

MEDICAL EFFECT OF SI JOINT BACK ORTHOSES ON THE CLINICAL AND FUNCTIONAL PARAMETERS OF PATIENTS WITH SI JOINT PAIN.

Hammer, N.^{1,2}; Hammer, K.-H.³; Klima, S.^{2,4}; Möbius, R.¹; Milani, T.M.⁵; Lange, J.S.⁵; Schleifenbaum, S.²; Soisson, O.^{2,5}; Winkler, D.⁶

Abstract

The sacroiliac joint (SI joint) is one of the causes of low back pain. Inappropriate mechanical stresses or misalignment of the legs and spine can lead to irritation of the SI joint. Mild trauma, through lifting loads that are too heavy or as a result of the common occurrence of stepping onto nothing when you miss a step, for example, is a particularly typical trigger of SI joint syndrome. Additional causes include overloading or inappropriate mechanical stress on the lumbosacral junction or pregnancy-related changes to the forces exerted on the pelvis. Trauma or inappropriate mechanical stress can put increased strain on the ligaments, which can lead to restricted movement (blockage) in the joint because of the reactive tension of the muscles that stabilize the SI joint. People affected by this condition then mainly suffer from back pain on one side. SI joint pain can also occur because of wear (osteoarthritis) or inflammation, like in every other joint. However, clinical and functional correlations that could explain the cause of the pathophysiological development of SI joint pain remain largely undetermined.

Back orthoses are also successfully used to treat SI joint syndrome by combatting pain and increasing mobility. However, as yet, there is no evidence-based data to confirm this effect. The aim of this study is to compare clinical and functional data regarding SI joint syndrome in healthy individuals and in SI joint patients using a pelvic orthosis.

Study design

Non-randomized, prospective experimental study (evidence class 2a)

Methodology

Test groups: Healthy test subjects, n=17, age: 18-80, average age 43 ± 20 years / patients with SI joint syndrome,

n = 17, age: 18 - 80, average age 45 ± 11 years

Test orthosis: Pelvic orthosis (SacroLoc®, Bauerfeind AG)

Test method MRI (Magnetom Trio®, Siemens AG),

Electromyography (Bagnoli-8, Delsys Inc., Boston) to measure muscle activity in the muscles when walking. Gluteus maximus muscle, biceps femoris muscle, rectus femoris muscle, vastus medialis

muscle

Gait analysis to measure the cadence, walking speed

SF-36 (short form) questionnaire to quantify quality of life in relation to health, Numeric Rating Scale

(NRS) to quantify SI joint-related pain

Investigation period: 6 weeks (follow-up study)

Data analysis Evaluation: SPSS Version 20 (Armonk, USA);

R Software (The R Foundation for Statistical Computing, Vienna, Austria);

Shapiro-Wilk test for independent samples;

Mann-Whitney U test;

Univariate analysis of variance (ANOVA); analysis of variance at a significance level of 5%

Inclusion criteria Diagnostically verified, chronic SI joint syndrome

Adequate constitution and coordination for the measurements Restricted joint mobility and osteoarthritis in areas other than the SI joint,

Arthritis, pathological joint positions

Chronic pain in areas other than the SI joint

Fractures, ligament injuries, muscle injuries, soft tissue damage, somatoform disorders

Exclusion criteria

¹ Institute of Anatomy, Leipzig University

² Clinic and polyclinic for orthopedics, trauma surgery and plastic surgery, University Hospital Leipzig

 $^{^{3}}$ Specialist in orthopedics and chiropractic treatment, pain treatment, Kirchberg

⁴ Specialist in orthopedics and trauma surgery, Berlin

⁵ Chemnitz University of Technology, Human Movement Science, Chemnitz

⁶ Clinic and polyclinic for neurosurgery, University Hospital Leipzig]

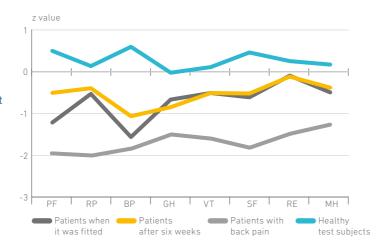
Data has been submitted for publication or is available in published form.

Results

When using the SacroLoc pelvic orthosis, SI joint patients showed a significant improvement in health-related quality of life, particularly in terms of the SF-36 subscores after six weeks, which illustrate the patients' physical health.

After using the SacroLoc pelvic orthosis for six weeks, a significant improvement in health-related quality of life was demonstrated in SI joint patients, especially in terms of the SF-36 subscores, which focused on physical health. The improvements in "physical functioning (PF)" and "bodily pain (BP)" were the most pronounced, with improvements of half a standard deviation ($\Delta z = +0.46$ and +0.50). The comparison with the control population with back pain showed that SI joint patients were significantly less limited in terms of their physical quality of life when using the pelvic orthosis.

The pain suffered by SI joint patients, measured using the one-dimenional pain intensity scale (NRS; 0 = no pain, 10 = maximum possible pain), was 5.0 ± 1.9 in the retrospective survey. After physical examination and without using the orthosis, the NRS score was 4.0 ± 1.8 . Under moderate and maximum tightening, the NRS score changed immediately to 3.4 ± 2.1 and 4.0 ± 1.9 . The reduction on the NRS was statistically significant both with and without the orthosis in comparison to the retrospective survey on pain intensity before the examination (p < 0.01; fig. 2). The consideration of the relative changes in pain perception (Δ NRS) under moderate and maximum tightening showed that moderate tightening tends to reduce pain more effectively (p = 0.07; fig. 2).



SF-36 health questionnaire

SF-36 score for SI joint patients and healthy test subjects with a pelvic orthosis on the day of the study and for SI joint patients after six weeks of using a pelvic orthosis

The SF-36 values of the healthy control group mirror the average values of the total population in Germany.

PF = physical functioning;

RP = role physical;

BP = bodily pain;

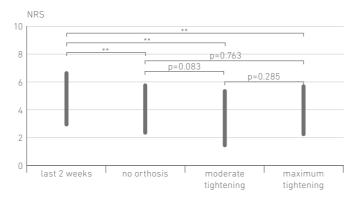
GH = general perception of health;

VT = vitality:

SF = social functioning;

RE = role emotional;

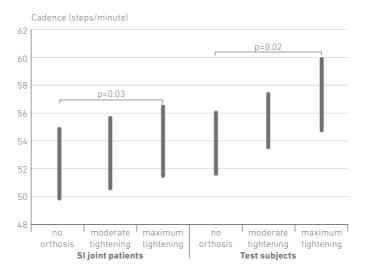
MH = mental health



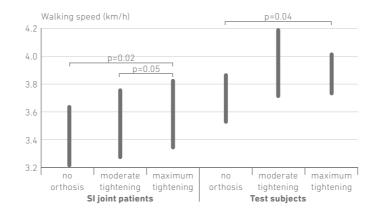
Numeric Rating Scale (NRS)

Pain score (NRS) given by SI joint patients on the day of the study with and without the pelvic orthosis

"Moderate" tightening corresponds to the manufacturer's specifications, "maximum" tightening is that which patients and healthy test subjects can only just tolerate.



The cadence (number of steps per minute) of SI joint patients and healthy test subjects in the control group increased by 2 or 4 steps per minute when they wore the pelvic orthosis compared to the test situation without the pelvic orthosis. The tightening of the pelvic orthosis had a positive effect on cadence. Walking speed was also influenced by the use of the pelvic orthosis. The speed increased by 0.2 km/h in patients (test subjects) with an orthosis compared to without an orthosis. Rising circumferential pressure increased walking speed.



Cadence and walking speed

n=17 SI joint patients with/without pelvic orthosis and n=17 control group/healthy test subjects with/without orthosis

"Moderate" pressure corresponds to the manufacturer's specifications, "maximum" pressure is that which patients and test subjects can only just tolerate.



Discussion

Wearing a pelvic orthosis for several weeks leads to a significant, clinically relevant improvement in quality of life in terms of pain

The SF-36 health questionnaire and the NRS are effective ways to compare illness-related changes in the level of pain over time or to measure the effect of therapeutic interventions. Treating SI joint syndrome with pelvic orthoses over several weeks increases patients' quality of life in terms of pain, particularly with regard to the physical components (SF-36), and reduces low back pain. The pain-reducing effects were minimal immediately after fitting the pelvic orthosis and were only detectable after the orthosis was moderately tightened. These findings suggest that the pain-reducing effects of the pelvic orthosis are only brought to bear after it is worn for several days or weeks. This result should be considered when instructing patients, in order to make the most of the pain-reducing potential of the pelvic orthosis.

Changes in muscle activity are particularly easy to detect when walking

While no immediate change in muscle activity was detected in SI joint patients and healthy test subjects standing on one leg wearing the pelvic orthosis, rectus femoris muscle activity decreased significantly in both groups when walking (data in the original work). The rectus femoris muscle is an important reference muscle for SI joint problems due to the long lever arm function which it exercises on the SI joint. This is also important for confirming SI joint syndrome in clinical trials in which the rectus femoris muscle is examined (including the active straight leg raise test). It is possible that pain in the SI joint is due to an excessive contraction of the rectus femoris muscle.

Wearing a pelvic orthosis has a positive effect on postural stability

Studying gait parameters also showed that pelvic orthoses have more of an influence on dynamic variables than static variables. While no immediate changes in the ground reaction forces were determined in SI joint patients or healthy test subjects standing on one leg, both cadence (number of steps per minutes) and walking speed increased straight away in both groups when they were wearing pelvic orthoses and walking. These findings point to an increase in postural stability, which may subjectively express itself in an improvement in the unsteady gait described by SI joint patients.

When wearing a pelvic orthosis, no compression effects on the SI joint can be determined using morphological imaging – the effect of the orthoses is probably based on the neuromuscular connections, in which the SI joint ligaments are important sensory elements and the pelvic muscles are positioning elements.

When wearing the pelvic orthosis when it is moderately tight, as well as when it is as tight as can be tolerated, no compression effects could be detected on the bones and joints of the pelvic ring or the SI joint, or in the lumbar spine area through morphological imaging. This data provides an argument against the assumption that isolated compression by the pelvic orthoses and the consequent immobilization of the posterior pelvic ring is the key to symptom improvement. At the same time, it ought to be analyzed whether it is sensible to impose strict time limits for wearing pelvic orthoses, particularly in view of the pain-reducing effect from wearing the orthosis in the long-term.

Computer simulations also showed that wearing a pelvic orthosis largely relieves pressure on the ligament structures in the SI joint in static situations too (data in the original work). These findings show the complexity of the control process for the interactions between ligaments and muscles in the SI joint and underline the role the ligaments have as SI joint sensing elements and the role the pelvic muscles have as positioning elements.

The overview of the morphological, functional and clinical findings shows that pelvic orthosis particularly achieve their therapeutic potential in dynamic situations and when they are used in the long term.

BAUERFEIND AG

Triebeser Straße 16 07937 Zeulenroda-Triebes Germany P +49 (0) 36628 66-10 00 F +49 (0) 36628 66-19 99 info@bauerfeind.com

UNITED KINGDOM

Bauerfeind UK Phyllis House 229 Bristol Road BIRMINGHAM B5 7UB P +44 (0) 121 446-5353 F +44 (0) 121 446-5454 info@bauerfeind.co.uk

USA

Bauerfeind USA, Inc. 1230 Peachtree St NE Suite 1000 Atlanta, GA 30309 P 1 800 423-3405 P +1 404 201-7800 F +1 404 201-7839 info@bauerfeindusa.com