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Which general functional outcome measure does a better job of capturing change in clinical status in pelvic and acetabular fracture patients? An analysis of responsiveness over the first year of recovery

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Abstract

Objective: To compare the responsiveness of the Short Form-36 (SF-36) physical component score (PCS) to the Short Musculoskeletal Function Assessment (SMFA) dysfunction index (DI) in pelvic and acetabular fracture patients over multiple time points in the first year of recovery.

Design: Prospective cohort study.

Setting: Level 1 trauma center.

Patients/Participants: Four hundred seventy-three patients with surgically treated pelvic and acetabular fractures (Orthopaedic Trauma Association B or C-type pelvic ring disruption or acetabular fracture) were enrolled into the center's prospective orthopaedic trauma database between January 2005 and February 2015. Functional outcome data were collected at baseline, 6 months, and 12 months.

Main outcome measurements: Evaluation was performed using the SF-36 Survey and Short Musculoskeletal Function Assessment. Responsiveness was assessed by calculating the standard response mean (SRM), the minimal clinically important difference (MCID), and floor and ceiling effects.

Results: Three hundred five patients had complete data for both outcome scores. SF-36 PCS and SMFA DI scores showed strong correlation for all time intervals ($r = -0.55$ at baseline, $r = -0.78$ at 6 months, and $r = -0.85$ at 12 months). The SRM of the SF-36 PCS was greater in magnitude than the SRM of SMFA DI at all time points; this was statistically significant between baseline and 6 months ($P < .001$), but not between 6 and 12 months ($P = .29$). Similarly, the proportion of patients achieving MCID in SF-36 PCS was significantly greater than the proportion achieving MCID in SMFA DI between baseline and 6 months (84.6% vs 69.8%, $P < .001$), and between 6 and 12 months (48.5% vs 35.7%, $P = .01$). There were no ceiling or floor effects found for SF-36 PCS at any time intervals. However, 16.1% of patients achieved the highest level of functioning detectable by the SMFA DI at baseline, along with smaller ceiling effects at 6 months (1.3%) and 12 months (3.3%).

Conclusions: SF-36 PCS is a more responsive measure of functional outcome than the SFMA DI over the first year of recovery in patients who sustain a pelvic ring disruption or acetabular fracture. This superiority was found in using the SRM, proportion of patients meeting MCID, and ceiling effects. Furthermore, the SF-36 PCS correlated with the more disease-specific SMFA DI.

Level of evidence: Prognostic Level II.

Keywords: acetabular fracture, functional outcome scores, pelvis fracture, Short Form-36 Survey, short musculoskeletal function assessment, unstable pelvic ring injury

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1. Introduction

Pelvic and acetabular fractures are complex injuries to treat, and are associated with significant morbidity, disability, and mortality.[1–5] The incidence of these injuries has been gradually increasing over the years, with 34.3 cases per 100,000 capita reported recently.[6] Modern advances in operative treatment of these fractures have improved functional outcomes and patient survival.[6–13] Concomitant polytrauma injuries and complications of treatment with pelvic and acetabular fractures present challenges for effective measurement and assessment of functional recovery in these patients. Currently, there is a new standard in the orthopaedic literature to focus on patient-reported functional outcome, as opposed to the more historical method of using unstandardized radiological measures.[14–19]

There has been a recent, evolving attempt in the orthopaedic literature to effectively report functional outcome.[20] This is performed by using outcome scores that are either disease-specific or generic. Disease-specific scores focus on a single-disease state, theoretically improving their ability to detect clinical change in that specific state, without necessarily demonstrating their effect on the patient's overall state of health. Generic outcome scores broadly evaluate all domains of patient health and allow comparison between disease states. By definition, they may not capture certain aspects of specific disease states. The Short Form (SF)-36 Survey and Short Musculoskeletal Function Assessment (SMFA) are 2 such generic scores that have been used in the orthopaedic trauma literature.[15] Fundamental properties of appropriate, scientifically rigorous outcome scores include validity (the extent to which an outcome score measures what it is supposed to measure), reliability (the ability to measure the same entity twice), and responsiveness (the measure of how an outcome instrument captures clinically important changes over time).[12,15,16]

A systematic review of the literature was recently performed to evaluate the use and interpretation of generic and disease-specific (or pelvic-specific) functional outcome instruments in the reporting of outcome after the operative management of pelvic ring disruptions.[21] Furthermore, there was a lack of rigorous validity, reliability, and responsiveness testing with the available pelvic-specific instruments, and all were found to be likely susceptible to a ceiling effect. Therefore, despite their descriptive value, there is no clear superiority in use of these instruments in routine assessment of functional outcome after treatment of pelvic fractures.

Another systematic review was similarly done to report the usage of functional outcome scores in acetabular fracture patients who underwent surgery.[22] Specific outcome instruments used for this patient population were similarly found to be fraught with lack of scientific rigor, as none of these instruments has been assessed for validity, reliability, or responsiveness. Furthermore, the majority were originally described for evaluating hip arthroplasty patients, or modifications thereof. Thus, these disease-specific instruments cannot be recommended in reporting functional outcome after acetabular fracture surgery.

Generic health outcome instruments have more commonly been used to measure function after pelvic and acetabular fractures. In the pelvic fracture literature, the SF-36 is by far the most commonly used, and is the most widely quoted generic outcome instrument in the medical literature.[23] The reporting of its results in pelvic fractures, however, was variable, making specific comparisons between series or treatment methods challenging. Several other generic outcome measures have also frequently been used, with the SMFA being the only other global function instrument used more than once in the pelvic fracture literature. It has been widely used to study differences in the functional outcome of patients with musculoskeletal disorders.[24] Two authors used more than 1 generic instrument (SF-36 and SMFA) in assessing function after pelvic fracture, but the relationship between them was not formally tested. For acetabular fracture patients, the most used generic outcome score is, conversely, the SMFA, followed by the SF-36. The more limited use of the SF-36 in this population and the lack of available psychometric testing highlights the need for more investigation into the use and comparison of these generic outcome scores in assessing functional outcome after acetabular fracture surgery.

In essence, the standards for reporting of functional outcome in patients with pelvic and acetabular fractures are still developing. Specific outcome scores for these patient populations are severely limited by lack of scientific rigor, and only add to respondent burden. The generic SF-36 and SMFA scores have both been used in the context of pelvic and acetabular fractures, but neither of them have received adequate testing of responsiveness.[21] There is also a paucity of prospective, longitudinal outcome studies following patients treated surgically for pelvic and acetabular fractures at multiple time points, which prevents conclusions on which generic outcome measure is more responsive, or better evaluates change over time.[22] Their combined use in study design also increases the burden on both patients and clinicians, and complicates the maintenance of a robust follow-up database.

The purpose of this study is to compare the responsiveness of the more general SF-36 to the more musculoskeletal-specific SMFA in patients with pelvic and acetabular fractures over the first year of recovery.

2. Methods

2.1. Subjects

Institutional ethics review board approval was obtained for this study (H04-70260, from the University of British Columbia) in accordance with the Declaration of the World Medical Association. Subjects gave informed consent as required. Data were prospectively collected on patients who sustained an unstable pelvic ring disruption (Orthopaedic Trauma Association B, or C-type pelvic ring disruption)[25] or acetabulum fracture requiring surgery at a Level 1 Trauma Center from 2005 to 2015. Basic demographic and injury information was collected, including age, gender, and injury severity score (ISS).[26]

2.2. Functional outcome measures

Patients completed 2 functional outcome questionnaires: the SF-36 and SMFA at baseline (preinjury recall), 6 months, and 12 months. Preinjury recall functional scores were collected upon hospital discharge and utilized for baseline scores, since it has been suggested that functional outcome questionnaires are more appropriate than general population norms, and can be accurately recalled up to 6 weeks after surgery.[27–29]

The SF-36 is a validated, reliable functional questionnaire constructed on normal population data to reflect the general health status of patients.[30] The SF-36 is a 36-item questionnaire that is summarized into a physical component score (PCS) and a mental component score (MCS). A higher SF-36 score implies higher function. The SMFA is a validated, 2-part 46-item

functional questionnaire specific to patients with musculoskeletal injuries.[24] It is divided into a dysfunction index (DI) and a bother index. With the SMFA, a lower score implies higher function.

2.3. Statistical analysis

The mean values of the PCS of the SF-36 and the DI of the SMFA were calculated at each time point. The Pearson correlation coefficient between the SF-36 and SMFA DI scores was calculated at each time point for all patients. Statistical significance was set at $P < .01$.

2.3.1. Responsiveness. Responsiveness is a measure of how an outcome instrument captures clinically important changes over time. This was assessed by calculating the standard response mean (SRM), the minimal clinically important difference (MCID), and floor and ceiling effects.

2.3.2. SRM. The SRM is the mean score change divided by the standard deviation of the score change between each time period.[31] A greater SRM implies superior responsiveness. The difference in standardized change scores for the SF-36 PCS and SMFA DI from 6 to 12 months was compared using a paired *t* test.

2.3.3. MCID. The MCID can be described as the smallest change in an outcome score that patients perceive as important.[32,33] To our knowledge, there is no established MCID for the above functional outcome measures in pelvic and acetabular fracture patients. In these instances, the MCID is accepted as one-half of the standard deviation of improvement in score between 2 time points, and the proportion of patients making this clinically important change at each time point is calculated.[31] The McNemar test was used to compare the proportion of patients experiencing MCID in SF-36 versus SMFA.

2.3.4. Ceiling and floor effects. SF-36 PCS and SMFA DI scores were assessed for both ceiling (scores reflecting maximal level of functioning) and floor (scores reflecting the lowest level of functioning) effects. To describe these effects for the outcome measures, the proportions of patients achieving the maximum and minimum level of function detectable by these outcome measures are reported at each time point.[17]

All statistical analyses were carried out using the R statistical computing environment (R Core Team (2018); R Foundation for Statistical Computing, Vienna, Austria), with *P* values <.05 considered statistically significant.

3. Results

Four hundred seventy-three patients were enrolled from 2005 to 2015. At the time of data analysis, 305 patients had complete data for the SF-36 PCS and SMFA DI at baseline, 6 months, and 12 months. In this patient group, 228 (75%) were male, mean age was 45.2 (range 14–86), and the mean ISS was 14.2 ± 8.6, with 68 (22%) patients having an ISS>18 (Table 1). The cohort consisted of 228 unstable pelvic ring injuries, 214 acetabular fractures, and 31 other injuries (Table 2). There was no statistically significant difference in mean age, gender distribution, or mean ISS between patients with complete versus incomplete data. A higher proportion of patients with incomplete data had an ISS >9 ($P < .001$), while a lower proportion of these patients had an ISS >18 ($P = .02$). However, the differences between these proportions were minimal. To ensure that all the following results are based on the same cohort of patients, the group of 305 patients with complete data was analyzed.

Table 1

Demographic data comparing groups (based on completeness of data).

Characteristics	Patients with complete data	Patients with incomplete data	*P* value
Number (%)	305 (64.5%)	160	
Sex			
Male	228 (74.8%)	108 (67.5%)	.1*
Female	77 (25.2%)	52 (32.5%)	.1*
Age			
Mean (SD)	45.2 (16.1)	42.6 (18.4)	.13†
Median (range)	46.0 (14–86)	41.0 (14–86)	
ISS			
Mean (SD)	14.2	14.5	.74†
Median (range)	9.0 (4–50)	9.0 (4–57)	
ISS >9 (%)	134 (43.9%)	69 (43.1%)	>.001*
ISS >18 (%)	68 (22.3%)	43 (26.9%)	.02*

ISS = Injury Severity Score, SD = standard deviation.
* Fisher exact test.
† Student *t* test.

The distribution of scores for SF-36 PCS and SMFA-DI at each time point is represented in Figure 1. The SF-36 PCS and SMFA DI scores showed strong correlation for all time intervals ($r = -0.55$ at baseline, $r = -0.78$ at 6 months, and $r = -0.85$ at 12 months). The SRM of the SF-36 PCS was greater in magnitude than the SRM of SMFA DI at all time intervals. This was statistically significant between baseline and 6 months ($P < .001$), but not between 6 and 12 months ($P = .29$) (Fig. 2). Similarly, the proportion of patients achieving MCID in SF-36 PCS was significantly greater than the proportion achieving MCID in SMFA DI between baseline and 6 months (84.6% vs 69.8%, $P < .001$) and between 6 and 12 months (48.5% vs 35.7%, $P = .01$) (Fig. 3).

There were no ceiling or floor effects found for SF-36 PCS at any time point, meaning no patients achieved either the highest or lowest level of functioning that was detectable by the SF-36 PCS. However, 16.1% of patients achieved the highest level of functioning detectable by the SMFA DI at baseline, along with smaller ceiling effects at 6 months (1.3%) and 12 months (3.3%) (Table 3).

4. Discussion

In the orthopaedic literature, increased emphasis is now placed on assessing patient-reported functional outcome scores after

Table 2

Demographic data based on injury type.

Injury type	Number (%)
Pelvic	228 (48.2%)
OTA B-type	150 (31.7%)
OTA C-type	78 (16.5%)
Acetabular	214 (45.2%)
Simple	96 (20.3%)
Complex	118 (24.9%)
Other (combined pelvic/acetabular; combined femoral head/acetabular)	31 (6.5%)

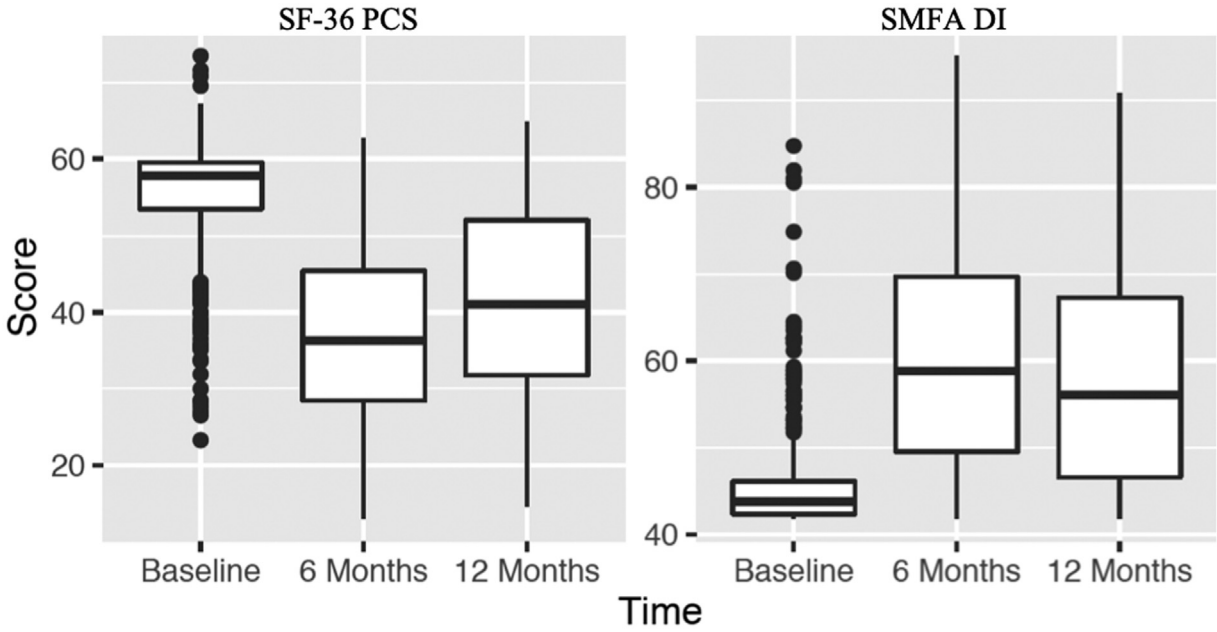

Figure 1. Distribution of functional outcomes at each time point.

operative treatment of injuries.[15] This is especially relevant in pelvic and acetabular fractures, given the challenges of associated polytrauma injuries and subsequent complications.

Effective measurement and assessment of functional recovery in pelvic fracture patients is affected by physical elements, urological and sexual dysfunction, as well as mental health issues, chronic pain, and long-term unemployment. Six different pelvic-specific instruments have been used in 19 studies, on a total of 978 patients.[21] The Majeed score[34] was used most frequently, followed by the Iowa Pelvic Score[35] and Orlando Pelvic Score.[36] However, with respect to reporting of the Majeed score, the literature has seen poor accuracy and considerable inconsistency.[37] Review of the limited psychometric testing performed on these pelvic-specific instruments at that time showed some construct validation with the physical elements of the SF-36, but with considerable variability with the reporting of correlation coefficients and *P* values.[38] None of these outcome scores have demonstrated adequate validity, reliability, and responsiveness, and all were found to be likely susceptible to a ceiling effect. A recent study on patients with surgically treated pelvic fractures confirmed this conclusion, and also found poor correlation of these scores with the SF-36 MCS. This indicates the failure of these pelvic-specific instruments to capture elements of affect, psychologic distress, and mental well-being, despite patients identifying these outcomes as some of the most important consequences of pelvic and acetabular fractures.[38] This is a significant weakness, given that 24 out of the 38 patients in that study cited "emotional stress/depression and family strain" as the most important consequences of their pelvic ring injuries, highlighting the importance of the SF-36 MCS. Therefore, in addition to poor psychometric qualities, these pelvic-specific instruments also do not capture the salient functional outcomes for these patients.

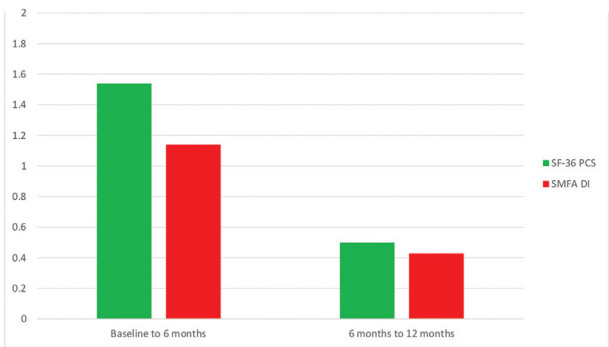

Figure 2. Comparison of the magnitude of the standardized response mean for SF36-PCS and SMFA-DI. SF36-PCS = Short Form-36 Survey Physical Component Score, SMFA-DI = Short Musculoskeletal Function Assessment-dysfunction index.

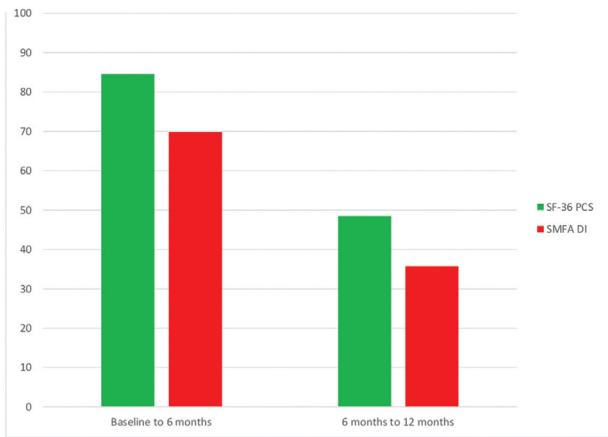

Figure 3. Percentage of patients achieving MCID between timepoints for SF36-PCS and SMFA-DI. MCID = minimal clinically important difference, SF36-PCS = Short Form-36 Survey Physical Component Score, SMFA-DI = Short Musculoskeletal Function Assessment- dysfunction index.

Table 3

Ceiling effects at all time points: number (%) of patients at the highest possible level of functioning.

Outcome measures	Time point		
	Baseline	6 months	12 months
SF-36 PCS	0 (0.0)	0 (0.0)	0 (0.0)
SMFA DI*	49 (16.1%)	4 (1.3%)	10 (3.3%)

SF36-PCS = Short Form-36 Survey Physical Component Score; Short Musculoskeletal Function Assessment Dysfunction Index.

* For SMFA-DI, the highest possible level of functioning corresponds to the lowest possible score.

Acetabular fractures are also complex injuries, with some similarities in clinical sequelae, but with separate morbidity due to intra-articular injury as opposed to the urologic and neurologic complications more often seen with pelvic fractures. Outcome assessment in this population, therefore, deserves the same representation and scientific rigor. However, the majority of this literature continues to use historical methods, such as radiographic appearance of reduction with arbitrary, inconsistent measurement cutoffs, and crude measures of lower extremity muscle strength.[5,39–41] Furthermore, the most commonly used disease-specific measure in these studies, the Merle D'Aubigne-Postel (DAP) hip score, was originally described for hip arthroplasty, and its modification by Matta has not been analyzed for validity, reliability, or responsiveness in these patients.[22,41] Only a moderate correlation was found between the modified DAP hip score and the SMFA, with the DAP having inadequate responsiveness with a significant ceiling effect. The next most commonly used disease-specific score is the Harris Hip Score, which is also from the post-traumatic hip arthritis population.[42] The Harris Hip Score has been validated in assessing outcome in acetabular fracture patients, but has also demonstrated ceiling effects, implying limited responsiveness.[43]

The generic SF-36 and SMFA scores have both been used in the context of pelvic and acetabulum fractures, but neither of them have received adequate investigation or psychometric testing, including that of responsiveness in these populations.[21] In the pelvic fracture literature, only 2 studies have used both in assessing function after pelvic fracture, and the relationship between them was not formally tested. Similarly, in a recent systematic review on functional outcome after acetabular fractures, only five of the 69 articles used either the SF-36 or SF-12 despite its widespread use in other populations, with no investigation into how it compares to the SMFA, which was only used in seven articles.[22] Some literature supports the use of both the SF-36 and SMFA in orthopaedic trauma patients since they measure different but complementary aspects of a patient's functional outcome. Recent studies, however, have shown the SMFA DI offering no significant psychometric advantages over the SF-36 PCS in patients with either operatively treated tibial shaft fractures or tibial plateau fractures.[44,45] Furthermore, the SF-36 PCS has been found to correlate with the more orthopaedic-specific SMFA DI and the physical function score of the Western Ontario McMaster Osteoarthritis questionnaire, and is clearly more responsive based both on the SRM and on the MCID than the SMFA DI or the Western Ontario McMaster Osteoarthritis PFS.[45] To our knowledge, however, this has not been formally assessed in patients with operatively managed pelvic or acetabulum fractures, who evidently represent a population in need of further guidance in the reporting of functional outcomes.

We have demonstrated that over the first year of recovery after sustaining a pelvic or acetabulum fracture, the SF-36 PCS is a more responsive measure of functional outcome than the SFMA DI, despite the theoretical advantage of a musculoskeletal-specific measure. This superiority was found in using the SRM, proportion of patients meeting MCID, and ceiling effects at 6 months (1.3%) and 12 months (3.3%). Furthermore, we found that the SF-36 PCS correlated with the more disease-specific SMFA DI. Given that there is no established standard for MCID for SF-36 and SMFA in pelvic and acetabular fracture patients, MCID was accepted as one-half of the standard deviation of improvement in score between 2 time points. Some would argue that the use of this method for calculation of MCID lacks certain clinical relevance; however, given the same method was used for both measures, and that the MCID findings fall in line with the other tests used here, the statistical relevance cannot be discounted. Our findings are in agreement with the conclusions from psychometric analyses of the SF-36 PCS and SMFA DI in operatively treated tibial shaft, tibial plateau, and tibial plafond fractures.[44–46]

Lack of complete follow-up was a limitation of this study. Of the 473 patients enrolled, 305 (64%) had complete data for both outcome scores at all time points, with the remainder of patients not included in the statistical analysis. This degree of loss-to-follow-up is commonly observed in trauma studies, given the tendency for a young, mobile patient population. This may also be a reflection of the respondent burden with regards to having patients complete both the SF-36 and SMFA questionnaires. Recall bias may be present given pre-injury recall was used for baseline functional outcome scores; however, preinjury recall has been shown to be accurately recalled up to 6 weeks after other orthopaedic surgeries including knee arthroscopy and total hip arthroplasty.[27–29]

Nonetheless, the findings of our study have significant research implications, given that the isolated use of the SF-36 PCS in these patients may be adequate to assess functional outcome while limiting the burden for both the patient and clinician, and maintaining adequate sensitivity to MCID. Similarly, Patient-Reported Outcomes Measurement Information System with computer adaptive tests may also be another strategy to improve functional outcomes reporting in this population, given that it has a short administration time and is also not likely to suffer from floor and ceiling effects.[47,48] Regardless, decreasing the time commitment required by patients to complete unnecessary questionnaires may also represent a feasible strategy to improve the loss of follow-up in future longitudinal outcome and comparative studies, which remains a particular challenge in trauma populations.[49] Our study offers further insight into the assessment of functional outcome after pelvic and acetabular fractures, which is an area that has clearly lacked scientific rigor.

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