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Using inpatient gradual diagnostics to identify the treatment strategy for lumbar back pain—Can treadmill gait analysis objectify the patients' declaration of pain relief?

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ABSTRACT

Background: Patients with chronic lumbar back pain (CLBP) often present with an altered gait profile, which is a crucial element of good functioning in everyday life. In patients with multisegmental spinal pathologies and incongruity between radiologic imaging and clinical presentation, inpatient gradual diagnostics (IGD) is performed to determine the precise origin of the disabling pain. The underlying principle of IGD is the assumption that by locally administering an analgesic and anti-inflammatory agent to possible surgical target areas, the surgical effect can be temporarily simulated. The conclusions drawn from IGD are, however, mostly based on the patients' subjective feedback about pain relief.

Research Question: The aim of this study was to evaluate whether reported pain relief during IGD can be objectified by gait analysis. We hypothesized that patients with greater pain relief during IGD would show greater improvement in their pathologic gait and stance.

Methods: Treadmill gait and stance analyses were prospectively performed on CLBP patients before and after a one-week IGD. Self-report measures included the numeric pain rating scale (NRS) and the Oswestry Disability Index (ODI).

Results and Significance: Compared with a reference group (n = 28), IGD patients (n = 57) at admission showed reduced velocity, cadence, step length, and swing phase (p < .01 each). Their stance phase was increased by 5% of the gait cycle, and a more asymmetrical total load distribution during stance was observed. No difference was seen in stride width or foot rotation. While many patients reported good pain relief during IGD, no correlation was observed between subjective improvement and treadmill measures.

We can thus confirm a pathologic gait profile in patients with CLBP. Based on our findings, gait analysis would not yet seem suitable to objectify IGD results. The short time interval between admission and discharge may not suffice to change a pathological gait that has developed over years.

1. Introduction

With a global incidence of 9.4%, low back pain is a daily challenge for orthopedic doctors [1]. Moreover, due to the conservative treatment strategies having been exhausted, it is essential to identify the chronic lumbar back pain (CLBP) patients who would substantially benefit from spinal surgery, such as lumbar fusion or local decompression. The

established methodical approaches to identify the pathologies of the human spine include requesting the patients' medical history and gathering results from clinical examination, radiographic imaging, and functional scores. Typically, summing up the relevant findings will provide an idea of the main pathology and guide the doctor toward the correct treatment strategy. However, there still seems to be a lack of consensus regarding the conditions surgeons should base their final

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	Consultation	Day 1		Day 2	Day 3	Day 4	
		preinf.	postinf.			preinf.	postinf.
Diagnostic	X-ray MRT clinical exam		Clinical exam				
Infiltration		•		•	•	•	•
NRS	•	•	•	•	•	•	•
Improvement (%)			•	•	•	•	•
Gait and stance analysis		•	•				•
ODI		•					•

Fig. 1. Study design. The light grey boxes depict study-independent standard examinations for inpatient gradual diagnostics; the dark grey boxes indicate study-based examination. NRS, numeric rating scale; ODI, Oswestry Disability Index; preinf., preinfiltration; postinf., postinfiltration.

decisions on, especially for patients with whom the clinical observation does not entirely match known structural pathologies [2,3]. Furthermore, in this specific population where clinical and radiologic findings do not match, the means for achieving a reliable identification of patients who will benefit from surgery are unclear.

One possible approach is performing inpatient gradual diagnostics (IGD) [4,5], the main underlying principle of which is the assumption that by locally administering an analgesic and anti-inflammatory agent to possible surgical target areas, the effect of surgery at these sites can be temporarily simulated [6]. Moreover, the surgeon can draw conclusions about the main pathologies causing pain to a patient from the latter's reported pain relief. Thus, as a tool that produces short-term pain-relieving effects for diagnostic reasons only, IGD does not generate a long-lasting alleviation.

Furthermore, conclusions and consequences derived from IGD, to date, have largely been based on the patient's subjective statement and improvements on the numeric pain rating scale (NRS). However, the problem with patient-reported outcome measures is that they are not only influenced by the objective physical abnormality but also by individual attitudes and beliefs, psychological distress, and illness behavior [7].

As since an intact gait is a crucial element of good functioning in everyday life [8,9], it has been demonstrated that patients with CLBP walk slower, take shorter steps, have increased stance phase, and present a more asymmetric gait profile when compared with their healthy peers [10–12]. Furthermore, impaired gait seems to correlate with values obtained from the Oswestry Disability Index (ODI) in patients with spinal stenosis [13].

The aim of this study was to evaluate whether patient-reported reduction in pain can be objectified quantitatively by means of treadmill gait analysis. Accordingly, we hypothesized that patients with greater pain relief during IGD would also show greater improvement in their pathologic gait and stance.

2. Methods

2.1. Participants

This prospective study included all consecutive patients with CLBP or sciatic pain due to a combination of a multisegmental degenerative disc disease between Th 12 to S 1 and with inconsistency between clinical findings and results from radiological investigations. The exclusion criteria contained myocardial infarction or apoplexy during the past six months, documented injury due to gait instability, recent fracture of the spine or lower extremities, neoplastic or infectious pathology of the spine, motor deficit of less than 4/5 on the Medical Research Council scale for muscle power, lack of capacity to give consent, elevated inflammation parameters, use of anticoagulation therapy, or hints for an additional psychological comorbidity as

evaluated by the PHQ-D [14] depression score and the Internality, Powerful Others, and Chance Scale [15]. Furthermore, by the time IGD (see "Procedure" for detailed description) was scheduled, each of the participants already had a long history of ineffective conservative treatment and were examined in addition to their clinical findings being compared with standardized standing lumbar radiographs (anteroposterior and lateral) and magnetic resonance imaging of the lumbar spine. Patients were asked to participate in this study at admittance. Subsequently, a reference group was formed of 28 healthy elderly volunteers, without any back pain and/or signs of lower limb osteoarthritis.

Full departmental, institutional, and ethical committee approvals (local ethical committee project number 030/2012BO2) were obtained before the commencement of the study. Written informed consent was taken from all subjects prior to their participation.

2.2. Procedure

During IGD, predefined targeted local infiltrations are typically performed during a four-day in-patient stay. Therefore, depending on the surgical question, the examination results, and radiologic imaging, the target sites may be facet joints, epidural space, sacroiliac joints, deep back muscles, or spinal nerves at their exit through the intervertebral foramen, as well as the hip as a differential diagnosis for CLBP. Only one site is targeted per day. However, facet joint infiltration is also performed at several motion segments on one day if this infiltration addresses the same diagnostic question. Over the course of several hours after the infiltration, the patient was asked to describe how far the pain was alleviated by the injection. The surgeon can thus draw conclusions about the main pathologies responsible for the patient's pain.

Upon admittance, the patients were asked to complete the ODI and rate their pain level on the NRS. Thereafter, a video-assisted treadmill gait analysis was performed (Fig. 1).

The first scheduled local infiltration to preselected target areas was performed after the completion of these examinations. Another treadmill analysis was performed at the end of the first day in order to analyze the effect of a single infiltration. From then on, injections were administered daily, with their effect being registered by measuring NRS and enquiring about pain alleviation in terms of percentage.

After the fourth infiltration-session (one for each day), gait analysis was performed once more, accompanied by the completion of the ODI.

Four weeks and six months after IGD, the participants received another version of the ODI and the NRS via mail to report their present level of pain and impairment.

2.3. Infiltration technique

Infiltrations were performed under fluoroscopic guidance and

Table 1
Demographic data.

Variable	Study group (n = 57)	Reference group (n = 28)	p-Value
Age* (y)	64.1 (13.3)	57.4 (5.9)	.001
Female* (no.)	39	16	.310 n.s.
Male* (no.)	18	12	
Body weight ^a (kg)	75 (52-120)	74 (52-110)	.656 n.s.
Body height ^b (m)	1.64 (0.1)	1.68 (0.1)	.044
BMI ^c (kg/m ²)	28.3 (19.1-42.2)	25.5 (18.2-36.1)	.122 n.s.

BMI, body mass index; ns, not significant; A significant difference exists for age due to the inclusion criteria of the reference group. Body height was also higher in the reference group. The values are shown as the mean (SD), median (minimum-maximum), or absolute values as appropriate. A p-value in bold type denotes a significant difference.

aseptic conditions. A specific mixture of an analgesic (bupivacaine 0.25%) and a corticosteroid (triamcinolone 10 mg/ml) were injected at the site (for epidural injection, 1.8 ml bupivacaine, 0.6 ml triamcinolone, and 0.6 ml 0.9% NaCl; for facet joint infiltration, 0.5 ml bupivacaine and 0.5 ml triamcinolone on each side).

According to suggestions in the literature, an improvement on the NRS of more than 75% was considered an excellent infiltration response, an improvement of 30%–74% was good, and an improvement below 30% was “not a technique-specific response” [16].

2.4. Treadmill stance and gait analysis

The stance and gait parameters were recorded as previously described [17,18]. Briefly, an FDM-T Treadmill (Zebris Medical GmbH, Germany) was used, equipped with an embedded electronic 150 x 50 cm sensor mat which contained 10,240 miniature 0.85 x 0.85 cm force sensors registering the exerted force at a rate of 120 Hz. Furthermore, the speed of the treadmill was adjustable at intervals of 0.1 km/h. Subsequently, two- to four-dimensional graphic representations were calculated by the software, in addition to the mean values and standard deviations (SD) of relevant parameters important for stance or gait characterization.

All analyses required the patients to be barefoot and standing without support from the railing. For stance registration, patients had to stand freely on the treadmill for ten seconds. For gait analysis, all subjects were familiarized with the treadmill in order to establish their individual walking speeds. Consequently, starting from an initial speed of 0.5 km/h, the belt speed was increased by steps of 0.1 km/h until the subjects affirmed that their maximum comfortable walking pace had

been reached. At this speed, the patients had to walk for approximately 30 s before the actual registration process was initiated. The FDM-T requires a measurement period of at least 10 s to deliver reliable and accurate values. Thus, in order to account for possible temporary imbalances in gait in the pathological cohort, the patients were asked to continue walking for 20 s at the final walking speed (the total walking time was 50 s).

2.5. Statistical analysis

Distributions of variables within the study groups were assessed by histograms and equality of variances by the Levene test. Therefore, depending on normality, continuous data has been reported as means (SD) or medians (minimum-maximum), with the categorical variables being reported as absolute or relative frequencies. Moreover, the graphic presentation is in the form of histograms, boxplots, scatterplots, and Bland-Altman plots, the latter being used to illustrate a possible connection between pain relief and changes in gait. The correlation between NRS and ODI was calculated using the Pearson correlation.

The demographic characteristics and read-outs of the different measurements between the different groups or time points were compared with the Welch, chi-squared, Wilcoxon, Mann-Whitney *U*, or *t*-test for independent samples, as appropriate. Furthermore, all reported p-values are 2-sided, with a significance level of $\alpha = .05$, and have not been adjusted for multiple testing. The 95% confidence interval is given in addition to the p-value. Additionally, a sample size calculation was performed before the commencement of the study based on the CohenEffectSize which—setting a power of 80% and an effect-size of 0.35 using a two-sided significance level of 0.05—yielded a sample-size of 67 participants.

When examining bilateral gait parameters, such as stance phase, swing phase, or foot rotation, values were organized into major and minor per measurement and thus used for further analyses. Consequently, the absolute differences between these two values were calculated as an indicator for gait symmetry. Following this, a statistical analysis was conducted using IBM SPSS version 22.

3. Results

3.1. Study and reference groups

A total of 57 patients (39 women and 18 men; Table 1) were prospectively included after the exclusion of 10 patients (two hip disorders, two sensorimotor local deficits, and six lost to view).

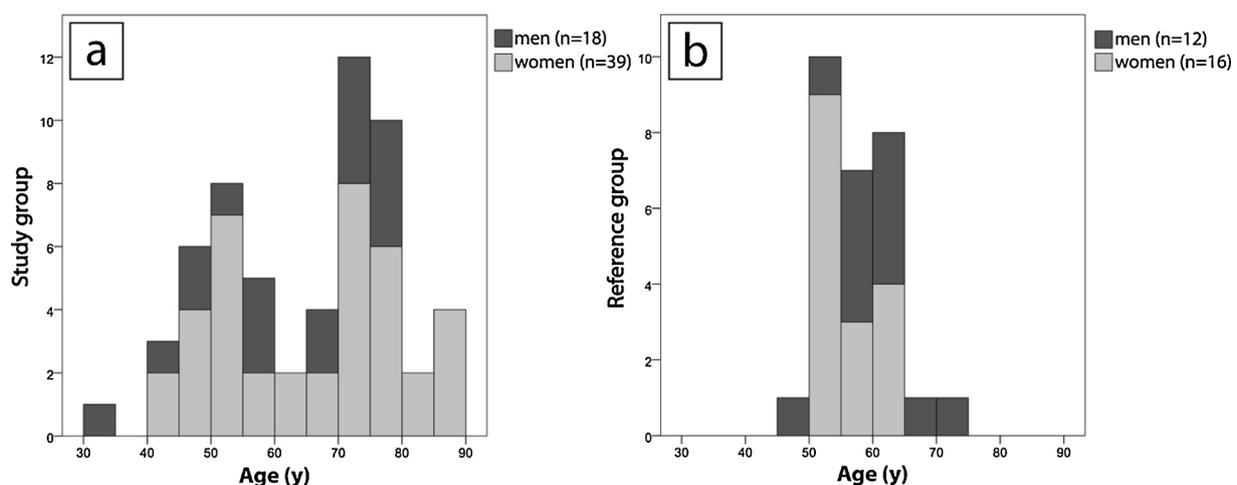


Fig. 2. Age distribution of the study and reference group (histograms) (a,b). Fifty-seven patients were included in the study group (a). It is noteworthy that 2 main peaks in age can be observed. The reference group (n = 28) (b) covers the lower peak, since for the older peak of around 75 years, no healthy control subjects without back pain could be recruited. y, years.

Table 2
Gait and stance analysis.

Variable	Study group admission	Study group discharge	Mean difference (95% CI)	p-Value*	Reference group	p-Value [#]
Total load MJ (%)	54 (50-82)	54 (50-74)	0 (-2/2)	.54	53 (50-58)	.04
Total load MN (%)	46 (18-50)	46 (26-50)	0 (-2/2)	.55	47 (42-50)	.04
Total load DiffMJMN (%)	8 (0-64)	9 (0-48)	1 (-3/6)	.55	5 (0-17)	.04
Speed (km/h)	1 (0.2-3.0)	1 (0.2-3.0)			2.5 (1.1-3.0)	< .01
Cadence (steps/min)	51 (13-86)	50 (14-83)	0 (-2/3)	.49	64 (42-160)	< .01
Stride width (cm)	12 (5-21)	12 (5-22)	1 (0/1)	.09	11 (2-18)	.31
Step length MJ (cm)	23 (6-53)	25 (7-52)	0 (-1/1)	.72	36 (23-55)	< .01
Step length MN (cm)	20 (2-53)	22 (4-52)	0 (-1/1)	.84	34 (22-54)	< .01
Step length DiffMJMN (cm)	2 (0-14)	2 (0-12)	0 (-1/1)	.66	1 (0-7)	.55
Stance phase MJ (% GC)	73 (63-87)	72 (64-83)	0 (0/1)	.25	68 (64-76)	< .01
Stance phase MN (% GC)	70 (57-85)	71 (63-83)	0 (-1/1)	.69	66 (61-73)	< .01
Stance phase DiffMJMN (% GC)	2 (0-13)	1 (0-7)	1 (0/2)	.15	1 (0-5)	.53
Swing phase MJ (%GC)	30 (15-37)	29 (17-37)	0 (-1/1)	.99	34 (27-39)	< .01
Swing phase MN (%GC)	27 (14-37)	28 (17-36)	0 (-1/0)	.24	33 (24-36)	< .01
Swing phase DiffMJMN (%GC)	1 (0-13)	1 (0-8)	0 (0/1)	.38	1 (0-5)	.74
Foot rotation MJ (°)	12 (3-32)	13 (4-29)	1 (0/1)	.02	12 (6-17)	.15
Foot rotation MN (°)	8 (-1-21)	9 (-1-21)	0 (-1/1)	.84	8 (1-15)	.71
Foot rotation DiffMJMN (°)	4 (0-15)	4 (0-14)	1 (0/2)	< .01	3 (0-8)	.12

Diff, difference; MJ, major; MN, minor; GC, gait cycle. Treadmill analysis at admission before the first infiltration and prior to discharge. Speed was kept constant for each patient throughout all measurements. Values are given as median (minimum- maximum) and mean difference (diff) with 95% confidence intervals (CIs). p-Values between admission and discharge* were calculated by the Wilcoxon test, and between admission and reference group by the Mann-Whitney *U* test.[#] For comparison, results of the reference group are also reported. Values for bilateral measurements were arranged according to their major and minor values at admission and the resulting difference calculated.

In the study group, two major peak ages could be observed (Fig. 2): the first, around the age of 50 years of mainly female patients, and the second, at around 75 years (mean age, 64.1 years). In the reference group (mean age, 57.4 years), no second peak age could be formed because of the corresponding inclusion criteria, which resulted in a significant difference between these two groups ($p = .001$).

3.2. Treadmill stance and gait analysis

In comparison with the reference group, patients with CLBP showed a more asymmetrical total load by a difference of 3% at admission (Table 2).

In addition, the patients presented a significantly ($p < .01$ each) reduced walking speed, cadence, step length, and swing phase, whereas stance phase increased by about 5% of the gait cycle (pre-IGD), compared to the standard values of human gait [19].

When we analyzed the study group throughout the week, a statistically significant difference in gait between admission and discharge was observed in the absolute difference of foot rotation ($p < .01$; Table 2). However, the median absolute difference in foot rotation remained unchanged at 4°. Moreover, no difference was seen in stride width, total foot rotation, or asymmetry of foot rotation during the week.

3.3. Infiltration effect

The response to infiltration was quite heterogeneous, with a higher proportion of women reporting good to excellent pain relief (Table 3). This difference in response to infiltration between men and women was not age-dependent. Thus, in order to check for a possibly stronger gait change in patients with a better infiltration response, we separated them into three different response groups and calculated the changes for each subgroup. However, no significant differences could be observed (Fig. 3) among these groups.

Consequently, most patients were discharged with a considerable reduction in pain, depending on the infiltration responses. Furthermore, by four weeks post-IGD ($n = 42/52$), symptoms had again strongly increased, and by six months post-IGD ($n = 41/46$), they had completely reached pre-IGD levels (Fig. 4 A, C; Table 4) (the follow-up dropout being explained by spine surgery had already been performed

Table 3
Declared Improvements.

		Improvement > 75%	Improvement 30%-75%	Improvement < 30%
Monday	M	1/14 (7%)	4/14 (29%)	9/14 (64%)
	W	9/38 (24%)	9/38 (24%)	20/38 (53%)
Thursday	M	4/15 (27%)	3/15 (20%)	8/15 (53%)
	W	16/35 (46%)	8/35 (23%)	11/35 (31%)

M, men; W, women;

Declared improvements obtained by localized infiltrations on Monday and Thursday evening. Values are reported as absolute and relative frequencies (percentage) allocated to 3 groups of improvement. The response to infiltration is much more pronounced in women than it is in men.

on some patients during that period).

3.4. Questionnaires

In order to investigate whether the improvement obtained could equally be ascertained by the ODI, we calculated its correlation with the NRS, both for the absolute values on the day of questionnaire completion and the relative improvement from Monday to Thursday in terms of percentage. Resultantly, a moderate correlation could be found in both cases, with $r = 0.490$ ($p < .001$, $n = 150$) for absolute values and $r = .459$ for relative values ($p = .002$, $n = 43$) (Fig. 4 B, D). Since the ODI, as a questionnaire, also evaluates aspects of everyday living, we chose the NRS for the day-to-day evaluation of achieved improvement after targeted infiltrations. Thus, as reported above, due to the correlation between changes in the ODI and NRS, no additional statistical analysis was performed for the ODI with respect to changes in gait.

4. Discussion

The aim of this study was to evaluate whether the pain relief reported by patients during IGD can be objectified by treadmill gait and stance analysis.

4.1. Infiltration and gait

The results obtained with treadmill gait analysis from the pre-IGD

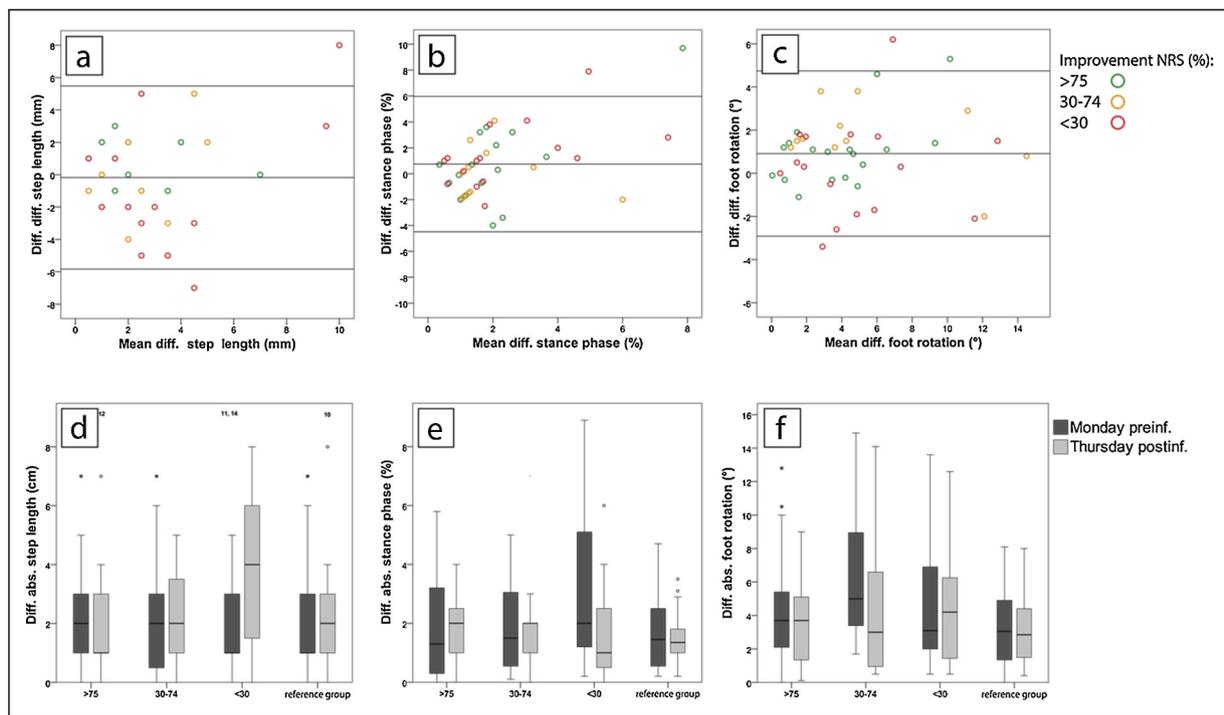


Fig. 3. Changes in gait during inpatient gradual diagnostics (IGD) from admission before the first infiltration to discharge. Bland-Altman plots (a-c) and Boxplots (d-f) illustrating the individual changes in gait parameters during IGD according to the pain relief obtained. No clear pattern can be detected for step length (a), stance phase (b), or foot rotation (c). For the boxplots results are grouped in categories of pain relief of more than 75%, 30%–74%, and less than 30%. For comparison, values of the reference group are also illustrated. No clear tendency can be observed for step length (d), stance phase (e), or foot rotation (f). Gait parameters are given as the absolute difference between the values for the right and left side as an indicator of gait symmetry. abs., absolute; diff., difference; NRS, Numeric Pain Rating Scale; postinf., postinfiltration; preinf., preinfiltration.

measurements of the study group aligned with previous reports on that topic [10–12]. Although a large proportion of patients reported good symptom reduction, no relevant differences could be observed in the technical analyses between admission and discharge. Furthermore, even a subgroup analysis of the patients with excellent infiltration response did not show any characteristic pattern. Therefore, while it is evidently desirable to apply the targeted infiltrations at the correct location during IGD, even misplaced injections should not have affected the main outcome of this study, since changes in gait or stance were compared with reported pain alleviation and not the actual targeted local anesthesia caused by the infiltrations. Moreover, it is unlikely that the lack of a connection between pain relief and gait or stance can be explained by inadequate measurement technology since the technique used in this study is known for its high precision. In addition, the coefficients of variation for the majority of gait parameters recorded by the Zebris treadmill system are reported to be below 5% and 7% for between- and within-day reliability, respectively [20].

A possible inconsistency between radiologic and clinical findings may, for example, be found in cases of multisegmental facet joint degeneration with some motion segments being chronically symptomatic and others being asymptomatic [21]. Alternatively, adaptational processes in the spine may lead to asymptomatic spinal stenosis despite severe radiomorphologic stenosis.

4.2. Time factor

Nevertheless, in patients with CLBP, gait parameters can improve by conservative [22] and operative [23] treatment over a period of several months. Despite this, divergent posture and stance develop over several years in patients with CLBP. This chronic condition leads not just to rigid stabilization by shortened muscles after learned and acquired pathologic evasive movement patterns, but also to altered connective tissue and even deformed vertebrae, including the formation of

spondylophytes. Hence, by simply interrupting the cause of the pain, these changes will not disappear quickly

- if at all - but will require intensive rehabilitation training. Further, with the third measurement performed on Thursdays, four days elapsed between the first infiltration with prior baseline measurement. As a result, it is conceivable that a longer interval until the third measurement would have led to a detectable improvement in the investigated parameters. However, as the study design targeted to measure if gait analysis could objectify subjective pain improvements over the same period of IGD-time, the endpoint was predetermined. Moreover, even after an adaptation period, subjective perception of pain can differ from gait parameters in one-third of patients with CLBP after spine surgery [24].

During follow-up, six patients had already been operated based on the recommendation obtained during IGD. In the other cases where the indication for surgery had been formulated, patients were still on the waiting list for surgery in our department or had decided against operative treatment.

5. Study limitations

The measured parameters are prone to postural and situational errors even though the equipment used in this study offers high resolution and precision. Moreover, the tested collective was heterogeneous with respect to their underlying pathologies. In accordance with the literature [16], we classified the subgroup with an infiltration response of less than 30% as a “not technique-specific response”, since the effect size observed cannot be clearly attributed any longer to the drug used and infiltration technique performed. Furthermore, the improvements reported by these patients could be explained by a placebo effect since a procedure was performed. It is important to consider when interpreting results that a placebo effect will have also affected the results reported in the patient groups reporting better improvement.

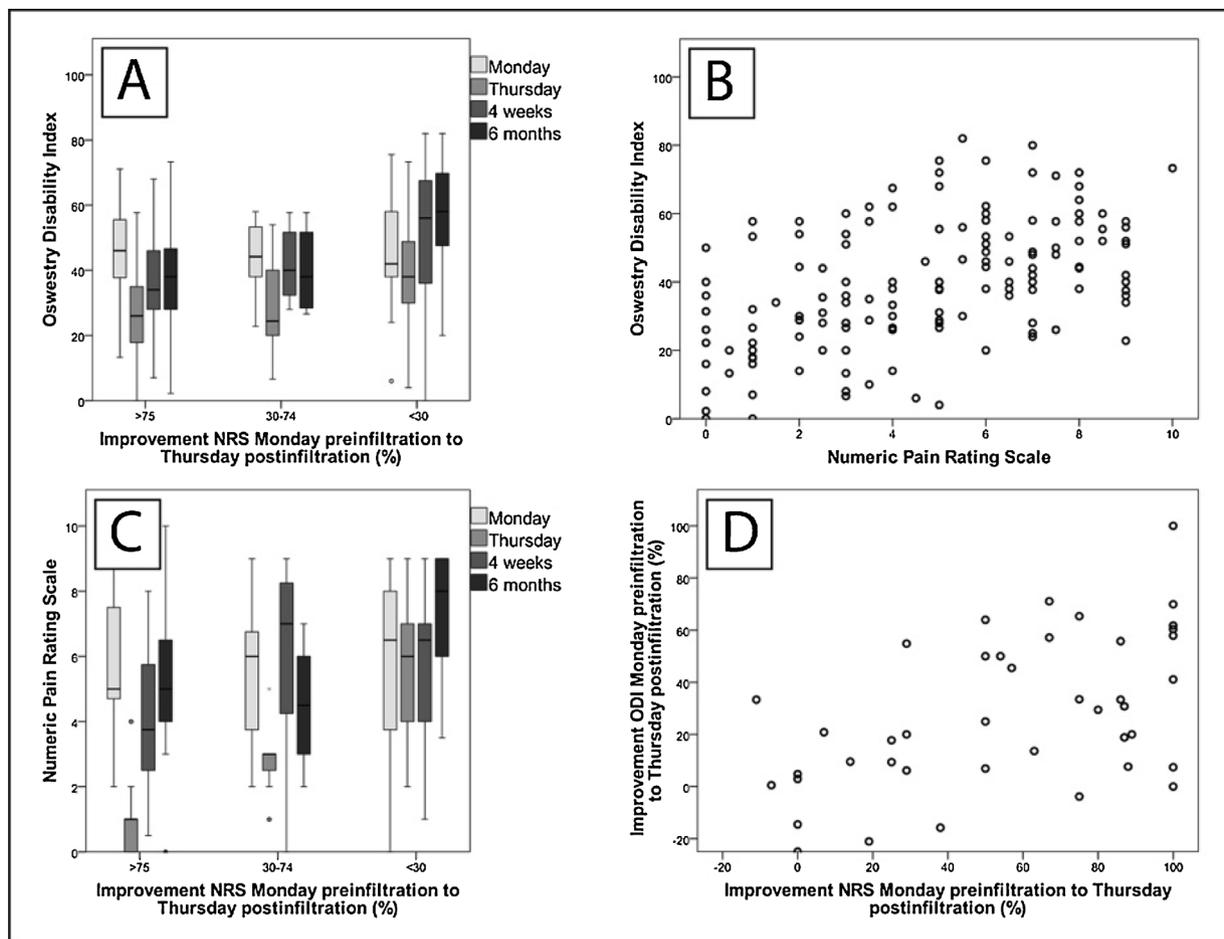


Fig. 4. Symptom development after inpatient gradual diagnostics (IGD). Boxplots illustrating the development of the Oswestry Disability Index (ODI) (A) and Numeric Pain Rating Scale (NRS) (C), grouped according to the pain relief obtained during IGD. By 4 weeks post-IGD, symptoms had almost reached pre-IGD levels, and by 6 months post-IGD, they had completely reached pre-IGD levels. (B,D) Scatterplots displaying the relationship between ODI and NRS for the absolute values (Pearson $r = 0.490$; $p < .001$; $n = 150$) (B), and the calculated improvement (%) from Monday preinfiltration to Thursday postinfiltration (Pearson $r = .459$; $p = .002$; $n = 43$) (D).

Table 4
Self-reported pain level and functional impairment.

Variable	Monday pre-infiltration	Thursday	4 weeks post-IGD	6 months post-IGD
NRS	6.0 (.0-9.0)	2.5 (.0-9.0)	5.5 (.0-8.0)	5.0 (.0-10.0)
ODI	48.0 (6.0-75.5)	32.7 (.0-73.3.0)	40.0 (.0-82.0)	45.2 (2.2-82.0)

Pain level and functional impairment evaluated by the self-reported outcome measures Numeric Pain Rating Scale (NRS) and the Oswestry Disability Index (ODI). Values are reported as median (minimum-maximum).

6. Conclusion

Although many patients reported strong pain relief during IGD, this short-term improvement cannot be objectified by gait or stance analyses. Since the medical recommendation concerning the treatment strategy is largely based on the effect obtained by these diagnostic infiltrations, for the time being, the evaluation of this effect will have to remain based on the direct and personal communication between the doctor and the patient.

Author contribution statement

Scheidt S: helped to conceive the study, worked on the statistical analyses and wrote the manuscript; Gesicki M: conceived the study,

helped with the measurements and helped to write the manuscript; Winnewisser J: performed the measurements and helped with the statistical analyses; Leichtle C: supervised the study and the infiltrations and helped gave advice for the study; Hofmann UK: wrote the manuscript, supervised the measurements, performed the statistical analyses and coordinated the study. All authors have read and approved the final manuscript.

Declaration of Competing Interest

All authors declare that they have no conflicting interests. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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