PROTOCOL- 27/02/2023

Study Title: Prospective Randomized Clinical Study to Analyze Functional, Radiological, and Strength Outcomes in Lateralized and Medialized Models of Reverse Arthroplasty.

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty.
Shoulder and Elbow Unit

INTRODUCTION

Shoulder osteoarthritis is a common and important health problem. Degenerative changes in this joint affect the tendon system of the rotator cuff, the articular cartilage of the humerus and the long tendon of the biceps and constitute one of the main causes of incapacity for work. For patients, it is a health problem comparable in their perception of illness to heart failure or diabetes.

Shoulder prosthesis, shoulder arthroplasty or prosthetic shoulder replacement is a surgical procedure in which the glenohumeral joint (the joint between the head of the humerus and the scapula) is replaced by a prosthetic implant. This procedure is indicated primarily in cases of advanced osteoarthritis or severe shoulder arthritis (as in rheumatoid arthritis) to control pain and regain lost function; and also after some proximal shoulder fractures in which surgical reconstruction is not possible. (Reverse total shoulder arthroplasty for irreparable rotator cuff tears and cuff tear arthropathy. Ramirez MA, Ramirez J, Murthi AM. Clin Sports Med. 2012 Oct;31(4):749-59. doi: 10.1016/j.csm.2012.07.009.) Review)

The anatomical shoulder prosthesis reproduces the natural anatomy of the shoulder. For proper function it requires that the tendon apparatus of the shoulder be preserved.

In the reverse shoulder prosthesis the humerus articulates over the scapular component, in this case hemispherical, in reverse of the natural arrangement of the joint. Reverse replacement allows the deltoid muscle to be used to perform shoulder function by dispensing with the tendons that constitute the rotator cuff, (Walker M1, Brooks J, Willis M, Frankle M. How reverse shoulder arthroplasty works. Relat Res. 2011 Sep;469(9):2440-51. doi: 10.1007/s11999-011-1892-0) .

It consists of several components: the humeral stem, the insert which is usually made of polyethylene and is implanted in the metaphyseal area of the humeral component,

the metaglenoid which is the component of the prosthesis that after milling the glenoid bone is implanted on the native glenoid by screwing it, and the glenosphere which would correspond to the humeral head and which in turn is fixed to the metaglenoid by means of a screw (figure 1).

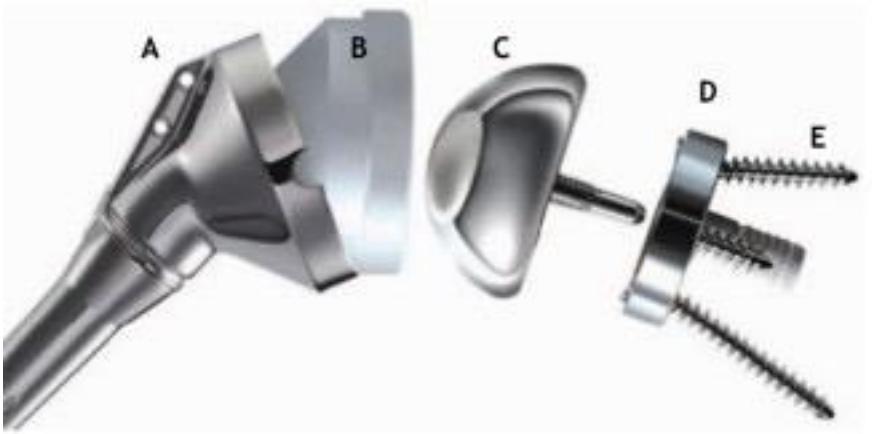

Figure 1- Components of the Reverse Arthroplasty: A: Stem, B: Insert, C: Glenosphere, D: metaglenoid, E: Screws.

This is very useful in patients who have irreparable damage to the shoulder tendons that form part of the rotator cuff, as occurs in a large part of the elderly population. Some of these patients have a serious functional alteration called "pseudoparalytic shoulder", in which they can hardly move their arm; for this situation there were no successful treatments until the appearance of the inverted prostheses.
the appearance of inverted prostheses; now, thanks to them, patients can recover adequate function in a fairly reproducible manner.

Since the appearance of the first inverted prosthesis designs, important design modifications have appeared in order to reduce or avoid complications and improve functional results (Kazley JM, Cole KP, Desai KJ, Zonshayn S, Morse AS, Banerjee S. Prostheses for reverse total shoulder arthroplasty. Expert Rev Med Devices. 2019;16(2):107-118. doi:10.1080/17434440.2019.1568237),

Similarly, the expansion of its indications (initially only used in rotator cuff arthropathies as etiology and later its use was extended to other etiologies such as

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit
massive ruptures, primary glenohumeral arthrosis, fractures or tumors) has influenced the emergence of different prosthetic models.

Currently we can classify the inverted arthroplasty according to the characteristics of the components (glenosphere, humeral component or both).

Glenospheres with a center of rotation (CoR) of 5 mm or less laterality with respect to the glenoid surface are considered medialized models (MG) and a glenosphere with a CoR >5 mm is considered a lateralized model (Figure 1). For a typical glenosphere and metaglenoid configuration, the position of the center of rotation is determined by the spherical radius and the thickness of the glenosphere, where the difference between the glenosphere thickness and the glenosphere radius determines the magnitude of the magnitude of CoR lateralization.
Designs with medialized glenospheres have a medialized center of rotation relative to the center of rotation of the native joint, which increases the abduction moment of the deltoid (its lever arm) theoretically requiring less force to elevate the arm (Terrier A, Reist A, Merlini F, Farron A. Simulated joint and muscle forces in reversed and anatomic shoulder prostheses. J Bone Joint Surg Br. 2008 Jun;90(6):751-6) (Ackland DC, Roshan-Zamir S, Richardson M, Pandy MG. Moment arms of the shoulder musculature after reverse total shoulder arthroplasty. J Bone Joint Surg Am. 2010 May;92(5):1221-30) (Henninger HB, Barg A, Anderson AE, et al. Effect of lateral offset center of rotation in reverse total shoulder arthroplasty: a biomechanical study. J Shoulder Elbow Surg. 2012 Sep;21(9):1128-35). (Hamilton MA, Roche CP, Diep P, et al. Effect of prosthesis design on muscle length and moment arms in reverse total shoulder arthroplasty.. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S31-5) (Hamilton MA, Diep P, Roche C, et al. Effect of reverse shoulder design philosophy on muscle moment arms. J Orthop Res. 2015 Apr;33(4):605-13) (Roche C, Crosby L. Kinematics and biomechanics of reverse total shoulder arthroplasty. In: Nicholson GP (ed): Orthopaedic Knowledge Update: Shoulder and Elbow. Rosemont, IL: American Academy of Orthopaedic Surgeons 2013, pp. 45-54) (Roche C, Hansen M, Flurin PH, et al. Biomechanical Summary of Reverse Shoulder Arthroplasty. Animation.AAOS Orthopaedic Video Theater. OVT-34. 2015. Available at: http://orthoportal.aaos.org/emedia/abstract).

However, medialized models shorten the residual rotator cuff which theoretically may affect the improvement in internal and external rotations if no action is taken on the

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit
humeral side. (Roche CP, Hamilton MA, Diep P, et al. Design rationale for a posterior/superior offset reverse shoulder prosthesis. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S18-24) (Hamilton MA, Roche CP, Diep P, et al. Effect of prosthesis design on muscle length and moment arms in reverse total shoulder arthroplasty. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S31-5). Roche CP, Diep P, Hamilton M, et al. Impact of inferior glenoid tilt, humeral retroversion, bone grafting, and design parameters on muscle length and deltoid wrapping in reverse shoulder arthroplasty. Bull Hosp Jt Dis (2013). 2013;71(4):284-93. Herrmann S, König C, Heller M, et al. Reverse shoulder arthroplasty leads to significant biomechanical changes in the remaining rotator cuff. J Orthop Surg Res. 2011 Aug 16;6:42).

Additionally, medialized prostheses have less deltoid wrapping effect which decreases the horizontal compression stabilizing forces increasing the risk of dislocation (Roche et al) if no action is taken on the humeral side. Finally, these medialized models have also been associated with more scapular erosion (escapula (notching) Sirveaux F, Favard L, Oudet D, et al. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. J Bone Joint Surg Br. 2004 Apr;86(3):388---95) (Werner C, Steinmann PA, Gilbart M, Gerber C. Treatment of painful pseudoparesis due to irreparable rotator cuff dysfunction with the Delta III reverse ball and socket total shoulder prosthesis. J Bone Joint Surg Am. 2005 Jul;87(7):1476---86) (Boileau P, Watkinson D, Hatzidakis AM, Hovorka I. The Grammont reverse shoulder prosthesis: results in cuff tear arthritis, fracture sequelae, and revision arthroplasty. J Shoulder Elbow Surg. 2006 Sep--- Oct;15(5):527---40. Stechel A, Fuhrmann U, Irlenbusch L, et al. Reversed shoulder arthroplasty in cuff tear arthritis, fracture sequelae, and revisión arthroplasty. Acta Orthop. 2010 Jun;81(3):367-72.

However, medialized models also have their advantages. Theoretically the forces to which the gleno-metaglenoid interface is subjected are lower which would decrease the risk of disimplantation by improving the initial fixation (Roche CP, Stroud NJ, Flurin PH, et al Reverse shoulder glenoid baseplate fixation: a comparison of flat---back versus curved-back designs and oval versus circular designs with 2 different offset glenospheres. J Shoulder Elbow Surg. 2014 Sep;23(9):1388-94) (Stroud N, DiPaola MJ, Flurin PH, Roche CP. Reverse shoulder glenoid loosening: an evaluation of the initial fixation associated with six different reverse shoulder designs. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S12-7)

Lateralized models, although so named because their CoR is more lateral than that of medialized models, are also medialized with respect to the anatomical situation. But as the thickness of the glenosphere is at least 5 mm more than its spherical radius, the

center of rotation is lateral to the glenoid surface. This lateral displacement would decrease the deltoid abduction moment relative to medialized designs but would be superior relative to the anatomic situation (Henninger HB, Barg A, Anderson AE, et al. Effect of lateral offset center of rotation in reverse total shoulder arthroplasty: a biomechanical study. J Shoulder Elbow Surg. 2012 Sep;21(9):1128-35) (Hamilton MA, Roche CP, Diep P, et al.

Effect of prosthesis design on muscle length and moment arms in reverse total shoulder arthroplasty. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S31-5). For this reason lateralized designs are associated with less efficient of the deltoid than medialized ones being the force required by the deltoid to elevate the arm greater with a lateralized model than a medialized model which theoretically could have implications on the maximal range of motion achieved postoperatively, in achieving stable fixation to the glenoid, and in the rate of acromion stress fractures (due to shear forces generated by the deltoid) (Henninger HB, Barg A, Anderson AE, et al. Effect of lateral offset center of rotation in reverse total shoulder arthroplasty: a biomechanical study. J Shoulder Elbow Surg. 2012 Sep;21(9):1128- 35) (Hamilton MA, Roche CP, Diep P, et al. Effect of prosthesis design on muscle length and moment arms in reverse total shoulder arthroplasty. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S31-5)(Levy JC, Anderson C, Samson A. Classification of postoperative acromial fractures following reverse shoulder arthroplasty. J Bone Joint Surg Am. 2013 Aug 7;95(15):e104). However, the lateralized models do stress the residual rotator cuff better, which theoretically improves internal and external rotations with respect to medialized models that do not act at the humeral level (Roche et al).

Lateralized designs also increase the deltoid wraparound effect relative to lateralized designs which increases horizontal compression forces increasing prosthetic stability (Roche et al). Finally, these designs appear to have lower rates of scapular notching.

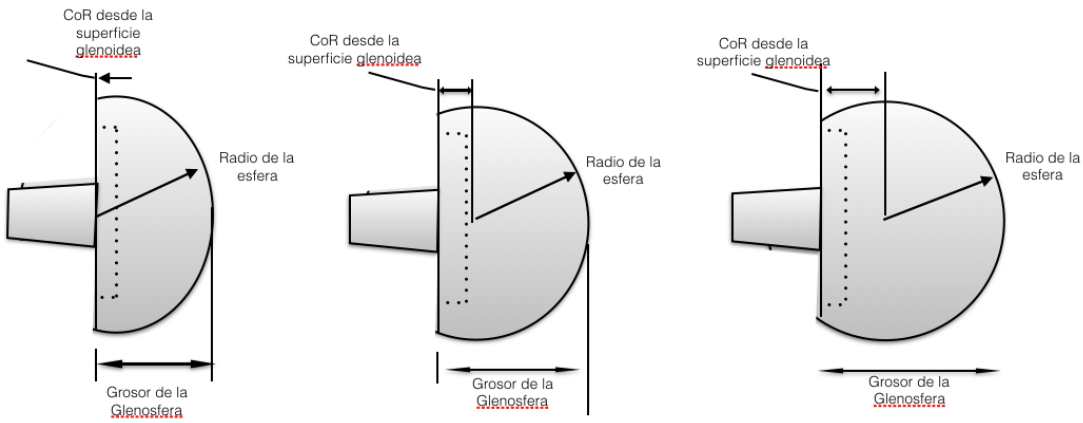

Figure 1- Medialized and lateralized glenospheres. Source: Own elaboration

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit

For the humeral component, each prosthetic model also presents variations in its characteristics. For its understanding, it is necessary to define the concept of humeral offset, which refers to the horizontal distance between the intramedullary canal and the humeral stem axis at the center of the insert. In turn, the metaphyseal component of the prosthesis can be sunk in the bone (Onlay prosthesis or on the Inlay bone) - Figure 2.

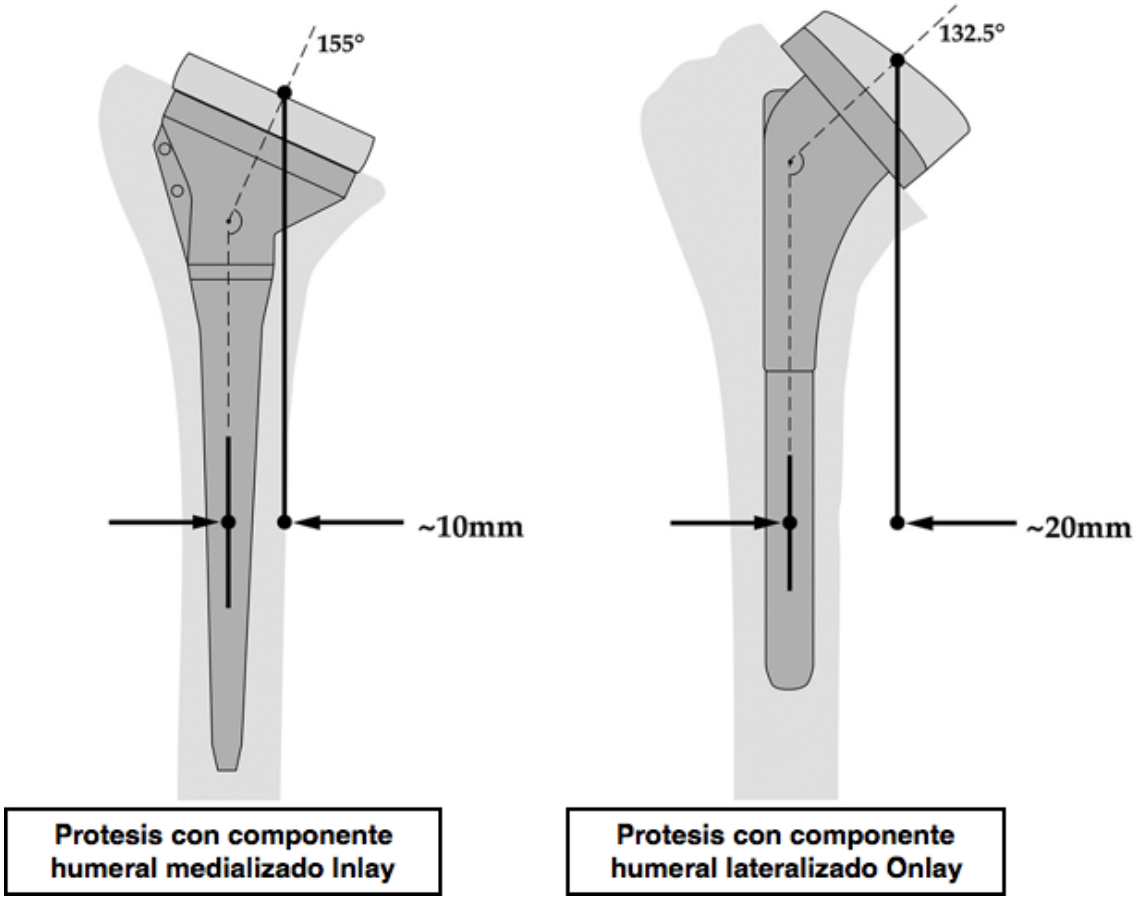

Figure 2. Medialization and lateralization of the humeral component with Inlay and Onlay humeral component respectively.

A humeral component with an offset of 15 mm or less is considered a medialized humerus and one with an offset greater than 15 mm is considered lateralized. The offset determines the amount of lateralization of the humerus and is influenced by the cervico-diaphyseal angle. The humeral osteotomy, and the use of stems with the proximal part sunk or not in the bone, when not sunk the tray that rests on the superior humeral cortex can be lateralized or not.

The medialized designs are traditionally Inlay (i.e. sunken proximal part) and with a non-anatomic 155º osteotomy. Doing so distalizes the humerus in relation to its anatomical situation and increases the tension on the deltoid. With these medialized humerus designs, the deltoid is lengthened, the enveloping effect of the deltoid is diminished and therefore the compressive forces are reduced. This results in little

improvement in the deltoid lever arm. In addition, the medialization of the humerus also moves the residual rotator cuff insertion, shortening its length, which can have its length, which can have negative implications for rotations.
Lateralized humeral designs are generally Onlay to position the tray and polyethylene over the anatomical cut of the osteotomy which distalizes the humerus increasing tension on the deltoid. However, the implantation of the tray over the anatomical cut of the osteotomy brings the humerus into a more lateral position than medialized humeral implants but still medial to the normal anatomical situation, resulting in a greater deltoid wrapping effect, greater rotator cuff tightness and lengthening of the deltoid lever arm (Hamilton MA, Roche CP, Diep P, et al. Effect of prosthesis design on muscle length and moment arms in reverse total shoulder arthroplasty. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S31-5) (Roche C, Crosby L. Kinematics and biomechanics of reverse total shoulder arthroplasty. In: Nicholson GP (ed): Orthopaedic Knowledge Update: Shoulder and Elbow. Rosemont, IL: American Academy of Orthpaedic Surgeons 2013, pp. 45-54) (Roche C, Hansen M, Flurin PH, et al. Biomechanical Summary of Reverse Shoulder Arthroplasty. Animation. AAOS Orthopaedic Video Theater. OVT-34. 2015. Available at: http://orthoportal.aaos.org/emedia/abstract.aspx?resource=EMEDIA_OSVL_15_34) (Roche CP, Diep P, Hamilton M, et al. Impact of inferior glenoid tilt, humeral retroversion, bone grafting, and design parameters on muscle length and deltoid wrapping reverse shoulder arthroplasty. Bull Hosp Jt Dis (2013). 2013;71(4):284-93) (Herrmann S, König C, Heller M, et al. Reverse shoulder arthroplasty leads to significant biomechanical changes in the remaining rotator cuff. J Orthop Surg Res. 2011 Aug 16;6:42.) (Boileau P, Watkinson DJ, Hatzidakis AM, Balg F. Grammont reverse prosthesis: design, rationale, and biomechanics. J Shoulder Elbow Surg. 2005 Jan- Feb;14(1 Suppl S):147S- 161S).

Finally, both components can be combined, although understanding the influence of each component on the biomechanical behavior of the reverse arthroplasty is important, the impact of the combination of both is essential. The combination of humeral components and medialized glenospheres accentuates all the negative aspects of medialization and forces subscapularis tendon repair for maintenance of prosthetic stability. (Edwards TB, Williams MD, Labriola JE, et al. Subscapularis insufficiency and the risk of shoulder dislocation after reverse shoulder arthroplasty. J Shoulder Elbow Surg. 2009 Nov- Dec;18(6):892-6) (Routman HD. The role of subscapularis repair in reverse total shoulder arthroplasty. Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:108-12). The medialized models also in the case of native glenoid erosion due to existing pathology cannot correct the existing deformity requiring bone grafts to lateralize the glenosphere.

When we lateralize the glenosphere and leave the humeral component medialized, the deltoid wrapping effect improves, improves the recruitment of the residual rotators and improves the stability of the implant, and the repair of the subscapularis tendon

can be dispensed with. However, the deltoid lever arm is less than when the glenosphere is medialized and the humeral component lateralized due to the greater lateralization of the center of rotation. (Henninger HB, Barg A, Anderson AE, et al. Effect of lateral offset center of rotation in reverse total shoulder arthroplasty: a biomechanical study. J Shoulder Elbow Surg. 2012 Sep;21(9):1128- 35) (Hamilton MA, Roche CP, Diep P, et al. Effect of prosthesis design on muscle length and moment arms in reverse total shoulder arthroplasty.

Bull Hosp Jt Dis (2013). 2013;71 Suppl 2:S31-5) (Langohr GD, Giles JW, Athwal GS, Johnson JA. The effect of glenosphere diameter in reverse shoulder arthroplasty on muscle force, joint load, and range of motion. J Shoulder Elbow Surg. 2015 Jun;24(6):972-9) (Hamilton MA, Diep P, Roche C, et al. Effect of reverse shoulder design philosophy on muscle moment arms. J Orthop Res. 2015 Apr;33(4):605-13) (Roche C, Crosby L. Kinematics and biomechanics of reverse total shoulder arthroplasty. In: Nicholson GP (ed): Orthopaedic Knowledge Update: Shoulder and Elbow. Rosemont, IL: American Academy of Orthpaedic Surgeons 2013, pp. 45-54) (Roche C, Hansen M, Flurin PH, et al. Biomechanical Summary of Reverse Shoulder Arthroplasty. Animation. AAOS Orthopaedic Video Theater. OVT-34. 2015. Available at: http://orthoportal.aaos.org/emedia/abstract.aspx?resource=EMEDIA_OSVL_15_34) A medialized Glenosphere and a lateralized Humerus lateralized humerus can enhance the more lateral position of the humerus to compensate for the medialization of the joint interlining caused by a thin glenosphere, further stressing the residual cuff, better restoring the deltoid wrapping effect and also increasing the lever arm of the deltoid. Additionally, this configuration would decrease scapular notching with respect to fully medialized models. Finally, there is the possibility of lateralizing both components. This configuration would theoretically further enhance the deltoid wrapping effect and residual rotator recruitment.

JUSTIFICATION

Inverted arthroplasty began to be used at the Hospital Clínico San Carlos in 2008. The model used since then has been a model with medialization of the center of rotation. In the last year a new implant with lateralization of the center of rotation has been introduced and approved by the center for the same indications. The learning curve for the implantation of a reverse arthroplasty has been estimated at 7 cases for one shoulder surgeon (Wierks C et al Reverse shoulder replacement: intraoperative and early postoperative complications. Clin Orthop Relat Res. 2009 Jan;467 (1):225-34) and is therefore considered outdated given that 12 such arthroplasties have been performed.

The absence of prospective randomized clinical studies that compare models with medialization of the center of rotation with those with lateralization of the center of rotation has led us to propose the present study in order to determine if there are differences in relation to function or strength between the two implants.

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit

THEORETICAL BASIS

As explained in the introduction, several biomechanical studies have analyzed theoretically the function and possible functional repercussions of each prosthetic model (medialized vs. lateralized). There are studies that publish the functional results of each prosthetic model separately. However, there are no prospective randomized clinical studies that analyze the functional outcomes (range of motion and strength) and complications with each type of implant in a homogeneous population. Determining whether the type of implant has any influence on these outcomes is essential to maximize functionality and decrease the number of complications, which would additionally imply a decrease in health and social costs for the patient. Therefore, our null hypothesis is that the use of implants with lateralization of the center of rotation does not offer superior clinical results compared to the use of medialized implants. medialized implants. The alternative hypothesis is that the use of lateralized implants offers superior clinical results compared to medialized implants.

OBJECTIVE

The objective of this study is to determine the functional results (range of motion) and strength as well as the percentage of complications that appear with the use of two inverted arthroplasty systems (one medialized and the other lateralized).

In the treatment of rotator cuff arthropathies or irreparable cuff tears.

INCLUSION CRITERIA

The inclusion criteria are as follows:

-Male or female patients over 65 years of age with rotator cuff arthropathy refractory to conservative treatment after six months.

-Ability to understand the Information Sheet, the Informed Consent and the evaluation scales.

EXCLUSION CRITERIA

The following will be excluded from the present study:

-Patients who do not grant their Consent.

-Patients with sequelae of fractures, rheumatoid arthritis, avascular necrosis, previous infectious processes, primary glenohumeral arthrosis, revision surgeries that have required conversion to an ITHA.

-Patients in whom another surgical procedure has been associated with ITHA, such as tendon transfer.

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit

-Glenoid bone defects in the horizontal plane (types B2 and C of Walch's classification Walch G, Badet R, Boulahia A, Khoury A. Morphologic study of the glenoid in primary glenohumeral osteoarthritis. J Arthroplasty 1999; 14:756-60)

-In the horizontal plane (types B2 and C of the Walch classification Walch G, Badet R, Boulahia A, Khoury A. Morphologic study of the glenoid in primary glenohumeral osteoarthritis. J Arthroplasty 1999; 14:756-60) or in the vertical plane (Sirveaux stages E3) Sirveaux F, Favard L, Oudet D, Huquet D, Walch G, Mol_e D. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. Results of a multicentre study of 80 shoulders. J Bone Joint Surg Br 2004;86: 388-95) requiring bone supplementation or augmented metaglens.

-Patients who have previously undergone surgery on the affected limb.

-Inability to understand the information sheet, informed consent, and
The evaluation scales.

WITHDRAWAL CRITERIA

Patients will be withdrawn if, after having accepted the consent, they freely decide to abandon the study or if they present an adverse event.
adverse event.

PRIMARY AND SECONDARY VARIABLES

The primary objective will be to compare functional outcomes (Constant scale score) 24 months after surgery in patients over 65 years of age with cuff arthropathies treated with either of the two options: medialized ITHA or lateralized ITHA, then the results obtained on the Constant scale at 24 m will be the variable of choice.

Constant scale at 24 m will be the primary variable. Secondary variables will include: visual analogue pain scale (VAS) and Quick-DASH and ASES questionnaires for functionality, range of motion, strength.

METHODOLOGY AND STATISTICAL ANALYSIS

This is an experimental, prospective, prospective, unblinded, randomized, comparative clinical trial between patients with two types of prosthetic implants (inverted arthroplasty with medialized center of rotation vs inverted arthroplasty with lateralized center of rotation). Those male or female patients who meet the inclusion criteria will be selected to form part of one of the two randomly distributed study groups.

Sample size

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit
Based on studies with similar characteristics but where lateralization is not performed with the implant but with a bone graft (Greiner S, Schmidt C, Herrmann S, Pauly S, Perka C. Clinical performance of lateralized versus non-lateralized reverse shoulder arthroplasty: a prospective randomized study. J Shoulder Elbow Surg. 2015 Sep;24(9):1397-404. doi: 10.1016/j.jse.2015.05.041. Epub 2015 Jul 7. PMID: 26163281) a sample size of 34 patients (17 in each group) assuming a 20% loss rate with a Type I error of 0.05 and a statistical power of 80% would be needed to show a 10-point difference on the Constant scale (the minimum difference
clinically important difference on the Constant scale for reverse arthroplasty is described as 8 points in previous comparative studies, so we consider the detection of a difference of 10 to be sufficient Torrens C, Guirro P, Santana F. The minimal clinically important difference for function and strength in patients undergoing reverse shoulder arthroplasty is described as 8 points in previous comparative studies.
undergoing reverse shoulder arthroplasty. J Shoulder Elbow Surg 2016;25:262-8. https:// doi.org/10.1016/j.jse.2015.07.020) the final n needed would be 42 patients (21 per group).

A randomization of patients will be performed to assign them to one or the other study group, which will be carried out by an independent assistant, who will generate a random sequence that will be unknown to the investigators. Each patient will be given a sealed and numbered envelope to choose from, in which the randomized group in which he/she has been included will be determined. The study will be blinded for the patient and rehabilitator but not for the surgeon.

Statistical analysis

A descriptive analysis of the variables under study will be performed. The description of quantitative variables such as age, Charlson comorbidity index, questionnaires for the assessment of functionality (Constant, Quick-DASH, ASES), VAS and RHB sessions, will be carried out using the mean and standard deviation.

Categorical variables such as affected and dominant limb or satisfaction will be described by frequency and percentage. The normality of the available data will be checked using the Kolmogorov-Smirnov test.

To determine that both groups are similar, the Student's t-test will be used for continuous variables such as age, Charlson index and RHB sessions, while for categorical variables (dominant and affected limb and sex) the Pearson's chi-square test or Fisher's exact test will be used, depending on the characteristics of the variables.

Once the characteristics of the groups have been described, comparisons will be made between the two interventions (medialized IHTA and lateralized IHTA) in the main study variables. To determine whether there are statistically significant differences in

the Constant scale at 24 months between the two procedures, a general linear model will be performed. The same analysis will be used with the quick-DASH and ASES questionnaire.

For the analysis of strength during movement, VAS, as well as the rest of the questionnaires (including the standardized or age- and sex-adjusted Constant and the subsections of this questionnaire) at the different evaluation times of the study (1, 3, 6, 12, 18 and 24 months), the Student's t-test will be used. To compare the complications that occurred in both groups, Pearson's Chi-squared test will be used. Similarly, Pearson's Chi-square test will be used to compare satisfaction with what happened in each group.

Finally, to establish the existence of a relationship between Constant and normalized Constant and patient satisfaction, Pearson's correlation will be used. The results of the statistical tests will be given with a confidence level of 95%; that is, statistical significance will be set at 0.05. The statistical study will be performed using the IBM SPSS program (v.25).

PROCEDURE
Visit 1: Attention at the HCSC Shoulder and Elbow Surgery Unit.
After an appropriate medical evaluation and physical examination, and having been diagnosed with rotator cuff arthropathy with the relevant complementary tests, the physician will evaluate whether the patient meets the inclusion criteria to be part of the present study. If so, he/she will explain in detail what the study consists of, in addition to handing him/her the Information Sheet and the Informed Consent Form, which he/she will read. Informed Consent, which will be read carefully and attentively. Once understood, and in case of accepting and signing the consent, the patient will be part of the study.

After being included in the surgical waiting list, the patient will be randomized to one of the two study groups: Group 1 treatment by means of inverted arthroplasty with medialized COR; Group 2 treatment by means of inverted arthroplasty with lateralized COR. Subsequently, the patient will be given the aforementioned functional assessment scales and the joint range of motion (ROM) will be measured using a manual goniometer.

Visit 2: Group 1 and 2. Admission and immediate postoperative period.
The patient will be admitted to undergo reconstructive surgery of the arthropathy, by means of one of the two mentioned Inverted Arthroplasty implants. The implants used will be registered, always following the same surgical technique with the same protocol (position, anesthesia, antibiotic prophylaxis...) and by one of the three surgeons of the shoulder unit, being always at least two of them present. Complications occurring during surgery or in the immediate postoperative period will be recorded. During admission, before hospital discharge, a hemogram will be obtained to assess the patient's anemization.

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit
to evaluate the patient's anemization and a three-plane X-ray of the shoulder as the first post-surgical control. If required, all the tests necessary for an integral medical evaluation will be performed. After the operation, patients will be immobilized and will start passive exercises after 24/48 hours assisted by a physiotherapist.

Visit 3 : Group 1 and 2. Three weeks.
Three weeks after surgery, new X-rays will be taken in three planes and referral to the Rehabilitation Center to begin active mobility, strengthening and gaining joint balance.

Visits 4, 5, 6 and 7: Groups 1 and 2. Three, Six, Twelve and 24 months after surgery.
Radiographic evaluation at each visit including the same three projections.
Clinical evaluation by means of the above mentioned scales and measurement of the BA to assess the functionality of the shoulder.

Finally in this phase, at the end of the follow-up of both groups (24 months), a cost analysis is performed by measuring direct costs (hospital stay, operating room costs, imaging tests, outpatient consultations, physiotherapy sessions, emergency visits, transport, medication consumption, etc.), medication consumption...) and indirect costs (need for home help, family leave...) and an isokinetic study of the shoulder (strength and mobility).

• PERIOD OF STUDY

PERIOD OF STUDY								
	Recruitment:	Randomization	Post-randomization					Closure
Starting point	-1	0	0w	1 W	1 M	6M	12 M	24 M
Recruitment:								
SelectionPatients	X							
Informed consent	X							
Randomization		x						
Interventions								
Lateralized RSA			X					
Medialized RSA			X					
AssessmentDemographic and epidemiological data, Constant, ASES, Quick Dash, VAS, RAM, Strength, Radiological		X						
			X					

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit

Adverse events		x	x	x	x	x	x	x

Study protocol. Diagram according to recommendations for intervention studies (SPIRIT).

ETHICAL ASSURANCE. RISKS AND BENEFITS.

The surgical procedure, follow-up and treatment of the patients operated by inverted arthroplasty with any of the two implants will be done in the same way as it is currently done in patients treated with these prosthetic systems and who are not included in any study.

Participation in this study does NOT carry any additional risk to the risks inherent to the operation to which the patient will be subjected. These risks inherent to the operation and which are NOT derived from the study are duly included in the Informed Consent for Surgical Intervention.

The participation of the patients in the study does NOT imply any additional cost (neither for the institution nor for the patient) directly related to the participation in the study. All procedures performed on patients participating in the study are those routinely performed on all patients treated by the shoulder unit in whom a reverse prosthesis has been implanted.

The procedure to be adopted to protect the identity and confidentiality of the data generated by the research complies with the Organic Law on Personal Data Protection (Law 3/2018). All data will be collected confidentially after assignment of a file number, avoiding nominal identification, with health labels and even initials. No patient will be personally identified in any report or publication resulting from this study. The study protocol proposed to you has been drafted in accordance with the Standards of Good with the European Union Standards of Good Clinical Practice and the current revision of the Helsinski Declaration.

INFORMATION TO PARTICIPANTS TITLE OF THE STUDY
INTRODUCTION

Dear Mr./Ms.,
You have been asked to take part in this study on a voluntary basis because the study doctor believes you are eligible for the study. To decide whether or not you want to participate in the research, you need to understand the study to make an informed

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit
decision. This document describes the purpose, procedures, and possible benefits and risks of the study, if any.

It also records how your health information will be used and who can access it. Your decision to participate in the study is voluntary. You are free to decide whether or not you want to participate in the study, knowing that your decision will not affect the medical care you will receive. Please read these pages carefully and take the time to decide whether you wish to participate; Feel free to ask any questions, or request an explanation or clarification at
respect.

Clinical studies allow to verify and collect more new clinical and radiographic data on specific orthopedic implants in a given population.

OBJECTIVE OF THE STUDY

The objective of this study is to compare the functional outcomes (joint range of motion and strength) of two models of inverted prosthesis. The inverted shoulder prosthesis that is the prosthesis that is going to be implanted for you due to the pathology you have in your rotator cuff can work from a biomechanical point of view in two different ways (with medialization or lateralization).
of the center of rotation of the prosthesis) which translates into two different prosthetic models. There are biomechanical studies that compare strength and function with each of these models in the scientific literature without obtaining clear Conclusions regarding the superiority of one implant or another, but there are no clinical studies (conducted in patients). Both prosthetic models are
used by the surgeons of the Shoulder and Elbow Surgery Unit for the treatment of their pathology. However, for a study to have scientific validity and we know if there are true clinical differences, the treatment must be randomized and the choice of implant must not be subject to other criteria (availability, sterilization,...).

The present study does not interfere with the decision to treat your condition, which will be evaluated by the study doctor who follows the study, based on the clinical picture you have. It also does not interfere with the type of evaluation of routine diagnostic tests, nor with the follow-up to which you will be subjected. The inclusion in one or the other treatment group (medialized or lateralized inverted prosthesis) will be carried out randomly, knowing that each
One of them has demonstrated satisfactory clinical and radiographic results separately in previous and independent studies, and that they are widely valid options for the treatment of your pathology.

WHAT PARTICIPATION IN THE STUDY ENTAILS?

Your participation is entirely voluntary and, if you wish to participate, you will be asked to sign the attached document called "Patient Informed Consent Module".

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit
The study doctor will explain this procedure in detail and answer all of your questions. To develop this study, the collaboration and availability of people who, like you, meet the clinical-scientific requirements corresponding to the evaluation to be carried out are necessary. For this reason, we propose you to participate in this study. This study will be conducted at the Hospital Clínico San Carlos,
and will involve patients who have rotator cuff arthropathy of the shoulder and who require reverse arthroplasty.

The study will last 24 months, and will include all patients who, like you, voluntarily agree to be part of it because they meet the above criteria. 7 control visits are planned. We will count the first visit as the one in which your participation in the study is proposed and after its acceptance the informed consent is signed. Randomization will be performed at this time.

Subsequently, after the intervention, the same revisions will be carried out as any patient operated on for inverted arthroplasty due to arthropathy at 1,3,6,12, 24 months in accordance with the usual clinical practice of the center for this type of pathology. During this period of time at each visit the joint range of motion of your shoulder will be recorded and you will be asked a series of questions related to the functional assessment scales commonly used in the assessment of shoulder function. At the end of the monitoring period, a measurement of the force during movement will be made.

PARTICULAR BENEFITS OF PARTICIPATION IN THE STUDY
The patient will not derive any benefit from participation in the study. The collection of clinical data in the course of the study will contribute greatly to increasing scientific clinical information in the orthopedic field.

POTENTIAL RISKS OF STUDY PARTICIPATION
Participation in this observational study implies accepting the potential risks inherent in the surgery to which you will be subjected regardless of the study group to which you are assigned.

There are foreseeable risks associated with any surgical intervention in which an inverted arthroplasty is implanted that are independent of the present study as well as the use of one or another prosthetic model and that have had to be explained independently and accepted by you in an independent informed consent where the possible benefits and risks of the intervention in particular are exposed.

WITHDRAWAL OF CONSENT
Your participation in the study is completely free and entirely voluntary and you may withdraw at any time without prior notice and without obligation to justify your decision. This will in no way affect the quality of medical care you will receive subsequently.

If you decide to stop participating in the study, you should tell your study doctor immediately. From the communication of your withdrawal, no data will be collected about you for this study.

CONFIDENTIALITY

All data relating to you and your health collected during the course of the study will only be used for the realization of the study and other possible future studies related to your pathology and that are previously approved by a Research Ethics Committee. Your data will be handled under the strictest confidentiality: your name and personal health information will be replaced by a code so that they cannot identify you; The only person who will have access to the code key is the study's principal investigator. The person responsible for the processing of your data is the Center, which will keep all the necessary security measures for the protection of your data. In accordance with Organic Law 3/2018, on the Protection of

Personal Data and guarantee of digital rights, you may withdraw the consent given and no new data will be added to the database, but those that have already been previously obtained will be used. You can ask at any time what data is being saved (right of access), who owns them
use and for what purpose; request a copy of the personal data provided by you to transmit to other persons (portability). In addition, you can correct personal data and limit the use of data that are incorrect (right of rectification and erasure), as well as oppose the use of your personal data or restrict it (right to object). To exercise your rights, please contact the principal investigator of the study.
You also have the right to contact the Data Protection Agency if you are not satisfied.

CONSENT TO STUDY PARTICIPATION

I, the undersigned

_____nacido/a_____.el_____
__

Declare

1. that I voluntarily participate in the aforementioned study;
2. have received from the study physician, Dr. ___
3. Have received a written document, attached to this act, called information sheet for the patient, in which the technical-scientific information about the activity and scope of the study is provided, apart from the risks that it may entail.

4. have had sufficient time available to be able to read carefully, understand and possibly have an explanation of what is contained in the attached information sheet, which I have signed by way of acknowledgment and which confirms everything that has been explained to me orally, in particular that the study will be carried out in compliance with international codes of ethics;

Prospective randomized clinical study to analyze the functional, radiological and strength results in lateralized and medialized models of reverse shoulder arthroplasty. Shoulder and Elbow Unit
5. have had the opportunity to ask questions and get answers
satisfactory on the study and, in particular, on possible diagnostic and therapeutic alternatives and on the consequences of non-compliance with the proposed procedure.

6. Understand that my participation is completely voluntary and that I can withdraw at any time, without negative consequences or disadvantages and without having to explain my reasons. In case of withdrawal, I consent to the processing of my clinical data collected in the field of the study.

7. Allow the anonymous processing of clinical data (related to date of birth, gender and/or identification code number, if applicable). This data can:
a. stored and processed electronically for the purposes of scientific evaluation
b. be sent to the competent authorities for registration and/or publication.

8. Allow the supervisor, audit and competent regulatory authorities to have direct access to my clinical documentation, for the purposes of supervision and verification.

9. that I have been assured that the medical record will remain strictly confidential and that the data will be used for the purposes indicated in the study; that it is my right to have access to the documentation that corresponds to me and to the express evaluation of the Ethics Committee; that I will be informed of any new data that may affect the risks or benefits, or simply of variations of the protocol that may affect them, that in the event of any problem or for possible subsequent information, I will be able to contact the study doctor indicated in the patient information leaflet;

10. Receive a dated and signed copy of this consent, together with a copy of the prospectus;