Rate of Torque Development in adolescents with Osgood-Schlatter: Protocol of a cross-sectional case-control study

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Background

Osgood-Schlatter is a growth-related condition involving multiple types of tissue in the tendon-bone interface at the tibial tubercle. Osgood-Schlatter affects one in ten adolescents causing persistent pain, reduced peak torque during knee extension, and reduced ability to maintain participation in sports and physical activity. Rate of torque development is linked to athletic performances, and reductions in rate of torque development is associated with decreased neuromuscular functioning and pain chronicity. As peak torque is reduced in Osgood-Schlatter, changes in rate of torque development is likely also affected, but this has not yet been investigated. This insight could help characterize the condition and guide management.

Aim

To investigate if early and peak rate of torque development during knee extension is reduced in the asymptomatic limbs or during knee flexion in adolescents with Osgood-Schlatter, compared to a matched group of asymptomatic adolescents.

Study design

A cross-sectional case control study.

Methods

The study design and analysis strategy have been published along with a trial registration (ClinicalTrials.gov NCT05789095). The study will include 13 adolescent participants with Osgood-Schlatter and a group of 13 pain free controls matched on sex, age, and sports participation on the group level. Testing will include bilateral rate of torque development measurements of knee extension and flexion, with a fixated handheld dynamometer, during a single test-session lasting approximately two hours. The examiner responsible for strength-testing will be blinded to case-status. Along with anthropometric data, participants will perform the anterior knee pain provocation test to assess pain-response to sustained knee loading, a countermovement jump test to assess power and jump height, and provide patient-reported measures of condition severity, pain, disability, and quality of life. Data collection will start February 2023 and is expected to be completed by May 2023.

Expected results and implications

As the condition affects the knee-extensor mechanism, we expect lower levels of rate of torque development in the affected knee during extension. The main interest, however, is if the level of rate of torque development is also significantly reduced in non-symptomatic limbs or in knee flexion, in cases compared to symptom-free healthy controls. This would indicate inhibited neuromuscular function on a central level, due to other factors than local tissue pathology, such as pain chronicity, central muscle inhibition, or other drivers.

Title

Rate of Torque Development in adolescents with Osgood-Schlatter: Protocol of a cross-sectional case-control study.

Dansk titel

Rate of Torque Development hos unge med Osgood-Schlatter: protokol på et case-kontrolstudie.

Trial registration

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Rationale and background

Osgood-Schlatter is an apophysitis of the tibial tubercle occurring in its primary form during adolescence. The condition affects one out of ten, and is even more prevalent in highly active adolescents.[1]

Adolescents with Osgood-Schlatter experience a reduced ability to participate in sports and physical activities.[2] A previous study from our group found that maximal strength and pain during isometric knee extension strength test on adolescents with Osgood-Schlatter, was moderately correlated to self-reported outcomes in terms of knee-related quality of life, sports participation satisfaction, mental health and pain beliefs.[3] Rate of force development is a measure of explosive strength, or the ability to develop force over a short time period and is correlated to explosive actions, such as sprinting and jumping.[4,5] In patients with prolonged or acute knee pain, rate of force has been found to be decreased.[6] Several studies have shown that changes in rate of force development is linked to decreased neuromuscular function, and thereby is affecting sports function and activities of daily living.[7] No previous investigations of rate of force development have been published for this group.

Measuring rate of force development in adolescents with Osgood-Schlatter, might further explain the relationship between features of knee function and self-reported outcomes. To account for differences in stature and bodyweight, normalizing for these variables will provide the more precise measure of rate of torque, often used in biomechanical research.

It would be interesting to investigate if rate of torque development is affected in this group. If it is, it could be explained by the theory that pain in local tissue, is affecting the ability to activate maximal muscle contraction in a limited time span.[8,9] Furthermore, we suspect that the non-affected leg in the Osgood-Schlatter group, also will have a lower rate of torque development. This is based on the hypothesis that Osgood-Schlatter, affects the central nervous system due its chronicity, and therefor the ability to develop maximum rate of torque.[6]

Hypotheses

The hypotheses being tested are

1. that adolescents with Osgood-Schlatter, has a lower knee extension RTD in their affected knee compared to matched controls
2. that adolescents with Osgood-Schlatter, has a lower knee extension RTD in their affected knee compared to their potential asymptomatic knee
3. that adolescents with Osgood-Schlatter, has a lower knee extension RTD in their potential asymptomatic knee compared to matched controls
4. that adolescents with Osgood-Schlatter, has a lower knee flexion RTD in their affected knee compared to matched control
5. that adolescents with Osgood-Schlatter, has a lower knee flexion RTD in their affected knee compared to their potential asymptomatic knee
6. that adolescents with Osgood-Schlatter, has a lower knee flexion RTD in their potential asymptomatic knee compared to matched controls
7. That levels of either early or late rate of torque development is negatively correlated with pain during rate of torque development-testing, countermovement jump height or power, anterior knee pain provocation test score, current pain, pain duration, KOOS child 'Pain', 'Sport/rec' or 'QoL' subscales,

Methods

Study design

In this study we will include adolescent participants with Osgood-Schlatter, presenting as anterior knee pain localized to the tibial tubercle (OSD-group), and a matched group of pain free controls (control group), matched on sex, age (<1 year group difference) and type of sports (weightbearing vs non-weightbearing). The study will be conducted at the International Olympic Research Center - Copenhagen (Sports Orthopaedic Research Centre - Copenhagen), at Hvidovre University Hospital. The project will be initiated March 2023, with recruitment of 26 participants: 13 participants in the OSD-group, and 13 in control group.

Approval has been obtained from the ethical review board of the Capital Region of Denmark (H-20072873), and the Data Management Agency of Capitol Region of Denmark (P-2021-73).

Recruitment

Recruitment will happen through social media advertisement, from patients referred to the Osgood-Schlatter clinic at the orthopedic department, Hvidovre University Hospital, and from local sport clubs. Participants from the control group, will be rewarded with a movie ticket after participation.

All possible participants will be screened over the phone, before clinical examination and are included if criteria is met.

Patients and guardians' consent

Before engaging in trial, participants and their parents/guardians will receive a pamphlet with written information. During their visit, they will receive verbal information and instructions regarding the context and aim of the study. Written consent will be collected from the parents/guardians of the participants, and verbal consent from the participants.

Processing of personal data

All personal data will be stored on logged secured servers, provided by the Capitol Region of Denmark. Journals of the treated cases will be stored electronically as per standard care.

Participants

Inclusion criteria

- Patients must be 9-16 years of age
- Presence of pain for 12 weeks or more
- Pain at tibial tubercle during loading activities
- Palpable pain at the tibial tubercle

Exclusion criteria

- Previous knee or hip surgery
- Other main diagnose of anterior knee pain (patellofemoral pain, Sinding-Larsen Johansson disease, Jumpers knee, etc.)
- Hip and/or back pain interfering with activities of daily living or physical activities
- Suspicion of other main diagnose such as meniscal tears and or ligamental tears
- Unable to communicate verbally or orally in Danish

Clinical examination and treatment

The study procedures will be conducted by two examiners (JL and HS). JL will be aware of the case status and conducts the screening and preliminary testing. To avoid bias, examiner HS will be blinded for the case status during trial and will not know the Numerical pain Rating Scale-scores (NRS, 0-10, ‘no pain’ to ‘worst pain imaginable’) of the participants during testing.[10] To strengthen the inter-reliability, the examiners will not change roles during the study.

The session starts with JL examining the potential participant in the OSD-case group, for Osgood-Schlatter. If the Osgood-Schlatter diagnosis is made, the participant is then enrolled. For the potential participant in the control group, JL screens for potential injury or pain in relation to the knee joint. In the absence of relevant pathology, the control-participant is enrolled.

Then, JL measures length of the lever arm and variables for peak hight velocity assessment. Participants will then answer the patient-reported outcome measures together with their parent/guardian.

For the rate of force development tests, HS will enter the room and conduct the tests as described below. For each attempt the participant will write down their NRS-rating on a piece of paper, out of sight from HS.

Before the rate of force development test is conducted, the participants are told that they can always abort the test, if they perceive that pain rises to such a degree that they can´t continue the

testing, or they start felling fearful or uncertain of their symptoms. They are ultimately told that potential pain felt during testing are not harmful and will subside within 24 hours, as is our experience from multiple earlier conducted tests.
HS leaves the room, for JL to conduct the Anterior Knee Pain Provocation test and save the NRS results.

HS returns to conduct the Counter Movement Jump Test, again blinded for the participants NRS-scores, which are written down on a piece of paper. HS leaves the room, and JL either treats the patient (case-group) or hands out compensation for participating (control-group).

Cases and controls will be instructed not to take any pain medication 24 hours prior to any assessment to ensure that this does not affect measurements.

Test protocols

Rate of Torque Development

Rate of force development is defined as a change in force over time (Newtons per second). To make the measurement more applicable in a group with diversity in gender, age and size, the length of the lever arm is considered, by measuring from the lateral joint space in the knee, to two centimetres above the lateral malleolus. Rate of torque development is denoted as Newton per meters per second per kilograms of bodyweight (Nm/s/kg).

A reliability study from 2019 showed that a fixated handheld dynamometer, a MicroFet 2 (Hoggan, Scientific L.L.C., Salt Lake City, USA) with a sampling rate of 100hz, has a good intra-tester reliability, and an acceptable measurement error (SEM ≤15.5%).[11]

Knee flexion

The participant is lying prone, with hip in neutral position, 0°. The knee is flexed about 20°, with the leg resting on the testers fist wedged between the examination table and the ankle. The participant will be instructed to hold onto the side of the examination table. A strap fixated to the floor, is used to fixate the handheld dynamometer. The dynamometer is placed central to the line of lever demarcation, approximately 2cm proximal to the lateral malleolus.

Knee extension

The participant is sitting with 90° hip flexion, knee flexed approximately 60°, with test leg resting in testers hand, and feet free of the floor. They will be instructed to hold onto the back of the examination table and keep their upper body upright. A strap fixated to the bottom of the examination bed, is used to fixate the handheld dynamometer anteriorly on the shin, corresponding to the line of lever demarcation. If the participant feels the metal of the gauge on their shinbone through the padding of the dynamometer, extra padding will be placed on the shin.

The participant will be instructed to *press against the dynamometer as fast and hard as possible, and to keep pushing until instructed to relax* (approximately 3-4sec.). Standardized verbal instruction is provided before each trial by the tester: *3-2-1-go-push-push-push and relax.* For the knee flexion, the participant will be instructed to bend their knee, and for the extension, to straighten the leg.

Participants will perform two test trials: one at 50% of self-estimated maximal force, and one at 100%. The assessor will hold the leg in starting position to allow full rest between trials, lasting 1-minute. Three maximal attempts are recorded. One tester will hold the dynamometer and instruct the patient (HS), while one tester (JL) manage data collection software (Hoggan Health Industries 2000, version 11.0.1, Quest Medical Group, Inc.). The order of the movements is decided by coin

toss. The affected leg is tested first in each movement. In the control group the affected leg will be decided by coin toss before tester HS enters the room.

Anterior knee pain provocation test

The anterior knee pain provocation test is a unilateral self-performed and self-rated test, designed to provoke known anterior knee pain. Only the affected or most affected knee is tested. In the control group, the "affected leg" is decided by coin toss.

The participant will be instructed to *stand on the affected leg, with the non-affected side against the wall, and their back straight*. The back of the hand is held against the wall as support. They will then be instructed to stand in a static single-legged squat position, with knee flexion about 60°, while the other leg is extended forward above the ground. The position is held for 45 sec and timed with a stopwatch. Standardized verbal instruction is provided before each trial by the tester: *are you ready to start the test? Start... and stop.*

Participants will provide their perceived pain intensity immediately before and after completing the 45s. hold.

Counter Movement Jump Test

The counter movement jump test measures jump height(cm), power(watt), and pain during trial (NRS 0-10). Increased countermovement jump height is associated with increased sprint performance, lower body power and enhanced force-velocity.[12–14] Likewise, the test is found feasible for adolescents.[12]

The participant is standing with their legs shoulder width apart, and with their hands placed on their hips. They will be instructed to *jump straight up and down, and as high as possible*. One test trial is conducted, and three trials where measurements are made.

Standardized verbal instruction is provided before each trial by the tester: *are you ready to jump? Go.* There will be a 30second rest between each attempt. After each test jump a written NRS is made by the participant, hidden from tester HS.

The attempts are recorded using the slow-motion function (>240frames per second) on a fixated iPhone. To analyse the recordings, the smartphone application MyJump 2 is used for a highly reliable slow-motion video analysis.[15–18]

Data will be normalized per MyJump 2 procedures to push-off distance (distance from the floor to trochanter major in a 90˚ squat position) combined with leg length (measured prone from the superior anterior iliac spine to the tiptoes in full plantar flexion). The mean of three trials will be used.

Patient Reported Outcome Measures

Participants will fill out a questionnaire, containing some basic information about their pain experience, such as: duration of pain, previously received treatment, current pain, worst pain during past 24 hours and week. Furthermore, there are questions about activity level, as well as questions from Knee Injury and Osteoarthritis Outcome Score (KOOS-child) and Tampa Scale of Kinesiophobia (TSK-17).

KOOS

KOOS is used for patients with knee pain and injuries. The questionnaire contains questions within five categories: symptoms, pain, physical function in daily life, physical function during sports and activities, and life quality. In this study, participants will fill out questions from the 'Sport/rec' and

'Quality of Life' subscales, and questions P1, P4, P6a, and P6b from the 'Pain' subscale. Questions are answered on a 1-4likert scale in normalized to a 0-100 score for each subscale with 100 being the optimal score[19,20].

TSK-17

The Tampa scale is a 17-item questionnaire to evaluate fear avoidance behaviour in patients experiencing pain. It consists of two subscales, activity avoidance and somatic focus. The questions are rated on a 1-4 likert scale by the patient. The sum of the points are ranged from 17-68points, with above 37 being defined as "high levels of kinesiophobia"21,22. All questions are used in the questionnaire.

Outcome measures

The outcome measures are rate of torque development and NRS-values in relation to the force-measurements. To calculate the rate of torque (Nm/s/kg), the rate of force development-variables (N/s) is multiplied with length of the lever (m) and divided with the participant's bodyweight (kg).

Outcome variables related to the specified hypotheses are rate of torque development during 0-100 ms, 0-200 ms, peak RTD, and time to peak force during knee extension and knee flexion for both cases and controls.

Descriptive variables

Variables collected for descriptive purposes are data on examination findings, pain intensity and duration, Peak Heigh Velocity, level of sports participation and anthropometrics

Statistical considerations

Sample size

No previous investigations of rate of torque have been published for adolescents with Osgood-Schlatter. One previous study using the same clinical test setup, equipment, and time-epochs (Early RTD: 0-100 ms, Late RTD: 0-200 ms, and peak RTD) for testing RTD over the hip in young (Under-19) professional soccer players found a mean of 9.57 Nm/kg/s and a standard deviation of 2.6 Nm/s/kg at 0-100 ms[23].

Considering that peak torque is around 30-50% lower for adolescents (U13 and U14) compared to U19 players[24], a similar difference might be expected for RTD, and thus we expect a group mean RTD of around 5 or 6 Nm/kg/s at 0-100 ms for asymptomatic adolescents. In adults with non-traumatic knee pain, investigations of RTD during maximal isometric hip extension, has shown differences between symptomatic participants and controls of >50 % during early RTD.[25]

As this study includes RTD of the knee, which is the affected joint, we expect at least similar differences for our primary measure, early RTD at 0-100 ms, this would correspond for example to a between-group difference of 6 vs. 3 Nm/kg/s. We will assume 2.6 Nm/kg/s as an asymptomatic population standard deviation for 0-100 ms. Based on a two-sided two-sample t-test at 80% power and 5% alpha level, 13 participants in each group would thus be needed to detect a 50% between-group difference (R 4.0.2, Foundation for Statistical Computing, Vienna, Austria; RStudio 1.0.153, power.t.test package).

Statistical methods

The outcome variables (rate of torque development 0-100 ms, 0-200 ms, peak RTD, time to peak RTD, time to peak torque for both knee extension and knee flexion, respectively) will be compared between groups using an unpaired two-sided students t-test, assuming the residuals will be normally distributed, otherwise the non-parametric alternative, the Wilcoxon rank sum test, will be used. The alfa and beta-1 level will be set for 5% and 80%, respectively.

As outcome variables have been a priori specified and prioritized, and also analyzed and reported in the pre-specified order, no corrections for multiple testing will be applied[26,27]. Data will be reported with between-group differences, standardized effect sizes based on Cohens d, exact p-values, and 95% confidence intervals. All data inspection, analysis, and visualizations will be conducted using R (R Foundation for Statistical Computing, Vienna, Austria), in the jamovi interface (The jamovi project 2023, version 2.4.1). All r-code and full data set will be shared with journal publication or in an open-access repository.

Risks and adverse events

In this context, adverse events will be any unintended symptoms or findings during examination, or severe increase in pain intensity during testing, to such extend that testing can't continue. In the case of adverse events, the data relevant to the participant will be excluded, and a new participant enrolled. A participant that can´t continue due to pain intensity will be treated with caution and observed for potential pain increase. If needed, they will be set in contact with a medical doctor from the orthopedic department, at Hvidovre University Hospital and still receive treatment/compensation. 48 hours after testing, a phone consultation will be made, to make sure that the pain intensity has decreased.

If problems with equipment or testing should occur to such an extent that test protocol can´t continue, a new date will, if possible, be set. Or else a new participant will be enrolled, and treatment/compensation is provided to the former participant.

In the case of unintended unblinding during testing (if allocation is revealed to HS), the data will be excluded from the collection due to risk of bias. If possible, a new set of participants (case and control) will be included, otherwise, subgroup analysis with participants with breach of blinding omitted will be performed.

An expected result from the test protocol is temporary pain and muscle soreness from the muscle force tests, in both cases and controls. Furthermore, an increase in symptoms from Osgood-Schlatter may be present after testing, in the case group. To our knowledge, this presents no safety hazard to the participants.

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