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Development and validation of a palpation device for arbitrary muscle stiffness measurements within subjects

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Abstract

Objective: Neuromuscular disorders can often be quantified by the amount of muscle activity and is generally measured through electromyography. However, this method cannot provide arbitrary data as it only detects fluctuations in electrical potential. There is a need for arbitrary and standardised assessments of muscle tone to enable physiotherapists to make correct diagnoses. In this work, we present the rationale and results of a newly developed device to measure arbitrary muscle stiffness. *Approach:* Three prototypes were developed and iteratively improved. The first one relied on the theory of electrical impedance myography and the two other models managed a mechanical approach using a palpation probe and two reference areas. The final mechanical palpation principle was optimised and tested for two devices and two operators. The experiments were conducted in 39 subjects for left and right arm for relaxed and tensioned m. biceps brachii. *Main results:* The results show the reliability of the palpation device in terms of repeatability between identical measurements (ICC = 0.93), between different operators (ICC = 0.84) and between the two devices (ICC = 0.88). The device detects significant differences between relaxed and tensioned biceps brachii conditions ($p < 0.001$). *Significance:* The study indicates the feasibility of a mechanical muscle stiffness method to provide arbitrary data. The opportunities of the mechanical palpation device to identify variations in neuromuscular impairments in a reproducible procedure is confirmed. Further studies are required to evaluate the tonus of various muscles under diverse circumstances and to pinpoint further applications in clinical practice.

1. Introduction

Assessment of neuromuscular impairments is highly important in clinical practice to make correct diagnoses. The evaluation of neuromuscular impairments does not only reflect fitness or well-being, it also indicates neuromuscular deficit, which might cause pain and disability or even indicate neuromuscular diseases. Quantification of neuromuscular impairments can be obtained using muscle condition measurements (Simons and Mense 1998).

Muscle tone measurements provide an indication to which extent a muscle is tensed. An increased muscle tone indicates that the muscle or muscle group has an increased tension when it is in resting state. The interpretation of the muscle tone particularly relies on the subjective experience of the physiotherapist and on the pain perception of the patients (Leonard *et al* 2001). One mechanism to objectify muscular activity is electromyography (EMG). In EMG, electrodes placed near muscles detect and acquire fluctuations in electric potential to recognise differences between relaxed and tensioned muscles using the subjective modified Ashworth clinical scale (Sterpi *et al* 2013). However, EMG does not provide arbitrary data to detect variations in muscle tone (Hussain *et al* 2018).

An alternative method to assess muscle conditions is through electrical impedance myography (EIM) (Rutkove *et al* 2006, Sanchez and Rutkove 2017, Rutkove *et al* 2014). In EIM, a high frequency alternating current (± 1 mA, 10-4000 kHz) is applied through two electrodes placed onto subject's skin. The electrical current flows through the muscle since the resistance of the muscle is significantly lower than the skin-fat layer. The electrical current causes a voltage drop and a phase shift between the applied current and the measured voltage signal. The impedance and phase shift is measured with passive electrodes and enables muscle impedance measurements since the impedance changes depending on the tensioning of the muscle (Ogunnika *et al* 2008, Rutkove *et al* 2006). The electrical current prefers to flow through the muscle along the direction of the fibres. Therefore, Ogunnika *et al* (2008) proposed an integrated EIM device based on muscle anisotropy for improved accuracy and reproducibility of the measurements. However, a major difficulty in EIM is the dispersion of the current before reaching the muscle due to the skin-fat layer (Rutkove 2009). Furthermore, the positioning of the electrodes on irregularly shaped surfaces as body parts is an issue as well. The positioning causes insufficient contact with the skin, which impedes the correctness and reproducibility of the measurements (Rutkove *et al* 2006).

In addition to EMG and EIM, also a mechanical approach to determine muscle condition is available. In the mechanical principle, the parameter to quantify neuromuscular impairments is the muscle stiffness, which is defined as the rigidity for deformation by applying forces on the muscle (Chuang *et al* 2012). This value is defined as the ratio between the applied force and the displacement induced by this force. The mechanical principle is used in the Myoton digital palpation technology, where a probe is pushed on the muscle to be measured. The palpation probe applies a certain force and induces a tissue displacement, which can be measured and converted in an arbitrary muscle stiffness value (Pruyn *et al* 2016, Jarocka *et al* 2012, Gubler-Hanna *et al* 2007, Leonard *et al* 2001). The main error in the current Myoton device appears in measuring muscle stiffness of small and thin or elusory muscles as in obese patients (Chuang *et al* 2012).

The purpose of this study was to obtain a scientifically, arbitrary and reproducible muscle tone measurement device in an easy-to-use manner for both user and subject to evaluate muscle tone changes. Both EIM and the mechanical approach provide interesting opportunities but currently have limitations (Rutkove 2009, Rutkove *et al* 2006, Chuang *et al* 2012, Hussain *et al* 2018). To find a valid device, it was first investigated if the EIM method by Rutkove (2009) could be optimised to assess muscle tone correctly. Subsequently, a mechanical muscle tone device was developed to improve the mechanical measuring method, evolving over multiple versions.

2. Methods

Three types of prototypes were developed along different measurement principles: a first prototype to assess muscle tone with EIM measurements, a second one that relies on mechanical properties and a third one, also with underlying mechanical measurement principle optimised towards usability and potential industrial production. This last one is currently considered for commercialisation (EP17207883.4) and was duplicated to investigate the consistency during muscle stiffness measurements on the m.biceps brachii between different subjects and operators.

2.1 Prototype I: EIM method

Firstly, the EIM mechanism (Ogunnika *et al* 2008, Rutkove 2009) was reproduced to evaluate difficulties in the original mechanism. In the initial principle, four electrodes were positioned in line on the muscle, each attached to interconnected air chambers to distribute air pressure equally over the electrodes and to ensure tight contact with the skin. An alternating voltage of 20 V (frequency 10 kHz) was applied across the two outer electrodes in series with a resistor, which restricted the amplitude of the current. The two inner electrodes were measuring points for the oscilloscope to measure the impedance value of the muscle. A prototype was developed that automatically adapts to geometric and elasticity variations to hold the measuring quantity of the muscle length consistent for various muscle conditions. However, the current was not returning through the skin to provide muscle tone values measurable at the oscilloscope measuring points (Verelst *et al* 2014).

To avoid this issue, an improved model only used two electrodes in combination with one reference area (Figure 1). The oscilloscope measured the voltage across the resistor to calculate the impedance of the muscle and avoid the influence of the skin-fat layer. The method was based on connected air chambers and flexible materials and ensured a perpendicular positioning on the muscle of the three electrodes (Baelus *et al* 2016). By contracting the muscle, the impedance and thus also the muscle tone increased, but simultaneously the distance between the electrodes and muscle decreased. This caused varying distances from electrode to muscle in two different muscle conditions. Therefore, detect changes in muscle tone between two muscle conditions was irrelevant in this electrical approach. It was impossible to detect the influence of both electrode-muscle distance and muscle tone variation separately, which impeded practical applications. Therefore, a mechanical approach was followed as in Prototype II.

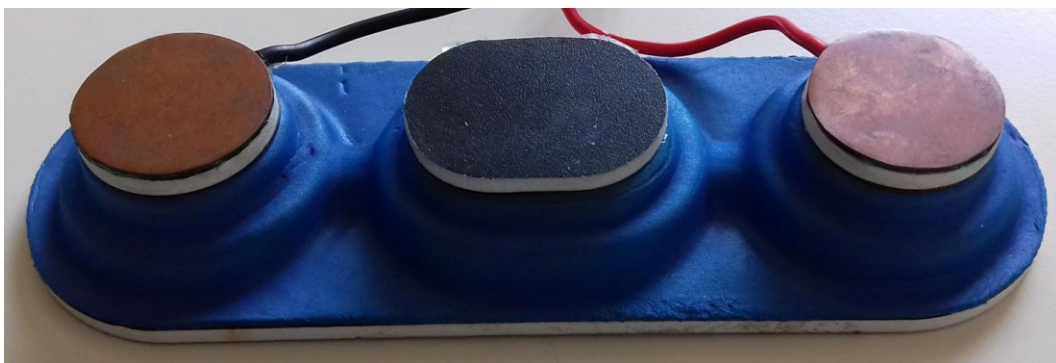


Figure 1. Practical model of prototype I using the EIM method. Two outer electrodes are used to perform impedance measurements, where the middle one is only used as reference area with the body. Interconnected air chambers and flexible materials ensured the perpendicular positioning of the electrodes on the muscle. An applied alternating voltage provided muscle impedance measurements.

2.2 Prototype II: Mechanical approach

The mechanical method for measuring muscle condition is elaborated and verified in the Myoton device. However, the disadvantage is that this method causes problems in small or elusive muscles

(Chuang *et al* 2012) and that the device inevitably interacts with the tissue by positioning the probe on the tissue. This interaction causes damping and might induce error, affecting accuracy and repeatability. Regarding this concern, we proposed a model where the tissue was fixated around the palpation probe using two reference areas, such that the distance to the skin is zero at the reference contact plane.

2.2.1 Version 1

The first mechanical version is shown in Figure 2. The reference contact plane [A] avoids balance and ground truth issues, which occur since the user's magnitude and angle of pushing is never consistent. The reference plane consists of two ring-shaped reference areas, spread apart by 100 mm to stay outside the muscle belly. The reference areas maintain a constant contact with the patient's skin to ensure a reproducible relative position of the device towards the subject's body. The reference areas are automatically substantially tangent onto the user's skin when the device is placed on the subject's muscle in the longitudinal direction. At both reference areas, two force sensors with an accuracy of 0.025 N and range 2.0-20.0 N were fitted to indicate when a perfect predefined amount of contact pressure on the reference plane appears.

The probe [B] extends through the reference plane and is attached to a series of pulling springs to restrict the size and guarantee a comfortable and accurate measurable palpation force. The probe pushes into the patient's skin and underlying muscles and varies in length depending on the counter force of the muscle. The depth by which the probe is pushed against the patient's skin and muscle is measured using an analog potentiometer (range 30 mm) and an analog-to-digital converter, which results in a resolution of 0.03 mm. For reliable and accurate measurements, it was ensured that the probe always interacts with the skin along the same direction, substantially perpendicular to the subject's tissue.

A combination of these hardware parts with a microprocessor was used to calibrate the device. The mechanism analyses the correctness of the force sensors in the reference plane by comparing the values with a predefined calibration range of 1.0 N. After checking this requirement, the device can measure the potentiometer's potential on the probe, which supplies an indication of muscle stiffness using a conversion via the spring constant.

However, this prototype had deficits in user-friendliness for both operator and subject. Firstly, applying equal pressure at both ends of the reference plane required adequate skills of the practitioner, but also caused pain for the subjects. Secondly, the applied force on the device influenced the outcome value of the palpation measurement as the distribution of forces was not substantially equal for both reference areas. Furthermore, the accuracy of the potentiometer and force sensors were expected to obtain improvements, which could be accomplished using alternative and additional sensors as accomplished in version 2.

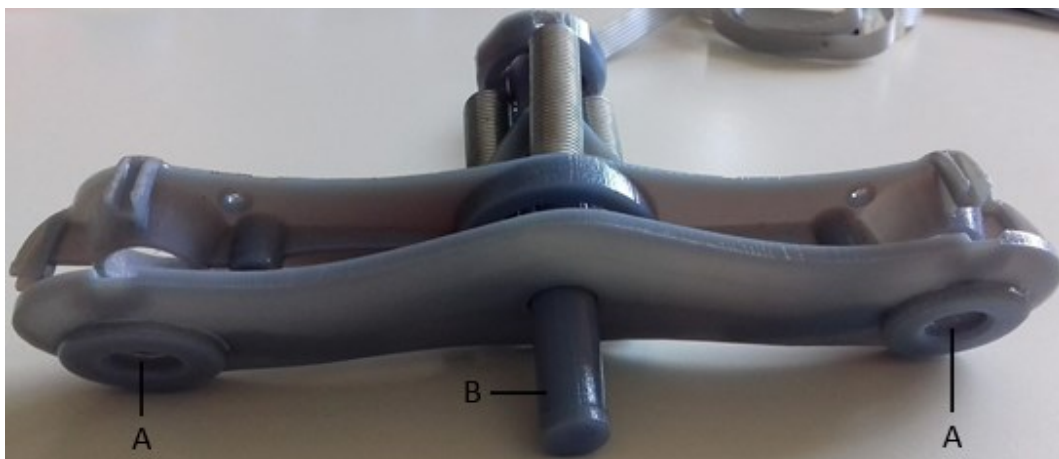


Figure 2. Version 1 of prototype II using the mechanical approach consisting of a reference plane with two reference areas [A] and a palpation probe [B]. The probe is positioned in the centre of the muscle and the reference areas ensure tight contact with the skin. The displacement of the probe is dependent on the muscle tone and represents an indication of muscle stiffness.

2.2.2 Version 2

The second version improved the ease of use by adjusting the reference plane and appending extra sensors. An air-chamber system connecting both sides of the device was employed to consistently obtain an equal force balance when pushing down the device. The interconnected air chambers spread the force equally over both sides to provide improved balance for the practitioner. Furthermore, a pressure sensor checks the air quantity in the air chambers to keep the mechanism working.

An optical distance sensor with sevenfold better accuracy (range 8-64 mm) substituted the potentiometer. Furthermore, the prototype was complemented with a surface skin temperature sensor to receive temperature changes at the contact surface. The upgraded device suggested improvements for the final prototype III, but evinced risks in implementing and towards industrialization as the air chamber system was not hermetically sealed.

2.3 Prototype III: Optimised mechanical model

2.3.1 Measurement principles

Figure 3 shows a scheme of the technical setup of the final prototype consisting of the central palpation probe [1] to be pushed down onto subject's muscle and the reference plane [2] with reference areas on each side. The reference plane consists of two sensors, one on each side, to verify the symmetry of the applied force. To obtain consistent measurements, the perpendicular applied force on the skin should be constant in the reference areas. Therefore, the muscle stiffness measurement of the palpation probe is compensated depending on the measurement of the force sensors.

During measurements, the palpation probe is placed at the centre of the muscle to be measured. The practitioner holds and pushes down the device by the swiveling handle [4], which acts as a reverse balance to ensure a substantially equal distribution of the force along both reference areas. Equally force distribution is consistently guaranteed whether or not the swiveling handle is pushed perpendicular to the subject's body and is no longer the operator's responsibility. In this way, the reference plane is positioned substantially parallel onto the subject's skin. Since the palpation probe is attached perpendicular to the reference plane, it also interacts perpendicular with the muscle. To push down the probe onto subject's skin and underlying muscles in a comfortable way, a spring [5] is used which also determines the palpation force. Muscle stiffness is calculated using a potentiometer and analog-to-digital converter, as the implementation of the optical distance sensor is impeded by the housing. Lastly, a force sensor [3] is applied between the palpation probe and the swiveling handle to check the palpation force.

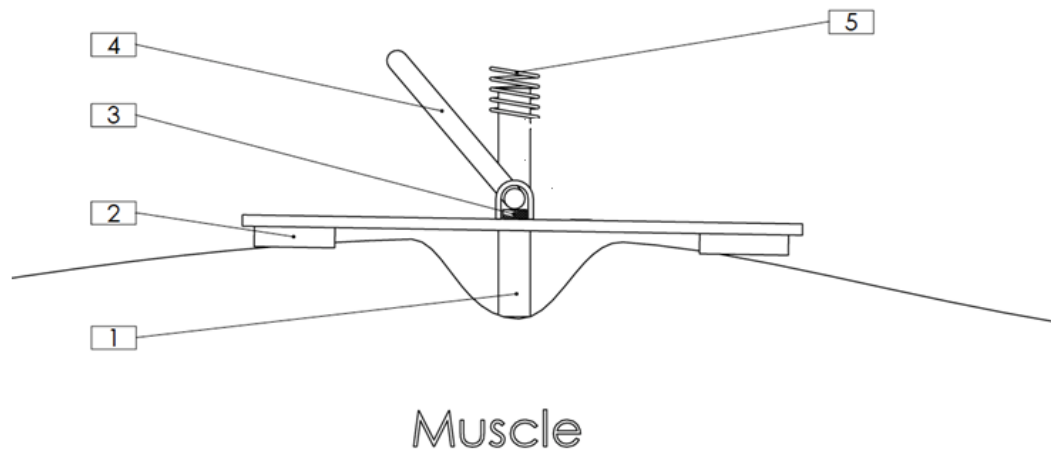


Figure 3. Measurement principle of the optimised mechanical prototype III consisting of [1] palpation probe, [2] reference plane with two reference areas, [3] force sensor, [4] swiveling handle and [5] spring. The swiveling handle ensures equally force distribution on both reference areas and perpendicular palpation to the muscle.

2.3.2 Practical design

The last prototype optimised the usability and efficiency using a 3D printed design as in Figure 4(a). Arbitrary values between 80 and 4000 are obtained on a linear scale using average values of ten measurements. Arbitrary values are used since there is no reference value for muscle stiffness and it is impossible to compare values between diverse muscles and subjects. These arbitrary measurements give an indication of muscle stiffness and make the interpretation of the variation and evolution of repeated identical muscle stiffness measurements within subjects relevant. To guarantee the inter-device reliability, a calibration method based on reference blocks from Figure 4(b) is used. Three reference blocks are used to calibrate novel devices and check the consistency of the devices before and after use. Calibration block 1 accords a completely relaxed arbitrary muscle stiffness value of 80. Block 3 represents a tensioned muscle with an arbitrary value of 3200. The last calibration block has an arbitrary value in between both previous ones of 1820.

The development of an accompanying App facilitates the execution of the measurement and provides automatically obtained muscle stiffness values as in Figure 4(c). The App visualises the correct use of the device in five steps: 1) the connection of the device with the App, 2) the confirmation of a successful connection by a green led, 3) an indication to hold the device by the swiveling handle and 4) to hold the handle centred, and 5) a reminder to press down the device slowly. As one of these steps is performed incorrectly, the led turns red and the App provides feedback on how to correct the measurement technique.

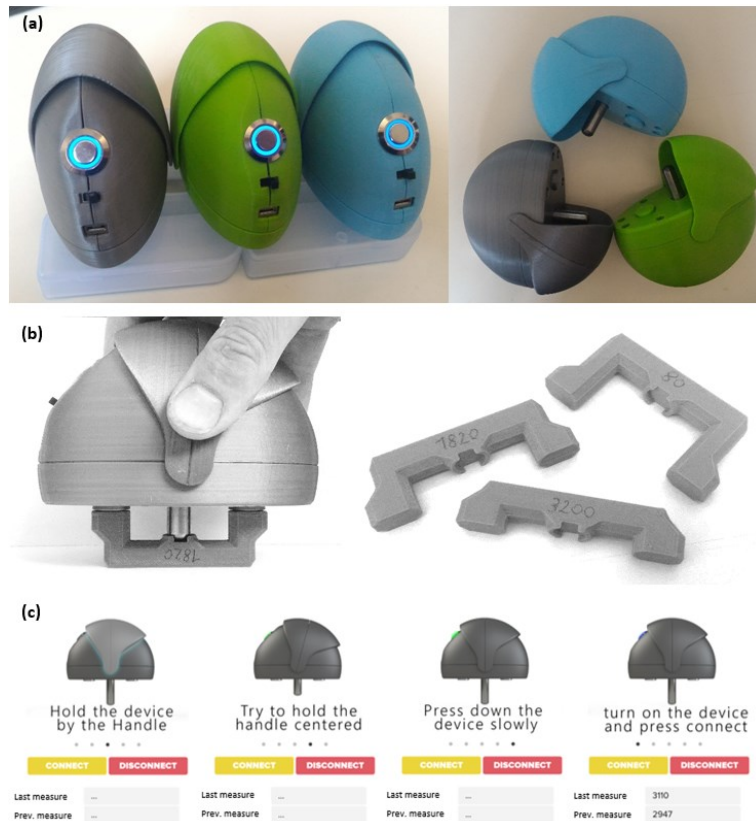


Figure 4. Practical model of prototype III, optimised for improved usability. (a) Identical devices of the prototype are developed according to the model in Figure 3. (b) Three calibration blocks are used for the calibration method to check the consistency of the palpation device, where block 1 represents a relaxed muscle (80), block 2 an average muscle tone (1820) and block 3 a tensioned muscle (3200). (c) App to clarify the use of the palpation device and to represent muscle stiffness measurement values.

2.4 Experiments and analysis

Firstly, a validity analysis was performed to verify the spring constant of both devices of prototype III to determine if the measurement values of the palpation device could be compared for specific muscle stiffness measurements within subjects and muscles. The palpation device was stabilized on a container which was placed on a scale on a 3D printer (Figure 5). The probe was pressed in steps of 1 mm until complete impression. Both force (on the scale, accuracy ± 1 g) and displacement (on the printer, accuracy ± 5 μ m) were determined to calculate the spring constant using a linear relation between force and displacement as in the following formula: *spring constant* $\left(\frac{N}{m}\right) =$

$$\frac{\text{force (N)}}{\text{displacement (m)}}$$

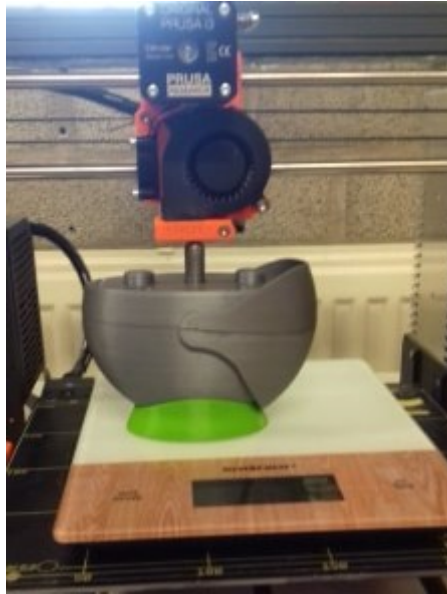


Figure 5. Validation of the spring constant of the palpation device. The device was positioned on a container. The 3D printer pressed the probe until complete impression and provides the displacement of the probe for each step. The known displacement could be represented as a function of the force measured on the scale.

The aim of the muscle stiffness measurement device was to detect changing muscle tone in an objective way. The feasibility was validated in a clinical study in 39 subjects for two palpation devices from Fig 4(a). In total, 35 subjects were right-handed and 29 were male subjects. Subject's age was 28 ± 12 years and their BMI was 22.1 ± 3.7 . Ethical filling of the University Hospital Antwerp (reference: B300201628307) was obtained and informed consent was accessed from all subjects. The consistency of the devices was checked using the reference blocks by performing the calibration procedure before and after the measurements. The mean relative error before and after measurements of the two devices compared to the standardised calibration values was calculated and analysed for three calibration blocks using the following formula: $\overline{\text{relative error (\%)}} = \frac{\text{value using calibration block} - \text{calibration value}}{\text{calibration value}} * 100$.

Furthermore, the efficiency of the palpation device was investigated on the m. biceps brachii for left and right arm. Initially, subjects were asked to lift a 4 kg weight while resting the elbow to indicate the centre of the short head of the biceps brachii for positioning the palpation probe. Subsequently, the two devices were tested on relaxed and tensioned biceps brachii using muscle stiffness values from the App. For measurements at rest, subjects were demanded to rest their arm on a table with hand palm upwards. Two operators (researcher A and subjects themselves B) performed three repetitions of the palpation measurement for the two devices for left and right biceps brachii. Subsequently, the same experiments were repeated while subjects raise the 4 kg weight to tension the biceps brachii muscle.

To validate the reproducibility of the device, variations in measurements between repetitions, operators and devices were analysed. The mean absolute error (MAE) between the repetitions was calculated for left and right as well as relaxed and tensioned biceps brachii to indicate the consistency of the measurements. Secondly, the Intraclass Correlation Coefficient (ICC) (Weir 2005) investigated the reliability of the measurements during the three repetitions. The Two-Way-Random ICC-model (type absolute agreement, since the between measures variance was included from the denominator variance) was calculated for the entire dataset.

Furthermore, the accuracy of the two devices (1 and 2) was analysed using average values of three repetitions. Again, MAE was determined for all operator-subject combinations (n) for the four

conditions as $\sum_{i=1}^n \frac{|\bar{1}-\bar{2}|}{n}$. The agreement of the values of apparatus 1 and 2 were studied using ICC.

The same MAE interpretation ($\sum_{i=1}^n \frac{|\bar{A}-\bar{B}|}{n}$) and ICC test was repeated for between operators analysis.

Lastly, the paired samples t-test was performed to investigate the significance of the difference between relaxed and tensioned biceps brachii values. All measurements of the left and right side were included to perform this test. The Repeated Measures ANOVA test indicated the variations between the 39 subjects.

3. Results

The validation of the spring constant provides a linear relation between applied force and displacement, which is 280 N/m for the first device and 271 N/m for the second device. The correlation between force and displacement is > 0.99 ($p < 0.001$) for both devices. Figure 6 shows the relative errors occurring during the calibration. The maximal MAE is 43 and appears for the second device at the last calibration block (3200).

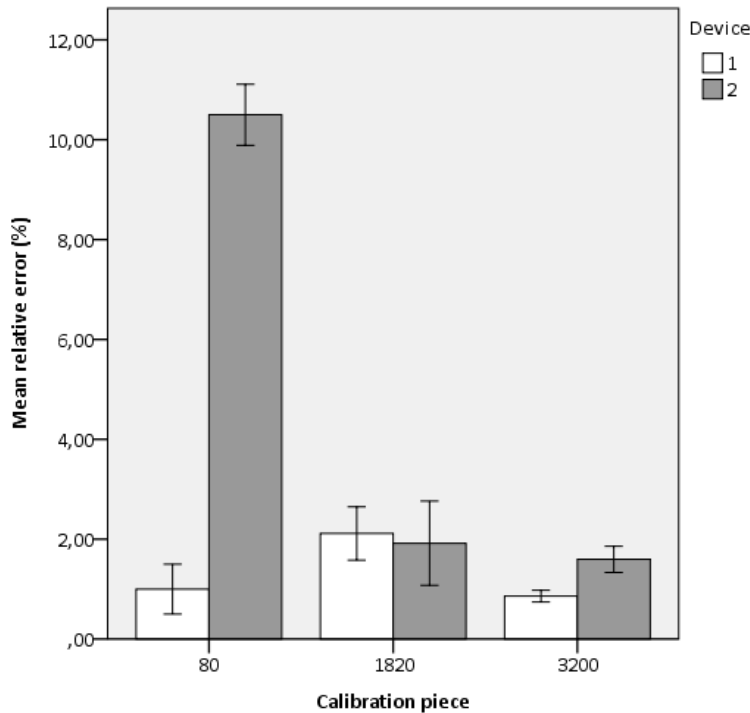


Figure 6. Mean relative errors and standard error during calibration before and after the measurements for two similar devices (1 and 2) of prototype III and three calibration blocks with accompanying values (80, 1820 and 3200).

The MAE and accompanying standard error between three repetitions per condition and average MAE is summarised in Table 1. The ICC between the three repetitions is 0.93 ± 0.0050 ($p < 0.001$).

Table 1. Summary of MAE values and standard errors between three repetitions for the four conditions and average MAE.

Condition	MAE inter repetitions
Relaxed Left	76 ± 4
Relaxed Right	87 ± 4
Tensioned Left	59 ± 3
Tensioned Right	62 ± 3
Total	71 ± 2

Table 2 shows the average relaxed and tensioned muscle tone values for device 1 and 2 and for operator A and B. Table 3 summarises the MAE between two devices and between two operators. The ICC between devices is 0.88 ± 0.027 ($p < 0.001$) and the ICC between the operators accords with 0.84 ± 0.019 ($p < 0.001$).

Table 2. Average muscle stiffness values and standard errors for relaxed and tensioned condition for the two devices (1 and 2) of prototype III and two operators (A and B). For the values of device 1 and 2, measurements of both operator A and B were included. Similarly for operator A and B, measurements of both device 1 and 2 were included.

	Condition
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Device/Operator	Relaxed	Tensioned
1	2766 ± 14	3071 ± 21
2	2699 ± 15	3044 ± 22
A	2726 ± 15	3063 ± 22
B	2739 ± 16	3052 ± 21

Table 3. Summary of MAE values and standard errors between two devices 1 and 2 and between two operators A and B for the four conditions and average MAE.

Condition	MAE inter devices	MAE inter operators
Relaxed Left	131 ± 11	127 ± 12
Relaxed Right	127 ± 9	141 ± 13
Tensioned Left	96 ± 9	99 ± 12
Tensioned Right	91 ± 8	111 ± 11
Total	111 ± 5	120 ± 6

Lastly, the paired samples t-test shows a significant difference between relaxed and tensioned biceps brachii ($p < 0.001$). The average muscle stiffness value of relaxed measurements is 2733 ± 11 , while the average tensioned value is 3057 ± 15 . The 95% confidence interval of the difference between both conditions is [296; 354]. The correlation between relaxed and tensioned measurements is 0.41 ($p < 0.001$). Figure 7 confirms the expected variations in values between the 39 subjects from the Repeated Measures ANOVA analysis ($p < 0.001$). There is no difference between measurement values on the left and the right side (paired samples t-test, $p = 0.42$).

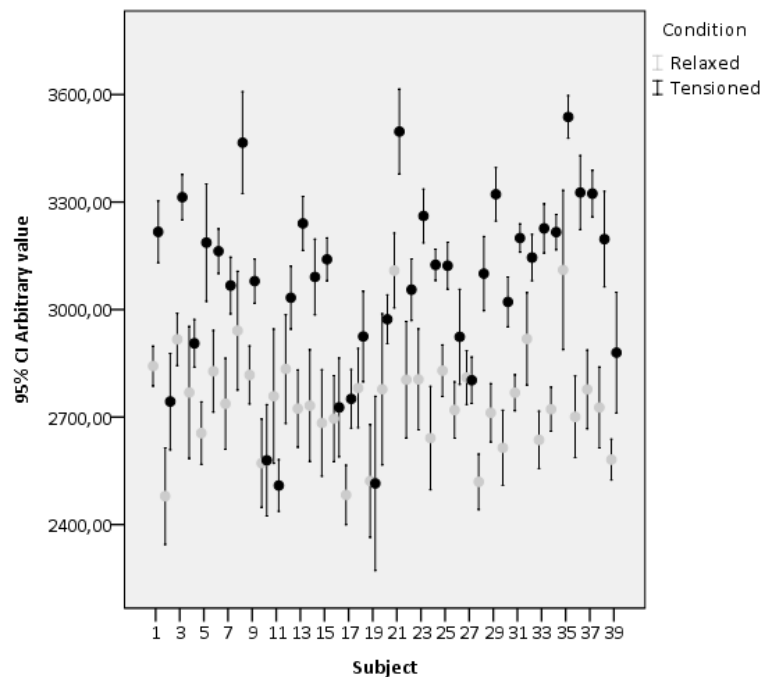


Figure 7. Variations in average relaxed (grey) and tensioned (black) muscle stiffness values and 95% confidence intervals (CI) for the 39 subjects.

4. Discussion

4.1 Evolution palpation device

Muscle tone measurements can objectify and prove the effectiveness of physiotherapeutic manipulation (Simons and Mense 1998). Ubiquitous EMG signals can detect differences between relaxed and tensioned muscles, where this paper describes the evolution of three prototypes to measure arbitrary muscle conditions. EIM and the mechanical principle indicate major opportunities to provide accurate and reproducible muscle stiffness measurements (de Hillerin *et al* 2015). In this study, firstly the EIM principle (Rutkove 2009) was optimised. However, obtaining reliable muscle tone measurements was not achieved since external factors as the skin-fat layer depth influence the muscle impedance. Therefore, our research encourages to follow a mechanical approach.

The first mechanical prototype was an improved version of the Myoton device (Gubler-Hanna *et al* 2007, Jarocka *et al* 2012, Pruyn *et al* 2016) and used a reference plane to eliminate the interaction effect between the palpation probe and the tissue to quantify the muscle conditions. The development finally led to a user-friendly third prototype. The palpation device makes use of a swiveling handle to ensure an equal distribution of forces on both reference areas and guarantee reliable muscle stiffness measurements within subjects as the palpation probe is consistently perpendicular positioned on the muscle. Applying a spring on the palpation probe increases the resistance during palpation to ensure a slow impression of the muscle to eliminate the influence of the skin layer. However, the resistance due to the spring might not impede the comfort of practitioner and subject and should provide a balance between comfort and quality of the measurement. The prototype is reproduced to determine the reliability for industrial application.

4.2 Reproducibility muscle stiffness data

The palpation device is validated in terms of accuracy and repeatability. The limitation of this validation is that there is no gold standard method to compare our arbitrary muscle stiffness measurements with. We can compare our results with validated techniques as ultrasound elastography or MR elastography, although this cannot directly confirm the accuracy of the arbitrary outcome values. Therefore we validated the spring constant using a verification set up. Our validation shows that the spring constant is consistent between different displacements and forces for both devices. This makes it possible to compare values within subjects and muscles and between both devices. The calibration method demonstrates that the maximal relative deviation for two produced devices is 10.5 %, appearing for the second device for the relaxed calibration position (80). However, the error is not manifest for the second (1820) and third (3200) calibration block, where the two devices achieve similar relative deviations. There is no consistent error for one of the devices during the calibration, which confirms the usability of the devices during the experiments. The aim of this study was to validate the consistency of the device. Therefore, the measurements were repeated on the same m. biceps brachii on same subjects. Comparing these values between subjects and different muscles is not relevant without taking into account extra factors as body mass index (BMI) and muscle location, which was therefore neglected in this study.

In the experiments, the ICC is excellent between three repetitions and between both devices and operators (ICC > 0.83) (Cicchetti 2001). Table 1 shows the variation in MAE of three repetitions between left and right side for relaxed and tensioned biceps brachii and indicates that the MAE is similar for the four conditions. Whether or not tensioning the biceps brachii has no influence on the accuracy of the measurement. The MAE between the two operators is 120, which is slightly higher than between several repetitions by one person, which induces the way practitioners use the device still has a minor effect on the muscle stiffness outcome. Table 2 and 3 show that the two devices provide similar MAE for both relaxed and tensioned conditions.

The mechanical method provides high resolution muscle stiffness data in an easy and comfortable manner for both operator and subject. The difficulty is found in the inconvenience to apply muscle tone measurements over time exactly at the centre of the muscle, which causes alterations in

outcomes. The consequence is that minor differences in muscle tone are not measurable and should be considered as equal values. To expect more accurate values or to detect minor differences between measurements, more repetitions per measurement are required.

Lastly, there is a moderate correlation between relaxed and tensioned biceps brachii muscles ($r = 0.41$). Differences between relaxed and tensioned biceps brachii are clearly noticeable using the palpation device. Generally, a difference in measurements higher than 296 indicates that there is a difference in tensioning of the biceps brachii muscle. This value slightly deviates for each individual person as muscle stiffness is person-specific (Figure 7). The disadvantage of this method is the lack of reference values of muscle stiffness as these are dependent on the subject and the muscle to be measured. Since each subject and muscle is different, it is unfeasible to compare them and therefore arbitrary muscle stiffness values are used. These values, however, can provide an indication of the evolution of repeated identical muscle stiffness measurements to make clinical diagnoses.

4.3 Clinical implications and future work

Generally, the palpation device has possible applications in musculoskeletal rehabilitation and neurology in the medical field, e.g. to see changes in muscle tone as a result of treatment, and in the detection of fatigue/overtraining and for injury prevention/recovery in sports. In both domains, the efficacy of this technique should be further examined.

Future studies should reveal the exact influence of variations in the arbitrary muscle stiffness values. Differences in muscle stiffness between more states of tensioning of the biceps brachii muscle should be considered. More variations in the weight to be lifted can gain insight into changes in various muscle conditions (Alamäki *et al* 2007). Furthermore, the long-term effect on muscle tone should be investigated by repeating the experiments for several weeks. Also, the effect for other muscles than biceps brachii, like these of the lower limbs, should be evaluated, as well as the influence of fat percentage and length and thickness of the muscle as this has an influence on muscle tone (Alamäki *et al* 2007). Also, parameters as gender, physical fitness, age, BMI, joint condition and range of motion influence muscle tone (Agyapong-Badu *et al* 2016) and should be considered in future studies. As these factors influence the results of the muscle stiffness measurements, the influence thereof should be analysed in in-depth studies. More extensive experiments in combination with techniques as muscle ultrasonography as used in (Avrillon *et al* 2018, Niitsu *et al* 2011) can be used to investigate the exact influence of extra factors on the outcome value as well as the reliability of the proposed palpation technique.

Muscle tone is also related to biomechanical performance, fatigue and recovery after sports performance (Wilke *et al* 2016). Furthermore, literature in EIM states that the impedance of the muscle in resting state does not return to its initial value after tensioning the muscle (Shiffman *et al* 2003), which should be investigated with the mechanical palpation device. Therefore, a follow-up study should investigate the effect of physical effort on the muscle stiffness by comparing measurements before and after labour.

5. Conclusions and future work

This study reports the working principle of three devices to measure muscle tone and validated the final mechanical prototype in his repeatability. The improvements of the final palpation device consists of adding a reference plane and swiveling handle to provide arbitrary muscle stiffness measurements which are repeatable within and between devices and operators. The mechanical palpation device is reliable and consistent for repeatable muscle stiffness values for a specific muscle of one subject. The analysis indicates opportunities for physiotherapists to detect the grade of muscle stiffness and to follow up muscle stiffness evolution to make accurate diagnoses for muscle pain.

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