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EDITORIAL

Alignment in total knee arthroplasty, still more questions than answers…

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The focus of the current issue is on technologies such as computer-assisted surgery (CAS) and patient-specific instrumentation (PSI) in total knee arthroplasty (TKA). CAS helps the surgeon navigate each individual patient's case based on bony landmarks in order to identify the correct positioning of the femoral and tibial cutting guides. The presumption was that component sizing and placement should be more accurate using CAS than the more conventional technique, resulting in both better alignment and clinical outcome. Many surgeons were convinced in the past that this technique would become the standard for TKA. Clinical studies have demonstrated that CAS reduces the number of outliers in component positioning and leg alignment as reported in the study by Lützen et al. [9]. Similar results have also been reported in a meta-analysis of level-I studies [6]. Unfortunately, the total time spent in the operating room and the lack of clinical amelioration has tempered its uniform acceptance by the surgical community [3, 14].

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Patient-specific instruments (PSI), recently introduced as a new technology, could demonstrate the same advantage of navigation in increasing accuracy, but without the practical inconveniences such as, the need to perform anatomical mapping or to position trackers during the procedure [10].

The virtual planning of the TKA procedure is outsourced to engineers who identify the anatomical landmarks needed for alignment on CT/MRI based 3D models, after which the information is transferred to patient-specific instruments that can be used during surgery. These instruments, created by laser sintering, can be produced in the most complex forms and are thus patient specific [1, 5].

The idea of finding anatomical landmarks on CT or MRI and relaying this virtual planning to the real-time environment of the operating room is innovative. Issues surrounding this innovation are of great importance and many questions remain unanswered. Despite the new technologies, we continue to rely on the same anatomical landmarks as used in the conventional technique. For instance, how accurately can the engineer plan a case without relevant clinical information on underlying fixed flexion deformity? The paper of Pietsch et al. published in the current issue showed that the surgeon has to revise the planing by the engineer quite regularly [12].

There can be a significant mismatch between planning by the engineer and the final component placement. How accurately can the surgeon position guides on flat surfaces like a dysplastic trochlea in the valgus knee?

How accurate are the pinning capacities of a surgeon and how much accuracy is lost when positioning the conventional instruments over the pins?

We are also cognisant of the cutting errors caused by the oscillating saw blade, which influences the accuracy of the surgery [18]. Accuracy in TKA is a multifactorial issue and extremely complex.

Recent literature has proven that PSI is probably not as reliable as stated before [5, 16], and this was also proven in one of the articles of this issue where patient-specific surgery was compared to conventional surgery in a multi-center, randomized clinical trial [4]. No difference in component alignment in the frontal plane was observed. However, there was a difference in the outliers of the femoral component alignment in the sagittal plane with higher percentages in the PSI group. It remains unclear whether PSI can provide better clinical and functional outcomes after total knee arthroplasty [1].

The principle of PSI introduction in knee arthroplasty is very similar to the introduction of ISO norms in surgery. Surgical planning is the work of the designer in the production of ISO-norm-rated materials. The choice of implant is comparable to the choice of the materials for production. The PSI guides transfer the surgical planning to the surgical procedure as an automated instrument would prepare the materials for finishing. Finally, radiographs or postoperative CT scan are a quality check of the finished product.

Innovation comes from the drive of surgeons to perform better and ensure their patients are happier and from their industrial partners who are continually striving to become smarter and quicker than their competitors. Innovation differentiates companies. PSI offers many theoretical bonuses for companies. Once these systems are fully proven, they could allow any surgeon to perform a knee arthroplasty with accurate three-plane alignment.

Furthermore, the production of single use instrumentation reallocates funds previously invested in instrument trays away from hospitals and back into the companies. This dramatic reduction in capital expenditure on equipment could provide the companies with the necessary cash flow in a maturing market where the product (TKA) is under price pressure. Innovation is therefore centred more on the technique of implanting TKA and less on the design itself, which seems to have been working well for the last 40 years.

New technologies should enable surgeons to become more effective, allowing them to evolve from 'doing things right' to 'doing the right things'. The cost of these new innovations should be covered by a reduction in surgical time, thereby allowing an additional case to be performed per day. And there should also be a subsequent reduction in costs of sterilising equipment, the avoidance of instruments loss and perhaps even a reduced infection risk.

Unfortunately, the cost of effort for both patient and surgeon is often forgotten in all this. The patient undergoing PSI-assisted surgery is required to attend to the hospital to have an MRI or CT scan done, during which time he is off work, thereby incurring a cost to society not to mention the direct cost of the MRI which is not a standard procedure for arthritis treatment in many countries.

The surgeon has to organise the MRI/CT scan, has to introduce the case, he (or a member of his staff) has to follow-up on the imaging and receive and respond to many emails. He has to make use of his personal time in order to check and validate each case, and finally, the PSI guides have to be received and sterilized prior to surgery. This entire supply chain is new for arthroplasty surgeons, and at each different level, mistakes can occur.

Despite the development of any new technology to improve TKA performance, there is still an ongoing discussion about optimal leg alignment in TKA.

Alignment remains a complicated issue because it includes the static and dynamic position of the leg, whereas we as surgeons, usually only focus on the frontal plane alignment in extension. The frontal plane alignment in flexion and the sagittal alignment are probably as important, if not more important, but have until today being less well studied compared to coronal and axial alignment.

With an accepted range of $\pm 3°$ of error from the 180° HKA angle and the intrinsic inaccuracies of conventional instruments, it becomes an even bigger challenge to aim for an exact amount of varus and not be off too much and subsequently arrive in the danger zone where TKAs fail [13].

Today, clinicians and researchers discuss whether coronal alignment should be neutral, defined as a 180° HKA angle, or if it should be in slight varus. It has been shown that many people have a constitutional varus during the majority of their lives and that the survival rate of implants does not seem to be negatively influenced by a limited amount of residual varus position [2, 11, 15]. Furthermore, some authors have published better clinical results using kinematic alignment [7]. Measurements of alignment after kinematically aligned TKA showed restoration of the joint line in 94 % [8].

At the end of this new innovation cycle, something positive should remain for surgeons and patients. As it appears at present, the patient-specific instrument cycle will have created an awareness of three-plane alignment and make pre-operative planning something more than just a glimpse at the radiographs just before the skin incision is made. We should also wonder if limited deviations of neutral alignment will influence the residual pain some patients may experience after TKA [17].

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