Author's response to reviews

Title: The Patella Pro study--effect of a knee brace on patellofemoral pain syndrome: design of a randomized clinical trial (DRKS-ID:DRKS00003291

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Answers to reviewers comments

Marco Paolini

1. Methods
1.1 In- and exclusion criteria

1.1.1 The patients are considered eligible whatever their pain level.

1.1.2 The grading scale is for osteoarthritis is

1.1.3 Patients without existing MRI scans and x ray were not recruited. Indeed, this could be selection bias. In the revision this was discussed as limitation in the discussion.

1.2 Intervention

1.2.1 The Patella move program foresees a gradualness of intensity, which is individually set on the basis of actual symptoms. In the instruction sheet the patients are instructed as follows: 1. “Do not stress yourself”, 2. “If you feel insecure, leave out an exercise.” This information was added to the revised manuscript. Please find the instruction sheet in the appendix. In our experience even older patients could perform those exercises.

1.2.2 In the revised version a more detailed description of the supervised
physiotherapy is given:

The patients got a prescription about supervised physiotherapy: Physical therapy on the device (Krankengymnastik am Gerät). In Germany, “Krankengymnastik am Gerät” is legally regulated by law (§ 125 Abs. 1 SGB V vom 1. August 2001 in der Fassung vom 1. Juni 2006) (http). On the prescription the diagnosis "patellofemoral pain syndrome" is noted. This prescription ensures a structured training program using the following exercises or devices: Functional leg press, treadmill, ergometer, stepper, angle table, vertical pull apparatus. After a detailed analysis, the physical therapist creates a customized training plan for each patient (http). The goal of “Krankengymnastik am Gerät” is to improve strength, coordination, endurance and flexibility of the lower exremity including the hip muscles (http). The duration of one session is 60 minutes (http). The prescription was accompanied by detailed instructions about the study for the physiotherapist.

1.3 Outcome parameters

1.3.1 In the revised version the outcome measures were classified in primary and secondary outcome measures:

Primary outcome measures are: 1. Subjective assessment of recovery on the 7-point Likert scale (10,27) and 2. A modified functional Kujala score (18) without the parameters muscular atrophy and flexion 3 month and one year. These parameters were used or the sample size calculation.

Secondary outcome measures are 1. The primary outcome measures at 6 weeks, 2.the German version of the Knee and Osteoarthritis Outcome Score (KOOS, 17), 3 pain at rest, walking, stair climbing, sitting and sports reported on a numerical scale (0 to 100), and 4. review of compliance and additional interventions. All these measurements are evaluated by a questionnaire at baseline, 6 weeks, 3 month and one year.

1.3.2 A table showing the 7 point Lickert scale was added to the revised manuscript.

Kujala score: The Kujala score measures is a disease specific validated disability scale ranging from 0 (complete disability) to 100 (fully functional).

The validated German version of the Knee Osteoarthritis Outcome Score (KOOS) was used to evaluate patient’s self-reported outcome after medial closing wedge osteotomy. This score is self-explanatory and consists of 5 different subscales; pain, symptoms, sports/recreational activities, activities of daily living, and function. Standardized answer options are given (5 Likert boxes) and each question is assigned a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale (http). A total score has not been validated and is not recommended.

Pain at rest, walking, stair climbing, sitting and sports was marked by the patient on a numerical scale (0 to 100).
All patients are asked by telephone interview at 6, 12 and 54 weeks if they adhere to treatment. It is noted if they did not continue brace use, exercises on their own or supervised physiotherapy.

This information was added to the revised manuscript.

1.3.3 In the revised version a para with the subheading “Expected results was added:

Expected results

In the study of Clark et al. ( ) functional recovery was significantly higher in a group of PFPS patients with supervised physiotherapy. We hypothesise that the passive realignment with the Patellapro brace decreases pain during exercises. Therefore we expect that the exercises in the brace group are more effective than in the non-brace group. This should result in a significantly higher recovery in the brace group.

In the study of van Linschoten et al. ( ) a decrease in pain at rest and activity as well as in function was observed after 3 months in a group with supervised physiotherapy. Therefore an increase in pain and function is also expected in the present study. Hypothesis of this study is that the brace use leads to higher results in the KOOS subscales, Kujala score and decreased pain levels compared to the non-braced patients.

2. Discussion

2.1 The trial started in April 2012 and ended in August 2013. These are the definite dates. During the course of the study the start and had been postponed several times. This explains these errors.

3. Abstract

3.1 Corrected as suggested.

4. Background

4.1 This sentence was added as suggested: “Some characteristics of PFPS such as patellar maltracking can be detected by careful clinical examination (Withrouw et al. 2005). “

4.2 Meta-analysis: Corrected as suggested.

4.3 Main characteristic of this patella brace is the dynamic tracking system. The risk of improper patella tracking is particularly high for lower flexion angles between 0° and 30°, when the patella is not guided by the patellofemoral groove. During this range of motion the tracking system of the Patella Pro works and it helps to track the patella. The pressure from the tracking system decreases with the increasing flexion angle. This mechanism should prevent the patella from pressure where it is not needed.

This information was added to the revised manuscript.

5. Methods
5.1 Study centers
5.1.1 Parameter: Corrected as suggested.

5.2 Patient selection
5.2.1 Recruitment period is April 2012 to August 2013

6. Background
6.1 “on the contrary” was deleted.

Jim Richards
1.-4. The revised paper was corrected by a native speaker.

Additional comments:
1. Background: Para 1 has been rewritten: A literature search of English language publications from January 2000 to December 2005 revealed a cited incidence of the PFPS between 3% to 40% (Selfe and Callahan 2007). This article showed that the evidence for the incidence of PFPS is taken almost entirely from source data in the sports medicine or the military settings (Selfe and Callahan 2007).

2. Structure of para 3 has been improved. Literature about proprioceptive effects has been included.

3. 1.-3. All these studies have been cited in the revised version.

I hope that the aims and objectives of the revised version are more clearly articulated.

James Selfe

Minor essential revisions

1. The first para has been rewritten: A literature search of English language publications from January 2000 to December 2005 revealed a cited incidence of the PFPS between 3% to 40% (Selfe and Callahan 2007). This article showed that the evidence for the incidence of PFPS is taken almost entirely from source data in the sports medicine or the military settings (Selfe and Callahan 2007).

2. In the revised version a neuromotor and proprioceptive perspective has been included: Besides these biomechanical effects there is evidence in the literature that braces have also neuromotor and proprioceptive effects. Thijs et al. (2010) have shown that there was a significantly higher level of brain activation with the application of the brace and sleeve, respectively, compared to the condition without a brace or sleeve. Callaghan et al. (2012) have shown that patellar taping modulates brain activity in several areas of the brain during a proprioception knee movement task.
3. Paragraph 7 has been deleted and replaced by some discussion about proprioception.

4. MRI and X rays are used to exclude patients with early OA.

5. Paragraph 2 of the discussion has been deleted and replaced by some discussion about proprioception.

The revised version has been proof read by a native speaker (EDanz).