The Use of Semi-Constrained Knee Prostheses

Andrés Puchiele,[*] Martín Sienra,[**] Daniel Maurente[**]
[*]*Instituto Nacional de Ortopedia y Traumatología, Montevideo, Uruguay*
[**]*Knee Unit, Casmu, Montevideo, Uruguay*

ABSTRACT
Introduction: Semi-constrained implants in TKA are indicated in cases where knee stability is compromised, either in primary or revision surgeries. **Materials and Methods:** 43 patients were evaluated at the same institution, treated by the same surgical team between 2015-2022, with Sigma TC3 (Johnson & Johnson™) implants. **Results:** the WOMAC, KSS function and Oxford functionality scales had good/very good results. The scores were lower in patients over 75 years of age if they used gait assistance and if they had previous pathologies (statistically significant). 86% had no pain, 91% were satisfied, 11% had complications. There were no infections or revision surgeries. **Conclusions:** TKAs with Sigma TC3 present good outcomes in the short and medium term with a low rate of complications in this series, with no statistical differences in function between primary and revision surgeries.
Keywords: Knee arthroplasty; semi-constrained prosthesis; TC3.
Level of Evidence: III

Artroplastia total de rodilla con implante semiconstreñido. Análisis de serie de casos

RESUMEN
Introducción: Los implantes semiconstreñidos en la artroplastia total de rodilla están indicados cuando hay compromiso de la estabilidad de la rodilla, ya sea en cirugías primarias o de revisión. **Materiales y Métodos:** Se evaluó a 43 pacientes tratados con implantes de constricción condilar varo-valgo, en una misma institución, por el mismo equipo quirúrgico, entre 2015 y 2022. **Resultados:** Los resultados en las escalas de función WOMAC, KSS y Oxford fueron buenos/muy buenos. Los puntajes fueron menores en pacientes >75 años, si utilizaban asistencia para caminar y si tenían enfermedades previas (estadísticamente significativo). El 86% no tuvo dolor, el 91% estaba satisfecho y el 11% sufrió complicaciones. No hubo infecciones, ni cirugías de revisión. **Conclusiones:** Respetando las indicaciones y la técnica quirúrgica, las artroplastias totales de rodilla semiconstreñidas con constricción condilar varo-valgo logran buenos resultados a corto y mediano plazo, con una tasa baja de complicaciones, sin diferencias estadísticas en la función entre las cirugías primarias y de revisión.
Palabras clave: Artroplastia de rodilla; prótesis semiconstreñida; implante TC3.
Nivel de Evidencia: III

INTRODUCTION

The first total knee arthroplasties (TKA) date back to 1840, in Germany, where Glück treated patients with sequelae of tuberculous arthritis with an ivory prosthesis. Implant design and materials evolved and improved and, in 1940, metallic models appeared in the femur (Boyd and Campbell) and with tibial plates (Mckeever and Macintosh).[1,2] In 1976, Insall et al. introduced condylar prostheses with a structure and composition similar to the current ones. Emphasis was placed on implant design, ligament balance, symmetrical bone resection, and good alignment to ensure the lasting success of the implant.[3]

Implants have been improved in recent years, adapting to the needs of patients. Constrained and semi-constrained implants were developed to improve prosthesis stability when knee stability is compromised, which can occur due to significant bone deformity, bone defect, or ligament instability, either in primary or revision TKA surgeries.[3]

Received on November 28th, 2022. Accepted after evaluation on July 3rd, 2023 • Dr. ANDRÉS PUCHIELE • puchiele.andres@gmail.com https://orcid.org/0000-0002-8227-6777
How to cite this article: Puchiele A, Sienra M, Maurente D. The Use of Semi-Constrained Knee Prostheses. *Rev Asoc Argent Ortop Traumatol* 2023;88(5):478-484. https://doi.org/10.15417/issn.1852-7434.2023.88.5.1686

In the United States, more than 900 thousand TKAs are performed every year;[4] in Uruguay, an average of 2,284 primary and 53.1 annual revisions (average 2015-2020) are performed.[5] In Uruguay, a single study has analyzed TKA replacements and their survival,[6] and it highlights that semi-constrained implants are used in 89.1% of cases. There are no studies evaluating the use of these implants in primary TKAs.

In this study, we analyze the epidemiology, outcomes and complications of the use of a semi-constrained implant in a series of patients operated on by the same surgical team, in the same institution, with a minimum follow-up of six months.

MATERIALS AND METHODS

The research protocol was approved by the Institutional Ethics Committee before starting the research.

All patients undergoing TKA with a semi-constrained implant with varus-valgus condylar constriction at the treating surgeon's (DM) institution were included. The implant placed was SIGMA® TC3 Knee System (DePuy Synthes/Johnson & Johnson, Warsaw, IN, USA) which is the only semi-constrained implant tendered in our country.

The institutional database was used, which includes patients operated on between September 18, 2015 (date on which the first TKA with TC3 prosthesis was performed at the institution) and March 30, 2022 (minimum date to have 6 months of follow-up).

Medical records were reviewed and all registered patients were assessed by telephone call, applying specific knee function instruments: the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Knee Society Score (KSS) and the Oxford Knee Score. Patients were asked about their satisfaction after surgery and the presence of complications.

Statistical Analysis

Tables are presented to describe the variables analyzed. The study of differences between means was performed with Student's t test for independent samples. A p-value of 0.05 was considered statistically significant. Statistical analysis was performed with Excel (Microsoft) v16.65.

We acted in accordance with the national regulations in force, following Decree 158/019 issued by the Executive Branch according to the National Research Ethics Commission. The study was approved by the CASMU Bioethics Commission, File No. 221518 (07 Sept 2022).

RESULTS

All patients who had undergone TKA with a TC3 implant between 2015 and 2022 were evaluated, taking as the start date the date of the first surgery performed with this implant and, as the last date, April 2022 to reach a minimum follow-up of six months.

The implant was cemented in the femur and tibia; in some occasions, stems and wedges were used as needed. Fifty-one TKAs were performed with a TC3 implant; 43 of these patients were fit for evaluation (3 were lost to follow-up, 1 died, 4 were no longer walking due to other conditions). 79% were female and 21% were male, and the mean age at the time of evaluation was 73.7 years (range 54-90). Follow-up ranged from 6 months to 7 years (average 27 months). 63% of the surgeries were primary (previous osteosynthesis or osteotomy); and 37% were replacements (aseptic and infected).

According to the WOMAC scale, pain and stiffness were minimal, functional capacity was moderate, and outcomes were good according to the KSS (Table 1).

Satisfaction was good or very good in 91% of patients. 7% reported poor satisfaction (3 patients), 2%, frank dissatisfaction (1 patient).

56% used some type of walking assistance: cane (17 patients), walker or two canes (7 patients). 56% had an associated disease that could alter gait, such as osteoarthritis in another territory (knee, hip or spine), another arthroplasty, lumbar canal stenosis, and rheumatoid arthritis.

Data from the scores separated by subgroups were compared to see if any variable affected the results. They were compared to the overall score as well as between scores (Table 1).

The score results are good/very good when each variable is separated.

No statistically significant differences were found in surgery (primary or revision) and follow-up time between the subgroups (Figures 1 and 2).

Table 1. Scores in each subgroup and statistical analysis

Variable	Subgroup	n	Score				
			WOMAC			Oxford	KSS Function
			Pain	Stiffness	Final score		
Global		43	1.5	0.6	13.5	36.3	59.9
Surgery	Primary	27	1.2	0.5	13.6	38	59.8
	Revision	16	2	0.8	13.2	33.5	60
	Student's t		-1.11	-0.89	0.10	1.81	0.02
	p		NS	NS	NS	NS	NS
Follow-up	<1 year	19	2.1	0.8	13.8	34.3	69.7
	>1 year	24	1	0.4	13.1	37.9	59.1
	Student's t		1.54	1.18	0.18	-1.47	0.20
	p		NS	NS	NS	NS	NS
Satisfaction	Satisfied	39	1.2	0.4	12.4	37.6	62.1
	Not satisfied	4	4.5	2.5	24.2	24.3	38.8
	Student's t		-2.79	-3.91	-2.02	3.54	1.76
	p		0.008	0.000	0.049	0.001	NS
Age	<75	25	1.9	1.9	9.9	38	70
	>75	18	1.1	0.4	19.1	34	44
	Student's t		1.11	2.12	2.67	1.63	3.74
	p		NS	0.04	0.01	NS	0.000
Assistance	No	19	1.9	0.4	7.8	39.4	76.8
	Yes	24	1.2	0.8	18	33.9	46.5
	Student's t		1.00	-1.18	-3.11	2.35	4.70
	p		NS	NS	0.003	0.024	0.000

WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index; Oxford = Oxford Knee Score; KSS = Knee Society Score; NS = not significant.

Figure 1. Revision total knee arthroplasty in a patient with aseptic loosening.

Figure 2. Primary total knee arthroplasty in a patient with unstable valgus.

Patients of advanced age (>75 years), those who were dissatisfied, and those who used some type of assistance had statistical differences with the control group, but still remained in good/very good values.

The risk of using assistance was higher if the patient had concomitant diseases affecting gait (osteoarthritis in other territories, rheumatoid arthritis, and lumbar canal stenosis) (odds ratio= 8.4; relative risk = 3).

Five patients suffered complications: two had pulmonary thromboembolic events in the immediate postoperative period; one had deep vein thrombosis; two reported dysmetria requiring shoe enhancement; one reported pain that made walking difficult. There were no infectious complications or reoperations during the study.

14% reported that pain was a regular symptom; 16% reported that it was occasional; and 70% reported no pain. One patient reported that pain was a daily and persistent problem.

DISCUSSION

The use of augmented stability implants always represents a challenging scenario. These implants are used in revision and complex primary surgeries due to poor bone stock or ligament instability.[7]

Semi-constrained implants include a number of features that improve stability and balance gaps in flexion and extension,[8] such as larger femoral and tibial components, tibial and femoral stems, tibial metaphyseal steps and wedges to complement bone defects, deeper sockets and larger inserts.[9]

Few articles have been published analyzing semi-constrained TKAs and their outcomes (Table 2). In our study, 43 patients were evaluated at the same institution and operated on by the same surgeon. All obtained good/very good scores on the Oxford and KSS function and pain scales. In dissatisfied patients, those over 75 years old, and those who require assistance walking, the results worsen (with a significant difference), but remain at good/moderate values. These function and functional capacity scores seem obvious in patients who are older and require walking assistance, but the high percentage of satisfaction despite functional outcomes is noteworthy.

Table 2. Published studies on semi-constrained total knee arthroplasty and their outcomes.

Authors, year	Quantity	Indication	Implant	KSS	Complications
Baier et al., 2013	78	Revision	TC3	61	28%
Wilke et al., 2014.	234	Revision	TC3	49	17%
Sabatini et al, 2017	18	Primary	TC3 and CCK	92	NR
Vedoya et al., 2018	40	Primary	TC3, Optetrak, PFC®, hinges	79	4%
Pintos et al., 2021	156	Revision	TC3, hinges	-	25%
Zhao et al., 2021	50	Primary	TC3	85	25%
This study	43	Revision, primary	TC3	59.9	11%

KSS = Knee Society Score; TC3 = TC3 implant; CCK = Constrained Condylar Knee.

Scores show minimal pain in all groups, except in dissatisfied patients, with a statistically significant difference. Zhao et al.[10] found pain in 10% of patients; Vedoya et al.[11], in 16%, both in primary surgeries; in our study, 14% usually had pain.

A complete medical record, complementary tests, imaging studies, and microbiological analysis are all required for successful pain management; in general, pain is multifactorial, and the approach should be multidisciplinary.[8]

The patients' functional survival was 89.5%. At the end of the study, all retained the implant, but actual survival was not evaluated, because follow-up was highly variable. Actual survival in 10-year replacements in the authors reviewed was 86%[6] and 85%.[9]

The intraoperative and postoperative complications that have been published are similar to those that occurred in the patients in our study, i.e., thromboembolic events, habitual pain, extensor apparatus tears, dysmetria.

No infectious complications occurred during follow-up. Sabatini et al.[12] also reported no complications in primary surgeries, while Zhao et al.[10] reported 10%. Reported complication rates are 14%,[6] 8%,[9] 4%[13] in revision surgeries with TC3, and 6%[14] and 7%[15] with other semi-constrained implants.

There are no specific studies evaluating the use of assistance after TKA or predisposing factors. Vedoya et al.[11] report an 11% rate of cane use with various semi-constrained implants. In our series, 56% required canes or a walker; this affected function scores significantly, but not pain (Table 1). The risk of using assistance triples if the patient already suffers from a disease that affects gait (odds ratio = 8.4; relative risk = 3).

It is considered that 20-30% of patients are not satisfied after TKA and that only 40% live without pain.[8] These are general values and do not differentiate the type of TKA. Satisfaction is subjective and depends on the patient's own perception. We rated patients as dissatisfied if they reported little or no satisfaction (9% of the total).

A systematic review showed that, in revision surgeries, complications vary from 5% to 50% and that the success of the surgery and the results of the scores depend on several factors, such as gender, systemic diseases and age.[16]

In our field, semi-constrained TKA continues to play an important role, especially when primary TKA fails and when there are bone defects that can hardly be compensated with soft tissue releases or larger inserts. Hinged arthroplasty is reserved for the most challenging cases with instability and major bone defects.

The limitations of this study are those of a retrospective design, the evaluation was not face-to-face, and the follow-up of the series was insufficient to evaluate prosthesis survival and the prevalence of long-term complications. The dissatisfaction group has an n=4 which could generate a type B error as it is a small sample. Patients who required stems or wedges were not analyzed in a differentiated manner, which may generate an information bias when presenting with more severe disease.

The strengths are the number of patients operated on by the same surgical team, in the same institution, the use of several rating scales and the statistical analysis.

CONCLUSIONS

The use of the Sigma TC3 semi-constrained implant with varus-valgus condylar constriction achieved good or very good functional outcomes in all the patients analyzed, with a statistical difference in elderly patients (>75 years), those with previous diseases, and those who use walking assistance. There are no statistical differences in the results according to the type of surgery (primary or revision). Pain scores are very low, with high satisfaction rates. At present, good outcomes are obtained with this implant, and it is necessary to continue evaluating its survival and the appearance of complications in the coming years.

Conflict of interest: The authors declare no conflicts of interest.

M. Sienra ORCID ID: https://orcid.org/0000-0001-8017-1130

D. Maurente ORCID ID: https://orcid.org/0009-0002-8693-5546

REFERENCES

1. Hernández Vaquero D, Paz Jiménez J, Rubio González A. La artroplastia total como tratamiento de afecciones de la rodilla. *Rev Esp de Cir Ost* 1984;19(112):239-79. Disponible en: http://www.cirugia-osteoarticular.org/adaptingsystem/intercambio/revistas/articulos/1903_239-279.pdf
2. Gili Ventura F. Historia y evolución de la artroplastía de rodilla en Clínica Alemana de Santiago. *Contacto Científico - Cirugía de Reemplazo Articular en Clínica Alemana* 2014:4(5):71-6. Disponible en: https://xdoc.mx/preview/revista-alemana-jaimoindd-5e961cfb8842d
3. Insall J, Ranawat CS, Scott WN, Walker P. Total condylar knee replacement: Preliminary report. *Clin Orthop Relat Res* 1976;(120):149-54. PMID: 975650
4. American Academy of Orthopaedic Surgeons. Annual Report of the AJRR on Hip and Knee Arthroplasty 2020. Disponible en: https://www.aaos.org/globalassets/registries/2020-aaos-ajrr-annual-report-preview_final.pdf
5. Fondo Nacional de Recursos. 2020. Disponible en: http://www.fnr.gub.uy/estadisticas
6. Pintos-Demichelis B, Pache S, Francescoli L. Recambios de artroplastía de rodilla en el Uruguay en un período de 10 años: supervivencia y resultados. *Acta Ortop Mex* 2021;35(3):276-81. https://doi.org/10.35366/102367

7. Ihekweazu U, Courtney PM, Baral EC, Austin MS, McLawhorn AS. Modular junction fractures in a modern rotating-platform knee arthroplasty system. *Arthroplast Today* 2018;5(1):43-8. https://doi.org/10.1016/j.artd.2018.11.003
8. Hirschmann MT, Becker R. *The unhappy total knee replacement. A comprehensive review and management guide*. Springer; 2015. https://doi.org/10.1007/978-3-319-08099-4
9. Wilke B, Wagner E, Trousdale R. Long-term survival of semi-constrained total knee arthroplasty for revision surgery. *J Arthroplasty* 2014;29(5):1005-8. https://doi.org/10.1016/j.arth.2013.10.025
10. Zhao EZ, Zeng WN, Ding ZC, Liu ZH, Luo ZY, Zhou ZK. A comparison between unstemmed and stemmed constrained condylar knee prostheses in primary total knee arthroplasty: A propensity score-matched analysis. *Orthop Surg* 2022;14(2):246-53. https://doi.org/10.1111/os.13093
11. Vedoya SP, Garabano G, del Sel H. Indicación y resultados de la prótesis con estabilidad aumentada en la artroplastia primaria de rodilla. *Rev Asoc Argent Ortop Traumatol* 2018;83(2):94-100. https://doi.org/10.15417/issn.1852-7434.2018.83.2.775
12. Sabatini L, Risitano S, Rissolio L, Bonani A, Atzori F, Massè A. Condylar constrained system in primary total knee replacement: our experience and literature review. *Ann Transl Med* 2017;5(6):135. https://doi.org/10.21037/atm.2017.03.29
13. Baier C, Lüring C, Schaumburger J, Köck F, Beckmann J, Tingart M, et al. Assessing patient-oriented results after revision total knee arthroplasty. *J Orthop Sci* 2013;18(6):955-61. https://doi.org/10.1007/s00776-013-0467-1
14. Barnoud W, Schmidt A, Swan J, Sappey-Marinier E, Batailler C, Servien E, et al. Condylar constrained knee prosthesis and rotating hinge prosthesis for revision total knee arthroplasty for mechanical failure have not the same indications and same results. *SICOT J* 2021;7:45. https://doi.org/10.1051/sicotj/2021046
15. Nakano N, Matsumoto T, Muratsu H, Ishida K, Kuroda R, Kurosaka M. Revision total knee arthroplasty using the modern constrained condylar knee prosthesis. *Acta Ortop Bras* 2016;24(6):304-8. https://doi.org/10.1590/1413-785220162406146213
16. Roman M, Russu O, Mohor C, Necula R, Boicean A, Todor A, et al. Outcomes in revision total knee arthroplasty. *Exp Ther Med* 2021;23(1):29. https://doi.org/10.3892/etm.2021.10951