Journal of Biomechanics 48 (2015) 742–749

Contents lists available at ScienceDirect

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com

The design and pre-clinical evaluation of knee replacements for osteoarthritis

Peter S Walker*

Laboratory for Orthopedic Implant Design, Department of Orthopedic Surgery, NYU Hospital for Joint Diseases, 301 East 17th Street, New York, NY 10003, United States

ARTICLE INFO

Article history:
Accepted 26 November 2014

ABSTRACT

One of the concepts that Rik Huiskes promoted was that implants such as knee and hip replacements could be analyzed and optimized using numerical models such as finite element analysis, or by experimental testing, an area he called pre-clinical testing. The design itself could be formulated or improved by defining a specific goal or asking a key question. These propositions are examined in the light of almost five decades of experience with knee implants. Achieving the required laxity and stability, was achieved by attempting to reproduce anatomical values by suitable radii of curvature and selective ligament retention. Obtaining durable fixation was based on testing many configurations to obtain the most uniform stress distribution at the implant–bone interface. Achieving the best overall kinematics has yet to be fully solved due to the variations in activities and patients. These and many other factors have usually been addressed individually rather than as a composite, although as time has gone on, successful features have gradually been assimilated into most designs. But even a systematic approach has been flawed because some unrecognized response was not accounted for in the pre-clinical model, a limitation of models in general. In terms of the design process, so far no method has emerged for systematically reaching an optimal solution from all aspects, although this is possible in principle. Overall however, predictive numerical or physical models should be an essential element in the design of new or improved knee replacements, a part of the design process itself.

1. Introduction

Rik Huiskes proposed that the biological response of bone to in vivo forces could be predicted using numerical modeling, and demonstrated this using the structure of the proximal femur as an example (Huiskes et al. 1987; Weinans et al. 1992). The essential theory was a cellular mechanism which responded to a mechanical stimulus to cause either the formation or resorption of bone. The criterion in the adaptive finite element models was strain energy density, while it was emphasized that some mechanical or structural optimization was not the mechanism but a possible result of the biological processes. The adaptive finite element methodology was applied to show how the interposition of implants would modify the stress field in the surrounding bone and cause remodeling (Huiskes et al., 1989). In some cases, this would result in a major change in the distribution of the bone tissue, for example, a substantial loss of bone around the proximal region of a well-fixed hip femoral stem, with the opposite effect at the distal region. Rik and his colleagues then went on to propose that implant components could be designed to minimize such negative effects, and to reach a design which could be considered 'optimal' in terms of minimizing the degree of bone remodeling (Huiskes and Boeklagen 1989).

However, bone remodeling was not the only important factor in relation to implants; the interface also needed to be considered for stress situations which could lead to loosening. This was well illustrated in the case of so-called 'isoelastic' hip stems, which would cause less proximal bone resorption but higher interface shear stresses, requiring some acceptable level to be reached for both factors simultaneously (Huiskes et al., 1992). Later, yet a further consideration was added, that of the bonding status of the acrylic cement to the implant surface, which affected the overall stresses around the implant (Huiskes and van Rietbergen, 1995; Verdonschot and Huiskes, 1996). Whether this adding of new factors over time followed or preceded clinical observations, impacts on the predictive power of pre-clinical methods, as opposed to simply modeling and explaining clinical phenomena. In reality there was an interaction between the two in the case of total hip replacements. It should be added that Rik also emphasized the importance of pre-clinical experimentation as well as numerical modeling, but in both cases he emphasized that both were 'models', an attempt to represent reality in such a way as to

* Tel.: +1 917 2175447.
E-mail address: Peter.walker@nyumc.org

http://dx.doi.org/10.1016/j.jbiomech.2014.12.012
0021-9290/

be predictive. Clearly, when designing implants, predicting and implementing successful design features was considered to be preferable to a trial and error method applied to patients.

For research and design studies overall, Rik was adamant in requiring a rationale or focus. He expressed this frequently at conferences by asking what the research question was. For example, if a study consisted of meticulous data on a phenomenon, use of an elaborate new methodology, or was merely descriptive, he would ask for a key question, a purpose, or a hypothesis. In an article entitled, 'If bone is the answer, what is the question?' (Huiskes, 2000) the importance of determining the appropriate scientific question was explained and the misleading research which could result if this was not done: 'Sensible hypotheses are needed before fortuitous experiments can be defined.'

These different principles expressed by Rik Huiskes can be considered in the framework of designing treatments for knee osteoarthritis, the most widely used treatment being total knee replacement. From the beginning, such implants have developed in a multi-disciplinary environment, with interactions between surgeons, bioengineers, and scientists; based at hospitals, universities, and manufacturing companies. As a result, numerous designs have evolved over time, with each new design attempting to address clinically observed problems, or to improve performance in some way. In many cases, extensive experimentation or analysis was carried out to test or optimize the design. It is often suggested that knee joint replacements have now reached a limit where further improvements to longevity or performance can only be incremental. It is even proposed that biological solutions are required for any new breakthrough.

Hence it is timely to look critically at the problem of osteoarthritis of the knee, and whether approaches as proposed by Rik Huiskes can lead to continued improvements in knee replacements, or point to new directions altogether. The process would involve defining the problems to be solved, asking the most appropriate questions, and developing and applying predictive pre-clinical models. This paper will first review the field of knee joint replacement from its beginnings, how new designs originated, their design criteria, and the research processes employed. The role and application of preclinical tests will then be examined, including their limitations and ongoing development. For illustration, some specific examples will be included from the author's laboratories. Finally, the role of predictive testing in the context of the design process as a whole will be discussed.

2. Development of knee joint replacements

2.1. Design concepts and types

In the 1950s, metal tibial spacers such as the McKeever and Macintosh emerged with the idea of realigning the knee, while at the other extreme, metal hinges such as the Walldius aimed to restore stability with a fixed-axis motion. The first cemented metal-plastic knee replacement which preserved the cruciate ligaments was designed by Gunston in the late 1960s (Gunston, 1971). The femoral components, in the form of hemi-discs, were inset into the condyles projecting just above the surface, while plastic tibial runners were similarly inset. The ideas here were restoration of the condylar contours, simplicity, and low cost manufacture. At around the same time, Freeman et al. (1973) took the opposite approach of resecting the cruciates, as well as the distal and posterior femur and the proximal tibia to establish limb alignments. Their cylinder-in-trough components provided the necessary stability as well as large contact areas for low bearing stresses. Seedhom et al., 1974 took yet a different approach by reasoning that a total knee should restore the anatomic shapes of the distal femur including the patella trochlea using metallic shells, and the proximal tibia with additional tibial dishing to account for the menisci.

Following these original contributions, in the 1970s there was a dramatic expansion in the number of designs, a number of which embodied successful design principles and features used to this day (Robinson, 2005). A summary of the various design types of total knee replacement at the end of the 1990s was provided in a review article (Walker and Sathasivam, 2000). Among the many fixed-bearing, cruciate-retaining (CR) and posterior stabilized (PS), and mobile bearing designs, the only one with asymmetric tibial bearing surfaces was the Medial Pivot, with a conforming medial side and low constraint lateral side, designed in an effort to replicate normal knee motion and provide AP stability (Blaha, 2004). It is remarkable that, considering the extensive biomechanical literature demonstrating the asymmetric nature of knee morphology, stability, and motion, that asymmetry had not been accepted as a design goal for a total knee. Nor was the question seriously investigated as to what benefits asymmetry would impart to the functional results.

Objectively, this overall situation would prompt the questions as to why there were several design types, with many designs of each type, which types and individual designs were the best, and why designs which replicated normal anatomy and motion were barely represented. Part of the answer lies in the indications, ranging from mild to severe arthritis. However, because short-medium term clinical results were often similar between types and designs, and were generally satisfactory, there were no compelling reasons for designers and companies to change this situation. Biomechanical laboratory testing often did reveal differences in certain performance characteristics, such as contact area, area of tibial coverage, plastic-tibial tray micromotion; but such individual factors were insufficient to represent an overall superiority of one design over another. The design processes themselves ranged from intuitive ideas, to a systematic defining of design criteria. However, even with the latter, there was no defined set of modeling or experimental methodologies that could produce the 'best design'. It was also recognized that other factors such as the surgical technique, the rehabilitation regime, and the condition of the patient, influenced the clinical results, as well as the implant design itself.

2.2. Laxity and stability

In the 1970s, it was generally considered that to restore normal knee mechanics, all of the ligaments should be retained, but if one or both cruciates were resected for any reason, the bearing surfaces of the components would have to compensate. However, the question as to which degrees of freedom should be stabilized and how much laxity to allow, was not well understood. Even when the cruciates were preserved, designs with very low bearing surface conformity as in the Townley, to the high conformity of the Geomedic, were introduced at about the same time. The 'double-dished' bearing surfaces of the original Total Condylar knee, designed by Walker et al. (1975), (1976), were based on studies of the laxity of the anatomic knee. It was found that when cyclic anterior–posterior (AP) shear force or axial torque was applied to an intact anatomic knee, the displacement–force and rotation–torque curves showed a region of low stiffness in the center, and a rapidly stiffening region at the extremes (Wang and Walker, 1974; Hsieh and Walker, 1976). When an axial force of 1–2 times body weight was applied to the knee however, there was a major reduction in the total laxity. This was attributed to geometrical factors, whereby as the femur was displaced or rotated on the tibia, there was an upwards displacement acting against the applied compressive force. This phenomenon was called the 'uphill