A retrospective study evaluating the survival and radiographic outcome of implants with low primary stability

Kwan-Joo Lee
Department of Dentistry
The Graduate School, Yonsei University

A retrospective study evaluating the survival and radiographic outcome of implants with low primary stability

Directed by Professor Ui-Won Jung

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Kwan-Joo Lee

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Thesis Supervisor : Ui-Won Jung

Seong-Ho Choi

Jae-Kook Cha

Sungtae Kim

Young-Taek Kim

The Graduate School

Yonsei University

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감사의 글

박사 과정을 마치며 도와주신 모든 분들께 깊은 감사 인사를 드립니다. 치주를 배우고 싶다는 설레는 마음으로 치주과학교실에 들어온 지 벌써 3년이라는 시간이 지났고 언제 완성할 수 있을까 항상 걱정했던 논문을 이제야 출판하게 되어 기쁜 마음입니다. 이 논문이 완성되기까지 끊임없이 지도해 주신 정의원 지도 교수님, 차재국 교수님께 진심으로 깊은 감사 드립니다. 따듯한 관심과 격려를 보내주신 채중규 교수님, 환자를 진심으로 대하는 마음가짐을 잊지 않게 해주신 조규성 교수님, 인생 전반에 걸쳐 많은 조언을 해주시는 최성호 교수님, 임상과 학문에 대한 열정으로 본보기가 되어주신 김창성 교수님과 이중석 교수님께 깊이 감사 드립니다. 제 논문의 초안 작성에 큰 도움을 주신 Ignacio Sanz-Martin 교수님과 마지막까지 꼼꼼히 첨삭 해주신 Mariano Sanz 교수님, 그리고 수련 기간 동안 도움이 필요할 때마다 조언을 아끼지 않으신 송영우 선생님께도 감사의 마음을 전합니다. 학위 과정 동안 늘 버팀목이 되어준 치주과 동기들과 모든 의국원 선생님들께도 고마운 마음을 전합니다.

마지막으로, 세상 그 누구보다 소중한 제 가족, 언제나 묵묵히 뒤에서 믿음으로 지켜봐 주시고 지지와 격려를 보내주시는 사랑하는 부모님과 치과의사인 저를 항상 자랑스러워 하시는 외할머니께 모든 기쁨을 함께 나누고 싶습니다.

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Abstract

A retrospective study evaluating the survival and radiographic outcome of implants with low primary stability

Kwan-Joo Lee, DDS, MSD;

Department of Dentistry
The Graduate School, Yonsei University

(Directed by Professor Ui-Won Jung, D.D.S., M.S.D., PhD.)

Purpose: There is a need of more studies on whether low primary implant stability would negatively influence the success of implant therapy. Therefore, this retrospective study analyzes outcomes of implants placed with low primary stability and factors that may be related to implant failures.

Materials and methods: This retrospective study included 156 patients, restored with 169 implants that presented manual rotation within an observed follow-up time of a minimum of 34 days and a maximum of 9.28 years. Descriptive statistics, survival analyses (life tables and Kaplan-Meier estimates), and radiographic assessment based on marginal

bone level measurements were performed. This original study was adherent to STROBE guidelines.

Results: Seven implants failed in 7 patients, rendering cumulative survival rates (CSR) of 94.74% (95% CI: 89.11-97.50) and 94.33% (95% CI: 88.30-97.30) at implant and patient levels, respectively. Kaplan-Meier estimates showed implant loss was found only in advanced surgery group (7 implant loss in 82 implants) when compared to simple surgery group (no implant loss in 87 implants) (p = 0.005), and no significant difference were found in CSRs between implants under bone quality (p = 0.059), position of the jaw (p = 0.254), and unit of prosthesis (p = 0.369). Marginal bone level (MBL) changes for 93 implants were measured and evaluated for a short-term MBL analysis. The mean MBL changes in simple and advanced surgery group were -0.19 ± 0.08 mm and -0.19 ± 0.11 mm (mean ± SD) during 0-2 year interval, and -0.56 ± 0.26 mm and -0.60 ± 0.28 mm (mean ± SD) in simple and advanced surgery group during 2-4 year interval, respectively. No statistical significant differences were found between MBL changes under type of surgery and implant position of the jaw.

Conclusions: Within the limitations of this retrospective study, implant placement with low primary stability might not negatively affect either the survival rates or marginal bone level changes of implants provided that a protected and unloaded healing is guaranteed.

Key words: dental implants, implant stability, osseointegration, survival rate, radiographic analysis

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Department of Dentistry
The Graduate School, Yonsei University

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I. Introduction

Primary stability of implants has been defined as the absence of mobility in bone bed after implant placement, mainly determined by the mechanical properties of the bone tissue at the implant site and how well the implant is engaged with that bone tissue, mainly through the picks of the threads into the host bone bed (Sennerby & Meredith, 1998). It is generally assumed that a minimum implant stability is needed for ensuring an undisturbed bone healing and for allowing the osseointegration process, and hence, the

secondary stability (Ostman et al., 2005). Nevertheless, primary stability can be compromised in clinical situations when poor bone quality or wide defect is present, or when the osteotomy preparation has been overdone in relation to the implant thread design (Meredith, 1998).

In presence of low quality bone, primary stability can be increased by selecting tapered implant designs or by using extensive self-tapping in under-prepared bone beds. In extreme situations, there are specific surgical techniques to maximize primary implant stability such as osteotome mediated bone compaction or undersized drilling (Martinez et al., 2001). In spite of this, surgeons often encounter clinical situations where once the implant is placed in position, there is inadequate mechanical stability. Another important factor is the implant surface topography. In implants with turned surfaces, the combination of primary stability and a long healing period without functional loading was considered to be pre-requisites to achieve osseointegration and high success rate (Albrektsson et al., 1981). With the advent of moderately rough implant surfaces, however, a compromised initial stability may be compensated by a more rapid osseointegration and achievement of secondary stability (Berglundh et al., 2003; Abrahamsson et al., 2004). Experimental *in vivo* studies have shown that implants with rough surfaces that lacked or had no primary stability reached the same degree of osseointegration as those with high primary stability, given the appropriate healing time (Abdel-Haq et al., 2011; Jung et al., 2012; Kim et al., 2014). A recent clinical case series study also showed that when implants were placed without contact in pristine bone, yet stabilized by allografts, acceptable osseointegration assessed by a reverse torque

of more than 30 Ncm could be achieved after 5 months of healing time (Bianconi et al., 2017).

However, attainment of primary stability is relevant when implant is placed with the absence of primary bone anchorage. According to the clinical report, acceptable stability and osseointegration of the implant was achieved only after primary stability was obtained by fixed external provisional prosthesis connected to other implants with initial torque more than 50 Ncm (Villa et al., 2010). Also, minimum insertion torques around 30-35 Ncm were reported to be used for utilizing immediate loading, attaining as high survival rates as 98.2 % when compared to 99.6% in conventional loading (Sanz-Sanchez et al., 2015). Depending on the implant surgical and prosthetic protocol, different primary stability may be required for the achievement of successful osseointegration.

In some studies, higher failure rates were reported when implants with low insertion torques (20 Ncm) versus high (≥32 Ncm) were compared (Ottoni et al., 2005) while, in other investigation, only 3 implant failures were reported out of 68 immediately loaded implants with insertion torques ≤25 Ncm with low rotational stability (Norton, 2011). However, there are a lack of clinical studies with a sufficient sample size that have reported the outcomes of implants placed under low primary stability, defined as presence of manual rotation at implant placement when screwing the cover or healing abutment (Rodrigo et al., 2010).

It was, therefore, the objective of this retrospective study to evaluate the survival outcome of the rotated implants and to assess whether such factors as type of surgery, bone

quality, implant position of the jaw, and unit of prosthesis might affect the survival and marginal bone level changes of the rotated implants.

II. Materials & Methods

1. Materials

This retrospective study initially included 156 patients restored with 169 implants within an observed follow-up time of a minimum of 34 days and a maximum of 9.28 years that presented manual rotation when placing the cover screw or healing abutment at the time of implant placement. All implant surgeries were performed by 11 experienced surgeons at a single specialist clinic, Department of Periodontology, Dental Hospital of Yonsei University, Seoul, Korea from 2008 to 2018. The enrolled patients were recalled for check-up from April, 2017 to May, 2018. The study was reviewed and authorized by the Institutional Review Board of Yonsei University Dental Hospital (approval no. 18-0007). The study was adherent to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines checklist as seen in Supplementary File.

2. Inclusion and exclusion criteria

Patients were selected if there was manual rotation during connection of the cover screw or healing abutment, which were recorded in the patients' dental records, during implant placement with insertion torque lower than 20 Ncm, except for 33 non-self tapping Straumann implants that experienced insertion torque higher than 20 Ncm. For survival analysis, among the initially selected 166 patients with 180 implants, only the rough surface implants that were implanted on healed ridge and supported fixed dental prostheses were

included; therefore, 2 machined surface implants, 3 immediately placed implants, and 4 implants used to support overdentures were excluded. One implant with follow-up loss and 1 Neobiotech IS III implant, a disparate implant system, were also excluded to reduce the clinical heterogeneity of the study. As a result, 156 patients with 169 implants were included in the study. For radiographic analysis, those patients having available radiographic records at baseline and at the latest follow-up visits were included. Resolution of radiographic images, status of initial marginal bone loss on mesial and distal sides of implants, and the number of radiographic samples required for statistical analysis were considered for sampling of the implants to be included as a part of radiographic analysis.

3. Surgical procedures

All of the patients had prophylactic antibiotic treatment with 1g of amoxicillin (or 600 mg of clindamycin, if allergic to penicillin) 1 hour before implant surgery. Then, patients rinsed with 15 mL of 0.2 % chlorhexidine (Hexamedine, Bukwang Pharmaceutical, Anshan, Korea) mouth-wash and underwent implant surgery under local anesthesia using lidocaine (2% lidocaine hydrochloride-epinephrine 1:100,000; Huons Pharmaceutical, Jecheon, Korea). After crestal incision and flap elevation, each selected implantation site was prepared with osteotomies according to the implant manufacturers' recommendations. Root form threaded implants with either cylindrical or conical design were used with diameter, length, and number determined by the surgeons at the time of surgery in accordance with the prosthetic planning. Depending on the surgeons' judgment after

implantation, implants underwent either submerged or transmucosal healing protocol until prosthesis delivery. All the rotated implants were standalone until the prostheses were delivered only after sufficient osseointegration was achieved.

All 169 implants were placed in the healed ridges. Depending on bone availability of the selected implantation sites, various types of advanced surgeries, such as guided bone regeneration (GBR), bone compaction with osteotome, osteotome sinus floor elevation (OSFE), bone added osteotome sinus floor elevation (BAOSFE), and lateral sinus augmentation were performed (Table 1). Five types of bone materials were used for bone augmentation procedures: Bio-Oss® (Geistlich Pharma, Wolhusen, Switzerland), Bio-Oss Collagen® (Geistlich Pharma, Wolhusen, Switzerland), Irradiated allogenic cancellous bone and marrow particulate, RM·CanPar® (Rocky Mountain Tissue Bank, CO, USA), The Graft® (Purgo Biologics, Sungnam, Korea), and Osteon III® (Genoss, Suwon, Korea). Five types of membranes were used for GBR procedures: Bio-Gide® (Geistlich Pharma, Wolhusen, Switzerland), Collagen membrane® (Genoss, Suwon, Korea), EZ Cure® (Purgo Biologics, Sungnam, Korea), Rapigide® (DalimTissen, Seoul, Korea), and Cytoplast TXT-200® (Osteogenics Biomedical, TX, USA).

4. Data collection

With a help of clinical data repository system that implements electronic medical and dental records as basis of the management of patients' individual health care (Chang et al., 2010), the following patient- and implant-related information were collected:

1) *Patient factors*: age, sex, and presence of any on-going or past systemic health condition at the time of surgery such as cardiovascular disease, diabetes, osteoporosis, thyroid disease, and chemotherapy treatment history.
2) *Site-related factors*: implant location (maxilla/mandible), anterior or posterior segment (anterior segment defined from canine to canine), bone availability at the implant site at the time of surgery according to the Lekholm and Zarb classification (Lekholm, 1985).
3) *Implant factors*: type, brand, diameter, and length.
4) *Surgical and restorative protocol*: (a) type of implant surgery performed including which regenerative procedures were done simultaneously with implant placement; (b) type of implant-supported reconstruction (single implant supported crowns and implant supported fixed dental prostheses (IS-FDP) with 2-4 prosthetic elements).

Once the definitive implant supported reconstruction were delivered, patients were recalled to receive a routine preventive program based on maintenance visits every 6 to 12 months.

5. Implant survival analysis

Implant survival was evaluated based on the presence or absence of the implant in the evaluated radiographs and dental records. Implant survival analysis was performed using life tables and Kaplan-Meier estimates. Four Kaplan-Meier analyses were performed, depending on: (a) the type of surgery (simple versus advanced surgery that included

simultaneous bone regenerative procedures such as GBR or bone grafts, bone compaction with osteotomes, OSFE, BAOSFE, and lateral sinus augmentation); (b) bone quality; (c) implant position of the jaw; and (d) unit of prosthesis.

6. Marginal bone level evaluation

Among 169 selected implants, a total of 118 implants were included for marginal bone level (MBL) measurement based on availability of the baseline and latest periapical radiographs. Five implants were excluded from measurement for low quality resolution images of periapical radiographs that did not show clear inter-thread spaces and 4 implants for having initial bone loss on mesial and distal sides of the implants: MBL measurement was performed on the remaining 109 implants. Once the measurements were calibrated with the known implant length, measurements were taken from the implant platform junction to the marginal bone level at both mesial and distal sides, using the Image J software (National Institute of Health, Bethesda). Then, peri-implant MBL change was calculated by comparing the MBL from the latest visit to those from the baseline radiographs. The mean values of these measurements on mesial and distal sides were used as the final MBL changes. The same measurement procedure was performed twice by a single examiner (K.J.L.). Among 109 implants measured, 16 implants, which fell into the yearly radiographic assessment interval from 4 to 10 years, were excluded from MBL evaluation due to a low number of samples. This rendered a final sample of 86 patients with 93 implants for the analysis, in which the mean MBL changes were first stratified into

yearly intervals and then categorized into the two groups of 0-2 year and 2-4 year interval. Then, MBL evaluation were performed under each interval group, depending on: (a) type of surgery (simple versus and advanced surgery); (b) bone quality (D2, 3, and 4); (c) implant position of the jaw (maxilla versus mandible); and (d) unit of prosthesis (1, 2, 3, and 4 unit of prosthesis).

7. Evaluation of biologic and prosthetic complications

During observation period of these rotated implants, they were examined for any potential biologic or prosthetic complications. Biologic complications that affected the implants supporting prostheses included were peri-implantitis, peri-implant mucositis, fixture thread exposure, and coverscrew exposure. Any prosthetic complications that occurred during the study period were also noted, and these included occlusal interference, crown fallen out, contact loosening, screw loosening, hypo-occlusion, and porcelain fractures.

8. Statistical analyses

Implant survival analyses were performed to include life tables presenting cumulative survival rate (CSR) with 95% confidence interval (CI) for survival proportions which were calculated by using 95% confidence limits of event rates. This calculation was performed using STATA/IC®, version 14 (Stata Corp.). Kaplan-Meier analyses were performed to show survival curves over the observational period. Log rank tests were

performed to detect any significant difference between survival curves.

For MBL analysis, the mean and standard deviation (SD) were calculated. Then, intra-examiner agreement test was performed between the measured values of the mean MBL changes using Intra-class correlation coefficient (ICC). Kolmogorov-Smirnov test was performed to assess normal distribution of these variables, and Levene's test to assess the homogeneity of variance for two or more groups. Student's T-test was performed to determine significant differences between the two sets of variables under type of surgery and implant position of the jaw for each 0-2 and 2-4 year interval, and Analysis of variance (ANOVA) for the three or four sets of variables under bone quality and unit of prosthesis for the same time intervals. When the assumption for the homogeneity of variance was violated by Levene's test in ANOVA, Welch's robust test was performed to determine any significant difference between 3 or more groups, which was, in fact, performed for MBL evaluation under bone quality during 0-2 year interval. When there was any significant difference found between groups compared via ANOVA, Tukey's honestly significant difference (HSD) post hoc test was performed. All data were entered into a statistical software (SPSS software, version 23, SPSS Inc., IBM Chicago, Illinois) for the analyses aforementioned. The level of statistical significance was set at 5%.

III. Results

1. Patient demographics

One hundred and fifty-six patients wearing 169 implants with low primary stability were selected. These samples had a minimum follow-up time of 34 days and a maximum of 9.28 years. This population consisted of 70 males (44.23 %) and 86 females (55.77 %), with the mean age of 59.88 ± 12.65 years (mean ± SD) ranging between 19 to 84 years at the time of surgery (Table 1). Sixty-one of 156 selected patients had at least one systemic disease present, being hypertension the most prevalent condition affecting 38.46 % of these patients.

2. Characteristics of implants

Table 1 depicts the characteristics of the 169 implants placed, being 70.41 % of the implants with 4.8 to 5 mm in diameter and 57.40 % with lengths between 9 and 10 mm. One hundred and fifty-four implants were placed in the posterior region (91.12 %) while only 15 were placed anteriorly (8.88 %). Within the posterior region, more implants were placed in the maxilla (97 implants; 62.99 %), compared with the mandible (57 implants; 37.01 %).

All five moderately rough surface implant systems (Straumann, Dentium, Osstem, Astratech, Shinhung) were used. Three implant brands (Straumann, Dentium, and Osstem)

represented 145 implants, accounting for 85.55 % of all the implants placed, being Straumann, the most frequently used brand with 91 implants (53.85 %). The remaining 24 implants were Astratech (8.28 %) and Shinhung (5.92 %).

3. Surgical protocols and prosthetic loading procedures

All the implants included in the study were inserted with their implant shoulder either at bone level or at marginal soft tissue level. The majority of 141 two-piece implants were positioned with the implant shoulder at bone level with the alveolar ridge and secured with either cover screw or healing abutment. Twenty-eight tissue-level Straumann SLA implants were placed transmucosally with the most coronal border of the rough surface placed at the level of alveolar bone crest.

Regarding healing protocol, 120 implants were placed with the classic submerged two-stage protocol, while 49 implants were placed transmucosally. The mean healing time between implantation to definitive prosthesis delivery for all 169 implants was 6.48 ± 2.91 months (mean ± SD). For 122 implants that were connected to coverscrew at the time of implantation, the mean time taken from implantation to second surgery was 4.26 ± 2.30 months (mean ± SD), from second surgery to prosthesis delivery 2.47 ± 2.21 months (mean ± SD), and from implantation to definitive prosthesis delivery 6.76 ± 2.87 months (mean ± SD). For 47 implants connected to healing abutment at the time of installation, the mean time between implantation to definitive prosthesis delivery was 5.81 ± 2.94 months (mean ± SD).

Several types of prosthetic restorations were used in the study: 81 single implant supported crowns were delivered to 81 implants (49.69 %), 52 2-unit IS-FDPs delivered to 56 implants (31.91 %), 18 3-unit IS-FDPs to 19 implants (11.04 %), and 12 4-unit IS-FDPs to 13 implants (7.36 %).

4. Implant survival and Kaplan-Meier estimates

In total, 7 implants in 7 patients failed during the observation period, accounting for CSRs of 94.74 % (95 % CI: 89.11 - 97.50) and 94.33 % (95 % CI: 88.30 - 97.30) at implant and patient levels, respectively. Kaplan-Meier survival analysis on the implants stratified by type of surgery demonstrated that all 87 implants in the simple surgery group survived with a CSR of 100.00 %, while 7 of 82 implants in advanced surgery group failed with a CSR of 88.85 % (95 % CI: 77.49 - 94.67) and showed the CSR was significantly lower (p = 0.005) in advanced surgery group when compared with the simple surgery group. When Kaplan-Meier estimates were stratified by bone quality, 4 of 45 implants failed in D2 surgical sites with a CSR of 87.10 % (95 % CI: 67.96 - 95.18), while no implant failed in D3 sites, and 3 of 63 implants failed in D4 sites with a CSR of 94.49 % (95 % CI: 83.73 - 98.21). The survival estimates stratified by implant position of the jaw showed 6 of 110 implants failed in maxilla with a CSR of 93.49 % (95 % CI: 85.87 - 97.07) while 1 of 59 implants failed in mandible with a CSR of 97.22 % (95 % CI: 81.87 - 99.60). The survival estimates stratified by unit of prosthesis showed 5 of 81 implants failed in a single unit prosthesis with a CSR of 91.03 % (95 % CI: 79.35 - 96.25). There were no significant

differences found in the CSR between the implants stratified by bone quality ($p = 0.059$), implant position of the jaw ($p = 0.254$), and unit of prosthesis ($p = 0.369$) (Table 2 & Figure 1).

5. Radiographic assessment

Intra-examiner agreement between the first and second measurement was statistically acceptable with Intra-class correlation coefficient (ICC) of 0.96 (range 0.94 - 0.97). The MBL change for 55 implants categorized under 0-2 year and 38 implants under 2-4 year interval were -0.19 ± 0.08 mm and -0.58 ± 0.27 mm (mean ± SD), respectively. When the changes in peri-implant MBL were compared under type of surgery in 0-2 year interval, -0.19 ± 0.08 mm (mean ± SD) was shown for 28 implants in simple surgery group, and -0.19 ± 0.11 mm (mean ± SD) was shown for 27 implants in advanced surgery group. The MBL changes in 2-4 year interval were -0.56 ± 0.26 mm (mean ± SD) for 21 implants in simple surgery group and -0.60 ± 0.28 mm (mean ± SD) for 17 implants in advanced group. According to Student's T-test, no statistically significant differences were found between the two groups during both 0-2 year ($p = 0.989$) and 2-4 year interval ($p = 0.694$). When stratified by implant position of the jaw, no significant differences were appreciated in regard to the MBL changes during both intervals. When stratified by bone quality, the mean MBL between three types of bone quality during 0-2 year interval were 0.18 ± 0.03 mm in D2, 0.15 ± 0.11mm in D3, and 0.22 ± 0.09 mm (mean ± SD) in D4 bone, respectively and had a tendency of difference according to Welch's robust test ($p = 0.042$). When stratified

by unit of prosthesis, statistically significant difference was found between 2- and 3-unit prosthesis ($p = 0.04$) during 0-2 year interval, each with the mean value of 0.23 ± 0.09 mm and 0.12 ± 0.10 mm (mean ± SD) with no clinical relevance due to low marginal bone loss (Table 3).

6. Biologic and prosthetic complications

A total of 8 biologic complications were recorded affecting 8 implants, resulting in a complication rate of 4.73 %. The most frequently observed complication was peri-implantitis (4 implants; 2.37 %), followed by peri-implant mucositis (2 implants; 1.18 %), fixture thread exposure (1 implant; 0.59 %), and coverscrew exposure (1 implant; 0.59 %). Reversible interventions as non-surgical and surgical peri-implant interventions and mucogingival surgery (free gingival graft) were performed accordingly.

A total of 16 prosthetic complications were registered affecting 16 implants, resulting in a complication rate of 9.47%. The most frequent complication was occlusal interference (5 implants; 2.96 %) followed by crown fallen out (3 implants; 1.78%), contact loosening (3 implants; 1.78%), screw loosening (2 implants; 1.18 %), hypo-occlusion (2 implants; 1.18 %), and porcelain fracture (1 implant; 0.59 %). As a consequence, reversible interventions as occlusal adjustment, recementation, occlusal and contact repair, and abutment screw retightening were performed. Irreversible intervention as crown remake was also performed accordingly.

7. Case analysis of failed implants

Seven implants failed in 7 patients (5 males and 2 females) with ages ranging between 50 to 60 years. Forty-three percent of these patients (3) presented at least one systemic disease: hypertension, diabetes mellitus, and treatment history of bisphosphonate injection. All implants that failed, except one soft-tissue level implant, were bone-level and needed advanced surgeries (Table 4).

For the failure outcome in relation to unit of prosthesis, 5 implants supporting a single-unit prosthesis, 1 implant supporting a 2-unit prosthesis, and 1 implant supporting a 4-unit prosthesis failed in the study. In the aspect of prosthetic loading, five implants failed before prosthetic installation while two failed after loading, each being loaded for 98, and 189 days until failure.

Implant failures occurred in association with 4 out of 11 surgeons involved in the study. The surgeon who experienced 3 implant failures (surgeon 9, with a failure rate of 8.10%) placed 37 rotated implants, one with 2 implant failures (surgeon 10, 3.33%) placed 60 implants, another with 1 implant failure (surgeon 2, 20.00%), and the other with 1 implant failure (surgeon 6, 100% failure).

Six implants failed (four before loading and two after) due to the loss of integration while one implant failed (before loading) due to sinus infection; in detail, one failed implant placed in conjunction with lateral sinus augmentation procedure had gone through sinus infection while the other placed with OSFE and GBR had failed due to extremely low bone quality and advanced atrophic edentulous ridge of the implantation site without any clinical

signs of post-operative infection present until the removal of implant was performed. All seven implant failures were considered as early failures with the mean time of 4.86 ± 3.72 months from implantation to the time of removal of implants (range 1.11 to 7.15 months).

IV. Discussion

The results of the present retrospective case series including 156 patients wearing 169 implants have shown that implants with low primary stability at placement may achieve high survival rates at implant and patient levels with the values of 94.74 % and 94.33 %, respectively. Similarly, the results from the radiographical evaluation have exhibited minimal changes in crestal bone levels after varied evaluation periods. These results appear to support that, with the use of implants with moderately rough surfaces, osseointegration may occur predictably in spite of low primary stability provided there is an undisturbed healing.

These obtained CSRs are comparable to those reported in the previous clinical studies assessing the outcome of implants placed with low primary stability. Orenstein et al documented the survival of 76 out of 81 movable implants, reporting a survival rate of 93.8 % at implant level (Orenstein et al., 1998). Similarly, Norton reported a survival rate of 96.7 % with 29 survived out of 30 implants in a closed cohort that were placed with the insertion torque lower than 20 Ncm at implant level (Norton, 2017).

However, a difference in survival rate can occur when it is attributed to the different implant surfaces utilized. This has been evidenced by a comparative study reporting higher survival rates for moderately rough surfaces compared to turned surfaces (96.8 % versus 84.8 %, respectively) when the implants were placed with low primary stability in regions of poor bone quality such as the posterior maxillary region (Khang et al., 2001).

Experimental studies have also evaluated the different biological behaviour depending on the macro-surface topography, demonstrating increased attachment strength and higher removal torque in implants with moderately rough surfaces (Johansson et al., 1991; Pebe et al., 1997). Moreover, when these modified surface implants were placed without mechanical engagement, although in intimate contact with the host bone, osseointegration predictably occurred via contact osteogenesis in the absence of inflammation (Jung et al., 2012; Kim et al., 2014; Shihab et al., 2017).

In this retrospective case series, 5 out 7 implants failed when implants were placed simultaneously with bone regenerative procedures due to insufficient bone availability. The bone augmentation interventions performed and their associated co-morbidities such as inflammation may have further de-stabilized the implants and ultimately caused the loss of integration (Chiapasco and Zaniboni, 2009; Zitzmann et al., 1997). In experimental studies evaluating osseointegration in surgically created defects, at the sites with wider defects, the lower primary stability was detected as a result of assessment by implant stability quotient parameter (Chan et al., 2010; Sennerby et al., 2005). Furthermore, rotated implants are more prevalent in the implants undergoing OSFEs since this intervention is used in poor quality bone and with the apical portion of the implant not being supported by bone, although whether increase of implant diameter is indicated to compensate atrophied residual bone height of sinus remains questionable (Pommer et al., 2014). It has also been reported that sinus infection induced by peri-implant bacterial infections onto grafted biomaterials in the sinus can occur as relatively a rare event when bone grafts other than

autogenous graft is used (Scarano et al., 2017).

This failure of osseointegration may also be partly attributed to the patient's health status since there was a systemic affectation present in 3 patients with failed implants. The deleterious effects of diabetes mellitus on integration have been clearly reported (Retzepi and Donos, 2010) although patients with well-controlled diabetes frequently enjoy similar survival rates (Oates et al., 2013). One implant failure was associated with bisphosphonate consumption although its possible influence on implant survival is poorly understood (Ata-Ali et al., 2016).

In the present study, in spite of the fact that all implants had a low primary stability, the changes in the crestal peri-implant bone levels were minimal and with small variations across follow-up time. These reported changes in MBLs are very similar to those reported in other published case series with implants with low primary stability, such as those reported by Norton in 54 implants with a change of MBL of 0.23 mm mesially and 0.20 mm distally after 2-year's follow-up (Norton, 2011). When comparing simple with advanced implant surgical procedures, no significant difference in MBL change was found under the interval of 0-2 years (0.19mm in both surgery groups) and 2-4 years (0.56mm in simple and 0.60mm in advanced surgery group, respectively) each. These changes are comparable to those reported in the controlled study by Mayfield and colleagues (Mayfield et al., 1998). The mean marginal bone loss reported in the advanced surgery group to be 0.60 mm under 2-4 year interval is also comparable to the range of MBL changes from 0.44 to 0.78mm that were reported in a recent systematic review (Lutz et al., 2015).

The data from this clinical investigation, however, must be interpreted with caution since the present study is not case-controlled, and the number of previous studies on the outcome of implants with low primary stability at clinical level, to date, is very few (Cobo-Vazquez et al., 2018; Rodrigo et al., 2010). Moreover, possible important factors such as the influence of smoking or patient's oral hygiene have not been accounted for in this evaluation. Nevertheless, considering that the evaluation of implants with low primary stability has mainly been assessed in experimental *in vivo* investigations and in a very limited number of clinical reports, mostly with limited samples, the current investigation may provide clinicians with useful information on the outcomes of implants with low primary stability. Moreover, the relatively large sample size, including the use of different implant systems, surgical techniques, and various implant locations may add to the external validity of the study.

V. Conclusion

Within the limitations of this retrospective study, implant placement with low primary stability might not negatively affect either the survival rates or marginal bone level changes of implants provided that a protected and unloaded healing is guaranteed.

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Figure legend

Figure 1. The implant survival analysis. (a) Kaplan-Meier survival estimates grouped by type of surgery show the survival rate was significantly lower (p = 0.005) in advanced surgery group. (b) Kaplan-Meier survival estimates grouped by bone quality did not show statistically significant difference (p = 0.059) in terms of the survival rate of the implants. (c) Kaplan-Meier survival estimates grouped by implant position of the jaw did not show statistically significant difference (p = 0.254) in terms of the survival rate of the implants. (d) Kaplan-Meier survival estimates grouped by unit of prosthesis did not show statistically significant difference (p = 0.369) in terms of the survival rate of the implants.

Tables

Table 1. Patient demographics and implant-related characteristics

1a) Demographics of Patients	**n (%)**
Age in years (mean ± SD)	59.88 ± 12.65
Gender (n)	
Male	70 (44.23)
Female	86 (55.77)
Systemic condition	
Hypertension	60 (38.46)
Diabetes mellitus	18 (11.54)
Osteoporosis	21 (13.46)
Thyroid	7 (4.49)
Chemotherapy treatment	3 (1.92)
1b) Characteristics of Implants	**Total n (%)**
Implant diameter, mm	
3 ~ 3.6	10 (5.92)
3.8 ~ 4.1	27 (15.98)
4.5	7 (4.14)
4.8 ~ 5	119 (70.41)
> 5	6 (3.55)
Implant length, mm	
7	2 (1.18)
8 ~ 8.5	44 (26.04)
9 ~ 10	97 (57.40)
11 ~ 11.5	13 (7.69)
> 11.5	13 (7.69)
Implant system	
Straumann	91 (53.85)
Dentium	28 (16.57)
Osstem	26 (15.38)
Astratech	14 (8.28)
Shinhung	10 (5.92)

Design of prosthetic reconstruction	
Single unit IS-FDP*	81 (49.69)
2 unit IS-FDP	52* (31.91)
3 unit IS-FDP	18* (11.04)
4 unit IS-FDP	12* (7.36)
1c) Surgical Procedure	**Total n (%)**
Type of surgery	
Standard placement without grafting procedure	89 (52.66)
GBR or bone graft	28 (16.57)
Bone compaction with osteotome	22 (13.02)
Osteotome sinus floor elevation	15 (8.87)
Bone added osteotome sinus floor elevation	10 (5.92)
Lateral sinus augmentation	5 (2.96)

IS-FDP*, Implant supported-fixed dental prosthesis
52*, 4 2-unit IS-FDPs are supported by 2 rotated implants within the given FDPs
18*, 1 3-unit IS-FDPs are supported by 2 rotated implants within the given FDPs
12*, 1 4-unit IS-FDPs are supported by 2 rotated implants within the given FDPs

Table 2. Life table analysis according to type of surgery, bone quality, implant position of the jaw, and type of prosthesis

Time of failure (days)	Implants entering (n)	Implant failures (terminal events)	Cumulative probability of surviving (%)	95% confidence interval
4a) Type of surgery				
Simple surgery				
0	87	0	100.00	-
2535	87	0	100.00	-
Advanced surgery				
0	82	0	100.00	-
34	82	1	98.78	91.66 - 99.83
53	78	1	97.51	90.42 - 99.37
70	77	1	96.25	88.81 - 98.77
84	74	1	94.95	87.09 - 98.07
218	51	1	93.09	83.95 - 97.11
281	45	1	91.02	80.67 - 95.96
298	42	1	88.85	77.49 - 94.67
3387	1	0	88.85	77.49 - 94.67
4b) Bone quality				
D2				
0	45	0	100.00	-
34	44	1	97.33	84.94 - 99.68
53	42	1	95.40	82.83 - 98.83
281	23	1	91.25	74-03 - 97.25
298	22	1	87.10	67.96 - 95.18
3387	1	0	87.10	67.96 - 95.18
D3				
0	61	0	100.00	-
1939	1	0	100.00	-
D4				
0	63	0	100.00	-
70	60	1	98.33	88.75 - 99.76
84	58	1	96.64	87.22 - 99.15
218	45	1	94.49	83.73 - 98.21
2535	1	0	94.49	83.73 - 98.21

Time of failure (days)	Implants entering (n)	Implant failures (terminal events)	Cumulative probability of surviving (%)	95% confidence interval
4c) Implant position of the jaw				
Maxilla				
0	110	0	100.00	-
34	110	1	99.09	93.72 - 99.87
53	105	1	98.15	92.79 - 99.53
70	104	1	97.20	91.58 - 99.09
84	100	1	96.23	90.27 - 98.57
218	74	1	94.93	88.13 - 97.88
281	66	1	93.49	85.87 - 97.07
3387	1	0	93.49	85.87 - 97.07
Mandible				
0	59	0	100.00	-
298	36	1	97.22	81.87 - 99.60
2535	1	0	97.22	81.87 - 99.60
4d) Type of prosthesis				
Single unit				
0	81	0	100.00	-
34	78	1	98.72	91.25 - 99.82
84	70	1	97.31	89.64 - 99.32
218	50	1	95.36	86.02 - 98.51
281	44	1	93.19	82.46 - 97.46
298	43	1	91.03	79.35 - 96.25
3387	1	0	91.03	79.35 - 96.25
2 unit				
0	56	0	100.00	-
53	55	1	98.18	87.79 - 99.74
3241	1	0	98.18	87.79 - 99.74
3 unit				
0	19	0	100.00	-
1840	1	0	100.00	-
4 unit				
0	13	0	100.00	-
70	13	1	92.31	56.64 - 98.88
1347	1	0	92.31	56.64 - 98.88

Table 3. Marginal bone level according to type of surgery, bone quality, implant position of the jaw, and type of prosthesis between 2 time intervals

3a) Type of surgery	**0-2 year mean ± SD [n]**	**2-4 year mean ± SD [n]**
Simple surgery	-0.19 ± 0.08 [28]	-0.56 ± 0.26 [21]
Advanced surgery mean ± SD [n]	-0.19 ± 0.11 [27]	-0.60 ± 0.28 [17]
p Value (Student's T)	0.989	0.694
3b) Bone quality		
D2	-0.18 ± 0.03 [11]	-0.57 ± 0.29 [10]
D3	-0.15 ± 0.11 [19]	-0.48 ± 0.19 [13]
D4	-0.22 ± 0.09 [25]	-0.67 ± 0.29 15]
p Value (ANOVA)	0.042 (Welch's robust test)	0.156
3c) Implant position of the jaw		
Maxilla	-0.19 ± 0.10 [36]	-0.59 ± 0.25 [15]
Mandible	-0.20 ± 0.08 [19]	-0.55 ± 0.30 [23]
p Value (Student's T)	0.588	0.660
3d) Type of prosthesis		
Single unit IS-FDP*	-0.18 ± 0.09 [26]	-0.57 ± 0.26 [14]
2 unit IS-FDP	-0.23 ± 0.09 [22]	-0.56 ± 0.30 [12]
3 unit IS-FDP	-0.12 ± 0.10 [6]	-0.56 ± 0.27 [5]
4 unit IS-FDP	NA*	-0.64 ± 0.26 [7]
p Value (ANOVA)	0.040*	0.931

IS-FDP*, Implant supported-fixed dental prosthesis
NA*, Not available
0.040*, Statistically significant difference was found between 2 and 3 unit IS-FDPs

Table 4. Characteristics of the failed implants

Patient characteristics			Implant characteristics					Surgery			Implant loss		
Age (years)	Sex	Systemic disease	System	Diameter (mm)	Length (mm)	Tooth number (FDI)	Prosthesis Type (unit)	Advanced surgery	Submerged/ Transmucosal healing protocol	Operator	Initial loading time (days)	Time before implant failure (days)	Reason for failure
69	M	HTN*	Straumann	4.8	12	14	1	GBR*	HA*	Surgeon 10	NA*	34	Loss of integration
69	M	DM*	Dentium	4.5	8	26	2	Lateral sinus augmentation	HA*	Surgeon 9	NA*	53	Sinus infection
60	F	N-S*	Shinhung	5	10	27	1	Osteotome	CS*	Surgeon 10	NA*	84	Loss of integration
61	M	N-S*	Dentium	5	8	26	1	OSFE*	HA*	Surgeon 9	92	281	Loss of integration
51	M	N-S*	Straumann	4.8	10	37	1	GBR*	HA*	Surgeon 9	200	298	Loss of integration
52	M	N-S*	Dentium	4.5	10	14	4	GBR*	HA*	Surgeon 6	NA*	70	Loss of integration
65	F	Bisphosphonate injection history	Straumann	4.8	8	16	1	OSFE* + GBR*	CS*	Surgeon 2	NA*	218	Loss of integration

GBR*, Guided bone regeneration; OSFE*, Osteotome sinus floor elevation
HTN*, Hypertension; DM*, Diabetes mellitus; *N-S, Non-specific
NA*, Not available
CS*, Cover screw; HA*, Healing abutment

Figure

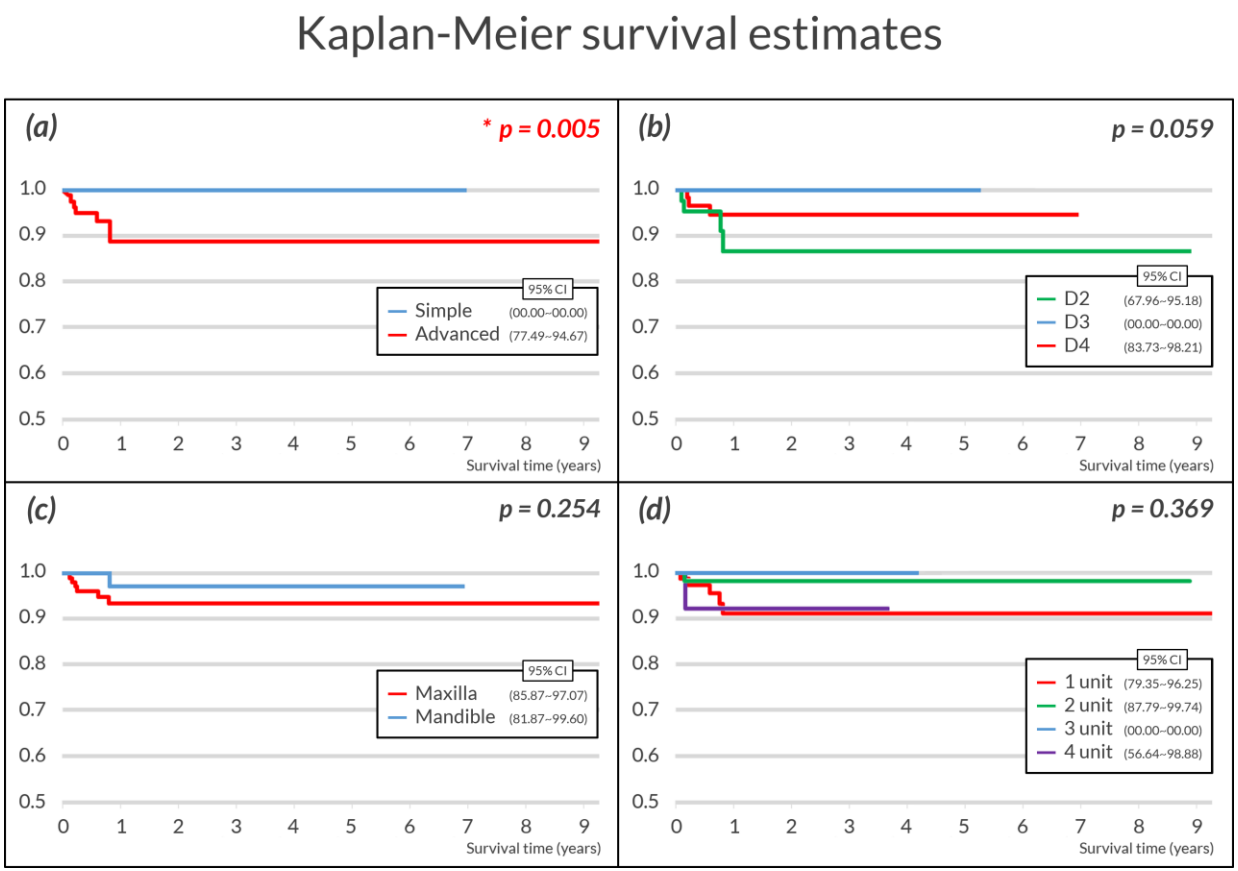

Figure 1. The implant survival analysis

국문요약

낮은 일차 안정도를 갖는 임플란트의 생존률 및 방사선학적 결과를 평가 분석한 후향적 연구

<지도교수 **정 의 원**>

연세대학교 대학원 치의학과

이 관 주

임플란트 치과학에서 임플란트의 성공적인 골유착을 얻기 위해서는 일차 안정도를 획득하는 것이 중요하다고 여겨져 왔다. 특히 불리한 골질에서는 적절한 초기 고정력을 얻기 위한 임플란트의 식립을 위해 작은 직경의 드릴, 셀프 태핑 드릴, 테이퍼형 임플란트를 이용하기도 한다. 이러한 수술적 기법을 사용 했음에도 불구하고 임플란트의 충분한 일차 안정도가 확보되지 않는 경우가 발생한다. 초기 고정력이 낮은 임플란트를 제거하지 않고 치유시켜 골유착을 확보하는 것에 대해 여러 문헌에서는 대립되는 연구 결과가 보고 되고 있다. 따라서 본 연구의 목적은 낮은 일차 안정도로 식립된 임플란트의 임상 결과와 임플란트 실패와 관련된 요소들을 후향적으로 분석하는 것이다.

2008년 1월부터 2018년 10월까지 연세대학교 치과병원 치주과를 내원한 환자들 중에서 초기 고정력이 낮아 커버 스크류나 임시 치유 지대주를 연결 시 회전된 임플란트로 치료를 시행한 156명 환자와 169개 임플란트를 연구 대상으로 최소 34일에서 최대 9.28년의 경과 관찰을 시행하였다. 환자들의 평균 나이는 59.9세였고 수술의 유형, 골질, 임플란트의 상하악 위치, 보철물의 갯수에 따른 기술 통계학적 분석, 생존분석 (생명표법 및 Kaplan-Meier 생존분석), 그리고 수직적 변연골 변화량 측정을 기반으로 한 방사선학적 분석을 시행하였다. 본 연구는 STROBE 지침을 준수하였다.

연구 결과, 7개 임플란트가 실패하여 임플란트 및 환자 수준에서 94.74 % (95% CI: 89.11 – 97.50), 94.33 % (95% CI: 88.30 -97.30)의 누적 생존율을 나타냈다. Kaplan-Meier 분석에 따르면 골이식 등 상위 술식을 동반하지 않고 식립한 군 (87개) 에서는 임플란트 실패가 없었고 상위 술식을 동반하고 식립한 군 (82개) 에서 7개 임플란트 실패가 발생 하였으며 두 군의 누적 생존률 간에는 유의미한 통계학적 차이가 있었다 ($p = 0.005$). 골질 ($p = 0.059$), 상하악의 위치 ($p = 0.254$), 보철물의 갯수 ($p = 0.369$) 에서는 군 간 유의미한 차이는 없었다.

93개의 임플란트에 대한 수직적 변연골 변화량을 측정하고 분석한 결과 상위 술식을 동반하여 식립한 군과 동반하지 않고 식립한 군의 0-2년 관찰 기간 내의 평균 변연골 변화량은 각각 -0.19 ± 0.08mm, -0.19 ± 0.11mm 였

고 2-4년 관찰 기간 내에서는 각각 -0.56 ± 0.26mm, -0.60 ± 0.28mm로 나타났다. 수술 유형과 임플란트의 상하악 위치에서 군 간 변연골 변화량 사이에서는 통계적으로 유의미한 차이는 없었다.

본 연구의 후향적 연구의 한계 내에서 일차 안정도가 낮은 임플란트의 식립은 임플란트에 부하를 가하지 않는 보호된 치유 과정이 이루어진다면 임플란트 생존률과 변연골 변화에 부정적인 영향을 미치지 않을 것으로 보인다.

핵심되는 말 : 치과 임플란트, 임플란트 안정도, 골유착, 생존율, 방사선학적 분석