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Which primary total knee replacement?

A review of currently available TKR in the United Kingdom

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Comparative information on total knee replacements (TKRs) is not readily available. With the help of implant manufacturers and distributors, we have compiled a list of TKRs on the market in the UK and summarised the information about these implants in a table.

There are 37 different TKRs, marketed by 14 companies; 54% have been introduced since 1990. The number of different implants is increasing. At least eight designs have undergone major modifications, while many have had minor alterations. Of the TKRs on the market, 60% are modular. Some 54% of TKRs have no published results in peer-reviewed journals; only one of the four most widely used prostheses has published survival figures. New and modified implants are introduced without clinical evidence of their superiority over other available designs.

Published results in peer-reviewed journals are currently the best evidence available on the reliability of an implant. When selecting an implant, surgeons should be aware if the prosthesis has any such results, the length of the follow-up, and the survival rates that are achieved. More detailed interpretation is difficult because of the different combinations used in modular implants and because of the frequent modification of existing designs. Properly conducted long-term clinical trials should be encouraged as they are the only means of evaluating new designs.

Health care providers, purchasers and orthopaedic surgeons are increasingly using published clinical results as their main criteria for selecting prostheses for joint replacements. We recently published a review of total hip replacements (THRs) on the market in the United Kingdom which demonstrated that 70% of the 62 THRs had no published data in peer-reviewed journals *(1)*. This study not only contributed to the increasing use of evidence in implant selection but also provided a useful database for this information. We now plan to repeat the process for total knee replacements (TKRs).

TKR has clinical results that equal or exceed those of hip replacement in terms of implant survival after 10 years, pain relief and function *(2,3)*. Presently in the UK, about 200 000 patients have already received a total knee replacement and possibly 400 000 more individuals would benefit from the procedure *(4,5)*. The number of TKRs performed each year in the UK is rising, but the current level of TKR operations carried out each year in the National Health Service (NHS) hospitals may not be in keeping with the demand *(6)*.

The rising numbers of TKRs performed will be accompanied by an increase in revision operations. Such procedures are more expensive, do not give as good a functional result, nor last as long as the primary replacement. Although the implant is only one of many factors influencing revision rates, reliable and long-lasting prostheses are essential.

Evidence of good performance in a TKR design must therefore be sought when selecting implants. However, the decision is difficult as there are large numbers of different TKRs on the market. Many new designs are introduced each year and, unlike new pharmacological products, there is at present no formal requirement for clinical tests before a new prosthesis is introduced onto the market. This may change with the introduction of the new European CE mark which will make clinical trials mandatory before marketing *(7)*.

The aim of this study is to review the TKRs that are currently available in the UK and to assess what is known about their performance.

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Table I. Details of total knee replacements on the UK market in 1996. Functional results and survival analyses are those reported in peer-reviewed journals only (see text). In the 'Clinical results' section, the numbers in parentheses are listing of the references

Implant	*Distributor (manufacturer)*	*Release UK (other)*	*Market share*	*Cost (£)*	*Fixation*	*Design features*	*Clinical results*	*<5 year functional*	*5 year survival*	*5–10 year functional*	*10 year survival*	*15 year survival*
Oxford	Biomet	1978	<5%	730	Cemented	Meniscal unicompartmental knee replacement. Totally congruent. For unicompartmental disease with intact cruciates	Carr, 1993 *(15)*	Good	Medial, ACL+: 99% (121–30)			
Endo-Model sled prosthesis	New splint (Waldamar Link)	1975 modified 1981	<5%	779	Cemented	Unicompartmental. Biconvex femoral component. Flat metal-backed PE tibial component. Low congruence. Developed from St Georg sled	Nieder, 1991 *(16)*				78% (1294–?)	
P.F.C. Uni	Johnson & Johnson	1993 (1992)	<5%	780–1040	Cemented	Low congruence unicompartmental. Metal backed or PE tibial tray	Kozinn, 1989 *(17)*	Good				
Furlong	JRI (a)	1994	<5%	795–1590	Cemented or cementless	Modular. HAC uncemented. Ti tibial tray & PE insert, CoCr J-shaped geometry femoral component for anatomic kinematics	No published results					
Robert Brigham Uni	Johnson & Johnson	1974, Modified 1980	5–20%	810	Cemented	Low congruence unicompartmental. Metal backed tibial component	Scott, 1981 *(18)* Knutson 1994 *(8)*	Good	97% (389–?)			
Total condylar	Howmedica	1974	<5%	840	Cemented	Symmetrical femoral component. PE or metal backed tibial component	Scuderi, 1989 *(19)* Ranawat, 1993 *(20)*	Good			91% (224–79)	94% (112–56)
Allegretto	STRATEC (Sulzer Orthopaedics Ltd)	1994 (1991)	<5%	888	Cemented	Unicompartmental, 3 femoral sizes. Tibial fixation with wire mesh. CoCr, PE, Ti alloy	No published results					
Condylar knee	3M	1993	<5%	986	Cemented	Asymmetric femoral component. Low congruence. PCL+. Optional patella button	No published results					
Search	Aesculap	1994 (1988)	<5%	1000	Cemented	Modular, for unicompartmental, total primary or revision. PCL+, PCL−, ACL+, ACL−. Asymmetric femur, symmetric tibia. Low congruence	No published results					
Series 7000	Osteonics	1992	<5%	1000	Cemented or cementless	Modular, PCL+, PCL− or revision (stems, wedges). Asymmetrical femoral component (CoCr). Snap-fit PE tibial inserts with various constraint designs. PE patella. HAC cementless	D'Antonio, 1996 *(21)*	2-year: Good				
Kinemax	Howmedica	1988	>20%	1050	Cemented or cementless	Modular. PCL+, PCL− or revision (stems, wedges & Superstabiliser). Symmetrical femoral component. Universal tibial tray. Offset dome patella. PE tibial component available. Successor to Kinematic	No published results†					
P.F.C. knee	Johnson & Johnson	1986 (1984) PCL− 1989	>20%	1000–1825	Cemented or cementless	Modular. PCL+, PCL− and revision. Four levels of congruence. Universal tibial components. Stems, wedges & augmentation components. Oval, inset or dome patella	Scott, 1989 *(22)* Wright, 1990 *(23)*	PCL− Good		PCL+ Good		
Freeman–Samuelson integral knee	STRATEC (Sulzer Orthopaedics Ltd)	1995	<5%	1051	Cemented	Cemented monobloc. Asymmetric femoral component, PCL+. High congruence. Intra- or extra-medullary alignment. CoCr, PE. Developed from F/S Modular	No published results†					
AMK	DePuy	1990 (1987)	5–20%	1179	Cemented or cementless	Matched semi-congruent femoral (CoCr) and tibial articulating surfaces. Unique instrumentation. Proportionally sized asymmetrical femoral component for optimal patellofemoral function	Engh, 1991 *(24)*	Good				
Genesis	Smith Nephew Orthopaedics	1990 (1988)	5–20%	1200–1500	Cemented or cementless	Modular, PCL+, PCL−, or revision (constraint options, stems & wedges). Asymmetrical femoral (CoCr) and tibial (Ti- based or PE) components. Biconvex patella (PE)	Kitsugi, 1994 *(25)*			Good		
Tricon	Smith Nephew Orthopaedics	1987 (1984)	<5%	1200–1500	Cemented or cementless	Non-modular PCL+. Long stem for revision. Asymmetrical femoral and tibial components. Domed patella (PE). Congruent articulation	Briggs, 1995 *(26)* Knutson, 1994 *(8)*	2-year (Hybrid): Good	89% (?–?)			
Insall Burstein posterior stabilised (IB I)	Johnson & Johnson	1978, Modified 1980	<5%	1220	Cemented	Posterior stabilised for PCL−. Symmetrical femoral component. Low congruence. Metal backed tibial component	Stern, 1992 *(27)*	Good	99.6% (289–244.5)	Good	95.6% (289–172)	
Insall Burstein II	Fry	1988	5–20%	1250	Cemented	Modular. Interchangeable tibial inserts, wedges and stems. Posterior stabilised for PCL−. High congruence. Successor to IB1	No published results*					
Scan Knee	Fry	1996 (1988)	<5%	1250	Cemented	Modular, non-anatomic. PCL+, CoCr femoral component and tibial tray. PE patella and tibial inserts	Knutson, 1994 *(8)*		4 year 97% (?–?)			

Duracon	Howmedica	1990	<5%	1250	Cemented or cementless	Asymmetrical femoral component. Asymmetric patella, metal-backed or not. Modular tibial component. Intra- and extramedullary alignment	No published results				
LCS	DePuy	1985 (1977)	5–20%	1260–1480	Cemented or cementless	CoCr mobile bearing TKR, meniscal and rotating bearing platform options. ACL+, PCL+ or PCL−. Congruent rotating patella	Beuchel, 1990 *(28)*	Good	Cementless: 98% (147–?)	Good	
Miller Galante II	Zimmer (a)	1990	<5%	1285–2078	Cemented or cementless	PCL+, Modular, primary or revision. Anatomically shaped. Multi-radius. PMMA precoat or porous. Successor to MGI	No published results†				
Hybrid Condylar Knee	3M	1996	<5%	1300	Cemented tibial, uncemented femoral	Asymmetric femoral component with Ultrapore (TM) surface for bone ingrowth. PCL+, optional patella	No published results				
Insall Burstein II	Zimmer (a)	1987	>20%	1363	Cemented	Posterior-stabilised. Modular, primary or revision. High congruence. CoCr femur, Ti tibia. Successor to IB1	No published results*				
Freeman–Samuelson Modular Knee	STRATEC (Sulzer Orthopaedics Ltd)	1990	<5%	1388	Cemented	Modular. Asymmetric femoral component. High congruence. PCL+. Intra- or extramedullary alignment CoCr, PE, Ti alloy. Developed from F/S MkII	No published results†				
Nuffield	Corin	1988	<5%	1432	Cemented or cementless	HAP or porous-coated cementless. Asymmetrical femoral components, pegs or stems available. Highly congruent. Bone-preserving PCL+ or PCL−. Intra- or extramedullary instrumentation	No published results				
AGC	Biomet	1985 (1983) PCL− 1986	>20%	1440	Cemented or cementless	Modular or monobloc, PCL+, PCL−, revision. Symmetrical and asymmetrical femoral component. Same tibial component for PCL+ and PCL−. PE patella	Knutson, 1994 *(8)* Ritter, 1995 *(29)*	PCL+: Good	PCL+: 98% (?–?)		PCL+, exclude patellar failures: 98% (2001–71)
Natural Knee	Sulzer Orthopaedics Ltd	1993 (1986)	<5%	1450–1975	Cemented or cementless	Modular. Unicompartmental, primary, revision, PCL+ or PCL−. Low congruence. Asymmetrical tibia and femur. Optional porous coating and screw fixation. PE or metal-backed patella	Hofmann, 1991 *(30)*	Cementless: Good			
Rotaglide	Corin	1986	<5%	1485	Cemented or cementless	HAP or porous-coated cementless. Asymmetrical femoral component. Rotating and gliding meniscal component. Highly congruent. Pegs or stems available. PE patella. PCL+ or PCL−	No published results				
TACK	New Splint (Waldamar Link)	1988	<5%	1500	Cemented or cementless	Bicondylar asymmetric femoral replacement. Rotating PE tibial platform. Congruent in extension. PCL+, PCL−, ACL+, ACL−	No published results				
Profix	Smith Nephew Orthopaedics	1996 (1994)	<5%	1500	Cemented or cementless	Modular system. PCL+, PCL−, or revision. Asymmetrical femoral (CoCr) and tibial (Ti or PE) components. External rotation built into articular insert. Biconvex patella (PE)	No published results				
Minns	Corin	1984	<5%	1565	Cemented or cementless	HAP or porous-coated cementless. Meniscal bearing PCL+, PCL−. Asymmetrical femoral component, optional pegs or stems. Highly congruent. Metal or non-metal backed patella	Minns, 1989 *(31)*	Good			
Wallaby	STRATEC (Sulzer Orthopaedics Ltd)	1995 (1994)	<5%	1652	Cemented or cementless	Modular. Assymetric femoral component, load distribution principle, high patellar congruency. PCL+. Extra- or intramedullary alignment. CoCr, PE, Ti components	No published results				
NexGen	Zimmer (a)	1996	<5%	1675–2221	Cemented	Modular for primary or revision. PCL+, PCL− posterior stabilised or constrained options	No published results				
Blauth	Aesculap	1991 (1973) Modified 1985	<5%	2000	Cemented	Hinged. Stemmed. Fully constrained. Fully congruent. CoCr	Blauth, 1990 *(32)*				89% (497–?)
Dual Articular	Biomet	1990	<5%	2501	Cemented	Modular for complex primaries or revision. Stemmed components. Semi-constrained. Rotating PE tibial plateau. Asymmetric femoral component	No published results				
Endo-Model total rotational knee	New Splint (Waldamar Link)	1983	<5%	2506	Cemented or cementless	Modular with stemmed components for primary or revision. Semi-constrained. PCL−. Optional patella. Rotating hinge. Congruent surfaces. Asymmetrical femur	Nieder, 1991 *(16)*			Good	

(a) JRI and Zimmer did not provide the tabulated information

Definitions and abbreviations: modular, range of different inserts for tibial component; HAC, hydroxyapatite coated; PE, high-density polyethylene; CoCr, cobalt–chrome–molybdenum alloy, Ti, titanium alloy, ACL+, anterior cruciate ligament-sparing; ACL−, anterior cruciate ligament-sacrificing; PCL+, posterior cruciate ligament-sparing; PCL−, posterior cruciate ligament-sacrificing.

*The TKR is developed from, or based upon the concept of another TKR which has published clinical results included in the table

†The TKR is developed from, or based upon the concept of another TKR which has published clinical results: F/S 1(R): Knutson *et al.*, 1994 *(8)*; Kinematic(R): Wright *et al.*, 1990 *(3)*, Emmerson *et al.*, 1996 *(33)*; Miller–Galante 1(R): Kienapfel *et al.*, 1991 *(34)*, Rorabeck *et al.*, 1993 *(35)*

Method

We identified all manufacturers and distibutors of knee prostheses in the UK and requested information regarding all the primary TKR prostheses that they were marketing. Specifically, they were asked to provide the year of release to the market, the estimated market share, the cost, the design features and for published clinical results. These were reviewed critically and summarised. The information was collated into a table and sent back to the manufacturer or distributor who was asked to validate the data and to suggest any corrections or additions which were necessary. This checking process was carried out twice. The data were compiled in September 1996, reflecting the available information of the TKRs at that time.

The implants were tabulated according to price, with the cheapest first (Table I). Other information is shown under the following headings:

Year of release in the UK (other). This is the year in which the prosthesis was released on to the market in the UK. The year in parentheses indicates the year of release on to any other market if this was earlier than that for the UK.

Market share. This is the manufacturer's estimate of the proportion of the UK market in broad ranges: <5%, 5–20% and >20%.

Cost (£). This is the list price in pounds sterling for the complete TKR. This includes the femoral, tibial and, if appropriate, the patellar components.

Fixation. This indicates if the TKR is cemented, cementless or both.

Design features. This section describes the key design features, information about the materials and whether the implant has been derived from a forerunner.

Clinical results. We considered only those published in peer-reviewed journals relating to either clinical function or implant survival. If none of these were found, we indicate with 'No published results'. We selected representative series for each TKR.

<5-year and >5-year functional assessment. This records only series of at least ten TKRs which have been assessed for pain and function and followed up for either less or more than 5 years. We recorded the result as good if the scoring system used gave an average result described as either good or excellent.

5-year, 10-year, and ⩾15-year survival analysis. These include survival analyses with ten or more patients at risk in the year of analysis. The definition of failure in the survival analyses was revision. After the survival rate, we record the number of knees at risk at the start of the trial and at the time of the analysis. If a number is not quoted, this is indicated with a question mark. Very large or important studies of slightly shorter duration have also been included.

Results

There are 14 different manufacturers and implant distributors. Two manufacturers (JRI and Zimmer) failed to respond to our request for information. The information about the implants sold by these two companies are freely available and have thus been included. However, the information may not be entirely correct, as it was not confirmed by the manufacturers.

We identified 37 different TKRs (Table I). The number of implants introduced on to the UK market has increased steadily: 5 (14%) were introduced before 1980, 12 (32%) were introduced in between 1980 and 1989, and 20 (54%) since 1990. In the last 18 months alone, six new implants were introduced on to the UK market.

Seven of the implants marketed in the UK were developed in the 1970s. Of these, three have been modified some time later. The published functional and survival data either include, or are exclusively for, the pre-modification designs. Five other implants are based on older concepts, and thus 8 (22%) of the currently marketed TKRs have undergone major design modifications.

Four implants (AGC®, IB® II, Kinemax® and P.F.C.®) are said to have >20% market share, while three other prostheses (AMK®, Genesis®, LCS®) claimed a market share of between 5% and 20%. The price range is between £730 and £2506. Most manufacturers offer discounts, but this is not reflected in Table I. The prices in the table are true only for implants purchased in the UK; prices in other countries are often very different owing to factors such as distribution costs.

Seven (18%) are unicompartmental, while the rest replace both condylar surfaces, with or without patellar components. The majority (20, 54%) offer a choice of cemented or cementless fixation while 17 (46%) are cemented. Two designs (Blauth and Endo-Model total rotational) are hinged.

Of the TKRs, 22 (60%) are claimed by the manufacturers to be modular. There are 16 (43%) of the TKRs which have components that can be used with either posterior cruciate ligament sacrifice or posterior cruciate ligament retention. Furthermore, modular stems and wedges can be used in 14 (38%). In 17 (45%), there is option for polyethylene tibial inserts of variable shape conformity, with or without cams. Patellar resurfacing option is available in 25 (68%).

Of the TKRs, on the UK market, 20 (54%) do not possess any functional or survival results whatsoever in peer-reviewed journals. All of these implants were introduced on to the UK market recently (in the late 1980s and 1990s), suggesting that these new TKRs are introduced with little evidence of superior results.

Five implants (AGC, Blauth, Endo-Model Sled Prosthesis, IB® I, and Total Condylar) have published survival analyses of 10 years or more. Of these, only the AGC is in common use. Five other implants (Oxford, LCS, Robert Brigham Uni, Scan Knee, Tricon) have published 5-year survival rates. In all, only 10 (27%)

designs possess survival for 5 years or more. Early functional results (under 5 years) have been published for 12 (32%) implants, while five other designs (14%), possess 5–10-year functional results.

Discussion

Apart from publications from national registers *(8)*, there are few sources of comparative information on the currently marketed TKRs. The tabulated data (Table I) offer such information but should be used in conjunction with more detailed information from the manufacturers and from the journals. The references quoted were obtained from the manufacturers as we believe that they should have such information readily available.

We have identified 37 different implants marketed widely in the UK. This figure excludes designs that are on trial with a limited number of surgeons and older implants that have been withdrawn from the market but are still used by a small number of orthopaedic surgeons. Manufacturers have indicated that more designs will be introduced in the 3rd and 4th quarters of this year and by 1997 the number of implants on the UK market may exceed 40.

At least 22% of the TKRs marketed have undergone major design modifications, while many others have seen smaller changes. It should be remembered that any modification can cause problems and do not automatically produce better results. The new 'improved' designs can be accompanied by difficulties with instrumentation and learning curve. Modified implants should be vigorously evaluated like new designs. In our survey, none of the new or modified TKRs are backed by published short-term clinical data nor long-term survival analysis before their introduction to the market. This, of course, is not surprising as there is at present no regulation for pre-introduction clinical trials.

The frequent modifications also contribute to the difficulty in using clinical results as a basis for selection. In the advertisements, manufacturers often quote the results of long-term trials of the predecessors of these modified implants. Such results are of little relevance to the model that is currently used. We have stressed this by excluding from our table the published results of the forebears of the current versions.

There are many factors that can influence the surgeon's choice of implants, but good clinical results must rank as the major consideration. In the era of evidence-based practice, health providers and purchasers alike are increasingly demanding this as the main criteria in the choice of treatments. The gold standard of demonstrating the superiority of one treatment over another in surgical practice is the randomised controlled trial. Ideally, this should be performed in multiple centres and utilise patient-based assessments *(9)*. Unfortunately, few are performed owing to the difficulties involved and the fact that these trials need at least 10 years to produce any meaningful comparison between implants. They should, however, be encouraged.

The most readily available outcome measures in joint replacement surgery are functional assessments and survival analyses. We have used such studies to compare the prostheses in the UK. We selected results that are published in peer-reviewed journals only as we believe that such data must be subjected to critical evaluation. Results that are not published in peer-reviewed journals must be interpreted with caution. There are, of course, limitations with these outcome measures. The assessment of function relies on a combination of symptoms, knee function and clinical findings which are variably weighted. Patients do not always report their symptoms to their surgeons *(10)*. These systems are subjective, and the numerous different scoring systems do not lend themselves to direct comparison. Furthermore, such schemes have not been validated *(11)*. Survival analysis is a useful tool to measure longevity, but there are inherent pitfalls *(11,12)*. In addition, we have found that by the time survival data are available, the TKR may not be in wide usage. Only one of the TKRs with 10-year survival data (the AGC) is in common use. Interpretation of these survival studies must be made with care, particularly with respect to the definition of failure. In the AGC study, an impressive 10-year survival data of 98% was given, but the study excluded patellar failure even though there were many more patellar failures compared with tibial and femoral component failures *(29)*.

Increasingly, manufacturers are developing systems of TKRs that are able to cope with the demands of any knee within the same design concept. Many, for instance, have options for fixation with or without cement, for retention or sacrifice of the posterior cruciate ligament, with full or partial constraint, and various sizes of stems and wedges. This extensive array of implants that are interchangeable while using the same basic instruments has major advantages for the surgeon. However, it means that clinical follow-up is becoming meaningless. Any series of one make of TKR will contain so many combinations of components, each used in so few patients, that it becomes impossible to draw any conclusions about the various designs.

We have shown that 54% of the TKRs on the UK market do not possess any published results whatsoever. Using such implants may well be causing harm to the recipients. Are surgeons in the UK guided by clinical results when selecting TKRs? The most widely used implants in the UK at the moment are the IB II, Kinemax, PFC and the AGC, based on the market share data that the manufacturers provided. This was substantiated by an independent postal survey of Fellows of the British Orthopaedic Association *(13)*. Of these four implants, only one (the AGC) possesses published survival figures. The IB II and the Kinemax do not possess any clinical results, although clinical results are available for their forebears. It would appear that factors other than published clinical data are perceived to be more important to the UK surgeon when choosing TKRs. While a recent survey has shown that great diversity exists in the UK in the surgical practice of total knee

replacement *(14)*, our study has shown that this diversity is extended to the choice of implant.

Conclusions

The choice of implants should be made on sound clinical grounds. Published data are difficult to interpret owing to the frequent modification of the prostheses and the increased use of modular designs with multiple options.

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