TITLE OF THE INVENTION

Computer-Assisted Surgery Planner and Intra-Operative Guidance System

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part application of application Serial Number 08/803,993, filed February 21, 1997. Now US Patent No 5,880,976

RF 4/1/00

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

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BACKGROUND OF THE INVENTION

The present invention is directed generally to the implantation of artificial joint components osteochondral grafts, and osteotomy and more particularly, to computer assisted surgical implantation of artificial joint components during replacement and revision procedures, computer-assisted osteochondral grafts, and computer-assisted osteotomy

Total hip replacement (THR) or arthroplasty (THA) operations have been performed since the early 1960s to repair the acetabulum and the region surrounding it and to replace the hip components, such as the femoral head, that have degenerated Currently approximately 200 000 THR operations are performed annually in the United States alone, of which approximately 40,000 are redo procedures, otherwise known as revisions The revisions become necessary due to a number of problems that may arise during the lifetime of the implanted components, such as dislocation component wear and degradation and loosening of the implant from the bone

Dislocation of the femoral head from the acetabular component or cup, is considered one of the most frequent

early problems associated with THR, because of the sudden physical, and emotional, hardship brought on by the dislocation   The incidence of dislocation following the primary THR surgery is approximately 2-6% and the percentage is even higher for revisions   While dislocations can result from a variety of causes such as soft tissue laxity and loosening of the implant the most common cause is impingement of the femoral neck with either the rim of an acetabular cup implant, or the soft tissue or bone surrounding the implant   Impingement most frequently occurs as a result of the malposition of the acetabular cup component within the pelvis

Some clinicians and researchers have found incidence of impingement and dislocations can be lessened if the cup is oriented specifically to provide for approximately 15° of anteversion and 45° of abduction, however, this incidence is also related to the surgical approach   For example, McCollum et al cited a comparison of THAs reported in the orthopaedic literature that revealed a much higher incidence of dislocation in patients who had THAs with a posterolateral approach   McCollum D E and W J Gray, "Dislocation after total hip arthroplasty (causes and prevention)", Clinical Orthopaedics and Related Research, Vol 261, p 159-170 (1990)   McCollum's data showed that when the patient is placed in the lateral position for a posterolateral THA approach, the lumbar lordotic curve is flattened and the pelvis may be flexed as much as 35° If the cup was oriented at 15-20° of flexion with respect to the longitudinal axis of the body, when the patient stood up and the postoperative lumbar lordosis was regained, the cup could be retroverted as much as 10°-15° resulting in an unstable cup placement Lewinnek et al performed a study taking into account the surgical approach utilized and found that the cases falling in the zone of 15°±10° of anteversion and 40°±10° of abduction have an instability rate of 1 5%, compared with a 6% instability rate for the cases falling outside this zone

Lewinnek G E , et al , "Dislocation after total hip-replacement arthroplasties", Journal of Bone and Joint Surgery, Vol 60-A, No 2 p 217-220 (March 1978) The Lewinnek work essentially verifies that dislocations can be correlated with the extent of malpositioning, as would be expected The study does not address other variables, such as implant design and the anatomy of the individual, both of which are known to greatly affect the performance of the implant

The design of the implant significantly affects stability as well A number of researchers have found that the head-to-neck ratio of the femoral component is the key factor of the implant impingement, see Amstutz H C , et al , "Range of Motion Studies for Total Hip Replacements", Clinical Orthopaedics and Related Research Vol 111, p 124-130 (September 1975) Krushell et al additionally found that certain long and extra long neck designs of modular implants can have an adverse effect on the range of motion Krushell, R J , Burke D W , and Harris W H , "Range of motion in contemporary total hip arthroplasty (the impact of modular head-neck components)" The Journal of Arthroplasty, Vol 6, p 97-101 (February 1991) Krushell et al also found that an optimally oriented elevated-rim liner in an acetabular cup implant may improve the joint stability with respect to implant impingement Krushell, R J , Burke D W , and Harris W H , "Elevated-rim acetabular components Effect on range of motion and stability in total hip arthroplasty", The Journal of Arthroplasty Vol 6 Supplement, p 1-6 (October 1991) Cobb et al have shown a statistically significant reduction of dislocations in the case of elevated-rim liners, compared to standard liners Cobb T K , Morrey B F Ilstrup D M , "The elevated-rim acetabular liner in total hip arthroplasty Relationship to postoperative dislocation", Journal of Bone and Joint Surgery, Vol 78-A, No 1, p 80-86, (January 1996) The two-year probability of dislocation was 2 19% for the elevated liner, compared with 3 85% for standard liner

Initial studies by Maxian et al using a finite element model indicate that the contact stresses and therefore the polyethylene wear are not significantly increased for elevated rim liners, however, points of impingement and subsequent angles of dislocation for different liner designs are different as would be expected Maxian T A , et al "Femoral head containment in total hip arthroplasty Standard vs extended lip liners", 42nd Annual meeting, Orthopaedic Research society, p 420, Atlanta, Georgia (February 19-22, 1996), and Maxian T A , et al "Finite element modeling of dislocation propensity in total hip arthroplasty", 42nd Annual meeting, Orthopaedic Research society, p 259-64, Atlanta, Georgia (February 19-22, 1996)

An equally important concern in evaluating the dislocation propensity of an implant are variations in individual anatomies As a result of anatomical variations there is no single optimal design and orientation of hip replacement components and surgical procedure to minimize the dislocation propensity of the implant For example, the pelvis can assume different positions and orientations depending or whether an individual is lying supine (as during a CT-scan or routine X-rays) in the lateral decubitis position (as during surgery) or in critical positions during activities of normal daily living (like bending over to tie shoes or during normal gait) The relative position of the pelvis and leg when defining a "neutral" plane from which the angles of movement, anteversion abduction etc , are calculated will significantly influence the measured amount of motion permitted before impingement and dislocation occurs Therefore, it is necessary to uniquely define both the neutral orientation of the femur relative to the pelvis for relevant positions and activities and the relations between the femur with respect to the pelvis of the patient during each segment of leg motion

Currently, most planning for acetabular implant placement and size selection is performed using acetate

templates and a single anterior-posterior x-ray of the pelvis Acetabular templating is most useful for determining the approximate size of the acetabular component, however, it is only of limited utility for positioning of the implant because the x-rays provide only a two dimensional image of the pelvis Also, the variations in pelvic orientation can not be more fully considered as discussed above

Intra-operative positioning devices currently used by surgeons attempt to align the acetabular component with respect to the sagittal and coronal planes of the patient B F Morrey, editor, "Reconstructive Surgery of the Joints", chapter Joint Replacement Arthroplasty, pages 605-608, Churchill Livingston, 1996 These devices assume that the patient's pelvis and trunk are aligned in a known orientation, and do not take into account individual variations in a patient's anatomy or pelvic position on the operating room table These types of positioners can lead to a wide discrepancy between the desired and actual implant placement, possibly resulting in reduced range of motion, impingement and subsequent dislocation

Several attempts have been made to more precisely prepare the acetabular region for the implant components U S Patent No 5,007,936 issued to Woolson is directed to establishing a reference plane through which the acetabulum can be reamed and generally prepared to receive the acetabular cup implant The method provides for establishing the reference plane based on selecting three reference points, preferably the 12 o'clock position on the superior rim of the acetabulum and two other reference points, such as a point in the posterior rim and the inner wall, that are a known distance from the superior rim The location of the superior rim is determined by performing a series of computed tomography (CT) scans that are concentrated near the superior rim and other reference locations in the acetabular region

In the Woolson method, calculations are then performed to determine a plane in which the rim of the acetabular cup

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