

POSITIONER SUPPORT FOR HIP ARTHROPLASTY

DESCRIPTION OF THE TECHNOLOGY

Hip arthroplasty is a successful procedure in most cases. Approximately 1.5 million hip implants are performed annually worldwide (164 per 100,000 population per year). Despite successive technological improvements in implants, the usual surgical technique has changed little in 50 years. It is considered a cost-effective surgery (one of the most beneficial operations for the patient) but the number of complications and replacements related to mechanical failure is worrying. Being technique-dependent, sequelae and re-interventions due to lack of precision should be minimized.

A percentage of poor results and replacements are due to the orientation and position of components together with differences in limb length, and there is no reliable and cost-effective method to help the surgeon in real time during surgery to check that the plan is being followed. It is estimated that 50% of cups remain in unsafe margins; with 3-4% of dislocations. Dismetries greater than 1cm represent 6-7% and are poorly tolerated.

Two types of references help the surgeon:

1. the spatial references in relation to the position and restraint of the patient on the table
2. intra-operative anatomical references

We can distinguish three types of errors:

- I. by the initial positioning of the patient
- II. due to movements during surgery
- III. due to surgeon's estimation errors

The technologies developed historically have been the following: mechanical guides and calibration gauges to aid visual orientation until the 90's, when computer-guided intervention was developed, in 2010 digital inclinometers were tested and more recently customized prostheses and robotics. Direct real-time fluoroscopic (Rx) assistance is advocated by some professionals, but almost exclusively in supine and anterior approach patients (more minority).

The oblique orientation of the acetabulum means

that the surgeon must estimate 2 angles, called inclination and anteversion, during the placement of the acetabulum. Inclinometers cannot measure 2 angles simultaneously, i.e., with the patient in lateral decubitus - the most common - only the inclination can be measured and in supine decubitus only the anteversion. The surgeon needs to make adjustments to calculate the other angle, which leads to error (type III) due to estimation or parallax. This is a procedural gap not solved so far with cost-effective technologies.

In order to solve the problem of angle measurement and achieve perfect positioning of the acetabulum, the Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (Fisabio) and the Instituto de Biomecánica de Valencia (IBV) have developed a new patient positioning system that includes pelvic support devices (posterior and anterior) and a leg support. In addition, both the anterior and posterior pelvic support will have inclinometers that allow the patient's position to be known at all times.

Preclinical studies have been performed in cadaver and bone models.

With the developed system, if the surgeon prefers to operate in strict lateral decubitus (technique conventionally used by most orthopedic surgeons) he/she can do so. Or if he/she uses the innovation of the oblique position, the system is adjustable and it is possible to fix the supports in the conventional way, but with better control of the pelvis. In addition, the limb position control leg allows reliable length control references during the whole operation (dysmetries).

The present innovation in operating table instruments is aimed at solving the problems of precision in acetabular cup positioning and evaluation of limb symmetries, with the flexibility to adapt the different elements of the system to the technique.

MARKET APPLICATION SECTORS

Surgical instruments and prosthetic implants companies for orthopedic surgery.

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TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

The system has the following advantages:

- Allows digital inclinometer measurement of the 2 cup angles: inclination and anteversion (no need for readjustment in oblique position).
- The support leg allows a reliable position to measure the leg length avoiding possible asymmetries.
- Improved visualization of the cup anatomy during implantation.
- Minimal learning curve or increased surgical time.
- Universal application to different implants, approach routes and complexity of interventions.
- No irradiation, no complex equipment in the operating room is needed, no septic risks.
- Allows different positions and approach routes (usable by a variety of surgeons).
- Cost-effective.

CURRENT STATE OF DEVELOPMENT

A prototype validated with mannequins is available at the Lluís Alcanyís Hospital in Xàtiva.

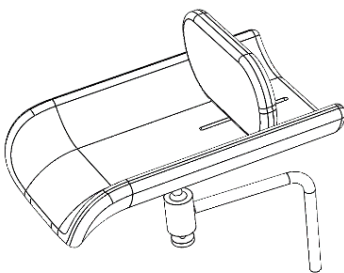
INTELLECTUAL PROPERTY RIGHTS

The device has been registered at the Spanish Patent and Trademark Office with application number U202032522 and priority date November 23, 2020.

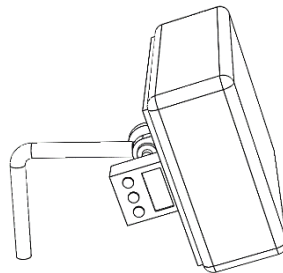
COLLABORATION SOUGHT

License agreement with companies willing to commercialize the technology..

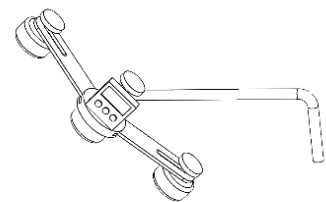
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Leg.



Lumbar back support with inclinometer.



Anterior pelvic support with inclinometer.

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