Effect of patellar strap and sports tape on jumper’s knee symptoms: protocol of a randomised controlled trial

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Human research ethics approval committee: METc UMCG
Human research ethics approval number: METc 2012/378
Conflict of interest declaration: All authors declare that they have no conflict of interest.

INTRODUCTION

Patellar tendinopathy (jumper’s knee) is a clinical condition of gradually progressive activity related pain of the patellar tendon (Blazina et al 1973). Prolonged repetitive stress of the knee-extensor apparatus can lead to this common tendinopathy in athletes from different sports. In sports characterized by high demands on the leg extensors, like volleyball and basketball, the overall prevalence of patellar tendinopathy is high. In elite athletes, the point prevalence in these sports is 45% and 32%, respectively (Lian et al 2005) and in non-elite the point prevalence is 15% and 12% respectively (Zwerver et al 2011b).

Patellar tendinopathy is one of the most common injuries seen by sports physicians or physiotherapists at sports medicine departments (Lian et al 2005, Zwerver et al 2011a). Patellar tendinopathy sometimes contributes to the decision to quit an athletic career and also causes long lasting (mild) symptoms after the end of an athletic career (Kettunen et al 2002). The high prevalence, low function scores, and chronic nature of the condition cause an impairment in athletic performance that is comparable with acute injuries (Lian et al 2005). Currently, there are no patellar tendinopathy treatments that can guarantee recovery (Larsson et al 2012). As a result, many athletes play on, often at lower performance levels, with long lasting symptoms (Kettunen et al 2002). At the moment, load management and physical training including eccentric training are the most effective treatment options (Gaida and Cook 2011, Larsson et al 2012). Visnes and Bahr (2007) estimated the effect of eccentric training
in patellar tendinopathy to be a 50–70% chance of improvement in pain and knee function (Visnes and Bahr 2007).

A patellar strap or sports tape is used by numerous athletes to reduce patellar tendon pain and to remain active in sports. There are several theories how such orthoses might work: a patellar strap or tape could increase the patella-patellar tendon angle and reduce the effective length of the patellar tendon (Lavagnino et al 2011). This might reduce the strain on the tendon. Excessive tendon strain can cause microdamage at the patellar tendon what eventually can result in a lesion (Lavagnino et al 2008). Others hypothesised it might improve the proprioception (Callaghan et al 2002) and hereby helps to protects the joint from re-injury (Purdam et al 2003) or it might change the sensory input (Boetje et al 2012). Wilgen et al (2011) demonstrated an increased sensitisation in patients with patellar tendinopathy (Wilgen et al 2011). This low pain threshold might be influenced by the strap and could therefore result in a decrease in the amount of pain that is perceived. In addition to an acute effect of these orthoses, it is also possible that by reducing the load on the tendon, these orthoses improve the balance between load and load capacity in the long term. A gradually increasing load in which a small amount of pain is allowed is thought to be important for the recovery of a tendon (Silbernagel et al 2007). More research is needed to confirm these hypotheses.

Many athletes say they experience less pain when wearing a strap (anecdotal evidence). However, there is currently little scientific evidence for the effectiveness of a patellar strap and sports tape in patellar tendinopathy. Only a small pilot study (cross-over design) investigated the effect of a patellar strap on pain in patellar tendinopathy subjects (Boetje et al 2012). In this pilot study, patients performed ten single leg decline squats, the maximal jumping test and the triple hop test with and without a patellar strap and were asked to score on the Visual Analogue Scale (VAS) the experienced pain during the tests. A significant decrease in VAS pain score was found during the single leg decline squat and the maximal jump test when wearing the strap compared to control. So, this pilot study showed that a strap might have a positive effect on pain. However, this study measured the effect on pain only in a small group of athletes (n = 53) and no placebo condition was included. Furthermore, the effect of sports tape on patellar tendinopathy symptoms has never been studied. High quality research with more athletes is necessary to determine the actual effect of both orthoses.
In addition, it is interesting to study if the effect of sports tape and a patellar strap differs between athletes and if so, which patients could benefit the most from the use of a strap or sports tape. This information can be used by physiotherapists and other practitioners to advice their patients. It seems reasonable to think that not all persons may benefit equally from the orthoses, because amongst others the exact location of the pain, the duration and the severity of the injury in patellar tendinopathy can be very different (Peers and Lysens 2005). This suggestion is supported by Lavagnino et al (2011) who demonstrated that the reduction in patella tendon strain as a result of the patellar strap was not present in all subjects. In about 25% of the subjects no decrease in strain was found (Lavagnino et al 2011). Because very little is known about the effectiveness of orthoses in general and nothing is known about the characteristics or factors that influence the effectiveness in patellar tendinopathy, an explorative study is needed.

This study is divided into two parts. The primary aim of the first part of the study is to investigate the effect of the use of a patellar strap and sports tape on pain in subjects with patellar tendinopathy performing functional tests in a controlled situation. The first parts’ secondary aim is to study the relationship between personal characteristics, injury specific factors and sports related factors and the effectiveness of a patellar strap and sports tape in order to find out which patients benefit the most from the use of a patellar strap or sport tape. The aim of the second part of the study is to investigate the effect of the use of a patellar strap and sports tape on pain and sports participation in subjects with patellar tendinopathy in the sports specific situation.

**METHOD**

**First part:**

**Study design**

The first part is a randomized controlled crossover experiment in which the effect of a patellar strap and sports tape will be examined during several functional tests in a controlled situation (see figure 1 for a flow chart of this part of the study).
Recruitment of patellar tendinopathy subjects from a.o. physical therapy practices and sports medicine departments

140 eligible patellar tendinopathy subjects

Informed consent

Baseline questionnaire

Warming up (5 minutes)

Four conditions (randomised, balanced order)

Control

Patellar strap

Sports tape

Placebo

Three functional tests:
- Single leg decline squat (1x & 10x)
- Counter movement jump
- Triple hop test

VAS pain score directly after each test

Ineligible
- fail inclusion criteria
- meet exclusion criteria

Participants

140 subjects with symptomatic patellar tendinopathy who meet the following criteria will be recruited for inclusion in the study:

- Age 18-50 years
- Current symptoms of knee pain in the patellar tendon or its patellar or tibial insertion in connection with training and competition in one or both knees.

Figure 1: Flow chart of the study design of the first part of the study. All subjects will be measured in a controlled environment where they perform three functional tests under four conditions.
- Duration of symptoms for over three months (to exclude acute inflammatory tendon problems and de novo partial ruptures).
- VISA- P score < 80
- Palpation tenderness of the patellar tendon
- (Still) active in sports (at least once per week)

The exclusion criteria for subjects are:

- Acute knee and acute patellar tendon problems
- Chronic joint disease(s)
- Signs or symptoms of other knee pathologies
- Inability to perform the tests

**Intervention**

All subjects will perform the three functional tests under four different conditions. The four conditions are: control, patellar strap, sports tape and placebo tape (kinesiotape applied in a non functional way) (see figure 2 for images of the four conditions).

- Control condition. No intervention is used in this condition.
- Patellar strap. The strap will be adjusted to the knee according to manufacturer’s instructions: the straps’ pressure point should be placed just below the patella and the length of the strap must be adjusted until it fits the leg properly.
- Sports tape. The tape will be administered by the researcher. At least four pieces of tape are used. One piece will be administered on the anterior side of the knee, between the patella and the tuberositas tibia. This piece of tape must be administered in such a way that it gives pressure on the patella tendon. After this, another piece of tape will be taped on the posterior side of the knee, overlapping the anterior piece. This procedure will be repeated with the other two pieces of tape.
- Placebo tape. Kinesiotape will be administered in a non-functional way by the researcher between the patella and the tuberositas tibia. Only one piece of kinesiotape will be used. The tape will be applied at the anterior side of the knee, and should only slightly be stretched so no pressure is felt on the patella tendon.
Figure 2: The four conditions tested. A control condition (A), a patellar strap condition (B), a sports tape condition (C) and a placebo condition (D). On the pictures the single leg decline squat is performed.

Outcome measures

*Primary outcome measure:* The Visual Analogue Scale (VAS) for pain will be used as the main study outcome in this study. With this measure, subjects indicate on a continuous line of 100 mm between two end points (no pain (0) and most severe pain (100)) their level of pain. The VAS pain scale is a valid and reliable measure of chronic and acute pain intensity (Bijur et al 2001, Downie et al 1978)

The VAS pain score during ten single leg decline squats (Zwerver et al 2007) is the primary study parameter in this first part of the study.

The VAS pain score will be obtained directly after this (and subsequent) tests through asking the following question: ‘how much pain did you experience in your patellar tendon during this test? Please indicate on this line’. The VAS for pain is held in front of the subject when asking this question.
Secondary outcome measure: The secondary study parameter is the VAS pain score after the counter movement jump and the triple hop test. Furthermore, the height of the highest jump during the counter movement jump test for each condition and the distance that is covered by three jumps during the triple hop test will be considered secondary study outcomes.

Explanatory variables to address secondary aim: In order to investigate the secondary aim, general information (date of birth, gender, length and weight), sports specific information (which sports, the amount of athletic performance during a week, number of years competing and level of sports participation) and injury specific information (duration, location and severity of injury) will be collected through a baseline questionnaire.

The severity of the injury will be determined on forehand with the Dutch version of the VISA-P questionnaire. The VISA-P questionnaire is a simple, reliable instrument for measuring the severity of patellar tendinopathy and is sensitive to small changes in symptoms (Visentini et al 1998, Zwerver et al 2009). It was specifically designed for patellar tendinopathy, rating pain, simple tests of function and the ability to play sports. The maximum VISA score for an asymptomatic athlete is 100 points. The score on this questionnaire will be used to determine if one can participate in the study (inclusion criterion is VISA-P <80), but also to answer the second research question.

In addition, the severity of the injury will be established with the phases defined by Blazina et al 1973 and adapted by Roels et al 1978 and Lian et al 1996 (see table 1). These phases will also be used in this study for stratification of the subjects for the second part of the study, where subjects will be divided into four groups.

Table 1: Phases of patellar tendinopathy symptoms as defined by Blazina et al 1973 and adapted by Roels et al 1978 and Lian et al 1996.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Symptoms</th>
</tr>
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<tbody>
<tr>
<td>Phase 1</td>
<td>Pain after exercise</td>
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<tr>
<td>Phase 2</td>
<td>Pain at the start of an activity, which subsides after warming-up but returns after exercise</td>
</tr>
<tr>
<td>Phase 3a</td>
<td>Pain during and after activity, but the athlete may participate in competition and training at their usual level</td>
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<td>----------</td>
<td>---------------------------------------------------------------------------------------------------</td>
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<tr>
<td>Phase 3b</td>
<td>Pain during and after activity but the athlete cannot participate at the previous level</td>
</tr>
</tbody>
</table>

**Procedure**

**Recruitment**

Subjects with symptomatic patellar tendinopathy who meet the inclusion criteria will be invited to participate in the study. Subjects will be recruited from sports medicine departments and physical therapy practices. Furthermore, advertisements about the study will be posted on the websites of participating sport federations and regional sports clubs and in regional, national and social media. All subjects will receive information about the study. Subjects who are willing to participate in the study are asked to provide written informed consent before participating. Recruitment for the study started in February of 2013 and the anticipated date of completion is January 2014.

**Randomisation**

The order of the four conditions tested (patellar strap, sports tape, kinesio tape and control) is randomised and balanced between subjects to prevent that an order effect will occur. A complete counterbalancing design will be used. In total 24 different options are available.

**Measurements**

The effect of the orthoses on pain will be examined using three functional tests: 1) the single leg decline squat 2) the counter movement jump 3) and the triple hop test. The tests will be preceded by a warming up period of five minutes. This warming up will consist of running or walking, dependent on the subjects’ own preference. Subjects will be allowed to practice all tests on forehand. The three functional tests are explained below:

1) **Single leg decline squat (1x & 10x):** the participant stands on one leg (at first with the left leg) on a platform with a slope of 20 degrees (toes towards the lower side of the platform). The upper body is kept straight above the leg. From this position a squat movement of maximal 60 degrees flexion is made in about 3 seconds (see figure 2).
Subsequently, the participant pushes its body with both legs up to an upright position. This procedure will be repeated ten times with the left leg and after this ten times with the right leg. The single leg decline squat is a simple and effective test to determine a difference in pain in patellar tendinopathy (Purdam et al 2003).

2) Counter movement jump with arm swing: the counter movement jump with arm swing is at first executed with both legs and after this with each leg separately (first left, then right). The subject has to jump three times as high as possible. By touching the wall at the highest point with the tip of the fingers (dipped in chalk) the height of the jump can be established. The counter movement jump is found to be the most reliable and valid test to estimate explosive power of the legs (Markovic et al 2004, Slinde et al 2008).

3) Triple hop test: the participant jumps three times in the horizontal plane on the left leg (landing each time on the same leg). After three hops the subject has to stand still for minimally two seconds and the distance is measured. The same procedure will be repeated with the right leg. The triple hop test is a suitable and reliable test to determine the lower extremity strength and power (Hamilton et al 2008).

Directly after each test, the participant scores on a VAS pain scale the experienced pain during the test. In addition, the height of the counter movement jump and the covered distance of the triple hop test will be documented for each subject. All subjects will execute all tests under all conditions during one session. The order of the tests will be kept the same for all subjects (order as presented above). There will be at least a one minute break between tests and a three minute break between conditions to allow for physiological recovery.

**Data analysis**

All data will be analyzed with SPSS and a p-value lower than 0.05 will be considered as statistically significant.

**Primary aim**

The Linear Mixed model will be used in the first part of the study to determine a possible difference in pain score (VAS) and in distance and height between the conditions during the functional tests.
Secondary aim

To determine if there is a relation between personal characteristics, sports related factors and injury specific factors and the effectiveness of the orthoses also a Linear Mixed model will be used. Using this analysis it can be investigated to what extend the difference in VAS score between wearing an orthosis and not wearing an orthosis (or placebo) in the first part of the study can be predicted by personal factors, sports related factors and the severity of injury.

Sample size calculation

To be able to detect a difference in the primary outcome variable - VAS pain score - with an effect size of 0.3 (based on pilot data mean difference 12 mm, SD 20 mm), a fixed effect omnibus one way ANOVA in G*Power (Faul et al 2007) with a power of 80% and an alpha of 0.05 is used. Then 128 subjects are needed. When a drop-out percentage of 10% is considered, a total of 140 subjects are required in this study. The mean difference in VAS pain score found in the pilot study and used in this sample size calculation (12 mm) is in accordance with the Minimal Clinical Significant Difference (MCSD) found by Kelly et al (2001). This MCSD indicates that when a difference in VAS pain score of 12 mm or more is found, the pain is changed noticeable for the subject (Kelly 2001).

Second part:

Study design

This second part of this study is a randomized controlled trial (parallel group design) in the normal sports environment. All subjects will fill in a log for two weeks (control week and intervention week) about their sports participation and the pain they experience during and after sports (see figure 3 for a flow chart of the study design of this second part).
Figure 3: Flow chart of the study design of the second part of the study. In this second part of the study subjects will document the amount of pain and sports participation during two weeks in the normal sports environment (control week and intervention week).

**Participants**

All participants who participate in the first part, participate in the second part too. Therefore, they meet the criteria described in the ‘participants’ section in the first part.

**Intervention**

All subjects will practice and play their matches for two weeks in their normal sports environment. In the first week, all subjects will be asked to sport without an orthosis for at least one training session. This week is the control week for all subjects. The second week is the intervention week. In this week, 75% of the subjects will sport with an orthosis (see figure 3). Subjects will receive instructions from the researcher on how to administer the orthosis and they will be allowed to practice as much as is necessary to feel confident that one is able
to administer the orthosis in a proper way.

Outcome measures

*Primary outcome measure:* In this part of the study, the primary study parameter is the difference on the VAS pain scale between the control week and the intervention week in the average score during sports.

*Secondary outcome measure:* The difference in average VAS pain score between the control week and the intervention week in the two hours after sports and the next morning, are secondary study parameters. The difference in sports participation (the number and duration of training/matches) between the control week and the intervention week is also a secondary study outcome.

Procedure

Recruitment

The recruitment of subjects is identical to part one, because all participants who participate in the first part, participate in the second part too.

Randomisation

After the first part of the study, subjects will be randomly divided into four groups: a control group, a patellar strap group, a placebo group and a sports tape group. The division into the groups is random, after stratification for severity of injury (based on the four phases defined by Blazina et al 1973 and adapted by Roels et al 1978 and Lian et al 1996, table 1) to make sure that a possible difference in pain and sports participation between groups is not caused by a difference in severity of injury.

Measurements

Subjects will be instructed to document in a log for two weeks: 1) the amount of pain during sports on a VAS pain scale 2) the amount of pain two hours after sports on a VAS pain scale 3) the amount of pain the first two hours the next morning on a VAS pain scale 4) the duration of training/matches 5) the number of training/matches. Also, pain killer use (dose
and amount) and additional knee loading activities during both weeks will be documented by the subjects. After the second week, subjects’ experience with the orthosis will be documented in addition.

**Data analysis**

In the second part of the study the Linear Mixed Model will be used to determine a possible difference between the four groups (control, patellar strap, sports tape and placebo tape) in average difference between the control and intervention week on the VAS pain score during and after sports and in the amount of sports participation.

In this model, corrections for modifying agents like pain killer use and additional knee loading activities during the week will be included.

**DISCUSSION**

This is the first study that investigates the effect of a patellar strap and sports tape on pain and sport participation in patellar tendinopathy. These orthoses are commonly used by athletes with patellar tendinopathy, but to our best knowledge no studies on their effectiveness have been published so far.

As discussed before, one of the most effective treatment options in patellar tendinopathy is physical training (Gaida and Cook 2011, Larsson et al 2012). Eccentric training is until now, the most often used and one of the most effective physical training types, even though the most ideal timing and training protocol is still unknown (Visnes and Bahr 2007). Promising results are also found for a physical training type in which eccentric as well as concentric movements are trained: heavy slow resistance training. Kongsgaard and colleagues showed that this type of training potentially has even more benefit than eccentric training solely, especially on the long term (Kongsgaard et al 2009). Orthoses could potentially play a role in load management, as was demonstrated by Lavagnino et al (2011) who found a decrease in tendon strain as a result of wearing a patellar strap. If a positive effect is found in our study this would support this laboratory finding. On the other hand, if our study shows that these orthoses turn out to be ineffective, this would be important information too. It would be extremely unfortunate if patients do not try treatments, like physical training, because of faith
in orthoses if there is evidence of ineffectiveness of this approach. Therefore, knowledge about the effectiveness of these orthoses is very essential for athletes and practitioners.

A major strength of the current study is that the effect of the orthoses is investigated in a controlled situation as well as in the normal sports environment. In the first part of the study, all subjects perform the same three tests in a controlled environment under four different conditions in a randomized order, so a possible difference on pain will be discovered. Because these tests are performed by a large group of subjects, it is also possible to investigate the relation of a potential effect with personal, sports specific and injury specific characteristics. The functional tests used, however, do not completely resemble the normal sports environment. Therefore, in the second part of the study the effectiveness of the orthoses will be studied during normal training and competition. In this part of the study, not only effects on pain during sports, but also the effect on sports participation will be taken into account. Both parts together increase knowledge and give insight into the acute effect of patellar strap and sports tape use in patellar tendinopathy.

A limitation of this study is that no long term follow-up is included. Relief on the short term as a result of a brace or strap does not always mean that the benefit in pain and function can be found on the longer term too, as was demonstrated in patients with epicondylitis lateralis (Öken et al 2008). So, from the current study no conclusions can be drawn about a potential effect on the long term. Therefore, a suggestion for future research about this subject will be to perform a longitudinal study where patellar tendinopathy patients are measured multiple times over a period of time to determine the long term effect of wearing a patellar strap or sports tape. Another suggestion for future research is to combine the use of orthoses in patellar tendinopathy with physical training programs in a factorial design study to determine if a combination of both is potentially more effective than both treatments separately.

This study will be the first one to provide knowledge about a potential positive effect of a patellar strap and/or sports tape on pain and sports participation in patellar tendinopathy patients with different characteristics. This knowledge can be used by physiotherapists and other practitioners in their advice to athletes with patellar tendinopathy about patellar strap and sports tape use during sports.
References


