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PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

Manuscript NO: 56046

Title: Early clinical outcome and learning curve following unilateral primary total knee arthroplasty after introduction of novel total knee arthroplasty system

Reviewer's code: 02444715
Position: Peer Reviewer
Academic degree: FRSC, MD, PhD
Professional title: Professor
Reviewer's Country/Territory: Egypt
Author's Country/Territory: Denmark
Manuscript submission date: 2020-04-17
Reviewer chosen by: Xiao-Quan Yu
Reviewer accepted review: 2020-05-13 20:57
Reviewer performed review: 2020-05-13 21:04
Review time: 1 Hour

Scientific quality	[ ] Grade A: Excellent [ ] Grade B: Very good [ ] Grade C: Good [Y] Grade D: Fair [ ] Grade E: Do not publish
Language quality	[ ] Grade A: Priority publishing [ ] Grade B: Minor language polishing [Y] Grade C: A great deal of language polishing [ ] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [Y] Major revision [ ] Rejection
Re-review	[Y] Yes [ ] No
Peer-reviewer statements	Peer-Review: [ ] Anonymous [Y] Onymous Conflicts-of-Interest: [ ] Yes [Y] No

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SPECIFIC COMMENTS TO AUTHORS

the paper need an abstract The authors need to clarify in the paper text any fund from the manufacturers or suspected bias that could affect the methodology or results and conclusions longer follow-up is needed and that need to be a very clear point of weakness in the discussion

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PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

Manuscript NO: 56046

Title: Early clinical outcome and learning curve following unilateral primary total knee arthroplasty after introduction of novel total knee arthroplasty system

Reviewer's code: 00505434
Position: Peer Reviewer
Academic degree: MD
Professional title: Professor, Surgeon
Reviewer's Country/Territory: United States
Author's Country/Territory: Denmark

Manuscript submission date: 2020-04-17
Reviewer chosen by: Ya-Juan Ma
Reviewer accepted review: 2020-07-21 13:43
Reviewer performed review: 2020-07-23 13:31
Review time: 1 Day and 23 Hours

Scientific quality	[ ] Grade A: Excellent [Y] Grade B: Very good [ ] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish
Language quality	[ ] Grade A: Priority publishing [Y] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [Y] Accept (General priority) [ ] Minor revision [ ] Major revision [ ] Rejection
Re-review	[ ] Yes [Y] No
Peer-reviewer statements	Peer-Review: [Y] Anonymous [ ] Onymous Conflicts-of-Interest: [ ] Yes [Y] No

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SPECIFIC COMMENTS TO AUTHORS

This manuscript describes a study on how implementation of a new TKA system influences perioperative and surgical outcome. The authors found an increase in operation time of 14 minutes (from 50 to 64 minutes) immediately after introduction, with a median intraoperative blood loss significantly increased from 200 mL to 250 mL following the introduction. The differences diminish one year after the introduction of the new implant. The manuscript is well written. The study design is reasonable. The study was well conducted and analyzed. The discussion is balanced. The findings support previous published data. The study does add new information to the field. This is a clinical study therefore if it were done in the United States it would need IRB review and approval. The authors stated "No approval from the National Ethics Committee was necessary as this was a non-interventional observational study. Permission to store and review patient data was obtained from the Danish Data Protection Agency Jr, No. 2007-58-0015.", so please double check that this will meet the criteria by Danish regulatory agency, and meet the standard of publication by the Journal. It is not clear if surgeons used tourniquet or not during surgery. With recently almost universal use of tranexamic acid, intra-op blood loss is truly minimal. Please add this info and briefly discuss why patient in the study had average of 250 ml blood loss. Thanks for submitting your study to WJO.

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PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

Manuscript NO: 56046

Title: Early clinical outcome and learning curve following unilateral primary total knee arthroplasty after introduction of novel total knee arthroplasty system

Reviewer's code: 02488945
Position: Editorial Board
Academic degree: MD

Professional title: Doctor, Lecturer

Reviewer's Country/Territory: India

Author's Country/Territory: Denmark

Manuscript submission date: 2020-04-17

Reviewer chosen by: Ya-Juan Ma

Reviewer accepted review: 2020-07-21 08:21

Reviewer performed review: 2020-07-24 11:48

Review time: 3 Days and 3 Hours

Scientific quality	[ ] Grade A: Excellent [ ] Grade B: Very good [ ] Grade C: Good [Y] Grade D: Fair [ ] Grade E: Do not publish
Language quality	[ ] Grade A: Priority publishing [Y] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [Y] Major revision [ ] Rejection
Re-review	[ ] Yes [Y] No
Peer-reviewer statements	Peer-Review: [Y] Anonymous [ ] Onymous Conflicts-of-Interest: [ ] Yes [Y] No

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SPECIFIC COMMENTS TO AUTHORS

The article "Introduction of novel Total Knee Arthroplasty system influences surgery related factors and implant positioning immediately following implementation" does not have any new message. Any new procedure is bound to have a learning curve and some difficulties. The title mentions about Novel system but have evaluated only one new implant viz Persona® (Zimmer-Biomet, Warsaw, Indiana, USA). The title "Outcomes after first 75 consecutive unilateral primary TKA using Persona® (Zimmer-Biomet, Warsaw, Indiana, USA)"..would be more appropriate. Increase the operation time by 14 minutes, though statistically significant, is clinically insignificant. Blood loss increase of 50 ml..or 25% may sound a lot but is totally insignificant in ASA II adult patients. Also, were patient blood management (PBM) measures for decreasing blood loss were same in all groups? Was tranexamic acid was used in all patients? Was the type of anesthesia same in all patients.. regional or general anesthesia? The authors need to look at the post-operative pain factor too, especially as the LOS in the hospital was halved. These patients should be followed up after 1 year, 2 years and 3 years (and 5 years if possible) for the degree of movement and any other complications and compared with the control group. Line 106…? 71-, 54-, and 75 % by the….do you mean 71%, 54% and 75%

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PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

Manuscript NO: 56046

Title: Early clinical outcome and learning curve following unilateral primary total knee arthroplasty after introduction of novel total knee arthroplasty system

Reviewer's code: 02696233
Position: Peer Reviewer
Academic degree: MD

Professional title: Doctor

Reviewer's Country/Territory: France

Author's Country/Territory: Denmark

Manuscript submission date: 2020-04-17

Reviewer chosen by: Ya-Juan Ma

Reviewer accepted review: 2020-07-21 16:36

Reviewer performed review: 2020-07-26 13:49

Review time: 4 Days and 21 Hours

Scientific quality	[ ] Grade A: Excellent [Y] Grade B: Very good [ ] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish
Language quality	[Y] Grade A: Priority publishing [ ] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [ ] Accept (General priority) [Y] Minor revision [ ] Major revision [ ] Rejection
Re-review	[Y] Yes [ ] No
Peer-reviewer statements	Peer-Review: [ ] Anonymous [Y] Onymous Conflicts-of-Interest: [ ] Yes [Y] No

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SPECIFIC COMMENTS TO AUTHORS

Comments Manuscript NO: 56046 Title: Introduction of novel Total Knee Arthroplasty system influences surgery related factors and implant positioning immediately following implementation Manuscript Type: Retrospective Study Dear authors, Thank you to give me the opportunity to review your article. You will f ind some comments in the reviewed manuscript enclosed. the topic is very interesting and innovative specialy in the context of the new regulations applied in the European community " medical device regulation". In the introduction it would be helpful to cite an article dealing with this topic. Klar E. Medical Device Regulation als aktuelle Herausforderung für die rechtssichere Einführung neuer Technologien [Medical Device Regulation as current challenge for the legally safe introduction of new technologies]. Chirurg. 2018;89(10):755-759. doi:10.1007/s00104-018-0705-3 Melvin T, Torre M. New medical device regulations: the regulator's view. EFORT Open Rev. 2019;4(6):351-356. Published 2019 Jun 3. doi:10.1302/2058-5241.4.180061 Martelli N, Eskenazy D, Déan C, et al. New European Regulation for Medical Devices: What Is Changing?. Cardiovasc Intervent Radiol. 2019;42(9):1272-1278. doi:10.1007/s00270-019-02247-0 Material and methods The study is nicely constructed but for a better understanding of the selection process please provide to the lector a flow chart of the selection to identify each group of patients. If we consider that the patient factors are the same, that the surgical factor is not biased by a study with 3 surgeons, that the prosthesis is almost conceptually identical (CR design), what are the factors that can significantly influence this lengthening of operating time and bleeding? What was the fixation of Persona compared to control group cemented or cementless? What about the instruments? What are the main differences between Persona and the other instruments you regularly used in the control group? You need to analyze the concept of the ancillary which

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may be the "roots" cause of this difference? Intramedullary rods? Difficulties in locating the axes and cutting levels etc... Basically the implant alone cannot disturb an experienced surgeon as much. The work is very interesting but the analysis of the root causes of these differences is not reported in the study. There is simply an analysis of the side effects but no analysis of the causes. You have to look in detail for differences that may exist between the two systems outside the implant. However, if the implant is fundamentally different (e.g. fixation method) this factor can be considered as discriminating in the differences in results. Have you abandoned this system? The work is very interesting but the analysis of the root causes of these differences is not reported in the study.

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RE-REVIEW REPORT OF REVISED MANUSCRIPT

Name of journal: World Journal of Orthopedics

Manuscript NO: 56046

Title: Early clinical outcome and learning curve following unilateral primary total knee arthroplasty after introduction of novel total knee arthroplasty system

Reviewer's code: 02444715
Position: Peer Reviewer
Academic degree: FRSC, MD, PhD
Professional title: Professor
Reviewer's Country/Territory: Egypt
Author's Country/Territory: Denmark
Manuscript submission date: 2020-04-17
Reviewer chosen by: Jia-Ping Yan
Reviewer accepted review: 2020-08-19 15:40
Reviewer performed review: 2020-08-19 15:45
Review time: 1 Hour

Scientific quality	[ ] Grade A: Excellent [ ] Grade B: Very good [ ] Grade C: Good [ ] Grade D: Fair [Y] Grade E: Do not publish
Language quality	[ ] Grade A: Priority publishing [ ] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [Y] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [ ] Major revision [Y] Rejection
Peer-reviewer statements	Peer-Review: [ ] Anonymous [Y] Onymous Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

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In a new system of arthroplasty the risk of bias can affect the methodology and the analysis and interpretation of data The short term follow-up give the reader no conclusive data about the real efficacy nor safety of any new system in arthroplasty