Principles of brain plasticity in improving sensorimotor function of the knee and leg: A double-blind randomized exploratory trial

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Abstract

Background: Training is included in the treatment of knee injury to improve patient-reported function and sensorimotor function. However, impairment in sensorimotor function often persists despite training. Therefore, it was suggested that training programs need to be more effective to improve sensorimotor function after knee injury. The aim was to investigate if principles of brain plasticity that have been successfully used on the hand and foot to improve sensorimotor function can be applied on the knee. We hypothesized that temporary anesthesia of the skin area above and below the knee would improve sensorimotor function of the ipsilateral knee and leg.

Methods: In a first double-blind exploratory study, 28 uninjured subjects (mean age 26 years, range 19-34, 50% women) were randomized to temporary local cutaneous application of anesthetic (EMLA®) (n=14) or placebo cream (n=14). Fifty grams of EMLA, or placebo, was applied on the leg 10 cm above and 10 cm below the center of patella, leaving the area around the knee without cream. Measures of sensory function (perception of touch, vibration sense, knee kinesthesia) and motor function (knee muscle strength, hop test) were assessed before and after 90 minutes of treatment with EMLA or placebo. The paired t-test was used for comparisons within groups and the independent t-test for comparisons between groups. The number of subjects needed was determined by an a priori sample size calculation.

Results: No statistically significant or clinically relevant differences were seen over time (before vs. after) in the measures of sensory or motor functions in the EMLA group or in the placebo group. There were no differences between the groups in effects of treatment (EMLA vs. placebo).

Conclusion: We found no effect of temporary cutaneous anesthesia on sensorimotor function of the ipsilateral knee and leg in uninjured subjects. The principles used in this study remain to be tested in subjects with knee injury.
Background

Training is included in the treatment of knee injury and knee osteoarthritis (OA) to improve patient-reported function and objective function, such as joint range of motion and sensorimotor (neuromuscular) function. However, impairment in sensorimotor function often persists after knee injury and knee OA despite training [1] [2] [3]. It has been suggested that good sensorimotor function is of importance for reducing the risk of knee injury [4] [5], for achieving better objective and patient-reported knee function after injury [6] [7], and in preventing or slowing the progression of OA [8] [2]. Longitudinal, prospective studies show that poor muscle function, such as muscle weakness, is a predictor of OA development [9] [10] [11]. In this perspective, any treatment leading to improved sensorimotor function would be of value for patients with knee injury or OA in the short and long term.

The primary motor (M1) and sensory (S1) cortex is organized somatotopically, where different body parts project to different parts of the M1 and S1. The somatotopic map does not represent the body in its actual proportions [12] [13]. Instead, larger cortical areas are being assigned to sensitive parts or parts with complex motor demands such as the hands and face [14] [15]. The cortical representation of different body parts changes constantly, depending on the pattern of afferent nerve impulses, injury and increased or decreased use [16] [17]. In order to improve sensory and motor function, more nerve cells are needed [18]. For example, the forearm is located next to the hand in the somatotopic map [12] [13] and by anaesthetizing the forearm, the cortical hand area can expand over the forearm area [19]. Thus, more nerve cells can be available for the hand, resulting in improved hand function. To utilize the central nervous systems’ (CNS) ability to change for therapeutic purposes, guided plasticity [20] is an attractive concept with promising results. The potential for cerebral
plasticity is, for example, used in treatment of patients to strengthen or promote CNS functions that are lost or weakened [21].

Temporary cutaneous anesthesia of the volar aspect of the forearm, using an anesthetic cream (EMLA®), resulted in improved sensory function of the hand in healthy controls [22]. In a randomized controlled trial (RCT), sensory re-learning training in combination with cutaneous forearm anesthesia improved sensory function of the hand compared with sensory re-learning training and placebo in patients with ulnar or median nerve repair [23]. The participants received treatment twice a week for two consecutive weeks, and the effects lasted 4 weeks after the last EMLA treatment. These results suggest that sensory recovery is enhanced by combining training with temporary anesthesia of adjacent body parts. The long lasting effect indicates that this treatment is clinically useful and relevant.

Recently, the same principle of temporary cutaneous anesthesia as that used for the hand has been applied on the foot in uninjured subjects [24]. In this RCT, improvement in sensory function of the foot was observed after cutaneous anesthesia of the lower leg compared with placebo [24]. To our knowledge, the principle of temporary cutaneous anesthesia in improving sensorimotor function of the knee has not yet been tested.

In this first study of a series of experiments, we included subjects without injury. The aim was to investigate if the principle of brain plasticity that has been successfully used on the hand to improve sensory and motor functions, and on the foot to improve sensory function, can be applied on the knee. We hypothesized that temporary anesthesia of the skin area above and below the knee would improve sensorimotor function of the ipsilateral knee and leg.
Subjects and methods

Subjects and randomization

Twenty-eight (14 women) physically active subjects aged 18-35 years were included in this exploratory double-blind RCT. Patient characteristics, including self-reported outcomes assessed by the Knee injury and Osteoarthritis Outcome Score (KOOS) [25] [26], are given in Table 1. Exclusion criteria were a history of major orthopedic lesions, such as knee injury or fracture, and allergic reactions to anesthetic agents. The physical activity and age distribution of the subjects in this study were chosen in order to match patients with ligament injuries in the knee. The subjects were randomly allocated, using a random number generator, stratified by gender, to temporary anesthesia using a local anesthetic cream (EMLA®) (EMLA group) or a placebo cream (oil and water emulsion) (placebo group). The Research Ethics committee of Lund University approved the study, and all subjects gave their written informed consent.

Protocol and masking

Fourteen subjects received a local anesthetic cream containing 2.5% lidocaine and 2.5% prilocaine (EMLA®, AstraZeneca, Södertälje, Sweden) and 14 subjects received a placebo cream of an oil and water emulsion (DAX, Opus Health Care Inc., Malmö, Sweden). The two creams were identical in color, consistency and packaging. Fifty grams of EMLA, or placebo [24], was applied on the leg 10 cm above and 10 cm below the center of patella, leaving the area around the knee without cream (Figure 1). The skin areas where the EMLA/placebo was applied were covered with film wrap and a Tubigrip® stocking (MEDLOCK Medical, Oldham, UK). After 90 minutes, during which time the subject was seated, the EMLA/placebo was carefully washed off. The test leader and the subjects were blinded to group allocation, and the subjects were told not to reveal any possible anesthetic sensation.
Outcome measures

Measures of sensory and motor functions were assessed before and after 90 minutes of treatment with EMLA or placebo. The tests were performed in the order that they are described below. All tests were performed on the right leg only.

Measures of sensory function

Three measures of sensory function were used; perception of touch, vibration sense and knee kinesthesia. Lower values in these tests indicate better sensory function.

Perception of touch

Semmes-Weinstein monofilaments (SWM) were used for assessing perception of touch at the most prominent point of the medial femoral condyle, just proximal of the joint space. Prior to the test, the SWM (nr 4.31, 2.0 g) was demonstrated on the patient’s styloid process of the hand, so that the subjects could familiarize themselves with the test. Thereafter, the subjects lay in a supine position and were asked to close their eyes, concentrate on their knee and respond when they felt any sensation of touch. The assessment was performed according to a standardized procedure [27]. Each monofilament, starting with the thinnest and continuing with thicker until response to sensation, was applied perpendicular to the skin for 1.5 seconds and lifted 1.5 seconds. The filament was applied 3 times to the same spot and was bent each time to exert the specific pressure. Feeling the monofilament was recorded when at least one out of three applications was identified by the patient [27].

Vibratory perception threshold

Vibratory perception threshold (VPT) was assessed by a biothesiometer (Bio-Medical Instrument, Newbury, OH, USA), according to the manufacturers’ manual and previously
published methods [28]. Prior to the test, the Biothesiometer was demonstrated on the
patient’s styloid process of the hand, so that the subjects could familiarize themselves with the
test. Thereafter, the subjects lay in a supine position and were asked to close their eyes,
concentrate on their foot/knee and respond when they felt any sensation of vibration. The
biothesiometer tip was held with uniform pressure at two sites: the most prominent point of
the medial malleolus and the medial femoral condyle (same location as that for testing
perception of touch). Three consecutive measurements were taken on each site, and the
amplitude was replaced to zero between each measurement without moving the
biothesiometer tip from the location. The amplitude was increased by 1 Volt per second until
the subjects responded to a sensation of vibration. This was noted as the VPT. The first
measurement was regarded a trial test, and was, thus, excluded from the analysis. If the
difference between the second and third measurement was more than 20%, 2 additional tests
were taken. The mean of the second and third, or fourth and fifth, measurements was used in
the analysis. High reliability has been reported for the Biothesiometer in healthy subjects [28]
[29].

Knee kinesthesia

Kinesthesia was measured in a specifically designed apparatus, which has been used and
described in detail in previous studies, see for example [30] [31]. The subjects lay in a lateral
decubitus position, were asked to close their eyes, concentrate on their knee and respond
when they felt any sensation of movement in their knee. Measurements of the threshold for
detection of passive motion (TDPM) were performed towards knee extension (TE) and knee
flexion (TF) from the starting position of 20º knee joint flexion, giving the variables TE20
and TF20. The median values of three consecutive measurements of these two variables were
determined. The variables from the 20º starting position (TE20 and TF20) have been found to
be reliable in uninjured subjects [32]. The sum of TE20 and TF20, giving an index value, was used for statistical analysis.

**Measures of motor function**

Two measures of motor function were used; the one-leg hop test for distance and isokinetic knee muscle strength. Higher values in these tests indicate better motor function.

**One-leg hop test for distance**

The one-leg hop test for distance with the arms free, aiming at a more functional execution of the hop, was used. The subjects were told to hop as far as possible, taking off and landing on the same foot, maintaining their balance for about 2-3 seconds. The test was performed three times with each leg, alternating the right and left leg, the hop distance being measured (in cm) from toe in the starting position to heel in the landing position. If the subject improved more than 10 cm between the second and third hop, additional hops were performed until an increase of less than 10 cm was measured. A trial one-leg hop preceded the measurements. The subjects wore shoes, e.g., sneakers. The mean value of the three best hops was used in the analysis. The reliability of this test is high in uninjured subjects [33].

**Isokinetic knee muscle strength**

Measurements of concentric isokinetic strength of the knee muscles were performed with a Biodex Multi-Joint System III isokinetic dynamometer (Biodex Medical Systems Inc., Shirley, New York, NY, USA) with Biodex Advantage software, version 4.0. The standard Biodex knee unit attachment was used. Subjects were placed in an upright position with 90º hip flexion on the Biodex dynamometer chair, and were secured with straps across the chest, pelvis, thigh and ankle. The resistance pad was placed as distally as possible on the tibia while
still allowing full dorsiflexion at the ankle. The center of motion of the lever arm was aligned as accurately as possible with the slightly changing flexion-extension axis of the knee joint. The range of motion of the knee joint was set at 5 to 90°. The subjects had their arms crossed over the chest during the test. Standardized verbal instructions and encouragement were given. The subjects were allowed trial tests in order to familiarize themselves with the equipment and the test procedure, before five maximal reciprocal concentric isokinetic knee extensions and flexions at an angular velocity of 60°·s⁻¹ were made. Peak torque/body weight (Nm) was used in the analysis. High test-retest reliability has been reported for isokinetic testing at 60°·s⁻¹ using the Biodex dynamometer [34].

**Statistical analysis**

The number of subjects needed was determined by an a priori sample size calculation. No primary outcome measure was determined, since the study has an exploratory character. We expected to find an improvement in more than one of the variables to interpret the results as an effect from treatment. For knee kinesthesia, sample size calculations revealed that at least 24 (or 12) subjects were needed to detect an improvement by treatment of 20% (or 30%) within groups (SD\textsubscript{diff} 0.49), with 80% power at the 5% significance level. For vibration sense, 13 subjects were needed to detect an improvement of 20% (SD\textsubscript{diff} 3.3). For the one-leg hop test, and knee extension peak torque, 2 and 5 subjects, respectively, were needed to detect an improvement by treatment of 10%, with 80% power at the 5% significance level. Based on these sample-size calculations, we included 28 subjects. The paired t-test was used for comparisons within groups and the independent t-test for comparisons between groups. All variables had Shapiro-Wilk statistic of >0.90, except knee kinesthesia. The results were confirmed using non-parametric statistics. Wilcoxon signed rank test, or Mann-Whitney test, was used for ordinal data (perception of touch). Fischer’s exact test was used for between-
group comparisons in the number of patients with improvement by treatment. Effect size was calculated by taking the difference between the means before and after EMLA/placebo and dividing it by the SD of the same measure before EMLA/placebo [35]. A level of p≤0.05 was chosen to indicate statistical significance.

Results

No statistically significant or clinically relevant differences were seen over time (before vs. after) in the measures of sensory or motor functions in the EMLA group or in the placebo group. There were no differences between the groups in effects of treatment (EMLA vs. placebo) (Table 2).

Sensory function before and after treatment with EMLA or placebo

No differences were found between assessments (before vs. after) for perception of touch, vibration sense, or kinesthesia in the EMLA group. No differences were found before vs. after treatment for perception of touch, or vibration sense in the placebo group. A lower value for TDPM, indicating better knee kinesthesia, was found after compared with before treatment in the placebo group (p=0.026). There were no differences between the groups in effects of treatment for the measures of sensory function (Table 2, Figure 2). The effect sizes were generally small in the EMLA group (between 0.02 and 0.44) and in the placebo group (between 0.11 and 0.56).

Motor function before and after treatment with EMLA or placebo

No differences were found between assessments (before vs. after) for the one-leg hop test, knee extension or flexion muscle strength in the EMLA group or placebo group. There were no differences between the groups in effects of treatment for the measures of motor function
(Table 2, Figure 2). The effect sizes were generally small in the EMLA group (between 0.03 and 0.19) and in the placebo group (between 0.05 and 0.15).

**Discussion**

In this first exploratory study on principles of brain plasticity in improving sensorimotor function of the knee, we found no effect of temporary anesthesia of the skin area above and below the knee on sensorimotor function of the ipsilateral knee and leg in uninjured subjects.

Although self-reported and objective function is improved by training, it is unclear whether sensorimotor function can be fully restored after knee injury and knee OA. In a recent study, we found that at least one-third of patients with anterior cruciate ligament (ACL) injury or reconstruction had not recovered normal muscle function 2 to 5 years after injury [36]. Possible reasons for this may be that the injury causes a disturbance in the sensory system [37] with possible effects on the central mechanisms and motor response [1], and/or that training programs are not sufficiently effective in improving or restoring sensorimotor function. Moreover, it has been questioned whether training after knee injury can lead to improvement in sensory function although improvement in motor function can be obtained [38] [39].

Since good sensorimotor function is of importance for the overall outcome after injury [6] and in preventing OA [2] [8], it can be argued that training programs need to be more effective in order to improve or restore sensorimotor function after knee injury and knee OA. Hypothetically, the principle of temporary cutaneous anesthesia of adjacent body parts in combination with training, that has been shown to be more effective in improving sensorimotor function of the hand than training only [23], could also be used to improve
sensorimotor function of the knee. An advantage is that the selective anesthesia does not affect motor function of the leg. Thus, the individual can use the leg during training while parts of the leg are anesthetized.

The only difference that we found was a lower value for TDPM, indicating better knee kinesthesia, after compared with before treatment in the placebo group. However, since the 95% CI is close to zero (Table 2), and there may be a learning effect in TDPM [32], the clinical relevance of this improvement of 0.40 degrees can be questioned.

There may be several reasons for the lack of effect from temporary cutaneous anesthesia of the skin area above and below the knee on sensorimotor function of the ipsilateral knee and leg in the uninjured subjects in our study. Sensorimotor function may not be impaired in uninjured subjects. Thus, the chance of achieving an improvement in sensorimotor function in these subjects by the short-term intervention that we used is most likely limited. For example, a ceiling effect was noted in some of the measures. The subjects in our study had low values (good sensory function) for both knee kinesthesia and skin sensitivity before EMLA/placebo, limiting the chance of improving these measures by treatment. In addition, the effect sizes were generally small, indicating that the magnitude of change by treatment was small. In previous studies on knee kinesthesia, patients with knee injury have higher values (poorer kinesthesia) than uninjured subjects [38] [31]. Thus, the possibility of improving kinesthesia by temporary cutaneous anesthesia may be greater in subjects with knee injury than in uninjured subjects. We tested one site for perception of touch, while several sites were tested in the corresponding study of the foot [24]. In an effort to reduce the ceiling effect, several sites around the knee could be tested in further studies. However, the perception of touch of the knee is not as delicate and discriminative as in the hand or the foot sole. Thus, large
effects from temporary cutaneous anesthesia may be needed to detect a change in perception of touch of the knee. Due to the exploratory character of our study, the a priori sample size calculation was based on predictions. A post-hoc sample size calculation estimated that about 30 subjects in each group would be needed to detect improvement in the EMLA group compared with the placebo group for the measures of sensory function and between 5 and 9 subjects in each group for the measures of motor function, with 80% power at the 5 % significance level. Thus, the risk of a type II error in the present study cannot be ruled out, implying a need for a larger group of subjects in further studies.

It is well known from animal and human experiments that temporary cutaneous anesthesia of one body part leads to cortical re-organization resulting in a corresponding silent area in the sensory cortex. This allows adjacent nearby body parts to rapidly expand at the expense of the silent cortical area [16] [17]. We believe that the amount of EMLA that we used (50 grams) and placing of the anesthetic cream (above and below the knee) is adequate in order to expect an increased cortical knee representation. However, the cortical area of the knee is smaller than the cortical area of the hand [12] [13]. Thus, larger effects of treatment are needed in order to detect an increase in the cortical area of the knee than in that of the hand. We did not find an effect of temporary cutaneous anesthesia in the measures of sensory or motor functions. This could be due to lack of cortical re-organization following the cutaneous anesthesia or that the re-organization was too small to result in a detectable improvement. However, we did not investigate whether the lack of improvement in these measures corresponds to a lack of cortical re-organization. In further studies, neuroimaging methods, such as functional magnetic resonance imaging, can be used to address this question.
Due to the loss of mechanoreceptors after knee injury, the sensory system is disturbed [37], possibly causing effects on sensory and motor functions. Thus, any treatment leading to improved sensorimotor function would be of value for patients with knee injury. In line with observations in individuals with hand nerve injury, the sensory deficiency after knee injury can, at least hypothetically, be associated with functional re-organization of the somatosensory cortex of the brain. Thereby, it can be argued that the principle of temporary cutaneous anesthesia in improving sensorimotor function can be used also on the knee. In current training programs for patients with knee injury, principles of brain plasticity such as training of the contralateral extremity are included [1] [3]. The aim of these programs is to enhance unconscious motor responses by stimulating both afferent signals and central mechanisms responsible for dynamic joint control [40] [1]. From the present study, we cannot exclude that there is no effect of temporary cutaneous anesthesia of the skin area above and below the knee on sensorimotor function of the ipsilateral knee and leg in uninjured subjects. However, based on the reasoning above, studies on the effect of temporary cutaneous anesthesia for improving sensorimotor function in patients with knee injury are warranted.

**Conclusion**

In this exploratory randomized study, we found no effect of temporary cutaneous anesthesia on sensorimotor function of the ipsilateral knee and leg in uninjured subjects. The principles of brain plasticity used in this study remain to be tested in subjects with knee injury.

**Competing interests**

The authors declare that they have no competing interests.

**Authors’ contributions**
All authors contributed to the design of the study. EA and ER were responsible for acquisition, analysis and interpretation of data. EA drafted the manuscript. All authors critically revised the manuscript, and read and approved the final version.

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References

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**Figure legends**

**Figure 1. Application of local anesthetic or placebo cream.** EMLA, or placebo, applied on the leg 10 cm above and 10 cm below the center of patella, leaving the area around the knee without cream.

**Figure 2. Perception of touch before and after treatment.** Perception of touch (grams), measured with Semmes-Weinstein monofilaments (SWM), before and after treatment with EMLA or placebo. The box includes the first to third quartiles with median values shown as a line through the box. The whiskers show values below 1.5 box lengths from the upper or lower edge of the box. The circles denote outliers. The lowest value noted was 0.008 g (SWM nr 1.65) and the highest was 0.6 g (SWM nr 3.84). No differences were noted within or between groups (p-values ranging from 0.125 to 0.769).
### Tables

#### Table 1. Characteristics of the subjects.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>EMLA group (n=14)</th>
<th>Placebo group (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y) (^a)</td>
<td>27 (4.8)</td>
<td>25 (3.9)</td>
</tr>
<tr>
<td>Women (n)</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>BMI (^a)</td>
<td>23.0 (2.4)</td>
<td>24.2 (1.8)</td>
</tr>
<tr>
<td>Tegner activity level (^b)</td>
<td>5.5 (4 – 8)</td>
<td>5 (4 – 8)</td>
</tr>
<tr>
<td>KOOS subscales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>100 (1.6)</td>
<td>98 (3.7)</td>
</tr>
<tr>
<td>Symptoms</td>
<td>99 (2.1)</td>
<td>98 (5.2)</td>
</tr>
<tr>
<td>ADL</td>
<td>100 (0.8)</td>
<td>100 (0.3)</td>
</tr>
<tr>
<td>Sport/Rec</td>
<td>98 (4.7)</td>
<td>99 (3.1)</td>
</tr>
<tr>
<td>QOL</td>
<td>97 (6.3)</td>
<td>95 (6.5)</td>
</tr>
</tbody>
</table>

\(^a\)Mean (SD), \(^b\)median (quartiles), BMI; body mass index. The Tegner Activity Scale, ranges from 0 to 10, least to hardest strenuous activity for the knee [41]. A Tegner activity level of 4 is equal to recreational sports such as jogging, aerobics, or cross-country skiing and a Tegner activity level of 5 is equal to recreational sports such as orienteering or down-hill skiing.
Table 2. Results for outcomes of sensory and motor functions in the EMLA and placebo groups. Mean and standard error (SE) and mean difference (95 % CI) (after minus before) for the tests of sensory function (vibration sense, kinesthesia) and motor function (one-leg hop test, knee extension and flexion peak torque/body weight) before and after treatment with EMLA/placebo, and mean difference (95 % CI) (EMLA minus placebo) between the EMLA and placebo groups (t-test).

<table>
<thead>
<tr>
<th></th>
<th>EMLA group</th>
<th>Placebo group</th>
<th>EMLA vs. placebo</th>
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<tr>
<td></td>
<td>Before Mean (SE)</td>
<td>After Mean (SE)</td>
<td>Mean diff (95% CI) (after minus before)</td>
</tr>
<tr>
<td>Sensory function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration sense med mall</td>
<td>11.46 (0.99)</td>
<td>13.11 (1.27)</td>
<td>1.65 (-0.54, 3.82)</td>
</tr>
<tr>
<td>(Volt)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration sense med fem cond</td>
<td>19.64 (1.71)</td>
<td>21.25 (1.48)</td>
<td>1.61 (-2.12, 5.33)</td>
</tr>
<tr>
<td>(Volt)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee kinesthesia (degrees)</td>
<td>2.23 (0.38)</td>
<td>1.95 (0.45)</td>
<td>-0.28 (-1.00, 0.43)</td>
</tr>
<tr>
<td>Motor function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One-leg hop (cm)</td>
<td>134.56 (6.85)</td>
<td>135.21 (6.31)</td>
<td>0.65 (-3.17, 4.48)</td>
</tr>
<tr>
<td>Knee ext peak torque/body weight (Nm)</td>
<td>246.81 (9.90)</td>
<td>239.62 (11.10)</td>
<td>-7.19 (-16.26, 1.89)</td>
</tr>
<tr>
<td>Knee flex ext peak torque/body weight (Nm)</td>
<td>129.56 (7.43)</td>
<td>128.30 (7.41)</td>
<td>-1.26 (-6.66, 4.15)</td>
</tr>
</tbody>
</table>

Med mall = medial malleolus, Med fem cond = medial femoral condyle
Ext = extension, Flex = flexion
Figure 2