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## Using the Oxford Foot Model to assess construct validity of the AOFAS ankle-hindfoot scale and the Foot Function Index

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3 1 **Using the Oxford Foot Model to assess construct validity of the AOFAS ankle-**  
4 2 **hindfoot scale and the Foot Function Index**

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46 64 **The authors declare the following potential conflicts of interests:**47  
48 65 All authors declare no financial and personal relationships with other people or  
49 66 organizations that could inappropriately influence their work or the outcome of this  
50 67 publication.  
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56 69 **The authors declare the following contribution of authorship:**  
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70 TK: developing the concept of the study together with SL, writing of manuscript,  
71 recruiting of patients and financial support for the patients' insurance was made from  
72 a research funding price TK and SL got from the German foot and ankle society in  
73 2010.

74 FS gait lab examination and data analysis, revising the manuscript with regard to  
75 gait lab examination), recruiting of healthy adults for standard values determination  
76 KH gait lab examination and data analysis, revising the manuscript with regard to  
77 gait lab examination and as an American native speaker, recruiting of healthy adults  
78 for standard values determination

79 FK statistical concept and factor analysis, critical review of the manuscript  
80 concerning methods and statistics

81 AM providing the gait lab for carrying out the study (owner of gait lab), has made  
82 substantial contributions to data interpretation.

83 MA recruiting of patients, has made substantial contributions to revising the article  
84 critically for important intellectual content, approval of the submitted and final  
85 version.

86 MHB recruiting of patients, has made substantial contributions to revising the article  
87 critically for important intellectual content, approval of the submitted and final  
88 version.

89 KS doing the statistical analyses and has made substantial contributions regarding  
90 the approval of the final version.

91 SL developing the concept of the study together with TK, providing of a part of the  
92 literature, critical review of the manuscript concerning the study concept and  
93 financial support for the patients' insurance was made from a research funding price  
94 TK and SL got from the German foot and ankle society in 2010.

95

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97 In order to conduct this study, the ethics committee required participants to be  
98 insured for the procedure due to the fact that the gait lab examination was done for  
99 this study only. This insurance was funded through a research grant from the  
100 German Foot and Ankle Society.

101

#### 102 **Data sharing:**

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3 103 No additionally data is available.  
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6  
7 105 **ABSTRACT**

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9 106 **Objective:**

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11 107 After cross-cultural adaption for the German translation of the Ankle and Hindfoot  
12 108 Scale of the American Orthopaedic Foot and Ankle Society (AOFAS-AHS) and  
13 109 agreement analysis with the Foot Function Index (FFI-D), the following gait analysis  
14 110 study using the Oxford Foot Model (OFM) was carried out to show which of the two  
15 111 scores better correlates with objective gait dysfunction.  
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22 113 **Design and participants:**

23 114 Results of the AOFAS-AHS and FFI-D, as well as data from three-dimensional gait  
24 115 analysis were collected from 20 patients with mild to severe ankle and hindfoot  
25 116 pathologies.  
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29 117 Kinematic and kinetic gait data was correlated with the results of the total AOFAS  
30 118 scale and FFI-D as well as the results of those items representing hindfoot function in  
31 119 the AOFAS-AHS assessment. An analysis of correlations with confidence intervals  
32 120 between the FFI-D and the AOFAS-AHS items and the gait parameters was  
33 121 performed by means of Jonckheere-Terpstra test; furthermore, exploratory factor  
34 122 analysis was applied to identify common information structures and thereby  
35 123 redundancy in the FFI-D and the AOFAS-AHS items.  
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43 125 **Results:**

44 126 Objective findings for hindfoot disorders, namely a reduced range of motion (ROM) in  
45 127 the ankle and subtalar joints, respectively, as well as reduced ankle power generation  
46 128 during push-off, showed a better correlation with the AOFAS-AHS total score – as  
47 129 well as AOFAS-AHS items representing ROM in the ankle, subtalar joints and gait  
48 130 function - compared to the FFI-D score.  
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53 131 Factor analysis, however, could not identify FFI-D items consistently related to these  
54 132 three indicator parameters found in the AOFAS-AHS. Furthermore, factor analysis  
55 133 did not support stratification of the FFI-D into two subscales.  
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**Conclusions:**

Use of gait analysis in combination with theoretical mathematical considerations for the evaluation of scores can make a valuable contribution to the development and evaluation of survey instruments and patient-reported outcome questionnaires in clinical research.

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**Article summary****Strengths and limitations of the study:**

Strengths of this study are the objective gait parameters as well as the extensive statistical procedures.

Limitations of this study are the inhomogeneity of the group and the limited number of patients. When focusing on a certain group of foot disorders, a more homogenous group should be examined. In order to develop a new score dealing with different kinds of foot disorders using gait analysis, a larger group should be taken into account.

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**Keywords:**

Gait analysis, foot and ankle surgery, questionnaires, scores, patient reported outcome measures

154

**Main text:**

156

**Introduction**

A variety of questionnaires are available for assessing pain, disability and functional limitations of patients suffering from foot and ankle pathologies. The Ankle and Hindfoot Scale of the American Orthopaedic Foot and Ankle Society (AOFAS-AHS) is one of them and is commonly used to estimate and describe the outcome of conservative or surgical treatment of ankle or hindfoot pathologies [1]. This score is widely used despite the legitimate criticism of its theoretical mathematical weaknesses [2, 3]. In contrast, several publications have shown a high level of

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3 165 responsiveness and acceptable criterion validity for the AOFAS-AHS [4], as well as a  
4 166 satisfactory degree of reliability for the subjective component of the AOFAS scale [5],  
5 167 which justifies its application. In addition, the Foot Function Index (FFI) is also  
6 168 commonly used in the clinical setting [6, 7, 8, 9].

9 169 Cross-cultural adaption of the AOFAS-AHS in its German translation and agreement  
10 170 analysis with the FFI-D by Naal et al. [10] were previously performed and published  
11 171 [11, 12]. The agreement analysis showed that the scores are not interchangeable,  
12 172 but rather complementary [12]. However, these self-reported questionnaires assess  
13 173 patient perception and are not necessarily indicative of actual disabilities. Therefore,  
14 174 it is important that research considers other methods of assessing functionality. Gait  
15 175 analysis has widely been accepted as an objective measure of physical function [13],  
16 176 allowing researchers and clinicians to better understand the biomechanics of gait. In  
17 177 particular, the Oxford Foot Model (OFM) [14] is a multi-segment kinematic model that  
18 178 can be used to quantify the functionality of the foot complex during gait in patients  
19 179 with different pathologies [15-17]. In patients with osteoarthritis and pre-osteoarthritic  
20 180 disorders in the ankle and subtalar joints, reduced walking speed, reduced step  
21 181 length, reduced range of motion (ROM) within different sections of the foot and ankle  
22 182 joint and reduced ankle power generation during push-off have been shown [18-21].

23 183 Since agreement analysis [12] did not determine which of the two scores is better  
24 184 suited to reflect function in patients with ankle and hindfoot disorders, the aim of the  
25 185 present study was to determine the association between physical foot dysfunction  
26 186 using the OFM and perceived disability in patients with mild to severe ankle and  
27 187 hindfoot pathologies. Higher correlation was expected for the FFI-D with respect to its  
28 188 rather elaborate scoring system as compared to the AOFAS-AHS scale system.

29 189 In addition, exploratory factor analysis was applied to identify common information  
30 190 structures and redundancy contained in the FFI-D and the AOFAS-AHS items.

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## 32 192 **Methods and materials**

### 33 193 **Subjects**

34 194 AOFAS-AHS and FFI-D results were consecutively collected from 20 patients with  
35 195 mild to severe ankle and hindfoot pathologies (10 female and 10 male patients) and a  
36 196 median age of 45 (interquartile range 35-54) years. Body mass index (BMI) was 27.8



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3 197 (24.7-31.6) kg/cm<sup>2</sup> in median. We deliberately chose a heterogeneous group of  
4 198 patients to reflect the wide range of patients who were evaluated using the AOFAS-  
5 199 AHS. The 20 patients suffered from pathologies such as primary or post-traumatic  
6 200 osteoarthritis (10 / 20), osteochondral lesions / subchondral cysts (5 / 20),  
7 201 chondromatosis / corpora libra (2 / 20) or osteoarthritis due to hemophilia (3 / 20).  
8 202 Exclusion criteria included neuromuscular dysfunction (e.g., Parkinson's disease,  
9 203 stroke, epilepsy and Alzheimer's disease), a leg length discrepancy of more than 1  
10 204 cm and chronic joint infection. All patients underwent three-dimensional gait analysis  
11 205 on the same day the two questionnaires AOFAS-AHS and FFI-D were applied.  
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### 207 ***Ethical approval***

208 The approval of the local independent Ethics Committee (Ruhr University Bochum  
209 ICE; vote reference no. 4126-11) was obtained in 2011.

210 The study was carried out in accordance with the Helsinki Declaration. Accordingly,  
211 written informed consent was obtained from all patients prior to participation in the  
212 study.

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### 214 ***Questionnaires***

215 The FFI-D questionnaire is based on a ten-point scale for each item and enables  
216 overall continuous scoring by means of an equally weighted normalizing evaluation  
217 system and providing two subscales including eight items for pain and ten items for  
218 disability, respectively. The AOFAS-AHS includes nine items (five to be answered by  
219 patients and four to be answered by the physician) with two to four feature  
220 characteristics and an asymmetric assignment of score points. The AOFAS-AHS  
221 over represents the pain item with 40 of the maximum 100 score points assigned to  
222 this item alone.

223

### 224 ***Gait analysis methods***

225 Three-dimensional gait analysis was performed using a 200 Hz, eight-camera motion  
226 capture system (VICON™ Motion Systems, Oxford, UK) in combination with a 1000  
227 Hz AMTI™ force plate (Advanced Mechanical Technology, Inc., Watertown, MA,

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3 228 USA) to detect gait cycle events and to calculate ankle power generation during the  
4 229 push off phase. Reflective markers were placed over prominent anatomical  
5 230 landmarks along the lower extremity, as well as the ankle and foot complex according  
6 231 to the multi-segment OFM [14, 22, 23]. The OFM allows for a differentiated analysis  
7 232 of movement within different sections of the foot and ankle joint. Repeatability of the  
8 233 OFM has been demonstrated for healthy children and adults [18, 24, 25] and has  
9 234 also been applied in patients with foot pathologies/disorders [16, 22, 23, 26]).

14 235 Kinematic and kinetic data that represent mobility in the ankle and subtalar joints and  
15 236 that are relevant for osteoarthritis patients were collected from barefoot participants  
16 237 during level walking at a self-selected speed. In cases with bilateral pathology, the  
17 238 more severely affected side was analyzed. After each acquisition session, 3D marker  
18 239 trajectories were reconstructed and missing frames were handled with a fill-gap  
19 240 procedure. The data was smoothed with a Woltring filter and using spline smoothing  
20 241 [27]. Average values from three trials were selected based on good quality of marker  
21 242 trajectories and ground reaction forces.

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### 23 244 **Statistical analysis**

24 245 A sample size calculation based on the fact that in healthy persons an AOFAS-Score  
25 246 of 80-100 points are expected, while in patients with relevant disorders a Score of 30-  
26 247 35 points is expected, was performed. The power was assumed with 80%. A group of  
27 248 20 patients was calculated as suitable.

28 249 In a first step, basic spatio-temporal gait parameters (i.e., walking speed, cadence,  
29 250 step length, stride length, step width) as well as discrete kinematic and kinetic gait  
30 251 data were correlated with the total scores for the AOFAS-AHS (range 0 – 100 points)  
31 252 and the FFI-D. The FFI-D scale was transformed to the range 0 - 100 points with 100  
32 253 points indicating optimum rating in all items to make the scores directly comparable  
33 254 to those derived from the AOFAS-AHS. Both overall scores were handled as  
34 255 continuous endpoints, i.e. methods for continuous data evaluation were applied. This  
35 256 means that score descriptions were based on medians and quartiles (graphic  
36 257 description on nonparametric box whisker plots, accordingly) with regard to the  
37 258 moderate sample size. Bivariate correlations between gait parameters and the total  
38 259 FFI-D and AOFAS-AHS scores were estimated by means of the Spearman  
39 260 coefficient and its asymptotic 95% confidence interval. For the sake of aggregation

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3 261 and interpretation of the various bivariate correlation profiles a previously established  
4 262 categorization of correlation ranges based on the Spearman point estimates was  
5 263 adopted [29, 30]: correlations were classified “low” for Spearman coefficients less  
6 264 than 0.30, as “medium” for coefficients between 0.30 and 0.65 and otherwise as high.  
7  
8 265 For further correlation analyses AOFAS-AHS items were taken into account that  
9 266 represent the function of the subtalar and ankle joints, and were related to the  
10 267 corresponding gait analysis parameters representing the function of the respective  
11 268 joints. The respective bivariate associations were described by means of gait  
12 269 parameter distribution (medians and quartiles) stratified for the respective AOFAS  
13 270 item scale levels. Furthermore, Jonckheere-Terpstra test were applied to test for  
14 271 trends in the gait parameters levels alongside the respective AOFAS item scale  
15 272 levels. The results of these trend tests were summarized by means of p-values. In  
16 273 accordance with the exploratory character of this evaluation, the latter were not  
17 274 formally adjusted for multiplicity, but rather considered as indicators of local statistical  
18 275 significance in the case of p-values  $\leq 0.05$ .

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27 276 To determine those FFI-D items representing the ROM in the ankle and the subtalar  
28 277 joints as well as gait function – note, that these can be derived from the AOFAS  
29 278 items, but not from the FFI-D assessment– exploratory factor analysis for the total set  
30 279 of the 9 AOFAS-AHS and the 18 FFI-D items was performed. In the case of several  
31 280 FFI-D items being aggregated with the AOFAS item(s) of interest, these FFI-D items  
32 281 could be considered as ROM related. Since the AOFAS-AHS individual items are  
33 282 more or less categorical, whereas the FFI-D parameters should be treated as  
34 283 continuous, both score systems’ items were binarized for simultaneous use in factor  
35 284 analysis by means of the following criteria: the AOFAS-AHS item dealing with pain  
36 285 was defined to indicate a “negative response” for a score of 20 points or less.  
37 286 Accordingly, a score representing pathological findings (0-4 points) in one of the  
38 287 remaining AOFAS-AHS items was defined as a “negative response”. For the FFI-D,  
39 288 results of five or more points were regarded as a “negative response” (note the  
40 289 scaling direction of the FFI-D items). The total set of 9 binarized AOFAS-AHS items  
41 290 and of 18 binarized FFI-D items was then analyzed by means of exploratory factor  
42 291 analysis, where factors were identified by means of principle component analysis and  
43 292 application of the varimax criterion (75% variance to be explained by identified  
44 293 factors).

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3 294 Statistical and graphic analyses were performed using SPSS® for Windows 21.0™  
4 295 (IBM Corporation, New York, USA)].

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## 7 8 297 **Results**

### 9 10 298 ***Gait analysis***

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12 299 Only moderate correlation coefficients ( $r= 0.51-0.64$ ) could be found between the  
13 300 total AOFAS-AHS / total FFI-D score and objective gait parameters as shown in  
14 301 Table 1. With moderate correlation coefficients between the AOFAS-AHS total score  
15 302 and six gait parameters representing mobility in the ankle joint, two representing the  
16 303 ROM in the subtalar joint, as well as ankle maximum power generation during the  
17 304 push-off phase (Table 1), the AOFAS-AHS showed slightly more and higher  
18 305 correlation coefficients with the gait parameters than the FFI-D total score. Regarding  
19 306 the FFI-D, only six moderate correlations could be found between the overall score  
20 307 and gait parameters representing mobility in the ankle (one parameter) and subtalar  
21 308 joints (five parameters, Table 1).

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24 310 In addition, we focused on the individual items of the AOFAS-AHS that represent gait  
25 311 function and passive ROM (AOFAS-AHS items five to seven). The AOFAS-AHS  
26 312 items representing passive ROM in the ankle joint complex and the corresponding  
27 313 gait parameters representing the total ROM during the gait cycle in the ankle joint  
28 314 and the subtalar joints, respectively, as well as spatio-temporal gait parameters,  
29 315 showed encouraging association (Figures 1 and 2; all presented trends were found  
30 316 locally significant), as also demonstrated in terms of the Jonckheere-Terpstra test  
31 317 with a significance at the 5% level between the three groups (= three different items  
32 318 for the answer) indicating monotonic association. As a result of extensive exploratory  
33 319 analysis those gait parameters were taken into account, which best represented  
34 320 mobility (Figure 1) and gait function (Figure 2) in the respective joints.

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### 37 38 322 ***Factor analysis***

39 323 Factoranalysis based on the binarized individual AOFAS-AHS and FFI-D items  
40 324 proposed three factors arising out of the joint information pattern, but could not reveal

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3 325 any FFI-D items to represent either mobility in the ankle and subtalar joints or gait  
4 326 function (Table 2). Furthermore, although the FFI-D is divided into the two subscales  
5 327 “pain” and “disability” [7, 10] by its authors, this subdivision could not be reproduced  
6 328 in the factor analysis patterns. Only three items of the FFI-D pain subscale showed  
7 329 an involvement in factor 2 (representing “pain and disability”). In addition, only one  
8 330 item from the pain subscale and one item from the disability subscale were involved  
9 331 with factor 3 (representing “mobility and gait function”), while all remaining questions  
10 332 from the subscales were aggregated into factor 1. The authors could not construct a  
11 333 generic term for this predominant factor 1, as it encompasses a wide variety of items,  
12 334 which could hardly be assigned to one common category (Table 2). In contrast, the  
13 335 AOFAS-AHS items showed either a high involvement with factor 2 (representing  
14 336 “pain and disability”) or with factor 3 (representing “mobility and gait function”).  
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## 338 **Discussion**

339 Since both scores are still used throughout the world to evaluate treatment outcomes  
340 of foot and ankle disorders and a validated German translation of the AOFAS-AHS  
341 did not yet exist, we carried out a validation study for the German language version of  
342 the AOFAS-AHS [12]. The present study was the final step in this procedure. The  
343 main goal was to determine the association between objective foot function using the  
344 OFM and perceived disability in patients with mild to severe ankle and hindfoot  
345 pathologies.

346 Our expectation that – due to its better evaluation methodology and the two  
347 respective subscales – the FFI-D, in comparison with the AOFAS-AHS, is better  
348 suited to assess the functionality of the foot could not be supported. The comparison  
349 of the Spearman correlations between the overall results of both scores and  
350 functionality during gait indicates a slightly better suitability of the AOFAS-AHS. In  
351 particular, the analysis of the respective functional pattern under consideration of the  
352 individual items from the AOFAS-AHS was able to show good agreement with  
353 objective parameters from gait analysis. Additionally, the moderate positive  
354 correlation between the AOFAS-AHS and ankle power generation during push-off  
355 indicates that the AOFAS-AHS is well suited to evaluate limitations in foot function  
356 during gait.

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3 357 Although the FFI-D is divided into two subscales, this could not be confirmed by  
4 358 factor analysis. The opposite was found for the AOFAS-AHS, which represents pain  
5 359 and ability issues on the one hand and questions dealing with hindfoot and ankle  
6 360 function on the other hand. This was shown in the factor analysis for the transformed  
7 361 individual questions, even if this was not postulated by its developers themselves [1].

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11 362 The mathematical weaknesses of the AOFAS-AHS - especially the over-  
12 363 representation of the pain question and the limited number of feature expressions,  
13 364 leading to a floor and ceiling-effect - are undeniable [2]. Nevertheless, the items in  
14 365 the AOFAS-AHS give a good representation of ankle and hindfoot disorders, as  
15 366 shown by the Spearman correlations with gait function, ROM in the ankle and  
16 367 subtalar joints, as well as by the Jonckheere-Terpstra test. Reduced ankle power  
17 368 generation during push-off showed a significant correlation with the AOFAS-AHS total  
18 369 score, which suggests that the AOFAS-AHS total score is a sensitive indicator for  
19 370 ankle osteoarthritis. Due to its mathematical weaknesses, the AOFAS-AHS should be  
20 371 applied with care, even if its individual questions show a good representation of pain,  
21 372 disability and function. These items can be used, but should be combined with better  
22 373 methods for scoring and interpreting the results.

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31 374 In contrast, the FFI-D did not show the same clear correlations for these three  
32 375 functional items. The FFI-D did not show any clear items representing gait function or  
33 376 ROM in the ankle and subtalar joints in factor analysis. Therefore, it did not make any  
34 377 sense to compare the results of individual questions to corresponding gait  
35 378 parameters. As a consequence, the application of the FFI-D as a score to evaluate  
36 379 disability and functional limitations of patients suffering from foot and ankle  
37 380 pathologies should be critically discussed.

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43 381 The best consequence would be to develop a new score with items derived from  
44 382 objective measurements such as gait analysis including mature biometrical means for  
45 383 scoring and evaluating results.

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51 385 **Limitations:**

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53 386 Limitations of this study are the inhomogeneity of the group and the limited number of  
54 387 patients. Nevertheless, we deliberately choose a heterogeneous group of patients to  
55 388 reflect the wide range of patients who were evaluated using the AOFAS-AHS. For

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3 389 focusing on a certain group of foot disorders, a more homogenous group should be  
4 390 examined. In order to develop a new score dealing with different kinds of foot  
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6 391 disorders using gait analysis, a bigger group should be taken into account.  
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### 10 11 393 **Conclusion:**

12 394 Our findings show that the use of gait analysis in combination with theoretical  
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14 395 mathematical considerations for the evaluation of scores will make a valuable  
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16 396 contribution to the development and evaluation of survey instruments and patient-  
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18 397 reported outcome questionnaires in clinical research. The AOFAS-AHS showed a  
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20 398 good agreement with objective gait parameters and is therefore better suited to  
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22 399 evaluate disability and functional limitations of patients suffering from foot and ankle  
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24 400 pathologies compared to the FFI-D.  
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### 28 29 403 **Acknowledgement:**

30 404 The gait analysis study was the subject of the doctoral thesis of co-author Kirsten  
31  
32 405 Hartmann.  
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494 **Tables:**

Parameter	AOFAS-AHS total score r (95% CI)	FFI-D total score r (95% CI)
Hindfoot vs. tibia maximum dorsiflexion during stance [°]	0.51 <b>(-0.15; 0.83)</b>	0.16 (-0.40; 0.66)
Hindfoot vs. tibia ROM (plantarflexion/dorsiflexion) during gait cycle [°]	<b>0.53</b> (0.18; 0.75)	0.47 (0.00; 0.78)
Hindfoot vs. tibia ROM (inversion/eversion) during gait cycle [°]	<b>0.55</b> <b>(0.24; 0.78)</b>	<b>0.55</b> <b>(0.02; 0.85)</b>
Hindfoot vs. tibia ROM (internal/external rotation) during gait cycle [°]	0.41 (-0.06; 0.78)	<b>0.51</b> <b>(0.03; 0.83)</b>
Forefoot vs. hindfoot maximum dorsiflexion during stance [°]	-0.57 (-0.83; 0.07)	-0.36 (-0.72; 0.3)
Forefoot vs. hindfoot maximum plantarflexion during push-off-phase [°]	<b>-0.64</b> <b>(-0.87; -0.25)</b>	-0.26 (-0.76; 0.26)
Forefoot vs. hindfoot ROM (adduction/abduction) during gait cycle [°]	<b>0.63</b> <b>(0.28; 0.86)</b>	<b>0.57</b> <b>(0.12; 0.84)</b>
Forefoot vs. hindfoot ROM (supination/pronation) during gait cycle [°]	0.45 (0.14; 0.72)	<b>0.52</b> <b>(0.10; 0.80)</b>
Forefoot vs. tibia ROM (adduction/abduction) during gait cycle [°]	0.45 (0.05; 0.77)	<b>0.57</b> <b>(0.21; 0.79)</b>
Forefoot vs. tibia maximum plantarflexion during push-off-phase [°]	<b>-0.61</b> <b>(-0.88; -0.29)</b>	<b>-0.55</b> <b>(-0.84; -0.09)</b>
Forefoot vs. tibia ROM (plantarflexion/dorsiflexion) during gait cycle [°]	<b>0.57</b> <b>(0.13; 0.87)</b>	0.38 (-0.10; 0.78)
Ankle maximum power generation during push-off-phase [W/kg]	<b>0.55</b> <b>(0.18; 0.84)</b>	0.34 (-0.11; 0.72)

495 **ROM = range of motion; CI = confidence interval**

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497 **Table 1:** Spearman correlation coefficients with 95% confidence intervals between the  
 498 AOFAS-AHS total score as well as the FFI-D total score, respectively and selected gait  
 499 parameters representing mobility in the ankle (six parameters) and the subtalar joint (five  
 500 parameters) as well as the ankle-osteoarthritis indicator-parameter ankle maximum power  
 501 generation during stance [W/kg], respectively. Significant correlations (>0.5 / <-0.5) are  
 502 printed in bold.

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(binarized) score items	factor and factor weight		
	1	2 "pain and disability"	3 "mobility and gait function"
AOFAS-AHS "pain"		.810	
AOFAS-AHS "activity restriction"		.807	
AOFAS-AHS "walking distance"			.597
AOFAS-AHS "walking surfaces"		.780	
AOFAS-AHS "gait abnormality"			.747
AOFAS-AHS "sagittal motion"			.747
AOFAS-AHS "hindfoot motion"			.780
AOFAS-AHS "ankle-hindfoot stability"			.480
AOFAS-AHS „alignment“			.508
FFI-D PAIN „worst pain“		.792	
FFI-D PAIN „pain in the morning“	.446		
FFI-D PAIN „pain while walking barefoot“	.741		
FFI-D PAIN „pain while standing barefoot“			.620
FFI-D PAIN „pain while walking with shoes“	.741		
FFI-D PAIN „pain while standing with shoes“	.704		
FFI-D PAIN „pain at the end of the day“		.824	
FFI-D PAIN „pain during the night“		.477	
FFI-D DISABILITY „problems while walking outside“			.656
FFI-D DISABILITY „problems while walking on uneven ground“	.846		
FFI-D DISABILITY „problems while walking distances $\geq 1$ km“	.846		
FFI-D DISABILITY „problems while walking up the stairs“	.690		
FFI-D DISABILITY „problems while walking down the stairs“	.767		
FFI-D DISABILITY „problems while walking on tiptoes“	.767		
FFI-D DISABILITY „problems while standing up from a chair“	.442		
FFI-D DISABILITY „problems while walking fast or during running“	.846		
FFI-D DISABILITY „problems during leisure activities or sports“	.846		
FFI-D DISABILITY „problems while wearing special shoes (high heels, sandals etc.)“			

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507 **Table 2:** Factor analysis results for the respective binarized 9 items of the AOFAS-AHS and  
508 the binarized 18 items of the FFI-D: rotated factor weights for the 9 + 18 items after  
509 identification of three joint factors by means of the variance maximization criterion. Factor  
510 weights < 0.500 have been omitted to emphasize the rotation-based aggregation of the 9 +

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511 18 items into three factors, a posteriori declared representing “pain and disability” (factor 2)  
512 and “mobility and gait function” (factor 3), respectively.

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3 514 **Legend figures 1+2:**

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5 515 **Figure 1:**

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7 516 Nonparametric box plots for an association analysis between AOFAS-AHS items 5 – 7 and  
8 517 respective content-corresponding gait parameters. Box plot horizontals indicate medians and  
9 518 quartiles, verticals indicate minimum and maximum observations, circles indicate statistical  
10 519 outliers with a deviation of at least 1.5 x interquartile range from the respective median.

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13 520 AOFAS-AHS item 5 (gait abnormality) represents a normal gait or slight gait abnormality with  
14 521 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points  
15 522 and a considerable gait abnormality with 0 points.

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18 523 AOFAS-AHS item 6 (sagittal motion, flexion plus extension) represents a normal or mild  
19 524 restriction (30° or more) with 8 points, a moderate restriction (15°–29°) with 4 points and a  
20 525 severe restriction (less than 15°) with 0 points.

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23 526 AOFAS-AHS item 7 (hindfoot motion, inversion plus eversion) represents a normal or mild  
24 527 restriction (75%–100% normal) with 6 points, a moderate restriction (25%–74% normal) with  
25 528 3 points and a severe restriction (less than 25% normal) with 0 points

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32 530 (a) box plots for the maximum ankle power generation during push-off stratified for  
33 531 AOFAS-AHS points achieved by 20 patients

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35 532 (b) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion  
36 533 of the forefoot vs. the tibia angle stratified for AOFAS-AHS points achieved by 20  
37 534 patients

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40 535 (c) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion  
41 536 of the forefoot vs. the hindfoot angle stratified for AOFAS-AHS points achieved by 20  
42 537 patients

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45 538 (d) box plots for the total range of motion during gait cycle in internal to external rotation  
46 539 of the hindfoot vs. the tibia angle stratified for AOFAS-AHS points achieved by 20  
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50 541 (e) box plots for the total range of motion during gait cycle in adduction to abduction of  
51 542 the forefoot vs. the tibia angle stratified for AOFAS-AHS points achieved by 20  
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546 **Figure 2:** Nonparametric box plots for an association analysis between AOFAS-AHS item 5  
547 and corresponding spatio-temporal gait parameters with regard to content. Box plot  
548 horizontals indicate medians and quartiles, verticals indicate minimum and maximum  
549 observations, circles indicate statistical outliers with a deviation of at least 1.5 x interquartile  
550 range from the respective median.

551 AOFAS-AHS item 5 (gait abnormality) represents normal gait or a slight gait abnormality with  
552 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points  
553 and a considerable gait abnormality with 0 points.

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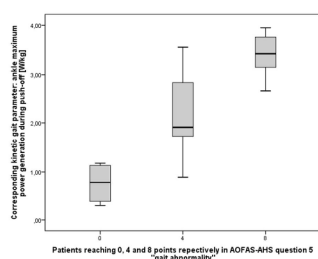
555 (a) box plots for walking speed stratified for AOFAS-AHS points achieved by 20 patients

556 (b) box plots for step length stratified for AOFAS-AHS points achieved by 20 patients

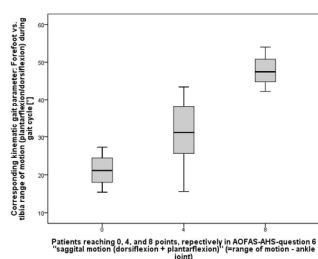
557 (c) box plots for step time stratified for AOFAS-AHS points achieved by 20 patients

558 (d) box plots for step width stratified for AOFAS-AHS points achieved by 20 patients

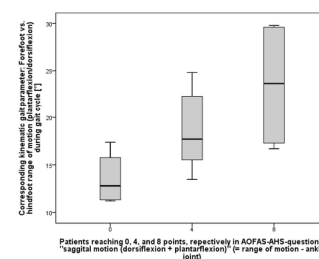
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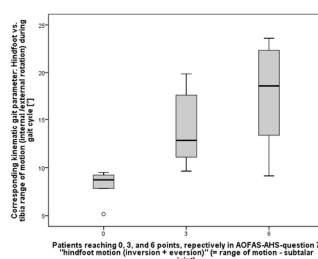
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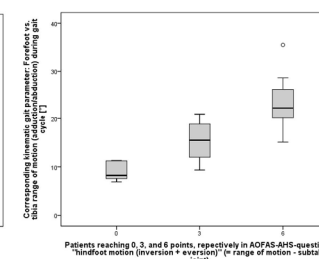
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(e)

Nonparametric box plots for an association analysis between AOFAS-AHS items 5 – 7 and respective content-corresponding gait parameters. Box plot horizontals indicate medians and quartiles, verticals indicate minimum and maximum observations, circles indicate statistical outliers with a deviation of at least 1.5 x interquartile range from the respective median.

AOFAS-AHS item 5 (gait abnormality) represents a normal gait or slight gait abnormality with 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points and a considerable gait abnormality with 0 points.

AOFAS-AHS item 6 (sagittal motion, flexion plus extension) represents a normal or mild restriction (30° or more) with 8 points, a moderate restriction (15°–29°) with 4 points and a severe restriction (less than 15°) with 0 points.

AOFAS-AHS item 7 (hindfoot motion, inversion plus eversion) represents a normal or mild restriction (75%–100% normal) with 6 points, a moderate restriction (25%–74% normal) with 3 points and a severe restriction (less than 25% normal) with 0 points

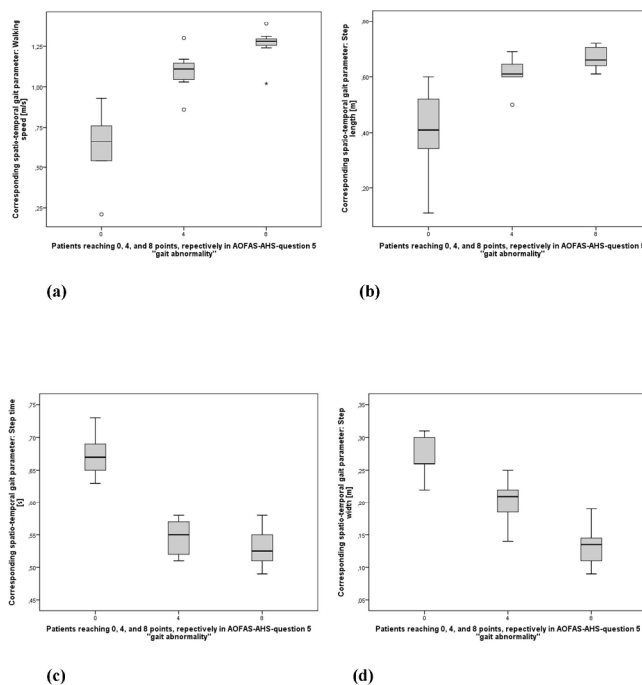


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4 (a) box plots for the maximum ankle power generation during push-off stratified for AOFAS-AHS points  
5 achieved by 20 patients  
6 (b) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion of the forefoot  
7 vs. the tibia angle stratified for AOFAS-AHS points achieved by 20 patients  
8 (c) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion of the forefoot  
9 vs. the hindfoot angle stratified for AOFAS-AHS points achieved by 20 patients  
10 (d) box plots for the total range of motion during gait cycle in internal to external rotation of the hindfoot vs.  
11 the tibia angle stratified for AOFAS-AHS points achieved by 20 patients  
12 (e) box plots for the total range of motion during gait cycle in adduction to abduction of the forefoot vs. the  
13 tibia angle stratified for AOFAS-AHS points achieved by 20 patients

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Nonparametric box plots for an association analysis between AOFAS-AHS item 5 and corresponding spatio-temporal gait parameters with regard to content. Box plot horizontals indicate medians and quartiles, verticals indicate minimum and maximum observations, circles indicate statistical outliers with a deviation of at least 1.5 x interquartile range from the respective median.

AOFAS-AHS item 5 (gait abnormality) represents normal gait or a slight gait abnormality with 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points and a considerable gait abnormality with 0 points.

- (a) box plots for walking speed stratified for AOFAS-AHS points achieved by 20 patients
- (b) box plots for step length stratified for AOFAS-AHS points achieved by 20 patients
- (c) box plots for step time stratified for AOFAS-AHS points achieved by 20 patients
- (d) box plots for step width stratified for AOFAS-AHS points achieved by 20 patients

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**STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies***

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	4,6-8
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	4/5
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5/6
Objectives	3	State specific objectives, including any prespecified hypotheses	6, 11
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	6-9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6/7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6/7
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6/7
Bias	9	Describe any efforts to address potential sources of bias	8 + 12/13
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8-10
		(b) Describe any methods used to examine subgroups and interactions	---
		(c) Explain how missing data were addressed	---
		(d) If applicable, explain how loss to follow-up was addressed	---
		(e) Describe any sensitivity analyses	---
<b>Results</b>			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6/7
		(b) Give reasons for non-participation at each stage	---
		(c) Consider use of a flow diagram	---
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6/7
		(b) Indicate number of participants with missing data for each variable of interest	---
		(c) Summarise follow-up time (eg, average and total amount)	---
Outcome data	15*	Report numbers of outcome events or summary measures over time	10
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10/11
		(b) Report category boundaries when continuous variables were categorized	9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	---
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	---
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	11
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12/13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	3

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## Using the Oxford Foot Model to determine the association between objective measures of foot function and results of the AOFAS Ankle-Hindfoot Scale and the Foot Function Index - a prospective gait analysis study in Germany

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Keywords:	Gait analysis, foot and ankle surgery, questionnaires, scores, patient reported outcome measures

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3 **1 Using the Oxford Foot Model to determine the association between objective measures of foot**  
4 **2 function and results of the AOFAS Ankle-Hindfoot Scale and the Foot Function Index - a**  
5 **3 prospective gait analysis study in Germany**

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71 **The authors declare the following potential conflicts of interests:**



1  
2  
3 72 All authors declare no financial and personal relationships with other people or  
4 73 organizations that could inappropriately influence their work or the outcome of this  
5 74 publication.  
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10 76 **The authors declare the following contribution of authorship:**

11  
12  
13 77 TK: Substantial contributions to the conception or design of the work, drafting the article,  
14 78 final approval of the version published.

15 79 FS: acquisition, analysis or interpretation of data gait lab, revising it critically for  
16 80 important intellectual content. Final approval of the version published.

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18  
19 81 KH: acquisition, analysis or interpretation of data from gait lab, revising it critically for  
20 82 important intellectual content. Final approval of the version published.

21 83 FK: acquisition, analysis or interpretation of data from gait lab, revising it critically for  
22 84 important intellectual content.

23  
24  
25 85 AM: providing the gait lab for carrying out the study (owner of gait lab), has made  
26 86 substantial contributions to data interpretation.

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29 87 MA: acquisition, analysis or interpretation of data from gait lab, revising it critically  
30 88 for important intellectual content.

31  
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33 89 MHB: acquisition, analysis or interpretation of data from gait lab, revising it critically  
34 90 for important intellectual content KS: acquisition, analysis or interpretation of data  
35 91 with respect to statistics (Jonckheere-Terpstra test, exploratory factor analysis),  
36 92 revising it critically for important intellectual content.

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39 93 SL: Substantial contributions to the conception or design of the work, revising it  
40 94 critically for important intellectual content.

41  
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44  
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46 97 In order to conduct this study, the ethics committee required participants to be  
47 98 insured for the procedure due to the fact that the gait lab examination was done for  
48 99 this study only. This insurance was funded through a research grant from the  
50 100 German Foot and Ankle Society.

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54 102 **Data sharing:**

55 103 No additionally data is available.  
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**ABSTRACT****Objective:**

After cross-cultural adaption for the German translation of the Ankle-Hindfoot Scale of the American Orthopaedic Foot and Ankle Society (AOFAS-AHS) and agreement analysis with the Foot Function Index (FFI-D), the following gait analysis study using the Oxford Foot Model (OFM) was carried out to show which of the two scores better correlates with objective gait dysfunction.

**Design and participants:**

Results of the AOFAS-AHS and FFI-D, as well as data from three-dimensional gait analysis were collected from 20 patients with mild to severe ankle and hindfoot pathologies.

Kinematic and kinetic gait data was correlated with the results of the total AOFAS scale and FFI-D as well as the results of those items representing hindfoot function in the AOFAS-AHS assessment. With respect to the foot disorders in our patients (osteoarthritis and prearthritic conditions) we correlated the total range of motion in the ankle and subtalar joints as identified by the OFM with values identified during clinical examination “translated” into score values. Furthermore, reduced walking speed, reduced step length and reduced maximum ankle power generation during push-off were taken into account and correlated to gait abnormalities described in the scores. An analysis of correlations with confidence intervals between the FFI-D and the AOFAS-AHS items and the gait parameters was performed by means of the Jonckheere-Terpstra test; furthermore, exploratory factor analysis was applied to identify common information structures and thereby redundancy in the FFI-D and the AOFAS-AHS items.

**Results:**

Objective findings for hindfoot disorders, namely a reduced range of motion , in the ankle and subtalar joints, respectively, as well as reduced ankle power generation during push-off, showed a better correlation with the AOFAS-AHS total score – as

1  
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3 135 well as AOFAS-AHS items representing ROM in the ankle, subtalar joints and gait  
4 136 function - compared to the FFI-D score.

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6 137 Factor analysis, however, could not identify FFI-D items consistently related to these  
7  
8 138 three indicator parameters (pain, disability and function) found in the AOFAS-AHS.  
9  
10 139 Furthermore, factor analysis did not support stratification of the FFI-D into two  
11 140 subscales.

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## 14 142 **Conclusions:**

15  
16 143 The AOFAS-AHS showed a good agreement with objective gait parameters and is  
17  
18 144 therefore better suited to evaluate disability and functional limitations of patients  
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20 145 suffering from foot and ankle pathologies compared to the FFI-D.

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## 23 147 **Article summary**

### 24 148 **Strengths and limitations of the study:**

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  - Strengths of this study are the objective gait parameters,
  - as well as the extensive statistical procedures.
  - Limitations of this study are the inhomogeneity of the group and the limited

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33 152 number of patients. When focusing on a certain group of foot disorders, a  
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35 153 more homogenous group should be examined. In order to develop a new  
36  
37 154 score dealing with different kinds of foot disorders using gait analysis, a larger  
38 155 group should be taken into account.

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### 41 157 **Keywords:**

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44 158 Gait analysis, foot and ankle surgery, questionnaires, scores, patient reported  
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46 159 outcome measures

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48 160

## 49 161 **Main text:**

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51 162

## 52 163 **Introduction**

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3 164 A variety of questionnaires are available for assessing pain, disability and functional  
4 165 limitations of patients suffering from foot and ankle pathologies. The Ankle and  
5 166 Hindfoot Scale of the American Orthopaedic Foot and Ankle Society (AOFAS-AHS) is  
6 167 one of them and is commonly used to estimate and describe the outcome of  
7 168 conservative or surgical treatment of ankle or hindfoot pathologies [1]. This score is  
8 169 widely used despite the legitimate criticism of its theoretical mathematical  
9 170 weaknesses, such as over-representation of the pain question and the limited  
10 171 number of feature expressions, leading to a floor and ceiling-effect [2, 3]. In contrast,  
11 172 several publications have shown a high level of responsiveness and acceptable  
12 173 criterion validity for the AOFAS-AHS [4], as well as a satisfactory degree of reliability  
13 174 for the subjective component of the AOFAS scale [5], which justifies its application. In  
14 175 addition, the Foot Function Index (FFI) is also commonly used in the clinical setting  
15 176 [6, 7, 8, 9].

16 177 Cross-cultural adaption of the AOFAS-AHS in its German translation and agreement  
17 178 analysis with the FFI-D by Naal et al. [10] were previously performed and published  
18 179 [11, 12]. The agreement analysis showed that the scores are not interchangeable,  
19 180 but rather complementary [12]. However, these self-reported questionnaires assess  
20 181 patient perception and are not necessarily indicative of actual disabilities. Therefore,  
21 182 it is important that research considers other methods of assessing functionality. Gait  
22 183 analysis has widely been accepted as an objective measure of physical function [13],  
23 184 allowing researchers and clinicians to better understand the biomechanics of gait. In  
24 185 particular, the Oxford Foot Model (OFM) [14] is a multi-segment kinematic model that  
25 186 can be used to quantify the functionality of the foot complex during gait in patients  
26 187 with different pathologies [15-17]. In patients with osteoarthritis and pre-osteoarthritic  
27 188 disorders in the ankle and subtalar joints, reduced walking speed, reduced step  
28 189 length, reduced range of motion (ROM) within different sections of the foot and ankle  
29 190 joint and reduced ankle power generation during push-off have been shown [18-21].

30 191 Since agreement analysis [12] did not determine which of the two scores is better  
31 192 suited to reflect function in patients with ankle and hindfoot disorders, the aim of the  
32 193 present study was to determine the association between physical foot dysfunction  
33 194 using the OFM and perceived disability in patients with mild to severe ankle and  
34 195 hindfoot pathologies. Higher correlation was expected for the FFI-D with respect to its  
35 196 rather elaborate scoring system as compared to the AOFAS-AHS scale system. In

197 addition, exploratory factor analysis was applied to identify common information  
198 structures and redundancy contained in the FFI-D and the AOFAS-AHS items.

199

## 200 **Methods and materials**

### 201 ***Subjects***

202 AOFAS-AHS and FFI-D results were consecutively collected from 20 patients with  
203 mild to severe ankle and hindfoot pathologies (10 female and 10 male patients) and a  
204 median age of 45 (interquartile range 35-54) years. Body mass index (BMI) was 27.8  
205 (24.7-31.6) kg/cm<sup>2</sup> in median. We deliberately chose a heterogeneous group of  
206 patients to reflect the wide range of patients who were evaluated using the AOFAS-  
207 AHS. The 20 patients suffered from pathologies such as primary or post-traumatic  
208 osteoarthritis (10 / 20), osteochondral lesions / subchondral cysts (5 / 20),  
209 chondromatosis / corpora libra (2 / 20) or osteoarthritis due to hemophilia (3 / 20).  
210 Exclusion criteria included neuromuscular dysfunction (e.g., Parkinson's disease,  
211 stroke, epilepsy and Alzheimer's disease), a leg length discrepancy of more than 1  
212 cm and chronic joint infection. All selected patients were recruited during a polyclinic  
213 consultation by an experienced foot and ankle surgeon and demonstrated pain,  
214 stiffness or reduced ROM in different sections of the foot and ankle joint. They all  
215 showed clearly osteoarthritis or preartritic conditions in X-rays as well as magnetic  
216 resonance imaging scans. All patients underwent three-dimensional gait analysis on  
217 the same day the two questionnaires AOFAS-AHS and FFI-D were applied.

218

### 219 ***Ethical approval***

220 The approval of the local independent Ethics Committee (Ruhr University Bochum  
221 ICE; vote reference no. 4126-11) was obtained in 2011.

222 The study was carried out in accordance with the Helsinki Declaration. Accordingly,  
223 written informed consent was obtained from all patients prior to participation in the  
224 study.

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### 226 ***Questionnaires***

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3 227 The FFI-D questionnaire is based on a ten-point scale for each item and enables  
4 228 overall continuous scoring by means of an equally weighted normalizing evaluation  
5 229 system and providing two subscales including eight items for pain and ten items for  
6 230 disability, respectively. The AOFAS-AHS includes nine items (five to be answered by  
7 231 patients and four to be answered by the physician) with two to four possible  
8 232 responses and an asymmetric assignment of score points. The AOFAS-AHS over  
9 233 represents the pain item with 40 of the maximum 100 score points assigned to this  
10 234 item alone.  
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### 18 236 ***Gait analysis methods***

20 237 Three-dimensional gait analysis was performed using a 200 Hz, eight-camera motion  
21 238 capture system (VICON™ Motion Systems, Oxford, UK) in combination with a 1000  
22 239 Hz AMTI™ force plate (Advanced Mechanical Technology, Inc., Watertown, MA,  
23 240 USA) to detect gait cycle events and to calculate ankle power generation during the  
24 241 push off phase. Reflective markers were placed over prominent anatomical  
25 242 landmarks along the lower extremity, as well as the ankle and foot complex according  
26 243 to the multi-segment OFM [14, 22, 23]. The OFM allows for a differentiated analysis  
27 244 of movement within different sections of the foot and ankle joint. Repeatability of the  
28 245 OFM has been demonstrated for healthy children and adults [18, 24, 25] and has  
29 246 also been applied in patients with foot pathologies/disorders [16, 22, 23, 26]).

31 247 Kinematic and data that represent mobility in the ankle and subtalar joints (for  
32 248 example the ROM plantarflexion to dorsiflexion for the hindfoot versus tibia as well as  
33 249 inversion to eversion or forefoot versus hindfoot adduction to abduction) and that are  
34 250 relevant for osteoarthritis patients were collected from barefoot participants during  
35 251 level walking at a self-selected speed. In cases with bilateral pathology, the more  
36 252 severely affected side was analyzed. After each acquisition session, 3D marker  
37 253 trajectories were reconstructed and missing frames were handled with a fill-gap  
38 254 procedure. The data was smoothed with a Woltring filter and using spline smoothing  
39 255 [27]. Average values from three trials were selected based on good quality of marker  
40 256 trajectories and ground reaction forces.  
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### 56 258 ***Statistical analysis***

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3 259 A sample size calculation was performed based on the fact that an AOFAS-Score of  
4 260 80-100 points is expected for healthy people, while in patients with relevant foot and  
5 261 ankle disorders a score of 30-35 points is expected,. The power was assumed to be  
6 262 80%. A group of 20 patients was calculated as suitable.

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9 263 In a first step, basic spatio-temporal gait parameters (i.e., walking speed, cadence,  
10 264 step length, stride length, step width) as well as discrete kinematic and kinetic gait  
11 265 data were correlated with the total scores for the AOFAS-AHS (range 0 – 100 points)  
12 266 and the FFI-D. The FFI-D scale was transformed to the range 0 - 100 points with 100  
13 267 points indicating optimum rating in all items to make the scores directly comparable  
14 268 to those derived from the AOFAS-AHS. Both overall scores were handled as  
15 269 continuous endpoints, i.e. methods for continuous data evaluation were applied. This  
16 270 means that score descriptions were based on medians and quartiles (graphic  
17 271 description on nonparametric box whisker plots, accordingly) with regard to the  
18 272 moderate sample size. Bivariate correlations between gait parameters and the total  
19 273 FFI-D and AOFAS-AHS scores were estimated by means of the Spearman  
20 274 coefficient and its asymptotic 95% confidence interval. For the sake of aggregation  
21 275 and interpretation of the various bivariate correlation profiles a previously established  
22 276 categorization of correlation ranges based on the Spearman point estimates was  
23 277 adopted [28, 29]: correlations were classified “low” for Spearman coefficients less  
24 278 than 0.30, as “medium” for coefficients between 0.30 and 0.65 and otherwise as high.  
25 279 For further correlation analyses AOFAS-AHS items were taken into account that  
26 280 represent the function of the subtalar and ankle joints, and were related to the  
27 281 corresponding gait analysis parameters representing the function of the respective  
28 282 joints. The respective bivariate associations were described by means of gait  
29 283 parameter distribution (medians and quartiles) stratified for the respective AOFAS  
30 284 item scale levels. Furthermore, Jonckheere-Terpstra test were applied to test for  
31 285 trends in the gait parameters levels alongside the respective AOFAS item scale  
32 286 levels. The results of these trend tests were summarized by means of p-values. In  
33 287 accordance with the exploratory character of this evaluation, the latter were not  
34 288 formally adjusted for multiplicity, but rather considered as indicators of local statistical  
35 289 significance in the case of p-values  $\leq 0.05$ .

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38 290 To determine those FFI-D items representing the ROM in the ankle and the subtalar  
39 291 joints as well as gait function – note, that these can be derived from the AOFAS  
40 292 items, but not from the FFI-D assessment – exploratory factor analysis for the total

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3 293 set of the 9 AOFAS-AHS and the 18 FFI-D items was performed. In the case of  
4 294 several FFI-D items being aggregated with the AOFAS item(s) of interest, these FFI-  
5 295 D items could be considered as ROM related. Since the AOFAS-AHS individual items  
6 296 are more or less categorical, whereas the FFI-D parameters should be treated as  
7 297 continuous, both score systems' items were binarized for simultaneous use in factor  
8 298 analysis by means of the following criteria: the AOFAS-AHS item dealing with pain  
9 299 was defined to indicate a "negative response" for a score of 20 points or less.  
10 300 Accordingly, a score representing pathological findings (0-4 points) in one of the  
11 301 remaining AOFAS-AHS items was defined as a "negative response". For the FFI-D,  
12 302 results of five or more points were regarded as a "negative response" (note the  
13 303 scaling direction of the FFI-D items). The total set of 9 binarized AOFAS-AHS items  
14 304 and of 18 binarized FFI-D items was then analyzed by means of exploratory factor  
15 305 analysis, where factors were identified by means of principle component analysis and  
16 306 application of the varimax criterion (75% variance to be explained by identified  
17 307 factors).

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19 308 Statistical and graphic analyses were performed using SPSS® for Windows 21.0™  
20 309 (IBM Corporation, New York, USA)].  
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## 32 33 311 **Results**

### 34 35 312 ***Gait analysis***

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37 313 Only moderate correlation coefficients ( $r= 0.51-0.64$ ) could be found between the  
38 314 total AOFAS-AHS / total FFI-D score and objective gait parameters as shown in  
39 315 Table 1. With moderate correlation coefficients between the AOFAS-AHS total score  
40 316 and six gait parameters representing mobility in the ankle joint, two representing the  
41 317 ROM in the subtalar joint, as well as ankle maximum power generation during the  
42 318 push-off phase (Table 1), the AOFAS-AHS showed slightly more and higher  
43 319 correlation coefficients with the gait parameters than the FFI-D total score. Regarding  
44 320 the FFI-D, only six moderate correlations could be found between the overall score  
45 321 and gait parameters representing mobility in the ankle (one parameter) and subtalar  
46 322 joints (five parameters, Table 1).  
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3 324 In addition, we focused on the individual items of the AOFAS-AHS that represent gait  
4 325 function and passive ROM (AOFAS-AHS items five to seven). The AOFAS-AHS  
5 326 items representing passive ROM in the ankle joint complex and the corresponding  
6 327 gait parameters representing the total ROM during the gait cycle in the ankle joint  
7 328 and the subtalar joints, respectively, as well as spatio-temporal gait parameters,  
8 329 showed encouraging association (Figures 1 and 2; all presented trends were found  
9 330 locally significant), as also demonstrated in terms of the Jonckheere-Terpstra test  
10 331 with a significance at the 5% level between the three groups (= three different items  
11 332 for the answer) indicating monotonic association. As a result of extensive exploratory  
12 333 analysis those gait parameters were taken into account, which best represented  
13 334 mobility (Figure 1) and gait function (Figure 2) in the respective joints.  
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### 336 **Factor analysis**

337 Factor analysis based on the binarized individual AOFAS-AHS and FFI-D items  
338 proposed three factors arising out of the joint information pattern, but could not reveal  
339 any FFI-D items to represent either mobility in the ankle and subtalar joints or gait  
340 function (Table 2). Furthermore, although the FFI-D is divided into the two subscales  
341 “pain” and “disability” [7, 10] by its authors, this subdivision could not be reproduced  
342 in the factor analysis patterns. Only three items of the FFI-D pain subscale showed  
343 an involvement in factor 2 (representing “pain and disability”). In addition, only one  
344 item from the pain subscale and one item from the disability subscale were involved  
345 with factor 3 (representing “mobility and gait function”), while all remaining questions  
346 from the subscales were aggregated into factor 1. The authors could not construct a  
347 generic term for this predominant factor 1, as it encompasses a wide variety of items,  
348 which could hardly be assigned to one common category (Table 2). In contrast, the  
349 AOFAS-AHS items showed either a high involvement with factor 2 (representing  
350 “pain and disability”) or with factor 3 (representing “mobility and gait function”).  
351

351

### 352 **Discussion**

353 Since both scores are still used throughout the world to evaluate treatment outcomes  
354 of foot and ankle disorders and a validated German translation of the AOFAS-AHS  
355 did not yet exist, we carried out a validation study for the German language version of

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3 356 the AOFAS-AHS [12]. The present study was the final step in this procedure. The  
4 357 main goal was to determine the association between objective foot function using the  
5 358 OFM and perceived disability in patients with mild to severe ankle and hindfoot  
6 359 pathologies.

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9 360 Our expectation that – due to its better evaluation methodology and the two  
10 361 respective subscales – the FFI-D, in comparison with the AOFAS-AHS, is better  
11 362 suited to assess the functionality of the foot could not be supported. The comparison  
12 363 of the Spearman correlations between the overall results of both scores and  
13 364 functionality during gait indicates a slightly better suitability of the AOFAS-AHS. In  
14 365 particular, the analysis of the respective functional pattern under consideration of the  
15 366 individual items from the AOFAS-AHS was able to show good agreement with  
16 367 objective parameters from gait analysis. Additionally, the moderate positive  
17 368 correlation between the AOFAS-AHS and ankle power generation during push-off  
18 369 indicates that the AOFAS-AHS is well suited to evaluate limitations in foot function  
19 370 during gait.

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21 371 Although the FFI-D is divided into two subscales, this could not be confirmed by  
22 372 factor analysis. The opposite was found for the AOFAS-AHS, which represents pain  
23 373 and ability issues on the one hand and questions dealing with hindfoot and ankle  
24 374 function on the other hand. This was shown in the factor analysis for the transformed  
25 375 individual questions, even if this was not postulated by its developers themselves [1].

26  
27 376 The mathematical weaknesses of the AOFAS-AHS - especially the over-  
28 377 representation of the pain question and the limited number of feature expressions,  
29 378 leading to a floor and ceiling-effect - are undeniable [2]. Nevertheless, the items in  
30 379 the AOFAS-AHS give a good representation of ankle and hindfoot disorders, as  
31 380 shown by the Spearman correlations with gait function, ROM in the ankle and  
32 381 subtalar joints, as well as by the Jonckheere-Terpstra test. Reduced ankle power  
33 382 generation during push-off is discussed as a possible indicator for ankle arthritis [17,  
34 383 19, 21]. Since reduced ankle power generation during push-off showed a significant  
35 384 correlation with the AOFAS-AHS total score, this suggests that the AOFAS-AHS total  
36 385 score might be an indicator of ankle osteoarthritis.

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38 386 Due to its mathematical weaknesses, the AOFAS-AHS should be applied with care,  
39 387 even if its individual questions show a good representation of pain, disability and  
40 388 function. These items can be used, but should be combined with better methods for

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3 389 scoring and interpreting the results. In contrast, the FFI-D did not show the same  
4 390 clear correlations for these three items (pain, disability and function). In addition, the  
5 391 FFI-D did not demonstrate any clear items representing gait function or ROM in the  
6 392 ankle and subtalar joints in the factor analysis. Therefore, it did not make any sense  
7 393 to compare the results of individual questions to corresponding gait parameters. As a  
8 394 consequence, the application of the FFI-D as a score to evaluate disability and  
9 395 functional limitations of patients suffering from foot and ankle pathologies should be  
10 396 critically discussed.

11 397 Our findings show that the use of gait analysis in combination with theoretical  
12 398 mathematical considerations for the evaluation of scores will make a valuable  
13 399 contribution to the development and evaluation of survey instruments and patient-  
14 400 reported outcome questionnaires in clinical research. The best consequence would  
15 401 be to develop a new score with items derived from objective measurements such as  
16 402 gait analysis including mature biometrical means for scoring and evaluating results.

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#### 18 404 **Limitations:**

19 405 Limitations of this study are the inhomogeneity of the group and the limited number of  
20 406 patients. Nevertheless, we deliberately choose a heterogeneous group of patients to  
21 407 reflect the wide range of patients who were evaluated using the AOFAS-AHS. For  
22 408 focusing on a certain group of foot disorders, a more homogenous group should be  
23 409 examined. In order to develop a new score dealing with different kinds of foot  
24 410 disorders using gait analysis, a bigger group should be taken into account.

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#### 26 412 **Conclusion:**

27 413 The AOFAS-AHS showed a good agreement with objective gait parameters and is  
28 414 therefore better suited to evaluate disability and functional limitations of patients  
29 415 suffering from foot and ankle pathologies compared to the FFI-D.

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#### 32 418 **Acknowledgement:**

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3 419 The gait analysis study was the subject of the doctoral thesis of co-author Kirsten  
4 420 Hartmann.

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508 **Tables:**

Parameter	AOFAS-AHS total score r (95% CI)	FFI-D total score r (95% CI)
Hindfoot vs. tibia maximum dorsiflexion during stance [°]	0.51 <b>(-0.15; 0.83)</b>	0.16 (-0.40; 0.66)
Hindfoot vs. tibia ROM (plantarflexion/dorsiflexion) during gait cycle [°]	<b>0.53</b> (0.18; 0.75)	0.47 (0.00; 0.78)
Hindfoot vs. tibia ROM (inversion/eversion) during gait cycle [°]	<b>0.55</b> <b>(0.24; 0.78)</b>	<b>0.55</b> <b>(0.02; 0.85)</b>
Hindfoot vs. tibia ROM (internal/external rotation) during gait cycle [°]	0.41 (-0.06; 0.78)	<b>0.51</b> <b>(0.03; 0.83)</b>
Forefoot vs. hindfoot maximum dorsiflexion during stance [°]	-0.57 (-0.83; 0.07)	-0.36 (-0.72; 0.3)
Forefoot vs. hindfoot maximum plantarflexion during push-off-phase [°]	<b>-0.64</b> <b>(-0.87; -0.25)</b>	-0.26 (-0.76; 0.26)
Forefoot vs. hindfoot ROM (adduction/abduction) during gait cycle [°]	<b>0.63</b> <b>(0.28; 0.86)</b>	<b>0.57</b> <b>(0.12; 0.84)</b>
Forefoot vs. hindfoot ROM (supination/pronation) during gait cycle [°]	0.45 (0.14; 0.72)	<b>0.52</b> <b>(0.10; 0.80)</b>
Forefoot vs. tibia ROM (adduction/abduction) during gait cycle [°]	0.45 (0.05; 0.77)	<b>0.57</b> <b>(0.21; 0.79)</b>
Forefoot vs. tibia maximum plantarflexion during push-off-phase [°]	<b>-0.61</b> <b>(-0.88; -0.29)</b>	<b>-0.55</b> <b>(-0.84; -0.09)</b>
Forefoot vs. tibia ROM (plantarflexion/dorsiflexion) during gait cycle [°]	<b>0.57</b> <b>(0.13; 0.87)</b>	0.38 (-0.10; 0.78)
Ankle maximum power generation during push-off-phase [W/kg]	<b>0.55</b> <b>(0.18; 0.84)</b>	0.34 (-0.11; 0.72)

509 **ROM = range of motion; CI = confidence interval**

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511 **Table 1:** Spearman correlation coefficients with 95% confidence intervals between the  
512 AOFAS-AHS total score as well as the FFI-D total score, respectively and selected gait  
513 parameters representing mobility in the ankle (six parameters) and the subtalar joint (five  
514 parameters) as well as the ankle-osteoarthritis indicator-parameter ankle maximum power  
515 generation during stance [W/kg], respectively. Significant correlations (>0.5 / <-0.5) are  
516 printed in bold.

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(binarized) score items	factor and factor weight		
	1	2 "pain and disability"	3 "mobility and gait function"
AOFAS-AHS "pain"		.810	
AOFAS-AHS "activity restriction"		.807	
AOFAS-AHS "walking distance"			.597
AOFAS-AHS "walking surfaces"		.780	
AOFAS-AHS "gait abnormality"			.747
AOFAS-AHS "sagittal motion"			.747
AOFAS-AHS "hindfoot motion"			.780
AOFAS-AHS "ankle-hindfoot stability"			.480
AOFAS-AHS „alignment“			.508
FFI-D PAIN „worst pain“		.792	
FFI-D PAIN „pain in the morning“	.446		
FFI-D PAIN „pain while walking barefoot“	.741		
FFI-D PAIN „pain while standing barefoot“			.620
FFI-D PAIN „pain while walking with shoes“	.741		
FFI-D PAIN „pain while standing with shoes“	.704		
FFI-D PAIN „pain at the end of the day“		.824	
FFI-D PAIN „pain during the night“		.477	
FFI-D DISABILITY „problems while walking outside“			.656
FFI-D DISABILITY „problems while walking on uneven ground“	.846		
FFI-D DISABILITY „problems while walking distances $\geq 1$ km“	.846		
FFI-D DISABILITY „problems while walking up the stairs“	.690		
FFI-D DISABILITY „problems while walking down the stairs“	.767		
FFI-D DISABILITY „problems while walking on tiptoes“	.767		
FFI-D DISABILITY „problems while standing up from a chair“	.442		
FFI-D DISABILITY „problems while walking fast or during running“	.846		
FFI-D DISABILITY „problems during leisure activities or sports“	.846		
FFI-D DISABILITY „problems while wearing special shoes (high heels, sandals etc.)“			

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521 **Table 2:** Factor analysis results for the respective binarized 9 items of the AOFAS-AHS and  
522 the binarized 18 items of the FFI-D: rotated factor weights for the 9 + 18 items after  
523 identification of three joint factors by means of the variance maximization criterion. Factor  
524 weights < 0.500 have been omitted to emphasize the rotation-based aggregation of the 9 +

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525 18 items into three factors, a posteriori declared representing “pain and disability” (factor 2)  
526 and “mobility and gait function” (factor 3), respectively.

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3 528 **Legend figures 1+2:**

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5 529 **Figure 1:**

6  
7 530 Nonparametric box plots for an association analysis between AOFAS-AHS items 5 – 7 and  
8 531 respective content-corresponding gait parameters. Box plot horizontals indicate medians and  
9 532 quartiles, verticals indicate minimum and maximum observations, circles indicate statistical  
10 533 outliers with a deviation of at least 1.5 x interquartile range from the respective median.

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14 534 AOFAS-AHS item 5 (gait abnormality) represents a normal gait or slight gait abnormality with  
15 535 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points  
16 536 and a considerable gait abnormality with 0 points.

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19 537 AOFAS-AHS item 6 (sagittal motion, flexion plus extension) represents a normal or mild  
20 538 restriction (30° or more) with 8 points, a moderate restriction (15°–29°) with 4 points and a  
21 539 severe restriction (less than 15°) with 0 points.

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24 540 AOFAS-AHS item 7 (hindfoot motion, inversion plus eversion) represents a normal or mild  
25 541 restriction (75%–100% normal) with 6 points, a moderate restriction (25%–74% normal) with  
26 542 3 points and a severe restriction (less than 25% normal) with 0 points

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32 544 (a) box plots for the maximum ankle power generation during push-off stratified for  
33 545 AOFAS-AHS points achieved by 20 patients

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35 546 (b) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion  
36 547 of the forefoot vs. the tibia angle stratified for AOFAS-AHS points achieved by 20  
37 548 patients

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41 549 (c) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion  
42 550 of the forefoot vs. the hindfoot angle stratified for AOFAS-AHS points achieved by 20  
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46 552 (d) box plots for the total range of motion during gait cycle in internal to external rotation  
47 553 of the hindfoot vs. the tibia angle stratified for AOFAS-AHS points achieved by 20  
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51 555 (e) box plots for the total range of motion during gait cycle in adduction to abduction of  
52 556 the forefoot vs. the tibia angle stratified for AOFAS-AHS points achieved by 20  
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**Figure 2:** Nonparametric box plots for an association analysis between AOFAS-AHS item 5 and corresponding spatio-temporal gait parameters with regard to content. Box plot horizontals indicate medians and quartiles, verticals indicate minimum and maximum observations, circles indicate statistical outliers with a deviation of at least 1.5 x interquartile range from the respective median.

AOFAS-AHS item 5 (gait abnormality) represents normal gait or a slight gait abnormality with 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points and a considerable gait abnormality with 0 points.

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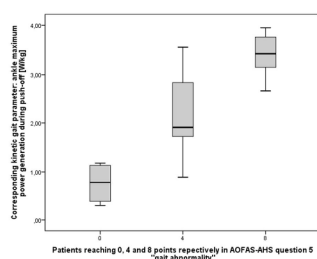
(a) box plots for walking speed stratified for AOFAS-AHS points achieved by 20 patients

(b) box plots for step length stratified for AOFAS-AHS points achieved by 20 patients

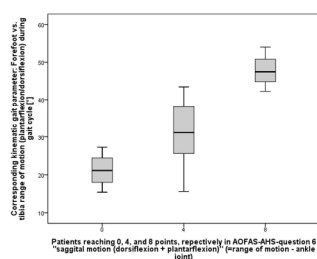
(c) box plots for step time stratified for AOFAS-AHS points achieved by 20 patients

(d) box plots for step width stratified for AOFAS-AHS points achieved by 20 patients

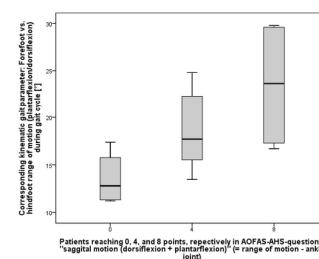
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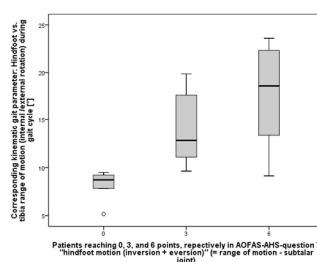
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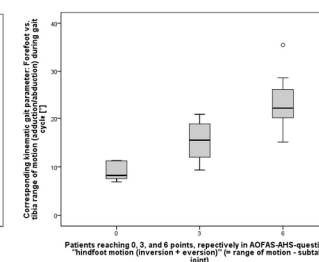
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Nonparametric box plots for an association analysis between AOFAS-AHS items 5 – 7 and respective content-corresponding gait parameters. Box plot horizontals indicate medians and quartiles, verticals indicate minimum and maximum observations, circles indicate statistical outliers with a deviation of at least 1.5 x interquartile range from the respective median.

AOFAS-AHS item 5 (gait abnormality) represents a normal gait or slight gait abnormality with 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points and a considerable gait abnormality with 0 points.

AOFAS-AHS item 6 (sagittal motion, flexion plus extension) represents a normal or mild restriction (30° or more) with 8 points, a moderate restriction (15°–29°) with 4 points and a severe restriction (less than 15°) with 0 points.

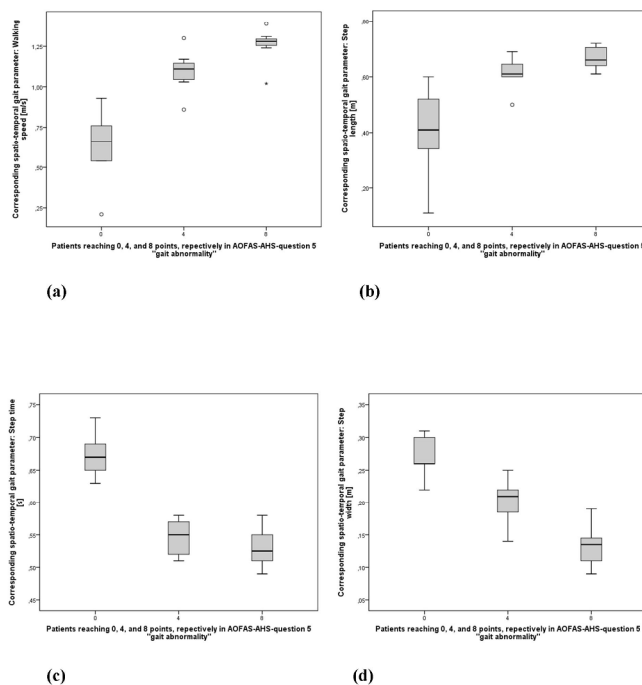
AOFAS-AHS item 7 (hindfoot motion, inversion plus eversion) represents a normal or mild restriction (75%–100% normal) with 6 points, a moderate restriction (25%–74% normal) with 3 points and a severe restriction (less than 25% normal) with 0 points

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4 (a) box plots for the maximum ankle power generation during push-off stratified for AOFAS-AHS points  
5 achieved by 20 patients  
6 (b) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion of the forefoot  
7 vs. the tibia angle stratified for AOFAS-AHS points achieved by 20 patients  
8 (c) box plots for the total range of motion during gait cycle in dorsiflexion to plantarflexion of the forefoot  
9 vs. the hindfoot angle stratified for AOFAS-AHS points achieved by 20 patients  
10 (d) box plots for the total range of motion during gait cycle in internal to external rotation of the hindfoot vs.  
11 the tibia angle stratified for AOFAS-AHS points achieved by 20 patients  
12 (e) box plots for the total range of motion during gait cycle in adduction to abduction of the forefoot vs. the  
13 tibia angle stratified for AOFAS-AHS points achieved by 20 patients

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Nonparametric box plots for an association analysis between AOFAS-AHS item 5 and corresponding spatio-temporal gait parameters with regard to content. Box plot horizontals indicate medians and quartiles, verticals indicate minimum and maximum observations, circles indicate statistical outliers with a deviation of at least 1.5 x interquartile range from the respective median.

AOFAS-AHS item 5 (gait abnormality) represents normal gait or a slight gait abnormality with 8 points, an obvious gait abnormality (walking/running is possible but irregular) with 4 points and a considerable gait abnormality with 0 points.

- (a) box plots for walking speed stratified for AOFAS-AHS points achieved by 20 patients
- (b) box plots for step length stratified for AOFAS-AHS points achieved by 20 patients
- (c) box plots for step time stratified for AOFAS-AHS points achieved by 20 patients
- (d) box plots for step width stratified for AOFAS-AHS points achieved by 20 patients

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**STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies***

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	4,6-8
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	4/5
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5/6
Objectives	3	State specific objectives, including any prespecified hypotheses	6, 11
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	6-9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6/7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6/7
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6/7
Bias	9	Describe any efforts to address potential sources of bias	8 + 12/13
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8-10
		(b) Describe any methods used to examine subgroups and interactions	---
		(c) Explain how missing data were addressed	---
		(d) If applicable, explain how loss to follow-up was addressed	---
		(e) Describe any sensitivity analyses	---
<b>Results</b>			



Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6/7
		(b) Give reasons for non-participation at each stage	---
		(c) Consider use of a flow diagram	---
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6/7
		(b) Indicate number of participants with missing data for each variable of interest	---
		(c) Summarise follow-up time (eg, average and total amount)	---
Outcome data	15*	Report numbers of outcome events or summary measures over time	10
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10/11
		(b) Report category boundaries when continuous variables were categorized	9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	---
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	---
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	11
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12/13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	3

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).