Routine monitoring of isometric knee extension strength in patients with muscle impairments using a new portable device: cross-validation against a standard isokinetic dynamometer

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Abstract

Objective: Muscle strength is a critical clinical hallmark in both health and disease. The current study introduces a novel portable device prototype (MyoQuad) for assessing and monitoring maximal voluntary isometric knee extension torque (MVIT). *Approach:* Fifty-six patients with inclusion body myositis were studied. Knee extension weakness is a key feature in this inflammatory muscle disease. Cross-validation with an isokinetic dynamometer (Biodex System 3 Pro) was performed. Between-day reproducibility and ability to monitor changes in muscle strength over time compared to the gold standard method as a reference, were also investigated. *Main results:* The measurement was feasible even in the weakest patients. Agreement between methods was excellent (standard error of measurement (SEM) was 3.8 Nm and intra-class correlation coefficient (ICC) was 0.973). Least significant difference (LSD) was 4.9 and 5.3 Nm for the MyoQuad and the Biodex, respectively Measurements using the MyoQuad exhibited excellent between-day reproducibility (SEM was 2.4 Nm and ICC was 0.989 versus 2.6 Nm and 0.988 using the Biodex). Changes in MVIT at 6 and 12 months were similar between methods (timepoint × method interaction was not significant; all $p > 0.19$); strength changes classified according to LSD at 6 and 12 months were consistent between methods (>70% consistent classification)). *Significance:* The measurement of maximal voluntary isometric knee extension torque using the MyoQuad offers a cost-effective, portable and immediate alternative for the routine measurement of maximal voluntary isometric strength of the quadriceps. The MyoQuad offers a comfort and stability that cannot be provided by standard hand-held dynamometers. These results support quantitative muscle strength assessment using fixed yet flexible dynamometry within clinical routine and multicenter trials.

Keywords: device; muscle strength dynamometer; muscle weakness; myositis; outcome measures

List of abbreviations

MMT, manual muscle testing; HHD, hand-held dynamometry; MVIT, maximal isometric knee extension voluntary torque; SD, standard deviation; CIM, change in mean; ICC, intra-class correlation coefficient; SEM, standard error of measurement; LSD, least significant change

Introduction

Muscle weakness has been demonstrated to be an independent predictor of all-cause mortality in an apparently healthy population (Garcia-Hermoso et al., 2018). Knee extension has been identified as a preferential target for detecting muscle weakness in various chronic disorders and other conditions such as aging or immobilization. Availability of a simple portable setup and methodology for assessing knee extensor strength is critical to generalize the measurement of this important clinical hallmark.

Strength assessment within clinical settings is most frequently performed using manual muscle testing (MMT) (Hogrel et al., 2006). As a semi-quantitative and operator-dependent method, MMT is poorly responsive (Bohannon, 2005). MMT may be used for rough detection of muscle weakness but not to finely quantify its severity and its evolution over time. Quantitative measurement of muscle strength allows precise temporal monitoring of muscle strength and enables the use of Z-scores or percentage of predicted values computed from datasets and predictive equations (Hogrel et al., 2007; Harbo et al., 2012; Seymour et al., 2010; McKay et al., 2016). Portable dynamometers have been demonstrated to be particularly relevant for quantifying muscle strength at low-cost and ease of use within daily clinical practice and multicenter research trials. Good agreement has been reported between isometric strength measurement using hand-held dynamometry (HHD) and the "gold standard" isokinetic dynamometer (Stark et al., 2011). However, evaluator strength limits the magnitude of isometric force that can be measured using HHD (Deones et al., 1994). For powerful muscle groups such as the quadriceps, belt-stabilization may be used to improve the reliability and the range of measurable muscle strength using HHD (Bohannon et al., 2011; Bohannon et al., 2012; Bachasson et al., 2014). However stabilized HHD is mostly achieved using home-made methods that may be imperfectly adapted, may lead to discomfort and are unlikely to be standardized for repeated testing (Hansen et al., 2015). Some approaches may also fail to

provide accurate assessment of muscle strength in the weakest patients, partly due to design flaws and metrological limitations inherent in the hardware used, as typically observed in patients with muscle dystrophy for instance (Servais et al., 2013).

The current manuscript introduces a novel portable device prototype (namely, the MyoQuad) for the assessment and monitoring of isometric knee extension strength that may be used in most clinical setups. This article is organized as follows: description of the device, evaluation of the device in patients including cross-validation with the gold standard, between-day reproducibility of measurements and ability to monitor changes in muscle strength over time with the gold standard method as a reference.

Methods

Participants

The device was tested in patients with inclusion body myositis enrolled in a natural history study (NCT00898989) and in a pharmacological trial (NCT02481453). The patients were included according to the criteria defined by Benveniste and Hilton-Jones (2010). These studies conformed to the Declaration of Helsinki and were approved by the local ethics committee (CPP-Ile de France VI). All participants gave written informed consent. All tests were performed between April 2013 and April 2017.

Description of the device for the assessment of isometric knee extension strength

The device used in the present study was a first-generation prototype. The MyoQuad was specifically designed for the assessment of maximal isometric strength, even in very weak individuals. It embeds a high precision load cell (Interface SML-300, Scottsdale, Arizona, USA) and electronic board dedicated to signal acquisition and processing, wireless signal transmission (Bluetooth), and operating-energy controls. The current prototype has a measurement range from 0 to 136 kg with 10 g resolution and 50 g accuracy over the whole

nominal range. The load cell and the board are included in a 3D-printed case, which can be firmly and securely attached to the structure of any examination bed/table using a clamp (see Figure 1A). A dedicated software was developed allowing the visualization and analysis of the acquired strength signal. The software can be run from a phone/tablet or laptop. One extremity of the load cell is equipped with a hook on which a strap can be attached (see Figure 1B). Other interfaces may also be screwed directly onto the load cell for other applications in traction and compression. The MyoQuad device was checked for calibration using strict standardized operating procedures. A set of M3 class masses from 0.2 to 50 kg was used for calibration. The calibration was checked every week, then every month after 6 months, then every 2 months after 12 months. The metrological properties of the device were always within the requirements (50-g accuracy over the whole range of measurement). A typical calibration curve is presented in Figure 2.

Measurement protocol

Subjects were seated on a standard examination table with the hip and knee flexed to 90°. A small dense foam pillow was placed below the tested thigh (see Figure 1.A. and Figure 1.B.), so that the leg was vertical in order to avoid any effects of gravity effect, which can be detrimental for the assessment of very weak patients. The desired strap location (lower part of the strap above the medial malleolus) and the medial tibiofemoral joint space were marked on the skin. The distance between the two marks i.e. the lever arm, was carefully measured to the nearest half-centimeter using a measuring tape (Figure 2) to compute the torque as force × lever arm, allowing direct comparison between methods (MyoQuad *vs.* isokinetic dynamometer). The ankle strap was then fixed and attached to the dynamometer. The height of the table was adjusted to ensure the strap was horizontal. Participants were asked to keep their hands on their thighs. The evaluator secured the patient at the thigh and shoulder levels on the tested side in order to limit compensatory movements.

Isokinetic dynamometer

Participants sat (85° hip flexion) on an ergometer (Biodex System 3 Pro, Biodex Medical, Shirley, NY, USA). The upper body was stabilized with straps across the thorax and the abdomen. Knee joint axis of rotation was aligned with the measurement axis of the system. The thigh was strapped around the mid-thigh of the leg to be tested. The knee angle was placed at 90° to cancel the effect of gravity. All measurements were performed in an isometric mode.

Assessment of maximal voluntary isometric knee extension voluntary torque (MVIT)

Patients were instructed to perform maximal effort during a static knee extension and to limit countermovement. Three maximal voluntary contractions were recorded for each dynamometer. A fourth and possibly fifth trial were performed if the value reached during the last trial was higher than the preceding ones, or if the difference between trials was greater than 10%. Strong verbal encouragements were provided to the subjects. For MyoQuad measurements, the patient was stabilized using one hand on the thigh and the other on the shoulder on the measured side. Measurements were performed on both sides. The maximal value from all trials was used for analyses.

Data analysis

Torque were expressed as absolute values and as percentage of predictive values using previous published equations (Hogrel et al., 2007).

Statistics

Data within text and tables are shown as mean ± standard deviation (SD) or mean [lower 95% confidence interval, upper 95% confidence interval]. The assumptions of normality and sphericity were confirmed using the D'Agostino K-squared and Mauchly tests, respectively. For cross-validation and between-day reproducibility, change in mean (CIM) and paired t-tests were used for detection of systematic bias. Standard error of measurement (SEM) was

used to study absolute reliability. Relative reliability was assessed using intra-class correlation coefficients ($ICC_{2,1}$). Regression analysis and Bland–Altman plots were also performed. Individual coefficients of correlation were computed for between-day measurements and a paired sample t-test was used to compare individual coefficients of correlation between methods. The same approach was used to compare change between methods at follow-up. In addition, a two-way ANOVA (timepoint × method) was used to compare methods. Tukey's honest significant difference post-hoc tests were conducted when a significant main and/or interaction effect was found. Least significant difference was defined as SEM × 2 and outcome at follow-up was defined as impaired, unchanged, and improved. A Fisher exact probability test was used to compare contingency tables of outcomes at follow-up. All analyses were performed in the computing environment R Version 3.2.3. Statistical significance was set at $p < 0.05$ for all tests.

Results

A total of 56 patients (age = 67 ± 9 years) with inclusion body myositis were included. Thirty-three patients were assessed for between-day reproducibility. Thirty-two of which were reassessed after 6 and 12 months. Amongst them, 29 were tested using both methods. The reason for the smaller number of patients at follow-up was time constraints or unavailability of the MyoQuad. Ultimately, a total of 287 observations using both methods were gathered. Agreement of methods are summarized in Table 1 and Figure 3. The MVIT measured using the MyoQuad was significantly lower than the MVIT measured using the Biodex. Between-day reproducibility results for both methods are displayed in Table 2 and Figure 4. No systematic bias was detected and least significant difference was 4.9 and 5.3 Nm for the MyoQuad and the Biodex, respectively. Individual coefficients of variation for between-day measurements were 5.4 ± 7.4 % and 6.7 ± 6.6 % using MyoQuad and the Biodex with no

significant difference between methods (mean of the differences = -1.4 Nm; 95%CI: [-3.7, 0.9] Nm; $p = 0.26$).

Change in MVIT at 6 and 12 months using both methods is shown in Figure 5. When performed using absolute values (at baseline, 6, and 12 months), ANOVA showed significant main effects of method and time (both $p < 0.01$) and no significant timepoint × method interaction ($p = 0.19$) (Figure 5.A). When performed using absolute changes at 6 and 12 months, ANOVA showed significant main effects of method and time (both $p < 0.05$) and no significant timepoint × method interaction ($p = 0.46$) (Figure 5.B). Variability in changes between methods at follow-up is displayed in Table 3. A contingency table of outcomes at follow-up is shown in Table 4.

Discussion

The aim of this study was to introduce a novel device for the assessment of isometric strength of knee extensors, for use in most clinical environments. Agreement with the gold standard, between-day reliability, and the ability of the device to monitor changes in muscle strength over time compared to the gold standard method as a reference were investigated. Main results are as follows: i) the device demonstrates excellent metrological accuracy, ii) measurements obtained using the device exhibit excellent agreement with the gold standard, iii) reliability of measurements obtained using the device was excellent and comparable to results obtained using the gold standard, iii) change in strength over time was similar using the device and the gold standard.

The MyoQuad device was developed in order to conveniently assess quadriceps strength within routine clinical practice, including in very weak patients. This may be commonly performed using HHD, which, however, presents several limitations. In very strong patients, the evaluator may have difficulties in maintaining the dynamometer in a steady hold, whereas

the influence of the evaluator may be too important in the weakest patients leading to possible large relative errors. Fixed dynamometers are attractive to tackle these limitations (Mentiplay et al., 2015). However, muscle strength may be improperly or even impossible to assess if the device is improperly designed. For instance, within a recent therapeutic trial in IBM, the system was designed in a way that patients had to carry the weight of the strain gauge before strength produced could be actually measured. As a result, knee extensor strength could not be measured in 3 out of 12 (25%) patients and the consistency of the measurements in other patients was largely flawed (unpublished results). The design of the proposed device tackles these issues as the MyoQuad is directly secured on a fixed frame. HHD have been repeatedly observed to underestimate knee extension strength compared to isometric measurements using an isokinetic dynamometer (Stark et al., 2011; Martin et al., 2006). This is particularly true in stronger individuals where the evaluator may have difficulties stabilizing the measurement chain (Martin et al., 2006; Bohannon et al., 2012). The high agreement between measurements performed using the MyoQuad and the Biodex support that fixed dynamometry improves the robustness of assessments through improved comfort and stability. These data are in line with previous work reporting higher consistency of measurements using a modified procedure of stabilized HHD as compared to standard HHD (Kim et al., 2014; Hansen et al., 2015).

Our data shows a low SEM < 8.5 % Nm and high ICC > 0.98 for between-day reproducibility when using the MyoQuad. This was similar to that observed using the Biodex (SEM was < 10.0% and ICC was > 0.98). We also reported similar individual coefficients of variation for between-day measurement using the MyoQuad and the Biodex. This high reproducibility yielded similar least significant change using both methods. These data are in line with previous reports that have investigated between-day reliability using gold standard methods (Ruschel et al., 2015; Kean et al., 2010). Importantly, our data showed no significant

difference between methods for monitoring change in MVIT over time (Figure 5) and good agreement when comparing changes at follow-up (Table 3). This was confirmed by consistent classification of strength changes using both methods at follow-up (Table 4). To the best of our knowledge, this is the first report that compares temporal changes in knee extensors using fixed dynamometry and standard isokinetic dynamometry.

As this study was only performed in patients with inclusion body myositis, generalizability of findings to other disorders remains to be demonstrated. However, similar findings regarding the reliability of MVIT have been previously reported in various clinical fields (Nuzzo et al., 2019). Volitional maneuvers such as maximal voluntary contraction embraces both peripheral and central factors, which render its estimation variable (Millet et al., 2012). Therefore, observed differences between Biodex and MyoQuad also reflect this variability. Another potential source of error using the MyoQuad is the measurement of the lever arm to compute torque that is circumvented when using torque meter as in standard isokinetic dynamometers like the Biodex (Ruschel et al., 2015).

Conclusions

Measurement of maximal voluntary isometric knee extension torque using the MyoQuad offers a cost-effective, portable and immediate alternative for the routine measurement of maximal voluntary isometric contraction of the quadriceps by offering comfort and stability that cannot be provided using hand-held dynamometry. It may be used for both baseline and follow-up assessments of muscle strength and may also be used to assess other muscle groups (e.g. knee flexion, shoulder abduction) using proper patient positioning and adapted interfaces. Altogether, our results support the adoption of quantitative muscle strength assessment using fixed yet flexible dynamometry within routine clinical practice and multicenter trials.

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Tables

Table 1. Agreement of measurements obtained using the MyoQuad and the Biodex (n = 52 participants with a total of 283 measurements).

MyoQuad (Nm)	Biodex (Nm)	CIM (Nm) [95% CI]	P value	ICC [95% CI]	SEM (Nm) [95% CI]
29.46 ± 23.12	31.14 ± 24.68	1.68 [1.06, 2.30]	< 0.001	0.973 [0.966, 0.979]	3.76 [3.47, 4.10]

CIM = change in mean; SEM = standard error of measurement; ICC = intra-class correlation coefficient.

Table 2. Test-retest reliability of maximal isometric knee extension voluntary torque using the MyoQuad and the Biodex (n = 33 participants with a total of 66 measurements).

Method	Test (Nm)	Retest (Nm)	CIM (Nm) [95% CI]	*p* value	ICC [95% CI]	SEM (Nm) [95% CI]
MyoQuad	32.20 ± 23.58	31.72 ± 22.78	-0.48 [-1.33, 0.36]	0.258	0.989 [0.982, 0.993]	2.44 [2.08, 2.94]
Biodex	33.36 ± 24.88	32.90 ± 23.98	-0.46 [-1.37, 0.46]	0.323	0.988 [0.981, 0.993]	2.64 [2.25, 3.18]

CIM = change in mean; SEM = standard error of measurement; ICC = intra-class correlation coefficient.

Table 3. Variability of changes in maximal isometric knee extension voluntary torque at follow-up using the MyoQuad and the Biodex (n = 44 participants with a total of 88 measurements).

Biodex (Nm)	MyoQuad (Nm)	CIM (Nm) [95% CI]	*p* value	ICC [95% CI]	SEM (Nm) [95% CI]
-3.15 ± 9.01	-3.17 ± 7.57	-0.02 [-1.29, 1.24]	0.971	0.756 [0.648, 0.836]	4.22 [3.68,4.96]

CIM = change in mean; ICC = intra-class correlation coefficient; SEM = standard error of measurement.

Table 4. Contingency table illustrating classified changes in strength using the MyoQuad and the Biodex.

	6 months			*12 months*		
Progression	**MyoQuad**	**Biodex**	**% match**	**MyoQuad**	**Biodex**	**% match**
Impaired	13/44	11/44	85%	13/44	15/44	87%
Unchanged	29/44	29/44	100%	29/44	28/44	97%
Improved	2/44	4/44	50%	2/44	1/44	50%

Least significant change determined from between-day reliability was used to classify changes in strength after 6 and 12 months.

Figure legends

Figure 1. Patient installation and device. Close-up view of the device paired with tablet computer (A); Close-up view of the device attached to table legs with round (B) or rectangular section (C); Overview of the setup with one participant and stabilization by one evaluator (D). A small pillow is inserted under the distal part of the thigh to ensure the thigh is horizontal.

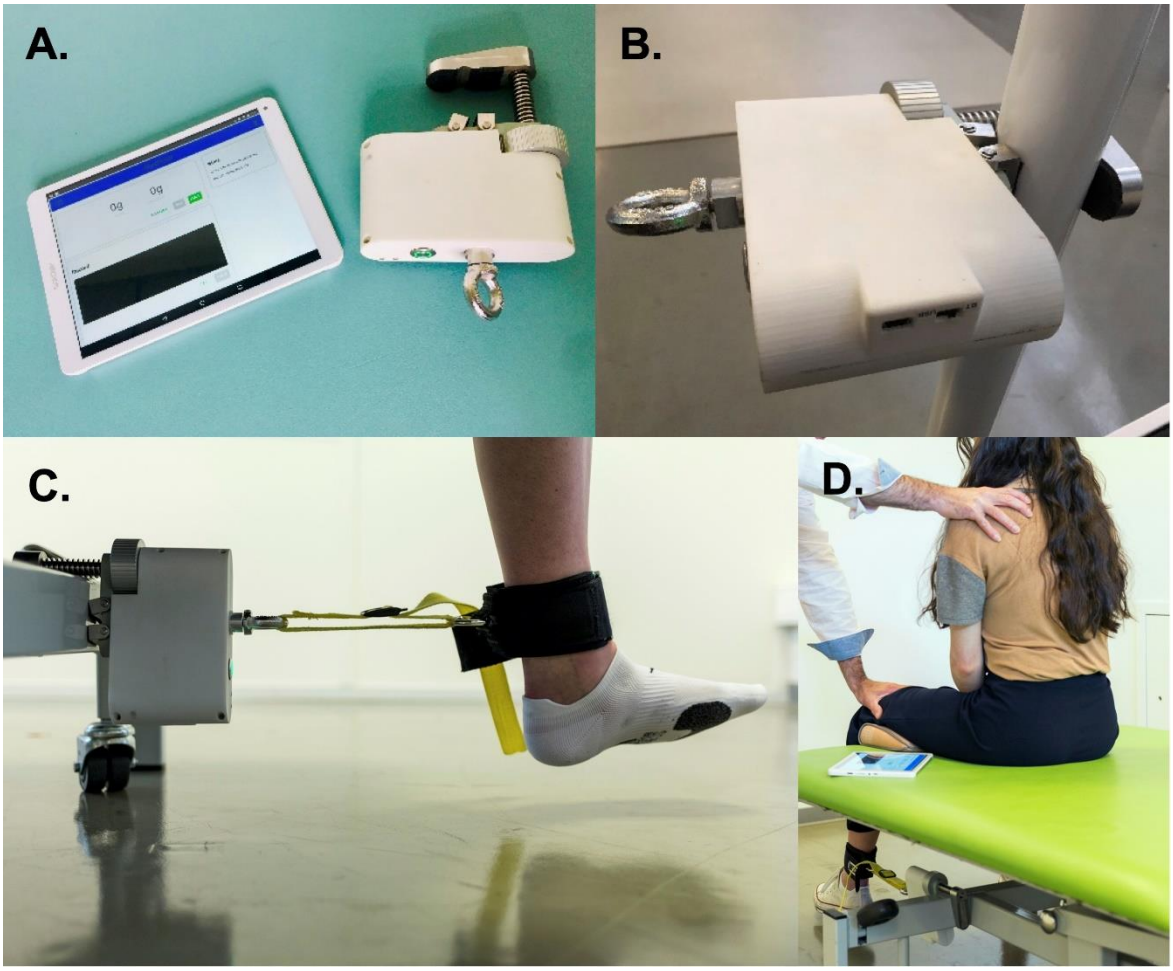
Figure 2. Typical calibration curve. The dashed line represents the identity line, and the solid line indicates the linear regression line.

Figure 3. Agreement of measurements obtained using the MyoQuad *versus* the Biodex. Bland–Altman plots (A) and regression analysis (B) of measurements obtained using the MyoQuad and the Biodex. In A, the solid line indicates the mean difference between the measurements and dashed lines the limits of agreement. In B, the dashed line represents the identity line, and the solid line indicates the linear regression line.

Figure 4. Between-day reproducibility of measurements obtained using the MyoQuad and the Biodex. Bland–Altman plots (A, C) and regression analysis (B, D) for between-day reliability of measurements obtained using the MyoQuad and the Biodex, respectively. In A and C, the solid line indicates the mean difference between the measurements and the dashed line indicates the limit of agreements. In B and D, the dashed line represents the identity line, and the solid line indicates the linear regression line. Logarithmic scales are used for better data visualization.

Figure 5. Change in torque over time using the MyoQuad and the Biodex. Absolute (A) values and change (B) in knee extensor strength over time.

Figure 1



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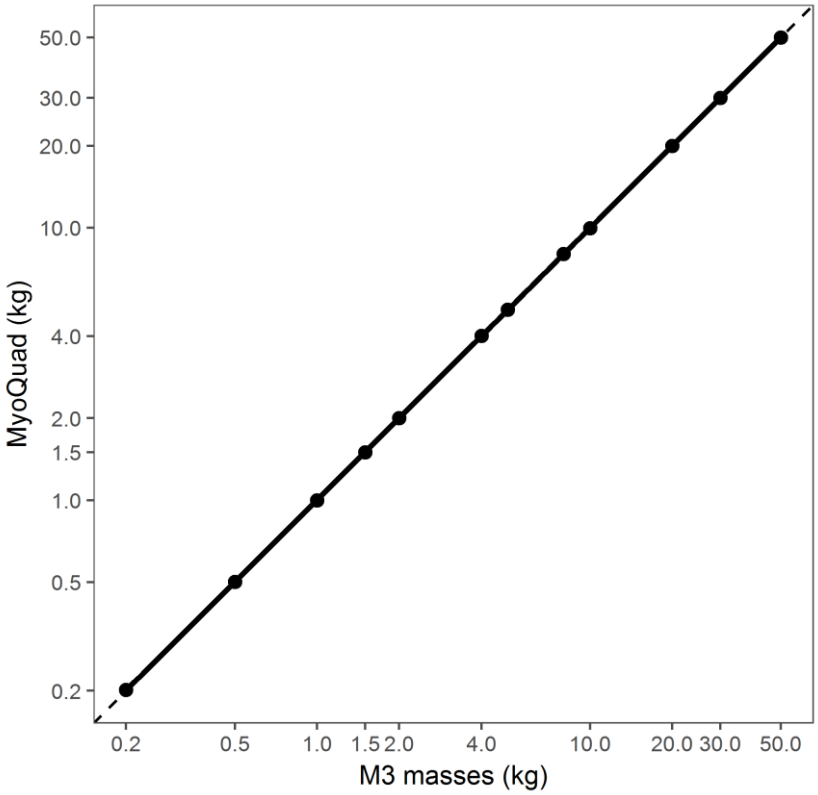

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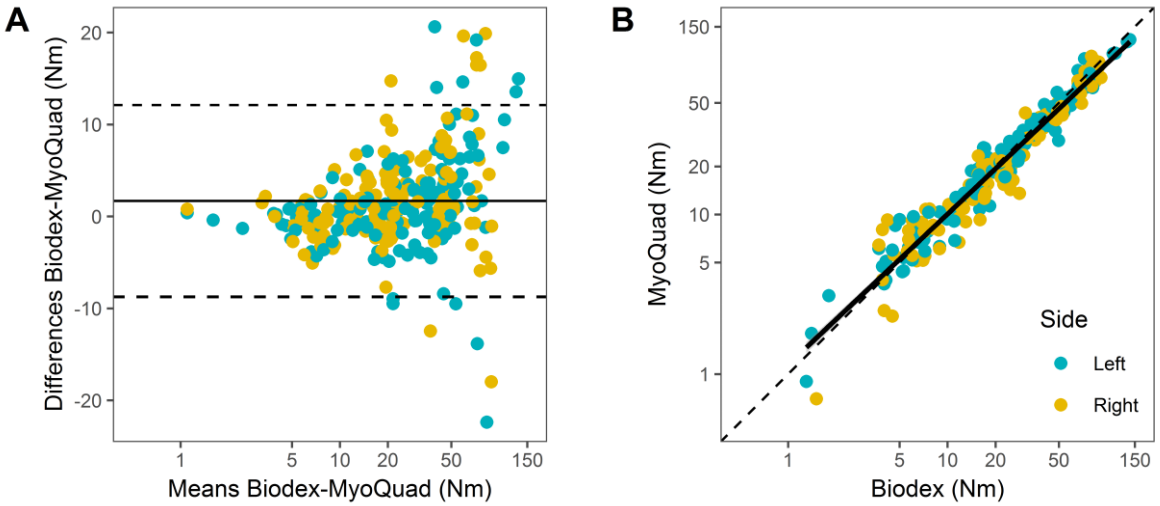

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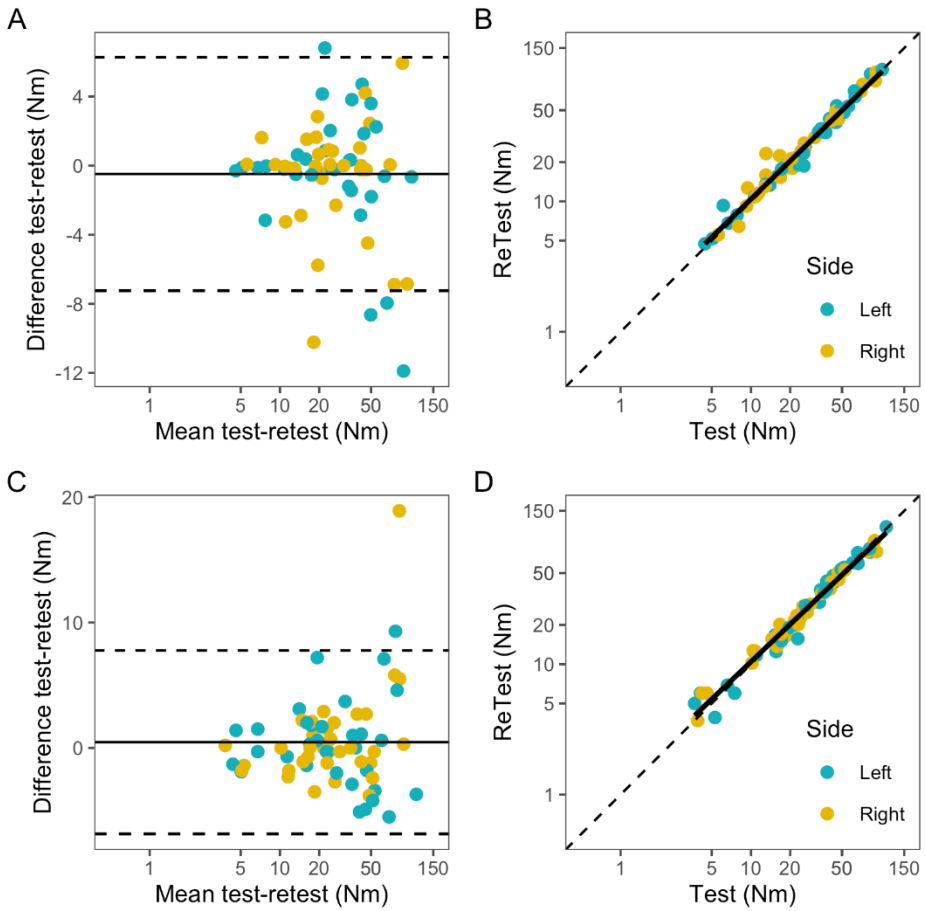

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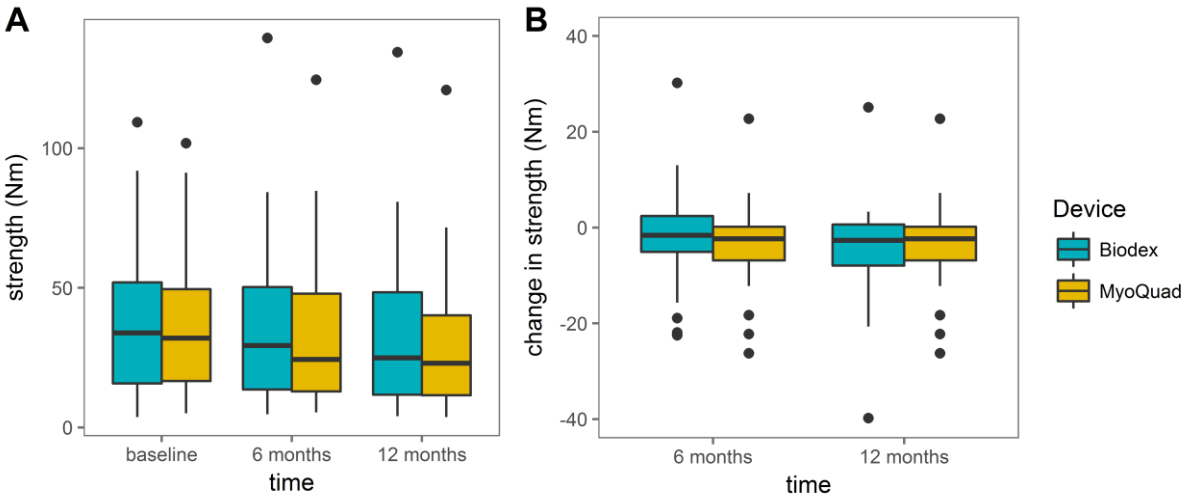
405 Figure 5



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