No differences in functional results and quality of life after single radius or multiradius TKA

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ABSTRACT

Purpose: The main objective of this study was to compare the functional results and the impact on quality of life after a single radius or a multiradius TKA implantation. The secondary objectives were to compare range of motion, satisfaction and the ability to perform daily life activities with both types of implant.It was hypothesized that the single radius TKA would lead to better functional results and better quality of life than the multiradius TKA.

Methods: This is a prospective non-randomized study that included 250 cases of a single radius TKA and 224 of a multiradius posterior-stabilized TKA implanted with the same surgical and rehabilitation protocol.

Results: In the 1-year and 5-year follow-up, we found similar knee KSS scores (89.7 ± 12.1 in the multiradius group, 90.3 ± 11.7 in the single radius group) and functional KSS scores (78.6 ± 21.4 in the multiradius group, 75.8 ± 20.9 in the single radius group). The pain and the Physical SF-36 scores were also similar. Range of motion (112º ± 12º in the multiradius group and 112 ± 12º in the single radius group), patients' satisfaction and the ability to perform daily life activities were also similar in both groups.

Conclusion: The use of a single radius or a multiradius posterior-stabilized knee prosthesis can improve the function of the knee and the patients´ quality of life in a similar way at the short-term and mid-term follow-up. Moreover, range of motion, patient satisfaction and the ability to perform daily life activities are similar with both types of prosthesis. As both types of prosthesis can improve the function and quality of life of the patients in a similar way, the sagittal radius of the femoral component should not be considered the main factor when choosing the model of TKA.

KEYWORDS: Single radius, Multi-radius, Total Knee Arthroplasty, Function, Quality of Life, Total Knee Replacement, TKA, TKR

Level of Evidence: Level II. Therapeutic study: Prospective comparative study.

INTRODUCTION

The classical multiradius (MR) design of the total knee arthroplasty (TKA) has considered that there are multiple centres of rotation of the knee, which move posteriorly and distally as the knee flexes in a J-curve pattern [13]. On the other hand, in the past decade, single-radius (SR) design of TKA has considered that the centre of rotation of the knee remains almost stable on an axis that is fixed to the femur and close to the transepicondylar axis [7], and the radius in the SR designs is more posterior than the radius in the MR designs.

Some studies have stated that an SR TKA might lead to more uniform movement with lower contact stresses on the insert [17], more efficient quadriceps force in human knee specimens [6,24] and better stability in flexion in vitro [9,28]. Nevertheless, some of the theoretical improvements in knee kinematics of the SR designs went undemonstrated when analysed in vivo [30]. Few studies have compared the functional results with SR versus MR designs 6 months to 2 years after TKA surgery. The results from those studies were not conclusive because some of them suggested superior results with SR designs [8,10,25] and others suggested similar results with both types of TKA [11,15,19,21,23]. As far as we know, no study has compared the functional results between both types of TKA at 5 years.

The main objective of this study was to compare the functional results and the impact on quality of life in two groups of patients at the short-term and medium-term follow-up after a an SR or an MR TKA had been implanted. The secondary objectives were to compare the knee's range of motion (ROM) and the ability of patients to perform some daily life activities

like ascending or descending stairs, kneeling or squatting. It was hypothesized that the SR TKA would lead to better functional results and better quality of life than the MR TKA.

MATERIALS AND METHODS

This is a prospective non-randomized study with 580 posterior-stabilized (PS) TKA operated on at one institution between September 2007 and October 2008. In those patients, either a Triathlon® total knee system (n=295) (Stryker Orthopaedics, Mahwah, NJ, USA), a femoral SR TKA or a Genutech® total knee system (n=285) (Surgival, Valencia, Spain), a femoral MR TKA had been implanted (Figure 1).

Both implants have a cobalt-chrome femoral component and relatively unconstrained inserts. The use of one or the other implant type was chosen by alternating their deployment in patients and not decided by the surgeon for clinical reasons. That means that it was based on surgical order (in the first, third and fifth cases of each day one type of implant was used, while the other type was used in the second and fourth). A total of 9 surgeons were responsible for all the procedures and all of them used both types of TKA. All the surgeons had extensive experience with both types of implant, so no learning curve effect was to be expected.

The inclusion criteria were a diagnosis of osteoarthritis, osteonecrosis or posttraumatic arthritis with an indication for a TKA. All patients had the ability and will to comply with postoperative rehabilitation as well as to submit to clinical preoperative and postoperative evaluations which included the Knee Society Score (KSS) and Short Form-36 (SF-36) outcome questionnaires.

The exclusion criteria were revision TKA, compromised bone stock requiring metallic augments, a diagnosis of either rheumatoid arthritis or systemic lupus arthritis.

Operative technique

Prophylactic antibiotics were used (usually cephazolin, but vancomycine was used instead in penicillin allergic patients) in all cases.

A standard anterior incision and a medial parapatellar approach were used in each case. The prosthetic posterior-stabilized components were implanted with cement after standard bone cuts, and soft tissue releases when necessary. The patella was replaced in all the cases. Wound closure was done in flexion and one deep drain was left in the knee for 24 hours.

Post-operatively, enoxaparin was used at 40 mg/24 hours for 4 weeks, starting at 6 hours post-operatively. Compression stockinet was used on the operated lower limb.

Rehabilitation protocol

All the patients followed the same postoperative rehabilitation protocol. Following the hospital clinical pathway, it began with continuous passive motion (CPM) of the knee 24 hours after surgery and at 2 CPM sessions per day for 6 to 7 days until hospital discharge. Patients began crutch-assisted full weight-bearing ambulation 48 hours after surgery. After discharge, the patients came to the hospital for 10 additional physiotherapy sessions.

Post-operative follow-up

All the patients visited at one and five years after surgery have been included. A total of 45 patients were excluded in the Triathlon (SR) group and 61 patients were excluded in the Genutech (MR) group. Therefore, a total of 250 cases from the SR group and 224 cases in the MR group were available for analysis (Figure 2).

Outcome score analysis

At the preoperative visit and at 1 and 5 years after surgery, KSS outcome scoring was performed [3].The follow-up assessment at 1 and 5 postoperative years was done by a study nurse and an orthopaedic resident; both were blinded to the type of prosthesis used.

Moreover, an SF-36 survey [2] was self-administered by the patients at the preoperative visit and at 1 and 5 years after surgery. Pain was assessed with the Visual Analogic Scale (VAS) score with a ruler with values from 0 to 10.

The changes in the KSS scores and in the SF-36 scores between the preoperative and the postoperative visits were calculated and analysed.

Passive range of motion was measured with the patient in a supine position with a manual 30 cm plastic goniometer 0-to-360º per 1º.

The 17-item Hospital for Special Surgery expectations score [22] was also requested in the preoperative period and at 1-year and 5-years after surgery.

The patients were asked to evaluate satisfaction on a continuous scale from 0 (absolutely dissatisfied) to 10 (absolutely satisfied) at the 1-year and 5-year follow-up visits.

Radiographic analysis

In the preoperative period and in the last follow-up visit, a long-leg standing radiograph was performed. The alignment of the extremity was analysed taking the hip-knee-ankle (HKA) angle as the intersection between the femoral mechanical and the tibial mechanical axis. Varus alignment was considered a negative value and valgus alignment a positive value. The stage of osteoarthritis was considered in the preoperative radiograph in accordance with the Ahlbäck classification [1]. A lateral radiograph at 30º of flexion was done at the preoperative and at the last follow-up visit and the tibial slope was studied [16].

This study received IRB approval (Parc de Salut Mar 2006/2476). All patients signed informed consent for the study.

Statistical analysis

All data collected for this study was entered into an Excel database (Microsoft Office 2003, Redmond, WA) and analysed using the SPSS 18.0 (IBM Corp) statistical program. A descriptive analysis of the sample was done using rates for categorical variables, and the mean and standard deviations for continuous variables. To compare differences between the two implant types (Triathlon and Genutech), either a Chi-square or a Fisher exact test was used for the analysis of categorical variables and the Student's t-test was used for continuous variables. A power analysis was done and to detect a difference between both groups of at least 3 points in the KSS score, with a power of 80 % and an alpha error 0.05, with a standard deviation of 11 points, and considering a drop-off rate of 20 %, at least 264 cases enrolled in each group were necessary (at least 211 patients analysed in each group). The level of significance was set at $p<0.05$.

RESULTS

The patient population that received either type of arthroplasty were similar in all the demographic and radiographic parameters studied (Table 1). The KSS and SF-36 preoperative values were also similar in both groups (Table 2).

There were no differences in the preoperative flexion contracture of the knee between the MR group: 3º (SD 6º) and SR group: 3º (SD 5º) (n.s.). The maximal flexion of the knee: 110º (SD 16º) in the MR group and 110º (SD 13º) in the SR group was also similar in both groups (n.s.).

The mean operating time was similar in both groups: 70 (SD 16) minutes in the MR group and 70 (SD 14) minutes in the SR group (n.s.).

Radiographic analysis showed a similar coronal alignment in both groups, with HKA angle in the last radiograph that was -3.2º (SD 2.6) in the MR group and -3.1º (SD 2.3) in the SR group (n.s.). The tibial slope in the last sagittal study was 4.4 (SD 3.1) in the MR group and 4.4 (SD 3.2) in the SR group (n.s.).

Both groups showed a significant improvement in the outcome scores at both the 1-year and 5-year post-operative follow-ups. There was no significant difference between the groups in terms of the KSS knee, KSS function, and KSS total scores (Table 3), or in the changes in the KSS at the follow-up.

At 1-year post-operative visit, both groups showed similar changes in the SF-36 scores, without significant differences in the SF-36 Physical or Mental scores or in the SF-36 changes. At 5-year follow-up, the SF-36 Physical scores were also similar but there was

a small difference in the SF-36 Mental score. It was worse in the SR group. This small difference (less than 3 points, on average) could be considered of no clinical relevance (table 3).

The average ROM between both groups was similar 1-year after surgery (107º (SD 12) for MR and 108º (SD 12) for SR; n.s.) and 5-years after surgery (112º (SD 12) for MR and 112º (SD 12) for SR; n.s.).

The average in the expectations achieved in the Hospital for Special Surgery expectations score for ascending stairs, descending stairs, kneeling, squatting or ability to perform activities of daily life was similar in both groups at 1-year and 5-years follow-up (Table 4).

The average satisfaction scores at 1-year follow-up between MR TKA (8.5 points (SD2.3)) and SR TKA (8.8 points (SD 2.2)) (n.s.) groups and at 5-years follow-up between 8.6 points (SD2.4) and 8.8 points (SD 2.4), respectively, (n.s.) were also similar.

DISCUSSION

The main finding of this study is that we have failed to prove better functioning with an SR over an MR TKA, at the short-term or medium-term follow-up. The impact of the surgery on quality of life seems to be similar for both types of implants. Moreover, ROM is equivalent after either SR or MR TKA. In the clinical setting, we failed to prove that patients could sit, ascend or descend stairs better with a SR TKA than with an MR TKA.

177 Excellent outcomes have been reported after SR TKA in terms of KSS scores [5,12,20,27],
178 improvements in quality of life [20] and patients' satisfaction [27]. Gómez-Barrena et al.
179 observed better functional KSS in a small group of patients receiving a SR design TKA with
180 respect to another group after MR TKA. However, there were no differences in the clinical KSS
181 [10]. On the other hand, Molt et al. found similar KSS scores in SR and MR implants after 3
182 months, at 1 year and 2 years after surgery in a randomised trial. Then again, it was done with
183 a small number of patients [23]. Cook et al. compared 436 SR TKA with 133 MR TKA in a
184 retrospective study and they found greater postoperative KSS knee and function scores with
185 an SR arthroplasty, but the groups were not comparable because the patients were quite a bit
186 younger in the SR group and the approach was different [8]. Palmer et al. also found better KSS
187 function and KSS knee scores in a retrospective study up to 2 years after surgery when a SR
188 TKA was used [25]. Hall et al. analysed the results of a randomized trial and found similar
189 results in terms of KSS scores in SR TKA or MR TKA when cruciate-retaining (CR) implants were
190 used [11]. Mahoney et al. did not find differences between KSS scores (knee or functional) in
191 SR and MR TKA in a consecutive series study [21]. Our results also failed to demonstrate a
192 significant improvement in knee KSS scores and functional KSS scores in both groups, without
193 any differences between groups, at least up to 5 years after surgery.

194 Several factors have been described having an influence on ROM after a TKA. The main one is
195 likely to be the preoperative ROM [18]. Schurman and Rojer compared the ROM after surgery
196 with 5 different TKA types and they found no differences, suggesting that the type of TKA has
197 little relevance in the postoperative ROM and that preoperative ROM is the main factor [25].
198 Mahoney et al. compared 83 MR TKA with 101 SR TKA and found greater flexion at 6 weeks
199 after surgery in the SR group. However, this difference did not exist at 3 months
200 postoperatively and onwards [21]. Other studies found similar flexion at any point in the
201 follow-up period between MR and SR designs with CR TKA, but the authors stated that this

finding could only be applicable to non-PS designs [11,14]. In a similar way, we have not found any differences in ROM with either design in PS TKA.

Mahoney et al. found that more patients with an SR TKA were able to rise from a chair without using their arms than those in the MR group. It suggests a more efficient extensor mechanism functioning [21], and was demonstrated by the increased muscle activation in the MR group in an electromyographic study [29]. Nevertheless, another work found that the ability to rise from a chair or the incidence of anterior knee pain while rising was not affected by the MR or SR design at any point during the follow-up period [11]. We have not specifically analysed the ability to rise from a chair but the ability to carry out daily activities and activities that require extensor mechanism involvement like kneeling or squatting. Moreover, patient satisfaction was the same in both groups.

No differences in the reported ability to ascend or descend stairs in patients with an SR or MR design TKA were found. Some influence of the implant design on kinematics during stair-climbing has been reported, but the CR or PS design seems to be more important than the femoral centre of rotation [4]. Moreover, Molt et al. found an inferior KOOS score in terms of activities of daily life 1-year and 2-year after TKA with the SR design, and this score covers rising from a chair as well as ascending and descending stairs [23].

Several limitations of this study are recognized: the main one is that this is a non-randomized study, but the selection of the type of implant was not based on clinical aspects and was not done by the surgeon. Moreover, both groups were similar in terms of all the variables compared. Additionally, the type of arthroplasty was blinded to the examiner in the follow-up analysis. Another limitation is that follow-up was limited to 5 years. Some late complications like patellar loosening might be more frequent in TKA designs with higher patellofemoral compressive forces. In the limited follow-up of our study, we did not observe an increase in patellofemoral complications in either of the groups. Moreover, the 5-year follow-up is the

longest of any study comparing SR and MR designs. Finally, a single type of MR and a single type of SR TKA have been tested and different designs might affect knee function differently.

CONCLUSION

The hypothesis that SR TKA might lead to better functional results and better quality of life than the MR TKA was not proven.The use of a MR posterior-stabilized TKA may significantly improve the function of the knee and patients' quality of life in a similar way to SR TKA at a maximum 5 year follow-up. Moreover, range of motion, satisfaction and the patient's ability to perform daily life activities are similar with both types of arthroplasties. As both types of prosthesis can improve the function and quality-of-life of the patients in a similar way, the sagittal radius of the femoral component should not be considered the main factor when choosing the TKA model.

ACKNOWLEDGEMENTS

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest relative to the funding of the research presented. One author (the 1st) has done paid presentations for Stryker and three authors (the first, second and last) has provided consultative assistance to Surgival.

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Figure 1-A

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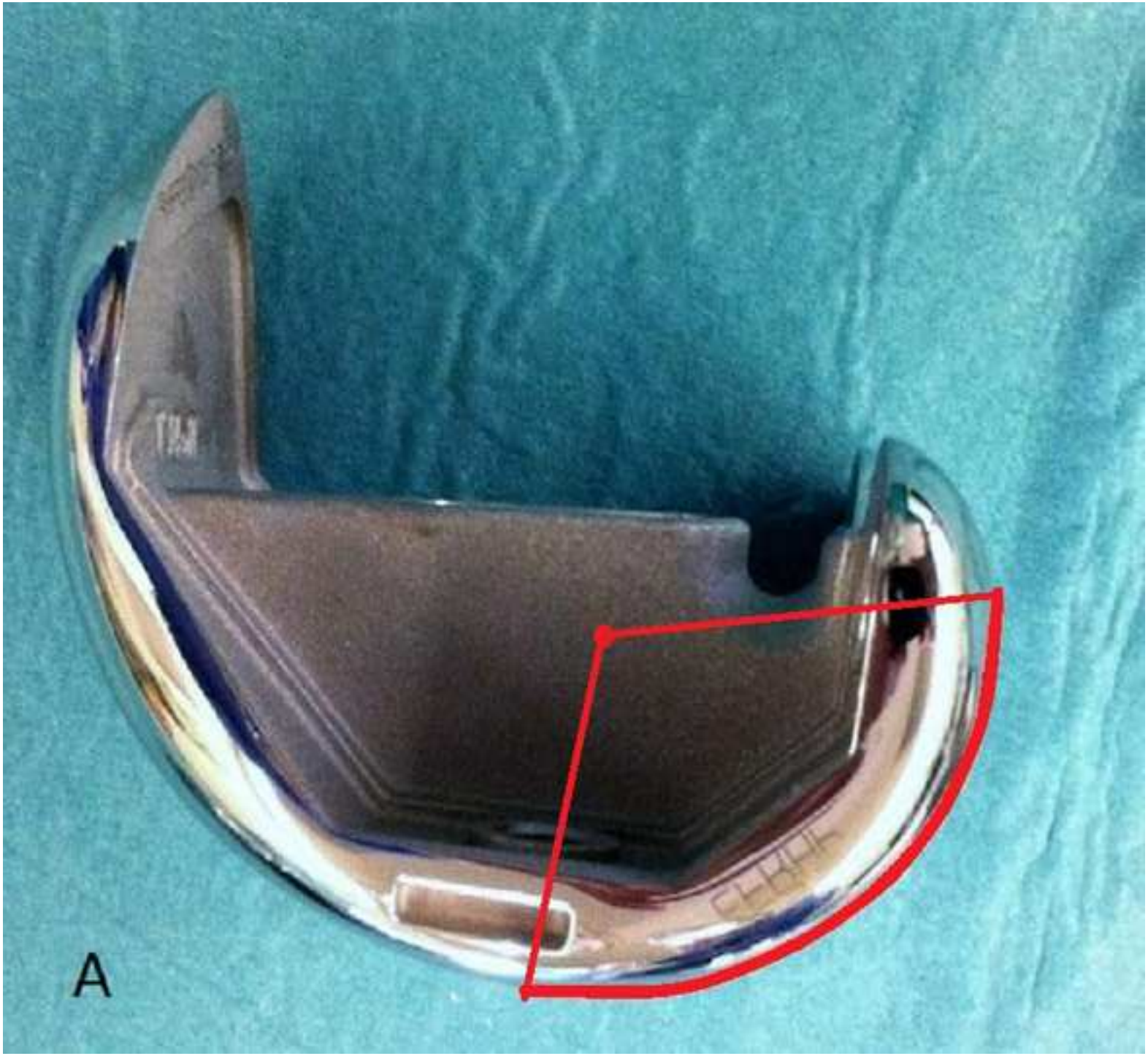

Figure 1-B

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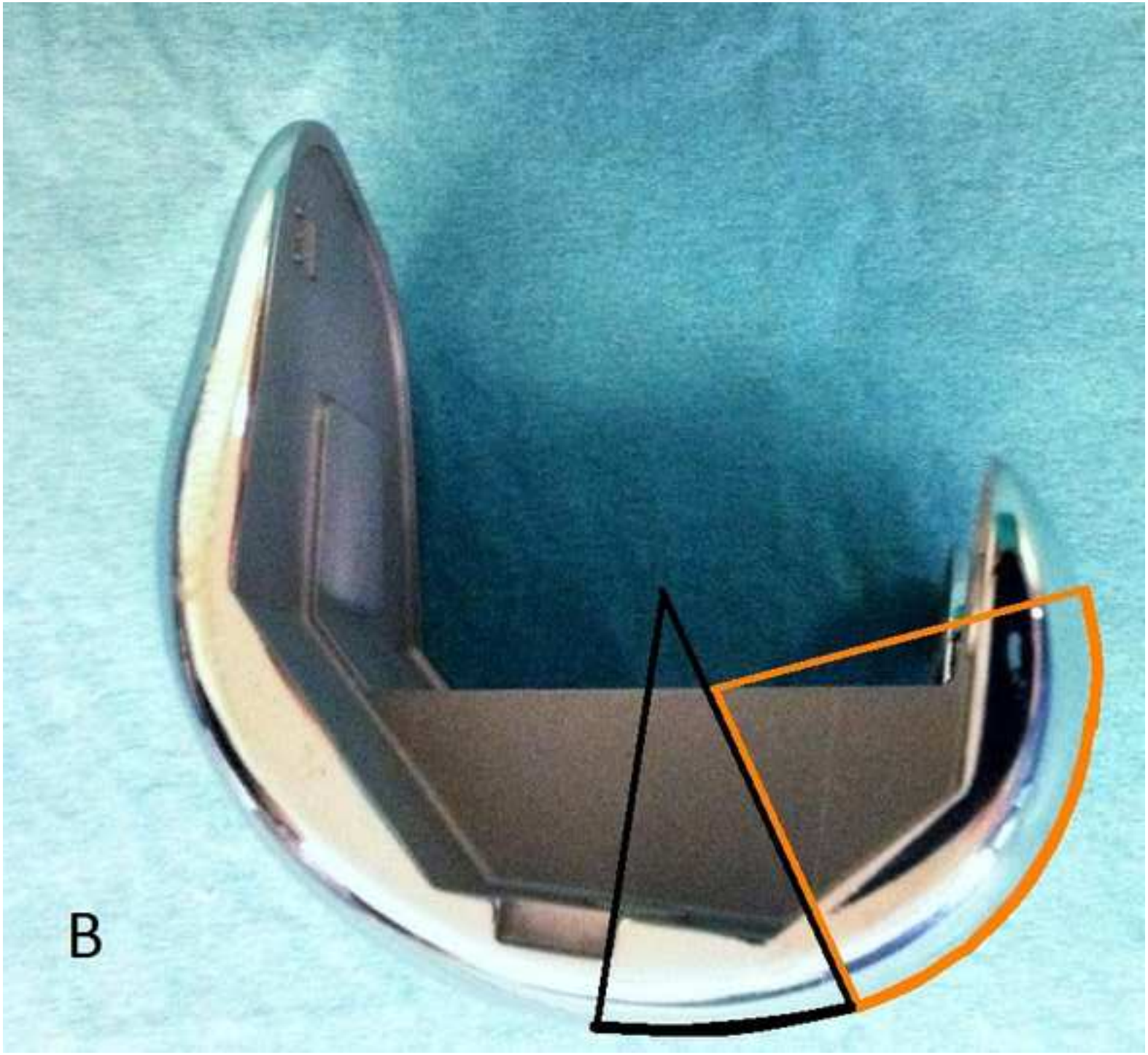
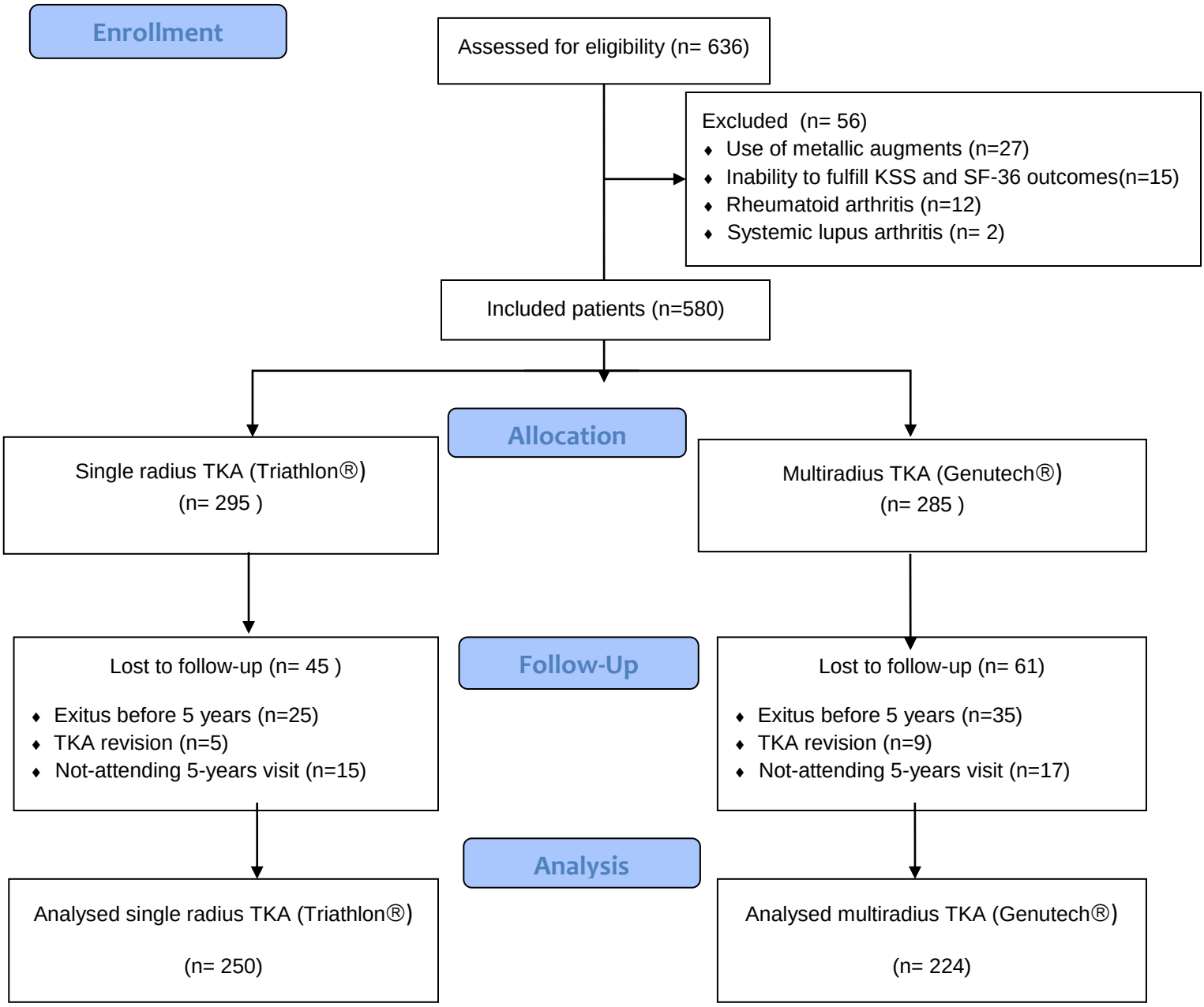


Figure 2


Enrollment
Assessed for eligibility (n= 636)
Excluded (n= 56)
Use of metallic augments (n=27)
Inability to fulfill KSS and SF-36 outcomes(n=15)
Rheumatoid arthritis (n=12)
Systemic lupus arthritis (n= 2)
Included patients (n=580)
Allocation
Single radius TKA (Triathlon®)
(n= 295)
Multiradius TKA (Genutech®)
(n= 285)
Follow-Up
Lost to follow-up (n= 45)
Exitus before 5 years (n=25)
TKA revision (n=5)
Not-attending 5-years visit (n=15)
Lost to follow-up (n= 61)
Exitus before 5 years (n=35)
TKA revision (n=9)
Not-attending 5-years visit (n=17)
Analysis
Analysed single radius TKA (Triathlon®)
(n= 250)
Analysed multiradius TKA (Genutech®)
(n= 224)

Table

VARIABLE	MR (Genutech®)	SR (Triathlon®)	p Value
Age (years)	72.1 (6.7)	72.3 (7.2)	n.s.
Gender % (Male/Female)	25.3/74.7	23.0/77.0	n.s.
Weight (Kg)	77.2 (12.4)	77.6 (13.8)	n.s.
Height (cm)	157.4 (8.1)	157.1 (8.1)	n.s.
BMI (Kg/cm^2)	31.2 (4.8)	31.4 (5.1)	n.s.
Charlson comorbidity index	0.7 (0.9)	0.9 (1.0)	n.s.
HKA angle	-7.9 (4.7)	-8.0 (4.7)	n.s.
Ahlback stage	2.2 (0.8)	2.2 (0.7)	n.s.

TABLE 1- Preoperative demographic data. Values are expressed as mean (and standard deviation in parentheses)

BMI- Body Mass Index

HKA- Hip-Knee-Ankle

Table

VARIABLE	MR (Genutech®)	SR (Triathlon®)	p Value
VAS score (pain)	6.9 (1.4)	6.9 (1.5)	n.s.
KSS Knee score	46.5 (19.2)	45.1 (17.7)	n.s.
KSS Functional score	52.7 (12.6)	53.2 (13.2)	n.s.
KSS Total score	99.2 (25.8)	98.2 (24.5)	n.s.
SF-36 Phyisical sum	32.6 (7.6)	31.3 (7.9)	n.s.
SF-36 Mental sum	46.6 (15.3)	47.4 (14.4)	n.s.

TABLE 2- Preoperative outcome scores. Values are expressed as mean (and standard deviation in parentheses)

VAS – Visual Analogical Score

KSS – Knee Society Score

SF-36 – Short Form -36

Table

	1-year Follow-up			5-years Follow-up		
VARIABLE	MR (Genutech®)	SR (Triathlon®)	p Value	MR (Genutech®)	SR (Triathlon®)	p Value
VAS score (pain)	2.6 (2.1)	2.6 (2.2)	n.s.	2.8 (2.2)	2.5 (2.0)	n.s.
KSS Knee score	89.9 (12.2)	91.1 (8.9)	n.s.	89.7 (12.1)	90.3 (11.7)	n.s.
KSS Functional score	83.1 (19.0)	82.4 (15.1)	n.s.	78.6 (21.4)	75.8 (20.9)	n.s.
KSS Total score	173.4 (28.0)	173.4 (21.1)	n.s.	168.3 (30.5)	166.1 (27.8)	n.s.
SF-36 Physical sum	43.0 (9.8)	43.3 (9.2)	n.s.	41.5 (10.6)	39.7 (10.5)	n.s.
SF-36 Mental sum	47.5 (14.1)	48.0 (12.7)	n.s.	47.2 (12.7)	44.6 (13.1)	0.026 *

TABLE3- Postoperative outcome scores. Values are expressed as mean (and standard deviation in parentheses)

VAS – Visual Analogical Score

KSS – Knee Society Score

SF-36 – Short Form -36

Table

VARIABLE	MR (Genutech®)	SR (Triathlon®)	p Value
1-yr Ascending stairs	2.0 (1.0)	1.9 (0.9)	n.s.
1-yr Descending stairs	2.2 (1.0)	2.2 (1.0)	n.s.
1-yr Kneeling	3.8 (0.6)	3.8 (0.5)	n.s.
1-yr Squatting	3.8 (0.4)	3.7 (0.7)	n.s.
1-yr Daily Life Activities	1.6 (0.9)	1.6 (0.8)	n.s.
5-yr Ascending stairs	2.1 (1.0)	2.1 (1.1)	n.s.
5-yr Descending stairs	2.4 (1.2)	2.3 (1.1)	n.s.
5-yr Kneeling	3.1 (1.4)	3.1 (1.4)	n.s.
5-yr Squatting	2.8 (1.5)	3.1 (1.4)	n.s.
5-yr Daily Life Activities	1.7 (1.0)	1.9 (1.0)	n.s.

TABLE 4- Postoperative expectations achievement of the Hospital for Special Surgery expectations at 1-year and 5-years follow-up. Values are expressed as mean (and standard deviation in parentheses)