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Study Folder Spinomed®

Spinal orthoses for the management of osteoporosis

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German S3 Guideline for the Prevention, Diagnostics and Therapy of Osteoporosis (DVO, 2023)

According to the S3 Guideline “Prevention, Diagnostics and Therapy of Osteoporosis in Postmenopausal Women and in Men 50 Years and Older” published by the German speaking umbrella organisation Dachverband Osteologie e. V. (DVO), **early mobilisation after minor traumatic stable vertebral fractures should be performed** to avoid complications, which might occur following immobility such as pneumonia, pulmonary embolism and functional deficits (**highest grade of recommendation A**).

For the painless mobilisation following acute stable osteoporotic vertebral fractures, different therapy approaches are available. According to the S3 Guideline, conservative treatment with spinal orthoses such as the Spinomed® or Spinomed® active may be considered. Furthermore, spinal orthoses should be used in combination with physiotherapeutic exercises and posture training.

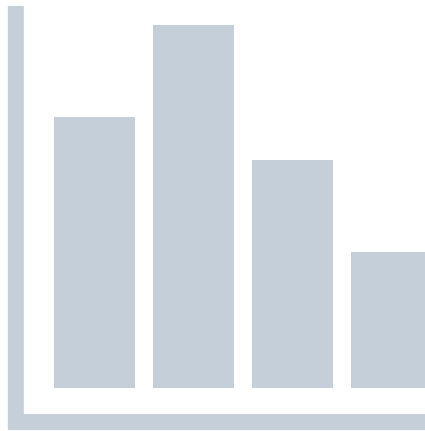
- As evidence for pain reduction, enhanced posture and improved function, the S3 Guideline refers to the publication by Hettchen et al. (2022) among others.
- In this randomised controlled trial, the efficacy of the spinal orthosis **Spinomed® active** has been proven in women with older osteoporotic vertebral fractures and hyperkyphosis (see page 17).

Reference: DVO e.V. S3-Guideline “Prophylaxe, Diagnostik und Therapie der Osteoporose bei postmenopausalen Frauen und bei Männern ab dem 50. Lebensjahr”; AWMF-register number: 183 - 001; Status: 06/09/2023. Published online at: <https://www.awmf.org/leitlinien/detail/ll/183-001.html> (Last access 19/02/2024).

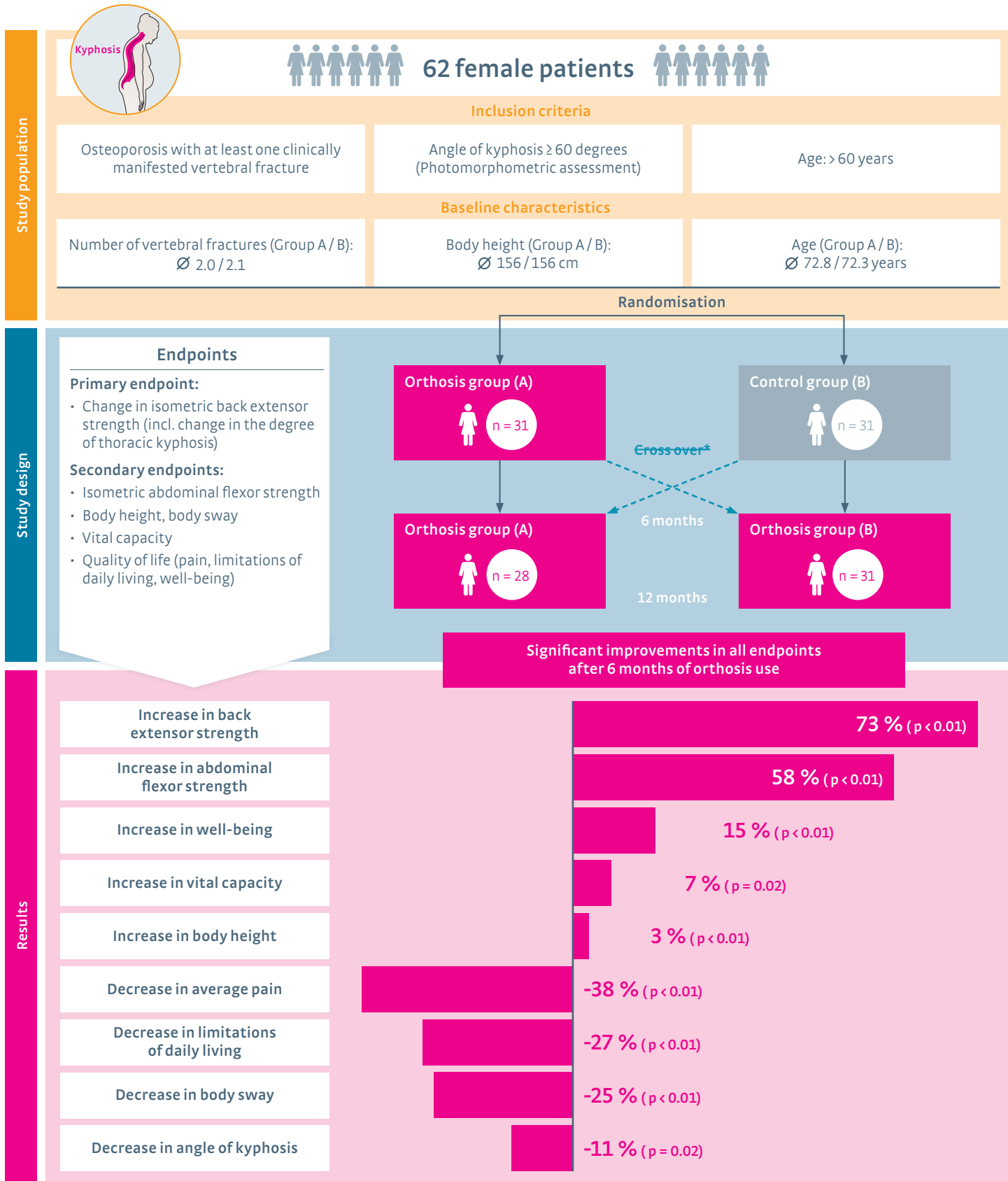




Clinical Trials – Scientific Evidence



Spinomed® – Efficacy in women with postmenopausal osteoporosis (Pfeifer et al., 2004)



* The initially planned cross-over-design was modified due to ethical reasons. Patients in group A refused to stop wearing the orthosis after six month.
 Reference: Pfeifer M et al. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil 2004;83(3):177-186.



In a prospective randomised controlled trial, Pfeifer et al. (2004) proved the efficacy of the Spinomed orthosis in postmenopausal women with osteoporosis.

The originally planned cross-over-design was modified after six months due to the high efficacy of the **Spinomed** orthosis:

- Patients in the orthosis-group (group A) refused to stop wearing the **Spinomed** after six months. Therefore, this group used the orthosis for a total of twelve months.
- The control group (group B) started the orthotic treatment after six months. In this group, the efficacy of the **Spinomed** was observed over a period of a total of six months.

The study results revealed that wearing the **Spinomed** orthosis led to an increase in back extensor and abdominal flexor strength, a decrease of the angle of kyphosis and a reduction of body sway. All the improvements were statistically significant. Besides the efficacy and tolerability of the spinal orthosis, improvements in well-being led to a very high patient compliance rate. All of the patients wore the **Spinomed** orthosis for at least six months. The authors rated the overall compliance with the **Spinomed** during the total study period as excellent.

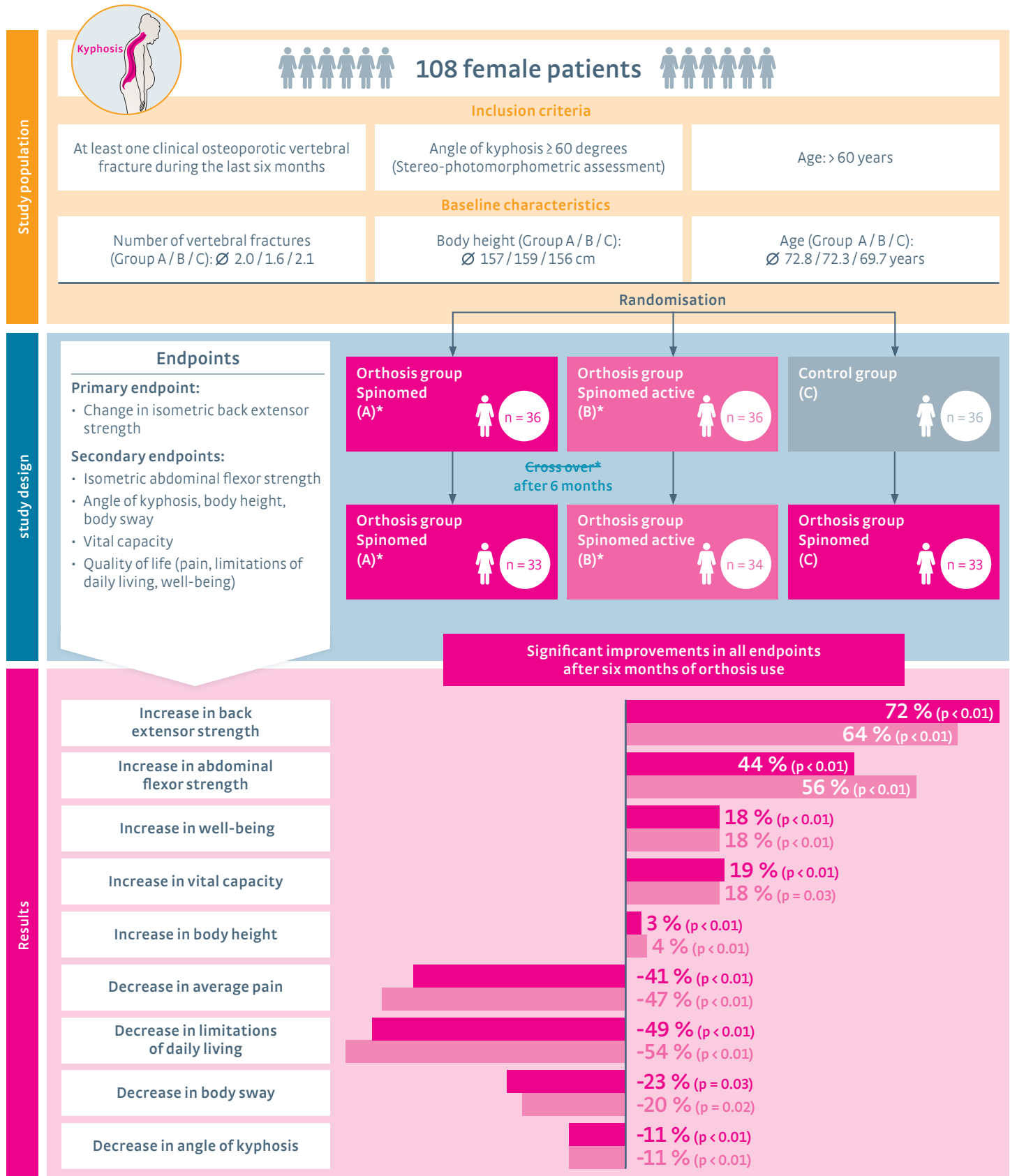
Reference: Pfeifer M et al. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil 2004;83(3):177-186.

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Spinomed® / Spinomed® active – Efficacy in postmenopausal women with osteoporosis (Pfeifer et al., 2011)



* The initially planned cross-over-design was modified due to ethical reasons. Patients in group A and B refused to stop wearing the orthosis after six months.
 Reference: Pfeifer M et al. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil 2011;90(10):805-815.



In 2011, the positive outcomes of the Spinomed orthosis (Pfeifer et al., 2004) were confirmed and the efficacy of the Spinomed active was proven.

Besides the **Spinomed** orthosis, the efficacy of the **Spinomed active** – a body variant with the same mode of action as the **Spinomed** – was examined. The study population consisted of postmenopausal women with osteoporosis and at least one osteoporotic vertebral fracture during the last six months.

The prospective randomised controlled clinical trial demonstrated that the use of the spinal orthoses of the **Spinomed** product family led to a significant increase in trunk muscle strength as well as an improved posture. Furthermore, using the orthoses led to pain relief, which in turn increased the amount of activities of daily living and therefore enhanced well-being and quality of life.



Reference: Pfeifer M et al. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. *Am J Phys Med Rehabil* 2011;90(10):805-815.

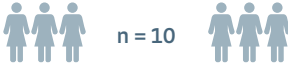
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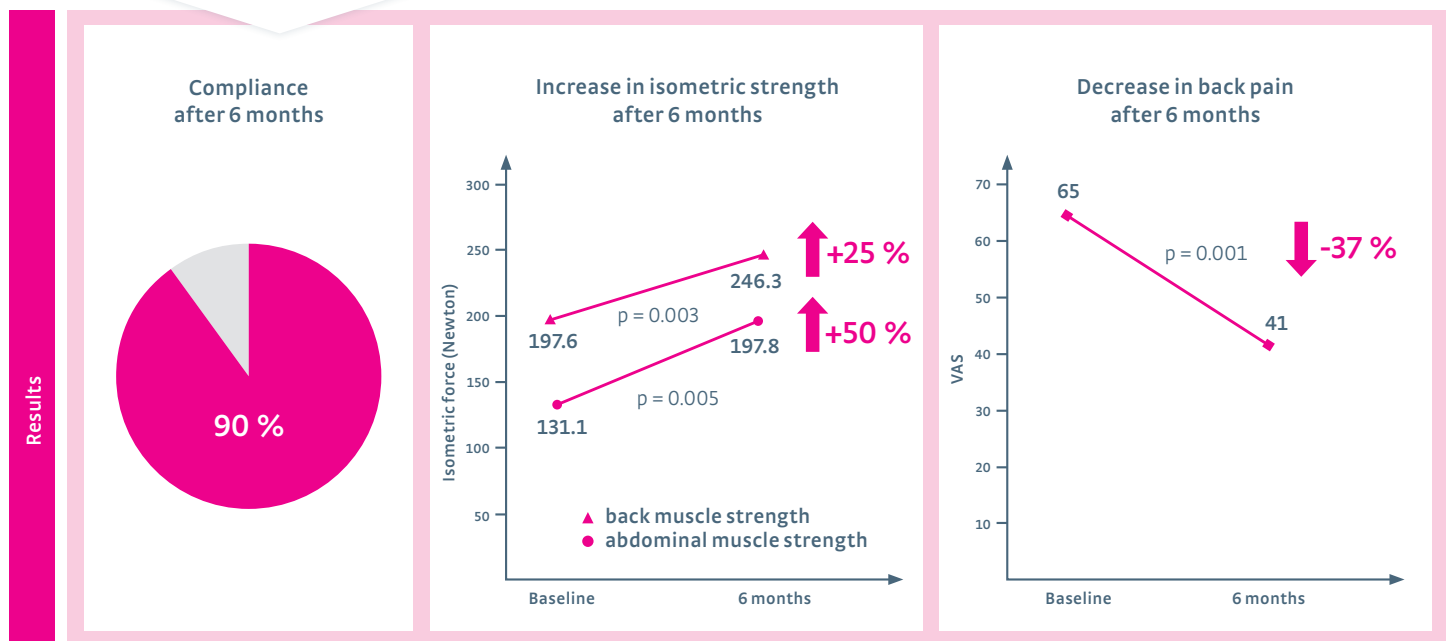
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Spinomed® – Increase in isometric muscle strength and high patient compliance (Dionyssiotis et al., 2015)

Study population	Subgroup analysis  10 female patients 			
	Inclusion criteria			
	Age: ≥60 years	Osteoporosis (at least one vertebral fracture in the thoracic or lumbar spine)	Reduction in vertebral height of at least 20 %	Angle of kyphosis > 55°
	Exclusion criteria			
	Disorders affecting bone mineral metabolism	Severe degenerative diseases	Secondary osteoporosis	

Study design	Endpoints <ul style="list-style-type: none"> Compliance after 6 months Change in isometric strength Change in back pain 	 Application of the spinal orthosis Spinomed
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Wearing the Spinomed orthosis significantly increased trunk muscle strength and decreased pain. The good efficacy is accompanied by a high patient compliance rate.

Reference: Dionyssiotis Y et al. Prospective study of spinal orthoses in women. Prosthet Orthot Int 2015;39(6):487-495.



Wearing the Spinomed orthosis for six months leads to increased muscle strength and pain relief with good patient compliance at the same time.

In 2015, Dionyssiotis et al. conducted a subgroup analysis to examine the efficacy of the **Spinomed** orthosis regarding the change in isometric muscle strength (abdominal and back muscles) and pain after six months. An additional study focus was on the patients' compliance.

The study demonstrated that wearing the **Spinomed** orthosis for six months led to an increase in abdominal muscle strength by 50 percent and back muscle strength by 25 percent. In addition, pain was alleviated by 37 percent. Furthermore, analyses regarding the patients' compliance delivered positive results: the compliance rate of patients wearing the **Spinomed** over a duration of six months was 90 percent.

Reference: Dionyssiotis Y et al. Prospective study of spinal orthoses in women. *Prosthet Orthot Int* 2015;39(6):487-495.

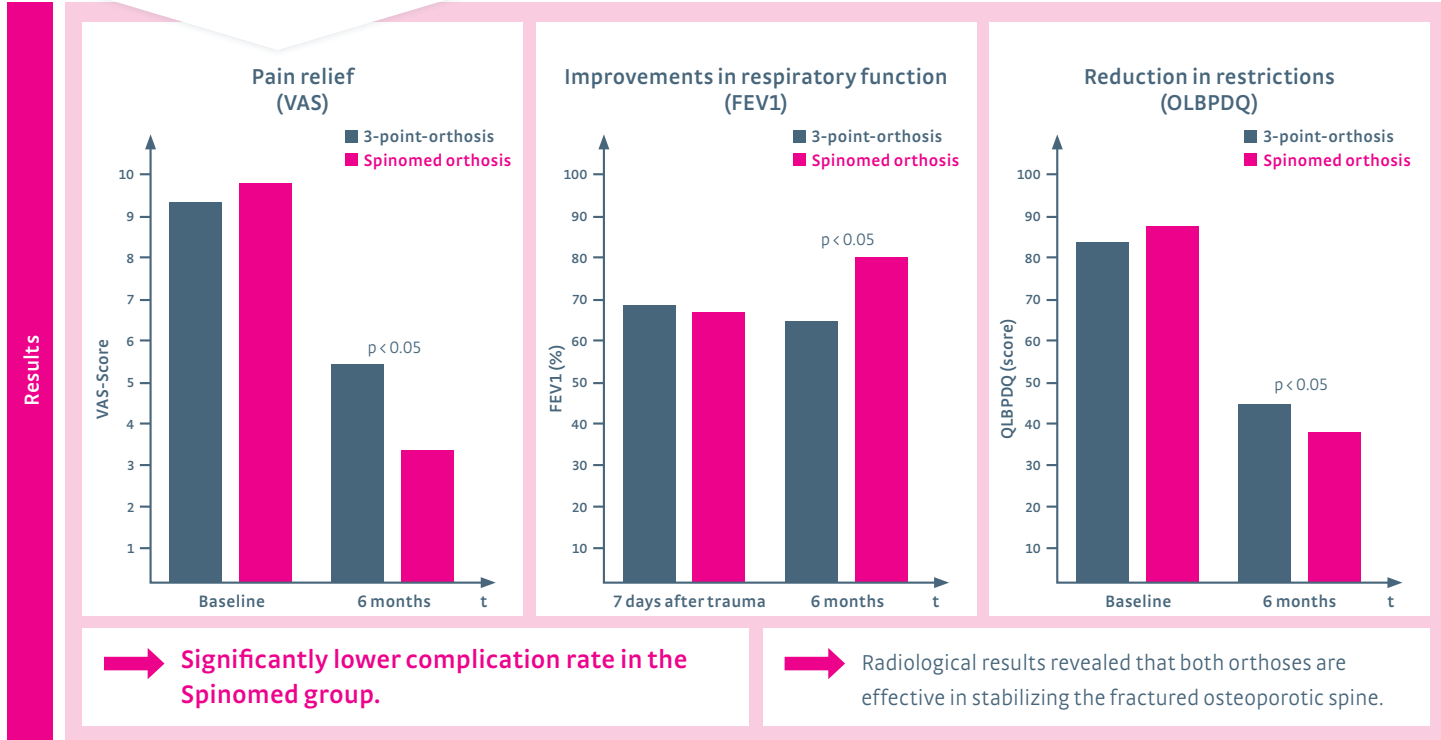
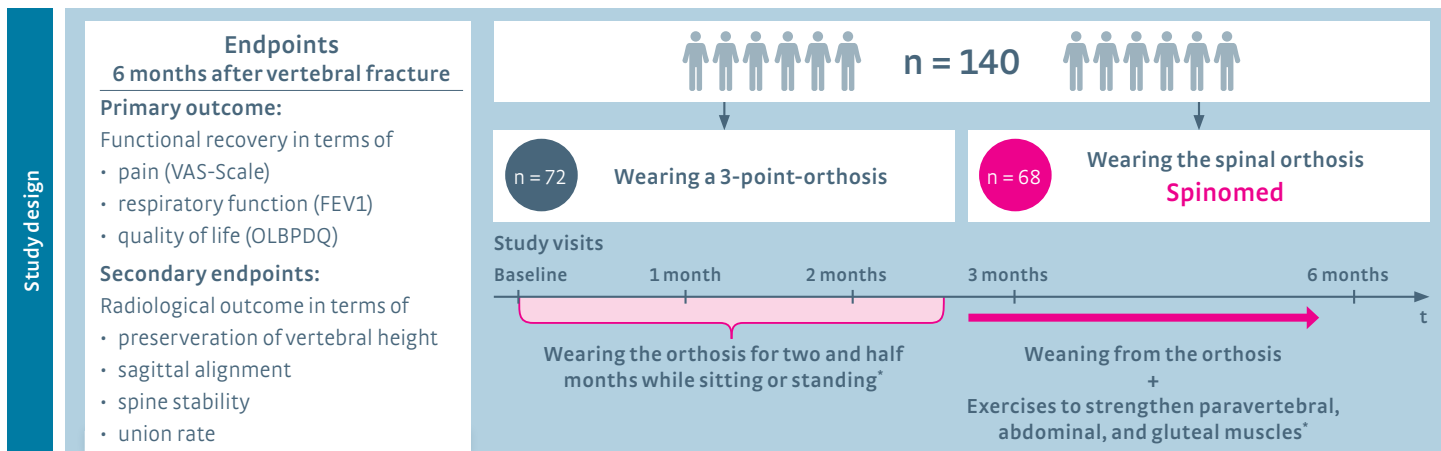
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Spinomed® – Pain relief and improved quality of life (Meccariello et al., 2017)

Study population	140 patients		
	Inclusion criteria		
	Age: ≥60 years	Acute back pain caused by single-level osteoporotic vertebral fracture from T6 to L3, which was due to minor trauma or strain, and without neurological symptoms	
	Exclusion criteria (i. a.)		
	Multiple or previous vertebral fractures	Disorders which affect bone metabolism	Severe lung diseases



* Additionally, all patientes were given medical treatment for osteoporosis with vitamin D and bisphosphonates.
 OLBPDQ = Oswestry Low Back Pain Disability Questionnaire; lower values indicate a higher quality of life
 Reference: Meccariello L et al. Dynamic corset versus three-point brace in the treatment of osteoporotic compression fractures of the thoracic and lumbar spine: a prospective, comparative study. Aging Clin Exp Res 2017;29(3):443-449.



Wearing the spinal orthosis Spinomed leads to a significant pain relief and a significant improvement in respiratory function compared to a 3-point-orthosis.

In a prospective controlled clinical trial, Meccariello et al. examined the influence of a 3-point-orthosis compared to the spinal orthosis **Spinomed** on pain, respiratory function and back pain related restrictions in patients with osteoporotic vertebral fractures.

Patients were divided into two groups and wore either a rigid 3-point-orthosis or the spinal orthosis **Spinomed** for the duration of two and half months. Afterwards, patients began weaning from the orthoses and started exercising regularly to strengthen paravertebral, abdominal, and gluteal muscles. The last follow-up assessment took place six months after trauma.

In the **Spinomed** group, a significant reduction in pain was shown after three and six months compared to the 3-point-orthosis. In addition, significant improvements in respiratory function between the third and sixth month were detected in the **Spinomed** group. Furthermore, authors observed a significantly lower complication rate in the **Spinomed** group. Radiological results regarding the stabilisation of the fractured osteoporotic spine were comparable in both groups.

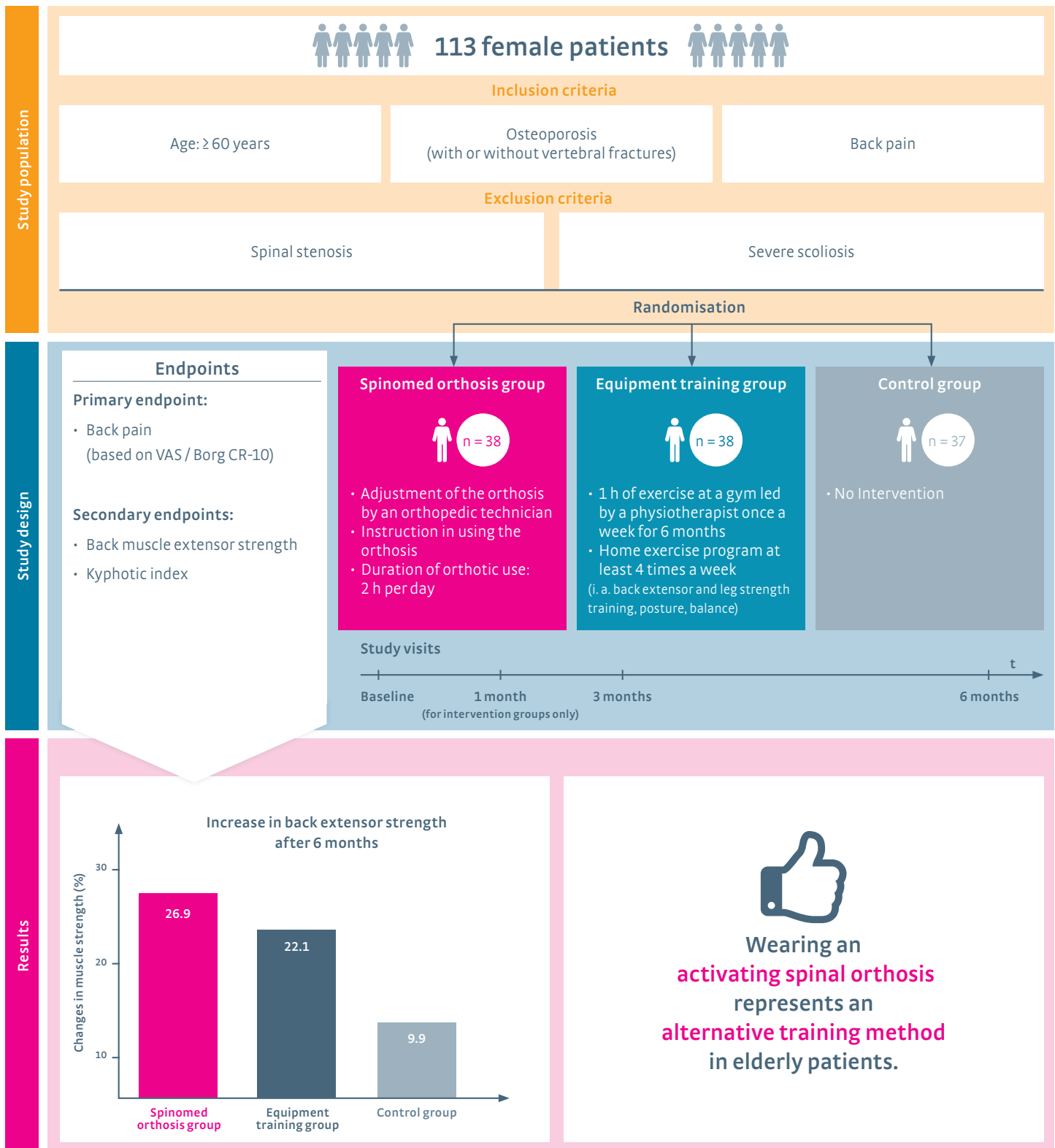
Reference: Meccariello Let al. Dynamic corset versus three-point brace in the treatment of osteoporotic compression fractures of the thoracic and lumbar spine: a prospective, comparative study. Aging Clin Exp Res 2017;29(3):443-449.

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Spinomed® – Wearing a spinal orthosis as an alternative training method (Kaijser Alin et al., 2019)



Reference: Kaijser Alin C et al. Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: a randomized controlled trial. Arch Osteoporos 2019;14(1):5.



Wearing the Spinomed orthosis for six months leads to similar effects regarding the increase in back muscle strength compared to physiotherapeutic exercise intervention and therefore represents an alternative training method.

In a prospective randomised controlled clinical trial, Kaijser Alin et al. (2019) examined the effects of a spinal orthotic therapy in patients with osteoporosis.

For the study, patients were divided into three groups. One group wore the **Spinomed** orthosis for a period of six months, while a second group received an exercise training program once a week guided by a physiotherapist, which was supplemented by a home exercise program four times a week. Patients in the third group did not receive any intervention (control group).

In the **Spinomed** orthosis group a noticeable improvement in back extensor muscle strength was observed. The increase in back muscle strength in the orthosis group was even higher than in patients completing the physiotherapeutic exercise program.

Therefore, using a spinal orthosis represents an alternative training method that is integrable in daily living – especially in older patients.

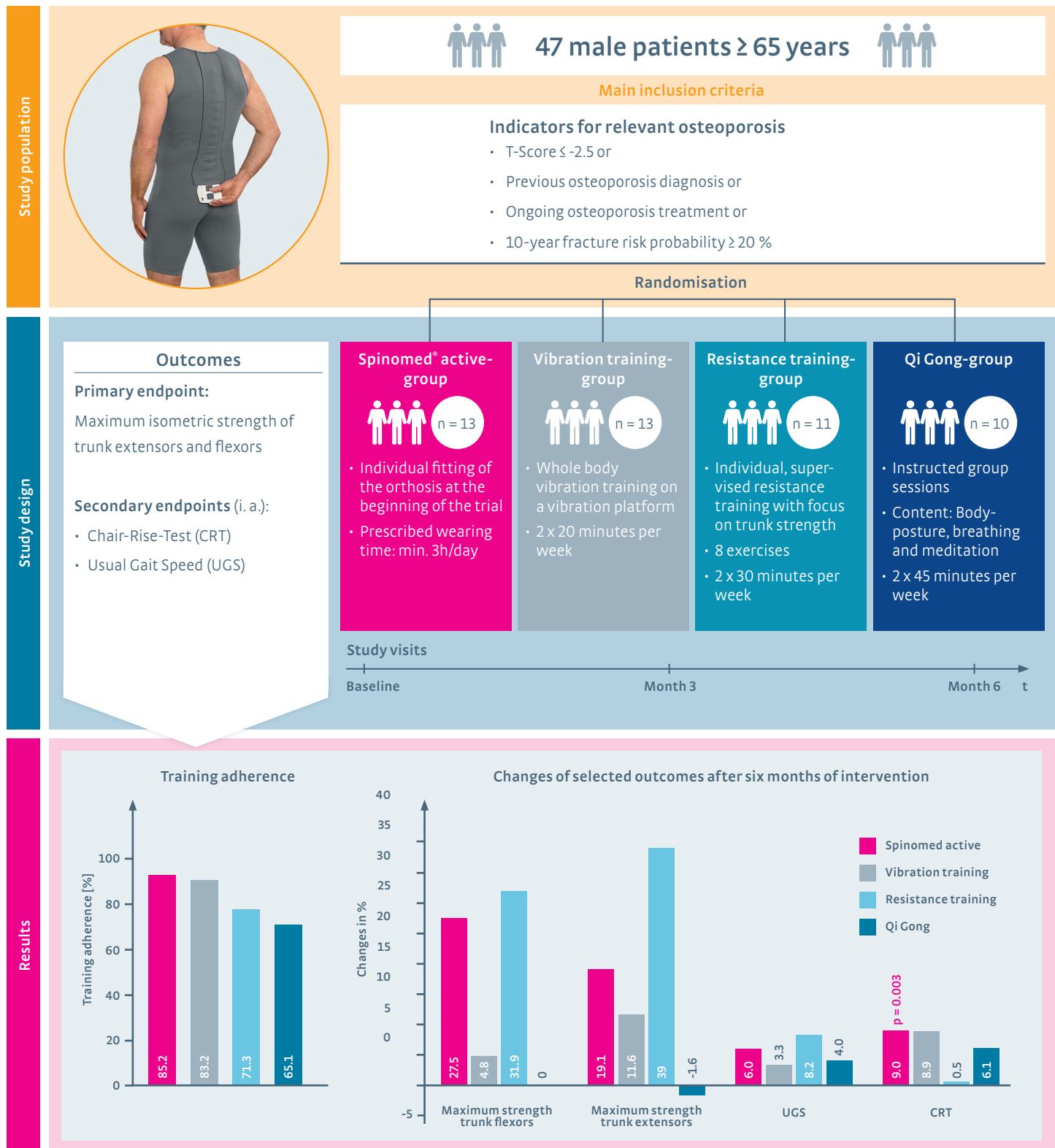
Reference: Kaijser Alin C et al. Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: a randomized controlled trial. Arch Osteoporos 2019;14(1):5.

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Spinomed® active – Positive effects on strength-based and functional outcomes in men with osteoporosis (Genest et al., 2021)



Reference: Genest F et al. Feasibility of simple exercise interventions for men with osteoporosis - A prospective randomized controlled pilot study. Bone Rep. 2021;15:101099.



Men with osteoporosis benefit from using the Spinomed active by means of an improved trunk and leg strength (Genest et al., 2021)

For a prospective, randomised, controlled pilot study by Genest et al. (2021), 47 men with indicators of a relevant osteoporosis were randomised in one of four different interventions: supervised resistance training, Qi Gong, vibration training or the use of the spinal orthosis **Spinomed® active**. The intervention period was six months. The aim of study was to examine the efficacy, feasibility and safety of different therapies in men with osteoporosis.

After six months, remarkable improvements of the trunk strength were observed in the **Spinomed® active**-group (flexion: + 27.5 percent; extension + 19.1 percent). Only the gold standard of professionally supervised resistance training led to even greater improvements regarding the trunk strength. Furthermore, using the **Spinomed® active** led to a statistically significant increase in the Chair-Rise-Test performance, which is an indicator for the leg strength. With regard to the training adherence, the **Spinomed® active**-group had the highest value among all groups (85.2 percent).

The authors conclude that less demanding interventions such as the use of the **Spinomed® active** are safe, feasible and effective with regard to strength-based outcomes. Therefore, the safety and efficacy of the **Spinomed® active** has been proven in men with osteoporosis.

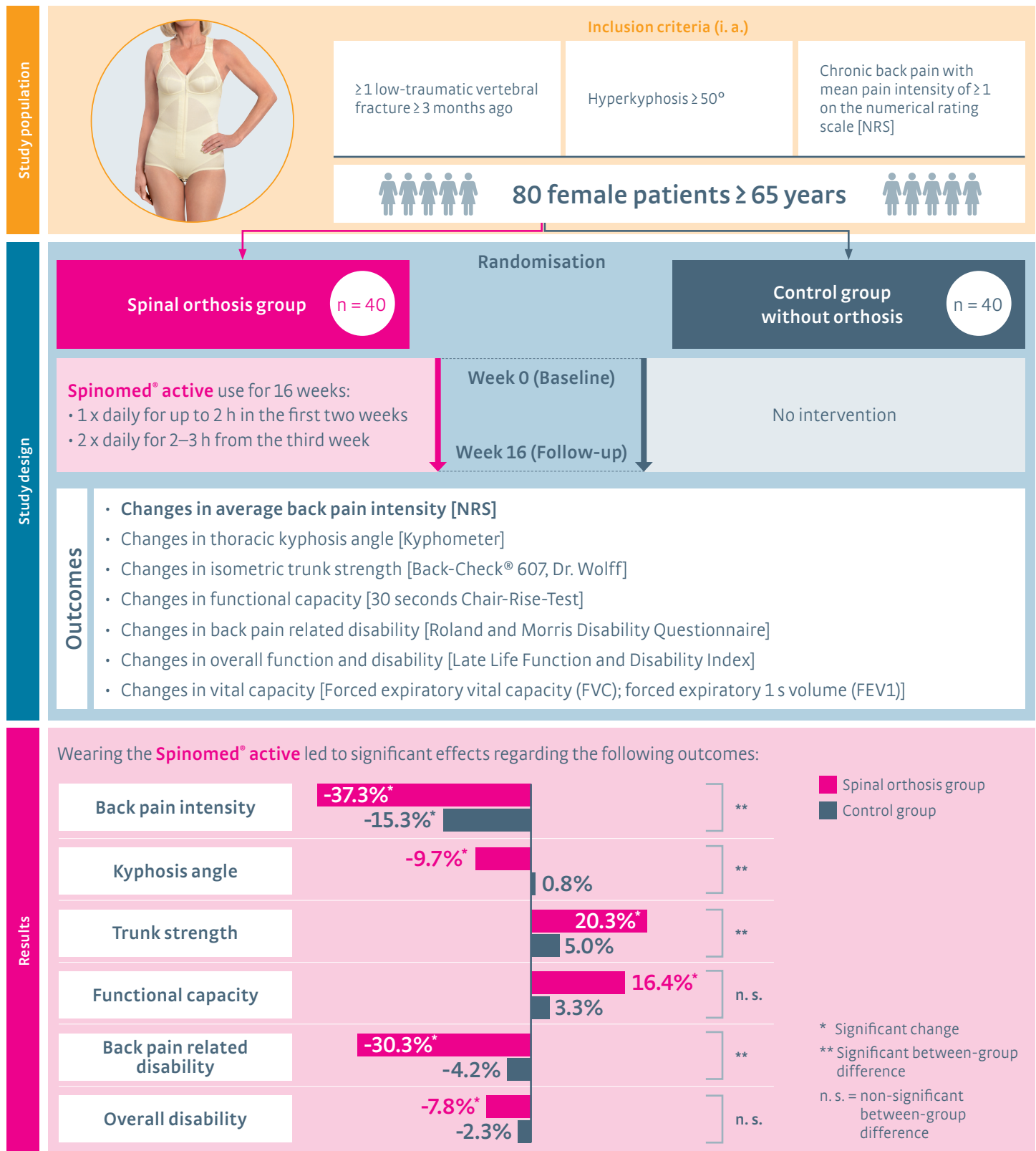
Reference: Genest F et al. Feasibility of simple exercise interventions for men with osteoporosis - A prospective randomized controlled pilot study. Bone Rep. 2021;15:101099

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Spinomed® active – Positive effects in women with older osteoporotic vertebral fractures (Hettchen et al., 2022)



Reference: Hettchen M et al. Effects of the „Spinomed active“ orthosis on chronic back pain in kyphotic women with osteoporotic vertebral fractures three months and older: A randomized controlled study. Front Pain Res (Lausanne). 2022;3:1038269.

Women with osteoporotic vertebral fractures three months and older benefit from using the Spinomed® active (Hettchen et al., 2022)

In a randomised controlled trial, Hettchen et al. (2022) examined the effects of the spinal orthosis **Spinomed® active** in women (≥ 65 years) with older (≥ 3 months) osteoporotic vertebral fractures, chronic back pain and thoracic hyperkyphosis. In total, 80 patients were randomised equally into an intervention group and a control group. The intervention period was 16 weeks.

At the end of the intervention period, a significant pain reduction was apparent in both groups, however the pain reduction was significantly more pronounced in the **Spinomed® active** group. Regarding the kyphosis angle, trunk strength, functional capacity and back pain related as well as overall disability, improvements were statistically significant in the **Spinomed® active** group. In the control group, no significant changes were observed. Furthermore, the days under pain medication significantly decreased in the **Spinomed® active** group and increased non-significantly in the control group. The vital capacity remained almost unchanged in both groups.

Based on the confirmed positive effects of the **Spinomed® active**, the authors suggest to expand the recommendation for using the **Spinomed® active** to kyphotic women with osteoporotic vertebral fractures and chronic back pain independently of the age of the fracture.

Reference: Hettchen M et al. Effects of the "Spinomed active" orthosis on chronic back pain in kyphotic women with osteoporotic vertebral fractures three months and older: A randomized controlled study. *Front Pain Res (Lausanne)*. 2022;3:1038269.

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Spinomed® – Use of a spinal orthosis following kyphoplasty (Schupfner et al., 2020)

In a prospective clinical comparative study, Schupfner et al. examined the effects of a surgical, conservative or combined treatment in patients with osteoporotic vertebral fractures. In total, 90 patients were included in the study, receiving one of the following interventions:

- conservative treatment with the spinal orthosis **Spinomed** (n = 30)
- surgical treatment with balloon kyphoplasty (BKP) (n = 30)
- combined therapy with balloon kyphoplasty and post-operative use of the **Spinomed** (n = 30)

Results

- Patients receiving a BKP perceived an acute pain relief which was significantly more pronounced compared to the conservative treatment
 - After six months, no differences were observed between the intervention groups regarding pain or quality of life
 - Pain reduction after six months was highest in the conservative treatment group receiving the **Spinomed** – though results were not statistically significant
 - The use of the **Spinomed** did not lead to an additional height reduction of the vertebral body in the time course
- In order to benefit from the positive acute (BKP) and long-term (**Spinomed**) effects of the single treatment options, the authors conclude: *"When used in combination with an activating orthosis, the therapy [kyphoplasty] has a positive effect on long-term vertebral straightening and thus also the sagittal plane of the spine."*

Reference: Schupfner R et al. Prospective Comparison of Osteoporotic Vertebral Fracture Treatment. *Ortho & Rheum Open Access J* 2020;16(2):555932.



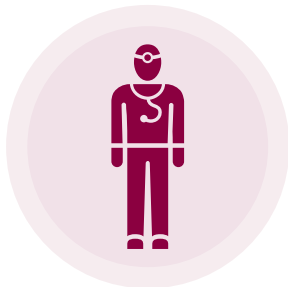
Further expert opinions regarding kyphoplasty



Prof. Dr. Christopher Niedhardt

In general, a recently fractured patient suffers from an increased refracturing risk. In order to improve the patient's safety, especially regarding the risk of falls, the use of a spinal orthosis is reasonable.

In this way, the patient receives a spinal straightening and therefore more stability. *"A patient with painful vertebral fractures requires an orthosis, no matter whether he had a surgery or not."*



Dr. Gerd Ivanic

Spinal orthoses represent an alternative to a surgical intervention. Based on the spinal straightening, the orthosis leads to a strengthening of the back muscles; in addition, improvements in the muscle corset result from the spinal straightening.

Following a surgery like a kyphoplasty or vertebroplasty, the patient should necessarily be kept in an upright position and therefore the use of an orthosis is reasonable.

"[...] because after a fracture is before a fracture."

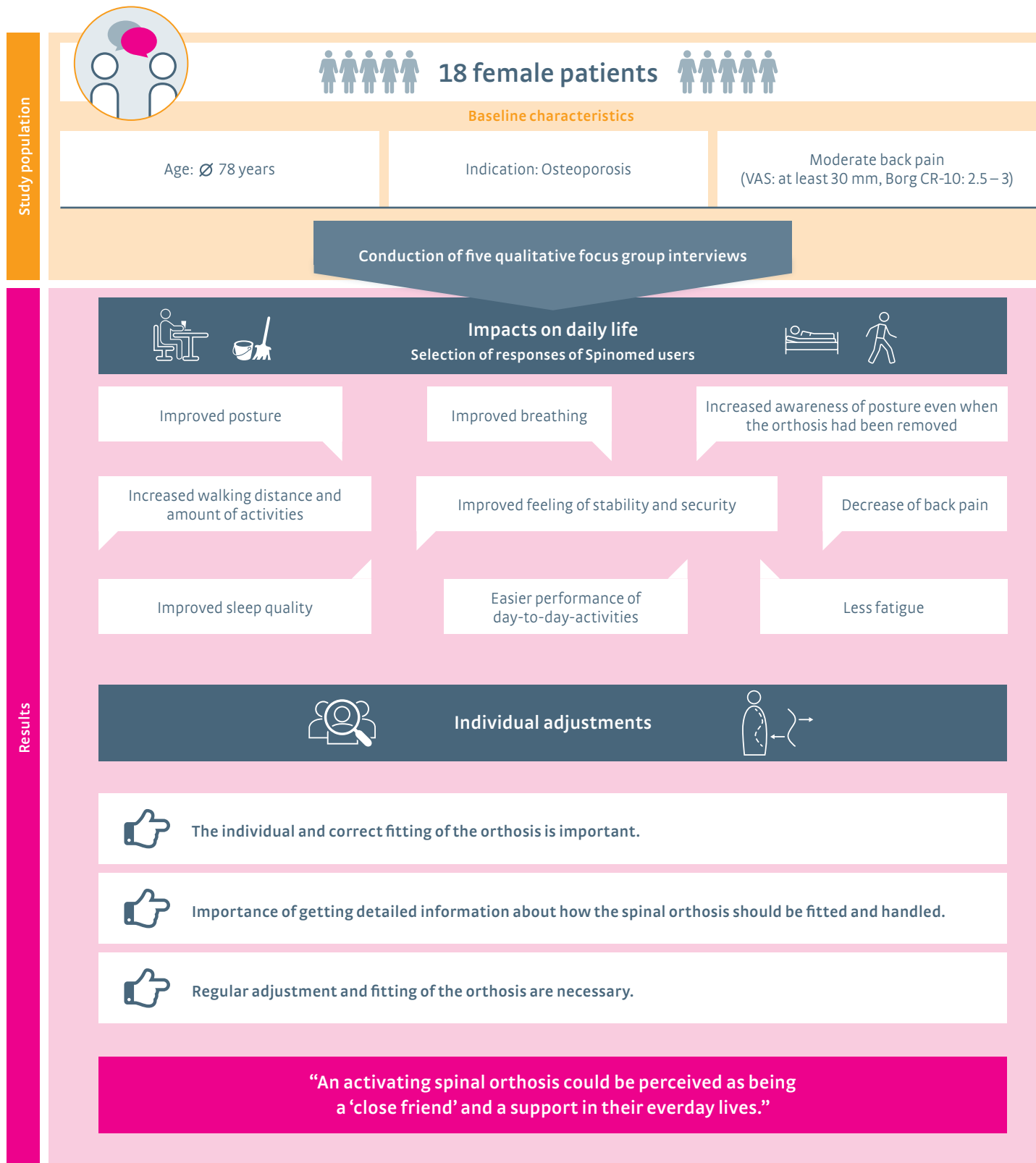


Patient Surveys – Real-Life-Setting

Patient Surveys – Real-Life-Setting	
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Spinomed® – Spinal orthosis supports activities of daily living (Kaijser Alin et al., 2020)



Reference: Kaijser Alin C et al. Experiences of using an activating spinal orthosis in women with osteoporosis and back pain in primary care. Arch Osteoporos 2020;15(1):171.



Qualitative focus group interviews show that the patient expectations regarding the efficacy of the spinal orthosis Spinomed are met. Furthermore, the orthosis serves as support in daily life.

Following the clinical trial in 2019, Kaijser Alin et al. (2020) additionally conducted qualitative focus group interviews within the same study population.

During the interviews, three main categories were addressed in particular: impact on daily life, individual adaptation and personal relationship.

Besides pain relief, **Spinomed** users reported improved breathing due to enhanced posture as well as increased feelings of stability and safety. On the basis of an increased walking distance, patients had an increased scope of activities.

Regarding the use of the **Spinomed** orthosis, it was shown that individual adjustment in connection with detailed information on handling and regular fitting are of great importance.

The patients' answers lead the authors to the conclusion that the expectations of the **Spinomed** users regarding the orthosis are met. Therefore, using a spinal orthosis might be a reasonable support in daily life.

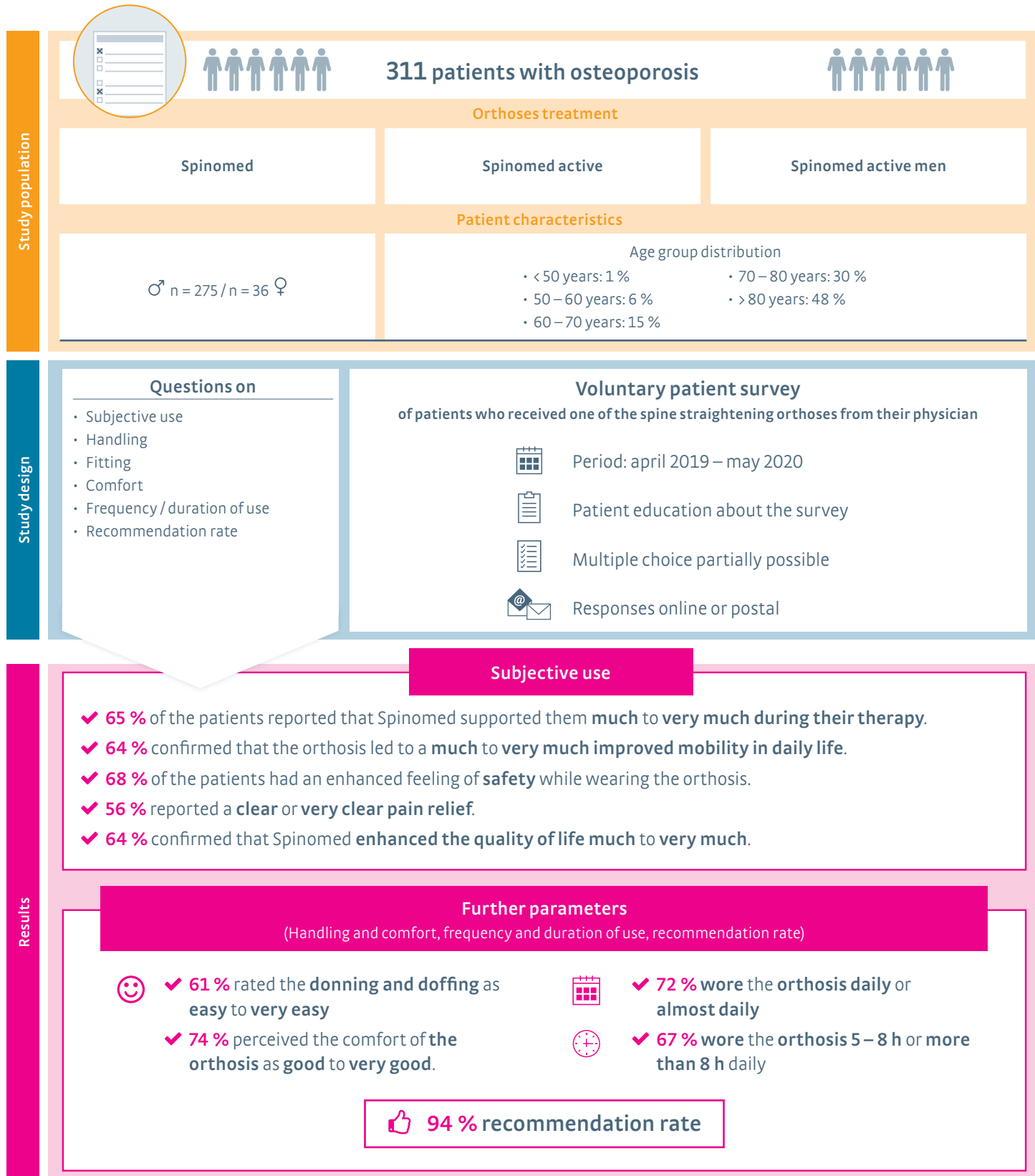
Reference: Kaijser Alin C et al. Experiences of using an activating spinal orthosis in women with osteoporosis and back pain in primary care. Arch Osteoporos 2020;15(1):171.

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Spinomed® – Representative patient survey confirms the efficacy of spinal orthoses in real-life-setting (medi GmbH & Co. KG, 2020)



Reference: medi GmbH & Co. KG, 2020



A patient survey regarding the application of the Spinomed, Spinomed active or Spinomed active men shows the patients' subjective satisfaction with the products concerning improved mobility, pain relief, enhanced feeling of safety and increased quality of life.

In a representative survey of more than 300 patients with osteoporosis, the subjective benefit and usage of spine straightening orthoses were examined.

Patients wearing the spinal orthoses **Spinomed**, **Spinomed active** or **Spinomed active men**, respectively were asked to answer a questionnaire concerning the use, duration of application and comfort of the products.

Two thirds of the patients reported that their orthosis helped them much or very much during the therapy and that the device led to an improved mobility and an increased feeling of safety. More than 50 percent of the participants confirmed that they experienced (very) clear pain relief by wearing the orthosis, which led to an increase in quality of life. Handling, fitting and comfort were mainly rated as good to very good, reflecting in a high adherence rate.

The mainly good to very good product ratings resulted in a very high recommendation rate of 94 percent.

Reference: medi GmbH & Co. KG, 2020

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Representative patient survey regarding the use of spinal orthoses as medical device (eurocom e. V., 2019)



References:
 eurocom e. V.: Rückenbandagen und Rückenorthesen: Weniger Schmerzen, mehr Mobilität. Ergebnisse der repräsentativen Umfrage des Instituts für Demoskopie Allensbach im Auftrag von eurocom e.V. Published online: https://www.eurocom-info.de/wp-content/uploads/2021/03/eurocom_Broschuere-Ruecken_Allensbach_web.pdf (Last access 19/02/2024).
 eurocom e. V. Nutzen und Wirksamkeit medizinischer Hilfsmittel: Steigende Lebensqualität durch weniger Schmerz und mehr Mobilität. Representative Umfrage des Instituts für Demoskopie Allensbach im Auftrag von eurocom e. V. Published online: https://www.eurocom-info.de/wp-content/uploads/2019/08/Allensbach-Brosch%C3%BCre_Webversion.pdf (Last access 19/02/2024).



A survey on behalf of eurocom e. V. confirms the increased demand for medical devices and the great effects of spinal soft supports and orthoses.

In 2019, the Allensbach Institute was commissioned by eurocom e. V. in order to conduct a representative patient survey on the use and subjective efficacy of medical devices (soft supports/orthoses, medical compression stockings and foot orthoses). The survey confirms the results of a first, identical survey conducted in 2014, underlining an increased demand for medical devices. For example, 7.8 million people in Germany use soft supports or orthoses of which 15 percent are wearing a spinal soft support/orthosis.

A particular subgroup analysis showed that 54 percent of patients who rely on the assistance of spinal soft supports/orthoses are wearing them due to chronic back pain. 81 percent of the users confirmed a high to very high benefit.

Survey participants reported that wearing spinal soft supports and orthoses led to an improved quality of life and increased mobility. In addition, the application contributed to pain relief which led to a reduced consumption of analgesics in more than two thirds of the users. Furthermore, 32 percent of the spinal soft support/orthosis users stated that they could avoid a surgery due to the medical device use.

References:

eurocom e. V.: Rückenbandagen und Rückenorthesen: Weniger Schmerzen, mehr Mobilität. Ergebnisse der repräsentativen Umfrage des Instituts für Demoskopie Allensbach im Auftrag von eurocom e.V. Published online: https://www.eurocom-info.de/wp-content/uploads/2021/03/eurocom_Broschuere-Ruecken_Allensbach_web.pdf (Last access 19/02/2024).

eurocom e. V. Nutzen und Wirksamkeit medizinischer Hilfsmittel: Steigende Lebensqualität durch weniger Schmerz und mehr Mobilität. Repräsentative Umfrage des Instituts für Demoskopie Allensbach im Auftrag von eurocom e. V. Published online: https://www.eurocom-info.de/wp-content/uploads/2019/08/Allensbach-Brosch%C3%BCre_Webversion.pdf (Last access 19/02/2024).

Intended purpose: Spinomed /Spinomed active/Spinomed active men are braces designed to actively relieve load and correct the lumbar spine / thoracic spine in the sagittal plane.



Headquarter
Medi GmbH & Co. KG
Medicusstraße 1
D - 95448 Bayreuth
Germany
P +49 921 912-0
F +49 921 912-783
export@medi.de
www.medi.de/en/doctors/

