



Clinical Evaluation of All Polyethylene Tibial Components in TKA

-Review Paper-

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Abstract:

This review summarizes published literature that reports on clinical studies and/or randomized controlled trials from 1989 to end 2009 regarding the clinical performance history of several designs / brands of an all-polyethylene (AP) Tibial component used as part of a primary cemented Total Knee System implanted using established Total Knee Arthroplasty procedures.

From the mid 1970's knee systems for replacement of knees diagnosed with osteoarthritis, rheumatoid (inflammatory) arthritis, osteonecrosis, avascular necrosis and other degenerative joint conditions used

a plastic tibial component articulating on a chrome - cobalt femoral component. Resurfacing of the patella if required also used a plastic artificial patella button attached surgically with PMMA bone cement.

Projections of increase in TKA of +600% increase in annual surgeries over the next 15 years has focused significant interest in reconsideration of using this style tibial component in the growing elderly population.

Key Words: *Total Knee Arthroplasty, polyethylene, tibial component, clinical performance*

Introduction:

Early 1970s generation of total knee implants consisted of two basic components: Chrome cobalt femoral component and an all polyethylene tibial component. The patella was for the most part ignored. These were classified as bi-condylar total knees and some like the Bechtol Knee had two different style tibial components. One was flat and the second design had more A/P stability with a contour shape.

Patella femoral pain remained a problem and the patella femoral component was born in 1974.



Bechtol Bi-Condylar and Patella Femoral System



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Often the patella femoral system was used with either Bi-Condylar Knee designs or the Uni-Condylar Marmor style implants. Trying to balance four to six components in one surgery was a challenge and was eventually addressed by the introduction of the Total Condylar Style Knee by Charles Townley, M.D. with his Anatomic Total Knee Design.

Review:

The gold standard by the 1980s was the Total Condylar Prosthesis. Originally this was semi-constrained, cruciate-sacrificing, tri-compartmental design and the tibial component was an All-polyethylene (AP) monoblock with a central stem or square keel with a wave-like under surface to cement to the resected tibia. Later the term referred generically to an AP monoblock tibial component in which the cruciate ligaments were also retained. Excellent long term survivorship after 15 years of 90.6% was reported by Scuderi et. al., for the Total Condylar Device. The authors also noted that good surgical technique including component positioning, knee alignment, soft-tissue balance and minimal tibial resection, are essential to obtain a long lasting arthroplasty in addition to design of the prosthesis.

However, some other AP tibial component designs did not prove to be as durable as the Total Condylar with significantly higher early failure rates and poorer long term outcomes due to excess wear of the plastic TC. Manufacturing and packaging of this component, in particular sterilization technique, was found to be highly influential on the wear characteristics of early design APTCs. Components sterilized in air were prone to rapid oxidation, leading to generation of in-vivo wear debris, osteolysis, loosening and ultimate failure of the tibial components after TKA. The main cause of failure of early TKA was failure of the APTC and polyethylene (UHMWPE) oxidation could have contributed to stress fracture of the plastic.

More recently, APTCs have been gamma irradiated in an oxygen-free environment and the moderate levels of cross-linking achieved have been shown to

enhance the durability of polyethylene implants in-vivo.^{2,3} Other early shortcoming of the all-poly tibial design are cited to be related to poor fixation resulting in aseptic loosening, condylar collapse and the development of progressive radiolucent lines, which was considered an early indication of mid-term failure of the device.⁴

Around 1997, the Press Fit Condylar (PFC) knee system by DePuy was changed to PFC Sigma range due to modification of the femoral component that included a deep and extended trochlear groove with a matching single radius dome all-polyethylene patella. The patellar articular surface has a central convexity and peripheral concavities to allow better patella-femoral contact. An AP tibial component was included in the range with thicknesses from 10-15 mm manufactured from GUR402 grade UHMWPE that was vacuum packed and gamma irradiated. It has a cruciform keel-style post and a flat-on-flat articulating surface. A number of institutions have conducted studies to compare the performance of this and other AP TC to the equivalent modular metal backed (MB) TC version of modern knee systems due to the potential cost benefits of the AP monoblock and the emergence of backside wear and prevalence of osteolysis using MB modular tibial implants.

Kaplan Meir Survivorship of All Poly Tibial Component

Table 2 presents the survivorship outcomes of several longer term studies involving APTC designs in primary TKA to treat predominately knee pain and lost of functional range/mobility associated with osteoarthritis but also from a range of other degenerative joint/bone diseases.



B.
Example of all poly PS tibial component

Table 2. Kaplan-Meier Survivorship Data from Clinical Studies involving All-Polyethylene Tibial Components # in Primary Total Knee Arthroplasty.

Major Author	Year	Device	Age years (range)	Kaplan-Meier Survivorship (95% C.I.)	Survivorship endpoint
Scuderi et al	1989	224 total condylar FB/ CR prostheses with AP TC (1974-1978), 289 PS AP TC (1978 -1981), 917 PS MB TC (1981-1986)	67 (20-87)	AP- 90.6% @15yrs	Revision or expiration
§Faris et al	1991	363 total condylar FB CR	N/A	AP- 94.7% @ 12 yrs	Revision or expiration
Ranawat et al	2005	AP PFC modular (23); Sigma PFC (31); patella AP button	57 (47-60)	AP- 1.8% failure rate @ 5yr	Revision for any reason
Dalury et al	2009	PFC Sigma Knee -AP	76 (> 70)	AP- 99.4% @ 7 yr	Revision for any reason
Gioe et al	2009 and 2000	PFC Sigma knee FB – AP; & MB	69 (>60)	AP- 91.6% @ 10 yr; MB - 88.9% @ 10 yr	Revision for any reason
Shen et al	2008	PFC; AP - PS	AP 62.0 (56-68) MB 60.4 (55-66)	AP -93.5% @ 5yr MB -93.75% @ 5 yr	Revision for any reason
Faris et al	2003	AGC Biomet AP or MB ; All total thickness=8mm	70.3 (34-91)	AP- 68.1% @ 10yr	Revision for any reason
Bettinson et al	2009	Kinemax Plus* AP and MB	69.3 (50-93)	AP=94.5% @ 10yr MB=96.8% @ 10yr	Revision for any reason

*symmetrical patellofemoral articulation

§*Semin Arthroplasty*. 1991

Code; FB- Fixed Bearing; TC- Tibial Component; PS- Posterior Stabilized; MB- Metal Backed TC; AP- All polyethylene TC

#Comparison with an equivalent design Metal Backed Tibial Component is included from applicable studies.

The Bad One!

Faris et al	2003	AGC Biomet AP or MB: All total thickness = 8mm	70.3 (34-91)	AP =68.1% @ 10 yr	Revision for any reason
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The authors attribute the high rate of clinical failure of this implant to the flat coronal plane geometry and low conformity of this tibial component, which contributed to peripheral-edge loading. The same coronal plane flat-on-flat geometry is also a feature

of the metal-backed (MB) AGC tibial component, which has been reported with a high rate of failure long-term survival. High stresses and discontinuities in the cement mantle promote crack initiation and propagation.

The PFC Sigma All-Poly knee system in patient populations over 60 years old gave excellent Kaplan Meier Survivorship rate of 91.6% at 10 yrs⁵ similar to those reported for the Total Condylar device and in very elderly patient population (age > 70 years) Dalury et. al², reported survival rates as high as 99.4% after 7 years. Bettinson et. al⁶, recently demonstrated similar consist long-term performance of an All Poly tibial component from the Kinemax Plus knee system (fixed bearing with symmetrical patella-femoral articulation) which was available in the 1990s with both AP and MB matched designs.

Shen et. al⁷, has also reported favorable outcomes mid-term with a Posterior Stabilized PFC Sigma knee system with an AP TC in an Asian population aged <70 years old. It is well known that the most challenging population for survivorship are those targeting patient less than 55 years old and a midterm study reported by Ranawat et al⁷, comparing the modern PFC Sigma to the original style PFC with an AP TC option has a comparatively low failure rate of <2% after 5 years. These authors state in head-to-head comparisons, no study has been able to demonstrate clinical superiority of a metal-backed tibial design^{2,7} and there is only one all poly study reporting on the outcomes from a single centre of 536 primary knee replacements with the AGC by Biomet that has demonstrated inferior long-term survivorship⁸.

Faris et al⁸, report the survivorship for an endpoint of revision for any reason, of the AGC prosthesis of only 68.1% at an average of 10 years post operative. The authors attributed the high rate of clinical failure of this implant to the flat coronal plane geometry and low conformity of this tibial component, which contributed to peripheral-edge loading. The same coronal plane flat-on-flat geometry is also a feature of the metal-backed (MB) AGC tibial component, which has been reported with a high rate of long-term survival.

In the case of the AP TC, however, peripheral-edge loading without the benefit of the load-diffusing effect of metal backing transferred load more directly to the subchondral region on the medial side

of the knee. 73% of all revisions in this study were due to TC failure beneath the medial tibial plateau with collapse and failure of the subchondral bone, suggesting that the load transfer was particularly important at the periphery of the medial plateau. The AGC was compression-moulded AP TC sterilized by gamma irradiation in argon with a minimum thickness of 10 mm and was designed with the same geometry as the moulded MB AGC total knee replacement. This would suggest that the clinical performance of a specific AP TC is design sensitive.

Failure Modes – Micromotion and Subsidence Studies

A common problem with cemented fixation of joint prostheses is that shear forces may be transmitted to the bone-cement interface and this can induce micromotion and aseptic loosening of the implant which ultimately may lead to early implant failure. A high-resolution method such as Roentgen Stereophoto-grammetric Analysis (RSA) is a well established technique to evaluate micro movement of a prosthesis with a resolution of 0.1 mm and precision of around 0.03 mm. This method is well suited to the knee, as orthogonal radiographic analysis is easy in a limb, radiation exposure is low for the patient and hence it is well tolerated on follow-up visits. It has been shown to be a reliable and reproducible predictor of late onset implant failure. Progressive migration of a knee implant of > 1 mm at two years, as detected by RSA motion analysis, is known to be associated with early loosening and subsequent clinical failure⁹.

In metal backed tibial designs, micro-movement at the linear tray interface is known to liberate polyethylene debris, despite the apparent security of the mechanism for capture of the liner. The size of this debris is within the biologically active range with respect to macrophage stimulation, which is likely to account for the observed increase in osteolysis seen from the time modularity was introduced in tibial components.

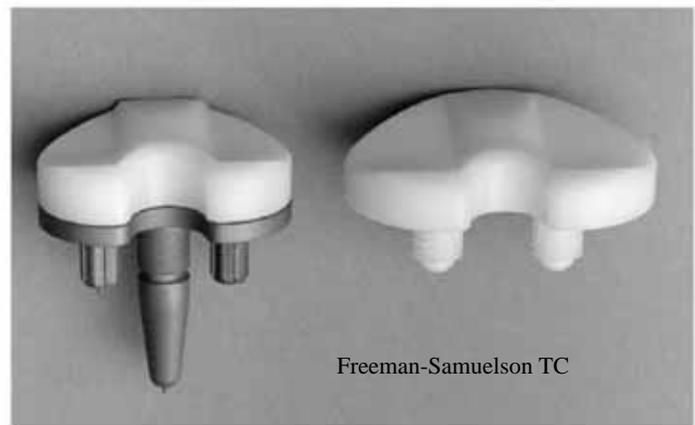
Muller et al, noted that the All-poly non-modular prostheses are perhaps technically more difficult to implant and do not offer the intra operative flexibility

of metal-backed tibial implants. In the case of primary TKA, however, the authors believe that there are significant clinical and economic benefits in avoiding modularity. These include failures associated with backside wear, liner dissociation, reduced polyethylene thickness or excessive bone resection. The table below is an excerpt from their publication⁹ and largely reflects the consensus of published opinion regarding the pros and cons of the All-Polyethylene tibial component versus metal backed to date.

The RSA study carried out by Norgen et al¹⁰ demonstrated that AP tibial components perform equally well as or some cases better than MB counterparts in regard to patterns and magnitude of migration. This finding is supported by literature data¹¹, Adalberth et al 2001 presented on different knee designs used in TKA with varying degrees of conformity i.e. the AGC design with flat-on-flat unconstrained articulation and the Freeman-Samuelson Mk IV design with conforming articulation in the sagittal plane and line to line contact in the frontal plane. This study further strengthens support for the contrary view that MB tibial components offer superior performance to an AP. All-poly also eliminates the risk of backside

wear and increased risk of osteolysis inherent with all MB tibial designs.

Norgen et al¹⁰, concluded from analysis of the failures ascribed to AP implants in the literature, that it is evident these failures were usually related to technical errors in achieving correct alignment of the knee, rather than caused by the absence of a metal backing per se (as MB was introduced to confer protection from shearing of the polyethylene and the bone by distributing stress more evenly across the bone-implant interface). The modern TKA instrumentation allows much better and reproducible alignment of the components.



All-polyethylene (AP) Tibial	Metal-backed (MB) Tibial
Advantages	
No backside wear	Liner selection after tray insertion
No liner dissociation	Compatible with mobile bearing total knee replacement
Increased polyethylene thickness/ More conservative bone resection	Addition of augments/additional fixation possible
Lower unit cost	Allows for cementless fixation
	Possible improved stress distribution to bone
	Possibility for liner exchange
	Possible smaller inventory
	Excellent long-term clinical results
Disadvantages	
Non-modular	Liner dissociation/dislocation
Possible difficulty retrieving posteriorly extruded cement	Backside wear
Few long-term clinical results	increased osteolysis
	Reduced polyethylene thickness
	Increased bone resection to accommodate adequate polyethylene thickness

Ryd et al 1995¹² demonstrated in a RSA study of 143 implants followed for up to 11 years that all the prostheses which were revised for mechanical loosening could be identified by RSA one to two years after operation, before the onset of symptoms. Mechanical loosening occurred exclusively in prostheses which migrated continuously and 20% of those identified in their study later became clinically loose requiring revision. The study included a range of brands including Total Condylar (19%), PCA (23%), Freeman Samuelson (22.3%) with half using cementless devices and approximately 14.6% with All Poly TC in a population with age range of 63 - 75 years. Further analysis showed that cementless components migrated significantly more than cemented during the first year, reaching a mean of about 1.7 mm. The cemented components had a mean migration of 0.7 mm (Mann-Whitney U test, $p < 0.0001$). Subsidence was determined along the vertical axis, but was reported with considerable scatter in both directions. Subsidence, of a mean of 1.0 mm, occurred almost exclusively in the cementless group, while cemented components seldom subsided. The author's suggest that continuous migration represents defective fixation which is established very early, possibly even during the operation.

Failure Modes – Osteolysis

From the early 1990's osteolysis has been reported in knee components inserted with cement with a prevalence from none to up to 16% of TKA cases. It is thought that debris gains access to the metaphyseal bone by way of voids in the cement mantle or by direct invasion of the metaphyseal bone by histiocyte-laden synovial tissue. Polyethylene, PMMA cement and metal debris are all known to elicit an inflammatory response that leads to bone resorption around the prosthesis by macrophages. The severity of this response depends on the size, shape, type and quantity of the released particles. The predominant mode of failure in TKA is thought to be fatigue rather than abrasive and adhesive wear. Wear debris generated is typically three times larger than from THA (using simulators) and delamination is the primary cause of most PE related knee failures.

This process occurs from material fatigue and repetitive stress that initiates and propagates subsurface cracks and tends to result in delamination of large flakes of PE > 0.5 mm.

The femur is prone to osteolysis in the region of the femoral condyles and near the attachments of the femoral collateral ligaments whereas osteolysis of the tibia tends to occur along the periphery of the component or along the access channels to the cancellous bone.¹³

Most patients are asymptomatic in early stages of this disease and the presence of osteolysis can be seen on plain radiographs with some difficulty however this later approach tends to underestimate the extent of the disease. Improvements in manufacture of PE inserts and AP components from cross linking in an inert atmosphere have allowed for substantial improvements in crack initiation properties however with some compromise in the yield strength of the material. Thickness of the PE is also a major consideration for wear properties and Bartel¹⁴ has shown that the contact stresses in polyethylene increase exponentially as thickness of the implant decreases. They concluded that a thickness of more than 8 mm of polyethylene should be used in clinical practice. There is little evidence to suggest that osteolysis is more prevalent in TKA with AP tibial implants and in general the AP devices have been reported to have generated less osteolytic wear than their modular counterparts¹⁵.

All Poly versus Metal Backed Variants of Fixed Bearing Non modular Tibial Components.

It can be seen from the studies comparing the AP to the MB tibial component from Table 2 that the AP variant of the predicate PFC Sigma total knee is highly comparable in survivorship performance to its MB counterpart in particular in the shorter term⁷ even in a younger patient population. During radiological assessment, no sign of subsidence of the tibial components was found in this Asian study. Shen et al, found in their in-vitro study that the load distribution on the proximal tibia is similar between the AP and the MB tibial components group provided the thickness of the AP tibial component is

≥10 mm. They observed radiolucent lines surrounding tibial components mainly in cases of rheumatoid arthritis (71.4%), which they attributed to poor bone quality and subsequent osteolysis induced by wear debris rather than loading of the tibial material.

The All-Poly performed slightly better or similarly to the Metal-backed variant with survivorship values >90% at 10 or more years in the limited number of published studies of longer duration typically in older patient populations. There seems little justification for the additional cost of the metal-backed tibial component in regard to performance or safety concerns now that improvements in the manufacture in UHMWPE tibial devices have been introduced. The modern All-Polyethylene tibial component is a safe, effective implant that should be considered as an option by the surgeon for most patients requiring primary TKA coupled with a suitable femoral design.

The Future:

There is little doubt that the future in total knee replacement surgery will be greatly influenced by economics both short and long-term. Surgical technique (alignment, instrumentation), material and design will always play a factor but might be secondary concerns after financial. We are already seeing a significant movement trying to classify TKA as a generic procedure. At risk are the experience and training of the total joint surgeon and design features and benefits of individual implants. There is a perception already that one surgeon and one design is no better or worse than another. As long as decisions are being made in the purchasing office, cost will be the hospitals major concern.

This leads us to believe the all polyethylene tibial component will have a significant role in the future.

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