Patella Pro

Quality for life

Clinical Study Summaries

This document summarizes clinical studies conducted with the Patella Pro. The included studies were identified by a literature search made on PubMed and within the Journal MedicalSportsNetwork.

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Table of content:

1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. gait analysis, clinical effects, satisfaction, etc). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Reference		Category						
		Functions and Activities						Participation
Author	Year	Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction
Petersen	2016						x	
Becher	2015	x						
Brüggemann	2010	x						
Total number: 3		2					1	

2 Summaries of categories

On the following pages you find summaries of categories researched in several studies (e.g. gait analysis, clinical effects, satisfaction, etc.). At the end of each summary you will find a list of reference studies contributing to the content of the particular summary.

Biomechanics – Static measures

Major Findings

With Patella Pro:

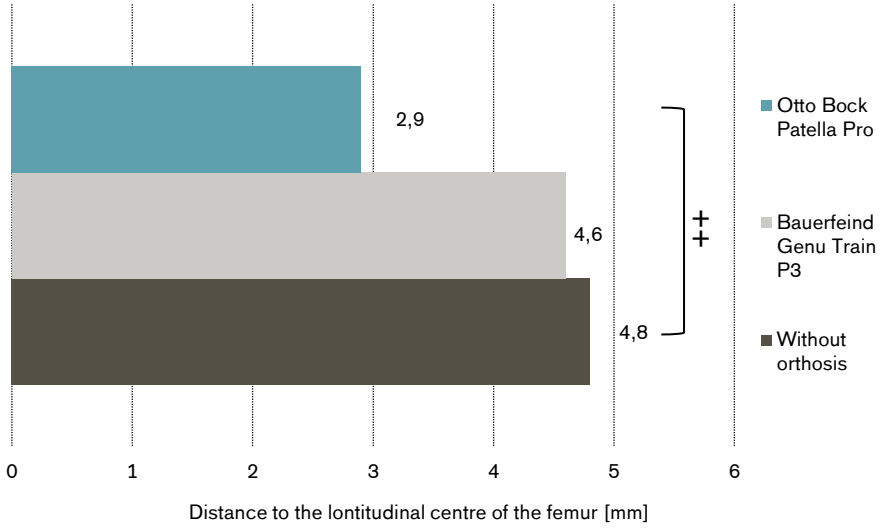
→ The patella was recentred at 0°, 15° and 30° knee flexion

Lower position

Medialization (up to 15.6%)

Reduced tilt (up to 5° reduction)

Reduced lateralisation with Patella Pro



(Brüggemann et al., 2010; The lateralization of the patella was analysed with video fluoroscopy; *Asterisks* indicate significant group differences with ++ = $p < 0.05$)

Clinical Relevance

Patients with Patellofemoral Pain Syndrome (PFPS) suffer from retro- and/or peripatellar pain, which worsens during activities involving heavy use of the patellofemoral joint – such as walking, running, climbing stairs, squatting and prolonged sitting. It is generally caused by a functional misalignment whenever the knee joint assumes a valgus position due to inner rotation of femur and tibia. This results in a decentralisation of the patella. (Rembitzki et al., 2013)

Instability of the patella occurs most often when the knee is between 0-30° flexion and happens because the patella is not fully engaged into the patellar groove. (Zaffagnini et al., 2010)

The Patella Pro recentering orthosis aims to keep the patella in the correct position within the entire flexion range.

Summary

Analyses with MRI and video fluoroscopy have shown that the decentralisation of the patella may be corrected with Patella Pro.

Brüggemann et al. (2010) found that patients who extended their knees from a 45° flexion angle under full or partial weight loading demonstrated a significantly reduced lateralization of the patella when wearing Patella Pro. The lateralization was reduced by 40% compared to the unbraced condition and by 37% compared to the

Bauerfeind Genu Train P3 orthosis (9.5 times greater medialization with Patella Pro).

These findings have been confirmed by Becher et al. (2015) who demonstrated that the patella was significantly medialized in a 0°, 15° and 30° knee flexion angle. Additionally they found, that the patella also was less tilted and in a more distal (lower) position when wearing Patella Pro.

The general function principle of the Patella Pro was investigated by Brüggeman et al. (2010) on cadaver legs. They moved the knee joint with pneumatic actuators and measured the lateralisation of the patella via Vicon motion analysis. Although the results failed to reach a statistical significance due to a high standard deviation of the measured values it could be shown that the patella was medialized by 1.04 – 1.66 mm.

References of summarized studies

Becher, C., Schumacher, T., Fleischer, B., Ettinger, M., Smith, T., & Ostermeier, S. (2015). The effects of a dynamic patellar realignment brace on disease determinants for patellofemoral instability in the upright weight-bearing condition. Journal of Orthopaedic Surgery and Research, 10:126.

Brüggemann, G.-P., Heinrich, K., Liebau, C., Ellermann, A., Potthast, W., & Rembitzki, I. (2010). Patella-Re-Zentrierungs-Orthese Patella Pro Biomechanische Evaluation: ex vivo und in vivo. Proceedings of the ISPO World Congress, Leipzig.

Other References

Petersen, W., Ellermann, A., Rembitzki, I. V., Scheffler, S., Herbort, M., Sprenker, F. S., Achtnich, A., Brüggemann, G.-P., Best, R., Hoffmann, F., Koppenburg, A. G., & Liebau, C. (2014). The Patella Pro study - effect of a knee brace on patellofemoral pain syndrome: design of a randomized clinical trial (DRKS-ID: DRKS00003291). BMC musculoskeletal disorders, 15, 200. Doi:10.1186/1471-2474-15-200

Rembitzki, I. V., Liebau, C., & Petersen, W. (2013). Patellofemoral Pain Syndrome: A multimodal therapeutic approach. Medicalsportsnetwork, 01.13.

Zaffagnini, S., Dejour, D., & Arendt, E. A. (2010). *Patellofemoral pain, instability, and arthritis: Clinical presentation, imaging, and treatment*. Berlin, London: Springer.

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Clinical effects

Major Findings

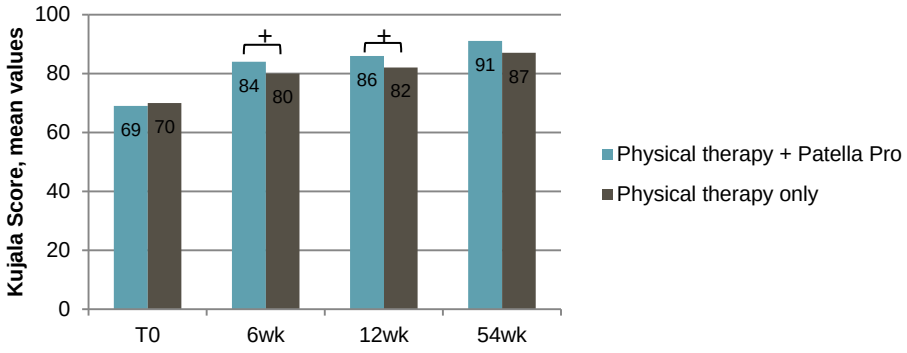
Patella Pro in combination with physical therapy (PT) compared to physical therapy only:

→ Patients with PT + Patella Pro had significantly higher KOOS subscale scores than patients with PT only (after 6 and 12 weeks)
- 16% and 11% improvement in subscore "symptoms", respectively
- 15% and 19% improvement in subscore "pain", respectively
- 11% and 8% improvement in subscore "ADLs", respectively
- 10% and 20% improvement in subscore "sports", respectively
- 23% and 15% improvement in subscore "QoL", respectively

→ Patients with PT + Patella Pro had significantly higher mean Kujala score than patients with PT only (after 6 and 12 weeks)
- 5% improvement after 6 weeks
- 5% improvement after 12 weeks

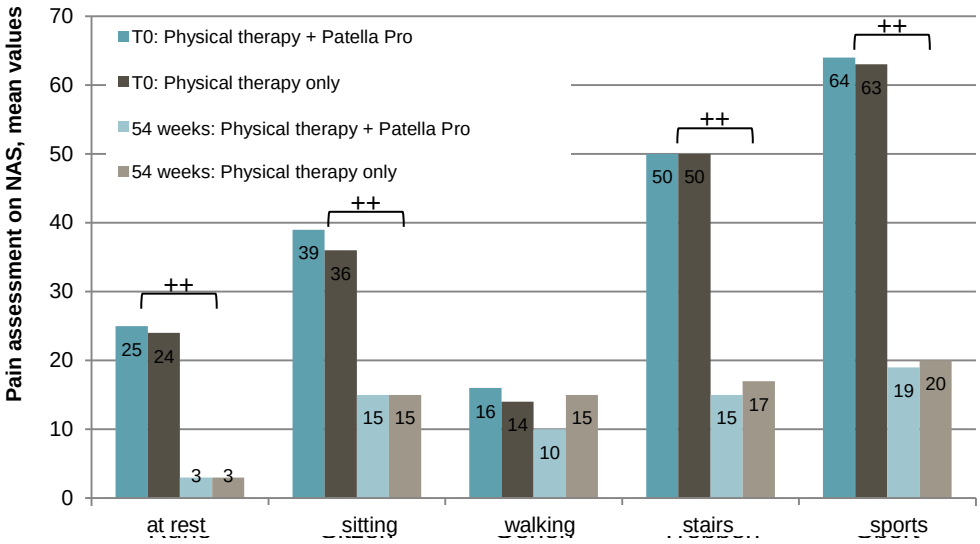
→ Patients with PT + Patella Pro had significantly less pain while climbing stairs and playing sports than patients with PT only (after 6 and 12 weeks)
- 38% reduction while climbing stairs after 6 weeks
- 39% reduction while climbing stairs after 12 weeks
- 33% reduction while playing sports after 12 weeks

Significant improvement in mean Kujala score after 6 and 12 weeks with PT + Patella Pro compared to PT only *(Petersen et al., 2016; Kujala score was adapted by eliminating "muscular atrophy" and "flexion parameters";* Asterisks *indicate significant group differences with + = p < 0.05)*



The results of both treatment groups showed significant improvements in all outcome measures over the study period

Decreased pain after one year. Pain assessment on numerical analog scale (NAS: 0= no pain at all, ..., 100= extreme pain) for both treatment groups *(Petersen et al., 2016;* Asterisks *indicate significant group differences with ++ = p < 0.001)*



Clinical Relevance

Patellofemoral Pain Syndrome (PFPS) is a common cause for anterior knee pain. Its incidence of 22 in 1,000 persons per year is quite high, and women are affected twice often as men. The causes are multifactorial. (Petersen et al. 2014).

Patients suffer from retro- and/or peri-patellar pain, which worsens during activities involving heavy use of the patellofemoral joint – such as walking, running, climbing stairs, squatting and prolonged sitting. (Rembitzki et al., 2013) Furthermore the symptoms cause many athletes to limit their sport activities (Blond & Hansen 1998).

Surveys like the KOOS or Kujala score are instruments to assess the patient's opinion about their knee and associated problems. Among others, activity and mobility are assessed to gain insights into the level of independence of the patient. An increased grade of mobility is crucial to reach a satisfying quality of life. Activities of daily living (ADLs) include self-care activities as functional mobility, dressing, eating and personal hygiene as well as activities to live independently in a community.

Summary

In patients with PFPS, Petersen et al. (2016) compared clinical outcomes after treatment with the realignment brace Patella Pro in combination with supervised exercise with clinical outcomes after supervised exercise alone. Within the first six weeks after recruitment all patients entered a supervised exercise program consisting of education on PFPS, self-directed exercises and physiotherapy. One group was also fitted with Patella Pro and had to wear it for a minimum of six hours per day within those six weeks.

There were no group differences at recruitment, and both groups improved significantly in all measured outcomes after one year.

With PT + Patella Pro there were significant improvements at 6- and 12-week follow-up compared to PT only. Such improvements were found for all KOOS subscales, Kujala score and pain while stair climbing and sports.

There is a synergistic effect of physical therapy and Patella Pro, which is most important during the first three months. It seems that Patella Pro facilitates early rehabilitation.

References of summarized studies

Petersen, W., Ellermann, A., Rembitzki, I. V., Scheffler, S., Herbort, M., Brüggemann, G. P., ... & Liebau, C. (2016). Evaluating the potential synergistic benefit of a realignment brace on patients receiving exercise therapy for patellofemoral pain syndrome: a randomized clinical trial. *Archives of orthopaedic and trauma surgery*, 1-8. DOI 10.1007/s00402-016-2464-2

Other References

Blond, L., & Hansen, L. (1998). Patellofemoral pain syndrome in athletes: a 5.7-year retrospective follow-up study of 250 athletes. *Acta orthopaedica Belgica*, *64*(4), 393-400.

Rembitzki, I. V., Liebau, C., & Petersen, W. (2013). Patellofemoral Pain Syndrome: A multimodal therapeutic approach. Medicalsportsnetwork, 01.13.

Petersen, W., Ellermann, A., Gösele-Koppenburg, A., Best, R., Rembitzki, I. V., Brüggemann, G. P., & Liebau, C. (2014). Patellofemoral pain syndrome. *Knee Surgery, Sports Traumatology, Arthroscopy*, *22*(10), 2264-2274. DOI 10.1007/s00167-013-2759-6

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3 Summaries of individual studies

On the following pages you find summaries of studies that researched Patella Pro. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

Reference

Petersen W, Ellermann A, Rembitzki IV, Scheffler S, Herbort M, Brüggemann GP, Best R, Zantop T, Liebau C.

Klinik fuer Orthopaedie und Unfallchirurgie, Martin Luther Krankenhaus Berlin, Grunewald, Caspar Theyß Strasse 27-31, 14193 Berlin, Germany.

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

Archives of Orthopaedic & Trauma Surgery 2016.

Published online: DOI 10.1007/s00402-016-2464-2

Products

Patella Pro

Major Findings

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

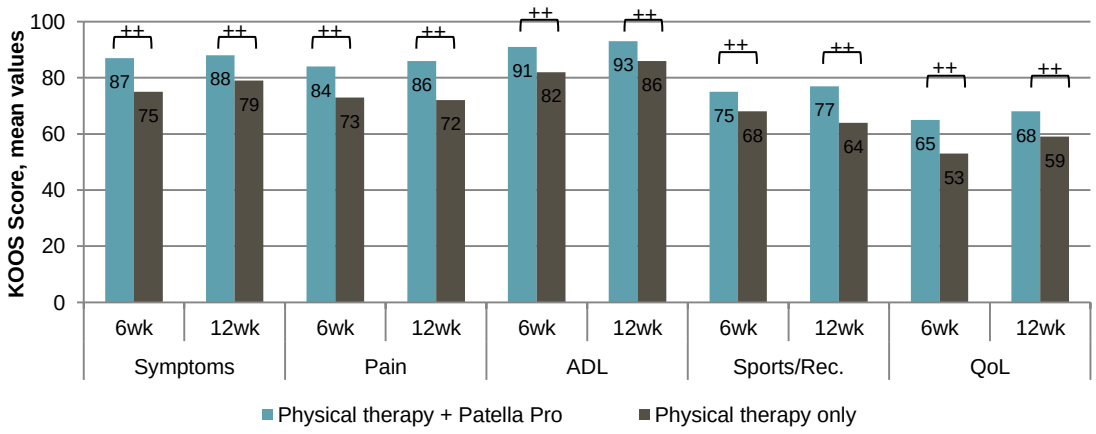
→ **Synergistic effect of Patella Pro, especially during the first 3 months after beginning of treatment, for Patello Femoral Pain Syndrome (PFPS) patients.**

→ 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.
Asterisks indicate significant group differences with ++ = $p < 0.05$.

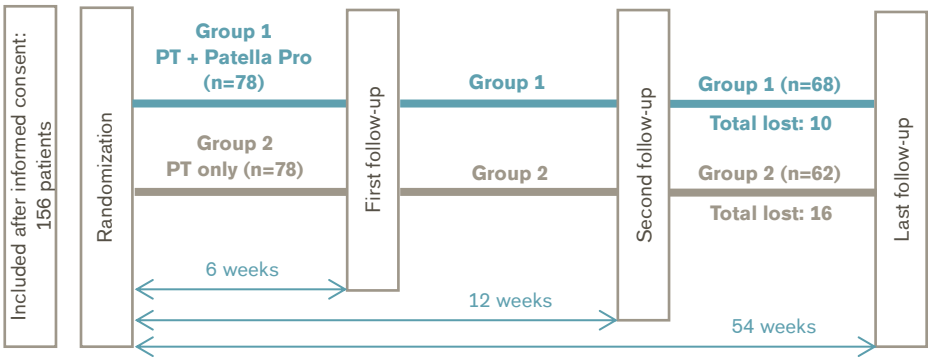


Population

	Group 1 (PT + Patella Pro)	Group 2 (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) • Anterior knee pain when running • Climbing stairs • Cycling • Sitting with a bent knee • Performing squats	

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 (numerical analog scale	**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.**	

PT + Patella Pro vs PT only

	Walking	At rest	Stairs	Sports
6 weeks	-14,9% +	13,6% +	**-36,9%** **++**	-23,6% +
12 weeks	-37,8% +	-22,4% +	**-37,4%** **++**	**-31,6%** **++**
54 weeks	-33,8% +	-3% +	-9% +	-1% +

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.*
	KOOS ("Knee injury and osteoarthritis outcome score")	**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.**					
			PT + Patella Pro vs PT only				
			Symptoms	Pain	ADL	Sports/Rec	QoL
		6 weeks	**+16,7% ++**	**+15% ++**	**+10,5% ++**	**+10,4% ++**	**+22,9% ++**
		12 weeks	**+11,7% ++**	**+18,5% ++**	**+8,8% ++**	**+20% ++**	**+14% ++**
		54 weeks	+4,1% +	+2,9% +	**+4,3% ++**	+5,9% +	+5,4% +
	KUJALA - score for anterior Knee Pain	*The KUJALA score for this study was adapted by eliminating "muscular atrophy" and "flexion parameters".*					
		KUJALA score was significantly improved after 6 (+4,7%) and 12 weeks (+5,3%) with Patella Pro compared to without.					**++**
		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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Reference

Becher, C., Schumacher, T., Fleischer, B., Ettinger, M., Smith, T., & Ostermeier, S.

Department of Orthopedic Surgery, Hannover Medical School

The effects of a dynamic patellar realignment brace on disease determinants for patellofemoral instability in the upright weight-bearing condition

Journal of Orthopaedic Surgery and Research 2015, 10:126

DOI: 10.1186/s13018-015-0265-x

Products

Patella Pro

Major Findings

With Patella Pro:

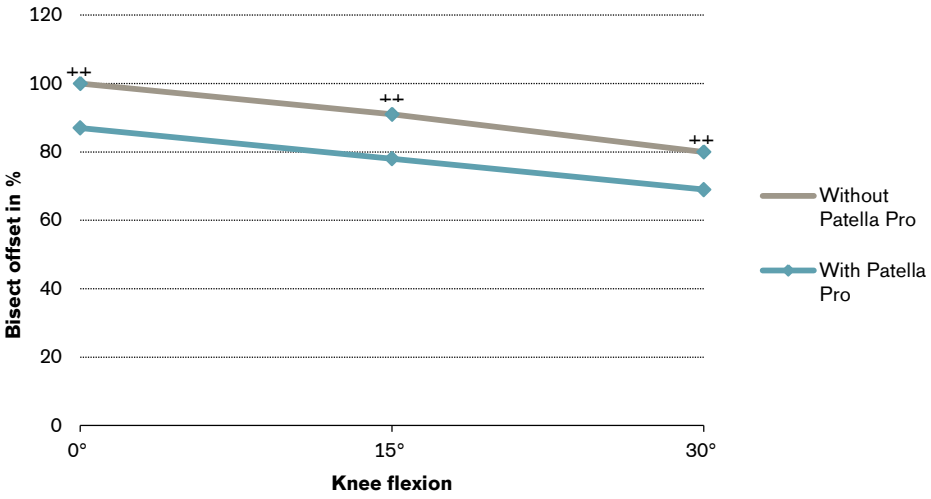
→ The patella was recentred at 0°, 15° and 30° knee flexion

Lower position

Medialization (up to 15.6%)

Reduced tilt (up to 5° reduction)

Significant medialization of the patella



The position of the patella was analysed with MRI.

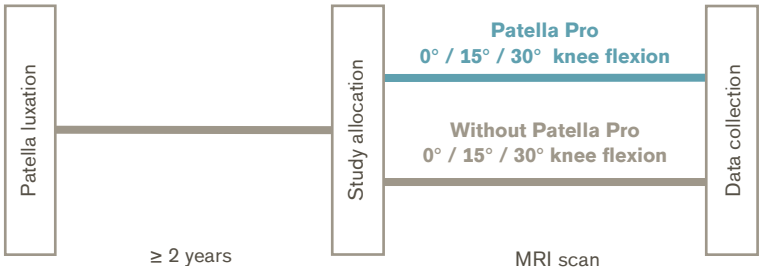
Asterisks indicate significant group differences with ++ = p ≤ 0.05.

Population

Subjects:	20 patients with status ≥ 2 years after patellar dislocation (12 female, 8 male)
Mean age:	25 yrs (range 17 – 39 yrs)

Study Design

Observational, comparative:



The knee joints were scanned in the MRI while they were weight loaded in a 0°, 15° and 30° flexed position. The horizontal and vertical position of the patella was assessed.

Results

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

Category	Outcomes	Results for Patella Pro	Sig.*
Biomechanics – Static measure	Patella height	**The patella was located significantly more distal.**	**++**
	Relative patella lateralisation	**The patella showed a significant medialisation.**	**++**
	Patella Tilt	**The patella was significantly less tilted.**	**++**
	Distance between the tibial tuberosity and the trochlear groove	**The distance between the tibial tuberosity and the trochlear groove was significantly reduced when the knee was flexed at 15° and 30°.**	**++**

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

Author's Conclusion

"From this study, it can be concluded that the dynamic patellar realignment brace, Patella Pro, ma be able to improve disease determinants in patients with lateral patellofemoral instability in the upright weight-bearing condition at 0°-30° flexion. If clinical symptoms can be meaningfully reduced and subluxation or dislocation can be prevented warrants further investigation." (Becher et al. 2015)

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Reference

Brüggemann, G.-P., Heinrich, K., Liebau, C., Ellermann, A., Potthast, W., & Rembitzi, I.

Institute of Biomechanics and Orthopaedics, German Sport University Cologne, Germany.

Patella recentering orthosis Patella Pro Biomechanical evaluation: ex vivo and in vivo

Patella-Re-Zentrierungs-Orthese Patella Pro Biomechanische Evaluation: ex vivo und in vivo

Proceedings of the ISPO World Congress, Leipzig 2010.

Products

Patella Pro vs. Genu Train

Major Findings

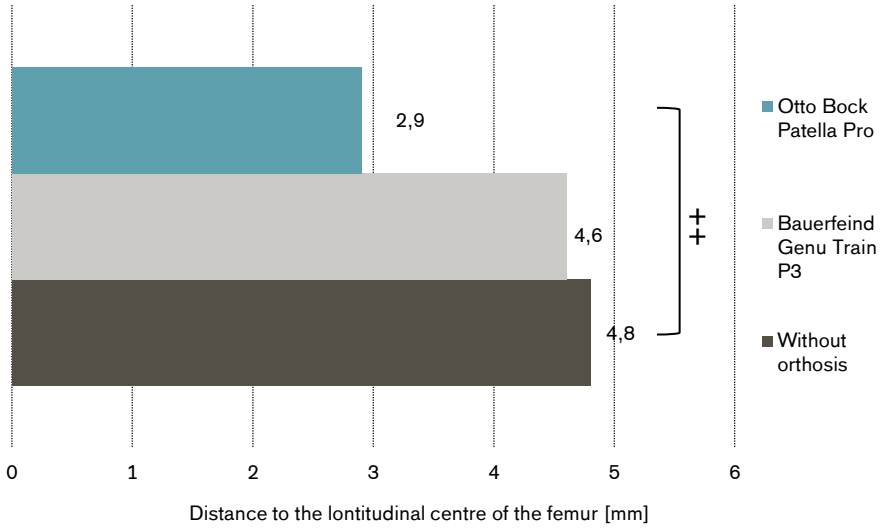
With Patella Pro:

→ The patella was medialized in the knee flexion range of 45° – 0°

Compared to Bauerfeind Genu Train: 9.5 times greater medialization

Compared to without orthosis: Reduced lateralization by 40%

Reduced lateralisation with Patella Pro



The lateralization of the patella was analysed with video fluoroscopy.

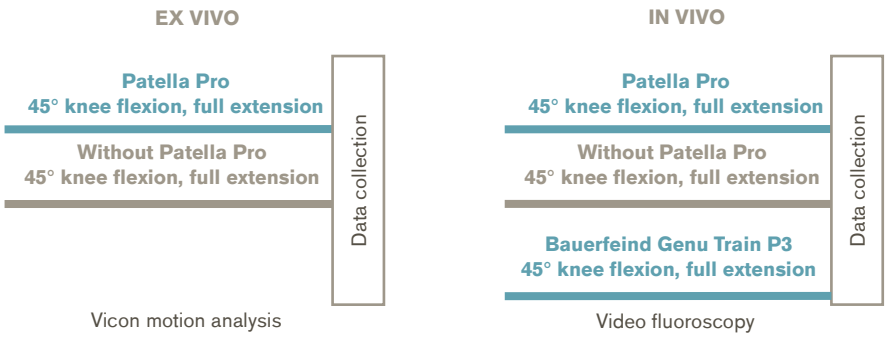
Asterisks indicate significant group differences with ++ = $p < 0.05$.

Population

Ex vivo:	6 cadaver legs (66-72 yrs)
Subjects (in vivo):	7 patients with patella femoral pain syndrome and clinically diagnosed patella instability
Mean age (in vivo):	34.5 yrs (± 7.6 yrs)

Study Design

Observational, comparative:



Ex vivo: Quadriceps was connected to three pneumatic actuators and moved with 100 N per muscle. Retroflective markers were attached on the femur, the patella and the tibia. Lateralization, tilt and rotation of the patella were measured for the knee flexion range of 45-30°, 30-15° and 15-0°.

In vivo: The patients flexed their knees under full or partial load to 45° and then extended them. The lateralisation of the patella in relation to the femur was measured.

Results

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

Category	Outcomes	Results for Patella Pro	Sig.*
Biomechanics – Static measure	**Ex vivo results**		
	Knee flexion 45-30°	Medialization of the patella by 1.04 ± 1.05 mm.	+
	Knee flexion 30-15°	Medialization of the patella by 1.57 ± 1.76 mm.	+
	Knee flexion 15-0°	Medialization of the patella by 1.66 ± 1.73 mm.	+
	In vivo results		
	Knee flexion 45°-0°	**Significantly reduced lateralization of the patella by 40% compared to the flexion without an orthosis. The medialization was 9.5 times greater than with Bauerfeind Genu Train P3.** Without the Patella Pro the lateralization was 4.8 ± 4.9 mm and 4.6 ± 6.7 mm with the Bauerfeind Genu Train P3.	**++**

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

Author's Conclusion

"The functional principle of the Patella recentering orthosis was confirmed by the ex vivo study with the preparation. Although the differences were not statistically different due to the different shapes of the trochleae and therefore high standard deviations of the mean values, the efficiency of the mechanism of the orthosis and the possibility of a progressive recentering of the patella could be demonstrated in 4 out of 6 cases. In patients with patella instability and patellofemoral pain syndrome (PFPS) the patella was significantly medialized with the Patella Pro compared to the neutral and the control condition (BA[1] orthosis). These results are according to previous published studies which did not find a significant influence of the BA but of medializing orthoses on the lateral shift of the patella and the reduction of anterior knee pain in patients with PFPS. It can be concluded, that the Patella Pro orthosis can contribute to a reduction of PFPS. With this study the mechanism of the progressive medialization and recentering of the patella by the Patella Pro was tested and the clinical application in patients with patella instability was shown. It shall be noted that it is remarkable that all previous clinical trials confirmed the biomechanical results and clinical effectiveness. A systematic review of the clinical results will be presentable soon." (Brüggemann et al., 2010)

[1] Bauerfeind Genu Train

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