

An optimal surgical aid system for Hip Resurfacing Arthroplasty

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Abstract

Hip Resurfacing Arthroplasty (HRA) is a treatment option for the patients with the advanced hip disease; it is considered as the most technically difficult techniques of all procedures recommended for osteonecrosis of the hip. Technically, the currently applied HRA surgeries lead to unstable and inconsistent results. Surgeons rely a lot on the manual technique and conventional tools as well as their skills to determine the right drilling angle for locating the implant system. Although the robotic and surgical planning systems are available for HRA, the drilling line is still defined geometrically and intra-operatively, not fully considering about the biomechanics aspects of the implant and bone structure. In this paper, an optimal surgical aid system for HRA is proposed. With the integration of the state of the art biomedical modelling, pre-operative planning and personalised surgical tools, knowledge based and expert system, as well as biomechanics modelling and analysis, the precision, safety and speed of surgery are improved, the complexity of surgery is reduced, and therefore the survival rate of the implant is increased. Especially, the proposed system provides a cheap and practically feasible solution with the integration of expertise from both engineering and medicine for improving the treatment quality of the patients.

Keywords: Hip resurfacing arthroplasty, surgical planning, surgical tools, biomedical modelling, implant

1. Introduction

The concept of Hip Resurfacing Arthroplasty (HRA) has evolved directly from the original mould arthroplasty introduced by Smith Petersen in 1948. In the early 1950s, the conventional THR was pioneered by Sir John Charnley, experimented with hip resurfacing using Teflon. In the 1960s, the metal-on-metal (MoM) HRA was developed in Switzerland and France [3, 4]. In the 1970s, cemented systems using a polyethylene acetabular component and a metal femoral cup were introduced in Italy, Japan, England, Germany, and the United States. In the HRA operations, only the diseased or damaged surfaces of

the head of the femur and the acetabulum are removed. The femoral head and hip socket are respectively fitted with a spherical shell and a thin spherical cup. Both spherical cups form a pair of metal bearings. The first generation of HRA (1970s – 1980s) showed the disappointing results and the procedure was largely abandoned by the mid 1980s [1, 6]. The failure was essentially a consequence of the use of inappropriate materials, poor implant design and inadequate instrumentation rather than an inherent problem with the procedure itself [2]. The second generation of HRA (1991 to Present) showed the good results. Figure 1 presents the radiograph of the Birmingham Hip Resurfacing and its spherical shell and cup. Early

implant loosening and femoral neck fracture now appear to be rare; only 4 % has the risk of the neck of the femur breaking at some time after the operation.

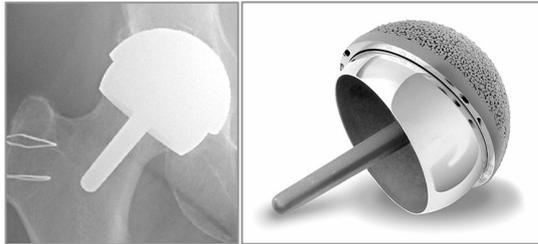


Fig.1. Radiograph of HRA and the spherical shell and cup of a Birmingham Hip Resurfacing system.

Approximately 70,000 primary Total Hip Replacements (THR) are performed in UK each year, of which 15% are revisions, and 15.5% are performed in the younger age group with the mean age of 57.5 years. Rheumatoid arthritis accounts for 6% of the indications for THR and moderate to severe osteoarthritis for over 75%. The proportion of patients who required device revisions, from HRA to THR, was reported in all but one study and ranged between 0% and 14.3% [1, 5]. The survival rate reports of HRA by different sources of clinical studies [1, 7] are as follows: (i) With the median follow-up of 8 years, 73% of the HRA patients were revised to THR, and 15% of THR were required for the revision; (ii) In the study of 93 patients, the survival rate is 70% at 5 years and 40 % at 8 years. The fracture of the neck is 4 %; and (iii) In the study of 403 patients less than 55 years of age, the survivorship over a 5 years study is 99.7%; and (iv) With a mean follow-up of 9 (range: 1-16) years for the survival of 114 HRA, the 5-year, 10-year and 15-year mean survival were respectively 92%, 47% and 30%.

Currently, HRA is recommended as one option for people with the advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement, principally individuals under the age of 65.

In this paper, the challenges and unsolved issues of HRA as well as the proposed treatment method and techniques are presented and discussed. The study is aimed at integration of the state of the art technologies, including Biomedical Modelling, Biomechanics, Intelligent Optimisation and Data Management, and Design and Manufacturing, for enhancing the surgery skills of the surgeons and improving the diagnosis and treatment quality for the patients.

2. Challenges and unresolved issues of HRA

HRA is considered as the most technically difficult techniques of all procedures recommended for osteonecrosis of the hip. The surgical technique requires the skills of well trained hip surgeons. The following are the current challenges for HRA.

2.1. Unresolved issues

Several unresolved issues of HRA have been addressed, including the failure rate, new osteonecrosis and fracture of resurfaced femoral heads, metal ion production secondary to wear debris or corrosion and subsequent hypersensitivity, and appropriate patient selection [1, 8]. The release of metal debris can occur with metal implants. These implants produce corrosion products that are biologically active and may cause chronic inflammatory reactions that can lead to loosening of the implant. It is reported that the concentration of metal debris is higher if the prosthesis is worn or loose, or if the joint is infected. It is not clear what the normal levels of ions in human tissue should be; however, animal studies show that cobalt doses up to 1,000 times normal may be tolerated. Larger doses than that can induce anemia, loss of appetite and weight, and an increase in the number of red blood cells, lesions in mucous membranes, local malignant skin tumors, and death. Additionally, though inconclusive, there is concern that extensive metal ion release may cause changes to the immune function which may lead to lymphomas and leukemia's [8].

2.2. Proper component positioning

There are technical challenges with proper component positioning in HRA. In most of the current HRA surgeries, the pre and intra-operative planning is still based on 2D X-ray images, conventional tools and manual methods, including (i) selection of an implant from standard ones, (ii) measuring the size of the femur head, and (iii) determining the drilling line for preparing the femur head and locating the implant. This leads to the high risk in surgery and unstable treatment quality, which is much dependent on the experiences and skills of the surgeons. The incorrect locating of the implant and the lack of supportive information about the biomechanics aspects between the device and bone structure could be one of the reasons causing the femoral neck fractures and reducing the survivorships of the spherical shell and cup.

2.3. Surgical planning and tools

Although several software and systems are available for surgical planning based on CT/MRI data, to transfer this surgical planning information into the operation rooms for implementation is not easy and straightforward. The computer assisted surgery therefore has been an interesting area of research in the recent decades. Since 2004, many efforts have been concentrated on developing the 3D surgical planning for HRA, including the following two main systems: (i) ORTHOsoft® (Zimmer Ltd., UK) - A navigation system for HRA, and (ii) Acrobot (The Acrobot Company Ltd, UK) - Surgical systems for computer-assisted 3D planning, surgical navigation and surgeon-controlled robotic surgery. The specialised surgical planning software allows the surgeon to visualise patient anatomy, decide on implants and their positioning. The surgical navigation allows the surgeon, during surgery, to guide tools into place and ensure that implants are positioned as planned. A robotic system is able to work with the surgeon to ensure that bone resection is performed optimally in line with the plan to accept implants and that cutting tools are confined to the regions requiring resection.

However, it is not clearly seen the benefits that the current medical image processing (MIP) software, robotic surgery and navigation systems contribute to HRA in term of the cost, diagnosis and treatment quality as well as the technology transfer to hospitals. The computer-assisted surgical systems are expensive and not always available in the most of the hospitals. In addition, the use of these systems requires the special training as well as the know-how and skills of the surgeons. Therefore, the manual surgical method and tools are practically and commonly used for pre- and intra- operative planning and surgeries of HRA in most hospitals, without the support of the computer system, 3D imaging techniques, and personalised surgical tools.

Additionally, although the position of the implant is determined based on MIP, currently, surgeons still base on their experiences and skills as well as the available conventional tools to determines the drilling line and prepare the femoral head for the implant insertion. Moreover, the methods used by the robotic surgery and navigation systems such are done intra-operatively; therefore it is time consuming, and it can not take the advantages of the pre-operative planning results. Especially, the implant angle and the position are determined based on the reference points collected

by the surgeons during the operation, with the aid of the MIP system. These lead to the long operation time, and the surgical procedure becomes more complex. Finally, as mentioned above, the investment of the robotic surgery systems is expensive; and it requires the use of both the MRI or CT data of the patient and the robotic system.

It is also noted that, most of the robotic surgery and navigation systems and MIP software for HRA are based only on the geometrical analysis of the femur for surgical planning. There has been no surgical system that is available for optimising the implant position in term of biomechanics's point of views, and then transferring the analysis and planning information into the actual surgery accurately. If the implant is not optimally located, and the aspects of biomechanics between the device and bone structure are not carefully considered, the survivorships of the implant system is reduced, and it may cause the fracture of the femoral neck. More over, if the personalised surgical aid tools are not available, it would be difficult for the surgeons to obtain the best surgical accuracy, and the treatment quality is still highly dependent on the experience and skills of the surgeons.

2.4. Knowledge based system for HRA

There has been no knowledge based system and tool existed for supporting surgeons in pre-operative planning, advising and supporting in diagnosis and treatment, managing the patient data, and monitoring patient database in HRA. Most of the current surgical planning systems for HRA are focusing on guiding and helping the surgeons about the surgical procedures and obtaining the surgical planning parameters. Especially, the survival of the HRA implant system is up to 15 years [1, 7] or more. Therefore, it would be necessary to construct a knowledge based computer system and tools to support surgeons not only obtaining the good surgery, but also managing the patient data and monitoring patient treatment progress, as well as obtaining the right information from the database for a new treatment.

3. An optimal surgical aid system for HRA

In order to overcome the above mentioned key challenges, an optimal surgical aid system for diagnosis and treatment of HRA (HIPOS) has been developed as shown in Fig. 2, with the integration of 4 surgical aid units, including (i) Pre-operative planning,

(ii) Personalised surgical tools, (iii) Biomechanics modelling and analysis, and (iv) Knowledge based and expert system. These 4 surgical aid units share the same database and work together to support the surgeons all necessary information and surgical tools in order to obtain the best diagnosis and treatment for the patients. In this way, the proposed optimal system for HRA is able to obtain the following objectives: (i) Enhancing the surgical skills of the surgeons and improving the treatment quality for the patients; (ii) Increasing the accuracy and reducing the time of the surgery and (ii) Providing a cheap technical and practical solution as well as improving patient and data management for diagnosis and treatment of hip disease.

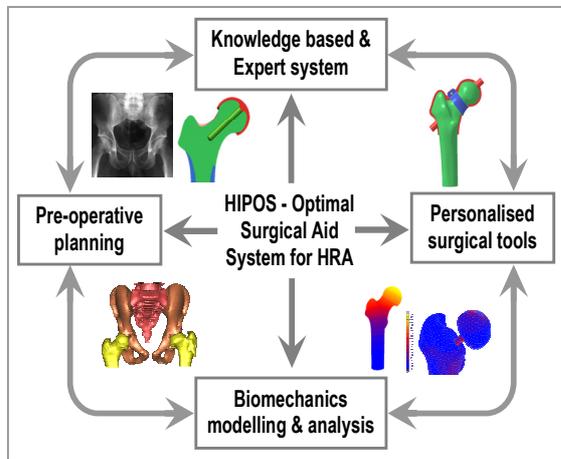


Fig. 2. An optimal system for HRA.

3.1 Enhancing the surgical skills of the surgeons and improving the treatment quality for the patients

With the use of the state of the art MIP and biomedical modelling technologies, complex surgical planning can be implemented preoperatively. In addition, the surgical risks and time can be reduced dramatically, and the skills of the surgeons are improved, since the surgeons can use the biomodels for surgical planning and rehearsals before the real operation is done [9, 10, 12]. Surgical tools such as the drilling guides proved the remarkable contribution of the biomedical modelling in improvement of the treatment quality for the patients; especially, for the complex surgeries.

A preoperative planning unit helps surgeons having better understanding of the anatomy and status of the patients, selecting the right size of an implant, determining correctly the optimal implant orientation,

conducting simulations and rehearsal of the operation. Finally, the diagnosis, treatment, and surgical planning are implemented via the MIP tool and a knowledge based and expert system (Section 3.3).

Figure 3 presents the results about investigation of the influence of femoral component placement on the load distribution on the femur neck in HRA [11].

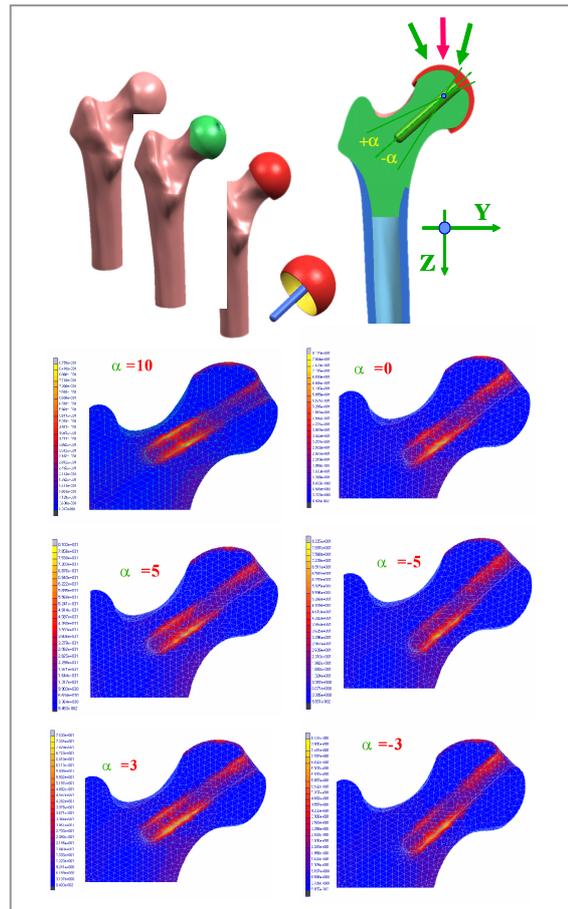


Fig.3. FEA study of the influence of an implant placement on the load distribution on the femoral neck in HRA. α is the angle between the stem of the spherical cup and the geometrically optimal centre line of the femoral neck.

It is clearly shown that the stress distribution on the femur changes and influences in the fracture tendency of the femoral neck when the angle of the stem of the spherical cup is changed. Moreover, technically, the traditional and currently applied techniques for determining the centre of the femur neck in HRA surgeries rely a lot on the manual technique and conventional tools as well as surgeons' skills to

determine the right drilling angle for locating the implant system. This leads to the inconsistent results. Even when the robotic system is used (Section 2.3), the drilling line is still defined geometrically and intra-operatively, not considering about the biomechanics aspects of the implant and bone structure. Finally, there is no surgical procedure and system which is currently and practically applied for HRA with the use of advanced biomechanics computation for determining the optimal orientation of the spherical cup.

With the the biomechanics modelling and analysis unit for computation of the optimal orientation of the implants, surgeons could plan and obtain the best solution based on the specialized Finite Element Analysis (FEA) tool which is integrated into the proposed HIPOS system. Biomedical Engineering (BME) experts can also work with surgeons via the collaborative Computer Aided Design and Engineering (CAD/CAE) and MIP environment. The optimal surgical planning and biomechanics analysis information for the orientation of the implants is transferred to the actual surgery via the personalised surgical tool (Section 3.2). In this way, the implant age and the treatment quality for the patients are improved.

3.2 Increasing the accuracy and reducing the time of the surgery with the use of personalised surgical tools to obtain the optimal implant positioning

In the proposed HIPOS system, the personalised surgical tools unit provides essential information and supportive devices for the surgeon to enhance the precision, safety and speed of surgery, as well as to decrease the complexity of surgery. It helps surgeons to implement complex surgeries without requiring high skills. First of all, the surgical planning can be preoperatively implemented to obtain the necessary surgical constraints based on MIP of the patient data in the form of CT/MRI images. From the biomechanics modelling and analysis (Section 3.1), the personalised surgical tools for guiding the surgeons to obtain the right orientation and position of the implant quickly and stably are designed and manufactured via the interface between MIP, CAD and CAE.

It is important that the surgical tools are also designed to be integrated with the traditional and standard HRA ones to help surgeons preparing the femoral head for implantation optimally. In this way, the accuracy of the operation is improved, and the operation time is remarkably reduced; especially, less skill is required for such a complex operation.

3.3 Providing a cheap technical and practical solution as well as improving patient and data management for diagnosis and treatment of hip disease

With the use the rapid prototyping (RP) and manufacturing as well as advanced technologies in MIP and CAD/CAE, the HRA based treatment can be done cheaply and effectively. Experts in engineering and medicine can collaborate and share the tasks to accomplish the complex surgery.

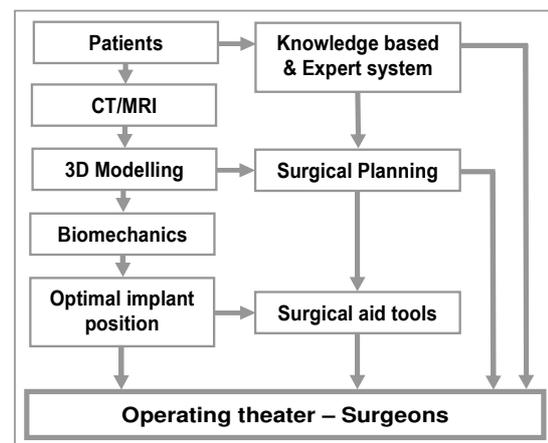


Fig.4. The workflow for practical implementation of the optimal surgical aid system for HRA

Figure 4 presents the key units and workflow for practical implementation of the proposed HIPOS system. The patient data can be sent from the hospitals to BME experts to work on the computational modelling and analysis. The analysis data as well as the clinical constraints generated from the surgical planning process is transferred to design and manufacturing experts to work on development of the personalised surgical tools. Experts in both engineering and medicine are able to share the surgical planning and database and work together via the collaborative MIP and CAD/CEA environment. Figures 5 and 6 present the FEA simulation of HRA and development of the surgical tool which is used to assist a surgeon to define the right position of the drilling line and install the traditional surgical device in order to prepare the femoral head for implantation of the spherical cup.

As mentioned in Section 2.4, the knowledge based and expert system is useful for the hospital in general and surgeons in particular in not only obtaining the best treatment results, but also managing the patient data and monitoring patient treatment progress. Especially the application of HRA for hip disease treatment is only acceptable with the development of

the second generation of HRA implants since 1991; and in the United States, the Food & Drug Administration (FDA) only approved the HRA based treatment in 2006. In addition, with the support of knowledge based and expert system, the surgeons and patients are able to obtain the right information for optimal surgical planning, diagnosis and treatment.

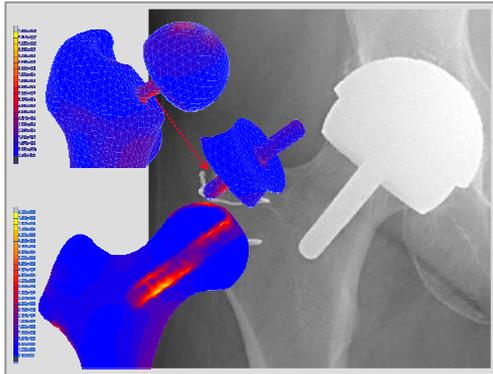


Fig.5. FEA simulation of HRA for determination of the optimal implant positioning

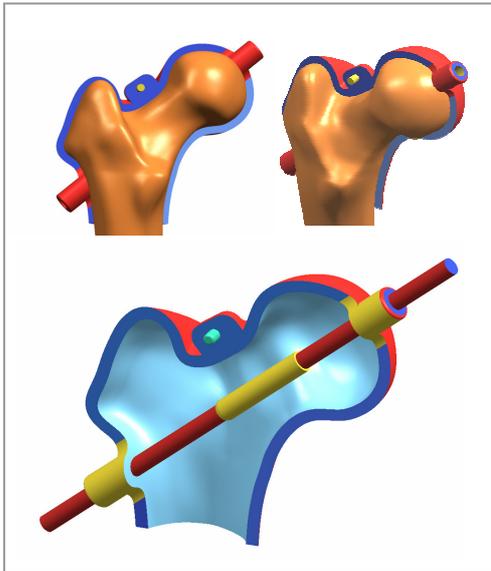


Fig.6. Development of the surgical tool for HRA

4. Conclusion

The traditional and currently applied methods for the HRA based treatment lead to expensive, unstable and inconsistent results which are highly dependent on the manual techniques and conventional surgical tools, as well as surgeons' skills and experiences. Although the

robotic and surgical planning systems are available for HRA, the drilling line for locating the implant is still defined geometrically and intra-operatively; the biomechanics aspects of the implant and bone structure are not fully considered. The optimal surgical aid system for HRA was therefore developed to solve the current challenges in HRA; it integrates the state of the art biomedical modelling, pre-operative planning and personalised surgical tools, knowledge based and expert system, and biomechanics modelling and analysis, in order to obtain the high precision, safety and speed of surgery. Especially, the proposed HIPOS system provides a cheap and practically feasible solution with the collaborative involvement of experts from both engineering and medicine for improving the diagnosis and treatment quality for the patients.

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