

Exhibit 1014

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HipNav: Pre-operative Planning and Intra-operative Navigational Guidance for Acetabular Implant Placement in Total Hip Replacement Surgery

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Abstract

The Hip Navigation or HipNav system allows a surgeon to determine optimal patient specific acetabular implant placement and accurately achieve the desired acetabular implant placement during surgery. Hip Nav includes three components: a pre-operative planner, a range of motion simulator, and an intra-operative tracking and guidance system. The goals of the current HipNav system are to 1) reduce dislocations following total hip replacement due to acetabular malposition, 2) determine and potentially increase the 'safe' range of motion, and 3) track in real time the position of the pelvis and acetabulum during surgery. This information will help the surgeon achieve more reliable and accurate positioning of the acetabular cup and take into account specific anatomy for individual patients. The HipNav system provides for a new class of research tools that can be used intra-operatively to permit surgeons to re-examine commonly held assumptions concerning bone and implant motion, range of motion testing, and the "optimal" alignment of acetabular cups.

Keywords: computer assisted surgery, total hip replacement, navigational guidance

1 Introduction

The incidence of dislocation following primary total hip replacement (THR) surgery is between 2-6% and even higher following revisions [5] [4]. It is therefore, one of the most commonly occurring complications following hip replacement surgery. Dislocation of a total hip replacement causes significant distress to the patient and physician and is associated with significant additional costs in order to relocate the hip. Another complication of THR surgery is impingement between the neck of the femoral implant and the rim of the acetabular component, as shown in Figure 1. Impingement can lead to advanced wear of the acetabular rim resulting in polyethylene wear debris shown to accelerate loosening of implant bone interfaces. The position at which impingement occurs is determined by the design and geometry of the implants (such as the size of the femoral head, the width of the neck, and the design of the acetabular liner), and more importantly by the relative position of the femoral and acetabular implants. In certain cases, impingement may result in dislocation, as seen in the X-Ray of Figure 2. The causes of dislocation following total hip replacement are multi-factorial and include not only malposition of the implants causing impingement, but also soft tissue and bone impingement, and soft tissue laxity [5]. The most common cause of both impingement and dislocation is malposition of the acetabular component [5].

A system has been developed to permit accurate placement of the acetabular component during surgery. As shown in Figure 3, the Hip Navigation or HipNav system includes three components: a pre-operative

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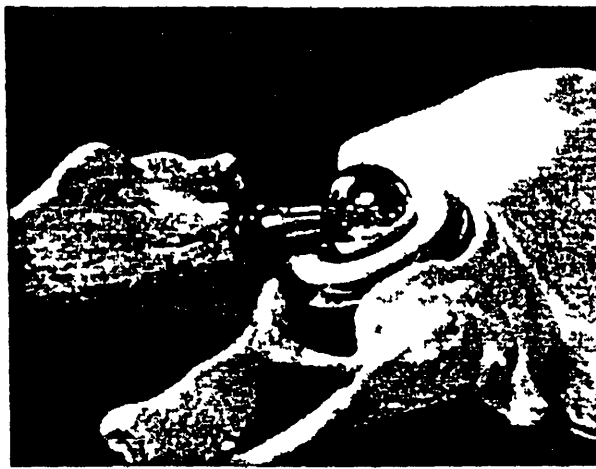


Figure 1 Implant impingement.



Figure 2 X-Ray showing pelvic dislocation

planner, a range of motion simulator, and an intra-operative tracking and guidance system. The pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis based upon pre-operative CT images. The range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-operative planner. The feedback provided by the simulator can aid the surgeon in determining optimal, patient specific acetabular implant placement. The intra-operative tracking and guidance system is used to accurately place the implant in the predetermined optimal position regardless of the position of the patient on the operating room table.

By accurately placing the acetabular component in an optimally selected position, the HipNav system has the potential to reduce the risk of dislocations and the generation of wear debris caused by impingement resulting from malpositioned components and increase the "safe" range of motion.

2 Current Practice

Current 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 commonly performed

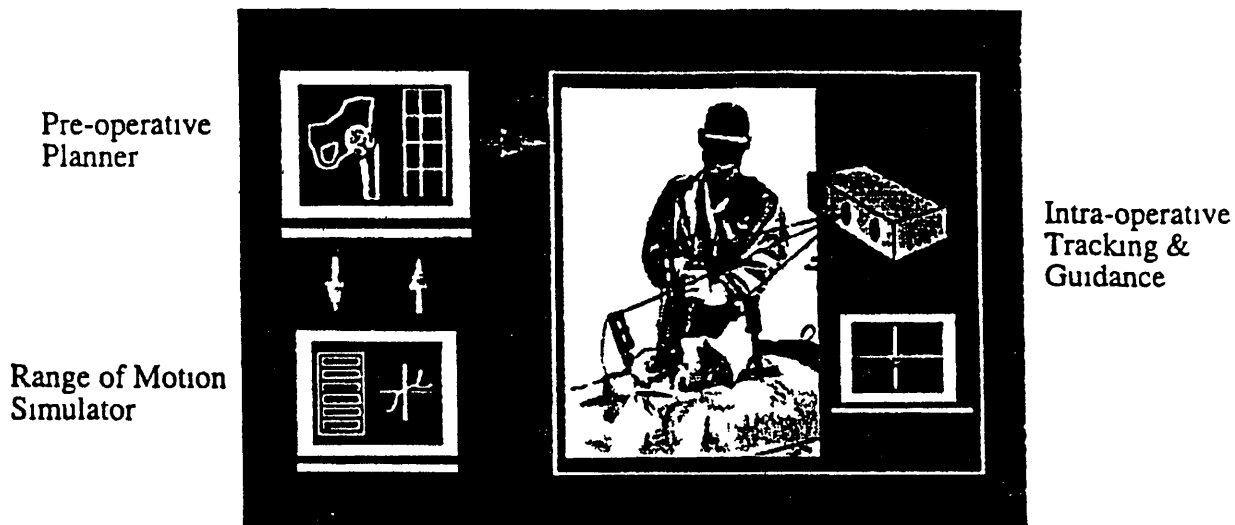


Figure 3 HipNav system overview

to determine the approximate size of the acetabular component, but there is little effort to accurately determine the ideal position of the implant

The 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 [6]. 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. Use of this type of positioner can lead to a wide discrepancy between the desired and actual implant placement, possibly resulting in reduced range of motion, impingement and subsequent dislocation.

3 System Description

The first step in using the HipNav system is the pre-operative CT scan which is used to determine the patient's specific bony geometry. The CT images are used in the pre-operative planner which allows the surgeon to determine appropriate implant size and placement. In the current version of the planner, the surgeon can position cross sections of the acetabular implant upon orthogonal views of the pelvis, as seen in Figure 4. We are investigating other methods of presenting CT data to the surgeon, including an approach which displays implant placement on multiple CT cross sections, each of which passes through the acetabulum's central axis (the axis which passes through the center of pelvic rotation and which is perpendicular to the plane of the acetabular rim).

Once the surgeon has selected the position of the acetabular implant, the range of motion simulator is used to determine the femoral positions (in terms of extension/flexion, abduction/adduction and internal/external rotation) at which impingement would occur for that specific implant design and position. Based upon this range of motion information, the surgeon may choose to modify the selected position in an attempt to achieve the "optimal" cup position for the specific patient. The range of motion simulator performs a kinematic analysis which determines an "envelope" of the safe range of motion, as seen in Figure 5. A more detailed description of the range of motion simulator appears in [3].

The optimal patient specific plan is used by the HipNav System in the operating room on the day of surgery. HipNav permits the surgeon to determine where the pelvis and acetabulum are in "operating room coordinates" at all times during surgery. Knowing the position of the pelvis during all phases of surgery and especially during preparation and implantation of the acetabular implant, permits the surgeon to accu-

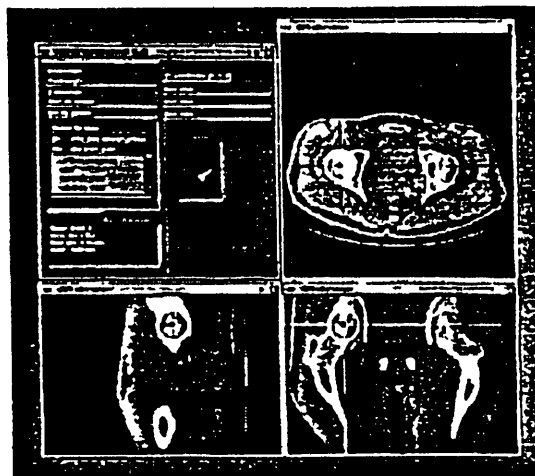


Figure 4 Pre-operative planner

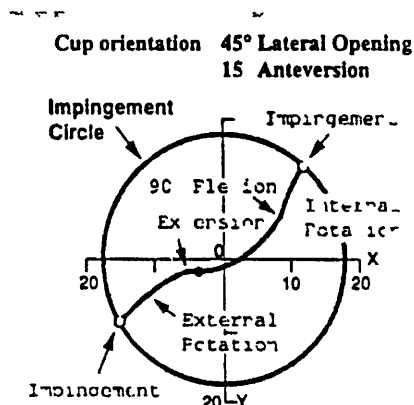
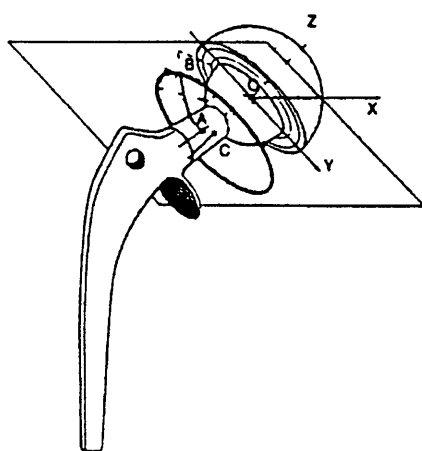


Figure 5 Kinematic simulations Left - implant geometry Right - motion envelope

rately and precisely position the cup according to the pre-operative plan. Alternately, using HipNav the surgeon can align the component to an accepted standard such as "true" 45 degrees of abduction and 20 degrees of anteversion.

There are several high-technology devices that are used intra-operatively to allow the surgeon to accurately execute the pre-operative plan, as seen in Figure 6. One such device is an 'Optotrak' optical tracking camera (Northern Digital Inc., Ontario, Canada) which is capable of tracking the position of special light emitting diodes or "LEDs". These LEDs can be attached to bones, tools, or other pieces of operating room equipment to allow highly reliable tracking. Optotrak can achieve accuracies of roughly 0.1mm at speeds of 100 measurements per second or higher.

In order to determine the location of the pelvis and the acetabular implant during surgery, Optotrak targets are attached to several conventional surgical tools, as seen in Figure 7. The pelvis is tracked by attaching a target to the pelvic portion of a Harris leg length caliper (Zimmer, Inc., Warsaw, IN), and inserting this device into the wing of the ilium. The acetabular implant is tracked by attaching a second target to the handle of an HGP II acetabular cup holder and positioner (Zimmer, Inc., Warsaw, IN). A third Optotrak target

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