

An innovative macro hybrid implant with a "body-shift" design: Results from a clinical study registry



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Introduction

One of the critical prerequisites for immediate tooth replacement therapy (ITRT) is achieving primary implant stability in extraction sockets enables the placement of immediate provisional restoration (1, 2). Wider-diameter implants are often used to gain high levels of stability; however, the design inherently minimizes the distance to the facial proximity as well as interproximal directions. Due to the anatomical limitations such as a thin bony wall and concavity at the apex of the facial bone, high incident of labial plate perforation has been reported (3, 4). Contrary, narrow-diameter implants provide greater space for facial and interproximal, however, lack of the level of primary stability required to support an immediate provisional restoration may occur by its limitation in engagement of the available bone of the extraction socket (5, 6).

Novel Macro-Hybrid Design Implant was introduced to overcome these dilemmas. The wider body in apical 60% allows high initial stability that enables ITRT and narrower coronal 40% of the body provide more distance to labial and interproximal bone therefore bony architecture of the socket can be protected (1, 4) [Figure 1]. This also provide more space for bone grafting which further helps maintain the labial plate (7, 8) [Figure 2].

Recent clinical and radiographic case-series reported high stability achieved by this design feature and better maintenance of labial plate, leading to long term esthetic results (1-4, 7, 9).

The aim of this study was to present one-year data from a prospective single arm multicenter study registry in clinical and radiographic evaluation including stability of ridge dimension, labial plate thickness and peri-implant soft tissue thickness.



Fig.1 Hybrid design implant with 'body-shift' concept. Narrower cylindrical thread on coronal section and wider tapered thread on apical section. Angulated screw channel provides optimal prosthetic angulation.

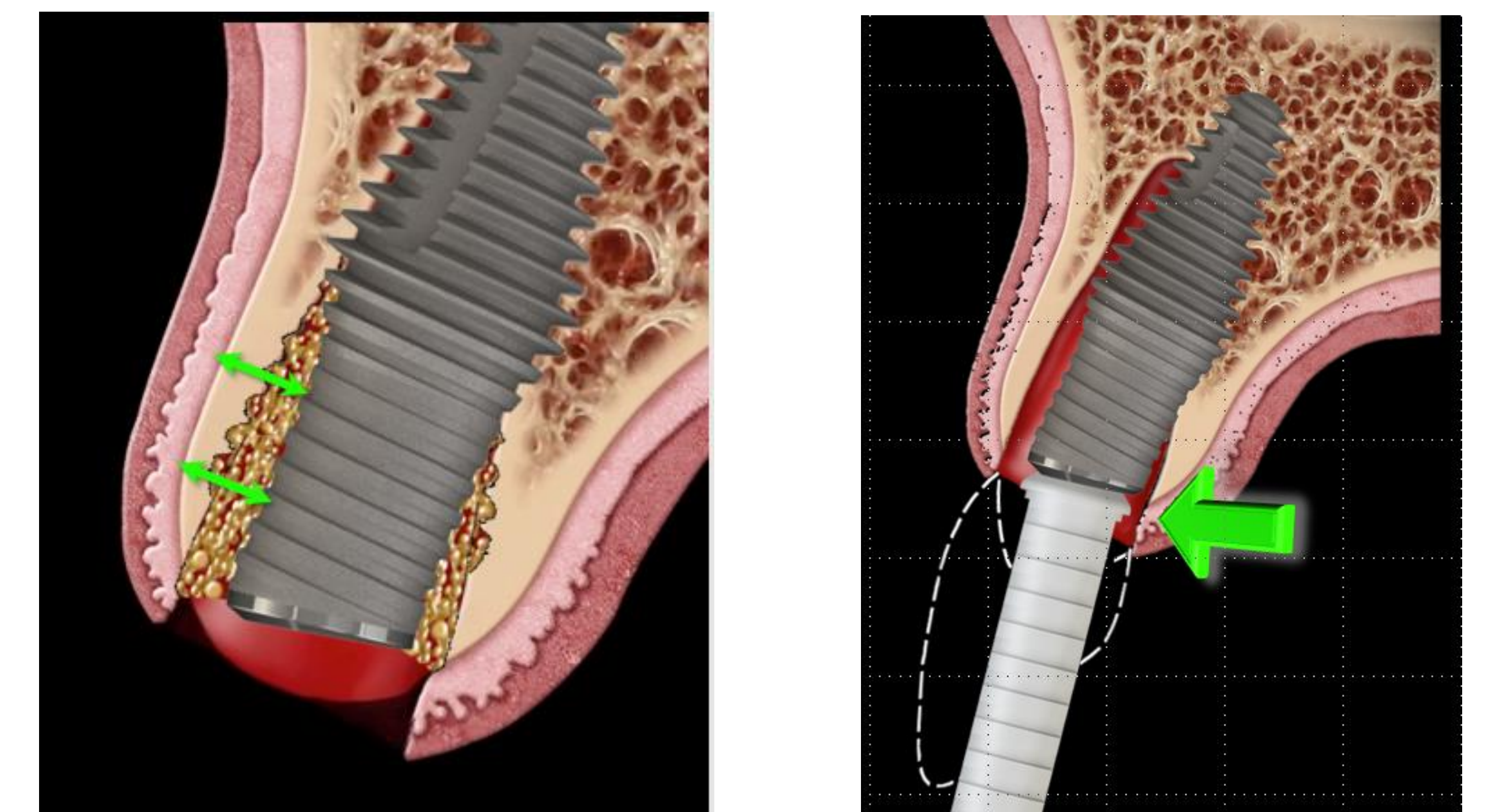


Fig.2. The Co-Axis hybrid implant allows a greater volume of graft materials to be placed into the gap because of its reduced diameter (0.5 – 0.75 mm) and shape in the coronal portion. Subcrestal angle correction design reduces the risk of apical perforation. The angle correction also enables the implant platform positions to be at the cingulum.



Materials and Methods

The data has been extracted from the Inverta Registry, a repository for clinical data of the patients treated Inverta implants (WIRB study# 1252367).

The data was extracted from the Registry based on the following criteria;

1. single tooth immediate tooth replacement therapy in maxillary incisors, canines and premolars
2. treated with Dual Zone technique (10) [Figure 3].

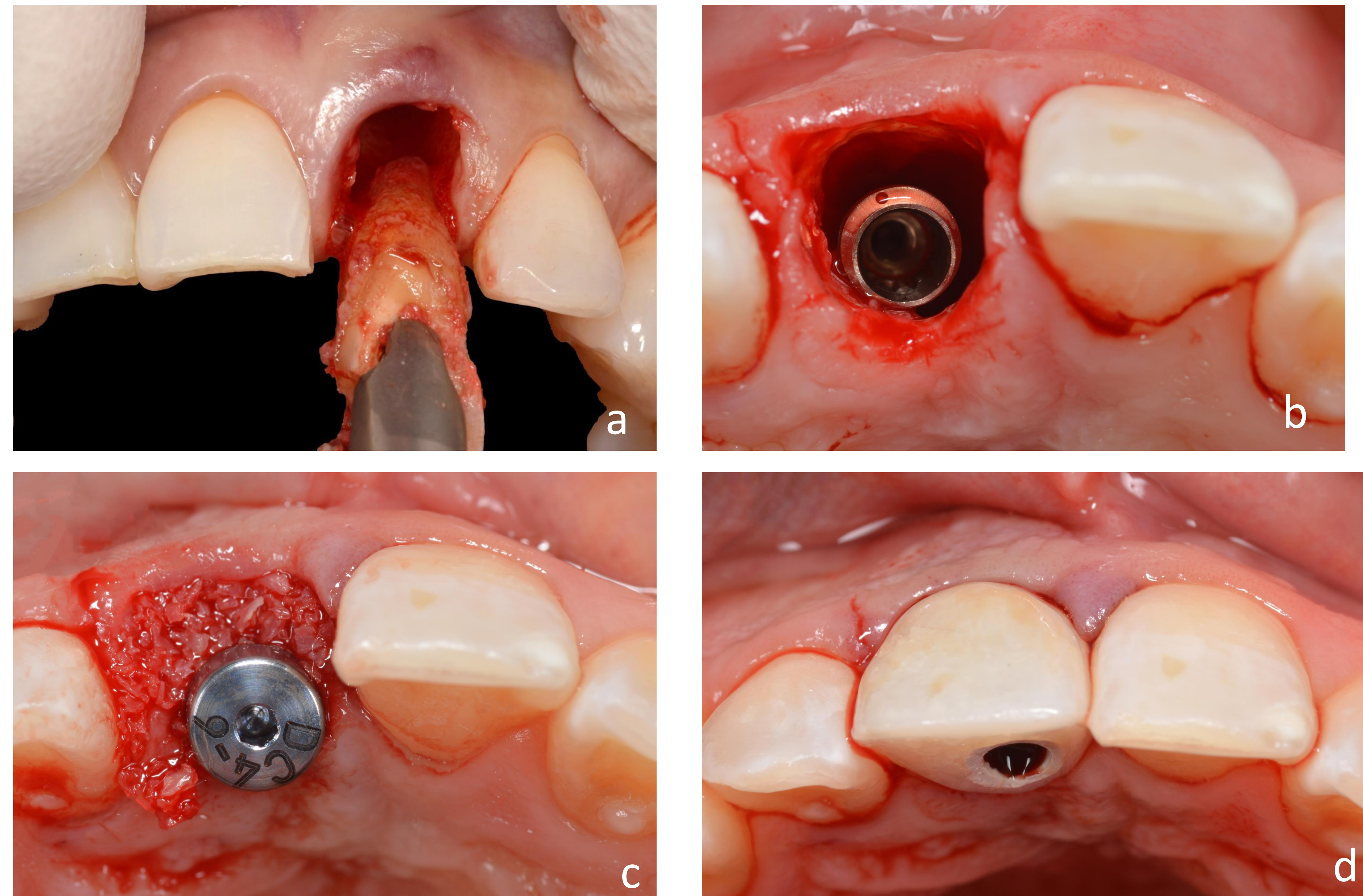


Fig.3: a) Flapless extraction; b) Implant placed 3-4 mm below FGM note the platform positioned at the gingulum; c) Grafting of the buccal gap. Healing abutment was placed to protect screw access hole. Note the graft material placed up to FGM; d) Placement of the provisional restoration. Excess graft material should be removed;

The study measurements include:

Radiographic Evaluation

Bucco-lingual ridge dimension: Bucco-lingual ridge dimension at two reference points, at FGM and 3 mm below were measured in the cone beam computed tomography (CBCT) taken preoperative and post-final restoration delivery.

Labial plate dimension (LPD): Measurements in millimeters (mm) were taken at two levels: L1 corresponded to the implant–abutment interface (IAI) equivalent to the midfacial labial plate bone crest; L2 matched the implant body roughly 5 mm from the IAI and bone crest coinciding with the upper portion of the INV implant transition zone, where the diameter and shape shifts from a tapered to cylindrical form, roughly 40% the implant length. Delivery [Figure 4].

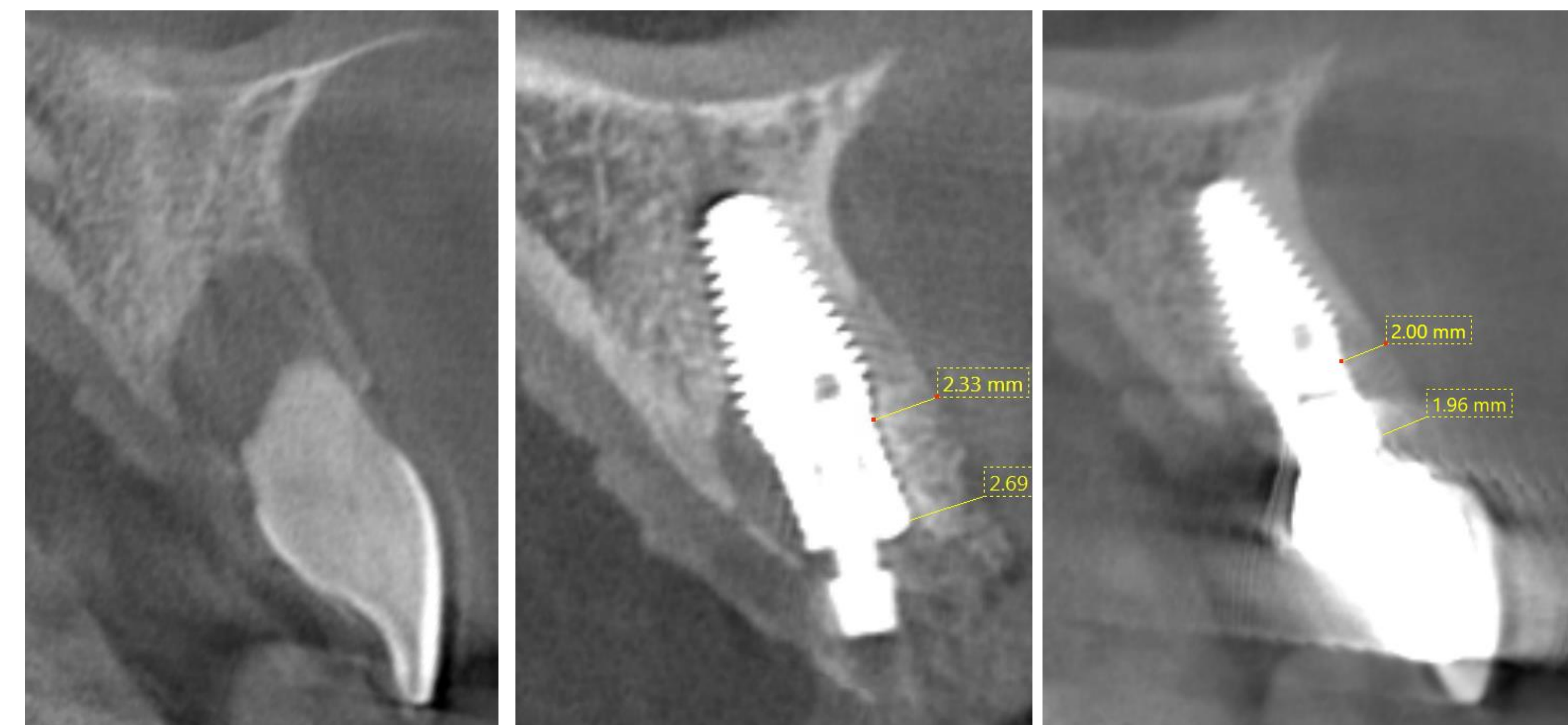


Fig.4: Labial plate dimension: pre-extraction, immediate post-implant placement with gap grafting and 6 months postoperative CBCTs. Changes in radiographic labial plate dimension at two points of references, L1 (implant platform) and L2 (4.5 to 5.5 mm from implant platform, respectively was calculated.



Clinical Evaluation

Implant primary stability: The insertion torque values were recorded in newton centimeters (Ncm) at the time of implant placement using an electric handpiece motor and manual torque wrench.

Pink esthetic score (PES): High-resolution photographic images were captured using a digital single lens reflex camera with a 105 mm macro lens and wireless twin (spot) flash system (D3200, R1C1, Nikon) at a 1:1 ratio and were rated by a single observer.

Peri-implant Soft Tissue Thickness (PISTT): The thickness of labial peri-implant soft tissue was measured at 2 mm below FGM using either intraoral scanner or scanned model from final impression [Figure 5].

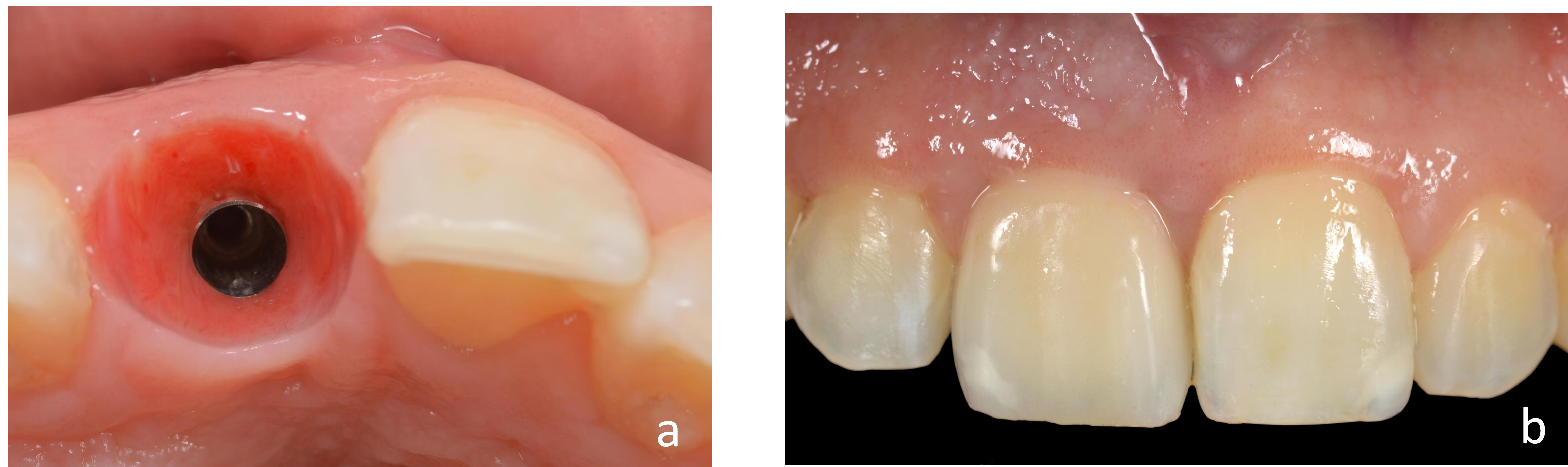


Figure 5: (a) 4 months postoperative peri-implant sulcus upon first removal of provisional restoration. Note the maintenance of labial-palatal ridge, (b) A final metal-ceramic screw-retained restoration was delivered 1-year post-surgery, (c) Using three-dimensional scanning of casts (CEREC inLab,Sirona) and three-dimensional software analysis (CEREC SW 4.3, Dentsply Sirona)facial mucosa thickness was measured 2.0 mm apical to the free gingival margin

Results

Radiographic Evaluation

Forty-two sets of CBCT taken at the time of ITRT and the delivery of final restoration were available for radiographic evaluation. The average ridge dimension at FGM and 3 mm below FGM at the time of ITRT were 7.54 (SD = 0.93) mm and 9.44 (SD = 2.36) mm, after the delivery of final restoration were 7.33 (SD = 0.91) mm and 9.85 (SD 2.39), respectively. Slight increase was noted at FGM 0.21 (SD = 1.03) mm and at 3mm 0.42 (SD = 0.80) mm but not statistically significant.

The average labial plate dimension at L1 and L2 at the time of ITRT were 2.81 (SD = 0.69) mm, 2.49 (SD = 0.76) mm and 2.27 (SD = 0.88) mm and 1.95 (SD = 0.95) mm, respectively. The average changes were 0.33 (SD = 0.41) mm at L1 and 0.34 (SD = 0.41) mm, respectively [Figure 7].

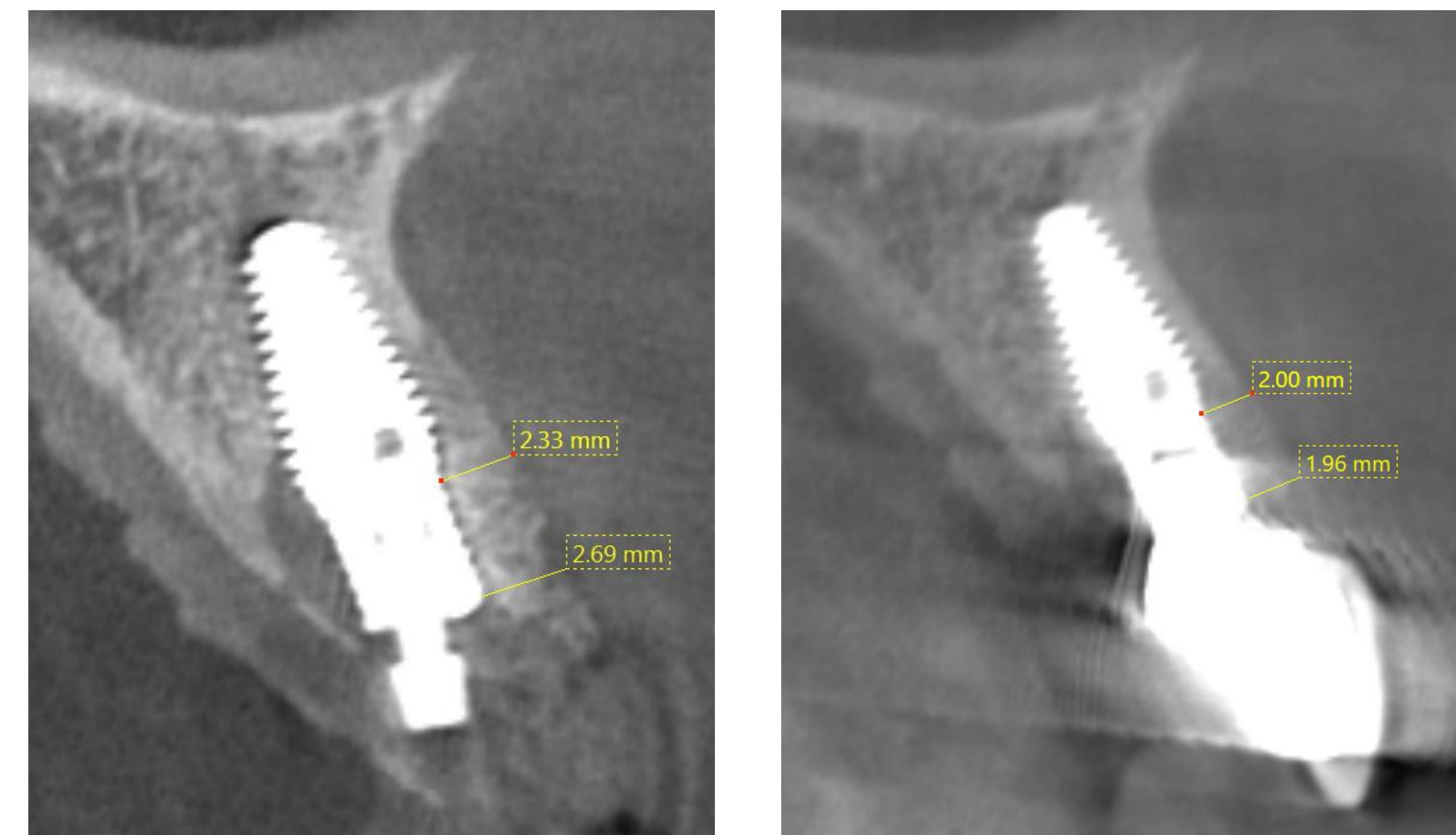


Figure 6: CBCT was immediate taken following implant placement, socket grafting, and temporary restoration. The labial plate dimension was recorded at L1 and L2 with values being above 2.0 mm at the time of immediate post-surgery. 1-year post-operative CBCT showing slight labial plate dimensional change at L1 and L2 with about a net width of 2.0 mm at both reference points.



Clinical Evaluation

Average PES was 12.79, with the distribution of 14 in 15 cases, 13 in 16 cases, 12 in 10 cases, 11 in 6 cases and 10 in one case.

Papilla height change was evaluated in 30 cases. No change in the interdental papillary height was noted in 26 cases [Figure 7, 8].

The average PISTT at the time of impression making for the final restoration was 3.29 (SD=0.73) mm. When divided by the phenotype, pretreatment thick phenotype group exhibited 3.22 (SD=0.73) mm and 3.34 (SD = 0.77) mm for think phenotype group.

Figure 7: Maintained papilla height noted compared to (a) before. (b) 1 tear post ITRT

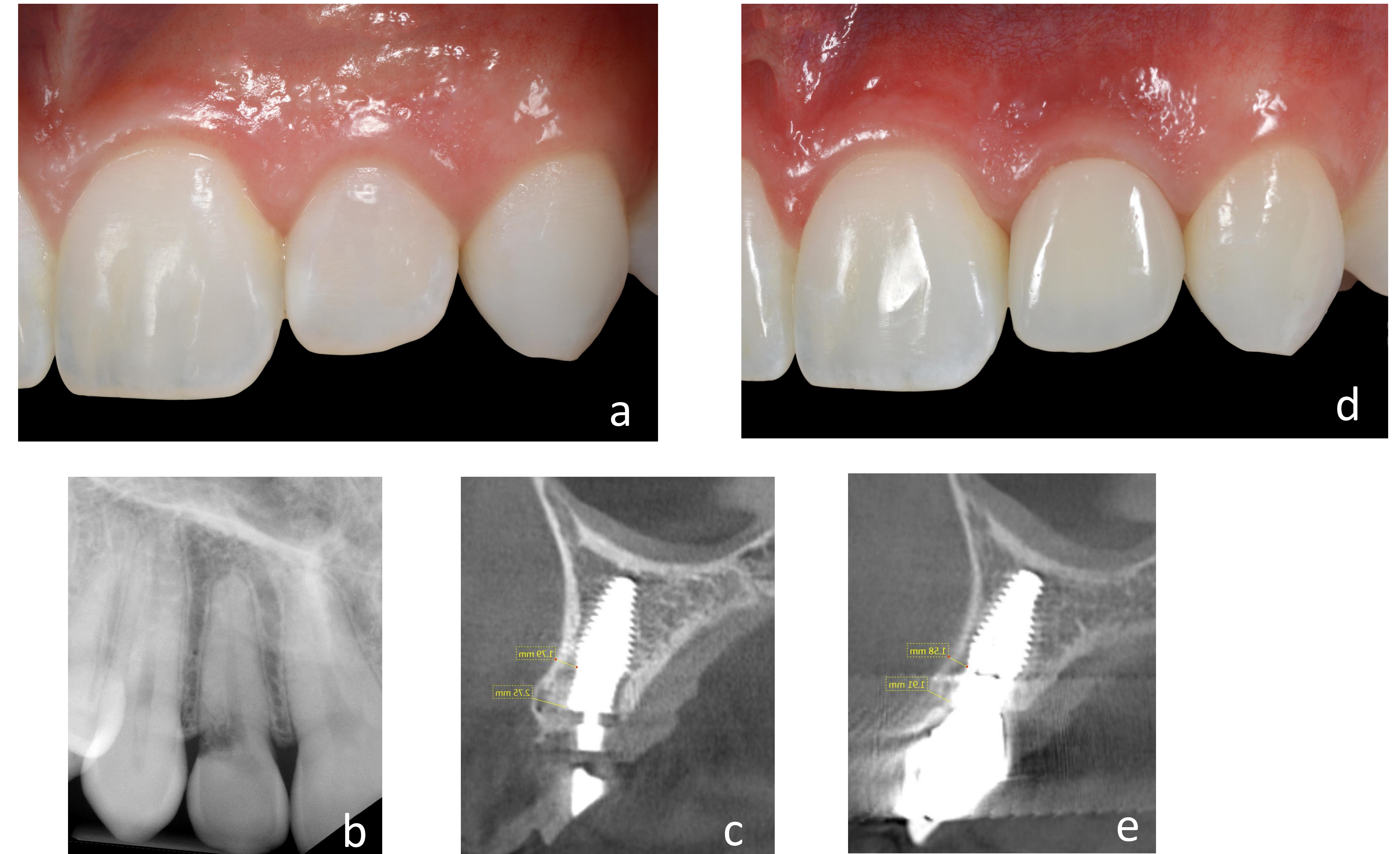


Figure 8: Case 2; Pre-operative intraoral image of a 28-year-old Caucasian female patient with a prior dental history of trauma tooth #10 (a &b). (c) Immediate post-treatment CBCT, (d) 1 year post ITRT clinical view, (e) 1 year post ITRT CBCT.

Conclusions

The hybrid implant evaluated in this prospective short-term study employs a “body shift” design concept with SAC that maximizes the benefit of a larger-diameter implant apically yet a smaller one coronally in postextraction sockets. These hybrid implants were able to achieve not only robust insertion torque values with prosthetic screw retention in immediate tooth replacement therapy, but also implant survival over a short-term period of 1 year.

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