



CLINICAL RESEARCH:

Gingival Changes During Orthodontic Treatment with Conventional and Self-Ligating Brackets: A Prospective Non-Randomized Comparative Study

Cambios gingivales durante el tratamiento ortodóntico con brackets convencionales y autoligables:
un estudio comparativo prospectivo no aleatorizado

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Received: 10-VII-2026

Accepted: 30-VII-2026

ABSTRACT: Fixed orthodontic appliances create retentive surfaces that promote biofilm accumulation and may alter gingival health. Conventional and self-ligating brackets differ in ligature system and bracket-wire interface geometry, factors theoretically linked to differential plaque retention. Systematic reviews have not demonstrated consistent periodontal superiority of either system, and patient-level factors may be at least as relevant as bracket selection. Prospective observational cohort study with non-randomized, clinician-determined bracket allocation (2024-1 to 2025-2), Faculty of Dentistry, Universidad de Cartagena, Colombia. Forty patients (20 conventional, 20 self-ligating), aged 16-40 years, were evaluated at baseline (T1) and after 6 months of active treatment (T2). Gingival outcomes were probing depth, gingival color, bleeding on probing, dental mobility, sensitivity, and gingival recession (Cairo classification); baseline gingival phenotype, age, sex, and oral hygiene were also recorded. Between-group change scores ($\Delta=T2-T1$) were compared using bivariate, non-parametric tests (Mann-Whitney U, Kruskal-Wallis). Mean age was 25.15 ± 8.10 years. No statistically significant between-group differences were detected during the six-month follow-up for any gingival outcome (all $p > 0.05$). In bivariate analysis, baseline gingival phenotype was associated with bleeding on probing ($p=0.004$) and, exploratorily, with dental mobility ($p=0.026$); neither association remained significant after correcting for the full set of 28 comparisons performed (adjusted $\alpha=0.0018$), and both should be regarded as hypothesis-generating. No statistically significant differences were detected between bracket types during this six-month, non-



randomized comparison; estimates were imprecise, and residual confounding by indication cannot be excluded. Gingival phenotype showed a preliminary, exploratory association with periodontal response that requires confirmation in larger, adequately controlled, multivariable studies before it can inform clinical practice.

KEYWORDS: Orthodontic brackets; Gingival diseases; Gingival recession; Cohort studies; Periodontal index; Dental prophylaxis; Risk assessment.

RESUMEN: Los aparatos ortodónticos fijos generan superficies retentivas que favorecen la biopelícula y pueden alterar la salud gingival. Los brackets convencionales y autoligables difieren en el sistema de ligadura y la geometría bracket-arco. La evidencia sistemática no ha demostrado superioridad periodontal consistente de ningún sistema, y los factores del paciente podrían ser al menos igual de relevantes que la selección del bracket. Estudio de cohorte observacional prospectivo con asignación de bracket no aleatorizada, determinada por el clínico tratante (2024-1 a 2025-2), Facultad de Odontología, Universidad de Cartagena, Colombia. Cuarenta pacientes (20 convencionales, 20 autoligables), 16-40 años, evaluados al inicio (T1) y tras 6 meses de tratamiento activo (T2). Desenlaces gingivales: profundidad de sondaje, color gingival, sangrado al sondaje, movilidad dental, sensibilidad y recesión gingival (Cairo); se registraron también fenotipo gingival basal, edad, sexo e higiene oral. Los cambios ($\Delta=T2-T1$) se compararon con pruebas bivariadas no paramétricas (U de Mann-Whitney, H de Kruskal-Wallis). Edad media 25.15 ± 8.10 años. No se detectaron diferencias significativas entre grupos durante el seguimiento de seis meses en ningún desenlace gingival (todo $p > 0.05$). En análisis bivariado, el fenotipo gingival basal se asoció con sangrado al sondaje ($p=0.004$) y, de forma exploratoria, con movilidad dental ($p=0.026$); ninguna asociación se mantuvo significativa tras corregir por las 28 comparaciones realizadas (α ajustado= 0.0018), por lo que deben considerarse generadoras de hipótesis. No se detectaron diferencias significativas entre tipos de bracket durante esta comparación no aleatorizada de seis meses; las estimaciones fueron imprecisas y no puede excluirse confusión residual por indicación. El fenotipo gingival mostró una asociación preliminar y exploratoria con la respuesta periodontal que requiere confirmación en estudios más amplios, controlados y multivariados antes de orientar la práctica clínica.

PALABRAS CLAVE: Brackets ortodónticos; Enfermedades gingivales; Recesión gingival; Estudios de cohortes; Índice periodontal; Profilaxis dental; Medición de riesgo.

INTRODUCTION

Fixed orthodontic appliances create retentive surfaces that facilitate biofilm accumulation and may alter gingival health, with effects ranging from reversible gingivitis to gingival recession in susceptible patients (1,2,3); compositional shifts in the subgingival microbiota have been reported within months of appliance placement (4).

Conventional brackets rely on elastic or metallic ligatures to engage the archwire, increasing wire-bracket friction and adding plaque-retentive surfaces near the gingival margin. Self-ligating brackets replace external ligatures with an integrated sliding mechanism, theoretically reducing biofilm retention and facilitating oral hygiene (5,6); these proposed advantages have been used to justify their higher cost and to

guide bracket selection in periodontally susceptible patients.

However, systematic reviews and meta-analyses report conflicting results, and a Cochrane review concluded that current evidence is insufficient to establish periodontal superiority of either system (7). Variability across studies has been attributed to patient-level factors such as oral hygiene, gingival phenotype, and individual biological susceptibility (8,9,10,11,12), and a randomized trial comparing passive self-ligating and conventional systems likewise found no significant periodontal advantage (13).

Host-related characteristics, rather than bracket design, may therefore be at least as relevant to periodontal outcomes. Gingival phenotype — defined by the thickness of the marginal periodontal tissues — has been proposed as one such modulating factor, with thinner phenotypes considered potentially more susceptible to recession and inflammatory response during orthodontic tooth movement (14,15,16); this construct is distinct from keratinized tissue width, per current periodontal classification terminology (17).

Local, prospective comparative evidence from Latin American teaching-service orthodontic programs is scarce, despite demographic and biological heterogeneity that may differ from populations studied in international trials (1,7). This study compared gingival changes in patients treated with conventional and self-ligating brackets at the Faculty of Dentistry, Universidad de Cartagena (2024-1 to 2025-2), and explored, on an exploratory basis, which baseline host-level characteristics were associated with periodontal change.

MATERIAL AND METHODS

STUDY DESIGN AND SETTING

This was a prospective observational cohort study with non-randomized, clinician-determined exposure allocation, conducted during the 2024-1 to 2025-2 academic periods at the Orthodontic Postgraduate Program, Faculty of Dentistry, Universidad de Cartagena, Cartagena de Indias, Colombia. Because the treating clinician selected the bracket system prior to enrollment, confounding by indication is possible — for example, bracket choice may have been influenced by perceived treatment complexity, periodontal status, or cost considerations — and this is treated as a central limitation of the study rather than a minor caveat (see Limitations). The study followed STROBE guidelines for reporting observational studies; the completed STROBE checklist is provided as Supplementary Material.

STUDY POPULATION AND ELIGIBILITY CRITERIA

Patients aged 16-40 years with permanent dentition were eligible. Inclusion criteria: dentoalveolar discrepancy permitting alignment without prior extractions; comparable relative anterior crowding in both arches; ability to provide written informed consent; and initiation of full fixed orthodontic treatment within the study period.

Exclusion criteria: active untreated periodontal disease or caries; temporomandibular disorders; retained or impacted canines; absence of any permanent tooth (excluding third molars); systemic conditions affecting periodontal tissues (uncontrolled diabetes, immunosuppres-

sion, phenytoin, cyclosporine, or calcium channel blockers); pregnancy or breastfeeding; and prior orthodontic treatment.

ALLOCATION AND GROUPS

Patients were allocated consecutively to two groups based on the bracket system prescribed by the treating clinician per institutional protocol; no randomization was performed. Group A (self-ligating, $n=20$) received passive self-ligating brackets; Group B (conventional, $n=20$) received pre-adjusted edgewise brackets with elastomeric ligatures. Because allocation was not randomized, the two groups may differ systematically on unmeasured characteristics related to bracket selection; between-group comparisons should therefore be interpreted as associational, not causal.

BRACKET SYSTEMS AND ORTHODONTIC PROTOCOL

Both groups received pre-adjusted, 0.022×0.028 -in slot, MBT-prescription stainless-steel brackets (American Orthodontics, Sheboygan, WI, USA). The self-ligating group received a passive self-ligating system; the conventional group received twin brackets engaged with elastomeric ligature modules, replaced at every appointment. All patients were bonded using the same protocol: 37% phosphoric acid etch for 30 seconds and a light-cured adhesive (Transbond XT, 3M Unitek, Monrovia, CA, USA), applied by direct bonding technique. The archwire sequence was standardized for both groups (0.014-in, 0.016-in, and 0.018×0.025 -in nickel-titanium, progressing to 0.019×0.025 -in stainless steel as tolerated); at the 6-month evaluation, all patients remained within the nickel-titanium leveling-and-aligning phase, and no auxiliary elastics or other adjunctive appliances had been used. Appointments were scheduled every 4 to 6 weeks. Each patient was treated by one of two postgraduate residents (Y.R.J. or D.L.J.) under direct supervision of a specialist

faculty member (J.B.A. or A.D.C.); residents were rotated across both bracket groups to reduce operator-related confounding. Oral hygiene instruction (modified Bass technique) was delivered once, at bonding, without a scripted reinforcement protocol at subsequent visits — a standardization gap that is acknowledged as a limitation. No scaling, root planing, or other periodontal therapy was performed during follow-up except for isolated supragingival prophylaxis administered to two patients (one per group) for localized calculus, noted here as a protocol deviation.

SAMPLE SIZE CALCULATION

Sample size was estimated for comparison of two independent proportions, based on Wang et al. (18): confidence level 95% ($\alpha=0.05$), power 80% ($\beta=0.20$), expected proportion of gingival change in the conventional group 45% versus 20% in the self-ligating group (25-percentage-point difference). Minimum: 18 patients per group; with 10% estimated dropout, 20 patients per group were enrolled ($n=40$). This calculation, based on independent proportions, does not correspond to the paired, repeated-measures change-score analysis ultimately performed, nor does it account for the multiple correlated outcomes evaluated; it is retained here for transparency, but the study should be considered underpowered for the analyses actually reported, and effect estimates should be interpreted as imprecise (see Limitations).

ETHICS

The original protocol was approved by the Institutional Ethics Committee of the Universidad de Cartagena prior to patient enrollment (Acta No. UDC-2023114, 14 December 2023); a subsequent amendment approving the final statistical analysis plan and the extended reporting period was approved on 26 November 2025 (Acta No. UDC-20251126). Both approvals were issued in accordance with the Declaration of Helsinki and

Colombian Resolution 8430 of 1993 (minimal-risk classification). Written informed consent was obtained from all participants, with parental consent for minors; data were anonymized for analysis.

VARIABLES AND MEASUREMENTS

Patients were evaluated at T1 (baseline, before bracket placement) and T2 (6 months $\pm$ 2 weeks after bracket placement) by a single calibrated examiner (Y.R.J.), who was not blinded to bracket type — an inherent limitation given the visibility of the appliance during clinical examination.

Gingival phenotype was defined as the thickness of the marginal gingival tissue, a construct distinct from keratinized tissue width (17). Thickness was assessed using the probe-transparency method: a periodontal probe was inserted into the gingival sulcus at the mid-facial aspect of each of the twelve index teeth (11, 14, 16, 21, 24, 26, 31, 34, 36, 41, 44, 46); phenotype was recorded as thin when the probe outline was visible through the marginal tissue and thick when it was not. No local anesthesia was required. A patient-level phenotype was assigned as thin if the probe was visible at a majority of the assessed sites, and thick otherwise. This technique provides a categorical rather than a metric estimate of thickness and was not cross-validated against transgingival probing or ultrasonographic measurement, which is acknowledged as a limitation.

Other individual characteristics (T1): age (categorized: <18, 18-29, $\geq$ 30 years); sex (female/male); oral hygiene by Silness & L  e plaque index (good: 0-0.9; fair: 1.0-1.9; poor: $\geq$ 2.0), recorded at T1 only.

Gingival outcomes (T1 and T2): all outcomes were assessed at the mid-facial site of the same twelve index teeth used for phenotype assessment,

using a single measurement per site at each time point (no repeated readings). A patient was classified as “present” for a given binary outcome if it was recorded at one or more of the twelve index teeth. Probing depth was measured with a manual periodontal probe (approximately 0.25 N force) and rounded to the nearest millimeter; a probing depth $\geq$ 4mm is reported descriptively as “probing depth $\geq$ 4mm” and should not be read as a diagnosis of periodontitis, since clinical attachment loss, extent of bleeding, and radiographic bone loss were not assessed. Gingival color was recorded as altered (erythema or edema) versus unaltered by non-standardized visual inspection, a method vulnerable to measurement bias and reported here as a descriptive, exploratory parameter. Bleeding on probing was recorded as present/absent 30 seconds after probing. Dental mobility (absent; grade 1: <1mm horizontal; grade 2: $\geq$ 1mm horizontal; grade 3: vertical component) and dental sensitivity to thermal stimulus (present/absent) were recorded as descriptive dental parameters and are not equivalent to markers of gingival inflammation. Gingival recession was classified using Cairo criteria (absent; RT1: no interproximal attachment loss; RT2–RT3: with attachment loss); Resc_max (maximum Cairo category per subject) and Resc_any (presence/absence) were derived.

EXAMINER RELIABILITY

Intra-examiner reliability was estimated before data collection using a separate calibration sample of 10 patients not included in the study population. Because outcome variables differed in measurement scale, reliability was estimated separately by variable type: Cohen's kappa for dichotomous variables (bleeding on probing, $\kappa=0.82$; probing depth $\geq$ 4mm, $\kappa=0.85$; gingival color, $\kappa=0.75$; dental sensitivity, $\kappa=0.77$); weighted kappa for ordinal variables (dental mobility, $\kappa_w=0.79$; Cairo recession category, $\kappa_w=0.81$); and

the intraclass correlation coefficient for the phenotype classification (probe-transparency method), ICC=0.88. All estimates indicated substantial to almost-perfect agreement (19).

STATISTICAL ANALYSIS

Absolute and relative frequencies were calculated for categorical variables; mean $\pm$ SD or median and IQR for continuous variables (Shapiro-Wilk normality test). Between-group differences in change scores (Δ =T2-T1) were assessed using Mann-Whitney U tests for binary and ordinal outcomes and Kruskal-Wallis tests for predictors with more than two categories. These bivariate, non-parametric tests do not exploit the paired baseline-follow-up structure of the data, do not adjust for baseline outcome values, and do not account for correlation among the seven gingival outcomes measured in the same patients; they are reported as an exploratory, first-pass analysis, and repeated-measures methods (e.g., generalized estimating equations or mixed-effects models with baseline adjustment) are recommended for confirmatory analysis in future, larger studies (see Limitations).

Table 3 evaluates seven change-score outcomes against four candidate predictors (bracket type, sex, gingival phenotype, age category), yielding 28 individual statistical comparisons. Because these comparisons were not prespecified as a smaller, distinct hypothesis family, Bonferroni correction was applied across the full set of 28 tests (adjusted α =0.05/28 $\approx$ 0.0018) rather than separately within each predictor's seven outcomes. Under this correction, no comparison in Table 3 remains

statistically significant; the nominal associations for bleeding on probing and dental mobility with phenotype (p =0.004 and p =0.026, respectively) are reported as exploratory, hypothesis-generating observations, not as confirmed findings. Statistical analysis was performed by J.B.A.

RESULTS

BASELINE CHARACTERISTICS

Forty patients completed both evaluation points (T1 and T2) with no losses to follow-up (retention 100%). Mean age was 25.15 $\pm$ 8.10 years (median 25; range 16–40): <18 years n =9 (22.5%), 18–29 years n =20 (50.0%), $\geq$ 30 years n =11 (27.5%). Sex: 21 females (52.5%), 19 males (47.5%).

Baseline gingival phenotype was predominantly thin: 32 patients (80.0%) thin, 8 (20.0%) thick, equally distributed between groups (p =1.00). Baseline oral hygiene was predominantly poor: good 30.0%, fair 17.5%, poor 52.5% (p =0.42) (Table 1).

Although no baseline between-group comparison reached statistical significance (Table 1), non-significant p -values do not by themselves establish equivalence between groups. Some between-group differences of potential clinical relevance were present at baseline — most notably, altered gingival color was recorded in 65% of the conventional group versus 40% of the self-ligating group (p =0.20) — and these baseline imbalances were not adjusted for in the between-group change-score analyses reported below.

GINGIVAL CHANGES DURING TREATMENT (T2-T1)

No statistically significant differences in Δ scores were observed between conventional and self-ligating groups for any of the six gingival outcomes evaluated (all $p > 0.05$; Table 2). Effect sizes were small to negligible across all outcomes (Cohen's d 0.00–0.48), and confidence intervals were wide given the sample size; these estimates should be interpreted as imprecise rather than as evidence that the two systems produce equivalent periodontal outcomes (Figure 1).

ASSOCIATION BETWEEN INDIVIDUAL FACTORS AND GINGIVAL CHANGES

In bivariate analysis, baseline gingival phenotype was associated with bleeding on probing ($p = 0.004$) and dental mobility ($p = 0.026$) (Table 3). Thin phenotype patients showed a mean increase in bleeding ($+0.125 \pm 0.554$), while thick phenotype patients showed a mean reduction (-0.625 ± 0.744); for mobility, thin phenotype

showed no net change (0.000 ± 0.440) while thick phenotype improved (-0.375 ± 0.744).

Neither association remained significant after Bonferroni correction across the full set of 28 comparisons performed in Table 3 (adjusted $\alpha = 0.0018$); both are therefore reported as exploratory, hypothesis-generating observations rather than confirmed findings. These estimates are additionally unstable: only eight participants presented a thick phenotype, so the observed group difference may be highly sensitive to the response of one or two individuals, and should not be interpreted as evidence of an independent or causal predictor of periodontal response in the absence of multivariable adjustment (Table 3, Figure 2).

Categorized age showed a borderline trend with mobility ($p = 0.073$); the study lacked power for formal subgroup analysis. Sex showed no significant associations. Baseline oral hygiene distribution by bracket group is summarized in Table 1.

Table 1. Baseline characteristics of the study population.

Variable	Conventional (n=20)	Self-ligating (n=20)	p-value
Age (years) mean±SD	24.85±7.82	25.45±8.57	0.82
<18 years, n	4	5	
18–29 years, n	10	10	
≥30 years, n	6	5	
Sex			0.53
Female, n	9	12	
Male, n	11	8	
Gingival phenotype			1.00
Thin, n	16	16	
Thick, n	4	4	
Oral hygiene (Silness & Loe)			0.42
Good, n	6	6	
Fair, n	5	2	
Poor, n	9	12	
Probing depth ≥4mm present, n	8	7	1.00
Altered gingival color, n	13	8	0.20
Bleeding on probing present, n	6	6	0.92
Dental mobility present, n	4	5	0.54
Dental sensitivity present, n	8	7	1.00
Gingival recession present, n	11	13	0.75
Resc_max, median	1.0	1.0	0.71

SD=standard deviation. p-values from Mann-Whitney U or Fisher exact tests. Source: own elaboration.

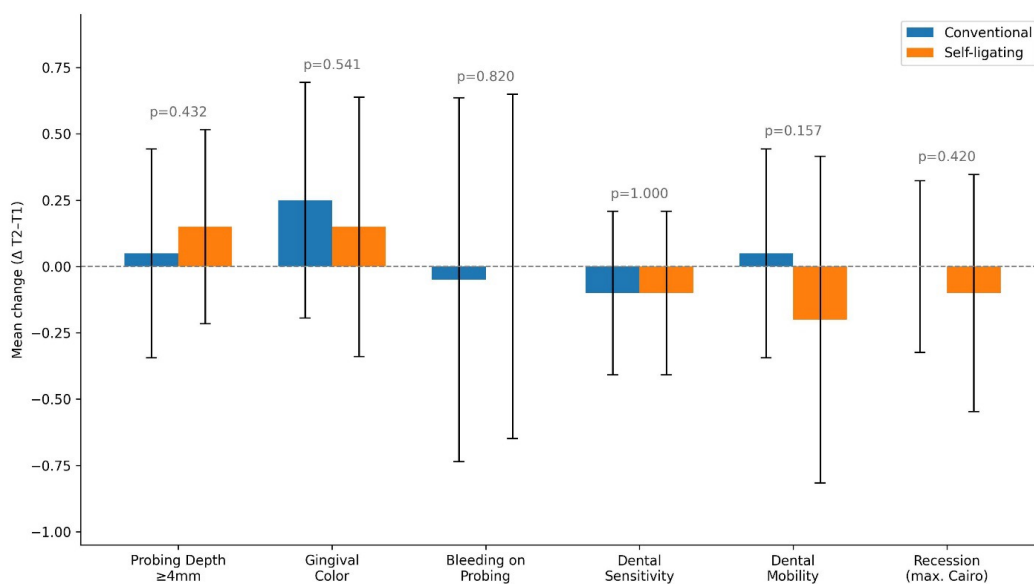


Figure 1. Mean gingival changes (±SD) by bracket type for six gingival outcomes. No significant between-group differences were observed (all $p > 0.05$); estimates are imprecise given the sample size. Negative values indicate improvement; positive values indicate worsening. Source: own elaboration.

Table 2. Gingival changes during treatment by orthodontic bracket group.

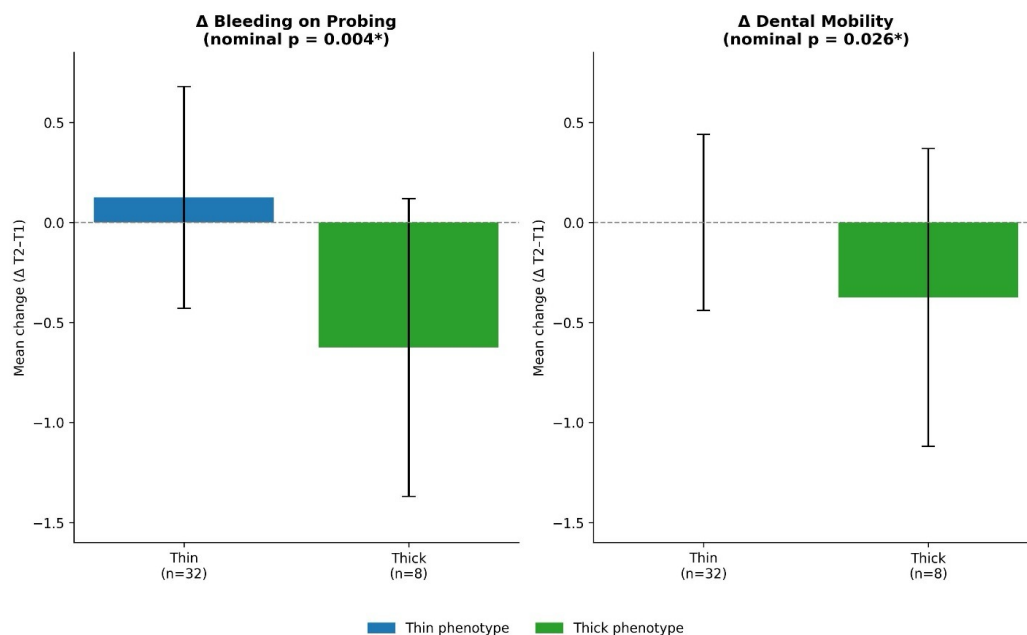
Change ($\Delta=T2-T1$)	Conventional (mean $\pm$ SD)	Self-ligating (mean $\pm$ SD)	p-value*
Δ Probing depth	0.050 $\pm$ 0.394	0.150 $\pm$ 0.366	0.432
Δ Gingival color	0.250 $\pm$ 0.444	0.150 $\pm$ 0.489	0.541
Δ Bleeding on probing	-0.050 $\pm$ 0.686	0.000 $\pm$ 0.649	0.820
Δ Dental sensitivity	-0.100 $\pm$ 0.308	-0.100 $\pm$ 0.308	1.000
Δ Dental mobility	0.050 $\pm$ 0.394	-0.200 $\pm$ 0.616	0.157
Δ Recession (max. Cairo)	0.000 $\pm$ 0.324	-0.100 $\pm$ 0.447	0.420

*Mann-Whitney U test. Negative values indicate improvement; positive values indicate worsening. All comparisons $p>0.05$. Source: own elaboration.

Table 3. Associations between individual factors and gingival changes (bivariate analysis, p-values).

Change ($\Delta=T2-T1$)	Bracket type	Sex	Phenotype T1	Age (cat.)
Δ Probing depth	0.432	0.983	0.461	0.138
Δ Gingival color	0.541	0.957	0.770	0.110
Δ Bleeding on probing	0.820	0.474	0.004†	0.124
Δ Dental mobility	0.157	0.151	0.026†	0.073
Δ Sensitivity	1.000	0.263	0.313	0.418
Δ Recession (max. Cairo)	0.420	0.471	0.567	0.810
Δ Recession (presence)	0.672	0.203	0.837	0.716

†Nominal $p<0.05$; does not survive Bonferroni correction across the full set of 28 comparisons performed (adjusted $\alpha=0.05/28\approx0.0018$) and is reported as exploratory only. Mann-Whitney U or Kruskal-Wallis tests. Source: own elaboration.



*Nominal p-value (bivariate analysis). Does NOT survive Bonferroni correction across the 28 comparisons performed in Table 3 (adjusted $\alpha = 0.05/28 \approx 0.0018$). Exploratory / hypothesis-generating only.

Figure 2. Gingival changes by baseline gingival phenotype (exploratory, bivariate analysis). Nominal associations for bleeding on probing ($p=0.004$) and mobility ($p=0.026$) did not survive correction for the 28 comparisons performed; the thick-phenotype subgroup was small ($n=8$). Source: own elaboration.

DISCUSSION

The principal finding of this study — the absence of statistically significant differences in gingival changes between conventional and self-ligating brackets across all evaluated outcomes — is consistent with the preponderance of current systematic evidence (7,8,9,10,11,12), which has generally failed to demonstrate consistent periodontal superiority of either system. However, because bracket allocation in this study was non-randomized and clinician-determined, confounding by indication cannot be excluded, and the imprecise effect estimates obtained here do not permit a conclusion of equivalence. The appropriate interpretation is that no statistically significant differences were detected during this six-month comparison, not that the two systems produce identical periodontal outcomes.

These findings are broadly consistent with a split-mouth trial by Cardoso *et al.* (20), a design that controls for patient-level confounders more effectively than parallel-group studies and likewise found no significant differences in plaque or gingival bleeding indices between systems, and with Folco *et al.* (21) and Scott *et al.* (13), both of which reported comparable gingival responses between bracket types. The systematic review by Coronel-Zubiate *et al.* (8), published in the Journal of Clinical and Experimental Dentistry, similarly concluded that reported plaque reductions with self-ligating brackets lack consistent clinical relevance.

In bivariate analysis, thin gingival phenotype was associated with increased bleeding on probing and less favorable mobility outcomes; however, as detailed in Results, neither association survived correction for multiple comparisons, and the thick-phenotype subgroup was small ($n=8$). These observations are therefore exploratory and should not be interpreted as evidence that phenotype is an independent determinant of periodontal response.

Gingival phenotype — understood here as marginal tissue thickness rather than keratinized tissue width (17) — has nonetheless been proposed elsewhere as a factor modulating tissue resilience to mechanical and inflammatory stimuli (14,15), with thin phenotype associated with heightened recession risk when tooth movement approaches alveolar bone limits (14).

This study has several important limitations. First, bracket allocation was determined by the treating clinician rather than randomized, introducing a risk of confounding by indication that cannot be resolved with the available data. Second, the sample-size calculation was based on comparison of two independent proportions and does not correspond to the paired, repeated-measures change-score analysis ultimately performed; the study should be considered underpowered, and effect estimates imprecise. Third, only bivariate non-parametric tests were used; these do not adjust for baseline outcome values and do not account for correlation among the seven outcomes measured in the same patients — repeated-measures methods (e.g., generalized estimating equations or mixed-effects models) are recommended for future confirmatory analyses. Fourth, several plausible confounders were not measured or controlled, including plaque index at T2, smoking or vaping status, glycaemic control, prior periodontal treatment, socioeconomic and educational factors, severity of orthodontic crowding, and treatment operator. Fifth, the examiner was not blinded to bracket type, and gingival color was assessed with a non-standardized visual method, both of which are vulnerable to measurement bias. Sixth, follow-up was limited to 6 months, insufficient to capture late-developing recession. Finally, gingival phenotype was assessed using the probe-transparency method, a categorical, non-cross-validated technique, and the thick-phenotype subgroup was small ($n=8$), limiting the stability and generalizability of phenotype-related findings.

Within these limitations, this study does not provide evidence to support bracket system selection as a periodontal risk-mitigation strategy, nor does it establish gingival phenotype as an independent predictor of periodontal response. The exploratory association between phenotype and periodontal change observed here is best regarded as hypothesis-generating, supporting further investigation — ideally with randomized allocation, quantitative phenotype measurement, multivariable adjustment, and extended follow-up — before phenotype-based risk stratification protocols can be recommended for routine pre-orthodontic practice.

CONCLUSIONS

Within the limitations of this prospective, non-randomized study, no statistically significant differences were detected between conventional and self-ligating brackets in any of six evaluated gingival outcomes during a six-month follow-up; however, estimates were imprecise, and residual confounding by indication cannot be excluded given the observational design.

In bivariate analysis, baseline gingival phenotype showed a preliminary association with

bleeding on probing and, exploratorily, with dental mobility; neither association survived correction for the 28 comparisons performed, and the thick-phenotype subgroup was small (n=8). These findings are hypothesis-generating and should not be interpreted as establishing phenotype as an independent predictor of periodontal response.

Larger, ideally randomized studies with multivariable adjustment, quantitative phenotype measurement, repeated-measures statistical methods, and extended follow-up are needed before these observations can inform clinical practice or pre-orthodontic protocols.

PROPOSED FRAMEWORK FOR FUTURE VALIDATION

The exploratory, non-significant-after-correction association between gingival phenotype and periodontal change observed in this study does not, on its own, justify changes to clinical practice. Table 4 presents a tentative, hypothesis-generating framework for phenotype-informed periodontal monitoring, offered strictly as a starting point for future prospective, randomized or adequately powered, multivariable validation studies — not as a validated clinical protocol.

Table 4. Tentative, hypothesis-generating framework for future phenotype-informed periodontal monitoring research.

Tentative Risk Level	Patient Profile	Possible Future Validation Action
Higher	Thin phenotype + pre-existing recession + poor oral hygiene	Candidate for pre-orthodontic periodontal evaluation and closer monitoring in future controlled studies
Intermediate	Thin phenotype + adequate hygiene OR thick phenotype + poor hygiene	Candidate for baseline periodontal charting and standard monitoring
Lower	Thick phenotype + good oral hygiene + no baseline recession	Candidate for routine periodontal monitoring

Proposed framework based on the exploratory findings of this study (n=40, non-randomized, single center) and prior literature (14,15,22); it has not itself been validated and should not be implemented clinically without confirmatory research. Source: own elaboration.

DECLARATIONS

AUTHOR CONTRIBUTION STATEMENT: Conceptualization and Design, Y.R.J. and A.D.C.; Literature Review, Y.R.J.; Methodology and Validation, J.B.A.; Formal Analysis, J.B.A.; Investigation and Data Collection, Y.R.J. and D.L.J.; Resources, A.D.C.; Data Analysis and Interpretation, Y.R.J. and J.B.A.; Writing – Original Draft Preparation, Y.R.J. and D.L.J.; Writing – Review & Editing, J.P.R. and A.D.C.; Supervision, A.D.C.; Project Administration, A.D.C.; Funding Acquisition, not applicable (no external funding).

CONFLICT OF INTEREST: The authors declare no conflicts of interest related to the present work.

ETHICS: Evaluated and approved by the Institutional Ethics Committee of the Universidad de Cartagena, Colombia (original protocol approval, Acta No. UDC-2023114, 14 December 2023, prior to patient enrollment; amendment approving the final statistical analysis plan and extended reporting period, Acta No. UDC-20251126, 26 November 2025), in accordance with the Declaration of Helsinki and Colombian Resolution 8430 of 1993 (minimal-risk classification). Written informed consent from all participants; parental consent for minors. Data anonymized for analysis.

SOURCE OF FUNDING: No external funding. Conducted as part of the Orthodontic Postgraduate Residency Program, Faculty of Dentistry, Universidad de Cartagena, Colombia.

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