Biomechanical determinants of reversed total shoulder arthroplasty efficacy and safety

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" BIOMECHANICAL DETERMINANTS OF REVERSED TOTAL SHOULDER ARTHROPLASTY EFFICACY AND SAFETY "

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2. SUMMARY

Total replacement of the shoulder joint may be required in case of severe dysfunction of the glenohumeral joint. Initial implants reproducing native shoulder joint anatomy have shown limited efficacy and safety in presence of associated dysfunction of the rotator cuff. Investigation of technical solutions allowing for simultaneous replacement of glenohumeral articular surfaces and rotator cuff function has promoted alternatives to native shoulder biomechanics, leading to the development of reversed total shoulder arthroplasty (rTSA).

Evidence of efficacy of rTSA to restore shoulder function in absence of a functional rotator cuff has broadened indication for the procedure. Initially targeted at glenohumeral osteoarthritis associated with tendinous lesions of the rotator cuff, rTSA has emerged as an indication for severe fractures of the proximal humerus, irreparable tears of the rotator cuff, severe alterations of shoulder osseous anatomy and tumor surgery. Incidence of the procedure has steadily increased to become the most frequently used implant for shoulder arthroplasty.

Breaking free from the anatomy to restore shoulder function using reversed shoulder arthroplasty has opened fields of investigation in the analysis and understanding of new biomechanical parameters for arm motion. Relative limitation of range of motion by abutment of repositioned humerus against surrounding structures has shown to be a major concern regarding efficacy and safety of the procedure. Prosthetic instability has been reported to represent the main complication following rTSA. Progressive understanding of the parameters determining implant efficacy and stability have evidenced a complex interplay of implant and patient specific factors. Maximizing efficacy of procedure in term of restoration of range of motion appears to compete with safety objective of maximizing implant stability. Balance between both aspects for optimization of patient-specific procedure is reported to represent a trade-off process.

Technical advances in the fields of robotics and digital health have generated new tools for investigation of balance between efficacy and safety in rTSA. Axes of research comprise development of in vitro models recreating constrained experienced by rTSA implants in vivo, as well as tools assisting surgeons in the planification, realization and functional outcomes assessment of rTSA procedures. Implementation of those new data in the clinical management of patients is meant to allow surgeons for evidence-based optimization of procedures.

3. BACKGROUND

Modification of native shoulder biomechanics by reversed total shoulder arthroplasty (rTSA) has evolved as the favored technique for replacement of the shoulder joint [1]. Incidence is reported to have more than doubled from 2012 to 2017, reaching 19,3 cases per 100'000 persons in the USA (62'075 procedures) [2], surpassing devices reproducing native gleno-humeral anatomy: anatomical total shoulder arthroplasty (aTSA) and hemiarthroplasty (HA). Key feature of rTSA is the device's ability to compensate for insufficiency of the rotator cuff tendons [3], allowing to restore shoulder function in shoulder pathologies associated with rotator cuff disorders. Engineering of reversed shoulder arthroplasty has relied on breaking free from attempting to reproduce native anatomy [4]. Assessment of efficacy and safety of this disruptive approach represents an intensive field of investigations.

Rotator cuff musculature provides the balanced forces imparting mobility and stability of the shoulder joint [5] (Fig. 1). Disruption of these force couples impacts joint kinematics as the stable fulcrum for motion of the humeral head on the glenoid articular surface is lost, potentially leading to range of motion limitation and pain. Rotator cuff disorders represent the main etiology leading to consultation for shoulder problem [6] and represent a major socioeconomic burden.

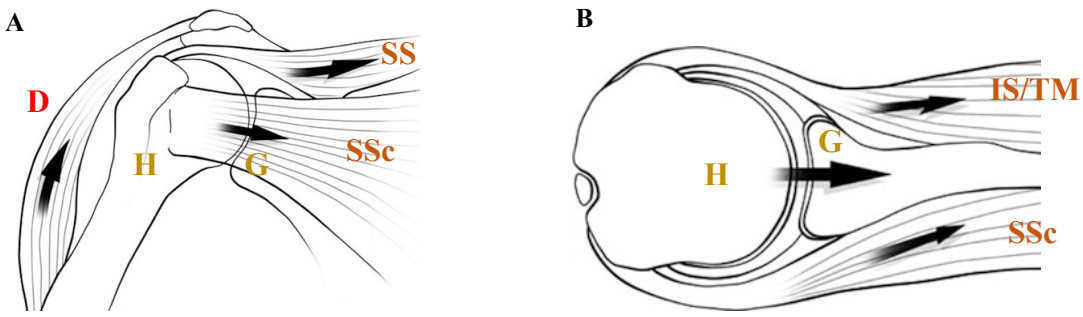

Figure 1 *Rotator cuff biomechanics, adapted from[7]*

A. *Vector lines of suspraspinatus (SS) and subscapularis muscle act synergistically with deltoid (D)* **B**. *vector line for centering of humeral head (H) onto glenoid cavity (G) during glenohumeral motion. Balance of vector line between subscapularis and infraspinatus (IS)/teres minor (TM) act as dynamic shoulder stabilizers.*

Mechanical principle of rTSA is the generation of a fixed fulcrum for glenohumeral motion by reversing morphology of the articular surfaces (Fig. 2C). Constraint of the humeral center of rotation achieved by rTSA design allows for substitution of rotator cuff tendons in conditions were recovery of rotator function is deemed unachievable. Initially developed for the management of glenohumeral osteoarthritis associated with rotator cuff lesion (rotator cuff arthropathy [8] Fig. 2B), spectrum of indications encompass severe bone alterations of the glenoid bone morphology (posterior glenoid deficiency/wear), complex fractures of the proximal humerus as well as revision arthroplasty, glenohumeral instability and tumor surgery [1].

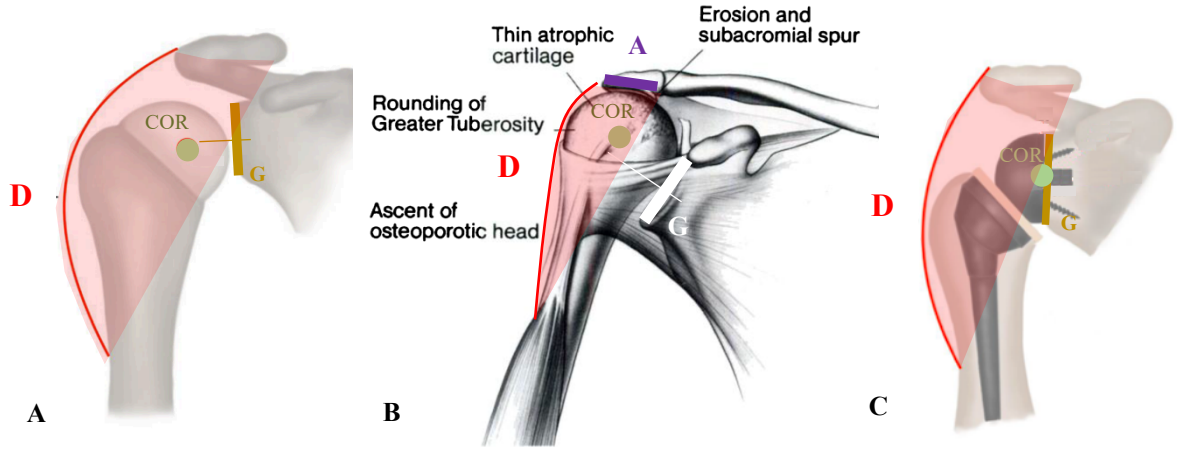

Figure 2 *Reversed Total Shoulder Arthroplasty Biomechanics, adapted from [8, 9]*

A. Native shoulder biomechanics depends on rotator cuff mediated dynamic stabilization of the joint center of rotation (COR) balancing deltoid (D) forces. **B**. Rotator cuff tear arthropathy secondary to rotator cuff dysfunction results in loss of humeral head centering relative to the glenoid articular surface (G) transferring joint loads to the inferior acromial surface (A) and leading to severe degenerative articular changes (see figure labels). **C**. Reversed Total Shoulder Arthroplasty constrains glenohumeral joint motion around a fixed, medialized, center of rotation; allowing for compensation of rotator cuff insufficiency.

Assessment of efficacy of rTSA implants relies in vitro on biomechanical determination of range of motion and in vivo on clinical measurements and scores(i.e. joint range of motion) [10]. Safety of the procedure is monitored using revision surgery as endpoint for calculation of implant survival rate [11]. Failure of implant anchorage to the scapula (glenoid lossening) has been a major concern in rTSA design [3, 4, 12, 13]. Principal complication leading to rTSA

revision surgery is represented by instability of the implant [14-16]. Further reported complications comprise failure of implant anchorage to humerus as well as fractures and nerve dysfunction related to soft tissue tension alterations with rTSA design [17].

Range of motion, tension and stability achieved following rTSA procedures may be modulated by implant design as well as positioning by the operator during surgery [3, 18, 19]. In presence of multiple implant designs (Fig. 4F), method for optimal choice of implant and positioning remains debated [1, 18]. Objective of this work is the description of biomechanical parameters of rTSA pertaining to the choice of patient specific implants in respect to efficacy and safety of the procedure.

4. REVERSED TOTAL SHOULDER ARTHROPLASTY BIOMECHANICS

4.1 Evolution of rTSA

Combined lesions of the glenohumeral joint and rotator cuff present a major therapeutic challenge in the management of shoulder disorders [3, 4, 8, 20, 21]. Necessity to compensate for loss of rotator cuff function has early led to experimenting non-anatomical designs in shoulder arthroplasty. The first documented shoulder arthroplasty was attempted by Dr J Péan on March 11th 1893 in a patient affected by destructive tuberculous abscess of the shoulder [22, 23]. Implant was composed of a constrained universal pivot joint rigidly fixed to the remaining humerus and scapula. The procedure allowed the patient to work as a waiter for two years before needing removal due to periprosthetic infection (Fig. 3A).

Sustained work on shoulder articular replacement of the humeral head later led to experimenting hemiarthoplasty implants for the management of severely displaced fractures of the humeral articular surface [24] (Fig. 3B). Evidence of limited functional outcome in the presence of rotator cuff tear insufficiency led to the development of constrained prototype implants with non-anatomical reverse ball and socket configuration (Neer Fixed Fulcrum, Fig 3C). Unacceptable rate of mechanical failure by avulsion (loosening) of the glenoid component from the scapula caused abandon of these initial reversed design [12] and redirection of research efforts toward development of unconstrained anatomical total shoulder arthroplasty (aTSA, Fig. 3D). In presence of rotator cuff insufficiency aTSA was shown to suffer from high rates of implant failures linked to asymmetric loading and glenoid implant loosening [20, 21]. In the absence of surgical alternatives, hemiarthroplasty was then the recommended treatment for

glenohumeral osteoarthritis associated with severe rotator cuff dysfunction. Without restoration of rotator cuff function, outcomes in these patients were reported to have low predictability in terms of range of motion restitution and pain relief and the term “limited goals rehabilitation” was coined to describe those procedures [8].

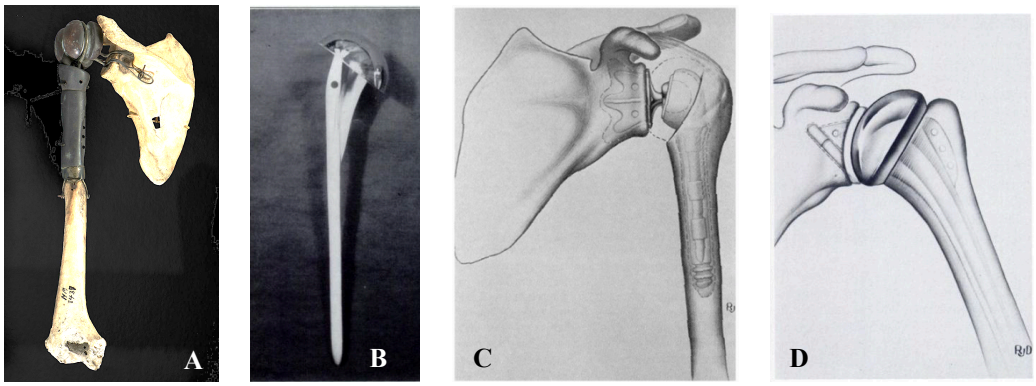

Figure 3 *Shoulder arthroplasty implants*

A. Péan prosthesis, 1893[22, 23] **B.** Neer Mark I Hemiarthroplasty, 1953[24] **C.** Neer Mark I Fixed Fulcrum prosthesis [24] **D**. Neer Total Articular Surface Replacement [24]

Further anatomical and engineering research on rotator cuff deficiency led to design and test successive prototype implants by pioneer of reversed shoulder arthroplasty, Dr Paul Grammont [25]. First generation prototypes were designed to constrain glenohumeral center of rotation retaining anatomical shoulder configuration (Fig. 4). High rate of implant failure due to loosening of glenoid and/or acromial components led to re-investigation of reversed shoulder arthroplasty design [4](Fig. 4). Key concepts to avoid mechanical failure observed in previous reversed designs was the modification of deltoid muscle balance by strengthening the abduction component and lessening the elevation component responsible for loosening stresses on the glenoid. Mechanical strategy was medialization and distalization of the glenohumeral joint center of rotation. Follow up of initial patient cohort was reported to restore functional range of motion with shoulder elevation achieving 100° to 130° and implant survival observed up to 15 years [4](Fig. 4D).

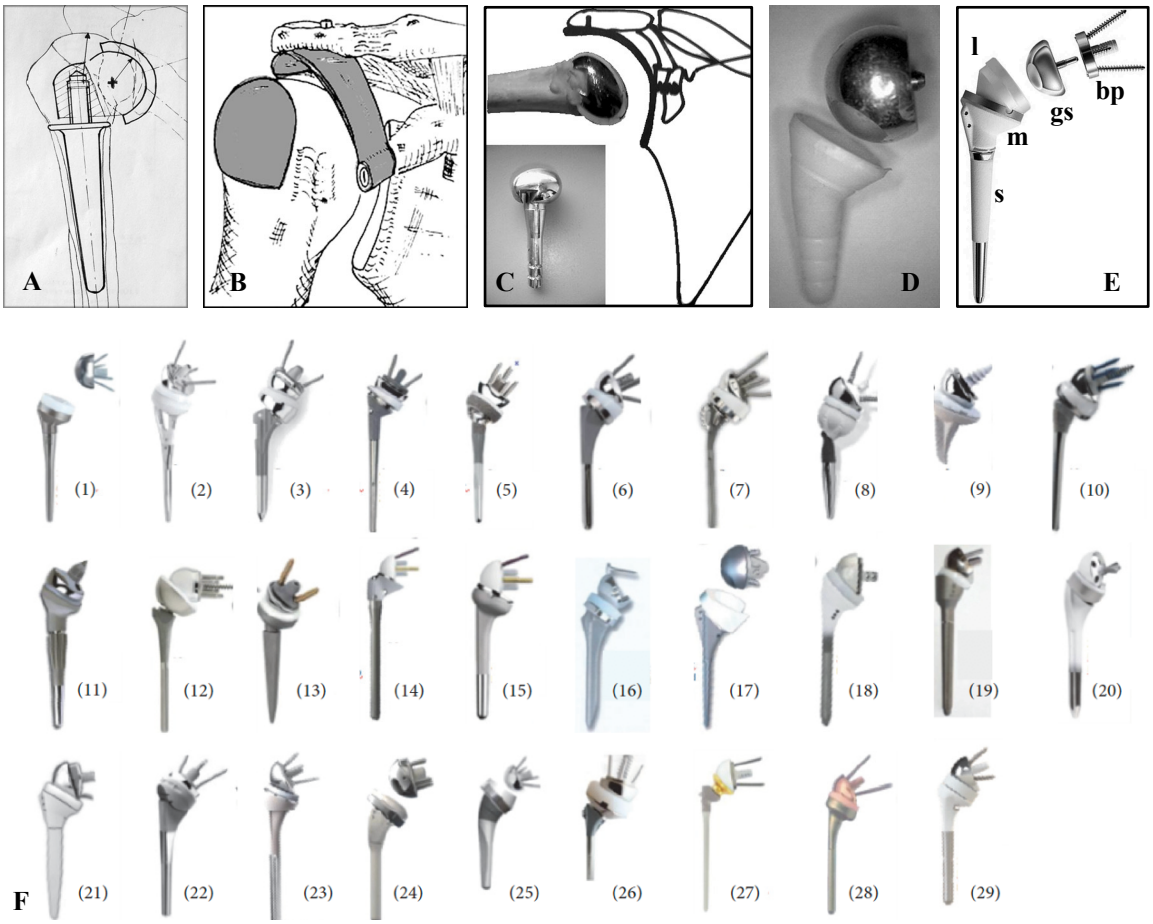

Figure 4 *Grammont reverse prosthesis evolution [3, 4]*

A. "Medializing" prosthesis prototype, standard ball and socket design **B**. "Acropole" prosthesis, acromio-humeral resurfacing design. **C**. Medinov "Ovoid" prosthesis, acromio-humeral resurfacing design. **D**. Medinov "Trompette" prosthesis, medializing reversed ball and socket design. **E**. Medinov Delta III, 1991 (Grammont) reverse prosthesis; bp - baseplate; gs - glenosphere; s - stem; m - metaphyis; l - liner. **F**. Models of commercially available rTSA [26].

First generation of marketed implants was released in 1991 (Medinov Delta III prosthesis, Fig. 4E), constituted of 5 modular components that varying in size and shape for patient specific adaption. The glenoid components (metaglene) comprise the baseplate and glenosphere, it constitutes anchorage point to scapula. The humeral components comprise the humeral stem assembled to the humeral metaphysis as well as the liner, interfacing glenoid and humeral components. Numerous models are commercially available with differences reported on the baseplate, glenospheres, liner and humeral component (Fig. 4F)

4.2 rTSA biomechanics - glenohumeral center of rotation (COR) and humeral position

Key modification of native shoulder anatomy in rTSA is relocation of the articular COR[27]. Various methods to estimate joint COR are reported in the literature with no agreement on the best suited methodology for the glenohumeral joint [28, 29]. For radiographic analysis purposes, musculoskeletal modeling may represent the native glenohumeral joint as a single rotation point defined as the geometric center of a sphere fitted through the humeral head-[30] (Fig 5A). After rTSA surgery, new COR is the center of the glenoid component anchored to the scapula [31](Fig. 5b). Position of the new COR after rTSA is determined by the design of the glenoid implants (baseplate and glenosphere) as well as by operator dependant positioning of the implant on the scapula (Fig. 5C). Postoperative final position of the humerus is further determined by design of the humeral implant. Noteworthy, glenohumeral COR after rTSA is displaced outside of the geometric center of the humeral head (Fig 5D). Difference determines the global postoperative humerus displacement and is affected by design from both glenoid and humeral components (Fig. 5e). Global humeral displacement determines the limits of motion of the humerus during gleno-humeral mobilization before abutment against surrounding structures (impingement free range of motion) as well as the tension of muscles and soft tissues spanning the joint.

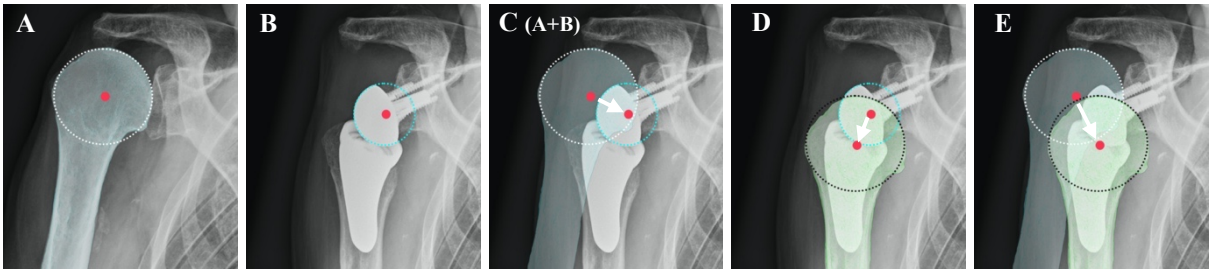

Figure 5 *rTSA associated modification of center of rotation (COR) and humeral position*

A. Anatomic humeral COR determined as the geometric center of the humeral head[30]. **B.** post-operative rTSA COR defined as the geometric center of the glenosphere[31]. **C.** Overlay of anatomic and rTSA CORs; arrow: COR displacement relative to geometrical center. **D** Alignement of anatomic COR on rTSA humerus position showing displacement of rTSA COR outside of geometrical center of humeral head; arrow shows COR displacement relative to geometrical center **E**. Overlay of pre- and post-operative humerus position; arrow: global humeral displacement consisting of distalization and medialization components.

4.3 rTSA design: glenoid and humeral components

Glenoid component

Design of the glenoid component of reversed shoulder determines implant new COR. It results from the assembly of the baseplate and glenosphere (Fig. 4E), both displaying heterogenous designs [32]. Anchorage of the glenosphere to bone is achieved by the baseplate component. Baseplate designs comprise varying combination of peg and screw fixations as well as an array of sizes adapting to heterogeneity in bone morphology (Fig. 6A,B). Similaraly, glenosphere implant diameter may vary in size and shape (Fig. 6F, G), affecting range of motion and risk of impingement between humerus and surrounding structures [33].

Implantation requires preparation of bone surface by reaming. Depth, version (antero-posterior inclination) and tilt angle (supero-inferior angulation) of reaming are determining parameters in the final position of the implant and COR. Baseplate may be set directly onto the articular surface (Fig. 6C), medializing the COR and minimizing shear forces on anchorage as well as risk of implant failure by loosening of the glenoid implant [3, 27, 34].

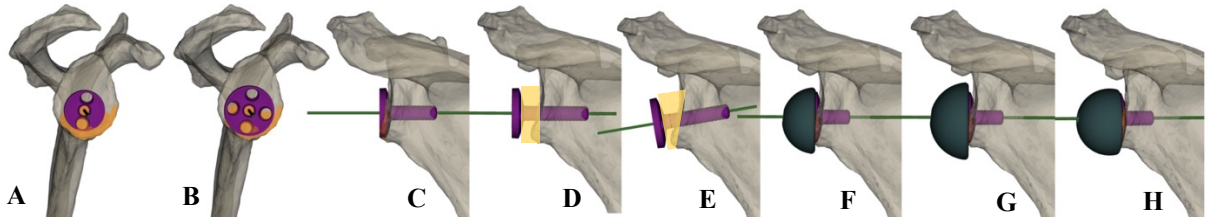

Figure 6 *Glenoid implant modularity (adapted from MyShoulder software, Medacta Intl)*

Baseplate (purple component) may vary in size and anchoring options **A**. and **B**. It may be positioned directly onto articular surface **C**. or lateralized **D**. and/or tilted **E**. using a bone graft (yellow component). Glenosphere (grey component) may vary in diameter **F**. and **G**. as well as thickness (lateralized glenosphere) **H**.

Concerns regarding limitations of excessive medialization on functional outcomes and implant stability (see below) have led to the development of means for baseplate lateralization relative to scapular articular surface.

Augmentation of the scapula with bone graft ("Bony Increased Offset" BIO rTSA, Fig. 6D) has been designed to lessen medialization without increasing shear stresses on glenoid anchorage by augmenting lateral extent of scapular articular surface [35]. Implant COR and bone interface distance is thus maintained. Stable implantation is dependent on graft incorporation into native scapula (osseointegration) [36].

Lessening medialization with lateralized glenospheres (Fig. 6H) has been re-investigated[37] despite high rates of reported glenoid loosening in early designs [3, 4, 12]. Glenoid loosening is reported to remain the leading complication of such implants, with risk significantly reduced by second generation designs[13].

Development of BIO rTSA design with harvesting of angled grafts (Fig. 7 & Publication 1) has emerged as a technical solution for achieving lateralization while maintaining the prosthetic COR at the prosthesis-bone interface, thus minimizing lever arm on the glenoid component. It allows as well for the management of glenoid bone deficiencies with compensation of complex vertical and horizontal deficits[17].

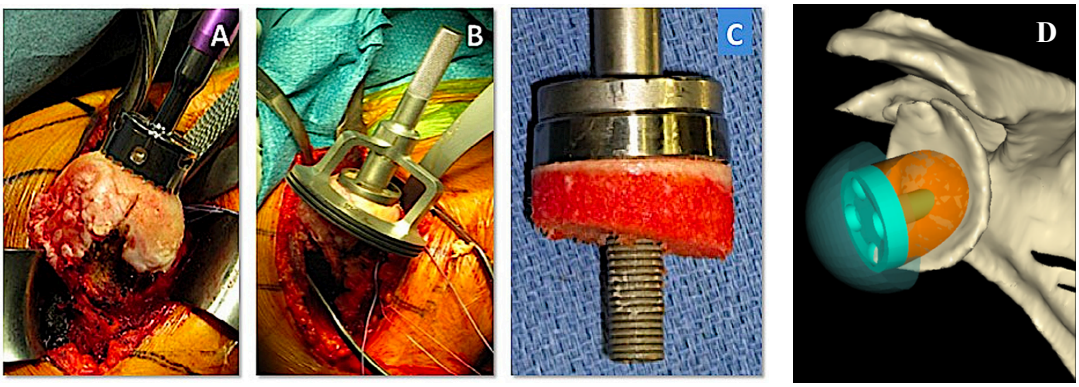

Figure 7 *Angled BIO-rTSA graft for glenoid bone deficiency (adapted from Publication 1*[17])

A. Harvesting of humeral autograft from resected humeral head. **B**. Angled (12°) surgical guide for harvesting of trapezoidal bone graft **C**. **D**. Asymetrical graft positioned for compensation of posterosuperior bone deficiency of glenoid.

Humeral component

Design of the humeral implant modulates final humeral position relative to new COR. Stem shape design may be straight (Fig. 4, Fig 8. A-D) or curved (Fig 8E-H), modulating

horizontal and vertical final position of the humerus [38]. Angulation of interface between stem and metaphyseal component may vary, determining neck-shaft angle (NSA).

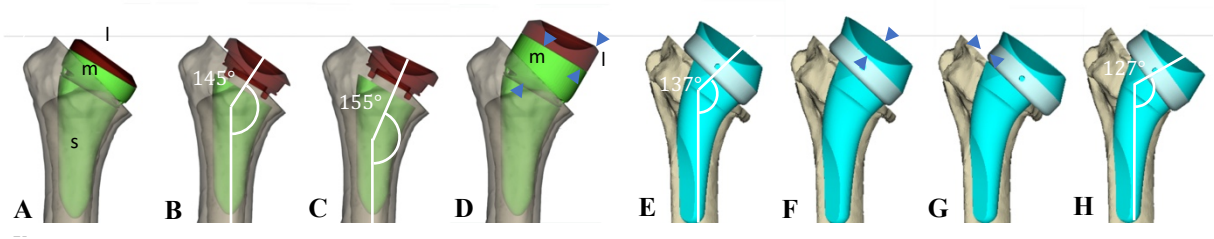

Figure 8 *Humeral implant modularity*
(adapted from MyShoulder software, Medacta Intl. and Blueprint Software, Stryker Intl.)

Inlay metaphysis implant design (A to F) and Onlay metaphyseal "tray" implant design (F-H) stem designs. **A.** Humeral implant components **s** stem, **m** metaphysis, **l** liner. **B**. Liner may determine neck-shaft angle of 145° and **C**. 155° in inlay implants (metaphyseal component removed for visualization). **D**. Metaphyseal component may be augmented in size and liner thickness may be increased (arrow points for comparison with A). **E**. Onlay metaphyseal tray may be set on stems displaying neck-shaft angle of 137° or **H**. 127°. **F**. Liner cup depth may be increased (arrow points). **G**. Metaphyseal tray may be translated to modulate humerus horizontal and vertical position (arrow points for comparison with positioning in E).

Metaphyseal component design (Fig 8) distinguishes two types. Seating of the implant metaphysis within remaining humeral bone defines "Inlay" implants (Fig. 8A-D). Seating of the metaphyseal implant on top of the remaining humeral bone defines "Onlay" implants (Fig 8E-H). Onlay metaphyseal implant design with flat undersurface may be referred to as metaphyseal "tray". Final position of humeral implant is characterized by vertical displacement (distalization) and horizontal displacement (offset). Modulation can be achieved by modifying NSA, increasing thickness of metaphyseal or translating the metaphyseal tray (Fig 8) [39, 40]. Definition of NSA and NSA values may differ between rTSA implant types. Inlay NSA may be defined by the angle between humerus axis and liner component (Fig 8B,C Pr Hertel, unpublished data). Onlay NSA may be defined as the angle between humerus axis and metaphyseal component (Fig 8E, H [41])

Liner thickness can be increased (Fig. 8D) and liner cup deepened (Fig. 8F) increasing joint tension and congruency of the humeral component around the glenoid component respectively [40].

4.4 **rTSA efficacy - impingement free range of motion**

Implant mobility following rTSA procedures is limited by abutment of repositioned humerus and/or humeral implant against surrounding structures (Fig. 9) [33, 35, 42-50]. Range of motion delimited by those contacts defines impingement free range of motion [42, 50]. Scapular notching by abutment of liner component with lateral border of scapula in adduction has been reported to be the logical consequence of absence of a prosthetic neck on the glenoid side in early designs [3] (Fig 9A). More recently, it has been reported to be the consequence of friction in extension as well as rotations [47].

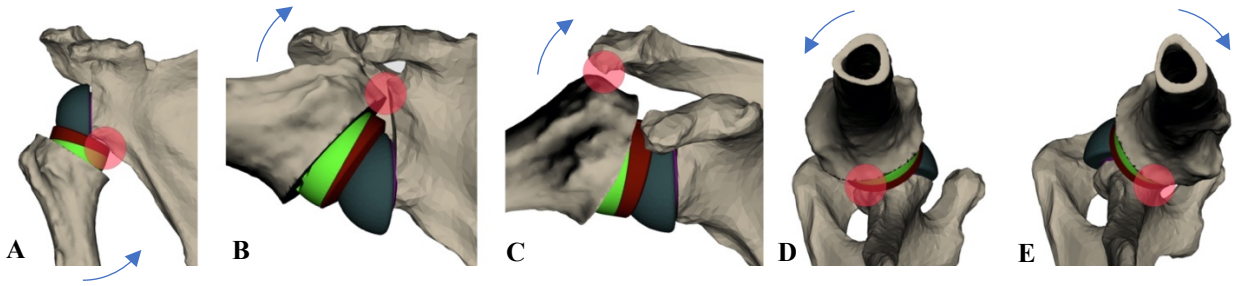

Figure 9 *Impingements in rTSA (Adapted from MyShoulder software, courtesy of Medacta Intl)*
Abutement of humeral component may occur against **A**. Lateral scapular border in adduction, potentially leading to local bone alteration (notching); **B**. Superior glenoid articular surface or **C**. Acromion in abduction; **D**. Posterior or **E**. anterior glenoid in external and internal rotation respectively.

Several technical solutions have been proposed to limit liner abutment:

- Nyffeler et al. have reported increased clearance of liner component in respect to scapular border with inferior positioning of the baseplate and extension of the glenospheres beyond the scapular neck [34].
- Gutiérrez et al. described a model of hierarchy of factors limiting abutment in adduction with largest effect provided by reduction of NSA, followed by the inferior positioning of glenoid implant proposed by Nyffeler et al. [34], lateralization of the center of rotation (10 mm), inferior tilt of the glenosphere and use of larger glenospheres diameter [50]. Same factors displayed a different hierarchy regarding impact on impingement free range of motion. Hence, largest increase was linked to lateralization of the center of rotation (10 mm), followed by inferior positioning of implant, inferior tilt of the glenospheres, reduction of NSA and larger glenospheres diameter.

- Huish et al., using 3D bone modeling, studied impact on implant positioning on the balance of impingement free internal rotation with other motions. Studied parameters comprised glenospheres overhang, NSA, humeral version and glenoid lateralization. They report greatest improvement in internal rotation by combination of all parameters [51].
- Arenas-Miquelez et al. evaluated influence of humeral design (inlay/onlay), NSA, COR lateralization and glenoid component overhang using 3D modelization, concluding that only glenoid lateralization had significant effect on increasing rTSA impingement free range of motion [52].

4.5 **rTSA safety - determinants of implant stability**

Prosthetic instability represent the major causes of indication for reintervention in rTSA [14, 16, 53, 54], [Publication 2]. Causes for rTSA instability are reported to be multifactorial, comprising active and passive constraints. Parameters determining implant stability include COR lateralization, NSA, liner cup depth, arm position and position of the glenoid [55-60].

Evaluation of hierarchy of stability factors in rTSA reported joint contact forces on glenohumeral articulation as the most significant element, followed by liner cup depth, and glenospheres diameter [60, 61] (Fig. 11A). Parameters determining joint contact forces include tensioning associated with horizontal and vertical displacement of soft tissue insertions on the humerus. Modulation of these forces may be achieved by modifying humeral and glenoid component designs and positioning (Figure 11).

Peroperative measurement of joint contacts is reported in total knee arthroplasty for the purpose of soft tissue balancing[62-65]. Methods consist in the use of smart trial liners equipped with force transducers. Application of the technique to rTSA procedure has been reported in pre-clinical setting [19] and represents a promising field of investigation (See Appendix 2)

Reported quantitative measurement of stability include Balance Stability Angle [57, 66] and Stability Ratio [59]. Balance Stability Angle represents the maximal angle that can be reached between the 3D joint contact force and border of concavity of the liner before tipping of the glenosphere over the liner edge and implant dislocation occurs (Fig 11A, B). It is influenced by depth of the cup (Fig 8F), positioning of the liner and neck-shaft angle (Fig 8 B,C, E, H and 11 A, B). Stability ratio is defined as the ratio between forces required to dislocate rTSA implant with joint contact forces obtained by compression along a defined axis [59]. It has been reported to be critically determined by positioning (version) of the humeral component.

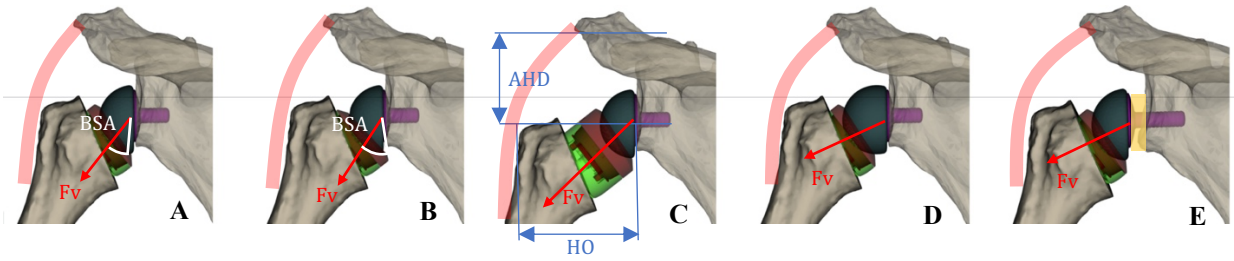

Figure 11 *rTSA implant stability (Adapted from MyShoulder software, courtesy of Medacta Intl)* **A.** Joint reaction forces Fv is reported to be the most significant determinant of rTSA stability. Angle with liner cup border defines the Balance Stability Angle B as the maximal angle that the net joint reaction can form with concavity before instability occurs[66]. **B**. B angle increase with 155° liner component in comparison to 145° (see A). Increase in joint reaction forces may be obtained by **C**. augmentation of metaphyseal and liner component thicknesses on the humeral implant allowing for humerus distalization (AHD: acromiohumeral distance) and lateralization (HO: humeral Offset)[39]; **D**. lateralization of COR using lateralized glenospheres; **E**. lateralization of COR using bone graft at the bone-implant interface.

In the clinical setting, rTSA implant stability results from the complex combination of multiple variables comprising passive and active constraint as well joint position [57].

Conduct of rTSA procedures requires balancing implant parameters choice in respect to safety and efficacy consideration, mainly implant stability and mobility, respectively. Simultaneous maximization of both aspects appears utopist as stability and mobility appear to be competing objectives requiring a trade-off approach [40]. Further research is warranted for understanding of clinically optimum designs adapted to patient specific needs.

5. **PERSPECTIVES**

Axes of investigation in the research field of rTSA implant efficacy and safety comprise development of models for in vitro pre-clinical biomechanical testing (see Appendix 1), design of pre-operative planning software providing outcome predictions, development of devices providing surgical assistance for implant positioning[67], development of strategies and devices for intra-operative assessment of mobility/stability balance [19, 62-65] (see Appendix 2). Post-operative rehabilitation adaptation using biomechanical in vivo analysis (see Publication 4) represents an associated area of investigation in the optimization of functional outcomes after rTSA.

5.1 **In vitro pre-clinical biomechanical testing** [Appendix 1]

Biomechanical testing of human joints is commonly performed using universal testing machines [68]. While providing precise position and force measurements, the related protocols are often limited to only one or two degrees of freedom (DoF) [69]. To overcome this issue, several studies have been oriented toward the use of robotic manipulator with multiple DoFs [56, 68, 70]. To the best of our knowledge, these protocols remain performed in extra-corporal conditions by fixing a bony segment and mobilizing another one. In the context of the shoulder complex, such an approach may produce results quite far from physiological bone movements of this kinematic chain with various DoFs. In this context, we have assessed the reliability and validity of a robotic manipulator to reproduce quasi-static humerus motions based on operator-induced movements on cadaveric specimens, allowing to develop various experimental protocols to robustly assess rTSA kinematics pertaining to mobility and stability (Figure 12).

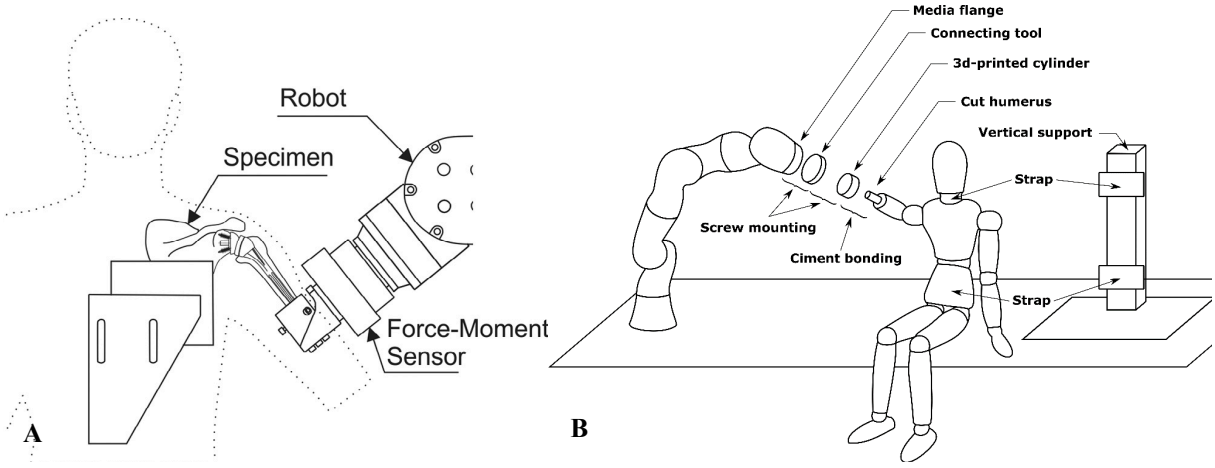

Figure 12 *Advanced biomechanical testing of shoulder surgical devices [Appendix 1]*
A. Extra-corpora glenohumeral testing[55] **B**. Whole shoulder girdle biomechanical testing.

5.2 **3D planning and intra-operative navigation** [Publication 3] [71]

Success of total shoulder arthroplasty depends on the ability of the surgeon to determine the appropriate location and orientation for the glenoid implant. Glenoid version and inclination may need to be corrected at the time of prosthetic glenoid.

Preoperative computed tomography measurements of glenoid version and inclination are recommended for planning glenoid implantation in shoulder arthroplasty. However, current manual or semi-automated 2-dimensional (2D) and 3-dimensional (3D) methods are user-dependent and time-consuming. Development of automated surgeon-operated image analysis software to evaluate 3D glenoid anatomy eliminates interobserver and intraobserver discrepancies, improves the accuracy of preoperative planning for shoulder replacement, and offers a potential gain of time for the surgeon.

Intra-operative navigation tools have been developed for other types of implants [72-74]. In an ongoing Interreg project (Humerus Clausus, n°5177) we are developing navigation hardware and software, based on Aruco markers and Hololens mixed reality smartglasses. This project involves 2 universities (University of Geneva and Université Savoie Mont Blanc) HES-SO HEPIA (Geneva Engineering School) and 2 companies (Gait Up, Oneortho Medical). It aims at developing a toolkit for diagnosis, simulation, navigation and patient follow-up in various shoulder pathologies.

Implementation of planning software features allowing calculation of impingement free range of motion based on patient specific osseous anatomy provides surgical assistance in the

choice of implant configuration. Further evolution taking in account influence of soft tissue constraint represent a next step of investigation in the prediction of rTSA efficacy and safety.

5.3 **Intra-operative biomechanical testing** [Appendix 2]

Trial implants are used for testing medical devices (prosthesis) during surgical procedures to ensure proper sizing and orientation before the final replacement of human joints (arthroplasty). During the trial phase, individual trial components of the prosthesis can be adapted in size and shape until the situation is judged satisfactory and the final prosthesis chosen. In common practice, joint mobility and stability are manually assessed by the surgeon to avoid limited range of motion, instability, pain and fractures. Both elements are determinants of surgical outcomes in terms of performance and safety.

A key component during this trial phase is the polyethylene liner representing the articulating surface between prosthetic joint sides. Trial liners with varying designs are temporarily interposed between implant components and evaluated by operator dependent manual testing, allowing for fine tuning of joint contact forces without the need for modification of implant parts already anchored to joint sides.

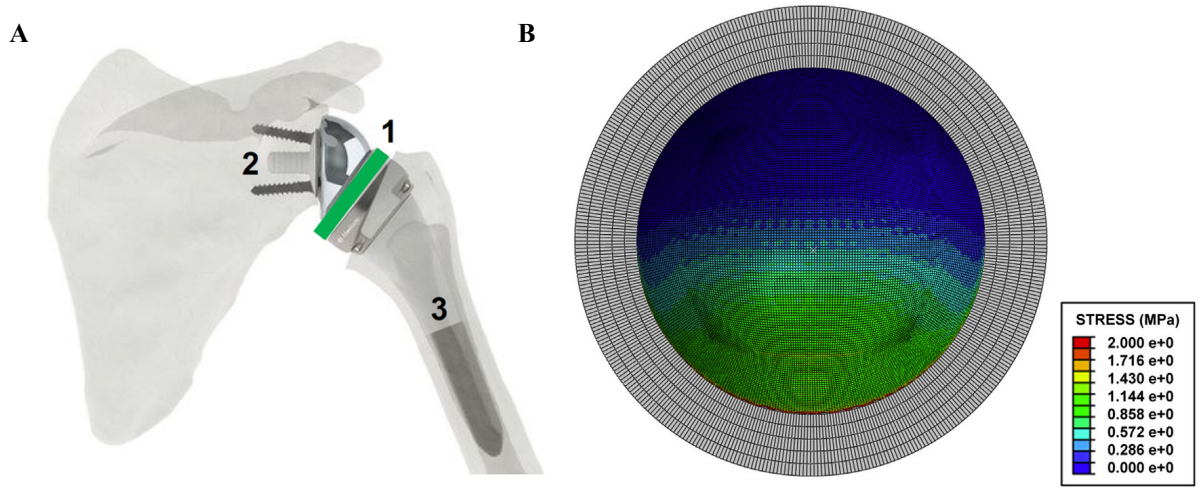

Figure 13 *Smart Polyethylene Trial Implant Project (POLYSMART) [Appendix 2] and adapted from [75]*
A. Interposition of trial implants of varying size and shapes between glenoid (2) and humeral (3) components allows for modulation of prostetic joins biomechanics including range of motion and tension. **B.** Joint reaction forces simulation map obtained by finite element analysis. POLYSMART project objective is prototyping of smart polyethylene trial implant allowing for objective measurement of joint contact forces during trial phase of reverse shoulder arthroplasty procedures.

Development of smart surgical devices featuring diagnostic capabilities emerges as a technical solution allowing for refinements in implant designs, surgical techniques and strategies for postoperative care and rehabilitation. Smart implants have embedded sensors providing real-time information positioning of the implant during the surgical procedure as well as post-operative evaluation for better patient care throughout the treatment pathway. Development of smart trial implants allowing for objective quantification of implant stability and mobility allows to take advantage of potential benefits of smart implant without concern for fragilization that could result from embarked technology in real implants. Technology is reported in knee arthroplasty with improved patient outcomes [62-65].

We aim at prototyping and validating an instrumented polyethylene liner for objective measurements of joint mobility and stability [Appendix 2]. This first prototype will be developed in the context of reversed shoulder arthroplasty. The first phase will consist of prototyping and reliability/validity assessments of an instrumented polyethylene liner hosting a set of sensors for joint mobility and stability measurements. The second phase will consist of assessing the impact of implant size and positioning combinations on joint mobility and stability. A unique facility developed by the principal investigators (B-Lab) will be used, consisting of an advanced joint simulator allowing for in vitro replication of physiological motions executed by patients. Strategies for translational application of POLYSMART project are investigated in the context of the i-Teams program under the supervision of the Translational Accelerator of Geneva Universita Faculty of Medicine. Next planned steps will be assessment of potential industrial partnerships for design of early clinical trials.

5.4 **In vivo biomechanical assessment of postoperative rehabilitation** [Publication 4] [76]

Shoulder strength training exercises represent a major component of rehabilitation protocols designed for postsurgical management of shoulder pathologies. Numerous methods are described for exercising each shoulder muscle or muscle group. Limited information is available to assess potential deleterious effects of individual methods with respect to specific shoulder surgical procedures. Patient-specific 3D measurement techniques coupling medical imaging and optical motion capture can be used for evaluation of shoulder strength training exercises. Screening of rehabilitation exercises has been conducted by our team using this technique, showing significant differences on shoulder biomechanical parameters. Studied parameters included glenohumeral, labral and subacromial high variations in excursion of

muscle span leading to recommendation to avoid sets of exercises during early phase of rehabilitation.

Assessment of variations in the magnitude and distribution of contact forces at specific anatomic locations allows gathering valuable data for the design of post-surgical rehabilitation programs (Fig 13). Strength training exercises may be selected and timed according to the anatomic structures involved during surgery and expected healing times of bony, ligamentous, tendinous and muscular structures.

Methodology could with further studies be generalized to the other joints and structures for assessment of global impact of rehabilitation program strength training exercises taking in account the whole musculoskeletal system.

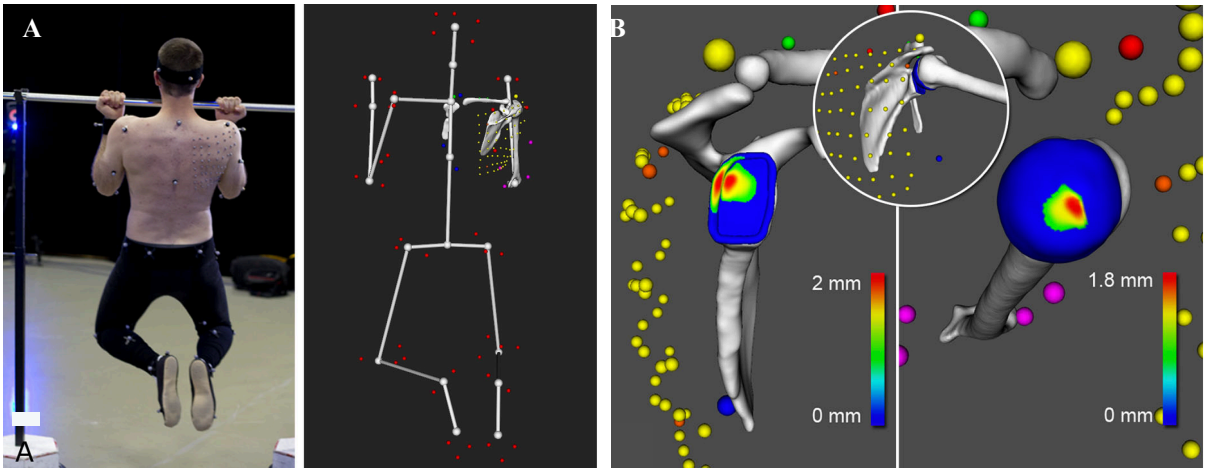

Figure 13 *Person specific simulation of constraint generated by shoulder strengthening exercises on shoulder anatomical structures adapted from [Publication 4] [76]*

A. Example of motion capture recording of shoulder strengthening exercise and virtual skeleton used for visualization. B. Contact tzones during motion evidencing areas of peak stresses on glenoid and humeral articular surfaces.

In the previously mentioned Interreg project (Humerus Clausus, n°5177), we are also investigating the potential of inertial measurement units (IMUs) to assess patient-specific shoulder range of motion. In collaboration with the company Gait Up, we aim at developing a fast and simple setup that could be used to quantify motion amplitudes during various dynamic tasks. Such a setup could for example be used to achieve instrumented common clinical shoulder tests such as the Constant-Murley test [77]. Rehabilitation exercises and auto assessment tools could also be developed using this technology.

Further research will provide unique data for health professionals in the goal of safely rehabilitating patients after rTSA.

6. CONCLUSION

Rise of reverse shoulder arthroplasty as the favored procedure for total shoulder replacement represents a paradigm in the approach of breaking free from anatomy for therapeutic management. Numerous implant designs have evolved with variation occurring on each sub-component. Balancing efficacy and safety of the procedure requires to compromise between antagonistic effects. Development of in vitro models allowing for assessment of the performance and safety of implant designs in patient specific conditions represents a first line of investigation. Development of digital health solutions comprising planification software for pre-operative planification as well as postoperative care represent high potential approaches for optimization of outcomes after RTSA procedures.

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