GMK® REVISION STUDY REPORT: 2-YEAR FOLLOW-UP

SINGLE-CENTER, RETROSPECTIVE TWO-YEAR STUDY RESULTS TO MONITOR POSTOPERATIVE CLINICAL OUTCOMES OF MEDACTA GMK REVISION

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INTRODUCTION

The purpose of this study is to report the clinical outcomes of both primary and revision Total Knee Arthroplasties (TKA) using **GMK Revision**, a **varus/valgus constrained knee implant** (Figure 1)**. Patient Reported Outcomes** were collected using the Likert Scale and the Knee Society Score (KSS), as well as the patient satisfaction score. Radiological outcomes were also assessed.

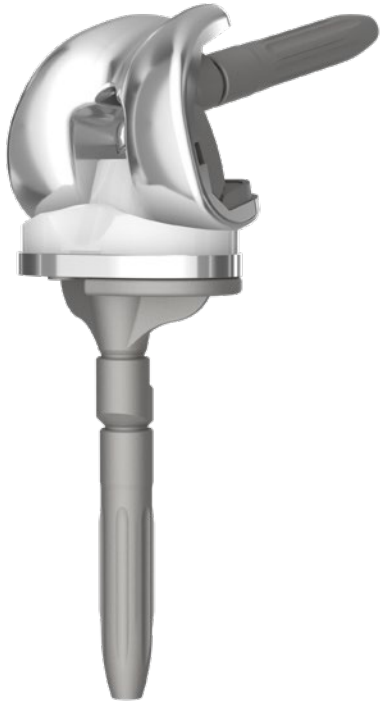

Figure 1. GMK Revision

OBJECTIVE

The objective of this **retrospective, observational study**, run at the Saint Alphonsus Medical Group (Boise, Idaho, United States) was to collect **minimum two-year post-treatment results of primary or revision TKA using Medacta GMK Revision knee** (posterior stabilized femoral components, varus/valgus constrained tibial inserts). The study was designed to **assess clinical outcomes, such as the Knee Society Score (KSS)**[2], which includes evaluation of stability and alignment, **patient satisfaction, adverse events, and complications data** at a minimum of two years post-treatment. The study hypothesized that following TKA using the GMK Revision knee implant, a minimum of 75% of the study cohort will report a good to excellent patient satisfaction rating at a minimum average cohort follow-up of 2 years[3].

PATIENTS AND METHODS

Patients were screened for eligibility, and informed consent was obtained from those who met the screening criteria during the **time period of November 2010 to March 2015**. There was an enrollment goal of up to 50 qualified subjects who had undergone primary or revision TKA with the Medacta GMK Revision knee implant. 19 patients agreed to provide postoperative information for the study[4]. Subjects that were at least two years post-treatment completed the postoperative clinical evaluation.

Participant demographics are shown in Table 1.

TABLE 1. PARTICIPANT DEMOGRAPHICS

Patient demographics	n.	%
GENDER		
Female	13/19	68%
Male	6/19	32%
OPERATIVE SIDE		
Right	10/19	53%
Left	9/19	47%
KIND OF SURGERY		
Primary TKA	1/19	5.3%
Revision TKA	18/19	94.7%
BMI [kg/m²]		
Mean	30.8 ± 6.6	-
Median	29	-
Min/Max	22/48	-

RESULTS

Among the 19 participants, there **were no surgical complications, adverse events, nor any cases showing loosening or infection**.

Utilizing the Likert Scale[5], patient satisfaction was rated from "Poor" to "Excellent" (Table 2).
- **84.2%** (16/19) of the patients **rated their satisfaction** as "**Good**", "**Very Good**", and "**Excellent**".
- 15.8% (3/19) of the participants reported their satisfaction as "Poor" or "Fair".

Three participants had medical conditions that might affect the results related to this evaluation.[a]

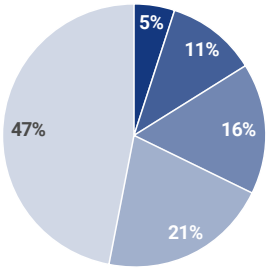

TABLE 2. PATIENT SATISFACTION LIKERT SCALE[5]

Poor	1/19 [a]
Fair	2/19 [a]
Good	3/19
Very good	4/19
Excellent	9/19

[a] One participant rated their satisfaction as "Poor": they had other diagnoses listed as "previous infection", "obesity", "diabetes", and "rheumatoid arthritis". Two participants rated their satisfactions as "Fair": they both had medical conditions listed as "previous infection", "osteoporosis", "diabetes", and "other articular problems affecting walking capacity". These diagnoses or medical conditions might affect clinical evaluations and results related to the study.

KSS data were collected across all categories and the results were the following (Tables 3A, 3B):

- the mean KSS Objective Score was 76.2 ± 17.2
- the mean KSS Expectation and Satisfaction Score was 43.1 ± 10.9
- the mean KSS Functional Activity Score was 69.3 ± 20.8.

TABLE 3A. KNEE SOCIETY SCORE (KSS)

	KSS Objective Score[b]	KSS Expectation and Satisfaction Score[c]	KSS Functional Activity Score[d]
N. of participants	18 [e]	19	19
Mean	**76.2**	**43.1**	**69.3**
Median	78	45	73
Standard deviation	17.2	10.9	20.8
Minimum	40	17	17
Maximum	105	55	95
Test Min/Max Score	2 / 105	3 / 55	0 / 100

TABLE 3B. SUBGROUPS OF THE KSS FUNCTIONAL ACTIVITY SCORE

	Functional - Standing & Walking	Functional - Standard	Functional - Advanced	Functional - Discretionary
N. of participants	19	19	19	19
Mean	**23.2**	**23.2**	**12.4**	**10.6**
Median	26	25	13	12
Standard deviation	7.5	6.3	5.5	4.6
Minimum	5	8	2	1
Maximum	30	30	20	15
Test Min/Max Score	0 / 30	0 / 30	0 / 25	0 / 15

(b) The KSS Objective Score is assessed mainly by the surgeon (objective evaluation), considering the following post-op parameters: knee alignment on X-rays, knee stability in full extension and at 90° of flexion, and knee range of motion. Knee symptoms score is included in this section even if it is based on the patient's feedback, Max value: about 105 (no limits with Range of Motion).
(c) The KSS Expectation and Satisfaction Score is based on the patient's feedback. Patients are asked to compare their pre-op expectation with the post-op condition. Patients are also asked to rate their satisfaction on the level of post-op pain and knee functionality when performing some daily activities.
(d) The KSS Functional Score is based on the patient's feedback. Information with respect to the level of comfort when performing specific activities (standing and walking, standard, advanced and discretionary activities) is asked of the patients. Max value: 100.
(e) Referring to the Patient Satisfaction shown in Table 2 (Likert Scale[5]):
- the ROM of the participant who rated their satisfaction as "Poor" was not evaluated. It was not possible to calculate the KSS Objective Score for them.
- one participant who rated their satisfaction as "Fair" scored below the participant's Objective KSS average. The other participant who rated their satisfaction as "'Fair" scored above the participant's KSS Objective Score average.

Radiographs were analyzed to evaluate the presence of radioluciencies for all 19 patients. None of the 19 patients showed any relevant radiolucencies (i.e., radiolucent lines ≥ 2 mm) in their knees. The outcomes are specified and explained in Table 4.

TABLE 4. RADIOLUCENCY OUTCOMES IN THE TIBIA, PATELLA, AND FEMUR COMPONENTS

Radiolucency	Tibia	Patella	Femur
Radiolucency <1mm	n= 1 [f]	n= 0	n= 1 [g]
Radiolucency 1-2mm [i]	n= 0	n= 1 [h]	n= 3 [i]

(f), One participant presented a radiolucency measuring <1mm in the Tibia, but did not present any radiolucencies in their Patella or Femur
(g), One participant presented a radiolucency measuring <1mm in the Femur, but did not present any radiolucencies in their Tibia or Patella
(h), One participant presented a radiolucency measuring 1-2mm in the Patella, but did not present any radiolucencies in their Tibia or Femur
(i), Three participants presented a radiolucency measuring 1-2mm in the Femur but did not present any radiolucencies in their Tibia or Patella. The patella radiographs of one of these participants were not recorded.
(j), Referring to the Patient Satisfaction shown in Table 2 (Likert Scale [5]), for the three participants who reported their satisfaction as "Poor" or "Fair":
- one participant did not have any radiolucencies in the Patella, Tibia, or Femur
- one participant had radiolucencies 1-2 mm in their Patella
- one participant had radiolucencies 1-2 mm in their Femur.

CONCLUSIONS

84.2% of the participants rated their satisfaction with Medacta GMK Revision knee from "Good" to "Excellent". Moreover, even if functionality is often considered limited with a varus/valgus constrained prosthesis, the **patients reported remarkable levels of functionality in terms of KSS Functional Activity Score**.

Future larger long-term studies could certainly contribute to reinforcing the robustness of this result, but, given the rarity of the indications, the evidence presented in this report constitutes a significant contribution to the assessment of the improvement that can be achieved by GMK Revision. Also, the **absence of serious adverse events**, in spite of the rather demanding patient population, is a good indicator of the reliability of the device, the dedicated instruments and the surgical technique.

[1] Saint Alphonsus Medical Group (Boise, Idaho, United States) [2] The Knee Society. The 2011 Knee Society Knee Scoring System Licensed User Manual. December 2012 [3] Medacta USA. A Post-Market, Single-Center, Retrospective Study to collect Clinical Outcomes and Complications Data from patients who have undergone Revision Total Knee Arthroplasty using Medacta GMK Revision Prosthesis and are at least 2 years past surgery. Protocol # K102437-01. June 2015 [4] The center attempted to contact all patients but was unable to collect data on all the subjects due to a lack of interest. [5]Joshi A. et al. Likert Scale: Explored and Explained. 7(4): 396-403, 2015 BJAST 2015.157. February 2015

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