

Patient satisfaction - A comparison between patient-specific implants and conventional total knee arthroplasty

Pia Reimann^{a,*}, Martin Brucker^a, Dariusch Arbab^a, Christian Lüring^a

^a Department of Orthopedic Surgery, Klinikum Dortmund gGmbH, Beurhausstraße 40, 44137 Dortmund, Germany

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ABSTRACT

Background: Despite recent innovations in total knee arthroplasty, 20% of the patients are not completely satisfied with the clinical results. Regarding patient-specific implants (PSI), the study aims to compare individual and off-the-shelf implant (OSI) total knee arthroplasty (TKA) concerning the postoperative outcome like function and global patient satisfaction.

Methods: In 2013/14 228 patients received a TKA due to primary osteoarthritis with an indication for a bicondylar, cruciate retaining prosthesis. 125 patients received a PSI and 103 an OSI TKA. The outcome after surgery was evaluated retrospectively by two questionnaires and a clinical follow-up examination. The Knee Society Score (KSS) was used to evaluate function. To compare the satisfaction the Knee Injury and Osteoarthritis Outcome Score (KOOS) and a modified EuroQol (EQ) including five additional questions were used. Finally, 84 patients with PSI and 57 with OSI completed follow-up.

Results: Concerning demographic data, the PSI group showed a significantly younger age, five years on average. The ROM was comparable in both groups. The KSS and the separate function score achieved significantly better results in the PSI group. For subjects with PSI TKA, the global satisfaction showed significant better values.

Conclusions: The significantly higher values in KSS and its function score lead to a better basic daily function in PSI group. In addition, the PSI TKA achieved a higher global patient satisfaction. Nevertheless, both should mainly be assessed in the context of average younger age and the influence of expectations.

1. Introduction

Even though total knee arthroplasty (TKA) is a standardised routine operation 20% of patients are still not completely satisfied with the results.^{1–4} Regarding the rates of other interventions in orthopedic surgery like hip replacement, the satisfaction is capable of improvement. Several innovations in the design of the prosthesis or the accuracy of alignment have been developed to increase the rate of satisfaction. Currently, none of these, neither computer-navigated systems nor mobile-bearing prostheses nor gender implants, achieved substantial improvement in clinical outcome and global satisfaction.^{5–8} The patient-specific implants are part of the progress. Hypothetically, patient-specific manufacturing leads to more natural knee kinematics, which might improve patient satisfaction.

Patient-specific implant applies the data of a computerized tomography (CT) to produce a 3-D-image. Hence the disposable instruments and implants are based on the individual anatomy of the knee. The ConforMIS iTotal® (ConforMIS, Burlington, Massachusetts, USA) as a patient-specific cruciate-retaining TKA (PSI) contains individually

printed custom-cutting-blocks (iJig®), a planning overview (iView®) and the individual implants. It enables the individual adjustment of the femoral J-curves, the individual distal and posterior offset and includes a preset neutral mechanical alignment. In addition, bone resection and implant overhang are reduced.^{9–11} Regardless these advantages current literature lacks data focusing on clinical outcome of these design benefits. It was therefore the aim of our retrospective study to compare the postoperative clinical outcome of patients with off-the-shelf (OSI) and PSI TKA.

2. Methods

The study was based on a retrospective design. Between 01.01.2013 and 31.12.2014 all patients, operated in one institution, with primary osteoarthritis of the knee and an indication for a bicondylar, cruciate retaining (CR) TKA were invited for a follow-up examination. Exclusion criteria were indications other than primary osteoarthritis (e.g. post-traumatic arthritis, inflammatory disease and others), deformities over 20° of leg axis, patients who received a stemmed or constraint implant

* Corresponding author.

E-mail address: pia.reimann@klinikum-bochum.de (P. Reimann).

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and a unicondylar prosthesis. 228 patients were identified. 125 of these received a PSI TKA (ConforMIS iTotal) and 103 an off-the-shelf TKA (Triathlon Total Knee, Stryker). Both implants are bicondylar, non-stabilised and cruciate-retaining. The operations were performed by different surgeons. In each operation a tourniquet was applied. The patients were asked to join examination by postal invitation. No expenses were offered for the participants.

The Knee Injury and Osteoarthritis Outcome Score (KOOS)¹² with its five subscores Symptoms, Pain, Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality of life (QOL) were used to refer patient satisfaction (0–100 indicates worst to best). The Knee Society Score (KSS) (Version 1989)¹³ enabled to compare the range of motion (ROM) and function after TKA.

A modified EuroQol (mEQ) (scoring 0 to 20) including four additional questions was used to regard the satisfaction in the context of function, pain and expectation and the global fulfilment. The questions contained of five answers options, varying from ‘very satisfied’ to ‘very unsatisfied’ on a Likert scale (0–4 indicates worst to best). The motivation for the same operation under same conditions was tested with a fifth question contain of three answers (yes, no, unsure). The clinical follow-up was performed by an independent investigator (P.R.) between July and September 2016 in our institution. Hence the data contains values of a two to three years follow-up after surgery.

Statistical analysis was performed by using Statistica 12 (©StatSoft GmbH) and Excel® 2016 MSO. The figures were generated with Statistica 12 (©StatSoft GmbH). A p -value < 0.05 was considered to indicate statistical significance. The analysis of normal distributed values was performed with the unpaired t -test. In case of non-parametric data the Mann-Whitney U Test was used. This study was approved by a local ethics committee (EK 110/16).

3. Results

Finally, 84 (67%) patients in the PSI group and 57 (55%) with an off-the-shelf implant finished the complete follow-up (Fig. 1). In both groups one revision surgery had to be performed, which led to exclusion. The main cause for dropouts was the requirement of arrival. The distribution of reasons was similar.

Demographic data showed several differences (Table 1): mean age in PSI group was 65.5 years compared to 70.9 years in OSI. The period between operation and the follow-up was significantly shorter in subjects with PSI TKA. The averages differ about 160 days. The other variables like body mass index (BMI) or gender distribution were comparable. In each, more females were operated and the BMI was mean higher than 30 kg/m².

The range of motion was similar (Fig. 2). Maximum flexion was mean about 105° and the extension was 0° on average. Compared to the preoperative range of motion (ROM) the average flexion showed a decrease of 5°. This was equal for both implants.

Regarding the Knee Society Score, two significant differences were found. For both, the entire KSS and the separate function score values were significantly better in subjects with PSI TKA (Fig. 3). Concerning the total Knee Society Score, the PSI group demonstrated a mean result of 164 points and 146 points in the conventional group ($p < 0.002$). On average, the function score was 82 points for PSI and 68 points for OSI ($p < 0.0002$).

The subcategories of the KOOS demonstrated no significant difference between PSI and OSI. Each showed comparable results (Fig. 4). The modified EuroQol showed 15.6 points on average in OSI and 16.6 points for PSI. The p -value was closely under < 0.05 , which is valued to be not clinically relevant. Concerning to patient satisfaction, the global satisfaction was significantly better in PSI group ($p < 0.03$) (Fig. 5). Neither fulfilment with pain nor with function or the expectations before surgery varies between the two types of prosthesis. In addition, the willingness to be operated under the same conditions is comparable. The rate of unsatisfied patients which includes the answer options ‘very

unsatisfied’ and ‘unsatisfied’ is 5.3% in OSI and 4.8% in PSI group.

4. Discussion

The most important finding of this study is that the PSI group achieved a higher global patient satisfaction. Further, the Knee Society Score presented higher values which lead to a better basic daily function in PSI group. Nevertheless, it should mainly be assessed in the context of average younger age.

Concerning age, the PSI group is statistically significantly younger to OSI, by mean of five years. This should be regarded in other aspects of the study. Especially in cases of comparing the outcome of knee function. Despite, elder age increases the risk for several diseases. Further, this might influence values like mobility and the general fitness level. To search for explanations for younger age in PSI a few reasons are conceivable. At first, it is possible that an unintended selection was caused by our institution during preoperative consultation. This did not happen in an active way. Second, the younger patients might be better informed about alternative prosthesis types. Receiving an individual implant could attract them more because of its new technology. Further, a younger age leads to the possibility of a second operation regarded to complete lifetime. The PSI with reduction of bone loss faces these considerations.^{9,10,14} The studies’ setting does not allow any conclusion in differences of age between the types of prosthesis. Nevertheless, it seems to be more likely that patients with younger age are informed about alternatives and demanded the PSI actively. The period between operation and follow-up is shorter in PSI group because the implantation of PSI TKA started in our institution in 2013. Then in 2014, the rate of operation became similar to the off-the-shelf prosthesis.

The ROM is not significantly different. Two studies by Schwarzkopf et al.¹⁵ and White et al.¹⁶ presented the same result. Schwarzkopf et al. consist of a retrospective follow-up of 621 TKAs (PSI:307/OSI:314) investigating economic values. No clinical differences in range of motion are described. White et al. demonstrated in the prospective three-armed study with 72 TKAs (PSI:21/OSI:11/psOSI:42) a mean maximum flexion of 115°. Other single-arm studies showed mean maximum flexion of over 120°. In comparison, a detected mean range of motion of 105° must be evaluated to be an average value. There is no indication that this leads to a decrease of satisfaction in our study.

Knee Society Score values were statistically higher in the PSI group. The is due to the reason for that the Function Score showed stat. sig. superior results. Hence the basic daily function like walking distance and the ability to step stairs succeed in PSI group in a better way. Weiss et al.¹⁷ showed that there are activities which are important for patients after surgery, like gardening or stretching. Further, the basic function like walking stairs or getting in or out of a car correlates with higher satisfaction.¹⁸ Hence a connection between function and satisfaction is set. Besides the attribution to prosthetic design the higher KSS in this study might be mainly depended on the difference in mean age. The younger age in PSI group influences the basic functions and consecutively the results of Knee Society Score. An exertion of influence cannot be excluded. White et al. received significantly lower values in KSS for PSI compared to both, conventional cruciate-retaining and posterior-stabilised prosthesis. The patients with individual implant had an increased rate of knee stiffness two years after surgery.¹⁶ Nevertheless, the fact that the mean KSS was over 160 points for PSI was unnoticed by the authors. Regarding to Asif et al.,¹⁹ this leads an ‘excellent’ scoring which is a satisfiable result.

Concerning the KOOS no significant differences between the groups are shown. Hence the complex daily activities which are tested by KOOS, like getting in and out of a car or gardening, are similar. Further, there is no distinction in pain and quality of life. Every category of KOOS except ‘sport’ showed normal to high average. In sub-category ‘sport’ the mean value is under 60 for both. The reason is that many patients refuse either to run, jump or kneel. Especially kneeling was

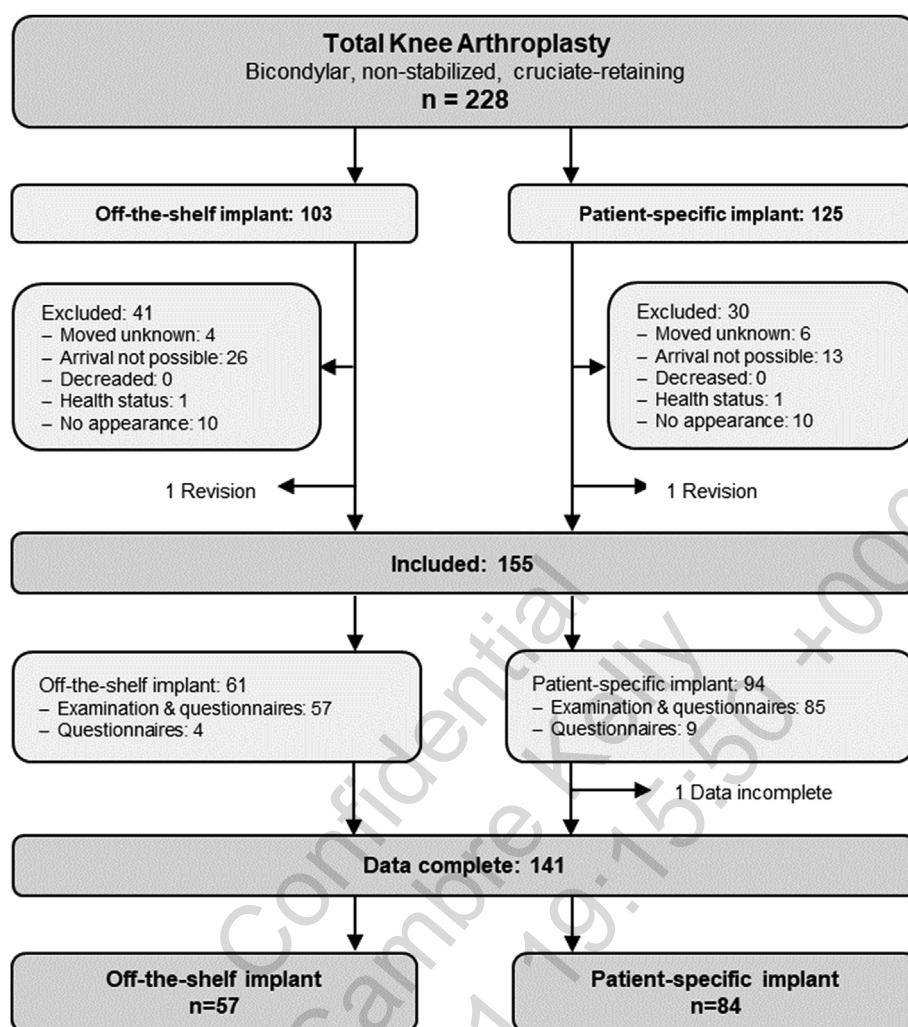


Fig. 1. Flowchart. Presentation of follow-up data.

rejected by most patients in this study which lead to lower values. None of the analogous studies included KOOS in follow-up, hence no comparison of results is possible.

In terms of patient satisfaction, the global satisfaction is significantly better in subjects with PSI TKA. Aspects of the fulfilment of expectations or the satisfaction with pain and function are comparable. Evidence of the correlation between patients' expectations and satisfaction is given in several studies.^{1,3,20–23} Especially less pain and improvement in daily function are what patients expect after TKA.^{20,22} In addition, unrealistic expectations should be prevented by pre-operative communication.²⁴ Regarding our result, it seems convincing that expectation influences the results. In general, higher expectations in younger patients are more likely, hence the potential of developing unrealistic hopes increases. Our results are contrasting these considerations because the PSI consisted on the average younger patient but also of higher mean satisfaction. Perhaps the knowledge of receiving an individual implant, manufactured especially for themselves influence the fulfilment of expectations in a positive way.

The rate of unsatisfied patients is lower than in general. An unintended selection might be caused by inviting the patients to a follow-up in our institution. Maybe satisfied patients are more likely interested in responding questionnaires and take part in a clinical follow-up. On account of the retrospective design, neither statement towards possible reasons for the higher satisfaction in PSI group nor the low rate of dissatisfaction is permissible. White et al. prospectively compared the patient satisfaction in a three-arm study. As a result, the PSI TKA

showed significant worth values for satisfaction two years post-operatively.¹⁶ Hence the results are contrasting the outcome in our study. The comparability of both studies is limited because patient satisfaction was measured with different methods. That is why further investigations concerning causes appear appropriate.

Especially the influence of alignment and kinematics on patient satisfaction should be analysed. In the study of Arbab et al.²⁵ the patient-specific TKA demonstrated fewer outliers from neutral leg alignment compared to conventional technique.

Concerning Zeller et al.²⁶ subjects with PSI TKA showed more natural kinematics compared to conventional TKA. The study compared data from a deep knee bend and the share arrays recorded by a mobile fluoroscopy of 24 PSI TKAs and 14 OSI TKAs. In addition, kinematic alignment is a technique to reference the leg axis to the individual preoperative constitution of the knee. Calliess et al.²⁷ have recently shown a better clinical outcome with kinematic alignment in a prospective study. Both, the KSS and WOMAC improved significantly one year after implantation in the group of kinematic alignment. For the future, the individualisation of TKA to the patient-specific anatomy is a promising procedure.

Our study has some limitations. Besides the retrospective design, there was no randomisation and blinding. In addition, the rate of dropouts was quite high. Hence, a selection cannot be certainly excluded. Satisfied patients might be more willing to take part in a study with an examination compared to unsatisfied.

To our knowledge, the study is one of the first to compare PROMs

Table 1

Mean $\pm$ standard deviation for demographic data, range of motion, scores and satisfaction. Data of patients with total follow-up was included for off-the-shelf implants (OSI) and patient-specific implants (PSI). Abbreviations: Body Mass Index (BMI), Modified EuroQol (mod. EuroQol), Knee Injury and Osteoarthritis Outcome Score (KOOS), Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality of life (QOL).

Mean $\pm$ SD	OSI	PSI	Stat. significance
age (years)	70,9 ($\pm$ 7.1)	65.5 ($\pm$ 9.3)	$p < 0.0009$
height (cm)	167.8 ($\pm$ 9.4)	170.2 ($\pm$ 8.7)	n.s.
weight (kg)	88.6 ($\pm$ 17.8)	88.3 ($\pm$ 16.9)	n.s.
BMI (cm/m ²)	31.4 ($\pm$ 5.5)	30.5 ($\pm$ 5.2)	n.s.
gender (% female)	68.4	63.1	n.s.
days postop.	991.5 ($\pm$ 226.6)	824.2 ($\pm$ 169.8)	$p < 0.00003$
Range of Motion			
preoperative			
flexion (°)	110 ($\pm$ 13,8)	110 ($\pm$ 15,0)	n.s.
extension (°)	0 ($\pm$ 0)	0 ($\pm$ 0,5)	n.s.
postoperative			
flexion (°)	105 ($\pm$ 9,2)	105 ($\pm$ 9,9)	n.s.
extension (°)	0 ($\pm$ 0)	0 ($\pm$ 0)	n.s.
Scores			
Knee Society Score	146.3 ($\pm$ 27.3)	164.5 ($\pm$ 26.4)	$p < 0.002$
knee score	78.3 ($\pm$ 13.8)	82.4 ($\pm$ 13.1)	n.s.
function score	68.0 ($\pm$ 18.7)	82.0 ($\pm$ 19.2)	$p < 0.0002$
mod. EuroQol	15.6 ($\pm$ 3.2)	16.6 ($\pm$ 3.3)	$p < 0.05$
mobility	3,1 ($\pm$ 1,0)	2,7 ($\pm$ 0,9)	$p < 0,003$
KOOS			
symptoms	79.8 ($\pm$ 15.5)	82.7 ($\pm$ 17.4)	n.s.
pain	87.4 ($\pm$ 12.1)	89.5 ($\pm$ 12.4)	n.s.
ADL	80.0 ($\pm$ 16.3)	83.8 ($\pm$ 16.1)	n.s.
sport/rec	50.0 ($\pm$ 28.0)	58.9 ($\pm$ 21.8)	n.s.
QOL	66.2 ($\pm$ 20.6)	69.3 ($\pm$ 21.8)	n.s.
Satisfaction			
global	3,0 ($\pm$ 0,82)	3,3 ($\pm$ 0,81)	$p < 0,025$
function	3,2 ($\pm$ 0,78)	3,3 ($\pm$ 0,82)	n.s.
pain	3,3 ($\pm$ 0,80)	3,4 ($\pm$ 0,79)	n.s.
expectations	3,1 ($\pm$ 0,91)	3,2 ($\pm$ 0,92)	n.s.
same operation	–	–	n.s.

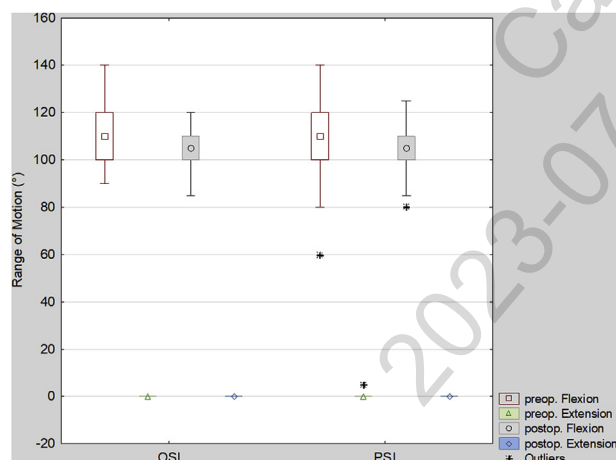


Fig. 2. Range of Motion (°). The flexion and extension for off-the-shelf implants (OSI) and patient-specific implants (PSI) is presented for flexion and extension in separate box-plots divided in preoperative (preop.) and postoperative (postop.) data.

and objective clinical data in subjects with PSI TKA and conventional TKA on a larger scale.

5. Conclusion

In conclusion, the results indicate that the patient-specific prosthesis might increase patients' satisfaction. The reason why patients with PSI TKA are more satisfied remains unclear because of study design. Our

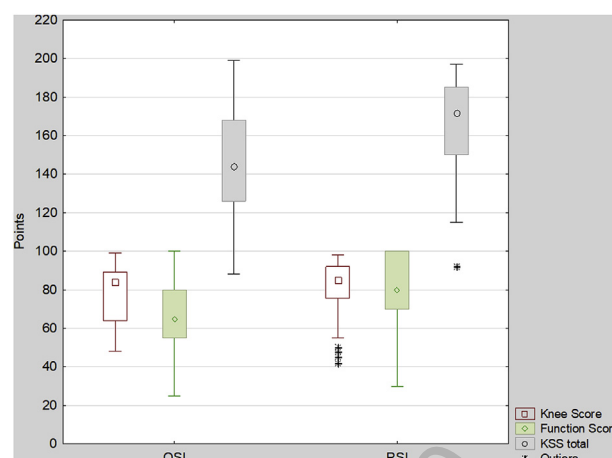


Fig. 3. Knee Society Score. The Knee Society Score (KSS), Knee Score and the Function Score are presented for off-the-shelf implants (OSI) and patient-specific implants (PSI) in separate boxplots. The Knee and Function score consists of maximum 100 points and the total score of 200 points.

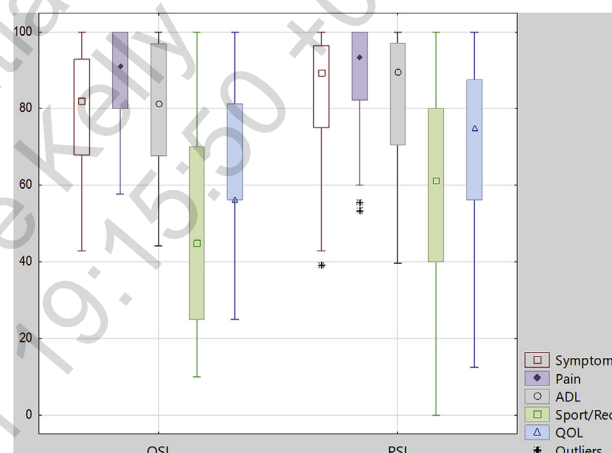


Fig. 4. Knee Injury and Osteoarthritis Outcome Score. The five subscores Symptoms, Pain, Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality of life (QOL) are presented for off-the-shelf implants (OSI) and patient-specific implants (PSI) in separate box-plots.

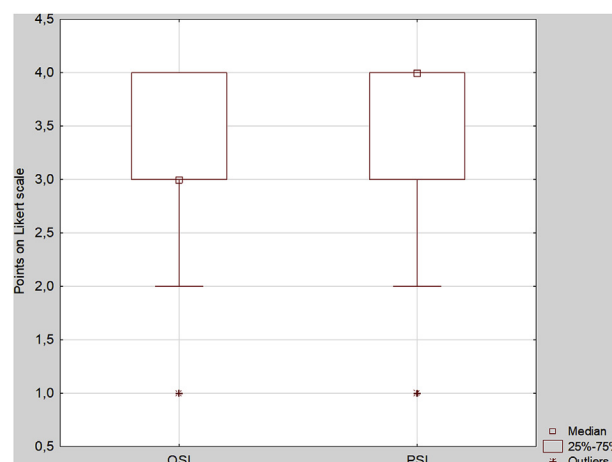


Fig. 5. Global satisfaction. The patients with off-the-shelf implants (OSI) and patient-specific implants (PSI) were asked if they are satisfied with the result of the total knee arthroplasty. Therefore, a Likert scale with five answer options (very unsatisfied, unsatisfied, neutral, satisfied, very satisfied) was used. Four points correspond to 'very satisfied' and zero to 'very unsatisfied'.

data cannot reveal whether it is because of prosthetic design or of other parameters like expectations and awareness of receiving an individual implant. Further studies which investigate expectations, PROMS and kinematics, in particular, are necessary.

Conflicts of interest

All Authors declare that there is no conflict of interest.

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