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ORIGINAL STUDY

A systematic literature review of the Profix® in primary total knee arthroplasty

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Despite more than a decade of use, there are currently no comprehensive reviews summarising clinical results with the Profix Total Knee System in primary total knee arthroplasty. Searching the PubMed and Google Scholar databases revealed 17 potentially relevant Profix manuscripts. After author review and exclusion of studies not meeting predetermined variables, 8 manuscripts were selected. Knee Society data were provided in all 8 and implant survival data in 4. Data for 987 patients (1152 knees) were available. The overall estimated implant survival was 98.6% at 5 years and 94.2% at 10 years with revision for any reason as an endpoint, and 100% at both time points with radiographic loosening as an endpoint. Mean/median preoperative Knee Society knee scores improved from 39.2/24.7 at baseline, to 91.4/92.1 at the last postoperative follow-up visit. Good medium- to long-term clinical results can be expected with the Profix in primary total knee arthroplasty.

Keywords : knee arthroplasty ; Profix knee ; mid-term results ; survivorship.

INTRODUCTION

The Profix Total Knee System (Smith and Nephew, Memphis, USA) has been in wide clinical use since its introduction in 1994. This system was developed to be highly adaptable to allow for its use in a diversity of indications. It offers the possibility for full uncemented total knee arthroplasty (TKA), with press-fit or cemented femoral components, titanium femoral stems and wedges, cemented or uncemented titanium primary tibial components, and the possibility for porous coating on the primary femoral and tibial components.

Despite more than a decade of clinical use, there are currently no comprehensive systematic reviews summarising the clinical results of the Profix in primary TKA. The current systematic literature review was therefore undertaken to address this need. Its purpose is to gauge the medium- to long-term utility of the Profix by concentrating on two key outcome measures : Kaplan-Meier survivorship (*5*) and Knee Society (KS) knee scores (*4*). It was also asked whether there would be any differences in outcomes between cemented and uncemented fixation of the Profix.

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METHODS

A systematic search of the literature was conducted using the PubMed database and the Google Scholar search engine. Studies were excluded if they met any of the following criteria : (1) non-English language ; (2) dealt with revision TKAs (unless primary TKA data could be extracted) ; (3) Profix system was used with a mobile bearing option ; (4) failed to include either survival data with at least 5 years of follow-up or post-operative KS scores ; (5) meeting abstract ; (6) study from a non-peer-reviewed journal ; or (7) considered a non-clinical study (single case study, level V evidence, expert opinion, review paper, or basic science study [biomechanical, cadaveric, laboratory]).

The following search terms were entered : "Profix," "Smith & Nephew," "total knee arthroplasty," "total knee replacement," "fixed bearing," "clinical outcome," "clinical score," and "survivorship."

A final search of the literature was conducted in April 2011, at which point 17 potentially relevant manuscripts featuring clinical results with the Profix system had been discovered. These manuscripts were reviewed by the authors, who determined whether they merited inclusion. Following this process, 10 manuscripts (*3,7,8,10,12-1517,18*) were available that fit the criteria of reporting clinically relevant survivorship times and/or KS clinical rating system scores. Two studies by Smith *et al* (*12,13*) were thought to repeat information from a larger prospective, randomised trial of Profix TKA by this author (*14*). Rather than risk repeating case information and corrupting aggregated results, it was decided to exclude the two earlier manuscripts by Smith *et al* (*12,13*) in favour of the latter analysis (*14*). This left a final count of 8 manuscripts (*3,7,8,10,14,15,17,18*) for inclusion in this systematic review (Fig. 1).

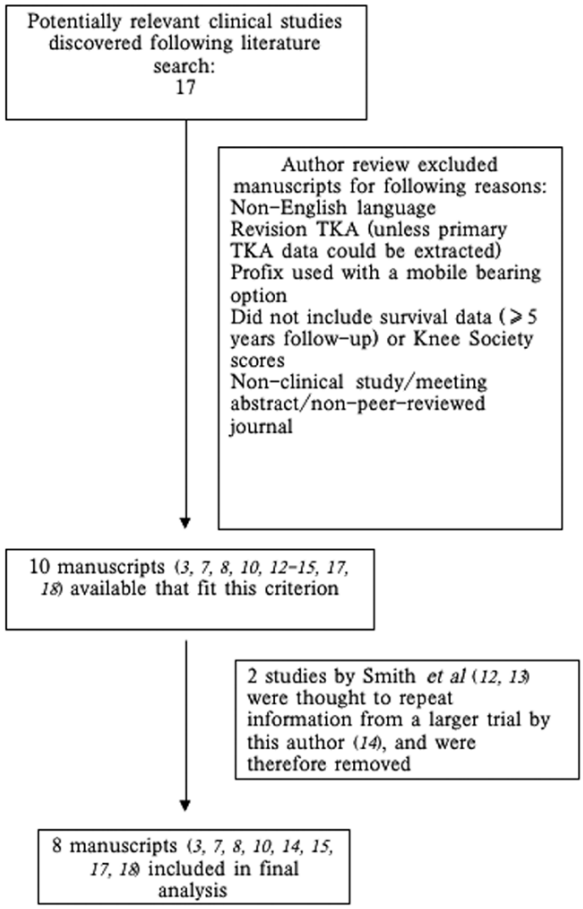

Fig. 1. — Flow-chart detailing the selection of manuscripts used in this systematic review.

Although each of these individual manuscripts presented a range of clinical data, it was decided to focus on survivorship and KS knee scores because these two outcome measures have a long-established utility in evaluating the clinical performance of knee implants and are a common enough feature of analyses in TKA to allow for grouping and comparing data among different studies. By concentrating on these two variables, it was also possible to present accumulated data from a number of studies in order to develop an initial understanding of what outcomes might be expected with the Profix. Additionally, both implant survival as determined by Kaplan-Meier survivorship (*5*) and KS knee scores (*4*) employ a specific set of commonly used criteria and are therefore ideal for comparing outcomes between studies, which is of special importance given the heterogeneity in other areas of the chosen manuscripts.

All studies were prospective analyses published between 2003 and 2009 (*3,7,8,10,14,15,17,18*). Four of the studies were randomised (*7,8,10,14*). Implant survival data were available in 4 studies (*3,15,17,18*) : in 3 studies survival data came from Kaplan-Meier analysis (*3,15,18*) and in the other study (*17*) a survivorship of 100% was implied by a lack of revisions. All 3 studies (*3,15,18*) with Kaplan-Meier data considered revision for any reason as the endpoint, although this was also referred to as 'worst-case survivorship' in the study by Whiteside and Vigano (*18*). As two of these studies (*15,18*) also considered radiographic loosening as an endpoint, it was decided to also include this as an endpoint in the current analysis as well.

Table I. — Estimated survival of the Profix knee system at 5 and 10 years with revision for any reason and/or radiographic loosening as the endpoint

Study	Number of knees	Minimum follow-up in months	Survival rate at 5 years, revision for any reason (95% CI)	Survival rate at 5 years, radiographic loosening (95% CI)	Survival rate at 10 years, revision for any reason (95% CI)	Survival rate at 10 years, radiographic loosening (95% CI)
Hardeman *et al* (*3*)	115	96	98.2% (± 2.4%)	NR	97.1% (± 4.4%)	NR
Vigano *et al* (*15*)	64	61	98.4% (95.4% to 100%)	100%	98.4% (95.4% to 100%)	100%
Whiteside *et al* (*17*)	330	60	100%	NR	NR	NR
Whiteside & Vigano (*18*)[a,b]	334	60	98.8%	100%	92.4%	100%
Pooled estimates	843	69.25	98.6 (97.8 to 99.4)		94.2 (92.5 to 95.9)	

Abbreviations : CI = confidence interval ; NR = not reported.

[a] Follow-up information was provided in years as an uneven number in this study (mean of 7.3 years) and translated into months for the current analysis.

[b] Survival data was averaged together from 2 patient cohorts ; no 95% confidence interval available.

KS knee scores were available in all 8 studies (*3,7,8,10, 14,15,17,18*). Three studies exclusively used cemented components (*8,10,14*), 4 used uncemented components (*3, 15,17,18*), and one study used both cemented and uncemented components (*7*).

Patient age is presented as an average based on available results from studies. Age data were not provided by Whiteside and Nakamura (*17*).

For the purposes of this analysis, primary knee osteoarthritis and post-traumatic osteoarthritis are all grouped under the term 'osteoarthritis.'

The reporting of follow-up periods also varied considerably from study to study. Whereas some studies only reported a general range (e.g., 8-10 years in Harderman *et al* (*3*)), in others a much higher level of description was provided (e.g., a mean of 83 ± 6 months in Vigano and Whiteside (*15*)). Follow-up times are provided for individual studies and cumulatively using pooled, weighted estimates of the minimum follow-up points in Tables I and II.

Cumulative implant survival rates were generated by averaging the rates in the 4 studies providing these data (*3,15,17,18*). In addition, survival time was stratified by 5- and 10-year follow-up points, and according to the two survival definitions used in more than one study (revision for any reason and radiographic loosening).

The reporting of KS data was generated and stratified using identical methods to that of implant survival rates. For the 4 randomised analyses (*7,8,10,14*), averages were obtained for all relevant treatment groups combined and counted once per study (i.e., in the study from Smith and Wood (*14*) post-operative KS was 92 and 93 for patients with and without patellar surfacing, respectively, but was averaged as 92.5 rather than counting 92 and 93 individually for larger analyses).

KS knee scores were reported as means in 5 studies (*3, 10,15,17,18*), as medians in 2 studies (*7,8*), and in one study (*14*) preoperative KS was reported as a mean but postoperative KS was reported as a median. As KS knee scores can have a highly skewed distribution, it is not advisable to pool mean and median results. Therefore, KS data were only considered individually for means and medians.

The small amount of clinical studies available precluded the development of a meta-analysis, the conducting of which is not recommended without a certain number of studies of similar design, especially in the presence of (potential) heterogeneity. As such, the current systematic review functions solely as a descriptive summary of the chosen studies. It has no predictive value outside of offering initial, non-statistical observations about the Profix system in primary TKA.

RESULTS

The 8 studies selected for this analysis provided clinical outcomes data for 987 patients (1152 knees). The mean age of the patients was 64.5 years. Of the 1152 knees included in this review, 1007 were treated for osteoarthritis and 115 for rheumatoid arthritis, and 906 received uncemented components

Table II. — Knee Society knee score data

Study	Fixation	Number of knees	Minimum FU (months)	Mean preop KSS (range or SD)	Mean postop KSS (range or SD)	Median preop KSS (range or IQR)	Median Postop KSS (range or IQR)
Hardeman *et al* (*3*)	Uncement	115	96	49.3 (± 25.6)	93.1 (± 8.9)	NR	NR
Nilsson *et al* (*7*)	Cemented	34	24	NR	NR	28 (0-64)	95 (56-100)
Nilsson *et al* (*7*)	Uncement	63	24	NR	NR	23 (0-60)	95 (54-100)
Norgren *et al* (*8*)[a]	Cemented	23	24	NR	NR	24.5 (1-50)	76.5 (55-98)
Saari *et al* (*10*)	Cemented	30	24	44 (15-91)	93.5 (72-99)	NR	NR
Smith *et al* (*14*)[b]	Cemented	159	52.5	39.35 (± 16.35)	87.6	NR	92.5 (11.5)
Vigano *et al* (*15*)	Uncement	64	61	34 (± 11)	88 (± 9)	NR	92.5 (12)
Whiteside *et al* (*17*)	Uncement	330	60	47 (± 5)	94 (± 6)	NR	NR
Whiteside & Vigano (*18*)[b]	Uncement	334	60	28.5 (± 11)	90.5 (± 8.5)	NR	NR
Pooled estimates		1152	57.9	39.2	91.4	24.7	92.1
Pooled estimates uncemented		906	62.1	39.0	92.0	23.0	95.0
Pooled estimates cemented		246	42.4	40.1	88.5	26.6	91.2

Abbreviations : KSS = Knee Society knee score ; preop = preoperative ; postop = postoperative ; FU = follow-up ; CI = confidence interval ; IQR = interquartile range ; NR = not reported ; SD = standard deviation.

[a] An official range of follow-up was not provided by this study. Instead, the range was inferred from a description of missing observations.

[b] Follow-up information was provided in years as uneven numbers in this study and translated into months for the current analysis. In Smith *et al* (*14*) it was given as 4.37 years (3 to 7.03), and in Whiteside and Vigano (*18*) as a mean of 7.3 years.

and 246 received cemented components. One study, accounting for 30 knees, did not identify the primary diagnosis leading to TKA (*10*). The average minimum follow-up for all studies combined was 57.9 months (range : 24 to 96 months).

Implant survival

Implant survival findings were reported in 4 of the studies, all of which used uncemented components (*3,15,17,18*). The overall estimated implant survival with revision for any reason as an endpoint was 98.6% (95% ; confidence interval [CI] : 97.8-99.4%) at 5 years and 94.2% (95% ; CI : 92.5-95.9%) at 10 years. Survival was 100% at both 5 and 10 years when radiographic loosening was selected as the survival endpoint (Table I).

Knee Society knee scores

KS knee scores were reported in all 8 studies (*3,7, 8,10,14,15,17,18*). Mean and median preoperative KS knee scores improved from 39.2 and 24.7, respectively, to 91.4 and 92.1, respectively, at the last postoperative follow-up point. Results were similar regardless of whether cemented or uncemented fixation was used (Table II).

Cemented versus uncemented Profix systems

The only study in this analysis to directly compare Profix TKA with cemented and uncemented components found no significant difference in KS knee scores between the fixation methods (*7*).

DISCUSSION

This systematic review of 8 studies assessing the use of the Profix system for primary TKA was undertaken to provide an initial overview of clinical experience with this device. It was decided to focus exclusively on implant survival (*5*) and KS knee scores (*4*), as these two endpoints are clinically relevant indicators for assessing the performance of a device, and are in such wide use in the literature that they easily facilitate grouping and comparing data across studies. Additionally, potential discrepancies in clinical outcomes between cemented and uncemented Profix TKA were sought, in order to gauge whether one method of fixation produced superior results.

This systematic review has several key limitations. Firstly, only 8 studies met the inclusion criteria for this review. Although this is a satisfactory number of manuscripts for an orthopaedic device with the Profix's years of clinical usage, it was not large enough to overcome key differences in design among the studies and allow for the conducting of a meta-analysis, which can yield precise estimates of treatment effect. In particular, the use of only 4 studies upon which to base our survival analysis is relatively insufficient. Instead, the current review serves primarily as a resource for future studies by means of offering an early comparative resource for the two chosen endpoints. Secondly, the decision to only analyse implant survival and KS knee scores necessitated overlooking several potentially useful clinical variables, such as knee pain, patient satisfaction, and range of motion. Clinicians and patients alike have a multifaceted view of implant success, and no analysis concentrating solely on two variables will be able to address the full scope of their concerns. Lastly, the Profix was designed to be used in an assortment of procedures and clinical indications, which is reflected in the diverse study designs of these manuscripts. The chosen studies were significantly heterogeneous in terms of surgical approaches, implant components, fixation methods, patient groups, and other factors. In turn, this greatly impairs the ability to extrapolate these results to any specific treatment setting. As more clinical studies of the Profix appear in the literature in the coming years, it will be possible to develop reviews that are stratified according to these disparate elements, but currently such a tactic is impossible. Although these limitations are fully recognised by the study's authors, they do not detract from the stated goal of this review ; namely, to offer an initial overview of the clinical performance of the Profix knee system.

Good-to-excellent results were observed in this series of 987 patients (1152 knees) undergoing primary TKA with the Profix knee system. The implant survival rate was 95.9% at 10 years in knees followed up to that time period (*3,15,17,18*). These latter results are made more compelling by the fact that one of the studies (*3*) was conducted in patients with an average age of 73 years and another (*15*) exclusively in patients with rheumatoid arthritis, both utilising uncemented fixation. Due to deficiencies in their supporting bone stock, both older patients and those with rheumatoid arthritis are commonly thought to do best with cemented fixation (*13,16*). The positive outcomes observed here in those with rheumatoid arthritis are in line with earlier analyses of uncemented TKA in this patient population (*1,2,6,11,16*).

Encouraging results were also noted with the second outcome analysed in this review, with preoperative mean and median KS knee scores improving from 39.2 and 24.7, respectively, to 91.4 and 92.1, respectively, at the last postoperative follow-up point (Table II).

Survival data were not available for Profix TKA with cemented components, so it was impossible to draw any conclusions regarding the possible influence of fixation methods on this element of clinical performance. However, when stratified by fixation methods, studies in which cemented (*7,8,10,14*) and uncemented components (*3,7,15,17,18*) were used reported similar KS knee scores at the time of final follow-up (uncemented : mean 92, median 95 ; cemented : mean 88.5, median 91.2). Although no significant differences in KS knee scores were noted in the one study in this analysis to directly compare Profix TKA with cemented and uncemented components, other study variables favoured the use of an uncemented hydroxyapatite-coated tibial component without additional screw fixation (*7*).

Further randomised trials will be needed to determine the optimal fixation method for Profix TKA in several specific patient groups.

This systematic review indicates that good medium- to long-term clinical results have been noted when the Profix knee system is used in primary TKA. Survival data at 10 years seems to confirm the osseointegrative properties of the Profix design in tandem with uncemented components, especially in older patients and those with deficient bone stock. In terms of KS knee scores, there does not appear to be a significant difference in outcomes between cemented and uncemented fixation. Additional randomised controlled trials of this system are required to determine if these initial observations hold true over time.

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