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Ultrasound joint examination by an automated system versus by a rheumatologist: from a patient perspective

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Abstract

Background: The Arthritis Ultrasound Robot (ARTHUR) is an automated system for ultrasound scanning of the joints of both hands and wrists, with subsequent disease activity scoring using artificial intelligence. The objective was to describe the patient's perspective of being examined by ARTHUR, compared to an ultrasound examination by a rheumatologist. Further, to register any safety issues with the use of ARTHUR.

Methods: Twenty-five patients with rheumatoid arthritis (RA) had both hands and wrists examined by ultrasound, first by a rheumatologist and subsequently by ARTHUR. Patient-reported outcomes (PROs) were obtained after the examination by the rheumatologist and by ARTHUR. PROs regarding pain, discomfort and overall experience were collected, including willingness to be examined again by ARTHUR as part of future clinical follow-up. All ARTHUR examinations were observed for safety issues.

Results: There was no difference in pain or discomfort between the examination by a rheumatologist and by ARTHUR ($p = 0.29$ and $p = 0.20$, respectively). The overall experience of ARTHUR was described as very good or good by 92% (n = 23), with no difference compared to the examination by the rheumatologist ($p = 0.50$). All (n = 25) patients were willing to be examined by ARTHUR again, and 92% (n = 23) would accept ARTHUR as a regular part of their RA clinical follow up. No safety issues were registered.

Conclusions: Joint ultrasound examination by ARTHUR was safe and well-received, with no difference in PRO components compared to ultrasound examination by a rheumatologist. Fully automated systems for RA disease activity assessment could be important in future strategies for managing RA patients.

Trial registration: The study was evaluated by the regional ethics committee (ID: S-20200145), which ruled it was not a clinical trial necessary for their approval. It was a quality assessment project, as there was no intervention to the patient. The study was hereafter submitted and registered to Odense University Hospital, Region of Southern Denmark as a quality assessment project and approved (ID: 20/55294).

Keywords: Rheumatoid arthritis, Artificial intelligence, Robotics, Automated ultrasound scanning, Patient reported outcomes

Background

Rheumatoid arthritis (RA) is a common systemic inflammatory disease that untreated, can lead to joint destruction and severe disability. Early diagnosis and effective disease monitoring is essential for long term remission

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and to reduce the risk of permanent joint damage [1]. RA affects around 0.5–1.0% of the population and reduces the quality of life and work capacity [2].

RA is a significant challenge for the health care sectors worldwide due to population growth, ageing, and lack of personnel specialised in rheumatology [1, 3, 4]. In the United States alone, by 2040, the number of patients suffering from arthritis disease is projected to increase by 49%, affecting 78.4 million patients [3]. At the same time, by 2030, rheumatology providers (physicians, nurse practitioners and physician assistants) will decline in the United States by 25% [4]. Another risk for RA patients is the high inter- and intra-observer variability in clinical joint assessment (joint palpation) [5]. Further, in a study across 17 European countries including about 600 rheumatologists, only 14% of the rheumatologists reported performing a formal joint count at each visit of each RA patient [6].

Due to the combination of all these challenges, there is an urgent need to develop new strategies for early disease detection and objective timely monitoring for all RA patients [3]. Therefore, ultrasound has become a useful clinical tool in many rheumatological clinics. Ultrasound examination of joints can detect RA earlier than clinical joint examination, and in established RA patients predict radiographic progression and disease flare [7–9]. In suspected arthritis patients, ultrasound may reduce the time to final diagnosis and number of needed hospital visits [10]. In addition, systematic ultrasound scanning of the hands and wrists in RA patients can be used to detect subclinical disease, monitor treatment response and monitor remission in established RA [11–15].

Joint ultrasound scanning is often criticized for being operator-dependent which improves with training and with developed consensus-based and validated ultrasound definitions and scoring systems for synovial hypertrophy and Doppler activity [16, 17]. However, many departments do not acknowledge the time needed for training and performing the ultrasound examination in routine care. Furthermore, the intra- and inter-observer variability in image acquisition and interpretation of disease activity is also an issue [5, 18]. In addition, a lack of qualified rheumatologists able to perform ultrasound may result in suboptimal patient assessment. This can also lead to increased waiting lists for ultrasound assessment, affecting the effectiveness of both the patient and the hospital.

These issues challenge the current and future use of ultrasound for diagnosing and monitoring RA patients and potentially other arthritis conditions. A strategy to address these challenges could be implementing new technologies in arthritis patients' assessment, such as robotics and artificial intelligence (AI). An arthritis ultrasound robot (ARTHUR) has been developed (Fig. 1), combining the two fields.

ARTHUR is an automated imaging platform designed to perform ultrasound examinations of the hand and wrist joints. ARTHUR guides the patient using audio and screen instructions throughout the ultrasound examination. The platform automatically detects the joints of the patients' hands when placed on the screen and then moves a robotic arm with an ultrasound probe over each joint—one at a time (Fig. 1B–H). ARTHUR takes both a grey scale and Doppler ultrasound images of each joint. ARTHUR uses convolutional neural networks (CNN) to assess disease activity on the joint ultrasound images. Disease activity is assessed on both the greyscale and Doppler images, by separate CNN´s. CNN's have been established as the state-of-the-art approach for automatic image recognition and analysis. ARTHURS Doppler CNN's have a high sensitivity and specificity, compared to expert disease activity assessment (ground truth) [19, 20]. An example of grey scale ultrasound image of the same joint by respectively ARTHUR and the rheumatologist is shown in Fig. 2.

This study investigates the patients' perspective of having an ultrasound examination performed by ARTHUR compared to an ultrasound examination by a rheumatologist.

Methods

The aim was to describe the patient's perspective of being examined by ARTHUR, compared to an ultrasound examination by a rheumatologist. Further, to register any safety issues with the use of ARTHUR.

Patients

Patients were included from the Department of Medicine, Section of Rheumatology, at Svendborg Hospital—Odense University Hospital. Patients were eligible for inclusion if they had RA, defined by the 2010 EULAR/ACR RA classification criteria, and were at least 18 years of age. The study is an observational cross-sectional study. Participants were identified using consecutive screening and enrollment, based on time for the patients planned regular RA activity assessment visit. Using this method, patients with planned time in the outpatient clinic, on the days where ARTHUR was installed, could thereby be enrolled in the study. The patient was first examined by ultrasound by a rheumatologist, then ARTHUR. All participants signed informed consent. Exclusion criteria were RA with severe joint destruction.

The study was initially evaluated by the regional ethics committee (ID: S-20200145), which ruled it a quality assessment project. There was no intervention in the study, so ethical approval was not needed. The study

Fig. 1 **A** The rheumatologist performs the first ultrasound examination. **B** The ARTHUR system used in this trial used a GE Logiq 10 ultrasound scanner. **C** The patient scans their ID card and receives instructions by both audio and on the touchscreen on how to proceed. **D** The patient places ultrasound gel on one hand. **E** ARTHUR starts to ultrasound scanthe patient. ARTHUR instructs the patient when its time to remove the gel and place ultrasound gel on the other hand. **F** ARTHUR scans the wrist joint, see also Fig. 2. **G** ARTHUR ultrasound scans a PIP joint. **H** ARTHUR ultrasound scans MCP 1

was hereafter submitted to Odense University Hospital, Region of Southern Denmark as a quality assessment project and approved (ID: 20/55294). A data user and data handling agreement regarding this study between OUH and ROPCA Holding were signed 4/12-2020. The Danish Medicine Agency evaluated ARTHUR as not to be applied as a new medical device, as all parts are CE approved and used as approved (Danish Medicines Agency (Lægemiddelstyrelsen), Ref.: 2017123702).

Ultrasound examinations

Rheumatologist

The rheumatologist used a GE Logiq 10 ultrasound scanner with an ML-6-15 probe from GE (GE Healthcare, Chicago, USA) for the ultrasound assessment of hands and wrists bilateral. The patients were seated with their hands resting on an examination bed (Fig. 1A). The ultrasound examination followed the EULAR guidelines [21].

ARTHUR

ARTHUR is a system developed first as a University of Southern Denmark (SDU) and Odense University Hospital (OUH) project, then developed into a company called ROPCA Holding (Odense, Denmark). The version of ARTHUR used in this trial (Fig. 1B) is composed of; (1) A table with a touch screen where the hands are placed. (2) A camera to detect the individual joints of the hand. (3) A clinically approved (IEC 60601-1 and IEC 62304) robotic arm (Model: LBR Med 7 R800, Kuka Robotics, Augsburg, Germany). (4) With an attached ML-6-15 probe from GE (GE Healthcare, Chicago, USA) connected to a GE Logiq 10 scanner to record ultrasound images of the joints (Fig. 1E–H). (5)

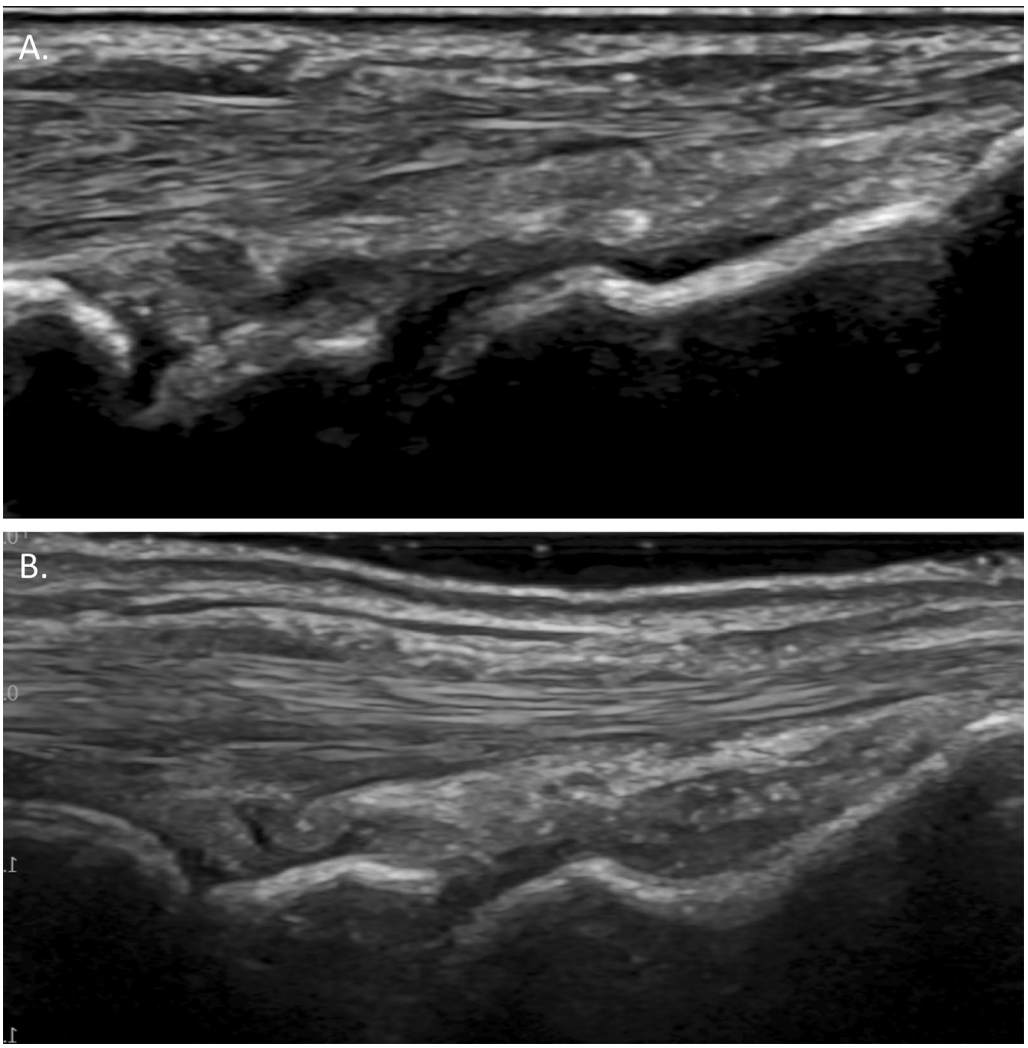

Fig. 2 Representative grey scale ultrasound image of the wrist (radiocarpal and intercarpal joint) from the same patient by respectively ARTHUR (**A**) and the rheumatologist (**B**)

The system used a CE approved AI system, DIANA, to score RA disease activity on Doppler ultrasound images. (6) Through audio and instructions on the touch screen, the patient is guided through the process. (Fig. 1C). The patient is instructed how to apply and remove ultrasound gel in this process, one hand at a time (Fig. 1D). All examinations were observed for any safety issues.

Patient-reported outcomes (PRO)

Questionnaires were obtained after scanning by the rheumatologist and after examination by ARTHUR and were related to the patients' view of the examinations (Respectively Survey 1 and 2, see Additional file 1).

PRO data collected after examination by the rheumatologist

Gender and age were noted. Next, the patient was asked about the mood before arriving at the department (Angry, Surprised, Afraid, Sad, Expectant, Happy and Comfortable), the experience with the doctor (ranging from Good to Could have been much better with a possibility to elaborate on the answers in the free text box). The mood after the examination was then assessed (same categories as before the examination) followed by a question regarding pain during examination with ten discrete values from 0 (no pain) to10 (max pain). A follow-up question was asked to identify in which joint the pain was felt. Finally, the patient was asked about discomfort on the same 0 to 10 discrete scale followed by a question related to concerns of having an

examination by ARTHUR(with five possibilities ranging from Completely unconcerned to Very concerned).

PRO data collected after ARTHUR examination

Experience, mood, pain and discomfort with ARTHUR was assessed on the same scales as after the rheumatologist. Then came a series of 6 statements regarding (Entertained, Excited, Relaxed, Freedom, Satisfied, and Confidence) during the ARTHUR examination. Each with four answer possibilities ranged from Strongly Agree to Strongly Disagree. Then came two questions on what is essential for the patient when ultrasound scanned. The patient could choose more than one answer, e.g., the ultrasound scan is fast and the doctor's presence (see Additional file 1 for all answer possibilities). Then came a question regarding sufficient patient information before ARTHUR scanning. Then came six questions, all with three answer possibilities on the graphical user interface (GUI) of ARTHUR, asking if it was clear, understandable, informative, readable, and on the colors applied. Then came two questions on the need for more entertainment during the scanning and what it should be. Then on if ARTHUR should move faster, and after that, something else should be changed in the scanning process. The last two questions were on willingness to be examined by ARTHUR again and if they would accept to be scanned by ARTHUR as a part of their future RA follow-up.

Statistics

All PRO data was collected on questionnaires as categorical data. Pain and discomfort evaluations described discrete values from 0 to 10, not continuous scales. PRO data is paired, as it was the same patient, first assessed by the rheumatologist and then by ARTHUR. Statistical comparison was performed applying the marginal homogeneity test (Stuart–Maxwell test). STATA (StataCorp, Texas, USA) Version 17 was used for analysis, and p values < 0.05 were significant.

Results

Twenty-five RA patients were included in the study. Three patients were asked to participate but declined due to lack of time. Patients and disease characteristics are presented in Table 1.

In the following, the PRO data collected is presented, comparing the experience of the rheumatologist scanning and ARTHUR.

Safety

No safety issues occurred during the trial.

Table 1 Baseline characteristics

Characteristics	Patients
Patients, n	25
Age (SD)	63,7 (12,22)
Female, n (%)	17 (68%)
Erosive disease, n (%)	10 (40%)
RF and/or CCP-positive, n (%)	17 (68%)
DAS28CRP (SD)	2.8 (1.2)

CRP, C-reactive protein; DAS28CRP, Disease Activity Score in 28 joints combined with CRP value, RF, Rheumatoid factor antibody, CCP, cyclic citrullinated peptide antibodies

Mood

After rheumatologist examination, the patient's mood descriptions were positive (8% Expectant, 40% Happy and 52% Comfortable) and remained so after ARTHUR scanning (68% Happy and 32% Comfortable).

Overall experience

A comparison of the overall experience with being scanned by a rheumatologist versus ARTHUR is shown in Fig. 3. The overall experience of an examination by the rheumatologist was described as very good or good by 96% (n = 24) versus 92% (n = 23) for ARTHUR. There was no significant difference in overall evaluation comparing rheumatologist and ARTHUR examination ($p = 0.50$).

Pain and discomfort

Next, the patients' pain and discomfort during the examination by the rheumatologist and ARTHUR, respectively, were investigated. The results are shown in Fig. 4.

The concern before the ARTHUR scanning

The patients' concern about being scanned by ARTHUR before the examination is shown in Fig. 5.

This shows that the majority of patients (84%, n = 21) were either completely unconcerned or unconcerned about being scanned by ARTHUR, while two were neither unconcerned nor concerned (8%) and two (8%) were concerned.

Patients experience during ARTHUR scanning

Regarding experiencing the scanning as entertaining, 84% answered strongly agree or agree, while 12% disagreed and 4% strongly disagreed. 64% found it exciting to be scanned (either strongly agrees or agree), while 36% did not (strongly disagree or disagree). 92% found the experience relaxing, while 8% did not agree with this statement. 64% agreed that the possibility of scanning by ARTHUR gave them more freedom, while 36% did not agree. 76%

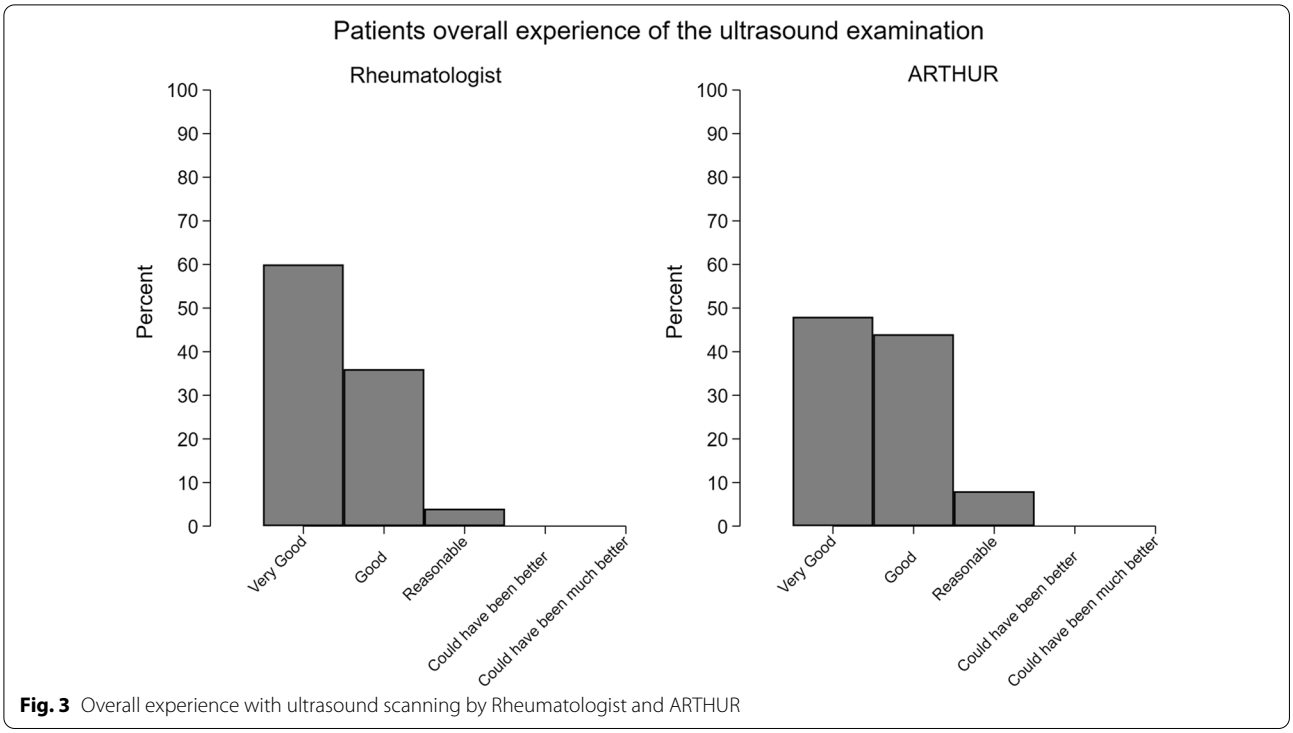

Fig. 3 Overall experience with ultrasound scanning by Rheumatologist and ARTHUR

agreed that ARTHUR joint scanning gave them a satisfying feeling, while 24% disagreed. Finally, 88% felt confident after ARTHUR scanning, while 12% did not agree with this statement.

Overall, the patients evaluated the scanning by ARTHUR positively based on the assessment of the described statements. Of the statements of what's most important for you when using ARTHUR, the top 4 was: It results in I receive good treatment, I feel there is time for it, there is a good atmosphere, and I know I get a consistent scanning (for a complete list, please see Additional file 1: Survey 2).

Graphical user interface

All patients wrote that they received necessary information during the examination by ARTHUR.

Here, 92% of the participants found the GUI design clear, and 96% found the GUI to be understandable. Furthermore, 96%of the participants found that the GUI had a readable text size and font. Finally, 88% found the colours to be attractive. One of the three comments elaborating on the above was that the patient wanted an interpretation of the scanned images in real-time.

84% of the patients did not want entertainment during scanning, while 12% wanted the possibility of audiobooks, and 4% wanted other types of entertainment not defined.

Ninety-six% of the patients wanted ARTHUR to scan them faster. However, regarding changing the way ARTHUR scans, 84% would not change it while 16% would. Here there were four comments, where three mainly focused on changing the way ARTHUR moved the probe while one wanted the audio volume increased. Asked if ARTHUR performed better scans than the rheumatologist, 64% of the patients said they did not know, while 32% answered no and 4% yes.

Future use of ARTHUR

Patients' willingness to be examined by ARTHUR again and accept ARTHUR as a part of future RA control visits are shown in Fig. 6.

All the participating RA patients were willing to be examined by ARTHUR again. It was also investigated the patients view on whether ARTHUR could become a permanent part of their rheumatological follow-up here 92% (n = 23) of the RA patients would find this acceptable.

Discussion

We have presented results showing, to our knowledge, the first data on the rheumatological patient's perspective on interacting with a fully automated ultrasound system.

When developing automated examination systems, the patient's safety during examination is essential. The robot arm used in the ARTHUR system is the LBR Med 7 R800 from Kuka Robotics. It is approved for use in the clinical

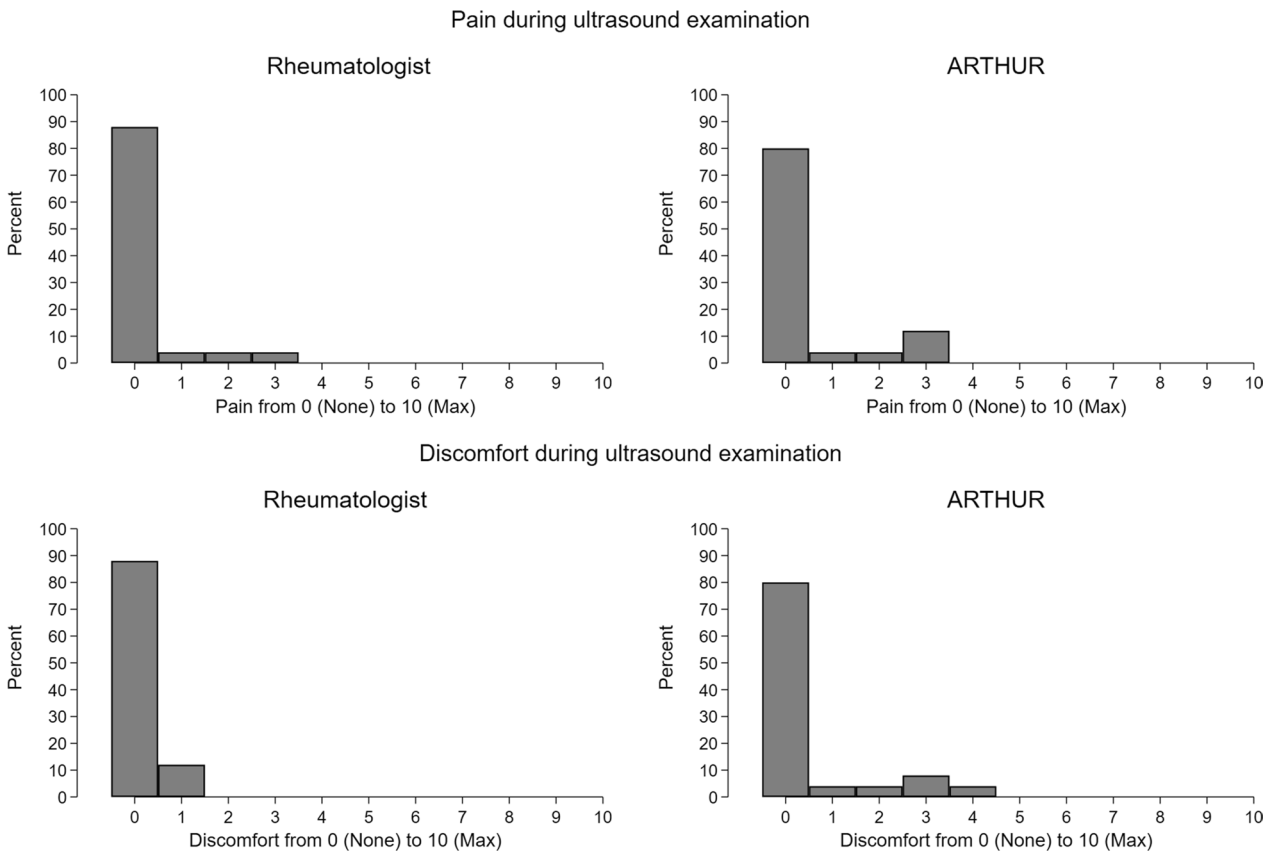

Fig. 4 Comparing pain and discomfort by examination by respectively rheumatologist and ARTHUR. There was no difference in pain or discomfort between examination by a rheumatologist and by ARTHUR ($p = 0.29$ and $p = 0.20$, respectively). For details on which joint is affected by pain or discomfort, please see Additional file 1: Survey 1 and 2

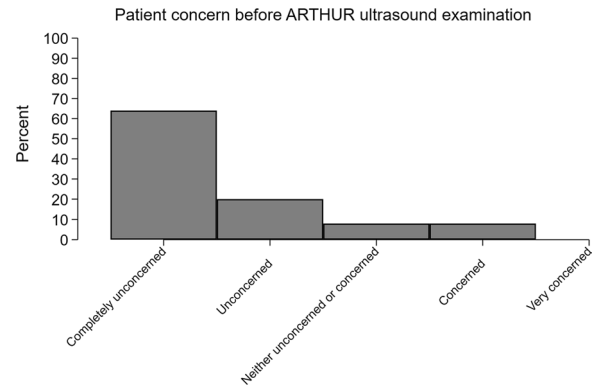

Fig. 5 Patients concern about being scanned by ARTHUR before the examination

setting (IEC 60601-1 and IEC 62304 certified) and has several built-in safety measures. These include force/torque sensor systems so that if ARTHUR meets unsuspected resistance in a movement, it will immediately stop. Also, ARTHUR is configured only to apply a low pressure when performing an ultrasound examination.

The system also has a stop button, clearly visible for the patient, that, if pressed, returns ARTHUR to its starting position. This study found no safety issues in the interaction between patient and ARTHUR, as all examinations were unproblematic. Automated clinical systems should always have a healthcare professional nearby if the patient has questions or concerns.

Several factors affect the reporting of PRO data, e.g. the patients age, length of education, cultural background, and how data is collected in a trial [22]. The age of our participants had a mean of 64 years, which we find to represent the RA patients mean age in general. Whether PRO data from much younger or older RA patients are in line with the findings in our study needs to be assessed in future studies.

Another factor affecting PRO data is the patient's mood before the intervention. For example, patients may be more likely to report negative content when in a negative mood, potentially introducing bias [23]. In addition,

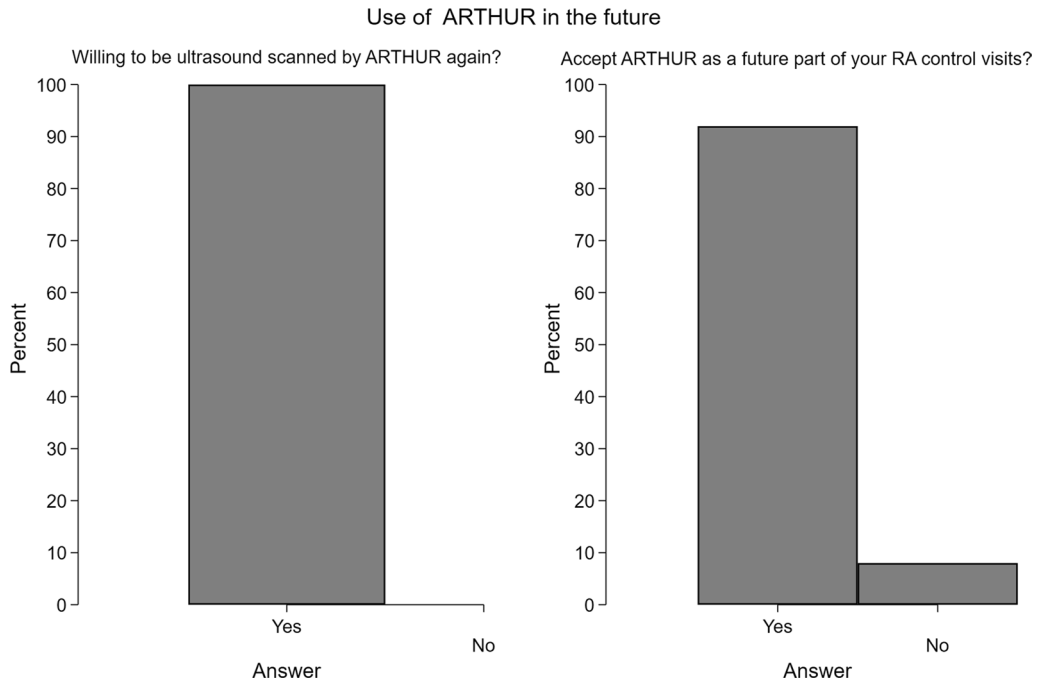

Fig. 6 Patient's willingness to be ultrasound scanned by ARTHUR again and accept ARTHUR as part of future RA control visits

patients and professionals' acceptance of innovative medical technology relies on understanding their anxieties and feelings of insecurity [24]. Therefore, we also included questions regarding mood and concerns in this study when assessing ARTHUR.

The patient's mood was overall positive before and after the rheumatologist and ARTHUR examination, so we do not think this factor has affected the other PRO data. The majority were unconcerned when assessing concerns before ARTHUR evaluation, while 8% were concerned and 0% very concerned. Although this latter group is a minority, it is crucial to describe this group in future studies further. What are the concerns, and do these patients have characteristics to be identified before scanning and possibly receiving further information and guidance. In this study, the patient was first scanned by a rheumatologist and then by ARTHUR. We do not know how it would affect PRO data in this trial, if this was reversed, or the ultrasound scanning was done only by ARTHUR. Continues collection of PRO data when ARTHUR is used in the clinic or in trials is therefore essential to confirm the findings in this trial.

The assessment of the overall experience was evaluated positively after both examinations, with no significant difference. However, the question is how much the study setup has affected this evaluation. The patient was not alone with the robot, as there was an observer, so social interaction was possible. This aspect can be further evaluated in future trials, where ARTHUR is used without an observer. Nevertheless, the evaluation of the overall experience with ARTHUR was very positive. It is important to note that the patients are familiar with the assessment by the rheumatologist but have never experienced a fully automated system before. A part of the overall evaluation is also the scores of pains and discomfort during the two examinations. Here there was no significant difference between the rheumatologist and ARTHUR. Although not significant, it should be noted that there was an evaluation of scores 2, 3 and 4 on the discomfort scale by ARTHUR, not expressed after the examination by the rheumatologist. This could be because the patient must have the arm in the same position during ARTHUR scanning, while under rheumatologist examination, it is possible to adjust the position somewhat. The data collected will further develop ARTHUR for a more comfortable positioning during scanning. The point that there was no significant difference in pain or discomfort is an important finding, as it shows that automated joint ultrasound scanning is possible from a patient's perspective.

Patients found the GUI and information received during scanning clear, and the majority of patients did not find a need for entertainment during the examination.

All patients were willing to be scanned by ARTHUR again, and the majority (92%) would accept ARTHUR as part of their future RA follow up. Therefore, future trials

with ARTHUR should again focus on the 6% that did not, their reason for this. This could be interesting from a developmental viewpoint and give more knowledge on implementing new technologies for RA patients.

The study has limitations. One is the small cohort (n = 25). Important data not collected was the length of education, comorbidity, degree of disability and disease duration. These data could give further insights into their view on both examinations by rheumatologists and ARTHUR. Also, adding what the patient thinks of the possibility of ultrasound examination when it suits the patient.

Automated imaging systems for screening and/or disease activity assessment are being developed within several specialities, including ophthalmology and oncology [25, 26]. Patient involvement is essential in all phases of the development of these systems [24].

Conclusion

To our knowledge, ARTHUR is the first system that performs fully automated ultrasound scanning of arthritis patients. Here RA patients have been a part of the development process and, in this trial, deliver the first feedback on using it in an outpatient clinic.

In conclusion, this is the first study to assess the use of an automated ultrasound system in a rheumatologic outpatient clinic from the patients' perspective. ARTHUR was well received by the patients, and no safety concerns were identified. However, future studies are needed to validate these findings and the role of automated systems in future RA screening and monitoring strategies.

Abbreviations

ARTHUR: The Arthritis Ultrasound Robot; RA: Rheumatoid arthritis; PROs: Patient-reported outcomes; AI: Artificial intelligence; CNN: Convolutional neural networks; GUI: Graphical user interface; CRP: C-reactive protein; DAS28CRP: Disease Activity Score in 28 joints combined with CRP value; RF: Rheumatoid factor antibody; CCP: Cyclic citrullinated peptide antibodies; PIP: Proximal interphalangeal joint; MCP: Metacarpophalangeal joint.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s42358-022-00263-2.

Additional file 1. Additional PRO data.

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Author contributions

All authors have contributed substantially to the process of completing this study, specified as follows: Conception of the study: SAJ, LT, HLI, TRS. Designing the study: SAJ, TRS, LT, HLI, MS. Aggregation of data: BF, MS. Statistics: SAJ, MS Interpretation of data: SAJ, BF, MS, LT, HLI. Drafting and revising, final approval, and agreement to be accountable: All authors. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request. Ultrasound images are not available for sharing.

Declarations

Ethics approval and consent to participate

All patients signed informed consent to participate. The study was first evaluated by the regional ethics committee (ID: S-20200145), which ruled it was not necessary for their approval. It was a quality assessment project where there was no intervention to the patient. The study was hereafter submitted to Odense University Hospital, Region of Southern Denmark as a quality assessment project and approved (ID: 20/55294). A data user and data handling agreement regarding this study between OUH and ROPCA Holding were signed 4/12-2020. The Danish Medicine Agency evaluated ARTHUR as not to applied as a new medical device, as all parts are CE approved and used as approved (ID: 2017123702).

Consent for publication

Not applicable.

Competing interests

Employees of Ropca Holding were not involved in data analysis or in developing conclusions based on data. SAJ and TRS are cofounders of Ropca Holding. SAJ and TRS have received no salary or consultant fees from Ropca Holding.

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