Clinical and Radiographic Assessment of Circular Versus V-Shaped Implants in the Posterior Maxilla: A Randomised Controlled Trial

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Abstract:

A new implant with a triangular neck was recently introduced to provide a better environment for peri-implant bone. The primary objective of this study was to compare clinical and radiological outcomes of circular (C1) *versus* V-shaped (V3) implants 1-year after loading. The secondary objectives were to assess the posterior Pink Esthetic Score (pPES) and patient satisfaction.

A total of 34 implants, 17 of each group, were placed in 34 patients. Immediately after surgery and 1 year after final restoration, a cone beam CT (CBCT) was performed to assess proximal bone remodelling and buccal bone thickness. Furthermore, pPES and patient-reported outcome measures were recorded.

The mean peri-implant proximal bone remodelling from baseline to 1-year after loading were 0.22 (min: 0 – max: 0.79) and 0.32 (min: 0 – max: 2.8) mm for the V3 and the C1 group, respectively. No statistical significant difference was observed between the 2 groups (p=0.25). Peri-implant remodelling exceeding 2 mm was observed in a single implant in the C1 group leading to an implant success rate of 94.1% and 100% respectively for the circular and V-shaped group. However, no statistical difference was observed between the 2 groups (p=0.27). Buccal bone thickness remained stable and results were not statistically different between the 2 groups. The pPES (V3: 8.9 ± 2.3– C1: 8.7± 2.0) and patient satisfaction were similar.

Both circular and V-shaped implants present excellent clinical outcomes. Although not significant, a slightly higher implant success rate was found with the V-shaped design after 1 year of loading.

Clinical trial registration number: NCT02591706

Keywords: implant design, implant success, buccal bone thickness, posterior Pink Esthetic Score, patient satisfaction

Introduction

The success of dental implant osseointegration has been demonstrated over the last 50 years and millions of patients have benefited from implant-supported oral rehabilitations (Berglundh et al., 2002; Pjetursson et al., 2007). Currently, the main challenge is to maintain the stability of the peri-implant bone level over time and to prevent peri-implant disease (De Bruyn et al., 2013). An early peri-implant bone remodelling can occur for different reasons, and can lead to an opportunity for bacterial colonisation of the rough surface and therefore initiate peri-implantitis.

Several factors influence those early peri-implant bone losses, such as soft tissue thickness in the implant site (Van Eekeren 2016; Akcali et al., 2016), buccal bone thickness (Spray et al., 2000; Buser et al., 2004), repeated unscrewing of the transgingival components (Rompen 2012; Luongo et al., 2015; Becker et al. 2012), undetected subgingival cement excess (Linkevicius et al. 2011; Linkevicius et al., 2013a, 2013b; Vindasiute 2015, Staubli et al., 2017), and also the design of the implant-abutment connection. The use of platform-switching implants has been widely suggested to limit early peri-implant bone loss (Atieh et al., 2010; Al-Nsour et al., 2012; Annibali et al., 2012, Santiago et al., 2016) in comparison with butt-joint connections (Sasada and Cochran, 2017).

According to a preclinical study, the implant neck design could also influence marginal bone stability. A new implant with a triangular neck (V-shape) in its coronal portion was recently introduced in order to provide a better environment for the peri-implant bone. The triangular implant neck design leaves some spaces to provide a reservoir for blood support and to offer compression-free areas reducing stress on the crestal bone, which ensures ideal conditions for osseointegration. Moreover, by placing the flat part of the neck in the buccal aspect, the buccal bone thickness would be enhanced. Finally, the V-shaped implant presents an internal conical connection that permits formation of an optimal seal against bacterial colonisation and allows platform switching. However, the potential benefit of the V-shape implant design has never been investigated clinically.

The primary objective of this randomised controlled trial was to compare implant survival and success rates of circular (C1) versus V-shaped implants (V3) after a 1-year follow-up period. The secondary objectives were to assess the buccal hard tissue thickness and proximal bone levels. Finally, aesthetical aspects and patient reported outcome measures in each group were assessed.

Materials and methods

Study design

This study was designed as a randomised controlled trial comparing 2 dental implants with different neck configurations (**figure 1**). Thirty-four consecutive patients from the Department of Periodontology and Oral Surgery at the University of Liege, Belgium were enrolled from March 2015 to January 2016. All patients needed replacement of a single hopeless tooth in the maxilla and were seeking implant therapy. Three experienced surgeons were involved in the surgical procedures. All clinical parameters and outcomes were recorded at implant placement, after 4 months and at 1 year after the final restoration. The study protocol was approved by the Ethical Committee of the University Hospital of the University of Liège, Belgium (file number: B707201423142). The study was registered on clinicaltrial.gov (file number: NCT02591706), and was performed according to the CONSORT statement for transparent reporting of randomised clinical trials (http://www.consort-statement.org/).

Study population

Each of the patients met the following inclusion criteria: good general health (ASA I, II), 12-week healing period after extraction or loss of tooth, at least 10 mm and 6 mm of bone in the vertical and bucco-lingual dimensions, respectively, aged >18 years old or with signed approval by the parents or guardians, cigarette smoking status of <10 cigarettes per day, and signed informed consent. Exclusion criteria were as follows: use of bisphosphonate drugs intravenously, infection (local or systemic), uncontrolled diabetes, current breastfeeding, pregnancy, autoimmune disease that requires medical treatment, alcoholism and immunodeficiency.

Clinical procedures

Pre-treatment evaluation

Prospective participants were screened for enrolment in the study according to the inclusion and exclusion criteria. Participants who complied with the inclusion criteria were enrolled in the study and were provided with written information concerning the study requirements and possible risks. Patients were examined clinically using a cone beam CT scan to ensure that they complied with the requirements of the study.

Surgical procedures

All subjects received pre-operative antibiotic (amoxicillin 2 g, or if allergic, clindamycin, 600 mg). After local anaesthesia, a crestal incision was made above the treatment site and full thickness flaps were reflected to allow access to the site. The implantation procedure was carried out according to a standard surgical protocol and according to the manufacturers' protocol. Patients were randomly assigned to 1 of the 2 groups after flap opening using the software S-plus version 8.1 (TIBCO Software Inc., Palo Alto, USA) and were treated similarly. They remained unaware of the allocation throughout the study. The implant stability was measured using the wrench key and recorded in Ncm. Transgingival healing abutments were placed for a period of 4 months. The area was sutured with thin nylon sutures for a primary passive fit closure. Immediately after surgery a standard parallel periapical X-ray was taken, in order to index the level of the implant in the apico-coronal direction and a CBCT was performed in the area of interest to assess hard tissue volume.

Post-operative instructions and follow-up

Patients were instructed to rinse twice daily with an aqueous solution of 0.2% chlorhexidine. In addition, analgesics (400 mg Ibuprofen up to 4/d) were prescribed for the next 2 days according to individual needs. Patients were also instructed to refrain from mechanical plaque removal in the area of implantation for 1 week. The sutures were removed after 10 to 14 days. After a healing period of at least 4 months, patients received restoration with screw-retained crowns made of Zirconia framework veneered with cosmetic ceramic. The crowns were bonded on titanium bases with adhesive resin composites (RelyX Ultimate®, 3M, Minneapolis, MN, USA) of various heights according to the trans-mucosal thickness. The final visit was scheduled 1 year after the final restoration. At each appointment, patients received instructions to improve their oral hygiene if needed.

Data Collection

Radiographic measurements

Peri-implant bone remodelling on the mesial and distal sides was assessed based on parallel CBCTs performed immediately after surgery and 1 year after the final prosthetic restoration using the image-processing software Image J64 (National Institutes of Health, Bethesda, MD, USA).

On the buccal side, bone thickness was measured on 3 points (implant neck level (0), 2 (-2) and 4 mm (-4) apically to the implant neck). Changes in bone thickness were assessed using the software Jaw Bone Quant 2012 (Medical Imaging Research Centre, Leuven, Belgium).

Implant success

Implant success was evaluated according to Albrektsson et al (1986). The implant was considered a success if the following parameters were achieved: no mobility of the implant when tested, no radiographic peri-implant radiolucency, bone loss inferior to 1 to 1.5 mm in the first year and 0.2 mm annually following the first year of loading and no persistent pain, discomfort or infection. Peri-implant soft tissue health was also assessed by scoring peri-implant bleeding on probing (BOP): 0 = no bleeding on probing, 1 = slight bleeding, 2 = spontaneous bleeding.

Posterior Pink Esthetic Score (pPES)

As the PES introduced by Fürhauser et al (2005) was described to assess soft tissue quality around a single-tooth implant in the aesthetic area, a modified PES was used here for the posterior region: the variables “soft tissue colour” and “soft tissue texture” were combined together into “soft tissue appearance”. This new index was defined as the posterior Pink Esthetic Score (pPES; **Table I**).

Directly after the prosthetic procedures and at 1 year after the final restoration, patients were evaluated for aesthetic outcomes using the pPES index. A score of 2, 1, or 0 was assigned to each pPES parameter.

Patient-reported outcome measures (PROMs)

Patient-related data was recorded using a self-reporting visual analogue scale questionnaire that employed a graduated scale of 0 to 10. The following parameters were collected: (i) pain level during treatment and (ii) at implant placement (1=low to 10=high), (iii) implant sensation compared with contralateral natural teeth (1=not similar to 10=very similar), (iv) general aesthetic result (1=not satisfied to 10=very satisfied) and (v) implant aesthetic compared to contralateral natural teeth (1=not similar to 10=very similar). Additionally, the patients were asked if they would redo the treatment (1=not at all to 10=absolutely).

Statistical Analyses

Results were summarised as mean and standard deviation (SD) for quantitative variables and as frequency tables for categorical findings at each time point. Longitudinal data were displayed graphically and analysed by the general linear mixed model, which accounts for repeated values within patients. Success rates were calculated and associated with 95% confidence intervals (95%CI). The sample size was determined to reach a level of power of 80%. The significance level was set at 5% ($P<0.05$). Data were analysed with the SAS (SAS Institute, Cary, USA) and S-PLUS statistical software.

Results

Patient characteristics

A total of 59 patients were examined for potential inclusion in the present study. Of these 59 patients, 34 patients met the inclusion criteria of the present study (**figure 2**). Among the 34 patients included, 24 were female (71%) and 10 were male (29%), with a mean age of 47 years (ranging from 21 to 66 years). They were equally distributed within the control and the test groups. No patients dropped out of this study. Patient-related and implant-related descriptive analyses are displayed in **table II**.

Clinical parameters

Implant survival and success rates

Surgical procedures for the 34 patients were performed according to the study protocol. Three implants (2 C1, 1 V3) out of 34 did not reach an insertion torque of at least 15 Ncm and were therefore submerged and uncovered after 3 months. The 34 implants were followed for a period of 1 year after the crown placement. No implants failed over the follow-up period, leading to an implant survival rate of 100%.

The mean proximal peri-implant bone remodelling from baseline to 1 year post loading were 0.22 (min: 0 – max: 0.79) and 0.32 (min: 0 – max: 2.81) mm respectively for the V-shaped (V3) and for circular (C1) implants. No statistically significant difference was observed between the 2 groups ($p=0.25$). Peri-implant remodelling exceeding 1.5 mm was observed in a single implant in the C1 group leading to an implant success rate of 94.1%

and 100% respectively for the circular and V-shaped group; however, no statistical differences were observed between the 2 groups (p=0.27). Details are available in **table III**.

Out of the 34 evaluated implants, slight bleeding on probing was found on 5 circular (41%) and 3 V-shape (18%) implants and no implants displayed spontaneous bleeding (**table IV**). Clinical parameters are displayed in **figures 3** and **4**.

Buccal hard tissue thickness

At baseline (post-surgery), no statistical difference between the 2 groups was observed in terms of buccal bone thickness at all measured levels (0, -2, -4mm; **table V**). From baseline to the 1-year follow-up, the buccal bone thickness was considered as statistically identical in the 2 groups (stable thickness) (**Figure 5**).

Patient reported outcome measures (PROMs)

Patients from the two groups recognized a significant aesthetic and comfort improvement from baseline to 1 year. Regarding all criteria recorded by the VAS, no significant differences were observed between the test (42 ± 1.768) and control (41 ± 3.00) groups (p = 0.25).

Posterior Pink Esthetic Score (pPES)

The overall pPES scores were equivalent in the control and in test group (V3: 8.9 ± 2.3– C1: 8.7± 2.0) (p = 0,45). Details for each variable are expressed in **figure 6**.

Discussion

The objective of the present randomised controlled trial was to compare clinical outcomes for circular versus triangular neck implants, by assessing implant survival, peri-implant bone remodelling and peri-implant soft tissue health. To our knowledge, this is the first clinical study comparing a traditional and a triangular neck shape of

implants. The 2 tested groups were very homogeneous, since the patients were equally distributed between the control and test groups.

Implant success/survival

After 1 year of loading, both implant designs yielded a 100% survival rate: on average, peri-implant bone loss was inferior to 0.5 mm. This minimal peri-implant bone remodelling is comparable with that described in the literature when using platform-switching implants (Canullo, 2010; Atieh et al., 2010; Al-Nsour et al., 2012; Santiago et al., 2016). However, higher implant success rate (100% versus 94.1%) was found for the V-shaped implants, although it was not found to be significant. However, this should be interpreted cautiously because the difference is based on a single implant displaying a 2.8 mm bone loss in the C-shape group. This loss can be the consequence of other confounding factors irrespective of the implant neck design. For example, the inconsistent height of the titanium bases may have an influence on crestal bone loss as described by some authors (Galindo Moreno et al., 2014, 2016; Nóvoa et al., 2017; Blanco et al., 2018).

In the present study, all measurements for proximal peri-implant bone remodelling were carried out based on CBCT images because 3-D imaging was anyways performed for the buccal bone thickness measurements. Indeed, it has been shown that measurements of the peri-implant bone level on intraoral non-standardised X-rays can be distorted according to the angulation of the radiological film (Sewerin, 1990; Benn, 1992; Malloy et al., 2017) and measurements by CBCT were considered more accurate by some authors (Pinsky et al., 2006; Timock et al., 2011)

As suggested by recent European Federation of Periodontology consensus statements, peri-implant soft tissue health is an important criterion for implant success (Tonetti et al., 2015), and bleeding on probing may be the first indicator of peri-implant disease such as mucositis or peri-implantitis (Jepsen et al., 1996, 2015; Lindhe and Meyle, 2008; Lang et al., 2011). In the present study, after 1 year of loading, most of the implants displayed healthy peri-implant soft tissues, a slight bleeding was observed in 23% of the tested implants, which is less than the 50% reported by Lindhe and Meyle (2008). However, bleeding on probing should be interpreted carefully since the force exerted on the probe is operator-dependent and probing around an implant is more sensitive than around a natural tooth and could cause false evaluations of positive bleeding on probing (Gerber et al., 2009).

The aesthetic of the peri-implant soft tissue is also a critical parameter for implant success especially since patient expectations tend to increase even in the posterior region in the maxilla when they show up to the first molar when smiling. Moreover, the PES can be used for the monitoring of soft tissue quality over time. Based on the PES described by Furhaüser et al (2005), a reproducible tool to assess soft tissue quality in the aesthetic area, a modified "posterior Pink Esthetic Score" (pPES) was used in the present study to evaluate soft tissue characteristics. The PES was thereby adapted by combining "soft tissue colour" and "soft tissue texture" as "soft tissue appearance".

The pPES was high for both groups and the variable with the lowest score was generally the alveolar process resorption, which is related to centripetal bone resorption after extraction at the upper maxilla. Indeed, the study criteria excluded previous ridge preservation techniques or extraction and immediate implants that may have limited this buccal bone remodelling (Lambert et al., 2012; Tan et al., 2012; Vanhoutte et al., 2014; Tomlin et al., 2014). Also, the score related to the papilla is dependent on the anatomy of the bone level of the adjacent teeth and anatomy (Tarnow et al., 1992; Choquet et al., 2001). These parameters are not related to the implant design and therefore this data should be interpreted cautiously.

Taking into account not only the peri-implant bone remodelling but also the bleeding on probing and the PES, the clinical outcomes after 1 year of implant loading are rather promising for the V-shaped group; however, longer follow-up would be needed to confirm this tendency. Also, the present results are valid for the posterior maxilla only and further studies should be performed to assert similar conclusions for the mandible and for the aesthetic zone. Indeed, the maxilla displays a better blood supply than the mandible and implants placed in a more cortical bone may behave differently, although the literature to support that is scanty (Tolstunov, 2007).

Buccal hard tissue thickness

The buccal bone thickness at the implant site is a key factor for long-term success and for preventing buccal recession (Buser et al., 2004). One of the presumed advantages of the V-shaped implant is that the buccal off shift leaves more space for buccal bone; it would consequently prevent buccal recession. The present results did not show any difference between the 2 groups; however, this feature may be more relevant in the anterior zone of the maxilla where recession could lead to aesthetic problems.

Patient-reported outcomes

According to some authors, patient reported outcomes should also be taken into account for reporting on implant success (Levi et al. 2003, De Bruyn et al. 2015, Tey et al., 2017). In the present study, all of the 34 patients were very satisfied by the implant treatment they received for the replacement of a single missing tooth. All were pleased with the aesthetic aspect of their crown, the level of comfort when chewing and all would recommend such treatment to their family and friends. However, there are few controlled studies about patient-centred outcomes for single implant therapy since no recommendation exists (de Bruyn et al. 2015). The satisfaction questionnaire in the present study might be useful in the absence of other tools to assess patient-reported outcomes for single tooth replacement with an implant. Moreover, in the present study, enrolled patients required only a straightforward implant therapy, without any additional surgery: the degree of overall satisfaction could therefore have been positively influenced in comparison with a more complex treatment requiring, for example, bone grafting (Cosyn et al., 2013). Finally, these data have to be interpreted cautiously since patients were aware of their participation in a study in which they had a financial benefit, which could have influenced their overall satisfaction.

Conclusion

Within the limitations of the present clinical study, the following conclusions were drawn:

- Both implant neck designs (circular and V-shape) presented excellent survival rates of 100% after 1 year of loading.
- Although not significant, a slightly higher implant success rate was found with the V-shaped design (100% *vs* 94.1%) after 1 year of loading.
- Similar buccal bone thickness was found for both implant necks in the posterior maxilla.
- Similar posterior Pink Esthetic Scores were found with the V-shaped and regular implant necks
- Both implant designs allowed significant improvement in patient satisfaction

Those results should be re-evaluated after a longer follow-up period to confirm the long-term success of V-shaped implants, as well as on a larger patient number.

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