Reviewer's report

Title: Navigation of TKA: Rotation of components and clinical results in a prospectively randomized study

Version: 3 Date: 21 August 2010

Reviewer: Biasca Nicola

Reviewer's report:

Major compulsory revisions are necessary:

A. GENERAL IMPRESSION:

The authors have done an interesting study. However, the authors are using the CT free KneeTrac Software version 1.0, which is the first system generation and the first software version of the Stryker Company. The authors are making some conclusions on the value of the navigation in TKA using the first Hard and Software Navigation system from the period 2001 and 2002, which are very questionable. The authors have to specify this! This is also very important in order to not discredit the result and utility of the navigation in TKA.

B. BY SECTIONS:

ABSTRACT:

The abstract is well prepared.

However, methods and conclusions of this manuscript are not specifying which type of navigation system and which type software has been used. These two points are very important because the readers can be deceive of the value of the knee navigation, if the value of the navigation today has been and will be estimated on the basis of the first Hard and Software generation from the period 2001 and 2002!!!

Further details will be specifying below.

KEY WORDS:

Ok.

1. BACKGROUND:

This section should be ameliorate and review with the recent literature:

Second paragraph:

The sentence “Most studies were not able to give statements on rotational alignment …….” must be reconsider and be specify more in details, because there have been a lot of publications which has demonstrated, also on CT scans,
the superiority and accuracy of computer-navigated TKA in order to reconstruct the rotational alignment of the femoral component. Although it has been reported that the rotational mismatch between the femoral and tibial components is decreased with navigation, controversy still exists as to whether navigation systems do improve the rotational alignment of the tibial component in the axial plane.

Third paragraph:
The sentence “Clinical data is scarce”. This sentence is also very imprecise and it should be ameliorate thought a detailed research in the literature. Here two examples:

1. A recent prospective randomized controlled study has demonstrated a positive correlation between accurate mechanical alignment after TKA and functional and quality-of-life patients’ outcomes. At all post-operative follow-up intervals from 6 weeks to 12 months the total IKSS score were significantly better in patients with a mechanical axis within 3° of neutral compared to those greater than 3°. Moreover, the SF-12 physical scores at all intervals from 3 months were also significantly better for patients with a mechanical axis within 3° of neutral, and at 12 months these patients demonstrated better SF-12 mental scores as well. [Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? A prospective randomized controlled trial comparing conventional and computer-assisted total knee arthroplasty. J Arthroplasty 2008, 24(4):560-9]

2. Furthermore, another recent study showed, that TKA with good alignment lead to better function with quicker rehabilitation and earlier hospital discharge as well. [Longstaff LM, Sloan K, Stamp N, Scadden M, Beaver R. Good alignment after Total Knee Arthroplasty leads to faster rehabilitation and better function. J Arthroplasty 2008, 24(4):570-8].

The conclusions of the third paragraph “no functional differences…between navigated and conventional TKA” is also not supported by the current literature and must be specify in details and review with the recent literature!

2. METHODS:

First paragraph:
Ok, however the time of occurrence of this study is NOT mentioned at all! This is very important because the authors were using the FIRST generation of the Stryker Knee Navigation system! The readers must know this detail.

Second paragraph:
Ok

Third paragraph:
Ok
Fourth paragraph:
The authors should specify more in details the following points:
- How did they measure the slope of the tibial plateau?
- Which transepicondylar axis has been chosen for determining the TEA (anatomical versus surgical)?
- Why this reference points and specify more in details the differences of these measurements.
- Who did analyze the CT scans and x-rays prior to the operation? An independent observer, a radiologist or the surgeons?

Fifth paragraph:
It is well done.
Who did measure and analyze the CT scans and x-rays?

Sixth paragraph:
Ok.
In this paragraph the authors have written and specified “At latest FU .....two independent examiners.” who have done the analysis of the radiographs and CT-scans.

In this paragraph and also earlier in the chapter Methods the authors did not specify how did they measure the rotational alignment of the tibial component!

The authors should specify why rotational deviations of 3o were ideal and > 6o were outliers. Which are the references of this measure?

In the analysis of the rotational alignment is also very important to know which type of prosthesis has been used. The authors should specify more in details which type of prosthesis and which type of polyethylene inlay did they used (NexGen LPS and Stryker Scoprio PS).

Here is also important to specify which slope is included in the polyethylene inlay of these types of prosthesis.

Seventh paragraph:
The authors should specify which type of anesthesia has been used and which type of post-operative pain medication has been used.

The authors should also specify more in details how often are they using the knee navigation and how many knee navigations have been done before to start this study. This is important in order to correct interpret the operation time and final results. This is also important in order to understand why the authors did have more wound healing problems with the navigation and why the authors have to abandoned the navigation in tree cases. This is also important in order to
understand why the authors have a longer skin incision for the navigation groups. This is also important in order to understand why the navigation groups have a longer hospital stay. These factors are very important for the correct interpretation of the results!

Eight paragraph:
The authors are using the CT free KneeTrac Software version 1.0, which is the first system generation and the first software version of the Stryker Company. The authors have to specify this! This is also very important in order to not discredit the result and utility of the navigation in TKA.

The authors have also to specify when this study was done. This is also very important in order to not discredit the result and utility of the navigation in TKA.

Ninth paragraph:
Ok

3. RESULTS:
Ok

First paragraph:
Ok

Second paragraph:
Operation time, incision length, and hospital stay: These results must be interpreted cautiously (cp. Chapter Methods).

Third paragraph:
Postoperative radiological and CT-scans: These results must be interpreted cautiously (cp. Chapter Methods).

Fourth paragraph:
Clinical examination: These results must be interpreted cautiously (cp. Chapter Methods).

Fifth paragraph:
FU clinical evaluation: These results must be interpreted cautiously (cp. Chapter Methods).

4. DISCUSSION:
It is well done.

The authors should discuss more in details the following points:

First paragraph:
- Why were the incision lengths longer with navigation? The authors should discuss this more in details.

- Why were the KSS in the navigated groups significantly lower then the conventional groups? The authors should discuss this more in details.

Second paragraph:

- This is one of the question posed by the authors and should be discussed more in details. Which are the interpretations of these results. How can the authors explain that there is no significant difference between navigated and conventional groups in the analysis of the component rotation?

Third paragraph:

- Why did the author have more outliers in the navigation groups? The authors should discuss this more in details.

Fourth paragraph:

- Is a repetition of the first paragraph?
- Why were the incision lengths longer with navigation? The authors should discuss this more in details.

Fifth paragraph:

- The digitalization of the different bone landmark is one of the most important steps in the navigation. Debate continues with regard to how accurately and easily the transepicondylar axis can be located intra-operatively. However, this accuracy must be explained by the higher or lower ability of the surgeon to identify intra-operatively the medial epicondyle with its bone ridge and sulcus and the attachment of the deep and superficial fibers of the medial ligament, by the learning curve of the surgeon associated with the use of navigation and finally by the individual surgeon’s skills. The discussion in this regard must be ameliorated.

- Furthermore the authors have to explain and inform the readers that the navigation system used in this study was the first software version of the navigation!!! The authors have to explain which measures can be accurately analyze with this system, and the value of benefit of this basic system in the navigation. Furthermore, there are a lot of recent publications which have shown, that the newer and recent algorithm of the Stryker Knee Navigation Softwares allows to establish the proper femoral rotational alignment by averaging the angle subtented by the Whiteside’s line and the transepicondylar axis and gives the surgeon the possibility to improve the accuracy of the femoral rotational alignment without excessively increasing operative time.

Sixth paragraph:

- The sentence “improvement by new technologies might be hard to perform…”
must be explained more in details.

Seventh paragraph:
- This sentence should be analyzed more in details and should be review with the recent literature.

Eight paragraph:
- The first sentence “No clinical benefits…” does NOT correlate with the recent literature!!! This should be discussed more in details and should be review with the comments in the section Method.
- The sentence “functional outcome was lower in the navigated group”. This conclusion should be analyzed more precisely and must be also discussed in regard by which navigation system has been used.

Seventh paragraph:
- Ok

Eight paragraph:
- The section “rotational malalignment” must be discussed more in details. There is no differentiation in the discussion between the issue of the rotational alignment of the femoral and of the tibial components (cf. also the comments on Methods).
- Although it has been reported that the rotational mismatch between the femoral and tibial components is decreased with navigation, controversy still exists as to whether navigation systems do improve the rotational alignment of the tibial component in the axial plane. This must be discussed more precisely.

Ninth paragraph:
- This is good. However, the authors have to explain more in details the comments on the section Methods.

Tenth paragraph:
- This sentence must be reviewed and specify more in details considering the comments in the section Methods.

5. CONCLUSION
- This sentence must be reviewed and specify more in details considering the comments in the section Methods.

6. REFERENCES
The authors have to review and integrate recent manuscripts (cf. Methods).

7. FIGURES / TABLES
Ok.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
I declare that I have no competing interests