Research Square

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A Gravitational Lever-Arm Reference Technique for Validating a Digital Test Instrument Used to Verify Implant Torque-Limiting Device Accuracy: An Experimental Study

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Additional Declarations: Competing interest reported. One of the co-authors, Dr. Wadhwani is the developer and shareholder of the device evaluated in this study. The study device was provided free of charge by ImplantWise. The company had no role in the study design, data collection, data analysis, manuscript preparation, or the decision to publish.

Abstract

Background

Implant torque limiting devices exhibit drift over time and require regularly verification for accuracy and precision.This in vitro study assessed the accuracy, reproducibility, and agreement of a digital implant torque verification (ITV) instrument using a gravitational lever-arm reference method.

Material and methods

Six ITV instruments were evaluated. One instrument underwent accuracy testing across 23 torque conditions generated by calibrated masses suspended at measured distances on a rigid beam. Experiments were conducted in Mainz, Germany, where gravitational acceleration is 9.8109 m/s². Beam deflection was negligible, and environmental conditions were controlled (21°C, 61% relative humidity). Each torque condition was measured 10 times (230 measurements). Instrument readings were compared with reference torques using linear regression, Bland–Altman analysis, and the concordance correlation coefficient (CCC). Five additional instruments underwent reproducibility testing with 10 repeated measurements each. Mean bias was evaluated using a one-sample *t* test against zero.

Results

Agreement between instrument readings and the reference torques was excellent (CCC = 0.9993to 0.9996). Regression analysis demonstrated near-perfect linearity (slope = 1.0012, intercept = 0.0375 Ncm, R^2 = 0.9999). Bland–Altman analysis showed low variability (SD = 1.6%) and a small proportional bias (r = − 0.246, *P* = .002).All five additional instruments demonstrated consistent reproducibility with mean bias 0.54% to 1.72%.

Conclusions

The gravitational lever-arm method provides a robust reference standard for validating implant torque-measurement instruments. The ITV instrument demonstrated high accuracy, precision, and reproducibility across clinically relevant torque values.The evaluated instrument delivers highly reliable and precise measurements, supporting its use for routine verification of implant torque-limiting instruments.

Background

Torque is a critical quantitative metric commonly used in implant dentistry. Knowing and controlling torque from the insertion torque that defines primary implant stability to the torque recommended to achieve adequate screw-joint preload is essential for achieving long-term success [1–3]. Specialized

instruments in the form of torque limiting devices are used for this purpose. However, variability in torque delivery has been shown to occur in both new and used devices due manufacturing tolerances, repeated clinical use, sterilization cycles, internal spring fatigue [4–7]. The result of improper torque application ranges from; Implant stability issues, screw loosening/ fracture, prosthetic instability, and biological complications [8, 9]. Although there are general guidelines from the International Organization for Standardization (ISO) 6789-2 on how to validate and calibrate mechanical torque-limiting devices [10], two surveys in the US and Europe revealed that there is a lack of information about testing and calibrating implant specific torque-limiting devices [11, 12].

To address this challenge, Wadhwani et al introduced a simple, physics-based lever-arm technique for evaluating both toggle- and beam-type torque wrenches [13, 14]. The method used calibrated masses and measured lever-arm distances to generate known torque values, providing clinicians with a reproducible in-office calibration approach. Hoelken et al later applied the same principle to mechanical torque devices by additionally accounting for the shortening of the lever arm and the change in the force application angle during ratchet activation [15]. This demonstrated that the method is applicable across different torque delivery systems while maintaining high accuracy and precision. The present study extends this methodology to a new category of device: an implant-specific torque limiting device measurement instrument (ImplantWise, Bellevue, WA, USA). Unlike torque-limiting devices used on implants and implant screws, this measuring instrument is designed to validate the torque-limiting devices themselves, offering clinicians a direct quantitative assessment. Therefore, this study evaluated the accuracy, precision, and agreement of the implant torque validation (ITV) measuring instrument relative to the lever-arm reference standard. The null hypothesis was that the measurement values from the ITV instrument would not differ from the lever-arm reference standard.

Methods

Reference Torque Calculation

The lever-arm method described was used to generate known torque values. Calibrated masses were suspended at predetermined distances from the rotational center of a rigid beam. Torque was calculated using:

$$M = m \cdot g \cdot l$$

where *M* = torque (Nm), *m* = mass (kg), *g* = gravitational acceleration, *l* = lever-arm distance, m; under environmental conditions 21°C and relative humidity 61%. Since all measurements were conducted in Mainz, Germany, the local gravitational acceleration (g = 9.8109 m/s²) was used for all force calculations instead of the standard acceleration due to gravity (g = 9.80665 m/s²) [16].

Test Setup and Measurement Procedure

Masses were verified using a laboratory scale with ± 0.1 g accuracy (Sartorius AG, Göttingen, Germany). Lever-arm distances were measured using an attached ruler and Caliper.

The digital ITV instrument (Implantwisedental.com) was mounted in a vice such that the lever arm was parallel with the horizon using an attached spirit level gauge (Figs. 1 & 2). Various lever arm lengths were recorded with varying weights attached and the corresponding measuring instrument reading recorded (Fig. 3). For each experimental condition, the complete measurement procedure was repeated independently ten times. Between consecutive measurements, the beam was removed and repositioned, the ruler was reset, and the measurement distance was re-established and adjusted. This protocol ensured that each replicate represented an independent experimental setup rather than repeated measurements under identical conditions, thereby capturing the variability associated with repositioning and experimental setup.

Assessment of Beam Deflection

Beam deflection was determined for each beam length by measuring the initial vertical distance between the tabletop and the end of the lever arm. After bending the lever arm, the vertical distance was measured again. The difference between both measurements corresponds to the vertical displacement of the lever arm (*h*). As the beam rotates about its fixed support, the horizontal distance between the pivot point and the force application point is reduced. Assuming that the beam length (*l*) remains constant, the projected horizontal lever arm (*l**) was calculated from the measured vertical displacement using the Pythagorean theorem:

$l^* = \sqrt{l^2 - h^2}$

Evaluation of Different Lever Arm Lengths

To evaluate the influence of lever arm length on torque measurements, additional measurements were performed using lever arms of 3, 5, 7, 12, 15, and 15.3 cm. Each configuration was established following the same experimental protocol as the primary measurements. Twenty-three torque conditions were tested, each repeated ten times (230 total measurements were made). To minimize parallax error, all distance readings were performed under magnified viewing while maintaining a perpendicular line of sight to the ruler.

Evaluation of Additional Devices

To assess measurement reliability across instruments, five additional, independent instruments were evaluated, each with repeated measurements using an ASTM Class 1 200 g calibration weight.

Statistical Analysis - Agreement Analysis

The data was subject to analysis using linear regression with slope, intercept, and coefficient of determination (R^2), and residual standard error calculated. Bland-Altman analysis provided bias, limits of agreement (LoA), and proportional bias. The concordance correlation coefficient (CCC) was used to assess agreement between digital ITV instrument measurements and reference torque values, incorporating both precision and accuracy components.

Statistical Analysis - instrument-level measurement accuracy

To assess instrument-level measurement accuracy, the mean bias for each of the five instruments was compared with zero using a one-sample t-test. A mean bias of zero was considered indicative of no systematic deviation from the reference torque values.

Statistical Analysis - Power Analysis and Sample Size

A priori power analysis was performed using an alpha level of 0.05 and a statistical power of 80%. Based on the expected measurement variability, eight measurements were required; therefore, 10 repeated measurements per ITVinstrument were performed. All data was coded for R script and ran through R statistical package.

Hypothesis Testing

Hypotheses testing was performed to evaluate the proportional bias, constant bias, agreement and ITV instrument level measurement accuracy. The null hypotheses were as follows:

H0-1: Linear regression (1:1) relationship; the regression slope = 1 and intercept = 0.

H0-2: Bland-Altman; mean bias was 0 and no proportional bias existed.

H0-3: If CCCs were equaled 0, indicating no agreement beyond chance.

H0-4: Reproducibility across ITV instruments; the mean bias for each instrument was equal zero, indicating no systematic deviation from the reference torque value.

Results

Test Setup and Measurement Characteristics

The maximum vertical displacement of the beam (5 mm at a beam length of 153 mm) reduces the effective horizontal lever arm by 0.082 mm (0.054%). Consequently, the resulting error in the calculated torque is below 0.02 Ncm for the investigated torque range (15 Ncm to 30 Ncm).

Measurements obtained with the shorter lever arms (3, 5, and 7 cm) showed greater variability than those obtained with the longer lever arms. Therefore, only measurements obtained with the 12, 15, and 15.3 cm lever arms were included in the primary statistical agreement analysis.

Agreement Between Instrument and Reference Measurements

ITV instrument measurements demonstrated a linear relationship with the reference torque values. Regression analysis resulted in a slope of 1.0012 and an intercept of 0.0375 Ncm, with an R^2 value of 0.9999 (Fig. 4, Table 1).

Table 1
Concordance correlation coefficient-, Linear regression and Bland–Altmann analysis

Analysis	Parameter	Result
Concordance correlation coefficient (CCC)	12 cm lever length	0.9993 (95% CI: 0.9989–0.9996)
	15 cm lever length	0.9995 (95% CI: 0.9992–0.9997)
	15.3 cm lever length	0.9996 (95% CI: 0.9993–0.9998)
	Global	0.9994 (95% CI: 0.9992–0.9996)
	Measurements analyzed	n = 150
Linear regression	Slope	1.0012
	Intercept	0.0375 N·cm
	R^2	0.9999
	Residual standard error	0.1441 N·cm
Bland–Altman analysis	Measurements analyzed	n = 150
	SD of differences	1.6%
	Correlation between torque and % difference	r = − 0.246
	P value	.002
	95% confidence interval of bias	−0.39% to − 0.10%
	Overall interpretation	High agreement with minor proportional bias

SD = Standard Deviation; CI = Confidence Interval.

Bland–Altman analysis demonstrated a standard deviation of differences of 1.6% and a proportional bias (r = − 0.246, P = .002) across the tested torque range (Fig. 5, Table 2). The concordance correlation coefficient (CCC) values ranged from 0.9993 to 0.9996 for all tested lever lengths (Table 1).

Measurement Accuracy Across Instruments

Regarding measurement accuracy across the five units, the mean bias values ranged from 0.54% to 1.72%, with standard deviations of bias ranging from 0.10% to 0.32% (Table 2).

Table 2
Repeatability t-test assessment of 5 ITV instruments (M1-M5). α = .05

Subject	Mean measured (Ncm)	SD measured	Mean Bias (%)	SD Bias (%)	95% CI Low	59% CI High	p-value
M1	30.45	0.067	1.5%	0.22%	1.03%	1.97%	< .0001
M2	30.517	0.029	1.72%	0.10%	1.55%	1.89%	< .000
M3	30.161	0.073	0,54%	0.24%	0.05%	1.03%	.036
M4	30.165	0.068	0.55%	0.23%	0.08%	1.02%	.031
M5	30.369	0.095	1.23%	0.32%	0.61%	1.85%	.001

SD = Standard Deviation; CI = Confidence Interval.

Discussion

This in vitro study assessed the performance of a digital ITV instrument using a gravitational lever-arm reference method. Based on these results, the null hypotheses H0-2 for proportional bias and agreement H0-3 (CCC) were rejected, whereas the regression null hypothesis H0-1 (slope = 1, intercept = 0) was not rejected, supporting the expected 1 :1 relationship between device- measured and the reference torque values. All five devices exhibited a mean bias that differed significantly from zero (P < .05); therefore, the null hypothesis H0-4 was rejected.

The results indicate that the ITV device accurately reproduced reference torque values under controlled laboratory conditions. The near 1:1 relationship observed in regression analysis and the high CCC values demonstrate close agreement with the gravitational lever-arm reference method. The Bland–Altman analysis showed low variability between measurements and only minor systematic deviations across the tested torque range. The observed proportional effect suggests that measurement differences varied slightly depending on the applied torque level, with lower relative deviations at higher torque values. However, the overall measurement behavior remained consistent across the evaluated range. Together, these findings support the accuracy and reproducibility of the ITV device as a tool for verification of implant torque-limiting instruments.

The low variability observed across all five devices demonstrates consistent measurement performance among independent units. These findings support the reliability of the measurement system and indicate that the observed performance was not limited to a single device.

This study applied the lever-arm method originally described by Wadhwani et al[13,14] and later adapted by Hoelken et al[15] to validate an implant-specific torque-measurement device. They also compared a manual torque verification method with a digital torque measurement system and demonstrated comparable accuracy between the two methods.[15] The findings of the present study complement these results by further validating a digital torque verification approach against a gravitational lever-arm reference method. The strength of this method lies in its reliance on fundamental physical principles, using mass, distance, and gravity, which can be measured with high precision. However, several factors that could influence torque accuracy were evaluated:

Beam deflection was directly measured and found to be negligible confirming that the applied torque closely matched theoretical values. This strengthens the validity of the reference method.

Mass and length measurement error: Masses were verified to ± 0.1 g accuracy. Even at the highest torque levels, this introduced less than 0.05 Ncm potential error that was well below the limits of agreement observed. Temperature and humidity can affect frictional interfaces and material elasticity. Testing at 21°C and 61% humidity ensured stable conditions.

Variations outside this range could introduce small differences in torque behavior, but the controlled environment minimized this risk. Statistical analysis provided additional insight into the agreement between the measurement device and the reference torque values by assessing the magnitude and distribution of measurement differences across the entire torque range.

The increased variability observed at shorter lever arms (3, 5 and 7 cm) can be explained by the inverse relationship between lever arm length and the relative contribution of positioning errors to torque calculation. At reduced lever arm lengths, even small deviations in force application point or alignment result in proportionally larger effects on the calculated torque. Therefore, these configurations were considered less representative for evaluating the intrinsic accuracy of the measurement system and were not included in the primary agreement analysis.

An in-house torque verification system may offer economic, practical, and sustainability-related advantages. It could reduce costs, transportation, and turnaround time by eliminating the need to ship torque wrenches to external calibration facilities. It may also reduce unnecessary replacement of reusable instruments and extend their service life. However, a formal cost-effectiveness or life-cycle analysis was beyond the scope of this study and could be done in future studies.

Limitations of this study include that the validation approach using a lever arm reference method relies on gravitational force for torque calculation. Because all testing was performed in Mainz, Germany, the local gravitational acceleration ($g = 9.8109\ m/s^2$) was used instead of the standard acceleration due to

gravity ($g_{\square}$ = 9.80665 m/s²) with information sourced through Bureau Gravimetrique Internatioanl (BGI).[16] Although the numerical difference is small (approximate 0.04%), torque calculations based on mass × distance × gravitational acceleration are linearly dependent on this parameter, resulting in minor differences in the calculated values. Operator-dependent variability may have influenced the results, as bending torque was adjusted manually based on visual feedback until the target value was reached. Although measures were taken to minimize parallax errors (perpendicular viewing angle and magnification), residual observer-dependent uncertainty cannot be excluded. Beam deflection was measured under all loading conditions and found to be negligible, confirming that the applied torque closely matched theoretical values. Minor mass-measurement errors (less than 0.1 g), length and environmental factors (21°C, 61% humidity) may introduce small variations, although these were controlled and monitored throughout testing.

Future research should investigate the clinical implementation of the ITV instrument and determine whether routine torque verification improves the performance and maintenance of implant torque-limiting instruments over time.

Conclusion

1. The lever-arm method is an effective reference standard for validating implant torque-measurement instruments s.
2. The ITV instrument demonstrated excellent accuracy, precision, and agreement across clinically relevant torque values.
3. Beam deflection, mass-measurement error, and environmental conditions were controlled and found to have negligible influence on results.
4. The ITV instrument demonstrated consistent and reliable performance across all tested devices.

Abbreviations

ITV = Implant torque verification

M = torque (Nm),

m = mass (kg),

g = gravitational acceleration,

l = lever-arm distance

h = lever arm

*l** = projected horizontal lever arm

LoA = limits of agreement

CCC = concordance correlation coefficient

SD = Standard Deviation

CI = Confidence Interval

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing Interests

One of the co-authors, Dr. Wadhwani is the developer and shareholder of the device evaluated in this study. The study device was provided free of charge by ImplantWise. The company had no role in the study design, data collection, data analysis, manuscript preparation, or the decision to publish.

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Author Contribution

FH and CW conceptualized the study, developed the methodology, conducted the investigation, and wrote the original draft. AKC contributed resources, supervised the study, performed visualization, and reviewed and edited the manuscript. CW performed the formal analysis and validation. FH contributed to the visualization. AKC and SAA contributed resources and visualization, managed the project administration, and reviewed and edited the manuscript.

Data Availability

The datasets used during the current study are available from the corresponding author on reasonable request.

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Figures



Figure 1

Materials: Measuring device, spirit level, ruler, beam with holder for ruler / spirit level.

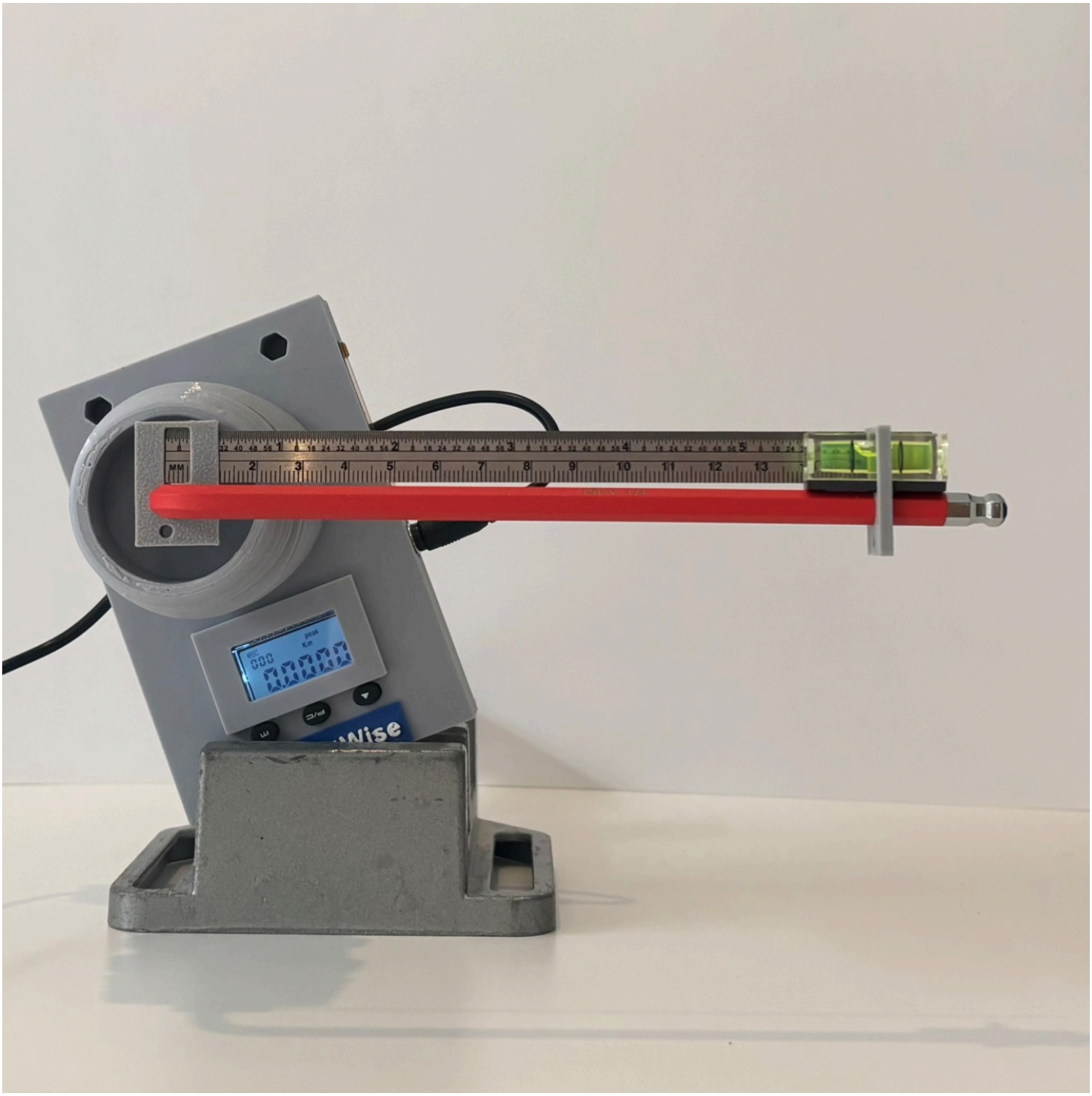


Figure 2

Experimental setup: beam secured within the testing device, horizontally aligned to the ground. Initial position.

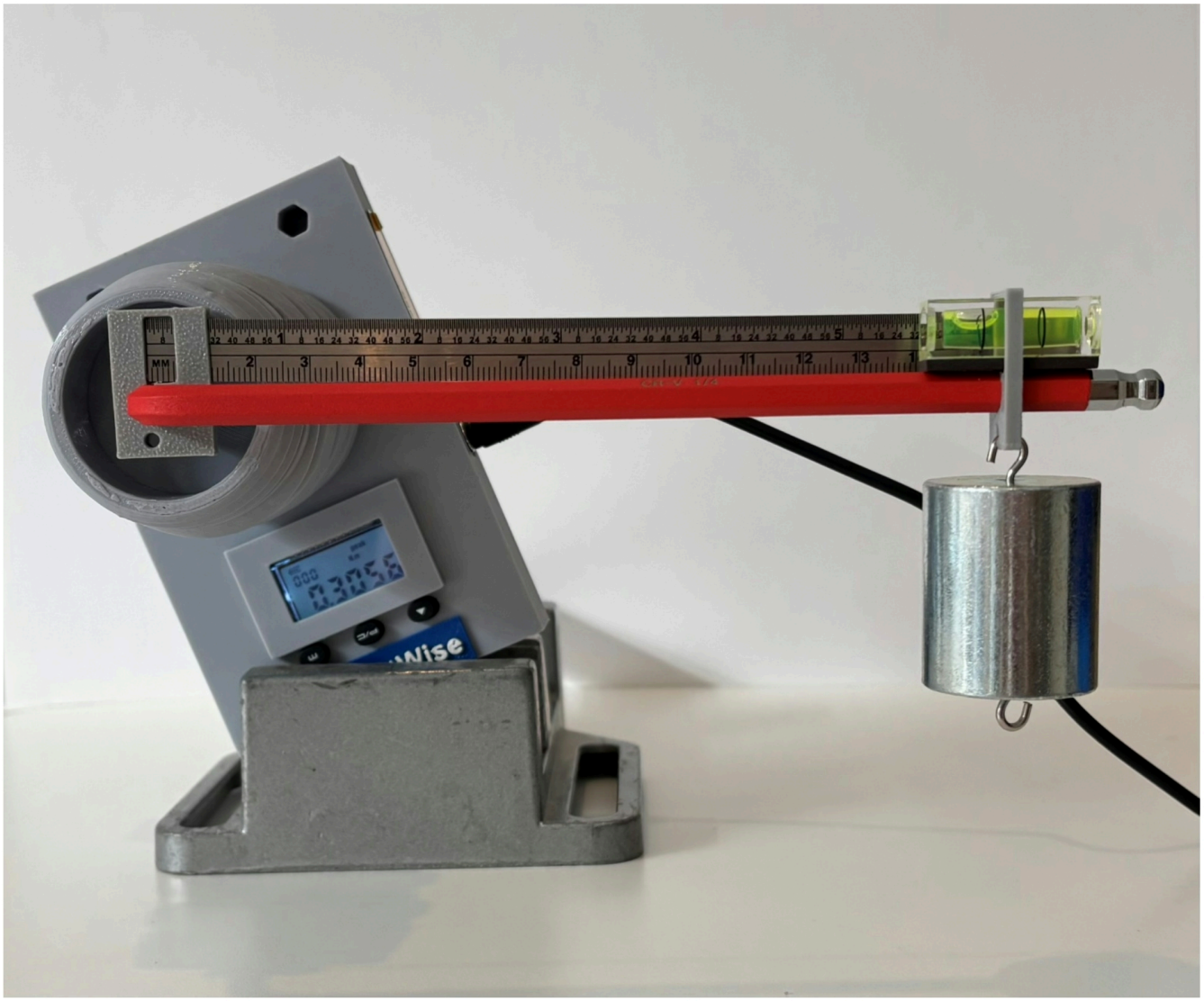


Figure 3

Experimental setup: Suspended weight attached to the beam. Deflected position.

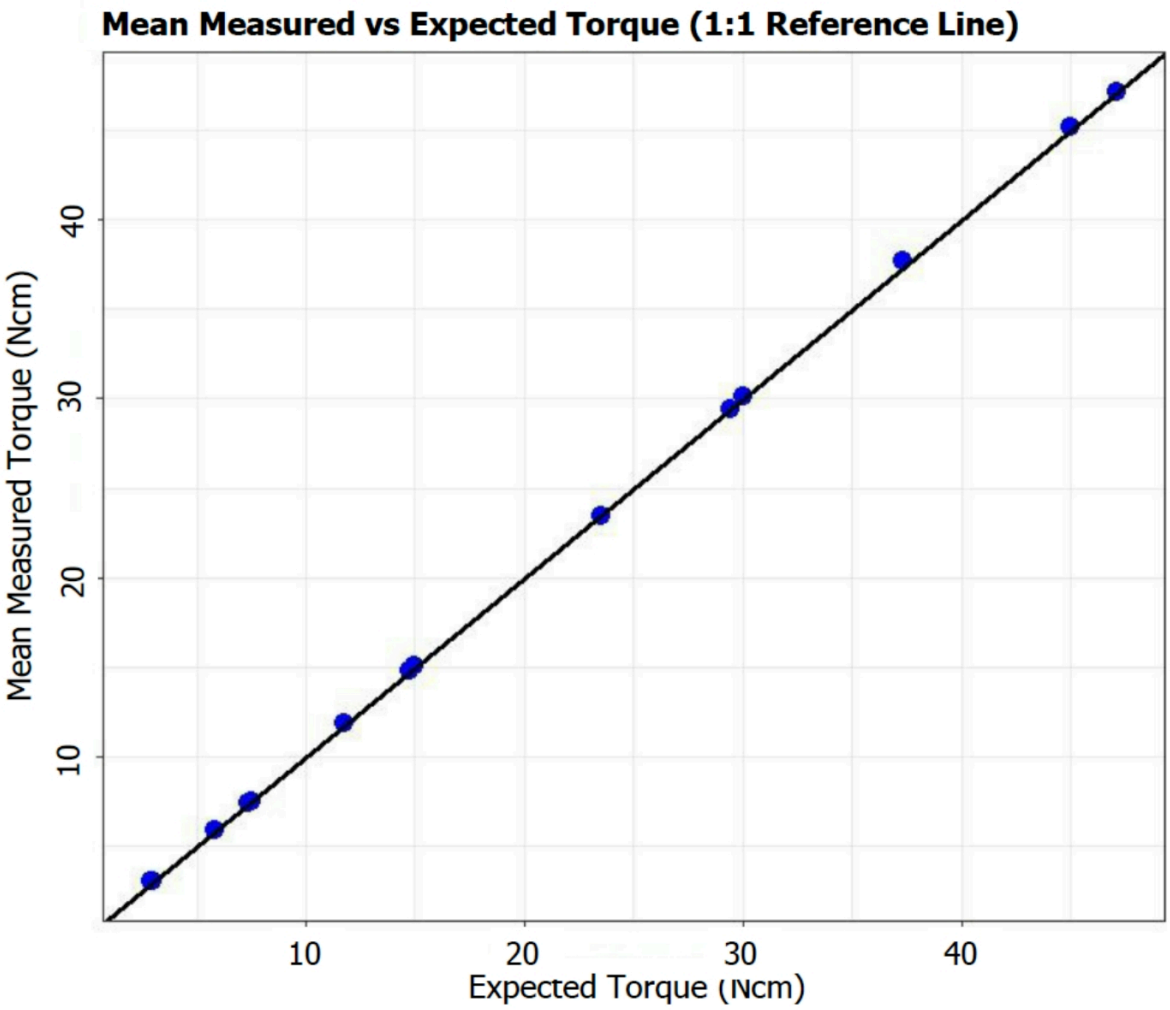


Figure 4

Regression analysis of device measurements versus expected torque value.

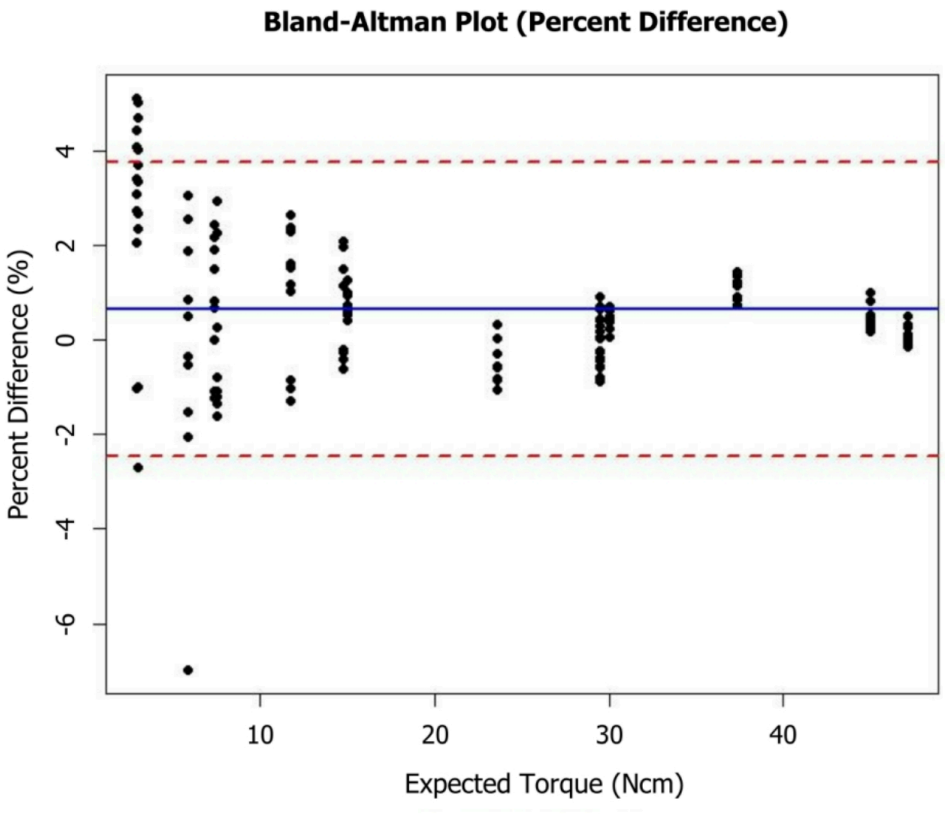


Figure 5

Bland–Altman analysis of measurement agreement across the tested torque range.