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ORIGINAL PAPER

Long-term follow-up of a non-randomised prospective cohort of one hundred and ninety two total knee arthroplasties using the NexGen implant

Alfredo Schiavone Panni[1] · **Franceso Falez**[2] · **Rocco D'Apolito**[1] · **Katia Corona**[3] · **Carlo Perisano**[1] · **Michele Vasso**[1]

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Abstract

Purpose The purpose of this study was to retrospectively analyse the clinical, functional and radiological outcomes, and the long-term survivorship of the NexGen Legacy Posterior Stabilised (LPS) knee prosthesis (Zimmer Biomet, Warsaw, IN, USA).

Methods Between 1996 and 2001, 197 primary NexGen LPS total knee arthroplasties (TKAs) were implanted by a single surgeon; 132 prostheses in 124 patients with a minimum follow-up of 15 years were included in the study. Surgical procedure and post-operative care were the same for all patients. All patients were assessed through the International Knee Society (IKS) scores and range of motion (ROM). A complete radiological study was performed for all patients. Failure was defined as revision of at least one prosthetic component for any cause.

Results IKS knee and function scores, as well as ROM and leg alignment, significantly improved at the latest follow-up ($p \leq 0.05$). No significant differences were found between fixed- and mobile-bearing groups. Seven implant failures were reported; the implant survival rate (overall) was 94.7% at the latest follow-up.

Conclusions This study showed optimal survivorship of the NexGen LPS, associated with a significant improvement in overall outcomes at a minimum follow-up of 15 years.

Keywords Total knee arthroplasty · Posterior-stabilised · Follow-up · Osteoarthritis · Long-term outcome

Level of evidence IV: retrospective case-series study

✉ Rocco D'Apolito
roccodapolito@hotmail.it

[1] Dipartimento Multidisciplinare di Specialità Medico-Chirurgiche e Odontoiatriche, Università degli Studi della Campania Luigi Vanvitelli, Via Luigi De Crecchio 6, 80138 Naples, Italy

[2] UOC Ortopedia e Traumatologia, Ospedale Santo Spirito in Saxia, ASL Roma 1, Lungotevere in Saxia 1, 00193 Rome, Italy

[3] Dipartimento di Medicina e Scienze della Salute, Università del Molise, Via Francesco De Sanctis, 86100 Campobasso, Italy

Introduction

Total knee arthroplasty (TKA) is one of the most frequently performed orthopaedic operations, and demand for this procedure is expected to rise to as high as 3.48 million per year in the United States by 2030 [1]. Literature has widely showed as TKA provides excellent ten year survivorship and significant improvement (by more than 30%) of the main knee scores [2–4]. The goals of TKA are to relieve pain and restore function, therefore allowing a return to normal daily and recreational activities [5]. The success of TKA depends on re-establishment of correct leg alignment, proper implant design and positioning, as well as adequate soft tissue balancing [6]. Additionally, knee function following TKA may be influenced by multiple factors such as patient's gender and age, pre-operative range of motion (ROM), primary diagnosis, surgical technique and rehabilitation program [7, 8].

Posterior-stabilised (PS) TKA is a common option for patients suffering from end-stage knee osteoarthritis. The NexGen Legacy® Posterior Stabilised (LPS) knee (Zimmer Biomet, Warsaw, IN, USA) was introduced in the mid-1990s as an evolution of the first-generation non-modular prosthesis (e.g. Insall-Burstein I [IB-I]) and second-generation modular PS prosthesis (e.g. Insall-Burstein II [IB-II]) with the aim of enhancing kinematics, patellar tracking and reducing patellofemoral (PF) complications compared to the previous design [9, 10].

Improvements included the introduction of side-specific femoral components, enhanced later flange of the femur, a deepened and lengthened trochlea, the addition of femoral lugs to avoid flexion of the femoral component during cementation. The spine-cam interaction has a similar pathway and angle of contact as IB-II, but is placed more posteriorly due to the different design of the trochlea. The tibial component is symmetrical [10–12]. The baseplate incorporates a dovetail locking mechanism for a compression-moulded, gamma-irradiated polyethylene (PE) PS insert. Both components consist of a titanium Ti-6Al-4 V alloy. The system includes a three-pegged, all-PE, modified-dome patellar component.

This third-generation prosthesis led to an overall decrease of PF complications and to the disappearance of patellar clunk compared to IB II. Moreover, it showed good results in terms of survivorship and clinical outcomes at short and intermediate follow-up. Anyway, long-term data are lacking. The aim of this study was, therefore, to analyse the clinical, functional and radiological outcomes, and the 15-year survivorship of the NexGen LPS TKA.

Materials and methods

Patients

Between 1996 and 2001, 197 primary NexGen TKAs were implanted in 189 patients by a single senior surgeon (A.S.P.). These included 179 NexGen LPS TKAs and 18 NexGen cruciate-retaining (CR) TKAs. The 18 NexGen CR TKAs were excluded from the study. Patients were not randomised to receive a PS or a CR implant, but the final decision was left to the senior surgeon. During the follow-up period, 13 patients died and 11 patients were lost. Eight additional patients were excluded due to the onset of decreased mental capacity or critical medical conditions. Among the remaining 147 prostheses, 132 NexGen LPS TKAs in 124 patients were available for follow-up and were, therefore, included in the study. The 132 NexGen LPS TKAs of the present study included 93 fixed-bearing and 39 mobile-bearing implants. Patients were not randomised to receive either a fixed or a mobile bearing. Mobile bearings were generally preferred in younger patients with less severe frontal deformities; fixed bearings were always used in older patients and in case of severe deformities, posterior cruciate ligament deficiency and systemic inflammatory arthritis. The primary diagnosis was primitive osteoarthritis in 106 knees, rheumatoid arthritis in 14 knees, avascular necrosis in five knees, psoriatic arthritis in four knees, and post-traumatic arthritis in three knees. Table 1 shows the demographic characteristics and clinical parameters of the study sample.

Surgical technique

All surgery was performed in a laminar airflow room, and all the members of the surgical team wore body exhaust suits. One-shot antibiotic prophylaxis (cefazolin, 2 g) was performed 45–60 minutes before the incision; in patients with hypersensitivity to cephalosporins or at high risk of methicillin-resistant *Staphylococcus aureus* contamination, vancomycin (1 g) was used 90 minutes before the incision. A tourniquet was positioned preoperatively but inflated, at a pressure of 350 mmHg, only during the component cementation. The surgical technique and instrumentation used were the same for both mobile and fixed implants. A standard medial parapatellar approach was used for all the knees, and both cruciate ligaments were sacrificed. The distal femoral cut was performed using an intramedullary guide which was set at between 5 and 7° of valgus in order to perform the cut perpendicular to the femoral mechanical axis. The axial femoral cuts were always performed at 3° of external rotation relative to the posterior femoral condyles using the Multi-Reference 4-in-1 Femoral Instrumentation® (Zimmer Biomet) as usually done in mechanically aligned TKAs [13]. The tibial cut was performed with an extramedullary guide, and set perpendicular to the tibial mechanical axis. In the sagittal plane, a 7° posterior tibial slope was planned in all cases.

After the bone cuts, spacers of different sizes were used to check the flexion and extension gaps, and ligament balancing was performed accordingly. Denervation of the patella and

Table 1 Demographics and clinical parameters

	Total	Fixed	Mobile
Number LPS TKAs	132	93	39
Sex	37 M - 95 F	27 M - 66 F	10 M - 29 F
Mean age	71.7 (range, 57-81) years	74.3 (range, 59-81) years	65.6 (range, 57-72) years
Side	52 left - 80 right	38 left - 55 right	14 left - 25 right
Pre-operative deformity	114 varus - 18 valgus	82 varus - 11 valgus	32 varus - 7 valgus
Pre-operative alignment	81.8° (range, 76-98°)	80.3° (range, 76-98°)	83.4° (range, 81-96°)
BMI	24.9 (range, 21.8-29.3) kg/m^2	25.2 (range, 22.7-29.3) kg/m^2	24.3 (range, 21.8-28.6) kg/m^2

osteophytes removal were always performed. Patellar resurfacing (with an all-PE component) was performed in 37 (28.0%) knees (34 knees in the fixed group, 3 knees in the mobile group). Similarly, no randomisation for patellar resurfacing was done. The reasons for patellar resurfacing were: severe PF degeneration or maltracking, and systemic inflammatory arthritis. All prosthetic components were cemented with gentamycin-loaded cement. Lateral release (without patellar resurfacing) was performed in three patients with a pre-operative valgus knee in whom a moderate patellar tilt persisted after component cementation. Intra-articular drain was used and removed 24 hours post-operatively, taking care to avoid accidental suturing and entrapment as described by Chen et al. [14].

Post-operative care

The patients received antithrombotic prophylaxis consisting of daily subcutaneous low-molecular-weight heparin starting 12 hours after surgery, and antithrombotic stockings. On the first post-operative day, the knee was placed in a continuous passive-motion (CPM) machine. The flexion angle of the CPM was initially set at 40°; thereafter, it was increased by 10° daily to reach 120° of maximum flexion. The CPM was used for three weeks. At the same time, patients started to perform knee active and passive mobilisation, as well as muscle strengthening exercises, under the supervision of a physical therapist; these were continued for at least five weeks. On the second post-operative day, they began standing and walking. Full weight-bearing was allowed immediately. Crutches were used for two weeks.

Clinical and radiological assessment

The patients were assessed using the International Knee Society (IKS) knee and function scores [15] and ROM. Weight-bearing long-leg AP view X-rays as well as Rosenberg, Merchant and lateral views of the knee were taken in all the patients. The clinical and radiological evaluations were performed preoperatively and at three, six and 12 months post-operatively, and yearly thereafter. The X-rays were used to calculate mechanical limb alignment, and to evaluate the

Fig. 1 A 68-year-old woman: pre-operative X-rays (**a**), 6 months follow-up (**b**), 16 years follow-up (**c**)

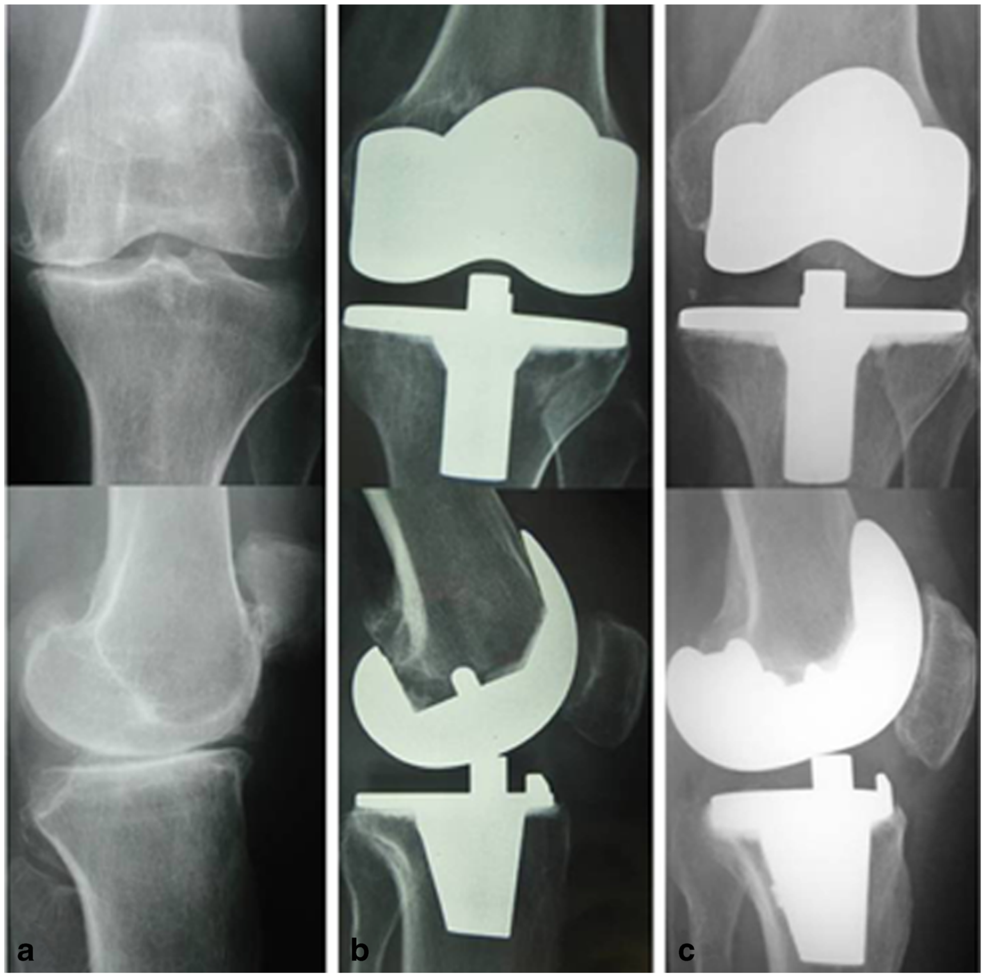

Fig. 2 A 62-year-old woman: pre-operative X-rays (**a**), 6 months follow-up (**b**), 16 years follow-up (**c**)

presence of radiolucent lines, osteolysis, component loosening and component subsidence. All the radiographs were analysed by a single author blinded to the patient names and data, and the findings were recorded by a research assistant blinded to the patient identities. No intra-observer or inter-observer analysis of the radiological findings was performed.

Table 2 Mean clinical, functional and radiological outcomes

TKAs	*n*	Score		
			Pre-operative	Final follow-up
Total	132	IKS knee (points)	42.5 (range, 35-52)	81.9 (range, 75-86) *
		IKS function (points)	48.2 (range, 40-55)	84.1 (range, 70-95)
		ROM	97.9° (range, 88-109°)	123.6° (range, 116-138°) *
		Leg alignment	81.8° (range, 76-98°)	89.5° (range, 87-92°)
Fixed	93	IKS knee (points)	39.7 (range, 35-48)	81.5 (range, 75-84) *
		IKS function (points)	46.5 (range, 40-50)	82.3 (range, 70-90) *
		ROM	96.1° (range, 88-104°)	121.4° (range, 117-128°) *
		Leg alignment	80.3° (range, 76-98°)	89.2° (range, 87-92°)
Mobile	39	IKS knee (points)	45.4 (range, 38-52)	82.4 (range, 78-86) *
		IKS function (points)	49.9 (range, 45-55)	85.9 (range, 75-95) *
		ROM	99.7° (range, 95-109°)	125.9°(range, 116-138°)
		Leg alignment	83.4° (range, 81-96°)	89.8° (range, 88-91°) *

*$p < 0.05$, indicating a statistically significant difference

TKA failure was defined as revision of at least one prosthetic component for any cause. All data were retrospectively collected. The ethics committee of the University of Molise does not require approval for the retrospective analysis of patient records and images.

Statistical analysis

Data analysis was performed using SPSS 23 (SPSS Inc., Chicago, Illinois) for Windows. Patient demographics and outcomes were described using means and ranges. A Student *t*-test was used to analyse mean radiographic changes and improvements relative to mean IKS scores and ROM values. The degree of statistical significance was set at $p \leq 0.05$. Kaplan-Meier survivorship analysis with 95% CI was performed to assess the survival of the prostheses at 15 years of follow-up.

Results

A total of 132 Nexgen LPS TKAs in 124 patients were retrospectively assessed for a minimum follow-up of 15 years (Figs. 1 and 2). The mean follow-up was 16.8 (range, 15-19) years. Mean clinical and radiological outcomes are described in Table 2. Significant improvements in all the parameters ($p \leq 0.05$) were found at the latest follow-up. No significant differences in postoperative IKS scores, ROM values and leg alignment were found between the fixed- and mobile-bearing groups (non-significant [n. s.]). Non-progressive radiolucent lines were observed in 12% of the fixed implants and 14% of the mobile implants (n. s.); in all these cases, the radiolucencies were not associated to pain or component loosening or subsidence. Minimal osteolysis (<5 cm) was observed in 3% of the fixed group and 5% of the mobile group (n. s.); in all these cases, osteolysis was not associated with pain,

Fig. 3 Aseptic loosening after 11 years (**a**). Revision with a CCK implant (**b**)

component loosening or subsidence. Seven (5.3%) TKA failures were reported (Fig. 3): two cases of infection (an acute infection in the fixed group occurring within 30 days post-operatively, and a chronic infection in the mobile group occurring eight months post-operatively); one case of instability occurring in the mobile group three years postoperatively; two cases of aseptic loosening in the mobile group occurring, respectively, six and 11 years post-operatively; one case of patellar component loosening in the fixed group occurring five years post-operatively; one case of pain in the fixed group occurring two years post-operatively. Moreover, one case of deep venous thrombosis and five cases of anterior knee pain (one of these requiring a secondary patellar resurfacing) were reported. The overall survival rate was, therefore, 94.7% [95% confidence interval (CI) 90.9-98.5%] at the latest follow-up (Fig. 4).

Discussion

TKA is considered to be the "gold standard" in the management of end-stage knee osteoarthritis. A massive increase in demand for primary and revision total joint procedures over the next two decades has been projected, and implant longevity is one of the key factors to address this trend [1]. The Nexgen LPS was introduced in 1995 as a comprehensive redesign of the IB-II [16] to optimise PF joint kinematics and reduce complication. Although good short- and mid-term results of this prosthesis have been reported [9, 10, 12, 16–22], long-term results are lacking. In the present series of 132 PS prostheses at a minimum follow-up of 15 years, we found an implant survivorship of 94.7% with significant improvement of clinical, functional and radiological outcomes. Additionally, two out of the seven failures were due to deep infection, whereas only five were due to mechanical reasons, including one case of unexplained pain.

The long-term results found in this series are similar to those reported about NexGen prostheses in other studies with shorter follow-up periods. Bozic et al. [22] reported a 95.9% survivorship at a five to eight year follow-up. A mean ten year follow-up study showed a survivorship of 96.7% for the fixed-bearing group (91 knees) and 98.8% (83 knees) for the mobile-bearing group [21]. Differently, a 100% survivorship of NexGen LPS in 100 patients undergoing bilateral TKA and receiving whether NexGen LPS or NexGen LPS-Flex at ten years of follow-up was reported [20]. Similarly, other authors showed no revisions in 46 NexGen LPS at ten years [10]. Recently, three mechanical failures were reported in a cohort of 132 TKAs with a 12-year follow-up: one patient with a neuropathic-like arthropathy underwent bilateral revision for loosening of the femoral components, whereas another patient was revised at 12 years for PE wear/osteolysis [9]. Finally, according to the Australian Orthopaedic Association

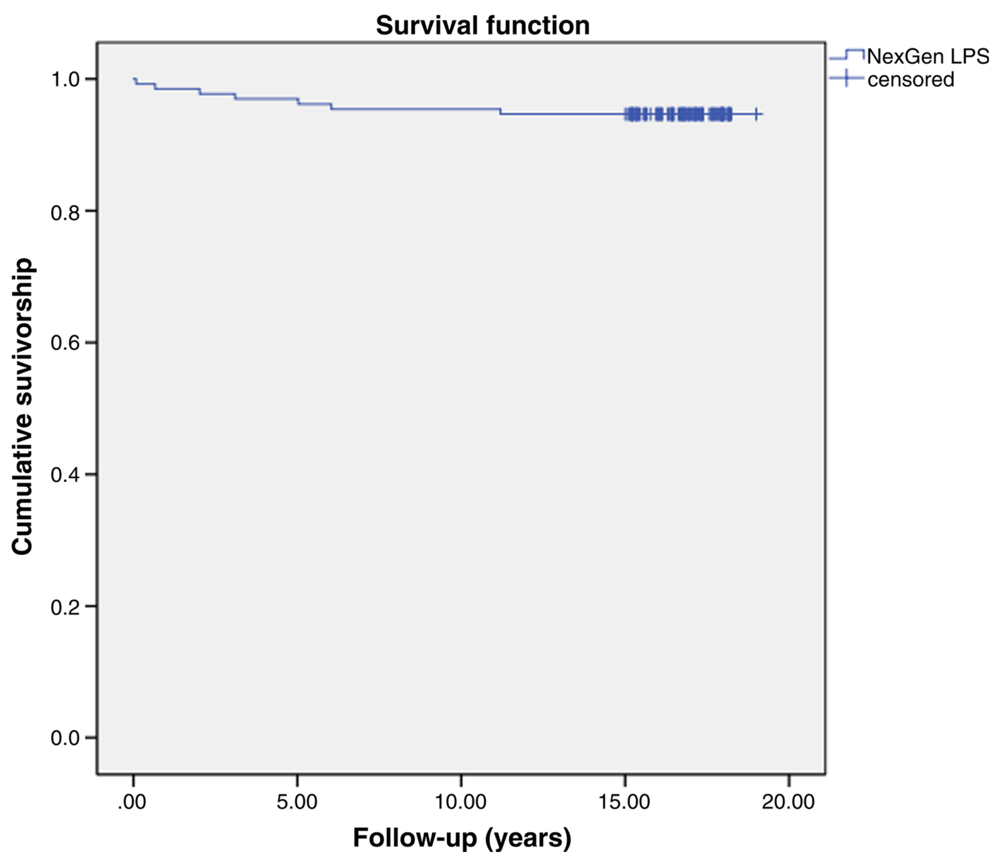

Fig. 4 Kaplan-Meier cumulative survivorship (94.7%) at 15 years with all failures as endpoint

National Joint Replacement Registry 2016 Annual Report the ten and 15-year cumulative percent revision for NexGen LPS have been reported to be 4.8 and 5.7, respectively [23].

Reports on the long-term results of TKAs different from the NexGen LPS show variable results, but the majority of the studies include old-generation implants. Roberts et al. [24] in a multicentre observational study of 4,606 TKAs of various manufacturers implanted between 1990 and 1992 showed that survival at 15 years was 92.2% in the best-case scenario and 81.1% in the worst-case scenario; revision was a result of aseptic loosening in 81 TKAs (34%), infection in 40 TKAs (16.7%) and wear of PE in 33 TKAs (13.8%). Lachiewicz and Soileau [25] published the long-term results of IB-II, reporting a 15-year survival of 96.8%; anyway, when failure was defined as any re-operation for any cause, the 15-year survival was 90.6%. The authors reported six re-operations: three re-operations were due to mechanical failure (flexion instability, aseptic loosening of the tibial component and tibial osteolysis) and three to other reasons. More recently, Victor et al. [26] reported a 98.1% survivorship at 15 years of follow-up for Genesis II® (Smith & Nephew, Memphis, TN, USA), with one revision for PE wear occurring 11 years after the index procedure. In the same study, the authors showed a 90.1% survivorship for Genesis I® at 15.5 years of follow-up; a total of ten revisions occurred, with five revisions due to PE wear, two to patella loosening, one to femoral loosening, one to infection and one to dislocation.

In the present case series, good radiological results were obtained, and close-to-neutral limb alignment was constantly achieved, regardless of pre-operative knee conditions or bearing (fixed or mobile) used (Table 2). A non-significant higher incidence of radiolucencies (14%) and minimal osteolysis (5%) were observed in the mobile group, although these findings were neither pathological nor associated with pain or implant loosening. It is well recognised that radiolucent lines and isolated minimal osteolysis after TKA occur mostly in the absence of any mechanical complication and explanation [27, 28]. In the above-mentioned studies, the reported incidence of non-progressive radiolucencies and/or non-pathological osteolysis was strongly variable, ranging from 0 to 32% and from 0 to 12% of the knees, respectively [9–18].

The main limitation of this study was that a non-randomised case-series was presented. Moreover, the results were not compared with any control group. Additionally, a selection bias could have occurred towards the specific kind of implant, i.e. PS or CR, mobile or fixed bearing, or patellar resurfacing or not. PS fixed implants were always used in older patients and in case of severe deformities, posterior cruciate ligament insufficiency or chronic inflammatory arthritis. Mobile bearings were generally preferred in younger patients with less severe frontal deformities. Although the differences reported between the fixed- and mobile-bearing groups in overall outcomes, incidence of pathological radiolucencies and osteolysis were not statistically significant, longer follow-up is needed to verify whether higher functional demands in younger patients might lead to PE wear, osteolysis and/or implant loosening in the mobile group. Patellar resurfacing was reserved for patients with severe PF degeneration and/or maltracking, and in those with chronic inflammatory arthritis. The reduced width and thickness of the femoral flange and the deepened patellar groove of the NexGen LPS system relieves pressure on the extensor mechanism therefore reducing anterior knee pain, patellar component loosening, and incidence of lateral retinacular release. In the present series, only one case of patellar component loosening occurred out of a total of 37 (2.7%), whereas lateral release was necessary only for three (2.3%) knees with pre-operative valgus.

Despite these limitations, the present report provided valuable information of clinical relevance. The NexGen LPS system allowed the achievement of satisfactory clinical and radiological results, and a high implant survival rate (94.7%) at 15 years (Fig. 4). Moreover, these optimal results were obtained through a relatively simple and conventional surgical approach. Our results confirm those of other authors, who have already showed the good outcomes of the NexGen knee replacement system [9, 10, 12, 16–22], although with shorter follow-ups.

Compliance with ethical standards

Funding This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest Alfredo Schiavone Panni, Francesco Falez, Rocco D'Apolito, Katia Corona, Carlo Perisano and Michele Vasso declare that they have no conflicts of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional 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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