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Original article

Reporting items for capillaroscopy in clinical research on musculoskeletal diseases: a systematic review and international Delphi consensus

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Abstract

Objectives. The level of detail included when describing nailfold videocapillaroscopy (NVC) methods varies among research studies, making interpretation and comparison of results challenging. The overarching objective of the present study was to seek consensus on the reporting standards in NVC methodology for clinical research in rheumatic diseases and to propose a pragmatic reporting checklist.

Methods. Based on the items derived from a systematic review focused on this topic, a three-step web-based Delphi consensus on minimum reporting standards in NVC was performed among members of the European League against Rheumatism (EULAR) Study Group on Microcirculation in Rheumatic Diseases and the Scleroderma Clinical Trials Consortium.

Results. A total of 319 articles were selected by the systematic review, and 46 items were proposed in the Delphi process. This Delphi exercise was completed by 80 participants from 31 countries, including Australia and countries within Asia, Europe, North America and South America. Agreement was reached on items covering three main areas: patient preparation before NVC (15 items), device description (5 items) and examination details (13 items).

Conclusion. Based on the available evidence, the description of NVC methods was highly heterogeneous in the identified studies and differed markedly on several items. A reporting checklist of 33 items, based on practical suggestions made (using a Delphi process) by international participants, has been developed to provide guidance to improve and standardize the NVC methodology to be applied in future clinical research studies.

Key words: nailfold capillaroscopy, reporting standard, consensus, musculoskeletal diseases, connective tissue disease

CLINICAL SCIENCE

Rheumatology key messages

- This study identified three overarching areas for reporting capillaroscopy: patient preparation, device description, examination details.
- This international consensus will improve the harmonization of capillaroscopy reporting in future research studies.

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Introduction

Nailfold videocapillaroscopy (NVC) is a safe non-invasive investigation for assessing structural microvascular abnormalities. NVC is being increasingly incorporated into rheumatology research and clinical practice as both a valuable diagnostic and prognostic tool [1].

Since the early descriptions of its predictive and prognostic value in scleroderma-spectrum disorders, NVC is constantly gaining ground internationally. Nowadays, NVC is widely used in European countries [2], while it is available to only a small minority of the scleroderma centres in the USA [3]. An international survey suggested NVC as the gold standard capillaroscopy technique for assessing RP and found that most clinicians are familiar with it [2]. Moreover, NVC is now part of the EULAR/ACR classification criteria for the very early diagnosis of SSc [4, 5].

The increasing number of scientific publications and the significant developments in NVC technology document its mainstream use, and NVC has been introduced as mandatory in the rheumatology fellow curriculum in Europe and USA [6].

NVC is a highly operator-dependent imaging tool, thus methodological standardization is desirable for NVC applicability in both everyday practice and clinical research. This has been a core mission of the EULAR study group on microcirculation in rheumatic diseases (SG MC/RD) since its inception in 2015 [7–9]. The EULAR SG MC/RD has recently published an international consensus among experts concerning methods of acquiring and analysing nailfold capillaries [1].

The specific aim of this study, representing novelty from previous related initiatives, was to explore methodological standards in reporting NVC in clinical research.

The overarching objective was to gather opinions from members of the EULAR SG MC/RD and the Scleroderma Clinical Trials Consortium (SCTC) and to develop a consensus on the reporting standards for NVC methodology for clinical research. Here we describe the conclusions of a Delphi exercise conducted with members of the EULAR SG MC/RD and the SCTC (based on items derived from a systematic literature review) and the resulting consensus on important methodological standards in reporting NVC in clinical research. In order to enhance applicability of the minimum reporting standards that reached a consensus, a practical reporting checklist was then proposed.

Methods

Systematic literature review

Our systematic literature review protocol was registered on PROSPERO (CRD42018104660). The manuscript will conform to the preferred reporting items for systematic reviews and meta-analyses guidelines for reporting systematic reviews [10].

To obtain appropriate evidence-based background for our considerations, a systematic literature search was undertaken from database inception to 22 July 2018, using MEDLINE, Embase and Scopus. The search strategy was planned to capture all studies in which the study population were adults and children with musculoskeletal diseases, and dealt with nailfold capillaroscopy (videocapillaroscopy, stereomicroscopy, dermoscopy, dermatoscopy, microscopic angioscopy, smartphone/USB microscopy, and ophthalmoscopy).

To be eligible, studies needed to meet the following criteria: studies on adult patients or children with musculoskeletal diseases; original articles on clinical studies, clinical trials, observational studies (cross-sectional, prospective, case–control), case series (if subjects were $\geq$5); studies in English language. Studies involving patients without musculoskeletal diseases, unpublished material, retrospective studies, case reports, editorials, letters and reviews were excluded.

The full search strategy is detailed in the supplementary material, search strategy section, available at *Rheumatology* online. During the first screening from the list of records retrieved, two reviewers (N.U. and F.B.) excluded duplicates and independently screened titles and abstracts. In cases of disagreement, a decision was made by consensus. The full papers were sought when abstracts were felt to be relevant. Reference lists of the review articles were also examined for relevant studies. In cases of disagreement, a decision was made by consensus. Two independent reviewers (F.I. and T.S.) assessed the articles. Data concerning study design, country, age range, gender ratio and total number of participants, diagnosis, patient preparation before NVC, device description and examination details were collected using a standardized form.

During the 2019 EULAR annual meeting, the results of this review were discussed among the SG MC/RD members in preparation for the Delphi process, seeking further input.

Delphi consensus

A panel of international participants from the EULAR SG MC/RD and the SCTC were invited by e-mail to participate in the Delphi exercise.

The Delphi consensus process was based on a three-stage on-line survey (Google Forms). In the first round, participants were asked to consider the items identified by the systemic literature review that were believed to reflect the available evidence, to focus on new items that might have been omitted and to clarify items that might be ambiguous. The second round was based on the results of the first round, and participants were asked to rate each item from 1 (not appropriate) to 9 (completely appropriate). In the third and last round, participants reviewed the responses to each item obtained in the second round, including basic summary statistics for each question, and to again rate the items. To achieve agreement, the answers' median score for each item had to be $\geq$7, and $^1/_3$ or less of the

participants were required to be in the range of 1–3 [11]. Based on the comments, the expert committee (M.C., V.S. and A.H.) proposed topics for a research agenda. Moreover, a practical reporting checklist summarizing the minimum reporting standards that reached a consensus was proposed.

Results

Literature review

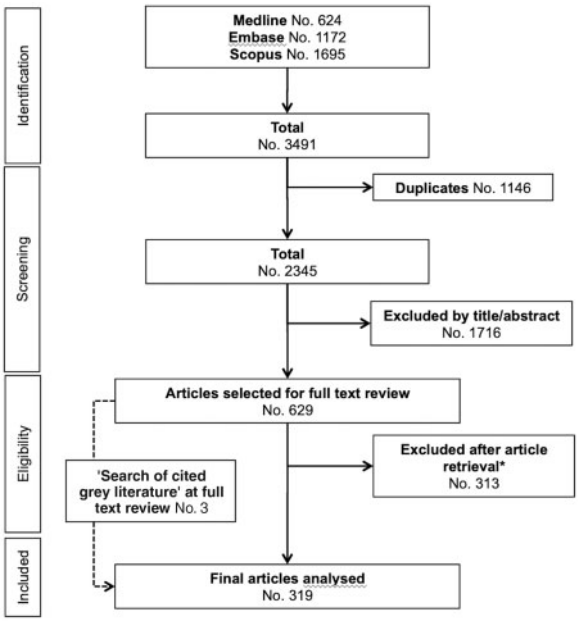
A total of 3491 references were retrieved in the initial search strategy in Medline via PubMed, Embase and Scopus. The review flow process is outlined in Fig. 1. Briefly, 2862 records were excluded due to duplication or after title/abstract screening, leaving 629 papers; an additional 3 papers were included from the grey literature search, making a total of 632; Of these, a further 313 manuscripts were excluded (for reasons are reported in the supplementary material exclusion criteria section, available at *Rheumatology* online), and 319 references fulfilled the inclusion criteria (see the supplementary material for a list of the 319 manuscripts selected for the final analysis, available at *Rheumatology* online).

Data from the 319 articles were extracted and reported in ad hoc forms: 280 studies were prospective and 39 were retrospective; 228 were monocentric and 91 multicentric; 283 were national and 36 international. There were 104 studies conducted in Italy; 26 in the USA; 23 in the UK; 21 in Belgium and Brazil; 14 in France; 13 in Germany; 11 in Poland; 10 in Turkey; 9 in Canada, Japan, Sweden and Switzerland; 8 in the Netherlands; 7 in Iran, Montenegro and Serbia; 6 in Australia, South Korea and Spain; 5 in Egypt; 4 in Bulgaria, Greece, Hungary, Portugal and Taiwan; 3 in Austria, Czech Republic and Israel; 2 in Denmark and Mexico; 1 in Argentina, China, India, Ireland, Norway, Romania and New Zealand.

Of the 319 studies, 115 reported the number of patients that had been included, and the total number of patients was 41 793 with a median number of patients per study of 67 [interquartile range (IQR) 35–115.5]. Based on the data available, the median age was 48 years (287 studies) and the number of females was 28 214 (81.5%, 282 studies). There were 189 studies on SSc, 74 on CTDs (SLE, SS, CTD, MCTD, UCTD, APS, cutaneous lupus), 54 on RP (primary and/or secondary), 37 on inflammatory myositis (DM, PM, JDM and IBM), 31 on inflammatory arthritis (RA, JIA, seronegative arthritis and PsA), 10 on vasculitis (Behçet disease, IgA vasculitis and Kawasaki disease) and 13 on other diseases (FMF, mixed cryoglobulinemia, OA, FM, localized scleroderma, chilblains, acrocyanosis). Only 109 studies included healthy controls.

Four studies were published before 1980, 27 between 1981 and 1990, 45 between 1991 and 2000, 91 between 2001 and 2010, 152 between 2011 and 2018.

Fig. 1 Flow diagram of the systematic review process



*See supplementary material exclusion criteria section, available at *Rheumatology* online, for exclusion reasons.

In Fig. 2A , information about patient preparation before the exam is reported: 121 (37.9%) articles reported on acclimatization, and 109 of those 121 reported the period of acclimatization (mean 19.5 ± 7.3 min); 17 (5.3%) studies reported whether or not patients were asked to avoid smoking; <5% of studies reported all the other information (washing hands, and avoiding caffeine, manicures and alcohol).

Regarding technical aspects (Fig. 2B), most studies reported information about the type of instrument, model and magnification—288 (90.3%), 247 (77.4%) and 228 (71.5%), respectively. Fewer than half of the studies reported information about type of oil, room temperature and use of software for image analysis—145 (45.5%), 126 (39.5%) and 111 (34.8%), respectively. Only 2 articles (0.6%) reported time of day.

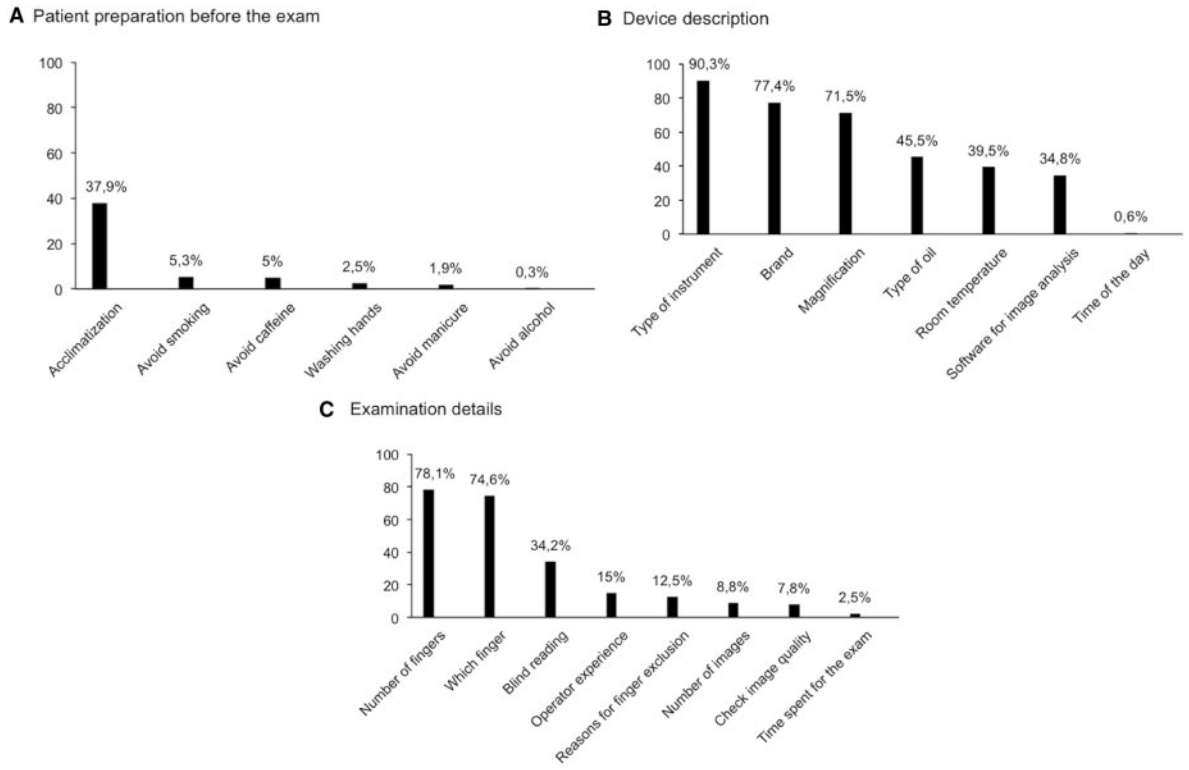
Examination details are provided in Fig. 2C : 249 (78.1%) reported the number of fingers examined (mean 7 ± 3), and 238 (74.6%) studies reported which fingers were examined. Moreover, 109 (34.2%) studies reported whether images were analysed blindly, 48 (15%) reported the level of operator experience and 40 (12.5%) reported the reasons for finger exclusion. Fewer than 10% of the studies reported information about total number of images, image quality check and time spent for the exam—28 (8.8%), 25 (7.8%) and 8 (2.5%), respectively.

Delphi consensus

Delphi participants

In the first round, there were 88 participants, mainly rheumatologists (79.5%) and those familiar with NVC

FIG. 2 Summary of capillaroscopy details reported in the 319 selected manuscripts



(90.9% declared use of NVC in routine clinical practice); in the second round there were 85 participants; 80 participants completed all the three rounds: 44 from Europe, 19 from North America, 9 from South America, 6 from Asia and 2 from Oceania. Of the 80, 13 (16.25%) respondents were from the USA; 11 (13.75%) from Italy; 5 (6.25%) from each of Canada, France, the Netherlands and the UK; 3 (3.75%) from each of Brazil and Colombia; 2 (2.5%) from each of Argentina, Belgium, Denmark, India, Israel, Spain and Switzerland; and 1 (1.25%) from each of Australia, Bulgaria, Chile, Germany, Greece, Iran, Japan, Mexico, Myanmar, Poland, Portugal, Romania, South Korea, Sweden, Turkey and Ukraine.

Delphi results on patient preparation

Based on the results of the review and participants' suggestions, 21 items were identified. The final results are reported in Table 1. According to this consensus, patients should undergo a period of acclimatization before the exam and the exam should not be performed during a RP attack or, if present, it should at least be reported. Patients should be asked to describe digital colour changes in detail. Moreover, patients should be asked about their age, jobs, hobbies, sports, physical activities, dominant hand, specific medications or other agents with vasoactive effects, comorbidities, recent finger trauma, onychophagy, habit of self-injuring the cuticles and history of digital ulcers. Lastly, patients should be asked to remove nail polish and artificial or gel nails before the procedure and to avoid manicures.

Delphi results on device technical description

Six items were identified and five of them reached the consensus (Table 2). The make and the model of the device, as well as magnification, the use of an automated grid and the use of oil should be reported. Moreover, when applicable, details of computer software for image analysis should be reported.

Delphi results on practical examination details

Of 19 items selected, 13 reached an agreement at the second round, but 6 did not (Table 3). In particular, participants agreed to report: details about experience or qualifications of each person responsible for image acquisition and interpretation, details on image reading (e.g. blind reading), the number of fingers and the particular fingers examined, reason for finger exclusion, the global condition of the hands, and the number and quality of images.

Moreover, fingers should be analysed and reported separately or together based on the study design, and images should be coded, numbered and stored in order to allow comparative or prospective studies. The overall pattern and the validated scleroderma pattern should be reported [9, 12].

Table 1 Results of the Delphi process on patient preparation before capillaroscopy

	1–3	4–6	7–9	Median	Agreement
Patients should undergo a period of acclimatization	4	8	73	8	Yes[a]
Patients should be asked to remove nail polish prior to procedure	10	14	61	9	Yes[a]
Patients should be asked to remove artificial or gel nails prior to procedure	9	13	63	9	Yes[a]
Patients should be asked to avoid manicures prior to procedure	0	10	75	9	Yes[a]
Patients should be asked about their job and hobbies	4	10	71	9	Yes[a]
Patients should be asked about their sport and physical activities (i.e. outdoor/indoor activities)	10	14	61	8	Yes[a]
Patients should be asked about their dominant hand	6	14	65	8	Yes[a]
Patients should be asked about specific medications (i.e. beta-adrenergic blockers, vasodilators, anticoagulants and antihypertensive drugs) and other agents with vasoactive effects (i.e. marijuana, cocaine, amphetamines)	2	6	77	9	Yes[a]
Patients should be asked about their comorbidities	5	3	77	9	Yes[a]
Patients should be asked about recent finger trauma, nail biting (onychophagy) and/or habit of self-injuring the cuticles	2	4	79	9	Yes[a]
Patients should be asked to provide a detailed description of digital colour changes (to ascertain the diagnosis of RP)	2	9	74	9	Yes[a]
Specify whether the exam is performed during a Raynaud's attack	13	15	57	8	Yes[a]
Patients should be asked about their age	3	8	74	9	Yes[a]
Patients should be asked about history of digital ulcers	6	5	69	9	Yes[b]
Capillaroscopy should not be performed during RP attack	13	12	55	8	Yes[b]
Patients should be asked to wash their hands prior to procedure	24	27	29	5	No
Patients should be asked to avoid manicures for a 1-month period before the procedure	30	24	26	5	No
Patients should be asked to avoid manicures for a 3-week period before the procedure	18	25	37	6	No
Patients should be asked to avoid hand moisturizing lotion on the day of the procedure	38	24	18	4	No
Patients should be asked to avoid caffeine prior to the procedure	25	24	31	5	No
Patients should be asked to avoid alcohol prior to the procedure	28	22	30	5	No

[a]Agreement reached at the second round.
[b]Agreement reached at the third round.

Table 2 Results of the Delphi process on device description

	1–3	4–6	7–9	Median	Agreement
The make and model of the nailfold capillaroscopy device should be reported	1	12	72	9	Yes[a]
Details of magnification should be reported	0	2	83	9	Yes[a]
The use of automated grid should be reported	0	10	75	8	Yes[a]
The use of oil should be reported	14	13	58	8	Yes[a]
Details of computer software for image analysis should be reported	8	11	66	9	Yes[a]
The type of oil should be reported	19	23	38	5.5	No

[a]Agreement reached at the second round.

Finally, we provide a checklist concerning the NVC information that should be regularly reported in research studies using NVC (Table 4).

Research agenda

Despite various international efforts, there is still limited evidence for some NVC items that have been proposed

TABLE 3 Results of the Delphi process on capillaroscopy examination details

	1–3	4–6	7–9	Median	Agreement
Details of experience or qualifications of personnel responsible for image acquisition and interpretation should be reported	9	16	60	8	Yes[a]
In case of more than one examiner, training for each examiner should be specified	10	15	60	8	Yes[a]
The number of fingers examined should be reported	1	0	84	9	Yes[a]
It should be reported which fingers have been examined	2	2	81	9	Yes[a]
Each finger should be analysed separately and reported separately or together based on the study design	18	17	50	7	Yes[a]
Images of each finger should be coded, numbered and stored in order to allow comparative/prospective studies	2	14	69	8	Yes[a]
Reasons for finger exclusion should be reported	2	6	77	9	Yes[a]
Number of images collected at each nailfold should be reported	6	17	62	8	Yes[a]
Details of image quality (and missing data) should be reported	2	15	68	8	Yes[a]
Details of global condition of the hands (e.g. flexion contractures) should be reported	6	15	64	8	Yes[a]
Details on image reading (e.g. blind reading) should be reported	7	8	70	9	Yes[a]
Report the overall pattern (i.e. normal: stereotype normal and non-specific abnormalities *vs* abnormal: scleroderma patterns) [9]	1	8	76	9	Yes[a]
Report the validated scleroderma patterns (i.e. early, active, late or scleroderma-like) [12]	0	8	77	9	Yes[a]
Details on time taken to conduct image acquisition should be reported	41	23	16	3	No
Time of the day of image acquisition should be reported	41	21	18	3	No
Report the scleroderma patterns (i.e. slow and active) according to Maricq [15]	23	20	37	6	No
Report blood flow characteristics	15	33	32	6	No
Report the level of the examined hand with respect to the hearth level	41	24	15	3	No
Report subtypes of bleeding	28	21	31	5	No

[a]Agreement reached at the second round.

for a research agenda. These include issues related to patient preparation (i.e. allergies to the oil, impact of smoking prior to the procedure) and examination details (i.e. significance of pericapillary oedema, abnormal capillary shapes, ramifications, microhaemorrhages and giant capillaries) [13].

Discussion

The principal aim of this project was to develop a framework to facilitate standardization of NVC reporting in clinical research. We met our objective of gathering a broad group of international participants to appraise the problem. We identified three overarching areas for reporting NVC: patient preparation before NVC, device description and examination details. To our knowledge this is the first time this has been done.

The available evidence derived from the systematic review suggested that the degree of description of NVC methods varied among research studies; hence, interpreting individual studies and making comparisons between studies was challenging.

A strength of this project is that we engaged a panel of participants from 31 nations, spanning five continents. While participation was heavily weighted toward individuals from Europe and North America, this was reflective of the clinical and research expertise in the field of NVC and membership of the international consortia.

We have identified areas requiring further assessment and/or research, including the impact of smoking cigarettes before the exam and the significance of pericapillary oedema and capillary ramifications. The latter are encompassed in the EULAR SG MC/RD definition of abnormal shapes [8].

Table 4 Checklist derived from the international consensus on standardization of reporting capillaroscopy

(A) Description of patient preparation before NVC

- Patients should undergo a period of acclimatization
- Patients should be asked to remove nail polish prior to procedure
- Patients should be asked to remove artificial or gel nails prior to procedure
- Patients should be asked to avoid manicures prior to procedure
- Patients should be asked about their job and hobbies
- Patients should be asked about their sport and physical activities (i.e. outdoor/indoor activities)
- Patients should be asked about their dominant hand
- Patients should be asked about specific medications (i.e. beta-adrenergic blockers, vasodilators, anticoagulants and antihypertensive drugs) and other agents with vasoactive effects (i.e. marijuana, cocaine, amphetamines)
- Patients should be asked about their comorbidities
- Patients should be asked about recent finger trauma, nail biting (onychophagy) and/or habit of self-injuring the cuticles
- Patients should be asked to provide a detailed description of digital colour changes (to ascertain the diagnosis of RP)
- Specify whether the exam is performed during a Raynaud's attack
- Patients should be asked about their age
- Patients should be asked about history of digital ulcers
- Capillaroscopy should not be performed during RP attack

(B) Details of device description

- The make and model of the nailfold capillaroscopy device should be reported
- Details of magnification should be reported
- The use of automated grid should be reported
- The use of oil should be reported
- Details of computer software for image analysis should be reported

(C) Description of examination details

- Details of experience or qualifications of personnel responsible for image acquisition and interpretation should be reported
- In case of more than one examiner, training for each examiner should be specified
- The number of fingers examined should be reported
- It should be reported which fingers have been examined
- Each finger should be analysed separately and reported separately or together based on the study design
- Images of each finger should be coded, numbered and stored in order to allow comparative/prospective studies
- Reasons for finger exclusion should be reported
- Number of images collected at each nailfold should be reported
- Details of image quality (and missing data) should be reported
- Details of global condition of the hands (e.g. flexion contractures) should be reported
- Details on image reading (e.g. blind reading) should be reported
- Report the overall pattern (i.e. normal: stereotype normal and non-specific abnormalities *vs* abnormal: scleroderma patterns) [9]
- Report the validated scleroderma patterns (i.e. early, active, late or scleroderma-like) [12]

Although the available evidence is insufficient to make definitive recommendations, our suggestions are a further step towards standardization, and should facilitate development of a future 'NVC core set', building upon a very recent expert consensus from the EULAR SG MC/RD, which dealt on one hand with defining capillaroscopic characteristics to be evaluated (density, dimension, abnormal shape and haemorrhages), and on the other hand with categorizing a capillaroscopic image as a scleroderma pattern or not (normal images versus images with non-specific abnormalities) [1, 7–9, 14].

With our Delphi consensus, we have had the opportunity to define areas in which research communities can harmonize and facilitate NVC reporting in future research studies.

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Supplementary data

Supplementary data are available at *Rheumatology* online.

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