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Total knee replacement survivorship by Design Philosophy: are we ignoring medial pivot design? Analysis based on the UK National Joint Registry

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The UK National Joint Registry(NJR) has not reported total knee replacement (TKR) survivorship based on design philosophy alone, unlike its international counterparts. We report outcomes of implant survivorship based on design philosophy using data from NJR's 2020 annual report. All TKR implants with an identifiable design philosophy from NJR data were included. Cumulative revision data for cruciate-retaining(CR), posterior stabilised(PS), mobile-bearing(MB) design philosophies was derived from merged NJR data. Cumulative revision data for individual brands of implants with the medial pivot (MP) philosophy were used to calculate overall survivorship for this design philosophy. The all-cause revision was used as the endpoint and calculated to 15 years follow-up with Kaplan-Meier curves. 1,144,384 TKRs were included. CR is the most popular design philosophy (67.4%), followed by PS(23.1%), MB (6.9%) and least commonly MP (2.6%). MP and CR implants showed the best survivorship (95.7% and 95.6% respectively) at 15 years which is statistically significant at, and beyond, 10 years. Observed survivorship was lower at all time points with the PS and MB implants (94.5% for both designs at 15 years). While all design philosophies considered in this study survive well, CR and MP designs offer statistically superior survivorship at and beyond 10 years. MP design performs better than CR beyond 13 years yet, remain the least popular design philosophy used. Publishing data based on knee arthroplasty design philosophy would help surgeons when making decisions on implant choice.

Keywords: Knee replacement; survivorship; cruciate retaining; posterior stabilised; medial pivot.

INTRODUCTION

Total knee replacement [TKR] is an effective and successful surgery that improves the pain and function of patients with end-stage knee osteoarthritis[1] numerous studies using historic TKA implants suggest only 82% to 89% of primary TKA patients are satisfied. We reexamined this issue to determine if contemporary TKA implants might be associated with improved patient satisfaction. We performed a cross-sectional study of patient satisfaction after 1703 primary TKAs performed in the province of Ontario. Our data confirmed that approximately one in five (19%. With ageing populations and better health scores, the demand for total knee replacement continues to grow worldwide, which is estimated to increase 600% by 2030 in the United States[2,3] whether most of these extra years are spent in good health is unclear. This information would be crucial to both contain health-care costs and increase labour-force participation for older people. We investigated inequalities in life expectancies and healthy life years (HLYs. Furthermore, the aspiration for higher functional levels and the expectation of long-term survivorship of implants challenge the arthroplasty surgeon. As such, several TKR design philosophies have evolved to confront these challenges. The principles of these philosophies have developed through a desire to address the competing issues of constraint, polyethylene wear, range of motion and replication of kinematics. Broadly, four overriding philosophies have evolved: cruciate-retaining (CR), posterior stabilised (PS), mobile-bearing (MB) and medial pivot (MP). This paper examines specifically the survivorship of TKR implants based on the design philosophy.

The existence of several design philosophies demonstrates that challenges remain in TKR surgery, particularly in the reproduction of normal knee kinematics[4]. Improvements in prosthetic design evolved from better knowledge of knee anatomy, biomechanics, and kinematics[5]with a minimum follow-up of one year. Outcome measurements included clinical scores (Knee

Society Score (KSS. However, the use of new materials and improved technologies have not been replicated a concurrent progression in design philosophy, as the implant manufacturers often relied on the “4-bar linkage theory” first described in 1904[6]. The later kinematic studies have disproven this principle.

Early constrained knee designs, including hinged prostheses, were found to have high complication rates and have been largely abandoned in primary knee arthroplasty[7]. Hence, the implant designs progressed to minimal or unconstrained, utilising the native knee ligaments to provide stability[8], however, the dilemma of replicating ‘femoral rollback’ and anteroposterior (AP) stability posed difficulties to the TKR designers. Femoral rollback, first described in 1904, was the notion that the tibia translates anteriorly with knee flexion[6]. It was based on lateral 2D radiographs of the knee. This idea guided the design for cruciate-retaining (CR) implants, using implant geometry and a retained posterior cruciate ligament to guide this anterior translation with flexion[9]. A horseshoe-shaped polyethylene tibial insert developed in the 1960s allowed retention of the posterior cruciate ligament, thereby theoretically retaining the AP stability during femoral rollback[10]. The CR design remains the predominant TKR design philosophy, although femoral rollback as a concept has primarily been disproven[11].

Difficulties in achieving desired post-operative flexion with CR designs and the challenges of retaining the posterior cruciate ligament, particularly in complex deformities, led to the next major design philosophy; posterior cruciate sacrificing or posterior stabilised (PS) technique. The PS design philosophy again aimed to replicate femoral rollback by adding a ‘cam and post’ feature to the implant geometry. Over time, the PS design philosophy was modified to increase knee flexion and femoral rollback while reducing dislocation risk in high flexion[12]. Again, the concept of femoral rollback does not agree with the current understanding of native knee kinematics[13]. Indeed, in vivo studies suggest kinematics of CR and PS knees show the paradoxical posterior translation of the tibia with flexion, and femoral rollback isn’t achieved, despite the intentions of the design philosophy[14].

The CR and PS designs did not address the rotational element of knee kinematics, the often-cited ‘screw home mechanism’[15]. Therefore, the wear rates of early non-conforming polyethylene tibial inserts, required for CR and PS designs, were high[16]. The next philosophy arose from a desire to address these issues. A mobile polyethylene within a fixed tibial tray allow rotation in the knee joint and a higher congruence of the primary articulation[17]. This mobile ‘meniscal’ bearing surface (MB) was the third major design philosophy. MB design philosophy theoretically reduces implant loosening, and subsequent failure, by reducing contact stresses and eventual wear of the polyethylene at the primary articulation. However, it had two drawbacks; backside wear- a second articulation on the backside of the mobile tibial insert generating wear particles, and the second, rotation occurring about the centre of the knee, whereas rotation in the native knee has been demonstrated to occur about the medial compartment[18].

More recently, in vivo studies of native knee kinematics have shown that the normal knee is essentially a medial ball and socket, in which a more mobile lateral side moves around the constrained medial side[19]. This concept led to the latest design philosophy in the 1990s[20]. Here a ‘ball-and-socket’ articulation of the medial tibiofemoral compartment provides a medial pivot (MP) and subsequent stability on the medial side with entire ROM. The increased curvature and conformity of the medial articulation reduce contact stresses and minimises polyethylene wear[21]with their clinical and radiological outcome. This implant has a highly congruent medial compartment, with the femoral component represented by a portion of a sphere which articulates with a matched concave surface on the medial side of the tibial insert. There were 78 men (17 bilateral TKRs. The pivoting of the lateral condyle around the medial condyle occurs due to the asymmetry of the tibial insert. This is the most recent design philosophy and never adopted by the market-leading orthopaedic implant manufacturers, therefore remains the least popular. However, Australian registry data suggests it is the fastest-growing design in knee arthroplasty[22].

TKR failure and revision can occur for various reasons, including infection, loosening, instability, pain, and fracture. Analysis of survival of an implant is defined as the time from primary surgery to any ‘failure event’ requiring revision of the prosthesis. Due to difficulties in delineating the cause of failure specifically, all-cause revision is accepted as the primary outcome of most survival analyses performed by joint registries[23]. The strength of large volumes of primary procedures ensures that any variability in revision for non-implant related reasons, such as infection or fracture, can be presumed constant. Therefore, all-cause revision rates reflect the true implant survivorship due to aseptic loosening or implant failure.

The UK National Joint Registry (NJR) 17th Annual Report was the first to present survivorship data on

TKR implants by design philosophy (CR, PS and MB). However, it did not consider the medial pivot philosophy. The Australian Orthopaedic Association's (AOA) annual registry report does present TKR survivorship by design philosophy, including the MP design. Reporting the survival of TKR implants by design philosophy can more comprehensively inform surgeons making decisions on TKR implants.

MATERIAL AND METHODS

An observational study was performed by applying secondary data analysis to cumulative data sets derived from the NJR 17th Annual Report. Cumulative revision data for CR, PS, and MB design philosophies was derived from the combined data originally presented by the fixation method (cemented, uncemented, hybrid). Any prosthesis utilising a mobile bearing, regardless of the constraint insert was considered mobile bearing (MB) design philosophy. UK-NJR does not present cumulative revision data on medial pivot implants however it does report survivorship of individual branded prostheses, which we merged to calculate the survivorship of MP design philosophy (MRK, Advance, Advance Stature, Evolution, Saiph and Sphere).

Survivorship of all the design philosophies for all-cause revision with 95% confidence intervals (CI) is presented at 1, 3, 5, 10, 13 and 15 years and Kaplan-Meier survival curves were calculated. First, the standard error and variance on each NJR data series were calculated, then the combined variance for the design was calculated. Confidence intervals at 95% for each time point were subsequently determined. There were no exclusions. All data presented in the NJR was included, and the derived data sets were not altered or manipulated before statistical analysis. Censored data resulting from incomplete follow-up was adequately accounted for by the Kaplan-Meier method. For these reasons, the derived cumulative data used in this study is representative of the original sample with high fidelity.

Statistical significance was determined with 95% confidence intervals (CI). Where CI do not overlap, it can be assumed that the survival curves are significantly different. This qualitative method tends to underestimate significant differences; therefore, we can be confident that any observed difference in survival is significant. Whilst true that a quantitative method can still find significant differences even when the confidence intervals intersect, it was impossible to quantify differences between the survival curves without the raw data.

RESULTS

1,144,384 TKRs from the UK-NJR were included. Of the implant's studied, CR is the most used design philosophy (67.4%), followed by PS (23.1%), MB (6.9%) and least commonly MP (2.6%) (Table I). Cementation is the most common fixation method (Table II) and was used for fixation in 96.9% of CR implants, 98.5% of PS implants, 81.2% of MB implants and 100% of MP implants.

Table I. — Cumulative usage by design philosophy

Design Philosophy	Patients (n=)	Percentage (%)
CR	771,626	67.43
PS	264,593	23.12
MB	78,702	6.88
MP	29,463	2.58
Total	1,144,384	

Table II. — Cumulative fixation method by design philosophy

Design Philosophy	Cemented (%)	Uncemented (%)	Hybrid (%)	Total
CR	747669 (96.9)	17554 (2.27)	6403 (0.83)	771626
PS	260493 (98.45)	3366 (1.27)	734 (0.28)	264593
MB	51879 (65.92)	24702 (31.39)	2121 (2.69)	78702
MP	29463 (100)			29463

The demographics mirror those of the original data set published in the NJR 17th Annual Report. The median age of a TKR patient was 70 years with an interquartile range of 64-76. Females were more likely to receive a TKR, and osteoarthritis was the most common indication[23]. Overall survival of knee replacements at 15 years is excellent, regardless of design philosophy; however, cruciate-retaining, and medial pivot designs have better survival for all-cause revision (Figure 1) at all time points. Both CR and MP showed statistically significant superior survivorship at, and beyond, 10 years (95% CI) than PS and MB knees. CR and MP survival curves closely mirror each other. Posterior stabilised and mobile-bearing implants also have similar survival curves; however, they perform inferior to CR and MP. Beyond 10 years, the PS and MB survival curves are closely matched.

Table III. — Cumulative percent survival with confidence intervals by design philosophy

	Cumulative survival (% with 95% CI) [years from implantation]					
Design Philosophy	1	3	5	10	13	15
CR	99.61 (99.608-99.612)	98.57 (98.56-98.58)	97.98 (97.96-98)	96.91 (96.88-96.94)	96.13 (96.09-96.17)	95.56 (95.46-95.66)
PS	99.52 (99.519-99.521)	98.26 (98.25-98.27)	97.41 (97.39-97.43)	95.91 (95.85-95.97)	95.06 (94.93-95.19)	94.5 (94.32-94.68)
MB	99.47 (99.462-99.478)	98.09 (98.07-98.11)	97.26 (97.23-97.29)	95.91 (95.86-95.96)	95.15 (95.07-95.23)	94.49 (94.32-94.66)
MP	99.56 (99.51-99.61)	98.38 (98.12-98.64)	97.74 (97.23-98.25)	96.57 (95.94-97.2)	96.1 (95.1-97.1)	95.74 (94.54-96.94)

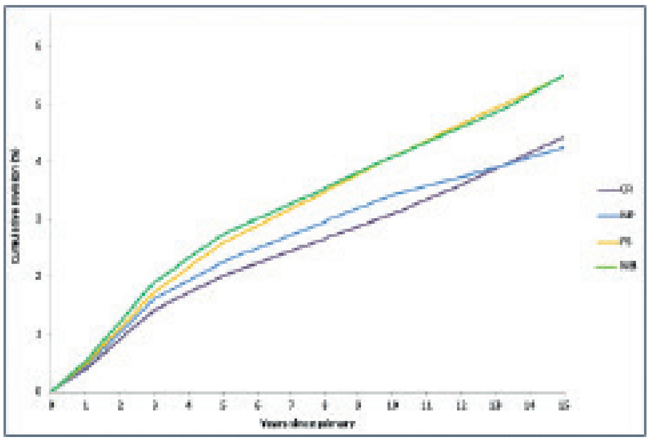

Figure 1. — Cumulative revision rate (%) comparison of all design philosophies.

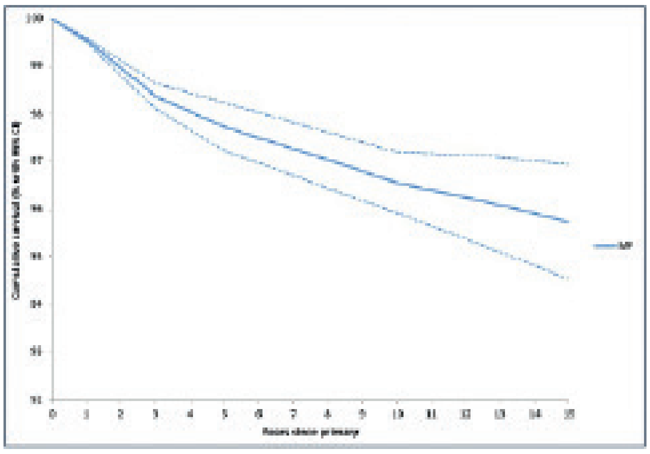

Figure 2. — Cumulative survival (% with 95% confidence interval) for Medial Pivot implants.

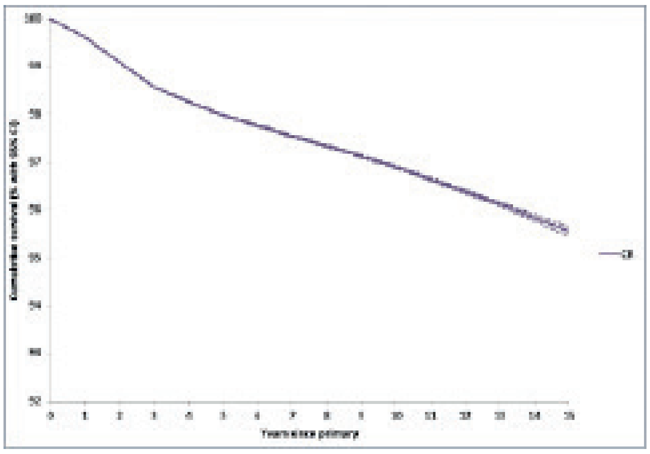

Figure 3. — Cumulative survival (% with 95% confidence interval) for Cruciate Retaining implants.

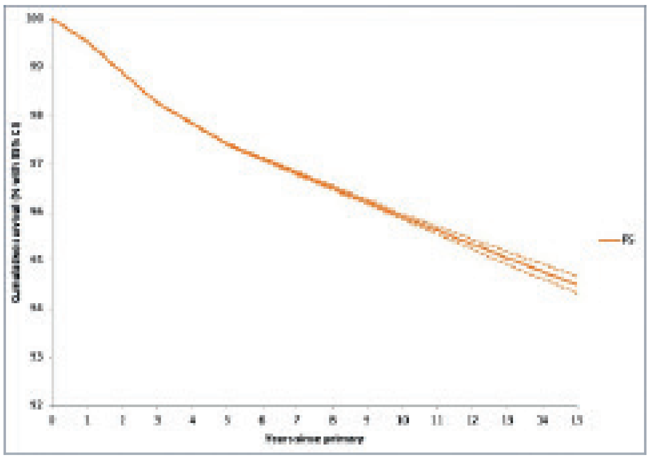

Figure 4. — Cumulative survival (% with 95% confidence interval) for Posterior Stabilised implants.

Posterior stabilised and mobile-bearing implants had a survival at 15 years of 94.49% (Figures 4 and 5). Medial pivot implants had the best survivorship (95.75% at 15 years) but a large confidence interval (Figure 2 and Table III) due to a relatively lower number of primary procedures (29,463 knees). Cruciate retaining implant survival at 15 years was 95.56% (Figure 3). CR implants demonstrate superior survivorship to all other design philosophies up to 13 years. Beyond this point, the survivorship of CR implants is marginally superseded by the MP design philosophy.

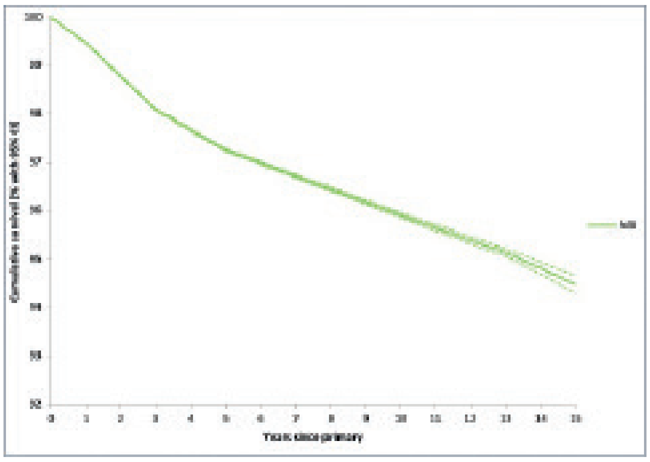

Figure 5. — Cumulative survival (% with 95% confidence interval) for Mobile Bearing implants.

DISCUSSION

The design philosophy is arguably more important to the knee arthroplasty surgeon than the brand or fixation method, yet data specifically examining survivorship by design philosophy is not reported by the UK-NJR. Analysing survivorship by design philosophy demonstrates CR implants are the most popular and have good survivorship. Generally, total knee arthroplasty survival is excellent, irrespective of design philosophy. All four philosophies studied can be considered to have good survivorship at 15 years (the worse performing still had 94.49% survival). However, with the ever-increasing annual incidence of TKR, any significant difference in survivorship between design philosophies will translate into a corresponding reduction of the future revision surgeries[24].

Our analysis of UK NJR showed medial pivot design has the best survivorship at 15 years of all the design philosophies (95.75%), with a total of 29,463 procedures. Australian registry reported similar results with medial pivot design having the best survivorship at 15 years (93.9%) with 23,148 procedures[22]. A small cohort of patients (total 15 patients) who underwent Advance I medial pivot arthroplasty was excluded from the Australian data as they showed a higher than anticipated revision rate. However, even with the inclusion of this outlier, the medial pivot by design philosophy remains significantly better than the other philosophies (93.7% at 15 years). Cruciate retaining TKR had the next best-observed survival at 15 years (95.56%) in the UK-NJR, followed by the posterior stabilised and mobile-bearing designs (94.49%). An identical sequence of survivorship by design philosophy was observed in the Australian registry, with CR outperforming PS by 1% at 15 years (93.0% and 92.0%, respectively).

Orthopaedic literature has usually debated the superiority of CR and PS knees however, our study showed significant long-term survival of MP knees. Multiple studies reported variable survivorship and patient satisfaction for CR and PS knees[25,26]. Some studies favoured PS[27-29] and some favoured CR[30], while some showed no difference[31,32], and some authors even questioned the relevance of the posterior cruciate ligament[33,34]. Based on the principle of femoral rollback, CR designs are believed to increase flexion and range of movements, thereby improving squatting, kneeling, and stair climbing[27,28]; however, recent studies reported paradoxical anterior translation of the femur on the tibia during flexion[35]. On the other hand, PS design supporters argue post and cam improve the range of movements ensuring femoral rollback mechanically[27]. Also, the posterior femoral translation improves clearance over the tibia and hence better flexion[35]. A meta-analysis published recently found statistically significant but clinically doubtful improved flexion and range of motion favouring PS knees. However, the authors advised using the design which the surgeon is comfortable with[36]. The 'sliding' motion on the CR and PS knee designs for femoral rollback generates abnormal contact stresses at the primary articulation, increase wear particle generation, and explain the observed higher revision rate with increasing time from implantation. Higher revision rates for aseptic loosening have historically been reported for PS and constrained implants[37]. The same is true for this study. Mobile bearing designs have high conformity at the primary articulation, with the principle to reduce polyethylene wear; however, the design resulted in a rotational movement at the tibial plate-polyethylene interface. Hence it caused backside wear, increasing aseptic loosening.

Interestingly, the medial pivot design showed superior survivorship to cruciate-retaining implants from 13 years onwards; before this point, CR was the best performing implant. Again this crossover from CR to MP can also be observed in the Australian registry at around 13 years post-implantation[22]. The observed better survival of the medial pivot philosophy beyond 13 years would indicate that aseptic loosening is less pronounced with this design; however, it remains the least popular design philosophy. Medial pivot designs show low rates of aseptic loosening in mid to long term follow up studies[38-41]. This finding has been supported by a meta-analysis of medial pivot knees which reported an aseptic loosing rate of 0.26% in 1,146 knees at 8 years follow-up[42]. The specific design philosophy of medial articular conformity (ball and socket), reducing polyethylene wear, and decreasing aseptic loosening may account for improved survivorship of medial pivot over CR designs after 13 years[43]. Additionally, the kinematics of a medial pivot knee replacement more accurately reflect those of a native knee[18].

Since the Australian Arthroplasty Registry started reporting TKR implant survival by design philosophy, MP implants are now the fastest-growing design philosophy in Australasia. Currently, 9.2% of their TKRs are medial pivot design[s22]. It is significantly higher than the UK data (2.6% in this report), where it has not been reported. The Dutch Arthroplasty Register report a mean cumulative revision rate of 9.7% for MP knees at 11 years44, higher than their overall cumulative TKR rate of 6.5% at 11 years. This is significantly higher than both the UK NJR and AOA; however, the Dutch registry is considerably smaller, with only 1,815 MP implants included (1/13th magnitude of the NJR and AOA registries). Our study demonstrates a cumulative revision rate for the medial pivot design TKR at 15 years of 4.25%. A literature review performed in 2020, evaluating medially stabilised designs using national joint registry data, concluded that MP designs demonstrate comparable survival to the best surviving other TKR designs philosophies[45].

One strength of registry data is the large volumes of implants and operations studied, and our study reports on the results of over a 1.1million TKRs. This fact ensures any variability in revision for non-implant related reasons, such as infection or fracture, can be presumed constant. Therefore, the all-cause revision rate can be safely presumed to match aseptic loosening. The extensive volume data set facilitates the selection of large sample sizes and the production of narrow confidence intervals. This study is exposed to the limitations of any study using registry data. One limitation of joint registry data is that it is subject to administrative censoring or censoring due to an event such as death. NJR analysis of all-cause revision provides an estimate of implant failure in the absence of death, and as such, are not adjusted to account for the risk of death[23]. The discrepancy in revision rates between NJR-HES linked data and NJR-NJR linked data has previously been acknowledged to underestimate the true rate of implant failure in the NJR[46,47]. This is unlikely to introduce bias in our study as the adjustments are likely to have underestimated to the same degree across the design philosophies. As a registry is essentially a prospectively collected case series, missing data could potentially introduce bias. Data collection in the UK is very strong, with 96.7% of all primary and revision procedures uploaded to the NJR; hence, missing data should be a random occurrence. Therefore, it can be assumed that missing data would be spread equally across the design philosophies, minimising any potential introduction of bias.

We appreciate implant survival is only one aspect of the outcome in TKR. Patient recorded outcome measures (PROMS), functional scores, and quality of life improvements are equally crucial to the patient and the Orthopaedic surgeon. Registry data does not consider these factors and, as such, they are equally beyond to scope of this article.

CONCLUSIONS

Annual reports of orthopaedic registries constitute a significant conduit to understanding the survival analysis of total knee arthroplasty implants. The outcome-based on design philosophy is helpful for knee arthroplasty surgeons to choose implants. Design philosophy-based survival analysis is reported in several international registries; however, not in the UK National Joint Registry. While all designs demonstrated good 15-year survivorship, CR and MP designs were statistically superior beyond 10 years. Data comparing PROMS and functional scores with these designs will likely guide which philosophy ultimately prevails in TKR.

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