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Contribution of patient-specific cutting guides to lower limb alignment for total knee arthroplasty

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Patient-specific cutting guides (PSCG) are an extension of preoperative planning for total knee arthroplasty (TKA). We wanted to evaluate their contribution to postoperative lower limb alignment. This study involved primary TKA cases being performed with PSCG between 10/05/2010 and 05/03/2013 and then followed prospectively. The analysis involved the PSCG usage and postoperative measurement of the patient’s HKA, medial distal femoral joint angle (MDFA) and medial proximal tibia joint angle (MPTA). Of the 104 eligible cases, 68 were included; 11 of these cases were not performed completely with the PSCG as initially planned. Thus we compared these 11 cases with the 57 where PSCG were used. The preoperative HKA in the included cases was 175.8° ± 7.8; the postoperative angles on average were 179.2° ± 2.9 for the HKA, 89.9° ± 1.6 for the MDFA and 89.0° ± 2.3 for the MPTA. The average postoperative deviation from the target values was 2.22° ± 2.14 for the HKA angle, 1.07° ± 1.15 for the MDFA and 1.66° ± 1.90 for the MPTA. There were no significant differences between the two groups in any of the measurements. The lower limb alignment goal was achieved in 50 cases (73%), with 41 of these achieved with PSCG (82%). Of the 18 cases where the target was not achieved, PSCG were used 16 times (88%). In this study cohort, lower limb alignment was not significantly closer to an HKA of 180° or achieved more often with the use of PSCG versus standard instrumentation. Since the results of the two groups can be superimposed, we found no evidence that use of PSCG improves postoperative lower limb alignment.

Level of evidence: IV.
Study type: Cohort.

1. Introduction

Total knee arthroplasty (TKA) is a procedure with demonstrated clinical and financial benefits for patients suffering from advanced knee osteoarthritis [1,2]. The 10-year survival of these implants is typically more than 90% [3–5]. However, a more detailed analysis of failed cases reveals that mechanical failures occur early in more than half the cases, with 40% occurring before 5 years according to Fehring et al. [6] and 50% at 3.7 years according to Sharkey et al. [7]. A multicentre study in France reported in 2011 that loosening occurred at 4.43 years on average [8]. This raises questions about the reproducibility of this treatment method when a 100% increase in demand for TKA is expected in the upcoming years [9].

Although recently brought into question [10], restoring neutral mechanical alignment in the frontal plane is a proven factor for implant survival [11–14]. Computer navigation was introduced in the 1990s to reproducibly achieve this neutral alignment. Its efficacy has been demonstrated since then, to the point where it is now the gold standard technique for lower limb alignment [15,16]. However, the cost, increased surgery time, learning curve and complications have hindered widespread acceptance of this technique [17,18]. Patient-specific cutting guides (PSCG) were designed with similar goals in mind to those of computer navigation (limb alignment, absence of morbidity related to intramedullary instrumentation) but also to simplify the procedure. The intent was to move the navigation step from the intra-operative period to the preoperative period, while keeping the precision associated with computer assisted surgery. Here we report on our experience with patient-specific cutting guides during TKA and evaluate if PSCG can help restore the mechanical axis of the leg.

2. Material and methods

This was a prospective, observational, single-centre, multi-surgeon study. The study involved patients undergoing primary

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OTSR-951; or
knee
PDF
by
patient's
are
exclusion
PSCG
patients
be
were
included.
The
dynamic
standing
radiographs
were
incomplete
orthopedics
incomplete
of
in the
femoral
of
prospective
and
postoperative
long-leg
radiographs,
along
with
implant
alignment
in
the
frontal
plane,
which
was
quantiﬁed
on
postoperative
long-leg
standing
views
through
the
medial
distal
femoral
and
medial
proximal
tibial
joint
angles
[20].
Angles
were
measured
on
digital
X-rays
of
long-leg
standing
radiographs
as
described
by
Ramadier
et
al.[21]
using
computerized
tools
(OrthoView®,
Jacksonville,
USA)
integrated
into
our
facility's
digital
archiving
system.
The
goal
was
to
achieve
a
neutral
mechanical
leg
axis,
defined
as
an
HKA
gle
of
180 ± 3°. So
as
to
not
alter
the
comparison
of
averages
due
to
bias
of
deformity
distribution
around
180°,
we
also
evaluated
the
deviation
from
180°
calculated
as
the
absolute
value
of
the
difference
between
the
postoperative
HKA
angle
and
180°.
A
similar
analysis
was
performed
with
the
medial
distal
tibial
joint
angle
(MDFA)
and
medial
proximal
tibia
joint
angle
(MPTA)
relative
to
the
90° target
value.
We
defined
a
well-aligned
knee
as
one
where
the
postoperative
HKA
angle
was
between
177°
and
183°,
inclusively.
In
bilateral
TKA
cases,
the
two
knees
were
analysed
as
independent
samples.
Non-parametric
statistical
tests
were
used
because
of
the
low
number
of
patients
in
which
the
PSCG
were
not
used.
Statistical
tests
were
performed
using
StatView
4.1.4
software
(ABACUS
Concepts,
Inc.,
Piscataway,
NJ,
USA).
The
Mann-Whitney
U
test
was
used
to
compare
group
averages.
Two-tailed
tests
were
performed
and
the
null
hypothesis
(H0)
was
defined
as
no
difference
or
correlation
between
the
two
groups.
The
type
I
risk
was
set
at
0.05.

3. Results

The
3
surgeons
included
68
cases
in
62
patients
(6 bilateral),
thus
an
inclusion
rate
of
65.4%.
Of
these
68
patients,
57
were
performed
with
the
PSCG
and
11
(16%)
were
not
performed
fully
with
the
PSCG
as
initially
planned.
We
compared
the
results
of
these
11
cases
(performed
fully
or
partially
with
standard
instrumentation)
to
the
57
cases
performed
with
PSCG.
In
the
11
cases
performed
without
PSCG:
5
because
of
the
tibial
cut
and
6
because
of
the
femoral
cut.
In
5
cases,
the
PSCG
were
not
used
because
the
distal
femur
had
to
be
resected
due
to
a
flexion
defor-
Table 1
X-rays measurements and assessment of outliers in the groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>HKA preop</th>
<th>HKA at FU</th>
<th>Difference from 180° HKA</th>
<th>Difference from 90° MDFA</th>
<th>Difference from 90° MPTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSCG (n = 57)</td>
<td>174.9 ± 6.68</td>
<td>178.8 ± 2.82</td>
<td>2.17 ± 2.13</td>
<td>0.96 ± 1.02</td>
<td>1.79 ± 2.03</td>
</tr>
<tr>
<td>Standard instrumentation (n = 11)</td>
<td>180.2 ± 11.4</td>
<td>181.0 ± 3.26</td>
<td>2.45 ± 2.25</td>
<td>1.64 ± 1.63</td>
<td>1.00 ± 0.63</td>
</tr>
<tr>
<td>Total</td>
<td>175.8 ± 7.8</td>
<td>179.2 ± 2.9</td>
<td>2.22 ± 2.14</td>
<td>1.07 ± 1.15</td>
<td>1.66 ± 1.90</td>
</tr>
</tbody>
</table>


Only a few studies have reported on the lower limb alignment after TKA performed with patient specific cutting guides [24–28]. One of these studies was a prospective, randomized study evaluating four different types of PSCG (Signature®, Biomet Inc.; TruMatch®, DePuy Inc.; Visionaire®, Smith & Nephew Inc. and Patient-Specific Instruments®, Zimmer Inc.) [29]. These studies found no benefit in terms of improving the lower limb alignment or quality of implant positioning, with a strong trend toward postoperative varus of the tibial component. Conversely, Ng et al. [30] reported a 10% improvement (88% vs 78%) in postoperative alignment when using PSCG in a significant number of patients (569 TKA with PSCG vs. 155 TKA with standard instrumentation). Ball et al. reported similar findings in a smaller number of cases [31].

This brings up questions about the lack of precision. Is it intrinsic to the technique or is it related to the user who does not place the PSCG properly? Two studies have attempted to answer this question by evaluating the alignment of bone cuts proposed by the Visionaire PSCG system with computer navigation [22,23]. The main error rate was intrinsic to the technique and mostly occurred in the sagittal plane; however there were a significant number of errors in the frontal plane, mostly affecting the tibia. This leads us to hypothesize that using long-leg standing radiographs to plan the bone cuts does not take into account bone rotation. This mainly impacts the tibia; it induces varus because it is externally rotated relative to the wear on the posterior medial tibial plateau, which is secondary to chronic ACL rupture.

The limitations of the current study revolve mainly around the small number of patients, heterogeneity, lack of control group. The latter would have allowed us to have adequate statistical power to compare TKA patients operated with PSCG with TKA patients operated with standard instrumentation. The prospective nature of the study was tempered by the fact that the inclusion rate was only 65.4%. In addition, this study included all the TKA that had been planned to be performed with PSCG at our facility by three different surgeons, without excluding any patients operated on during our initial learning curve with the Visionaire technology (MRI quality, long-leg standing film quality, availability of patients and time needed to make the PSCG in conflict with the surgery date). Nevertheless, it accurately reproduced our experience with the technique and rigorously challenged the expectations that we had relative to improving post-TKA lower limb alignment.

It would be incorrect to limit the potential contribution of PSCG to TKA implant positioning. Benefits in terms of less bleeding, shorter surgical time and lower instrumentation sterilization costs can also be expected, although such evaluations were beyond the scope of our study [31,32].

4. Discussion

The primary finding of this study was that in 16% of cases where the surgeon expects to use PSCG, a standard instrumentation set must also be available. The second finding is that using PSCG did not optimise the postoperative lower limb alignment in the patients evaluated. In this cohort study, lower limb alignment was not significantly closer to an HKA angle of 180° or achieved more often with the use of PSCG compared to standard instrumentation. This result must be interpreted with caution because of the two groups had an unequal number of patients. Based on our findings, we found no evidence that use of PSCG improves postoperative lower limb alignment. As a consequence, we cannot recommend that PSCG be used to primarily optimize the postoperative alignment of TKA patients [22,23].

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Disclosure of interest

J. Brillhaut discloses the following conflicts of interest:

• clinical trials: co-investigator, associate researcher collaborator in studies sponsored by Smith & Nephew other than the one reported here;
• ad-hoc work: expert reports for Smith & Nephew;
• symposiums: invited as contributor by Smith & Nephew.

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