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Original article

Patient specific instrumentation in total knee arthroplasty

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Summary. *Background and aim of the work*: The international literature and analysis of the prosthetic registers highlight a significant relationship between the alignment of the components and the survival of prosthetic implants of the knee. The patient specific instrumentation (PSI) technology exploits the data obtained with the MRN for the production of cutting blocks (CB) useful to a TKA. Revisiting the recent international literature, comparing the results of the conventional method and PSI, numerous studies confirm a statistically significant difference of inliers (± 3 degrees) for HKA. The purpose of this retrospective study was to investigate whether these statistically significant difference is also present in our group. *Methods*: Postoperative radiographic measures of alignment based on a mechanical limb axis (hip-knee-ankle angle, HKA) of 180° were sought. A range of 180° ± 3° varus/valgus was defined as optimal for mechanical axis. *Results:* The percentage of knees that had a HKA within ±3° of the desired value was 92.2. *Conclusion:* the CB did accurately produce the desired HKA. The PS system is an effective and reproducible, whose organizational effort is fully justified. (www.actabiomedica.it)

Key words: TKA, PSI, HKA

The international literature and analysis of the prosthetic registers reveal a significant relationship between the alignment of the components and the survival of TKA (1-3). There are many scientific evidences that the navigation (CAS) ensures a better alignment both on the coronal and sagittal axis compared to the classical method (4-7); however, the procedure, considering the difficult learning curve and the increase in surgical time, appears to be no so much used.

The patient specific instrumentation technology (PSI) uses data obtained with the MRI (or CT) for the realization of cutting masks (cutting blocks, CB) useful for TKA; in addition to the morphometric data obtained with the MRI, decisive for the correct anchoring of the masks to the osteo-cartilaginous surfaces of the femur and the tibia, it's also used the data obtained by X-ray of the lower limb; these data guide the engineer and the surgeon in determining the desired positioning of the prosthetic components. This is possible because the CB determine the cutting thicknesses and angles, as well as the rotations of the prosthetic components; these aspects are to be selected by the surgeon at the time of the pre-operative planning. Comparing the results of the conventional method and PS, Pfitzner et al.8 (2014) report a statistically significant difference of inliers (± 3 degrees) to the HKA, reporting values of 57 and 93% respectively; Drnek et al.9 (2014) report similar values, 73 and 93%; Heyse et al.10 (2012) values of 77 and 98%; Daniilidis et al.11 (2013) 79 and 91% with statistical significance ($p<0.05$). The purpose of this retrospective study was to investigate whether these statistically significant difference is also present in our group.

Methods

The study population consisted of 570 TKA done from November 2010 to December 2016. Two senior

staff surgeons using a standard medial parapatellar approach supervised all total knee arthroplasties. The Legion Genesis II and Legion Primary Systems (Smith and Nephew) were used.

Postoperative radiographic measures of alignment based on a mechanical limb axis (hip-knee-ankle angle, HKA) of 180° were sought. Deviance from optimal was extracted for all implant and limb alignment measures reported. A range of 180°±3° varus/valgus was defined as optimal for mechanical axis.

Results

The mean difference from the desired HKA was –1.40° (SD, ±.62°). The percentage of knees that had a HKA within ±3° of the desired value was 92.2.

PSI pitfalls

In contrast to the traditional method and CAS, the preoperative path is definitely more complex; the patient must be properly educated and informed before being sent to radiology; overall, the preoperative organizational effort is not to be underestimated, also in consideration of a fairly high percentage (15-20%) of MRI not valid at the end of the realization of the masks; there is very much important the radiologist's learning curve, who can recognize the erroneous sequences, resulting from patient movement, and then order the replay of the exam before uploading to the reference center; otherwise, if the sequences were inadequate, in order to obtain the patient's PSI it's necessary to rearrange the MRI examination, preferably prior sedation.

Once obtained the morphometric data of the patient, through the application of the surgeon's preferences, it is produced a pre-operative planning, that the surgeon has to approve to start the production and their subsequent shipment. Overall, our experience with PSI Visionaire (Smith & Nephew), not less than 4 weeks are needed to obtain the cutting masks, which are delivered a few days before the date specified online.

The PSI procedure remains a method with a necessary learning curve; is essential to clean the CB's bearing zones and to pay close attention to the correct position, and also continuously check resections and angles. The use of threaded speed-pin may be usefull (Fig. 1); to ensure a good grip, the conservation of upper-front femoral and anteromedial tibial osteophytes is required. Each resection must be controlled through the alignment rods provided in the standard instruments; most of the axial deviations are caused by an erroneous positioning of the CB, which needs to be corrected and rechecked; in a small percentage of cases, 14 cases (3 femurs and 11 tibia), the chondral erosion and osteophytes were so important to make them unusable.

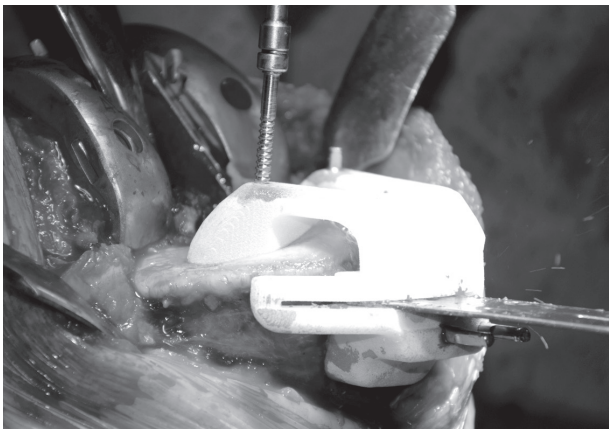

Figure 1. Application of CB after cleaning of the support zones, threaded speed-pin con be usefull.

Conclusions

Our retrospective radiographic study suggests that the cutting block method was an accurate technique for producing the distal femoral and proximal tibial cuts; the CB did accurately produce the desired HKA.

The surgeon has to set preferences regarding the positioning of the prosthetic components; as well as the determination axis coronal desired, the surgeon must choose the rotation and the level of resection; it is evident that certain preoperative choices can determine other intraoperative, such as re-cuts or releases ligament; for this reason, these can not be regarded as failure of PSI, but, on the contrary, as the consequences of pre-operative choices. The PSI are based on bony

landmarks, without any information on the patient's ligament tension: it's clearly a "non ligaments balancing" system.

The PSI System is an effective and reproducible system. The surgical times can be reduced and the instrumentation is simplified. The results of radiographic HKA are statistically superior to those obtained with the classical method, and there is a valid literature in support of this claim. There are some important technical factors, such as the formation of the radiology staff and the correct setting of the MRI, which can be a big obstacle for those wishing to approach the technology; These factors, combined with logistical problems, organizational and economic, are important reasons that limit the spread of the PS technology. However in our opinion, the organizational effort needed to get the CB is fully justified

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