Radiostereometric analysis of hip implants: a critical review of methodology and future directions

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Abstract

Introduction

Early migration of endoprostheses is predictive for aseptic failure in the long term. Radiostereometric analysis (RSA) is able to measure highly accurate micromotions and can therefore evaluate the quality of endoprostheses or fixation techniques in a short period of time. A systematic search of the entire PubMed database was carried out. It was limited to publications in English or German published since 1980. Inclusion of articles was performed by two examiners who initially read the abstracts, then read full text articles selected from the abstracts and critically summarised the most relevant publications. The aim of this review was to discuss RSA of hip implants.

Discussion

Due to the current lack of standardisation, there is a deficit of comparability between the results of different RSA studies. In case that no trauma or clinical symptoms of loosening appear, RSA examinations can substitute the annual follow-up Roentgen examinations after joint replacements. Thus, RSA can reduce the patient’s radiation exposure. In contrast to other techniques, like conventional radiographs or the Einzel Bild Roentgen analyse, RSA is able to detect early migrations of the implant. The potential of RSA is being recognised by different regulatory organs. At present, a standard protocol for early preclinical studies of joint implants—including RSA—is in preparation. Model-based RSA simplifies the method, helping to save time and money.

Conclusion

Despite some shortcomings of RSA, the potential of the method as a screening device for new joint implants in addition to regulatory and technical developments will facilitate wider application in the future.

Introduction

Osteoarthritis (OA) and trauma are common indications for the implantation of total joint replacements. OA is a severe disabling disease caused by mechanical factors, cell biological phenomena and a dysregulation of tissue homeostasis. Especially in the ageing western societies, the number of OA patients grows. Hence the number of joint replacements increases too and the number of revision surgeries is likely to increase as well. On average, fifteen to twenty years after a primary total hip arthroplasty (THA), revision becomes necessary. In many cases, subsequent revision surgery is technically demanding and leading to considerable costs to the public health systems. As a consequence, it is worthwhile to avoid implantation of joint prostheses of poor quality and to extend lifespan of hip prostheses. Mechanical loosening of the implant starts with micromotions in the range of 0.2–1 mm. It continues and leads to migrations over larger distances. Radiostereometric analysis (RSA) is able to quantify these early migrations. In the seventies of the last century, Selvik developed this highly accurate method for the in vivo measurement of musculoskeletal kinematics. Today the potency of RSA is to investigate micromotions of a joint implant within a relative short follow-up interval, most commonly two years. Prostheses showing an excessive and—even more important—a continuous migration in these first two postoperative years are likely to fail in the long term. Short-term RSA studies can predict the long-term clinical success of new joint implants or fixation techniques. This conclusion enables RSA to be considered as a screening device for novel orthopaedic implant components.

The intention of this review is to provide a survey of the potentials and shortcomings of this method and an outlook on possible future developments regarding RSA of joint implants. The focus of this review is on RSA of total hip prostheses as these are the most frequently RSA-examined artificial joints.

Methodology

A systematic literature research using the PubMed database applying the following search items in the title or abstract was carried out: “RSA”, “radiostereometry”, “radiostereometric analysis” and “Roentgen stereophotogrammetric analysis”. Results were further filtered using Boolean operators (AND, OR, NOT) and combinations of specific keywords as for example, “loosening of joint implants” and “migration analysis of joint prostheses”. The search was limited to publications in English or German published from 01 Jan 1980 to 01 Sep 2013. Inclusion of articles was performed by two examiners who initially read the abstracts, then read full text articles selected from the abstracts and critically summarised the most relevant publications. The aim of this review was to discuss RSA of hip implants.

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performed by two examiners—Stefan Sesselmann and Franz Tschunko—who initially read the abstracts then read full text articles selected from the abstracts and later equalised their results. The inclusion criteria set for this review were: Case reports, original research papers, review papers, in vitro/in vivo studies and animal studies on RSA. Exclusion criteria consisted of studies that did not meet the inclusion criteria mentioned above. We reviewed the abstracts of these publications and critically summarised the most relevant of them.

The primary electronic search produced 309 articles. Applying inclusion and exclusion criteria, 304 articles were retrieved. After reading the abstracts, respectively the full texts, the two examiners compared their results. This left 32 relevant articles from which results and conclusions were drawn.

**Discussion**

The authors have referenced some of their own studies in this review. These referenced studies have been conducted in accordance with the Declaration of Helsinki (1964) and the protocols of these studies have been approved by the relevant ethics committees related to the institution in which they were performed. All human subjects, in these referenced studies, gave informed consent to participate in these studies. One of the shortcomings of RSA is the fact that neither the radiation doses nor the length of follow-up intervals for RSA examinations are standardized and they vary between different studies and research centres. The radiation doses of RSA images are lower than those of corresponding conventional radiographs, as they are exposed with higher voltage and lower amperage\(^4\). As often reported, following surgery, several conventional radiographs are taken during the first year and later on annually to follow up the joint implant as long as no trauma or symptoms of loosening appear. Performing RSA studies, radiographs are commonly scheduled up to 1 week after the operation, then at 6 weeks, 3 and 6 months, 1, 2 and possibly 5 and 10 years postoperatively\(^4\). In case that no trauma or clinical symptoms of loosening appear, RSA examinations can substitute the regular follow-up Roentgen examinations. Thus, RSA can reduce the patient’s radiation exposure.

The lack of comparability of results in between different RSA studies is an important problem of RSA. As mentioned above, the radiation doses and the follow-up intervals are not standardized. Furthermore, there are different numbers and sizes of marker beads or methods of image acquisition in use. In most reports, translations and rotations are measured at the implant’s centre of gravity, whereas some study groups use a different technique, measuring migration for each single marker attached to the prosthesis. An important topic is the need of standardisation of statistics. In 2005, Valstar et al. stated that, for every RSA study, accuracy and precision of the arrangement should be presented\(^4\). Precision—usually assessed by double examinations—is the basis of power calculations. It should be assessed for each model-based RSA study. Due to higher radiation doses per patient, in many cases the local ethics committees often restrict these double examinations. Unfortunately, this lack of information about the study’s precision might lead to false conclusions drawn from this examination\(^4\).

To determine accuracy, different cadaver models have been used, various phantoms have been designed and several methods for calculating accuracy have been proposed, resulting in divergent values obtained\(^15,16\). There are many RSA reports that quote accuracy values; however, they do not explain how these values were obtained. Thus, it becomes difficult to compare the results of different studies (Figure 1).

Therefore, it is important to establish standards for RSA examinations to guarantee comparability of results in between different studies. In 2005, Valstar et al. Published ‘Guidelines for standardisation of radiostereometry...
of implants’ to which all RSA study groups should adhere to. The markers used for RSA usually consist of tantalum. Tantalum is an element with a high atomic number. It is radiopaque and easy to identify on radiographs. In previous studies, no serious tissue reactions were observed. In the past decades, tantalum has been used as a bone marker in thousands of patients and no side effects were known. Nevertheless, further studies of the marker’s biocompatibility should be accomplished in in vivo studies to affirm previous observations and to achieve reliable results.

As already mentioned, mechanical loosening starts with implant migration of 0.2–1 mm relative to the bone. Normally, the prosthesis does not cause any clinical symptoms showing migration values in the mentioned range. In clinical practice, joint prostheses are assessed in standard radiographs. The accuracy of migration measurements in those standard radiographs of total hip arthroplasties ranges between 5 and 12 mm. Due to different technical improvements in assessing these standard radiographs, the so-called single-image Roentgen analysis (Einzel Bild Roentgen analyse (EBRA)) reaches an accuracy of up to 1 mm. Hence the accuracy of both techniques is not sufficient to detect early stages of implant loosening.

With a reported accuracy ranging between 0.05 and 0.5 mm for translational movements and 0.15° to 1.15° for rotational movements, the RSA technique is able to detect these relevant early migrations of the joint prostheses. The method’s high accuracy depends on several factors, such as the radiographic technique, the RSA analysis software package used or the positioning of the tantalum spheres. Since the association between early migration and long-term loosening of joint replacements has been proven by various studies, RSA is able to evaluate the quality of endoprostheses in a short period of time. As another consequence of the method’s extraordinary accuracy, only a small sample size of 15–25 patients is required to obtain reliable results. Further advantage of RSA is the possibility to measure migrations in three dimensions. This is of particular interest since the loosening process of implants seems to consist of a complex combination of translational and rotational movements.

In 1990, the bone cement Boneloc (Polymers Reconstructive, Farum, Denmark) was brought onto the market. The lower curing temperature and its decreased release of toxic monomers were mentioned to lead to a decrease of aseptic loosening of implants. During the first years after its introduction, only experimental

Figure 2: Marker-based radiostereometric analysis (RSA) radiograph. A total hip prosthesis in situ with Tantalum markers at the collar, tip and shoulder (blue), markers inserted into the femur (red) and cage markers (green and yellow). Centre of gravity (A).
studies were published—most of them recommending the product. Five years later; radiostereometric migration analyses and register-based articles were published. Most of them reported inferior results. The average revision rate in sample-based studies exceeded the reference value in the Norwegian Arthroplasty Register 7.35-fold. When Boneloc was taken from the market in April 1995, 30,694 units of Boneloc bone cement had been in use. The Capital Hip (3M Health Care Ltd., London borough, United Kingdom)—a total hip replacement—was released in the market in 1991. About 5000 patients received a Capital Hip. Five years after implantation, 20% of these prostheses had to be revised.

The potency of RSA is to measure micromotions of joint prostheses—thus also assessing fixation techniques—within a short period of time and with low patient numbers. If all newly developed implants and fixation techniques were studied by RSA before definitely bringing them onto the open market, excessively migrating prostheses and inferior fixation techniques could be identified and patients would be prevented from further disasters. In case of Boneloc or the Capital Hip, only a few patients would have been exposed to the hazard of these products in RSA studies.

Future directions

In 1994, Freeman and Plante-Bordeneuve already considered RSA as a screening method for new joint prostheses. They gave the opinion, that every newly designed femoral prosthesis should be monitored by using RSA to measure its migration rate in a small number of patients for two years. Thus, excessively migrating implants could be detected and abandoned.

Nelissen et al. compared the five-year revision rate of RSA-tested total knee prostheses with that of non-RSA-tested knee prostheses. In 2011, they concluded that RSA studies with a two-year follow-up of new joint implants would lead to a better patient care, a reduction of cases of revision surgery and therefore also a noticeable reduction of costs associated with those revision arthroplasties. In particular, they recommended combining RSA studies with post-market surveillance in national joint registries to evaluate the quality of implants.

The potential role of RSA as a method of assessment of joint implants before their release to the open market is being recognised by different regulatory organs. If authorities demanded reliable premarketing examinations of orthopaedic components like hip or knee prostheses, RSA studies with a follow-up interval of two years could be an alternative to long-term clinical studies. For example, the NICE (National Institute for Health and Clinical Excellence, London, United Kingdom) guidelines advise RSA as a method to achieve suitable clinical data. At present, the International Organization for Standardisation (ISO) and the European Standards Working Group on Joint Replacement Implants prepare a standard protocol for early preclinical studies. This protocol will include RSA helping to avoid the implantation of failing endoprostheses in large quantities. This would mean a further revaluation of the RSA method.

Model-based RSA utilises bone markers and a three-dimensional surface model of the implant to compute the in vivo migration of prostheses. In contrast to marker-based RSA, no tantalum markers have to be placed on the implant. As no special implants have to be manufactured and no separate certification is needed, the model-based technique can help save time and costs. Compared to marker-based RSA, performing model-based methods leads to a negligible lower data quality. The use of model-based RSA may facilitate a wider application of the RSA method.

Efforts have been made to establish a completely markerless RSA. This would open the possibility of performing migration and wear measurements on larger groups of patients in clinical follow-ups. At the moment, accuracy and precision of the completely markerless approach are lower than that of marker-based RSA to a degree which precludes the use of this method for measuring implant migration in its present form. To carry out a markerless RSA of an orthopaedic implant, the examined joint has to be CT scanned prior to the implantation of the prosthesis and further CT follow-up examinations have to be performed after surgery. Thus, a markerless RSA study entails a significantly higher radiation exposure compared to marker-based and model-based RSA studies.

Performing RSA requires an expensive special RSA-software, a second Roentgen tube and specially trained personnel. Furthermore, carrying out an RSA study is time consuming. These high requirements possibly prevent RSA from being used in clinical routine.

Conclusion

At present, there are still some downsides of RSA, such as a lack of standardisation. Despite some shortcomings, the high accuracy of RSA to measure micromotions of a joint implant in three dimensions and its ability to identify excessively migrating prostheses in a short period of time, using a small sample size are well-known facts. In addition, the efforts to standardize RSA, the prospect that regulatory organs will demand preclinical RSA studies of new orthopaedic implant components, and the progress provided by the current technical developments of the method might lead to a wider use of RSA in the future.

Abbreviations list


Competing interests: none declared. Conflict of interests: none declared. All authors contributed to conception and design, manuscript preparation, read and approved the final manuscript.

All authors abide by the Association for Medical Ethics (AME) ethical rules of disclosure.

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Institute for Health and Clinical Excellence; OA, osteoarthritis; RSA, radiostereometric analysis; THA, total hip arthroplasty

References
24. Valstar ER, Nelissen RG, Reiber JH, Rozing PM. The use of Roentgen stero- photocopy to study micromotion of orthopaedic implants. ISPRS J Photo-

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