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# Tip and Torque Accuracy According to the ISO 27020:2019 Norm in Currently Available Pre-Adjusted Orthodontic Brackets

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**Featured Application: Manufacturing accuracy is paramount in an orthodontic straight wire system. A correctly dimensioned bracket, bearing precise information, ensures full contact at the archwire-slot interface, allowing the required force system to be delivered and the goals established by the treatment plan to be achieved. Appraisals of bracket accuracy help the clinician choose the correct appliance and increase their awareness of the risks of manufacturing inaccuracy.**



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**Abstract:** Background: The precision of bracket manufacturing is fundamental to ensure the correct expression of the inbuilt information. The objective of this study was to determine the actual tip and torque values of a pool of stainless steel brackets, pre-adjusted according to the MBT prescription values, and to compare these actual values with those stated by the manufacturers in order to test their compliance with the tolerance limits reported in the ISO 27020:2019. Methods: A sample of 360 stainless steel brackets, from 12 different providers, were evaluated. All brackets had a nominal slot size of 0.022 in., belonged to the upper right central incisor, and were manufactured with the metal injection molding technique (MIM). For each provider, three different batches of the same bracket series were tested. A single-blind design was used for bracket coding. Results: Only five systems displayed torque mean values that matched the declared values ($p > 0.05$). Only one system did not respect the tolerance limits established in the ISO 27020:2019 norm. The tip values were different from those declared in seven of the assessed systems; however, none exceeded the tolerance limits. The inter-batch variability in most cases was not statistically significant. Conclusions: In most of the assessed systems, there can be a difference between the actual and the declared torque values, while tip information is usually accurately incorporated into the bracket slot. Lack of precision in the manufacturing process can reduce the efficacy of the appliance and force the clinician to compensate for dimensional inaccuracy through wire bending.

**Keywords:** orthodontic brackets; torque values; tip values; angulation values; ISO standard; manufacturing accuracy

## 1. Introduction

The ideal objectives of orthodontic treatment are to achieve good functional occlusion, proper aesthetic, and finally to ensure the stability of the result. Correct axial inclination and angulation of the dentition are essential to achieve these treatment goals [1–3].

Until the introduction of the first straight wire bracket system by Andrews in the 1970s, orthodontic brackets had no information built into the slot or at the base. Orthodontists would therefore add the required force system by forming bends in the archwire [1,4].

Today, the vast majority of brackets on the market are pre-adjusted, with torque and angulation built into the bracket slot or base [1,3,4].

The full expression of the information is achieved by inserting an archwire with a cross-sectional size that fully engages the bracket slot. From a theoretical point of view, in a pre-adjusted system, the teeth should be guided to their ideal position without the need for additional wire bending due to the information incorporated in the bracket slot [5,6]. Despite the information incorporated in the bracket slot, in a clinical setting, it is still necessary to bend the archwires to achieve correct alignment and intercuspation at the end of treatment. Third order (torque) compensation on working or finishing wires is needed in most cases, resting efficiency and simplicity to the straight wire appliance protocol [6,7]. The lower performance in the full expression of the inbuilt information can be due to a variation in tooth morphology, errors in bracket placement, or the inaccuracy of the bracket manufacturing process. The precision of the manufacturing process is a grounding assumption of the straight wire technique, as a variation of the inbuilt information from that declared will obviously imply lower appliance performance [7,8].

Thanks to Andrews' work, we know how the correct expression of the bracket mesio-distal inclination (tip) is needed to express the desired tooth/root angulation in the bucco-palatal direction (torque) incorporated into the bracket slot [9]. Tip and torque information are therefore closely related and mutually dependent regarding their correct clinical expression. Establishing the correct torque in the anterior segment of the dentition is a key factor in obtaining proper intercuspation in the posterior segments and achieving a class I molar relation [7,8].

Due to the importance of bracket accuracy, quality standards have been established. The European Committee for Normalization released the ISO 27020:2019 as a reference norm in the European Union for orthodontic brackets and tubes. The norm specifies the standardized protocol to test the dimensional accuracy and reports the tolerance limits between those declared by the manufacturers and the real limits [10]. The objective of our study was to evaluate the inclination (tip) and angulation (torque) values of a pool of McLaughlin, Bennett and Trevisi (MBT) prescription stainless steel brackets from different providers and to compare the actual values with the nominal values. In addition, the compliance with the tolerance limits established by the ISO 27020:2019 norm was assessed in the different batches from the same provider.

## 2. Materials and Methods

### *2.1. Study Sample*

A sample of 360 stainless steel pre-adjusted orthodontic brackets from 12 different providers was evaluated. All brackets had a declared slot size of 0.022 by 0.028 in., belonged to the right upper central incisor, and were pre-adjusted according to the MBT prescription values. All bracket bodies were produced by metal injection molding (MIM) and bear torque information in the base. The sample belonged to the following bracket systems: Synthesis® (Ormco, Orange, CA, USA); Nu-Edge® (TP Orthodontics, La Porte, IN, USA); Mini Twin® (Lancer Orthodontics, Carlsbad, CA, USA); Fli Twin® (RMO, Denver, CO, USA); Mini Prevail® (G&H Orthodontics, Franklin, IN, USA); Omniarch+® (Dentsply GAC, Bohemia, NY, USA); Jazz® (Modern Orthodontics, Ludhiana, India); Scape® (Ah Kim Pech Corporation, Ciudad de Mexico, Mexico); Mini Master® (American Orthodontics, Sheboygan, WI, USA); Mini Sprint® (Forestadent, Phorzheim, Germany); Discovery Smart® (Dentaurum, Ispringen, Germany); and Victory® (3M, Monrovia, CA, USA). For each manufacturer, 30 brackets belonging to three different batches were evaluated, with 10 brackets per batch. Before the study, the required sample size was estimated using Raosoft® Version 5.0 software (Raosoft, Inc., Seattle, WA, USA). A sample size of 9 was considered enough to detect a difference of 0.03 degrees, assuming a standard deviation of 0.02 degrees with a power of 90% and a significance level of $p < 0.05$. The testing protocol reported in the ISO 27020:2019 norm suggests including six brackets for every batch in the procedure. Upon reception of the brackets, a member of the research group (MA) randomly coded each bracket using a single-blind design. The brackets were arranged in such a way that the team members, who performed the dimensional tests (LB and DG), were not aware of which system or batch number they were assessing.

### 2.2. Measurement Protocol

The test protocol reported by the ISO 27020:2019 norm was followed to assess the torque and tip values pre-adjusted in each bracket.

The brackets' torque and tip values were assessed on bracket images captured by a digital stereo microscope LEICA® DMS 1000 (Leica Microsystems gmbh, Wetzlar, Germany) and processed using LAS V4.5® CORE software, as shown in Figure 1.

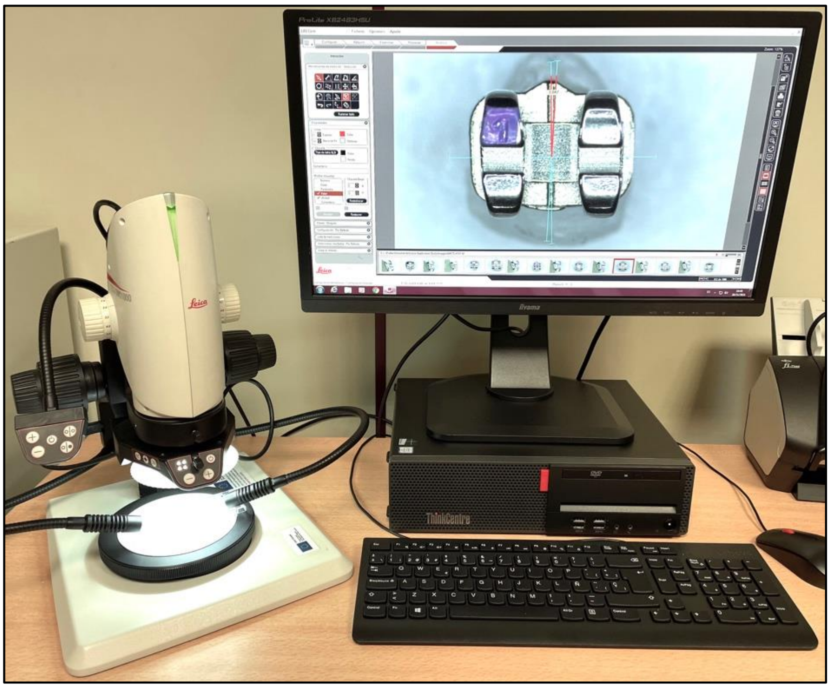


**Figure 1.** Overview of the research hardware: the properly oriented and focused bracket slot is displayed on the computer screen as captured by the digital stereo microscope.

For torque assessment, the brackets were fixed on the microscope tray using a piece of HYGENIC wax stick (Coltene Whaledent, Altstätten, Switzerland) with the slots oriented vertically and with the distal side up, so that the line of view on the microscope was parallel to the main axis of the slot. For tip assessment, the brackets were positioned with their bases secured on the microscope tray using wax, and with the frontal side (vestibular side) up, so that the line of view on the microscope was parallel to the slot mesio-distal main axis. Light was adjusted until a sharp, well-focused image was obtained on the screen and digitally captured.

The ISO 27020:2019 defines the torque value as the angle ($\theta$) formed by the line bisecting the slot in the occluso-gingival dimension and the orthogonal plane to the bracket base. If the angle is oriented gingivally to the bisecting slot line, it is regarded as positive, otherwise as negative. The measurement protocol is summarized in Figure 2.

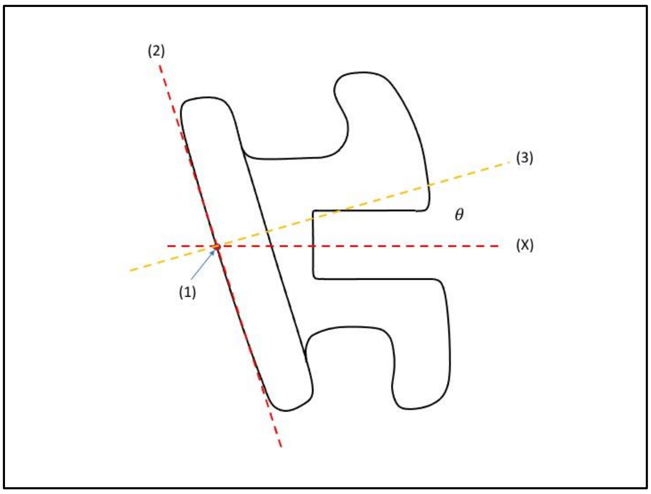


**Figure 2.** Determination of torque in base according to ISO 27020:2019 protocol. (X): bisecting line of the slot in the gingival occlusal direction; (1): point of intersection of line (X) with the surface of the bracket base on the tooth side; (2): tangent line to the surface of the bracket base on the tooth side; (3): orthogonal plane to line (2) through point (1). Torque angle is the angle between line (X) and (3).

The norm defines tip as the angle ($\alpha$) formed occlusally by the line perpendicular to the slot mesio-distal main axis and the line passing along the occluso-gingival main axis. If the angle is oriented distally to the main occluso-gingival axis, it is considered as positive, otherwise as negative. The measurement protocol is summarized in Figure 3.

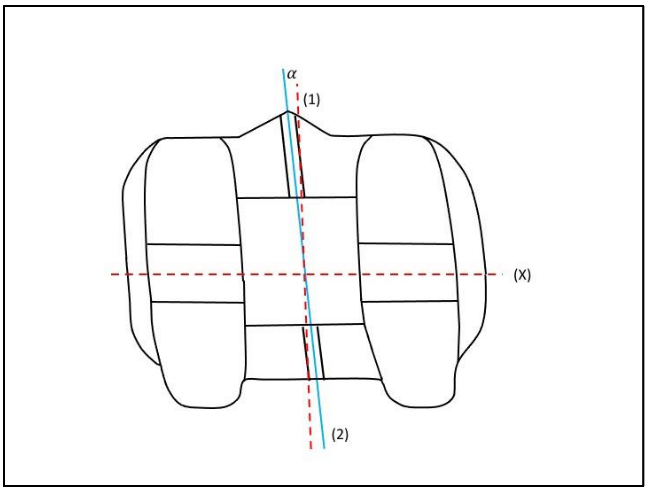


**Figure 3.** Assessment of the mesio-distal angulation (tip) according to ISO 27020:2019 protocol. (X): slot mesio-distal main axis; (1): line perpendicular to (X) axis; (2): slot occluso-gingival main axis. Bracket slot angulation (tip) is the angle between lines (1) and (2).

The intra-operator reliability was calculated by measuring twice, at a two-week interval, the same set of 15 randomly selected brackets belonging to the study group. The inter-operator reliability was calculated by measuring the same set of brackets with a second operator.

### 2.3. Statistical Analysis

Torque and tip values were recorded on an Excel data sheet (Microsoft Office for Mac 2011 package). Statistical analyses were performed using SPSS software (version 25.0; IBM Corp., Armonk, NY, USA). The method error, and the intra- and inter-operator reliability were appraised through the Dalberg formula and the Intraclass Correlation Coefficient

(ICC). A 95% confidence interval (CI 95%) was chosen. The data distribution was assessed using a Kolmogorov–Smirnov test, and a non-parametric Wilcoxon test was employed to compare the actual with the declared values.

A multivariate ANOVA test was used to compare the mean torque and tip values of the different batches from the same provider in the case of a normal data distribution. A Kruskal–Wallis test was used in the cases when the data distribution was not normal.

## 3. Results

### *3.1. Intra- and Inter-Operator Reliability*

Regarding torque assessment, the Dahlberg formula for repeated measurements was 0.15° for intra-operator reliability and 0.28° for inter-operator reliability. Regarding tip assessment, it was 0.11° for the intra-operator reliability and 0.25 for inter-operator reliability. In both cases, the ICC displayed values higher than 0. These results suggest a low method error and a high repeatability of the measurements.

### *3.2. Torque Assessment*

All brackets had torque information in the base. The torque value declared by the manufacturer for the upper central incisor was 17°. The ISO 27020:2019 admits a tolerance of ±1° in relation to the declared value, the acceptable range being between 16° and 18°. The descriptive statistics for the torque values along the different systems are reported in Table 1.

**Table 1.** Torque in base in the analyzed systems. In boldface, the systems with a mean torque out of ISO 27020:2019 tolerance limit.

| Bracket System | N | Mean (±SD) | Min | Max | MD | $Z_W$ | *p* |
|---|---|---|---|---|---|---|---|
| SYNTHESIS | 30 | 17.14 (±0.418) | 16.25 | 18.38 | 0.145 | −1.903 | 0.057 |
| NU-EDGE | 30 | 16.36 (±0.959) | 13.15 | 17.55 | −0.640 | −3.723 | <0.001 *** |
| DISCOVERY | 30 | 17.20 (±0.331) | 16.35 | 18.18 | 0.197 | −2.993 | 0.003 ** |
| FLI TWIN | 30 | 17.15 (±0.695) | 15.32 | 18.78 | 0.154 | −1.286 | 0.199 |
| MINI SPRINT | 30 | 17.06 (±0.344) | 16.06 | 17.72 | 0.057 | −1.255 | 0.210 |
| OMNIARCH+ | 30 | 17.18 (±0.318) | 16.53 | 17.73 | 0.180 | −2.581 | 0.010 ** |
| **SCAPE** | **30** | **18.07 (±0.802)** | **15.37** | **19.52** | **1.070** | **−4.268** | **<0.001 *****|
| MINI-TWIN | 30 | 17.17 (±0.414) | 16.53 | 18.16 | 0.166 | −1.923 | 0.054 |
| JAZZ | 30 | 17.33 (±0.937) | 15.11 | 19.32 | 0.329 | −2.026 | 0.043 * |
| MINI MASTER | 30 | 17.81 (±0.579) | 16.98 | 19.17 | 0.812 | −4.741 | <0.001 *** |
| MINIPREVAIL | 30 | 17.21 (±0.390) | 16.36 | 18.20 | 0.213 | −2.777 | 0.005 ** |
| VICTORY | 30 | 17.05 (±0.275) | 16.35 | 17.60 | 0.051 | −0.309 | 0.758 |

SD: Standard deviation; Min: Minimum torque value; Max: Maximum torque value; MD: Mean difference between nominal and actual values; $Z_W$: Wilcoxon standardized rank; Wilcoxon test * $p \leq 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Only five systems, SYNTHESIS®, FLI TWIN®, MINI SPRINT®, MINI-TWIN®, and VICTORY®, presented a mean torque value not statistically different ($p > 0.05$). From the one declared by the manufacturer. In only one case (SCAPE®), the mean value was outside the tolerance limit reported in the ISO 27020:2019 norm. In only one system, NU-EDGE®, the mean torque value was lower than the declared value, whereas in the others it was higher (Table 1 and Figure 4). The minimum and maximum torque values of the sample were 13.15° (NU-EDGE) and 19.52° (SCAPE®), than the declared value.

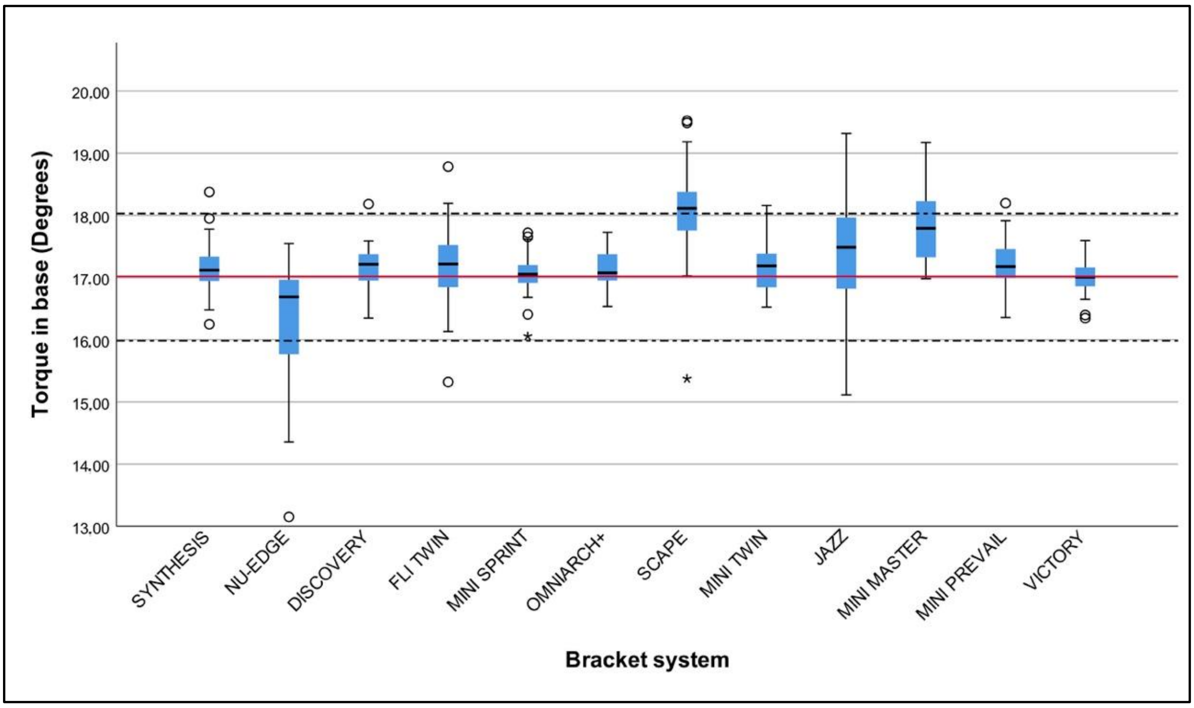


**Figure 4.** Boxplot showing the median and interquartile ranges for torque. Outliers (O) and extremes (*) are reported. The solid red line represents the declared torque value. Dashed lines mark the upper and lower tolerance limits of the ISO 27020:2019 norm.

The distribution of torque values in all systems is shown in Figure. The boxplot shows the median and interquartile ranges for the torque values. The systems displaying a higher dispersion were NU-EDGE®, with torque values mainly lower than the declared values, and JAZZ® with torque values higher than the nominal values. VICTORY®, SYNTHESIS®, and MINI SPRINT® were the systems that showed a lower dispersion. MINI SPRINT®, OMNIARCH+®, and VICTORY® were the systems in which all torque values respected tolerance limits. In contrast, SCAPE® presented most of the torque values above the tolerance limit reported by the ISO 27020:2019 norm.

### 3.3. Tip Assessment

The tip value declared by the manufacturer for the upper central incisor was 4° for all systems, except SYNTHESIS® and NU-EDGE® with a declared value of 5°. The ISO 27020:2019 admits a tolerance of ±1° in relation to the declared value. The descriptive statistics for the bracket tip values are shown in Table 2.

Seven out of the twelve systems presented a statistically significant difference ($p < 0.05$) between the actual mean tip value and that declared by the manufacturer. In eight systems, the mean tip value was higher than the declared value, while it was lower in the rest of the systems. All mean tip values were within the tolerance limits reported by the ISO 27020:2019 norm. SYNTHESIS®, DISCOVERY®, and OMNIARCH+® were the systems whose mean tip values were closer to those declared. The minimum and maximum tip values of the sample were 2.81° (FLI TWIN®) and 5.50° (JAZZ®), these values being 1.19° (−29.75%) lower and 1.50° (+37.5%) higher, respectively, than the declared value.

The distribution of tip values in each system is shown in Figure 5. The boxplot shows the median and interquartile ranges for the tip value. NU-EDGE® and JAZZ® were the systems that displayed a larger data dispersion, while SYNTHESIS® presented the smallest, with all actual values closer to those declared.

**Table 2.** Slot angulation (tip) in the analyzed systems.

| Bracket System | N | Mean (±SD) | Min | Max | MD | $Z_W$ | *p* |
|---|---|---|---|---|---|---|---|
| SYNTHESIS | 30 | 5.03 (±0.095) | 4.85 | 5.28 | 0.029 | −1.611 | 0.107 |
| NU-EDGE | 30 | 4.64 (±0.272) | 4.11 | 5.00 | −0.363 | −4.782 | <0.001 *** |
| DISCOVERY | 30 | 4.04 (±0.118) | 3.83 | 4.43 | 0.036 | −1.525 | 0.127 |
| FLI TWIN | 30 | 3.92 (±0.378) | 2.81 | 4.59 | −0.078 | −0.422 | 0.673 |
| MINI SPRINT | 30 | 4.30 (±0.205) | 3.91 | 4.82 | 0.301 | −4.680 | <0.001 *** |
| OMNIARCH + | 30 | 3.97 (±0.139) | 3.56 | 4.19 | −0.029 | −0.782 | 0.434 |
| SCAPE | 30 | 3.94 (±0.204) | 3.18 | 4.29 | −0.060 | −1.718 | 0.086 |
| MINI-TWIN | 30 | 4.08 (±0.136) | 3.82 | 4.43 | 0.077 | −2.478 | 0.013 * |
| JAZZ | 30 | 4.71 (±0.343) | 3.99 | 5.50 | 0.712 | −4.762 | <0.001 *** |
| MINI MASTER | 30 | 4.16 (±0.172) | 3.92 | 4.76 | 0.162 | −4.247 | <0.001 *** |
| MINIPREVAIL | 30 | 4.09 (±0.186) | 3.88 | 4.85 | 0.093 | −2.509 | 0.012 * |
| VICTORY | 30 | 4.11 (±0.180) | 3.90 | 4.60 | 0.110 | −2.887 | 0.004 ** |

SD: Standard deviation; Min: Minimum angulation value; Max: Maximum angulation value; MD: Mean difference between nominal and actual values; $Z_W$: Wilcoxon standardized rank; Wilcoxon test * $p \leq 0.05$; ** $p < 0.01$; *** $p < 0.001$.

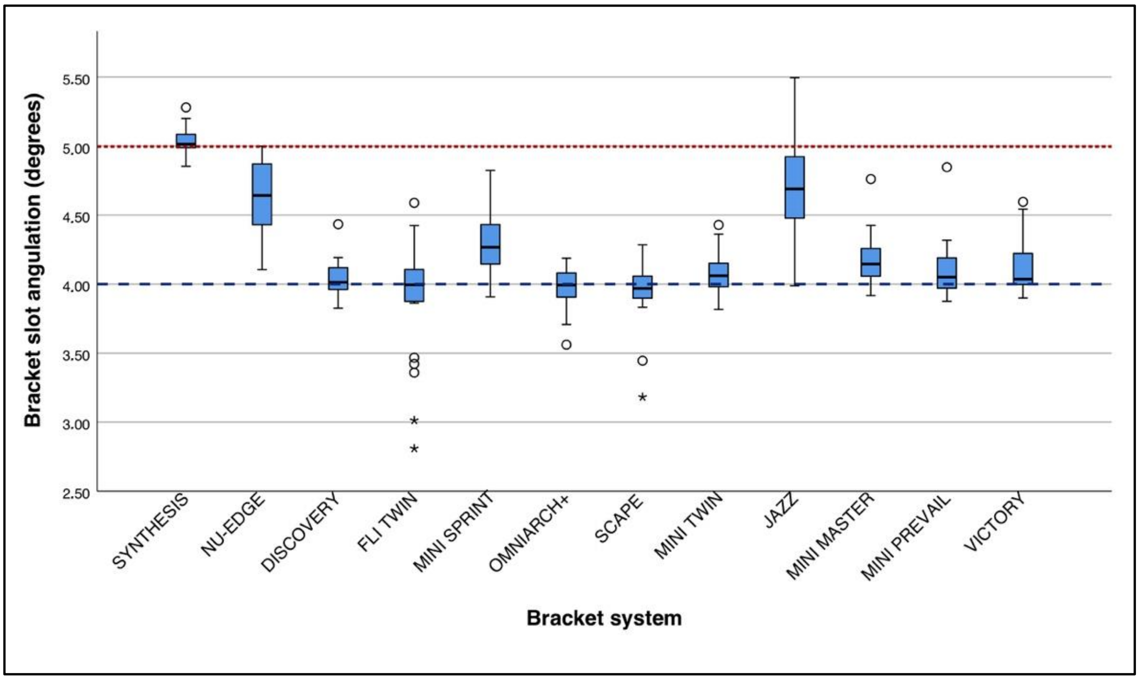


**Figure 5.** Boxplot reporting the median and interquartile ranges for bracket angulation. Outliers (O) and extremes (*) are reported. The dotted red line shows the declared values of slot angulation for NU-EDGE® and SYNTHESIS® (5°), and the dashed blue line shows the 4° of tip declared by the rest of the systems.

### *3.4. Inter-Batch Variability*

As highlighted in Table 3, the differences in torque values were statistically different among the three batches in four of the twelve systems: SYNTHESIS®, NU-EDGE®, FLI TWIN®, and SCAPE®.

**Table 3.** Actual torque values in different batches for each system (inter-batch variability).

| Bracket System | Batch 1 | | Batch 2 | | Batch 3 | | |
|---|---|---|---|---|---|---|---|
| | N | Mean (±SD) | N | Mean (± SD) | N | Mean (±SD) | *p* |
| SYNTHESIS | 10 | 17.07 (±0.45) | 10 | 17.42 (±0.44) | 10 | 16.94 (±0.19) | 0.026 * |
| NU-EDGE | 10 | 15.64 (±1.24) | 10 | 16.73 (±0.44) | 10 | 16.71 (±0.61) | 0.019 * |
| DISCOVERY | 10 | 17.00 (±0.28) | 10 | 17.36 (±0.36) | 10 | 17.24 (±0.26) | 0.051 |
| FLI TWIN | 10 | 16.69 (±0.60) | 10 | 17.02 (±0.50) | 10 | 17.75 (±0.55) | 0.001 ** |
| MINI SPRINT | 10 | 17.09 (±0.28) | 10 | 17.01 (±0.48) | 10 | 17.06 (±0.25) | 0.870 |
| OMNIARCH+ | 10 | 17.24 (±0.35) | 10 | 17.02 (±0.14) | 10 | 17.29 (±0.38) | 0.140 |
| SCAPE | 10 | 17.93 (±0.56) | 10 | 17.66 (±0.89) | 10 | 18.63 (±0.64) | 0.014 * |
| MINI-TWIN | 10 | 16.92 (±0.36) | 10 | 17.33 (±0.44) | 10 | 17.24 (±0.35) | 0.062 |
| JAZZ | 10 | 17.24 (±0.87) | 10 | 17.53 (±0.84) | 10 | 17.22 (±1.14) | 0.719 |
| MINI MASTER | 10 | 17.78 (±0.62) | 10 | 17.71 (±0.49) | 10 | 17.95 (±0.64) | 0.632 |
| MINIPREVAIL | 10 | 17.37 (±0.43) | 10 | 17.10 (±0.37) | 10 | 17.16 (±0.35) | 0.271 |
| VICTORY | 10 | 17.05 (±0.22) | 10 | 16.99 (±0.32) | 10 | 16.96 (±0.29) | 0.758 |

SD: Standard deviation. A multivariate ANOVA was performed for all systems except NU-EDGE® and DISCOVERY® where a Kruskal–Wallis test was performed. * $p \leq 0.05$; ** $p < 0.01$.

In seven systems, all the batches presented torque values that did not outreach the tolerance limits reported by the norm. NU-EDGE®, FLI TWIN®, and SCAPE® were the systems with a higher inter-batch variability, with SCAPE® presenting a batch with all torque values out of the tolerance limits. MINI SPRINT® and VICTORY® presented the lowest variability between batches (Figure 6).

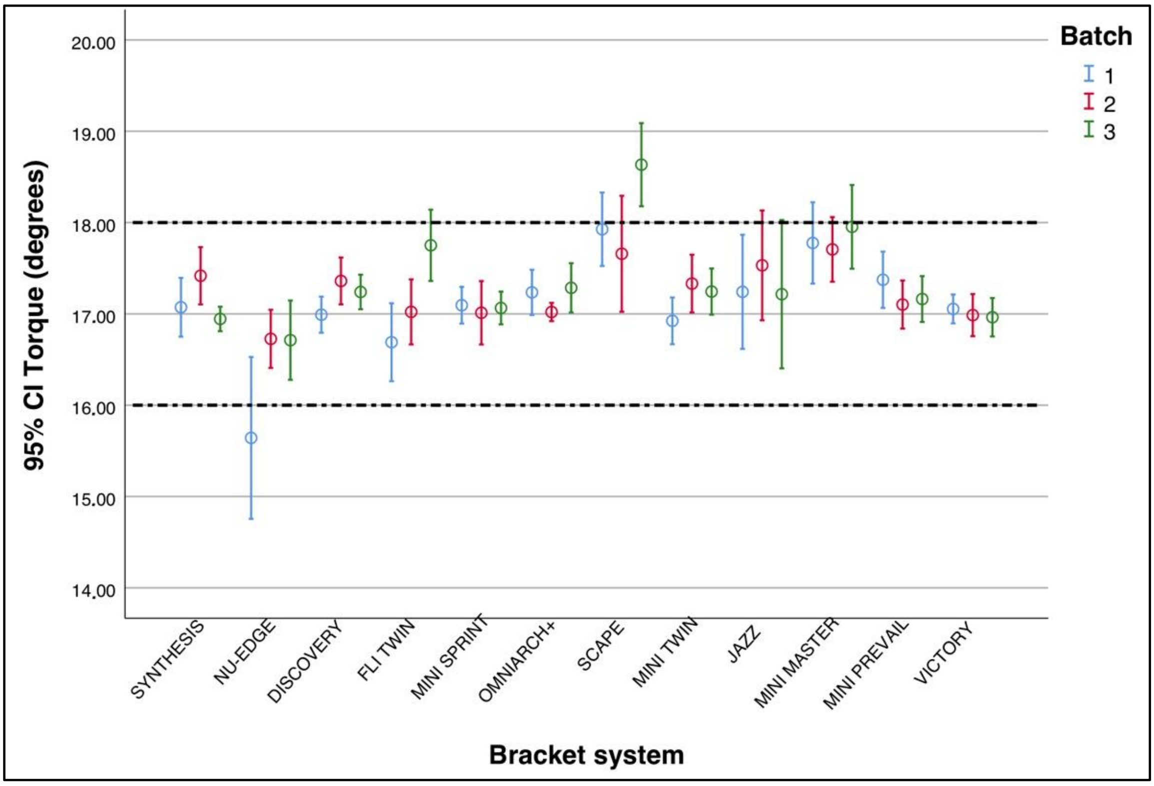


**Figure 6.** Torque values of the different batches (inter-batch variability), displayed as the confidence interval (CI) in degrees. The dashed lines represent the upper and lower tolerance limits of the ISO 27020:2019 norm.

Regarding tip values, only three of the twelve systems, FLI TWIN®, MINI SPRINT®, and JAZZ®, presented a statistically significant difference between the three batches (Table 4). The same systems displayed a larger value dispersion. JAZZ® was the only system in which one batch had tip values outside the tolerance limits (Figure 7). SYNTHESIS®, DISCOVERY®, and MINI-TWIN® had low inter-batch variability and lower value dispersion.

**Table 4.** Actual slot angulation in the different batches for each system (inter-batch variability of slot angulation). The declared tip values were 5° for NU-EDGE® and SYNTHESIS® and 4° for the rest of the systems.

| Bracket System | Batch 1 | | Batch 2 | | Batch 3 | | |
|---|---|---|---|---|---|---|---|
| | N | Mean (±SD) | N | Mean (±SD) | N | Mean (±SD) | *p* |
| SYNTHESIS | 10 | 5.00 (±0.08) | 10 | 5.04 (±0.08) | 10 | 5.05 (±0.12) | 0.492 |
| NU-EDGE | 10 | 4.69 (±0.27) | 10 | 4.65 (±0.30) | 10 | 4.57 (±0.25) | 0.584 |
| DISCOVERY | 10 | 4.06 (±0.15) | 10 | 4.06 (±0.09) | 10 | 3.98 (±0.10) | 0.224 |
| FLI TWIN | 10 | 3.74 (±0.40) | 10 | 3.85 (±0.37) | 10 | 4.18 (±0.22) | 0.006 ** |
| MINI SPRINT | 10 | 4.45 (±0.20) | 10 | 4.28 (±0.16) | 10 | 4.17 (±0.16) | 0.005 ** |
| OMNIARCH+ | 10 | 4.00 (±0.08) | 10 | 3.91 (±0.20) | 10 | 4.01 (±0.11) | 0.266 |
| SCAPE | 10 | 3.90 (±0.27) | 10 | 3.90 (±0.18) | 10 | 4.01 (±0.14) | 0.596 |
| MINI-TWIN | 10 | 4.09 (±0.13) | 10 | 4.11 (±0.18) | 10 | 4.04 (±0.08) | 0.484 |
| JAZZ | 10 | 5.04 (±0.28) | 10 | 4.48 (±0.25) | 10 | 4.62 (±0.21) | <0.001 *** |
| MINI MASTER | 10 | 4.23 (±0.23) | 10 | 4.06 (±0.08) | 10 | 4.19 (±0.14) | 0.067 |
| MINIPREVAIL | 10 | 4.19 (±0.26) | 10 | 4.10 (±0.14) | 10 | 4.00 (±0.06) | 0.064 |
| VICTORY | 10 | 4.11 (±0.12) | 10 | 4.18 (±0.26) | 10 | 4.05 (±0.12) | 0.290 |

SD: Standard deviation. Kruskal–Wallis test was performed for SYNTHESIS®, DISCOVERY®, FLI TWIN®, and SCAPE®. A multivariate ANOVA was performed for the other systems. ** $p < 0.01$; *** $p < 0.001$.

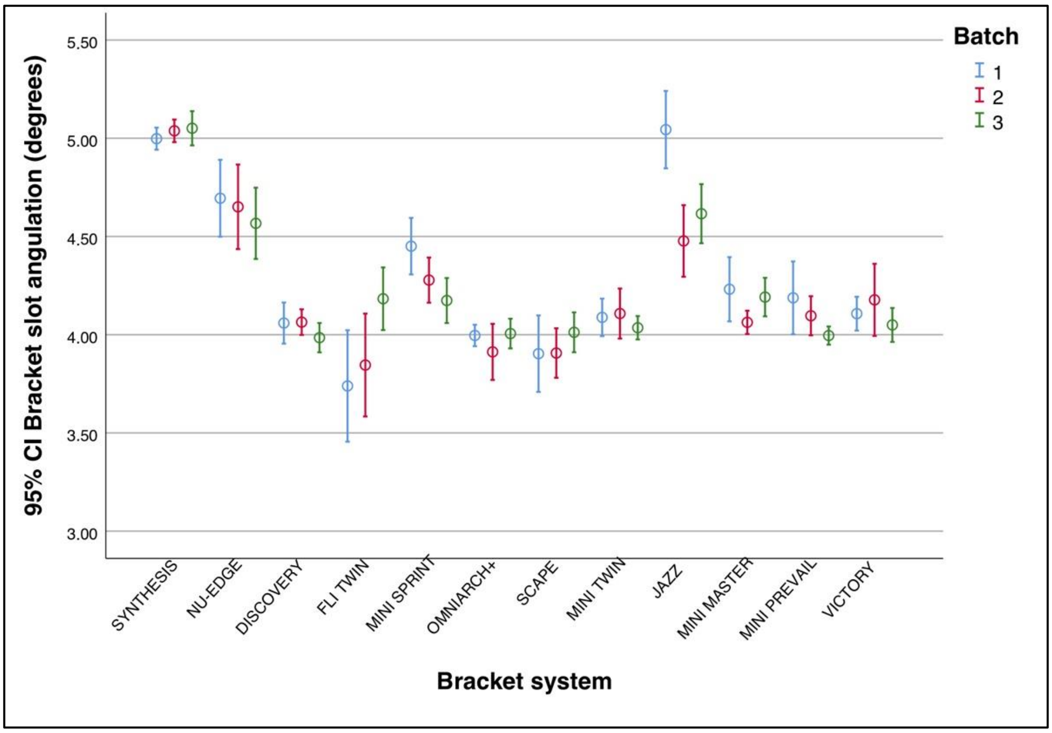


**Figure 7.** Bracket slot angulation in the different batches (inter-batch variability), displayed as the Confidence interval (CI) in degrees. Declared values were 5° for NU-EDGE® and SYNTHESIS® and 4° for the rest of the systems.

## 4. Discussion

Incisor torque values are regarded as crucial to achieve treatment goals and, depending on treatment philosophies, a different torque range has been proposed ranging from the 7° of the original straight wire appliance to the 22° of the Bioprogressive prescription [11].

The full expression of the information integrated in the bracket slot depends on the cohesive contact of a full-size wire with the slot walls. The efficiency of torque expression is reduced if play exists between the wire and the bracket slot [12]. The errors introduced during the fabrication process, in terms of slot height and depth, can increase play and reduce the ability of the appliance to effectively express the inbuilt torque information [5,8,11,13]. It is therefore of paramount importance to assess if the brackets available in the market are respecting the nominal declared values. In addition, aspects related to orthodontic materials have always been of special interest for both researchers and orthodontic clinicians [14,15].

All analyzed systems had bodies manufactured by a metal injection molding (MIM) process. MINI TWIN® and MINI MASTER® were the only systems that combined MIM technology with bracket body fabrication and slot milling. MIM is at present the most popular and cost-effective technology in the bracket industry [14]; it relies on oversized molds to compensate for the contraction that occurs after sintering. Dimensional contraction can change due to different factors (alloy, powder type, debinding method, sintering heat rate, sintering hold time) and has a variable impact on actual dimensions achieved at the end of the manufacturing process [14].

Dimensional inaccuracy can be related to one of the various steps of the manufacturing process and results in a dimensional difference between the different batches. Dimensional homogeneity within a batch and consistency between batches are the ultimate target of procedure validation protocols. A production procedure, if validated, should be secured from factors that could introduce bias to the production process and its output [15].

To our best knowledge, this is the first study to assess the torque and tip values of currently marketed stainless steel brackets according to the ISO 27020:2019 norm, which sets tolerance limits for the dimensions of the bracket slot and the inbuilt torque and tip. In a previous report, bracket dimensions and torque were tested according to the DIN 13971-2 norm. The DIN norm describes a similar testing protocol but provides a significantly different tolerance range [13]. Furthermore, the current study is the first to test the variability in different batches of the same bracket system.

The low method error, as defined by the inter- and intra-operator reliability, the number of brackets systems tested, the number of providers involved, the inter-batch assessment, and the single-blind design employed can be regarded as strengths of our study.

However, some limitations should also be acknowledged. We did not include stainless steel brackets manufactured by procedures other than MIM or different types of brackets, such as ceramic or self-ligating brackets.

### *4.1. Torque*

The working wires of the straight wire technique are not full-dimension archwires, leading to a lack of intimate contact between the bracket and the wire. The dimensional difference between the wire and the slot is called the torsional play or the engagement angle [8]. The torsional play of a 0.019 × 0.025 in. archwire in a bracket slot with nominal dimensions of 0.022 in. could theoretically be estimated at approximately 7° to 10° [11]. Most authors have focused only on torsional play to assess the efficiency of the appliance in torque expression. Tepedino et al. (2020) found a torsional play ranging from 11.42 ± 0.29 to 15.84° ± 0.68° in the three systems analyzed in their study which engaged a 0.019 × 0.025 in. archwire in a bracket slot of 0.022 in. [16]. Arreghini et al. (2014) found a torsional play ranging from 13.80° ± 0.12° to 28.68° ± 0.48° while engaging a 0.019 × 0.025 in. archwire in a 0.022 in. bracket slot [17]. It is in fact clear how torsional play affects clinical torque expression; however, if the inbuilt torque value is not assessed, it is not possible to know if torque expression is affected by an oversized slot height or by an inaccuracy in the inbuilt torque information. Torque play can nullify the amount of torque information built into the bracket slot. The amount of torque play in any direction is a cumulative value that does not specify the causing factors, such as an inaccuracy of slot height, a lack of slot parallelism, or an anomalous slot geometry [8,18]. According to our results, only seven of the twelve analyzed systems had brackets respecting the tolerance limits of the torque information in the bracket base, while the information was defective in four of them. The torque values in the study group varied between −3.85° and +2.52° from the declared value. The inaccuracy of the torque information built into the bracket can thus worsen the defective torque expression to a great extent due to the torsional play highlighted in previous studies. Streva et al. (2010) analyzed 120 MBT prescription, maxillary canine brackets and 120 MBT prescription, mandibular canine brackets from six different manufacturers, and found their mean torque values were significantly different from those declared in four bracket series from three different manufacturers [6]. The authors concluded that for only one manufacturer was the torque value deviation high enough to be clinically significant. Vianez Pereira et al. (2019) evaluated the incorporated torque of 360 Roth prescription, upper and lower brackets from six different manufacturers, and found the mean torque value was significantly different from the declared value in two bracket series from two different manufacturers. The authors concluded that, despite the mean value not being statistically different in many bracket series, the standard deviation in the study sample was high enough to highlight a clear manufacturing inaccuracy or a defective quality check [19]. Plaza et al. (2002) assessed 220 MBT prescription, maxillary central incisors from four different manufacturers and found a torque significantly different from the declared value in two bracket series from two different manufacturers with a value range of 13.17° to 19.43°, very similar to the one of the current study [2]. It should be underlined that, despite the non-significant difference of the mean value from the declared value, a range of torque variation of 5° was observed in a third manufacturer.

### 4.2. Tip

Tip information is one of the key factors in the straight wire technique. Tooth inclination in the mesio-distal plane greatly affects the correct expression of the inbuilt torque information, and also affects the relative tooth dimension and the related Bolton index [4,18]. However, tip expression is one of the main factors involved in anchorage loss and tip information is usually expressed early in treatment [2]. It is indeed surprising how only a few studies have addressed the issue of bracket tip fabrication accuracy.

According to the results of our study, in the evaluated bracket systems, all mean tip values were within the tolerance limit established by the ISO 27020:2019 norm. When the different batches were analyzed separately, one system in one of the three batches presented values that exceeded the tolerance limits. Other authors who analyzed the tip inbuilt in the bracket slot found greater deviations than those in the current study. Mendonca et al. (2014) in vitro tested 60 Roth prescription, pre-adjusted metal brackets, with a bracket slot size of 0.022 in., from three different manufacturers and found a variation in mean tip angulation between 2.13° and 3.90°, between the different systems [4]. The magnitude of the variation can be considered significant since the theoretical tip value is 5° in the Roth prescription.

Plaza et al. (2002) evaluated 220 MBT prescription, maxillary central incisors from four different manufacturers and found tip values significantly different from those declared in three brackets series from three different manufacturers, with a value range of 3.29° to 7.13° while the declared value was 4°. The authors underline that, despite the large range found in the total sample, the brackets from 3M™ and Dentaurum™ displayed smaller ranges and standard deviation when compared to the other manufacturers [2]. Analyzing their results according to the ISO 27020:2019, we can state that in their sample only these two brands respected the given tolerance limits. Awasthi et al. (2015) assessed a pool of 0.022 in. metal brackets, MBT prescription from six different manufacturers and found a mean tip value ranging from 1.67° to 6°, the mean actual value being significantly different from those declared in all the evaluated bracket series [1]. In their sample, the Agile Mini® Bracket from 3M™ presented a mean value closer to the declared (4.33°) and within the tolerance limits. Generally speaking, according to the previously cited author, the largest deviations were observed in locally available bracket brands and the smaller in brackets from worldwide providers. This could reflect a better validation of the manufacturing process and quality check in industries with a greater background.

## 5. Conclusions

In this sample of currently available MBT prescription, stainless steel brackets, the torque information built into the bracket base can be different from the one declared by the manufacurer. Torque values up to 3.85° (−22.65%) lower and 2.52° (+14.82%) higher than the declared values were highlighted. In five systems, at least one batch presented torque values out of the tolerance limit established by ISO 27020:2019. The mismatch between the declared and the actual values should therefore be compensated with wire-bending if needed.

The tip information was accurate in most of the assessed brackets and within the tolerance limits. The clinician should therefore rely on the tip value declared by the manufacturers and wire-bending should not be needed to compensate for the inaccuracy in second order information.

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