



Patient Specific Instrumentation (PSI): Early Results in a Danish Orthopaedic Department

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Abstract

Introduction: A new way of improving quality and logistics in Total Knee Arthroplasty (TKA) surgery might be Patient-Specific Instrumentation (PSI), providing cutting guides and predetermining component sizes from a MR scan preoperatively.

Methods: A retrospective review of 38 patients operated at Næstved Hospital with a TKA using PSI. All knees were operated between October 2014 and June 2015. We searched the medical records, The Danish Knee Arthroplasty Register and the files from the Zimmer® PSI- online management system.

Results: 42 patients were selected for PSI. 4 patients dropped out. Thus 38 patients were reviewed: 16 men, mean age 66, 1 year (50-82), BMI 29 (21-44), all suffering from osteoarthritis. It took 70, 8 days (32-139) from indication to operation. Intraoperatively, 12 of the 38 (31,6%) operations were converted to conventional technique, because the predetermined size did not fit. 9/12 of the converted patients got larger sizes that pre-planned, equally divided between femoral and tibial components. The converted operations had an operating time of 57, 9 minutes compared to 54, 4 minutes using PSI. In the Danish Knee Arthroplasty Register (2013) the operating time was on average 68 minutes.

Conclusion: With an average time from indication to operation of almost 71 days, and a conversion rate of 31, 6% (12/38), our early results with PSI were not good. However, given proper education of surgeons, the potential logistic advantages warrants further research.

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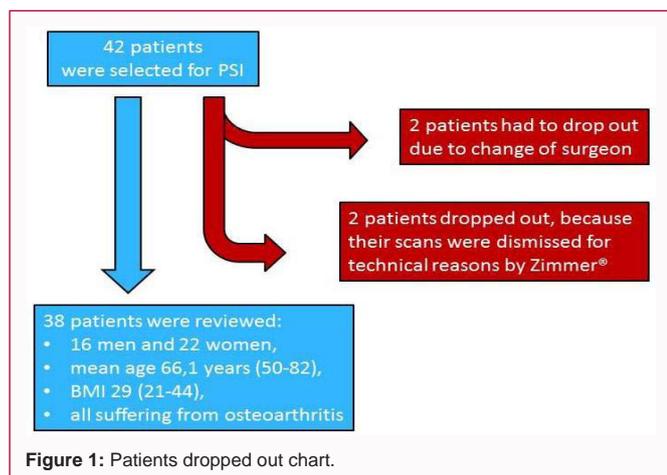
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Introduction

With an increasing number of elderly citizens and thereby increased need of total knee arthroplasty surgery, new ways of improving surgical quality and logistics in departments of elective knee orthopaedic surgery have developed, including the concept of fast-track [1]. Previously, computer assisted navigation was introduced for optimizing the precision of component alignment and kinematics, thus improving the clinical result. Improvement of both alignment and rotation has been demonstrated [2,3], and in difficult cases navigation is of significant value. Despite these advantages, the overall clinical impact seems insignificant when navigation is generally applied, and both complications and extra-time spend preoperatively are in the opposite [4]. A recent innovation is Patient-specific instrumentation by Zimmer, where premanufactured cutting guides are made from preoperative MRI or CT scans, also predicting the component sizes to be used. This should help reduce operative time and improve logistics by reducing 1) the time used to determine size intraoperatively, 2) the number of boxes (guides, trials, etc.) needed intraoperatively, 3) the interval between operations because of fewer boxes needed to be handled, and 4) the need for a large stock of components being stored in the department, all together making this technique more interesting than navigation. Thus, PSI should be able to comply with the present demands for reduced time consumption per operation without risking surgical quality. The aim of the present study was to evaluate our early results with the use of patient-specific instrumentation in a Danish orthopaedic department.

Methods

The study was a retrospective review of use of Zimmer's PSI. We included and collected data on all patients offered a primary total knee arthroplasty (TKA) with Zimmers Nex Gen in combination with use of PSI at the orthopedic department in Næstved, Denmark from October 2014- June 2015. During that period, a total of 470 TKA's were performed in Næstved by 5 surgeons. Two experienced surgeons were chosen to work with the PSI system and they randomly



selected patients, who accepted the long waiting-time until operation. Both surgeons received brief training in the use of the PSI system and how to template and approve the preoperative plans made by the PSI system. Preoperatively, all patients had a MR or CT scans, which were uploaded in the Zimmer® PSI- online management system. Evaluating the scans, assessments regarding size and alignment were done by the surgeons, which then lead to the manufacturing of individual cutting guides for both femur and tibia for each patient. All patients had insertion of a Zimmer® NexGen hybrid TKA. Medical records were reviewed for each patient from time of indication until operation. Zimmer®'s PSI-online management system as well as the Danish Knee Arthroplasty register was reviewed for data collection. The data collected included dates of preoperative events, age, gender, BMI, side, surgeon, diagnosis of disorder, assessment of axes before the operation, earlier operation in the knee, sizes determined by Zimmer and sizes used at the operation for both components, type of component, time of operation, use and time of tourniquet, need for cementation, size of liner, need for patella component, perioperative complications, use of drain and days of admission in the hospital. The study was approved by the Danish Data Protection Agency (Study ID: REG-17-2015). Since no intervention was performed it could be conducted without approval from the Ethics Committee according to Danish legislation on research (Committee Act § 1).

Results

Of the 42 patients included 4 patients dropped out (Figure 1). Two due to change in surgeon because of a change in date of operation on patients request and 2 patients MRI scans were dismissed by Zimmer because of artefacts in the scans. In one of the scans a small metal artefact was suspected, which could have originated from an osteotomy done earlier in the patient's life, the other because Zimmer found the MRI scan in poor quality. Of the 38 patients only one had a CT scan due to another metal implant, the rest had all MRI scans. Preoperatively patients had to wait 18, 2 days (4-95) for the MRI/CT. The scans were uploaded the same day in Zimmer's online management system. It took another 18, 1 day (9-51) for Zimmer to have the cutting guides ready for shipment. Included in this period the surgeons had to do the templating and approve the preoperative plans online, which caused a delay of 3 days (0-10). It took 35, 5 days (9-61) from shipment to surgery. In total the preoperative time between the day of indication and operation was 70, 8 days (32-139). Due to wrong predetermined size 31, 6% (12/38) operations were converted to conventional operating technique.

Table 1: Operating time.

With use of PSI (no 26)	54,4 min
Converted operations (no 12)	57,9 min
Conventional technique*	68 min

Either femoral or tibial guides were converted but never both guides during same procedure. Four femurs and 8 tibias were converted. In 9 out of 12 of the converted operations the predetermined size was too small, equally divided between femoral and tibial components. Not surprisingly the operation time was prolonged when conversion needed, but compared to the national average of operation time, it was still shorter using the PSI partially (Table 1). No other complications related to PSI were observed. There were no variables like age, gender, BMI, side, surgeon, previous knee operations, diagnosis of disorder, assessment of axes before the operation, type of component, time of operation, use and time of tourniquet, need for cementation, size of liner, need for patella component, perioperative complications, use of drain and days of admission in the hospital, that influenced the rate of converted operations.

Discussion

Thirty-eight patients is a limited number of patients. Surgeons with high-volume PSI experience have done 100-300 PSI assisted TKA [5,6]. In our study one of the surgeons only did 9 operations, which hardly provides proper experience with the use of PSI. Never the less this did not affect the conversion rate, compared to the other surgeon that operated 29 with use of PSI. Patients selected for the use of PSI were chosen because they agreed to prolong their preoperative waiting time until operation. This might imply that it was patients with a higher functional level and less pain, than patients selected for conventional technique. But with 16 men and 22 women, mean age 66, 1 year (50-82), BMI 29 (21-44), all suffering from osteoarthritis, our patient group demographics resembles other studies [7-10]. However, the random selection of patients also implied that this study did not in a proper way test the possible logistical opportunities, but more the ability of the surgeons to work with the system. With a public health care guaranteed maximum preoperative waiting time until TKA operation of 30 days, 70, 8 days is not acceptable. We saw a wide variation of the waiting time, both regarding pre-scanning time, Zimmer's time to produce the cutting guides, and time after shipment. The large variation might to some extent be caused by the occurrence of various holidays. Shortest total preoperative wait seen was 32 days, which shows that the waiting-time pre-scan and after shipment of the cutting guides could be reduced considerably. But even though the wait can be shortened it will probably not be enough to meet the guaranteed waiting time. Since Zimmer have a goal of 18 days until the cutting guides have to be ready for shipment (which they were able to fulfill in this study), this time span takes up too much of the guaranteed waiting time of 30 days. This limits the use of testing the PSI system in a larger scale and it can – for now - only be used for patients accepting a longer preoperative wait. Correct sizes and alignment depend on the ability of the surgeons to template the scans. This calls for proper education of the surgeons, but also for the necessary time consumption evaluating each scan. In our experience these factors were perhaps underestimated. This issue should be carefully addressed if testing PSI in a controlled trial.

The PSI system uses MRI or CT scans. MRI have in some studies been proven to give better placement of the tibia component than CT scans [11,12], while other studies hasn't found any differences

between MRI and CT [13,14]. Because of the ability of MRI scans to showcase soft tissue including cartilage, it should be a bit more precise. In our study, 41/42 scans were MRI. At first we were astonished by the high number of converted operations of 31.6%, but two recent meta-analyses reports of pre-planned component sizes not matching intraoperative assessment of size [5,15] resulting in prolonged operating time and reduced efficiency [15]. Rates of converted operations in different meta-analysis and RCT studies are quite similar. Cavaignac et al. [5] reported of a rate of 22, 6% (no 133), DeHaan et al. [6] 25, 7% (no 272, femur 15, 1%, tibia 7, 0% and both components 3, 6%), and Renson et al. [10] 14, 1% for femoral components and 21, 1% for tibial (no 71). Some studies excluded converted patients, but in other studies reviewed in the meta-analysis by Cavaignac the numbers of converted operations were not mentioned. This potentially means that the true rate of converted operations is unknown. We attribute that the slightly higher rate of converted operations seen in our study is due to the lack of experience of the surgeons in use of the PSI system and the limited training they received before starting using PSI. We found no variables that influenced on the rate of converted operations. We have not collected data on the presence of osteophytes, but osteophytes can reduce the fit of the cutting guides, which should be taken to account when planning contact points [9]. Surgeons should be aware that choosing or changing PSI systems from different companies can result in different preplans with both differences in alignment, component size and amount of bone resection [16]. The same goes for using different types of component-designs with the same PSI system, differences in bone resection is seen [17].

The use of the PSI system has yet failed to show improvement in operative time [15,18,19] and increased operative times have been reported [4,5,7]. Only a few studies show decreased operating time [6,10]. Improvements in logistics have been reported as a decreased number of surgical trays needed for the PSI operations [7,10,15] and in lowered turn-over time between operations [6,10]. We saw a reduced operating time then PSI was used successfully. And a noticeable difference compared with the national average from the Danish knee arthroplasty register. Our limited number of included patients gives us no foundation to significantly conclude that the use of PSI reduces the operating time, but we saw an insignificant trend towards shorter operating time. Unfortunately we had no data on turn-over time. The conversion of the operation did not affect the amount of days of admission in the hospital.

The use of PSI was launched with no protocol or greater thoughts on what logistic problems it might create. In a future prospective study with a better set-up, the potential advantages in logistics warrant further research. PSI could reduce: time spent before and in-between the operations, the number of surgical trays needed and the storage size, which if it works, could be a significantly cost reduction. This future study is planned to be performed at our department. However, the only clear indication for PSI so far seems to be the difficult knees, where standard instrumentation cannot be used [20]. The industry is -of cause -interested in selling their new products/ technologies. It is our job as doctors to remain critical to all new products, in order to ensure our patients' best interest. This study shows how implementation of a new technology is not always easy or free of problems. We advise that it should only be done with thorough preparations and proper education of all staff involved.

Conclusion

With an average time from indication to operation of almost 71

days, and a conversion rate of 31, 6% (12/38), our early results with PSI were not good. However, given proper education of surgeons, the potential logistic advantages warrants further research. The largest problem for testing a more generalized utilization in our country seems to be political decided waiting time guarantees.

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