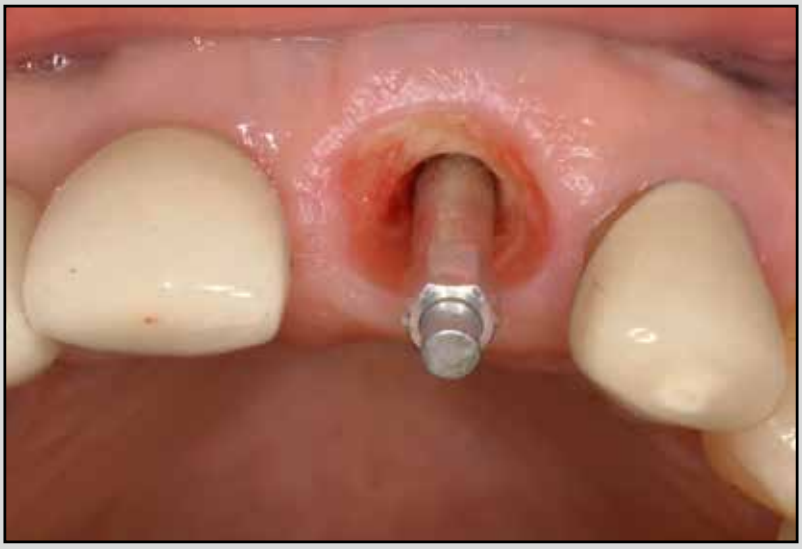

A Novel Implant Design for Immediate Extraction Sites: Determining Primary Stability

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Achieving primary stability is a critical challenge presented by immediate implant therapy. Surgeons often utilize wider, tapered implants for this purpose, or they use longer implants to achieve primary stability. Both strategies are associated with negative ramifications. Prosthetically guided implant placement must respect biologic principles, such as tooth-implant and implant-implant distance, gap space between the implant and the facial cortex, and, when possible, screw-retention of the prosthesis. A novel implant design geared toward achieving a predictable level of primary stability while adhering to the aforementioned physiologic principles was recently introduced. Both primary and secondary implant stability, along with hard and soft tissue stability, are demonstrated in this study of 107 consecutively placed implants. Rotational and axial stability can be produced with this newly designed implant, along with predictable osseointegration and tissue preservation.
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Immediate implant placement is a common and successful procedure, particularly in the anterior maxilla.[1] As this procedure evolved and provided that adequate primary stability is achieved, immediate provisional restoration[2] gives clinicians the opportunity *(1)* to preserve existing anatomy via flapless placement, and *(2)* to perform hard and soft tissue augmentation at time of surgery.[3] In most cases, the favorable anatomy of facially positioned root apices provides a palatal and apical region of bone for implant placement and stabilization.[4–7] Although bone is often available for implant insertion, the long axis of the implant frequently emerges through a plane coinciding with the incisal edge or facial third of the future restoration.[8] This often results in restorations requiring custom abutments and cement-retained restorations. Sung et al[9] demonstrated a high likelihood of facial bone perforation when implants are placed along the long axis of the root to be extracted. This facial angulation has also been demonstrated to reduce facial soft tissue thickness and, ultimately, esthetics.[9] Angle correction is often required if screw-retention of the final crown is desired. This can be accomplished either with a custom abutment, an angle-correction abutment, or a subcrestal angle correction (SAC) implant design (Fig 1).

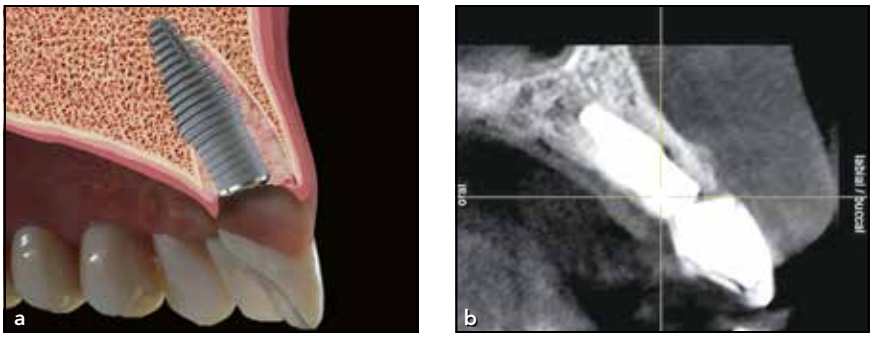


Fig 1 (a) *Diagram of the INV implant placed with a palatal bias and the SAC facilitating screw-retention. The apical half contains a tapered design with aggressive threads for greater stability. The narrow coronal half provides increased space for grafting between the implant and the facial socket wall.* (b) *A CBCT scan taken at the 1-year follow-up demonstrates the presence of an intact, thick facial cortex and coronal bone levels above the implant platform.*

Recently, a novel implant featuring an inverted body-shift (INV) design available with a 12-degree SAC was introduced for immediate tooth replacement therapy.[10,11] The apical half of this implant features a tapered design with aggressive cutting threads intended to achieve high levels of primary stability via high insertion torque. A preclinical study of this implant demonstrated average insertion torque values (ITVs) of 100 Ncm in extraction sites.[12] The coronal half of this novel implant features a cylindrical body with shallow threads and a smaller diameter (by about 1.0 mm circumferentially) compared to the widest portion of the tapered apical half. This design facilitates greater horizontal distance from the implant body to the facial bone and to the proximal surfaces of adjacent teeth and implants.

Biologically, this facilitates preservation of hard and soft tissues, allowing for augmentation and maintenance of esthetics.[13] It has been demonstrated that thinner facial bone is preserved by maintaining the buccal gap distance.[14,15] This concept has led to the use of narrower-diameter implants in the esthetic zone to avoid the facial cortical bone. A recent study by Levin[16] that investigated implant primary stability in extraction sockets using a parallel-walled implant design failed to demonstrate a significant correlation between ITV and the implant stability quotient (ISQ), with relatively low ITV and moderate ISQ values.

Therefore, the purpose of the present study was to evaluate 94 patients with 107 novel INV implants consecutively placed in extraction sockets and whether a correlation exists between ITV and ISQ at the time of placement and longitudinally in time. The null hypothesis was that no correlation would exist at implant placement or follow-up.

Methods and Materials

All 94 patients were treated in a private periodontal practice by one periodontist (B.P.L.). Following thorough recording of medical and dental histories, comprehensive periodontal examinations were performed to rule out any preexisting diseases and confirm patients were suitable candidates for immediate implant surgery. All patients signed informed consent. Patients were included in the study if they required at least one extraction of a single-rooted tooth, were medically healthy enough for surgery, and demonstrated a willingness to undergo treatment. Exclusion criteria included patients with generalized medical conditions that can negatively affect wound healing, such as uncontrolled diabetes mellitus, chemotherapy for malignancies, and intravenous bisphosphonate therapy. Teeth presenting with suppuration due to endodontic lesions, mucogingival deficiencies, or untreated periodontal disease were not included. Preoperative CBCT scans (Galileos, Dentsply Sirona) were acquired for all patients to confirm immediate implant placement with anticipation of achieving primary stability via engaging palatal and apical bone. With a 12-degree angle correction, the path of implant placement is biased palatally, avoiding perforation of the apical facial bone, and resulting in abutment screw access through the cingulum region of the restoration. In total, 107 INV implants were placed in premolar, canine, or incisor locations. Of the 107 implants, 95 were placed in maxillary sites, and 12 were placed in mandibular premolar

or canine positions. Implant stability was achieved with the tapered, apical portion of the INV implant, engaging the apical, palatal/lingual, and, to varying degrees, proximal bone of the extraction socket. Immediate placement was performed in a flapless manner, with the implant platform 3.0 to 4.0 mm apical to the facial gingival margin. This resulted in implant placement at the level of or slightly apical to the facial bone crest.

Insertion torque was measured with either electronic implant motors (Implantmed, W&H) or a manual torque wrench (Southern Implants) when necessary to fully seat the implant to its desired depth. Subsequently, wireless transducers (SmartPeg Type 38, Osstell) were manually attached to the implant with a specific plastic device designed to click when the transducer is tightened to 5 Ncm. Using a wireless device (Osstell Beacon, Osstell), ISQ values were recorded on the direct facial and palatal aspects of the transducer. The transducer was disconnected, and augmentation and temporization (when possible) were performed. Fifty-three implants were placed in anterior sites where patients requested a fixed, temporary restoration and a provisional restoration could be placed out of occlusal contact with the antagonist tooth or teeth. Some patients did not meet these criteria, and thus for 54 implants, removable transitional restorations were delivered postoperatively. Because all implants required an ITV of at least 20 Ncm to seat completely, removing the transducer did not rotate any implants. Augmentation was performed after recording ISQ values, as to not affect the accuracy of stability recordings in native bone. At approximately 10 to 16 weeks postsurgery, healing abutments or screw-retained provisional crowns were removed, and ISQ values were recorded a second time.

Statistical Analysis

For statistical analysis, the implants are considered statistically independent. The main outcome variable of this study is the Pearson correlation coefficient calculated between the ITV and mean ISQ values from the facial and palatal aspects at the two different time points, implant placement (ISQ1) and at a follow-up visit several months after surgery (ISQ2). Confirmation of the hypothesis would be a statistically significant correlation (R2) between ITV and ISQ at time of implant placement and follow-up with an R value greater than 0.00.

Case Examples

Patient 1

A 79-year-old man presented for extraction and immediate tooth replacement for the maxillary left central incisor (Fig 2a). Following sulcular incisions, the tooth was carefully extracted without flap-reflection. With a palatal bias, an INV implant (5.0 × 13.0 mm) with a 12-degree SAC was placed with an ITV of 70 Ncm (Fig 2b). ISQ1 values were 73 and 74 from the facial and palatal aspects, respectively (Fig 2c). Dual-zone bone grafting, described by Chu et al,[17] was performed with modifications: A composite graft of mineralized cortical bone allograft (Symbios, Dentsply Sirona) and xenograft (ZenGro, Southern Implants) were used in a 4:1 ratio. A screw-retained provisional crown was fabricated, and a dermal allograft 0.4 to 0.8 mm thick (PerioDerm, Dentsply Sirona) was adapted over the provisional abutment/crown and inserted into a subperiosteal pouch. After confirming no occlusal contact with the mandibular anterior teeth, a resorbable figure-eight suture was applied for hemostasis and gentle compression (Fig 2d). The postoperative radiograph demonstrated the novel body design of the implant and the adequate distance from the implant platform to the adjacent teeth (Fig 2e). At approximately 10 weeks postsurgery, the provisional crown was disconnected to obtain follow-up ISQ2 values, which were 76 at both facial and palatal aspects (Fig 2f). A screw-retained porcelain-fused-to-metal crown was fabricated by the patient's general dentist thereafter (Fig 2g).

Patient 2

A 73-year-old woman presented with chronic attachment loss, caries, and mobility associated with the maxillary right premolars. Prior nonsurgical and surgical periodontal therapy had been performed on these teeth, prolonging their lifespan; however, it was deemed necessary to extract and

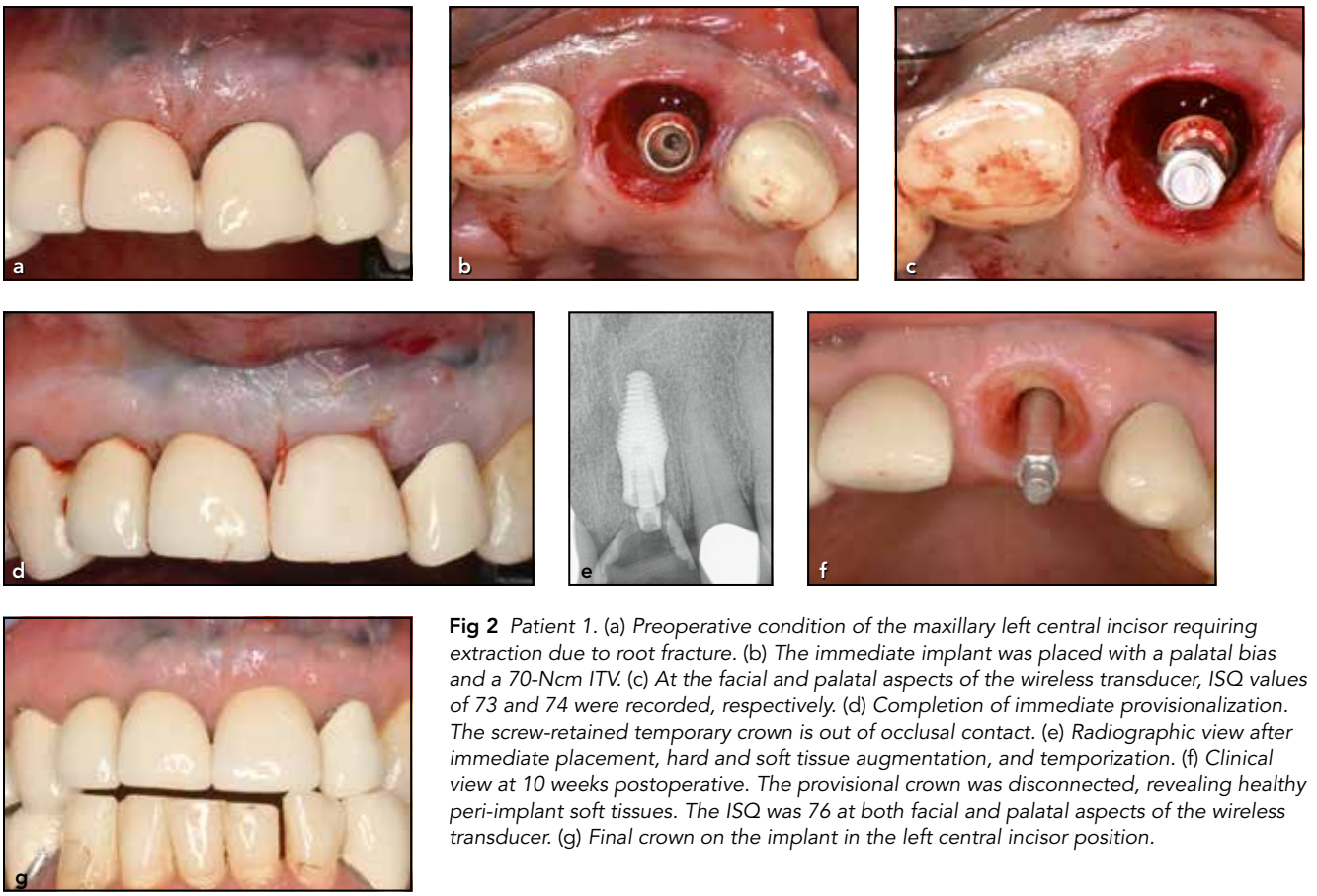


Fig 2 *Patient 1.* (a) *Preoperative condition of the maxillary left central incisor requiring extraction due to root fracture.* (b) *The immediate implant was placed with a palatal bias and a 70-Ncm ITV.* (c) *At the facial and palatal aspects of the wireless transducer, ISQ values of 73 and 74 were recorded, respectively.* (d) *Completion of immediate provisionalization. The screw-retained temporary crown is out of occlusal contact.* (e) *Radiographic view after immediate placement, hard and soft tissue augmentation, and temporization.* (f) *Clinical view at 10 weeks postoperative. The provisional crown was disconnected, revealing healthy peri-implant soft tissues. The ISQ was 76 at both facial and palatal aspects of the wireless transducer.* (g) *Final crown on the implant in the left central incisor position.*

replace both teeth due to unsuccessful disease control (Figs 3a and 3b). Following flapless extractions and socket debridement, both teeth were replaced with INV implants (4.5 × 13.0 mm), both with a 12-degree SAC (Fig 3c). The ITV was 60 Ncm for both implants. The facial ISQ1 values for the first and second premolars were 77 and 72, respectively; the palatal ISQ1 values for the same teeth were and 69 and 71, respectively (Fig 3d). Bone grafting was performed as done in the previous case, followed by application of a dermal allograft over two stock healing abutments via a subperiosteal tunneling[18] technique (Fig 3e). A postoperative radiograph (Fig 3f) demonstrates implant positioning, with the restorative platform 3 to 4 mm apical to the buccal gingival margins. At 10 weeks, the healing abutments were removed so follow-up ISQ values could be obtained (Fig 3g). The first-premolar implant demonstrated an increased ISQ, up to 77 facially and palatally. The ISQ2 values for the second premolar were 73 facially and palatally. The patient was then referred back to her dentist for restorative therapy. Two individual, screw-retained crowns were fabricated (Fig 3h). At 13 months postsurgery (approximately 9 months after delivery of the final restorations), proximal bone levels were positioned at the level of the implant platforms (Fig 3i).

Results

A total of 107 implants in 94 consecutively treated patients were evaluated in this study. The average ITV at time of immediate implant placement was 51.42 Ncm (range: 20 to 80 Ncm). The average facial ISQ1 value was 68.11 (range: 39 to 87), and the average palatal ISQ1 was 68.62 (range: 41 to 87). This data is represented in Fig 4. At the 10- to 16-week follow-up, the mean ISQ2 facial value was 74.10 (range: 33 to 85) and the mean ISQ2 palatal value

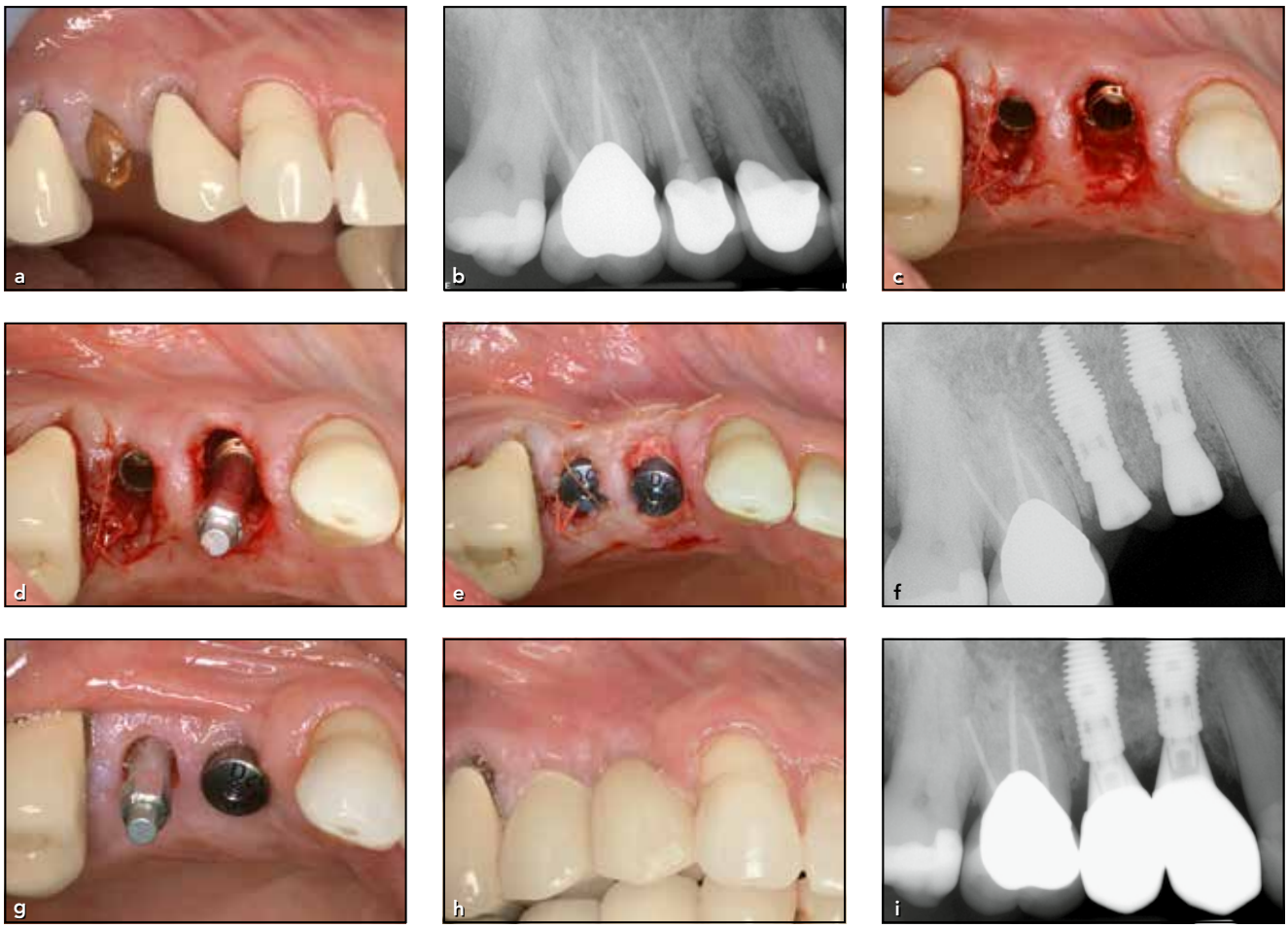


Fig 3 *Patient 2.* (a) *Preoperative clinical situation of the maxillary right first and second premolars. Due to advanced caries, the crown on the second premolar was lost.* (b) *Radiographic view of the preoperative situation. Significant attachment loss is evident around the first premolar.* (c) *Two INV implants with a 12-degree SAC were immediately placed at time of tooth extraction. Both implants required a 60-Ncm ITV for complete seating.* (d) *ISQs were recorded for both implants prior to augmentation procedures.* (e) *A composite bone graft of freeze-dried bone allograft/xenograft (4:1 ratio) was used to graft the hard and soft tissues around both implants. The area was covered with a dermal allograft via a subperiosteal tunneling technique.* (f) *Radiographic view at time of surgery, after immediate implant positioning.* (g) *Clinical view at 10 weeks postoperative. The ISQ values were recorded again, confirming secondary stability (osseointegration) of both implants.* (h) *Clinical view 9 months after delivery of the final restorations, consisting of two individual, screw-retained crowns.* (i) *Radiographic view 13 months postoperative. The bone levels are even with or slightly coronal to both implant platforms.*

was 73.74 (range: 23 to 85). This data is represented in Fig 5. Two recorded failures are represented by the low follow-up ISQ1 and ISQ2 scores of 23 and 57, respectively, at the facial aspect, and of 33 and 57, respectively, at the palatal aspect. The overall success rate of the implants is 98% (105 of 107). What is apparent from the data is that an increase of approximately 5 to 6 ISQ points occurs after a 10- to 16-week healing period after immediate placement in single-rooted extraction sockets, indicating a changeover from primary (mechanical) to secondary (biologic) stability.

A statistically significant correlation (R^2) existed between ITV and ISQ at time of implant placement (ISQ1), with facial- and palatal-aspect values of 0.0353 and 0.0549, respectively (Fig 6). Alternatively, a weak and nonsignificant correlation existed at the follow-up times between ITV and ISQ2, with R^2 values of 0.0001 and 0.0005 at the facial and palatal aspects, respectively (Fig 7).

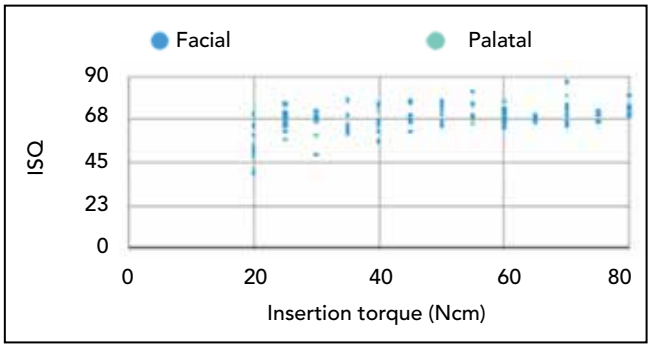


Fig 4 *Distribution of insertion torque and ISQ values at implant placement. A total of 107 implants were placed at time of tooth extraction.*

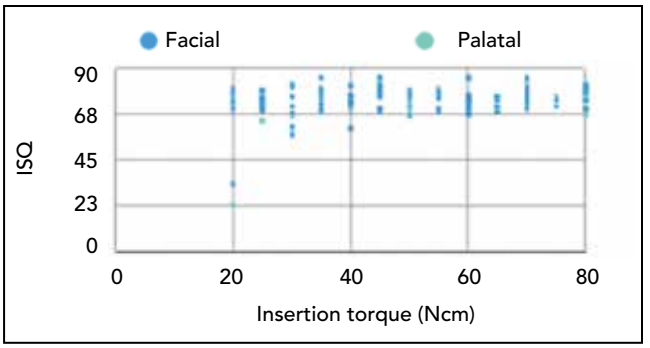
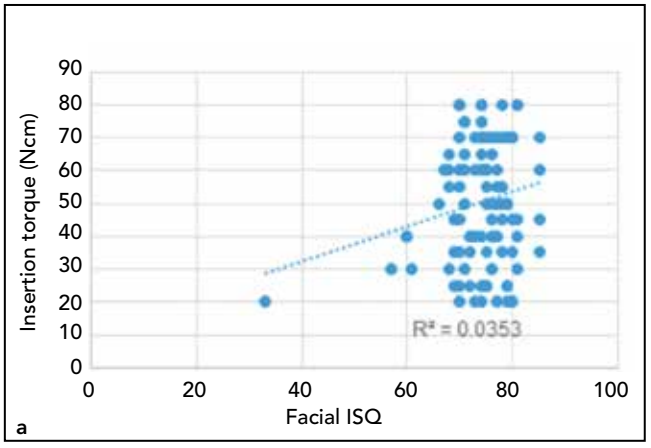


Fig 5 *Distribution of Insertion Torque and ISQ Values at follow-up (10 to 16 weeks).*



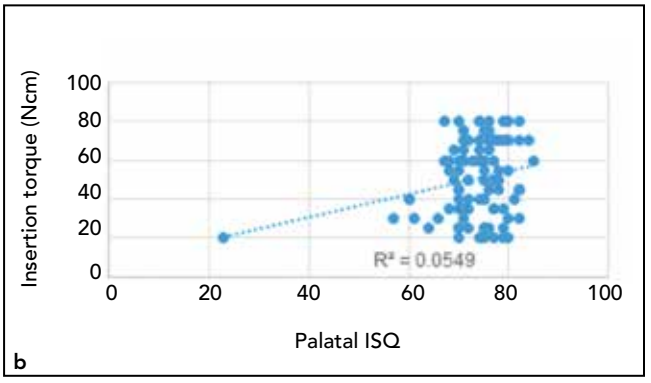


Fig 6 *A statistically significant correlation exists between insertion torque and ISQ1 values at the* (a) *facial and* (b) *palatal aspects for the 107 immediately placed implants.*

Discussion

Primary stability is commonly cited as a prerequisite for successful treatment. Insertion torque, measured in Ncm, is a measure of rotational or frictional stability, recorded at the time of implant insertion. Though this parameter has merit regarding the perception of mechanical stability at time of placement, it cannot be repeated at various times throughout the healing phase of treatment, and linear changes are not possible to detect. Numerous investigators have proposed various thresholds of ITV criteria.[19–21] Resonance frequency is another method for quantifying implant stability.[22] Rowan et al[23] used resonance frequency values or ISQs to ascertain implant stability and criteria for loading times. This is a repeatable test that measures the axial stability of the implant related to the stiffness of the surrounding bone and its quality, as well as to the stiffness of the implant-bone interface. It can also detect negative changes in stability longitudinally that may warrant additional healing times or revision therapy.[24]

A statistically significant correlation (R^2) existed between ITV and ISQ at time of implant placement (ISQ1), and the hypothesis statement was rejected. However, a weak and nonsignificant correlation existed at the follow-up times between ITV and ISQ2, partially accepting the null hypothesis.

Huwiler et al[25] followed implant placement over a 12-week time period, with serial measurements of implant stability via ISQ. The authors found an early decrease in stability at the 2- to 4-week period, followed by an increase toward and slightly

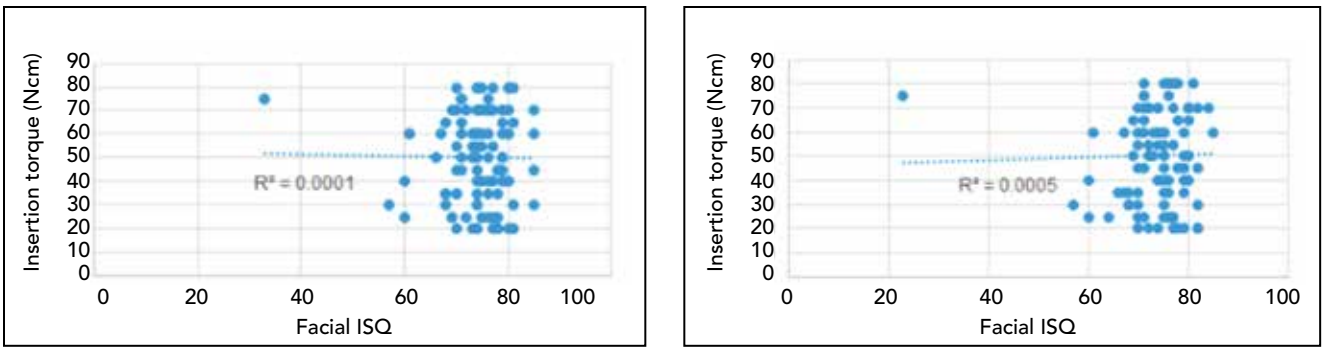


Fig 7 *A statistically significant correlation was absent between insertion torque and ISQ2 values at the* (a) *facial and* (b) *palatal aspects at the follow-up period (10 to 16 weeks).*

above the initial values at the conclusion of 12 weeks. It was speculated that this early "dip" followed by a gradual increase in ISQ represented the changeover from mechanical or frictional stability at placement to biologic stability or osseointegration. The implant used in the present study features several novel characteristics not seen in other implant designs, including the narrower, cylindrical coronal half of the implant. In extraction sockets, this portion of the implant is free from contacting the facial and, to lesser degrees, the proximal and palatal walls of the alveolus. It should therefore not be surprising that ISQ values were lower than one would anticipate, especially if the high ITVs correlated to ISQ. Initial mechanical stability is achieved with this implant, primarily via the wider, tapered, apical half of its body engaging in native bone. In a study evaluating ISQ 1 year after delivery of the final prostheses, Balleri et al[26] found that implants experiencing marginal bone loss had lower ISQ values compared to those not demonstrating marginal bone reduction. Though different in nature, this is consistent with immediate implants lacking cortical bone at the crest, contributing to implant stability. Another feature of the implant used in the present study is the wider, tapered apical half of the implant body. Atieh et al[27] demonstrated that wider, tapered implants achieve higher ISQ values in delayed and immediate mandibular molar sites.

The value of follow-up ISQ values in the present study, typically recorded at 10 to 16 weeks after implant placement, are in line with Huwiler et al,[25] who speculated that osseointegration or secondary stability is found at this time point. Because the ISQ values increased, it can be extrapolated in the present study that the coronal portion of the implant has osseointegrated, further validating the use of this implant for purposes of immediate tooth replacement. The relatively high ITVs support placing provisional crowns at time of surgery. The baseline ISQ measurement (ISQ1) serves as a starting point for monitoring the changeover from initial stability to secondary or biologic stability prior to definitive restoration.

A predictable increase in ISQ values occurred for most implants in the present study, indicating a trend toward greater implant stability via osseointegration or secondary stability for INV SAC implants placed in immediate extraction sites. The presence of a higher ITV does not necessarily correlate with greater secondary stability, as the majority of implants achieve similar ISQ values. This denotes the importance of a repeatable, noninvasive method of monitoring the transition of primary to secondary implant stability.

Compared to a similar study with parallel-walled implants,[16] almost twice the ITV was required to seat the present novel-designed implant in extraction sockets (average ITV = 28 Ncm; ITV in the present study = 51 Ncm), without any modification to osteotomy preparation, such as undersizing or bone condensing. Therefore, the present INV implant achieves significantly greater primary stability compared to traditional implants and may be preferable in extraction sockets, especially those selected for immediate temporization.

Conclusions

Several conclusions can be drawn from this study. The results of this study reject the null hypothesis, as a significant correlation between ITV and initial ISQ exists for this novel implant, which was designed to achieve high primary stability at immediate implant placement. However, this correlation was not significant at follow-up. More studies with larger patient populations should be conducted to confirm the present findings.

Acknowledgments

The authors declare no conflicts of interest.

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