SUPPLEMENTARY MATERIALS

Clinical Validation and Outcome Measures From Bend Ease: A Novel, Sensor-Based Digital Measurement Tool for Assessing At-Home Morning Stiffness and Spinal Range of Motion in Axial Spondyloarthritis

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Extended Methods

Sample Size Determination

The sample size calculation was based on an assumed concordance coefficient of 0.98 and a variance term of 0.96. To ensure the lower limit of the one-sided 95% confidence interval for the concordance coefficient would be at least 0.9, a sample size of 6 participants per cohort was initially determined. These concordance coefficient and variance term estimates were derived from a preliminary dataset comprising 7 healthy volunteers. To accommodate potential unobserved variations or deviations from the preliminary data, a final sample size of 30 participants per cohort was selected.

Video Tutorial for Bend Ease Application

The instructional script provided below was developed in collaboration with an advisory board of experts. Its objective was to guide study participants in effectively performing a modified Schober/Bath Ankylosing Spondylitis Metrology Index (BASMI) forward-flexion motion using their smartphones.

“Please stand with your feet shoulder-width apart. Hold the phone in both hands against your chest in landscape, or ‘wide’ position with the phone screen facing outwards. When you are ready to start your bend, press the button on the phone screen once, and continue holding the phone steadily against your chest. Then, safely and comfortably try to bend at your waist without moving your hips or bending your knees. Keep an even, steady pace and bend as if you are trying to pick up an item on the ground, but don’t bend so far forward that you lose your balance or experience pain. After the forward bend, safely and steadily come back up to a full standing position, and press the button on the phone screen once to indicate you have completed the task. Now, complete two more bends just like the first for a total of three bends. Thank you!"

Bend Angle Calculation With Bend Ease

The processing of accelerometry data followed methodology from our previous work [1]. During the signal processing procedure, the original signal was first cropped to select the region of interest. Then, the low-pass filter (frequency: 3 Hz, 4th order Butterworth filter) was applied to obtain a smoothed signal. After the flexion activity signals were pre-processed, the time series representing the beginning and ending accelerations were also identified according to two time points of button-pressed events. Alignment of the visual recording with the accelerometry signal revealed that the beginning of the flexion task occurs at the maximum of the accelerometry trace on z-axis while the ending is at the minimum. The gradient descent method was used to detect the flexion signals. Gradient descent was an iterative first-order optimization algorithm used to find a local minimum/maximum of a given signal. The local maximum gradient value indicated the start of the flexion activity, and the local minimum gradient value indicated the end of the flexion activity. Thus, we defined the flexion start signals and the flexion end signals as follows:

$$\overrightarrow{\mathrm{S_{Start}}} = \{\mathrm{S_i}, \mathrm{i} = 1, \dots, \mathrm{T}\}, \mathrm{S_i} \in [\mathrm{S_{Max}} - \nabla\partial, \mathrm{S_{Max}} + \nabla\partial]$$

$$\overrightarrow{\mathrm{S_{End}}} = \{\mathrm{S_i}, \mathrm{i} = 1, \dots, \mathrm{T}\}, \mathrm{S_i} \in [\mathrm{S_{Min}} - \nabla\partial, \mathrm{S_{Min}} + \nabla\partial]$$

where $\overrightarrow{S_{Start}}$ and $\overrightarrow{S_{End}}$ denoted the signal sequence, S_i was one time point signal, S_{Max} was the local maximum signal and S_{Min} was the local minimum signal detected by the gradient descent method, $\nabla\partial$ was the predefined range, and T was the length of the signal sequence. The signals in the range $[S_{Max} - \nabla\partial, S_{Max} + \nabla\partial]$ were marked as the flexion start signals, and the signals in the range $[S_{Min} - \nabla\partial, S_{Min} + \nabla\partial]$ were marked as the flexion end signals. The signals based on the local maximum and minimum values were denoted as the detected flexion activity for the next angle calculation.

Because the signal at each timepoint t could be denoted by using 3 channels value as $[x_t, y_t, z_t]$, the acceleration between two timepoint (e.g., t1and t2) signals could be vectorized as $[\overrightarrow{x_{t1}x_{t2}}, \overrightarrow{y_{t1}y_{t2}}, \overrightarrow{z_{t1}z_{t2}}]$. Then, the flexion angle would be between two vectorized acceleration signals. In our method, the flexion angle could be derived using the dot product (scalar product). Note that the angle between two vectorized flexion signals always falls within the range of 0° to 180°. In the feature extraction procedure to measure the flexion activity, the most commonly used method to find the angle between the vectors involved in the dot product, whereby: Let a be two vectorized signals and θ be the angle between them. In our method, a was defined as the mean vector of $\overrightarrow{S_{Start}}$ while b was defined as the mean vector of $\overrightarrow{S_{End}}$, i.e., $a = \overline{\overrightarrow{S_{Start}}}$ and $b = \overline{\overrightarrow{S_{End}}}$ .Then, by the definition of the dot product, $a \cdot b = |a|\,|b| \cos\theta$; this was then solved for cos θ by dividing both sides using |a| |b|.

$$\cos\theta = (a \cdot b) / (|a|\,|b|)$$

$$\theta = \cos^{-1} [\, (a \cdot b) / (|a|\,|b|) \,]$$

This was the formula for the angle between two vectorized signals in terms of the dot product (scalar product). Here, $\cos^{-1}$ was the inverse cosine function, and θ was the desired angle for the Bend Ease angle measurement.

Bend Angle Calculation With Video-Based Measurements

The pose estimation model was implemented through the MediaPipe Python API. MediaPipe is an open-source framework demonstrating high accuracy in detecting and tracking human body joints and landmarks from real-time video [2]. Shoulder and hip pose estimation landmarks from each video frame were captured. Right hip and right shoulder landmarks were used to calculate the bend angle. Assuming that $\mathrm{P}_\mathrm{t}^\mathrm{h}$ is the right hip position in the video frame of time t and $\mathrm{P}_\mathrm{t}^\mathrm{S}$ is the right shoulder position in the video frame of time t, a vector was established at timepoint t between the right hip and right shoulder landmarks in the video frame as $\overrightarrow{\mathrm{P}_\mathrm{t}} = \overrightarrow{\mathrm{P}_\mathrm{t}^\mathrm{h}\mathrm{P}_\mathrm{t}^\mathrm{S}}$. The forward-flexion angle between two timepoints (e.g., t1and t2) was derived from the two vectors $\overrightarrow{\mathrm{P}_{\mathrm{t1}}}$ and $\overrightarrow{\mathrm{P}_{\mathrm{t2}}}$. Similar to the accelerometry signal-based bend angle derivation method, the flexion angle could also be derived by using the dot product. If ϑ was the desired angle for the video-based bend activity measurement between two timepoints, t1and t2, then ϑ could be calculated as:

$$\vartheta = \cos^{-1} [(\overrightarrow{\mathrm{P}_{\mathrm{t1}}} \cdot \overrightarrow{\mathrm{P}_{\mathrm{t2}}}) / (| \overrightarrow{\mathrm{P}_{\mathrm{t1}}}| |\overrightarrow{\mathrm{P}_{\mathrm{t2}}}|)]$$

The maximal bend angle from the video was identified and used for comparative analysis with the accelerometry-based angle. To establish a baseline, we first recorded the position vector between the right hip and right shoulder landmarks while the participant stood in a straight, upright position. This served as a reference point for further measurements and comparisons. During each frame of the bend activity, a corresponding vector was established. Assuming n frames after the baseline ("standing straight") frame, bend angles were derived, i.e., $\{\vartheta_i, i = 1, \ldots, n-1\}$. Thus, the derived video-based bend angle was defined as the maximal value of the angles set, which could be denoted as $\vartheta_{video} = \max(\vartheta_i, i = 1, \ldots, n-1)$. The video-based angles were captured for each clinical visit and used as the reference angle.

Semi-Structured Exit Interview

Bend Ease does not return the results of each bend angle calculation to the user during the study; however, after completion of the 7-day study period, bend angle data were presented to the user to allow them to comment on the utility of the returned results during semi-structured exit interviews. The below guidance outlines instructions for interviewers on how to conduct these interviews. All interviews were recorded using a secure audio recording program and manually transcribed and subsequently examined by a team member to identify patterns or themes. Any discrepancies were reviewed by additional team members and resolved with input from the lead researcher. Additionally, consistent themes in participant feedback were identified using ChatGPT version 3.5 with the following prompt. "The documents provided contain feedback on a mobile application used in a study for patients with Ankylosing Spondylitis (AS). Please identify the key themes and quotes.”

Overall guidance for conducting interviews:

- While you are welcome to rephrase a question to help with their understanding, please do not "lead" their responses or "put words in their mouth."
- Probe, probe, probe! Please prompt patients with the following:
    - o “Can you tell me more about that?”
    - o “It’s whatever it means to you"—this one can be useful when patients ask for clarity around a question.
- Do not be afraid of silence—sometimes the silence is a person gathering their thoughts and we want to allow them the time they need to think.

Start of interview:

“Thank you for participating in this study. Now, I would like to ask you some questions about your experience in the study. Your responses will help us gain insight into how people feel about participating in the study, and this can help us design better studies in the future. Please answer each question honestly, and there are no right or wrong answers. We will also not share your responses in this interview with your doctor.

Before we get started – do you have any questions for me?” [pause to answer questions]

“I will be asking you questions in two main categories: the study itself and the iPhone app you used at home.

First, let’s talk about the study.”

Study questions:

1. Overall, what did you think about the study?

2. Is there anything the study team (such as the people who designed the study) could have done to make your experience better or easier?
3. You were asked to participate in the study for one week. What did you think about this length of time—was it too long, too short, just right?
4. Why did you decide to participate in this study?
5. Is there anything you want the study team to know?

Application questions:

"You were asked to use the iPhone app to do a variety of activities, such as bending movements and answering questions. This portion of the interview will focus on your experience with using the app."

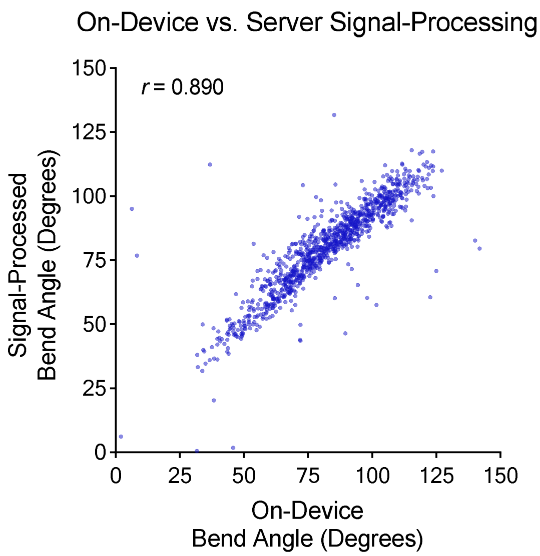
1. Overall, what do you think of the app?
2. Do you think the average person could understand and use the app easily?
3. At the end of your week using the app, it told you your bend angles captured by the app. Did you think this was helpful?
4. [Related to above] What other information about your study participation, if any, would you have like to have learned?
5. Imagine you had the ability to use the app on your own and share the results with your doctor, for example. Personally, would you use it?
6. Do you think people with conditions similar to yours might find this app useful?

References

1. Peters S, He T, Xing Y, et al. Actigraphy-Based Algorithm for Spinal Range of Motion Assessment for Axial Spondyloarthritis Patients. 2023 19th International Conference on Wireless and Mobile Computing, Networking and Communications (WiMob). 2023:24-9.

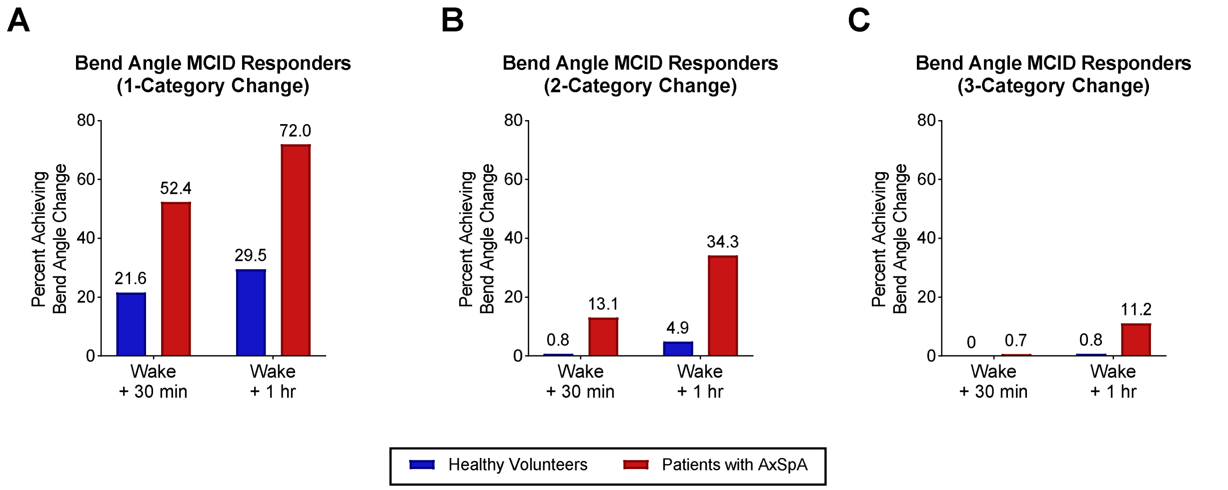
2. Kim J-W, Choi J-Y, Choi J-H. Human pose estimation using mediapipe pose and optimization method based on a humanoid model. *Applied Sciences* 2023;13.

Figure S1. Comparison of On-Device Versus Signal-Processed Signal With Bend Ease



A comparison between the ‘on-device,’ immediately calculated bend angle and the ‘backend’ signal-processed results. *r*, Pearson correlation coefficient.

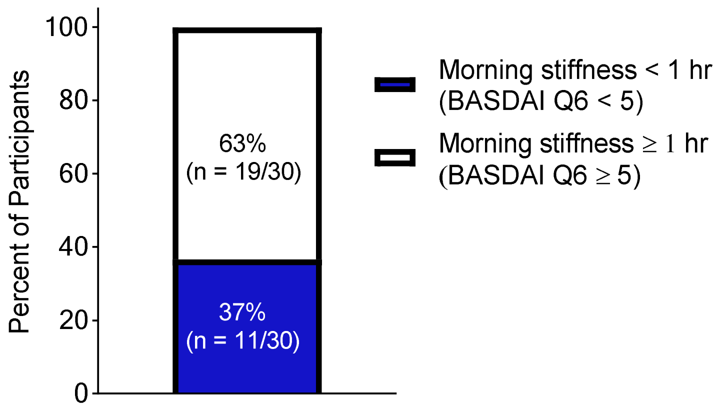
Figure S2. Analysis of Various Thresholds for Minimally Clinically Important Differences in Bend Angle



Proportions of participants in each group that experienced bend angle change MCID over time compared to the waking bend angle. In addition to our newly established MCID, which implements a change of 2 severity categories on the PGIS scale (panel **B**), the effect of using 1- and 3-category changes was also evaluated (panels **A** and **C**, respectively) on the proportion of participants experiencing the resulting MCID thresholds at 30 minutes and 1 hour after waking.

axSpA, ankylosing spondyloarthritis; MCID, minimal clinically important difference; PGIS, Patient Global Impression of Severity.

Figure S3. Proportion of Patients with Axial Spondyloarthritis Experiencing Morning Stiffness Duration of Above and Below 1 Hour



The proportion of patients with axSpA who responded to BASDAI Q6 ("How long is your morning stiffness") with a score of at least 5 or below 5. This score corresponds to a morning stiffness duration of 1 hour.
BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; Q6, question 6.

Table S1. System Usability Score Ratings From Bend Ease Study Participants

	Median (95% CI)
Day 1 total SUS score	92.5 (86.6–92.1)
Day 7 total SUS score	92.5 (87.4–93.6)
Usability sub-score	95.3 (86.2–93.0)
Learnability sub-score	100.0 (91.1–97.2)

The System Usability Scale (SUS) survey was completed by all study participants on clinic visit days 1 and 7 to assess the participants' perception of the usability of the Bend Ease application. The SUS survey is a short 10-item questionnaire (ranging from "strongly disagree" to "strongly agree") and overall scores ranged from 0 to 100, with higher scores indicating a higher level of usability and user satisfaction. The usability sub-score focuses on how users feel about their overall experience with the system, including factors such as ease of use. Learnability focuses on how quickly users can understand how the application works and its features, as well as how easily they can remember and use that knowledge when they interact with it again.

Table S2. Summary of Patients' Experiences With Bend Ease From Semi-Structured Interviews

Theme	Concepts	Selected comments
1. The app is user-friendly and easy to use.	The app was generally found to be user-friendly, simple to navigate, and straightforward in its instructions. Even users without much technology experience found the app easy to navigate.	“The app was easy to execute, instructions were clear, did not take much of my time, and was incredibly easy to use.” “I was trying to almost look for problems and couldn’t find any. I have 2 grandparents who are 90 years old, and I think they could use this.” “As a non-iPhone user, I thought the app was very easy to use. If I can use it, anyone can use it.”
2. Patients would share results with their doctors and feel empowered to communicate their symptoms more effectively.	Users found the app data very useful for medical consultations. They expressed that the objective data could illustrate their symptoms more accurately to their doctors as opposed to subjective reporting of symptoms, especially if the appointments were much later in the day when they felt less stiff. They believe this data could also be used to monitor the effectiveness of medications or treatments.	“Data is much more effective [to show my doctor] than asking for my pain or symptoms on a scale from 1 to 10 because that is one of my least favorite questions.” “My doctor’s appointments are usually in the afternoon, and by then, I usually feel pretty good. When they ask me to bend, it is not exactly how I feel in the morning.” “It would help me describe what’s going on to them with values rather than just [recalling] from memory. There’s a lot of doctors or people who think [we] are making it up or blowing [symptoms] out of proportion. It would help to see if patients need surgery based on the [bend] values.” “By the time you go to the doctor, you’re feeling better than you did in the morning. It’s easier to move around. The app lets them see the joint pain and stiffness at home in the morning.”
3. The app was perceived as a tool that could provide patients with a sense of control over their condition.	The app allowed them to track their progress, understand their condition better, and adjust their daily routines or treatment regimens based on the data. Seeing the bend angles provided users with objective data that confirmed their subjective feelings of stiffness, especially in the morning. This was a	“Going into the study, I would have thought that the bend angles would increase consistently throughout the day, but that was not the case. It depended on what I was doing that day [in the morning] and changed depend on doing work, getting my son ready, how I slept, level of activity throughout the day. It was interesting and surprising to see.” “I knew that I had certain time frame that I was stiff, but I didn’t know how much because I just sit on the couch and wait for it to pass. It was nice to see that I can check it and think, ‘Hm, 30 minutes is good.’ Now, when I get asked the question of ‘how long does your stiffness last?’, I can say ’45 minutes’ then I’m good.”

Theme	Concepts	Selected comments
	revelation for many users who had never realized the extent of their stiffness.	"I was diagnosed a year ago but probably had AS for 25 years. I like the idea of having control, and with AS it is a disease where you don't have control over anything. The app made me feel like I had some level of control by seeing my progression."
4. App as a Long-Term Tracking tool	Most users thought the app would be beneficial if used continuously, especially to capture symptoms between doctor's visits. Many expressed interest in continuing to use the app after the study.	"By the time I get to the doctor, months have gone by, and I can't remember what I felt during a bad episode or how bad it was. With the app, I can show them when it was and the severity during a bad day from two weeks ago." "That baseline data is so good to have. I'm 37 now and how I feel at 57 is going to be different. Being able to have that comparison is so useful. I wish I had this for comparison when I was 27 versus now. If this came out and I could download it on my phone, I would use it." "For conditions like I have, [doctors] try a lot of different medications. There's a lot of variety, and you're constantly trying to find the right one. Instead of just going by how you feel all the time, which can be clouded by different things, being able to have measurable data that shows 'as soon as I start X medication, my numbers changed by 10%' is helpful when working with your doctor."
5. App Improvement Features	Almost all participants suggested the addition of an in-app alarm or notification system to remind users of their next task or bending schedule. Some participants faced issues with notifications not appearing on time. Some users suggested improvements such as incorporating more intervals throughout the day, providing more context on what a "good" bend range is, and comparing their bend range to a normal person's or other patients with the same condition.	"My only suggestion would be to add an audible alarm because it created a lot of paranoia on my part in term of making sure I caught my window." "I suggest adding alerts for when you need to do next task. Jumping to personal phone to add an alarm was not as efficient." "The phone itself is slippery when holding it. I would suggest something to strap it to your chest like a GoPro camera or a phone case." "I believe there was a glitch in with how app tracks time. The daily activities and when the notifications show up was inconsistent." "…would suggest adding ability to measure range of motion in elbows, knees, hands." "…could be used even longer into the day. For me, my pain lasts 2 hours after waking up. I've been desperate for solutions, so [it would not be a burden] to spend an extra few minutes a day to do more intervals."

Semi-structured interviews were conducted with the axSpA cohort on the day 7 clinic visit. All interviews were recorded using a secure audio recording program. The interview questions were designed to assess the participants' views on the frequency and duration of the surveys, application rating scales, suggestions for additional features, and views on the usefulness of sharing results with physicians in clinical care. All interviews were manually transcribed, and consistent themes in participant feedback were identified using a large language model (ChatGPT version 3.5) with the following prompt. "The documents provided contain feedback on a mobile application used in a study for patients with Ankylosing Spondylitis (AS). Please identify the key themes and quotes."
AS, ankylosing spondylitis; axSpA, axial spondyloarthritis.