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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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3 1 Routine monitoring of isometric knee extension strength in patients with muscle
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6 2 impairments using a new portable device: cross-validation against a standard
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9 3 isokinetic dynamometer

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3 **Abstract**
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5 *Objective:* Muscle strength is a critical clinical hallmark in both health and disease. The
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7
8 current study introduces a novel portable device prototype (MyoQuad) for assessing and
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12 monitoring maximal voluntary isometric knee extension torque (MVIT). *Approach:* Fifty-six
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15 patients with inclusion body myositis were studied. Knee extension weakness is a key feature
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18 in this inflammatory muscle disease. Cross-validation with an isokinetic dynamometer
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21 (Biodex System 3 Pro) was performed. Between-day reproducibility and ability to monitor
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24 changes in muscle strength over time compared to the gold standard method as a reference,
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26
27 were also investigated. *Main results:* The measurement was feasible even in the weakest
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30 patients. Agreement between methods was excellent (standard error of measurement (SEM)
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33 was 3.8 Nm and intra-class correlation coefficient (ICC) was 0.973). Least significant
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36 difference (LSD) was 4.9 and 5.3 Nm for the MyoQuad and the Biodex, respectively
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38
39 Measurements using the MyoQuad exhibited excellent between-day reproducibility (SEM
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41
42 was 2.4 Nm and ICC was 0.989 versus 2.6 Nm and 0.988 using the Biodex). Changes in
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45 MVIT at 6 and 12 months were similar between methods (timepoint \times method interaction was
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47
48 not significant; all $p > 0.19$); strength changes classified according to LSD at 6 and 12 months
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50
51 were consistent between methods ($>70\%$ consistent classification)). *Significance:* The
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54 measurement of maximal voluntary isometric knee extension torque using the MyoQuad
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57 offers a cost-effective, portable and immediate alternative for the routine measurement of
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60 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.

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3 47 **Keywords:** device; muscle strength dynamometer; muscle weakness; myositis; outcome

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10 50 **List of abbreviations**

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12 51 MMT, manual muscle testing; HHD, hand-held dynamometry; MVIT, maximal isometric

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14 52 knee extension voluntary torque; SD, standard deviation; CIM, change in mean; ICC, intra-

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16 53 class correlation coefficient; SEM, standard error of measurement; LSD, least significant

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56 **Introduction**

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

63 Strength assessment within clinical settings is most frequently performed using manual
64 muscle testing (MMT) (Hogrel et al., 2006). As a semi-quantitative and operator-dependent
65 method, MMT is poorly responsive (Bohannon, 2005). MMT may be used for rough detection
66 of muscle weakness but not to finely quantify its severity and its evolution over time.

67 Quantitative measurement of muscle strength allows precise temporal monitoring of muscle
68 strength and enables the use of Z-scores or percentage of predicted values computed from
69 datasets and predictive equations (Hogrel et al., 2007; Harbo et al., 2012; Seymour et al.,
70 2010; McKay et al., 2016). Portable dynamometers have been demonstrated to be particularly
71 relevant for quantifying muscle strength at low-cost and ease of use within daily clinical
72 practice and multicenter research trials. Good agreement has been reported between isometric
73 strength measurement using hand-held dynamometry (HHD) and the “gold standard”
74 isokinetic dynamometer (Stark et al., 2011). However, evaluator strength limits the magnitude
75 of isometric force that can be measured using HHD (Deones et al., 1994). For powerful
76 muscle groups such as the quadriceps, belt-stabilization may be used to improve the reliability
77 and the range of measurable muscle strength using HHD (Bohannon et al., 2011; Bohannon et
78 al., 2012; Bachasson et al., 2014). However stabilized HHD is mostly achieved using home-
79 made methods that may be imperfectly adapted, may lead to discomfort and are unlikely to be
80 standardized for repeated testing (Hansen et al., 2015). Some approaches may also fail to

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3 81 provide accurate assessment of muscle strength in the weakest patients, partly due to design
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5 82 flaws and metrological limitations inherent in the hardware used, as typically observed in
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8 83 patients with muscle dystrophy for instance (Servais et al., 2013).
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10 84 The current manuscript introduces a novel portable device prototype (namely, the MyoQuad)
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12 85 for the assessment and monitoring of isometric knee extension strength that may be used in
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14 86 most clinical setups. This article is organized as follows: description of the device, evaluation
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17 87 of the device in patients including cross-validation with the gold standard, between-day
18
19 88 reproducibility of measurements and ability to monitor changes in muscle strength over time
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21 89 with the gold standard method as a reference.
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26 91 **Methods**

29 92 **Participants**

31 93 The device was tested in patients with inclusion body myositis enrolled in a natural history
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33 94 study (NCT00898989) and in a pharmacological trial (NCT02481453). The patients were
34
35 95 included according to the criteria defined by Benveniste and Hilton-Jones (2010). These
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38 96 studies conformed to the Declaration of Helsinki and were approved by the local ethics
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40 97 committee (CPP-Ile de France VI). All participants gave written informed consent. All tests
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43 98 were performed between April 2013 and April 2017.

45 99 **Description of the device for the assessment of isometric knee extension strength**

47 100 The device used in the present study was a first-generation prototype. The MyoQuad was
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49 101 specifically designed for the assessment of maximal isometric strength, even in very weak
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51 102 individuals. It embeds a high precision load cell (Interface SML-300, Scottsdale, Arizona,
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53 103 USA) and electronic board dedicated to signal acquisition and processing, wireless signal
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55 104 transmission (Bluetooth), and operating-energy controls. The current prototype has a
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57 105 measurement range from 0 to 136 kg with 10 g resolution and 50 g accuracy over the whole
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3 106 nominal range. The load cell and the board are included in a 3D-printed case, which can be
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5 107 firmly and securely attached to the structure of any examination bed/table using a clamp (see
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7 108 Figure 1A). A dedicated software was developed allowing the visualization and analysis of
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9
10 109 the acquired strength signal. The software can be run from a phone/tablet or laptop. One
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12 110 extremity of the load cell is equipped with a hook on which a strap can be attached (see
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14 111 Figure 1B). Other interfaces may also be screwed directly onto the load cell for other
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17 112 applications in traction and compression. The MyoQuad device was checked for calibration
18
19 113 using strict standardized operating procedures. A set of M3 class masses from 0.2 to 50 kg
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21 114 was used for calibration. The calibration was checked every week, then every month after 6
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23 115 months, then every 2 months after 12 months. The metrological properties of the device were
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26 116 always within the requirements (50-g accuracy over the whole range of measurement). A
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28 117 typical calibration curve is presented in Figure 2.

30 118 **Measurement protocol**

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33 119 Subjects were seated on a standard examination table with the hip and knee flexed to 90°. A
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35 120 small dense foam pillow was placed below the tested thigh (see Figure 1.A. and Figure 1.B.),
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37 121 so that the leg was vertical in order to avoid any effects of gravity effect, which can be
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40 122 detrimental for the assessment of very weak patients. The desired strap location (lower part of
41
42 123 the strap above the medial malleolus) and the medial tibiofemoral joint space were marked on
43
44 124 the skin. The distance between the two marks i.e. the lever arm, was carefully measured to the
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46 125 nearest half-centimeter using a measuring tape (Figure 2) to compute the torque as force \times
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48 126 lever arm, allowing direct comparison between methods (MyoQuad vs. isokinetic
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51 127 dynamometer). The ankle strap was then fixed and attached to the dynamometer. The height
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53 128 of the table was adjusted to ensure the strap was horizontal. Participants were asked to keep
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55 129 their hands on their thighs. The evaluator secured the patient at the thigh and shoulder levels
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58 130 on the tested side in order to limit compensatory movements.
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131 **Isokinetic dynamometer**

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

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

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

147 **Data analysis**

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

150 **Statistics**

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

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3 156 used to study absolute reliability. Relative reliability was assessed using intra-class correlation
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5 157 coefficients (ICC_{2,1}). Regression analysis and Bland–Altman plots were also performed.
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7 158 Individual coefficients of correlation were computed for between-day measurements and a
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10 159 paired sample t-test was used to compare individual coefficients of correlation between
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12 160 methods. The same approach was used to compare change between methods at follow-up. In
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14 161 addition, a two-way ANOVA (timepoint × method) was used to compare methods. Tukey’s
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16 162 honest significant difference post-hoc tests were conducted when a significant main and/or
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18 163 interaction effect was found. Least significant difference was defined as SEM × 2 and
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20 164 outcome at follow-up was defined as impaired, unchanged, and improved. A Fisher exact
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22 165 probability test was used to compare contingency tables of outcomes at follow-up. All
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24 166 analyses were performed in the computing environment R Version 3.2.3. Statistical
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26 167 significance was set at $p < 0.05$ for all tests.
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32 33 169 **Results**

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36 170 A total of 56 patients (age = 67 ± 9 years) with inclusion body myositis were included. Thirty-
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38 171 three patients were assessed for between-day reproducibility. Thirty-two of which were
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40 172 reassessed after 6 and 12 months. Amongst them, 29 were tested using both methods. The
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42 173 reason for the smaller number of patients at follow-up was time constraints or unavailability
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44 174 of the MyoQuad. Ultimately, a total of 287 observations using both methods were gathered.
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46 175 Agreement of methods are summarized in Table 1 and Figure 3. The MVIT measured using
47
48 176 the MyoQuad was significantly lower than the MVIT measured using the Biodex. Between-
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50 177 day reproducibility results for both methods are displayed in Table 2 and Figure 4. No
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52 178 systematic bias was detected and least significant difference was 4.9 and 5.3 Nm for the
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54 179 MyoQuad and the Biodex, respectively. Individual coefficients of variation for between-day
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56 180 measurements were 5.4 ± 7.4 % and 6.7 ± 6.6 % using MyoQuad and the Biodex with no
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3 181 significant difference between methods (mean of the differences = -1.4 Nm; 95% CI: [-3.7,
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5 182 0.9] Nm; $p = 0.26$).
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8 183 Change in MVIT at 6 and 12 months using both methods is shown in Figure 5. When
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10 184 performed using absolute values (at baseline, 6, and 12 months), ANOVA showed significant
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12 185 main effects of method and time (both $p < 0.01$) and no significant timepoint \times method
13
14 186 interaction ($p = 0.19$) (Figure 5.A). When performed using absolute changes at 6 and 12
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16 187 months, ANOVA showed significant main effects of method and time (both $p < 0.05$) and no
17
18 188 significant timepoint \times method interaction ($p = 0.46$) (Figure 5.B). Variability in changes
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20 189 between methods at follow-up is displayed in Table 3. A contingency table of outcomes at
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22 190 follow-up is shown in Table 4.
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27 28 29 192 **Discussion**

30
31 193 The aim of this study was to introduce a novel device for the assessment of isometric strength
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33 194 of knee extensors, for use in most clinical environments. Agreement with the gold standard,
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35 195 between-day reliability, and the ability of the device to monitor changes in muscle strength
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37 196 over time compared to the gold standard method as a reference were investigated. Main
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39 197 results are as follows: i) the device demonstrates excellent metrological accuracy, ii)
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41 198 measurements obtained using the device exhibit excellent agreement with the gold standard,
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43 199 iii) reliability of measurements obtained using the device was excellent and comparable to
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45 200 results obtained using the gold standard, iii) change in strength over time was similar using
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47 201 the device and the gold standard.
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52 202 The MyoQuad device was developed in order to conveniently assess quadriceps strength
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54 203 within routine clinical practice, including in very weak patients. This may be commonly
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56 204 performed using HHD, which, however, presents several limitations. In very strong patients,
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58 205 the evaluator may have difficulties in maintaining the dynamometer in a steady hold, whereas
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3 206 the influence of the evaluator may be too important in the weakest patients leading to possible
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5 207 large relative errors. Fixed dynamometers are attractive to tackle these limitations (Mentiplay
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7 208 et al., 2015). However, muscle strength may be improperly or even impossible to assess if the
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9 209 device is improperly designed. For instance, within a recent therapeutic trial in IBM, the
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11 210 system was designed in a way that patients had to carry the weight of the strain gauge before
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13 211 strength produced could be actually measured. As a result, knee extensor strength could not
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15 212 be measured in 3 out of 12 (25%) patients and the consistency of the measurements in other
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17 213 patients was largely flawed (unpublished results). The design of the proposed device tackles
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19 214 these issues as the MyoQuad is directly secured on a fixed frame. HHD have been repeatedly
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21 215 observed to underestimate knee extension strength compared to isometric measurements using
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23 216 an isokinetic dynamometer (Stark et al., 2011; Martin et al., 2006). This is particularly true in
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25 217 stronger individuals where the evaluator may have difficulties stabilizing the measurement
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27 218 chain (Martin et al., 2006; Bohannon et al., 2012). The high agreement between
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29 219 measurements performed using the MyoQuad and the Biodex support that fixed dynamometry
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31 220 improves the robustness of assessments through improved comfort and stability. These data
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33 221 are in line with previous work reporting higher consistency of measurements using a modified
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35 222 procedure of stabilized HHD as compared to standard HHD (Kim et al., 2014; Hansen et al.,
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37 223 2015).
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39 224 Our data shows a low SEM < 8.5 % Nm and high ICC > 0.98 for between-day reproducibility
40
41 225 when using the MyoQuad. This was similar to that observed using the Biodex (SEM was <
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43 226 10.0% and ICC was > 0.98). We also reported similar individual coefficients of variation for
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45 227 between-day measurement using the MyoQuad and the Biodex. This high reproducibility
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47 228 yielded similar least significant change using both methods. These data are in line with
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49 229 previous reports that have investigated between-day reliability using gold standard methods
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51 230 (Ruschel et al., 2015; Kean et al., 2010). Importantly, our data showed no significant
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3 231 difference between methods for monitoring change in MVIT over time (Figure 5) and good
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5 232 agreement when comparing changes at follow-up (Table 3). This was confirmed by consistent
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7 233 classification of strength changes using both methods at follow-up (Table 4). To the best of
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10 234 our knowledge, this is the first report that compares temporal changes in knee extensors using
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12 235 fixed dynamometry and standard isokinetic dynamometry.
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14 236 As this study was only performed in patients with inclusion body myositis, generalizability of
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16 237 findings to other disorders remains to be demonstrated. However, similar findings regarding
17
18 238 the reliability of MVIT have been previously reported in various clinical fields (Nuzzo et al.,
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20 239 2019). Volitional maneuvers such as maximal voluntary contraction embraces both peripheral
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22 240 and central factors, which render its estimation variable (Millet et al., 2012). Therefore,
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24 241 observed differences between Biodex and MyoQuad also reflect this variability. Another
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26 242 potential source of error using the MyoQuad is the measurement of the lever arm to compute
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28 243 torque that is circumvented when using torque meter as in standard isokinetic dynamometers
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30 244 like the Biodex (Ruschel et al., 2015).
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246 **Conclusions**

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

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3 **339 Tables**
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7 **340 Table 1. Agreement of measurements obtained using the MyoQuad and the Biodex (n =**
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9 **341 52 participants with a total of 283 measurements).**
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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]

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19 **342 CIM = change in mean; SEM = standard error of measurement; ICC = intra-class correlation**
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21 **343 coefficient.**
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346 **Table 2. Test-retest reliability of maximal isometric knee extension voluntary torque using**
 347 **the MyoQuad and the Biodex (n = 33 participants with a total of 66 measurements).**

Method	Test (Nm)	Retest (Nm)	CIM (Nm) [95% CI]	<i>p</i> 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]

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

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3 352 **Table 3. Variability of changes in maximal isometric knee extension voluntary torque at**
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5 353 **follow-up using the MyoQuad and the Biodex (n = 44 participants with a total of 88**
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7 354 **measurements).**
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Biodex (Nm)	MyoQuad (Nm)	CIM (Nm) [95% CI]	<i>p</i> 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]

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16 355 CIM = change in mean; ICC = intra-class correlation coefficient; SEM = standard error of
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360 **Table 4. Contingency table illustrating classified changes in strength using the MyoQuad**
 361 **and the Biodex.**

	<i>6 months</i>			<i>12 months</i>		
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%

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

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366 **Figure legends**

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

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

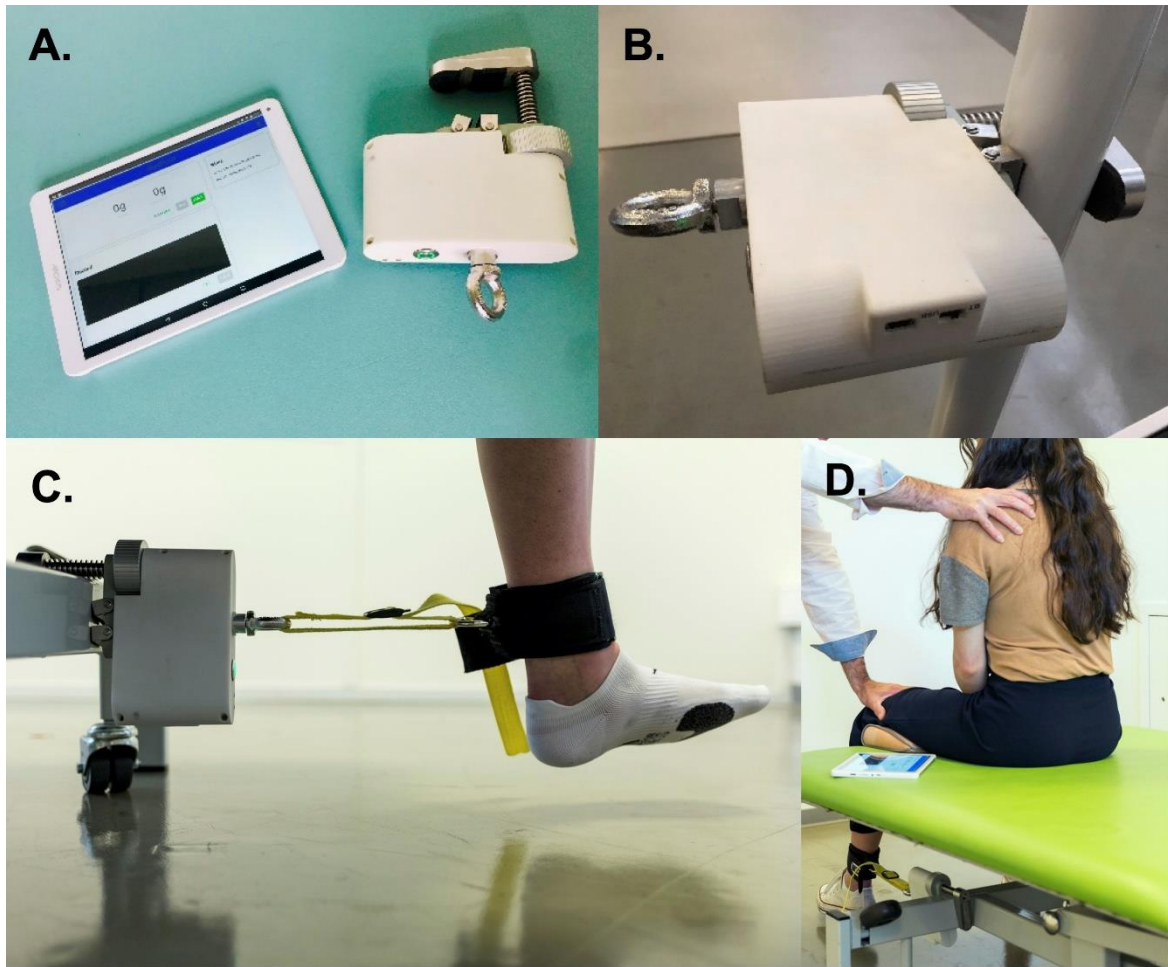
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376 **Figure 3. Agreement of measurements obtained using the MyoQuad *versus* the Biodex.**
377 **Bland–Altman plots (A) and regression analysis (B) of measurements obtained using the**
378 **MyoQuad and the Biodex.** In A, the solid line indicates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

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

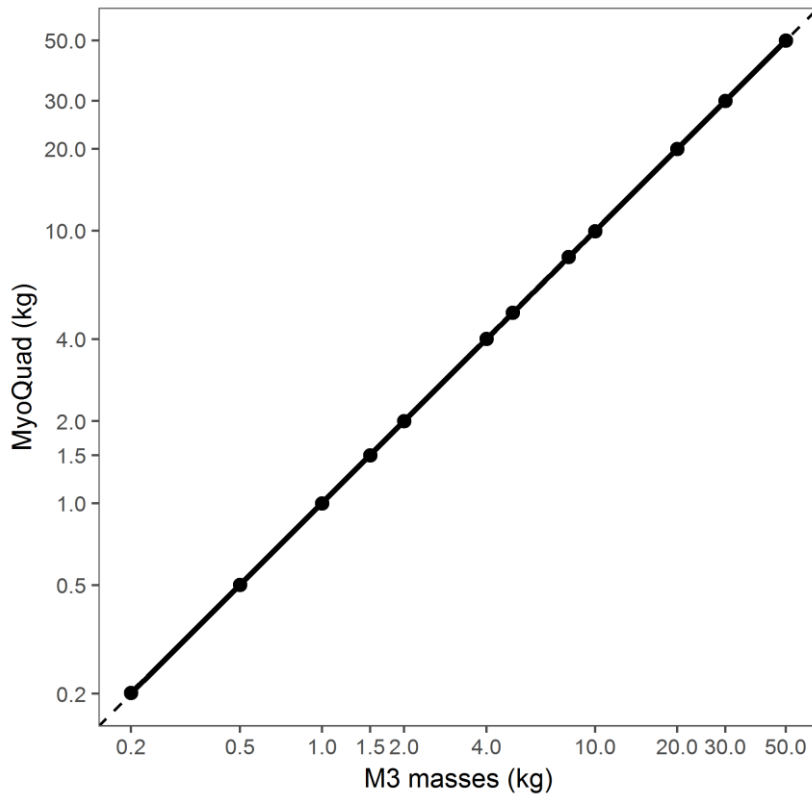
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3 390 **Figure 5. Change in torque over time using the MyoQuad and the Biodex.** Absolute (A)
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5 391 values and change (B) in knee extensor strength over time.
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393 Figure 1

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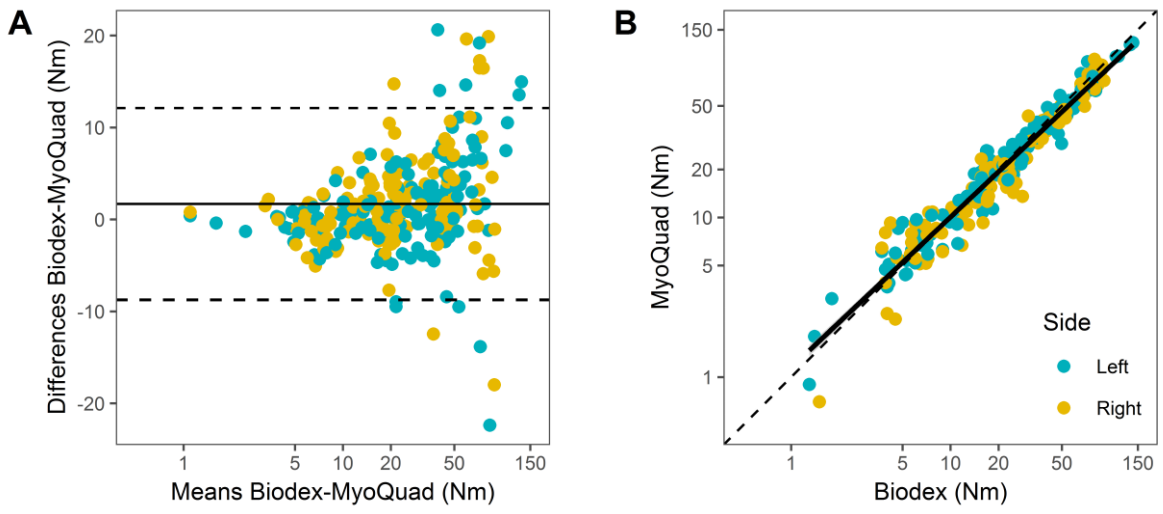
396 Figure 2



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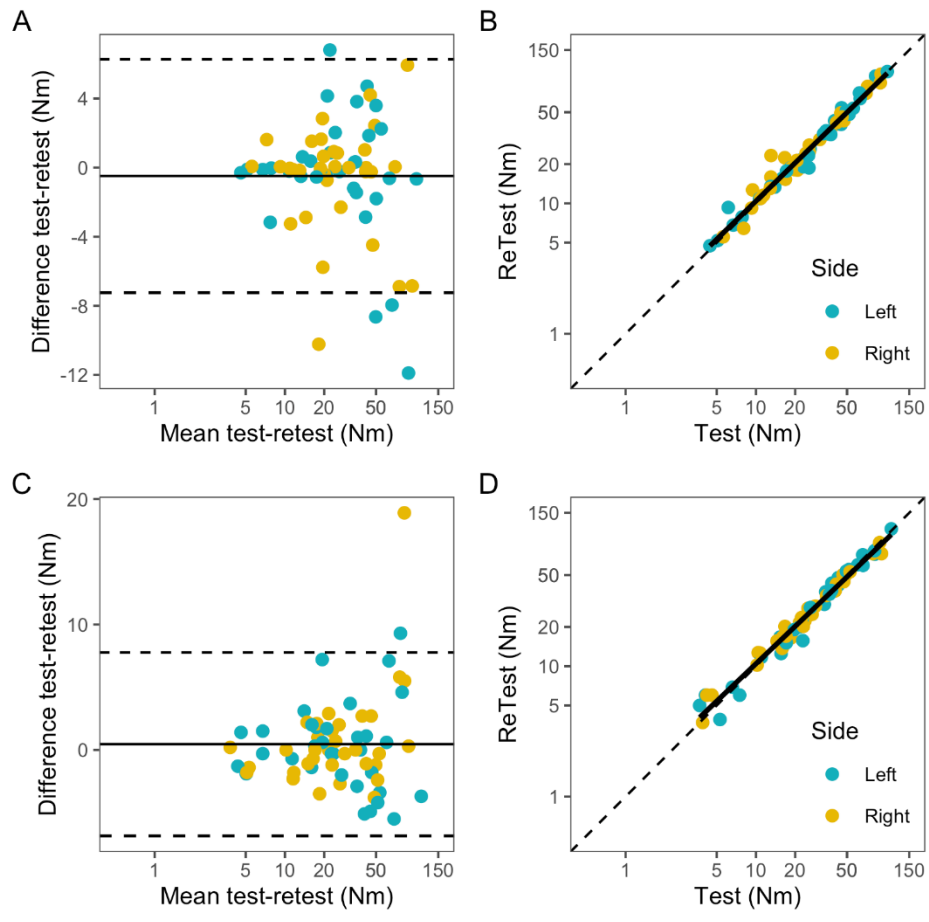
399 Figure 3



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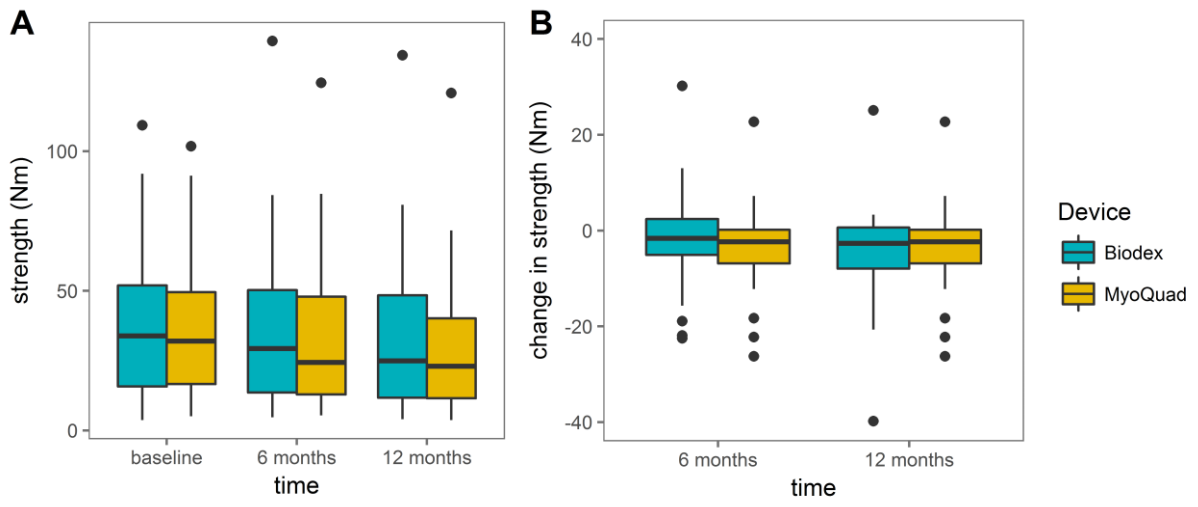
402 Figure 4



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405 Figure 5



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