Development of a Tool for Component Positioning in THA Surgeries


*Industrial Design Engineering, Delft University of Technology, Delft, The Netherlands
**Biomet, Biomet Europe BV, Dordrecht, The Netherlands
***Orthopedics Group, Reinier de Graaf Hospital, Delft, The Netherlands

Summary

Improper component positioning during total hip arthroplasty (THA) is the most common surgical error that takes place during the procedure. Though developments in the individual components have taken place, the positioning of these components during the surgery continues to be a challenge for surgeons, resulting in dislocations with a frequency between 1-10 % [1,2,3]. A practical and elegant solution in the form of a guidance tool was developed to be used by surgeons during placement of the acetabular cup component. The tool accounts for differing patient anatomy and patient position.

1 Background

The most common complication of total hip arthroplasty (THA), or replacement (THR), surgeries is post surgical dislocation of the joint [4]. Surgical factors contributing to dislocation are due to one or a combination of these factors: the combination of components used, the experience of the surgeon, the method of fixation of the acetabular cup, orientation of the acetabular cup, and the surgical approach [2]. Of these factors, improper component positioning is the leading cause of dislocations [5].

![Figure 1 Hip Components. Reprinted from Innovations in Total Hip Replacement, by E. Smith, n.d., Retrieved 11 October 2012, from http://evertsmith.com/innovations/. Copyright 2008 by Evert Smith.](image)

The components used during a THA surgery can be seen in Figure 1. The shell, also known as the cup, is the component which is placed in the acetabular cup of the pelvis during a THA. The liner is then placed within the shell to simulate the effect of cartilage between the ball and socket joint. If impingement occurs, it is possible for this liner to crack while the patient is going about daily activities [2]. The head is the prosthetic which replaces the femoral head. It is attached to the stem, which is adjusted to the particular patient during surgery. The leg component is carefully inserted into the femur using a surgical hammer.

The propensity of complications due to acetabular cup malpositioning led to a focus on this particular part of the THA surgery. The range of motion in the joint in multiple anatomical planes complicates the process of placing a new acetabular cup in the socket because surgeons must account for combined measurements from two separate planes. These measurements are called anteverision and inclination. Anteverision is the degree measure between the coronal and sagittal planes from the transverse plane (angle between the patient’s front and side as seen from an aerial view). Inclination is the angle between the patient’s sagittal and transverse planes (longitudinal median axis and horizontal axis, as if patient is viewed from the front).

Current guidance tools on the market are not favored by surgeons for two reasons in particular. One group of guidance devices is invasive, which is unappealing to surgeons. These devices are often also not specific enough in their measurements for the surgeon’s preference. The other grouping of existing products is non-invasive and accurate [6]. The vast majority of these guidance tools, however, are cost prohibitively expensive for hospitals to purchase. Given the information surrounding existing guidance tools for acetabular component placement there is a need for a guidance device which combines accuracy, non-invasive methodology, and affordability.

2 Methods

Various methods were used to gain additional insights and develop the guidance tool. Observational research was conducted during THA surgeries, interviews were carried out with a variety of medical professionals and academics, and a creative design and development session was conducted with medical professionals and design students at a medical center.

Observational Research

The observational research was conducted at a medical center and consisted of four observations of hip surgeries broken into two separate days. The patients were all between 55 and 75 years of age. One of these surgeries was a hip revision replacing an existing prosthetic hip, and three...
of the surgeries were THA’s. Both the lead surgeon and surgical assistants had extensive experience.

The first surgical observation day which consisted of two surgeries was conducted to gain familiarity with the surgical procedure, techniques, tools, and components. The goal of the second observational day including two surgeries was to more closely investigate the inner workings of the hip joint and the methods surgeons use to carry out the surgery.

The surgeries lasted between 2 hours and 2.5 hours each with the patient either completely sedated or semi-sedated. During the three THA’s the patients were all in the supine position with the surgeon using an anterior approach. The same procedural steps were used for each of the THA’s.

Expert Interviews

Interviews and meetings relating to the project were carried out multiple times with orthopedic surgeons. These interviews were used to determine their impressions of THA’s and their preferred methods and any difficulties they encounter. Additional interviews were conducted with a variety of experts in the fields of image processing and visualization, 3D imaging, and 3D perception. Several meetings were also held with Biomet experts for discussions on their current product line, manufacturing, and new product goals.

Design Session

A design insights and development session was also carried out at the hospital to obtain insights into acetabular cup placement and determine the qualities which placement tools should possess. The surgical staff participants, which consisted of two surgeons, one researcher, and six OR nurses, along with three student participants all worked together to complete a total of five different sessions. The sessions included illustrating the cup placement process, word associations with cup placement, explaining likes and dislikes of current OR products, surgeons instructing design students to place the cup using models, and designing their own optimal cup placement tool. Each of these sessions provided interesting findings which could be used in the product development of the placement tool.

Analysis and Design Ideation Process

Following the observations, interviews, and design sessions, the development of product requirements and criteria commenced. Following the creation of guidelines the product development began using various methods and mediums. Morphological charts, sketches, cardboard and wooden models were all used as part of the development phase. Next, 3D models were developed followed by 3D printing of models. The 3D printing, testing, and making alterations process was repeated a number of times until the tool was deemed satisfactory. Discussions with surgeons and Biomet experts were integral throughout the development phase of the guidance tool.

3 Results

Based on the data collected during the research phase, a series of product requirements was developed to fulfill the needs of the surgical team, patient anatomy, and Biomet. Navigation and special orientation for the guidance tool was deemed to be of high importance due to the need for successful acetabular cup placement in two separate anatomical planes and differences in patient anatomical geometry. Maintenance and manufacturing requirements were also considered important for hygiene, sterilization, and cost of the device. Other requirements were broken into two main categories: use requirements and interaction requirements.

Requirements

Use Requirements:

Workflow - Must fit within normal workflow of surgeon (not add an extensive amount of time to the surgical procedure or length of time a patient must be under anesthesia.)

Simple - The process of using the device should be clear and require minimal instruction

Performance - The device must be simple to adjust and use during the course of surgery

User Interaction Requirements:

Readability - The degree display must be easy to read for surgeons in the OR atmosphere

Size - The device should be developed to be attached to an existing cup impactor (insertion) tool.

Aesthetics - The product should be clean cut and well designed in appearance

Feedback - The device should provide visual feedback for the surgeons to align the cup properly. Surgeons currently use visual cues such as the wall as a reference point for cup positioning. Maintaining this visual guidance will help with their comfort level with using a new device.

Trustworthy - The device should be believable and demonstrate measurement accuracy

Ergonomics - Must be easy to handle and adjust measurements

Final Design

The resulting guidance tool consists of a three part assembly as seen in Figure 3. It is easy for surgeons to use intra-surgery and for nurses to handle for assembly and disassembly. The top and bottom pieces are outfitted with grooves for easy handling and fit firmly together with a bayonet lock closure. The interior of the two pieces are curved in a spherical shape so that the internal rotating centerpiece can pivot but be firmly grasped by the top and bottom pieces.

![Figure 3 3D model of guidance tool](Image)

The rotating centerpiece is spherical in shape with an adapted keyhole cutout and ribs on the top to fit snugly on the cup impactor. This prevents it from rotating around the longitudinal axis (z), only allowing movement in the horizontal x and y-axis of the cup impactor.

The tool is used by aligning an inserted trial cup (used normally in surgery to determine the proper cup size for the patient) with the bottom of the guidance tool, the internal sphere will then be aligned so that it’s keyhole is completely vertical surgeon using the impactor tool. At this point the sphere will be locked in place by the top and bottom piece and will maintain the aligned angles. This will maintain the perfectly vertical angle within the cylinder aligned with the test cup so that it can later be replicated.

When the surgeon locks the spherical centerpiece in place, it is the correct angles for that particular patient in two planes, the coronal and transverse planes. Degree
measures for anteversion and inclination are then displayed
providing the additional reference for the surgeon. The tool
is then removed from its alignment with the test cup and
slid onto the straight handled Biomet cup impactor tool
where it fits snugly onto the middle of the tool by a spring
and a clip-lock fixture.

The proper cup component is next selected by the
surgeon and attached to the inserter. The surgeon can then
use the alignment tool by orienting the tool so that its top
surface becomes parallel to the operating table. By aligning
the tool parallel to the operating table the surgeon is
replicating the chosen anteversion and inclination aligned
when it is held up to the trial cup. This ensures that the
correct degrees are maintained from the original anatomical
planes.

Degree measures were determined by first investigating
the normal total version used for patients in the supine
position. The vast majority of patients require a total
version, the combination of inclination and anteversion, of
50-55 degrees. Given this, coordinate systems were made to
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This was done for multiple combinations adding up to
50 degrees. The system for finding the degree
measurements for the tool was developed by using
projections of the total version coordinates which all added
to 50 degrees (45&5, 40&10, 35&15). When projected, the
coordinate pairs all intersect at one point as seen in Figure
5. This point represents the point where the total version is
50 degrees. The same was done for 55 degrees, 45 degrees,
and 40 degrees so that reference points were attained for
every 5 degrees of total version. This means that when the
surgeon lines up this measurement tool to his trial cup for
the patient he or she can determine the total version within
5 degrees and use his or her expertise to assess whether this
is an appropriate degree measurement for the patient.

The guidance tool is not intended to replace the
expertise of the surgeon, but only to give a feedback
reference system so the surgeon knows the range, within 5
degrees of total combined version. The original prototype
diameter was 58mm, a size chosen because of the range of
the average trial cup used during THA’s. Using the
alignment method illustrated in Figure 4 additional
diameters of the guidance tool would be necessary so
aligning to a variety of trial cups would be possible.

To ensure structural reliability throughout the tool’s
lifespan 17-4 stainless steel was chosen as an ideal material.
17-4 was selected for its known strength, durability, and
current use in the medical goods industry. It is also resistant
to wear during the sterilization process.
4 Interpretations

Proof of Concept

A proof of concept meeting was held with three orthopedic surgeons in order to determine the feasibility of the product and what improvements could be made. The surgeons experience with the tool was positive overall with suggestions on additional testing to connect the trial cup more securely to the guidance tool during the alignment process. The surgeons all agreed that the interaction the guidance tool had with existing surgical tools was successful and easy to handle. They were comfortable with the tool, felt it was trustworthy, and were confident that using visual alignment to guide the tool parallel to the operating table was a simple yet effective solution. The consensus regarding accuracy was that the tool would function successfully and also prove to be more accurate than other existing THA guidance tools.

During testing it was also realized that although the intended patient position is supine for the development of the tool it was also noted by the surgeons that the tool could be used on patients in any position on the operating table. This opens the application of the tool up to surgeons to may have a preference to operate on a patient in alternative positions and also have a successful experience with the tool.

Overall, the guidance tool was well received by the orthopedic surgeons who interacted with it. All agreed, however, that in order to gain thorough data, the accuracy of the device must be tested and documented. This would require use of a cadaver along with CT scans which would be compared to the measurements determined using the guidance tool. Only at this point would enough data be compiled to determine the true range of accuracy of the device.

Reflection

The combination of analysis of THA surgeries, interviews, surgical observations, and a design session led to the development of design requirements for a new tool for component positioning during total hip arthroplasties. Reviewing the product based on these design requirements helped to evaluate the success of the product. Each aspect was considered to ensure that the product did, in fact, meet each requirement set.

The intended use was to develop a product to aid in component placement for varying patient anatomies by way of a simple solution. The simplicity displayed in the final design only came about after extensive amounts of research and studies into the topic. After guidelines were developed and the core problem was revisited plausible solutions arose leading to a final design which fulfilled the requirements of the involved parties.

5 References


