

## Reference

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# Evaluating the potential synergistic benefit of a realignment brace on patients receiving exercise therapy for patellofemoral pain syndrome: a randomized clinical trial

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## Products

### Patella Pro

## Major Findings

Patella Pro in combination with physical therapy (PT) compared to physical therapy only:

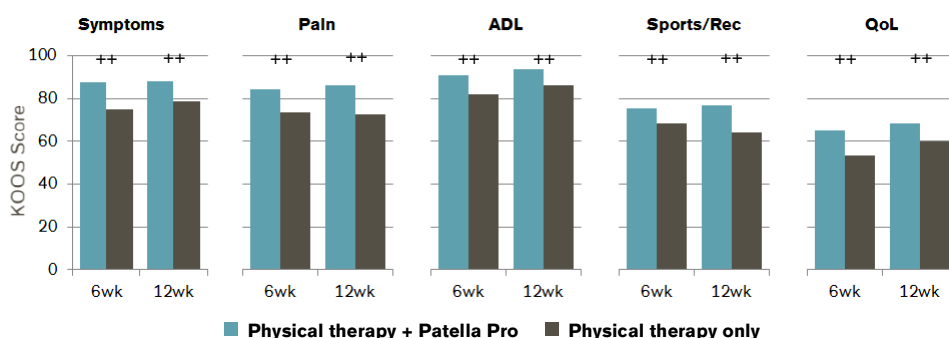
→ **Synergistic effect of Patella Pro, especially during the first 3 months after beginning of treatment, for Patello Femoral Pain Syndrome (PFPS) patients.**

→ Pain decreased significantly with Patella Pro while “climbing stairs” (after 6 and 12 weeks) and “playing sports” (after 12 weeks).

→ Significant improvement of KOOS (“Knee injury and osteoarthritis outcome score”) in all five domains after 6 and 12 weeks with Patella Pro.

→ KUJALA (score for anterior knee pain) was significantly improved after 6 and 12 weeks with Patella Pro.

**Significant improvement in mean KOOS scores in all five domains within first the first three months when using Patella Pro.**

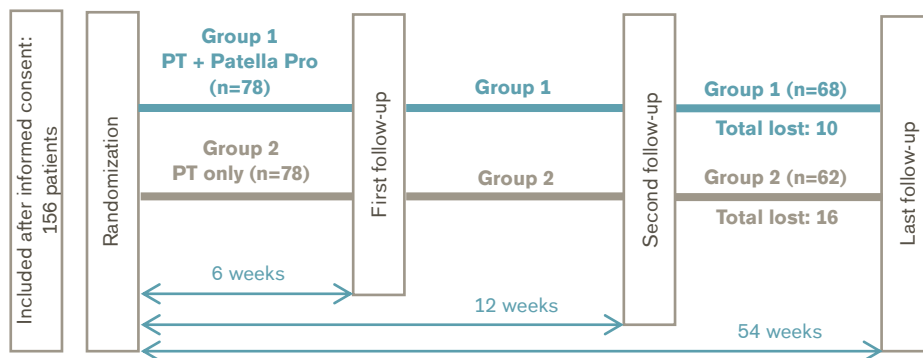


## Population

	<u>Group 1</u> (PT + Patella Pro)	<u>Group 2</u> (PT only)
Subjects:	68 (66% females)	62 (79% females)
Mean age:	28 ± 9.4 years	28 ± 8.1 years
Inclusion criteria:	Presence of three of the following symptoms (lasting longer than two months, not longer than two years)	
	<ul style="list-style-type: none"><li>• Anterior knee pain when running</li><li>• Climbing stairs</li><li>• Cycling</li><li>• Sitting with a bent knee</li><li>• Performing squats</li></ul>	

## Study Design

Observational, comparative with randomization:



Within the six weeks after randomization both groups were treated with:

- Education about Patellofemoral pain syndrome (PFPS)
- Self-directed exercises (Patella move program)
- Supervised physiotherapy (12 sessions) within first 6 weeks

Group 1 was also fitted with Patella Pro and had to wear the orthosis for at minimum six hours per day within those six weeks.

## Results

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for PT with Patella Pro compared to PT only	Sig.*
Clinical Effects	Pain – NAS (Numeric Analog scale)	<b>A significant difference in the decrease in limb pain was found for “climbing stairs” (after 6 and 12 weeks) and “playing sports” (after 12 weeks) for PT with Patella Pro compared to PT only.</b>	
		<b>PT + Patella Pro vs PT only</b>	
		<b>Walking</b>	<b>At rest</b>
		<b>Stairs</b>	<b>Sports</b>
	<b>6 weeks</b>	-14,9% +	13,6% +
		-36,9% ++	-23,6% +
	<b>12 weeks</b>	-37,8% +	-22,4% +
		-37,4% ++	-31,6% ++
	<b>54 weeks</b>	-33,8% +	-3% +
		-9% +	-1% +
KOOS (“Knee injury and osteoarthritis outcome score”)		<b>Significant differences were found in the improvements reported for therapy with Patella Pro compared to therapy only, for all five following subscales after 6 and 12 weeks and for activities of daily living (ADL) after 54 weeks.</b>	
		<b>PT + Patella Pro vs PT only</b>	
		<b>Symptoms</b>	<b>Pain</b>
		<b>ADL</b>	<b>Sports/Rec</b>
		<b>QoL</b>	
	<b>6 weeks</b>	+16,7% ++	+15% ++
		+10,5% ++	+10,4% ++
	<b>12 weeks</b>	+11,7% ++	+18,5% ++
		+8,8% ++	+20% ++
	<b>54 weeks</b>	+4,1% +	+2,9% +
		+4,3% ++	+5,9% +
		+5,4% +	+5,4% +

Category	Outcomes	Results for PT with Patella Pro compared to PT only	Sig.*
	KUJALA - score for anterior Knee Pain	<i>The KUJALA score for this study was adapted by eliminating "muscular atrophy" and "flexion parameters".</i>	
		<b>KUJALA score was significantly improved after 6 (+4,7%) and 12 weeks (+5,3%) with Patella Pro compared to without.</b>	<b>++</b>
		KUJALA score showed the tendency to be improved after 54 weeks (5,1%) with Patella Pro compared to without.	+
	Recovery	No significant between-group differences were reported.	0

\* no difference (0), positive trend (+), negative trend (-), significant (++/--), not applicable (n.a.)

### Author's Conclusion

"... the results of this study allow us to make the conclusion that there is a synergistic effect of a patellar realignment brace and exercise for patients with PFPS, which is most important during the first 3 months after the beginning of treatment." (Petersen, 2016)

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