

Optimization Of Biodegradable Radiopaque Tape Demarcating The Landmark For Placing The Implant

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Abstract

For a successful implant treatment, it is important to place the implant at an accurate predetermined position. The mesio-distal position of the implant should be such that it helps in papilla preservation and provides an esthetic restoration. When more than one implant has to be placed, they should be placed parallel to each other or it might lead to non-axial loading that might result in failure of implants. To achieve these objectives, the use of radiographic and surgical stents has been advocated. According to the literature, implants that have been positioned using stents are more accurately placed. A surgical guide allows the placement of the implant along planned prosthetic axes during surgery. A radiographic stent allows visualizing the planned implant axis, position of the definitive prosthesis, emergence site, available space for the attachment components, and thickness of the mucosa overlying the bone. The radiographic stent can be transformed into a surgical stent after the treatment planning has been completed. During surgery, this removable surgical stent offers ease in implant placement without compromising access to the implant sites. In the current study barium sulfate radiopaque marker is placed over a radiographic stent which is converted into a surgical stent which helps in position pilot drill. This study compares a novel biodegradable radiopaque tape with conventional zirconia markers in 3Shape Implant Studio to determine their efficacy in implant placement.

Keywords: Surgical stents, Biodegradable, Radiopaque, Implant, barium sulfate

I. INTRODUCTION

Dental implants have become a treatment option widely used for the replacement of lost teeth. (1,2)The development of dental implants has had a major impact on the patients and the implant supported oral restoration has become an increasingly used treatment option for partially edentulous and completely edentulous patients, also even in patients with severe bone loss and in locations which all previously considered unsuitable for implant placement has been made possible by means of bone augmentation, regeneration and soft tissue regeneration procedures (3). The success of dental implants in the treatment of patients is directly related to patient evaluation and good treatment planning.(4–6) The concept of prosthetic-driven implantology has dominated the practice of implant placement in dentistry (7).One of the most challenging parts of communication is the accurate transference of planning data between the restorative doctor and the surgeon(8). While the restorative doctor prepares models and provisional prostheses that address the patient's clinical issues, the surgeon must likewise address bone and soft tissue quality and quantity while designing a supporting foundation for the patient-specific prosthesis.(9–11)

This communication challenge comes to the forefront when the team must decide the number, location, size, depth, and long axis of each of the dental implants to be utilized in the case.How does the surgeon assay the appropriateness of his implant selection and placement for the support of the planned prosthesis? The answer to that question could lie in the provisional prosthesis, but how is the data in the prosthesis transferred to the surgical plan? Answer to question is by using converted surgical stents by adding marker over radiographic stents.The surgical guide/template has served as the communication tool for transfer of the treatment planning which is highly sophisticated at times. (12,13)

Surgical guides (stents) are templates that transfer information regarding tooth position(s) to the dentist prior to implant placement .To achieve the above mentioned objectives use of radiopaque stent has been suggested. It has been well documented in literature that the implants placed using stents are more accurately positioned than those without the stent (14). Accurate placement is required to achieve best functional and esthetic result. Positioning of surgical stent is verified radiographically by adding radiopaque markers (15,16). There are various problems while adding radiopaque makers in surgical stents in terms of longevity, durability and solubility in presence of saliva (17). What types of radiopaque makers are also important for visibility over radiographs?Since the oral cavity is a relatively restricted space, a high degree of accuracy in placement of the implant is very important for the success of the prostheses. This can be achieved by means of a surgical guide

which provides adequate information regarding implant placement and at the time of surgery it fits on to the existing dentition or on to the edentulous span. In the current study reographic converted surgical stent is used, and barium sulfate radiopaque maker is placed and reason of placing Barium sulfate as radiopaque maker and it's advantages and disadvantages are mentioned. Radiographic examination aid as a tip of the iceberg in implant dentistry as the bone places a crucial role for the implants site. In order to demarcate the accuracy of the landmark, radiopaque tape as a marker is used. Radiopaque markers are used to ensure the accurate landmark during implant placement. (18)

What this invention is meant to do is to create radiopaque tape that is coated in barium sulfate and acts as a marker to demarcate the landmarks for implant placement. Barium sulfate are utilized to provide a clear radiopaque image. Barium sulfate has some amazing uses like insoluble properties and can be safely swallowed. Radiographs are used to evaluate the Width and height of available bone, Density of available bone, surrounding vital structures and its relation to the implant site, Pathology in relation to the implant site, evaluation of remaining teeth present. (19)

II. MATERIAL AND METHODOLOGY:

This study is conducted in Green lab at Saveetha Dental college. Aim of the study was OPTIMIZATION OF BIODEGRADABLE RADIOPAQUE TAPE DEMARCATING THE LANDMARK FOR PLACING THE IMPLANT designed as a comparative analysis between a novel biodegradable radiopaque tape and conventional zirconia markers in 3Shape Implant Studio.

Inclusion criteria included full mouth implant surgery

Exclusion criteria encompassed individuals with systemic diseases affecting bone metabolism or contraindications for dental implant surgery

Fabricating a Radiographic Stent:

Radiographic stents have evolved from an added advantage to a mandatory diagnostic exercise for all implant cases. There are many techniques / designs of radiographic stents used for implant diagnosis. Many radiopaque materials, including gutta percha, barium sulfate, radiopaque putties, metals like amalgam and steel, and provisional restorative material (Cavit; 3M ESPE, St. Paul, Minn.), have been employed in the creation of radiographic guides. Various methods and materials each have unique benefits and drawbacks. This article describes how to create a guide that can be used for both radiographic and surgical procedures in a completely and partially edentulous. On a CBCT scan, the guide's radiopaque marker shows the size, location, and contours of the intended prosthesis.

Materials

Gelatin was obtained from Himedia, chitosan with low molecular weight was obtained from SRL and Barium sulfate was obtained from Rankem. Deionised (DI) water is used for all steps unless stated otherwise.

Preparation of stock materials

A stock solution of 5% gelatin was prepared by adding 5g of gelatin in 100ml of DI water stirred at 37 C for 3hrs. 1% chitosan was prepared by dissolving 1g of chitosan in 100 ml of 0.5% acetic acid. The solutions were stored at room temperature. (Figure1)



Figure1-Preparation of the material

Fabrication of the Membrane

Stock solution of 5% gelatin and 1% chitosan were prepared. Gelatin and chitosan solution were mixed in the ratio 5:1 respectively and 40% Barium sulfate was added and stirred to form a homogeneous solution. The homogenous mixture is transferred to six well plates and stored at -20 C for 12 hrs and -80 C overnight. The samples were lyophilised for 24 hrs. The prepared materials were then cross linked using 3% glutaraldehyde and lyophilised. The material is stored at 4° C for further use.(Figure2)

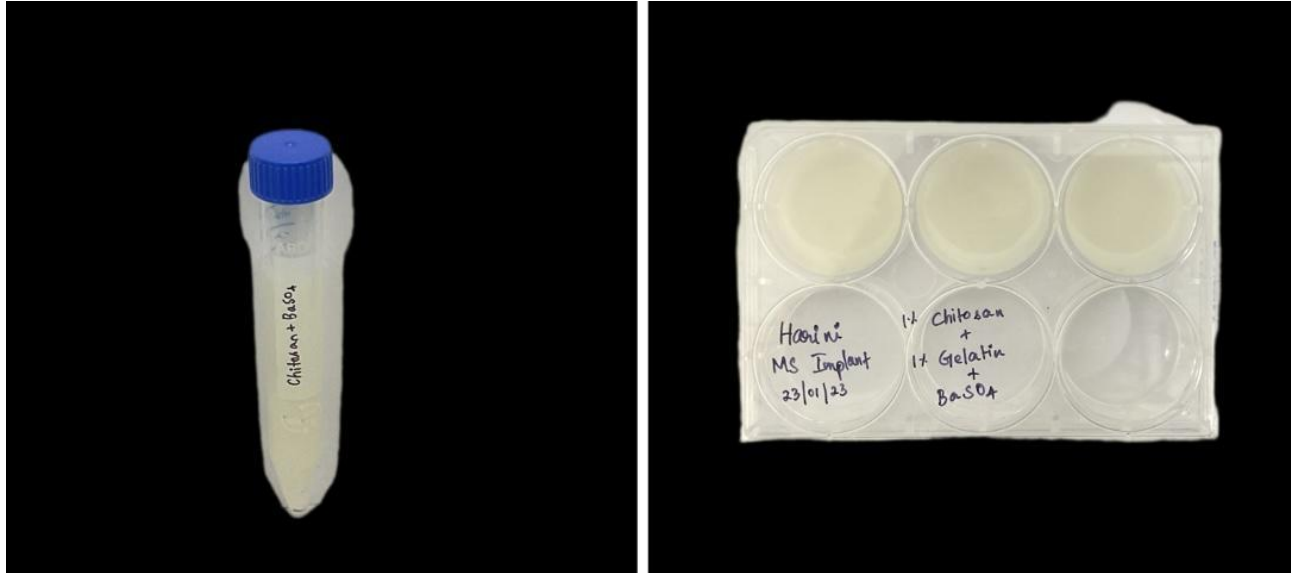


Figure 2 Stock solution of gelatin, chitosan, BaSO₄, Lyophilised material

The markers were fabricated and then embedded in dentures for evaluation using CBCT (Cone Beam Computed Tomography) and 3Shape Planning Studio.

Biodegradable Radiopaque Tape:

Using a Custom-fabricated biodegradable polymer infused with radiopaque compounds.

Zirconia Markers

Commercially available zirconia markers (ZirMark™, Implant Solutions Ltd.).

Biodegradable Radiopaque Tape Placement:

The fabricated tapes were cut into 5 mm x 5 mm pieces. Each piece was carefully embedded into the dentures. Placement ensured the tape was flush with the denture surface to avoid discomfort and interference during imaging.(Figure-3)

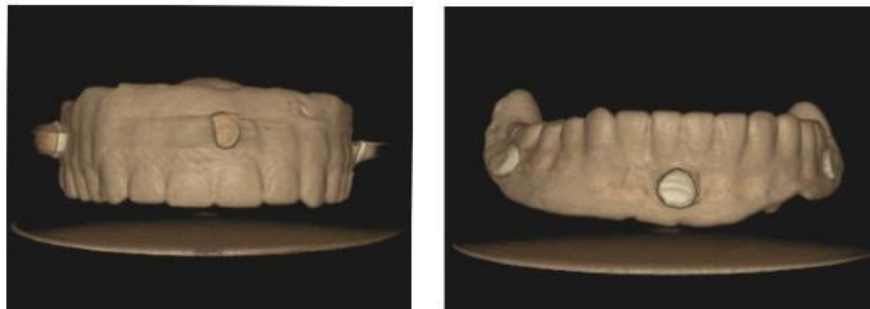


Figure-3 Placement of biodegradable radiopaque marker in the denture

Zirconia Marker Placement:

ZirMark™ markers, measuring 5 mm in diameter, were similarly embedded into the slots prepared in the dentures. Adhesive (dental resin) was used to secure the markers in place.(Figure-4)

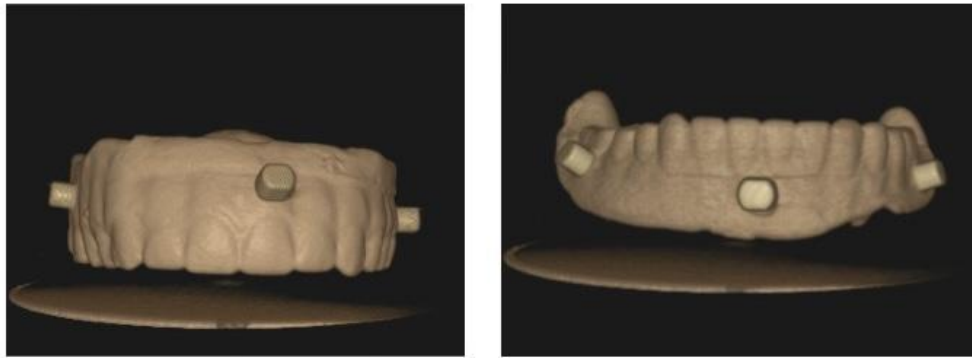


Figure 4- Placement of zirconia marker in the denture

Imaging Protocol

Following the placement of markers, the dentures were subjected to CBCT scanning to assess the radiopacity and visibility of the markers.

CBCT Scanning:

Scans were conducted using a standard dental CBCT machine, parameters included a voxel size of 0.2 mm, 90 kVp, and 10 mA. The resulting DICOM images were exported for further analysis. (Figure-5)

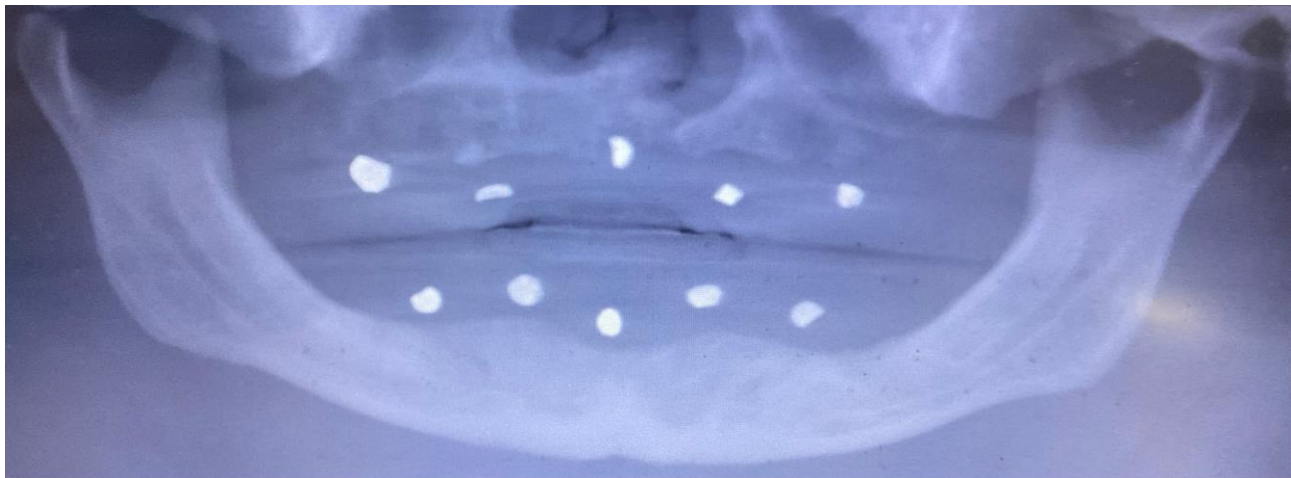


Figure 5- CBCT of Fabricated Adhesive biodegradable radiopaque marker

3Shape Planning Studio Analysis

The CBCT images were imported into 3Shape Planning Studio software. The software was used to assess the visibility and accuracy of the marker placements. Deviation measurements were taken by comparing the planned positions to the actual positions of the markers on the digital models. (Figure-6,7)

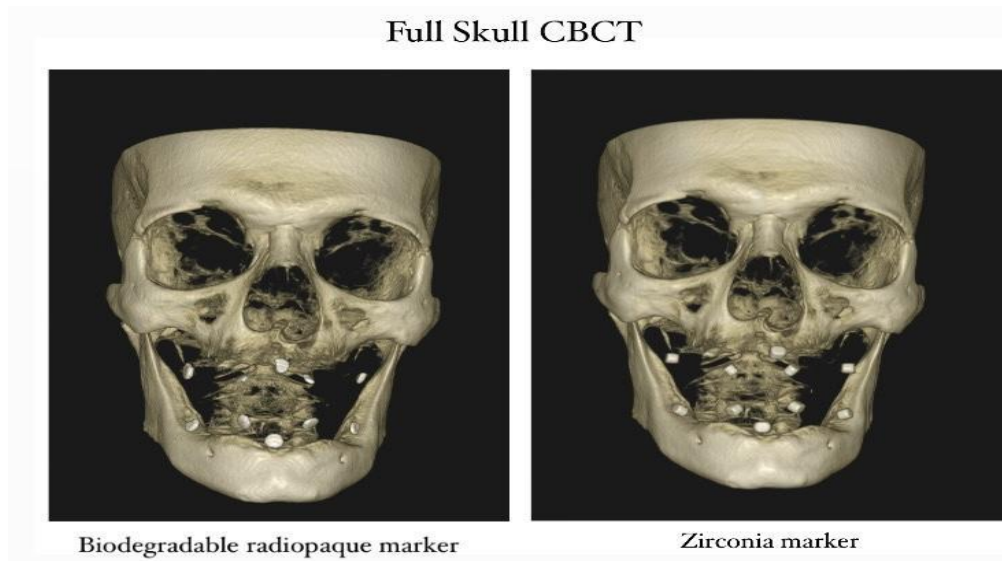


Figure 6- Full skull CBCT of the biodegradable radiopaque marker and zirconia marker

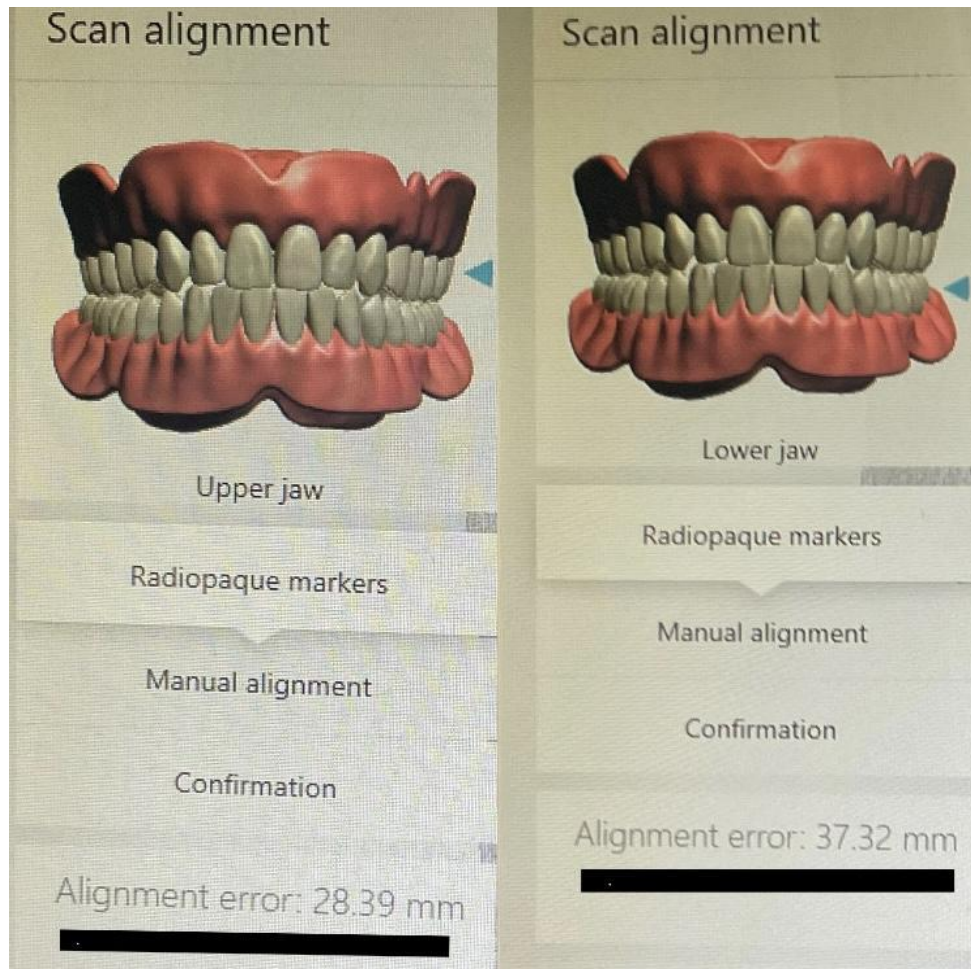


Figure 7-Alignment error analysis using 3Shape software of biodegradable radiopaque marker and zirconia marker

Statistical analysis:

For the statistical analysis, IBM SPSS version 24.0 (SPSS Inc., Chicago, IL, USA) was utilised. Means, standard deviations, standard errors, as well as the median, minimum, and maximum values were computed in a descriptive analysis. Descriptive test, One Sample T test, Pearson Correlation Test was performed, keeping the level of significance at 0.05.

III. RESULTS

The following sections present a detailed analysis of the accuracy and visibility of biodegradable radiopaque tape compared to zirconia markers, along with statistical evaluations including one-sample t-tests and Pearson's correlations.

| Parameters | Mean | SD | SE | Coefficient of variation |
|---|--------|-------|-------|--------------------------|
| Biodegradeable Radio Opaque Accuracy | 32.533 | 4.643 | 1.199 | 0.143 |
| Zirconia Marker Accuracy (mm) | 31.931 | 4.557 | 1.177 | 0.143 |
| Biodegradeable Radio Opaque Marker - Visibility | 7.533 | 1.060 | 0.274 | 0.141 |
| Zirconia Marker - Visibility | 7.533 | 1.060 | 0.274 | 0.141 |

Table 1-Accuracy and Visibility of the biodegradable radiopaque marker and zirconia marker

Accuracy Analysis of both biodegradable radiopaque tape and zirconia markers

The results indicate that both biodegradable radiopaque tape and zirconia markers exhibit comparable accuracy in implant placement. The mean accuracy for biodegradable radiopaque tape was 32.533 mm (SD = 4.643, SE = 1.199) while for zirconia markers it was 31.931 mm (SD = 4.557, SE = 1.177). The coefficient of variation for both materials was 0.143, indicating consistent performance. The one-sample t-tests for both markers yielded t-values of 27.137 and p-values of less than 0.001, demonstrating statistically significant accuracy results for both materials.[Table 2,3]

| Parameters | t | df | p |
|---|--------|----|--------|
| Biodegradeable Radio Opaque Accuracy | 27.137 | 14 | < .001 |
| Zirconia Marker Accuracy (mm) | 27.137 | 14 | < .001 |
| Biodegradeable Radio Opaque Marker - Visibility | 27.522 | 14 | < .001 |
| Zirconia Marker - Visibility | 27.522 | 14 | < .001 |

Table 2- Accuracy And Visibility Analysis of both biodegradable radiopaque tape and zirconia markers

Visibility Analysis of both biodegradable radiopaque tape and zirconia markers

Both markers showed identical visibility scores with a mean of 7.533 (SD = 1.060, SE = 0.274) and a coefficient of variation of 0.141. The one-sample t-test for visibility yielded t-values of 27.522 and p-values of less than 0.001, indicating highly significant visibility results for both markers. The Pearson's correlation coefficient between the visibility of biodegradable radiopaque tape and zirconia markers was 0.746 (p = 0.001), indicating a strong positive correlation. This suggests that improvements in the visibility of one marker type are associated with similar improvements in the other.[Table 2,3]

| Parameters | Pearson's r | p | |
|---|-------------------------------|--------|-------|
| Biodegradeable Radio Opaque Marker - Visibility | Zirconia Marker - Visibility | 0.746 | 0.001 |
| Biodegradeable Radio Opaque Accuracy | Zirconia Marker Accuracy (mm) | -0.214 | 0.443 |

Table-3 Accuracy and visibility Analysis of both biodegradable radiopaque tape and zirconia markers

The stark contrast between these correlations suggests that while the visibility of the two marker types is closely related, their respective accuracies appear to be largely independent of each other. This dichotomy in results underscores the complexity of the relationship between

these variables and highlights the importance of considering multiple aspects (such as visibility and accuracy) when evaluating marker performance. The findings may have implications for the selection and application of these markers in relevant clinical or research contexts. This suggests a robust, linear relationship between the visibility of these two marker types, indicating that as the visibility of one marker increases, the visibility of the other tends to increase proportionally. [Table-4]

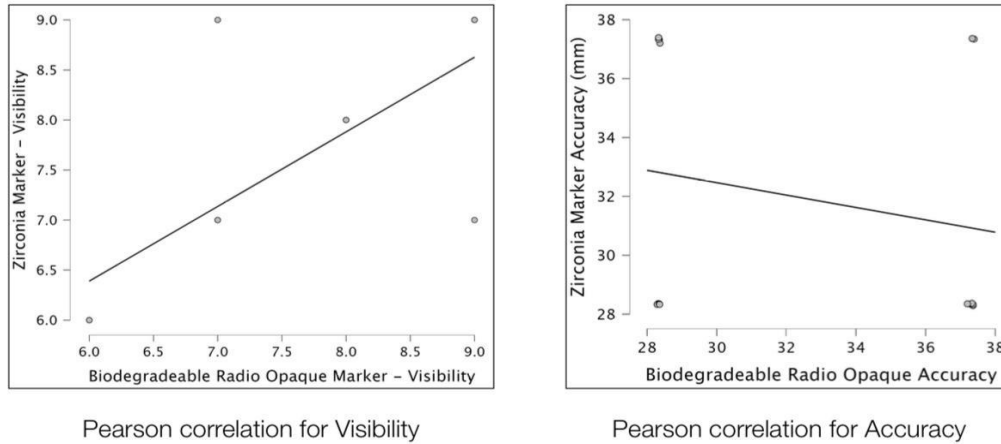
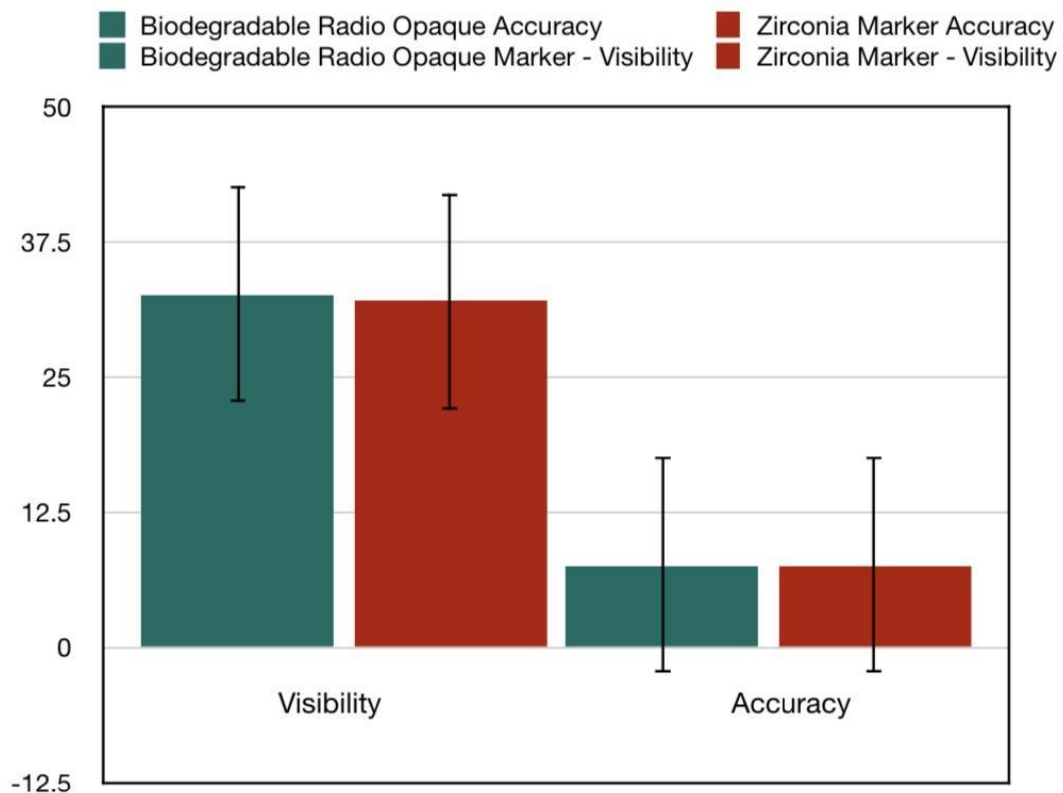


Figure-8: Scatterplot for Pearson correlation for visibility and accuracy



Graph-1: Comparing the visibility and accuracy

IV. DISCUSSION

It is challenging in dentistry to establish a technology for assessing the 3D fit of dental prostheses.(20) For this purpose, in this study, it was attempted to provide radiopacity to a fit-testing material through the addition of contrast agents.Zirconia, barium sulfate, and alumina powder, which were in widespread clinical use, were applied as contrast agents. Barium sulphate plays a vital role here.(21) Zirconia has been used in flaming all-ceramic crowns and full-contour restorations in recent years. Rominu et al. used it as a contrast agent and reported that an adhesive agent containing zirconia powder could be observed by CT. (22)

Barium sulfate has been added to gelatin,chitosan as a filler, and this improves both its mechanical properties and X-ray contrast. Alumina is widely used in fabricating and sandblasting dental prostheses.It is important for the added agents to disperse uniformly within the base material to enable uniform radiopacity. (23)Radiographic guides exist to provide information regarding the proposed implant placement, the positioning of future prostheses, and assistance with imaging the soft tissue positions. Radiopaque markers are required to improve X-ray absorption by self-expandable metal stents (SEMSs) to enable precise stent placement. Radiopaque markers are used in dentistry to help identify specific structures on an X-ray image. These marker appears as a bright white spot on the X-ray image, making it easier for the dentist to locate and identify certain structures.(24) Radiopaque markers can be used to help identify the position of dental implants, the location of impacted teeth, the presence of root canal fillings, and other structures of interest. They can also be used to help ensure that the X-ray image is properly oriented and aligned. In addition to metal markers, there are also other types of radiopaque markers used in dentistry, such as markers made from acrylic or composite resin. (25)

These markers may be more comfortable for the patient and can be easily removed after the X-ray is taken.In the fabrication of radiographic guides, a number of radiopaque materials have been used, including provisional restorative material like gutta percha, barium sulfate, radiopaque putties, lead oxide and metals such as amalgam and steel. Different techniques and materials have their specific advantages and disadvantages. Gutta percha is one of the simplest materials to use as it can be applied over existing prostheses or inserted into circular channels and over the tooth surfaces in the radiographic guide as markers. (26) The use of radiopaque teeth to create a surgical guide offers the advantage of displaying the complete 3-dimensional form of the tooth in the CBCT-generated volumetric image. The process for creating this type of guide again begins with the accurate mounting of diagnostic study casts. Now a days even radiopaque teeth are adapted and placed onto the cast to represent the position of the planned implant-related prostheses with acknowledgment of the estimated position of the planned implant.Lead oxide is also used as radiopaque nanoparticles but the major disadvantage were it's high solubility and toxicity. A radiopaque marker as a tape using Barium sulfate was developed as a radiopaque marker that outlines the size, position, and contours of the planned prosthesis in a CBCT image. (27)The brightness scores of these markers were also similar like other markers but had a significantly higher total brightness score because the Barium sulfate is available in the form of powdered particles, which enables it to be mixed with gelatin and chitosan. The fabricated material can be different diameters 6mm ,8mm. The advantage of these markers is that the manufacturing process is straightforward. Markers were prepared using sandwich technique, which provides a new means of achieving smooth uniform adhesiveness on the denture. This study demonstrated that our technique was able to accurately describe the location of placing implants. This technique has the advantage of being able to observe the percentage of magnification in a radiograph and can be used to locate ideal implant locations. This adhesive radiopaque marker helps to achieve better treatment planning,is relatively inexpensive and can instantly convert an existing complete or partial denture into a radiographic stent.(28)

The successful placement of dental implants relies heavily on precise planning and accurate execution. Radiographic and surgical stents play a crucial role in achieving this precision by providing visual and physical guides for implant placement. In this study, we compared a novel biodegradable radiopaque tape with a conventional zirconia marker in terms of visibility and accuracy.(29) The findings of this comparison provide valuable insights into the potential benefits and limitations of these materials in clinical practice.Radiographic visibility is a critical factor in evaluating the suitability of markers used in surgical stents. The zirconia marker, with its well-established radiopaque properties, demonstrated a slightly higher average visibility score compared to the biodegradable radiopaque tape. This finding is consistent with previous literature that highlights zirconia's excellent radiographic contrast (30,31).

Zirconia's high atomic number contributes to its ability to absorb X-rays effectively, making it highly visible on radiographs.However, the biodegradable radiopaque tape also showed high visibility scores, indicating its effectiveness as a radiographic marker. The inclusion of barium sulfate in the tape enhances its radiopacity, making it discernible on radiographs(32). While the visibility score of the tape was marginally lower than that of the zirconia marker, it was still within an acceptable range for clinical use. The slight difference in visibility may not be clinically significant, especially when considering the other benefits of the biodegradable tape.Accuracy in implant placement is paramount for ensuring optimal functional and esthetic outcomes (33). In this study, the biodegradable radiopaque tape demonstrated slightly better accuracy compared to the zirconia marker. The average deviation from the planned implant position was smaller for the tape, suggesting that it provides a more precise guide for implant placement.The consistency in accuracy observed with the biodegradable tape can be attributed to its ability to adhere firmly to the radiographic stent. The homogeneous distribution of barium sulfate within the gelatin and chitosan matrix ensures uniform radiopacity and stability (34). This stability is crucial during surgical procedures, as it minimizes the risk of marker displacement, which can compromise the accuracy of implant placement.The slightly lower accuracy observed with the zirconia marker may be due to its rigid nature. While zirconia offers excellent radiopacity, its rigidity can sometimes make it challenging to integrate seamlessly with the flexible radiographic

stents (35).

This integration challenge might lead to minor deviations in the placement of the marker, affecting the overall accuracy of the implant positioning. One of the significant advantages of the biodegradable radiopaque tape is its biocompatibility. The tape is composed of gelatin and chitosan, both of which are natural and biodegradable materials. Gelatin, derived from collagen, is widely used in medical and pharmaceutical applications due to its biocompatibility and biodegradability (36). Chitosan, a natural polysaccharide, has excellent biocompatibility, antimicrobial properties, and promotes wound healing (37). The use of these biodegradable materials in the radiopaque tape ensures that it does not elicit any adverse biological reactions. In contrast, zirconia, while biocompatible, is not biodegradable. Any residual zirconia particles left in the surgical site might not be absorbed by the body and could potentially interfere with the healing process (38). The biodegradable tape's ease of use is another notable advantage. Its flexible nature allows it to conform easily to the contours of the radiographic stent, ensuring a snug fit. This adaptability simplifies the process of converting a radiographic stent into a surgical guide (39).

The tape's adhesive properties, enhanced by the inclusion of gelatin and chitosan, ensure that it remains securely attached to the stent during the surgical procedure, reducing the risk of displacement. The Pearson correlation analysis provided further insights into the relationship between visibility and accuracy. For the biodegradable radiopaque tape, the Pearson correlation coefficient (r) was -0.583 with a p -value of 0.023 , indicating a statistically significant negative correlation. This suggests that as the visibility score increases, the accuracy improves. The significant correlation highlights the importance of visibility in achieving precise implant placement with the biodegradable tape. In contrast, the Pearson correlation coefficient for the zirconia marker was -0.459 with a p -value of 0.086 . This correlation, although negative, was not statistically significant. This result implies that other factors, in addition to visibility, may influence the accuracy of implant placement when using zirconia markers. These factors could include the rigidity of the marker and its integration with the stent. The findings of this study have several practical implications for clinical practice. The biodegradable radiopaque tape offers a promising alternative to zirconia markers for implant placement. Its comparable visibility, slightly better accuracy, and superior biocompatibility make it an attractive option for clinicians. The ease of integration with radiographic stents further enhances its utility in clinical settings. The use of biodegradable materials aligns with the growing trend towards sustainable and environmentally friendly medical practices.

By reducing the reliance on non-biodegradable materials like zirconia, the biodegradable tape contributes to more eco-friendly healthcare solutions. While the results of this study are promising, there are some limitations to consider. The sample size of 30, though adequate for preliminary analysis, may need to be expanded in future studies to confirm these findings across a broader population. Additionally, the long-term stability and performance of the biodegradable radiopaque tape need to be evaluated through *in vivo* studies. Future research could also explore the potential modifications to the composition of the biodegradable tape to enhance its radiopacity further and ensure even better integration with various types of radiographic stents. Investigating the use of other biodegradable materials and contrast agents could lead to the development of even more effective radiopaque markers.

V. CONCLUSION

A novel radiopaque marker as a tape was successfully developed via the use of Gelatin, chitosan, BaSO₄ and Cosmetic glue for adhesion. The radiopaque marker has flexible manipulation by adding gelatin, chitosan that have strong water-keeping ability, high viscosity to bind the BaSO₄ crystals together and maintain the integrity of the material, and the ability of lowering frictional resistance to improve the adhesiveness of the material. The Gelatin has high stability and can be used as a thickening and gelling agent. The BaSO₄ achieves the required properties radiocontrast imaging uses due to its water insolubility and radio-opaque properties. The Chitosan which is a natural biodegradable polysaccharide discloses an adhesive composition. In CBCT analysis shows that the radiopaque marker has appropriate radiopacity and creating precise data points helps to correlate the tooth position and tissue in relation to available bone and vital structures. In conclusion, the biodegradable radiopaque tape demonstrated comparable visibility and slightly better accuracy than the zirconia marker for implant placement. Its biocompatibility, ease of use, and strong correlation between visibility and accuracy make it a viable alternative to traditional zirconia markers. The findings of this study support the potential of biodegradable radiopaque tape as an innovative solution for enhancing the precision and success of dental implant procedures. As the field of implant dentistry continues to evolve, the adoption of such advanced materials could lead to improved patient outcomes and more sustainable clinical practices.

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