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Original Research Article

Breaking the code of guided implant surgery with an innovative blend of convenience & precision: A pilot study on accuracy of an ingenious 3d implant surgical guide

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A B S T R A C T

Statement of Problem: The aim in our pilot research study is to evaluate accuracy of implant placed using guided surgery with an ingeniously developed guide, therefore the deviation between the virtual planning and the postoperative implant position has to be evaluated.

Materials and Methods: 7 patients were randomly selected from the Out Patient Department of our hospital and 10 implants were placed in them with the help of an indigenously developed 3D surgical guide. Pre-operative & Post-operative CBCT was compared in a software for the evaluation of precision. Site specific comparative evaluation was done in 4 parameters i.e., entry deviation, apex deviation, depth deviation in single plane and angulation between long axis of placed and planned implants.

Results : The results were tabulated and standard statistical analyses were done. Mean ± Standard deviation of entry deviation were 0.4 ± 0.29 mm., exit deviation 0.7 ± 0.33 mm., angulation deviation 3 ± 1.7 deg. And depth deviation 0.2 ± 0.13 mm. All the P values were < 0.001. So statistically highly significant fewer chances of errors are seen in cases where this surgical guide was used.

Conclusion: This evidence backed ingeniously designed implant template reliably guides precise & predictable implant placement in each & every case thus promulgating the best care for all concept further with a vision for the future.

1. Introduction

Prosthetic rehabilitation with dental implants has gradually become a routine procedure with high implant survival rates and reliable predictability. The number of specialists and general practitioners placing implants with varying experience is rapidly increasing. To achieve high success rates, detailed clinical and radiological preoperative diagnosis & treatment planning are of paramount importance.[1,2]

Nowadays, cone beam computed tomography (CBCT), advanced technology at reasonable costs and low radiation dose made it possible to better visualize the underlying bone structures for a more precise implant rehabilitation comparing to the standard two-dimensional (2D) radiography. Proper implant position, "prosthetically driven," is fundamental in order to achieve an aesthetic and functional implant-supported restoration and can be analyzed and planned with the assistance of numerous types of dedicated software.[3]

Today, there are three practical ways to apply this technique in a clinical setting: guided surgery using drill guides processed by stereo lithographic rapid prototyping,

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computer-milled templates, or computer navigation systems. Computer-milled templates are fabricated by drilling the final position of the implants in the scanning template itself using a drilling machine. Computer navigation systems allow an intraoperative real-time bur tracking according to the preoperative planned trajectory.[4,5]

3D Guided implant surgery is a revolutionary surgical technique that takes digital treatment planning one step further with custom drilling templates. But it is a costly & technology dependent affair thus making it unavailable for most patients and clinicians.

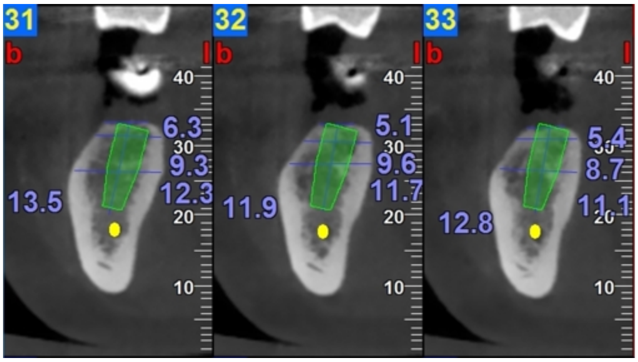


Fig. 1: CBCT Analysis

Figure 2a b

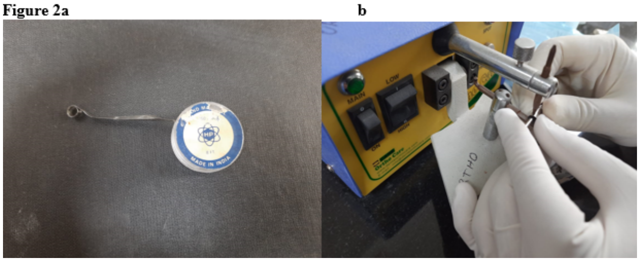
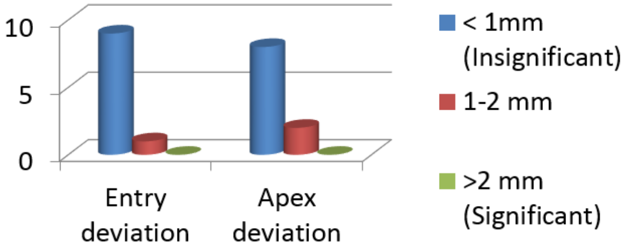


Fig. 2: (a)Orthodontic band (b) Spot band welder



Graph 1:

Figure 3a b

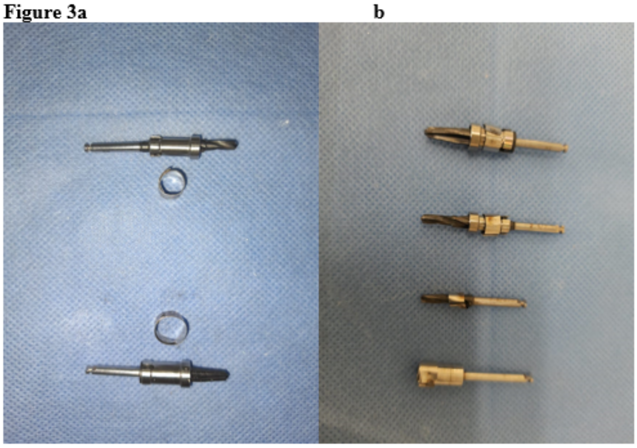


Fig. 3: (a).Guide sleeve with corresponding drills (b). Corresponding drills inserted inguide sleeves

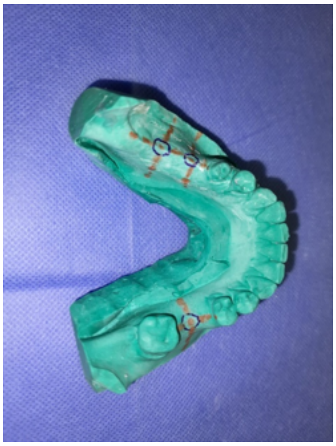


Fig. 4: Transfermarkings in cast

Fig. 5: Singleguide multiple sleeve

Table 1:

Sl no.	Site	Type of stent	Stent support	Entry deviation (mm.)	Apex deviation (mm.)	Angulation deviation (deg.)	Depth deviation (mm.)
1.	Mandible	Single	Tooth	0.3	0.6	2	0.2
2.	Mandible	Multiple	Tooth- tissue	0.1	0.4	1	0.1
3.	Mandible			0.3	0.6	3	0.2
4.	Mandible	Single	Tooth	0.5	1	1	0.3
5.	Mandible	Single	Tooth	0.5	0.9	5	0.3
6.	Mandible	Multiple	Tooth	0.0	0.1	1	0.0
7.	Maxilla	Multiple	Tooth	0.2	0.7	2	0.2
8.	Maxilla	Multiple	Tooth	0.4	0.8	4	0.3
9.	Maxilla	Single	Tooth- tissue	0.5	0.7	4	0.2
10.	Maxilla			1.1	1.4	6	0.5

Table 2:

	Mean	SD	68% CI	Min/Max
Entry deviation (mm.)	0.4	0.29	0.11- 0.69	0.0/1.1
Apex deviation (mm.)	0.7	0.33	0.37-1.03	0.1/1.4
Angulation deviation (deg.)	3	1.7	1.3-4.7	1/6
Depth deviation (mm.)	0.2	0.13	0.07-0.33	0.0/0.5

Fig. 6: Transfermarkings in multiple cast

Fig. 7: Colourcoded multiple guide

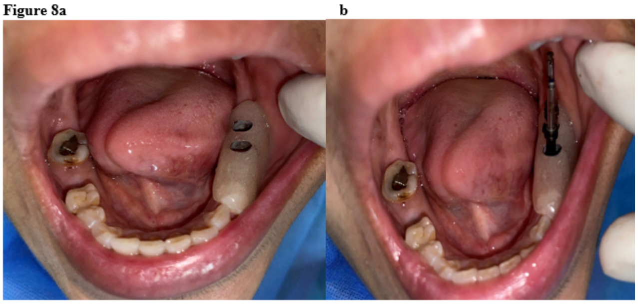


Fig. 8: (a).Guide in situ (b). Drills through guide in situ

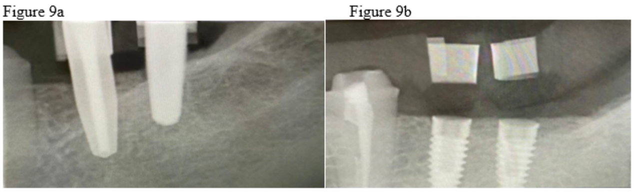


Fig. 9: (a).RVG of drills through guide in situ (b). RVG of implants placed with guide insitu

To break this barrier of logistics & disparity especially in developing countries, it was our endeavor to develop an indigenously developed 3D implant surgical guide. The aim in our research study was to evaluate accuracy using guided surgery with an ingeniously developed guide, thus the deviation between the virtual planning and the postoperative position has to be evaluated.

Fig. 10: Postoperative CBCT analysis

2. Materials and Methods

The aim in our research study is to evaluate accuracy using guided surgery with an indigenously developed guide, the deviation between the virtual planning and the postoperative position has to be evaluated. Also the difference between the level of precision is calculated between Maxilla Vs. Mandible, No. of implants placed, Type of Surgical guide and its Support.

2.1. Patients

7 patients were randomly selected from the Out Patient Department and 10 implants was placed in them from July 2020 to December 2020 were included in our study. The patients consisted of 6 males and 4 females with a mean age of 40 years (range 22 to 64 years). This study was conducted in accordance with the Institutional Ethics Committee.

2.2. Exclusion criteria

D4 bone, additional procedure requirement, limited mouth opening & presence of systemic disease were the exclusion criteria.

2.3. Clinical procedure

The clinical procedure would start with preoperative CBCT & virtual planning, followed by ingenious Surgical guide fabrication which would then be used for a flapless implant surgery. After which a post-operative CBCT scan would be done which will be used for comparative evaluation. Preoperative CBCT scan of all the patients is taken in our department with a Newtom CBCT scanner with customized FOV& minimum slice thickness of 0.3mm. Virtual Implant Planning is carried out in integrated NNT software where the initial site location, bone density and nerve tracing are carried out (Figure 1).

3 Dimensional bone evaluation is done in each specific site, following which the specific size and type of implant to be placed is chosen. In this case Paltop active conical implant was chosen from the digital library for simulation. Prosthetic driven 3D planning is also done to simulate the desirable prosthesis outcome. To transfer the planned implant positions onto the surgical guide measurements were taken from the adjacent tooth and the buccolingual inclinations from the cortical plates. Guide sleeves gives the guide a complete limiting design by controlling the angulation. 0.006 * 0.6 inch dimension easily available orthodontic band material is adapted around the maximum dimensions of the punch, pilot and final drills with stoppers multiple times (Figure 2 a). Following which it is spot welded with a spot band welder and later trimmed with a scissor to finish it (Figure 2 b).

The transfer markings are marked in the diagnostic cast onto which the sleeves are fixed with wax in desired angulation, which is later picked in autopolymerizing clear resin (Figure 3 a). In single guide multiple sleeves technique the maximum dimension sleeve is picked in acrylic and inside which the smaller sleeves are snugly fitted sequentially (Figure 3 b). During sequential drilling, each smaller diameter sleeve is removed after corresponding drilling and the same guide is used for larger diameter drilling.

To avoid the inconvenience of removing and placing the sleeves, in multiple guide technique each dimension sleeves are picked up in a different surgical guide which are also color coded for ease of identification (Figures 4 and 5).

Implant surgery were carried out following standard aseptic protocol under local anesthesia. The indigenously designed 3D implant guide is used in all steps of drilling i.e, from punch drill, pilot drill through to the final drill for precise implant placement (Figures 6, 7 and 8 a, b, Figure 9 a, b).

2.4. Comparative evaluation

Post-operative CBCT scan was done in our department where we could appreciate proper positioning of implants in respect to parallelism and safe distance from adjacent teeth, cortical walls and nerve.

2D superimposition was carried out by integrating preoperative and postoperative DICOM & STL images in the software. Placed implant position which is radiopaque in nature and color coded planned implant position can be appreciated. Following which measurements were taken and compared with planning dimensions.

The 3D superimposition was performed with point registration, by setting the landmark points on the neighboring teeth. The software then calculated the matrix for the best fit between stl files, treatment plan was set as reference, and the locations of the placed implants were compared to the virtually planned implants (Figure 10).

Site specific comparative evaluation was done in 4 parameters i.e. entry deviation, apex deviation, depth deviation in single plane and angulation between long axis of placed and planned implants.[6,7]

Sample size was divided into 60 to 40 percent in both mandible to maxilla and single to double implant placement. Single & Multiple surgical guide was equally used each in half of the cases. While tooth supported stent was used in $3/4^{th}$ of cases.

Results were recorded in tabulated form (Table 1). Columns of site, type of stent and Stent support was recorded along with 4 deviation parameters. In case of tooth supported guide, single tooth Anterior & posterior to the edentulous site was included in the design. While in tooth tissue supported guide 2-3 teeth was included in one side to compensate for soft tissue instability.

Statistical analysis i.e mean, standard deviation & 68% Confidence interval is calculated with a software.

3. Results

Mean central deviation at implant entry point and apex was 0.4 mm (standard error [SE] ±0.29 mm; 68% confidence interval [CI]: 0.11–0.69) and 0.7 mm (SE± 0.33 mm; 68% CI: 0.37–1.03), respectively. Mean angulation deviation was 3 degrees (SE ±1.7 degrees; 68% CI: 1.3–4.7) and the average depth deviation was 0.2 mm (SE ± 0.13 mm; 68% CI: 0.07–0.33). For the total number of implants placed, the maximum error was 1.1 mm at entry point, 1.4 mm at apex, 6 degrees in angular deviation, and 0.5 mm in depth deviation. All the P values were < 0.001 (Table 2). So statistically highly significant fewer chances of errors were seen in cases where this surgical guide was used. Non-significant differences in errors were more seen in maxilla than mandible, during multiple implant placement over single implant placement & in tooth tissue supported guide vis a vis completely tooth supported guide.

There is no consensus about the accuracy needed in computer-guided implantation, though a categorization was given by Valente et al which characterizes deviation exceeding 2 mm as clinically relevant, considering the generally recommended safety margin of 2 mm around vital structures while less than 1 mm produces clinically acceptable error (Graph 1).[8] In our pilot study 9 out of 10 cases in entry deviation and 8 out of 10 in exit was less than 1 mm while none was above 2mm. Thus giving a positive evidence support to our implant guide.

4. Discussion

Although surgical guide template is a quite commonly used practice, whether it can actually increase the accuracy of implants is not yet inconclusively proven though it definitely increases operator compliance. Nickenig et al. (2010) indicated that implant placement using a surgical implant guide was higher and significantly more precise than with free-hand insertion.[9] Brief et al. (2005) found that although image-guided insertion of implants was more accurate, the accuracy achieved by unguided placement was sufficient for most clinical situations.[10] It seems certain that a surgical guide could increase the accuracy of implant placement to some extent in every clinical scenario.

D'haese et al. calculated a mean deviation of 1.04 mm (95% CI: 0.20– 1.45) at the implant entry point and 1.64 mm (95% CI: 0.95–2.99) at the apex. Mean angular deviation calculated was 3.54 degrees (95% CI: 0.17–7.90).[6] Schneider et al. reported deviations of 1.07 mm (95% CI: 0.76– 1.22) at the implant entry point, 1.63 mm (95% CI: 1.26–2.00) at the apex, 0.43 mm (95% CI: 0.12–0.74) vertical, and between 5 and 6 degrees in angulation.[11] When examining in vivo studies, a meta-analysis of Van Assche et al. showed a mean deviation error of 1.0 mm (95% CI: 0.7–1.3) at the implant entry point, 1.4 mm (95% CI: 1.1–1.7) at the apex, and 4.2 degrees (95% CI: 3.6–5.0) in angulation.[12] The present in vivo study also shows similar accuracy. Potential errors leading to deviation of the implant position can be accumulated through a sequence of diagnostic and therapeutic series of procedures. Valente et al. described that single errors during image acquisition and data processing on average are less than 0.5 mm and errors in surgical template production are typically around 0.2 mm for templates fabricated with stereolithography.[8] Improper template position, template instability during drilling, tolerance of the guide sleeve, and removal of the template because of insufficient mouth opening of the patient are mentioned as additional errors that can be accumulated and thereby may result in a loss of accuracy.

Notably our ingenious guide which omits the expensive step of 3D printed template doesn't increase the errors and shows comparable results. Also, accuracy was less in maxilla due to comparative less denser bone while single implant placement showed higher accuracy due to better precision over the template fabrication and placement intra-operatively. Tooth-tissue supported template showed higher deviations due to soft tissue compressibility leading to instability of the template.

Advantages of our Surgical guide are that it is inexpensive and operator friendly. It is fabricated with easily available materials, independent of any labs/ manufacturer support even compatible with any implant system & 2D imaging giving predictable result every time with minimal invasive approach and not compromising on safety. Our Research was a pilot study, where random allocation of samples was done with multiple operator performed surgeries to reduce bias even further. The parameters chosen for comparative evaluation were on similar lines with the existing literature in the same topic. Though this study has a smaller sample size & is yet to be tried on completely edentulous cases. Hence, a Multicenter research project was required and is being taken up for further evaluation.

5. Conclusion

In accordance with the ethical principles of healthcare, it is a patient's right & doctor's obligation to provide best treatment modality to each & every patient. This novel technique ranks high in operator compliance and cost effectiveness. This evidence backed ingeniously designed implant template reliably guides precise & predictable implant placement in each & every case thus promulgating the best care for all concept further with a vision for the future. This new 3D implant guide can breech the economic hurdle between the larger and smaller prosthodontics practices which are especially very common in developing countries by providing an inexpensive template for reliable implant placement in every case.

6. Source of Funding

None.

7. Conflict of Interest

None.

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