Prospective, Comparative Assessment of Peri-Implant Mucosal Architecture at Different Implant Abutment Interfaces. A 1 year Evaluation.

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A thesis submitted to faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in the school of Dentistry, (Prosthodontics).

Chapel Hill
2013

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ABSTRACT

PRAEPHUN LIMPIPHIPATANAKORN: Prospective, Comparative Assessment of Peri-Implant Mucosal Architecture at Different Implant Abutment Interfaces. A 1 year Evaluation.
(Under the direction of Lyndon F Cooper)

The purpose of this study is to compare the buccal soft tissue changes occurring around single-tooth replacements in the maxilla using three different implant-abutment interface designs over a one year period. The study was an open, prospective, randomized multicenter study in 141 subjects. Subjects were randomized to Group A (Conical interface, n=48), B (Flat-to-flat interface, n=49) or C (Platform switch, n=44). This study evaluated the soft tissue changes longitudinally through collection of standardized oral photographs using Canfield apparatus. Comparisons between restorative platform types and between time points were evaluated statistically. There was not statistically significant change of buccal soft tissue level (mean -0.1 ± 0.7 mm) at 12 month followed implant placement, with no statistically significant difference between three implant abutment designs. Overall papilla height showed slight increase (mesial papilla 0.3±0.5 mm, distal papilla 0.2±0.5 mm), with no statistically significant difference between treatment groups.

ACKNOWLEDGEMENTS

To my mentor and program director, Dr. Lyndon F. Cooper for providing me with the opportunity to be one part of UNC graduated prosthodontics residents and for sharing experience, knowledge and skill with me.

To my committee member: Dr. Ingeborg De Kok and Dr. John Moriarty for all help, patient and teaching during the research project.

To my two best sisters Sandra and Ghadeer, thank you for all of your help, love and care. You are always being there for me.

To UNC graduated prosthodontics residents for friendship and all great memories.

To my family and Golf, thank you for all of your love, support, and motivation. I am so lucky to have all of you beside me in every step of my life.

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1. Introduction

1.1 The evolution of single tooth implant replacement.

Ever since dental implant therapy evolved as a treatment option for replacement of missing teeth, the success of this treatment modality was defined as Osseointegration[1]. Presently this would not be sufficient to describe successful implant based restorations unless osseointegration is accompanied by a pleasing esthetic appearance and patient satisfaction both functionally and esthetically. Therefore, there have been continuous efforts for optimizing all factors related to producing a satisfactory esthetic result especially when dealing with restorations in the esthetic zone, and among the most challenging restorations in this regard are the single implant tooth replacements. In this regard, there exists several treatment options for single tooth replacement including resin-bond prostheses, fixed partial denture, removable partial denture and implant supported single crown. Decision making not only depends upon clinical examination and radiographic assessment, but a long term survival and complication rate of each of treatment modality should be considered. There exists continued controversy regarding whether to preserve and restore a problematic tooth or to extract and replace missing teeth with a single implant. Guidance in this arena must be multifaceted.

The fixed partial denture has been used in dentistry for replacing missing teeth for decades. Several studies[2,3] evaluated the average of survival rate of fixed partial denture in a least 5 year follow up. Survival of 93.8% and 92.3% for conventional fixed partial denture and cantilever designed fixed partial dentures were calculated. A more recent systematic review[4] compared the survival rate of tooth supported fixed prostheses and implant supported single crowns. The authors indicated that the 5 year single implant crown survival (94.5%) was not statistically different than the 5 year survival rate of conventional (93.8%) and cantilever fixed partial dentures (91.4%). At the 10 year evaluation point, however, conventional fixed partial denture and implant supported single crown have equal estimate survival rate of 89.4% and cantilever fixed partial dentures demonstrated a reduced survival rate of 80.3%. If outcomes could be measured purely from a survival estimate alone, implant and tooth restorations represent comparable solutions for tooth replacement. One critical consideration is the condition of adjacent teeth. Conservation of tooth structure adjacent to the missing area seems to be one of the superior advantages compare to other treatment options.

With good survival rates, fixed partial dentures seem to be a reasonable treatment option for replacing missing tooth when adjacent teeth needs restoration or retreatment. Conversely, removing good tooth structure of adjacent teeth is aggressive and might cause more complication for adjacent natural dentition in the future.

In addition, there have been a number of complications reported for fixed partial dentures. According to a systematic review[4] observed complication rate of tooth

supported fixed partial dentures and implant supported single crown showed that the 5 year observation period found complication in conventional fixed partial denture of 15.7% and in cantilever fixed partial restorations of 20.6%.The most frequency complication were biological complications; whereas, technical complication were more commonly reported in implant restorations. Another review that evaluated the clinical complications for fixed partial dentures over the average of 8 year follow up[5] indicated a high complication incidence in conventional fixed partial denture (27%). The most common complications were caries; follow by need of endodontic treatment, loss of retention, esthetics, periodontal disease, tooth and prosthetic fracture. While resin boned prostheses (26%) also present similar rate of complication and prosthetic debonding was the most common complication. Little or no mention of patient satisfaction or esthetics was discussed in this or other reports of fixed dental prosthesis outcomes.

Resin bonded fixed prostheses are minimally invasive alternative solution to replacing missing single tooth. However, systematic reviews[4,6] reported that resin bonded fixed prostheses (87.7%) had lower survival rated compared to conventional fixed prosthesis (93.8%) and implant supported single crown (94.5%) in 5 year follow up. In addition, a more recent study[7] also supported that resin bonded bridges are technique sensitive and the longevity of the restoration is still limited. New materials had been introduced to improve outcome of resin bonded prostheses included fiber-reinforced resin-bonded bridges and alumina ceramic. Van Heumen et al, reported the estimate of the overall survival rate of fiber-reinforced resin bonded bridges was 73.4% at 4.5 year; however, the author also reported complications including

fracture of the restoration and delamination of veneer composite[8]. Whereas, Kern and Sasse presented the 10-year survival rate of glass-infiltrated alumina ceramic resin-boned restoration was 73.9%[9]. However, there is no other evidence supporting that new materials will decrease complication rates of resin bonded prostheses.

Location of the edentulous area is an important factor that should be considered prior to decision making. Cantilever fixed restoration has been used to replace single missing tooth especially in unbound edentulous space. A systematic review by Pjetterson et al, reported that cantilever showed inferior survival rate with higher complication especially posterior cantilever restorations [4]. In addition, survival and complication might depend on abutment teeth condition.

The condition of tooth-supported fixed partial dentures is one of the main concerns for making treatment decision. A clinical study by De Baker et al presented the survival rate of 3-unit FPDs decreased in root canal treated abutment follow by post and core (60.5%) compare to vital abutment tooth (83.2%) at 20 year follow up. The study concluded that a post and core abutment significantly increase failure rate especially when used as abutment supported several unit fixed restorations [10]. This finding also confirmed by another prospective study[11] that non-vital abutment tooth supported fixed restoration decreased the survival rate compared to vital abutment tooth. Therefore, single implant restoration might be a proper treatment option, in case fixed partial denture abutment teeth have questionable prognosis due to root canal treatment and/or heavily restored.

Another factor that also influences complication and success rate of the fixed restoration is restorative material. Metal-ceramic fixed partial restorations has high survival, with a significantly greater 5-year survival rate than all-ceramic fixed partial restorations [5]. Recently, All-ceramic material has been the primary focus for clinicians due to esthetic and economic advantages. Differences in complications were unknown, but evidence indicated that the complication incidence of metal-ceramic FDPs was lower than that of all-ceramic FDPs. A systematic review by Schley et al, reported that estimate 5 year survival rate of zirconia based fixed partial restoration was 94.29% (range from 70.54-100%) which is comparable to the survival rate of metal ceramic material (93.8%)[4]. However, zirconia based fixed restoration present several complications include porcelain chipping (79.4% complication free), marginal inaccuracy, loss of retention, and biological complications such as caries, loss of tooth vitality and abutment teeth fracture[12]. Another study by Christensen and Ploeger, compared clinical performance between metal, zirconia, and alumina 3 unit posterior fixed partial restoration frameworks reported that metal framework provided the highest survival rate of 95%, follow by zirconia framework of 85%, and alumina framework had an unacceptable survival rate of 64%. The veneer chipping had higher incidences in zirconia framework (56%) than metal framework (28%) posterior 3 unit fixed restoration. [13]. These results were also confirmed by a recent study[14] where zirconia all ceramic restoration had higher complication rate compared to metal ceramic fixed partial restoration. Therefore, metal ceramic material is still a standard material of choice and veneer ceramics for zirconia still need improvement to reduce the incidence of complications.

Furthermore, the cost of treatment is usually a concern for the patient. According to Torabinejad et al, reported 3-unit fixed partial denture (2,300-3,000 USD) had comparable initial cost as implant supported single crown (2,850 USD include extraction, implant, abutment and crown). However, the author calculated only initial fee of each treatment and did not include clinical and radiographic examination fee, and other additional treatment fee such as provisional restoration, foundation (core built up) and soft and hard tissue graft[15]. Another recent study by Buchard et al utilized cost effectiveness model compared between single implant restorations and 3 unit fixed partial prostheses. The study reported fixed partial prostheses (6286+/-3774 euros/success) presented higher mean cost-effectiveness than implant restorations (3819+/-1454 euros/success), whereas; single implant restorations (92%) presented higher success rate in 20 year compare to fixed prostheses (62%). The author concluded that implant therapy is the first-line treatment is less costly and more efficient over time than bridge first-line therapy[16].Table 1 presents implicating factors for decision making between fixed partial denture and single implant crown as a treatment modality for single tooth replacement.

Table 1. Factors implicating tooth preservation or replacement

Potentially Relevant Outcomes in Evaluation Tooth Replacement	
FDP	Implant
Failure (FDP removed from the mouth)	Failure (Implant removed from the mouth)
Major Mechanical complications (Connector failure)	Major Mechanical complication (implant or abutment fracture)
Reversible mechanical complications (e.g. porcelain fracture)	Reversible mechanical complications (e.g. porcelain fracture, screw-loosening)
Reversible biological complication (caries)	Reversible biological complication (peri-mucositis)
Irreversible biological complication (periodontitis)	Irreversible biological complication (peri-implantitis)
Objective esthetic scores (not presently available)	Objective esthetic scores (PES/WES)
Subjective esthetic scores	Subjective esthetic scores
Patient-centered (QoL) outcomes	Patient-centered (QoL) outcomes
Cost Utility	Cost utility.

In addition to all the factors involved in decision making that consider options for single tooth replacement, it's noteworthy that the decision to restore pulpal and/or apical pathological condition dentition with root canal therapy or extract the tooth and replace with single implant restoration has been an issue of controversy for many years. A systematic review by Torabinejad et al[15] , presented that in patient with periodontally sound teeth, root canal therapy (97%) present survival rate equally to single tooth implant (97%) therapy but higher than fixed partial prostheses (82%) at 6 year follow up. The study also reported that the successful rate of single implant therapy was higher than root canal (84%) and fixed partial denture treatment (80%). The author concluded that implant supported restoration has similar survival rate as root canal treated tooth; however the implant restoration showed longer time to function. Other systematic reviews[17,18] evaluated the difference of survival rate

between root canal treated tooth and single tooth implant also concluded that there was no significant difference in survival rate between two treatment modalities.

Since the survival rate between implant and root canal therapy are not different, the decision must be based on other factors such as final restoration after root canal treatment and its survival and complication rate, remaining sound tooth structure, patient perception and preference and economic outcome[19].

A recent review by Jiloski et al, reported that the presence of a 1.5- to 2-mm ferrule has a positive effect on fracture resistance of endodontically treated teeth[20]. However, several evidences support that root canal treated tooth followed by post and core increased the complication rate, according to Goodacre et al reported that post and core had at least 10% complication incidences[5]. In addition, Holm-Pederson reported that existing periapical pathology dramatically decreased the survival of non-vital teeth to less than 80% after 5 years[21]. Moreover, the high risk for tooth loss appears to be the presence of perforation during retreatment decreasing the 5 year survival rate to as low as 42%[22]. Therefore, condition of tooth should be taken in consideration before decision making. In addition, overall oral rehabilitation plan will play a part in the definitive decision for keeping or removing the tooth in question.

Patient perception and preference also have influence on treatment decision. Gatten et al evaluated patient's perception of quality of life compare between endodontic treatment and implant restoration using the Oral Health Impact Profile (OHIP-14) as a quality of life assessment. The study presented that both treatment modality have

present similar overall OHIP score with high satisfaction rate. The major concerns for patient included overall health status, treatment fee and insurance coverage, patient perception, treatment outcome, treatment duration and number of visits[23].

Cost of treatment is also another factor influencing patient decisions. Review studies[18,24] reported that endodontically treated teeth followed by definitive restoration show less expensive and less clinical visits than implant supported restoration. However, Derhalli et al recommended that a treatment cost analysis should be considered in all possible treatment required. For example, crown lengthening and foundation restorations should be included in root canal treatment plan, on the other hand; hard and soft tissue graft and 3-dimention x-ray must also be concerned in implant restoration therapy[25]. A recent study by Pennington et al reported that root canal treatment is highly cost effective as a first line intervention. Re-treatment is also cost-effective, but surgical re-treatment is not. Therefore, extraction and replacement with single implant should be considered when endodontic re-treatment is not effective[26].

1.2 Survival of single tooth implants

Implant supported single crowns are growing as a first choice treatment modality for replacing missing single tooth[164]

. Long term studies have reported excellent implant survival rate in single tooth implant replacement. A systematic review by Jung et al reported that the average survival of single implant crown was 96.8% after 5 year and 94.5% after 5 year of function[6]. A systematic review by Pjetursson and Lang in 2008 compared the 5 and 10 year survival rate between single implant and variety of fixed partial prostheses

(Table 2) showed that in 5 year, single implant restoration (94.5%) presented similar high survival rate as conventional fixed restoration (93.8%) and cantilever restoration (91.4%). Resin bond prosthesis showed the acceptable survival rate of 87.7%. After 10 year of service, single implant restoration and conventional fixed restorations showed reasonable survival rate around 89% and cantilever showed inferior survival rate of 80.3%. Whereas, resin boned prosthesis show unacceptable survival rate of 65%[27].

Table 2. Estimate survival rate of single tooth replacement in 5 and 10 year follow-up

5- and 10- year survival estimates for single tooth replacement *		
Replacement method	5 year survival	10 year survival
Conventional FDP	93.8 (87.9-96.9)	89.2 (76.1-95.3)
Cantilever FDP	91.4 (86.9 – 94.4)	80.3 (75.2-84.4)
Implant supported SC	94.5 (91.8-96.3)	89.4 (79.3-95.6)
Resin bonded bridge	87.7 (81.6 – 91.9)	65.0 (51.4-76.9)

*Adapted from Pjetursson and Lang, 2008

This implies that the design of fixed partial prosthesis has a high influence to survival of the restoration in long term. Conventional fixed prostheses or implant supported single crown represent first treatment options. A more recent systematic review by Jung et al(2012), also reported the 5 year survival rate of implant supported single crown was 96.3% and 89.4% after 10 year[28]. This fact reinforces the previous conclusions that single implant restorations are a predictable treatment modality with a longer term evidence base of support.

1.3 Complications for single tooth Implants

According to published evidence, single implant restorations present high survival rate in long term follow up studies. Success of treatment should not be reflected only

by how long the restoration remains in oral cavity but should reflect complications of the implant supported restoration that affect its appearance, its biologic influence on local and systemic tissue, and patient acceptance.

Berglundh et al[29] reported implant loss was the most commonly reported complication in literature(96-100% described in the study) while other biological complication (40-60%) and technical complications (60-80%) were underestimated. The author also reported that the incidence of implant loss in treatment of single implant crown over at least five year showed 0.76% of implant loss prior prosthetic placement and an incident of 2.06-2.50% loss during 5 years of function. This review also indicated that incident of overall implant loss prior to function (2.5%) and during function (2-3%) was three time higher than incident of single tooth implant loss (0.76%)[29]. A recent review by Jung et al[28], reported in systematic review that the 5 year survival rate of implants supported single crowns was 97.2% whereas the survival rate of single crowns supported by implant showed was 95.2%. After 10 year of function, the survival rate of implants supported single crowns decreased to 96.3% whereas the survival rate of single crown supported by implant showed was 89.4% This implies that complications that occur in restoration that supported by implant might increase the failure rate of overall single implant restoration therapy.

Complications found in single implant restoration can be divided to technical, biological and esthetic complications. Systematic reviews[4,6] reported the annual technical complication rate of complication in single implant crown was 0.92. The common technical complications in implant supported restoration were abutment screw loosening (12.7%), veneer fracture (4.5%), implant abutment fracture (0.35%)

and implant fracture (0.14%). More recent review[28] also reported similar result that the most common technical complication was screw loosening of 8.8%, followed by loss of retention (4.1%), fracture of veneer (3.5%) and implant fracture (0.18%) and screw fracture (0.18%). In addition, Salinas and Eckert mentioned that all-ceramic restorations presented more biomechanical and technical complication incidences that with metal-ceramic restorations[30].

Biological complications include peri-implant hard and soft tissue changes, infection and inflammation. Overall soft tissue complication is limited in presenting with 0.1-0.3 per person incident rate and among dental implant complications[29]. Systematic reviews[4,6] reported the annual complication rates of implant supported single crown were 2.03 in 5 year follow up. Biological complications were presented with peri-implant soft tissue complication (9.7%) and bone loss more than 2 mm (6.3%). More recent review in 2012[30] reported that the 5 year soft tissue complications, including peri-implantitis, were observed in 9.7%, whereas bone loss exceeding 2 mm was reported on 6.3%.

Esthetic complications can be determined by clinician or patient interpretations of the appearance of the restoration itself and/or appearance of soft tissues around the implant restoration. Biological complications have high influence on the esthetic outcome of single implant restorations. A systematic review of dental implant complication by Goodacre et al[31] showed that peri-implant soft tissue complication were a concern for the single tooth implant. Peri implant soft tissue complication includes dehiscence, fistula and gingival inflammation. Soft tissue dehiscence in highly esthetic areas can lead to soft tissue deficit that compromises the final

esthetic outcome and affect patient satisfaction. Causes of soft tissue complications include poor oral hygiene, abutment implant misfit or micro-gap at abutment implant junction, which can lead to bacterial migration and changes of soft tissue level around implants-abutments which affects the esthetic result adversely[30].

A recent review by Jung et al reported the esthetic complication due to dis-satisfaction of esthetic appearance was 7.1%[28] and 9% of esthetic complication rate was also reported by Salinas et al[30] who also mentioned that minimizing esthetic complications is challenging and related to both technical and biological complication.

1.4 The issues with evolving single tooth implant therapy

A conventional concept of dental implant therapy recommend placement of dental implant in healed extraction sites with two stage surgery and a 3-6 months unloading period[32]. Due to long treatment duration, number of surgeries and complicated prosthetic procedures, new concepts include one stage surgery, immediate placement, immediate loading, and early loading have been introduced.

Evidence[33,34] shows that there was no difference in survival rate of implant restoration between 1-stage and 2-stage surgical protocol. However, a 2-stage protocol could be indicated when an implant has not obtained an optimal primary stability. In addition, A systematic review by Den Hartog et al[35] compared treatment outcome of immediate, early and conventional single-tooth implants in the esthetic zone, also reported that there is no statistically significant difference of survival rate between immediate, early and conventional concepts with overall survival rate of

95.5% after 1 year. A recent systematic review by Strub et al also supported that immediate loading had high survival rate ranged from 96.4-100%[36]. On the other hand, a review by Atieh et al, 2009 reported that immediate loading in single implant crown increased risk of implant failure (relative risk 5.07) compared to conventional method[37].Therefore, immediate loading protocol is considered a successful procedure in selective cases.

In addition, these contemporary approaches were reported to help minimizing peri-implant bone loss and provide better soft tissue healing by which possibly improving the esthetic result especially in anterior esthetic areas. A clinical study by Cooper et al[38], of single-tooth implants reported that early/ immediate loading of single implant restoration within 3 weeks after implant placement using 1-stage surgical protocol provided a good survival rate of 94% and acceptable mean marginal bone changes of 0.4 mm per year. In addition, the authors also reported that 1-stage surgical protocol and early loading with proper abutment and provisional restoration improve peri implant soft tissue outcome (A mean gain in papilla length was 0.61 mm at 1 year and 0.74 mm at 3 year and a gain in buccal gingiva was 0.34 mm.at one year and 0.51mm at 3 year). More evidence[39-41] supported that shortening of loading period and establishing proper provisional crown allow soft tissue adaptation and permit papilla formation. While, 2-stage surgical protocol might limit soft tissue healing and inhibit formation of soft tissues that follow anatomical contour. A recent clinical study[42] showed that there is an improvement of papilla level after 1 year follow up with immediate placement and provisionalization procedure. This has been supported by a systematic review by Sanz et al, 2011 that immediate and early

implant placement protocol provided advantages to hard and soft tissue preservation. In this review, the author also reported that early placement presented higher level of patient satisfaction compared to conventional procedure [43].

These more aggressive approaches such as immediate placement and immediate loading should be implemented with caution and should be preceded by careful patient selection and treatment planning. In the esthetic zone, tooth loss or removal is associated with reduced or insufficient facial wall bone which may be a major factor affecting soft tissue recession when placing an implant immediately in the socket [44]. This can lead to failure of esthetic results such as loss of harmonious gingival margin, exposure of metal collar, and improper contour of definitive restoration. A clinical study[45] suggested that immediate placement did not alter the fact that after extraction, there is a decrease of bone dimension which affects soft tissue changes. De Rouck et al, 2008 also reported that immediate implant placement in anterior maxilla provide a good survival rate (range 78.6-100%) and predictable papilla level (-0.39-0.53 mm in 1 year), but undesirable mid facial soft tissue outcome (-0.55-0.75 mm in 1 year) with average of buccal bone loss range 0.22-1.05 [46].This implied that managing soft tissues around implant restorations is unpredictable and it might need additional steps or procedures to establish satisfactory outcome. Placement of implant immediately in extraction socket in patients with insufficient bone might increase the risk of hard tissue defect which affect long term esthetic outcome. A prospective, randomized-controlled clinical study by Sanz et al, reported that the immediate placement of an implant resulted in significant alterations of the dimension of the buccal bone (both horizontal and

vertical dimension) in 16 weeks after implant placement[47]. In addition, a recent study evaluated the thickness of buccal bone at the maxillary anterior region using cone beam computed tomography (CBCT). The study reported limitation of buccal bone thickness in majority of patients (the median thickness at the midroot was 1.03 mm in the premolar area and 0.70 mm for the other anterior maxillary teeth)[48].

Therefore, several surgical techniques have been used to correct the bony defect prior to implant placement such as ridge perseveration following extraction, onlay grafting, guide bone regeneration (GBR) with barrier membrane, and a combination of block bone grafts and barrier membrane. These bone augmentation procedures have been well documented. The ridge preservation approach has demonstrated success in preserving ridge dimension[49]. In addition, clinical studies[50] demonstrated that horizontal bone augmentation can be predictably obtained with GBR technique, whereas vertical bone augmentation seems to be more difficult to achieve satisfy outcome. Bone grafting procedures improve tissue contour and allow clinicians to place implant in favorable position which affects the esthetic result. A more recent study by Hof et al, 2011 reported that bone augmentation at anterior maxilla prior implant placement allow achieving favorable esthetic results[51]. This result was also supported by Buser et al, 2013 that the follow-up of 5 to 9 years presented low risk of soft tissue recession with early implant placement and bone augmentation with guided bone regeneration (GBR) maintained a facial bone wall in 95% of patients which improve satisfactory esthetic outcomes[52].

However, implant placement in augmented site might leave a question to the clinician about survival rates compared to non-augmented site. A 2009 review by

Jensen and Terheyden [53] provided strong evidence that implants placed in augmented bone have comparable survival rates as implants placed in good quality bone, however; the available data did not allow identifying one surgical procedure offered better esthetic outcomes than another. Moreover, success rate of implant therapy with or without bone augmentation also depend on various factors including patient health status and life style, size and site of bony defect and surgical procedures[54].

1.5 Implant esthetics

Providing reproducible, highly esthetic outcomes is a challenge of dental implant therapy. The general esthetic goal of dentistry is to establish the harmonious appearance the restoration with adjacent teeth and tissue. For implant restorations, both the peri-implant soft tissue to the surrounding mucosa around the adjacent teeth and the final restoration have distinctly different supports (abutment and implant) compared to the natural roots and tissue of the adjacent natural dentition. Soft tissue changes around implants affect the esthetic outcome of the implant restoration such as absence of interdental papilla, gingival recession and might lead to esthetic failure of final restoration. Meanwhile, underlying hard tissue structure plays a key role in the establishment of esthetic soft tissue especially in anterior maxilla.

To achieve satisfactory outcome, good planning prior implant placement is important. To establish a treatment plan, understanding architecture and bio-

physiological response of soft and hard tissue surrounding dental implant is necessary.

Maintenance of the interproximal papillae height is one main esthetic goal in single tooth implant restoration. Published evidence showed that the level of interproximal bone crests affects the presence of interproximal papilla. According to a clinical study [55], showed that if the distance between the contact point of the restoration to crest of the bone was greater than 5 mm then this would be a critical point at which the papilla no longer predictably filled the interdental space. This observation has been confirmed with implant-supported restorations[56]. In addition, not only crestal bone height has influence on preserving interproximal soft tissues but the distance between implants is also associated to papilla response. A study by Tarnow et al, demonstrated that the mesio-distal distance between implants more than 3 mm (0.45 mm bone loss) present less interproximal bone loss than distance less than 3 mm (1.04 mm bone loss) [57]. The same author also reported that the mean height of papillary tissue between two adjacent implants was 3.4 mm (range of 1 mm to 7 mm). This implied that esthetic outcome related interproximal papilla might be limited when placing implant adjacent to each other [58]. Zetu et al introduced aesthetic triangle as a reference of management of interproximal papilla explained that in order to achieve optimal esthetic outcome, management of interproximal papilla should be planned prior to tooth extraction. Having good bone foundation for support soft tissue will lead to higher esthetic satisfaction; however, in case that hard and soft tissue esthetic cannot achieve by surgical procedure, restorative procedure should be done to overcome the esthetic complication and improve satisfactory

outcome[59]. A prospective clinical study in 2006[60] evaluated a mean marginal bone resorption at the facial and lingual aspect of the implant was 0.7 and 1.3mm at the time of abutment connection, while mean proximal bone loss was only 0.1mm. This small interproximal bone change might lead to positive papilla response around the implant crown. The study reported the interproximal papilla fill of more than 50% was shown in 32% at crown placement visit and 86% at 1 year. The result showed the improvement of papilla height, while facial soft tissue presented negative response. Gingival biotype is also widely considered to influence the esthetic outcomes for dental implants. Kois et al described that a thick gingival biotype is more resistant to recession but more prone to create periodontal pocket at teeth. On the other hand, thin gingival biotype usually has less osseous supported and high risk to recess after the surgery [61]. A clinical study by Kan et al evaluated that gingival biotype has influence on final position of implant platform. A thin biotype will require implant placement more palatal to hide metal color show-through. However, placing implant too far palatal will limit establishment of ideal emergence profile[62]. Therefore, patient who has thin gingival biotype with high smile line should be offered less esthetic expectations. In addition, recent studies[63,64] evaluated relationship of thickness of facial plate and gingival biotype using CBCT as an assessment, found that there is a relationship between thickness of facial plate and gingival biotype. Another study by Kan et al indicated that gingival biotype associated with midfacial soft tissue changes but have no strong influence on interproximal papilla level[42]. In contrast, a study by Si et al reported that thickness of gingival mucosa prior to implant placement can help predict papilla alteration around single implant restorations[65]. It

appears that a complex situation involving more than gingival biotype affects peri implant tissue. Various factors including implant position, the implant abutment interface, implant/abutment materials, and bone dimension may influence tissue responses and esthetics.

Evidence supported that the concept of a physiological response responsible for the biological seal around natural dentition is known as the biological width[66]. This organization of connective tissue and epithelium also occurs around dental implant. This biological seal which forms along the implant abutment consisted of junctional epithelium and avascular connective tissue attachment with an average of 3 mm in height. This process of the soft tissue attachment around non-submerged dental implant that was reported to be properly established after several weeks following surgery [67]. According to Linkevicius et al[68], biologic width is a stable biological response that acts as a soft tissue protector around dental implants, and the interference of biologic width might lead to hard and soft tissue changes. A more recent study also reported that biological width around one-piece implants occurred with similar manner comparing between immediate, early and conventional loading procedures[69] and one-piece implant present similar biologic respond to natural dentition in comparison to 2-piece implant[70]. The aggregate information concerning biologic width at dental implants suggests this anatomic organization of connective tissue and epithelium is consistently observed at all implants.

A series of animal studies by Hermann et al indicated that a chronic inflammatory response influenced the crestal bone loss as a result of biofilm accumulation and the nature of the interface, particularly micromotion, influences connective tissue contact

biology. Biologic response of crestal bone starts around a 2-piece implant after abutment installation and crestal bone remodels to a level approximately 2.0 mm apical to the implant abutment interface[71-74]. A study by Collan et al, used DNA probe analysis to identify location of bacteria colonization reported that the bacteria colonization found at internal surfaces and healing abutment screw-threads within 25 days after second stage surgery and placement of healing abutment. This implies that a microgap at implant abutment interface allow bacterial infiltration creates inflammation that might lead to peri-implant hard tissue changes[75].

A longitudinal radiographic study by King et al, evaluated the influence of microgap on crestal bone level showed that 2-piece implant presented greater crestal bone loss compared with 1-piece implants. The stability of the interface has an influence on the early wound healing stage around implant but not the size of interface [76]. Moreover, several studies[73,77,78] also demonstrated that the location of implant abutment junction has an influence on vertical bone loss around implants. The vertical bone remodeling will be increased (average 1.3-1.8 from animal studies) if the implant abutment junction is located deeper into the bone. Therefore, placement of implant too far sub-crestal (apical position of implant abutment interface) might lead to unnecessary bone loss around implant. Bone loss that occurred due to implant abutment microgap not only affected interproximal crestal bone but also affects the facial bone resorption which might lead to facial soft tissue deficiency. Thus, good examination of facial bone dimension prior tooth extraction will lead to better decision of surgical procedures that improve the final esthetic outcome.

Facial bone is an important anatomical architectural feature that affects the final esthetic outcome of single implant restoration. Deficiency of height and thickness of facial bone affected the stability and harmony of facial soft tissue around implant restoration and adjacent teeth[79]. Clinical and radiographic examination will help determine amount of facial bone which leads to proper management. A prospective multicenter study evaluated the thickness of buccal and palatal bone walls at extraction site prior implant placement using a caliper instrument. The study reported the reduction of buccal bone height (-0.1 mm) was more significant than palatal bone loss (-0.5mm) at extraction site [47]. A study by Lau et al analyzed the thickness of the buccal bone at their mid-root and apical level using 300 cone beam radiographs reported that the mean thickness of buccal bone at the mid root level was 0.9+/-0.4 mm and at the apical level was 2.04+/-1.01 mm. This information showed that there is a limitation of patient facial bone width and a traditional protocol with site preparation prior to implant placement might provide more pleasing esthetic outcome[80]. Kan et al also reported facial bone influenced the clinical outcome of recession facial gingival tissue stability following immediate placement and provisionalization of maxillary anterior single implant. The study showed that absence of grafting the gap between the implant might affect the facial tissue recession[42]. Due to limitation of anatomic structure, tissue augmentation might be an answer to create proper adequate bone volume that lead to esthetic success.

According to Buser et al, to achieve esthetic outcome, placement of implant in a correct three dimensional position is crucial [44]. The three dimensional concept has also been reviewed in an article by Leblebicioglu et la. The studies recommended

that in mesio-buccal view, a minimum of 1.5-2 mm of distance between adjacent tooth and implant was recommended to provide space for prosthetic restoration and allow establishing proper physiological response of peri-implant tissue. The thickness of facial bone and emergence profile of the restoration are used to determine the bucco-lingual position. Limitation of facial bone that leads to place implant more palatal might result in an unsatisfactory emergence profile. The apico-coronal position, placing implant too shallow will affect esthetic outcome but placing the implant too deep might result in an undesirable hard and soft tissue loss around implant[81]. A more recent article by Cooper in 2008 explained esthetic objective criteria for single implant in anterior areas. The author recommended using gingival zenith level which is the most apical point of definitive crown as a reference level for implant placement in esthetic zone. The author explained that it is suggested to place implant 3 mm apical and 2 mm palatal to the planned gingival zenith in order to provide proper implant position in esthetic areas, however, if facial bone is insufficient to follow this guideline, bone augmentation prior to implant placement must be performed[82]. Several guidelines and recommendations have been introduced attempting to achieve esthetic satisfaction. However, to obtain high patient satisfaction, careful examination and diagnostic procedure seems to be a leading key to proper management in each particular patient. In addition, clinicians should understand patient's perspective and expectation to minimize failure of esthetic outcome.

1.6 Patient satisfaction

Esthetics is subjective; therefore, satisfaction of single implant restoration must depend on each individual perceptions, preference and experience. To assess the satisfaction of esthetic outcome of implant supported single crown is challenging. Visual analog scale (VAS) and questionnaires have been used to evaluate single implant crown satisfaction. A study[83] compared patient and dentist satisfaction of esthetic outcome of implant single crown in maxillary anterior areas showed that patient give higher values of outcome satisfaction compared to dental professional. Most variables in the patients' assessments revealed mean values above 90%. Factors considered by dental professionals to be of significance for the esthetic result such as surrounding soft tissue appearance and form of the crown may not be of decisive importance for the patient's satisfaction. Another study[84] that used VAS to evaluate patient's satisfaction of implant single crown in esthetic zone compared to the contralateral natural tooth, reported similar result with high degree of patient satisfaction (mean value of 96%). A more recent study by Meijndert et al[85] reported that the score Implant Crown Aesthetic Index showed that only 66% of the cases had acceptable esthetic outcome from dental professionals, while the score from satisfaction questionnaire by patient showed 100% acceptable result. However, both patient and dental professional rated less satisfactory of peri-implant mucosa than the implant-supported crown. This result implies that peri-implant mucosal changes have high influence to dental professional perception but might be of minor concern to patient. Another retrospective study[86] evaluated outcome of early placed maxillary anterior single implant using pink and white esthetic score (PES/WES) as an

objective esthetic assessment showed that there is no statistically significant correlations between total of PES/WES and patient satisfaction using VAS. Some patients provide high outcome satisfaction whereas PES/WES scores from dental professional did not correlate with VAS score. This supported previous studies that the patient's perception of dental restoration from esthetic point of view differs from dental professionals. On the other hand, A recent study by Cho et al used PES/WES to evaluate maxillary single implant restoration in esthetic zone and found that there was a statistically significant correlation between patients' esthetic perception and dentists' perception except in premolar region. In this study also reported that soft tissue augmentation has been performed in some patients who have high smile line and thin gingival biotype which helped to increase level of patient satisfaction[87].

From all these evidences, it may be implied that the level of patient satisfaction is the overall appearance when smiles. Surgical procedures such as soft tissue grafting will help minimize the soft tissue defect and lead to higher patient satisfaction.

1.7 Implant esthetics assessment

Several assessment measures (Table 3) for single implant restoration have been developed to help determine success of the esthetic outcome. In 1997, Jemt[88] developed a Papilla Filled Index (PFI), an assessment of interproximal gingival papilla size around single tooth implant; however, this index does not assess other esthetic influences of the soft tissue around implant such as facial soft tissue level, color, and texture. Another esthetic evaluation instruments is Implant Crown Aesthetic Index (ICAI) developed by Meijer et al in 2005. The ICAI evaluated both restoration itself and surrounding soft tissue (color, anatomic contour and surface texture of crown and soft tissue)[89]. In the same year, Furhauser et al[90] introduced Pink Esthetic Scores (PES), an objective esthetic assessment for single implant crown in the esthetic zone using clinical photographs for evaluation. PES evaluates only soft tissue and seven soft tissue characteristics were utilized compare to a reference tooth including mesial and distal papillae, soft tissue level and contour, alveolar process deficiency, and the color and texture of the facial marginal peri-implant mucosa. Among all variable, level of soft tissue margin (facial recession) and color presented lowest scores, while papilla present has the best score. Evidence supports PES as a reproducible esthetic assessment of single implant crowns in both the short and long term[51,91-94].

In 2009, Belser et al[86] evaluated esthetic outcome in early placed maxillary anterior single tooth implants using a new objective esthetic assessment called Pink Esthetic Score/White Esthetic Score (PES/WES). PES/WES is an index that is modified from PES by combining the seven variables in PES into five soft tissue variables

including: mesial and distal papillae, curvature of facial mucosa, level of facial mucosa, and root convexity/soft tissue color and texture, then adding 5 implant restoration variables consist of tooth form, tooth outline/volume, tooth color and surface texture, and translucency. This index evaluates both soft tissue and implant restoration using both clinical photographs and diagnostic models. Belser also reported that PES/WES index is a suitable assessment for evaluation of esthetic outcome of single implant restoration.

In a recent study by Weinlander et al[96], another esthetic evaluation method of the peri implant mucogingival complex by collection of standardized photographs and computer-assisted measurement of reproducible data was used. Six soft tissue parameters have been used which include mesial and distal papillae areas and heights, soft tissue-crown perimeter, and gingival recession. The study found that a standardized oral photograph is considered an accurate and reproducible method for the evaluation and measurement of soft tissue changes that can affect the esthetic outcome.

According to esthetic assessment indexes, facial soft tissue around implant is one of the main variables that use to determine esthetic outcome in almost of implant esthetic. A study by Furhauser el al, reported that level of soft tissue margin presented lowest scores while gingival papilla has high esthetic score[90]. A study by Lai et al evaluated soft tissue around single tooth implant also reported that soft tissue level present significant changes compare of other variable[91]. In addition a study by Kan el al reported that facial soft tissue presented significant changes,

while papilla height showed small change [42].Therefore, soft tissue margin level should be given special attention by the clinician.

Table 3. Description of indices for assessment of single implant esthetics*

Index	Reference	Score	Evaluating variables
Papilla Index (PI)	Jermt (1997)	0-4	Papilla fill
Implant Crown Esthetic (ICE)	Meijer et al (2005)	0-45	Five characteristics of crown(mesiodistal dimension, incisal ledge, labial convexity, color and translucency, and surface) and four characteristics of soft tissue(position of facial margin, position of mucosa in the embrasure, facial soft tissue contour, color and surface of facial mucosa)
Pink Esthetic Score (PES)	Furhauser et al (2005)	0-14	Seven soft tissue characteristics: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiency, soft tissue color and soft tissue contour
Pink and White Esthetic Score (PES/WES)	Belser et al (2009)	0-20	PES (modified): mesial papilla, distal papilla, curvature of facial mucosa, level of facial mucosa, root convexity/soft tissue color and texture WES: general tooth form, outline and volume of the clinical crown, color, surface texture and translucency and characterization

*Modified from Benic et al, 2012[97]

1.8 Factors Affecting Peri Implant Buccal Tissues

Buccal soft tissue changes affect esthetic outcome of single implant restoration. Various factors influence facial soft tissue responses and range from surgical protocol, augmentation procedure, gingival biotypes, implant design and implant abutment interface.

Different implant surgical techniques might have influence to facial soft tissue responses differently. A review study by De Rouck et al, reported that immediate placement and provisionalization showed unpredictable buccal soft tissue recession and the changes of facial soft tissue occurred since tooth extraction[46]. Van Keresteren et al compared immediate protocol and delayed implants placement after extraction and ridge preservation utilizing Straumann Tissue level implants with a 1.8 mm transgingival collar. The study reported that the overall mid facial recession is small (0.17 +/- 0.47 mm) without significant difference between the immediate and delayed treatment groups. The authors also reported that immediate placement group showed a greater ridge resorption compared to ridge preservation and delayed placement group[98]. Another study by Raes et al compared between immediate and conventional implant placement in anterior areas found that immediate placement presented fairly stable midfacial soft tissue levels with only 7% of cases showing advanced recession. In addition, the investigators also reported that less midfacial recession in flapless surgery compared to flap surgery[99]. Moreover, in a prospective study of 35 immediate implants with an overall follow up time of 4 years, the tissue changes at Sterioss replace implants was measured. The midfacial mucosal changes at 1 year (0.55mm +/- 0.55 mm) were extended to 1.13 mm (+/- 0.87 mm) at the terminal evaluation period[42]. The authors also reported that 11% of patients complained about esthetic issues which might be the result for gingival tissue changes. The relationship of surgical protocol and facial tissue recession has been controversial. Facial hard and soft tissue might also depend on individual patient anatomical structure and pattern of bone remodeling.

Augmentation procedure is recommended in situations where there is inadequate bone volume to place implant in proper position. Therefore, augmentation procedure is also another factor that could affect facial soft tissue.

Due to the limitation of facial bone volume, several augmentation techniques have been recommended to improve hard and soft tissue contour. Several studies were interested in the changes of facial soft tissue around single implant restoration with and without augmentation procedure. A study by Cosyn et al evaluated the esthetic outcome of crown and soft tissue around single tooth implant with early placement following extraction and GBR. The study reported that clinical crown and facial soft tissue presented small changes (0.3 mm) in 21 months and that patient satisfaction might be related to adequate bone volume at implant placement due to bone augmentation[100]. Verdugo et al reported the onlay graft technique would predictably reconstruct function and esthetics. The study also reported stable bone volume around implants at an average of 3.5 years. [101]. Moreover, Kan et al reported in the study of immediate placement of single tooth implant that the absence of grafting the gap between the implant and facial bone could have influenced the clinical outcome of recession[42]. On the other hand, Jemt and Lekholm performed a 6-year prospective clinical study evaluated the stability of facial contour after buccal block bone graft from patient bone. The author reported that block graft procedure provided sufficient bone volume for implant placement after 6 months, however, bone remodeling patterns in each individual might lead to unpredictable results for long-term prognosis. The author also reported that proper abutment and crown contour are beneficial in maintaining the buccal contour[102]. Therefore, bone grafting

prior to implant placement to establish adequate bone volume represents one management approach to minimize undesirable facial soft tissue deficiency. However, there is not a gold standard protocol to recommend what type of bone graft procedure can maintain buccal contour of implant restoration better than others.

In addition, gingival biotype is another factor that might be related to facial soft tissue around the implant crown. A study by Verdugo et al, reported grafted site phenotype did not seem to be influenced by the adjacent teeth biotype[101]. Kan et al, 2010 reported in an immediate implant placement study that a thin biotype was statistically associated with greater midfacial recession at implants and not relate to interproximal tissue levels[42]. Van Keresteren et al compared immediate protocol and delayed implants placement reported that no effect of biotype on the changes of soft tissues[98]. Raes et al[99] similarly concluded that biotype did not affect facial soft tissue alterations. A recent review by Lee et al, presented the relationship of gingival biotype and peri-implant soft tissue found that thin gingival biotype present higher risk of hard and soft tissue changes after implant surgery. Furthermore, modified implant abutment interfaces such as platform switched design also failed to maintain peri-implant soft tissue in thin gingival biotype. The relationship between immediate/delayed placement, gingival biotype and soft tissue recession is still controversial. According to this review, several investigators presented that immediate placement in patient who have thin biotype may increase risk of gingival recession more than with thick biotype, while some studies reported no significant relation between biotype and immediate placement protocol. Moreover, the author

also mentioned that in thin gingival biotype abutment material color might affect color of marginal soft tissue. Zirconia abutment is recommended that can be used for esthetic purposes in all gingival biotype[103]. On the other hand, Bressan et al reported that the thickness of the peri-implant soft tissue did not appear to be a crucial factor in the abutment impact on the soft tissue color. The peri-implant soft tissue color differs from the soft tissue color around natural teeth, no matter which type of restorative material is selected and the grey colored and titanium abutments invoked significantly higher color differences than gold or zirconia abutments.

Implant design is another factor that might have influence on facial hard and soft tissue contour. A contemporary implant design of rough neck surface reported that preserve marginal bone level compares to smooth neck surface implant. Reduction of smooth surface minimized marginal bone resorption around implant. Micro-rough and nano-rough surface extending to the implant neck and a fine thread in the cervical region has shown that the crestal bone level was stabilized by with transmitting loading force to the adjacent bony structures [104]. A study of immediate loading/provisionalization of single implant in esthetic zone showed that micro threaded, TiO2 grit-blasted implants maintains crestal bone level and improved soft tissue dimension[105]. Moreover, Den Hartog et al compared marginal bone level changes in different neck designs for single anterior tooth replacement. Three different implant neck designs included Steri Oss replace (smooth group), Replace Groovy (rough group) and Nobel Perfect implant (scalloped group) systems. They observed greater marginal bone loss over one year at the scalloped neck design, compared to the smooth neck and rough neck systems. Interestingly, while they

measured changes in interproximal tissues, they failed to measure changes from baseline to 6 months for the midfacial tissues[106].

Recent studies pay more attention to implant abutment interface and micro motion that influence hard and soft tissue changes. Micro gap formation during function may induce bacteria invasion into the connection between implant and abutment and the continued micromotion of transmucosal abutment may also create mechanical irritation of peri implant soft tissue, causing chronic inflammation and subsequent vertical bone resorption[107]. In addition, a study by Todescan et al demonstrated the closer the implant abutment junction to the crest of the bone, the more bone resorption occurred[77]. Therefore, implant designs that allow microbial leakage and/or micromotion of the implant-abutment connection can lead to chronic inflammation and bone loss. Ryser et al demonstrated that implants with connections that possess micromotion (flat-to-flat) are associated with reactionary crestal bone loss[108]. A current strategy to reduce the related inflammatory impact of flat-to-flat interface designs is the lateralization of the interface from the implant bone connection or "platform switching" [109]. Canullo et al, reported that in immediate single implant restorations in anterior area, the use of platform switching help preserve peri-implant alveolar bone-level. The study showed that the average of bone reduction level of 0.30 mm (SD = 0.16 mm) in platform switching group, while the average reduction in the control group is 1.19 mm (SD = 0.35 mm)[110]. A systematic review about platform switching by Atieh et al, reviewed 10 studies with 1,239 implants showed that the marginal bone loss around platform-switched implant was significantly less than platform-matched implant. However, there is no randomized clinical trial study that

proved platform-switching design preserve peri-implant facial soft tissue better than platform-match design[111]. A recent study by Pieri et al compared peri implant soft tissue level between two different implant abutment interfaces (one platform switched, the other flush), the authors measured bone and soft tissue changes one year following implant placement into premolar extraction sockets. The control implants (flat-to-flat) revealed 0.73 +/- 0.52mm midfacial recession while the test (platform switched) implant revealed 0.61mm +/-0.54 mm midfacial recession (NS). Most of the changes were recorded during the first 4 months of evaluation. The radiographic measures for control and test groups at 12 months revealed the average mesial and distal bone level changes were 0.49 +/-0.25mm and 0.19+/-0.17 mm change for control and test groups respectively. The authors observed that the soft tissue changes did not reflect the bone changes as suggested previously by many investigators (greater bone loss in control group than test group but no significant change for facial soft tissues) [112].

Rather than platform-switching or flat-to-flat interfaces, several studies have revealed the relative absence of reactive bone loss at implants with conical implant abutment connections that lack micromotion and lead to decrease marginal bone loss. A clinical trial on single-tooth replacements with the Astra Tech implant system demonstrated minimum marginal bone loss (0.06 mm at first year and mean total bone loss 0.14 mm in 5 years)[113]. Another retrospective study of immediate placement and provisionalization using micro-threaded Astra conical implant-abutment interface implants. The study reported that conical implant-abutment interface with immediate placement might prevent crestal bone loss (mean mesial

bone loss 0.33+/-0.40 and distal bone loss 0.28+/-0.37) and maintain soft tissue around implants[105]. A more recent prospective multicenter clinical study evaluated marginal bone level of immediate loading of single implants between placed in healed ridges and placed in extraction sockets. A 1 year result showed that there is increasing of mean marginal bone level of 1.30 mm in extraction socket group whereas in healed ridged group present a reasonable 0.40 mm of mean marginal bone loss. In addition, the investigators also observed with conical implant abutment interface, the mucosal zenith was stable or gain following definitive crown placement in both groups[114]. The evidence supports that conical interfaces help preserve marginal bone due to elimination of inflammatory zone at implant abutment interface and might lead to maintaining facial soft tissue level. A systematic review comparing long term marginal bone responses of different implant systems illustrates the potential influence of implant design on outcomes [115].

The implant abutment interface design is another factor affecting peri-implant tissue responses. The different facial soft tissue responses to different implant abutment interfaces are of current interest. Unfortunately, no systematic, prospective comparison of peri-implant tissue responses at implants of varying implant/abutment interface designs has been undertaken. Therefore, the aim of this study is to compare the buccal soft tissue changes occurring around single-tooth replacement in the maxilla using three different implant-abutment interface designs. The null-hypothesis of this prospective clinical study is there is no statistically significant of facial soft tissue changes around single implant in esthetic areas compare between

three different implant-abutment interface designs, namely, conical interface, flat-to-flat, and platform switch design.

2. Materials and methods

The study was an open, prospective, randomized multicenter study. The study population consisted of individuals requiring one or more single tooth replacement in the maxilla within region 5 to 12. 141 Subjects distributed among four centers were treated and followed for one year duration. The treatment included implant and abutment installation in a one-stage procedure with immediate provisionalization followed by final restoration. Eight main clinic visits were involved. Subjects were randomized into three groups: group A (Conical interface design-OsseoSpeed), group B (Flat-to-flat interface design-NobelSpeedy Replace) or group C (Flat platform switch design-NanoTite Certain Prevail) (Figure.1).

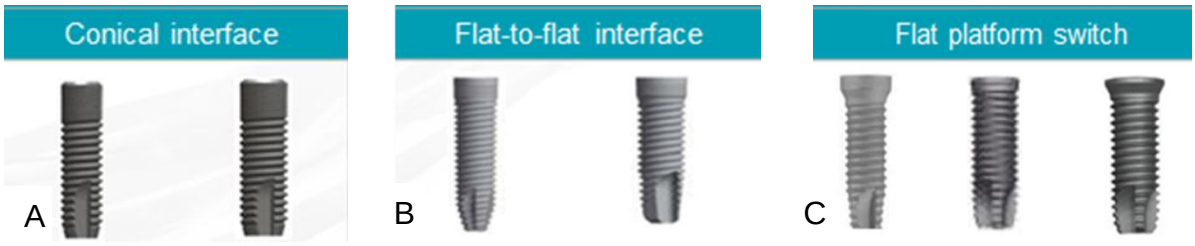

Figure 1. Implant abutment interfaces: (A) Conical, (B) Flat-to-flat, and (C) Flat platform switch

The change in peri-implant tissue from baseline (provisional restoration) to one year was compared. Measurements of peri-implant mucosal changes were made from standardized photographs at visit 4 (4 weeks after implant placement and provisionalization), visit 6 (provisional restoration, more than 8 weeks after implant

placement prior delivery final crown) visit 6 (permanent restoration, 3 months after implant placement), visit 7 (6 month follow up), and visit 8 (12 month follow up). The study protocol, as well as, the informed consent forms, was approved by the Institutional Review Board (IRB) of the University of North Carolina, Chapel Hill.

2.1 Patient selection

A total of 171 subjects, requiring one or more single tooth replacement in the maxilla within esthetic zone (5 to 12) were examined in visit 1. Thirty subjects were excluded according to exclusion and inclusion criteria. Therefore, 141 subjects were enrolled and randomized into one of three treatment group among 4 centers.

Inclusion criteria

The study subjects were required to be systemically healthy or controlled medical condition by physician, between ages of 18 and 70 years, who needed one or more single tooth replacements in the maxilla within region 5 to 12 and edentulous for at least 5 months at study site. Teeth adjacent to study site must consist of two stable teeth on natural roots without signs of periodontal bone loss and/or significant soft tissue loss. Teeth adjacent to study site must demonstrate a stable occlusal guidance that will allow non-functional disclusion in all eccentric positions. An opposing dentition must be teeth, implants or fixed prosthesis.

Exclusion criteria

Patients who used tobacco within the last 6 months, current alcohol or drug abuse, used any substances that would influence bone metabolism or any medication that would influence post-operative healing and osseointegration were excluded from the

study. Patient with uncontrolled diabetes and systemic or local disease or conditions that would compromise post-operative healing and/or osseointegration were also excluded. Untreated rampant caries and/or uncontrolled periodontal disease, class II malocclusion and insufficient inter-occlusal distance for implant placement and restoration at study site were also included in exclusion criteria.

Randomization

In each center, subjects meeting all inclusion and none of the exclusion criteria were randomized to group A (Conical interface design), group B (Flat-to-flat interface design) or group C (Flat platform switch design) the day of implant surgery. Randomization was done using a computer-generated randomization list and the result was not accessible for the investigators until the end of the study.

2.2 Clinical protocol and procedures

Eight main clinical visits were involved in this study over a 1 year period (Figure.2). All implants were placed in healed sited using immediate provisional protocol. Measurements of peri-implant mucosal changes made from standardized photographs at visit 4 (IP+4 weeks), visit 6 (IP+8 weeks-both provisional and permanent crown), visit 7(IP+6 month) and visit 8(IP+12 month).

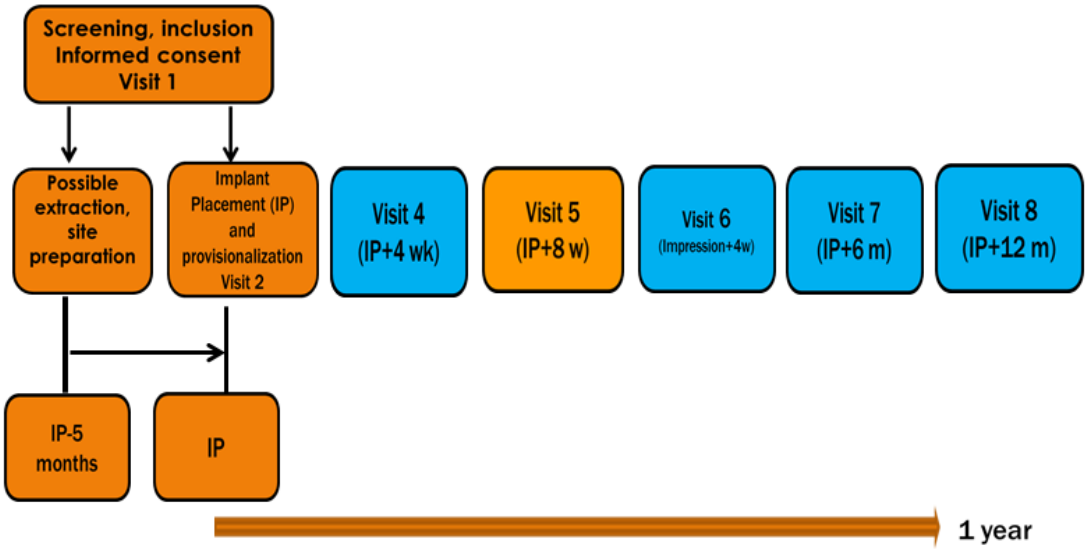

Figure 2. Flowchart of clinical protocol and procedures over a 1 year period

Before any assessment was carried out for study purposes, eligible patients providing informed consent were enrolled (IRB number: 08-2024). Patient characteristics and diagnostic information, including cone beam computer tomographic radiograph were recorded.

Subjects that fulfilled all inclusion and none of the exclusion criterion without going through site preparation were immediately scheduled for implant placement. Subjects with existing teeth, infection, residual alveolar ridge defects or insufficient soft tissue height were enrolled and prepared for a 5 month prerequisite site preparation phase. Recombinant Human Bone Morphogenetic Protien-2 (rhBMP-2) was used as bone graft material and a collagen membrane was used to cover augmentation material prior to flap closure procedure. Subjects only requiring soft tissue graft procedures were enrolled and prepared for at least a 6 week site

preparation phase. After at least 5 months of healing, radiographic assessment was taken and evaluated before scheduling for implant placement.

In each center, subjects were randomized to group A (Conical interface design-OsseoSpeed), group B (Flat-to-flat interface design-NobelSpeedy Replace) or group C (Flat platform switch design-NanoTite Certain Prevail) the day of implant surgery. Subjects not fulfilling the criteria were terminated from the study and received an appropriate treatment and followed according to the clinic's routines.

Prior to implant surgery, patients were pre-medicated with 2 g of Amoxicillin (600 mg of Clindamycin if penicillin allergy) and 800 mg Ibuprofen. The antibiotic prescription was extended for a period of 7 days postoperatively. Patients were also given 0.12% Chlorhexidine gluconate solution as perioral lavage before surgical procedure. The surgery followed applicable surgical guidelines from the manufacturers. Implant placement involved a tissue punch access and a flapless surgical procedure using the information provided by the surgical guide and radiographic assessments.

The cases in which bone grafting material was required and used in conjunction with implant placement were considered as protocol deviations. In cases where primary stability could not be obtained, the conventional two-stage approach and an extended healing period were used. In cases where immediate provisionalization could not be applied an appropriate delayed loading protocol was used.

After implant placement, a Direct Abutment (group A), Snappy Abutment (group B) or Provide Abutment (group C) was appropriately adjusted for facial and or incisal clearance and subsequently seated. For NanoTite Certain Prevail (group C) with an

endosteal diameter of 3.25 mm, the temporary abutment was chosen at the discretion of the Investigator. The abutment screw was tightened to a minimum of 15 Ncm followed by cementation of provisional crowns. Occlusion was monitored (no centric and excursive contacts). Seven days after implant placement, the patients returned for follow up visit. Any implant demonstrating mobility at abutment connection was considered a failure and was recorded and included in failure analysis. At 1 month after implant placement, first standardized clinical photograph was taken as a base line to evaluate soft tissue changes (gingival zenith, mesial and distal papillae) occurring around single-tooth replacement in the esthetic maxilla area. Eight weeks after implant placement, implant level impression was made and all models were sent for the manufacturing of zirconia Atlantis abutments except for NobelSpeedy Replace 3.5 (NP) for which Procera Abutment was used instead. All permanent ceramic crowns from all centers were fabricated from one laboratory.

After impression visit 4 week, zirconia Atlantis permanent abutment was placed and torqued followed each manufacturer recommendation. An all-ceramic (Lithium disilicate) permanent crown was permanent cemented with Rely X Unicem. Oral hygiene instructions were provided and a periapical radiographs was obtained. The clinical photograph was taken for the evaluation of soft tissue changes around single tooth implants in this visit. All subjects returned for follow-up visits at 6 and 12months after implant placement. Standardized clinical photographs were taken to evaluate gingival zenith and papilla changes.

2.3 Data Collection

This study evaluated the soft tissue changes around single tooth implant in the esthetic zone (site #5-#12) longitudinally through collection of standardized oral photographs. In order to acquire standardized clinical photograph, digital camera was connected to a stereo tactic device (canfield apparatus), which created reproducible patients and camera positions appear in figure. 3.

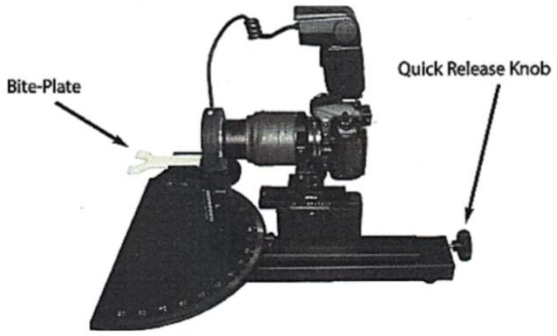

Figure 3. Canfield apparatus

All centers used the same camera model that has a standard setting with regards to: distance, f-stop, ISO speed, and related parameters. All photographs were taken with standardized internal mm markers (UNC 15 mm periodontal probe). Two standardized clinical photographs were taken of each site at each visit (one with periodontal probe and one without periodontal probe) as present in figure. 4.

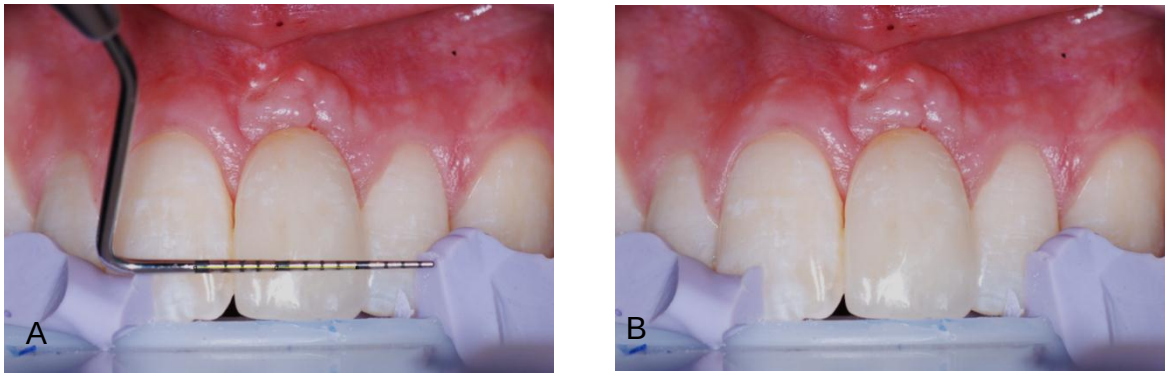

Figure 4. Standardized clinical photograph of each site in each visit, (A) one with periodontal probe and (B) without periodontal probe

Each photograph included the gingival zenith of replaced tooth, mesial and distal papillae of replaced tooth, incisal edges of replaced tooth and incisal edges of adjacent teeth. Clinical photographs of each subject were collected at 4 main visits: visit 4 (IP +1 month-provisional crown), visit 6 (IP+3 month-both provisional and permanent crown), visit 7(6 month follow up after implant placement), visit 8(12 months follow up). All photographs were saved as JPEG files for each subject using numbering identifiers.

2.4 Evaluation Methods

Soft tissue responses were evaluated by measuring the changes in the gingival zenith, mesial and distal papillae parameters from standardized clinical photographs using image J software. The unaltered images were imported as .jpg files (X pixels) from a PC computer into the software. Image containing millimeter probes were calibrated by a process in which the number of pixels within a measured distance between the probe's millimeters marking was recorded. After determining how many pixels were contained in 1 mm the images that did not contain such probes were considered measurable. All photographs were measured by 2 observers. All study

measurements were performed by the blinded investigators. Mean values between the 2 investigators were used and sent to statistician for statistical analysis.

Two methods of measurement were used in this study. First, assessment method for buccal soft tissue change is to measure the vertical distance from mid-incisal edge of implant crown to mid-buccal of gingival zenith as appears in figure 5

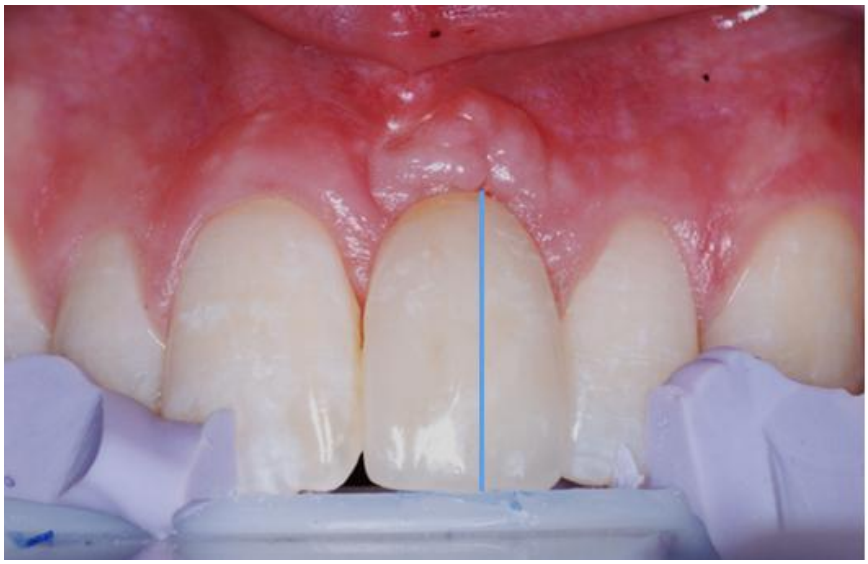

Figure 5. Assessment method for buccal soft tissue change

Second method is used to evaluate papilla height by using the gingival zeniths of the adjacent teeth as a reference points to draw a reference line and make vertical measurements from mesial and distal papillae perpendicular to the reference line as appears in figure. 6.

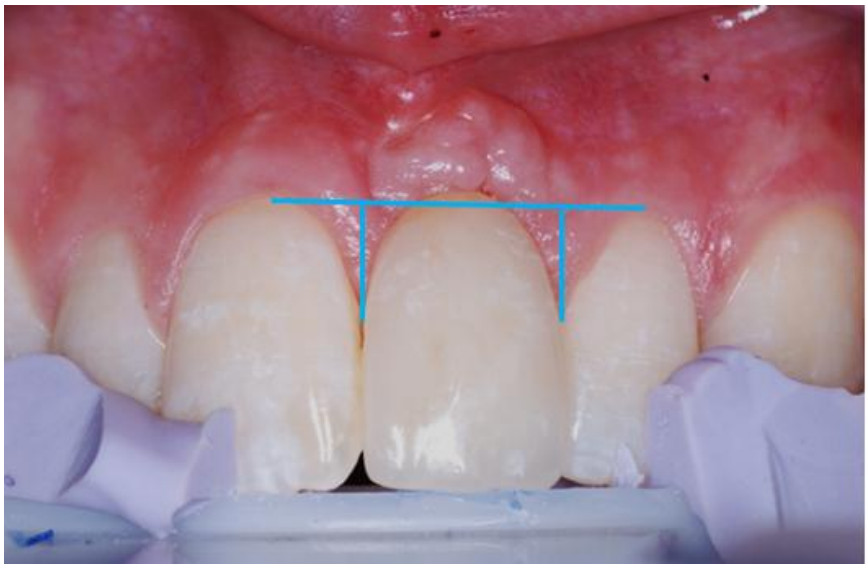

Figure 6. Assessment method for papilla height change

The changes in the gingival zenith, mesial and distal papillae from baseline to each time point were calculated for each implant location. The changes for each implant were compared longitudinally. The average for each treatment group were calculated and compared among treatment groups for each evaluation period.

2.5 Statistical Methods

In previous reports of soft tissue recession values ranging from almost 0 up to 0.9 mm have been reported when investigating the change from baseline to one year[116389842]. The reported standard deviations range from close to 0 up to almost 1 mm. A clinically relevant difference with regard to soft tissue dimensions is between 0.5 and 1.0 mm. A practical number of subjects per treatment group at each center is 12, resulting in 48 subjects per group in total with 4 centers. With an estimated drop-out rate of 15% this gave 41 evaluable subjects per group. 41 subjects gave about 90% power to detect a difference of 0.5, which was considered clinically

relevant to detect, with a standard deviation of 0.7 mm in each group. 123 patients were considered sufficient as effect sizes and in this study 141 patients were used to analyze the soft tissue change over time.

Demographics characteristics were presented by means of descriptive statistics. Continuous variables were presented by means of number of observations (N), minimum (min), median, maximum (max), mean and standard deviation (SD), and discrete variables by frequency and percentage.

Inter-group comparisons were performed using Mann Whitney U-test. A P-value of $P \leq 0.05$ was considered to be statistically significant.

3. Results

A total of 141 subjected were included and distributed among four centers: 38 in center 1, 38 in center 2, 26 in center 3, and 42 in center 4. These 141 were randomly assigned to 3 groups as following: 48 in group A, 49 in group B and 44 in group C. A total of 156 implants were placed. Fifteen subjects had two randomized implants; one of these implants in each subject was excluded by tossing a coin. Hence, a total of 141 implant sites in 141 subjects were included in the analysis; 48 in group A, 49 in group B and 44 in group C. The demographic and implant characteristics of the study subjects are summarized in Table 4.

Table 4. Demographic and implant characteristics of the study sample

	Treatment group			
Characteristic	A (n=48)	B (n=49)	C (n=44)	Total (n=141)
Sex (n and % of subjects)				
Male	25 (17.7)	14 (9.9)	22 (15.6)	61 (43.2)
Female	23 (16.3)	35 (24.8)	22 (15.6)	80 (56.7)
Age (years)				
Mean (±SD)	43 (15)	46 (17)	46 (16)	45 (16)
Median	44	49	48	45.5
Range	(18,70)	(19,78)	(18,81)	(18,81)
Race/ethnicity (n and %)				
Asian	2 (1.4)	2 (1.4)	1 (0.7)	5 (3.5)
Black	5 (3.6)	2 (1.4)	6 (4.3)	13 (9.3)
White	40 (28.4)	45 (31.9)	35 (24.8)	120 (85.1)
Other	1 (0.7)	0 (0.0)	2 (1.4)	3 (2.1)
Implant site (n and %)				
Central incisor	13 (9.2)	17 (12.1)	14 (9.9)	44 (31.2)
Lateral incisor	21 (15.0)	13 (9.2)	15 (10.6)	49 (34.8)
Canine	4 (2.8)	6 (4.3)	3 (2.1)	13 (9.2)
First premolar	10 (7.1)	13 (9.2)	12 (8.5)	35 (24.8)

During the one year evaluation period, 13 of 141 implants failed (Figure 7). Two of the failures were observed in an implant loaded 1 week following placement, 5 implants were lost 1 month after implant placement, 3 implants were lost 3 month after implant placement, 3 implants were lost after delivery of the permanent crown within a 6 months period, and four implants were lost to follow up. No additional implant failures were recorded after 6 month follow up. This resulted in an overall implant survival rate of 92.91%.

There was no implant loss in group A over 1 year period. Majority of implants lost in early stage were in group B, while group C implants were lost later on.

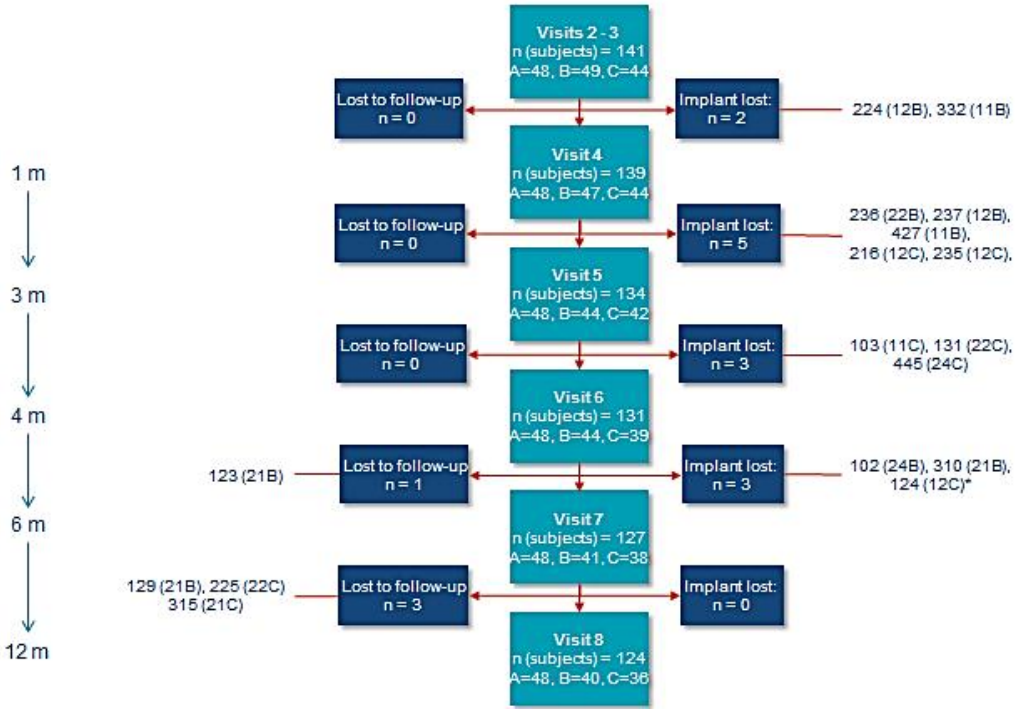

Figure 7. Study population flow chart

3.1 Buccal soft tissue (Gingival zenith) response

Mean values and standard deviations of the changes of gingival zenith height for all study groups are presented in Table 5.

Table 5. Comparison of mean gingival zenith changes (±SD) between groups over time

Time\Treatment group	A (Conical)	B (Flat-to-flat)	C (Platform Switch)	Total
Value (mean ± SD, range) mm				
Visit 4 pro	8.8 ± 1.6, 3.8 to 12.9	8.9 ± 1.5, 5.1 to 11.6	9.3 ± 1.5, 5.8 to 12.9	9.0 ± 1.5, 3.8 to 12.9
Visit 6 pro	9.0 ± 1.7, 3.6 to 14.2	9.0 ± 1.5, 5.1 to 12.4	9.2 ± 1.5, 5.9 to 12.1	9.1 ± 1.6, 3.6 to 14.2
Visit 6	9.5 ± 1.6, 6.1 to 13.7	9.2 ± 1.6, 5.8 to 12.3	9.8 ± 1.2, 7.6 to 12.2	9.5 ± 1.5, 5.8 to 13.7
Visit 7	9.5 ± 1.6, 5.9 to 14.0	9.4 ± 1.7, 6.2 to 12.1	9.7 ± 1.2, 7.3 to 12.4	9.5 ± 1.5, 5.9 to 14.0
Visit 8	9.6 ± 1.6, 6.0 to 13.7	9.3 ± 1.7, 6.6 to 13.0	9.6 ± 1.2, 7.3 to 12.5	9.5 ± 1.5, 6.0 to 13.7
Change (mean ± SD, range) mm				
Visit4 pro-Visit6pro	-0.1 ± 0.5, -1.6 to 0.8	0.0 ± 0.3, -0.8 to 0.7	0.1 ± 0.8, -3.9 to 1.1	0.0 ± 0.5, -3.9 to 1.1
Visit6-Visit 7	0.0 ± 0.4, -1.2 to 0.9	-0.1 ± 0.3, -0.8 to 0.8	0.0 ± 0.3, -0.8 to 0.6	0.0 ± 0.4, -1.2 to 0.9
Visit6-Visit 8	0.0 ± 0.5, -2.0 to 1.1	-0.2 ± 1.0, -5.6 to 1.0†	0.0 ± 0.4, -1.3 to 1.0	-0.1 ± 0.7, -5.6 to 1.1

The mean (±SD) changes of gingival zenith height from the time of delivery of permanent crown (visit6) to 1 year followed implant placement (visit8) was 0.0±0.5 mm in group A (range -0.2 to 1.1 mm),-0.2±1.0 mm in group B (range -5.6 to 1.0 mm), and 0.0±0.4 mm in group C (range -1.3 to 1.0 mm). A total mean (±SD) gingival zenith height changes was -0.1±0.7 mm (range -5.6 to 1.1 mm) over a 1 year period. These differences between the three groups were not statistically significant both at 6 months and at 1 year period of time (Mann Whitney U-test, p >0.05). Only mean changes of gingival zenith of provisional restorations at implant placement visit (visit 4) and provisional restoration at visit6 showed significant different between group A vs. C and group B vs. C, no significant different between

group A and B (The mean changes in group A was -0.1 ± 0.5, group B was 0.0 ± 0.3, and group C was 0.1 ± 0.8) (Mann Whitney U-test, p <0.05). The changes of gingival zenith height between delivery of permanent crown visit and 6 months followed implant placement were smaller range than the changes up to 1 year follow up. The mean changes of gingival zenith height from delivery permanent crown (visit6) to 6 months followed implant placement (visit7) were evaluated in three groups: 0.0±0.4 mm in group A (range -1.2 to 0.9 mm),-0.1±0.3 mm in group B (range -0.8 to 0.8 mm), and 0.0±0.3 mm in group C (range -0.8 to 0.6 mm). A total mean gingival zenith height change was 0.0±0.4 mm (range -1.2 to 0.9 mm). At one year period, the changes of gingival zenith height in all study groups presented similar proportion between stable or gain of gingival zenith height and loss of gingival zenith height as presented in figure 8

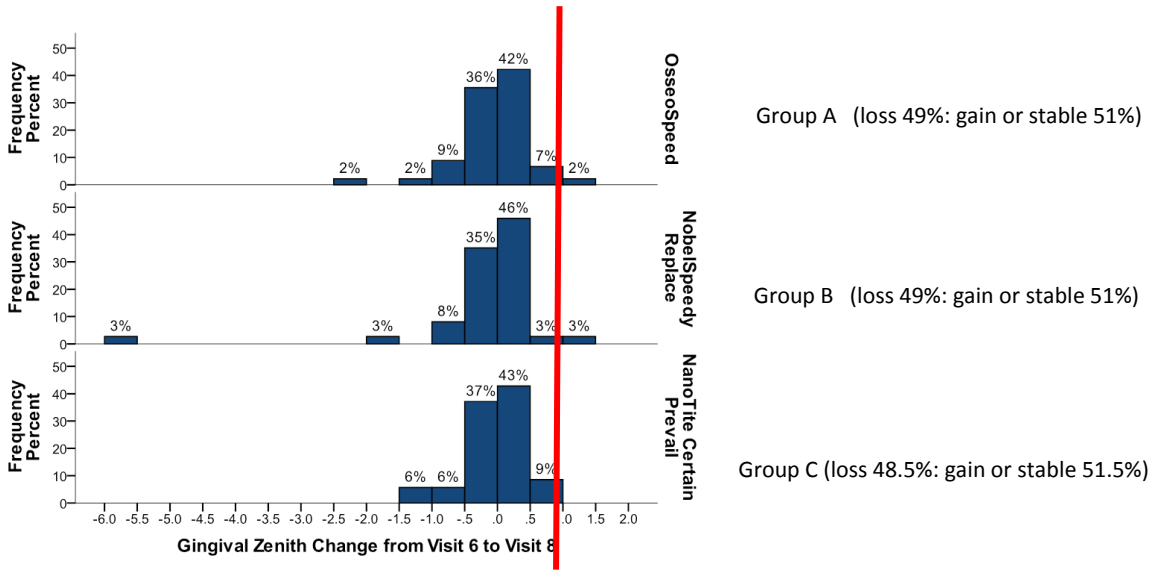

Figure 8. Comparison of gingival zenith change between implant types from placement of permanent crown to 1 year follow up.

3.2 Mesial papilla response

Mean values and standard deviations of the changes of mesial papilla height for all study groups are presented in Table 6.

Table 6. Comparison of mean mesial papilla changes (±SD) between groups over time

Time\Treatment group	A (Conical)	B (Flat-to-flat)	C (Platform Switch)	Total
Value (mean ± SD, range) mm				
Visit 4 pro	3.7 ± 1.1, 1.5 to 6.1	3.3 ± 1.1, 0.7 to 5.5	3.8 ± 0.9, 2.1 to 5.5	9.0 ± 1.5, 3.8 to 12.9
Visit 6 pro	3.8 ± 1.2, 1.5 to 7.9	3.6 ± 1.1, 1.3 to 5.8	3.9 ± 0.9, 2.0 to 5.5	9.1 ± 1.6, 3.6 to 14.2
Visit 6	3.9 ± 1.2, 0.5 to 8.1	3.5 ± 1.0, 1.3 to 5.8	4.0 ± 0.9, 2.0 to 5.5	9.5 ± 1.5, 5.8 to 13.7
Visit 7	4.1 ± 1.4, 0.6 to 8.6	3.7 ± 0.9, 1.1 to 5.2	4.1 ± 0.9, 2.0 to 6.3	9.5 ± 1.5, 5.9 to 14.0
Visit 8	4.2 ± 1.3, 0.5 to 8.3	3.7 ± 0.9, 1.1 to 5.2	4.2 ± 0.9, 1.8 to 6.2	9.5 ± 1.5, 6.0 to 13.7
Change (mean ± SD, range) mm				
Visit4 pro-Visit6pro	0.2 ± 0.7, -1.2 to 2.8	0.2 ± 0.6, -0.9 to 2.2	0.1 ± 0.6, -1.5 to 1.3	0.1 ± 0.6, -1.5 to 2.8
Visit6-Visit 7	0.2 ± 0.5, -0.9 to 1.7	0.1 ± 0.6, -0.6 to 1.8	0.2 ± 0.4, -1.0 to 1.3	0.2 ± 0.5, -1.0 to 1.8
Visit6-Visit 8	0.2 ± 0.5, -1.1 to 1.4	0.4 ± 0.5, -0.6 to 2.1	0.2 ± 0.6, -0.9 to 1.7	0.3 ± 0.5, -1.1 to 2.1

The mean (±SD) changes of mesial papilla from delivery permanent crown (visit6) to 1 year followed implant placement (visit8) was 0.2±0.5 mm in group A (range -1.1 to 1.4 mm),0.4±0.5 mm in group B (range -0.6 to 2.1 mm), and 0.2±0.6 mm in group C (range -0.9 to 1.7mm). A total mean (±SD) gingival zenith height changes was -0.3±0.5 mm (range -1.1 to 2.1 mm) over a 1 year period. The mean change of mesial papilla between the three groups were not statistically significant at over a 1 year period(Mann Whitney U-test, $p > 0.05$). The changes of mesial papilla response showed gain in medial papilla height in all three study groups. Mesial papilla gain in group B (flat to flat) more than group A (conical) and group C (platform switch) as presented in figure 9

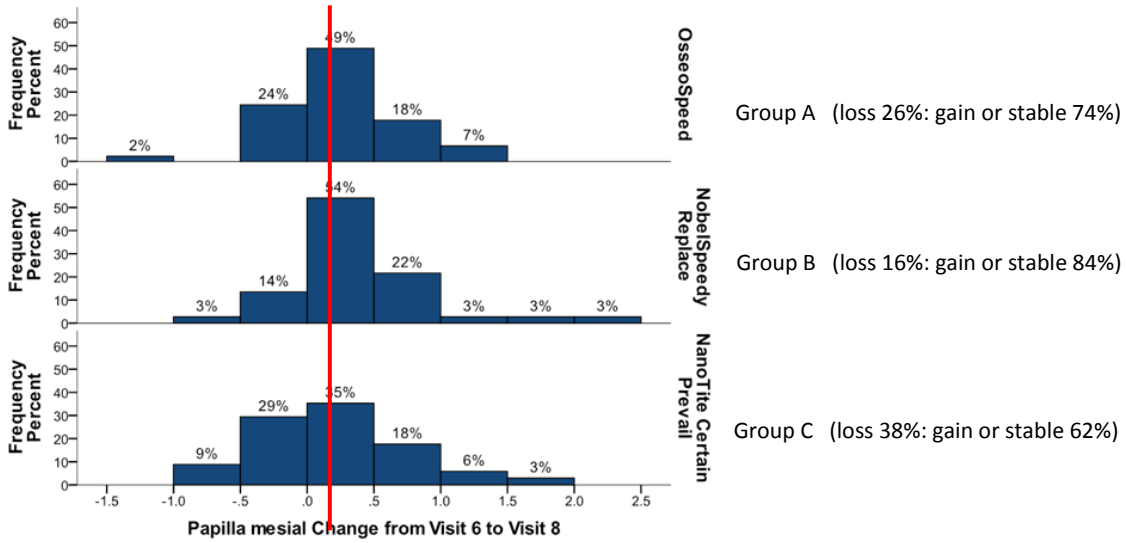

Figure 9. Comparison of mesial papilla changes between implant types from placement of permanent crown to 1 year follow up

3.3 Distal papilla response

Mean values and standard deviations of the changes of distal papilla height for all study groups are presented in Table 7.

Table 7. Comparison of mean distal papilla changes (±SD) between groups over time

Time\Treatment group	A (Conical)	B (Flat-to-flat)	C (Platform Switch)	Total
Value (mean ± SD, range) mm				
Visit 4 pro	3.0 ± 1.0, 0.7 to 4.9	2.8 ± 1.0, 1.2 to 4.9	3.3 ± 1.2, -0.7 to 5.6	3.1 ± 1.1, -0.7 to 5.6
Visit 6 pro	3.3 ± 1.0, 1.2 to 5.0	3.0 ± 1.0, 1.1 to 5.5	3.6 ± 1.1, 0.3 to 5.7	3.3 ± 1.1, 0.3 to 5.7
Visit 6	3.2 ± 0.9, 1.1 to 5.2	3.1 ± 1.0, 1.2 to 5.5	3.6 ± 1.1, 0.4 to 5.8	3.3 ± 1.0, 0.4 to 5.8
Visit 7	3.4 ± 1.2, 1.3 to 6.3	3.0 ± 1.0, 1.1 to 4.7	3.5 ± 1.0, 0.4 to 5.0	3.3 ± 1.1, 0.4 to 6.3
Visit 8	3.5 ± 1.0, 1.5 to 6.1	3.3 ± 1.0, 1.6 to 5.7	3.7 ± 1.0, 0.5 to 5.7	3.5 ± 1.0, 0.5 to 6.1
Change (mean ± SD, range) mm				
Visit4 pro-Visit6pro	0.3 ± 0.4, -0.4 to 2.2	0.1 ± 0.5, -1.5 to 1.7	0.2 ± 0.5, -0.6 to 1.3	0.2 ± 0.5, -1.5 to 2.2
Visit6-Visit 7	0.2 ± 0.4, -0.7 to 1.8	0.1 ± 0.4, -0.8 to 0.9	0.1 ± 0.4, -0.5 to 1.2	0.1 ± 0.4, -0.8 to 1.8
Visit6-Visit 8	0.2 ± 0.3, -0.3 to 1.1	0.2 ± 0.6, -0.9 to 2.0	0.2 ± 0.5, -0.9 to 1.1	0.2 ± 0.5, -0.9 to 2.0

The mean (±SD) changes of distal papilla from delivery permanent crown (visit6) to 1 year followed implant placement (visit8) was 0.2±0.3 mm in group A (range -0.3 to 1.1 mm),0.2±0.6 mm in group B (range -0.9 to 2.0 mm), and 0.2±0.5 mm in group C (range -0.9 to 1.1mm). A total mean (±SD) gingival zenith height changes was -0.2±0.5 mm (range -0.9 to 2.0 mm) over a 1 year period. The mean change of distal papilla between the three groups were not statistically significant at over a 1 year period(Mann Whitney U-test, p >0.05). The changes of distal papilla response showed gain in distal papilla height more than loss in all three study groups. Distal papilla gain in group A (conical) more than group B (flat to flat) which equal as group C (platform switch), as presented in fig 10

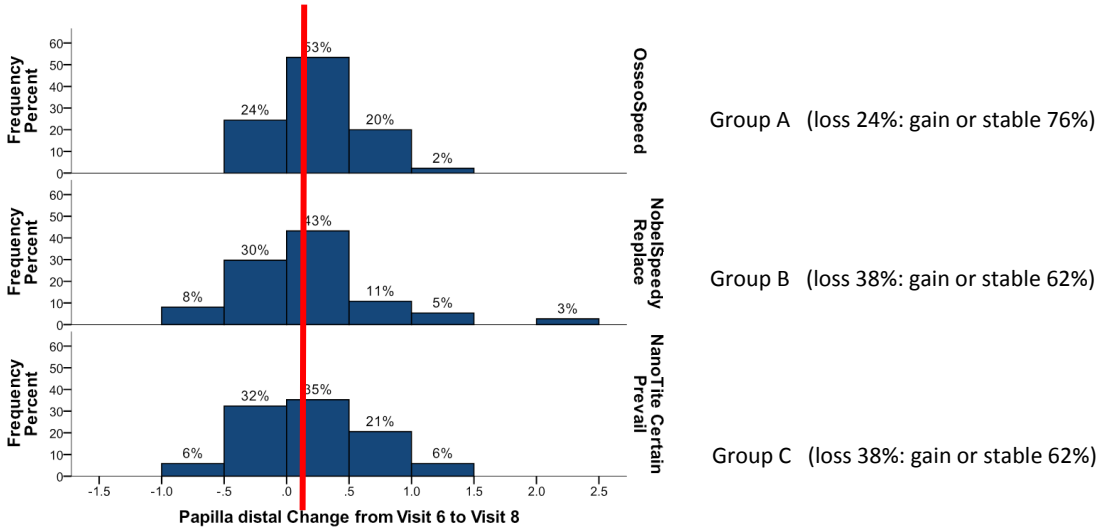

Fig.10. Comparison of distal papilla changes between implant types from placement of permanent crown to 1 year follow up

4. Discussion

Buccal soft tissue recession is a current concern in single implant esthetics. Recent studies[107,112,114]reported implant abutment interface designs have influence peri implant hard tissue responses which potentially reflect as soft tissue alteration and might compromise the esthetic outcome. Therefore, this study was designed to evaluate the changes of buccal soft tissue level (gingival zenith) around single implants in esthetic areas comparing between three different implant-abutment interface designs: conical interface, flat-to-flat, and platform switch design over a 1 year period.

The results of this study indicate no statistically significant difference regarding the changes of buccal soft tissue level (gingival zenith) between three implant-abutment interface designs during the 12 months follow up. According to published study, the micro gap between implant abutment connection in flat to flat design promote the bacterial infiltration and micro motion that lead to chronic inflammation around implant-abutment interface which affect marginal bone loss[108]. While, platform switch design was introduced to minimize the zone of inflammation by moving the area of inflammation further away from the marginal bone crest that help minimized the reduction of the peri implant bone level[110,111]. In addition, due to a design of elimination of inflammatory zone at implant abutment interface, conical interface was reported help

preserve marginal bone level[114,115]. According to previous publications, the changes of marginal bone level should be different between these three implant-abutment interface designs. Thus, it might be implied that changes of hard tissue does not represent the soft tissue response in this study, and that it probably it depends on factors other than implant-abutment interface design.

There have been few studies that prospectively compare the peri-implant tissue responses at different implant abutment interface designs. A recent study by Pieri et al[112] evaluated the changes of peri-implant hard and soft tissue response between two implant abutment interface design (flat-to-flat and platform switch). The study reported no statistically significant changes of mid buccal soft tissue level (0.73 +/- 0.52mm in flat to flat group and 0.61mm +/-0.54 mm in platform switch group), whereas greater bone loss was observed at flat-to-flat group (0.51+/-0.24mm) compare to platform switch group (0.2+/-0.17 mm). The study by Pieri provided similar conclusion as the current study that the changes of hard tissue might not reflect soft tissue alteration and there are some other factors that have more influence on the stability of buccal soft tissue level in this study. Den Hartog et al reported the mid-facial gingival level of the adjacent teeth remain stable, with no statistically different between three treatment groups (a mean recession of 0.81+/-0.45 mm in Replace Select Tapered, 0.28+/-0.36 mm in NobleReplace Groovy, 0.25+/-0.29 mm in NoblePerfect Groovy). While, NoblePerfect Groovy group showed significant more radiographic bone loss compared with Replace Select Tapered and NobleReplace Groovy group[106].

In addition, it is interesting that the total mean change in buccal soft tissue level (gingival zenith) was less than 0.2 mm at 12 months followed implant placement. While, several previous investigators[116-119] reported higher number of buccal soft tissue change. However, majority of these previous studies[117-119] reported advance facial soft tissue recession (more than 1 mm) in immediate implant placement whereas all implants in this current study were placed in healed extraction site with immediate provisionalization. There are well documents supported immediate provisionalizations in both healed ridge and fresh extraction site followed immediate placement that promote soft tissue response[98,114,120,121]. In addition, following the present study protocol, site preservation followed extraction, ridge augmentation and soft tissue graft had already been done prior implant placement. Majority of implants were placed with flapless procedure placing the implants 3 mm apical and 2 mm palatal to the planned gingival zenith to provide proper implant position in esthetic areas[82]. The absence of flap reflection has been reported in several studies to minimize the buccal soft tissue alteration[122-124]. These careful surgical protocols in this current study might promote the stability of buccal soft tissue level.

Limited buccal soft tissue changes in single implant crown (both immediate placement and conventional placement) have been reported in recent studies[46,125]. Van Kesteren et al[98] reported minimum recession (mean 0.17+/-0.47 mm) of mid facial soft tissue level over 6 months, with no different between immediate and delayed implant placement protocol. Van Kesteren and co-workers explained that the surgical protocol of their study might affect the limitation of soft tissue level change between treatment groups. For example, same implant type (Sandblasted,

acid-etched surface, SLA Struamann) were utilized in both treatment groups and ridge preservation had been done in delay treatment group whereas immediate treatment group required less number of flap procedure and bone graft were also provided if defect was greater than 2 mm.

In the present study, all treatment groups received similar type of implant design with nano rough surface and small threaded. Several studies reported nano rough surface and micro threaded implant designs maintain bone level and promote soft tissue response[104,105]. Moreover, zirconia Atlantis abutments were used as the permanent abutments for all implant crowns in this present study. Several studies[6,103,126] reported zirconia abutment is recommended to use in anterior esthetic zone due to biological compatibility and reflect better soft tissue color. A recent systematic review reported the cumulative rate for biological complications with ceramic abutments (5.2%) was less than metal abutments (7.7%)[126]. Thus, zirconia abutments might be one factor that minimized buccal soft tissue recession in this study. However, biologic response of buccal soft tissue level to zirconia abutment is still unclear. A systematic review by Sailer et al[127], reported higher buccal soft tissue recessions in zirconia abutment (8.9%) compare with titanium abutment (3.8%). Sailer and co-worker explained that higher recession found with zirconia abutment might relate to area of implant placement, zirconia abutment usually used in anterior esthetic area which is an area that prone to observe soft tissue recession while titanium abutment in literature review commonly utilized in posterior region.

Gingival biotype might be another factor that affects buccal soft tissue around implant restoration. Several recent studies[42,101,103] reported that a thin biotype was

statistically associated with greater midfacial recession at implants. Platform switch design was reported that increase thickness of buccal soft tissue due to the lateralization of the interface from the implant bone[128]. However, there are number of studies reported that gingival biotype is not associated with peri-implant buccal soft tissue recession[98,99].

The changes of interproximal papilla height have also been evaluated in this study. Overall changes of papilla height show little improvement in all treatment groups over 1 year period (total mean mesial papilla gain 0.3±0.5 mm, distal papilla gain 0.2±0.5 mm), with no statistically significant difference between three implant abutment interface designs. There are several clinical studies evaluated papilla level changes in single implant crown with minimum changes[42,98,125,129,130]. The improvement of papilla height had also been reported by other investigators[106,120,125]. Possible explanations might similar as explained buccal soft tissue stability. However, when pay more attention into details between three different implant-abutment interface designs, conical interface (76% gain) presents higher proportions of distal papilla height gain compare to flat-to-flat (62% gain) and platform switch design (62% gain). While, the proportions of mesial papilla gain flat-to-flat design (84% gain) were higher than conical interface (74% gain) and platform switch presents with lower proportions (62% gain). From the study results, it can be implied that platform switch design provided less advantages in preserve papilla height compare to other designs. While, conical interface seems to be the most reliable design that promote interproximal papilla soft tissue.

Further long-term studies with evaluation of the changes of peri-implant soft tissue between these three implant-abutment interface designs up to 3 years are necessary.

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