

Spinal Orthoses: The Crucial Role of Comfort on Compliance of Wearing – Monocentric Prospective Pilot Study of Randomized Cross-Over Design

Pátevní ortézy: rozhodující vliv komfortu na dodržení režimu nošení – monocentrická prospektivní pilotní randomizovaně překřížená studie

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ABSTRACT

PURPOSE OF THE STUDY

Various spine disorders are regularly treated by orthoses, and success of treatment depends on wearing these devices. In this study we examined the compliance, wear comfort, subjective stabilization and side effects associated with spinal orthoses using an individualized questionnaire and the Compact Short Form-12 Health Survey (SF-12).

MATERIAL AND METHODS

In this prospective pilot study of randomized cross-over design, twelve healthy volunteers with a mean age of 31.2 years wore three different types of orthoses, each for one week: A hyperextension brace (HB), a custom-made semirigid orthosis (SO) and a custom-made rigid orthosis (RO). The daily duration of wearing the orthosis was defined as primary endpoint; contentment was measured using an individualized questionnaire and the standardized SF-12.

RESULTS

In the study population calculated probability of wearing the HB and RO was between 0.2 and 38.5% (95% confidence interval). No volunteer wore the SO orthosis for the predefined time. The SO and RO each displayed high subjective stabilization, while the RO was more often associated with side effects like skin pressure marks than the SO. The need for rework due to discomfort was mainly necessary with the RO. We observed no substantial differences in feeling compression and sweating. Noteworthy, eight of 12 subjects complained of uncomfortable sternal pressure due to the upper pad of the HB. The SF-12: scores ranged from 52.1 to 48.6 on the physical (PCS), and from 53.7 to 50.8 on the mental component score (MCS), demonstrating an influence on QoL.

DISCUSSION AND CONCLUSIONS

The design as well as the orthosis itself influence the compliance of wearing and exert a moderate negative, but acceptable impact on QoL. The SO appeared to correlate with the best overall compromise between comfort and subjective stabilization. Further investigations are necessary in patients with spinal diseases, for whom the effect of orthosis wearing may surpass the potential discomfort.

Key words: thoracolumbar spine, orthoses, SF-12 – Quality of Life – QoL, comfort, compliance.

Physical and Mental Impact as Measured by the Compact Short Form-12 Health Survey (SF-12) Quality of Life (QoL) Tool and Evaluation of Side Effects.

Trial registration: DRKS00005604. Registered 22 January 2014.

The study protocol was reviewed and approved by the ethical committee of the University Freiburg (AZ: 476/13).

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INTRODUCTION

Various spinal diseases including scoliosis, fracture and spinal metastasis are treated by external stabilization using orthoses, and success of treatment depends on wearing these devices (3, 5, 8). There are different styles and designs to facilitate this immobilization, alleviate back pain, and ensure correct posture (3, 5, 8, 14).

There is controversy in the literature on the effectiveness, necessity and possible complications associated with this external stabilization by orthoses (7, 9). The latter includes skin defects, discomfort (1, 16) and emotional distress (10). These factors can affect the compliance of wearing an orthosis and influence the quality of life (QoL).

This health-related QoL is now widely accepted as a key outcome measure in patients with chronic illness, including heart diseases, cancer and others (6, 11, 13, 18). As a result, health care providers and clinicians are paying more attention to patients' perceptions of their health status and the effectiveness of the treatments they are receiving (13).

The purpose of this prospective pilot study was to

- compare three different spinal orthoses with respect to the compliance as measured by wearing time.
- to evaluate stabilization and side effects subjectively such as comfort, skin pressure marks, and sweating.
- to measure physical and mental impacts by administering the compact short form-12 Health Survey (SF-12) quality of life tool.

MATERIAL AND METHODS

Study population

Twelve individuals volunteered for this study. All were in good health, none had any history of back pain during the last few years, and none had spinal surgery in the medical history.

Orthoses

One commercially available spinal orthosis and two custom-made orthoses were compared:

- The 3-point hyperextension brace (HB) with ratchet-closer (medi® GmbH & Co. KG, Bayreuth, Germany),
- A custom-made semirigid orthosis (SO), and
- A custom-made rigid orthosis (RO, HeJu Orthosis, Storch&Beller, Karlsruhe, Germany) (Fig. 1).

Prior to fitting the HB, an orthotist took detailed trunk measurements and each subject was fitted with the best-suited orthosis. The custom-made SO was constructed directly on each subject by applying plaster bandages using 3M™ *Soft Cast* (3M Medica, Neuss, Germany) and Cellacast® Xtra (Lohmann & Rauscher GmbH & Co. KG, Neuwied, Germany). For the RO, the orthotist took detailed trunk measurements orthosis and a three-dimensional scan. The orthosis was then produced via CAD technique out of polyethylene. The same orthotist was present at all testing sessions and was responsible for fitting and adjusting the orthoses prior to and during data collection.

Volunteers' data

The volunteers' data covers age, sex, weight, height and BMI.

Study design

Monocentric pilot study of randomized cross-over design (three therapies one week each). As specified in the study protocol, the primary endpoint was the compliance with the scheduled daily duration of wearing the orthosis: 14 hours per day on five of seven days of the week and at least ten hours on the remaining two days. The full analysis set (FAS) includes all randomized patients. The defined endpoint was analysed according to the intention-to-treat (ITT) principle using a logistic mixed model. Statistical programming was performed with the SSPS Predictive Analytics (IBM).

Data from the individualized questionnaire

Data from the individualized questionnaire included comfort (overall comfort, comfort when sitting and standing, respectively), compression and sweating measured by a rating scale from 1–6 (1: excellent, 2: very good, 3: good, 4: fair, 5: poor, 6: very poor). Side effects like skin pressure marks, discomfort (during movements,



Fig. 1. a – 3-point hyperextension brace (medi®, Bayreuth, Germany), b, c – custom-made semirigid orthosis, d, e – custom-made rigid orthosis.

breathing, eating), the need for rework and subjective stabilization were evaluated as absolute numbers.

The Short Form-12 Health Survey (SF-12)

We used the SF-12v2 as a generic self-report health status instrument. Information from all 12 items was utilized to calculate the physical component score (PCS) representing the physical health (PH) domain and the mental component score (MCS) representing the mental health (MH) domain. Scores were obtained using the standard scoring algorithm and descriptive statistics calculated; they range from 0 (worst possible health QoL) to 100 (best possible QoL). The mean values of SF-12 scores calculated for this study cohort were compared with general US populations, including healthy adults and patients with chronic diseases as reported by the National Survey of Functional Health Status (12). Statistical significances of PCSs and MCSs between the different orthoses were calculated using the t test.

RESULTS

Demographic data

Mean age of the 12 volunteers (3 males and 9 females) was 31.3 years (range 22–67 years). The mean weight was 71.8 kg (range, 51–99 kg), mean height 1.71 m (range, 1.60–1.94 m) and mean BMI 24.2 (range 17.4–33.1). All except one (long size) were standard size HBs, and all SOs and ROs, respectively, were custom made.

Descriptive analysis data

a) Primary endpoint – compliance with the planned daily period of wearing the orthoses

In the study population the calculated probability of wearing the HB and RO, respectively, was between 0.2 and 38.5%. For the SO no confidence interval could be calculated as none of the volunteers wore the orthosis for the predefined time. To further analyse the compliance, we calculated the wearing time of each orthosis separately. Descriptive analysis is as follows: mean wearing time in hours (mean \pm SD) was 11.75 ± 1.02 with a minimum of 9.9 and a maximum of 13.5 for HB, 11.57 ± 1.22 with a minimum of 9.3 and a maximum of 12.9 for SO

and 10.63 ± 2.1 with a minimum of 7 and a maximum of 13.1 for RO (Table 1).

b) Summary of further descriptive statistics for variables of interest (comfort, side effects)

Assessments of comfort and side effects are illustrated in table 2. Applying a rating scale from 1–6 (1: very good, 2: good, 3: satisfactory, 4: fair, 5: poor, 6: very poor), overall comfort was 2.9 ± 1.0 (range: 2–5) for HB, 2.2 ± 0.7 (range: 1–3) for SO and 3.2 ± 0.8 (range: 2–4) for RO. The overall compression feeling as well as sweating ranged from 1 to 4 for all orthoses, except for compression in conjunction with the SO (range: 1–5). The highest overall wearing comfort value was „good“ in 41.7% with the HB, 50% „good“ with the SO and 41.7% „fair“ with the RO. The difference in overall comfort was significant ($p = 0.02$). We detected no other significant correlations. The SO and RO demonstrated high subjective stabilization (in seven volunteers for each), the HB the worst stabilization. Skin pressure marks were detected in conjunction with the HB (1x), the SO (3x) and the RO (4x), and the RO triggered the most rework due to side effects. Eight of 12 subjects complained of uncomfortable sternal pressure from the HB's upper pad.

In summary, 11 of 12 volunteers found the SO to be the best compromise between stabilization and subjective comfort.

c) Impact on the physical and mental component of QoL – SF-12 Evaluation

Table 3 presents the means and standard deviations of the PCS and MCS of volunteers wearing the three different orthoses and the comparison with the scores from the National Survey of Functional Health Status (NSFHS) with healthy adults and individuals having different chronic conditions (12).

Scores on the PCS ranged from a high of 54.3 (SD 6.2) for healthy adults to a low of 38.8 (SD 10.0) for patients with heart disease (12). It was 52.1 (SD 4.3) for the HB, 51.4 (8.6) for the SO and 48.6 (SD 7.7) for the RO. All orthoses ranked under the first 5 of 10 items in between the healthy adults and the general US population. The MCS score was 50.8 (SD 11.4) for the HB,

Table 1. Wearing time of each different spinal orthosis

Daily wearing time of orthosis (hours)		Mean \pm SD	95% CI	Minimum	Maximum
Mean	HB	11.75 ± 1.02	11.1-12.4	9.93	13.50
	SO	11.57 ± 1.22	10.8-12.4	9.29	12.86
	RO	10.63 ± 2.05	9.3-11.9	7.00	13.14
Minimum	HB	9.54 ± 1.23	8.8-10.3	7.00	12.00
	SO	9.67 ± 2.00	8.4-10.9	6.00	12.00
	RO	8.67 ± 1.83	7.8-10.1	6.00	12.00
Maximum	HB	13.71 ± 1.63	12.7-14.7	11.00	16.50
	SO	13.38 ± 1.82	12.2-14.5	11.00	17.50
	RO	12.21 ± 2.39	10.7-13.7	8.00	15.50

HB = 3-point hyperextension brace, SO = semirigid orthosis, RO = rigid orthosis, SD = standard deviation, CI = confidence interval

Table 2. Comfort and side effects of three different orthoses

N = 12	HB		SO		RO	
	mean	SD	mean	SD	mean	SD
Comfort (overall)	2.9 ± 1.0	(range, 2–5)	2.2 ± 0.7	(range, 1–3)	3.2 ± 0.8	(range, 2–4)
Comfort when sitting	3.8 ± 1.1	(range, 2–6)	2.8 ± 1.5	(range, 1–5)	3.5 ± 1.1	(range, 1–5)
Comfort when standing	2.3 ± 0.9	(range, 1–4)	1.8 ± 0.6	(range, 1–3)	2.2 ± 1.2	(range, 1–5)
Practicability	2.9 ± 1.2	(range, 1–5)	2.3 ± 1.0	(range, 1–4)	3.2 ± 0.9	(range, 2–5)
Compression feeling	2.3 ± 0.9	(range, 1–4)	3.0 ± 1.4	(range, 1–5)	3.0 ± 0.9	(range, 1–4)
Sweating	3.6 ± 1.8	(range, 1–6)	2.6 ± 1.4	(range, 1–5)	2.9 ± 1.2	(range, 1–5)
Side effects*						
Best subjective stabilization	–		7		7	
Worst subjective stabilization	12		–		–	
skin pressure marks	1		3		4	
corrections / rework	1		1		4	
sternal compression	8		–		–	
displacement during move.	3		–		5	
discomfort (breathing)	–		3		1	
discomfort (eating)	1		1		–	
Best compromise (c + s)	–		9		1	
Best choice	0		11		1	

HB = 3-point hyperextension brace, SO = semirigid orthosis, RO = rigid orthosis, move = movements, c = comfort, s = stabilization, SD = standard deviation. Rating scale: 1: very good, 2: good, 3: satisfactory, 4: fair, 5: poor, 6: very poor. * Side effects were given as absolute numbers

Table 3. Physical and mental component scores of volunteers wearing different spinal orthoses compared with general US populations, including healthy adults and patients with chronic diseases

	PCS		MCS	
	Mean (SD)	Rank*	Mean (SD) Rank*	Rank*
Healthy adults†	54.3 (6.2)	1	52.3 (7.9)	3
Hyperextension brace	52.1 (4.3)	2	50.8 (11.4)	4
Semirigid orthosis	51.4 (8.6)	3	53.7 (4.8)	1
General US population†	49.6 (9.9)	4	49.4 (9.8)	5
Rigid orthosis	48.6 (7.7)	5	53.1 (5.6)	2
Depression†	45.6 (11.7)	6	37.4 (10.8)	10
Hypertension†	43.7 (10.3)	7	49.1 (9.5)	6
Liver disease †	42.0 (12.1)	8	44.1 (12.9)	9
Rheumatoid arthritis†	40.6 (10.5)	9	47.2 (10.3)	8
Heart disease†	38.8 (10.0)	10	48.3 (10.1)	7

MCS = mental component score, PCS = physical component score, SD = standard deviation, NIDDM = Non-insulin-dependent diabetes mellitus. *Higher rank indicates better functioning. † according to (18)

53.7 (SD 4.8) for the SO and 53.1 (SD 5.6) for the RO. Also in that score, all of the orthoses ranked in the first half of all ten items. No significant differences were found in the PCS or in the MCS between the volunteers who have worn the three different orthoses.

DISCUSSION

Spinal diseases such as scoliosis, fracture, spondylodiscitis and bone metastasis can be treated conservatively by spinal orthoses (2, 3, 5, 8, 9, 14, 15). Success of such treatment depends on wearing the devices, while the “ideal” orthosis is functional, fits well, and is cosmetically acceptable. Further, it should be light in weight and easy to use.

In addition, to assessing the radiological and functional outcomes of wearing orthoses, patient-centred outcomes need to be evaluated. These include pain, anxiety, acti-

vity status, and QoL (7). In this study, we investigated three different spinal orthoses including a commercially available 3-point hyperextension brace (HB), a custom-made semirigid orthosis (SO), and a custom-made rigid orthosis (RO). All of these are used daily in routine activities. We carried out the investigation to evaluate potential side effects by paying particular attention to the compliance with treatment while assessing wearing times. Furthermore, we studied comfort, subjective stabilization, and side effects via a questionnaire. The SF-12 was administered to measure the health-related QoL (6, 11, 18, 19).

The first and most obvious of our results was that almost none of the volunteers wore their orthosis for the entire specified time (only two of the volunteers revealed 100% compliance). This may be because healthy people do not tend to perceive any advantage or positive effect from wearing an orthosis. In contrast, the use of orthoses

in patients with different spinal diseases may alleviate pain by stabilization and limiting movements. The SO and RO correlated with the best subjective stabilization. The HB exhibited the worst stabilization (as rated by all subjects), and orthosis may primarily work as a “reminder” of an upright position.

All three orthoses triggered side effects. Every orthosis by definition causes some degree of compression on the body. Remarkably, even the HB with its relatively small pad caused sternal compression and discomfort in eight of 12 volunteers. Skin pressure marks were detected in conjunction with the HB (1x), the SO (3x) and the RO (4x). Sweating was another relevant side effect. That factor was most disturbing in conjunction with the HB, but less so in the SO and RO – surprising, since the latter two cover more of the body surface. In a study by Tezer et al. of 48 patients who suffered a thoracolumbar fracture treated non-surgically with a brace, two patients fitted with a body cast complained of sweating and three patients treated with TLSO complained of skin problems; other complications such as emotional distress were not reported (16).

It is notable that, besides side effects, 75% of our subjects graded the HB as good or satisfactory, as did 83.3% the SO and 58.5% the RO. 11 of 12 subjects ultimately found the SO to be the best compromise between stabilization and subjective comfort.

We administered the SF-12v2 in this study as a generic self-report health status instrument in addition to the individualized questionnaire to obtain further information on the impact of orthoses on QoL. This includes a subset of 12 items from SF-36 (11–13, 15) covering (as a valid alternative) the same eight domains of health outcomes, including physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH) (11, 18).

The standardized physical component score (PCS) and mental component score (MCS) from the present sample were evaluated. They were compared with the scores from the National Survey of Functional Health Status (NSFHS), with healthy adults, the general US population, and individuals having different chronic conditions (e.g., depression, hypertension, liver disease, rheumatoid arthritis, and for patients with heart disease) (12). In our healthy volunteers the scores on the PCS ranged from 52.1 (SD 4.3) in conjunction with the HB, 51.4 (8.6) with the SO to 48.6 (SD 7.7) with the RO, while scores ranged from a high of 54.3 (SD 6.2) for healthy adults (US population) to a low of 38.8 (SD 10.0) for patients heart disease. The MCS score was 50.8 (SD 11.4) for the HB, 53.7 (SD 4.8) for the SO and 53.1 (SD 5.6) for the RO. It is remarkable, that the PCS as well as the MCS ranged in between the healthy adults and the general US population. Moreover, PCS and MCS of the chronic diseases were all below these values, in keeping with the perceived burden of these disorders

Several other studies have investigated the impact of orthoses on QoL. They mainly addressed the treatment

of scoliosis. Climent found in his investigation, that the type of brace has an impact on QoL as measured by the QoL Profile for Spine Deformities (QLPSD), a specific instrument that measures QoL in five areas categorized as psychosocial functioning, sleep disturbances, back pain, body image, and back flexibility (4). No loss of QoL during brace wearing was reported in adolescents, in contrast to their counterparts in another study (17). A recent Cochrane review assessed the efficacy of braces in adolescents with scoliosis versus no treatment or other therapies (12). Those authors concluded that two (low quality) studies showed that bracing did not change QoL during treatment (12).

In summary, we demonstrate that the mean PCS values for healthy volunteers wearing orthoses were lower than that of healthy adults, but higher than those for patients with several chronic diseases. Regarding the MCSs: The SF-12 MCS results also vary depending on the design of the orthosis and place the different types in between healthy adults and the general US population. Therefore, findings indicate that wearing orthoses tends to have a moderate negative impact on QoL.

Limitations

Appreciation for the limitations of this study is warranted: First and foremost, the data were taken from healthy volunteers with no history of spinal disease, and the (daily) activities may not have reproduced all of the spinal movements that occur during the course of a typical day. Secondly, the study group was relatively young with a mean age of 31.3 years. Patients with back pain due to spinal metastases for example, tend to be older. Nevertheless, we believe that these minor concerns do not detract from the overall validity of our results.

CONCLUSIONS

Wearing an orthosis influences QoL. Almost none of our volunteers complied with the entire wearing time schedule. This may be due to the restriction of movements, a desired effect in patients with spinal disease. Stabilization was found to be good in conjunction with the RO and SO, while the HB seems to act primarily as a reminder to maintain an upright position and as a proprioceptive tool. Beside this, the orthoses' designs triggered negative side effects like sweating and skin pressure marks. In reference to the SF-12 as a generic self-report health status instrument, we noted in our cohort of volunteers that the orthoses have a moderate negative impact on QoL. The emotional aspects are influenced similar to the physical components.

Therefore and because of the side effects, patients should be continually observed for any complications, and orthoses should be fitted for a specific period. In patients with spinal diseases the stabilization and proprioceptive effects may overwhelm moderate negative impact on short term QoL, when compared to other longterm disease states. And, it has to be expected, that possible initial unhappiness or loss of freedom, will

pass, if the underlying condition improves and patients grow to tolerate the orthotic more routinely.

Abbreviations

HB: 3-point hyperextension brace
MCS: mental component score
PCS: physical component score
QoL: Quality of Life
RO: rigid orthosis
SF-12: Short Form-12 Health Survey
SO: semirigid orthosis

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