Causes of Failure in Total Knee Arthroplasty

Rapeepat Narkbunnam MD, FRCOST*,
Keerati Chareancholvanich MD*

* Department of Orthopaedics Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

mat.or.th*

J Med Assoc Thai 2012; 95 (5): 667-73
Full text. e-Journal: http://www.jmat.mat.or.th

Total knee arthroplasty is a highly successful orthopedic procedure. The procedure is highly effective, and it is beneficial in terms of clinical outcomes, patient satisfaction, and long-term survival. In most studies, the 10 to 15-year survival rate of the implant is more than 90 to 95%[1-5]. Because of these results, the number of total knee arthroplasty performed is rapidly increasing. Kurtz et al[6] project that the number of total knee arthroplasty procedures will increase by 601% between 2005 and 2030. Likewise, the number of failures and poor results requiring revision surgery are also going to increase. From the study mentioned above, they projected that the rate of revision surgery will double by 2015.

Revision total knee arthroplasty is far more complex than primary surgery; it requires high surgical skill and an experienced surgeon. It also comes with a highly constraining prosthesis, high cost and a high risk of complications. Rates of revision total knee arthroplasties are going to increase in the near future. Causes of surgical failure will be essential information for planning treatments and prevention of this problem.

There are many causes of failure in total knee arthroplasty. Previous studies have categorized these failures as early or late failures based on time from primary surgery to revision surgery, but there are differences cutoff points for defining early versus late failure. In 1994, Ferhing et al[7] reported 440 revision cases. They defined early failure as failure in the first five years after primary surgery. They found that 38% of early failures were caused by infection. Sharkey et al[8] (2002) (212 cases) and Mulhall et al[9] (2006) (318 cases) defined early failure as failure in the first two years after primary surgery. They reported that 25% of early failures were due to infection. The most common causes of late failure were found to be polyethylene wear, aseptic loosening, and instability.

Narkbunnam R, Department of Orthopaedics Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.
Phone: 0-2419-7528-30, Fax: 0-2411-5011
E-mail: mai_parma@hotmail.com

J Med Assoc Thai Vol. 95 No. 5 2012 667

Background: *The number of primary total knee replacement procedures has rapidly increased worldwide because of the high success rates. The incidence of failure of total knee replacements has concurrently increased. Determining the causes of failure is very important for devising treatment and plan for future prevention strategies.*
Material and Method: *A retrospective study was done with patients who underwent revised total knee replacements in Siriraj Hospital between September 2003 and March 2009. Patient demographic data, laboratory tests, radiographic studies, and intra-operative findings were used to categorize the causes of failure.*
Results: *One hundred eighty nine patients (31 male, 158 female) were included in the present study. The average age was 70.8 years. The average survival time after surgery was 6.42 years (ranging from 1 month to 22 years). The major causes of failure included aseptic loosening (52%), polyethylene wear (43%), and infection (31%). Infection (61%) was found in more than half the cases of early failure (< 3 years). Most cases of late failure (> 3 years) were due to aseptic loosening (74%), polyethylene wear (68%), and infection (14%). Male sex and early failure were strongly associated with failure secondary to infection, with odds ratios 4.5 and 8.8, respectively.*
Conclusion: *There are different causes of early and late failure. The major cause of early failure was infection, while aseptic loosening and polyethylene wear played major roles in late failure. The number of failures due to infection was higher than observed from previous studies. Identification of the causes of failure of total knee replacement surgery from the same country or region will be useful for devising plans to manage and prevent failure in future surgeries.*

Keywords: *Causes, Failure, Knee joint, Arthroplasty, Knee replacement, Knee prosthesis, Infection*

This problem of arthroplasty failure is currently being studied extensively; unfortunately, few studies are investigating the causes of failure. No consensus criteria exist that classify the exact causes of failure and the cutoff point that divides failure into early and late failure. Moreover, that there should be different incidence and causes of failure in the different regions of the world. Most data were reported from developed regions such as North America and Europe. There are scant data from developing countries. The authors hypothesized that the rate of failure, especially failure caused by infection, would be higher than in previous studies.

Material and Method

This was a retrospective study reviewed from all revision total knee arthroplasty performed at Siriraj Hospital between September 2003 and March 2009. Patient demographics data including age, gender, height, and body weight were collected. Physical exam findings, time from primary surgery, intraoperative finding, intraoperative culture, laboratory investigation, radiographic study, surgical procedure, prosthesis type, and bone defect management were also recorded. After all data was collected, cause of failure was determined by diagnostic criteria according to studies of Sharkey et al[8] and Mulhall et al[9]. If there was more than one cause of failure in the same patient, all causes were documented. Early and late failures were divided by a cutoff point of three years after primary surgery because this cutoff point was the most appropriate representation of the incidence of infection, which is the most common cause of early failure (See discussion).

Ethical consideration was approved by Siriraj ethics committee. Study protocols were approved by institutional review board. All of the patients' identification records were undisclosed. Statistical analysis of collected data was done with descriptive statistics. Survival time analysis was shown by a Kaplan-Meier scale. Categorical data were compared with chi-squared tests. Risk estimates for infection and early failure were determined using odds ratios

Results

One hundred eighty nine subjects who underwent revision total knee arthroplasties were included in the present study and included 158 females and 31 males. The mean age was 70.8 years (SD = 8.5, range 42-87). Mean BMI was 25.94 (SD = 3.43, range 18-39.5). The mean interval time from primary

surgery to failure was 6.42 years (1 month to 22 years). Survival time analysis is shown in Fig. 1.

The different causes of arthroplasty failure are shown in Fig. 2. The most common cause of failure was aseptic loosening (52%), followed by polyethylene wear (43%). Infection was the third most common cause of failure (31%). The other causes were instability (13%), prosthesis malalignment (10%), periprosthetic fracture (3%), and patellofemoral problems (4%).

Distribution curve of survival time analysis for aseptic and septic cases was shown in Fig. 3. The mean survival time for aseptic group was 7.8 years and for septic group was 3.3 years. The cut point times to represent infection as the major problem in the early failure group was three years after primary surgery.

There were 69 patients in the early failure group (< 3 years). Infection was the most common cause of failure in this group, at a rate of 61% (n = 42). Instability was the second most common cause of failure (20%, n = 14). Other causes of failure were
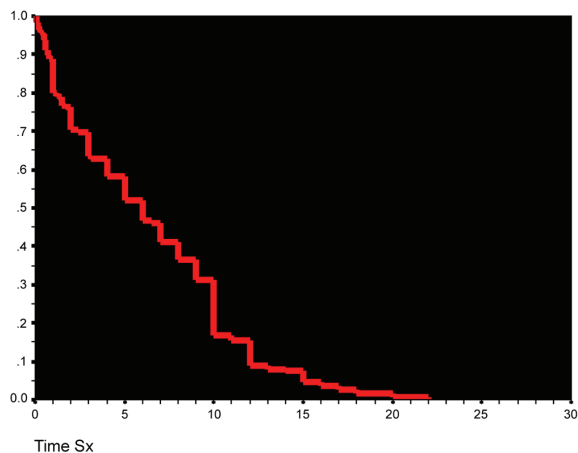

Time Sx

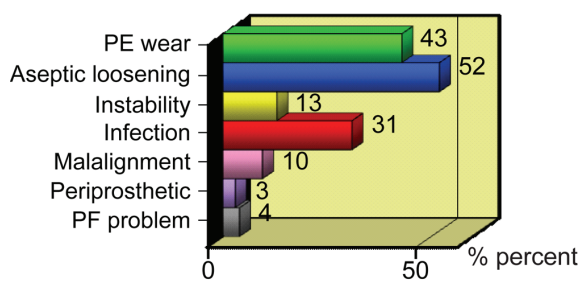**Fig. 1** Survival time analysis for overall fail TKA cases

Fig. 2 Overall causes of failure

aseptic loosening (16%, n = 11), malalignment (15%, n = 10), polyethylene wear (3%, n = 2), periprosthetic fracture (4%, n = 3), and patellofemoral problems (3%, n = 2).
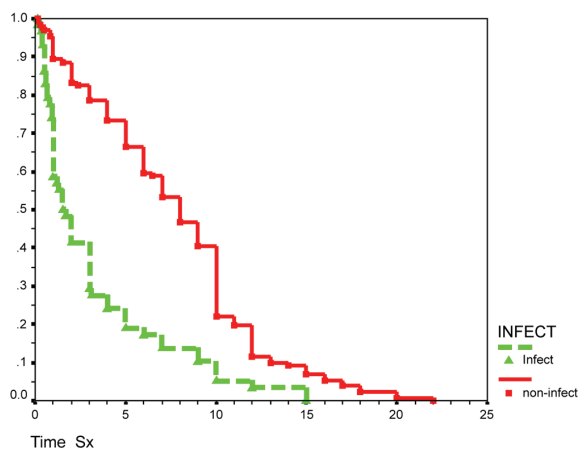
One hundred twenty patients were in the late failure group (> 3 years). Aseptic loosening and polyethylene wear were the most common causes, at 74% (n = 89) and 68% (n = 81), respectively. In most cases, aseptic loosening was accompanied by polyethylene wear. Conversely, infection was the third most common cause of failure in this group (14%, n = 17). The other causes of failure were instability (9%, n = 11), prosthesis malalignment (7%, n = 8), periprosthetic fracture (3%, n = 3), and patellofemoral problems in (4%, n = 5). Fig. 4 shows a comparison between the causes of early and late failure.

Because infection appeared to be the most common cause of failure, the authors determined the risk factors for infection in the present study. The

Fig. 3 Survival time analysis for aseptic vs. septic group

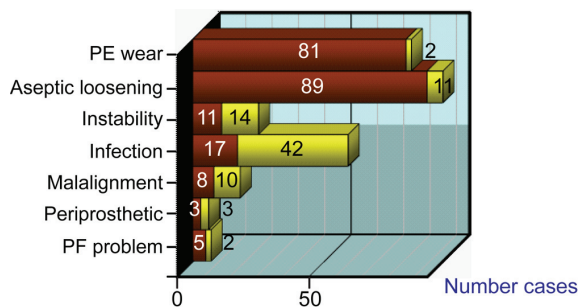**Fig. 4** Comparison causes of failure for early and late failure

results showed that early failure (< 3 years) and male sex were strongly associated risk factors (odds ratio = 8.8 and 4.5, respectively). ESR and CRP were significantly elevated in the septic group. Mean ESR and CRP were 90 and 30, respectively, in the septic group and 30 and 1, respectively, in the aseptic group. There were no significant differences in WBC count and percent neutrophils between the septic and aseptic groups. (6,750 and 58% in the aseptic group, respectively, and 7,780 and 62% in the septic group respectively). Positive cultures were found in 41% of the septic group (24 of 59 cases), and MRSA was the most common organism isolated (23.7%). The second common organism grown in culture was Enterococcus species, seen in 6% of the cases. Mycobacterium tuberculosis was found in one case.

Locations of prosthesis loosening in failure total knee arthroplasty were most commonly found at both femur and tibia in 38% of cases. Loosening only tibia or femur were 13%, 12% of cases respectively. Loosening at only the tibia or femur was seen in 13% and 12% of cases respectively. Loosening of all components including the patella was found in 10% of cases, and there were no loose parts in 27% of all cases.

Management of bone defects required metal augmentation in 61% (98 cases) of revision cases, and 6% (10 cases) of cases had major defects requiring filling with structural allograft. Most cases (36%) required metal augmentation at the femoral condyle, distal or posterior defects. Twenty-nine percent of all cases only required augmentation at the medial condyle, and 12% required augmentation at the lateral condyle. Augmentation at the tibia was required in 11% of cases, and anterior wedge augmentation was required in 10% of the cases.

Discussion

Failure after total knee arthroplasty have trend to increase incidence in the near future. Information about the causes of failure is essential for planning management and revision surgeries. Unfortunately, few studies have investigated the causes of failure. Furthermore, available studies did not use the same study designs, data collection methods, classification, and diagnostic criteria. Moreover, there are no data reported for many regions of the world, especially developing countries. Thus, studies so far have had variable results in terms of long-term outcome and causes of arthroplasty failure (see Table 1).

Table1. Data from previous studies of failure TKA

Paper	Patient number	Survival times (mean)	Ratio, aseptic:septic	Ratio, early:late
Ahlberg 1981[10]	31	3.9 yrs	24:7 (22%)	NS
Cameron 1982[11]	94	4.7 yrs	75:19 (20%)	NS
Fehring 1994[7]	279	Within 5 yrs	174:105 (38%)	279 (5 yrs)
Sharkey 2002[8]	212	3.7 yrs	175:37 (17%)	118:94 (2 yrs)
Mulhall 2006[9]	318	7.9 yrs	262:56 (17%)	99:219 (2 yrs)
Current study	189	6.4 yrs	131:58 (0.31%)	69:120 (3 yrs)

From early reports, in 1981, Ahlberg and Lunden[10] reported 31 failed TKA from 254 patients. In 1982, Cameron and Hunter[11] reported 94 failed TKA from 700 patients. Mean survival time was 3.9 and 4.7 years respectively. Most common cause was aseptic loosening and infection. In 1994, Fehring[7] reported early failure within first five years after primary operation. From 279 failed TKA patients, infection was found to be the most common cause, which rated as high as 38% of all patient. Instability and aseptic loosening from failure of ingrowth in porous-coated surface was the second and third common. They concluded host factors and sterile technique was the essential roles for prevent infection. They recommended to routinely using cemented implant and careful ligamentous balancing, the number of revision rate from early failure could be reduced approximately 40% and 25% for overall cases. In 2002, Sharkey et al[8] reported 212 failed TKA. They classified early failure as revision surgery within the first two years after operation. Mean survival time was 3.7 years and more than half of cases (55.6%) were in early failure group. Polyethelene wear was the most common cause (25%) for overall cases. Infection was found 17% for all of cases and turned to be the most common cause in early failure group, which was responsible for 25.4% of cases. Component loosening found 24.1% of overall cases, most of cases were late failure and found as the coincidence with polyethelene wear. They suggested to abandon surface cementing technique for tibial component. Furthermore, they stated to be careful in use of cementless implant because these factors related to more incidence of early failure compared to standard cementing technique[12]. Mullhall et al[9] reported 318 failed TKA with mean survival time at 7.9 years. They defined early failure at within two years same as in study by Sharkey[8]. The proportion of early to late failure was different from the former study. Most of patients were in late failure group (69%), in contrast to Sharkey's study[8], which were predominant in early failure group (55.6%). More than two out of three cases had coexisting causes of failure. Common causes of failure were instability (28.9%), polyethelene wear (24.5%), bone lysis (27.5% for tibia, 22.5% for femur, 9.5% for patella), and infection ((significantly high in early failure (25.4%) and decreasing to 17.6% for total cases). For the present study, 189 failed TKA were included. Mean survival time was 6.4 years. This appears longer than most studies except from the most recent study by Mulhall[9] in 2006 (7.9 years). The proportion of early to late failure was predominant in late failure (63.5%), reflecting proportion of Mulhall's study[9].

The causes of failure were different by times. In early failure, infection was the primary cause of failure. These results were the same in all studies[7-11]. However, the cut point time to divide between early and late failure had no standard agreement. Ferhing[7] defined cut point time at five years but Sharkey[8] and Mullhall[9] were at two years from primary surgery. There was no explanation about the reason of cut point time from previous studies. For the present study, the authors defined the cut point time at three years. This is because the mean survival times of the infected group was 3.3 years and, from the survival time analysis graph (see Fig. 3) slope of the curve, it plateau after three years. Because the authors gave priority for early failure groups, they were found to be primary caused by infection. The appropriated time of cut point for early failure should represent the infected group. Data from a previous study by Mullhall[9] showed the result of mean survival time in the infection group as 2.5 years. They classified the early failure within two years. Because of this, their results did not reflect the largest group of infected failure. This makes their cut point time at two years, not representing the infection cause. For this reason, the authors recommend a further study to analyze mean survival time and the plateau curve from the survival analysis graph in infection failure

case to define the most appropriate time to classify as a standard cut point for early and late failure.

The incidence of failure from infection from the current study was high (31% of overall, 61% of early group) when compared to previous studies (Sharkey[8] 17% overall/25.4% early, Mullhall[9] 17.6% overall/25.4% early, Ferhing[6] 38% in five years). This data have clinical importance for Thailand and other developing countries. The incidence of infection from developed countries could not be used in developing countries. Every country or region should have their own incidence of infection for patient education before surgery. Infection control strategies to reduce infection rate should be the important plan for every hospital.

In the late failure group, aseptic loosening and polyethylene wear were the main causes of failure. Incidence was similar to previous studies[7-9]. These modes of failure were responsible for 70% of the late failure group and mostly found to be coincidence. In the present study, most common locations of loosening were at both femur and tibia component (38%), loosening only at tibia or femur has closely the same incidence at 13%, 12% respectively. This data was different from a prior study which show tibia component has more significant loosening than femur component[7-9]. All cases in the present study had performed all cementing technique with standard techniques of cementation; no surface cementing techniques were used. Because most studies found significant loosening of tibia component found in cementless implant and in surface cementing technique of tibia component. Many long-term studies found excellent results from standard cementing technique at both femur and tibia component. For this reason, the authors recommend to routinely use the standard cementing techniques because in today's data there is no superiority for long-term results of other technique better than the standard technique.

Incidence of instability of the present study was low (13%) compared to prior studies. Because most of studies diagnosed instability only by preoperative physical examination, they found instability in varus-valgus plane or anteroposterior plane. This makes over diagnosis of failure by instability cause likely. The authors defined instability as ligament and soft tissue instability or imbalance flexion/extension gap. The present study had excluded the cases that had instability caused by polyethylene wear or mark loosening of prosthesis. This problem was from diagnostic criteria. Each study had failure

classification mode different from each other. Therefore, there is confusion in evidence to clearly define this as standard criteria. Most studies divided mode of failure by consideration of the surgeon from intraoperative finding. Because most cases had more than two modes of failure such as 50% from the current study and two third from Mullhall[9], these results can make different incidence of failure causes. The authors expect a global agreement of diagnostic criteria for cause of failure in TKA. Then, all the regions in the world should have their own data to show the causes of failure in TKA, a plan of management, and protection for the high rising rate of revision TKA.

In conclusion, information about the causes of total knee arthroplasty failure is essential for planning treatment and preventive strategies. The incidence of revision total knee arthroplasty is going to rise in the future. However, there are very few studies investigating this problem. There is no standard criteria for classifying causes of failure, and different cutoff points exist for categorizing failure into early and late failure. This lack of consensus leads to variable results in the literature. Recent studies have shown that causes of failure are different in each country and region, especially the rate of failure due to infection. Knowledge of the local incidence of infection is important for patient education purposes. More studies with more cases, from many regions of the world, that use the same materials and methods will provide valuable information that will help with managing and preventing total knee arthroplasty failure.

Potential conflicts of interest
None.

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สาเหตุของการล้มเหลวของข้อเทียมภายหลังการผ่าตัดเปลี่ยนข้อเข่าเทียม

ระพีพัฒน์ นาคบุญนำ, กีรติ เจริญชลวานิช

ภูมิหลัง*: เนื่องจากการผ่าตัดรักษาโดยวิธีการเปลี่ยนข้อเข่าเทียมนั้นถือเป็นการผ่าตัดที่ได้ผลการรักษาที่ดีมาก ทำให้อัตราการผ่าตัดชนิดนี้เพิ่มขึ้นอย่างรวดเร็วในระยะหลัง ในระยะยาวมีผลทำให้โอกาสเกิดการล้มเหลวหลังจากการผ่าตัดเปลี่ยนข้อเข่าเทียมสูงขึ้นตามมาได้ และถือเป็นปัญหาที่สำคัญที่จำเป็นต้องมีการศึกษาถึงสาเหตุของการล้มเหลวภายหลังการผ่าตัดเปลี่ยนข้อเข่าเทียม เพื่อใช้เป็นแนวทางในการวางแผนป้องกัน และการรักษาในระดับชาติต่อไป*

วัสดุและวิธีการ*: ลักษณะการศึกษาชนิดย้อนหลัง โดยการเก็บรวบรวมข้อมูลจากผู้ป่วยที่มารับการรักษา โดยวิธีการผ่าตัดซ้ำเพื่อแก้ไขภาวะการล้มเหลวของการผ่าตัดเปลี่ยนข้อเข่าเทียมภายในโรงพยาบาลศิริราช ในระยะเวลาตั้งแต่ เดือนกันยายน พ.ศ. 2546 จนถึง เดือน มีนาคม พ.ศ. 2552 ข้อมูลทั่วไปของผู้ป่วย การตรวจทางห้องปฏิบัติการ การศึกษาจากภาพถ่ายรังสี รวมทั้งข้อมูลจากการผ่าตัด ได้ถูกรวบรวมเพื่อใช้เป็นข้อมูลในการศึกษา*

ผลการศึกษา*: ผู้ป่วยทั้งหมด 198 คน หญิง 159 คน ชาย 31 คน ได้ถูกรวบรวมข้อมูลเพื่อใช้ในการศึกษานี้ อายุเฉลี่ยของผู้ป่วย 70.8 ปี ระยะเวลาของการล้มเหลวภายหลังการผ่าตัดครั้งแรกเฉลี่ย 6.42 ปี ระยะตั้งแต่ 1 เดือน จนถึง 22 ปี สาเหตุหลักของการล้มเหลวโดยรวมได้แก่ การหลวมของข้อเทียมชนิดไม่ติดเชื้อ 52%, การสึกกร่อนของ poly-ethylene 43% และการติดเชื้อของข้อเทียม 31% แต่หากแยกเป็นการล้มเหลวที่เกิดขึ้นในระยะสั้นภายใน 3 ปีแรก จะพบว่าการติดเชื้อของข้อเทียมเป็นสาเหตุของการล้มเหลวมากที่สุดถึง 61% โดยปัจจัยที่มีความสัมพันธ์ต่อความเสี่ยงที่เพิ่มขึ้นของการติดเชื้อคือ เพศชาย และการล้มเหลวที่เกิดขึ้นเร็วภายใน 3 ปีแรก โดยมีความเสี่ยงเพิ่มขึ้นเป็น 4.5 และ 8.8 เท่าตามลำดับ*

สรุป*: การล้มเหลวภายหลังการผ่าตัดเปลี่ยนข้อเข่าเทียมมีสาเหตุแตกต่างกันไประหว่างการล้มเหลวในระยะสั้น และระยะยาว โดยการติดเชื้อของข้อเข่าเทียมนั้นถือเป็นสาเหตุหลักที่ทำให้อายุการใช้งานของข้อเข่าเทียมสั้นกว่าความคาดหวัง ซึ่งเมื่อเปรียบเทียบกับผลการศึกษาอื่น ๆ ที่รวบรวมในประเทศที่พัฒนาแล้ว ถือว่าผลของการศึกษานี้มีอัตราการเกิดการติดเชื้อที่สูงกว่ามาก เห็นได้ว่าการใช้ข้อมูลจากการศึกษาถึงสาเหตุของการล้มเหลวของข้อเข่าเทียมเพื่อการวางแผนการป้องกันในระยะยาวนั้น ข้อมูลที่นำมาใช้ควรได้จากสาเหตุที่เกิดขึ้นจริงจากในแต่ละประเทศ หรือแต่ละพื้นที่นั้น ๆ*