

Dyneva



Quality for life

Clinical Study Summaries

This document summarizes clinical studies conducted with the Dyneva. The included studies were identified by a literature search made on PubMed and within the journal *Orthopädie Technik*.

Table of content:

1 Overview table p 3

2 Summaries of categories..... p 4-10

 Functional tests p 5

 Clinical effects..... p 7

 Satisfaction p 9

3 Summaries of individual studies..... p 11-16

 Schnake et al. 2019 p 12

 Lang et al. 2017..... p 15

4 Copyright p 17

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		<u>Category</u>						
		Functions and Activities						Participation
Author	Year	<u>Biomechanics – Static measures</u>	<u>Biomechanics – Gait analysis</u>	<u>X-Ray</u>	<u>EMG</u>	<u>Functional tests</u>	<u>Clinical effects</u>	<u>Satisfaction</u>
Schnake	2019					x	x	
Lang	2017						x	x
Total number:	1	0	0	0	0	1	2	1

2 Summaries of categories

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

Functional tests

Major Findings

With Dyneva (compared to no orthosis):

→ All functional tests improved significantly

- 27.6% more number of passes in the stairs-up-and-down-test (p = 0.001)
- 18.8% more number of passes in the chair-rising-test (p = 0.002)
- 13.3% extended distance in the 6-minute-walking distance (p = 0.06)

Clinical Relevance

Back pain is one of the most common conditions in industrialized countries (Brömme et al., 2015; Slade et al., 2014). Typically, the most painful problems are caused by muscle tension or imbalances, degenerated intervertebral discs and joints and / or irritated nerves (Ehrlich, 2003).

Especially patients with radicular problems often suffer from severe mobility impairments. Thus, the complaints increase with movement, for example, the distance walked, and force the patients to stop after a certain distance. The activity and mobility of these patients is significantly restricted by the pain and makes therapeutic measures indispensable. In fact, mobility is essential for functional independence, reduced risk of fall, and quality of life (Runge et al., 2004)

Timed walk tests are validated measures of physical performance and overall mobility in patients with various medical conditions (Rossier & Wade, 2001).

Stair negotiation is a commonly performed activity in daily life and useful as a functional measure in a variety of populations / and the need for more challenging tests other than level walking has been recognized, particularly for more able populations. (Nightingale et al., 2014)

Stair-climbing and walk tests are tasks widely used to evaluate functional capacities and quality of life. (Harada et al., 1999; Kirkley et al., 1999)

Summary

A general, also secondary preventive recommendation for back pain is the regular stretching or movement of the back in the pain-free area (Sherman, 2011). This can lead to improved blood circulation, stretching of the shortened musculature and the semi-elastic soft tissues as well as general relief of the affected structures (Khalil et al., 1992).

The approach of dynamic relief of the lumbar spine is pursued by Dyneva. In addition to the well-known and proven of 3-point principle, Dyneva also offers a dynamic component that influences muscle activity and can be used in conjunction with therapy to stretch and strengthen the relevant muscles.

Schnake et al. (2019) could show that Dyneva could statistically significant improve the stairs-up-and-down-test, the chair-rising-test and the 6-minute-walk-test. This is in line with improvements, found in clinical outcomes, evaluated with questionnaires on pain, physical function and quality of life.

References of summarized studies

Schnake, K. J., Seeger, A. (2019). Targeted treatment of lumbar spinal stenosis with a spinal orthosis. Gezielte Therapie lumbaler Spinalkanalstenosen mit einer Wirbelsäulenorthese. *OT: Orthopädie Technik* 01: 14-17.

Other References

- Brömme, J.; Mohokum, M.; Disch, A. C.; Marnitz, U. (2015). Interdisziplinäre, multimodale Schmerztherapie vs. konventionelle Therapie. *Der Schmerz*, 29(2): 195-202. DOI: 10.1007/s00482-014-1508-1
- Ehrlich, G. E. (2003). Low back pain. *Bulletin of the World Health Organization* 81(9): 671–676.
- Harada, N. D.; Chiu, V.; Stewart, A. L. (1999). Mobility-related function in older adults: assessment with a six-minute walk test. *Arch Phys Med Rehabil*, 80: 837-41.
- Khalil, T. M.; Asfour, S. S.; Martinez, L. M.; Waly, S. M.; Rosomoff, R. S.; Rosomoff, H. L. (1992). Stretching in the rehabilitation of low-back pain patients. *Spine*, 17(3): 311–317.
- Kirkley, A.; Webster-Bogaert, S.; Litchfield, R.; Amendola, A.; MacDonald, S.; McCalden, R.; Fowler, P. (1999). The effect of bracing on varus gonarthrosis. *J Bone Joint Surg Am*, 81: 539-48.
- Nightingale, E. J.; Pourkazemi, F.; Hiller, C. E. (2014). Systematic review of timed stair tests. *JRRD*, 51(3): 335-350. <http://dx.doi.org/10.1682/JRRD.2013.06.0148>
- Rossier, P.; Wade, D. T. (2001). Validity and reliability comparison of 4 mobility measures in patients presenting with neurologic impairment. *Archives of physical medicine and rehabilitation*, 82(1): 9-13.
- Runge, M.; Rittweger, J.; Russo, C. R.; Schiessl, H.; Felsenberg, D. (2004). Is muscle power output a key factor in the age-related decline in physical performance? A comparison of muscle cross section, chair-rising test and jumping power. *Clin Physiol Imaging*, 24: 335-340.
- Sherman, K. J. (2011). A Randomized Trial Comparing Yoga, Stretching, and a Self-care Book for Chronic Low Back Pain. *Arch Intern Med*, 171(22): 2019 - 2026. Doi:10.1001/archinternmed.2011.524
- Slade, S. C.; Patel, S.; Underwood, M.; Keating, J. L. (2014). What are patient beliefs and perceptions about exercise for nonspecific chronic low back pain? a systematic review of qualitative studies. *The Clinical journal of pain*, 30(11): 995-1005.

[↑ Back to overview table](#)

Clinical effects

Major Findings

With Dyneva:

Validated questionnaires improved significantly (Schnake et al., 2019)

- improvement in EQ-5D part 1 (p = 0.037) and part 2 (p = 0.001)
- improvement in Zurich Claudication Questionnaire (p = 0.002)
- improvement in Oswestry Disability Questionnaire (p = 0.023)
- improvement in pain rating on visual analog scale (VAS) for pain at rest (p = 0.041) and pain during activity (p = 0.011)
- improvement in pain medication

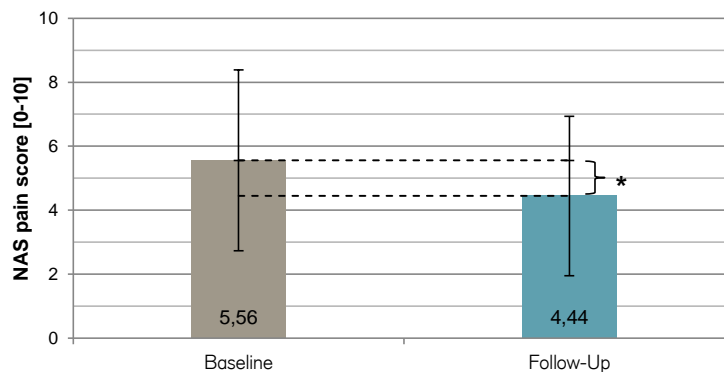
Pain level on NAS (0-10)

- Significant pain reduction of 21% (Lang et al., 2017)

Walking distance

- Significant improvement of 700 meters (88%) (Lang et al., 2017)
- Significant improvement of 39 meters (13.3%) in 6-minute-walk-test (p = 0.06) (Schnake et al., 2019)

Pain reduction with Dyneva after 4-week use



NAS pain score: 0= no pain at all, ..., 10= extreme pain. * p<0.01 (Lang et al., 2017)

Clinical Relevance

Back pain is one of the most common conditions in industrialized countries (Brömme et al., 2015, Slade et al., 2014). In Germany alone, between 80% - 85% of the population develop at least once in their life complaints in the back (Brömme et al 2015). In one tenth of the affected patients, the pain manifests itself as chronic. The financial burden to the health care system by treatment costs and loss of productivity are substantial and amounted to approximately 6% of all medical costs in Germany in 2008 (DESTATIS 2010). In the period from 2006 to 2014, the number of inpatient treatments for lumbar back pain increased by about 50% (Bitzer et al., 2015). The proportion of early retirement due to back pain of 18% is an important factor in an aging society (Werber et al., 2014).

Summary

Lumbar orthoses are often utilized to restrict lumbar motion as part of a treatment regimen for a wide range of degenerative or musculoskeletal conditions in an attempt to provide mechanical support, and to enhance patient comfort. Aside from limiting the range of motion of the spine, lumbar orthoses may also unload the spinal column indirectly by increasing intra-abdominal pressure and acting as an external splint. (Jegede et al. 2011)

Lang et al. (2017) could show that Dyneva was effective in reducing the pain situation of the patients to a significant amount and to prolong the pain-free walking distance from 800 to 1500 meters.

Schnake et al. (2019) could also show an improvement in walking distance. This improvement was with 13.3% statistically significant. Additionally, all validated questionnaires (EQ-5D, ODI, ZCQ, pain on VAS) improved significantly, indicating less problems, less pain and more quality of life. These findings are reinforced by a reduction in pain medication.

References of summarized studies

Lang, M., Schnake, J., Rembitzki, I.V., Lidolt, K., Vollbrecht, M., Wagner, K., Liebau, C. (2017). Effect of a Dynamic Lumbar Flexion Orthosis on Back Pain and Pain-free Walking Distance – Results of a Prospective Clinical Observational Study. Der Einfluss einer dynamischen Lumbalflexionsorthese auf Rückenschmerz und schmerzfreie Gehstrecke. *OT: Orthopädie Technik* 01: 32-35.

Schnake, K. J., Seeger, A. (2019). Targeted treatment of lumbar spinal stenosis with a spinal orthosis. Gezielte Therapie lumbaler Spinalkanalstenosen mit einer Wirbelsäulenorthese. *OT: Orthopädie Technik* 01: 14-17.

Other References

Bitzer, E. M., Lehmann, B., Bohm, S., Priess, H.-W. (2015). BARMER GEK Report Krankenhaus 2015. Schwerpunkt: Lumbale Rückenschmerzen. Asgard-Verlagsservice GmbH.

<https://www.barmer.de/blob/37826/788aab584c80c6cba0e5eebe1d5a6b79/data/pdf-report-krankenhaus-2015.pdf> [access 26.04.2017]

Brömme, J., Mohokum, M., Disch, A. C., Marnitz, U. (2015). Interdisziplinäre, multimodale Schmerztherapie vs. konventionelle Therapie. *Der Schmerz*, 29(2), 195-202. DOI: 10.1007/s00482-014-1508-1

DESTATIS - Statistisches Bundesamt (2010). Gesundheit 2002, 2004, 2006 und 2008. Krankheitskosten. Fachserie 12 Reihe 7.2. Statistisches Bundesamt, Wiesbaden 2010. https://www.destatis.de/DE/Publikationen/Thematisch/Gesundheit/Krankheitskosten/Krankheitskosten2120720089004.pdf;jsessionid=4F980D221315C6816CFCA B90A0075F0E.cae3?__blob=publicationFile [access 26.04.2017]

Jegede, K. A., Miller, C. P., Bible, J. E., Whang, P. G., Grauer, J. N. (2011). The effects of three different types of orthoses on the range of motion of the lumbar spine during 15 activities of daily living. *Spine*, 36(26): 2346-2353.

Slade, S. C., Patel, S., Underwood, M., Keating, J. L. (2014). What are patient beliefs and perceptions about exercise for nonspecific chronic low back pain? a systematic review of qualitative studies. *The Clinical journal of pain*, 30(11), 995-1005.

Werber, A., Schiltewolf, M. (2014). Kampf dem chronischen Rückenschmerz. Leitliniengerechte Diagnostik und Therapie. *CME*, 11(2):53-64.

[↑ Back to overview table](#)

Satisfaction

Major Findings

With Dyneva:

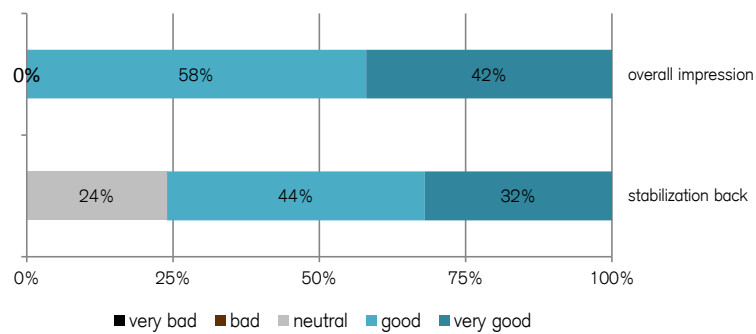
Satisfaction

- 100% rated the overall impression as “good” or “very good”
- 76% rated the perceived stabilization effect as “good” or “very good”

Compliance

- Dyneva is worn
 - daily by 54%
 - 4-5 times per week by 25%
 - less than 3 times per week by 21%
- The daily wearing time amounts for
 - all day in 8%
 - 5-8 hours in 25%
 - 2-4 hours in 67%

Dyneva showed a high patient satisfaction



(Lang et al. 2017)

Clinical Relevance

Satisfaction is a very meaningful parameter to investigate since it has a direct impact on the patients' well-being and compliance. It is also correlated with the usage of the medical device. Studies on the non-use of devices suggest that, on average, one third of all devices provided are not used (Scherer 2002). Reasons for non-use involve lack of consumer involvement, inadequate performance of the product, failure of the product to improve function, and difficulty in operating the product (Batavia & Hammer 1990, Wielandt & Strong 2000). Obtaining user perspectives and satisfaction is therefore fundamental.

The patients' satisfaction is influenced by other categories and can therefore be seen as a summary of possible pain reduction and better performance of ADLs.

Summary

The majority of patients were satisfied with the Dyneva in terms of the overall impression and the perceived stabilization effect. The overall impression was rated as good or very good by all patients. The same answer options were chosen by 76% of patients for the perceived back stabilization and the remaining 24% stated the stabilization effect as neutral.

This high satisfaction is also correlated with compliance. More than half of the patients wore Dyneva daily and an additional quarter 4-5 days per week. The majority of patients used Dyneva for 2-4 hours a day, a quarter for 5-8 hours and 8% wore Dyneva all-day long. (Lang et al. 2017)

References of summarized studies

Lang, M., Schnake, J., Rembitzki, I.V., Lidolt, K., Vollbrecht, M., Wagner, K., Liebau, C. (2017). Effect of a Dynamic Lumbar Flexion Orthosis on Back Pain and Pain-free Walking Distance – Results of a Prospective Clinical Observational Study. Der Einfluss einer dynamischen Lumbalflexionsorthese auf Rückenschmerz und schmerzfreie Gehstrecke. *OT: Orthopädie Technik* 01: 32-35.

Other References

Batavia, A. I., & Hammer, G. S. (1990). Toward the development of consumer-based criteria for the evaluation of assistive devices. *Journal of rehabilitation research and development*, 27(4):425-436.

Scherer, M. J. (2002). The change in emphasis from people to person: introduction to the special issue on Assistive Technology. *Disability and rehabilitation*, 24(1-3):1-4.

Wielandt, T., & Strong, J. (2000). Compliance with prescribed adaptive equipment: a literature review. *The British Journal of Occupational Therapy*, 63(2):65-75.

[↑ Back to overview table](#)

3 Summaries of individual studies

On the following pages, you find summaries of studies that researched Dyneva. 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

Schnake, K. J., Seeger, A.

Gezielte Therapie lumbaler Spinalkanalstenosen mit einer Wirbelsäulenorthese

Targeted treatment of lumbar spinal stenosis with a spinal orthosis

OT: Orthopädie Technik 01 / 2019: 14-17.

Products

Dyneva

Major Findings

With Dyneva compared to no orthosis:

→ All functional tests improved significantly

- 27.6% more number of passes in the stairs-up-and-down-test (p = 0.001)
- 18.8% more number of passes in the chair-rising-test (p = 0.002)
- 13.3% extended distance in the 6-minute-walk-test (p = 0.06)

→ All questionnaires improved significantly

- EQ-5D part 1 (p = 0.037) and part 2 (p = 0.001)
- Zurich Claudication Questionnaire (p = 0.002)
- Oswestry Disability Index (p = 0.009)
- Pain rating on visual analog scale (VAS) for pain at rest (p = 0.007) and pain during activity (p = 0.012)

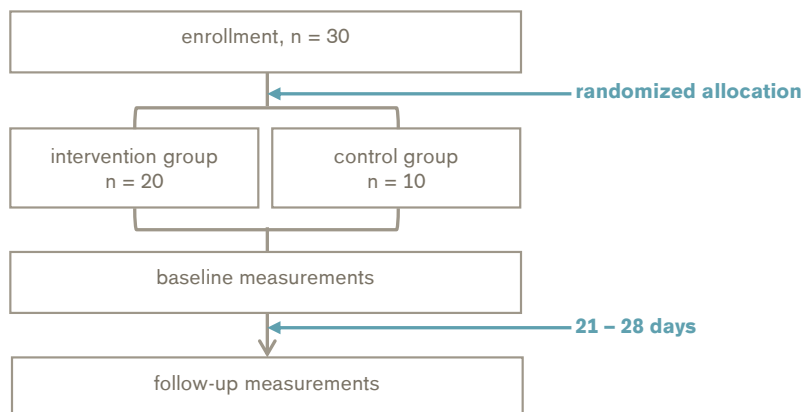
→ Less pain medication in 25% of patients in Dyneva group

Population

Subjects: 30 patients
 Age range: 18 - 80 years
 Inclusion criteria:
 - lumbal stenosis,
 - degenerative lumbar instability, or
 - disc prolapse

Study Design

Prospective randomized trial:



Results

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

Category	Outcomes	Results for Dyneva compared to no orthosis	sig.*		
Functional tests	Stairs-up-and-down-test	Number of passes within 60 sec. increases by 27.6%	++		
		Dyneva	Control		
		baseline 10.4	9.7		
	follow-up 12.3	9.9			
	Chair-rising-test	Number of passes within 30 sec. increases by 18.8%	++		
		Dyneva	Control		
		baseline 7.6	6.2		
	follow-up 9.7	6.6			
	6-minute-walk-test	Walking distance within 6 minutes extended by 13.3%	++		
Dyneva		Control			
baseline 291m		279m			
follow-up 330m	265m				
Clinical effects	EQ-5D	Significant improvement in EQ-5D part 1 (mobility, self-care, ADLs, pain, anxiety), and significant improvement in EQ-5D part 2 (quality of life). An increasing number indicates an improvement	++		
		part 1	part 2		
		Dyneva	Control	Dyneva	Control
		baseline 60	80	64	63
		follow-up 65	70	67	58
	Zurich Claudication Questionnaire	Disease-specific self-report outcome for patients with lumbar spinal stenosis. A decreasing sum of points indicates an improvement. Significant improvement was found for Dyneva group	++		
		Dyneva	Control		
		baseline 19.5	19.1		
	follow-up 17.9	20.3			
	Oswestry Index	Disability	Measure of a patient's permanent functional disability. A decreasing number indicates an improvement. Significant improvement was found for Dyneva group	++	
Dyneva			Control		
baseline 14.9			12.6		
follow-up 14.0	13.4				

Kommentar [SS1]: Die Tabelle ist jetzt ausführlicher. Die Informationen stammen aus der Auswertung und sind NICHT veröffentlicht

Kommentar [HA2]: In dieser Sektion ist so genau als möglich über die Verbesserungen Auskunft zu geben.

Was misst der in welchen Einheiten ? Wie groß ist die absolute Verbesserung ? Wichtig um klinische Relevanz abschätzen zu können.

Was genau ist gemeint mit part 1 und part 2 ? Den Gesamtscore vs. VAS ? Oder die ersten beiden Teile der Likert-Scala ? Welcher EQ 5D (5L ?).

Kommentar [SS3]: Ich finde weder in der Veröffentlichung, noch in den Studienunterlagen einen Hinweis, welcher EQ-5D verwendet wurde. Zugriff auf die CRFs habe ich nicht.

Results

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

Category	Outcomes	Results for Dyneva compared to no orthosis				sig.*	
Pain on visual analog scale	Significant improvement for pain at rest and pain during activity. A decreasing number indicates an improvement	Pain at rest		Pain during activity		++	
		Dyneva	Control	Dyneva	Control		
		baseline	1.8	2.6	7.0		7.3
		follow-up	1.3	3.3	6.3		7.4
		Pain medication	25% of patients in Dyneva group and 0% in control group could reduce their medication				n.a.

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

Author's Conclusion

The study comes to the conclusion that wearing the orthosis leads to a reduction of back pain, improvement in movements relevant to daily living and to improving the quality of life. The application of the Dyneva flexion orthosis [...] showed significant improvements in clinical parameters and assessments compared to the control group. The flexion orthosis can be recommended as a building block in conservative therapy, particularly with regard to longer walking distance and reduced pain.

“Die Studie kommt zu dem Ergebnis, dass das Tragen der Orthese zu einer Reduktion von Rückenschmerzen, zu Verbesserungen bei alltagsrelevanten Bewegungen und zu einer Verbesserung der Lebensqualität führt. [...] Die Anwendung der Dyneva-Flexionsorthese [...] führte im Vergleich zur Kontrollgruppe zu signifikanten Verbesserungen klinischer Parameter und Assessments. Vor allem im Hinblick auf eine Verlängerung der Gehstrecke und eine Verringerung der Schmerzen kann die Flexionsorthese als Baustein in der konservativen Therapie empfohlen werden.” (Schnake et al. 2019)

[↑ Back to overview table](#)

Kommentar [HA4]: In dieser Sektion ist so genau als möglich über die Verbesserungen Auskunft zu geben.

Was misst der in welchen Einheiten? Wie groß ist die absolute Verbesserung? Wichtig um klinische Relevanz abschätzen zu können.

Was genau ist gemeint mit part 1 and part 2? Den Gesamtscore vs. VAS? Oder die ersten beiden Teile der Likert-Scala? Welcher EQ 5D (5L)?

Reference

Lang, M., Schnake, J., Rembitzki, I.V., Lidolt, K., Vollbrecht, M., Wagner, K., Liebau, C.

Effect of a Dynamic Lumbar Flexion Orthosis on Back Pain and Pain-free Walking Distance – Results of a Prospective Clinical Observational Study

Der Einfluss einer dynamischen Lumbalflexionsorthese auf Rückenschmerz und schmerzfreie Gehstrecke

OT: Orthopädie Technik 01 / 2017: 32-35.

Products

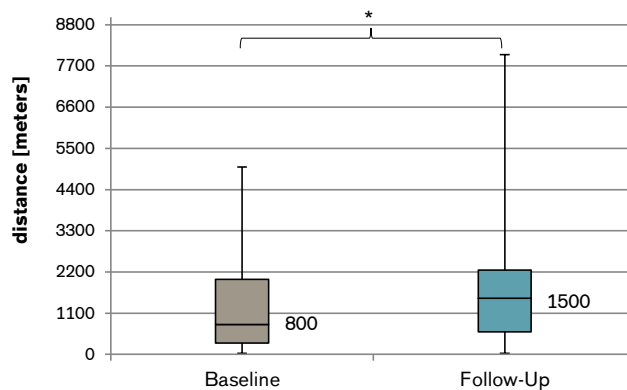
Dyneva

Major Findings

With Dyneva:

- **The pain was reduced significantly ($p < 0,01$) by 21%**
- **The pain-free walking distance was increased significantly ($p < 0,01$) by 88%**
- **The patient satisfaction was very high**
 - The *overall impression* was very good (42%) or good (58%)
 - The *stabilization effect* was very good (32%) or good (44%)
- **The compliance was high**
 - Dyneva was worn daily (54%) or 4-5 times / week (25%)
 - Dyneva was worn 5-8h (25%) or 2-4h (67%) per day

Pain-free walking distance improved significantly with Dyneva



Significant improvement: * $p < 0.01$

Population

Subjects: 31 patients (15 male, 16 female)
 Mean age: 65.0 ± 11.5 years
 Inclusion criteria:
 - chronic back pain (lasting for at least 6 months)
 - limited pain-free walking distance

Study Design

Prospective before-and-after study with 4-week follow-up (with Dyneva):



Results

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction
Category	Outcomes	Results for Dyneva				Sig.*
Clinical effects	Pain level on NAS	- 21% (from 5.6 to 4.4 points)				++
	Pain-free walking distance	+ 88% (from 800 to 1500 meters)				++
		increase	no change	reduction		
		61%	39%	0%	of patients	
Satisfaction	Satisfaction	overall impression		stabilization back		
		very good	42%	32%	n.a.	
		good	58%	44%	n.a.	
		neutral	0%	24%	n.a.	
		bad / very bad	0%	0%	n.a.	
	Compliance	Wearing period during 4-week intervention				n.a.
		daily	4-5 times / week	2-3 times / week	<2 times / week	
		54%	25%	17%	4%	
		Daily wearing time				n.a.
		all-day	5-8 hours	2-4 hours	<1 hour	
8%	25%	67%	0%			

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

Author's Conclusion

In summary, it can be stated that the new lumbar flexion orthosis shows the desired relief of the lumbar spine by reducing the muscular force-induced compression of the vertebral facet joints, intervertebral disc structures and the spinal foramina in the patients, reduces pain and increases the walking distance, sometimes even doubles it.

“Zusammenfassend kann festgestellt werden, dass die neue Lumbalflexionsorthese die gewünschten Effekte der Entlastung der LWS durch Reduktion der muskelkraftinduzierten Kompression auf Wirbelgelenke, Bandscheibenstrukturen und der spinalen Foramina am Patienten zeigt, Schmerzen reduziert und die Gehstrecke verlängern, zum Teil sogar verdoppeln kann.” (Lang et al. 2017)

[↑ Back to overview table](#)

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