

Does low-constraint mobile bearing knee prosthesis give satisfactory results for severe coronal deformities? A five to twelve year follow up study

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Abstract

Purpose Severe varus and valgus knee deformities traditionally are replaced with constrained implants, with a number of disadvantages. We present our results in this challenging group using a low constraint deep-dish mobile bearing implant design.

Methods One hundred fifty-four patients (170 arthroplasties) who underwent primary TKA using a deep-dish, mobile bearing posterior-stabilized implant for severe varus (HKA < 170°) or valgus (HKA > 190°) deformity between 2004 and 2009 were evaluated at a mean of 6.6 years post-operatively (minimum of 5 years).

Results Alignment improved from a pre-operative mean (±SD) varus deformity of 167.4° (±2.6°) and a mean (±SD) valgus deformity of 194.1° (±4.0°) to an overall mean (±SD) post-operative mechanical alignment of 178.6° (±3.2°). Twenty-three patients had post-operative varus alignment, five patients had post-operative valgus alignment and 134 knees were in neutral alignment (within 3° spread). Clinical scores at final follow-up were excellent (IKS score 93.8 (±7.4) and function score 82.4 (±20.2)). Three patients were re-operated upon: one deep infection, one periprosthetic fracture

and one revision at 144 months for aseptic loosening of the femoral component. No patient was revised for instability or implant failure. The survival rate at five years was 99.4% and at ten years 98.6%.

Conclusions Satisfactory outcomes can be achieved in patients with substantial varus or valgus deformities using low constraint deep-dish mobile bearing implant, standard approach and appropriate soft tissue releases.

Keywords LOW-constraint · MOBILE bearing · Severe coronal deformity · Total knee arthroplasty

Introduction

Total knee arthroplasty (TKA) has become an effective treatment of knee osteoarthritis [1]. The achievement of normal limb alignment and a stable balanced implant are key factors influencing outcome. These goals are challenging to obtain in patients with significant coronal knee deformity. Several surgical techniques have been described to combine correct limb alignment with a balanced stable implant [2–4]. If appropriate soft tissue balance is not achieved a higher constraint implant is required such as a condylar constrained knee (CCK) implant [5, 6]. In the opposite situation an implant with low constraint, such as an ultra congruent mobile bearing insert, can be safely used. These implants have been extensively reported for minor preoperative deformity, but current literature is scarce regarding severe pre-operative deformity.

We present the results of a single surgeon case series with low constraint TKA in a population of patients with major (>10°) coronal, varus and valgus deformity. We hypothesized that use of ultra congruent mobile bearing insert of primary TKA system is a reliable solution with good clinical and radiological outcomes at midterm follow-up.

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Patients and methods

Amongst 897 patients operated on for a TKA between December 2002 and December 2010 in our institution by a single senior surgeon, 162 patients presented a severe $>10^\circ$ coronal deformity. In this group eight patients received high-constrained implants and 154 low-constraint (deep-dish, mobile bearing posterior-stabilized) single manufacture (SCORE®, Amplitude, Valence, France) prosthesis [7].

Medical records of 154 subjects, containing the prospectively collected data, were retrospectively analysed. The post-operative controls were done at two, six and 12 months and every two years after surgery. At every check-up a complete set of X-rays and clinical examination, focusing on range of motion and knee stability, was performed. Knee Society score (KS) forms were fulfilled [8]. The results from the last follow-up control were worked out in our study.

Radiological analysis

The standardized preoperative X-ray set, consisted of full-length weight bearing, monopodal anteroposterior and lateral, stress varus–valgus and patella Merchant’s view at 30° of knee flexion, was carried out for each subject. Experienced radiologists performed the roentgenographic calculations in the PACS system (Centricity Enterprise, GE Healthcare, Barrington, IL, USA). The varus of $\geq 10^\circ$ was defined as the hip-knee-ankle (HKA) angle lower or equal than 170° and the valgus knee of $\geq 10^\circ$ as the HKA superior or equal to 190° [2]. The progression of osteoarthritis was estimated according to Ahlback classification [9].

Surgical technique

A single senior surgeon (TG) performed all surgeries. Standard antibiotic prophylaxis and pneumatic tourniquet were systematically used. The standard medial parapatellar quadriceps approach was used in the majority of both varus and valgus knees (98%). Three valgus knees (2%) required a lateral approach. If the patella was not stable an anterior tibial tubercle (TTA) osteotomy was performed (26%). The measured bone cutting technique for the femur was posterior referenced. The balancing of gaps in extension and flexion was assessed manually with spacers. For soft tissue equilibration in varus the algorithmic approach by Verdonk et al. [2] was used and in valgus the inside-out release technique as described by Ranawat et al. [3]. After bone cuts and balancing completed bone quality was assessed if uncemented was appropriate. We utilized uncemented implants in 121 cases, cemented in seven and hybrid in 42 (tibia 41, femur 1).

All patients followed a physiotherapy rehabilitation protocol fully weight bearing from post-operative day one.

Statistical analysis

The obtained data was analysed with “R” program, version 3.2.3, a free software package for statistical computing and graphics [10]. We used the Kruskal-Wallis test to compare the differences in pre and postoperative clinical outcomes in the varus and valgus groups. The survival analysis was performed according to Kaplan-Meier method.

Results

Population

Between December 2002 and December 2010 154 patients (97 female, 57 male) with knee osteoarthritis and severe ($\geq 10^\circ$) coronal deformity with deep-dish, mobile bearing posterior-stabilized implant (SCORE® Amplitude) were performed. During the same period of time 743 primary TKAs were performed for minor ($<10^\circ$) coronal deformity or using constrained implants. Inclusion criteria were preoperative deformity $\geq 10^\circ$ and minimum follow-up of five years.

There were four deaths (two male, two female) and four patients (one male, three female) were lost from follow-up; 146 patients (162 TKAs, varus $n = 105$, valgus $n = 57$) were followed for a mean of 6.6 years (range 5–12.8 years) (Fig. 1). Pre-operative primary OA was stage III in 76% (Ahlback classification, Table 1). Isolated medial femorotibial compartment OA was identified in 94% of varus knees. In valgus knees the lateral and medial compartments were involved in 64 and 34% respectively.

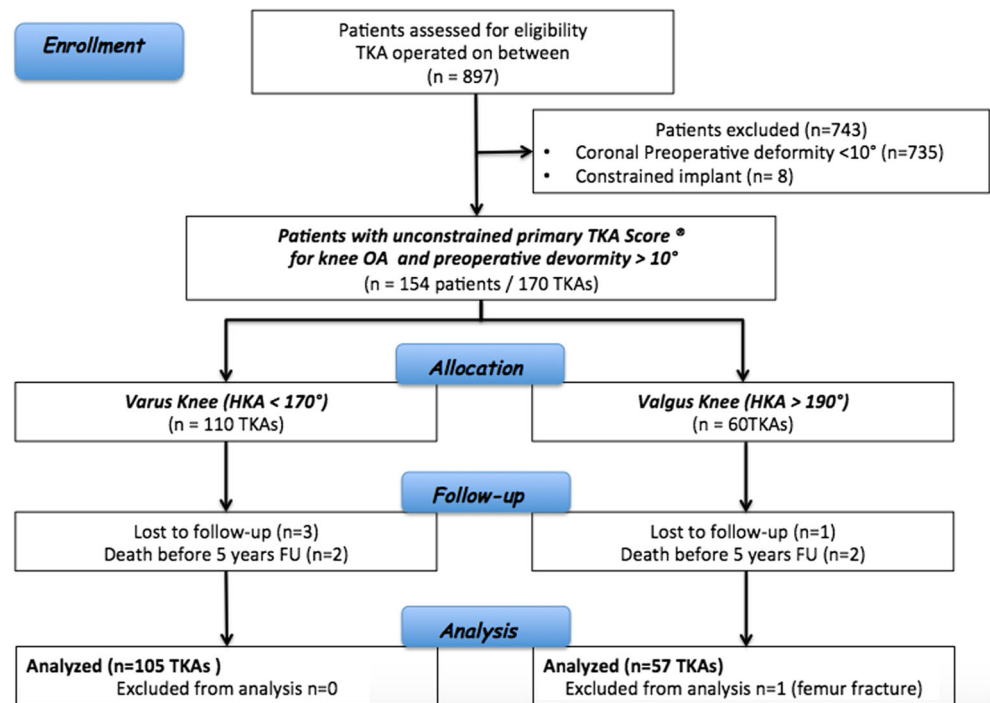
Radiological results

Pre-operative radiological analysis of valgus and varus HKA angles is demonstrated in Table 1. The global post-operative mean HKA value was $178.6^\circ \pm 3.2^\circ$. The valgus and varus groups respectively were $181.2^\circ \pm 2.7^\circ$ and $177.5^\circ \pm 2.7^\circ$ (Table 2).

The neutral alignment, defined as less than 3° of varus or valgus deviation from HKA of 180° , was reached in 82.7% (134 cases) (Figs. 2 and 3). In the varus group 23 knees had HKA lower than 177° with mean HKA of $174.3^\circ \pm 3.4^\circ$ (range 160.0° – 176.0°). In the valgus group the desired correction was not obtained in five knees with mean HKA of $185^\circ \pm 1.2^\circ$ (range 184.0° – 187.0°).

Clinical results

The pre-operative range of motion was decreased in all knees with global mean flexion of 109.6° (Table 2) with no significant differences between varus or valgus groups (Table 1). Post-operative increase in knee range of motion was not

Fig. 1 Flow diagram illustration: patient's enrolment, allocation, follow-up and analysis

significant with an average of 4° increase in flexion and no influence of pre-operative deformity was identified ($p = 0.2$, $\alpha = 0.05$, Kruskal-Wallis test) (Table 2).

The mean pre-operative knee and functional KS scores for the group of all subjects were poor with values of 27.8 ± 13.0

and 55.5 ± 15.8 respectively. Post-operatively significant improvement of mean outcomes in functional and global KS scores for both with the varus group significantly greater than the valgus group ($p = 0.004$, $\alpha = 0.05$, Kruskal-Wallis test) (Table 2).

Table 1 General demographic, preoperative radiological and clinical data of the varus and valgus groups

Patients	146
Male	54
Female	92
Age	75.1 ± 7.3 (56–109)
Knees	162
Varus	105
HKA	167.4 ± 2.6 (155.0–170.0)
Flexion	109.4 ± 11.1 (80.0–140.0)
Valgus n	57
HKA	194.1 ± 4.0 (190.0–204.0)
Flexion	109.9 ± 10.3 (90.0–130.0)
Diagnosis n (%)	
OA	151 (88.9%)
RA	5 (2.9%)
2°OA	14 (8.2%)
OA stage [1]	
I	0%
II	4%
III	76%
IV	0%
V	20%

OA primary osteoarthritis, RA rheumatoid arthritis, 2°OA secondary osteoarthritis

Complications

Ten patients (10 out of 162 knees, 6.2%) had a post-operative complication. Knee stiffness was the main complication ($n = 3$, 1.8%) followed by femoral periprosthetic fractures ($n = 2$, 1.2%, one 72 months post surgery, requiring open reduction and internal fixation (Fig. 4), infections ($n = 2$, 1.2%, one superficial wound infection managed with oral antibiotics and one deep infection requiring two stage revision), anterior knee pain ($n = 2$, 1.2%) and aseptic loosening ($n = 1$, 0.6%). Manipulation under anaesthesia was indicated for stiffness ($n = 3$) if present at 8 weeks post surgery. Three patients required surgical intervention (one fracture, one deep infection and one aseptic loosening). Aseptic loosening of femoral component appeared 12 years following primary TKA and no cause for failure was identified.

Survival

The Kaplan-Meier survival analysis demonstrated implant survival of 99.4% at mean five year and mean ten year follow-up with the endpoint defined as prosthesis revision, complete or partial, for any cause (Fig. 5a). The mean midterm survival rate (5-years follow up), with re-operation for any

Table 2 Post-operative values, expressed as mean \pm standard deviation (range), of HKA, knee flexion and Knee Society scores in groups of pre-operative varus and valgus knees

	Varus	Valgus	<i>p</i> *	Global	
				pre-OP	post-OP
HKA	177.5 \pm 2.7 (160.0–183.0)	181.2 \pm 2.7 (175.0–187.0)			178.6 \pm 3.2 (160.0–187.0)
Flexion	112.6 \pm 10.2 (70.0–130.0)	115.1 \pm 8.8 (90.0–130.0)	=0.2	109.6 \pm 10.8 (80.0–140.0)	113.5 \pm 9.8 (70.0–130.0)
KS knee	94.1 \pm 8.5 (45.0–100.0)	93.3 \pm 4.8 (85.0–100.0)	=0.1	27.8 \pm 13.0 (0.0–74.0)	93.8 \pm 7.4 (45.0–100.0)
KS function	86.2 \pm 17.1 (40.0–100.0)	76.0 \pm 23.2 (0.0–100.0)	=0.004	55.5 \pm 15.8 (5.0–90.0)	82.4 \pm 20.2 (0.0–100.0)
KS global	181.2 \pm 23.0 (85.0–200.0)	171.6 \pm 18.0 (132.0–198.0)	=0.004	83.3 \pm 23.9 (19.0–138.0)	177.9 \pm 21.8 (85.0–200.0)

The right side of table shows the comparison between preoperative and postoperative global results of examined variables

* Kruskal-Wallis test (CI 95%)

reason as endpoint, was 99.4% and long-term rate (10 years) was 98.2% (Fig. 5b).

Discussion

The important finding in our study is that low constraint mobile bearing knee prosthesis can give satisfactory results for severe ($>10^\circ$) coronal deformities when alignment is corrected and soft tissue balance is achieved. The implant used in our series (SCORE®, Amplitude) was a cruciate sacrificing with anteroposterior stability provided by a highly congruent insert. In primary TKA for a standard population this implant design is reported to have very satisfactory results at mid-term (6.6 years follow-up) with high satisfaction rate and 100% of survival rate [7]. Our series is the first published using this design of implant for severe coronal deformity.

In general, not specified for degree of deformity, in the population of patients with osteoarthritic knee, low constraint implants with highly congruent bearings are being increasingly used. Their clinical and radiographic results are comparable

with other low constraint TKA constructs [11] with satisfactory knee stability [12]. The long-term survival of these designs is reported to be up to 96% at ten years follow-up [13]. Nevertheless, in severe valgus and varus knees, which require special pre-operative assessment and adaptation of intra-operative technique, the use of a constrained TKA needs to be considered and may be demanded if intra-operative soft tissues balance fails. Some authors propose the use of higher constrained implants, e.g. CCK, in valgus of more than 5° [5] or severe varus (mean 10°) and valgus (mean 15°) [6]. We believe assessment based only on degree of deformity for implant constraint choice is too limiting. Other criteria should be considered, particularly the ability to balance soft tissues in both extension and flexion. If there is ligamentous insufficiency and instability a higher level of constraint is required [14].

Despite good clinical results of CCK implants in primary TKA with survival rates varying between 89.8% [14] up to 100% [15] at ten years follow-up the complication rate can reach almost 20% [14]. A disadvantage is secondary to the increasing stability mechanism, the prominent polyethylene post, which engages with the metallic femoral prosthetic

Fig. 2 Seventy-four year old woman with 19° pre-operative varus deformity. A lateral approach with tibial tubercle osteotomy was performed. At 112 months follow-up, the clinical and radiological result was satisfactory, with neutral alignment, good balancing and range of motion 0/0/120°



Fig. 3 Sixty-four year old man with 11° pre-operative varus alignment. At 128 months follow-up, the clinical and radiological result was satisfactory, with 2° residual varus alignment, good balancing and range of motion 0/0/115°



box. This provides coronal, horizontal and rotational stability which results in stress concentration on the post potentially inducing polyethylene wear [16]. The torque stress transmission between femoral box and tibial post may lead to design dependent failures with implant breakage and dislocations [17]. The femoral prosthetic box requires large metaphyseal cuts and excessive bone may inadvertently be removed. This could affect the implant stability. Diaphyseal medullary stems are usually used to avoid implant loosening from the augmented forces transfer. This raises the risk of diaphyseal femoral and tibial pain. The increased bone resection to accommodate CCK implants and use of diaphyseal stems makes the eventual future revisions more complex. The higher cost of constrained implants also needs to be taken into consideration [18]. Above

limitations of constrained implants favour the use of low constrained implants in major deformities under the condition of appropriate alignment and tissue balancing attained [5, 14].

There are numerous surgical techniques described for different approaches and order of soft tissue releasing or preservation. In varus knees a medial approach combined with a deep medial collateral ligament (MCL) release and medial osteophytes removal often is sufficient in minor deformities [2]. To compensate for more significant laxity of lateral soft tissues further release on the medial side may be required. Insall et al., in his classical technique, proposed subperiosteal extensive medial soft tissue elevation with detachment of MCL from its tibial insertion [19]. This extensive release and subsequent medial gap laxity

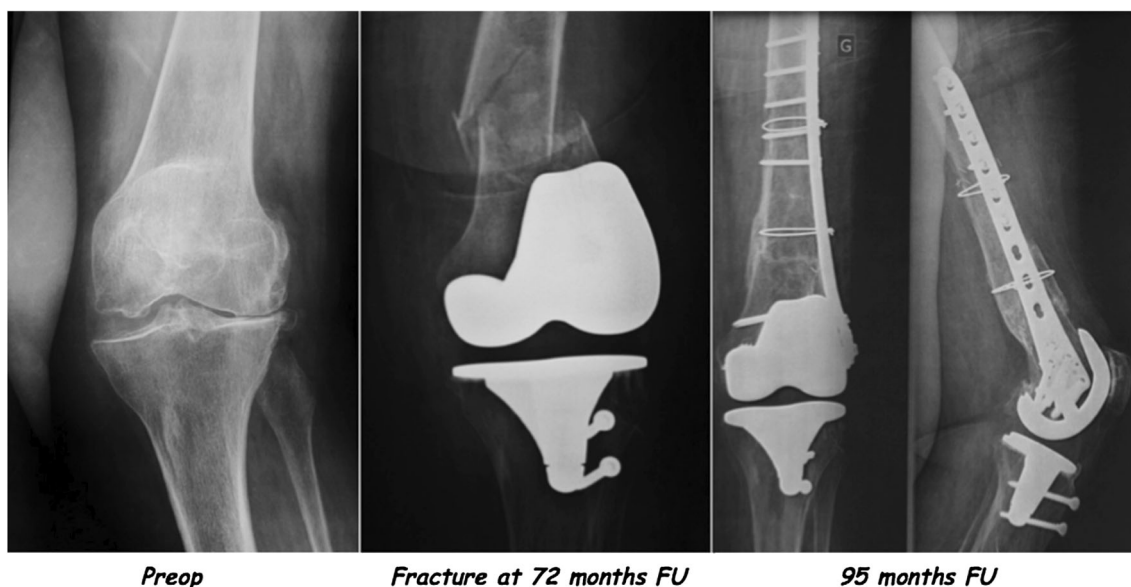


Fig. 4 Seventy-eight year old woman with pre-operative deformity of 198°. After 72 months, she presented a periprosthetic fracture needing reoperation for open reduction and internal fixation of the femur. At 95 months FU, healing was achieved and functional results acceptable with range of motion 0/0/95

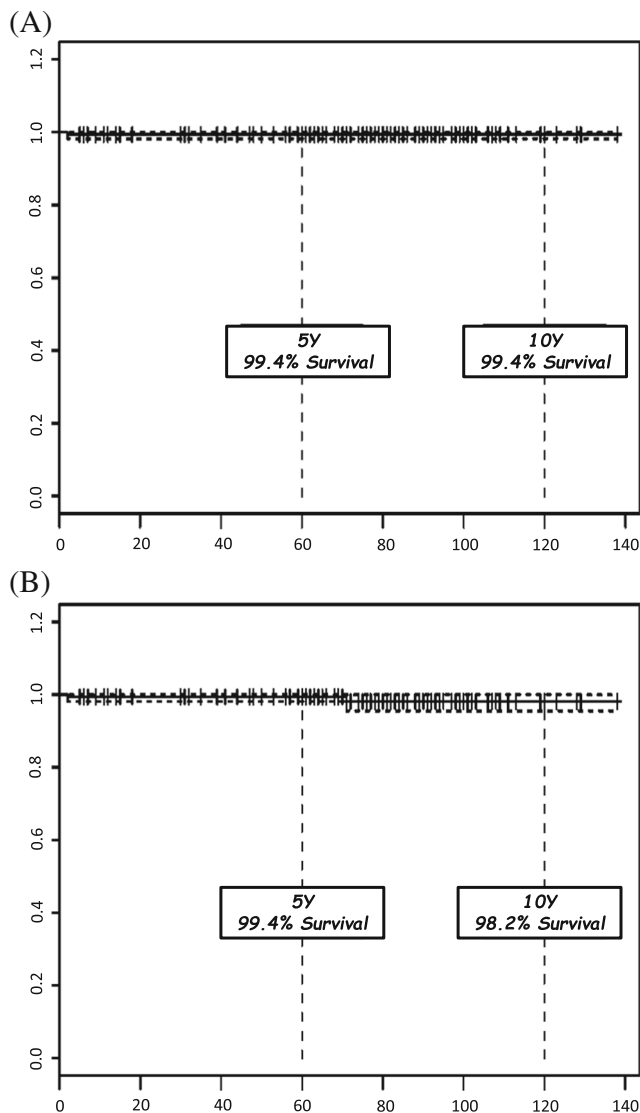


Fig. 5 Survival curves (Kaplan-Meier) presenting the mid-term (mean 5-years) and long-term (mean 10-years) follow-up survival rate considering as the endpoint the revision of implant (a) or surgical re-operation for any reason (b)

requires the use of thicker polyethylene or the need to change to higher constrained implant. It was suggested that such complete MCL release is not necessary even with severe varus knees and less aggressive techniques of medial side release have become popular. Step by step pie-crusting of anterior or posterior MCL fibres can give up to 8 mm lengthening and 8° of HKA correction [2]. It can be increased to 10 mm with additional posteromedial structure (posterior oblique ligament and semimembranosus) release [20]. These methods of soft tissue release have not shown to influence the clinical outcomes of TKA in varus knees but rather a significant decrease in use of constrained implants [21].

In valgus knees the balancing strategy begins by considering either a lateral [22] or medial parapatellar approach combined, if needed, with anterior tibial tubercle osteotomy [23]. Neither the medial nor lateral approach has been shown to have statistically significant advantages in clinical outcomes [24]. Further release of lateral tight structures may be required by sectioning or pie-crusting the lateral capsulo-ligamentous envelope of the knee [4].

If we compare our series to those published with severe varus/valgus deformities, the population characteristic of our series is similar (Tables 1 and 3). The mean age of our subjects (75.1 years) classifies our group as the oldest. The average age is reported between 63 years [25] and 74.9 years [26]. A similar or greater prevalence of female patients (63%) in our population was found in other papers [27, 28]. Primary knee osteoarthritis was the most common (up to 97.7%) indication for TKA [20].

The coronal pre-operative deformities mean HKA of 194.1° and 167.4° in our valgus and varus groups, respectively, correlates with those previously published (Table 3). Post-operative limb alignment assessment correction of HKA in both groups is illustrated in Table 2. In 26.3% of knees the neutral alignment, defined as HKA of $180^\circ \pm 3^\circ$, was not attained. This corresponds to other authors, with prevalence of post-operative misalignment ranging from 19% [27] to 36.5% [29].

We observed a non significant improvement in range of motion, mean of 4° , which was comparable to those reported varying from 4° [26] to 20° [30].

The clinical outcomes demonstrated a significant increase in post-operative values in each element of the KS scores. We found that the varus deformity group had statistically better post-operative results in functional and global KS scores compared to the valgus group (Table 2). The nine patients identified with post-operative function KS score lower than 50 points had advanced osteoarthritis in hips and contralateral knee, which could influence their poor results.

Our implant survival rate of 99.4% at ten year follow-up is in line with the best results reported in the literature, between 79% at ten year [29] and 98.8% [28] at 12-year. The overall complications rate, 10 knees (6.2%), is acceptable and was in the lower rank of published results, with complication rates reported up to 26.9% [29].

Our study has several limitations. Firstly, it is a retrospective case series study. Secondly, there was no standard surgical technique, which was determined by both pre-operative and intra-operative assessment. There was no standard fixation of implants with cementation based on the subjective quality of the bone. Finally, intra-operative assessment of appropriate ligamentous balance was subjective and based on the experience of the surgeon.

Strengths of this paper are the large sample size and single implant design. A single surgical operator ensured

Table 3 Comparison of reported clinical, KSS, and radiological outcomes in patients who underwent the TKA with low constraint implants for OA for severe (>10°) varus or valgus deformed knees

Author	Mullaji et al. 2005	Matsumoto et al. 2014	Matsumoto et al. 2014	Ahn et al. 2016	Ha et al. 2016	Koskinen et al. 2011	Huang et al. 2016	Sekiya et al. 2014	Sekiya et al. 2014	De Muijlder et al. 2015	Ritter et al. 2004
Deformity	Var	Var	Var	Var	Var	Val	Val	Val	Val	VarG (n 30) ValG (n 16)	VarG (n 39) ValG (n 43)
n patients (♂/♀)	117	16	88 (7/81)	60 (9/51)	501	48(2/46)		44		44	75 (18/56)
n knees (♂/♀)	173 (56/137)	20 (4/16)	100	78	729 (67/662)	52	28	24	24	46	82
Age years	67 (45–84)	73 (57–87)	74 (60–86)	71 (59–83)	68 (47–94)	66 (36–86)	71 (64–85)	63±7	66±7	74±9	71±11
BMI kg/m ²	28±6				27 (15–41)		27 (20–38)	31±6			
FU years	3 (2–9)	min 2	min 2	3 (2–4)	3 (2–5)	9 (1–17)	5 (2–7)	4±1	4±1	3±2	6±3
Surgeons	1	2	2	1	1	1	1	1	1	1	
Approach	medial	medial	medial	medial	medial	medial	medial	lateral	medial	medial	
Constraint	PS	CR	PS	PS	CR, CS	CR	CR, CS	PS	PS	PS	CR
Alignment °	TFA	CA	CA	MA	HKA	MA	HKA	MA	MA	HKA	AN
preOP	23 Var ±8	10 Var ±1	11 Var ±1	12 Var ±3	169 ± 3	18 (3–45) Val	194 (191–196)	13 ± 6	14 ± 6	165 ± 3 VarG 196 ± 4 ValG	>20° Var >20° Val
postOP	5 Val ±1			1 Var ±2	180 ± 2	2 Val (15Val–5Var)	178 (176–184)	2 ± 1	1 ± 2	178 ± 1 VarG 180 ± 3 ValG	3 ± 5 VarG 6 ± 4 ValG
ROM ° flexion											
preOP	116 (80–140)	122 (100–135)	116 (95–130)	113 (89–143)	127	92 (10–125)	99 (90–120)	112 ± 15	113 ± 17		
postOP	111 (85–130)	126 (100–140)	124 (100–135)	135 (117–162)	141	105 (40–130)	115 (105–125)	124 ± 11	109 ± 14	126 ± 10	
Knee KSS											
preOP	23 (0–64)			56 (25–70)	52 (27–82)	31 (0–61)	39 (16–60)	35 ± 13	36 ± 11		44 ± 20
postOP	91 (52–99)	96 (81–100)	96 (82–100)	89 (80–100)	83 (53–94)	59 (0–100)	34 (20–50)	89 ± 4	87 ± 4	89 ± 9	88 ± 16
Function KSS											
preOP	29 (0–64)			58 (38–86)	58 (38–86)	39 (0–100)	98 (90–100)				
postOP	72 (5–100)	88 (72–100)	83 (40–100)	92(57–100)	92(57–100)	61 (0–100)	97 (90–100)	77 ± 18			

Values are approximated to round numbers, comparing to original papers and are presented as mean, ± standard deviation, (range) Var varus, Val valgus, VarG varus group, ValG valgus group, ♂ male, ♀ female, min minimum, PS postero-stabilized, CR cruciate retaining, CS cruciate substituting, ROM range of motion, preOP preoperative, postOP postoperative, KSS Knee Society score, TFA tibiofemoral angle, CA coronal alignment, MA mechanical axis, HKA hip knee ankle angle, AN anatomic norm

standardized pre-operative and intra-operative assessment, management and rehabilitation.

Our study is in accordance with previously published papers. We have demonstrated satisfactory outcomes and mid-term survival rate of low constraint implants in patients with major ($>10^\circ$) coronal deformity. In previous studies, however, the designs utilized were different, either cam-posterior-stabilized or cruciate retaining (Table 3), thus differentiating our paper. Sorrells et al. used cementless low contact stress (LCS) mobile bearing design, which is similar but has a differing congruency of polyethylene. In their group of 138 severely deformed ($>10^\circ$), varus and valgus knees the 10-year survival rate was 89.7% [31]. They stated, that those kinds of implants could be successfully used in a wide range of angulated deformed knees, even though preoperatively deformed knees did less well than undeformed knees. A conclusion which is supported by our study.

Conclusion

TKA with ultra congruent mobile bearing insert is a reliable option in severe knee deformity ($>10^\circ$) provided correction of alignment and adequate soft tissue balancing is achieved. Ongoing follow up of patients is required to assess the long-term outcomes of these implants in such conditions.

Compliance with ethical standards

Conflict of interest JC and RG declare that they have no conflict of interest.

TG: royalties from Amplitude TM.

SL: consultant for Smith & Nephew, consultant for Medacta, institutional research support to Tornier-Wright and Amplitude.

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Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

For this type of study formal consent is not required.

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