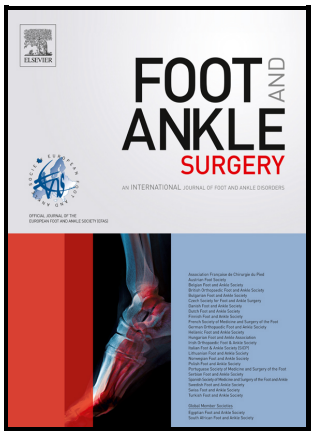
Journal Pre-proof

What's the Clinical Significance of VAS, AOFAS, and SF-36 in Progressive Collapsing Foot Deformity



Cheng Chen, ZhenDong Li, Yi Zhang, HaiChao Zhou, YongQi Li, WenBao He, TianBao Ye, YunFeng Yang

PII: S1268-7731(23)00190-X

DOI: https://doi.org/10.1016/j.fas.2023.10.002

Reference: FAS1936

To appear in: *Foot and Ankle Surgery*

Received date: 7 August 2023
Revised date: 15 September 2023
Accepted date: 12 October 2023

Please cite this article as: Cheng Chen, ZhenDong Li, Yi Zhang, HaiChao Zhou, YongQi Li, WenBao He, TianBao Ye and YunFeng Yang, What's the Clinical Significance of VAS, AOFAS, and SF-36 in Progressive Collapsing Foot Deformity, *Foot and Ankle Surgery,* (2023) doi:https://doi.org/10.1016/j.fas.2023.10.002

What's the Clinical Significance of VAS, AOFAS, and SF-36 in Progressive Collapsing Foot Deformity

Cheng Chen[1†], ZhenDong Li[1†], Yi Zhang[1†], HaiChao Zhou[1], YongQi Li[1], WenBao He[1], TianBao Ye[2*], YunFeng Yang[1*]

[1] Department of Orthopedics, Tongji Hospital, School of Medicine, Tongji University, Shanghai 200092, China

[2] Shanghai JiaoTong University Affiliated Sixth Peoples Hospital, Shanghai 200233, China

[†] These authors have contributed equally to this work and share the first authorship.

*** Correspondence:**

TianBao Ye, Email: yetb0220@163.com

YunFeng Yang, Email: dr_yangyf123@163.com

Declaration

The article is original, and all the authors are aware of its content and approve its submission. The article has not been published previously, and it is not under consideration for publication elsewhere. No conflict of interest exists. If published, the article will not be published elsewhere in the same form, in any language, without the written consent of the publisher.

Ethics approval and consent to participate

This study was approved by the Institutional Ethics Committee of Tongji Hospital (approval number: K-2023-007) and all patients provided informed consent. The analysis did not require any clinical intervention, and the participations in the study

were clearly below minimum risk. The study was conducted in compliance with the Helsinki Declaration.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available because the data sets contain sensitive identifying information, but are available from the corresponding author on reasonable request.

Competing Interest

All the authors declare no competing interest.

Funding

The study was sponsored by the National Key R&D Program of China (Grant No. 2022YFC2009505).

Author's Contributions

Y. Yang and C. Chen conceptualized the study. C. Chen designed the figure and table. C. Chen and Z. Li drafted the manuscript. Y. Zhang, H. Zhou, Y. Li, and W. He collected patients' information. T. Ye reviewed the literature. Y. Zhang, Y. Yang and T. Ye revised the manuscript. All authors read and approved the final version.

Acknowledgments

The authors would like to thank the parents who participated in the survey.

Abstract

Background: This study aimed to ascertain the minimal clinically important difference (MCID), and substantial clinical benefit (SCB) of the American Orthopedic Foot and Ankle Society (AOFAS) scale, visual analog scale (VAS) for pain, and Short Form-36 Health Survey (SF-36) in progressive collapsing foot deformity (PCFD) surgery.

Methods: In this retrospective cohort study, a total of 84 patients with PCFD (84 feet) who underwent surgery between July 2015 and April 2021 were included. The study assessed the patients' subjective perception, as well as their VAS, AOFAS, and SF-36 scores at a minimum two-year follow-up, and these data were subjected to statistical analysis. The study utilized Spearman correlation analysis to determine the degree of correlation between patients' subjective perception and their VAS, AOFAS, and SF-36 scores. The minimal detectable change (MDC), MCID, and SCB for VAS, AOFAS, and SF-36 were calculated using both distribution- and anchor-based methods. The classification outcomes obtained from the distribution- and anchor-based methods were assessed using Cohen’s kappa.

Results: Based on the subjective perception of the patients, a total of 84 individuals were categorized into three groups, with 7 in the no improvement group, 14 in the minimum improvement group, and 63 in the substantial improvement group. Spearman's correlation analysis indicated that the patients' subjective perception exhibited a moderate to strong association with VAS, AOFAS, SF-36 PCS, and SF-36 MCS, with all coefficients exceeding 0.4. The MCID of VAS, AOFAS, SF-36 PCS, and SF-36 MCS in PCFD surgery were determined to be 0.93, 5.84, 4.15, and 4.10 points using the distribution-based method and 1.50, 10.50, 8.34, and 3.03 points using the anchor-based method. The SCB of VAS, AOFAS, SF-36 PCS, and SF-36 MCS in PCFD surgery were 2.50, 18.50, 11.88, and 6.34 points, respectively. Moreover, the preliminary internal validation efforts have demonstrated the practical application and clinical utility of these findings. With the exception of the distribution-based MCID of SF-36 PCS, which showed fair agreement, all other measures demonstrated moderate to almost perfect agreement.

Conclusions: The MDC, MCID, and SCB intuitively enhance the interpretation of VAS, AOFAS, and SF-36 in PCFD surgery, assisting all stakeholders to better understand the therapeutic benefits and limitations of clinical care, and thus to make a more rational decision. Each of these parameters has its own emphasis and complements the others. These parameters are recommended for evaluating the clinical relevance of the results, and their promotion should extend to other areas of foot and ankle surgery.

Keywords: Minimal detectable change, Minimal clinically important difference, Substantial clinical benefit, Progressive collapsing foot deformity.

1.Introduction

1.1.PCFD

Progressive collapsing foot deformity (PCFD) is a debilitating disorder with complex pathological changes. It is a familiar occurrence with an incidence of 2.2%[1]. There are a number of historical nomenclatures for the PCFD, such as adult acquired flatfoot deformity, the adult flexible flatfoot deformity, posterior tibial tendon dysfunction, and peritalar subluxation[2]. PCFD causes various deformities and symptoms of different degrees, which ranges from mild limitations to severe disability and pain affecting the patients' quality of life[3]. In addition, PCFD was reported to have a underlying relationship with other diseases[4]. Surgery is among the first-line treatment modalities for PCFD in clinic. The incidence of surgery increased from 0.26 per 100000 in 1996 to 3.04 per 100000 in 2014, accompanied by substantial health care costs[5]. Although many procedures and techniques have been invented for the treatment, the optimal management of PCFD is confusing and challenging[6-8]. Pleasingly, in recent years, attention has increasingly been focused on PCFD and several consensuses have been reached[2,9,10].

1.2. MDC, MCID, SCB

Despite the extensive research conducted on PCFD, elucidating the interpretation of its outcomes remains challenging. It is imperative to underscore that statistical

significance does not necessarily equate to clinical significance. In evidence-based healthcare, clinical significance serves as a novel link between statistical and clinical findings. In recent times, scholars have directed their attention towards several compelling and valuable concepts to delve into clinical significance, such as the minimal detectable change (MDC), minimal clinically important difference (MCID), and substantial clinical benefit (SCB)[11-13]. The Minimum Detectable Change (MDC) is defined as the smallest discernible alteration that can be identified by an instrument beyond the scope of measurement error. In essence, MDC pertains to individual-level modifications that exceed measurement error, which is associated with the standard error of measurement[14]. It is noteworthy that MDC prioritizes within-individual changes over group-level disparities, whereas the Minimum Clinically Important Difference (MCID) obfuscates this differentiation. Consequently, MDC and MCID are distinct concepts that should not be conflated[15]. In contrast, the concept of MCID pertains to the minimal difference that patients discern as having the least amount of benefit, encompassing both statistical and clinical significance, and is considered the minimum threshold[16]. Other related concepts, such as minimal important difference and minimally important change, have also been introduced[17]. Additionally, SCB is defined as a significant improvement that patients perceive as the optimal benefit[18]. These values serve as crucial reference points for evaluating the efficacy of clinical management, facilitating doctor-patient communication, and promoting shared decision-making.

1.3. Aim of the present study

The American Orthopedic Foot and Ankle Society (AOFAS) scale, visual analog scale (VAS) for pain, and Short Form-36 Health Survey (SF-36) have been identified as the three most commonly used scales in the foot and ankle literature, including in the context of PCFD[19]. However, the literature on clinical significance in PCFD surgery is limited, making it imperative to address the translation of these scores into clinical guidelines. The present study aims to investigate MDC, MCID, and SCB of VAS, AOFAS, and SF-36 in the context of PCFD surgery.

2.Methods

2.1.Patients and study design

This retrospective cohort study comprised patients diagnosed with PCFD who underwent surgery at Shanghai Tongji Hospital between July 2015 and April 2021. The analysis did not require any clinical intervention, and the participations in the study were clearly below minimum risk. The study adhered to the Helsinki Declaration, and all patients provided informed consent. Patient medical records were scrutinized through an electronic database.

The surgical procedure was recommended to be performed by experienced foot and ankle specialists. The criteria for surgery included the absence of symptom relief following six months of conservative treatment, the absence of systemic or local signs of infection, the absence of severe systemic disorders that would preclude surgery, and the need for postoperative rehabilitation.

The study's inclusion criteria comprise of patients with PCFD who have undergone surgery, are 18 years or older, and have provided informed consent, with a follow-up period exceeding 2 years. Conversely, patients who underwent secondary operations in the same lower limb, except for internal fixation removal during the follow-up period, those who underwent bilateral surgery for PCFD, those with a history of pathological fractures or malignancy, those with severe internal medical disease, those unwilling to participate, and those lost to follow-up or missing clinical data are excluded from the study.

A total of 115 patients were initially included in the study based on the inclusion criteria. However, patients who underwent secondary operations in the same lower limb (with the exception of internal fixation removal) during the follow-up period (n = 3), those who underwent bilateral surgery for PCFD (n = 7), those who were unwilling to participate (n = 4), and those who were lost to follow-up or had missing clinical data (n = 17) were excluded from the analysis, resulting in a final cohort of 84 patients (73.0%).

2.2.Data collection

At baseline, demographic characteristics of all participants were recorded, encompassing gender, age, and body mass index, as well as detailed data on trouble

side, disease duration, and Bluman-Myerson classification[20]. Additionally, questionnaires pertaining to health status, including VAS, AOFAS, and SF-36, were administered. At the final postoperative follow-up, evaluations were conducted on VAS, AOFAS Ankle-Hindfoot scale, SF-36, and patients' subjective perception. Patients' subjective perception was recorded using a Five-levels Likert scale (substantial worsening, minimum worsening, no change, minimum improvement, substantial improvement). The patients were seen both before the surgery and at the final follow-up. As patient reported instruments, VAS, SF-36, and Five-levels Likert scale were reported by patients themselves. A clinician would provide explanation and guidance if patients experienced difficulty in comprehending the questionnaire. Three trained foot and ankle surgeons assessed the AOFAS scores while blinded to patients' identities. In rare cases of uncertainty, senior clinicians' opinions would be sought, and decisions would be made through joint discussions.

The VAS is a commonly employed tool for the assessment of pain. The scale is graded from 0 to 10, with the highest score of 10 indicating the most severe pain. The AOFAS Ankle-Hindfoot scale is a standardized measure utilized to evaluate the clinical status of the ankle-hindfoot. It comprises of three domains, namely pain (1 item), function (7 items), and alignment (1 item). The scale was first introduced by Foot and Ankle International in 1994[21]. The scores on the AOFAS Ankle-Hindfoot scale range from 0 to 100, with a score of 100 indicating a healthy ankle. The SF-36 questionnaire is a patient-reported measure of health-related quality-of-life consisting of 36 items. It encompasses 8 domains of health, each with a score range of 0 to 100, where higher scores indicate a more favorable health status. The 8 domains are underpinned by 2 principal factors, namely the physical component scale (PCS) and mental component scale (MCS). In this study, the standard scoring algorithm for the Chinese-specific SF-36 PCS and MCS was utilized[22].

2.3.Statistical analysis

Continuous variables were presented as mean ± standard deviation (SD), and qualitative variables were expressed as proportions. Statistical analysis was conducted using the SPSS software (version 26.0; IBM, Armonk, NY, USA). Two-tailed t-test was

employed to compare continuous data, and Fisher's exact tests was employed to compare qualitative data. Statistical significance was set at $P < 0.05$.

The Likert scale was used as anchor questions in this analysis. No change, minimum improvement, and substantial improvement were generalized to no improvement. Spearman's correlation coefficient was calculated to determine the degree of correlation[23]: negligible (0.0 - 0.1), weak (0.1 - 0.4), moderate (0.4 - 0.7), strong (0.7 - 0.9), and very strong (0.9 - 1.0).

We estimated MDC by distribution-based method, according to its basic concept. To calculate 80%, 90%, and 95% confidence interval (CI) (respectively as MDC 80, MDC 90, and MDC 95), the formula was: MDC = √2 * standard error of measurement (SEM) * z, in which SEM = SD of the baseline * √ (1 - intraclass correlation coefficient) and "z" equals 1.28 to MDC 80, 1.64 to MDC 90, and 1.96 to MDC 95[11]. Previous studies reported the intraclass correlation coefficients for VAS, AOFAS and SF-36 were 0.97, 0.95 and 0.98, respectively[24-26].

According to distribution-based method, the formula was: MCID = 0.5 * SD of changes from baseline to follow-up[27]. As the distribution-based method was not applicable to SCB, we exclusively utilized the anchor-based method to calculate it. The anchor-based method was formulated through the utilization of the receiver operating characteristic curve (ROC). The state variable for MCID and SCB was defined as patients reporting minimum improvement and substantial improvement, respectively. The anchor-based threshold was calculated by the cut-off value.

Results classified by distribution- and anchor-based method were evaluated by Cohen's kappa (κ), a method of evaluating agreement. The κ coefficient was assessed according to the Landis and Koch criteria[28]: poor (0.0 - 0.2), fair (0.2 - 0.4), moderate (0.4 - 0.6), substantial (0.6 - 0.8), and almost perfect (0.8 - 1.0).

3.Results

The duration of follow-up was 46.2 ± 18.7 months (range, 25 - 94 months). A comparison of the characteristics of the included (n = 84) and excluded (n = 31) patients did not yield statistically significant results (Table 1). The differences between

preoperative and last follow-up values for VAS, AOFAS, SF-36 PCS, and SF-36 MCS were -4.10 ± 1.86, 25.58 ± 11.68, 15.09 ± 8.30, and 11.39 ± 8.20, respectively, for all patients. Based on the patients' subjective perception, 84 patients were categorized into three groups (7 in the no improvement group, 14 in the minimum improvement group, and 63 in the substantial improvement group) (Fig. 1).

Spearman's correlation coefficients for the patients' subjective perception with VAS, AOFAS, SF-36 PCS, and SF-36 MCS were 0.760 (95% CI: 0.636 - 0.835), 0.745 (95% CI: 0.634 - 0.824), 0.658 (95% CI: 0.526 - 0.756), and 0.643 (95% CI: 0.494 - 0.750), respectively (all $P < 0.01$). Spearman's correlation analysis implied the patients' subjective perception had a moderate to strong relationship with VAS, AOFAS, SF-36 PCS, and SF-36 MCS.

Generally, MCID should be no lower than MDC 95 and SCB is greater than MCID. Otherwise, the validity would be doubtful. MDC 80, 90, 95, MCID, and SCB were listed in Table 2. MCID of VAS were 0.93 points by distribution-based method and 1.50 points by anchor-based method, both higher than the corresponding MDC 95 (0.48 points) and lower than the corresponding SCB (2.50 points). MCID of AOFAS were 5.84 points by distribution-based method and 10.50 points by anchor-based method, higher than the corresponding MDC 95 (4.90 points) and lower than the corresponding SCB (18.50 points). MCID of SF-36 PCS were 4.15 points by distribution-based method and 8.34 points by anchor-based method, which were higher than the corresponding MDC 95 (2.66 points) and lower than the corresponding SCB (11.88 points). MCID of SF-36 MCS were 4.10 points by distribution-based method and 3.03 points by anchor-based method, which were higher than the corresponding MDC 95 (2.86 points) and lower than the corresponding SCB (6.34 points).

The number and proportion of patients attaining MDC, MCID, and SCB were listed in Table 3. As expected, the percentage attaining MDC was greater than for MCID, and the percentage attaining MCID was greater than for SCB. Further, analysis of classification concordance by distribution- and anchor-based method were shown in Table 4. With the exception of the distribution-based MCID of SF-36 PCS (fair agreement), each attained moderate to almost perfect agreement.

4.Discussion

In this research endeavor, we undertook an exploration of the clinical significance in PCFD surgery, with the aim of addressing a gap in the existing literature. Our findings indicate that the MCID values for VAS, AOFAS, SF-36 PCS, and SF-36 MCS in PCFD surgery were 0.93, 5.84, 4.15, and 4.10 points, as determined by the distribution-based method, and 1.50, 10.50, 8.34, and 3.03 points, as determined by the anchor-based method. Additionally, the SCB values for VAS, AOFAS, SF-36 PCS, and SF-36 MCS in PCFD surgery were 2.50, 18.50, 11.88, and 6.34 points. Furthermore, our preliminary internal validation efforts have demonstrated the practical application and clinical utility of these findings. It is believed that these values, which enhance the interpretation of trial data, assist all stakeholders to better understand the therapeutic benefits and limitations of clinical care, and thus to make a more rational decision. The clinical relevance of the results, as well as their intuitive interpretation, can aid clinicians in quantitatively evaluating the effectiveness and facilitating future research.

4.1.Clinical significance

Researchers are encountering a significant obstacle in the translation of statistical findings into clinical relevance. The concept of statistical significance merely denotes that the disparity between two groups surpasses the variability within a single group. Nonetheless, statistical significance, which does not preclude clinically insignificant alterations, poses a challenge in its interpretation into clinical relevance. Therefore, statistical significance does not necessarily equate to clinical significance, and the actual magnitude of clinical change that is perceptible to patients remains elusive. Researchers have introduced several concepts, including MDC, MCID, and SCB, to aid in the interpretation of outcomes[11-13,17]. MDC is a statistical threshold that reflects the measurement instrument's ability to detect changes, while MCID and SCB are focused on patient-detectable changes[15]. It is generally understood that score changes below the MCID threshold may indicate treatment failure, while those exceeding the SCB threshold often suggest treatment success. It is important to note that SEM describes the characteristics of the measurement tool rather than those of the sample. Moreover,

alterations in scores between MCID and SCB may be considered as patients' subjective perceptions, yet they do not attain outstanding outcomes. In summary, these metrics, which augment the comprehension of trial data, aid all parties involved in comprehending the therapeutic advantages and constraints of clinical care, thereby enabling them to make more informed and pragmatic decisions.

The clinical significance is theoretically linked to particular diseases and scoring systems. Hung et al[29] conducted a study to estimate the MCID of Patient Reported Outcomes Measurement Information System instruments and Foot and Ankle Ability Measure Sports subscale in a foot and ankle orthopedic population of 3069 patients, utilizing both anchor-based and distribution-based methods. However, despite the substantial sample size, the study did not distinguish between various diseases, ranging from amputation to mallet toe, which may account for the broad range of MCID values. The presence of multiple diseases within a study population may hinder the attainment of highly specific results.

Revicki et al[30] recommended a systematic review of previously published clinical trials and the use of target measurement tools to determine MCID and assess efficacy changes. Conti et al[31] reported MCID of Patient Reported Outcomes Measurement Information System for flexible adult-acquired flatfoot deformity solely through the distribution-based method. Comparable studies have been conducted on other foot and ankle diseases, such as hallux valgus, ankle arthritis, and insertional Achilles tendinopathy[32-35]. However, there is a dearth of prior research on the clinical significance of VAS, AOFAS, or SF-36 in PCFD, rendering a parallel comparison impossible. Therefore, further investigation is necessary to enhance our comprehension of the current outcome scores and optimize their utilization.

4.2.Comparison of different methods

Various techniques are suggested, primarily encompassing anchor-based, distribution-based, and the Delphi method[36,37]. The anchor-based method, which frequently employs the patient's subjective perception as an anchor, is a prevalent approach. Among these methods, the ROC is highly regarded for its validity and precision. ROC facilitates the determination of a cut-off value by maximizing

sensitivity and specificity[38,39]. Nevertheless, the distribution characteristics are not taken into account, and the use of a subjective anchor may introduce unknown biases into the results. In contrast, the distribution-based method, which focuses on the statistical characteristics of the patient sample, is straightforward to implement, but its primary limitation is its reliance on statistical distribution. The distribution-based method is insufficient in addressing patient-perceived clinical change, resulting in challenges in explaining clinical outcomes. The Delphi method, which relies on expert panel consensus, is subject to significant subjectivity and expert experience, and is often used as a supplementary approach to the aforementioned methods[40].

Given the distinct emphases of each method, they should be viewed as complementary rather than conflicting. Therefore, it is advisable to adopt a comprehensive and multidimensional approach when interpreting values obtained through different methods. While the distribution-based method accounts for measurement error, the anchor-based method does not. Conversely, the distribution-based method may prove challenging in elucidating clinical relevance. In contrast, the anchor-based method, which relies on patient-reported changes rather than an arbitrary sample distribution, is more persuasive and easier to interpret. The correlation between the anchor and target is a crucial prerequisite for the anchor-based method. Therefore, we performed a Spearman correlation analysis to establish the relevance. Our study yielded Spearman correlation coefficients greater than 0.4, indicating more than a weak correlation. In comparison to the approach of determining the alteration in the outcome score that corresponds to the designation of a range of anchor instrument outcomes, the utilization of the entire cohort through ROC may be deemed more precise[41]. It is important to acknowledge that each method has a tendency to exhibit a mutable attribute, which may differ depending on the population and context, even when employing a singular method[17,42].

4.3.Limitations of this study

There are several limitations that require discussion in this study. Firstly, being a retrospective and single-center cohort study, it is subject to the typical limitations that are inherent to such studies. Secondly, the relatively small sample size and specific

sample characteristics may have an impact on the calculation of MDC, MCID, and SCB. Lastly, 31 patients (27.0%) were excluded from the analysis, however, a comparison between the study cohort and excluded patients revealed similar baseline characteristics, which we deemed acceptable. Fourthly, it must be acknowledged that these values are accompanied by an inherent risk of a trial participant establishing an endpoint, the realism and reasonableness of which remain uncertain[43]. The mean duration of follow-up in our investigation was 46.2 months, with a minimum of 25 months. Prior research has indicated that the median periods for resuming sports and physical activity were 9 - 12 months, and the durations for achieving maximum preoperative participation levels were 12 - 18 months[7]. Consequently, we contend that our observation period of no less than 2 years was justifiable. Nonetheless, it is important to note that the findings of this study may not be applicable to patients with an extended duration of follow-up. Additionally, the utilization of the novel PCFD classification system was not feasible due to its recent development in 2020[2]. Prior to this, the documentation of this classification system was insufficient.

4.4.Conclusion

The MDC, MCID, and SCB intuitively enhance the interpretation of VAS, AOFAS, and SF-36 in PCFD surgery, assisting all stakeholders to better understand the therapeutic benefits and limitations of clinical care, and thus to make a more rational decision. Each of these parameters has its own emphasis and complements the others. These parameters are recommended for evaluating the clinical relevance of the results, and their promotion should extend to other areas of foot and ankle surgery.

Abbreviations

PCFD, progressive collapsing foot deformity; MDC, minimal detectable change; MCID, minimal clinically important difference; SCB, substantial clinical benefit; AOFAS, American Orthopedic Foot and Ankle Society; VAS, visual analog scale; SF-36, Short Form-36; PCS, physical component score; MCS, mental component score; SD, standard deviation; CI, confidence interval; SEM, standard error of measurement; ROC, receiver operating characteristic curve.

References

[1] Shibuya N, Jupiter DC, Ciliberti LJ, et al. Characteristics of adult flatfoot in the United States. J Foot Ankle Surg 2010; 49(4):363-8.

[2] Myerson MS, Thordarson DB, Johnson JE, et al. Classification and Nomenclature: Progressive Collapsing Foot Deformity. Foot Ankle Int 2020; 41(10):1271-6.

[3] Ross MH, Smith M, Plinsinga ML, et al. Self-reported social and activity restrictions accompany local impairments in posterior tibial tendon dysfunction: a systematic review. J Foot Ankle Res 2018; 11:49.

[4] Tong JW, Kong PW. Association between foot type and lower extremity injuries: systematic literature review with meta-analysis. J Orthop Sports Phys Ther 2013; 43(10):700-14.

[5] Jackson JB, 3rd, Goodwin TM, Gonzalez TA. 18-Year Operative Incidence and Cost Analysis of the Treatment of Adult Acquired Flatfoot Deformity. Foot Ankle Orthop 2021; 6(1):2473011420985864.

[6] Tao X, Chen W, Tang K. Surgical procedures for treatment of adult acquired flatfoot deformity: a network meta-analysis. J Orthop Surg Res 2019; 14(1):62.

[7] Fuller RM, Eble SK, Day J, et al. Return to Physical Activity Following Flatfoot Reconstruction. Foot Ankle Int 2022; 43(6):772-82.

[8] Jackson JB, 3rd, Pacana MJ, Gonzalez TA. Adult Acquired Flatfoot Deformity. J Am Acad Orthop Surg 2022; 30(1):e6-e16.

[9] Sangeorzan BJ, Hintermann B, De Cesar Netto C, et al. Progressive Collapsing Foot Deformity: Consensus on Goals for Operative Correction. Foot Ankle Int 2020; 41(10):1299-302.

[10] De Cesar Netto C, Myerson MS, Day J, et al. Consensus for the Use of Weightbearing CT in the Assessment of Progressive Collapsing Foot Deformity. Foot Ankle Int 2020; 41(10):1277-82.

[11] Sun Z, Li J, Luo G, et al. What constitutes a clinically important change in Mayo Elbow Performance Index and range of movement after open elbow arthrolysis? Bone Joint J 2021; 103-b(2):366-72.

[12] Ogura T, Ackermann J, Barbieri Mestriner A, et al. Minimal Clinically Important Differences and Substantial Clinical Benefit in Patient-Reported Outcome Measures after Autologous Chondrocyte Implantation. Cartilage 2020; 11(4):412-22.

[13] Çelik D, Çoban Ö, Kılıçoğlu Ö. Minimal clinically important difference of commonly used hip-, knee-, foot-, and ankle-specific questionnaires: a systematic review. J Clin Epidemiol 2019; 113:44-57.

[14] De Vet HC, Terwee CB, Ostelo RW, et al. Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. Health Qual Life Outcomes 2006; 4:54.

[15] Turner D, Schünemann HJ, Griffith LE, et al. The minimal detectable change cannot reliably replace the minimal important difference. J Clin Epidemiol 2010; 63(1):28-36.

[16] Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials 1989; 10(4):407-15.

[17] King MT. A point of minimal important difference (MID): a critique of terminology and methods. Expert Rev Pharmacoecon Outcomes Res 2011; 11(2):171-84.

[18] Glassman SD, Copay AG, Berven SH, et al. Defining substantial clinical benefit following lumbar spine arthrodesis. J Bone Joint Surg Am 2008; 90(9):1839-47.

[19] Hunt KJ, Hurwit D. Use of patient-reported outcome measures in foot and ankle research. J Bone Joint Surg Am 2013; 95(16):e118(1-9).

[20] Bluman EM, Title CI, Myerson MS. Posterior tibial tendon rupture: a refined classification system. Foot Ankle Clin 2007; 12(2):233-49, v.

[21] Kitaoka HB, Alexander IJ, Adelaar RS, et al. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int 1994; 15(7):349-53.

[22] Lam CL, Tse EY, Gandek B, et al. The SF-36 summary scales were valid, reliable, and equivalent in a Chinese population. J Clin Epidemiol 2005; 58(8):815-22.

[23] Schober P, Boer C, Schwarte LA. Correlation Coefficients: Appropriate Use and Interpretation. Anesth Analg 2018; 126(5):1763-8.

[24] Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. Acad Emerg Med 2001; 8(12):1153-7.

[25] Conceição CS, Neto MG, Neto AC, et al. Analysis of the psychometric properties of the American Orthopaedic Foot and Ankle Society Score (AOFAS) in rheumatoid arthritis patients: application of the Rasch model. Rev Bras Reumatol Engl Ed 2016; 56(1):8-13.

[26] Guermazi M, Allouch C, Yahia M, et al. Translation in Arabic, adaptation and validation of the

SF-36 Health Survey for use in Tunisia. Ann Phys Rehabil Med 2012; 55(6):388-403.

[27] Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Med Care 2003; 41(5):582-92.

[28] Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1977; 33(1):159-74.

[29] Hung M, Baumhauer JF, Licari FW, et al. PROMIS and FAAM Minimal Clinically Important Differences in Foot and Ankle Orthopedics. Foot Ankle Int 2019; 40(1):65-73.

[30] Revicki D, Hays RD, Cella D, et al. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. J Clin Epidemiol 2008; 61(2):102-9.

[31] Conti MS, Caolo KC, Nguyen JT, et al. Preoperative Patient-Reported Outcome Measures Relationship With Postoperative Outcomes in Flexible Adult-Acquired Flatfoot Deformity. Foot Ankle Int 2021; 42(3):268-77.

[32] Sutton RM, Mcdonald EL, Shakked RJ, et al. Determination of Minimum Clinically Important Difference (MCID) in Visual Analog Scale (VAS) Pain and Foot and Ankle Ability Measure (FAAM) Scores After Hallux Valgus Surgery. Foot Ankle Int 2019; 40(6):687-93.

[33] Chan HY, Chen JY, Zainul-Abidin S, et al. Minimal Clinically Important Differences for American Orthopaedic Foot & Ankle Society Score in Hallux Valgus Surgery. Foot Ankle Int 2017; 38(5):551-7.

[34] Coe MP, Sutherland JM, Penner MJ, et al. Minimal clinically important difference and the effect of clinical variables on the ankle osteoarthritis scale in surgically treated end-stage ankle arthritis. J Bone Joint Surg Am 2015; 97(10):818-23.

[35] Mccormack J, Underwood F, Slaven E, et al. THE MINIMUM CLINICALLY IMPORTANT DIFFERENCE ON THE VISA-A AND LEFS FOR PATIENTS WITH INSERTIONAL ACHILLES TENDINOPATHY. Int J Sports Phys Ther 2015; 10(5):639-44.

[36] Copay AG, Subach BR, Glassman SD, et al. Understanding the minimum clinically important difference: a review of concepts and methods. Spine J 2007; 7(5):541-6.

[37] Van Der Heijde D, Lassere M, Edmonds J, et al. Minimal clinically important difference in plain films in RA: group discussions, conclusions, and recommendations. OMERACT Imaging Task Force. J Rheumatol 2001; 28(4):914-7.

[38] Thigpen CA, Shanley E, Momaya AM, et al. Validity and Responsiveness of the Single Alpha-numeric Evaluation for Shoulder Patients. Am J Sports Med 2018; 46(14):3480-5.

[39] Nwachukwu BU, Fields K, Chang B, et al. Preoperative Outcome Scores Are Predictive of Achieving the Minimal Clinically Important Difference After Arthroscopic Treatment of Femoroacetabular Impingement. Am J Sports Med 2017; 45(3):612-9.

[40] Oliveira A, Machado A, Marques A. Minimal Important and Detectable Differences of Respiratory Measures in Outpatients with AECOPD(†). Copd 2018; 15(5):479-88.

[41] Turner D, Schünemann HJ, Griffith LE, et al. Using the entire cohort in the receiver operating characteristic analysis maximizes precision of the minimal important difference. J Clin Epidemiol 2009; 62(4):374-9.

[42] Chung AS, Copay AG, Olmscheid N, et al. Minimum Clinically Important Difference: Current Trends in the Spine Literature. Spine (Phila Pa 1976) 2017; 42(14):1096-105.

[43] Wu X, Liu J, Tanadini LG, et al. Challenges for defining minimal clinically important difference (MCID) after spinal cord injury. Spinal Cord 2015; 53(2):84-91.

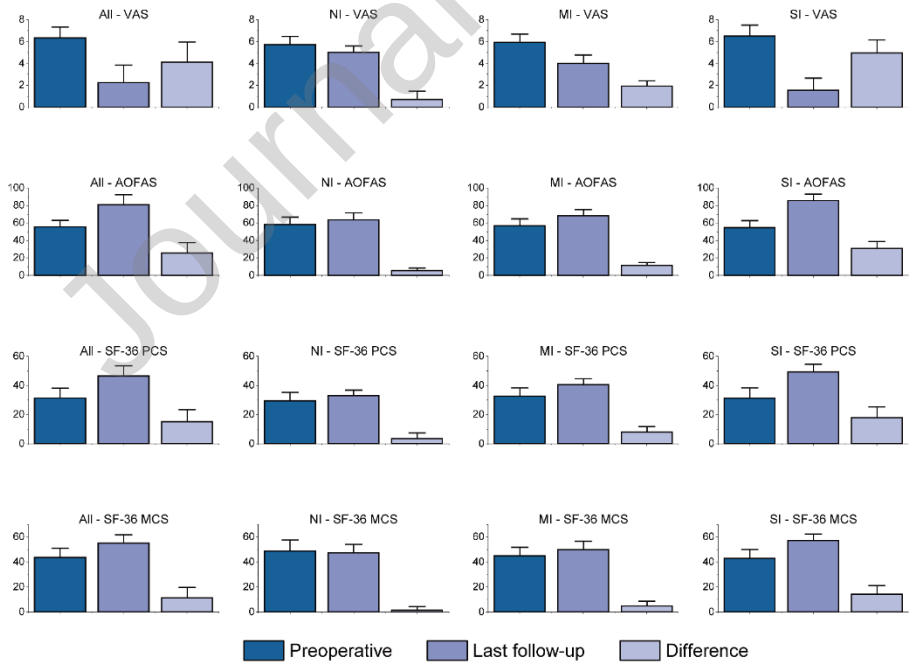


Fig. 1. Comparison of VAS, AOFAS, SF-36 PCS, and SF-36 MCS between preoperation, last follow-up, and difference of all and subgroups in PCFD surgery

Abbreviations: NI, no improvement; MI, minimum improvement; SI, substantial improvement; VAS, visual analog scale; AOFAS, American Orthopedic Foot and Ankle Society; SF-36, Short Form-36; PCS, physical component score; MCS, mental component score.

Table 1. Comparison of characteristics between study cohort and excluded patients

	Study cohort (84 patients, 84 feet)	**Excluded patients (31 patients, 38 feet)**	**P value**
Right feet, n	43 (51.2%)	21 (55.3%)	0.700
Female, n	50 (59.5%)	13 (41.9%)	0.093
Age, years	49.33 ± 11.17	51.06 ± 14.34	0.497
BMI, kg/m^2	24.02 ± 2.90	24.60 ± 3.50	0.370
Disease duration, months	15.82 ± 4.77	16.16 ± 5.05	0.739
Bluman-Myerson classification[20]			0.648
II	44 (52.4%)	23 (60.5%)	
III	29 (34.5%)	10 (26.3%)	
IV	11 (13.1%)	5 (13.2%)	
Operative procedures			0.680
Osteotomy	42	25	
Tendon transfers	18	8	
Arthrodesis	43	16	
Others	12	5	

Continuous variables are described as mean ± standard deviation. Qualitative variables were described as numbers and proportions.

Abbreviations: BMI, Body Mass Index.

Table 2. MDC, MCID, and SCB of VAS, AOFAS, SF-36 PCS, and SF-36 MCS in PCFD surgery

		VAS	AOFAS	SF-36 PCS	SF-36 MCS
MDC*	MDC 80, points	0.31	3.20	1.74	1.87
	MDC 90, points	0.40	4.10	2.22	2.39
	MDC 95, points	0.48	4.90	2.66	2.86
Distribution-based MCID, points		0.93	5.84	4.15	4.10
Anchor-based MCID, points		1.50	10.50	8.34	3.03
Anchor-based SCB, points		2.50	18.50	11.88	6.34

*Calculated with confidence intervals reflecting 80%, 90%, and 95% certainty reported, respectively, as MDC 80, MDC 90, and MDC 95

Abbreviations: VAS, visual analog scale; AOFAS, American Orthopedic Foot and Ankle Society; SF-36, Short Form-36; PCS, physical component score; MCS, mental component score; MDC, minimal detectable change; MCID, minimal clinically important difference; SCB, substantial clinical benefit.

Table 3. The number and proportion of patients attaining MDC, MCID, and SCB in PCFD surgery

		VAS	AOFAS	SF-36 PCS	SF-36 MCS
MDC*	MDC 80	81 (96.4%)	82 (97.6%)	82 (97.6%)	75 (89.3%)
	MDC 90	81 (96.4%)	81 (96.4%)	82 (97.6%)	73 (86.9%)
	MDC 95	81 (96.4%)	81 (96.4%)	81 (96.4%)	72 (85.7%)
Distribution-based		81 (96.4%)	80 (95.2%)	81 (96.4%)	65 (77.4%)

MCID				
Anchor-based MCID	76 (90.5%)	72 (85.7%)	64 (76.2%)	70 (83.3%)
Anchor-based SCB	64 (76.2%)	60 (71.4%)	52 (61.9%)	57 (67.9%)
According to patients' subjective perception, patients attaining improvement was 77 (91.7%), patients attaining substantial improvement was 63 (75.0%).				

*Calculated with confidence intervals reflecting 80%, 90%, and 95% certainty reported, respectively, as MDC 80, MDC 90, and MDC 95.

Abbreviations: MDC, minimal detectable change; MCID, minimal clinically important difference; VAS, visual analog scale; AOFAS, American Orthopedic Foot and Ankle Society; SF-36, Short Form-36; PCS, physical component score; MCS, mental component score; SCB, substantial clinical benefit.

Table 4. Results classified by distribution- and anchor-based method

		Distribution-based MCID	**Anchor-based MCID**	**Anchor-based SCB**
VAS	TP	77 (91.7%)	75 (89.3%)	63 (75.0%)
	TN	3 (3.6%)	6 (7.1%)	20 (23.8%)
	FN	0 (0.0%)	2 (2.4%)	0 (0.0%)
	FP	4 (4.8%)	1 (1.2%)	1 (1.2%)
	Kappa	0.579 (0.186)	0.780 (0.122)	0.968 (0.032)
	P value	**<0.0001**	**<0.0001**	**<0.0001**
	Sensitivity	77/77 (100.0%)	75/77 (97.4%)	63/63 (100.0%)
	Specificity	3/7 (42.9%)	6/7 (85.7%)	20/21 (95.2%)
	PPV	77/81 (95.1%)	75/76 (98.7%)	63/64 (98.4%)
	NPV	3/3 (100.0%)	6/8 (75.0%)	20/20 (100.0%)
AOFAS	TP	76 (90.5%)	72 (85.7%)	60 (71.4%)
	TN	3 (3.6%)	7 (8.3%)	21 (25.0%)
	FN	1 (1.2%)	5 (6.0%)	3 (3.6%)

	FP	4 (4.8%)	0 (0.0%)	0 (0.0%)
	Kappa	0.516 (0.187)	0.706 (0.122)	0.909 (0.051)
	P value	**0.001**	**<0.0001**	**<0.0001**
	Sensitivity	76/77 (98.7%)	72/77 (93.5%)	60/63 (95.2%)
	Specificity	3/7 (42.9%)	7/7 (100.0%)	21/21 (100.0%)
	PPV	76/80 (95.0%)	72/72 (100.0%)	60/60 (100.0%)
	NPV	3/4 (75.0%)	7/12 (58.3%)	21/24 (87.5%)
SF-36	TP	76 (90.5%)	64 (76.2%)	50 (59.5%)
PCS	TN	2 (2.4%)	7 (8.3%)	19 (22.6%)
	FN	1 (1.2%)	13 (15.5%)	13 (15.5%)
	FP	5 (6.0%)	0 (0.0%)	2 (2.4%)
	Kappa	0.368 (0.198)	0.451 (0.117)	0.595 (0.090)
	P value	**0.017**	**<0.0001**	**<0.0001**
	Sensitivity	76/77 (98.7%)	64/77 (83.1%)	50/63 (79.4%)
	Specificity	2/7 (28.6%)	7/7 (100.0%)	19/21 (90.5%)
	PPV	76/81 (93.8%)	64/64 (100.0%)	50/52 (96.2%)
	NPV	2/3 (66.7%)	7/20 (35.0%)	19/32 (59.4%)
SF-36	TP	65 (77.4%)	70 (83.3%)	54 (64.3%)
MCS	TN	7 (8.3%)	7 (8.3%)	18 (21.4%)
	FN	12 (14.3%)	7 (8.3%)	9 (10.7%)
	FP	0 (0.0%)	0 (0.0%)	3 (3.6%)
	Kappa	0.474 (0.119)	0.625 (0.126)	0.652 (0.091)
	P value	**<0.0001**	**<0.0001**	**<0.0001**
	Sensitivity	65/77 (84.3%)	70/77 (90.9%)	54/63 (85.7%)
	Specificity	7/7 (100.0%)	7/7 (100.0%)	18/21 (85.7%)
	PPV	65/65 (100.0%)	70/70 (100.0%)	54/57 (94.7%)
	NPV	7/19 (36.8%)	7/14 (50.0%)	18/27 (66.7%)

Qualitative variables were described as numbers and proportions. Cohen's kappa is described as kappa coefficient (standard error).

All P-value is less than 0.05, which means the difference is significant.

Abbreviations: VAS, visual analog scale; AOFAS, American Orthopedic Foot and Ankle Society; SF-36, Short Form-36; PCS, physical component score; MCS, mental component score; TP, true positives; TN, true negatives; FN, false negatives; FP, false positives; PPV, positive predictive value; NPV, negative predictive value.

Conflict of Interest Statement

The authors declare no conflicts of interest.