

P0320 Usability Study of a Smartphone-Based Calprotectin Home Test

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BACKGROUND

Inflammatory Bowel Disease (IBD) is a chronic inflammation of the gut presenting with phases of active inflammation, remission and relapses. IBD treatment goals are mucosal healing and persistent remission. Calprotectin measured in patients' stool samples is a well-established biomarker to measure the inflammatory activity in the gut. Periodical assessment of calprotectin levels is important to measure effectiveness of the treatment as well as predicting relapses. Until now this meant that patients send in their stool sample for laboratory analysis, leading to long time spans between sample collection and final test result. A newly developed calprotectin home test called IBDoc[®] ensures real-time information about the inflammatory activities in the gut for both, the patient and the clinician. The IBDoc[®] consists of a stool collection and extraction device (CALEX[®] Valve) and an immunochromatographic calprotectin rapid test, which is measured using a smartphone App (CalApp[®]) controlling the phone's camera. Once the test is measured the result is sent to a webserver (IBDoc[®] Portal) allowing the treating physician immediate access to the result.

METHODS

8 voluntary patients suffering from IBD and naïve to the IBDoc[®] system were trained by their IBD nurse to perform the test. The patients were then asked to perform a calprotectin stool test every other week over a period of two months by themselves at home using the IBDoc[®] system. The patients were asked to fill in a questionnaire after the first and the last test performed. The questionnaires were based on 5-point Likert scale questions concerning all steps of the test in respect of usability aspects. It also contained free commentary sections and system usability scale (SUS) score question. The SUS is commonly used for measuring and comparing the usability of software and integrated software systems.^[1]

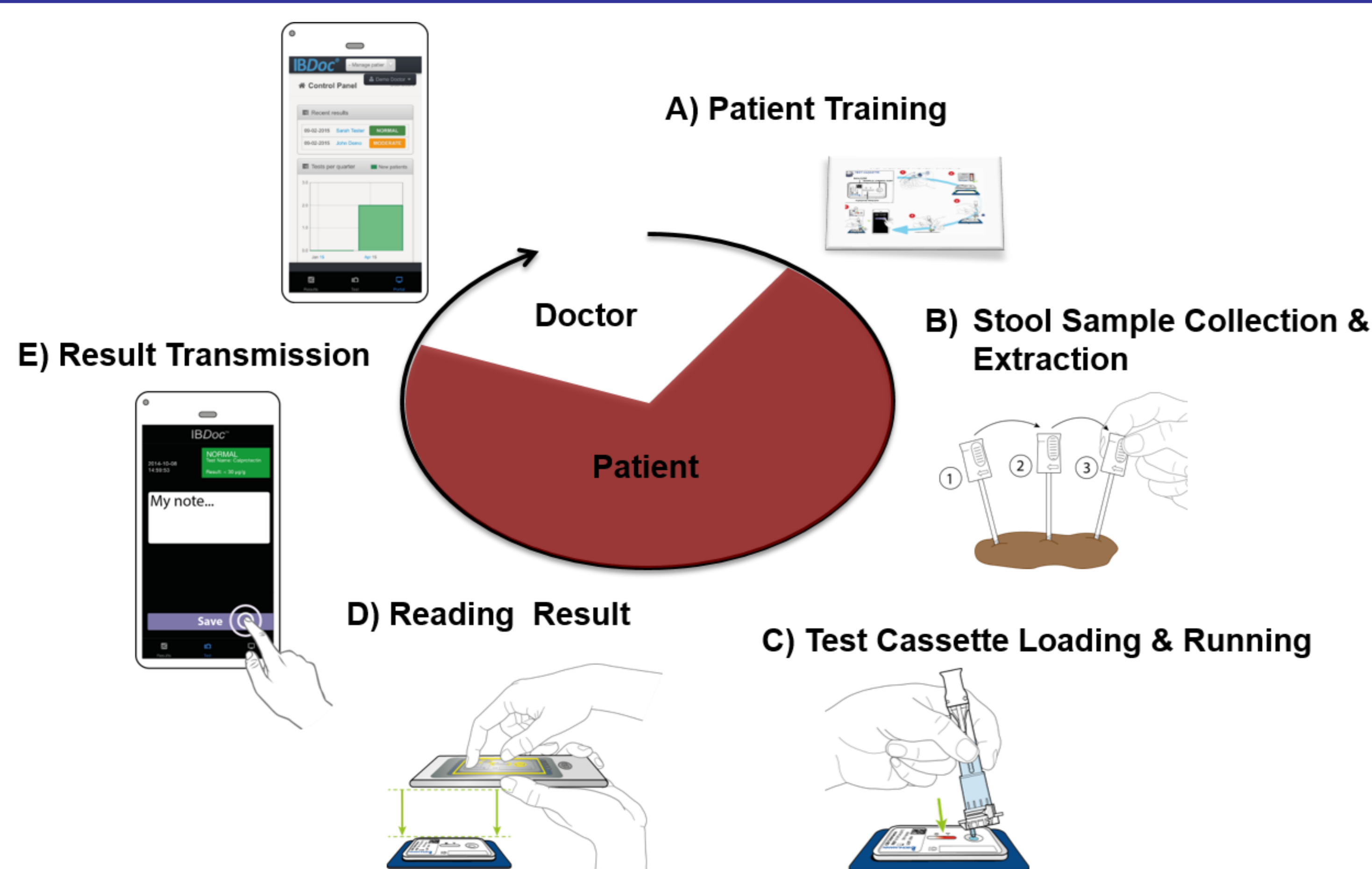


Figure 1 IBDoc[®] System Workflow (A) Patients are being initiated and trained by their clinic and receive the test kit to perform a calprotectin test at home. (B) The patient collects stool with the stool collection paper and takes a sample with the sampling pin of the CALEX[®] Valve device containing the extraction buffer. (C) A precise amount of stool sample extract is applied onto the immunochromatographic calprotectin test cassette. (D) After 12 minutes the test cassette is ready and a picture is taken with the CalApp[®] smartphone application. (E) The result is calculated by CalApp[®] and automatically sent via a secure internet connection to the IBDoc[®] Portal database, where it can be accessed and reviewed by the patient's treating physician.

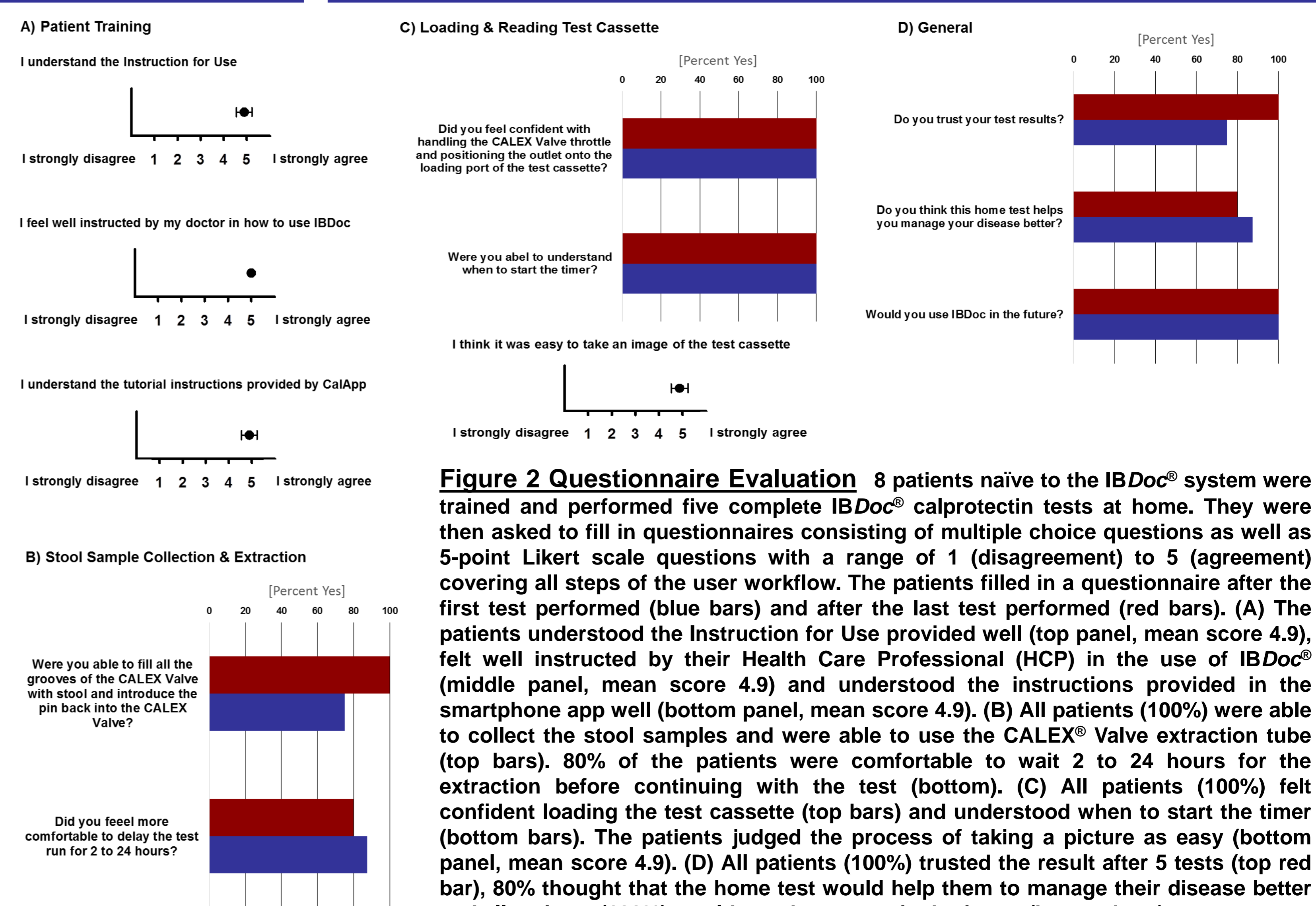


Figure 2 Questionnaire Evaluation 8 patients naïve to the IBDoc[®] system were trained and performed five complete IBDoc[®] calprotectin tests at home. They were then asked to fill in questionnaires consisting of multiple choice questions as well as 5-point Likert scale questions with a range of 1 (disagreement) to 5 (agreement) covering all steps of the user workflow. The patients filled in a questionnaire after the first test performed (blue bars) and after the last test performed (red bars). (A) The patients understood the instruction for use provided well (top panel, mean score 4.9), felt well instructed by their Health Care Professional (HCP) in the use of IBDoc[®] (middle panel, mean score 4.9) and understood the instructions provided in the smartphone app well (bottom panel, mean score 4.9). (B) All patients (100%) were able to collect the stool samples and were able to use the CALEX[®] Valve extraction tube (top bars). 80% of the patients were comfortable to wait 2 to 24 hours for the extraction before continuing with the test (bottom). (C) All patients (100%) felt confident loading the test cassette (top bars) and understood when to start the timer (bottom bars). The patients judged the process of taking a picture as easy (bottom panel, mean score 4.9) and understood the instructions provided in the smartphone app well (middle panel, mean score 4.9). (D) All patients (100%) trusted the result after 5 tests (top red bar), 80% thought that the home test would help them to manage their disease better and all patients (100%) would use the system in the future (bottom bars).

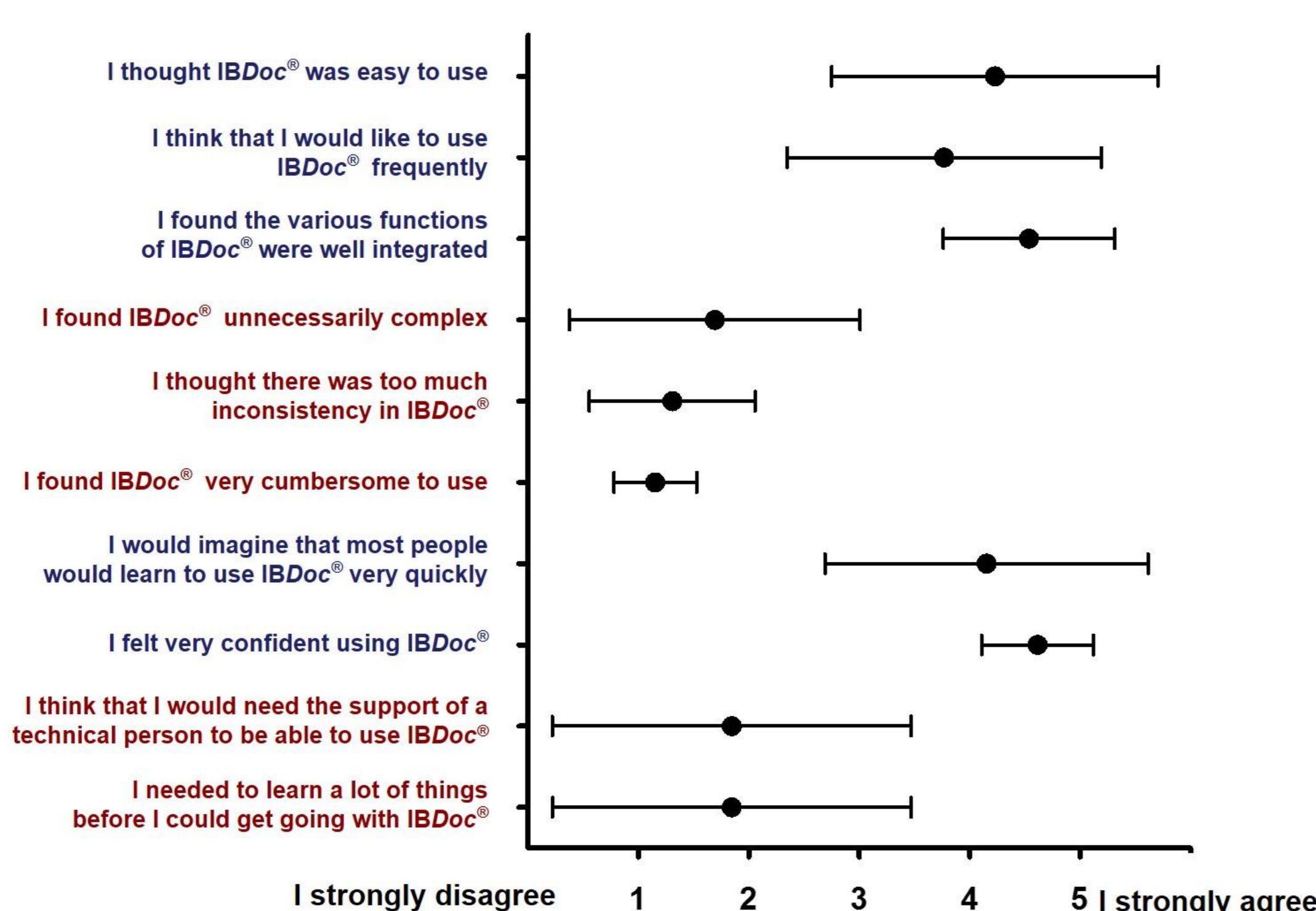


Figure 3 System Usability Scale Score 8 Patients naïve to the IBDoc[®] system were trained and performed five complete IBDoc[®] calprotectin tests at home. They were then asked to fill in a questionnaire consisting of multiple choice questions as well as 5-point Likert scale questions with a range of 1 (disagreement) to 5 (agreement). The patients filled in a questionnaire after the first test performed and after the last test performed. The questionnaire included in random order the 10 standardized questions of the System Usability Scale (SUS) to score the overall usability of the IBDoc[®] system. Depending on the question a positive response would be either shifted to the left (highlighted in red) or to the right (highlighted in blue). All the answers of the questionnaires after the first test were then used to calculate the mean score of all from all patients (n=8) of 93 on a scale from 0 (poor usability) to 100 (very good usability). After the last test the SUS score increased to 95 (data not shown).

RESULTS

All patients were able to perform using the IBDoc[®] home testing system during the course of the test period. All patients (100%) felt well instructed and the instructions for the test were well understood (4.9 on a 5-point Likert Scale). When asked how easy it was to measure the test cassette with the smartphone, the patients judged this question with an average score of 4.9 on a 5-point Likert scale. The test result was displayed by the smartphone app in a clear way with a traffic light interpretation and quantitative results within the measuring range of 30-1000 µg/g of calprotectin. All patients felt confident in handling the physical test components as well as the smartphone app. All patients would use the IBDoc[®] system in the future (100%) and 87% of the patients felt that the home test helps them to manage their disease better. The IBDoc[®] system reached a mean SUS score of 93 on a scale from 0 to 100. This SUS is well above the software industry's average score of 68.^[2] When asked if they trusted the result, 75% of the patients answered with yes after the first test compared to 100% after last test.

CONCLUSIONS

This study shows that calprotectin home testing using a smartphone as measuring system was well accepted among IBD Patients. The complexity of the application is low, the entire IBDoc[®] system can be considered very user-friendly and is easy to handle by lay users without prior knowledge or experience with stool extraction and immunochromatographic rapid tests.

References:
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² Sauro, J., & Lewis, J. R. (2012). Quantifying the user experience: Practical statistics for user research. Morgan Kaufmann, Waltham MA, USA.

Disclosure:
In relation to this presentation, I declare the following, real or perceived conflicts of interest:
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