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Commentary on an article by C.-E. Thelu et al.: "Poor results of the Optetrak™ cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses"

By William Petty[a], MD, Gary Miller[b], PhD, and Albert Burstein[c], PhD

[a] *Optetrak Design Team member, Chairman & CEO, Exactech, Inc.*
[b] *Optetrak Design Team member, Executive VP, R&D, Exactech, Inc.*
[c] *Optetrak Design Team member, Senior Scientist Emeritus, Hospital for Special Surgery.*

Total knee implants have evolved over time, taking advantage of new technologies. As changes are suggested and implemented, it is crucial to ensure that any potential modifications to existing designs maintain or improve clinical outcomes.

On initial view, the article by Thelu et al is proffered to be an evaluation of the effects of a knee system's evolution on clinical outcomes in a meaningful way. The authors present a Level IV retrospective study of a continuous series of 110 prostheses (106 patients) implanted between 2005 and 2007, analyzed with a mean follow-up of 25 months (range: 12-42 months) by an independent observer. Evaluation included International Knee Society (IKS) scores and radiological assessments conducted by three senior surgeons. The report states that the prostheses had "satisfactory mechanical axes", with a mean Hip-Knee-Ankle (HKA) angle of 177.4°±4°. However, 25 prostheses (22%) presented with fixation interfaces evolving toward tibial implant loosening, and 24 (21%) had developed signs of patellofemoral problems. In fewer than 5 years, nine implants were revised for tibial loosening, three for patellofemoral instability, and one for patellofemoral pain. The authors conclude that design modifications from previous designs had altered clinical outcomes and, as a result, note they have suspended implantation of this prosthesis at their hospital.

While we agree that the reported clinical outcomes are far from being satisfactory, we do question the arguments presented by Thelu et al. in this article. If we assume that the current article is based on the same cohort of patients presented for the general medicine thesis[1] of Dr. Thelu (presided by Dr. Migaud) in December 2009, it is surprising the authors have omitted important study shortcomings that would assist readers in fully understanding the reported performance of the device in question.

In the source thesis [1], Thelu stated that an instrument from an unrelated competitive total knee arthroplasty system was used for the ligament balancing step of the Optetrak PS knee components in flexion and extension. This instrument was used in 70% of the cases in the study. This deviation directly contradicts the Optetrak Instructions for Use, which clearly specifies Optetrak Comprehensive Knee System components should be implanted with the instrumentation specifically designed for this purpose, as significant inaccuracies

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may result otherwise. For example, as demonstrated by Edwards et al. [2], there are significant differences between true tıbial insert thicknesses and nominal thicknesses in different knee systems. In other words, tibial insert thickness suggested using competitive system instrumentation may not indicate the appropriate thickness selection of an Optetrak tibial component, potentially leading to an incorrectly tensioned joint.

In addition, Thelu et al. report satisfactory reproduction of the mechanical axis with a mean HKA angle of 177.4°±4°. However, analysis of the HKA angles reported in the source thesis [1] for each individual case of tibial loosening results in an actual mean HKA angle of 174° for patients associated with confirmed tibial loosening. It would have been appropriate for the authors to disclose the implications of this residual varus misalignment in those patients with loosening. Observational data from numerous series [3-12] have led to the understanding that a neutral mechanical axis is important in providing durability and good function following surgery, and that wear and premature failure can occur if the total knee replacements are mechanically aligned in varus.

Finally, the source thesis [1] stated *"…the cementation is of paramount importance and a sensible step, requiring accurate technique in order to ensure an appropriate fixation. The author cannot ensure that in our study, every steps of the cementation were perfectly done; which may be in part responsible for the loosening of the tibial implant."* However, the authors do not discuss this in describing the observed performance problems they report.

Cementation technique is crucially important for any cemented knee system. Figure 3B of the article indicates a total absence of cement extrusion in the medial and lateral undercuts of the tibial tray, leading to serious questions about effective cement mantle pressurization. The lack of proper pressurization indicated by this illustration is very significant and should have been properly recognized in the discussion section.

We propose that Thelu et al. should have discussed in detail the effects of their improper implantation technique (i.e., use of non-approved instrumentation, significant residual implant varus associated with loosening, and questionable cementation technique) on the clinical outcomes reported.

Instead, the authors attributed potential causes of poor results and failure to the design modifications used to create the Optetrak implants as compared to its predecessor, the Insall Burstein II (IB II) system. Toward this end, we respectfully maintain that the authors have significantly misinterpreted basic biomechanical fundamentals in their analysis, leading to erroneous and incorrect assertions.

One potential cause of failure cited by the authors is the Optetrak tibial spine being higher than the tibial spine of the IB II potentially causing higher stresses at the tibial bone-implant interface. While the Optetrak tibial insert spine is slightly higher overall than the IB II spine to inhibit femoro-tibial subluxation, increased loading of the tibial baseplate-cement interface is a result of *elevation of the contact point* between the femoral cam and posterior part of the tibial insert spine, not simply a function of the overall spine height. The Optetrak cam-post *contact point is actually lower* than the contact point for the IB II, resulting in reduction of the stress at the tibial baseplate-cement interface. The lower contact point is the result of optimizing the location of the femoral cam relative to the condyles and using a more elongated shape. Thus the outcome to be associated with the higher Optetrak PS tibial insert spine should include a higher jumping height, **not** increased stress at the implant-cement interface.

Second, the authors continuously describe the Optetrak design as "ultra-congruent," attributing this feature as a possible cause of loosening. However, in fact, the Optetrak is not an "ultra-congruent" device. Typically, "ultra-congruent" refers to knee systems with high sagittal plane congruency. In the sagittal plane, the Optetrak knee system is **less** congruent than the IB II in extension (0.67 for the Optetrak versus 0.90 for the IB II) and comparably congruent in flexion (0.39 for Optetrak versus 0.43 for IB II). Optetrak increased congruency as compared to the IB II (0.96 vs. 0.94) should refer to frontal congruency, not sagittal congruency. As shown by Bartel et al. [13], a higher frontal congruency decreases contact stresses on the UHMWPE tibial insert. The frontal congruency of the Optetrak, a patented technology, provides proven advantages in terms of reduced wear rates, as established by Li [14] and Angibaud [15]. The authors' depiction of the Optetrak as an ultra-congruent system is incorrect and misleading.

Third, the authors state the wave-shaped profile of the rotating-bearing Optetrak system tibial inserts could increase stress. This statement directly contradicts the principles of the wave design, which predictably distributes load over a larger area around the center of the tray to avoid the type of radial edge-loading potential observed in devices featuring flat-on-flat bearings.

The authors also repeatedly describe the finned (or "winged") Optetrak tibial baseplate stem as short and small, notably depicting it as shorter and smaller than its rectangular Optetrak counterpart.

In actuality, the two baseplates feature stems of the exact same length. Considering both the frontal and sagittal planes, the "winged" baseplate stem also features a larger overall surface area than the rectangular stem.

In addition to the incorrect implantation technique and misrepresented implant design parameters, the article misrepresents a study published in the Journal of Arthroplasty by Dr. Robinson [16]. While Robinson reported 42% of the Optetrak tibias in his study displayed radiolucent lines, he also states no knee was radiographically loose, an important contrasting omission by Thelu et al.

Significantly, other studies report good clinical outcomes for the Optetrak system, which has been in use for 15 years [17-19]. The conclusions of Thelu et al. regarding patellofemoral complications contradict a recent study by Ehrhardt and co-workers from HSS concluding design modifications for the posterior-stabilized Optetrak knee have successfully reduced patellofemoral complications, including patellar clunk and patellar fracture, in comparison to the IB II. In addition, Gougeon recently reported a survival rate of 99.5% with the same implant system and follow-up times [20] similar to those reported by Thelu et al.

In summary, the authors investigated the effects of a knee system's evolution on clinical outcomes and concluded progressive design modifications from previous designs altered clinical outcomes. It is regretful the authors omitted the limitations and shortcomings of the source thesis [1]. By doing so, the authors produce a biased conclusion that will mislead readers.

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