Accuracy And Efficacy Of Patient-specific Instrumentations For Total Knee Arthroplasty: Analyses Of Three Different Systems

Claudio Belvedere, PhD1, Michele d’Amato, MD2, Paolo Barbadoro, MD2, Alessandro Feliciangeli, MD2, Alberto Leardini, PhD1, Sandro Giannini, Professor3, Andrea Ensini, MD3.

1Movement Analysis Laboratory, Rizzoli Orthopaedic Institute, Bologna, Italy, 2I Division of Orthopaedic Surgery, Rizzoli Orthopaedic Institute, Bologna, Italy, 3I Division of Orthopaedic Surgery & Movement Analysis Laboratory, Rizzoli Orthopaedic Institute, Bologna, Italy.


Introduction: In Total Knee Arthroplasty (TKA), Patient-Specific Instrumentation (PSI) for generating custom-made cutting-blocks has been recently introduced to optimize prosthesis positioning and to save surgical time/costs when compared to conventional TKA instrumentation. PSIs are derived from several image-scanning techniques, these being used to work out computer-designed models and manufactured according to surgeon’s recommendations. Particularly, PSIs can be manufactured to meet novel surgical approaches which may be in contrast with standard surgical techniques.

As an example, although the literature on TKA reports that Neutral Overall Lower-limb mechanical Alignment (NOLA), i.e. at 0° ± 3°, is considered the gold standard for obtaining good clinical results and longer implants survivorship, this was questioned by a number of recent studies [1]. Accordingly, a novel implantation approach in TKA emerged recently, this being referred to as Kinematic Alignment (KA) and based on the pre-disease lower limb alignment. In more detail, KA implies the adoption of a novel axis for the femoral component alignment, i.e. the line passing through the centers of the posterior femur condyles modeled as cylinders. This novel reference is an alternative to the conventional trans-epicondylar axis, and it is thought to allow better knee soft tissue balance during knee motion [2].

Within the manufacturing process of PSIs currently available on the market, tools for virtual preoperative implant planning according to either MA or KA approaches can be provided for subsequent intra/postoperative prosthesis component alignment [3].

Unfortunately, to date, the literature reporting PSI reliability using accurate assessment methodologies is limited, whereas related functional results on patient, i.e. obtained via kinematic/kinetic and electromyography (EMG) analysis, are still poor and inconsistent [3]. This study is aimed at reporting three different techniques to evaluate the efficacy of three PSIs manufactured according to either NOLA or KA approaches.

Methods: Seventy patients affected by primary osteoarthritis were analyzed, grouped according to the TKA implant and corresponding PSI. Group A is compound of twenty-five patients implanted with posterior-stabilized GMK® prosthesis and using MyKnee® PSI (both by Medacta®, Castel S. Pietro, CH); Group B is compound of twenty-five patients implanted with posterior-stabilized Journey® prosthesis and using Visionaire® PSI (both by Smith&Nephew®, London, UK); Group C is compound of twenty patients in Group C implanted with cruciate-retaining Triathlon® prosthesis and using ShapeMatch® PSI (both by Stryker® Orthopedics, Mahwah, NJ-USA). In PSI manufacturing, femoral and tibial cutting-blocks were derived from pre-operative imaging at the knee, hip and the ankle in the impaired leg using...
computer tomography (CT) in Group A and magnetic resonance imaging (MRI) in Group C; in Group B, these were derived from a panoramic X-ray image of the impaired lower limb combined with MRI at the corresponding knee.

In group A and B, NOLA was targeted and corresponding data for cutting-locks positioning and osteotomy orientations were registered intra-operatively during surgery [4] using a surgical navigation system (Stryker® leibinger, Freiburg im Breisgau, Germany) and also post-operatively using static X-ray images (CAT Medical System, Monterotondo, Italy) for 3-Dimensional Video-fluoroscopy Analysis (3DVA) suitably adapted to this scope [5]. In Group C, KA was targeted and, at six month follow-up, functional assessments were assessed via dynamic 3DVA during stair climbing, chair rising, and extension against gravity by synchronizing the X-ray emitter with EMG (Wave Wireless, Cometa, Milan, Italy) using a novel protocol for an in-depth activity assessment of knee flexor-extensor muscles. Particularly, in 3DVA a shape-matching technique [6] for 2D-to-3D pose detection was used to reconstruct femur/tibial component-to-bone pose from static X-ray images and femur-to-tibia component pose from dynamic X-ray images.

For the three groups, all measurements were compared with the corresponding planning; discrepancies larger than 3° between these measurements were considered as outliers. Mean values and standard deviations over the patients in each group were worked out.

**Results:** In group A and B, the absolute discrepancy between planned and corresponding intra-operative alignments assessed via navigation ranged from about 1° to 3° on the three anatomical planes. The smallest percentage of outliers was observed on the coronal plane in group B. These discrepancies assessed using 3DVA ranged from about 0 mm to 6 mm and from about 0° for 4° for translations and rotations, respectively, on the three anatomical planes. By considering Group A and C in aggregated, good matching was generally found between the planned and final implantation, the mean overall discrepancies being smaller than 3 mm and 2° over the three anatomical planes.

In group C at the follow-up, better clinical scores were found using KA than NOLA. Particularly, knee and functional scores in patients implanted using NOLA were respectively 78±19 and 80±23; these were 90±12 and 90±15 in patients implanted using KA. Kinematic and EMG analysis revealed more consistent motion patterns using KA than NOLA, and an abnormally prolonged activation of vasti muscles using NOLA. However, physiological ranges of knee flexion-extension and ad-abduction were found generally using both NOLA and KA. As for coupled axial rotations in the three analyzed motor tasks, these were, respectively, 9.2°±3.5°, 11.0°±3.4° and 6.7°±3.7° using NOLA, and 8.2°±4.0°, 11.5°±2.5° and 9.8°±7.0° using KA. Corresponding knee rotation pivoting using both KA and NOLA was generally positioned on the central/lateral portion of the tibial plate (see figure from well representative patients) and associated to paradoxical anterior translation of medial tibio-femoral contact points.

**Discussion:** These results show that PSI technology represents a reliable advancement for successful TKAs in terms of bone cut execution and prosthetic components positioning when compared to the pre-operative planning. Even overall post TKA knee functional recovery seems to take advantage of PSIs suitably manufactured according to novel surgical approaches. In fact, better clinical scores seem derived using KA than NOLA, though paradoxical contact point motion was generally observed. A novel suitably adapted three-dimensional video-fluoroscopy analysis, either alone or in combination with electromyography, was exploited in the present study, this being an important and useful advancement in the investigation methodology. Particularly, in each analysed TKA patients, evaluations
were performed successfully both in static conditions and also dynamically during a number of active motor tasks resulting in original findings.

In conclusion, this study points out the effectiveness of PSI in TKA. Additional patient cases at more and longer follow-ups are needed to confirm the goodness of PSI performances, these being currently under investigation.

**Significance:** This study shows evidence on the good efficacy in-vivo of patient-specific instrumentation for TKA in terms of prosthesis component alignment, clinical scores and functional performances.

*ORS 2015 Annual Meeting*

*Poster No: 1651*