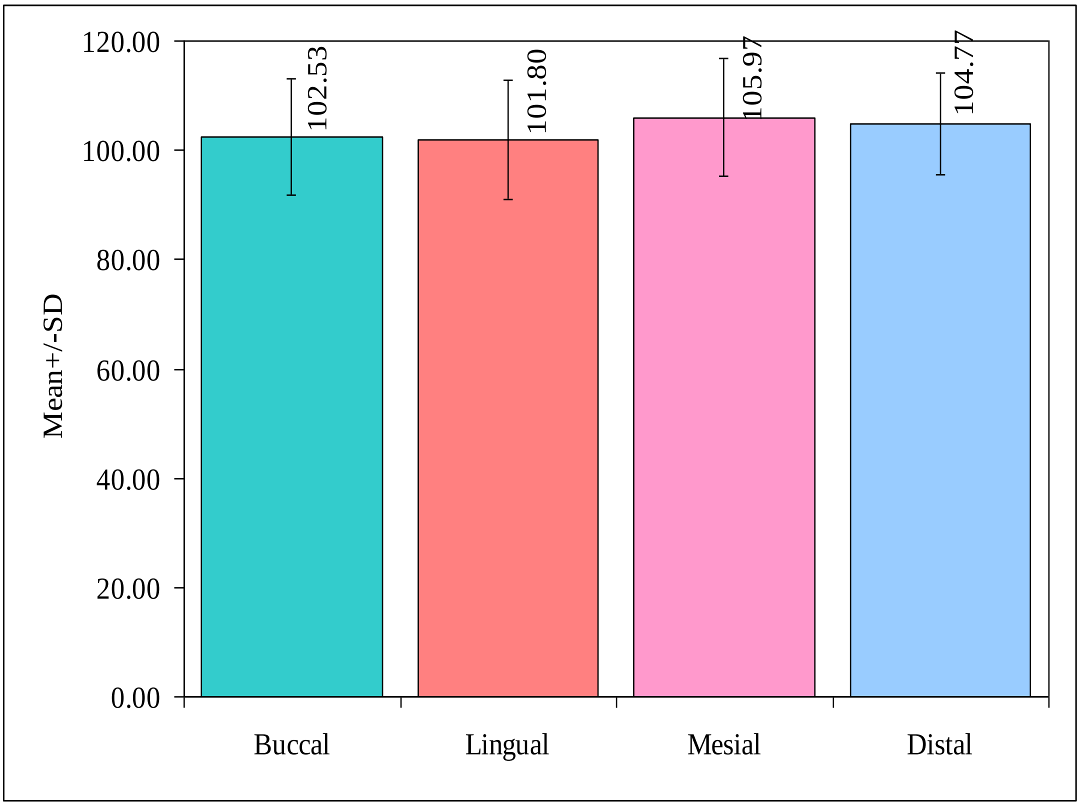
Table 6: Pair wise comparison of marginal gap in micro meter (µm) of f4 sections using Tukeys multiple posthoc procedures

Groups	Buccal	Lingual	Mesial	Distal
Mean	102.53	101.80	105.97	104.77
SD	10.63	10.92	10.76	9.31
Buccal	-	p=0.9932	p=0.5880	p=0.8440
Lingual	p=0.9932	-	p=0.4212	p=0.6953
Mesial	p=0.5880	p=0.4212	-	p=0.9711
Distal	p=0.8440	p=0.6953	p=0.9711	-

The above table represents pair wise mean marginal gap comparison of four different sections of both the study groups. This comparison was done using Tukeys multiple posthoc procedures.

The least mean marginal gap value of 101.80 µm was seen on lingual section and highest marginal gap value of 105.97 µm was seen on mesial section but there was a lack of statistical significance seen between the four sections regarding the marginal gap of the implant supported crown.

Graph 2: Comparison of 4 sections with marginal gap in micro meter (µm)



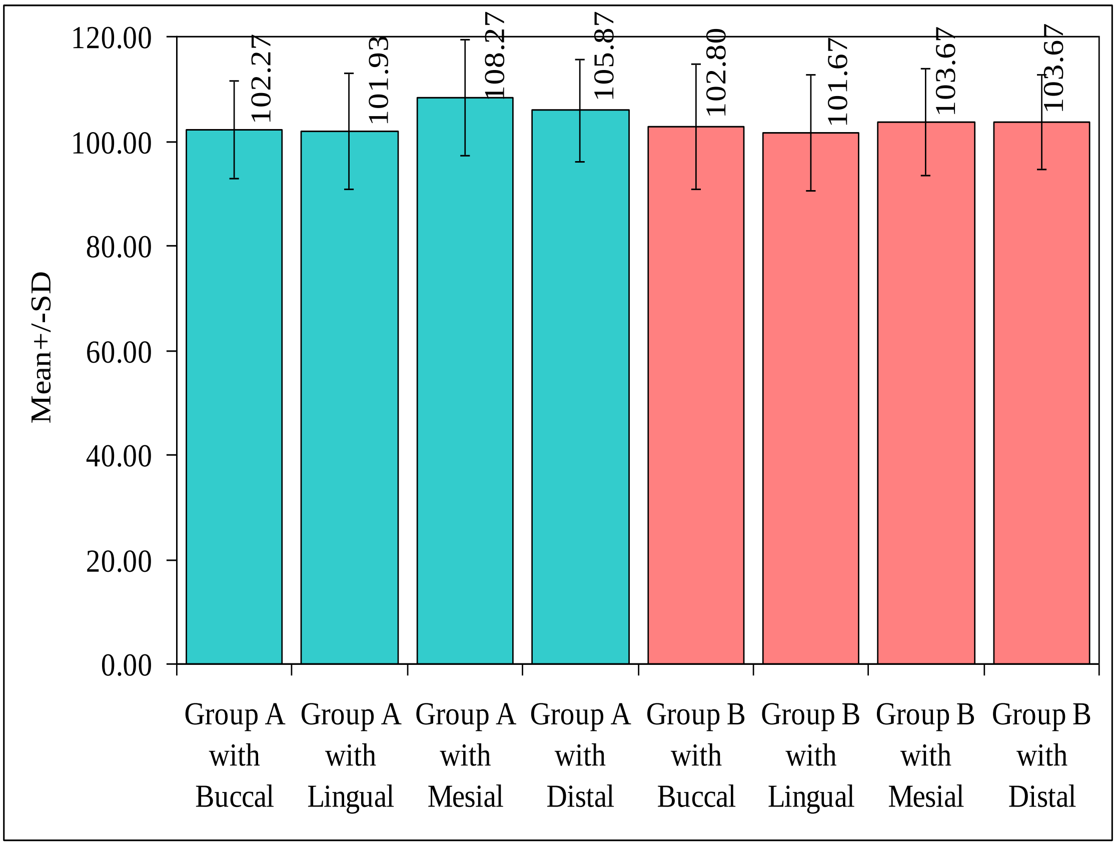
The above graphical representation shows comparison of mean marginal gap (µm) values of 4 different sections obtained from two both A and B study groups. Here the comparison between four different sections (buccal, lingual, mesial, distal) was done. The lowest mean marginal gap (µm) was shown by lingual section with mean value 101.80 µm and highest was shown by mesial section with mean value 105.97 µm

Table 7: Pair wise comparison of interactions of group A and B and 4 sections with marginal gap in micro meter (μm) by Tukeys multiple posthoc procedures

Interactions	Group A with Buccal	Group A with Lingual	Group A with Mesial	Group A with Distal	Group B with Buccal	Group B with Lingual	Group B with Mesial	Group B with Distal
Mean	102.27	101.93	108.27	105.87	102.80	101.67	103.67	103.67
SD	9.38	11.11	11.04	9.80	12.07	11.12	10.31	8.98
Group A with Buccal	-							
Group A with Lingual	p=1.0000	-						
Group A with Mesial	p=0.7720	p=0.7200	-					
Group A with Distal	p=0.9818	p=0.9700	p=0.9985	-				
Group B with Buccal	p=1.0000	p=1.0000	p=0.8450	p=0.9930	-			
Group B with Lingual	p=1.0000	p=1.0000	p=0.6759	p=0.9571	p=1.0000	-		
Group B with Mesial	p=1.0000	p=0.9998	p=0.9313	p=0.9992	p=1.0000	p=0.9996	-	
Group B with Distal	p=1.0000	p=0.9998	p=0.9313	p=0.9992	p=1.0000	p=0.9996	p=1.0000	-

The above table represents pair wise comparison of interactions of the 2 study groups and 4 sections. The comparison was done using Tukeys multiple posthoc procedures. The highest value for marginal gap (μm) was shown in Group A (conventional workflow) with mean value of 108.27 μm on mesial section and lowest by Group B (Digital workflow) with mean value of 101.67 μm on lingual section. However, lack of significance was seen between interactions of two study group A and B and four sections regarding the marginal gap of the crown.

<u>Graph 3: Comparison of interactions of 2 study groups & 4 sections with marginal gap in micro meter (µm)</u>



The above graph represents comparison of mean marginal gap values of the 2 study groups and 4 sections. The highest values of marginal gap (µm) were shown by Group A (conventional workflow) with mean value of 108.27 µm on mesial section and lowest by Group B (Digital workflow) with mean value of 101.67 µm on lingual section, with no statistically significant difference.

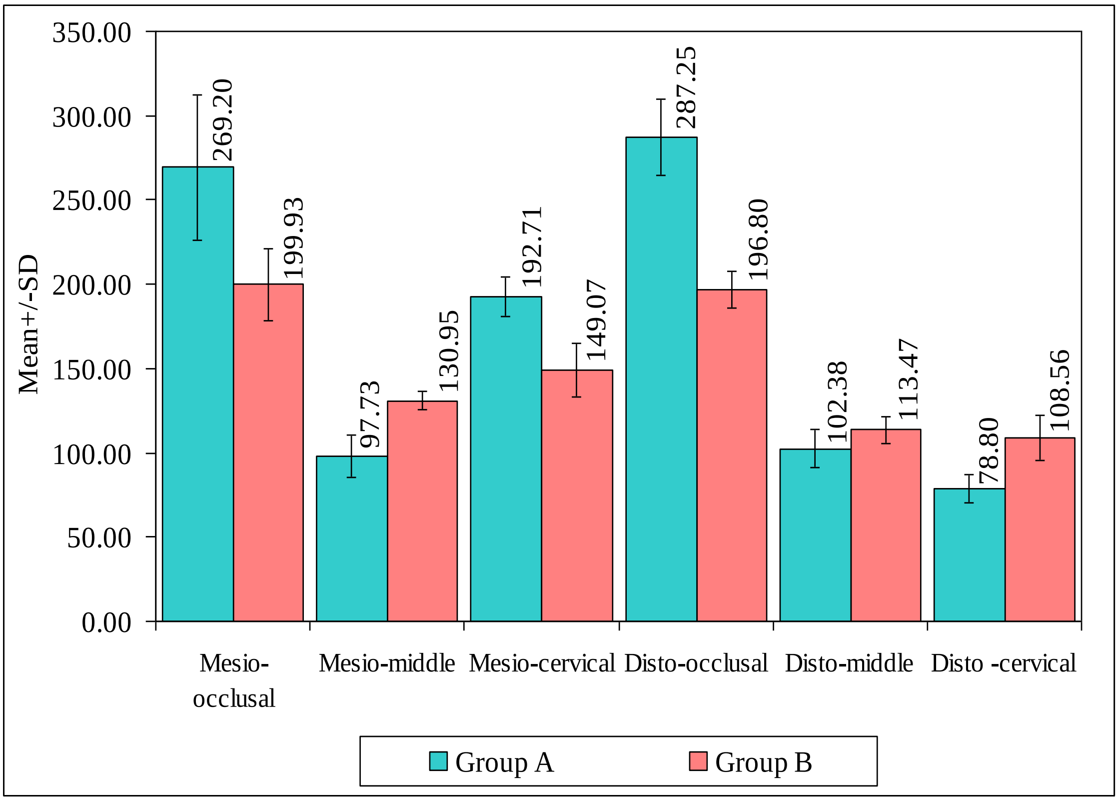
Table 8: Comparison of Group A and Group B with internal gap in micro metre (µm) at 6 points by t test

Points	Group A		Group B		Effect size	t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.			
Mesio-occlusal	269.20	42.81	199.93	21.44	2.16	5.6038	0.0001*
Mesio-middle	97.73	12.59	130.95	5.43	-3.69	-9.3823	0.0001*
Mesio-cervical	192.71	11.78	149.07	16.25	3.11	8.4229	0.0001*
Disto-occlusal	287.25	22.76	196.80	11.21	5.33	13.8087	0.0001*
Disto-middle	102.38	11.26	113.47	7.81	-1.16	-3.1362	0.0001*
Disto -cervical	78.80	8.30	108.56	13.33	-2.75	-7.3400	0.0001*

*$p<0.05$

The above table represents comparison of mean internal gap values of the two study groups i.e. Group A and B at 6 predetermined points was done using independent t test. In Group A lowest mean internal gap value (µm) was seen at disto-cervical point with mean value of 78.80 µm and highest at disto-occlusal point with mean value 287.25 µm. In Group B lowest mean internal gap (µm) value of was seen 108.56 µm in disto-cervical point and highest value of 199.93 at mesio-occlusal point. At each of the six points, the internal gap values between the two research groups showed a statistically significant difference.

Graph 4: Comparison of Group A and Group B with internal gap in micro metre (µm) at 6 points



The above graphical representation shows comparison of mean internal gap (µm) values of the two study groups at 6 predetermined points. In Group A lowest mean internal gap value (µm) was seen at disto-cervical point with mean value of 78.80 µm and highest at disto-occlusal point with mean value 287.25 µm. In Group B lowest mean internal gap (µm) value of 108.56 was seen in disto-cervical point and highest value of 199.93 at mesio-occlusal point.

DISCUSSION

In prosthetic dentistry, edentulous space rehabilitation is essential to improving patients' overall quality of life, function, and appearance. Fixed partial dentures (FPDs) and dental implants are two of the most popular methods for restoring lost teeth. [1]

Dental implants offer a higher survival rate than FPDs, dental implants have a survival rate of approximately 95–98%, but FPDs typically have a survival rate of approximately 85–90% in a 10 year follow period. [55]

Over a time, FPDs may experience caries or periodontal disease that affects the supporting abutments, can cause decementation, fracture, or wear of the prosthesis. The total lifespan of FPDs may be shortened by these problems, which may call for regular repairs or replacements. Therefore, when considering only longevity, dental implants provide a more reliable and long-lasting option than FPDs.[56]

For implant restorations to be successful over the long term in prosthetic dentistry, precise internal and marginal fit in implant crowns is crucial. Clinical outcomes include prevention of peri-implantitis by avoiding microbiological infiltration, improves crown stability, and patient comfort are all directly impacted by how well an implant crown fits.[3]

Digital impressions and traditional implant impressions are two popular methods for fabricating implant crowns which can affect the marginal & internal fit. Digital impressions have drawn a lot of interest because of their potential benefits in terms of accuracy, usability, reproducibility and time efficiency, even if traditional methods have long been the gold standard.[3]

According to recent studies, digital impressions offer a better internal fit than traditional impressions. A study by Ender et al. (2014) found that implant crowns made from digital impression had marginal gaps that were considerably narrower than those made with traditional methods. The possibility of distortion or shrinkage, which is more likely to happen with traditional impression materials because of handling, setting time, or storage circumstances, is decreased by digital systems' capacity to collect detailed surface data with high precision. Additionally, digital impression techniques have demonstrated fewer differences in marginal adaptation, which has resulted in fewer clinical issues, including crown remakes or adjustments.[57] Many of the potential causes of inaccuracy that might arise during the traditional impression process are eliminated by the digital impression approach, including deformation, blood or saliva contamination, and irregularities in the flow of impression material. [58]

Therefore, digital workflow when carried out by skilled practitioners, digital dentistry is a good substitute for the traditional workflow.[53]

Manuel António Sampaio-Fernandes conducted an in vitro study comparing 3 digital impression methods: digitization using an IOS, digitization of the traditional impression (without dental casts), & digitization of the die stone cast. According to the findings, intraoral scanning is quicker and less expensive option than traditional impression techniques, with benefits like less material consumption and shorter procedure times.[49]

Considering all of the above, in the present study we have evaluated marginal and internal fit between the traditional and digital workflow.

In the rapidly developing field of implant prostheses, to fabricate implant supported PFM crowns many techniques can be used such as conventional lost wax technique, contemporary methods like subtractive manufacturing like CAD CAM and additive manufacturing like Direct Metal Laser Sintering (DMLS). [16]

A laser is used in the extremely sophisticated additive manufacturing technique known as Direct Metal Laser Sintering (DMLS) to fuse metal powder layer by layer. Because DMLS can create extremely accurate restorations with little distortion, it has become a potential method for fabricating implant crowns (Sabet et al., 2018). The computer-controlled aspect of DMLS, which enables the creation of complicated geometries with high dimensional accuracy and consistency, is largely responsible for its precision. [59]

Though there are many advantages of DMLS technique, but the system necessitates specific tools and a larger cost for both equipment and technician training. Furthermore, even though DMLS offers exceptional accuracy, it might not be appropriate for all crown types, particularly those that need extremely intricate aesthetics or are composed of particular materials that are incompatible with laser sintering. Additionally, to attain a satisfying aesthetic result, the surface finish of DMLS crowns may need post-processing, such as polishing or smoothing, which can lengthen the workflow.[38]

The present study was conducted to evaluate the marginal & internal adaptation between the implant abutment and the PFM crown fabricated with digital and conventional impression workflow.

The marginal fit of implant-supported metal copings made using casting, milling, and milling-sintering techniques was assessed by Paşalı et al. For the lost wax process, they reported a mean marginal gap value of 89 µm, for CAD-milling, 79 µm, and for milling-sintering, 100 µm. [20]

According to in vitro tests, the typical distance between the internal and marginal surfaces of metal-ceramic crowns on implant abutments is 111 µm and 130 µm, respectively.[60,61]

The marginal fit of Co-Cr alloy copings made by selective laser melting, milling-sintering, casting, and milling was assessed by Kim et al. 59 to 69 µm for casting, 119 to 133 µm for milling, 100 to 129 µm for selective laser melting, and 59 to 62 µm for milling-sintering were the marginal fit values they reported.[19]

In the present study, mean marginal gap values of PFM implant supported crowns for Group A (conventional impression work flow) were 104.58 µm while for Group B (Digital impression workflow) were 102.95 µm. Though there was slight difference in the marginal gap values between two study groups but, there was lack of statistical significance seen between 2 groups. However, crowns fabricated with digital workflow showed better marginal fit than conventional workflow but, crowns fabricated with both the workflows had a marginal adaptation within an acceptable range.

The marginal gap values of our study are in accordance with the McLean and von Fraunhler study. In their study they reported that the maximum clinically acceptable marginal gap values were found to be 120 micro meters.[44]

For internal fit, the measurements were taken at 6 different points. Highest mean internal gap values at disto occlusal point of Group A i.e. conventional showed a gap of 287.35µm while that of Group B i.e. digital showed a gap of 199.93 µm on mesio-occlusal point. Lowest mean internal gap in Group A was 78.80 µm at disto cervical point while that of Group B it was 108.56 µm at disto cervical point. There was statistically significant difference seen at all 6 different points in the internal adaptation of crowns fabricated by both the workflows. The highest mean gap values were measured at the occlusal surface as reported in previous studies.[62] In our study the crowns fabricated by digital impression workflow showed better internal fit than the crowns of another group.

This may be due to the digital workflow including both the digital impression workflow as well as digital fabrication workflow using DMLS technology.

The results of the current study are in accordance with the previous studies conducted to compare the fit of the prosthesis depending upon impression technique which showed, the crowns fabricated using digital scans had better fit than the crowns fabricated using conventional impression technique. [36]

This accuracy of DMLS is due to the high-resolution laser that sinters the metal powder with micrometric accuracy. Crowns with nearly perfect marginal adaptation may be produced, which also reduces material shrinkage, a major problem with traditional casting techniques. [35]

In 2019, Bengisu Yildirim et al. carried out an in vitro investigation to assess the internal and marginal fit of implant-supported metal copings made using 3 distinct fabrication techniques: DMLS, CAD/CAM, & Lost Wax (LW). According to the study's findings, copings manufactured using the LW process & DMLS had an internal and marginal fit that was within a range that was clinically acceptable. Copings made using CAD/CAM technology, however, revealed marginal misfit that was marginally greater than the values that are clinically acceptable. [44]

Huang et al evaluated clinical marginal and internal fit of crowns fabricated using different CAD/CAM technologies. They found a marginal gap width of 69.89 µm, axial gap width 25.59 µm, and occlusal gap width 314.43 µm for selective laser melting metal-ceramic crowns. They found marginal gap width of 87.41 μm, axial gap width of 147.35 μm, and occlusal gap width of 266.87 μm with CAD/CAM zirconium-oxide-based ceramic crowns. They found marginal gap width of 89.93 μm, axial gap width of 150.29 μm, and occlusal gap width of 276.74 μm for CAD/CAM lithium disilicate ceramic crowns.[63]

Our digital method with DMLS technology crowns demonstrated higher internal adaptability than the traditional workflow, which is consistent with the aforementioned findings. The occlusal portion of the crown has the largest internal gap. This can be because the laser scanner's optical characteristics or the camera it uses cause sharp edges to become rounded. Additionally, a spacer/cement thickness of 30 micrometres is added from all sides of the abutment and 0.8 mm away from the borders during the crown's CAD design. Therefore, this might be the cause of higher axial and occlusal internal gap values than those near the boundary.[61]

Crown fit is evaluated using a number of conventional methods. The most straightforward and widely used technique in clinical practice is visual inspection. It entails checking the crown in situ for any obvious fit irregularities on the inside or at the edges. This approach does have some significant drawbacks, though. It is subjective and frequently fails to identify subtle differences, particularly at the inside surfaces where they are difficult to see. Visual inspection is also an unreliable method for accurate evaluation because it is unable to measure minute gaps.[25]

Another popular technique is impression-based, which captures the crown and surrounding tissues using elastomeric materials. We then look for differences in the marginal fit between these impressions. Impressions still have limitations when it comes to assessing the interior fit, even if they can provide greater accuracy than visual assessment. Fit assessment may become inaccurate due to distortion of the impression material. Additionally, this approach relies on the clinician's expertise and technique, which further adds unpredictability to the outcomes.[25]

Another method for evaluating crown fit is sectioning, which is slicing the crown into thin pieces so that the fit of the interior and marginal surfaces may be directly examined. Sectioning is quite damaging even if it yields very exact data. The crown cannot be used again after it has been sectioned, which makes it inappropriate for therapeutic settings where the crown must be intact. Because of this, sectioning is more helpful in lab settings than in standard clinical evaluations.[64]

The non-destructive nature of the silica replica process is one of its main advantages. The silica replica procedure keeps the crown intact for future usage, in contrast to sectioning, which destroys it. Because it is non-invasive, it is an especially useful technique in clinical situations where the crown must stay in place for the patient to use following the fit assessment. Additionally, this method can be employed with a variety of crown materials, which are frequently utilized in prosthodontics.[39] but, silicon replica has its own drawback such as, it cannot detect over or under extended marginal fit of crown.

Numerous investigations have repeatedly demonstrated the superiority of the silica replica approach when compared to conventional procedures. For instance, compared to conventional impression techniques, the silica replica technique was substantially more accurate in identifying internal and marginal fit differences, as well as it saves time & money according to a study by Nematollahi et al. [64]

The silica replica technique performed better than sectioning in another investigation by Meyer et al. (2014) in terms of delivering accurate, repeatable, and non-destructive measurements of the internal and marginal fits. These investigations demonstrate the increasing agreement in the literature that the silica replica approach provides a degree of accuracy and dependability that is unmatched by conventional techniques.[65]

By taking into consideration of all these factors, in our in vivo study, marginal and internal fit of the crowns were measured by using silica replica technique.

The overall findings of the present research indicate that there is a difference in marginal and internal fit of implant supported PFM single crowns fabricated by conventional and digital workflow and there was statistically significant difference only in the internal fit of the crowns. The crowns fabricated by digital impression workflow had better internal fit than the conventional impression workflow. The present study provides direct evidence that digital impression workflow produces metal ceramic single implant crown restorations with both “marginal and internal adaptation” which are clinically admissible. Within the limitations of the present research there is a scope for improvement and further research can be done to demonstrate superiority of one method over the other.

SCOPE OF THE STUDY

1. A study can be performed in which micro-CT can be used for assessing marginal & internal adaptation of implant retained crown fabricated using different fabrication methods, as micro-CT has better accuracy in comparison with silicone replica method.
2. The current study was performed using 10X magnification, similar comparative study can be conducted using under different higher magnification.
3. Research can be performed to evaluate the marginal & internal adaptation of bridges supported by implants with long and short spans.
4. A long-term clinical study can be performed to compare the clinical survival of the single implant supported metal ceramic crown fabricated by DMLS & traditional lost wax method.
5. Using various materials and digital fabrication methods, such as 3D printing and milling, a study can be performed to evaluate the internal & marginal gap of implant-supported crowns.

LIMITATION OF THE STUDY

1. Light body material was injected into the intaglio surface of crown & seated was seated over the transfer abutment under controlled finger pressure, however the force applied could not be standardized.
2. The current study was carried out under 10X magnification.
3. The abutment dimensions and angulation could not be standardized for each subject.
4. The effect of thermal expansion of investment material cannot be controlled for each metal coping as it might have impact on the accuracy of metal coping adaptation.
5. A single technician may not be able to perform all laboratory tests, even though all clinical procedures were performed by a single operator.

CLINICAL IMPLICATIONS

1. In the present research, statistically significant difference was seen in internal adaptation of single posterior implant crown fabricated by digital impression workflow. Therefore, DMLS method and intra oral scanning can be used successfully for fabrication of implant retained metal ceramic restoration.
2. Overall restoration fabricated by DMLS method exhibited better accuracy with respect to internal & marginal fit which is of clinical significance. Improved adaptation of restoration will increase long-term clinical survival of the implant.

CONCLUSION

The following inferences could be made based on the limitations of this in-vivo study and its results analysis:

1. When compared to restorations fabricated using a conventional workflow (Group A), crowns fabricated using a digital workflow (Group B) demonstrated better internal & marginal adaptability.
2. Compared to crowns fabricated using a conventional workflow, those made using a complete digital approach showed statistically significant difference and a more accurate internal fit.
3. Though the marginal fit of the implant retained crowns fabricated by digital workflow was superior than the crowns fabricated by conventional workflow, there was lack of statistical significance seen between the two workflows regarding marginal fit.

SUMMARY

The present research was conducted with the aim of evaluating as well as comparing marginal & internal fit of single posterior implant retained crown fabricated using two different workflow i.e. conventional & digital impression workflows.

For this research, 15 patients who have completed stage I of implant procedure in upper or lower back teeth region, attending to the Department of Prosthodontics and Crown & Bridge were recruited in the study.

All these 15 patients undergone both conventional impression workflow and digital impression workflow for the fabrication of two different types of crowns for a single implant supported PFM crown i.e. 2 crowns were fabricated for each patient-one from each technique. As a result, thirty crowns were fabricated.

Silicone replica technique was used to measure internal and marginal gap. Silicone replica of the implant crown was made by injecting light body consistency polyvinylsiloxane into the intaglio surface of PFM crown & seating on the abutment; this represented ‘cement space’. After setting of the light body putty consistency polyvinylsiloxane was placed in the space to stabilize the light body and both pulled out of the casting together. The replicas were made for all 30 crowns. The silicone replica was sectioned in two planes and the internal as well as the marginal gap was noted at 10 predetermined locations using Digital Stereomicroscope.

SPSS software V 2.0 was used to statistically analyse the collected data. The dependent t test was used to compare the marginal as well as internal fit within the groups, while the independent t test was used to compare the internal and marginal

gap (μm) between the two groups. The findings demonstrated that the internal fit of implant-retained crowns made using a digital impression workflow and a conventional impression workflow differed statistically significantly. When compared to crowns made using a traditional impression technique, the crowns made using a digital workflow demonstrated a statistically significant variation and a more accurate internal fit.

The study led to the conclusion that, while there was no statistically significant difference in the crowns' marginal fit, the metal ceramic implant retained crown made using the digital impression workflow demonstrated noticeably better internal fit than metal ceramic crowns made using the conventional impression workflow.

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ANNEXURES

ANNEXURE – I

Research and Ethics Committee
KLE VK INSTITUTE OF DENTAL SCIENCES
A Constituent Unit of KLE Academy of Higher Education & Research
Accredited 'A' Grade by NAAC — Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State

☎: 0831-2470362 — Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 — E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1657

CERTIFICATE

This is to Certify that the synopsis titled Comparative Evaluation of Marginal and Internal Fit of Single Posterior Implant Retained Crown Fabricated using Conventional and Digital Impression Workflow – An In vivo study *Submitted by Dr.* **REG. NO- IM0222002** *P. G. Student / Staff, Guided by* ______ *from Department of* Prosthodontics Crown and Bridge *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 15/04/25

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

MEMBER SECRETARY
Research & Ethical Committee
KLEVK Institute of Dental Sciences
BELAGAVI.

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLE VK Institute of Dental Sciences
Belgaum

ANNEXURE - II

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PDF of Trial
CTRI Website URL - http://ctri.nic.in

Clinical Trial Details (PDF Generation Date :- Sun, 29 Dec 2024 06:05:36 GMT)

CTRI Number	CTRI/2024/09/074333 [Registered on: 25/09/2024] - **Trial Registered Prospectively**
Last Modified On	09/09/2024
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Dentistry
Study Design	Other
Public Title of Study	evaluation of the accuracy of implant crown fabricated by two different methods
Scientific Title of Study	Comparative evaluation of marginal and internal fit of single posterior implant retained crown fabricated using conventional and digital impression workflow- an in vivo study.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	[illegible]
Designation	Postgraduate student
Affiliation	KLE VK INSTITUTE OF DENTAL SCIENCE
Address	Department number 3, Department of prosthodontics crown and bridge ground floor, KAHER KLE Vishwanath Katti Institute of Dental Sciences, JNMC Campus,Nehru Nagar Belgaum KARNATAKA 590010 Belgaum K.L.E.V.K.INSTITUE OF DENTAL SCIENCE, Belgaum KARNATAKA 590010 India
Phone	[illegible]
Fax	
Email	[illegible]

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	[illegible]
Designation	Professor
Affiliation	KLE VK INSTITUTE OF DENTAL SCIENCE
Address	Department number 3, Department of prosthodontics crown and bridge ground floor, KAHER KLE Vishwanath Katti Institute of Dental Sciences, JNMC Campus,Nehru Nagar Belgaum KARNATAKA 590010 Belgaum K.L.E.V.K.INSTITUE OF DENTAL SCIENCE, Belgaum KARNATAKA 590010 India
Phone	[illegible]
Fax	
Email	[illegible]

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	[illegible]
Designation	Postgraduate student
Affiliation	KLE VK INSTITUTE OF DENTAL SCIENCE
Address	Department number 3, Department of prosthodontics crown and bridge ground floor, KAHER KLE Vishwanath Katti Institute of Dental Sciences, JNMC Campus,Nehru Nagar Belgaum KARNATAKA 590010 Belgaum K.L.E.V.K.INSTITUE OF DENTAL SCIENCE,

	Belgaum KARNATAKA 590010 India
Phone	
Fax	
Email	

Source of Monetary or Material Support

Source of Monetary or Material Support
> KAHER's KLE Vishwanath Katti Institute of Dental Sciences, JNMC Campus, Nehru Nagar, Belagavi, 590010, Karnataka, India

Primary Sponsor

Primary Sponsor Details	
Name	
Address	Department number 3, Department of prosthodontic crown and bridge ground floor. Belgaum KARNATAKA
Type of Sponsor	Other [self]

Details of Secondary Sponsor

Name	**Address**
prerna kalyani	Department number 3, Department of prosthodontic crown and bridge ground floor. Belgaum KARNATAKA

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	**Name of Site**	**Site Address**	**Phone/Fax/Email**
	KAHER KLE Vishwanath Katti Institute of Dental Sciences, JNMC Campus,Nehru Nagar	Department number 3, Department of prosthodontoc crown and bridge, second floor. Belgaum KARNATAKA Belgaum KARNATAKA	

Details of Ethics Committee

Name of Committee	**Approval Status**	**Date of Approval**	**Is Independent Ethics Committee?**
Institutional Research and Ethics Committee KLE VKIDS	Approved	16/11/2023	No

Regulatory Clearance Status from DCGI

Status	**Date**
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	**Condition**
Patients	
Patients	Complete loss of teeth

Intervention / Comparator Agent

Type	**Name**	**Details**
Intervention	digital workflow	accuracy of implant crown
Comparator Agent	conventional workflow	accuracy of implant crown

Inclusion Criteria

Inclusion Criteria	
Age From	21.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1 Patient age between 21-60 years. 2 Patient in need of an implant supported crown in the molar region who have successfully

		completed stage 1 of implant treatment. 3 Absence of any medical condition. 4 Absence of any periodontal disease. 5 Opposing dentition should be natural teeth or fixed definitive restoration on teeth or implant. 6 Presence of at least one intact adjacent tooth or fixed definitive restoration on teeth or implant. 7 Patients who are willing to participate in the present study and willing sign the informed consent form.
Exclusion Criteria	**Exclusion Criteria**	
	Details	1 Participants with inadequate oral hygiene. 2 Implants showing signs of peri-implantitis. 3 Presence of periapical radiolucency at adjacent teeth. 4 Periodontitis or persistent intraoral infections. 5 Absence of adjacent teeth. 6 Untreated mucosal diseases. 7 Presence of parafunctional habits
Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	Sequentially numbered, sealed, opaque envelopes	
Blinding/Masking	Participant and Outcome Assessor Blinded	
Primary Outcome	**Outcome**	**Timepoints**
	• To evaluate marginal and internal fit of single posterior implant retained crown fabricated using conventional and digital impression workflow	• baseline
Secondary Outcome	**Outcome**	**Timepoints**
	• To compare marginal & internal fit of single posterior implant retained crown fabricated using conventional & digital impression workflow.	baseline
Target Sample Size	**Total Sample Size**=30 **Sample Size from India**=30 **Final Enrollment numbers achieved (Total)**=Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)**=Applicable only for Completed/Terminated trials	
Phase of Trial	N/A	
Date of First Enrollment (India)	30/09/2024	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	**Years**=0 **Months**=5 **Days**=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Not Yet Recruiting	
Publication Details	N/A	
Brief Summary	Implant-supported fixed dental prostheses have become a well-accepted treatment option with acceptable success rates for partially edentulous patients. This success can only be achieved with a precise fit of the implant supported restoration, which is critical to the long-term success of any dental restoration. The gap between the implant abutment and the restoration allows bacteria to adhere, causing inflammatory reaction in the peri implant soft tissues and biologic complications of the surrounding tissues.	

ANNEXURE – III

CONSENT FORM

DEPARTMENT OF PROSTHODONTICS AND CROWN AND BRIDGE

KLE V.K. INSTITUTE OF DENTAL SCIENCES BELAGAVI.

CONSENT FORM

To evaluate and compare marginal and internal fit of single posterior implant retained crown fabricated using conventional and digital impression workflow"

An In Vivo Study

I,________________________ aged _______________ have been informed about my involvement in the study.

I agree to give my personal details like name, age, sex, address, previous dental history and the required details for the study to the best of my knowledge.

I will cooperate with the dentist for my intra oral and /or extra oral examination.

I will follow the instruction given by the doctor during the study.

I permit the operator to utilize the information given by me and results obtained from this study for presentation and publication.

I will not claim any returns for my cooperation in the study, even if it is being sponsored by an agency. I am participating with my own will and wish.

In my full consciousness and presence of mind, after understanding all the procedure in my vernacular language, I am willing and give my consent to participate in this study.

Patient's name: Dentist's Name:

Patient's signature: Dentist's signature:

Address:

CONSENT FORM

DEPARTMENT OF PROSTHODONTICS AND CROWN AND BRIDGE

KLE V.K. INSTITUTE OF DENTAL SCIENCES BELAGAVI.

ಒಪ್ಪಿಗೆ ಪತ್ರ

" ಸಾಂಪ್ರದಾಯಿಕ ಮತ್ತು ಡಿಜಿಟಲ್ ವರ್ಕ್‌ಫ್ಲೋ ಬಳಸಿ ನಿರ್ಮಿಸಲಾದ ಇಂಪ್ಲಾಂಟ್ ಉಳಿಸಿಕೊಂಡಿರುವ ಪ್ರಾಸ್ಥೆಸಿಸ್‌ನ ಮಾರ್ಜಿನಲ್ ಮತ್ತು ಇಂಟರ್ನಲ್ ಫಿಟ್‌ನ ತುಲನಾತ್ಮಕ ಮೌಲ್ಯಮಾಪನ- ವಿವೋ ಅಧ್ಯಯನದಲ್ಲಿ."

ನಾನು, ____________________________ ವಯಸ್ಸಿನ ______________ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯ ಬಗ್ಗೆ ತಿಳಿಸಲಾಗಿದೆ.

ನನ್ನ ವೈಯಕ್ತಿಕ ವಿವರಗಳಾದ ಹೆಸರು, ವಯಸ್ಸು, ಲಿಂಗ, ವಿಳಾಸ, ಹಿಂದಿನ ಹಲ್ಲಿನ ಇತಿಹಾಸ ಮತ್ತು ಅಧ್ಯಯನಕ್ಕೆ ಅಗತ್ಯವಾದ ವಿವರಗಳನ್ನು ನನ್ನ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮವಾಗಿ ನೀಡಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ.

ನನ್ನ ಮೌಖಿಕ ಮತ್ತು / ಅಥವಾ ಹೆಚ್ಚುವರಿ ಮೌಖಿಕ ಪರೀಕ್ಷೆಗೆ ನಾನು ದಂತವೈದ್ಯರೊಂದಿಗೆ ಸಹಕರಿಸುತ್ತೇನೆ.

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ವೈದ್ಯರು ನೀಡಿದ ಸೂಚನೆಯನ್ನು ನಾನು ಅನುಸರಿಸುತ್ತೇನೆ

ನಾನು ನೀಡಿದ ಮಾಹಿತಿ ಮತ್ತು ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಸ್ತುತಿ ಮತ್ತು ಪ್ರಕಟಣೆಗಾಗಿ ಬಳಸಿಕೊಳ್ಳಲು ಆಪರೇಟರ್‌ಗೆ ನಾನು ಅನುಮತಿ ನೀಡುತ್ತೇನೆ.

ಏಜೆನ್ಸಿಯಿಂದ ಪ್ರಾಯೋಜಿಸಲ್ಪಟ್ಟಿದ್ದರೂ ಸಹ, ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಸಹಕಾರಕ್ಕಾಗಿ ನಾನು ಯಾವುದೇ ಆದಾಯವನ್ನು ಪಡೆಯುವುದಿಲ್ಲ. ನಾನು ನನ್ನ ಸ್ವಂತ ಇಚ್ ಾಶಕ್ತಿ ಮತ್ತು ಆಶಯದೊಂದಿಗೆ ಭಾಗವಹಿಸುತ್ತಿದ್ದೇನೆ.

ನನ್ನ ಪೂರ್ಣ ಪ್ರಜ್ಞೆ ಮತ್ತು ಮನಸ್ಸಿನ ಉಪಸ್ಥಿತಿಯಲ್ಲಿ, ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿನ ಎಲ್ಲಾ ಕಾರ್ಯವಿಧಾನಗಳನ್ನು ಅರ್ಥಮಾಡಿಕೊಂಡ ನಂತರ, ನಾನು ಸಿದ್ಧನಾಗಿದ್ದೇನೆ ಮತ್ತು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.

ರೋಗಿಯ ಹೆಸರು:

ರೋಗಿಯ ಸಹಿ:

ವಿಳಾಸ:

ದಂತವೈದ್ಯರ ಹೆಸರು: ದಂತವೈದ್ಯರ ಸಹಿ

DEPARTMENT OF PROSTHODONTICS AND CROWN AND BRIDGE

KLE V.K. INSTITUTE OF DENTAL SCIENCES BELAGAVI.

संमतीफॉर्म

पारंपारकि आणि डिजिटिल वर्कफ्लो वापरून तयार केलेल्या प्रत्यारोपणाच्या सीमांत आणि अंतर्गत फटिचे तुलनात्मक मूल्यमापन राखून ठेवलेले प्रोस्थेससि- एक इन व्हवि्हो अभ्यास

दंतवैद्यांनी माझ्या भाषेत मला कार्यप्रक्रयिास्पष्ट करून मला सांगतिलेली आहे. फक्सि्ड पार्शि अल डेंचर बनवण्यिासाठी नवीन रोटरीडायमंडबरचावापरहोणारआहे. हेबर नंतर सूक्ष्म जीव तपासणी आणि वैज्ञानकि पद्धतीने साफ करायला पाठवलेि जाणार. ह्याचे नकिाल भवष्यिात प्रकाशति होऊ शकता तह्याचे मला ज्ञान आहे.

या अभ्यसात माझ्या सहभागा बद्दल सांगतिले आहे.

1. मी माझ्या वैयक्तकि तपशीलांसह नाव ______________, वय,_____ लगिं __________, पत्ता आणि अभ्यासण्यासाठी लागणारे तपशील माझ्या चांगल्या ज्ञानास देण्यासाठी सहमत आहे.

2.मी दंतवैद्याला माझ्याकडून दलिेल्या माहतिीचा वापर करण्यास परवानगी देतो आणि ह्या अभ्यासातून प्राप्त झालेल्या परणिामांचे प्रस्तुतीआणि प्रकाशन हेतूसाठी वापर करण्याची परवानगी देतो.

3.मी ह्या अभ्यासात माझ्या सहकार्यासाठी कोणत्या ही परताव्याचा दावा करणार नाही जरी तो कोणत्या ही संस्थेद्वारा प्रायोजति असेल. मी स्वतःच्या इच्छे सहसह भागी होतआहे.

4. मी दंतवैद्यांनी दलिेल्या नर्दिेशांचे पालन करनि.

माझ्या प्रादेशकि भाषेतील सर्व प्रक्रयिा समझून घेतल्या नंतर माझ्या पूर्ण चेतनेने आणि मनाच्या उपस्थतिी मध्ये, मी ह्या अभ्यासात सहभागी होण्यासाठी माझी सहमती आणि संमती देत आहे.

तारीख: स्थान:

संमतीदाराची स्वाक्षरी साक्षीदाराची स्वाक्षरी

ANNEXURE – IV

MASTER CHART of MARGINAL GAP OF GROUP A SAMPLES IN MICRO METRE (µm)

Sr.no	Buccal	Lingual	Mesial	Distal
1	90	85	90	88
2	110	90	95	96
3	100	90	110	100
4	90	105	95	100
5	100	120	126	110
6	86	86	100	100
7	100	98	106	110
8	95	98	105	99
9	108	100	120	108
10	100	110	120	110
11	120	110	100	126
12	110	105	109	120
13	110	102	120	115
14	105	110	108	100
15	110	120	120	106

ANNEXURE V –

MASTER CHAT OF MARGINAL GAP GROUP B IN MICRO METRE (μm)

Sr.no	Buccal	Lingual	Mesial	Distal
1	100	108	120	110
2	98	95	100	100
3	105	109	107	110
4	120	110	105	106
5	80	85	89	82
6	90	95	94	93
7	91	98	100	102
8	98	95	100	98
9	102	109	102	108
10	110	105	109	107
11	106	108	109	110
12	110	105	109	110
13	130	125	126	120
14	102	98	89	100
15	100	80	96	99

ANNEXURE VI –

MASTER CHAT OF INTERNAL GAP OF GROUP A IN-MICRO METRE (µm)

Sr.no	MO	MM	MC	DO	DM	DC
1	354	115.7	191.3	300.2	91.8	87.4
2	200	80.7	179.3	218.6	123.9	86.6
3	255	89	179	280	109	80
4	265	95	196	308	98	82
5	248	81	198	315	115	83
6	301	86	203	299	87	84
7	350	105	223	278	82	86
8	286	108	201	287	96	89
9	247	93	195	300	97	71
10	263	88.5	180	296	95	80
11	298	89	181	287	109	77
12	245	102	191	293	105	67
13	268	123	200	284	112	69
14	228	104	188	265	106	61
15	230	106	185	298	109	79

ANNEXURE VII –

MASTER CHAT OF INTERNAL GAP OF GROUP B IN MICRO METRE (µm)

Sr.no	MO	MM	MC	DO	DM	DC
1	170	126.4	126	184	120	110
2	246	141.4	177	224	104.6	78.4
3	220	128	165	196	110	88
4	190	130	159	190	121	120
5	188	136.5	165	189	118	125
6	1169	126	160	199	110	115
7	178	124.5	157	205	125	108
8	185	132.5	168	210	119	127
9	200	136	136	206.5	108	103
10	202.5	127	145	184.5	106.5	117
11	199	129	144	201	125.5	110
12	210.5	123	129	188	110	105
13	202	131	136	189	102	103
14	230	135	131	199	118	99
15	209	138	138	187	104.5	120