Operator variation in applying a knee loading device for evaluation of tibial component loosening in total knee arthroplasty

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Faculty Disclosure Information

- Leendert Blankevoort, Arthur J. Kievit and Matthias U. Schafroth are listed as inventors on a patent for a loading device and method to be used to quantify and visualise implant displacement
- The remaining authors declare no conflict of interest
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SHARED CHALLENGES, SMART SOLUTIONS

- This study was funded in part by Zimmer Biomet as part of a larger cohort study. This sub-analysis was performed independent of Zimmer Biomet.

ZIMMER BIOMET

The problem

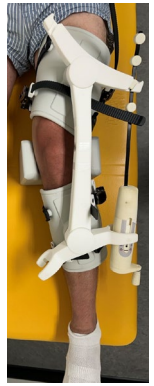
- Aseptic loosening of the total knee arthroplasty (TKA) is an indication for revision surgery[1]
- Imaging modalities that are used in the diagnostic process do not measure looseness [2,3]
- A CT-based method was developed to measure tibial component displacement under a valgus and varus load as applied by a loading device[4]
- The valgus-varus loading device is apllied by an operator
- Operator variation of applying the valgus-varus loading device may affect the measurement of the displacement of the tibial component

The question

- What is the inter-operator variation, in terms of reliability and measurement error metrics, of applying the loading device for detecting tibial TKA component displacement?

Methods – measurement of load-induced displacement

AtMoves* Knee Loading Device



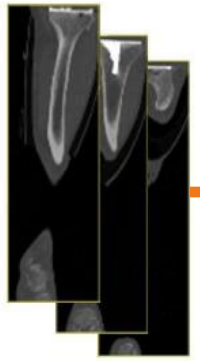
valgus

varus

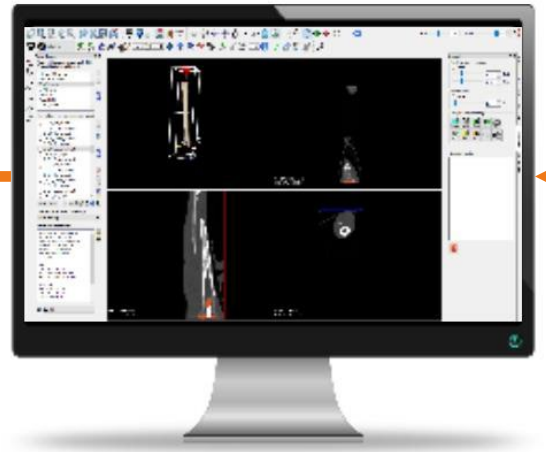
Applied load 20 Nm

Siemens Somatom Force

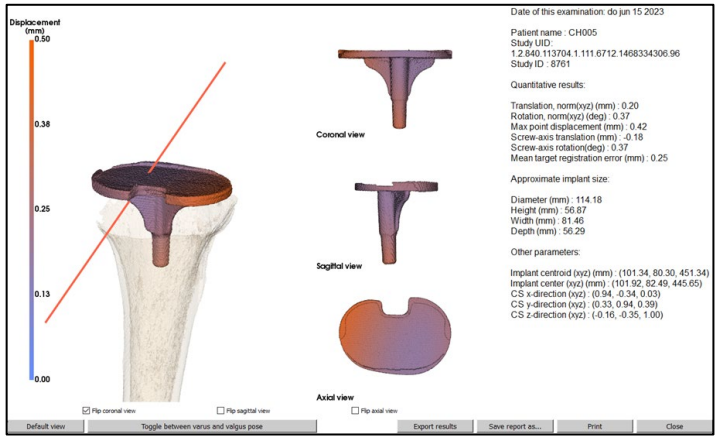
CT valgus



CT varus



AtMoves* CT analysis



Implant Loosening Report

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* AtMoves, Amsterdam, The netherlands

Orthopedic Surgery and Sports Medicine

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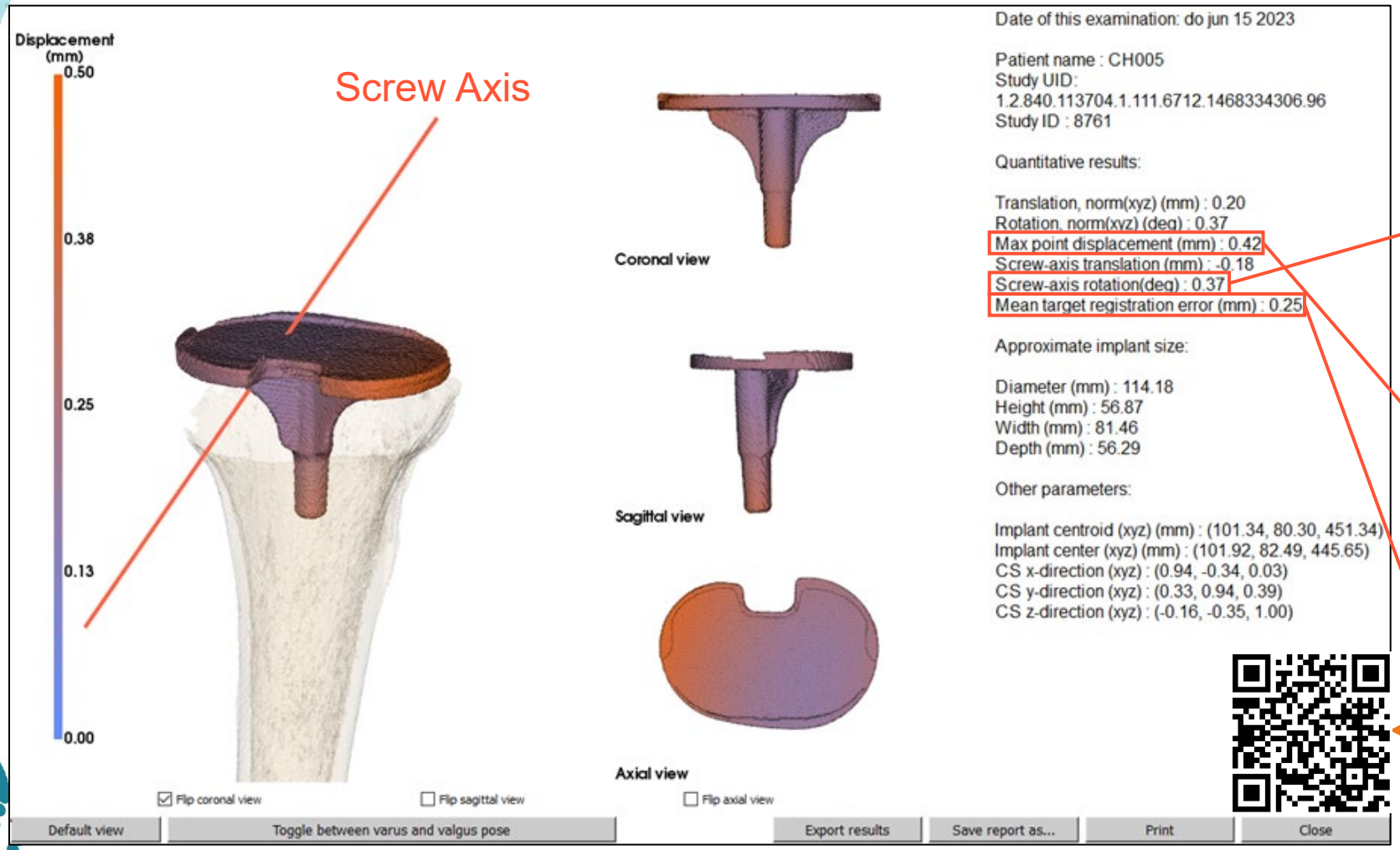
Methods – Implant displacement report



Key variables

Screw axis rotation

Maximum total point motion (MTPM)

Mean target registration error (mTRE)

Scan QR-code for animation

Methods

Patient selection

- Subgroup of clinical follow-up of a Zimmer Biomet TKA
  - ✓Vanguard PS Open Box Porous Femoral component
  - ✓Implantation between 2009 and 2013
  - ✓Surgery conducted at Amsterdam UMC
- Required sample size: n=16

Methods

Procedures

- Two immediately consecutive CT scans with loading device
  - ✓ Two independent and blinded operators
  - ✓ Identical scan protocol
- Evaluation of the CT scans
  - ✓ One operator
  - ✓ Identical evaluation protocol
- Statistical analyses[5]

* Previous results showed no influence of the operator on the assignment of the score

Results – Patient characteristics – n=16

Age in years mean (SD)	59.1	(9.5)
Sex n (%)		
Male	5	(31.2)
Female	11	(68.8)
Time interval between arthroplasty and Scan in years median (IQR)	11.9	(11.4-12.5)
Charnley score n (%)		
0:	8	(50)
1:	4	(25)
2:	4	(25)
ASA score n (%)		
1:	10	(62.5)
2:	6	(37.5)

KOOS sub scores	(median, [IQR])
KOOS-Pain	94.4 (83.3-100)
KOOS-Other Symptoms	85.7 (79.4-93.8)
KOOS-ADL	91.9 (86.4-96.3)
KOOS-Sport/Rec	45.0 (20.0-70.0)
KOOS-QoL	75.0 (60.9-90.6)

n	Number
ASA	American Society of Anesthesiologists
KOOS	Knee Osteoarthritis Outcome Score
ADL	Activities of Daily Living
QoL	Quality of Life

Results – error statistics

Intraclass Correlation Coefficient

	ICC	CI
Rotation [°]	**0.64**	0.24 – 0.86
MTPM [mm]	**0.81**	0.55 – 0.93
mTRE [mm]	**0.84**	0.61 – 0.94

Rotation Rotation about screw axis [°]
MTPM Maximum Total Point Motion [mm]
mTRE meam Total Registration Error [mm]
ICC Intraclass Correlation Coefficient
CI 95% Confidenc Interval

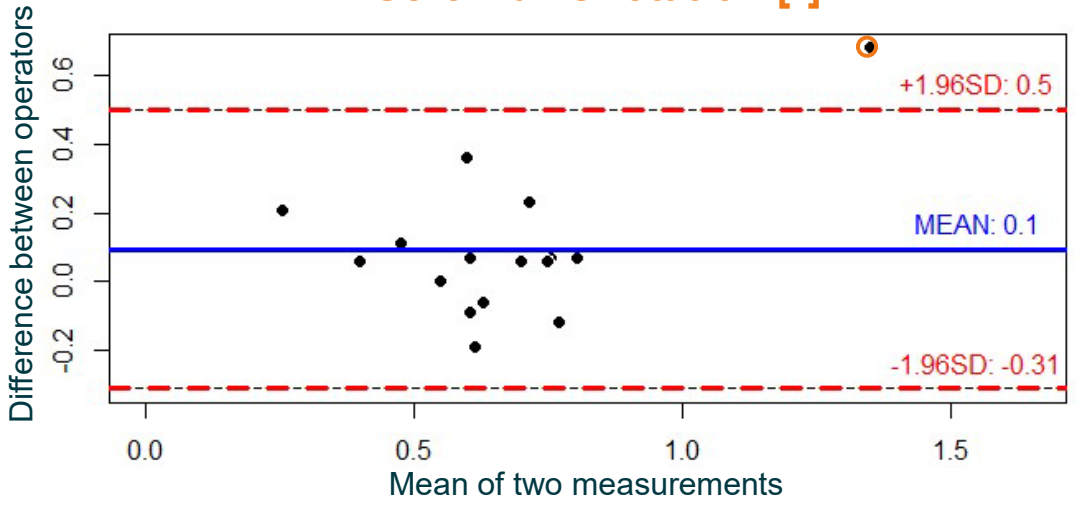
Error Statistics

	SEM
Rotation [°]	**0.14**
MTPM [mm]	**0.10**
mTRE [mm]	**0.06**

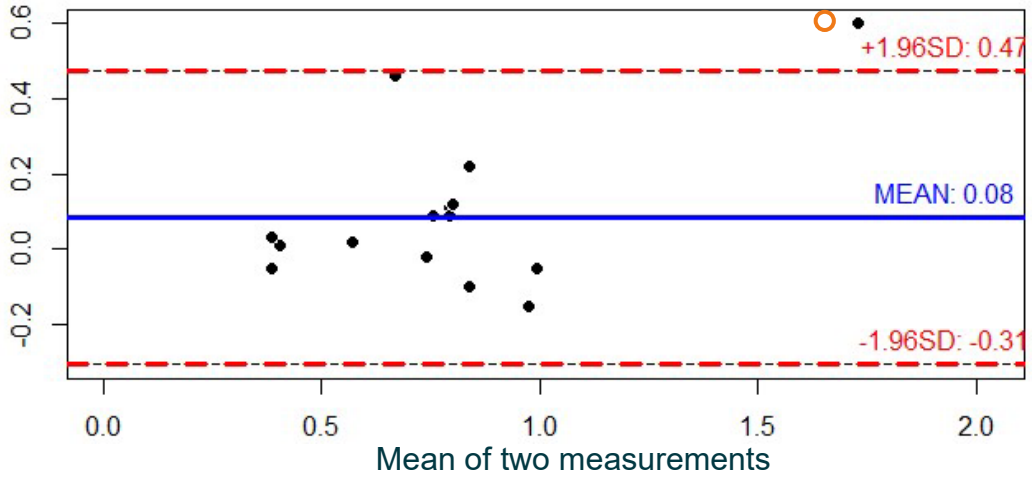
SEM Standard Error of Measurement

Results – Bland-Altman plots

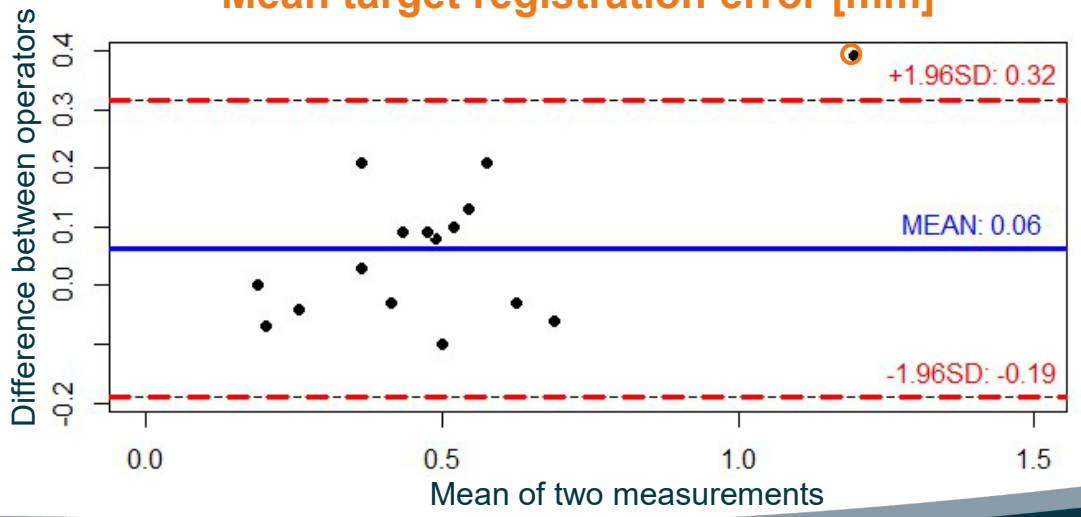
Screw axis rotation [°]



Maximum total point motion [mm]



Mean target registration error [mm]



○ Abberant measurement explained:
Retrospective evaluation of CT-scan revealed incorrect placement of loading device on the knee joint during the second examination

Discussion

- Operator variation does not affect implant displacement measurement.
  - The inter-operator difference in applying the loading device resulted in a standard error of measurement (SEM) of 0.06–0.14 mm or ˚, which aligns with the previously established measurement error in an experimental cadaver setting (0.07–0.13 mm or ˚)[6].
- Apart from the identified abberant measurment, the findings do not suggest a need for further standardization of operator training.
- A single total knee arthroplasty design was included; only tibial component motion was evaluated.
- The relatively small and uniform population may limit the generalizability of the results to a broader and more diverse patient population as seen in clinical practice.

Conclusion

The **inter-operator reliability** of applying the loading device for detecting load-induced implant displacement is **moderate** for the rotation measure and **good** for the measures maximum total point motion (MTPM) and mean target registration error (mTRE).

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