

Bukti Korespondensi Publikasi Tri Wahyu Martanto, dr., Sp. OT(K)

Judul : Validity of measurement of femoral anteversion angle using FEMORA® software based on two-dimensional radiographic imaging examination femur in children with cerebral palsy in Indonesia
Jurnal : Heliyon; Vol. 9; Issue: 11; No. e22243; November 2023

Penulis : **Tri Wahyu Martanto (Penulis ke-1)**, Yusuf Rizal, Irwanto (Penulis Korespondensi), Sulis Bayu Sentono, Rosy Setiawati, Sri Andreani Utomo, Prastiya Indra Gunawan, Nurul Kusuma Wardani, Prima Hari Nastiti, Rachmat Agung Widodo, Moon Seok Park, Arif Zulkarnain, Hizbillah Yazid, Hendra Cahaya Kumara, Muhammad Ihsan Kitta

DAFTAR BUKTI KORESPONDENSI

1. Confirming submission to the journal (3 Mei 2023)
2. Confirm co-authorship of submission to Heliyon (3 Mei 2023)
3. Decision on submission HELIYON-D-23-17881 to Heliyon (9 Agustus 2023)
4. Rebuttal Letter Response to Reviewer (21 Agustus 2023)
5. Revision Submitted (21 Agustus 2023)
6. Decision on submission: minor formatting and/or administrative changes (3 November 2023)
7. Response to Editorial and Reviewer (6 November 2023)
8. Revisions 2 Submitted (7 November 2023)
9. Manuscript has been accepted for publication (7 November 2023)
10. Production begun on article (11 November 2023)
11. Proofs of the article (11 November 2023)
12. Rights and Access form completed (13 November 2023)
13. Article Available Online (18 November 2023)
14. Invoice Payment (20 November 2023)
15. Invoice Information Change for Article (24 November 2023)

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1. Confirming submission to the journal (3 Mei 2023)

Confirming submission to Heliyon

1 pesan

Heliyon <em@editorialmanager.com>

3 Mei 2023 pukul 16.36

Balas Ke: Heliyon <info@heliyon.com>

Kepada: Tri Wahyu Martanto <tri-wahyu-m@fk.unair.ac.id>

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VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

Dear Prof Irwanto,

We have received the above referenced manuscript you submitted to Heliyon. It has been assigned the manuscript number HELIYON-D-23-17881. To track the status of your manuscript, please log in as an author at <https://www.editorialmanager.com/heliyon/>, and navigate to the "Submissions Being Processed" folder.

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2. Confirm co-authorship of submission to Heliyon (3 Mei 2023)

Confirm co-authorship of submission to Heliyon

1 pesan

Heliyon <em@editorialmanager.com>

3 Mei 2023 pukul 16.36

Balas Ke: Heliyon <info@heliyon.com>

Kepada: Tri Wahyu Martanto <tri-wahyu-m@fk.unair.ac.id>

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VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA by Prof Irwanto Irwanto

Dear Dr. Martanto,

You have been listed as a contributing author for the above referenced manuscript. Please confirm whether you are a contributing author by clicking one of the following links.

Yes, I made a significant contribution to this manuscript and meet the criteria for authorship (detailed in the Guide for Authors of Heliyon)

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Thank you in advance for your confirmation.

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3. Decision on submission HELIYON-D-23-17881 to

Heliyon (9 Agustus 2023)

Fwd: Decision on submission HELIYON-D-23-17881 to Heliyon

1 pesan

Agisa Prawesti <agisaprawesti@gmail.com>

16 Mei 2024 pukul 11.59

Kepada: "tri-wahyu-m@fk.unair.ac.id" <tri-wahyu-m@fk.unair.ac.id>

----- Original message -----

From: Irwanto Irwanto <irwanto@fk.unair.ac.id>

Date: 8/10/23 07:07 (GMT+07:00)

To: yusuf.cap.ortho@gmail.com

Subject: Fwd: Decision on submission HELIYON-D-23-17881 to Heliyon

----- Forwarded message -----

Dari: Heliyon <em@editorialmanager.com>

Date: Rab, 9 Agu 2023 pukul 15.23

Subject: Decision on submission HELIYON-D-23-17881 to Heliyon

To: Irwanto Irwanto <irwanto@fk.unair.ac.id>

Ref.: Ms. No. HELIYON-D-23-17881

VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

Heliyon

Dear Prof Irwanto,

Thank you for submitting your manuscript to Heliyon. We have completed the review of your manuscript. A summary is appended below. While revising the paper please consider the reviewers' comments carefully. We look forward to receiving your detailed response and your revised manuscript.

To submit a revision, go to <https://www.editorialmanager.com/heliyon/> and log in as an Author where you will see a menu item called 'Submission Needing Revision'.

Please note that our ethics requirements are now updated. Please choose all applicable statements in our ethics declarations list (available here: <https://www.cell.com/heliyon/ethics>) and include them as a complete ethics statement in the declarations section at the end of your manuscript.

Please resubmit your manuscript by Aug 30, 2023.

I look forward to receiving your revised manuscript.

Kind regards,

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Editorial Section Manager
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Reviewer's Responses to Questions

Note: In order to effectively convey your recommendations for improvement to the author(s), and help editors make well-informed and efficient decisions, we ask you to answer the following specific questions about the manuscript and provide additional suggestions where appropriate.

1. Are the objectives and the rationale of the study clearly stated?

Please provide suggestions to the author(s) on how to improve the clarity of the objectives and rationale of the study. Please number each suggestion so that author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:

Not Applicable No and here is how they should be improved Yes, there is no need for improvement

Provide further comments here:

Reviewer #2: Mark as appropriate with an X:

Not Applicable No and here is how they should be improved Yes, there is no need for improvement

Provide further comments here:

Reviewer #3: Mark as appropriate with an X:

Not Applicable No and here is how they should be improved Yes, there is no need for improvement

Provide further comments here:

2. If applicable, is the application/theory/method/study reported in sufficient detail to allow for its replicability and/or reproducibility?

Please provide suggestions to the author(s) on how to improve the replicability/reproducibility of their study. Please number each suggestion so that the author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:

Reviewer #2: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

Reviewer #3: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

3. If applicable, are statistical analyses, controls, sampling mechanism, and statistical reporting (e.g., P-values, CIs, effect sizes) appropriate and well described?

Please clearly indicate if the manuscript requires additional peer review by a statistician. Kindly provide suggestions to the author(s) on how to improve the statistical analyses, controls, sampling mechanism, or statistical reporting. Please number each suggestion so that the author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:
See comments below

Reviewer #2: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

Reviewer #3: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:

4. If applicable, are the existing tables and/or figures complete and acceptable for publication?

Please provide specific suggestions for improvements, removals, or additions of figures or tables. Please number each suggestion so that the author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:
See comments below

Reviewer #2: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

Reviewer #3: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

5. If applicable, are the interpretation of results and study conclusions supported by the data?

Please provide suggestions (if needed) to the author(s) on how to improve, tone down, or expand the study interpretations/conclusions. Please number each suggestion so that the author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:
See comments below

Reviewer #2: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

Reviewer #3: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

6. Have the authors clearly emphasized the strengths of their study/theory/methods/argument?

Please provide suggestions to the author(s) on how to better emphasize the strengths of their study. Please number each suggestion so that the author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:
See comments below

Reviewer #2: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

Reviewer #3: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

7. Have the authors clearly stated the limitations of their study/theory/methods/argument?

Please list the limitations that the author(s) need to add or emphasize. Please number each limitation so that author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:
See comments below

Reviewer #2: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

Reviewer #3: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

8. Is the manuscript's structure, flow, or writing acceptable for publication? (Think for example of the addition of subheadings, shortening of text, reorganization of sections, or moving details from one section to another)

Please provide suggestions to the author(s) on how to improve the manuscript structure and flow. Please number each suggestion so that author(s) can more easily respond.

Reviewer #1: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved [x] Yes, there is no need for improvement
Provide further comments here:
See comments below

Reviewer #2: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

Reviewer #3: Mark as appropriate with an X:
Not Applicable No and here is how they should be improved Yes, there is no need for improvement [x]
Provide further comments here:

9. Could the manuscript benefit from language editing?

Reviewer #1: Yes

Reviewer #2: No

Reviewer #3: Yes

Reviewer #1: The subject addressed in the article seems interesting and justifies the research carried out, however some aspects should be clarified: Explain better how FEMORA® software works? What kind of femur projections needs to be obtained? The conventional FAA biplanar measurement methodology was used? The accuracy of this methodology and FEMORA® software could be interesting.... To test the interchangeability measurement methodology a paired t Test is recommended, why it was not used? The ICC lower limit CI under 0.75 is not considered acceptable for interchangeability methodology!!!!
Table 1 : there is no mention to females?
Revise numbers: "Most patients were female (n=11; 61,1%)...."

Reviewer #2: VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA
Well written and concise discussion.

Reviewer #3: Thank you very much for inviting me to review the current manuscript. The manuscript follow nice idea and have acceptable quality in methods and discussion. Only I can recommend some minor language revisions before publishing

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4. Rebuttal Letter Response to Reviewer (21 Agustus 2023)

Dear Prof. Uthayakumar,

Re.: Re-Submission of Ms. No. HELIYON-D-23-17881

VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

We would like to express our gratitude to you and the reviewers for providing us with your insightful comments. Your feedback has proven invaluable in enhancing the standard of our manuscript. Below, we provide our responses to the corrections made by the reviewer as outlined:

Reviewer #1: The subject addressed in the article seems interesting and justifies the research carried out, however some aspects should be clarified:

Explain better how FEMORA® software works? What kind of femur projections needs to be obtained?

The conventional FAA biplanar measurement methodology was used? The accuracy of this methodology and FEMORA® software could be interesting....

To test the interchangeability measurement methodology a paired t Test is recommended, why it was not used? The ICC lower limit CI under 0.75 is not considered acceptable for interchangeability methodology!!!!

Table 1 : there is no mention to females?

Revise numbers: "Most patients were female (n=11; 61,1%)...."

Author Responses #1 :

Thank you reviewer #1 for highly insightful and detailed comments. It helps us to further improve our manuscripts and escalate our manuscript quality. We have addressed each of these comments in detail as outlined below::

- We agree to provide a detailed explanation on how to use the FEMORA® software in our amended manuscript.
- Thank you for your suggestion using paired t-test to test interchangeability method. We only used ICC for reliability comparisons between FEMORA® software examiners (ICC, 0.918; 95% CI, 0.858-0.955),
- And to analyse the validity between the FEMORA® software and CT Scan, we present the results using the Pearson correlation coefficient that is commonly used by most researchers. We are aware that the Pearson correlation coefficient has both advantages and disadvantages. Therefore, to our understanding, it is best to include careful visual analysis such as Bland-Altman and scatter plot, which are already included in this manuscript. Furthermore, we extracted the range of numbers used to

present the results from a similar study as a reference and included them in the revised version.

- Female references are not included in Table 1. They have already been referred to in the paragraph above the tables. Only male data are included in Table 1 for simplicity. Thank you for pointing this out to us.
- Thank you for pointing out the incorrect data summary. As a result, we have made the necessary changes to the figures in our revised manuscript.

Reviewer #2: VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

Well written and concise discussion.

Author Responses #2 :

- Thank you very much, Reviewer #2, for reviewing our manuscript and helping us to improve it.

Reviewer #3: Thank you very much for inviting me to review the current manuscript. The manuscript follow nice idea and have acceptable quality in methods and discussion. Only I can recommend some minor language revisions before publishing

Author Responses #3 :

We would like to thank Reviewer #3 for assisting us in enhancing this manuscript.

Prior to submission, we had used a professional language editing service provided by our institution. After proofreading, the language of the manuscript was reworked. We anticipate that our manuscripts will gain greater acceptance.

Please find attached our first language editing certificate. We believe that we would miss the deadline for submission of revised manuscripts if we had to go through another round of language editing.

Language Editing Certificate



Editing Certificate

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MANUSCRIPT TITLE

VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON CONVENTIONAL TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN AGED 2-12 YEARS OLD WITH CEREBRAL PALSY IN INDONESIA

AUTHORS

Tri Wahyu Martanto, dr. SpOT(K)

ISSUED ON

March 18, 2023

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5. Revision Submitted (21 Agustus 2023)

Heliyon

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--Manuscript Draft--

Manuscript Number:	HELIYON-D-23-17881R1
Article Type:	Original Research Article
Section/Category:	Medical Sciences
Keywords:	CT SCAN; x-ray; Femoral Anteversion Angle; Cerebral palsy
Manuscript Classifications:	130: Health Sciences; 130.260.150: Orthopedics; 130.350: Pediatrics; 130.490: Radiology; 130.510.160: Diagnostics
Corresponding Author:	Irwanto Irwanto, M.D., Ph.D. Airlangga University Faculty of Medicine INDONESIA
First Author:	Tri Wahyu Martanto, M.D.
Order of Authors:	Tri Wahyu Martanto, M.D. Yusuf Rizal, M.D. Irwanto Irwanto, M.D., Ph.D. Sulis Bayu Sentono Rosy Setiawati Sri Andreani Utomo Prastiya Indra Gunawan Nurul Kusuma Wardani Prima Hari Nastiti Rachmat Agung Widodo Moon Seok Park Arif Zulkarnain Hizbillah Yazid Hendra Cahaya Kumara Muhammad Ihsan Kitta
Abstract:	<p>Introduction: Children with a spastic type of cerebral palsy (CP) often show an increase in femoral anteversion angle (FAA). A computed tomography (CT) scan is the main modality for evaluating FAA in these patients but, due to significant radiation exposure, carries a high carcinogenic risk. FEMORA® software is expected to be able to accurately assess FAA even with conventional X-ray images that only require low radiation exposure. However, its validity has not been tested in various populations or CT devices. This study aims to validate the FEMORA® software by comparing it to CT scans done on an Indonesian population. Material and Methods: All spastic CP patients who attended the outpatient clinic at Dr Soetomo Hospital between March 2022 and November 2022, were included. The FEMORA® Software evaluation was performed by three examiners. The calculation results will be averaged and compared with those of the The CT scan. Intraclass correlation coefficient (ICC), reliability, and correlation will be assessed. Results: There were 36 patients included in this study. Most were female (n=22; 61,1%) and the the average age was 7,28 years old. Interobserver preoperative analysis using ICC showed good outcomes (p=0.918; 95% CI, 0.858-0.955). FAA measurement results using FEMORA® and CT scans were 41,71 ± 12,90</p>

	and $32,68 \pm 11,85$, respectively. Correlation coefficient between the two values is 0.634 ($p < 0.001$). Conclusion: FEMORA® software is found to have good and significant correlation with FAA measurement using CT scan.
Opposed Reviewers:	

Editor-in-Chief

Pediatric Neurology

6 April 2023

Dear Editor-in-Chief Pediatric Neurology,

I am writing to submit a manuscript, research paper titled “**Validity of Measurement of Femoral Anteversion Angle using FEMORA® Software based on Two-Dimensional Radiographic Imaging Examination Femur in Children with Cerebral Palsy in Indonesia**” to hopefully be published in your esteemed journal.

In this study, we further discuss the comparison of femoral anteversion angle (FAA) measurement in children with a spastic type of cerebral palsy (CP) using FEMORA® software and computed tomography (CT) scan on Indonesian population.

On behalf of all the contributors, I, Prof. Irwanto, will correspond with the journal from this point onward and certify that this manuscript is a unique submission and is not being considered for publication, in part or in full, with any other source in any medium. All authors involved in this study have agreed to be listed as well as have seen and approved the manuscript, its consent, and submission to Pediatric Neurology. None of the authors has any commercial association or financial disclosure that might pose or create a conflict of interest with information presented in this article. We appreciate this opportunity to submit our manuscript and hope that your reviewers and editorial staff find our report relevant and of great interest to your journal.

Thank you for your kind attention and if you have any queries, please don't hesitate to contact us.

Yours sincerely,

Prof. Irwanto, M.D, Ph.D

Department of Child Health, Faculty of Medicine, Universitas Airlangga – Dr. Soetomo General Academic Hospital, Surabaya, Indonesia, 60131. Telephone: +62 813-3243-9990. Email: irwanto@fk.unair.ac.id

Dear Prof. Uthayakumar,

Re.: Re-Submission of Ms. No. HELIYON-D-23-17881
VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING
FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC
IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN
INDONESIA

We would like to express our gratitude to you and the reviewers for providing us with your insightful comments. Your feedback has proven invaluable in enhancing the standard of our manuscript. Below, we provide our responses to the corrections made by the reviewer as outlined:

Reviewer #1: The subject addressed in the article seems interesting and justifies the research carried out, however some aspects should be clarified:

Explain better how FEMORA® software works? What kind of femur projections needs to be obtained?

The conventional FAA biplanar measurement methodology was used? The accuracy of this methodology and FEMORA® software could be interesting....

To test the interchangeability measurement methodology a paired t Test is recommended, why it was not used? The ICC lower limit CI under 0.75 is not considered acceptable for interchangeability methodology!!!!

Table 1 : there is no mention to females?

Revise numbers: "Most patients were female (n=11; 61,1%)...."

Author Responses #1 :

Thank you reviewer #1 for highly insightful and detailed comments. It helps us to further improve our manuscripts and escalate our manuscript quality. We have addressed each of these comments in detail as outlined below::

- We agree to provide a detailed explanation on how to use the FEMORA® software in our amended manuscript.
- Thank you for your suggestion using paired t-test to test interchangeability method. We only used ICC for reliability comparisons between FEMORA® software examiners (ICC, 0.918; 95% CI, 0.858-0.955),
- And to analyse the validity between the FEMORA® software and CT Scan, we present the results using the Pearson correlation coefficient that is commonly used by most researchers. We are aware that the Pearson correlation coefficient has both advantages and disadvantages. Therefore, to our understanding, it is best to include careful visual analysis such as Bland-Altman and scatter plot, which are already included in this manuscript. Furthermore, we extracted the range of numbers used to

present the results from a similar study as a reference and included them in the revised version.

- Female references are not included in Table 1. They have already been referred to in the paragraph above the tables. Only male data are included in Table 1 for simplicity. Thank you for pointing this out to us.
- Thank you for pointing out the incorrect data summary. As a result, we have made the necessary changes to the figures in our revised manuscript.

Reviewer #2: VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

Well written and concise discussion.

Author Responses #2 :

- Thank you very much, Reviewer #2, for reviewing our manuscript and helping us to improve it.

Reviewer #3: Thank you very much for inviting me to review the current manuscript. The manuscript follow nice idea and have acceptable quality in methods and discussion. Only I can recommend some minor language revisions before publishing

Author Responses #3 :

We would like to thank Reviewer #3 for assisting us in enhancing this manuscript.

Prior to submission, we had used a professional language editing service provided by our institution. After proofreading, the language of the manuscript was reworked. We anticipate that our manuscripts will gain greater acceptance.

Please find attached our first language editing certificate. We believe that we would miss the deadline for submission of revised manuscripts if we had to go through another round of language editing.

Language Editing Certificate



Editing Certificate

This document certifies that the manuscript listed below has been edited to ensure language and grammar accuracy and is error free in these aspects. The logical presentation of ideas and the structure of the paper were also checked during the editing process. The edit was performed by professional editors at Editage, a division of Cactus Communications. The author's core research ideas were not altered in any way during the editing process. The quality of the edit has been guaranteed, with the assumption that our suggested changes have been accepted and the text has not been further altered without the knowledge of our editors.

MANUSCRIPT TITLE

VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON CONVENTIONAL TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN AGED 2-12 YEARS OLD WITH CEREBRAL PALSY IN INDONESIA

AUTHORS

Tri Wahyu Martanto, dr. SpOT(K)

ISSUED ON

March 18, 2023

JOB CODE

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Vikas Narang
Chief Operating Officer - Editage

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7 **VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING**
8 **FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC**
9 **IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN**
10 **INDONESIA**
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13 Tri Wahyu Martanto¹, Yusuf Rizal¹, Irwanto², Sulis Bayu Sentono¹, Rosy Setiawati³, Sri
14 Andreani Utomo³, Prastiya Indra Gunawan², Nurul Kusuma Wardani⁴, Prima Hari Nastiti²,
15 Rachmat Agung Widodo¹, Moon Seok Park⁵, Arif Zulkarnain¹, Hizbillah Yazid¹, Hendra
16 Cahaya Kumara⁶, Muhammad Ihsan Kitta⁷
17

18 ¹Department of Orthopaedic and Traumatology, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo
19 General Academic Hospital, Surabaya 60286, Indonesia.

20 ²Department of Child Health, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo General Academic
21 Hospital, Surabaya 60131, Indonesia.

22 ³Department of Radiology, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo General Academic
23 Hospital, Surabaya 60131, Indonesia.

24 ⁴Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo
25 General Academic Hospital, Surabaya 60131, Indonesia.

26 ⁵Department of Orthopaedic Surgery, Seoul National University College of Medicine/ Seoul National University
27 Bundang Hospital, Sungnam, Gyeonggi, South Korea

28 ⁶Department of Orthopaedic and Traumatology, Prof. Dr. R. Soeharso Orthopaedic Hospital, Sebelas Maret
29 University, Surakarta 57126, Indonesia

30 ⁷Department of Orthopaedic Surgery, Muhammadiyah University of Makassar, Makassar 90221, Indonesia

31 Correspondence to Irwanto; irwanto@fk.unair.ac.id

32 Running title: VALIDITY OF FAA measurement using FEMORA®

33 Manuscript word count: 2169 words
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ABSTRACT

Introduction: Children with a spastic ~~type of~~ cerebral palsy (CP) often show an increase in femoral anteversion angle (FAA). ~~CA~~ computed tomography (CT) scan is the main modality for evaluating FAA in these patients, ~~however~~ but, due to significant radiation exposure, ~~it~~ carries a high carcinogenic risk. FEMORA® software is expected to be able to accurately assess FAA even with conventional X-ray images that only require low radiation exposure. However, its validity has not been tested in various populations or CT devices. This study ~~aimed~~ to validate the FEMORA® software by comparing it to CT scans done on an Indonesian population.

Material and Methods: All spastic CP patients ~~who attended~~ of the outpatient clinic at Dr. Soetomo Hospital between March ~~2022~~ and November 2022, were included. The FEMORA® Software evaluation was performed by three examiners. The calculation results ~~will be~~ were averaged and compared with those of the CT scan. Intraclass correlation coefficient (ICC), reliability, and correlation ~~will were~~ be assessed.

Results: There were 36 patients included in this study. Most were female (n=22; 61,1%) and the ~~the~~ average age was 7,28 years old. Interobserver preoperative analysis using ICC showed good outcomes (p=0.918; 95% CI, 0.858-0.955). FAA measurement results using FEMORA® and CT scans were $41,71 \pm 12,90$ and $32,68 \pm 11,85$, respectively. Correlation coefficient between the two values is 0.634 (p<0.001).

Conclusion: FEMORA® software ~~is found to have~~ demonstrates a good and significant ~~correlation~~ -good and significant correlation- with FAA measurement using CT scan.

Keywords: CT Scan, X-ray, Femoral Anteversion Angle, Cerebral Palsy

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7 **Introduction**

8 The femoral anteversion angle (FAA) is the angle formed between the axis of the
9 femoral neck and the axis of the coronal plane of the femoral condyle (condylar plane)^{1,2}. An
10 increase in FAA will decrease the arm abduction moment of the hip abductor and lead to a
11 cosmetically poor gait pattern,³ inefficient gait, and functional limitations⁴⁻⁷.

12 In measuring FAA, a physician may do physical examination, conventional
13 radiography, or computed tomography (CT) scans. Clinical examination using the Trochanteric
14 Prominence Angle Test is reliable for measuring FAA and is a useful screening tool. The
15 advantage of this examination is that it can be performed repeatedly, is inexpensive, safe and
16 does not involve radiation exposure^{8,9}. However, this method is less accurate and reliable due
17 to muscle spasticity, deviation in the position of the femur and deformity of the bones¹⁰.

18 Conventional 2D radiography is generally used for the diagnosis and follow-up of the
19 lower extremities, but it has the disadvantage of being sensitive to the orientation of the patient
20 and bone deformities. A CT scan overcomes this disadvantage and provides more accurate
21 calculations¹¹⁻¹³. By being able to scan through multiple slices and even create a 3D
22 reconstruction of the affected site, CT is considered the “gold standard” imaging technique for
23 evaluating FAA^{2,14} and is a reliable and valid method¹⁰. The disadvantage of a CT scan is that
24 it has a high carcinogenic risk due to the high radiation exposure, especially in the pediatric
25 population¹⁵.

26 FEMORA® Software developed by Didim Co., Ltd. tries to solve the radiation and cost
27 problem of CT scans. By using only biplanar X-rays and the help of FEMORA® software, 3D
28 images can be reconstructed and the need for a CT scan is reduced¹⁶. If validity and reliability
29 are proven, it will help reduce the burdens of cost and radiation exposure in patients.
30 Consequently, this program may replace the need for CT scans or as reference standards for
31 measuring FAA.

32 To prove the validity and reliability of this software before use as a standard for
33 measuring FAA in a clinical setting, it is important for the software to pass repeated tests and
34 carry out in research centers and different populations^{17,18}. In assessing the capacity of this
35 software to measure FAA, patients with highly variant FAA are needed.

36 Cerebral palsy (CP) is a chronic condition with considerable impact on affected
37 individuals. Children with CP suffer from motor problems, frequent seizure/epilepsy, and other
38 disorders^{19,20}. Such chronic disorder combined with immature femur results in changes on FAA
39 angle¹⁰. Thus, patients with spastic CP tend to have varied FAA and will be ideal candidates for
40 assessing this software.

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As of the conduction of this study, the validity and reliability testing of the FEMORA® software has been performed in only one study¹⁶. Therefore, this study was conducted to evaluate and re-validate the application of FEMORA® medical 3D image software measurement by focusing on FAA measurements.

Methods

This is an observational analytic study with a cross-sectional approach to evaluate the validity of using plain radiographs of the anteroposterior and lateral femur calculated using the FEMORA® Software to assess FAA in patients with CP 2 to 12 years old who attended the outpatient clinic at Dr. Soetomo General Hospital from March 2022 to January 2023. Informed consent was obtained from each participant and ethical approval was obtained from the Ethics Committee of the Dr. Soetomo General Hospital Surabaya.

The criteria in this study were: (1) patients with Spastic CP willing to undergo pelvic radiography, femur radiography, and CT scan, (2) patients who are not currently being treated for other diseases, (3) adequate radiographic coverage or quality, (4) no femur fracture, hip joint contracture, or hip joint dislocation, and (5) patients had never had implants.

FAA was assessed using clinical examination⁷, femur radiography²¹, FEMORA® software, and CT scans¹² of the patient femur. A sample picture of the measurement using Femora® and CT scan are shown in Figures 1 and 2, respectively.

To obtain FAA from FEMORA® software we first obtained conventional radiograph from the patient femur. We obtain anteroposterior and lateral images. Then, software application is embedded in ipad and the camera took images of both radiographs. The images the application was developed to provide not only automatic contouring with a graph-cut algorithm but also an intuitive touch interface for modifying the contour of a radiograph and navigating the 3D view to verify the reconstruction result¹⁶. Then, the software will calculate the FAA angle automatically. The test was repeated three times for each femur.

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-Validity and reliability were determined by three examiners (T.W.M., H.C.K., and M.I.K.). The appraiser was not involved in the development of the software.

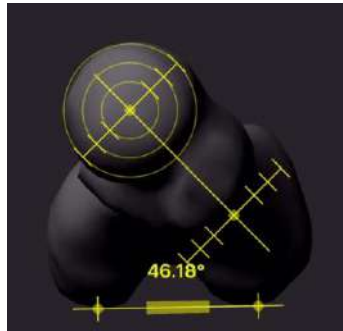


Figure 1. Sample image of the 3D reconstruction from two plane X-rays and the angle measurement using FEMORA® software.

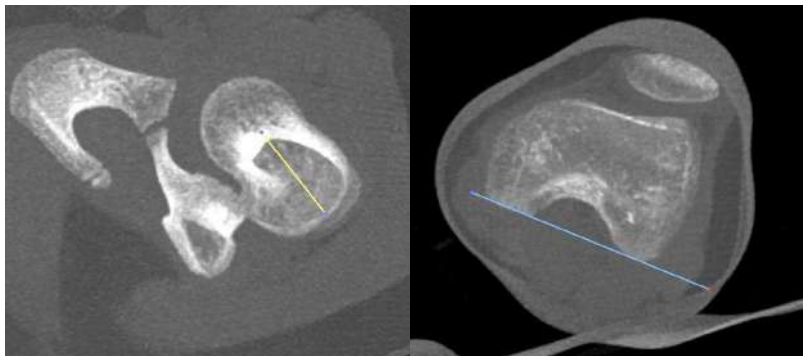


Figure 2. Sample image of the measured CT scan. The measurement method is as described by Hernandez et al¹². On the left is the angle taken from the femur neck. On the right is the angle taken from the posterior border of the medial and lateral condyle. The measured angle is the difference between the two lines.

After the three examiners conducted their assessment, interobserver reliability was assessed visually and quantitatively. Visually, an analysis was carried out using the Bland-Altman test to compare the results of the assessments between examiners 1 and 2, examiners 2 and 3, and examiners 1 and 3. Quantitatively, the intraclass correlation coefficient (ICC) of the three examiners was calculated.

ICC and 95% confidence interval (CI) are used to infer interobserver reliability and was calculated using a 2-way random effects model assuming absolute agreement. An ICC of 1 indicates perfect reliability and an ICC of ≥ 0.8 indicates excellent reliability²². [Pearson](#)

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7 correlation coefficients were used to determine the validity of the measurement of FAA with
8 use of the FEMORA® software. The Pearson correlation coefficient was characterized as poor
9 (0.00 to 0.2), fair (0.21 to 0.4), moderate (0.41 to 0.6), good (0.61 to 0.8), or excellent (0.81 to
10 1.00)²². The Bland-Altman comparison was performed to assess the validity of the assessment
11 using FEMORA® software visually based on a scattered plot²³.

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14 Statistical analysis was performed using SPSS software for Windows (version 25.0;
15 IBM), and the null hypothesis of no difference was rejected if the p-value was <0.05

16 17 **Results**

18 Overall, a total of 36 patients participated in this study. The evaluation results and
19 sample demographic data are tabulated in Table 1. Most patients were female (n=22~~4~~; 61,1%)
20 and the mean age was 7,28 years with a range of 3-12 years.

21
22 **Table 1.** Patient Demographics and Measurements

23 Description	24 N	25 Value	26 Range
27 Gender (Males)	14	14/36 (38,9%)	
28 Age (Years)		7,17 ± 2,24	3-12
29 Measurement Using Physical Examination	36	26,85 ± 6,26	14-48
30 Measurement Using Conventional Radiograph	36	45,09 ± 17,97	14,9-83,2
31 Measurement Using CT Scan 3D	36	32,68 ± 11,85	7,95-65,3
32 Measurement Using FEMORA® Software	36	41,71 ± 12,90	18,3-72,1

33
34 An interobserver reliability test was conducted to determine whether the results of the
35 analysis of the three examiners were consistent and free of bias. This test was carried out
36 visually using the Bland-Altman chart and quantitatively using the ICC.

37
38 Visually, from the Bland-Altman chart, as shown in Figures 3, 4, and 5, it was found
39 that only three of the 36 data points were outside the reasonable range, so it can be concluded
40 that the risk of bias in the assessment is minimal.
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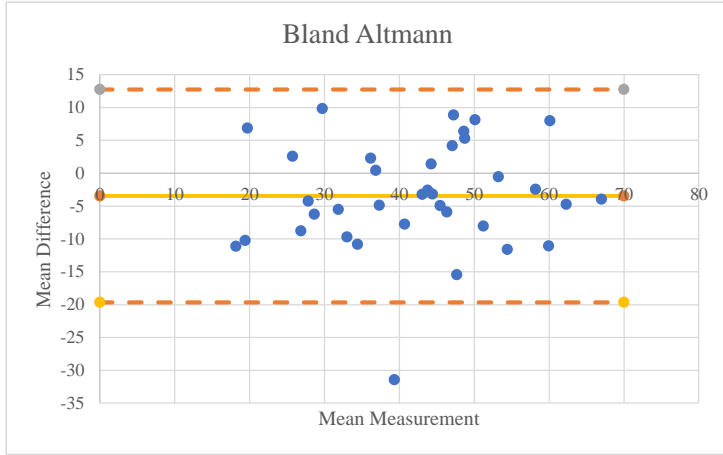


Figure 3. Bland-Altman chart comparison between the 1st and 2nd examiners.

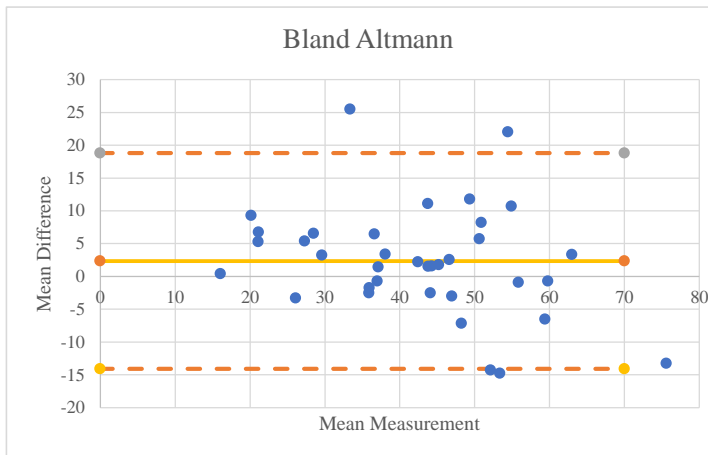


Figure 4. Comparison of the Bland-Altman chart between the 2nd and 3rd examiners.

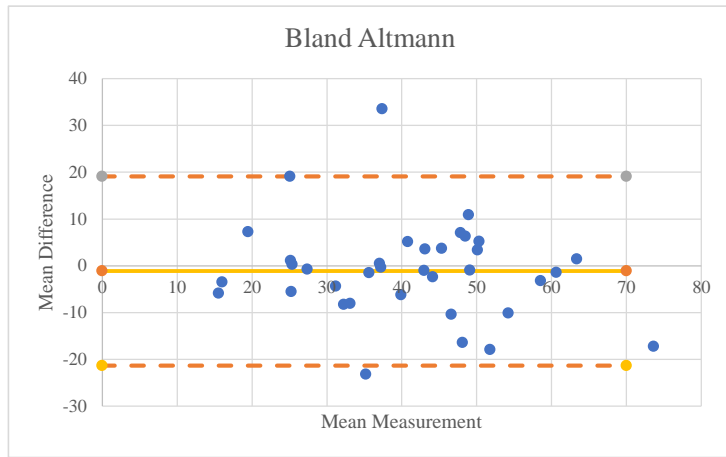


Figure 5. Bland-Altman chart comparison between the 1st and 3rd examiners.

The ICC analysis showed ~~excellent~~ ~~a very good~~ correlation between examiners (ICC, 0.918; 95% CI, 0.858-0.955) which indicated that the results of the FAA angle assessment using X-ray processed with the FEMORA® software were consistent across multiple examiners. In future use in the field, measurements by several trained experts will not show a significant difference.

The measurement results from the CT scan and FEMORA® software were compared using Pearson's correlation test which found a ~~significant~~ and ~~good~~ ~~good~~ correlation ($r=0.634$; $p<0.001$). From The scatter plot (Figure 6), It can be observed that the point of association between these two assessment methods showed a clear trend. This shows that the relationship between these two measurement methods is ~~good~~ ~~fairly strong~~.

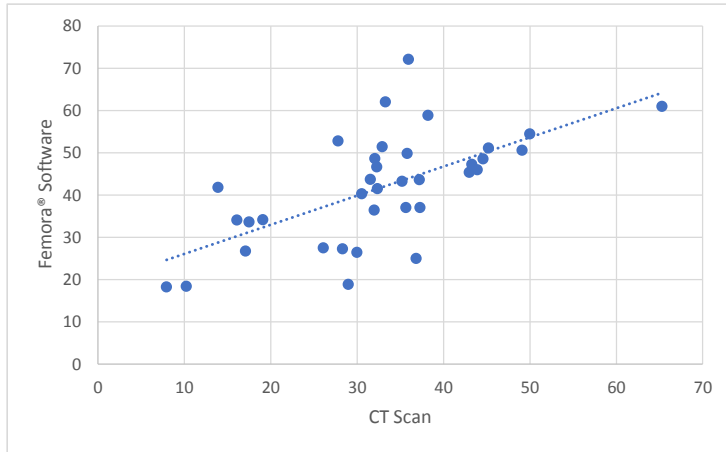


Figure 6. Scatter plot showing the correlation between CT scans and FEMORA® software.

Discussion

FEMORA® is a newly developed software that can reconstruct 3D images of the femur from conventional radiographs. In previous studies, this application has shown convergence validity and good interobserver reliability¹⁶. This study aims to review these results to determine whether validity and reliability also apply to the study population in different centers and geographic locations.

FEMORA® is made to reduce radiation exposure in patients who require routine checkup with CT scans, such as patients with CP. Several notable advantages of FEMORA® compared to CT scans are, firstly, the app only requires a mobile device and a conventional radiograph to visualize a 3D image of the femur. Second, the FEMORA® software could cover a wide FAA: from 18° to 83°, and thus it can be used for ~~a~~-various cases. Third, FEMORA® does not require the patient to remain still for long time periods like on CT scans, making it even more convenient for assessing children who are usually less cooperative.

The mobile application FEMORA® has similar research by Sung et al. They found similarly ~~good~~-excellent interobserver reliability (ICC, 0.953; 95% CI, 0.917-0.975). Visual analysis using Bland-Altman plots was also similarly excellent, with only a few points outside the upper/lower limit. Validity is also similar but the correlation by Sung et al was ~~near to excellent~~-higher score at 0.968¹⁶. Younger patients might have contributed to the lower correlation in our study. Measurement of angles in younger patients are usually more prone to errors due to smaller bone diameters and more non-ossified cartilage in the bones²⁴.

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7 An alternative method that can be used is a biplanar X-ray which is interpreted using a
8 specific system/program. One program that most closely resembles FEMORA® is EOS
9 imaging. EOS was originally used for 3D reconstruction of the spine, but has been found to
10 have good validity and reliability for the measurement of femoral anteversion angle^{25,26}. The
11 radiation dose of the EOS imaging system has been reported to be much less than that of a CT
12 scan. Folinais et al. showed that the mean radiation dose from the EOS system was 0.18 mGy
13 for the AP view and 0.45 mGy for the LAT view, and from a CT scan it was 8.4 to 15.6 mGy.²⁷
14 In addition, Deschenes et al. demonstrated that full spinal EOS imaging yields 6 to 9 times less
15 radiation than conventional radiography²⁸. This huge difference in radiation dose would be
16 similar as in FEMORA®. However, the EOS system is not suitable for use in some hospitals
17 and countries due to its high cost, the need for specialized equipment, and space limitations.

18
19 The limitations of this study are the limited ~~amount~~ number of patients and the lack of
20 repeated CT scan measurement. More patients included in this study would certainly increase
21 the validity of this study. Moreover, CT scan result is also subjective because the measurement
22 is done by single radiologist. Therefore, the data can be false. Repeated CT scan measurement
23 by different assessor will increase the validity of the CT scan measurement.

24 25 26 27 28 29 **Conclusion**

30 The FAA of the samples measured using FEMORA® software and CT scan was,
31 consequently, $41,71 \pm 12,90$ and $32,68 \pm 11,85$. We also found ~~a good~~ excellent reliability
32 ($p=0.918$; 95% CI, 0.858-0.955) and a ~~good~~ good correlation with the CT scan results ($r=0.634$;
33 $p<0.001$). Thus, FEMORA is a good alternative to CT scans as it shows a good correlation and
34 reliability and reduces patient radiation exposure.

35 36 37 38 39 **Ethical Approval**

40 Approval for this study was obtained from our ethic and medico-legal committee of Dr
41 Soetomo Hospital, Surabaya, Indonesia (Reference number: 2009/KEPK/VI/2020).

42 43 44 **Conflicts of Interest**

45 The authors declare that they have no conflict of interest. Each author certifies that he or she
46 has no commercial associations (e.g., consultancies, stock ownership, equity interest,
47 patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the
48 submitted article.

49 50 51 **Acknowledgments**

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7 In memory of Sulis Bayu Sentono. We want to express our gratitude to the chancellors of
8 Airlangga University, the director of Soetomo General Hospital, and our patients, as they are
9 our real teacher that makes this research possible.

10 **Funding Sources**

11 This work was supported by Universitas Airlangga, award number 419/ UN3.14/PT/2020.
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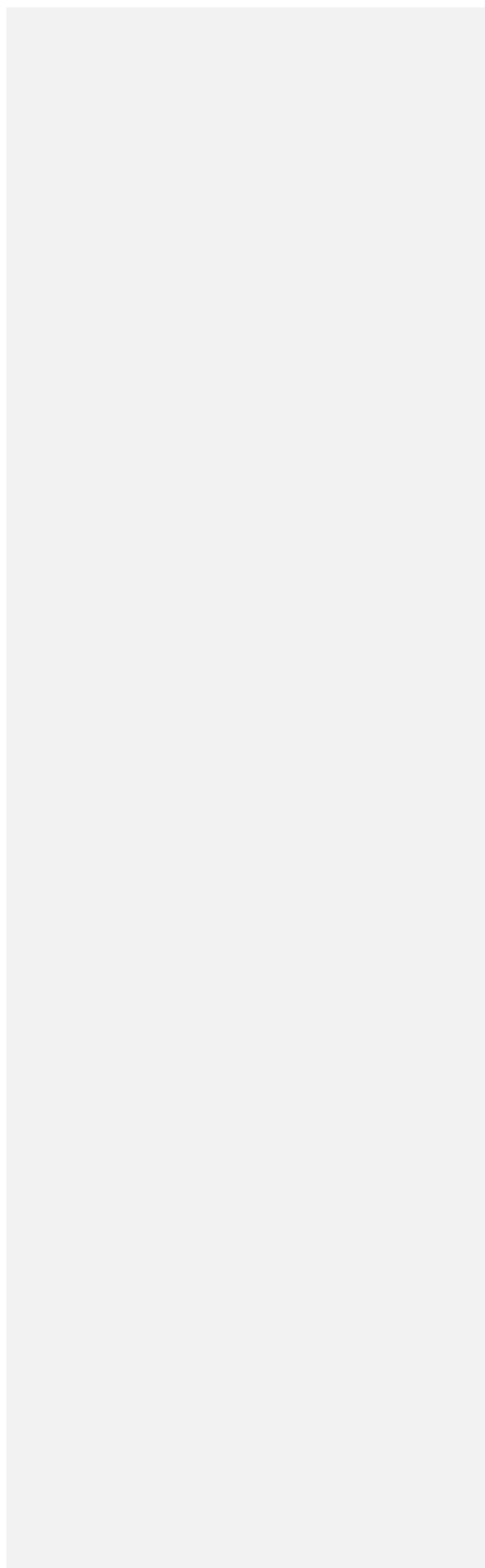
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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Bukti Korespondensi Publikasi Tri Wahyu Martanto, dr., Sp. OT(K)

Judul : Validity of measurement of femoral anteversion angle using FEMORA® software based on two-dimensional radiographic imaging examination femur in children with cerebral palsy in Indonesia

Jurnal : Heliyon; Vol. 9; Issue: 11; No. e22243; November 2023

Penulis : **Tri Wahyu Martanto (Penulis ke-1)**, Yusuf Rizal, Irwanto (Penulis Korespondensi), Sulis Bayu Sentono, Rosy Setiawati, Sri Andreani Utomo, Prastiya Indra Gunawan, Nurul Kusuma Wardani, Prima Hari Nastiti, Rachmat Agung Widodo, Moon Seok Park, Arif Zulkarnain, Hizbillah Yazid, Hendra Cahaya Kumara, Muhammad Ihsan Kitta

6. Decision on submission: minor formatting and/or
administrative changes (3 November 2023)

Fwd: Decision on submission HELIYON-D-23-17881R1 to Heliyon

Agisa Prawesti <agisaprawesti@gmail.com>
Kepada: tri-wahyu-m@fk.unair.ac.id

19 Juni 2024 pukul 11.25

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Dari: **Heliyon** <em@editorialmanager.com>

Date: Jum, 3 Nov 2023 pukul 21.04

Subject: Decision on submission HELIYON-D-23-17881R1 to Heliyon

To: Irwanto Irwanto <irwanto@fk.unair.ac.id>

Ms. No.: HELIYON-D-23-17881R1

Title: VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

Journal: Heliyon

Dear Prof Irwanto,

Thank you for submitting your manuscript to Heliyon.

We have now received all of the editor and reviewer comments on your recent submission to Heliyon. Your paper will become acceptable for publication after implementation of minor formatting and/or administrative changes outlined below.

We also request you to ensure the following about data availability.

While first submitting your manuscript, you were asked two questions regarding data availability. The questions and your responses to them are as follows,

Additional Information

3. Irwanto Irwanto, M.D., Ph.D.

	Question	Response
Data Availability		
	Sharing research data helps other researchers evaluate your findings, build on your work and to increase trust in your article. We encourage all our authors to make as much of their data publicly available as reasonably possible. Please note that your response to the following questions regarding the public data availability and the reasons for potentially not making data available will be available alongside your article upon publication.	No
	Has data associated with your study been deposited into a publicly available repository?	
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reasons for potentially not making data available will be available alongside your article upon publication.

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Kind regards,

David Fernández Munuera, MSc
Editorial Section Manager
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7. Response to Editorial and Reviewer (6 November 2023)

Dear **David Fernández Munuera, MSc**
Editorial Section Manager of Heliyon

Subject: Decision on submission HELIYON-D-23-17881R1 to Heliyon
Title: VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

Regarding the recent revision of our manuscript, we concluded from the revision listed below:

- 1. Editorial Comments:** Please ensure that all figure panels are labelled and the figure captions describe each panel. Currently, Figure [2] contains unlabeled panels.
Author Response: We believe that our manuscript already contained a label, especially in figure [2], please correct us if there are any differences.
- 2. Editorial Comments:** Similarities or overlap with previous article in cross-check database with article: <https://2023.koa.or.kr/eposter/sub1.php>
Author Response: In this case, both are the same research. where we were asked to present research at the Korean orthopaedic association event (according to the link listed) and have mentioned at the time of submission that in this case, our manuscript is under review in the Heliyon journal. please provide your input regarding this matter.
- 3. Editorial Comments:** Data Availability Statement
Author Response: we corrected and stated our data availability in the revised manuscript as you suggested, thank you
- 4. Editorial Comments:** Numbered Reference
Author Response: Thank you for the correction, hopefully, our new revised manuscript has already corrected as suggested by you.

Kind regards,
Prof. Irwanto, M.D., Ph.D.

Bukti Korespondensi Publikasi Tri Wahyu Martanto, dr., Sp. OT(K)

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8. Revisions 2 Submitted (7 November 2023)

VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA

--Manuscript Draft--

Manuscript Number:	HELIYON-D-23-17881R2
Article Type:	Original Research Article
Section/Category:	Medical Sciences
Keywords:	CT scan; X-ray; Femoral Anteversion Angle; Cerebral Palsy
Manuscript Classifications:	130: Health Sciences; 130.260.150: Orthopedics; 130.350: Pediatrics; 130.490: Radiology; 130.510.160: Diagnostics
Corresponding Author:	Irwanto Irwanto, M.D., Ph.D. Airlangga University Department of Child Health INDONESIA
First Author:	Tri Wahyu Martanto, M.D.
Order of Authors:	Tri Wahyu Martanto, M.D. Yusuf Rizal, M.D. Irwanto Irwanto, M.D., Ph.D. Sulis Bayu Sentono Rosy Setiawati Sri Andreani Utomo Prastiya Indra Gunawan Nurul Kusuma Wardani Prima Hari Nastiti Rachmat Agung Widodo Moon Seok Park Arif Zulkarnain Hizbillah Yazid Hendra Cahaya Kumara Muhammad Ihsan Kitta
Abstract:	<p>Introduction: Children with spastic cerebral palsy (CP) often show an increase in femoral anteversion angle (FAA). Computed tomography (CT) scan is the main modality for evaluating FAA in these patients, however, due to significant radiation exposure, it carries a high carcinogenic risk. FEMORA® software is expected to be able to accurately assess FAA even with conventional X-ray images that only require low radiation exposure. However, its validity has not been tested in various populations or CT devices. This study aimed to validate the FEMORA® software by comparing it to CT scans done on an Indonesian population.</p> <p>Material and Methods: All spastic CP patients of the outpatient clinic at Dr. Soetomo Hospital between March and November 2022, were included. The FEMORA® Software evaluation was performed by three examiners. The calculation results were averaged and compared with those of the CT scan. Intraclass correlation coefficient (ICC), reliability, and correlation were assessed.</p> <p>Results: There were 36 patients included in this study. Most were female (n=22; 61,1%) and the average age was 7,28 years old. Interobserver preoperative analysis using ICC showed good outcomes (p=0.918; 95% CI, 0.858-0.955). FAA measurement</p>

	<p>results using FEMORA® and CT scans were $41,71 \pm 12,90$ and $32,68 \pm 11,85$, respectively. Correlation coefficient between the two values is 0.634 ($p < 0.001$). Conclusion: FEMORA® software demonstrates a good and significant correlation with FAA measurement using CT scan.</p>
Opposed Reviewers:	
Additional Information:	
Question	Response
Clinical Study	Yes
Does your study include a clinical study?	
Is your study an (interventional) clinical trial or an observational study? as follow-up to " Clinical Study "	Observational
Does your study include a clinical study? "	
Publication ethics	I confirm
Please confirm that you have reviewed our guidelines for Ethics in Publishing as well as Heliyon's Ethics and Editorial Policies .	

Editor-in-Chief

Pediatric Neurology

6 April 2023

Dear Editor-in-Chief Pediatric Neurology,

I am writing to submit a manuscript, research paper titled “**Validity of Measurement of Femoral Anteversion Angle using FEMORA® Software based on Two-Dimensional Radiographic Imaging Examination Femur in Children with Cerebral Palsy in Indonesia**” to hopefully be published in your esteemed journal.

In this study, we further discuss the comparison of femoral anteversion angle (FAA) measurement in children with a spastic type of cerebral palsy (CP) using FEMORA® software and computed tomography (CT) scan on Indonesian population.

On behalf of all the contributors, I, Prof. Irwanto, will correspond with the journal from this point onward and certify that this manuscript is a unique submission and is not being considered for publication, in part or in full, with any other source in any medium. All authors involved in this study have agreed to be listed as well as have seen and approved the manuscript, its consent, and submission to Pediatric Neurology. None of the authors has any commercial association or financial disclosure that might pose or create a conflict of interest with information presented in this article. We appreciate this opportunity to submit our manuscript and hope that your reviewers and editorial staff find our report relevant and of great interest to your journal.

Thank you for your kind attention and if you have any queries, please don't hesitate to contact us.

Yours sincerely,

Prof. Irwanto, M.D, Ph.D

Department of Child Health, Faculty of Medicine, Universitas Airlangga – Dr. Soetomo General Academic Hospital, Surabaya, Indonesia, 60131. Telephone: +62 813-3243-9990. Email: irwanto@fk.unair.ac.id

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Editorial Section Manager of Heliyon

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Author Response: Thank you for the correction, hopefully, our new revised manuscript has already corrected as suggested by you.

Kind regards,
Prof. Irwanto, M.D., Ph.D.

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7 **VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING**
8 **FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC**
9 **IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN**
10 **INDONESIA**
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13 Tri Wahyu Martanto¹, Yusuf Rizal¹, Irwanto², Sulis Bayu Sentono¹, Rosy Setiawati³, Sri
14 Andreani Utomo³, Prastiya Indra Gunawan², Nurul Kusuma Wardani⁴, Prima Hari Nastiti²,
15 Rachmat Agung Widodo¹, Moon Seok Park⁵, Arif Zulkarnain¹, Hizbillah Yazid¹, Hendra
16 Cahaya Kumara⁶, Muhammad Ihsan Kitta⁷
17

18 ¹Department of Orthopaedic and Traumatology, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo
19 General Academic Hospital, Surabaya 60286, Indonesia.

20 ²Department of Child Health, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo General Academic
21 Hospital, Surabaya 60131, Indonesia.

22 ³Department of Radiology, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo General Academic
23 Hospital, Surabaya 60131, Indonesia.

24 ⁴Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Universitas Airlangga/ Dr. Soetomo
25 General Academic Hospital, Surabaya 60131, Indonesia.

26 ⁵Department of Orthopaedic Surgery, Seoul National University College of Medicine/ Seoul National University
27 Bundang Hospital, Sungnam, Gyeonggi, South Korea

28 ⁶Department of Orthopaedic and Traumatology, Prof. Dr. R. Soeharso Orthopaedic Hospital, Sebelas Maret
29 University, Surakarta 57126, Indonesia

30 ⁷Department of Orthopaedic Surgery, Muhammadiyah University of Makassar, Makassar 90221, Indonesia

31 Correspondence to Irwanto; irwanto@fk.unair.ac.id

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ABSTRACT

Introduction: Children with a spastic ~~type of~~ cerebral palsy (CP) often show an increase in femoral anteversion angle (FAA). ~~CA~~ computed tomography (CT) scan is the main modality for evaluating FAA in these patients, ~~however~~ but, due to significant radiation exposure, ~~it~~ carries a high carcinogenic risk. FEMORA® software is expected to be able to accurately assess FAA even with conventional X-ray images that only require low radiation exposure. However, its validity has not been tested in various populations or CT devices. This study ~~aimed~~ to validate the FEMORA® software by comparing it to CT scans done on an Indonesian population.

Material and Methods: All spastic CP patients ~~who attended~~ of the outpatient clinic at Dr. Soetomo Hospital between March ~~2022~~ and November 2022, were included. The FEMORA® Software evaluation was performed by three examiners. The calculation results ~~will be~~ were averaged and compared with those of the CT scan. Intraclass correlation coefficient (ICC), reliability, and correlation ~~will were~~ be assessed.

Results: There were 36 patients included in this study. Most were female (n=22; 61,1%) and the ~~the~~ average age was 7,28 years old. Interobserver preoperative analysis using ICC showed good outcomes (p=0.918; 95% CI, 0.858-0.955). FAA measurement results using FEMORA® and CT scans were $41,71 \pm 12,90$ and $32,68 \pm 11,85$, respectively. Correlation coefficient between the two values is 0.634 (p<0.001).

Conclusion: FEMORA® software ~~is found to have~~ demonstrates a good and significant ~~correlation~~ -good and significant correlation- with FAA measurement using CT scan.

Keywords: CT Scan, X-ray, Femoral Anteversion Angle, Cerebral Palsy

Introduction

The femoral anteversion angle (FAA) is the angle formed between the axis of the femoral neck and the axis of the coronal plane of the femoral condyle (condylar plane)^{1,2}. An increase in FAA will decrease the arm abduction moment of the hip abductor and lead to a cosmetically poor gait pattern,³ inefficient gait, and functional limitations⁴⁻⁷.

In measuring FAA, a physician may do physical examination, conventional radiography, or computed tomography (CT) scans. Clinical examination using the Trochanteric Prominence Angle Test is reliable for measuring FAA and is a useful screening tool. The advantage of this examination is that it can be performed repeatedly, is inexpensive, safe and does not involve radiation exposure^{8,9}. However, this method is less accurate and reliable due to muscle spasticity, deviation in the position of the femur and deformity of the bones¹⁰.

Conventional 2D radiography is generally used for the diagnosis and follow-up of the lower extremities, but it has the disadvantage of being sensitive to the orientation of the patient and bone deformities. A CT scan overcomes this disadvantage and provides more accurate calculations¹¹⁻¹³. By being able to scan through multiple slices and even create a 3D reconstruction of the affected site, CT is considered the “gold standard” imaging technique for evaluating FAA^{2,14} and is a reliable and valid method¹⁰. The disadvantage of a CT scan is that it has a high carcinogenic risk due to the high radiation exposure, especially in the pediatric population¹⁵.

FEMORA® Software developed by Didim Co., Ltd. tries to solve the radiation and cost problem of CT scans. By using only biplanar X-rays and the help of FEMORA® software, 3D images can be reconstructed and the need for a CT scan is reduced¹⁶. If validity and reliability are proven, it will help reduce the burdens of cost and radiation exposure in patients. Consequently, this program may replace the need for CT scans or as reference standards for measuring FAA.

To prove the validity and reliability of this software before use as a standard for measuring FAA in a clinical setting, it is important for the software to pass repeated tests and carry out in research centers and different populations^{17,18}. In assessing the capacity of this software to measure FAA, patients with highly variant FAA are needed.

Cerebral palsy (CP) is a chronic condition with considerable impact on affected individuals. Children with CP suffer from motor problems, frequent seizure/epilepsy, and other disorders^{19,20}. Such chronic disorder combined with immature femur results in changes on FAA angle¹⁰. Thus, patients with spastic CP tend to have varied FAA and will be ideal candidates for assessing this software.

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As of the conduction of this study, the validity and reliability testing of the FEMORA® software has been performed in only one study¹⁶. Therefore, this study was conducted to evaluate and re-validate the application of FEMORA® medical 3D image software measurement by focusing on FAA measurements.

Methods

This is an observational analytic study with a cross-sectional approach to evaluate the validity of using plain radiographs of the anteroposterior and lateral femur calculated using the FEMORA® Software to assess FAA in patients with CP 2 to 12 years old who attended the outpatient clinic at Dr. Soetomo General Hospital from March 2022 to January 2023. Informed consent was obtained from each participant and ethical approval was obtained from the Ethics Committee of the Dr. Soetomo General Hospital Surabaya.

The criteria in this study were: (1) patients with Spastic CP willing to undergo pelvic radiography, femur radiography, and CT scan, (2) patients who are not currently being treated for other diseases, (3) adequate radiographic coverage or quality, (4) no femur fracture, hip joint contracture, or hip joint dislocation, and (5) patients had never had implants.

FAA was assessed using clinical examination⁷, femur radiography²¹, FEMORA® software, and CT scans¹² of the patient femur. A sample picture of the measurement using Femora® and CT scan are shown in Figures 1 and 2, respectively.

To obtain FAA from FEMORA® software we first obtained conventional radiograph from the patient femur. We obtain anteroposterior and lateral images. Then, software application is embedded in ipad and the camera took images of both radiographs. The images the application was developed to provide not only automatic contouring with a graph-cut algorithm but also an intuitive touch interface for modifying the contour of a radiograph and navigating the 3D view to verify the reconstruction result¹⁶. Then, the software will calculate the FAA angle automatically. The test was repeated three times for each femur.

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-Validity and reliability were determined by three examiners (T.W.M., H.C.K., and M.I.K.). The appraiser was not involved in the development of the software.

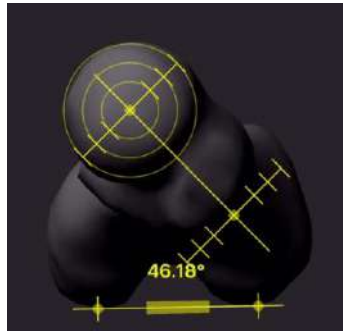


Figure 1. Sample image of the 3D reconstruction from two plane X-rays and the angle measurement using FEMORA® software.

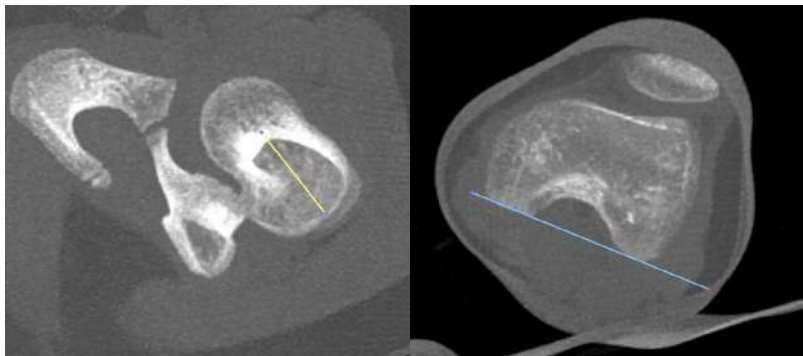


Figure 2. Sample image of the measured CT scan. The measurement method is as described by Hernandez et al¹². On the left is the angle taken from the femur neck. On the right is the angle taken from the posterior border of the medial and lateral condyle. The measured angle is the difference between the two lines.

After the three examiners conducted their assessment, interobserver reliability was assessed visually and quantitatively. Visually, an analysis was carried out using the Bland-Altman test to compare the results of the assessments between examiners 1 and 2, examiners 2 and 3, and examiners 1 and 3. Quantitatively, the intraclass correlation coefficient (ICC) of the three examiners was calculated.

ICC and 95% confidence interval (CI) are used to infer interobserver reliability and was calculated using a 2-way random effects model assuming absolute agreement. An ICC of 1 indicates perfect reliability and an ICC of ≥ 0.8 indicates excellent reliability²². [Pearson](#)

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7 correlation coefficients were used to determine the validity of the measurement of FAA with
8 use of the FEMORA® software. The Pearson correlation coefficient was characterized as poor
9 (0.00 to 0.2), fair (0.21 to 0.4), moderate (0.41 to 0.6), good (0.61 to 0.8), or excellent (0.81 to
10 1.00)²². The Bland-Altman comparison was performed to assess the validity of the assessment
11 using FEMORA® software visually based on a scattered plot²³.

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14 Statistical analysis was performed using SPSS software for Windows (version 25.0;
15 IBM), and the null hypothesis of no difference was rejected if the p-value was <0.05

16 17 **Results**

18 Overall, a total of 36 patients participated in this study. The evaluation results and
19 sample demographic data are tabulated in Table 1. Most patients were female (n=22~~4~~; 61,1%)
20 and the mean age was 7,28 years with a range of 3-12 years.

21
22 **Table 1.** Patient Demographics and Measurements

23 Description	24 N	25 Value	26 Range
27 Gender (Males)	14	14/36 (38,9%)	
28 Age (Years)		7,17 ± 2,24	3-12
29 Measurement Using Physical Examination	36	26,85 ± 6,26	14-48
30 Measurement Using Conventional Radiograph	36	45,09 ± 17,97	14,9-83,2
31 Measurement Using CT Scan 3D	36	32,68 ± 11,85	7,95-65,3
32 Measurement Using FEMORA® Software	36	41,71 ± 12,90	18,3-72,1

33
34 An interobserver reliability test was conducted to determine whether the results of the
35 analysis of the three examiners were consistent and free of bias. This test was carried out
36 visually using the Bland-Altman chart and quantitatively using the ICC.

37
38 Visually, from the Bland-Altman chart, as shown in Figures 3, 4, and 5, it was found
39 that only three of the 36 data points were outside the reasonable range, so it can be concluded
40 that the risk of bias in the assessment is minimal.
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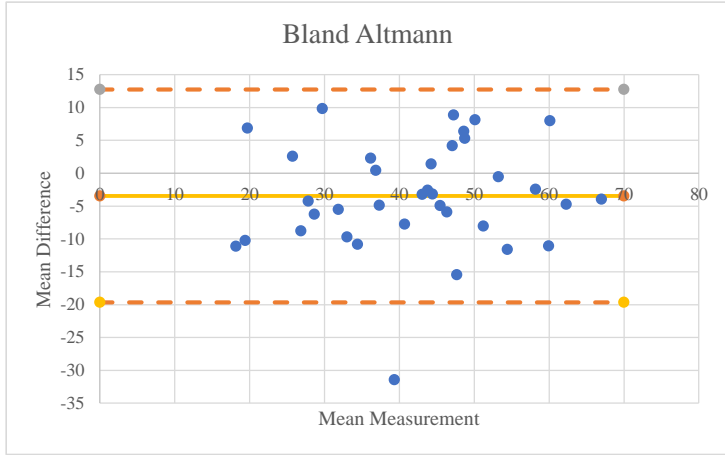


Figure 3. Bland-Altman chart comparison between the 1st and 2nd examiners.

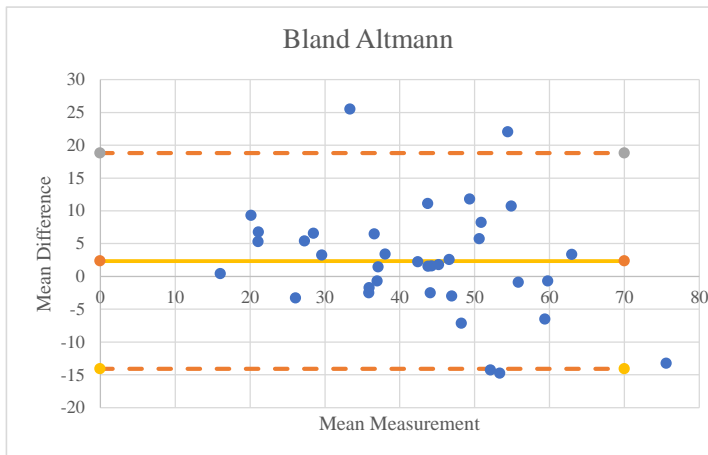


Figure 4. Comparison of the Bland-Altman chart between the 2nd and 3rd examiners.

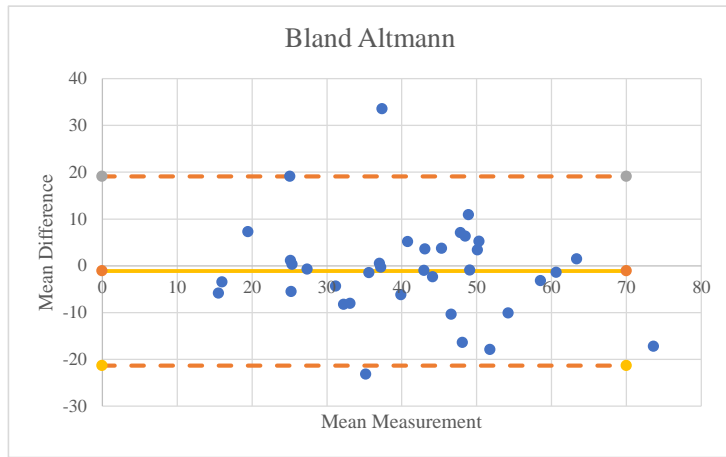


Figure 5. Bland-Altman chart comparison between the 1st and 3rd examiners.

The ICC analysis showed ~~excellent~~ ~~a very good~~ correlation between examiners (ICC, 0.918; 95% CI, 0.858-0.955) which indicated that the results of the FAA angle assessment using X-ray processed with the FEMORA® software were consistent across multiple examiners. In future use in the field, measurements by several trained experts will not show a significant difference.

The measurement results from the CT scan and FEMORA® software were compared using Pearson's correlation test which found a ~~significant~~ and ~~good~~ ~~good~~ correlation ($r=0.634$; $p<0.001$). From The scatter plot (Figure 6), It can be observed that the point of association between these two assessment methods showed a clear trend. This shows that the relationship between these two measurement methods is ~~good~~ ~~fairly strong~~.

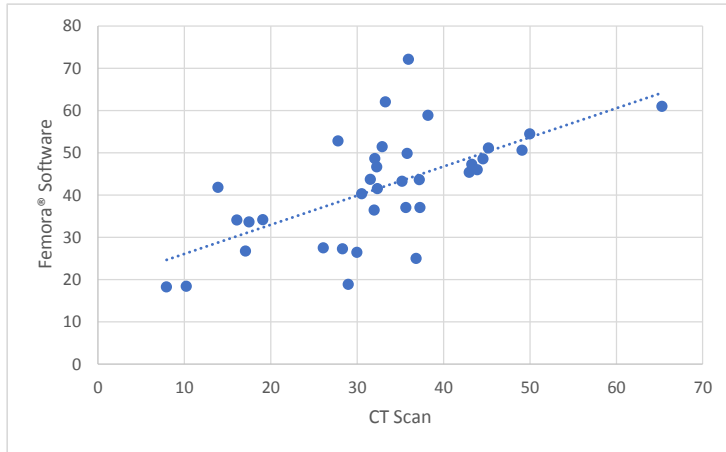


Figure 6. Scatter plot showing the correlation between CT scans and FEMORA® software.

Discussion

FEMORA® is a newly developed software that can reconstruct 3D images of the femur from conventional radiographs. In previous studies, this application has shown convergence validity and good interobserver reliability¹⁶. This study aims to review these results to determine whether validity and reliability also apply to the study population in different centers and geographic locations.

FEMORA® is made to reduce radiation exposure in patients who require routine checkup with CT scans, such as patients with CP. Several notable advantages of FEMORA® compared to CT scans are, firstly, the app only requires a mobile device and a conventional radiograph to visualize a 3D image of the femur. Second, the FEMORA® software could cover a wide FAA: from 18° to 83°, and thus it can be used for ~~a~~-various cases. Third, FEMORA® does not require the patient to remain still for long time periods like on CT scans, making it even more convenient for assessing children who are usually less cooperative.

The mobile application FEMORA® has similar research by Sung et al. They found similarly ~~good~~-excellent interobserver reliability (ICC, 0.953; 95% CI, 0.917-0.975). Visual analysis using Bland-Altman plots was also similarly excellent, with only a few points outside the upper/lower limit. Validity is also similar but the correlation by Sung et al was ~~near to excellent~~-higher score at 0.968¹⁶. Younger patients might have contributed to the lower correlation in our study. Measurement of angles in younger patients are usually more prone to errors due to smaller bone diameters and more non-ossified cartilage in the bones²⁴.

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7 An alternative method that can be used is a biplanar X-ray which is interpreted using a
8 specific system/program. One program that most closely resembles FEMORA® is EOS
9 imaging. EOS was originally used for 3D reconstruction of the spine, but has been found to
10 have good validity and reliability for the measurement of femoral anteversion angle^{25,26}. The
11 radiation dose of the EOS imaging system has been reported to be much less than that of a CT
12 scan. Folinais et al. showed that the mean radiation dose from the EOS system was 0.18 mGy
13 for the AP view and 0.45 mGy for the LAT view, and from a CT scan it was 8.4 to 15.6 mGy.²⁷
14 In addition, Deschenes et al. demonstrated that full spinal EOS imaging yields 6 to 9 times less
15 radiation than conventional radiography²⁸. This huge difference in radiation dose would be
16 similar as in FEMORA®. However, the EOS system is not suitable for use in some hospitals
17 and countries due to its high cost, the need for specialized equipment, and space limitations.

18
19 The limitations of this study are the limited ~~amount-number~~ of patients and the lack of
20 repeated CT scan measurement. More patients included in this study would certainly increase
21 the validity of this study. Moreover, CT scan result is also subjective because the measurement
22 is done by single radiologist. Therefore, the data can be false. Repeated CT scan measurement
23 by different assessor will increase the validity of the CT scan measurement.

24 25 26 27 28 29 **Conclusion**

30 The FAA of the samples measured using FEMORA® software and CT scan was,
31 consequently, $41,71 \pm 12,90$ and $32,68 \pm 11,85$. We also found ~~a good-excellent~~ reliability
32 ($p=0.918$; 95% CI, 0.858-0.955) and a ~~good-good~~ correlation with the CT scan results ($r=0.634$;
33 $p<0.001$). Thus, FEMORA is a good alternative to CT scans as it shows a good correlation and
34 reliability and reduces patient radiation exposure.

35 36 37 38 39 **Ethical Approval**

40 Approval for this study was obtained from our ethic and medico-legal committee of Dr
41 Soetomo Hospital, Surabaya, Indonesia (Reference number: 2009/KEPK/VI/2020).

42 43 44 45 **Conflicts of Interest**

46 The authors declare that they have no conflict of interest. Each author certifies that he or she
47 has no commercial associations (e.g., consultancies, stock ownership, equity interest,
48 patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the
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Data availability statement

The data will be made available upon request. Contact the corresponding author to retrieve the data.

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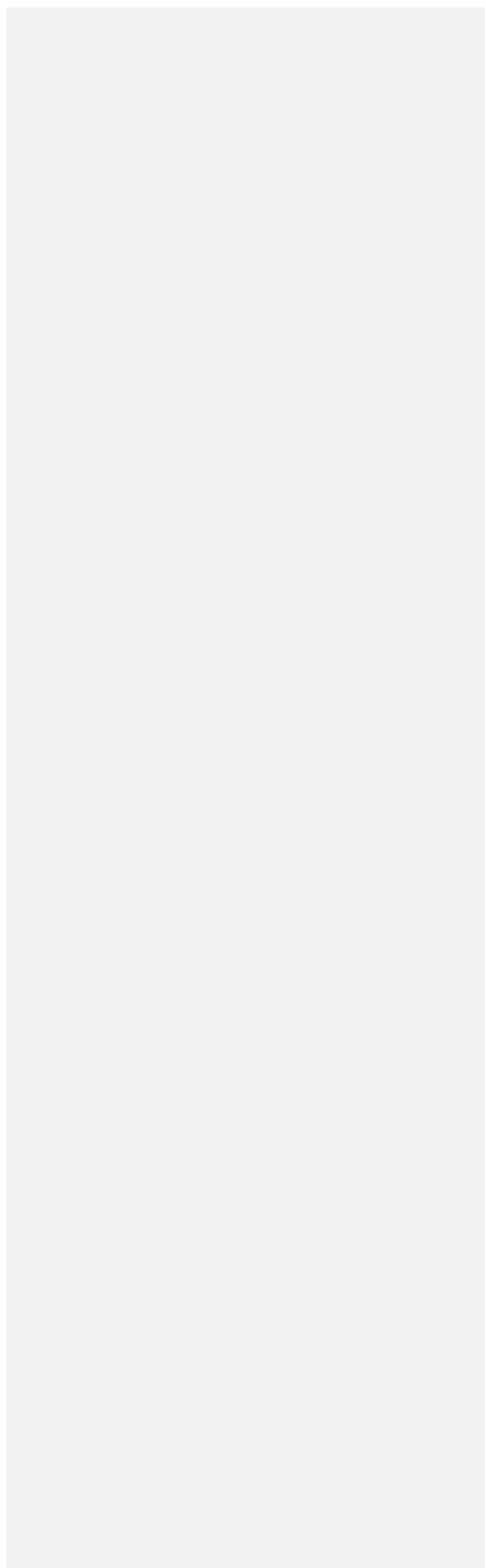
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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Judul : Validity of measurement of femoral anteversion angle using FEMORA® software based on two-dimensional radiographic imaging examination femur in children with cerebral palsy in Indonesia

Jurnal : Heliyon; Vol. 9; Issue: 11; No. e22243; November 2023

Penulis : **Tri Wahyu Martanto (Penulis ke-1)**, Yusuf Rizal, Irwanto (Penulis Korespondensi), Sulis Bayu Sentono, Rosy Setiawati, Sri Andreani Utomo, Prastiya Indra Gunawan, Nurul Kusuma Wardani, Prima Hari Nastiti, Rachmat Agung Widodo, Moon Seok Park, Arif Zulkarnain, Hizbillah Yazid, Hendra Cahaya Kumara, Muhammad Ihsan Kitta

9. Manuscript has been accepted for publication (7
November 2023)

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Subject: Decision on submission to Heliyon

Manuscript Number: HELIYON-D-23-17881R2
Title: VALIDITY OF MEASUREMENT OF FEMORAL ANTEVERSION ANGLE USING FEMORA® SOFTWARE BASED ON TWO-DIMENSIONAL RADIOGRAPHIC IMAGING EXAMINATION FEMUR IN CHILDREN WITH CEREBRAL PALSY IN INDONESIA
Journal: Heliyon

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Judul : Validity of measurement of femoral anteversion angle using FEMORA® software based on two-dimensional radiographic imaging examination femur in children with cerebral palsy in Indonesia

Jurnal : Heliyon; Vol. 9; Issue: 11; No. e22243; November 2023

Penulis : **Tri Wahyu Martanto (Penulis ke-1)**, Yusuf Rizal, Irwanto (Penulis Korespondensi), Sulis Bayu Sentono, Rosy Setiawati, Sri Andreani Utomo, Prastiya Indra Gunawan, Nurul Kusuma Wardani, Prima Hari Nastiti, Rachmat Agung Widodo, Moon Seok Park, Arif Zulkarnain, Hizbillah Yazid, Hendra Cahaya Kumara, Muhammad Ihsan Kitta

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Our reference: HLY e22243

Article reference: HLY_HELIYON-D-23-17881

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Prof Irwanto Irwanto
Heliyon

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Phone : +62 81332439990
Email : irwanto.fk.unair.ac.id

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