A Randomized Controlled Trial Comparing Trumatch Instrument and Conventional Instrument in Total Knee Arthroplasty

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Introduction: Most orthopaedic surgeons use conventional instruments to achieve accurate bone cuts in total knee arthroplasty. It has been criticized that outliers are not uncommon with conventional instruments even in experienced hands.
Patient specific instruments became available for use. The patients need MRI or CT scans before the operation to define the anatomy of the knee, hip and ankle. The data is used to fabricate customized templates that can be placed snugly over the distal femur and proximal tibia. The possible advantages are the short operation time and improved accuracy in bone cuts. The downsides of this method include the additional costs and time required. The accuracy of the cuts had also been challenged.
The purpose of this study is to compare the surgical time taken and accuracy of the above two methods in TKA.
Methods: Sixty knees in 51 patients (6 men and 45 women) were recruited into the study. The average age was 69±8.3 years. The diagnosis was osteoarthritis in 56 knees and inflammatory arthritis in 4 knees. The average pre-operative mechanical alignment of the lower limb was in 13.0°±7.2° varus.
The sixty knees were randomized in 1:1 ratio into one of the two groups - conventional instruments (CON) and TruMatch instruments (TMT). The surgical techniques were standardized apart from the instruments that were used to guide the jigs used for the bone cuts. The prostheses used were PFC Sigma knee system.
We recorded the tourniquet time and the operative time (skin-to-skin). We measured the individual component positions in the coronal and sagittal planes and the overall lower limb alignment. The outliers were defined as more than ±3° of desired positioning/alignment.
Results: Tourniquet Time and Operation Time
The tourniquet times were 42.6±14.7 minutes for CON group and 42.9±9.6 minutes for TMT group ($p = 0.92$). The operation times were 68.4±16.3 minutes for CON group and 69.8±17.9 minutes for TMT group ($p = 0.75$).
We compared the tourniquet time and operation time of the first 15 TMT knees and the second 15 TMT knees. The tourniquet times were 45.2±10.6 minutes and 40.7±8.3 minutes respectively ($p = 0.20$). The operation times were 69.3±12.7 minutes and 70.2±22.4 minutes respectively ($p = 0.89$).
Component Positions and Overall Lower Limb Alignment
The average femoral component positioning in the coronal plane was 1.9°±1.5° deviation from the neutral position for CON group and 1.8°±1.8° for TMT group (figure 1). The average tibial component position in the coronal plane was 2.2°±1.5° deviation for CON group and 2.4°±1.7° for TMT group (figure 3). The average tibial component position in the sagittal plane was 6.0°±2.0° deviation for CON group and 6.7°±2.8° for TMT group ($p>0.05$) (figure 4). The average femoral component position in the sagittal plane was 6°±3.1° deviation for CON group and 3.4°±2.7° for TMT group ($p=0.001$) (figure 2). The overall mechanical axis alignment of the lower limb in the coronal plane was 3.9°±2.5° deviation from neutral axis for CON group and 4.2°±2.6° ($p=0.65$) (figure 5).
Table 1 summarized the percentages of component positions and overall lower limb alignment that were outside the normal ranges for the three groups. For the femoral component in the sagittal plane, there were significantly more outliers in the CON group than both the TMT group ($p=0.002$).
Discussion: One claimed advantage of using patient specific templates is the possible reduction in the tourniquet and operation times. The mean tourniquet time and operative time of the TMT group showed no difference compared to the conventional instruments.
The second claimed advantage was possible better component position and lower limb alignment after the TKA. TMT instrumentation resulted in higher incidence of outliers in majority of the measurements and overall lower limb alignment (table 1), although the differences were not significant. This apparent inferiority in the accuracy of the TMT instrument could be explained by the image acquisition technique and the template design. CT, unlike MRI, has the limitation in delineating the articular cartilage. Before TMT template fabrication, the surgeons needed to estimate the percentage of articular cartilage loss of the knee. This could be a potential source for error. The conformity between the TMT templates and the bones depends on 3 contact points on the femur and tibia. The total contact area is limited; the osteophytes are not taken into account. Intro-operatively, surgeons often faced the situation that the templates could be placed at different positions and all of them seemed to be the 'best fit'. To compensate for the lack of 'snug-fit', especially on the tibial side, surgeons always need to verify the

coronal and rotational alignment with the extramedullary alignment guide, which is also specially designed for TMT instruments. On the other hand, we also found that conventional instrument was more likely to result in an excessively flexed femoral component (p=0.002). This could be explained by the common occurrence of sagittal femoral bowing in our patient population1. The femoral intramedullary rod followed the curvature of the distal femur and thus resulted in a flexed femoral component relative to the lateral femoral mechanical axis.

Significance: In this trial, we found that the tourniquet time and operation time of TMT instruments in TKA were similar to that of conventional instrument. The post-operative lower limb alignment and individual component positioning were similar in most measurements except for femoral component flexion in the sagittal plane, in which the TMT instruments resulted in significantly less outliers. The overall accuracy of the TMT instruments is still undetermined as the incidence of outliers was high.

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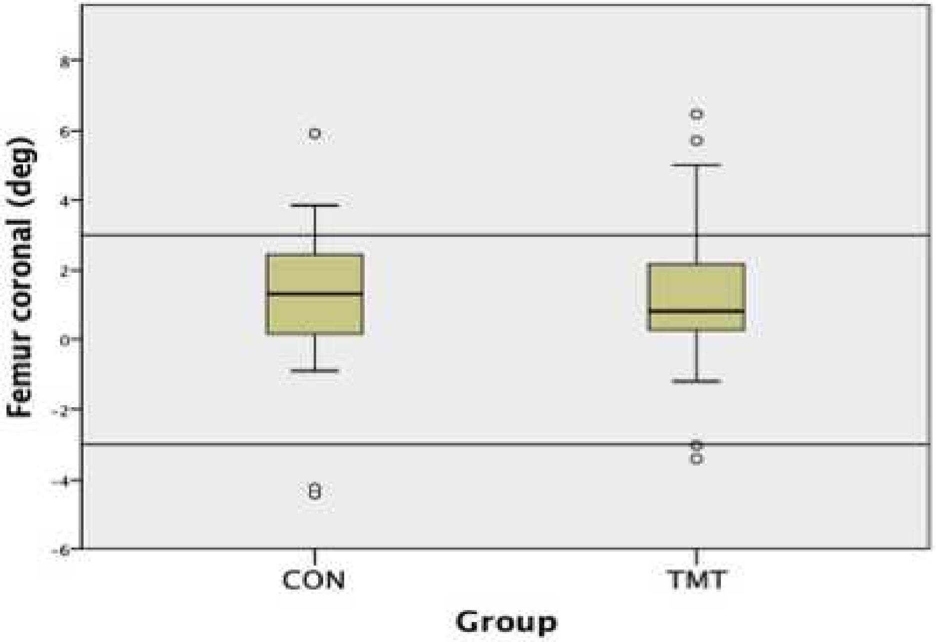
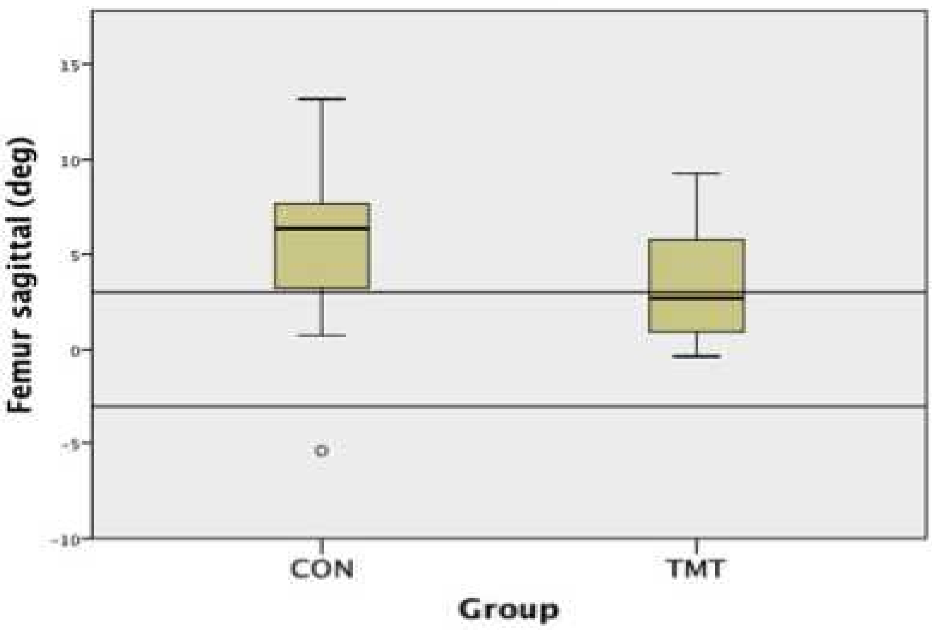
Outliers in component positions and lower limb alignment

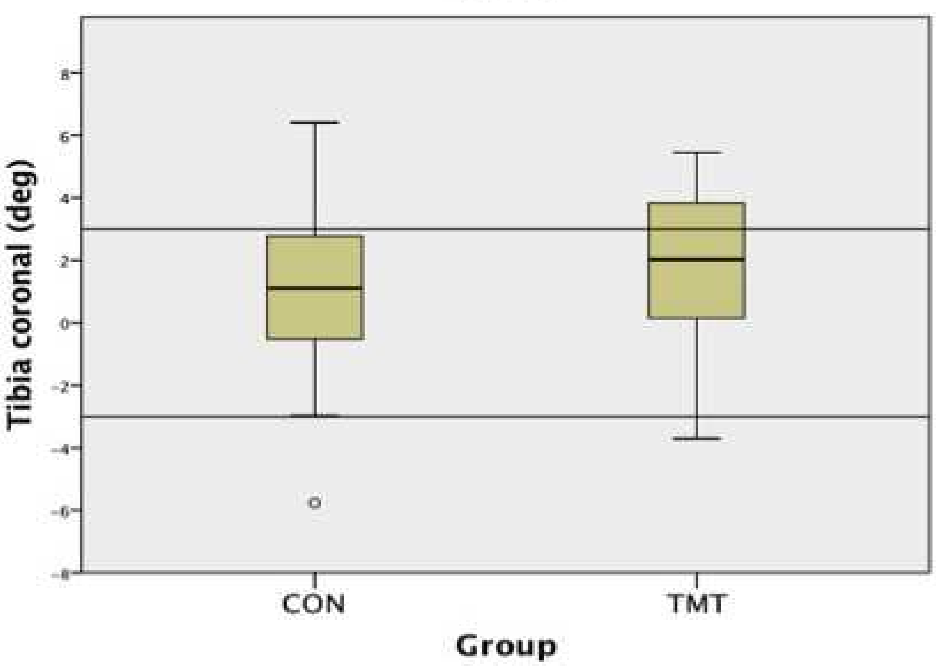
		Conventional	TruMatch
Coronal plane	Femoral component	20%	26.7%
Coronal plane	Tibial component	6.7%	23.3%
Sagittal plane	Femoral component	70%	30%
Sagittal plane	Tibial component	53.3%	63.3%
Coronal plane	Lower limb alignment	43.3%	50%



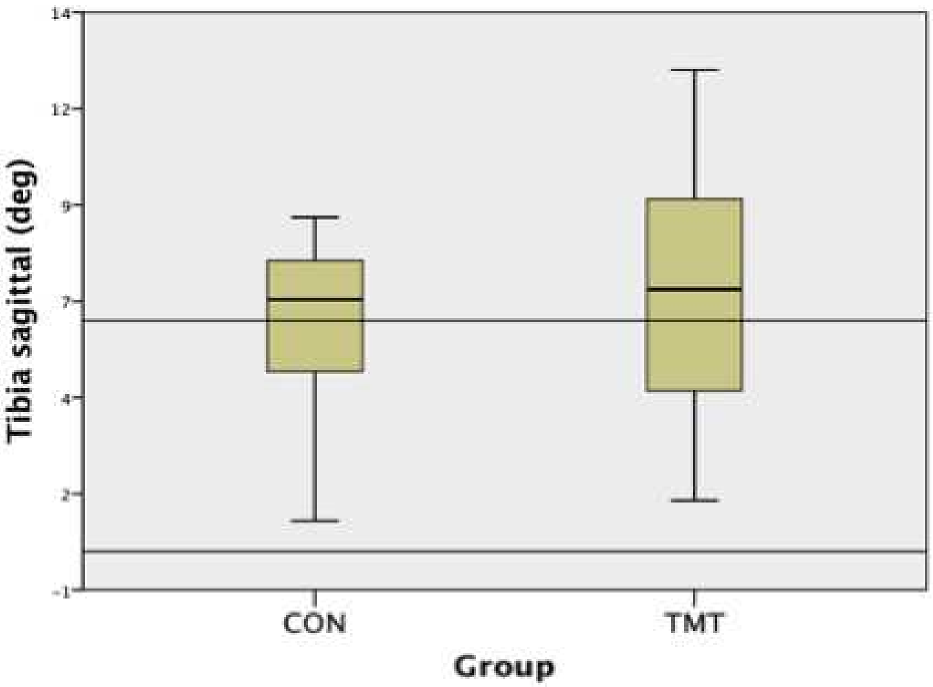
Femur coronal (deg)
8
6
4
2
0
-2
-4
-6
CON
TMT
Group

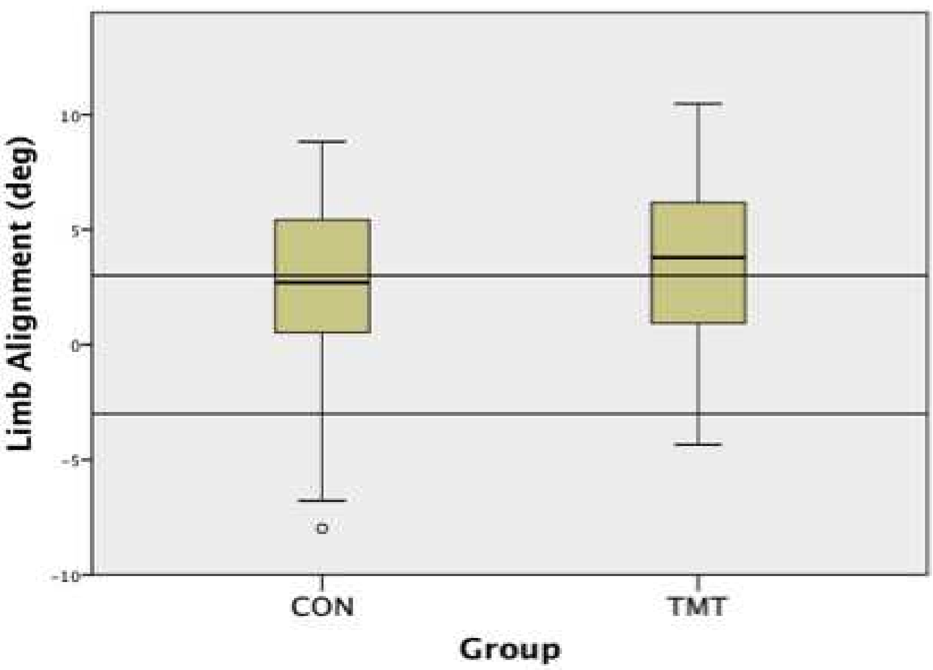


Femur sagital (deg)
15
10
5
0
-5
-10
CON
TMT
Group



Tibia coronal (deg)
8
6
4
2
0
-2
-4
-6
-8
CON
TMT
Group





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