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Original article

Cement augmentation of glenoid baseplate screws does not improve primary stability in reversed shoulder arthroplasty: A cadaveric study

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ABSTRACT

Introduction: Cuff tear arthritis and complex proximal humeral fractures are common pathologies that are frequently addressed by the implantation of a reversed shoulder prosthesis. The present cadaveric study aimed to analyze the effect of cement augmentation of the glenoid component on the primary stability in geriatric patients.
Hypothesis: Cement augmentation of glenoid baseplate screws has an influence on primary stability in reversed shoulder arthroplasty (RSA).
Materials and methods: Glenoid base plates (Delta Xtend, DePuy Synthes, Westchester, USA) were implanted in 6 pairs of formalin-fixated scapulae of 4 female and 2 male donors (average age 83 years). Two angle stable screws were placed at the superior and inferior position. Cement augmentation was performed with 2 ml bone cement (Kyphon, Medtronic, Minneapolis, USA) per screw in right specimens. Afterwards, biomechanical testing with 600 to 1000 N (100 cycles) at a 65° abduction angle was performed. Finally, a load-to-failure analysis was conducted.
Results: No implant loosening was observed during cyclic tests from 600 N to 1000 N. In addition no difference in the plastic deformation was detected at 600 N ($p = 0.301$), 700 N ($p = 0.522$), 800 N ($p = 0.480$), 900 N ($p = 0.521$) and 1000 N ($p = 0.748$). Load-to-failure analyses revealed implant loosening at 3314 N (SD 823 N) in the cement-augmented implants and at 3059 N (SD 974 N) in scapulae with non-cemented screws ($p = 0.522$).
Discussion: Cement-augmented fixation of the glenoid component did not result in an increased primary stability in this study. Thus, the application of cement should be critically assessed considering associated risks and increased costs.
Level of proof: Basic science study, controlled laboratory study.

1. Introduction

Severe cuff tear arthritis causing malfunction of the glenohumeral joint is a common disease in the aging population [1]. In recent years, the implantation of reversed shoulder arthroplasty (RSA) has helped to reconstruct a stable center of rotation in these complex situations [2].

Furthermore, RSA represents an option in the primary treatment of complex proximal humeral fractures [1,3] with increasing evidence of an improved outcome as compared to hemiarthroplasty [4].

Solid fixation of all components at the bone-implant interface represents a crucial step in RSA [5]. To prevent loosening of the glenoid component, various studies aimed to identify the optimal placement and number of inserted screws. Hoenig et al. demonstrated that the posterior glenoid screw significantly influences the integrity of the reversed glenoid baseplate, while James et al. were able to show that the placement of 2 (superior and inferior) or 4 screws (superior and inferior, ventral and dorsal) resulted in a comparable baseplate motion [6,7].

While cementing the humeral stem represents the standard of fixation in patients suffering from reduced bone quality [8],

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cement-augmented screw fixation of the glenoid component has not been previously investigated. Thus, the hypothesis of the present study was that cement augmentation of glenoid baseplate screws has an influence on primary stability in RSA.

2. Methods

2.1. Cadaver preparation

For the present study, six pairs of adult human cadaver scapulae donated by the affiliated Institute of Anatomy and Cell Biology were used. The specimens had been fixated with 15 liters of an ethanol solution containing 96% ethanol and 2% formaldehyde.

Surrounding rotator cuff tissue was dissected from the bones. In order to preserve humidity, the scapulae were then cloaked in cloths containing the above mentioned ethanol solution. Storage of the specimen was conducted in deep freezers at −30 °C at our research department. Specimens were defrosted at room temperature for 24 hours before mechanical testing.

2.2. Ethical approval

Prior to inclusion, all donors gave full written consent and confirmed a donation of their own free will for the use of their body for research purposes. Approval by the local ethics committee was obtained (file number 96/16).

2.3. Pre-test power analysis

Adapting data from the abovementioned work by James et al. with respect to maximum anterior edge glenosphere displacement for loading in a superior direction (after 100 cycles and 30% loading level), a pre-test power analysis was performed [6]. Based on a fixed alpha of 1% and a power of 80%, a calculated sample size of 6 bones per group was considered adequate for this experimental set-up.

2.4. Cadaveric scapulae

The specimens were derived from 2 male and 4 female donors with an average age of 83 years (range 77–87 years). Before biomechanical testing, a coin was tossed that assigned right scapulae for cement-augmented screw fixation (group CA), while no cement was used for left scapulae (group CAx). To exclude influences due to pre-existing fractures or osteolyses, all bones were examined with a CT scan including 3D reconstructions (Somatom Volume Zoom, Siemens Medical Solutions, Erlangen, Germany).

2.5. Implantation

For the current study, 4 screw hole glenoid baseplates of the Delta Xtend™ prosthesis system (DePuy Synthes, West Chester, USA) were implanted following the manufacturer's instructions. Each scapula was reamed using a motorized 27 mm glenoid resurfacing reamer before insertion of the base plate. Reaming was only performed on chondral level to preserve the subchondral bone. All metaglenes were placed on the inferior circular area of the glenoid (Fig. 1). The metaglene central peg was positioned in the centre of the inferior circle of the glenoid and 2 screws were placed in the superior and inferior screw hole. Screw placement followed a standardized protocol, following the three-column concept of Humphrey et al. [9]. The superior screw was placed in a horizontal fashion along the spina scapulae (Zone 2), while the inferior screw was inserted along the scapular pillar (Zone 3), using maximal angulation of the screw hole. In right scapulae, the screws were then removed and 2 ml of bone cement (Kyphon®, Medtronic, Minneapolis, USA) were injected using a syringe. The screws were inserted and the cement was hardened at room temperature. In left scapulae, the screws were removed and inserted again.

2.6. Positioning and final preparation

The scapula were shortened in an oblique standardized fashion 4 cm medially of the glenoid surface, producing an abduction angle of 65° as described by Hoenig et al. (Fig. 1b) [7]. The inferior angles of the scapulae were dissected horizontally 3 cm inferior to the inferior edge of the glenoid and embedded in Technovit 3040© (Heraeus, Wehrheim, Germany) blocks of 3 cm thickness. A 38 mm glenosphere was installed on the baseplate as recommended by the manufacturer and a fitting standard humeral polyethylene cup was

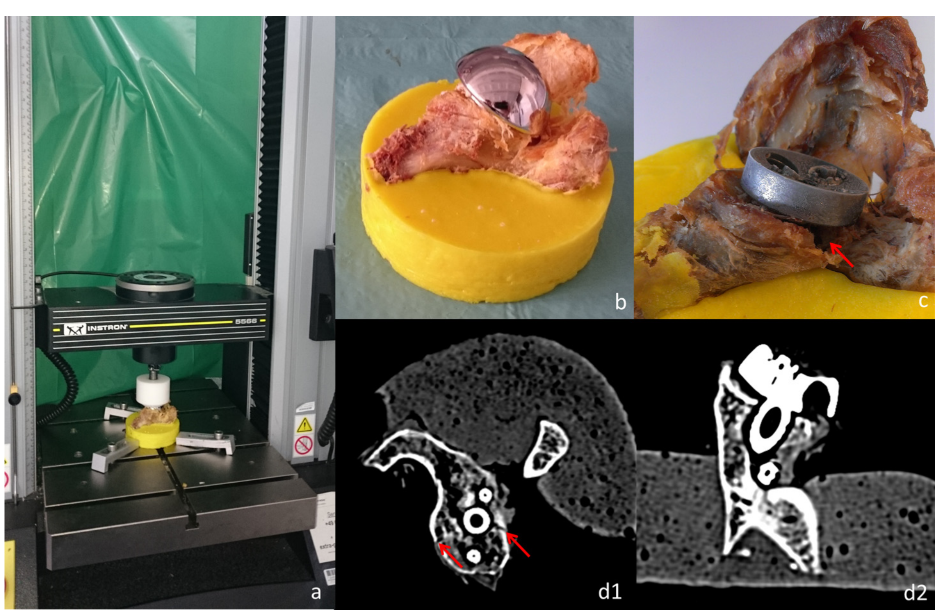

Fig. 1. a: experimental testing set-up with hydraulic loading machine; b: embedded cadaver showing glenoid in 65° abduction angle; c: failed implant with multifragmentary glenoid fracture; d1: glenoid neck fracture accompanying screw cutout (parasagittal view); d2: glenoid neck fracture accompanying screw cutout (axial view).

attached to the testing module in order to apply a constant pressure distribution.

2.7. Biomechanical testing protocol

Testing was performed using a hydraulic testing machine (Instron 5566©, Instron Corp., Darmstadt, Germany). All specimens were fixed in the testing machine including a compensator allowing horizontal evasion (Fig. 1a).

As a preload, 100 N was applied to compress the specimen. Biomechnical testing was started at 600 N following the models used by James and Westerhoff [6,10]. After 100 cycles, a load increase of 100 N was applied until a final load of 1000 N was reached. Constructs were tested until implant failure occurred defined as a deformation of more than 10 mm or a sudden loss of force of more than 20%. Afterwards a load-to-failure analysis was performed. Starting at 1000 N, the force was increased by 20 N every 5 seconds until a failure occurred. Data was collected by a commercially available software (Instron Bluehill 2, Instron Corp., Darmstadt, Germany), which gathered data at 100 ms intervals.

Following biomechanical testing, scapulae were CT-scanned, characteristics of peri-implant fractures were identified and documented.

2.8. Statistics

Before biomechnical testing, the null hypothesis was defined as "There is no difference in primary stability of reversed shoulder prosthesis glenoid constructs after the use of cement augmentation". All results were electronically saved and analyzed using IBM SPSS statistics 22 (Statistical Package for the Social Science, IBM Cooperation, Armonk, N.Y., USA). Values were tested for standard distribution using the Kolmogorov-Smirnov-test. Normally distributed parameters were further analyzed using the analysis of variances (ANOVA), for parameters that differed significantly from the normal distribution the Mann-Whitney-U-test was used. A p-value < 0.05 was considered statistically significant.

2.9. Pre-test radiographic results and screw lengths

None of the tested scapulae showed relevant osseous lesions before inclusion in the present study. After implantation of the baseplates no fractures were detected in the CT scans.

The lengths of the superior (group CA: mean 35 mm, SD 6 mm, group CAx: mean 38 mm, SD 7 mm; $p = 0.397$) and the inferior (group CA: mean 37 mm, SD 7 mm, group CAx: mean 38 mm, SD 6 mm; $p = 0.760$) screws did not differ between group CA and CAx.

3. Results

3.1. Results of biomechanical testing

No implant loosening was detected during cyclic testing from 600 N to 1000 N. The results for maximum plastic deformation are shown in Fig. 2a. No difference of maximum plastic deformation between group CA and group CAx could be detected at 600 N (group CA: 2.5 mm, group CAx: 1.3 mm, $p = 0.301$), 700 N (group CA: 0.8 mm, group CAx: 0.8 mm, $p = 0.522$), 800 N (group CA: 0.6 mm, group CAx: 0.7 mm, $p = 0.480$), 900 N (group CA: 0.7 mm, group CAx: 1.0 mm, $p = 0.521$) and 1000 N (group CA: 1.2 mm, group CAx: 0.9 mm, $p = 0.748$). During load-to-failure testing, 4 scapulae from group CA showed superior stability, while group CAx failed at higher load in 2 cases (Fig. 2b). Cement-augmented baseplates loosened at 3314 N (SD 823 N), while baseplates without augmentation failed at 3059 N (SD 974 N) without reaching statistical significance ($p = 0.522$).

3.2. Fractures accompanying biomechanical failure

While all specimens showed radiologic signs of screw wear out, 5 scapulae showed fractures accompanying screw loosening after load-to-failure testing. In 2 cadavers of each group, simple scapulae neck fractures occurred (Fig. 1d1 and Fig. 1d2). Additionally, 1 case from group CA showed a multifragmentary fracture of the scapula neck (Fig. 1c).

4. Discussion

The improvement of the primary stability of reversed shoulder prostheses is a challenge in shoulder surgery [11]. Especially in older patients with reduced bone quality, which is frequently present in this population, fixation of the glenoid component represents a crucial step. Therefore, the main question of our work was if cement augmentation of glenoid baseplate screws improves primary stability. Our study failed to show improved primary stability by using cement, both at cyclic loading and during load-to-failure.

Several concepts have been presented to optimize stability at the glenoid-implant interface. In previous studies, the use of implants with lateralized center of rotation prevented scapular notching [12]. Concerning screw fixation in the scapula,

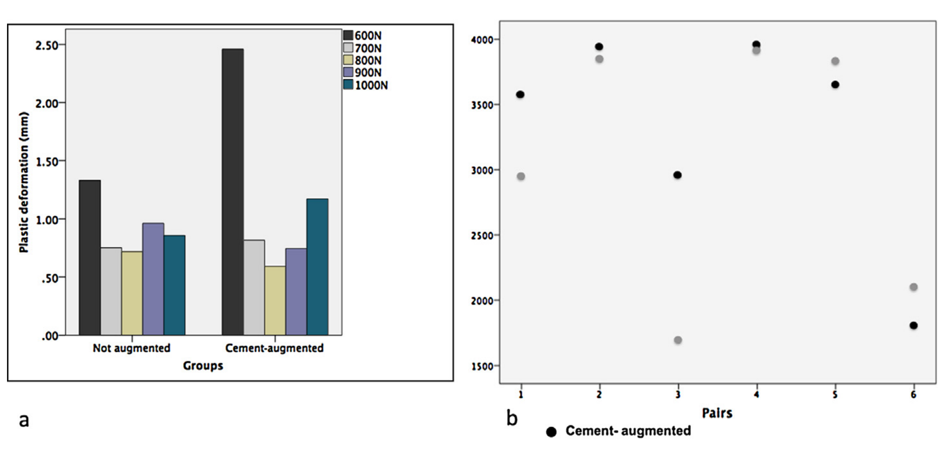

Fig. 2. a: Plastic deformation of group CA and CAx from 600 N to 1000 N (plastic deformation: *déformation plastique*; cement-augmented: *renforcement par ciment*; not augmented: *sans renforcement*; groups: *des groups*; load until failure: *charge de rupture*); b: results for load-to-failure analysis for each pair (pairs: *des couples*; cement-augmented: *renforcement par ciment*; not augmented: *sans renforcement*).

"columns of fixation" were defined in 2008, including the base of the coracoid, the spine, and the pillar [9]. Utilization of a baseplate with variable-angle locking screws was recommended for optimal initial fixation of the glenosphere [9]. Interestingly, in a biomechanical study investigating the number of fixation screws, 4 screws did not result in an increased stability as compared to 2 screws [6]. Regarding screw directions, Parsons et al. demonstrated that the horizontal placement of the inferior screw perpendicularly to the baseplate led to an increased possible screw length [13]. Considering these recent results, the insertion of 2 screws seems to be an adequate fixation of the glenoid baseplate.

To the best of our knowledge, this is the first study evaluating the use of cement augmentation of the glenoid component in RSA in a biomechnical setting. The use of cement augmentation of implants represents a standard technique for the osteosynthetic therapy of various injuries [14–17]. One of the major advantages is the reduction of movement at the bone-implant interface [15] in particular in osteoporotic bone. Furthermore, the vast majority of these studies demonstrated increased failure loads for augmented implants [15–17]. Especially in geriatric patients, cement augmentation of screws seems to be a feasible method to enhance stability.

However, no biomechanical superiority of cement-augmented screws was detected in the experimental setting of the present study. A possible reason could be the different direction of the force vector that was applied to the glenoid by the humeral head. In contrast to distal femoral fractures and proximal humeral fractures, loading is not limited to an axial force but also includes shear stress [10,14,15,18]. As a consequence, the load-to-failure in the present study is almost five times higher as compared to experimental models simulating proximal humeral fractures [15,16]. The fact that cement augmentation did not increase the primary stability following the used biomechanical testing protocol supports results from another study showing no significant difference between the stabilization of 2 and 4 screws [6] indicating a ceiling effect of the primary stability.

Despite the lack of biomechanical improvement, two other major aspects have to be considered. Several complications were described when using bone cement including embolism, dislodgement, bone cement implantation syndrome and leakage [19,20]. Since fluoroscopy is not routinely used in shoulder arthroplasty, cement leakage at the back of the scapulae would not be detected during the surgical procedure. In addition, use of bone cement causes significant extra costs of approximately 50 $ per patient creating an additional burden to the health system [21].

The authors are aware of the limitations of this study. Designed as a biomechanical cadaver- based study, only the primary stability was evaluated not allowing conclusions regarding implant integration and long-term stability. Only one cement product was used in the present study. It cannot be excluded that different results may have been obtained with cement from other manufacturers. Additionally, all screws were implanted twice into each scapula: The first implantation was used for thread cutting, the second to augment all scapula in group CA with cement. This proceeding might have weakened the surrounding osteoporotic bone. Eventually, motion at the bone-implant interface could not be recorded as precisely as it was done in previous studies due to technical reasons [15].

On the other hand, our cadaveric model based on geriatric human bones represents a viable approximation of the complex biomechanical conditions following RSA in elderly patients.

5. Conclusion

Cement augmentation of glenoid fixation screws did not result in an improved primary stability. The use of cement should be critically assessed considering the associated risks and costs.

Disclosure of interest

The authors declare that they have no competing interest.

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Contribution

The conception and design of the study (BB, PL, RA, CB, SR, MF), acquisition of data (MB, RK, JF, LO), or analysis and interpretation of data (BB, SR, MF) or drafting the article or revising it critically for important intellectual content (BB, PL, CB, RA, SR, MF).

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