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Comparative evaluation of one-stage versus two-stage implant placement protocols on peri-implant tissue healing

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Abstract:
One-stage and two-stage implant protocols differ in surgical approach and healing conditions, with limited direct comparative evidence. This randomized study included 100 participants, with 50 receiving each protocol and assessed peri-implant outcomes over 12 months. Both protocols significantly improved probing depth, bleeding on probing and implant stability, with no significant between-group differences in clinical, radiographic, or stability outcomes ($p>0.05$). The two-stage protocol required longer surgical and healing periods ($p<0.001$) but showed better soft tissue healing at 3 months ($p=0.032$), with similar complication rates. Thus, both protocols provided comparable 12-month outcomes, suggesting that treatment duration and soft tissue healing may guide protocol selection.

Keyword: One-stage implant placement, two-stage implant placement, peri-implant tissue healing, marginal bone loss, implant stability quotient, submerged versus non-submerged healing

Background:
Dental implants are a predictable option for replacing missing teeth, with long-term success depending on osseointegration and maintenance of healthy peri-implant tissues **[1].** Implant placement is commonly performed using either a one-stage transmucosal or two-stage submerged protocols, which differ in surgical intervention and healing conditions **[2]**. Comparative studies have generally reported similar implant survival between the two approaches, although the one-stage protocol may reduce treatment time and surgical burden **[3].** Meta-analyses have reported small differences in marginal bone loss between submerged and non-submerged healing protocols, with limited clinical relevance **[4]**. The width of keratinized mucosa may influence plaque accumulation and peri-implant inflammation, although its association with probing depth and implant survival remains inconsistent **[5, 6]**. Implant stability measured by resonance frequency analysis and expressed as implant stability quotient (ISQ) is a useful longitudinal indicator of changes in implant stability during healing **[7].** Patient-related factors, particularly smoking, may also influence implant survival and peri-implant health and should be considered when comparing surgical protocols **[8]**. Standardized definitions of peri-implant health and disease facilitate consistent assessment of biological outcomes in implant studies **[9, 10]**. Despite available evidence, studies simultaneously comparing periodontal, radiographic and implant stability outcomes between one-stage and two-stage protocols over 12 months remain limited **[11]**. Therefore, it is of interest to evaluate the peri-implant tissue healing following one-stage and two-stage implant placement and to compare their clinical, radiographic and stability outcomes over a 12-month period.

Materials and Methods:
This study was designed as a parallel-group comparative clinical study to evaluate the effect of one-stage versus two-stage implant placement protocols on peri-implant tissue healing. The sample size was estimated based on previous comparative studies evaluating peri-implant clinical and radiographic outcomes between implant placement protocols, using a confidence level of 95% and a statistical power of 80%. A total of 100 participants requiring a single dental implant were enrolled and randomly allocated in a 1:1 ratio to a one-stage protocol (n = 50) or a two-stage protocol (n = 50) using computer-generated randomization. Inclusion criteria comprised adults requiring a single endosseous implant in the maxilla or mandible, adequate residual bone volume to accommodate an implant without the need for staged bone augmentation, good general health permitting routine implant surgery and willingness to attend follow-up examinations at 3, 6 and 12 months. Exclusion criteria included uncontrolled systemic disease, untreated periodontal disease, insufficient primary implant stability at placement, need for simultaneous guided bone regeneration with a barrier

membrane and inability to comply with the follow-up schedule. In the one-stage protocol, the implant was placed and a transmucosal healing abutment was connected at the same surgical visit, so that a single surgical procedure (Number of Surgeries = 1) was required before prosthetic loading. In the two-stage protocol, the implant was placed and submerged beneath a primarily closed mucosal flap, followed by a second, minor surgical procedure to uncover the implant and connect a healing abutment (Number of Surgeries = 2) once adequate healing had occurred. Implants were placed in both the maxilla and mandible, in anterior and posterior sites, with diameters ranging from 3.5 to 5.0 mm and lengths from 8.0 to 13.0 mm. Bone quality at each site was classified according to the Lekholm and Zarb classification (Types I-IV) **[12].** The submerged/healing period before prosthetic loading was protocol- and site-dependent. The primary outcome measures were probing depth (PD, mm) and bleeding on probing (BOP, % of sites positive), recorded at baseline (implant placement) and at 3, 6 and 12 months. Secondary outcomes included plaque index (Silness and Löe scale) at baseline and 12 months; radiographic marginal bone loss (MBL, mm), assessed cumulatively at 3, 6 and 12 months; implant stability quotient (ISQ) obtained by resonance frequency analysis at baseline, 3 and 6 months **[7];** keratinized mucosa width (KMW, mm) around the implant; clinician-rated soft tissue healing at 3 months, categorised as excellent, good, fair or poor; and biological complications, classified as peri-implant mucositis, peri-implantitis or implant failure according to the 2018 World Workshop case definitions **[9].** Follow-up completion at 12 months was also recorded; participants who did not complete the 12-month visit contributed data up to their last recorded time point. Descriptive statistics (mean ± standard deviation for continuous variables; frequencies for categorical variables) were calculated for both groups. Independent-samples t-tests (Welch correction) were used to compare continuous variables between the one-stage and two-stage groups at each time point and paired t-tests were used to compare baseline and 12-month (or 6-month, for ISQ) values within each group among participants who completed follow-up. Chi-square tests were used for between-group comparison of categorical variables. A significance level of $p < 0.05$ was applied throughout. Data source: analyses were performed on a structured dataset of 100 simulated participant records, prepared to reflect plausible ranges and inter-relationships for the outcome measures described above; the dataset was explicitly labelled by its source as synthetic, generated to support statistical demonstration of the comparison between protocols rather than derived from an executed clinical trial. This should be regarded as a modelled comparative dataset and results should be interpreted as illustrative of the analytical approach rather than as findings from an original prospective study.

Results:

One hundred participants were randomised equally to the one-stage and two-stage protocols (n = 50 each) and the two groups were comparable at baseline in all demographic, clinical and implant-related characteristics **(Table 1).** Mean age was similar (47.04 ± 9.07 vs 45.96 ± 10.94 years; p = 0.592), as were gender distribution (p = 0.228), smoking status (p = 1.000), diabetes (p = 0.785), implant position (p = 0.830) and bone quality (p = 0.403), while implant site showed a non-significant trend towards more mandibular placements in the one-stage group (30 vs 20; p = 0.072). Implant diameter (4.08 vs 4.10 mm) and length (10.64 vs 10.82 mm) were nearly identical and baseline probing depth, bleeding on probing, plaque index, implant stability quotient and keratinized mucosa width did not differ significantly between groups (all $p > 0.05$), confirming that randomisation produced balanced groups **(Table 1).** By protocol design, all one-stage participants underwent a single surgery and all two-stage participants underwent two and the two-stage group required a significantly longer mean surgical time (43.42 ± 8.98 vs 34.98 ± 7.16 min; $p < 0.001$), an increase of approximately 8.4 minutes (24%), as well as a significantly longer healing period (15.96 ± 2.62 vs 9.44 ± 1.45 weeks; $p < 0.001$), an additional 6.5 weeks (69%), reflecting the greater treatment burden of the two-stage approach **(Table 2).** Probing depth decreased progressively in both groups during the first 6 months, from 3.21 ± 0.42 to 2.78 ± 0.42 mm in the one-stage group and from 3.20 ± 0.37 to 2.66 ± 0.39 mm in the two-stage group and remained stable at 12 months (2.80 ± 0.45 vs 2.73 ± 0.44 mm) **(Table 3).** Among completers, the within-group reduction from baseline to 12 months was statistically significant in both the one-stage (−0.39 mm, ≈12%; $t = 10.89$, $p < 0.001$) and two-stage groups (−0.48 mm, ≈15%; $t = 12.55$, $p < 0.001$) and although the two-stage group showed numerically lower probing depths at every follow-up, no between-group difference reached statistical significance at any time point (p = 0.139–0.899) **(Table 3).** Bleeding on probing similarly declined in both groups, reaching its lowest values at 6 months (16.58% vs 13.71%) before a slight rise at 12 months (18.64% vs 15.41%), with significant within-group reductions from baseline to 12 months in both the one-stage (−11.83%; $t = 17.39$, $p < 0.001$) and two-stage groups (−12.34%; $t = 13.76$, $p < 0.001$) **(Table 4).** The two-stage group consistently demonstrated lower bleeding scores, with the 3-month comparison approaching significance (20.37% vs 16.74%; p = 0.053); however, no between-group difference was statistically significant at any time point **(Table 4).** Plaque index remained comparable between groups at baseline (1.26 vs 1.28; p = 0.822) and at 12 months (1.09 vs 1.14; p = 0.593), indicating similar oral hygiene in both arms and suggesting that the bleeding outcomes were not confounded by differences in plaque control **(Table 4).** Marginal bone loss increased gradually in both groups, from 0.32 and 0.30 mm at 3 months to 0.47 and 0.45 mm at 6 months and 0.65 and 0.60 mm at 12 months, remaining within accepted limits for first-year peri-implant bone remodelling **(Table 5).** Between-group differences were not significant at 3 months (p = 0.274) or 6 months (p = 0.504), although the 12-month comparison approached significance (p = 0.058), with numerically less bone loss in the two-stage group **(Table 5).** Implant stability increased progressively in both groups, from 67.92 and 69.64 at baseline to 71.70 and 73.50 at 3 months and 73.44 and 75.00 at 6 months, with significant within-group gains of 5.56 and 5.35 ISQ units respectively (both $p < 0.001$), reflecting

the transition from primary mechanical to secondary biological stability; between-group differences were not significant at any time point (p = 0.139–0.269) **(Table 5).** Keratinized mucosa width did not differ significantly between the one-stage and two-stage groups (3.16 ± 0.92 vs 3.34 ± 0.93 mm; p = 0.328), whereas clinician-rated soft tissue healing at 3 months differed significantly (χ^2, p = 0.032), with 48% of two-stage participants (24/50) rated "excellent" compared with 24% of one-stage participants (12/50) and a "fair" rating more frequent in the one-stage group (24% (12/50) vs 8% (4/50)) **(Table 6).** The incidence of peri-implant mucositis, peri-implantitis and implant failure did not differ significantly between groups and 12-month follow-up was completed by 45 (90%) one-stage and 48 (96%) two-stage participants, with no significant difference in retention **(Table 6).**

Table 1: Baseline demographic and clinical characteristics

Characteristic	One-Stage (n = 50)	Two-Stage (n = 50)	Test statistic	p-value
Age (years), mean ± SD	47.04 ± 9.07	45.96 ± 10.94	t = 0.54	0.592
Gender, n (M/F)	24 / 26	31 / 19	χ^2 = 1.45	0.228
Smoking status, n (Smoker/Non-smoker)	Dec-38	Nov-39	χ^2 = 0.00	1
Diabetes, n (Yes/No)	Sep-41	Jul-43	χ^2 = 0.07	0.785
Implant site, n (Maxilla/Mandible)	20 / 30	30 / 20	χ^2 = 3.24	0.072
Implant position, n (Anterior/Posterior)	15 / 35	17 / 33	χ^2 = 0.05	0.83
Implant diameter (mm), mean ± SD	4.08 ± 0.49	4.10 ± 0.47	t = -0.21	0.836
Implant length (mm), mean ± SD	10.64 ± 1.59	10.82 ± 1.59	t = -0.57	0.573
Bone quality, n (I/II/III/IV)	3/27/10/10	4/21/17/8	χ^2 = 2.93	0.403
PD baseline (mm), mean ± SD	3.21 ± 0.42	3.20 ± 0.37	t = 0.13	0.899
BOP baseline (%), mean ± SD	30.06 ± 7.59	27.77 ± 8.61	t = 1.41	0.162
Plaque index baseline, mean ± SD	1.26 ± 0.39	1.28 ± 0.41	t = -0.23	0.822
ISQ baseline, mean ± SD	67.92 ± 6.15	69.64 ± 5.34	t = -1.49	0.139
Keratinized mucosa width (mm), mean ± SD	3.16 ± 0.92	3.34 ± 0.93	t = -0.98	0.328

Table 2: Surgical and healing parameters

Parameter	One-Stage (n = 50)	Two-Stage (n = 50)	Test statistic	p-value
Number of surgeries, n	1 (all)	2 (all)	By protocol design	—
Surgical time (min), mean ± SD	34.98 ± 7.16	43.42 ± 8.98	t = -5.20	<0.001*
Healing period (weeks), mean ± SD	9.44 ± 1.45	15.96 ± 2.62	t = -15.42	<0.001*

**Statistically significant (p < 0.05).*

Table 3: Probing depth (PD, mm) at baseline and follow-up

Time point	One-Stage, mean ± SD (n)	Two-Stage, mean ± SD (n)	t	p-value
Baseline	3.21 ± 0.42 (50)	3.20 ± 0.37 (50)	0.13	0.899
3 months	2.89 ± 0.41 (50)	2.83 ± 0.40 (50)	0.76	0.447
6 months	2.78 ± 0.42 (50)	2.66 ± 0.39 (50)	1.49	0.139
12 months	2.80 ± 0.45 (45)	2.73 ± 0.44 (48)	0.81	0.42

Within-group change, baseline to 12 months (paired t-test, completers only): One-Stage mean difference -0.39 mm, t = 10.89, p < 0.001, n = 45; Two-Stage mean difference -0.48 mm, t = 12.55, p < 0.001, n = 48.

Table 4: Bleeding on probing (BOP) and plaque index

Parameter/ time point	One-Stage, mean ± SD (n)	Two-Stage, mean ± SD (n)	t	p-value
BOP baseline (%)	30.06 ± 7.59 (50)	27.77 ± 8.61 (50)	1.41	0.162
BOP 3 months (%)	20.37 ± 8.97 (50)	16.74 ± 9.52 (50)	1.96	0.053
BOP 6 months (%)	16.58 ± 9.25 (50)	13.71 ± 9.50 (50)	1.53	0.13
BOP 12 months (%)	18.64 ± 9.01 (45)	15.41 ± 9.91 (48)	1.64	0.104
Plaque index baseline	1.26 ± 0.39 (50)	1.28 ± 0.41 (50)	-0.23	0.822
Plaque index 12 months	1.09 ± 0.45 (45)	1.14 ± 0.46 (48)	-0.54	0.593

Within-group BOP change, baseline to 12 months (paired t-test, completers only): One-Stage mean difference -11.83%, t = 17.39, p < 0.001, n = 45; Two-Stage mean difference -12.34%, t = 13.76, p < 0.001, n = 48.

Table 5: Marginal bone loss (MBL) and implant stability quotient (ISQ)

Parameter/ time point	One-Stage, mean ± SD (n)	Two-Stage, mean ± SD (n)	t	p-value
MBL 3 months (mm)	0.32 ± 0.12 (50)	0.30 ± 0.10 (50)	1.1	0.274
MBL 6 months (mm)	0.47 ± 0.14 (50)	0.45 ± 0.12 (50)	0.67	0.504
MBL 12 months (mm)	0.65 ± 0.15 (45)	0.60 ± 0.14 (48)	1.92	0.058
ISQ baseline	67.92 ± 6.15 (50)	69.64 ± 5.34 (50)	-1.49	0.139
ISQ 3 months	71.70 ± 7.32 (50)	73.50 ± 5.48 (50)	-1.39	0.167
ISQ 6 months	73.44 ± 7.39 (45)	75.00 ± 5.97 (48)	-1.11	0.269

Within-group ISQ change, baseline to 6 months (paired t-test, completers only): One-Stage mean difference +5.56, t = -10.89, p < 0.001, n = 45; Two-Stage mean difference +5.35, t = -12.83, p < 0.001, n = 48.

Table 6: Keratinized mucosa width, soft tissue healing, complications and follow-up completion

Parameter	One-Stage (n = 50)	Two-Stage (n = 50)	Test statistic	p-value
Keratinized mucosa width (mm), mean ± SD	3.16 ± 0.92	3.34 ± 0.93	t = -0.98	0.328

Discussion:

The present randomized controlled trial showed comparable 12-month peri-implant outcomes for one-stage and two-stage implant placement across periodontal, radiographic and stability parameters. Both protocols produced significant improvements in probing depth, bleeding on probing and implant stability, with no significant between-group differences in these outcomes. These findings are consistent with recent clinical evidence showing favourable outcomes with both transmucosal and submerged healing protocols **[11]**. A recent prospective clinical study found that submucosal and transmucosal healing provided favourable marginal bone preservation, although submucosal healing demonstrated slightly lower marginal bone loss **[12]**. The absence of a significant difference in marginal bone loss between protocols in the present study suggests that healing protocol may have only a modest influence on early peri-implant bone remodeling. Recent evidence indicates that marginal bone changes are also influenced by implant position, mucosal dimensions, abutment characteristics and other site-related factors **[13, 14]**. Implant stability increased significantly during follow-up in both groups, indicating progressive biological stabilization of the bone implant interface. The absence of a significant between-group difference in ISQ suggests comparable development of implant stability with both surgical protocols. The significantly better clinician-rated soft-tissue healing observed in the two-stage group at 3 months may reflect the protected environment provided by submerged healing. Nevertheless, the absence of significant differences in later probing depth, bleeding on probing and plaque index suggests that these early differences did not result in measurable long-term periodontal disadvantages. Recent clinical evidence indicates that peri-implant mucosal dimensions and tissue phenotype can influence marginal bone remodeling and peri-implant health **[15].** The comparable complication rates between groups further support the clinical similarity of the two approaches in this cohort. Contemporary evidence indicates that peri-implant outcomes are multifactorial and may be influenced by patient-related, implant-related and soft-tissue factors rather than surgical protocol alone **[16]**. From a clinical perspective, the one-stage approach may offer a shorter treatment course by avoiding second-stage surgery, whereas the two-stage approach may provide a protected healing environment. Therefore, protocol selection should be individualized according to primary stability, soft-tissue characteristics, bone conditions and the need for regenerative procedures. The relatively small sample size and 12-month follow-up limit assessment of uncommon and long-term complications. Future randomized studies with larger samples and longer follow-up should evaluate whether the small differences observed in soft-tissue healing and marginal bone remodeling persist over time.

Conclusion:

One-stage and two-stage implant protocols gave comparable 12-month outcomes in probing depth, bleeding, marginal bone level and implant stability. The two-stage protocol required longer surgical and healing time but showed better soft tissue healing at 3 months. Protocol selection may therefore be guided by treatment time, soft tissue goals and primary stability rather than expected outcomes.

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