

Research Article

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Logic is Enough: A Clinical Evaluation of All-Poly Cruciate Retaining Total Knee System for Treating Osteoarthritis Patients (Three-Year Follow up Study)

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Abstract

Introduction. Osteoarthritis (OA) is the single most common cause of disability in older adults. Total Knee Arthroplasty (TKA) is a surgical procedure that is beneficial to a majority of patients suffering from OA. Still many are not able to access TKA because it is expensive. And yet despite advancement in technology that have driven increase in total costs of knee devices many aspects of these newer design and material components continue to be debated. Logic 1.0 is an all-poly, cruciate retaining total knee device that incorporates essential design features that adhere to basic principles of proven long-term results in order to lower down costs. It is potentially a cost-effective device to resource challenged patients without compromising on good clinical outcomes.

Aim: To review the clinical outcomes for efficacy and performance of Logic 1.0 Total Knee System for the management of Osteoarthritis (OA), at a minimum of three years follow up.

Materials and Methods: For this retrospective study, a review of clinical data of patients treated with Logic 1.0 Knee System whose age are 60 and older and who completed at least 3 years follow-up. Patients treated for OA were included while the patients who received the implant for treatment of rheumatoid arthritis, burn-out TB of the knee and traumatic injury were excluded. The performance endpoint was defined as the absence of any revision TKA, absence of aseptic loosening, and absence of implant failure at three-years follow up. Secondary efficacy endpoint was to determine the clinical and functional performance of patients as per the American Knee Society Score (AKSS)

Results: A total of 72 implants were followed up on 62 patients. Ten (10) patients who received bilateral knee replacements at index surgery. Thirty-five (35) implants were fitted in the left knee while 37 implants were fixed in the right. The study group is comprised of 22.5% men and 77.4% women with a male: female ratio of 1:3. The mean age of the patients was 69.4 years at index surgery. One (1) had revision for periprosthetic joint infection and one (1) had patellar instability resulting to a complication rate of 1.38% each. Performance at 3 years is 98.61% successful. A comparison of means AKSS using Student's T-test with significance at $p < 0.05$ before surgery and after 3 years follow-up was done. Clinical AKSS improved from 48.46 to 94.29 (p value 0.0031) before TKA and at 3 years follow-up, respectively. Functional AKSS score improved from 44.99 to 93.49 (p value 0.028) and range of motion likewise increased from 88.82° to 106.53° (p value 0.0350).

Conclusion: The evaluation of Logic 1.0 Knee System for TKA in treating OA, at a minimum of three years follow up showed excellent outcomes in terms of performance (98.61%), increases range of motion of the knee, improved clinical results and enhanced functionality of patients.

Introduction

Osteoarthritis (OA) is the single most common cause of disability in older adults. According to the United Nations [1], by 2050 people aged over 60 will account for more than 20% of the world's population. Of that 20%, a conservative estimate of 15% will have symptomatic OA, and one-third of these people will be severely disabled. This means that by 2050, 130 million people will suffer from OA worldwide, of whom 40 million will be severely disabled by the disease. Total Knee Arthroplasty (TKA) is a commonly performed surgical procedure that is beneficial to a majority of patients suffering from OA [2]. Over the past five decades, Total Knee Arthroplasty (TKA) has evolved as a successful procedure for the management of pain, deformity and motion restriction related to severe degenerative arthritis [3]. The increasing global geriatric population will be a major factor in boosting TKA utilization and market growth. Global Market Insights, Inc. has recently added a new report on the knee replacement devices market which estimates the global market valuation will cost USD \$12 billion by 2026. [4] Advancement in technology in terms of design and building materials has made TKA a highly effective, safe, and predictable orthopedic procedure and will further increase its utilization specially in more developed and advanced economies [5-7].

In the Philippines, despite its growing elderly population TKA is underutilized because of poor access and high cost of the procedure. Only in focusing to address these factors will the elderly benefit from this life-enhancing technology. Logic 1.0 Total Knee System is an artificial prosthetic device for primary total knee replacement that is simple and straight-forward. It is a system that resulted from numerous experiences of other surgeons. Its pragmatic design principle is culled from volumes of historical and validated clinical data resulting to a relatively economical total knee system without sacrificing effective clinical outcomes. The present study was conducted to retrospectively review the clinical outcomes for efficacy and performance of Logic 1.0 in TKA.

Materials and Method

This is a study to evaluate clinical results of patients who underwent total knee replacement with Logic 1.0 TKA. Patients were required to affirm consent as prerequisite to surgery. Pre-operative evaluation included each patient to answer questionnaire from the American Knee Society Score.

Three hundred and fifty (350) patients underwent TKA using Logic 1.0 done in various level 1, level 2 and level 3 hospitals in the Philippines from January, 2013 to December 2019. The senior author either operated as primary surgeon or primarily assisted another surgeon. Patients who qualified under the inclusion criteria were enrolled into the study.

All the patients above the age of 60 years and who completed at least three years after index primary TKA were observed for the study purpose. Only patients diagnosed with degenerative OA were included. Patients who received the implant for treatment of rheumatoid arthritis and post burn-out infection (TB) or traumatic

arthritis were excluded.

Study Device

The study device is a cruciate retaining femoral prosthesis with aspect ratio of 1.06 that fits in a generally smaller and rounder Asian knee. It has a distal articulating thickness of 9 mm and a posterior condylar thickness of 10 mm. The anterior flange is relatively thin and shallow. The device comes in 3 sizes based on antero-posterior (AP) dimensions: 62.7 mm, 56.8 mm, and 60.8 mm with corresponding laterality (Left and Right).

The all-poly mono-block tibial base plate is made from Ultra High Molecular Weight Polyethylene (UHMWPE) and is available only in posterior cruciate ligament-retaining (CR) design. The UHMWPE tibial component has a single central peg with fins for rotational stability. The undersurface is cut in honey-combed design with pocket depth of 1.5 mm for bone cement fixation. The articulating surface is relatively flat and is designed to allow substantial femoral roll-back and providing high flexion of the knee.

Components are double sterilized with gas plasma (J&J Sterrad®).

Surgical procedure

All patients underwent cardio-pulmonary evaluation and clearance by an Internist. They were given pre-operative prophylactic antibiotics and single dose of Tranexamic acid prior to induction of anesthesia. Spinal epidural anesthesia was induced on all patients. Tourniquet was applied on the proximal thigh ipsilateral to the surgical site. The operative procedure was performed via the mid-vastus approach [8]. The gap technique for tissue balancing was performed in all knee patients. Insertion of components were fixed with bone cement mixed with 2 grams of vancomycin.

Postsurgical bleeding and swelling were controlled by using ice packs. Circular elastic bandaging of the limb was used to prevent deep venous thrombosis. Early quads setting exercises were initiated once the drainage tube was removed two to three days post-surgery or when drainage reached < 100 ml. The day after removal of the drainage tube, passive knee joint exercises were initiated with gradual progression towards weight-bearing and walking. These were done during hospitalization while intravenous antibiotics were being administered for 2 days. Patients were discharged after the fourth or fifth day along with continuance of oral antibiotics and pain relievers. Arrangements for physical therapy at home were arranged prior to discharge. Home physical therapy program was continued to 6 weeks. Skins staples were removed after 2 weeks. Monthly follow-up was advised until six months and subsequent yearly visits were advised.

At the end of three years following the index TKA procedure, patients were contacted either through social media or through their primary surgeons in the provinces who have direct contact with the patients in their clinic. Patients were assessed using the AKSS during clinic visit. They were asked to fill-up individually the (AKSS) Sheets available in the clinic or the internet [9]. Their

AKSS scores were digitally sent or hard copies made available to the clinic upon follow-up. The performance endpoint was defined as the absence of any revision TKA, absence of aseptic loosening, and absence of implant failure at three-years follow up. Secondary efficacy endpoint was to determine the clinical and functional performance of patients as per the American Knee Society Score (AKSS) [10].

Results

A total of 72 implants were followed up in 62 patients. Ten (10) patients received bilateral knee replacements at index surgery. Thirty-five (35) implants were installed in the left knee while 37 implants were installed in the right. The study group is comprised of 22.5% men and 77.5% women with a male:female ratio of 1:3 (Figure 1). The mean age of the patients was 69.4 years (Figure 2).

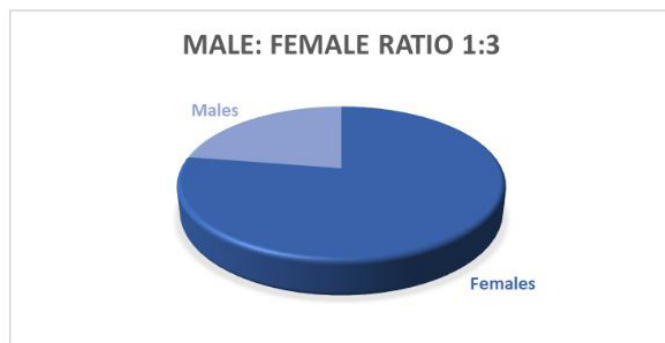


Figure 1: Gender Distribution of TKA Patients, N=62.

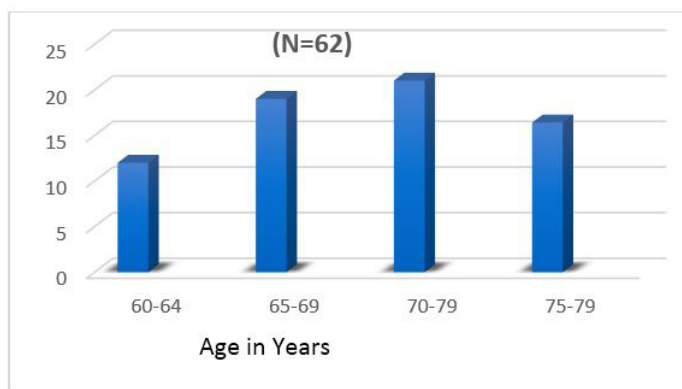


Figure 2: Age Distribution of TKA Patients Infection.

One implant on a bilateral knee had to be revised because of infection *S. epidermidis*. The device was removed and replaced with antibiotic beads spacer (vancomycin mixed in PMMA with gentamicin). After twelve weeks on antibiotics and with the infection controlled clinically with improved CRP, diminished ESR and negative gram stain results of the surgical site; revision arthroplasty was done on the involved knee. The index surgery and the revision surgery were both performed in a provincial hospital in Mindanao. No other revisions were done for any complication arising from implant failure or loosening. Infection rate from this series was 1.38%.

Patellar instability

There was one case of patellar instability on the right knee of a post bilateral TKA which was advised surgery. This instability occurred in a 74-year-old female patient with previous bilateral genu valgus of 15 degrees on the right and 5 degrees on the left. The left was performed first without complications using an all poly tibia with a thickness of 11 mm. The right knee was exposed using the same standard median para-patellar approach. Both patellae were not resurfaced. The latter had greater bone loss and a 15 mm AP tibia was introduced. Alignment was corrected for both knees and post-operative course was unremarkable. Six months after TKA patient's range of motion on the left knee improved from 90° to 110° of ROM and that of the right from 80° to 110° of flexion. Occasionally she would complain of anterior knee pain which was relieved by rest. On her 7 months after surgery as she was doing her daily chores while standing she twisted her body to the left causing her to forcibly externally rotate her right knee. She felt a sudden "clunk" and fell and noted her knee to swell gradually. No consult was done. During the ensuing weeks she noticed her knee-cap to dislocate laterally upon sitting down. Physical examination confirmed a lateral patellar instability. The condition was explained to the patient and was advised medial parapatellar repair at this time for which she refused; she opted to observe and to wear a patellar brace instead. At 18 months post-op, a visit to the clinic revealed that the instability has not improved. At this time, she was advised revision TKA. She again refused the operation and she sought for another opinion.

Clinical outcome by American Knee Society Score (Table 1).

American Knee Society Score comparison between preoperative and three-year follow up				
Variables	Preoperative (N=72)	3-year follow up (N=69)	p-value<0.05 is significant	
Clinical AKSS Score	48.46 ± 13.15	94.29 ± 3.74	0.0031	Significant
Functional AKSS Score	44.99 ± 8.42	93.49 ± 5.88	0.0028	Significant
Range of motion (mean SD)	88.82 ± 5.87	106.53 ± 7.55	0.035	Significant

Table 1: Comparison of AKSS between pre-operative and 3 years follow-up of patients with Logic 1.0.

The mean preoperative clinical AKSS score was 48.46 ± 13.15 (s.d.) and the score after 3 years follow up increased to 94.29 ± 3.74 (s.d.). The final outcomes at three-year follow up were significantly higher than the pre-operative scores at $p < 0.5$. Therefore, there was improvement of clinical performance of the knees who underwent TKA with Logic 1.0 Total Knee System. With regard to range of motion of the affected knee from a mean of 88.82 ± 5.87 (s.d.), there was an increase of 17.708 to 106.53 ± 7.55 (s.d.). The difference the means of those patients' knees measured prior to surgery compared to those after 3 years follow-up was statistically significant. Functional capabilities were assessed using the AKSS on the patients' ability to walk a certain distance, ability to climb stairs and whether or not walking aids were used during ambulation. The mean of scores before surgery was 44.99 ± 8.42 (s.d.) and at 3 years follow-up there was an increase of 48.5 to 93.49 ± 5.88 (s.d.). The difference was statistically significant with the p value of 0.0028 ($P < 0.05$).

Discussion

Technological advancement and increasing sophistication of healthcare will enhance focus on quality of life for the elderly as the average lifespan becomes much longer than in the past. The increase in the geriatric population will spur the demand for knee replacement, and this will fuel the incessant investments in research and development of medical device manufacturing companies. Newer claims by medical device manufacturing companies that use these claims for marketing strategies eventually contribute to increasing unit cost of the device in the global market. Since the 1860's when the first primitive hinge joints made of ivory were surgically implanted better understanding of biomechanics and knee kinetics, materials engineering, advances in knee device design and surgical techniques have contributed to clinical outcomes that have even outlasted the patient's life span. However, certain aspects of knee implant design continue to be debated in the orthopedic community. Corollary to this, newer knee components and concepts may not necessarily perform better than older ones. Logic 1.0 TKA Sytem is designed and manufactured from proven and verifiable clinical evidence in order to make available this sophisticated technology to financially challenged patients or economies.

All-polyethylene (APT) versus Metal-Backed Tibial component (MBT)

The design of the tibial component is an important factor for implant failure in total knee arthroplasty [11-13]. The metal-backed (MBT) design of tibial component has become predominant in TKA because it is thought to perform better than the all-polyethylene tibial component designs [14]. In theory, the MBT component reduces bending strains in the stem, reduces compressive stresses in the cement and cancellous bone beneath the baseplate (especially during asymmetric loading), and distributes load more evenly across the interface [15,16]. When TKA was introduced in the early 1970s, implants included APT components. The shift in surgeon preference from APT to MBT components occurred in the 1980s following unfavorable results from early laboratory finite element and in-vitro biomechanical studies with APT.

However, critics of the MBT component claim that these are expensive implants owing to its additional metal tibial tray; there is also corresponding reduced polyethylene thickness with the same amount of bone resection. There are issues on backside wear, and increased tensile stresses at the metal- bone interface during eccentric loading which contribute to "poorer" results [11,14,16,17]. In the early 2000s to the present several metanalyses of RCTs and clinical trials with short and long-term follow-up were published to compare of AP versus MB tibial components. They have concluded that AP tibial component was comparable with or better than the MB tibial component in TKA [17-25].

In the modern era of TKA, however, a majority of orthopedic surgeons utilize MBT components rather than nonmodular, mono-block all-poly tibial component [26]. Interestingly, current clinical evidence does not explain this disproportionate practice by surgeons despite evidence from current studies that have revisited the AP versus MB tibial components which demonstrate similar implant survivorship and patient outcomes. The study devise is all-polyethylene tibia (AP) non-modular mono-block which cost less than tibial metal backed tibial components. It utilizes knee instruments with an external alignment guide to create a proximal tibial cut perpendicular to the mechanical axis of the lower limb. The APT come in thickness of 10mm, 13mm and 15mm based on the most common thickness among Filipino or Asian knees.

Cruciate Retaining versus Posterior Stabilized Knee Design

Posterior-stabilized (PS) and posterior Cruciate Retaining (CR) total knee arthroplasty prostheses have had high success rates, but it is unclear whether one design has superior outcomes [27]. This debate of CR versus posterior stabilized (PS) designs in total knee arthroplasty is ongoing. With the posterior cruciate ligament retained, the TKA is supposed to function better in terms of proprioception, balance and kinematics. In contrast to that, PS designs are supposed to lead to higher degrees of flexion and a better femoral rollback [28]. However, in terms of long-term implant survival in more than 63,416 TKAs showed posterior Cruciate-Retaining (CR) implants had significantly improved survival rates compared to posterior cruciate-stabilizing prostheses [29]. Likewise, Abdel et al [30] reviewed retrospectively at 15 years of more than 8000 TKAs showed that CR had improved survival compared to PS. This ongoing debate suggests that the choice of implant could be based on surgeon's preference. For consideration of simplicity and effectiveness and unlike other prostheses which offer options between CR and PS this study device limits its inventory to cruciate retaining design and therefore, effectively lessen production and inventory cost.

Patellar Resurfacing versus Non-patellar Resurfacing

The ideal management of the patella during Total Knee Arthroplasty (TKA) is still controversial. Patellar retention is generally associated with an increased rate of anterior knee pain; however, patient satisfaction is similar in cases of replacement or retention. When the patella is replaced, potential severe complications can occur [31]. Some surgeons advocate resurfacing in all patients, while others restrict resurfacing to patients with known patellofemoral arthritis. Conclusions in many studies were limited, with methodological failures and biases, meaning that the true value of the procedure is still constantly debated [32,33]. This study device is a non-resurfacing TKA system. It does not carry in its inventory patellar implants nor instruments for patellar resurfacing effectively lowering total cost. Thus, from the typical four component device consisting of: 1] a metallic femoral component; [2] metallic tibial tray; [3] a polyethylene plastic tibial articulating insert; and [4] a plastic patellar button, this device has only two components i.e. a metallic femoral component coupled with all-poly tibial mono-block UHMWPE which are cruciate retaining. (Figure 3).

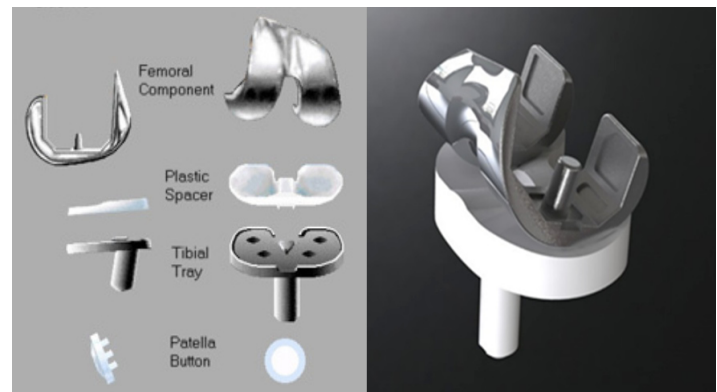


Figure 3: The typical 4-component TKA device (left figure) compared with the 2-components: metallic femoral component and all-polyethylene mono-block tibial component (right figure).

Clinical Outcomes

In 1989, [34] the “American Knee Society” group published an examiner-dependent clinical evaluation system known as the “American Knee Society Score” (AKSS) scale, divided into two components. The first assesses the knee clinically through the physical examination (Clinical AKSS - “Knee Score”), and the second assesses the individual’s functionality (Functional AKSS - “Function Score”), while both attain a total of 100 points each. The objective of this separation was to make the scoring of the Clinical AKSS independent on the Functional AKSS, not being influenced by variables such as comorbidities and advanced age. The Clinical AKSS evaluates pain, and range of motion, and stability. The maximum score of 100 points is reached when there is no pain, with good alignment of the knee in extension, and at least 125° of range of motion, without any anteroposterior or mediolateral instability. Deductions are made for flexion contracture, loss of extension and poor alignment. The Function AKSS evaluates the walking ability. The maximum score of 100 points is attributed to the individual capable of walking unlimited distances without walking aids, and of climbing and descending stairs normally. Deductions are made for the use of canes, crutches or walking frame [35-37]. The AKSS is currently the scale of choice in the United Kingdom for evaluation between the pre and postoperative results of TKA [36].

A study by Martibianco, et al [37] aimed to analyze the reproducibility of the “American Knee Society Score” (AKSS) scale in comparison to the SF-36 and WOMAC questionnaires. This study concluded that the AKSS (“American Knee Society Score”) scale is useful and reliable for evaluating individuals with osteoarthritis or submitted to TKA, demonstrating good measurements of psychometric properties. The Clinical AKSS scores and Functional AKSS of patients who underwent TKA using Logic 1.0 showed marked improvement at 3 years after surgery compared to the AKSS scores before surgery (Figures 4 & 5). This was statistically affirmed using a Student’s T-test with $p < 0.05$.



Figure 4: Patient with genu valgus treated with Logic 1.0 Before TKA (Left) and after TKA (right).

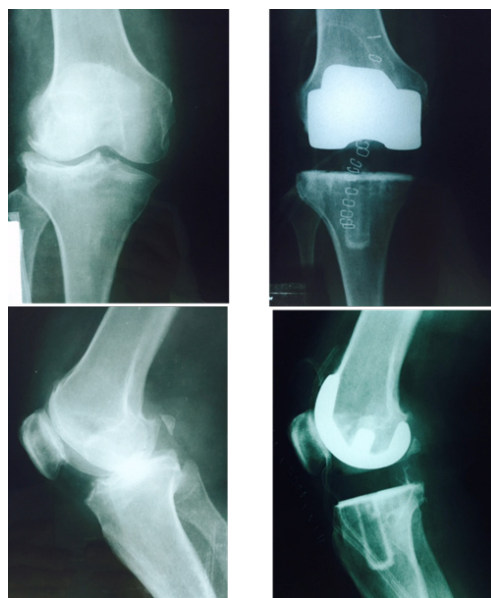


Figure 5: Pre-operative (Left) and post-operative (Right) radiographs of patient with Logic 1.0.

Patellar instability

An expected consequence of exponential rise of primary TKAs done worldwide is an increase of failures and revision TKAs.

And the reasons for most failure of total knee arthroplasty in the short term i.e., 3 years depend on several factors. These included surgical techniques, implants, demographic variants, etc. Taking knee implant designs and biomaterials into consideration the one factor that influence the number of revisions is the experience of the surgeon. Gomez, et al. [38], in a review of factors associated with TKA revision within 3 years from index surgery showed that revisions were statistically significant ($p < 0.001$) in teams with no expert in arthroplasty. The percentage of revision for instability as a factor was 8.3%; in teams with one expert, it was 4%; and in teams with two experts, it was 0%. All 72 TKAs in this study were performed with the senior surgeon either as the primary surgeon or assisting another surgeon. There was one case of patellar instability on the right knee of a bilateral TKA as was discussed earlier (refer to Results section of this paper).

Review of this case concluded that this resulted from a technical error during surgery probably secondary to component malrotation. Of note is the fact that the contralateral TKA on the left knee was performing well until the last follow-up. This case represented 1.4% (1/72 TKAs) complication well within the 8.3% for instability and 4% complication rate reported by Gomez, et al. with only one expert in the surgical team.

Infection

Infection after total knee arthroplasty (TKA) is a topic of great interest for orthopedists. Despite extensive research in order to decrease TKA infection rates they have continued to be between 0.4% and 2% after primary arthroplasty and between 3.2% and 5.6% after revision arthroplasty [39-43]. Long-term follow-up has shown a periprosthetic infection rate of 1.55% over the first two years after TKA and 0.46% per year after this period, until the tenth year [44,45]. This series of 72 TKAs had one infection on the left knee of 69-year-old female 6 months from bilateral TKA. Culture from her draining site revealed *S. epidermidis* that resulted to removal of the TKA components and exchanged with temporary antibiotic cement spacer. After administering 6 weeks of antibiotics and improvement of clinical signs the patient underwent revision TKA and has since presented no signs of infection. This series has an infection of 1.4% which is comparable to 1.55% periprosthetic TKA infection rate as reposted by Kurtz, et al and Berberi, et al. Periprosthetic joint infections can be a devastating complication. As such numerous literatures were published to identify risk factors and mitigate these risks inherent on patient’s clinical condition and the environment [46]. In the hospital setting measures including exhaust suits, laminar air flow operating rooms, ultraviolet lighting, perioperative antibiotics, and antibiotic-impregnated cement have been introduced in an attempt to control infection rates after joint replacement surgery. In most provincial hospitals in the Philippines only the latter three conditions are conformed to. While it is difficult to draw any assumptions from this limited series with comparable infection rate of 1.4% it is noteworthy to underscore that adherence to meticulous identification of possible patient clinical factors by improving and correcting them prior to surgery is of utmost importance.

Cost and benefit

Southeast Asia's population is 668,000,000 in 2019 and is expected to exponentially increase because of its relatively young population. However, the elderly (65 years old and above) constitute roughly around 87 Million representing 13.13% average among 10 member nations including the Philippines. The Philippines with a projected elderly population of 10.2 Million accounts for almost one-fifth of the old people in Southeast Asia and along with Indonesia and Vietnam, these three nations make up two-thirds of elderlies in the region. Total knee arthroplasties have significantly increased worldwide in the last decade. Based on prevalence studies established from the Framingham study, [47] there are 1.2 Million Filipinos alone who are suffering from degenerative osteoarthritis of the knee (OA). While 27% of this cohort will present radiographic evidence of OA (KL=2), almost 35,000 individuals will experience severe pain needing total knee replacement.

The personal benefit of a total knee procedure [48] is well established. Based on a study by Kurts, et al [49] the average total knee replacement was 175 /100,000 population. A nearly 27-fold range of TKA utilization rates was observed between the 18 different countries included in the survey. It is apparent from the results of this study that the demand for TKA has risen substantially over the past decade in countries around the world. The Philippine health system is undergoing major changes in its structure due to adoption of Universal Healthcare Law in 2019 that assures access to quality health services. The law assures better quality services to the poor, the marginalized and the elderly. The national population demographics although skewed favoring a younger population has a projected average total knee replacement of 32/100,000 population. However, because of various factors such as cost, access, personal biases and fear the Philippines average only about 0.9 TKAs per 100,000 population. While no prospective studies have been published on the matter affecting utilization rates of TKA in the Philippines the senior author suspects that cost of knee (Table 2) replacement device in the context of TKA is a major hindrance in limiting the country's elderly population from accessing and benefitting from this life-enhancing technology.

Comparison of Prices (in USD) Total Knee Devices in the Philippines			
Logic 1.0	OI Axis	U2	Other US Brands
990.89	1,415.56	2,022.24	3,033.36 to 4,044.48

Table 2: Comparison of Prices (in USD) Total Knee Devices in the Philippines.

The study established the effectiveness and performance of the Logic 1.0 Total Knee System for total knee replacement in patients with osteoarthritis. It is indicated for patients 65 years and older and clinical results showed improvement in the patients' functions capability and pain by AKSS. This all-poly mono-block tibial design and the Asian-fit femoral CR component produce effective clinical outcomes and offer substantial cost-lowering stratagems.

Limitation

Small patient population and a relatively medium-length follow up period were the main limitations of the study. A study with a larger patient population followed up for longer duration of 10-15 years is required to establish long term efficacy, performance and survivorship of the knee implant.

Conclusion

The evaluation of Logic 1.0 Knee System for TKA in treating OA, at a minimum of three years follow up showed excellent outcomes in terms of performance, increases range of motion of the knee, improved clinical results and enhanced functionality of patients.

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