人工関節（股および膝）の耐用性と安全性評価のための全国的登録体制の確立

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National arthroplasty register は人工関節置換術に対する疫学研究に極めて有用な情報を提供している。本邦においては、2006 年 2 月から 2012 年 9 月まで、日本整形外科学会インプラント委員会および 2011 年５月より日本人工関節学会を主体として日本人工関節登録制度が実施されている。人工股関節置換術を施行した患者情報、手術情報およびインプラント情報を登録用紙に記載し、人工関節登録事務局に送付し、データ管理を行っている。

2012 年 10 月末現在、事前参加登録病院は 120 施設である。人工股関節置換術は 27811 例のデータが登録されている。初回手術は 25196 例、再置換術は 2615 例であり、男性 16.48%、女性 83.45%である。原疾患の 59.96%は DDH であり、一次性 OA は 21.14%、ION は 6.9%、RA は 3.44%であった。基本解析結果（平成２２年度まで）は、日本人工関節学会ホームページ（http://jsra.info/）で公開されている。

national arthroplasty register は、インプラントや手術手技の臨床成績を短期間で予想でき、また、不具合のあるインプラントや成績不良な手術手技を患者および医師に迅速に周知することができる極めて有用な手段である。諸外国では、再置換術の頻度減少を達成し、また meta-on-metal インプラントの高再置換率をいち早く報告し、現在その重要性は公知となっている。日本人工関節登録制度を成功させるためには、出来るだけ多くの施設の参加が必須である。アジアで初めての national arthropalsty register は本邦の人工関節置換術の疫学解析や人工関節置換術の開発にも寄与することが期待される

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ORIGINAL ARTICLE

A pilot project for the Japan arthroplasty register

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Abstract
Background National arthroplasty registers are valuable tools for reporting on an updated epidemiologic survey of arthroplasties and for evaluating the performance of implants and operative procedures through the early identification of failure risk factors. More than ten registers have been launched globally, but no national register has been reported in Asia.
Methods In February 2006, a pilot project of the Japan Arthroplasty Register (JAR) for total hip arthroplasty (THA) and total knee arthroplasty/unicompartmental knee arthroplasty (TKA/UKA) was launched by the Japanese Orthopaedic Association (JOA). Data obtained include information about patients, primary and revision arthroplasty operative procedures, and implants and materials used. The JAR office accumulated and processed all data and reports annually.
Results Up to May 2011, 83 of 130 hospitals nominated by the JOA (64 %) participated in the JAR pilot project. From 2006 to 2011, 33,080 data collection forms were submitted; 17,534 for THA and 17,269 for TKA/UKA. A brief summary of the annual report of the JAR is available from The Japanese Society for Replacement Arthroplasty web site at http://jsra.info/.
Conclusion A national arthroplasty register is a useful tool for evaluating the outcomes of interventions and the

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materials used in arthroplasties and for providing rapid feedback to practitioners and patients about any failure of THA and TKA/UKA. As the first national arthroplasty register in Asia, the JAR will help guide the development of registers of arthroplasty characteristics specific to Asian populations.

Introduction

Total joint arthroplasty, especially of the hip and the knee, is used to realign or reconstruct diseased joints and is one of the most successful interventions used to treat various joint disorders, including osteoarthritis, rheumatoid arthritis, osteonecrosis, and rare joint disorders; to relieve pain; and to improve patient health-related quality of life. Recent trends toward a longer life expectancy and an increased prevalence of joint arthroplasty, along with advances in general medical practice and implant technology, allow arthroplasty to be performed in younger and older patients. These trends have increased the number of complications, failures, and inferior results. Revision arthroplasty is more complex and technically much more demanding than primary arthroplasty and is associated with a longer hospital stay and higher risk of complications. The medical expenditure contributes to the financial burden of health care costs within Japan's medical care insurance system. Thus, from the perspective of both patient care and medical economy, a nationwide system of outcome measures is needed for continuous monitoring and improving outcomes.

The first arthroplasty register was launched in Sweden in 1975 [1, 2], and other Nordic countries, Finland [3], Norway [4], and Denmark [5], followed. In Scandinavia, national arthroplasty registers comprise prospective observational nationwide data of patients, implants, and operative procedures. The particular advantage of these registers is that the continuous observation provides rapid feedback to the medical profession and early detection of any failures. Indeed, the burden of revision procedures has decreased significantly in Sweden [6]. In recent years, a number of registers have been founded in other countries by adapting the successful Scandinavian register system [7–11]. The European Arthroplasty Register (http://www.ear.efort.org/), a European Foundation of National Associations of Orthopaedics and Traumatology project, aims to enhance cooperation within the network and to realize further benefit through registers by fostering scientific activities.

In Japan, the Japanese Orthopaedic Association (JOA) initiated a pilot project comprising an arthroplasty register for total hip arthroplasty (THA) and total knee arthroplasty/unicompartmental knee arthroplasty (TKA/UKA) at ten hospitals between February 2006 and April 2008 and at 83 hospitals between May 2008 and May 2011. The aim of this pilot project was to identify the types of data that should be registered in the databases and to establish methods for submitting data collection forms for encouraging surgeons' participation and accumulating data in the Japan Arthroplasty Register (JAR) office. Here we report on the current status of the JAR.

Patients and methods

Between February 2006 and May 2011, the JOA initiated a pilot project of the JAR for recording information about THA and TKA/UKA. Immediately after performing each arthroplasty, the surgeon completed a two-page data collection form including information about the patient, the operative procedures for both primary and revision arthroplasties, and the implants and materials used (Appendix 1; Supplementary material). In cases involving revision, a new report on the operation was sent to the register and was added to the previous data on the patient. The surgeon sent the completed form in paper format by mail or fax to the JAR office. The JAR office accumulated and processed all data and asked the surgeons to check and correct missing information or inconsistent data. The JAR office produced and sent out an annual report to the participating surgeons.

Permission to participate in the JAR pilot project was obtained from the ethics committee of each institution.

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The JOA and institutional review board approvals were obtained for publication of the study. The patients were asked to sign a consent form permitting collection and analysis of their information.

Results

The JOA selected 130 hospitals that performed more than 50 THA or TKA/UKA operations annually. Participation was not mandatory, and up to May 2011, 83 of 130 hospitals (64 %) participated in the JAR pilot project (Fig. 1; Table 1). From 2006 to 2011, 33,080 data collection forms were submitted: 17,534 for THA and 17,269 for TKA/UKA (Fig. 2). For the fiscal year 2009–2010, 10,899 JAR forms were submitted: 5,392 for THA and 5,507 for TKA/UKA. Primary THA was performed on 15,811 hips and revision THA on 1,723 hips. THA was performed on 2,963 men and 14,557 women; the patient's sex was unknown for 14 procedures. Primary TKA was performed on 15,398 knees, primary UKA on 1,249 knees, and revision TKA/UKA on 622 knees. TKA/UKA was performed on 3,008 men and 14,237 women; the patient's sex was unknown for 24 procedures. The distribution of patients' ages at primary and revision THAs and TKAs/UKAs is shown in Fig. 3. Data reported to the JAR are summarized in Table 2 for primary and revision THAs and in Table 3 for primary and revision TKAs/UKAs.

Discussion

Since the first arthroplasty register was launched in Sweden in the 1970s [1, 2, 12], many countries have created national arthroplasty registers [13, 14]. These registers are effective in providing quality assurance for joint replacements by identifying poor-quality prostheses and operative procedures and by recording problems with certain materials. These registers are often cited as examples of a nonrandomized design that have made an essential contribution to advances in assessing arthroplasty procedures. However, no national arthroplasty registers have been reported for Asian countries. In 2006, the JOA started a pilot project of a national arthroplasty register for THA and TKA/UKA in Japan.

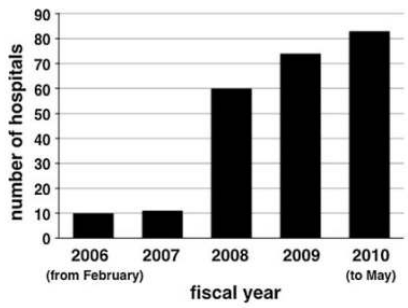

Fig. 1 Number of hospitals participated in the JAR pilot project

Documentation

Patient consent is mandatory before patient data are recorded. Data for each patient are managed using two unique identification numbers: One is a 13-digit number based on date of birth, sex, initial of the given name, and place of birth. The other is the hospital chart number. Basic surgical data are separated according to primary and revision arthroplasties, and details of operative procedures are recorded in a separate section. The JAR does not collect clinical scores and patient-based questionnaires. The JAR procedure is unique in that all information about implants and materials used in the operation are collected and the barcode labels are attached to the second page of the data collection form. The main goals of this register are to measure the outcome for each implant and to identify poorly performing implants and problematic operative procedures. This information will help identify the best products and operative procedures for arthroplasty surgery. Another purpose is to quickly track and identify patients who have implants or materials recalled by a company or are performing poorly. Thus, the JAR requires all details about the implants and product information to be recorded.

Several weak points remain in the JAR. First, to measure the outcome of the implants, revision should be set as the endpoint of failure to define the periods from the primary arthroplasty to the next intervention needed to change or remove the prosthesis. Therefore, precise implant survival rates cannot be calculated because it is difficult to follow-up patients and record mortality rates. Japan now has a basic resident register network system (Juki Net) with a national online citizen identification number system, but this system cannot be linked to the JAR because of privacy protection. In addition, the JAR is not yet linked to other data sources, including the national health insurance system and implant manufacturing companies. Therefore, we must consider strategies for validating participation rates, information completeness, data quality, and the follow-up method. Second, the JAR currently offers only a paper-base method of documentation, and surgeons must mail or fax data collection forms to the JAR office. We are planning to establish an online register system and electronic data transfer system to improve completeness, accuracy, and compliance of data collection. Third, this register does not integrate clinical evaluation and radiological findings

Table 1 Participants

Yamanote do-ri Yagi Hospital
Hokkaido Orthoprediec Memorial Hospital
Yamagata Saisei Hospital
Tohoku Rosai Hospital
Kawaguchi Kogyo General Hospital
Shonan Kamakura Joint Reconstruction Center
Funabashi Orthopaedic Hospital
Nagano Matsushiro General Hospital
Niigata Central Hospital
Tamauchi Hospital
Hyogo Prefectural Rehabilitation Central Hospital
Tamatsukuri Kosei-Nenkin Hosital
Hiroshima Prefectural Rehabilitation Center Medical Center
Kurashiki Central Hospital
Kawasaki Hospital
Fukuoka Orthopaedic Hospital
Kyushu Rosai Hospital
Kyushu Medical Center
Kumamoto Kinoh Hospital
Tachibana Hospital
Orthopaedic Hospital Yonemori
Tomishiro Central Hospital
Hokkaido University Hospital
Asahikawa Medical University Hospital
Hirosaki University Hospital
Akita University Hospital
Yamagata University Hospital
Iwate Medical University Hospital
Fukushima Medical University Hospital
Niigata University Medical and Dental Hospital
Jichi Medical University Hospital
Dokkyo Medical University, University Hospital
Saitama Medical University Hospital
National Defense Medical College Hospital
Chiba University Hospital
Nihon University School of Medicine, Itabashi Hospital
The University of Tokyo Hospital
Tokyo Medical and Dental University, University Hospital of Medicine
Juntendo University Hospital
Nippon Medical School Hospital
Keio University Hospital
Tokyo Medical University Hospital
Tokyo Women's Medical University Hospital
Showa University Hospital
Toho University Omori Medical Center
Kyorin University Hospital
Yokohama City University Hospital
Kitasato University Hospital
University of Yamanashi Hospital
Shinshu University Hospital
Kanazawa University Hospital
Kanazawa Medical University Hospital
University of Fukui Hospital
Hamamatsu University School of Medicine, University Hospital
Nagoya University Hospital
Fujita Health University Hospital
Aichi Medical University, University Hospital
Gifu University Hospital
Mie University Hospital
Nara Medical University Hospital
Kyoto University Hospital
University Hospital, Kyoto Prefectural University of Medicine
Osaka University Hospital
Osaka City University Hospital
Osaka Medical College Hospital
Kansai Medical University Hirakata Hospital
Kinki University Hospital
Wakayama Medical University Hospital
Kobe University Hospital
Hyogo College of Medicine Hospital
Kawasaki Medical School Hospital
Hiroshima University Hospital
Tottori University Hospital
Yamaguchi University Hospital
Kagawa University Hospital
Ehime University Hospital
Kyushu University Hospital
Saga University Hospital
Nagasaki University Hospital
Kumamoto University Hospital
Oita University Hospital
Kagoshima University Medical and Dental Hospital
Hospital, University of the Ryukyus

during the follow-up period because this extra workload carries a heavy burden of documentation, which is likely to have a negative effect on surgeons' compliance and therefore on data completeness and accuracy.

Compliance

The success of the register analysis depends largely on data quality, including validity, reliability, coverage, and completeness. Registers might be expected to have a validated completeness >90 % of the national data [15], although only a few registers in others countries have achieved this value [7, 16, 17]. The German arthroplasty register had to suspend its work because of the low rate of participation

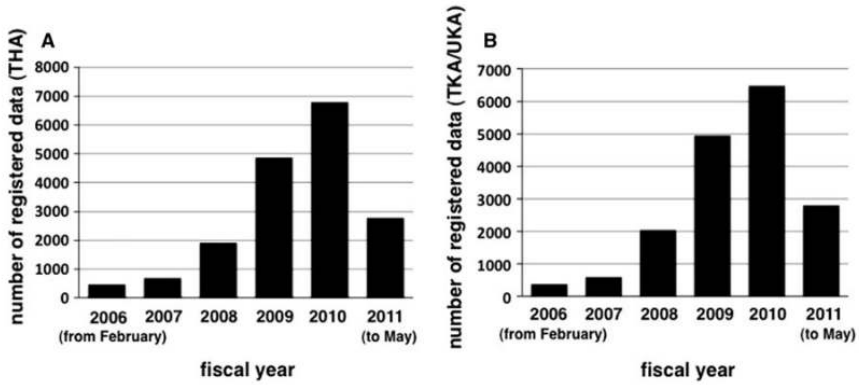

Fig. 2 Number of data registered in the JAR office: **a** total him arthroplasty (THA) and **b** total knee arthroplasty/unicompartmental knee arthroplasty (TKA/UKA)

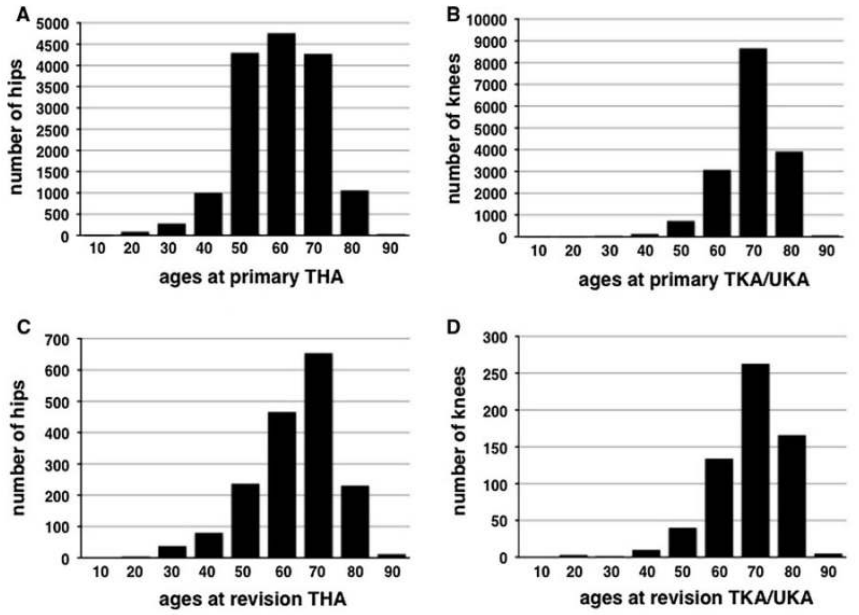

Fig. 3 Distribution of patients' ages at primary total hip arthroplasty (THA) (**a**), primary total knee arthroplasty/unicompartmental knee arthroplasty (TKA/UKA) (**b**), revision THA (**c**), and revision TKA/UKA (**d**)

[18]. Surgeons' participation in the register is generally voluntary, and it is important to encourage participation and maintain motivation to participate in the register process. To simplify the surgeon's task, the JAR data collection form is only two pages and requires only a few minutes to complete and attach the barcode labels. The form is then sent by mail or fax to the JAR office. During a pilot project, surgeons and patients were not allowed online access to the database. Surgeons received annual reports instead, and participating hospitals were able to provide public access to the reports through the web site of The Japanese Society for Replacement Arthroplasty (JSRA),

Table 2 Primary and revision total hip arthroplasties (THAs) reported to the JAR from 2006 to 2011

	Primary THA (15,881 hips) (%)		Revision THA (1,723 hips) (%)
Diagnosis			
Primary OA	21.8	Aseptic loosening (acetabulum)	36.9
DDH	59.7	Aseptic loosening (femur)	24.3
ION	7.0	Infection	16.9
RA	3.7	Polyethylene wear	12.9
Trauma	2.0	Osteolysis (acetabulum)	14.3
Others	5.8	Osteolysis (femur)	9.6
		Implant fracture (acetabulum)	7.3
		Implant fracture (femur)	1.3
		Fracture (acetabulum)	0.8
		Fracture (femur)	4.1
		Displacement/ instability	8.5
		Others	7.7
Sex			
Men	16.5		20.7
Woman	83.5		79.1
Unknown	0.0		0.2
Approach			
Anterior	14.9		4.0
Lateral	34.6		37.9
Posterior	49.6		56.5
Others	0.8		1.0
Unknown	0.1		0.6
MIS			
Yes	36.0		4.4
No	63.1		90.4
Unknown	2.7		5.2
Navigation			
With	5.1		4.9
Without	93.2		91.5
Unknown	1.7		3.5
Cementing			
Cement	19.0		43.4
Cementless	72.3		47.0
Hybrid	8.6		9.2
Unknown	0.1		0.4
Antibiotic-loaded cement			
With	51.5		68.7
Without	48.5		31.3
Unknown	0.0		
Bone graft			
With	38.0		59.5
Without	61.5		39.6
Unknown	0.4		0.9

OA osteoarthritis, *DDH* developmental dysplasia of the hip, *ION* idiopathic osteonecrosis of the femoral head, *RA* rheumatoid arthritis, *MIS* minimally invasive surgery

which coordinated this project from April 2011 in collaboration with the JOA. In addition, hospital-specific results will be reported to each participating hospital. Several full-time employees in the JAR office will provide continuous feedback to check and correct missing or inconsistent data. This effort is expected to increase data quality. In Japan, more than 40,000 THAs and 70,000 TKAs/UKAs are performed annually, and the number of joint replacement surgeries is increasing. In addition, there are about 9,000 hospitals and clinics in Japan, and more than 5,000 hospitals have the potential to install operation equipment to perform joint replacement surgery. However, in reality, about 400 hospitals cover 80 % of all joint arthroplasties in Japan, and therefore our initial goal is to collect data from these hospitals.

Organization

National registers can be established and maintained successfully with a fully implemented organization and structure. Most registers were created as an initiative of an orthopedic association, except for registers in Canada, England/Wales, and Finland, which were initiatives of health authorities [14, 15]. In February 2006, a pilot project of the JAR for THA and TKA/UKA was initiated by the JOA, and since April 2011, the JSRA has coordinated the JAR project in collaboration with the JOA.

The summary of the JAR annual report is available on the JSRA web site (http://jsra.info/). In the JSRA, the JAR board is represented by eight members. The JAR office is located in the Department of Orthopaedics, Kyoto University, Kyoto, Japan, and employs one orthopedic surgeon and one full-time and three part-time employees. The most vulnerable point in the JAR is funding. Most registers are supported financially by the government and associations

Table 3 Primary total knee arthroplasty/unicompartmental knee arthroplasty (TKA/UKA) reported to the JAR from 2006 to 2011

	Primary TKA/UKA (16,647 knees) (%)		Revision TKA/UKA (622 knees) (%)
Diagnosis			
OA	85.6	Aseptic loosening (femur)	17.8
RA	10.5	Aseptic loosening (tibia)	23.8
ION	2.8	Aseptic loosening (patella)	1.6
Trauma	0.4	Infection	33.8
Charcot	0.2	Polyethylene wear (tibia)	19.6
Others	0.5	Polyethylene wear (patella)	4.3
		Implant fracture (femur)	1.4
		Implant fracture (tibia)	4.2
		Implant fracture (patella)	1.4
		Trauma	2.6
		Displacement/instability	10.8
		Disturbance of excursion	3.1
		Others	14.8
Sex			
Men	17.4		18.4
Women	82.5		81.3
Unknown	0.1		0.3
Approach			
Parapatella	53.7		86.7
Midvastus	32.7		7.2
Subvastus	7.2		1.9
Undervastus	0.2		0
QS	3.1		1.3
Lateral	1.0		1.4
Trivector	0.7		0
Others	1.3		1.0
Unknown	0.1		0.5
MIS			
Yes	31.6		6.6
No	68.2		93.1
Unknown	0.2		0.3
Navigation			
With	4.3		0.5
Without	95.2		98.9
Unknown	0.5		0.6
Patella replacement			
With	50.8		45.2
Without	49.0		53.4
Unknown	0.2		1.4
Cementing			
Cement	82.5		79.6
Cementless	13.0		18.6
Hybrid	4.2		1.0
Unknown	0.3		0.8

OA osteoarthritis, *RA* rheumatoid arthritis, *ION* idiopathic osteonecrosis of the femoral head, *MIS* minimally invasive surgery, *QS* quadriceps-sparing

[15]. In England/Wales, register funding is obtained by levies placed on the sale of implants. However, the JAR has not been supported by the government and is now funded by Kyoto University and a grant from the Hip Joint Foundation of Japan. Financial collaboration between the government, scientific societies, and implant manufacturing companies seems to be a basic requirement for maintenance and continuity of the JAR. Their collaboration is needed to collect and maintain these data to assess the effectiveness of arthroplasty interventions at the national level.

Future directions

The JAR will be open to all hospitals in Japan in February 2012. We believe that this study provides useful and systemic evidence about implant performance, operative procedure outcomes, and patient care in Japan. The JAR is the first national arthroplasty register in Asia. We are optimistic about its future role in the collection and analysis of information about THA and TKA/UKA in Asia countries and the application of these data to understanding and comparing outcomes and procedures in different populations.

Acknowledgments We thank Ms. Aiko Okazaki for her valuable help. This work was supported by the Hip Joint Foundation of Japan to HA.

Appendix 1

Japan Arthroplasty Register
Total Hip Arthroplasty (THA)
FAX: 075-751-8409

I. Hospital, Surgeon, Patient

Hospital name (ID)……

Surgeon's initial……. **Mentor's initial……**

Patient ID

1. Birth date……/……/…….(yy/mm/dd)

2. Sex (male, female)

3. Initial of given name……

4. Birth place (Prefecture)……..

5. Hospital chart number……

II. Primary THA

1. Date……/……/…….(yy/mm/dd)

2. Operation side (R, L)

3. Previous operation (none, osteotomy:acetabulum, femur, other……)

4. Diagnosis (primary OA, DDH, ION, Trauma, RA, other……)

III. Revision THA (defined as implant removal or replacement)

1. Primary THA

Date……/……/…….(yy/mm/dd) **Hospital name …….**

Diagnosis (primary OA, DDH, ION, Trauma, RA, other……)

2. Date……/……/…….(yy/mm/dd)

3. Operation side (R, L)

4. Number of revision THA (1, 2, 3, 4, more……., unknown)

5. Diagnosis: aseptic loosening (acetabulum/femur); infection; implant fracture (acetabulum/femur); polyethylene wear; osteolysis (acetabulum/femur); fracture (acetabulum/femur); displacement; instability; other……..

6. Operation: implant removal/ revision (acetabulum, femur, insert, head)

Removed implant (manufacturer and brand)……

IV. Operative procedure

1. Operation time……..h……..min

2. Approach: anterior/lateral/posterior/other……

3. Detachment of greater trochanter (no, partial, total)

4. MIS (no, yes)

5. Navigation (without, with)

6. Cementing (no, yes, hybrid: acetabulum, femur)

7. Antibiotic-loaded cement (without, with: ……(antibiotic name)……g/1 pack of cement)

8. Bone graft (without, small, large: autograft, allograft; acetabulum, femur)

9. Bioactive materials (without, small, large: acetabulum, femur…… (brand))

10. Augmentation, etc. (without, with: augment, plate, mesh, other……: acetabulum, femur)

Japan Arthroplasty Register
Total Hip Arthroplasty (THA) (implant information)
FAX: 075-751-8409

Hospital Name……
Birth date……/……/……(yy/mm/dd)
Operation side (R, L)

V. Component label

Acetabular component
Liner

Outer cup or cement socket

Femoral component
Stem

Head

Cement

Screw

Bioactive material

Augmentation, etc.

Other

continued

Japan Arthroplasty Register
Knee Arthroplasty (TKA/UKA)
FAX: 075-751-8409

I. Hospital, Surgeon, Patient

Hospital name (ID)…….

Surgeon's initial……. Mentor's initial…….

Patient ID

1. Birth date……/……/…….(yy/mm/dd)

2. Sex (male, female)

3. Initial of given name…….

4. Birth place (Prefecture)……..

5. Hospital chart number……

II. Primary TKA/UKA

1. Date……/……/…….(yy/mm/dd)

2. Operation side (R, L); in case of UKA (medial, lateral)

3. Previous operation (none, HTO, arthroscopic surgery , other……)

4. Diagnosis (OA, RA or collagen disease, ION, trauma, Charcot, other……)

III. Revision TKA/UKA (defined as implant removal or replacement)

1. Primary THA

Date……/……/…….(yy/mm/dd) Hospital name…….

Diagnosis (OA, RA or collagen disease, ION, trauma, Charcot, other……)

2. Date……/……/…….(yy/mm/dd)

3. Operation side (R, L) ; in case of UKA (medial, lateral)

4. Number of revision TKA/UKA (1, 2, 3, 4, more……., unknown)

5. Diagnosis: aseptic loosening (femur, tibia, patella); infection; displacement・instability; implant fracture (femur, tibia, patella); polyethylene wear; osteolysis (tibia, patella); trauma; disturbance of excursion; Other……..

6. Operation: implant removal/ revision (femur, tibia, patella, insert)

Removed implant (manufacturer and brand)……

IV. Operative procedure

1. Operation time……..h……..min

2. Approach: para-patella/mid-vastus/sub-vastus/lateral/QS

3. MIS (no, yes)

4. Navigation (without, with)

5. Patella replacement (without, with)

6. Cementing (no, yes, hybrid: femur, tibia, patella)

7. Antibiotic-loaded cement (without, with: ……(antibiotic name)……g/1 pack of cement)

8. Bone graft (without, small, large: autograft, allograft; femur, tibia, patella)

9. Bioactive materials (without, small, large: femur, tibia, patella……(brand))

10. Augmentation, etc. (without, with: augment, long stem, other……)

continued

Japan Arthroplasty Register
Knee Arthroplasty (TKA/UKA) (implant information)
FAX: 075-751-8409

Hospital name……
Birth date……/……/……(yy/mm/dd)
Operation side (R, L)

V. Component label

Femoral component **Screw**

Tibial component **Bioactive material**
Base plate

Augmentation, etc.
Insert

Patella component **Other**

Cement

continued

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