

Original article

Full Title: Platform switching in two-implant bar-retained mandibular overdentures: 1-year results from a split-mouth randomized controlled clinical trial.

Running Title: Platform switching in bar-retained overdentures

Authors: **Dr. med. dent. Samir Abou-Ayash ***

Department of Reconstructive Dentistry and Gerodontology,
University of Bern, Switzerland

Prof. Dr. med. dent. Martin Schimmel *

Department of Reconstructive Dentistry and Gerodontology,
University of Bern, Switzerland

Division of Gerodontology and Removable Prosthodontics,
University of Geneva, Switzerland

Dr. med. dent. Dominik Kraus Department of Prosthodontics,
Preclinical Education and Dental Material Science, University of
Bonn, Germany

Prof. em. Dr. med. dent. Regina Mericske-Stern, School of Dental
Medicine, University of Bern, Switzerland;

Dr. med. Dr. med. dent. Dominic Albrecht, Private Practice, St.
Gallen, Switzerland

Prof. Dr. med. dent. Norbert Enkling

Department of Reconstructive Dentistry and Gerodontology,
University of Bern, Switzerland

Department of Prosthodontics, Preclinical Education and Dental
Materials Science, University of Bonn, Germany

*-equal contribution as first author

Corresponding author:

Dr. med. dent. Samir Abou-Ayash

Department of Reconstructive Dentistry and Gerodontology, University of Bern

Switzerland

Freiburgstrasse 7

3010 Bern, Switzerland

E-Mail: samir.abou-ayash@zmk.unibe.ch

Tel: +41 (0)31 632 8705

Author contribution:

S.A.-A.: data analysis/ interpretation, final article, approval of article

M.S.: data analysis/ interpretation, drafting article, approval of article

D.K.: data acquisition, drafting article, approval of article

R. M.-S.: concept/design, drafting article

D.A.: data acquisition, drafting article, approval of article

N.E.: concept/design, data acquisition, drafting article, approval of article

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Abstract

Objectives: The concept of platform switching is widely applied in current implant dentistry, however, the influence on peri-implant bone level alterations (Δ IBL), especially in the field of implant overdentures (IODs), remains inconclusive. Therefore, the present study aimed to test the alternative hypothesis that there is an equivalent Δ IBL at platform-switching and platform-matching implant abutments in 2-implant bar-retained IODs.

Materials and Methods: Two interforaminal implants were placed in 32 subjects, who were randomly assigned to either an immediate- or a 3-month post-placement loading group. Furthermore, one implant in each subject was randomly assigned to receive a platform-switched (test), and one a platform-matching abutment (control). The implants were splinted with prefabricated, chairside customized bars. Δ IBL was recorded by using customized radiograph holders at implant placement, implant loading, 3 months, 6 months, and 12 months after loading.

Results: After one year, equivalent Δ IBL could be identified (test: -0.51 mm \pm 0.49 vs. control: -0.56 mm \pm 0.52 ; $p < 0.001$). Δ IBL increased over time and was more pronounced in the delayed-loaded (-0.87 mm \pm 0.61) relative to the immediately loaded implants (-0.35 mm \pm 0.43 ; $p = 0.022$).

Conclusions: The prosthetic concept of platform switching does not necessarily lead to reduced bone loss. Immediate loading of implants, primarily splinted with a bar, might be beneficial regarding peri-implant bone-level changes over a short-term period.

Introduction

Dental implant treatment has become an integral part of current dentistry (Quirynen et al. 2014). Its popularity has been increasing within the last decades, as it has been proven as a predictable treatment option, with high success and survival rates even in long-term observations (De Bruyn et al. 2017; Chappuis et al. 2018). Today, implants are used in various clinical situations when single or multiple teeth have to be replaced (Buser et al. 2017). Many authors have described criteria evaluating the success of dental implant treatment (Smith & Zarb 1989; Buser et al. 1991; Misch et al. 2008). However, one of the main criteria defining implant success is peri-implant bone stability (Papaspriidakos et al. 2012). As dental implant treatment has improved, the success criteria regarding peri-implant bone stability were also expected to become stricter. In the mid-1980s, an implant was defined to be successful if the peri-implant bone loss was less than 1.5mm within the first year, and less than 0.2mm in the following years (Albrektsson et al. 1986). These criteria are still well accepted today, despite reports of reduced peri-implant bone-level changes (Δ IBL) (Papaspriidakos et al. 2012; Salvi et al. 2018).

Several major factors influencing bone level changes have been identified, including the vertical and horizontal implant position within the bone (Chen & Buser 2014; Mailoa et al. 2015), the implant design (Steigenga et al. 2003; Albrektsson & Wennerberg 2019), the timing of implant placement loading (Gallucci et al. 2018), the type of restoration (Vigolo et al. 2015; Clelland et al. 2016), and the integrity and design of the implant-abutment connection (Schwarz et al. 2014; Messias et al. 2019). Regarding the design of the implant-abutment connection, the concept of platform switching has been reported to have a direct influence on bone-level changes (Hsu et al. 2017). According to the current edition of the glossary of prosthodontic terms,

platform switching is defined as “a concept of using a dental implant abutment of smaller diameter than the dental implant” (The Glossary of Prosthodontic Terms: Ninth Edition 2017), relocating the micro-gap between the implant and the abutment toward the center of the implant and away from the bone. Some studies have shown that positioning the micro-gap close to the bone can lead to enhanced bone resorption (Lazzara & Porter 2006; Hsu et al. 2017). Furthermore, *in vitro* studies have shown that the concept of platform switching leads to reduced stress on the marginal bone, and consequently may decrease crestal bone loss (Liu et al. 2014; Bouazza-Juanes et al. 2015). However, the available evidence for the influence of platform switching on Δ IBL changes is inconclusive. There are studies supporting a positive effect of platform switching on the amount of peri-implant bone loss, whereas other studies show no effect of this approach (Enkling et al. 2013; Chrcanovic et al. 2015; Meloni et al. 2016).

One explanation for this discrepancy could be the heterogeneity of the currently available literature regarding platform switching; the discussion on its effect omits other contributing factors, including the type of prosthetic rehabilitation (Chrcanovic et al. 2015). In particular for removable implant-supported dentures in partially or completely edentulous subjects, the effect of platform switching on Δ IBL remains unclear. To the best of the authors’ knowledge, there is currently no controlled clinical study focusing on the influence of platform-switching on Δ IBL in implant overdentures (IODs) available. Therefore, the aim of this split-mouth randomized controlled clinical trial was to analyze the influence of platform-switching on Δ IBL in two-implant bar-retained IODs. Furthermore, the influence of the implant loading protocol (i.e. immediate vs. delayed loading after 3 months) on Δ IBL, as well as the clinical outcomes (technical and biological complications), were

to be analyzed. The alternative hypothesis set for this study was that there would be equivalent Δ IBL for a circular platform switch of 0.35mm and matching diameter abutments.

Materials and Methods

This study was conducted in compliance with ethical standards as prescribed by the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155, as well as fulfilling all the national legal and regulatory requirements (General Assembly of the World Medical Association 2014). The study protocol was approved by the Cantonal Ethics Committee of Bern (CEC N°. 157/08). Written informed consent was signed by all study participants.

Participant eligibility criteria

Fully edentulous subjects were evaluated at the School of Dental Medicine, University of Bern (Switzerland), for possible participation in the present study based on the following eligibility criteria:

Inclusion criteria

- Good general health (ASA classification 1 or 2)
- Minimum period of edentulism of 6 months or more
- Minimum bone width of 7mm at the desired implant sites
- Minimum bone height of 11mm
- Minimum adaptation period to the current complete dentures of at least 2 months

Exclusion criteria prior to surgical treatment

- Presence of any systemic medical conditions that are contraindications for implant placement/therapy
 - Osteoporosis

- Under any medication that may influence bone metabolism
- Dental anxiety
- Drug abuse

Exclusion criteria during surgery

- Insufficient bone height after ostectomy
- Implant insertion torque < 35Ncm

Randomization

For randomization, volunteers fulfilling the eligibility criteria were grouped in pairs of two according to gender (same gender) and age (maximum difference of 5 years). If grouping was not possible based on these two criteria, subjects were excluded from the study. Within each group, one patient was randomized into the immediate and the other into the 3-month post-placement loading group loading group (allocation ratio 1:1). For each patient, the implant abutments were randomized to be either platform-switched (test group) or platform-matching (control group) (allocation ratio 1:1). Both randomizations were performed using a computer-generated list only accessible to an independent researcher not involved in the clinical procedure. During surgery, the surgeon was not aware of the participant's allocation in terms of the abutment platform or the loading protocol, to avoid any influence of the surgery by knowing about the allocation.

Implant surgery and bar connection

Before implant surgery, the existing mandibular complete dentures were ground in the interforaminal region and reinforced at the lingual aspect for subsequent incorporation of a bar. The dentures were then used as a template to identify the desired implant

positions in the region of the lower canines. After elevating a mucoperiosteal flap with a symphyseal releasing incision, the bone width at the planned implant positions was measured, and if necessary, a vertical osteotomy resulting in an alveolar ridge width of at least 7mm was performed. Afterward, an osteotomy was performed according to manufacturer's instructions, and the implants (SICace®; SIC invent, Basel, Switzerland: length 9.5mm / diameter 4mm) were placed with at minimum distance of 20 mm in canine sites using a surgical torque-controlled handpiece, without pre-tapping of the implant bed. The SICace is a bone-level type implant with a medium rough surface and a self-tapping thread design. The implant surface is ZrO₂ blasted and acid-etched. All implants were placed epicrestally, relative to the buccal crest.

Either a 3.3 mm diameter SFI-bar adapter abutment (Cendres+Métaux, Biel, Switzerland), resulting in a 0.35 mm circular platform switch (test group), or a 4 mm diameter platform-matching SFI-bar adapter abutment (control group) was mounted with an insertion torque of 20 Ncm on the designated implants. An SFI-bar implant adapter is a rotation-free abutment with a connection for later bar fitting, available in heights of 2 – 5 mm. The height was selected in order to create an approximate 1 mm supragingival position at both implant sites. The same implant abutment height of 3 mm was used in the test and control implants for each individual participant. Subsequently, a round titanium bar (SFI-Bar; Cendres+Métaux, Biel, Switzerland) system which can be intraorally adapted was used for primary splinting of the implants. The length of the bar was customized with a cutting gauge, including a notch for the application of a cutting disc. Afterwards, the bar and the abutments were fused intraorally. Depending on the bar length, the related matrices were cut and also intraorally polymerized into the existing denture using a cold-polymerizing resin

(Pala-Press; Heraeus-Kulzer, Hanau, Germany) (Figs. 1a – 1d). A standardized radiograph film holder was customized for each implant site in every patient, using a silicone putty and light-body material. Afterwards, the customized film holders were positioned onto the abutments-screws and post-surgical radiographs were taken (Figs. 2a – 2d).

Depending on each participants' allocation to the immediate or the delayed loading group, the bar was either left in place or removed including the adapter abutments. In the delayed loading group, healing abutments were mounted, which were left in place for transmucosal healing. The mucoperiosteal flap was sutured with simple interrupted sutures. In the delayed loading group, the denture was relined with a soft relining material. The participants were instructed to use a mouth rinse during the first week after implant placement and to gently clean the gums using a soft toothbrush. After suture removal one week post-surgery, the participants were trained in using soft interdental brushes to clean the gums below the bar. Additionally, they were advised to follow a soft diet for 8 weeks after implant placement.

In the delayed loading group, the healing-abutments were removed after 3 months and the previously adapted bar was mounted and the soft relining material removed.

Evaluation of Δ IBL and clinical parameters

In both study groups, radiographs were taken with a paralleling technique, using customized film holders at the following time points: implant placement (baseline), implant loading, 3 months, 6 months, and 12 months after loading, resulting in a total of four (immediate loading group) or five (delayed loading group) images of each implant. The digital evaluation of each radiograph was performed independently by two calibrated clinicians using a software application (DBS-Win 4.5; Dürr Dental

AG, Bietigheim-Bissingen, Germany) with a digital 20-fold magnification. The distance from the implant apex to the implant shoulder was defined to be 9.5 mm, resulting in the correct dimension for the measurements. Afterwards, the distances from the implant shoulder to the first bone-to-implant contact were measured at the mesial and distal aspects of the implants. Both clinicians performed each evaluation at two different timepoints. When there were intra- or interrater discrepancies higher than 0.1 mm, the radiographs were inspected together by the two clinicians, discussing the position of the first bone-to-implant contact, to reach a consensus. Afterwards, the measurements were repeated independently. Intra- and interrater discrepancies were not statistically analyzed. For each implant at every time point, the average distance from the implant shoulder to the first bone-to-implant contact was calculated from eight values (two measurements each: clinician A mesial + distal and clinician B mesial + distal). Δ IBL was calculated by subtracting the distance at follow-up visits from the BL values.

Clinical peri-implant parameters were recorded 1 month, 3 months, 6 months, and 12 months after implant loading. A periodontal probe was used to measure probing depths around each implant at 4 sites (mesial, buccal, distal, oral). Bleeding on probing (BOP), and the presence of plaque (yes/no) was evaluated at the same four sites. Furthermore, technical complications, e.g. loss of retention, loosening of the matrices, and denture and/or bar fractures were recorded. Complication-free IODs were rated as prosthetic success. Implant success was defined according to the PISA consensus conference (Misch et al. 2008).

Statistical Analyses

A sample size calculation for the primary outcome Δ IBL was performed based on the data of previous studies (Enkling et al. 2011a, 2013), assuming an equivalence range

of [-0.4; +0.4] (Astrand et al. 1999; Hilden 2003). The resulting sample size for demonstrating equivalent bone level changes with an α of 0.05 and power above 80% was $n = 30$ (15 pairs of participants; 30 implants in each group).

For descriptive analyses, means and standard deviations (SD) (clinical parameters), or medians and interquartile ranges (IQR) respectively, were calculated. For equivalence testing of Δ IBL between the test and control implants at each time-point, a two-sided non-parametric test (Wilcoxon Signed Rank Test) with a Bonferroni-correction, resulting in a confidence intervals (CIs) of 96.66%, was used. Furthermore, the influence of platform switching, the longitudinal time after implant placement, the loading protocol, and the combination of these factors on Δ IBL, were analyzed with a Brunner-Langer model. Two independent software programs were used for the Wilcoxon Signed Rank (R; The R Foundation, Vienna, Austria) and the Brunner-Langer-model (SAS 9.2; SAS Institut, Heidelberg, Germany), respectively.

Results

Description of participants

32 subjects (16 male, 16 female) with a mean age of 65.8 years (+/- 11.8) fulfilling the eligibility criteria were recruited and randomized into either an immediate (8 male, 8 female; mean age 67.6 +/- 9.7 years) or a 3 months post implant placement (delayed) loading group (8 male, 8 female; mean age 63.7 +/- 12.5 years). Among the immediate loading group, the mean age of participants receiving the test abutment at position lower right canine ($n = 8$) was 68.6 +/- 10.2 years, and the age of those receiving the test abutment at position lower left canine ($n = 8$) was 67.8 +/- 9.8 years. Among the conventional loading group, the mean age of participants receiving the test abutment at position lower right ($n = 8$) was 61.1 +/- 11.4 years, and the age of those

receiving the test abutment at position lower left ($n = 8$) was 66.1 ± 9.3 years. All participants completed each follow-up appointment during the first year of the study. Figure 3 summarizes the randomization procedure (Fig. 3).

Bone level alterations

After 1 year, the mean Δ IBL was -0.51mm ($\pm 0.49\text{mm}$) in the test group (platform-switched abutments) and -0.56mm ($\pm 0.52\text{mm}$) in the control group (platform-matching abutments), with a median difference between the two groups of 0.04mm (IQR: 0.47mm). The median differences at the follow-up appointments are given in Table 1. Equivalence testing of Δ IBL (Wilcoxon Signed Rank Test) in test and control implants was statistically significant at all time points (all $p < 0.001$). Thus, Δ IBL with the different abutment types were equivalent. Applying the Brunner-Langer model, there was also no statistically significant difference between platform-switched (test) and platform-matching abutments (control) ($p = 0.609$), the interaction of the abutment type and the longitudinal time after implant placement ($p = 0.661$), the interaction of the abutment type and the loading protocol ($p = 0.945$), and the combination of the abutment type, the loading protocol and the longitudinal time after implant placement ($p = 0.466$). However, a statistically significant influence of the longitudinal time after implant placement ($p < 0.001$), the applied loading protocol ($p = 0.022$), and the interaction of the time after implant placement and loading protocol ($p = 0.015$) on Δ IBL could be identified. Δ IBL was more pronounced when a delayed loading protocol was applied, and increased over time relative to baseline values (Figs. 4a and 4b). An overview of Δ IBL in immediately and delayed loaded implants relative to the time of implant placement is given in Table 2.

Clinical parameters

No implant was lost within the first year, resulting in an implant survival rate of 100%. The number of BOP-positive sites was low, whereas there was plaque on approximately 40% of the implants in both groups. Table 3 gives an overview of the clinical parameters evaluated during the follow-up appointments. The implant-success-rate was 100%.

In each study group, one IOD fractured in the matrix region after 3 and 12 months, respectively. No other complications occurred, resulting in a prosthetic success rate of 93.3%.

Discussion

The aim of this randomized controlled clinical study was to analyze the influence of platform switching in two-implant bar-retained overdentures on Δ IBL. No influence of the abutment diameter (platform-switched vs. platform-matching) on Δ IBL could be identified. Thus, the alternative hypothesis, of equivalent Δ IBL with platform-switched and platform-matching abutments in 2-implant bar-retained mandibular overdentures, was confirmed. Nevertheless, less peri-implant bone loss occurred in the immediately loaded implants, relative to implants loaded after 3 months.

Due to the split-mouth design of the present study, Δ IBL could be compared within the same subjects. Therefore, observations can be directly compared to the design of the abutment, as the risk for interindividual contributing factors (e.g. the individual healing ability) was minimized (Zhu et al. 2017). Nevertheless, the risk for intraindividual differences, e.g. bone quantity and bone quality at the respective implant sites, remained. Pairwise randomization in terms of the loading protocol was applied prospectively, resulting in two study groups with a uniform age and gender

distribution and facilitating a high degree of comparability between the groups (Imbens & Rubin 2015). The mandatory number of participants was included for demonstrating equivalent bone level changes with a statistical power greater than 80%, according to the sample size calculation. The customization of the stock radiograph holders and the positioning on top of the abutment-screws resulted in reproducible radiographic recordings, minimizing the risk for projection-dependent measuring errors (Aimetti et al. 2015).

The short follow-up period of one year is a limiting factor. However, major bone-level changes are typically found during the first year after implant placement (Papaspolidakos et al. 2012). Therefore, it would appear prudent to report these results even after this shorter observation period. The baseline for evaluating bone-level alterations was defined to be implant placement, but the follow-up appointments were scheduled in relation to implant loading, i.e. that in all follow-up appointments, the implants in the immediate loading group have been in place three months less than those of the conventional loading group. This difference should be considered in order to correctly interpret the results of this study. All participants will continue to be followed-up at future time points to generate long-term data regarding the concept of platform switching.

In this study, no influence of platform switching on Δ IBL was observed. Similarly, other studies have also shown no influence of platform switching on peri-implant bone-level changes (Enkling et al. 2013; Meloni et al. 2016). On the other hand, several systematic reviews on the platform switching concept have concluded that it can help reduce the amount of marginal bone loss (Atieh et al. 2010; Annibaldi et al. 2012; Chrcanovic et al. 2015; Hsu et al. 2017). Therefore, there may be

additional factors related to platform switching, for example the amount of the mismatch, the type of implant-abutment connection, or the prosthetic restoration, which determines the success of this approach.

One factor which may have contributed to the equal bone level changes in the two study groups of this study could be the relatively small circular platform switch of only 0.35mm. Atieh et al. concluded in their review that the degree of marginal bone resorption is inversely related to the extent of the implant-abutment-mismatch and that abutments with a mismatch $> 0.4\text{mm}$ were associated with a more favorable bone response relative to abutments with a smaller mismatch (Atieh et al. 2010). However, another study focusing on the amount of abutment mismatch could not verify this conclusion (Galindo-Moreno et al. 2016).

Another factor that has been reported to influence ΔIBL in both platform-switched and platform-matching implants is the type of implant-abutment connection, due to the presence of a micro-gap in two-piece implants (Scarano et al. 2016). The implant-abutment interface has been researched intensively over the last decades, without giving decisive evidence for the superiority of a certain connection (Rack et al. 2010; Khorshidi et al. 2016). A review focusing on the implant-abutment connection concluded that morse-taper or hybrid-connection implants with a platform-switching abutment should be preferred in order to reduce marginal bone loss (Liu & Wang 2017). Even though the implant system used here has an internal, hexagonal parallel-walled implant-abutment connection, a reduction in ΔIBL by platform-switching was described previously in a study using an implant system with a very similar implant design and the same implant-abutment connection (Enkling et al. 2011b; Sesma et al. 2016). In contrast to our study, the circular platform switch in Sesma et al, was 0.5mm, which may have positively influenced ΔIBL .

The type of prosthetic restoration has also been reported to play a role in bone-level changes after implant placement, but only a single clinical study on platform switching in implant overdentures (IODs) could be identified (Bilhan et al. 2010), demonstrating a positive effect of platform switching on Δ IBL. An *in vitro* study analyzing strain distribution in IODs with non-splinted abutments did not favor platform switching (Sabet et al. 2009) due to the strain on the surrounding bone of the individual implants. In the present study, the two interforaminal implants were directly splinted with a bar. Therefore, the strain on the crestal peri-implant bone might have been equally distributed across both implants, and the effect of decreased strain when using a platform-switched abutment may have also manifested in the group with non-platform-switched abutments due to the splinting of implants. This would also explain the relatively low Δ IBL in the immediate loading group.

A recently published systematic literature review including only controlled clinical trials reported equal bone-level changes in immediate- and delayed-loading groups in IODs (Sanda et al. 2019). With the exception of one included study, all studies reported on IODs supported by single, unsplinted implants. The one study comparing the two loading protocols in bar-supported IODs showed significantly lower Δ IBL in the immediate loading group after one year, confirming the results of our study (Stephan et al. 2007). After two years, no difference between the two study groups was reported. Therefore, the results of the present study have to be interpreted with caution in terms of the loading protocol, taking the short follow-up of only one year into account.

The implant success rate according to currently applied criteria was 100% in both study groups (Misch et al. 2008). Another study analyzing long-term (14-year) outcomes of bar-retained IODs with either an immediate or a delayed loading

protocol also found no difference in any of the evaluated parameters (implant success, oral health related quality of life, denture satisfaction) (Alfadda et al. 2019). Evaluating the clinical parameters in the present study, no difference between the test and control implants could be identified. One technical complication (denture fracture) occurred in each study group. Plaque was highly present in around 40% of the measured implant sites in both groups. Nevertheless, peri-implant conditions were mainly healthy, with a small number of BOP-positive measuring points, and mean probing depths of around 2 mm. In summary, clinical parameters in two-implant supported IODs do not seem to be influenced by platform switching or the applied loading protocol.

Conclusion

The concept of platform switching in mandibular IODs is not necessarily accompanied by decreased bone loss. In terms of Δ IBL, immediate loading of implants in the edentulous mandible, primarily splinted with a bar, might be beneficial compared to delayed loading over a short-term follow-up period. Implant success and peri-implant parameters did neither depend on the abutment type, nor on the loading protocol. Further research on platform-switching concept is needed for identifying clinical situations that would benefit from the application of this protocol.

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References

- Aimetti, M., Ferrarotti, F., Mariani, G.M., Ghelardoni, C. & Romano, F. (2015) Soft tissue and crestal bone changes around implants with platform-switched abutments placed nonsubmerged at subcrestal position: a 2-year clinical and radiographic evaluation. *The International journal of oral & maxillofacial implants*, 30, 1369–1377.
doi: 10.11607/jomi.4017. Epub 2015 Oct 16.
- Albrektsson, T. & Wennerberg, A. (2019) On osseointegration in relation to implant surfaces. *Clinical Implant Dentistry and Related Research*, 21, 4–7.
doi: 10.1111/cid.12742. Epub 2019 Feb 28.
- Albrektsson, T., Zarb, G., Worthington, P. & Eriksson, A.R. (1986) The long-term efficacy of currently used dental implants: a review and proposed criteria of success. *The International journal of oral & maxillofacial implants*, 1, 11–25.
- Alfadda, S.A., Chvartzaid, D. & AlFarraj Aldosari, A. (2019) Clinical outcomes of immediately loaded implant-supported overdentures: A long-term prospective clinical trial. *The Journal of Prosthetic Dentistry*, 121, 911–915.
doi: 10.1016/j.prosdent.2018.10.001
- Annibali, S., Bignozzi, I., Cristalli, M.P., Graziani, F., La Monaca, G. & Polimeni, A. (2012) Peri-implant marginal bone level: a systematic review and meta-analysis of studies comparing platform switching versus conventionally restored implants. *Journal of clinical periodontology*, 39, 1097–1113.
doi: 10.1111/j.1600-051X.2012.01930.x
- Astrand, P., Engquist, B., Dahlgren, S., Engquist, E., Feldmann, H. & Gröndahl, K. (1999) Astra Tech and Brånemark System implants: a prospective 5-year comparative study. Results after one year. *Clinical implant dentistry and related research*, 1, 17–26.
- Atieh, M.A., Ibrahim, H.M. & Atieh, A.H. (2010) Platform switching for marginal bone preservation around dental implants: a systematic review and meta-analysis. *Journal of periodontology*, 81, 1350–1366.

- Bilhan, H., Mumcu, E., Erol, S. & Kutay, Ö. (2010) Influence of Platform-Switching on Marginal Bone Levels for Implants With Mandibular Overdentures: A Retrospective Clinical Study. *Implant Dentistry*, 19, 250–258.
doi: 10.1902/jop.2010.100232.
- Bouazza-Juanes, K., Martinez-Gonzalez, A., Peiro, G., Rodenas, J. & Lopez-Molla, M. (2015) Effect of platform switching on the peri-implant bone: A finite element study. *Journal of Clinical and Experimental Dentistry*, 7, e483–e488.
doi: 10.4317/jced.52539.
- De Bruyn, H., Christiaens, V., Doornewaard, R., Jacobsson, M., Cosyn, J., Jacquet, W. & Vervaeke, S. (2017) Implant surface roughness and patient factors on long-term peri-implant bone loss. *Periodontology 2000*, 73, 218–227.
doi: 10.1111/prd.12177.
- Buser, D., Sennerby, L. & De Bruyn, H. (2017) Modern implant dentistry based on osseointegration: 50 years of progress, current trends and open questions. *Periodontology 2000*, 73, 7–21.
doi: 10.1111/prd.12185.
- Buser, D., Weber, H.P., Bragger, U. & Balsiger, C. (1991) Tissue integration of one-stage ITI implants: 3-year results of a longitudinal study with Hollow-Cylinder and Hollow-Screw implants. *The International journal of oral & maxillofacial implants*, 6, 405–12.
- Chappuis, V., Rahman, L., Buser, R., Janner, S.F.M., Belser, U.C. & Buser, D. (2018) Effectiveness of Contour Augmentation with Guided Bone Regeneration: 10-Year Results. *Journal of dental research*, 97, 266–274.
doi: 10.1177/0022034517737755.
- Chen, S. & Buser, D. (2014) Esthetic Outcomes Following Immediate and Early Implant Placement in the Anterior Maxilla—A Systematic Review. *The International Journal of Oral & Maxillofacial Implants*, 29, 186–215.
doi: 10.11607/jomi.2014suppl.g3.3.
- Chrcanovic, B.R., Albrektsson, T. & Wennerberg, A. (2015) Platform switch and dental implants: A meta-analysis. *Journal of dentistry*, 43, 629–646.
doi: 10.1016/j.jdent.2014.12.013.

- Clelland, N., Chaudhry, J., Rashid, R. & McGlumphy, E. (2016) Split-Mouth Comparison of Splinted and Nonsplinted Prostheses on Short Implants: 3-Year Results. *The International Journal of Oral & Maxillofacial Implants*, 31, 1135–1141.
doi: 10.11607/jomi.4565.
- Enkling, N., Jöhren, P., Katsoulis, J., Bayer, S., Jervøe-Storm, P.-M., Mericske-Stern, R. & Jepsen, S. (2013) Influence of platform switching on bone-level alterations: a three-year randomized clinical trial. *Journal of dental research*, 92, 139S–145S.
doi: 10.1177/0022034513504953.
- Enkling, N., Jöhren, P., Klimberg, T., Mericske-Stern, R., Jervøe-Storm, P.M., Bayer, S., Gülden, N. & Jepsen, S. (2011a) Open or submerged healing of implants with platform switching: A randomized, controlled clinical trial. *Journal of Clinical Periodontology*, 38, 374–384.
doi: 10.1111/j.1600-051X.2010.01683.x.
- Enkling, N., Jöhren, P., Klimberg, V., Bayer, S., Mericske-Stern, R. & Jepsen, S. (2011b) Effect of platform switching on peri-implant bone levels: A randomized clinical trial. *Clinical Oral Implants Research*, 22, 1185–1192.
doi: 10.1111/j.1600-0501.2010.02090.x.
- Galindo-Moreno, P., León-Cano, A., Monje, A., Ortega-Oller, I., O'Valle, F. & Catena, A. (2016) Abutment height influences the effect of platform switching on peri-implant marginal bone loss. *Clinical Oral Implants Research*, 27, 167–173.
doi: 10.1111/clr.12554.
- Gallucci, G.O., Hamilton, A., Zhou, W., Buser, D. & Chen, S. (2018) Implant placement and loading protocols in partially edentulous patients: A systematic review. *Clinical Oral Implants Research*, 29, 106–134.
doi: 10.1111/clr.13276.
- General Assembly of the World Medical Association (2014) World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *The Journal of the American College of Dentists*, 81, 14–18.

- Hsu, Y.-T., Lin, G.-H. & Wang, H.-L. (2017) Effects of Platform-Switching on Peri-implant Soft and Hard Tissue Outcomes: A Systematic Review and Meta-analysis. *The International journal of oral & maxillofacial implants*, 32, e9–e24. doi: 10.11607/jomi.5140.
- Imbens, G. & Rubin, D. (2015) *Pairwise Randomized Experiments*. In: *Causal Inference for Statistics, Social, and Biomedical Sciences*. Cambridge: Cambridge University Press.
- Khorshidi, H., Raoofi, S., Moattari, A., Bagheri, A. & Kalantari, M.H. (2016) In Vitro Evaluation of Bacterial Leakage at Implant-Abutment Connection: An 11-Degree Morse Taper Compared to a Butt Joint Connection. *International Journal of Biomaterials*, 2016, 1–5. [epub] doi: 10.1155/2016/8527849
- Lazzara, R.J. & Porter, S.S. (2006) Platform switching: a new concept in implant dentistry for controlling postrestorative crestal bone levels. *The International journal of periodontics & restorative dentistry*, 26, 9–17.
- Liu, S., Tang, C., Yu, J., Dai, W., Bao, Y. & Hu, D. (2014) The effect of platform switching on stress distribution in implants and periimplant bone studied by nonlinear finite element analysis. *The Journal of Prosthetic Dentistry*, 112, 1111–1118. doi: 10.1016/j.prosdent.2014.04.017
- Liu, Y. & Wang, J. (2017) Influences of microgap and micromotion of implant–abutment interface on marginal bone loss around implant neck. *Archives of Oral Biology*, 83, 153–160. doi: 10.1016/j.archoralbio.2017.07.022.
- Mailoa, J., Fu, J.-H., Chan, H.-L., Khoshkam, V., Li, J. & Wang, H.-L. (2015) The Effect of Vertical Implant Position in Relation to Adjacent Teeth on Marginal Bone Loss in Posterior Arches: A Retrospective Study. *The International Journal of Oral & Maxillofacial Implants*, 30, 931–936. doi: 10.11607/jomi.4067.
- Meloni, S.M., Jovanovic, S.A., Pisano, M. & Tallarico, M. (2016) Platform switching versus regular platform implants: 3-year post-loading results from a randomised controlled trial. *European journal of oral implantology*, 9, 381–390.

- Messias, A., Rocha, S., Wagner, W., Wiltfang, J., Moergel, M., Behrens, E., Nicolau, P. & Guerra, F. (2019) Peri-implant marginal bone loss reduction with platform-switching components: 5-Year post-loading results of an equivalence randomized clinical trial. *Journal of Clinical Periodontology*, 46, 678–687.
doi: 10.1111/jcpe.13119.
- Misch, C.E., Perel, M.L., Wang, H.-L., Sammartino, G., Galindo-Moreno, P., Trisi, P., Steigmann, M., Rebaudi, A., Palti, A., Pikos, M.A., Schwartz-Arad, D., Choukroun, J., Gutierrez-Perez, J.-L., Marenzi, G. & Valavanis, D.K. (2008) Implant Success, Survival, and Failure: The International Congress of Oral Implantologists (ICOI) Pisa Consensus Conference. *Implant Dentistry*, 17, 5–15.
doi: 10.1097/ID.0b013e3181676059.
- Papaspyridakos, P., Chen, C.-J., Singh, M., Weber, H.-P. & Gallucci, G.O. (2012) Success Criteria in Implant Dentistry: a systematic review. *Journal of Dental Research*, 91, 242–248.
doi: 10.1177/0022034511431252. Epub 2011 Dec 8.
- Quirynen, M., Herrera, D., Teughels, W. & Sanz, M. (2014) Implant therapy: 40 years of experience. *Periodontology 2000*, 66, 7–12.
doi: 10.1111/prd.12060.
- Rack, A., Rack, T., Stiller, M., Riesemeier, H., Zabler, S. & Nelson, K. (2010) In vitro synchrotron-based radiography of micro-gap formation at the implant–abutment interface of two-piece dental implants. *Journal of Synchrotron Radiation*, 17, 289–294.
doi: 10.1107/S0909049510001834.
- Sabet, M.E., EL-Korashy, D.I. & El-Mahrouky, N.A. (2009) Effect of Platform Switching on Strain Developed Around Implants Supporting Mandibular Overdenture. *Implant Dentistry*, 18, 362–370.
doi: 10.1097/ID.0b013e3181b4f98c.
- Salvi, G.E., Monje, A. & Tomasi, C. (2018) Long-term biological complications of dental implants placed either in pristine or in augmented sites: A systematic review and meta-analysis. *Clinical Oral Implants Research*, 29, 294–310.
doi: 10.1111/clr.13123.

- Sanda, M., Fueki, K., Radke, P. & Baba, K. (2019) Comparison of immediate and conventional loading protocols with respect to marginal bone loss around implants supporting mandibular overdentures : A systematic review and meta-analysis. *Japanese Dental Science Review*, 55, 20–25.
doi: 10.1016/j.jdsr.2018.09.005.
- Scarano, A., Mortellaro, C., Mavriqi, L., Pecci, R. & Valbonetti, L. (2016) Evaluation of Microgap With Three-Dimensional X-Ray Microtomography: Internal Hexagon Versus Cone Morse. *The Journal of craniofacial surgery*, 27, 682–685.
doi: 10.1097/SCS.0000000000002563
- Schwarz, F., Alcoforado, G., Nelson, K., Schaer, A., Taylor, T., Beuer, F. & Strietzel, F.P. (2014) Impact of implant-abutment connection, positioning of the machined collar/microgap, and platform switching on crestal bone level changes. *Camlog Foundation Consensus Report. Clinical Oral Implants Research*, 25, 1301–1303.
doi: 10.1111/clr.12269.
- Sesma, N., Garaicoa-Pazmino, C., Zanardi, P.R., Chun, E.P. & Laganá, D.C. (2016) Assessment of Marginal Bone Loss around Platform-Matched and Platform-Switched Implants - A Prospective Study. *Brazilian Dental Journal*, 27, 712–716.
doi: 10.1590/0103-6440201601160.
- Smith, D.E. & Zarb, G.A. (1989) Criteria for success of osseointegrated endosseous implants. *The Journal of prosthetic dentistry*, 62, 567–572.
- Steigenga, J.T., al-Shammari, K.F., Nociti, F.H., Misch, C.E. & Wang, H.-L. (2003) Dental implant design and its relationship to long-term implant success. *Implant dentistry* 12, 306–317.
- Stephan, G., Vidot, F., Noharet, R. & Mariani, P. (2007) Implant-retained mandibular overdentures: a comparative pilot study of immediate loading versus delayed loading after two years. *The Journal of prosthetic dentistry* 97: S138-145.
doi: 10.1016/S0022-3913(07)60017-1.
- The Glossary of Prosthodontic Terms: Ninth Edition (2017) *The Journal of Prosthetic Dentistry*, 117, e69.
doi: 10.1016/j.prosdent.2016.12.001.

- Vigolo, P., Mutinelli, S., Zaccaria, M. & Stellini, E. (2015) Clinical Evaluation of Marginal Bone Level Change Around Multiple Adjacent Implants Restored with Splinted and Nonsplinted Restorations: A 10-Year Randomized Controlled Trial. *The International Journal of Oral & Maxillofacial Implants*, 30, 411–418.
doi: 10.11607/jomi.3837.
- Wellek, S. (2002). *Testing Statistical Hypotheses of Equivalence*. Boca Raton, FL: Chapman & Hall/CRC
- Zhu, H., Zhang, S. & Ahn, C. (2017) Sample size considerations for split-mouth design. *Statistical methods in medical research*, 26, 2543–2551.
doi: 10.1177/0962280215601137.

Tables

Table 1: Differences in peri-implant bone level alteration (Δ IBL) between test- and control implants

Follow-up	Difference [mm]	IQR	96.66% CI
3 months	-0.10	0.61	-0.22; 0.18
6 months	-0.05	0.46	-0.15; 0.13
12 months	0.04	0.47	0.09; 0.20

Table 1: Median differences in peri-implant bone loss alterations (Δ IBL) between test and control implants, interquartile ranges (IQR), and respective 96.66% confidence intervals (CI) after Bonferroni correction. The follow-up gives the time after loading in each group. A negative difference indicates a higher median Δ IBL, and positive difference indicates a smaller median Δ IBL in the test group.

Table 2: Peri-implant bone level alteration (Δ IBL) in immediately and delayed-loaded implants.

Follow-up	Delayed loading		Immediate loading	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Baseline (3 months)	-0.51	0.55	-	-
3 months (6 months)	-0.66	0.56	-0.14	0.33
6 months (9 months)	-0.76	0.6	-0.24	0.36
12 months (15 months)	-0.87	0.61	-0.35	0.43

Table 2: Mean peri-implant bone level alterations (Δ IBL) and standard deviations (SDs) compared to implant placement, at implant loading and the subsequent follow-up appointments. As implant placement and implant loading were done in the same visit in the immediate loading group, no Δ IBL could be recorded at the baseline visit. The follow-up gives the time after implant placement in the immediate loading group, and inside the brackets of the delayed loading group.

Table 3: Clinical peri-implant parameters

	Test (platform-switched)		Control (non-platform-switched)	
	Mean	SD	Mean	SD
Presence of plaque [%]	39	32	40	36
BOP positive sites [%]	9	15	8	11
Probing depths [mm]	2.0	0.4	2.1	1.0

Table 3: Means and standard deviations (SDs) of clinical parameters evaluated at each follow-up appointment (data of all follow-ups pooled; BOP = bleeding in probing).

Figure legends

Figure 1: (a) Extraoral preparation of the round bar with the cutting gauge for defining the length, (b) intraoral adjustment of the length, using the cutting gauge, (c) extraoral cutting of the bar, guided by the notch of the cutting gauge, (d) intraoral situation after chairside customization of the bar.

Figure 2: (a) A stock X-ray film holder, positioned onto the screw of the bar abutment, (b) customization of the film holder with a silicone putty & light body, (c) standardized radiographs of an implant with one platform-switched (test) and (d) one platform-matching abutment (control).

Figure 3: Study flow chart summarizing the randomization and follow-up procedures.

Figure 4a: Mean peri-implant bone level changes (Δ IBL) and standard deviations (SDs) of control implants with an immediate or a delayed loading protocol. The x-axis represents the time after implant placement

Figure 4b: Mean peri-implant bone level changes (Δ IBL) and standard deviations (SDs) of test implants with an immediate or a delayed loading protocol. The x-axis represents the time after implant placement