Original article

No demonstrable benefit for coronal alignment outcomes in PSI knee arthroplasty: A systematic review and meta-analysis

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ARTICLE INFO

Article history:
Received 22 July 2014
Accepted 15 December 2014

Keywords:
Total knee arthroplasty
Patient-specific instrumentation
Computer-assisted surgery
Meta-analysis

ABSTRACT

Aim: A systematic review and meta-analysis of clinical studies assessing alignment outcomes in patient-specific instrumented (PSI) knee arthroplasty was conducted.

Materials and methods: PRISMA compliant data was extracted from literature databases up to January 2014.

Results: Twenty-six studies met the inclusion criteria, reporting a total of 1792 knees. Twenty-three studies reported alignment outcomes in the coronal plane, 11 in the sagittal plane. In all but three series, MRI was the preoperative imaging modality. Range of mean postoperative alignment (hip–knee–ankle [HKA] angle) was 176.5 to 181.70. The proportion of three degrees of outliers showed an overall mean of 18.6%. In total, fifteen studies compared alignment outcomes between standard and PSI. From these, four studies showed significantly higher accuracy of coronal plane alignment with PSI (HKA angle). Meta-analysis of seven high-quality comparative studies demonstrated no significant increased accuracy in postoperative mechanical axis (HKA angle) with PSI. Subgroup meta-analysis of both femoral and tibial rotation was not feasible due to a low number of inclusive high-quality series.

Conclusions: PSI knee arthroplasty is shown not to confer increased accuracy in reconstituting the postoperative mechanical axis. Further studies are required to demonstrate both clinical and radiological alignment outcomes in PSI knee arthroplasty with focus upon tibial and femoral rotation.

Level of evidence: Level 2 – meta-analysis.

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1. Introduction

The requirement of necessary restoration of a correct mechanical axis in total knee arthroplasty has been supported in biomechanical [1], finite element [2] and clinical [3] studies. Malalignment typically is present in either the coronal or sagittal planes or is rotational in nature, and may lead to wear, loosening and patellar instability often necessitating revision procedures [4,5]. Coronal malalignment specifically has been shown to be associated with altered pressure distribution and load bearing upon the medial and lateral compartments of the tibial component [6], higher failure rates and lower functional scores [7]. The reconstitution of a coronal plane postoperative mechanical axis within a target range of: zero degrees ± three degrees (valgus/varus) has been shown to reduce the occurrence of negative outcomes including implant failure [8]. The limitations of conventional instrumentation in effecting full precision in bone cuts and accuracy of alignment has previously been reported [9,10]. Computer-assisted navigation has been shown to improve mechanical axis alignment over conventional instrumentation [11], but has been associated with longer operative duration and no significant enhancement in short-term clinical outcomes [12]. Additionally, in the absence of a preoperative computed tomography scan, navigated knee arthroplasty has not been shown to significantly improve rotational alignment outcomes as compared to conventional instrumentation [13]. These factors have promoted efforts to pursue a ‘precise’ surgical technology model with the key goal of improving postoperative alignment and positioning.

Patient-specific instrumentation (PSI) is a recent technology that presents an alternative to conventional instrumentation and computer navigation, with the primary aim of achieving accurate alignment and positioning of implants [14]. PSI exploits preoperative anatomical data obtained by either computer tomography.

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http://dx.doi.org/10.1016/j.otsr.2014.12.018
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Box 1: MEDLINE search strategy.

- Total knee replacement.tw.
- Exp. Total knee arthroplasty
- OR/1,2
- Conventional.ti,ab
- Patient-specific.ti,ab
- Custom-fit.ti,ab
- Alignment.ti,ab
- OR/4-7
- Exp. clinical trial/
- Randomised controlled trial.ti,ab
- Exp.randomized controlled trial
- OR/9-11

(CT) imaging or magnetic resonance imaging (MRI) to create disposable patient-specific bone resection guides, individualized to reflect the patient’s anatomy [14]. Although PSI is principally a modern system, several (prospective and retrospective) series have been published documenting alignment outcomes. The aim of this systematic review was to document and describe the current literature and evidence in alignment outcomes relating to PSI knee arthroplasty, and additionally to apply meta-analysis methods to compare alignment outcomes in PSI versus conventional instrumentation or navigation techniques studies. Through this, we aimed to answer the following research question: what are the alignment outcomes in patients who undergo patient-specific instrumented knee arthroplasty procedures.

2. Methods

A detailed search of relevant literature within the period January 2006–January 2014 was performed, including the following databases: Pubmed, the Cochrane Collaboration Trial Registry and Library, MEDLINE and EMBASE. The specific search terms used for the MEDLINE search strategy are presented in Box 1. These were modified for each of the individual databases. A search of the grey literature/unpublished literature databases and trial registries was also undertaken. These included: ISI Web of Knowledge and Open Grey (System for Information on Grey Literature in Europe), and the trial registries: the WHO International Clinical Trials Registry Platform, Current Controlled Trials, the United States National Institute of Health Trials Registry, and NIHR Clinical Research Portfolio Database.

Two investigators independently reviewed all search terms, abstracts and full text of articles potentially eligible for abstract review. Further examination of reference lists of retrieved articles was conducted to cross-reference any further studies that met selection criteria. All abstracts and references were selected in consensus with the PRISMA flowchart (Fig. 1).

Selection criteria included studies that documented:

- primary PSI TKA;
- prospective/retrospective/case controlled and cohort studies;
- postoperative implant position and limb alignment outcomes;
- minimum of 10 patients in either PSI (or conventional series when documented in the same study);
- exclusion with fracture deformity and tumour;
- exclusion of animal and cadaver studies;
- exclusion of ‘kinematic restorative’ PSI knee implants (as these do not specifically aim to correct mechanical axis);
- studies specifically examining unicondylar knee implants.

Eligible studies were evaluated independently by two investigators. Data was obtained from each included study, entered into a data extraction form, verified for accuracy and then analysed.

Further studies were sought via examination of reference lists. The primary outcome measure was deviation from the postoperative hip–knee–ankle (HKA) angle (i.e. the angle between the mechanical axis of the femur and the tibia, with both lines crossing at the knee). This endpoint was documented as the number/proportion of three-degree outliers (i.e. $\theta \pm 3$ degrees varus/valgus). Secondary outcomes included: femoral coronal alignment (i.e. the angle between the articular margin of the femoral component and the femoral axis); tibial component alignment (angle between tibial component surface and the tibial axis); and the zone of mechanical axis (where the tibial base plate is divided into three equal zones i.e. medial, central and lateral, and the proportion/number in which the mechanical axis bisected the central zone). Finally, sagittal outcome measures were documented, these included tibial slope angle (FTA) and femoral component flexion (FCC), the endpoint being the number and proportion of three-degree outliers.

Methodological quality of comparative studies (comparing PSI versus conventional instrumentation) was assessed by the Detsky Quality Assessment scale [15]. The Detsky scale includes 14 items that assess reporting quality among five categories. These include:

- randomisation;
- outcome measures;
- eligibility criteria and patient exclusion;
- interventions;
- statistical analysis.

This validated and established scoring criteria assesses the quality of study design, methodology and also outcome reporting.

Where appropriate, a random-effects model meta-analysis was performed to evaluate the clinical primary outcomes. Meta-analysis was deemed appropriate in the absence of clinical and statistical heterogeneity. Clinical heterogeneity was assessed through observation of data extraction tables whilst statistical heterogeneity between studies was evaluated with $\chi^2$ with demonstration of values for $P$ and $I^2$, $P < 0.1$ and $I^2 > 50\%$ indicating heterogeneity. Deviance from a postoperative neutral mechanical axis was measured as the proportion of three-degree outliers. RevMan 5.0 (The Cochrane Collaboration) was used for purposes of statistical analysis. For dichotomous variables, odds ratio (OR) and 95% confidence intervals (CI) were calculated and graphical output was documented by forest plots. A funnel plot was constructed to assess small sample size publication bias for the primary outcome measure. A sensitivity analysis was undertaken of higher quality studies (Detsky score $\geq 16$) on meta-analysis.

3. Results

3.1. Search results

The results of the search strategy are presented in Fig. 1’s PRISMA flowchart. A total of 259 studies were identified from the keywords search. Two hundred and twenty-eight studies were excluded from review of abstracts. In addition, two studies examined animal models [16,17], three studies focused on ‘kinematic’ knee arthroplasty [18–20], two studies reported on outcomes in unicondylar knee replacement [21,22], three studies reported on series less than 10 in number [23–25], three studies examined accuracy of templating with computer navigation and one study examined 3D implant position with exclusion of reference to coronal and sagittal plane outcomes [24,26–28].

One study examined the role of extra-articular deformity in alignment outcomes [29]. Overall, 26 studies met the criteria reporting on a total of 1792 knees (Table 1). Twenty-one studies were prospective and five retrospective. Twenty-three studies examined outcomes in the coronal plane and 11 in sagittal plane.
(Table 2). Six studies reported femoral component rotation as an outcome (Table 3). In all but three studies, MRI was the preoperative imaging modality.

3.2. Level of evidence and Detsky Quality Assessment scores

In 15 studies, the level of evidence was either III or IV (Appendix 1). Eleven studies were demonstrably stronger (Level I–II). Of the 15 included comparative studies, eight had a Detskey score ≥ 16 therefore classified as of high methodological quality. The Detskey score mean was 15.6 (Appendix 2).

3.3. Publication bias

Fig. 2 illustrates an asymmetry to the funnel plot for the primary outcome (proportion of three-degree outliers from HTA measure). This suggests evidence of small sample size publication bias.

Fig. 1. PRISMA flow diagram for selection of included studies.

Fig. 2. Funnel plot for studies that included number of 3-degree outliers as primary outcome measure. SE(log[OR]): standard error (log [odds ratio]); OR: odds ratio.
Table 1
Patient-specific knee instrumentation studies: coronal plane alignment outcomes.

<table>
<thead>
<tr>
<th>Study</th>
<th>Location/centre</th>
<th>Implant</th>
<th>Preoperative imaging</th>
<th>Total PSI</th>
<th>HKA mean (range)</th>
<th>HKA (outliers) %</th>
<th>ZMA: (M zone) %</th>
<th>FFC: mean (range)</th>
<th>FTC: mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Howell et al., 2008</td>
<td>Sacramento, USA</td>
<td>Vanguard, Biomet Genesis II</td>
<td>MRI</td>
<td>48</td>
<td>178.6 ± 2.8</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>and Tibesku, 2013</td>
<td>Hannover, Germany</td>
<td>Smith &amp; Nephew</td>
<td></td>
<td>124</td>
<td>178.5 ± 1.7</td>
<td>(174.0–183.4)</td>
<td>11%</td>
<td>75%</td>
<td>–</td>
</tr>
<tr>
<td>Lustig et al., 2013</td>
<td>Sydney, Australia</td>
<td>VISIONAIRE, Smith &amp; Nephew</td>
<td>MRI</td>
<td>60</td>
<td>180.6 ± 2.9</td>
<td>(173.0–189.5)</td>
<td>20.7%</td>
<td>–</td>
<td>89.9 (±1.8)</td>
</tr>
<tr>
<td>Nunley et al., 2012</td>
<td>Washington, USA</td>
<td>Signature/OrisMed, Smith &amp; Nephew</td>
<td>MRI</td>
<td>100</td>
<td>179.35 ± −1.35 to 0.04</td>
<td>Signature: 18% OtisMed: −177.24 ± −3.46 to −2.06</td>
<td>90.7</td>
<td>89.9</td>
<td></td>
</tr>
<tr>
<td>Ng et al., 2012</td>
<td>Ohio, USA</td>
<td>Signature, Biomet VISIONAIRE, Smith &amp; Nephew</td>
<td>MRI</td>
<td>105</td>
<td>180.6</td>
<td>9%</td>
<td>C: 88%</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Boonen et al., 2012</td>
<td>Sittard-Geleen, Netherlands</td>
<td>Biomet VISIONAIRE, Smith &amp; Nephew</td>
<td>MRI</td>
<td>40</td>
<td>181 (171–188)</td>
<td>29%</td>
<td>–</td>
<td>90 (84–93)</td>
<td>91 (87–96)</td>
</tr>
<tr>
<td>Spencer et al., 2009</td>
<td>PA, USA</td>
<td>OrisMed, Hayward</td>
<td>MRI</td>
<td>21</td>
<td>178.8 ± (−4 to +6)</td>
<td>9.5%</td>
<td>–</td>
<td>91 (88–94)</td>
<td>87.1 (86–96)</td>
</tr>
<tr>
<td>Barrack et al., 2012</td>
<td>Missouri, USA</td>
<td>VISIONAIRE, Smith &amp; Nephew</td>
<td>MRI</td>
<td>100</td>
<td>178.3 (±2.5)</td>
<td>31%</td>
<td>57%</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Lombardi et al., 2008</td>
<td>Ohio, USA</td>
<td>Vanguard, Biomet</td>
<td>MRI</td>
<td>40</td>
<td>–</td>
<td>100%</td>
<td>(4–8 degrees valgus)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Conteveda et al., 2012</td>
<td>Rome, Italy</td>
<td>VISIONAIRE, Smith &amp; Nephew</td>
<td>MRI</td>
<td>15</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>91.2 (±0.6)</td>
<td>91.2 (±1.2)</td>
</tr>
<tr>
<td>Heyse et al., 2012</td>
<td>Marburg, Germany</td>
<td>Genesis II, Smith &amp; Nephew</td>
<td>MRI</td>
<td>46</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Bali et al., 2012</td>
<td>Victoria, Australia</td>
<td>Genesis II, Smith &amp; Nephew</td>
<td>MRI</td>
<td>32</td>
<td>179.9 (±2)</td>
<td>12.5%</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Victor et al., 2013</td>
<td>Ghent, Belgium</td>
<td>Signature, Biomet</td>
<td>MRI</td>
<td>61</td>
<td>179.4</td>
<td>24.6%</td>
<td>–</td>
<td>89.9 (85.5–95)</td>
<td>89.7 (83–95)</td>
</tr>
<tr>
<td>Daniliidis et al., 2013</td>
<td>Hannover, Germany</td>
<td>Biomet Genesis II, Smith &amp; Nephew</td>
<td>MRI</td>
<td>170</td>
<td>178.4</td>
<td>9.3%</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Roh et al., 2013</td>
<td>Seoul, South Korea</td>
<td>Signature, Biomet</td>
<td>CT</td>
<td>42</td>
<td>179.5</td>
<td>12%</td>
<td>–</td>
<td>Varus 1.0 (±1.4)</td>
<td>Valgus 0.2 (±1.4)</td>
</tr>
<tr>
<td>Boonen et al., 2013</td>
<td>Netherlands</td>
<td>VISIONAIRE, Smith &amp; Nephew</td>
<td>MRI</td>
<td>86</td>
<td>179</td>
<td>30%</td>
<td>–</td>
<td>89 (82–93)</td>
<td>90 (84–94)</td>
</tr>
<tr>
<td>Chareancholvic et al., 2013</td>
<td>Bangkok, Thailand</td>
<td>Nexgen, Zimmer</td>
<td>MRI</td>
<td>40</td>
<td>179.7</td>
<td>2.5%</td>
<td>–</td>
<td>90.1 (87–93)</td>
<td>89.8 (87–93)</td>
</tr>
<tr>
<td>Paratte et al., 2013</td>
<td>Marseille, France</td>
<td>Nexgen, Zimmer</td>
<td>MRI</td>
<td>20</td>
<td>179</td>
<td>20%</td>
<td>–</td>
<td>90.1 (84–93)</td>
<td>89.1 (85–96)</td>
</tr>
<tr>
<td>Noble et al., 2013</td>
<td>New Orleans, USA</td>
<td>VISIONAIRE, Smith &amp; Nephew</td>
<td>MRI</td>
<td>15</td>
<td>181.7 (180–186)</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Chen et al., 2013</td>
<td>Singapore</td>
<td>Nexgen, Zimmer</td>
<td>MRI</td>
<td>29</td>
<td>179.2 (±3.4)</td>
<td>31%</td>
<td>–</td>
<td>89.9 (±2.1)</td>
<td>89.8 (±1.9)</td>
</tr>
<tr>
<td>Barrett et al., 2013</td>
<td>Seattle, USA</td>
<td>PFC, Depuy</td>
<td>CT</td>
<td>66</td>
<td>182.23 (±1.9)</td>
<td>19%</td>
<td>–</td>
<td>89.8 (±1.3)</td>
<td>90.0 (±1.1)</td>
</tr>
<tr>
<td>Macdessi et al., 2013</td>
<td>Sydney, Australia</td>
<td>Nexgen, Zimmer</td>
<td>MRI</td>
<td>115</td>
<td>179.9 (−5 to +7)</td>
<td>8.7%</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Yaffe et al., 2013</td>
<td>Chicago, USA</td>
<td>Nexgen, Zimmer</td>
<td>–</td>
<td>44</td>
<td>180.98 (±2.3)</td>
<td>22.7%</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Koch et al., 2013</td>
<td>Zurich, Switzerland</td>
<td>CMK, MyKnee</td>
<td>CT</td>
<td>301</td>
<td>180.1 (±2.0)</td>
<td>12.4%</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Nam et al., 2013</td>
<td>New York, USA</td>
<td>Signature, Biomet</td>
<td>MRI</td>
<td>41</td>
<td>180.8 (±2.9)</td>
<td>29.3%</td>
<td>–</td>
<td>89.9 (±1.5)</td>
<td>89.6 (±1.6)</td>
</tr>
</tbody>
</table>

3.4. Clinical outcomes

Fifteen studies compared alignment outcomes between standard instrumentation and PSI knees (Table 1). The ‘OtisMed’ arm of the study by Nunley et al. [32] was excluded, as it is a kinematic system that operates upon an anatomical and not mechanical model. For purposes of meta-analysis calculations, Noble and Vundelinckx et al.’s series [45,52] were excluded as the proportion of three-degree outliers from a neutral postoperative axis was not listed.

3.5. Primary outcome measure

In total, from 15 studies reporting a total of 1847 knees (PSI and standard instrumentation), a postoperative HKA malalignment of...
Table 2
Patient-specific knee instrumentation studies: sagittal plane alignment outcomes.

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean sagittal LFC (range)</th>
<th>3-degree outliers</th>
<th>Mean sagittal LFC (range)</th>
<th>3-degree outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conteduca et al., 2012 [27]</td>
<td>86.3 ± 2.0</td>
<td>–</td>
<td>93.8 ± 2.4</td>
<td>–</td>
</tr>
<tr>
<td>Boonen et al., 2012 [34]</td>
<td>85 (74–94)</td>
<td>41%</td>
<td>94 (87–102)</td>
<td>40.00%</td>
</tr>
<tr>
<td>Lustig et al., 2012 [28]</td>
<td>87.1 ± 2.8</td>
<td>34.6%</td>
<td>90.1 (±2.6)</td>
<td>19.3%</td>
</tr>
<tr>
<td>Roh et al., 2013 [41]</td>
<td>86.8 (±2.3)</td>
<td>10%</td>
<td>93 (±2.0)</td>
<td>4%</td>
</tr>
<tr>
<td>Paratte et al., 2013 [44]</td>
<td>81.85 (76–88)</td>
<td>–</td>
<td>84.1 (91–97)</td>
<td>–</td>
</tr>
<tr>
<td>Boonen et al., 2013 [42]</td>
<td>96 (81–112)</td>
<td>49%</td>
<td>92 (86–101)</td>
<td>33%</td>
</tr>
<tr>
<td>Victor et al., 2013 [39]</td>
<td>86.8 (±2.3)</td>
<td>52.5%</td>
<td>93 (±2.0)</td>
<td>21.3%</td>
</tr>
<tr>
<td>Chen et al., 2013 [40]</td>
<td>87.7 (±2.6)</td>
<td>24%</td>
<td>84.2 (±3.4)</td>
<td>24%</td>
</tr>
<tr>
<td>Yaffe et al., 2013 [40]</td>
<td>88.6 (±4.8)</td>
<td>–</td>
<td>87.2 (±5.0)</td>
<td>–</td>
</tr>
<tr>
<td>Macdessi et al., 2013 [48]</td>
<td>–</td>
<td>5.2%</td>
<td>83</td>
<td>8.7%</td>
</tr>
<tr>
<td>Koch et al., 2013 [50]</td>
<td>–</td>
<td>9.0%</td>
<td>–</td>
<td>12.3%</td>
</tr>
</tbody>
</table>

Table 3
Patient-specific knee instrumentation studies: femoral rotation alignment outcomes.

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean femoral rotation conventional</th>
<th>Mean femoral rotation PSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heyse and Tibesku, 2012 [37]</td>
<td>2.6 (±2.6)</td>
<td>2.1 (±1.5)</td>
</tr>
<tr>
<td>Lustig et al., 2013 [28]</td>
<td>1.6 (±2.6)</td>
<td>0.6 (±2.5)</td>
</tr>
<tr>
<td>Magdessi et al., 2013 [48]</td>
<td>0.2 (±2.6)</td>
<td>0.5 (±2.6)</td>
</tr>
<tr>
<td>Paratte et al., 2013 [44]</td>
<td>7/92 (8.7%)</td>
<td>11/115 (8.7%)</td>
</tr>
<tr>
<td>Roh et al., 2013 [41]</td>
<td>6/48 (13%)</td>
<td>4/42 (10%)</td>
</tr>
<tr>
<td>Victor et al., 2013 [39]</td>
<td>0.6 (±2.6)</td>
<td>0.5 (±2.6)</td>
</tr>
</tbody>
</table>

Results did not show a significantly increased accuracy with PSI based on an incidence of less than three degrees of malalignment (P > 0.05). The sensitivity analysis, where only those studies with a Detskey score greater than 10 were included, reported a similar finding (OR: 1.03; 95% CI: 0.72–1.14; Fig. 3).

3.6. Secondary outcome measures

3.6.1. Coronal plane alignment: HKA/knee/ankle angle (FKA)

In total, 16 studies reported the HKA. Overall, 17% of patients had deviation in the mechanical axis greater than three degrees of neutral. Range of mean alignment was 178.3 to 181.7 degrees. There was a wide (mean) range of three-degree outliers from 2.5 to 31%.

3.6.2. Coronal plane alignment: zone of mechanical alignment (ZMA)

Four studies examined the ZMA as an alignment outcome in a total of 429 patients. Central zone alignment was achieved in 36 to 88% (mean 71.9%) of knees.

Coronal plane of alignment: frontal femoral component (FFC) angle and frontal tibial component (FTC) angles. Thirteen studies reported upon deviation of femoral and tibial components from the mechanical axis in the coronal plane in a total of 484 knees (Table 4). In these studies, range of mean alignment was: FFC (89.9 to 91.3 degrees) and FTC (87.1 to 91.9 degrees).

3.6.3. Femoral rotation

Six studies documented femoral implant rotation as an outcome measure in 342 knees with a 12% proportion of three-degree outliers. Five studies compared PSI to conventional instrumentation [37,39,41,44,54], which showed 12.9% three-degree outliers on postoperative CT scan (Table 3). These two studies showed PSI

Fig. 3. Relative risk of producing deviation greater than 3 degrees from neutral in mechanical axis: patient-specific vs. conventional instrumentation (all comparative studies).

to be significantly more accurate [37,44]. Subgroup meta-analysis of quality studies (Detskey score ≥ 16) was not possible due to the low number of qualifiable studies [39,41,44].

3.6.4. Sagittal plane alignment: LTC/LFC

Sagittal alignment of both femoral (LFC) and tibial (LTC) components was described in 11 studies (Table 2). In these series, range of mean alignment was: LFC (81.85 to 96 degrees) and LTC (83 to 94 degrees). The proportion of three-degree outliers ranged between 5.2 and 52.5% for LFC and 4 to 40% for LTC.

4. Discussion

Findings of this systematic review and meta-analysis demonstrate a lack of increased accuracy in coronal alignment outcomes in PSI total knee arthroplasty, demonstrated by the number of three-degree outliers from a neutral HKA angle in the coronal plane. Included studies were of all demonstrably high-quality as defined by the Detskey scoring system however with a variable level of methodological rigor, in particular with regards to randomisation and allocation concealment. There was variability in the method of measurement of postoperative alignment i.e. a combination of CT scanograms, long leg radiographs, and computer-assisted technology. Within the literature, disparity has previously been shown in accuracy of mechanical axis measurements when comparing long leg radiographs and coronal scout CT scans [53]. Recommendations should therefore be viewed with consideration. The outcomes from this study are supported by findings from a recent meta-analysis showing no increased risk of malalignment in mechanical axis with PSI versus conventional TKR. However, eligibility criteria and methodological scoring differed when compared to our study [54].

Implant malalignment has been directly associated with early failure as evidenced from previous studies [14]: a varus or valgus malalignment specifically predicting an increased risk of failure [56]. Jeffrey et al. documented rates of aseptic loosening in implants with less than ± three degrees malalignment at 24% as compared to just 3% in TKAs falling within the ± three-degree range [57]. However, restoration of the mechanical axis has not clearly been shown to predict a more positive functional outcome [58], with regard to the computer-navigated model. In fact, computer-assisted navigation improves precision and accuracy of alignment over manual instrumentation [59], but disadvantages include: lengthy landmark registration, longer operative duration, greater cost, risk of pin loosening and a significant learning curve. With specific regard to varus malalignment, Collier et al. [60] demonstrated three factors predictive of increased medial compartment wear: shelf age of the liner, age of the patient and postoperative varus alignment on HKA measurement. It has more recently been postulated that three degrees is an arbitrary figure and that any deviation from a neutral axis of alignment will reduce longevity by a degree proportional to the malalignment.

Within the small number of comparative studies examining accuracy of femoral implant rotation, subgroup meta-analysis of conventional against patient-specific instrumentation was not feasible given the current paucity of quality studies reporting upon this outcome. The role of patient-specific instrumentation in achieving accurate rotational placement of implants is further verified by findings that computer navigation has limited control on axial positioning of implants [61,62]. To date, computer-assisted navigation has been shown to be effective in reducing outliers in both the

<table>
<thead>
<tr>
<th>Study</th>
<th>PSI: HKA mean (outliers)</th>
<th>PSI: HKA mean (outliers)</th>
<th>P value</th>
<th>Accuracy conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrett et al., 2013 [53]</td>
<td>179.5 (23%)</td>
<td>178.3 (31%)</td>
<td>0.203</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Nunley et al., 2012 [32] (Signature)</td>
<td>180.08 (16%)</td>
<td>179.35 (18%)</td>
<td>1.0</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Paratte et al., 2013 [44]</td>
<td>178.3 (10%)</td>
<td>179 (20%)</td>
<td>n.s</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Boonen et al., 2012 [34]</td>
<td>179 (46%)</td>
<td>181 (29%)</td>
<td>0.1</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Boonen et al., 2013 [42]</td>
<td>178 (18%)</td>
<td>179 (18%)</td>
<td>n.s</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Victor et al., 2013 [39]</td>
<td>179.1 (28.1%)</td>
<td>179.6 (24.6%)</td>
<td>0.69</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Roh et al., 2013 [41]</td>
<td>179.5 (16%)</td>
<td>179.5 (12%)</td>
<td>0.542</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Chareanchovarnich et al., 2013 [43]</td>
<td>179.7 (7.5%)</td>
<td>179.7 (2.5%)</td>
<td>0.615</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Ng et al., 2012 [33]</td>
<td>181.1 (22%)</td>
<td>180.6 (9%)</td>
<td>0.018</td>
<td>PSI more accurate</td>
</tr>
<tr>
<td>Daniilidis and Tibesku, 2013 [31]</td>
<td>178.7 (21.2%)</td>
<td>178.4 (9.3%)</td>
<td>0.0031</td>
<td>PSI more accurate</td>
</tr>
<tr>
<td>Noble et al., 2013 [45]</td>
<td>181.7 (180–186)</td>
<td>182.8 (180–185)</td>
<td>0.03</td>
<td>PSI more accurate</td>
</tr>
<tr>
<td>Chen et al., 2013 [46]</td>
<td>180.2 (16%)</td>
<td>179.2 (31%)</td>
<td>0.045</td>
<td>PSI less accurate</td>
</tr>
<tr>
<td>Barrett et al., 2013 [47]</td>
<td>182.09 (23%)</td>
<td>182.23 (19%)</td>
<td>0.646</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Yaffe et al., 2013 [49]</td>
<td>179.76 (32.5%)</td>
<td>180.98 (22.7%)</td>
<td>0.164</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Magdessi et al., 2013 [48]</td>
<td>179.4 (19.6%)</td>
<td>179.9 (8.7%)</td>
<td>0.039</td>
<td>PSI more accurate</td>
</tr>
</tbody>
</table>
coronal and sagittal planes [33], but has not been shown to increase accuracy of rotational alignment [63–65]. It has been proposed that reproducible and accurate registration of bony landmarks for optimal rotational alignment is more difficult to achieve with navigation [66].

Malposition of tibial and femoral implants in the axial plane is an important predictor of postoperative pain and patello-femoral complications [53,67]. Further determination of the role of PSI in determining rotational accuracy is therefore advocated.

5. Conclusion

This systematic review describes alignment outcomes in PSI within the current literature. Meta-analysis confirms no demonstrable overall benefit in coronal plane outcomes with particular regard to the HKA angle (three-degree outliers). Further quality studies are required to determine rotational alignment outcomes.

Disclosure of interest

A.M., T.S., C.S. and P.J.A.M. declare that they have no conflicts of interest concerning this article.

N.L.: consultant for Zimmer and received personal fees.

Appendix A. Supplementary data

Supplementary data (Appendices 1 and 2) associated with this article can be found in the online version, at doi:10.1016/j.otsr.2014.12.018.

References