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ORIGINAL STUDY

The TRAC-PS dual radius total knee arthroplasty : Disappointing medium and long terms results.

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The TRAC prosthesis is a dual radius, mobile bearing, posterior stabilized prosthesis, to increase stability by optimizing contact area and control wear using a mobile polyethylene. Between February 1995 and January 2000, a single surgeon performed a continuous series of 85 TRAC-PS TKAs in 85 patients at the University Hospital Brussels. A retrospective review on patient charts was performed. Patients available were scored clinically using the Knee Society Score, WOMAC osteoarthritis index, SF 36 and a Visual Analogue Scale for pain. 43 patients had died at time of evaluation, three were unavailable for examination due to bad general health and five were lost to follow up. The remaining 35 patients were examined with a mean follow-up of 13 years. The mean age of the patients at follow up was 83 years. The mean WOMAC score was 78,4(SD 17,9). The mean Knee Society Score was 86.8(SD 8,4) clinical and 42,6(SD 28) functional. The mean range of flexion was 105°. The mean SF-36 score was 59,8(SD 15,4). The VAS for pain was 6(SD 9). With revision (8 cases) as endpoint, survival rate of the prosthesis was estimated to be 92% at 13 years. Twenty-three Serious Adverse Events (28%) in 17 patients, related to the prosthesis were registered in this patient group. Long term results of this prosthesis were satisfying but a large number of serious adverse events led to abandonment of the TRAC-prosthesis.

Key words: total knee arthroplasty ; long term survival ; complications

INTRODUCTION

Optimization of joint stability and control of polyethylene wear remain major issues in total knee arthroplasty (TKA) (*28*). Improving stability can be achieved by increasing the tibiofemoral congruency, i.e. by maximizing the contact area between the femoral and the tibial component throughout the full range of motion (*32*). However, improved congruency can favour polyethylene wear. This can be controlled with the use of a mobile-bearing insert able to minimise the interface and bearing stresses (*2*).

The Two Radii Area Contact Posterior Stabilized TKA (TRAC-PS, Biomet Inc., Warsaw, IN) is a posterior-cruciate substituting mobile-bearing total knee prosthesis. The design objectives of the TRAC-PS knee were: (i) minimising the bearing stresses to reduce the potential for poly-ethylene wear, (ii) minimising the interface stresses to reduce the potential for implant loosening and (iii) maximising the quadriceps efficiency to optimize patient mobility and enhancing the anterior and posterior stability (*10*).

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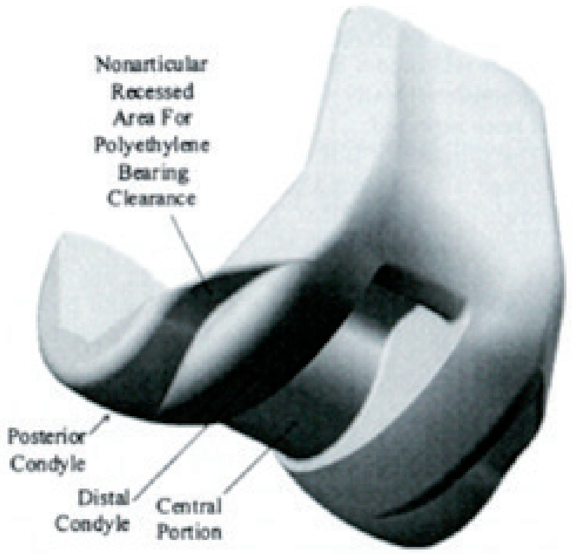
To optimize the tibiofemoral contact area, two radii of curvature were created on both the tibial and femoral component (Fig. 1). As such, the TRAC-PS has a congruent contact from full extension to full flexion, the mobile bearing insert allowing freedom of internal and external rotation. The femoral component has two radii of curvature in the sagittal plane, one for the distal femoral condyles and one for the posterior femoral condyles. The distal femoral condyles articulate congruently with the inner tracks of the polyethylene, whereas the posterior femoral condyles articulate with the outer tracks. The inner distal femoral condyles maintain a congruent relationship with the inner tracks of the bearing from 5° of hyperextension to 8° of flexion. The outer posterior femoral condyles maintain a congruent relationship with the outer tracks of the mobile bearing from 8° to >120° of flexion. At 8° of flexion, the tibiofemoral contact area transfers from the distal to the posterior radius and the post-cam mechanism engages. As such, the central post of the mobile bearing insert of the TRAC-PS TKA engages with the central portion (the "cam") of the femoral component through a congruent contact that resists anterior subluxation of the femur.

Both, the transfer of the contact area from the distal to the posterior radius of the femoral condyle and the engagement of the post-cam mechanism, produce a posterior roll back of the femoral component compared to the tibia. This controls anterior and posterior sliding of the femoral condyles on the bearing surface of the tibial tray and maximizes the quadriceps lever arm in flexion. To resist posterior subluxation of the femur both posterior lips of the tibial bearing are elevated.

The motion of the poly-ethylene bearing on the tibial tray is limited to internal and external rotation

A



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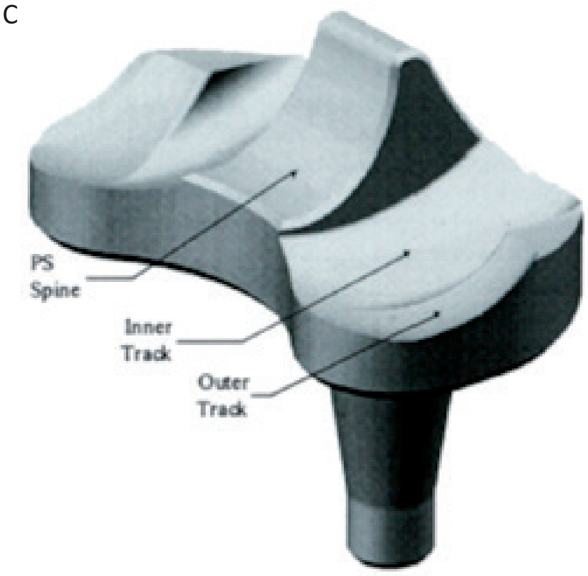

Fig. 1. — TRAC PS femoral component, intermediate bearing element and tibial component.

without rotation stop. The stem, that prevents antero-posterior translation of the tibial plate, is centered over the long axis of the tibia, anterior to the center of the tibial plate. This position was selected to reduce the possibility of impingement of the stem on the posterior cortex of the tibia (*10*).

Taking into account the design goals of the TRAC-PS TKA and favorable experiences with other mobile bearing PS TKA's in general, the idea of a dual radius TKA is of interest. However, very little medium- or long-term clinical information is available regarding this unique concept. One study hypothesised that the TRAC-PS TKA has a similar internal-external rotation and varus-valgus stability compared to a normal knee, but that it is more stable in antero-posterior direction (*10*). The TRAC PS has a large area of tibiofemoral contact in flexion and extension. This amount of area is substantially larger compared to the LCS meniscal bearing (DePuy) and fixed bearing TKA's. However, the internal and external rotation of the tibia with respect of the femur were not significantly different for the TRAC PS from those of the healthy control subjects at 90° of flexion. The same conclusion was found for the varus and valgus laxity at 30° of flexion (*10*). However, this means that normal ligament balancing can be achieved with the TRAC PS. This normal internal-external rotation of the knee in the TRAC PS was maintained 2 years after the surgery.

Another study examined the extent of femoral rollback and the influence on gait and stair climbing. The patterns and magnitudes of knee flexion during gait and stair climbing were similar when comparing the TRAC PS with a control group. Also the peak knee flexion moments generated during stair climbing were not significantly different from the control group. This can be explained by the initiation of the femoral rollback. In normal knees, rollback begins as soon as the knee flexes from full extension. In the TRAC PS designs, this femoral rollback is maximized at 8° of flexion (*11*).

The objectives of this study were to evaluate the medium- and long-terms survival as well as the clinical and radiological outcome of a continuous series of TRAC-PS TKA's performed in a single center by a single surgeon.

MATERIALS AND METHODS

Between February 1995 and January 2000, a single surgeon performed a continuous series of 85 TRAC-PS TKAs in 85 patients at the University Hospital Brussels (UZ Brussel) (Fig 2).

Information concerning the operation, the implants used and the early post-operative period were collected retrospectively from the hospital records and patient charts.

Clinical follow-up was based on the Knee Society Score (KSS) (*18*). This scoring system reports a Knee score and a Function score both on 100 points. To evaluate the knee function during activities of daily living we used the Womac Knee Osteoarthritic Index (*27*). Pain was measured with a Visual Analogue Scale (VAS) on 100 points, were 0 represented no pain, 100 unbearable pain To assess the emotional, functional and overall health of the patients the SF-36 scoring system was used (*17*).

The radiological evaluation consisted of weight-bearing anterior-posterior and lateral radiographs of the knee as well as a skyline view of the patella. Each radiograph was evaluated based on the Knee Society Röntgenographic Evaluation and Scoring System (*13*) (Fig. 3). All radiographs were assessed for evidence of loosening, implant position, radiolucencies and osteolysis.

Finally, we performed a survival analysis according to the Kaplan-Meier method (*8,35*). Two endpoints were used, one was revision of the prosthesis for any reason, the other was the worst case scenario, assuming that all patients lost to follow-up had been revised.

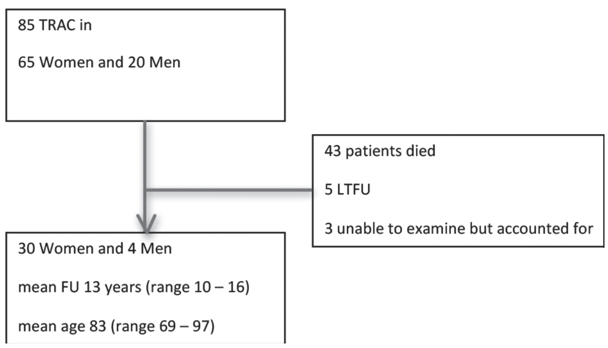

Fig. 2. — Patient disposition

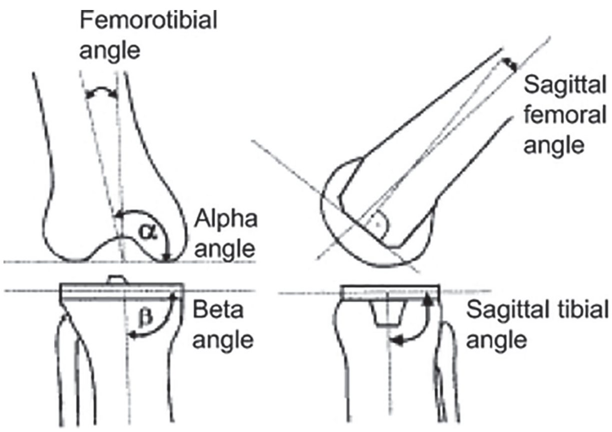

Fig. 3. Radiographic measurements according to the Knee Society Radiographic Scoring System

RESULTS

Between February 1995 and December 2000, a total of 85 TRAC-PS TKA were implanted in 85 patients (65 women, 20 men). Implantation occurred at the right side in 45 and at the left side in 40 cases. In most cases (84/85), the preoperative diagnosis was degenerative osteoarthritis. In one case a TKA was implanted for rheumatoid arthritis. Preoperatively, 75% knees were in varus (64/85) and 16% in valgus (14/85). At surgery, the mean age was 72 years (SD, 6.43) and men (70 ± 5.65 years) were a younger than women (73 ± 6.51 years). Put data in a table. (table I: patient disposition)

From the 85 patients who had a TRAC-PS TKA implanted in the UZ Brussel between February 1995 and December 2000, 43 patients had died at the time of the study, three were unable to be examined because of a bad general health and five were lost to follow up. The remaining 34 patients (30 women, 4 men) were examined in the hospital (*17*) or at home (*17*) after a mean follow-up period of 13 ± 1 years (range, 10 to16 years). The mean age of the patients at follow up was 83 ± 7.59 years (range, 69 to 97 years).

34 patients were available for clinical examination and were evaluated based on the KSS Knee and Functional score, the SF 36 score and the Womac score.

The mean flexion was 105° (range 81°-125°) (17.6 % of the patients had an extension deficit. The mean KSS functional score was 42,6 (SD 28). 47% of the patients had to use a walking aid during the daily activities. 85% of the patients could walk up and down the stairs with the use of the railing. The mean clinical score was 86.8 (SD 8.4).

The mean score of the WOMAC was 78,4 (SD 17,2) (Fig. 2). The mean score for the pain was 89,6 (SD 12,2), for stiffness 79,4 (SD 19,7) and loss of function 74,9 (SD 21,5). The activities causing the most pain were walking, going up and down the stairs and standing for a long time. (Fig .4)

With the visual analogue scale (VAS), the pain was additionally measured. At the time of examination the mean pain was 6 (SD 9,6).

The mean score of the SF-36 was 59,8 (SD 15,35). 73.5% of the patients had a mean score of 50 or higher (*5*).

For the radiographic evaluation, the radiographs of 47 patients (34 female, 13 male) were available for evaluation, using the Knee Society Röntgenographic Scoring System. The mean follow time was 10 years (range 5-14 years). (l[e] II)

Table I. — position of the components: angle α and β in the coronal plane, angle γ en σ in the sagittal plane according to the Knee Society Radiographic Scoring System.

	Mean	**Range**
Femoral angle α	96,42553	78 - 105
Tibial angle α	87,14894	80 - 91
Vr-Vl: (α+ α)	185,1064	162 – 197
Femoral flexion angle α	4,851064	0 - 14
Tibiale flexion angle α	88,53191	79 - 95

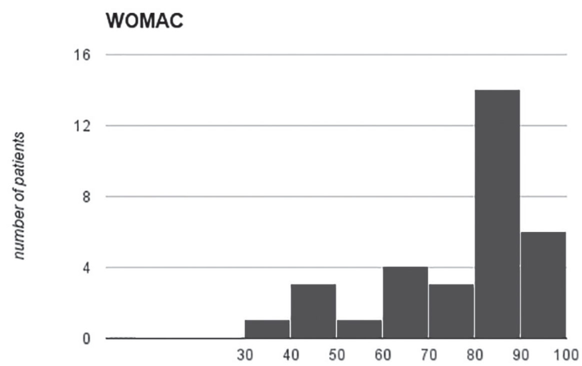

Fig. 4. — total Womac score at final follow up

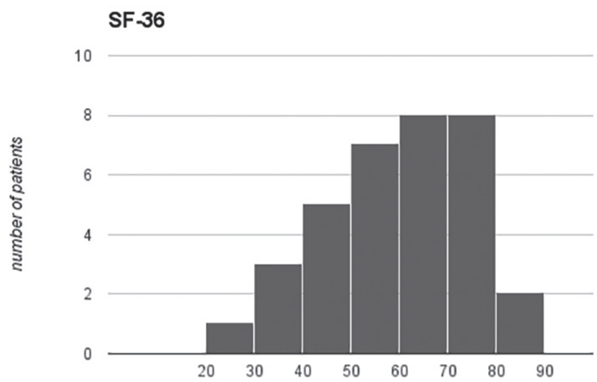

Fig. 5. — SF 36 global score.

The mean femoral angle α is 96.4° (rang 78°-105°). The normal anatomical value lies between 94° and 101°.

In 36 patients, the femoral component has an anatomical position in the coronal plan. The mean tibiale angle β is 87.1° (range 80°-91°). The normal anatomical value lies between 84° and 90°.

In 47 patients, the tibial component has an anatomical position in the coronal plane. In the sagittal plane, the position of the femoral component (angle γ) and the tibial component (σ) are evaluated. The mean angle of the femoral component is 4.9° (range 0°-14°). The mean tibial angle is 88.5° (range 79-95).

In 4 patients radiolucent lines of more than 4 mm width were seen. At the femoral component, loosening was seen in one patient of more than 9 mm. This patient showed also loosening at the coronal and sagittal plane of the tibial component. This TKA was revised. The other 46 patients showed no signs of loosening of the femoral component. (table 2).

In the coronal plane, 2 patients showed radiolucent lines of the tibial component, 5mm and 9 mm. This was at 10 years and 12 years of follow-up. These 2 patients have already died.

Serious adverse events were reported in 23 instances.

In total, at least one component was revised in eight cases. Four TKA's were revised for aseptic loosening of the tibial and femoral component (3 cases) or the tibial component alone (1 case). An additional four patellar components were revised, either for aseptic loosening or dislocation.

Seven patients (8 dislocations: 9,4%) had a tibiofemoral posterior dislocation, mostly occurring within the first two years (6/8) after surgery but one occurred after 6 years and one after 8. Six of 8 dislocations were treated in a closed fashion. One had a poly exchange and dislocated again at a later time-point and managed again with a closed reduction.

In five other patients, hypertrophic synovial tissue, moving between the posterior and distal condyles of the femoral component and the mobile bearing, had to resected because of pain and clicking. Three of these also had their patella revised at a different time-point.

Table II. —Radiolucenties of femoral and tibial components.

Component	Patients	Radiolucent lines
femoral component	46	< 4 mm
	0	5 tot 9 mm
	1	> 9 mm
Cor. tibial component	44	< 4 mm
	2	5 tot 9 mm
	1	> 9 mm
Sag. tibial component	44	< 4 mm
	1	5 tot 9 mm
	2	> 9 mm

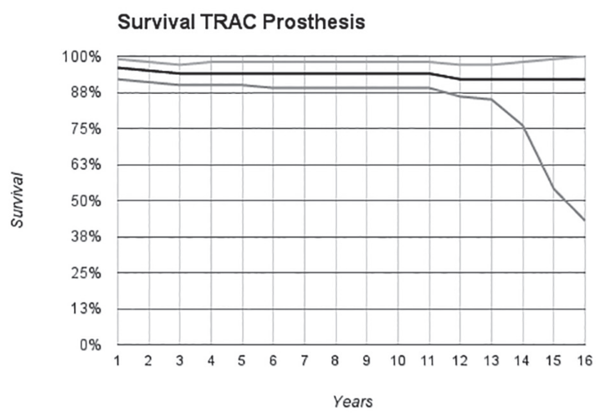

Fig. 6. — Kaplan-Meyer survival curve of the TRAC prosthesis. Grey lines represent upper and lower confidence intervals

Other complications such as infection, extra-articular calcifications and the patellar clunk syndrome occurred just once. (table III).

Kaplan Meyer survival analysis shows a survival at 10 years of 94% and at a mean follow up at 13 years of 92% (CI 85%-97%) with revision as endpoint. In a worst case scenario with patients lost to FU accounted for as failures 10 year survival was 88% and 13 year survival was 86% (CI 79%-93%). (Fig. 6).

DISCUSSION

Several designs of TKA components have shown highly satisfactory long-term results (*2,4,5,10,18,20,28,32*). Till now it is unclear which stabilising mechanism (cruciate retaining [CR], posterior stabilized [PS]or Guided Motion) and which type of bearing (fixed or mobile) should be favoured.

Changes in component geometry and modularity of PS TKA's have led to improved short- and long-term results (*21,32,33*). In some series, PS designs have demonstrated less flexion instability (*13*), less clinical and radiographic laxity, fewer complications and greater range of motion compared to CR TKA's (*26,30,31*). However, the overall survivorship of CR and PS designs is similar (*9*). On the other hand, and despite the excellent clinical and functional results of PS designs, some have been associated with patello-femoral symptoms , anterior knee pain, patellar clunk and backside wear (*6,9,14,19,22-24*).

There are a number of theoretical benefits to the mobile bearing TKA, although few prospective, randomized studies have shown actual benefits.

The presence of anterior knee pain is one of the major short-term complaints after TKA (*2*). Since the introduction of the mobile-bearing prosthesis, some studies postulate that PS mobile bearing TKA reduce de incidence of anterior knee pain. Theoretically the mobile-bearing prosthesis has the ability to self-align and therefore accommodate small mismatches of rotation, so decreasing the incidence of anterior knee pain (*7*).

Study findings have been inconsistent in confirming advantages for mobile-bearing compared with fixed-bearing TKA's. These advantages include increased survivorship and restoration of more natural knee kinematics compared to a standard fixed-bearing design. A review was published in the Journal of Arthroplasty in 2010 describing survivorship and clinical function. There was no difference in survivorship and clinical function at 12 to 23 years. These findings are confirmed by other studies and reviews (*2*).

In the last decade, various laboratory studies showed potential advantages of mobile-bearing TKA's. Finite Element Analysis of mobile and fixed TKA's have consistently shown less PE contact stresses in the mobile varieties. The mobile varieties have shown to be more forgiving in terms of contact stress distribution than the fixed-bearing ones (*29*).

Other study's showed no advantages of the mobile bearing TKA in femoral rollback and axial rotation patterns, weight bearing, maximum flexion and condylar lift off (*16,25*).

A described disadvantaged is the mechanical failure due to bearing dislocation using a mobile-bearing TKA. A second disadvantage is the volumetric wear rate that is higher because of a larger contact area (*1,7,29*).

In this series of 85 patients a rather high rate of complications is reported in 23 instances in

Table III. — List of complications and occurrence over time of the TRAC prosthesis

	1 m	2 m	1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year	11 year	12 year
1. Loosening TKP						x								x
2. Loosening of the tibiale component							x							
3. Patellar complicaties			x x x	x										
4. Luxation	x x		x x x	x				x		x				
5. Infection				x										
6. Extra-articular calcifications		x												
7. Patellar clunck syndrome						x								
8. Hypertrofic synoviale tissue			x x x	x			x							

17 patients. In almost 10% of cases there was a tibiofemoral knee dislocation that was treated with closed reduction in most cases. At least in 2 of these patients a rotational spin out of the bearing has been documented. This means that the hypothesis of an increased anterior posterior stability could not be validated.

In a comparison of five PS prostheses the TRAC prosthesis showed a highly conforming post with rather anterior position causing the prosthesis to go into rollback very early in comparison to most contemporary designs (*3*). The high congruence creates less contact stress unless in case of femoral lift-off. On the other hand, the anterior position and the slope in the posterior surface of the cam that is gradual, might decrease the resistance to dislocation in case of flexion instability and low jump distance.

Another frequent complication was revision of the patello-femoral compartment due to loosening, dislocation and formation of excessive scar tissue. In 1996 already Eckhoff published his findings on the location of the trochlear groove in relation to the femoral condyles (*12*). It is not in the midline but more lateral in osteoarthritic and also healthy knees. The TRAC prosthesis has a centrally located groove, which increases the tendency of the patella to tilt and even sublux laterally causing a higher rate of problems and loosening. The centrally located trochlear groove probably is partly responsible for the patello-femoral problems seen in this patient group, despite the mobile bearing, which is supposed to compensate for this relative rotational malalignment.

The same patello-femoral problems have been reported in other posterior stabilized designs with a centralized sulcus such as in the Insall-Burstein I and II, although Larson et al reported a rate of 4,2% complications using a more specific technique to resurface their patellae. (*22*)

In the 2012 annual report of the Australian registry, the TRAC prosthesis is one of the designs with a higher than expected revision rate that was abandoned. The registry itself does not specify as to what is the cause of this higher rate. The rate specified in the registry goes as high as 14.4 (CI 9.3-22). Our rate of revision was 6% (CI 2-11) which is an almost normal revision rate when compared to the same Australian numbers but the high rate of adverse events is distressing (*15*).

The results reported in this study are cross sectional and this is a disadvantage in the design of this paper. On the other hand, this can also explain why the results on mobility and PROMS are moderate. The high age in this patient group with long follow can largely account for this, as the major part of this group are octogenarians.

To conclude one can say that this prosthetic design could not fulfil its design purposes such as better stability through better congruency and higher flexion. Instead a high rate of anterior posterior dislocations of almost 10% and a high number of patello-femoral complications led us to discontinue the use of this prosthesis.

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